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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,865	04/21/2005	Kenneth A. Gall	557640-31

CONFIRMATION NO. 5339

POWER OF ATTORNEY NOTICE

OC000000063085010

24628
HUSCH BLACKWELL LLP
HUSCH BLACKWELL SANDERS LLP WELSH & KATZ
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

Date Mailed: 10/11/2023

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/26/2023.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(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**.

/cnguyen/

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EX. 1004

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,865	04/21/2005	Kenneth A. Gall	557640-31

CONFIRMATION NO. 5339

195585
HUSCH BLACKWELL LLP
HUSCH BLACKWELL/ENOVIS
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

POA ACCEPTANCE LETTER

OC000000063085071

Date Mailed: 10/11/2023

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/26/2023.

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.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
11/112,865	**09/26/2023 12:44:03 PM ET**	**557640-31**

Title of Invention

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	7985222
CONFIRMATION #	5339	FILED BY	Joanne Wickenhauser
PATENT CENTER #	62869545	FILING DATE	04/21/2005
CUSTOMER #	24628	FIRST NAMED INVENTOR	Kenneth A. Gall
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Bryan Stewart

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
37 CFR 3.73c-09-26-2023 - 557640-31.pdf	3	Assignee showing of ownership per 37 CFR 3.73	119 KB
POA-09-26-2023 - 557640-31.pdf	2	Power of Attorney	244 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
37 CFR 3.73c-09-26-2023 - 557640-31.pdf	5FF4B9F74AAC32B20CE51458F669729F493B6869E330709B03B41F74EECE27321FC0EB0EF4BF50D70DF95120CC6140C3152

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FA9FAA1BF2885DFD23601ED97955A

POA-09-26-2023 - 557640-31.pdf	E5BFA8A42249A52E11A513EF11DE05D3C401FC102B05A76691562D9772A17EFDD78D4BC01F55ED4BAC628F309F0AD9D933A0A93969FA2E3C522B6FA287F787D1

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall
Title	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Art Unit	3775
Examiner Name	ANURADHA RAMANA
Attorney Docket Number	557640-31

SIGNATURE of Applicant or Patent Practitioner

Signature	/Bryan D. Stewart/	Date (Optional)	2023-09-26
Name	Bryan D. Stewart	Registration Number	66941
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

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

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PETITIONER ARTHREX
EX. 1004

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 195585

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

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

MedShape, Inc.

☐ Inventor or Joint Inventor (title not required below)

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

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

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

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied b DocuSigned by: act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Susan Payne A4D54EC9B70747...	Date (Optional)	9/1/2023
Name	SUSAN PAYNE		
Title	Vice President & Assistant General Counsel of MedShape, Inc.		

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

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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PTO/AIA/96 (08-12)
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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: MEDSHAPE, INC.

Application No./Patent No.: 11/112,865 Filed/Issue Date: April 21, 2005

Titled: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

MEDSHAPE, INC., 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: GALL, KENNETH A. et. al. To: MEDSHAPE SOLUTIONS, INC.

   The document was recorded in the United States Patent and Trademark Office at

   Reel 016308, Frame 0583, or for which a copy thereof is attached.

2. From: MEDSHAPE SOLUTIONS, INC. To: MEDSHAPE MERGER SUB, INC.

   The document was recorded in the United States Patent and Trademark Office at

   Reel 020189, Frame 0034, or for which a copy thereof is attached.

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.

PTO/AIA/96 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: MEDSHAPE MERGER SUB, INC. To: MEDSHAPE SOLUTIONS, INC.

The document was recorded in the United States Patent and Trademark Office at
Reel 020702, Frame 0220, or for which a copy thereof is attached.

4. From: MEDSHAPE SOLUTIONS, INC. To: MEDSHAPE, INC.

The document was recorded in the United States Patent and Trademark Office at
Reel 029207, Frame 0564, 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.

/Bryan D. Stewart/	2023-09-26
Signature	Date
Bryan D. Stewart	66941
Printed or Typed Name	Title or Registration 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.

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EX. 1004

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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,865	04/21/2005	Kenneth A. Gall	557640-31

CONFIRMATION NO. 5339

105215
Furman IP Law
P.O. Box 1575
Boulder, CO 80306

POWER OF ATTORNEY NOTICE

OC000000135082530

Date Mailed: 07/11/2022

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/08/2022.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(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**.

/sltorres/

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,865	04/21/2005	Kenneth A. Gall	557640-31

CONFIRMATION NO. 5339

24628
HUSCH BLACKWELL LLP
HUSCH BLACKWELL SANDERS LLP WELSH & KATZ
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

POA ACCEPTANCE LETTER

OC000000135082537

Date Mailed: 07/11/2022

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

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/sltorres/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall
Title	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Art Unit	3775
Examiner Name	Anuradha Ramana
Attorney Docket Number	557640-31

SIGNATURE of Applicant or Patent Practitioner

Signature	/Bryan D. Stewart/	Date (Optional)	July 8, 2022
Name	Bryan D. Stewart	Registration Number	66,941
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

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

☐ *Total of _____ forms are submitted.

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PETITIONER ARTHREX
EX. 1004

Doc Code: PA..
Document Description: Power of Attorney

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 24628

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

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

MedShape, Inc.

☐ Inventor or Joint Inventor (title not required below)

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

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

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

SIGNATURE of Applicant for Patent

The undersigned (DocuSigned by: Susan Payne A4D54EC9B707471...) below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Susan Payne		
Title	Vice President & Assistant General Counsel of MedShape, Inc.		

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

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PETITIONER ARTHREX
EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	46145786
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	105215
Filer:	Bryan David Stewart/Kaylin Hood
Filer Authorized By:	Bryan David Stewart
Attorney Docket Number:	036302-010201
Receipt Date:	08-JUL-2022
Filing Date:	21-APR-2005
Time Stamp:	13:57:05
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	Assignee showing of ownership per 37 CFR 3.73	557640-31-373.pdf	122865 dc5d37c749d1515ca2a9f6f4d6d10d93077dd373	no	3

Warnings:

PETITIONER ARTHREX
EX. 1004

Information:					
2	Power of Attorney	557640-31-PowerOfAttorney.pdf	211762 f371ced764e03848c1c2da96a79c062d44d87d87	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	334627	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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 displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: MEDSHAPE, INC.

Application No./Patent No.: 11/112,865 Filed/Issue Date: 2005-04-21

Titled: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

MEDSHAPE, INC., 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: GALL et al. To: MEDSHAPE SOLUTIONS, INC.

   The document was recorded in the United States Patent and Trademark Office at

   Reel 016308, Frame 0583, or for which a copy thereof is attached.

2. From: MEDSHAPE SOLUTIONS, INC. To: MEDSHAPE MERGER SUB, INC.

   The document was recorded in the United States Patent and Trademark Office at

   Reel 020189, Frame 0034, or for which a copy thereof is attached.

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.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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 displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: MEDSHAPE MERGER SUB, INC. To: MEDSHAPE SOLUTIONS, INC.

The document was recorded in the United States Patent and Trademark Office at
Reel 020702, Frame 0220, or for which a copy thereof is attached.

4. From: MEDSHAPE SOLUTIONS, INC. To: MEDSHAPE, INC.

The document was recorded in the United States Patent and Trademark Office at
Reel 029207, Frame 0564, 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.

/Bryan D. Stewart/	2022-07-08
Signature	Date
Bryan D. Stewart	66941
Printed or Typed Name	Title or Registration 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.

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PTO/SB/123 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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CHANGE OF CORRESPONDENCE ADDRESS
Patent

Address to:
Mail Stop Post Issue
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Patent Number	7,985,222
Issue Date	July 26, 2011
Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall, Denver, CO
Attorney Docket Number	036302.010201

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

☑ The address associated with Customer Number: 105215

OR

☐ **Firm or Individual Name**

Address

City | **State** | **ZIP**

Country

Telephone | **Email**

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

This form will not affect any "fee address" provided for the above-identified patent. To change a "fee address" use the "Fee Address Indication Form" (PTO/SB/47).

I am the:

☐ Patentee.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☑ Attorney or agent of record. Registration Number 61,313

Signature

Typed or Printed Name Wm. Alex Furman

Date June 26, 2012 | Telephone

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Post Issue, 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:	13566604
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	William Alexander Furman
Filer Authorized By:	
Attorney Docket Number:	036302-010201
Receipt Date:	22-AUG-2012
Filing Date:	21-APR-2005
Time Stamp:	23:26:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Change of Address	036302-010201_MSI-001G.pdf	192532 2ecece6dbe389675f1d75f33b9f06694526b75a3	no	1
Warnings:					
Information:					

PETITIONER ARTHREX
EX. 1004

Total Files Size (in bytes):	192532

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.

PETITIONER ARTHREX
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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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	07/26/2011	7985222	036302-010201	5339

37705 7590 07/06/2011

GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

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 1768 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):

Kenneth A. Gall, Denver, CO;
Jeffrey A. Tyber, Boulder, CO;
Douglas J. Pacaccio, Alexandria, VA;

IR103 (Rev. 10/09)

PETITIONER ARTHREX
EX. 1004

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	07/26/2011	7985222	036302-010201	5339

37705 7590 07/06/2011

GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

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

Kenneth A. Gall, Denver, CO;
Jeffrey A. Tyber, Boulder, CO;
Douglas J. Pacaccio, Alexandria, VA;

IR103 (Rev. 10/09)

PETITIONER ARTHREX
EX. 1004

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

Bib Data Sheet

CONFIRMATION NO. 5339

SERIAL NUMBER	FILING OR 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/112,865	04/21/2005 RULE	606	3775	036302-010201

APPLICANTS

Kenneth A. Gall, Denver, CO;
Jeffrey A. Tyber, Boulder, CO;
Douglas J. Pacaccio, Alexandria, VA;

**** CONTINUING DATA ***************************

This appln claims benefit of 60/563,952 04/21/2004

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

IF REQUIRED, FOREIGN FILING LICENSE GRANTED
** 05/17/2005

		STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
Foreign Priority claimed	☐ yes ☐ no	CO	10	26	3
35 USC 119 (a-d) conditions met	☐ yes ☐ no ☐ Met after Allowance				
Verified and Acknowledged	Examiner's Signature Initials				

ADDRESS
37705

TITLE

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

FILING FEE RECEIVED		
2040	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

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)

37705 7590 06/01/2011
GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

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

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

TITLE OF INVENTION: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	~~$785~~ 1510	$300	$0	~~$1085~~ 1810	09/01/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
RAMANA, ANURADHA	3775	606-072000

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 Greenberg Traurig LLP
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: MEDSHAPE SOLUTIONS, INC.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Atlanta, Georgia

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 credit any overpayment, to Deposit Account Number 50-2775 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☒ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Wm. Alex Furman Date June 13, 2011

Typed or printed name Wm. Alex Furman Registration No. 61,313

This collection of information 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.

Electronic Patent Application Fee Transmittal	
Application Number:	11112865
Filing Date:	21-Apr-2005
Title of Invention:	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
First Named Inventor/Applicant Name:	Kenneth A. Gall
Filer:	William Alexander Furman/Marilyn Morris
Attorney Docket Number:	036302-010201
Filed as Large Entity	

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1510	1510
Publ. Fee- early, voluntary, or normal	1504	1	300	300

PETITIONER ARTHREX
EX. 1004

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1810**

PETITIONER ARTHREX
EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	10294098
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	William Alexander Furman/Marilyn Morris
Filer Authorized By:	William Alexander Furman
Attorney Docket Number:	036302-010201
Receipt Date:	13-JUN-2011
Filing Date:	21-APR-2005
Time Stamp:	19:46:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1810
RAM confirmation Number	5795
Deposit Account	502775
Authorized User	
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)	

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EX. 1004

File Listing:					
Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1	Issue Fee Payment (PTO-85B)	036302-010201-Issue-Fee-Trans-filed.pdf	103985 ff613c1363f85884a3827250c882806a52af862c	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32009 5a5fce259a4f9f29ed431637e1190e3f0abe0a84	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	135994		

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

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EX. 1004

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

37705 7590 06/01/2011
GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

DATE MAILED: 06/01/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

TITLE OF INVENTION: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	09/01/2011

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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)

37705 7590 06/01/2011
GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

TITLE OF INVENTION: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	09/01/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
RAMANA, ANURADHA	3775	606-072000

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 _____

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 credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

37705 7590 06/01/2011

GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

DATE MAILED: 06/01/2011

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

The Patent Term Adjustment to date is 1129 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1129 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.

PETITIONER ARTHREX
EX. 1004

Notice of Allowability	Application No.	Applicant(s)	
	11/112,865	GALL ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3775	

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

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

1. ☒ This communication is responsive to *the after-final amendment filed on 3/22/2011*.

2. ☒ The allowed claim(s) is/are *47-49 and 51-57*.

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

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).

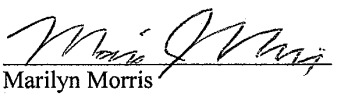
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Anu Ramana/ Primary Examiner, Art Unit 3775	May 23, 2011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)	Group Art Unit: 3775
Kenneth A. Gall et al.	)	Examiner: Ramana, Anuradha
Serial No.: 11/112,865	)	
Filed: April 21, 2005	)	**RESPONSE TO FINAL OFFICE ACTION MAILED JANUARY 24, 2011**
Confirmation No.: 5339	)	
Atty. File No.: 036302-010201	)	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on March 22, 2011.
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	)	Signed:  Name: Marilyn Morris

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

OK TO ENTER: /A.R./

Dear Sir:

This correspondence is responsive to the Final Office Action having a mailing date of January 24, 2011.

A listing of the Claims begins on Page **2** of this paper.

Remarks begin on Page **4** of this paper.

It is not believed that any additional fees are due in connection with this correspondence. However, any necessary additional fees may be charged to Deposit Account No. 502775.

PETITIONER ARTHREX EX. 1004

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	**Art Unit**
	ANU RAMANA	3775

ORIGINAL		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
606	60	A	6	1	B	17 / 58 (2006.01.01)	A	6	1	B	17 / 58 (2006.01.01)
CROSS REFERENCE(S)		A	6	1	F	2 / 30 (2006.01.01)	A	6	1	F	2 / 30 (2006.01.01)
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)										

☐ 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	47														
2	48														
3	49														
5	51														
4	52														
6	53														
7	54														
8	55														
9	56														
10	57														

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 10	
/ANU RAMANA/ Primary Examiner, Art Unit 3775 (Primary Examiner) (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 8

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	0	(insert$3 same (device$1 implant $1) same shape same memory same (stretch$3 elongat$3) same (fix$3 attach$3) same first same second same (fragment$1 piece $1) same temperature$1 same greater same austenit$2). clm.	US-PGPUB; USPAT; UPAD	OR	OFF	2011/05/23 17:14

5/23/2011 5:14:59 PM

PETITIONER ARTHREX
EX. 1004

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

BIB DATA SHEET

CONFIRMATION NO. 5339

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/112,865	04/21/2005 RULE	606	3775	036302-010201

APPLICANTS
Kenneth A. Gall, Denver, CO;
Jeffrey A. Tyber, Boulder, CO;
Douglas J. Pacaccio, Alexandria, VA;

**** CONTINUING DATA **************************** OK. AR. 5/23/2011.
This appln claims benefit of 60/563,952 04/21/2004

**** FOREIGN APPLICATIONS ************************** None. AR. 5/23/2011.

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/17/2005

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/ANU RAMANA/ Examiner's Signature	☐ Initials	CO	10	~~20~~ 10	~~3~~ 1

ADDRESS
GREENBERG TRAURIG (DEN)
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202
UNITED STATES

TITLE
Osteosynthetic implants and methods of use and manufacture

FILING FEE RECEIVED		
1740	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

BIB (Rev. 05/07).

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	3775

SEARCHED			
Class	Subclass	Date	Examiner
606	60, 62, 63, 300, 301, 308, 320	2/15/2010	A. Ramana

SEARCH NOTES		
Search Notes	Date	Examiner
Conducted a search in the EAST database. See attached search report.	2/15/2010	A. Ramana
Conducted an inventor name search in PALM.	2/15/2010	A. Ramana
Updated search.	1/18/2011	A. Ramana
Updated search.	5/23/2011	A. Ramana

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
	Conducted an interference search. See the attached search report.	5/23/2011	A. Ramana

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

37705 7590 03/31/2011

GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

NOTIFICATION DATE	DELIVERY MODE
03/31/2011	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):

denipmail@gtlaw.com
clairt@gtlaw.com
cadanoc@gtlaw.com

PTOL-90A (Rev. 04/07)

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
11112865	4/21/2005	GALL ET AL.	036302-010201

GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER
Anu Ramana

ART UNIT	PAPER
3775	20110325

DATE MAILED:

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

Commissioner for Patents

The after-final amendment filed on March 22, 2011 overcomes the rejections made in the previous office action. However, the IDS filed on March 22, 2011 has not been considered by the Examiner because it does not meet the requirements of 37 CFR 1.97(d). A statement under 37 CFR 1.97(e) (1) or (2) has not been provided. In order for the IDS to be considered, Applicant must file a Request for Continued Examination.

Encl.

IDS dated March 22, 2011.

March 25, 2011

/Anu Ramana/
Primary Examiner, Art Unit 3775

PTO-90C (Rev.04-03)

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EX. 1004

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302-010201	Application Number 11/112,865
	Applicant(s) Kenneth A. Gall	
	Filing Date 04/21/2005	Group Art Unit 3775

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	5,882,444	03-16-1999	Flomenblit et al.			
	2	5,976,138	11-09-1999	Baumgart et al.			
	3	6,579,293	06-17-2003	Chandran			

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO
	4	CN 2472682Y (abstract only in English)	01-23-2002	China				

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	5	Extended European Search Report from related European Patent Application No. 06758489.6, dated March 4, 2010.

EXAMINER	DATE CONSIDERED

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

SHEET 1 OF 1

DEN 97,430,586v1 2-7-11

PETITIONER ARTHREX EX. 1004

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302-010201	Application Number 11/112,865
	Applicant(s) Kenneth A. Gall	
	Filing Date 04/21/2005	Group Art Unit 3775

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
	4	CN 2472682Y (abstract only in English)	01-23-2002	China				

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	5	Extended European Search Report from related European Patent Application No. 06758489.6, dated March 4, 2010.

EXAMINER	DATE CONSIDERED

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

SHEET 1 OF 1

DEN 97,430,586v1 2-7-11

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Internal fixer for femoral fracture

Publication number: CN2472682 (Y)
Publication date: 2002-01-23
Inventor(s): HUANG QUNCHENG [CN] +
Applicant(s): NANXIANG HOSPITAL JIADING DIST [CN] +
Classification:
- international: ***A61B17/74;*** **A61B17/68;** (IPC1-7): A61B17/74
- European:
Application number: CN20012038902U 20010417
Priority number(s): CN20012038902U 20010417

Abstract of **CN 2472682 (Y)**
The utility model relates to an inner fixer which is applied in the thighbone intertrochanteric thrypsis use. Because adopting the nickel-titanium shape memory alloy as the material and designing the hook nail shape armor plate and the radiation shape steel nail so as to make the fracture surface has bigger crushing stress and better fixing effect, the utility model not only effectively prevents the coxa enstrophe, but also provides best dynamics environment to the healing of the fracture. The utility model has simple and convenient method which is easy to be popularized.

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[19]中华人民共和国国家知识产权局

[51]Int. Cl[7]
A61B 17/74

[12]实用新型专利说明书

[21] ZL 专利号 01238902.1

[45]授权公告日 2002 年 1 月 23 日

[11]授权公告号 CN 2472682Y

[22]申请日 2001.4.17 [24]颁证日 2002.1.23

[73]专利权人 上海市嘉定区南翔医院

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[72]设计人 黄群成

[21]申请号 01238902.1

[74]专利代理机构 上海市嘉定专利事务所

代理人 许忠高

权利要求书 1 页 说明书 4 页 附图页数 3 页

[54]实用新型名称 一种应用于股骨骨折的内固定器

[57]摘要

本实用新型提供了一种应用于股骨粗隆间粉碎性骨折使用的内固定 器,由于采用了镍钛形状记忆合金作材料和设计了钩钉状钢板及发散状钢 钉,从而使骨折面有较大的压应力和较好的固定作用,既能有效防止髋内 翻又为骨折愈合提供最佳的力学环境,方法简便,易于推广。



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01.04.24

权 利 要 求 书

1、一种应用于股骨粗隆间骨折的内固定器，其特征在于它是由镍钛形状记忆合金制成的钩钉钢板 3 和镍钛形状记忆合金制成的主钉 a、辅钉 b、板钉 c 组成；

2、根据权利要求 1 所述的固定器，其特征在于所述的钩钉钢板 3 是一紧贴股骨外缘形状的条状钢板，中轴线占有 6—8 个孔；

3、根据要求 1 所述的内固定器，其特征在于所述的钩钉钢板 3 的上端开叉并内弯成左边大钩钉 1 和右边小钩钉 2，也可做成右边大钩钉 1 和左边小钩钉 2；

4、根据权利要求 1 所述的内固定器，其特征在于所述的主钉 a、辅钉 b、板钉 c 的尾部均为发散状；

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说　明　书

一种应用于股骨骨折的内固定器

本实用新型涉及一种医疗器械，特别是涉及一种由钩钉钢板和钢钉组成的用于股骨粗隆间骨折的内固定器。

在临床上，由于股骨粗隆间粉碎性骨折很不稳定，如果没有坚强、可靠的内固定，将来容易造成髋内翻，影响患肢功能，目前一般常使用的采用碳钢材料制成的内固定器械尚不能做到十分满意，例如使用理查德（Richard）钉，则不能有效地防止骨折近端的旋转且手术时创伤较大；如使用伽玛钉来固定，虽能承受较大的压应力，但不能有效地将张应力转化为压应力，而且操作较复杂，对设备要求较高，基层医院较难实施此手术；如使用多枚空心螺纹钉及安达氏（Ender）钉的话，又不能达到坚强内固定的要求。设计一种新的股骨骨折内固定器械已成为医疗界非常迫切之事。

本实用新型的目的在于要设计出一种既能防止髋内翻又具有能承受坚强压应力及将张应力转化为压应力的内固定器械，并且要求操作简便，易于推广使用。

本实用新型由钩钉钢板和钢钉两部分组成，首先，本实用新型选用镍钛形状记忆合金作材料、镍钛形状记忆合金是一种具有记忆功能的金属材料，在某一低温下使用外力可以产生一定的变形，待升高到某一温度时会

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自动恢复成原来（未变形前）的形状；其次将此合金钢板制成一长条形钩钉钢板 3，此钢钉钩板 3 的形状必须是紧贴股骨及大粗隆外缘的，钩钉钢板 3 的上端开叉并内弯成左大右小两个尖状钩钉 1 和 2，大钩钉 1 和小钩钉 2 的钩尖用以固定到大粗隆的股骨颈基底部梨状窝，以承受股骨粉碎部分的张应力，有利于始终密贴骨折端，钩钉钢板 3 是一条相对长度 210—230 毫米、15—20 毫米宽、1.5—5 毫米厚的长条钢板，分大、中、小三档长度，以适应不同人群的需要，在钢板中轴线有 6—8 个钻孔 4，用来固定钢钉之用，钢钉分主钉 a、辅钉 b 和板钉 c，主钉 a 的长度一般 7—12 厘米、直径 6—8 毫米，辅钉长度一般为 6—10 厘米、直径 4—6 毫米；板钉长度一般为 3—6 厘米、直径 4—6 毫米，各钢钉尾部均用形状记忆合金制成发散状，考虑到人体股骨形状是左右对称的，所以本实用新型的钩钉钢板 3 的尖状钩钉也可以做成右大左小，临床应用时，经消毒后的钩钉钢板 3 的尖状钩钉部位放入冰水中降温，在摄氏零度时，大钩钉 1 和小钩钉 2 可撑开弧度，使整个钩钉钢板 3 紧贴股骨，钩钉 1 和钩钉 2 紧贴股骨大粗隆，使钩钉 1 和钩钉 2 的钉尖固定到大粗隆的股骨颈基底部梨状窝，待温度升高到接近体温时，钩钉钢板 3 即自动恢复到原始的形状，此恢复原始形状的回复力，起到了对骨折端的固定加压作用，使钩钉 1 和钩钉 2 的加压段处于对抗骨折部分张应力的最有利位置，主钉 a、辅钉 b、和板钉 c 的尾部做成发散状，在冰水温度下可收缩起来，主钉 a 插入股骨颈并紧贴股骨矩，辅钉 b 插入股骨小粗隆，板钉 c 插入股骨干，随着温度升高，尾部即散开回复到原始发散形状，把骨折部分和钩钉钢板 3 紧紧固定，和钩钉 1 和钩钉 2 一起对骨折部分起加压作用，保证整个骨折面均处于一定的压缩

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应力之下，为骨折愈合提供最佳的力学环境。并可以有效的避免股骨头旋转和髋内翻畸形的发生，本实用新型在形状相同的情况下可制成不同尺寸的系列规格，以适应男女、成人、小孩等多种人群使用。

本实用新型的优点在于:

1、内固定性强：该钩钉钢板由于具有独特的设计，可以将股骨、钢钉、钩钉钢板构成一整体固定，并且克服由于大粗隆骨折上移，臀中肌张力降低等后遗症，形成了十分坚强的内固定，患者可早期恢复肢体功能，减少骨折后遗症的发生。

2、带钩弧形钢板，有效地克服骨折断端的张应力，将张应力转化为有利于骨折愈合的压应力，从而避免发生髋内翻畸形。

3、本实用新型采用钢钉固定，不用一般螺钉，可防止股骨头、股骨颈被螺纹割破，股骨颈内的主钢钉 a 和辅钢钉 b 的头部呈发散状，具有抗扭转的作用，防止股骨头的旋转。

4、记忆合金带有预应力，对骨折断端起持续加压作用，促进骨折早期愈合。

5、手术较为简便、易于使用，不需要较复杂的仪器设备，广大基层医院均能开展。

下面结合附图给出本实用新型的实施例:

图 1　钩钉钢板形状示意图;

图 2　钩钉钢板与钢钉的配合示意图;

图 3　本实用新型应用实例示意图;

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实施例：

一种应用镍钛形状记忆合金制成的应用于成年男性股骨粗隆间骨折的内固定器，各参数如下：钢板厚度=2.5 毫米、钢板宽度=15 毫米、相对长度 230 毫米、主钉 a=90 毫米*φ6、铺钉 b_1=60 毫米*φ4、b_2=50 毫米*φ4、板钉 c_1=c_2=c_3=c_4=35 毫米*φ4

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说 明 书 附 图

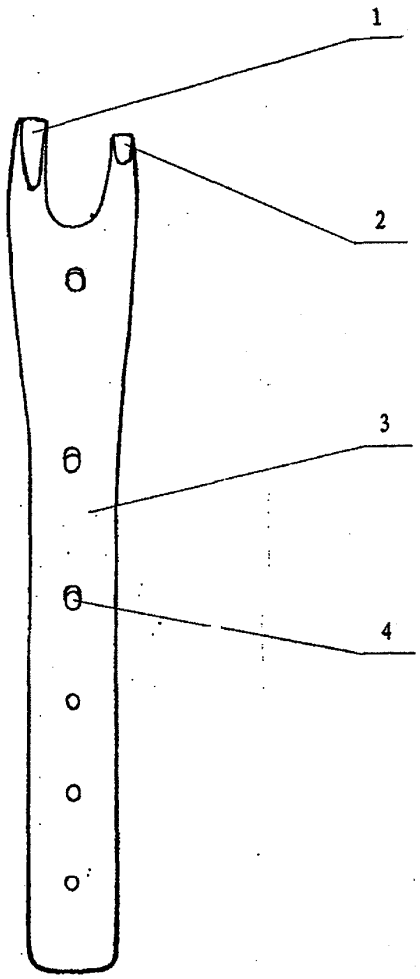


图 1

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01.04.24

说 明 书 附 图

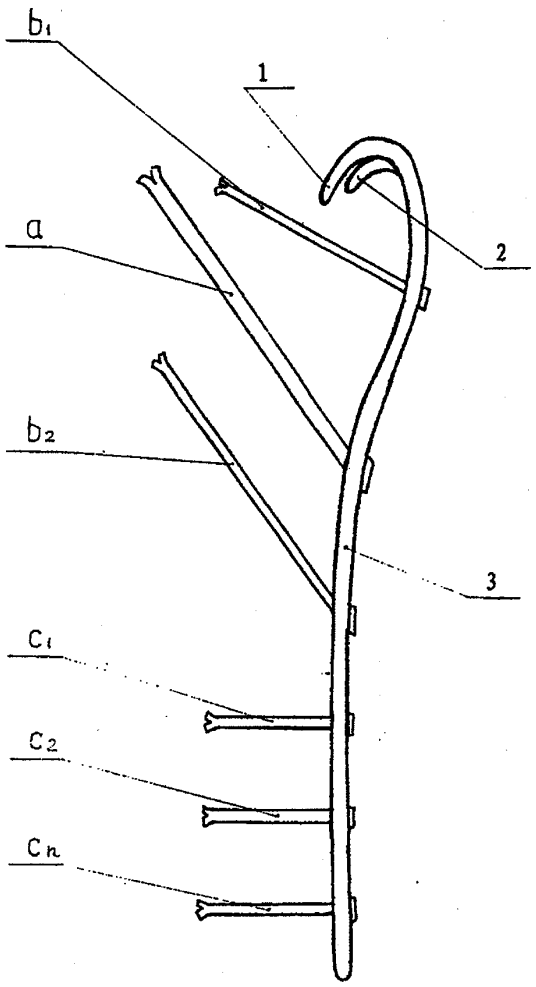


图 2

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说 明 书 附 图

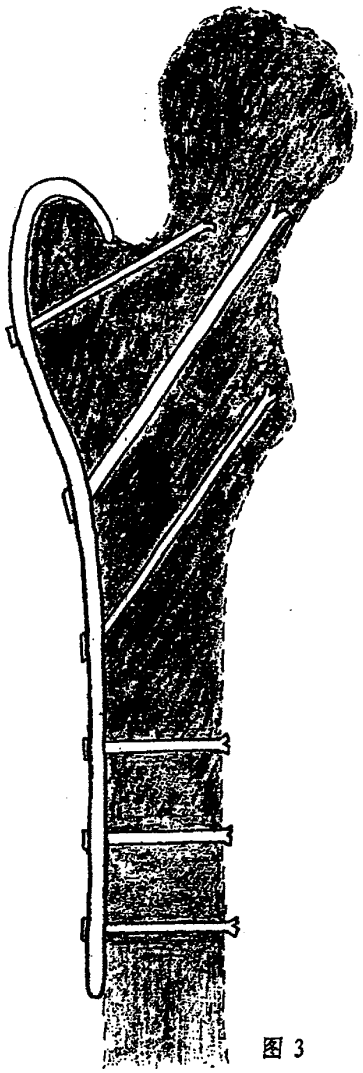


图 3

3

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Electronic Patent Application Fee Transmittal	
Application Number:	11112865
Filing Date:	21-Apr-2005
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Filer:	William Alexander Furman/Marilyn Morris
Attorney Docket Number:	036302-010201
Filed as Large Entity	

Utility under 35 USC 111(a) Filing Fees

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

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Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

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Electronic Acknowledgement Receipt	
EFS ID:	9716052
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	William Alexander Furman/Marilyn Morris
Filer Authorized By:	William Alexander Furman
Attorney Docket Number:	036302-010201
Receipt Date:	22-MAR-2011
Filing Date:	21-APR-2005
Time Stamp:	19:03:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	5473
Deposit Account	502775
Authorized User	
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)	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		036301-010201-Amendment-AF-IDS.pdf	425053 dc06180fe5e2e7fac9bb06303fae00eb17b58d5e	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment After Final	1	1
Claims	2	3
Applicant Arguments/Remarks Made in an Amendment	4	6
Transmittal Letter	7	9
Information Disclosure Statement (IDS) Filed (SB/08)	10	10

Warnings:

Information:

2	Foreign Reference	CN2472682Y.pdf	294009 3ade78abe57b2dd7a8d9b1ddac2dfa0b8508883d	no	10

Warnings:

Information:

3	NPL Documents	EP-Search-3-4-10.pdf	223207 0cb8e66594e30a7e41531a769cbff6dfa2000403	no	7

Warnings:

Information:

4	Fee Worksheet (PTO-875)	fee-info.pdf	29937 c792b946d24ecbe372b3812103fc7316db42d819	no	2

Warnings:

Information:

Total Files Size (in bytes):	972206

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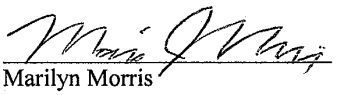
New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3775
Kenneth A. Gall et al.	Examiner: Ramana, Anuradha
Serial No.: 11/112,865	
Filed: April 21, 2005	**RESPONSE TO FINAL OFFICE ACTION MAILED JANUARY 24, 2011**
Confirmation No.: 5339	
Atty. File No.: 036302-010201	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on March 22, 2011.
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	Signed:  Name: Marilyn Morris

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

Dear Sir:

This correspondence is responsive to the Final Office Action having a mailing date of January 24, 2011.

A listing of the Claims begins on Page **2** of this paper.

Remarks begin on Page **4** of this paper.

It is not believed that any additional fees are due in connection with this correspondence. However, any necessary additional fees may be charged to Deposit Account No. 502775.

PETITIONER ARTHREX
EX. 1004

Amendments to the Claims

This Listing of Claims will replace all prior versions, and listings, of claims in the application:

1-46. (Cancelled)

47. (Previously Presented) A method, comprising:

inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;

wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis;

after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and

wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

48. (Previously Presented) The method of claim 47, wherein stretching the bone device is performed with the bone device substantially in an austenitic phase.

49. (Previously Presented) The method of claim 47, further comprising:

before performing the stretching, fixing the bone device to the first bone fragment.

50. (Cancelled)

51. (Previously Presented) The method of claim 47, further comprising:

PETITIONER ARTHREX
EX. 1004

holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching is performed.

52. (New) The method of claim 49, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed.

53. (New) The method of claim 47, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.

54. (New) The method of claim 47, wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase.

55. (New) The method of claim 47, wherein inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase.

56. (New) The method of claim 47, wherein the first portion comprises the shape memory alloy.

57. (New) The method of claim 47, wherein the second portion comprises the shape memory alloy.

PETITIONER ARTHREX
EX. 1004

REMARKS

This correspondence is responsive to the Office Action of January 24, 2011. Before amendment herein, Claims 27-35, 37-38, 47-49 and 51 were pending. By amendment herein, Applicant has cancelled Claims 27-35, 37-38 without prejudice. Applicant has also added new dependent Claims 52-57, each depending from allowable independent claim 47. Thus, Claims 47-49 and 51-57 are now pending in the application.

In the Office Action of January 24, 2011, the Examiner allowed Claims 47-49 and 51. By amendment herein, the only pending claims are these allowed Claims 47-49 and 51 and the newly-added dependent Claims 52-57 which all depend from allowed Claim 47. Newly-added dependent Claims 52-57 correspond to previously pending Claims 33, 34, 28, 29, 37 and 38 respectively and have been re-written to depend from Claim 47.

Support for the newly-added dependent Claims 52-57 was previously presented for Claims 33, 34, 28, 29, 37 and 38 and these claims each find support in the specification at least as shown below.

52. (New) The method of claim 49, further comprising: holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed.	Body temperature will be the surrounding temperature of the osteosynthetic device after the device is inserted into the patient. Para. [0034] states "In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature." Para. [0052] states "The PE (pseudo elastic) state is observed when T_a (the surrounding temperature) is greater than T_t (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. Skilled artisans recognize the austenite finish temperature as the transition temperature (T_t) of shape memory alloys for the purposes of creating pseudo-elastic behavior. Namely, the austenite finish temperature is the temperature at/above which the alloy "finishes" its transformation to the austenite phase and at/above which the only existing martensitic phase must be a stress-induced martensitic phase.
53. (New) The method of claim 47, further comprising: holding the	See directly above.

PETITIONER ARTHREX
EX. 1004

responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.	
54. (New) The method of claim 47, wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase.	Para. [0035] states the "Superelastic effect of Nitinol refers to the return to its pre-set austenite configuration upon unloading after elastic deformation. The initiation of superelastic behavior of Nitinol requires the formation of stress induced martensite (SIM) from the austenite phase, such as by the application of an external load or stress. Reduction of the external load or stress induces formation of the austenite phase and hence its pre-set configuration." Para. [0037] states "Formation of SIM [stress-induced martensitic] phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement." Thus, in one embodiment, SIM is not present prior to inserting of the nail, which may be just one portion of surgical placement of a nail, e.g., hammering or otherwise driving the nail. *See* Para. [0049].
55. (New) The method of claim 47, wherein inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase.	See directly above.
56. (New) The method of claim 47, wherein the first portion comprises the shape memory alloy.	Para. [0047] states "In one embodiment, a bone fixation rod or nail 800 has a first end 810 and a second end 812, with a middle section 814 disposed therebetween. In one embodiment, some or all of rod 800 comprises a shape memory alloy...."
57. (New) The surgical method of claim 47, wherein the second portion comprises the shape memory alloy.	See directly above.

Applicant respectfully submits that all pending Claims are allowable, including new Claims depending from allowed Claim 47, and such action is respectfully requested. This Response is believed to be responsive to each issue raised in the Office Action. If the

PETITIONER ARTHREX
EX. 1004

Examiner believes that it would be helpful to discuss any of the amendments or remarks presented herein, the Examiner is invited to contact the undersigned at the telephone number provided.

It is not believed that any additional fees are due in connection with this response. However, any necessary fees may be charged to Deposit Account No. 502775.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date: March 22, 2011

Wm. Alex Furman, Reg. No. 61,313
1200 17th Street, Suite 2400
Denver, CO 80202
Phone: (303) 572-6500
Fax: (303) 572-6540

PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth A. Gall et al.	Examiner:	Ramana, Anuradha
Serial No.:	11/112,865	Group Art Unit:	3775
Filed:	April 21, 2005	Docket No.	036302-010201
Title:	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE		
Customer No.:	37705	Confirmation No.:	5339

CERTIFICATE OF TRANSMISSION

I hereby certify that this document is being transmitted electronically to the United States Patent and Trademark Office via the EFS Web e-Filing system on March 22, 2011.

Name: Marilyn Morris

INFORMATION DISCLOSURE STATEMENT [37 C.F.R. § 1.56]

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Sir/Madam:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicant brings the references listed on the attached Form to the examiner's attention. 37 C.F.R. § 1.56. Do not construe the filing of this information disclosure statement as a representation that applicant has made a search (37 C.F.R. § 1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists. We enclose copies of any cited foreign documents. Copies of the U.S. references are not enclosed.

This Information Disclosure Statement is being submitted:

☐ 1. Within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d), or within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or before the mailing date of a first Office action on the merits; or before the mailing of a first Office action after

the filing of a request for continued examination under § 1.114; and therefore, Applicant believes no fee is required;

☐ 2. After the period specified in paragraph (1) above of this section, but before the mailing date of either a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311, whichever occurs first, and is accompanied by either:

☐ a. A statement that:

(i) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months before the filing of the information disclosure statement; or

(ii) 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 statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months before the filing of the information disclosure statement; or

☐ b. The fee for filing an Information Disclosure Statement under 37 C.F.R. § 1.17(p) is $180.00.

☒ 3. After the period specified in paragraph (2) of this section, but on or before payment of the issue fee and is accompanied by:

☐ a. A statement that:

(i) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months before the filing of the information disclosure statement; or

PETITIONER ARTHREX
EX. 1004

(ii) 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 statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months before the filing of the information disclosure statement;

☒ b. The fee set forth in 37 C.F.R. § 1.17(i).

Applicant would appreciate the examiner initialing and signing a copy of attached Form SB-08 indicating that he or she considered the information and made the information of record.

If the transmittal letter is separated from this document and the PTO determines that an extension or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 50-2775.

Authorization is hereby given to charge any fees due, or credit any overpayment of fees, to Deposit Account No. 50-2775.

Respectfully submitted,

Date: March 22, 2011

Wm. Alex Furman
Reg. No. 61,313

Customer Number 37705
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PETITIONER ARTHREX
EX. 1004

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,865	04/21/2005	

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	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 03/22/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

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

Legal Instrument Examiner:
/CHERYL CLARK/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PETITIONER ARTHREX
EX. 1004

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.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

37705 7590 01/24/2011

GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

NOTIFICATION DATE	DELIVERY MODE
01/24/2011	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):

denipmail@gtlaw.com
clairt@gtlaw.com
cadanoc@gtlaw.com

PTOL-90A (Rev. 04/07)

PETITIONER ARTHREX
EX. 1004

Office Action Summary	Application No.	Applicant(s)	
	11/112,865	GALL ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3775	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *19 August 2010*.

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

3)☐ 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

4)☒ Claim(s) *27-35,37,38,47-49 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *47-49 and 51* is/are allowed.

6)☒ Claim(s) *27-35,37 and 38* is/are rejected.

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

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

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

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

Claims 27-35, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 27, Applicant's disclosure, as originally filed, does not provide support for the method steps of "fixing a first portion of the intramedullary nail to the first bone element; after fixing the first portion, creating a stress-induced martensitic phase in a responsive portion of the intramedullary nail, ...; and after creating the stress-induced martensitic phase, fixing a second portion of the intramedullary nail to the second bone element of the patient, wherein the responsive portion is disposed between the first portion and the second portion."

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive with respect to the rejections under 35 USC 112 first paragraph.

Applicant's arguments are directed to mixing features of various embodiments, resulting in an embodiment not supported by Applicant's disclosure, as originally filed. It is the Examiner's position that Applicant's disclosure as originally filed, including now cancelled claim 23, provides support for the claimed method steps with an elongate element, not an intramedullary nail.

**PETITIONER ARTHREX
EX. 1004**

Allowable Subject Matter

Claims 47-49 and 51 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

PETITIONER ARTHREX
EX. 1004

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.

AR
January 18, 2011

/Anu Ramana/
Primary Examiner, Art Unit 3775

**PETITIONER ARTHREX
EX. 1004**

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	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	09/14/2009	02/16/2010	01/18/2011						
	1	-	-	-						
	2	-	-	-						
	3	-	-	-						
	4	-	-	-						
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	8	-	-	-						
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	25	-	-	-						
	26	-	-	-						
	27	÷	✓	✓						
	28	÷	✓	✓						
	29	÷	✓	✓						
	30	÷	✓	✓						
	31	÷	✓	✓						
	32	÷	✓	✓						
	33	÷	✓	✓						
	34	÷	✓	✓						
	35	÷	✓	✓						
	36	÷	✓	-						

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	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	09/14/2009	02/16/2010	01/18/2011						
	37	÷	✓	✓						
	38	÷	✓	✓						
	39	÷	-	-						
	40	÷	-	-						
	41	÷	-	-						
	42	÷	-	-						
	43	÷	-	-						
	44	÷	-	-						
	45	÷	-	-						
	46	÷	-	-						
	47	÷	✓	=						
	48	÷	✓	=						
	49	÷	✓	=						
	50	÷	✓	-						
	51	÷	✓	=						
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	62	÷	-	-						
	63	÷	-	-						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	**Art Unit**
	Anu Ramana	3775

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**
606	60, 62, 63, 300, 301, 308, 320	2/15/2010	A. Ramana

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Conducted a search in the EAST database. See attached search report.	2/15/2010	A. Ramana
Conducted an inventor name search in PALM.	2/15/2010	A. Ramana
Updated search.	1/18/2011	A. Ramana

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (07-09)
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PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)	Docket Number (Optional) 036302-010201

First named inventor: Kenneth A. Gall

Application No.: 11/112,865 Art Unit: 3775

Filed: April 21, 2005 Examiner: Ramana, Anuradha

Title: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional

1. Petition Fee

☐ Small entity-fee $_____(37 CFR 1.17(m)). Application claims small entity status. See 37 CFR 1.27.

☑ Other than small entity-fee $ 1,620 (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of Response to Non-Final Office Action (identify type of reply):

☐ has been filed previously on _____.

☑ is enclosed herewith.

Adjustment date: 10/01/2010 CKHLOK
08/19/2010 INTEFSU 00010424 502775 11112865
02 FC:1253 1110.00 CR

B. The issue fee and publication fee (if applicable) of $_____.

☐ has been paid previously on _____.

☐ is enclosed herewith.

This collection of information is required by 37 CFR 1.137(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 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. Terminal disclaimer with disclaimer fee

☑ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $_____for a small entity or $_____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

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.

/Wm. Alex Furman/	August 19, 2010
Signature	Date
Wm. Alex Furman	61,313
Type or Printed name	Registration Number, If applicable
1200 17th Street, Suite 2400	303-572-6500
Address	Telephone Number
Denver, CO 80202	
Address	

Enclosures:

☑ Fee Payment

☑ Reply

☐ Terminal Disclaimer Form

☐ Additional sheets containing statements establishing unintentional delay

☐ Other: _____

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

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August 19, 2010	/Wm. Alex Furman/
Date	Signature
	Wm. Alex Furman
	Typed or printed name of person signing certificate

UNITED STATES PATENT & TRADEMARK OFFICE
Washington, D.C. 20231

REQUEST FOR PATENT FEE REFUND

1 Date of Request: 09/28/10	2 Serial/Patent # 11/112,865

	3 Please refund the following fee(s):	4 PAPER NUMBER	5 DATE FILED	6 AMOUNT
	Filing			$
	Amendment			$
X	Extension of Time	PET.OP	08/19/10	$ 1,110.00
	Notice of Appeal/Appeal			$
	Petition			$
	Issue			$
	Cert of Correction/Terminal Disc.			$
	Maintenance			$
	Assignment			$
	Other			$

7 TOTAL AMOUNT OF REFUND: $ 1,110.00

8 TO BE REFUNDED BY:

	Treasury Check
X	Credit Deposit A/C #:

9 5 0 -- 2 7 7 5

10 REASON:

	Overpayment
	Duplicate Payment
X	No Fee Due (Explanation):

Extension of time unnecessary, no fee due.

11 REFUND REQUESTED BY:

TYPED/PRINTED NAME: Diane Goodwyn TITLE: Paralegal

SIGNATURE: /dgoodwyn/ PHONE: 571-272-6735

OFFICE: Petitions

****

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APPROVED: [signature] DATE: 10/1/10

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Crystal Park One, Room 802B

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(01/90)

PETITIONER ARTHREX
EX. 1004

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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www.uspto.gov

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OCT 01 2010

OFFICE OF PETITIONS

GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET,
SUITE 2400
DENVER CO 80202

In re Application of	:	
Kenneth A. GALL, et al	:	
Application No. 11/112,865	:	DECISION ON PETITION
Filed: April 21, 2005	:	
Attorney Docket No. 036302-010201	:	

This is a decision on the renewed petition under the unintentional provisions of 37 CFR 1.137(b), filed August 19, 2010, to revive the above-identified application.

The petition is **GRANTED**.

The application became abandoned for failure to reply in a timely manner to the non-final Office action mailed, February 18, 2010, which set a shortened statutory period for reply of three (3) months. No extensions of time under the provisions of 37 CFR 1.136(a) were obtained. Accordingly, the application became abandoned on May 19, 2010.

The petition satisfies the requirements of 37 CFR 1.137(b) in that petitioner has supplied (1) the reply in the form of an amendment; (2) the petition fee of $1620; and (3) a proper statement of unintentional delay.

An extension of time under 37 CFR 1.136 must be filed prior to the expiration of the maximum extendable period for reply. *See* In re Application of S., 8 USPQ2d 1630, 1631 (Comm'r Pats. 1988). Since the $1110 extension of time fee submitted with the petition on August 19, 2010, was subsequent to the maximum extendable period for reply, this fee is unnecessary and will be credited to petitioner's Deposit Account .No. 50-2775.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-6735.

This application is being referred to Technology Center AU 3775 for appropriate action by the Examiner in the normal course of business.

/DCG/
Diane C. Goodwyn
Petitions Examiner
Office of Petitions

PETITIONER ARTHREX
EX. 1004

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (07-09)
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First named inventor: Kenneth A. Gall

Application No.: 11/112,865 Art Unit: 3775

Filed: April 21, 2005 Examiner: Ramana, Anuradha

Title: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

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☐ has been filed previously on _____.

☑ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of $ _____.

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/Wm. Alex Furman/	August 19, 2010
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Wm. Alex Furman	61,313
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Denver, CO 80202	
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August 19, 2010	/Wm. Alex Furman/
Date	Signature
	Wm. Alex Furman
	Typed or printed name of person signing certificate

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.

PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)	Group Art Unit: 3775
	)	
Kenneth A. Gall et al.	)	Examiner: Ramana, Anuradha
	)	
Serial No.: 11/112,865	)	
	)	**RESPONSE TO NON-FINAL OFFICE ACTION MAILED FEBRUARY 18, 2010**
Filed: April 21, 2005	)	
	)	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on August 19, 2010.
Confirmation No.: 5339	)	
	)	
Atty. File No.: 036302-010201	)	
	)	
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	)	Signed: /Wm. Alex Furman/ Name: Wm. Alex Furman
	)	

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

Dear Sir:

This correspondence is responsive to the Non-Final Office Action having a mailing date of February 18, 2010.

A listing of the Claims begins on Page **2** of this paper.

Remarks begin on Page **5** of this paper.

The due date for responding to the Office Action was May 18, 2010. Applicant hereby requests a three-month extension of time to respond, thereby extending the due date for filing a response to August 18, 2010. Please charge the extension fee of $1,110 to Deposit Account No. 502775. This Amendment and Response is accompanied by a Petition for Revival under CFR 1.137(b) due to the entire delay between August 18, 2010 and August 19, 2010 being unintentional. The required fee for the Petition of $1,620 is also included. It is not believed that any additional fees are due in connection with this correspondence. However, any necessary additional fees may be charged to Deposit Account No. 502775.

PETITIONER ARTHREX
EX. 1004

Amendments to the Claims

This Listing of Claims will replace all prior versions, and listings, of claims in the application:

1-26. (Cancelled)

27. (Currently amended) A surgical method, comprising:

creating a first cavity in a first bone element of a patient;

creating a second cavity in a second bone element in the patient;

inserting an intramedullary ~~intermedullary~~ nail into the second cavity;

inserting the intramedullary ~~intermedullary~~ nail into the first cavity;

fixing a first portion of the intramedullary ~~intermedullary~~ nail to the first bone element of the patient;

after fixing the first portion, creating a stress-induced martensitic phase in a ~~into a~~ responsive portion of the intramedullary ~~intermedullary~~ nail, wherein the responsive portion comprises a shape memory alloy; and

after creating ~~inducing~~ the stress-induced martensitic phase, fixing a second portion of the intramedullary ~~intermedullary~~ nail to the second bone element of the patient, wherein the responsive portion is disposed between the first portion and the second portion.

28. (Currently amended) The surgical method of claim 27, wherein inserting the intramedullary ~~intermedullary~~ nail into the second cavity is performed while the responsive portion is substantially in an austenitic phase.

29. (Currently amended) The surgical method of claim 27, wherein inserting the intramedullary ~~intermedullary~~ nail into the first cavity is performed while the responsive portion is substantially in an austenitic phase.

30. (Previously presented) The surgical method of claim 27, wherein creating the stress-induced martensitic phase is performed by straining the responsive portion.

PETITIONER ARTHREX
EX. 1004

31. (Previously presented) The surgical method of claim 30, wherein straining is performed by applying a stress between the first portion and the second portion.

32. (Currently amended) The surgical method of claim 27, further comprising:

holding the responsive portion above an austenite finish temperature of the shape memory alloy while the creating the stress-induced martensitic phase is performed.

33. (Previously presented) The surgical method of claim 32, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while fixing the first portion is performed.

34. (Previously presented) The surgical method of claim 33, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.

35. (Previously presented) The surgical method of claim 27, wherein the shape memory alloy is an alloy including nickel and titanium.

36. (Cancelled)

37. (Previously presented) The surgical method of claim 27, wherein the first portion comprises the shape memory alloy.

38. (Previously presented) The surgical method of claim 27, wherein the second portion comprises the shape memory alloy.

39-46. (Cancelled)

47. (Currently amended) A method, comprising:

inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;

PETITIONER ARTHREX
EX. 1004

wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

~~after inserting the bone device,~~ creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis;

after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and

wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

48. (Currently amended) The method of claim 47, wherein stretching ~~inserting~~ the bone device is performed with the bone device substantially in an austenitic phase.

49. (Previously presented) The method of claim 47, further comprising:

before performing the stretching, fixing the bone device to the first bone fragment.

50. (Cancelled)

51. (Currently amended) The method of claim 47, further comprising:

holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching ~~inserting~~ is performed.

PETITIONER ARTHREX
EX. 1004

REMARKS

This correspondence is responsive to the Office Action of February 18, 2010. Before amendment herein, Claims 27-38 and 47-51 were pending. By amendment herein, Applicant has cancelled Claims 36 and 50 without prejudice. Thus, Claims 27-35, 37-38, 47-49 and 51 are now pending in the application.

Claim Objections - Claims 27-29

The Examiner objected to Claims 27-29 as each containing a typographical error of reciting "intermedullary" rather than "intramedullary". Applicant appreciates the Examiner's discovery of this error and, by amendment herein, Applicant has corrected this typographical error.

Claim Rejections - - 35 U.S.C. § 102(b)

The Examiner rejected Claims 47-49 as anticipated by Campbell et al. (US Pat. 5,425,660). Campbell does not anticipate Claim 50 because it does not teach the limitation "after performing the stretching, fixing the second portion of the bone device to the second bone fragment." Applicant has rewritten the limitation of Claim 50 into the amended Claim 47. Applicant submits that Claims 47-49 are in condition for allowance as written.

Claim Rejections - 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 27-38 and 47-51 as failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Claims 36 and 50 have been cancelled without prejudice, rendering further discussion moot. A detailed chart illustrating support for Claims 27-35, 37-38, 47-49 and 51 is provided further below.

Claims 27-35, 37-38, 47-49 and 51 find at least the following exemplary support in the specification, with references to specification paragraphs and figures as shown in the published application:

Claim/Limitation	Exemplary Support:
1-26. (Cancelled).	
27. (Currently Amended) A surgical method, comprising: creating a first cavity in a first bone element of a patient;	Para. [0049] states "As shown in FIG. 8, rod or nail 800 is inserted into a bone 850. Rod 800 insertion occurs, in one embodiment, by reaming the bone's medullary canal, and hammering or otherwise

PETITIONER ARTHREX
EX. 1004

creating a second cavity in a second bone element in the patient; inserting an intramedullary ~~intermedullary~~ nail into the second cavity; inserting the intramedullary ~~intermedullary~~ nail into the first cavity;	driving nail 800 into place." Reaming the medullary canal in the bones of joint 860 and driving the nail, inherently discloses creating a first and second cavity and then inserting the intramedullary nail. Furthermore, Fig. 8 shows an intramedullary nail after insertion in at least two cavities in two bone elements of the joint 860.
fixing a first portion of the intramedullary ~~intermedullary~~ nail to the first bone element of the patient;	Para. [0049] states "Nail 800 then may be locked relative to the bone with one or more interference screws." These interference screws are shown in Fig. 8 as screws 820.
after fixing the first portion, creating a stress-induced martensitic phase in a ~~into a~~ responsive portion of the intramedullary ~~intermedullary~~ nail, wherein the responsive portion comprises a shape memory alloy; and	Para. [0037] states "Formation of SIM [stress-induced martensitic] phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement." Para. [0039] states "In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in FIG. 2B." This elongation is indicated by the arrows parallel to the longitudinal axis in Fig. 2B. The depicted stretching/elongation of the shank creates the stress-induced martensitic phase and occurs after the screw head is fixed in the first portion of bone and while the screw threads are

PETITIONER ARTHREX
EX. 1004

	driven into the second portion of bone. Para. [0050] states "In some embodiments, nail or rod 800 is designed to allow for the release of the responsive element or zone portion thereof, allowing the rod or nail 800 to shorten. This is accomplished, at least in part, by having the responsive zone of rod 800 comprise a shape memory alloy such as Nitinol as described above in conjunction with screw 300."
after creating ~~inducing~~ the stress-induced martensitic phase, fixing a second portion of the intramedullary ~~intermedullary~~ nail to the second bone element of the patient,	Para. [0049] states "Nail 800 then may be locked relative to the bone with one or more interference screws."
wherein the responsive portion is disposed between the first portion and the second portion.	Para. [0047] states "In one embodiment, a bone fixation rod or nail 800 has a first end 810 and a second end 812, with a middle section 814 disposed therebetween…. For example, in one embodiment, middle section 814 is a responsive zone…."
28. (Currently amended) The surgical method of claim 27, wherein inserting the intramedullary ~~intermedullary~~ nail into the second cavity is performed while the responsive portion is substantially in an austenitic phase.	Para. [0035] states the "Superelastic effect of Nitinol refers to the return to its pre-set austenite configuration upon unloading after elastic deformation. The initiation of superelastic behavior of Nitinol requires the formation of stress induced martensite (SIM) from the austenite phase, such as by the application of an external load or stress. Reduction of the external load or stress induces formation of the austenite phase and hence its pre-set configuration." Para. [0037] states "Formation

PETITIONER ARTHREX
EX. 1004

	of SIM [stress-induced martensitic] phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement." Thus, in one embodiment, SIM is not present prior to inserting of the nail, which may be just one portion of surgical placement of a nail, e.g., hammering or otherwise driving the nail. *See* Para. [0049].
29. (Currently amended) The surgical method of claim 27, wherein inserting the intramedullary ~~intermedullary~~ nail into the first cavity is performed while the responsive portion is substantially in an austenitic phase.	See Claim 28 above.
30. (Previously presented) The surgical method of claim 27, wherein creating the stress-induced martensitic phase is performed by straining the responsive portion.	Para. [0035] states "The initiation of superelastic behavior of Nitinol requires the formation of stress induced martensite (SIM) from the austenite phase, such as by the application of an external load or stress." Furthermore, FIGS. 9A and 9B show exemplary stress-strain relationships of a shape memory alloy exhibiting pseudo elastic behavior due to the creation of a stress-induced martensitic phase.
31. (Previously presented) The surgical method of claim 30, wherein straining is performed by applying a stress between the first portion and the second portion.	See Claim 30 above.

PETITIONER ARTHREX
EX. 1004

32. (Currently amended) The surgical method of claim 27, further comprising: holding the responsive portion above an austenite finish temperature of the shape memory alloy while the creating the stress-induced martensitic phase is performed.	Body temperature will be the surrounding temperature of the osteosynthetic device after the device is inserted into the patient. Para. [0034] states "In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature." Para. [0052] states "The PE (pseudo elastic) state is observed when T_a (the surrounding temperature) is greater than T_t (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. Skilled artisans recognize the austenite finish temperature as the transition temperature (T_t) of shape memory alloys for the purposes of creating pseudo-elastic behavior. Namely, the austenite finish temperature is the temperature at/above which the alloy "finishes" its transformation to the austenite phase and at/above which the only existing martensitic phase must be a stress-induced martensitic phase.
33. (Previously presented) The surgical method of claim 32, further comprising: holding the responsive portion above the austenite finish temperature of the shape memory alloy while fixing the first portion is performed.	See directly above.
34. (Previously presented) The	See Claim 32 above.

PETITIONER ARTHREX
EX. 1004

surgical method of claim 33, further comprising: holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.	
35. (Previously presented) The surgical method of claim 27, wherein the shape memory alloy is an alloy including nickel and titanium.	Para. [0047] states "This is accomplished, at least in part, by having the responsive zone of rod 800 comprise a shape memory alloy such as Nitinol." Nitinol is known to be an alloy including nickel and titanium. Para. [0034] states "In a particular embodiment, bone screw 100 is formed from nickel titanium, a shape memory alloy referred to as Nitinol."
36. (Cancelled)	
37. (Previously presented) The surgical method of claim 27, wherein the first portion comprises the shape memory alloy.	Para. [0047] states "In one embodiment, a bone fixation rod or nail 800 has a first end 810 and a second end 812, with a middle section 814 disposed therebetween. In one embodiment, some or all of rod 800 comprises a shape memory alloy…."
38. (Previously presented) The surgical method of claim 27, wherein the second portion comprises the shape memory alloy.	See directly above.
39-46. (Cancelled)	
47. (Currently amended) A method, comprising:	Para. [0038] states "As shown in Fig. 2A, bone screw 100 is inserted at an angle relative to a

PETITIONER ARTHREX
EX. 1004

inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;	fracture site 210. Screw 100 is rotated to draw the two bone fragments 220 towards one another, creating a compressive force therebetween." Furthermore, Fig. 2A shows a bone device with a first portion contacting a first bone fragment and a second portion contacting a second bone fragment, the second portion different from the first portion. Para. [0049] states "As shown in FIG. 8, rod or nail 800 is inserted into a bone 850. Rod 800 insertion occurs, in one embodiment, by reaming the bone's medullary canal, and hammering or otherwise driving nail 800 into place." Furthermore, Fig. 8 shows an intramedullary nail after insertion in at least two cavities in two bone elements of the joint 860.
wherein the bone device comprises a shape memory alloy having an austenite finish temperature;	An austenite finish temperature is a property of a shape memory alloy, see Para. [0062] and discussion related to Claim 32 above.
~~after inserting the bone device,~~ creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis;	Para. [0037] states "Formation of SIM [stress-induced martensitic] phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement." Para. [0039] states "In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in FIG. 2B." This elongation is indicated by the arrows parallel to the longitudinal axis in Fig. 2B. The depicted stretching/elongation of the shank creates the stress-induced martensitic phase.

PETITIONER ARTHREX
EX. 1004

after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and	Para. [0039] states "In one embodiment, the elongation of shank portion 110 occurs during the insertion process, as depicted in FIG. 2B." Fig. 2B shows stretching/elongation due to turning the screw. Fig. 2C shows the second portion of the bone device (e.g., the threaded end) in the fixed position after the stretching/elongation of the shank has completed.
wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.	Body temperature will be the surrounding temperature of the osteosynthetic device after the device is inserted into the patient. Para. [0034] states "In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature." Para. [0052] states "The PE (pseudo elastic) state is observed when T_a (the surrounding temperature) is greater than T_t (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. Skilled artisans recognize the austenite finish temperature as the transition temperature (T_t) of shape memory alloys for the purposes of creating pseudo-elastic behavior. Namely, the austenite finish temperature is the temperature at/above which the alloy "finishes" its transformation to the austenite phase and at/above which the only existing martensitic phase must be a stress-induced martensitic phase.
48. (Currently amended) The	Body temperature will be the surrounding

PETITIONER ARTHREX
EX. 1004

method of claim 47, wherein stretching ~~inserting~~ the bone device is performed with the bone device substantially in an austenitic phase.	temperature of the osteosynthetic device after the device is inserted into the patient. Para. [0034] states "In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature." Para. [0052] states "The PE (pseudo elastic) state is observed when T_a (the surrounding temperature) is greater than T_t (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. Skilled artisans recognize the austenite finish temperature as the transition temperature (T_t) of shape memory alloys for the purposes of creating pseudo-elastic behavior. Namely, the austenite finish temperature is the temperature at/above which the alloy "finishes" its transformation to the austenite phase and at/above which the only existing martensitic phase must be a stress-induced martensitic phase.
49. (Previously presented) The method of claim 47, further comprising: before performing the stretching, fixing the bone device to the first bone fragment.	Para. [0039] states "In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in FIG. 2B." For example, in FIGS. 2A and 2B, the depicted stretching/elongation of the shank creates the stress-induced martensitic phase and occurs after the screw head is fixed in the first portion of bone while the screw threads of the bone device are driven into the second portion of bone.

PETITIONER ARTHREX
EX. 1004

50. (Cancelled)	
51. (Currently amended) The method of claim 47, further comprising: holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching ~~inserting~~ is performed.	See Claim 48 above.

In light of the above amendments and remarks, Applicant respectfully submits that all pending claims are in condition for allowance, and such action is respectfully requested. This Response is believed to be responsive to each issue raised in the Office Action. If the Examiner believes that it would be helpful to discuss any of the amendments or remarks presented herein, the Examiner is invited to contact the undersigned at the telephone number provided.

It is not believed that any additional fees are due in connection with this response. However, any necessary fees may be charged to Deposit Account No. 502775.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date: August 19, 2010

/Wm. Alex Furman/

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Fax: (303) 572-6540

PETITIONER ARTHREX
EX. 1004

Electronic Patent Application Fee Transmittal	
Application Number:	11112865
Filing Date:	21-Apr-2005
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Filer:	William Alexander Furman
Attorney Docket Number:	036302-010201
Filed as Large Entity	

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition-revive unintent. abandoned appl	1453	1	1620	1620
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

PETITIONER ARTHREX
EX. 1004

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	1253	1	1110	1110
Miscellaneous:				
		Total in USD ($)		**2730**

PETITIONER ARTHREX
EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	8250471
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	William Alexander Furman
Filer Authorized By:	
Attorney Docket Number:	036302-010201
Receipt Date:	19-AUG-2010
Filing Date:	21-APR-2005
Time Stamp:	12:31:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2730
RAM confirmation Number	10424
Deposit Account	502775
Authorized User	
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)	

PETITIONER ARTHREX
EX. 1004

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	Petition for review by the Office of Petitions.	sb0064.pdf	355070 4b473e68aaef98bc05e92493003144c926728eed	no	3
Warnings:					
Information:					
2		036302-010201-Response-filed-with-petition-Aug-19.pdf	128672 abbc4c598061356da74a18189368b6fb9dacb57b	yes	14

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	4
Applicant Arguments/Remarks Made in an Amendment	5	14

Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	31629 02e736d93c2c9d5058daff3fd79a7c812a31ee23	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	515371		

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.

PETITIONER ARTHREX
EX. 1004

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,865	04/21/2005	

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	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	08/19/2010	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 15	Minus	** 37	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***4	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KIMBERLY COOPER/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

37705 7590 02/18/2010

GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	
MAIL DATE	DELIVERY MODE
02/18/2010	PAPER

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

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

PTOL-90A (Rev. 04/07)

PETITIONER ARTHREX
EX. 1004

Office Action Summary	Application No.	Applicant(s)	
	11/112,865	GALL ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3775	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *15 October 2009*.

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

3)☐ 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

4)☒ Claim(s) *27-38 and 47-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-38 and 47-51* is/are rejected.

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

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2009* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/26/09;12/8/08;10/28/08;8/24/07;5/07/07;9/15/06;8/22/05

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the invention of Group I (claims 27-38 and 47-51) in the reply filed on 10/15/09 is acknowledged. Accordingly, claims 27-38 and 47-51 have been examined on the merits in this office action.

Claim Objections

Claims 27-29 are objected to because of the following informalities. In the claims, "intermedullary" should be - - intramedullary - - to correct a minor typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

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

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

Claims 27-38 and 47-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's disclosure, as originally filed, does not describe the method steps of claims 27-30, 32 and 33-34.

Regarding claim 36, Applicant's disclosure, as originally filed, does not provide support for the recitation "contains substantially only nickel and titanium."

Regarding claim 47, Applicant's disclosure, as originally filed, does not provide support for the steps "after inserting the bone device, creating in a responsive portion of the bone device at least a partial transformation into a

PETITIONER ARTHREX
EX. 1004

stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis; and wherein the creating is performed at a temperature greater than the austenitic finish temperature of the shape memory alloy."

Regarding claim 48, Applicant's disclosure, as originally filed, does not provide support for the step "wherein inserting the bone device is performed with the bone device substantially in an austenitic phase."

Regarding claim 49, Applicant's disclosure, as originally filed, does not provide support for "before performing the stretching, fixing the bone device to the first bone fragment."

Regarding claim 50, Applicant's disclosure, as originally filed, does not provide support for "after performing the stretching, fixing the second portion of the bone device to the second bone fragment."

Regarding claim 51, Applicant's disclosure, as originally filed, does not provide support for "holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the inserting is performed."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al. (US 5415660).

Campbell et al. disclose an intramedullary nail 25 for bone fixation wherein the nail has a drive mechanism 150 with a shape memory alloy. Campbell discloses a resistance wire that is wrapped around the shape memory driver and provides for shape recovery and expansion through heating of the shape

**PETITIONER ARTHREX
EX. 1004**

memory alloy. Initially, the shape memory driver is in a martensitic phase and upon subjection to heat the shape memory driver regains its original shape (Figs. 2A and 2B, col. 5, lines 24-60, col. 7, lines 23-68, col. 8 and col. 9, lines 1-33).

The method steps of claim 47-48 are inherently performed when the Campbell et al. device is used for bone fixation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

PETITIONER ARTHREX
EX. 1004

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.

