8434512

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

November 22, 2023

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APPLICATION NUMBER: ***18/058,058***
FILING DATE: ***November 22, 2022***
PATENT NUMBER: ***11771561***
ISSUE DATE: ***October 03, 2023***

Certified by

Kathi

Performing the Functions and Duties of the
Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

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

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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: 20995

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):

Shoulder Innovations, 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 below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Robert Ball		
Title	Chairman		

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

☑ Total of 1 forms are submitted.

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

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

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7
708
704
714
706
720
722
724

Figure 8

FIG. 8A

FIG. 8B

FIG. 8C

Fig. 8D

Fig. 8E

Fig. 8F

Fig. 8G

FIG. 8H

FIG. 8I

Fig. 8J

FIG. 8K

Fig. 8L

Fig. 8M

Fig. 8N

Fig. 8O

Fig. 8P

FIG. 8Q

FIG. 8R

Fig. 8S

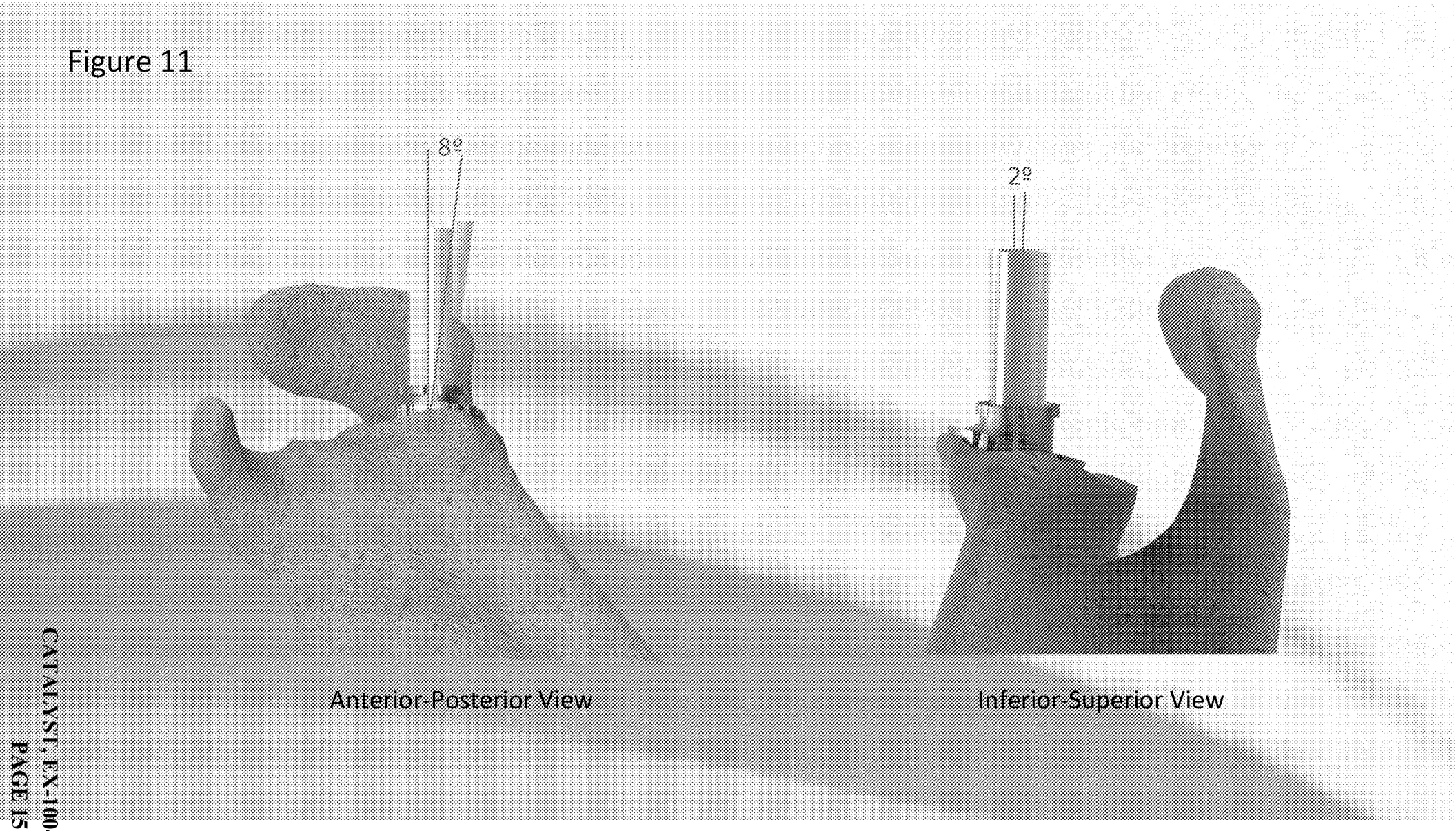
Fig. 8T

Fig. 8U

Figure 9

Figure 10

Figure 11



CATALYST, EX-1004
PAGE 15

Figure 12

Figure 13

Figure 14

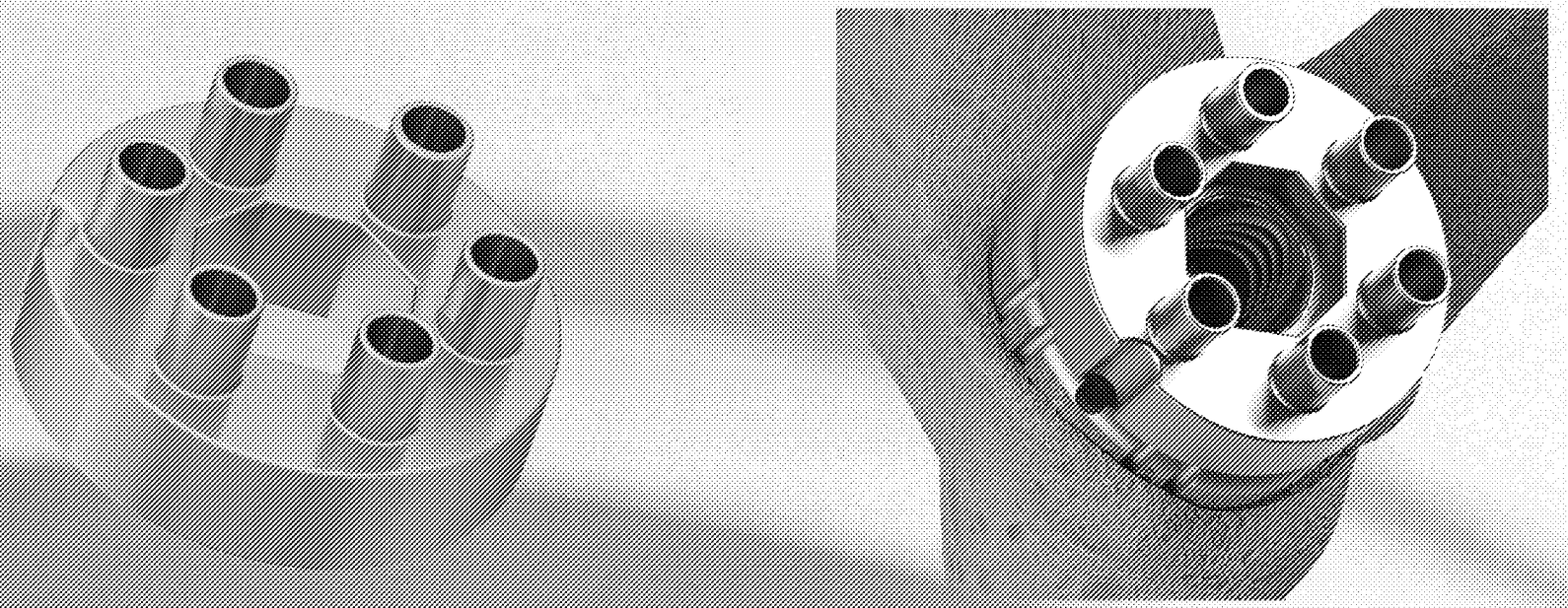


Figure 15

Figure 16

Figure 17

Figure 18

Figure 19

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

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

First Named Inventor:	Robert J. Ball	Nonprovisional Application Number (if known):	Unassigned
Title of Invention:	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS		

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

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

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

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

---OR---

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

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

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

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

Signature /Andrew Kimmel/	Date November 22, 2022
Name (Print/Typed) Andrew Kimmel	Practitioner Registration Number 58,855

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

☐ *Total of _____ forms are submitted.

Privacy Act Statement

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

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.

UNITED STATES
PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/058,058	11/22/2022 04:21:16 PM ET	SHOLD.013C1

Title of Invention

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5500	FILED BY	Aimee Kazan
PATENT CENTER #	61211452	AUTHORIZED BY	Andrew Kimmel
CUSTOMER #	20995	FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Donald E. Running

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 2549	E2022ALG23592392	Aimee Kazan

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
111410	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	70.00	1	70.00
2817	REQUEST FOR PRIORITIZED EXAMINATION	2100.00	1	2100.00
2111	UTILITY PATENT APPL. SEARCH FEE	350.00	1	350.00
4011	BASIC FILING FEE- UTILITY	80.00	1	80.00
2051	SURCHARGE- LATE FILING FEE,	80.00	1	80.00

	SEARCH FEE, EXAMINATION FEE, INVENTOR'S OATH OR DECLARATION, OR APPLICATION FILED WITHOUT AT LEAST ONE CLAIM OR BY REFERENCE			
2311	EXAMINATION OF ORIGINAL PATENT APPLICATION	400.00	1	400.00
			TOTAL AMOUNT:	**$3,080.00**

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.

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Donald	E.	Running	

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

City	State/Province	Country of Residence
Missoula	MT	US

Mailing Address of Inventor:

Address 1	13827 Port Sheldon Street
Address 2	
City	Holland
State/Province	MI
Postal Code	49424
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert	J.	Ball	

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

City	State/Province	Country of Residence
Holland	MI	US

Mailing Address of Inventor:

Address 1	13827 Port Sheldon Street
Address 2	
City	Holland
State/Province	MI
Postal Code	49424
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jason		Slone	

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

City	Silver Lake	State/Province	IN	Country of Residence	US

Mailing Address of Inventor:

Address 1	13827 Port Sheldon Street		
Address 2			
City	Holland	**State/Province**	MI
Postal Code	49424	**Country**	US

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

Correspondence Information:

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

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

Customer Number	20995		
Email Address	efiling@knobbe.com	Add Email	Remove Email

Application Information:

Title of the Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS		
Attorney Docket Number	SHOLD.013C1	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	21	**Suggested Figure for Publication (if any)**	

Filing By Reference:

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

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

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

Publication Information:

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

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

Representative Information:

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

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	20995		

Domestic Benefit/National Stage Information:

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	17/435333	2021-08-31
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17/435333	a 371 of international	PCT/US2020/022094	2020-03-11
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2020/022094	Claims benefit of provisional	62/816708	2019-03-11

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

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

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

Remove

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

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

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

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

Applicant Information:

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

Applicant 1 — Remove

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	SHOULDER INNOVATIONS, INC.		
Mailing Address Information For Applicant:			
Address 1	13827 Port Sheldon Street		
Address 2			
City	Holland	**State/Province**	MI
Country	US	Postal Code	49424
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

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

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
	Application Number	
Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

Assignee 1

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	SHOLD.013C1
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Title of Invention	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

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TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

BACKGROUND

[0001] This application is a continuation of U.S. Application No. 17/435,333, filed August 31, 2021, which is the national phase of International Application No. PCT/US2020/022094, filed March 11, 2020, which claims the benefit of priority from U.S. Provisional No. 62/816,708, filed March 11, 2019, which are all hereby incorporated by reference in their entireties.

[0002] Shoulder replacement is a commonly performed medical procedure for treatment of osteoarthritis, rheumatoid arthritis, as well as for treatment of certain deformities related to oncological indications as well as trauma. There are two primary types of articulations available to surgeons for treatment: anatomic and reverse. With anatomic, the surgeon replaces the articular surfaces with industrial materials such that the articulating surfaces are substantially the same shape as the natural anatomy. A stem can be commonly fixed inside the canal of the humerus, a metallic articular head can be rigidly fixed to the proximal aspect of the same, the articular head having a convex articular surface adapted to articulate with the glenoid implant. The glenoid implant can include on its back side (medial side) certain pegs or posts or fins adapted to be rigidly fixed within the glenoid fossa of the scapula and on its front side a concave or flat articular surface adapted to articulate with the humeral head of the humeral implant.

[0003] When a reverse prosthesis is used, the articular surface is reversed in that the metallic ball is rigidly fixed to the glenoid fossa of the scapula, and the concave articular surface is rigidly fixed to the humeral bone, thereby reversing the fashion of articulation of the prosthesis.

[0004] The surgeon chooses between the two types of prostheses by assessing a number of conditions of the patient including level of pain, patient activity level, deformity or severity of the boney degradation, the strength of surrounding soft tissues, and present or absence of prior surgery, and particularly the health and strength of the rotator cuff muscle and tendon. Disease of the rotator cuff is common among patients with arthritis of the shoulder. In

this circumstance, it is commonly observed that the absence of insufficiency of the rotator cuff leads to a condition where the anatomic shoulder replacement prosthesis is not sufficiently stabilized by surrounding soft tissue. In this case, a reverse shoulder replacement prosthesis can be preferred in some cases due to the higher inherent stability of the articulation. In addition, the reverse prosthesis can advantageously utilize the remaining muscles in a way they can be more effective in the absence of the other soft tissue structures by adjusting the position of the articular surfaces within the joint.

SUMMARY

[0005] In some embodiments, disclosed herein is a reverse shoulder system, comprising any number of a glenoid baseplate comprising a longitudinal axis, the glenoid baseplate further comprising a stem and a central channel within a sidewall of the stem, the stem comprising a longitudinal axis. The longitudinal axis of the glenoid baseplate can be angled with respect to the longitudinal axis of the stem, wherein the longitudinal axis of the glenoid baseplate is not perpendicular with respect to the longitudinal axis of the stem.

[0006] In some configurations, the glenoid baseplate comprises a generally disc-shaped portion extending radially outward from the central channel.

[0007] In some configurations, the stem comprises a sidewall that extends superiorly with respect to the disc portion.

[0008] In some configurations, the glenoid baseplate comprises a peripheral edge.

[0009] In some configurations, the peripheral edge comprises spaced-apart anti-rotation features.

[0010] In some configurations, the anti-rotation features comprise slots.

[0011] In some configurations, an inferior portion of the peripheral edge comprises a porous coating.

[0012] In some configurations, an inferior surface of the generally disc-shaped portion comprises a porous coating, but a superior surface does not comprise a porous coating.

[0013] In some configurations, the peripheral edge and/or an inferior surface of the baseplate comprises a conical geometry.

[0014] In some configurations, an inferior surface of the baseplate is concave.

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[0015] In some configurations, the stem comprises a Morse taper lock superior to a superior-most portion of the generally disc-shaped portion of the glenoid baseplate.

[0016] In some configurations, the system further comprises a glenosphere.

[0017] In some configurations, the glenosphere comprises a superior dome-shaped surface comprising a rotational control feature configured such that an inserter tool can lock the glenosphere and the baseplate to allow for rotation of the glenosphere and the baseplate together.

[0018] In some configurations, the rotational control feature comprises a spline.

[0019] In some configurations, the system further comprises a central set screw and locking nut.

[0020] In some configurations, the system further comprises a central compression screw non-integral with the baseplate and configured for placement adjacent and distal to the central set screw.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] These drawings are illustrative embodiments and do not present all possible embodiments of this invention.

[0022] FIG. 1 illustrates an embodiment of components of a total reverse shoulder system.

[0023] FIG. 2 illustrates various embodiments of humeral trays that can be utilized with total reverse shoulder systems, according to some embodiments.

[0024] FIG. 3 illustrates a variety of humeral bearing components that can be utilized with total reverse shoulder systems, according to some embodiments.

[0025] FIG. 4 illustrates schematically an embodiment of a glenoid baseplate configured to be inset into the glenoid.

[0026] FIG. 5 illustrates schematically an embodiment of a glenoid baseplate 500 configured to be inset into the glenoid.

[0027] FIG. 6 illustrates a threaded locking insert for a central channel of a stem/post, according to some embodiments.

[0028] FIG. 7 illustrates various views of glenospheres, according to some embodiments.

[0029] FIG. 8 illustrates a schematic cross-section of a fully assembled glenosphere with a locking bolt, according to some embodiments.

[0030] FIGS. 8A-8U illustrate a glenoid surgical technique, according to some embodiments.

[0031] FIG. 9 illustrates an embodiment of a sizer/angle guide.

[0032] FIG. 10 illustrates an embodiment of a stem drill guide.

[0033] FIG. 11 schematically illustrates a stem angle change with a rotational adjustment.

[0034] FIG. 12 schematically illustrates views of a glenoid baseplate inserter (alone on the left and together with a baseplate on the right), according to some embodiments.

[0035] FIG. 13 schematically illustrates views of a calibrated central drill, according to some embodiments.

[0036] FIG. 14 schematically illustrates views of fixed angle peripheral drill guides, according to some embodiments.

[0037] FIG. 15 schematically illustrates views of variable angle peripheral drill guides, according to some embodiments.

[0038] FIG. 16 schematically illustrates side and top views of central screws, according to some embodiments.

[0039] FIG. 17 schematically illustrates side and top views of fixed angle peripheral compression screws, according to some embodiments.

[0040] FIG. 18 schematically illustrates side and top views of variable angle peripheral screws, according to some embodiments.

[0041] FIG. 19 schematically illustrates views of a glenosphere inserter, according to some embodiments.

DETAILED DESCRIPTION

[0042] In some embodiments, disclosed herein are various embodiments of a total reverse shoulder system, including a variety of humeral trays, humeral bearings, inset glenoid baseplates, threaded locking inserts, and glenospheres. Glenoid surgical techniques are also described, which can utilize various tools including but not limited to sizer/angle guides, stem drill guides, glenoid baseplate inserters, calibrated central drills, peripheral drill guides with

fixed or variable angles, central screws, fixed angle peripheral compression screws, variable angle peripheral screws, and glenosphere inserters. Dimensions listed on the accompanying Figures are non-limiting examples only.

[0043] FIG. 1 illustrates an embodiment of components of a total reverse shoulder system, including a glenosphere 200 and a glenoid baseplate 102 which can be partially or completely inset in some embodiments. The glenoid baseplate 102 can be a generally disc-shaped structure and include a central aperture defining a surface of (e.g., integral with an elongate stem), or configured to fit an elongate stem or post therethrough. The glenoid baseplate 102 can include a longitudinal axis that is at an angle to a longitudinal axis of the elongate stem 100. The longitudinal axis of the glenoid baseplate 102 can be at an angle, such as generally oblique with respect to the longitudinal axis of the elongate stem 100. In some embodiments, the angle is an acute angle, and not a right angle. The angle between the two intersecting longitudinal axes of the respective baseplate 102 and the stem 100 could be, for example, about, at least about, or no more than about 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, or more or less degrees, or ranges including any two of the foregoing values.

[0044] FIG. 2 illustrates various embodiments of humeral trays that can be utilized with total reverse shoulder systems, according to some embodiments. The humeral trays can include various inner diameters IDs and outer diameters ODs, including 30mm, 32mm, 34mm, 36mm, 38mm, 40mm, 42mm, or more or less IDs and/or ODs, and ranges including any two of the foregoing values. The trays can include one or more pegs, such as a central peg extending from a medial surface. The trays can be neutral, or include extensions (e.g., in thickness) that can be, for example, +2, 4, 6, 8, 10, 12mm, or ranges including any two of the foregoing values. The trays can include various cross-sections, including oval or round cross-sections. The trays can be compatible with the same poly bearing surfaces in some cases. In some embodiments, a kit can include at least four different sizes of trays (34mm oval neutral; 34mm oval +6mm extension; 38mm round neutral; 38mm round +6mm extension.

[0045] FIG. 3 illustrates a variety of humeral bearing components that can be utilized with total reverse shoulder systems, according to some embodiments, including humeral trays as illustrated and described in connection with FIG. 2. The bearing components can include, for example, a peripheral ring 302 and a central recessed portion that can be

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outlined radially outwardly by an inner edge of the peripheral ring, and an inner bowl-shaped portion 304. The peripheral ring can include indicia, such as a slot or other marking 399 illustrating the highest point of the bearing component. Also illustrated is the recessed poly dome 395, and a partial or full annular barb 397 around the outer circumference of the bearing component. The bearing component can include a variety of geometries include neutral, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20 degree angles to horizontal, or ranges including any two of the foregoing values. In some embodiments, the bearing component does not change the joint center. In some embodiments, the bearing component can include 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45mm, or more or less spherical diameters, or ranges including any two of the foregoing values. In some embodiments, systems and methods can include an offset of 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10mm, or ranges including any two of the foregoing values.

[0046] FIG. 4 illustrates schematically an embodiment of a glenoid baseplate configured to be inset into the glenoid G as illustrated. The longitudinal axis of the baseplate can be angled with respect to the longitudinal axis of the stem/post as described, for example, with respect to FIG. 1, and can include a version change 499 to compensate for posterior bony defects. In some embodiments, the glenoid baseplate includes a central channel therethrough defining a surface of (e.g., integral with an elongate stem), or configured to fit configured to house a stem/post as shown. The glenoid baseplate can include a generally conical shape with a concave undersurface configured to rest within a reamed surface of glenoid bone, which advantageously allows for a single rotary reamer to be utilized, in contrast to conventional glenoid baseplates with flat undersurfaces that require a two-step reaming process. The post 493 can have a length of about, at least about, or no more than about 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15mm or more or less, or ranges including any two of the foregoing values. In some embodiments, the central channel and/or stem can include a female Morse taper 497 of about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more or less degrees, including ranges incorporating any two of the foregoing values. As shown in the right illustration of FIG. 4, the baseplate can be configured to pivot around the stem/taper at arrow 495 for version correction and to allow for a direct bone-implant interface without requiring augmentation. In some embodiments, the system can be configured to provide version angle corrections of, for example, about 0, 2.5, 5, 7.5, 10, 12.5, 15, 17.5, 20 degrees or more or less,

or ranges including any two of the foregoing values. In some embodiments, the baseplate could have a diameter of about, at least about, or no more than about 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40mm, or more or less, or ranges including any two of the foregoing values. The baseplate can advantageously pivot around the central stem with a Morse taper for version correction and allows for a direct bone-implant interface.

[0047] FIG. 5 illustrates schematically an embodiment of a glenoid baseplate 500 configured to be inset into the glenoid (not shown in FIG. 5). The longitudinal axis of the baseplate 500 can be angled with respect to the longitudinal axis of the stem/post 510 as described, for example, with respect to FIGS. 1 and 4 above. The baseplate 500 could have a generally arcuate peripheral edge. The peripheral edge could include spaced-apart anti-rotational slots 521 directed generally transverse to a longitudinal plane of the baseplate 500. In some embodiments, the peripheral edge of the baseplate 500 can taper (e.g., decrease) in diameter from a superior to inferior dimension. A central channel can extend through the baseplate 500, as well as include a superiorly-extending sidewall or lip 511 somewhat similar to the side slopes of a volcano. The central channel can define a surface of (e.g., integral with an elongate stem), or configured to fit be configured to house the stem/post 510 therethrough. The baseplate 500 can also include a plurality of regularly or irregularly spaced-apart secondary (peripheral) channels 555 spaced radially outward from the central channel of the baseplate and configured to house fixed and variable angle screws therethrough. The secondary channels 555 can be asymmetric and include superiorly-extending portions 556 that can extend into and interrupt the superiorly-extending sidewall or lip 511 of the central channel of the baseplate 500. The baseplate 500 can include a porous coating 585 on the entire, or only a part of the peripheral edge and/or an inferior surface (e.g., undersurface) of the baseplate 500 to promote bone ingrowth, for example.

[0048] Still referring to FIG. 5, the stem/post 510 could have an internal taper, such as a Morse taper, of about, at least about, or no more than about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 degrees, or more or less, or ranges including any two of the foregoing values. The stem/post 510 can also include a rotational control feature 545 along an outer diameter of the stem/post 510, and in some embodiments superiorly with respect to the uppermost surface of the sidewall 511 of the central channel of the glenoid baseplate 500 as shown. The rotational control feature 545 could be non-circular or non-arcuate, such as a hexagonal shape as shown

for example. The stem/post 510 can also include a central channel and include a Morse taper lock 535 configured to mate with a glenosphere (not shown). The Morse taper lock can extend superiorly with respect to the uppermost surface of the sidewall 511 of the central channel of the glenoid baseplate 500. The central channel of the stem/post 510 can be configured to house a primary screw (not shown) therethrough, which can be a variable angle primary screw, and optionally locking.

[0049] FIG. 6 illustrates a threaded locking insert 600 for a central channel of a stem/post, according to some embodiments. The insert 600 can include an outer male thread 602 and configured to go into the central channel of a baseplate. The outer diameter of the insert can also include a hexagonal geometry portion 604 at the superior end, of about, at least about, or no more than about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 mm or more or less, or ranges including any two of the foregoing values. The hexagonal geometry portion 604 can be configured to serve as a rotational control feature in some embodiments. The insert 600 can also include a female thread 608 configured to receive a supplemental glenosphere locking screw (not shown), and a spherical surface 612, for example, at its inferior end to lock a variable angle screw.

[0050] FIG. 7 illustrates various views of glenospheres, according to some embodiments. The left image illustrates a glenosphere with a rotational control feature 702, which can include a spline, such as an asymmetric spline, and configured to advantageously allow for rotational control about the spline and allow an inserter tool to lock and rotate the glenosphere together with another component, such as a baseplate. The glenosphere can also include one or more indicia, such as an eccentric rotational mark 704. The glenosphere can include a generally dome-shaped surface 714, a cavity 706 with an inferior-facing opening 708, and a hollow post including a morse taper lock 711 into the baseplate. The glenosphere could be a full hemisphere, or short of a full hemisphere by a distance 720 of about, at least about, or no more than about 0.5 mm, 0.75 mm, 1 mm, 1.25 mm, 1.5 mm, 1.75 mm, 2 mm, 2.25 mm, 2.5 mm, 2.75 mm, 3 mm, or more or less, or ranges including any two of the foregoing values.

[0051] Still referring to FIG. 7, in some embodiments, the glenosphere can include an articulating diameter of about, at least about, or no more than about 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50 mm, or more or less,

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or ranges including any two of the foregoing values. In some embodiments, systems and methods can include an offset and/or eccentric dimension of 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 mm, or ranges including any two of the foregoing values. In some embodiments, the glenosphere has a neutral geometry. In some embodiments, a glenosphere 724 is offset by about +3 mm or about 6 mm, for example. In some embodiments, a glenosphere 722 has an eccentric dimension of between about 2 mm and about 4 mm. In some embodiments, a secondary locking screw can be utilized together with the glenosphere.

[0052] FIG. 8 illustrates a schematic cross-section of a fully assembled glenosphere with a locking bolt, according to some embodiments, along with the baseplate. The glenosphere can include a central channel therethrough including a rotational control feature 702 at, for example, a superior-most portion that can be as described elsewhere herein. The central channel can also include a threaded surface 808 for an inserter/head extractor, such as inferior to the rotational control feature 702, and optionally be configured to accommodate a secondary locking screw at 810, to push and/or rotate with the post of the baseplate. A post of the glenosphere can be placed at least partially within a central channel of the baseplate as illustrated. A central set screw/locking nut 814 can be connected to, and in some cases removably attachable to a central channel, e.g., of the glenoid baseplate, and have an end adjacent or directly touching an end of a central compression screw 816, which can include a diameter of, for example, of about, at least about, or no more than about 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10 mm, or more or less, or ranges including any two of the foregoing values. The central compression screw can be configured to angulate with respect to the baseplate, and advantageously allow for the use of a locking screw.

[0053] Figures 8A-8U illustrate a glenoid surgical technique, according to some embodiments, which can include any number of the following actions. FIG. 8A illustrates a glenoid surface with an A3-E3 defect. A sizer/angle guide can be placed as in FIG. 8B. A wire guide/wire can be placed in FIG. 8C. The wire guide and sizer/angle guide can be removed, as in FIG. 8D. The glenoid surface can then be reamed for the baseplate, as in FIGS. 8E and 8F. The stem drill guide can then be placed and adjusted in FIG. 8G. A hole for a stem can then be drilled in FIGS. 8H and 8I. The baseplate can then be inserted, as shown in FIG. 8J, and the threaded rod removed, as shown in FIG. 8K. A central cavity can be drilled, and the length of a central screw to be placed determined, in FIG. 8L. The drill can be removed in FIG. 8M, and

the screw and screwdriver placed through the shaft, and the screw tightened in FIG. 8N. The baseplate inserter handle can be removed in FIG. 8O, and holes can be drilled for the peripheral locking screws in FIG. 8P. Holes can be drilled for variable angle screws, as shown in FIG. 8Q. The peripheral screws can be inserted and tightened in FIG. 8R. The central set screws and secondary locking nuts can be inserted and tightened in FIG. 8S. The glenosphere can be inserted in FIG. 8T, and the locking bolt inserted and tightened in FIG. 8U.

[0054] FIG. 9 illustrates an embodiment of a sizer/angle guide including an inferior tilt mechanism 902. The mechanism could be fixed to a set angle (e.g., about 0, 5, 10, 15, 20, 25 degrees, or ranges including any two of the foregoing values), or adjustable in some embodiments. The mechanism could be round or oval shaped in some embodiments, and include a slot (e.g., posterior or posterior inferior) to allow for removal. The inferior tilt mechanism 902 could include a set screw with a calibrated window, or individual depth screws in some cases.

[0055] FIG. 10 illustrates an embodiment of a stem drill guide, that can include a diameter of about, at least about, or no more than about 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 mm or more or less, or ranges including any two of the foregoing values. The drill guide could include a version angle of, for example, about 0, 5, 10, 15, 20, 25 degrees or more or less, or ranges including any two of the foregoing vales. In some embodiments, the larger the version angle, the more stem tilt is generated as rotation occurs.

[0056] FIG. 11 schematically illustrates a stem angle change with a rotational adjustment (e.g., about 30 degrees), and an angled version plate (e.g., about 15 degrees) as a non-limiting example. Anterior-posterior and inferior-superior views are illustrated.

[0057] FIG. 12 schematically illustrates views of a glenoid baseplate inserter (alone on the left and together with a baseplate on the right), according to some embodiments. The baseplate inserter can be configured for any number of: positive rotational control; slim design to allow visualization through screw holes to know when seated; and/or a multi-function handle allows for drilling central screw hole, and inserting a central screw.

[0058] FIG. 13 schematically illustrates views of a calibrated central drill, according to some embodiments. Calibrated marks/indicia 902 at spaced-apart desired increments (e.g., 5mm increments in some embodiments) near the proximal end of the

instrument can help to determine the length of a central screw that may be needed. The calibration length can start at, for example, about, at least about, or no more than about 15 mm, 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, or more or less, including any two of the foregoing values and may advantageously allow for a surgical step to be cut out.

[0059] FIG. 14 schematically illustrates views of fixed angle peripheral drill guides, according to some embodiments. The drill guides can be configured to fit over a geometry, such as a polygonal shaped portion (e.g., octagon) on the top of the baseplate, and the operator can then determine which fixed angle screws to drill.

[0060] FIG. 15 schematically illustrates views of variable angle peripheral drill guides, according to some embodiments.

[0061] FIG. 16 schematically illustrates side and top views of central screws, according to some embodiments, including a head 1601, threaded shaft 1602, and distal tapered portion. In one embodiment, the screw can have a 6.5mm head, and 6mm threaded shaft, although various size ranges and increments are possible, including about, at least about, or no more than about 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10 mm, or more or less head and/or threaded shaft diameters, or ranges including any two of the foregoing values. In some embodiments, a central screw can include a total or working length of about, at least about, or no more than about 10, 11, 12, 13, 14, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70 mm, or more or less, or ranges including any two of the foregoing values. In some embodiments, anodization of the screw can optionally be present to help differentiate the screws. The screw head could have various internal feature geometries 1603, including a T20 hexalobe configuration in some embodiments.

[0062] FIG. 17 schematically illustrates side and top views of fixed angle peripheral compression screws, according to some embodiments, including a head 1701, double-lead thread 1703 proximal to a threaded shaft 1702, and distal tapered portion. The screws can be various size ranges and increments, and include T20 hexalobe or other internal head feature geometries 1704 as described elsewhere herein. In one embodiment, the head could be about 5.7 mm in diameter, with a 4.5 mm threaded shaft diameter, or dimensions listed elsewhere herein, such as in connection with FIG. 16 for example.

[0063] FIG. 18 schematically illustrates side and top views of variable angle peripheral screws, according to some embodiments, including a head 1801, threaded shaft

1802, and distal tapered portion. The screws can be various size ranges and increments, and include T20 hexalobe or other internal head feature geometries 1803 as described elsewhere herein. In one embodiment, the head could be about 5.7 mm in diameter, with a 4.5 mm threaded shaft diameter, or dimensions listed elsewhere herein, such as in connection with FIGS. 16 or 17 for example.

[0064] FIG. 19 schematically illustrates views of a glenosphere inserter, according to some embodiments, which can include a distal end with a feature complementary to a spline on the glenosphere, such as described in connection with FIG. 7, for example. The glenosphere inserter can be configured to, for example, advantageously provide positive attachment to the glenosphere; allow for solid rotational control while inserting; and/or may involve a secondary impaction step after removal.

[0065] In some embodiments, embodiments of the invention can be used or modified with use with particular advantages of using inset glenoid fixation technology in anatomic shoulder arthroplasty, such as described, for example, in U.S. Pat. Nos. 8,007,538 and/or 8,778,028 to Gunther, which are hereby incorporated by reference in their entireties. Furthermore, embodiments of the invention can be used or modified with use with systems and methods as disclosed, for example, in U.S. Pub. No. 2018/0368982 to Ball, which is hereby incorporated by reference in its entirety.

[0066] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative

forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "insetting an implant into a glenoid cavity" includes "instructing the insetting of an implant into the glenoid cavity." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least," "greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

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PAGE 49

WHAT IS CLAIMED IS:

1. A reverse shoulder system, comprising:

a glenoid baseplate comprising a longitudinal axis,

the glenoid baseplate further comprising a stem and a central channel within a sidewall of the stem, the stem comprising a longitudinal axis,

wherein the longitudinal axis of the glenoid baseplate is angled with respect to the longitudinal axis of the stem, wherein the longitudinal axis of the glenoid baseplate is not perpendicular with respect to the longitudinal axis of the stem.

2. The system of Claim 1, wherein the glenoid baseplate comprises a generally disc-shaped portion extending radially outward from the central channel.

3. The system of Claim 2, wherein the stem comprises a sidewall that extends superiorly with respect to the disc portion.

4. The system of Claim 1, wherein the glenoid baseplate comprises a peripheral edge.

5. The system of Claim 4, wherein the peripheral edge comprises spaced-apart anti-rotation features.

6. The system of Claim 5, wherein the anti-rotation features comprise slots.

7. The system of Claim 4, wherein an inferior portion of the peripheral edge comprises a porous coating.

8. The system of Claim 1, wherein an inferior surface of the generally disc-shaped portion comprises a porous coating, but a superior surface does not comprise a porous coating.

9. The system of Claim 4, wherein the peripheral edge and/or an inferior surface of the baseplate comprises a conical geometry.

10. The system of Claim 1, wherein an inferior surface of the baseplate is concave.

11. The system of Claim 1, wherein the stem comprises a Morse taper lock superior to a superior-most portion of the generally disc-shaped portion of the glenoid baseplate.

12. The system of Claim 1, further comprising a glenosphere.

13. The system of Claim 12, wherein the glenosphere comprises a superior dome-shaped surface comprising a rotational control feature configured such that an inserter tool can lock the glenosphere and the baseplate to allow for rotation of the glenosphere and the baseplate together.

14. The system of Claim 13, wherein the rotational control feature comprises a spline.

15. The system of Claim 12, further comprising a central set screw and locking nut.

16. The system of Claim 15, further comprising a central compression screw non-integral with the baseplate and configured for placement adjacent and distal to the central set screw.

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

A reverse shoulder system can include, for example, a glenoid baseplate comprising a longitudinal axis, the glenoid baseplate further including a stem and a central channel within a sidewall of the stem. The stem can include a longitudinal axis. The longitudinal axis of the glenoid baseplate can be angled with respect to the longitudinal axis of the stem, wherein the longitudinal axis of the glenoid baseplate is not perpendicular with respect to the longitudinal axis of the stem. Other components including a glenosphere, tools, and methods of use are also disclosed.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/058,058	**11/22/2022 04:21:16 PM ET**	**SHOLD.013C1**

Title of Invention

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5500	FILED BY	Aimee Kazan
PATENT CENTER #	61211452	FILING DATE	-
CUSTOMER #	20995	FIRST NAMED INVENTOR	Donald E. Running
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Andrew Kimmel

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
SHOLD-013C1_ADS.pdf		9	Application Data Sheet	1227 KB
SHOLD-013C1_TRACK1.pdf		2	Track One Request	111 KB
SHOLD-013C1_POA.pdf		2	-	1122 KB
SHOLD-013C1_POA-TRAN.LET.pdf	(1-1)	1	Transmittal Letter	220 KB
SHOLD-013C1_POA-PA...pdf	(2-2)	1	Power of Attorney	970 KB
SHOLD-013C1_SPECIFICATION.pdf		16	-	82 KB

SHOLD-013C1_SPECIFICATION-SPEC.pdf	(1-13)	13	Specification	74 KB
SHOLD-013C1_SPECIFICATION-CLM.pdf	(14-15)	2	Claims	15 KB
SHOLD-013C1_SPECIFICATION-ABST.pdf	(16-16)	1	Abstract	11 KB
SHOLD-013C1_DRAWINGS.pdf		21	Drawings-only black and white line drawings	9695 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
SHOLD-013C1_ADS.pdf	3BF8D274D59A863B8C9EA6367B621A41893E137C1D48CE5B64B8A1A32C929B48DB668947694D6520177A6A01FCF7665B48E4A3E0992F27784E862E35344A35E0
SHOLD-013C1_TRACK1.pdf	37AA845D25CA36631482C1B408FFC1DDDBA05A73BC52DC258E6E044F3073CA6F854318608C2C48DFAB64F64F8B5D7BB021EE189C2A4A8833EFE7786AC888957C
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SHOLD-013C1_POA-PA..pdf	8BED6EA7CFE787EAD19AB23A9CBE9C550424D6C1946D3A19CC5C33D550529EA220D730932E0C383C847E4034348349E43F68163F9ACA401F1259DEB0BACFF5AE

SHOLD-013C1_SPECIFICATION.pdf	1B18C061A78CFA4D8B1826F4D6060997C468914F598B978F245C6B49C5DB85A22BE563F4BB32F3D90FF5F450E746031A0169BB42E21DC1565791BBC713AF32F6
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SHOLD-013C1_DRAWINGS.pdf	3BFADBB19D236D22F5FF9FAFF7FF3DF249BCD3F64EE1BEA23A49CAC5CC1F42E3852EE9123AF65E839747C246936DBBF974DB71E47AB21CEFD1B544F5CEAF4460

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 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

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

New International Application Filed with the USPTO as a Receiving Office

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

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

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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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	Unassigned
Filing Date	Herewith
First Named Inventor	Donald E. Running
Title	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	SHOLD.013C1

SIGNATURE of Applicant or Patent Practitioner

Signature	/Andrew Kimmel/	Date (Optional)	
Name	Andrew Kimmel	Registration Number	58855
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Shoulder Innovations, Inc.		

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 1 forms are submitted.

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

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/058,058	11/22/2022	Donald E. Running	SHOLD.013C1

CONFIRMATION NO. 5500

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

INFORMAL NOTICE

OC000000051618026

Date Mailed: 12/12/2022

INFORMATIONAL NOTICE TO APPLICANT

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

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

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

  Donald E. Running
  Robert J. Ball
  Jason Slone

  An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor must be submitted no later than the date on which the issue fee is paid in response to a notice requiring such fee. See 37 CFR 1.53(f).

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**.

/tgebre/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 18/058,058

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	16 minus 20 =	* 0	x =	0	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x =	0			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	830		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

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

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

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

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

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/058,058	11/22/2022		910	SHOLD.013C1	16	1

CONFIRMATION NO. 5500

FILING RECEIPT

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

OC000000051618023

Date Mailed: 12/12/2022

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Donald E. Running, Missoula, MT;
Robert J. Ball, Holland, MI;
Jason Slone, Silver Lake, IN;

Applicant(s)

SHOULDER INNOVATIONS, INC., Holland, MI;

Power of Attorney: The patent practitioners associated with Customer Number 20995

Domestic Priority data as claimed by applicant

This application is a CON of 17/435,333 08/31/2021
which is a 371 of PCT/US2020/022094 03/11/2020
which claims benefit of 62/816,708 03/11/2019

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

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 12/09/2022

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/058,058**

Projected Publication Date: 03/23/2023

Non-Publication Request: No

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

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Preliminary Class

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

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

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

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

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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To: jayna.cartee@knobbe.com,efiling@knobbe.com,
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 20995

Dec 12, 2022 03:20:38 AM

Dear PAIR Customer:

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2040 MAIN STREET
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UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
18058058	M327	12/12/2022	SHOLD.013C1
	APP.FILE.REC	12/12/2022	SHOLD.013C1

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Thank you for prompt attention to this notice,

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

CD Submission Review Results

Internal Worksheet Only - Do Not Scan

Application Number	18058058	Receipt Date	Nov 22, 2022

X	New Application		Response To Notice	Date Of Response

	Jumbo – Large tables are included on the
X	There are no problems with the CDs in the submission

Items checked below are to be selected in the PALM Pre-Exam CD problem

Omitted Items

	Files on compact disc are unreadable:
	Disc(s) of either set not readable:
	Disc(s) do not contain file names listed:
	Amended CD missing unamended files
	Missing compact discs

Missing Parts

	Disc(s) do not contain file names listed
	Discs contains files that are non-ASCII files:
	Only one copy of the CD, no duplicate:
	Wrong media type, e.g., CD-RW:
	The transmittal letter and specification do not list information:
	Both disc(s) contain unreadable files:
	One disc(s) contain unreadable files:
	Compact disc(s) contain viruses, but are still readable:
	EFS/Paper Submission:
	Table does not maintain data in proper alignment:
	Not proper subject matter for CD's:

Informality

	No statement in transmittal letter that CD's are the same:
	No incorporation by reference statement for the CD's:
	CD's not labeled "Copy 1" and "Copy 2":
	Deficient CD packaging:
	Deficient Labeling on CD's:
	The transmittal letter does not list information:
	The specification does not list information:
	Table less than 51 pages submitted on CD:

File Directory Attachment

	Copy of file directory listing is attached and should be mailed to applicant
	Copy of file directory listing is not attached
	Copy of file directory listing is not attached because it is over one page long

Additional Comments

/scoredcm/OIPE/syousuf@USPTO.GOV/S180580582022121306421 2/disk1/SHOLD-013C1_DRAWINGS.pdf

DocCode - SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 18058058 Document Date: 11/22/2022

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

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- Drawing

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- USPTO employees may access SCORE content via DAV or via the SCORE web page.
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Form Revision Date: March 1, 2019

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
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/058,058	11/22/2022	Donald E. Running	SHOLD.013C1	5500

20995 7590 01/10/2023

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
OPAP	

NOTIFICATION DATE	DELIVERY MODE
01/10/2023	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):

efiling@knobbe.com
jayna.cartee@knobbe.com

Decision Dismissing Request for Prioritized Examination (Track I)	Application No. 18/058,058	Applicant(s) Running et al.	
	Examiner FIKIRTE A GEREMEW	Art Unit OMBL	AIA (FITF) Status Yes

1. THE REQUEST FILED 22 November 2022 IS **DISMISSED** BECAUSE:

A. ☐ The application is not a utility application under 35 U.S.C. 111(a) filed by Patent Electronic System or a plant application under 35 U.S.C. 111(a):
   i. ☐ The application is a utility application that was not filed by Patent Electronic System.
   ii. ☐ The application is neither a utility application nor a plant application, but rather is a _____ , which is excluded from the Track I program.

B. ☐ The request was not filed with the application or on the same date of the application.

C. ☐ One or more of the following fees were not filed with the application:
   i. ☐ Basic filing fee, as set forth in 37 CFR 1.16(a), or for a plant application, 37 CFR 1.16(c).
   ii. ☐ Search fee, as set forth in 37 CFR 1.16(k), or for a plant application, 37 CFR 1.16(m).
   iii. ☐ Examination fee, as set forth in 37 CFR 1.16(o), or for a plant application, 37 CFR 1.16(q).
   iv. ☐ Publication fee, as set forth in 37 CFR 1.18(d).
   v. ☐ Track I processing fee, as set forth in 37 CFR 1.17(i).
   vi. ☐ Track I prioritized examination fee, as set forth in 37 CFR 1.17(c).
   vii. ☐ Application size fee, due because the specification and drawings exceed 100 sheets of paper, as set forth in 37 CFR 1.16(s).
   viii. ☐ Excess independent claim fee, due because the number of independent claims exceeds three, as set forth in 37 CFR 1.16(h).
   ix. ☐ Excess claim fee, due because the number of claims exceeds twenty, as set forth in 37 CFR 1.16(i).

D. ☐ The executed inventor's oath or declaration, or an application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) was not filed with the application or on the same date the application was filed.

E. ☐ The application contains or has been amended to contain:
   i. ☐ More than four independent claims.
   ii. ☐ More than thirty total claims.
   iii. ☐ One or more multiple dependent claims.

F. ☐ The Track I program has exceeded its limit of 15,000 requests for the current fiscal year.

G. ☑ Other: See Continuation Sheet

2. CONCLUSION

☐ **ALL of the above defect(s) consist only of one or more of items E (i-iii). Applicant is hereby accorded a non-extendable ONE MONTH time period from the mailing date of this Decision to (1) correct the subject defect(s) and (2) file a petition under 37 CFR 1.181 requesting reconsideration of prioritized examination. If no such petition is timely filed, the application will not undergo prioritized examination.**

- OR -

☑ **The application will not undergo prioritized examination, because the request was not accompanied by all of the required items.**

Telephone inquiries with regard to this decision should be directed to FIKIRTE A GEREMEW at (703) 756-1930. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/FIKIRTE A GEREMEW/ PROGRAM SUPPORT ASSISTANT, OMBL	

Continuation of 1(g) Other. The first named inventor has not been listed correctly in the Certification And Request For Prioritized Examination Request. For this reason, the application is disqualified from the Track 1 Prioritized Examination Program.

To: jayna.cartee@knobbe.com,efiling@knobbe.com,
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 20995

Jan 11, 2023 03:19:33 AM

Dear PAIR Customer:

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2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 20995 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

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Application	Document	Mailroom Date	Attorney Docket No.
18058058	TRACK1.DENY	01/10/2023	SHOLD.013C1

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PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

PRELIMINARY AMENDMENT

First Inventor: Running, Donald E.	**Conf. No.:** 5500
App. No.: 18/058,058	
Examiner: N/A	**Art Unit:** N/A
Title: TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

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

Dear Commissioner:

Prior to examination, please amend the above-captioned application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

1.-16. (Canceled)

17. (New) A reverse shoulder implant, comprising:

a baseplate configured to be secured to a glenoid of a scapular bone of patient, the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end;

a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient;

a locking nut having a cylindrical shape, an external thread on an outside surface of the locking nut and an internal thread on an internal surface of the locking nut, the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient, wherein the external thread is configured to secure the locking nut to the central channel of the baseplate;

a glenosphere, having a lateral, convex articular side, a medial side, and a central channel extending from the convex articular side to the medial side and configured to interface with the baseplate; and

a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut.

18. (New) The reverse shoulder implant of Claim 17, wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate.

19. (New) The reverse shoulder implant of Claim 17, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.

20. (New) The reverse shoulder implant of Claim 17, wherein the baseplate has a circular shape.

21. (New) The reverse shoulder implant of Claim 17, wherein the glenosphere is configured to surround the baseplate.

22. (New) The reverse shoulder implant of Claim 17, wherein the glenosphere is configured to be secured to the baseplate with a morse taper.

23. (New) The reverse shoulder implant of Claim 17, wherein a diameter of the locking nut is greater than a length of the locking nut.

24. (New) The reverse shoulder implant of Claim 17, wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw.

25. (New) A reverse shoulder implant, comprising:

a baseplate configured to be secured to a glenoid of a scapular bone of patient, the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end;

a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient;

a locking nut having a cylindrical shape, an external thread on an outside surface of the locking nut and an internal thread on an internal surface of the locking nut, the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient, wherein the external thread is configured to secure the locking nut to the central channel of the baseplate; and

a glenosphere, having a lateral, convex articular side, a medial side, and a central channel extending from the convex articular side to the medial side and configured to interface with the baseplate.

26. (New) The reverse shoulder implant of Claim 25, wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate.

27. (New) The reverse shoulder implant of Claim 25, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.

28. (New) The reverse shoulder implant of Claim 25, wherein the baseplate has a circular shape.

29. (New) The reverse shoulder implant of Claim 25, wherein the glenosphere is configured to surround the baseplate.

30. (New) The reverse shoulder implant of Claim 25, wherein the glenosphere is configured to be secured to the baseplate with a morse taper.

31. (New) The reverse shoulder implant of Claim 25, wherein a diameter of the locking nut is greater than a length of the locking nut.

32. (New) The reverse shoulder implant of Claim 25, wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw.

REMARKS

Claims 1-16 were pending. With the present Preliminary Amendment, Applicant cancels Claims 1-16 without prejudice or disclaimer and adds new Claims 17-32; therefore, Claims 17-32 remain pending for consideration.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 30, 2022

By: /Andrew I. Kimmel/
Andrew I. Kimmel
Registration No. 58,855
Registered Practitioner
(949) 760-0404

56703825

Electronic Acknowledgement Receipt

EFS ID:	47363655
Application Number:	18058058
International Application Number:	
Confirmation Number:	5500
Title of Invention:	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS
First Named Inventor/Applicant Name:	Donald E. Running
Customer Number:	20995
Filer:	Andrew I. Kimmel/Jennifer Neat
Filer Authorized By:	Andrew I. Kimmel
Attorney Docket Number:	SHOLD.013C1
Receipt Date:	12-JAN-2023
Filing Date:	22-NOV-2022
Time Stamp:	18:28:42
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		SHOLD-013C1_PRELIMINARYAMENDMENT.pdf	29517 0ef80c1c016e7f1d1aaaa80fbdd9610f4a55a5ba	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5
Warnings:			
Information:			
	Total Files Size (in bytes):	29517	

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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.

PETITION TO EXPEDITE REVIEW OF PETITION TO GRANT REQUEST FOR PRIORITIZED EXAMINATION (TRACK I)

First Inventor: Donald E. RUNNING	**Conf. No.:** 5500
App. No.: 18/058,058	**Filed:** November 22, 2022
Examiner: N/A	**Art Unit:** N/A
Title: TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

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

Dear Commissioner:

Pursuant to 37 C.F.R. 1.182, Applicant hereby petitions the Director to expedite review of the PETITION TO GRANT REQUEST FOR PRIORITIZED EXAMINATION (TRACK I) filed on even date herewith.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 9, 2023

By: /Andrew I. Kimmel/
Andrew I. Kimmel
Registration No. 58,855
Registered Practitioner
(949) 760-0404

57260738

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

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

First Named Inventor:	Donald E. Running	Nonprovisional Application Number (if known):	18/058,058
Title of Invention:	TOTAL REVERSE SHOULDER SYSTEMS AND METHODS		

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

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

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

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

---OR---

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

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

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

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

Signature /Andrew Kimmel/	Date January 19, 2023
Name (Print/Typed) Andrew Kimmel	Practitioner Registration Number 58,855

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

☐ *Total of _____ forms are submitted.

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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.

PETITION TO GRANT REQUEST FOR PRIORITIZED EXAMINATION (TRACK I)

First Inventor: Donald E. RUNNING	**Conf. No.:** 5500
App. No.: 18/058,058	**Filed:** November 22, 2022
Examiner: N/A	**Art Unit:** N/A
Title: TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

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

Dear Sir:

Applicant hereby petitions the Director under 37 C.F.R. § 1.181 to withdraw the Decision Dismissing Request for Prioritized Examination (Track I) (the "Decision") in the above-captioned application (the "Application") and to grant the Certification and Request for Prioritized Examination Under 37 CFR 1.102(3) filed with the Application on November 22, 2022 (the "Request") or the revised Certification and Request for Prioritized Examination Under 37 CFR 1.102(3) filed with this petition (the "Revised Request"). Applicant also submits herewith a petition to expedite review, and respectfully requests the same.

Statement of Facts

The above-captioned Application was filed on November 22, 2022, with the Request and an Application Data Sheet (the "ADS"). The ADS listed Donald E. Running as the first named inventor and Robert J. Ball as the second named inventor. However, the Request listed Robert J. Ball as the first named inventor.

On January 10, 2023, The United States Patent and Trademark Office (the "USPTO") issued the Decision. The Decision dismissed the Request and indicated, "The first named inventor has not been listed correctly in the Certification And Request For Prioritized Examination Request. For this reason, the application is disqualified from the Track 1 Prioritized Examination Program."

On March 9, 2023, Applicant submitted this petition with the Revised Request to correct the name of the first named inventor to Donald E. Running.

Action Requested

Applicant respectfully requests that the USPTO grants the Request or the Revised Request and examine the Application under the Track I Prioritized Examination Program (the "Program"). No other defects in the Request have been identified, and the Application is otherwise eligible for participation in the Program.

Conclusion

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 9, 2023

By: /Andrew I. Kimmel/
Andrew I. Kimmel
Registration No. 58,855
Registered Practitioner
(949) 760-0404

57260741

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/058,058	**03/09/2023 02:21:53 PM ET**	**SHOLD.013C1**

Title of Invention

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5500	FILED BY	Debbie Munson
PATENT CENTER #	61715251	FILING DATE	11/22/2022
CUSTOMER #	20995	FIRST NAMED INVENTOR	Donald E. Running
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Andrew Kimmel

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
SHOLD-013C1_PETITIONTOEXPEDITEREVIEW.pdf	1	Petition for review by the Office of Petitions	16 KB
SHOLD-013C1_TRACK1.pdf	2	Track One Request	111 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
SHOLD-013C1_PETITIONTOEXPEDIT	F119ACE076C125E4203B085C5CD6FF309B86CC0962FD0E621501AEE1575E81F81E35F1C6A7D6CE772CE0446375EFEA1A0D

EREVIEW.pdf	5E6EAE634F48E806831F2AA140D3D4
SHOLD-013C1_TRACK1.pdf	8E3B1C1B190BD65B34996A3A0E96C9FFB80CD23AFBFB7E257A3BA9C871F539CC02D86F1558CDD572C6A5C5637ABBD0556517FCE65801526ACAEB5985D822A2FD

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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 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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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/058,058	**03/09/2023 05:15:39 PM ET**	**SHOLD.013C1**

Title of Invention

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5500	FILED BY	Debbie Munson
PATENT CENTER #	61718047	FILING DATE	11/22/2022
CUSTOMER #	20995	FIRST NAMED INVENTOR	Donald E. Running
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Andrew Kimmel

Documents

TOTAL DOCUMENTS: 0

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

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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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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/058,058	03/09/2023 05:15:39 PM ET	SHOLD.013C1

Title of Invention

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Application Information

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CONFIRMATION #	5500	FILED BY	Debbie Munson
PATENT CENTER #	61718047	AUTHORIZED BY	Andrew Kimmel
CUSTOMER #	20995	FILING DATE	11/22/2022
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Donald E. Running

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 2598	E202339H16465224	Wendy Castorena

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
111410	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2462	PETITIONS REQUIRING THE PETITION FEE SET FORTH IN 37 CFR 1.17(F) (GROUP I)	168.00	1	168.00
			TOTAL AMOUNT:	$168.00

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/058,058	11/22/2022	Donald E. Running	SHOLD.013C1	5500

20995 7590 03/16/2023

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
OPAP	

NOTIFICATION DATE	DELIVERY MODE
03/16/2023	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):

cassie.wolf@knobbe.com
efiling@knobbe.com

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Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.:18/058,058

The petition filed March 9, 2023, under 37 CFR 1.182, is GRANTED. The requirements of 37 CFR 1.182 to expedite the petition, filed March 9, 2023, have been fully satisfied. The petition, filed March 9, 2023, requesting reconsideration of the decision issued January 10, 2023 is GRANTED. The original request for prioritized examination, filed November 22, 2022, is hereby accepted in view of the properly filed request for prioritized examination submitted on March 9, 2023.

1. THE REQUEST FILED November 22, 2022 IS **GRANTED.**

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

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

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

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Vanitha Elgart at 571-272-7395.

/VANITHA M ELGART/
Petitions Examiner, OPET

TO: cassie.wolf@knobbe.com,efiling@knobbe.com
FROM: noreply@uspto.gov
CC: PatentCenter_eOfficeAction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 20995

Fri Mar 17 05:04:10 EDT 2023

Dear Patent Center Customer:

Correspondence Address:

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Application	Document	Mailroom Date	Attorney Docket No.
18058058	TRACK1.GRANT	03/16/2023	SHOLD.013C1

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The Patent Center Team

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/058,058	11/22/2022	Donald E. Running	SHOLD.013C1

CONFIRMATION NO. 5500

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

PUBLICATION NOTICE

OC000000137625947

Title:TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Publication No.US-2023-0090753-A1
Publication Date:03/23/2023

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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

TO: cassie.wolf@knobbe.com,efiling@knobbe.com
FROM: noreply@uspto.gov
CC: PatentCenter_eOfficeAction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 20995

Fri Mar 24 05:02:54 EDT 2023

Dear Patent Center Customer:

Correspondence Address:

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UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
18058058	NTC.PUB	03/23/2023	SHOLD.013C1

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Sincerely,

The Patent Center Team

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	18/058058
	Filing Date	November 22, 2022
	First Named Inventor	Running, Donald E.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Schillinger, Ann M.
SHEET 1 OF 12	Attorney Docket No.	SHOLD.013C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	2,781,758	02-19-1957	Jacques	
	2	3,979,778	09-14-1976	Stroot	
	3	4,003,095	01-18-1977	Gristina	
	4	4,045,826	09-06-1977	Stroot	
	5	4,206,517	06-10-1980	Pappas et al.	
	6	4,261,062	04-14-1981	Amstutz et al.	
	7	4,404,693	09-20-1983	Zweymuller	
	8	4,550,450	11-05-1985	Kinnett	
	9	4,865,605	09-12-1989	Dines, et al.	
	10	4,964,865	10-23-1990	Burkhead et al.	
	11	4,986,833	01-22-1991	Worland	
	12	4,990,161	02-05-1991	Kampner	
	13	5,030,219	07-09-1991	Matsen, III, et al.	
	14	5,032,132	07-16-1991	Matsen, III, et al.	
	15	5,080,673	01-14-1992	Burkhead, et al.	
	16	5,108,440	04-28-1992	Grundei	
	17	5,282,865	02-01-1994	Dong	
	18	5,314,479	05-24-1994	Rockwood, Jr., et al.	
	19	5,314,489	05-24-1994	Hoffman et al.	
	20	5,344,458	09-06-1994	Bonutti	
	21	5,358,525	10-25-1994	Fox, et al.	
	22	5,370,694	12-06-1994	Davidson	
	23	5,437,677	08-01-1995	Shearer et al.	
	24	5,462,563	10-31-1995	Shearer, et al.	
	25	5,489,309	02-06-1996	Lackey, et al.	
	26	5,489,310	02-06-1996	Mikhail	
	27	5,507,819	04-16-1996	Wolf	
	28	5,514,184	05-07-1996	Doi	
	29	5,549,683	08-27-1996	Bonutti	

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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	18/058058
	Filing Date	November 22, 2022
	First Named Inventor	Running, Donald E.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Schillinger, Ann M.
SHEET 2 OF 12	Attorney Docket No.	SHOLD.013C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	5,593,448	01-14-1997	Dong	
	31	5,702,486	12-30-1997	Craig et al.	
	32	5,755,811	05-26-1998	Tanamal et al.	
	33	5,769,856	06-23-1998	Dong, et al.	
	34	5,800,551	09-01-1998	Williamson et al.	
	35	5,928,285	07-27-1999	Bigliani et al.	
	36	6,037,724	03-14-2000	Buss et al.	
	37	6,228,119	05-08-2001	Ondria, et al.	
	38	6,231,913	05-15-2001	Schwimmer et al.	
	39	6,290,726	09-18-2001	Pope, et al.	
	40	6,334,874	01-01-2002	Tornier et al.	
	41	6,364,910	04-02-2002	Shultz et al.	
	42	6,368,353	04-09-2002	Arcand	
	43	6,379,386	04-30-2002	Resch, et al.	
	44	6,458,136	10-01-2002	Allard, et al.	
	45	6,514,287	02-04-2003	Ondria, et al.	
	46	6,520,964	02-18-2003	Tallarida, et al.	
	47	6,589,281	07-08-2003	Hyde, Jr.	
	48	6,610,067	08-26-2003	Tallarida, et al.	
	49	6,620,197	09-16-2003	Maroney	
	50	6,673,115	01-06-2004	Resch, et al.	
	51	6,783,549	08-31-2004	Stone et al.	
	52	6,679,916	01-20-2004	Frankle et al.	
	53	6,679,917	01-20-2004	Ek	
	54	6,699,289	03-02-2004	Iannotti, et al.	
	55	6,709,463	03-23-2004	Pope et al.	
	56	6,712,823	03-30-2004	Grusin, et al.	
	57	6,761,740	07-13-2004	Tornier	
	58	6,783,549	08-31-2004	Stone, et al.	

Examiner Signature	Date Considered

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	Filing Date	November 22, 2022
	First Named Inventor	Running, Donald E.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Schillinger, Ann M.
SHEET 3 OF 12	Attorney Docket No.	SHOLD.013C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,875,234	04-05-2005	Lipman et al.	
	60	7,011,686	03-14-2006	Ball et al.	
	61	7,044,973	05-16-2006	Rockwood et al.	
	62	7,238,089	07-03-2007	Tsumuraya et al.	
	63	7,238,208	07-03-2007	Camino et al.	
	64	7,294,149	11-13-2007	Hozack et al	
	65	7,320,709	01-22-2008	Felt et al.	
	66	7,329,284	02-12-2008	Maroney et al.	
	67	7,465,319	12-16-2008	Tornier	
	68	7,517,364	04-14-2009	Long et al.	
	69	7,618,462	11-17-2009	Ek	
	70	7,678,151	03-16-2010	Ek	
	71	7,749,278	07-06-2010	Frederick et al.	
	72	7,776,098	08-17-2010	Murphy	
	73	7,892,287	02-22-2011	Deffenbaugh	
	74	7,922,769	04-12-2011	Deffenbaugh et al.	
	75	8,007,538 (SHOLD.001A)	08-30-2011	Gunther	
	76	8,038,719 (SHOLD.001C3)	10-18-2011	Gunther	
	77	8,048,161	11-01-2011	Guederian et al.	
	78	8,048,167	11-01-2011	Dietz et al.	
	79	8,529,629	09-10-2013	Angibaud et al.	
	80	8,608,805	12-17-2013	Forrer et al.	
	81	8,778,028 (SHOLD.001CP1)	07-15-2014	Gunther et al.	
	82	8,840,671	09-23-2014	Ambacher	
	83	8,920,508	12-30-2014	Iannotti et al.	
	84	8,940,054	01-27-2015	Wiley et al.	
	85	9,283,083	03-15-2016	Winslow et al.	

Examiner Signature	Date Considered

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	18/058058
	Filing Date	November 22, 2022
	First Named Inventor	Running, Donald E.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Schillinger, Ann M.
SHEET 4 OF 12	Attorney Docket No.	SHOLD.013C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	86	9,381,086 (SHOLD.003A)	07-05-2016	Ries et al.	
	87	9,545,311	01-17-2017	Courtney, Jr. et al.	
	88	9,545,312	01-17-2017	Tornier et al.	
	89	9,610,166 (SHOLD.001P1C1)	04-04-2017	Gunther et al.	
	90	9,693,784 (SHOLD.001C4)	07-04-2017	Gunther	
	91	9,867,710	01-16-2018	Dalla Pria et al.	
	92	10,143,559 (SHOLD.003C1)	12-04-2018	Ries et al.	
	93	10,492,926 (SHOLD.006A)	12-03-2019	Gunther	
	94	10,702,390	07-07-2020	Chavarria et al.	
	95	10,779,952 (SHOLD.001P1C2)	09-22-2020	Gunther et al.	
	96	10,786,265 (SHOLD.001C5)	09-29-2020	Gunther	
	97	11,065,125 (SHOLD.009A)	07-20-2021	Ball	
	98	D 977,643 (SHOLD.014DA)	02-07-2023	Ball et al.	
	99	2001/0011192	08-02-2001	Ondria et al.	
	100	2001/0037153	11-01-2001	Rockwood, Jr., et al.	
	101	2001/0047210	11-29-2001	Wolf	
	102	2002/0055783	05-09-2002	Tallarida et al.	
	103	2002/0082702	06-27-2002	Resch et al.	
	104	2002/0087213	07-04-2002	Bertram, III	
	105	2002/0095214	07-18-2002	Hyde, Jr.	
	106	2002/0111689	08-15-2002	Hyde, Jr., et al.	
	107	2002/0138148	09-26-2002	Hyde, Jr., et al.	
	108	2003/0100952	05-29-2003	Rockwood, Jr. et al.	
	109	2003/0114933	06-19-2003	Bouttens et al.	

Examiner Signature	Date Considered

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	18/058058
	Filing Date	November 22, 2022
	First Named Inventor	Running, Donald E.
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(Multiple sheets used when necessary)	Examiner	Schillinger, Ann M.
SHEET 5 OF 12	Attorney Docket No.	SHOLD.013C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	110	2003/0125809	07-03-2003	Iannotti et al.	
	111	2003/0144738	07-31-2003	Rogalski	
	112	2003/0158605	08-21-2003	Tournier	
	113	2003/0163202	08-28-2003	Lakin	
	114	2003/0236572	12-25-2003	Bertram, III	
	115	2004/0002766	01-02-2004	Hunter et al.	
	116	2004/0039449	02-26-2004	Tournier	
	117	2004/0039451	02-26-2004	Southworth	
	118	2004/0059424	03-25-2004	Guederian, et al.	
	119	2004/0064187	04-01-2004	Ball, et al.	
	120	2004/0064189	04-01-2004	Maroney, et al.	
	121	2004/0064190	04-01-2004	Ball, et al.	
	122	2004/0107002	06-03-2004	Katsuya	
	123	2004/0122519	06-24-2004	Wiley et al.	
	124	2004/0122520	06-24-2004	Lipman et al.	
	125	2004/0167629	08-26-2004	Geremakis et al.	
	126	2004/0167630	08-26-2004	Rolston	
	127	2004/0193168	09-30-2004	Long et al.	
	128	2004/0193275	09-30-2004	Long et al.	
	129	2004/0193276	09-30-2004	Maroney et al.	
	130	2004/0193277	09-30-2004	Long et al.	
	131	2004/0193278	09-30-2004	Maroney et al.	
	132	2004/0220674	11-04-2004	Pria	
	133	2004/0230311	11-18-2004	Cyprien et al.	
	134	2004/0260398	12-23-2004	Kelman	
	135	2005/0043805	02-24-2005	Chudik	
	136	2005/0049709	03-03-2005	Tornier	
	137	2005/0065612	03-24-2005	Winslow	
	138	2005/0107882	05-19-2005	Stone et al.	

Examiner Signature	Date Considered

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	Filing Date	November 22, 2022
	First Named Inventor	Running, Donald E.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Schillinger, Ann M.
SHEET 6 OF 12	Attorney Docket No.	SHOLD.013C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	139	2005/0119531	06-02-2005	Sharratt	
	140	2005/0177241	08-11-2005	Angibaud et al.	
	141	2005/0261775	11-24-2005	Baum et al.	
	142	2005/0278030	12-15-2005	Tornier et al.	
	143	2006/0036328	02-16-2006	Parrott et al.	
	144	2006/0069443	03-30-2006	Deffenbaugh et al.	
	145	2006/0069444	03-30-2006	Deffenbaugh et al.	
	146	2006/0069445	03-30-2006	Ondrla et al.	
	147	2006/0195194 (SHOLD.001A)	08-31-2006	Gunther	
	148	2006/0200249	09-07-2006	Beguin et al.	
	149	2007/0038302	02-15-2007	Shultz et al.	
	150	2007/0050042	03-01-2007	Dietz et al.	
	151	2007/0055380	03-08-2007	Berelsman et al.	
	152	2007/0112433	05-17-2007	Frederick et al.	
	153	2007/0225817	09-27-2007	Ruebelt et al.	
	154	2007/0225818	09-27-2007	Reubelt et al.	
	155	2008/0021564 (SHOLD.002A)	01-24-2008	Gunther	
	156	2008/0082175	04-03-2008	Holovacs et al.	
	157	2008/0177327	07-24-2008	Malandain et al.	
	158	2008/0234820	09-25-2008	Felt et al.	
	159	2009/0105837	04-23-2009	LaFosse et al.	
	160	2009/0125113	05-14-2009	Guederian, et al.	
	161	2009/0228112	09-10-2009	Clark et al.	
	162	2009/0287309	11-19-2009	Walch et al.	
	163	2010/0087876 (SHOLD.001C2)	04-08-2010	Gunther	
	164	2010/0087877 (SHOLD.001C1)	04-08-2010	Gunther	
	165	2010/0114326	05-06-2010	Winslow et al.	

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	166	2010/0161066	06-24-2010	Ionetti et al.	
	167	2010/0217399	08-26-2010	Groh	
	168	2010/0249938 (SHOLD.001CP1)	09-30-2010	Gunther et al.	
	169	2010/0274360 (SHOLD.002C1)	10-28-2010	Gunther	
	170	2011/0029089	02-03-2011	Giuliani et al.	
	171	2011/0106266	05-05-2011	Schwyzer et al.	
	172	2011/0112648 (SHOLD.001C3)	05-12-2011	Gunther	
	173	2011/0137424	06-09-2011	Lappin et al.	
	174	2011/0144758	06-16-2011	Deffenbaugh	
	175	2011/0276144	11-10-2011	Wirth et al.	
	176	2011/0313533 (SHOLD.002C2)	12-22-2011	Gunther	
	177	2012/0172996 (SHOLD.003A)	07-05-2012	Ries et al.	
	178	2012/0209392	08-16-2012	Angibuad et al.	
	179	2012/0239156	09-20-2012	De Wilde et al.	
	180	2013/0060346	03-07-2013	Collins	
	181	2013/0090736	04-11-2013	Katrana et al.	
	182	2013/0166033 (SHOLD.001C4)	06-27-2013	Gunther	
	183	2013/0197651	08-01-2013	McDaniel et al.	
	184	2014/0107794	04-17-2014	Deffenbaugh et al.	
	185	2014/0253641	09-11-2014	Furuya	
	186	2014/0257499	09-11-2014	Winslow et al.	
	187	2015/0105861 (SHOLD.001P1C1)	04-16-2015	Gunther et al.	
	188	2015/0223941	08-13-2015	Lang	
	189	2015/0265411	09-24-2015	Deransart et al.	
	190	2016/0045323	02-18-2016	Kovacs et al.	

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	191	2017/0000617 (SHOLD.003C1)	01-05-2017	Ries et al.	
	192	2017/0056187	03-02-2017	Humphrey et al.	
	193	2017/0071749	03-16-2017	Lappin et al.	
	194	2017/0202674 (SHOLD.001P1C2)	07-20-2017	Gunther et al.	
	195	2017/0273806	09-28-2017	Cardon et al.	
	196	2017/0304063	10-26-2017	Hatzidakis et al.	
	197	2017/0360456 (SHOLD.001C5)	12-21-2017	Gunther	
	198	2018/0071104	03-15-2018	Kovacs et al.	
	199	2018/0078377	03-22-2018	Gargac et al.	
	200	2018/0161169	06-14-2018	Cardon et al.	
	201	2018/0193150	07-12-2018	Winslow et al.	
	202	2018/0200067	07-19-2018	Axelso, Jr. et al.	
	203	2018/0368982 (SHOLD.009A)	12-27-2018	Ball	
	204	2019/0336293	11-07-2019	Kehres	
	205	2021/0038401 (SHOLD.009NP)	02-11-2021	Ball et al.	
	206	2021/0137692	05-13-2021	Budge	
	207	2021/0137693 (SHOLD.011NP)	05-13-2021	Ball et al.	
	208	2021/0244547 (SHOLD.001P1C3)	08-12-2021	Gunther et al.	
	209	2021/0251640 (SHOLD.001C6)	08-19-2021	Gunther	
	210	2021/0338446 (SHOLD.009C1)	11-04-2021	Ball	
	211	2022/0151795 (SHOLD.013NP)	05-19-2022	Running et al.	
	212	2022/0175543 (SHOLD.009C2)	06-09-2022	Ball	

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	213	2022/0175544 (SHOLD.009NPC1)	06-09-2022	Ball et al.	
	214	2023/0078024 (SHOLD.001P1C4)	03-16-2023	Gunther et al.	
	215	2023/0080207 (SHOLD.001P1C5)	03-16-2023	Gunther et al.	
	216	2023/0081505 (SHOLD.001C7)	03-16-2023	Gunther	
	217	13/018,341 (SHOLD.001C3)	01-31-2011	Gunther	
	218	13/088,976 (SHOLD.002C2)	04-18-2011	Gunther	
	219	16/701118 (SHOLD.006C1)	12-02-2019	Gunther	
	220	29/870,666 (SHOLD.014DD1)	02-01-2023	Ball et al.	

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Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	221	DE 4220217	12-01-1993	S & G IMPLANTS GmbH		Abs
	222	DE 10164328 A1	07-17-2003	HOHMANN, ET AL.		Abs
	223	EP 0299889 A2	01-08-1989	GRAMMONT		
	224	EP 0339530 A2	11-02-1989	S&G IMPLANTS GMBH		
	225	EP 1464305 A1	10-06-2004	DEPUY PRODUCTS, INC.		
	226	EP 0570816 A1	11-24-1993	MITSUBISHI ELECTRIC CORP.		
	227	EP 1858453 B1 (SHOLD.001VEP)	11-28-2007	SHOULDER INNOVATIONS, LLC		
	228	EP 1952788 A1	08-06-2008	TORNIER		
	229	EP 2083759 B1	09-02-2015	INNOVATIVE DESIGN ORTHOPAEDICS LTD		
	230	FR 2248820 A1	05-23-1975	BENOIST GIRARD		Abs

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FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	231	FR 2567019 A1	01-10-1986	FOURNIER		Abs
	232	FR 2695313 A1	03-11-1994	SOCIETE DE FABRICATION		Abs
	233	JP 2013-158909	08-19-2013	SEIKO EPSON CORP.		Abs
	234	JP 2014-515651	07-03-2014	ZIMMER GmbH		Abs
	235	WO 2006/093763 A3 (SHOLD.001VPC)	8/9/2006	GUNTHER		
	236	WO 2008/011078 A2	01-24-2008	GUNTHER		
	237	WO 2009/071940 A1	06-11-2009	BISHOP, ET AL.		
	238	WO 2011/112425 (SHOLD.001P1WO)	09-15-2011	SHOULDER INNOVATIONS, LLC		
	239	WO 2012/075183 (SHOLD.003WO)	04-10-2014	SHOULDER INNOVATIONS, LLC		
	240	WO 2014/0195909	12-11-2014	LIMACORPORATE S.P.A.		
	241	WO 2018/022227	02-01-2018	TORNIER INC.		
	242	WO 2018/129286	07-12-2018	ZIMMER INC.		Abs
	243	WO 2018/181420 (SHOLD.009WO)	10-18-2018	SHOULDER INNOVATIONS, LLC		
	244	WO 2019/178104 (SHOLD.009WO2)	09-19-2019	SHOULDER INNOVATIONS, LLC		
	245	WO 2019/178104	09-19-2019	SHOULDER INNOVATIONS, LLC		
	246	WO 2019/213073 (SHOLD.011WO)	11-07-2019	SHOULDER INNOVATIONS, LLC		
	247	WO 2020/185893 (SHOLD.013WO)	09-17-2020	SHOULDER INNOVATIONS, LLC		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	248	Biomet, "Absolute ™ Bi-Polar." 2001 in 2 pages.	

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NON PATENT LITERATURE DOCUMENTS			
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	249	Biomet, "Copeland" ™ Humeral Resurfacing Head, Interlok®/HA Coated Implant Information," 2003 in 1 page.	
	250	Biomet, "Copeland" ™ Humeral Resurfacing Head," 2001 in 12 pages.	
	251	Biomet, "Copeland™ Humeral Resurfacing Head, Macrobond™ Implant Information," 2003 in 1 page.	
	252	Biomet, "Copeland™ Humeral Resurfacing Head, Surgical Technique," 2003 in 2 pages.	
	253	Boileau et al., "The Three-Dimensional Geometry of the Proximal Humerus. Implications for Surgical Technique and Prosthetic Design," J. Bone Joint Surg. Br. 79: 857-865, 1997.	
	254	Braun, et al., Modular Short-stem Prosthesis in Total Hip Arthroplasty: Implant Positioning and the Influence of Navigation, ORTHO SuperSite (Oct. 2007) in 8 pages.	
	255	Clavert et al. Glenoid resurfacing: what are the limits to asymmetric reaming for posterior erosion? J. Shoulder and Elbow Surg. 2007 November/December: 843-848	
	256	Dalla Pria, Paolo. Slide presentation, entitled "Shoulder Prosthesis Design and Evolution", to the Naples International Shoulder Congress in Italy (2000) in 55 pages.	
	257	DePuy, "Global C.A.P., Surgical Technique Resurfacing Humeral Head Implant," 2004 in 23 pages.	
	258	Inset Mini-glenoid Brochure, Titan Modular Shoulder System Brochure, Ascension Orthopedics, 2011, 4 pages	
	259	Karduna et al. Glenhumeral Joint Translations before and after Total Shoulder Arthroplasty. J. Bone and Joint Surg. 79(8) (1997): 1166-1174.	
	260	Redacted letter from a third party dated August 24, 2012 in 2 pages.	
	261	Levy et al., "Cementless Surface Replacement Arthroplasty of the Should. 5- to 10-year Results with the Copeland Mark-2 Prosthesis," J. Bone Joint Surg. Br. 83: 213-221, 2001.	
	262	Lima-Lto Medical Systems Glenoidi/Glenoids catalogue (2001) in 1 page.	
	263	Lima-Lto MINIGLENOIDE CEMENTATA document 7560.50.030 (1999) in 1 page.	
	264	Panisello, et al., Bone remodelling after total hip arthroplasty using an uncemented anatomic femoral stem: a three-year prospective study using bone densitometry, J Ortho Surg 14(1):32-37 (2006)	
	265	Ross, Mark and Duke, Phillip, "Early Experience In The Use of a New Glenoid Resurfacing Technique" Glenoid Presentation, SESA November 4, 2006, Session 4/0800-0930 p. 93 in 1 page.	
	266	Tight Fit Tools, Right Angle Drill Attachment, Serial No. 00400 www.tightfittools.com/riganat.html in 1 page/downloaded March11, 2005.	
	267	TITAN(™) Modular Shoulder System Brochure, 2011, available at http://www.ascensionortho.com/Assets/PDF/TitanModular/TITANModularShoulder_Brochure-revD.pdf (2 pages)	

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	268	Tournier et al., Enhancement of Glenoid Prosthesis Anchorage using Burying Technique. Techniques in Shoulder & Elbow Surgery 9(1)(2008): 35-42.	
	269	Wang et al., Biomechanical Evaluation of a Novel Glenoid Design in Total Shoulder Arthroplasty. J. Shoulder & Elbow Surgery (2005) 15: 129S-140S.	
	270	Statement of Grounds and Particulars of Opposition for Australian Patent Application No. 2006218936 dated October 5, 2012 in 8 pages.	

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Examiner Signature	Date Considered

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BIOMET

ABSOLUTE™

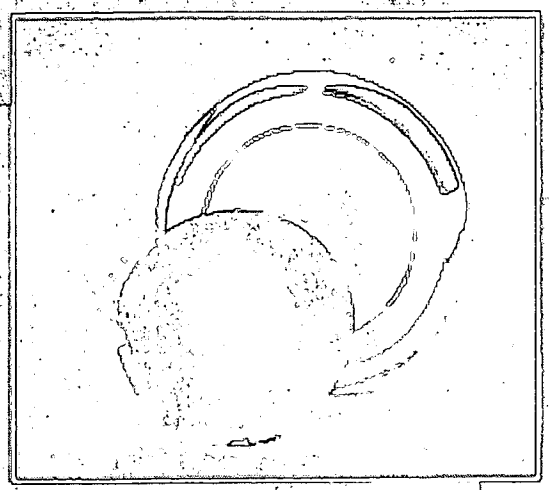
BI-POLAR

The Next Evolution in Bi-Polar Shoulder Arthroplasty

Features:

- Simple Assembly
- Superb Bi-Polar Range of Motion
- "Positive Feedback" Locking Mechanism
- Superior Pull-Out and Lever-Out Strength*
- Industry Minimum Lateral Offset*

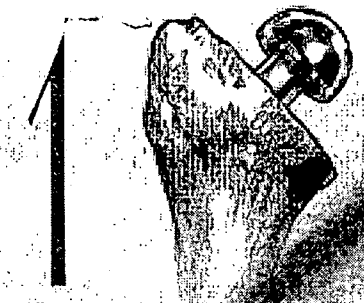
*Data on file at Biomet



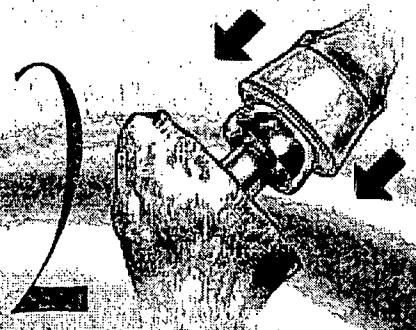
BIOMET ORTHOPEDICS INC

ABSOLUTE™ BI-POLAR ASSEMBLY–Surgical Technique

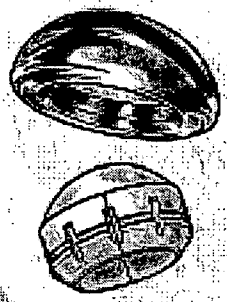
(After humeral stem implantation, complete cement curing, and bi-polar trialing)



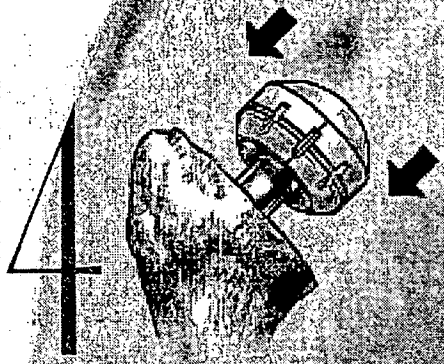
Thoroughly clean and dry the Morse taper. This is important because any foreign materials will impede the establishment of a "cold weld" between the humeral component and the cobalt chrome inner head.



Impact the cobalt chrome inner head onto the stem with 8–10 taps on the inner head using the impacting tool. Be sure the impacting is not done at an angle.

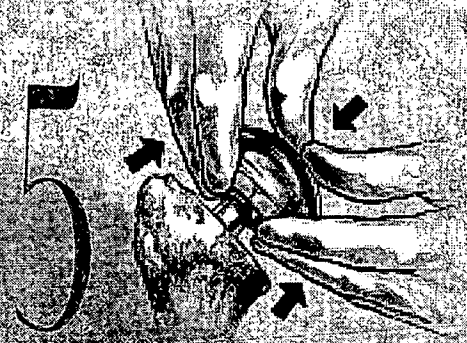


Unpack the box containing the proper diameter bi-polar shell and also the box containing the ArCom® polyethylene component.



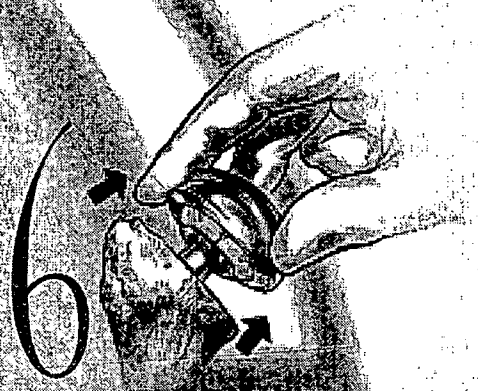
Snap the polyethylene liner onto the inner head.

* **Do not snap the polyethylene component into the shell without first snapping the polyethylene component over the inner head.**



Ensure the titanium locking ring is in place inside the cobalt chrome bi-polar shell, then slide the shell over the polyethylene liner. A "snap" sound will be heard to confirm the complete seating of the polyethylene into the shell.

* Assembly can be completed on the back table prior to taper impaction, but this is not the preferred method of the designing surgeon.



Test the assembly by gently pulling on the shell portion. If secure, relocate the shoulder and reduce the joint.

If disassembly is necessary, a **removal ramp** is available to remove the bi-polar assembly and inner head from the stem. An **inner head holder** and **liner removal tool** can then be used to disassemble the inner head and outer shell.

Ordering Information

Bi-Polar Shell		
Part No.	**Trial**	**Description**
113150	408450	40mm
113153	408453	44mm
113156	408456	48mm
113159	408459	52mm
113162	408462	56mm
113165	408465	60mm

(Shell includes CoCr outer shell and titanium locking ring)

Bi-Polar Polyethylene Component	
Part No.	**Description**
113169	ArCom® Absolute Liner

Bi-Angular® Inner Head		
Part No.	**Trial**	**Description**
113101	408408	Standard
113141	408410	+2mm
113142	408412	+4mm

Bio-Modular® Inner Head		
Part No.	**Trial**	**Description**
113143	408418	Standard
113144	408420	+2mm
113145	408422	+4mm
113146	408424	-2mm
113147	408426	-4mm

Inner Head Removal Ramp
408433

Bi-Polar Liner Removal Tool
408446

Bi-Polar Inner Head Holder
408449

Bi-Angular® Bi-Polar X-ray template
414458

Bio-Modular® Bi-Polar X-ray template
414459

This is the surgical technique of Richard Worland, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate technique for such procedure for each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

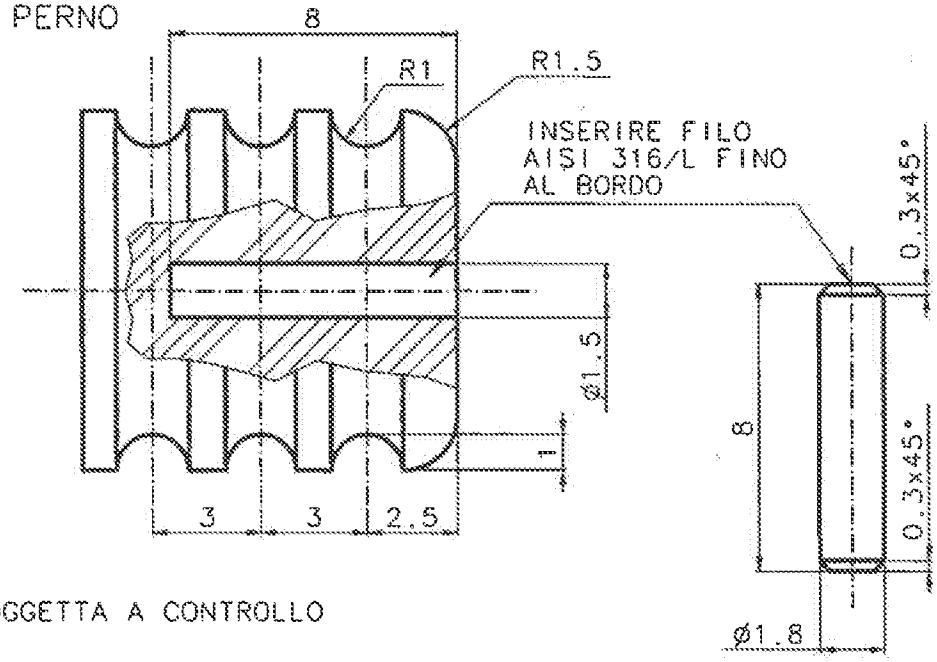
For further information, please refer to package insert.

All trademarks are the property of Biomet, Inc.

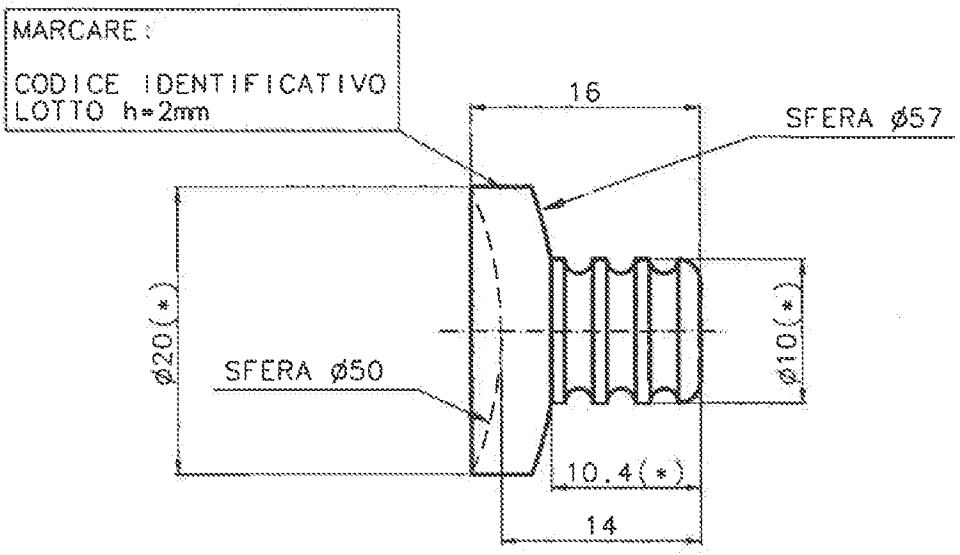
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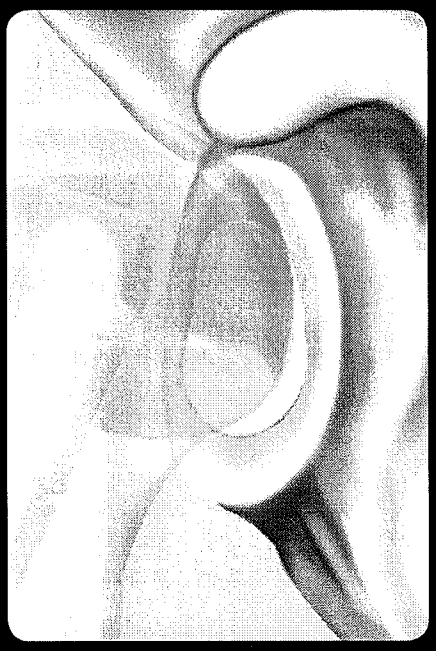
CONFIDENTIAL

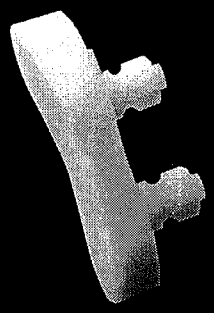
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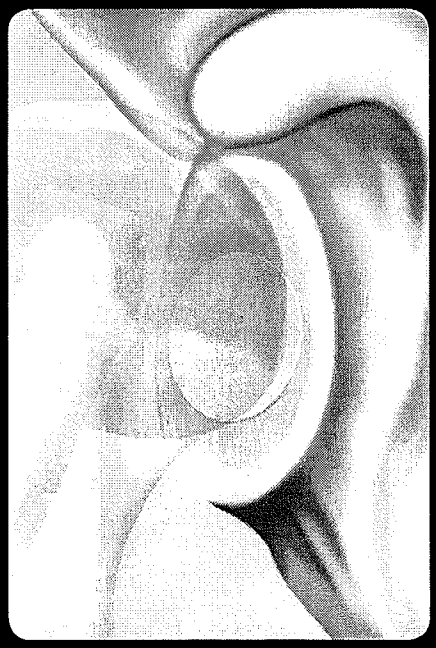
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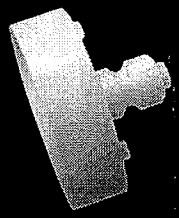
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NOTE		

inset mini glenoid









TITAN™
MODULAR
SHOULDER SYSTEM

Ascension Orthopedics

design rationale

The TITAN Modular Shoulder System provides a unique way to address gleno-humeral arthritis. The Inset Mini Glenoid prosthesis is designed to resurface the central portion of the glenoid as well as provide load-sharing with the peripheral glenoid bone. Minimal forces are transmitted onto the edge of the Mini Glenoid prosthesis – helping reduce the pain and erosion seen in a hemiarthroplasty while minimizing the risk of glenoid loosening in a total shoulder due to edge loading.

Complications in Hemiarthroplasty with Metal Implants

- Glenoid erosion with metal implants
- Pain, decreased function, and limited ROM over time
- Compromised revision path to total shoulder arthroplasty (TSA)
  - Asymmetric glenoid wear can alter revision to TSA
  - Corrective reaming to address glenoid wear removes valuable bone stock

Parsons IM 4th, Millett PJ, Warner JJ. Glenoid wear after shoulder hemiarthroplasty: quantitative radiographic analysis. *Clin Orthop Relat Res.* 2004; 421:120-5.

Carroll RM, Izquierdo R, Vazquesz M, Blaine TA, Levine WM, Bigliani LU. Conversion of painful hemiarthroplasty to total shoulder arthroplasty: long-term results. *J Shoulder Elbow Surg.* 2004; 13:599-603.

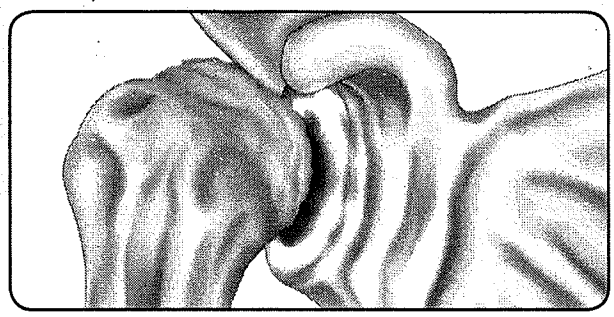
Bryant D, Litchfield R, Sandow M, Gartsman GM, Guyatt G, Kirkley A. A comparison of pain, strength, range of motion, and function outcomes after hemiarthroplasty and total shoulder arthroplasty in patients with osteoarthritis of the shoulder. A systematic review and meta-analysis. *J Bone Joint Surg* Am. 2005; 87:1947-1956.

Complications in Total Shoulder Arthroplasty

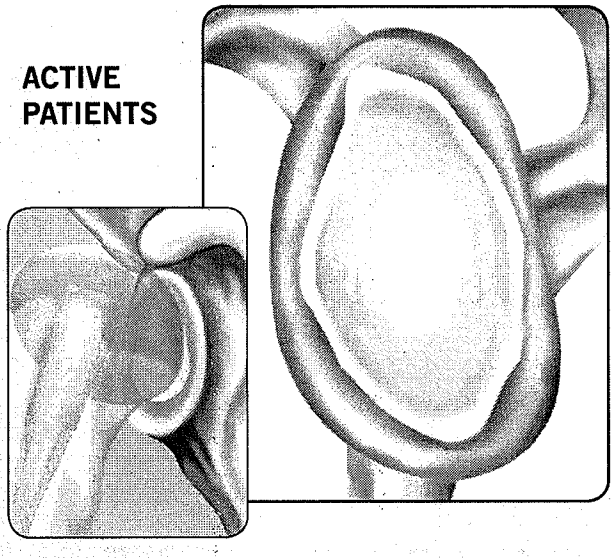
- Younger patients are not seen as ideal total shoulder candidates
- Revision difficulties – large amount of glenoid bone removal
- Glenoid loosening cited as main reason for total shoulder arthroplasty failure

Williams GR, Abboud JA. Total shoulder arthroplasty: Glenoid component design. *J Shoulder Elbow Surg* 2005; 14:122S-128S.

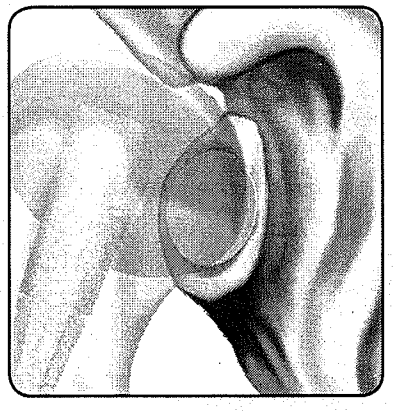
Rodosdky MW, Bigliani LU. Indications for glenoid resurfacing in shoulder arthroplasty. *J Shoulder Elbow Surg* 1996; 5:231-48

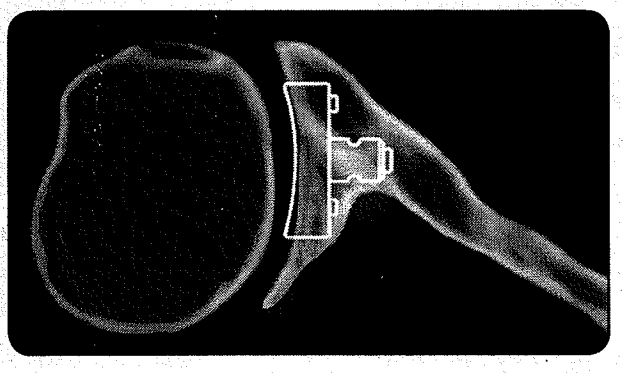


ACTIVE PATIENTS



GLENOID BONE DEFICIENCY





features & benefits

IMPLANT BENEFITS

- **Addresses small focal lesions**
- **Addresses worn glenoids** that may have decreased diameters and vault depth
- **Performed in severely deficient glenoid bone** without any structural bone grafting*
- **May reduce central medial erosion** – typical in hemi-arthroplasty, leads to pain and reduced joint space
- **Allows load sharing with native peripheral glenoid bone** – reduces edge loading which can lead to glenoid loosening in TSA
- **Retention of the labrum and healthy peripheral cartilage** – allows load sharing with native tissues that are removed for a standard glenoid replacement
- **Allows rigid fixation** within rim of hard surface bone*
- **Reduces possibility of overstuffing the joint** – the implant sits flush with the native glenoid minimizing joint lateralization
- **Open revision path** – small size component aids in preserving valuable bone stock for future procedures
- **Partial or full correction of version** without reaming down the high side of the glenoid*

SYSTEM BENEFITS

5 Implant Options with Multiple Shapes and Sizes

- Round (1 central peg): 31 or 44 mm radius of curvature
- Small Oval (2 pegs): 31 or 44 mm radius of curvature
- Large Oval (2 pegs): 44 mm radius of curvature

5.5 x 7 mm Pegs

- Minimize bone stock removal
- Pathway for possible revision

Utilizes Same Instrumentation as TITAN Modular Shoulder Standard Pegged and Keeled Glenoid Set

- Familiarity with existing system instrumentation
- Standard glenoid options available as alternative

Small instrumentation enables easier access to the glenoid

"A novel approach of inset glenoid fixation for severely deficient bone.*"

*Gunther SB, Lynch TL. Total shoulder replacement surgery with custom glenoid implants for severe bone deficiency. J Shoulder Elbow Surg (2011), 1-10.

"In some cases of glenoid deficiency, the best available support structures for a new glenoid component are the rim and the vault. Therefore, it might be best to put the component 'in' the glenoid rather than 'on' it."

Williams GR Jr, Iannotti JP. Options for glenoid bone loss: Composites of prosthetics and biologics. J Shoulder Elbow Surg 2007; 16:S267-72.

EARLY EXPERIENCE IN THE USE OF A NEW GLENOID RESURFACING TECHNIQUE:

"All implants remain in situ and all patients are satisfied with both pain relief and range of motion. There has been no radiographic loosening."

Ross M, Duke P. Early experience in the use of a new glenoid resurfacing technique. 2006 Shoulder & Elbow Society of Australia Conference Handbook. Nov 4; Session 4: 0800 – 0930.