AR
February 16, 2010

/Anu Ramana/
Primary Examiner, Art Unit 3775

PETITIONER ARTHREX
EX. 1004

Notice of References Cited	Application/Control No. 11/112,865	Applicant(s)/Patent Under Reexamination GALL ET AL.	
	Examiner Anu Ramana	Art Unit 3775	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,415,660	05-1995	Campbell et al.	606/62
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
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	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302.010201	Application Number 11/112,865
	Applicant(s) Gall et al.	
	Filing Date Apr. 21, 2005	Group Art Unit 3733

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	5,505,734	Caniggia, et al.	Apr. 9, 1996	606	63	
	2	2005/0107791	Manderson, E.	May 19, 2005	606	62	

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
	3	DE19708279 (machine translation)	Sept. 10, 1998	Germany			X	
	4	WO2005/094705	Oct. 13, 2005	WIPO				
	5	WO1995/24870 (machine translation)	Sept. 21, 1995	WIPO			X	

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

EXAMINER	DATE CONSIDERED
/Anuradha Ramana/	02/16/2010

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

SHEET 1 OF 1

DEN 96,766,409v1 1-26-09

PETITIONER ARTHREX EX. 1004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Kenneth Gall et al.	
	Filing Date: April 21, 2005	Group Art Unit: 3733

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,056,322	06/06/2006	Davison et al.			
	6,986,774	01/17/2006	Middleman et al.			
	6,533,805	03/18/2003	Jervis			
	6,451,025	09/17/2002	Jervis			
	6,447,523	09/10/2002	Middleman et al.			
	6,306,141	10/23/2001	Jervis			
	6,004,330	12/21/1999	Middleman et al.			
	5,964,770	10/12/1999	Flomenblit et al.			
	5,904,690	05/18/1999	Middleman et al.			
	5,820,628	10/13/1998	Middleman et al.			
	5,749,879	05/12/1998	Middleman et al.			
	5,720,754	02/24/1998	Middleman et al.			
	5,632,746	05/27/1997	Middleman et al.			
	5,601,572	02/11/1997	Middleman et al.			
	5,597,378	01/28/1997	Jervis			
	5,486,183	01/23/1996	Middleman et al.			
	5,190,546	03/02/1993	Jervis			
	5,067,957	11/26/1991	Jervis			
	4,665,906	05/19/1987	Jervis			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 2006/120355	16 NOV 2006	PCT			X	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

EXAMINER	/Anuradha Ramana/	DATE CONSIDERED	02/16/2010

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PETITIONER ARTHREX
EX. 1004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Kenneth Gall et al.	
	Filing Date: April 21, 2005	Group Art Unit: 3733

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		English Translation of WO 2006/120355 (listed above)
		ANKLE ARTHRODESIS NAIL SURGICAL TECHNIQUE, Biomet, Inc., Form No. Y-BMT-596R/021500/H, ©2000 Biomet, Inc. Warsaw, IN
		PANTA™ Arthrodesis Nail. Datasheet [online]. Integra LifeSciences Corporation, 2006, [retrieved on 1/12/2007]. Retrieved from the Internet: <http://www.ilstraining.com/Mid%20%20Hindfoot%20Solutions/panta/panta_00.html>
		RETRONAIL ANKLE ARTHRODESIS ARTHRITIC DEFORMITY, FRACTURES, FAILED FUSION. Products [online]. ©2007 orthofix.com, [retrieved on 04/04/2007]. Retrieved from the Internet: <http://www.orthofix.com/products/retronail.asp?cid=5>
		T2™TIBIAL NAILING SYSTEM. Operative Technique. Stryker, pp. 1-31
		TIBIOTALOCALCANEAL NAILING SYSTEM OPTIONS MADE EASY. Surgical Technique. Stryker, 2006. pp.1-19

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

EXAMINER	/Anuradha Ramana/	DATE CONSIDERED	02/16/2010

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

PETITIONER ARTHREX
EX. 1004

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PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Gall, Kenneth A.
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

U.S. PATENT DOCUMENTS+

Examiner Initials*	Cite No.[1]	Document Number Number Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-2004/0230193	11-18-04	Cheung et al.	
	AB	US-			
	AC	US-			
	AD	US-			
	AE	US-			
	AF	US-			
	AG	US-			
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	AJ	US-			
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	AP	US-			
	AQ	US-			
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	AS	US-			
	AT	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	AU					☐
	AV					☐
	AW					☐
	AX					☐
	AY					☐
	AZ					☐
	BA					☐
	BB					☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

Examiner Signature	/Anuradha Ramana/	Date Considered	02/16/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] **Applicant's** unique citation designation number **(optional)**. [2] Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Unsaved Document

PETITIONER ARTHREX
EX. 1004

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	**Art Unit**
	Anu Ramana	3775

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**
606	60, 62, 63, 300, 301, 308, 320	2/15/2010	A. Ramana

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Conducted a search in the EAST database. See attached search report.	2/15/2010	A. Ramana
Conducted an inventor name search in PALM.	2/15/2010	A. Ramana

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	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	09/14/2009	02/16/2010							
	1	-	-							
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	34	÷	✓							
	35	÷	✓							
	36	÷	✓							

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	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	09/14/2009	02/16/2010							
	37	÷	✓							
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Attorney Docket No.: 036302-010201

INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Gall, et al.	
	Filing Date: 04/21/2005	Group Art Unit: 3732

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,688,828	02/10/2004	Post			
	6,637,995	10/28/2003	White			
	5,265,456	11/30/1993	Kennedy et al.			
	5,120,175	06/09/1992	Arbegast et al.			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Courtesy Copy of International Search Report, PCT/US06/15207
		El Feninat, Fatiha et al., *Shape Memory Materials for Biomedical Applications*, ADVANCED ENGINEERING MATERIALS 2002, 4, No. 3, pp. 83, 86, 91-104
		Gall, Ken et al., *Thermomechanics of the shape memory effect in polymers for biomedical applications*, 2005 WILEY PERIODICALS, INC., pp. 339-348
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		Lin, J. R. at al., *Study on Shape-Memory Behavior of Polyether-Based Polyurethanes. I. Influence of the Hard-Segment Content*, JOURNAL OF APPLIED POLYMER SCIENCE, Vol. 69, (1998), pp. 1563-1574

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

EXAMINER	/Anuradha Ramana/	DATE CONSIDERED	02/16/2010

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

PETITIONER ARTHREX
EX. 1004

Attorney Docket No.: 036302-010201

INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Gall, et al.	
	Filing Date: 04/21/2005	Group Art Unit: 3732

		Lin, J.R. et al., *Study on Shape-Memory Behavior of Polyether-Based Polyurethanes. II. Influence of Soft-Segment Molecular Weight*, JOURNAL OF APPLIED POLYMER SCIENCE, Vol. 69, (1998), pp. 1575-1586
		Liu, Changdeng et al., *Chemically Cross-Linked Polycyclooctene: Synthesis, Characterization, and Shape Memory Behavior*, MACROMOLECULES, 2002, 35, pp. 9868-9874
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		Metzger, Melodie F. et al., *Mechanical Properties of Mechanical Actuator for Treating Ischemic Stroke*, BIOMEDICAL MICRODEVICES, Vol. 4, No. 2, May 2002, pp. 89-96
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		Tobushi, H. et al., *Thermomechanical Constitutive Modeling in Shape Memory Polymer of Polyurethane Series*, JOURNAL OF INTELLIGENT MATERIAL SYSTEMS AND STRUCTURES, Vol. 8, Aug. 1997, pp. 711-718
		Tobushi, Hisaaki, et al., *Thermomechanical properties in a thin film of shape memory polymer of polyurethane series*, SMART MATER. STRUCT. 5 (1996), pp. 483-491
		Wache, H.M. et al., *Development of a polymer stent with shape memory effect as a drug delivery system*, JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE 14 (2003), pp. 109-112
		Yahia, L., (Ed.), *Shape Memory Implants*, SPRINGER-VERLAG BERLIN HEIDELBERG NEW YORK, 2000, (copy of complete book - out of print)
		Yakacki, Christopher M. et al., *Strong and Biocompatible Shape Memory Polymers for Soft Tissue Orthopedic Fixation*, Submitted to NATURE MATERIALS, 2006, pp. 1-27
		Zhu, G. et al., *Shape-Memory Effects of Radiation Crosslinked Poly(ε-caprolactone)*, JOURNAL OF APPLIED POLYMER SCIENCE, Vol. 90, (2003), pp. 1589-1595

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

EXAMINER	/Anuradha Ramana/	DATE CONSIDERED	02/16/2010

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

PETITIONER ARTHREX
EX. 1004

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Gall, Kenneth A.
Art Unit	3733
Examiner Name	Annette R Reimers
Attorney Docket Number	025843-000100US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US-5,120,175 A	06-09-1992	Arbegast et al.	
	A2	US-5,265,456 A	11-30-1993	Kennedy wt al.	
	A3	US-6,637,995 B1	10-28-2003	White	
	A4	US-6,688,828 B1	10-02-2004	Post	
	A5				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		Country Code[3]	Number[4]	Kind Code[5] (if known)				
	B1							☐
	B2							☐

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C1		☐
	C2		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

Examiner Signature	/Anuradha Ramana/	Date Considered	02/16/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

60869554 v1

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302.010201	Application Number 11/112,865
	Applicant(s) Gall et al.	
	Filing Date Apr. 21, 2005	Group Art Unit 3733

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	4,452,236	Jun. 5, 1984	Utsugi, M.	128	4	

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	2	Andreasen et al., *Laboratory and Clinical Analyses of Nitinol Wire*, American Journal of Orthepedics, Vol. 73, No. 2, pp. 142-151 (Feb. 1978).
	3	Cragg et al., *A New Percutaneous Vena Cava Filter*, American Journal of Roentgenology, Vol. 141, pp. 601-604 (Sep. 1983).
	4	Wasilewski, R., *Stress-Assisted Martensite Formation in TiNi*, Scripta Metallurgica, Vol. 5, No. 2, pp. 127-130 (1971).
	5	Watanabe, K., *Studies on New Superelastic NiTi Orthodontic Wire (Part 1) Tensile and Bend Test*, Dental Material and Devices Magazine, Vol. 23, No. 61, pp. 1-61 (1982).
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./

EXAMINER	DATE CONSIDERED
/Anuradha Ramana/	02/16/2010

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

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302.010201	Application Number 11/112,865
	Applicant(s) Gall et al.	
	Filing Date Apr. 21, 2005	Group Art Unit 3733

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	1	Results of the Partial International Search from corresponding PCT Application No. PCT/US2008/055188.
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.R./		

EXAMINER	DATE CONSIDERED
/Anuradha Ramana/	02/16/2010

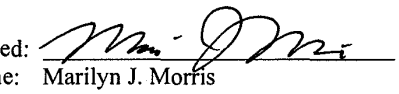
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SHEET 1 OF 1

DEN 96,757,887v1 12-8-08

PETITIONER ARTHREX EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3775
Kenneth A. Gall et al.	Examiner: Ramana, Anuradha
Serial No.: 11/112,865	
Filed: April 21, 2005	**RESPONSE TO RESTRICTION REQUIREMENT AND SUBMISSION OF FORMAL DRAWINGS**
Confirmation No.: 5339	
Atty. File No.: 036302-010201	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on October 15, 2009.
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	Signed:  Name: Marilyn J. Morris

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

Dear Sir:

This correspondence is responsive to the Restriction Requirement having a mailing date of September 16, 2009.

Amendments to the Claims are reflected in the **Listing of Claims**, which begins on Page **2** of this paper.

Amendments to the Drawings begin on Page **5** of this paper.

Remarks begin on Page **6** of this paper.

It is not believed that any extension(s) of time or additional fees are due in connection with this correspondence. However, any necessary extension(s) of time is/are hereby requested and any necessary additional fees may be charged to Deposit Account No. 502775.

PETITIONER ARTHREX
EX. 1004

Amendments to the Claims

This Listing of Claims will replace all prior versions, and listings, of claims in the application:

1-26. (Cancelled).

27. (Previously presented) A surgical method, comprising:

creating a first cavity in a first bone element of a patient;

creating a second cavity in a second bone element in the patient;

inserting an intermedullary nail into the second cavity;

inserting the intermedullary nail into the first cavity;

fixing a first portion of the intermedullary nail to the first bone element of the patient;

after fixing the first portion, creating a stress-induced martensitic phase into a responsive portion of the intermedullary nail, wherein the responsive portion comprises a shape memory alloy; and

after inducing the stress-induced martensitic phase, fixing a second portion of the intermedullary nail to the second bone element of the patient, wherein the responsive portion is disposed between the first portion and the second portion.

28. (Previously presented) The surgical method of claim 27, wherein inserting the intermedullary nail into the second cavity is performed while the responsive portion is substantially in an austenitic phase.

29. (Previously presented) The surgical method of claim 27, wherein inserting the intermedullary nail into the first cavity is performed while the responsive portion is substantially in an austenitic phase.

30. (Previously presented) The surgical method of claim 27, wherein creating the stress-induced martensitic phase is performed by straining the responsive portion.

31. (Previously presented) The surgical method of claim 30, wherein straining is performed by applying a stress between the first portion and the second portion.

PETITIONER ARTHREX
EX. 1004

32. (Previously presented) The surgical method of claim 27, further comprising:

holding the responsive portion above an austenite finish temperature of the shape memory alloy while the creating is performed.

33. (Previously presented) The surgical method of claim 32, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while fixing the first portion is performed.

34. (Previously presented) The surgical method of claim 33, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.

35. (Previously presented) The surgical method of claim 27, wherein the shape memory alloy is an alloy including nickel and titanium.

36. (Previously presented) The surgical method of claim 35, wherein the alloy contains substantially only nickel and titanium.

37. (Previously presented) The surgical method of claim 27, wherein the first portion comprises the shape memory alloy.

38. (Previously presented) The surgical method of claim 27, wherein the second portion comprises the shape memory alloy.

39-46. (Cancelled).

47. (Previously presented) A method, comprising:

inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;

wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

PETITIONER ARTHREX
EX. 1004

after inserting the bone device, creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis; and

wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

48. (Previously presented) The method of claim 47, wherein inserting the bone device is performed with the bone device substantially in an austenitic phase.

49. (Previously presented) The method of claim 47, further comprising:

before performing the stretching, fixing the bone device to the first bone fragment.

50. (Previously presented) The method claim 49, further comprising:

after performing the stretching, fixing the second portion of the bone device to the second bone fragment.

51. (Previously presented) The method of claim 47, further comprising:

holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the inserting is performed.

52-63. (Cancelled).

PETITIONER ARTHREX
EX. 1004

AMENDMENTS TO THE DRAWINGS

In response to the Examiner's comment that some of the drawings are illegible due to heavy shading, substitute formal drawings, pages 1-10, in compliance with 37 CFR 1.21(d) are submitted herewith.

PETITIONER ARTHREX
EX. 1004

REMARKS

This correspondence is responsive to the Restriction Requirement of September 16, 2009. Prior to amendment herewith, Claims 27-63 were pending.

In the Restriction Requirement, the Examiner restricted the claims to:

Group I: claims 27-38 and 47-51, drawn to a surgical method, class 606/60.

Group II: claims 39-46, drawn to a system, class 606/62.

Group III: claims 52-63, drawn to a method of manufacturing, class 148/563.

Applicant hereby elects the Group I invention for prosecution in this case, namely, claims drawn to a surgical method. By amendment herewith, 39-46 and 52-63 have been cancelled. Claims 1-26 were cancelled in a previous amendment. Thus, Claims 27-38 and 47-51 are now pending in the application.

In response to the Examiner's comment that the some of the drawings are illegible due to heavy shading and appear to be photocopies of black and white photographs, formal drawings in compliance with 37 CFR 1.121(d) are submitted herewith. Please substitute sheets 1-10 of the drawings filed on April 21, 2005 with the attached Replacement Sheets 1-1-10.

In light of the above amendments and remarks, Applicant respectfully submits that all pending claims are in condition for allowance, and such action is respectfully requested. If the Examiner believes that it would be helpful to discuss any of the amendments or remarks presented herein, the Examiner is invited to contact the undersigned at the telephone number provided.

It is not believed that any additional fees are due in connection with this response. However, any necessary fees may be charged to Deposit Account No. 502775.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date: October 15, 2009

Wm. Alex Furman, Reg. No. 61,313
1200 17th Street, Suite 2400
Denver, CO 80202
Phone: (303) 572-6500
Fax: (303) 572-6540

PETITIONER ARTHREX
EX. 1004

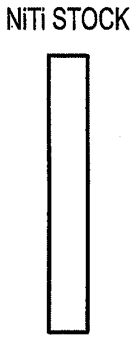


FIG.1B

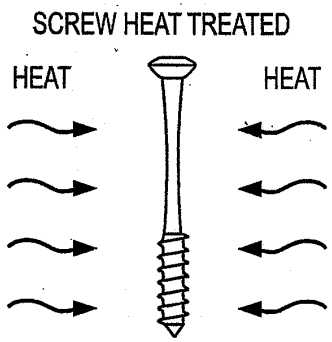


FIG.1C

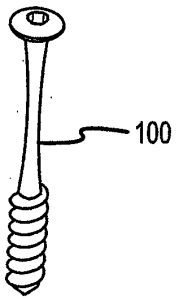


FIG.1A

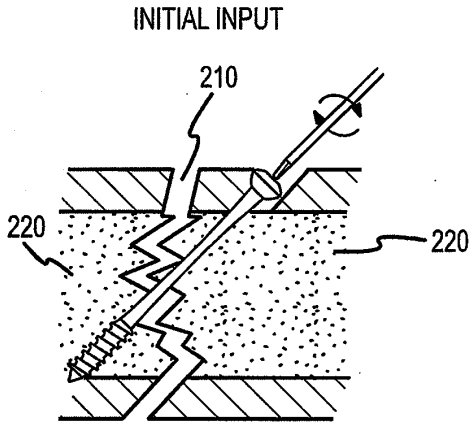


FIG.2A

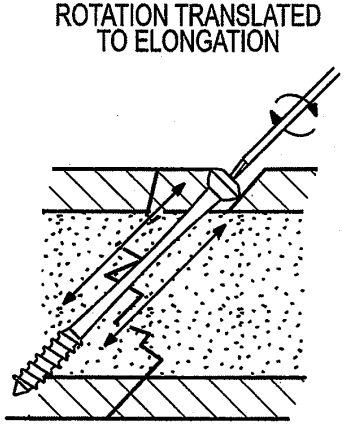


FIG.2B

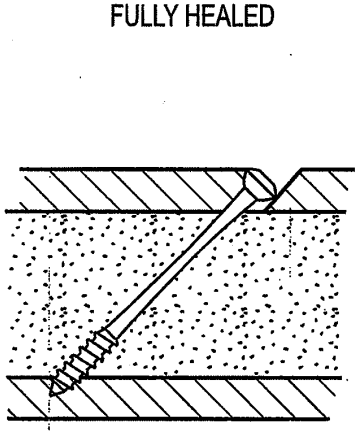


FIG.2C

FIG.3A

FIG.3B

FIG.3C

FIG.3E

FIG.3D

FIG.3F

3/10

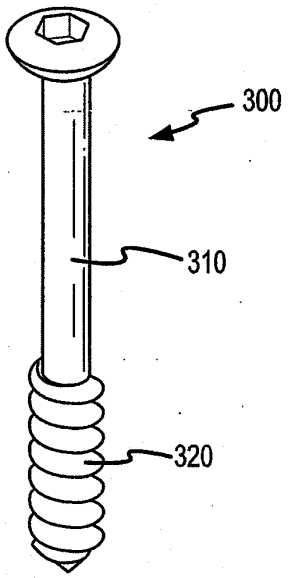


FIG.3G

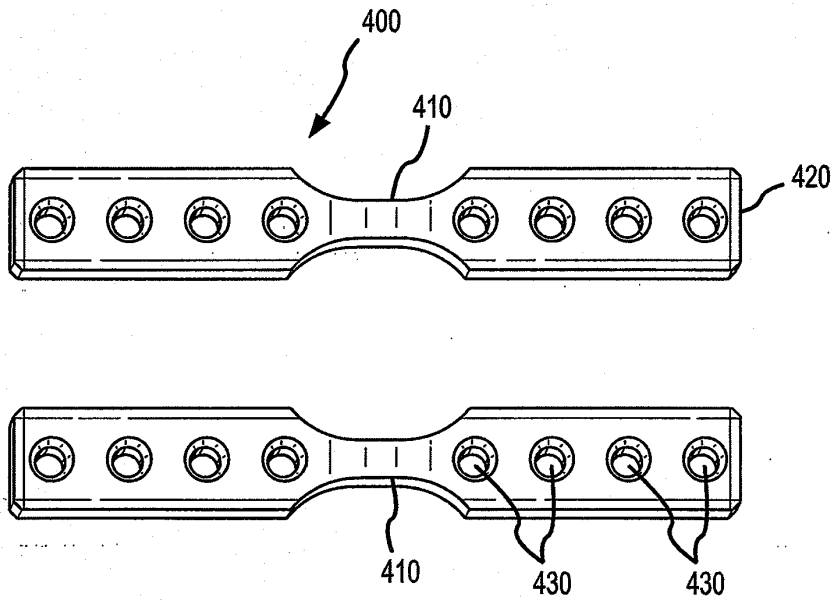


FIG.4

PETITIONER ARTHREX
EX. 1004

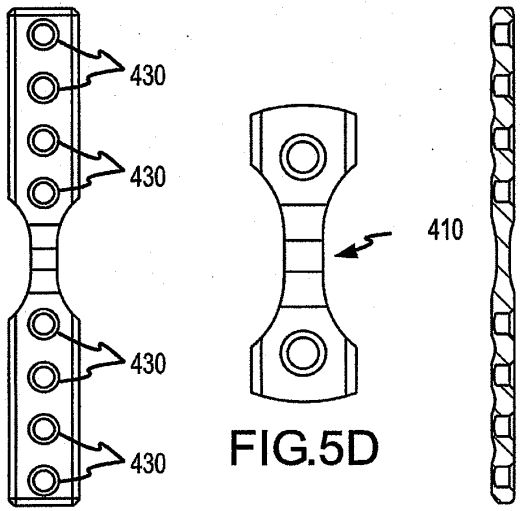


FIG.5A

FIG.5D

FIG.5C



FIG.5H

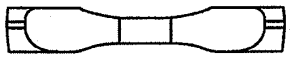


FIG.5G

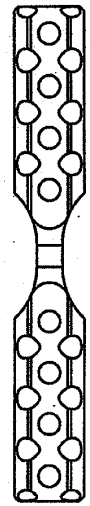


FIG.5B

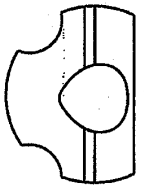


FIG.5I

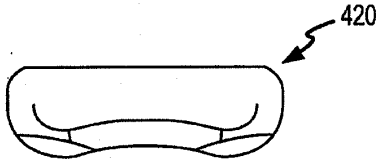


FIG.5E

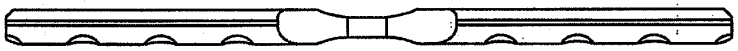


FIG.5F

5/10

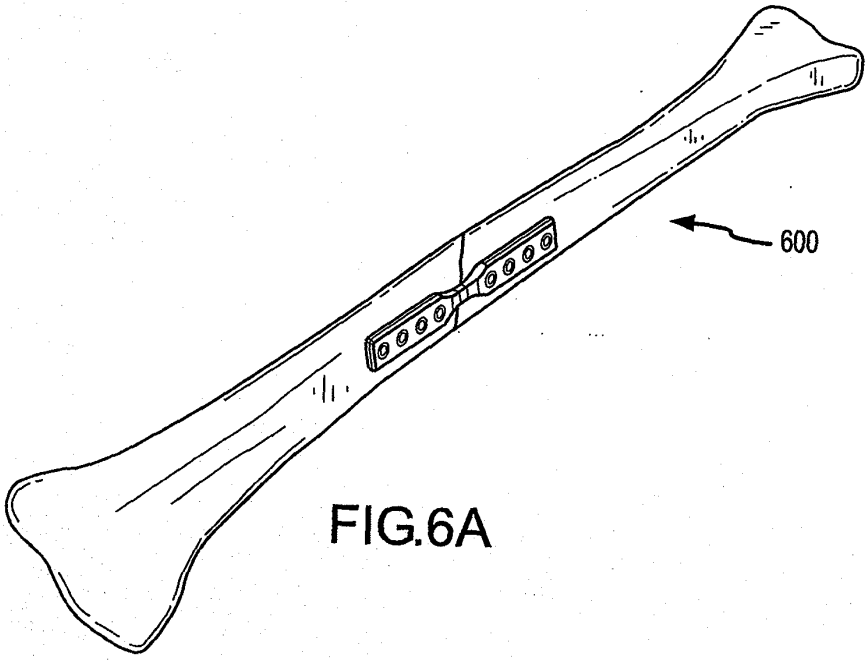


FIG.6A

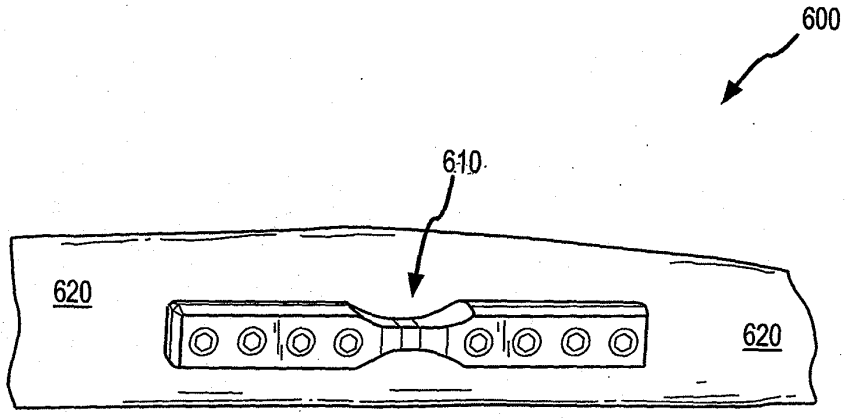


FIG.6B

PETITIONER ARTHREX
EX. 1004

6/10

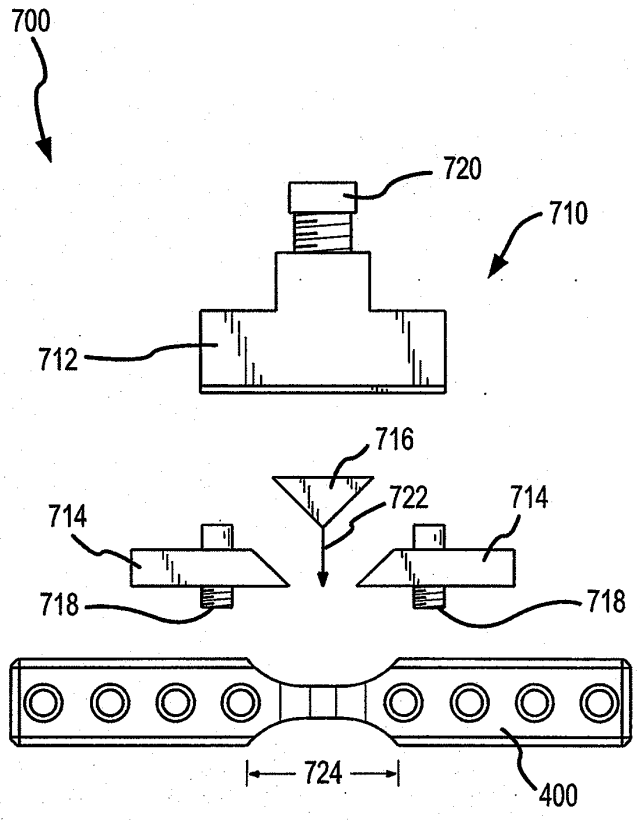


FIG.7A

PETITIONER ARTHREX
EX. 1004

7/10

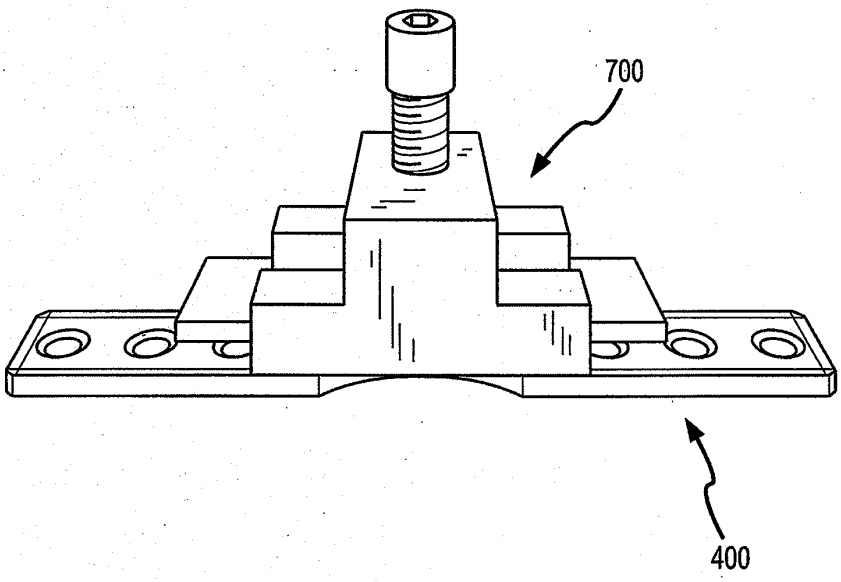


FIG.7B

PETITIONER ARTHREX
EX. 1004

8/10

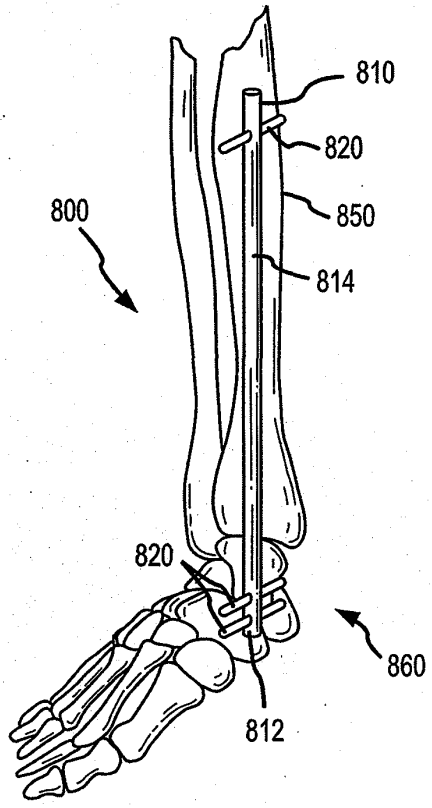
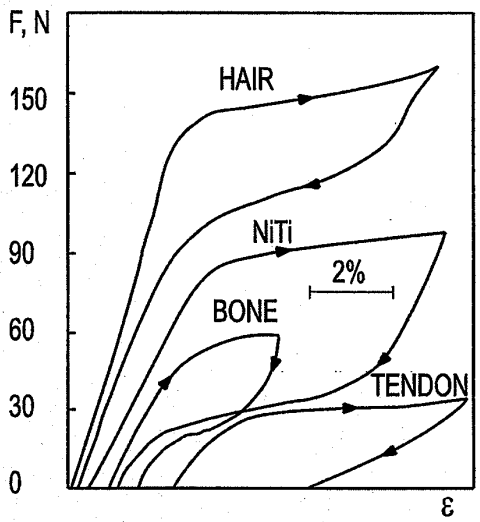


FIG.8

PETITIONER ARTHREX
EX. 1004

9/10



THE STRESS-STRAIN DIAGRAM FOR LIVING TISSUES AND A NiTi ALLOY [I].

FIG.9A

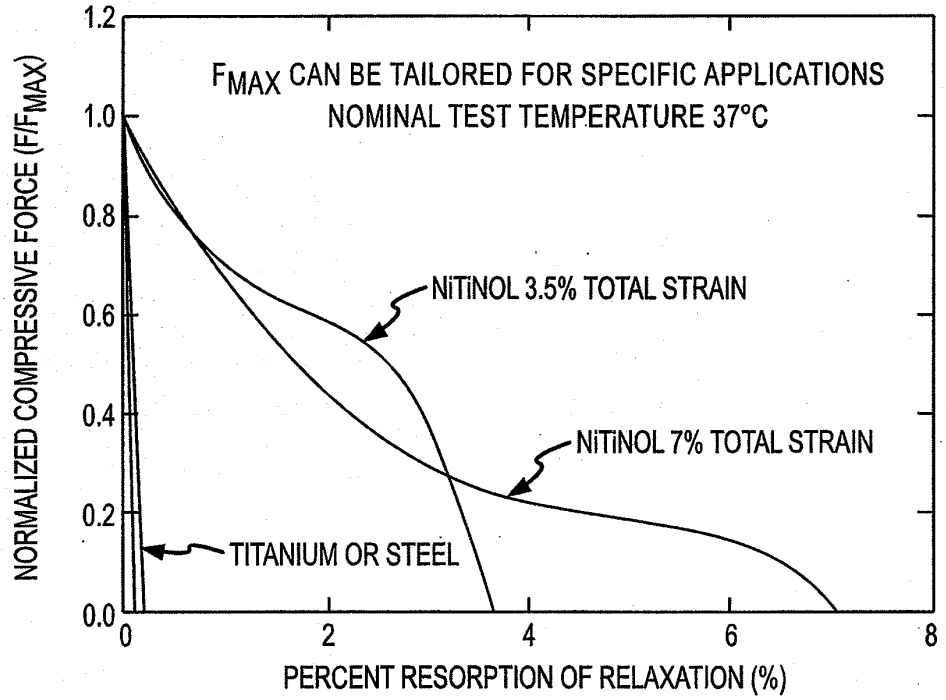


FIG.9B

PETITIONER ARTHREX
EX. 1004

10/10

$A=F_R/\sigma_R$ (1) $L=\Delta L/\varepsilon$ (2)

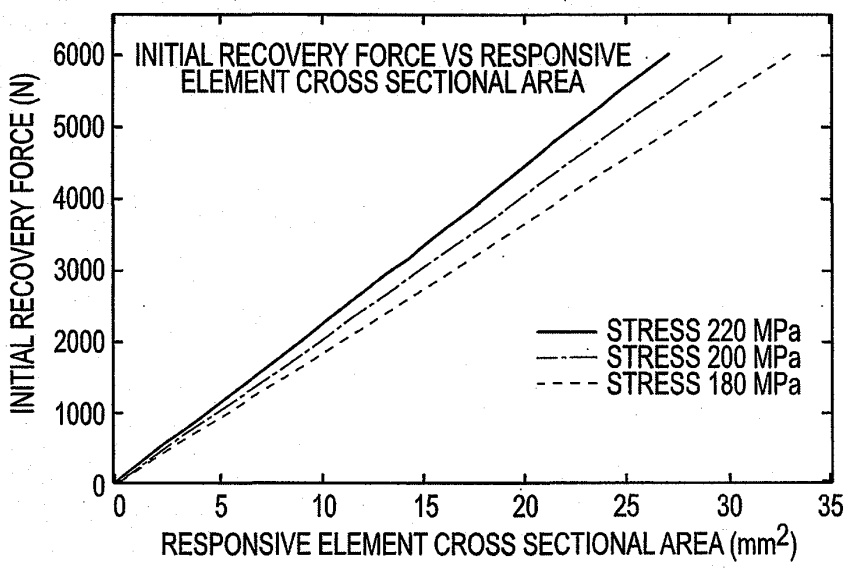


FIG.10A

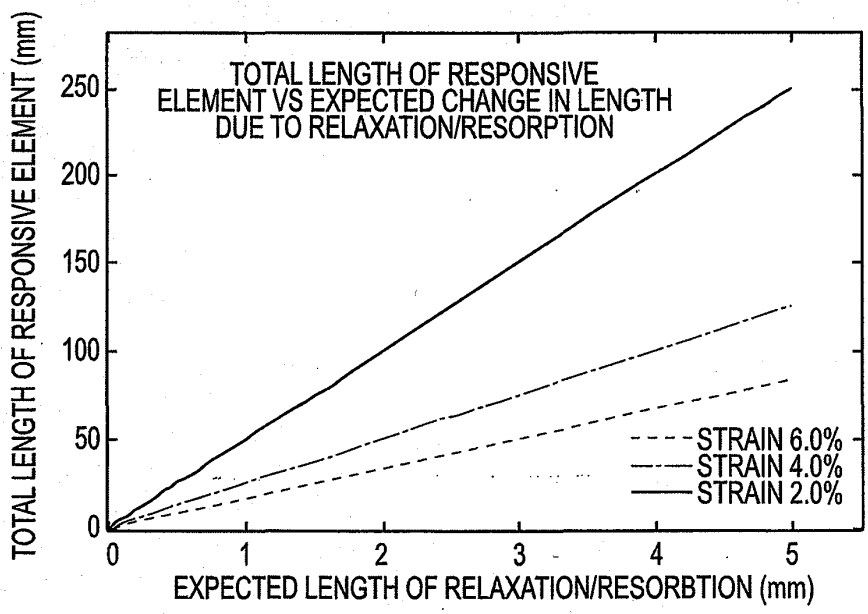


FIG.10B

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EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	6273092
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	William Alexander Furman/Marilyn Morris
Filer Authorized By:	William Alexander Furman
Attorney Docket Number:	036302-010201
Receipt Date:	15-OCT-2009
Filing Date:	21-APR-2005
Time Stamp:	20:09:48
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		036301-010201-Resp-Rest-Req-filed-10-15-09.pdf	548134 90786bb9e78aa8c5c956d897ea6043a46d20fb63	yes	16

PETITIONER ARTHREX
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	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response to Election / Restriction Filed	1	1
	Claims	2	4
	Drawings-only black and white line drawings	5	5
	Applicant Arguments/Remarks Made in an Amendment	6	6
	Drawings-only black and white line drawings	7	16
Warnings:			
Information:			
	Total Files Size (in bytes):	548134	

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.

PETITIONER ARTHREX
EX. 1004

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/112,865	04/21/2005	

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	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	10/15/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 17	Minus	** 37	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***4	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/CRYSTAL QUEEN/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PETITIONER ARTHREX
EX. 1004

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	036302-010201	5339

37705 7590 09/16/2009

GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	
MAIL DATE	DELIVERY MODE
09/16/2009	PAPER

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

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

PTOL-90A (Rev. 04/07)

PETITIONER ARTHREX
EX. 1004

Office Action Summary	Application No.	Applicant(s)	
	11/112,865	GALL ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3775	

-- 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 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *14 February 2007*.

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

3)☐ 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

4)☒ Claim(s) *27-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

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

8)☒ Claim(s) *27-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

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

I. Claims 27-38 and 47-51, drawn to a surgical method, classified in class 606, subclass 60.

II. Claims 39-46, drawn to a system, classified in class 606, subclass 62.

III. Claims 52-63, drawn to a method of manufacturing, classified in class 148, subclass 563.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus could be used for long-bone fracture fixation without creation of first and second cavities.

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product could be made by cold rolling.

Inventions I and III are directed to distinct processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to different processes, namely, surgical insertion and manufacturing, respectively. Furthermore, the inventions as claimed do not encompass

PETITIONER ARTHREX
EX. 1004

overlapping subject matter and there is nothing of record to show them to be obvious variants.

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 examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a 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 on the elected invention.

**PETITIONER ARTHREX
EX. 1004**

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(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner's Comment on Drawings:

Some of the drawings filed on 04/21/05 are illegible due to heavy shading. The drawings appear to be photocopies of black and white photographs. Legible drawings in compliance with 37 CFR 1.121 (d) must be submitted in the response to this office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

PETITIONER ARTHREX
EX. 1004

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.

AR
September 14, 2009

/Anu Ramana/
Primary Examiner, Art Unit 3775

**PETITIONER ARTHREX
EX. 1004**

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	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	09/14/2009								
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	4	-								
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11112865	GALL ET AL.
	Examiner	Art Unit
	Anu Ramana	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	09/14/2009								
	37	÷								
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3733
Gall et al.	Examiner: Annette R. Reimers
Serial No.: 11/112,865	**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b)(3))**
Filed: April 21, 2005	
Confirmation No.: 5339	
Atty. File No.: 036302-010201	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on January 26, 2009.
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	Signed:  Name: Stephen S. Gruber

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

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Information Disclosure Citation are brought to the attention of the Examiner.

This Information Disclosure Citation should be considered because it is submitted before the mailing date of a first Office Action on-the-merits (37 C.F.R. § 1.97(b)(3)). Accordingly, no fee is due for consideration of the items listed on the enclosed Information Disclosure Citation. In accordance with 37 C.F.R. § 1.98(a)(2), a legible copy of each foreign patent, publication and unpublished U.S. application cited in the Information Disclosure Citation is provided herewith.

The filing of this Information Disclosure Citation should not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), and should not be construed as an admission that the information cited in the Information Disclosure Citation is, or is considered to be, material to patentability as defined in § 1.56(b) (37 C.F.R. § 1.97(h)).

Consideration of the cited items is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Information

PETITIONER ARTHREX EX. 1004

Disclosure Citation, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 50-2775.

Respectfully submitted,

1/26/09

Date

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Fax: (720) 904-6131

PETITIONER ARTHREX
EX. 1004

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302.010201	Application Number 11/112,865
	Applicant(s) Gall et al.	
	Filing Date Apr. 21, 2005	Group Art Unit 3733

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	5,505,734	Caniggia, et al.	Apr. 9, 1996	606	63	
	2	2005/0107791	Manderson, E.	May 19, 2005	606	62	

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO
	3	DE19708279 (machine translation)	Sept. 10, 1998	Germany			X	
	4	WO2005/094705	Oct. 13, 2005	WIPO				
	5	WO1995/24870 (machine translation)	Sept. 21, 1995	WIPO			X	

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER	DATE CONSIDERED

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

SHEET 1 OF 1

DEN 96,766,409v1 1-26-09

PETITIONER ARTHREX EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	4673212
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	Stephen Spencer Gruber
Filer Authorized By:	
Attorney Docket Number:	036302-010201
Receipt Date:	26-JAN-2009
Filing Date:	21-APR-2005
Time Stamp:	17:30:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	DE19708279A1.pdf	616721 ec54c0bf0023e0a6271f0e2bbe81ca041adebee3	no	16

Warnings:
Information:

PETITIONER ARTHREX
EX. 1004

2	Foreign Reference	WO05094705.pdf	2241879 16aef1fd2c0e3bec2f72be36568ff1b9b2e4f8e0	no	59
Warnings:					
Information:					
3	Foreign Reference	WO95024870.pdf	1207646 9c6012b7807900b3765e92881ac6e3fb28bde109	no	29
Warnings:					
Information:					
4		IDS_010201.pdf	105360 9b9a64afc254db259de4927c9c6a57bd2317a526	yes	3

Multipart Description/PDF files in .zip description

Document Description	Start	End
Information Disclosure Statement Letter	1	2
Information Disclosure Statement (IDS) Filed (SB/08)	3	3

Warnings:	
Information:	
Total Files Size (in bytes):	4171606

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.

PETITIONER ARTHREX
EX. 1004

Description of DE19708279

Invention relates to these traction system for tube bones with Mark nail, which exhibits a cavity limiting wall with a distal end and proximal driving, and with proximal driving Mark nail in slide fit enclosing guide sleeve, whereby the Mark nail in the cavity prolonged-slidable disposed inner part, into which itself on the basis of its proximal driving directed face a coaxial bore with internal thread extended, in the cavity in the distance of driving planned abutment, a bar, which has an external thread, which stands in screwing interference with the internal thread of the bore of the inner part, and which is coupled with a rotary drive resting upon disposed within the cavity at the abutment, in the range of the distal end in the wall adjustment hole for the execution of a proximal adjustment pin, aligned limiting the cavity, by distal adjustment pin, a distal of the abutment disposed, across the cavity limiting wall passing through slot parallel to the longitudinal extension of the Mark nail and at least crosswise duch inner part the passing through thing, aligned to the slot in the wall, exhibits crosswise passing through adjustment holes for execution, disposed in the distance.

If the Mark nail has an open profile, D. h. on a side, can the slot so disposed exhibits a longitudinal slot, which becomes limited of two opposite parallel edges become that it faces the slot. If the Mark nail has a closed profile, two opposite slots in the wall of the Mark nail must become provided for the execution of the adjustment pins.

The Mark nail inserted with this arrangement is from the EP 0,432,253 B1 and the DE 39 21 972 C2 known. With this Mark nail are bone extensions and segment shifts toward the Kallusdistraktionsmethode possible. By use of integrated drives the entire Mark nail is more implantable and can work without material connection outward, which lowers the Infektrisiko significant. Usually two opposite slots are and/or in the wall of the Mark nail. the adjustment holes in pairs in each case opposite provided. With use of Mark nails also in its longitudinal direction open wall however also an adjustment slotted hole knows and/or. in each case an adjustment hole in the wall are sufficient, because the wall on the opposite side is open. With the Mark nail in that managing extensions at femur of up to 10 cms also in combination with axle corrections the successful can described embodiment be accomplished.

Indications to segment shifts exist with large bone defects starting from approximately 2 to 3 cm, like them z. B. more immediate as primary bone loss after impact, in addition, more secondary due to infection or necrosis to develop can. Furthermore the operations required with malignant bone tumors leave large bone defects.

If one uses the known Mark nail for segment shift, an additional latch of the proximal main fragment provided does not have to become, thus itself the leg twisted or shortened. Frequent one is present also the situation that already a shortening occurred, so that the defect with the segment shift can become bridged, but additional for segment shift subsequent is also still another extension of the extremity required.

In order to secure during a segment shift the proximal bone segment separate against axial displacement, are in the Mark nail after the DE 39 21 972 C2 in the range of its proximate end u-shaped incisions formed, whose leg parallel to the axis run and whose soil connecting sections that are driving directed. By the u-shaped incisions lamellas become formed. In the proximate end of the Mark nail a capsule-shaped wedge member with countersinking hurrying is guided,

PETITIONER ARTHREX
EX. 1004

which becomes through tricks of a screw axial displaced held in the use by driving in threaded engagement and spreads by its countersinking hurry the lamellas into a keying situation outward, whereby a form closure with the proximal tube bone and thus its situation safety device becomes achieved.

This embodiment serves the axial and rotatorischen stabilization of the proximal bone main fragment, as it is required for the segment shift. A segment shift in combination with an extension is possible however not with this embodiment. In addition the later removal of the Mark nail is difficult due to expanding the lamellas.

It has itself furthermore shown that growing together between the shifting segment and the main fragment at the contact point, which becomes also designated as Dockingstelle at the end of the segment shift is problematic. Those relative unreactive front surfaces have to bridge if necessary bottom compression the tendency, so that usually additional pressure osteosyntheses or an operative Anfrischung and the attachment of Spongiosa, usually from the basin comb, required become.

From the literature place R., Betz A., Kettler M., Zeiler C, Schweiberer L tree-refines.: Perspectives of the Kallusdistraktion, accident surgeon 99, 84-91, 1996, which shows the genericin accordance with-eaten state of the art, is already the arrangement of a guide sleeve in the slide fit around the proximal driving of the Mark nail around known. The purpose of the arrangement of the guide sleeve exists mainly in a significant stabilization effect, if the Mark nail at the end of the treatment moved far into the bone, since in this position otherwise at its proximate end high voltage peaks would be to be expected. With the guide sleeve the Trochantermassiv is also included into the proximal force admission, with which the risk of a Auslockerung of the Mark nail or a proximal fracture of the Femurs becomes reduced.

In addition the guide sleeve contributes substantial to the simplification of the Mark nail distance, since with far Mark nails at the end of the these traction, penetrated into the Mark area, with large extension distances the discovery Marknagelendes and setting the extraction instruments can prepare difficulties.

The guide sleeve finds lateral stop in the Trochantermassiv by a supernatant tab with an opening, by which can become passed as fasteners at the tube bone for example a screw, so that the position of the guide sleeve both axial and rotatorisch secured is. The axial fuse against displacement is in each case required, there both sliding after distal into the Mark area, above all in addition, proximal from the Mark area adverse is and/or. to a function loss leads.

The use of a such these traction system is on extensions of the tube bone limited, segment shifts and combinations from segment shifts and extensions cannot not be accomplished.

From the DE 195 27 822 c1 a Mark nail is known to the fixed connection of parts of a bone. The Mark nail exhibits a sheath fastenable at a bone part, is received in which a rotatable sleeve. The rotatable sleeve is more connectable by a longitudinal guide with an other bone part, introduced in the sheath. The rotatable sleeve affects positive a threaded spindle. The threaded spindle is connected, which is more connectable with an other with a transport element, bone segment

PETITIONER ARTHREX
EX. 1004

disposed severed of a German type end between two bone parts. The transport element is translational along the longitudinal axis in the sheath by rotation of the rotatable sleeve more movable. The attachment of the bone segment made by means of a bone screw, severed of a German type end, which is guided by a longitudinal guide in the sheath. The two bone parts are connected by bone screws in each case with the sheath and stand thereby in that for operative predetermined position to each other. It means that the if necessary shortened bone can become only intraoperative stabilized in the original length. The structure of the Mark nail allowed limited radial angular movements of the distal bone part, which reacted over a teeth with direction barrier and the threaded spindle become into an axial movement of the transport element, which shifts the bone segment in the defect between the bone parts. With the known Mark nail a segment shift can be only reached. A bone extension or also a combination from segment shift and after extension the Kallusdistraktionsmethode is not possible.

Those the invention underlying object consists therefore of out-arranging the these traction system of the genericin accordance with-eaten type in such a way that additional are to the extension also a segment shift as well as a segment shift in combination with an extension without renewed operation possible, whereby a sufficient pressure of the bone contact areas at the Dockingstelle without extra operation generated is to become.

This object becomes on the basis of the these traction system that initially mentioned type by at least a nose managing from the wall of the Mark nail and by at least a slot dissolved parallel formed in the guide sleeve to their axis, with which the nose stands in guidance interference, without managing over the outer wall of the guide sleeve.

The stability of the guide sleeve against rotation can be improved thereby more other that at their outside at least one becomes too their axis parallel schneidenförmig formed longitudinal rib provided, favorable-proves from its proximate end after distal extended.

The guide sleeve prevented that with segment shifts a shortening occurs and effected that the proximal main fragment is rotation-stable with the distal main fragment and thus with the bottom thigh connected. Both objects are transferred by the nose or better by two noses opposite at the circumference to engagement with an associated in each case slot. Rotation stability is alone given thereby that the distal main fragment is drehfest by the distal locking bolts with the Mark nail connected, the Mark nail by that or the noses over the slot with the guide sleeve connected is drehfest and the guide sleeve by the lateral supernatant tab and the screw in the opening drehfest with the proximal main fragment in connection stands. The position of the noses is to beginnings of the these traction treatment at the end of the operation the proximal slotted hole delimitation, with which a shortening of the extremity becomes prevented by the muscle course.

An additional rotation stability supplies at the medial Zirkumferenz disposed klingenförmige longitudinal rib, which is driven into the densified Spongiosa in the vicinity of the solid Kalkar.

The guide sleeve effected furthermore a compression of the front surfaces to the Dockingstelle without renewed operation alone by that other acting drive during the extension phase and thus a stimulus to the spontaneous Durchbauung. An other osteosynthesis for the compression of the

PETITIONER ARTHREX
EX. 1004

contact points or a Spongiosaplastik, thus an accumulation of bone usually from the basin comb, can be avoided in such a way.

If the bone defect requires only one segment shift, only the object of rotation stabilization comes to the guide sleeve. The nose or the noses remains securing the length of the extremity at the proximal slotted hole end of positioned and during the entire treatment. The Mark nail gets over ordinary proximally about 2 cms or locks flush with the upper edge of the Trochanters. Distal one the made latch in the main fragment, as it is also conventional with the extension. About 3 cm the distal proximal front surface of the distal main fragment a made fabric-careful Kortikotomie. The latch of the mobilized bone segment with an adjustment pin made at the distal end of the slot in the Mark nail. At the end of the segment shift, with reaching the Dockingstelle, the shifting segment with its proximal front surface becomes pressed to the distal front surface of the proximal main fragment. With sufficient contact pressure the drive stopped, bone rain advice solidifies itself, and the Dockingstelle becomes bridged.

For a partial closure at least of the slot in the guide sleeve can become into this inserted positive in his distal range a wall member. The wall member forms a continuation of the interior and/or. Outer wall of the guide sleeve and becomes held with the help of a slight rear cutting. By the use of such dimensioned wall members corresponding in the length, if the shifting element has the Dockingstelle achieved, an eventual undesirable extension can be avoided, which could become effected by the train of the drive required for the contact pressure, as the proximal face of the wall member works as stop for the nose of the Mark nail. With this embodiment the guide sleeves become manufactured with slots of same maximum length in each case. The adaptation to the desired effect-prolonged of the slot the corresponding required extension distance made then by insertion of the dimensioned wall member into the slot of the guide sleeve, corresponding in the length.

If a bone defect connected with a shortening of the extremity is present, then the introduction of the Mark nail and the segment shift take place in same way as with a sole bone defect. With reaching the Dockingstelle the drive becomes however not stopped but continues to pull unchanged, so that now without renewed operation the automatic extension procedure begins. If the range is achieved, the drive becomes stopped and bone rain advice solidifies itself.

For the dimensioning of the slots in the Mark nail and in the guide sleeve it is to be noted that the slot is in the guide sleeve alone these also limited for the extension required and, while the slot in the Mark nail must become both for the segment shift and dimensioned for the extension. For a segment shift of for example 3 cm and an extension of 5 cm required one a slot in the guide sleeve of 5 cm, while the length of the slot in the Mark nail must amount to 8 cm, whereby these indicated sizes of the slots the diameter of the guide pin must become added in each case, which usually corresponds to the width of the slot.

On the basis designs embodiments of the invention become more near explained. It shows:

Fig. 1 in a side view a Mark nail for the these traction system according to invention,

Fig. 2 a longitudinal section of the Mark nail of Fig. 1,

PETITIONER ARTHREX
EX. 1004

Fig. 3 the isometric guide sleeve of the these traction system,

Fig. 4 the isometric proximate end of the these traction system existing from a guide sleeve and a Mark nail,

Fig. 5 a schematic bone with a defect place and a shortening,

Fig. 6 the schematic bones of Fig. 5 with the inserted these traction system,

Fig. 7 in a view such as Fig. 6 the end of the segment shift and

Fig. 8 in a view such as Fig. 7 the end of the bone extension subsequent to the segment shift.

In Fig. to 1 and 2 Mark nail shown 10 corresponds to 39 21 972 in its structure of the DE (Fig. 1 and 2). The Mark nail 10 has a distal end 13 and a proximate end 14 as well as a wall 11, which have essentially the form of a cylinder with an axis 40. In the wall 11 three in the distance disposed, itself vertical 40 adjustment holes 15 for the execution of distal adjustment pins 80a, are 80b, 80c in the range of the distal end (Fig extending to the axis. 6) provided. Within the wall 11 of the Mark nail 10 an inner part is 20 disposed, which exhibits a bore 21 with an internal thread on the basis of its proximal front surface, with which a coaxial bar 30 with an external thread 33 in screwing interference stands. The bar 30 is 18 coupled at their free end with a rotary drive, which rests upon at an abutment 17 on the inside of the wall 11. Vertical to the axis 40 extended itself by inner part 20 the adjustment hole 22 to which aligned two opposite oh savings alleles of slots are 16 in the wall 11 for the execution of a proximal adjustment pin 81 aligned, of those in Fig. 6 to 8 due to the representation only one to see is.

If the bone between the adjustment holes 15 and the adjustment hole becomes 22 severed, through tricks of the bar 30 by the drive 18 and the threaded engagement between the bar 30 and the central bore 21 in the inner part 20, held to the abutment, the edges of the Osteotomie 82 (Fig become. 6) gradual from each other remote, whereby itself the extending gap with new formed bone tissue 86 (Fig. 7) fills.

With the these traction system the Mark nail 10 is provided in the range of its proximal driving end of 14 with a nose 41. To the these traction system belongs, as in Fig. 3 and 4 to see is, a guide sleeve 42, which has an outgoing oh savings allele slot 43 from its proximate end, in which the nose 41 of the Mark nail 10 intervenes. As from Fig. 4 to see is, is two opposite slots 43 provided. In this embodiment of the these traction system 14 two opposite noses are 41 at the circumference formed at the Mark nail 10 in the range of the proximal driving end. The guide sleeve 42 has a lateral reciprocally supernatant tab 44 at the proximate end, in which on a side an opening is 45 for accomplishing a fastener not shown formed. On that the opening 45 opposite side a sound-like longitudinal rib is 46 formed, itself the oh savings allele and radial outward below a lateral projection of the tab 44 extended at the circumference of the guide sleeve 42. The Mark nail 10 sits in the guide sleeve 42 in the slide fit, whereby the noses 41 do not get over a twist between Mark nail 10 over the contour of the outer wall of the guide sleeve 42 and by their engagement into the slots 43 and prevents guide sleeve 42.

PETITIONER ARTHREX
EX. 1004

As from Fig. 5 to see is, has the bone shown a proximal main fragment 83 and a distal main fragment 84, which is from each other separate by a defect place in the distance of DELTA D. Furthermore the bone is around the length DELTA L shortened.

As from Fig. 6 to see is, is in the two main fragments 83 and 84 an aligned drilling out 50 formed. From a guide sleeve 42 and a these traction system existing into their axial slidable Mark nail 10 50 in the proximal main fragment 83 introduced become into drilling out. The guide sleeve 42 is on the one hand by one by the opening 45 (Fig. 4) in the tab 44 led screw 47 and on the other hand fixed in the proximal main fragment 83 held axial twist-safe by the sound-like longitudinal rib 46, which into the proximal main fragment 83 is driven, and. By the engagement of the noses 41 into the slots 43 is the Mark nail 10 42, however axial limited slidable, held twist-safe concerning the guide sleeve.

Into the slot 43 of the guide sleeve 42 the slot 43 can become a partly locking wall member 48 positive inserted in its distal range, whereby the distal front surface of the wall member 48 rests against the distal end surface of the slot 43. The eye and/or. Inner wall essentially corresponds to the contour of the eye and/or. Inner wall of the guide sleeve 42, whereby the support of the wall member 48 a slight rear cutting in the slot can become 43 provided. Because after a predetermined shifting way the nose fastens 41 of the Mark nail 10 at the distal front surface of the wall member 48, the displacement of the Mark nail becomes 10 after distal on a predetermined length limited, which is a small as those of the slot 43.

By the adjustment holes 15 (Fig. 1 and 2) becomes, like Fig. , adjustment pin 80a, 80b and 80c passed and in the distal main fragment 84 anchored shows 6. Furthermore 16 in the wall 11 of the Mark nail becomes and by the adjustment hole 22 in the inner part 20 an adjustment pin 81 passed and in the shifting element 85 anchored by the slots.

After implementing the Kortikotomie or Osteotomie 82 distal of the guide pin 81 the drive 18 (Fig becomes. 2) activated, whereby itself proximally of the Kortikotomie 82 formed shifting segment 85 toward the Dockingstelle 87 at the proximal main fragment 83 after the Kallusdistraktionsmethode bottom formation of a knöchernen rain advice 86 moved, whereby the defect place becomes DELTA n eliminated. By keeping running letting of the drive 18 applied at the Dockingstelle 87 a relative high pressure, which promotes a growing together of the shifting segment 85 with the proximal main fragment 83, becomes.

As from Fig. 8 to see is, can without other operation by moving the drive 18 on (Fig. 2) a bone extension by the length DELTA L after the Kallusdistraktionsmethode performed becomes, whereby the Mark nail 10 moves in the interior of the guide sleeve 42, whose length is so dimensioned that a tilt-free Lagestabilität ensured remains.

By the fixation of the Mark nail 10 by the guide pins 80a, 80b and 80c in the distal main fragment 84 and by the guide pin 81 of the guide pins 80a, 80b, 80c, by the formation of the Kortikotomie or Osteotomie 82 distal of the guide pin 81 and by the turningfixed fixation of the Mark nail 10 by the guide sleeve 42 and thus concerning the proximal main fragment 83 both during the closure of the defect place and during the bone these traction the exact alignment of

PETITIONER ARTHREX
EX. 1004

the main fragments 83 and 84 including shifting segment 85 to each other ensured remains proximal.

PETITIONER ARTHREX
EX. 1004

Claims of DE19708279

1. These traction system for a tube bone with a Mark nail (10), which a cavity (12) limiting wall (11) with a distal end (13) and proximal driving (14) exhibits, and with a guide sleeve (42), enclosing the proximal driving (14) of the Mark nail (10) in the slide fit, whereby the Mark nail (10)

-- in the cavity (12) prolonged-slidable disposed inner part (20), in itself on the basis of its proximal driving (14) directed face a coaxial bore (21) with internal thread extended,
-- in the cavity (12) in the distance abutment intended of driving (14) (17),
-- a bar (30), which has an external thread (33), which in screwing interference with the internal thread of the bore (21) of the inner part (20) stands, and who is with one within the cavity (12) disposed, rotary drive (18), resting upon at the abutment (17), coupled,
-- in the range of the distal end by the wall (11) crosswise passing through adjustment holes (15) for the execution of distal adjustment pins, disposed in the distance,
-- a distal of the abutment (17) disposed, across the cavity (12) limiting wall (11) passing through slot (16), parallel to the longitudinal extension of the Mark nail (10), and
-- at least across inner part (20) passing through, aligned wall (11), limiting to the slot (16) into the cavity (12), aligned adjustment hole (22) for the execution of a proximal adjustment pin exhibits, characterized by at least a nose (41), managing from the wall (11) of the Mark nail (10), and by at least a slot (43), parallel formed in the guide sleeve (42), to their axis, with which the nose (41) stands in guidance interference, without managing over the outer wall of the guide sleeve (42).

2. These traction system according to claim 1, characterized in that the guide sleeve (42) at their outside at least one too its axis parallel schneidenförmig formed longitudinal rib (46) exhibits.

3. These traction system according to claim 2, characterized in that itself the longitudinal rib (46) of proximal driving the guide sleeve (42) from extended.

4. These traction system after one of the preceding claims, characterized by a wall member (48), which is more insertable in the distal range at least slot (43) in the guide sleeve (42) for its partial closure a positive, without managing inside and outer over the wall outline of the guide sleeve (42).

PETITIONER ARTHREX
EX. 1004

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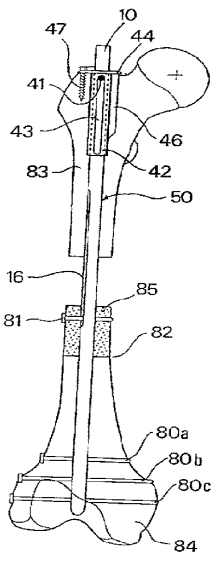
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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Distraktionssystem für Röhrenknochen

(57) Das Distraktionssystem für Röhrenknochen besteht aus einer Führungshülse (42) und einem Marknagel (10). Es soll zusätzlich zur Verlängerung auch eine Segmentverschiebung sowie eine Segmentverschiebung in Kombination mit einer Verlängerung ohne erneute Operation ermöglichen unter Gewährleistung eines ausreichenden Drucks an den Knochenkontaktflächen der Dockingstelle. Der Marknagel (10) ist dabei an seiner Außenwand mit einer Nase (41) versehen, die in ein Langloch (43) in der Führungshülse (42) eingreift, wodurch der Marknagel (10) über die im Röhrenknochen fixierte Führungshülse (42) rotatorisch gesichert, jedoch axial verschieblich ist.



DE 197 08 279 A 1

PETITIONER ARTHREX
EX. 1004

Beschreibung

Die Erfindung betrifft ein Distraktionssystem für Röhrenknochen mit einem Marknagel, der eine einen Hohlraum begrenzende Wand mit einem distalen Ende und einem proximalen Eintreibende aufweist, und mit einer das proximale Eintreibende des Marknagels im Schiebesitz umschließenden Führungshülse, wobei der Marknagel einen in dem Hohlraum längsverschiebbar angeordneten Innenteil, in das sich ausgehend von seiner dem proximalen Eintreibende zugewandten Stirnseite eine koaxiale Bohrung mit Innengewinde erstreckt, ein im Hohlraum im Abstand vom Eintreibende vorgesehenes Widerlager, eine Stange, die ein Außengewinde hat, das in Schraubeingriff mit dem Innengewinde der Bohrung des Innenteils steht, und die mit einem innerhalb des Hohlraums angeordneten, am Widerlager aufliegenden Drehantrieb gekoppelt ist, im Bereich des distalen Endes durch die Wand quer hindurchgehende, im Abstand angeordnete Fixierungslöcher für die Durchführung von distalen Fixierungsbolzen, ein distal vom Widerlager angeordnetes, quer durch die den Hohlraum begrenzende Wand gegebenenfalls auf gegenüberliegenden Seiten jeweils hindurchgehendes, zur Längserstreckung des Marknagels paralleles Langloch und wenigstens ein quer durch das Innenteil hindurchgehendes, fluchtend zu dem Langloch in der den Hohlraum begrenzenden Wand ausgerichtetes Fixierungsloch für die Durchführung eines proximalen Fixierungsbolzens aufweist.

Der bei dieser Anordnung eingesetzte Marknagel ist aus der EP 0 432 252 A1 und der DE 39 21 972 C2 bekannt. Mit diesem Marknagel sind Knochenverlängerungen und Segmentverschiebungen nach der Kallusdistraktionsmethode möglich. Durch Einsatz von integrierten Antrieben ist der gesamte Marknagel implantierbar und kann ohne materielle Verbindung nach außen arbeiten, was das Infektrisiko erheblich senkt. In der Regel sind in der Wand des Marknagels zwei gegenüberliegende Langlöcher bzw. die Fixierungslöcher jeweils paarweise gegenüberliegend vorgesehen. Bei Verwendung von Marknägeln mit in ihrer Längsrichtung offener Wand kann jedoch auch ein Fixierungslangloch bzw. jeweils ein Fixierungsloch in der Wand genügen, weil die Wand auf der gegenüberliegenden Seite offen ist. Mit dem Marknagel in der vorstehend beschriebenen Ausgestaltung lassen sich Verlängerungen am Femur von bis zu 10 cm auch in Kombination mit Achsenkorrekturen erfolgreich durchführen.

Indikationen zu Segmentverschiebungen bestehen bei großen Knochendefekten ab etwa 2 bis 3 cm, wie sie z. B. unmittelbar als primärer Knochenverlust nach Gewalteinwirkung, aber auch sekundär infolge Infektion oder Nekrose entstehen können. Ferner hinterlassen die bei bösartigen Knochentumoren erforderlichen Operationen große Knochendefekte.

Setzt man den bekannten Marknagel zur Segmentverschiebung ein, muß eine zusätzliche Verriegelung des proximalen Hauptfragments vorgesehen werden, damit sich das Bein nicht verdreht oder verkürzt. Häufig liegt auch die Situation vor, daß bereits eine Verkürzung eingetreten ist, so daß der Defekt mit der Segmentverschiebung zwar überbrückt werden kann, aber zusätzlich zur Segmentverschiebung anschließend auch noch eine Verlängerung der Extremität erforderlich ist.

Um bei einer Segmentverschiebung das proximale Knochensegment separat gegen axiale Verschiebung zu sichern, sind in dem Marknagel nach der DE 39 21 972 C2 im Bereich seines proximalen Endes U-förmige Einschnitte ausgebildet, deren Schenkel parallel zur Achse verlaufen und deren Bodenverbindungsabschnitte dem Eintreibende zugewandt sind. Durch die U-förmigen Einschnitte werden Lamellen gebildet. In dem proximalen Ende des Marknagels ist ein hülsenförmiges Keilelement mit Außenkeilen geführt, das durch Drehen einer im Einsatz am Eintreibende in Gewindeeingriff gehaltenen Schraube axial verschoben wird und durch seine Außenkeile die Lamellen in eine Verkeilungslage nach außen spreizt, wodurch ein Formschluß mit dem proximalen Röhrenknochen und somit dessen Lagesicherung erreicht wird.

Diese Ausgestaltung dient der axialen und rotatorischen Stabilisierung des proximalen Knochenhauptfragments, wie es für die Segmentverschiebung erforderlich ist. Eine Segmentverschiebung in Kombination mit einer Verlängerung ist mit dieser Ausgestaltung jedoch nicht möglich. Außerdem ist das spätere Entfernen des Marknagels aufgrund der Aufspreizung der Lamellen nicht möglich.

Es hat sich ferner gezeigt, daß das Zusammenwachsen zwischen dem Verschiebesegment und dem Hauptfragment an der Kontaktstelle, die auch als Dockingstelle bezeichnet wird, am Ende der Segmentverschiebung problematisch ist. Die relativ reaktionsarmen Stirnflächen haben allenfalls unter Kompression die Tendenz zu überbrücken, so daß meist zusätzliche Druckosteosynthesen oder gar eine operative Anfrischung und die Anlagerung von Spongiosa, meist aus dem Beckenkamm, erforderlich werden.

Aus der Literaturstelle Baumgart R., Betz A., Kettler M., Zeiler C., Schweiberer L.: Perspektiven der Kallusdistraktion, Unfallchirurg 99, 84–91, 1996, die den gattungsgemäßen Stand der Technik wiedergibt, ist bereits die Anordnung einer Führungshülse im Schiebesitz um das proximale Eintreibende des Marknagels herum bekannt. Der Zweck der Anordnung der Führungshülse besteht in erster Linie in einem erheblichen Stabilisierungseffekt, wenn der Marknagel am Ende der Behandlung weit in den Knochen gewandert ist, da in dieser Position sonst an seinem proximalen Ende hohe Spannungsspitzen zu erwarten wären. Mit der Führungshülse wird das Trochantermassiv in die proximale Kraftaufnahme mit einbezogen, womit die Gefahr einer Auslockerung des Marknagels oder einer proximalen Fraktur des Femurs reduziert wird.

Die Führungshülse trägt außerdem wesentlich zur Vereinfachung der Marknagelentfernung bei, da bei weit in den Markraum eingedrungenen Marknägeln am Ende der Distraktion bei großen Verlängerungsstrecken das Auffinden des Marknagelendes und das Ansetzen der Extraktionsinstrumente Schwierigkeiten bereiten kann.

Die Führungshülse selbst findet im Trochantermassiv lateral Halt durch eine überstehende Lasche mit einer Öffnung, durch die als Befestigungsmittel am Röhrenknochen beispielsweise eine Schraube hindurchgeführt werden kann, so daß die Position der Führungshülse sowohl axial als auch rotatorisch gesichert ist. Die axiale Sicherung gegen Verschiebung ist in jedem Fall erforderlich, da sowohl ein Gleiten nach distal in den Markraum, vor allem aber auch proximal aus dem Markraum heraus nachteilig ist bzw. zu einem Funktionsverlust führt.

Die Verwendung eines derartigen Distraktionssystems ist auf Verlängerungen des Röhrenknochens beschränkt, Segmentverschiebungen und Kombinationen aus Segmentverschiebungen und Verlängerungen lassen sich nicht durchführen.

Die der Erfindung zugrundeliegende Aufgabe besteht deshalb darin, das Distraktionssystem der gattungsgemäßen Art so auszugestalten, daß zusätzlich zur Verlängerung auch eine Segmentverschiebung sowie eine Segmentverschiebung in Kombination mit einer Verlängerung ohne erneute Operation möglich sind, wobei ein ausreichender Druck der Knochenkontaktflächen an der Dockingstelle ohne extra

PETITIONER ARTHREX
EX. 1004

Operation erzeugt werden soll.

Diese Aufgabe wird ausgehend von dem Distraktionssystem der eingangs genannten Art durch wenigstens eine aus der Wand des Marknagels vorstehende Nase und durch mindestens ein in der Führungshülse ausgebildetes zu ihrer Achse paralleles Langloch gelöst, mit dem die Nase in Führungseingriff steht, ohne über die Außenwand der Führungshülse vorzustehen.

Die Stabilität der Führungshülse gegen Verdrehen läßt sich dadurch weiter verbessern, daß an ihrer Außenseite mindestens eine zu ihrer Achse parallele schneidenförmig ausgebildete Längsrippe vorgesehen wird, die sich vorteilhafterweise von ihrem proximalen Ende aus nach distal erstreckt.

Die Führungshülse verhindert, daß bei Segmentverschiebungen eine Verkürzung eintritt und bewirkt, daß das proximale Hauptfragment rotationsstabil mit dem distalen Hauptfragment und damit mit dem Unterschenkel verbunden ist. Beide Aufgaben werden von der einen Nase oder besser von zwei am Umfang gegenüberliegenden Nasen in Eingriff mit einem jeweils zugeordneten Langloch übernommen. Die Rotationsstabilität ist allein dadurch gegeben, daß das distale Hauptfragment durch die distalen Verriegelungsbolzen drehfest mit dem Marknagel verbunden ist, der Marknagel durch den oder die Nasen drehfest über das Langloch mit der Führungshülse verbunden ist und die Führungshülse durch die lateral überstehende Lasche und die Schraube in der Öffnung drehfest mit dem proximalen Hauptfragment in Verbindung steht. Die Position der Nasen ist zu Beginn der Distraktionsbehandlung am Ende der Operation die proximale Langlochbegrenzung, womit eine Verkürzung der Extremität durch den Muskelzug verhindert wird.

Eine zusätzliche Rotationsstabilität liefert die an der medialen Zirkumferenz angeordnete klingenförmige Längsrippe, die in die verdichtete Spongiosa in der Nähe des massiven Kalkar eingetrieben wird.

Die Führungshülse bewirkt ferner eine Kompression der Stirnflächen an der Dockingstelle ohne erneute Operation allein durch den weiter wirkenden Antrieb während der Verlängerungsphase und dadurch einen Anreiz zur spontanen Durchbauung. Eine weitere Osteosynthese zur Kompression der Kontaktstellen oder eine Spongiosaplastik, also eine Knochenanlagerung meist aus dem Beckenkamm, läßt sich so vermeiden.

Wenn der Knochendefekt nur eine Segmentverschiebung erfordert, kommt der Führungshülse lediglich die Aufgabe der Rotationsstabilisierung zu. Die Nase oder die Nasen bleiben an dem proximalen Langlochende positioniert und sichern die Länge der Extremität während der gesamten Behandlung. Der Marknagel steht gewöhnlich proximal etwa 2 cm über oder schließt bündig mit der Oberkante des Trochanters ab. Distal erfolgt die Verriegelung im Hauptfragment, wie es auch bei der Verlängerung üblich ist. Etwa 3 cm distal der proximalen Stirnfläche des distalen Hauptfragments erfolgt eine gewebeschonende Kortikotomie. Die Verriegelung des mobilisierten Knochensegments mit einem Fixierungsbolzen erfolgt am distalen Ende des Langlochs im Marknagel. Am Ende der Segmentverschiebung, bei Erreichen der Dockingstelle, wird das Verschiebesegment mit seiner proximalen Stirnfläche an die distale Stirnfläche des proximalen Hauptfragments gepreßt. Bei ausreichendem Anpreßdruck wird der Antrieb gestoppt, das Knochenregenerat verfestigt sich, und die Dockingstelle wird überbrückt.

Für einen teilweisen Verschluß des wenigstens einen Langlochs in der Führungshülse kann in dieses in seinem distalen Bereich ein Wandelement formschlüssig eingesetzt werden. Das Wandelement bildet eine Fortsetzung der Innen- bzw. Außenwand der Führungshülse und wird mit Hilfe einer geringfügigen Hinterschneidung gehalten. Durch den Einsatz solcher in der Länge entsprechend bemessener Wandelemente läßt sich, wenn das Verschiebeelement die Dockingstelle erreicht hat, eine eventuell unerwünschte Verlängerung vermeiden, die durch den für den Anpreßdruck erforderlichen Zug des Antriebs bewirkt werden könnte, indem die proximale Stirnseite des Wandelements als Anschlag für die Nase des Marknagels wirkt. Bei dieser Ausgestaltung werden die Führungshülsen jeweils mit Langlöchern gleicher maximaler Länge hergestellt. Die Anpassung an die gewünschte Wirkungslänge des Langlochs entsprechend der geforderten Verlängerungsstrecke erfolgt dann durch Einsetzen des in der Länge entsprechend bemessenen Wandelements in das Langloch der Führungshülse.

Liegt ein Knochendefekt verbunden mit einer Verkürzung der Extremität vor, so erfolgen die Einbringung des Marknagels und die Segmentverschiebung in gleicher Weise wie bei einem alleinigen Knochendefekt. Bei Erreichen der Dokkingstelle wird der Antrieb jedoch nicht angehalten sondern zieht unverändert weiter, so daß nun ohne erneute Operation automatisch der Verlängerungsvorgang beginnt. Wenn der Längenausgleich erreicht ist, wird der Antrieb gestoppt und das Knochenregenerat verfestigt sich.

Für die Dimensionierung der Langlöcher im Marknagel und in der Führungshülse ist zu beachten, daß das Langloch in der Führungshülse allein für die Verlängerung erforderlich ist und diese auch begrenzt, während das Langloch im Marknagel sowohl für die Segmentverschiebung als auch für die Verlängerung dimensioniert werden muß. Für eine Segmentverschiebung von beispielsweise 3 cm und eine Verlängerung von 5 cm benötigt man ein Langloch in der Führungshülse von 5 cm, während die Länge des Langlochs im Marknagel 8 cm betragen muß, wobei zu diesen angegebenen Größen der Langlöcher jeweils der Durchmesser des Führungsbolzens addiert werden muß, der in der Regel der Breite des Langlochs entspricht.

Anhand von Zeichnungen werden Ausführungsbeispiele der Erfindung näher erläutert. Es zeigt:

Fig. 1 in einer Seitenansicht einen Marknagel für das erfindungsgemäße Distraktionssystem,

Fig. 2 einen Längsschnitt des Marknagels von **Fig.** 1,

Fig. 3 perspektivisch die Führungshülse des Distraktionssystems,

Fig. 4 perspektivisch das proximale Ende des Distraktionssystems bestehend aus einer Führungshülse und einem Marknagel,

Fig. 5 schematisch einen Knochen mit einer Defektstelle und einer Verkürzung,

Fig. 6 schematisch den Knochen von **Fig.** 5 mit dem eingesetzten Distraktionssystem,

Fig. 7 in einer Ansicht wie **Fig.** 6 das Ende der Segmentverschiebung und

Fig. 8 in einer Ansicht wie **Fig.** 7 das Ende der Knochenverlängerung anschließend an die Segmentverschiebung.

Der in **Fig.** 1 und 2 gezeigte Marknagel **10** entspricht in seinem Aufbau der DE 39 21 972 (**Fig.** 1 und 2). Der Marknagel **10** hat ein distales Ende **13** und ein proximales Ende **14** sowie eine Wand **11**, die im wesentlichen die Form eines Zylinders mit einer Achse **40** hat. In der Wand **11** sind im Bereich des distalen Endes drei im Abstand angeordnete, sich senkrecht zur Achse **40** erstreckende Fixierungslöcher **15** für die Durchführung von distalen Fixierungsbolzen **80**a, **80**b, **80**c (**Fig.** 6) vorgesehen. Innerhalb der Wand **11** des Marknagels **10** ist ein Innenteil **20** angeordnet, das ausgehend von seiner proximalen Stirnfläche eine Bohrung **21** mit einem Innengewinde aufweist, mit dem koaxial eine Stange **30** mit einem Außengewinde **33** in Schraubeingriff steht. Die Stange **30** ist an ihrem freien Ende mit einem Drehan-

PETITIONER ARTHREX
EX. 1004

trieb **18** gekoppelt, der seinerseits an einem Widerlager **17** auf der Innenseite der Wand **11** aufliegt. Senkrecht zur Achse **40** erstreckt sich durch das Innenteil **20** ein Fixierungsloch **22**, zu dem fluchtend zwei gegenüberliegende achsparallele Langlöcher **16** in der Wand **11** für die Durchführung eines proximalen Fixierungsbolzens **81** ausgerichtet sind, von denen in **Fig.** 6 bis 8 aufgrund der Darstellung nur eines zu sehen ist.

Wenn der Knochen zwischen den Fixierungslöchern **15** und dem Fixierungsloch **22** durchtrennt wird, werden durch Drehen der Stange **30** durch den am Widerlager festgehaltenen Antrieb **18** und den Gewindeeingriff zwischen der Stange **30** und der zentralen Bohrung **21** im Innenteil **20** die Ränder der Osteotomie **82** (**Fig.** 6) allmählich voneinander entfernt, wobei sich der erweiternde Spalt mit neu gebildetem Knochengewebe **86** (**Fig.** 7) füllt.

Bei dem Distraktionssystem ist der Marknagel **10** im Bereich seines proximalen Eintriebsendes **14** mit einer Nase **41** versehen. Zu dem Distraktionssystem gehört, wie in **Fig.** 3 und 4 zu sehen ist, eine Führungshülse **42**, die von ihrem proximalen Ende ausgehend ein achsparalleles Langloch **43** hat, in das die Nase **41** des Marknagels **10** eingreift. Wie aus **Fig.** 4 zu ersehen ist, sind zwei gegenüberliegende Langlöcher **43** vorgesehen. In dieser Ausgestaltung des Distraktionssystems sind an dem Marknagel **10** im Bereich des proximalen Eintriebsendes **14** zwei gegenüberliegende Nasen **41** am Umfang ausgebildet. Die Führungshülse **42** hat am proximalen Ende eine seitlich beidseitig überstehende Lasche **44**, in der auf einer Seite eine Öffnung **45** für das Durchführen eines nicht gezeigten Befestigungsmittels ausgebildet ist. Auf der der Öffnung **45** gegenüberliegenden Seite ist am Umfang der Führungshülse **42** eine klingenartige Längsrippe **46** ausgebildet, die sich achsparallel und radial nach außen unterhalb eines seitlichen Überstands der Lasche **44** erstreckt. Der Marknagel **10** sitzt in der Führungshülse **42** im Schiebesitz, wobei die Nasen **41** nicht über die Kontur der Außenwand der Führungshülse **42** überstehen und durch ihren Eingriff in die Langlöcher **43** eine Verdrehung zwischen Marknagel **10** und Führungshülse **42** verhindern.

Wie aus **Fig.** 5 zu ersehen ist, hat der gezeigte Knochen ein proximales Hauptfragment **83** und ein distales Hauptfragment **84**, die durch eine Defektstelle im Abstand von ΔD voneinander getrennt sind. Der Knochen ist ferner um die Länge ΔL verkürzt.

Wie aus **Fig.** 6 zu ersehen ist, ist in den beiden Hauptfragmenten **83** und **84** eine fluchtende Aufbohrung **50** ausgebildet. Das aus einer Führungshülse **42** und einem in ihr axial verschiebbaren Marknagel **10** bestehende Distraktionssystem wird in die Aufbohrung **50** im proximalen Hauptfragment **83** eingeführt. Die Führungshülse **42** ist einerseits durch eine durch die Öffnung **45** (**Fig.** 4) in der Lasche **44** geführte Schraube **47** und andererseits durch die klingenartige Längsrippe **46**, die in das proximale Hauptfragment **83** eingetrieben wird, verdrehungssicher und axial fixiert im proximalen Hauptfragment **83** gehalten. Durch den Eingriff der Nasen **41** in die Langlöcher **43** ist der Marknagel **10** bezüglich der Führungshülse **42** verdrehungssicher, jedoch axial begrenzt verschiebbar, gehalten.

In das Langloch **43** der Führungshülse **42** kann in dessen distalen Bereich ein das Langloch **43** teilweise verschließendes Wandelement **48** formschlüssig eingesetzt werden, wobei die distale Stirnfläche des Wandelements **48** an der distalen Endfläche des Langlochs **43** anliegt. Die Außen- bzw. Innenwand entspricht im wesentlichen der Kontur der Außen- bzw. Innenwand der Führungshülse **42**, wobei zur Halterung des Wandelements **48** eine geringfügige Hinterschneidung im Langloch **43** vorgesehen werden kann. Dadurch, daß nach einem vorgegebenen Verschiebeweg die Nase **41** des Marknagels **10** an der distalen Stirnfläche des Wandelements **48** anschlägt, wird die Verschiebung des Marknagels **10** nach distal auf eine vorgegebene Länge begrenzt, die kleiner als die des Langlochs **43** ist.

Durch die Fixierungslöcher **15** (**Fig.** 1 und 2) werden, wie **Fig.** 6 zeigt, Fixierungsbolzen **80**a, **80**b und **80**c hindurchgeführt und im distalen Hauptfragment **84** verankert. Ferner wird durch die Langlöcher **16** in der Wand **11** des Marknagels und durch das Fixierungsloch **22** im Innenteil **20** ein Fixierungsbolzen **81** hindurchgeführt und in dem Verschiebeelement **85** verankert.

Nach Ausführen der Kortikotomie oder Osteotomie **82** distal vom Führungsbolzen **81** wird der Antrieb **18** (**Fig.** 2) aktiviert, wodurch sich das proximal von der Kortikotomie **82** gebildete Verschiebesegment **85** in Richtung der Dockingstelle **87** am proximalen Hauptfragment **83** nach der Kallusdistraktionsmethode unter Bildung eines knöchernen Regenerats **86** bewegt, wodurch die Defektstelle ΔD beseitigt wird. Durch Weiterlaufenlassen des Antriebs **18** wird an der Dockingstelle **87** ein relativ hoher Druck ausgeübt, der das Zusammenwachsen des Verschiebesegments **85** mit dem proximalen Hauptfragment **83** fördert.

Wie aus **Fig.** 8 zu ersehen ist, kann ohne weitere Operation durch Weiterbewegung des Antriebs **18** (**Fig.** 2) eine Knochenverlängerung um die Länge ΔL nach der Kallusdistraktionsmethode ausgeführt werden, wobei der Marknagel **10** ins Innere der Führungshülse **42** wandert, deren Länge so bemessen ist, daß eine verkippungsfreie Lagestabilität gewährleistet bleibt.

Durch die Fixierung des Marknagels **10** durch die Führungsbolzen **80**a, **80**b und **80**c im distalen Hauptfragment **84** und durch den Führungsbolzen **81** proximal von den Führungsbolzen **80**a, **80**b, **80**c, durch die Ausbildung der Kortikotomie oder Osteotomie **82** distal vom Führungsbolzen **81** und durch die drehfeste Fixierung des Marknagels **10** durch die Führungshülse **42** und damit bezüglich des proximalen Hauptfragments **83** bleibt sowohl während der Schließung der Defektstelle als auch während der Knochendistraktion die exakte Ausrichtung der Hauptfragmente **83** und **84** einschließlich Verschiebesegment **85** zueinander gewährleistet.

Patentansprüche

1. Distraktionssystem für einen Röhrenknochen mit einem Marknagel (**10**), der eine einen Hohlraum (**12**) begrenzende Wand (**11**) mit einem distalen Ende (**13**) und einem proximalen Eintreibende (**14**) aufweist, und mit einer das proximale Eintreibende (**14**) des Marknagels (**10**) im Schiebesitz umschließenden Führungshülse (**42**), wobei der Marknagel (**10**)
   - einen in dem Hohlraum (**12**) längsverschiebbar angeordneten Innenteil (**20**), in das sich ausgehend von seiner dem proximalen Eintreibende (**14**) zugewandten Stirnseite eine koaxiale Bohrung (**21**) mit Innengewinde erstreckt,
   - ein im Hohlraum (**12**) im Abstand vom Eintreibende (**14**) vorgesehenes Widerlager (**17**),
   - eine Stange (**30**), die ein Außengewinde (**33**) hat, das in Schraubeingriff mit dem Innengewinde der Bohrung (**21**) des Innenteils (**20**) steht, und die mit einem innerhalb des Hohlraums (**12**) angeordneten, am Widerlager (**17**) aufliegenden Drehantrieb (**18**) gekoppelt ist,
   - im Bereich des distalen Endes durch die Wand (**11**) quer hindurchgehende, im Abstand angeordnete Fixierungslöcher (**15**) für die Durchführung von distalen Fixierungsbolzen,

PETITIONER ARTHREX
EX. 1004

– ein distal vom Widerlager (**17**) angeordnetes, quer durch die den Hohlraum (**12**) begrenzende Wand (**11**) gegebenenfalls auf gegenüberliegenden Seiten jeweils hindurchgehendes, zur Längserstreckung des Marknagels (**10**) paralleles Langloch (**16**) und

– wenigstens ein quer durch das Innenteil (**20**) hindurchgehendes, fluchtend zu dem Langloch (**16**) in der den Hohlraum (**12**) begrenzenden Wand (**11**) ausgerichtetes Fixierungsloch (**22**) für die Durchführung eines proximalen Fixierungsbolzens aufweist,

gekennzeichnet durch wenigstens eine aus der Wand (**11**) des Marknagels (**10**) vorstehende Nase (**41**) und durch mindestens ein in der Führungshülse (**42**) ausgebildetes, zu ihrer Achse paralleles Langloch (**43**), mit dem die Nase (**41**) in Führungseingriff steht, ohne über die Außenwand der Führungshülse (**42**) vorzustehen.

2. Distraktionssystem nach Anspruch 1, dadurch gekennzeichnet, daß die Führungshülse (**42**) an ihrer Außenseite mindestens eine zu ihrer Achse parallele schneidenförmig ausgebildete Längsrippe (**46**) aufweist.

3. Distraktionssystem nach Anspruch 2, dadurch gekennzeichnet, daß sich die Längsrippe (**46**) von dem proximalen Eintreibende der Führungshülse (**42**) aus erstreckt.

4. Distraktionssystem nach einem der vorhergehenden Ansprüche, gekennzeichnet durch ein Wandelement (**48**), das im distalen Bereich des wenigstens einen Langlochs (**43**) in der Führungshülse (**42**) für dessen teilweisen Verschluß formschlüssig einsetzbar ist, ohne innen und außen über die Wandkontur der Führungshülse (**42**) vorzustehen.

Hierzu 3 Seite(n) Zeichnungen

PETITIONER ARTHREX
EX. 1004

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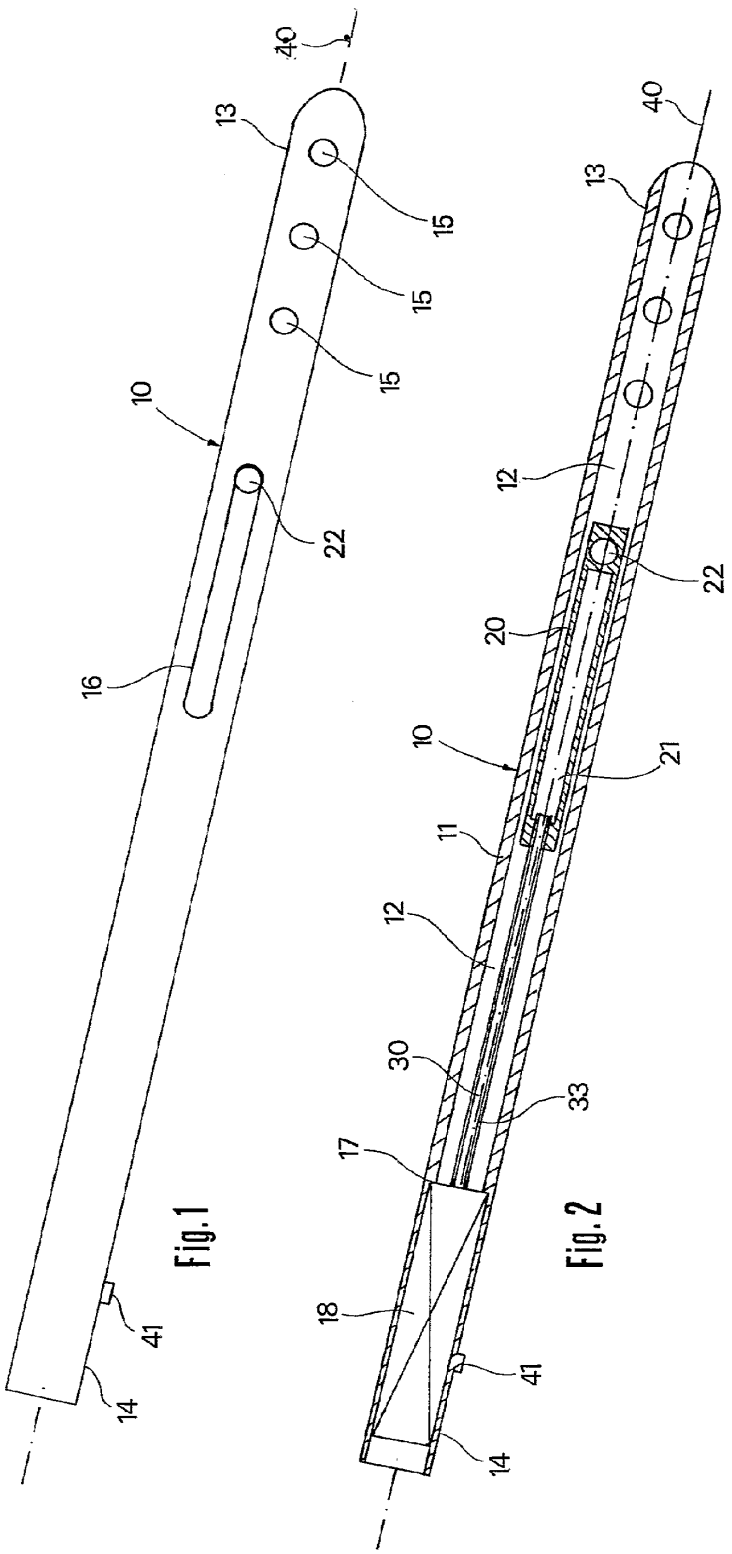


Fig. 1

Fig. 2

802 037/87

PETITIONER ARTHREX
EX. 1004

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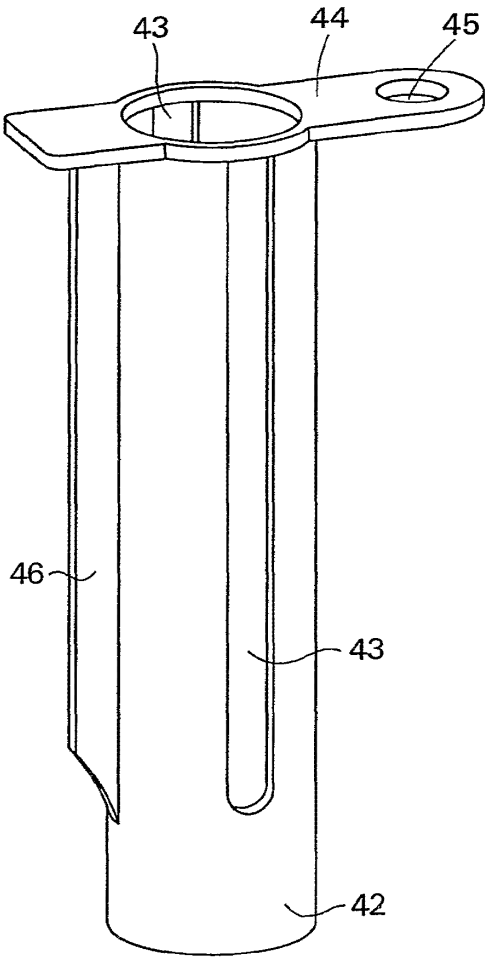


Fig. 3

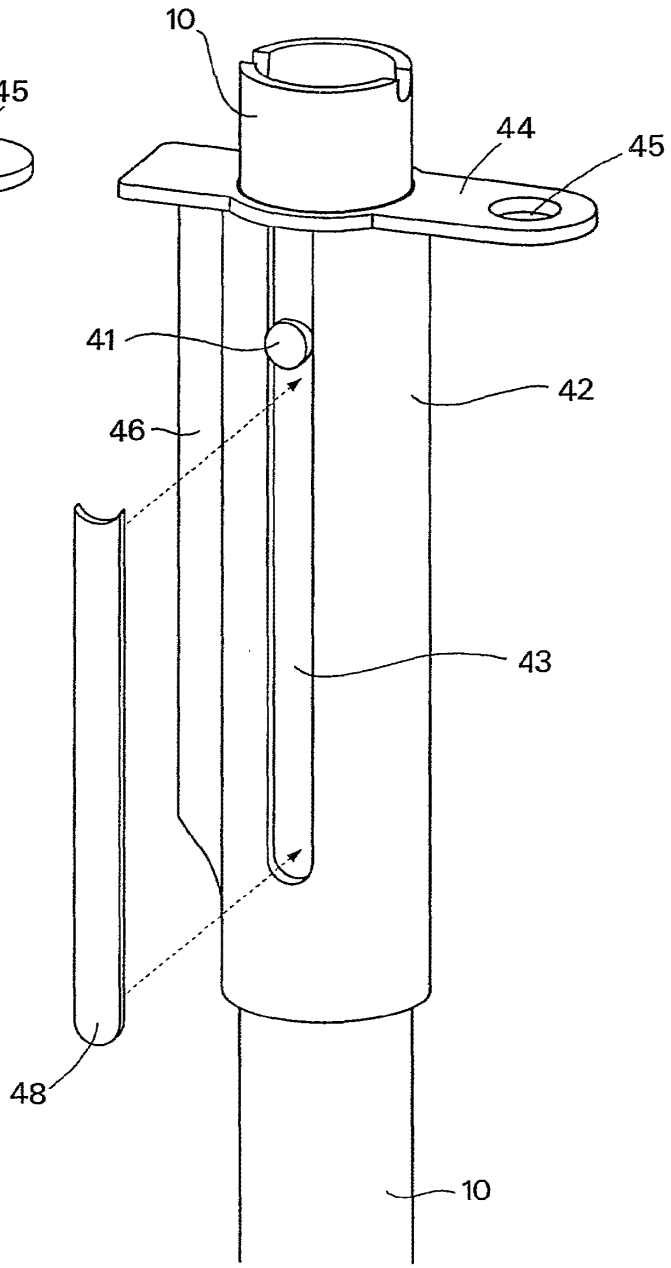
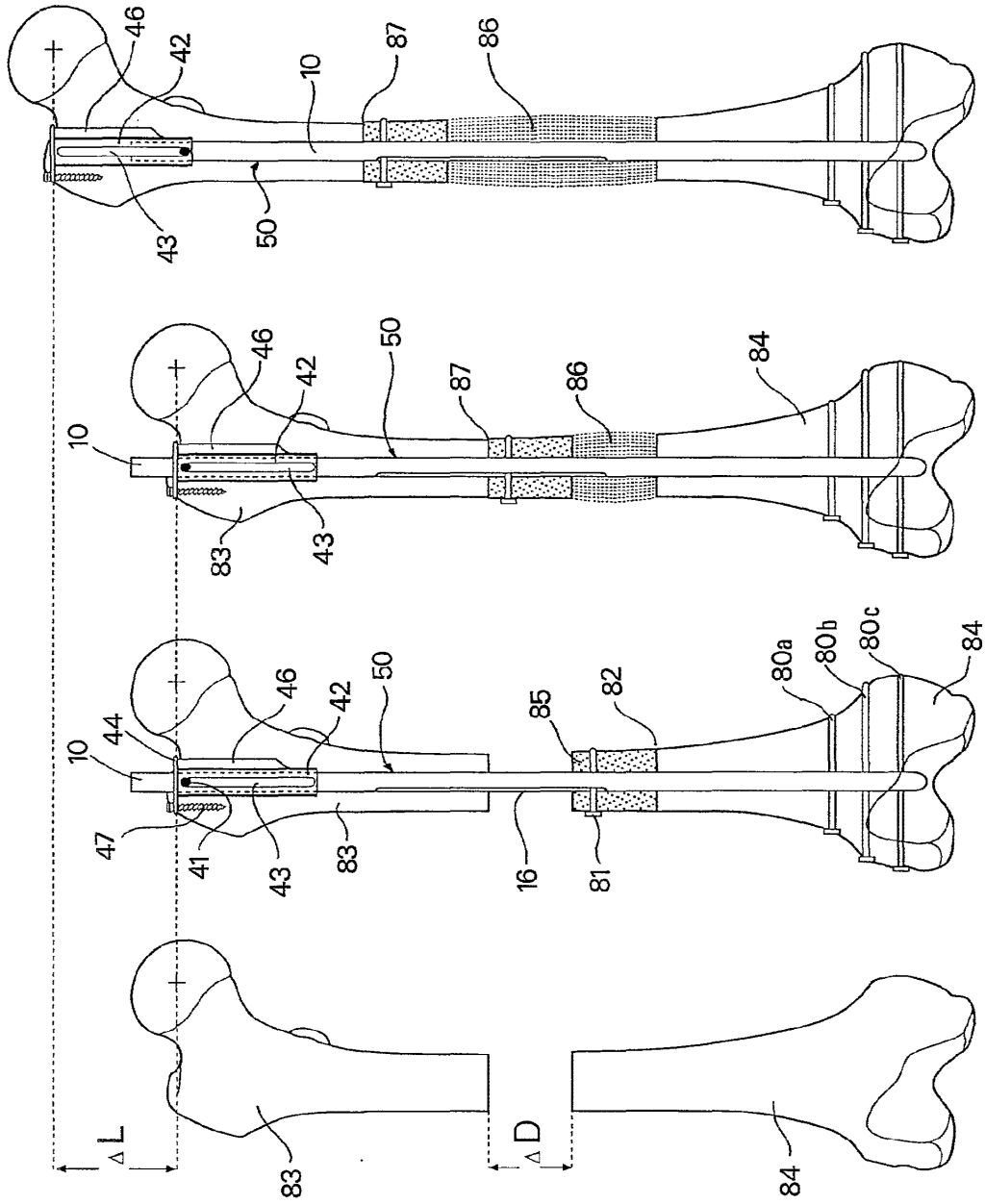


Fig. 4

802 037/87

PETITIONER ARTHREX
EX. 1004

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PETITIONER ARTHREX
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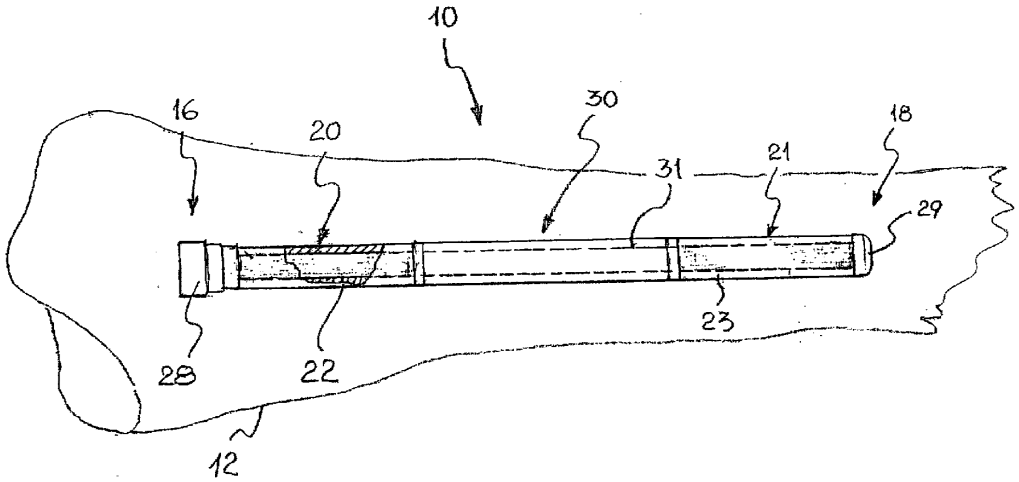
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[Continued on next page]

(54) Title: INTRAMEDULLARY NAIL PROVIDED WITH EXPANSION FIXING MEANS OPERATED BY ONE OR MORE DRIVING ELEMENTS



(57) Abstract: An intramedullary nail (10) suitable for insertion in a fractured elongate bone (12) and for an unusually simple fixation therein comprises a substantially straight stem (14, 114, 214, 314) extending between a proximal end (16, 116, 216, 316) and a distal end (18, 118, 218, 318), one of said ends (16, 18; 116, 118; 216, 218; 316, 318) comprising expansion means (20, 120, 220, 320) for the nail fixation to the bone, said expansion elements (20, 120, 220, 320) comprising at least an element (20a, 120a, 220a, 320a) realised with a shape-memory material.

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PETITIONER ARTHREX
EX. 1004

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PETITIONER ARTHREX
EX. 1004

Title: "Intramedullary nail provided with expansion fixing means operated by one or more driving elements"

DESCRIPTION

FIELD OF APPLICATION

The present invention relates in its more general aspect to an intramedullary nail suitable for insertion in a fractured elongate bone and an application method of said nail in said bone.

In particular, the invention relates to an intramedullary nail suitable for insertion in a fractured elongate bone, such as a femur or a tibia, comprising a substantially straight stem extending between a proximal end and a distal end.

PRIOR ART

Intramedullary nails are known, which, during a surgical operation, are inserted in a fractured elongate bone and fixed therein, in order to reconstruct the original bone shape and in the meantime to recover the bone solidity, so that callus regeneration mechanisms can correctly occur.

The stems of these intramedullary nails are generally substantially cylinder-shaped and they can be both solid and hollow.

In order to fix the intramedullary nail to the bone portions to be reconstructed, two or more offset holes are usually provided on the nail, having axes lying on parallel or crossing planes and extending diametrically across the stem, in correspondence with the nail distal end, and two or more similar offset holes, having axes not necessarily lying on parallel planes, in correspondence with the nail proximal end. Said holes are suitable for housing bone screws, which are inserted, after a convenient bone drilling, in the bone, with the subsequent fixation of the intramedullary nail to the bone portions.

Although advantageous under different points of view, intramedullary nails being structured as above schematically described have known drawbacks mainly occurring when bone drillings are to be performed for

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PETITIONER ARTHREX
EX. 1004

bone screw insertion. This step is particularly critical since it is known that a good nail fastening essentially depends on the correct realisation of these bone drillings, obviously made in correspondence with the holes of the inserted intramedullary nail.

However the precise location of the intramedullary nail holes is made difficult by the fact that the holes are no more visible, being the nail inserted in the bone. It is then worth underlining a further location problem, i.e the fact that the intramedullary nail can be, when being inserted, slightly bent, so that the holes at the nail distal end are no more, with respect to the proximal end, in the same position as before installing the nail.

The traditional technique for locating the holes of an inserted intramedullary nail provides the use of X rays, involving however the well known risks of cumulative exposure of the operating staff, besides being quite awkward during the surgical operation.

Specific mechanical devices have thus been studied and realised, such as for example the one described in the European patent no. EP 772 420 in the name of the same Applicant.

These devices do not require the use of X rays, but they have the drawback of requiring several operational steps, all to be performed quite carefully and precisely.

An intramedullary nail being fixed without using bone screws is also known from the international patent application no. WO 0134045,

The fixation is performed through a radial expansion of two nail portions, positioned near the distal and proximal end of the nail stem. In other words, at least one of said ends comprises expansion means for the nail fixation to the bone.

These portions are sleeves provided with longitudinal slots: the sleeve radial expansion is performed by applying an axial compression mechanical action to the ends of said sleeves. The compression is performed through an axial movement of a further stiff sleeve, which is moved by screwing it by hand on the stem.

PETITIONER ARTHREX
EX. 1004

Although advantageous under different points of view with respect to the above-mentioned prior art, the intramedullary nail structured as schematically above described has well-known drawbacks.

First, rotations of the nail in the bone can actually occur, since only the friction of the expansion portions against the bone causes the nail fixation.

Moreover, as a result of the expansion step of the two nail portions, with the subsequent shortening thereof in the axial direction, an undesired shortening of the bone whereon operation occurs is obtained, since the two sleeves equipped with slots are approaching to each other.

Still further, in the case of bone lyses in the contact area between the expanded sleeves and the bone, the nail fixation becomes insecure and it is necessary to operate from the outside to recover, as much as possible, a proper pressure in this contact area.

SUMMARY OF THE INVENTION

The problem underlying the present invention is to provide an intramedullary nail suitable for insertion in a fractured elongate bone, capable to meet the above-mentioned requirement, meanwhile overcoming, in a simple and effective way, all the drawbacks mentioned with reference to the prior art.

This problem is solved, according to the present invention, by an intramedullary nail suitable for insertion in a fractured elongate bone, as above described as defined in the independent claims.

Further features and the advantages of the intramedullary nail suitable for insertion in a fractured elongate bone, as well as of the application method of said nail in said bone, according to the present invention, will be apparent from the following description of some embodiments thereof made with reference to the attached drawings, given by way of non-limiting example.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic perspective view of a first embodiment of an

PETITIONER ARTHREX
EX. 1004

intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 2 is a schematic perspective view of a second embodiment of an intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 3 is a schematic enlarged-scale perspective view of a portion of the nail of figure 2.

Figure 4 is a schematic perspective view of a third embodiment of an intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 5 is a schematic enlarged-scale perspective view of a portion of the nail of figure 4.

Figure 6 is a schematic enlarged-scale perspective view of a further portion of the nail of figure 4.

Figure 7 is a schematic enlarged-scale perspective view of a component of the nail of figure 4.

Figure 8 is a schematic perspective view of an alternative embodiment of a portion of an intramedullary nail according to the present invention.

Figure 9 is a schematic perspective view of a further alternative embodiment of the nail portion of figure 8.

Figure 10 is a schematic plan view of an alternative embodiment of the nail portion of figure 8.

Figure 11 schematically shows a side-elevation cross-section of the nail of figure 10, taken according to the traced V-V plane.

Figure 12 is a further schematic enlarged perspective view of a further embodiment of the nail portion of figure 8.

Figure 13 is a schematic perspective view of the entire nail of figure 12.

Figure 14 is a schematic perspective view of an intramedullary nail

PETITIONER ARTHREX
EX. 1004

suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 15 is a schematic front-elevation view of the nail of figure 14.

Figure 16 is a schematic front-elevation view of a first alternative embodiment of the nail of figure 15.

Figure 17 is a schematic perspective view of a alternative embodiment of an intramedullary nail according to the present invention.

Figure 18 is a schematic front-elevation view of the nail of figure 17.

Figure 19 is a schematic front-elevation view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 20 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 21 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 22 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 23 is a schematic perspective view of the intramedullary nail of figure 22, in a different configuration.

Figure 24 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 25 is a schematic perspective view of an intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 26 is a schematic perspective exploded view of the nail of figure 25.

Figure 27 is a schematic perspective view of an alternative embodiment of an intramedullary nail according to the present invention.

Figure 28 is a schematic perspective exploded view of an portion of an intramedullary nail, suitable for insertion in a fractured elongate bone,

PETITIONER ARTHREX
EX. 1004

according to the present invention.

Figure 29 is a schematic side-elevation view of the nail of figure 28, in a different configuration.

Figure 30 is a schematic plan view from above of the nail of figure 29.

Figure 31 schematically shows a detail of the nail of figure 28.

Figure 32 schematically shows a detail of the nail of figure 29.

Figure 33 is a schematic plan view from above of an alternative embodiment of a nail according to the present invention.

Figure 34 schematically shows a cross-section of the nail of figure 33, taken according to the traced VII-VII plane of figure 33.

Figure 35 is a schematic plan view from above of the nail of figure 33, in a different configuration.

Figure 36 schematically shows a cross-section of the nail of figure 35, taken according to the traced IX-IX plane of figure 35.

Figure 37 is a schematic perspective view of a portion of an alternative embodiment of the intramedullary nail according to the present invention.

Figure 38 is a schematic perspective view of an alternative embodiment of an intramedullary nail according to the present invention.

Figure 39 is a schematic perspective view of the intramedullary nail of figure 38, in a different configuration.

Detailed description

Referring first to figure 1, an intramedullary nail according to the present invention is shown and globally indicated with 10, suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia.

The nail 10 comprises a substantially straight stem 14 extending between a proximal end 16 and a distal end 18.

The stem 14 is preferably composed of a cylindrical tube, realised for

PETITIONER ARTHREX
EX. 1004

example with a titanium alloy. The stem 14, according to an aspect of the present invention, comprises, near said proximal 16 and distal 18 ends, expansion means 20 and 21 respectively for the fixation of the nail 10 to the bone 12, said expansion means 20 and 21 being operated by at least one driving element 30, interposed between said expansion means 20 of said proximal end 16 and said expansion means 21 of said distal end 18 and realised with a shape-memory material.

Shape memory material means a material having a given initial starting shape and taking, under predetermined external conditions (for example a temperature rise and/or drop) or undergoing a predetermined activation condition, i.e. after a so-called "material instruction" step, a given new shape.

Known shape-memory material, which are suitable for use in the present invention, are, for instance, certain nickel-titanium alloys.

The invention is based on the following principle: subjecting an element realised in a shape memory material, having a predetermined initial shape at rest, to said so-called "material instruction" step (for example to a predetermined temperature variation), said element takes a shape being maintained as long as the "instruction" step effect persists; said shape, being different from the initial shape, can be called transient shape and it is temporary or unstable. When the "instruction" step effect stops, the element leaves said transient shape and, coming back towards the initial shape, takes a working shape. Depending on the type of material and on the working temperature, in the working shape, said material can arrive at the initial shape or it can go further on the initial shape, arriving at a final shape. It is worth pointing out that the more this final shape is far from the initial shape, the more the available shape memory energy of the material is high.

The invention has been reached as result of the intuition that an element realised in a shape memory material, in the passage from the transient shape towards the working shape, can create the fixing of the intramedullary nail in the bone.

Expansion means 20 of the proximal end 16 comprise a cylindrical sleeve 22 which is worn around the stem 14. The cylindrical sleeve 22,

PETITIONER ARTHREX
EX. 1004

undergone an axial compression, buckles taking a cask configuration, outside the stem 14, even taking an almost spherical configuration.

Expansion means 21 of the distal end 18 comprise a cylindrical sleeve 23 which is worn around the stem 14. Also the cylindrical sleeve 23, undergone an axial compression, buckles taking a cask configuration, outside the stem 14, even taking an almost spherical configuration.

Said at least one driving element 30 is interposed between the cylindrical sleeve 22 and the cylindrical sleeve 23. The driving element 30 comprises an intermediate cylindrical sleeve 31, worn around the stem 14, with a radial dimension being substantially equal to the radial dimension of the two sleeves 22 and 23 and realised with a shape-memory material: in the final shape, causing the fixation of the nail 10 to the bone 12, said intermediate cylindrical sleeve 31 undergoes an extension.

The stem 14 has at the distal end 18 or at the proximal end 16 an thickening 28, a front end of the cylindrical sleeve 23 or a front end of the cylindrical sleeve 22 respectively abutting on a surface thereof. The intermediate cylindrical sleeve 31 and the cylindrical sleeve 22 (or the cylindrical sleeve 23 respectively) are then mounted on the stem 14, said two cylindrical sleeves 22 and 23 abutting on the two front ends of the intermediate cylindrical sleeve 31.

The stem 14 has, in correspondence with the proximal end 16 or the distal end 18 respectively, a thread wherein a retaining ring 29 of the series of the first 22, second 23 and intermediate cylindrical sleeve 31 is screwed. Preferably, the ring 29, which is realised for example with a titanium alloy, is screwed on the stem 14 up to exert a slight pressure on the series of the sleeves 22, 23 and 31, i.e. said sleeves 22, 23 and 31 are positioned with an axial preload.

In order to screw the ring 29, two or more side flats (preferably parallel at a calibrated distance) are provided thereon for using a suitable control spanner.

At the top of the stem 14, on the side wherein the ring 29 is mounted, for example an hexagon-shaped profile is advantageously obtained, to fasten the stem 14 (with respect to the ring 29) by means of a spanner for socket

PETITIONER ARTHREX
EX. 1004

hexagonal head.

The intermediate cylindrical sleeve 31 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 21 and on the second sleeve 23 said axial compression buckling the first 22 and second 23 sleeve as above described.

In an alternative embodiment, the intermediate cylindrical sleeve 31 is realised with a titanium alloy, while the driving element 30 is composed of the stem 14, which is realised with a shape-memory material: in the final shape, causing the fixation of the nail 10 to the bone 12, said stem 14 undergoes a shortening. In other words, the stem 14 undergoes an instruction step causing it, in the final shape, to axially shorten: this deformation causes on the first sleeve 22 and on the second sleeve 23 said axial compression buckling the first 22 and second 23 sleeve as above described.

According to a further alternative embodiment of the invention, the two cylindrical sleeves 22 and 23 are realised with a shape-memory material: said cylindrical sleeves 22 and 23 undergo an instruction step causing them, in the final shape, to take a cask configuration, outside the stem 14, even taking an almost spherical configuration.

Therefore, in this alternative embodiment, both expansion means 20 and 21, and the intermediate cylindrical sleeve 31 are realised with shape-memory materials. The intermediate cylindrical sleeve 31 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 22 and on the second sleeve 23 a compression load tending to further increase the deformation of the first 22 and second sleeve 23.

Referring now to figures 2 and 3, a second embodiment of intramedullary nail is shown, according to the present invention, and globally indicated with 110, suitable for insertion in a fractured elongate bone 112. In this embodiment, the elements being structurally or functionally similar to the elements of the intramedullary nail 10 are indicated with the same reference number increased by 100 and the detailed description thereof is not repeated hereafter.

PETITIONER ARTHREX
EX. 1004

The nail 110 comprises a substantially straight stem 114 extending between a proximal end 116 and a distal end 118.

The stem 114 is preferably composed of a cylindrical tube, realised for example with a titanium alloy. The stem 114, according to an aspect of the present invention, comprises, near each of said proximal 116 and distal 118 ends, expansion means 120 and 121 respectively for the fixation of the nail 110 to the bone 112, said expansion means 120 and 121 being operated by at least one driving element 130, interposed between said expansion means 120 of said proximal end 116 and said expansion means 121 of said distal end 118 and realised with a shape-memory material.

Expansion means 120 and 121 of the proximal 116 and distal ends are of a same type; they comprise a plurality of inserts 122 and 123, sliding in corresponding openings 124 and 125 provided around the cylindrical sleeve of the stem 114 between an initial position, wherein an upper end 122a and 123a of the inserts 122 and 123 is substantially positioned below or on the outer side surface of the stem 114, and a final position, wherein the upper end 122a and 123a of the inserts 122 and 123 is positioned outside the outer side surface of the stem 114. The final position of said inserts 122 and 123 is defined by striker elements 122b and 123b abutting on a surface of the stem 114 positioned around the openings 124 and 125, inside the stem 114.

The upper end 122a and 123a of the inserts 122 and 123 is, for example, flat or slightly convex.

A flare 122c and 123c respectively is also preferably realised above the inserts 122 and 123, for example countersunk at 45°, towards the central part of the stem 114.

A housing groove 122d and 123d respectively of an elastic clamping ring (not shown in the figures) is also provided above the inserts 122 and 123, joining together the plurality of inserts 122 and 123 respectively.

The inserts 122 and 123 have a lower sloping surface 126 and 127, preferably flat, sloping from the side positioned towards the two ends of the stem 114 respectively.

PETITIONER ARTHREX
EX. 1004

Each of the expansion means 120 and 121 also comprises a driving element 132 and 133 to bring said inserts 124 and 125 in said final position: each of said driving elements 132 and 133 slides in the cylindrical sleeve of the stem 114 and it is equipped with a plurality of sloping surfaces, sloping from the opposite side with respect to the two respective ends of the stem 114, each of said sloping surfaces being conjugated to a corresponding lower sloping surface 126 and 127 of the inserts 122 and 123.

More precisely, the plurality of sloping surfaces of the driving elements 132 and 133 is realised, in the example of the figures, with a single frustum conical surface 134 and 135 respectively.

Said at least one driving element 130 is interposed between the two driving elements 132 and 133, in the cylindrical sleeve of the stem 114. The driving element 130 comprises a spring 131 realised with a shape-memory material: in the final shape, causing the fixation of the nail 110 to the bone 112, said spring 131 undergoes an extension along the direction of the axis of the stem 114.

Preferably, the inserts 122 and 123 and the driving elements 132 and 133 are realised with a titanium alloy.

Referring now to figures 4, 5, 6 and 7, a third embodiment of intramedullary nail is shown, according to the present invention, and globally indicated with 210, suitable for insertion in a fractured elongate bone 212. In this embodiment, the elements being structurally or functionally similar to the elements of the intramedullary nail 10 are indicated with the same reference number increased by 200 and the detailed description thereof is not repeated hereafter.

The nail 210 comprises a substantially straight stem 214 extending between a proximal end 216 and a distal end 218.

The stem 214 is preferably composed of a cylindrical tube, realised for example with a titanium alloy. The stem 214, according to an aspect of the present invention, comprises, near each of said proximal 216 and distal 218 ends, expansion means 220 and 221 respectively for the fixation of the nail 210 to the bone 212, said expansion means 220 and 221 being

PETITIONER ARTHREX
EX. 1004

operated by at least one driving element 230, interposed between said expansion means 220 of said proximal end 216 and said expansion means 221 of said distal end 218 and realised with a shape-memory material.

The expansion means 220 of the proximal end 216 comprise a cylindrical sleeve 222 which is worn around the stem 214. The cylindrical sleeve 222 preferably comprises a plurality of longitudinal slots 222a, for example equally spaced around the cylinder of the first sleeve 222, the slots 222a defining a plurality of staves 222b.

Moreover, the first sleeve 222 comprises at least one first tongue-shaped appendix 222c extending, in a longitudinal direction, outside the stem 214: the appendix 222c is housed in a corresponding first tongue housing 222d provided on an thickening 228 of the stem 214, realised at the proximal end 216 of the stem 214, beyond the cylindrical sleeve 222.

The thickening 228, having a cylindrical shape and a radial dimension being substantially equal to the dimension of the cylindrical sleeve 222, preferably comprises holes 228a for bone screws, for example two.

In the final shape, causing the fixation of the nail 210 to the fractured bone 212, said cylindrical sleeve 222, undergoing an axial compression, takes a cask configuration outside the stem 214, with a subsequent shortening of the longitudinal dimension of the sleeve 222; in the preferred embodiment with the staves 222b, in the final shape, the staves 222b take the cask stave configuration, with a subsequent shortening of the longitudinal dimension of the sleeve 222.

The first tongue-shaped appendix 222c, when passing from the initial shape to the final shape, slides in the first tongue housing 222d and also in said final shape the first tongue-shaped appendix 222c is inserted in the corresponding tongue housing 222d.

The expansion means 221 of the proximal end 218 comprise a cylindrical sleeve 223 which is worn around the stem 214. The cylindrical sleeve 223 preferably comprises a plurality of longitudinal slots 223a, for example equally spaced around the cylinder of the first sleeve 223, the slots 223a defining a plurality of staves 223b.

PETITIONER ARTHREX
EX. 1004

Moreover, the first sleeve 223 comprises at least one second tongue-shaped appendix 223c extending, in a longitudinal direction, outside the stem 214: the appendix 223c is housed in a corresponding second tongue housing 223d provided on an thickening 229 of the stem 214, realised at the proximal end 218 of the stem 214, beyond the cylindrical sleeve 223.

The thickening 229, having a cylindrical shape and a radial dimension being substantially equal to the dimension of the cylindrical sleeve 223, preferably comprises holes 229a for bone screws, for example two.

In the final shape, causing the fixation of the nail 210 to the fractured bone 212, said cylindrical sleeve 223, undergoing an axial compression, takes a cask configuration outside the stem 214, with a subsequent shortening of the longitudinal dimension of the sleeve 223; in the preferred embodiment with the staves 223b, in the final shape, the staves 223b take the cask stave configuration, with a subsequent shortening of the longitudinal dimension of the sleeve 223.

The second tongue-shaped appendix 223c, when passing from the initial shape to the final shape, slides in the second tongue housing 223d and also in said final shape the second tongue-shaped appendix 223c is inserted in the corresponding tongue housing 223d.

Said at least one driving element 230 is interposed between the cylindrical sleeve 222 and the cylindrical sleeve 223. The driving element 230 comprises an intermediate cylindrical sleeve 231, worn around the stem 214, with a radial dimension being substantially equal to the radial dimension of the two sleeves 222 and 223 and realised with a shape-memory material: in the final shape, causing the fixation of the nail 210 to the bone 212, said intermediate cylindrical sleeve 231 undergoes an extension.

Preferably, as shown in the example of the figures, the thickening 229 comprises a cylindrical sleeve and the distal end 218 of the stem 214 has a thread. A retaining ring 232 of the series of the first 222, second 231 and cylindrical sleeve 223 is screwed on said thread. Preferably, the ring 232 is screwed on the stem 214 up to exert a slight pressure on the series of the sleeves 222, 223 and 231, i.e. said sleeves 222, 223 and 231 are positioned with an axial preload. In this shape, the cylindrical sleeve of the

PETITIONER ARTHREX
EX. 1004

thickening 229 is fixed to the stem 214, for example by positioning, in a radial direction, a pin 229b between the sleeve and the stem 214.

The intermediate cylindrical sleeve 231 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 222 and on the second sleeve 223 said axial compression buckling the first 222 and second sleeve 223 as above described.

According to an alternative embodiment of the invention, the two cylindrical sleeves 222 and 223 are realised, at least partially, with a shape-memory material: said cylindrical sleeves 222 and 223 undergo an instruction step causing them, in the final shape, to take a cask configuration, outside the stem 214.

More precisely, the staves 222b and 223b are realised with a shape-memory material. By way of example, nitinol can be used, which, as it is well known, is a nickel-titanium alloy created in 1962 by Buehler, a metallurgist at the U.S. Naval Ordinance Laboratory. The staves 222b and 223b can thus comprise nitinol fillets.

Instead of nitinol, a superelastic material can be used, i.e. allowing considerable constant-load deformations: such a material is a nickel-titanium alloy and it differs from nitinol only for the percentages of these components.

It must be underlined that the staves 222b and 223b can also comprise wires made of nitinol or other shape-memory material, instead of said nitinol fillets.

Therefore, in this alternative embodiment, both the expansion means 220 and 221 and the intermediate cylindrical sleeve 231 are, at least partially, realised with shape-memory materials. The intermediate cylindrical sleeve 231 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 222 and on the second sleeve 223 a compression load tending to further increase the deformation of the first 222 and second sleeve 223.

It is specified that, in the third embodiment of the nail 210 of the invention, the positions of the components of the nail 210 can be

PETITIONER ARTHREX
EX. 1004

obviously inverted with respect to the proximal 216 and distal 218 ends of the stem 214, in the sense that the ring 232 can be positioned at the proximal end 216 rather than at the distal end 218.

Referring now to figure 8, a further embodiment of intramedullary nail, according to the present invention, is shown and globally indicated with 310, suitable for insertion in a fractured elongate bone 312. More precisely in figure 8, only a portion of the nail 310 is shown.

The nail 310 comprises a substantially straight stem extending between a proximal end 316 and a distal end.

The substantially straight stem preferably comprises a cylindrical sleeve, while expansion means 320 are provided in correspondence with at least one of the two ends for a fixation of the nail 310 to said fractured bone 312.

More precisely, according to an aspect of the present invention, these expansion means 320 comprise at least an element 320a realised with a shape-memory material.

In particular, expansion means 320 of the same type are provided both at the proximal end 316 and at the distal end.

The elements 320a realised with a shape-memory material of the expansion means 320 are, in this case, each of the proximal 316 and distal ends, whereon a plurality of longitudinal cuts 324 are provided, said cuts 324 cutting the thickness of the cylindrical sleeve of the stem 314. The cuts 324 are preferably equally spaced around the stem cylindrical sleeve and they define a plurality of foils 324a. The cuts 324 abut in grooves 324b being shaped according to a circumference arc.

It is specified that the stem cylindrical sleeve is bounded, at the proximal 316 and distal ends, by a bevelled surface 340, split by said cuts 324, said bevelled surface 340 being for example a portion of a spherical cap.

Referring now to figures 10 and 11, an alternative embodiment of said intramedullary nail 310 is shown.

The elements 320a realised with a shape-memory material of the

PETITIONER ARTHREX
EX. 1004

expansion means 320 are, in this case, two inserts 344 positioned the one at the proximal end 316 and the other at the distal end of the nail 310, in correspondence with respective lowered-cross-section portions of the stem 314.

Each insert 344 is shaped as a cylindrical sleeve comprising, at the end outside the stem 314, a plurality of longitudinal cuts 324, said cuts 324 cutting the thickness of the cylindrical sleeve of the insert 344. The cuts 324 are preferably equally spaced around the cylindrical sleeve of the insert 344 and they define a plurality of tongues 346. In the case shown in the figures the tongues 346 are four. In the initial shape, starting from the cylindrical sleeve without cuts 324, each tongue 346 has a first bend 348 outside the nail 310 and a following second bend 350 inwards the nail 310, so that the end section of the tongue 346 is positioned in a substantially axial direction with respect to the stem 314.

In a further alternative embodiment of said intramedullary nail 310, shown in figure 9, ring-shaped grooves 342 are provided, realised in correspondence with the two ends of the stem cylindrical sleeve: said ring-shaped grooves 342 are broken, along the circumference, by the cut 324 crossing.

The above description corresponds to the initial shape of the expansion means 320 realised with a shape-memory material. In the final shape, the free ends of the foils 324a or of the tongues 346 bend outside the stem, the foils 324a or the tongues 346 thus positioning in a substantially radial way.

Referring now to figures 12 and 13, a further embodiment of intramedullary nail, according to the present invention, is shown and globally indicated with 410, suitable for insertion in a fractured elongate bone 412.

The nail 410 comprises a substantially straight stem extending between a proximal end and a distal end.

The substantially straight stem is preferably composed of a cylindrical tube, while expansion means are provided in correspondence with at least one of the two ends for a fixation of the nail 410 to said fractured bone.

PETITIONER ARTHREX
EX. 1004

An element 420a consist of a first cylindrical sleeve 423 comprising a plurality of longitudinal cuts crossing the thickness of the cylindrical sleeve 423, said cuts starting from an end of the sleeve 423 and abutting in corresponding grooves 425b. The cuts are preferably equally spaced around the cylindrical sleeve 423 and they define a plurality of foils 425a. In the example of the figures, the foils 425a are four; the grooves 425b of the cuts 425 are shaped according to a circumference arc. Ring-shaped grooves 443 are also provided, realised in correspondence with the free ends of the foils 425a: said ring-shaped grooves 443 are broken, along the circumference, by the cut crossing.

The cylindrical tube of the stem has, in correspondence with the proximal end, a first narrow section, wherein the cylindrical sleeve is worn, so that the free end of the foils 425a is turned towards a stem central portion and it abuts in correspondence with the stem outer diameter change, wherein the first narrow section is provided. Preferably, the first narrow section has an outer prismatic shape corresponding to an inner conjugated prismatic shape of the central hole of the first cylindrical sleeve 423.

The foils 425a are not realised with a shape-memory material. In this case, in the final shape, the first cylindrical sleeve 423 is moved towards a stem central portion by driving means 444, so that the foils 425a are bent outside the first narrow section.

Driving means 344 are realised for example with a cylinder 346, made of a shape-memory material, which shortens in the final shape, inserted in the stem hole and fixed in said stem and in said first cylindrical sleeve 323.

It must be noticed that the cylinder 446 of the driving means 444 is, in the example of figure 13, realised enbloc with the second cylindrical sleeve 423, and it is practically an extension thereof. In this case, the cylinder 446 is obviously not directly fixed to the stem, since the fixation indirectly occurs by means of the second cylindrical sleeve 423 which, as already mentioned, is directly fixed to the narrow section of the stem.

With reference to figures 14 to 24, an intramedullary nail according to the invention which is suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia, comprises a substantially straight stem extending between a proximal end and a distal end. The stem is

PETITIONER ARTHREX
EX. 1004

preferably composed of a cylindrical tubular body.

According to an aspect of the present invention, the stem comprises at least a substantially longitudinal distribution of expansion means for the nail fixation to the bone. The substantially longitudinal distribution comprises at least an element realised with a shape-memory material, a free end of said at least one element positioning outside the stem to perform said fixation.

In the example of figures 14 and 15, the substantially longitudinal distributions 520 are three and they are angularly equally spaced around the side surface of the cylindrical tubular body of the stem 514

The element 522 made of a shape-memory material of each distribution 520 shapes in a substantially rectangular tongue 526, with the longest side being longitudinally developed with respect to the stem 514 and about as long as the stem 514. The tongue 526 is connected outside the stem 514 by a longest side thereof, while the opposite longest side is the free end 524 of said element 522.

In the final shape, i.e. when the shape-memory material is activated, the tongues 526 are positioned in a substantially tangential way with respect to the cylindrical tubular body of the stem 514, the tongues 526 being all positioned with a same rotation direction, i.e. the free ends 524 of the tongues 526 being all for example arranged in an angular position preceding (once the clockwise direction is set) the angular position of the longest side connected to the stem 514.

In the initial shape the tongue 526 is bent towards the side surface of the stem 514, it abuts for example on the side surface of the stem 514, and according to the width thereof, it can partially abuts on the adjacent tongue 526 (i.e. the tongue being arranged in an angular position preceding the angular position of the tongue 526 being concerned, the clockwise direction being always set).

The tongues 526 have connection arcs with the stem 514 being such as to reduce the stress concentration; meanwhile, these arcs have a limited extension, since it is worth allowing the deformation of most of each tongue 526.

PETITIONER ARTHREX
EX. 1004

The stem 514, at one end, has a head 528 having a substantially cylindrical shape and an axis substantially coinciding with the stem 514 axis: said head 528 has traditional means for hooking the nail 510, during the insertion thereof in the bone 12, with a traditional external guide device.

In the alternative embodiment of figure 16, the nail 610 according to the invention is shown, having a similar structure to the structure of the nail 510 of figure 14, with an additional covering element 630 enveloping the tongues 526 of the stem 514.

The covering element 630 shapes in a flat spiral spring which is preferably constrained to the free end 524 of a tongue 526.

The flat spiral spring, being longitudinally developed with respect to the stem 514, has a rest inner diameter being substantially equal to the cylindrical dimension of the tongues 526 in the initial position thereof. When the tongues 526 are operated, the inner diameter of the spiral spring is expanded according to the position taken by the free ends 524 of the three tongues 526.

Preferably, the spiral spring has outwardly a considerably rough surface.

In the alternative embodiment of figures 17 and 18, the nail 710 according to the invention is shown, wherein the substantially longitudinal distributions 520 are four and they are angularly equally spaced around the side surface of the cylindrical tubular body of the stem 14

Similarly to the nail 510, the element 522 made of a shape-memory material of each distribution 520 shapes in a substantially rectangular tongue 526, with the longest side being longitudinally developed with respect to the stem 14 and about as long as the stem 514. The tongue 526 is connected outside the stem 514 by a longest side thereof, while the opposite longest side is the free end 524 of said element 522.

In the final shape, i.e. when the shape-memory material is activated, the tongues 526 are positioned in a substantially tangential way with respect to the cylindrical tubular body of the stem 514, the tongues 526 being all positioned with a same rotation direction, i.e. the free ends 524 of the

PETITIONER ARTHREX
EX. 1004

tongues 526 being all for example arranged in an angular position preceding (once the clockwise direction is set) the angular position of the longest side connected to the stem 514.

In the final shape shown in figures 17 and 18, the tongues 526 are bent outside the stem 514: more precisely, the tongue concavity is the one deriving from the fact that the free end 524 of the tongue 526 is arranged in an angular position following (once the clockwise direction is set) the angular position of the respective tangent to the cylindrical tubular body of the stem 514.

In the initial shape the tongue 526 is bent towards the side surface of the stem 514, it abuts for example on the side surface of the stem 514, and according to the width thereof, it can partially abuts on the adjacent tongue 526 (i.e. the tongue being arranged in an angular position preceding the angular position of the tongue 526 being concerned, the clockwise direction being always set).

The tongues 526 have connection arcs with the stem 514 being such as to reduce the stress concentration; meanwhile, these arcs have a limited extension, since it is worth allowing the deformation of most of each tongue 526.

The stem 514, at one end, has a head 528 having a substantially cylindrical shape and an axis substantially coinciding with the stem 514 axis: said head 528 has traditional means for hooking the nail 510, during the insertion thereof in the bone 512, with a traditional external guide device.

In the alternative embodiment of figure 19 the nail 810 according to the invention is shown, wherein the elements 522 made of a shape-memory material of the substantially longitudinal distributions 520 shape in a plurality of corrugations 832 of a tubular structure 834 realised with a shape-memory material. The corrugations 832 are continuously distributed along the side surface of the tubular structure 834, which is internally constrained to the cylindrical tubular body of the stem 514. Alternatively, the tubular structure 834 is self load-bearing.

More precisely, the tubular structure 834 undergoes an instruction step of

PETITIONER ARTHREX
EX. 1004

the shape-memory material wherein, starting from a tubular structure with a circular outer profile (final shape of the nail 810), a tubular structure with a more reduced outer dimension is obtained (initial shape of the nail 810), by forming successive corrugations 832.

It is evident that in this alternative embodiment the free ends 524 of the corrugations 832 are practically the grooves of the corrugations 832, which, in the final shape of the nail 810, are positioned outside the initial dimension of the tubular structure 834, to perform the nail fixation to the bone.

By way of example, the outer diameter of the tubular structure 834 in the final shape (shown with dotted lines in the figure) can be of 20 mm, while the thickness of the tubular structure 834 can be of 0,4 mm.

In the alternative embodiment of figure 20 the nail 910 according to the invention is shown, wherein the element 522 made of a shape-memory material of the substantially longitudinal distribution 520 shapes in a covering element 930 enveloping the stem 514.

The covering element 930 shapes in a flat-spiral-shaped bent plate.

An end of said plate is connected to the stem 514 through traditional connection means, such as welding or mechanical joint, so to be substantially tangent to the cylindrical tubular body of the stem 514.

An opposite end of the bent plate is the free end 524 of the shape-memory element 522. In the final shape, this free end 524 is positioned, with respect to the stem 514, far outside than in the initial shape of the nail 910. In other words, the plate flat spiral enlarges, i.e. it radially expands when passing from the initial shape to the final shape.

The bent plate can also be split into pieces, to limit the risk of rotation of the nail 910 in the bone in the plate expansion step.

In the alternative embodiment of figure 21 the nail 910 according to the invention is shown, wherein the element 522 made of a shape-memory material of the substantially longitudinal distribution 520 shapes in a covering element 930 enveloping the stem 514.

PETITIONER ARTHREX
EX. 1004

The covering element 930 shapes in a flat-spiral-shaped bent plate.

An end of said plate is connected to the stem 514 through traditional connection means, such as welding or mechanical joint, so that the flat spiral strays in a substantially radial direction with respect to the stem 514 and it is preferably developed for about a turn and a half.

An opposite end of the bent plate is the free end 524 of the shape-memory element 522. In the final shape, this free end 524 is positioned, with respect to the stem 514, far outside than in the initial shape of the nail 910. In other words, the plate flat spiral enlarges, i.e. it radially expands when passing from the initial shape to the final shape.