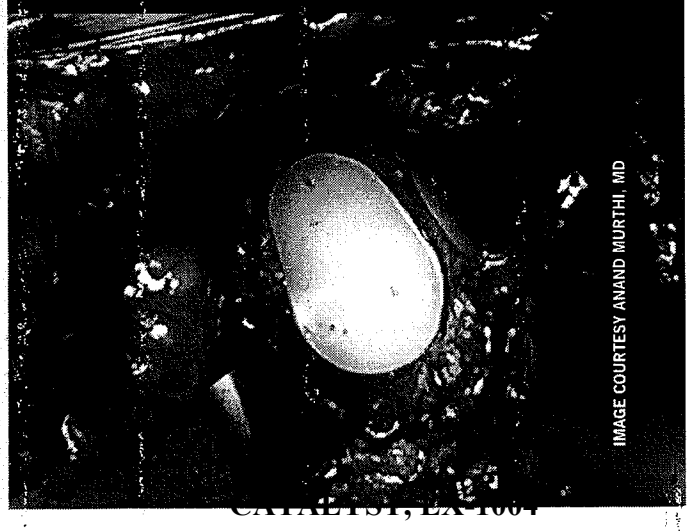


IMAGE COURTESY ANAND MURTHI, MD

redefining modularity

TITAN Modular Shoulder System:

Heads

- Eccentric 38-52 mm diameters
- Concentric 42-52 mm diameters

Bodies

- Primary (8 options)
- Fracture (3 Options)

Stems

- Press-fit 6-16 mm (1 mm increments)
- Cemented 6-14 mm (2 mm increments)

Glenoids

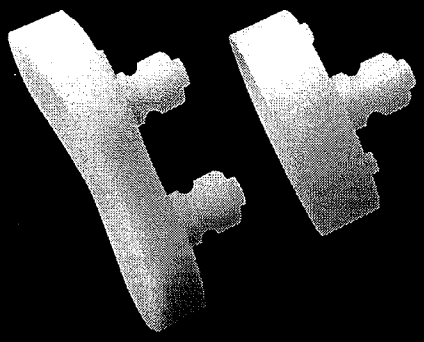
- Standard Pegged (4 options, X Small-Large)
- Standard Keeled (4 options, X Small-Large)
- **Inset Mini Glenoid (5 options: 2 Round, 3 Oval)**

Humeral Resurfacing Implant

- 8 size options based on anatomic data analysis

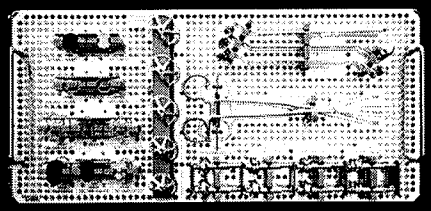


TITAN Inset Mini Glenoids



GLN-0940-030-31R	Mini Glenoid, Round, 31mm
GLN-0940-030-44R	Mini Glenoid, Round, 44mm
GLN-0940-030-31S	Mini Glenoid, Oval-Small, 31mm
GLN-0940-030-44S	Mini Glenoid, Oval-Small, 44mm
GLN-0940-030-44L	Mini Glenoid, Oval-Large, 44mm

Instrumentation



INS-0920-05	TITAN Modular Shoulder System: Glenoid Tray with Mini Glenoid

Ascension Orthopedics

8700 Cameron Rd
Austin, TX 78754
512.836.5001 ph
512.836.6933 fax

www.ascensionortho.com

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

MK-0927-005 rev A
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INFORMATION DISCLOSURE STATEMENT

First Inventor: Running, Donald E.	**Conf. No.:** 5500
App. No.: 18/058058	**Filed:** November 22, 2022
Examiner: Schillinger, Ann M.	**Art Unit:** 3774
Title: TOTAL REVERSE SHOULDER SYSTEMS AND METHODS	

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

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted. Any foreign references may also include English abstract(s) and/or machine translation(s), but no representation is made as to their accuracy.

If the Examiner would like additional information regarding these references or if anything is unclear, the Examiner is invited to contact the undersigned for assistance.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed before the receipt of a First Office Action on the merits, and presumably no fee is required. If a First Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 CFR 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 6, 2023

By: /Andrew I. Kimmel/
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Registration No. 58,855
Registered Practitioner
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(74) Agent: **CLARK, Paul, T.**; Clark & Elbing LLP, 101 Federal Street, Boston, MA 02110 (US).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2008/011078 A2

(54) Title: HUMERAL HEAD RESURFACING IMPLANT AND METHODS OF USE THEREOF

(57) Abstract: The invention features a monoblock (non-modular) humeral head (shoulder) resurfacing implant designed to replace a portion of the patient's humeral head. The humeral head may need replacing due to trauma, osteonecrosis, infection, arthritis, or other causes. The implant of the invention is designed to be performed either as a hemiarthroplasty or as a component of a total shoulder replacement along with a standard glenoid or inset glenoid implant.

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(71) Applicant *(for all designated States except US)*: **SHOULDER INNOVATIONS, LLC** [US/US]; 4670 Fulton St., East, Suite 202, Grand Rapids, MI 49301 (US).

(72) Inventors; and

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(54) **Title**: STEM FOR USE IN JOINT ARTHROPLASTY

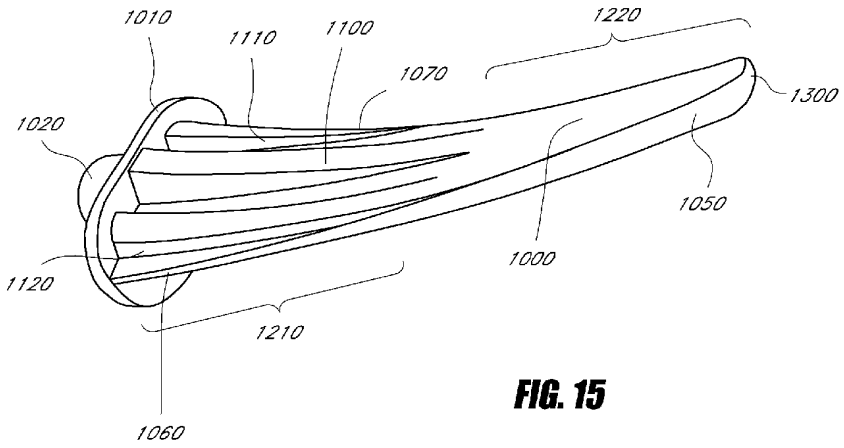


FIG. 15

(57) **Abstract**: The invention relates to a prosthesis for implantation into a long bone during joint arthroplasty, particularly Total Shoulder Arthoplasty and Total Hip Arthroplasty, and a method for use of the implant.

WO 2012/075183 A2

STEM FOR USE IN JOINT ARTHROPLASTY

PRIORITY CLAIM

[0001] This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application No. 61/418,346, filed on November 30, 2010; the entirety of which is incorporated by reference herein and made a part of the present specification.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The invention relates to, in some aspects, the geometry of a stem for implantation within long bones during joint arthroplasty, particularly as it relates to Total Hip Arthroplasty or Total Shoulder Arthroplasty.

Description of the Related Art

[0003] Total joint arthroplasty is an established surgical treatment of diseased joints and is effective in the relief of pain and the restoration of function of disease compromised joints. Successful joint arthroplasty results in the restoration of functionality, mobility, and quality of life to patients who would otherwise be disabled as a result of joint disease.

[0004] A typical surgical procedure involves the surgical exposure of the affected joint, resection and excision of diseased bone tissue and the replacement of the excised tissue with a manufactured, mechanical joint set. The joint components may be attached to native bone by means of conventional fasteners, bone cements or interference fitting of the components within prepared cavities in the native bone structure.

[0005] A typical joint set comprises a rigid stem placed within the medullary canal of the long bone of the joint, typically manufactured from stainless steel, titanium, chromium cobalt alloy or other bio-compatible metal, a generally spherical or convex articulating component, typically manufactured of a metallic alloy or ceramic material and a corresponding concave articulating surface, typically manufactured from a polymer or ceramic material.

[0006] Exposure of the joint structure may be accomplished by a surgical approach which is directed posteriorly or by an approach which is directed anteriorly to the femur or humerus. In hip surgery the posterior approach is currently used by many surgeons as it allows for a wide exposure of the bone structures and good visualization within the wound. In shoulder surgery an anterior approach is typical. In many instances the surgical approach is dictated by the size and geometry of the implant devices being used. The current approaches typically result in a large incision size with associated muscle dissection and may be disruptive to patient anatomy. Recently, various minimally invasive techniques have been developed which require smaller incision sizes. An anterior approach to the hip joint structure has been developed and attempts are being made to minimize the incision and exposure of the shoulder joint. Associated with these techniques is a reduced exposure of, and access to, the bones within the joint structure. In addition, the reduced exposure and access pose substantial challenges to the surgeon as they relate to resecting diseases of the bone, preparing the native bone to receive implant devices, and inserting many of the implant devices currently available. The degree of difficulty associated is often higher, can result in higher complication rates when compared to conventional procedures with larger surgical exposures, and may require extended surgery times. Further, surgical outcomes are varied, depending upon surgeon skill and the nature of the defects in the native bone. As a consequence there is a need for implant components, particularly long bone implant components, which are compatible with smaller incisions and more restricted access to the native bone.

[0007] A further consequence of the small exposure is the limited space available to the surgeon within the joint wherein inter-operative adjustment of implant position can be made.

[0008] The axial position of the stem within the femoral or humeral bone is of particular importance. Misalignment of the stem with respect to the natural axis of the bone (known as varus and valgus mal-alignment) can result in abnormal biomechanics of the joint and atypical stress distributions within the bone structure which may result in implant loosening, dislocation, pain, or may cause fractures of the bone. Mal-alignments may result from poor surgical technique, inadequate exposure of the femur, incompatibility of

instruments and implants with the surgical approach, or from natural deformities of the native bone within the medullary canal or metaphyseal regions of the bone.

[0009] Mal-alignment of the implanted stem may result in aseptic loosening of the implant or localized remodeling of the native cortical bone over time, ultimately causing failure of the implant and requiring additional revision surgeries to be performed to repair or replace the implant. These problems are well described and discussed in the published literature, including but not limited to, Panisello et al., (Journal of Orthopedic Surgery; 2006 Apr; 14(1): 32-37), Braun et al. (OrthoSupersite; Oct 2007), Ozturk et al. (June 3, 2010), U.S. Patent Pub. No. 2004/0107002 to Katsuya, U.S. Patent Pub. No. 2008/0091274 to Murphy, U.S. Patent 5,314,489 to Hoffman et al., and U.S. Patent 5,514,184 to Doi et al., the descriptions of the clinical issues associated with stem alignment, biomechanics and implant failure being incorporated herein by reference in their entireties.

[0010] The aforementioned patents, publications, and articles incorporated by reference contain therein various designs and methods directed at addressing the previously discussed issues.

[0011] Various embodiments of implant stems have been described in the prior art in an attempt to resolve the issues previously described. Certain conventional stems have a proximal portion designed to locate within the metaphysis of the femur or of the humerus and a distal portion disposed to be located within the medullary canal of the bone. The proximal portions of these stems are either generally cylindrical or rectilinear (rectangular, triangular or trapezoidal) in shape when viewed in cross section along the proximal to distal axis of the implant and are intended to generally fill the metaphyseal region of the bone, the distal portion of each embodiment being narrow forms and being elongated so as to fit within the intramedullary canal of the distal region bone.

[0012] In general, the design of currently available implant stems involves the axial cross sections of the implant along the axis from the proximal portion to the distal end wherein the cross sectional profile is constant but the cross sectional area of the implant taken in a plane substantially perpendicular to the longitudinal axis reduces from the proximal to distal end.

[0013] Further, the cross sections are generally wider at the medial side than at the lateral side all along the axis of the implant. The distal portions of some implants may be cylindrical and may incorporate a variety of features including protrusions or secondary components in order to center the distal portion within the medullary canal and aid with implant alignment and fixation.

[0014] Disclosed herein is a novel design for a stem to be used within long bones during joint repair surgery.

SUMMARY OF THE INVENTION

[0015] There is provided in accordance with some embodiments a long bone implant for use in joint arthroplasty comprising a first end, a second end comprising a blunt tip, and a stem of the implant disposed between the first and second ends, such that a proximal portion of the stem comprises an anterior surface, a posterior surface, a medial surface and a lateral surface, wherein a measure of said medial surface taken in a plane perpendicular to the longitudinal axis of the implant is greater than a measure of said lateral surface taken in the same plane and a distal portion of the stem comprises an anterior surface, a posterior surface, a medial surface, and a lateral surface wherein a measure of said lateral surface taken in a plane perpendicular to the longitudinal axis of the implant is greater than a measure of the medial surface taken in the same plane..

[0016] In some embodiments, in the proximal portion of the stem, the medial surface dimension or measure (e.g., a transverse dimension) taken in a first plane perpendicular to the longitudinal axis of the implant comprises a dimension or measure 5% to 100%, or more, greater than the lateral surface measure in the same plane and, in the distal portion of the stem, the lateral surface taken in a second plane perpendicular to the longitudinal axis of the implant comprises a dimension or measure 5% to 100%, or more, greater than the medial surface dimension measure taken in the same plane. This results in large load bearing areas on the wide medial surface proximally and on the wide lateral surface distally. This also promotes self-centering of the implant in the medullary canal, avoiding varus or valgus mal-alignment.

[0017] In one embodiment of the invention, the implant is a femoral implant for use in hip arthroplasty. In some embodiments, the implant has one, two, three, four, or more axially oriented protrusions on the anterior surface, posterior surface, or both, which act, during implantation, as guide rails. In some embodiments, there are relatively medial and lateral guide rails on the anterior and posterior surfaces. In some embodiments of the invention, the medial guide rail extends further distally than the lateral guide rail, the lateral guide rail extends further distally than the medial guide rail, or they can extend the substantially same distance. The guide rails can serve multiple purposes. They help guide the implant during insertion, prevent rotation of the implant during and after insertion, and provide spaces between the rails for compacted cancellous bone, which increases the stability of the inserted implant. In another embodiment of the femoral implant, there are one, two, three or more voids on the proximal portion of the implant on the anterior surface, posterior surface, or both. These voids may be round, or any appropriate shape. The voids accommodate compressed cancellous bone during insertion or accommodate bone cement dispensed to assist fixation of the implant. In other embodiments, there are no voids.

[0018] In a further embodiment of the femoral implant, there is a lateral keel. Where the lateral keel arises on the proximal portion of the implant, there is a localized reduction in the cross section of the implant, when compared to adjacent sections of the keel laterally and stem medially. This allows minimized displacement of cancellous bone during insertion, reducing forces during insertion and also resists rotation of the implant both during and after insertion. In other embodiments, there is no lateral keel, or a keel without localized reduced cross section of the implant. In some embodiments, the length of the femoral implant is 100 to 130 mm. In other embodiments, it may be less than 100 mm or more than 130 mm.

[0019] In a further embodiment, the implant is a humeral implant for use in shoulder arthroplasty. In some embodiments, the implant has one, two, three, four or more stabilization ribs which provide mechanical structure, resist rotation of the implant within the bone, and enhance stability of the implant within the bone after implantation. In some embodiments, the ribs are on the anterior surface, posterior surface, or anterior and posterior surfaces. In other embodiments, there is a stabilization fin on the lateral aspect of the proximal surface. In some embodiments of the invention, the implant includes a collar

proximally to rest on the cortical bone and prevent subsidence of the implant into the humerus after implantation. In other embodiments, there is no collar. In some embodiments the implant has an overall length of 70 to 90 mm. In other embodiments, the implant has a length less than 70 mm, preferably about 60 mm. In some embodiments of the invention, the medial and lateral surfaces of the implant are curved, e.g., arcuate longitudinally. In other embodiments, the medial surface is arcuate, while the lateral surface is straight, or having an axis that is parallel or substantially parallel to a central longitudinal axis of the implant. In still other embodiments, neither the medial nor lateral surface is curved, e.g., arcuate along the length of the implant.

[0020] In accordance with a further aspect, there is provided an implant comprising a first end, a second end comprising a distal tip, e.g., a blunt distal tip, and disposed between the first and second ends, a stem comprising an anterior surface, a posterior surface, a medial surface, and a lateral surface, wherein either or both of a measure or dimension of the medial surface and a measure of the lateral surface taken in a plane substantially perpendicular to the longitudinal axis of the implant change from proximal to distal, such that a ratio of the medial measure to the lateral measure changes from proximal to distal along the longitudinal axis of the implant.

[0021] In some embodiments, the width of the medial surface and width of the lateral surface change continuously along the length of the stem. In other embodiments, the change is not continuous.

[0022] In some embodiments, the measure of the medial surface taken in a plane substantially perpendicular to the longitudinal axis of the implant generally decreases from proximal to distal along the stem and the measure of the lateral surface taken in a plane substantially perpendicular to the longitudinal axis of the implant generally increases from proximal to distal along the stem.

[0023] In some embodiments, the entire stem portion, or a portion thereof, is coated with a porous material for aiding in the fixation of the stem in the long bone for a press fit implant. In other embodiments, the implant is designed for cement fixation and can have a smooth surface or a roughened, textured surface.

[0024] In accordance with a further embodiment, there is provided a method for implanting a stem in a long bone during joint arthroplasty. The method comprises identifying a patient having identifying a patient having a diseased joint, surgically exposing the joint surface, excising an articulating portion of a long bone, preparing a proximal portion of the long bone to receive an implant, implanting a stem into the proximal portion and intramedullary canal of the long bone, said stem comprising a medial, a lateral, an anterior, and a posterior surface, the surfaces comprising a geometry such that the ratio of medial surface measure to lateral surface measure taken in a plane substantially perpendicular to the longitudinal axis of the stem changes along the stem from proximal to distal

[0025] The method may additionally comprise the step of securing the implant using bone cement, such as polymethylmethacrylate (PMMA) or a compatible fixation material. Alternatively, the implant can be press-fit.

[0026] Another aspect of the invention features a minimal incision shoulder arthroplasty technique that allows replacement of the glenoid surface and humeral head with only a small incision and less extensive soft tissue stripping. The "mini-incision" procedure also leaves the pectoralis tendon and the majority of the inferior capsule intact. The advantages of the "mini-incision" procedure include a shorter incision with less scarring, increased safety, and a more simple exposure of the glenoid, thus allowing general orthopedists to perform a shoulder replacement with less difficulty and potentially fewer complications. The skin incision is preferably less than 10 cm. in length, more preferably between 7 and 10 cm.

[0027] Further features and advantages will become apparent to those of skill in the art in view of the detailed description of embodiments which follows, when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] FIG. 1 is an anterior surface view of an implant device for implantation in the humerus.

[0029] FIG. 2 is an anterior surface view of an implant device for implantation in the femur.

[0030] FIG. 3 is an anteromedial surface view of a long bone implant.

[0031] FIG. 4 is a medial surface view of a long bone implant.

[0032] FIG. 5 is a view of a femoral implant with varus mal-alignment.

[0033] FIG. 6 is a view of a humeral implant placed in varus mal-alignment.

[0034] FIG. 7 is a view of a femoral implant placed in valgus mal-alignment with associated peri-prosthetic femur fracture.

[0035] FIG. 8 is an anterior surface view of a femoral implant showing the varying width of the medial surface from proximal to distal along the stem.

[0036] FIG. 9 is an anterior surface view of a femoral implant showing the varying width of the lateral surface from proximal to distal along the stem.

[0037] FIG. 10A-10I are schematic cross sectional areas (not necessarily to scale) of a femoral implant at approximately 10 mm intervals from a first end of the implant to a second end of the implant.

[0038] FIG. 11 is an anterior view of a femoral implant showing guide rails along the anterior surface of the implant.

[0039] FIG. 12 is an anterolateral view of a femoral implant showing guide rails along the anterior surface.

[0040] FIG. 13 is an anterior view of a femoral implant showing voids disposed in the proximal portion of the implant and a secondary keel feature in the lateral proximal portion of the implant.

[0041] FIG. 13A is a cross-sectional view of the proximal section of the implant of FIG. 13 showing the secondary keel feature.

[0042] FIG. 14 is another view of the femoral implant of FIG. 13 showing the voids in the proximal portion and the lateral keel.

[0043] FIG. 15 is an anterolateral view of a humeral implant also showing stabilizing fins and arcuate medial and lateral surfaces.

[0044] FIG. 16 is an anteromedial view of a humeral implant showing stabilizing fins and arcuate medial and lateral surfaces.

[0045] FIGS. 17A-17F are schematic cross sectional areas (not necessarily to scale) of a humeral implant from a first, e.g., proximal end to a second, e.g., distal end of the implant at approximately 10 mm intervals.

[0046] FIG. 18 is an image of a humeral implant placed within the bone.

[0047] FIG. 19 is an anteromedial view of a humeral implant showing a supplemental stabilization fin.

[0048] FIG. 20 is an anterolateral view of a humeral implant showing a supplemental stabilization fin.

[0049] FIG. 21 is an anterior view of a humeral implant showing an arcuate medial surface and straight lateral surface.

[0050] FIG. 22 is another view of a humeral implant showing an arcuate medial surface and straight lateral surface.

DETAILED DESCRIPTION

[0051] Referring now to figures 1 and 2, these figures illustrate current implant devices for implantation in humeral and femoral bones respectively. Implants used in the humerus (100) during joint arthroplasty have a proximal region (101) and a stem portion (102), the distal portion terminating in a distal tip (103). The proximal portion of the humeral implant may have flanges (104) protruding radially from the proximal stem region, these flanges being disposed in a manner to resist rotation of the implant within the cancellous bone after implantation within the humerus. The proximal portion will further have a receiving feature (105) for the purpose of mechanically coupling to an articulating component of the joint replacement system. Humeral stem implants will typically have a flange feature (106) intended to restrict the penetration of the implant within the native bone and to resist post-operative subsidence of the implant under anatomical loading conditions. Humeral stem implants are typically 120mm to 160mm in length and femoral stems are typically in the range of 150mm to 200mm in length.

[0052] Implants used in the femur during joint arthroplasty are of a similar construct to those used in humeral joint arthroplasty. Referring to figure 2 the implant (200) has a distal region (202), a blunt distal tip (203), a proximal region (201), and a coupling

means (205) to receive an articulating surface component. The proximal region (201) may have various features or surface treatments (204) thereon for the purpose of improving torsional stability of the implant within the bone after implantation. The implant may or may not also have a medial collar (206) proximally to rest on cortical bone and prevent subsidence of the implant.

[0053] Referring now to figures 3 and 4, all long bone implants can be generally described as having a medial surface (307), a lateral surface (308) an anterior surface (309) and a posterior surface (310), these surfaces corresponding to the orientation of the implant within the bone after implantation.

[0054] In the implants currently available or disclosed within prior art the proportionate relationship between the medial surface and the lateral surface is generally constant; at any distance along the stem, the medial surface being greater than that of the lateral surface, or vice-versa.

[0055] The surgical technique associated with these stems in both humeral and femoral applications is generally similar, irrespective of the implant design; the joint structure is surgically exposed through an incision that is generally 120 mm to 200 mm in length, the spherical component of the long bone is resected and removed from the joint, a cavity is prepared within the long bone to receive the stem implant by removing native cancellous bone from within the bone by drilling and broaching, and the stem implant is fitted within the long bone. The distal portion of the implant extends through and within the intramedullary canal of the bone; the proximal portion is embedded within cancellous tissue at the proximal aspect of the bone. The implant may be secured by press fitting within the native bone, by the application of bone cements, or by other secondary fastening means.

[0056] The final position and orientation of the implant device is at best variable, being subject to influences of the surgeon's skill, the access to the bony structures available through the surgical incision, the trajectory established by the drilling and broaching steps in the procedure, native anomalies of the bone structure, and the patient's general anatomy.

[0057] As a consequence of this variability, it is not unusual to have implants that are in sub-optimal or compromising positions. Mal-position of the implant may lead to adverse clinical outcomes, including loosening of the implant, post-operative mechanical

instability of the joint, overstuffing of the joint, or peri-prosthetic fracture of the bone during or after surgery.

[0058] Referring now to figure 5, a femoral implant is shown located within the femur; the proximal portion of the implant (501) has a medial bias while the distal portion of the implant (502) has a lateral bias. This is known as varus mal-alignment. In this position the implant device transfers anatomic loads (F) through the implant and couples these loads to the native bone disproportionately at the proximal medial position (503) and the distal lateral position (504) and effectively induces a cantilever effect which concentrates forces at the distal region (504). These forces may cause peri-prosthetic fractures of the bone in the distal region of the implant (504).

[0059] Similarly, now referring to Figure 6, a humeral implant (601) has been mal-positioned in a similar varus manner, with which results in overstuffing of the joint (610) and an increased risk of peri-prosthetic fracture at the distal lateral region (604).

[0060] Referring to Figure 7, a femoral implant is shown located within the femur. The proximal portion of the implant (701) has a lateral bias and the distal portion of the implant (702) has a medial bias. This is known as valgus mal-alignment of the implant. Loads are disproportionately borne at the proximal lateral position (706) and distal medial position (704) of the bone. Further shown here is a peri-prosthetic fracture (705) of the femur which has resulted from forces (F) being inappropriately communicated to the medial aspect of the distal tip of the implant (704) and therefrom through the femur bone resulting in a fracture.

[0061] There remains a need for an implant device which can be implanted within long bone structures during joint arthroplasty which eliminates the variability of positioning, reduces the surgical variability, and is less invasive and less traumatic to the patient.

[0062] Referring then to figures 8 and 9, there is disclosed one embodiment of a femoral implant stem (800) for use in hip joint arthroplasty, the implant having a proximal portion (809), a distal portion (802), a medial surface (803), a lateral surface (804), an anterior surface (801), a posterior surface (805) and a coupling feature (806) adjacent to the neck of the implant for receiving the articulating element of a joint arthroplasty system.

[0063] The implant stem (800) has a first, longitudinal axis. The first, e.g., medial surface (803) has an axial dimension, such as a width, larger than that of an axial dimension of the second, e.g., lateral surface in the proximal region of the stem along a second axis transverse to the longitudinal axis and which in some embodiments is generally continuously decreasing in dimension (e.g., width) from the proximal end (803) to the distal end (810) of the implant (in other words, along the longitudinal axis of the stem (800)) and a lateral surface (804) at the distal end which has an axial dimension (e.g., width) which is larger than that of an axial dimension of the medial surface in the distal region of the stem and which is generally increasing in dimension (e.g., width) from the proximal (809) to the distal end (809). In some embodiments, the axial dimension of the medial surface (803) in a plane transverse to the longitudinal axis of the stem in the proximal region of the stem is at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 50%, 75%, 100%, or more greater than a corresponding axial dimension of the lateral surface in the proximal region of the stem along an axis transverse to the longitudinal axis of the stem in the proximal region of the stem in the same plane. The axial dimension of the lateral surface (804) in a plane transverse to the longitudinal axis of the stem the distal region of the stem can, in some cases, be at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 50%, 75%, 100%, or more greater than the axial dimension of the medial surface in the distal region of the stem transverse to the longitudinal axis of the stem in the distal region of the stem in the same plane. In some embodiments, the axial dimension of the medial surface (803) with respect to the axial dimension of the lateral surface (804) at a given first cross-sectional level (e.g., through a proximal, central, or distal section of the stem (800)) defined by an axis transverse to the longitudinal axis of the stem (800) comprises a first ratio or fraction. The axial dimension of the medial surface (803) with respect to the axial dimension of the lateral surface (804) at a given second cross-sectional level (e.g., through a proximal, central, or distal section of the stem) defined by an axis transverse to the longitudinal axis of the stem (800) comprises a second ratio or fraction. The first ratio or fraction can be, for example, at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%, 125%, 150%, 200%, 300%, or more of the second ratio or fraction. This results in an implant construct which has a large load bearing surface area on the medial surface (803) in the proximal region of the stem implant and a large load bearing surface area

on the lateral surface of the distal region of the implant (802). Further, this construct produces an implant where the lateral surface dimension (e.g., width) of the proximal region (809) is relatively small when compared to that of the corresponding medial surface width (803), and the medial surface dimension of the distal region (810) is substantially smaller than that of the corresponding lateral surface dimension (802).

[0064] As a consequence of these medial to lateral surface area transitions, the implant may potentially be inserted into the native bone without the need for drilling or reaming prior to insertion. In addition, this construct effectively self-centers the implant within the intramedullary canal of the native bone, substantially reducing the risk of varus or valgus mal-positioning.

[0065] The embodiment illustrated in figures 8 and 9 has a length in the range of, for example, about 100mm to about 130mm.

[0066] Figures 10a through 10i illustrates the continuously changing cross sectional area (900) and the differences in dimension, e.g., width of the medial (902) and lateral surfaces (901) of the femoral implant (905), the illustrated cross sections being shown at even increments of approximately 10mm measured from the proximal end (Figure 10a) to the distal end (Figure 10i) respectively. In some embodiments as schematically illustrated, the ratio of medial (902) surface dimension to lateral (901) surface dimension at a particular transverse cross-section of the stem changes from a first, e.g., proximal or distal portion (e.g., Figure 10a) of the stem to a second, e.g., proximal or distal portion (e.g., Figure 10i) of the stem. In some embodiments, the ratio of medial (902) surface dimension to lateral (901) surface dimension (e.g., Figure 10a) is greater than 1:1, such as greater than 1.1:1, 1.2:1, 1.3:1, 1.4:1, 1.5:1, 1.75:1, 2:1, 2.5:1. 3:1, 4:1, 5:1, 6:1, 7:1, 8:1, 9:1, 10:1, or more, while the ratio of medial (902) surface dimension to lateral (901) surface dimension (e.g., Figure 10i) is less than 1:1, such as less than 0.9:1, 0.8:1, 0.7:1, 0.6:1, 0.5:1, 0.4:1, 0.3:1, 0.2:1 or less. In some embodiments, the ratio of medial (902) surface dimension to lateral (901) surface dimension changes (e.g., increases or decreases) by at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 60%, 70%, 75%, 80%, 90%, 100%, 150%, 200%, 250%, 300%, 350%, 400%, 450%, 500%, 600%, 700%, 800%, 900%, 1000%, or more, or increases by at least 2x, 3x, 4x, 5x, 6x, 7x, 8x, 9x, 10x, 12x, 14x, 16x, 18x, 20x, 25x, or more with respect to

two different transverse cross sections spaced longitudinally 10mm, 20mm, 30mm, 40mm, 50mm, 60mm, 70mm, 80mm, 90mm, 100mm, or more apart from each other, or spaced longitudinally by 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or more of the entire axial length of the implant, or transverse cross sections taken at the two ends of the implant. In some embodiments, the medial (902) surface dimension is greater than the lateral (901) surface dimension at the proximal end of the implant while the medial (902) surface dimension is smaller than the lateral (901) surface dimension at the distal end of the implant, or vice versa. However, in some embodiments the absolute medial (902) surface dimension is larger (or smaller) than the lateral (901) surface dimension at cross-sections throughout the axial length of the stem, while the ratio of medial (902) surface dimension to lateral (901) surface dimension changes with respect to at least two, three, or more different transverse cross sections.

[0067] Figure 11 and Figure 12 are an alternate embodiment of the femoral implant previously described, having one, two, three, four, or more supplemental generally axially-oriented guide rails (920) (921) located on the anterior and posterior surfaces of the implant, these guide rails (920) (921) disposed to provide supplemental centering and trajectory control of the implant during the final insertion within the proximal bone of the femur. The supplemental guide rails shown are positive protrusions located on the anterior and posterior surfaces of the proximal region of the implant, the medial rail (920) extending further distally than the lateral guide rail (921) such that the distal ends of the guide rails (922 and 923) engage cancellous bone sequentially as the implant is inserted into the native bone so as to assist in continuous guidance of the implant during the insertion of the implant. During the final insertion of the implant within the bone, cancellous bone tissue is compacted in the spaces between each of the guide rails (940 and 950) so as to increase the stability of the implant in the inserted position.

[0068] Referring now to Figure 13 and Figure 14, yet another embodiment of the femoral implant is described. The anterior and posterior surfaces of the proximal region of the implant have therein one, two, three, four, or more voids (980) disposed to accommodate compressed cancellous bone displaced during the insertion of the implant or to accommodate bone cement dispensed to assist fixation of the implant within the bone. Further illustrated is

a secondary keel feature (990), disposed to substantially reduce the cross section of the lateral aspect of the implant locally in the proximal region so as to minimize the displacement of cancellous bone, thereby reducing insertion forces, and to minimize the tendency to introduce a medial turning moment during the final insertion. Figure 13a is a cross section through the proximal region of the implant showing the reduced cross sectional dimension at the secondary keel (990) relative to, for example, the dimension of the medial surface (902) of the implant, the dimension at the secondary keel (990) being at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, or less with respect to the dimension of the medial surface (902). .

[0069] Referring now specifically to figure 15 and figure 16, another embodiment of a stem for use in humeral applications in shoulder joint arthroplasty is described. The implant (1000) is similar in construction principle to that previously described for the femoral stem, the stem having a proximal region (1210), a distal region (1220), a receiving means (e.g., a cavity, threaded region, complementary interlocking connector, joint, and the like) (1020) to accept an articulating element of a joint arthroplasty system, one, two, or more proximal flanges (1010) disposed to prevent subsidence of the implant stem into the cancellous bone after implantation, and one or a series of stabilization ribs (1120, 1100, and 1110) disposed to provide mechanical structure, resist rotation of the implant within the bone, and enhance the stability of the implant within the bone after implantation. The implant shown herein has an overall length of 70mm to 90mm.

[0070] The medial to lateral surface dimension relationship of the humeral implant can be similar to that previously described in detail for the femoral implant; the axial dimension (e.g., width) of the medial surface (1070) in the proximal region (1210) is substantially wider than the dimension, (e.g., width) of the corresponding lateral surface (1060) such that the axial dimension of the medial surface (1070) in the proximal region (1210) is at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 50%, 75%, 100%, 200%, 300%, 400%, 500%, 600%, 700%, or more greater than the axial dimension of the corresponding lateral surface (1060) on an axis transverse to the longitudinal axis of the stem that includes the medial surface (1070). The width of the lateral surface (1050) in the distal region is substantially wider than that of the corresponding medial surface (1080), such that the axial dimension of the lateral surface (1050) in the distal region is at least about 5%, 10%,

15%, 20%, 25%, 30%, 35%, 40%, 50%, 75%, 100%, 200%, 300%, 400%, 500%, 600%, 700%, or more greater than the axial dimension of the corresponding medial surface (1080) on an axis transverse to the longitudinal axis of the stem that includes the lateral surface (1050). In some embodiments, the ratio of medial (902) surface dimension to lateral (901) surface dimension changes (e.g., increases or decreases) by at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 60%, 70%, 75%, 80%, 90%, 100%, 150%, 200%, 250%, 300%, 350%, 400%, 450%, 500%, 600%, 700%, 800%, 900%, 1000%, or more, or increases by at least 2x, 3x, 4x, 5x, 6x, 7x, 8x, 9x, 10x, 12x, 14x, 16x, 18x, 20x, 25x, or more with respect to two different transverse cross sections spaced longitudinally 10mm, 20mm, 30mm, 40mm, 50mm, 60mm, 70mm, 80mm, 90mm, 100mm, or more apart from each other, or spaced longitudinally by 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or more of the entire axial length of the implant, or transverse cross sections taken at the two ends of the implant. Figures 17a to 17f illustrate the relative dimensions, e.g., widths of the lateral surface (1050) and the medial surface (1080), the figures represent transverse cross sections across the implant device progressing at 10mm increments from the proximal end of the implant device (1000) to the distal end of the device. Further illustrated is the change in the origin of the included angle (A) between the anterior and posterior surfaces of the implant device from lateral to medial, or vice versa as shown by the transition of the base of a triangle formed by the included angle from the medial surface 1050 of the implant device in Figure 17a to the lateral surface 1050 of the implant device in Figure 17f. As illustrated, the angle A could change from positive to negative or negative to positive in successive cross-sections in a first direction to a second direction, and be, for example, less than about 80, 70, 60, 50, 40, 30, 20, 10, or less degrees in a first, e.g., proximal region of the implant and greater than about 20, 30, 40, 50, 60, 70, 80, or more degrees in a second, e.g., distal region of the implant. The below table lists one example of transverse dimensions at various cross-sectional levels as illustrated in Figures 17a-17f:

Figure	Lateral Surface Dimension (mm)	Medial Surface Dimension (mm)	Medial:Lateral Surface Dimension Ratio
17a	1.0	6.0	6:1
17b	2.0	5.0	5:2
17c	3.0	4.5	3:2
17d	3.5	3.5	1:1
17e	4.5	2.5	5:9
17f	7.0	2.5	5:14

[0071] Further shown in figure 15 and figure 16 are one or a series of stabilizing fins (1100, 1110, 1120) protruding from the anterior and/or posterior surfaces of the implant device. During the insertion of the proximal aspect of the implant (1210) said fins engage the soft cancellous bone tissue and compress it within the interspaces between the stabilizing fins thereby enhancing the stability within the bone, reducing the propensity to subside post operatively and improving the rotational stability of the implant within the native bone.

[0072] Of further note is the arcuate nature of the medial and lateral surfaces (1070 and 1060 respectively). Referring now to Figure 18, a radiographic image of one embodiment located within a humeral bone (1500) described in Figures 15, 16 and 17 (a-f) inclusive can be seen. The arcuate medial (1060) and lateral (1070) surfaces are shown engaging the intramedullary channel (1600). The larger medial surface (1070) is shown engaging the cortical bone at the medial aspect of the humerus in the proximal region while the wider lateral surface (1060) is shown engaging the cortical bone distally.

[0073] Referring now to Figures 19 and 20, an alternate embodiment of the humeral implant device previously described is shown. The humeral implant has a supplemental stabilization fin (1800) located, for example, at the lateral aspect of the proximal surface. Fin (1800) is disposed to further enhance the mechanical stability of the final implant within the bone and resist torsional loads on the implant to bone interface.

[0074] Figures 21 and 22 are alternate embodiments of a humeral stem having an curved, e.g., arcuate medial surface (1070) and a straight lateral surface (1060).

[0075] Although certain embodiments of the disclosure have been described in detail, certain variations and modifications will be apparent to those skilled in the art, including embodiments that do not provide all the features and benefits described herein. It will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative or additional embodiments and/or uses and obvious modifications and equivalents thereof. Certain embodiments of humeral implants as described, for example, in U.S. Pat. App. No. 13/088,976 to Gunther filed on April 18, 2011 and glenoid implants described, for example, in U.S. Pat. Pub. No. 2010/0249938 to Gunther et al., both of which are hereby incorporated by reference in their entireties, can be used or modified for use with stem embodiments as described herein In addition, while a number of variations have been shown and described in varying detail, other modifications, which are within the scope of the present disclosure, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the present disclosure. For example, while the features and embodiments shown herein have been described in the context of applications specific to individual bone structures, the various features described can be used individually, or in combination, to produce prosthetic bone implants for use in multiple and varied skeletal applications. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the present disclosure. Thus, it is intended that the scope of the present disclosure herein disclosed should not be limited by the particular disclosed embodiments described above. For all of the embodiments described above, the steps of any methods need not be performed sequentially.

WHAT IS CLAIMED IS:

1. An implant for use in a long bone during joint arthroplasty, said implant comprising:

   a first end;

   a second end comprising a blunt tip; and

   a stem of the implant disposed between the first and second ends, wherein

      a proximal portion of the stem comprises an anterior surface, a posterior surface, a medial surface and a lateral surface, wherein a dimension of said medial surface taken in a first plane substantially perpendicular to the longitudinal axis of the implant is greater than a dimension of said lateral surface taken in the same first plane, and

      a distal portion of the stem comprises an anterior surface, a posterior surface, a medial surface, and a lateral surface, wherein a dimension of said lateral surface taken in a second plane substantially perpendicular to the longitudinal axis of the implant, the second plane spaced distally apart from the first plane is greater than a dimension of the medial surface taken in the same second plane.

2. The implant of Claim 1, wherein the medial surface dimension taken in the first plane is at least 5% greater than the lateral surface dimension in the first plane and the lateral surface dimension taken in the second plane is at least 5% greater than the medial surface dimension taken in the same second plane.

3. The implant of Claim 1, wherein said implant is a femoral implant.

4. The implant of Claim 3, where the proximal portion of the stem further comprises a keel arising from the lateral surface of the stem, the medial origin of the keel comprising a section narrower in an anterior to posterior measurement than adjacent sections of the stem medially and the keel laterally to said medial origin section.

5. The implant of Claim 3, where said implant further comprises at least one axially oriented longitudinal protrusion on the anterior and posterior surfaces of the proximal portion of the stem.
6. The implant of Claim 5, where said stem further comprises at least two protrusions, one relatively medial and one relatively lateral, disposed along the longitudinal axis on the anterior and posterior surfaces of the proximal portion of the stem.
7. The implant of Claim 6, wherein the medial protrusion extends further distally on the stem than the lateral protrusion extends distally.
8. The implant of Claim 1, where said implant is a humeral implant.
9. The implant of Claim 8, where said implant further comprises a proximal collar disposed between the first end and the stem portion of the implant.
10. The implant of Claim 8, further comprising at least one anterior or posterior protrusion disposed along the proximal portion of the stem.
11. The implant of Claim 8, where the stem further comprises a curved medial surface and a curved lateral surface along the length of the stem.
12. The implant of Claim 8, where the stem further a curved medial surface and a substantially straight lateral surface along the length of the stem.
13. An implant for use in a long bone during joint arthroplasty, said implant comprising:

    a first end;

    a second end comprising a blunt distal tip; and

    a stem disposed between the first and second ends, said stem comprising an anterior surface, a posterior surface, a medial surface having a transverse dimension, and a lateral surface having a transverse dimension, the stem having a first medial:lateral dimension ratio defined by the transverse dimension of the medial surface taken in a first plane with respect to the transverse dimension of the lateral surface taken in the first plane, the stem also having a second medial:lateral dimension ratio defined by the transverse dimension of the medial

surface taken in a second plane with respect to the transverse dimension of the lateral surface taken in the second plane,

wherein the first plane is substantially transverse to a longitudinal axis of the implant, the first plane being near the first end of the implant and wherein the second plane is substantially transverse to the longitudinal axis of the implant, the second plane being near the second end of the implant,

wherein the second medial:lateral dimension ratio is different than the first medial:lateral dimension ratio.

14. The stem of Claim 13, wherein the second medial:lateral dimension ratio is at least about 10% less than the first medial:lateral dimension ratio.

15. A method of treating a patient, comprising the steps of:

identifying a patient having a joint for replacement;

surgically exposing the joint surface;

excising an articulating portion of a long bone;

preparing a proximal portion of the long bone to receive an implant; and

implanting a stem into the proximal portion and intramedullary canal of the long bone, said stem comprising a medial, a lateral, an anterior, and a posterior surface, the surfaces comprising a geometry such that the ratio of medial surface transverse dimension to lateral surface transverse dimension taken in a plane substantially perpendicular to the longitudinal axis of the stem changes along the axial length of the stem from the proximal end of the stem to the distal end of the stem.

16. The method of treating a patient as in Claim 16, wherein said joint is the shoulder and said long bone is the humerus.

17. The method of treating a patient as in Claim 17, additionally comprising the step of accessing the humerus via an incision no more than about 10 cm. in length.

18. The method of treating a patient as in Claim 16, wherein said joint is the hip and said long bone is the femur.

19. The method of treating a patient as in Claim 16, wherein the proximal portion of the long bone is prepared to receive an implant without reaming or drilling.

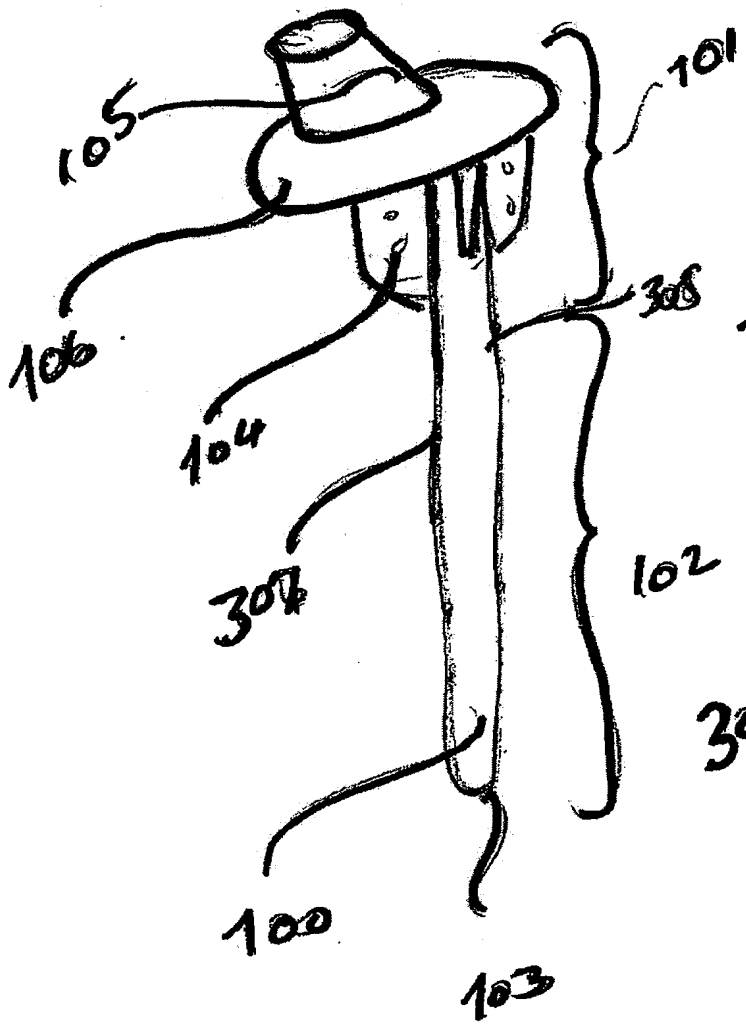


FIG 1

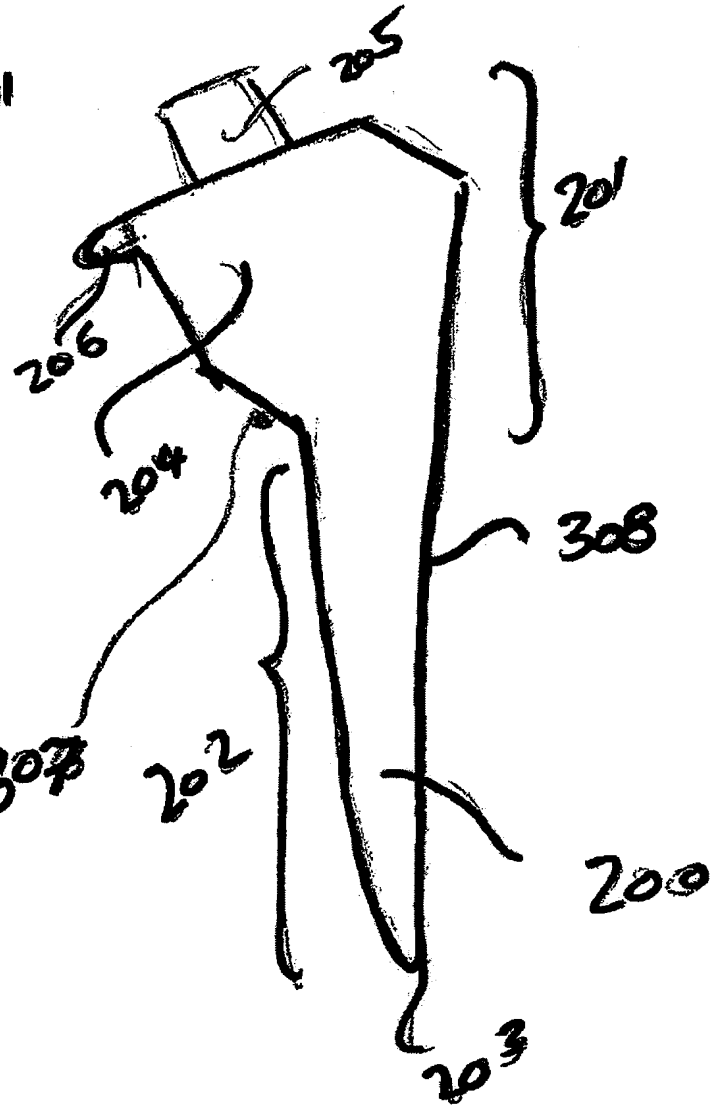


FIG 2

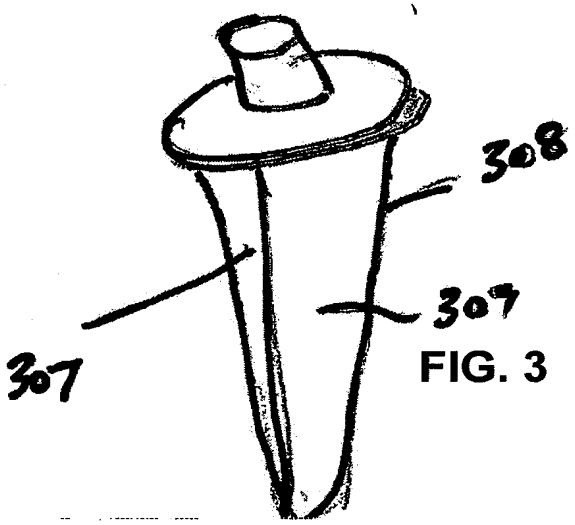


FIG. 3

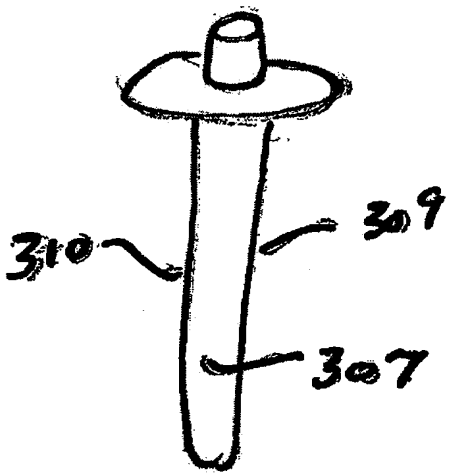


FIG. 4

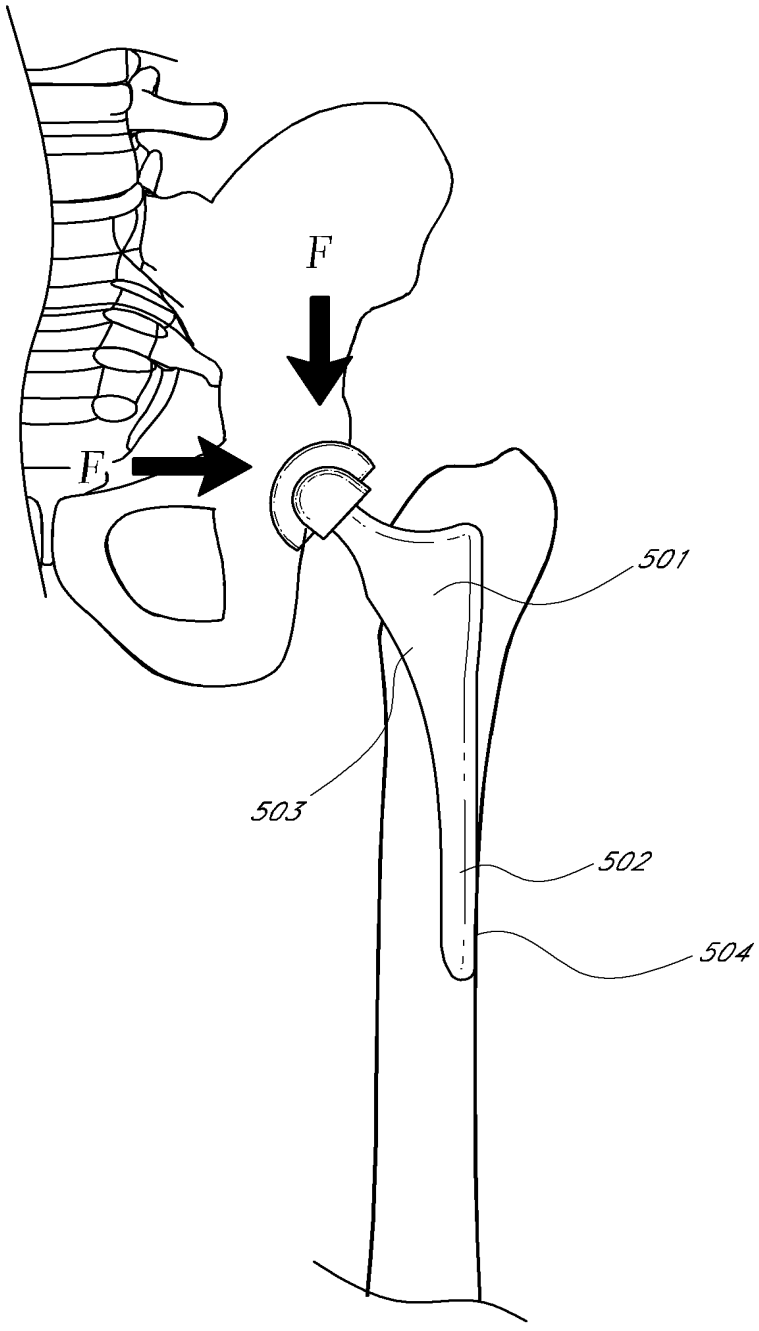


FIG. 5

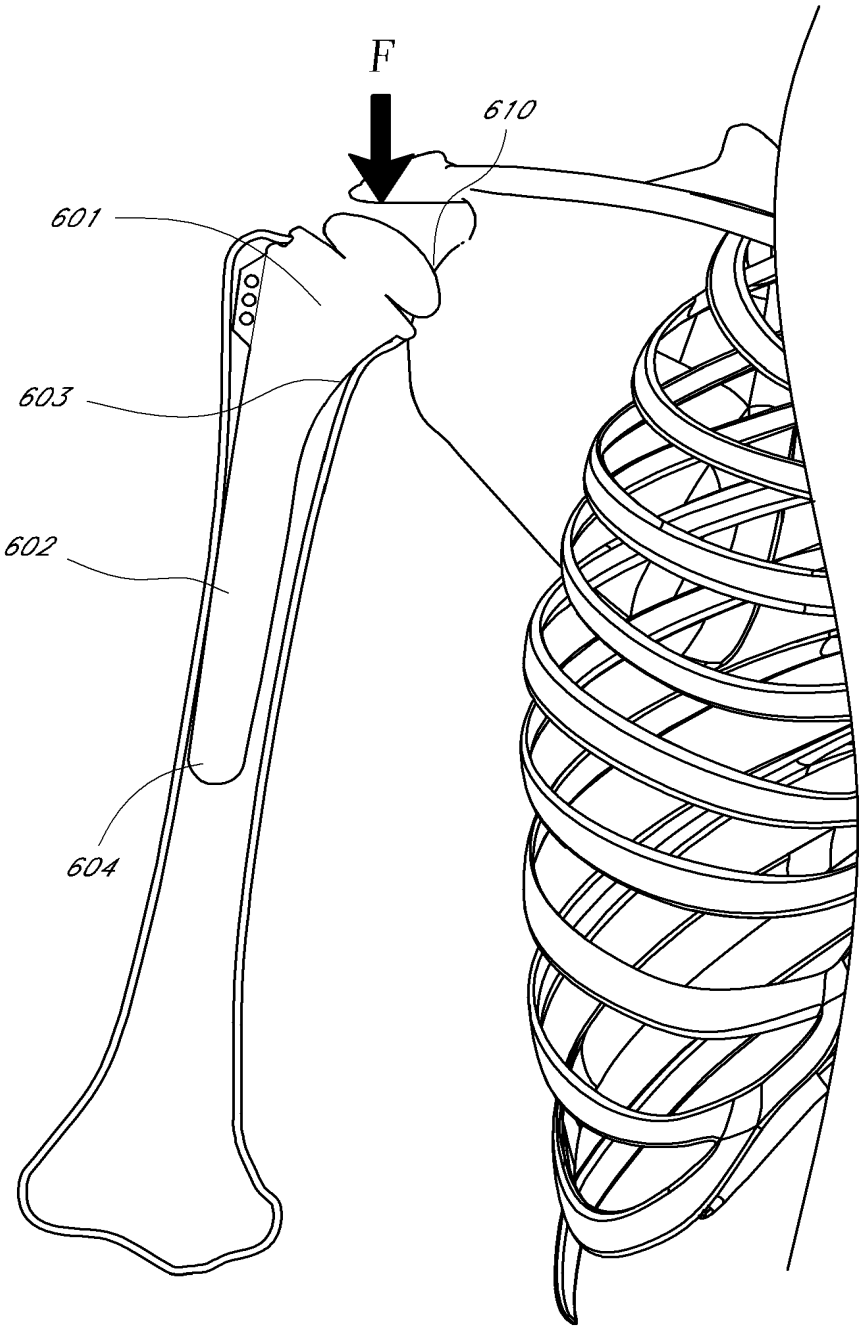


FIG. 6

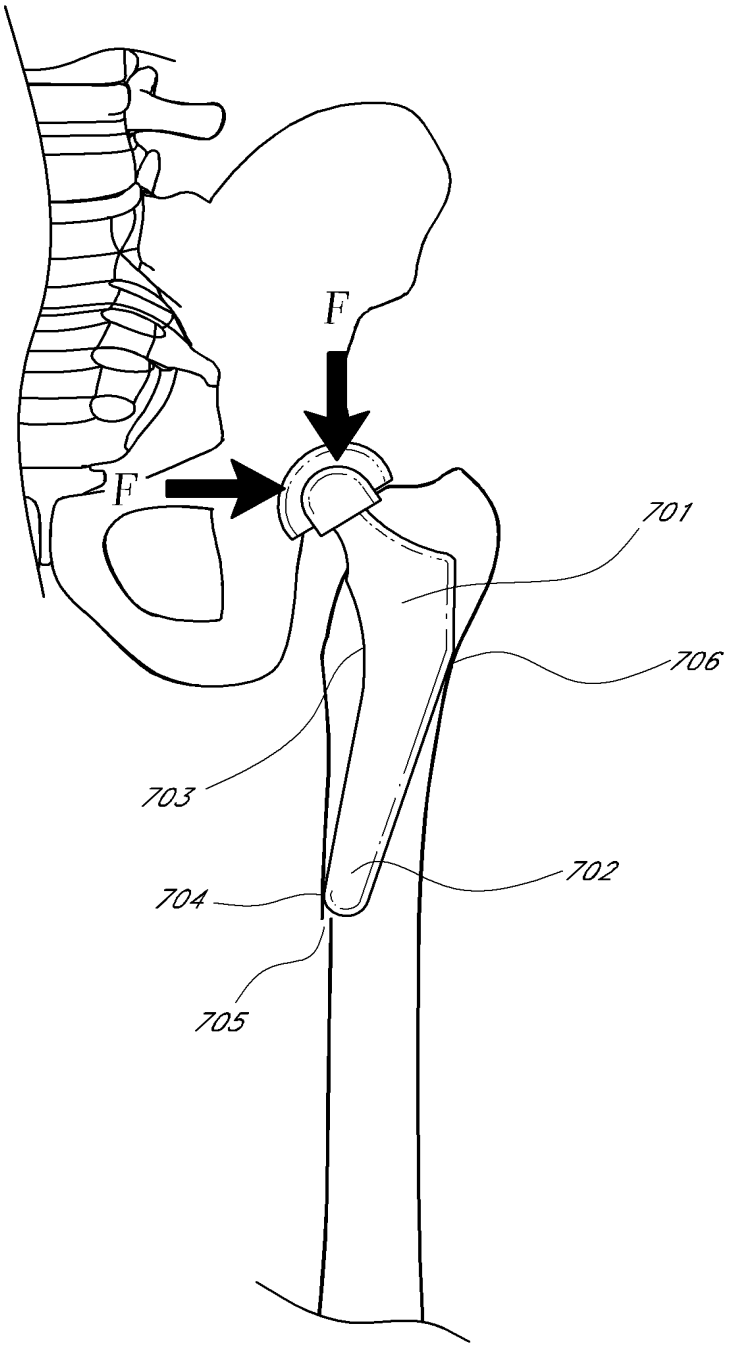


FIG. 7

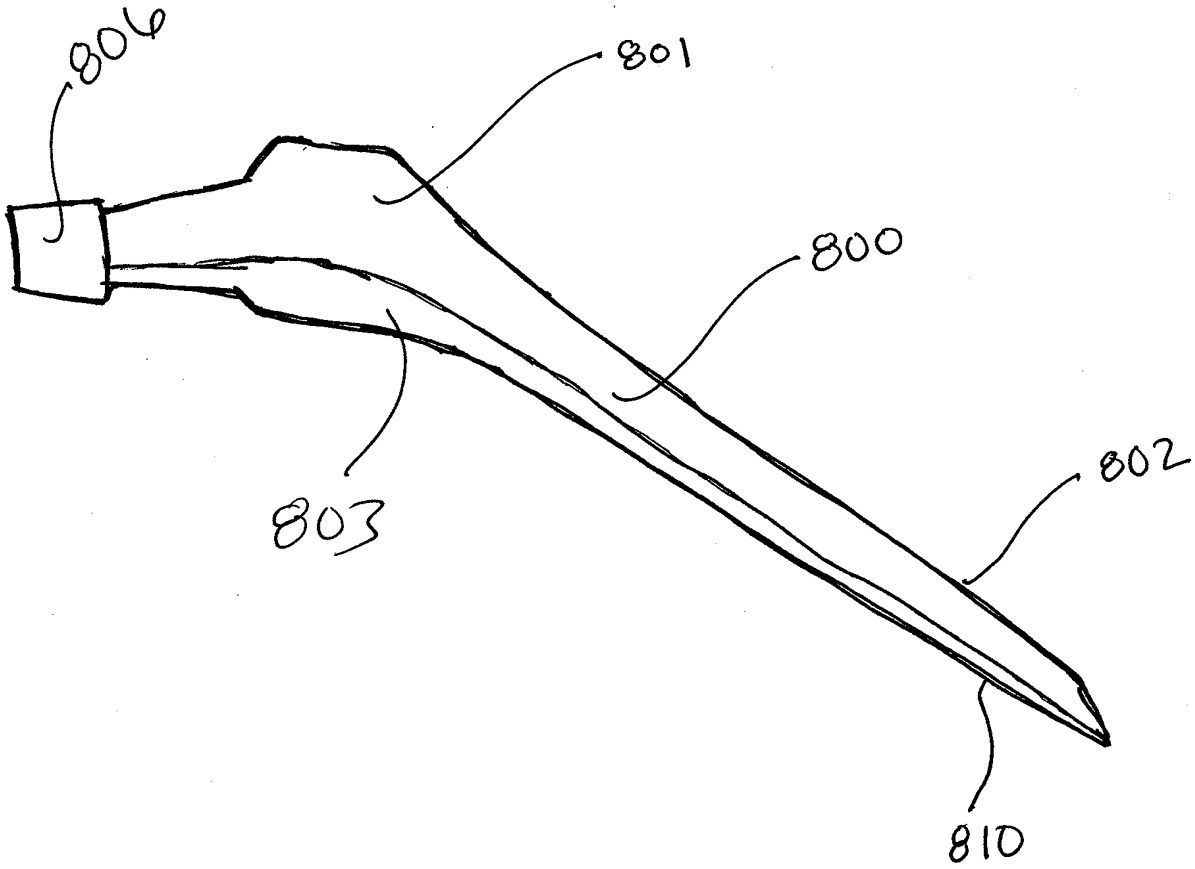


FIG 8

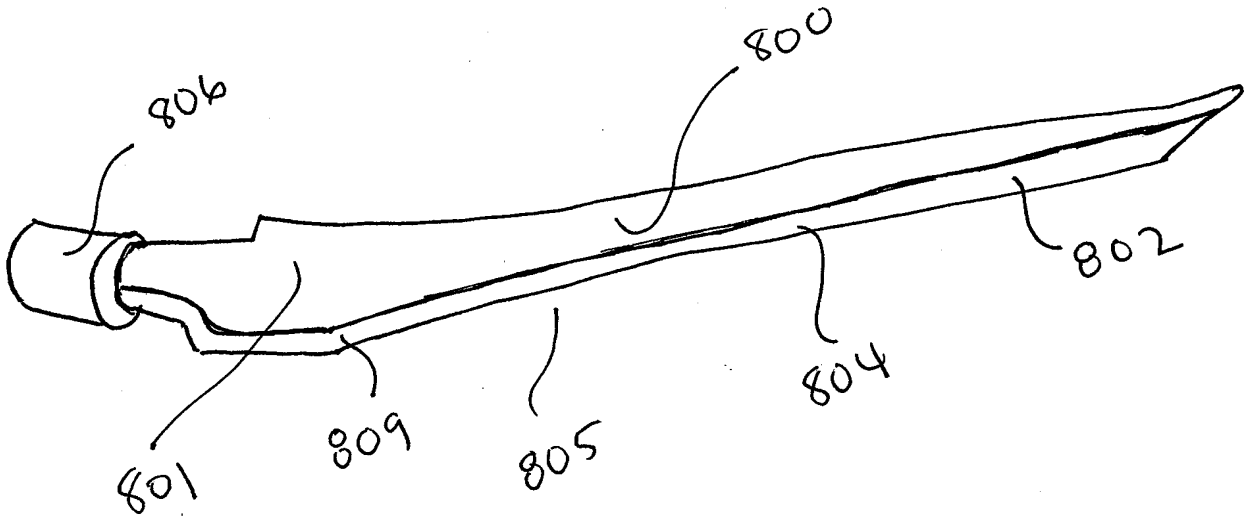
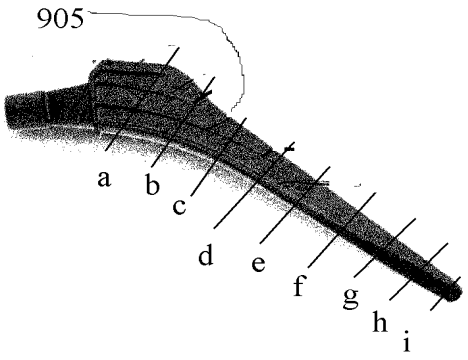


FIG 9



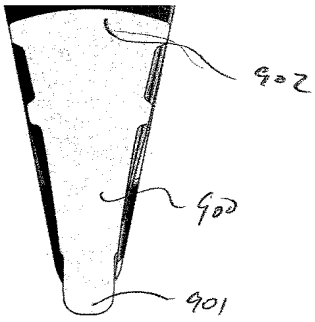


FIG 10a

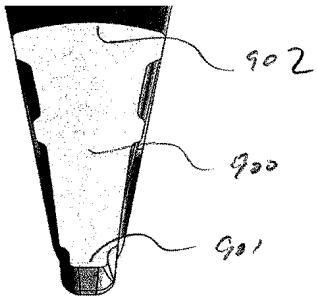


FIG 10b

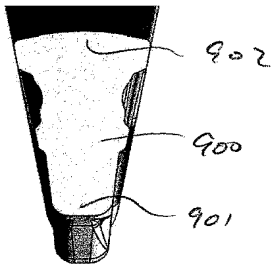


FIG 10c

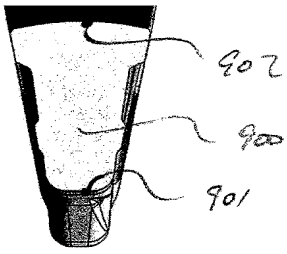


FIG 10d

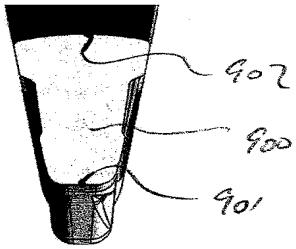


FIG 10e

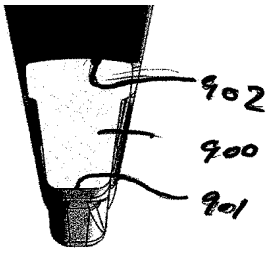


FIG 10f

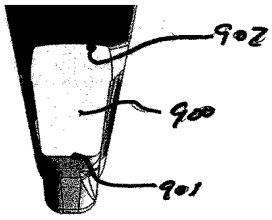


FIG 10g

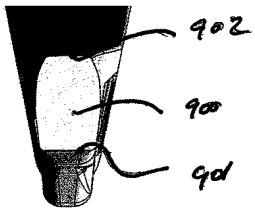


FIG 10h

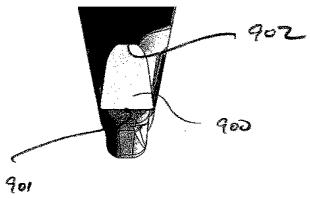


FIG 10i

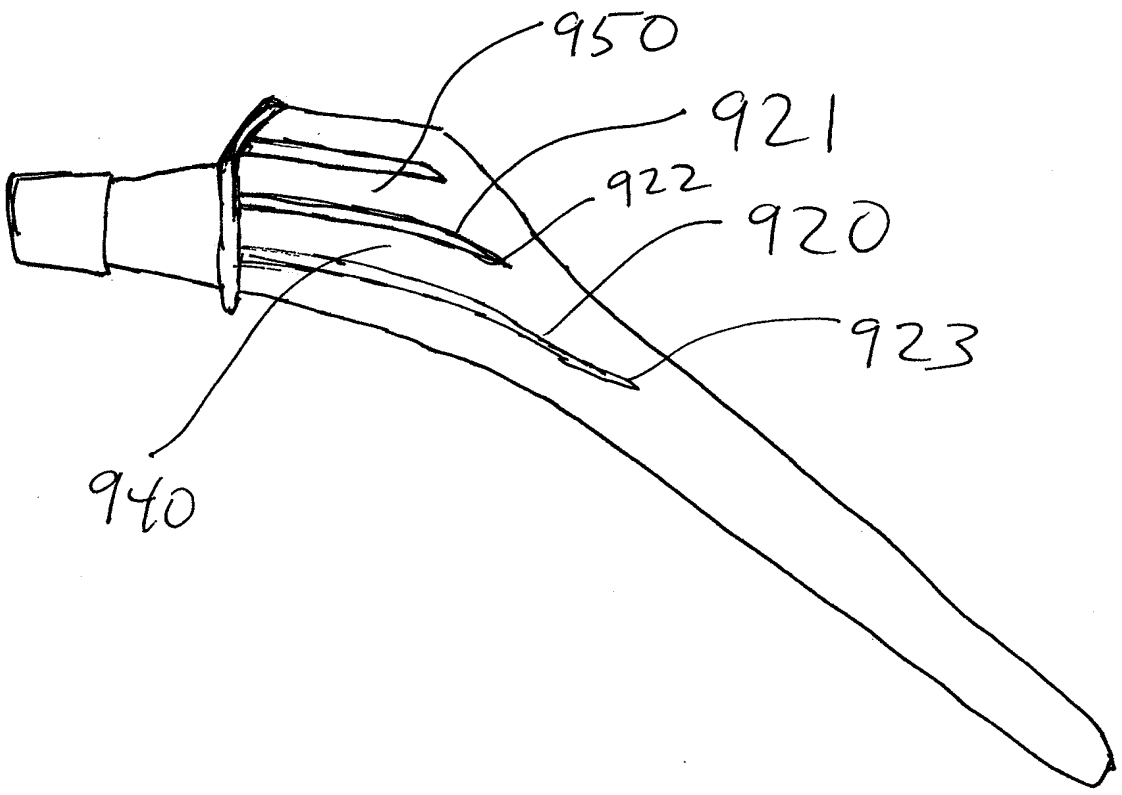


FIG. 11

4

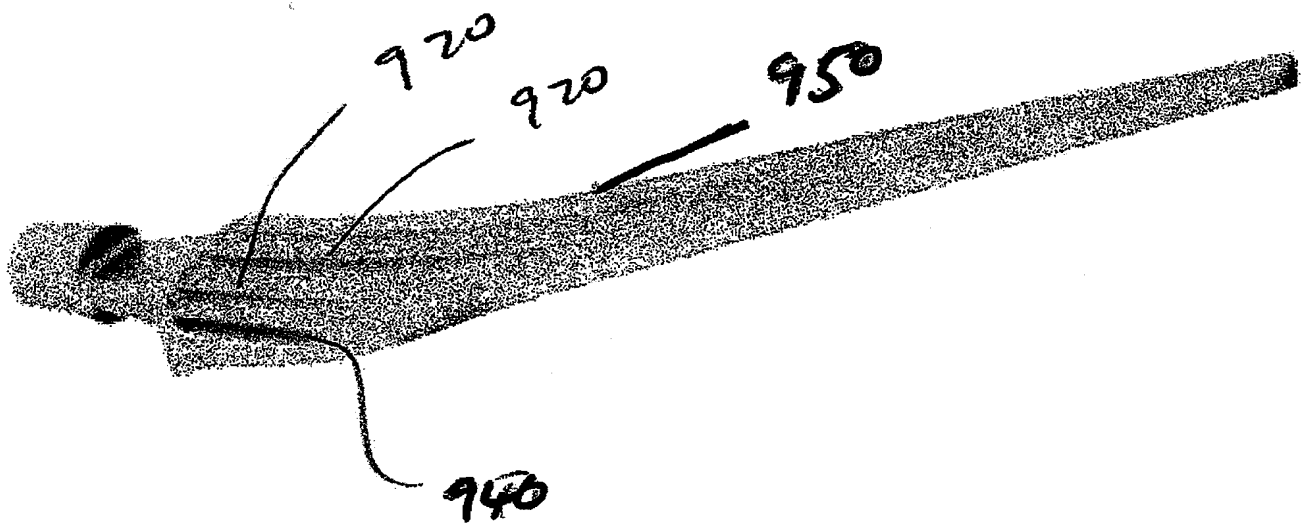


FIG 12

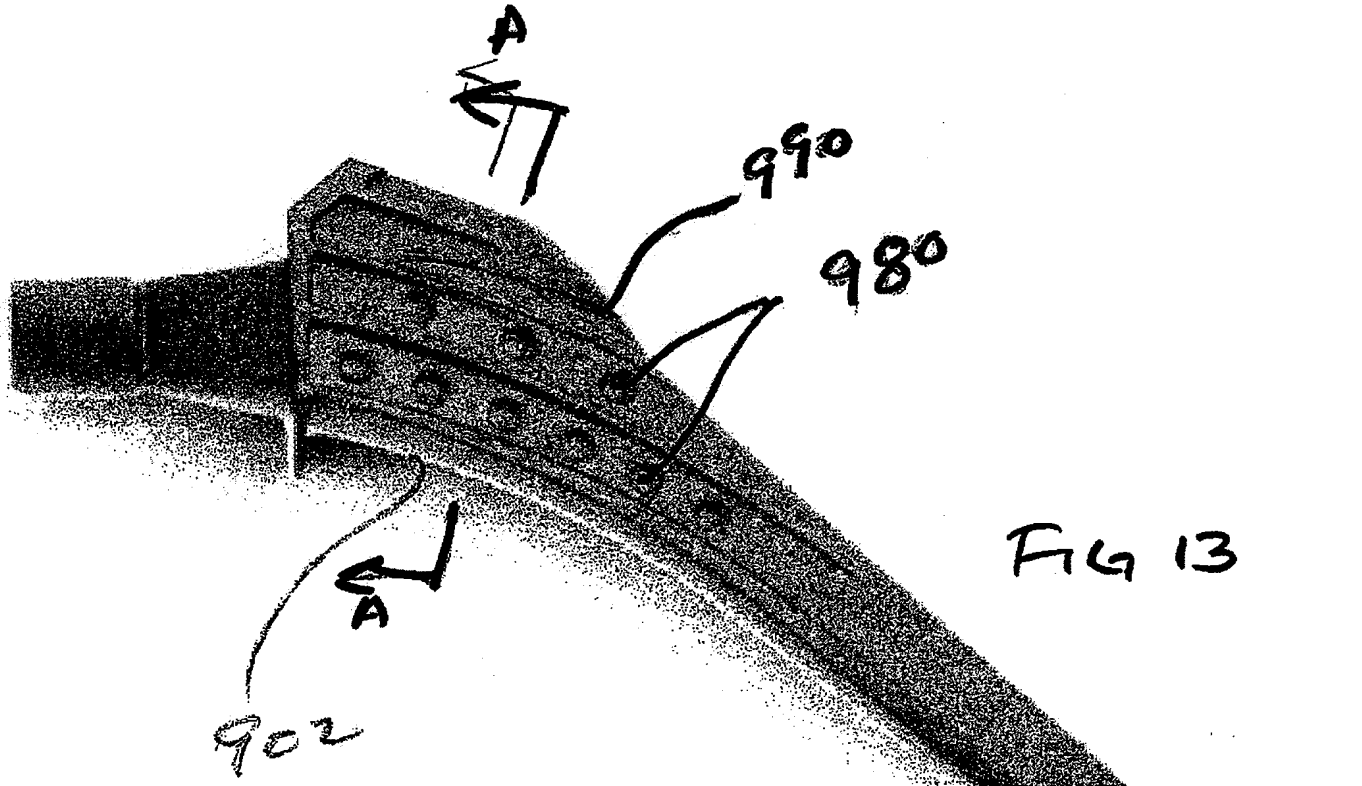


FIG 13

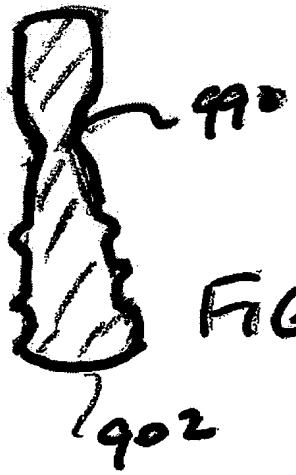


FIG 13a

SEC A-A

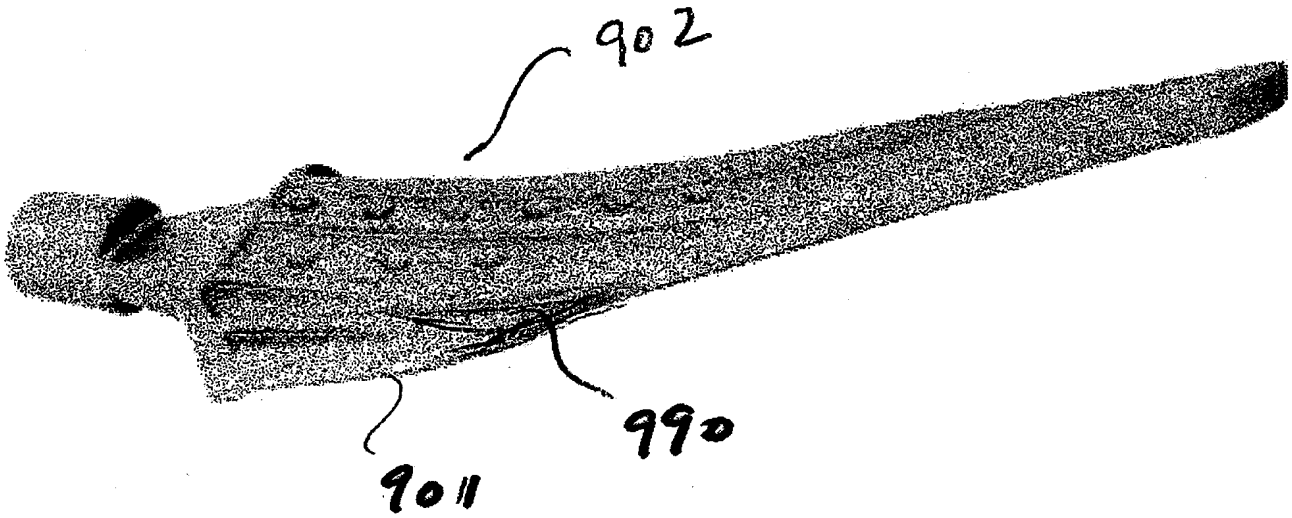


FIG14

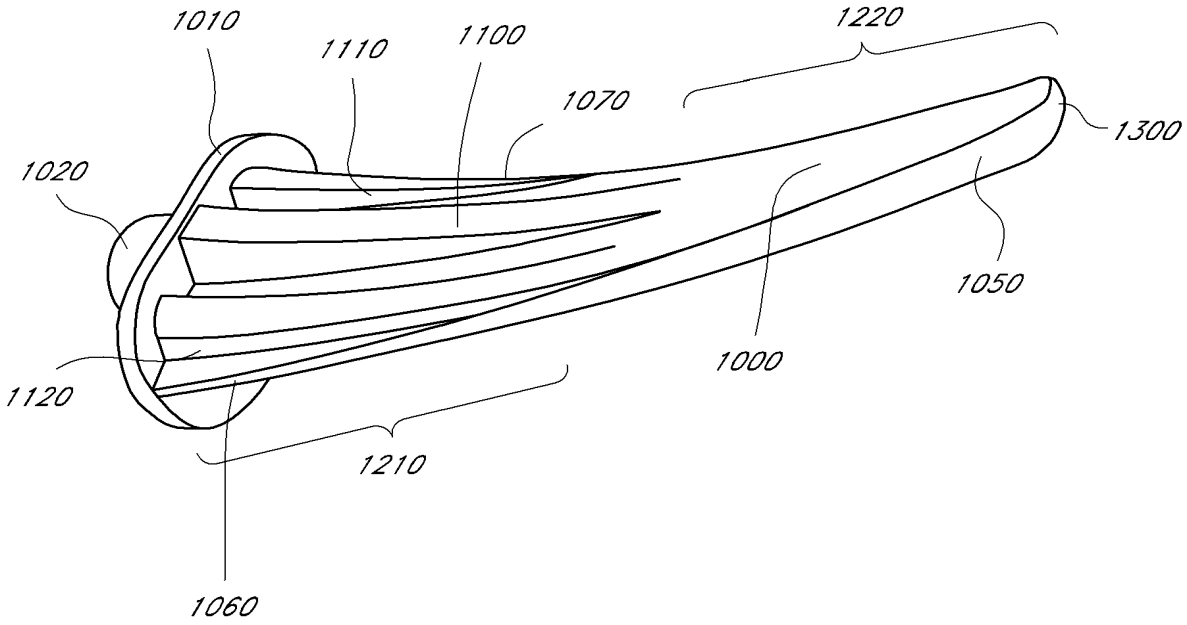


FIG. 15

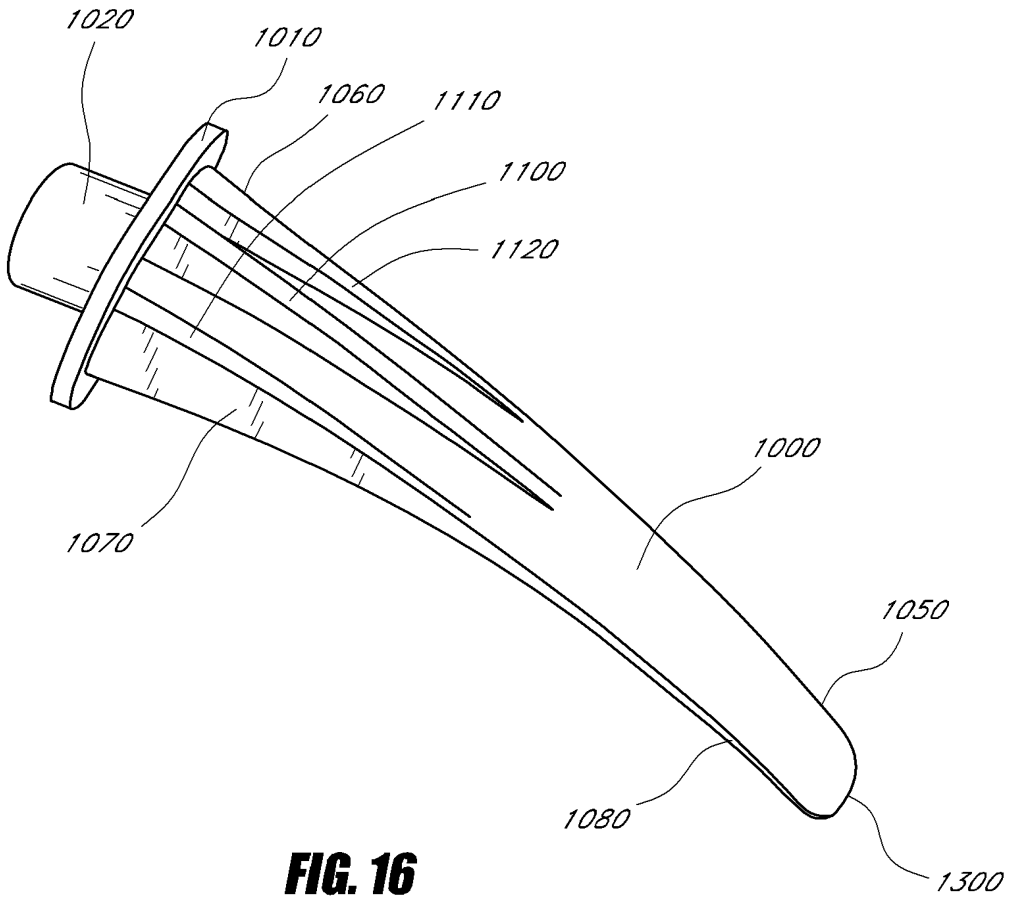


FIG. 16

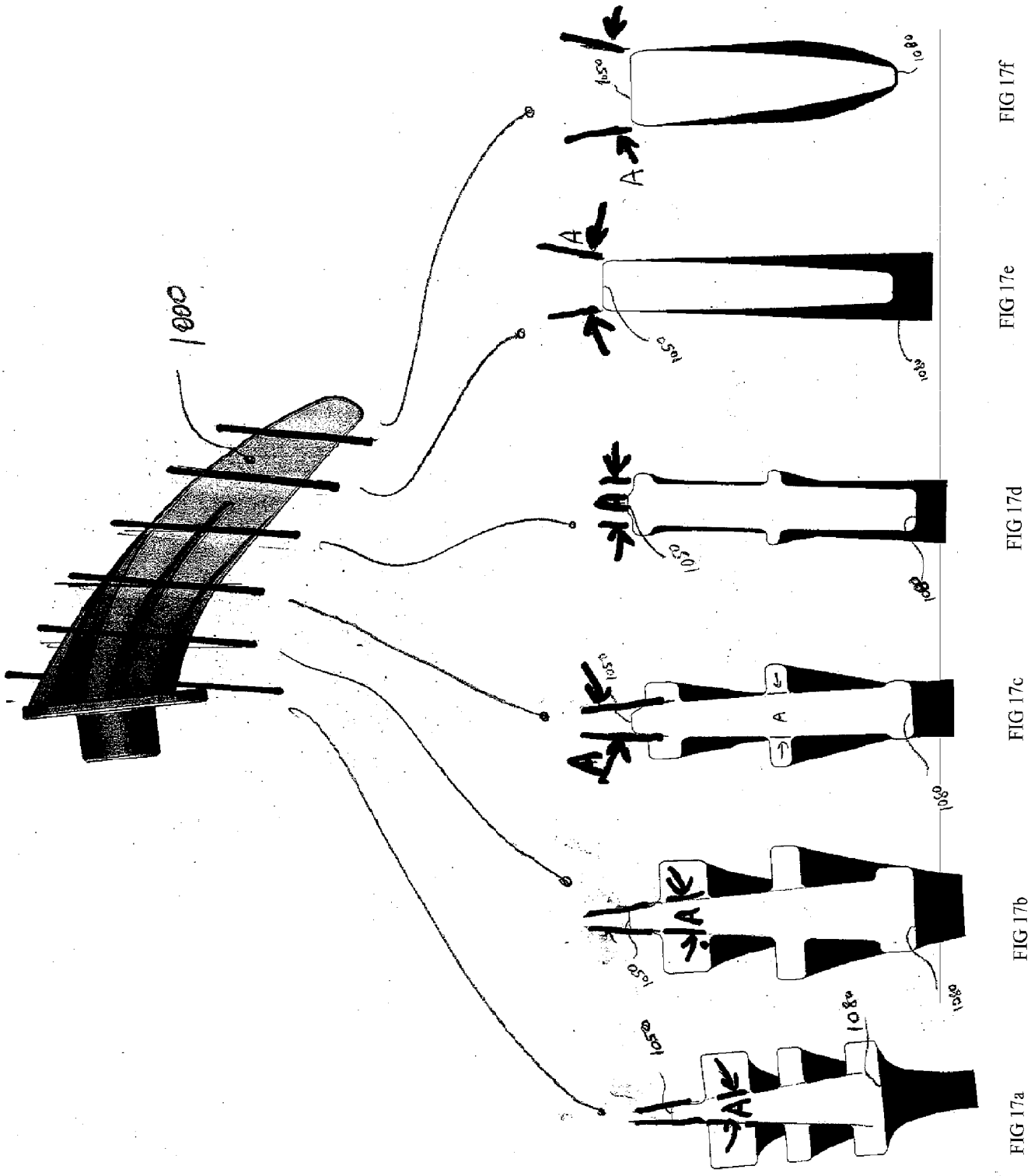


FIG 17a FIG 17b FIG 17c FIG 17d FIG 17e FIG 17f

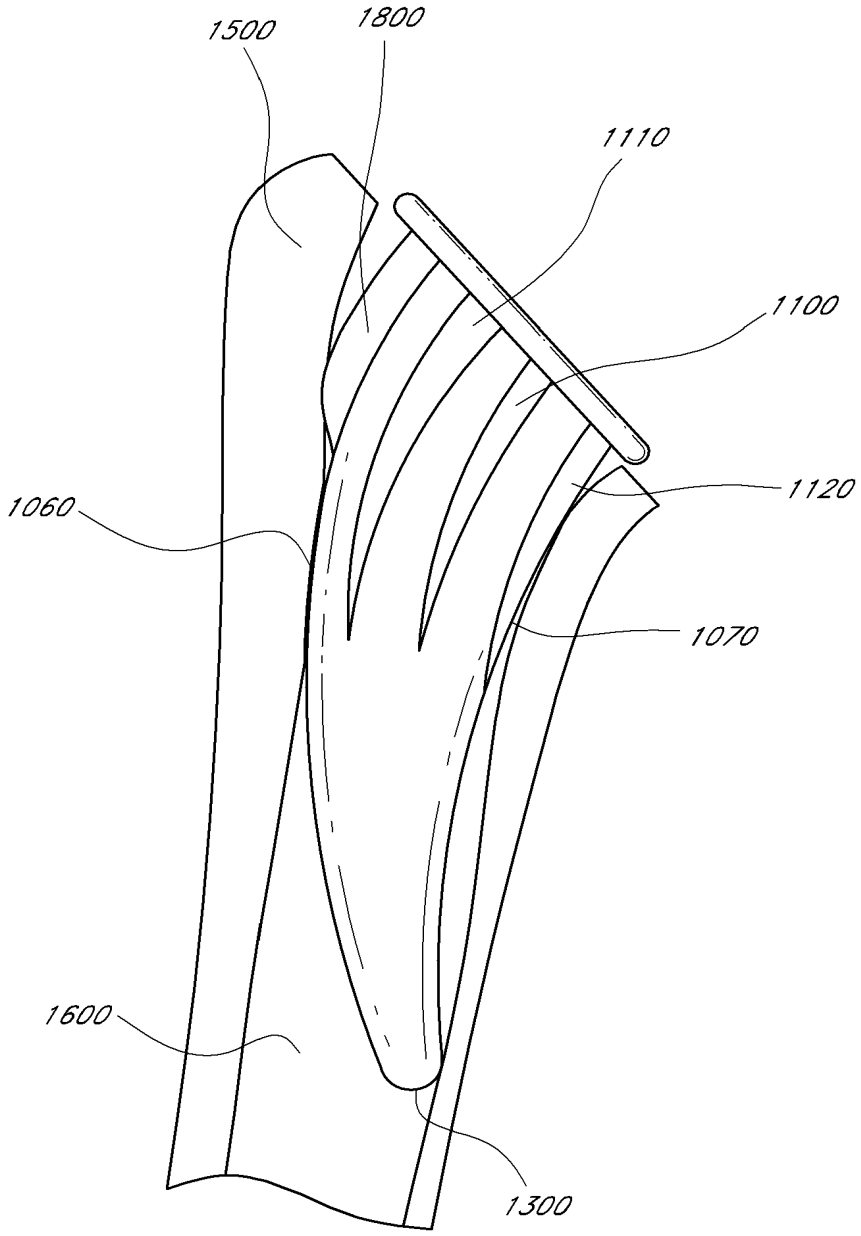


FIG. 18

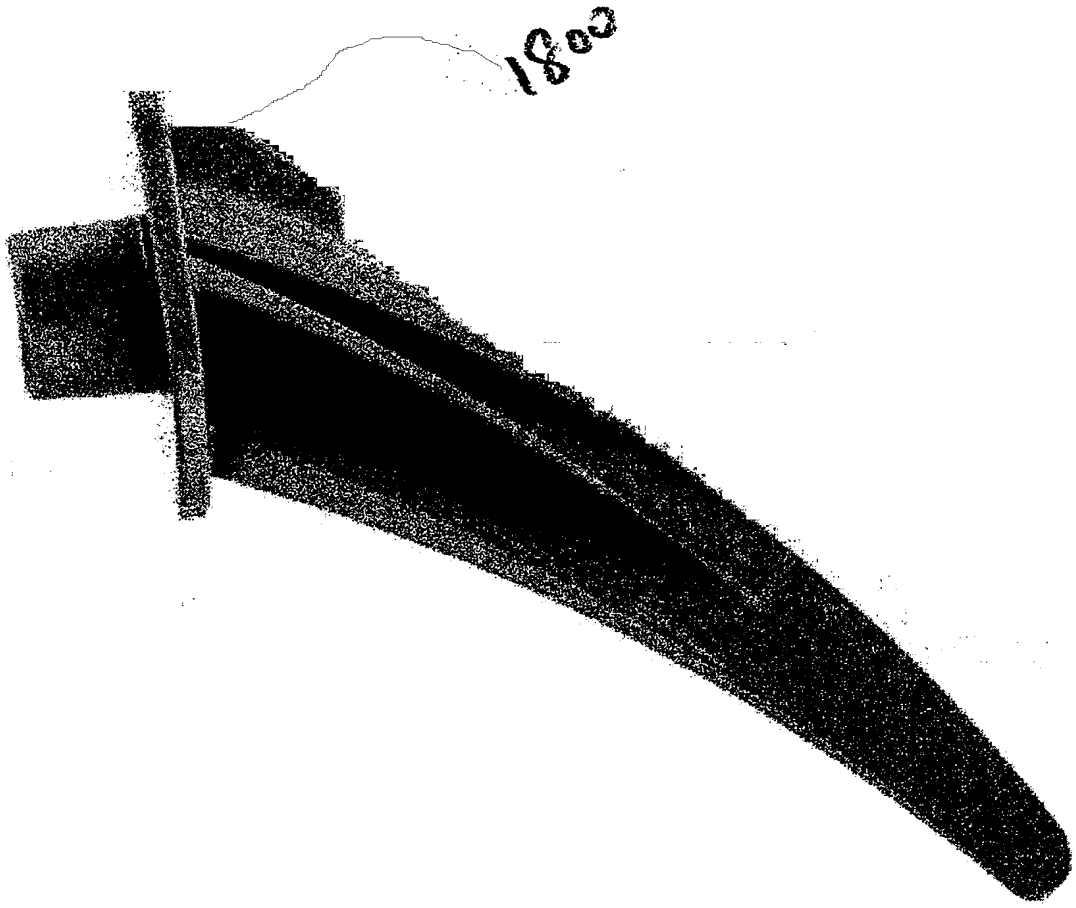


FIG 19

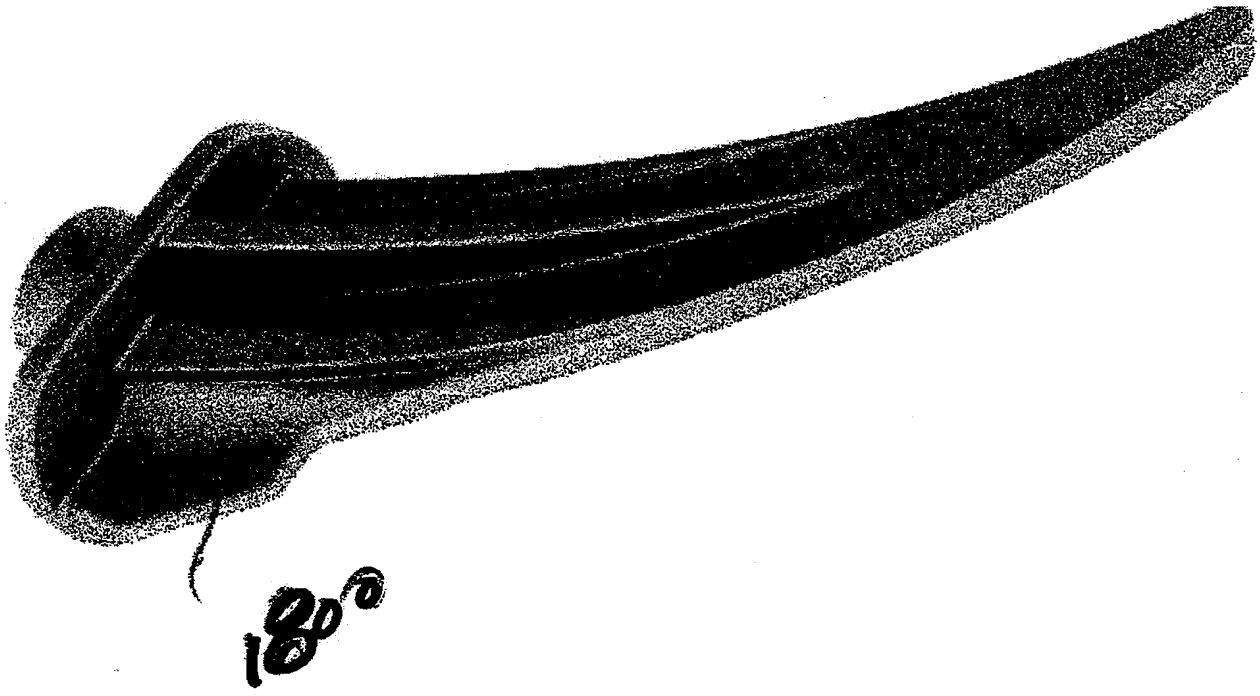


FIG 20

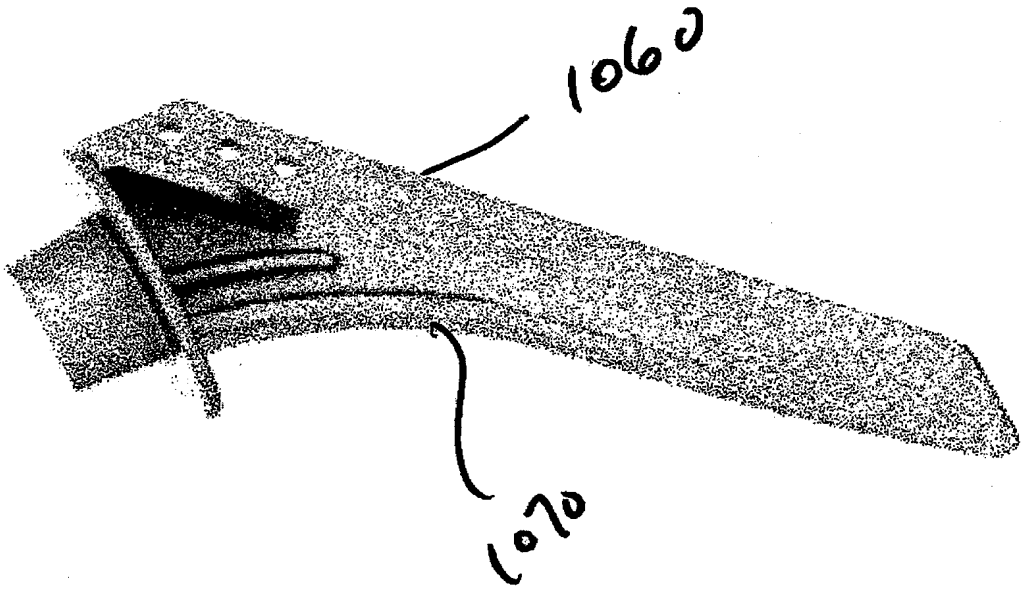


Fig 21

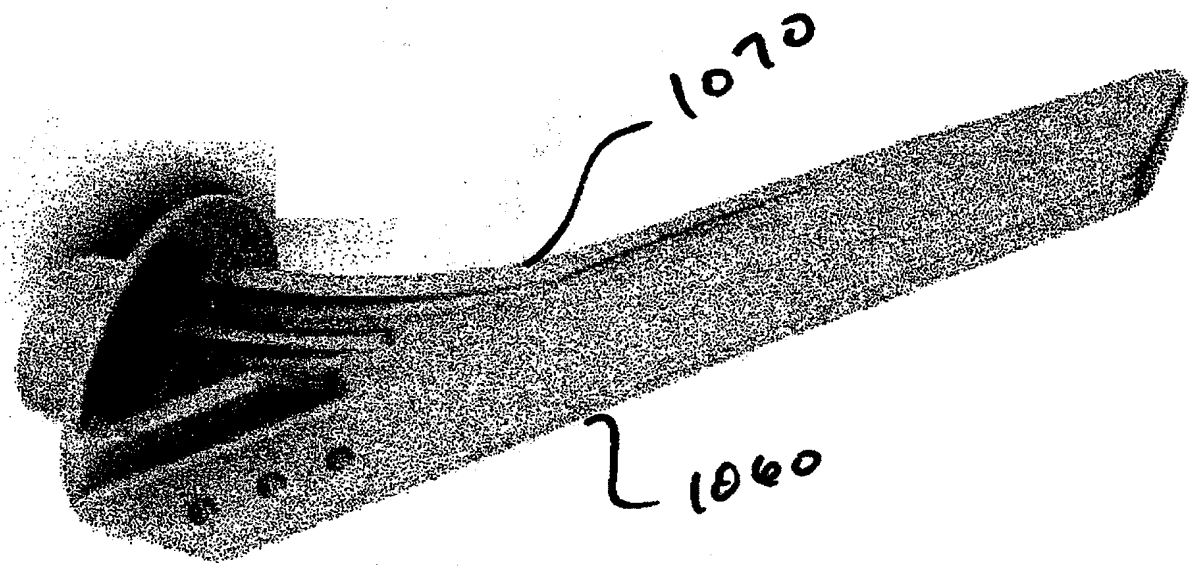
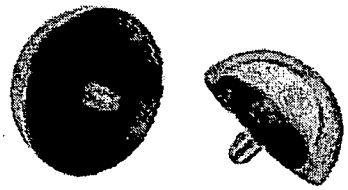


FIG 22

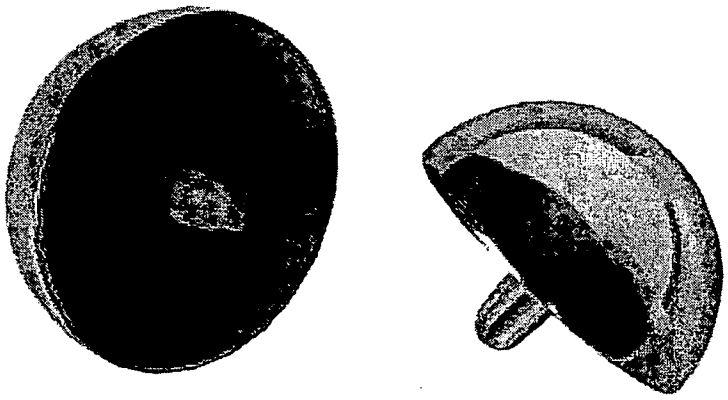
INTERLOK®/HA COATED IMPLANT INFORMATION

Copeland™
Humeral Resurfacing Head

Copeland™ Humeral Surface Replacement Arthroplasty System

Product Photo	Part Number	Description	Size
	114641 114642 114647 114643 114644	Copeland™ HA Coated HRS Copeland™ HA Coated HRS Copeland™ HA Coated HRS Copeland™ HA Coated HRS Copeland™ HA Coated HRS	Small Medium Medium + Large X-Large

This version of the Copeland™ Humeral Resurfacing Head is the third generation (Mark 3) prosthesis that is used on a clinical basis in Europe. It has an Interlok® blast finish topped with a Hydroxyapatite coating.



The Copeland™ Surface Replacement Arthroplasty (CSRA) of the shoulder was developed by Steven A. Copeland, F.R.C.S., Consultant Orthopaedic Surgeon at the Royal Berkshire Hospital, Reading, England, U.K.

This device is intended to be used in the United States as described in the product labeling.

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Bone remodelling after total hip arthroplasty using an uncemented anatomic femoral stem: a three-year prospective study using bone densitometry

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Department of Orthopedic Surgery, Miguel Servet University Hospital, Zaragoza, Spain

ABSTRACT

Purpose. To evaluate the clinical, radiological, and densitometric changes in the bone-remodelling patterns of femoral stems aligned in neutral, valgus, or varus positions.
Methods. Between February and October 2000, 70 patients underwent unilateral total hip arthroplasty for primary osteoarthritis using an uncemented Anatomique Benoist Girard (ABG) II stem. 69 patients (30 males and 39 females) with a mean age of 59 years (range, 38–76 years) and a mean body weight of 79.3 kg (range, 29–110 kg) completed 3 years' follow-up on bone remodelling. The clinical, radiological, and densitometric changes of the neutral, valgus, and varus groups were evaluated, and the difference in bone-remodelling patterns between the 3 groups was analysed.
Results. 54 patients had neutrally placed stems, while varus and valgus malalignment occurred in 6 and 9 patients, respectively. Clinical and radiological evaluations were very similar among the 3 groups. Only densitometry could detect traceable changes resulting from the differing biomechanics of the neutral, varus, and valgus stem alignments.
Conclusion. The ABG II stem design made moderate errors in alignment biomechanically tolerable. Alignment defects had no clinical consequences and resulted in minimal differences in bone remodelling.

Key words: *arthroplasty, replacement, hip; bone density; durapatite; densitometry; hip prosthesis*

INTRODUCTION

Bone densitometry (dual energy X-ray absorptiometry, DEXA) has been used to analyse the bone-remodelling pattern associated with different femoral stem implant designs (cemented or uncemented) for the past 15 years.[1-5] Varus or valgus malalignment of the femoral stem has been reported to result in different load transmission patterns than in neutral alignment,[6]

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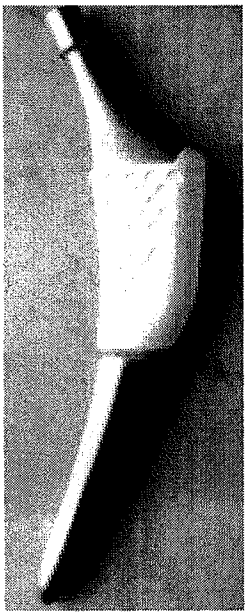


Figure 1 An ABG II stem is scale-shaped in the metaphyseal area, coated with a hydroxyapatite layer, and has a thin short ultrapolished tail.

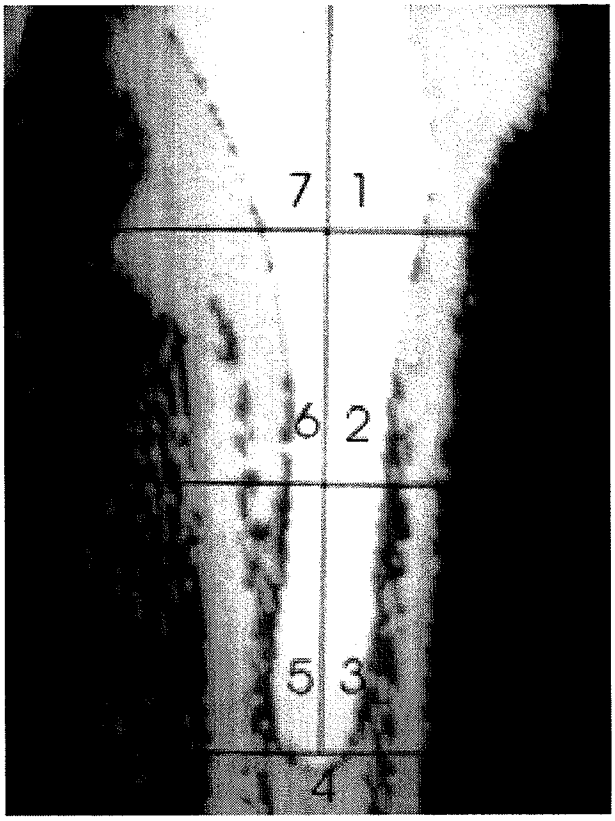


Figure 2 Bone densitometry showing the 7 Gruen zones.

with poor long-term results.[7] Some implant designs have proved to be more clinically and radiologically tolerant of these alignment errors by virtue of the specific geometries, load transmission patterns, and the higher elasticity of the titanium alloys.[8,9] We assessed the clinical, radiological, and densitometric results of 70 patients who underwent total hip arthroplasty (THA) using an uncemented anatomic femoral stem, and analysed the differences in bone-remodelling patterns among implants aligned in a neutral position, at >5° varus, and at >5° valgus.

MATERIALS AND METHODS

Between February and October 2000, 70 patients underwent unilateral THA in the Miguel Servet University Hospital using an uncemented anatomic femoral stem (Anatomique Benoist Girard [ABG] II; Stryker Howmedica, Staines, England). Patients were followed up for 3 years on bone remodelling with the ABG II stem. Patients diagnosed with unilateral (the healthy opposite hip was used as a control) primary osteoarthritis (not metaphyseal deformity or severe osteoporosis) and given informed consent were included. The local research ethics committee approved this prospective controlled study. The diagnoses of the patients were hip osteoarthrosis (n=64), avascular necrosis (n=5), and rheumatoid arthritis (n=1). 69 patients (30 males and 39 females) with a mean age of 59 years (range, 38–76 years) and a mean body weight of 79.3 kg (range, 29–110 kg) completed the 3-year follow-up. The remaining one patient was lost to follow-up who had a neurovascular stroke and became wheelchair-bound 19 months after THA.

All patients were implanted with the ABG II stem and uncemented cup (the cup was not part of the study). The ABG II is an uncemented and anatomic stem, with press fit metaphyseal fixation, made of titanium, molybdenum, zirconium, and iron. The stem features a scale-shaped design to increase stability at the metaphyseal level, and is coated with a 70-microns-deep hydroxyapatite layer. The tail of the implant is short and thin so as to avoid endomedullary contact with the diaphysis, and is ultrapolished to avoid bone fixation at this level (Fig. 1). The ABG II evolved from the earlier ABG I design, which has a longer and more voluminous tail to facilitate neutral positioning. However, the ABG I surface is often susceptible to bone growth and causes proximal bone malfunction.

Patients were operated on by 4 different surgeons through the posterolateral approach. The acetabulum was progressively reamed to the cup diameter calculated preoperatively. The cup was inserted by

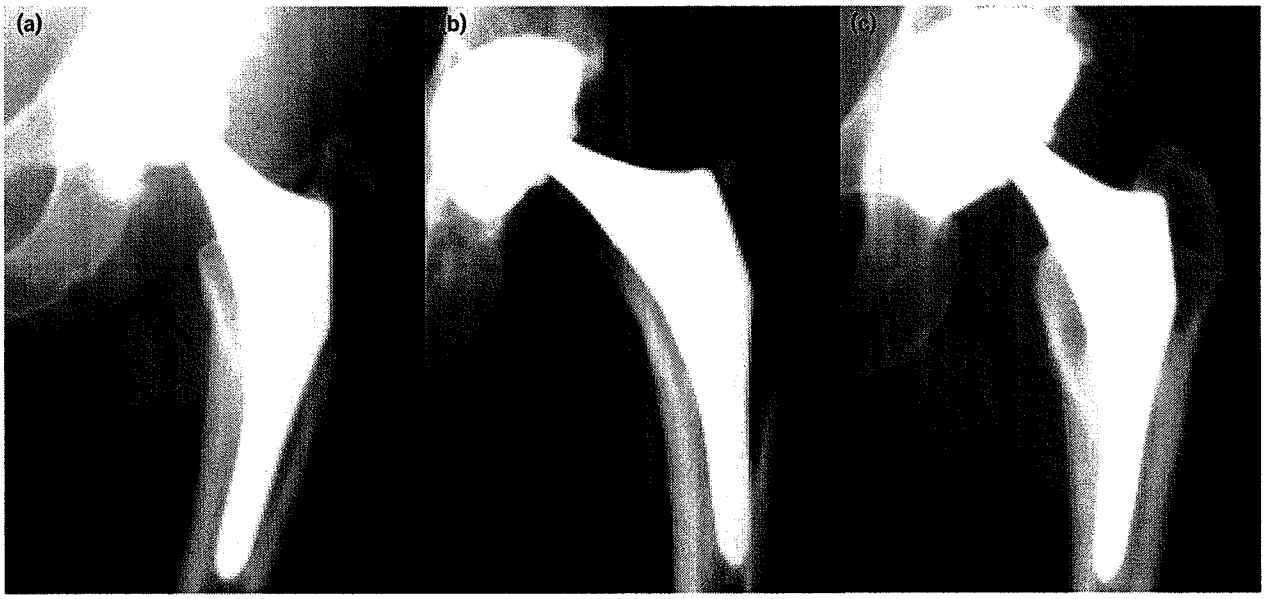


Figure 3 Anteroposterior radiographs taken at postoperative 3 years showing **(a)** a neutrally aligned femoral stem with cortical atrophy in zones 1 and 7 and cortical thickening in zones 2 and 6. **(b)** A varus-aligned femoral stem with significantly more cortical atrophy in zone 1 than the neural group. **(c)** A valgus-aligned femoral stem with significantly more cortical atrophy in zone 7 than the neural group.

press fit, usually with 3 pins. After osteotomy of the femoral neck, a piece of cancellous bone was removed using a box chisel to allow direct access to the femoral canal, which was prepared by progressive broaching. With the final broach in place, along with a modular trial neck and head, a trial reduction was performed to check hip stability. The trial insert was removed, the cup interior was cleaned and dried, and the definitive polyethylene layer and stem were placed. The capsule was sutured, enclosing the femoral head, and the short rotator muscles were attached to the greater trochanter with transosseous sutures. Fascia lata, subcutaneous tissues, and skin were carefully sutured.

Patients were clinically evaluated according to the Merle d'Aubigne and Postel (MAP) score[10] measuring pain, joint mobility, and ability to walk. Varus and valgus angulation (the difference between the femoral diaphyseal axis and the stem's main axis) were measured and a difference of >5° was considered varus or valgus. The 7 Gruen zones were inspected for the presence of radiolucent lines, osteolysis, cancellous condensation, cortical hypertrophy or atrophy, reactive lines, and pedestal formation according to the criteria by Engh et al.[11] Bone stock variation was measured in each of the 7 Gruen zones in a 30x30-pixel square using a Hologic QDR 1000 densitometer (Hologic, Waltham [MA], US) [Fig. 2]. Patients were placed in a supine position on the scanner table, with knees and hips in full extension. The whole limb was in a neutral position supported by a rigid plastic device fastened by Velcro tape to guarantee measurement reliability.

The preoperative and postoperative first-year and third-year MAP scores, radiographs, and bone stock densitometric measurements among the neutral, varus, and valgus groups were compared using parametric or nonparametric tests, depending on the number of patients and whether the samples were independent or related. Chi squared test was used with Pearson correlation for qualitative variables. A p value of <0.05 was considered statistically significant.

RESULTS

Femoral stems of 54 patients (19 men and 35 women) were neutrally aligned (Fig. 3a). Six patients (4 men and 2 women) were varus aligned (Fig. 3b), with a mean angle of 6° (standard deviation [SD], 1.94°) immediately after surgery, and 6.2° (SD, 1.67°; range, 5°–9°) 3 years after surgery. Nine patients (7 men and 2 women) were valgus aligned (Fig. 3c), with a mean angle of 6.1° (SD, 1.21°) immediately after surgery, and 6.2° (SD, 1.34°; range, 5°–9°) 3 years after surgery. There were no significant differences in age, weight,

Table 1
Clinical evaluation using Merle d'Aubigne and Postel score[10]

Clinical evaluation	Neutral group, n=54		Varus group, n=6		Valgus group, n=9	
	Preoperative	Postoperative year 3	Preoperative	Postoperative year 3	Preoperative	Postoperative year 3
Pain	2.23	5.86	2.07	5.71	2.09	6.0
Joint mobility	3.07	5.34	2.85	5.07	2.81	5.36
Ability to walk	2.34	5.74	2.57	5.64	2.18	6.0
Total	7.65	16.93	7.50	16.43	7.09	17.36

Table 2
Bone stock evaluation using bone densitometry

Bone mineral density*	Neutral group, n=54			Varus group, n=6			Valgus group, n=9		
	Preoperative	Postoperative		Preoperative	Postoperative		Preoperative	Postoperative	
		year 1	year 3		year 1	year 3		year 1	year 3
Zone 1									
Mean	754	718	712	759	648	584	749	685	658
SD	191.6	215.9	206.5	171.8	137.6	172.0	156.7	172.4	170.8
Change (%)	NA†	-4.77	-5.57	NA	-14.62	-23.06	NA	-8.54	-12.15
p value	NA	NA	NA	0.937	0.376	0.272	0.830	0.541	0.680
Zone 2									
Mean	1236	1272	1332	1239	1212	1255	1238	1278	1328
SD	295.1	328.1	369.7	309.6	263.3	284.7	181.0	295.2	274.8
Change (%)	NA	+2.91	+7.77	NA	-2.18	+1.29	NA	+3.23	+7.27
p value	NA	NA	NA	0.726	0.712	0.450	0.975	0.662	0.691
Zone 3									
Mean	1597	1599	1652	1541	1544	1554	1577	1602	1681
SD	290.8	309.9	311.0	270.4	234.5	240.5	163.1	126.0	113.2
Change (%)	NA	+0.13	+3.44	NA	+0.19	+0.84	NA	+1.59	+6.59
p value	NA	NA	NA	0.483	0.605	0.257	0.407	0.918	0.977
Zone 4									
Mean	1761	1762	1751	1802	1731	1776	1742	1714	1743
SD	310.2	308.6	306.9	371.4	368.6	371.7	224.0	210.0	192.1
Change (%)	NA	+0.06	-0.57	NA	-3.94	-1.44	NA	-1.61	+0.06
p value	NA	NA	NA	0.804	0.911	0.914	0.299	0.560	0.580
Zone 5									
Mean	1645	1671	1670	1762	1745	1715	1626	1577	1604
SD	349.5	355.2	323.0	365.2	318.2	276.3	187.8	247.5	292.5
Change (%)	NA	+1.58	+1.52	NA	-0.96	-2.67	NA	-3.01	-1.23
p value	NA	NA	NA	0.483	0.376	0.746	0.443	0.322	0.334
Zone 6									
Mean	1450	1485	1547	1586	1743	1778	1442	1469	1549
SD	363.0	289.1	273.1	370.2	358.4	414.2	223.9	234.8	243.0
Change (%)	NA	+2.41	+6.69	NA	+9.9	+12.11	NA	+1.87	+7.42
p value	NA	NA	NA	0.275	0.096	0.250	0.902	0.838	0.670
Zone 7									
Mean	1093	976	919	1202	1073	953	1195	1004	936
SD	275.5	266.5	276.8	372.6	456.6	350.8	274.5	267.0	257.2
Change (%)	NA	-10.7	-15.92	NA	-10.73	-20.72	NA	-15.98	-21.67
p value	NA	NA	NA	0.755	0.782	0.829	0.634	0.911	0.909

* Bone mineral density is expressed in mg of hydroxyapatite/cm²; p values are compared between neutral and varus groups, and neutral and valgus groups.
† NA not applicable

or height among the neutral, varus, and valgus groups.

Clinical outcomes of the 3 groups were not significantly different in pain, joint mobility, or ability to walk (Table 1). Nonetheless, thigh pain was present in 2 varus patients (one was serious) caused by contact between the prosthesis tail and the antero-external

face of the medullar channel. No major clinical complications occurred.

Radiological results of bone-remodelling patterns of the 3 groups at postoperative 3 years were similar; no patients had instability sign: the neutral group demonstrated cortical atrophy in zones 1 and 7 due to stress shielding, and slight cortical thickening in zones 2 and 6 (0.2–0.6 mm). The varus group had significantly more cortical atrophy in zone 1 than the neutral group ($p=0.026$). The valgus group had significantly more cortical atrophy in zone 7 than the neutral group ($p=0.034$). The differences may be due to different stem alignments, as greater proximal cortical atrophy occurs in zones receiving smaller loads. In the neutral group, cancellous condensation in zones 2, 3, 5 and 6 was present in 72%, 45%, 36%, and 74% of patients, respectively. Osteolytic damage (in the form of small granulomas) in zones 1 and 7 was present in 26.2% and 9.5% of patients, respectively. Reactive lines in the distal stem in zones 3 and 5 were present in 5% and 17% (33% for the valgus group) of patients, respectively. No radiolucent lines were seen in any zone in any group. These findings of the neutral group were similar in the other 2 groups.

Densitometric bone stock findings (Table 2) were similar to the radiological findings. In the neutral group, significant loss of proximal bone stock was found in zone 1 (5.57%) and zone 7 (15.92%) in postoperative year 3; increase of bone stock was seen in other zones. Compared with the neutral group, the varus group had greater loss in zones 1 and 7 and greater increase in zone 6, while the valgus group had greater increase in zone 3 and greater loss in zone 7.

DISCUSSION

Varus or valgus alignment of femoral stems is often associated with poor outcomes. Malalignment may result in an anomalous load transmission pattern and may lead to prosthetic loosening, pain, and periprosthetic fractures.[12] However, the effect of malalignment could be effectively offset by the stem geometry (wedge-shaped) and the use of elastic alloys.[8,9] The results of the use of the anatomical ABG I stem was not worse in varus or valgus alignment.[13]

The ABG II stem evolved from the ABG I to obtain greater proximal bone fixation and avoid stress shielding. Changes included shifting the load transfer zone to the proximal stem and shortening the polished stem tip with a smaller diameter distally. Both stems and rasps were 2 cm shorter, with slightly modified metaphyseal section.

We failed to achieve neutral alignment of the rasps and stems in the proximal femur when the ABG II was first introduced into our hospital. The number of malalignment decreased progressively as surgical techniques improved and longer rasps introduced to eliminate the problems of preparing an aligned bed for the stem in the metaphyseal and diaphyseal areas.

Clinical and radiological outcomes of the 3 groups were not significantly different. The bone remodelling patterns of the ABG II was very similar to the ABG I.[13,14] In the neutral group, proximal cortical atrophy was in zones 1 and 7 due to stress shielding, and slight cortical thickening in zones 2 and 6 (metaphyseal-diaphyseal zones) due to load transmission from the implant to bone. The varus group had significantly more cortical atrophy in zone 1 than the neutral group because of shifting of the load transmission to the medial and distal lateral cortical area. The valgus group had significantly more cortical atrophy in zone 7 than the neutral group because of shifting of the load transmission to the lateral and distal medial cortical area. All radiological findings suggested stable and well-integrated stems.

Densitometric findings of bone remodelling patterns agreed with the radiological findings. Loss of bone stock in zones 1 and 7 and increase of bone stock in zones 2 to 6 were confirmed and consistent with previous study.[15] The 6% to 16% loss of proximal bone stock in the present study was slightly lower than other studies of 20% to 25% using different anatomical implant designs.[4,5,16,17] Wedge-shaped femoral stems had excellent preservation of bone stock in medial and distal zones, but 5% to 30% of bone stock loss in the proximal zone remained, depending on the implant used.[3,18,19] Custom-made stems were used for optimal metaphyseal adjustment, but were still associated with 10% to 20% of bone stock loss in zones 1 and 7 within 3 years.[20–24] Reduced-stiffness femoral stems could reduce bone stock loss in the proximal zone to 2% to 15% in 2-year studies,[17,25] but the risks of nonunion between layers and long-term failure remained. Compared with the neutral group, the varus group had greater loss of bone stock in zones 1 and 7 and greater increase of bone stock in zone 6, while the valgus group had greater increase in zone 3 and greater loss in zone 7. This suggests that the implant geometry (voluminous metaphyseal section, thin and short tail) reduced negative biomechanical effects on bone remodelling.

The validity of the present study may be limited by the small number of the varus and valgus patients. It is difficult to obtain sufficient malaligned cases,

multicentre study is therefore necessary to obtain conclusive results.

CONCLUSION

Bone densitometry is the most reliable tool to evaluate bone remodelling after THA using different femoral stem designs. Follow-up must be at least 3 years as biomechanical adaptation to the prosthesis occurs mostly in this period. Longer-term follow-up may detect bone loss in proximal zones caused by osteolysis or late bone remodelling due to involutional bone loss. The ABG II stem design made moderate errors in alignment biomechanically tolerable. Alignment defects had no clinical consequences and resulted in minimal differences in bone remodelling.

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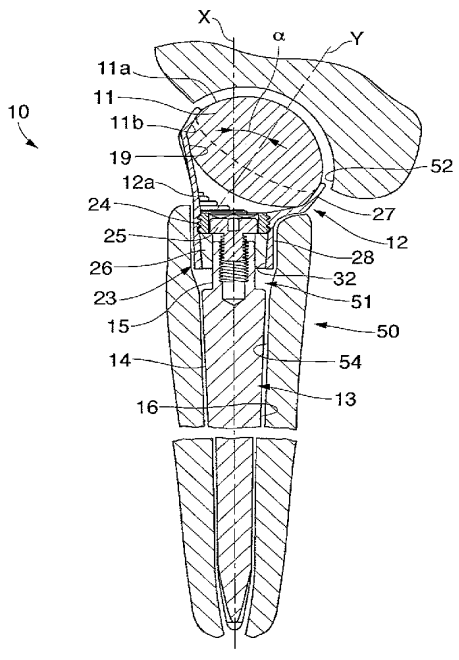


fig. 1

(57) **Abstract**: A modular humeral prosthesis suitable for implant in a humeral seating (51) of a humerus (50) comprises an articulation component (11, 111), a distal joint element (13, 113) able to be inserted into said humeral seating (51) along an insertion axis (X), and an adapter body (12) provided with a support (12a) positionable in the humeral seating (51) and that has a coupling seating (19) to connect said articulation component (11, 111) and provided with a connection unit (23) inserted into said support (12a) to connect said distal joint element (13, 113) to said adapter body (12) in a releasable manner. The connection unit (23) comprises an achoring element (24), an attachment element (25) and a clamping element (26) associated in a selectively releasable manner to the distal joint element (13, 113) and the support (12a) has a through coupling seating (32) configured to receive and position said clamping element (26) inside it, and also configured to allow the insertion and extraction of said distal joint element (13, 113) through said support (12a) without removing said support (12a) from the humeral seating (51).

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"MODULAR HUMERAL PROSTHESIS"

* * * * *

FIELD OF THE INVENTION

The present invention concerns a humeral prosthesis, able to be configured anatomically or inversely for the reconstruction of the humerus in the articulation of the shoulder. In particular the humeral prosthesis of the present invention is the modular type and comprises an articulation component, a distal joint element and an adapter body which acts as a metaphyseal module.

BACKGROUND OF THE INVENTION

It is known that arthroprostheses used to reconstruct the shoulder joint can be the anatomical or inverse type. Anatomical humeral prostheses are provided with a hemispherical head that artificially reconstructs the human anatomy and are suitable to articulate in the glenoid cavity of the shoulder blade or possibly in a mating artificial seating attached to the glenoid cavity. On the contrary, inverse prostheses provide a concave articular insert able to allow the rotation of an artificial spherical body attached to the glenoid seating, commonly called glenosphere.

It is known that humeral prostheses, whether anatomical or inverse, generally include a distal joint element, also called rod or pin, inserted inside the humerus along the diaphyseal axis, to support the humeral head in anatomical humeral prostheses or the concave articular insert in inverse prostheses.

Distal joint elements of various types are known, for example with an elongated tubular shape, to define an elongated rod, or a small-sized pin, typically used for mini-invasive humeral prostheses. The shape and size of the distal joint element can also depend on the type and size of the humeral prosthesis, for example inverse humeral prostheses can need a distal joint element that is bigger than anatomical ones.

It is possible, for example due to degeneration of the tissues of the shoulder, that operations may have to be carried out to revise the prosthesis, for example to replace the prosthesis, or operations to convert an anatomical prosthesis into a inverse prosthesis or vice versa.

It is known, for example from the patent application EP-A-1.472.999, to make a modular humeral prosthesis, comprising an adapter body, which functions as a

metaphyseal module, to be positioned in a seating made under the head of the humerus and connectable on one side to a rod inserted in the humerus and on the other side to the semi-spherical humeral head, in the case of anatomical prostheses, or to the concave articular insert in the case of inverse prostheses. Indeed, by varying the adapter body, the known modular humeral prosthesis can be made as anatomical or inverse. Moreover, in the field of the same type of prosthesis, anatomical or inverse, it may be possible to change the shape or size of the adapter body, releasing it from the rod and keeping the latter inserted in the humerus, whenever its sizes or characteristics are suitable for the humeral prosthesis to be grafted.

However, one possible disadvantage of this known modular humeral prosthesis is that it cannot be converted from anatomical to inverse without having to replace the adapter body. This latter operation, which entails extracting the adapter body from the bone seating, can be invasive and destructive.

Another possible disadvantage of the known humeral prosthesis is that it does not allow to completely replace the rod with another element inserted in the humerus, such as a rod with a different conformation or size, or a nail for osteosynthesis, preserving the adapter body already inserted, that is, without extracting the adapter body from the humerus which, as we said above, can be difficult and invasive.

It is known for example that, in the event of fractures of the humerus, for the purposes of osteosynthesis, it may be necessary to introduce inside the humerus a humeral nail that reproduces the correct alignment of the bone fragments to allow reciprocal welding thereof. The humeral nail can be introduced in antegrade fashion, with a passage through the proximal part of the humerus (antegrade nail), or retrograde, through an aperture in the olecranon fossa (retrograde nail). The antegrade solution is generally preferable, since it is less invasive and less complex.

However, in the state of the art and with the humeral prostheses available, if there is a fracture of the humerus and there is a humeral prosthesis present, it may be necessary to completely remove the prosthetic implant, or alternatively to use external synthesis means, such as osteosynthesis plates which in any case do not always guarantee a successful synthesis.

One disadvantage of known solutions is therefore that it it is not possible to act in an antegrade manner to remove the rod or pin and insert the nail without removing the adapter body, in the event of fractures of the humerus where there is a humeral prosthesis present.

Document US-A-2005/0125067 describes a modular prosthesis of the known type, provided with a head and a rod coupled to the head. The rod has a proximal portion coupled with the head and a distal portion configured to extend in a long bone of the patient. The distal portion can be removed from the rod after the prosthesis has been implanted, without removing the proximal portion.

Document WO-A-99/47081 also describes a modular orthopedic prosthesis having a body that has a through hole that receives a connection bushing that in turn receives a rod having a proximal neck and a distal shaft. The connection bushing can be expanded radially in order to clamp the rod and the body together.

Purpose of the present invention is to obtain a modular humeral prosthesis that allows revisions or conversions of the prosthesis, keeping the adapter body of the humeral prosthesis in the humeral seating and allowing to replace the distal joint element, either rod or pin.

SUMMARY OF THE INVENTION

The present invention is set forth and characterized in the independent claim, while the dependent claims describe other characteristics of the invention or variants to the main inventive idea.

In accordance with the above purpose, a modular humeral prosthesis according to the present invention, which overcomes the limits of the state of the art and eliminates the defects therein, is suitable to be implanted in a humeral seating of a humerus and comprises an articulation component and a distal joint element insertable in the humeral seating along an insertion axis. The humeral prosthesis also comprises an adapter body, which acts as a metaphyseal module, provided with a support that can be positioned in the humeral seating and that has a coupling seating to connect the articulation component and provided with a connection unit inserted into the adapter body support to connect the distal joint element to the adapter body in a releasable manner.

According to the present invention, the connection unit comprises a clamping element associated in a selectively releasable manner to the distal joint element.

Moreover, the adapter body support has a through coupling seating configured to receive and position the clamping element inside it. The through coupling seating is also configured to allow the insertion and extraction of the distal joint element through the adapter body support, without removing the support from the humeral seating.

In this way, allowing the complete passage, or crossing, of the distal joint element along the through coupling seating, it is possible, once the clamping element is removed, to position and remove the distal joint element as well, operating advantageously from above, without needing to extract the adapter body support from the humeral seating.

Therefore, with the present invention, it is possible to carry out revision or conversion operations of the prosthesis maintaining the adapter body support of the humeral prosthesis in the humeral seating. In particular, with the present invention, it is possible to change the articulation component, for the conversion for example from anatomical prosthesis to inverse prosthesis or vice versa, without extracting the adapter body support. Moreover, with the present invention it is also possible to replace the distal joint element, rod or pin, also maintaining in this case the adapter body support of the humeral prosthesis in the seating on the head of the humerus. For example, in the case of conversion of the prosthesis, it might be necessary to change the type or size of the distal joint element, while in the case of a fracture of the humerus for example, in the presence of a modular prosthesis which has already been implanted, it could be necessary to insert an osteosynthesis nail in its place, and in any case the present invention allows to intervene to remove and/or replace the distal joint element operating from above in an antegrade manner, without removing the adapter body support.

In variant forms of embodiment, the clamping element is configured to clamp a movement of axial extraction of the distal joint element toward the outside of the humeral seating.

In variant forms of embodiment, the clamping element is configured to achieve a same-shape coupling with a one-directional constraint toward the inside of the humeral seating with the through coupling seating of the support.

In variant forms of embodiment, the clamping element is configured to

achieve a same-shape coupling with a one-directional constraint toward the outside of the humeral seating with the distal joint element.

In variant forms of embodiment, the clamping element is coupled externally to the distal joint element.

In variant forms of embodiment, the clamping element has a truncated cone configuration, both internally and externally. The truncated cone configuration can be inverted between outside and inside. For example, the clamping element can be shaped internally like a truncated cone, while externally it can be shaped like a truncated cone inverse with respect to the inside.

In possible implementations, the clamping element comprises a hollow truncated cone element that has an external clamping surface shaped like a truncated cone with a section that reduces toward the inside of the humeral seating, an internal clamping cavity delimited by internal lateral walls shaped like a truncated cone inverse with respect to the external clamping surface, to receive a mating connection portion of the distal joint element.

In other variant forms of embodiment, internally the clamping element has a truncated cone configuration and externally a cylindrical configuration.

In yet other variant forms of embodiment, internally the clamping element has a cylindrical configuration and externally a truncated cone configuration.

In implementations where the clamping element is at least internally configured as a truncated cone, the distal joint element has a similar truncated cone connection portion to be inserted into the clamping element.

In other variant forms of embodiment, the clamping element has a cylindrical configuration, both internally and externally.

In a possible implementation, internally the clamping element has threaded connection means to cooperate with the distal joint element. This implementation can be used, for example, in the case where the clamping element internally has a cylindrical configuration and the distal joint element has a similar cylindrical connection portion to be inserted in the clamping element.

Depending whether the clamping element is externally configured as a truncated cone or as a cylinder, the through coupling seating will consequently be configured as a truncated cone or a cylinder.

Moreover, according to some forms of embodiment of the present invention,

the connection unit comprises an anchoring element configured to clamp a movement of axial extraction of the clamping element toward the outside of the humeral seating.

The anchoring element can be configured to be constrained bi-directionally to the adapter body support.

In possible variation forms of embodiment, the anchoring element comprises an externally threaded annular body that has an external threaded anchoring surface and a shaped central aperture.

In other variants, the anchoring element comprises an elastically deformable ring, in particular a Seeger ring.

In some forms of embodiment, the clamping element is inserted between the distal joint element and the anchoring element.

In some forms of embodiment of the present invention, the connection unit also comprises an attachment element associated with the clamping element and the distal joint element to clamp the axial movement thereof toward the inside of the humeral seating with respect to the clamping element.

In possible variants, the attachment element is mounted on the clamping element and is attached to the distal joint element.

In some forms of embodiment, the attachment element comprises a screw, provided with a shaped head, configured to abut against the clamping element, from which a threaded rod extends, configured to be inserted into the clamping element and able to be screwed into an attachment cavity of the distal joint element to define overall a one-directional constraint of the distal joint element toward the inside of the humeral seating.

Moreover, in possible variants, the clamping element is configured to define an axial stopping abutment for the attachment element.

These and other aspects, characteristics and advantages of the present disclosure will be better understood with reference to the following description, drawings and attached claims. The drawings, which are integrated and form part of the present description, show some forms of embodiment of the present invention, and together with the description, are intended to describe the principles of the disclosure.

The various aspects and characteristics described in the present description can

be applied individually where possible. These individual aspects, for example aspects and characteristics described in the attached dependent claims, can be the object of divisional applications.

It is understood that any aspect or characteristic that is discovered, during the patenting process, to be already known, shall not be claimed and shall be the object of a disclaimer.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other characteristics of the present invention will become apparent from the following description of some forms of embodiment, given as a non-restrictive example with reference to the attached drawings wherein:

- fig. 1 is a section of a modular humeral prosthesis, in its anatomical configuration, according to forms of embodiment of the present invention;
- fig. 2 is a section of a modular humeral prosthesis, in its inverse configuration, according to forms of embodiment of the present invention;
- fig. 3 is a section in separate parts of a modular humeral prosthesis according to forms of embodiment of the present invention;
- fig. 4 is a perspective view in separate parts of a modular humeral prosthesis according to other forms of embodiment of the present invention;
- fig. 5 is a perspective view of a part of a modular humeral prosthesis according to forms of embodiment of the present invention;
- fig. 6 is a section of a part of a modular humeral prosthesis according to forms of embodiment of the present invention;
- fig. 7 is a section of a modular humeral prosthesis according to a form of embodiment of the present invention;
- fig. 8 is a perspective view in separate parts of a part of fig. 7.

To facilitate comprehension, the same reference numbers have been used, where possible, to identify identical common elements in the drawings. It is understood that elements and characteristics of one form of embodiment can conveniently be incorporated into other forms of embodiment without further clarifications.

DETAILED DESCRIPTION OF FORMS OF EMBODIMENT

We shall now refer in detail to the various forms of embodiment of the present invention, of which one or more examples are shown in the attached drawing.

Each example is supplied by way of illustration of the invention and shall not be understood as a limitation thereof. For example, the characteristics shown or described insomuch as they are part of one form of embodiment can be adopted on, or in association with, other forms of embodiment to produce another form of embodiment. It is understood that the present invention shall include all such modifications and variants.

Figs. 1 and 2 are used to describe forms of embodiment of a modular humeral prosthesis 10 suitable to be implanted in a humeral seating 51 of a humerus 50.

The modular humeral prosthesis 10 can comprise, or be associated with, an articulation component that can be a humeral head 11 for example, or a concave articular insert 111, depending on whether the modular humeral prosthesis 10 is anatomical or inverse, a distal joint element 13, 113 and an adapter body 12.

According to some forms of embodiment of the present invention, the distal joint element 13, 113 can have an axial symmetry with respect to an insertion axis X. The axis X can generally coincide with the diaphyseal axis along which the distal joint element 13, 113 is located in the humerus 50, even if situations can be hypothesized wherein the insertion axis X does not coincide with the diaphyseal axis.

In some forms of embodiment, the modular humeral prosthesis 10 is generally inserted in the direction defined by the axis X, toward the inside of the humerus 50, and also extracted in the direction defined by the axis X, however in the opposite direction, that is toward the outside of the humerus 50 and the humeral seating 51.

In some forms of embodiment, the adapter body 12 is intended to be positioned in the humeral seating 51, typically along the axis X, and can be connected on one side to the distal joint element 13, 113, insertable in its turn in the humerus 50, and on the other side, opposite to the articulation component, to the humeral head 11, or concave articular insert 111. The adapter body 12 can also be configured to allow the bone integration with the internal surface of the humeral seating 51.

In some forms of embodiment, the adapter body 12 is the modular type, comprising components, including for example the following, indicated by the reference numbers 12a and 23, that can be coupled to each other in a selectively

releasable manner, according to requirements.

In particular, in possible implementations the adapter body 12 can comprise a support 12a to support the articulation component, humeral head 11, or concave articular insert 111. The support 12a of the adapter body 12 can typically be inserted in a stable manner into the humeral seating 51.

In some forms of embodiment, the adapter body 12 can also comprise a connection unit 23 for the releasable connection of the distal joint element 13, 113 to the support 12a. In possible implementations, the connection unit 23 can be axial-symmetric with respect to the axis of symmetry X, or diaphyseal axis. The connection unit 23 can be inserted into the support 12a, advantageously releasably, and coupled with the distal joint element 13, 113 subsequently to the positioning of the support 12a in the humeral seating 51.

In some forms of embodiment, the adapter body 12 can also comprise coupling means to associate the articulation component to the support 12a, that is, to stably connect it for the purposes of articulation. In possible implementations, the coupling means of the adapter body 12 can comprise a concave shaped coupling seating 19, provided in the support 12a, to which the articulation component is coupled, whether it is the humeral head 11 or the concave articular insert 111.

Moreover, the support 12a of the adapter body 12 can comprise a through coupling seating 32 for the connection of the connection unit 23, opposite to the coupling means, to constrain the articulation component. In possible implementations, the through coupling seating 32 can be shaped, for example, for the insertion and the geometric coupling of the connection unit 23.

In possible implementations, the through coupling seating 32 can be internally shaped as a truncated cone, typically with a section that reduces toward the inside of the humeral seating 51.

In some forms of embodiment, the through coupling seating 32 can be configured to allow the insertion and extraction of the distal joint element 13, 113 through the support 12a, without removing the support 12a itself from the humeral seating 51.

Typically, moreover, the through coupling seating 32 can be provided with a diameter greater than the maximum diameter, or maximum equivalent diameter,

of the cross section of the distal joint element 13, 113. In this way, the distal joint element 13, 113 can be inserted and can pass completely through the through coupling seating 32.

In possible forms of embodiment, the adapter body 12 can be made completely of metal material, such as alloys of titanium or cobalt.

In other forms of embodiment, the components of the adapter body 12 can be made of different materials, preferably biocompatible with mechanical and chemical properties suitable for the functions provided. Some examples of such materials are, apart from metal materials such as alloys of titanium or cobalt, ceramic materials for medical use or plastic polymer materials, such as polyethylene with high or very high reticulation, or PEEK, possibly loaded with carbon.

According to some forms of embodiment of the present invention, the distal joint element 13, 113 can comprise an insertion portion 14, 114, typically inserted in the humerus 50, and a connection portion 15, for connection to the connection unit 23 of the adapter body 12.

According to some forms of embodiment of the present invention, as described by way of example using figs. 1 and 2, the insertion portion 14, 114 and the connection portion 15 can be made as a single body. Typically the distal joint element 13, 113 can be made entirely of metal material suitable for biomedical use, such as for example alloys of titanium or alloys with a cobalt base.

According to other forms of embodiment, the connection portion 15 can be made as a distinct element from the insertion portion 14, 114 and can for example be made with other materials than the insertion portion 14, 114.

According to some forms of embodiment described here, the connection unit 23 can be the modular type, or formed by components, including for example those indicated hereafter by the reference numbers 24, 25, 26, selectively associable with respect to each other.

For example, the connection unit 23 can comprise a clamping element 26, such as for example a bushing, associated, typically in a selectively releasable manner, to the distal joint element 13, 113. In particular, the clamping element 26, can be coupled externally to the distal joint element 13, 113 to clamp a

movement of axial extraction thereof toward the outside of the humeral seating 51 with respect to the support 12a. The support 12a in its turn has the through coupling seating 32 configured to clamp an axial movement of the clamping element 26 toward the inside of the humeral seating 51. In particular, the through coupling seating 32 is configured to receive and position the clamping element 26 inside it. For example, the through coupling seating 32 can be mating with the clamping element 26, which therefore can be stably inserted inside it. Moreover, as said above, the through coupling seating 32 is configured to allow the complete passage, for example during the steps of insertion or extraction of the distal joint element 13, 113 into/from the humeral seating 51, advantageously without removing or extracting the support 12a from the humeral seating 51.

According to some forms of embodiment described here, the connection unit 23 can also comprise an anchoring element 24, which can be configured to clamp a movement of axial extraction of the clamping element 26 toward the outside of the humeral seating 51. The anchoring element 24 is for example configured to be constrained, advantageously in a releasable manner, to the support 12a bi-directionally along the axis X. For example, the anchoring element 24 can be provided above the clamping element 26.

In possible implementations (see fig. 3 for example), the anchoring element 24 can be an externally threaded annular body, which in particular has an external threaded anchoring surface 33 and a shaped central aperture 24a, delimited by an internal drive surface 34, for example polygonal, typically hexagonal, to be driven by a mating key or similar polygonal tool. An advantage of the solution in which the anchoring element 24 is threaded can be that, by means of screwing, it is possible to take the connection unit 23 completely in abutment, that is, packed, preventing unwanted movements of its components, even minimal, which could cause wear.

In other possible implementations, the anchoring element 24 can be an elastically deformable ring, such as an interrupted ring, for example a Seeger ring. For example, in this case the deformable ring can be selectively inserted in a suitable recess made in the through coupling seating 32, such as for example one or more hollows, or an annular groove, typically made above the clamping element 26.

In other possible implementations, the anchoring element 24 can be a deformable portion of the clamping element 26 itself. For example, the clamping element 26 can be suitably coupled to the through coupling seating 32 and in so doing a deformation of the material can be achieved, such as a protruding lip or fin, of the clamping element 26, for example an upper portion thereof, which is selectively constrained in a suitable recess made in the through coupling seating 32 as described above for example.

According to some forms of embodiment described here, the connection unit 23 can also comprise an attachment element 25 associated to the clamping element 26, assembled on the latter for example and which can be attached for example, advantageously in a releasable manner to the distal joint element 13, 113, in particular to the connection portion 15, in order to clamp the axial movement thereof toward the inside of the humeral seating 51 with respect to the clamping element 26. For its connection to the attachment element 25, the connection portion 15 can have an attachment cavity 20.

For example, in possible implementations, the attachment element 25 can be a screw, typically provided with a shaped head 35, circular or polygonal for example. The shaped head 35 can be provided with a blind coupling seating 38, drivable for example by means of a key, typically with a hexagonal head. A threaded rod 36 extends from the shaped head 35, destined to be screwed to the connection portion 15. The attachment cavity 20 of the latter, for example, can be a coordinated threaded seating, to receive the threaded rod 36 of the attachment element 25. In this way, the attachment element 25 can define overall a one-directional constraint of the distal joint element 13, 113 toward the inside of the humeral seating 51.

For example, the attachment element 25 can be inserted through the anchoring element 24, in particular having the shaped head 35 for example housed in the central shaped aperture 24a and the threaded rod 36 protruding from the latter toward the distal joint element 13, 113.

According to other forms of embodiment, the attachment element 25 can provide different configurations, for example with a fixed-joint mechanism. In other possible implementations, the attachment element 25 can be an internally threaded surface of the clamping element 26 configured to cooperate screwing

with a mating external threaded surface present on the distal joint element 13, 113, in particular on the connection portion 15.

In possible forms of embodiment, the clamping element 26 can be configured to define an axial stopping abutment for the attachment element 25, in practice preventing movements thereof toward the inside of the humeral seating 51.

In possible forms of embodiment, the clamping element 26 can be inserted between the distal joint element 13, 113 and the anchoring element 24. In particular, the clamping element 26 can be configured to receive the distal joint element 13, 113 inside it through coupling, in particular the connection portion 15 and also part of the attachment element 25 attached to the distal joint element 13, 113, the threaded rod 36 for example.

As we said, the clamping element 26 can also be configured to achieve a same-shape coupling with one-directional constraint toward the inside of the humeral seating 51 with the through coupling seating 32 of the support 12a.

Moreover, the clamping element 26 can be configured to achieve a same-shape coupling with one-directional constraint toward the inside of the humeral seating 51 with the distal joint element 13, 113.

In possible implementations, the clamping element 26 can comprise an internally hollow body to receive the distal joint element 13, 113, in particular the connection portion 15. For example, the clamping element 26 can be shaped as a truncated cone both externally and internally.

For example, the clamping element 26 can comprise a hollow truncated cone element, which has an external clamping surface 41 shaped like a truncated cone with a section that reduces toward the inside of the humeral seating 51. The external clamping surface 41 can define the same-shape coupling with the through coupling seating 32. Moreover, the clamping element 26 shaped like a hollow truncated cone can provide an internal clamping cavity 40, delimited for example by internal lateral walls 43 shaped like a truncated cone inverse with respect to the external clamping surface 41, that is, with a section that widens toward the inside of the humeral seating 51. The internal clamping cavity 40 can define the same-shape coupling with the connection portion 15 of the distal joint element 13, 113. The internal clamping cavity 40 can be sized so that the connection portion 15 does not protrude toward the outside from the clamping

element 26. The clamping element 26 can also have an upper clamping surface 42, to define the stopping abutment for the attachment element 25.

In other variants, the clamping element 26 can be shaped externally like a cylinder and internally like a truncated cone, or vice versa. Or again, the clamping element 26 can be shaped like a cylinder both externally and internally. In the case where the clamping element 26 is configured at least internally like a cylinder, a coupling by screwing with the distal joint element 13, 113 can be provided, in particular the connection portion 15, shaped like a cylinder in a coordinated manner, providing one or more suitable threaded surfaces inside the clamping element 26 and outside the distal joint element 13, 113. Moreover, in possible variant forms of embodiment, the clamping element 26 can also have one or more threaded surfaces outside, for coupling with the through coupling seating 32 by screwing.

Therefore, in some forms of embodiment, the clamping element 26 can be coupled to the distal joint element 13, 113 and also the clamping element 26 itself can be coupled to the through coupling seating 32 of the adapter body 12 and can axially clamp the attachment element 25. Furthermore, the clamping element 25 is stably positioned thanks to the attachment element 25 which, being attached to the distal joint element 13, 113, also clamps the clamping element 26 in an intermediate position. Finally, the clamping element 26 is also constrained in its axial movement toward the outside by the anchoring element 24.

Consequently, with the present invention it is possible to position and extract the connection unit 23 and the distal joint element 13, 113 in/from the humeral seating 51, without extracting and removing the support 12a of the adapter body 12.

Indeed, to position the modular humeral prosthesis 10, typically the support 12a of the adapter body 12 can be inserted in the humeral seating 51 suitably prepared.

Moreover, it is possible for example to insert the distal joint element 13, 113 in the clamping element 26 and attach the distal joint element 13, 113 to the attachment element 25, thus obtaining a single insertion body 44. In this condition, the attachment element 25 abuts against the clamping element 26 at the upper part, typically against the upper clamping surface 42.

The single insertion body 44 can be inserted from above into the humeral seating 51, passing through the through coupling seating 32. In this way, the clamping element 26 geometrically couples with the through coupling seating 32 as well.

Then, the anchoring element 24 is positioned from above, which anchors inside the adapter body 12, thus clamping possible movements of the single insertion body 44 toward the outside of the humeral seating 51.

Possible movements of the distal joint element 13, 113 toward the inside of the humeral seating 51 are instead prevented by the upper abutment of the attachment element 25 against the clamping element 26 inserted on the connection portion 15 and interposed between insertion portion 14, 114 and anchoring element 24.

In this way, since the connection unit 23 and the distal joint element 13, 113 can be installed with positioning in sequence from above, that is in antegrade fashion, with the support 12a already positioned in the humeral seating 51, it is also possible to extract, in inverse order, the connection unit 23 and the distal joint element 13, 113, always keeping the support 12a in position.

Similarly, the present invention easily allows operations to remove and/or replace the distal joint element 13, 113 without needing to remove the support 12a disposed in the humeral seating 51, advantageously operating in antegrade fashion. Indeed, it is sufficient to remove the components of the connection unit 23 in sequence, for example first the anchoring element 24 and then the single insertion body 44, formed by the attachment element 25, the clamping element 26 and the distal joint element 13, 113, which is removed through the through coupling seating 32.

With reference for example to forms of embodiment described using figs. 1, 2 or 3, the distal joint element 13, 113 can be an oblong shape and the insertion portion 14 of the distal joint element 13 can therefore be an elongated rod. The insertion portion 14 can be provided with an external insertion surface 16 suitable to be coupled to the internal surface 54 of the humeral seating 51 of the humerus 50.

The coupling of the external insertion surface 16 and the internal surface 54 can generally occur by percussion or by screwing, so as to allow the distal joint

element 13 to remain attached to the humerus 50.

According to some variant forms of embodiment, the external insertion surface 16 can comprise a plurality of longitudinal fins, possibly present in only one of its portions, which can allow to increase the interference and the gripping capacity of the contact surfaces. According to another variant the fins are integrated with, or replaced by screw threads.

In the case where the insertion portion 14 has an elongated rod, in a variant solution provided for example to increase the stability and longevity of the graft, the external insertion surface 16 can have a triple or double conical development. According to other solutions, the conicity can be single or with a different multiple value, quadruple for example. The sequence of the conicity is such as to shape the insertion portion 14 overall as a tapered body along the axis X in the insertion direction.

With reference for example to forms of embodiment described using fig. 4, the insertion portion 114 of the distal joint element 113 can be a simple protuberance or reduced protrusion, that is, it can have a reduced size, in particular in length, and for example be suitable for use in mini-invasive humeral prostheses. In particular, in possible implementations, described for example with reference to fig. 4, the insertion portion 114 can have a front surface shaped like a spherical cap 114a. In other forms of embodiment a different shape of the front end of the insertion portion 114 can be provided, for example conical, truncated cone or cylindrical.

In other possible implementations, the distal joint element 113 can be an antegrade nail which has the insertion portion elongated, insertable in a suitable channel in the humerus 50 for the function of osteosynthesis, and the connection portion 15, for connection to the adapter body 12.

With reference for example to fig. 3, the connection portion 15 of the distal joint element 13, 113 can comprise an external connection surface 17.

The external connection surface 17 of the connection portion 15 can have a shape complementary to that of the internal clamping cavity 40 of the clamping element 26. For example, the external connection surface 17 can be provided with a truncated cone shape tapered along the axis of symmetry X, toward the outside of the humeral seating 51, as for example described using fig. 3. In other

forms of embodiment, the external connection surface 17 can be shaped as an only partly truncated cone.

The internal clamping cavity 40 of the clamping element 26 can therefore have a truncated cone shape complementary to that of the external connection surface 17 defining a conical coupling.

This conical coupling prevents the clamping element 26 from sliding along the distal joint element 13 toward the insertion portion 14, once they have reached their final positioning shown more clearly in fig. 1.

With reference for example to fig. 3, the connection portion 15 can also comprise an upper surface 18 with an annular shape that develops around the attachment cavity 20 inside the distal joint element 13. The attachment cavity 20 is delimited by an internal attachment surface 21 and, for example, by a bottom 22. The internal attachment surface 21 can be cylindrical in shape and have an inner threading.

According to possible forms of embodiment, the support 12a of the adapter body 12 can comprise a proximal portion 27 and a distal portion 28. According to possible forms of embodiment, the proximal portion 27 can be shaped, for example concave, in order to accommodate the humeral head 11 in an anatomical configuration, or a concave articular insert 111 in an inverse configuration. In particular, the proximal portion 27 can have the coupling seating 19. Typically, during normal use the proximal portion 27 can be protruding, that is, on the outside with respect to the humeral seating 51. On the contrary, the distal portion 28 can have the through coupling seating 32. During normal use, the distal portion 28 can be inserted inside the humeral seating 51.

The proximal portion 27 can comprise in its turn an upper portion 29 and a lower portion 30, which can define the coupling seating 19.

The upper portion 29 can be, for example, a seating with a cylindrical shape. The upper portion 29 can have an axial symmetry along an axis Y inclined by an angle α with respect to the axis X, or diaphyseal axis, of the distal joint element 13, 113, to which the adapter body 12 will be connected.

According to some forms of embodiment, moreover, the lower portion 30 can be for example a truncated cone shaped seating.

In possible implementations, the lower portion 30 can provide a hollow

truncated cone shape obtained by a cone having the axis Y for its axis of symmetry. Moreover the lower portion 30 can taper starting from the section of the upper portion 29 until it joins the distal portion 28. This form of embodiment, in particular, can define a truncated cone lower portion 30 obtained by sectioning a cone in two planes which are not parallel to each other.

In variant forms of embodiment, the proximal portion 27 of the support 12a is solid (see for example fig. 3). According to variant forms of embodiment, the proximal portion 27 of the support 12a, in particular the lower portion 30 for example, can provide a configuration such as to allow bone integration, for example with bone fragments of the humerus 50 in the case of reconstruction of a fracture. In possible implementations, described for example with reference to fig. 5, the proximal portion 27, for example the corresponding lower portion 30, can have through apertures or windows 31 for this purpose, for example defined by lateral support elements 30a which join the upper portion 29 with the distal portion 28. The through apertures or windows 31 can allow to position the bone fragments. In this way, the proximal portion 27 can have a cage configuration for example.

With reference to fig. 5, the upper portion 29 can have a hollow cylindrical shape and the support elements 30a can be a different length and shape from each other.

The support elements 30a can be configured to obtain a desired inclination of the upper portion 29.

For example, providing that the upper portion 29 has a symmetry along an axis Y different to the axis X of symmetry of the distal joint element, an angle α is thus defined between the two axes.

For example, the distal portion 28 of the support 12a, able to connect the connection unit 23 to the support 12a, can be connected to the lower portion 30.

Typically the distal portion 28 can have an axial symmetry along the axis X of symmetry, or diaphyseal axis, of the distal joint element 13, 113. The distal portion 28, in this embodiment, also has an external shape of the cylindrical type, and hollow inside.

According to other forms of embodiment, the distal portion 28 can have other external shapes, keeping the inside hollow, for example parallelepiped or cubic.

In some forms of embodiment, the distal portion 28 can connect to the lower portion 30 of the proximal portion 27, defining a cylinder sectioned in two planes which are not parallel with each other.

The distal portion 28 can provide the through coupling seating 32, able to cooperate with the connection unit 23. According to some forms of embodiment, the through coupling seating 32 can be delimited internally by an upper surface 31a configured to cooperate with the anchoring element 24 and by a lower surface 31b to cooperate with the clamping element 26, in sequence one after the other along the axis X. The upper surface 31a can provide a cylindrical shape for example and have a threading for screwing to the threaded external anchoring surface 33 of the anchoring element 24. The lower distal surface 31b on the contrary can have a truncated cone shape, tapered at the lower part. For example, the external clamping surface 41 of the clamping element 26 can be configured to be coupled with the lower surface 31b, and these surfaces can have complementary shapes. As described for example with reference to fig. 3, the upper surface 31a and the external clamping surface 41 can both be truncated cone shaped and have the same size, to achieve a conical coupling which prevents the movement of the clamping element 26 along the axis X, in the direction of insertion of the distal body 13, 113 into the adapter body 12, once the clamping element 26 has been inserted in the distal portion 28.

As discussed above, the connection unit 23 of the adapter body 12 is configured to allow the insertion of the distal joint element 13, 113 from the upper part of the adapter body 12, that is, on the side where the humeral head 11 or the concave articular insert 111 are inserted. The distal joint element 13, 113 can therefore be inserted passing first through the proximal portion 27 and then through the proximal portion 28 of the adapter body 12 to then be constrained to the adapter body 12 itself. In possible implementations, the connection unit 23 is provided in the distal portion 28 of the support 12a when the distal joint element 13, 113 is inserted in the adapter body 12.

Fig. 1 is used to describe possible implementations of the modular humeral prosthesis 10 in making an anatomical prosthesis, while fig. 2 is used to describe possible implementations of the modular humeral prosthesis 10 in making an inverse prosthesis.

With reference for example to fig. 1, the modular humeral prosthesis 10 can be configured as an anatomical prosthesis to allow the articulation of the humerus 50 in a corresponding glenoid cavity 52, only partly shown, of a shoulder or possibly in a mating artificial seating attached to the glenoid cavity 52.

In the forms of embodiment described by way of example in fig. 1, the modular humeral prosthesis 10 is shown in an anatomical configuration and comprises a humeral head 11, a distal joint element 13 and an adapter body 12, provided with a connection unit 23, suitable to constrain the humeral head 11 to the distal joint element 13, and with a coupling seating 19.

With reference to forms of embodiment described using fig. 1 for example, a humeral head 11 which can be associated to the modular prosthesis 10 can be formed by a single body and have a convex articulation surface 11a configured to articulate in the glenoid cavity 52 and a coupling surface 11b to the adapter body 12.

With reference to forms of embodiment described using for example figs. 7 and 8, the humeral head 11 can be the modular type, formed by a connection element 45 and by a convex articulation element 46, which can be connected to each other by coupling means 47.

The connection element 45 can have the coupling surface 11b and is inserted for example in the upper portion 29 to support the convex articulation element 46, which, on the contrary, is the part nearest the glenoid cavity 52, and has the convex articulation surface 11a.

The coupling means 47 can comprise a coupling cavity 48, made in the convex articulation element 46, and a coupling pin 49 provided protruding from the connection element 45. For example, the coupling cavity 48 and the coupling pin 49 are configured to achieve a conical coupling.

Instead, with reference to fig. 2 for example, the modular humeral prosthesis 10 can be configured as an inverse prosthesis to allow the articulation of the humerus 50 with respect to an artificial convex portion, semi-spherical for example, also called glenosphere, positioned in the glenoid.

In the forms of embodiment described by way of example in fig. 2, a concave articular insert 111 is provided, able to be used in a modular humeral prosthesis 10 in an inverse configuration, constrained to the adapter body 12, as an

alternative to the humeral head 11 in figs. 1, 7 and 8.

With reference to forms of embodiment described using fig. 2 for example, the concave articular insert 111 associable to the modular humeral prosthesis 10, in the inverse configuration, can have a concave articulation surface 111a, for example to allow the articulation of a glenosphere attached to the glenoid cavity 52, and a support surface 111b to be inserted and attached in the adapter body 12.

It is clear that modifications and/or additions of parts may be made to the modular humeral prosthesis 10 as described heretofore, without departing from the field and scope of the present invention.

It is also clear that, although the present invention has been described with reference to some specific examples, a person of skill in the art shall certainly be able to achieve many other equivalent forms of humeral prosthesis, having the characteristics as set forth in the claims and hence all coming within the field of protection defined thereby.

CLAIMS

1. Modular humeral prosthesis suitable for implant in a humeral seating (51) of a humerus (50), comprising an articulation component (11, 111), a distal joint element (13, 113) able to be inserted into said humeral seating (51) along an insertion axis (X), and an adapter body (12) provided with a support (12a) positionable in the humeral seating (51) and that has a coupling seating (19) to connect said articulation component (11, 111) and provided with a connection unit (23) inserted into said support (12a) to connect said distal joint element (13, 113) to said adapter body (12) in a releasable manner, **characterized in that** said connection unit (23) comprises:

a clamping element (26) associated in a selectively releasable manner to the distal joint element (13, 113),

an anchoring element (24) configured to clamp a movement of axial extraction of the clamping element (26) toward the outside of the humeral seating (51),

an attachment element (25) associated with the clamping element (26) and the distal joint element (13, 113) to clamp the axial movement of the distal joint element (13, 113) toward the inside of the humeral seating (51) with respect to the clamping element (26),

and in that said support (12a) has a through coupling seating (32) configured to receive and position said clamping element (26) inside it, and also configured to allow the insertion and extraction of said distal joint element (13, 113) through said support (12a) without removing said support (12a) from the humeral seating (51).

2. Humeral prosthesis as in claim 1, **characterized in that** the clamping element (26) is configured to clamp a movement of axial extraction of the distal joint element (13, 113) toward the outside of the humeral seating (51).

3. Humeral prosthesis as in claim 1 or 2, **characterized in that** the clamping element (26) is configured to achieve a same-shape coupling with a one-directional constraint toward the outside of the humeral seating (51) with the through coupling seating (32) of the support (12a).

4. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the clamping element (26) is configured to achieve a same-shape coupling with a one-directional constraint toward the inside of the humeral seating (51) with the

distal joint element (13, 113).

5. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the clamping element (26) is coupled externally to the distal joint element (13, 113).

6. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the clamping element (26) has a truncated cone configuration, both internally and externally.

7. Humeral prosthesis as in claim 6, **characterized in that** the clamping element (26) comprises a hollow truncated cone element that has an external clamping surface (41) shaped like a truncated cone with a section that reduces toward the inside of the humeral seating (51), an internal clamping cavity (40) delimited by internal lateral walls (43) shaped like a truncated cone inverse with respect to the external clamping surface (41), to receive a mating connection portion (15) of the distal joint element (13, 113).

8. Humeral prosthesis as in any claim from 1 to 5, **characterized in that** internally the clamping element (26) has a truncated cone configuration and externally a cylindrical configuration.

9. Humeral prosthesis as in any claim from 1 to 5, **characterized in that** internally the clamping element (26) has a cylindrical configuration and externally a truncated cone configuration.

10. Humeral prosthesis as in any claim from 1 to 5, **characterized in that** the clamping element (26) has a cylindrical configuration both internally and externally.

11. Humeral prosthesis as in claim 9 or 10, **characterized in that** at least internally the clamping element (26) has threaded connection means to cooperate with the distal joint element (13, 113).

12. Humeral prosthesis as in any claim hereinbefore, **characterized in that** said anchoring element (24) is configured to be constrained bi-directionally to said support (12a).

13. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the anchoring element (24) comprises an externally threaded annular body that has a threaded external anchoring surface (33) and a shaped central aperture (24a).

14. Humeral prosthesis as in any claim from 1 to 12, **characterized in that** the anchoring element (24) comprises an elastically deformable ring, in particular a

Seeger ring.

15. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the clamping element (26) is inserted between the distal joint element (13, 113) and the anchoring element (24).

16. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the attachment element (25) is mounted on the clamping element (26) and is attached to the distal joint element (13, 113).

17. Humeral prosthesis as in any claim hereinbefore, **characterized in that** the attachment element (25) comprises a screw, provided with a shaped head (35), configured to abut against the clamping element (26), from which a threaded rod (36) extends, configured to be inserted into the clamping element (26) and able to be screwed into an attachment cavity (20) of the distal joint element (13, 113) to define overall a one-directional constraint of the distal joint element (13, 113) toward the inside of the humeral seating (51).

18. Humeral prosthesis as in any claim hereinbefore , **characterized in that** the clamping element (26) is configured to define an axial stopping abutment for the attachment element (25).

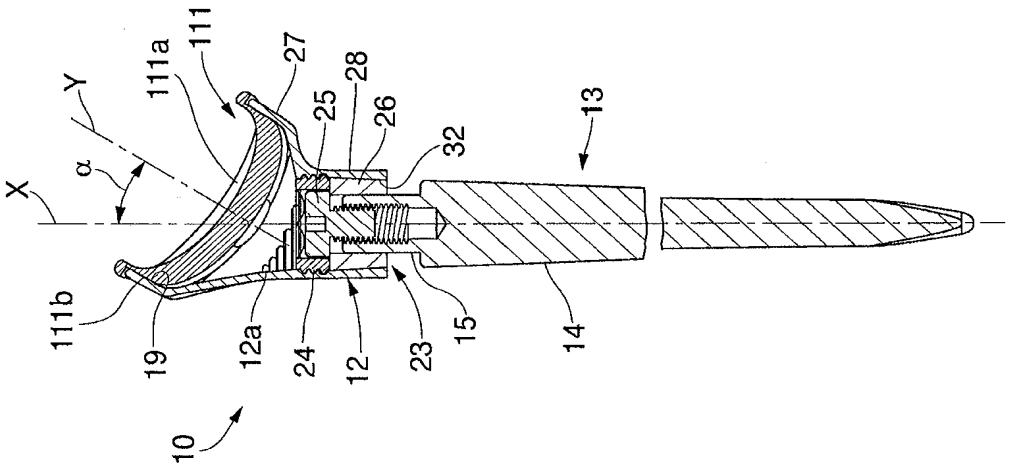

111
111a
27
28
25
26
32
13
Y
α
X
111b
19
12a
24
12
23
15
14
10

fig. 2

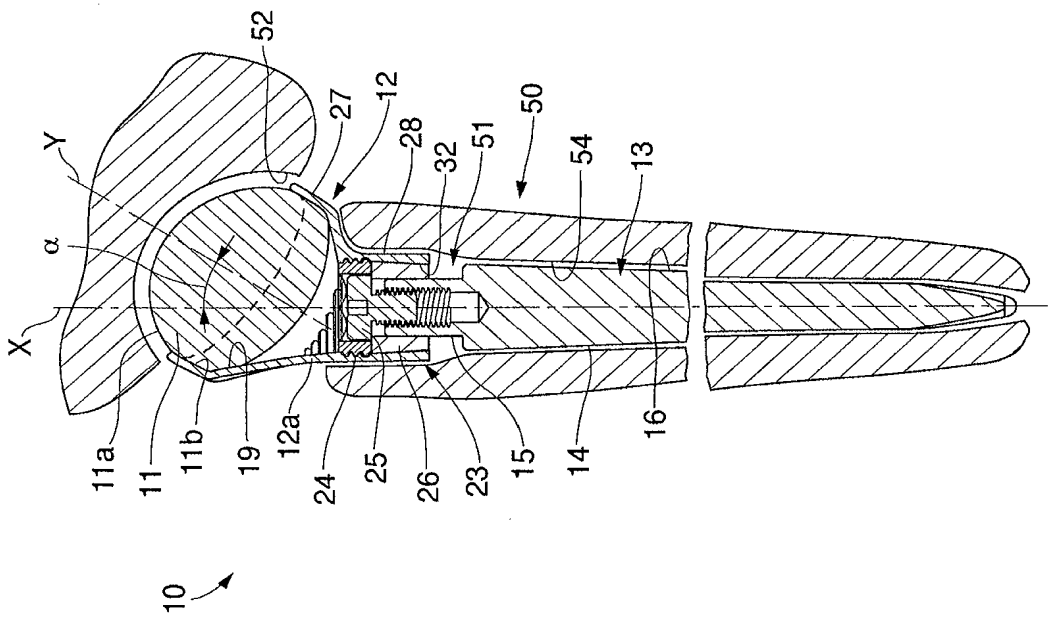

52
27
12
28
32
51
50
54
13
Y
α
X
11a
11
11b
19
12a
24
25
26
23
15
14
16
10

fig. 1

2/4

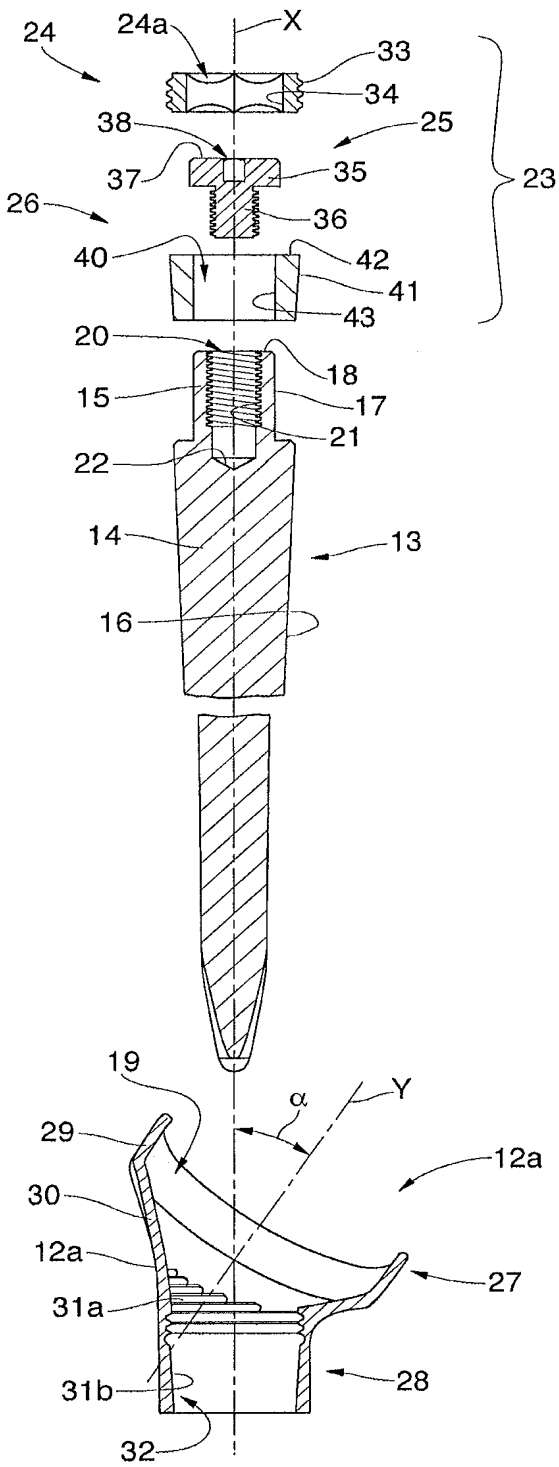

24
24a
X
33
34
38
25
37
35
23
26
36
40
42
41
43
20
18
15
17
21
22
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α
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12a
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27
31a
28
31b
32

fig. 3

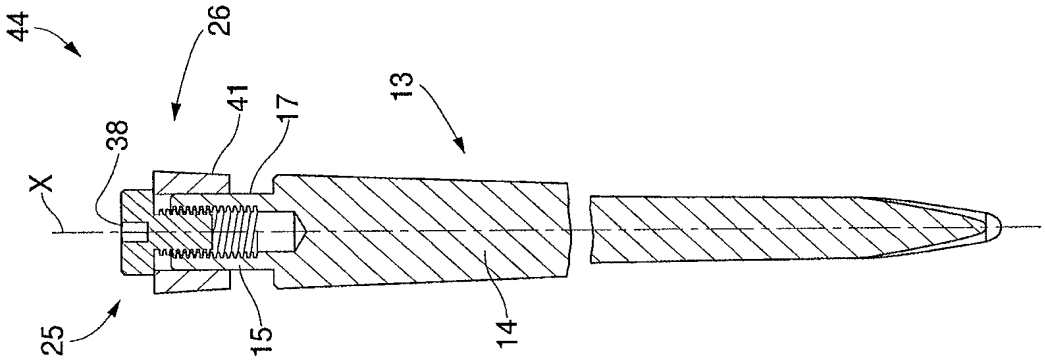


fig. 6

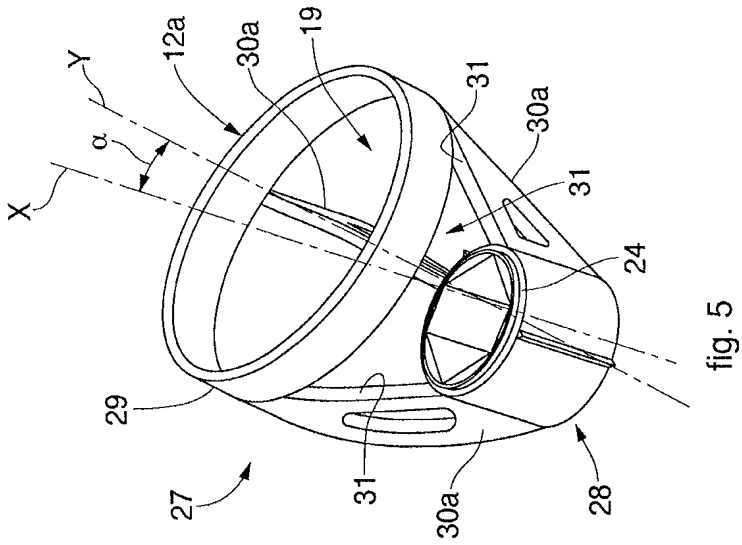


fig. 5

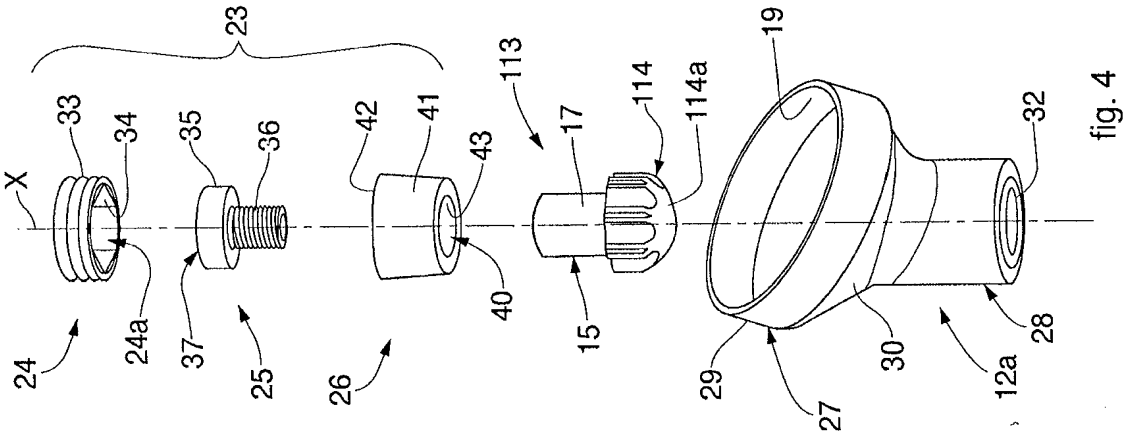


fig. 4

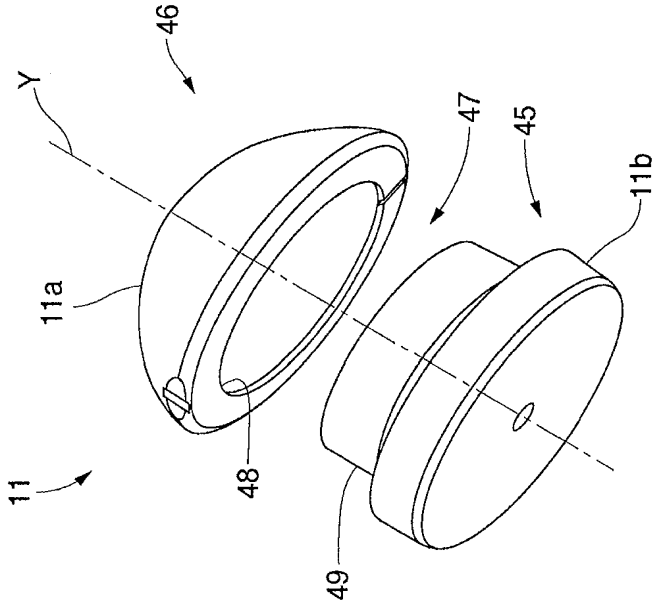

46
Y
47
45
11b
11a
11
48
49

fig. 8

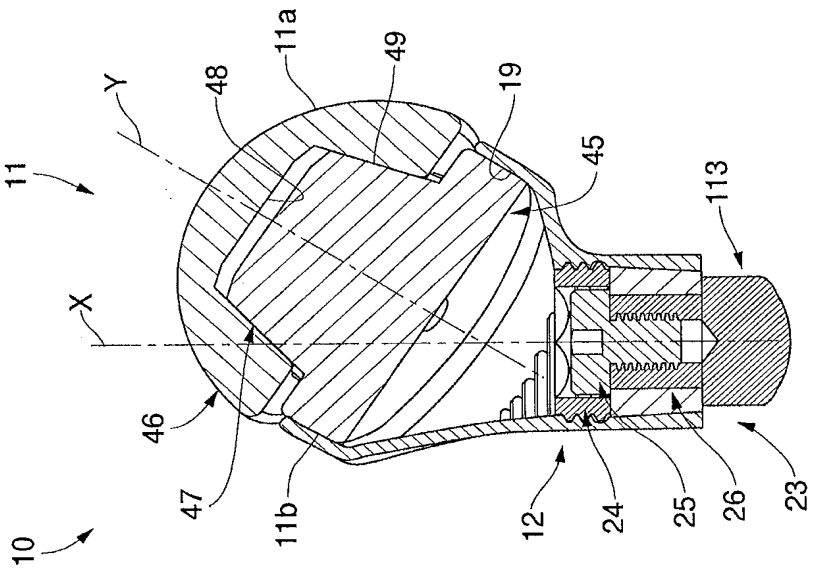

11a
49
48
Y
19
45
113
11
X
46
47
11b
10
12
24
25
26
23

fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/062002

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/40 A61F2/30
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/125067 A1 (SWEENEY PATRICK J [US]) 9 June 2005 (2005-06-09) figures 2-8 paragraphs [0008], [0009], [0030], [0032] -----	1-18
A	WO 99/47081 A1 (WHITE PATRICK MICHEL [US]) 23 September 1999 (1999-09-23) figures 1,4,8,14,16 abstract -----	1-18
A	EP 1 472 999 A1 (LIMA LTO SPA [IT]) 3 November 2004 (2004-11-03) cited in the application figures 2,4 -----	1

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

☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 August 2014	04/09/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Josten, Stefan

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/058,058	**04/06/2023 07:44:33 PM ET**	**SHOLD.013C1**

Title of Invention

TOTAL REVERSE SHOULDER SYSTEMS AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5500	FILED BY	Ping-Ping Tang
PATENT CENTER #	61882463	FILING DATE	11/22/2022
CUSTOMER #	20995	FIRST NAMED INVENTOR	Donald E. Running
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Andrew Kimmel

Documents

TOTAL DOCUMENTS: 52

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FOR_EP0339530A2.pdf	5	Foreign Reference	293 KB
FOR_EP2083759.PDF	12	Foreign Reference	483 KB
FOR_EP0570816A1.pdf	10	Foreign Reference	658 KB
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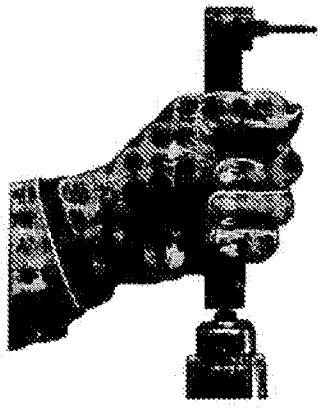
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(54) Shoulder prosthesis

(57) The shoulder prosthesis is adapted for implantation of a glenoid surface (G) of a scapula (S), the prosthesis comprising a glenoid component (10) having an articular face (11A) and an opposing face (11B), a bone graft (2) with a medial surface (2C) having a shape complementary to the glenoid surface (G) and a distal surface (2B) having a shape complementary to at least a part of said opposing face, and anchor means (12) extending from said opposing face, through the bone graft and into the glenoid surface.

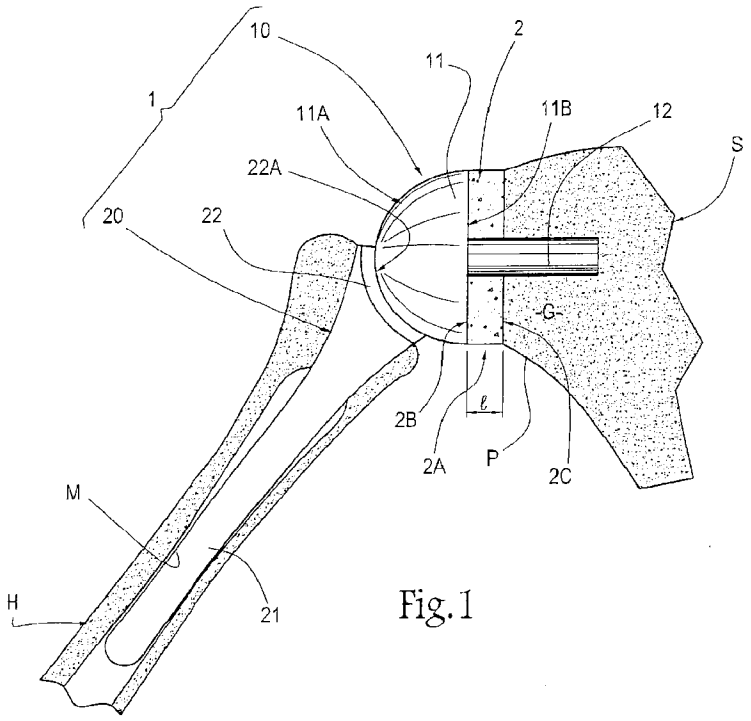


Fig. 1

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Description

[0001] The present invention relates to a shoulder prosthesis, in particular a total inverted shoulder prosthesis.

[0002] In the field of total shoulder prostheses, prostheses are commonly said to be inverted when they comprise, on the one hand, a glenoid part integral with the glenoid surface of a scapula of a patient's shoulder and delimiting a convex articular surface and, on the other hand, a humeral part integral with the humerus of the shoulder and delimiting a concave articular surface, the cooperation of these articular surfaces allowing an articulated connection to be reproduced at the shoulder. With this type of prosthesis, it is common, during adduction movement of the shoulder, for the lower portion of the humeral prosthetic part to strike the pillar of the scapula, i.e. the lower portion of the bone glenoid surface located, when the patient stands upright, just below the glenoid prosthetic part. This interference between the humeral prosthetic part and the scapula limits the range of the adduction movement and may cause pain to the patient or even lead to the prosthesis becoming dislodged, in particular by osteolysis of the scapula.

[0003] The object of the present invention is to propose a shoulder prosthesis, allowing the risks of interference between the scapula and the humeral part of an inverted or an anatomical shoulder prosthesis to be limited without having recourse to complex configurations of this prosthesis and, indeed, using for the most part existing inverted prostheses. All references to a shoulder prosthesis should be interpreted to include a total shoulder prosthesis with a humeral component and a glenoid component, or a partial shoulder prosthesis with a glenoid component with an anatomical or resurface humeral head.

[0004] For this purpose, the invention relates to a shoulder prosthesis as defined in claim 1.

[0005] Besides, here is proposed a corresponding surgical method for implanting a shoulder prosthesis, especially an inverted shoulder prosthesis, on a glenoid surface of a scapula, comprising the steps of:

preparing a bone graft with a medial surface and a distal surface;
engaging the medial surface of the bone graft with the glenoid surface;
engaging an opposing face of a glenoid component with the distal surface of the bone graft so an articular surface, especially a convex articular surface, on the glenoid component is laterally off-set from the glenoid surface; and
anchoring the glenoid component to the glenoid surface through the bone graft.

[0006] Thus, the basic idea of the invention is to "lateralize" the glenoid component relative to the patient's scapula, i.e. to withdraw it from the patient's scapula in a plane frontal to this patient, by interposing the bone graft between this glenoid component and the glenoid surface. In other words, this bone graft forms an outer lateral extension of the glenoid surface, extending the scapula, whereas the combination of this graft and the prosthetic glenoid component forms a composite prosthetic unit. It will be understood that a glenoid component of a current prosthesis, of which the design has been tried and tested, can thus be implanted so as to cover the side of the graft opposing the glenoid surface, wherein it will be noted that, for purposes of secure fixing, this component must have bone anchoring structure, such as a central tail, sufficiently elongate to pass straight through the graft and be secured in the bone of the scapula delimiting the glenoid surface. Once the bone graft has fused with the glenoid surface, the distal surface of the bone graft becomes the effective glenoid surface. References to glenoid surface should be interpreted to include a prepare or an unprepared exposed surface of a glenoid cavity.

[0007] As the articular face of the glenoid component occupies, relative to the scapula, a position laterally more remote than the position that this face would occupy were the graft omitted, there is a significantly reduced risk of interference between the pillar of the scapula and the lower portion of the humeral prosthetic part cooperating with the glenoid articular face. The lateralization of the prosthetic glenoid component also leads to an increase in the tension in the rotator muscles of the shoulder and an increase in the co-adaptation vector of the deltoid muscle. The prosthetic glenoid and humeral components are thereby stabilized and thus benefit from better mobility in relative rotation, without running the risk of dislocation of the shoulder.

[0008] In a preferred embodiment, the geometric centre of articulation of the prosthesis is situated at the bone face in the glenoid surface. The radius of curvature of convex articular surface of the glenoid component is preferably selected so the center of rotation is in or behind a plane comprising distal surface of the bone graft.

[0009] Furthermore, compared to an inverted shoulder prosthesis from the prior art and which can thus be described as a "medialized prosthesis", the "lateralized" prosthesis according to the invention restores some of the curved surface of the patient's shoulder, thus giving it a more pleasing appearance than the "coat hanger" appearance conferred by medialized prostheses.

[0010] The surgical method is simple, quick, easy and reproducible. In practice it has the advantage of not having to completely expose the patient's glenoid surface, exposure actually being able to be limited to the positioning of the graft. In the preferred embodiment, the bone graft is taken from the patient so as to minimize the risk of contamination, although allografts, xenografts, natural or synthetic materials may be used.

[0011] Advantageous features of the prosthesis according to the invention are recited in claims 2 to 16.

[0012] Thus, according to a particularly advantageous implementation of the invention, in order to provide the

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bone graft in preferably taken from the upper epiphysis of the humerus of the patient's shoulder. In this way, the graft used originates from the patient, and this limits the risk of rejection, poor biological compatibility, transmission of disease or infection. Furthermore, advantageous use is made of the fact that, in order to implant the humeral prosthetic part, it is necessary to prepare the epiphysis of the patient's humerus, by withdrawing a substantial part of the cancellous bone matter forming this epiphysis which, in accordance with this aspect of the invention, can be used to provide the graft whereas, up until now, this matter was scrapped.

[0013] In practice, the method includes a shaping step in which the bone matter forming the upper humeral epiphysis is shaped into a one-piece volume extending in length about an axis inclined relative to the longitudinal direction of the humerus, and a cutting step in which the volume of bone matter is removed from the humerus by cutting the humeral epiphysis transversely to the axis of this volume, the volume of bone matter thus removed forming the graft. The set of instruments according to the invention allows implementation of the fitting method defined hereinbefore, the shaping and cutting steps of which are respectively carried out by the shaping and cutting ancillary instrument. The volume of bone matter removed from the humerus using the cutting ancillary instrument can thus be used as the bone graft for carrying out the general fitting method defined hereinbefore in order laterally to offset the articular surface of a glenoid component of the prosthesis relative to the scapula of the patient's shoulder, during implantation of this glenoid component.

[0014] The method may include one or more of the following steps:

- the length of the graft is adjusted along the axis of the volume of bone matter;
- the longitudinal end faces of the graft are respectively shaped to be substantially complementary to said opposing face of the glenoid component and the glenoid surface previously prepared;
- during the shaping step, the shaped volume of bone matter is chosen from a cylinder and a frustum of a cone, centered on the axis of this volume;
- before or during the shaping step, the end of the upper humeral epiphysis is resected;
- the upper humeral epiphysis is resected over a first plane and in which, during the cutting step, the humeral epiphysis is cut over a second plane, said first and second plane being transverse to the axis of the volume of bone matter;
- the relative inclination of said first and second planes is adjusted;
- during or after the shaping step, a recess centered on the axis of the volume of bone matter is dug in the humeral epiphysis, and in which, during the step, the glenoid component is anchored in the glenoid surface through this recess;
- before carrying out the shaping step, there is inserted into the humeral epiphysis a marker pin allowing, during the shaping step, positioning of the axis of the volume of bone matter relative to the humerus.

[0015] In accordance with another possibility according to the invention, rather than taking the bone graft from the patient's humeral epiphysis, the bone graft provided in step i) is chosen from a graft taken from a bone region in the patient other than the upper humeral epiphysis, in particular from the patient's ilium, an allograft and a graft of synthetic origin.

[0016] In accordance with an option of the method according to the invention that can be used equally well with a graft taken from the humeral epiphysis or elsewhere and with an allograft or else a graft of synthetic origin, during step ii), a protection layer is attached to at least a part of the graft that is not in contact with the glenoid surface, and, during step iii), at least a part of the opposing face of the glenoid component is supported on the protection layer.

[0017] In one embodiment, some or all of the surfaces on the glenoid component that engage with the bone graft are covered with hydroxyapatite or materials having a functionally similar surface state, such as a honeycomb surface state, allowing bone adhesion and rehabilitation to be improved. Selected surface of the glenoid component may be constructed of materials that facilitate fusion with bone, such as disclosed in U.S. Patent No. 7,250,550.

[0018] According to yet another possibility of the invention, the bone graft provided in step i) consists of a purée of bone substance, it being appreciated that this bone substance can originate either from the patient, in particular from the upper epiphysis of his humerus, or from another, possibly synthetic, source. This purée of bone substance is advantageously used with a structure of protection as defined hereinbefore, which comprises a lattice shaped into a cage filled with the purée. This lattice cage allows good exchange of biological flows between the purée forming the graft and the surrounding tissues of the shoulder.

[0019] A better understanding of the invention will be facilitated on reading the following description given merely by way of example and with reference to the drawings, in which:

Fig. 1 is a basic schematic illustration of an inverted shoulder prosthesis, implanted at a patient's shoulder;

Fig. 2 is a schematic elevation of an ancillary instrument of a set of instruments used in order to fit the prosthesis of Fig. 1;

Fig. 3 is a view similar to Fig. 2, illustrating another ancillary instrument pertaining to the set of instruments, to be applied to the patient's humerus after use of the ancillary instrument of Fig. 2;

Fig. 4 is a schematic perspective view of a further

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ancillary instrument pertaining to the set of instruments;

Fig. 5 is a view similar to Fig. 2, illustrating the humerus after use of the ancillary instrument of Fig. 3 and 4;

Fig. 6 is a schematic perspective view of another ancillary instrument pertaining to the set of instruments;

Fig. 7 is a view similar to Fig. 2, illustrating the application of the ancillary instrument of Fig. 6 to the humerus after use of the ancillary instrument of Fig. 4;

Fig. 8 to 12 show a second embodiment of a set of instruments according to the invention, Figs. 8, 9, 11 and 12 being similar respective schematic elevations of four ancillary instruments pertaining to this set and used in succession, to fit the prosthesis from Fig. 1, whereas Fig. 10 is a partial perspective view of the ancillary instruments from Fig. 9, shown alone;

Fig. 13 is a basic schematic illustration of the glenoid part of an other inverted shoulder prosthesis according to the invention.

Fig. 14 is a view similar to Fig. 13 of a variation of the prosthesis according to the invention;

Figs. 15-21 illustrate various uses of a bone graft to lateralize the glenoid component of an inverted shoulder prosthesis according to different embodiments;

Figs. 22-26 illustrate various uses of a bone graft to lateralize the glenoid component of an anatomical shoulder prosthesis according to different embodiments;

Figures 27-29 illustrate various uses of a bone graft to lateralize the glenoid component of an inverted shoulder prosthesis according to different embodiments;

Figs. 30A-30E illustrate a method and tool set for preparing a bone graft in accordance with another embodiment.

[0020] Fig. 1 shows a shoulder prosthesis 1 comprising a glenoid component 10 and a humeral component 20, respectively implanted in the scapula S and the humerus H of a patient's shoulder. The glenoid components shown herein are illustrated schematically. The method and apparatus of the various embodiments disclosed herein may be used with a variety of other glenoid components, such as for example those disclosed in U.S. Patent Nos. 7,033,396; 6,953,478; 6,761,740; 6,626,946; 5,702,447 and U.S. Publication Nos. 2004/0220673; 2005/0278030; 2005/0278031; 2005/0278032; 2006/0020344.

[0021] The glenoid component 10 comprises a head 11 which has, on the side opposing the glenoid surface G of the scapula S, a convex articular surface 11A of generally hemispherical shape and, on the side turned toward the glenoid surface, an opposing face 11B. In the example considered in the Figs., this face 11B is generally planar but, in non-illustrated variations, this face 11B can have a more elaborate geometry, being, for example, substantially concave or convex.

[0022] The glenoid component 10 also comprises an anchoring tail 12 which extends transversely so as to protrude from the face 11B, in the direction opposing the face 11A, and the free end part of which is securely anchored in the glenoid surface G, thus joining the glenoid component to the scapula S. In practice, in a manner not shown, the anchoring tail 12 can be provided, at its end turned toward the head 11, with a base accommodated inside the head 11, being securely joined thereto. In other words, more generally, the connection between the tail 12 and the head 11 can assume a broad range of forms, such as material continuity, respective wedging surfaces, attached mechanical assembly structures, etc. Also by way of non-illustrated variation, the tail 12 can be externally threaded or, generally, have a surface state promoting the anchoring thereof.

[0023] Between the face 11B of the glenoid head 11 and the glenoid surface G of the scapula S there is interposed a bone graft 2 having a substantially cylindrical outer shape with a circular base, the external diameter of which is substantially equal to that of the head 11. The outer lateral face 2A of the graft 2 thus extends substantially in the extension of the hemispherical face 11A. The graft 2 has, on its side opposing the glenoid surface G, a longitudinal end face or distal surface 2B covered by the face 11B of the head 11 and, on its side directed toward the glenoid surface, a longitudinal end face or medial surface 2C resting against the glenoid surface G. Once the bone graft 2 fuses with the glenoid surface G, the effective glenoid surface is displaced laterally outward to the distal surface 2B of the bone graft 2.

[0024] In the example considered in the Figs., the longitudinal end faces 2B and 2C are planar; this has proven to be an embodiment that is simple to handle and easy to obtain, as will be referred to hereinafter. However, in practice, these faces 2B and 2C can have more elaborate geometries: on one side, the face 2B is provided to be covered in a substantially complementary manner with the face 11B of the head 11, including in this face the zones or the structure for connecting to the tail 12, it being understood that, as indicated hereinbefore, this face 11B can be generally concave, convex or planar; on the opposing side, the face 2C is provided to embrace the surface of the glenoid surface G, which has been previously prepared for this purpose, so that the face 2C and the glenoid surface are substantially complementary and can equally well be planar or curved.

[0025] The bone graft can be a one-piece bone graft, a plurality of random or pre-formed bone pieces, one or more layers of bone material, a purée of bone substance, or combinations thereof. The bone graft can be formed from the patient's bone, an allograft, a xenograft, or a combination thereof. The bone graft can optionally be resorbable. The bone graft may be used alone or in combination with bone replacements, bone fillers, bone ce-

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ments and/or bone adhesives. Various bone replacements, bone fillers, bone cements and bone adhesives are disclosed in U.S. patent No. 6,692,563 (Zimmerman). Various additives can be included in the bone graft, such as for example, bone growth agents or pain inhibitors. In one embodiment, reinforcing fibers are added to the purée of bone substance.

[0026] Alternatively, the bone graft can be materials into which native bone will grow to create a structure with properties comparable to native bone, such as for example, a three-dimensional porous matrix or scaffold. Examples of a porous matrix or scaffold include a reticulated bioceramic framework, structured porous tantalum, synthetic fiber mesh, and the like. Various porous matrices and scaffoldings are disclosed in U.S. Patent Nos. 4,479,271; 6,511,511; 6,605,117; 6,797,006; 6,902,584; and 7,250,550.

[0027] The bone graft can be made from a variety of synthetic compounds, such as for example, polyglycolide, polylactides, polycaprolactones, polytrimethylenecarbonates, polyhydroxybutyrates, polyhydroxyvalerates, polydioxanones, polyorthoesters, polycarbonates, polytyrosinecarbonates, polyorthocarbonates, polyalkylene oxalates, polyalkylene succinates, poly(malic acid), poly (maleic anhydride), polypeptides, polydepsipeptides, polyvinylalcohol, polyesteramides, polyamides, polyanhydrides, polyurethanes, polyphosphazenes, polycyanoacrylates, polyfumarates, poly(amino acids), modified polysaccharides (e.g., cellulose, starch, dextran, chitin, chitosan, etc.), modified proteins (e.g., collagen, casein, fibrin, etc.) and their copolymers, or combinations thereof. Other polymers include polyglycolide, poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(L-lactide), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), polycaprolactone, poly(L-lactide-co-caprolactone), poly(D,L-lactide-co-caprolactone) polytrimethylenecarbonate, poly(L-lactide-co-trimethylenecarbonate), poly(D,L-lactide-co-trimethylen-ecarbonate), polydioxanone and copolymers, and polymer blends thereof. Various methods of manufacturing the bone graft from a synthetic compound can be found in U.S. Patent Nos. 6,767,928; 6,730,252; 6,541,022; 6,454,811.

[0028] Optionally, before or during the fitting of the prosthesis, the bone graft 2 is secured to the glenoid component by an additional means, known in the art, such as a biocompatible adhesive layer, strongly enough to allow the surgeon to handle the two elements as one piece.

[0029] The tail 12 passes straight through the graft 2, in the longitudinal direction thereof. In other words, the length of the tail is much greater than that of the graft 2, so that at least a substantial part of this tail is anchored securely in the native layer of the glenoid surface G.

[0030] In optional embodiments (not shown), the securing of the graft to the glenoid surface can be reinforced by fasteners additional to the tail 12, such as screws distributed around this tail and passing through the graft over at least part of the length thereof.

[0031] The humeral component 20 comprises a tail 21 for anchoring in the medullary cavity M of the humerus H. At its upper end, this tail is provided with a head 22 having, on its side opposing the tail 21, a concave articular face 22A in the form of a portion of a sphere, the radius of which is substantially equal to that of the face 11A. When the prosthesis 1 is implanted, as in Fig. 1, the faces 11A and 22A are in mutual surface contact, thus allowing the various desired shoulder articular movements.