In the alternative embodiment of figures 22 and 23 the nail 1010 according to the invention is shown, wherein the substantially longitudinal distributions 520 shape in two shaped plates 1036 and 1038, realised with a shape-memory material.

The shaped plates 1036 and 1038, in the final shape, are substantially flat and they are substantially rectangle-shaped, with the longest side being developed with the axis of the stem 514 and about as long as the stem 514.

More particularly, each of said shaped plates 1036 and 1038 is connected to the stem 514, along an intermediate line between the rectangle longest sides of the respective plates 1036 and 1038, in a substantially tangential way to the stem 514, for example by welding.

The intermediate connection lines are positioned substantially parallel to the axis of the stem 514, and they are for example offset on the outer surface of the stem 514 by about a right angle.

The planes of the two so-arranged plates 1036 and 1038 intersect: respective material lacks 1040 and 1042 allowing such an arrangement are thus provided.

More precisely, in the first shaped plate 1036, these lacks 1040 shape in rectangular slits, positioned in series in the direction of the longest side of the rectangle of the plate 1036. In the second shaped pate 1038, these lacks 1042 shape in rectangular slots, positioned in series in the direction

PETITIONER ARTHREX
EX. 1004

of the longest side of the rectangle of the plate 1038. The slots are realised starting from a longest side of the rectangle of the plate 1038 and they thus define a series of teeth 1044, being positioned in correspondence with the rectangular slits and having suitable dimensions for passing through these slits.

The above description corresponds to the final shape of the two shaped plates 1036 and 1038 having thus globally four series of free ends 524 for the fixation and i.e. the two longest sides of the rectangle of the plate 1036, the teeth 1044 and the longest side of the rectangle of the plate 1038 being opposite to the teeth 1044.

In the initial shape, the two plates 1036 and 1038 are bent with the concavity towards the stem 514; in other words, they lie enveloped on the outer surface of the stem 514.

By way of example, in the final shape, the plates 1036 and 1038, intersecting with each other as above described, have an outer dimension equal to a cylinder with a diameter of 19 mm.

It must be noticed that it is possible to have two plates 1036 and 1038 with free ends 524 distributed only in some areas (for example close to the ends of the stem 514), conveniently selecting for example the position of the teeth 1044.

A ferrule 1046 is preferably positioned at one end of the stem 514 to improve the insertion of the nail 1010. This ferrule shapes in an ellipsoid portion, centrally drilled in correspondence with the axis of the stem 514.

In the alternative embodiment of figure 24 the nail 1110 according to the invention is shown, wherein the substantially longitudinal distributions 520 shape in three plates 1148, 1150 and 1152, realised with a shape-memory material.

In the final shape, the three plates 1148, 1150 and 1152 are substantially flat and rectangular, with the longest side along the axis of the nail 1110.

They are connected to each other, by means of welds and/or joints. The connection occurs by joining a longest side of a plate to an intermediate and parallel line to the longest sides of the rectangle of the adjacent plate.

PETITIONER ARTHREX
EX. 1004

In other words, an equilateral-triangle-shaped section exists, with each of the three sides extending on a same side with respect to the single side being considered.

In the initial shape, the plates 1148, 1150 and 1152 are bent in correspondence with the respective intermediate lines of the mutual connection, so that, reasoning in the section terms, the extension of each side of the equilateral triangle is bent towards the side connected to the side being considered.

The stem 514 is inserted in the three so-connected plates 1148, 1150 and 1152 and it is constrained thereto.

With reference to figures 25-27, an intramedullary nail according to the present invention is shown.

The nail, in the embodiment described at first, is globally indicated with 1210, while in the alternative embodiment the nail of the invention is indicated with 1310.

The nail 1210 shown in figures 25 and 26, which is suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia, comprises a substantially straight stem 1214, having a predetermined X-X axis, extending between a proximal end 1216 and a distal end 1218. The stem 1214 is preferably composed of a cylindrical tubular body.

According to an aspect of the present invention, the nail 1210 comprises an helical element 1220 realised in a shape-memory material, said helical element 1220 being positioned along said axis X-X and elongation-constraint means 1221 being provided in correspondence with said proximal 1216 and distal 1218 ends, said helical element 1220 elongating in the helical development thereof so that coils thereof 1222 are positioned outwards said axis X-X for the nail fixation to the bone.

In the embodiment of figures 25 and 26, the helical element 1220, for example with circular cross-section, is positioned in the cylindrical tubular body of the stem 1214.

More precisely, the stem 1214 is elastically deformable in a direction being substantially radial to the axis X-X. Preferably, a plurality of longitudinal

PETITIONER ARTHREX
EX. 1004

slots 1224, developed for example for most of the length of the stem 1214 and angularly equally spaced, are provided around the cylindrical tubular body.

In correspondence with each of the two proximal 1216 and distal 1218 ends, said elongation-constraint means 1221 shape in a closing element 1226 which is connected to the cylindrical tubular body of the stem 1214: said closing element 1226 closes the central hole of the cylindrical tubular body of the stem 1214. Preferably, the closing element 1226 is cylinder-shaped.

In the initial shape, the helical element 1220 is inserted in the cylindrical tubular body of the stem 1214 and it has a longitudinal development being lower or substantially equal to the distance between the two closing elements 1226. The radial dimensions of the coils 1222 or the helical element 1220 are such as to be comprised in the cylindrical tubular body of the stem 1214, without causing a deformation thereof.

In the final shape, i.e. when the shape-memory material of the helical element 1220 is activated, the helical element 1220 is elongate: being however constrained to the longitudinal elongation by the constraint means 1221, it results that the radial dimensions of the coils 1222 increase and consequently the cylindrical tubular body of the stem 1214 is radially expanded.

In the alternative embodiment of figure 27, the nail 1310 according to the invention is shown, wherein the helical element 1220, for example with quadrilateral cross-section, is positioned outwards the stem 1214.

More precisely, the stem 1214 is composed of a cylindrical tubular body.

Said elongation-constraint means 1221 in correspondence with an end of the stem 1214, for example in correspondence with the distal end 18, shape in an enlargement 1328 of the stem 1214. The enlargement 1328 is equipped, on the side towards the centre of the stem 1214, with a beat collar 1330 for an end of the helical element 1220. Preferably, the enlargement 1328 is tapered on the opposite side with respect to the beat collar 1330, to help in inserting the nail 1310.

PETITIONER ARTHREX
EX. 1004

At the opposite end, i.e. for example at the proximal end, the elongation-constraint means 1221 shape in a further enlargement 1329 of the stem 1214. Similarly to the enlargement 1328, the enlargement 1329 is equipped, on the side towards the centre of the stem 1314, with a beat collar 1331 for the opposite end of the helical element 1220. Preferably, the enlargement 1329 is cylinder-shaped.

In the initial shape, the helical element 1220 is put around the cylindrical tubular body of the stem 1214 and it has a longitudinal development being lower or substantially equal to the distance between the enlargement 1328 and the further enlargement 1329.

In the final shape, i.e. when the shape-memory material of the helical element 1220 is activated, the helical element 1220 is elongate: being however constrained to the longitudinal elongation by the constraint means 1221, it results that the radial dimensions of the coils 1222 increase.

With reference to figures 28-39, an intramedullary nail according to the present invention is shown.

The nail 1410 shown in figures 28, 29 and 30, which is suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia, comprises a substantially straight stem 1414, having a predetermined axis X-X, extending between a proximal end 1416 and a distal end 1418.

According to an aspect of the present invention, the nail 1410 comprises expansion means 1420 for the nail fixation to the bone, said expansion means 1420 being operable by at least one driving element 1422 realised with a shape-memory material.

In the example of figures 28, 29 and 30, the stem 1414 comprises a plurality of longitudinal portions 1424 forming, close to each other, a cylindrical tubular body.

In other words, the longitudinal portions 1424 have a circular-crown-sector-shaped section. In the case being shown, the longitudinal portions 1424 are four and the angle at the circular crown sector centre is a right

PETITIONER ARTHREX
EX. 1004

angle.

Expansion means 1420 shape in said longitudinal portions 1424, which can be radially spaced apart from the axis X-X of the stem 1414.

Said at least one driving element 1422, for example in the shape of a V-or-U-bent cylindrical body 1426, is provided between the longitudinal portions 1424. The cross section of the cylindrical body 1426 can be, for example, circular or square.

The cylindrical body 1426 is fixed, at the two opposite ends, to two longitudinal portions 1424, generally in correspondence with surfaces being turned towards the axis X-X.

Preferably, recesses 1428, being accessible from the axis X-X, are provided in said longitudinal portions 1424. Said recesses 1428 of the longitudinal portions 1424 are conjugate to each other: in other words, when the longitudinal portions 1424 are close to each other, said recesses 1428 define an area 1430 comprising said bent cylindrical body 1426 which is connected, at two opposite ends, to the two longitudinal portions 1424 being concerned.

In the case of the four longitudinal portions 1424 being shown, four cylindrical bodies 1426 are provided in correspondence with each end 1416 and 1148 of the stem 1414. Preferably, the four cylindrical bodies 1426 of each end 1416 and 1418 are symmetrically positioned with respect to the axis X-X, generally at a same height with respect to the axis X-X.

In the initial shape, shown in figure 28, the longitudinal portions 1424 are close to each other and the cylindrical bodies 1426 are bent.

In the final shape, shown in figures 29 and 30, i.e. when the shape-memory material of the cylindrical bodies 1426 is activated, the cylindrical bodies 1426 tend to straighten, i.e. the angle between the directions of two opposite ends tends to increase, as it can be seen by comparing figures 31 and 32 showing a cylindrical body 1426 in the initial shape and in the final shape. As a consequence of this straightening, the longitudinal portions 1424, connected by means of the cylindrical bodies 1426, are

PETITIONER ARTHREX
EX. 1004

spaced apart, having moved in a substantially radial direction with respect to the axis X-X.

In the alternative embodiment of figures 33, 34 and 35, the nail 1510 according to the invention is shown, wherein at least one driving element 1422, shaping in a X-shaped structure 1526, is provided between the longitudinal portions 1424.

The structure 1526 has thus four ends 1526a, 1526b, 1526c and 1526d: in correspondence with two first adjacent ends 1526a and 1526b, the structure 1526 is fixed to two longitudinal portions 1424, generally in correspondence with surfaces being turned towards the axis X-X. The fixation is performed for example through buckling with plastic deformation.

Preferably, grooves 1528, being accessible from the axis X-X, are provided in said longitudinal portions 1524. Said grooves 1528 of the longitudinal portions 1424 are conjugate to each other: in other words, when the longitudinal portions 1424 are close to each other, said grooves 1528 define an area 1530 comprising said structure 1526 when being bent, i.e. when the two first adjacent ends 1526a and 1526b are close to each other and when also the two remaining adjacent ends 1526c and 1526d are close to each other.

The two remaining ends 1526c and 1526d are able to slid in said grooves 1528.

In the case being shown, the longitudinal portions 1424 are four and four structures 1526 are provided in correspondence with each end 1416 and 1418 of the stem 1414. Preferably, the four structures 1526 of each end 1416 and 1418 are symmetrically positioned with respect to the axis X-X, generally at a same height with respect to the axis X-X.

In the initial shape, shown in figures 33 and 34, the longitudinal portions 1424 are close to each other and the structures 1526 are bent as above described.

In the final shape, shown in figures 35 and 36, i.e. when the shape-memory material of the structures 1526 is activated, the first two adjacent

PETITIONER ARTHREX
EX. 1004

ends 1526a and 1526b tend to space apart, as the remaining adjacent ends 1526c and 1526d tend to space apart by sliding in the grooves 1528, i.e. the structures 1526 become X-shaped. As a consequence of this straightening, the longitudinal portions 1424, connected by means of the structures 1526, are spaced apart, having moved in a substantially radial direction with respect to the axis X-X.

It must be noticed that the X-shaped structures 1526 can be alternatively obtained by joining pairs of V-or-U-bent cylindrical bodies 1426, in correspondence with the bent area. It is evident that in this case, in order to achieve the same effect as structures 1526, the cylindrical bodies 1426 will be so instructed as to be bent in the final shape and to be substantially straight in the initial shape.

In the alternative embodiment of figure 37, the nail 1610 according to the invention is shown, which is similar to the nail 1410 and it has thus V-or-U-bent cylindrical bodies 1426. However, in this alternative embodiment the adjacent cylindrical bodies 1426 are positioned with the bend arranged on opposite sides: in other words, in the case of four longitudinal portions 1424 with four cylindrical bodies 1426, the cylindrical bodies 1426, which face to each other, are specular.

It must be noticed that the radial expansion is linked to the length of the cylindrical bodies 1426.

In the alternative embodiment of figures 38 and 39, the nail 1710 according to the invention is shown, wherein expansion means 1720 shape in a rod 1732, two opposite ends 1734 and 1736 of said rod 1732 being spaceable in a substantially radial way from the axis X-X of the stem 14.

More precisely, the rod 1732 is hinged, in an intermediate position thereof, on the stem 1414 by means of a pin 1738. In particular, the rod 1432 is hinged in an intermediate position of the stem 1414.

The rod 1732 is rectangle-shaped and substantially as long as the stem 1414. The rod 1732 is also equipped with a groove 1440, in correspondence with the area wherein the pin 338 is positioned. A torsion spring 1742 realised with a shape-memory material is positioned around

PETITIONER ARTHREX
EX. 1004

the pin 1738: this is the driving element 1422 of the nail 1710.

An end of the spring 1742 is constrained to the stem 1414, while the opposite end is positioned in front of a wall of the groove 1740, or preferably it is connected thereto.

In the final shape, the spring 1742 is expanded, with an increase in the angle between the two ends of the spring 1742 causing, through the thrust of the opposite end of the spring 1742 on the wall of the groove 1740, a rotation of the rod 1732.

The rod 1732 is preferably equipped, at the two ends 1734 and 1736, with sharp portions for an improved fixation of the nail 1710.

The main advantage achieved by the intramedullary nail suitable for insertion in a fractured elongate bone, as well as by the application method of said nail in said bone, according to the present invention, is the fact of unusually simplifying the fixation step of the intramedullary nail inserted in the bone: the expansion of expansion means occurs in fact without a mechanical manual intervention, the shape-memory material used in the nail of the invention expanding instead by heat absorption. In practise, the nail fixation is obtained simultaneously with the insertion thereof in the bone, since the shape-memory elements, cooled at first to take the initial shape, take in the bone their final shape, due to the heat released by the patient's body.

Another advantage of the intramedullary nail suitable for insertion in a fractured elongate bone, according to the present invention, is to prevent undesired nail torsions or rotations, since the tongue-shaped appendix is held in the housing thereof.

Another advantage of the intramedullary nail according to the present invention is to preserve the length of the bone on which the intervention occurs, since the tongue-shaped appendix slides in the housing thereof, the nail stem thus keeping the starting position thereof.

A further advantage of the intramedullary nail according to the present invention is that, in case of bone lyses in the contact area between the expanded cylindrical sleeves and the bone, the nail fixation is however

PETITIONER ARTHREX
EX. 1004

ensured, with no need for an external intervention, since the final shape of the cylindrical sleeves realised with a shape-memory material have a higher radial dimension than the radial dimension of the cylindrical sleeves in the fixation step of the nail to the bone, so that a considerable contact pressure is preserved.

A still further advantage of the intramedullary nail according to the present invention is to be easy to produce, because of the reduced number of different pieces (reminding that the two cylindrical sleeves are identical).

Another advantage of the intramedullary nail suitable for insertion in a fractured elongate bone, according to the present invention, is to prevent undesired nail torsions or rotations.

Another advantage of the intramedullary nail according to the present invention, is to prevent undesired nail torsions or rotations in the bone during the application step, due to the structural continuity of the described embodiments.

A further advantage of the intramedullary nail according to the present invention is that the stem in the shape of a cylindrical tubular body allows an easy insertion in the bone by using a guide wire.

In the case of the nail, it must be noticed that the load applied on the medullary canal of the bone by the three tongues is advantageously distributed along the circumference of the stem.

The shortest side of the rectangle of the tongues can be very long, exploiting all the space of the stem lying between one tongue and the other.

Obviously, in order to meet specific and contingent requirements, a skilled in the art could bring several changes to the above-described intramedullary nail suitable for insertion in a fractured elongate bone and application method of said nail in said bone, all however comprised in the scope of protection of the present invention, as defined in the following claims.

PETITIONER ARTHREX
EX. 1004

CLAIMS

1. Intramedullary nail (10, 110, 210) suitable for insertion in a fractured elongate bone (12, 112, 212), comprising a substantially straight stem (14, 114, 214) extending between a proximal end (16, 116, 216) and a distal end (18, 118, 218), characterised in that said stem (14, 114, 214) comprises, near each of said proximal (16, 116, 216) and distal (18, 118, 218) ends, expansion means (20, 120, 220; 21, 121, 221) for the nail fixation to the bone, said expansion means (20, 120, 220; 21, 121, 221) being operated by at least one driving element (30, 130, 230), interposed along the axis of the stem (14, 114, 214) between said expansion means (20, 120, 220) of said proximal end (16, 116, 216) and said expansion means (21, 121, 221) of said distal end (18, 118, 218) and realised with a shape-memory material.

2. Intramedullary nail (10, 210) according to claim 1, characterised in that said expansion means (20, 220) comprise a cylindrical sleeve (22, 23, 222, 223) which is worn around the stem (14, 214), the cylindrical sleeve (22, 23, 222, 223), undergoing an axial compression, buckling and taking a cask configuration, outside the stem (14, 214).

3. Intramedullary nail (10) according to claim 2, characterised in that, said at least one driving element (30) is interposed between the two cylindrical sleeve (22, 23), the driving element (30) comprising an intermediate cylindrical sleeve (31), worn around the stem (14), with a radial dimension being substantially equal to the radial dimension of the first (22) and second sleeve (23), in the final shape, causing the fixation of the nail (10) to the bone (12), said intermediate cylindrical sleeve (31) undergoing an extension.

4. Intramedullary nail (110) according to claim 1, characterised in that the stem (114) is composed of a cylindrical tube and in that said expansion means (120, 121) of the proximal (116) and distal end respectively comprise a plurality of inserts (122, 123), sliding in corresponding openings (124, 125) provided around the cylindrical sleeve of the stem (114) between an initial position, wherein an upper end (122a, 123a) of the inserts (122, 123) is positioned substantially below or on the outer side surface of the stem (114), and a final position, wherein the

PETITIONER ARTHREX
EX. 1004

upper end (122a, 123a) of the inserts (122, 123) is positioned outside the outer side surface of the stem (114).

5. Intramedullary nail (110) according to claim 4, characterised in that the inserts (122, 123) have a lower sloping surface (126, 127), sloping from the side positioned towards the two ends (116, 118) of the stem (114), that each of the expansion means (120, 121) comprises a driving element (132, 133) to bring said inserts (124, 125) in said final position and that each of said driving elements (132, 133) slides in a cylindrical sleeve of the stem (114) and it is equipped with a plurality of sloping surfaces, sloping from the opposite side with respect to the two ends (116, 118) of the stem (114), each of said sloping surfaces being conjugated to a corresponding lower sloping surface (126, 127) of the inserts (122, 123).

6. Intramedullary nail (110) according to claim 5, characterised in that said at least one driving element (130) is interposed between the two driving elements (132, 133), in the cylindrical sleeve of the stem (114), the driving element (130) comprising a spring (131) realised with a shape-memory material: in the final shape, causing the fixation of the nail (110) to the bone (112), said spring (131) undergoing an extension along the direction of the axis of the stem (114).

7. Intramedullary nail (210) suitable for insertion in a fractured elongate bone (212), comprising a substantially straight stem (214 extending between a proximal end (216) and a distal end (218), at least one of said ends (218) comprising expansion means (220) for the nail fixation to the bone, characterised in that said expansion elements (220) comprise at least an element (220) realised with a shape-memory material.

8. Intramedullary nail (210) according to claim 7, characterised in that said substantially straight stem (214) is a cylindrical tube and in that said elements (220a) realised with a shape-memory material of the expansion means (220) are each of said proximal (216) and distal ends, whereon a plurality of longitudinal cuts (224) are provided, said cuts (224) cutting the thickness of the cylindrical sleeve of the stem (214), defining a plurality of foils (224a). and abutting in grooves (224b), the free ends of the foils (224a) bending outside the stem (214) in a final shape corresponding to the fixation of the nail (210) to said fractured bone (212).

PETITIONER ARTHREX
EX. 1004

9. Intramedullary nail (410) according to claims 1 and 7, characterised in that the substantially straight stem (414) is a cylindrical sleeve and in that said driving element (444) is realised with a cylinder (446), made of shape-memory material, which shortens in the final shape, said cylinder (446) being inserted in the stem hole and fixed in said stem.

10. Intramedullary nail (510, 610, 710, 810, 910, 1010, 1110) suitable for insertion in a fractured elongate bone (12), comprising a substantially straight stem (514) extending between a proximal end (516) and a distal end (518), characterised in that said stem (514) comprises at least a substantially longitudinal distribution (520) of expansion means for the nail fixation to the bone, said expansion means comprising at least one element (522) realised with a shape-memory material, a free end (524) of said at least one element (522) positioning outside the stem (514) to perform said fixation.

11. Intramedullary nail (510, 610, 710, 810, 910, 1010, 1110) according to claim 10, characterised in that the element (522) made of a shape-memory material of each distribution (520) shapes in a substantially rectangular tongue (526), with the longest side being longitudinally developed with respect to the stem (514) and about as long as the stem (514).

12. Intramedullary nail (510, 610, 710, 810, 910, 1010, 1110) according to claim 11, characterised in that the tongue (526) is connected outside the stem (514) by a longest side thereof, the opposite longest side being the free end (524) of said element (522).

13. Intramedullary nail (510) according to claim 12, characterised in that it provides a covering element (630) enveloping the tongues (526) of the stem (514).

14. Intramedullary nail (510) according to claim 13, characterised in that the covering element (630) shapes in a flat spiral spring, longitudinally developed with respect to the stem (514).

15. Intramedullary nail (710) according to claim 10, characterised in that the elements (522) made of a shape-memory material of the substantially longitudinal distributions (520) shape in a plurality of corrugations (732)

PETITIONER ARTHREX
EX. 1004

of a tubular structure (734) realised with a shape-memory material.

16. Intramedullary nail (1210, 1310) suitable for insertion in a fractured elongate bone (12), comprising a substantially straight stem (1214), having a predetermined axis (X-X), extending between a proximal end (1216) and a distal end (1218), characterised in that it comprises an helical element (1220) realised with a shape-memory material, said helical element (1220) being positioned along said axis (X-X) and elongation-constraint means (1221) being provided in correspondence with said proximal (1216) and distal (1218) ends, said helical element (1220) elongating in the helical development thereof so that coils thereof (1222) are positioned outwards said axis (X-X) for the nail fixation to the bone.

17. Intramedullary nail (1210) according to claim 16, characterised in that the helical element (1220) is positioned in the cylindrical tubular body of the stem (1214).

18. Intramedullary nail (1210) according to claim 17, characterised in that the stem (1214) is elastically deformable in a substantially radial direction with respect to said axis (X-X).

19. Intramedullary nail (1310) according to claim 1, characterised in that the helical element (1220) is positioned outwards the stem (1214).

20. Intramedullary nail (1410, 1510, 1610, 1710) suitable for insertion in a fractured elongate bone (12), comprising a substantially straight stem (1414), having a predetermined axis (X-X), extending between a proximal end (1416) and a distal end (1418), characterised in that it comprises expansion means (1420) for the nail fixation to the bone, said expansion means (1420) being operable by at least one driving element (1422) realised with a shape-memory material.

21. Intramedullary nail (1510) according to claim 20, characterised in that at least one driving element (1422), shaping in a X-shaped structure (126) is provided between longitudinal portions (1424) of the stem (1414).

22. Intramedullary nail (1710) according to claim 20, characterised in that expansion means (1420) shape in a rod (1732), two opposite ends (1734, 1736) of said rod (1732) being spaceable in a substantially radial

PETITIONER ARTHREX
EX. 1004

way from the axis (X-X) of the stem (1414).

PETITIONER ARTHREX
EX. 1004

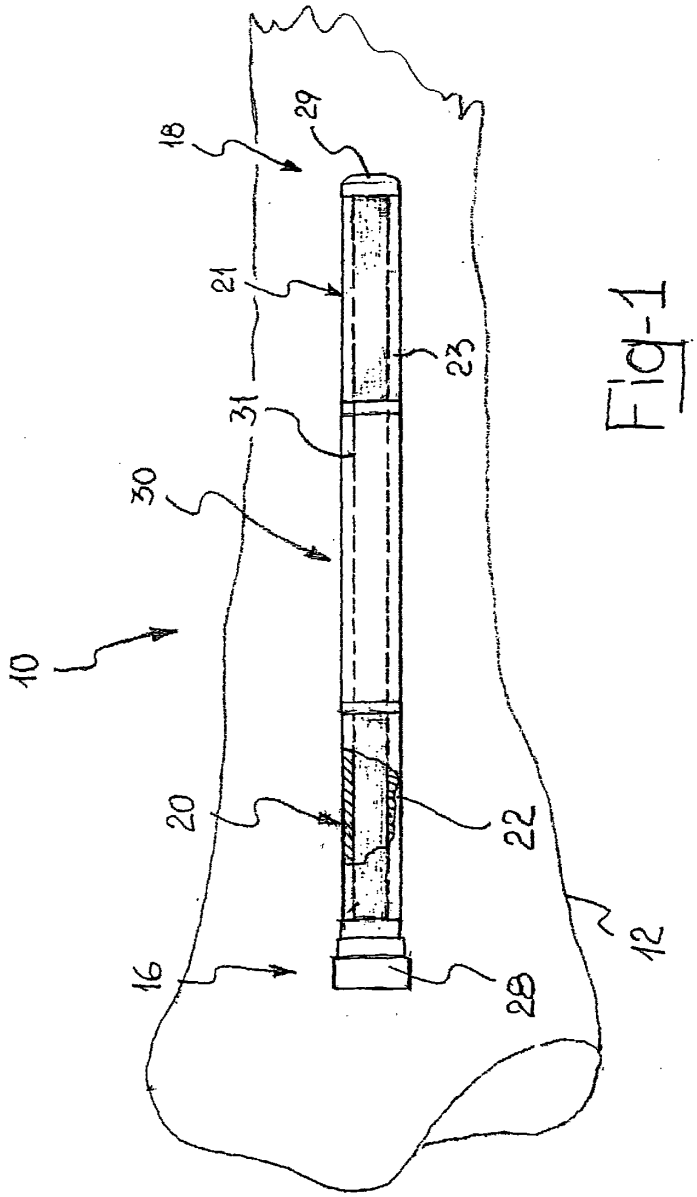


Fig-1

PETITIONER ARTHREX
EX. 1004

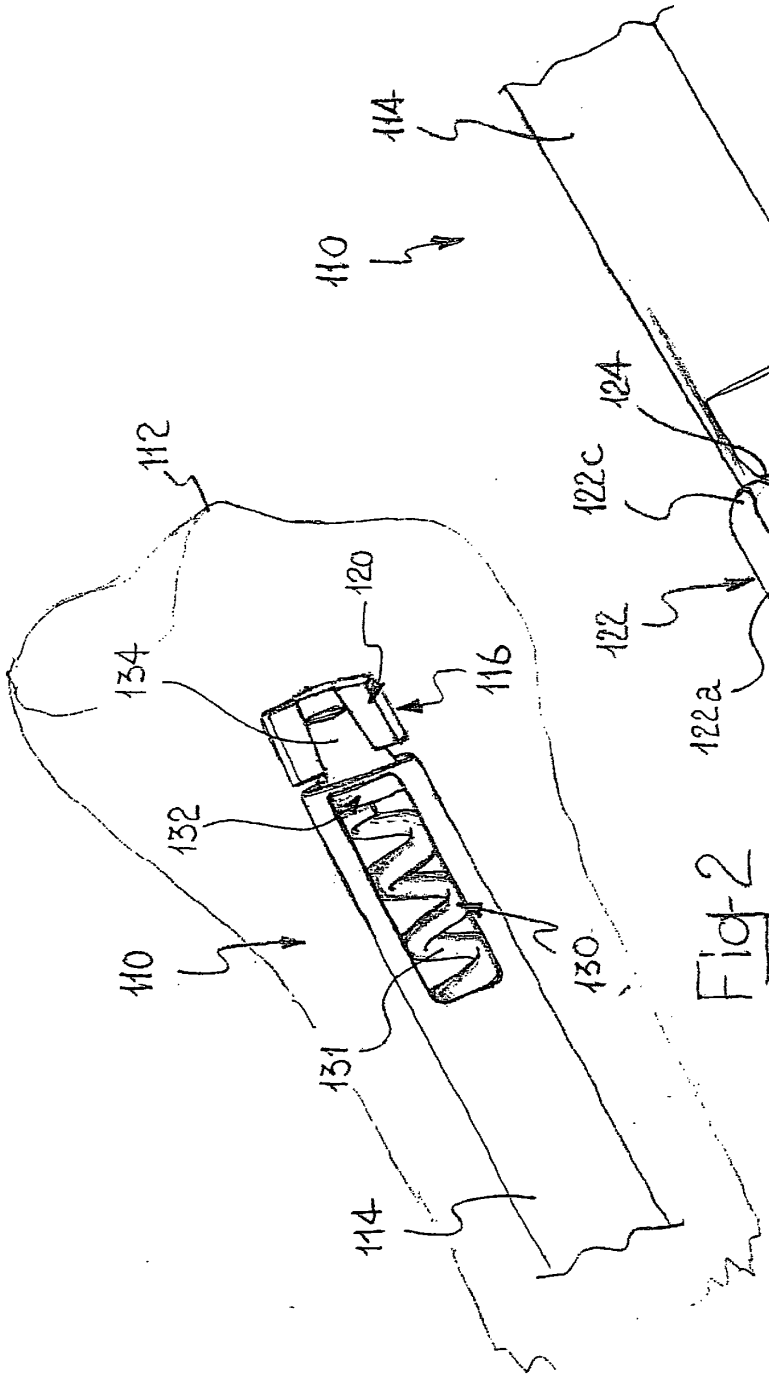


Fig-2

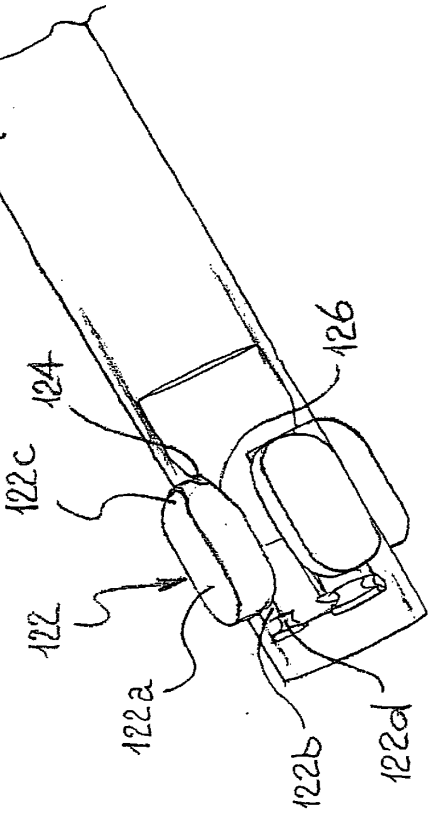


Fig-3

PETITIONER ARTHREX
EX. 1004

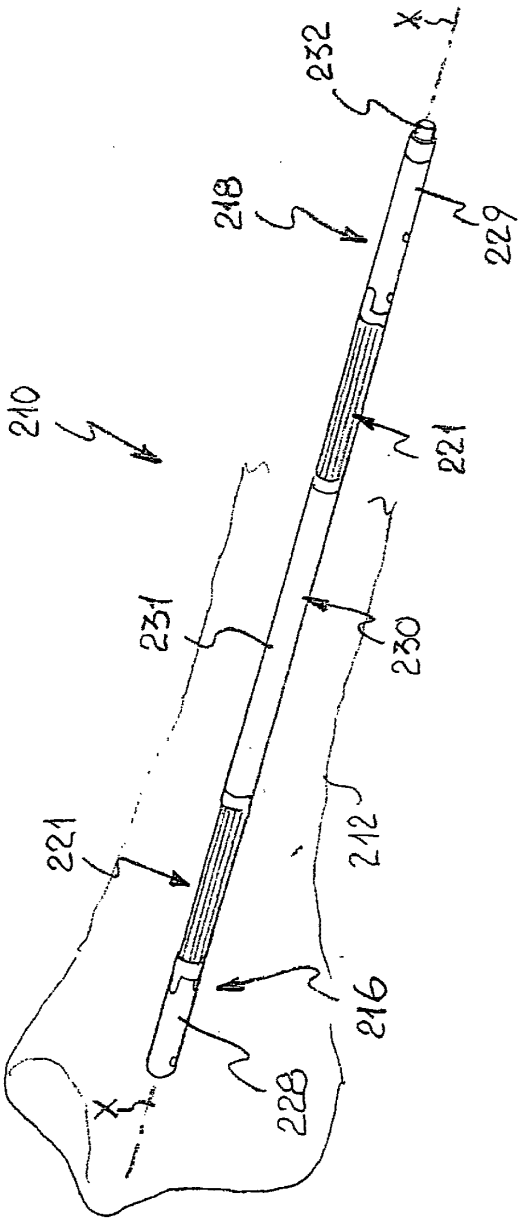


Fig-4

PETITIONER ARTHREX
EX. 1004

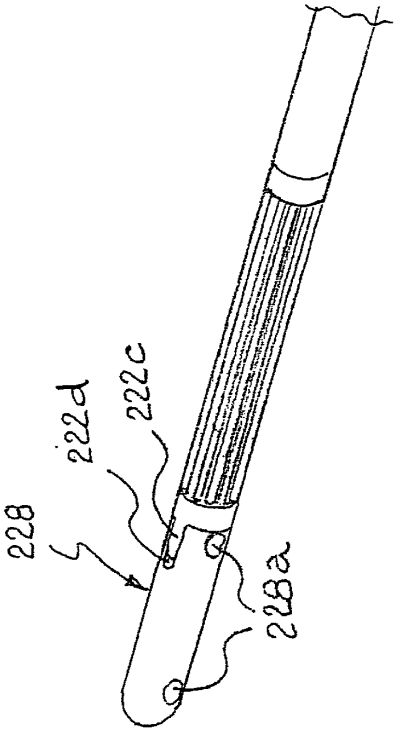


Fig-6

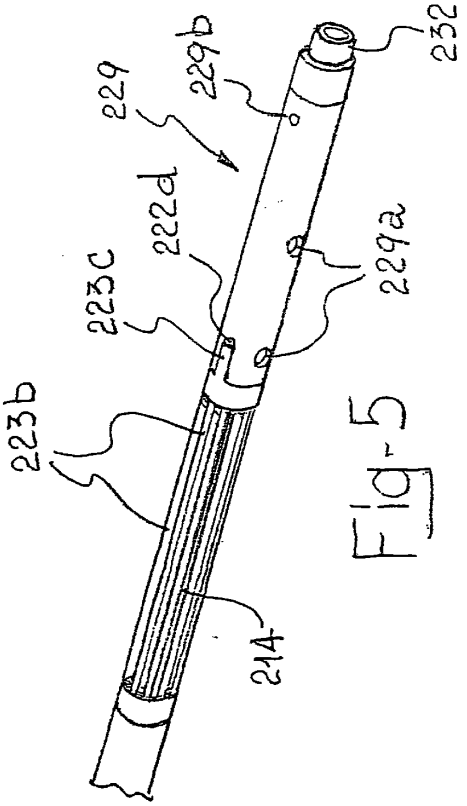


Fig-5

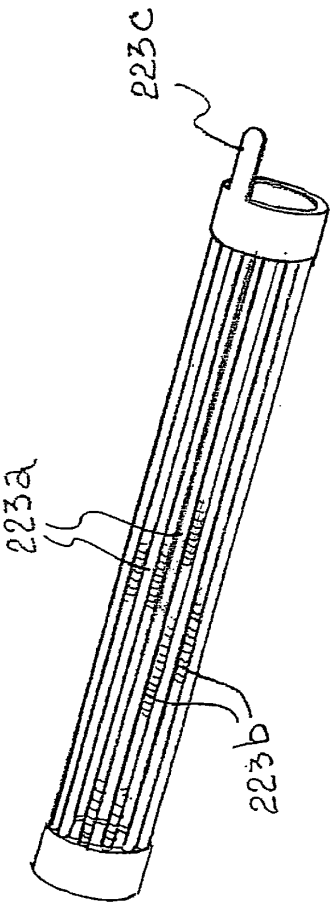


Fig-7

PETITIONER ARTHREX
EX. 1004

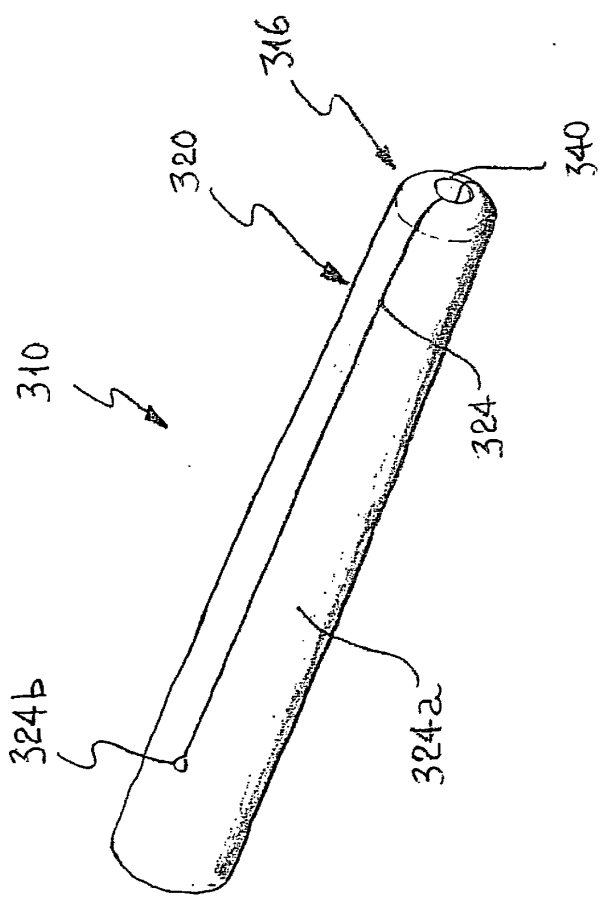


Fig-8

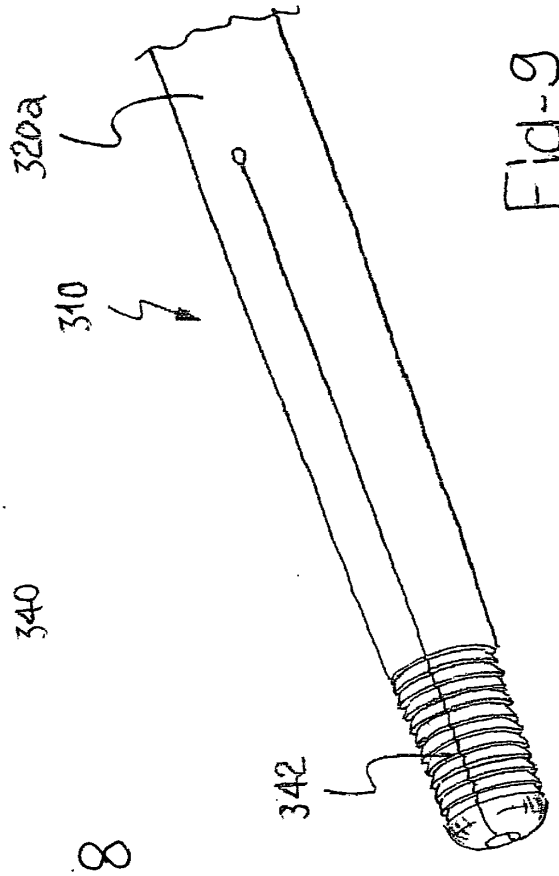


Fig-9

PETITIONER ARTHREX
EX. 1004

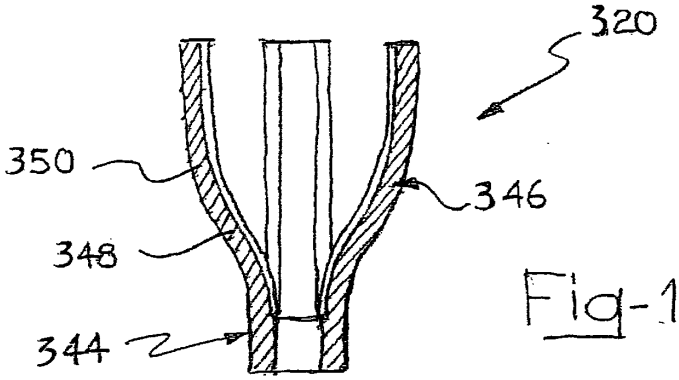


Fig-11

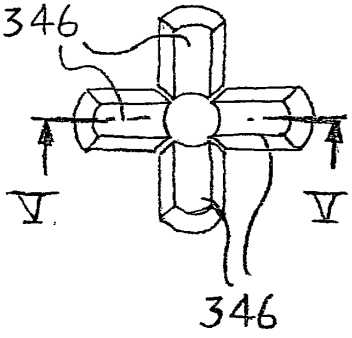


Fig-10

PETITIONER ARTHREX
EX. 1004

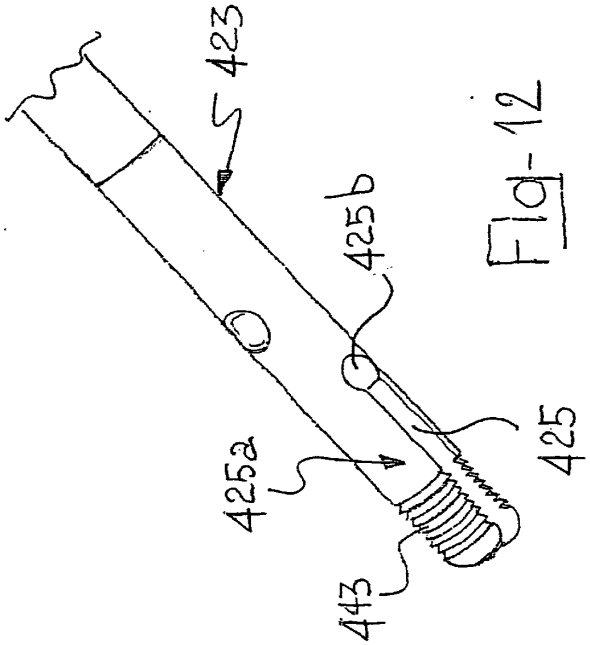


Fig-12

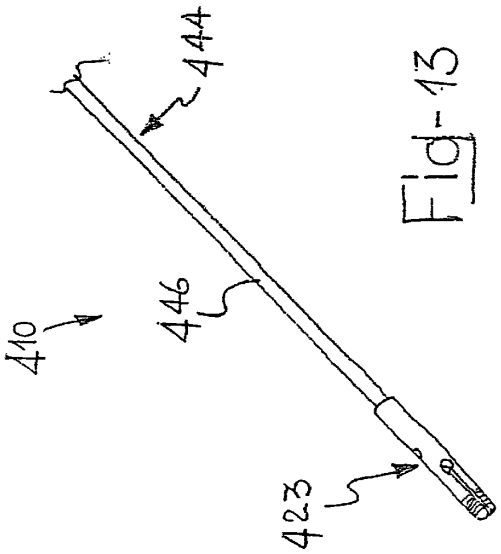


Fig-13

PETITIONER ARTHREX
EX. 1004

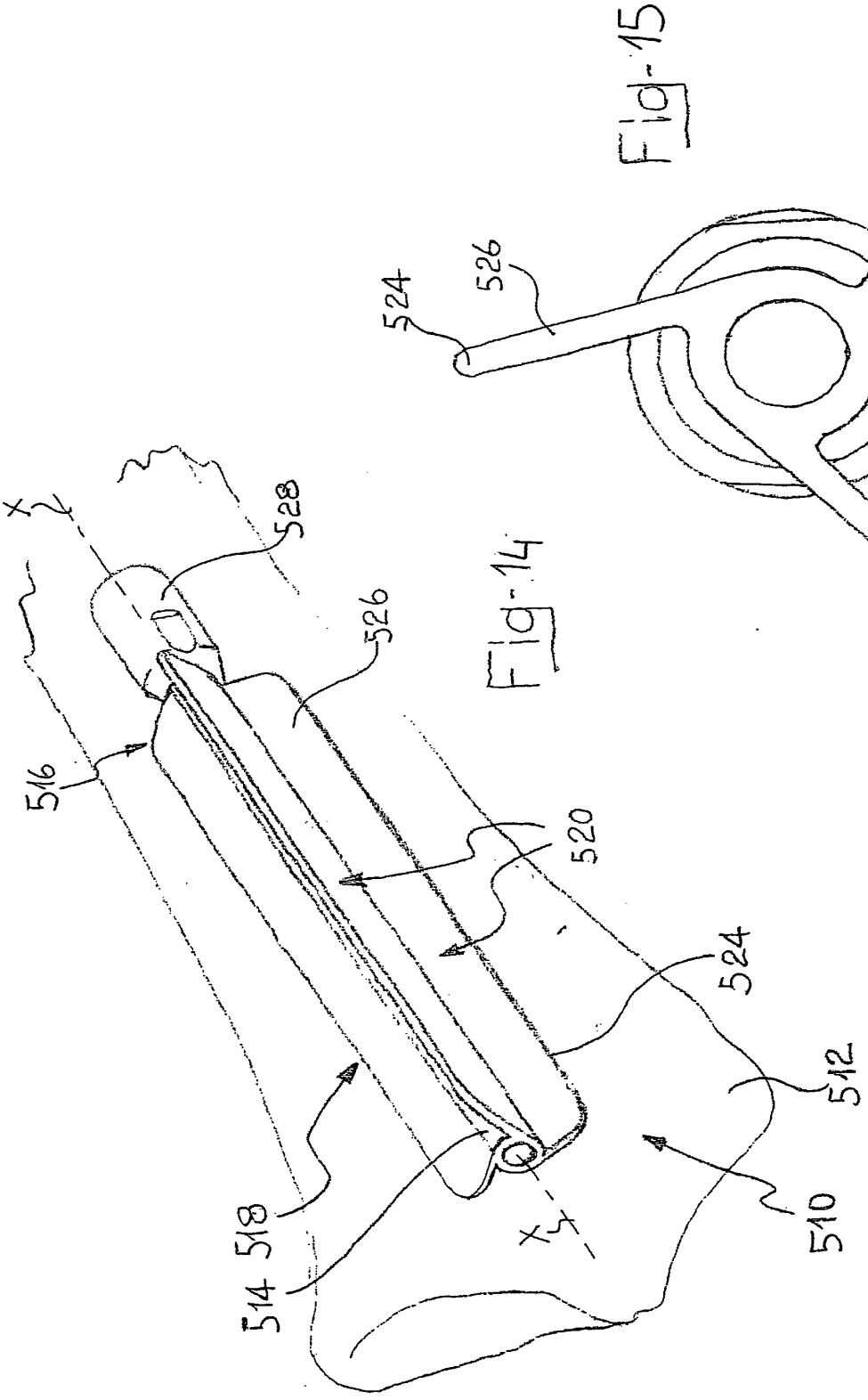


Fig-14

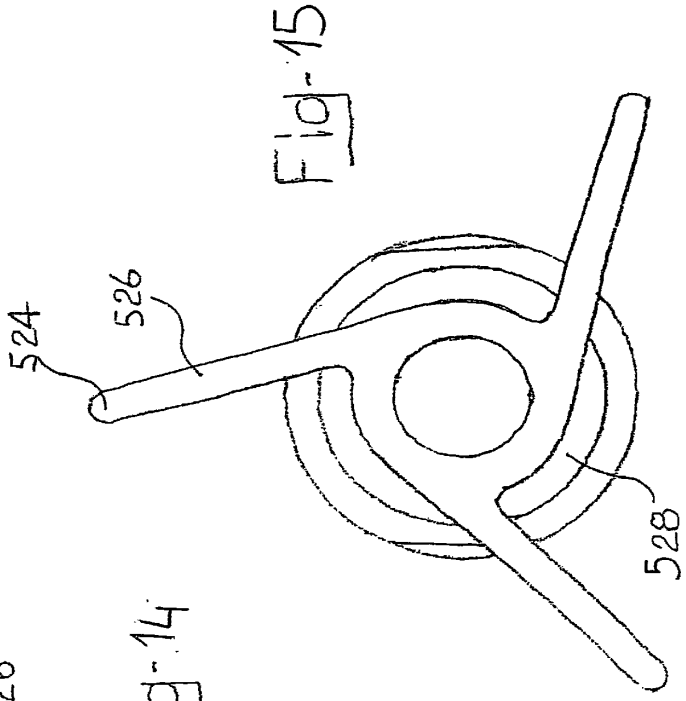


Fig-15

PETITIONER ARTHREX
EX. 1004

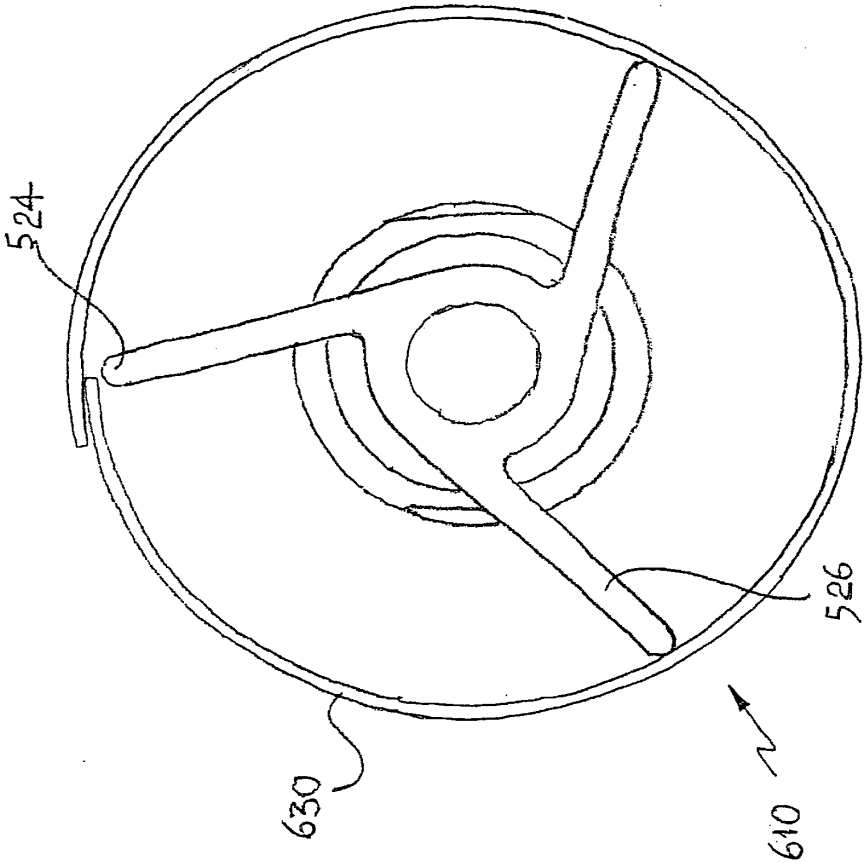


Fig-16

PETITIONER ARTHREX
EX. 1004

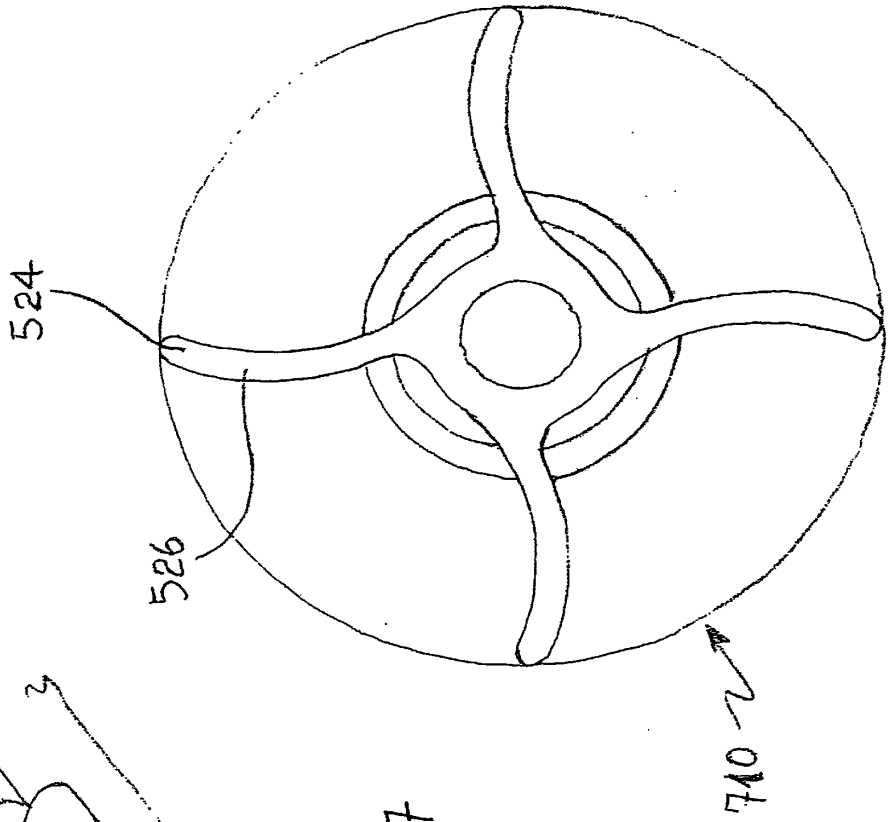


Fig-18

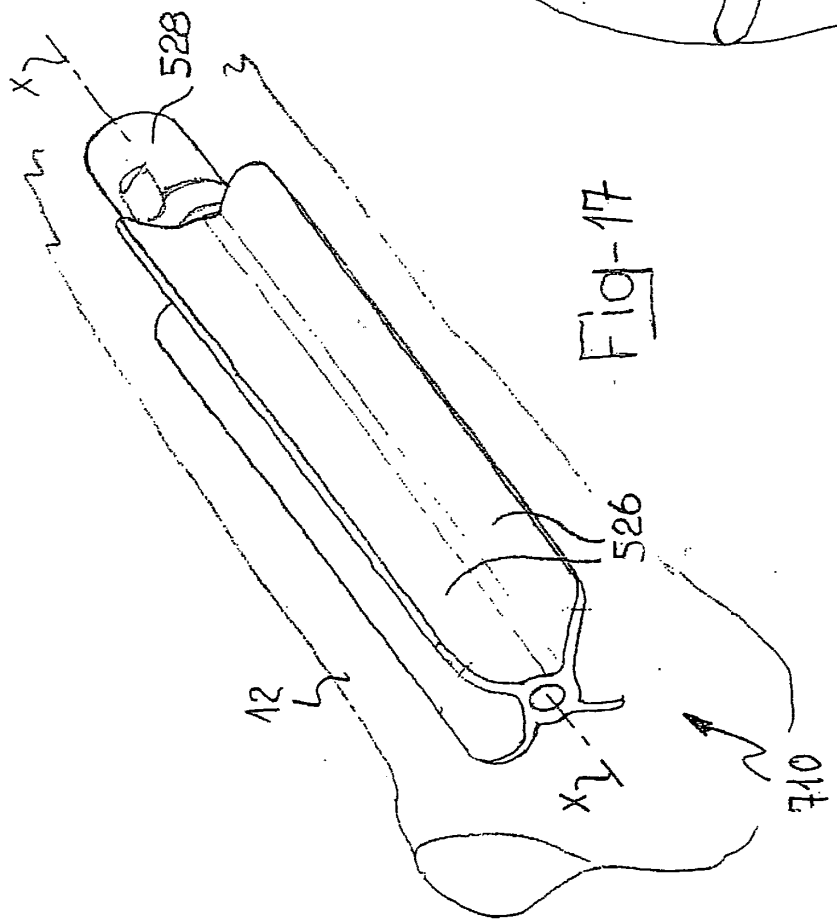
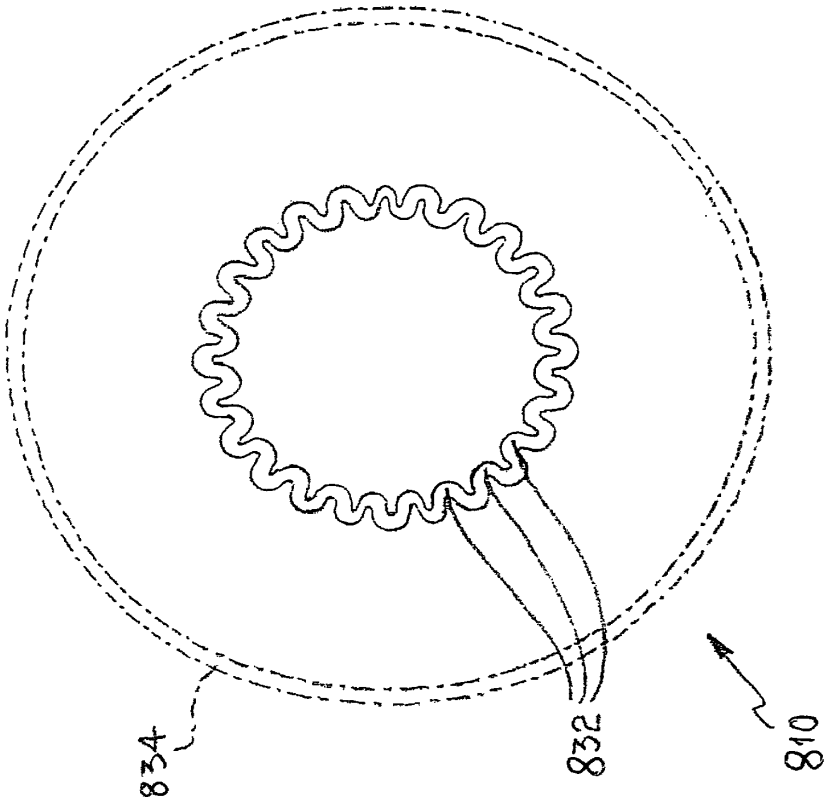


Fig-17

PETITIONER ARTHREX
EX. 1004

Fig. 19



PETITIONER ARTHREX
EX. 1004

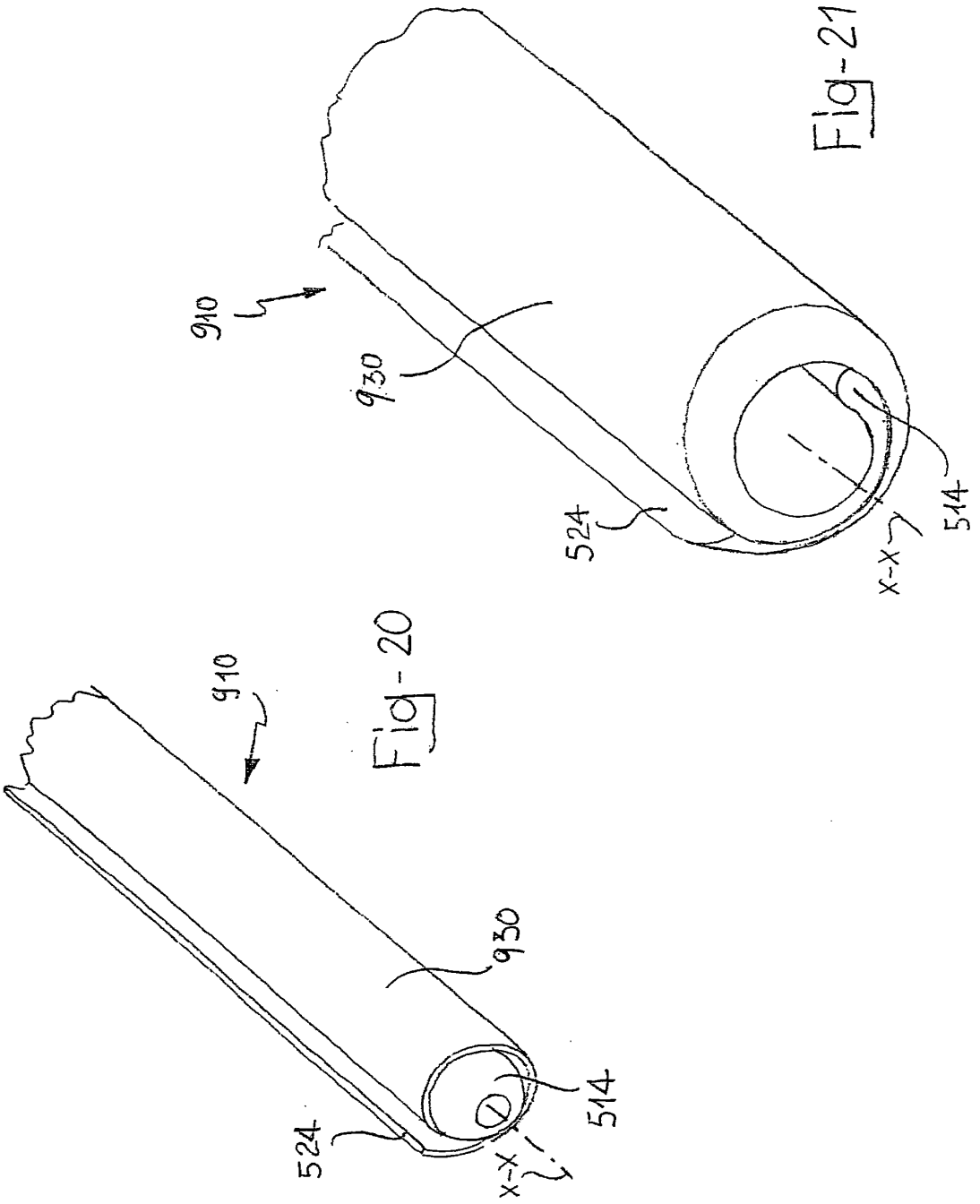


Fig-20

Fig-21

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EX. 1004

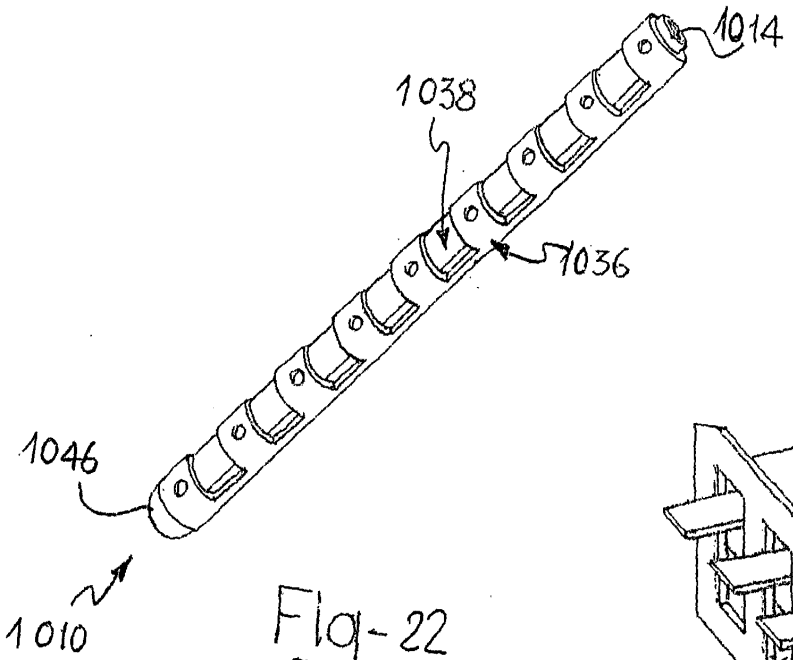


Fig- 22

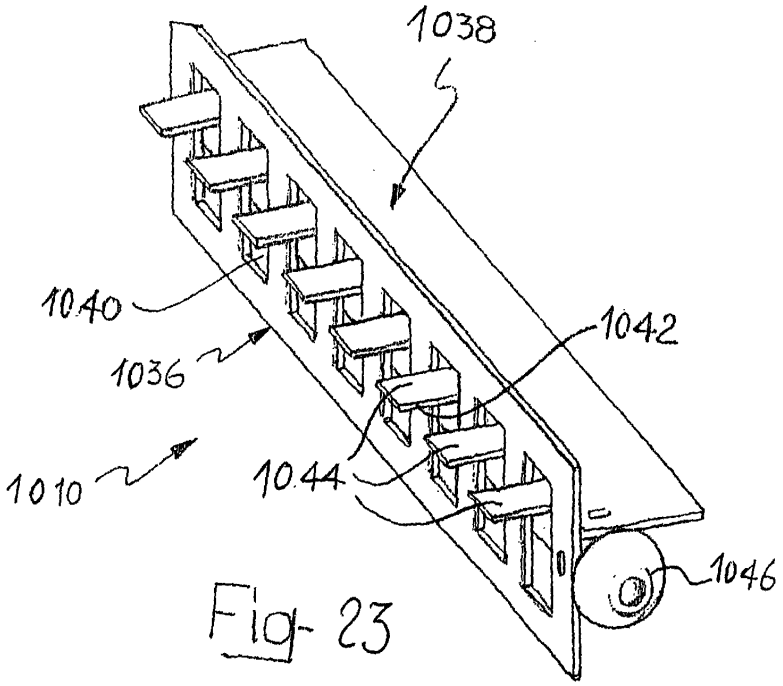


Fig- 23

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EX. 1004

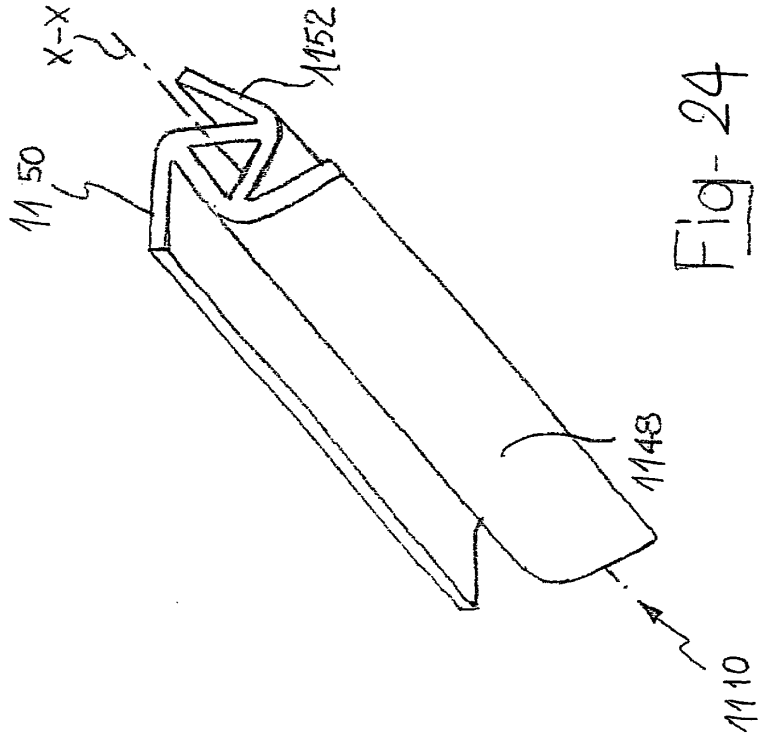


Fig- 24

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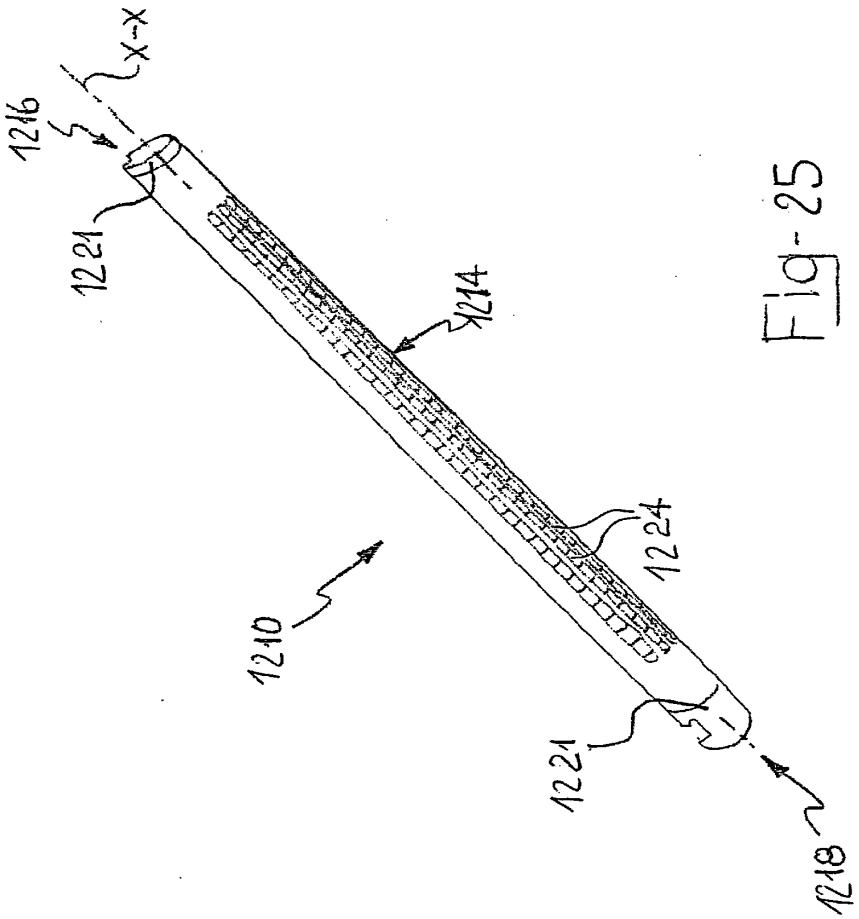


Fig-25

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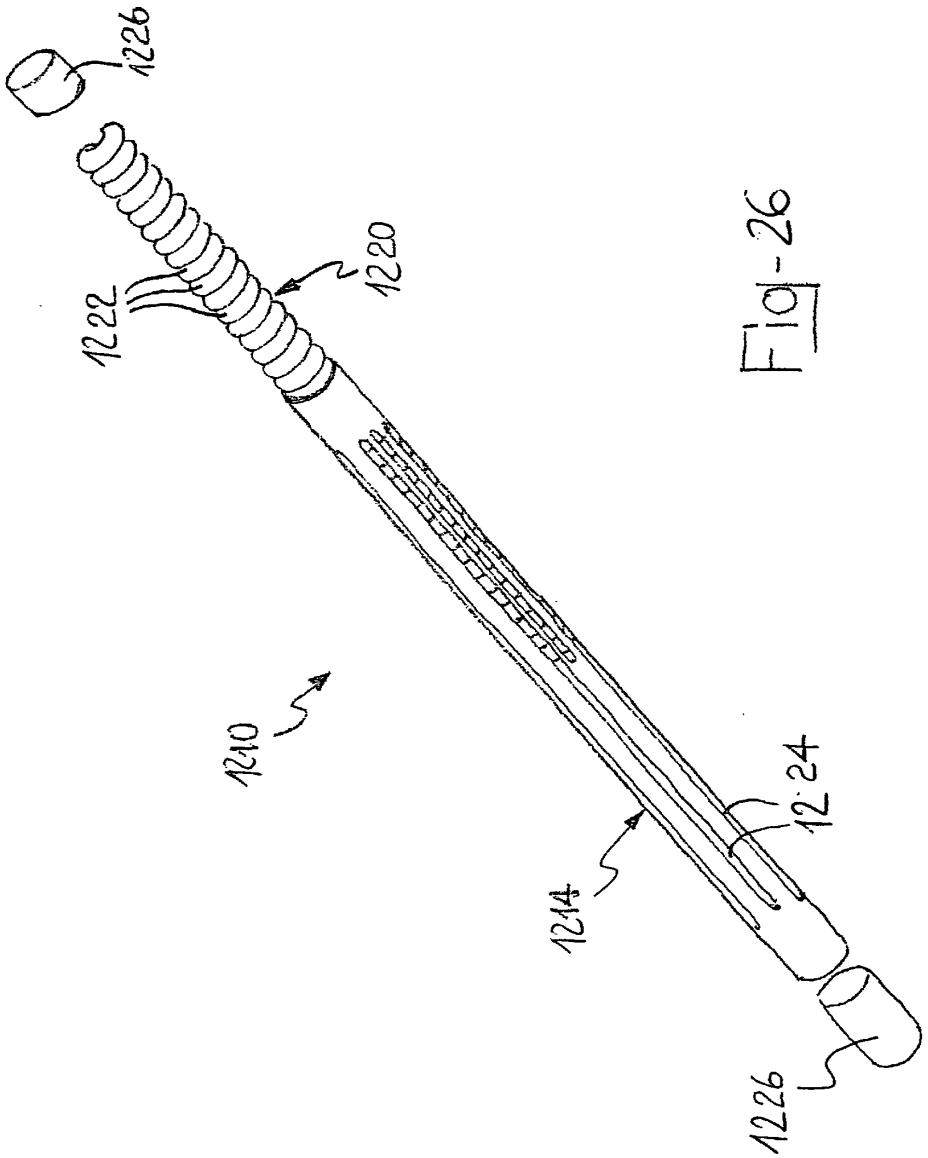


Fig-26

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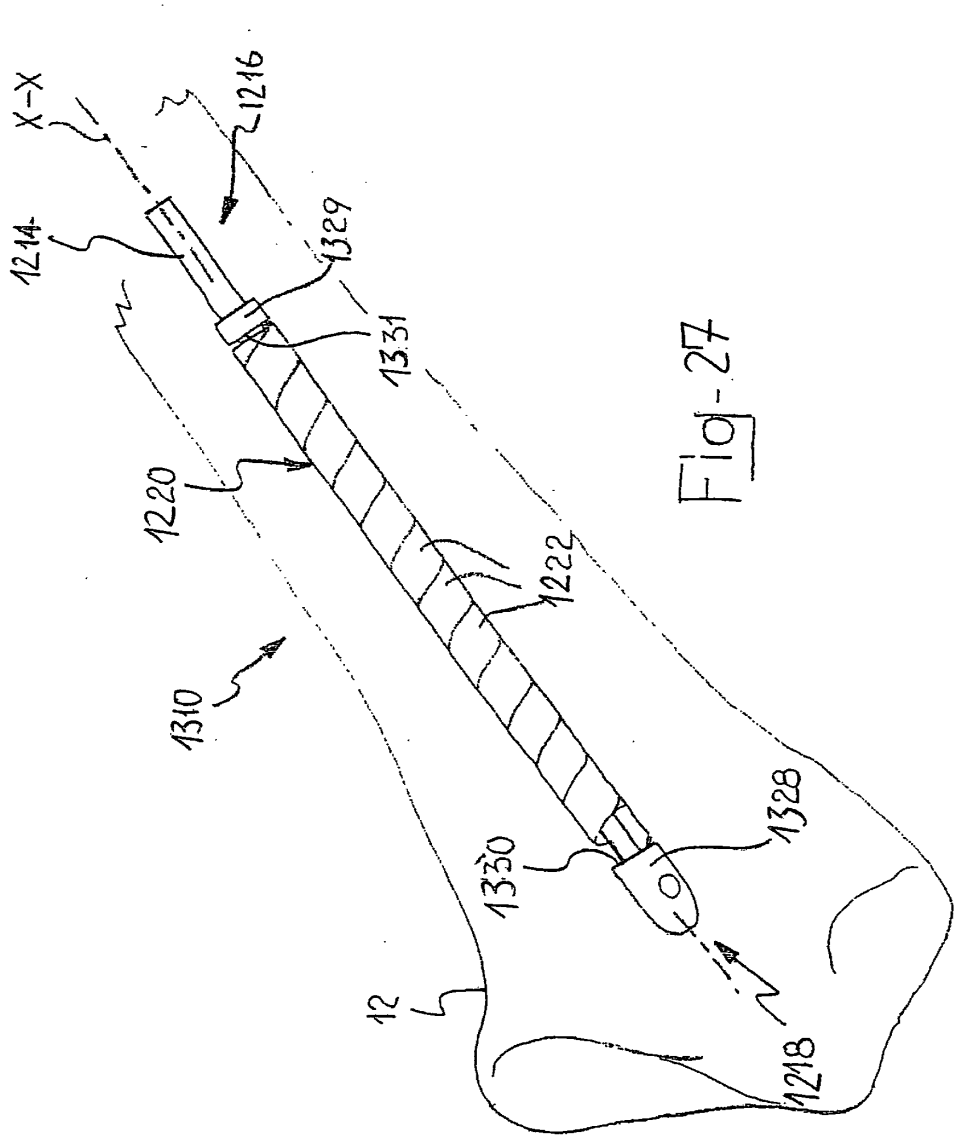


Fig-27

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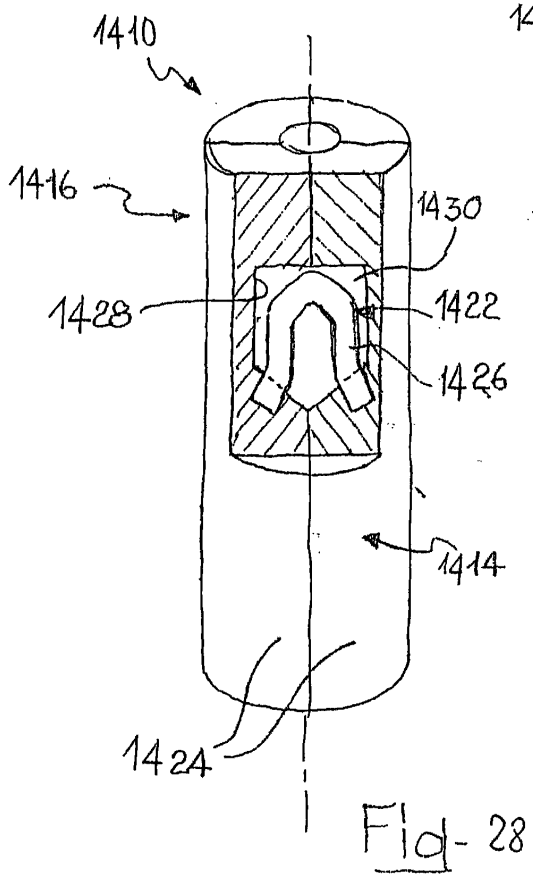


Fig- 28

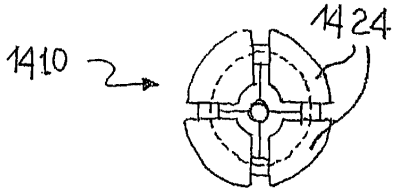


Fig- 29

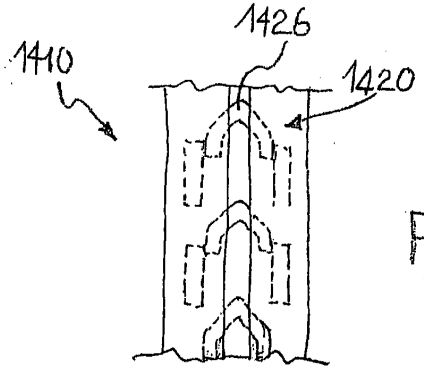


Fig- 30

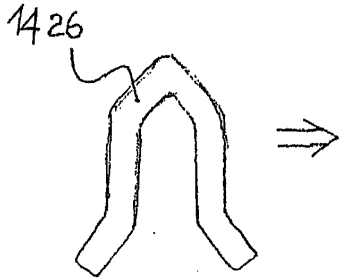


Fig- 31

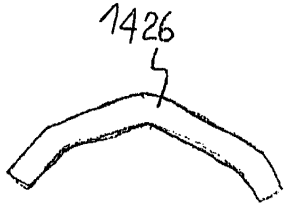


Fig- 32

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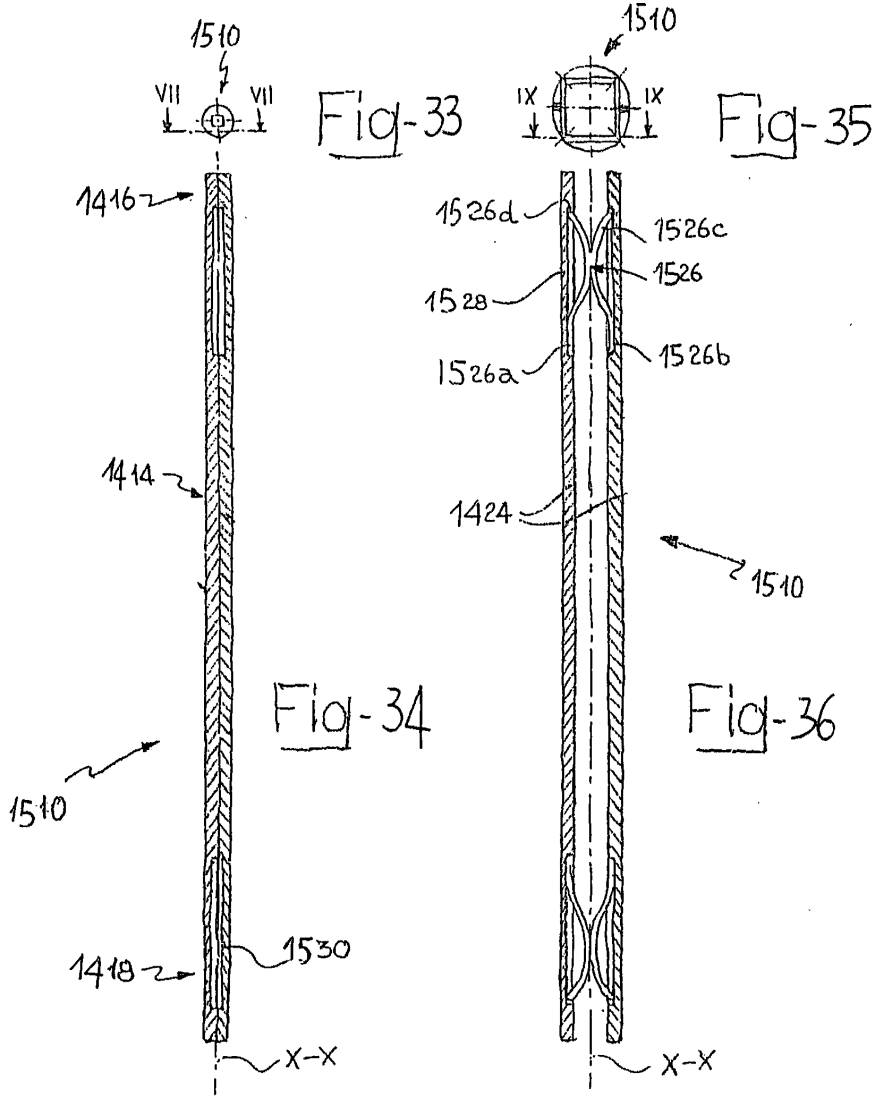


Fig-33

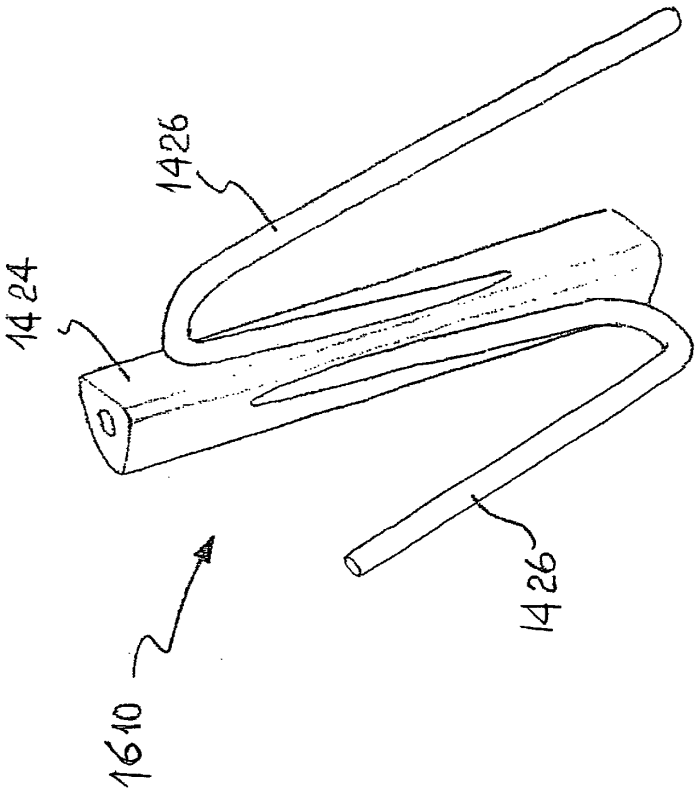
Fig-34

Fig-35

Fig-36

PETITIONER ARTHREX
EX. 1004

Fig- 37



PETITIONER ARTHREX
EX. 1004

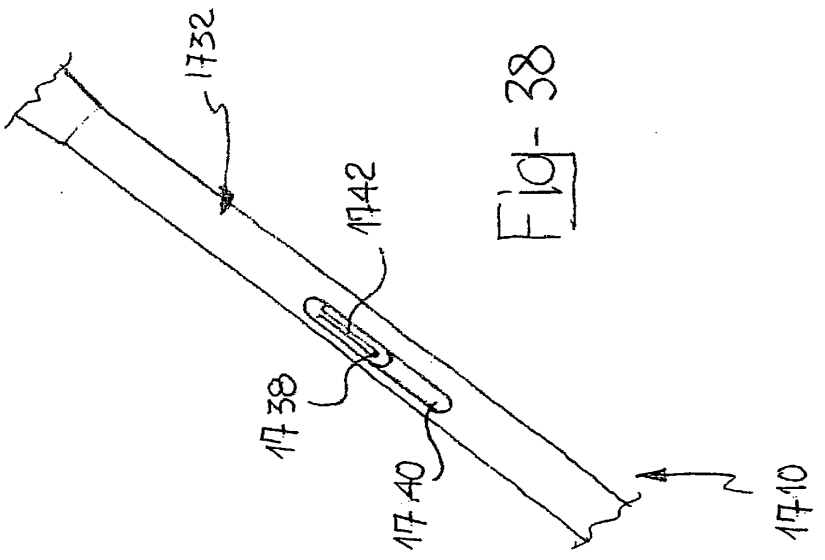


Fig- 38

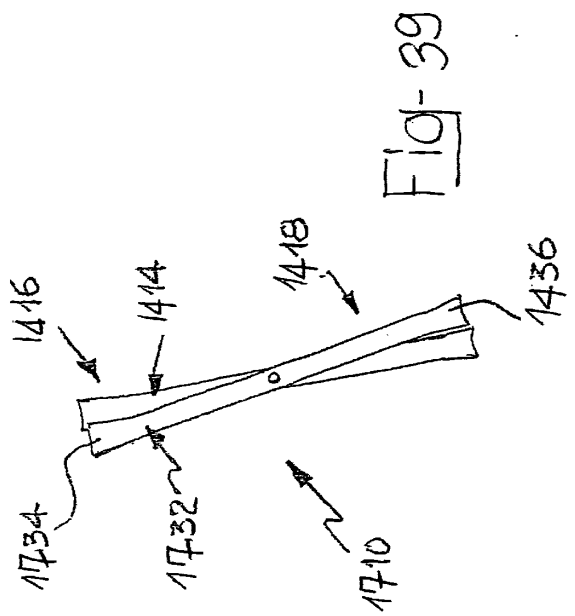


Fig- 39

PETITIONER ARTHREX
EX. 1004

SPECIFICATION

Device for transport of a bone fragment

The invention relates to the technical area of orthopedics, including the treatment of bone defects.

For the treatment of loss of bone substances (post-traumatic, post-arthroplasty by prosthesis) in the case of major reconstruction or sarcomas requiring the removal of a home carcinogenic, the surgeon must use an infusion of bone substitute.

Typically, two surgical techniques are being used.

According to a first technique, the surgeon obtains a bank bone, a bone fragment needed for a transplant. This technique is not entirely satisfactory, because it can reveal risk of rejection of bone substitute, which very often is not tolerated by the body and requires several successive interventions, because there are phenomena of prénarthroses.

A second technique, there is a transport bone, which is to conduct an osteotomy both ends of healthy bones, above or below the missing. The aim is to enable the formation of a cal bone and draw on this cal, to extend a length equal to the loss of bone substance. Indeed, at the end of lengthening, the cal bone replace the loss of substance. The bone transport is performed using an external fixator.

If the principle of this technique is satisfactory, it is not the same, in the means of implementation. Indeed, by

definition, this type of fixator is located outside the body, using an apparatus, parts of which pass through soft tissue to reach the bone, to be solidarisées. It appears from the aesthetic problems and difficulties for the user to bear such a departure. Finally, the risk of infection are not negligible.

The invention aims to overcome these drawbacks, a simple, safe, efficient and rational.

The problem is expected to solve the present invention is to ensure the transport of a bone fragment, between the two parts of a bone, using a device that is completely internal to the body.

To resolve this problem, it has been designed and developed a device that includes a series of elements within the tubular body, in order to be attached to both sides of bones, some of those elements being arranged to be fixed the bone fragment, those elements being subject to means to ensure the movement controlled translation of the party receiving the bone fragment. This shift can be made by various means and mechanisms, such as external movements applied to members, engines or other type of hydraulic, mechanical, electronic ...

To solve the problem of ensuring the removal of the element is coupled to a bone fragment to its transfer, it appeared advantageous angle to act directly on one part of the bone of the patient.

PETITIONER ARTHREX
EX. 1004

To this end, the series of elements within the organization, includes:

- A sheath tube set in the medullary canal of one part of bone,

- A tube set in the medullary canal of the other bone and end up with the sheath capacity limited angular displacement - a sliding axis mounted inside the tube and arranged to be fixed in the bone fragment being able to be driven angle when the bone is fixed when the tube is subject to a couple rotation alternative

- The end of the axis, inside the sheath is coupled to the means to authorize, where the bone coupled with the tube is subject to a couple rotation, in a sense, moving in translation axis with the bone fragment, and in the other direction, blocking the translation of that axis.

To solve the problem of ensuring the movement of bone fragment, under a rotation torque applied to any parts of bones, the means are formed by a threaded socket screw thread in a bore of the sheath Said socket presenting each end fixtures mating cooperating with complementary fittings from the end of the axis and the end of a body of support, such arrangements are disengaged.

The fixtures of the tube are threaded through systems pawls willing to face at each end of the socket, each system pawls being reversed.

To solve the problem to allow the training in rotation of the tube, only in one direction of rotation, the threaded sleeve and the axis are subject to a system under load. The system is under load and the type coaxial

This screw engaged freely within the socket and a body support cooperating with the socket, being screwed at the end of the shaft, said screw cooperating with a resilient, mounted in conjunction with the organ support. The body of this support fixtures blocking rotation within the bore of the threaded sleeve.

Favorably, a ratchet system of tube cooperate with complementary teeth formed facial at the end of the axis, to ensure, in a rotation, training accompanying the axis of the tube and while the other system pawls cooperate with teeth formed facial at the end of the body of support, to ensure, in the opposite direction of rotation, the free rotation of the axis relative to the socket.

To solve the problem of ensuring the translation movement of bone fragment, where one party bone is subject to a couple rotational axis is equipped with a hole for the engagement of a screw fixation of bone fragments, through an oblong light, which is mounted in a key axis of solidarity, in order, first, that axis of sliding into the tube and on the other hand, the entrainement angular axis that, when a rotation torque is applied to the bone of solidarity tube.

The invention is described below in more detail using the drawings, in which:

Figure 1 is a perspective view before assembly of the main components of Figures 2 and 3 are

PETITIONER ARTHREX
EX. 1004

the views of a schematic

showing how the arrangements according to the invention.

Figure 4 is a longitudinal view of the device.

Figure 5 is a view corresponding to Figure 4, showing the movement of bone fragment.

Figures 6, 7, 8, 9, 10 and 11 are views in cross considered along the lines respectively 6.6, 7.7, 8.8, 9.9, 10.10, 11.11 in Figure 4.

As shown in Figure 1, the device includes a sheath (1) at the end of which is fitted with capacity limited angular displacement, a tube (2). Tubes (1) and (2) are impacted in the medullary canal of a bone (O). In particular, the sheath (1) is set by using a screw proximal (3), established through a hole oblique (1a), in a part of bone (01). The tube (2) is fixed by a distal screw (4) located through a hole (2a), in a part of bone (02) (Figure 2).

The sheath (1) and tube (2) have a constant length. The tube (2) is coupled in the end sheath (1), through a ring (5) screwed the end of sheath (1) and which is mounted in turn, a colerette (2c) of the tube (2).

The tube (2) is hollow and receives internally, an axis (6) fitted with sliding capacity and angular displacement. The axis (6) is also engaged in the bore (1b) of the sheath (1). In addition, the axis (6) has a key (7) engaged in a groove (2d) of the tube (2) to allow the movement of the axis relative to the tube and the concomitant training in rotation, the tube (2) and the axis (6), as will be shown later in the description.

The rotational movement of the whole tube (2) and the axis (6), compared with the sheath (1) occurs in a limited way. To this end, the axis (6) has a key (8) cooperating with a slot in an arc (1b1), formed part of the bore (1b) of the sheath (1). The key (8) moves into the groove (1b1), according to an arc of central angle (α).

The axis (6) shall be fixed according to the bone fragment (03) should be transferred between the bone (01) and (02). To this end, the axis (6) has a hole (6a) for the engagement of a screw (9), set in the bone fragment (03) and committed through the light (2b) of the tube (2).

The axis (6) is coupled to the means to authorize, where the bone (02) coupled with the tube (2) shall be subject to a couple rotation, in a sense, the movement of translation axis (6) and in the other direction, blocking its translation.

To this end, the axis (6) cooperate with, at its end, a threaded socket (10) screwed into a threaded part of the bore (1b) of the sheath (1). This socket (10) present, at one end, fixtures coupling (10a), together with additional fixtures (6b) of the axis (6), these arrangements are disengaged.

For example, as shown in Figure 1, these agencies (10a) and (6b) are formed by systems willing pawls facial ends of the tube (10) and the axis (6). The end of the axis (6) This facial teeth

PETITIONER ARTHREX
EX. 1004

complementary to ratchet system of tube (10), the teeth (6b) being followed to ensure, in a rotation, training accompanying the axis (6) and the socket (10). The tube (10) this facial the other end, a ratchet system (10b), able to cooperate with

complementary teeth (12b) formed facial after a body of support (12), in the form of a ring. The ratchet systems (10a) and (10b) of the socket (10) are reversed, so that in the opposite direction of the torque exerted on the tube (2), it will not affect the socket (10), thus prohibiting the movement in reverse of the previous one, the axis (6).

The tube (10) and the axis (6) are subject to a coaxial system under load. For this purpose, as shown in Figure 4, the system includes a screw (11) committed freely within the socket and the ring (12) working in support of the socket (10), the pawls (10b) and teeth (12b). The screw is screwed into the end of the axis (6). An elastic-type spring (13) is interposed between the screw head (11a) and ring (12) to ensure the pressure. Given these provisions, it is that training in rotation in a certain direction of the axis (6), through the tube (2), will, given the system pawls (10a) (6b), cause rotating sleeve (10) and, as a concurrent rise in the linear displacement of the translation axis, which the advance is not based on the screws. Conversely, in the opposite direction of torque, and in view of the entire set pressure (12) (13), the ratchet system (10a) (6b) is set free, so that the rotation axis (2) will not affect the socket (10), the ratchet system (10b) is taken with the teeth (12b) of the support ring (12), blocked in rotation in the sheath (1).

The ring (12) is blocked in rotation in the bore thread (1b1) of the sheath (1), using a pin (12a) engaged in the groove (1c).

It should analyze how the arrangements under

Invention and indirectly the procedure, considering the case of a loss of brain substance.

The practitioner will have access to the bone in question (O), using the usual way, remove the tumor, then the boring part of the medullary canal yet available. It will then be osteotomy of the cortex in the healthy, so that the bone (O) will be fragmented into three distinct parts, namely, the proximal (01), the distal part (02) and middle (03) corresponding to the bone fragment that you want to transfer.

The operator then affects the entire device, the length of the sheath (1) and tube (2) in particular, is determined by the length of the limb. He then proceeded, through a viewfinder, at the drilling of two cortical bone, to make the holes at each side of bone (01) (02) and (03) in order ensure locking the whole system.

To this end, the screw (3) is engaged in the hole (1a) of the sheath (1) to ensure liaison with the proximal (01) of the bone. Screw (4) is engaged in the hole (2) tube (2), for his liaison with the distal part (02) of bone. Finally, the screw (9) is engaged through the light (2b) of the tube (2) in the hole (6) of the axis (6), to ensure the coupling of bone fragment (03).

The device is set up, the operator applies an external rotation torque in the lower part (02) of the bone with an angle (α1) corresponding to the degree of freedom of the key (8) in the

PETITIONER ARTHREX
EX. 1004

corresponding groove (1b1) (Figure 7). It follows the training rotation of all tube (2) - axis (6) bound by the key (7) and, therefore, training in rotation of the socket (10) by the ratchet (6b) (10a).

The training in rotation of the socket (10) leads to a concomitant shift in the translation of the axis (6) and consequently, the bone fragment (03). In return for a couple internal rotation of the lower (02), teeth (6b) of the axis (6), is the ratchet system, so that the axis is in a position to drive the tube at the next rotation.

As stated in the sense of rotation of the tube, through its system pawls (10b) is blocked in relation to the teeth (12b), the support ring (12).

It is understandable that these couples rotary passed at the party (02) of the bone, according to frequency intervals determined by the operator, will have the effect of moving the bone fragment (03) from the proximal (01) to the level of the distal part (02), causing, as the extension of cal bone to replace the loss of substance.

It is obvious that the training system in the axis of translation (6) on the bone fragment (03) should not be considered restrictive.

Note that the sheath (1) is sealed by a cap (14).

The benefits far out of the description, especially on highlights and reiterates the possibility of a bone transport, using elements within the body, thus avoiding the use of external source of infection and inconvenience to the patient.

PETITIONER ARTHREX
EX. 1004

CLAIMS

-1 - A method of transferring a bone fragment (03) between two parts of bone (01) and (02), wherein a series of elements (1) (2) (6) internal the organization, in order to be attached to both sides of bone (01) (02), some of those elements being arranged to be attached to the bone fragment (03), said elements (1) (2) (6) is subject to means to ensure the movement controlled by shifting the party receiving the bone fragment.

-2 - A method of claim 1, wherein the series of elements includes:

- A tubular sheath (1) set in the medullary canal of one part of bone (01) - a tube (2) set in the medullary canal of the other bone (02) and mounted After the sheath (1) with the capacity for limited angular displacement,

- An axis (6) mounted sliding inside the tube (2) and designed to be attached to the bone fragment being able to be caused when the angle of bone (02) where the tube is set (2) is subject to a couple rotation,

- The end of the axis (6), inside the sheath (1), being subject to means (10a) (6b) and (10b) (12b) able to authorize, where the bone (02) coupled with the tube (2) is subject to a couple rotation, in a sense, the translation movement of the axis (6) on the bone fragment, and in the other direction, blocking the translation of that axis.

-3 - A method of claim 1, wherein the means are formed by a threaded socket (10) screwed in a tapped bore (1b) of the sheath (1), with the socket at each end

acouple of fixtures (10) (10b) cooperating with complementary arrangements (6b) (12b) by the end of the line (6a) and a body of support (12), these arrangements being disengageable .

-4 - A method of claim 3, wherein the arrangements of the threaded sleeve (10) consists of systems pawls (10a) (10b) arranged to face each end of the socket, each system is pawls reversed.

-5 - A method of claim 3, wherein the threaded sleeve (10) and the axis (6) are subject to a system under load.

-6 - A method of claim 5, wherein the system is under load of coaxial type and has a screw (11) committed freely within the socket (10) and a body of support (12) cooperating with the socket, being screwed at the end of the axis (6), said screw cooperating with an elastic (13), mounted in conjunction with the body of support.

-7 - A method of claim 6, wherein the body support (12) this arrangement blocking rotation within the bore of the threaded sleeve (1).

-8 - A method of claim 3, wherein a ratchet system (10a) of the socket (10), cooperates with complementary teeth (6b) formed facial at the end of the axis (6) to ensure, in a rotation, training

PETITIONER ARTHREX
EX. 1004

accompanying the axis (6) and the socket (10), while the other system pawls (10b), cooperates with teeth (12b) formed facial at the end of the body support (12), to ensure, in the opposite direction of rotation, the free rotation

the axis relative to the socket.

-9 - A method of claim 2, wherein the axis (6) has a hole (6a) for the engagement of a screw fragment of bone, through a light oblong (2b), which is mounted in a key (7) attached to the axis, in order, first, that axis of sliding into the tube (2) and, secondly, the training of angular axis When couples rotation is applied to the bone (02) solidarity of the tube.

-10 - A method of claim 2, wherein the part of the axis (6) engaged in the sheath (1), receives a key (8) cooperating with a groove (1b1) formed in the bore of the sheath to be moved in a circular arc angle in the center (α) determined to match the value of a tooth ratchet system, the socket (10).

-11 - A method of claim 2, wherein the tube (2) is coupled to its sheath (1), in combination with a ring (5) permitting limited angular rotation and ensuring the axial rigidity of the whole.

PETITIONER ARTHREX
EX. 1004

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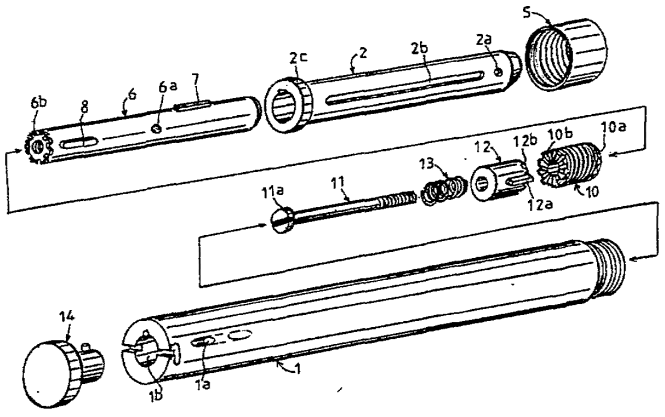
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(54) Title: BONE FRAGMENT TRANSPORT DEVICE

(54) Titre: DISPOSITIF DE TRANSPORT D'UN FRAGMENT OSSEUX



(57) Abstract

A device for transporting a bone fragment (O3) between two bone portions (O1 and O2), including a series of intracorporeal elements (1, 2, 6) shaped for attachment to the two bone portions (O1, O2), one part of said elements being attachable to said bone fragment (O3), and said elements (1, 2, 6) being controlled by an assembly for controllably translating the portion receiving the bone fragment.

PETITIONER ARTHREX
EX. 1004

(57) Abrégé

Le dispositif de transfert d'un fragment osseux (O3) entre deux parties d'os (O1 et O2), comprend une série d'éléments (1, 2, 6) internes à l'organisme, conformés pour être fixés aux deux parties d'os (O1, O2), une partie desdits éléments étant agencée pour être fixée au fragment osseux (O3), lesdits éléments (1, 2, 6) étant assujettis à des moyens aptes à assurer le déplacement contrôlé en translation de la partie recevant le fragment osseux.

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PETITIONER ARTHREX
EX. 1004

Dispositif de transport d'un fragment osseux

L'invention se rattache au secteur technique de l'orthopédie, notamment du traitement des défects osseux.

Pour le traitement des pertes de substances osseuses (post-traumatiques, post-arthroplastie par prothèse), dans le cas de grandes reconstructions ou de sarcomes nécessitant l'ablation d'un foyer cancérigène, le chirurgien doit recourir à un apport de substitut osseux. Généralement, deux techniques opératoires sont actuellement utilisées.

Selon une première technique, le chirurgien se procure auprès d'une banque d'os, un fragment osseux nécessaire pour réaliser une greffe. Cette technique ne donne pas entière satisfaction, car il peut apparaître des risques de rejet du substitut osseux qui, très souvent, n'est pas toléré par l'organisme et, nécessite plusieurs interventions successives, car l'on rencontre des phénomènes de prénarthroses .

Selon une seconde technique, on procède à un transport osseux, qui consiste à réaliser une ostéotomie d'une des deux extrémités osseuses saines, au dessus ou en dessous de la partie absente. Le but recherché est d'activer la formation d'un cal osseux et de tirer sur ce cal, pour l'allonger d'une longueur correspondant à la perte de substance osseuse. En effet, en fin d'allongement, le cal osseux remplace la perte de substance. Ce transport osseux est exécuté au moyen d'un fixateur externe.

Si le principe de cette technique donne satisfaction, il n'en est pas de même, au niveau des moyens de mise en oeuvre. En effet, par

PETITIONER ARTHREX
EX. 1004

définition, ce type de fixateur est situé à l'extérieur du corps, en utilisant un appareillage dont certaines parties traversent les tissus mous, pour atteindre l'os, en vue d'y être solidarisées. Il apparait des problèmes d'esthétisme et des difficultés pour l'utilisateur, de supporter un tel appareillage. Enfin, les risques d'infections ne sont pas négligeables.

L'invention s'est fixée pour but de remédier à ces inconvénients, de manière simple, sûre, efficace et rationnelle.

Le problème que se propose de résoudre l'invention, est d'assurer le transport d'un fragment osseux, entre les deux parties d'un os, en utilisant un dispositif qui soit totalement interne au corps.

Pour résoudre un tel problème, il a été conçu et mis au point un dispositif qui comprend une série d'éléments tubulaires internes à l'organisme, conformés pour être fixés aux deux parties d'os, une partie desdits éléments étant agencée pour être fixée au fragment osseux, lesdits éléments étant assujettis à des moyens aptes à assurer le déplacement contrôlé en translation de la partie recevant le fragment osseux.

Ce déplacement peut être effectué par différents moyens et mécanismes, tels que mouvements externes appliqués aux membres, motorisations ou autres dispositifs du type hydraulique, mécanique, électronique...

Pour résoudre le problème posé d'assurer le déplacement de l'élément accouplé au fragment osseux en vue de son transfert, il est apparu avantageux d'agir angulairement directement sur l'une des parties de l'os du patient.

Dans ce but, la série d'éléments internes à l'organisme, comprend :

PETITIONER ARTHREX
EX. 1004

- un fourreau tubulaire fixé dans le canal médullaire de l'une des parties d'os,

- un tube fixé dans le canal médullaire de l'autre partie d'os et monté en bout du fourreau avec capacité de déplacement angulaire limité,

- un axe monté à coulissement à l'intérieur du tube et agencé pour être fixé au fragment osseux en étant apte à être entrainé angulairement lorsque la partie d'os où est fixé ledit tube est soumise à un couple rotatoire alternatif,

- l'extrémité de l'axe, située à l'intérieur du fourreau étant accouplée à des moyens aptes à autoriser, lorsque la partie d'os accouplée au tube est soumise à un couple rotatoire, dans un sens, le déplacement en translation de l'axe portant le fragment osseux et, dans l'autre sens, le blocage en translation dudit axe.

Pour résoudre le problème posé d'assurer le déplacement du fragment osseux, sous l'effet d'un couple rotatoire, appliqué à l'une des parties d'os, les moyens sont constitués par une douille filetée vissée dans un alésage taraudé du fourreau, ladite douille présentant à chacune de ses extrémités, des agencements d'accouplement coopérant avec des agencements complémentaires de l'extrémité de l'axe et de l'extrémité d'un organe d'appui, lesdits agencements étant débrayables.

Les agencements de la douille filetée sont constitués par des systèmes à cliquets disposés facialement à chacune des extrémités de ladite douille, chaque système de cliquets étant inversé.

Pour résoudre le problème posé de permettre l'entrainement en rotation de la douille, seulement dans un sens de rotation, la douille filetée et l'axe sont assujettis à un système de mise en pression.

Le système de mise en pression est du type coaxial et

PETITIONER ARTHREX
EX. 1004

présente une vis engagée librement à l'intérieur de la douille et d'un organe d'appui coopérant avec la douille, en étant vissée à l'extrémité de l'axe, ladite vis coopérant avec un organe élastique, monté en combinaison avec l'organe d'appui.

L'organe d'appui présente des agencements de blocage en rotation, à l'intérieur de l'alésage taraudé du fourreau.

Avantageusement, l'un des systèmes à cliquets de la douille, coopère avec une denture complémentaire formée facialement à l'extrémité de l'axe, pour assurer, dans un sens de rotation, l'entrainement concomitant de l'axe et de la douille, tandis que l'autre système à cliquets, coopère avec une denture formée facialement à l'extrémité de l'organe d'appui, pour assurer, dans l'autre sens de rotation, la libre rotation de l'axe par rapport à la douille.

Pour résoudre le problème posé d'assurer le déplacement en translation du fragment osseux, lorsque l'une des parties d'os est soumise à un couple rotatoire, l'axe est équipé d'un trou pour l'engagement d'une vis de fixation du fragment osseux, au travers d'une lumière oblongue, dans laquelle est montée une clavette solidaire de l'axe, en vue, d'une part, du coulissement dudit axe dans le tube et, d'autre part, de l'entrainement angulaire dudit axe, lorsqu'un couple rotatoire est appliqué à la partie d'os solidaire dudit tube.

L'invention est exposée, ci-après plus en détail à l'aide des dessins annexés, dans lesquels :

La figure 1 est une vue en perspective avant montage des principaux éléments du dispositif

Les figures 2 et 3 sont des vues à caractère schématique,

PETITIONER ARTHREX
EX. 1004

montrant le fonctionnement du dispositif selon l'invention.

La figure 4 est une vue en coupe longitudinale du dispositif.

La figure 5 est une vue correspondant à la figure 4, montrant le déplacement du fragment osseux.

Les figures 6, 7, 8, 9 , 10 et 11 sont des vues en coupe transversale considérées respectivement selon les lignes 6.6, 7.7, 8.8, 9.9, 10.10, 11.11 de la figure 4.

Comme le montre la figure 1, le dispositif comprend un fourreau (1) au bout duquel est monté avec capacité de déplacement angulaire limité, un tube (2). Les tubes (1) et (2) sont impactés à l'intérieur du canal médullaire d'un os (O). Notamment, le fourreau (1) est fixé au moyen d'une vis proximale (3), implantée à travers un trou oblique (1a), dans une partie d'os (O1). Le tube (2) est fixé par une vis distale (4) implantée à travers un trou (2a), dans une partie d'os (O2) (figure 2).

Le fourreau (1) et le tube (2) ont une longueur constante. Le tube (2) est accouplé en bout du fourreau (1), par l'intermédiaire d'une bague (5) vissée en bout du fourreau (1) et dans lequel est montée tournant, une colerette (2c) du tube (2).

Le tube (2) est creux et reçoit intérieurement, un axe (6) monté avec capacité de coulissement et de déplacement angulaire. L'axe (6) est par ailleurs engagé dans l'alésage (1b) du fourreau (1). En outre, l'axe (6) présente une clavette (7) engagée dans une rainure (2d) du tube (2), pour permettre le déplacement dudit axe par rapport au tube et l'entrainement concomitant en rotation, du tube (2) et de l'axe (6), comme il sera indiqué dans la suite de la description.

PETITIONER ARTHREX
EX. 1004

Le déplacement en rotation de l'ensemble du tube (2) et de l'axe (6), par rapport au fourreau (1), s'effectue d'une manière limitée. Dans ce but, l'axe (6) présente une clavette (8) coopérant avec une rainure profilée en arc de cercle (1b1), formée sur une partie de l'alésage (1b) du fourreau (1). La clavette (8) se déplace dans la rainure (1b1), selon un arc de cercle d'angle au centre (α).

L'axe (6) est conformé pour être fixé au fragment osseux (O3) qu'il convient de transférer entre les parties d'os (O1) et (O2). Dans ce but, l'axe (6) est équipé d'un trou (6a) pour l'engagement d'une vis (9) fixée dans le fragment osseux (O3) et engagée au travers de la lumière (2b) du tube (2).

L'axe (6) est accouplé à des moyens aptes à autoriser, lorsque la partie d'os (O2) accouplé au tube (2), est soumise à un couple rotatoire, dans un sens, le déplacement en translation dudit axe (6) et, dans l'autre sens, son blocage en translation.

Dans ce but, l'axe (6) coopère avec, au niveau de son extrémité arrière, une douille filetée (10) vissée dans une partie taraudée de l'alésage (1b) du fourreau (1). Cette douille (10) présente, à l'une de ses extrémités, des agencements d'accouplement (10a), coopérant avec des agencements complémentaires (6b) de l'axe (6), ces agencements étant débrayables.

Par exemple, comme le montre la figure 1, ces agencements (10a) et (6b) sont constitués respectivement par des systèmes à cliquets disposés facialement aux extrémités de la douille (10) et de l'axe (6). L'extrémité de l'axe (6) présente facialement une denture complémentaire au système à cliquets de la douille (10), cette denture (6b) étant conformée pour assurer, dans un sens de rotation, l'entrainement concomitant de l'axe (6) et de la douille (10). La douille (10) présente facialement à son autre extrémité, un système à cliquets (10b), apte à coopérer avec une

PETITIONER ARTHREX
EX. 1004

denture complémentaire (12b) formée facialement en bout d'un organe d'appui (12), sous forme d'une bague. Les sytèmes à cliquets (10a) et (10b) de la douille (10) sont inversés, de sorte que dans l'autre sens du couple de rotation exercé sur le tube (2), ce dernier sera sans effet sur la douille (10), interdisant par conséquent, le déplacement en translation inverse du précédent, de l'axe (6).

La douille (10) et l'axe (6) sont assujettis à un système coaxial de mise en pression. Dans ce but, comme le montre la figure 4, ce système comprend une vis (11) engagée librement à l'intérieur de la douille et de la bague (12) coopérant en appui sur la douille (10), par les cliquets (10b) et la denture (12b). La vis est vissée dans l'extrémité de l'axe (6). Un organe élastique du type ressort (13) est interposé entre la tête de vis (11a) et la bague (12) pour assurer la mise en pression.

Compte-tenu de ces dispositions, on conçoit que l'entrainement en rotation dans un certain sens de l'axe (6), par l'intermédiaire du tube (2), aura pour effet, compte-tenu du système à cliquets (10a) (6b), d'entrainer en rotation la douille (10) et, d'une manière concomitante, provoquer le déplacement linéaire en translation dudit axe, dont l'avance est fonction du pas de vis. Inversement, dans l'autre sens du couple de rotation, et compte-tenu de l'ensemble de mise en pression (12) (13), le système d'encliquetage (10a) (6b) se trouve en position libre, de sorte que la rotation de l'axe (2) sera sans effet sur la douille (10), dont le système à cliquets (10b) est en prise avec la denture (12b) de la bague d'appui (12), bloquée en rotation dans le fourreau (1).

La bague (12) est bloquée en rotation dans l'alésage taraudé (1b1) du fourreau (1), au moyen d'un ergot (12a) engagé dans la rainure (1c).

Il convient d'analyser le fonctionnement du dispositif selon

PETITIONER ARTHREX
EX. 1004

l'invention et indirectement le mode opératoire, en considérant le cas d'une perte de substance de corticale.

Le praticien va accéder à l'os considéré (O), au moyen de la voie habituelle, retirer la tumeur, puis aléser la partie du canal médullaire encore disponible. Il sera ensuite procédé à l'ostéotomie de la corticale dans la partie saine, de sorte que l'os (O) sera fragmenté en trois parties distinctes, à savoir, la partie proximale (O1), la partie distale (O2) et la partie médiane (O3) correspondant au fragment osseux que l'on veut transférer.

L'opérateur impacte ensuite, l'ensemble du dispositif, la longueur du fourreau (1) et du tube (2) notamment, étant déterminée en fonction de la longueur du membre. Il est alors procédé, au moyen d'un viseur approprié, au perçage des deux corticales de l'os, pour réaliser les trous, au niveau de chacune des parties d'os (O1) (O2) et (O3) en vue d'assurer le verrouillage de l'ensemble du dispositif.

Dans ce but, la vis (3) est engagée dans le trou (1a) du fourreau (1) pour assurer sa liaison avec la partie proximale (O1) de l'os. La vis (4) est ensuite engagée dans le trou (2a) du tube (2), pour assurer sa liaison avec la partie distale (O2) de l'os. Enfin, la vis (9) est engagée au travers de la lumière (2b) du tube (2) dans le trou (6a) de l'axe (6), pour assurer l'accouplement du fragment osseux (O3).

Le dispositif étant ainsi mis en place, l'opérateur applique un couple rotatoire externe à la partie inférieure (O2) de l'os avec un angle (α1) correspondant au degré de liberté de la clavette (8), dans la rainure correspondante (1b1) (figure 7). Il en résulte l'entrainement en rotation de l'ensemble tube (2) - axe (6) lié par la clavette (7) et, par conséquent, l'entrainement en rotation de la douille (10) par le système à cliquets (6b) (10a).

PETITIONER ARTHREX
EX. 1004

L'entrainement en rotation de la douille (10) provoque, d'une manière concomitante, le déplacement en translation de l'axe (6) et par conséquent, du fragment osseux (O3). Au retour, correspondant à un couple rotatoire interne de la partie inférieure (O2), la denture (6b) de l'axe (6), échappe le système à cliquets, de sorte que ledit axe est en position d'entrainement de la douille, lors de la prochaine rotation.

Comme indiqué, dans ce sens de rotation inverse, la douille, par son système à cliquets (10b) est bloquée par rapport à la denture (12b), de la bague d'appui (12).

On conçoit que ces différents couples rotatoires transmis au niveau de la partie (O2) de l'os, selon des fréquences d'intervalles déterminées par l'opérateur, auront pour effet de déplacer le fragment osseux (O3) depuis la partie proximale (O1) jusqu'au niveau de la partie distale (O2), en provoquant, au fur et à mesure, l'allongement du cal osseux, afin de remplacer la perte de substance.

Il est bien évident que le système d'entrainement en translation de l'axe (6) portant le fragment osseux (O3) ne doit pas être considéré comme limitatif.

A noter que le fourreau (1) est obturé par un bouchon (14).

Les avantages ressortent bien de la description, en particulier on souligne et on rappelle la possibilité de procéder à un transport osseux, au moyen d'éléments internes à l'organisme, évitant ainsi l'emploi d'éléments externes, source d'infections et de désagrements pour le patient.

PETITIONER ARTHREX
EX. 1004

REVENDICATIONS

-1- Dispositif de transfert d'un fragment osseux (O3) entre deux parties d'os(O1) et (O2), caractérisé en ce qu'il comprend une série d'éléments (1) (2) (6) internes à l'organisme, conformés pour être fixés aux deux parties d'os (O1) (O2), une partie desdits éléments étant agencée pour être fixée au fragment osseux (O3), lesdits éléments (1) (2) (6) étant assujettis à des moyens aptes à assurer le déplacement contrôlé en translation de la partie recevant le fragment osseux.

-2- Dispositif selon la revendication 1, caractérisé en ce que la série d'éléments comprend :

- un fourreau tubulaire (1) fixé dans le canal médullaire de l'une des parties d'os (O1),
- un tube (2) fixé dans le canal médullaire de l'autre partie d'os (O2) et monté en bout du fourreau (1) avec capacité de déplacement angulaire limité,
- un axe (6) monté à coulissement à l'intérieur du tube (2) et agencé pour être fixé au fragment osseux en étant apte à être entrainé angulairement lorsque la partie d'os (O2) où est fixé ledit tube (2) est soumise à un couple rotatoire,
- l'extrémité de l'axe (6), située à l'intérieur du fourreau (1), étant assujettie aux moyens (10a) (6b) et (10b) (12b) aptes à autoriser, lorsque la partie d'os (O2) accouplée au tube (2) est soumise à un couple rotatoire, dans un sens, le déplacement en translation de l'axe (6) portant le fragment osseux et, dans l'autre sens, le blocage en translation dudit axe.

-3- Dispositif selon la revendication 1, caractérisé en ce que les moyens sont constitués par une douille filetée (10) vissée dans un alésage taraudé (1b) du fourreau (1), ladite douille présentant, à chacune de ses extrémités,

PETITIONER ARTHREX
EX. 1004

des agencements d'acouplement (10a) (10b) coopérant avec des agencements complémentaires (6b) (12b) de l'extrémité de l'axe (6a), et d'un organe d'appui (12), lesdits agencements étant débrayables.

-4- Dispositif selon la revendication 3, caractérisé en ce que les agencements de la douille filetée (10) sont constitués par des systèmes à cliquets (10a) (10b) disposés facialement à chacune des extrémités de ladite douille, chaque système de cliquets étant inversé.

-5- Dispositif selon la revendication 3, caractérisé en ce que la douille filetée (10) et l'axe (6) sont assujettis à un système de mise en pression.

-6- Dispositif selon la revendication 5, caractérisé en ce que le système de mise en pression est du type coaxial et présente une vis (11) engagée librement à l'intérieur de la douille (10) et d'un organe d'appui (12) coopérant avec ladite douille, en étant vissée à l'extrémité de l'axe (6), ladite vis coopérant avec un organe élastique (13), monté en combinaison avec l'organe d'appui.

-7- Dispositif selon la revendication 6, caractérisé en ce que l'organe d'appui (12) présente des agencements de blocage en rotation, à l'intérieur de l'alésage taraudé du fourreau (1).

-8- Dispositif selon la revendication 3, caractérisé en ce que l'un des systèmes à cliquets (10a) de la douille (10), coopère avec une denture complémentaire (6b) formée facialement à l'extrémité de l'axe (6), pour assurer, dans un sens de rotation, l'entrainement concomitant de l'axe (6) et de la douille (10), tandis que l'autre système à cliquets (10b), coopère avec une denture (12b) formée facialement à l'extrémité de l'organe d'appui (12), pour assurer, dans l'autre sens de rotation, la libre rotation

PETITIONER ARTHREX
EX. 1004

de l'axe par rapport à la douille.

-9- Dispositif selon la revendication 2, caractérisé en ce que l'axe (6) est équipé d'un trou (6a) pour l'engagement d'une vis de fixation du fragment osseux, au travers d'une lumière oblongue (2b), dans laquelle est montée une clavette (7) solidaire de l'axe, en vue, d'une part, du coulissement dudit axe dans le tube (2) et, d'autre part, de l'entrainement angulaire dudit axe, lorsqu'un couple rotatoire est appliqué à la partie d'os (O2) solidaire dudit tube.

-10- Dispositif selon la revendication 2, caractérisé en ce que la partie de l'axe (6) engagée dans le fourreau (1), reçoit une clavette (8) coopérant avec une rainure (1b1) formée dans l'alésage du fourreau pour être déplacé selon un arc de cercle d'angle au centre (α) déterminé pour correspondre à la valeur d'une dent du système à cliquets, de la douille (10).

-11- Dispositif selon la revendication 2, caractérisé en ce que le tube (2) est accouplé au fourreau (1), en combinaison avec une bague (5) permettant la rotation angulaire limitée et assurant la rigidité axiale de l'ensemble.

PETITIONER ARTHREX
EX. 1004

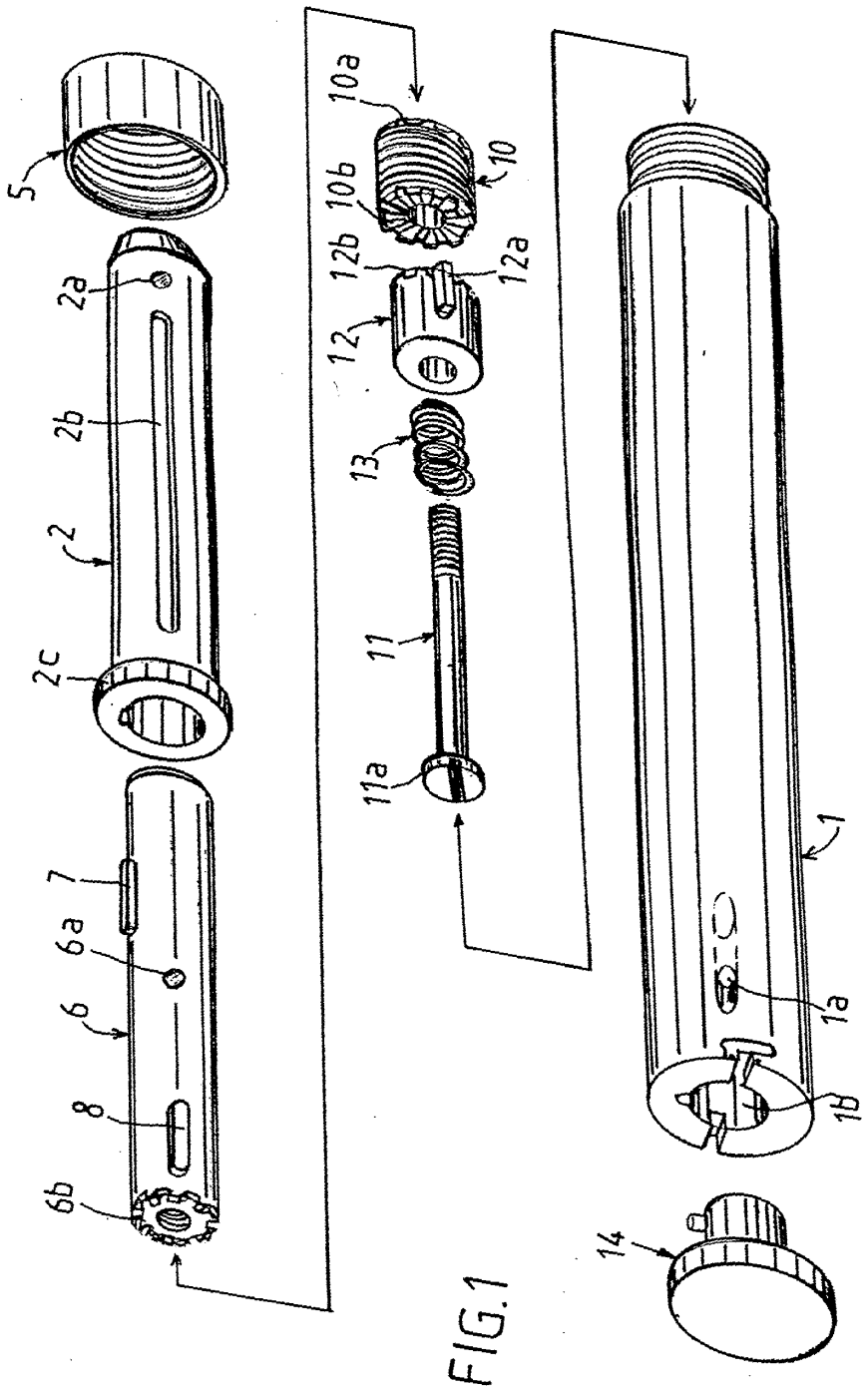


FIG.1

PETITIONER ARTHREX
EX. 1004

FIG.2

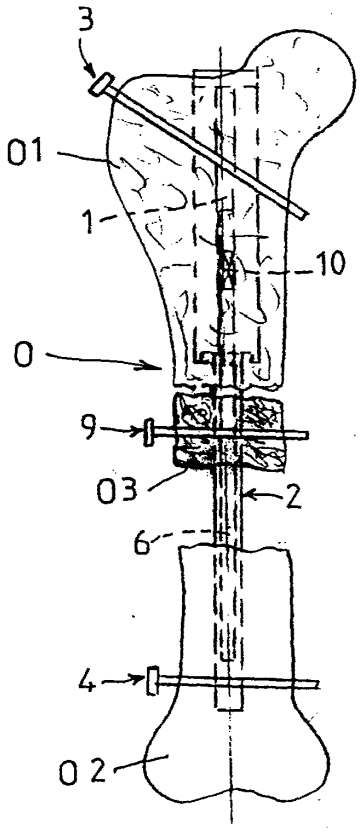
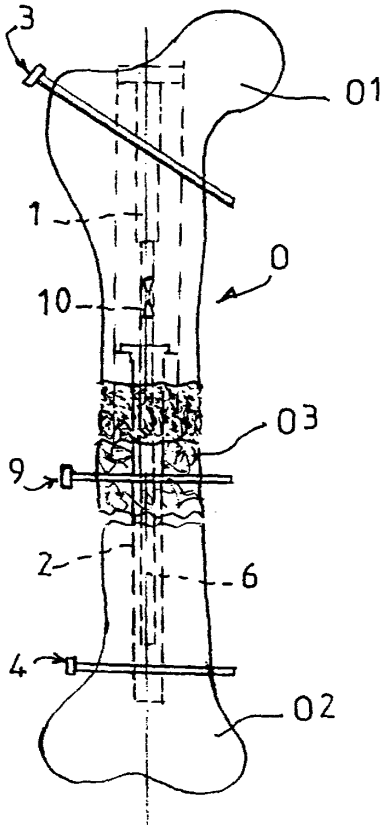


FIG.3



PETITIONER ARTHREX
EX. 1004

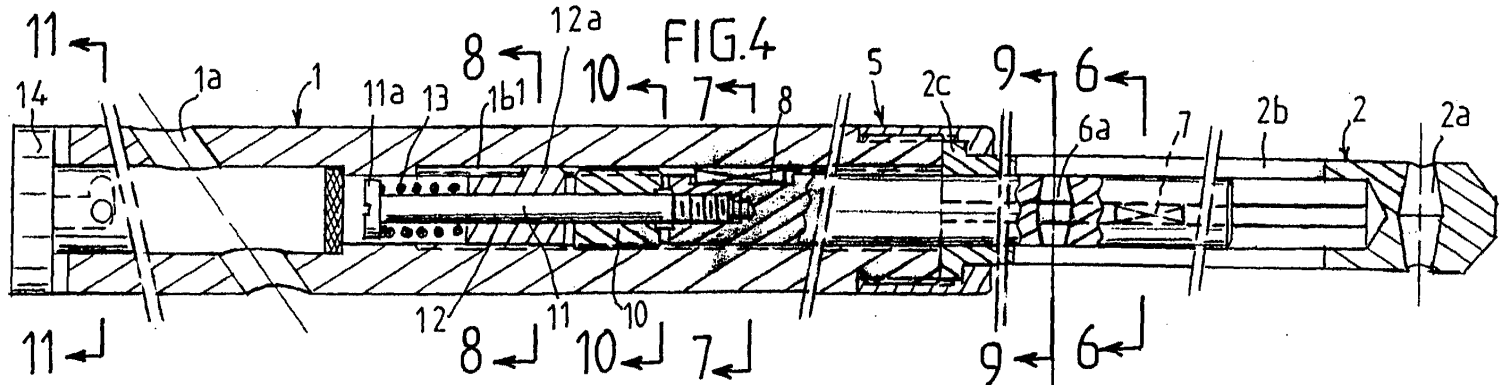


FIG.4

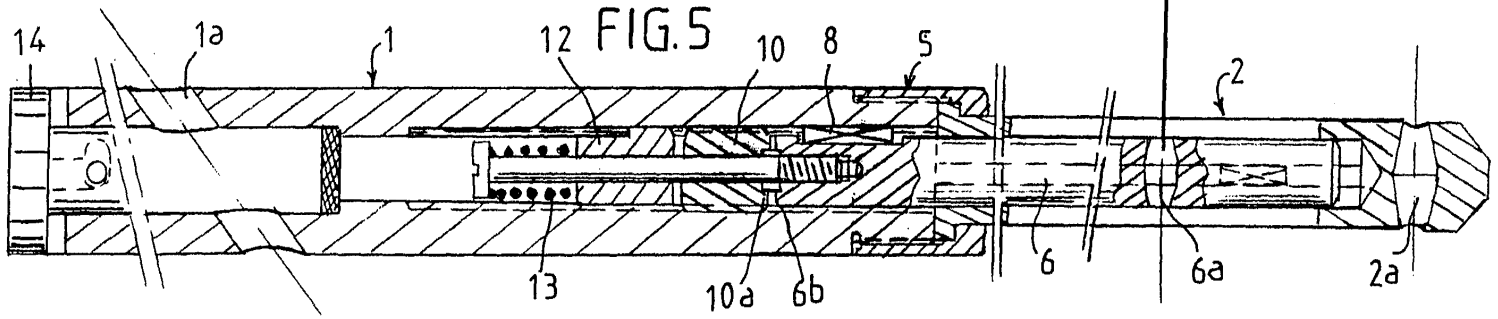


FIG.5

PETITIONER ARTHREX
EX. 1004

FIG.6

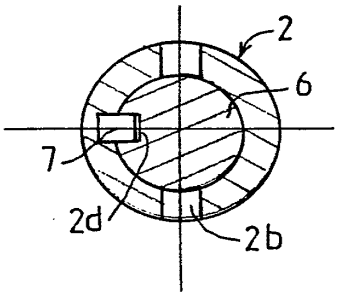


FIG.7

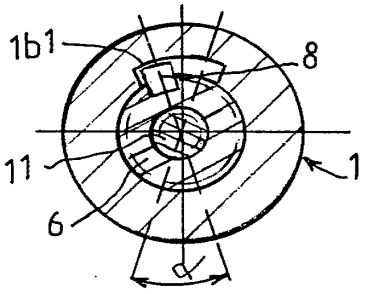


FIG.8

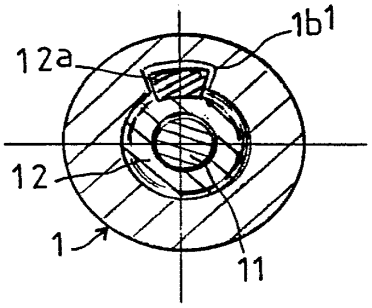


FIG.9

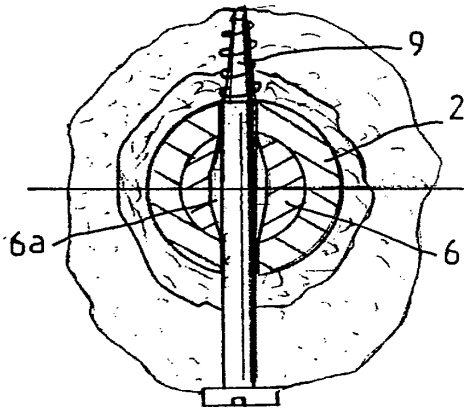


FIG.10

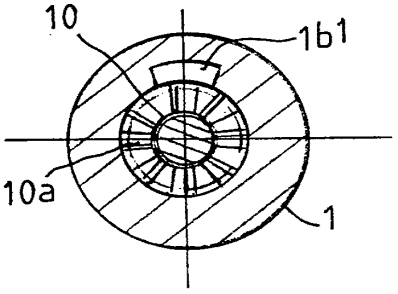
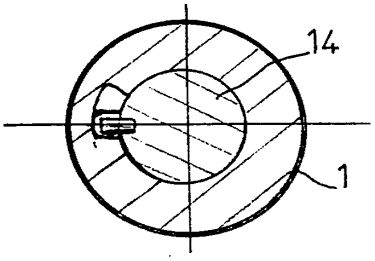


FIG.11



PETITIONER ARTHREX
EX. 1004

INTERNATIONAL SEARCH REPORT

Internatic Application No
PCT/FR 95/00139

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/58

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 6 A61B

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 346 247 (MEDINOV) 13 December 1989 see abstract; figure 1	1
A	GB,A,2 114 891 (JAQUET) 1 September 1983 see abstract; figure 2	1
A	US,A,4 946 459 (BRADSHAW) 7 August 1990	
A	US,A,5 112 333 (FIXEL) 12 May 1992 see abstract; figure 2	

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

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search
26 July 1995

Date of mailing of the international search report
03. 08. 95

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+ 31-70) 340-3016

Authorized officer
Barton, S

Form PCT/ISA/210 (second sheet) (July 1992)

PETITIONER ARTHREX
EX. 1004

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati Application No
PCT/FR 95/00139

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0346247	13-12-89	FR-A-	2632514	15-12-89
		AT-T-	116834	15-01-95
		DE-D-	68920483	23-02-95
		DE-T-	68920483	14-06-95
		ES-T-	2069602	16-05-95
		US-A-	5074882	24-12-91
GB-A-2114891	01-09-83	CH-A-	630798	15-07-82
		AT-B-	384946	25-01-88
		BE-A-	881135	14-07-80
		CA-A-	1152827	30-08-83
		DE-A-	3000432	24-07-80
		FR-A,B	2446627	14-08-80
		GB-A,B	2040168	28-08-80
		JP-C-	1471913	27-12-88
		JP-A-	55096148	22-07-80
		JP-B-	63018505	19-04-88
		NL-A-	8000052	18-07-80
		SE-B-	443706	10-03-86
		SE-A-	8000208	17-07-80
		US-A-	4365624	28-12-82
		US-A-	4535763	20-08-85
US-A-4946459	07-08-90	AU-A-	5333390	26-06-91
		WO-A-	9107920	13-06-91
US-A-5112333	12-05-92	NONE		

Form PCT/ISA/210 (patent family annex) (July 1992)

PETITIONER ARTHREX
EX. 1004

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No
PCT/FR 95/00139

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 6 A61B17/58

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 6 A61B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela est réalisable, termes de recherche utilisés)

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	EP,A,0 346 247 (MEDINOV) 13 Décembre 1989 voir abrégé; figure 1	1
A	GB,A,2 114 891 (JAQUET) 1 Septembre 1983 voir abrégé; figure 2	1
A	US,A,4 946 459 (BRADSHAW) 7 Août 1990	
A	US,A,5 112 333 (FIXEL) 12 Mai 1992 voir abrégé; figure 2	

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

* Catégories spéciales de documents cités:

"A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent

"E" document antérieur, mais publié à la date de dépôt international ou après cette date

"L" document pouvant jeter un doute sur une revendication de priorité ou cité pour déterminer la date de publication d'une autre citation ou pour une raison spéciale (telle qu'indiquée)

"O" document se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens

"P" document publié avant la date de dépôt international, mais postérieurement à la date de priorité revendiquée

"T" document ultérieur publié après la date de dépôt international ou la date de priorité et n'appartenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention

"X" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive par rapport au document considéré isolément

"Y" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier

"&" document qui fait partie de la même famille de brevets

1

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
26 Juillet 1995	03. 08. 95

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Barton, S

Formulaire PCT/ISA/210 (deuxième feuille) (juillet 1992)

PETITIONER ARTHREX
EX. 1004

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No
PCT/FR 95/00139

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
EP-A-0346247	13-12-89	FR-A-	2632514	15-12-89
		AT-T-	116834	15-01-95
		DE-D-	68920483	23-02-95
		DE-T-	68920483	14-06-95
		ES-T-	2069602	16-05-95
		US-A-	5074882	24-12-91
GB-A-2114891	01-09-83	CH-A-	630798	15-07-82
		AT-B-	384946	25-01-88
		BE-A-	881135	14-07-80
		CA-A-	1152827	30-08-83
		DE-A-	3000432	24-07-80
		FR-A,B	2446627	14-08-80
		GB-A,B	2040168	28-08-80
		JP-C-	1471913	27-12-88
		JP-A-	55096148	22-07-80
		JP-B-	63018505	19-04-88
		NL-A-	8000052	18-07-80
		SE-B-	443706	10-03-86
		SE-A-	8000208	17-07-80
		US-A-	4365624	28-12-82
		US-A-	4535763	20-08-85
US-A-4946459	07-08-90	AU-A-	5333390	26-06-91
		WO-A-	9107920	13-06-91
US-A-5112333	12-05-92	AUCUN		

Formulaire PCT/ISA/210 (annexe familles de brevets) (juillet 1992)

PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3733
Gall et al.	Examiner: Annette R. Reimers
Serial No.: 11/112,865	**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b)(3))**
Filed: April 21, 2005	
Confirmation No.: 5339	
Atty. File No.: 036302-010201	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on December 8, 2008.
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	Signed: _____ Name: Stephen S. Gruber

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

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Information Disclosure Citation are brought to the attention of the Examiner.