[0032] Given the presence of the graft 2, the face 11A is remote from the resected surface of the glenoid surface G in the sense that, if this graft were omitted, this face 11A would be directly juxtaposed with the resected surface of the glenoid surface. Thus, on account of the graft 2, the glenoid articular face 11A and, accordingly, the humeral articular face 22A are laterally remote from the glenoid surface G, limiting the risk of the lower portion of the head 22 interfering with the bottom of the glenoid surface G, i.e. with the pillar P of the scapula S. In addition, it will be understood that, as a consequence resulting from this lateralization desired within the scope of the invention, the graft 2 acts as bone matter to make good any bone deficit in the glenoid surface.

[0033] In practice, the glenoid component 10 can be of a broad range of sizes, to which the graft 2 is adapted. Typically, the head 11 is available in at least two different sizes, namely with an external diameter of 36 mm or 42 mm, it being understood that other sizes are conceivable. Similarly, the length / of the graft 2 can have a broad range of values, distributed in practice in a uniform sequence, in a manner adapted to the morphology and/or to the pathology of the patient. The graft 2 can thus have lengths of 3, 6, 8 or 10 mm, whereas the tail 12 has a length of between 15 and 25 mm, possibly greater.

[0034] A surgical method seeking to implant the shoulder prosthesis 1 of Fig. 1 will be described hereinafter, it being understood that the prosthesis in question is merely a non-limiting illustrative example of the method and the surgical instruments used to implant this prosthesis. In other words, the method and the instruments specified hereinafter can be used to implant shoulder prostheses of a broad range of structures, of which, for example, the glenoid and/or humeral components consist of a plurality of metallic, plastic and/or ceramic-type parts joined together. Thus it is possible, for example, to use a humeral component without an anchoring tail.

[0035] Figs. 2-12 illustrate various methods and instruments for forming the bone graft in situ. In a first stage of the operation, once the soft parts of the shoulder has been removed using a deltopectoral or supero-external approach, the shaft 31 of an ancillary instruments 30 is introduced into the medullary cavity M of the humerus H, passing straight through the upper epiphysis E of the humerus H, as illustrated in Fig. 2. In order to do this, the point of entry in the humeral epiphysis is determined beforehand by radiograph analysis of the face and profile of the humerus.

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[0036] In its common part, the shaft 31 is secured, in particular detachably, to a body 32 in the shape of an upwardly rounded bell. This body 32 is generally arranged transversely to the shaft 31, extending in length about a central geometrical axis 33. Projected in a plane mediolateral to the patient and containing the longitudinal axis of the shaft 31, as shown in Fig. 2, this axis 33 is inclined relative to the longitudinal axis of the shaft at an angle α of between 10 and 70°, it being noted that, spatially, the two aforementioned axes do not necessarily intersect but cross in a somewhat mutually remote manner in an anteroposterior direction.

[0037] The body 32 has on its inside a concave surface 34, of which the main center of curvature and the peak pertain substantially to the axis 33. This surface 34 is provided to reproduce approximately the surface features of the upper epiphysis of a normal anatomical humerus, it being understood that, in practice, the surgeon has a range of a plurality of homothetic ancillary instruments 30, the bodies 32 of which have respective dimensions associated with the size and the state of the patient's bones. On its outer face, the body 32 is provided with a protruding tube 35 centered on the axis 33 and opening into the interior of the body 32, on its inner surface 34.

[0038] The shaft 31 is inserted into the medullary cavity M of the humerus H until contact is established between the surface 34 and the humeral epiphysis E, the body 32 then covering the epiphysis in the manner of a cap. Then, advantageously, the shaft 31 is driven in rotation about itself, over a short course, in order to allow for the retroversion of the humerus H. In a manner known per se, the shaft 31 is provided, in its proximal end part, with diametral through-orifices 36 angularly offset from one another about the longitudinal axis of the shaft 31 and, as a function of the retroversion of the patient determined by the surgeon, an elongate rod (not shown) is introduced into one of these orifices in order effectively to display the retained direction of retroversion, so that the shaft 31 is rotated on itself until this retroversion rod is aligned with the patient's forearm.

[0039] A guide pin 40, at the pointed distal end 41, is then introduced into the tube 35, from the free end thereof, and is inserted into the humeral epiphysis E over a substantial depth, as indicated by arrow 42 in Fig. 2, until its point pierces and passes at least partially through the outer cortex of the humerus H. It will be understood that the ancillary instruments 30 allows the pin to be inserted in a suitable direction relative to the humerus, the tube 35 acting as a guide for introducing and feeding through the pin. In order to prevent interference between the pin and the shaft 31, when this pin passes through the central zone of the humerus, the corresponding common part 37 of the shaft 31 advantageously tapers: this part 37 of the shaft thus has a smaller cross-section than the proximal and distal end parts forming the remainder of the shaft.

[0040] Once the guide pin 40 has reached an insertion depth in, or even through, the humerus H sufficient securely to anchor it, the ancillary instruments 30 is withdrawn, without removing the pin. The humerus is then in the state illustrated by solid lines in Fig. 3.

[0041] In a variation, when carrying out the first stage of the operation, the guide pin 40 is inserted in the humerus H without being guided, i.e. without using the ancillary instrument 30.

[0042] In a second stage, the surgeon will resect the end of the humeral epiphysis E, using an ancillary instrument 50 illustrated in Fig. 3. This ancillary instrument 50 comprises a tubular body 51, the internal central bore in which has a diameter equal to the external diameter of the guide pin 40. At the distal end of this body 51, the ancillary instrument 50 comprises a planar cutter 52, extending in a plane substantially perpendicular to the longitudinal axis of the body 51. In the distal projection of this cutter 52 and in a manner centered on the longitudinal axis of the body 51, the ancillary instrument 50 further comprises a terminal drill 53 internally delimiting a central bore communicating with the bore in the body 51. The external diameter of the drill 53 is provided so as to be equal to the external diameter of the anchoring tail 12 of the glenoid component 10 to be implanted, for reasons which will become apparent hereinafter.

[0043] The surgeon threads the ancillary instrument 50 around the guide pin 40, by introducing it by the terminal drill 53 thereof, as indicated by arrow 54 in Fig. 3. When this drill reaches the end of the epiphysis E, it drills the bone matter so as to form a cylindrical recess E_1 centered about the guide pin 40 and indicated by broken lines in Fig. 3. Similarly, as the ancillary instrument 50 moves downward along the guide pin 40, the cutter 52 gradually resects the end of the humeral epiphysis E, over a depth of a few millimeters, until there is obtained a cutting plane E_2 perpendicular to the guide pin 40, also indicated by broken lines in Fig. 3.

[0044] In a third stage, once the ancillary instrument 50 has been removed from the guide pin 40, the surgeon will cut the humeral epiphysis E in a manner centered on the guide pin 40, i.e. he will shape the bone matter forming this epiphysis into a cylinder E_3 having a center axis E_{X-X} corresponding to this axis 33, as illustrated in Fig. 5. For this purpose, the surgeon uses an ancillary instrument 60 illustrated in Fig. 4. This ancillary instrument 60 comprises a central rod 61, bored internally in a manner complementary to the guide pin 40 and having an external diameter equal to that of the drill 53. This rod 61 carries, in its common part, a crown saw 62 which is of annular shape centered on the rod 61 and the distal end edge of which has teeth 63.

[0045] The rod 61 of the ancillary instrument 60 is slipped around the guide pin 40, which is left in place in the humeral epiphysis E, until its distal end is received in a complementary manner in the recess E_1. In doing this, the saw 62 gradually cuts out the bone matter from the epiphysis so as to obtain the bone cylinder E_3, it being noted that a corresponding part of the recess E_1 passes

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through the entire length of said bone cylinder. The length of the cylinder E_3 thus obtained, i.e. its dimension along its axis E_{X-X}, is determined by the depth of action of the saw 62, wherein this depth can easily be marked along the rod 61, in particular by markings.

[0046] Once the ancillary instrument 60 has been removed, the humerus H is in the state illustrated in Fig. 5.

[0047] In a fourth stage, the surgeon will remove the cylinder of bone matter E_3 from the humerus H using a cutting ancillary instrument 70 illustrated in Fig. 6 and 7. This ancillary instrument comprises a tubular block 71, the internal diameter of which is equal to that of the saw 62. At its distal end, the block 71 forms a protruding outer edge 72 in which there is delimited a transverse slot 73 opening into the internal volume of the block. At its proximal end, the block 71 is closed by a base wall 74, from the central zone of which there protrudes, inside the block, a centering stud 75, the external diameter of which is equal to that of the drill 53.

[0048] After having removed the guide pin 40, the ancillary instrument 70 is slipped around the humeral cylinder E_3, as indicated by arrow 76 in Fig. 7. The cylinder E_3 is received in a complementary manner in the block 71 until the edge 72 rests against the bone surface surrounding the base of the cylinder E_3. A planar saw blade (not shown) is then introduced from outside into the slot 73 in order to cut the base of the cylinder E_3 over a cutting plane E_4 substantially perpendicular to the axis E_{X-X} and indicated by broken lines in Fig. 7. During sawing, most of the cylinder E_3 is protected by the block 71 and the base wall 74, it being noted that the stud 75 is accommodated in a complementary manner in the upper end part of the central recess E_1.

[0049] Once the ancillary instrument 70 has been removed, the surgeon recovers the cylinder of bone matter E_3 thus separated from the humerus H.

[0050] In a non-illustrated variation, the slot 73 can be provided so as to be inclined relative to the longitudinal direction of the block 71 so that, in contrast to the cylinder E_3 described hereinbefore, the bone cylinder thus obtained has longitudinal end faces inclined relative to one another. The graft is thus able to make good the wear to a peripheral portion of the glenoid surface G, it being noted that the inclination of the slot 73 is advantageously adjustable as a function of the wear noted by the surgeon during the operation.

[0051] Before describing the following stage of the operation, namely the fifth stage, Fig. 8 to 12, which illustrate a set of instruments forming a variation of the unit comprising the ancillary instrument 30, 50, 60 and 70 described hitherto, will now be considered.

[0052] Thus, Fig. 8 shows an ancillary instrument 130 as a variation of the ancillary instrument 30 from Fig. 2. This ancillary instrument 130 comprises a distal body 132 which is functionally similar to the body 32 of the ancillary instrument 30. In particular, the body 132 is designed to cover the upper humeral epiphysis E in the manner of a cap. Unlike the body 32 of the ancillary instrument 30, the body 132 is perforated, in particular to give the surgeon a better view of the humeral epiphysis when positioning the body 132. Like the body 32 of the ancillary instrument 30, the body 132 is provided with a proximal tube 135 projecting from its external face and centered on the axis 133 round which the body 132 extends.

[0053] The ancillary instrument 130 allows the guide pin 40 to be inserted in the humeral epiphysis E so as to be close-fitted relative to the humerus H, as indicated by the arrow 142 in Fig. 8.

[0054] As a variation of both the ancillary instrument 50 and the ancillary instrument 60 in Fig. 3 and 4, an ancillary instrument 160 is shown in Fig. 9 and 10. This ancillary instrument 160 comprises an elongate shaft 161 provided, at its distal end, with a crown saw 162 of annular shape centered on the shaft 161 and of which the distal end edge has teeth 163. The shaft 161 has an internal bore throughout its length so that it can be slipped, in a close-fitting and coaxial manner, round the guide pin 40 which is left in position in the humeral epiphysis E, as indicated by the arrow 164 in Fig. 9. Unlike the saw 62 of the ancillary instrument 60, the saw 162 has perforations in its lateral wall and comprises a base wall 165 which extends perpendicularly to the longitudinal direction of the shaft 161 and of which the distal face forms a planar reamer 166.

[0055] Hence, when the ancillary instrument 160 is slipped round the guide pin 40, the teeth 163 of the saw 162 gradually cut out the bone matter of the humeral epiphysis E so as to obtain the bone cylinder E_3. Once the entire height of the saw 162 has thus been introduced into the epiphysis, the reamer 166 begins to cut the upper end of this epiphysis and thus progressively resects this end until the cutting plane E_2 is obtained.

[0056] Once the ancillary instrument 160 has been released, the humerus H is in the state shown in Fig. 11.

[0057] The surgeon then uses a drilling ancillary instrument 167 comprising a bored shaft 168 of which the distal end is provided with a drill 153. By slipping the shaft 168 round the guide pin 40, as indicated by the arrow 169 in Fig. 11, the surgeon, by the action of the drill 153, digs the central part of the cylinder of bone matter E_3 round the guide pin 40 so as to form the recess E_1. centered on the axis E_{x-x} of the cylinder E_3, as indicated in broken lines in Fig. 12, in which the ancillary instrument 168 has been released.

[0058] In practice, the drilling ancillary instrument 167 can also be used after a variation of the ancillary instrument 50, depleted of the drill 53, has been used and/or after a variation of the ancillary instrument 60, of which the rod 61 does not project on the distal side of the base wall of the saw 62 has been used.

[0059] As a variation of the ancillary instrument 70 in Fig. 6 and 7, Fig. 12 shows an ancillary instrument 170. This ancillary instrument 170 comprises an annular body 171 equipped at a point of its periphery with a proximal handling shaft 176. The annular body 171 is designed to be mounted on the humeral epiphysis E while surround-

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ing the entire portion of the epiphysis in which the cylinder of bone matter E_3, previously cut out by the ancillary instrument 160, is delimited. On its distal side, the body 171 delimits a surface 173 for application and guidance of a bone cutting instrument, not shown, such as a saw blade or the like.

[0060] Hence, by manipulating the shaft 176, the surgeon positions the annular body 171 round the humeral epiphysis E so as to position the guide surface 173 in a suitable manner relative to the cylinder of bone matter E_3. The surgeon then applies the cutting instrument against this surface 173 in a guided manner in order to cut the base of the cylinder E_3 over the cutting plane E_4 and release this cylinder from the humerus H.

[0061] Advantageously, the guide surface 173 forms an angle of approx. 155 ° with the longitudinal direction of the shaft 176, and this allows the ancillary instrument 170 also to be used to prepare the implantation of the humeral component 20 at a later stage, by positioning the shaft 176 in such a way that its longitudinal direction is substantially aligned with the longitudinal direction of the humerus H, as illustrated in Fig. 12.

[0062] In a fifth stage, the cylinder of bone matter E_3 is used to form the bone graft 2 described hereinbefore. In order to do this, this cylinder is fitted on the glenoid surface C. The glenoid surface is previously prepared for this purpose, being opened up and, if necessary, resected. The glenoid component 10 is then implanted in the configuration described hereinbefore with reference to Fig. 1. It will be understood that the anchoring tail 12 is introduced coaxially, in a substantially close-fitting manner, into the central recess E_1 in the cylinder E_3.

[0063] If the longitudinal end faces of the bone cylinder have been formed so as to be inclined relative to each other, it will be understood that the interposing of this cylinder, as the graft, between the glenoid component 10 and the glenoid surface G allows inclination, in particular downward inclination, of the glenoid articular face 11A.

[0064] More generally, it will be understood that the dimensions desired by the surgeon for the graft 2, in particular as a function of the size of the glenoid component 10, determine the dimensions of the ancillary instrument 50, 60 and 70 or the ancillary instrument 160, 168 and 170 used to take the bone cylinder E_3 from the humeral epiphysis E. In particular, the internal diameter of the saw 62 or 162 determines the external diameter of the graft 2. Similarly, the depth of action of this saw determines the length l of the graft while at the same time allowing for any adjustment in length resulting from the positioning of the sawing slot 73 or the guide surface 173.

[0065] Furthermore, the geometry desired for the longitudinal end faces 2B and 2C of the graft 2 directly conditions the embodiment of the resection ancillary instrument 50 and cutting ancillary instrument 70 or the ancillary instrument 160 and 170, in the sense that the parts of these ancillary instrument that determine the incision profile of the bone are shaped to form an appropriate incision in the humeral epiphysis. Optionally, these ancillary instruments 50 and 70 can be associated with one or more ancillary instrument for resurfacing the longitudinal end faces of the removed cylinder E_3.

[0066] In practice, the surgeon also takes account of the state of the cancellous bone matter forming the epiphysis E in order, if necessary, to remove the graft with as healthy a constitution as possible. For this purpose ancillary instrument for gripping and storing the graft 2 after it has been released from the humerus H can optionally be provided, in order to limit the risks of damaging the graft.

[0067] Furthermore, in non-illustrated variations, the graft 2 can have volume forms other than a cylinder as in the Figs., provided that the volume of bone matter forming this graft has a shape generally centered about a longitudinal axis of the type of the axis E_{X-X}, while at the same time defining a lateral face and longitudinal end faces of the type of the faces 2A, 2B and 2C. For example, the graft can thus be truncated in shape, having a longitudinal axis E_{X-X}; in this case, the inner surface of the crown saw 62 or 162 is, for example, provided so as to be truncated.

[0068] Optionally, the bone graft 2 can be protected laterally by a reinforcing structure, such as for example ring 80 shown merely in Fig. 13. In practice, the ring 80 is configured to surround in an appropriate manner the lateral face 2A of the graft 2, over the entire length of this graft. The ring 80 is thus, in conjunction with the graft 2, interposed between the glenoid component 10 and the glenoid surface G. It will be understood that this ring can, for example, be used if the graft has, at least over a part of its length, an external diameter less than that of the glenoid head 11, the ring thus compensating for the difference in diameter.

[0069] If the ring 80 is implanted in conjunction with the graft 2, it protects the lateral face 2A of the graft and forms a support for at least a part of the face 11B of the glenoid component 10, thus limiting the stresses applied to the graft. Advantageously, the ring 80 is covered with hydroxyapatite or, more generally, has a porous or honeycomb surface state allowing improved bone adhesion and rehabilitation of the ring to the graft and to the resected surface part of the glenoid surface G that is not covered by this graft. In one embodiment, the ring 80 is attached to the glenoid component 10.

[0070] In practice, it will be understood that the inner surface of the ring 80 is advantageously complementary with the face 2A of the graft, whereas its outer face can have advantageous optional configurations. This outer surface can thus be provided so as to be truncated and diverged toward the glenoid surface G, so holes passing through the ring in respective directions substantially perpendicular to the outer surface thereof are able to receive screws or the like in order to reinforce the securing of the graft to the glenoid surface. Similarly, the bottom portion of the ring 80 can be provided so as to be less thick than the remainder of the ring so as not subsequently to disturb the humeral component 20 during adduction movements

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on the part of the patient.

[0071] In a variation of the fitting method, rather than delivering a one-piece bone volume such as the cylinder E_3, in the upper humeral epiphysis E, the graft 2 can consist of a purée of bone substance. This substance is taken from the spongy bone zones of the humeral epiphysis, in particular when preparing the humerus for the fitting of the humeral implant. In practice, in order to contain this purée of bone substance during implantation of the glenoid component 10, a reinforcing structure, such as for example a lattice 90 shaped as a cage 92 for receiving this puree will advantageously be used, as shown in Fig. 14. The cage 92 is designed to be interposed between the glenoid component 10 and the previously prepared glenoid surface G, according to an arrangement similar to the one-piece graft illustrated in Fig. 1. In particular the cage 92 has, for example, a generally cylindrical shape of which the external diameter corresponds to that of the glenoid head 11 and of which the length corresponds to the aforementioned length l.

[0072] The lattice 90 forming the cage 92 allows exchanges of biological fluids between the purée of bone substance with which the cage is filled and the surrounding tissues of the patient. The cage 92 thus prevents necrosis of the purée of bone substance while mechanically protecting it. In particular the cage 92 absorbs a proportion, or even the majority, of the stresses applied to the graft 2 consisting of the purée of bone substances by forming, in the region of its lateral end walls 92A and 92B, supports for the face 11B of the glenoid component 10 and the previously prepared surface of the glenoid surface G respectively. The bone substance preferably chemically bonds with the glenoid surface G through the lattice 90. In effect, the glenoid surface G is extended laterally outward to engage with the face 11B of the glenoid component 10.

[0073] In another embodiment, the cage 92 is constructed from a porous matrix or scaffold, without the purée of bone substance. The cage 92 can be, for example, reticulated bioceramic framework, structured porous tantalum, synthetic fiber mesh, and the like. The native bone of the glenoid surface G grows into the porous matrix or scaffold to create a bone graft with structure properties comparable to native bone.

[0074] Before or after implanting of the glenoid component 10, the humeral component 20 is implanted in the humerus H, advantageously using ancillary instrument (not shown), the handling of which is marked by the end part of the recess E_1 remaining in the humeral epiphysis E after removal of the bone volume such as the cylinder E_3. If the surgical actions applied to the humerus for implanting the component 20 by way of the recess E_1 are dispensed with and these actions are therefore generally independent of those applied to the humerus for taking the graft 2, the ancillary instrument 30 can be simplified, as it is in this case no longer necessary to take account of the retroversion of the patient's forearm in order to insert the guide pin 40. The shaft 31 may in this case assume the form of an intramedullary humeral rod.

[0075] According to a variation of the fitting method, the graft 2, whether in the form of a one-piece bone volume or of a purée of bone substance, is not taken from the humeral epiphysis E but rather is taken from another of the patient's bones, in particular from his ilium, or consists of an allograft or a graft of synthetic origin, it being understood that the dimensions of this synthetic graft are provided so as to be appropriate for the glenoid component 10 to be implanted, as stated hereinbefore for the removed cylinder E_3 or cone frustum. Obviously, the protection ring 80 and the cage 92 described hereinbefore can be used in conjunction with a graft of this type of alternative origin.

[0076] Fig. 15 is a schematic illustration of a glenoid component 200 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. The glenoid component 200 includes a recess 202 that substantially receives the bone graft 204. The recess 202 acts as a reinforcing structure that protects the bone graft 204 laterally, similar to the ring 80 in the embodiment of Fig. 13. Consequently, the bone graft 204 can be a one-piece bone volume or a purée of bone substance. In an embodiment where the bone graft 204 is a purée of bone substance, reinforcing fibers 279 are optionally added to the mixture. In the illustrated embodiment, lower portion 206 of the convex articular surface 208 extends beyond the pillar of the scapula S to minimize interference with the humeral prosthetic portion. The radius of curvature of convex articular surface 208 is preferably selected so the center of rotation 214 around the glenoid component 200 is preferably in plane 210 comprising a distal surface 212 of the bone graft 204 or between the plane 210 and the glenoid surface G. Once the bone graft 204 has fused with the glenoid surface G, the distal surface 212 of the bone graft 204 becomes the effective glenoid surface.

[0077] Fig. 16 is a schematic illustration of a glenoid component 220 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Reinforcing structure 222 extends over at least a portion of the bone graft 224. The reinforcing structure can be rigid or flexible. In one embodiment, the reinforcing structure is constructed from a mesh material made from metal, synthetics, ceramics, or a combination thereof. Consequently, the bone graft 224 can be a one-piece bone volume or a purée of bone substance. Screws 226 optionally secure the reinforcing structure 222 and/or bone graft 224 to the glenoid surface G.

[0078] The glenoid component 220 includes a recess 230 that engages with distal surface 232 of the reinforcing structure 222. Anchor 234 optionally extends through the reinforcing structure 222 and bone graft 224 to further secure the glenoid component 220 to the scapula S. In the illustrated embodiment, the anchor 234 includes a pointed tip 236 to facilitate insertion into the glenoid surface G. The radius of curvature of convex articular sur-

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face 235 is preferably selected so the center of rotation 233 of the glenoid component 220 is preferably either in or behind plane 237 comprising a distal surface 239 of the bone graft 224. Once the bone graft 224 has fused with the glenoid surface G, the distal surface 239 of the bone graft 224 becomes the effective glenoid surface.

[0079] Fig. 17 is a schematic illustration of a glenoid component 240 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Bone graft 242 is formed with a distal recess 244. Anchor 246 extends through the bone graft 242 into the glenoid surface G so that base plate 248 is positioned in the distal recess 244. Tension member 250 is optionally positioned in a center bore 252 of the anchor 246 to retain the base plate 248 against the glenoid surface G. A variety of glenoid components 240 can then be attached to the base plate 248 using a variety of attachment mechanisms. In one embodiment, the bone graft 242 is surrounded by reinforcing structure 257, such as for example a metal or synthetic mesh material. The radius of curvature of convex articular surface 258 is preferably selected so the center of rotation 259 around the glenoid component 240 is preferably in or behind a plane 254 comprising a distal surface 256 of the bone graft 242. Once the bone graft 242 has fused with the glenoid surface G, the distal surface 256 of the bone graft 242 becomes the effective glenoid surface.

[0080] Fig. 18 is a schematic illustration of a glenoid component 260 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Bone graft 262 is secure to the glenoid surface G using base plate 264 and anchor 266. The glenoid component 260 includes a first recess 268 sized to engage with the base plate 264 and a second recess 270 so that extensions 272 of the convex articular surface 271 extends onto a portion of the scapula S. The extensions 272 can optionally be flexible or semi-flexible to facilitate implantation. In one embodiment, the extensions 272 are attached to the scapula S using adhesives, fasteners, and the like. The bone graft 262 can be a one-piece bone volume or a purée of bone substance. The radius of curvature of convex articular surface 271 is preferably selected so the center of rotation 278 around the glenoid component 260 is preferably in or behind a plane 274 comprising a distal surface 276 of the bone graft 262.

[0081] Fig. 19 is a schematic illustration of a glenoid component 280 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Bone graft 282 is located between the glenoid surface G and the opposing surface 284 of the glenoid component 280. In the illustrated embodiment, the bone graft 282 is two or more layers 282a, 282b or bone graft material. Tension member 286 is positioned in center bore 288 to retain the glenoid component 280 against the glenoid surface G. The radius of curvature of convex articular surface 290 is preferably selected so the center of rotation 296 is in or behind plane 292 comprising distal surface 294 of the bone graft 282.

[0082] Fig. 20 is a schematic illustration of a glenoid component 300 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Reinforcing structure 302 is attached to the glenoid surface G using fasteners 304. Side walls 303 of the reinforcing structure 302 support the outer lateral face of bone graft 310. The reinforcing structure 302 preferably has a plurality of holes or perforations 306 to facility bone in-growth.

[0083] Opposite reinforcing structure 308 extends over the reinforcing structure 302 and bone graft 310. In the illustrated embodiment, opposite reinforcing structure 308 telescopically engages with the reinforcing structure 302. The bone graft 310 can be a one-piece bone volume or a purée of bone substance. The opposite reinforcing structure 308 optionally includes a plurality of holes 307 to facilitate bone in-growth.

[0084] Glenoid component 300 is optionally attached to distal surface 312 of the opposing reinforcing structure 308. In the illustrated embodiment, the glenoid component is mounted to the opposing reinforcing structure 308 off-center. The opposing reinforcing structure 308 preferably has a plurality of mounting features that permit the surgeon to locate the glenoid component 300 in a variety of locations. The radius of curvature of convex articular surface 314 is preferably selected so the center of rotation 319 is in or behind plane 316 comprising distal surface 318 of the bone graft 310. In another embodiment, the center of rotation is close to the plane 316.

[0085] Fig. 21 is a schematic illustration of a glenoid component 320 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. The glenoid surface G is resected at an angle 322 with respect to the medial line M of the patient. In order to compensate, the bone graft 324 is formed with non-parallel faces 326, 328. in the illustrated embodiment, the bone graft 324 is secured to the glenoid surface G using fasteners 330, although any of the structures disclosed herein could be used. The radius of curvature of convex articular surface 332 is preferably selected so the center of rotation 338 is in or behind plane 334 comprising distal surface 336 of the bone graft 324.

[0086] Fig. 22 is a schematic illustration of a glenoid component 340 of a shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. The exposed surface 342 of the glenoid surface G is non-planar. In order to compensate, the bone graft 344 is preferably formed with a complementary shaped surface 346. In the illustrated embodiment, opposing face 348 of the glenoid component 340 also is non-planar. Consequently, distal surface 350 of the bone graft 344 is also preferably formed with a complementary shape. The non-planar surfaces 346, 348 provide structural advantages for some applications.

[0087] In the illustrated embodiment, the glenoid component 340 is secured to glenoid surface G using a plurality of fasteners 352. Although distal surface 354 of the

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glenoid component 340 is illustrated as planar it can be configured for with either a convex or concave articular surface, depending on the application.

[0088] Fig. 23 is a schematic illustration of a glenoid component 360 of an anatomical shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Opposing face 362 of the glenoid component 360 is non-planar. In order to compensate, distal surface 364 of the bone graft 366 is preferably formed with a complementary shape. In the illustrated embodiment, the glenoid component 360 is secured to glenoid surface G using anchor 368, although any of the securing structures disclosed herein may be used. Distal surface 370 of the glenoid component 360 is illustrated as concave, but could be convex depending on the application.

[0089] Fig. 24 is a schematic illustration of a glenoid component 380 of an anatomical shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Opposing face 382 of the glenoid component 380 is non-planar and keel 384. The keel 384 optionally includes holes 390 to facilitate bone in-growth. Distal surface 386 of the bone graft 388 is preferably formed with a shape complementary to opposing surface 382. The bone graft 388 can be a one-piece bone volume or a purée of bone substance. In one embodiment, a cut-out is formed in the bone graft 388 to receive the keel 384. In another embodiment, the bone graft 388 is an annular ring and the keel is located in the center opening and secured using a purée of bone substance, bone cement, or a variety of adhesives.

[0090] Fig. 25 is a schematic illustration of a glenoid component 400 of an anatomical shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Exposed surface 402 of the glenoid surface G is non-planar. In the illustrated embodiment, the exposed surface 402 has a shape complementary to keel 404 on opposing face 406 of the glenoid component 400.

[0091] Fig. 26 is a schematic illustration of a glenoid component 420 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. Exposed surface 422 of the glenoid surface G is non-planar. In one embodiment, the various shapes 424a, 424b, 424c, 424d (collectively "424") illustrated in Fig. 26 are formed in the glenoid surface G, such as for example to remove defects in the surface of the glenoid surface G and to increase the stability of the glenoid component 420.

[0092] The bone graft 426 can be a one-piece volume, a plurality of pieces, purée of bone substance, or a combination thereof. In one embodiment, a plurality of preformed bone grafts of known shape are available to the surgeon during the procedure. The surgeon removes material from the exposed surface 422 of the glenoid surface G corresponding to the shape of one of the pre-formed bone grafts. The surgeon then places the pre-formed bone graft into the corresponding recess formed in the glenoid surface G.

[0093] Fig. 27 is a schematic illustration of a glenoid component 440 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. The glenoid component 440 includes a recess 442 that engaged with base plate 444. The bone graft 458 can be a one-piece bone volume or a purée of bone substance.

[0094] In the illustrated embodiment, anchor 446 of the base plate 444 and/or the glenoid component 440 are located off-set from the center axis 448 of the glenoid surface G. Lower portion 450 of the convex articular surface 452 extends beyond the pillar of the scapula S to minimize interference with the humeral prosthetic portion. The radius of curvature of convex articular surface 452 is preferably selected so the center of rotation around the glenoid component 440 is preferably in a plane 454 comprising a distal surface 456 of the bone graft 458 or between the plane 454 and the glenoid surface G.

[0095] In the illustrate embodiment, exposed surface 460 of the glenoid surface G includes one or more defects 462. These defects 462 are preferably repaired with a one-piece bone graft, a plurality of pieces, purée of bone substance, or a combination thereof 464. After the repair, the exposed surface 460 of the glenoid surface G is preferably generally planar and well suited to receive the bone graft 458.

[0096] Fig. 28 is schematic illustration of a glenoid component 480 of an inverted shoulder prosthesis attached to the glenoid surface G according to an embodiment of the present invention. End faces 482, 484 of the bone graft 486 are not parallel. In the illustrated embodiment, anchor 488 of the glenoid component 480 is at an angle with respect to horizontal axis 490 of the glenoid surface G. As a result, surface 492 of the bone graft 486 acts as an extension of a lower portion of the convex articular surface 494.

[0097] Fig. 29 is schematic illustration of the glenoid component 480 of Fig. 28 with the anchor 488 at a different angle with respect to the horizontal axis 490 of the glenoid surface G. Surface 496 of the bone graft 486 acts as an extension of an upper portion of the convex articular surface 494.

[0098] Figs. 30A-30F illustrate an alternate method and apparatus for forming a bone graft 500 ex vivo in accordance with an embodiment of the present invention. The humeral epiphysis E is resected from the humerus H (see e.g., Fig. 7). In the illustrated embodiment, the resected humeral epiphysis E includes a planar surface P created during the resection and a curvilinear surface C.

[0099] The curvilinear surface C of the humeral epiphysis E is located on base 502, as illustrated in Fig. 30A. Cover 504 illustrated in Fig. 30B secures the humeral epiphysis E to the base 502. As illustrated in Fig. 30C, boring instrument 506 is inserted through opening 508 in the cover 504. The boring instrument 506 may be operated by hand or a motorized driver. In an alternate em-

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bodiment, the instrument 506 is an impaction instrument that does not include teeth 510.

[0100] In one embodiment, the resulting bone graft 500 is an annular ring with a planar surface 512 and a curvilinear surface 514 as illustrated in Fig. 30D. In an alternate embodiment, cutting instrument 516 is inserted through slot 518 in cover 504 so that the bone graft 500 is an annular ring with opposing planar surfaces, as illustrated in Fig. 30F.

[0101] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features.

Claims

1. A shoulder prosthesis (1) adapted for implantation of a glenoid surface (G) of a scapula (S), the prosthesis comprising:

   - a glenoid component (10; 200; 220; 240; 260; 280; 300; 320; 340; 360; 380; 400; 420; 440; 480) having an articular face (11A; 208; 235; 258; 271; 290;314; 332; 354; 370; 452; 494) and an opposing face (11B; 202; 230; 270; 284; 348; 362; 382; 406; 442);
   - a bone graft (2; 204; 224; 242; 262; 282; 310; 324; 344; 388; 426; 458; 486) with a medial surface (2C; 328; 342; 484) having a shape complementary to the glenoid surface (G) and a distal surface (2B; 212; 239; 256; 276; 294; 318; 326; 350; 364; 386; 456; 482) having a shape complementary to at least a part of said opposing face; and
   - anchor means (12; 234; 246; 266; 286; 302, 304, 306; 330; 352; 368; 384; 404; 446; 488) extending from said opposing face, through or around the bone graft and substantially into the glenoid surface.

2. The shoulder prosthesis as claimed in claim 1, wherein the prosthesis further comprises a humeral component (20), the shoulder prosthesis being thus total.

3. The shoulder prosthesis as claimed in either claim 1 or claim 2, wherein the articular face (11A; 208; 235; 258; 271; 290; 314; 332; 452; 494) is convex, the shoulder prosthesis being thus inverted.

4. The inverted shoulder prosthesis as claimed in claim 3, wherein a center of rotation (214; 233; 259; 278; 296; 319; 338) around the glenoid component (10; 200; 220; 240; 260; 280; 300; 320; 440; 480) is located on the distal surface (2B; 212; 239; 256; 276; 294; 318; 326; 456; 482) of the bone graft (2; 204; 224; 242; 262; 282; 310; 324; 458; 486) or on the medial side of the distal surface.

5. The inverted shoulder prosthesis as claimed in either claim 3 or claim 4, wherein the bone graft (486) has an outer lateral surface (492; 496) acting as an extension of the convex articular face (494).

6. The shoulder prosthesis as claimed in either claim 1 or claim 2, wherein the articular face (370) is concave, the shoulder prosthesis being thus anatomical, and wherein a center of rotation around the glenoid component (360; 380; 400) is located on the lateral side of the distal surface (366; 386) of the bone graft (366; 388).

7. The shoulder prosthesis as claimed in any one of claims 1 to 6, wherein the prosthesis further comprises a reinforcing structure (80; 90; 202; 222; 230; 257; 270, 272; 302; 308) that at least partially surrounds outer lateral faces (2A) of the bone graft (2; 204; 224; 242; 262; 310), that are not in contact with the glenoid surface (G).

8. A shoulder prosthesis as claimed in claim 7, wherein the reinforcing structure includes a protection means (80; 90; 222; 308) for protecting the bone graft (2; 224; 310), the protection means forming a support for at least a part of said opposing face (11B; 230).

9. A shoulder prosthesis as claimed in claim 8, wherein the protection means has the shape of a ring (80) suitable for surrounding in a close-fitting manner said outer lateral faces (2A) of the bone graft (2).

10. A shoulder prosthesis as claimed in claim 8, wherein the protection means comprises a lattice (92) shaped as a cage (90) suitable for being filled with a bone matter purée forming the bone graft (2).

11. The shoulder prosthesis as claimed in any one of claims 6 to 10, wherein the reinforcing structure comprises a recess (202; 230; 270) which is delimitated in said opposing face of the glenoid component (200; 220; 260) and in which the bone graft (204; 224; 262) is received at least in part.

12. The shoulder prosthesis as claimed in any one of claims 7 to 10, wherein the reinforcing structure, especially the protection means (80; 90; 222; 308) is covered with hydroxyapatite or has a functionally similar surface state, such as a honeycomb surface state, allowing bone adhesion and rehabilitation to be improved.

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13. The shoulder prosthesis as claimed in any one of claims 1 to 12, wherein the anchor means (12; 234; 246; 266; 286; 330; 352; 368; 446; 488) passes straight through the graft (2; 204; 224; 242; 262; 282; 324; 344; 366; 458; 486) so that a free end part of the anchor means is adapted to be anchored into the native layer of the glenoid surface (G).

14. The shoulder prosthesis as claimed in any of claims 1 to 13, wherein the bone graft comprises an upper epiphysis of a humerus for the glenoid surface (G).

15. The shoulder prosthesis as claimed in any one of claims 1 to 13, wherein the bone graft is taken from a bone in the patient other than the upper humeral epiphysis.

16. The shoulder prosthesis as claimed in any one of claims 1 to 15, wherein the bone graft comprises one or more of an allografts, a xenografts, a natural or synthetic material.

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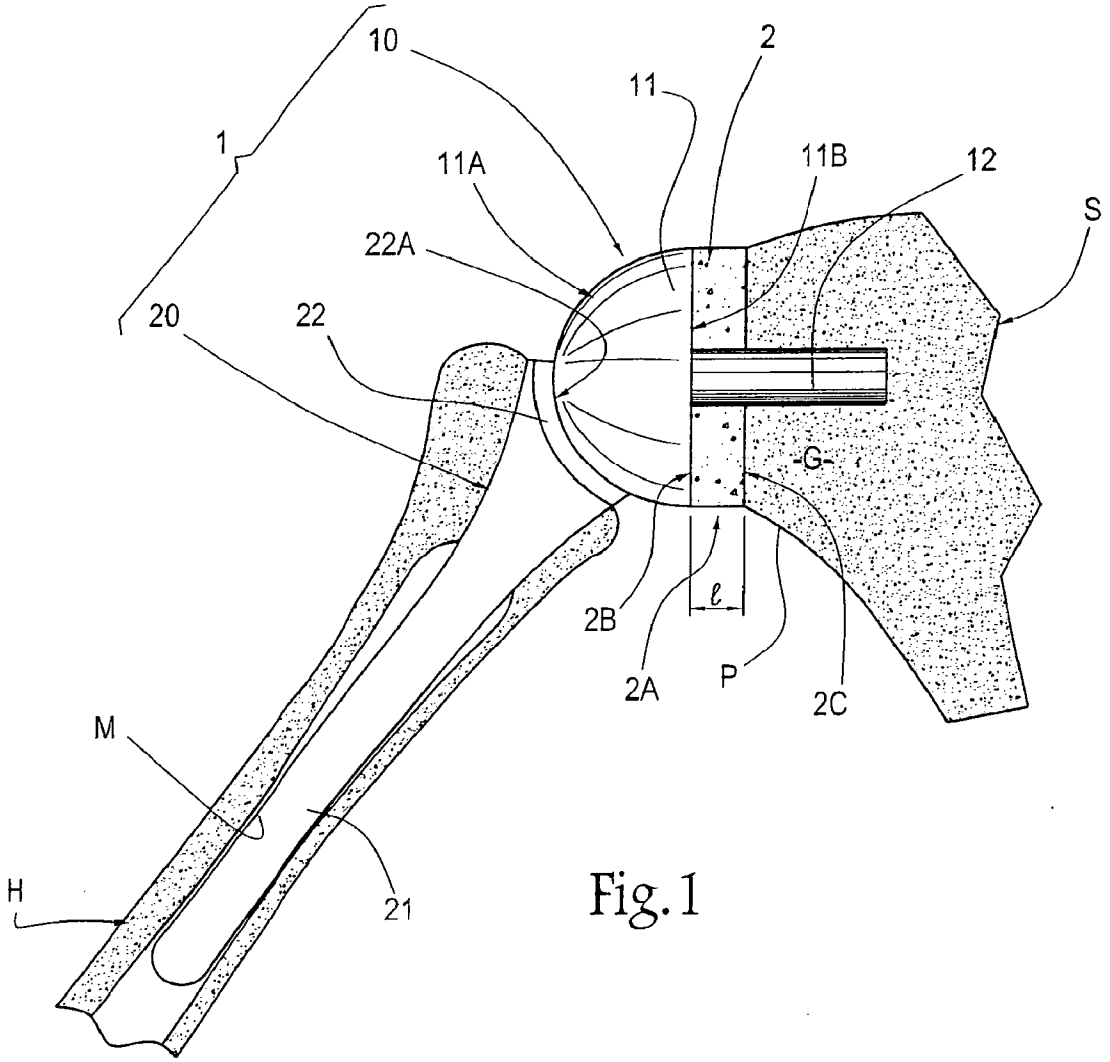


Fig.1

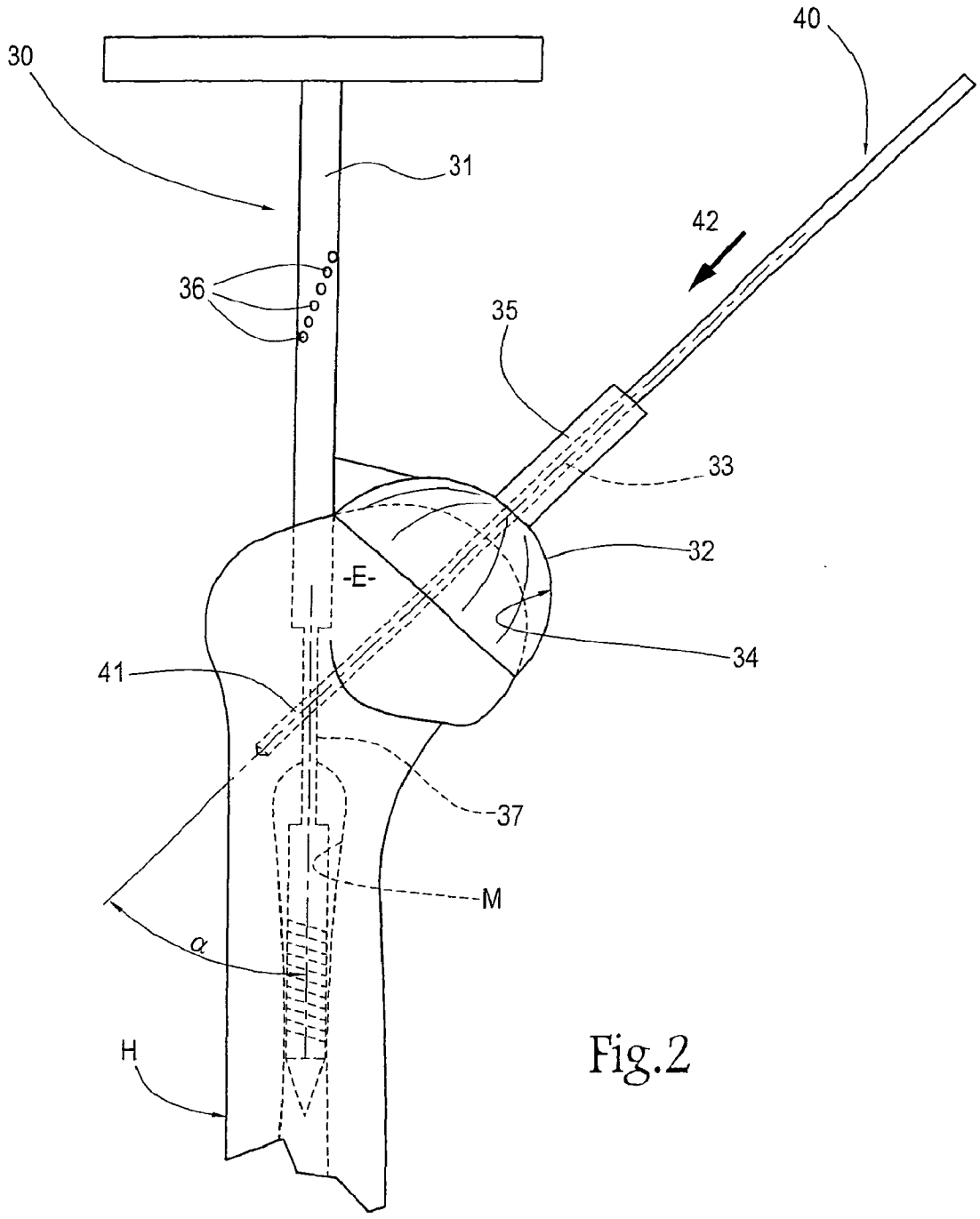


Fig.2

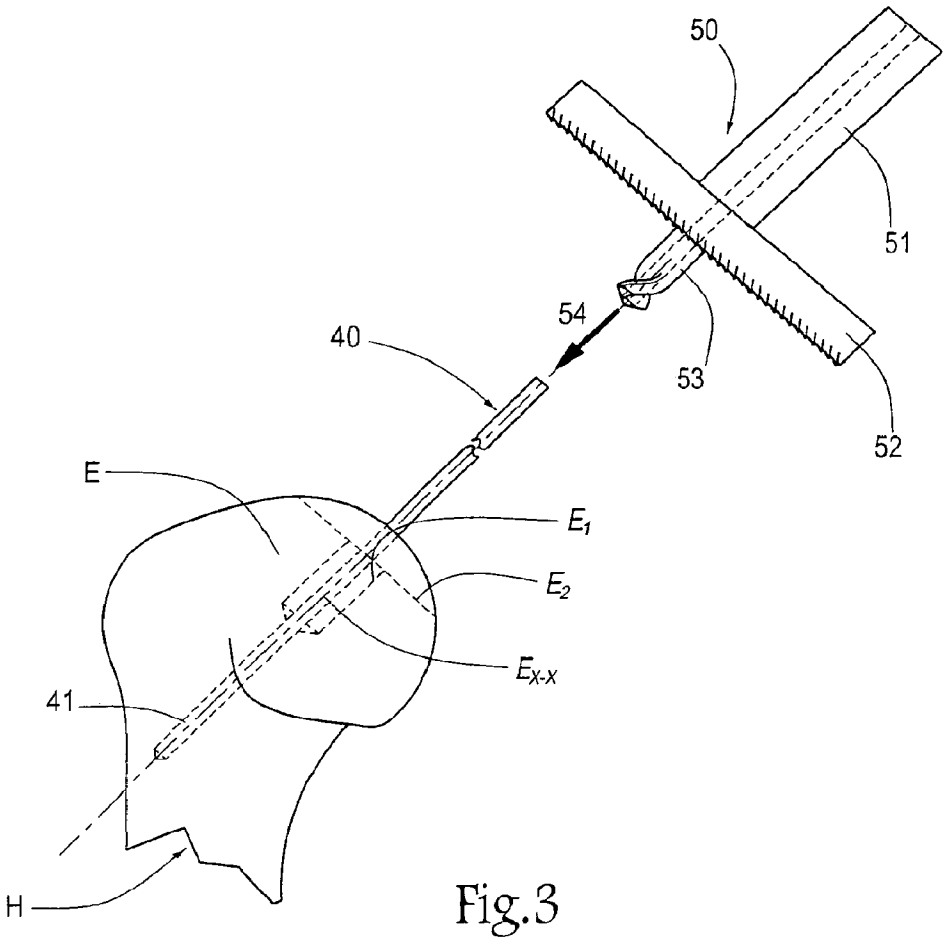


Fig.3

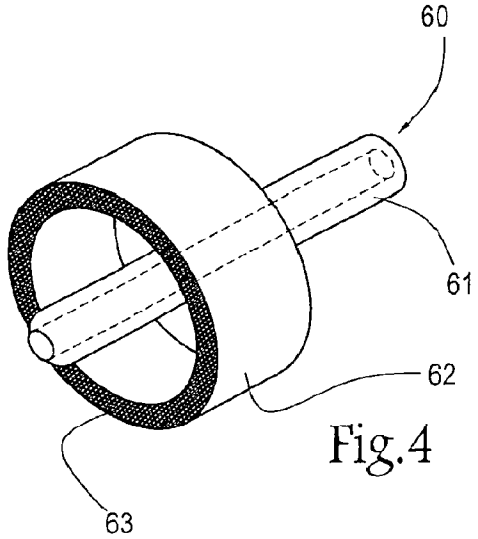


Fig.4

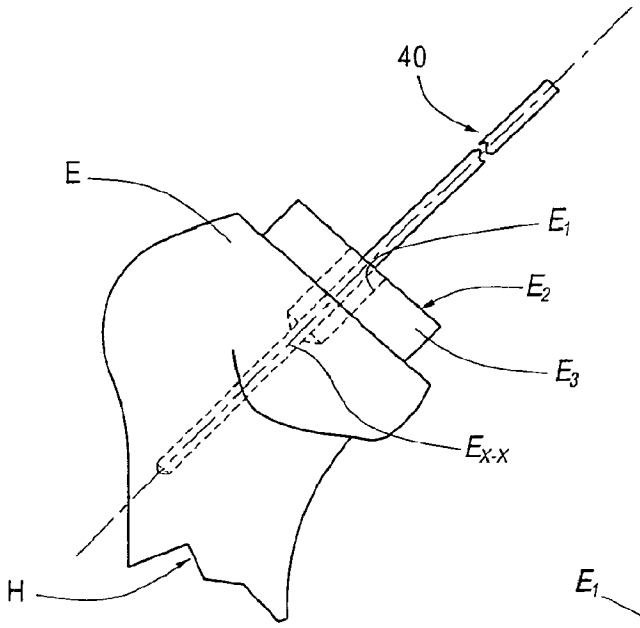


Fig.5

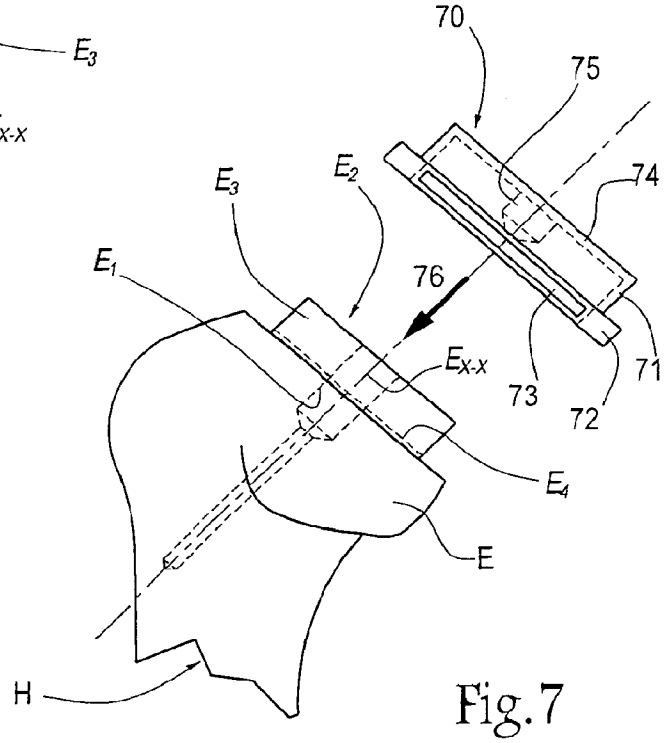


Fig.7

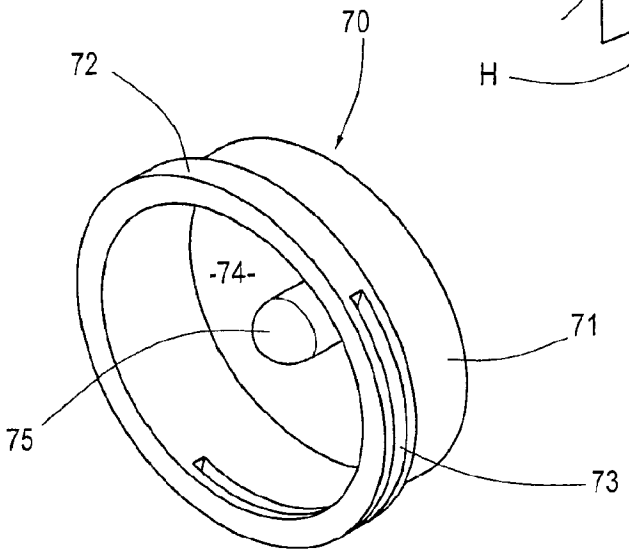


Fig.6

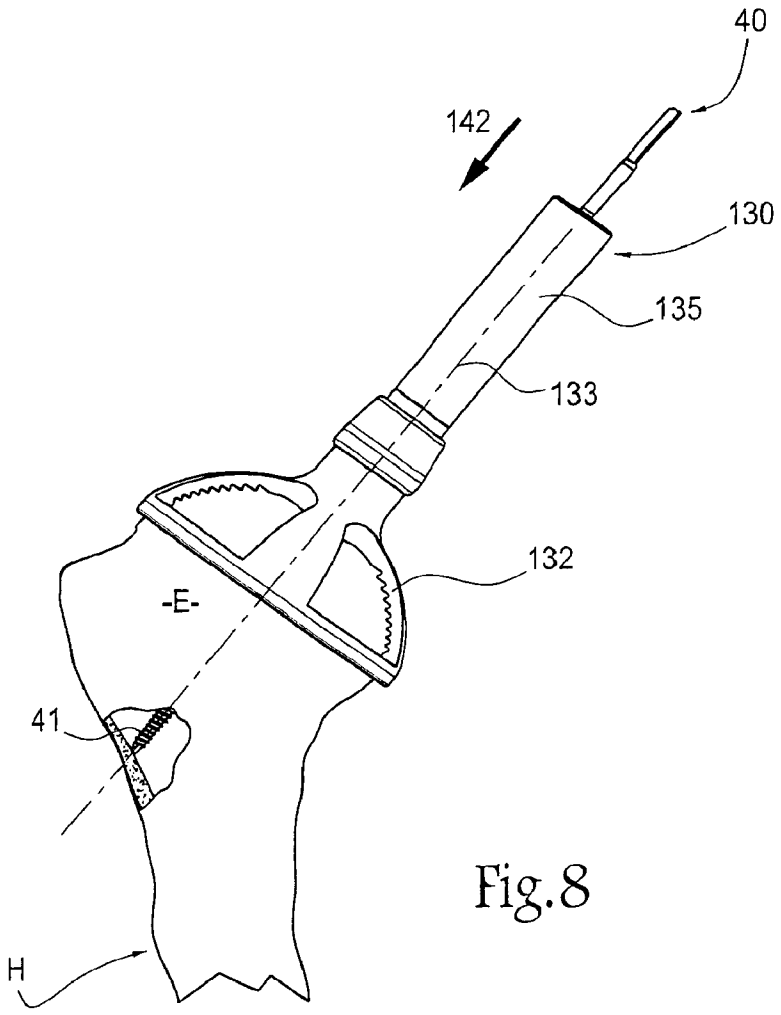


Fig.8

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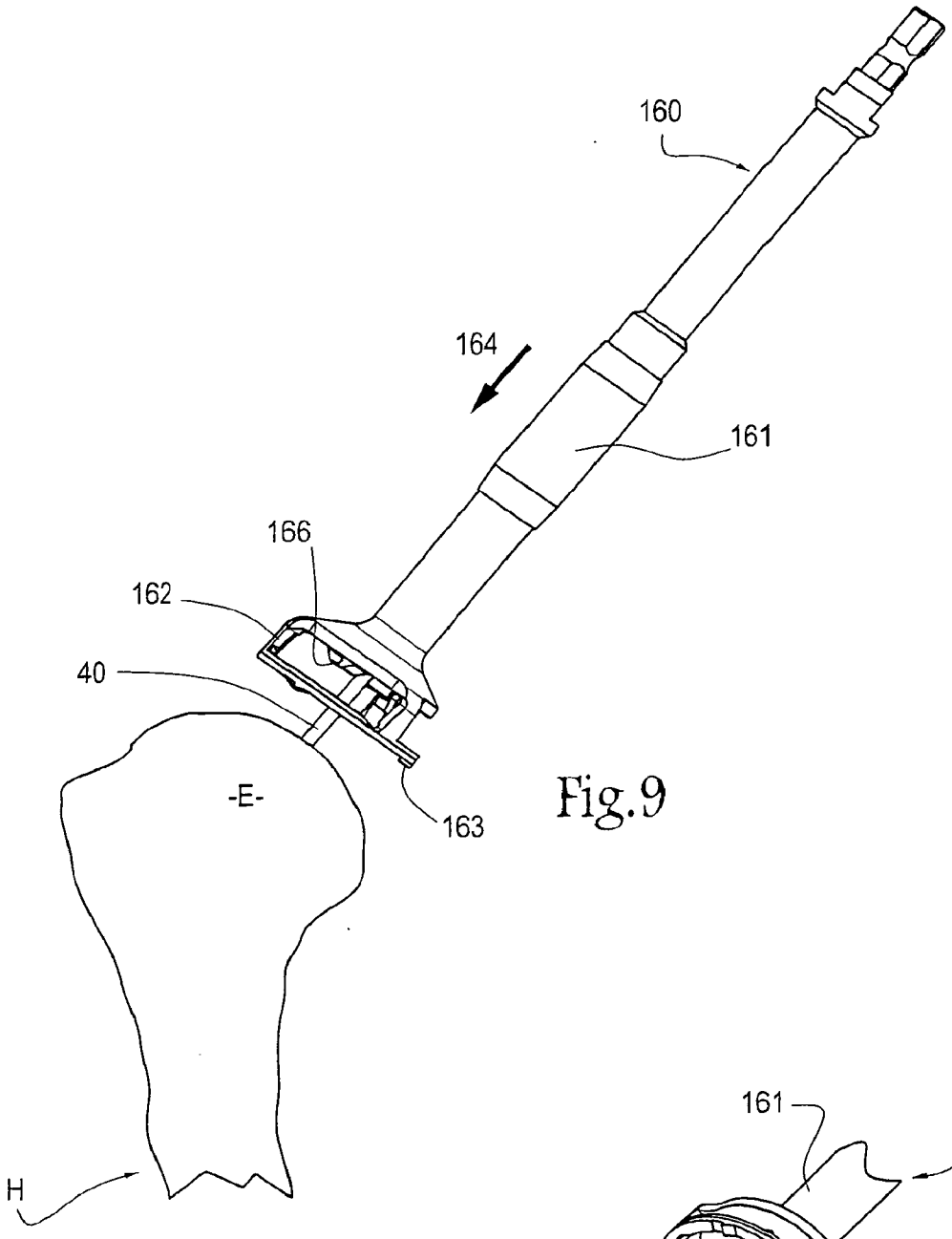


Fig.9

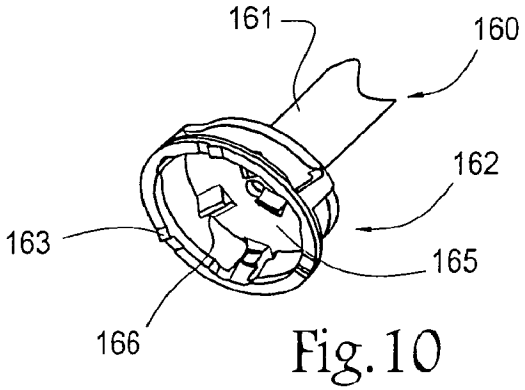


Fig.10

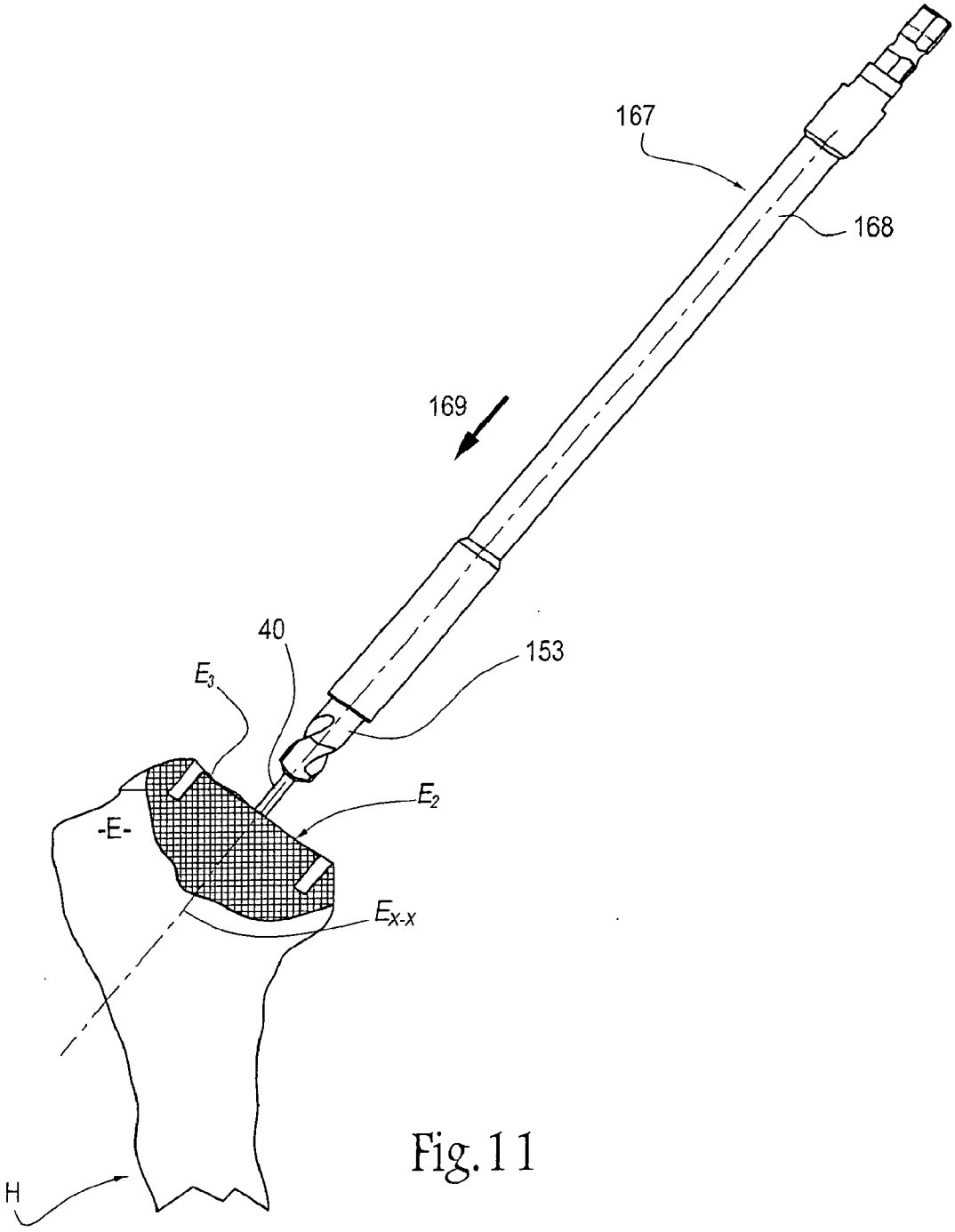


Fig.11

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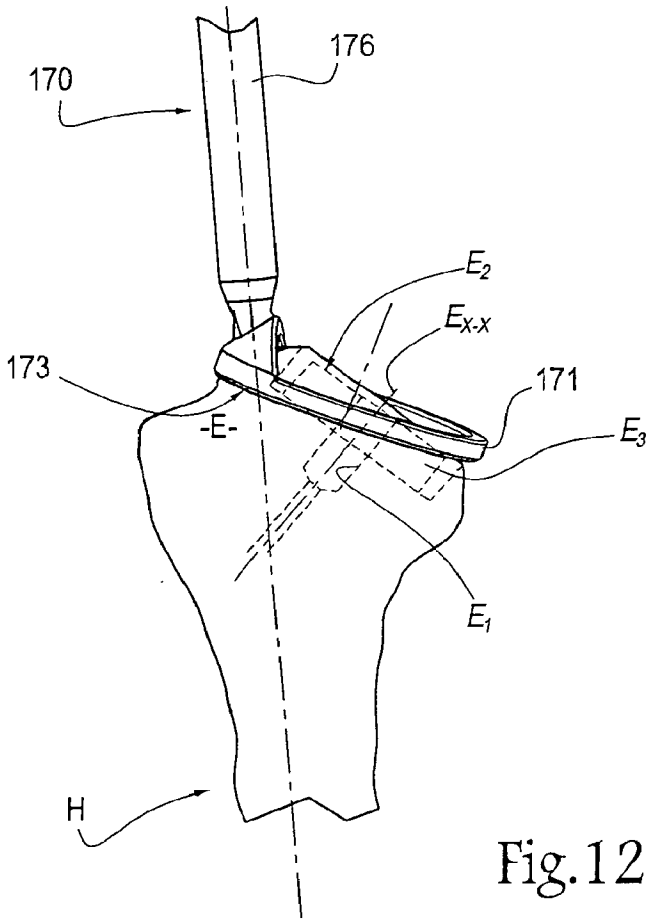


Fig.12

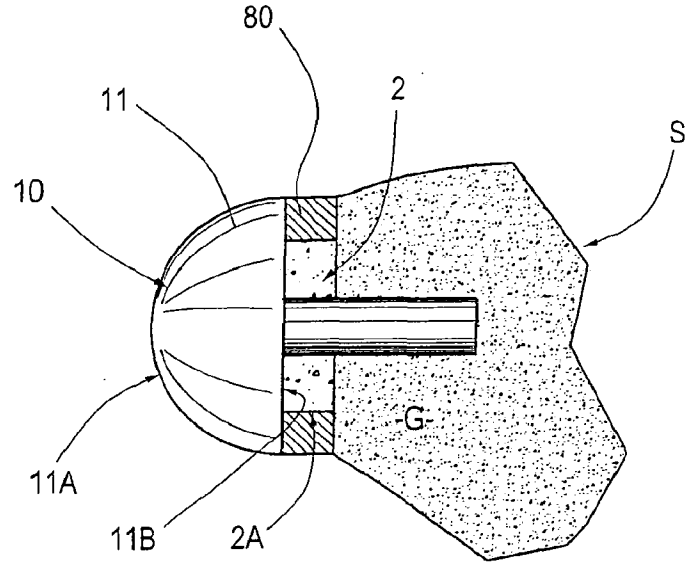


Fig.13

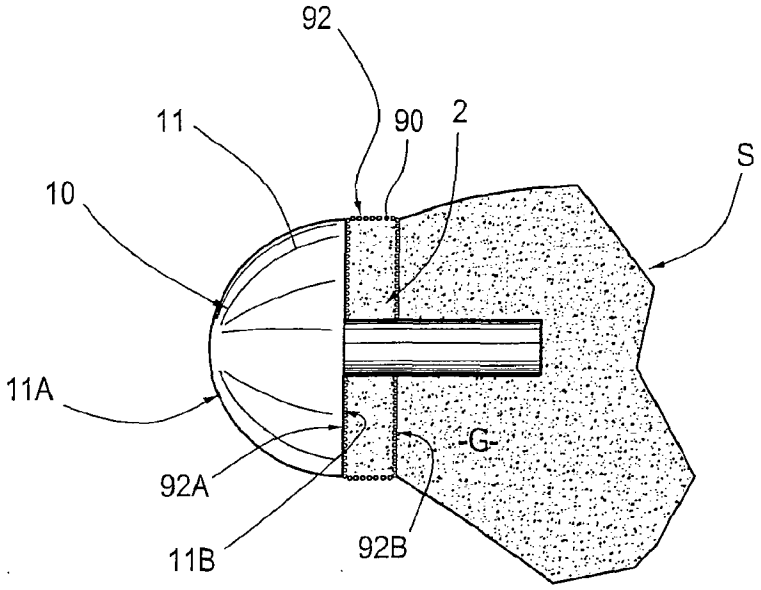


Fig.14

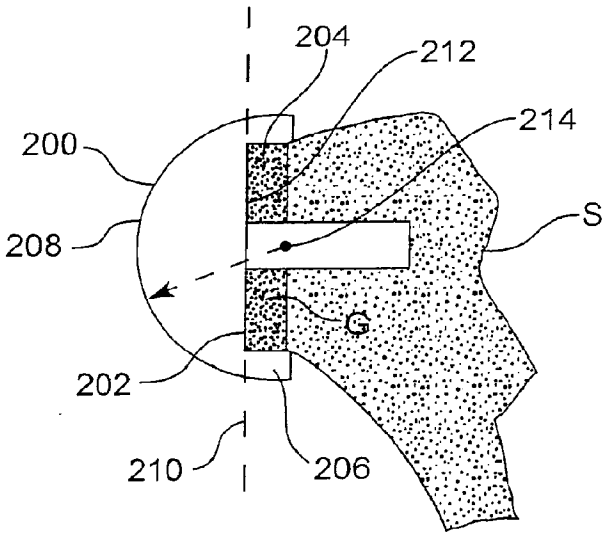


Fig. 15

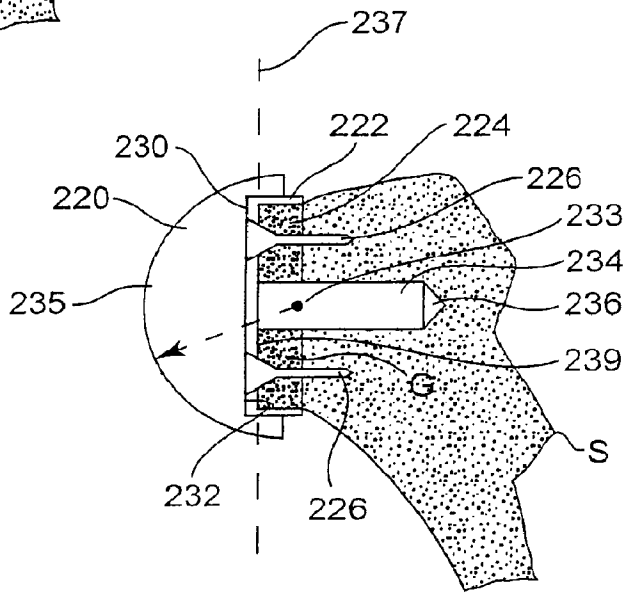


Fig. 16

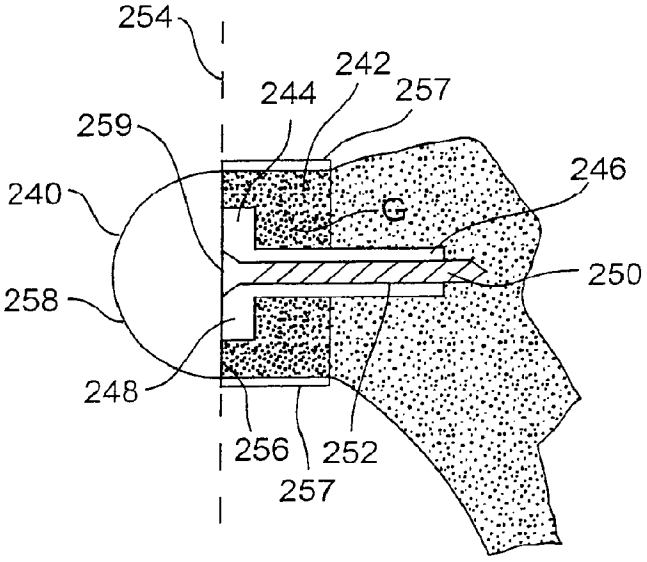


Fig. 17

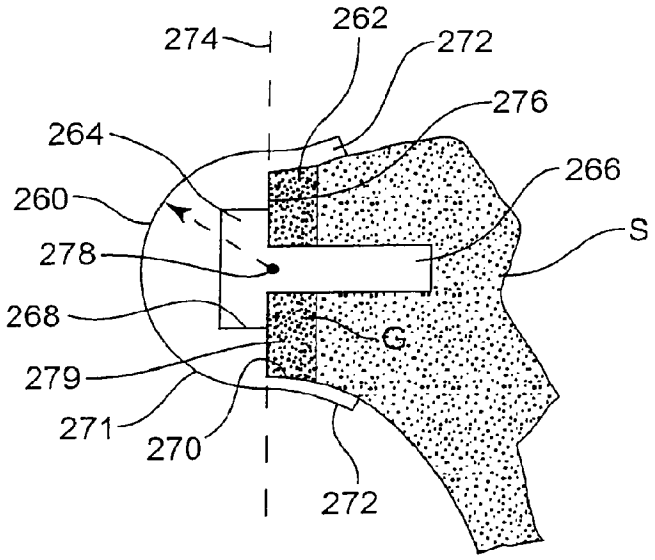


Fig. 18

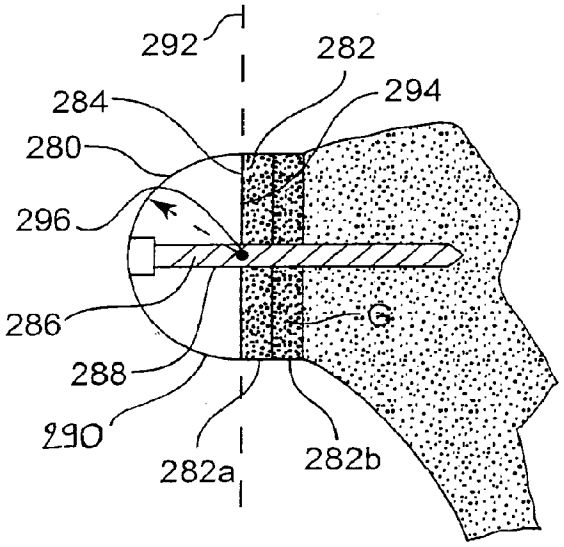


Fig. 19

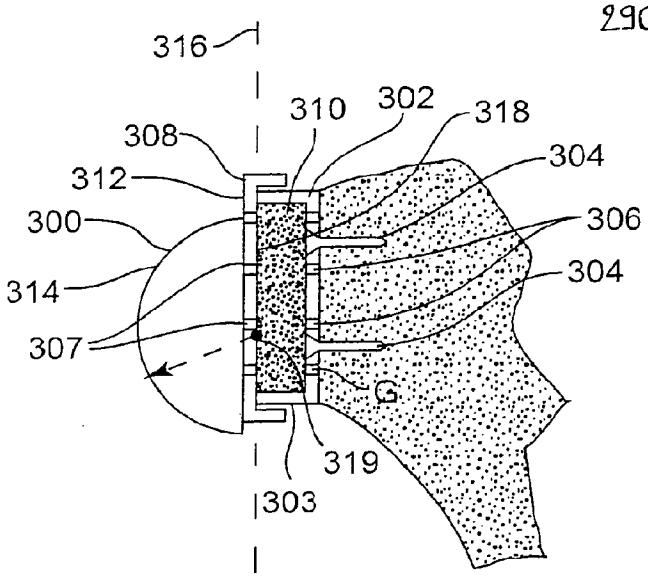


Fig. 20

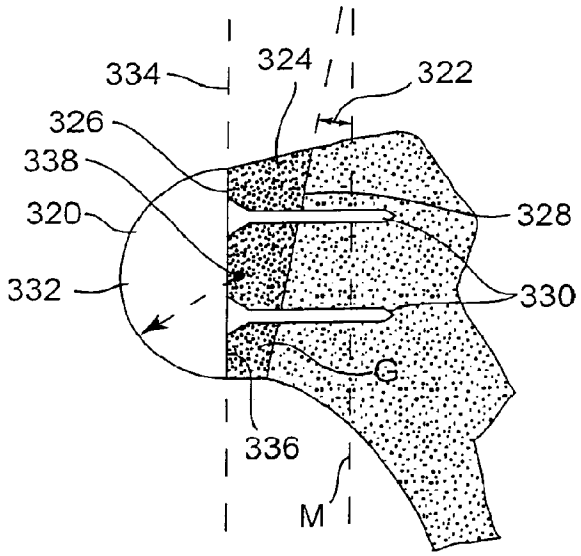


Fig. 21

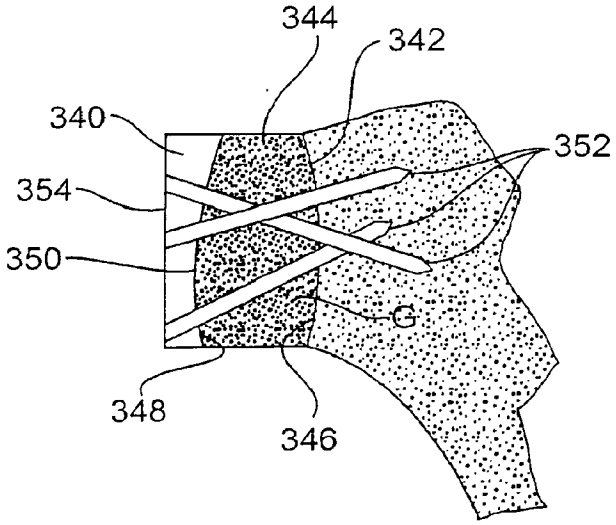


Fig. 22

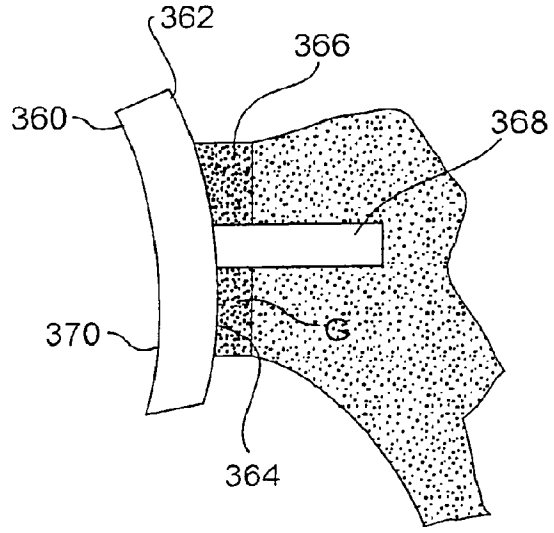


Fig. 23

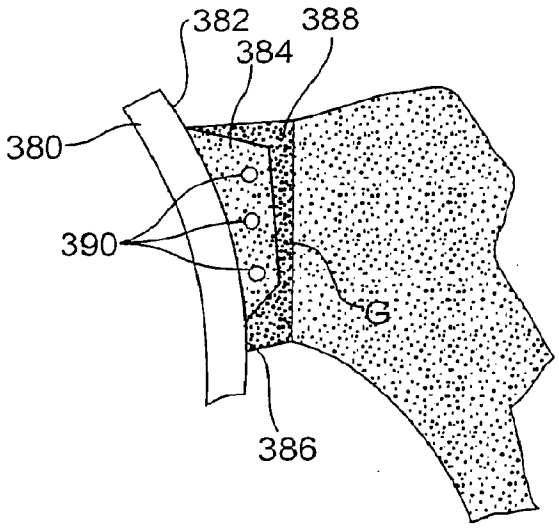


Fig. 24

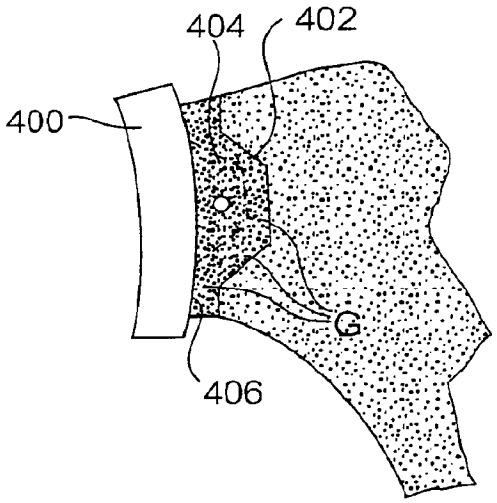


Fig. 25

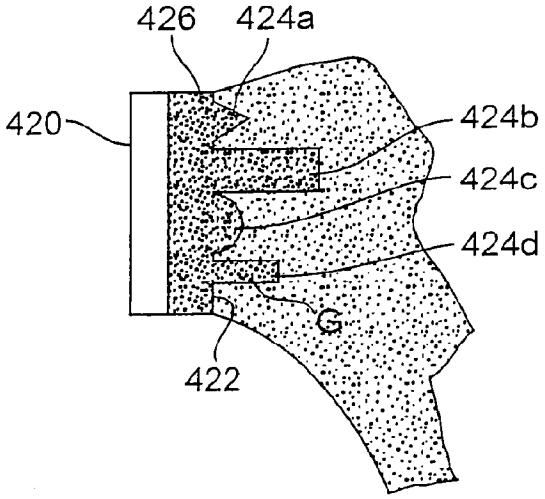


Fig. 26

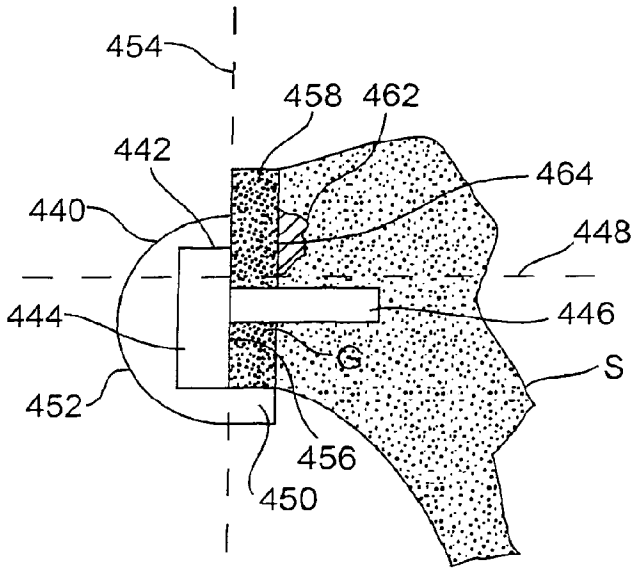


Fig. 27

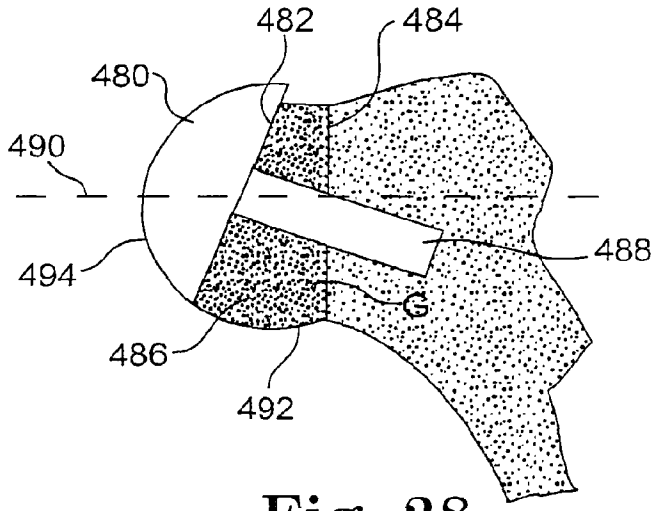


Fig. 28

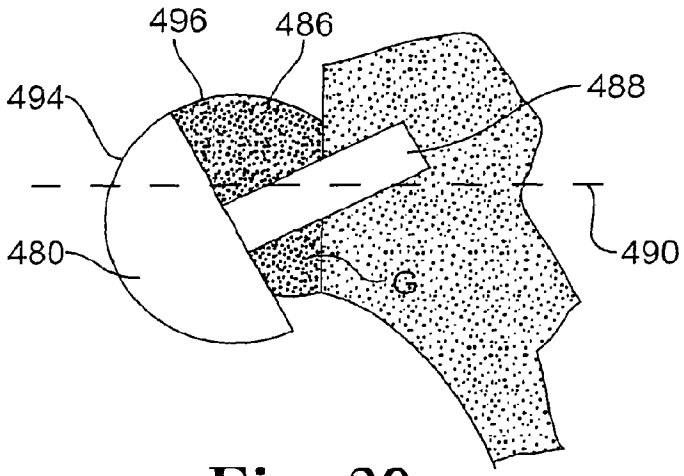


Fig. 29

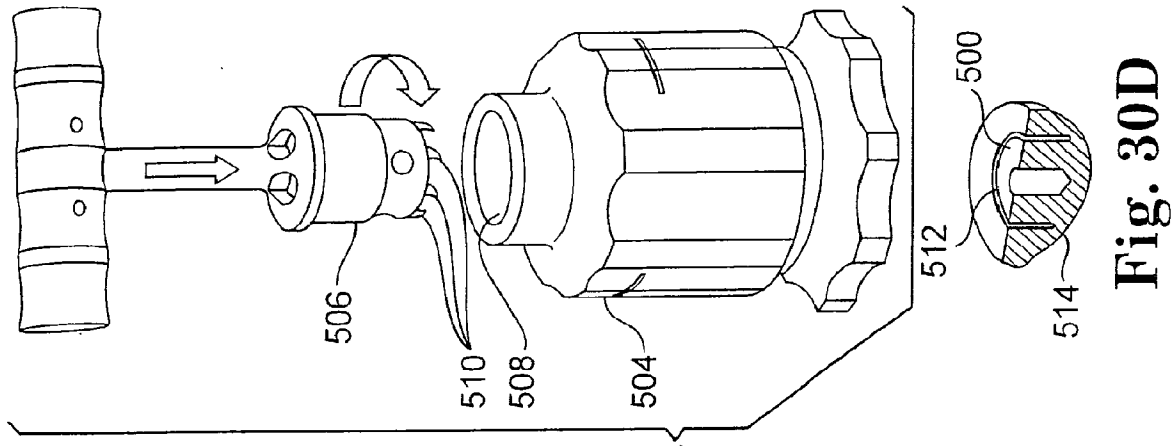


Fig. 30C

Fig. 30D

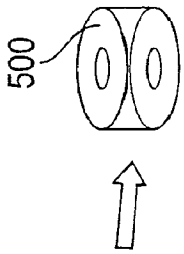


Fig. 30F

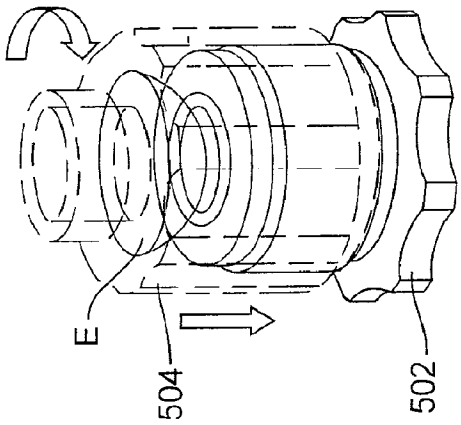


Fig. 30B

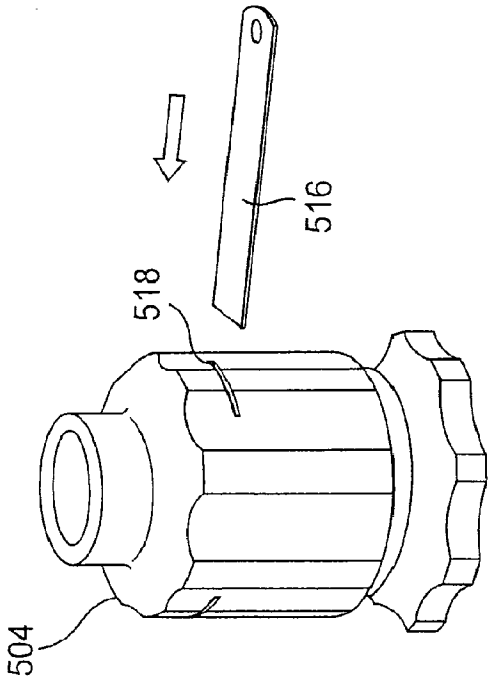


Fig. 30E

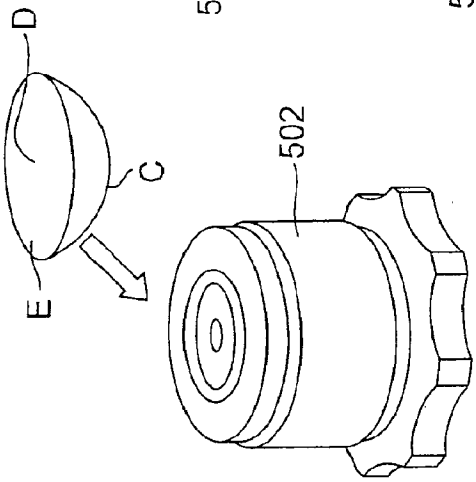


Fig. 30A

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 08 35 6018

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 5 080 673 A (BURKHEAD WAYNE Z [US] ET AL) 14 January 1992 (1992-01-14) * figures 1,18,19 * * column 8, line 34 - line 60 *	1,2,6-8, 10-16	INV. A61F2/40
X	EP 1 402 853 A (DEPUY PRODUCTS INC [US]) 31 March 2004 (2004-03-31) * figures 14,15 * * paragraphs [0050], [0057] - [0059] *	1,2,6, 13-16	
Y	EP 1 064 890 A (ASTON MEDICAL LTD [GB]; CAPON DIDIER [FR]; TROUILLOUD PIERRE [FR]; BUT) 3 January 2001 (2001-01-03) * figures 5-7 * * paragraphs [0020], [0026], [0027] *	1-6, 13-16	
Y	EP 1 323 395 A (DEPUY ORTHOPAEDICS INC [US]) 2 July 2003 (2003-07-02) * figures 22-25 * * paragraph [0038] *	1-6, 13-16	
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	5 June 2008	Josten, Stefan

CATEGORY OF CITED DOCUMENTS

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- US 6730252 B **[0027]**
- US 6541022 B **[0027]**
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THE THREE-DIMENSIONAL GEOMETRY OF THE PROXIMAL HUMERUS

IMPLICATIONS FOR SURGICAL TECHNIQUE AND PROSTHETIC DESIGN

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We have studied the three-dimensional geometry of the proximal humerus on human cadaver specimens using a digitised measuring device linked to a computer. Our findings demonstrated the variable shape of the proximal humerus as well as its variable dimensions. The articular surface, which is part of a sphere varies individually in its orientation as regards inclination and retroversion, and it has variable medial and posterior offsets.

These variations cannot be accommodated by the designs of most contemporary humeral components. Although good clinical results can be achieved with current modular and non-modular components their relatively fixed geometry prevents truly anatomical restoration in many cases.

To try to restore the original three-dimensional geometry of the proximal humerus, we have developed a new type of humeral component which is modular and adaptable to the individual anatomy. Such adaptability allows correct positioning of the prosthetic head in relation to an individual anatomical neck, after removal of the marginal osteophytes. The design of this third-generation prosthesis respects the four geometrical variations which have been demonstrated in the present study. These are inclination, retroversion, medial offset and posterior offset.

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Clinical studies of total shoulder arthroplasty have shown that restoration of the normal anatomy of the proximal humerus is desirable. This affects the lever arms of the deltoid and rotator cuff in the vertical plane and soft-tissue balance in the horizontal plane.[1-3] Changes in this anatomy may produce abnormal kinematics by malpositioning the joint line and by moving the instant centres of rotation.[4-6] There may also be an effect on the fixation of the glenoid component from increased loads in the long term.[2,7,8]

Despite this, few studies have examined the detailed anatomy of the proximal humerus and these have usually focused on its dimensions rather than its three-dimensional geometry.[9-15] Our experience with shoulder arthroplasty has shown consistent difficulties in recreating the normal anatomy, and we have indicated in a previous cinéradiological study that active elevation of a prosthetic shoulder produces abnormal kinematics.[16]

We report a detailed anthropometric study of the geometry of the proximal humerus, suspecting that this may not be as simple as has been previously reported. We considered that the articular surface may show variable orientation and translation in both the coronal and axial planes.

MATERIALS AND METHODS

We made surface measurements on fresh human cadaver specimens using a digitised measuring system to allow three-dimensional computerised modelling of the bones. There were three stages: first, we verified the sphericity of the cartilaginous surface, secondly we studied the distribution of the diameter and depth of the articular surface, and thirdly we defined both the orientation (inclination and retroversion) and location (possible anteroposterior and/or mediolateral offsets) of the articular surface.

From fresh Caucasian cadavers we obtained 65 humeri (32 left, 33 right; 26 paired) and dissected off all soft tissue, taking care to avoid damage to the articular cartilage. They came from 19 men and 20 women; their ages ranged from 67 to 95 years (mean 86 ± SD 13 years). We excluded specimens which showed any evidence of osteoarthritis, osseous pathology, or previous fractures.

A highly accurate three-dimensional digitised measuring

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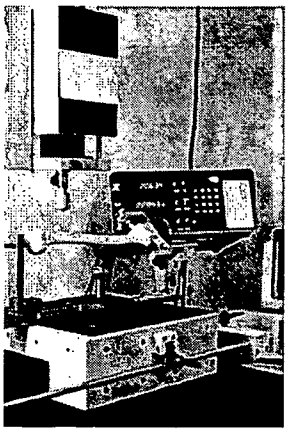


Fig. 1a

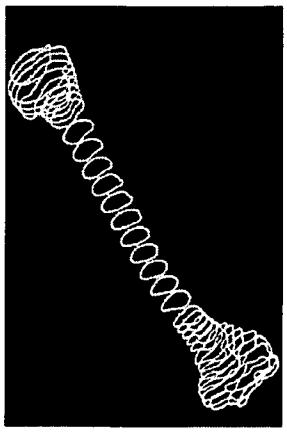


Fig. 1b

Apparatus used for the precision measurements (a) and the resulting three-dimensional image (b).

machine (Metrologic MTI; Metrologic Instruments, Meylan, France) was equipped with a special frame to hold a humerus (Fig. 1a), by supports at the humeral head and at the elbow, so that it could be rotated around its diaphyseal axis. After precalibration, surface measurements were made with a manual probe at rotations in 10° increments. This allowed parallel slices to be measured at every 5 mm at the level of the proximal and distal epiphyses and every 10 mm along the shaft. The bones were then fixed in rotation for the measurement of points on the articular surface of the humeral head. A total of over 1200 points was digitised for each humerus.

The data were collected in a computer equipped with manual software (Métrosoft-3D; Metrologic Instruments, Meylan, France), which produced three-dimensional images (Fig. 1b). Manipulation on a CAD workstation then gave surface reconstructions and multiplanar reformatted images. The computer software could calculate precisely the diameter, thickness, inclination and retroversion and also model the proximal humerus using simple geometrical figures (Fig. 2a).

The anatomical neck plane (C-D) was that best fitting the periphery of the articular surface.

The epiphyseal sphere was that which best fitted the edges of the articular surface of the humeral head with its centre calculated (O).

The metaphyseal cylinder was the cylinder which best fitted the shape of the upper humeral shaft, with its axis at O'. This cylinder was arbitrarily limited to the proximal half of the bone because there is a change in curvature in the coronal plane half way down the humeral shaft at 10.3 to 15.8 cm from the top of the articular surface.

We defined five axes (Fig. 2a):

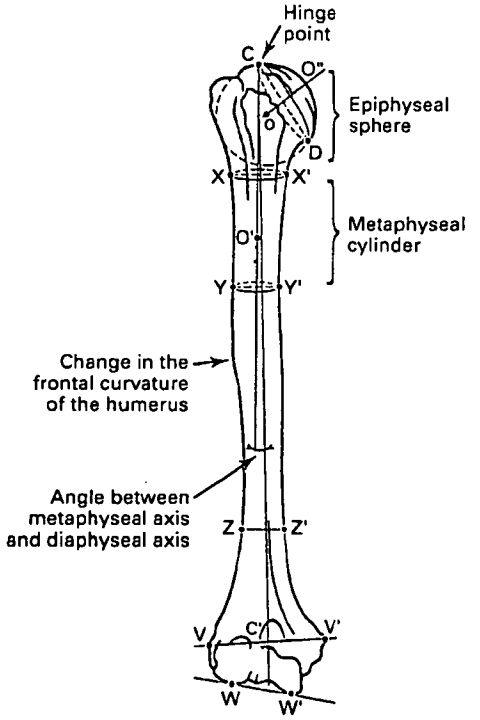


Fig. 2a

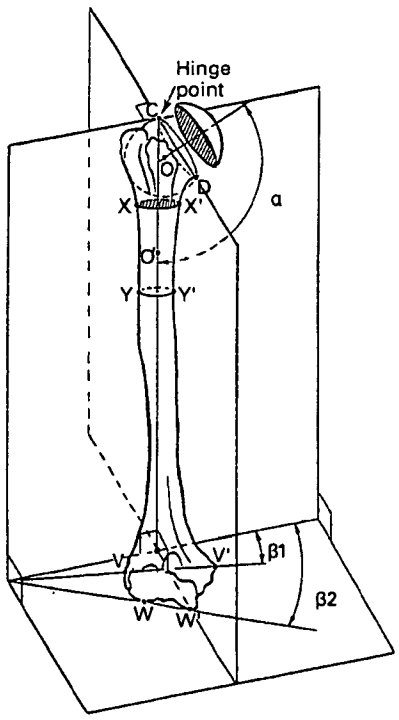


Fig. 2b

Figure 2a – Axes used to characterise the morphological factors: (1) humeral head axis; (2) diaphyseal axis; (3) metaphyseal axis; (4) transepicondylar axis; (5) tangent elbow axis. Figure 2b – Three-dimensional co-ordinate system (see text).

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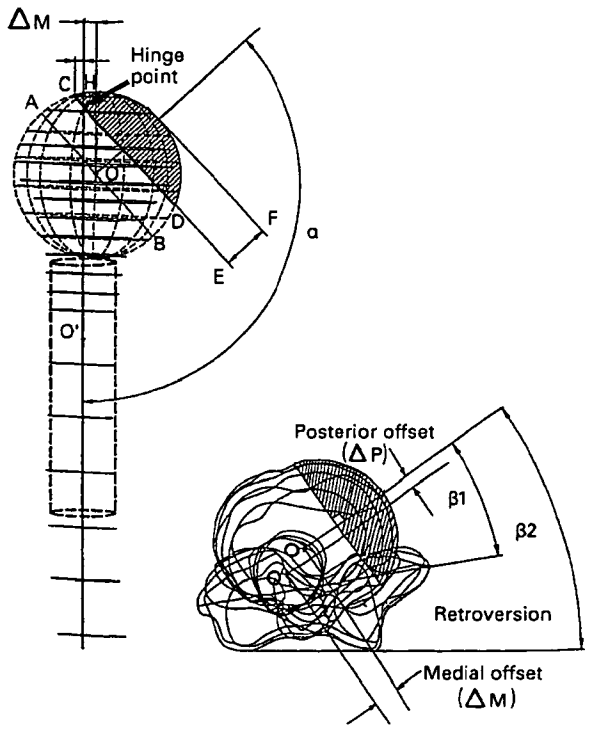


Fig. 3a Fig. 3b

Figure 3a – Measurements in the frontal view: diameter of curvature (A-B); articular surface diameter (C-D); articular thickness (E-F); medial offset (ΔM); 'hinge-point' distance (C-H); inclination angle (α). Figure 3b – Anatomical measurements made in the axial view: retroversion angle related to the transepicondylar axis (β1) and to the tangent axis (β2). Medial offset (ΔM) and posterior offset (ΔP).

1) *the humeral head axis (O-O")* was defined as that perpendicular to the anatomical neck taken to the periphery of the articular cartilage;
2) *the diaphyseal axis* represented the arbitrary axis of rotation of the bones (C-C');
3) *the proximal metaphyseal or intramedullary axis* is of interest because it represents the theoretical axis of the stem of a prosthesis (C-O');
4) *the transepicondylar axis* was defined by a line joining the most medial and the most lateral extremities of the distal humerus (V-V'); and
5) *the tangent elbow axis* was defined by a line parallel to the trochlea and the medial condyle (W-W').

All the morphological factors related to the orientation and location of the articular surface were calculated in relation to the proximal metaphyseal axis for inclination, anteroposterior translation and mediolateral translation, and to the transepicondylar and tangent axes for retroversion. We called the crossing point between the metaphyseal axis and the anatomical neck plane the **hinge point**.

The axes of reference for the three dimensions of space were then defined (Fig. 2b). The image of each proximal humerus was inclined until the proximal metaphyseal axis was vertical, defining the inferosuperior axis. The images of the bones were then rotated around the proximal metaphyseal axis until the anatomical neck plane appeared as a line. The projection of this line on to a perpendicular to the already defined X axis resulted in a vector which defined the anteroposterior axis. The plane perpendicular to the X-Y plane defined the mediolateral axis. A three-dimensional co-ordinate axis system was thus established with its origin within the metaphyseal cylinder. All the measurements were made in accordance with these projections.

The anatomical humeral parameters measured by this procedure for each specimen included the following (Figs 3a and 3b):
1) *the diameter of curvature* of the articular surface of the humeral head measured in both coronal and axial planes (distance A-B);
2) *the articular surface diameter* in both coronal and axial planes, defined as the diameter of the articular surface at the level of the margin of the cartilage (distance C-D);
3) *the articular surface thickness*, defined as the perpendicular distance from the articular margin to the apex of the diameter of curvature (distance E-F);
4) *the inclination angle* between the proximal metaphyseal (intramedullary) axis and that perpendicular to the articular margin plane (angle α);
5) *the retroversion angle* between a perpendicular to the articular margin plane and the transepicondylar (angle β1) or the tangent elbow axes (angle β2);
6) *the medial offset* which is the perpendicular distance between the axial planes containing the centre of the epiphyseal sphere and the central axis of the metaphyseal cylinder (ΔM = distance O-O' in the coronal plane);
7) *the posterior offset* which is the perpendicular distance between the coronal plane containing the centre of the epiphyseal sphere and that containing the central axis of the metaphyseal cylinder (ΔP = distance O-O' in the axial plane); and
8) *the hinge-point distance* which is the distance between the axial plane containing the axis of the cylinder and the upper border of the articular surface (distance C-H).

To verify the sphericity of the humeral head we used the classical method of least-square optimisation,[17] defined as the thickness of a theoretical spherical shell with outer (D1) and inner (D2) theoretical diameters which would contain all digitised points within its thickness. The standard deviation of all data points is a measure of sphericity. For this study we accepted that a three-dimensional shell in which the difference between the two extreme diameters was less than 1 mm (or 2% of the average diameter), could be considered to be a true sphere (D1-D2 < 1 mm).

Surface measurements were made on the outside of each humerus and it could be argued that these were less accurate than intramedullary measurements, and that fitting a cylinder to these data provided a poor geometrical model. To investigate this, we osteotomised ten humeri in the frontal plane and ten in the sagittal plane, then measured with a

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Table I. Summary of the variables characterising the humeral specimens

Dimensions	Mean	Standard deviation	Minimum	Maximum
Diameter of curvature (humeral head diameter) (mm)	46.2	5.4	37.1	56.9
Articular surface diameter (mm)	43.3	4.3	36.5	51.7
Articular surface thickness (mm)	15.2	1.6	12.1	18.2
Inclination (degrees)*	129.6	2.9	123.2	135.8
Retroversion (transepicondylar axis) (degrees)	17.9	13.7	-6.7	47.5
Retroversion (tangent elbow axis) (degrees)	21.5	15.1	-10.3	56.5
Posterior offset (mm)*	2.6	1.8	-0.8	6.1
Medial offset (mm)*	6.9	2.0	2.9	10.8

* inclination, posterior offset and medial offset have been calculated related to the metaphyseal axis or theoretical stem axis of a humeral component

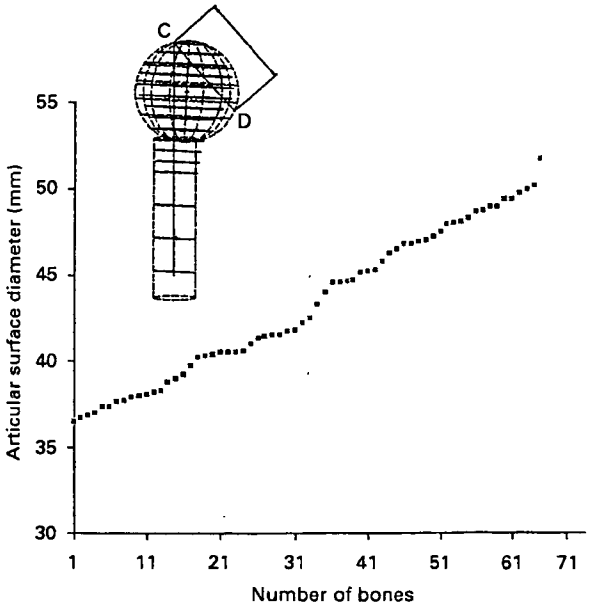


Fig. 4

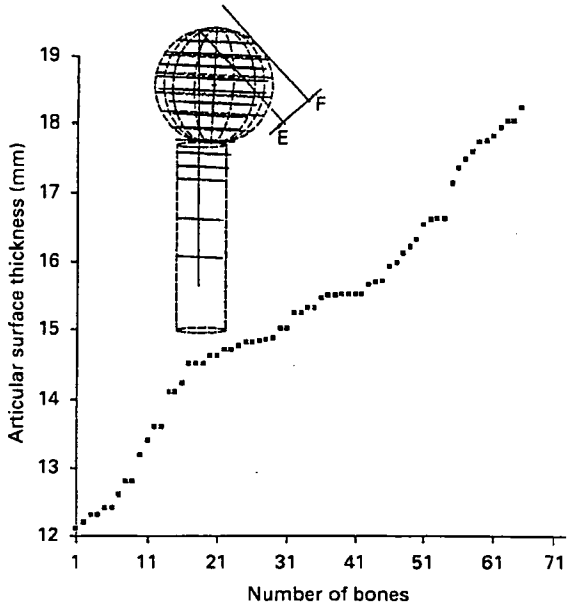


Fig. 5

Figure 4 – Distribution of diameters of the articular surface. Figure 5 – Distribution of the depth of the articular surface.

calliper at both the inside and outside of the proximal part of the bones. The margins of the cortical bone were nearly parallel with less than 1 mm of difference. The maximum deviation of the cylinder diameter was less than 5 mm from the top to the bottom of the cylinder. This confirmed that extramedullary were comparable with intramedullary measurements, and that a cylinder is an acceptable representation of the geometry of the humeral shaft. Even if the humeral shaft is not a true cylinder, its axis and the theoretical stem axis can be defined. Our use of only the proximal half of the humerus to define it is justified on two facts: first, a prosthetic stem is usually located in the proximal half and secondly, we had observed, from both the computer-generated pictures and our coronal sections of the humeri, that there is a change in curvature of the shaft in the frontal plane below the proximal 13 cm (see Fig. 2a).

The digitising machine was accurate to the order of 10 μm, considered to be insignificant for this application. To determine observer variability, we chose ten specimens randomly. They were independently digitised by two different observers, and the measurements were repeated three weeks later in a blinded format. Analysis of variance showed that the standard deviation for repeat readings by one observer and between two observers was less than 1 mm for linear measurements and less than 1° for angular measurements.

RESULTS

Table I gives a summary of our results. Our important findings are not the standard values but the large variations in the measured parameters.

The diameter of curvature varied from a minimum of 37.1 mm to a maximum of 56.9 mm (mean 46.2). The

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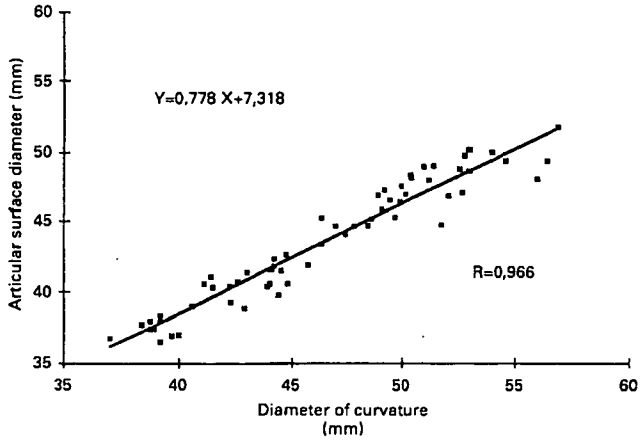


Fig. 6

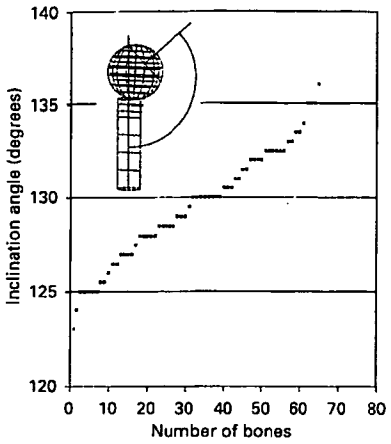


Fig. 7

Figure 6 – Relationship between the diameter and the depths of the articular surface. Figure 7 – Distribution of the inclination angle in relation to the metaphyseal axis.

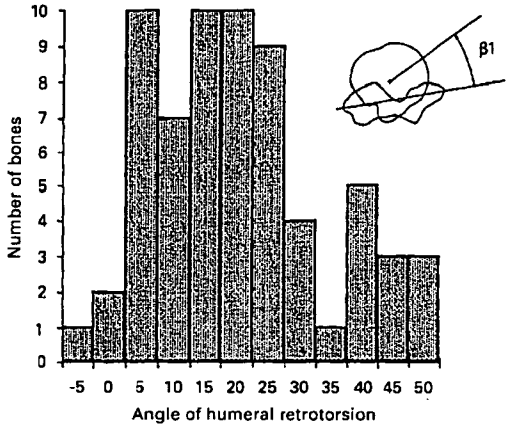


Fig. 8

Distribution of the retroversion angle in relation to the transepicondylar axis.

difference between the two extreme diameters for each single humeral sphere was less than 1 mm in 88.2% of the specimens, showing that most formed a true sphere as defined above.

The articular surface diameters (distance C-D) are shown in Figure 4 and the distribution of the depth of the humeral head (distance E-F) in Figure 5. We found a strong linear correlation between articular surface diameter and this 'thickness' of the humeral head. Regression analysis determined the equation of the regression line as $y = 0.78x + 7.32$, where y was the articular surface diameter and x was the thickness of the humeral head ($r = 0.96$; Fig. 6).

The distribution of the inclination angles of the articular surface with respect to the proximal metaphyseal axis (angle α, neck-shaft angle) is shown in Figure 7, and the distribution of the retroversion angles with respect to the transepicondylar axis (angle $\beta 1$) in Figure 8.

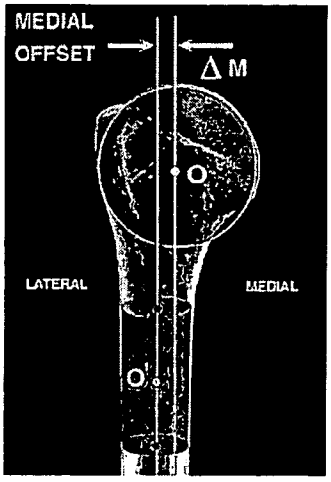


Fig. 9a

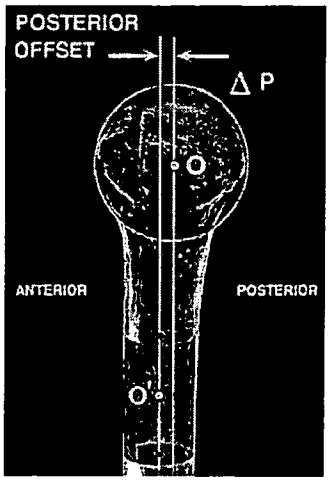


Fig. 9b

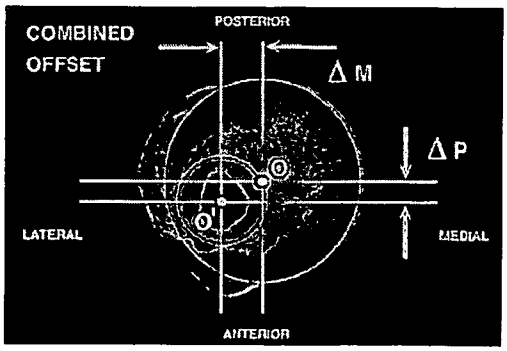


Fig. 9c

Translation of the articular head surface related to the theoretical stem axis shown on radiographs: a) medial offset; b) posterior offset; c) combined offset.

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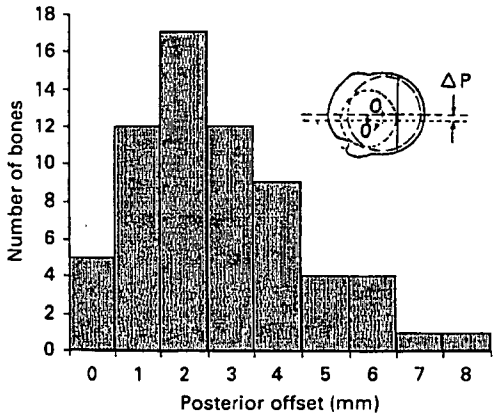


Fig. 10

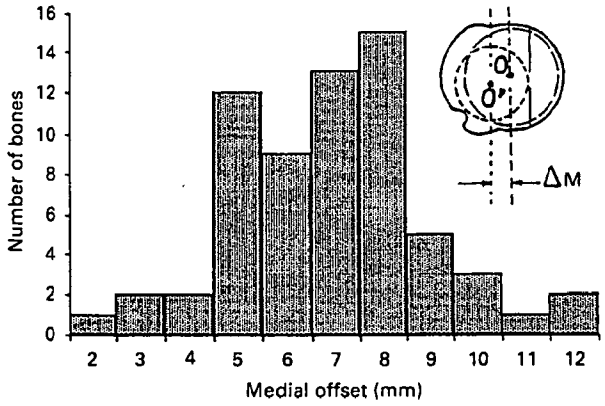


Fig. 11

Figure 10 – Distribution of the posterior offset of the centre of the humeral head relative to the metaphyseal axis. Figure 11 – Distribution of the medial offset of the centre of the humeral head relative to the metaphyseal axis.

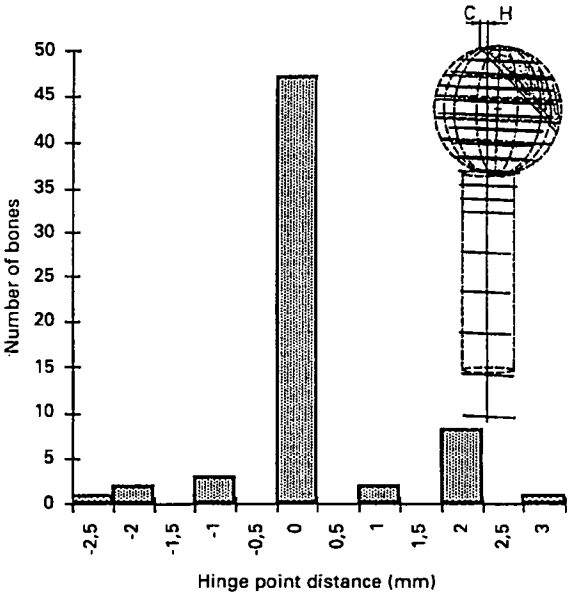


Fig. 12

Distribution of the 'hinge-point' distance (C-H). The intramedullary axis intersects the plane of the anatomical neck (C-D) almost constantly at point C (top of the articular surface). The distance C-H was less than 1 mm in 72.3% of the bones.

The epiphyseal sphere did not lie centrally on the base of the metaphyseal cylinder but was offset in both planes, leading to a combined, medial and posterior, offset of the articular surface (Fig. 9). The posterior offset averaged 2.6 mm (95% CI –0.8 to 6.1), with a distribution shown in Figure 10. The medial offset averaged 6.9 mm (95% CI 2.9 to 10.8) (Fig. 11).

The distance between the theoretical stem axis and the geometrical centre of the articular surface, the hinge-point distance, was less than 1 mm in 72.3% of the humeri, (Fig. 12).

DISCUSSION

Our study has emphasised that the shape of the proximal humerus is more important than its dimensions, because of its variable orientation (inclination and retroversion) and its variable medial and posterior offset. This suggests that restoration of normal anatomy during arthroplasty may be difficult with the relatively fixed geometry of existing prosthetic systems. Failure to match the shape has potential biomechanical consequences due to malposition of the joint line, moving the instant centres of rotation or both.[2,3,5,16,18,19] The degree of precision needed for the reconstruction of the proximal humerus is unknown, but other work suggests that it has fairly tight limits. Fischer et al[4] have shown that if the centre of curvature is displaced by 20% of its radius (5 mm for an average radius of 25 mm), the lever arm of the rotator cuff will be altered by 20%. Poor prosthetic design or poor surgical technique is known theoretically to lead to problems (Table II),[1, 20-23] and alteration of the bony anatomy may also lead to eccentric loading at the periphery of the glenoid, increasing glenoid wear and glenoid loosening.[2,7,8]

Coronal plane. In the coronal plane there are two variables which may interfere with the positioning of the articular surface: inclination angle and medial offset. The intersection point or hinge point which we describe between the metaphyseal axis and the superior margin of the articular head surface forms a useful surgical guide when performing a hemiarthroplasty. The medullary canal of the humerus should be reamed starting at a point which is lateral on the cut surface. The mean inclination angle of 130° in our study corresponds to those previously reported,[9,10,11,15] but the average value is completely relative; its considerable

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Table II. Variable orientation (inclination and retroversion) and location (medial offset and posterior offset) of the articular surface of the humeral head, with the pathological consequences and the surgical possibilities of control when using a fixed-design humeral component

	Articular head surface orientation and location	Potential pathological consequences of error	Surgeon-controllable variables*
Coronal plane	Inclination	Subacromial impingement (superior "bulging" of the prosthetic head)	Varus/valgus and / or Mediolateral translation
	Medial offset	Glenoid (posterior) impingement (inferior "sliding" of the prosthetic head)	
Axial plane	Retroversion	Coracoid impingement (anterior "bulging" of the prosthetic head)	Anteversion/retroversion and / or Anteroposterior translation
	Posterior offset	Anteroposterior instability (abnormal rotation and/or anteroposterior translation of the humeral component)	

* these possibilities are partially or totally reduced with cementless, close-fitting humeral components and/or humeral components with stems which are too long

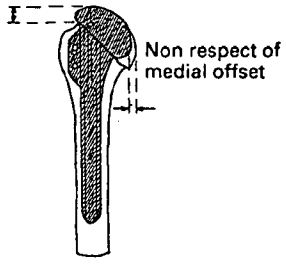


Fig. 13a

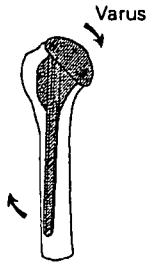


Fig. 13b

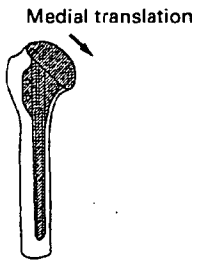


Fig. 13c

Two methods of correcting medial offset surgery (a) by implanting the prosthesis with some varus (loose-fit stem) (b) or implanting the prosthesis with some medial translation (loose-fit stem) (c).

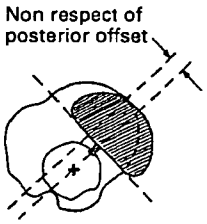


Fig. 14a

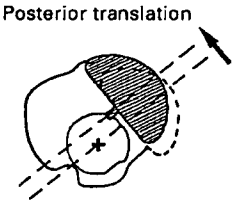


Fig. 14b

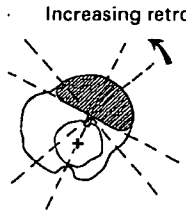


Fig. 14c

Two methods of correcting posterior offset at surgery (a) by posterior translation of the prosthetic head (loose-fit stem) (b) or increasing retroversion with a bone cut in excessive version (c).

variation in individuals must be kept in mind. Most prostheses limit the potential for reproducing the original anatomy: a humeral cut at 140° inclination in a patient who originally had only 125° inclination will displace the centre of rotation proximally and alter the kinematics.[8,24] A more useful guide is the orientation of a humeral component to the original true anatomical neck: this may be more appropriate for a specific shoulder than routine orientation to the same inclination.[24,25] The variable medial offset of the articular surface found in our study has not been reported previously – this too may create difficulties in restoring the original bony anatomy with a shoulder prosthesis of fixed design.[25]

Axial plane. In the axial plane there are also two variables: the retroversion angle and the posterior offset. The low average retroversion angle which we found (17.9°) confirms other anatomical studies by Broca,[26] Krahl and Evans[27] and Roberts et al[28] who reported values of 16, 15.6 and 21.4°, respectively. More importantly, however, retroversion of the proximal humerus is highly variable, ranging from –6.7° to 47.5°. Again, this means that anatomical reconstruction of the retroversion angle should be individual, following the landmarks of the true anatomical neck.[29,30] Posterior offset also varies, ranging from –0.8 to 6.1 mm. Roberts et al,[28] also using an extramedullary method, reported a posterior offset from 0 to 12 mm, but Ballmer et al,[6] using an intramedullary method, found an offset ranging from 3 mm anterior to 4 mm posterior. Our study, like those of Roberts et al[28] and Ballmer et al,[6] has shown that part of what is called retroversion is actually due to posterior offset; this should be taken into consideration by shoulder surgeons.

Surgical relevance. The monobloc prosthesis developed by Neer et al[1] for the humeral component remains the 'gold standard' associated with excellent and good results at long-term follow-up. The first-generation shoulder prosthesis met the needs of many patients, but offered only a mid-range of sizes and did not exactly reproduce the

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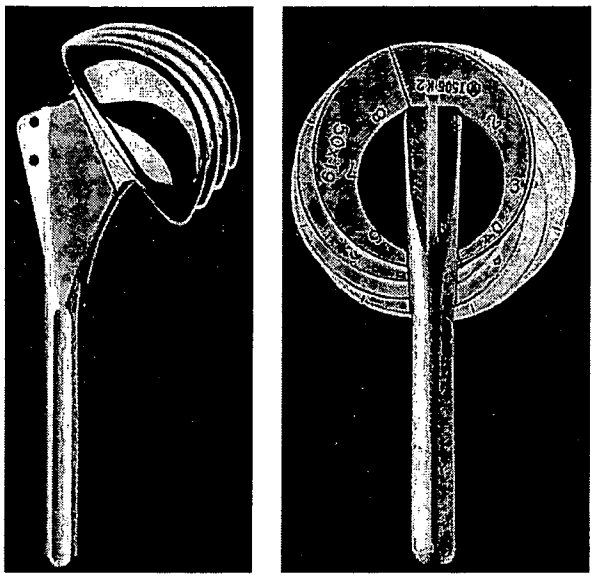


Fig. 15a Fig. 15b

An adaptable prosthesis: a) adaptation of inclination by a system of variable necks between the stem and the head, b) adaptation of mediolateral and anteroposterior offset through an eccentric indexing system.

coronal and axial geometry of the proximal humerus.[15,31]

Our study helped us to understand how surgical technique can compensate for the anatomical variation of proximal humeri by paying meticulous attention to details of placement (Table II). Surgical experience and judgement are required for the accurate orientation and location of the prosthesis.[7,24,32] For example, variation in medial offset or inclination or both may be compensated for by choosing a smaller stem and increasing the varus or medial translation, or both, for the humeral component[24] (Fig. 13). Such varus or medial positioning of the humeral component, however, may tighten some of the soft tissues by increasing separation between their glenoid and humeral attachments, and may therefore be of questionable value.[33] When a humeral head prosthesis seats eccentrically too anterior in the axial plane there are two technical possibilities: one is to choose a smaller stem to allow posterior translation and centralisation at the time of cementing; the other is to resect more bone posteriorly, limited by the rotator-cuff insertion, to allow an increase in prosthetic retroversion (Fig. 14). This may explain why the recommended surgical retroversion angle is higher at 30 to 40° than the anatomical angle.[34-36] Moving the prosthesis to face more posteriorly, however, may not restore the balance between the anterior and posterior structures and may also be questionable.[8,29,33]

The current proliferation of second-generation shoulder prostheses offers modular implants with a greater selection of sizes for both the prosthetic head and the stem. This choice may help the surgeon to match the variation in size of articular surface and improve the soft-tissue balancing.[6,7,18,33] The range of stems aims to allow better primary stabilisation and better fixation, but filling the medullary canal with a prosthetic stem may prevent accurate reproduction of the anatomical model by placing the head eccentrically. The close fit of a cementless stem will dictate the position of the prosthetic head and make it much more difficult, if not impossible, to match the medial and posterior offset and so achieve coverage of the bone cut. As emphasised by Ballmer et al[6] the fit of such a prosthesis eliminates all but two of the six degrees of freedom, leaving only the depth of insertion and the rotation of its stem to allow adjustment.[6] A loosely fitting prosthesis offers more possibilities as regards alignment but its fixation may be questionable. Stem length is another limiting factor: too long a stem may prevent insertion with enough varus, for example, to compensate for a large medial offset, because of the change in curvature of the proximal diaphysis which we observed.

Good clinical results can be achieved with both the modular and non-modular components that are available, but their relatively fixed geometry means that they cannot be truly anatomical when compared with the findings of our study. The shape of the proximal humerus is much more variable than most contemporary designs of humeral component suggest or can accommodate.[24,25,32]

To try to restore the original three-dimensional geometry, we have developed a new type of humeral component (Aequalis Prosthesis; Tornier Inc, Saint-Ismier, France).[37] This third-generation shoulder prosthesis is not only modular but also adaptable to the individual bony anatomy. Prosthetic adaptability, a new concept in shoulder arthroplasty, allows the correct placement of the prosthetic head, with the restoration of normal glenohumeral anatomy and kinematics. The prosthesis also fills the medullary canal with the stem to optimise fixation. The design of this new type of prosthesis allows the individual anatomy to be reproduced (Fig. 15) and incorporates variable inclination, using variably-angled neck components between the stem and the prosthetic head. Individual head retroversion is provided by osteotomy of the articular surface after removal of the crown of osteophytes. The design provides variable posterior and medial offset of the articular surface through an eccentric indexing system (Fig. 15). While soft-tissue balancing is achieved by performing an anterior release, the correct spatial positioning of the humeral head relative to the humerus results in 'bony balancing'. This combination should result in normal glenohumeral kinematics and decrease abnormal eccentric loads on the glenoid component.

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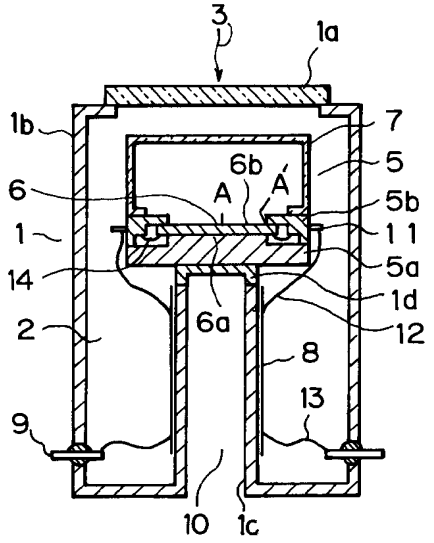
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(54) Infrared detector.

(57) An infrared detector wherein an infrared detecting device can be cooled efficiently without increasing thermal stresses generated in the device body owing to cooling during the operation of the detector, and intrusion of ambient light can be prevented. A container for the infrared detecting device, which includes a bottom plate having a projection formed in the center thereof, is provided on an inner end portion of an inner cylinder constituting a dewar, and the infrared detecting device is placed on and secured to the projection of the bottom plate. The container bottom plate is made of an Invar, while the end portion of the inner cylinder is made of a Kovar or an Invar.

Fig. 1



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The present invention relates to an infrared detector that detects infrared radiation from an object as image information. More particularly, the present invention relates to a structure for mounting an infrared detecting device accommodated in a dewar and driven while being cooled to cryogenic temperatures from the outside of the dewar.

Infrared detectors that utilize a semiconductor silicon Schottky junction are difficult to operate at room temperature because of their low junction barrier. Therefore, this type of infrared detector must be operated in a state where they are cooled to cryogenic temperatures (liquid nitrogen temperature of about 80 K) in order to remove temperature disturbance. For this reason, an infrared detecting device is mounted in a vessel called dewar, which has a special structure that is provided with a window for transmitting infrared radiation and capable of cooling the detecting device to cryogenic temperatures. In this state, the detecting device is driven to detect infrared radiation.

Fig. 2 is a sectional view showing the structure of a conventional infrared detector of the type described above. In the figure, reference numeral 1 denotes a dewar the inside of which is kept at a vacuum. The dewar 1 comprises an outer cylinder 1b having a window member 1a hermetically bonded thereto for transmitting incident infrared radiation 3, and an inner cylinder 1c that is united with the outer cylinder 1b so as to form a cooler insertion space 10, which will be described later. The inner cylinder 1c is made of a glass, ceramic or metallic material which exhibits a small thermal conductivity at cryogenic temperatures, for example, borosilicate glass, metallic titanium, etc. A container 4 for mounting a detecting device is attached to an inner cylinder end portion 1d made of a Kovar. The container 4 comprises a bottom plate 4a of aluminum nitride (AlN) or silicon carbide (SiC) which is secured to a surface of the inner cylinder end portion 1d that is disposed inside the dewar 1, and a frame 4b of alumina (Al_2O_3) or mullite (Al_2O_3:SiO_2 = 1:1) which is attached to the periphery of the bottom plate 4a and which is provided with terminals 11 for taking out an electric signal from a semiconductor infrared detecting device 6. Reference numerals 6a and 6b respectively denote first and second major surfaces of a semiconductor substrate that constitutes the detecting device 6. The first major surface 6a is formed with an infrared receiving part and a readout mechanism for reading out a signal from the infrared receiving part. The infrared detecting device 6 is disposed such that the first major surface 6a faces the bottom plate 4a of the container 4, and it is secured to the frame 4b of the container 4, thereby being mounted in the dewar 1. A cold shield 7 is attached to the frame 4b so as to cover the infrared detecting device 6, thereby forming a wall for shielding stray light of incident infrared radiation. A metallic conductor 14 electrically connects together a signal output part of the infrared detecting device 6 and an internal metallic lead formed inside the container 4. A dewar internal conductor 8 is connected to a terminal 11 of the frame 4b through a metallic conductor 12, disposed along the side wall of the inner cylinder 1c and led out of the dewar 1 through a metallic conductor 13 via an external terminal 9 extending through the outer cylinder 1b and hermetically sealed with glass. Reference numeral 10 denotes a cooler insertion space formed by the inner cylinder 1c.

The operation of the conventional infrared detector will be explained below.

Infrared radiation 3 that enters the dewar 1 through the window member 1a forms an image on the reverse surface of the semiconductor detecting device 6 (i.e., the first major surface 6a of the substrate), producing carrier charge in accordance with the intensity of the incident infrared radiation. The charge is read by a charge transfer part integrated with the detecting device 6 as one unit, and the read information is sent to an external signal processing circuit through the metallic conductors 14, the container internal metallic leads, the terminals 11, the metallic conductors 12, the dewar internal conductors 8, the metallic conductors 13 and the external terminals 9 and displayed as image information. During the detector operation, the detecting device 6 is cooled to a level of 80 K through the dewar inner cylinder end portion 1d by a cooling means, comprising a cooler, e.g., a Joule-Thomson or closed cycle cooler, which is inserted in the cooler insertion space 10 formed in the dewar 1.

In the conventional infrared detector with the above-described arrangement, the detecting device 6 is cooled through a heat transfer path formed from the dewar inner cylinder end portion 1d, the container bottom plate 4a and the frame 4b, and only the peripheral portion of the detecting device 6 is secured to the frame 4b. Accordingly, the thermal resistance is disadvantageously high, and it is difficult to realize efficient cooling.

In addition, since each member that constitutes the infrared detector is used over a wide temperature range of from room temperatures to cryogenic temperatures, a material for each member needs to be selected by taking into consideration characteristics, durability and thermal expansion under such temperature conditions. If the selection of a material is not properly made, the detecting device 6 or the container bottom plate 4a may be damaged by thermal stresses generated owing to a mismatch in thermal expansion during cooling.

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Fig. 4 is a fragmentary sectional view showing the right-hand half of the peripheral portion of the detecting device 6 in the conventional detector structure, shown in Fig. 2. In the figure, the same reference numerals as those in Fig. 2 denote the same elements or portions. The point A shows the central portion of the infrared detecting device 6. The point A' shows an area where the infrared detecting device 6 is bonded to the frame 4b. The arrows represent stresses generated in the device 6. Fig. 5 is a graph showing contraction stresses generated on the device surface (A-A' in Fig. 4) in a direction X (horizontal direction as viewed in Fig. 4) when the composite structure, which comprises the inner cylinder 1c of the dewar 1, the inner cylinder end portion 1d, the bottom plate 4a of the container 4, the container frame 4b, the infrared detecting device 6 and the cold shield 7, is cooled from a room temperature (300 K) to a cryogenic temperature (77 K). As will be clear from Fig. 5, stresses that are generated on the device surface in the conventional structure are in the range of 2.9 to 4.8 kgf/mm^2. Here, a positive value for stress represents tensile stress, whereas a negative value represents compressive stress. In general, a brittle material such as aluminum nitride or silicon carbide may be cracked by tensile stress. Therefore, in the conventional device structure, the container bottom plate 4a or the detecting device 6 may be damaged by thermal stresses generated during cooling.

Fig. 3 is a sectional view showing the structure of another conventional infrared detector disclosed in Japanese Patent Application Public Disclosure No. 2-214158 (1990). In the figure, a dewar 21 the inside of which is kept at a vacuum comprises a tubular portion 21a and a window portion 21b that is formed at the upper end of the tubular portion 21a for allowing infrared radiation to enter the dewar 21. A cooling means 23 is inserted into a recess formed in the tubular portion 21a. An infrared detecting device 26 is secured at its peripheral portion to a support 24. Reference numerals 26a and 26b respectively denote first and second major surfaces of the infrared detecting device 26. The first major surface 26a is formed with a readout mechanism for reading out a signal from an infrared receiving part. The first major surface 26a is directly placed on and secured to the inner surface of the upper end of the recess formed in the tubular portion 21a of the dewar 21. Internal metallic leads 27 are electrically connected to the infrared detecting device 26 through metallic conductors 28. External metallic leads 29 are provided to lead out an output from the infrared detecting device 26. Metallic leads 30 are secured to the inner surfaces of the tubular portion 21a. Electrodes 31 are used to take out the output signal from the detecting device 26 in the dewar 21 to the outside of the dewar 21. Metallic conductors 32 and 33 provide electrical connection between the metallic leads 29 and 30 and between the leads 30 and the electrodes 31.

In this infrared detector, since the first major surface 26a of the infrared detecting device 26 is directly placed on and secured to the upper end of the recess formed in the tubular portion 21a of the dewar 21, the thermal resistance between the cooling means 23 and the infrared detecting device 26 can be reduced, and the cooling efficiency can be improved by a large margin. Accordingly, the problems attendant on the structure of the first-described prior art are solved. In this structure, however, the infrared detecting device 26 is not provided in a container but directly placed on and secured to the upper end of the recess of the dewar 21. Accordingly, light that enters the dewar 21 from the outside and that is reflected from the inner wall of the dewar 21 may enter the device 26 through a surface thereof (first major surface 26a) to form a noise component, causing the device characteristics to be deteriorated. In addition, the device 26 may be damaged when mounted in the dewar 21, and if such occurs, the reliability of the device 26 lowers.

Thus, the first conventional infrared detector, shown in Fig. 2, suffers from the problem that the thermal resistance increases when the detecting device is cooled, and it is therefore difficult to realize efficient cooling. In addition, the detecting device or the container bottom plate may be damaged by thermal stresses generated owing to a mismatch in thermal expansion during cooling.

In the second conventional infrared detector, shown in Fig. 3, intrusion of ambient light cannot be prevented, so that the device characteristics may be deteriorated. The second prior art further suffers from the problem that the device may be damaged when mounted in the dewar.

In view of the above-described problems of the prior art, it is an object of the present invention to provide an infrared detector which is designed so that the detecting device can be cooled efficiently without increasing the thermal stresses generated in the device body owing to cooling during the operation of the detector, and it is also possible to prevent intrusion of ambient light and enable the device to be readily disposed in the dewar.

To this end, the present invention provides an infrared detector including a dewar having an outer cylinder with a window for transmitting incident infrared radiation, and an inner cylinder united with the outer cylinder so as to form a space for inserting cooling means, and an infrared detecting device accommodated in the dewar and driven while being cooled to a cryogenic temperature by the cooling means from the outside of the dewar. The

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infrared detector further includes a container for accommodating the infrared detecting device. The container includes a bottom plate having a projection projecting inwardly of the container from an inner surface thereof. The infrared detecting device is secured to the projection of the bottom plate, and the bottom plate is secured to an end portion of the inner cylinder which is disposed in the dewar, thereby disposing the container in the dewar.

The bottom plate of the container for the infrared detecting device may be made of an Invar.

In addition, the present invention provides an infrared detector including a dewar having an outer cylinder with a window for transmitting incident infrared radiation, and an inner cylinder united with the outer cylinder so as to form a space for inserting cooling means, and an infrared detecting device accommodated in the dewar and driven while being cooled to a cryogenic temperature by the cooling means from the outside of the dewar. The infrared detecting device is a silicon infrared detecting device, and an end portion of the inner cylinder which is disposed inside the dewar is made of a Kovar or an Invar. The silicon infrared detecting device is accommodated in a container which includes a bottom plate made of an Invar and having a projection projecting inwardly of the container from an inner surface thereof. The silicon infrared detecting device is secured to the projection of the bottom plate, and the bottom plate is secured to the end portion of the inner cylinder of the dewar, thereby disposing the container in the dewar.

In the present invention, the infrared detecting device is placed on and secured to the projection formed on the container bottom plate. Accordingly, heat that is generated from the device is transmitted to the cooling means through the container bottom plate and the end portion of the dewar inner cylinder, so that efficient cooling is realized. Further, since the device is provided in the container and this container is disposed in the dewar, intrusion of ambient light is effectively prevented, and it is easy to handle the device when it is mounted in the dewar.

In addition, since the container bottom plate, which has a projection formed in the center thereof, is made of an Invar, machining of the bottom plate is facilitated.

Further, since the device is placed on and secured to the container bottom plate, the cooling efficiency improves. Moreover, since the container bottom plate is made of an Invar, while the end portion of the inner cylinder is made of a Kovar or an Invar, machining of the bottom plate is facilitated, and thermal stresses that are generated in the peripheral portion of the device can be held down to a low level at which no damage is caused to the device. In addition, since the device is provided in the container, intrusion of ambient light can be prevented, and it is possible to facilitate handling of the device when it is mounted in the dewar.

The above and other objects, features and advantages of the present invention will become more apparent from the following description of the preferred embodiments thereof, taken in conjunction with the accompanying drawings, in which like reference numerals denote like elements, and of which:

Fig. 1 is a sectional view of an infrared detector according to one embodiment of the present invention;

Fig. 2 is a sectional view of a conventional infrared detector;

Fig. 3 is a sectional view of another conventional infrared detector;

Fig. 4 is a fragmentary enlarged view of a peripheral portion of a detecting device of a conventional infrared detector;

Fig. 5 is a graph showing stresses generated on the device surface of a conventional infrared detector;

Fig. 6 is a graph showing stresses generated on the device surface of an infrared detector according to one embodiment of the present invention; and

Fig. 7 is a graph showing stresses generated on the device surface of an infrared detector according to another embodiment of the present invention.

One embodiment of the present invention will be described below with reference to the accompanying drawings. Fig. 1 is a sectional view showing the structure of an infrared detector according to one embodiment of the present invention. In the figure, the same reference numerals as those in Fig. 2 denote the same elements or portions. However, reference numeral 5 denotes a container which comprises a bottom plate 5a made of an Invar (36% Ni - 64% Fe) and having a projection formed in the center thereof, and a frame 5b of alumina which is bonded to the peripheral portion of the bottom plate 5a. The feature of this embodiment resides in that the inner cylinder end portion 1d of the dewar 1 is made of a Kovar (29% Ni - 17% Co - 54% Fe), and the infrared detecting device 6 is directly placed on and secured to the projection formed in the center of the container bottom plate 5a made of the Invar.

It was decided to employ the above-described constituent materials on the basis of the results of a simulation carried out using a computer. That is, contraction stresses generated when the composite structure, which comprised the inner cylinder 1c of

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the dewar 1, the inner cylinder end portion 1d, the bottom plate 5a of the container 5, the container frame 5b, the infrared detecting device 6 and the cold shield 7, was cooled from a room temperature (300 K) to a cryogenic temperature (77 K) were measured by a computer numerical analysis based on the finite element method with each kind of constituent material used as a parameter, and utilized particularly for evaluation of stresses in the infrared detecting device 6.

Fig. 6 is a graph showing a distribution of stresses generated on the device surface of the infrared detector in this embodiment. As will be clear from the graph, the results of the analysis reveal that stresses generated on the surface of the device in this embodiment are in the range of -2.2 to 4.0 kgf/mm^2, and that the maximum stress in the detector of this embodiment is 4.0 kgf/mm^2, whereas the maximum stress in the conventional infrared detector, shown in Fig. 2, is 4.8 kgf/mm^2. Thus, in the detector of this embodiment, stresses generated in the device body are held down to a lower level than in the case of the conventional detector.

Further, in the conventional detector structure, shown in Fig. 2, cooling of the infrared detecting device is effected through container bottom plate and the frame. In the infrared detector of this embodiment, however, the detecting device 6 is mounted directly on the projection formed in the center of the container bottom plate 5a, so that efficient cooling can be performed through a heat transfer path which is formed from the dewar inner cylinder end portion 1d and the container bottom plate 5a.

Further, since in this embodiment the container 5 is comprised of the bottom plate 5a and the frame 5b, which is bonded to the peripheral portion of the bottom plate 5a, and the infrared detecting device 6 is placed on and secured to the projection of the bottom plate 5a, there is no likelihood that light that enters the dewar 1 and that is reflected from the dewar inner wall will enter the device 6 through the surface 6a thereof. Thus, it is possible to prevent intrusion of ambient light and hence possible to reduce noise and improve the device characteristics.

In addition, since the device 6 is disposed in the container 5, it is easy to handle the device 6 when it is mounted in the dewar 1. Accordingly, reliability of the device 6 is improved.

Further, since the container bottom plate 5a is made of an Invar, machining of the bottom plate 5a is facilitated.

Next, the structure of an infrared detector according to another embodiment of the present invention will be described with reference to Fig. 1. In the figure, the same reference numerals as those in Fig. 2 denote the same elements or portions. However, reference numeral 5 denotes a container which comprises a bottom plate 5a made of an Invar and having a projection formed in the center thereof, and a frame 5b of alumina which is bonded to the peripheral portion of the bottom plate 5a. In this embodiment, the inner cylinder end portion 1d of the dewar 1 is made of an Invar.

It was decided to employ the above-described constituent materials on the basis of the results of a simulation carried out using a computer in the same way as in the first embodiment. Fig. 7 is a graph showing a distribution of stresses generated on the device surface of the infrared detector in this embodiment. As will be clear from the graph, the results of the analysis reveal that stresses generated on the surface of the device in this embodiment are in the range of -3.6 to 4.0 kgf/mm^2, and that the maximum stress in the detector of this embodiment is 4.0 kgf/mm^2, whereas the maximum stress in the conventional infrared detector, shown in Fig. 2, is 4.8 kgf/mm^2. Thus, in the detector of this embodiment, stresses generated in the device body are held down to a lower level than in the case of the conventional detector.

Further, the infrared detector of this embodiment also provides advantageous effects similar to those in the first embodiment. That is, the cooling efficiency is high, and intrusion of ambient light can be prevented. Further, it is easy to mount the detecting device in the dewar, and it is also easy to effect machining during formation of the container bottom plate.

Thus, in the infrared detector of the present invention, the infrared detecting device is mounted directly on the projection formed in the center of the container bottom plate. Therefore, the device can be efficiently cooled during the operation. Further, since the bottom plate is made of an Invar and the inner cylinder end portion is made of an Invar or a Kovar, it is possible to minimize stresses generated in the periphery of the bonded portion of the device when it is cooled to cryogenic temperatures. In addition, since the device is provided in the container and this container is disposed in the dewar, intrusion of ambient light can be prevent, and it is easy to handle the device when it is mounted in the dewar. Further, since the container bottom plate is made of an Invar, machining of the bottom plate is facilitated.

Although the present invention has been described through specific terms, it should be noted here that the described embodiments are not necessarily exclusive and that various changes and modifications may be imparted thereto without departing from the scope of the invention which is limited solely by the appended claims.

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Claims

1. An infrared detector including;

a dewar having an outer cylinder with a window for transmitting incident infrared radiation, and an inner cylinder united with said outer cylinder so as to form a space for inserting cooling means, and

an infrared detecting device accommodated in said dewar and driven while being cooled to a cryogenic temperature by said cooling means from the outside of said dewar,

wherein the improvement comprises a container for accommodating said infrared detecting device, said container including a bottom plate having a projection projecting inwardly of said container from an inner surface thereof, so that said infrared detecting device is secured to said projection of said bottom plate, said bottom plate being secured to an end portion of said inner cylinder which is disposed in said dewar, thereby disposing said container in said dewar.

2. An infrared detector according to Claim 1, wherein said bottom plate of said container for said infrared detecting device is made of an Invar.

3. An infrared detector according to Claim 1, wherein said container for said infrared detecting device comprises said bottom plate, a frame secured to said bottom plate to constitute a part of said container, and a cold shield secured to said frame to constitute a part of said container, and an upper surface of said infrared detecting device is secured to said frame.

4. An infrared detector according to Claim 1, 2 or 3, wherein said infrared detecting device comprises a semiconductor substrate having a first major surface and a second major surface.

5. An infrared detector according to Claim 3, wherein said infrared detecting device comprises a semiconductor substrate having a first major surface and a second major surface, said first major surface being connected to said frame through metallic conductors, said frame being provided with terminals, which are connected through metallic conductors to dewar internal conductors attached to a side surface of said inner cylinder inside said dewar, and said dewar internal conductors being connected through metallic conductors to external terminals provided on said outer cylinder of said dewar.

6. An infrared detector according to Claim 1, wherein said end portion of said inner cylinder of said dewar is made of a Kovar.

7. An infrared detector according to Claim 3, wherein said infrared detecting device comprises a semiconductor substrate having a first major surface and a second major surface, said first major surface being secured to said projection of said bottom plate, and said second major surface being bonded at a peripheral edge thereof to said frame.

8. An infrared detector according to Claim 2, wherein said Invar contains 36% Ni and 64% Fe.

9. An infrared detector according to Claim 6, wherein said Kovar contains 29% Ni, 17% Co, and 54% Fe.

10. An infrared detector including;

a dewar having an outer cylinder with a window for transmitting incident infrared radiation, and an inner cylinder united with said outer cylinder so as to form a space for inserting cooling means, and

an infrared detecting device accommodated in said dewar and driven while being cooled to a cryogenic temperature by said cooling means from the outside of said dewar,

characterized in that said infrared detecting device is a silicon infrared detecting device, and an end portion of said inner cylinder which is disposed inside said dewar is made of a Kovar or an Invar, said silicon infrared detecting device being accommodated in a container, said container including a bottom plate made of an Invar and having a projection projecting inwardly of said container from an inner surface thereof, so that said silicon infrared detecting device is secured to said projection of said bottom plate, said bottom plate being secured to said end portion of said inner cylinder of said dewar, thereby disposing said container in said dewar.

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Fig. 1

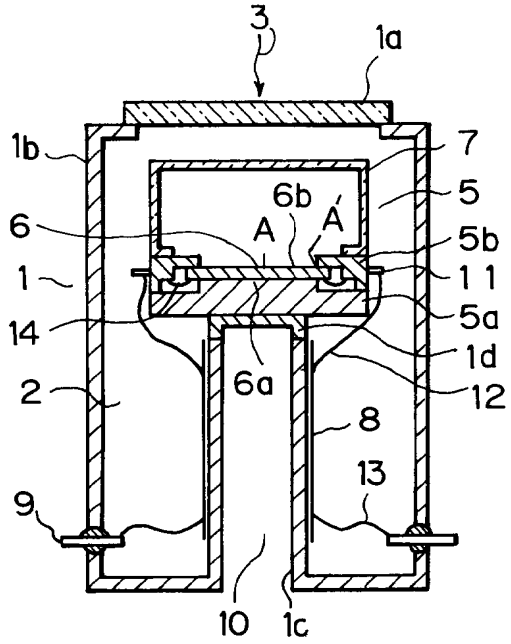


Fig. 2

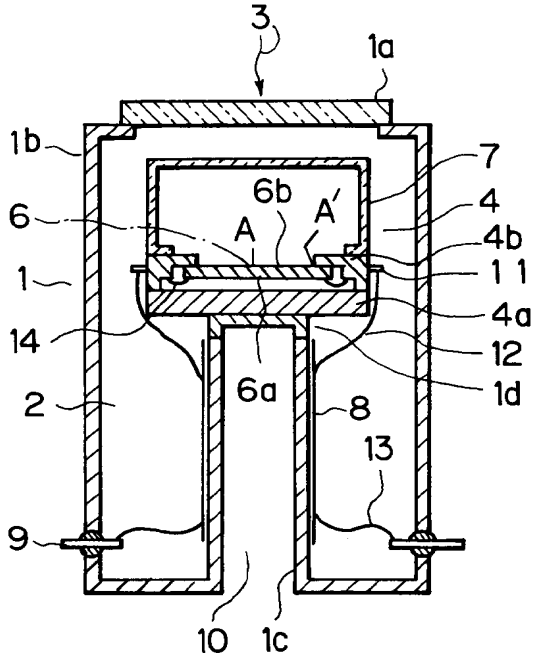


Fig. 3

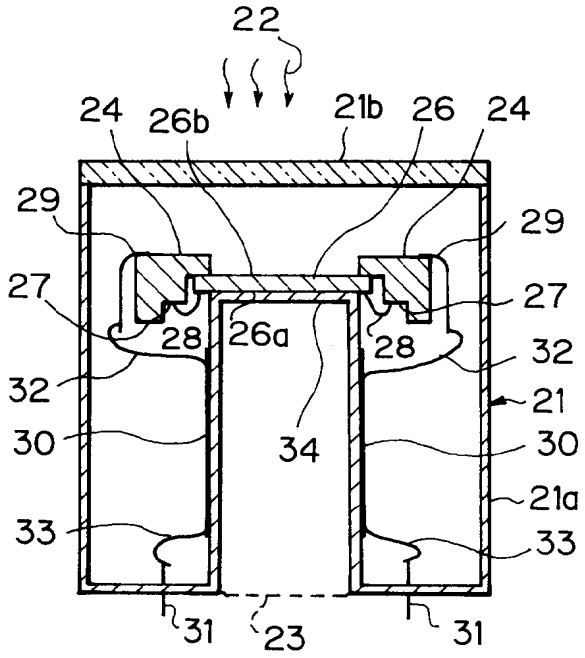


Fig. 4

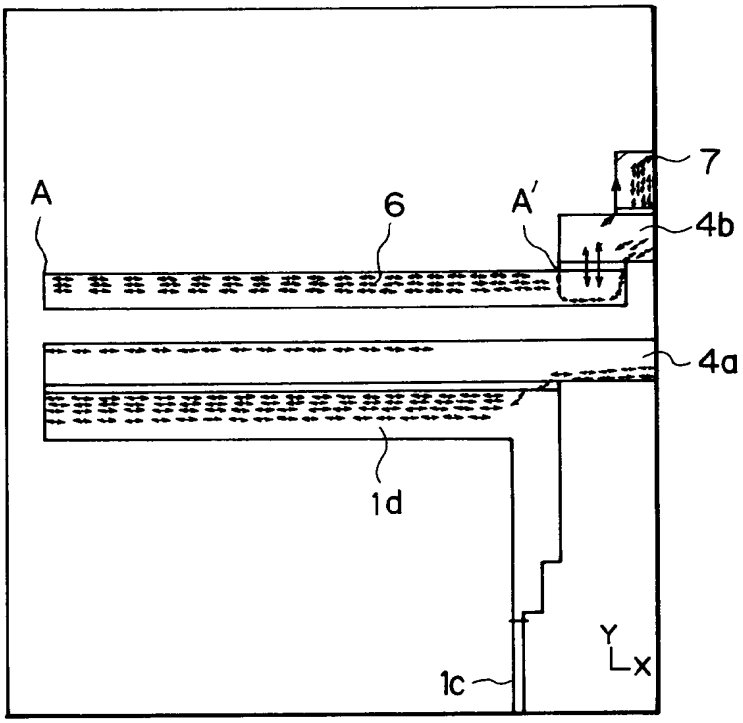


Fig. 5

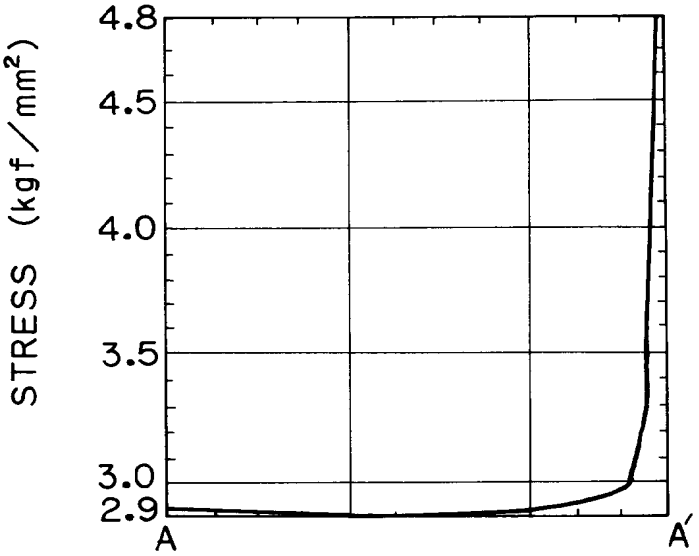


Fig. 6

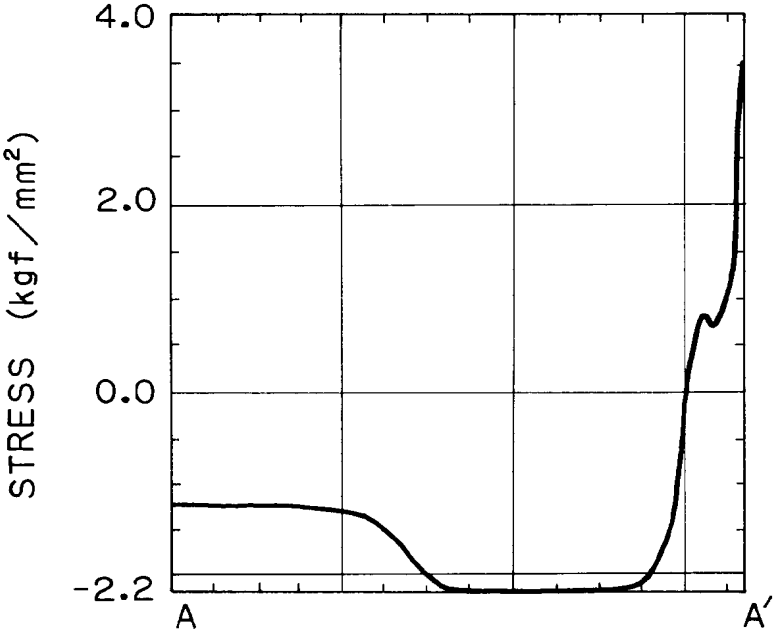
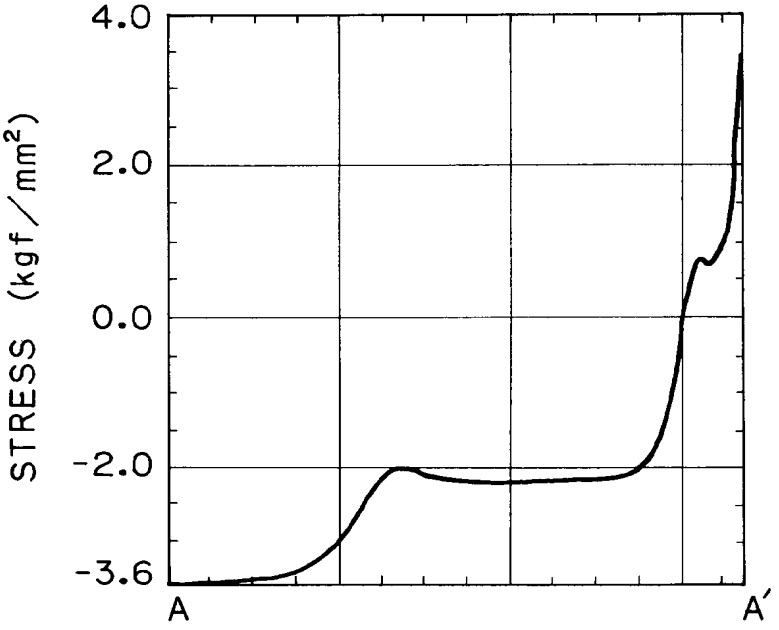


Fig. 7



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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 10 7668

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
D,Y	PATENT ABSTRACTS OF JAPAN vol. 14, no. 515 (E-1000)(4458) 13 November 1990 & JP-A-02 214 158 (MITSUBISHI ELECTRIC) 27 August 1990 * abstract *	1,4,10	G01J5/06 H01L31/024
A	---	5	
Y	PATENT ABSTRACTS OF JAPAN vol. 13, no. 26 (E-706)(3374) 20 January 1989 & JP-A-63 228 675 (NEC) 22 September 1988 * abstract *	1,4,10	

A	US-A-5 111 050 (MAASSEN ET AL.) * claims 1,7,9; figure 2 *	1,3-5,10	

A	EP-A-0 419 371 (SOFRADIR) * column 4, line 21 - column 5, line 52; figure 2 *	1,4,5,10	
	---		TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			G01J F25D H01L

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	27 AUGUST 1993	KRAMETZ E.M.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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(54) Title: STEMLESS PROSTHESIS ANCHOR COMPONENT

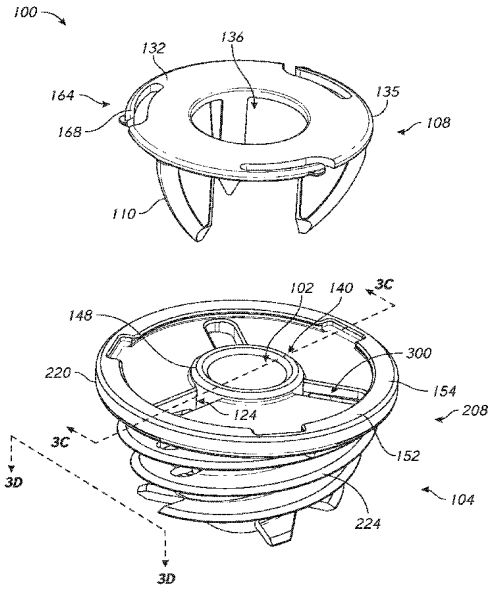


FIG. 2

(57) Abstract: A prosthesis assembly is provided that includes a base member (104) that has a helical structure (224) and one or more pathways. The helical structure extends between a first end and a second end. The pathway is accessible from the second end and is directed toward the first end through the helical structure. The pathway is located inward of an outer periphery of the helical structure, e.g., adjacent to an inner periphery of the helical structure. The pathway extends in a space between successive portions of the helical structure. The prosthesis assembly includes a locking device (108) that has a support member and an arm (110) that projects away from the support member. The arm is configured to be disposed in the pathway when the support member is disposed adjacent to the second end of the base member. The arm is disposed through bone in the space between successive portions of the helical structure when the prosthesis assembly is implanted.

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

STEMLESS PROSTHESIS ANCHOR COMPONENT

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present disclosure relates to a stemless prosthesis anchor component of a joint prosthesis.

Description of the Related Art

[0002] Skeletal joints have a variety of configurations providing for a wide range of smooth movement of two or more bones relative to each other. For example, in a shoulder joint, the head of the humerus interacts with the glenoid cavity of the scapula in a manner similar to a "ball and socket" joint. Over time, it may become necessary to replace a joint, such as the shoulder joint, with a prosthetic joint. The prosthetic joint can include components mounted to one, two or more than two bones at the joint. For example, the prosthetic joint can include a humeral component, a glenoid component or both a humeral and a glenoid component.

[0003] Conventional humeral components include a humeral head jointed to a stem. The stem is configured to be inserted into a medullary canal of the humerus. In certain cases, insertion of the stem disadvantageously requires bone to be removed to fit the stem to the medullary canal due to patient-to-patient anatomical variation. Another disadvantage of this approach is that integration of the stem into the bone through a natural process of bone ingrowth can make it difficult to remove the humeral component if it becomes necessary to replace the humeral component with another device.

[0004] A stemless humeral component may be used to address some of the disadvantages of conventional humeral components. Stemless humeral components can decrease the amount of bone loss in preparing the humerus to receive the component and decrease the complexity of the joint replacement procedure.

[0005] Stemless humeral component designs can be more challenging to secure to the humerus. Conventional stemless designs rely on bone ingrowth for strength. While such designs perform well over time, there is a risk in the early days and weeks after surgery where such ingrowth has not yet occurred that the stemless humeral component will be dislodged from the humerus. Dislodgement may also occur due to

backing out after being inserted, excessive wear, forces applied thereto during a revision surgery or other high load conditions.

SUMMARY OF THE INVENTION

[0006] Accordingly, there is a need for additional stemless components or prostheses designed to preserve bone in initial implantation while enhancing initial pull-out and back-out resistance. Preferably enhanced initial dislodgement resistance will also provide excellent long term fixation.

[0007] In one embodiment, a shoulder assembly is provided that includes a base member and a locking device. The base member includes a collar, a helical structure, and a first pathway projecting distally of the collar. The helical structure extends from the collar in a distal direction. The first pathway projects distally of the collar and through the helical structure. The first pathway is disposed adjacent to an inner periphery of the helical structure. The first pathway is generally transverse to the helical structure and extending in a space between successive portions of the helical structure. The locking device has a proximal support and a first arm that projects distally of the proximal support. The first arm is configured to be disposed in the first pathway that projects distally of the collar when the proximal support is disposed adjacent to the collar. The first arm is disposed through bone in the space between successive portions of the helical structure when the shoulder assembly is implanted.

[0008] In some embodiments, a kit can be provided that includes a shoulder assembly as described above, an anatomic articular component, and a reverse articular component. The anatomic articular component is mateable with the shoulder assembly. The anatomic articular component has a convex articular surface adapted to articulate with a concave surface of or on a scapula of a patient. The reverse articular component is mateable with the shoulder assembly. The reverse articular component comprises a concave articular surface adapted to articulate with a convex surface on a scapula of a patient. The reverse articular component can include a separate tray component for mating an articular surface to the base member.

[0009] In another embodiment, a prosthesis assembly is provided that includes a base member that has a helical structure and a first pathway. The base member has a first end and a second end. The helical structure extends between the first end and the second end. The first end comprises a distal or medial end in some applications. The second end comprises a proximal end or a lateral end in some applications. The first

pathway is accessible from the second end and is directed toward the first end through the helical structure. The first pathway is located inward of an outer periphery of the helical structure, e.g., adjacent to an inner periphery of the helical structure. The first pathway is generally transverse to the helical structure. The first pathway extends in a space between successive portions of the helical structure. The prosthesis assembly includes a locking device that has a support member and a first arm that projects away from the support member. The first arm is configured to be disposed in the first pathway when the support member is disposed adjacent to the second end of the base member. The first arm is disposed through bone in the space between successive portions of the helical structure when the prosthesis assembly is implanted.

[0010] The prosthesis assembly discussed above can be mated with a proximal humerus. The prosthesis assembly discussed above can be mated with other anatomy as well, such as a glenoid of a scapula. The prosthesis assembly discussed above can be mated with a bone adjacent to an elbow joint, such as a distal humerus or a proximal radius. The prosthesis assembly discussed above can be mated with a bone adjacent to a wrist joint, such as a distal radius. The prosthesis assembly discussed above can be mated with a bone adjacent to the hip, such as a proximal femur. The prosthesis assembly discussed above can be mated with a bone adjacent to a knee joint, such as a distal femur or a proximal tibia. The prosthesis assembly discussed above can be mated with a bone adjacent to an ankle joint, such as a distal tibia or a proximal talus

[0011] In another embodiment, a method of implanting a prosthesis is provided. The method includes advancing by rotation a base member into a bone adjacent to a joint. The bone can include an epiphysis of a humerus of a patient. The bone can include a glenoid of a scapula of a patient. The bone can include a distal portion of a humerus adjacent to an elbow joint. The bone can include a proximal portion of a radius adjacent to an elbow joint. The bone can include a distal portion of a radius adjacent to a wrist joint. The bone can include a proximal portion of a femur adjacent to a hip joint. The bone can include a distal portion of a femur adjacent to a knee joint. The bone can include a proximal portion of a tibia adjacent to a knee joint. The bone can include a distal portion of a tibia adjacent to an ankle joint. The bone can include a proximal portion of a talus adjacent to an ankle joint. The base member comprising a helical structure configured to engage cancellous bone of the epiphysis or other portion of any of the bones set forth above. A locking device is advanced by linear translation into

the base member. The locking device has at least one arm adapted to span a gap between adjacent portions of the helical structure. The locking device contacts the cancellous bone in the gap.

[0012] In another embodiment, a glenoid assembly is provided. The glenoid assembly includes a base member and a plate member. The base member has a medial end and a lateral end. The base member has a helical structure that extends between the medial end and the lateral end and a first pathway. The first pathway is accessible from the lateral end and is directed toward the medial end. The first pathway can extend through the helical structure and can be located inward of an outer periphery of the helical structure, e.g., adjacent to an inner periphery of the helical structure. The first pathway can be generally transverse to the helical structure and can extend in a space between successive portions of the helical structure. The plate member has a flange and a first arm that projects away from the flange. The first arm is configured to be disposed in the first pathway when the plate member is disposed adjacent to the lateral end of the base member. The first arm is disposed through bone in the space between successive portions of the helical structure when the prosthesis assembly is implanted.

[0013] Any feature, structure, or step disclosed herein can be replaced with or combined with any other feature, structure, or step disclosed herein, or omitted. Further, for purposes of summarizing the disclosure, certain aspects, advantages, and features of the inventions have been described herein. It is to be understood that not necessarily any or all such advantages are achieved in accordance with any particular embodiment of the inventions disclosed herein. No aspects of this disclosure are essential or indispensable.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] These and other features, aspects and advantages are described below with reference to the drawings, which are intended to illustrate but not to limit the inventions. In the drawings, like reference characters denote corresponding features consistently throughout similar embodiments. The following is a brief description of each of the drawings.

[0015] Figure 1 is a perspective view of one embodiment of a stemless shoulder assembly shown mounted in a humerus, and further illustrating a kit including anatomic and reverse shoulder articular components;

[0016] Figure 2 is an exploded view of the stemless shoulder assembly shown in Figure 1;

[0017] Figure 3A is a side view of the base member of Figure 2;

[0018] Figure 3B is a top view of the base member of Figure 2;

[0019] Figure 3C is a cross-sectional view of the base member of Figure 2 taken at section plane 3C-3C;

[0020] Figure 3D is a cross-sectional view of the base member of Figure 2 taken at section plane 3D-3D;

[0021] Figure 4 is a side view of one embodiment of a locking component, which is a component configured to control, e.g., reduce or eliminate and/or control rotation of a base member or of a helical structure of a prosthesis assembly;

[0022] Figure 5 is a top, proximal side, or medial side view of the locking component of the Figure 4;

[0023] Figure 6A is a detail view of one embodiment of an engagement feature that causes the locking component of Figure 4 and the base member of Figures 3A and 3B to be engaged;

[0024] Figure 6B is a detail view of another embodiment of an engagement feature that causes the locking component and the base member to be engaged at a location within the helical structure;

[0025] Figure 7 is a cross-sectional view of the stemless shoulder assembly of Figure 2 with the assembly disposed in the humeral head;

[0026] Figures 8-16 illustrate various methods for implanting a prosthesis assembly of Figures 1-7 into a portion of a bone;

[0027] Figure 17 is a side view of the stemless shoulder assembly of Figure 2 coupled with an anatomic articular component of the kit illustrated in Figure 1;

[0028] Figure 18A is a side view of the stemless shoulder assembly of Figure 2 coupled with a reverse articular component of the kit illustrated in Figure 1;

[0029] Figure 18B shows a reverse shoulder prosthesis including a reverse articular component coupled with the humerus and a convex glenoid component, sometimes referred to as a glenoid sphere, coupled with the scapula;

[0030] Figure 19 is a schematic side view of a glenoid of a scapula of a shoulder of a patient with a reverse shoulder prosthesis assembly disposed therein;

[0031] Figure 20 is a cross-sectional view of the reverse shoulder prosthesis assembly shown in Figure 19 taken at section plane 20-20;

[0032] Figure 21 is an exploded perspective view of the reverse shoulder prosthesis assembly illustrated in Figure 20 showing features of the articular surface of a glenoid sphere;

[0033] Figure 22 is an exploded view of the reverse shoulder prosthesis assembly illustrated in Figure 20 showing features of a bone engaging side of a plate member;

[0034] Figure 23 is a cross-sectional view of the reverse shoulder prosthesis assembly of Figure 20 taken at section plane 23-23 shown in Figure 22;

[0035] Figure 23A shows aspects of a base member of the shoulder assembly of Figure 19;

[0036] Figure 24 is a schematic side view of a proximal femur having a prosthesis assembly similar to that of Figures 1-7 disposed therein in connection with a hip joint procedure;

[0037] Figure 25 is a schematic side view of a distal portion of a long bone of an arm, e.g., of the humerus or radius, having a prosthesis assembly similar to that of Figures 1-7 disposed therein in connection with an elbow or wrist joint procedure;

[0038] Figure 26 is a schematic side view of a knee joint showing a prosthesis assembly similar to that of Figures 1-7 disposed in the distal femur and in the proximal tibia thereof;

[0039] Figure 27 is a schematic side view of an ankle joint showing a prosthesis assembly similar to that of Figures 1-7 disposed in the distal tibia and in the proximal talus thereof; and

[0040] Figure 28 shows comparative tip out performance of an embodiment as disclosed herein compared to a conventional stemless implant.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0041] While the present description sets forth specific details of various embodiments, it will be appreciated that the description is illustrative only and should not be construed in any way as limiting. Furthermore, various applications of such embodiments and modifications thereto, which may occur to those who are skilled in the art, are also encompassed by the general concepts described herein. Each and every feature described herein, and each and every combination of two or more of such features, is included within the scope of the present invention provided that the features included in such a combination are not mutually inconsistent.

[0042] Figure 1 shows a kit 80 that includes a shoulder assembly 100. The kit 80 can include one or both of an anatomic articular component 84 and a reverse articular component 88. The anatomic articular component 84 can comprise a one-piece structure including a convex articular surface 90 disposed on a proximal or lateral side and a tapered projection 92 disposed on a distal side thereof. The reverse articular component 88 can comprise a two-piece structure including a tray 94 and an insert 96. In other embodiments, the articular component 88 has a one-piece configuration. In other embodiments, the articular component 88 has a monolithic configuration. Monolithic embodiments can comprise a one material configuration. Monolithic embodiments can comprise two or more material. The insert 96 can mate with the tray 94 in any suitable manner, such as by interference fit or snap fit. The tray 94 can include a tapered projection 98. Figure 18B shows that the kit 80 also can include a glenoid sphere 99 and corresponding components for anchoring the glenoid sphere in a glenoid. The insert 96 is shown in just one embodiment in which the tray is angled, such that a plane intersecting the medial side of the insert 96 is at an angle to the side that faces the shoulder assembly 100 providing a thicker superior portion. In other embodiments the insert 96 is angled, such that a plane intersecting the medial side of the insert 96 is at an angle to the side that faces the shoulder assembly 100 providing a thicker inferior portion. In other embodiments the insert 96 is not angled, such that the plane intersecting the medial side of the insert 96 is substantially parallel to the side that faces the shoulder assembly 100.

[0043] Figure 1 shows the shoulder assembly 100, as further described below in connection with Figures 2-7, implanted in an exposed face F of a humerus H. The assembly 100 has a recess 102 in which further components of a prosthetic shoulder joint can be secured. The assembly 100 and the recess 102 enable the humerus H to be fitted with either an anatomical shoulder by receiving the anatomic articular component 84, more particularly, the projection 92 or a reverse shoulder component 88 by receiving the projection 98 either initially or as part of a revision procedure. Methods of using the kit 80 to implant the shoulder assembly 100 as part of a shoulder prosthesis are discussed below in connection with Figures 8-16. Figures 19-26 show that further embodiments can be used beyond humeral application and beyond shoulder joint procedures. Figure 27 illustrates the performance of certain embodiments compared to a prior art design. While incremental differences in these embodiments and methods are discussed below, it is to

be understood that features of each embodiment can be combined with features of the other embodiments, as appropriate.

I. HUMERAL SHOULDER ASSEMBLIES HAVING ROTATION CONTROL LOCKING DEVICES

[0044] Figures 1 and 7 show the shoulder assembly 100 applied to a shoulder joint. The assembly 100 can provide secure stemless connection to the humerus H. The shoulder assembly 100 provides for simple implantation because a base member thereof can be directly threaded into cancellous bone without being mated to another pre-placed base member. The shoulder assembly 100 can be fully retained within a head h of the humerus H. Figure 7 shows that the distal-most portion of the assembly 100 preferably can be disposed in the humeral head h. The assembly 100 does not have a stem or other member that protrudes beyond the head h into a medullary canal of the humerus. This approach is less invasive and simpler than procedures involving placement of a stem in a medullary canal. In other embodiments illustrated in part in Figure 10 by the creation of a recessed surface s having a depth accommodating a thickness of a proximal portion of the assembly 100, the assembly 100 may be recessed within the humeral head of the humerus H such that a proximal face 105 the assembly 100 is flush with respect to a cut surface of the bone.

[0045] Figure 2 shows that the assembly 100 includes a base member 104 and a locking device 108. The base member 104 is advanced into a bony structure such as cancellous bone in use. As discussed further below a bone surface may be exposed by resection or reaming, followed by threading of the base member 104 into a newly exposed bone surface. The assembly 100 also includes the locking device 108. The locking device 108 includes a plurality of arms 110. In particular, the arms 110 extend outward or distal from proximal support 132. The arms 110 can include a first arm, a second arm, and a third arm. The arms 110 can be circumferentially spaced equal distances from each other, e.g., about 120 degrees apart in one embodiment. In another variation, the arms 110 include three arms, with two of the three arms spaced 90 degrees from each other and a third arm spaced 135 degrees from one of the other two arms. The locking device 108 may include four or more arms 110. If the arms 110 include four arms, the arms can be circumferentially spaced 90 degrees apart. If the arms 110 include two arms, the arms can be circumferentially spaced 180 degrees apart. The arms 110 are

advanced through apertures 124 in the base member 104. In one embodiment, it should be noted that the number of arms 110 corresponds to an equal number of apertures 124. When so advanced, the arms 110 are disposed within the base member 104 in a manner that the arms 110 cross a space between portions, e.g., successive portions, of the base member 100. When so positioned, the arms 110 are also disposed within bone. Thus, two zones of the arms 110 can cross successive or adjacent portions of the base 104 and an intervening portion of the arms 110 can cross bone in a space between the successive or adjacent portion of the base. In this position, the arms 110 control, e.g., resist, rotation of the base member 104 relative to the bone such that the shoulder assembly 100 is secured against backing out of the bone upon implantation.

[0046] Figure 2 also shows that the locking device 108 also includes a proximal support 132. The proximal support 132 is coupled with the arms 110 in a manner discussed further below. The proximal support 132 has a central aperture 136 disposed within an inner periphery thereof and extends outward from the central aperture 136 to an outer periphery 135. The inner and outer periphery of the proximal support 132 are received in a recess 140 formed in the base member 104. In one configuration the recess 140 and the proximal support 132 are configured such that a flush connection is provided between the proximal support 132 and the proximal face of the base member 104. The proximal support 132 can be connected to the base member 104 in an at least partially recessed position in the proximal face of the base member as discussed further below in connection with Figure 6A.

[0047] Figures 2 and 3B show that the proximal face of the base member 104 can include a raised inner portion 148 and a raised outer portion 152. The outer raised portion 152 extends around an outer periphery 154 of the base member 104. The raised portion 148, 152 are proximally oriented projections relative to a recessed surface 156. The recessed surface 156 can be disposed distally of one or both of the inner portion 148 and the outer portion 152. The raised inner portion 148 can define an aperture for access into the recess 102, which is configured for mating with articular components as discussed below. Each of the raised inner portion and the raised outer portion 148, 152 can comprises annular structures. The recessed surface 156 can comprise an annular portion. The apertures 124 can be formed in the recessed surface 156. In one embodiment the apertures 124 extend radially between the inner raised portion 148 and

the outer raised portion 152. The apertures 124 can extend from the inner raised potion 148 to the outer raised portion 152.

[0048] The proximal face of the base member 104 also can include a tool interface 158 that enables the base member to be advanced by an inserter into bone, as discussed below in Figure 14. The tool interface 158 includes three notches in an inward side of the outer raised portion 152. In other embodiments, the tool interface 158 can include apertures in the recessed surface 156, notches in the inner raised portion 148, projections from any surface of the proximal face of the base member 104 or any combination of these features. Also, the tool interface 158 can provide access for a removal tool to engage the locking device 108. As discussed below, the locking device 108 includes a spring arm 168 and a removal tool can be applied at the tool interface 158 to compress the arm 168 to disengage the locking device from the base member 104. In some cases, an inserter tool can engage one or more apertures 124 in the base member 104 upon insertion.

[0049] One or more structures for securing the locking device 108 to the base member 104 can be provided as discussed further below. For example the locking device can have an engagement feature 164 disposed on the proximal support 132 that is adapted to engage a corresponding feature on the proximal face of the base member 104. The engagement feature 164 can include an actuatable member that can move into a secure position relative to the recess 140 of the base member 104. As discussed below in connection with Figures 5 and 6A, the engagement features 164 can include a spring arm 168 to engage an overhang of the recess 140. As shown in Figure 2, one embodiment comprises a plurality of actuatable members, e.g., a plurality of spring arms 168. The spring arms 168 can be spaced apart, e.g., providing equal angle separation between adjacent spring arms 168. In one embodiment, the number of spring arms 168 matches the number of arms 110. Each spring arm 168 can be spaced apart from each arm 110 as discussed further below.

[0050] In another embodiment, a serration 172 is provided between the arms 110 of the locking device 108 and the base member 104 as discussed in greater detail below in connection with Figure 6B. The serration 172 is an example of a one-way connection that can be provided between the arms 110 and the base member 104. Other one-way connections can be provided in addition or in place of the serration 172, such as a ratchet, a barb, or one or more spring arms.

[0051] Figures 2-3B show further details of embodiments of the base member 104. In some embodiments, the base member 104 can include various features described in PCT publication WO2016/094739, the entirety of which is hereby incorporated by reference herein. The base member 104 has a first end 204, a second end 208 and a body 212 that extends between the first end 204 and the second end 208. The base member 104 can comprise a length L between the first end 204 and the second end 208 that is less than a dimension of an articular surface of typical epiphysis to a medullary canal of a typical humerus. As such, the first end 204 can be disposed within the epiphysis when the second end 208 is at a surface of the bone, as shown in Figure 7. The second end 208 can be disposed at or on a superior medial resection plane of a humerus while the first end 204 is well within the epiphysis. This enables the first end 204 to stop short of a medullary canal of the humerus when the base 104 is fully implanted, which allows the bone between the first end 204 and the medullary canal to remain unaltered and also simplifies the procedure to the extent that any normal access to and preparation of the medullary canal is not needed. In various embodiments, the length L can be between about 15 mm and about 30 mm, between about 18 mm and about 25 mm, between about 18 mm and about 24 mm, between about 21 mm and about 27 mm, between about 24 mm and about 29 mm. The length L can be about 18 mm, about 21 mm about 23 mm, about 24, mm about 26 mm and about 29 mm. In one approach, at least a portion of the assembly 100 is patient specific. For example, the length L can be defined for a specific patient based on pre-operative planning, such as using two dimensional or three dimensional imaging. The base member 104 can thereafter be manufactured for that patient based on the determined dimension L.

[0052] The base member 104 can include a collar 220 and a helical structure 224. The helical structure 224 is disposed about a cylindrical portion 260 of the body 212 of the base member 104. In some embodiments, the helical structure 224 extends directly from the body 212 and may be considered threads of the body 212. The helical structure 224 can include one or a plurality of threads, e.g., two, three, four, or more threads, disposed between the first end 204 and the second end 208. The threads can start adjacent to the first end 204 and extend toward, e.g., entirely to the second end 208. Figure 3A shows that the threads or other helical structure 224 can end at or adjacent to the collar 220. The threads or other helical structure 224 can have inner portions 240 disposed at or on the body 212 about the recess 102 and outer portions 244 disposed

along the periphery of the base 104. Figure 3A shows that the helical structure 224 has a width defined as the distance between the inner and outer portions 240, 244 that is large, e.g., comprising more than one-quarter of, e.g., about one-third of, the width of the base 104 at a given location. These large threads or other helical structure 224 ensure large purchase in the bone. Large purchase provides strong resistance to pullout even prior to any bone ingrowth into the surfaces of the shoulder assembly 100. Generally one or more surfaces of the shoulder assembly 100 that are in direct contact with bone may be textured e.g., coated or layered with a porous material in order to accelerate tissue ingrowth such as bony ingrowth Therefor good initial resistance to pull-out is advantageous for the patient. At least one turn of a thread or other helical structure 224 completely surrounds the recess 102, e.g., by completely surrounding the body 212, in some embodiments.

[0053] The body 212 surrounds the recess 102, which is configured to mate with an articular component, such as humeral head or a glenoid sphere. In one embodiment, the body 212 includes a cylindrical portion 260 within which the recess 102 is disposed. The cylindrical portion 260 can have any suitable outside configuration, such as including a textured surface that is well suited to encourage bony ingrowth. The cylindrical portion 260 can include a generally tapered profile in which a portion at or adjacent to the first end 204 of the base member 100 has a first width and a portion at or adjacent to the second end 208 of the base member 100 can have a second width, the second width being greater than the first width. In some embodiments, the cylindrical portion 260 is generally rounded and formed a blunt but tapered profile. The cylindrical portion 260 can have a flat distal surface in some embodiments.

[0054] Figure 7 shows that the cylindrical portion 260 can include a plurality of layers. For example, an inner layer 264 can be disposed adjacent to the recess 102. The inner layer 264 can include the surface surrounding the recess 102 and can extend away from that surface toward an outer surface of the cylindrical portion 260. In one embodiment an outer layer 268 can be disposed adjacent to the outer surface of cylindrical portion 260. The outer layer 268 can extend from the external surface of the cylindrical portion 260 toward the recess 102. In one embodiment, the outer layer 268 is formed directly on the inner layer 264 although other arrangements are possible as well. The outer layer 268 can be a porous structure that is suitable for bony ingrowth.

[0055] Figure 7 also shows that a tool interface 272 can be disposed at or adjacent to the first end 204 of the base member 104. The tool interface 272 can include

a threaded portion that can mate with a delivery tool, as discussed further below. A lumen 276 can be provided at the first end 204 such that access can be provided from the first end 204 through the wall of the cylindrical portion 212 into the recess 102. The lumen 276 and recess 102 together provide access for a K-wire or other guiding device such that implanting the base member 104 can be controlled in an appropriate manner.

[0056] The collar 220 can be disposed at or can comprise the second end 208 of the base member 104. The collar 220 can have a transverse width, e.g., a diameter that is suitable for a given condition. For example, the diameter of the collar 220 can be selected such that the entire outer periphery of the base 104 is within the bone exposed by resection and/or recessed into such an exposed bone portion, e.g., as illustrated in Figures 8-12. In some embodiments the collar 220 has a diameter of more than about 25 mm and less than about 60 mm. The collar 220 can have a diameter of between about 30 mm and about 45 mm. The collar 220 can have a diameter of about 33 mm in one embodiment. The collar 220 can have a diameter of about 42 mm in one embodiment. Making the collar 220 as large as possible within such bounds provides for better load transfer between the collar 220 and the humerus H. In one approach, the diameter of the collar 220 can be defined for a specific patient based on pre-operative planning, such as using two dimensional or three dimensional imaging. The base member 104 can thereafter be manufactured for that patient based on the determined diameter of the collar. For example, the diameter of the collar 220 can be selected such that the collar covers the cortical rim exposed by resection. The collar 220 can attach to or can be integrally formed with the cylindrical portion 260 of the body 212. In one embodiment the collar 220 comprises a transverse flange 290 that extends outward of the recess 102 that is also disposed at the second end 208. An inner portion of the flange 290 can be disposed adjacent to the recess 102 and can include the inner raised portion 148. An outer portion of the flange 290 can be disposed outward of the inner portion. The flange 290 can define the proximal face of the base member 104. The flange 290 can accommodate the proximal support 132 of the locking device 108. Figure 6A shows that in some embodiments, the flange 290 can at least partially surround a space 294 disposed therein to receive a portion of the locking device 108. The space 294 can be an annular recess located proximal of the recessed surface 156 and between the inner portion 148 and the outer portion. The space 294 can be bounded by an inner edge of the outer portion 152 and an outer edge of the inner portion 148. The flange 290 can engage the spring arm

168 of the locking device 108 in the space 294 such that the locking device 108 will not be inadvertently disengaged from the base 104 and protrude from or be removed from the space 294.

[0057] Figures 2 and 7 show that in some embodiment, the shoulder assembly 100 includes a pathway 300 that projects distally of the collar 220. The pathway 300 can comprise a first pathway. The shoulder assembly 100 can include a plurality of pathways, 300 with each pathway corresponding to an arm 110 of the locking device 108. Figure 3B shows that the base 104 can define a plurality of such pathways, e.g., two or three pathways configured to receive corresponding arms 110. There can be four or more than four pathways 300. The pathway 300 can have a first end located at the opening or apertures 124 in the collar 220. The pathway 300 can continue down through the base member 104. Figure 3C shows that the pathway 300 can have one or more segments disposed through the helical structure 224. A first segment 300A of the pathway 300 extends from the aperture 124 to a first portion, e.g., a proximal-most turn or portion of the helical structure 224 immediately distal of the collar 220, e.g., immediately distal of one of the apertures 124. A second segment 300B of the pathway 300 extends from the first segment 300A to a second turn or portion of helical structure 224 immediately distal of the first portion of the helical structure. A third segment 300C of the pathway 300 can extend from the second segment to a third turn or portion of helical structure 224 immediately distal of the second portion of the helical structure 224.

[0058] Figures 3A and 3D illustrate that at specific locations along the length of the base 104 from the first end 204 to the second end 208, the pathway 300 can have a first boundary 304 corresponding to an outer surface or layer of the cylindrical portion 260, for example corresponding to a surface of the outer layer 268. The pathway 300 can have a second boundary 308 at a same location along the length of the base 104 from the first end 204 to the second end 208 formed by an adjacent portion of helical structure 224. The second boundary 308 can include a U-shaped opening in the inner portion 240 of the helical structure 224. The U-shaped opening in the inner portion 240 can extend across the width of the helical structure toward the outer portion 244 of the helical structure 224. The U-shaped opening can extend 25%, 35%, 45%, 50%, 60%, 70%, 75% or up to 90% of the distance across the width of the helical structure 224 from the inner portion 240 toward the outer portion 244. In one embodiment, the helical structure 224 has a tapered configuration in which transverse distance between opposite sides of the helical structure

224 is decreased in the direction of the first end 204 compared to the same dimension toward the second end 208. The length of the U-shaped opening in successive portions of the helical structure 224 in the direction toward the first end 204 is progressively less in some embodiments. As a result the width bounded by a turn of the helical structure 224 and the cylindrical portion 260 in the first segment 300A of the pathway 300 can be greater than the width bounded by a turn of the helical structure 224 and the cylindrical portion 260 in the second segment 300B. The width in the second segment 300B can be greater than the width in the third segment 300C bounded by a turn of the helical structure 224 and the cylindrical portion 260. This configuration is advantageous in accommodating embodiments of the locking device 108 having arms 110 that are tapered as discussed further below.

[0059] The pathway 300 can extend through one or more spaces between adjacent threads of the helical structure 224. The pathway 300 can comprise two or more segments surrounded by portions of the base member 104 and at least one exposed segment ES. The exposed segments comprise portions of the first and second segments 300A, 300B and between the second and third segments 300B, 300C in some embodiment. The exposed segments ES are exposed in that, unlike the segments 300A, 300B, 300C, the exposed segments of the pathway 300 are not enclosed circumferentially and thus bone disposed within the helical portion 224 can directly contact the arms 110 in the exposed segment. As such the pathway 300 is bounded by bone matter in the exposed segments.

[0060] Figures 2, 4 and 5 show the locking device 108 in detail. As discussed above, the locking device 108 has a proximal support 132 and a first arm 110 that projects distally of the proximal support 132. The proximal support 132 includes an inner periphery 358, an outer periphery 362 and an annular member 366 disposed therebetween. The inner periphery 358 surrounds the central opening 136, which is sized to receive the inner raised portion 148 of the base member 104 if present. The annular member 366 is configured to be received in the recess 140, as discussed above.

[0061] The first arm 110 is configured to be disposed in the first pathway 300. The pathway 300 projects distally of the collar 220. The first arm 110 is disposed distal of the collar 220 when the proximal support 132 is disposed adjacent to a proximal side of the collar 220 and the first arm 110 is in the first pathway 300.

[0062] The first arm 110 includes an outer edge 370, an inner edge 374 and a span 378 disposed therebetween. The first arm 110 includes a first end 382 disposed away from the support 132 and a second end 386 disposed adjacent to and in some cases directly coupled to the support 132. The first arm 110 can be tapered, for example with the outer edge 370 approaching the inner edge 374 in the direction toward the first end 382 and/or with the outer edge 370 diverging away from the inner edge 374 in the direction toward the second end 386. In one embodiment, opposite faces 390 of the span 378 are also tapered with at least one of, e.g., both of, the opposite faces 390 approaching a longitudinal mid-plane M of an arm 110. The tapering of the arms between the edges 370, 374 facilitates providing a tapered profile in the base member 104. The tapering of the arms between the edges 370, 374, sometimes referred to herein as a radial taper, facilitates insertion of the first end 382 into the aperture 124 because the first end 382 is much narrower in the dimension between the edges 370, 374 than the aperture 124 is in the radial direction. The tapering of the arms 110 between the faces 390, sometimes referred to herein as a circumferential taper, facilitates insertion of the first end 382 into the aperture 124 because the first end 382 is much narrower in the dimension between the faces 390 than the aperture 124 is in the circumferential direction.

[0063] At least one of the circumferential and radial tapers of the arms 110 enables the locking device 108 to easily be advanced through bone matter that is disposed along the pathway 300.

[0064] As discussed above, the first arm 110 is disposed through bone in the space between successive portions of the helical structure 224, e.g., in the first segment of the path 300 and in the second segment of the path 300, when the humeral shoulder assembly is implanted. The span 378 and/or other parts of the arms 110 can be porous to enhance bony ingrown when the assembly 100 is implanted. The porous properties can be provided by a porous metal surface or structure or by other porous layers disposed on an underlying layer of metal or another material. At least the widening of the arms 110 toward the second end 386 increases the purchase of bone in the widened area, e.g., in the first segment of the path 300 and also in the second segment of the path 300 compared to an arm that is not tapered.

[0065] In some embodiments, the arms 110 are not tapered in the radial direction. For example the arms 110 can have a constant radial dimension between the edges 370 and 374 at a length between, e.g., along the entire length between, the first end

382 and the second end 386. In some embodiments, the arms 110 are not tapered in the circumferential direction. For example the arms 110 can have a constant circumferential dimension between the first end 382 and the second end 386.

[0066] As discussed above, the locking device 108 facilitates retaining the base member 104 in the bone at least by opposing, and in some cases completely preventing, rotation of the base member that would cause the base member to back out of the bone into which it has been advanced. Additionally, in some embodiments, it is beneficial to oppose, and in some cases completely prevent, axial movement of the locking device 108 away from the base member 104. At the extreme, such movement could result in the arms 110 of the locking device 108 completely coming out of the pathways 300 and, indeed, out of the base member 104 completely. It also may be desirable to prevent even lesser movements of the locking device 108 relative to the base member 104. As shown in Figure 6A, a distal face 402 of the annular member 366 may be positioned in direct contact with a proximal face 404 of the transverse flange 290. Such contact can correspond to a proximal face 406 of the annular member 366 being distal of a proximal face 408 of the raised outer portion 152. By recessing the annular member 366, the interaction of the assembly 100 with the articular member of the kit 80 of Figure 1 is controlled. For example, the annular member 366 will not impede advancement of the articular members into secure engagement with the recess 102.

[0067] Figures 5 and 6A illustrate various embodiments of axial locking configuration that can be provided in the shoulder assembly 100. An axial locking configuration can include the engagement feature 164 disposed on the proximal support 132. The spring arm 168 of the engagement feature can include a first end 420 disposed away from the annular member 366 and a second end 424 coupled with the annular member 366. The spring arm 168 also has an elongate portion 428 that extends between the first end 420 and the second end 424. The elongate portion 428 preferably has an arcuate form and can, in some embodiments, have the same curvature as a portion of the annular member 366 adjacent to the second end 424. The elongate portion 428 can be separated from the annular member 366 along a radially inner edge 432 of the elongate portion 428 by a gap G. The gap G and the length of the elongate portion 428 can be such that the first end 420 can be moved sufficiently to allow for a snap-fit connection as discussed further below. In one embodiment, the first end 420 of the spring arm 168 has a deflector 436 that facilitates movement of the elongate portion 428 and specifically

movement of the first end 420. Figure 6A shows that the deflector 436 can include an angled surface 460 that initially engages a corresponding angled surface 464 on the base member 104, e.g., on the raised outer portion 152 at the proximal face of the base member. As the arms 110 of the locking device 108 are advanced into the paths 300, the annular member 366 eventually is received in the space 294. At that time, the angled surfaces 460, 464 engage each other, which engagement causes the deflection of the first end 420 of the spring arm 168. The first end 420 is deflected radially inwardly such that the gap G is reduced at least at the first end 420. This allows a proximal facing surface 472 to move to a position distal of a distal facing surface 476. After the proximal facing surface 472 is at a position distal of the distal facing surface 476, the spring arm 168 resiliently moves the deflector 436 back to the configuration shown in Figure 5. At this point, the proximal facing surface 472 is distal of and aligned with, e.g., positioned under, the distal facing surface 476, as shown in Figure 6A. In this configuration, the proximal facing surface 472 blocks the distal facing surface 476 from moving proximally. Thus the surfaces 472, 476 prevent the locking device 108 from disengaging from the base member 104.

[0068] Another advantageous aspect of the assembly 100 is that the locking device 108 can be quickly and easily disengaged from the base 104. The tooling interface 158 allows an extraction tool to be disposed between the raised outer portion 152 and the spring arm 168. The extraction tool can apply a radially inward force on an outer periphery of the elongate portion 428 of the spring arm 168. Compression of the spring arm 168 decreases the gap G as the proximal facing surface 472 is moved radially inward of the distal facing surface 476. Once the first end 420 is entirely radially inward of the distal facing surface 476, the engagement feature 164 is disengaged from the base 104. If more than one spring arm 168 is provided some or all of the spring arms can be compressed to allow the locking device 108 to be withdrawn from the base 104.

[0069] Figure 6B shows additional axial locking configurations that can be provided in the shoulder assembly 100. In these embodiments, axial locking can occur at an interface 490 between one or more of the arms 110 and one or more of the pathways 300. For example, the serrations 172 discussed above can be provided at the interface. In one variation, serrations 172 are disposed along the pathway, e.g., on a surface of the cylindrical member 212 and/or on a surface of the helical structure 224. The serrations 172 can be placed at both the surface of the cylindrical member 212 and at the helical

structure 224. In another embodiment, the serrations 172 could be provided on a surface of the arm 110, e.g., on one of the outer edge 370, the inner edge 374, and/or on one of the faces 390. The serrations 172 allow for relatively easy insertion of the arms 110 but bite into and oppose withdrawal of the locking device 108 to oppose axial disengagement of the locking device 108 from the base member 104.

[0070] The serrations 172 can be disposed along the entire length of the interface between the arms 110 and the base member 104 or just at a position where the base member 104 and the locking device 108 are fully engaged.

II. METHOD OF APPLICATOIN TO AN END PORTION OF A LONG BONE

[0071] Figures 8-16 illustrate various techniques for implanting the shoulder assembly 100 in a humerus H. The method illustrates placement in a proximal end of the humerus H, e.g., in the humeral head h.

[0072] Figure 8 illustrates an early step of one embodiment of a method including resecting the head h of the humerus H. Prior to resecting the head h of the humerus H a guide 600 is applied to the humerus H. The guide 600 includes structure for mating with the humerus H and the head h, for example, a plate 604 to mate with the humerus H and pins 608 to mate with the head h. The guide 600 also has a slot 612 to guide a saw to cut the humerus H to expose cancellous bone of the head h. Figure 9 shows that after resecting the head h of the humerus H the size of the head is evaluated with a template 620. To obtain a quick and accurate sizing, a guide pin 624 is first placed in the resected head h. The template 620 is advanced over the guide pin 624 into contact with the resected head. The size of the resected head h is determined from the template 620. The guide 600 can be a reusable guide that is not specific to any particular patients. In other embodiments, the guide 600 is formed with reference to a specific patient. That is, the guide 600 can be formed to mate with the patient, such as by conforming in whole in part on a bone facing side to the shape of the bone as observed or measured using imaging or other devices prior to surgery.

[0073] Figure 10 shows that the resected surface of the head h can be prepared, such as by using a planar or a reamer 632. The reamer 632 also can be guided by the guide pin 624. The reamer 632 can be used to form a recessed surface s to which the assembly 100 will be applied after further preparation.

[0074] Figure 11 shows a step of measuring depth of the recessed surface s. The purpose of this step is to provide a secondary confirmation that the assembly 100 will fit into the metaphysis without striking the lateral cortex. While the analysis of Figure 9 indicates a diameter of base member 104 that could be used, the depth gauge 637 of Figure 11 provides a depth sizing that confirms a maximum length, e.g., depth, that would fit in the recessed surface S surgeon is instructed to take the smaller of the two sizes determined.

[0075] Figures 12 illustrates that following depth measurement, a bore b is formed in the surface s in initial preparation of the surface s to receive the shoulder assembly 100. The bore b is formed using a drill 640. The drill 640 can be a convention cannulated design configured to be advanced over the guide pin 624. The drill 640 can be configured as a universal drill with a modular stop to obtain variable lengths. The drill 640 can be one of a plurality of drills, each drill of the plurality having a different size as appropriate. In certain methods, the process of forming the bore b and reaming the surface s as discussed above in connection with Figure 10 can be combined. For example, a drill 640 can have a reaming feature disposed proximally of the bore forming features such that a continuous motion toward the surface formed using the guide 600 can initially form the bore b and subsequently form the surface s. Figure 13 shows that once the bore b has been formed, the bore b can optionally be tapped to be prepared to receive the base member 104 of the shoulder assembly 100. The tapping process can be achieved by using a helical tap component 648 that is advanced over the guide pin 624. The helical tap 648 can follow the form of the helical structure 224 of the base member 104 such that the base member 104 can be easily advanced into the bore. The helical tap 648 can be secured to a shaft 654 that can be mounted to a motor driven drill or to a hand tool.

[0076] Figure 14 shows a step of inserting the base member 104. The base member 104 is secured to a distal end of an inerter 662. The inserter 662 has a stem 666 that is threaded at a distal end thereof. The threads of the stem 666 can be mated with the tool interface 272 (see Figure 7), e.g., with threads of the tool interface. Preferably the stem 666 is enlarged at a mid-section thereof providing at least a shoulder that can mate with the inner raised portion 148 of the base member 104. A separate member 668 of the inserter 662 is advanced over the stem 666 to the tool interface 158, and the force of advancing the base member 104 thus can be applied through the tool interface 272, through the inner raised portion 148, through the apertures 124 or through more than one

of these (or other) features of the base member 104. Splines 672 provide for good grip by the surgeon so that the surgeon can easily engage the stem 666 to the tool interface 272. In another variation, a driver with a torqueing device at a proximal end couples at its distal end directly with the tool interface 272, through the inner raised portion 148, through the apertures 124 or through more than one of these (or other) features of the base member 104 to enable more direct transfer of torque to the base member. Preferably inserting the base member 104 into the bone includes placing the outer periphery 154 in the recessed surface s, e.g., at least partially recessed into the resected bone of the humerus H.