This Information Disclosure Citation should be considered because it is submitted before the mailing date of a first Office Action on-the-merits (37 C.F.R. § 1.97(b)(3)). Accordingly, no fee is due for consideration of the items listed on the enclosed Information Disclosure Citation. In accordance with 37 C.F.R. § 1.98(a)(2), a legible copy of each foreign patent, publication and unpublished U.S. application cited in the Information Disclosure Citation is provided herewith.

The filing of this Information Disclosure Citation should not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), and should not be construed as an admission that the information cited in the Information Disclosure Citation is, or is considered to be, material to patentability as defined in § 1.56(b) (37 C.F.R. § 1.97(h)).

Consideration of the cited items is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Information

Disclosure Citation, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 50-2775.

Respectfully submitted,

12/08/08
Date

Stephen S. Gruber
Reg. No. 63,411
Greenberg Traurig LLP
1200 17th Street, Suite 2400
Denver, CO 80202
Tel: (303) 685-7431
Fax: (720) 904-6131

PETITIONER ARTHREX
EX. 1004

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302.010201	Application Number 11/112,865
	Applicant(s) Gall et al.	
	Filing Date Apr. 21, 2005	Group Art Unit 3733

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	1	Results of the Partial International Search from corresponding PCT Application No. PCT/US2008/055188.

EXAMINER	DATE CONSIDERED

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

SHEET 1 OF 1

DEN 96,757,887v1 12-8-08

PETITIONER ARTHREX EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	4415816
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	Stephen Spencer Gruber
Filer Authorized By:	
Attorney Docket Number:	036302-010201
Receipt Date:	08-DEC-2008
Filing Date:	21-APR-2005
Time Stamp:	17:47:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS.pdf	105303 755bb93f1fb985ea312a6c3ecac8995628024a83	yes	3

PETITIONER ARTHREX
EX. 1004

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Information Disclosure Statement Letter	1	2
	Information Disclosure Statement (IDS) Filed (SB/08)	3	3
Warnings:			
Information:			

2	NPL Documents	Partial_Search_in_PCTUS2008055188.pdf	292383 e2a43370bab45118113fc6c8afc66bb0ca3233d6	no	6
Warnings:					
Information:					
		Total Files Size (in bytes):	397686		

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.

PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)	Group Art Unit: 3733
	)	
Gall et al.	)	Examiner: Annette R. Reimers
	)	
Serial No.: 11/112,865	)	**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b)(3))**
	)	
Filed: April 21, 2005	)	
	)	
Confirmation No.: 5339	)	
	)	It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on October 28, 2008.
Atty. File No.: 036302-010201	)	
	)	
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	)	Signed: Steve Gruber Name: Steve Gruber
	)	

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

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Information Disclosure Citation are brought to the attention of the Examiner.

This Information Disclosure Citation should be considered because it is submitted before the mailing date of a first Office Action on-the-merits (37 C.F.R. § 1.97(b)(3)). Accordingly, no fee is due for consideration of the items listed on the enclosed Information Disclosure Citation. In accordance with 37 C.F.R. § 1.98(a)(2), a legible copy of each foreign patent, publication and unpublished U.S. application cited in the Information Disclosure Citation is provided herewith.

The filing of this Information Disclosure Citation should not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), and should not be construed as an admission that the information cited in the Information Disclosure Citation is, or is considered to be, material to patentability as defined in § 1.56(b) (37 C.F.R. § 1.97(h)).

Consideration of the cited items is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Information

PETITIONER ARTHREX
EX. 1004

Disclosure Citation, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 50-2775.

Respectfully submitted,

10-28-08
Date

Wm. Alex Furman
Reg. No. 61,313
Greenberg Traurig LLP
1200 17th Street, Suite 2400
Denver, CO 80202
Tel: (303) 572-6500
Fax: (303) 572-6540

PETITIONER ARTHREX
EX. 1004

INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*	Docket Number (optional) 036302.010201	Application Number 11/112,865
	Applicant(s) Gall et al.	
	Filing Date Apr. 21, 2005	Group Art Unit 3733

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	4,452,236	Jun. 5, 1984	Utsugi, M.	128	4	

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	2	Andreasen et al., *Laboratory and Clinical Analyses of Nitinol Wire*, American Journal of Orthepedics, Vol. 73, No. 2, pp. 142-151 (Feb. 1978).
	3	Cragg et al., *A New Percutaneous Vena Cava Filter*, American Journal of Roentgenology, Vol. 141, pp. 601-604 (Sep. 1983).
	4	Wasilewski, R., *Stress-Assisted Martensite Formation in TiNi*, Scripta Metallurgica, Vol. 5, No. 2, pp. 127-130 (1971).
	5	Watanabe, K., *Studies on New Superelastic NiTi Orthodontic Wire (Part 1) Tensile and Bend Test*, Dental Material and Devices Magazine, Vol. 23, No. 61, pp. 1-61 (1982).

EXAMINER	DATE CONSIDERED

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

Electronic Acknowledgement Receipt	
EFS ID:	4187820
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	William Alexander Furman/Steve Gruber
Filer Authorized By:	William Alexander Furman
Attorney Docket Number:	036302-010201
Receipt Date:	28-OCT-2008
Filing Date:	21-APR-2005
Time Stamp:	13:57:51
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		036302-010201_IDS.pdf	111365 54e5a166801c25f8d5e389ea52d07554cd45faf0	yes	3

PETITIONER ARTHREX
EX. 1004

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Information Disclosure Statement Letter		1	2	
	Information Disclosure Statement (IDS) Filed (SB/08)		3	3	
Warnings:					
Information:					
2	NPL Documents	Andreasen_1978.PDF	910529 2b8a32a02ba5a3554e30742eb01dec476352d54c	no	10
Warnings:					
Information:					
3	NPL Documents	Cragg_1983.PDF	396566 030132eaa0f7fa450e80c1ded8a4ed8396f68d47	no	5
Warnings:					
Information:					
4	NPL Documents	Wasilewski_1971.PDF	165881 df5ea3fcdbf4bbe6ed7cf9ed17861df068251849	no	4
Warnings:					
Information:					
5	NPL Documents	Watanabe_translation_1981.PDF	932226 6305ca5b648dd30ce9ac7cb5d78c85d24bb203cc	no	15
Warnings:					
Information:					
		Total Files Size (in bytes):	2516567		

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.

PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Kenneth A. Gall et al.

Serial No.: 11/112,865

Filed: April 21, 2005

Confirmation No.: 5339

Atty. File No.: 036302-010201

For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"

Group Art Unit: 3733

Examiner: Annette R. Reimers

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on August 24, 2007.

Signed: _____

Name: Kathy Johnston

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

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Supplemental Information Disclosures Statement (similar to USPTO Form 1449) are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing of a first Office Action on the merits. In accordance with 37 C.F.R. §1.98(a)(2), copies of non - U.S. patent documents listed on the enclosed Form are provided, unless previously submitted.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicant reserves the right, pursuant to 37 C.F.R. §1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicant does not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

PETITIONER ARTHREX
EX. 1004

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Information Disclosure Statement, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Respectfully submitted,

8/23/07
Date

George C. Lewis, Reg. No. 53,214
Greenberg Traurig LLP
1200 17th Street, Suite 2400
Denver, CO 80202
Tel: 303-572-6500
Fax: 303-572-6540

PETITIONER ARTHREX
EX. 1004

Attorney Docket No.: 036302-010201

INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Gall, et al.	
	Filing Date: 04/21/2005	Group Art Unit: 3732

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,688,828	02/10/2004	Post			
	6,637,995	10/28/2003	White			
	5,265,456	11/30/1993	Kennedy et al.			
	5,120,175	06/09/1992	Arbegast et al.			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Courtesy Copy of International Search Report, PCT/US06/15207
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

PETITIONER ARTHREX
EX. 1004

Attorney Docket No.: 036302-010201

INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Gall, et al.	
	Filing Date: 04/21/2005	Group Art Unit: 3732

		Lin, J.R. et al., *Study on Shape-Memory Behavior of Polyether-Based Polyurethanes. II. Influence of Soft-Segment Molecular Weight*, JOURNAL OF APPLIED POLYMER SCIENCE, Vol. 69, (1998), pp. 1575-1586
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

PETITIONER ARTHREX
EX. 1004

Electronic Acknowledgement Receipt

EFS ID:	2122207
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	George Cone Lewis/Kathy Johnston
Filer Authorized By:	George Cone Lewis
Attorney Docket Number:	36302-010201
Receipt Date:	24-AUG-2007
Filing Date:	21-APR-2005
Time Stamp:	15:24:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	036302_010201_IDS.pdf	208914 8bad2a0ce296aa39e5d2369eeac7c8fdbd26b491	no	4
Warnings:					

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EX. 1004

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This is not an USPTO supplied IDS fillable form					
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Information:					
16	NPL Documents	15_Liu.pdf	772257 d931e0b66b84b8b90496ae80112b78921ca8e2d7	no	8
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29	NPL Documents	28_Zhu.pdf	468321 ed22b495d3936115dbda1ab7b891037b86612f61	no	7
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Information:					
			Total Files Size (in bytes):	51955108	

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.

PETITIONER ARTHREX
EX. 1004

Attorney Docket No. 036302-010201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Kenneth A. Gall et al.

Serial No.: 11/112,865

Filed: April 21, 2005

Confirmation No.: 5339

Atty. File No.: 036302-010201

For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"

Group Art Unit: 3733

Examiner: Annette R. Reimers

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

It is hereby certified that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO electronic filing system no later than 11:59 PM local time on May 7, 2007.

Signed: Kathy Johnston

Name: Kathy Johnston

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

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Information Disclosures Statement (similar to USPTO Form 1449) are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing of a first Office Action on the merits. In accordance with 37 C.F.R. §1.98(a)(2), copies of non - U.S. patent documents listed on the enclosed Form are provided, unless previously submitted.

With respect to WO 2006/120355 A1, as required under 37 C.F.R. §1.98(a)(3)(i) the reference is relevant because it relates to an arthrodetic medical device.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicant reserves the right, pursuant to 37 C.F.R. §1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicant does not represent that a

PETITIONER ARTHREX
EX. 1004

reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Information Disclosure Statement, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Respectfully submitted,

5/7/07
Date

George C. Lewis, Reg. No. 53,214
Greenberg Traurig LLP
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Denver, CO 80202
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PETITIONER ARTHREX
EX. 1004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	Docket Number: 036302-010201	Application Number: 11/112,865
IN AN APPLICATION	Applicant: Kenneth Gall et al.	
(Use several sheets if necessary)	Filing Date: April 21, 2005	Group Art Unit: 3733

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,056,322	06/06/2006	Davison et al.			
	6,986,774	01/17/2006	Middleman et al.			
	6,533,805	03/18/2003	Jervis			
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	5,067,957	11/26/1991	Jervis			
	4,665,906	05/19/1987	Jervis			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 2006/120355	16 NOV 2006	PCT			X	

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

PETITIONER ARTHREX
EX. 1004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 036302-010201	Application Number: 11/112,865
	Applicant: Kenneth Gall et al.	
	Filing Date: April 21, 2005	Group Art Unit: 3733

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		English Translation of WO 2006/120355 (listed above)
		ANKLE ARTHRODESIS NAIL SURGICAL TECHNIQUE, Biomet, Inc., Form No. Y-BMT-596R/021500/H, ©2000 Biomet, Inc. Warsaw, IN
		PANTA™ Arthrodesis Nail. Datasheet [online]. Integra LifeSciences Corporation, 2006, [retrieved on 1/12/2007]. Retrieved from the Internet: <http://www.ilstraining.com/Mid%20%20Hindfoot%20Solutions/panta/panta_00.html>
		RETRONAIL ANKLE ARTHRODESIS ARTHRITIC DEFORMITY, FRACTURES, FAILED FUSION. Products [online]. ©2007 orthofix.com, [retrieved on 04/04/2007]. Retrieved from the Internet: <http://www.orthofix.com/products/retronail.asp?cid=5>
		T2™TIBIAL NAILING SYSTEM. Operative Technique. Stryker, pp. 1-31
		TIBIOTALOCALCANEAL NAILING SYSTEM OPTIONS MADE EASY. Surgical Technique. Stryker, 2006. pp.1-19

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

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EX. 1004

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle
Bureau international

PCT

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16 novembre 2006 (16.11.2006)

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WO 2006/120355 A1

(51) Classification internationale des brevets :
A61B 17/72 (2006.01) *A61B 17/17* (2006.01)

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(25) Langue de dépôt : français

(26) Langue de publication : français

(30) Données relatives à la priorité :
0504851 13 mai 2005 (13.05.2005) FR

(71) Déposant *(pour tous les États désignés sauf US)* : **NEWDEAL** [FR/FR]; 10, Place d'Helvétie, F-69006 Lyon (FR).

(72) Inventeurs; et

(75) Inventeurs/Déposants *(pour US seulement)* : **BRODSKY, James, White** [US/US]; 9930 Rockbrook Drive, Dallas, TX 75220 (US). **GAUNEAU, Bertrand, Xavier, François** [FR/FR]; 60, rue de la Madeleine, F-69007 Lyon (FR).

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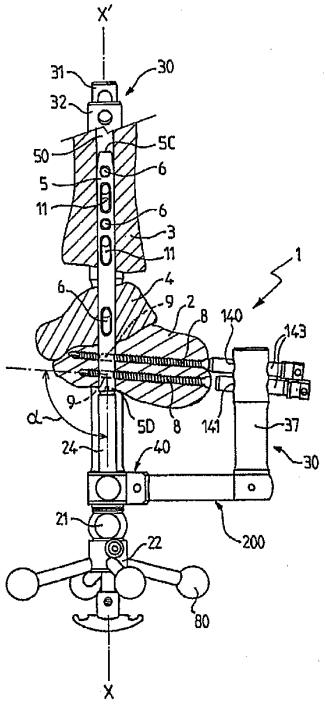
(81) États désignés *(sauf indication contraire, pour tout titre de protection nationale disponible)* : AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

[Suite sur la page suivante]

WO 2006/120355 A1

(54) Title: JOINT FUSION APPARATUS FOR THE ANKLE-TYPE JOINT AND ARTHRODETIC PIN FOR USE IN SAID APPARATUS

(54) Titre : APPAREILLAGE D'ARTHRODESE POUR UNE ARTICULATION, DU GENRE ARTICULATION DE LA CHEVILLE, ET CLOU D'ARTHRODESE DESTINE A ETRE UTILISE DANS UN TEL APPAREILLAGE



(57) Abstract: The invention relates to an arthrodetic apparatus for a first and second bone (2, 3), comprising a pin (5), an instrument (20) for positioning said pin (5) comprising a base (21) and a compression means (22, 23) with an operating means (22) to produce a displacement of the pin relative to the base (21) and an immobilisation means (23) for the second bone (3) relative to the base (21), whereby said pin comprises a guidance means (11). Said guidance means (11) and said immobilisation means (23) are embodied and arranged to cooperate together such as to permit the displacement of the pin relative to the immobilisation means (23) and the approach of the first bone (2) to the second bone (3). The invention further relates to arthrodetic apparatuses.

(57) Abrégé : L'invention concerne un appareillage d'arthrodèse pour un premier et un deuxième os (2, 3) comportant : - un clou (5), - un instrument (20) de mise en place dudit clou (5) comportant une base (21) et un moyen de compression (22, 23) comprenant : - un moyen de commande (22), générant un déplacement du clou relativement à ladite base (21), - un moyen d'immobilisation (23) du deuxième os (3) relativement à la base (21), ledit clou comportant un moyen de guidage (11), ledit moyen de guidage (11) et ledit moyen d'immobilisation (23) étant agencés et conformés pour coopérer ensemble de manière à autoriser le déplacement du clou relativement au moyen d'immobilisation (23) et le rapprochement des premier os (2) et deuxième os (3). Appareillages d'arthrodèse.

PETITIONER ARTHREX
EX. 1004

(84) **États désignés** *(sauf indication contraire, pour tout titre de protection régionale disponible)* : ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publiée :

— *avec rapport de recherche internationale*

— *avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues*

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

PETITIONER ARTHREX
EX. 1004

APPAREILLAGE D'ARTHRODESE POUR UNE ARTICULATION, DU GENRE ARTICULATION DE LA CHEVILLE, ET CLOU D'ARTHRODESE DESTINE A ETRE UTILISE DANS UN TEL APPAREILLAGE

DOMAINE TECHNIQUE

La présente invention se rapporte au domaine technique général des appareillages destinés à être utilisés pour réaliser une arthrodèse.

La présente invention se rapporte à un appareillage d'arthrodèse pour une articulation formée par au moins un premier et un deuxième os, du genre articulation de la cheville, ledit appareillage comportant :

- un clou d'arthrodèse, pourvu de moyens de fixation avec les os formant l'articulation,
- un instrument de mise en place dudit clou d'arthrodèse au sein de l'articulation, comportant une base ainsi qu'un moyen de compression, destiné à permettre le rapprochement des premier et deuxième os formant l'articulation,
- un moyen de liaison, servant d'interface entre l'instrument et le clou d'arthrodèse.

L'invention concerne également un clou d'arthrodèse destiné à être utilisé au sein de l'appareillage sus-mentionné.

L'invention concerne également une méthode chirurgicale pour réaliser une arthrodèse de cheville en utilisant l'appareillage sus-mentionné.

PETITIONER ARTHREX
EX. 1004

TECHNIQUE ANTERIEURE

Dans une application préférentielle, mais non exclusive, l'appareillage conforme à l'invention sera plus particulièrement destiné et conçu pour réaliser une arthrodèse de l'articulation de la cheville, étant entendu que des applications à d'autres articulations, notamment à celle de l'épaule, sont aussi envisageables.

Une arthrodèse est une intervention chirurgicale destinée à supprimer presque complètement la mobilité d'une articulation en provoquant une « *fusion osseuse* ». Une telle intervention chirurgicale peut s'avérer nécessaire dans le cas où le patient souffre d'arthrose sévère et finale.

Pour réaliser de telles interventions, il est connu d'utiliser un appareillage d'arthrodèse comportant d'une part un clou d'arthrodèse, destiné à être implanté au sein de l'articulation, et d'autre part un instrument de mise en place du clou d'arthrodèse.

Le clou d'arthrodèse est généralement introduit dans des logements ménagés successivement à travers les différents os formant l'articulation, et il comporte des trous de fixation destinés à coopérer avec des vis de fixation pour le solidariser avec les os formant l'articulation.

Il est connu, afin de mettre en place de tels clous d'arthrodèse, d'avoir recours à un instrument comportant un moyen de compression, destiné à permettre le rapprochement des os formant l'articulation, et par exemple, dans le cas de l'articulation de la cheville, le rapprochement du calcanéum et du tibia.

L'étape de compression revêt un caractère très important dans l'intervention chirurgicale dans la mesure où cette étape conditionne le positionnement

PETITIONER ARTHREX
EX. 1004

relatif des os formant l'articulation, un mauvais positionnement étant susceptible de générer une gêne pour le patient.

Or, dans le cas de l'articulation de la cheville, le moyen de compression est généralement réalisé à l'aide d'une portée, agencée pour venir en appui contre le talon et susceptible d'être déplacée pour exercer une pression contre ce dernier, rapprochant ainsi le calcanéum du tibia.

La technique opératoire généralement utilisée est la suivante :

- le chirurgien solidarise, à l'aide de vis de fixation, le clou d'arthrodèse avec le tibia,
- le chirurgien déplace ensuite la portée, de telle sorte qu'elle vienne en appui contre le talon et comprime l'articulation, rapprochant ainsi le tibia du calcanéum,
- le chirurgien solidarise enfin le clou avec le calcanéum, tout en maintenant la pression exercée par la portée sur le talon.

De tels appareillages d'arthrodèse, s'ils permettent d'obtenir des résultats intéressants en matière d'immobilisation de l'articulation, souffrent néanmoins d'inconvénients non négligeables.

En particulier, il existe un risque, avec les appareillages de l'art antérieur, que lors de l'étape de compression, le clou traverse le cortex plantaire du calcanéum et fasse saillie à l'extérieur du faciès plantaire.

Avec de tels appareillages, le chirurgien doit donc tout particulièrement veiller à ne pas effectuer une compression trop importante de l'articulation. Une telle contrainte constitue un inconvénient non négligeable pour le chirurgien, d'autant plus qu'il est souvent difficile, voire impossible, avec les

PETITIONER ARTHREX
EX. 1004

appareillages de l'art antérieur, de contrôler précisément l'intensité de la compression.

En outre, l'utilisation de tels appareillages peut conduire à un endommagement des tissus mous du faciès plantaire, tissus situés entre la portée de compression et le calcanéum.

En effet, si l'intensité de la compression est trop importante, la pression exercée par la portée peut générer une nécrose de la peau au niveau du talon.

Par ailleurs, le montage des vis de fixation dans le calcanéum et l'astragale étant effectué après l'étape de compression, c'est-à-dire après le déplacement de l'astragale et du calcanéum relativement au tibia, il peut arriver que les vis de fixation soient mal positionnées dans les os, c'est-à-dire qu'elles soient positionnées trop près de la périphérie d'un os, voire positionnées dans la zone de jonction entre deux os. Un clou d'arthrodèse ainsi fixé n'est alors pas en mesure d'assurer un maintien correct de l'articulation.

EXPOSE DE L'INVENTION

Les objets assignés à l'invention visent en conséquence à porter remède aux différents inconvénients énumérés précédemment et à proposer un nouvel appareillage d'arthrodèse pour une articulation du genre articulation de la cheville, qui permette d'effectuer une compression efficace de l'articulation sans risquer d'endommager d'une part le cortex, et d'autre part les tissus mous voisins des os formant l'articulation.

PETITIONER ARTHREX
EX. 1004

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse présentant une bonne rigidité d'ensemble lors de l'étape de compression.

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse permettant d'effectuer une compression contrôlée et précise de l'articulation.

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse permettant une fixation du clou d'arthrodèse adaptée à l'anatomie de l'articulation.

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse assurant un maintien confortable de l'articulation.

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse facilitant le montage des vis de fixation du clou relativement aux os formant l'articulation.

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse présentant un caractère modulable en fonction de l'anatomie de l'articulation tout en étant simple à utiliser.

Un autre objet de l'invention vise à proposer un nouvel appareillage d'arthrodèse dont la manipulation est facilitée et qui permet de réduire les erreurs opératoires.

Les objets assignés à l'invention visent également à proposer un clou d'arthrodèse destiné à être utilisé au sein de l'appareillage sus-mentionné.

PETITIONER ARTHREX
EX. 1004

Les objets assignés à l'invention visent également à proposer une méthode chirurgicale pour réaliser une arthrodèse de la cheville, dans laquelle on réalise une compression efficace et contrôlée de l'articulation, et ce sans endommager ni les os formant l'articulation, ni les tissus mous voisins.

Les objets assignés à l'invention sont atteints à l'aide d'un appareillage d'arthrodèse pour une articulation formée par au moins un premier et deuxième os, du genre articulation de la cheville, ledit appareillage comportant :

- un clou d'arthrodèse pourvu de moyens de fixation avec les os formant l'articulation,
- un instrument de mise en place dudit clou d'arthrodèse au sein de l'articulation, comportant une base ainsi qu'un moyen de compression, destiné à permettre le rapprochement des premier et deuxième os formant l'articulation,
- un moyen de liaison servant d'interface entre l'instrument et le clou d'arthrodèse,

caractérisé en ce que le moyen de compression comporte :

- un moyen de commande agencé de manière à générer, par l'intermédiaire dudit moyen de liaison, un déplacement du clou d'arthrodèse relativement à ladite base selon un axe longitudinal sensiblement parallèle à l'axe d'extension dudit clou,
- un moyen d'immobilisation, agencé pour immobiliser le deuxième os relativement à la base,

ledit clou comportant un moyen de guidage, ledit moyen de guidage et ledit moyen d'immobilisation étant agencés et conformés pour coopérer ensemble de manière à autoriser le déplacement du clou relativement au

PETITIONER ARTHREX
EX. 1004

moyen d'immobilisation, et à permettre, lorsque le clou est solidarisé avec le premier os, le rapprochement des premier et deuxième os.

Les objets assignés à l'invention sont également atteints à l'aide d'un clou d'arthrodèse utilisé dans l'appareillage d'arthrodèse sus-mentionné.

Les objets assignés à l'invention sont également atteints à l'aide d'une méthode chirurgicale pour réaliser une arthrodèse de l'articulation de la cheville, dans laquelle on utilise un appareillage d'arthrodèse, comportant un clou d'arthrodèse ainsi qu'un moyen de compression, ladite méthode chirurgicale comportant les étapes suivantes :

- une étape de solidarisation du clou avec le calcanéum,
- une étape de compression, au cours de laquelle d'une part on rapproche le calcanéum du tibia, en déplaçant le clou relativement au tibia à l'aide du moyen de compression et d'autre part on contrôle l'amplitude de déplacement du clou à l'aide de moyens de guidage ménagés sur ledit clou.

DESCRIPTIF SOMMAIRE DES DESSINS

D'autres avantages et objets de l'invention apparaîtront plus en détails à la lecture de la description qui suit, et à l'aide des dessins annexés fournis à titre purement illustratif et non limitatif, dans lesquels :

- La figure 1 illustre, selon une vue de côté, une partie de l'appareillage d'arthrodèse conforme à l'invention dans l'étape de solidarisation du clou d'arthrodèse avec le calcanéum.

- La figure 2 illustre, selon une vue en perspective, deux variantes de réalisation de clous d'arthrodèse conformes à l'invention.

PETITIONER ARTHREX
EX. 1004

- La figure 3 illustre, selon une vue de face, un appareillage d'arthrodèse conforme à l'invention, dans sa position d'avant la mise en compression.

- La figure 4 illustre, selon une vue de face, un appareillage d'arthrodèse conforme à l'invention dans sa position d'après la mise en compression.

- La figure 5 illustre, selon une vue en perspective, un appareillage d'arthrodèse conforme à l'invention lors de la fixation du clou d'arthrodèse (articulation non représentée).

- La figure 6 illustre, selon une vue en coupe, une variante de réalisation d'un appareillage d'arthrodèse conforme à l'invention, dans sa position d'avant la mise en compression.

MEILLEURE MANIERE DE REALISER L'INVENTION

Les figures 1, 3, 4 et 5 illustrent un appareillage 1 d'arthrodèse conforme à l'invention. Un tel appareillage est conçu pour être utilisé dans le cadre d'une arthrodèse, notamment lorsqu'une articulation, et particulièrement l'articulation de la cheville, se trouve dans un état si dégradé que d'autres interventions chirurgicales moins sévères, telles que par exemple celles consistant à poser des prothèses de cheville, s'avèreraient inefficaces. Il devient nécessaire, dans ce cas, d'immobiliser complètement l'articulation.

Au sens de l'invention, l'articulation est formée par au moins deux os, à savoir un premier os 2 et un deuxième os 3, mais peut également comporter un troisième os 4 situé entre le premier os 2 et le deuxième os 3.

L'appareillage 1 d'arthrodèse conforme à l'invention est tout particulièrement adapté à la réparation de l'articulation de la cheville. Toutefois, l'appareillage 1 d'arthrodèse selon l'invention peut également être utilisé

PETITIONER ARTHREX
EX. 1004

pour d'autres opérations d'arthrodèse, tel que l'enclouage centro-médulaire, et ce, sans sortir du cadre de l'invention. Pour ces autres applications, des adaptations devront cependant être prévues, notamment sur le plan dimensionnel.

Dans la suite de la description, on fera référence au premier os 2, au deuxième os 3 et éventuellement au troisième os 4 formant l'articulation, étant entendu que si l'articulation est une articulation de cheville, le premier os 2 correspond au calcanéum, le deuxième os 3 correspond au tibia et le troisième os 4 correspondant à l'astragale.

Selon l'invention, l'appareillage 1 d'arthrodèse comporte un clou 5 d'arthrodèse pourvu de moyens de fixation 6 avec les os 2, 3, 4 formant l'articulation (figures 1 et 5).

Tel que cela est représenté sur les figures 1 à 3, le clou 5 se présente avantageusement sous la forme d'un cylindre préférentiellement creux qui s'étend entre deux extrémités 5C, 5D. L'une des extrémités 5C est de préférence légèrement chanfreinée pour faciliter son implantation au sein de l'articulation. Le clou 5 est avantageusement réalisé à partir d'un matériau métallique bio-compatible par nature ou rendu bio-compatible à la suite d'un traitement.

Selon une variante de réalisation préférentielle, le clou 5 est monolithique.

De façon particulièrement avantageuse, le clou 5 d'arthrodèse est monté à l'intérieur d'un logement ménagé au sein de l'articulation, et dont au moins une partie se trouve dans chacun des os 2, 3, 4 formant l'articulation, de telle sorte que le clou 5 s'étende selon un axe longitudinal X-X' parallèle à l'axe d'extension du deuxième os 3, par exemple le tibia.

PETITIONER ARTHREX
EX. 1004

Avantageusement, les moyens de fixation 6 comportent deux trous de fixation 7 (figures 3, 4 et 5). Chacun des trous de fixation 7 est avantageusement destiné à coopérer avec au moins une vis de fixation 8 associée de manière à solidariser le clou 5 avec le deuxième os 3 (figure 4). Bien évidemment, les moyens de fixation 6 peuvent comporter un seul trou de fixation 7, mais la configuration à deux trous de fixation 7 est préférée car elle garantit *a priori* un meilleur maintien du clou au sein de l'articulation.

Les moyens de fixation 6 du clou 5 comportent de préférence au moins un orifice de fixation 9 destiné à coopérer avec au moins une vis de fixation 8 associée, de manière à solidariser le clou 5 avec le premier os 2 (figures 1, 3 et 4). Les vis de fixation 8 utilisées sont celles classiquement utilisées dans le domaine et sont bien connues de l'homme du métier.

De façon préférentielle, l'orifice de fixation 9 s'étend en oblique relativement à l'axe longitudinal X-X', c'est-à-dire qu'il forme un conduit, de préférence sensiblement cylindrique, dont l'axe principal d'extension est oblique par rapport à l'axe longitudinal X-X'. Cette obliquité est notamment destinée à améliorer la fixation du clou dans le premier os 2, par exemple le calcanéum, en tenant compte de l'anatomie particulière de ce dernier.

De façon particulièrement avantageuse, l'orifice de fixation 9 oblique s'étend selon une direction d'extension Y-Y' formant un angle α compris entre 95° et 100°, avec l'axe longitudinal X-X' (figure 1).

De façon encore plus avantageuse, et tel que cela est représenté sur la figure 1, les moyens de fixation 6 comportent deux orifices de fixation 9 du premier os 2. Ces deux orifices de fixation 9 s'étendent de préférence en oblique relativement à l'axe longitudinal X-X'.

PETITIONER ARTHREX
EX. 1004

Avantageusement, et tel que cela est représenté sur les figures 3, 4 et 5, les moyens de fixation 6 comportent une ouverture de fixation 10 agencée pour recevoir une vis de fixation associée lorsque l'articulation comporte un troisième os 4, par exemple l'astragale, situé entre le premier os 2 et le deuxième os 3, de manière à solidariser sensiblement le clou 5 avec le troisième os 4.

Bien évidemment, dans les cas où l'articulation ne comporte pas de troisième os 4, ou encore dans les cas où l'articulation comporte bien un troisième os 4 mais que ce dernier est fortement dégradé, une telle ouverture de fixation 10 n'est pas nécessaire.

De manière particulièrement avantageuse, l'ouverture de fixation 10 est de préférence oblongue, c'est-à-dire qu'elle est préférentiellement allongée dans la direction parallèle à l'axe longitudinal X-X'. Une telle forme de l'ouverture de fixation 10 est préférée à la forme circulaire afin d'autoriser une certaine mobilité axiale du troisième os 4 dans la direction de l'axe longitudinal X-X', de manière à améliorer sensiblement le confort du patient.

Selon l'invention, l'appareillage 1 d'arthrodèse comporte un instrument 20 de mise en place du clou 5 d'arthrodèse au sein de l'articulation.

L'instrument 20 comporte une base 21 fixe lors de l'opération chirurgicale, ainsi qu'un moyen de compression 22, 23 destiné à permettre le rapprochement des premier os 2 et deuxième os 3 formant l'articulation.

Selon l'invention, l'appareillage 1 d'arthrodèse comprend également un moyen de liaison 24 servant d'interface entre l'instrument 20 et le clou 5 d'arthrodèse.

PETITIONER ARTHREX
EX. 1004

Le moyen de liaison 24 peut avantageusement se présenter sous la forme d'une tige, apte à se déplacer longitudinalement le long de l'axe longitudinal X-X'. En particulier, le moyen de liaison 24 et la base 21 sont de préférence agencés de telle manière que le moyen de liaison 24 puisse coulisser à l'intérieur de ladite base 21 (figures 3 et 4).

A cet effet, la base 21 est préférentiellement formée par une platine de compression 210, de préférence fixe et métallique, au sein de laquelle est ménagé un alésage 60 permettant le passage de la tige 24 (figures 3 et 4).

Le clou 5 d'arthrodèse repose préférentiellement sur le moyen de liaison 24 de telle sorte que le déplacement du moyen de liaison 24 entraîne un déplacement sensiblement identique du clou 5.

Le moyen de liaison 24 s'étend avantageusement entre deux extrémités 24A, 24B (figures 3 et 4) et l'extrémité 24A se présente de préférence sous la forme d'un embout fileté, sur lequel l'extrémité 5D correspondante du clou 5 est destinée à être enfilée et vissée.

Afin de faciliter le positionnement du clou 5 relativement au moyen de liaison 24, et d'éviter au chirurgien de se tromper dans l'orientation du clou 5, le moyen de liaison 24 et le clou 5 comportent avantageusement des moyens de repérage 25, 26.

Tel que cela est représenté sur la figure 5, les moyens de repérage 25, 26 sont de préférence formés par trois ergots 25 et trois fentes 26 agencés de telle manière que chaque fente 26 ne puisse être associée qu'avec un seul ergot 25 correspondant.

Tel que cela est représenté sur la figure 2, les fentes 26 sont de préférence ménagées sur l'extrémité 5D du clou 5 destinée à venir en contact avec

PETITIONER ARTHREX
EX. 1004

l'extrémité 24A correspondante du moyen de liaison 24 dans laquelle sont ménagés les ergots 25.

Bien évidemment, il est également envisageable de pourvoir le clou 5 d'ergots destinés à coopérer avec des fentes correspondantes ménagées sur le moyen de liaison 24.

Selon une variante de réalisation préférentielle de l'invention, les moyens de repérage 25, 26 comportent donc trois paires formées chacune par un ergot 25 et une fente 26, lesdites paires étant situées sur le pourtour de la jonction entre le clou 5 et le moyen de liaison 24, et orientées sensiblement à 90 degrés les unes par rapport aux autres.

Une telle configuration des moyens de repérage 25, 26 permet notamment d'éviter que le chirurgien ne monte le clou 5 dans une autre orientation que celle prévue, ce qui provoquerait une mauvaise orientation des moyens de fixation 6 du clou 5 relativement aux os 2, 3, 4 formant l'articulation.

Tel que cela est représenté sur la figure 5, le clou 5 est ainsi avantageusement enfilé sur le moyen de liaison 24 par l'une de ses extrémités 5D pour venir occuper une position stable et fixe d'insertion.

Selon l'invention, le moyen de compression 22, 23 comporte un moyen de commande 22 agencé de manière à générer, par l'intermédiaire du moyen de liaison 24, un déplacement du clou 5 d'arthrodèse relativement à la base 21.

De façon préférentielle, le moyen de commande 22 se présente sous la forme d'un volant 80 (ou d'une molette), monté mobile en rotation autour de l'axe longitudinal X-X' sur la base 21 (ou sur la platine de compression 210) par l'intermédiaire d'une tige creuse 81 (figures 3 et 4).

PETITIONER ARTHREX
EX. 1004

La tige creuse 81 est montée avec une possibilité de rotation autour de l'axe longitudinal X-X', au sein de l'alésage 60.

La tige creuse 81 comporte un passage intérieur 82 au sein duquel le moyen de liaison 24 est susceptible de coulisser selon l'axe longitudinal X-X'.

La tige creuse 81 s'étend entre une première extrémité 81A, pourvue d'un filetage externe 83, et une deuxième extrémité 81B, solidarisée avec le volant 80, de telle sorte que la rotation du volant 80 autour de l'axe longitudinal X-X' entraîne la rotation identique de la tige creuse 81.

Tel que cela est illustré sur les figures 3 et 4, le moyen de liaison 24 est fixé à un embout creux 84, comportant un filetage interne 85, apte à coopérer avec le filetage externe 83 de la tige creuse 81, de telle sorte que la rotation du volant 80 suivant le sens de rotation S entraîne la rotation de la tige creuse 81 et, par coopération des filetages interne et externe 85, 83, la translation de l'embout creux 84, du moyen de liaison 24 et du clou 5 associés, selon une direction de compression F (figure 4) parallèle à l'axe longitudinal X-X'.

Ainsi, la mise en rotation du moyen de commande 22 relativement à la base 21 provoque la translation du moyen de liaison 24 et du clou 5 associés selon l'axe longitudinal X-X'.

Il est bien envisageable, sans sortir du cadre de l'invention, de remplacer le volant 80 par tout autre moyen de commande approprié, par exemple par un pistolet de compression du type à cliquet (non représenté), qui possède notamment l'intérêt de permettre un bon contrôle de l'intensité de la compression réalisée.

PETITIONER ARTHREX
EX. 1004

Selon l'invention, le moyen de compression 22, 23 comporte également un moyen d'immobilisation 23 agencé pour immobiliser le deuxième os 3, par exemple le tibia, relativement à la base 21 et plus précisément à la platine de compression 210 (figure 1).

Une telle immobilisation du deuxième os 3 est préférable afin d'éviter que le déplacement du clou 5 n'entraîne le déplacement du deuxième os 3.

Bien évidemment, le déplacement du clou 5 relativement au deuxième os 3 n'est possible que si ce dernier n'a pas été solidarisé avec le clou 5 à l'aide des vis de fixation 8, ce qui implique que l'étape de compression, dans laquelle on effectue un déplacement du clou 5 d'arthrodèse au sein de l'articulation, doit être réalisée avant l'étape de fixation du clou 5 relativement au deuxième os 3.

Selon l'invention, le clou 5 comporte un moyen de guidage 11, ledit moyen de guidage 11 et ledit moyen d'immobilisation 23 étant agencés et conformés pour coopérer ensemble de manière à autoriser le déplacement du clou 5 relativement au moyen d'immobilisation 23 et à permettre, lorsque le clou 5 est solidarisé avec le premier os 2 le rapprochement des premier os 2 et deuxième os 3.

Ainsi, afin de permettre le rapprochement des premier os 2 et deuxième os 3, il est préférable de solidariser au préalable le clou 5 avec le premier os 2 à l'aide des moyens de fixation 6, en faisant coopérer par exemple le ou les orifices de fixation 9 avec des vis de fixation 8 (figure 1).

Ainsi, lorsque le clou 5 est solidarisé avec le premier os 2, l'actionnement du moyen de commande 22 permet d'assurer le déplacement du clou 5 et du premier os 2 associé, rapprochant ainsi le premier os 2 du deuxième os 3.

PETITIONER ARTHREX
EX. 1004

Grâce à ce montage, et en particulier grâce à la coopération du moyen de guidage 11 avec le moyen d'immobilisation 23, on peut effectuer une compression efficace de l'articulation, tout en contrôlant, grâce à l'agencement particulier du moyen de guidage 11, l'amplitude de déplacement du clou 5 et donc l'intensité de la compression.

En outre, le premier os 2 étant solidarisé et se déplaçant avec le clou 5 lors de la compression, l'utilisation de l'appareillage 1 permet de réduire voire même d'éliminer complètement le risque de perforer le cortex du premier os 2 avec le clou 5 lors de la compression.

Avantageusement, et tel que cela est représenté sur les figures 3 et 4, le moyen de guidage 11 est formé par au moins une cavité 12 oblongue qui présente une forme sensiblement allongée selon l'axe longitudinal X-X'. La cavité 12 oblongue est préférentiellement ménagée dans l'épaisseur du clou 5 de manière à s'étendre selon un axe sécant de l'axe longitudinal X-X'. Ainsi, la cavité 12 oblongue pourra par exemple s'étendre en profondeur selon un axe perpendiculaire de l'axe longitudinal X-X'.

Selon une variante préférentielle de l'invention, la cavité 12 oblongue est traversante, c'est-à-dire qu'elle débouche de part et d'autre du clou 5 d'arthrodèse.

La cavité 12 oblongue s'étend de préférence sur une longueur d'environ 12 mm le long de l'axe longitudinal X-X' de manière à autoriser un déplacement sensiblement équivalent du clou 5 lors de la compression. Les extrémités 12A, 12B de la cavité 12, alignées sur l'axe longitudinal X-X', forment avantageusement des moyens de butée à l'encontre du moyen d'immobilisation 23 (figure 5).

PETITIONER ARTHREX
EX. 1004

De façon encore plus préférentielle, le moyen de guidage 11 est formé par au moins deux cavités 12 oblongues ménagées l'une au dessus de l'autre le long du clou 5 et en alignement l'une de l'autre selon l'axe longitudinal X-X' (figures 3 et 4).

Avantageusement, les trous de fixation 7, les cavités 12 et l'ouverture de fixation 10 traversent le clou 5 selon un axe sensiblement perpendiculaire à l'axe d'extension des orifices de fixation 9 de manière à permettre une fixation par abord latéral du deuxième os 3 et du troisième os 4, et au contraire une fixation par abord antérieur-postérieur du premier os 2.

Avantageusement, le moyen d'immobilisation du deuxième os 3 est formé par au moins une tige d'immobilisation 23 conformée de manière à traverser, au moins en partie, d'une part le deuxième os 3 pour le maintenir immobile relativement à la base 21 et d'autre part la ou les cavités 12 oblongues (figures 3 et 4).

Grâce à l'agencement particulier de la tige d'immobilisation 23 et de la cavité 12 oblongue, le clou 5 peut se déplacer relativement à la tige d'immobilisation 23 sur une longueur maximale correspondant sensiblement à la longueur de la cavité 12 oblongue, soit de préférence une longueur d'environ 12 mm.

De façon encore plus avantageuse, le moyen d'immobilisation est formé par deux tiges d'immobilisation 23. Une telle mesure a pour effet d'améliorer la rigidité globale de l'appareillage 1 d'arthrodèse lors de la mise en compression de l'articulation.

Chacune des tiges d'immobilisation 23 coopère alors avec une cavité 12 oblongue associée.

PETITIONER ARTHREX
EX. 1004

Avantageusement, et tel que cela est représenté sur les figures, l'instrument 20 comporte des moyens de visée 30 agencés de manière à faciliter le repérage du positionnement des moyens de fixation 6 sur le clou 5.

En particulier, les moyens de visée 30 sont préférentiellement agencés de manière à permettre le montage d'une part des vis de fixation 8 et leur guidage vers les moyens de fixation 6 ménagés sur le clou 5, et d'autre part des tiges d'immobilisation 23.

De façon particulièrement avantageuse, les moyens de visée 30 comportent au moins un bras 31 monté sur la base 21 de manière à s'étendre sensiblement parallèlement à l'axe longitudinal X-X'.

Le bras 31 est de préférence monté de façon solidaire sur la base 21 de manière à rester immobile relativement à ladite base 21 lors de l'étape de compression et en particulier lorsque le clou 5 est déplacé le long de l'axe longitudinal X-X'.

De façon particulièrement avantageuse, les moyens de visée 30 comportent deux bras 31 (figures 3 et 4). Les deux bras 31 sont de préférence disposés de part et d'autre du clou 5 positionné sur l'instrument 20 et en regard des cavités 12 oblongues. Les deux bras 31 sont ainsi préférentiellement disposés latéralement relativement à l'articulation, de manière à permettre la fixation des vis de fixation 8 par abord latéral (figure 4).

L'utilisation de deux bras 31 permet ainsi d'améliorer sensiblement la rigidité globale de l'instrument 20 lors de l'étape de compression, cette configuration permettant notamment d'obtenir des taux de compression élevés et ce sans générer de déflection indésirable du clou 5.

PETITIONER ARTHREX
EX. 1004

Selon la variante préférentielle de réalisation de l'invention illustrée sur les figures 3 et 4, le ou les bras sont fixés à la base 21 et s'étendent perpendiculairement à cette dernière de manière à former, avec ladite base 21, la platine de compression 210. De façon préférentielle, la base 21 et les bras 31 sont en métal, et la platine de compression 210 forme un ensemble métallique monobloc dissocié du moyen de liaison 24 et mobile vis-à-vis de ce dernier.

Selon une variante de réalisation de l'invention illustrée sur la figure 6, le bras 31 est monté sur la base 21 de manière amovible, par l'intermédiaire d'une patte 70. Selon cette variante, la base 21 se présente sous la forme d'un noyau central 21". La patte 70 comporte au moins une barrette 71, préférentiellement formée par un tube cylindrique s'étendant entre deux extrémités 71A, 71B, lequel traverse le bras 31 et est solidarisé avec ce dernier vers une de ses extrémités 71A à l'aide d'un bouton de serrage 73.

L'autre extrémité 71B de la barrette 71 est avantageusement montée sur la base 21. A cet effet, la base 21 comporte au moins un évidemment au sein duquel l'une des extrémités 71B de la barrette 71 peut être introduite.

De façon encore plus préférentielle, la patte 70 comporte deux barrettes 71 et la base 21 comporte deux évidements associés.

Un tel montage permet notamment de régler l'écartement entre le bras 31 et le clou 5, par translation du bras 31 le long des barrettes 71, et notamment de rapprocher le bras 31 du clou 5 afin d'améliorer la rigidité de l'appareillage lors de l'étape de compression.

Avantageusement, les moyens de visée 30 comportent au moins un manchon 32 monté mobile sur au moins l'un des bras 31 avec une

PETITIONER ARTHREX
EX. 1004

possibilité de coulissement selon l'axe longitudinal X-X' (figures 3 et 4). Ainsi, la figure 3 montre l'appareillage 1 d'arthrodèse dans lequel le manchon 32 présente une position précédant la mise en compression, tandis que la figure 4 illustre ce même manchon 32 dans une position suivant la mise en compression, c'est-à-dire après déplacement du manchon 32 le long de l'axe longitudinal X-X'.

De façon particulièrement avantageuse, et tel que cela est représenté sur les figures 3 et 4, le bras 31 est pourvu de passages 33 tandis que le manchon 32 est pourvu de trous de visée 34. Les trous de visée 34 et les passages 33 sont agencés de telle manière que par déplacement du manchon 32, au moins une partie des trous de visée 34 puisse être mise en regard d'une partie des passages 33, de manière à former ainsi des lumières de visée 35 situées chacune en vis-à-vis soit d'un moyen de fixation 6, soit d'une cavité 12 oblongue (figure 4).

De telles lumières de visée 35 permettent ainsi le montage respectivement d'une vis de fixation 8 ou d'une tige d'immobilisation 23 sur le clou 5.

Avantageusement, l'instrument 20 comporte un moyen de maintien 40 agencé pour solidariser le manchon 32 avec le moyen de liaison 24, et donc le clou 5 de telle sorte que le déplacement du clou 5 selon l'axe longitudinal X-X' entraîne un déplacement sensiblement identique du manchon 32 (figures 3 à 6).

Avantageusement, et tel que cela est illustré sur les figures 3 et 4, le moyen de maintien 40 est solidarisé avec le moyen de liaison 24 par l'intermédiaire de l'embout creux 84.

Le moyen de maintien 40 comprend également au moins une branche 41 solidarisée d'une part, vers une de ses extrémités, avec le

PETITIONER ARTHREX
EX. 1004

moyen de liaison 24, notamment avec l'embout creux 84, et d'autre part, vers l'autre extrémité, avec le manchon 32, de telle sorte que le déplacement de moyen de liaison 24 entraîne un déplacement sensiblement identique du manchon 32. L'instrument 20 comporte de préférence deux bras 31 et deux manchons 32 associés, et le moyen de maintien 40 comporte de préférence deux branches 41 associées respectivement à chacun des manchons 32.

De façon préférentielle, et tel que cela est illustré sur la figure 5, le moyen de maintien 40 et les manchons 32 forment un ensemble monobloc, apte à se déplacer de façon unitaire.

De façon particulièrement avantageuse, certains des passages 33 ménagés dans le bras 31 sont agencés pour supporter la ou les tiges d'immobilisation 23, et assurer l'immobilité de ces dernières relativement à la base 21. Parmi les passages 33, ceux qui sont associés aux tiges d'immobilisation 23 ont de préférence une forme sensiblement cylindrique (figures 3 et 4).

En outre, les passages 33 et les trous de visée 34 sont de préférence dimensionnés et espacés respectivement sur le bras 31 et sur le manchon 32 de telle manière que, quel que soit le déplacement du manchon 32, au moins une partie des passages 33 reste en regard des trous de visée 34 correspondants, dès lors que le déplacement du manchon 32 est inférieur à la course maximale admise correspondant sensiblement à la longueur des cavités 12 oblongues.

Selon une variante préférentielle de l'invention, le clou 5 d'arthrodèse se décline dans deux modes de réalisation préférentielle qui sont représentés sur la figure 5. Ainsi, dans le cas particulier de l'articulation de la cheville, le clou 5 peut se présenter sous la forme d'un premier clou 5A présentant une

PETITIONER ARTHREX
EX. 1004

longueur d'environ 150 mm, ce premier clou 5A étant plus spécifiquement adapté à des tibias assez courts.

Au contraire, pour des tibias relativement longs, le clou 5 peut se décliner sous la forme d'un deuxième clou 5B présentant une longueur d'environ 180 mm.

Afin de permettre une mise en place du clou 5 quelle que soit sa longueur et sa déclinaison, l'instrument 20 et en particulier les moyens de visée 30 sont agencés de manière à permettre le montage de l'un ou l'autre des premier et deuxième clous 5A, 5B. En particulier, les bras 31 et les manchons 32 comportent respectivement des passages 33 et des trous de visée 34 spécifiquement adaptés à chacun des premier et deuxième clous 5A, 5B.

En outre, des repères peuvent être ménagés sur les manchons 32, et par exemple gravés sur la surface externe des manchons 32, de manière à indiquer, pour chacun des premier et deuxième clous 5A, 5B, quels trous de visée 34 doivent être utilisés.

Avantageusement, et tel que cela est représenté sur la figure 1, les moyens de visée 30 comportent un support de visée 37 conçu pour faciliter le repérage du positionnement des moyens de fixation 6 du clou 5, notamment les orifices de fixation 9, avec le premier os 2 (i.e. le calcanéum). Le support de visée 37 est en particulier destiné à permettre, à l'aide d'orifices 140, 141 aptes à recevoir des canons de perçage 143, le montage des vis de fixation 8 assurant le maintien du clou 5 relativement au premier os 2.

De façon préférentielle, le support de visée 37 est solidarisé avec le ou les manchons 32 par l'intermédiaire du moyen de maintien 40 formant ainsi, avec le ou les manchons 32, une platine de visée 200 mobile relativement à la platine de compression 210.

PETITIONER ARTHREX
EX. 1004

Avantageusement; le support de visée 37 se situe dans un plan sensiblement perpendiculaire au plan reliant les manchons 32 de manière à permettre la fixation de l'avant vers l'arrière des vis de fixation 8 dans le premier os.

De façon préférentielle, le support de visée 37, et/ou les manchons 32 et/ou le moyen de maintien 40 sont en matière plastique, formant ainsi de préférence une platine de visée 200 en matière plastique, avantageusement radiotransparente, afin de limiter les interférences avec les instruments de visualisation lors de l'intervention chirurgicale.

Ainsi, lors de la mise en place du clou 5 au sein de l'articulation, et de sa fixation avec le calcanéum, seule la platine de visée 200, séparable de la platine de compression 210, est utilisée, de telle sorte que la seule partie métallique visualisable par le chirurgien soit formée par le clou 5.

La platine de visée 200 et la platine de compression 210 forment ainsi avantageusement des ensembles monobloc amovibles l'un par rapport à l'autre.

Selon une variante non représentée, le support de visée 37 peut être formé par une pièce indépendante des autres moyens de visée 30, montée de façon amovible sur la base 21 par l'intermédiaire d'un ou plusieurs barreaux.

L'appareillage 1 d'arthrodèse selon l'invention permet donc d'assurer un montage facilité du clou 5 d'arthrodèse au sein de l'articulation, tout en permettant un rapprochement efficace et contrôlé des os formant l'articulation.

PETITIONER ARTHREX
EX. 1004

Un autre avantage de l'appareillage 1 d'arthrodèse selon l'invention est qu'il permet, grâce au montage amovible des moyens de visée 30, une mise en place méthodique du clou 5 d'arthrodèse.

Un autre avantage de l'appareillage 1 d'arthrodèse conforme à l'invention est qu'il permet, grâce aux nombreux moyens de repérage utilisés, d'éviter les erreurs de manipulation de la part du chirurgien.

Un autre avantage de l'appareillage 1 d'arthrodèse conforme à l'invention est qu'il présente un caractère entièrement démontable, ce qui facilite son nettoyage.

L'invention concerne également un clou d'arthrodèse présentant les caractéristiques décrites précédemment et susceptible d'être utilisé au sein de l'appareillage 1 d'arthrodèse.

Plus particulièrement, l'invention concerne un clou d'arthrodèse pour une articulation formée par au moins un premier os 2 et un second os 3, ledit clou étant pourvu de moyens de fixation 6 et de moyens de guidage 11, et étant destiné à être utilisé dans un appareillage d'arthrodèse pourvu d'un moyen d'immobilisation 23 conforme à l'invention, ledit moyen de guidage 11 et ledit moyen d'immobilisation 23 étant agencés et conformés pour coopérer ensemble de manière à autoriser le déplacement du clou relativement au moyen d'immobilisation 23, et à permettre, lorsque le clou 5 est solidarisé avec le premier os 2, le rapprochement des premier os 2 et deuxième os 3.

L'invention concerne également une méthode chirurgicale pour réaliser une arthrodèse de l'articulation de la cheville, dans laquelle on utilise un appareillage 1 d'arthrodèse, comportant un clou 5 d'arthrodèse ainsi qu'un

PETITIONER ARTHREX
EX. 1004

moyen de compression 22, 23, ladite méthode comportant les étapes suivantes :

- une étape de solidarisation du clou 5 avec le calcanéum,
- une étape de compression, au cours de laquelle d'une part on rapproche le calcanéum du tibia, en déplaçant le clou 5 relativement au tibia à l'aide du moyen de compression 22, 23 et d'autre part on contrôle l'amplitude de déplacement du clou 5 à l'aide de moyens de guidage 11 ménagés sur ledit clou 5.

Avantageusement, l'étape de compression est de préférence réalisée en utilisant une tige d'immobilisation 23 que l'on solidarise avec une partie fixe de l'instrument 20 et que l'on introduit, d'une part dans le tibia de manière à l'immobiliser, et d'autre part dans un moyen de guidage 11, de préférence une cavité 12 oblongue ménagée le long du clou 5, de telle sorte que lors de la compression, le clou 5 et la cavité 12 associée puissent se déplacer relativement à ladite tige d'immobilisation 23 sur une distance maximale correspondant à la longueur de la cavité 12 oblongue.

Ainsi, la cavité 12, de par sa forme oblongue, constitue un moyen de guidage et de contrôle du déplacement du clou 5 et donc de l'intensité de la compression exercée sur l'articulation. En outre, en raison de la forme oblongue de la cavité 12, le déplacement du clou 5 est nécessairement une translation, ce qui permet d'éviter une éventuelle déflexion du clou 5 susceptible de se produire lors de l'étape de compression.

Par ailleurs, le positionnement de la tige d'immobilisation 23 en regard du clou 5 lors de l'étape de compression confère à l'appareillage 1 une bonne rigidité d'ensemble, et permet d'effectuer une compression selon un axe sensiblement parallèle à l'axe d'extension du tibia.

PETITIONER ARTHREX
EX. 1004

Le fonctionnement de l'appareillage 1 d'arthrodèse et la méthode de mise en place du clou 5 vont maintenant être décrits dans le cas particulier de l'arthrodèse de la cheville.

Avant de procéder à l'arthrodèse, le chirurgien effectue tout d'abord une radiographie lui permettant de visualiser l'articulation, et de choisir l'appareillage d'arthrodèse, c'est-à-dire le clou 5 et l'instrument 20 adaptés à l'anatomie de l'articulation.

En particulier, dans le cas d'une arthrodèse de cheville, le chirurgien pourra choisir, suivant le cas, l'un des premier et deuxième clous 5A, 5B. Dans tous les cas, l'instrument 20 utilisé sera le même et il suffira au chirurgien de sélectionner, à l'aide des moyens de repérage réalisés à cet effet sur les moyens de visée 30, les trous de visée 34 susceptibles d'être utilisés avec le clou sélectionné. Lorsque le choix du clou adapté est effectué, le chirurgien peut positionner le clou 5 sur le moyen de liaison 24 à l'aide des moyens de repérage 25, 26. Grâce à l'unicité de la position du clou 5 sur le moyen de liaison 24, le support de visée 37, et en particulier les orifices 140, 141 se trouvent automatiquement en vis-à-vis des orifices de fixation 9 du clou 5 (figure 1).

Tel que cela est bien connu de l'homme du métier, le chirurgien doit également réaliser un logement pour le clou 5 au sein de l'articulation, ce logement traversant d'une part le calcanéum et d'autre part une partie du tibia et éventuellement l'astragale.

Le logement est de préférence réalisé de telle manière que lorsque le clou est introduit à l'intérieur de l'articulation, une poche 50 située vers l'extrémité interne du logement ménagé à l'intérieur du tibia reste non occupée par le clou 5 (figures 3 et 4).

PETITIONER ARTHREX
EX. 1004

Lorsque le clou 5 est introduit dans le logement, le chirurgien procède à sa fixation relativement au calcanéum à l'aide du support de visée 37.

Le chirurgien peut alors procéder au montage des vis de fixation 8 (figure 1) dans les orifices de fixation 9, en utilisant les canons de perçage 143 comme guides.

Une telle fixation est bien connue de l'homme du métier et il n'est pas nécessaire de la décrire plus en détails.

Lors de cette première étape de fixation du clou 5 avec le calcanéum, la platine de compression 210, métallique, n'est préférentiellement pas utilisée, de manière à éviter la perturbation des instruments (amplificateur etc...) par des parties métalliques autres que le clou 5.

La platine de visée 200 étant avantageusement en matière plastique, elle n'est pas *« vue »* par les instruments de telle sorte que le chirurgien peut visualiser plus précisément le clou 5 au cours de l'intervention.

Lorsque le clou 5 est fixé de façon solidaire avec le calcanéum, le chirurgien peut procéder à l'étape de compression, c'est-à-dire l'étape consistant à rapprocher le calcanéum du tibia.

Le chirurgien assure alors le montage de la platine de compression 210 sur la platine de visée 200, en emmanchant le ou les bras 31 dans le ou les manchons 32 correspondant(s), et en montant la base 21 sur le moyen de liaison 24, avec une possibilité de coulissement relatif.

L'étape de compression est illustrée sur les figures 3 et 4. La figure 3 montre en effet l'appareillage 1 d'arthrodèse dans une position précédant la compression où l'on voit apparaître un jeu J non nul entre les os 2, 3, 4 de

PETITIONER ARTHREX
EX. 1004

l'articulation. Au contraire, la figure 4 illustre l'appareillage 1 d'arthrodèse dans une position après la mise en compression, dans laquelle le jeu J est sensiblement nul.

Pour procéder à la mise en compression, le chirurgien doit tout d'abord introduire les tiges d'immobilisation 23 du tibia d'une part à travers les passages 33 des bras 31 et d'autre part à travers les cavités 12 oblongues du clou 5. Les tiges d'immobilisation 23 traversent donc le tibia 3 de manière à l'immobiliser d'une part relativement au bras 31 et d'autre part relativement à la base 21.

Lorsque les tiges d'immobilisation 23 sont introduites, le chirurgien peut actionner le moyen de commande 22 notamment le volant 80, de manière à générer un déplacement discret ou continu du moyen de liaison 24 et donc du clou 5 associé relativement à la base 21 (ou platine de compression 210), fixe. Le déplacement maximal autorisé du clou 5 est pré-déterminé par la longueur des cavités 12 oblongues. Ce déplacement maximal autorisé est de préférence de l'ordre de 12 mm.

En interdisant un déplacement plus important du clou 5 d'arthrodèse, on évite que le chirurgien n'effectue une compression trop importante qui aurait pour effet de détériorer encore davantage l'articulation. La forme particulière des cavités 12 oblongues constitue donc un premier moyen de contrôle du taux de compression exercé sur l'articulation.

En se déplaçant, le clou 5 entraîne avec lui le calcanéum, et le rapproche progressivement du tibia tout en réduisant le volume occupé par la poche 50.

Les tiges d'immobilisation 23 qui, avant la mise en compression, se situent dans la partie supérieure des cavités oblongues 12, sont positionnées, après

PETITIONER ARTHREX
EX. 1004

la mise en compression, dans la partie centrale ou inférieure desdites cavités 12 (figure 4).

On voit ainsi que les extrémités 12A, 12B des cavités 12 constituent des butées contre lesquelles les tiges d'immobilisation 23 viennent en appui lors du déplacement du clou 5.

Le déplacement du clou 5 est de préférence continu mais pourrait être discontinu et s'effectuer par paliers, notamment à l'aide d'un système à cliquets (non représenté).

Lorsque la mise en compression est terminée, le chirurgien peut procéder à la fixation du clou 5 relativement au tibia, et éventuellement à l'astragale. Une telle étape de fixation est représentée sur la figure 4.

Lorsque le clou 5 est solidarisé avec tous les os 2, 3, 4 formant l'articulation, la platine de visée 200, peut être intégralement démontée de la base 21 (ou de la platine de compression 210), facilitant ainsi le nettoyage et la stérilisation de l'appareil en vue d'une future utilisation.

POSSIBILITE D'APPLICATION INDUSTRIELLE

L'invention trouve son application industrielle dans la réalisation d'appareillages et de clous d'arthrodèse.

PETITIONER ARTHREX
EX. 1004

REVENDICATIONS

1 - Appareillage d'arthrodèse pour une articulation formée par au moins un premier os (2) et un deuxième os (3), du genre articulation de la cheville, ledit appareillage comportant :

- un clou (5) d'arthrodèse, pourvu de moyens de fixation (6) avec les os (2, 3, 4) formant l'articulation,
- un instrument (20) de mise en place dudit clou (5) d'arthrodèse au sein de l'articulation, comportant une base (21) ainsi qu'un moyen de compression (22, 23), destiné à permettre le rapprochement des premier et deuxième os formant l'articulation,
- un moyen de liaison (24), servant d'interface entre l'instrument (20) et le clou (5) d'arthrodèse,

caractérisé en ce que le moyen de compression comporte :

- un moyen de commande (22), agencé de manière à générer, par l'intermédiaire dudit moyen de liaison (24), un déplacement du clou d'arthrodèse relativement à ladite base (21) selon un axe longitudinal (X-X') sensiblement parallèle à l'axe d'extension dudit clou,
- un moyen d'immobilisation (23), agencé pour immobiliser le deuxième os (3) relativement à la base (21),

ledit clou comportant un moyen de guidage (11), ledit moyen de guidage (11) et ledit moyen d'immobilisation (23) étant agencés et conformés pour coopérer ensemble de manière à autoriser le déplacement du clou relativement au moyen d'immobilisation (23), et à

PETITIONER ARTHREX
EX. 1004

permettre, lorsque le clou (5) est solidarisé avec le premier os (2), le rapprochement des premier os (2) et deuxième os (3).

2 - Appareillage selon la revendication 1 caractérisé en ce que le moyen de guidage (11) est formé par au moins une cavité (12) oblongue, ménagée dans l'épaisseur du clou de manière à s'étendre selon un axe sécant de l'axe longitudinal (X-X'), ladite cavité (12) présentant une forme sensiblement allongée selon l'axe longitudinal (X-X').

3 - Appareillage selon la revendication 2 caractérisé en ce que ladite cavité (12) oblongue est traversante.

4 - Appareillage selon la revendication 2 ou 3 caractérisé en ce que le moyen de guidage (11) est formé par au moins deux cavités (12) oblongues ménagées l'une au dessus de l'autre le long dudit clou (5) et en alignement l'une de l'autre selon l'axe longitudinal (X-X').

5 - Appareillage selon l'une quelconque des revendications 1 à 4 caractérisé en ce que les moyens de fixation (6) comportent deux trous de fixation (7), chacun destiné à coopérer avec au moins une vis de fixation (8) associée, de manière à solidariser le clou (5) avec le deuxième os (3).

6 - Appareillage selon l'une quelconque des revendications 1 à 5 caractérisé en ce que les moyens de fixation (6) du clou (5) comportent au moins un orifice de fixation (9), destiné à coopérer avec au moins une vis de fixation (8) associée, de manière à solidariser le clou (5) avec le premier os (2).

PETITIONER ARTHREX
EX. 1004

7 - Appareillage selon la revendication 6 caractérisé en ce que ledit au moins un orifice de fixation (9) s'étend en oblique relativement à l'axe longitudinal (X-X').

8 - Appareillage selon la revendication 7 caractérisé en ce que l'angle (α) formé entre la direction d'extension (Y-Y') dudit au moins un orifice de fixation (9) oblique et l'axe longitudinal (X-X') est compris entre 95 degrés et 100 degrés.

9 - Appareillage selon la revendication 7 ou 8 caractérisé en ce que les moyens de fixation (6) comportent deux orifices de fixation (9) du premier os.

10 - Appareillage selon l'une des revendications 1 à 9 caractérisé en ce que les moyens de fixation (6) comportent une ouverture de fixation (10), agencée pour recevoir une vis de fixation (8) associée lorsque l'articulation comporte un troisième os situé entre le premier et le deuxième os, de manière à solidariser sensiblement le clou avec le troisième os.

11 - Appareillage selon la revendication 10 caractérisé en ce que l'ouverture de fixation (10) est oblongue.

12 - Appareillage selon l'une des revendications 2 à 11 caractérisé en ce que le moyen d'immobilisation du deuxième os est formé par au moins une tige d'immobilisation (23), conformée de manière à traverser, au moins en partie, d'une part le deuxième os pour le maintenir immobile relativement à la base (21) et d'autre part ladite au moins une cavité (12) oblongue.

PETITIONER ARTHREX
EX. 1004

13 - Appareillage selon la revendication 12 caractérisé en ce que le moyen d'immobilisation est formé par deux tiges d'immobilisation (23).

14 - Appareillage selon l'une quelconque des revendications 1 à 13 caractérisé en ce que l'instrument (20) comporte des moyens de visée (30), agencés de manière à faciliter le repérage du positionnement des moyens de fixation (6) sur le clou.

15 - Appareillage selon la revendication 14 caractérisé en ce que les moyens de visée (30) comportent au moins un bras (31), monté sur ladite base (21) de manière à s'étendre sensiblement parallèlement à l'axe longitudinal (X-X').

16 - Appareillage selon la revendication 15 caractérisé en ce que les moyens de visée comportent deux bras (31), disposés de part et d'autre du clou (5) monté sur l'instrument (20), en regard des cavités (12) oblongues.

17 - Appareillage selon la revendication 15 ou 16 caractérisé en ce que les moyens de visée (30) comportent au moins un manchon (32) monté mobile sur au moins l'un des bras (31) avec une possibilité de coulissement suivant l'axe longitudinal (X-X').

18 - Appareillage selon l'une des revendications 2 à 4, la revendication 12 et la revendication 17 caractérisé en ce que le bras (31) est pourvu de passages (33) tandis que le manchon (32) est pourvu de trous de visée (34), lesdits trous de visée (34) et les lesdits passages (33) étant agencés de telle manière que par déplacement du manchon (32), au moins une partie des trous de visée (34) puisse être mise en regard d'une partie desdits passages (33), formant ainsi des lumières de visée (35) situées chacune en vis-à-vis soit d'un moyen de fixation (6),

PETITIONER ARTHREX
EX. 1004

soit d'une cavité (12) oblongue de manière à permettre le montage respectivement d'une vis de fixation (8) ou d'une tige d'immobilisation (23).

19 - Appareillage selon la revendication 17 ou 18 caractérisé en ce que l'instrument (20) comporte un moyen de maintien (40), agencé pour solidariser le manchon (32) avec le clou (5) de telle sorte que le déplacement du clou (5) selon l'axe longitudinal (X-X') entraîne un déplacement sensiblement identique du manchon (32).

20 - Appareillage selon l'une quelconque des revendications 1 à 19 caractérisé en ce que le moyen de liaison (24) et le clou (5) comportent des moyens de repérage (25, 26) agencés de manière à faciliter le positionnement du clou (5) relativement au moyen de liaison (24).

21 - Appareillage selon la revendication 20 caractérisé en ce que les moyens de repérage (25, 26) sont formés par trois ergots (25) et trois fentes (26), agencés de telle manière que chaque fente (26) ne puisse être associée qu'avec un seul ergot (25) correspondant.

22 - Appareillage selon l'une des revendications 14 à 19 caractérisé en ce que les moyens de visée (30) comportent un support de visée (37) conçu pour faciliter le repérage du positionnement des moyens de fixation (6) du clou (5) avec le premier os (2).

23 - Appareillage selon les revendications 19 et 22 caractérisé en ce que la base (21) et ledit au moins un bras (31) forment une platine de compression (210) et en ce que ledit au moins un manchon (32) et le support de visée (37) forment une platine de visée (200), ladite platine de visée (200) étant montée mobile relativement à la platine de compression (210).

PETITIONER ARTHREX
EX. 1004

24 - Appareillage selon la revendication 23 caractérisé en ce que la platine de compression (210) est montée de façon amovible relativement à la platine de visée (200).

25 - Appareillage selon la revendication 24 caractérisé en ce que la platine de compression (210) est en métal, et en ce que la platine de visée (200) est en matière plastique.

26 - Appareillage selon l'une des revendications 1 à 25 caractérisé en ce que le moyen de commande 22 est formé par un volant 80.

27 - Clou d'arthrodèse pour une articulation formée par au moins un premier os (2) et un second os (3), ledit clou étant pourvu de moyens de fixation (6) et de moyens de guidage (11), et étant destiné à être utilisé dans un appareillage d'arthrodèse pourvu d'un moyen d'immobilisation (23) conforme à l'une des revendications 1 à 26, ledit moyen de guidage (11) et ledit moyen d'immobilisation (23) étant agencés et conformés pour coopérer ensemble de manière à autoriser le déplacement du clou relativement au moyen d'immobilisation (23), et à permettre, lorsque le clou (5) est solidarisé avec le premier os (2), le rapprochement des premier os (2) et deuxième os (3).

PETITIONER ARTHREX
EX. 1004

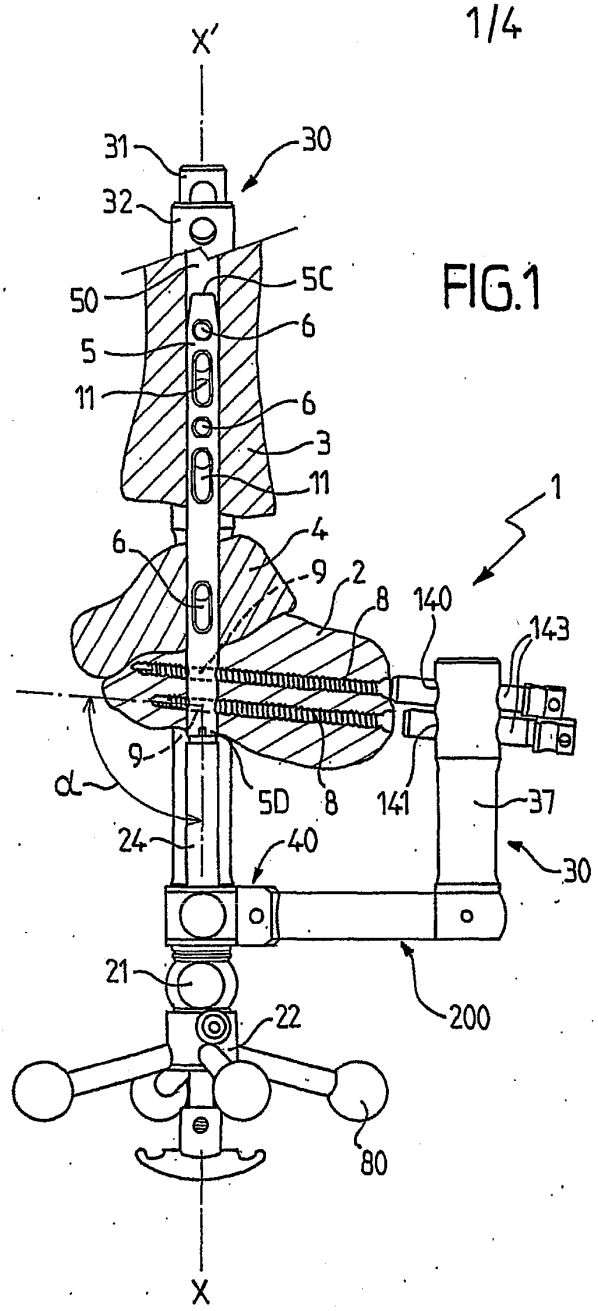


FIG.1

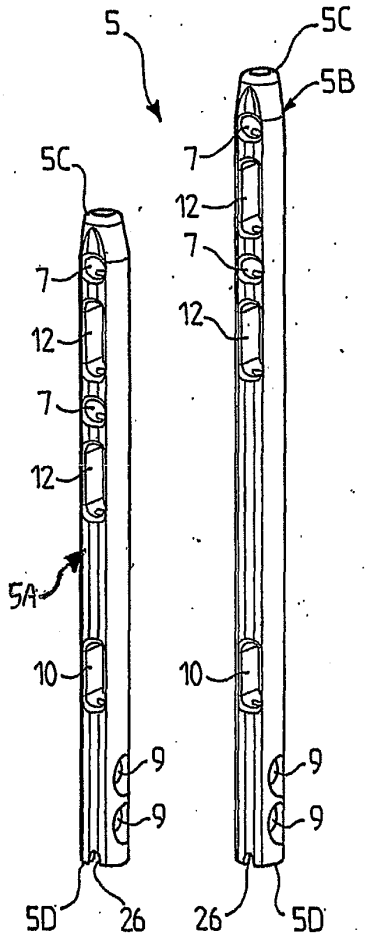


FIG.2

PETITIONER ARTHREX
EX. 1004

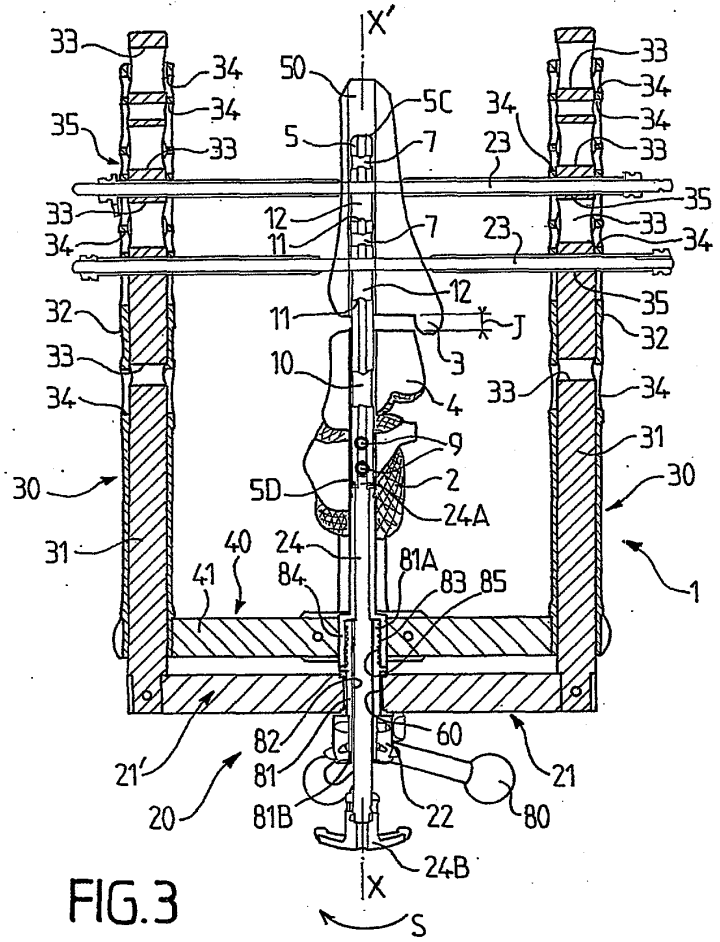


FIG.3

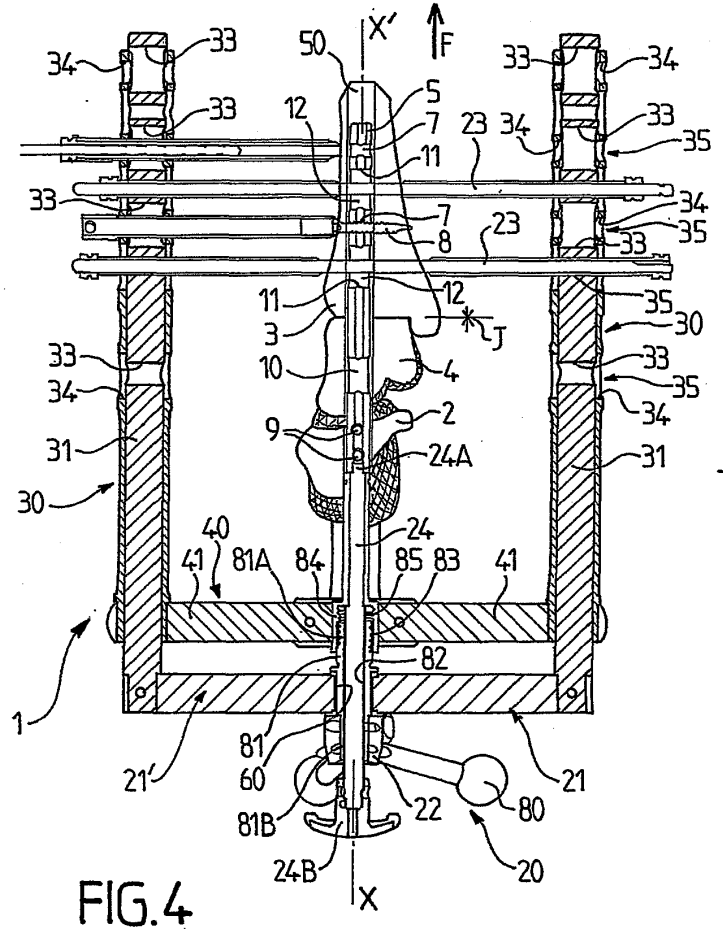


FIG.4

PETITIONER ARTHREX
EX. 1004

3/4

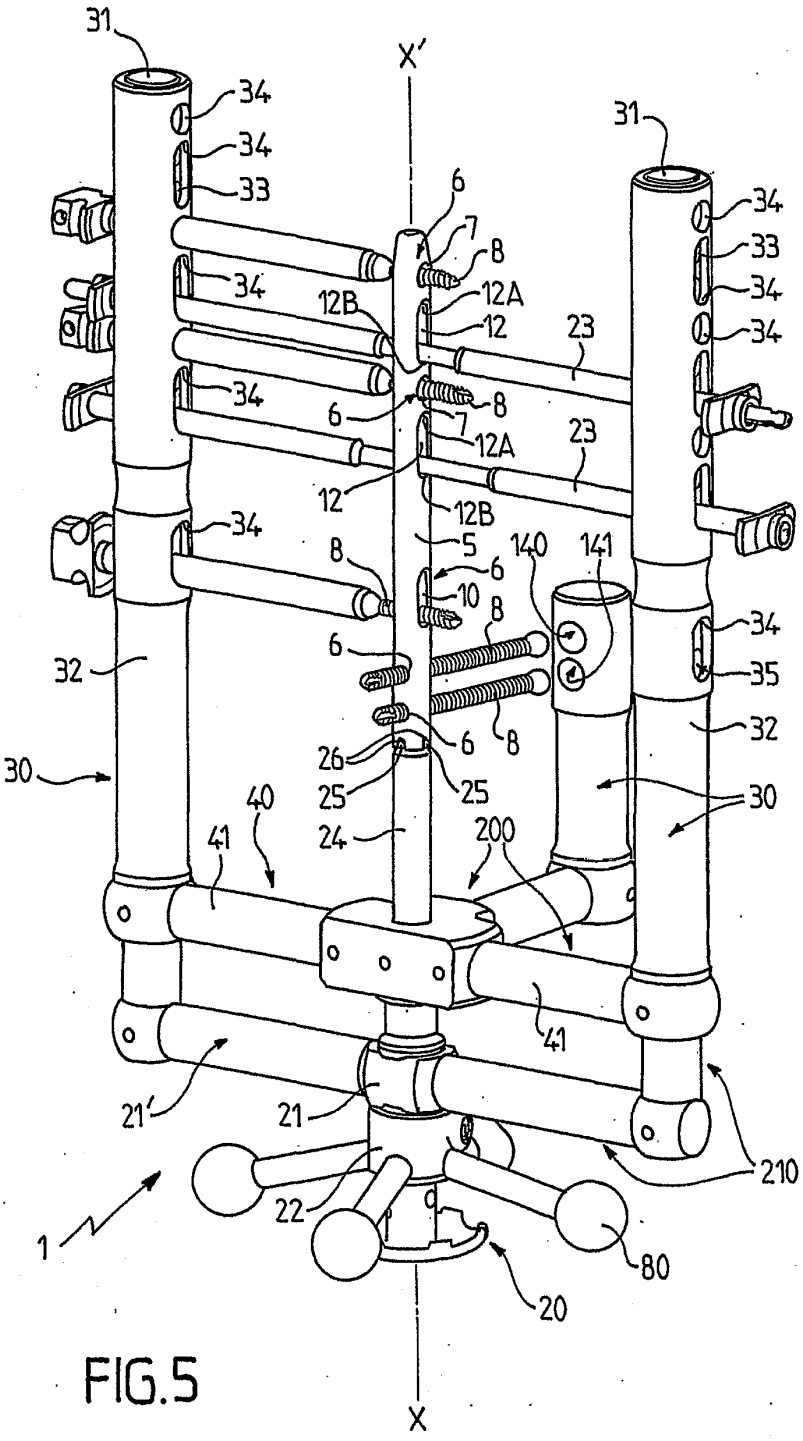


FIG.5

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EX. 1004

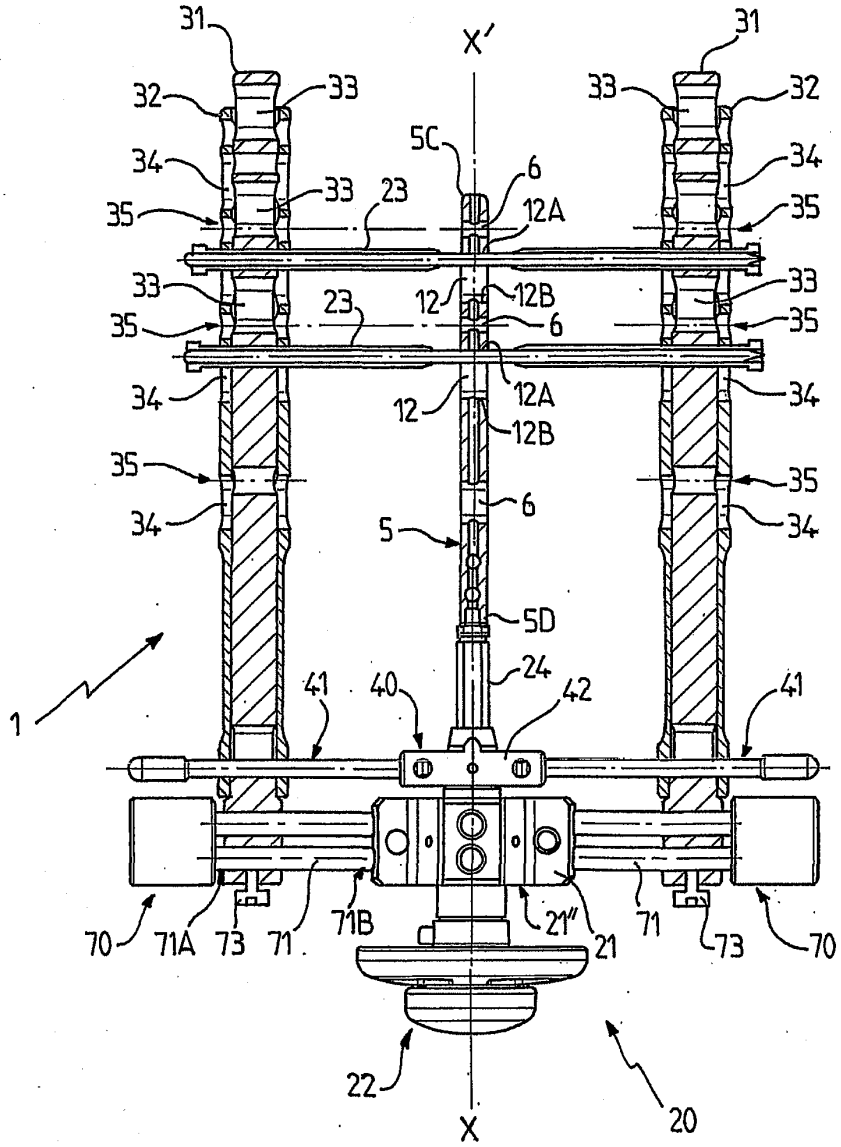


FIG.6

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EX. 1004

INTERNATIONAL SEARCH REPORT

International application No
PCT/FR2006/001070

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/72 A61B17/17

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A X	WO 2004/014243 A (WILLIAM, H., SIMON) 19 February 2004 (2004-02-19) abstract; figures 1,2	1 27
A	US 2003/097131 A1 (SCHON LEW C ET AL) 22 May 2003 (2003-05-22) abstract; claim 21; figures 1,2,4	1,27
A	EP 1 393 696 A (DEPUY PRODUCTS, INC) 3 March 2004 (2004-03-03) abstract; figures 1,6-8,11	1,27
A	US 6 197 029 B1 (FUJIMORI JUHRO ET AL) 6 March 2001 (2001-03-06) abstract; figures 1,5 column 3, lines 26-40	1,27

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 September 2006	14/09/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Macaire, Stéphane

Form PCT/ISA/210 (second sheet) (April 2005)

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EX. 1004

INTERNATIONAL SEARCH REPORT

International application No
PCT/FR2006/001070

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/151898 A1 (SOHNGEN GARY W ET AL) 17 October 2002 (2002-10-17)	1
X	abstract; figures 13,15 paragraph [0023]	27

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

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EX. 1004

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/FR2006/001070

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004014243 A	19-02-2004	AU 2003268050 A1	25-02-2004
		CA 2495110 A1	19-02-2004
		EP 1528895 A1	11-05-2005
US 2003097131 A1	22-05-2003	NONE	
EP 1393696 A	03-03-2004	AU 2003235085 A1	11-03-2004
		JP 2004130109 A	30-04-2004
		US 2004039394 A1	26-02-2004
US 6197029 B1	06-03-2001	JP 2711802 B2	10-02-1998
		JP 7222753 A	22-08-1995
US 2002151898 A1	17-10-2002	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

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EX. 1004

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale n°
PCT/FR2006/001070

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
INV. A61B17/72 A61B17/17

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
A61B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela estréalisable, termes de recherche utilisés)
EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie*	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	WO 2004/014243 A (WILLIAM, H., SIMON) 19 février 2004 (2004-02-19)	1
X	abrégé; figures 1,2	27
A	US 2003/097131 A1 (SCHON LEW C ET AL) 22 mai 2003 (2003-05-22) abrégé; revendication 21; figures 1,2,4	1,27
A	EP 1 393 696 A (DEPUY PRODUCTS, INC) 3 mars 2004 (2004-03-03) abrégé; figures 1,6-8,11	1,27
A	US 6 197 029 B1 (FUJIMORI JUHRO ET AL) 6 mars 2001 (2001-03-06) abrégé; figures 1,5 colonne 3, ligne 26-40	1,27

-/--

[X] Voir la suite du cadre C pour la fin de la liste des documents

[X] Les documents de familles de brevets sont indiqués en annexe

* Catégories spéciales de documents cités:

"A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent
"E" document antérieur, mais publié à la date de dépôt international ou après cette date
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"T" document ultérieur publié après la date de dépôt international ou la date de priorité et n'appartenenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention
"X" document particulièrement pertinent; l'inven tion revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive par rapport au document considéré isolément
"Y" document particulièrement pertinent; l'inven tion revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier
"&" document qui fait partie de la même famille de brevets

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
7 septembre 2006	14/09/2006

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Macaire, Stéphane

Formulaire PCT/ISA/210 (deuxième feuille) (avril 2005)

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RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale n°
PCT/FR2006/001070

C(suite). DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie*	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US 2002/151898 A1 (SOHNGEN GARY W ET AL) 17 octobre 2002 (2002-10-17)	1
X	abrégé; figures 13,15 alinéa [0023]	27

Formulaire PCT/ISA/210 (suite de la deuxième feuille) (avril 2005)

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RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale n°
PCT/FR2006/001070

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
WO 2004014243 A	19-02-2004	AU 2003268050 A1	25-02-2004
		CA 2495110 A1	19-02-2004
		EP 1528895 A1	11-05-2005
US 2003097131 A1	22-05-2003	AUCUN	
EP 1393696 A	03-03-2004	AU 2003235085 A1	11-03-2004
		JP 2004130109 A	30-04-2004
		US 2004039394 A1	26-02-2004
US 6197029 B1	06-03-2001	JP 2711802 B2	10-02-1998
		JP 7222753 A	22-08-1995
US 2002151898 A1	17-10-2002	AUCUN	

Formulaire PCT/ISA/210 (annexe familles de brevets) (avril 2005)

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EX. 1004

Electronic Acknowledgement Receipt

EFS ID:	1749349
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	George Cone Lewis/Kathy Johnston
Filer Authorized By:	George Cone Lewis
Attorney Docket Number:	36302-010201
Receipt Date:	07-MAY-2007
Filing Date:	21-APR-2005
Time Stamp:	13:40:17
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	036302_010201_SUPP_IDS .pdf	154333	no	4
Warnings:					

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Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO_2006_120355.pdf	1931298	no	47
Warnings:					
Information:					
3	Foreign Reference	English_Translation_of_PCT.pdf	1217541	no	20
Warnings:					
Information:					
4	NPL Documents	BIOMET.pdf	913819	no	20
Warnings:					
Information:					
5	NPL Documents	Panta.pdf	260502	no	11
Warnings:					
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6	NPL Documents	Retronail.pdf	94596	no	3
Warnings:					
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7	NPL Documents	T2.pdf	1500764	no	32
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8	NPL Documents	Versanail.pdf	695407	no	21
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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EX. 1004

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PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number: 11/112865

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BIC FEE (37 CFR 1.16(a), (b), or (c))							
ARCH FEE (37 CFR 1.16(k), (l), or (m))							
UMINATION FEE (37 CFR 1.16(a), (b), or (c))							
AL CLAIMS (37 CFR 1.16(i))	minus 20 =		X =		OR	X =	
EPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =		X =			X =	
ICATION SIZE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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).						
IPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 37	Minus	** 37	= 2	x 25 =	2	OR	x 50 =	
ependent (37 CFR 1.16(h))	* 4	Minus	*** 4	=	x 100 =		OR	x 200 =	
plication Size Fee (37 CFR 1.16(s))									
ST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					180		OR	360	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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

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

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 ess) 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, ing, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments [illegible] Patent

Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ID TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EX. 1004

1/1/12865

Claim		Date
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	150	

If more than 150 claims or 10 actions
staple additional sheet here

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PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)	Group Art Unit: 3733
	)	
Kenneth A. Gall et. al.	)	Examiner: Annette R. Reimers
	)	
Serial No.: 11/112,865	)	
	)	
Filed: April 21, 2005	)	
	)	PRELIMINARY
Confirmation No.: 5339	)	AMENDMENT
	)	
Atty. File No.: 36302-010201	)	
	)	
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	)	
	)	

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

Dear Sir:

This correspondence is a Preliminary Amendment.

Amendments to the Claims are reflected in the Listing of the Claims, which begins on Page 2 of this paper.

Remarks begin on Page 7 of this paper.

The Commissioner is hereby authorized to charge any required fees not included, or any deficiency of fees submitted herewith, or credit any overpayment to Deposit Account No. 502775.

PETITIONER ARTHREX
EX. 1004

Amendments to the Claims

This Listing of Claims will replace all prior versions and listings of claims in the application:

1-26. (canceled).

27. (new) A surgical method, comprising:

creating a first cavity in a first bone element of a patient;

creating a second cavity in a second bone element in the patient;

inserting an intermedullary nail into the second cavity;

inserting the intermedullary nail into the first cavity;

fixing a first portion of the intermedullary nail to the first bone element of the patient;

after fixing the first portion, creating a stress-induced martensitic phase into a responsive portion of the intermedullary nail, wherein the responsive portion comprises a shape memory alloy; and

after inducing the stress-induced martensitic phase, fixing a second portion of the intermedullary nail to the second bone element of the patient, wherein the responsive portion is disposed between the first portion and the second portion.

28. (new) The surgical method of claim 27, wherein inserting the intermedullary nail into the second cavity is performed while the responsive portion is substantially in an austenitic phase.

29. (new) The surgical method of claim 27, wherein inserting the intermedullary nail into the first cavity is performed while the responsive portion is substantially in an austenitic phase.

30. (new) The surgical method of claim 27, wherein creating the stress-induced martensitic phase is performed by straining the responsive portion.

31. (new) The surgical method of claim 30, wherein straining is performed by applying a stress between the first portion and the second portion.

32. (new) The surgical method of claim 27, further comprising:

holding the responsive portion above an austenite finish temperature of the shape memory alloy while the creating is performed.

33. (new) The surgical method of claim 32, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while fixing the first portion is performed.

34. (new) The surgical method of claim 33, further comprising:

PETITIONER ARTHREX
EX. 1004

holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.

35. (new) The surgical method of claim 27, wherein the shape memory alloy is an alloy including nickel and titanium.

36. (new) The surgical method of claim 35, wherein the alloy contains substantially only nickel and titanium.

37. (new) The surgical method of claim 27, wherein the first portion comprises the shape memory alloy.

38. (new) The surgical method of claim 27, wherein the second portion comprises the shape memory alloy.

PETITIONER ARTHREX
EX. 1004

39. (new) A bone-setting system, comprising:

an intermedullary nail with a first portion of the intermedullary nail contacting a first bone element and a second portion of the intermedullary nail contacting a second bone element;

a first locking element, wherein the first portion of the intermedullary nail is fixed to the first bone element by the first locking element;

wherein the intermedullary nail comprises a shape memory alloy of nickel and titanium, the shape memory alloy disposed between the first portion of the intermedullary nail and the second portion of the intermedullary nail; and

wherein the shape memory alloy is substantially in an austenitic phase.

40. (new) The bone-setting system of claim 39, wherein the second portion of the intermedullary nail comprises an interface element adapted to receive a second locking element, wherein the second bone element comprises a bone site adapted to be fixed to the second locking element.

41. (new) The bone-setting system of claim 40, wherein the interface element of the second portion of the intermedullay nail is closer to the first portion of the intermedullary nail than the bone site.

42. (new) The bone-setting system of claim 40, wherein the intermedullary nail has a longitudinal axis, and wherein the interface element of the second portion of the intermedullay nail is closer along the longitudinal axis to the first portion of the intermedullary nail than the bone site.

43. (new) The bone-setting system of claim 39, wherein the first portion of the intermedullary nail is inside the first bone element.

44. (new) The bone-setting system of claim 39, wherein the second portion of the intermedullary nail is inside the second bone element.

45. (new) The bone-setting system of claim 39, wherein the temperature of the shape memory alloy is above an austenite finish temperature of the shape memory alloy.

46. (new) The bone-setting system of claim 45, wherein the shape memory alloy has an austenite finish temperature below about 37 degrees Celsius.

PETITIONER ARTHREX
EX. 1004

47. (new) A method, comprising:

inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;

wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

after inserting the bone device, creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis; and

wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

48. (new) The method of claim 47, wherein inserting the bone device is performed with the bone device substantially in an austenitic phase.

49. (new) The method of claim 47, further comprising:

before performing the stretching, fixing the bone device to the first bone fragment.

50. (new) The method claim 49, further comprising:

after performing the stretching, fixing the second portion of the bone device to the second bone fragment.

51. (new) The method of claim 47, further comprising:

holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the inserting is performed.

PETITIONER ARTHREX
EX. 1004

52. (new) A method of manufacturing a hot-rolled shape memory alloy into a shape memory alloy medical device element, the method comprising:

primarily heat-treating the hot-rolled shape memory alloy to about 600 degrees Celsius for about 0.5 hours;

after primarily heat-treating, machining the hot-rolled shape memory alloy into the shape memory alloy medical device element; and

after machining, secondarily heat-treating the shape memory alloy medical device element to about 350 degrees Celsius for about 1.5 hours.

53. (new) The method of claim 52, further comprising:

deforming the shape memory alloy medical device element.

54. (new) The method of claim 53, wherein the deforming comprises:

creating a martensitic phase in at least part of the shape memory alloy medical device element.

55. (new) The method of claim 53, wherein the deforming is performed after the secondarily heat-treating is performed.

56. (new) The method of claim 53, wherein the deforming is performed while the shape memory alloy medical device element is inside a patient.

57. (new) The method of claim 56, further comprising:

primarily fixing the shape memory alloy medical device element to a first bone element of the patient.

58. (new) The method of claim 57, wherein the primarily fixing is performed before the deforming is performed.

59. (new) The method of claim 57, further comprising:

secondarily fixing the shape memory alloy medical device element to a second bone element of the patient.

60. (new) The method of claim 59, wherein the secondarily fixing is performed after the primarily fixing is performed.

61. (new) The method of claim 52, further comprising:

removing an oxide layer from shape memory alloy.

62. (new) The method of claim 61, wherein removing is performed mechanically.

63. (new) The method of claim 61, wherein removing is performed after primarily heat-treating the shape memory alloy.

PETITIONER ARTHREX
EX. 1004

Remarks

In view of the foregoing amendments and following remarks, reevaluation and further processing of the application is requested. Prior to amendment herewith, Claims 1-26 were pending in the application. By amendment herewith, Claims 1-26 are canceled, and new Claims 27-63 are added. Claims 27-63 are now pending in the application.

It is believed that the present application is in condition for allowance, and such action is respectfully requested. If the Examiner believes that it would be helpful to discuss any of the amendments presented herein, the Examiner is invited to contact the undersigned at the telephone number provided.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date: 2/14/02

George C. Lewis, P.E.
Attorney for Applicant
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PETITIONER ARTHREX
EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	1515778
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	George Cone Lewis/Kathy Johnston
Filer Authorized By:	George Cone Lewis
Attorney Docket Number:	36302-010201
Receipt Date:	14-FEB-2007
Filing Date:	21-APR-2005
Time Stamp:	14:49:59
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Preliminary Amendment	036302_010201_Prelim_Amendment.pdf	271567	no	7
Warnings:					

PETITIONER ARTHREX
EX. 1004

Information:	
Total Files Size (in bytes):	271567

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.

PETITIONER ARTHREX
EX. 1004

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/112,865	04/21/2005	Kenneth A. Gall	36302-010201	5339

37705 7590 02/05/2007
GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER	
REIMERS, ANNETTE R	
ART UNIT	PAPER NUMBER
3733	
MAIL DATE	DELIVERY MODE
02/05/2007	PAPER

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

PTOL-90A (Rev. 10/06)

PETITIONER ARTHREX
EX. 1004

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 11/11 2865	Applicant(s) Hall
	Examiner Reimers S	Art Unit 3733

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

The amendment document filed on 1/25/07 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, 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 **one month**, or thirty (30) days, whichever is longer, 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.

LaCon Bui Gray — 571-272-1556

Legal Instruments Examiner (LIE), if applicable — Telephone No.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3733
Kenneth A. Gall et. al.	Examiner: Annette R. Reimers
Serial No.: 11/112,865	
Filed: April 21, 2005	
Confirmation No.: 5339	PRELIMINARY AMENDMENT
Atty. File No.: 36302-010201	
For: "OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE"	

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

Dear Sir:

This correspondence is a Preliminary Amendment.

Amendments to the Claims are reflected in the Listing of the Claims, which begins on Page 2 of this paper.

Remarks begin on Page 7 of this paper.

The Commissioner is hereby authorized to charge any required fees not included, or any deficiency of fees submitted herewith, or credit any overpayment to Deposit Account No. 502775.

PETITIONER ARTHREX
EX. 1004

Amendments to the Claims

This Listing of Claims will replace all prior versions and listings of claims in the application:

1-26. (withdrawn).

27. (new) A surgical method, comprising:

creating a first cavity in a first bone element of a patient;

creating a second cavity in a second bone element in the patient;

inserting an intermedullary nail into the second cavity;

inserting the intermedullary nail into the first cavity;

fixing a first portion of the intermedullary nail to the first bone element of the patient;

after fixing the first portion, creating a stress-induced martensitic phase into a responsive portion of the intermedullary nail, wherein the responsive portion comprises a shape memory alloy; and

after inducing the stress-induced martensitic phase, fixing a second portion of the intermedullary nail to the second bone element of the patient, wherein the responsive portion is disposed between the first portion and the second portion.

28. (new) The surgical method of claim 27, wherein inserting the intermedullary nail into the second cavity is performed while the responsive portion is substantially in an austenitic phase.

29. (new) The surgical method of claim 27, wherein inserting the intermedullary nail into the first cavity is performed while the responsive portion is substantially in an austenitic phase.

30. (new) The surgical method of claim 27, wherein creating the stress-induced martensitic phase is performed by straining the responsive portion.

31. (new) The surgical method of claim 30, wherein straining is performed by applying a stress between the first portion and the second portion.

32. (new) The surgical method of claim 27, further comprising:

holding the responsive portion above an austenite finish temperature of the shape memory alloy while the creating is performed.

33. (new) The surgical method of claim 32, further comprising:

holding the responsive portion above the austenite finish temperature of the shape memory alloy while fixing the first portion is performed.

34. (new) The surgical method of claim 33, further comprising:

PETITIONER ARTHREX
EX. 1004

holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.

35. (new) The surgical method of claim 27, wherein the shape memory alloy is an alloy including nickel and titanium.

36. (new) The surgical method of claim 35, wherein the alloy contains substantially only nickel and titanium.

37. (new) The surgical method of claim 27, wherein the first portion comprises the shape memory alloy.

38. (new) The surgical method of claim 27, wherein the second portion comprises the shape memory alloy.

PETITIONER ARTHREX
EX. 1004

39. (new) A bone-setting system, comprising:

an intermedullary nail with a first portion of the intermedullary nail contacting a first bone element and a second portion of the intermedullary nail contacting a second bone element;

a first locking element, wherein the first portion of the intermedullary nail is fixed to the first bone element by the first locking element;

wherein the intermedullary nail comprises a shape memory alloy of nickel and titanium, the shape memory alloy disposed between the first portion of the intermedullary nail and the second portion of the intermedullary nail; and

wherein the shape memory alloy is substantially in an austenitic phase.

40. (new) The bone-setting system of claim 39, wherein the second portion of the intermedullary nail comprises an interface element adapted to receive a second locking element, wherein the second bone element comprises a bone site adapted to be fixed to the second locking element.

41. (new) The bone-setting system of claim 40, wherein the interface element of the second portion of the intermedullay nail is closer to the first portion of the intermedullary nail than the bone site.

42. (new) The bone-setting system of claim 40, wherein the intermedullary nail has a longitudinal axis, and wherein the interface element of the second portion of the intermedullay nail is closer along the longitudinal axis to the first portion of the intermedullary nail than the bone site.

43. (new) The bone-setting system of claim 39, wherein the first portion of the intermedullary nail is inside the first bone element.

44. (new) The bone-setting system of claim 39, wherein the second portion of the intermedullary nail is inside the second bone element.

45. (new) The bone-setting system of claim 39, wherein the temperature of the shape memory alloy is above an austenite finish temperature of the shape memory alloy.

46. (new) The bone-setting system of claim 45, wherein the shape memory alloy has an austenite finish temperature below about 37 degrees Celsius.

PETITIONER ARTHREX
EX. 1004

47. (new) A method, comprising:

inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;

wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

after inserting the bone device, creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis; and

wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

48. (new) The method of claim 47, wherein inserting the bone device is performed with the bone device substantially in an austenitic phase.

49. (new) The method of claim 47, further comprising:

before performing the stretching, fixing the bone device to the first bone fragment.

50. (new) The method claim 49, further comprising:

after performing the stretching, fixing the second portion of the bone device to the second bone fragment.

51. (new) The method of claim 47, further comprising:

holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the inserting is performed.

PETITIONER ARTHREX
EX. 1004

52. (new) A method of manufacturing a hot-rolled shape memory alloy into a shape memory alloy medical device element, the method comprising:

primarily heat-treating the hot-rolled shape memory alloy to about 600 degrees Celsius for about 0.5 hours;

after primarily heat-treating, machining the hot-rolled shape memory alloy into the shape memory alloy medical device element; and

after machining, secondarily heat-treating the shape memory alloy medical device element to about 350 degrees Celsius for about 1.5 hours.

53. (new) The method of claim 52, further comprising:

deforming the shape memory alloy medical device element.

54. (new) The method of claim 53, wherein the deforming comprises:

creating a martensitic phase in at least part of the shape memory alloy medical device element.

55. (new) The method of claim 53, wherein the deforming is performed after the secondarily heat-treating is performed.

56. (new) The method of claim 53, wherein the deforming is performed while the shape memory alloy medical device element is inside a patient.

57. (new) The method of claim 56, further comprising:

primarily fixing the shape memory alloy medical device element to a first bone element of the patient.

58. (new) The method of claim 57, wherein the primarily fixing is performed before the deforming is performed.

59. (new) The method of claim 57, further comprising:

secondarily fixing the shape memory alloy medical device element to a second bone element of the patient.

60. (new) The method of claim 59, wherein the secondarily fixing is performed after the primarily fixing is performed.

61. (new) The method of claim 52, further comprising:

removing an oxide layer from shape memory alloy.

62. (new) The method of claim 61, wherein removing is performed mechanically.

63. (new) The method of claim 61, wherein removing is performed after primarily heat-treating the shape memory alloy.

PETITIONER ARTHREX
EX. 1004

Remarks

In view of the foregoing amendments and following remarks, reevaluation and further processing of the application is requested. Prior to amendment herewith, Claims 1-26 were pending in the application. By amendment herewith, Claims 1-26 have been withdrawn, and new Claims 27-63 have been added. Claims 27-63 are now pending in the application.

It is believed that the present application is in condition for allowance, and such action is respectfully requested. If the Examiner believes that it would be helpful to discuss any of the amendments presented herein, the Examiner is invited to contact the undersigned at the telephone number provided.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date: 1/25/07

George C. Lewis, P.E.
Attorney for Applicant
Registration No. 53,214
Greenberg Traurig, LLP
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Denver, CO 80202
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Fax: (303) 572-6540
lewisg@gtlaw.com

PETITIONER ARTHREX
EX. 1004

Electronic Patent Application Fee Transmittal

Application Number:	11112865
Filing Date:	21-Apr-2005
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Filer:	George Cone Lewis/Sylvia Cei
Attorney Docket Number:	36302-010201
Filed as Small Entity	

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	37	25	925
Independent claims in excess of 3	2201	1	100	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

PETITIONER ARTHREX
EX. 1004

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1025**

PETITIONER ARTHREX
EX. 1004

Electronic Acknowledgement Receipt	
EFS ID:	1466817
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	37705
Filer:	George Cone Lewis/Sylvia Cei
Filer Authorized By:	George Cone Lewis
Attorney Docket Number:	36302-010201
Receipt Date:	25-JAN-2007
Filing Date:	21-APR-2005
Time Stamp:	19:35:22
Application Type:	Utility

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$1025
RAM confirmation Number	982
Deposit Account	502775
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 and 1.17	

File Listing:

PETITIONER ARTHREX
EX. 1004

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1		036302-010201_TransPrelim Amend.pdf	308383	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Miscellaneous Incoming Letter		1	1	
	Preliminary Amendment		2	8	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8288	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	316671		

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.

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

PETITIONER ARTHREX
EX. 1004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth A. Gall et al.	Examiner:	Annette R. Reimers
Serial No.:	11/112,865	Group Art Unit:	3733
Filed:	April 21, 2005	Docket:	036302-010201
Confirmation No.:	5339		
Title:	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE		

TRANSMITTAL

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

37705
PATENT TRADEMARK OFFICE

We are electronically transmitting herewith the following documents:

1. Transmittal Sheet
2. Preliminary Amendment

Additional claim fees are calculated below.

For	Claims Remaining After Amendment	Highest Number Previously Paid For		Extra Claims	Small Entity Rate		Additional Fee
Total Claims	63	- 26	=	37	x $25	=	$925
Independent Claims	4	- 3	=	1	x $100	=	$100
Multiple Dep. Claim	0	- 0	$360			=	$0
Total Fee						=	$1025

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. **502775**.

By: _____

George C. Lewis, P.E., Reg. No. 53,214
GREENBERG TRAURIG, LLP
The Tabor Center
1200 17th Street, Suite 2400
Denver, CO 80202
Tel: (303) 572-6500
Fax: (303) 572-6540

PETITIONER ARTHREX
EX. 1004

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,865	04/21/2005	Kenneth A. Gall	36302-010201

CONFIRMATION NO. 5339

OC000000022003671

37705
GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

Date Mailed: 01/16/2007

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/09/2007.

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.

MELKAM BEYENE
PTOSS (703) 308-9150 EXT 148

OFFICE COPY

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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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/112,865	04/21/2005	Kenneth A. Gall	025843-000100US

CONFIRMATION NO. 5339

OC000000022003604

20350
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

Date Mailed: 01/16/2007

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/09/2007.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

MELKAM BEYENE
PTOSS (703) 308-9150 EXT 148

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PETITIONER ARTHREX
EX. 1004

PTO/SB/81 (01-06)
Approved for use through 12/31/2008. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall et al.
Title	Osteosynthetic Implants and Methods of Use and ~~Manufacture~~
Art Unit	3732
Examiner Name	Unassigned
Attorney Docket Number	36302-010201

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

☑ Practitioners associated with the Customer Number: 37705

OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☑ The address associated with the above-mentioned Customer Number:

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☐ Applicant/Inventor.

☑ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature	[signature]	Date	1/4/07
Name	Ken Gall	Telephone	404 309 2892
Title and Company	CTO, Medshape Solutions		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PETITIONER ARTHREX
EX. 1004

PTO/SB/96 (09-06)
Approved for use through 03/31/2007. 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 displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Kenneth A. Gall et al.

Application No./Patent No.: 11/112,865 Filed/Issue Date: 04/21/2005

Entitled: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

Medtshape Solutions, Inc., a a Colorado company
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☑ the assignee of the entire right, title, and interest; or

2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is_____ %)

in the patent application/patent identified above by virtue of either:

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 016308, Frame 0583, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. 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.

2. 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.

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.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☑ As required by 37 CFR 3.73(b)(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.

Signature	Date: 1/4/07
Printed or Typed Name: Ken Gall	Telephone Number: 404 309 2892
Title: CTO, MedShape Solutions	

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.

Electronic Acknowledgement Receipt	
EFS ID:	1425401
Application Number:	11112865
International Application Number:	
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor/Applicant Name:	Kenneth A. Gall
Customer Number:	20350
Filer:	George Cone Lewis
Filer Authorized By:	
Attorney Docket Number:	025843-000100US
Receipt Date:	09-JAN-2007
Filing Date:	21-APR-2005
Time Stamp:	11:49:43
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	036302-010201_POA_Stmnt.pdf	154518	no	2
Warnings:					

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EX. 1004

Information:	
Total Files Size (in bytes):	154518

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.

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EX. 1004

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on September 15, 2006.

TOWNSEND and TOWNSEND and CREW LLP

By: /Noorjahan Gillow/
Noorjahan Gillow

PATENT
Attorney Docket No.: 025843-000100US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 5339
Kenneth A. Gall et al.	Examiner: Annette R Reimers
Application No.: 11/112,865	Art Unit: 3733
Filed: April 21, 2005	SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98
For: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE	

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

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are not enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Also enclosed is a copy of the Search/Examination report corresponding to the PCT application.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

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EX. 1004

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Date: September 15, 2006

/Nathan S. Cassell/
Nathan S. Cassell
Reg. No. 42,396

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 303-571-4000
Fax: 303-571-4321
DJG:ng
60869554 v1

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EX. 1004

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Gall, Kenneth A.
Art Unit	3733
Examiner Name	Annette R Reimers
Attorney Docket Number	025843-000100US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US-5,120,175 A	06-09-1992	Arbegast et al.	
	A2	US-5,265,456 A	11-30-1993	Kennedy wt al.	
	A3	US-6,637,995 B1	10-28-2003	White	
	A4	US-6,688,828 B1	10-02-2004	Post	
	A5				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		Country Code[3]	Number[4]	Kind Code[5] (if known)				
	B1							☐
	B2							☐

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C1		☐
	C2		☐

Examiner Signature		Date Considered	

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

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

60869554 v1

RECD
AUG 24 2006

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

NSC

To:
NATHAN S. CASSELL
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER, EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

025843-000110PC

Date of mailing (*day/month/year*)	18 AUG 2006
Applicant's or agent's file reference 25843-1-1PC	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US06/15207	International filing date (*day/month/year*) 21 April 2006 (21.04.2006)
Applicant MEDSHAPE SOLUTIONS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report. 10/18/06

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders** 10/01/06

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. 10/21/07 12/01/06

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Authorized officer Eduardo Robert
Facsimile No. (571) 273-3201	Telephone No. 000-0000

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

Docketed ___ Undocketed
___ Transferred ___ Noted
___ Not Docketed
___ Abandoned
Action: ot Response/Amdt; file IDS; ↓S
Due: 10/18/06, 11/18/06

PETITIONER ARTHREX
EX. 1004

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 25843-1-1PC	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US06/15207	International filing date (*day/month/year*) 21 April 2006 (21.04.2006)	(Earliest) Priority Date (*day/month/year*) 21 April 2005 (21.04.2005)
Applicant MEDSHAPE SOLUTIONS, 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. ☐ 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(b), 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. 16
      ☒ 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.

Form PCT/ISA/210 (first sheet) (April 2005)

PETITIONER ARTHREX
EX. 1004

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/15207

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 17/56**(2006.01)

USPC: 606/72
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/72, 61, 73

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,120,175 A (ARBEGAST et al) 09 June 1992 (09.06.1992), see whole document.	1-59
X	US 6,688,828 B1 (POST) 10 February 2004 (10.02.2004), see whole document.	1-59
A	US 6,637,995 B1 (WHITE) 28 October 2003 (28.10.2003), see whole document.	1-59
A	US 5,265,456 A (KENNEDY et al) 30 November 1993 (30.11.1993), see whole document.	1-59

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

* Special categories of cited documents:

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

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 July 2006 (09.07.2006)	18 AUG 2006
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Eduardo Robert Telephone No. 000-0000

Form PCT/ISA/210 (second sheet) (April 2005)

PETITIONER ARTHREX
EX. 1004

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
NATHAN S. CASSELL
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER, EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	18 AUG 2006
Applicant's or agent's file reference 25843-1-1PC	**FOR FURTHER ACTION** See paragraph 2 below 2/21/07

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US06/15207	21 April 2006 (21.04.2006)	21 April 2005 (21.04.2005)

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

IPC: **A61B 17/56**(2006.01)
USPC: 606/72

Applicant

MEDSHAPE SOLUTIONS, INC.

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

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

2. **FURTHER ACTION**

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

11/18/06

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

For further options, see Form PCT/ISA/220. 2/21/07

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	09 July 2006 (09.07.2006)	Eduardo Robert Telephone No. 000-0000

Form PCT/ISA/237 (cover sheet) (April 2005)

Docketed ____ Undocketed
Transferred ____ Noted
Not Docketed
Abandoned
Action: response to written opinion

PETITIONER ARTHREX
EX. 1004

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/15207

Box No. I Basis of this opinion

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

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

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

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Form PCT/ISA/237(Box No. I) (April 2005)

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EX. 1004

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US06/15207

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

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-59	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-59	NO
Industrial applicability (IA)	Claims 1-59	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-59 lack novelty under PCT Article 33(2) as being anticipated by Arbegast et al. (US Patent Number 5,120,175). Arbegast et al. discloses a bone fixation device/system and methods of stabilizing a fractured bone, preparing a bone fixation device/system, deploying a bone fixation device, and processing a shape memory material including all the structural limitations set forth in the claims. With regard to the functional language recited in the claims, it is noted that anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.

Claims 1-59 lack novelty under PCT Article 33(2) as being anticipated by Post (US Patent Number 6,688,828 B1). Post discloses a bone fixation device/system and methods of stabilizing a fractured bone, preparing a bone fixation device/system, deploying a bone fixation device, and processing a shape memory material including all the structural limitations set forth in the claims. With regard to the functional language recited in the claims, it is noted that anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.

Claims 1-59 meet the criteria set forth in PCT Article 33(4) because the claimed subject matter can be made and/or used in industry.

Electronic Acknowledgement Receipt

EFS ID:	1203788
Application Number:	11112865
Confirmation Number:	5339
Title of Invention:	Osteosynthetic implants and methods of use and manufacture
First Named Inventor:	Kenneth A. Gall
Customer Number:	20350
Filer:	Nathan S. Cassell/Noorjahan Gillow
Filer Authorized By:	Nathan S. Cassell
Attorney Docket Number:	025843-000100US
Receipt Date:	15-SEP-2006
Filing Date:	21-APR-2005
Time Stamp:	16:41:56
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1	Information Disclosure Statement (IDS) Filed	025843-000100US_Suppl_IDS.pdf	383858	no	9

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Warnings:	
Information:	
This is not an USPTO supplied IDS fillable form	
Total Files Size (in bytes):	383858

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.

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EX. 1004

JRW

PTO/SB/21 (09-04)

AUG 22 2005 PATENT & TRADEMARK OFFICE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Gall, Kenneth A.
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):

Return Postcard

Remarks The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Townsend and Townsend and Crew LLP		
Signature			
Printed name	Darin J. Gibby		
Date	August 18, 2005	Reg. No.	38,464

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature	Connie Larson		
Typed or printed name	Connie Larson	Date	August 18, 2005

60567134 v1

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EX. 1004

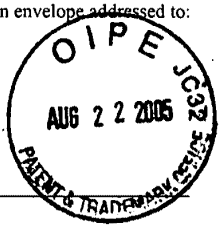
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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

On Aug 18, 2005

TOWNSEND and TOWNSEND and CREW LLP

By: Connie Larson



PATENT
Attorney Docket No.: 025843-000100US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kenneth A. Gall et al. Application No.: 11/112,865 Filed: April 21, 2005 For: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE	Examiner: Art Unit: 3732 INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

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

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are not enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

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EX. 1004

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Darin J. Gibby
Reg. No. 38,464

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 303-571-4000
Fax: 303-571-4321
DJG/cl
Unsaved Document

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EX. 1004

OIPE JC32 AUG 2 2 2005 PATENT & TRADEMARK OFFICE

PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

	Complete if Known
Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Gall, Kenneth A.
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

U.S. PATENT DOCUMENTS+

Examiner Initials*	Cite No.[1]	Document Number Number Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-2004/0230193	11-18-04	Cheung et al.	
	AB	US-			
	AC	US-			
	AD	US-			
	AE	US-			
	AF	US-			
	AG	US-			
	AH	US-			
	AI	US-			
	AJ	US-			
	AK	US-			
	AL	US-			
	AM	US-			
	AN	US-			
	AO	US-			
	AP	US-			
	AQ	US-			
	AR	US-			
	AS	US-			
	AT	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	AU					☐
	AV					☐
	AW					☐
	AX					☐
	AY					☐
	AZ					☐
	BA					☐
	BB					☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] **Applicant's** unique citation designation number **(optional)**. [2] Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Unsaved Document

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EX. 1004

IFW

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/112,865	04/21/2005	Kenneth A. Gall	25843-000100

CONFIRMATION NO. 5339

20350
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

FORMALITIES LETTER

OC000000016044846

OIPE JC118 JUN 17 2005 PATENT & TRADEMARK OFFICE

Date Mailed: 05/17/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

06/20/2005 LWONDIM1 00000008 201430 11112865

01 FC:2011 150.00 DA
02 FC:2111 250.00 DA
03 FC:2311 100.00 DA
04 FC:2051 65.00 DA
05 FC:2202 150.00 DA

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing.
  Applicant must submit $ **150** *to complete the basic filing fee for a small entity.*
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of $**150** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is $**715** for a Small Entity

- $**150** Statutory basic filing fee.

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EX. 1004

- **$65** Late oath or declaration Surcharge.

- The application search fee has not been paid. Applicant must submit **$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

- Total additional claim fee(s) for this application is **$150**

  - **$150** for **6** total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

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OIPE JC118 JUN 17 2005 PATENT & TRADEMARK OFFICE

PTO/SB/21 (09-04)

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Gall, Kenneth A.
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☒ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):
  - Return Postcard
  - Declaration
  - Power of Attorney
  - Required copy of Notice to File Missing Parts

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

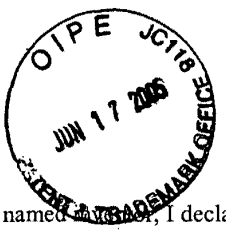
Firm Name	Townsend and Townsend and Crew LLP		
Signature			
Printed name	Darin J. Gibby		
Date	June 14, 2005	Reg. No.	38,464

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature			
Typed or printed name	Connie Larson	Date	June 14, 2005

60515436 v1



Attorney Docket No.: 025843-000100US

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE,** the specification of which was filed on April 21, 2005 as Application No. 11/112,865 and was amended on _____ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status

Full Name of Inventor 1:	Last Name: **Gall**	First Name: **Kenneth**	Middle Name or Initial: **A.**	
Residence & Citizenship:	City: **Denver**	State/Foreign Country: **Colorado**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **1501 Wazee Street, #2E**	City: **Denver**	State/Country: **Colorado**	Postal Code: **80202**
Full Name of Inventor 2:	Last Name: **Tyber**	First Name: **Jeffrey**	Middle Name or Initial: **A.**	
Residence & Citizenship:	City: **Boulder**	State/Foreign Country: **Colorado**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **315 Martin Drive**	City: **Boulder**	State/Country: **Colorado**	Postal Code: **80305**

PETITIONER ARTHREX
EX. 1004

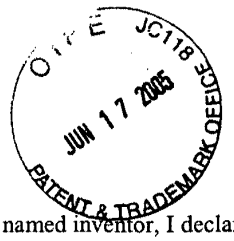
Full Name of Inventor 3:	Last Name: **Pacaccio**	First Name: **Douglas**	Middle Name or Initial: **J.**	
Residence & Citizenship:	City: **Alexandria**	State/Foreign Country: **Virginia**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **6300 Stevenson Ave. #317**	City: **Alexandria**	State/Country: **Virginia**	Postal Code: **22304**

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

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Kenneth A. Gall Date	Jeffrey A. Tyber Date	Douglas J. Pacaccio Date 6/6/05

60503008 v1

PETITIONER ARTHREX
EX. 1004



Attorney Docket No.: 025843-000100US

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE,** the specification of which was filed on April 21, 2005 as Application No. 11/112,865 and was amended on _____ (if applicable).

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Application No.	Date of Filing	Status

Full Name of Inventor 1:	Last Name: **Gall**	First Name: **Kenneth**	Middle Name or Initial: **A.**	
Residence & Citizenship:	City: **Denver**	State/Foreign Country: **Colorado**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **1501 Wazee Street, #2E**	City: **Denver**	State/Country: **Colorado**	Postal Code: **80202**
Full Name of Inventor 2:	Last Name: **Tyber**	First Name: **Jeffrey**	Middle Name or Initial: **A.**	
Residence & Citizenship:	City: **Boulder**	State/Foreign Country: **Colorado**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **315 Martin Drive**	City: **Boulder**	State/Country: **Colorado**	Postal Code: **80305**

PETITIONER ARTHREX
EX. 1004

Full Name of Inventor 3:	Last Name: **Pacaccio**	First Name: **Douglas**	Middle Name or Initial: **J.**	
Residence & Citizenship:	City: **Alexandria**	State/Foreign Country: **Virginia**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **6300 Stevenson Ave. #317**	City: **Alexandria**	State/Country: **Virginia**	Postal Code: **22304**

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

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Kenneth A. Gall Date	Jeffrey A. Tyber Date 6/5/05	Douglas J. Pacaccio Date

60503008 v1

PETITIONER ARTHREX
EX. 1004





Attorney Docket No.: 025843-000100US

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE,** the specification of which was filed on April 21, 2005 as Application No. 11/112,865 and was amended on _____ (if applicable).

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Application No.	Date of Filing	Status

Full Name of Inventor 1:	Last Name: **Gall**	First Name: **Kenneth**	Middle Name or Initial: **A.**	
Residence & Citizenship:	City: **Denver**	State/Foreign Country: **Colorado**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **1501 Wazee Street, #2E**	City: **Denver**	State/Country: **Colorado**	Postal Code: **80202**
Full Name of Inventor 2:	Last Name: **Tyber**	First Name: **Jeffrey**	Middle Name or Initial: **A.**	
Residence & Citizenship:	City: **Boulder**	State/Foreign Country: **Colorado**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **315 Martin Drive**	City: **Boulder**	State/Country: **Colorado**	Postal Code: **80305**

PETITIONER ARTHREX
EX. 1004

Full Name of Inventor 3:	Last Name: **Pacaccio**	First Name: **Douglas**	Middle Name or Initial: **J.**	
Residence & Citizenship:	City: **Alexandria**	State/Foreign Country: **Virginia**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **6300 Stevenson Ave. #317**	City: **Alexandria**	State/Country: **Virginia**	Postal Code: **22304**

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

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Kenneth A. Gall Date 6/7/05	Jeffrey A. Tyber Date	Douglas J. Pacaccio Date

60503008 v1

PETITIONER ARTHREX
EX. 1004

OIPE JC118 JUN 17 2005 PATENT & TRADEMARK OFFICE

PTO/SB/81 (11-04)

POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall
Title	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

☒ Practitioners associated with the Customer Number: **20350**

OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number:

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Fax			

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Signature	K. Gall	Date 6/7/05	
Name	Kenneth A. Gall	Telephone	303 908-3501
Title and Company	N/A		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of 3 forms are submitted.

60503072 v1

OIPE JC118
JUN 17 2005
PATENT & TRADEMARK OFFICE

PTO/SB/81 (11-04)

POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall
Title	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

☒ Practitioners associated with the Customer Number: **20350**

OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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☐ The address associated with Customer Number:

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☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Fax			

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Signature		Date	6/7/05
Name	Jeffrey A. Tyber	Telephone	
Title and Company	N/A		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of 3 forms are submitted.

60503057 v1

OIPE JC118
JUN 17 2005
PATENT & TRADEMARK OFFICE

PTO/SB/81 (11-04)

POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

Application Number	11/112,865
Filing Date	April 21, 2005
First Named Inventor	Kenneth A. Gall
Title	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Art Unit	3732
Examiner Name	
Attorney Docket Number	025843-000100US

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

☒ Practitioners associated with the Customer Number: **20350**

OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

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☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Fax			

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Signature	Douglas J. Pacaccio	Date	6/6/05
Name	Douglas J. Pacaccio	Telephone	(312)371-7938
Title and Company	N/A		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of 3 forms are submitted.

60503058 v1

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/112,865	04/21/2005	Kenneth A. Gall	25843-000100

CONFIRMATION NO. 5339

20350
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

FORMALITIES LETTER

OC000000016044846

Date Mailed: 05/17/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing.
  Applicant must submit $ **150** *to complete the basic filing fee for a small entity.*
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **$150** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$715** for a Small Entity

- **$150** Statutory basic filing fee.

PETITIONER ARTHREX
EX. 1004

- **$65** Late oath or declaration Surcharge.

- The application search fee has not been paid. Applicant must submit **$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

- Total additional claim fee(s) for this application is **$150**

  - **$150** for **6** total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Melanon
Office of Initial Patent Examination (703) 308-1202

PART 3 - OFFICE COPY

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EX. 1004

PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

11/112,865

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	26	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	26 minus 20=	* 6
INDEPENDENT CLAIMS	3 minus 3 =	* 0
MULTIPLE DEPENDENT CLAIM PRESENT		☐

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

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE		OR	BASIC FEE	
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1)		(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDI-TIONAL FEE		RATE	ADDI-TIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

1, 13, 20,

AMENDMENT B

	(Column 1)		(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

RATE	ADDI-TIONAL FEE		RATE	ADDI-TIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1)		(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

RATE	ADDI-TIONAL FEE		RATE	ADDI-TIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	

PETITIONER ARTHREX
EX. 1004

730025 U.S. PTO
11/112865
042105

20427 U.S. PTO

PTO/SB/05 (09-04)

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	25843-000100
First Inventor	Gall, Kenneth A. et al.
Title	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Express Mail Label No.	EV 470922784 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. ☒ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☒ **Specification** [*Total Pages* 22] Both the claims and abstract must start on a new page *(For information on the preferred arrangement, see MPEP 608.01(a))*
4. ☒ **Drawing(s)** *(35 U.S.C.113)* [*Total Sheets* 10]
5. **Oath or Declaration** [*Total Sheets* ____]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63 (d)) *(for a continuation/divisional with Box 18 completed)*
      i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☒ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM** or **CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission** *(if applicable, items a. - c. are required)*
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

730025 U.S. PTO 11/112865 042105

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☒ **Return Receipt Postcard** (MPEP 503) *(Should be specifically itemized)*
15. ☐ **Certified Copy of Priority Document(s)** *(if foreign priority is claimed)*
16. ☐ **Nonpublication Request** under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☒ Other: No fee transmittal is attached as Applicants are not paying the filing fee at this time and await a Notice of Missing Parts

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

☒ The address associated with Customer Number: **20350** *OR* ☐ Correspondence address below

Name	Roger T. Barrett, Reg. No. 41,599				
Address					
City		State		Zip Code	
Country		Telephone	(303) 571-4000 (Denver)	Fax	(303) 571-4321 (Denver)

Signature		Date	April 21, 2005
Name (Print/Type)	Roger T. Barrett	Registration No. (Attorney/Agent)	41,599

60474029 v1

PETITIONER ARTHREX
EX. 1004

730025 U.S. PTO
11/112865
042105

U.S. UTILITY PATENT APPLICATION EXPRESS MAIL FILING RECEIPT

Attorney Docket No.	25843-000100
Based on	Provisional Patent Application Ser. No. 60/563,952
Express Mail Label No.	EV 470922784 US
Date of Deposit:	April 21, 2005

This Utility Patent Application is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on:

DATE: April 21, 2005

to the following Address:

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

By: Sara B. McPeak Date: April 21, 2005

Sara B. McPeak

47030035 v1

PETITIONER ARTHREX
EX. 1004

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

ABSTRACT OF THE DISCLOSURE

[0063] The present invention provides bone fracture fixation devices, systems and methods of use and manufacture. One such bone fixation device includes an elongate element having a responsive zone. The element is adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture site in the bone. The responsive zone is adapted to apply a desired pressure to the bone when coupled thereto. In some embodiments, the responsive zone comprises a shape memory material, which may be nickel titanium or Nitinol, to apply compressive pressure across the fracture site for longer periods of time than standard bone screws.

60458161 v1

PETITIONER ARTHREX
EX. 1004

Application Data Sheet

Application Information

Application number::	
Filing Date::	April 21, 2005
Application Type::	Regular
Subject Matter::	Utility
Suggested classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R??::	
Number of CD disks::	
Number of copies of CDs::	
Sequence Submission::	
Computer Readable Form (CRF)?::	
Number of copies of CRF::	
Title::	OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE
Attorney Docket Number::	25843-000100
Request for Early Publication::	No
Request for Non-Publication::	No
Suggested Drawing Figure::	1
Total Drawing Sheets::	10
Small Entity?::	Yes
Latin name::	
Variety denomination name::	
Petition included?::	No
Petition Type::	
Licensed US Govt. Agency::	
Contract or Grant Numbers One::	
Secrecy Order in Parent Appl.::	No

Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Kenneth
Middle Name::	A.
Family Name::	Gall
Name Suffix::	
City of Residence::	Denver
State or Province of Residence::	CO
Country of Residence::	US
Street of Mailing Address::	1501 Wazee Street, #2E
City of Mailing Address::	Denver
State or Province of mailing address::	CO
Country of mailing address::	US
Postal or Zip Code of mailing address::	80202

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Jeffrey
Middle Name::	A.
Family Name::	Tyber
Name Suffix::	
City of Residence::	Boulder
State or Province of Residence::	CO
Country of Residence::	US
Street of Mailing Address::	315 Martin Drive
City of Mailing Address::	Boulder
State or Province of mailing address::	CO

Country of mailing address::	US
Postal or Zip Code of mailing address::	80305

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Douglas
Middle Name::	J.
Family Name::	Pacaccio
Name Suffix::	
City of Residence::	Alexandria
State or Province of Residence::	VA
Country of Residence::	US
Street of Mailing Address::	6300 Stevenson Avenue, #317
City of Mailing Address::	Alexandria
State or Province of mailing address::	VA
Country of mailing address::	US
Postal or Zip Code of mailing address::	22304

Correspondence Information

Correspondence Customer Number::	20350

Representative Information

Representative Customer Number::	20350

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	An Application claiming benefit under 35 USC 119(e) of	60/563,952	04/21/04

Foreign Priority Information

Country:: Application number:: Filing Date::

Assignee Information

Assignee Name::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

WHAT IS CLAIMED IS:

1. A bone fixation device, comprising:

an elongate element comprising a responsive zone, the element adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture site in the bone; and

wherein the responsive zone is adapted to apply a desired pressure to the bone when coupled thereto.

2. The bone fixation device as in claim 1 wherein the responsive zone comprises a shape memory material.

3. The bone fixation device as in claim 2 wherein the responsive zone comprises Nitinol.

4. The bone fixation device as in claim 1 wherein the elongate element comprises Nitinol.

5. The bone fixation device as in claim 1 wherein the responsive zone is pseudoelastic at a body temperature.

6. The bone fixation device as in claim 1 wherein the responsive zone is generally centrally located in the elongate element, the responsive zone having a smaller overall cross section than a cross section of an end of the elongate element.

7. The bone fixation device as in claim 1 further comprising a coupler adapted to couple the elongate element to the bone.

8. The bone fixation device as in claim 7 wherein the coupler comprises at least one bone screw.

9. The bone fixation device as in claim 8 wherein the bone screw comprises a shape memory material.

10. The bone fixation device as in claim 1 wherein the elongate element comprises a plate, the plate having first and second end sections each comprising at least one hole adapted to receive a coupler therethrough to couple the plate to the bone.

PETITIONER ARTHREX
EX. 1004

11. The bone fixation device as in claim 1 wherein the elongate element comprises a bone screw.

12. The bone fixation device as in claim 1 wherein the elongate element comprises a nail.

13. A bone fixation system, comprising:

an elongate element comprising a responsive zone of shape memory material; and

a coupler adapted to couple the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone.

14. The bone fixation system as in claim 13 further comprising a removable clamp, the removable clamp adapted to maintain the elongate element responsive zone in a desired position prior to coupling of the elongate element to the bone.

15. The bone fixation system as in claim 14 wherein the removable clamp is adapted to be removed from the elongate element after coupling of the elongate element to the bone.

16. The bone fixation system as in claim 13 wherein the responsive zone is adapted to apply a desired pressure to the bone when the elongate element is coupled to the bone.

17. The bone fixation system as in claim 13 wherein the responsive zone has a smaller cross-sectional area than a cross-sectional area of an end of the elongate element.

18. The bone fixation system as in claim 13 wherein the responsive zone comprises Nitinol.

19. The bone fixation system as in claim 13 wherein the elongate element comprises a nail.

20. A method of stabilizing a fractured bone, the method comprising:

providing an elongate element comprising a responsive zone of a shape memory material; and

PETITIONER ARTHREX
EX. 1004

coupling the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone;

wherein the responsive zone is adapted to apply a desired pressure to the bone when coupled thereto.

21. The method as in claim 20 further comprising:

applying a force to the elongate element to lengthen the responsive zone a desired amount;

maintaining the elongate element in the lengthened position;

coupling the elongate element to the bone so that the lengthened responsive zone is positioned adjacent the fracture site in the bone; and

releasing the elongate element.