[0077] Figure 15 shows that after the base member 104 has been inserted, the locking device 108 can be inserted. The base member 104 is inserted by a rotation of the member by rotation of the inserter which is directly connected to the base member as discussed above in connection with Figure 14. The locking device 108 is inserted along the pathway by linear translation, e.g., by a movement along a generally straight axis without rotation. An inserter 680 is provided that has an enlarged head 682 that can be secured to or can just rest upon the proximal face of the annular member 366 of the proximal support 132. The head 682 is then advanced over the splines 672 of the stem 666, with the stem 666 acting as an axial guide. In order to implant the locking device 108 the first end 382 of the arm 110 or arms is aligned with the aperture 124 or apertures if more than one. The arms 110 are radially and circumferentially tapered and the apertures 124 are sized for the wider proximal end of the arms.. This configuration helps guide the locking device 108 into the base member 104. The proximal end 684 of the inserter 680 in configured for impacting the locking device 108 into the base member 104.

[0078] Figure 16 shows later steps of a method of implanting an anatomic shoulder prosthesis. After the base member 104 and the locking device 108 are placed, an anatomic articular component 84 can be coupled with the recess 102. The anatomic articular component 84 comprises a convex surface 90, analogous to the natural anatomy. The anatomic articular component 84 is placed with an impactor 684A. Although shown as a separate, dedicated device the insertion and impaction functions illustrated in Figures 15 and 16 could be carried out by the same device. For example a contoured face to contact the surface 84 could have a portion configured for inserting the locking device 108 and/or the tray 94. Figure 16 shows an alternative step of a method of implanting a

reverse shoulder prosthesis. After the base member 104 and the locking device 108 are placed, a reverse articular component 88 can be coupled with the recess 102. In one form, the reverse articular component 88 includes a tray 94. The tray 94 can be coupled with an articular component 96 comprising a concave surface for articulating with a glenoid sphere disposed on a glenoid of a scapula (discussed further below). The tray 94 is placed with an impactor 684A. The reverse shoulder prosthesis including the shoulder assembly 100, the tray 94 and the articular component 96 is shown in Figures 18A and 18B. A glenoid sphere 99 mated with a glenoid is shown in Figure 18B. The shoulder joint provides movement of the patient's arm by articulating the component 96 over the glenoid sphere 99.

[0079] In one variation of these methods, assemblies, and kits the locking device 108 is inserted at the same time as some or all of the reverse articular component 88 or at the same time as the anatomic articular component 84. The locking device 108 can be a separate component that is loaded onto an inserter or impacting tool that can be previously loaded with the reverse articular component 88 or the anatomic articular component 84. The locking device 108 can be a separate component that is loaded onto an inserter or impactor with, but relatively moveable to, the reverse articular component 88 or the anatomic articular component 84. The locking device 108 and the reverse articular component 88 can be formed as a monolithic structure that can be loaded together onto an inerter. The locking device 108 and the anatomic articular component 84 can be formed as a monolithic structure that can be loaded together onto an inerter.

III. ADDITIONAL APPARATUSES AND METHODS

[0080] Figures 19-23 illustrate a shoulder assembly 800 that is adapted for securement to a glenoid. The shoulder assembly 800 is similar to the shoulder assembly 100 described above, except as described differently below. Any feature discussed above can be substituted in and supplement the features of the shoulder assembly 800. The features of the shoulder assembly 800 can be substituted in and supplement the features of the shoulder assembly 100.

[0081] Figure 19 shows that the shoulder assembly 800 can be implanted into a glenoid region g of a scapula SC. The shoulder assembly 800 includes a base member 804 and a plate member 808. The base member 804 has a medial end 816 and a lateral end 820. Figures 21-23 show that the base member 804 includes a body 812 that extends between the medial end 816 and the lateral end 820. A lumen 822 extends in the body

812 from the lateral end 820 toward and in some cases entirely to the medial end 816. A distal portion of the lumen 822 includes a threaded zone 823, discussed below. The base member 804 includes a helical structure 824, which is disposed along the body 812 between the medial and lateral ends 816, 820, respectively. The helical structure 824 extends from the medial end 816 to the lateral end 820 in some embodiments. In some embodiments a tool interface 826 is disposed lateral of a lateral end of the helical structure 824.

[0082] The base member 804 includes a first pathway 830 accessible from the lateral end 820 of the base member 804. The first pathway 830 is directed toward the medial end 816 through the helical structure 824. The first pathway 830 can be located adjacent to an inner periphery of the helical structure 824, as discussed above. The first pathway 830 can be partly defined by an outer surface of the body 812. The first pathway 830 can be disposed generally transverse to the helical structure 824. The first pathway 830 extends in a space 832 between successive portions of the helical structure 824. In one embodiment, a first segment 830A of the first pathway 830 is disposed through a proximal portion of the helical structure 824, a second segment 830B of the first path 830 is located medial of the first segment 830A, and a third segment 830C of the first path 830 is disposed medial of the second segment 830B. Figure 23A shows the segments 830A, 830B, 830C of the path 830 in more detail.

[0083] Figure 23A also shows that the base member 804 can include one or more barbs 835. The barbs 835 are configured to facilitate softer material attachment. In some embodiment the internal portion of the base member 804 couples with a structure made of a soft material, such as polyethylene. One example of such an assembly is an anatomic configuration where a convex articular surface may be coupled with the scapula using the base member 804. Another example is a reverse configuration with an inverse bearing surface (e.g. polyethylene glenoid sphere). The mode of connection between the base 804 and an articular or other component can include an interference fit between the barbs 835 and a projection of such component received in a space around which the barbs 835 are located, as described in connection with Figures 8A and 8B of WO2016/094739. In other embodiments the barbs 835 can be replaced with mating threads, mating threads and fins and/or mating fins, as described in connection with Figure 2 of US20120221111. In other embodiments, the barbs 835 can be replaced by a groove and a C-ring or other deflectable member that spans between the base member 804 and an articular or other

component as described in connection with Figures 4 and 5 of WO2014/067951. The entireties of each of WO2016/094739, US20120221111, and WO2014/067961, including the specific portions of each reference noted above are incorporated by reference herein.

[0084] The plate member 808 has a flange 842 and a first arm 846 that projects distally, medially away from or generally in a direction of implantation of the plate member 808 from the flange 842. The plate member 808 can have a second arm 846 that projects away from the flange 842. The first arm 846 is configured to be disposed in the first pathway 830 when the plate member 808 is disposed adjacent to the lateral end 820 of the base member 804. The first arm 846 is disposed through bone in the space 832 between successive portions of the helical structure 824 when the shoulder assembly 800 is implanted.

[0085] The plate member 808 also includes a boss 850 that extends laterally of the flange 842. The boss 850 comprises an arcuate outer periphery 854 and an aperture 858 that provides access to a lumen 862 through the aperture 858. The lumen 862 is defined by a tapered surface 864 that mates with a glenoid sphere 870, as discussed below. In another embodiment, the glenoid sphere 870 and the boss 850 are configured such that the glenoid sphere 870 coupled with the outer surface of the boss 850.

[0086] The glenoid sphere 870 comprises a recess 874 disposed on a medial side and a convex side 878 disposed opposite the recess 874. The glenoid sphere 870 has a tapered surface 882 disposed within the recess 874. The tapered surface 882 is partly disposed in the recess 874 and partly extends medially of the recess 874. The tapered surface 882 is disposed on a projection 890. The boss 850 receives the projection of the glenoid sphere 870 therein. The tapered surface 864 on the boss 850 mates with the tapered surface 882 on the medial side of the glenoid sphere 870 to form a connection between the glenoid sphere 870 and the plate member 808. The mating tapered surfaces 864, 882 can form a Morse taper connection between the glenoid sphere 870 and the plate member 808.

[0087] Figure 23 illustrates further features of the shoulder assembly 800 that relate to connecting the components thereof together. The glenoid sphere 870 has a lateral opening 892 at the convex surface 878. The opening 892 extends to a lumen 894 that extends from the opening 892 to a medial opening 898. The lumen 894 includes a threaded zone 902 adjacent to the medial opening 898. The threaded zone 902 can be used to couple the glenoid sphere 870 with an inserter. That is the threaded zone 902 can

be threaded onto a corresponding threaded tip of the inserter. While threads are shown, other couplers can be used, such as a bayonet coupling in place of or along with the threaded zone 902.

[0088] A fastener 910 is used to secure the glenoid sphere 870, the plate member 808, and the base member 804 together. The fastener 910 includes a medial end 914 with a threaded zone 918 and a lateral end 922. The lateral end 922 includes a tool interface 926.

[0089] The connection between the components of the shoulder assembly 900 is shown in Figure 20. The base member 804 can be advanced into the glenoid g following preparations similar to that discussed in connection with of Figures 8-13. Once so placed, the plate member 808 can be advanced into the base member 804. The plate member 808 is advanced in a manner similar to the locking device 108. The arms 846 are advanced into the helical structure 824. Following placement of the plate member 808 into the base member 804, the glenoid sphere 870 can be mated to the plate member. The projection 890 can be advanced into the lumen 862 (see Figure 23). Once the projection 890 is placed in the lumen 862 the fastener 910 can be advanced relative to the projection 890 and mated with the threaded zone 823. Further advancing of the fastener 910 into the threaded zone 823 induces a friction fit, e.g., a Morse taper, at the tapered surfaces 864, 882. In one embodiment, the threaded zone 918 of the fastener 910 engages first the threaded zone 902 of the glenoid sphere 870 and then mates with the threaded zone 823. In that embodiment, if the threaded zone 918 inadvertently disengage from the threaded zone 823 the back-out of the fastener 910 is limited such that the lateral end 922 of the fastener 910 does not protrude outside of the convex side 878 of the glenoid sphere 870. For example, even if the threaded zone 918 is disengaged form the threaded zone 834, lateral motion of the fastener 910 will be limited when a lateral end of the threaded zone 918 is disposed against a medial end of the threaded zone 902. When in this position, in one embodiment the distance between the lateral end of the threaded zone 918 and the lateral end 922 of the fastener 910 will be less than the distance within the lumen 894 from the lateral end of the threaded zone 902 to the convex side 878 of the glenoid sphere 870. Thus, the disengaged state of the fastener 910 will not result in the lateral end 922 protruding from the convex side 878.

[0090] The plate member 808 includes additional features for enhancing securement to the bone. The plate member 808 can includes one or more apertures 920.

The apertures 920 can receive bone screws to enhance securement of the plate member 808 to the bone, e.g., to the scapula SC. Advantageously, the bone screw will lock into the apertures 920 by a thread engagement. In some embodiments, the locking mechanism will be multi-directional providing the possibility to lock the bone screws at a variable angle from the axis of the flange 842. Additionally, the medial side of the plate member 808 can includes a textured surface 924 e.g., coated or layered with a porous material in order to accelerate tissue ingrowth such as bony ingrowth. Advantageously, the plate member 808 could be manufactured by additive manufacturing to incorporate the porous surface 924.

[0091] Though shown in use to secure a hard material (e.g. ceramic, pyrocarbon, or metal) glenoid sphere 99 to a glenoid, the assembly 800 could be used to secure a soft-material (e.g. polyethylene, polyurethane, PEEK) glenoid sphere. Though shown in use to secure a glenoid sphere 99 to a glenoid, the assembly 800 could be used to secure an atomic glenoid. Though shown in use to secure a glenoid sphere 99 to a glenoid, the assembly 800 could be used in other anatomy to achieve very secure connection to relatively shallow layers of bone, which can include cancellous bone that is exposed during a procedure.

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IV. ADDITIONAL APPLICATOINS

[0092] Figures 24-26 show a number of other applications for the prosthesis assemblies described herein. In particular, the shoulder assemblies 100, 800 can be applied to other bones and joints.

[0093] Figure 24 shows that a proximal femur f can be fitted with a prosthesis assembly 100f similar to the prosthesis assembly 100. The prosthesis assembly 100f is different from the shoulder assembly 100 in that it would be configured more particularly for the proximal femur.

[0094] Figure 25 shows that a distal humerus h or to a distal radius r can be fitted with a prosthesis assembly 100h, r similar to the prosthesis assembly 100. The prosthesis assembly 100h, r is different from the shoulder assembly 100 in that it would be configured more particularly for the distal humerus or radius.

[0095] Figure 26 shows that a distal femur df and/or to a proximal tibia t can be fitted with a prosthesis assembly 100df, 100t similar to the prosthesis assembly 100.

The prosthesis assemblies 100df, t, are different from the shoulder assembly 100 in that they would be configured more particularly for the distal femur or proximal tibia. Also, on both side of the knee joint, implant sizing such as threads external diameter, core diameter, overall length could be sized according to patient anatomy per pre-operative planning based on CT-scan, MRI or any other medical images modality.

[0096] Figure 27 shows that a distal tibia dt and/or to a proximal talus tal can be fitted with a prosthesis assembly 100dt, 100tal similar to the prosthesis assembly 100. The prosthesis assemblies 100dt, tal, are different from the shoulder assembly 100 in that they would be configured more particularly for the distal tibia or proximal talus. Also, on both side of the ankle joint, implant sizing such as threads external diameter, core diameter, overall length could be sized according to patient anatomy per pre-operative planning based on CT-scan, MRI or any other medical images modality.

[0097] Each of the applications illustrated in Figures 24-26 can employ the prosthesis assembly 800 with modifications similar to those discussed above in connection with the prosthesis assemblies 100h, 100r, 100f, and 100t.

V. PERFORMANCE OF EMBODMEINTS DISCLOSED HEREIN

[0098] Figure 28 shows comparative performance of embodiments disclosed herein with respect to a stemless apparatus that does not have the helical structures disclosed herein nor the locking devices. The graph shows maximum tip out force which is measured by applying an off axis load at a known or prescribed fixed distance from a surface at or to which a shoulder assembly similar to the assembly 100 was implanted. The tip out force represents the resistance of the device to tipping out or becoming dislodge from the surface when subject to off axis loading. The forces were observed using a load cell or force transducer. As can be seen, the force of one embodiment is more than four times the force that would dislodge the conventional stemless component. This represents a significant improvement in the retention of the apparatuses disclosed herein compared to conventional stemless design which rely to a large extent on ingrowth for securement which can be sufficient some time after implantation but which can be subject to dislodgement prior to full integration by ingrowth.

[0099] As used herein, the relative terms "proximal" and “distal” shall be defined from the perspective of the humeral shoulder assembly. Thus, distal refers the direction of the end of the humeral shoulder assembly embedded in the humerus, while

proximal refers to the direction of the end of the humeral shoulder assembly facing the glenoid cavity when the assembly is applied to the humerus. Distal refers the direction of the end of the humeral shoulder assembly embedded in the scapula, while proximal refers to the direction of the end of the humeral shoulder assembly facing the humerus when the assembly is applied to the glenoid. In the context of a glenoid component, the distal end is also sometimes referred to as a medial end and the proximal end is sometimes referred to as a lateral end.

[0100] Conditional language, such as "can," "could," "might," or "may," unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, and/or steps. Thus, such conditional language is not generally intended to imply that features, elements, and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, and/or steps are included or are to be performed in any particular embodiment.

[0101] The terms "approximately," "about," and "substantially" as used herein represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount. As another example, in certain embodiments, the terms "generally parallel" and "substantially parallel" refer to a value, amount, or characteristic that departs from exactly parallel by less than or equal to 15 degrees, 10 degrees, 5 degrees, 3 degrees, 1 degree, 0.1 degree, or otherwise.

[0102] Some embodiments have been described in connection with the accompanying drawings. However, it should be understood that the figures are not drawn to scale. Distances, angles, etc. are merely illustrative and do not necessarily bear an exact relationship to actual dimensions and layout of the devices illustrated. Components can be added, removed, and/or rearranged. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with various embodiments can be used in all other embodiments set

forth herein. Additionally, it will be recognized that any methods described herein may be practiced using any device suitable for performing the recited steps.

[0103] For purposes of this disclosure, certain aspects, advantages, and novel features are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the disclosure may be embodied or carried out in a manner that achieves one advantage or a group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

[0104] Although these inventions have been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present inventions extend beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the inventions and obvious modifications and equivalents thereof. In addition, while several variations of the inventions have been shown and described in detail, other modifications, which are within the scope of these inventions, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combination or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the inventions. It should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Further, the actions of the disclosed processes and methods may be modified in any manner, including by reordering actions and/or inserting additional actions and/or deleting actions. Thus, it is intended that the scope of at least some of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. The limitations in the claims are to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

WHAT IS CLAIMED IS:

1. A shoulder assembly comprising:

a base member comprising:

a collar;

a helical structure extending from the collar in a distal direction; and

a first pathway projecting distally of the collar and through the helical structure adjacent to an inner periphery thereof, the first pathway being generally transverse to the helical structure and extending in a space between successive portions of the helical structure; and

a locking device comprising a proximal support and a first arm projecting distally of the proximal support, the first arm configured to be disposed in the first pathway projecting distally of the collar when the proximal support is disposed adjacent to the collar;

wherein the first arm is disposed through bone in the space between successive portions of the helical structure when the shoulder assembly is implanted.

2. The shoulder assembly of Claim 1, wherein the base member further comprises an inner core projecting distally from the collar, an outer periphery of the helical structure surrounding the inner core, the first arm being located between the outer periphery of the helical structure and the inner core.

3. The shoulder assembly of Claim 2, wherein the inner core is tapered in a distal direction.

4. The shoulder assembly of Claim 2 or 3, wherein the base member further comprises a female taper extending from a central opening in the collar and at least partially through the inner core, the female taper configured to receive a mounting member of an anatomical or reverse joint interface.

5. The shoulder assembly of any one of Claims 2 to 4, wherein the inner core comprises a porous structure to support bone ingrowth.

6. The assembly of any one of Claims 1 to 5, wherein the first arm comprises an inner edge and an outer edge positioned radially outward of the inner edge, at least the outer edge of the first arm disposed in the helical structure along the first pathway.

7. The shoulder assembly of Claim 6, wherein the outer edge of the first arm is positioned radially inward of an outer periphery of the helical structure when the anchor is advanced into the base member.

8. The shoulder assembly of Claim 6 or 7, wherein the first arm further comprises a planar surface extending from the outer edge to the inner edge and from the proximal support to a distal end of the first arm.

9. The shoulder assembly of any one of Claims 6 to 8, wherein the outer edge of the first arm is tapered between the proximal support and a location away from the proximal support.

10. The shoulder assembly of any one of Claims 6 to 9, wherein a longitudinal axis of the first arm extends parallel to the longitudinal axis of the anchor.

11. The shoulder assembly of any one of Claims 1 to 10, wherein the proximal support comprises an annular member.

12. The shoulder assembly of any one of Claims 1 to 11, further comprising a second arm, the second arm being circumferentially spaced apart from the first arm.

13. The shoulder assembly of Claim 12 wherein the first and the second arms are spaced 180 degrees apart

14. The shoulder assembly of Claim 12 further comprising a third arm, each of the arms being spaced 120 degrees from the other two arms.

15. The shoulder assembly of any one of Claims 1 to 14, wherein the proximal support comprises an engagement feature to engage the collar.

16. The shoulder assembly of Claim 15, wherein the engagement feature comprises a spring arm positioned at an outer periphery of the proximal support and configured to engage an outer rim of the collar.

17. The shoulder assembly of any one of Claims 1 to 16, wherein at least one of the first arm and the first pathway comprise an engagement feature to the other of the first arm and the first pathway.

18. The shoulder assembly of any one of Claim 17, wherein the first arm comprises serrations permitting advancement of the first arm into the first pathway and resisting withdrawal of the first arm out of the first pathway.

19. The shoulder assembly of any one of Claims 1 to 18, wherein the first arm is disposed through bone between the collar and the helical structure.

20. The shoulder assembly of any of Claims 1 to 19, wherein the base member comprises a recess projecting distally from the collar to a location within the helical structure, the recess configured to couple with an articular component.

21. The shoulder assembly of Claim 20, the recess being tapered and further comprising a hemispherical articular component having a tapered projection disposed in the tapered recess, wherein the recess and the projection form a Morse taper connection.

22. The shoulder assembly of Claim 20, the recess being tapered and further comprising a concave articular component having a tapered projection disposed in the tapered recess, wherein the recess and the projection form a Morse taper connection.

23. A kit comprising:

the shoulder assembly of any of Claim 1-23;

an anatomic articular component mateable with the shoulder assembly, the anatomic articular component comprising a convex articular surface adapted to articulate with a concave surface of or on a scapula of a patient; and

a reverse articular component mateable with the shoulder assembly, the reverse articular component comprising a concave articular surface adapted to articulate with a convex surface on a scapula of a patient.

24. A prosthesis assembly comprising:

a base member having a first end and a second end, the base member comprising:

a helical structure extending between the first end and the second end; and

a first pathway accessible from the second end and directed toward the first end through the helical structure and being located adjacent to an inner periphery of the helical structure, the first pathway being generally transverse to the helical structure and extending in a space between successive portions of the helical structure; and

a locking device comprising a support member and a first arm projecting away from the support member, the first arm configured to be disposed in the first pathway when the support member is disposed adjacent to the second end of the base member;

wherein the first arm is disposed through bone in the space between successive portions of the helical structure when the prosthesis assembly is implanted.

25. The prosthesis assembly of Claim 24, wherein the base member comprises a portion of a stemless shoulder assembly, the base member also comprising a recess projecting to a location within the helical structure.

26. The prosthesis assembly of Claim 24 or Claim 25, wherein the helical structure and the locking device comprise portions of a base plate assembly of a glenoid assembly, the locking device comprising a periphery configured to mate with an articular component of a reverse shoulder assembly.

27. The prosthesis assembly of Claim 26, wherein the support member comprises a flange extending transverse to the first arm, the flange comprising the periphery configured to mate with the articular component of the reverse shoulder assembly.

28. The prosthesis assembly of Claim 26 or Claim 27, wherein the support member comprises a boss projecting away from the first arm, the boss configured to be received within a recess of the articular component of the reverse shoulder assembly.

29. The prosthesis assembly of Claim 26-28, further comprising a glenoid sphere having a tapered inner surface configured to mate a tapered surface at the periphery of the locking device.

30. The prosthesis assembly of Claim 26, wherein the base member comprises a portion of a stemless femoral assembly, and further comprises a convex component configured to articulate within an acetabulum when applied to a patient.

31. The prosthesis assembly of Claim 26, wherein the base member comprises a portion of a stemless humeral assembly, the prosthesis assembly comprising a convex component configured to articulate within a concavity at a head of a radius bone of an elbow joint when applied to a patient.

32. The prosthesis assembly of Claim 26, wherein the base member comprises a portion of a stemless radial assembly, the prosthesis assembly comprising an articular surface configured to articulate with a scaphoid bone or an ulna when applied to a patient.

33. The prosthesis assembly of Claim 26, wherein the base member comprises a portion of a stemless femoral assembly, the prosthesis assembly comprising an articular surface configured to articulate over a tibia at a knee joint when applied to a patient.

34. The prosthesis assembly of Claim 26, wherein the base member comprises a portion of a stemless tibial assembly, the prosthesis assembly comprising an articular

surface configured to articulate relative to a femur at a knee joint when applied to a patient.

35. The prosthesis assembly of Claim 26, wherein the base member is configured to be positioned in at least one a tibia, talus, calcaneous, and fibula.

36. A method of implanting a prosthesis, comprising:

advancing by rotation a base member into an epiphysis of a humerus of a patient, the base member comprising a helical structure configured to engage the cancellous bone of the epiphysis; and

advancing by linear translation a locking device into the base member, the locking device comprising at least one arm adapted to span a space between adjacent portions of the helical structure and to contact the cancellous bone in the space.

37. A glenoid assembly comprising:

a base member having a medial end and a lateral end, the base member comprising:

a helical structure extending between the medial end and the lateral end; and

a first pathway accessible from the lateral end and directed toward the medial end through the helical structure and being located adjacent to an inner periphery of the helical structure, the first pathway being generally transverse to the helical structure and extending in a space between successive portions of the helical structure; and

a plate member comprising a flange and a first arm projecting away from the flange, the first arm configured to be disposed in the first pathway when the plate member is disposed adjacent to the lateral end of the base member;

wherein the first arm is disposed through bone in the space between successive portions of the helical structure when the prosthesis assembly is implanted.

38. The glenoid assembly of Claim 37, further comprising a glenoid sphere comprising a tapered surface disposed within a recess disposed on a medial side thereof, the plate member comprising a tapered surface disposed on a side of the flange opposite the first arm, the tapered surface of the glenoid sphere and the tapered surface on the plate

member forming a Morse taper connection when the glenoid sphere and the plate member are coupled.

39. The glenoid assembly of Claim 38, wherein the plate member comprises a boss projecting away from the flange, the boss configured to be received within the recess of the glenoid sphere when the glenoid sphere and the flange are coupled.

40. The glenoid assembly of Claim 39 wherein the tapered surface of the plate member is disposed on an inner surface of the boss.

41. The prosthesis assembly of Claim 38 wherein the base member comprises a central body disposed within the helical structure, the central body comprising a threaded portion configured to couple with a fastener disposed through a lumen in the glenoid sphere, the fastener increasing pressure at an interface between the tapered surface of the plate member and the tapered surface of the glenoid sphere.

42. The glenoid assembly of Claim 41, wherein the articular surface of the glenoid sphere comprises an aperture connected to the lumen in the glenoid sphere.

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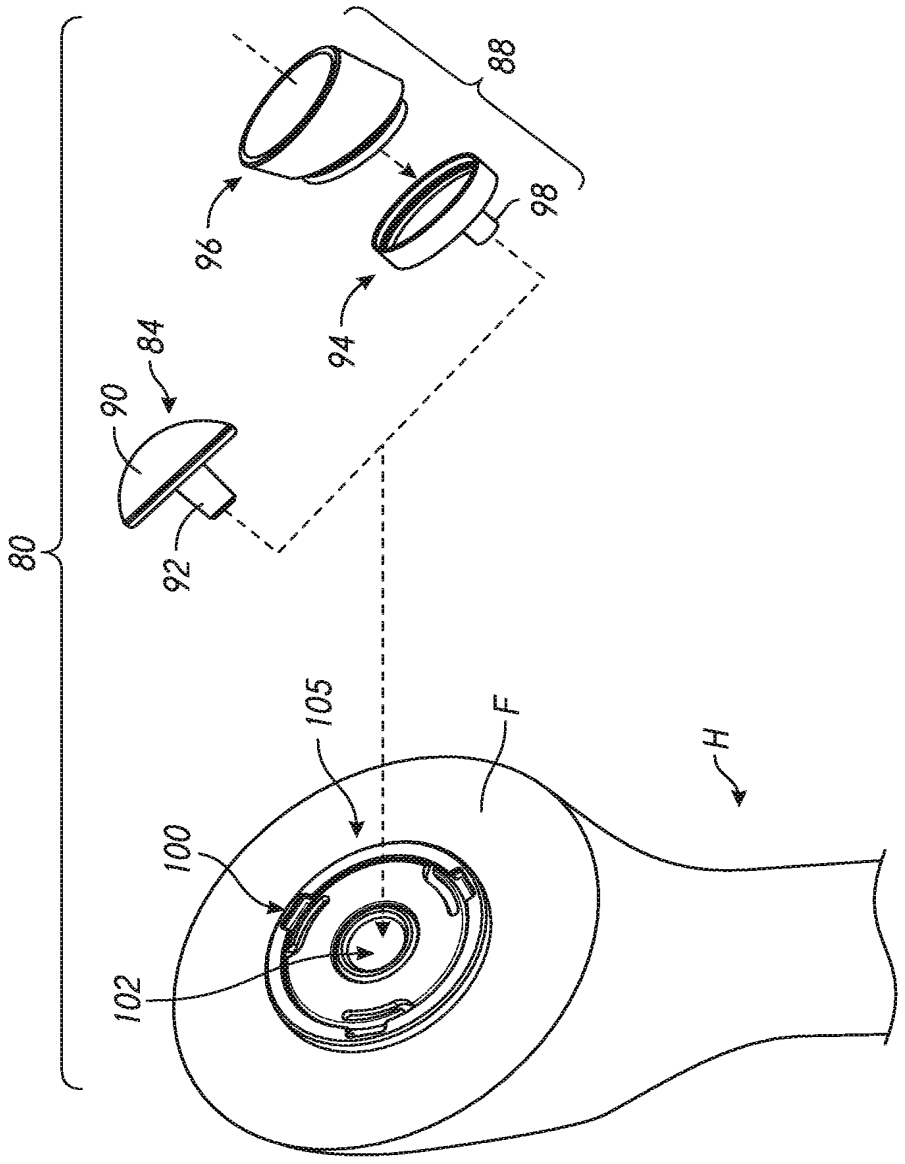


FIG. 1

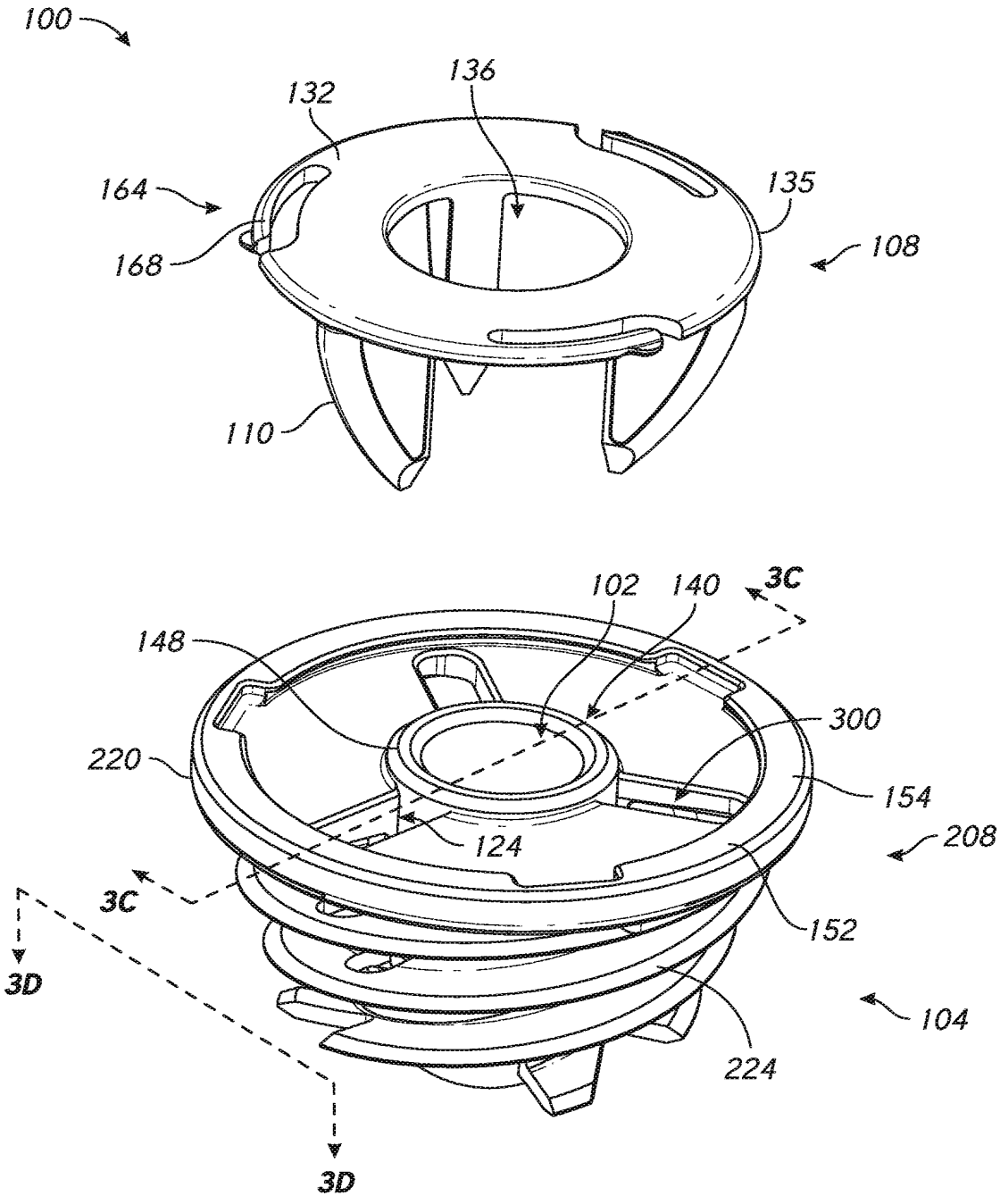

100
132
136
164
135
168
108
110
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3C
148
300
220
154
124
208
3C
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3D
104
224
3D

FIG. 2

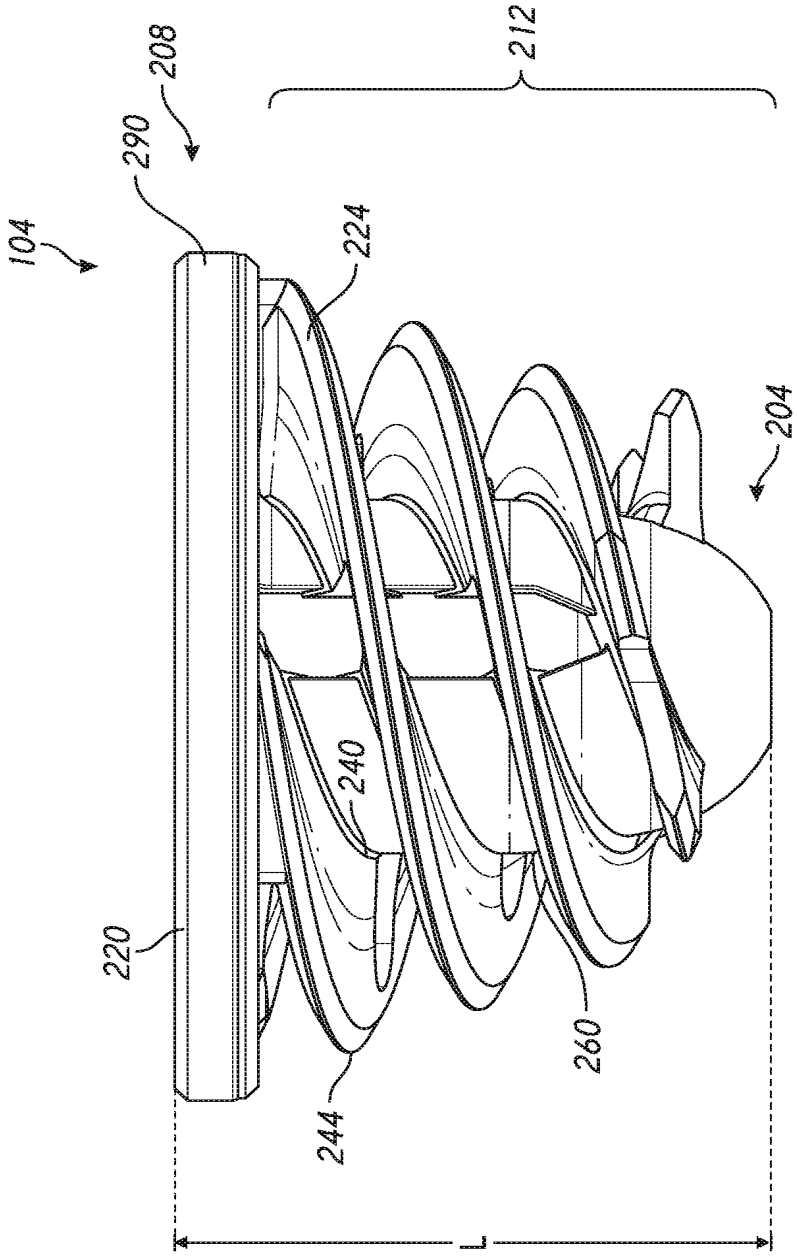


FIG. 3A

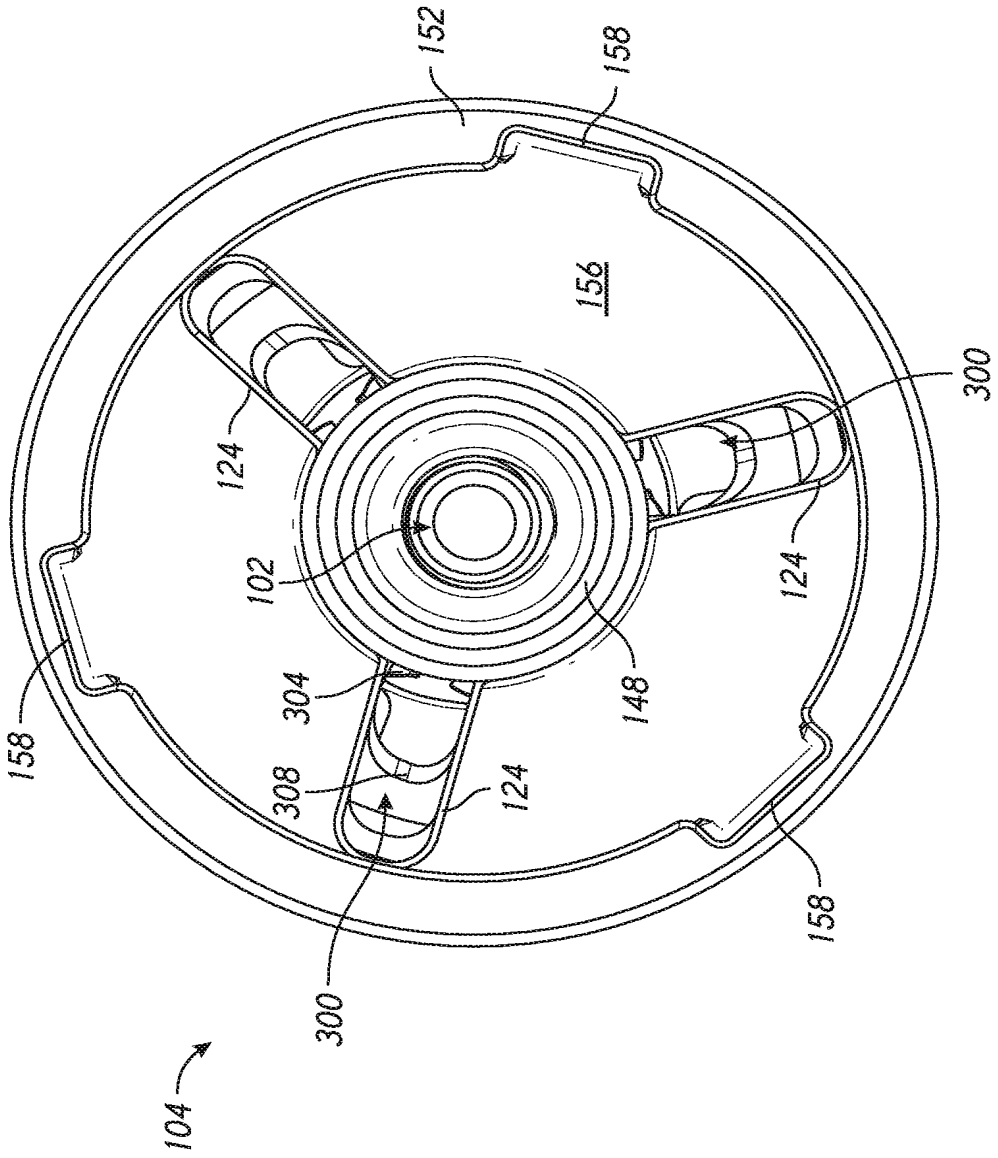


FIG. 3B

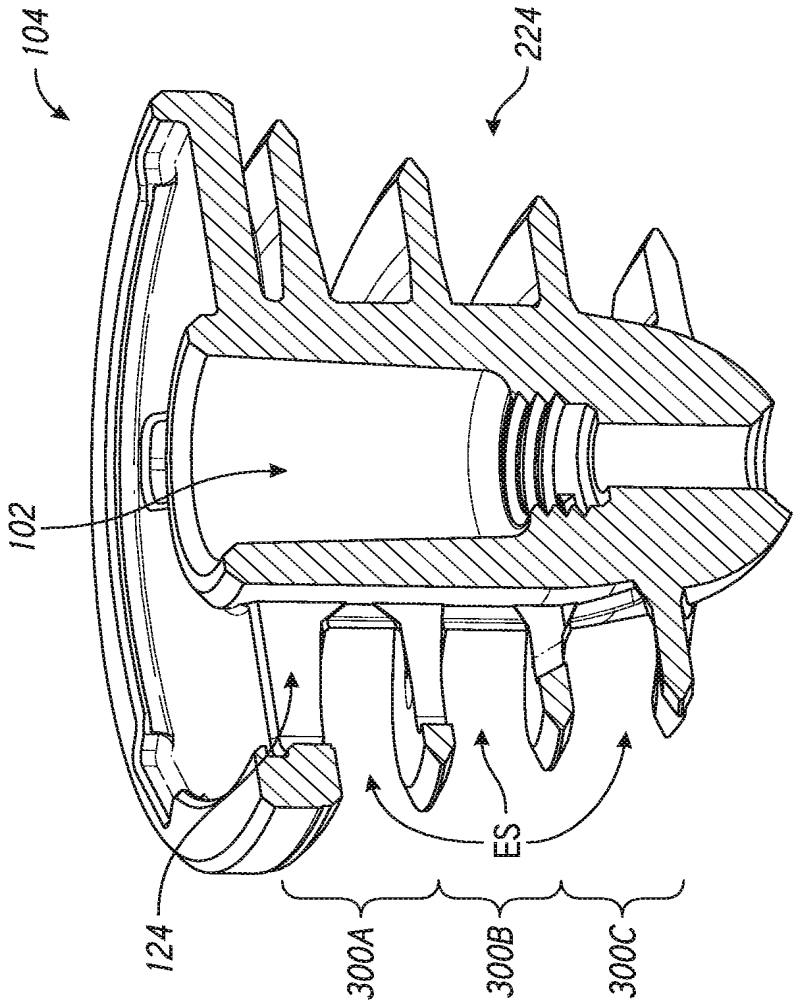


FIG. 3C

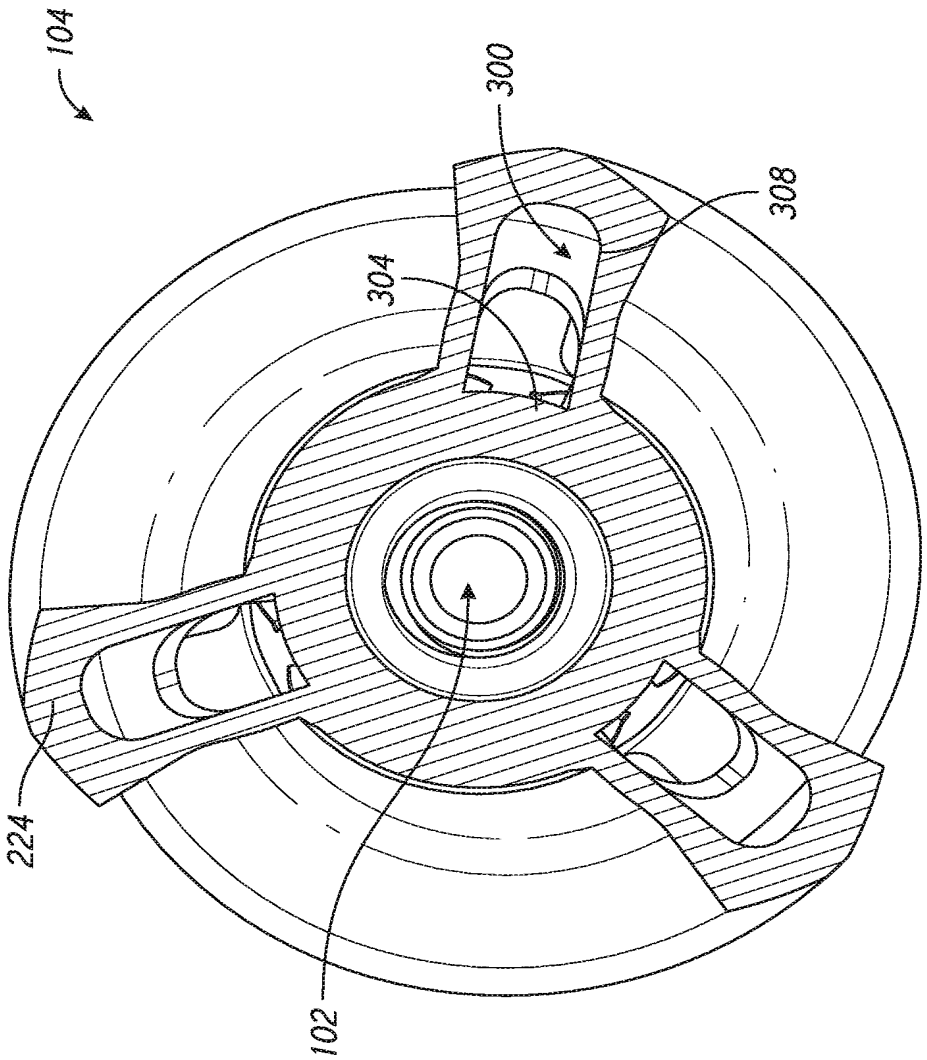


FIG. 3D

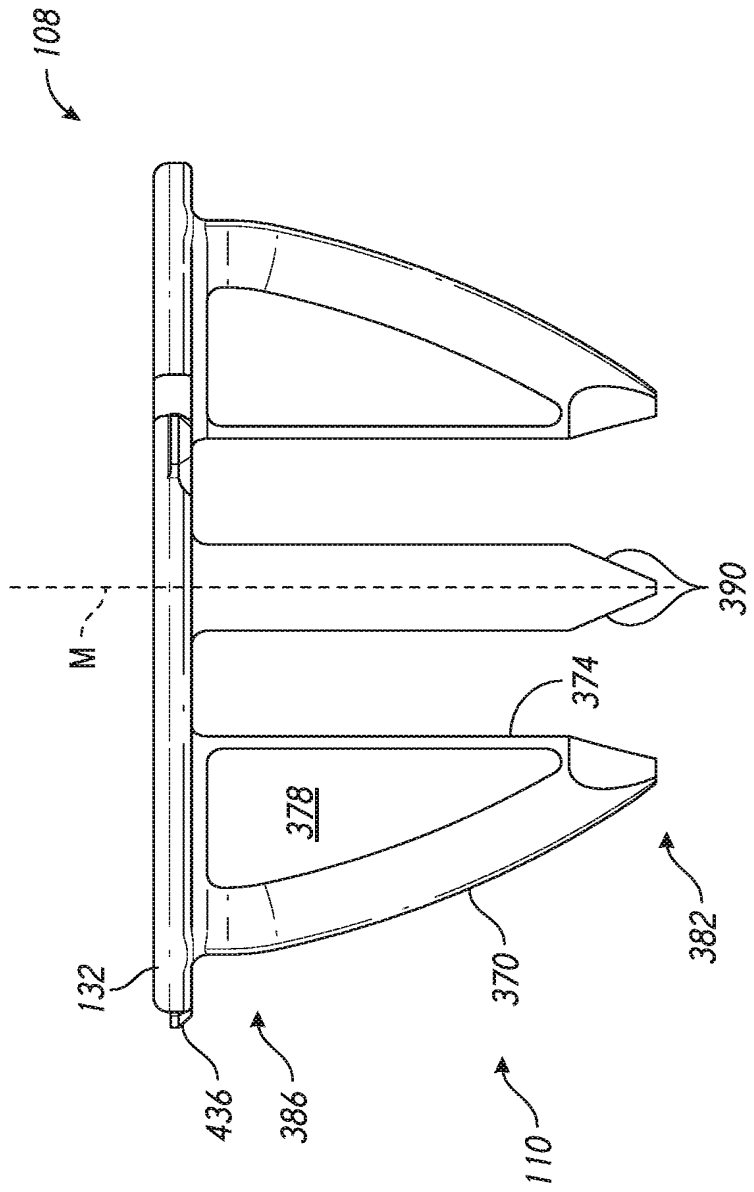


FIG. 4

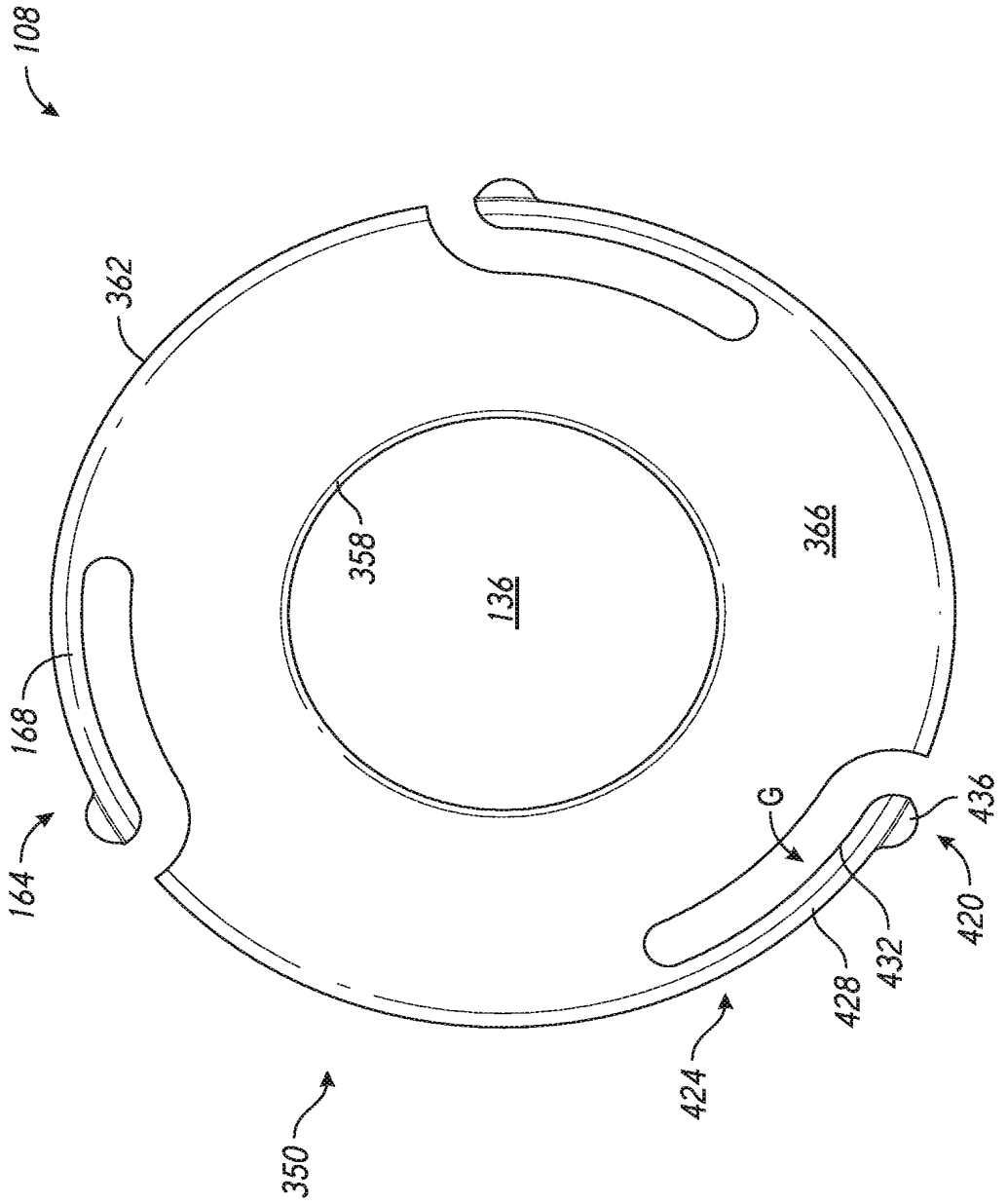


FIG. 5

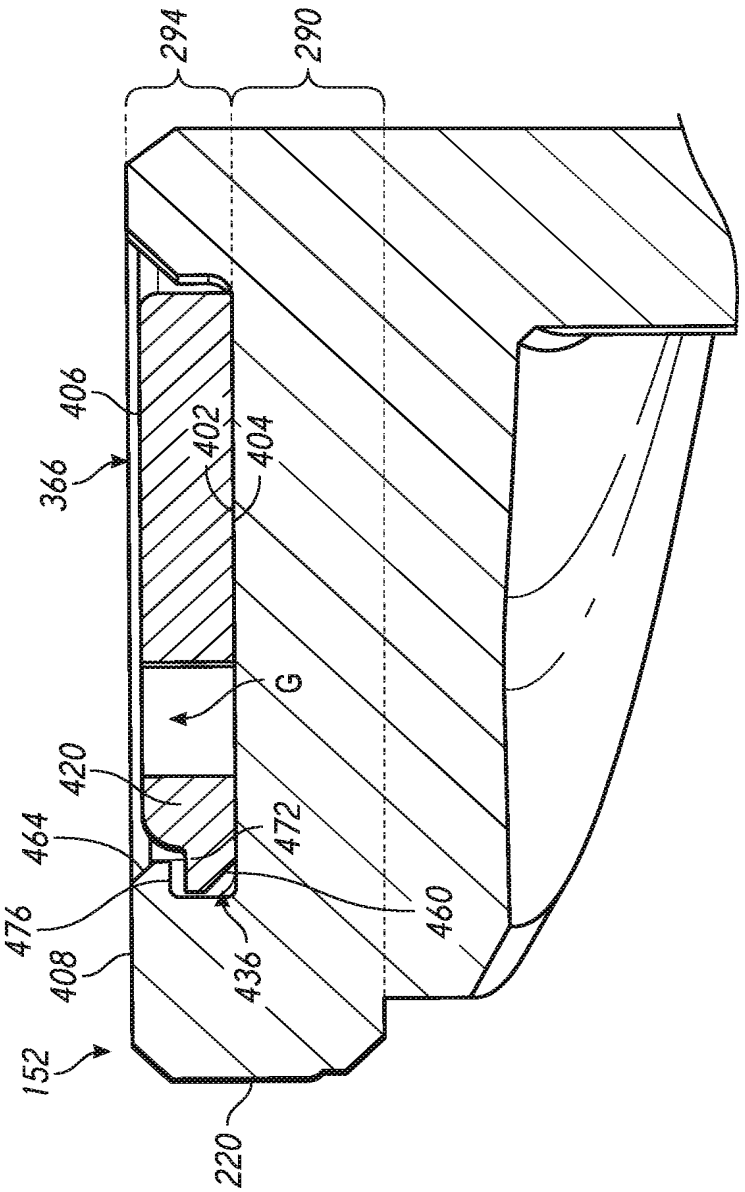


FIG. 6A

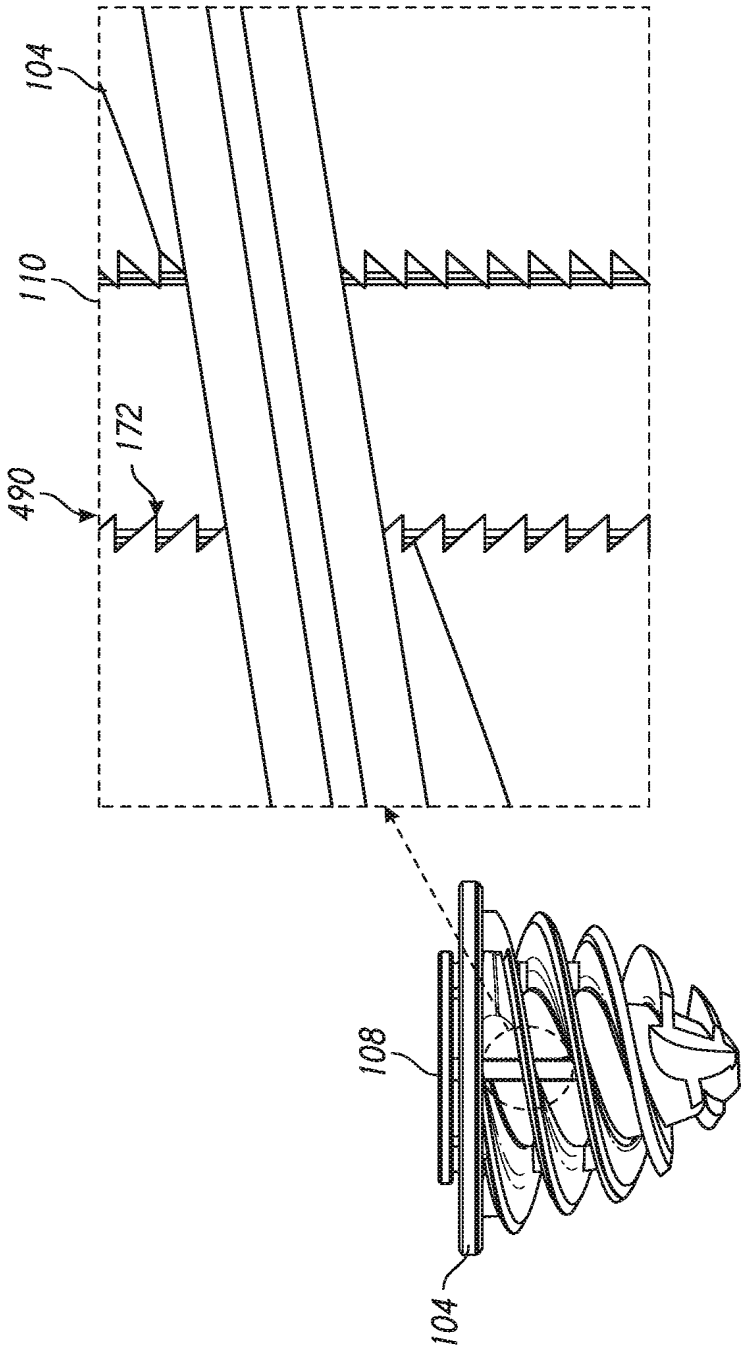


FIG. 6B

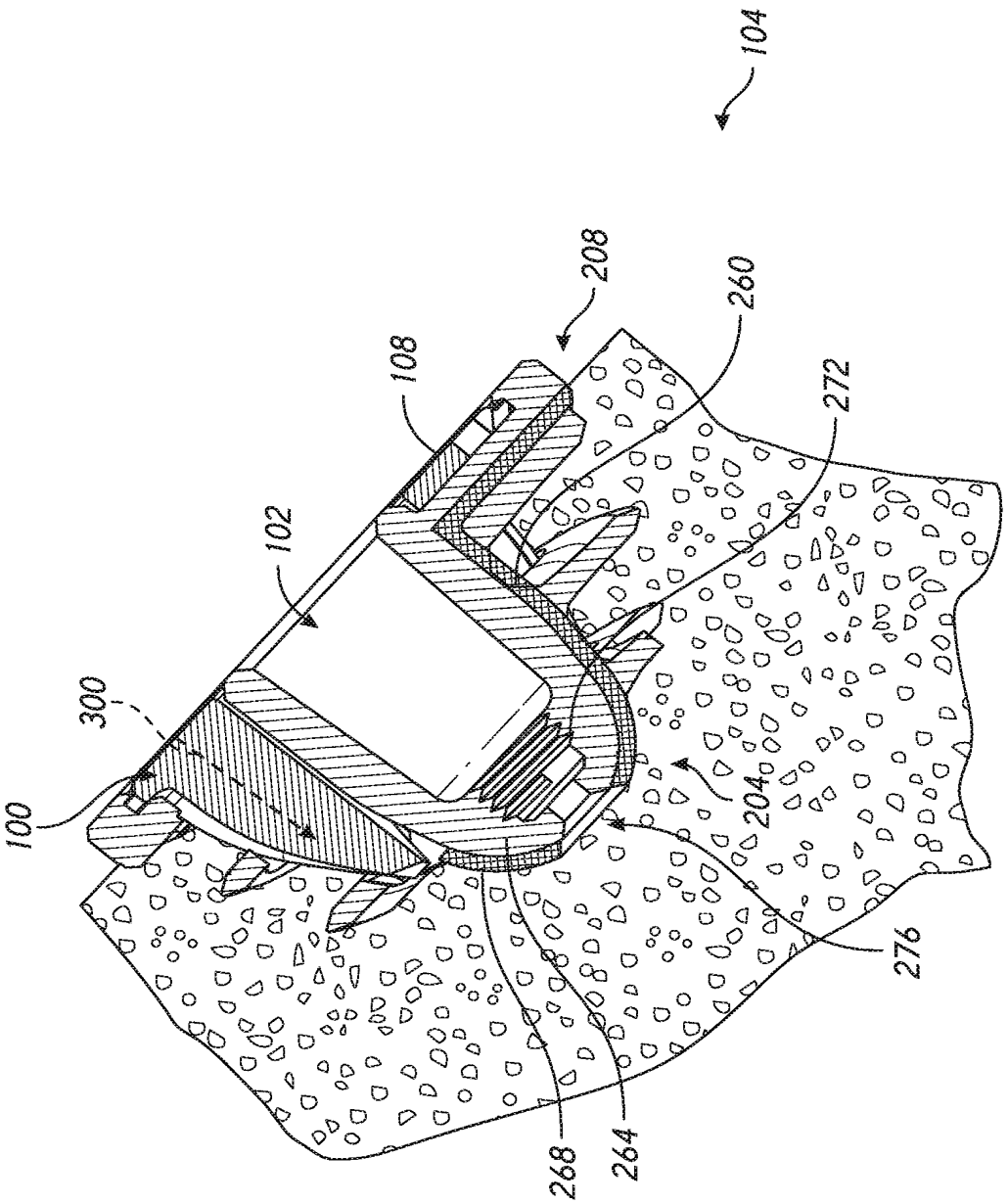


FIG. 7

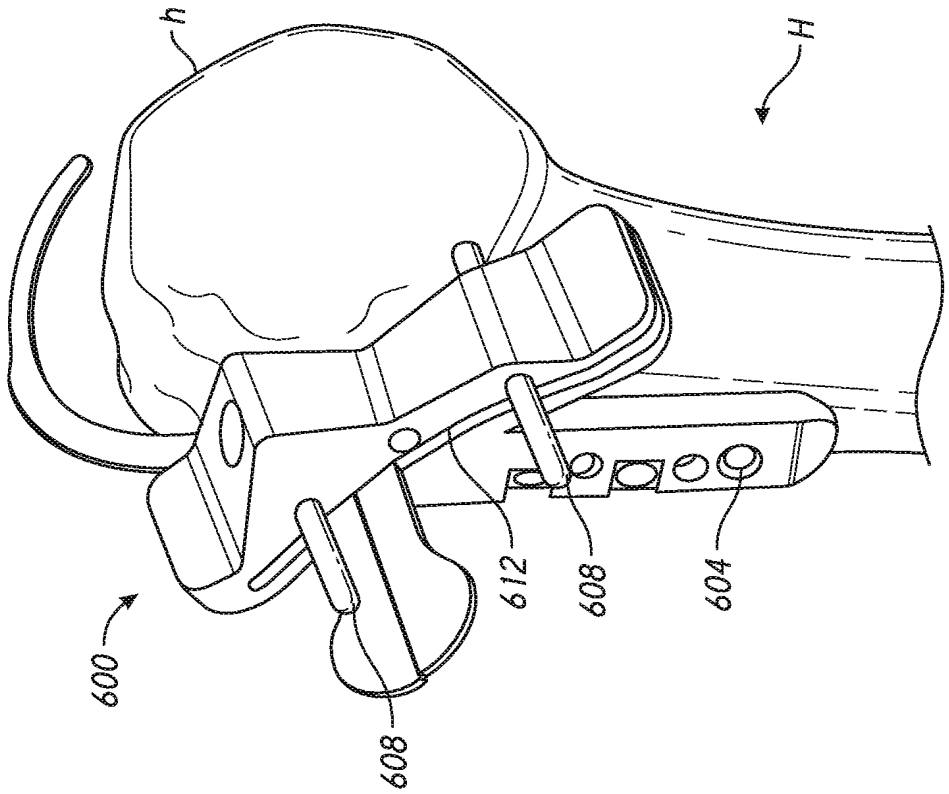


FIG. 8

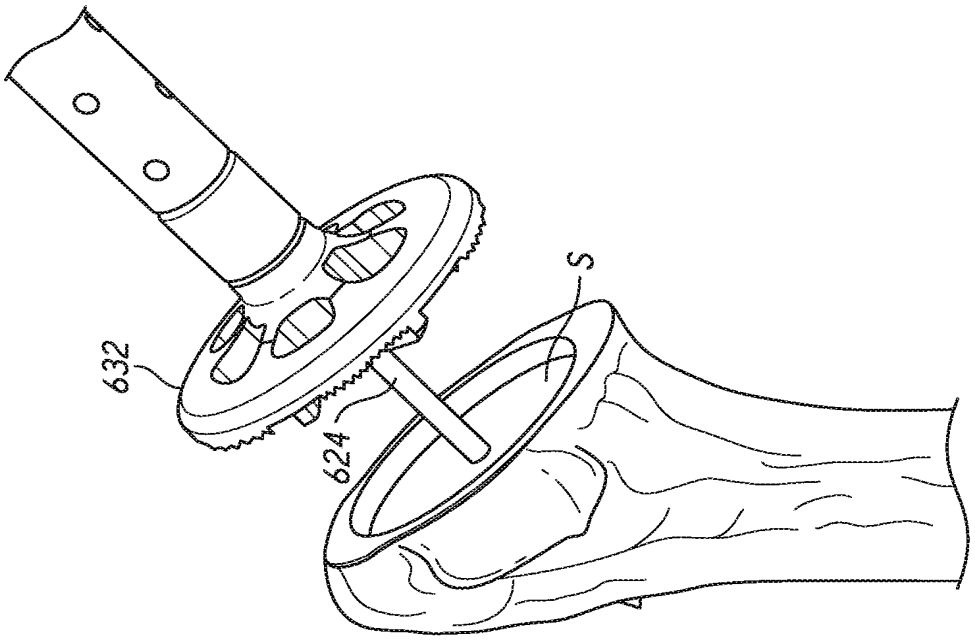


FIG. 10

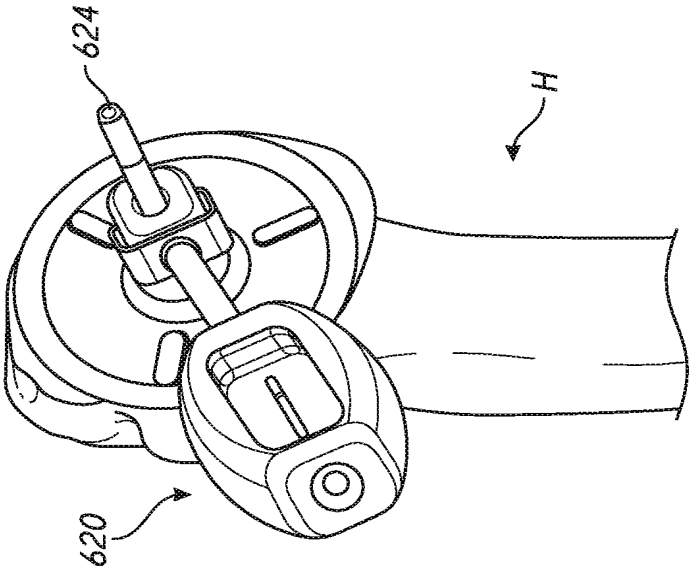


FIG. 9

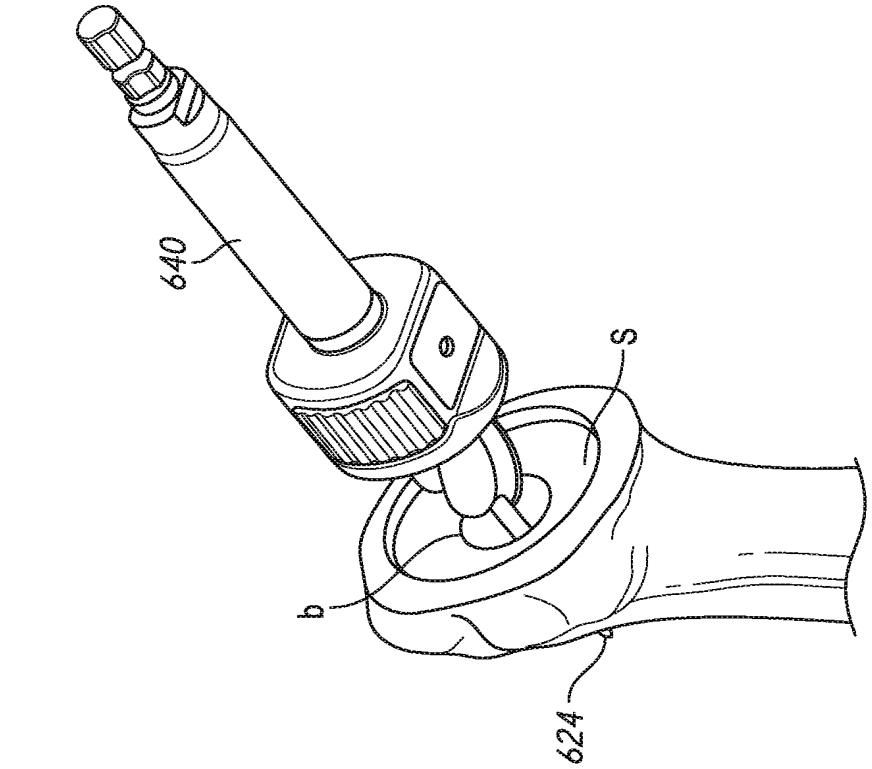


FIG. 12

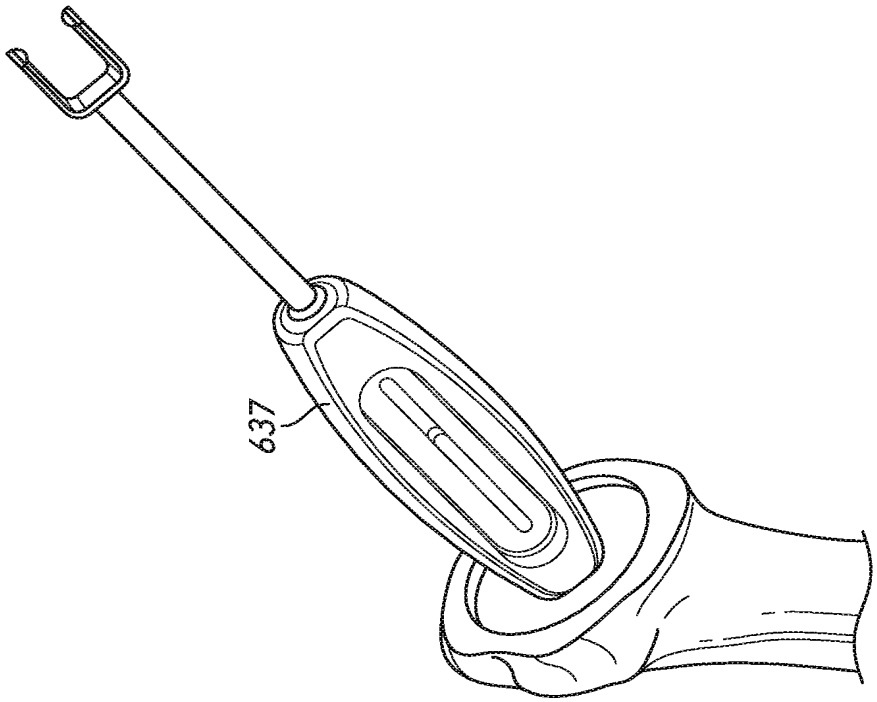


FIG. 11

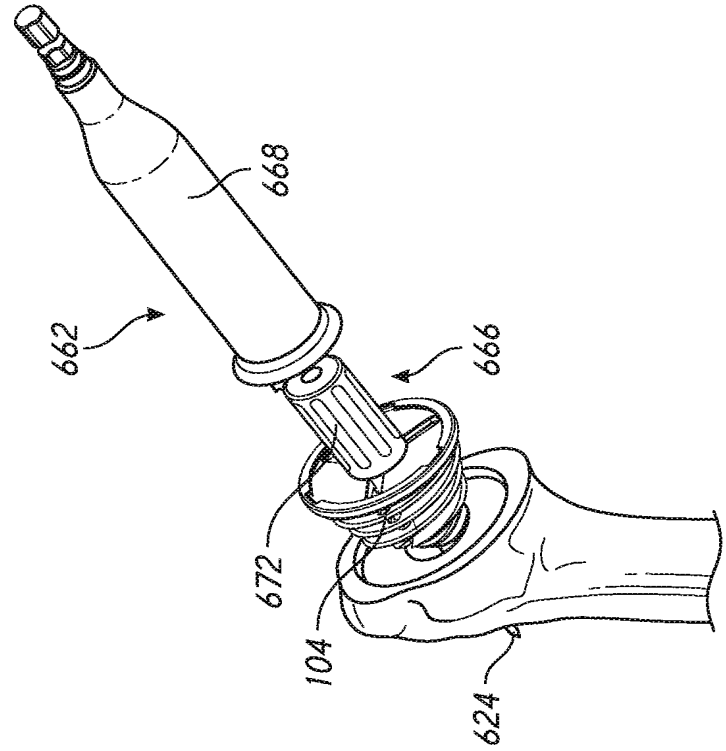


FIG. 14

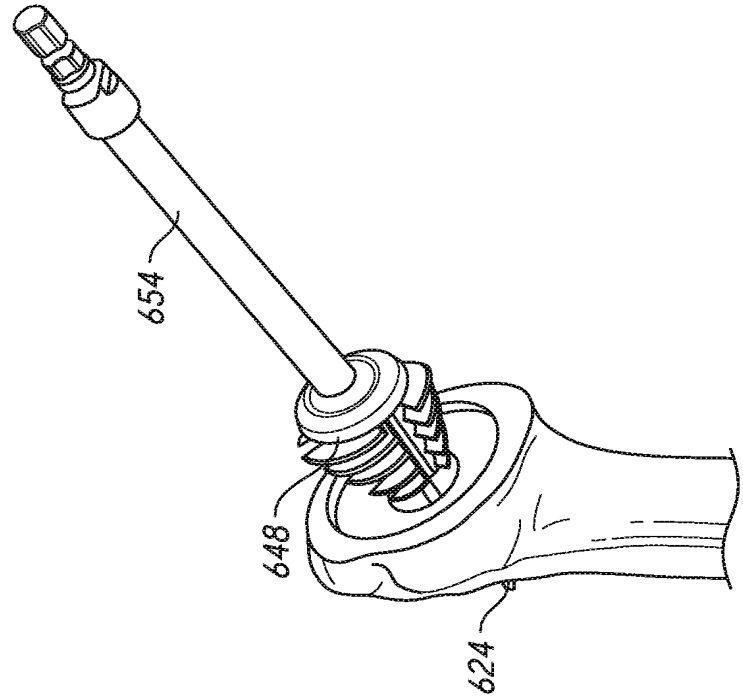


FIG. 13

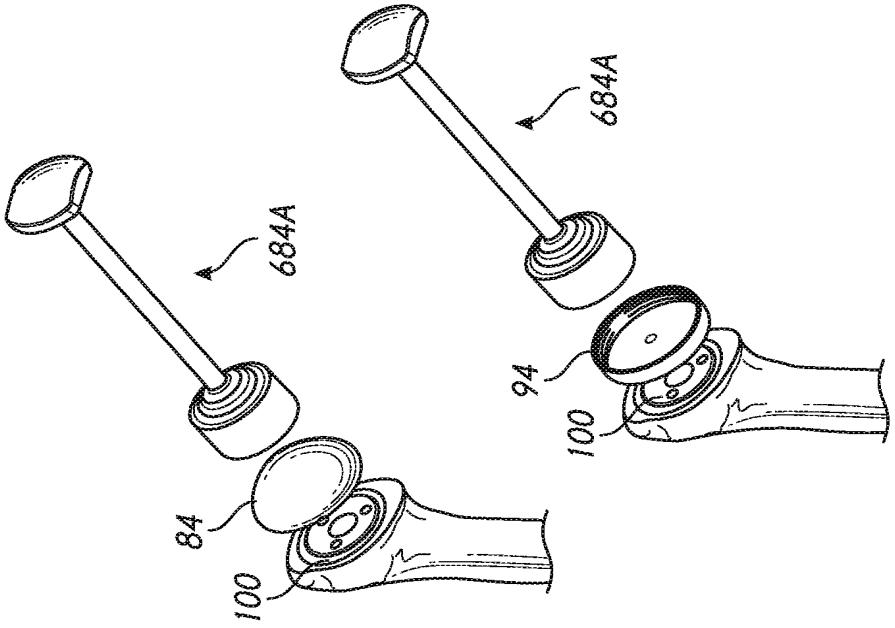


FIG. 16

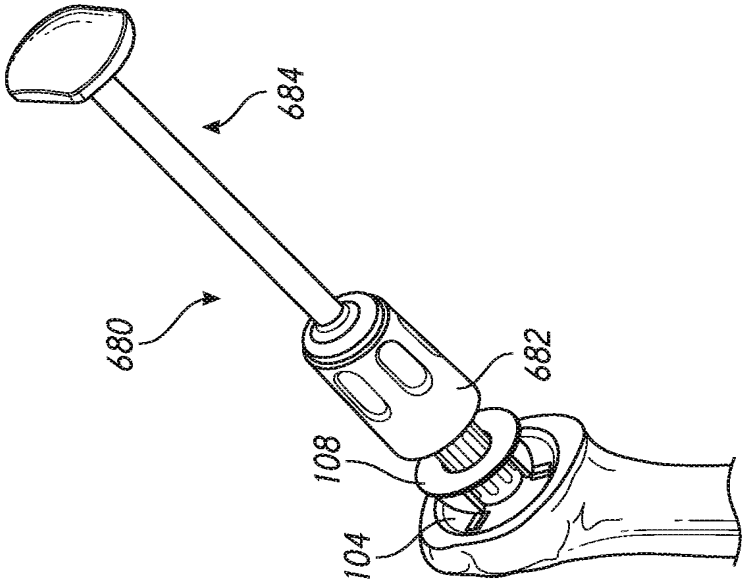


FIG. 15

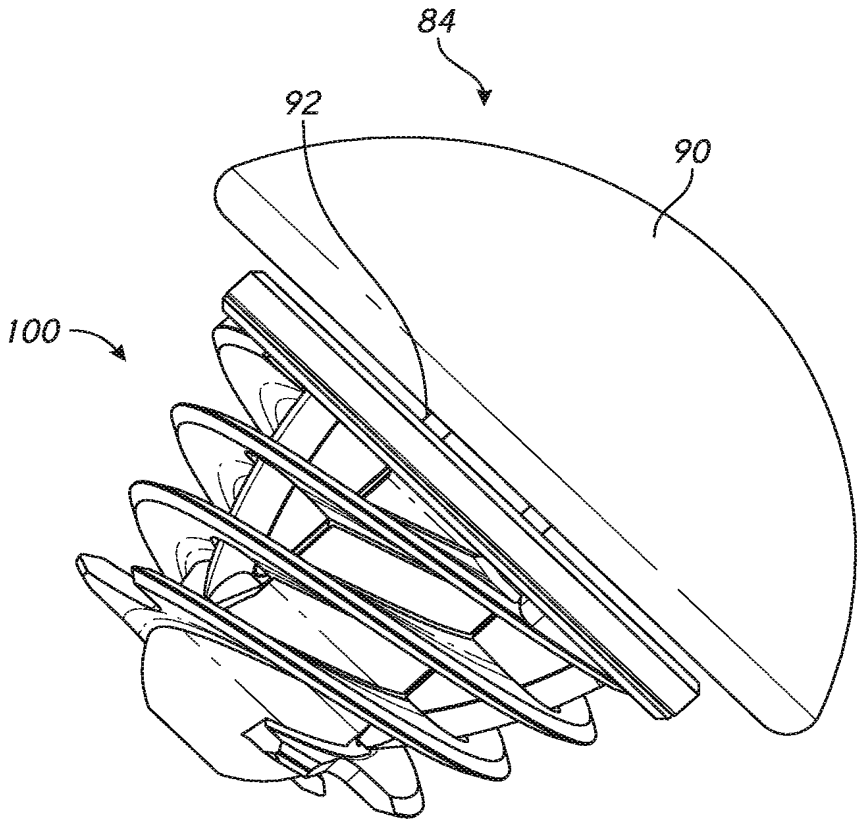


FIG. 17

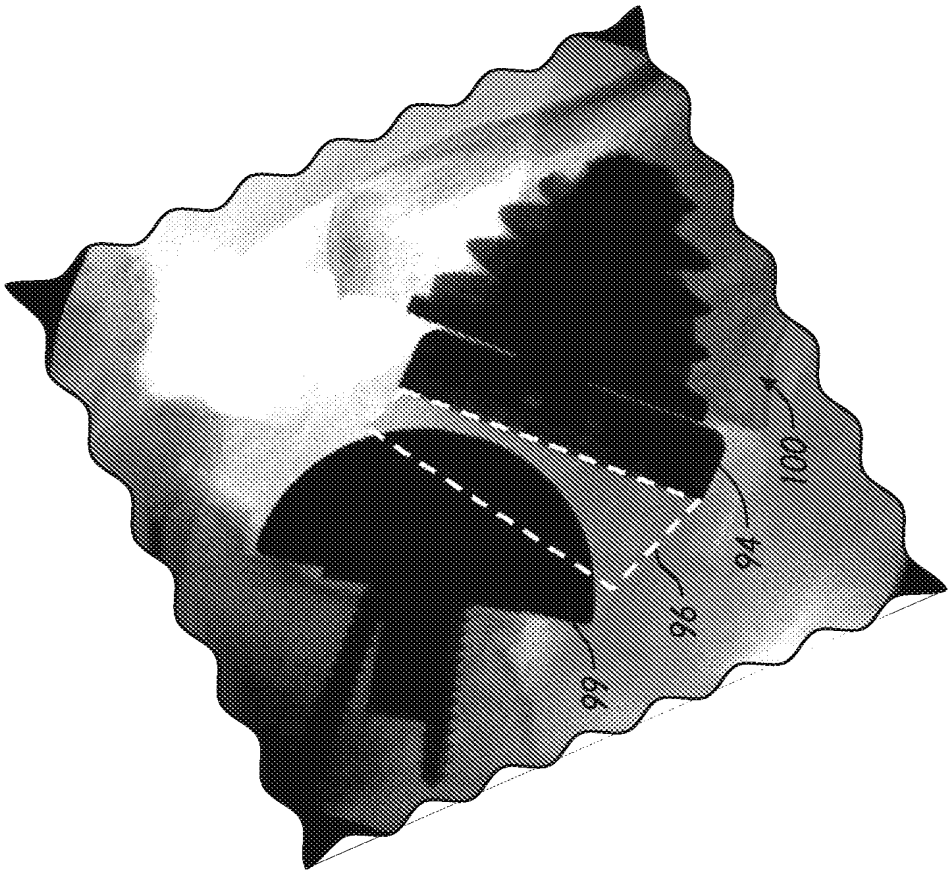


FIG. 18B

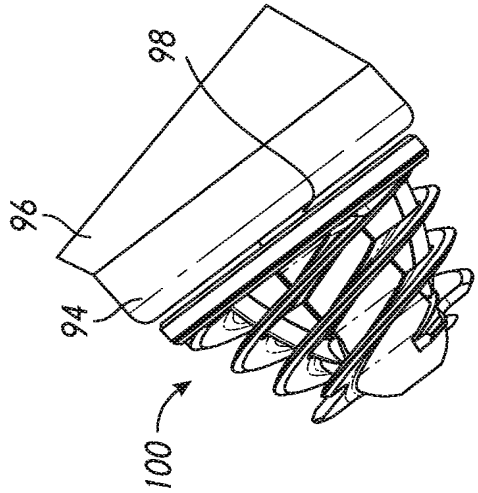


FIG. 18A

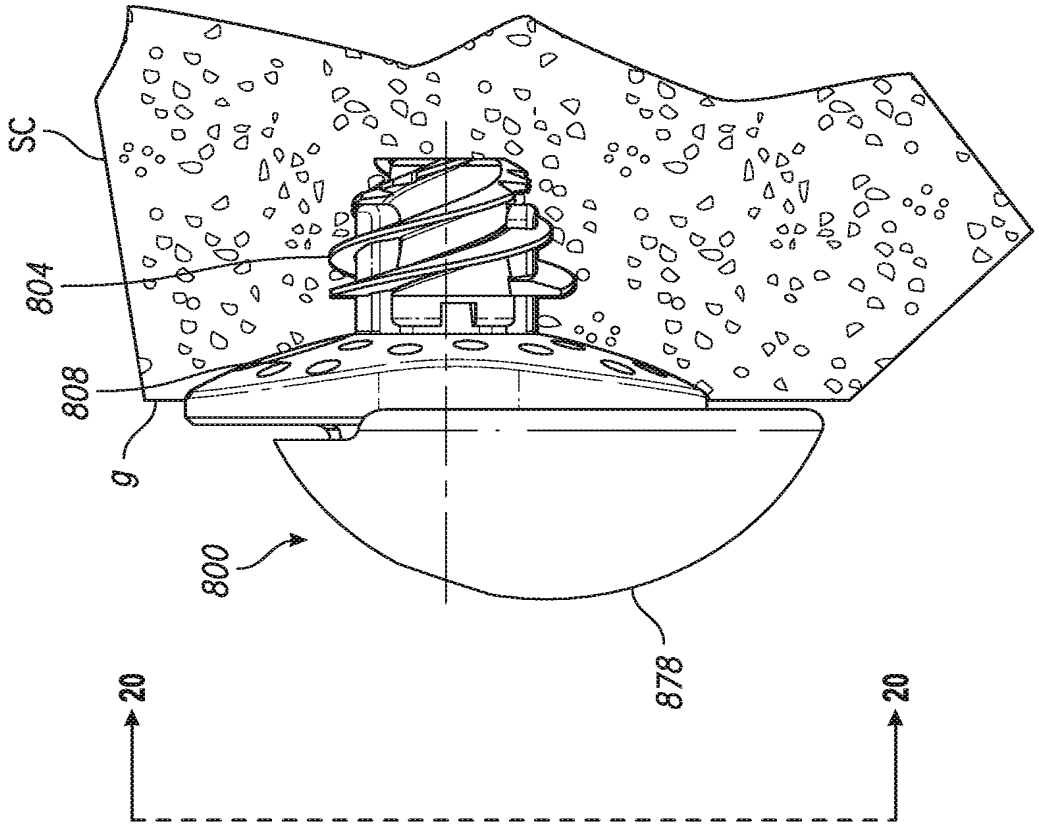


FIG. 19

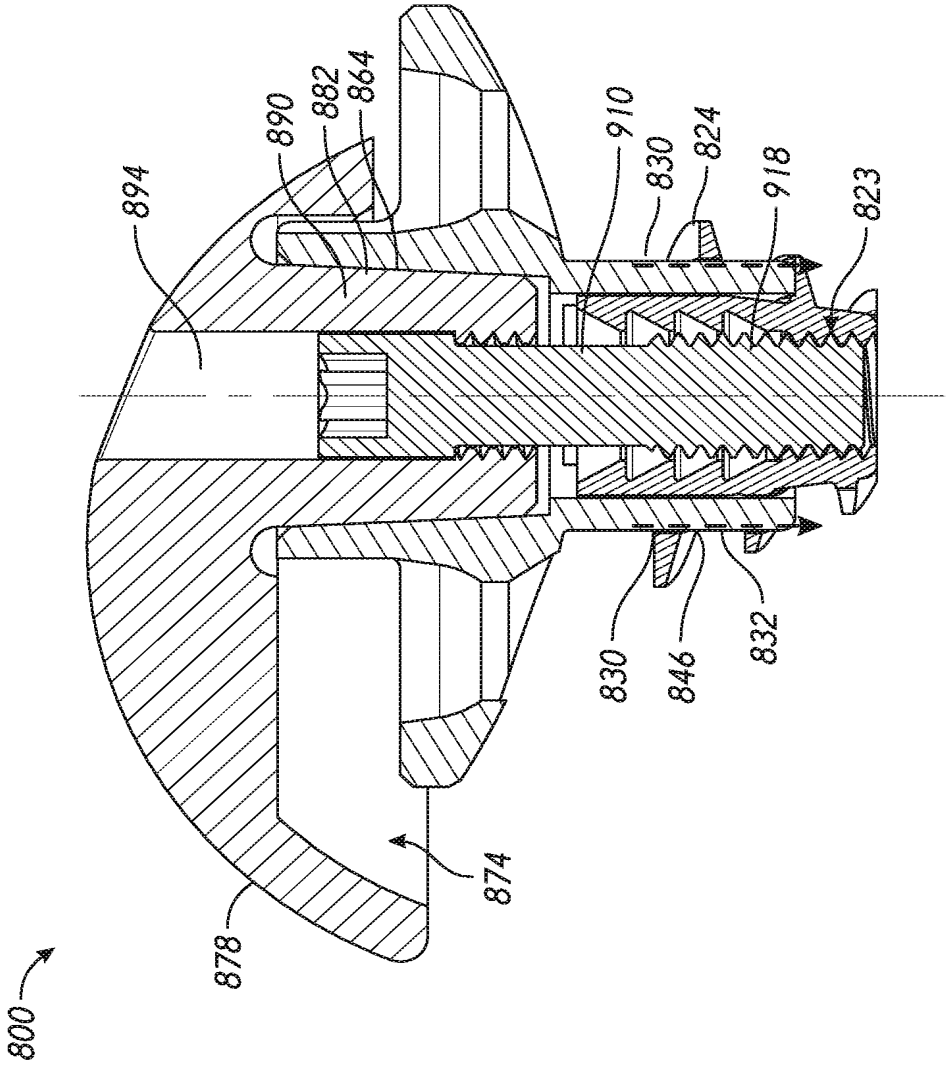


FIG. 20

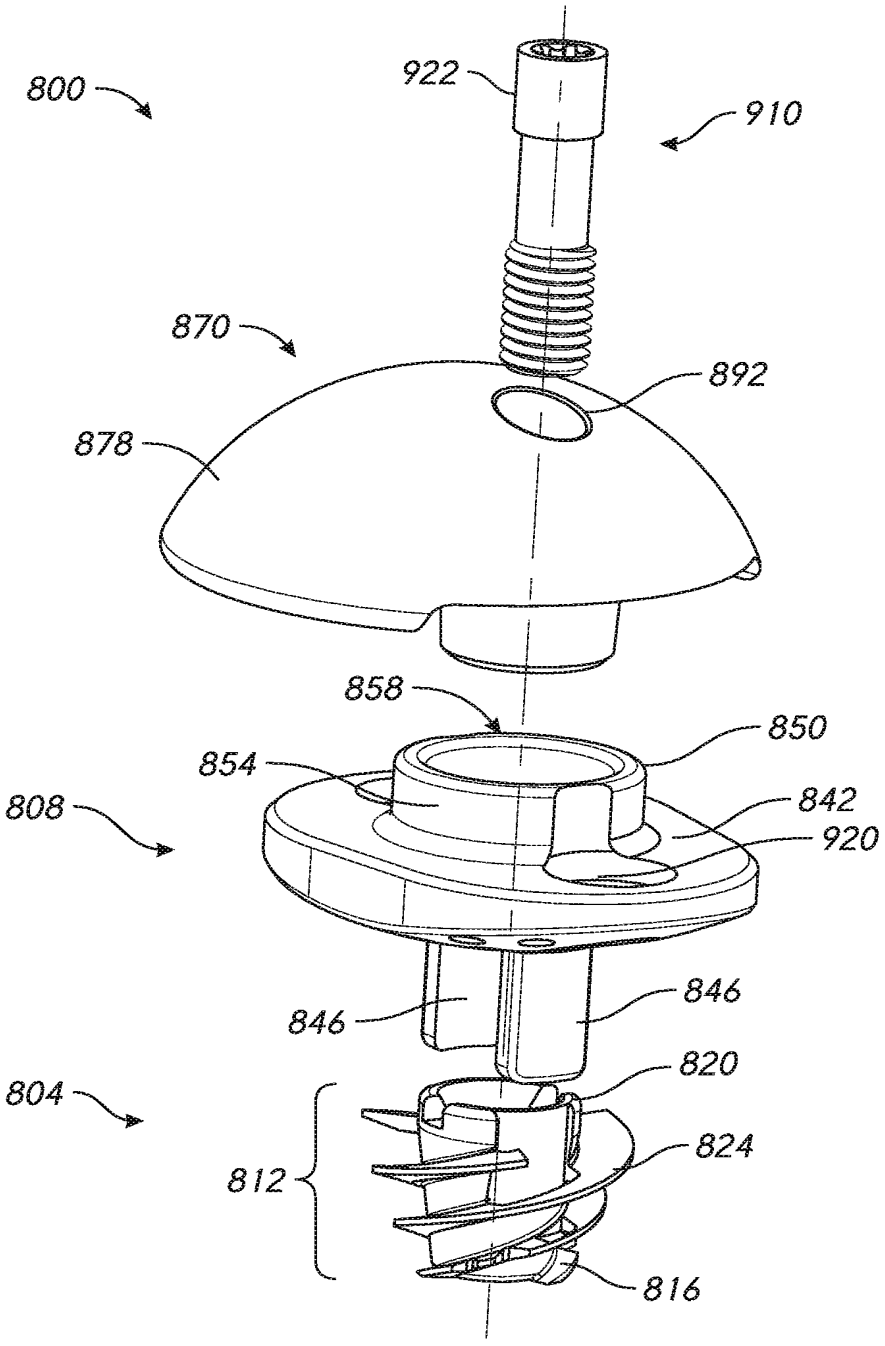

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FIG. 21

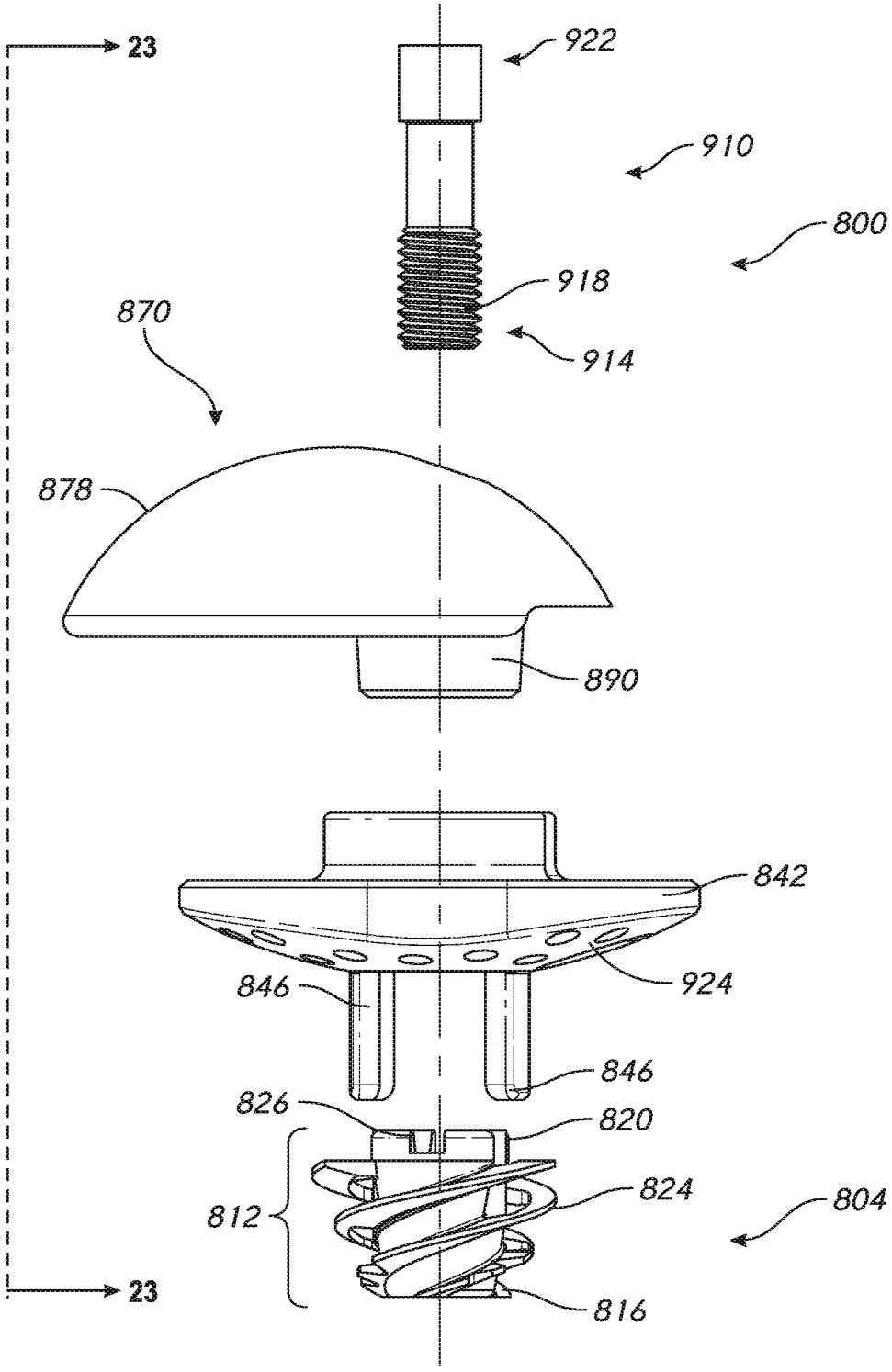

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FIG. 22

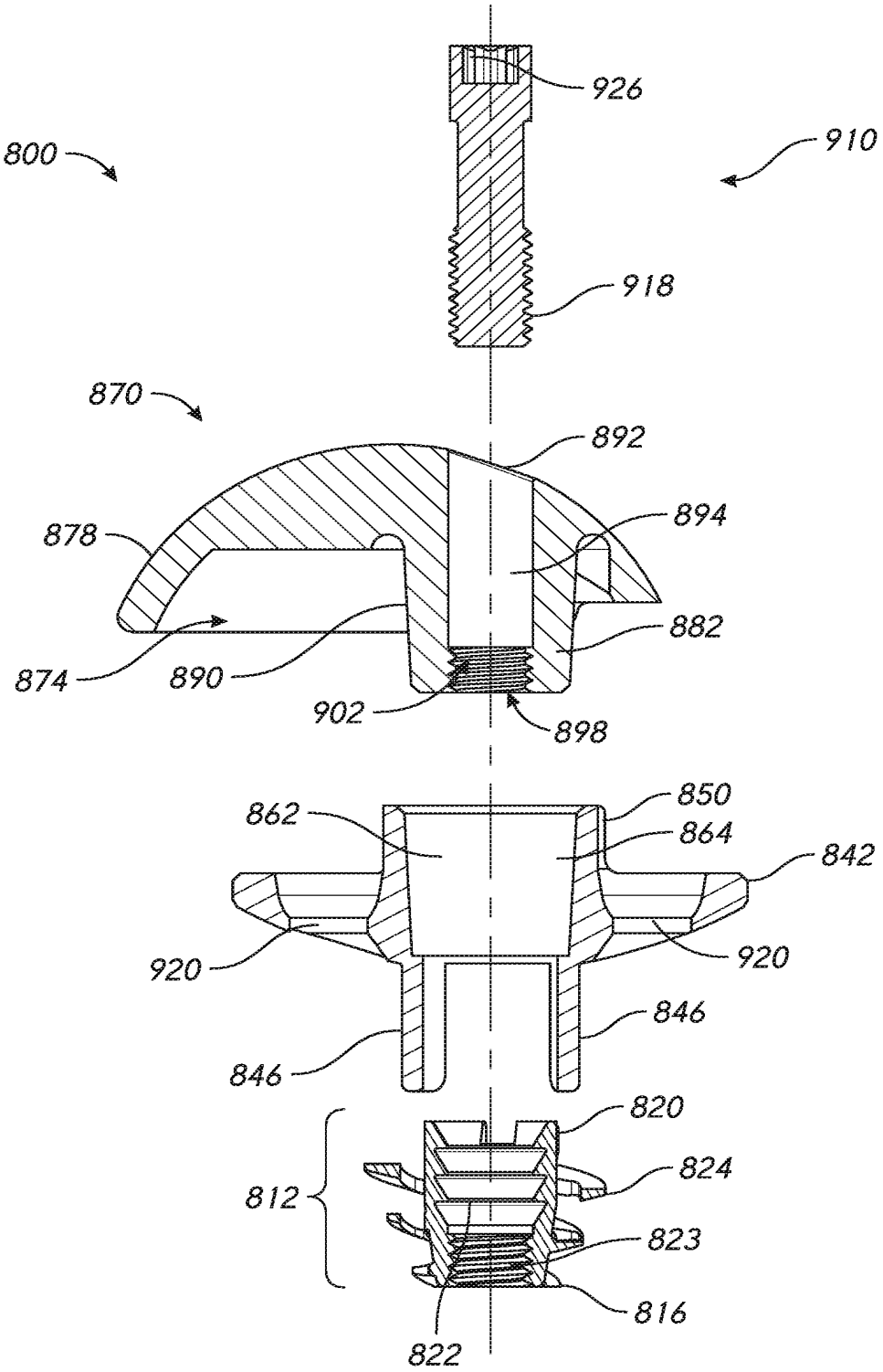

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FIG. 23

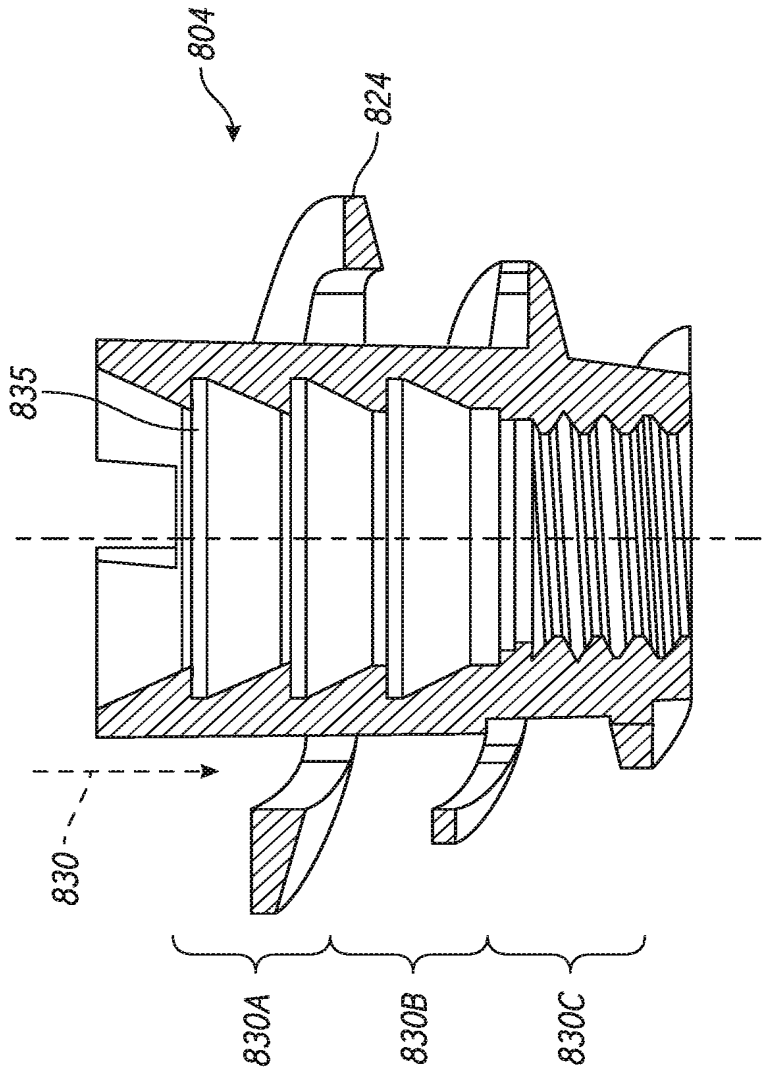


FIG. 23A

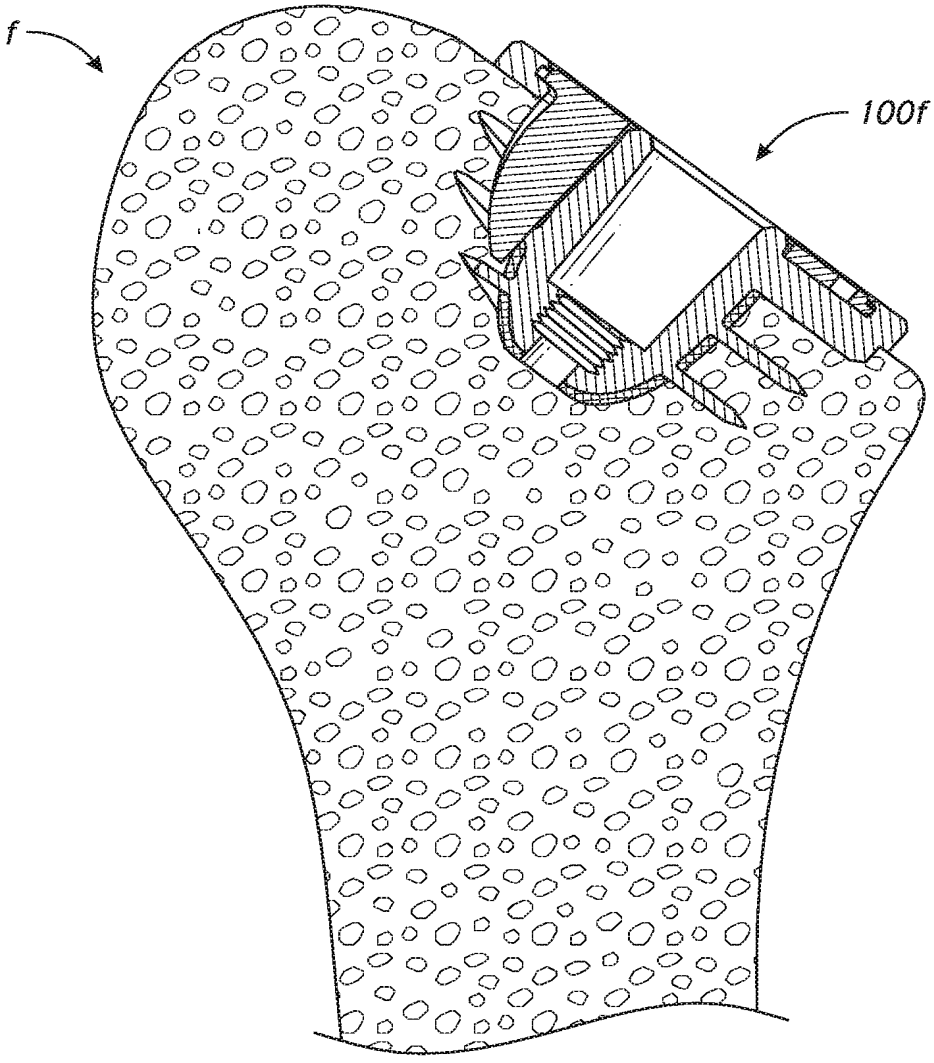


FIG. 24

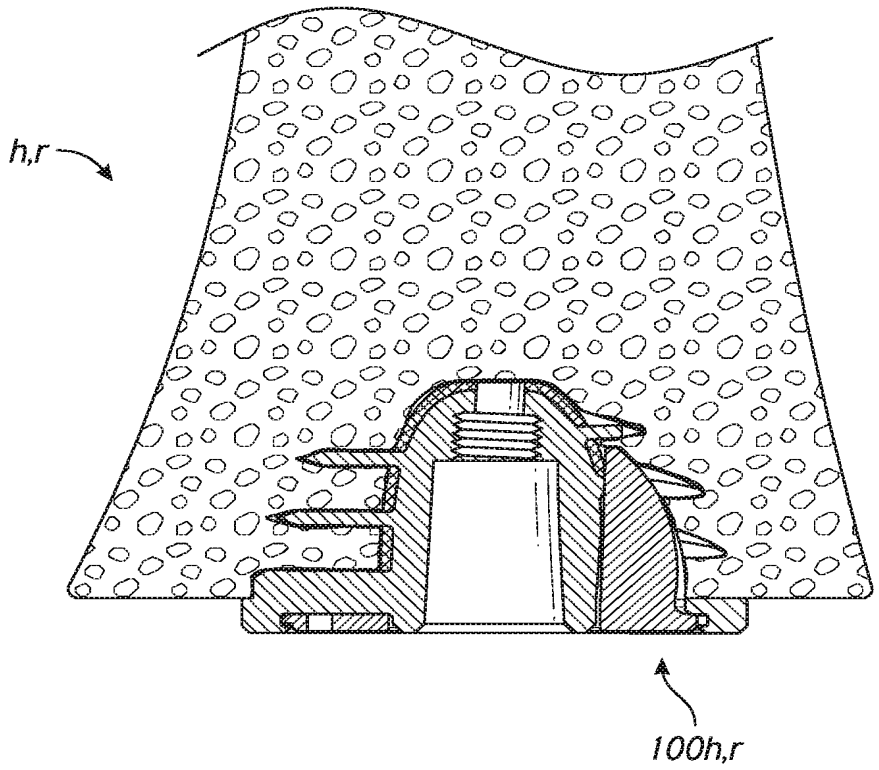


FIG. 25

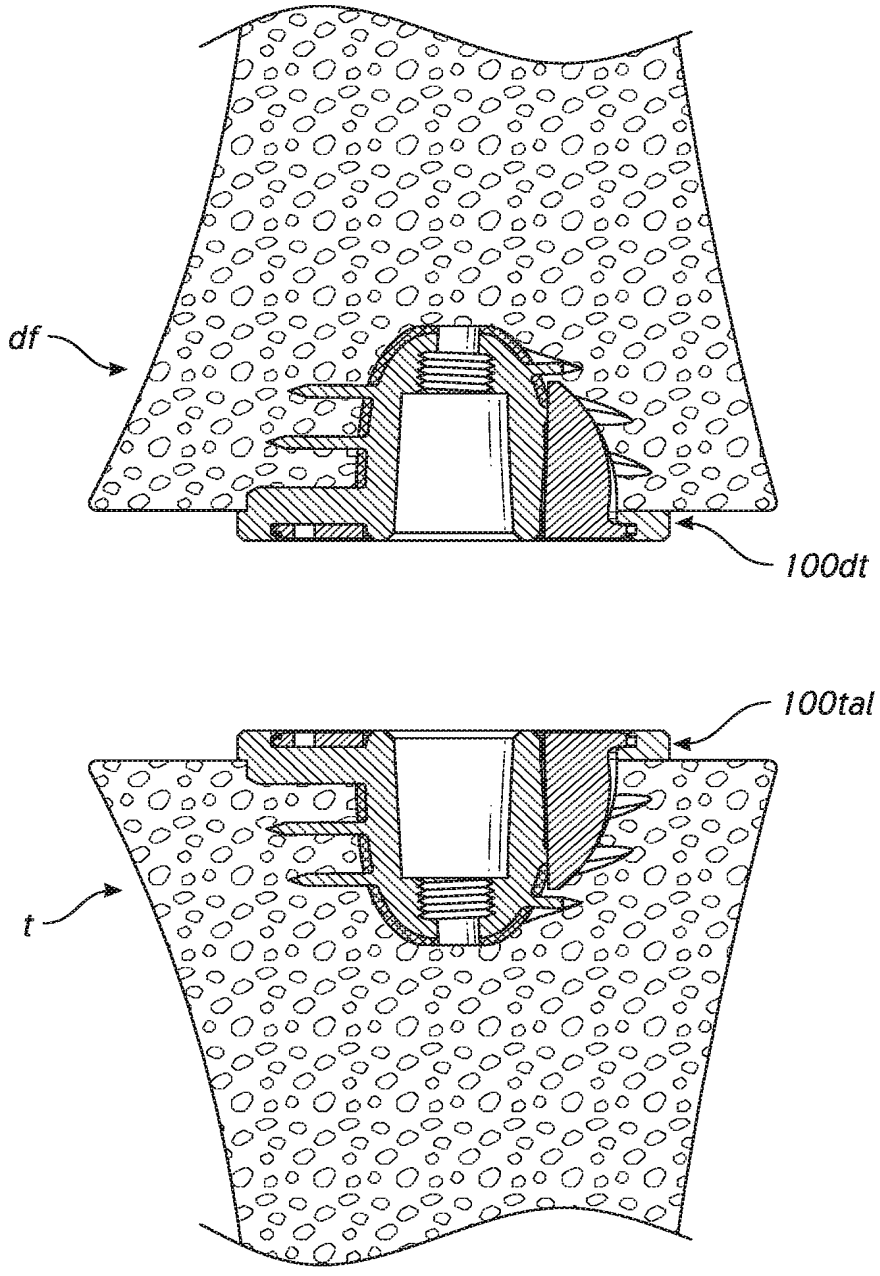


FIG. 26

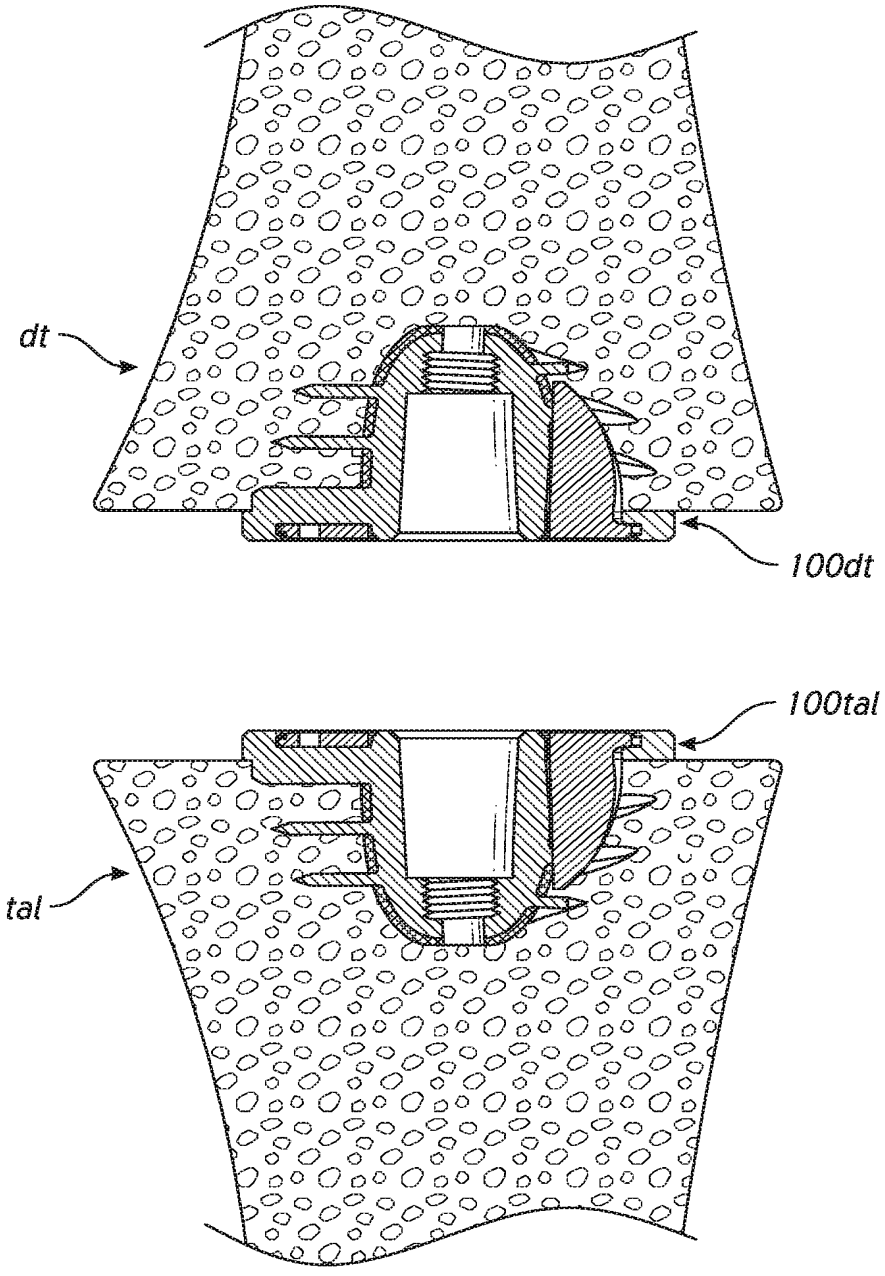


FIG. 27

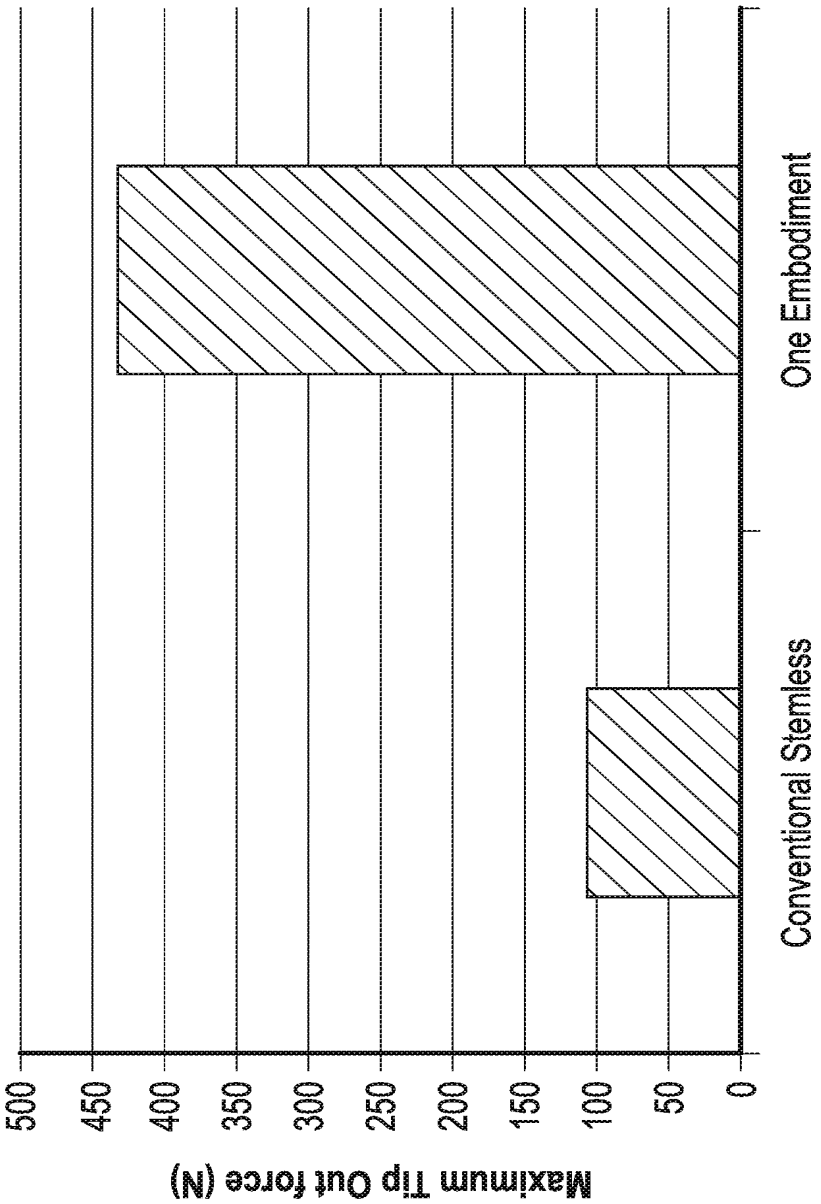

Maximum Tip Out force (N)
500
450
400
350
300
250
200
150
100
50
0
Conventional Stemless
One Embodiment

FIG. 28

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/038843

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/40 A61F2/46
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F 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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2015/112307 A1 (TORNIER INC [US]) 30 July 2015 (2015-07-30) the whole document	1-35, 37-42
A	US 2011/224673 A1 (SMITH MATTHEW J [US]) 15 September 2011 (2011-09-15) paragraphs [0037] - [0045]; figure 3	1-35, 37-42
A	EP 2 815 726 A1 (ARTHREX INC [US]) 24 December 2014 (2014-12-24) the whole document	1-35, 37-42

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 August 2017	28/08/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mingrino, Alessandra

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/038843

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2015112307 A1	30-07-2015	EP 3096714 A1	30-11-2016
		WO 2015112307 A1	30-07-2015
US 2011224673 A1	15-09-2011	AU 2011224329 A1	30-08-2012
		CA 2790589 A1	15-09-2011
		CN 102802564 A	28-11-2012
		EP 2544629 A2	16-01-2013
		JP 2013521889 A	13-06-2013
		US 2011224673 A1	15-09-2011
		WO 2011112779 A2	15-09-2011
EP 2815726 A1	24-12-2014	EP 2815726 A1	24-12-2014
		JP 2016522058 A	28-07-2016
		US 2014379089 A1	25-12-2014
		WO 2014202494 A1	24-12-2014

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/038843

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 36
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 36

According to Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT the International Search Authority, in the present case the EPO, is not required to carry out a search if the subject-matter of the international application relates to methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods. The method of implanting a prosthesis claimed in claim 36 is a method of treatment of the human by surgery and thus no search is performed.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 September 2019 (19.09.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/178104 A1

(51) International Patent Classification:
A61F 2/40 (2006.01) *A61F 2/46* (2006.01)
A61F 2/30 (2006.01)

(21) International Application Number:
PCT/US2019/021859

(22) International Filing Date:
12 March 2019 (12.03.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/641,990 12 March 2018 (12.03.2018) US

(71) Applicant: **SHOULDER INNOVATIONS, LLC** [US/US]; 13827 Port Sheldon Street, Holland, Michigan 49424 (US).

(72) Inventors: **BALL, Robert, J.**; 13827 Port Sheldon Street, Holland, Michigan 49424 (US). **RUNNING, Donald, E.**; 13827 Port Sheldon Street, Holland, Michigan 49424 (US).

(74) Agent: **CHRISTENSEN, Michael, R.**; Knobbe, Martens, Olson & Bear, LLP , 2040 Main Street , 14th Floor, Irvine, California 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) Title: CONVERTIBLE TOTAL SHOULDER PROSTHESIS

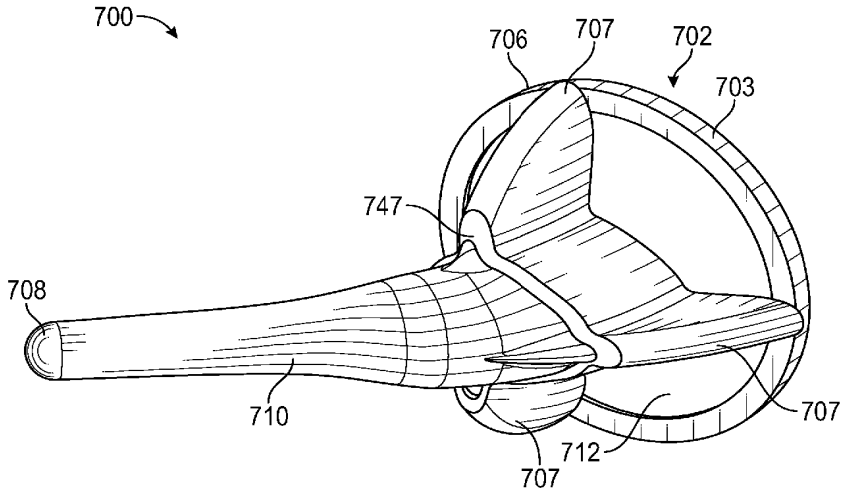


FIG. 7A

(57) Abstract: In some embodiments, disclosed is a glenohumeral implant with improved joint mobility. The implant can include a backing component; a neutral non-inclined bearing component on a concave side of the backing component, the bearing component made from a different material than the backing component and configured to touch a glenosphere having a center of rotation.

WO 2019/178104 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

CONVERTIBLE TOTAL SHOULDER PROSTHESIS

PRIORITY CLAIM

[0001] This application claims the benefit under 35 U.S.C. § 119(e) as a nonprovisional application of U.S. App. No. 62/641,990 filed on March 12, 2018, which is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] Shoulder Replacement is a commonly performed medical procedure for treatment of osteoarthritis, rheumatoid arthritis, as well as for treatment of certain deformities related to oncological indications as well as trauma. There are two primary types of articulations available to surgeons for treatment: anatomic and reverse. With anatomic, the surgeon replaces the articular surfaces with industrial materials such that the articulating surfaces are substantially the same shape as the natural anatomy. A stem can be commonly fixed inside the canal of the humerus, a metallic articular head can be rigidly fixed to the proximal aspect of the same, the articular head having a convex articular surface adapted to articulate with the glenoid implant. The glenoid implant can include on its back side (medial side) certain pegs or posts or fins adapted to be rigidly fixed within the glenoid fossa of the scapula and on its front side a concave or flat articular surface adapted to articulate with the humeral head of the humeral implant.

[0003] When a reverse prosthesis is used, the articular surface is reversed in that the metallic ball is rigidly fixed to the glenoid fossa of the scapula, and the concave articular surface is rigidly fixed to the humeral bone, thereby reversing the fashion of articulation of the prosthesis.

[0004] The surgeon chooses between the two types of prostheses by assessing a number of conditions of the patient including level of pain, patient activity level, deformity or severity of the boney degradation, the strength of surrounding soft tissues, and present or absence of prior surgery, and particularly the health and strength of the rotator cuff muscle and tendon. Disease of the rotator cuff is common among patients with arthritis of the

shoulder. In this circumstance, it is commonly observed that the absence of insufficiency of the rotator cuff leads to a condition where the anatomic shoulder replacement prosthesis is not sufficiently stabilized by surrounding soft tissue. In this case, a reverse shoulder replacement prosthesis can be preferred in some cases due to the higher inherent stability of the articulation. In addition, the reverse prosthesis can advantageously utilize the remaining muscles in a way they can be more effective in the absence of the other soft tissue structures by adjusting the position of the articular surfaces within the joint.

[0005] It is not uncommon that a surgeon selects to use an anatomic prosthesis and is provides effective treatment to the patient though the shoulder replacement operation. However, over time and during use of the prosthesis, the patient's rotator cuff complex can become insufficient, tear, or generally be diseased such that it can no longer perform its function associated with normal joint kinematics. In this case, the surgeon can elect to perform a second operation to remove the anatomic prosthesis, and replace the anatomic prosthesis with a reverse prosthesis.

[0006] Several attempts have been made to attempt to address the need of conversion of the articular surface without interruption of the fixation. Primarily, these are created using a two (or more) system, where there is a metallic fixation component which is rigidly fixed to the glenoid fossa, and a polyethylene (PE) articular component which is secondarily fixed to the metallic component, and provides the concave articular surface adapted to articular with the humeral prosthesis. While referred to herein as a PE component, some embodiments do not require the use of polyethylene and can be made of other biocompatible materials depending on the desired clinical result. The PE component is commonly fixed to the metallic fixation component by conventional industrial techniques such as snap fit mechanisms, snap rings, compression pins, overmolding of the PE and other such means.

[0007] A challenge of this particular articulation in some cases is that the glenoid fossa is relatively small, and commonly there is much reduced presence of bone in patients with arthritis. In this context, the surgeon has limited positioning and bone to work with in order to fit within the patient. In addition, the surgeon must be careful not to overstuff the joint, meaning implant components that move the new articulating surface far from its

original position such that the soft tissues is unnaturally tensioned, which can lead to instability, accelerated where, soft tissue failure, pain, reduced range of motion, or fracture of the prosthesis and surrounding bone. Facing these conditions, the prosthesis typically needs to be designed to remain relatively thin (commonly, 1 piece, where PE glenoid implants typically have a 4mm thick articular surface). In order to design these modular components, there can be little additional packaging space provided into which to fit the attachment mechanisms necessary for use without adversely affecting the performance of the overall joint replacement procedure. Thus, typically, these designs lead to "over-optimization" of the fixation and articular portions in order to provide sufficient attachment mechanisms such that either: the PE is too thin to be sufficiently strong, the metallic components are too small to provide sufficient fixation, or the overall mechanism is insufficiently rigid causing there to be secondary wear surfaces, and generation of wear particles leading to PE disease.

[0008] A problem that can exist is that in the case where the surgeon wants to change the prosthesis type, the anatomic prosthesis is commonly well fixed and adapted to the patient's body such that removal of the prosthesis can be very destructive, and leave natural bone remaining that is perhaps insufficient to support the fixation of the reverse prosthesis. What is needed is a prosthesis system that provides a means by which the articulating surfaces of the implant can be exchanged such that the anatomic surfaces can be converted to reverse surfaces, while not exchanging the fixation components.

[0009] What is also needed is a simple means by which the surgeon can implant an inset anatomic articulating glenoid implant whereby at a later date, can remove the anatomic articulating surface and replace it with a reverse articulating surface such that the primary means of fixation remains well fixed in the glenoid fossa at the moment of articular exchange.

[0010] Furthermore, conventional systems can change the inclination angle of the humerus by offering bearing components (e.g., polyethylene inserts) that are more and more inclined, thus medializing the center of rotation of the glenosphere and overstuffing the joint. Systems that can change the inclination angle of the humerus without changing the center of rotation of the glenosphere and/or overstuffing the joint to provide increased range of motion are needed.

SUMMARY

[0011] In some embodiments, disclosed is a glenohumeral implant with improved joint mobility. The implant can include a backing component; a neutral non-inclined bearing component on a concave side of the backing component, the bearing component made from a different material than the backing component and configured to touch a glenosphere having a center of rotation, wherein the bearing component is substantially radially symmetrical; and a peg extending from the backing component. The longitudinal axis of the peg of the backing component can be offset from the center of rotation of the glenosphere, while the central axis of the backing component (e.g., tray) can be aligned with the center of rotation of the glenosphere. The backing component can be inclined, for example, by an angle of between about 1.25 degrees and about 30 degrees, or between about 2.5 degrees and about 12.5 degrees with respect to a corresponding attachment surface of a humeral head. The glenoid implant when inserted into a patient does not change the center of rotation of the glenosphere in some embodiments, and can be convertible from an anatomic to a reverse prosthesis. In some embodiments, the bearing component has a depth of less than about 5.5mm, such as between about 3mm and about 5mm in some cases. The bearing component can include a plastic material, such as polyethylene. The backing component can include a metal material. The peg can have a Morse or other taper. The peg can be offset along the long axis of the backing component.

[0012] Also disclosed herein is a method of implanting a glenoid implant, comprising: reaming a cavity in the glenoid surface; sizing a first glenoid implant comprising a first angulation with respect to a stem, wherein the glenoid implant comprises a neutral bearing component and an inclined backing component comprising a first incline angle with respect to a corresponding attachment surface of a humeral head; sizing a second glenoid implant comprising a second angulation with respect to the stem, wherein the glenoid implant comprises a neutral bearing component and an inclined backing component comprising a second incline angle with respect to a corresponding attachment surface of a humeral head; implanting the second glenoid implant in the glenoid cavity; wherein the center of rotation of the glenosphere does not change between the first glenoid implant and the second glenoid

implant, allowing for adjustment of version and inclination without changing the center of rotation.

[0013] Some embodiments of the invention are focused on advantageously exchanging the articular surface of the glenoid from a concave shape to a convex shape, without removing the components or the interface having to do with fixation of the implant into the glenoid fossa, by utilizing a convertible humeral prosthesis.

[0014] In some embodiments, embodiments of the invention can be used or modified with use with particular advantages of using inset glenoid fixation technology in anatomic shoulder arthroplasty, such as described, for example, in U.S. Pat. No. 8,007,538 to Gunther, which is hereby incorporated by reference in its entirety.

[0015] In some embodiments, embodiments of the invention can be used as a modular platform for anatomic or reverse articulations.

[0016] In some embodiments, embodiments of the invention can be used to change the inclination angle of the prosthetic with respect to the humerus.

[0017] In some embodiments, a glenoid implant allowing for adjustable angles for anatomic or reverse arthroplasty is presented and comprises: a backing component; a bearing component on the concave side of the backing component, the bearing component made from a different material than the backing component; and a peg extending from the backing component. Further, in some embodiments the longitudinal axis of the backing component is offset from the center of rotation, but the center of rotation is not changed.

[0018] In some embodiments, the embodiments of the bearing component lining the backing component is made of an evenly distributed biologically compatible material.

[0019] In some embodiments, the bearing component is made of a material such as polyethylene.

[0020] In some of the embodiments, embodiments of the invention offer different angular placements, allowing for a range of inclination angles.

[0021] In some embodiments, disclosed herein is a shoulder implant with improved joint mobility. The implant can include a backing component; a neutral non-inclined bearing component on a concave side of the backing component, the bearing component made from a different material than the backing component and configured to

touch a glenosphere having a center of rotation, wherein the bearing component is substantially radially symmetrical; and a peg extending from the backing component and configured to be connected to a humeral stem. The longitudinal axis of the peg of the backing component can be offset from the center of rotation of the glenosphere. The longitudinal axis of the backing component can be aligned with the center of rotation of the glenosphere.

[0022] In some embodiments, the backing component is inclined by an angle of between about 1.25 degrees and about 30 degrees with respect to a corresponding attachment surface of a humeral head or stem.

[0023] In some embodiments, the backing component is inclined by an angle of between about 2.5 degrees and about 12.5 degrees with respect to a corresponding attachment surface of a humeral head or stem.

[0024] In some embodiments, the implant when inserted into a patient does not change the center of rotation of the glenosphere.

[0025] In some embodiments, the implant is configured for anatomic positioning, or for reverse positioning.

[0026] In some embodiments, the bearing component has a depth of less than about 5.5mm, or between about 3mm and about 5mm.

[0027] In some embodiments, the bearing component comprises a plastic material, such as polyethylene.

[0028] In some embodiments, the backing component comprises a metal material.

[0029] In some embodiments, the peg comprises a Morse taper.

[0030] In some embodiments, at least a portion of an inferior-facing surface of the backing component is configured to come in contact with a prepared humeral surface comprises an oval or elliptical cross-section, at least a portion of the inferior-facing surface of the bearing component comprises a circular cross-section, and at least a portion of the superior-facing surface of the backing component comprises a circular cross-section, the portion of the inferior-facing surface of the bearing component and the superior-facing surface of the backing component configured to snap or otherwise mate with each other.

[0031] In some embodiments, disclosed is a kit of shoulder implants, comprising a plurality of implants as in Claim 1, wherein the plurality of implants comprises a first

implant and a second implant, wherein the backing component of the first implant is inclined by a first angle, wherein the backing component of the second implant is inclined by a second angle different from the first angle, wherein the center of rotation of the glenosphere of the first implant and the second implant are in the same location.

[0032] Also disclosed herein is a method of implanting a shoulder implant. The method can include reaming a cavity in the glenoid surface; sizing a first implant comprising a first angulation with respect to a stem, wherein the implant comprises a neutral bearing component and an inclined backing component comprising a first incline angle with respect to a corresponding attachment surface of a humeral head; and sizing a second glenoid implant comprising a second angulation with respect to the stem. The glenoid implant can comprise a neutral bearing component and an inclined backing component comprising a second incline angle with respect to a corresponding attachment surface of a humeral head. The method can also include implanting the second glenoid implant in the glenoid cavity. The center of rotation of the glenosphere does not change between the first glenoid implant and the second glenoid implant, allowing for adjustment of version and inclination without changing the center of rotation.

[0033] In some embodiments, also disclosed herein is a humeral prosthesis, comprising a proximal end comprising at least three radially outwardly extending fins; and a stem extending distally from the proximal end to a distal end. The proximal end can include a proximal end diameter defined by a circle contacting radial outward-most proximal tips of the at least three radially outwardly extending fins. The distal end can include a distal end diameter. The proximal end diameter can be, for example, between about 30mm and about 50mm. The distal end diameter can be between, for example, between about 5mm and about 6mm. A ratio of the proximal end diameter and the distal end diameter can be between about 5 and about 9, or between about 5.5 and about 8.5. The proximal end can include a bowl-shaped concavity. The prosthesis can also include a central aperture in the proximal end configured to mate with a reverse component.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] FIG. 1 is a side perspective view of an embodiment of a convertible humeral prosthesis, according to some embodiments of the invention.

[0035] FIG. 2 is a bottom perspective view of the embodiment shown in FIG. 1;

[0036] FIG. 3 is a top view of the embodiment shown in FIG. 1 also showing an aperture in the center of the superior facing surface of the neck of the prosthesis and configured to be utilized as a reverse adapter for, in some cases, facilitating placement or removal of a spherical ball on the humeral head.

[0037] FIG. 4 is a side view of the embodiment shown in FIG. 1;

[0038] FIG. 5 is another side view of the embodiment shown in FIG. 1, also illustrating channel of the reverse adapter aperture extending within the neck and stem.

[0039] FIG. 6 is an inverted perspective view, also illustrating medial groove along the neck and stem of the prosthesis.

[0040] FIG. 7 is another perspective view of the prosthesis shown in FIG. 1.

[0041] FIG. 7A is a side perspective view of another embodiment of a convertible humeral prosthesis, according to some embodiments of the invention.

[0042] FIG. 7B is a bottom perspective view of the embodiment shown in FIG. 7A;

[0043] FIG. 7C is a top view of the embodiment shown in FIG. 7A also showing an aperture in the center of the superior facing surface of the neck of the prosthesis and configured to be utilized as a reverse adapter for, in some cases, facilitating placement or removal of a spherical ball on the humeral head.

[0044] FIG. 7D is a side view of the embodiment shown in FIG. 7A;

[0045] FIG. 7E is another side view of the embodiment shown in FIG. 7A, also illustrating channel of the reverse adapter aperture extending within the neck and stem.

[0046] FIG. 7F is an inverted perspective view, also illustrating medial groove along the neck and stem of the prosthesis.

[0047] FIG. 7G is another perspective view of the prosthesis shown in FIG. 7F.

[0048] FIGS. 8-11 illustrate various views of another embodiment of a humeral replacement prosthesis.

[0049] FIG. 12 is an illustration of one potential embodiment of the invention that depicts a conventional glenoid implant with an offset bearing component.

[0050] FIG. 13 is an illustration of one embodiment of the offset backing component allowing a 2.5 degree inclination.

[0051] FIG. 14 is an illustration of one embodiment of the offset backing component allowing a 7.5 degree inclination.

[0052] FIG. 15 illustrate the use of one embodiment of the offset backing component allowing a 12.5 degree inclination.

DETAILED DESCRIPTION

[0053] In particular, some embodiments of the invention are focused on advantageously exchanging the articular surface of the glenoid from a concave shape to a convex shape, without removing the components or interface having to do with fixation of the implant into the glenoid fossa, by utilizing a convertible humeral prosthesis.

[0054] In some embodiments, embodiments of the invention can be used or modified with use with particular advantages of using inset glenoid fixation technology in anatomic shoulder arthroplasty, such as described, for example, in U.S. Pat. No. 8,007,538 to Gunther, which is hereby incorporated by reference in its entirety. In some embodiments, an inset method includes identifying a patient having a glenoid surface; reaming a cavity into the glenoid surface; and inserting a glenoid implant having a body and a single, radially symmetric central peg oriented along a central axis of the implant, the body having a bearing surface on a peripheral edge thereof into the cavity, such that at least a portion of a peripheral edge of the body is inset with respect to the cavity and resides below the adjacent glenoid surface and the portion residing below the adjacent glenoid surface is circumferentially surrounded by cortical bone of the glenoid.

[0055] What is further described are methods by which the surgeon can achieve the use of the inset glenoid technology with an anatomic articulation, while after having the ability to convert the technology to a reverse articulation, without requiring removal the rigid fixation between the inset fixation and the scapula bone (in other words, allowing the rigid

fixation support between the inset fixation and the scapula bone to remain in place during conversion from an anatomic to a reverse prosthesis).

[0056] FIGS. 1-7 illustrate various views of a humeral replacement prosthesis 100, according to some embodiments of the invention. The prosthesis 100 can optionally include a proximal ring element 102, such as a collar (which can be configured to be attached to a spherical ball head portion, not shown) with a peripheral edge 103 that can be annular such as circular as shown, with an inferior-facing surface that can be optionally recessed (including a convex or flat bowl-like shape) and include a cavity, or inline in other embodiments. The humeral prosthesis 100 can include a superior-facing surface 114 of the proximal end 106, and be concave and bowl-shaped as shown with the base and deepest portion of the bowl proximate the center of the superior facing surface 114 of the proximal end 106 such that there is a space 113 between the inferior-facing surface of the humeral head portion (not shown) and the superior-facing surface 114 of the proximal end 106 of the prosthesis 100. In some embodiments the depth of the bowl at the center of concave curvature is between about 3mm and about 7mm, such as between about 4mm and about 6mm deep, such as about 5mm deep. The proximal end 106 of the prosthesis 100 can include spaced-apart flanges 107, such as three flanges 107 spaced equally apart, with vertices 111 of the flanges 107 extending radially outwardly while becoming narrower from the center of the proximal end 106 of the prosthesis 100. In some cases, a tri-flange design can provide for improved stability and rotation prevention, among other advantages. Extending distally from the proximal end 106 at an angle to the longitudinal axis of the proximal end/neck 106 is the stem 110 and distal end 108 of the prosthesis 100.

[0057] In some embodiments, the stem 110 and distal end 108 of the prosthesis has reduced thickness, e.g., tapering to no more than about 6mm, 5.5mm, 5mm, 4.5mm, 4mm, or less in width dimension, such as between about 5.5mm and about 6mm, and ranges incorporating any two of the foregoing values, to advantageously reduce the quantity of native humerus bone needed to be removed, and allows for a stem 110 that is 3-4mm or longer than a conventional stem 100 and allows for the majority of the fixation to occur in the proximal portion (e.g., neck 106) of the prosthesis. FIG. 1 is a side perspective view of an embodiment of the prosthesis; FIG. 2 is a bottom perspective view of the embodiment shown

in FIG. 1; FIG. 3 is a top view of the embodiment shown in FIG. 1 also showing an aperture 120 in the center of the superior facing surface 114 of the neck 106 of the prosthesis and configured to be utilized as a reverse adapter for, in some cases, facilitating placement or removal of a spherical ball on the humeral head. FIG. 4 is a side view of the embodiment shown in FIG. 1; FIG. 5 is another side view of the embodiment shown in FIG. 1, also illustrating channel 124 of the reverse adapter aperture 120 extending within the neck 106 and stem 110. FIG. 6 is an inverted perspective view, also illustrating medial groove 126 along the neck 106 and stem 110 of the prosthesis 100. FIG. 7 is another perspective view of the prosthesis shown in FIG. 1.

[0058] FIGS. 7A-7G illustrate views of another embodiment of a humeral replacement prostheses somewhat similar to, and which can incorporate any number of features shown, for example in FIGS. 1-7. FIG. 7A illustrates a perspective view of the prosthesis 700 including optional proximal ring element 702, such as a collar, with a peripheral edge 703 that can be annular such as circular as shown, with an inferior-facing surface that can be optionally recessed (including a convex or flat bowl-like shape) and include a cavity, or inline in other embodiments. The humeral prosthesis 700 can include a superior-facing surface 714 of the proximal end 706, and be concave and bowl-shaped as shown with the base and deepest portion of the bowl proximate the center of the superior facing surface 714 of the proximal end 106 such that there is a space 713 between the inferior-facing surface of the humeral head portion (not shown) and the superior-facing surface 714 of the proximal end 706 of the prosthesis 700. The proximal end 706 of the prosthesis 700 can include spaced-apart flanges 707, such as three flanges 707 spaced equally apart, with vertices 711 of the flanges 707 extending radially outwardly while becoming narrower from the center of the proximal end 706 of the prosthesis 700. Extending distally from the proximal end 106 at an angle to the longitudinal axis of the proximal end/neck 706 is the stem 710 and distal end 708 of the prosthesis 700. Also illustrated is transition zone 747, of which proximal to that zone 747 the prosthesis 700 includes a porous coating, and distal to that zone 747 the prosthesis 700 does not include a porous coating. The coating could include, for example, a plasma spray, porous metal, hydroxyapatite, or other

component which can facilitate cementless fixation to bone. However, cement fixation can be utilized in some embodiments.

[0059] FIG. 7A is a side perspective view of an embodiment of the prosthesis; FIG. 7B is a bottom perspective view of the embodiment shown in FIG. 7A; FIG. 7C is a top view of the embodiment shown in FIG. 7A also showing an aperture 120 in the center of the superior facing surface 114 of the neck 106 of the prosthesis and configured to be utilized as a reverse adapter for, in some cases, facilitating placement or removal of a spherical ball on the humeral head. FIG. 7D is a side view of the embodiment shown in FIG. 7A; FIG. 7E is another side view of the embodiment shown in FIG. 7A, also illustrating channel 124 of the reverse adapter aperture 120 extending within the neck 106 and stem 110. FIG. 7F is an inverted perspective view, also illustrating medial groove 126 along the neck 106 and stem 110 of the prosthesis 100. FIG. 7G is another perspective view of the prosthesis shown in FIG. 7.

[0060] FIGS. 8-11 illustrate various views of another embodiment of a humeral replacement prosthesis. FIG. 8 illustrates a humeral prosthesis that can be as described elsewhere herein, configured to be connected to a humeral head 801. FIG. 9 illustrates a perspective view of the humeral prosthesis 800, including stem 806, flanges 807, and adapter aperture 820 on the proximal end 806, as well as distal end 808. FIG. 10 illustrates a side view of the humeral prosthesis 800. FIG. 11 illustrates humeral head prosthesis 801 configured to be connected via projection 899 to the adapter aperture 820 of the humeral prosthesis 800, such as via press fit, threads, adhesive, or other techniques.

[0061] As shown, some potentially advantages of humeral implant configurations as described herein include that fixation is concentrated proximally, to conserve native bone. The prosthesis could be cemented, or cementless in some embodiments. The prosthesis geometry allows for ease of use, minimized surgical steps, and robust as errors can be readily absorbed. The prosthesis can also be convertible to reverse, which increases potentially for success and prevents or minimizing overstuffing. The prosthesis can also be advantageously inexpensive, logistically simple, and have minimal inventory requirements, as a diameter at or near the distal end of the stem can be constant, while the diameter at or near the proximal end of the stem can vary. For example, an operator could select a small number of humeral

stem implants, e.g., with 34mm, 38mm, and 44mm proximal diameters (which can be measured as the smallest circle that can encircle the proximal-most radially-outward end elements of the fins), all of which have the same distal-most diameter, such as about 5.5mm or about 6mm, or or no more than about 7mm, 6.5mm, 6mm, 5.5mm, 5mm, or less, or ranges including any two of the foregoing values. In some embodiments, the proximal-most diameter can be between about 25mm and about 50mm, such as about 25, 30, 35, 40, 45, 50mm, or ranges including any two of the foregoing values. In some embodiments, the humeral stem implants can have a ratio of proximal-most to distal-most diameter of the humeral stem of between about 5 and about 9, between about 5.5 and about 8.5, about 4.5, 4.75, 5, 5.25, 5.5, 5.75, 6, 6.25, 6.5, 6.75, 7, 7.25, 7.5, 7.75, 8, 8.25, 8.5, 8.75, 9, 9.25, 9.5, 9.75, 10, or ranges including any two of the foregoing values. The ability to provide a set or array of humeral stem implants that a physician can choose from with varying proximal-most diameters, each with the same or substantially the same small distal-most diameter can be in contrast to conventional humeral stem prostheses, in which within a set of different humeral stem sizes, the distal-most diameter generally also increases as the proximal-most diameter increases. In some embodiments, the prosthesis is collarless. In some embodiments, the prosthesis has a total length of about or at least about 50mm, 51mm, 52mm, 53mm, 54mm, 55mm, 56mm, 57mm, 58mm, 59mm, 60mm, 65mm, 70mm, or more, or ranges incorporating any two of the aforementioned values.

[0062] FIGS. 12-15 illustrate various views of several embodiments of components of a glenohumeral replacement prosthesis. FIG. 12 can be used to compare the effects of several different embodiments of the invention as depicted in FIGS. 13-15.

[0063] FIG. 12 depicts a conventional shoulder implant component embedded into the fossa of the scapula 201, such as the glenoid, or a humerus for example. FIG. 12, depicts an implant with an inclined, offset bearing component 204 (referring to the central axis of the bearing component being offset from the central axis of the backing component), with a backing component 205 which is aligned with center of rotation 208. The prosthetic is embedded on or within the bony cavity 203 comprises a bearing surface 204 embedded onto a backing component (e.g., a concave tray) 205. The bearing surface 204 lines the backing component 205 and can be made of any appropriate material, such as a non-metallic,

biologically compatible material (e.g. polyethylene). The backing component connects to an elongated stem 207 that is embedded into the bone 202. The backing component 205 connects with the elongated stem 207 by a peg or keel (e.g. a morse taper) 206. In FIG. 12, the stem has neck shaft angle of about 132.5 degrees α which is the angle created by intersection of the axis through the elongated stem 209 and the center of rotation 208. The backing component 205 is aligned with the axis of the fossa 210. Since the bearing component 204 is offset, the center of rotation 208 of the glenosphere 214 is medialized.

[0064] FIG. 13 illustrates a different embodiment wherein the inclination angle of the humerus angle is controllable exclusively by an offset backing component 211, while the bearing component is not offset. By offset, the peg 206 of the backing component 211 is positioned such that a first distance from the peg 206 to a first end of the offset backing component 211 is not equal to a second distance from the peg 206 to a second send of the offset backing component 211. In some embodiments, the first distance is at least about, about, or no more than about 5%, 10%, 15%, 20%, 25%, or more or less than the second distance, or ranges including any two of the foregoing values. This is in distinct contrast to FIG. 12 wherein the bearing component (e.g., polyethylene) is offset with respect to a central axis of the backing component. FIG. 13 shows the effect of a reverse articulation at 135 degrees using a backing component that provides a 2.5 degree incline 211 when attached to the elongated stem 207. The rotation β1 represents a rotation of 2.5 degrees about the axis of the glenoid fossa 210. When added to the angle α, a reverse articulation of 135 degrees is achieved. Since the bearing component is not offset as in FIG. 12, the center of rotation of the glenosphere 215 remains constant, and is not medialized (or lateralized) away from the center of rotation 208. Also, the central axis 290 of the backing component 211 is offset from the central axis 208 of the peg.

[0065] FIG. 14 is similar to FIG. 13 with the exception that the angle of inclination of the backing component is different. FIG. 14 shows a desired 140 degree angle with a backing component providing a 7.5 degree incline 212 when attached to the elongated stem 207. The rotation β2 represents a rotation of 7.5 degrees about the axis of the glenoid fossa 210. When added to the angle α, a reverse articulation of 140 degrees is achieved. Since the bearing component is not offset as in Figure 12, the center of rotation of the

glenosphere 215 is not medialized away from the center of rotation 208 and remains in the same position as it was in FIG. 13.

[0066] FIG. 15 illustrates a 145 degree angle with a backing component providing a 12.5 degree incline 213 when attached to the elongated stem 207. The rotation β3 represents a rotation of 12.5 degrees about the axis of the glenoid fossa 210. When added to the angle α, a reverse articulation of 145 degrees is achieved. Since the bearing component is not offset as in Figure 12, the center of rotation of the glenosphere 215 is not medialized away from the center of rotation 208 and remains in the same position as it was in FIG 13 and FIG. 14.

[0067] In some embodiments of the invention, the inclination angles produced by the backing component above and beyond the neck shaft angle of the elongated stem may range from about 1.25, 2.5, 3.75, 5, 7.5, 10, 12.5, 15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5, 35 degrees, or ranges including any two of the aforementioned values.

[0068] The native prepared surface of the humerus of which an inferior-facing surface of the backing component rests against after implementation generally has an oval or elliptical cross-section. In some embodiments, the inferior-facing surface of the backing component also has an oval or elliptical cross-section substantially matching that of the surface of the humeral bone. In some embodiments, at least a portion of the inferior facing surface of the bearing component (e.g., polyethylene component in some cases) has a circular cross-section, and is configured to snap into, or otherwise mate with a complementary portion of the superior-facing surface of the backing component, which can also have a circular cross-section.

[0069] Non-limiting potential advantages of the embodiments in FIG. 13-15 is observed by example when comparing FIG. 12 to FIG. 14. The depth of the backing component in FIGS. 13-15 can be about 5 mm, compared with about 7.5mm with respect to the FIG. 12 embodiment where the bearing component is offset with respect to the center of rotation of the glenosphere, as well as the central axis of the backing component. In some embodiments, the depth of the backing component is less than about 6, 5.5, 5, 4.5, 4, 3.5, 3mm or less, or ranges including any two of the aforementioned values. Changing the backing component angle in FIGS. 13-15, as opposed to changing the amount of polyethylene

plastic or other material in the bearing component, results in an additional amount of space, such as about 2.5mm or more or less of space formed in the bowl for rotation of the glenosphere. Therefore, in several of the embodiments presented, the joint is less "stuffed" and not overstuffed and can potentially have greater range of motion. Furthermore, a physician can select between a range of different backing components with varying inclination angles, while the bearing components are neutral (e.g., not inclined). As such, the inclination angle of the humerus can be controlled solely by selecting an appropriate backing component, and the center of rotation of the glenosphere remains constant irrespective of the potentially varying inclination angle of the backing component.

[0070] In some embodiments, a glenohumeral implant allowing for adjustable angles for anatomic or reverse arthroplasty is presented and comprises: a backing component; a bearing component on the concave side of the backing component, the bearing component made from a different material than the backing component; and a peg extending from the backing component. Further, in some embodiments the longitudinal axis of the backing component is offset from the center of rotation, but the center of rotation is not changed.

[0071] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited

to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "insetting an implant into a glenoid cavity" includes "instructing the insetting of an implant into the glenoid cavity." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least," "greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

WHAT IS CLAIMED IS:

1. A shoulder implant with improved joint mobility, comprising:

a backing component;

a neutral non-inclined bearing component on a concave side of the backing component, the bearing component made from a different material than the backing component and configured to touch a glenosphere having a center of rotation, wherein the bearing component is substantially radially symmetrical; and

a peg extending from the backing component and configured to be connected to a humeral stem;

wherein the longitudinal axis of the peg of the backing component is offset from the center of rotation of the glenosphere,

wherein the longitudinal axis of the backing component is aligned with the center of rotation of the glenosphere.

2. The shoulder implant of Claim 1, wherein the backing component is inclined by an angle of between about 1.25 degrees and about 30 degrees with respect to a corresponding attachment surface of a humeral head.

3. The shoulder implant of Claim 1, wherein the backing component is inclined by an angle of between about 2.5 degrees and about 12.5 degrees with respect to a corresponding attachment surface of a humeral head.

4. The shoulder implant of Claim 1, wherein the glenoid implant when inserted into a patient does not change the center of rotation of the glenosphere.

5. The shoulder implant of Claim 1, configured for anatomic positioning.

6. The shoulder implant of Claim 1, configured for reverse positioning.

7. The shoulder implant of Claim 1, wherein the bearing component has a depth of less than about 5.5mm.

8. The shoulder implant of Claim 1, wherein the bearing component has a depth of between about 3mm and about 5mm.

9. The shoulder implant of Claim 1, wherein the bearing component comprises a plastic material.

10. The shoulder implant of Claim 9, wherein the plastic material comprises polyethylene.

11. The shoulder implant of Claim 1, wherein the backing component comprises a metal material.

12. The shoulder implant of Claim 1, wherein the peg comprises a Morse taper.

13. The shoulder implant of Claim 1, wherein at least a portion of an inferior-facing surface of the backing component configured to come in contact with a prepared humeral surface comprises an oval or elliptical cross-section, at least a portion of the inferior-facing surface of the bearing component comprises a circular cross-section, and at least a portion of the superior-facing surface of the backing component comprises a circular cross-section, the portion of the inferior-facing surface of the bearing component and the superior-facing surface of the backing component configured to snap or otherwise mate with each other.

14. A kit of shoulder implants, comprising a plurality of implants as in Claim 1, wherein the plurality of implants comprises a first implant and a second implant, wherein the backing component of the first implant is inclined by a first angle, wherein the backing component of the second implant is inclined by a second angle different from the first angle, wherein the center of rotation of the glenosphere of the first implant and the second implant are in the same location.

15. A method of implanting a shoulder implant, comprising:

reaming a cavity in the glenoid surface;

sizing a first implant comprising a first angulation with respect to a stem, wherein the implant comprises a neutral bearing component and an inclined backing component comprising a first incline angle with respect to a corresponding attachment surface of a humeral head;

sizing a second glenoid implant comprising a second angulation with respect to the stem, wherein the glenoid implant comprises a neutral bearing component and an inclined backing component comprising a second incline angle with respect to a corresponding attachment surface of a humeral head;

implanting the second glenoid implant in the glenoid cavity;

wherein the center of rotation of the glenosphere does not change between the first glenoid implant and the second glenoid implant, allowing for adjustment of version and inclination without changing the center of rotation.

16. A humeral prosthesis, comprising:

a proximal end comprising at least three radially outwardly extending fins;

a stem extending distally from the proximal end to a distal end,

wherein the proximal end comprises a proximal end diameter defined by a circle contacting radial outward-most proximal tips of the at least three radially outwardly extending fins,

wherein the distal end comprises a distal end diameter,

wherein the proximal end diameter is between about 30mm and about 50mm,

wherein the distal end diameter is between about 5mm and about 6mm, and

wherein a ratio of the proximal end diameter and the distal end diameter is between about 5 and about 9.

17. The humeral prosthesis of Claim 15, wherein the ratio is between about 5.5 and about 8.5.

18. The humeral prosthesis of Claim 15, wherein the proximal end comprises a bowl-shaped concavity.

19. The humeral prosthesis of Claim 15, comprising a central aperture in the proximal end configured to mate with a reverse component.

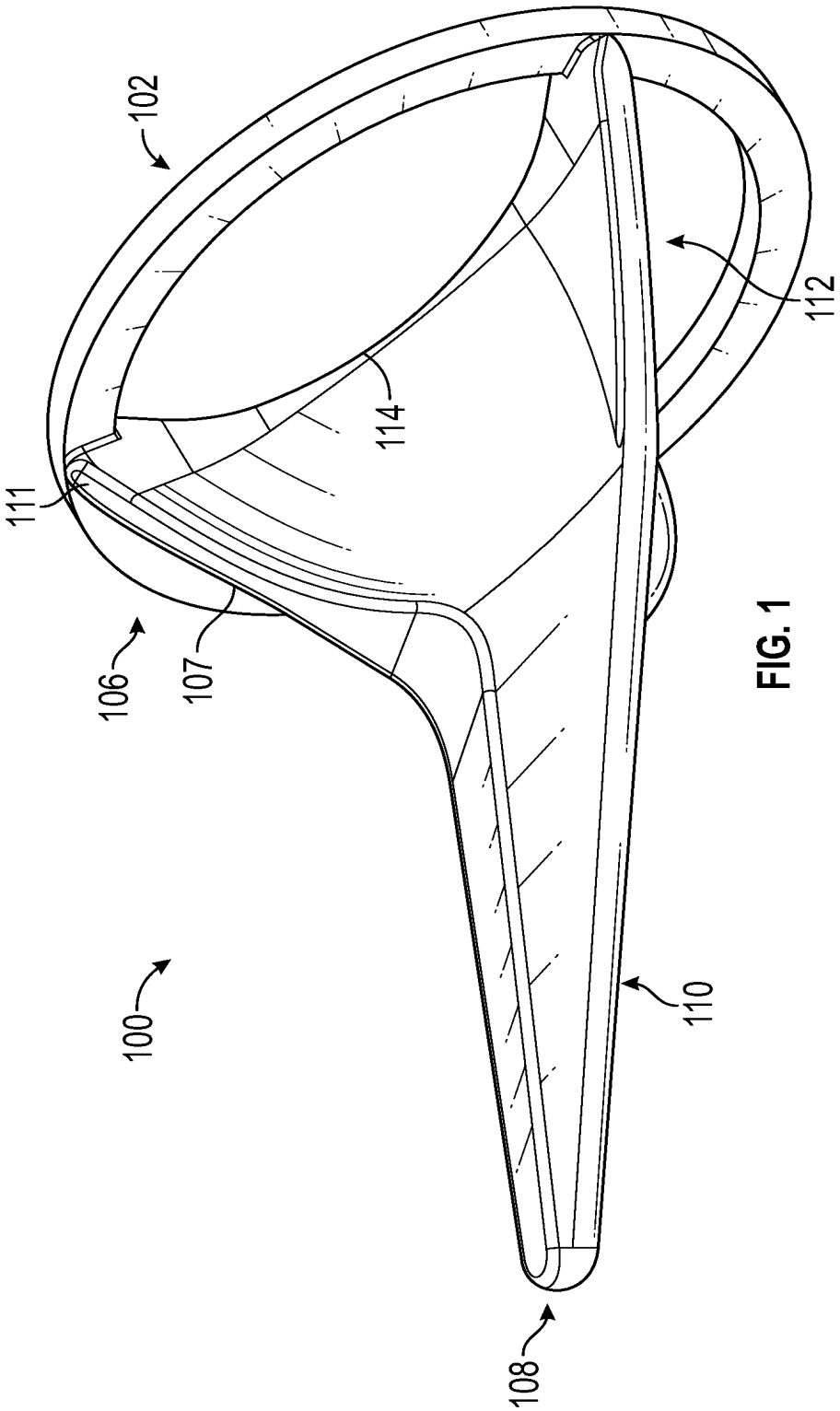


FIG. 1

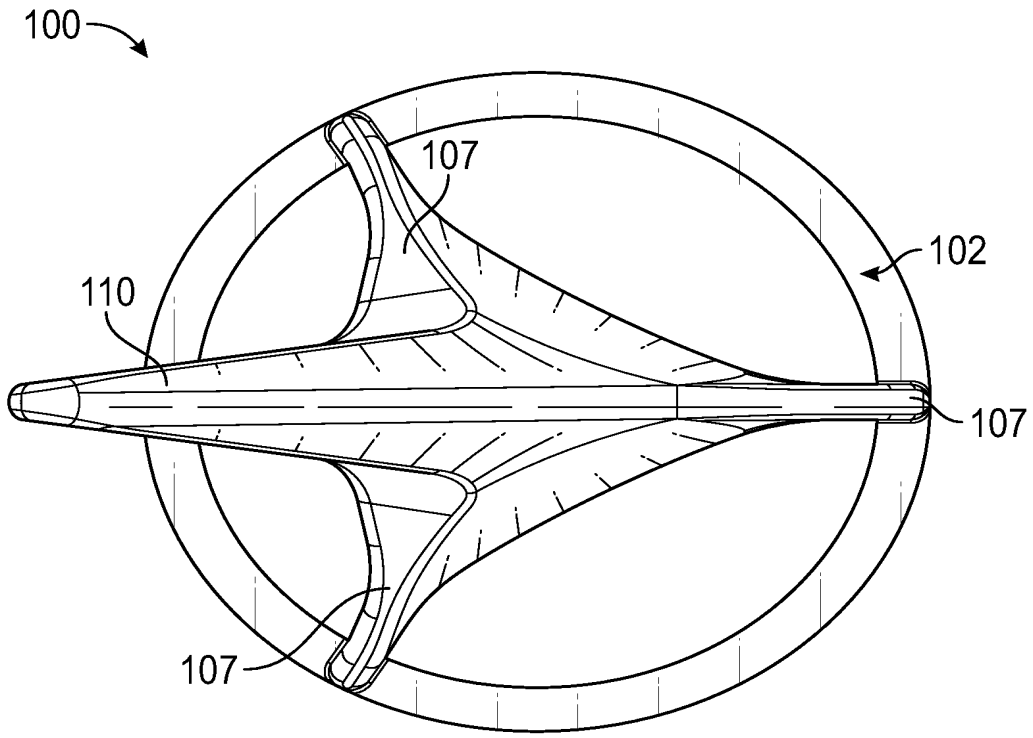


FIG. 2

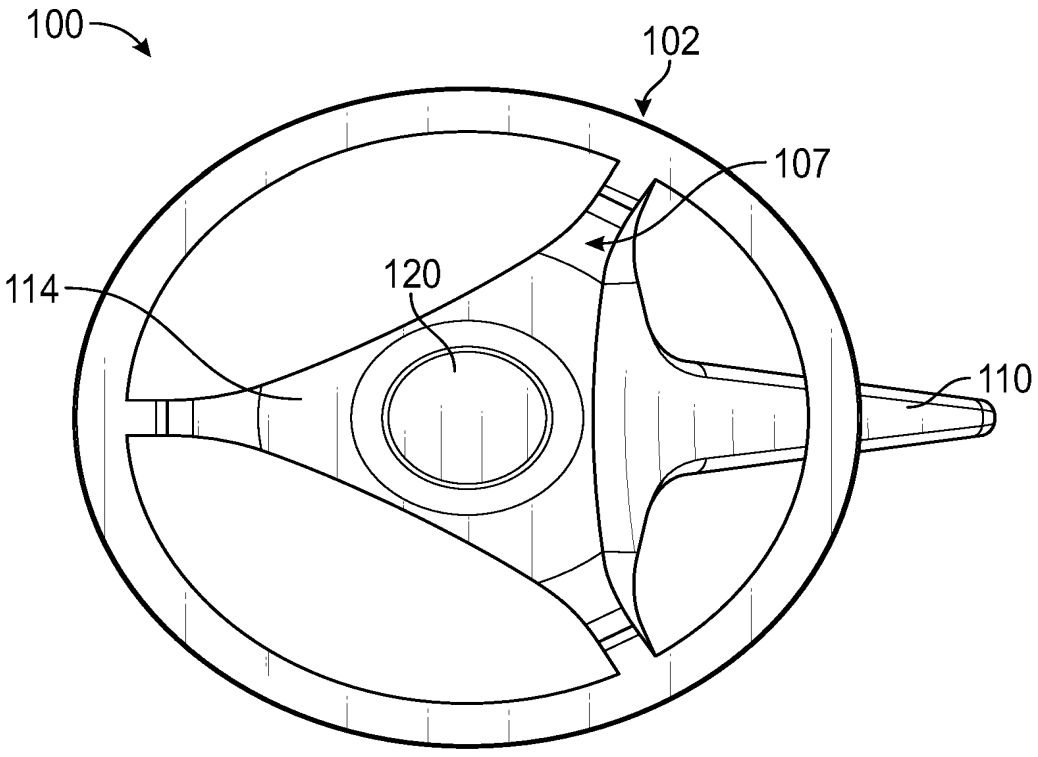


FIG. 3

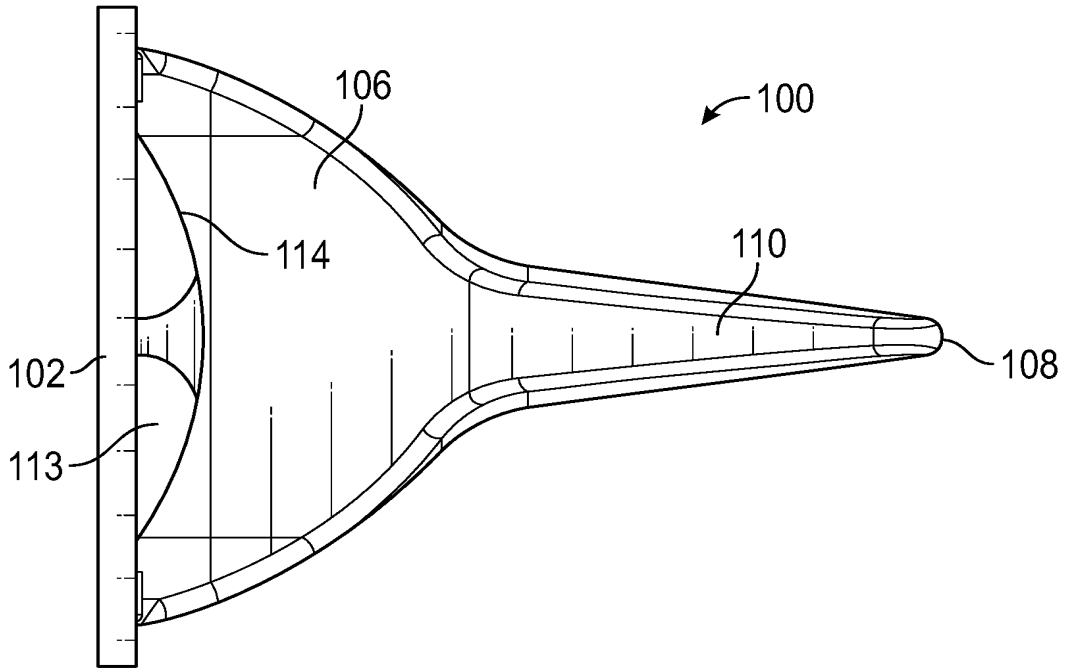


FIG. 4

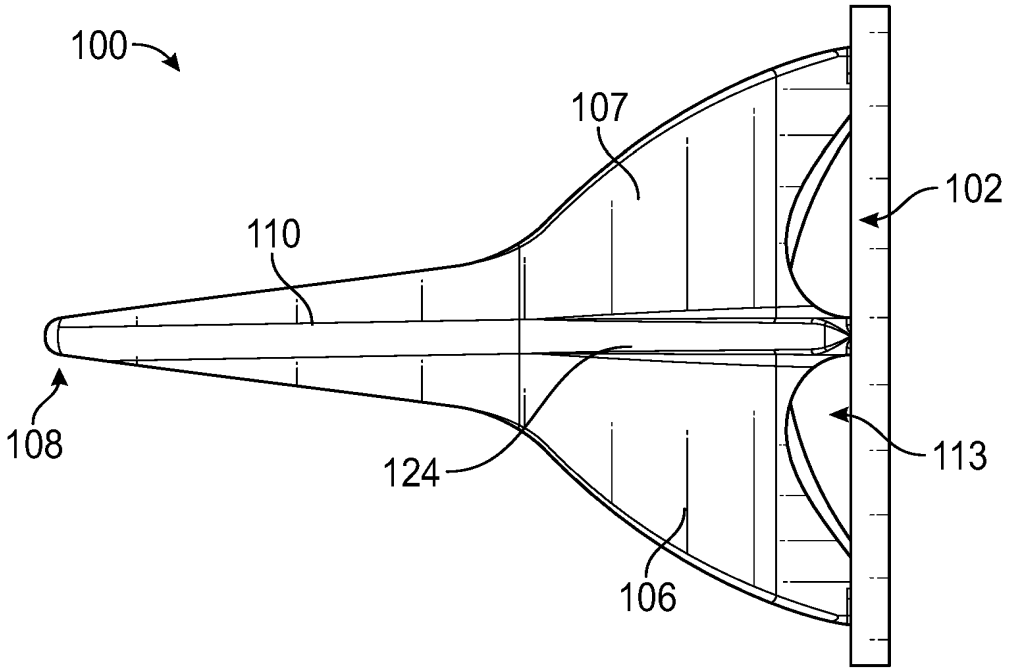


FIG. 5

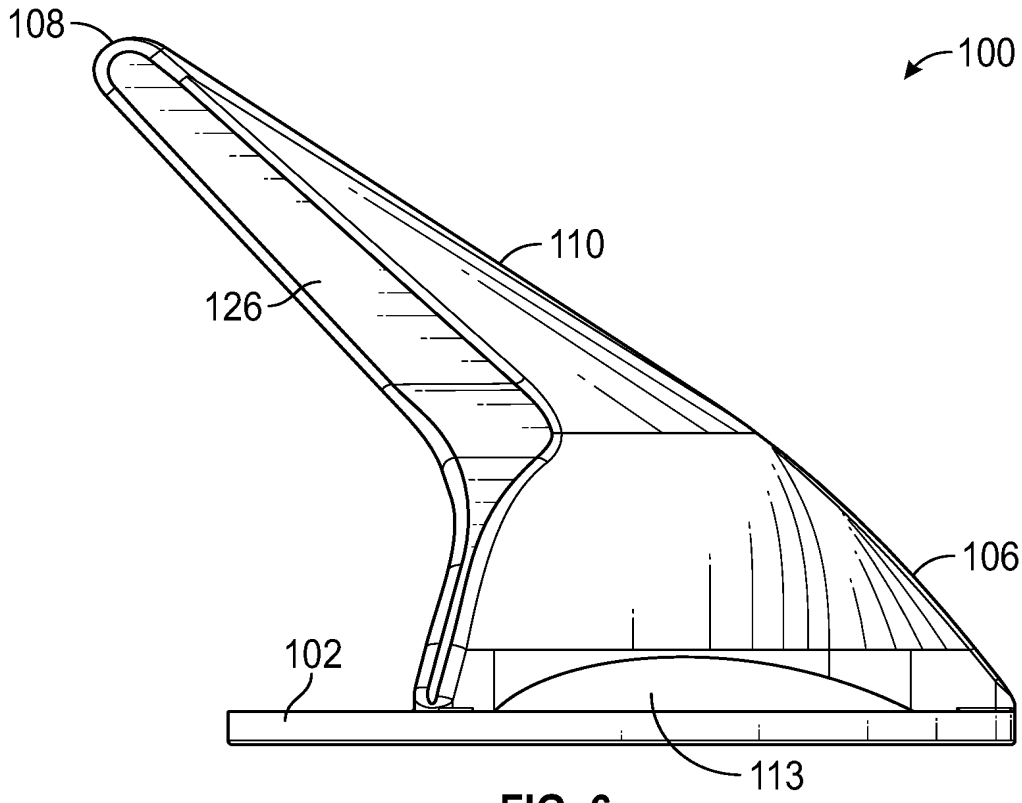


FIG. 6

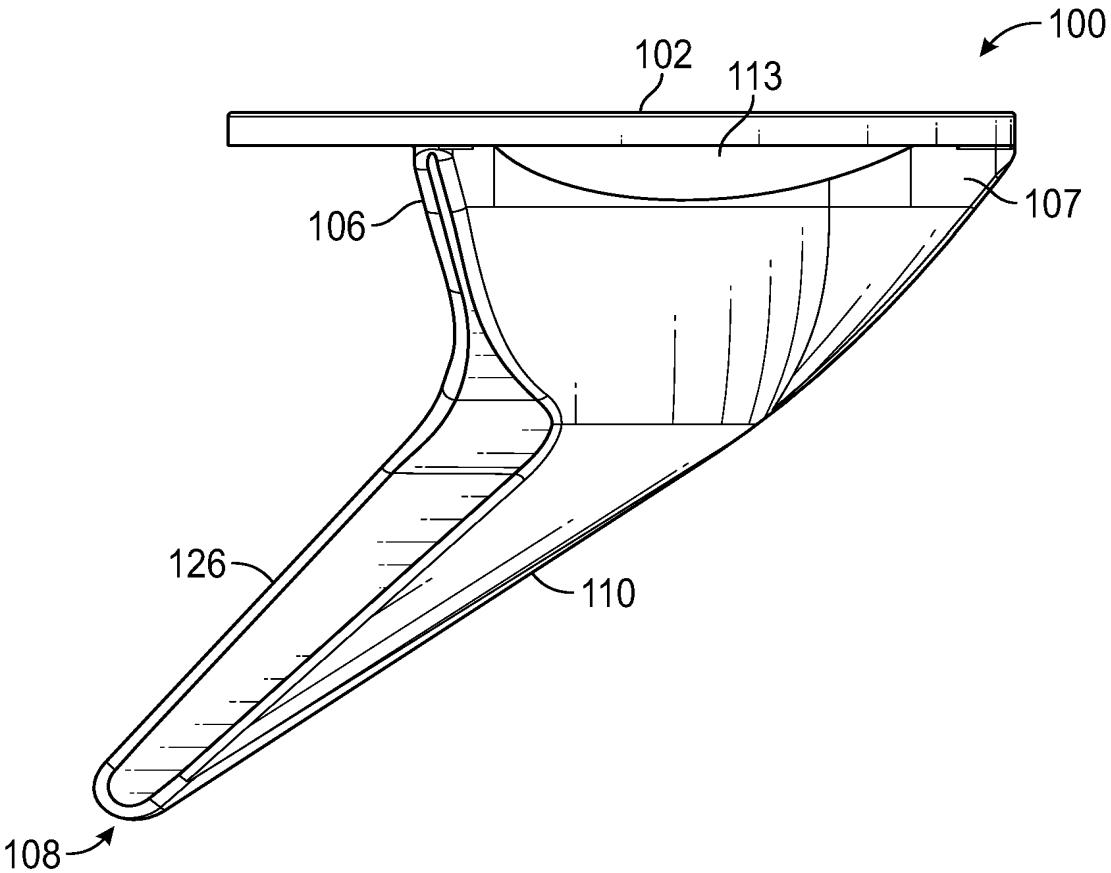


FIG. 7

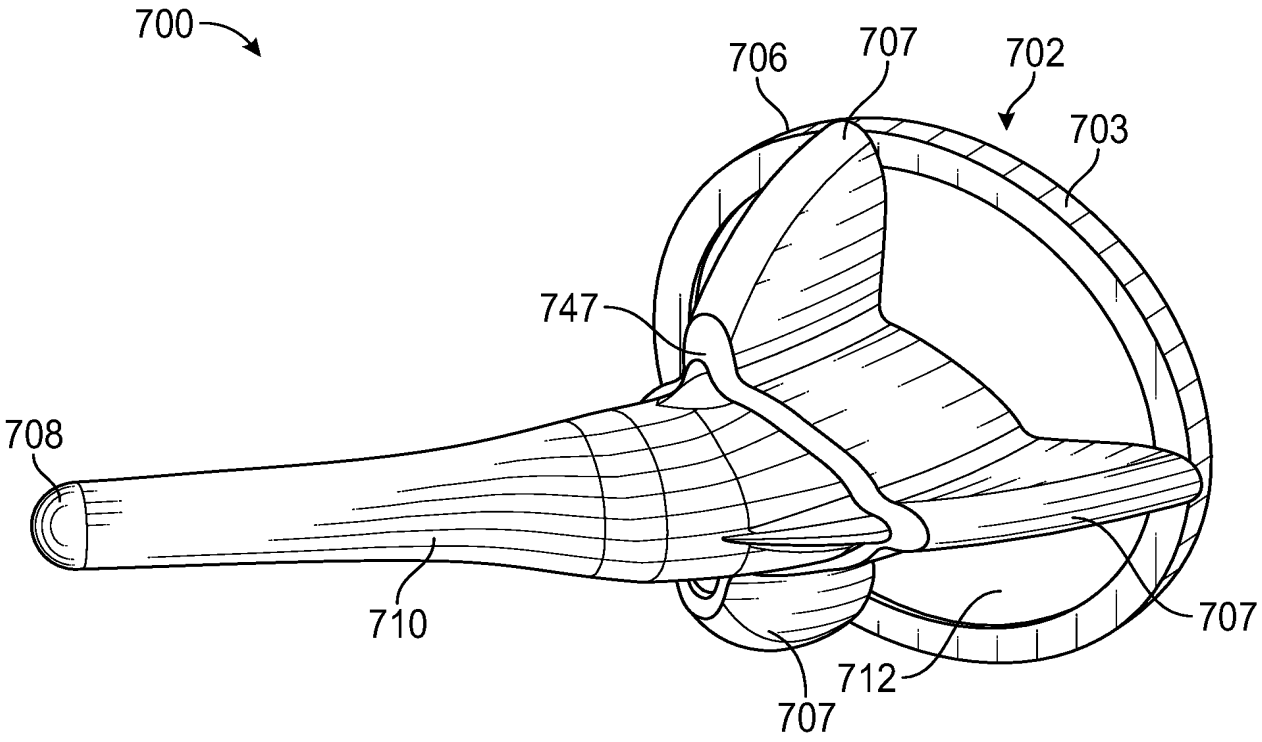


FIG. 7A

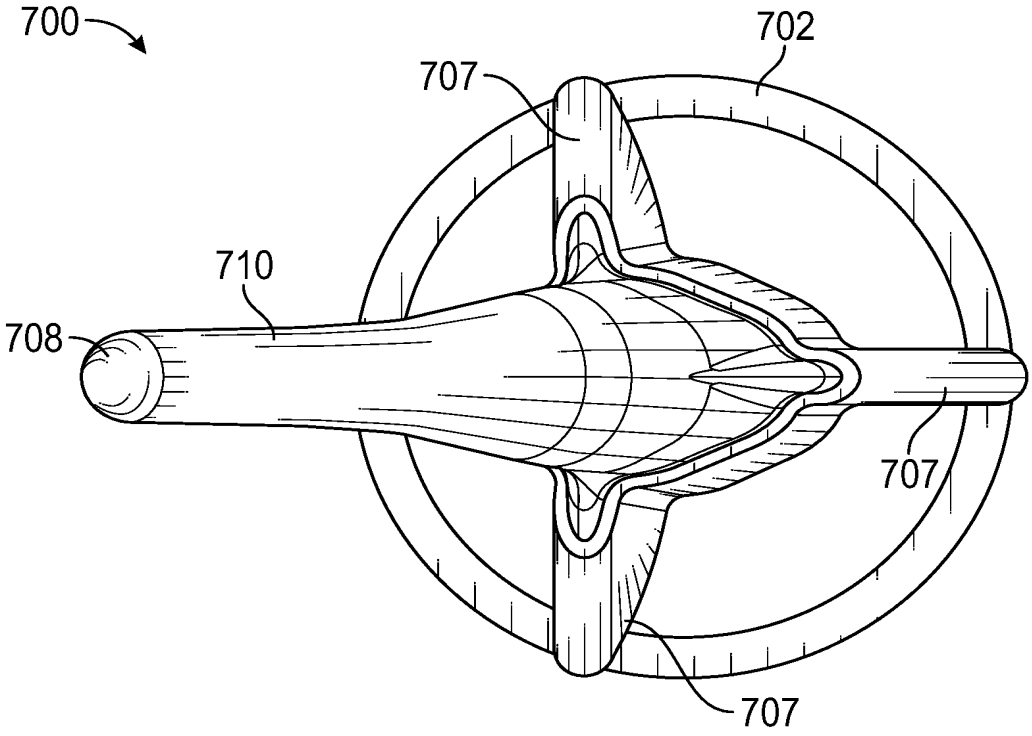


FIG. 7B

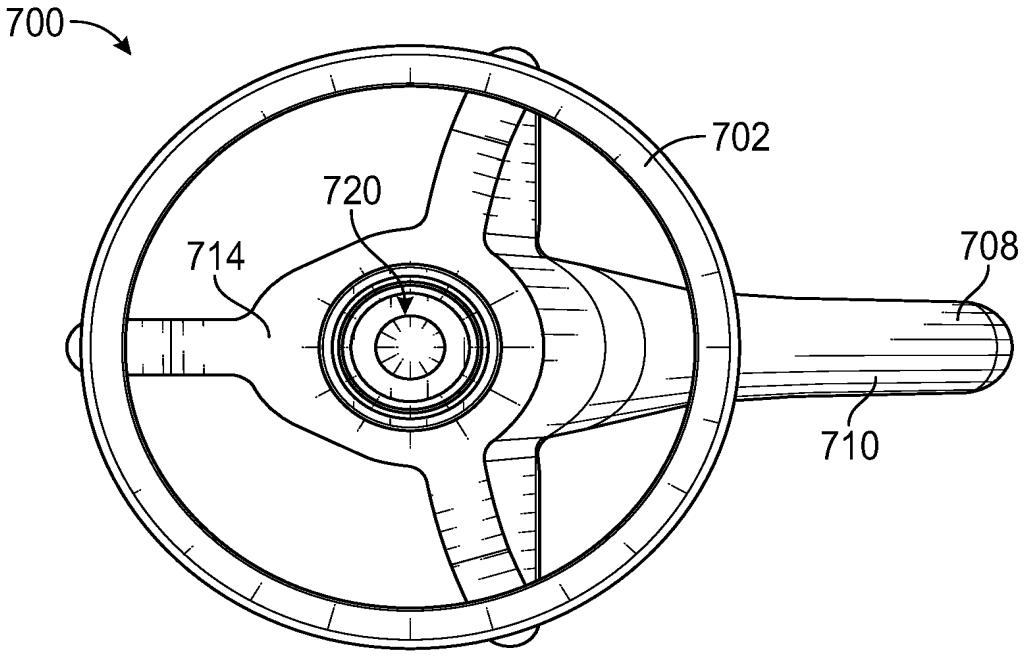


FIG. 7C

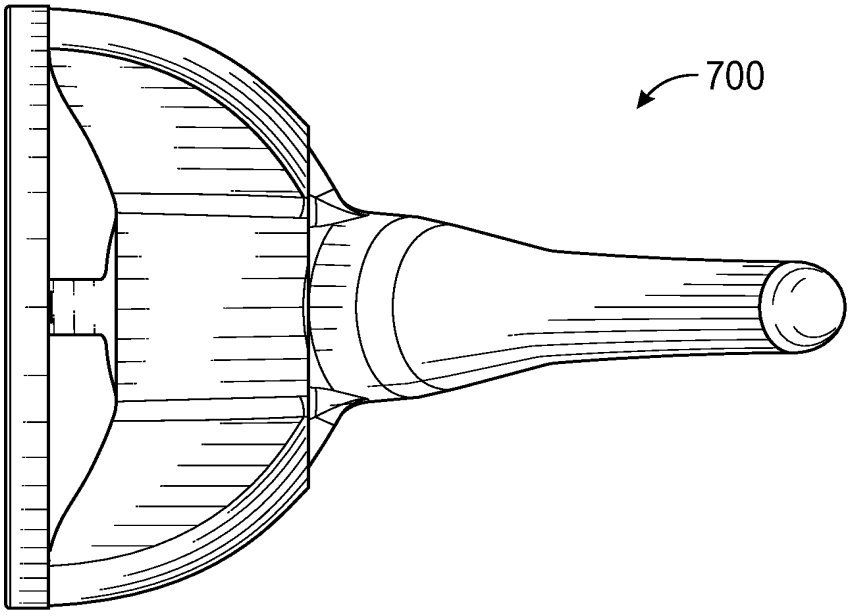


FIG. 7D

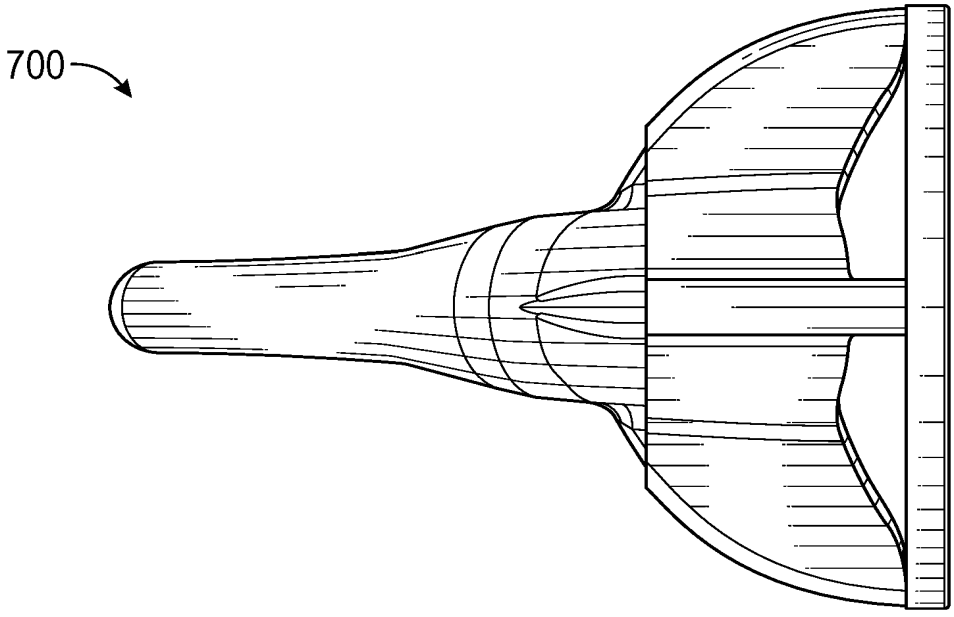


FIG. 7E

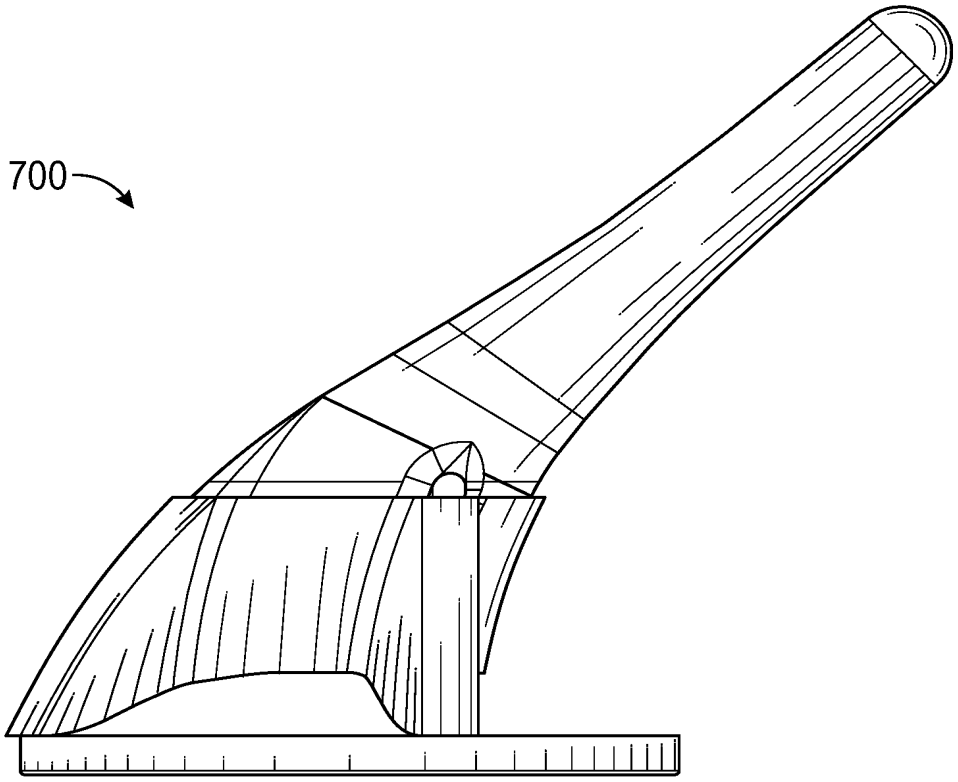


FIG. 7F

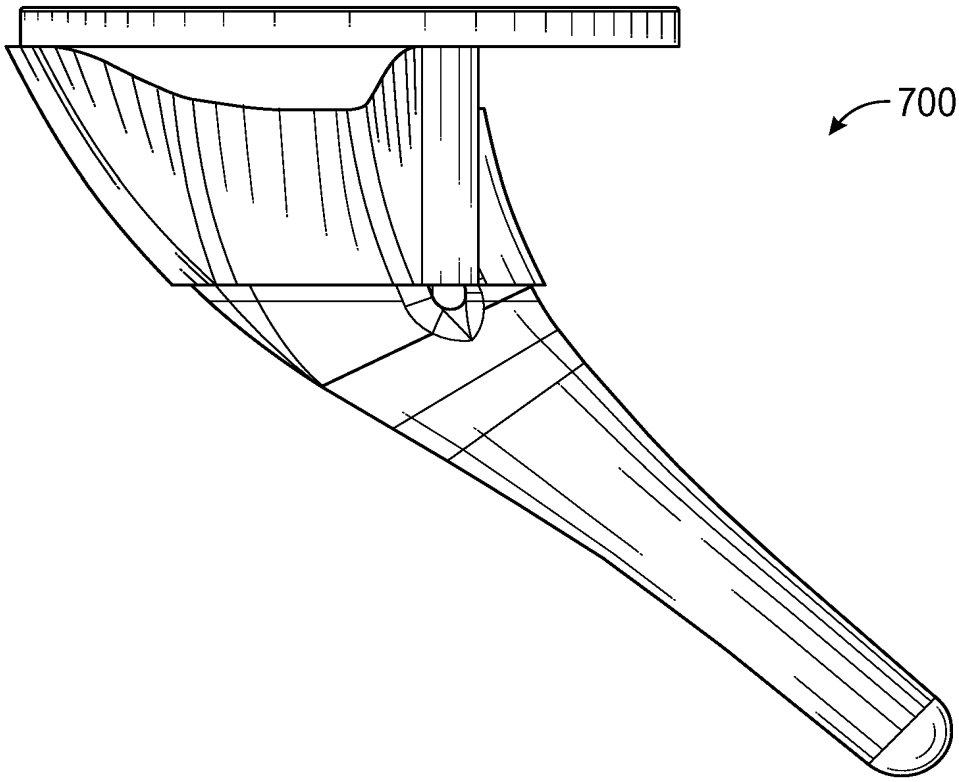


FIG. 7G

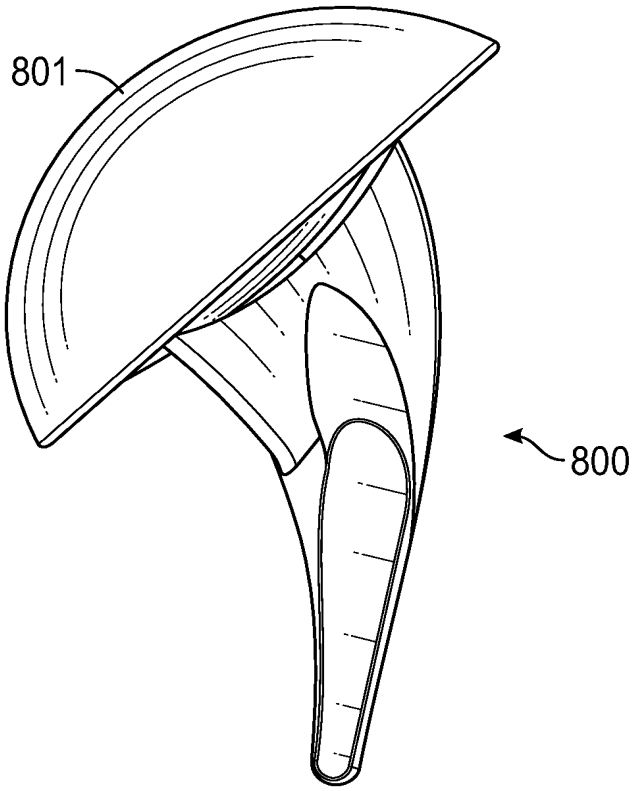


FIG. 8

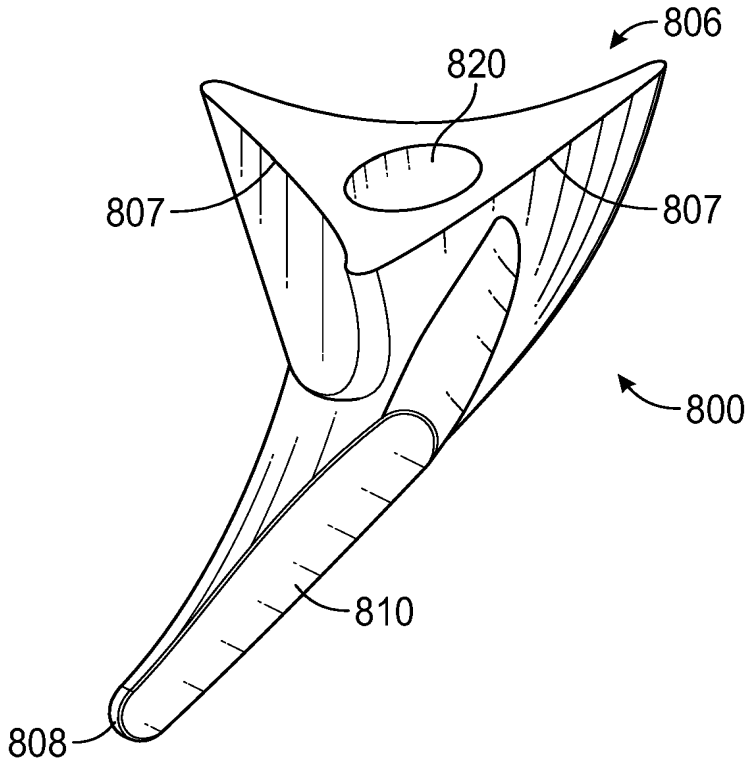


FIG. 9

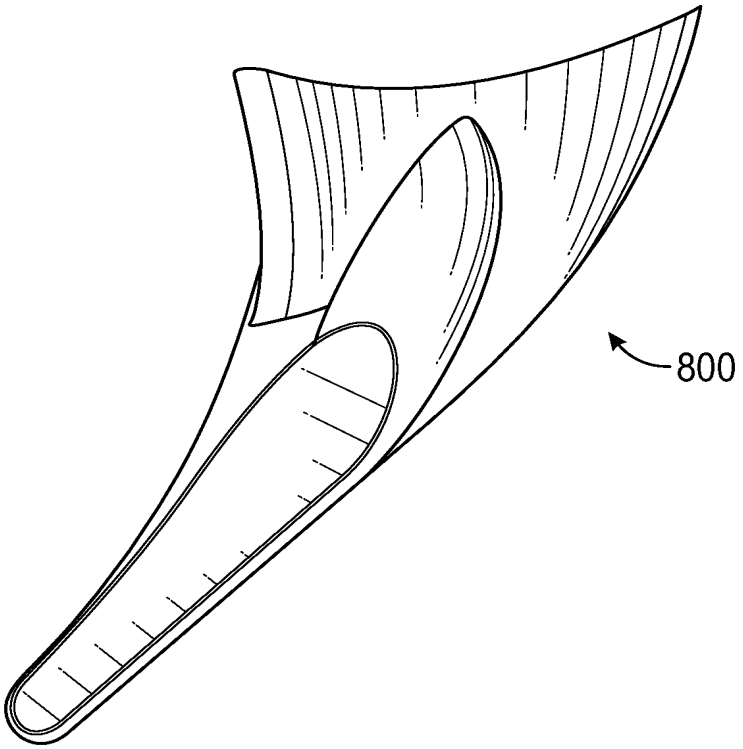


FIG. 10

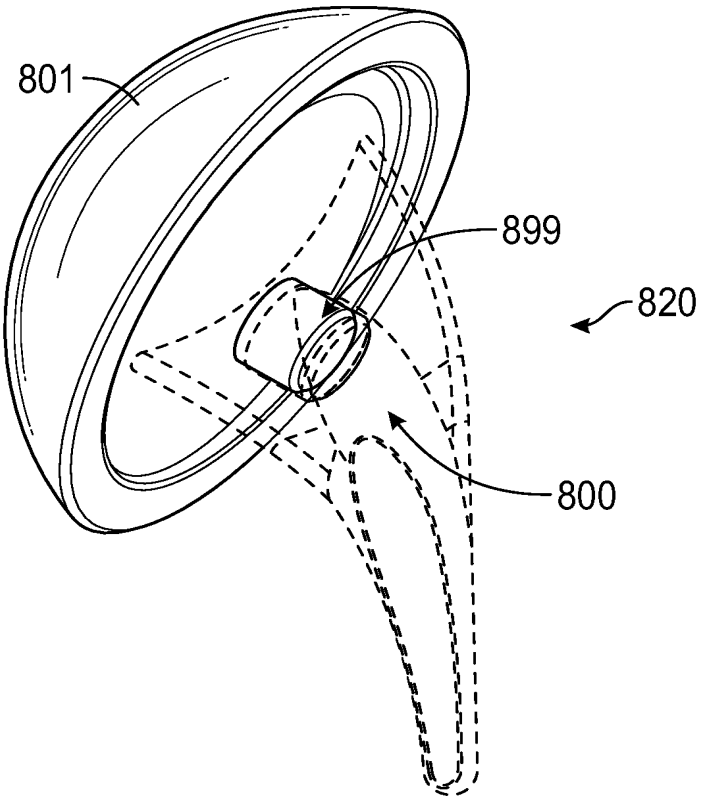


FIG. 11

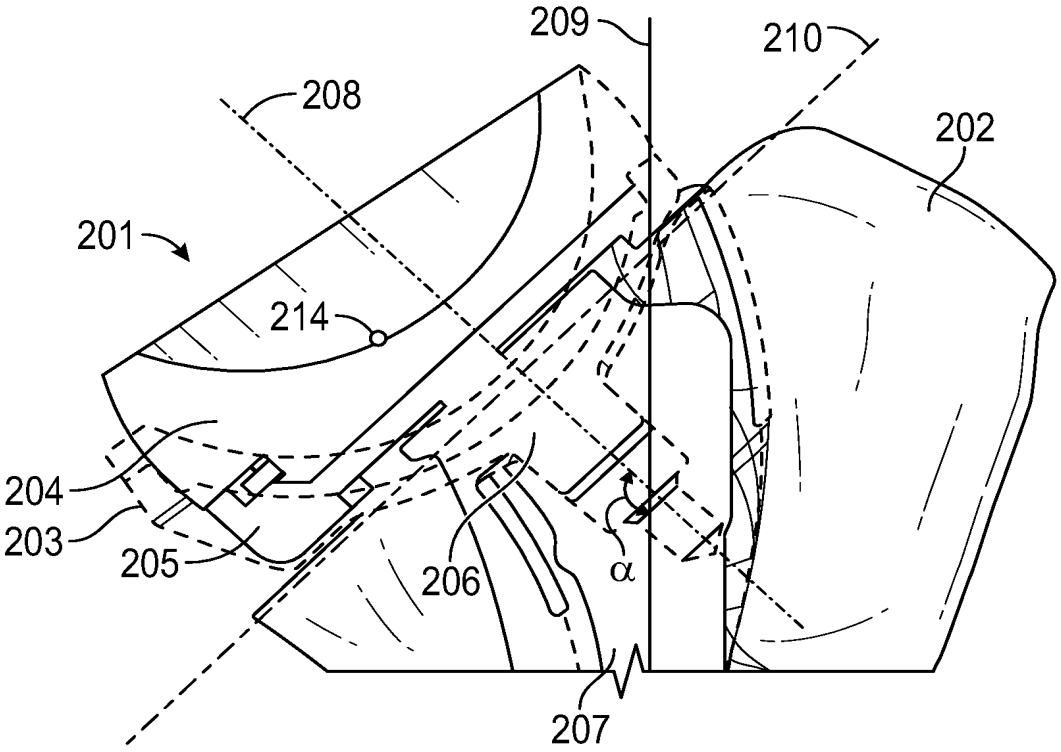

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FIG. 12

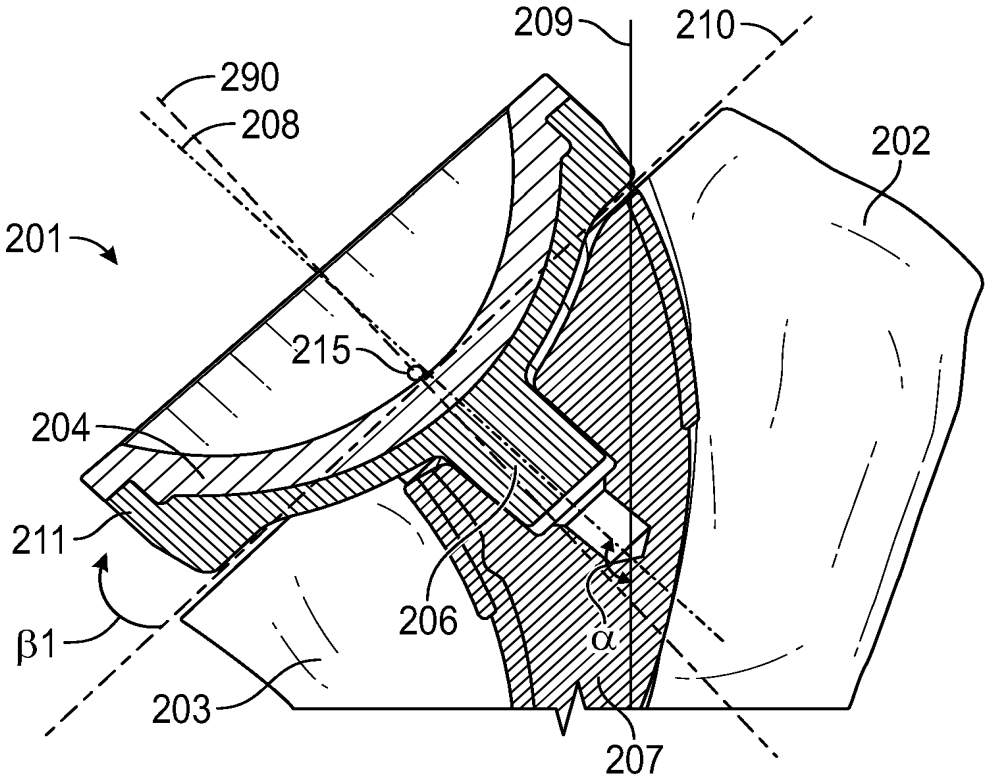

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FIG. 13

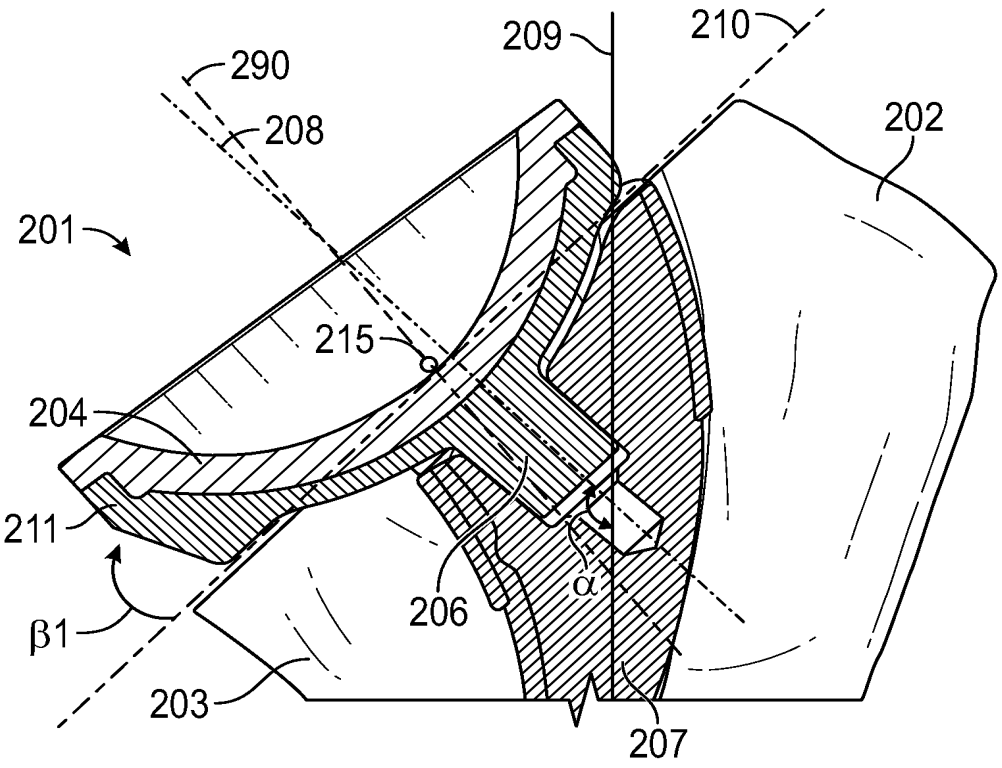

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FIG. 14

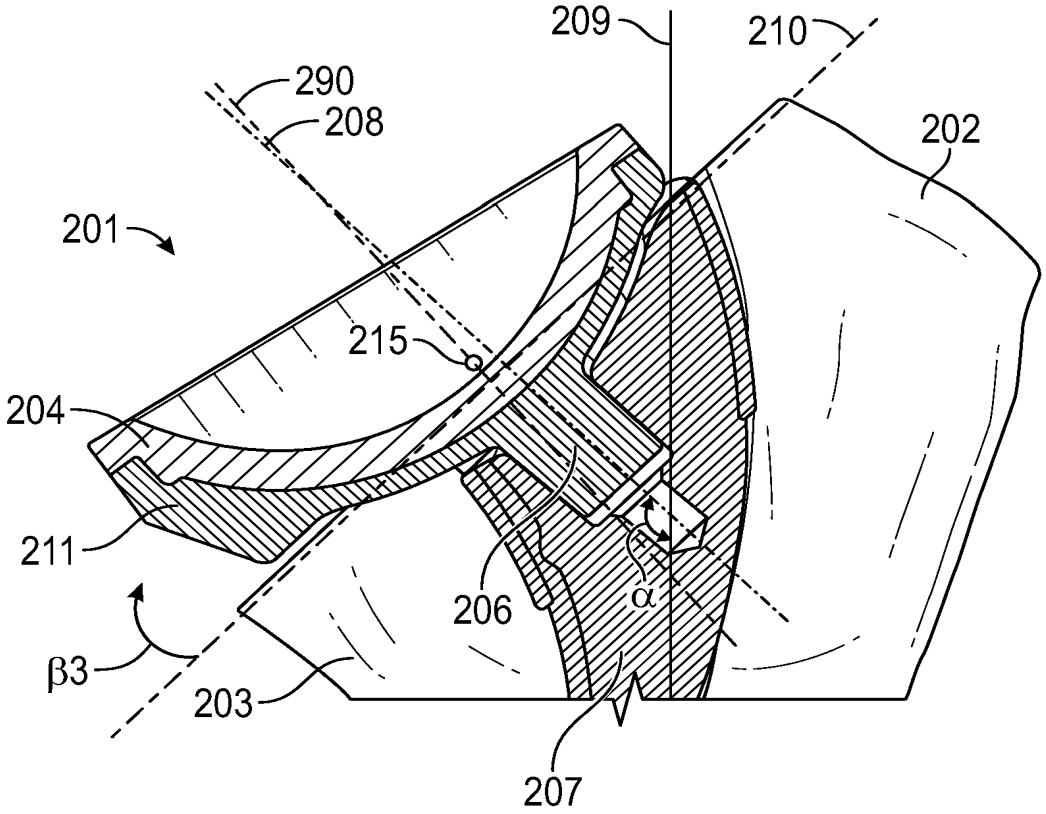

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FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/021859

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/40; A61F 2/30; A61F 2/46 (2019.01)
CPC - A61F 2/4014; A61F 2/4059; A61F 2/4081 (2019.05)

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

B. FIELDS SEARCHED

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

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 623/19.13; 623/19.11; 623/19.12 (keyword delimited)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0105837 A1 (LAFOSSE et al) 23 April 2009 (23.04.2009) entire document	16, 17, 19
Y	US 2017/0056187 A1 (ZIMMER INC) 02 March 2017 (02.03.2017) entire document	1-15
Y	US 8,940,054 B2 (WILEY et al) 27 January 2015 (27.01.2015) entire document	1-14
Y	US 2015/0223941 A1 (CONFORMIS INC) 13 August 2015 (13.08.2015) entire document	15

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2019	29 MAY 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

Espacenet

Bibliographic data: JP2013158909 (A) — 2013-08-19

LIQUID EJECTION HEAD AND LIQUID EJECTION APPARATUS

Inventor(s): HIRAI EIKI; YAZAKI SHIRO; SUMI KOJI; TAKABE HONKI; KATO JIRO; ITO HIROSHI; SHIMIZU TOSHIHIRO; KAMIJO TAKAHIRO; TORIMOTO TATSURO; KOJIMA TSUTOMU ± (HIRAI EIKI, ; YAZAKI SHIRO, ; SUMI KOJI, ; TAKABE HONKI, ; KATO JIRO, ; ITO HIROSHI, ; SHIMIZU TOSHIHIRO, ; KAMIJO TAKAHIRO, ; TORIMOTO TATSURO, ; KOJIMA TSUTOMU, ; 平井 栄樹, ; 矢崎 士郎, ; 角 浩二, ; ▲高▼部 本隆, ; 加藤 治郎, ; 伊藤 浩, ; 清水 稔弘, ; 上條 隆弘, ; 島本 達朗, ; 小島 力)

Applicant(s): SEIKO EPSON CORP ± (SEIKO EPSON CORP, ; セイコーエプソン株式会社)

Classification: - international: *B41J2/045; B41J2/055*
- cooperative: B41J2/045 (US); B41J2/14201 (US); B41J2/14233 (EP, US); B41J2/161 (EP, US); B41J2/1626 (EP, US); B41J2/1631 (EP, US); B41J2/1646 (EP, US); H01L41/0471 (US); H01L41/0805 (US); B41J2/14274 (US); B41J2002/14258 (US); B41J2002/14491 (EP, US)

Application number: JP20120019569 20120201 Global Dossier

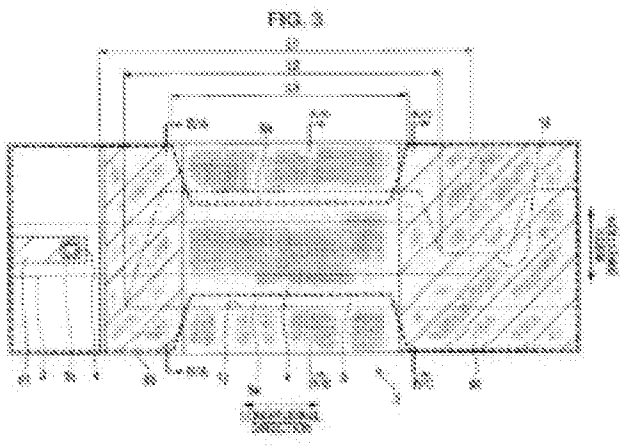
Priority number(s): JP20120019569 20120201

Also published as: CN103240994 (A) CN103240994 (B) EP2623323 (A1) EP2623323 (B1) JP5957914 (B2) more

Abstract of JP2013158909 (A)

PROBLEM TO BE SOLVED: To prevent the occurrence of a defect such as a crack in a piezoelectric layer.SOLUTION: A liquid ejection head includes: a substrate in which pressure generating chambers each communicating with a nozzle opening are formed; and a piezoelectric element having a piezoelectric layer, a first electrode that is formed on a side of the substrate of the piezoelectric layer so as to correspond to the pressure generating chamber, and a second electrode that is formed on a side opposite to a side on which the first electrode of the piezoelectric layer is formed so as to extend over a plurality of the pressure generating chambers, wherein the second electrode is

configured and formed extending to an outside of the pressure generating chamber in a longitudinal direction of the pressure generating chamber.