22. The method as in claim 21 wherein applying the force to the elongate element to lengthen the responsive zone the desired amount corresponds to a desired compressive force to be applied to the fractured bone when the elongate element is coupled thereto.

23. The method as in clam 20 wherein coupling the elongate element to the bone comprises attaching a first coupler to the elongate element and to the bone on a first side of the fracture site, and attaching a second coupler to the elongate element and to the bone on a second side of the fracture site.

24. The method as in claim 20 wherein the shape memory material comprises Nitinol.

25. The method as in claim 20 wherein the elongate element comprises a bone screw.

26. The method as in claim 20 wherein the elongate element comprises a nail.

PETITIONER ARTHREX
EX. 1004

Best Available Copy

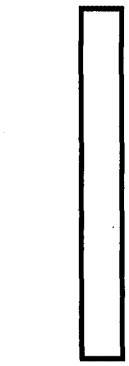


FIG. 1B

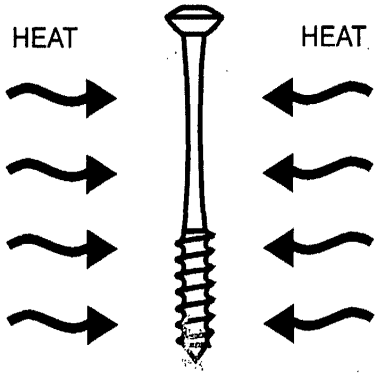


FIG. 1C

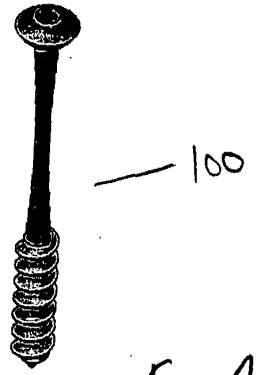


FIG. 1A

Initial Input

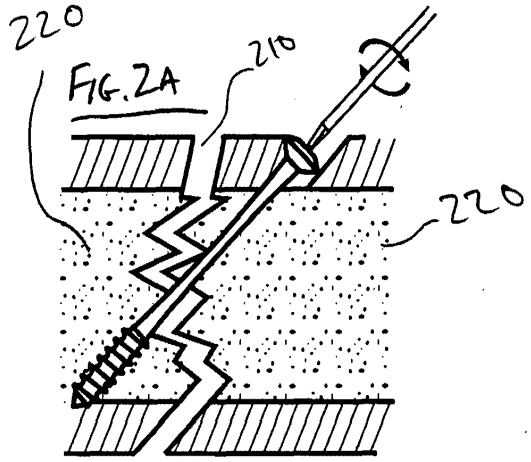


FIG. 2A

Rotation Translated to Elongation

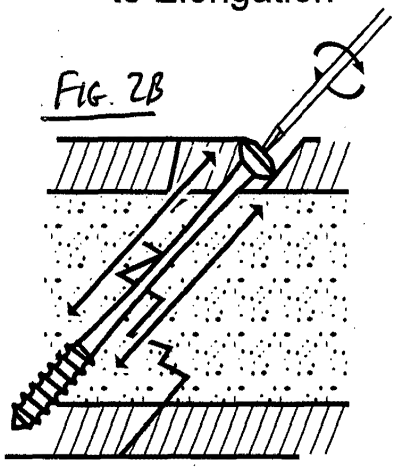


FIG. 2B

Fully Healed

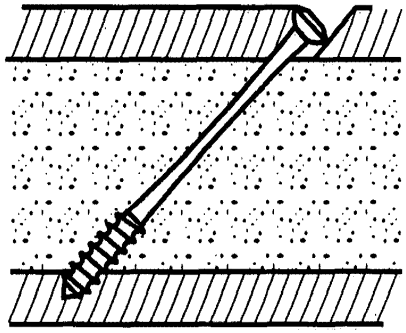


FIG. 2C

PETITIONER ARTHREX
EX. 1004

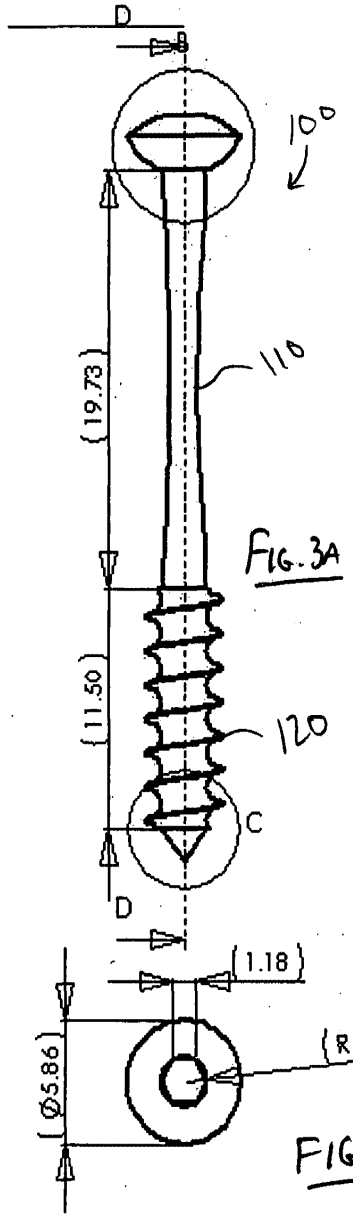


FIG. 3A

FIG. 3E

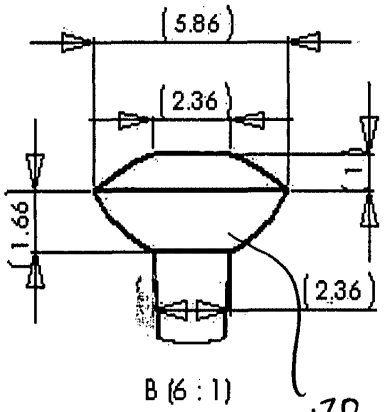


FIG. 3B

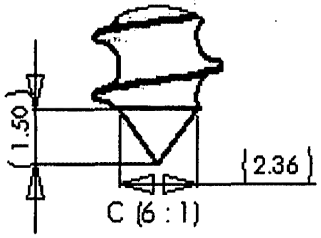


FIG. 3C

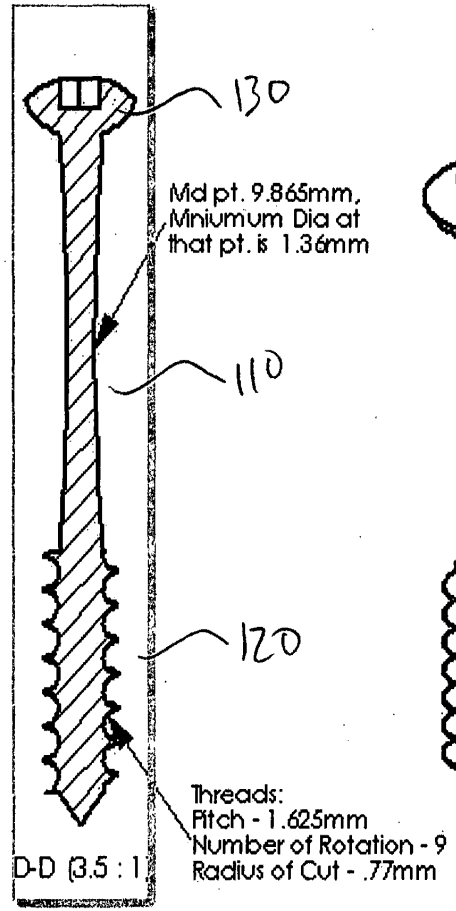


FIG. 3D

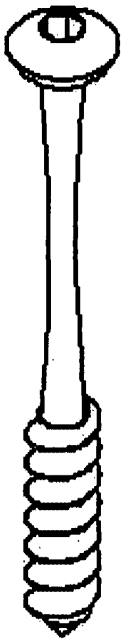


FIG. 3F

Atty. Dock. No. 25843-000100 filed 4-21-05
Pat. Priority claim to Ser. No. 60/563,952
Inventors: Kenneth A. Gall et al.
2/10

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EX. 1004

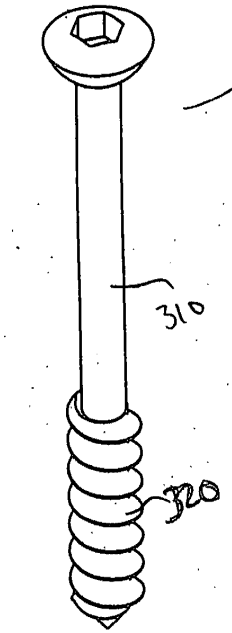


FIG. 3G

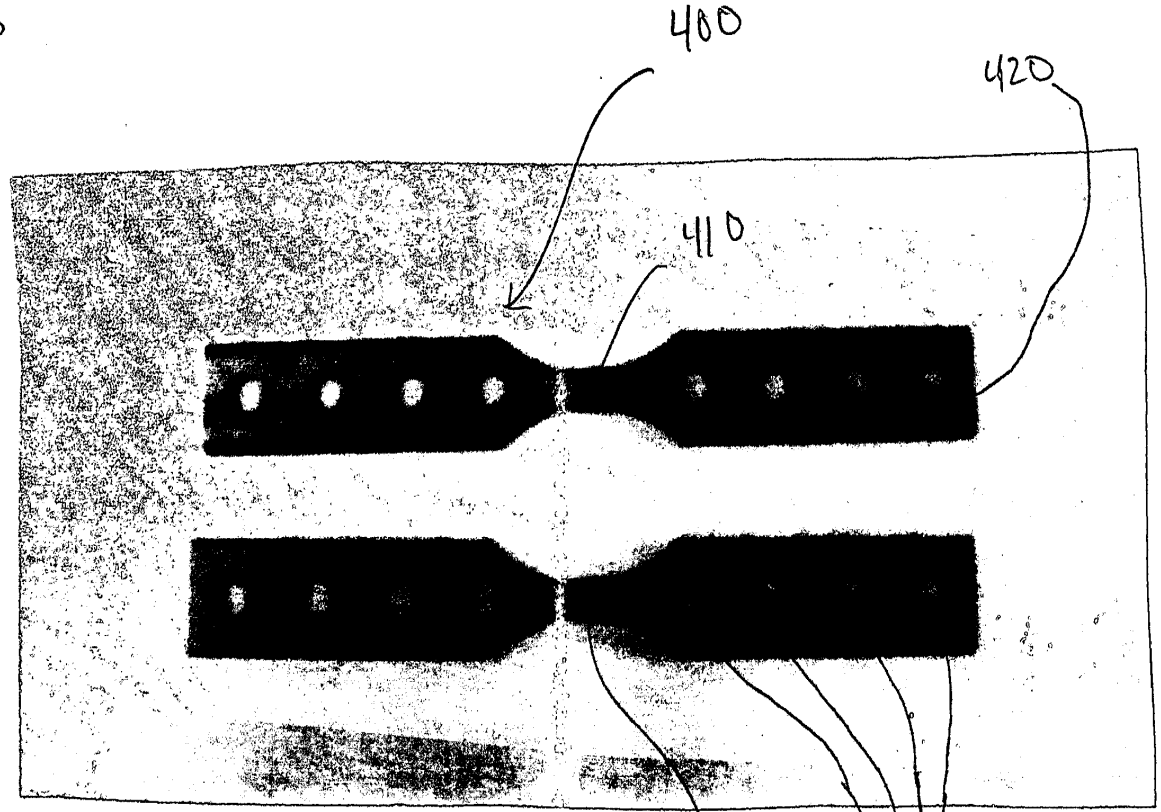
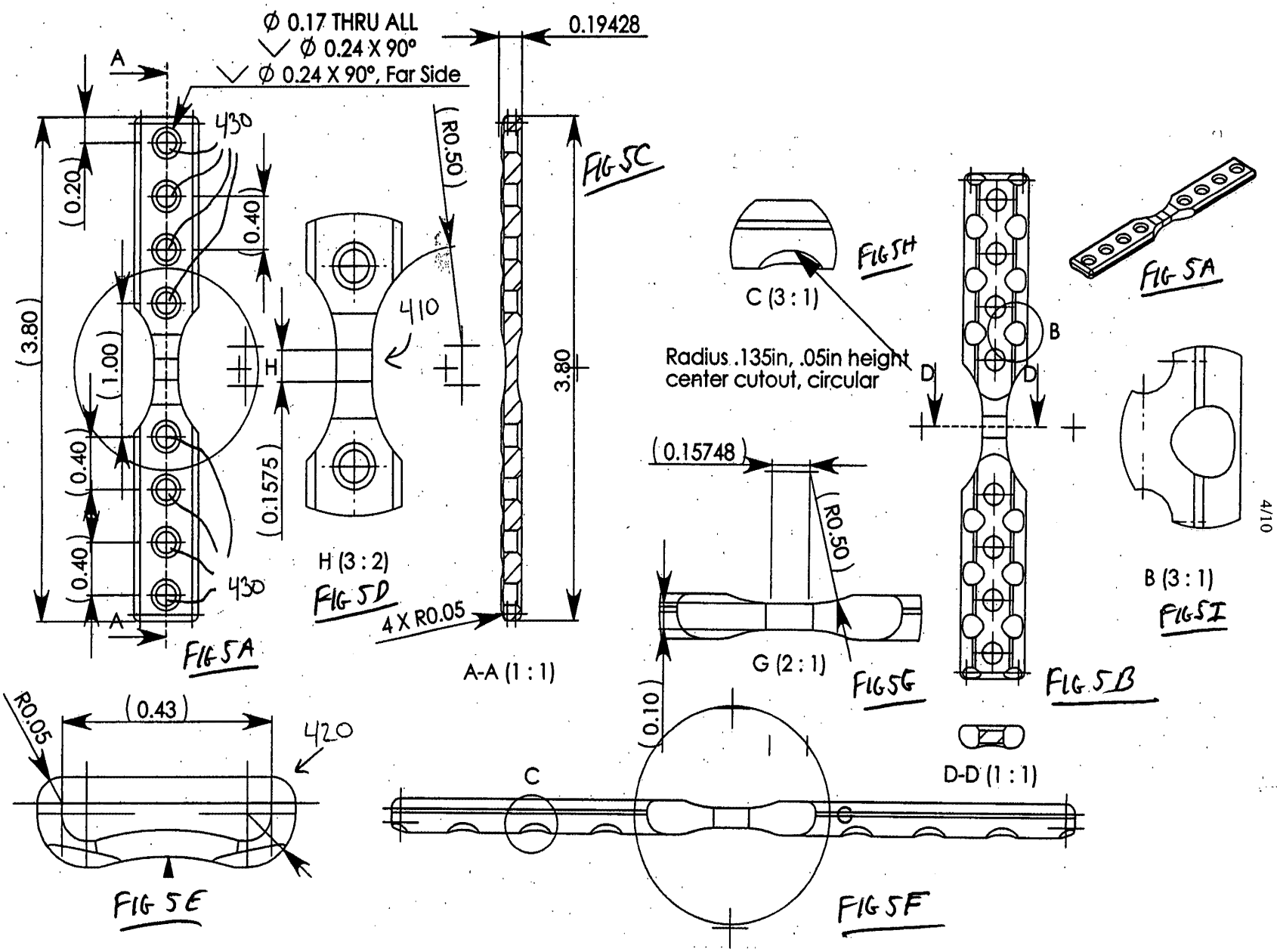


FIG. 4

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Pat. Priority claim to Ser. No. 60/563,952
Inventors: Kenneth A. Gall et al.
4/10

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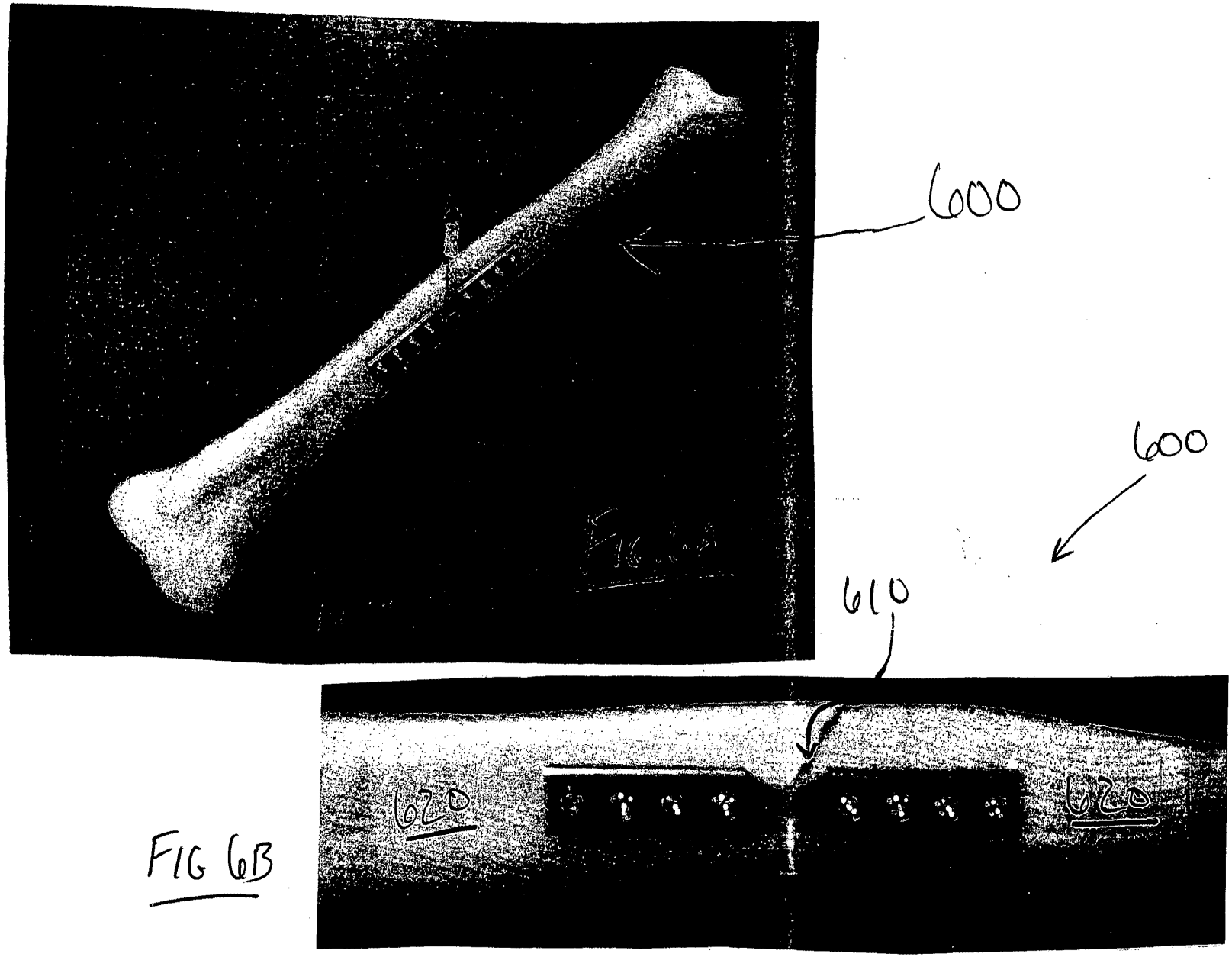


FIG 6B

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EX. 1004

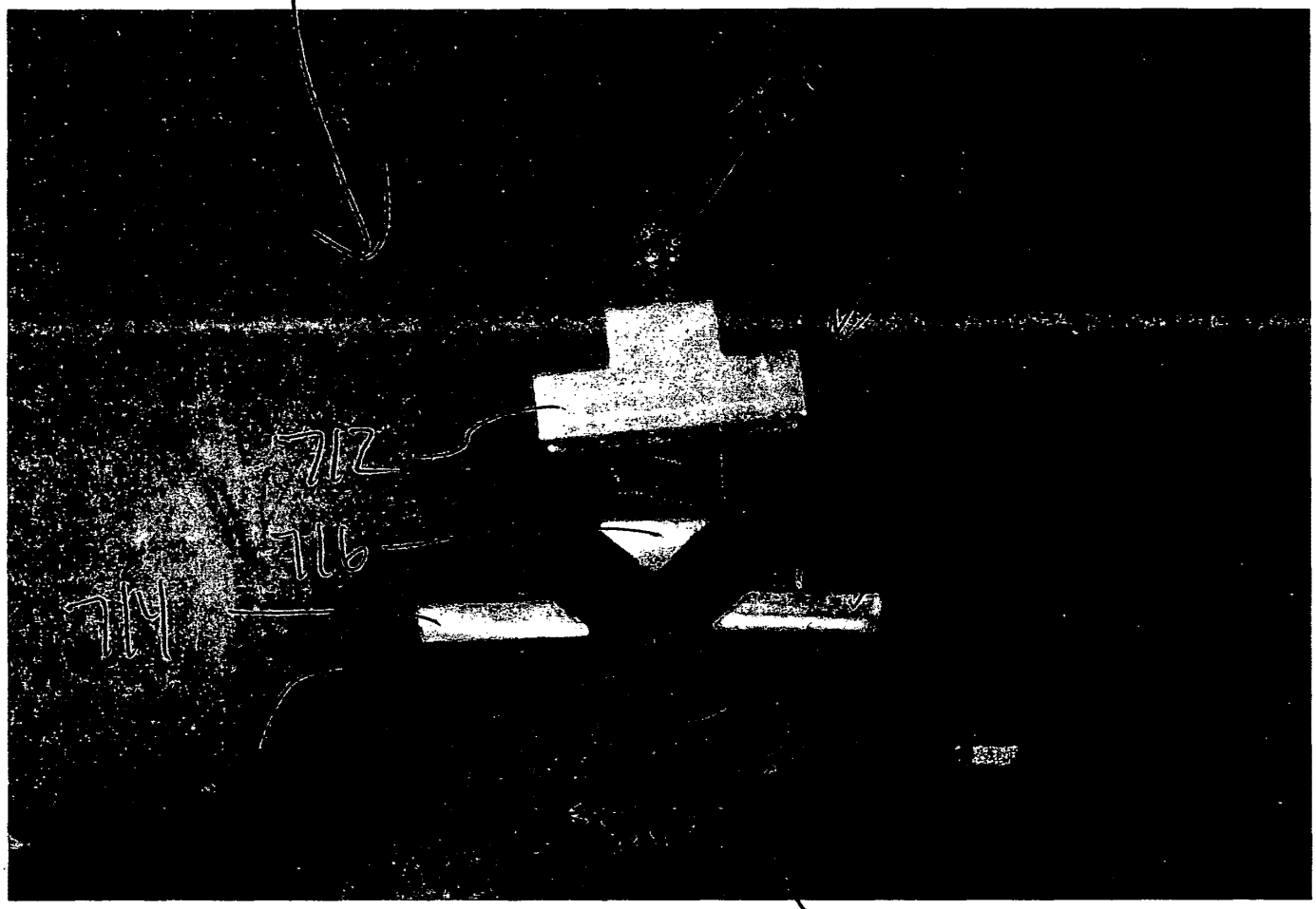


FIG 7A

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EX. 1004

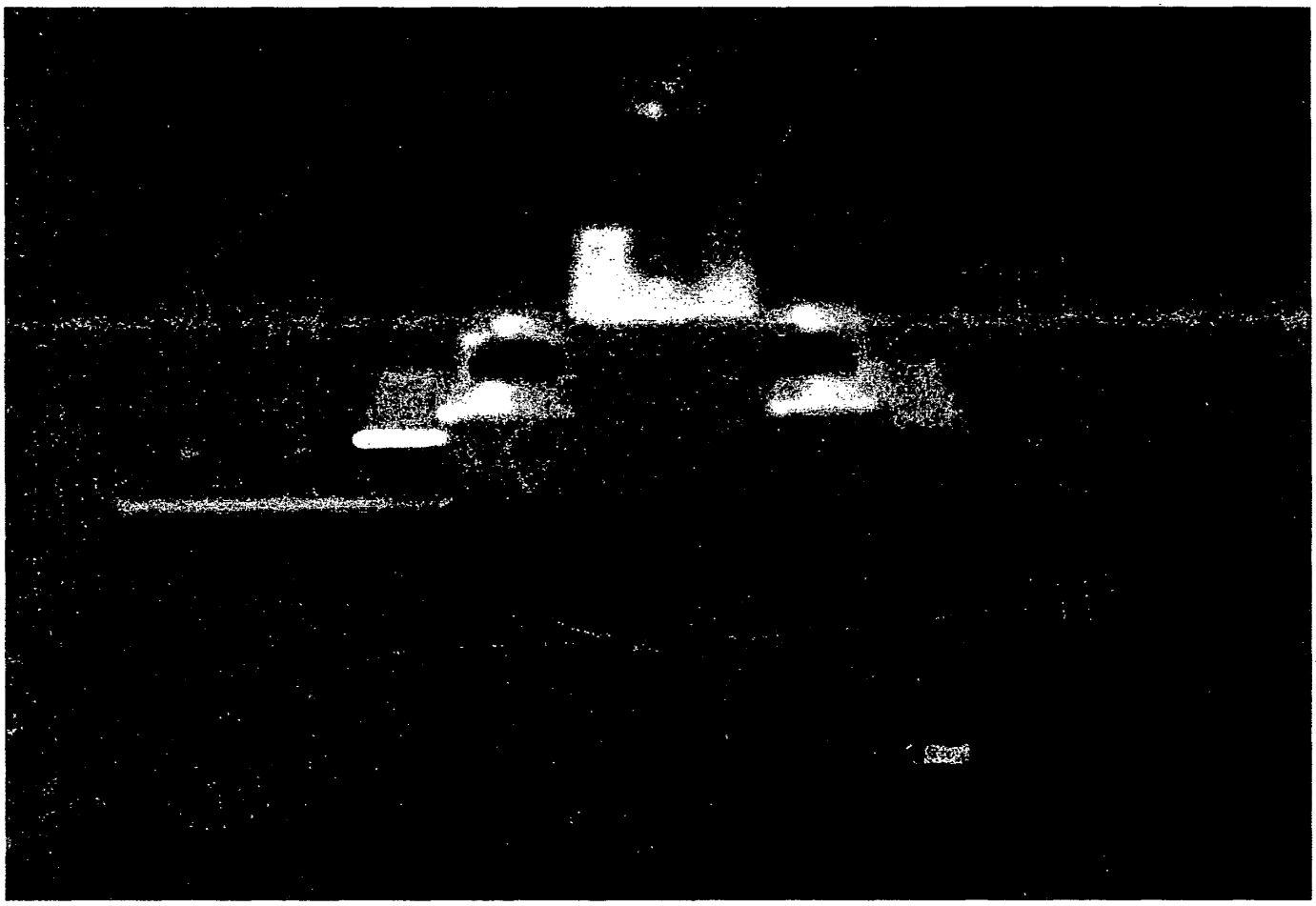


FIG. 7B

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EX. 1004

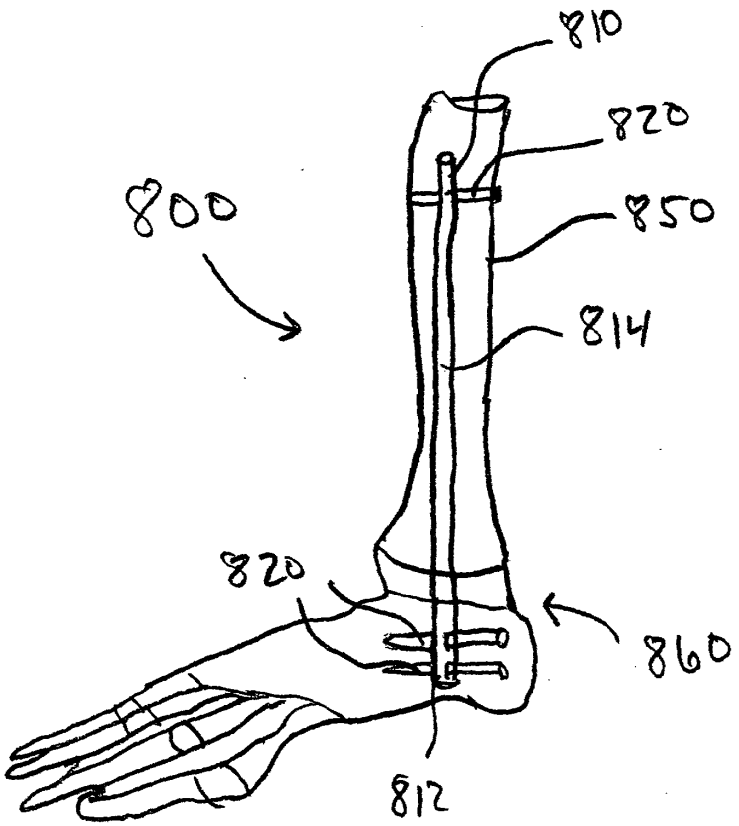


FIG. 8

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EX. 1004

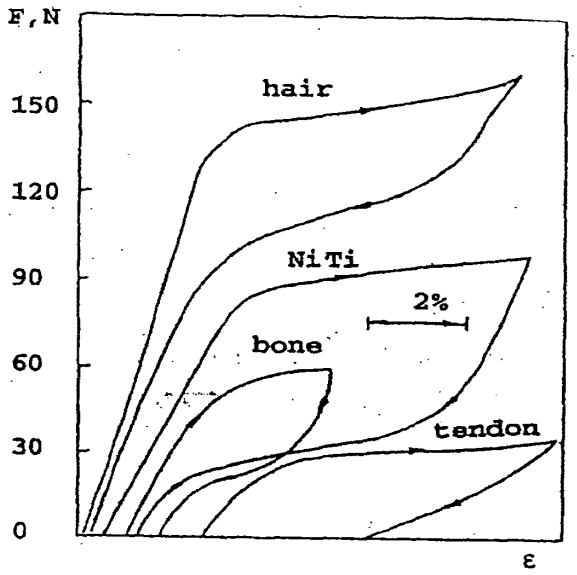


FIG. 9A.

The stress-strain diagram for living tissues and a NiTi alloy [1].

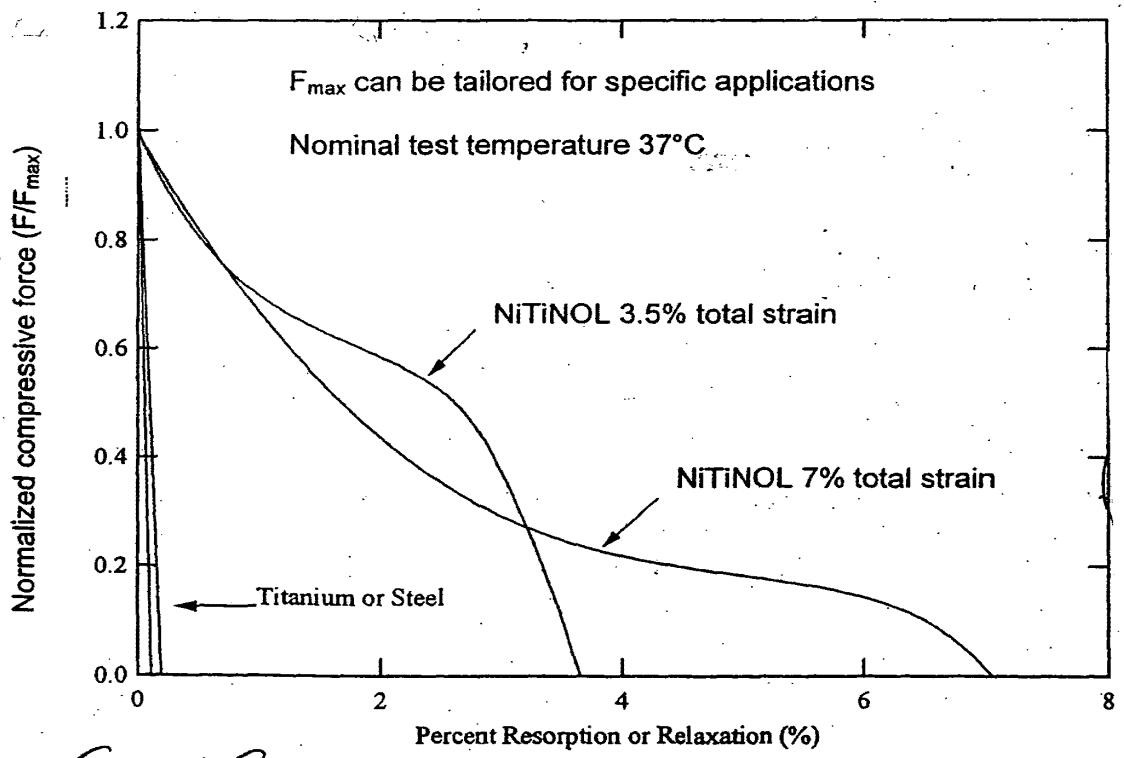


FIG. 9B

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EX. 1004

$$A=F_R/\sigma_R \qquad (1) \qquad\qquad L=\Delta L/\varepsilon \qquad (2)$$

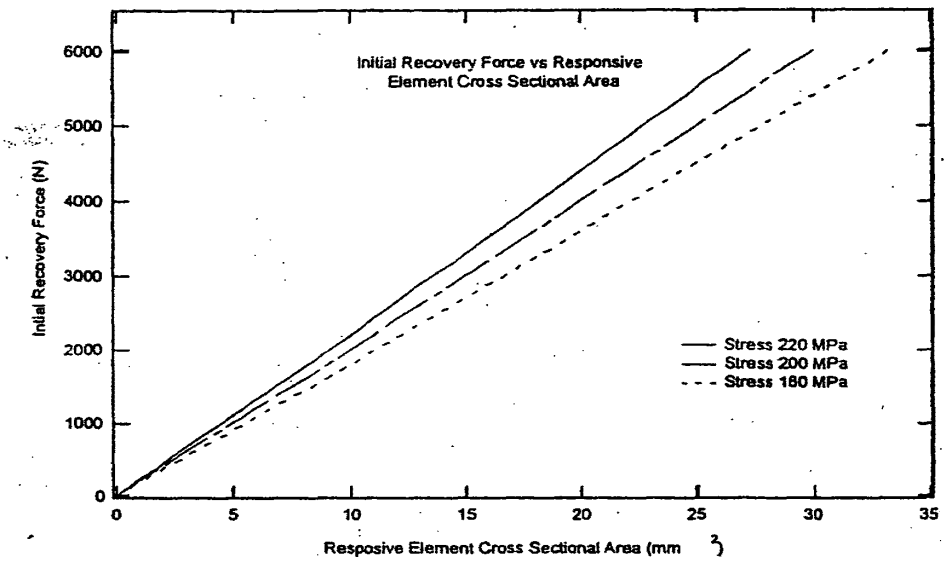


FIG. 10A

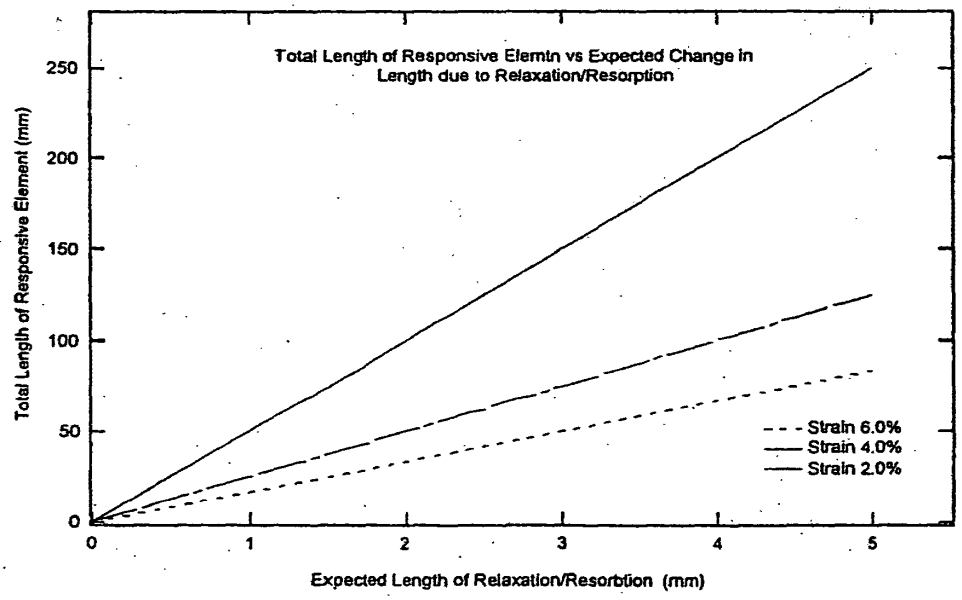


FIG. 10B

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EX. 1004

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Attorney Docket No.: 25843-000100

PATENT APPLICATION

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

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EX. 1004

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Application No. 60/563,952, filed April 21, 2004, entitled *Shape Memory Alloy Osteosynthetic Implants*, the complete disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND OF THE INVENTION

[0002] The present application relates generally to bone fracture repair, and more specifically, to osteosynthetic implants for fracture repair and methods of their use and manufacture.

[0003] In 1959, a group of Swiss Orthopedic and General Surgeons formed the Arbeitsgemeinschaft fur Osteosynthesefragen (AO), also known as the Association for the Study of Internal Fixation (ASIF). The AO/ASIF is now a multi-national group of doctors and scientists with the expressed purpose of studying bone healing and continuous development of fracture fixation techniques for patient care. In the United States, as well as most other countries, AO/ASIF guidance regarding skeletal fixation has become the standard of care for traumatic fracture as well as therapeutic osteotomy fixation techniques. It is under these AO/ASIF guidelines that the surgeon plans and carries out procedures to achieve the desired end result of bone healing and skeletal function.

[0004] Problems can arise when the bone fracture site is not sufficiently stabilized during the healing timeframe. Depending on the nature of the fracture, screws and plates may be used alone, or in combination. One objective of osteosynthetic implants is the anatomic reduction of the fracture. Another objective would be to minimize or eliminate interfragmentary motion. Still another objective involves increasing or maximizing blood supply to the fracture site by reducing or minimizing additional vascular damage. Excessive interfragmentary motion results in the formation of fibrous, unmineralized scar tissue (resulting in a non-union or pseuo-arthrosis) versus the regeneration of bone. The unmineralized scar tissue is not load supporting and skeletal function is lost. A sufficient blood supply must be maintained to support skeletal metabolism, bone regeneration, and

PETITIONER ARTHREX
EX. 1004

remodeling of the fracture site. The current standard of care includes osteosynthetic devices that are made of either stainless steel or titanium.

[0005] The use of stainless steel or titanium in osteosynthetic devices has a long history and reasonable record of success. Over time, however, the stainless steel and titanium fixation constructs (both screws and plates) do not maintain compression across the fracture fragments. The reduction of compression of certain standard material constructs has been observed to be thirty-two percent (32%) over a two week period. As the necrotic surfaces of the fracture are resorbed, a non-load bearing gap develops between the fragments, thereby decreasing compression and increasing the risk of interfragmentary motion and scar tissue formation. Loss of compression is contrary to the objectives of fracture fixation in general, and osteosynthetic implants in particular. Improvements are desired to help maintain compressive load across the fracture site over a longer period of healing.

BRIEF SUMMARY OF THE INVENTION

[0006] The present application relates generally to bone fracture repair, and more specifically, to osteosynthetic implants for fracture repair and methods of their use and manufacture. Fracture repair devices, systems and methods include those for repairing intentional fracture sites, such as but not limited to osteotomies, for reconstructive purposes. Bony fusions of surgically resected joints throughout the body are included as well within the scope of the present invention. Fracture fixation devices, systems and methods of the present invention help maintain compressive loads across the fracture site for longer periods of time compared to prior devices. In some embodiments, the use of shape memory materials, including nickel titanium, delivers improved fracture repair characteristics. The present invention further includes methods of use and methods of manufacture of such bone fixation devices and systems.

[0007] In one embodiment, a bone fixation device according to the present invention includes an elongate element having a responsive zone. The elongate element is a plate, a nail, or a bone screw in alternative embodiments. The elongate element is adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture site in the bone. The responsive zone is adapted to apply a desired pressure to the bone when coupled thereto. In a preferred embodiment, the responsive zone comprises a shape memory material, which may be nickel titanium or Nitinol.

PETITIONER ARTHREX
EX. 1004

[0008] In some embodiments, the elongate element comprises nitinol, while in other aspects, the responsive zone is pseudoelastic at a body temperature. In this manner, the elongate element may be used to apply desired forces at the fracture site. In some embodiments, the responsive zone is generally centrally located in the elongate element. In one aspect, the responsive zone has a smaller overall cross section than a cross section of an end of the elongate element. Such a configuration helps locate the stresses or pressures at a desired location within the elongate element, and more specifically, at the responsive zone.

[0009] In some aspects, the bone fixation device further includes a coupler adapted to couple the elongate element to the bone. The coupler may include one or more bone screws, which in some embodiments comprise a shape memory material. In a particular embodiment, the elongate element has first and second end sections each with at least one hole adapted to receive a coupler therethrough to couple the element to the bone. Other embodiments may use two, three, four, or more holes in one or both end sections to fixedly couple the device to the fractured bone.

[0010] The present invention further provides bone fixation systems. In one embodiment, the system includes an elongate element having a responsive zone of shape memory material, and a coupler adapted to couple the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone. In some embodiments, the system includes a removable clamp, with the clamp adapted to maintain the elongate element responsive zone in a desired position prior to coupling of the element to the bone, and may further be adapted to be removed from the elongate element after coupling of the element to the bone. In one aspect, the responsive zone is adapted to apply a desired pressure to the bone when the elongate element is coupled to the bone.

[0011] The present invention further provides methods of stabilizing a fractured bone. In one such embodiment, the method includes providing an elongate element, which may be a plate, a bone nail, a bone screw, or related devices. The elongate element has a responsive zone of a shape memory material, with the responsive zone adapted to apply a desired pressure to the bone when coupled thereto. The method includes coupling the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone.

[0012] In one aspect, the method includes applying a force to the elongate element to lengthen the responsive zone a desired amount, maintaining the element in the lengthened

PETITIONER ARTHREX
EX. 1004

position, coupling the element to the bone so that the lengthened responsive zone is positioned adjacent the fracture site, and releasing the elongate element. In some aspects, a clamp is used to maintain the element in the lengthened position. In this manner, the elongate element may be released by removing the clamp. As a result, the stress formed in the responsive zone can be applied to the bone to facilitate fracture site stability, healing, and the like.

[0013] In a particular aspect, coupling the elongate element to the bone includes attaching a first coupler to the element and to the bone on a first side of the fracture site, and attaching a second coupler to the element and to the bone on a second side of the fracture site. In this manner, the responsive zone is positioned adjacent the fracture site. In one aspect, the force applied to the elongate element to lengthen the responsive zone the desired amount corresponds to a desired compressive force to be applied to the fractured bone when the element is coupled thereto. Again, the shape memory material may be nitinol, or other shape memory materials compatible with the human body.

[0014] Additional embodiments and features are set forth in part in the description that follows, and in part will become apparent to those skilled in the art upon examination of the specification or may be learned by the practice of the invention. The features and advantages of the invention may be realized and attained by means of the instrumentalities, combinations, and methods described in the specification.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Fig. 1A is an overall view of a dynamic compression bone screw according to an embodiment of the present invention;

[0016] Figs. 1B and 1C are simplified views of steps for forming the dynamic compression bone screw depicted in Fig. 1A;

[0017] Figs. 2A-2C schematically depict the use of the dynamic compression bone screw of Fig. 1A for repairing a bone fracture;

[0018] Fig. 3A is a side view of the dynamic compression bone screw of Fig. 1A;

[0019] Figs. 3B and 3C are close-up views of the screw head and threaded portion, respectively, for the bone screw depicted in Fig. 3A;

PETITIONER ARTHREX
EX. 1004

[0020] Fig. 3D is a longitudinal cross-sectional view of the bone screw depicted in Fig. 3A;

[0021] Fig. 3E is a top view of the bone screw depicted in Fig. 3A;

[0022] Fig. 3F is an overall view of the bone screw depicted in Fig. 3A;

[0023] Fig. 3G is an overall view of a dynamic compression bone screw according to an alternative embodiment of the present invention;

[0024] Fig. 4 is an overall view of two bone fixation devices according to an embodiment of the present invention;

[0025] Fig. 5A is an overall view of the bone fixation device shown in Fig. 4;

[0026] Figs. 5B-5I are additional views of the fixation device shown in Fig. 5A, including a bottom view (Fig. 5A), a top view (Fig. 5B), a longitudinal cross-sectional view (Fig. 5C), a close-up bottom view of an expansive zone (Fig. 5D), an end view (Fig. 5E) and a side view (Fig. 5F);

[0027] Figs. 6A and 6B are overall views of a fixation device coupled to a bone having a fracture site;

[0028] Figs. 7A and 7B are exploded and assembled overall views, respectively, of a bone fixation system according to an embodiment of the present invention using the fixation device shown in Fig. 4;

[0029] Fig. 8 is an overall view of a bone fixation device according to an alternative embodiment of the present invention;

[0030] Figs. 9A and 9B are graphical views of material properties of bone fixation screws and devices according to an embodiment of the present invention; and

[0031] Figs. 10A and 10B are graphical depictions of characteristics of bone screws and fixation devices according to embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0032] It has been determined that when a bone is set and a compressive force is applied to the fracture fixation device, the force between the fragments ends decreases rapidly as a function of time. Ideally, the fixation device is able to maintain a compressive force, which will allow for the continuation of healing through reduction of the fracture gap, and stability

PETITIONER ARTHREX
EX. 1004

of the fracture gap. If this does not occur, a loss of compression may be followed by the lack of union and stability of the fracture site, which in turn reduces the healing. A fracture fixation device is put in place to stabilize the fracture site, however, if the compressive force is not present then micro-motion between the fracture ends may occur. This, in turn, may cause unnecessary resorption, which will lead to non-union of the bone or the presence of large voids. These reasons show the importance of a device to actively match the changes in the body, as well as have a similar response as bone.

[0033] Embodiments of the present invention include bone fixation devices, including plates, bone nails such as intramedullary nails, bone screws, and the like, that can provide sustained compression (spontaneous dynamic compression) across a bone fracture over time. The dynamic compressive forces are stable or generally stable as a function of bone surface resorption at the fracture site, facilitating improved bone healing and reducing non-union rates. Some bone fixation devices of the present invention will allow for approximately six percent (6%) relaxation before compressive force loss. In contrast, typical stainless steel or titanium bone screws lose their compressive forces after about one percent (1%) resorption at the fracture surface.

[0034] Figs. 1A-2C depict a dynamic compression bone screw 100 according to an embodiment of the present invention. Bone screw 100 shown in Fig. 1A is further described in conjunction with Figs. 3A-3F. In a particular embodiment, bone screw 100 is formed from nickel titanium, a shape memory alloy referred to as Nitinol. As shown in Fig. 1B and 1C, screw 100 is formed from a Nitinol stock or block, and may be heat treated to produce desired characteristics. Shape memory alloys, such as Nitinol, exhibit the capacity to recover relatively large strains (e.g., about 6%) by the application of heat (shape memory) or by gradual unloading (pseudo-elasticity). The present invention exploits the large strain capacity and recovery behavior of shape memory alloys such as Nitinol for bone repair with novel devices, systems, and methods. In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature. The overall screw geometry, responsive element geometry, and material heat treatment will be specified to sustain the necessary compressive forces as a function of fracture site conditions.

[0035] The shape memory effect of Nitinol is the temperature-induced transformation between the malleable martensite (lower temperature) phase and the more rigid austenite

PETITIONER ARTHREX
EX. 1004

phase (higher temperature) that exhibits the desired pre-set shape. Exploitation of the thermally driven phase change helps some embodiments of the present invention deliver desired bone fixation results. Superelastic effect of Nitinol refers to the return to its pre-set austenite configuration upon unloading after elastic deformation. The initiation of superelastic behavior of Nitinol requires the formation of stress induced martensite (SIM) from the austenite phase, such as by the application of an external load or stress. Reduction of the external load or stress induces formation of the austenite phase and hence its pre-set configuration. SIM Nitinol is able to accumulate large deflection (strain) at a nearly constant load (stress). The relatively flat region of the Nitinol load-to-deflection relationship can be used for some devices of the present invention.

[0036] Some embodiments of the present invention take advantage of the stress/strain (modulus) of NiTi, depicted in Fig. 9A. Such characteristics of NiTi are beneficial in the development and use of improved total joint implants, for example. This property of NiTi decreases overall bone to implant interface stresses, resulting in a longer implant lifetime. Embodiments of the present invention, particularly those using NiTi, help the bone maintain load, which increases healing and helps smaller implants to maintain the same or similar stability as larger ones in similar areas of fixation by reducing stress/strain and sheering forces.

[0037] Formation of SIM phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement. For the bone screws 100 depicted in Fig. 1A, the responsive zone of screw will be designed to initiate SIM formation as a result of the installation process. This occurs, at least in part, due to the elongating forces applied to the screw when the screw is used. Additional details on the responsive zone are discussed in conjunction with Figs. 3A-3F.

[0038] One technique for fracture fixation is the placement of a lag screw across the appositional ends of a break in the bony cortex. Inserting the screw across the fracture site helps generate the dynamic force capacity in the screw. As shown in Fig. 2A, bone screw 100 is inserted at an angle relative to a fracture site 210. Screw 100 is rotated to draw the two bone fragments 220 towards one another, creating a compressive force therebetween. The rotational torque used to turn screw 100 is translated into axial compression between bone fragments 220. The result is the proper alignment of bone fragments 220 as shown in Fig.

PETITIONER ARTHREX
EX. 1004

2B. Screw 100 maintains a compressive force on bone fragments 220 for a much longer period of time than traditional bone screws formed of steel, titanium, or the like. As a result, a more fully healed fracture site 210 results (Fig. 2C). During healing and bone absorption, the force generated by prior-art screws can decrease leaving a less compressive force acting across the fracture site 210 over time. In contrast, bone screws 100 of the present invention are a dynamic screw that can maintain higher compression values over a longer course of healing. Advantages of screw 100 includes better promotion of direct bone healing, reduction in non-union rates in high risk fracture sites, and a reduction in bone implant site resorption. In some embodiments, at least some of these advantages are achieved by the use of a shape memory material, such as Nitinol, and its inherently similar stress/strain properties to those of bone.

[0039] Fig. 3A-3F depict further details on bone screw 100 according to an embodiment of the present invention. It will be appreciated by those skilled in the art that Figs. 3A-3F depict a particular example, and the present invention is not limited to the dimensions and configurations shown therein. As can best be seen in Figs. 3A, 3D, and 3F, bone screw 100 has a shank portion 110 with a diminished thickness or radius compared to the radius or thickness of a threaded portion 120 or of a head 130. In this manner, the reduced area of shank portion 110 allows for a stress concentration to be localized over shank portion 110, which allows shank portion 110 to elongate to form a responsive element or zone. In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in Fig. 2B. By using the responsive element or shank portion 110, bone screw 100 is able to localize the force caused by the SIM over the fracture site. The non-responsive screw portions, such as head 130, stays generally strain-free and contributes little force to the bone due to SIM.

[0040] In an alternative embodiment, a bone screw 300 depicted in Fig. 3G has a generally uniform diameter through a shank portion 310. In this embodiment, only shank portion 310 is formed of a shape memory material, with threaded end portion 320 comprising a stiffer region less susceptible to elongation.

[0041] Turning now to Fig. 4, a bone fixation device 400 according to an embodiment of the present invention will be described. Bone fixation device 400 allows for a longer and greater sustained compressive force. For example, current bone plates applied to a fractured surface tend to lose compressive force within two days to two weeks after surgery, thus

PETITIONER ARTHREX
EX. 1004

slowing the healing process. Additional problems with prior-art plates, such as deflections and rigidness, also result in a greater chance of refracture and slow healing. In one embodiment of the present invention, bone fixation device 400 comprises a shape memory alloy, that may be Nitinol or the like. Fixation device 400 is a dynamic device that can change over time with the human body into which it is inserted. In a preferred embodiment, device 400 comprises Nitinol, due in part to its capacity to recover large strains over time. In one embodiment, this is accomplished through the creation of device 400 having a responsive zone section 410. In some embodiments, responsive zone 410 has a smaller overall cross-sectional area than the non-responsive zone(s) of device 400. Responsive zone 410 is used to localize the elongation of device 400 to that area. In one embodiment, device 400 is elongated based on the application of a force similar to or the same as the force required to stabilize the fracture to which device 400 is applied. Device 400 will be elongated based on the force required to stabilize the fracture and apply the necessary healing force. After device 400 has been elongated, in one embodiment it is held in an elongated state by an external clamp or similar structure to prevent recovery motion of device 400. After device 400 is affixed to the fracture site, the clamp, or other retaining mechanism can be removed. Further details on the use of device 400 are discussed in conjunction with Figs. 7A and 7B.

[0042] Figs. 5A-5I depict various views of device 400 or portions of device 400, according to particular embodiments of the present invention. Again, the dimensions, including the lengths, widths, thicknesses and radii of curvature, may vary within the scope of the present invention from those shown in the figures. More specifically, the figures include a longitudinal cross-sectional view (Fig. 5C), a top view (Fig. 5B), a bottom view (Fig. 5A), a side view (Fig. 5F), an end view (Fig. 5E), and a close-up bottom view of expansive zone 410 (Fig. 5D), of device 400. In a preferred embodiment, device 400 is coupled to a bone having a fracture site so that responsive zone 410 is disposed adjacent the fracture site. This arrangement can be seen in Figs. 6A and 6B.

[0043] As shown, device 400 has one or more holes 430 disposed on each side of responsive zone 410 so that device 400 may be coupled to a fractured bone 600. While Figs. 6A and 6B depict four holes 430 on each side of the fracture site, a greater or lesser number of holes 430 may be used within the scope of the present invention. In some embodiments, holes 430 are adapted to receive a screw or other fixation element to affix device 400 to bone 600. The coupling of device 400 to bone 600 preferably positions responsive zone 410 across or adjacent a bone fracture site 610. This may involve attaching one end of device 400 to one

PETITIONER ARTHREX
EX. 1004

bone segment 620 and the second end of device 400 to the opposing bone segment 620. In some embodiments, the screw or fixation element used to couple device 400 to bone segment 620 comprises a bone screw, which may be made of stainless steel, titanium or the like. In a particular embodiment, screws or fixation elements used to coupled device 400 to bone 600 comprise a shape memory alloy, such as Nitinol.

[0044] Figs. 7A and 7B depict a bone fixation system 700 according to an embodiment of the present invention. System 700 includes fixation device 400 as previously described, and a clamp 710. While Fig. 7A depicts a single example of clamp 710, other clamp types fall within the scope of the present invention. Further, alternative devices may be used in lieu of clamp 710, provided the alternative devices are capable of attaching to device 400, and preferably are capable of holding device 400 in a desired position or elongated state. In operation, an elongating force is applied to device 400 to stretch or elongate device 400 to a prescribed length. As described further below, the application of the prescribed force is determined at least in part by the necessary force to provide healing effect to the bone to which device 400 will be applied. Once device 400 is elongated to the desired length, clamp 710 is used to maintain device 400 in the elongated position. Clamp 710 maintains the elongated position of device 400 until device 400 is attached to the fractured bone. Once device 400 is attached to the fractured bone, clamp 710 may be removed from device 400. In this manner, device 400 is attached to the fractured site and, upon the release of clamp 710, device 400 provides the desired compressive force through the fractured location. Again, in some embodiments device 400 comprises a shape memory material, and in a particular embodiment comprises Nitinol. Preferably, the application of the compressive force is of sufficient duration to facilitate healing as well as to avoid some or all of the other problems associated with prior-art devices constructed of stainless steel, titanium, or similar materials.

[0045] In the depicted embodiment, clamp 710 comprises a main component 712, first and second device-engaging components 714, and a wedge element 716. In one embodiment, device-engaging components 714 are disposed so that screws, lugs, posts or the like 718 extending from components 714 pass at least partially through corresponding holes 430 in device 400. Main component 712 is then coupled to device-engaging components 714 with wedge element 716 positioned therebetween. By rotating or depressing a pressure applicator 720, which in one embodiment is a screw, a force is applied to wedge 716. The application of a force to wedge 716 in the direction shown by arrow 722 causes an outward force to be applied to components 714, as shown by arrows 724. As can be seen in Fig. 7A, the force

PETITIONER ARTHREX
EX. 1004

depicted by arrows 724 results in an elongating force being applied to device 400 through the use of screws, lugs, or posts 718. By controlling the physical relationship between pressure applicator 720 and components 714, the elongating force to device 400 may be controlled. The coupled configuration of clamp 700 with device 400 is generally depicted in Fig. 7B.

[0046] In another embodiment, a separate device or system is used to apply the elongating force to device 400. This may occur, for example, by pulling on opposing ends of device 400 to create an elongating force similar to that represented by arrows 724. Once device 400 has been elongated the desired amount, clamp 710 may be coupled to device 400 in the manner substantially as described above to hold device 400 in the elongated position. In this embodiment, pressure applicator 720 is operated so that the screws, lugs, or posts 718 engage holes 430 to hold device 400 in its desired elongated state. Again, device 400 is then coupled to bone 600, which preferably positions responsive zone 410 across or adjacent bone fracture site 610. This may involve attaching one end of device 400 to one bone segment 620 and the second end of device 400 to the opposing bone segment 620. Once device 400 is coupled to bone 600, clamp 700 is removed.

[0047] The present invention further provides bone fixation rods, nails and the like. In one embodiment, a bone fixation rod or nail 800 has a first end 810 and a second end 812, with a middle section 814 disposed therebetween. In one embodiment, some or all of rod 800 comprises a shape memory alloy, that in a preferred embodiment comprises Nitinol. For example, in one embodiment, middle section 814 comprises Nitinol. In this manner, middle section 814 is a responsive zone having the characteristics as generally described herein. In another embodiment, one or both of first end 810 and second end 812 comprise Nitinol. In still another embodiment, the entire rod 800 is Nitinol.

[0048] In one embodiment, rod 800 is a dynamic intramedullary nail. Such a device may be used, for example, in retrograde tibio-talo-calcaneal fusions. Nail 800 addresses fracture site compression problems, as described generally herein in conjunction with prior embodiments, as well as vascular preservation issues. For example, rod 800 may provide dynamic compression across a fusion site in a manner which allows for the use of smaller rods 800, or nails. By having a smaller diameter rod or nail 800 compared to prior art nails of titanium or the like, this would aid in preserving the medullary blood supply.

[0049] As shown in Fig. 8, rod or nail 800 is inserted into a bone 850. Rod 800 insertion occurs, in one embodiment, by reaming the bone's medullary canal, and hammering or

PETITIONER ARTHREX
EX. 1004

otherwise driving nail 800 into place. Nail 800 then may be locked relative to the bone with one or more interference or locking screws 820. While the embodiment shown in Fig. 8 depicts a single screw 820 near end 810 and two screws 820 near end 812, it will be appreciated by those skilled in the art that the number of screws 820 may vary within the scope of the present invention. Further, the interference or locking screws 820 may comprise nails, pins or the like. The dimensions of rod 800 and screws 820, including the lengths, widths, diameters, and thicknesses, may vary within the scope of the present invention and may determined, at least in part, by the particular bone(s) and/or joint(s) into which the device is being inserted or otherwise coupled.

[0050] In some embodiments, nail or rod 800 is designed to allow for the release of the responsive element or zone portion thereof, allowing the rod or nail 800 to shorten. This is accomplished, at least in part, by having the responsive zone of rod 800 comprise a shape memory alloy such as Nitinol as described above in conjunction with screw 300. In this manner, the release of the responsive element-portion of nail 800 draws locking screws 820 on opposing sides of the responsive zone closer together. Dynamic compression on bone 850 results. In one embodiment, the responsive zone, which may include ends 810, 812 and/or middle section 814, is positioned at a desired location(s) within bone 850 or joint 860 to facilitate bone healing. For example, the responsive zone may be positioned adjacent or spanning a fracture site within bone 850, may be positioned within a joint 860, or at other locations at which increased and/or sustained dynamic pressure is desired.

[0051] Bone fixation devices of the present invention, including nails 800, screws 300 and plates 400, may be inserted with one or more sets of instrumentation that also are included within the scope of the present invention. For example, the instrumentation for implantation may be comprised of screws and plates, hammers or other compression devices, clamps or other holding devices, torsion devices such as screwdrivers, torque wrenches or the like for inserting screws, rods and plates. In one embodiment, a torque wrench is provided having a preloaded setting that allows the surgeon to determine whether the screw 300 pseudo elasticity has been activated upon insertion at the fracture site.

[0052] Figs. 9A depicts the stress-strain diagram for living tissues and a nickel titanium alloy. Nickel titanium, and in particular Nitinol, exhibits desirable strain recovery characteristics. The temperature at which Nitinol recovers is known as the transformation temperature (T_t). The transformation temperature may be determined using various heat

PETITIONER ARTHREX
EX. 1004

treatments on the material. The material then may demonstrate pseudo elastic (PE) and shape memory (SM) properties, depending at least in part on the relationship between T_t and the surrounding temperature T_a (e.g., atmospheric temperature, internal body temperature, or the like). The PE state is observed when T_a is greater than T_t. When the material is stretched from an applied force, a permanent strain is observed. When the force is removed, the material recovers the strain. The SM state occurs when T_t is greater than T_a. The material is deformed at above T_a, and remains deformed until a temperature is applied which is above T_t. These characteristics are useful for fashioning fixation devices according to some embodiments of the present invention. Fig. 9B depicts the inventors experimental results showing the affect of total strain on the unloading profile of SIM Nitinol.

[0053] The force that the physician wants to place over fracture site 210 or 610 with screw 100, nail 800, plate 400 or other fixation devices within the scope of the present invention can be defined as F_R. The physician also can determine the anticipated change in length (ΔL) of relaxation/resorption needed to maintain the stability in the fracture. This may involve determining the distant or amount the bone and/or surrounding tissues will relax during the healing period. From this information the cross sectional area and length of a bone fixation device, such as screw 100, nail 800 and/or device 400 can be calculated, respectively.

[0054] Using equation (1) below, the cross sectional area can be calculated. Using equation (2) below, the total length of the responsive element can be calculated. In these equations, A is the cross-sectional area, F_R is the physician-specified recovery force, σ_R is the tensile recovery stress (a material property), L is the length of the responsive zone or element, ΔL is the physician-specified change in length of the responsive zone or element, and ϵ is the tensile strain (a material property). The total length and cross sectional area are used for the manufacturing of the plate or screw in order to meet the physician's needs. Figs. 10A and 10B show an example of possible areas and length, that can be determined by the physician.

$$A=F_R/\sigma_R \qquad (1) \qquad\qquad L=\Delta L/\epsilon \qquad (2)$$

[0055] The responsive element or responsive zone, in a preferred embodiment, has a smaller cross sectional area than the non-responsive part. This reduction of the area allows for the stress concentration to be localized over the element or zone, which in turn elongates only the responsive element or zone. By using the responsive element or zone, the application is able to localize the force caused by the Stress Induced Martensite (SIM) over

PETITIONER ARTHREX
EX. 1004

the fracture, while the non-responsive element stays generally strain free and contributes minimal forces to the bone due to SIM.

[0056] Several devices and systems of the present invention are developed from a Shape Memory Alloy (SMA) to actively respond to the changes of the human body, especially in the bone response. In some embodiments, the inventors studied and used the SMA nickel titanium, or Nitinol. NiTiNOL is biologically compatible with the endoskeleton structure, as well as being strong and durable. Several embodiments of the present invention harness the material characteristics of NiTiNOL.

[0057] The below discussion covers the steps to manufacture a dynamic compression bone screw, nail, bone fixation device or plate, and other active devices from NiTiNOL, and the machining of NiTiNOL devices. A brief description of the heat treating, composition and deformation techniques used will be addressed. It will be appreciated by those skilled in the art that the manufacturing techniques described represent just some of the embodiments of the present invention.

Material Preprocesses

[0058] It is desirable to develop an accurate stress strain response for various states of the NiTiNOL. Below are the steps used to characterize a particular composition of an SMA of NiTiNOL according to an embodiment of the present invention:

1. Bars of Hot Rolled Ti-50.9% at %Ni, and Cold Drawn Ti-50.9% at.%Ni. were obtained from Special Metals.

2. The materials are cut into desired bone plate, nail and screw shapes from the bars using Electro Discharge Machining (EDM). This process allowed for the presence of mechanical work to be minimal in the samples. The specimens were cut into dog bone samples for tension and rectangular blocks for compression. All tests are run in monotonic strain control.

3. Various heat treatments were applied to the Hot Rolled Material, based on the use of Ti_3Ni_4 precipitants to move the Martensite start (M_s) and finish (M_f) temperatures, as well as the Austenite start (A_s) and finish temperatures (A_f). The results were determined through the transformation peaks being observed using a Differential Scanning Calorimeter.

PETITIONER ARTHREX
EX. 1004

4. The various stress-strain responses were examined with regard to heat treatment. This allows for certain characteristics to be harnessed in the design. The uses of various heat treatments allow for the stress recovery and strain recovery to be changed.

5. Using the material response in its loaded condition, a cross sectional area is designed as briefly discussed in conjunction with Figs. 10A-10B.

Bone Screw/Nail

[0059] Some embodiments of bone fixation devices of the present invention are developed to actively adapt to the resorption across the fracture site. One such bone screw manufacturing process according to the present invention is provided below. The manufacture of other fixation devices within the scope of the present invention follow a similar or same process.

1. Using the manufacturing results 1-5 above, the actual design of the responsive element or responsive zone can be determined. The specific calculations of the responsive element for the bone screw are discussed briefly in conjunction with Figs. 10A-10B, and in more detail in Provisional Application No. 60/563,952, previously incorporated herein by reference.

2. The bars of NiTiNOL are sent to be EDM into smaller cylindrical sections. At this time, no heat treatment has been applied and the material is said to be in its as-received state.

3. The smaller cylinders are heat treated for about 600°C for about 30 minutes, which in turn reduces the hardness and places the material in a state more susceptible to machining.

4. The screw is machined, such as on a lathe, at a cutting speed similar to stainless steel (e.g., about 300 RPMs). Concurrently, the NiTiNOL is flooded with cutting fluid to reduce the work hardening effects of the cutting surface.

5. After machining, the final part is heat treated to the appropriate temperature based on the material characterization and design phase, listed above. In a particular embodiment, the heat treatment related to the material composition of 50.9 is about 350°C for about 1.5 hours.

PETITIONER ARTHREX
EX. 1004

6. The screw is autoclaved and deployed. The reactive element is stretched using the principle of the screws head and threads.

Bone Fixation Device or Plate

[0060] Use of a bone fixation device or a bone plate may be necessary to add a large area of stabilization over the fracture site. The device or plate may be used in unison with a bone screw. The bone fixation device or plate actively adapts to the resorption of a fracture site and compensates for the resorption located at the head and threads of the screws. Below are the instructions used to develop a NiTiNOL bone plate according to an embodiment of the present invention.

1. Using the manufacturing results 1-5, the actual design of the responsive element can be determined. The specifics of the responsive element are discussed briefly in conjunction with Figs. 10A-10B, and in more detail in Provisional Application No. 60/563,952, previously incorporated herein by reference.

2. Based on the type of fracture and amount of resorption expected, the final compressive force required for the plate to respond to the bone is designed using the stress / strain diagram.

3. The bars of the NiTiNOL are sent to be EDM into the final design of the plates. At this time, no heat treatment has been applied and the material is said to be in its as-received state.

   It is possible to use the above "softening" heat treatment to machine the plates on a mill. The smaller rectangles will be cut from the bar, and then heat treated at about 600°C for about 30 minutes, which in turn reduces the hardness and places the material in a more "machining friendly" state.

4. The plate has its oxide layer left from the EDM mechanically removed.

5. Based on the results of the material characterization stage, the as-received bone plates are heat treated to get the desired properties. Similar to the screw, the heat treatment related to the material composition of 50.9 is about 350°C for about 1.5 hours.

6. Once the application of the plate is known, it is stretched using an external device to a predetermined strain and held fixed in place with a brace.

PETITIONER ARTHREX
EX. 1004

7. The entire setup is then sterilized by autoclave and finally deployed over the fracture site.

Other NiTiNOL Devices Including a Responsive Element

[0061] Other devices can benefit from the use of NiTiNOL or other SMA in an active responsive element. For example an interlocking bone marrow nail can be formed. The design of the nail is similar to the screw, and encompasses a similar responsive element. The design comes from the characterization of the NiTiNOL as discussed herein. Still other devices that could incorporate the responsive element include an artificial disk replacement used in a patient's vertebra. The responsive element could be designed to allow different forces between particular vertebrae. For example, a person with a large upper torso has different stress contribution between the upper vertebrae and lower vertebrae, than a person with a smaller torso. Other uses of SMAs such as Nitinol also exist for creating actively responsive elements.

[0062] The invention has now been described in detail. However, it will be appreciated that the invention may be carried out in ways other than those illustrated in the aforesaid discussion, and that certain changes and modifications may be practiced within the scope of the appended claims. Accordingly, the scope of this invention is not intended to be limited by those specific examples, but rather is to be accorded the scope represented in the following claims.

PETITIONER ARTHREX
EX. 1004