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Notice

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DESCRIPTION JP2013158909

Abstract: It is possible to prevent the occurrence of defects such as cracks in a piezoelectric layer. A substrate in which a pressure generating chamber communicating with a nozzle opening is formed, a piezoelectric layer, a first electrode formed on the substrate side of the piezoelectric layer corresponding to the pressure generating chamber, and A liquid ejecting head comprising: a piezoelectric element having a second electrode formed across a plurality of the pressure generating chambers on the side opposite to the side where the first electrode of the piezoelectric layer is formed, The second electrode is formed to extend to the outside of the pressure generating chamber in the longitudinal direction of the pressure generating chamber. [Selection diagram] Figure 2

Abstract 【課題】圧電体層におけるクラック等の不良発生を防止する。 【解決手段】ノズル開口に連通する圧力発生室が形成された基板と、圧電体層と、前記圧電体層の前記基板側において前記圧力発生室に対応して形成された第１電極と、前記圧電体層の第１電極が形成された側とは逆側において複数の前記圧力発生室に亘って形成された第２電極と、を有する圧電素子と、を備える液体噴射ヘッドであって、前記第２電極は、前記圧力発生室の長手方向において前記圧力発生室の外側まで延出して形成される構成とした。 【選択図】図２

Liquid ejecting head and liquid ejecting apparatus

液体噴射ヘッドおよび液体噴射装置

[0001]

The present invention relates to a liquid ejecting head and a liquid ejecting apparatus.

本発明は、液体噴射ヘッドおよび液体噴射装置に関する。

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PAGE 363

[0002]
A substrate on which a pressure generating chamber communicating with a nozzle opening for ejecting a liquid is formed, a piezoelectric layer, a lower electrode formed on the lower side of the piezoelectric layer, and an upper electrode formed on the upper side of the piezoelectric layer. There is known a liquid ejecting head including a piezoelectric element having a (see Patent Documents 1 and 2).

液体を噴射するためのノズル開口に連通する圧力発生室が形成された基板と、圧電体層、圧電体層の下方側に形成された下電極および圧電体層の上方側に形成された上電極を有する圧電素子と、を備える液体噴射ヘッドが知られている（特許文献１，２参照）。

In such a liquid ejecting head, the lower electrode is an individual electrode corresponding to each pressure generating chamber, and the upper electrode is a common electrode for a plurality of piezoelectric elements corresponding to a plurality of pressure generating chambers.

このような液体噴射ヘッドでは、下電極を圧力発生室毎に対応した個別電極とし、上電極を複数の圧力発生室に対応する複数の圧電素子にとっての共通電極としている。

[0003]
JP, 2009-172878, A JP, 2009-196329, A

特開２００９－１７２８７８号公報 特開２００９－１９６３２９号公報

[0004]
The piezoelectric element is displaced when a voltage is applied between both electrodes, and bends into the pressure generating chamber.

上記圧電素子は、両電極間に電圧が印加されることにより変位し、圧力発生室内へ撓む。

When bending in this way, a large stress is generated at the boundary position between the range where the upper electrode, the piezoelectric layer and the lower electrode of the piezoelectric element overlap (active part) and the part which is not the active part (inactive part). Due to this stress, strain concentrates at the position. Such concentration of strain may cause defects such as cracks in the piezoelectric layer that constitutes the piezoelectric element in some cases, and therefore, a device for preventing the occurrence of such defects has been

demanded. Further, in addition to preventing the occurrence of the defect, the diaphragm deforms in accordance with the bending of the piezoelectric element to increase the amount of liquid that is ejected (ejected) from the pressure generating chamber to the outside of the nozzle opening to improve the performance of the liquid ejecting head. There was also a demand for improvement.

このように撓む際、圧電素子における上電極、圧電体層および下電極が重なる範囲（能動部）と、能動部では無い部分（非能動部）との境界位置には大きな応力が発生し、この応力によって当該位置には歪みが集中してしまう。このような歪みの集中は、場合によっては圧電素子を構成する圧電体層にひび割れ（クラック）等の不良を生じさせ得るため、当該不良の発生を防止するための工夫が求められていた。また、当該不良発生の防止とともに、圧電素子の撓みに応じて振動板が変形することにより圧力発生室内からノズル開口外へ排除（噴射）される液体量を増加させて液体噴射ヘッドの性能をより向上させることも求められていた。

[0005]

The present invention has been made to solve at least one of the above problems, and can suppress the occurrence of defects such as cracks in the piezoelectric layer, and can realize an increase in the amount of liquid to be jetted. A liquid ejecting head and a liquid ejecting apparatus are provided.

本発明は少なくとも上記課題の一つを解決するためになされたものであり、圧電体層のクラック等の不良発生を抑制し、また、上記噴射される液体量の増加を実現することが可能な液体噴射ヘッドおよび液体噴射装置を提供する。

[0006]

One of the aspects of the present invention is a substrate in which a pressure generating chamber communicating with a nozzle opening is formed, a piezoelectric layer, and a piezoelectric layer formed on the substrate side corresponding to the pressure generating chamber. A liquid ejecting head comprising: a piezoelectric element having one electrode and a second electrode formed across a plurality of the pressure generating chambers on the side opposite to the side where the first electrode of the piezoelectric layer is formed. The second electrode is formed to extend to the outside of the pressure generating chamber in the longitudinal direction of the pressure generating chamber.

本発明の態様の一つは、ノズル開口に連通する圧力発生室が形成された基板と、圧電体層と、前記圧電体層の前記基板側において前記圧力発生室に対応して形成された第１電極と、前記圧電体層の第１電極が形成された側とは逆側において複数の前記圧力発生室に亘って形成された第２電極と、を有する圧電素子と、を備える液体噴射ヘッドであって、前記第２電極は、前記圧力発生室の長手方向において前記圧力発生室の外側まで延出して形成されている。

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According to this structure, the second electrode is formed to extend to the outside of the pressure generating chamber in the longitudinal direction of the pressure generating chamber. Therefore, as compared with the case where the second electrode is formed only in the range that does not exceed the pressure generating chamber in the longitudinal direction, the concentration of strain at the boundary position in the piezoelectric element is alleviated, and defects such as cracks occur. Suppressed. Further, the resistance of the piezoelectric element to cracks and the like is improved as compared with the conventional one, and thus the withstand voltage of the piezoelectric element is also improved.

当該構成によれば、第２電極は圧力発生室の長手方向において圧力発生室の外側まで延出して形成されている。そのため、第２電極が当該長手方向において圧力発生室を越えない範囲にしか形成されていない場合と比較して、圧電素子における上記境界位置への歪みの集中が緩和され、クラック等の不良発生が抑制される。また、圧電素子のクラック等への耐性が従来よりも向上することで、圧電素子の耐電圧も向上する。

[0007]

In one aspect of the present invention, a range in which the first electrode, the piezoelectric layer, and the second electrode overlap is formed to extend to the outside of the pressure generating chamber in the longitudinal direction. May be In other words, the range where the first electrode, the piezoelectric layer, and the second electrode overlap (active part) is the part that is driven when a voltage is applied, so the active part extends in the longitudinal direction to the outside of the pressure generating chamber. By letting it out, the concentration of strain at the boundary position in the piezoelectric element is alleviated, and the occurrence of defects such as cracks is suppressed.

本発明の態様の一つは、前記第１電極と、前記圧電体層と、前記第２電極と、が重なる範囲が、前記長手方向において前記圧力発生室の外側まで延出して形成されているとしてもよい。つまり、第１電極、圧電体層および第２電極が重なる範囲（能動部）が、電圧が印加された際に駆動する部位であるため、能動部を当該長手方向において圧力発生室の外側まで延出させることで、圧電素子における上記境界位置への歪みの集中が緩和され、クラック等の不良発生が抑制される。

[0008]

One of the aspects of the present invention is to form an opening of a piezoelectric layer in which the piezoelectric layer is removed in a region substantially corresponding to the pressure generating chamber, and the opening is formed in the pressure generating chamber in the longitudinal direction. It may be formed to the outside of the end of. According to this configuration, since the opening is formed outside the end of the pressure generating chamber in

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the longitudinal direction, the displacement amount of the piezoelectric element near the end of the pressure generating chamber is improved, and as a result, the deflection of the piezoelectric element is increased. The amount of liquid to be ejected increases in accordance with.

本発明の態様の一つは、前記圧力発生室間に対応する領域において前記圧電体層を除去した圧電体層の開口部を形成し、当該開口部は、前記長手方向において前記圧力発生室の端よりも外側まで形成されているとしてもよい。当該構成によれば、開口部が当該長手方向において圧力発生室の端よりも外側まで形成されているため、圧力発生室の端付近における圧電素子の変位量が向上し、結果、圧電素子の撓みに応じて噴射される液体量が増加する。

[0009]

In one aspect of the present invention, a metal layer that is laminated on the second electrode and functions as a wiring may be formed at a position that straddles the inside and outside of the pressure generating chamber. According to this configuration, the metal layer is formed at a position that straddles the inside and outside of the pressure generating chamber, so that the concentration of strain at the boundary position in the piezoelectric element is further alleviated, and the occurrence of defects such as cracks is suppressed.

本発明の態様の一つは、前記第２電極に対して積層されて配線として機能する金属層が、前記圧力発生室の内外を跨ぐ位置に形成されているとしてもよい。当該構成によれば、金属層が圧力発生室の内外を跨ぐ位置に形成されることで、圧電素子における上記境界位置への歪みの集中がさらに緩和され、クラック等の不具合発生が抑制される。

[0010]

The technical idea according to the present invention is not realized only in the form of a liquid ejecting head, and for example, a liquid ejecting apparatus including the liquid ejecting head of any one of the above-described aspects can be understood as one invention. it can. Further, a manufacturing method including a manufacturing process of the piezoelectric element, the liquid ejecting head, or the liquid ejecting apparatus according to any one of the above-described aspects (a method for manufacturing a piezoelectric element, a method for manufacturing a liquid ejecting head, a method for manufacturing a liquid ejecting apparatus, etc.). The invention of can also be grasped.

本発明にかかる技術的思想は液体噴射ヘッドという形態のみで実現されるものではなく、例えば、上述したいずれかの態様の液体噴射ヘッドを備えた液体噴射装置も、一つの発明として把握することができる。また、上述したようないずれかの態様の圧電素子や液体噴射ヘッドや液体噴射装置の製造過程を含む製造方法（圧電素子の製造方法、液体噴射ヘッドの製造方法、液体噴射装置の製造方法など）の発明も把握することができる。

[0011]
FIG. 3 is an exploded perspective view showing the outline of a recording head. FIG. 6 is a cross-sectional view taken along a plane parallel to the longitudinal direction of the recording head. It is a top view about a partial field on a substrate. It is sectional drawing by each line in FIG. It is a figure which shows a part of manufacturing process of a piezoelectric element in order. It is a figure which shows a part of manufacturing process of a piezoelectric element in order. It is a top view about a partial field on a substrate concerning a modification. It is a figure for demonstrating the effect by a modification. It is a schematic diagram showing an example of an ink jet type recording device.

記録ヘッドの概略を示す分解斜視図である。記録ヘッドの長手方向に平行な面による断面図である。基板上の一部領域についての平面図である。図３における各線による断面図である。圧電素子の製造過程の一部を順に示す図である。圧電素子の製造過程の一部を順に示す図である。変形例にかかる基板上の一部領域についての平面図である。変形例による効果を説明するための図である。インクジェット式記録装置の一例を示す概略図である。

[0012]
Hereinafter, embodiments of the present invention will be described with reference to the drawings. 1. Schematic Configuration of Liquid Ejecting Head FIG. 1 is an exploded perspective view schematically showing an inkjet recording head 1 (hereinafter, recording head 1) which is an example of a liquid ejecting head. FIG. 2 is a vertical cross-sectional view taken along a plane parallel to the longitudinal direction of the pressure generating chamber 12 in the recording head 1 and passing through the lower electrode film 2 corresponding to one pressure generating chamber 12. The recording head 1 includes a substrate (flow path forming substrate) 10. The substrate 10 is made of, for example, a silicon single crystal substrate, and the diaphragm 50 is formed on one surface thereof. The diaphragm 50 includes, for example, an elastic film 51 made of an oxide film that is in contact with the substrate 10, and an insulator film 55 made of an oxide film made of a material different from that of the elastic film 51 and laminated on the elastic film 51. On the substrate 10, a plurality of pressure generating chambers 12 that are partitioned by partition walls 11 and one surface of which is closed by a diaphragm 50 are arranged in parallel in the lateral direction (width direction) thereof.

以下、図面を参照しながら本発明の実施形態について説明する。１．液体噴射ヘッドの概略構成図１は、液体噴射ヘッドの一例であるインクジェット式記録ヘッド１（以下、記録ヘッド１）の概略を、分解斜視図により示している。図２は、記録ヘッド１における圧力発生室１２の長手方向に平行な面であって一つの圧力発生室１２に対応する下電極膜２を通過する面による垂直断面図を示している。記録ヘッド１は、基板（流路形成基板）１０を備える。基板１０は、例えばシリコン単結晶基板からなり、その一方側の面には、振動板５０が形成されている。振動板５０は、例えば、基板１０に接する酸化膜からなる弾性膜５１と、弾性膜５１とは異なる材料の

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酸化膜からなり弾性膜５１に積層される絶縁体膜５５とを含む。基板１０には、隔壁１１によって区画されて一方側の面が振動板５０で閉じられた複数の圧力発生室１２が、その短手方向（幅方向）に並設されている。

[0013]
The substrate 10 is provided with an ink supply path 14 that is partitioned by the partition wall 11 and communicates with each pressure generation chamber 12 at one end side in the longitudinal direction of the pressure generation chamber 12. A communication portion 13 that communicates with each ink supply passage 14 is provided outside the ink supply passage 14. The communication portion 13 communicates with a reservoir portion 31 of the protective substrate 30 described later, and constitutes a part of the reservoir 9 that serves as a common ink chamber (liquid chamber) for each pressure generating chamber 12.

基板１０には、圧力発生室１２の長手方向の一端側に、隔壁１１によって区画されて各圧力発生室１２に連通するインク供給路１４が設けられている。インク供給路１４の外側には、各インク供給路１４と連通する連通部１３が設けられている。連通部１３は、後述する保護基板３０のリザーバ部３１と連通して、各圧力発生室１２の共通のインク室（液体室）となるリザーバ９の一部を構成する。

[0014]
The ink supply passage 14 is formed so that the cross-sectional area in the width direction is narrower than that of the pressure generating chamber 12, and keeps the flow resistance of the ink flowing from the communicating portion 13 into the pressure generating chamber 12 constant. There is. The cross-sectional area of the ink supply passage 14 may be narrower than the cross-sectional area of the pressure generating chamber 12 by narrowing it in the thickness direction of the substrate 10 instead of narrowing it in the width direction. The material of the substrate 10 is not limited to the silicon single crystal substrate, and glass ceramics, stainless steel, or the like may be used, for example.

インク供給路１４は、上記幅方向における断面積が圧力発生室１２よりも狭くなるように形成されており、連通部１３から圧力発生室１２に流入するインクの流路抵抗を一定に保持している。なお、インク供給路１４の断面積は、上記幅方向において絞るのではなく、基板１０の厚さ方向において絞ることで、圧力発生室１２の断面積よりも狭くなるようにしてもよい。基板１０の材料としては、シリコン単結晶基板に限定されず、例えば、ガラスセラミックス、ステンレス鋼等を用いても良い。

[0015]
The nozzle plate 20 is fixed to the surface of the substrate 10 opposite to the surface on which

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the vibration plate 50 is formed with an adhesive, a heat-welding film, or the like. The nozzle plate 20 is provided with a nozzle opening 21 corresponding to each pressure generating chamber 12 and communicating with the vicinity of the other end side in the longitudinal direction. The nozzle plate 20 is made of, for example, glass ceramics, a silicon single crystal substrate, stainless steel, or the like.

基板１０の、振動板５０が形成される面とは逆側の面には、ノズルプレート２０が接着剤や熱溶着フィルム等によって固着されている。ノズルプレート２０においては、各圧力発生室１２に対応して、上記長手方向の他端側近傍に連通するノズル開口２１が穿設されている。ノズルプレート２０は、例えば、ガラスセラミックス、シリコン単結晶基板、ステンレス鋼等からなる。

[0016]

A plurality of piezoelectric elements 3 each having a lower electrode film 2, a piezoelectric layer 5, and an upper electrode film 4 are formed side by side in the width direction on the surface of the diaphragm 50 opposite to the substrate 10. . The piezoelectric element 3 is formed corresponding to each pressure generating chamber 12. The lower electrode film 2 corresponds to a first electrode formed corresponding to each pressure generating chamber 12 on the substrate 10 side of the piezoelectric layer 3. On the other hand, the upper electrode film 4 corresponds to a second electrode formed over the region corresponding to the plurality of pressure generating chambers 12 on the side of the piezoelectric layer 5 opposite to the side on which the first electrode is formed. The piezoelectric element 3 includes a range (active portion) where the lower electrode film 2, the piezoelectric layer 5 and the upper electrode film 4 overlap. Further, the piezoelectric element 3 and the vibration plate 50 that is displaced by the driving of the piezoelectric element 3 are collectively referred to as an actuator device. Generally, in the piezoelectric element 3, one of the electrodes sandwiching the piezoelectric layer 5 is used as a common electrode and the other electrode is used as an individual electrode. However, in the present embodiment, the lower electrode film 2 includes the pressure generating chambers. 12 is an individual electrode for each piezoelectric element 3 and the upper electrode film 4 is a common electrode for each piezoelectric element 3 corresponding to each pressure generating chamber 12.

振動板５０の、基板１０とは逆側の面には、下電極膜２と、圧電体層５と、上電極膜４とを有する圧電素子３が複数上記幅方向に並んで形成されている。圧電素子３は、各圧力発生室１２に対応して形成されている。下電極膜２は、圧電体層３の基板１０側において圧力発生室１２毎に対応して形成された第１電極に該当する。一方、上電極膜４は、圧電体層５の第１電極が形成された側とは逆側において複数の圧力発生室１２に対応する領域に亘って形成された第２電極に該当する。圧電素子３は、下電極膜２、圧電体層５及び上電極膜４が重なる範囲（能動部）を含む。また、圧電素子３と当該圧電素子３の駆動により変位が生じる振動板５０とを合わせてアクチュエータ装置と称する。一般的に圧電素子３は、圧電体層５を挟むいずれか一方の電極を共通電極とし、他方の電極を個別電極として構成されるが、本実施形態では、下電極膜２が各圧力発生室

１２に対応する圧電素子３毎の個別電極であり、上電極膜４が各圧力発生室１２に対応する各圧電素子３にとっての共通電極である。

[0017]
Further, as shown in FIG. 1, the piezoelectric layer 5 is formed with a plurality of openings 5a which are recessed by removing the piezoelectric layer 5. The plurality of openings 5a are arranged side by side in the width direction, and are formed in substantially corresponding regions between the pressure generating chambers 12. In other words, the piezoelectric element 3 including the active portion and corresponding to one pressure generating chamber 12 is formed between the openings 5a. The surface of the opening 5 a is covered with the upper electrode film 4.

また図１に示したように、圧電体層５には、圧電体層５が除去されて凹部となった開口部５ａが複数形成されている。複数の開口部５ａは上記幅方向に並んでおり、圧力発生室１２間に略対応する領域に形成されている。言い換えると、開口部５ａと開口部５ａとの間に、能動部を含み一つの圧力発生室１２に対応する圧電素子３が形成されている。なお、開口部５ａの表面は上電極膜４によって覆われている。

[0018]
Further, the protective substrate 30 to which the compliance substrate 40 is fixed is fixed to the side of the vibration plate 50 on which the piezoelectric element 3 is formed. In this embodiment, the compliance substrate 40 side of the recording head 1 will be referred to as the upper side. and the nozzle plate 20 side will be referred to as the lower side. On the vibration plate 50 on which the piezoelectric element 3 is formed, a protective substrate 30 having a piezoelectric element holding portion 32 capable of ensuring a space that does not hinder the movement of the piezoelectric element 3 in a region facing the piezoelectric element 3 is provided with an adhesive 35. Are joined together. Since the piezoelectric element 3 is formed in the piezoelectric element holding portion 32, it is protected in a state where it is hardly affected by the external environment. Further, the protective substrate 30 is provided with a reservoir portion 31 in a region corresponding to the communication portion 13 of the substrate 10. The reservoir portion 31 is provided, for example, penetrating the protective substrate 30 in the thickness direction along the width direction of the pressure generating chamber 12, and communicates with the communicating portion 13 of the substrate 10 to connect the reservoir 9 to the reservoir 9 as described above. I am configuring. Examples of the material of the protective substrate 30 include glass, ceramic materials, metals, resins, and the like, but it is more preferable that the protective substrate 30 is formed of a material having substantially the same coefficient of thermal expansion as that of the substrate 10. In the present embodiment, it was formed using a silicon single crystal substrate of the same material as the substrate 10.

さらに、振動板５０の圧電素子３が形成される側には、コンプライアンス基板４０が固着された保護基板３０が固着されている。本実施形態では、記録ヘッド１のコンプライアンス基板４０側を上側、ノズルプレート２０側を下側として適宜説明を行なう。圧電素子３が形成された振動板５０上には、圧電素子３に対向する領域にその運動を阻害しない程度の空間を確保可能な圧電素子保持部３２を有する保護基板３０が接着剤３５を介して接合されている。圧電素子３は、圧電素子保持部３２内に形成されているため、外部環境の影響を殆ど受けない状態で保護される。また、保護基板３０には、基板１０の連通部１３に対応する領域にリザーバ部３１が設けられている。リザーバ部３１は、例えば、保護基板３０を厚さ方向に貫通して圧力発生室１２の幅方向に沿って設けられており、上述したように基板１０の連通部１３と連通してリザーバ９を構成している。保護基板３０の材料としては、例えば、ガラス、セラミックス材料、金属、樹脂等が挙げられるが、基板１０の熱膨張率と略同一の材料で形成されていることがより好ましく、本実施形態では、基板１０と同一材料のシリコン単結晶基板を用いて形成した。

[0019]

Further, as shown in FIG. 2, the lead electrode 60 is connected to the upper electrode film 4 as a common electrode, and the lead electrode 61 is connected to the lower electrode film 2 as an individual electrode. . In FIG. 1, lead electrodes 60, 61 and through holes 5 b (described later) penetrating the piezoelectric layer 5 for connecting the lead electrodes 61 to the lower electrode film 2 are not shown. The lead electrodes 60 and 61 are connected to a drive circuit 120 (FIG. 1) mounted with a drive IC or the like for driving the piezoelectric element 3 via a lead wire or the like (not shown). The lead electrode 60 corresponds to a metal layer that is stacked on the second electrode and functions as a wiring. Although the lead electrode 61 connected to the individual electrode is arranged on the other end side in the longitudinal direction in the example of FIG. 2, the position of the lead electrode 61 may be one end side in the longitudinal direction. Good.

さらに、図２に示すように、共通電極としての上電極膜４に対してはリード電極６０が接続しており、個別電極としての下電極膜２に対してはリード電極６１が接続している。図１では、リード電極６０、６１やリード電極６１を下電極膜２に接続するために圧電体層５を貫通するスルーホール５ｂ（後述）等については図示を省略している。リード電極６０，６１は、不図示のリード線等を介して、圧電素子３を駆動するための駆動ＩＣ等を実装した駆動回路１２０（図１）に接続される。リード電極６０は、第２電極に対して積層されて配線として機能する金属層に該当する。なお図２の例では、個別電極に接続するリード電極６１を、上記長手方向の他端側に配置した構成を示したが、当該リード電極６１の位置は上記長手方向の一端側であってもよい。

[0020]

A compliance substrate 40 including a sealing film 41 and a fixing plate 42 is farther bonded onto the protective substrate 30. The sealing film 41 is made of a material having low rigidity and flexibility, and one surface of the reservoir portion 31 is sealed by the sealing film 41. The

fixed plate 42 is formed of a hard material such as metal. Since the area of the fixing plate 42 facing the reservoir 9 is the opening 43 that is completely removed in the thickness direction, one surface of the reservoir 9 is sealed with only the flexible sealing film 41. Has been done.

保護基板３０上には、更に、封止膜４１及び固定板４２からなるコンプライアンス基板４０が接合されている。封止膜４１は、剛性が低く可撓性を有する材料からなり、この封止膜４１によってリザーバ部３１の一方面が封止されている。固定板４２は、金属等の硬質の材料で形成される。この固定板４２のリザーバ９に対向する領域は、厚さ方向に完全に除去された開口部４３となっているため、リザーバ９の一方面は可撓性を有する封止膜４１のみで封止されている。

[0021]

In the recording head 1 as described above, ink is taken in from an external ink supply unit (not shown), the interior from the reservoir 9 to the nozzle opening 21 is filled with ink, and then the pressure generating chamber 12 is generated according to the recording signa: from the drive IC. A voltage is applied to each piezoelectric element 3 corresponding to, and the piezoelectric element 3 is flexibly deformed. As a resuli, the pressure in each pressure generating chamber 12 increases, and an ink droplet (liquid) is ejected (jetted) from the nozzle opening 21.

このような記録ヘッド１では、図示しない外部のインク供給手段からインクを取り込み、リザーバ９からノズル開口２１に至るまで内部をインクで満たした後、上記駆動ＩＣからの記録信号に従い、圧力発生室１２に対応するそれぞれの圧電素子３に電圧を印加し、圧電素子３を撓み変形させる。その結果、各圧力発生室１２内の圧力が高まり、ノズル開口２１からインク滴（液体）が吐出（噴射）する。

[0022]

２． Forming Range of Active Portion Next, the structure of the piezoelectric element 3 according to the present embodiment will be described in detail with reference to FIGS. 1 and 2 and FIGS. FIG. 3 is a plan view of a partial area on the substrate 10 in which the piezoelectric element 3 corresponding to one pressure generating chamber 12 is formed. 4A is a vertical sectional view taken along the line AA 'in FIG. 3, FIG. 4B is a vertical sectional view taken along the line BB' in FIG. 3, and FIG. 4C is a vertical sectional view taken along the line CC 'in FIG. Are shown respectively.

２．能動部の形成範囲 次に、本実施形態にかかる圧電素子３の構造について図１，２および以下の図３，４に基づいて詳しく説明する。図３は、基板１０上の一部領域であって一つの圧力発生室１２に対応する圧電素子３が形成された領域についての平面図である。図４Ａは、図３におけるＡ－Ａ′線による垂直断面図、図４Ｂは、図３におけるＢ－Ｂ′線による垂直断面図、図４Ｃは、図３におけるＣ－Ｃ′線による垂直断面図をそれぞれ示している。

[0023]

In FIG. 3, the shapes of the pressure generating chamber 12 and the ink supply path 14 communicating with the pressure generating chamber 12 are illustrated by a two-dot chain line. The shapes of the pressure generating chamber 12 and the ink supply passage 14 shown in FIG. 3 are slightly different from those shown in FIGS. 1 and 2, but either shape may be adopted. In FIG. 3, the range of the lower electrode film 2 as an individual electrode is illustrated by a thin chain line, the range of the piezoelectric layer 5 is illustrated by a thick chain line, and the range of the upper electrode film 4 as a common electrode is painted in gray. Is illustrated by. Further, in FIG. 3, the range of the lead electrode 60 laminated on a part of the upper electrode film 4 and the range of the lead electrode 61 laminated on a part of the piezoelectric layer 5 are illustrated by hatching. The through hole 5b is formed in a part of the piezoelectric layer 5, and the lead electrode 61 is electrically connected to the lower electrode film 2 through the through hole 5b.

図３では、圧力発生室１２およびそれに連通するインク供給路１４の形状を、２点鎖線により例示している。なお、図３に示した圧力発生室１２およびインク供給路１４の形状は、図１，２に示したものと若干異なるが、どちらに示した形状を採用してもよい。また図３では、個別電極としての下電極膜２の範囲を細い鎖線で例示し、圧電体層５の範囲を太い鎖線で例示し、共通電極としての上電極膜４の範囲をグレーで塗ることにより例示している。さらに図３では、上電極膜４の一部に積層されるリード電極６０の範囲および圧電体層５の一部に積層されるリード電極６１の範囲を、ハッチングを付すことにより例示している。圧電体層５の一部には上記スルーホール５ｂが形成されており、リード電極６１は、スルーホール５ｂを介して下電極膜２と電気的に接続している。

[0024]

The lower electrode film 2 is formed so as to fit within the width of the pressure generating chamber 12 in the width direction and is longer than the pressure generating chamber 12 in the longitudinal direction. Specifically, the end portion of the lower electrode film 2 extends to the position of the ink supply path 14 on the one end side in the longitudinal direction, and the end portion of the lower electrode film 2 on the other end side in the longitudinal direction. It extends outward from the end of the pressure generating chamber 12. The lower electrode film 2 is covered with the piezoelectric layer 5 except for the area facing the through hole 5b. As a result, the leak current from the lower electrode film 2 is suppressed as much as possible, and it is possible to save the trouble of taking special measures (for example, protection by a protective film such as aluminum oxide) for suppressing the leak current.

下電極膜２は、上記幅方向においては圧力発生室１２の幅に収まるように形成され、上記長手方向においては圧力発生室１２よりも長く形成されている。具体的には、上記長手方向の一端側では、下電極膜２の端部はインク供給路１４の位置まで延伸しており、上記長手方向の他端側では、下電極膜２の端部は圧力発生室１２の端よりも外側へ延伸している。また、下電極膜２は、ス

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ルーホール５ｂと相対する範囲を除いて圧電体層５に覆われている。これにより、下電極膜２からのリーク電流が極力抑えられ、また、当該リーク電流を抑制するための特別な措置（例えば、酸化アルミニウム等の保護膜による保護）を施す手間を省くことができる。

[0025]
The above-mentioned opening 5a is formed in a part of the region substantially corresponding to the partition walls 11 on both sides of the pressure generating chamber 12 in the width direction, and the piezoelectric layer 5 is removed as shown in FIG. 4B. There is. Due to the presence of the opening 5a, the piezoelectric layer 5 on the pressure generating chamber 12 is formed so as to fit within the width of the pressure generating chamber 12 for the most part. On the other hand, in the longitudinal direction, both ends of the piezoelectric layer 5 are formed so as to extend to the outside of the pressure generating chamber 12 and completely cover the length of the pressure generating chamber 12. The upper electrode film 4 is formed to extend to the outside of the pressure generating chamber 12 not only in the width direction but also in the longitudinal direction, and completely covers the length of the pressure generating chamber 12. . That is, in this embodiment, the active portion corresponding to each pressure generating chamber 12 is formed to extend to the outside of the pressure generating chamber 12 in the longitudinal direction. In FIG. 3, it is understood that the length of the active part in the longitudinal direction is L1 and the length of the pressure generating chamber 12 is L2, and L1 covers the range of L2.

圧力発生室１２の上記幅方向における両側の隔壁１１上に略対応する領域の一部では、上述の開口部５ａが形成されており、図４Ｂからも判るように圧電体層５が除去されている。かかる開口部５ａの存在により、圧力発生室１２上の圧電体層５は、大部分において圧力発生室１２の幅に収まるように形成されている。一方、上記長手方向においては、圧電体層５の端部は圧力発生室１２の外側まで延出して形成されており、圧力発生室１２の長さを完全にカバーしている。上電極膜４は、上記幅方向においてはもちろんのこと、上記長手方向においても、圧力発生室１２の外側まで延出して形成されており、圧力発生室１２の長さを完全にカバーしている。すなわち本実施形態では、圧力発生室１２毎に対応する能動部は、上記長手方向において圧力発生室１２の外側まで延出して形成されている。図３では、上記長手方向における能動部の長さをＬ１、圧力発生室１２の長さをＬ２としており、Ｌ１はＬ２の範囲を覆っていることが判る。

[0026]
Since the configuration shown in FIG. 3 is repeatedly formed in the width direction on the substrate 10 (more precisely, on the insulating film 55) corresponding to each pressure generating chamber 12, the piezoelectric layer 5, Each of the upper electrode film 4 and the lead electrode 60 is continuously formed in the width direction (see FIG. 1 as appropriate). Further, in FIG. 3, the lead electrodes 60 (lead electrode 60 shown in FIG. 4A and lead electrode 60 shown in FIG. 4C) formed at two places are connected to each other at a predetermined position (not

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shown), and form one common electrode.

なお、基板１０上（正確には絶縁体膜５５上）には、図３に示した構成が各圧力発生室１２に対応して上記幅方向に繰り返し形成されているため、圧電体層５、上電極膜４およびリード電極６０の各々は、上記幅方向において連続して形成されている（適宜図１参照）。また、図３においては２か所に形成されているリード電極６０（図４Ａに示したリード電極６０と図４Ｃに示したリード電極６０）は不図示の所定位置で互いに接続しており、全体で一つの共通電極を形成している。

[0027]

As described above, in this embodiment, both ends of the active portion extend to the outside of the pressure generating chamber 12 in the longitudinal direction of the pressure generating chamber 12. Therefore, as compared with the configuration in which the end of the active portion does not extend to the outside of the pressure generating chamber 12 in the longitudinal direction of the pressure generating chamber 12, the active portion of the piezoelectric element 3 is driven and the piezoelectric element 3 is flexibly deformed. At this time, the concentration of strain at the boundary position between the active portion and the inactive portion in the piezoelectric element 3 is relieved, and the occurrence of defects such as cracks in the piezoelectric layer 5 is suppressed. In addition, the resistance of the piezoelectric element 3 to cracks and the like is improved as compared with the conventional one, so that the withstand voltage of the piezoelectric element 3 is also improved at the same time.

このように本実施形態では、圧力発生室１２の長手方向において能動部の両端が圧力発生室１２の外側まで延出するように構成した。そのため、圧力発生室１２の長手方向において能動部の端部が圧力発生室１２の外側まで延出していない構成と比較して、圧電素子３の能動部が駆動して圧電素子３が撓み変形する際に、圧電素子３における能動部と非能動部との境界位置への歪みの集中が緩和され、圧電体層５のクラック等の不良発生が抑制される。また、圧電素子３のクラック等への耐性が従来よりも向上することで、同時に圧電素子３の耐電圧も向上することとなる。

[0028]

Further, in the present embodiment, as can be seen from FIGS. 2 and 3, the lead electrode 60 is formed at a position straddling the inside and outside of the pressure generating chamber 12 (the end portion of the pressure generating chamber 12). By forming the lead electrode 60 at such a position, the concentration of strain on the boundary between the active portion and the inactive portion of the piezoelectric element 3 and the portion of the piezoelectric element 3 near the end portion is relaxed, and the crack The effect of suppressing the occurrence of defects such as is further enhanced.

また本実施形態では、図２，３から判るように、リード電極６０が、圧力発生室１２の内外（圧力発生室１２の端部）を跨ぐ位置に形成されている。このような位置にリード電極６０を形成することにより、圧電素子３における能動部と非能動部との境界や、当該端部近傍の圧電素子３の箇所への歪みの集中が緩和され、上記クラック等の不良発生の抑制効果がより高まる。

[0029]
The opening 5a plays a role of ensuring the elasticity of the active portion by thinning the film thickness around the active portion. Therefore, the size of the opening 5a greatly affects the flexibility of the active portion. Here, in this embodiment, as can be seen from FIG. 3, the length L3 of the opening 5a is formed so as to be within the length L2 of the pressure generating chamber 12 in the longitudinal direction. That is, both ends of the opening 5 a in the longitudinal direction are inside the both ends of the pressure generating chamber 12. Therefore, the piezoelectric layer 5 overlaps both ends of the pressure generating chamber 12 in the longitudinal direction, and as a result, the rigidity of the piezoelectric element 3 near the both ends of the pressure generating chamber 12 increases. As a result, the concentration of strain on the boundary between the active portion and the non-active portion of the piezoelectric element 3 and the portions in the vicinity of both ends of the piezoelectric element 3 is alleviated, and the effect of suppressing the occurrence of defects such as the cracks is further enhanced.

開口部５ａは、能動部周辺の膜厚を薄くすることで能動部のバネ性を担保する役割を果たす。従って、開口部５ａの広さは能動部の撓み易さに大きな影響を与える。ここで、本実施形態では図３から判るように、上記長手方向において開口部５ａの長さＬ３は圧力発生室１２の長さＬ２に収まるように形成されている。つまり、上記長手方向における開口部５ａの両端はいずれも、圧力発生室１２の両端よりも内側に在る。そのため、上記長手方向における圧力発生室１２の両端には圧電体層５が重なることとなり、結果、圧力発生室１２の当該両端近傍における圧電素子３の剛性が高まる。これにより、圧電素子３における、能動部と非能動部との境界や当該両端近傍の箇所への歪みの集中が緩和され、上記クラック等の不良発生の抑制効果がより高まる。

[0030]
３． Manufacturing Method Next, an example of a method of manufacturing the recording head 1 according to the present embodiment will be described. 5A, B and C and FIGS. 6A, B and C sequentially show a process of manufacturing the piezoelectric element 3 constituting the recording head 1. In FIGS. 5 and 6, a change in each process is shown by combining a vertical sectional view taken along a plane parallel to the longitudinal direction from the same viewpoint as in FIG. 2 and a vertical sectional view taken along the line DD′ in the drawings. Shows. However, in FIGS. 5 and 6, the substrate 10 and the like other than the constituent elements of the piezoelectric element 3 are appropriately omitted. First, an elastic film 51 made of silicon dioxide (SiO2) and an insulator film 55 made of zirconium oxide (ZrO2) are formed on a silicon single crystal substrate (not shown) which is a material of the substrate 10 (JP-A-2005-8841).

(See the gazette etc.) Then, for example, a lower electrode film is formed by laminating platinum and iridium on the insulator film 55 by a sputtering method or the like, and then a piezoelectric layer is formed on the lower electrode film by a sol-gel method or the like. Form thin. The term "thinly formed" as used herein means that the layer is formed at least thinner than the film thickness of the piezoelectric layer 5 required in the finally completed piezoelectric element 3.

３、製造方法 次に、本実施形態にかかる記録ヘッド１の製造方法の一例を説明する。図５Ａ，Ｂ，Ｃおよび図６Ａ，Ｂ，Ｃは、記録ヘッド１を構成する圧電素子３が製造される過程を順に示している。これら図５，６では、図２と同様の視点による上記長手方向に平行な面での垂直断面図と、図中のＤ－Ｄ’線による垂直断面図との組合せにより、各工程による変化を示している。ただし図５，６では、圧電素子３の構成要素以外の基板１０等は適宜省略している。まず、基板１０の素材となるシリコン単結晶基板（不図示）上に、二酸化シリコン（ＳｉＯ2）からなる弾性膜５１および酸化ジルコニウム（ＺｒＯ2）からなる絶縁体膜５５を形成（特開２００５－８８４１号公報等参照）する。そして、例えば、スパッタ法等により白金とイリジウムとを絶縁体膜５５上に積層することにより下電極膜を成膜後、下電極膜上に、例えばゾルーゲル法等を用いて圧電体層を薄く形成する。ここで言う、薄く形成するとは、少なくとも最終的に完成する圧電素子３において必要とされる圧電体層５の膜厚よりも薄く形成するという意味である。

[0031]

By performing photoetching on the lower electrode film and the piezoelectric layer formed in this way, the lower electrode film and the piezoelectric layer are formed into a predetermined shape corresponding to each position where each pressure generating chamber 12 is to be formed. Pattern. FIG. 5A shows the lower electrode film 2 formed by this patterning and the piezoelectric layer 500 on the lower electrode film 2. Next, with respect to the state shown in FIG. 5A, a piezoelectric layer is further formed by a sol-gel method or the like to a film thickness finally required in the piezoelectric element 3, and the piezoelectric layer is formed on the piezoelectric layer. Then, an upper electrode film made of, for example, iridium is thinly formed by a sputtering method or the like. Here, forming thin means forming at least thinner than the film thickness of the upper electrode film 4 required in the finally completed piezoelectric element 3. FIG. 5B shows the piezoelectric layer 501 and the upper electrode film 400 on the piezoelectric layer 501 formed by the steps so far.

このように形成された下電極膜および圧電体層に対して、フォトエッチングを施すことにより、各圧力発生室１２が形成される予定の各位置に対応する所定形状に下電極膜および圧電体層をパターニングする。図５Ａでは、このパターニングにより形成された下電極膜２および下電極膜２上の圧電体層５００を示している。次に、図５Ａに示した状態に対し、さらにゾルーゲル法等を用いて圧電体層を上記圧電素子３において最終的に必要とされる膜厚となるまで形成し、当該圧電体層上に、例えばイリジウムからなる上電極膜をスパッタ法等により薄く形成する。ここで言う、薄く形成するとは、少なくとも最終的に完成する圧電素子３において必要とされる上電極

膜４の膜厚よりも薄く形成するという意味である。図５Ｂでは、ここまでの工程により形成された圧電体層５０１および圧電体層５０１上の上電極膜４００を示している。

[0032]
Next, in the state shown in FIG. 5B, the upper electrode film 400 and the piezoelectric layer 501 are subjected to photo-etching, so that the piezoelectric layer of a predetermined thickness covering the lower electrode film 2 and the upper electrode thereon. Pattern so that the film remains. That is, a concave portion corresponding to the opening 5a is formed. In the present embodiment, the etching of the piezoelectric layer for forming such an opening 5a is appropriately referred to as "first piezoelectric layer etching step". FIG. 5C shows the piezoelectric layer 502 and the upper electrode film 401 on the piezoelectric layer 502 formed by the steps up to here.

次に、図５Ｂに示した状態において、上電極膜４００および圧電体層５０１に対してフォトエッチングを施すことにより、下電極膜２を覆う所定膜厚分の圧電体層およびその上の上電極膜が残るようにパターニングする。つまり、開口部５ａに相当する凹部を形成する。本実施形態ではこのような開口部５ａを形成するための圧電体層のエッチングを、適宜“圧電体層の第１エッチング工程”と呼ぶ。図５Ｃでは、ここまでの工程により形成された圧電体層５０２および圧電体層５０２上の上電極膜４０１を示している。

[0033]
Next, in the state shown in FIG. 5C, the upper electrode film 401 and the piezoelectric layer 502 are photoetched to form the through holes 5b that expose a part of the lower electrode film 2. In the present embodiment, the etching of the piezoelectric layer for forming the through hole 5b is appropriately referred to as the "second piezoelectric layer etching step". FIG. 6A shows the piezoelectric layer 5 and the upper electrode film 402 on the piezoelectric layer 5 formed by the steps up to here. As shown in FIG. 6A, a through hole 5b penetrates the piezoelectric layer 5 and the upper electrode film 402. As described above, in the present embodiment, after the state shown in FIG. 5B, etching of the piezoelectric layer for forming the opening 5a and etching of the piezoelectric layer for forming the through hole 5b are performed separately. ing. The reason will be described later.

次に、図５Ｃに示した状態において、上電極膜４０１および圧電体層５０２に対してフォトエッチングを施すことにより、下電極膜２の一部を露出させるスルーホール５ｂを形成する。本実施形態ではスルーホール５ｂを形成するための圧電体層のエッチングを、適宜“圧電体層の第２エッチング工程”と呼ぶ。図６Ａでは、ここまでの工程により形成された圧電体層５および圧電体層５上の上電極膜４０２を示している。図６Ａに示すように、圧電体層５および上電極膜４０２には、スルーホール５ｂが貫通している。このように本実施形態では、図５Ｂに示した状態以後において、開口部５ａを形成するための圧電体層のエッチングと、スルーホール５ｂを形

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成するための圧電体層のエッチングとを分けて行なっている。その理由については後述する。

[0034]
Next, with respect to the state shown in FIG. 6A, an upper electrode film is further formed by a sputtering method or the like until the film thickness finally required in the piezoelectric element 3 is formed. Photoetching is performed to pattern the upper electrode film into a predetermined shape corresponding to each position where each pressure generating chamber 12 is to be formed and a predetermined shape including the range of the through hole (see FIG. 3). FIG. 6B shows the upper electrode film 4 formed by this patterning. Next, with respect to the state shown in FIG. 6B, a metal layer (for example, a metal layer containing gold Au and nichrome NiCr) that is a material of the lead electrodes 60 and 61 is formed by a sputtering method, and a photo process for the metal layer is performed. The lead electrodes 60 and 61 are formed by performing etching. The lead electrode 60 is connected to the upper electrode film 4. On the other hand, the lead electrode 61 is connected to the lower electrode film 2 through the through hole 5b and the upper electrode film 4 (FIG. 6B) formed on the surface of the through hole 5b. The upper electrode film 4 (FIG. 6B) formed on the surface of the through hole 5b functions as a part of the wiring connecting the drive circuit 120 and the individual electrode (lower electrode film 2).

次に、図６Ａに示した状態に対し、さらにスパッタ法等により上電極膜を上記圧電素子３において最終的に必要とされる膜厚となるまで形成し、その上で、上電極膜に対してフォトエッチングを施すことにより、各圧力発生室１２が形成される予定の各位置に対応する所定形状およびスルーホールの範囲を含む所定形状（図３参照）に上電極膜をパターニングする。図６Ｂでは、このパターニングにより形成された上電極膜４を示している。次に、図６Ｂに示した状態に対し、リード電極６０，６１の素材となる金属層（例えば、金Ａｕおよびニクロム（ＮｉＣｒ）を含む金属層）をスパッタ法等により形成し、かつ当該金属層に対するフォトエッチングを行なうことにより、リード電極６０，６１を形成する。リード電極６０は上電極膜４に接続している。一方、リード電極６１は、スルーホール５ｂおよびスルーホール５ｂの表面に成膜された上電極膜４（図６Ｂ）を介して下電極膜２に接続している。なお、スルーホール５ｂの表面に成膜された上電極膜４（図６Ｂ）は、上記駆動回路１２０と個別電極（下電極膜２）とを接続する配線の一部として機能する。

[0035]
FIG. 6C shows the structure formed by the steps up to here. The configuration shown in FIG. 6C matches the configuration of the piezoelectric element 3 shown in FIGS. 2 and 3. After that, the protection substrate 30 is bonded to the piezoelectric element 3 side, the pressure generating chamber 12 and the ink supply path 14 are formed by etching the substrate 10, the nozzle plate 20 is bonded to the substrate 10, and the compliance on the protection substrate 30 is performed. The recording head 1 is completed through each process such as the bonding of the

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substrate 40. The method of manufacturing the recording head 1 described above is merely an example, and various modifications can be made. The method for forming the piezoelectric layer described above is not limited, and the piezoelectric layer may be formed by a sputtering method. In addition, as the material of the piezoelectric layer, lead-free zirconate titanate-based material, non-lead represented by barium titanate, etc. (lead is not used. Various materials such as the perovskite type oxide of (1) can be adopted.

図６Ｃでは、ここまでの工程により形成された構成を示している。図６Ｃに示した構成は、図２や図３に示した圧電素子３の構成と一致している。その後は、圧電素子３側への保護基板３０の接合、基板１０のエッチングによる圧力発生室１２やインク供給路１４等の形成、基板１０へのノズルプレート２０の接合、保護基板３０上へのコンプライアンス基板４０の接合といった各工程を経て、記録ヘッド１が完成する。なお、上述した記録ヘッド１の製造方法は、あくまで一例であり、種々の変更が可能である。上述した圧電体層の成膜方法も限定されず、スパッタ法で形成してもよい。また、圧電体層の材料としては、チタン酸ジルコン酸鉛系の材料やチタン酸バリウム等に代表される非鉛（鉛を使用しない。）のペロブスカイト型酸化物等、種々の材料を採用可能である。

[0036]

The reason why the piezoelectric layer first etching step and the piezoelectric layer second etching step are provided in the above manufacturing method will be described. As shown in FIG. 5B, when the piezoelectric layer 501 is formed so as to cover the lower electrode film 2 and the insulating film 55 around the lower electrode film 2, the piezoelectric material on the insulating film 55 is improved in manufacturing accuracy. It is not always easy to make the film thickness of the layer 501 and the film thickness of the piezoelectric layer 501 on the lower electrode film 2 the same. In particular, when the piezoelectric layer is formed by using a liquid as represented by the sol-gel method, such nonuniformity of the film thickness is remarkable. Therefore, the optimum etching amount of the piezoelectric layer 501 for exposing the insulator film 55 (for forming the opening 5a) and the optimum etching amount for exposing the lower electrode film 2 (for forming the through hole 5b). The amount of etching on the piezoelectric layer 501 is not the same. In such a situation, if the etching for exposing the insulator film 55 and the etching for exposing the lower electrode film 2 are simultaneously performed, it is difficult to accurately control the etching amount at each place, and thus the insulator film is difficult to control. One of 55 and the lower electrode film 2 may be over-etched (a state where it is excessively cut), and the other may be under-etched (a state where it is insufficiently cut).

上記製造方法において、圧電体層の第１エッチング工程と圧電体層の第２エッチング工程とをそれぞれ設けた理由について説明する。図５Ｂに示したように、下電極膜２および下電極膜２周囲の絶縁体膜５５を覆うように圧電体層５０１を成膜した場合、製造の精度上、絶縁体膜５５上の圧電体層５０１の膜厚と、下電極膜２上の圧電体層５０１の膜厚とを同じにすることは必ずしも容易ではない。特に、ゾル－ゲル法に代表されるように液体を用いて圧電体層を形成した場合に

、このような膜厚の不均一性が顕著である。そのため、絶縁体膜５５を露出させるため（開口部５ａを形成するため）に最適な圧電体層５０１のエッチング量と下電極膜２を露出させるため（スルーホール５ｂを形成するため）に最適な圧電体層５０１へのエッチング量も同じではない。このような状況において、絶縁体膜５５を露出させるためのエッチングと下電極膜２を露出させるためのエッチングを同時に実行すると、場所毎のエッチング量の正確なコントロールは困難であるため、絶縁体膜５５と下電極膜２の一方に対してはオーバーエッチング（削り過ぎの状態）となったり、他方に対してはアンダーエッチング（削り足りない状態）となったりし得る。

[0037]

For example, when the film thickness of the piezoelectric layer 501 on the insulating film 55> the film thickness of the piezoelectric layer 501 on the lower electrode film 2, when these etchings are performed at the same time, the piezoelectric layer on the insulating film 55 is formed. When attempting to remove 501, the lower electrode film 2 is over-etched, which may cause disconnection of the lower electrode film 2. In addition, when trying to avoid over-etching of the lower electrode film 2, the insulator film 55 may not be exposed. Alternatively, when the film thickness of the piezoelectric layer 501 on the insulating film 55 <the film thickness of the piezoelectric layer 501 on the lower electrode film 2, if these etchings are simultaneously performed, the piezoelectric layer on the lower electrode film 2 is formed. When attempting to remove 501, the insulator film 55 is over-etched. Then, the film thickness in the opening 5a becomes unnecessarily thin, the required rigidity cannot be obtained, and cracks or the like may occur in the opening 5a. Further, if it is attempted to avoid over-etching of the insulator film 55, the lower electrode film 2 may not be exposed.

例えば、絶縁体膜５５上の圧電体層５０１の膜厚＞下電極膜２上の圧電体層５０１の膜厚である場合、これらのエッチングを同時に行なうと、絶縁体膜５５上の圧電体層５０１を除去しようとする際に下電極膜２に対しオーバーエッチングとなり、下電極膜２の断線の可能性が生じる。また、下電極膜２のオーバーエッチングを避けようとすると、絶縁体膜５５を露出させられないことがある。あるいは、絶縁体膜５５上の圧電体層５０１の膜厚＜下電極膜２上の圧電体層５０１の膜厚である場合、これらのエッチングを同時に行なうと、下電極膜２上の圧電体層５０１を除去しようとする際に絶縁体膜５５に対しオーバーエッチングとなる。すると、開口部５ａにおける膜厚が必要以上に薄くなり、必要な剛性が得られず開口部５ａにクラック等が発生する可能性がある。また、絶縁体膜５５のオーバーエッチングを避けようとすると、下電極膜２を露出させられないことがある。

[0038]

Therefore, as described above, in the present embodiment, the piezoelectric layer first etching step and the piezoelectric layer second etching step are respectively provided, and the film thickness of the piezoelectric layer in the range to be processed in each step. Set the optimum etching amount. As a result, the optimum etching of the piezoelectric layer 501 for forming the

opening 5a and the optimum etching of the piezoelectric layer 501 for forming the through hole 5b are realized, and the over-etching and under-etching as described above are realized. It is possible to avoid the occurrence of etching. The execution order of the first etching step of the piezoelectric layer and the second etching step of the piezoelectric layer may be the reverse of the above description.

そこで上述したように、本実施形態では、圧電体層の第１エッチング工程と圧電体層の第２エッチング工程とをそれぞれ設け、それぞれの工程にて処理対象とする範囲の圧電体層の膜厚に最適なエッチング量を設定する。これにより、開口部５ａを形成するために最適な圧電体層５０１のエッチングと、スルーホール５ｂを形成するために最適な圧電体層５０１のエッチングとを実現し、上述したようなオーバーエッチングやアンダーエッチングの発生を回避することができる。なお、圧電体層の第１エッチング工程と圧電体層の第２エッチング工程の実行順序は、上記説明と逆であってもよい。

[0039]

４．Modifications The present invention is not limited to the above-described embodiments, and can be implemented in various modes without departing from the scope of the invention, and for example, the modifications described below are also possible. The contents obtained by appropriately combining the respective embodiments and modifications are also within the scope of the present disclosure. Hereinafter, points different from the above-described embodiment will be described, and description of configurations and operations common to the above-described embodiment will be appropriately omitted.

４．変形例 本発明は上述の実施形態に限られるものではなく、その要旨を逸脱しない範囲において種々の態様において実施することが可能であり、例えば以下に述べるような変形例も可能である。各実施形態や変形例を適宜組み合わせた内容も、本発明の開示範囲である。以下では、上述の実施形態と異なる点について説明し、上述の実施形態と共通する構成や作用は説明を適宜省略する。

[0040]

FIG. 7 is a plan view of a partial region on the substrate 10 according to one modification, showing a region in which the piezoelectric element 3 corresponding to one pressure generating chamber 12 is formed as in FIG. There is. When the configurations of FIG. 7 and FIG. 3 are compared, the length of the opening 5a in the longitudinal direction is different between the two configurations. Specifically, the opening 5a shown in FIG. 7 is longer, and the opening 5a is formed to the outside of both ends of the pressure generating chamber 12 in the longitudinal direction. That is, in FIG. 7, the length L3 of the opening 5a in the longitudinal direction is formed to include the length L2 of the pressure generating chamber 12. With this configuration, the rigidity of the piezoelectric element 3 near both ends of the pressure generating chamber 12

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in the longitudinal direction is reduced, and the displacement amount of the piezoelectric element 3 near both ends of the pressure generating chamber 12 is improved.

図７は、一つの変形例にかかる基板１０上の一部領域についての平面図であって、図３と同様に一つの圧力発生室１２に対応する圧電素子３が形成された領域を示している。図７と図３の構成を比較した場合、開口部５ａの上記長手方向の長さが両構成間で異なる。具体的には、図７に示した開口部５ａの方が長く、当該開口部５ａは、上記長手方向において圧力発生室１２の両端よりも外側まで形成されている。つまり、図７においては、上記長手方向の開口部５ａの長さＬ３は、圧力発生室１２の長さＬ２を含むように形成されている。かかる構成によれば、上記長手方向における圧力発生室１２の両端近傍における圧電素子３の剛性が低下し、圧力発生室１２の両端付近における圧電素子３の変位量が向上する。

[0041]

FIG. 8 is a diagram for explaining the effect of the modified example. in FIG. 8, the positional relationship between the pressure generating chamber 12 and the elastic film 51 closing the upper side of the pressure generating chamber 12 in the longitudinal direction is illustrated very simply. When a voltage is applied to the piezoelectric element 3 formed corresponding to the pressure generating chamber 12 to drive the active portion, the elastic film 51 bends into the pressure generating chamber 12 as the active portion is displaced. The amount of displacement Δh is the difference in the vertical direction between the position before bending (the position of the elastic film 51 shown by the solid line in FIG. 8) and the position in the bent state. Further, in FIG. 8, the position of the elastic film 51 in a bent state is illustrated by a chain line and a two-dot chain line. The position shown by the chain line is a position in the case where the configuration is formed so that the length L3 of the opening 5a fits within the length L2 of the pressure generating chamber 12, and the position shown by the two-dot chain line is The position when the length L3 of the opening 5a is formed so as to include the length L2 of the pressure generating chamber 12 (the structure of FIG. 7) is illustrated.

図８は、当該変形例による効果を説明するための図である。図８では、上記長手方向における圧力発生室１２と、圧力発生室１２の上側を閉じる弾性膜５１との位置関係をごく簡単に例示している。圧力発生室１２に対応して形成された圧電素子３に電圧が印加されて能動部が駆動すると、能動部の変位と共に弾性膜５１が圧力発生室１２内へ撓む。この撓む前の位置（図８において実線で示した弾性膜５１の位置）と撓んだ状態の位置との上下方向における差が変位量Δｈである。また、図８では、撓んだ状態の弾性膜５１の位置を、鎖線、２点鎖線のそれぞれで例示している。鎖線で示した位置は、開口部５ａの長さＬ３が圧力発生室１２の長さＬ２に収まるように形成された構成を採用した場合の位置を例示し、２点鎖線で示した位置は、開口部５ａの長さＬ３が圧力発生室１２の長さＬ２を含むように形成された構成（図７の構成）を採用した場合の位置を例示している。

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[0042]
As can be seen from FIG. 8, the displacement amount Δh in the central portion of the pressure generating chamber 12 in the longitudinal direction is substantially the same regardless of the difference in the length L3 of the opening 5a. However, in the vicinity of the end of the pressure generating chamber 12, the displacement amount Δh increases when the length L3 of the opening 5a is long. As the displacement amount Δh increases near the end of the pressure generating chamber 12 in this manner, the amount of liquid discharged by the bending of the piezoelectric element 3 increases. That is, according to the modified example shown in FIG. 7, the performance of the recording head 1 can be improved by further increasing the amount of the ejected liquid. In the structure shown in FIG. 7, the vertical sectional view taken along the line BB 'is the same as that shown in FIG. 4B. Also, in the vertical sectional view taken along the line AA 'and the line CC', the opening 5a appears in the same manner as the vertical sectional view taken along the line BB ', and the upper electrode is provided to the opening 5a. The film 4 and the lead electrode 60 are laminated.

図８から判るように、上記長手方向における圧力発生室１２の中央部での変位量Δｈは、開口部５ａの長さＬ３の上記違いによらずほぼ同じである。しかし、圧力発生室１２の端付近では、開口部５ａの長さＬ３が長い構成の方が、変位量Δｈが増えている。このように圧力発生室１２の端付近で変位量Δｈが増加することで、圧電素子３の撓みによって吐出される液体量が増加する。すなわち図７に示した変形例によれば、当該吐出される液体量をより増加させることで、記録ヘッド１の性能を向上させることができる。なお図７に示した構成においては、Ｂ－Ｂ´線による垂直断面図は、図４Ｂに示したものと同様となる。また、Ａ－Ａ´線による垂直断面図およびＣ－Ｃ´線による垂直断面図にも、Ｂ－Ｂ´線による垂直断面図と同様に開口部５ａが出現し、開口部５ａへは上電極膜４およびリード電極６０が積層される。

[0043]
Others: The recording head 1 described above constitutes a part of a recording head unit including an ink flow path communicating with an ink cartridge or the like, and is mounted on an inkjet recording apparatus as a liquid ejecting apparatus. FIG. 9 is a schematic diagram showing an example of the ink jet recording apparatus. As shown in FIG. 9, the recording head units 1A and 1B having recording heads are provided with the cartridges 2A and 2B constituting the ink supply means in a detachable manner, and the carriage 16 on which the recording head units 1A and 1B are mounted is A carriage shaft 18 attached to the apparatus body 17 is provided so as to be movable in the axial direction. The recording head units 1A and 1B are conf gured to eject a black ink composition and a color ink composition, respectively, for example. Then, the driving force of the drive motor 19 is transmitted to the carriage 16 via a plurality of gears (not shown) and the timing belt 7, so that the carriage 16 on which the recording head units 1A and 1B are mounted is moved along the carriage shaft 18. It On the other hand, the apparatus main body 17 is provided with a platen 8 along a carriage shaft 18, and a recording sheet S, which is a recording medium such as paper fed by a feed roller (not shown) or the like, is conveyed on the

platen 8. It has become so.

その他：上述した記録ヘッド１は、インクカートリッジ等と連通するインク流路を備える記録ヘッドユニットの一部を構成して、液体噴射装置としてのインクジェット式記録装置に搭載される。図９は、そのインクジェット式記録装置の一例を示す概略図である。図９に示すように、記録ヘッドを有する記録ヘッドユニット１Ａ，１Ｂは、インク供給手段を構成するカートリッジ２Ａ，２Ｂが着脱可能に設けられ、この記録ヘッドユニット１Ａ，１Ｂを搭載したキャリッジ１６は、装置本体１７に取り付けられたキャリッジ軸１８に軸方向移動自在に設けられている。この記録ヘッドユニット１Ａ，１Ｂは、例えば、それぞれブラックインク組成物及びカラーインク組成物を吐出するものとしている。そして、駆動モータ１９の駆動力が図示しない複数の歯車及びタイミングベルト７を介してキャリッジ１６に伝達されることで、記録ヘッドユニット１Ａ，１Ｂを搭載したキャリッジ１６はキャリッジ軸１８に沿って移動される。一方、装置本体１７には、キャリッジ軸１８に沿ってプラテン８が設けられており、図示しない給紙ローラなどによって給紙された紙等の記録媒体である記録シートＳがプラテン８上を搬送されるようになっている。

[0044]

Although the ink jet recording head has been described above as an example of the liquid ejecting head of the present invention, the liquid ejecting head is not limited to the one described above. The present invention is broadly applicable to all liquid jet heads, and can of course be applied to those that eject liquid other than ink. Other liquid ejecting heads include, for example, various recording heads used in image recording devices such as printers, color material ejecting heads used in manufacturing color filters such as liquid crystal displays, organic EL displays, and FEDs (field emission displays). Examples include an electrode material ejecting head used for forming electrodes, and a bioorganic substance ejecting head used for biochip manufacturing.

なお、上記においては、本発明の液体噴射ヘッドの一例としてインクジェット式記録ヘッドを説明したが、液体噴射ヘッドは、上述したものに限定されるものではない。本発明は、広く液体噴射ヘッドの全般を対象としたものであり、インク以外の液体を噴射するものにも勿論適用することができる。その他の液体噴射ヘッドとしては、例えば、プリンター等の画像記録装置に用いられる各種の記録ヘッド、液晶ディスプレー等のカラーフィルタの製造に用いられる色材噴射ヘッド、有機ＥＬディスプレー、ＦＥＤ（電界放出ディスプレー）等の電極形成に用いられる電極材料噴射ヘッド、バイオｃｈｉｐ製造に用いられる生体有機物噴射ヘッド等が挙げられる。

[0045]

Further, the piezoelectric element according to the present invention is not limited to the piezoelectric element used in the liquid jet head, but can be used in other devices. Examples of other devices include ultrasonic devices such as ultrasonic transmitters, ultrasonic motors, temperature-electric converters, pressure-electric converters, ferroelectric transistors,

piezoelectric transformers, and harmful light blocking filters such as infrared rays. , Optical filters using photonic crystal effect by quantum dot formation, optical filters utilizing optical interference of thin films, and the like. The present invention is also applicable to a piezoelectric element used as a sensor and a piezoelectric element used as a ferroelectric memory. Examples of the sensor using the piezoelectric element include an infrared sensor, an ultrasonic sensor, a heat sensor, a pressure sensor, a pyroelectric sensor, and a gyro sensor (angular velocity sensor).

また、本発明にかかる圧電素子は、液体噴射ヘッドに用いられる圧電素子に限定されず、その他のデバイスにも用いることができる。その他のデバイスとしては、例えば、超音波発信器等の超音波デバイス、超音波モータ、温度－電気変換器、圧力－電気変換器、強誘電体トランジスター、圧電トランス、赤外線等の有害光線の遮断フィルター、量子ドット形成によるフォトニック結晶効果を使用した光学フィルター、薄膜の光干渉を利用した光学フィルター等のフィルターなどが挙げられる。また、センサーとして用いられる圧電素子、強誘電体メモリーとして用いられる圧電素子にも本発明は適用可能である。圧電素子が用いられるセンサーとしては、例えば、赤外線センサー、超音波センサー、感熱センサー、圧力センサー、焦電センサー、及びジャイロセンサー（角速度センサー）等が挙げられる。

[0046]

DESCRIPTION OF SYMBOLS 1 ... Recording head, 1A, 1B ... Recording head unit, 2A, 2B ... Cartridge, 2 ... Lower electrode film, 3 ... Piezoelectric element, 4 ... Upper electrode film, 5 ... Piezoelectric layer, 5a ... Opening part, 5b ... Through Holes, 7 ... Timing belt, 8 ... Platen, 9 ... Reservoir, 10 ... Substrate, 11 ... Partition, 12 ... Pressure generating chamber, 13 ... Communication section, 14 ... Ink supply path, 16 ... Carriage, 17 ... Device body, 18 ... Carriage shaft, 19 ... Drive motor, 20 ... Nozzle plate, 21 ... Nozzle opening, 30 ... Protective substrate, 31 ... Reservoir section, 32 ... Piezoelectric element holding section, 40 ... Compliance board, 41 ... Sealing film, 42 ... Fixed Plate, 43 ... Opening, 50 ... Vibration plate, 51 ... Elastic film, 55 ... Insulator film, 60, 61 ... Lead electrode

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１…記録ヘッド、１Ａ，１Ｂ…記録ヘッドユニット、２Ａ，２Ｂ…カートリッジ、２…下電極膜、３…圧電素子、４…上電極膜、５…圧電体層、５ａ…開口部、５ｂ…スルーホール、７…タイミングベルト、８…プラテン、９…リザーバ、１０…基板、１１…隔壁、１２…圧力発生室、１３…連通部、１４…インク供給路、１６…キャリッジ、１７…装置本体、１８…キャリッジ軸、１９…駆動モータ、２０…ノズルプレート、２１…ノズル開口、３０…保護基板、３１…リザーバ部、３２…圧電素子保持部、４０…コンプライアンス基板、４１…封止膜、４２…固定板、４３…開口部、５０…振動板、５１…弾性膜、５５…絶縁体膜、６０，６１…リード電極

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CLAIMS JP2013158909

1.
A substrate on which a pressure generating chamber communicating with the nozzle opening is formed, a piezoelectric layer, a first electrode formed on the substrate side of the piezoelectric layer corresponding to the pressure generating chamber, A liquid ejecting head comprising: a piezoelectric element having a second electrode formed across a plurality of the pressure generating chambers on the side opposite to the side on which the first electrode is formed, wherein the second electrode is A liquid jet head, which is formed so as to extend to the outside of the pressure generating chamber in the longitudinal direction of the pressure generating chamber.

ノズル開口に連通する圧力発生室が形成された基板と、圧電体層と、前記圧電体層の前記基板側において前記圧力発生室に対応して形成された第１電極と、前記圧電体層の第１電極が形成された側とは逆側において複数の前記圧力発生室に亘って形成された第２電極と、を有する圧電素子と、を備える液体噴射ヘッドであって、前記第２電極は、前記圧力発生室の長手方向において前記圧力発生室の外側まで延出して形成されていることを特徴とする液体噴射ヘッド。

2.
The range in which the first electrode, the piezoelectric layer, and the second electrode overlap is formed to extend outside the pressure generating chamber in the longitudinal direction. The liquid ejecting head described.

前記第１電極と、前記圧電体層と、前記第２電極と、が重なる範囲が、前記長手方向において前記圧力発生室の外側まで延出して形成されていることを特徴とする請求項１に記載の液体噴射ヘッド。

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3.

An opening is formed in the piezoelectric layer from which the piezoelectric layer is removed in a region substantially corresponding between the pressure generating chambers, and the opening is formed outside the end of the pressure generating chamber in the longitudinal direction. The liquid jet head according to claim 1, wherein the liquid jet head is provided.

前記圧力発生室間に略対応する領域において前記圧電体層を除去した圧電体層の開口部を形成し、当該開口部は、前記長手方向において前記圧力発生室の端よりも外側まで形成されていることを特徴とする請求項１または請求項２に記載の液体噴射ヘッド。

4.

4. The metal layer, which is laminated on the second electrode and functions as a wiring, is formed at a position straddling the inside and outside of the pressure generating chamber. Liquid jet head.

前記第２電極に対して積層されて配線として機能する金属層が、前記圧力発生室の内外を跨ぐ位置に形成されていることを特徴とする請求項１～請求項３のいずれかに記載の液体噴射ヘッド。

5.

A liquid ejecting apparatus comprising the liquid ejecting head according to claim 1.

請求項１～請求項４のいずれかに記載の液体噴射ヘッドを備えることを特徴とする液体噴射装置。

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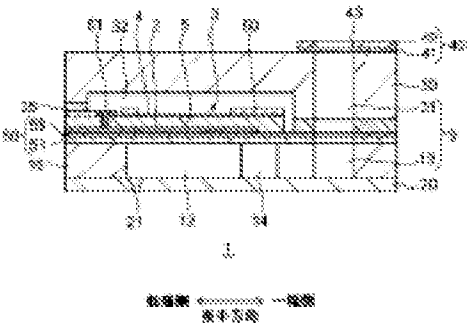
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(54)【発明の名称】液体噴射ヘッドおよび液体噴射装置

(57)【要約】
【課題】圧電体層におけるクラック等の不良発生を防止する。
【解決手段】ノズル開口に連通する圧力発生室が形成された基板と、圧電体層と、前記圧電体層の前記基板側において前記圧力発生室に対応して形成された第１電極と、前記圧電体層の第１電極が形成された側とは反側において複数の前記圧力発生室に亘って形成された第２電極と、を有する圧電素子と、を備える液体噴射ヘッドであって、前記第２電極は、前記圧力発生室の長手方向において前記圧力発生室の外側まで延出して形成される構成とした。
【選択図】図２



【特許請求の範囲】
【請求項１】
ノズル開口に連通する圧力発生室が形成された基板と、
圧電体層と、前記圧電体層の前記基板側において前記圧力発生室に対応して形成された第１電極と、前記圧電体層の第１電極が形成された面とは逆側において複数の前記圧力発生室に亘って形成された第２電極と、を有する圧電素子と、を備える液体噴射ヘッドであって、
前記第２電極は、前記圧力発生室の長手方向において前記圧力発生室の外側まで延出して形成されていることを特徴とする液体噴射ヘッド。
【請求項２】
前記第１電極と、前記圧電体層と、前記第２電極と、が重なる範囲が、前記長手方向において前記圧力発生室の外側まで延出して形成されていることを特徴とする請求項１に記載の液体噴射ヘッド。
【請求項３】
前記圧力発生室間に対応する領域において前記圧電体層を除去した圧電体層の開口部を形成し、当該開口部は、前記長手方向において前記圧力発生室の端よりも外側まで形成されていることを特徴とする請求項１または請求項２に記載の液体噴射ヘッド。
【請求項４】
前記第２電極に対して積層されて配線として機能する金属層が、前記圧力発生室の内外を跨ぐ位置に形成されていることを特徴とする請求項１～請求項３のいずれかに記載の液体噴射ヘッド。
【請求項５】
請求項１～請求項４のいずれかに記載の液体噴射ヘッドを備えることを特徴とする液体噴射装置。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、液体噴射ヘッドおよび液体噴射装置に関する。
【背景技術】
【０００２】
液体を噴射するためのノズル開口に連通する圧力発生室が形成された基板と、圧電体層、圧電体層の下方側に形成された下電極および圧電体層の上方側に形成された上電極を有する圧電素子と、を備える液体噴射ヘッドが知られている（特許文献１，２参照）。このような液体噴射ヘッドでは、下電極を圧力発生室毎に対応した個別電極とし、上電極を複数の圧力発生室に対応する複数の圧電素子にとっての共通電極としている。
【先行技術文献】
【特許文献】
【０００３】
【特許文献１】特開２００９－１７２８７８号公報
【特許文献２】特開２００９－１０６３２９号公報
【発明の概要】
【発明が解決しようとする課題】
【０００４】
上記圧電素子は、両電極間に電圧が印加されることにより変位し、圧力発生室内へ撓む。このように撓む際、圧電素子における上電極、圧電体層および下電極が重なる範囲（能動部）と、能動部では無い部分（非能動部）との境界部分には大きな応力が発生し、この応力によって当該位置には歪みが集中してしまう。このような歪みの集中は、場合によっては圧電素子を構成する圧電体層にひび割れ（クラック）等の不良を生じさせ得るため、当該不良の発生を防止するための工夫が求められていた。また、当該不良発生の防止とともに、圧電素子の撓みに応じて振動板が変形することにより圧力発生室内からノズル開口

外へ排除（噴射）される液体量を増加させて液体噴射ヘッドの性能をより向上させることも求められていた。

【０００５】

本発明は少なくとも上記課題の一つを解決するためになされたものであり、圧電体層のクラック等の不良発生を抑制し、また、上記噴射される液体量の増加を実現することが可能な液体噴射ヘッドおよび液体噴射装置を提供する。

【課題を解決するための手段】

【０００６】

本発明の態様の一つは、ノズル開口に連通する圧力発生室が形成された基板と、圧電体層と、前記圧電体層の前記基板側において前記圧力発生室に対応して形成された第１電極と、前記圧電体層の第１電極が形成された側とは逆側において複数の前記圧力発生室に亘って形成された第２電極と、を有する圧電素子と、を備える液体噴射ヘッドであって、前記第２電極は、前記圧力発生室の長手方向において前記圧力発生室の外側まで延出して形成されている。

当該構成によれば、第２電極は圧力発生室の長手方向において圧力発生室の外側まで延出して形成されている。そのため、第２電極が当該長手方向において圧力発生室を越えない範囲にしか形成されていない場合と比較して、圧電素子における上記境界位置への歪みの集中が緩和され、クラック等の不良発生が抑制される。また、圧電素子のクラック等への耐性が従来よりも向上することで、圧電素子の耐電圧も向上する。

【０００７】

本発明の態様の一つは、前記第１電極と、前記圧電体層と、前記第２電極と、が重なる範囲が、前記長手方向において前記圧力発生室の外側まで延出して形成されているとしてもよい。つまり、第１電極、圧電体層および第２電極が重なる範囲（能動部）が、電圧が印加された際に駆動する部位であるため、能動部を当該長手方向において圧力発生室の外側まで延出させることで、圧電素子における上記境界位置への歪みの集中が緩和され、クラック等の不良発生が抑制される。

【０００８】

本発明の態様の一つは、前記圧力発生室列に略対応する領域において前記圧電体層を除去した圧電体層の開口部を形成し、当該開口部は、前記長手方向において前記圧力発生室の端よりも外側まで形成されているとしてもよい。当該構成によれば、開口部が当該長手方向において圧力発生室の端よりも外側まで形成されているため、圧力発生室の端付近における圧電素子の変位量が向上し、結果、圧電素子の撓みに応じて噴射される液体量が増加する。

【０００９】

本発明の態様の一つは、前記第２電極に対して積層されて配線として機能する金属層が、前記圧力発生室の内外を跨ぐ位置に形成されているとしてもよい。当該構成によれば、金属層が圧力発生室の内外を跨ぐ位置に形成されることで、圧電素子における上記境界位置への歪みの集中がさらに緩和され、クラック等の不良発生が抑制される。

【００１０】

本発明にかかる技術的思想は液体噴射ヘッドという形態のみで実現されるものではなく、例えば、上述したいずれかの態様の液体噴射ヘッドを備えた液体噴射装置も、一つの発明として把握することができる。また、上述したようないずれかの態様の圧電素子や液体噴射ヘッドや液体噴射装置の製造過程を含む製造方法（圧電素子の製造方法、液体噴射ヘッドの製造方法、液体噴射装置の製造方法など）の発明も把握することができる。

【図面の簡単な説明】

【００１１】

【図１】記録ヘッドの概略を示す分解斜視図である。

【図２】記録ヘッドの長手方向に平行な面による断面図である。

【図３】基板上の一部領域についての平面図である。

【図４】図３における各線による断面図である。

【図５】圧電素子の製造過程の一部を順に示す図である。
【図６】圧電素子の製造過程の一部を順に示す図である。
【図７】変形例にかかる基板上の一部領域についての平面図である。
【図８】変形例による効果を説明するための図である。
【図９】インクジェット式記録装置の一例を示す概略図である。
【発明を実施するための形態】
【００１２】
以下、図面を参照しながら本発明の実施形態について説明する。
１．液体噴射ヘッドの概略構成
図１は、液体噴射ヘッドの一例であるインクジェット式記録ヘッド１（以下、記録ヘッド１）の概略を、分解斜視図により示している。
図２は、記録ヘッド１における圧力発生室１２の長手方向に平行な面であって一つの圧力発生室１２に対応する下電極膜２を通過する面による垂直断面図を示している。
記録ヘッド１は、基板（流路形成基板）１０を備える。基板１０は、例えばシリコン単結晶基板からなり、その一方側の面には、振動板５０が形成されている。振動板５０は、例えば、基板１０に接する酸化膜からなる弾性膜５１と、弾性膜５１とは異なる材料の酸化膜からなり弾性膜５１に積層される絶縁体膜５５とを含む。基板１０には、隔壁１１によって区画されて一方側の面が振動板５０で閉じられた複数の圧力発生室１２が、その短手方向（幅方向）に並設されている。
【００１３】
基板１０には、圧力発生室１２の長手方向の一端側に、隔壁１１によって区画されて各圧力発生室１２に連通するインク供給路１４が設けられている。インク供給路１４の外側には、各インク供給路１４を連通する連通部１３が設けられている。連通部１３は、後述する保護基板３０のリザーバ部３１と連通して、各圧力発生室１２の共通のインク室（液体室）となるリザーバ９の一部を構成する。
【００１４】
インク供給路１４は、上記幅方向における断面積が圧力発生室１２よりも狭くなるように形成されており、連通部１３から圧力発生室１２に流入するインクの流路抵抗を一定に保持している。なお、インク供給路１４の断面積は、上記幅方向において絞るのではなく、基板１０の厚さ方向において絞ることで、圧力発生室１２の断面積よりも狭くなるようにしてもよい。基板１０の材料としては、シリコン単結晶基板に限定されず、例えば、ガラスセラミックス、ステンレス鋼等を用いても良い。
【００１５】
基板１０の、振動板５０が形成される面とは逆側の面には、ノズルプレート２０が接着剤や熱溶着フィルム等によって固着されている。ノズルプレート２０においては、各圧力発生室１２に対応して、上記長手方向の他端側近傍に連通するノズル開口２１が穿設されている。ノズルプレート２０は、例えば、ガラスセラミックス、シリコン単結晶基板、ステンレス鋼等からなる。
【００１６】
振動板５０の、基板１０とは逆側の面には、下電極膜２と、圧電体層３と、上電極膜４とを有する圧電素子３が複数上記幅方向に並んで形成されている。圧電素子３は、各圧力発生室１２に対応して形成されている。下電極膜２は、圧電体層３の基板１０側において圧力発生室１２毎に対応して形成された第１電極に該当する。一方、上電極膜４は、圧電体層５の第１電極が形成された側とは逆側において複数の圧力発生室１２に対応する領域に亘って形成された第２電極に該当する。圧電素子３は、下電極膜２、圧電体層５及び上電極膜４が重なる範囲（能動部）を含む。また、圧電素子３と当該圧電素子３の駆動により変位が生じる振動板５０とを合わせてアクチュエータ装置と称する。一般的に圧電素子３は、圧電体層５を挟むいずれか一方の電極を共通電極とし、他方の電極を個別電極として構成されるが、本実施形態では、下電極膜２が各圧力発生室１２に対応する圧電素子３毎の個別電極であり、上電極膜４が各圧力発生室１２に対応する各圧電素子３にとっての

共通電極である。

【００１７】

また図１に示したように、圧電体層５には、圧電体層５が除去されて凹部となった開口部５ａが複数形成されている。複数の開口部５ａは上記幅方向に並んでおり、圧力発生室１２個に絶対応する領域に形成されている。言い換えると、開口部５ａと開口部５ａとの間に、振動部を含み一つの圧力発生室１２に対応する圧電素子３が形成されている。なお、開口部５ａの表面は上電極膜４によって覆われている。

【００１８】

さらに、振動板５０の圧電素子３が形成される側には、コンプライアンス基板４０が固着された保護基板３０が固着されている。本実施形態では、記録ヘッド１のコンプライアンス基板４０側を上側、ノズルプレート２０側を下側として適宜説明を行なう。

圧電素子３が形成された振動板５０上には、圧電素子３に対向する領域にその運動を阻害しない程度の空間を確保可能な圧電素子保持部３２を有する保護基板３０が接着剤３５を介して接合されている。圧電素子３は、圧電素子保持部３２内に形成されているため、外部環境の影響を殆ど受けない状態で保護される。また、保護基板３０には、基板１０の連通部１３に対応する領域にリザーバ部３１が設けられている。リザーバ部３１は、例えば、保護基板３０を厚さ方向に貫通して圧力発生室１２の幅方向に沿って設けられており、上述したように基板１０の連通部１３と連通してリザーバ９を構成している。保護基板３０の材料としては、例えば、ガラス、セラミックス材料、金属、樹脂等が挙げられるが、基板１０の熱膨張率と略同一の材料で形成されていることがより好ましく、本実施形態では、基板１０と同一材料のシリコン単結晶基板を用いて形成した。

【００１９】

さらに、図２に示すように、共通電極としての上電極膜４に対してはリード電極６０が接続しており、個別電極としての下電極膜２に対してはリード電極６１が接続している。図１では、リード電極６０、６１やリード電極６１を下電極膜２に接続するために圧電体層５を貫通するスルーホール５ｂ（後述）等については図示を省略している。リード電極６０、６１は、不図示のリード線等を介して、圧電素子３を駆動するための駆動ＩＣ等を実装した駆動回路１２０（図１）に接続される。リード電極６０は、第２電極に対して積層されて配線として機能する金属層に該当する。なお図２の例では、個別電極に接続するリード電極６１を、上記長手方向の他端側に配設した構成を示したが、当該リード電極６１の位置は上記長手方向の一端側であってもよい。

【００２０】

保護基板３０上には、更に、封止膜４１及び固定板４２からなるコンプライアンス基板４０が接合されている。封止膜４１は、剛性が低く可撓性を有する材料からなり、この封止膜４１によってリザーバ部３１の一方面が封止されている。固定板４２は、金属等の硬質の材料で形成される。この固定板４２のリザーバ９に対向する領域は、厚さ方向に完全に除去された開口部４３となっているため、リザーバ９の一方面は可撓性を有する封止膜４１のみで封止されている。

【００２１】

このような記録ヘッド１では、図示しない外部のインク供給手段からインクを取り込み、リザーバ９からノズル開口２１に至るまで内部をインクで満たした後、上記駆動ＩＣからの記録信号に従い、圧力発生室１２に対応するそれぞれの圧電素子３に電圧を印加し、圧電素子３を撓み変形させる。その結果、各圧力発生室１２内の圧力が高まり、ノズル開口２１からインク滴（液体）が吐出（噴射）する。

【００２２】

２．振動部の形成範囲

次に、本実施形態にかかる圧電素子３の構造について図１，２および以下の図３，４に基づいて詳しく説明する。図３は、基板１０上の一部領域であって一つの圧力発生室１２に対応する圧電素子３が形成された領域についての平面図である。図４Ａは、図３におけるＡ－Ａ′線による垂直断面図、図４Ｂは、図３におけるＢ－Ｂ′線による垂直断面図、

図４Ｃは、図３におけるＣ－Ｃ´線による垂直断面図をそれぞれ示している。

【００２３】

図３では、圧力発生室１２およびそれに連通するインク供給路１４の形状を、２点鎖線により例示している。なお、図３に示した圧力発生室１２およびインク供給路１４の形状は、図１、２に示したものと若干異なるが、どちらに示した形状を採用してもよい。また図３では、個別電極としての下電極膜２の範囲を細い実線で例示し、圧電体膜５の範囲を太い実線で例示し、共通電極としての上電極膜４の範囲をグレーで塗ることにより例示している。さらに図３では、上電極膜４の一部に積層されるリード電極６０の範囲および圧電体膜５の一部に積層されるリード電極６１の範囲を、ハッチングを付すことにより例示している。圧電体膜５の一部には上記スルーホール５ｂが形成されており、リード電極６１は、スルーホール５ｂを介して下電極膜２と電気的に接続している。

【００２４】

下電極膜２は、上記幅方向においては圧力発生室１２の幅に収まるように形成され、上記長手方向においては圧力発生室１２よりも長く形成されている。具体的には、上記長手方向の一端側では、下電極膜２の端部はインク供給路１４の位置まで延伸しており、上記長手方向の他端側では、下電極膜２の端部は圧力発生室１２の端よりも外側へ延伸している。また、下電極膜２は、スルーホール５ｂと相対する範囲を除いて圧電体膜５に覆われている。これにより、下電極膜２からのリーク電流が極力抑えられ、また、当該リーク電流を抑制するための特別な措置（例えば、酸化アルミニウム等の保護膜による保護）を施す手間を省くことができる。

【００２５】

圧力発生室１２の上記幅方向における両側の隔壁１１上に対応する領域の一部では、上述の開口部５ａが形成されており、図４Ｂからも判るように圧電体膜５が除去されている。かかる開口部５ａの存在により、圧力発生室１２上の圧電体膜５は、大部分において圧力発生室１２の幅に収まるように形成されている。一方、上記長手方向においては、圧電体膜５の両端は圧力発生室１２の外側まで延出して形成されており、圧力発生室１２の長さを完全にカバーしている。上電極膜４は、上記幅方向においてはもちろんのこと、上記長手方向においても、圧力発生室１２の外側まで延出して形成されており、圧力発生室１２の長さを完全にカバーしている。すなわち本実施形態では、圧力発生室１２毎に対応する能動部は、上記長手方向において圧力発生室１２の外側まで延出して形成されている。図３では、上記長手方向における能動部の長さをＬ１、圧力発生室１２の長さをＬ２としており、Ｌ１はＬ２の範囲を覆っていることが判る。

【００２６】

なお、基板１０上（正確には絶縁体膜５５上）には、図３に示した構成が各圧力発生室１２に対応して上記幅方向に繰り返し形成されているため、圧電体膜５、上電極膜４およびリード電極６０の各々は、上記幅方向において連続して形成されている（適宜図１参照）。また、図３においては２か所に形成されているリード電極６０（図４Ａに示したリード電極６０と図４Ｃに示したリード電極６０）は不図示の所定位置で互いに接続しており、全体で一つの共通電極を形成している。

【００２７】

このように本実施形態では、圧力発生室１２の長手方向において能動部の両端が圧力発生室１２の外側まで延出するように構成した。そのため、圧力発生室１２の長手方向において能動部の端部が圧力発生室１２の外側まで延出していない構成と比較して、圧電素子３の能動部が駆動して圧電素子３が撓み変形する際に、圧電素子３における能動部と非能動部との境界位置への歪みの集中が緩和され、圧電体膜５のクラック等の不良発生が抑制される。また、圧電素子３のクラック等への耐性が従来よりも向上することで、同時に圧電素子３の耐電圧も向上することとなる。

【００２８】

また本実施形態では、図２、３から判るように、リード電極６０が、圧力発生室１２の内外（圧力発生室１２の端部）を跨ぐ位置に形成されている。このような位置にリード電

膜６０を形成することにより、圧電素子３における能動部と非能動部との境界や、当該開口近傍の圧電素子３の領域への歪みの集中が緩和され、上記クラック等の不良発生の抑制効果がより高まる。

【００２９】

開口部５ａは、能動部周辺の膜厚を薄くすることで能動部のバネ性を担保する役割を果たす。従って、開口部５ａの広さは能動部の撓み易さに大きな影響を与える。ここで、本実施形態では図３から判るように、上記長手方向において開口部５ａの長さＬ３は圧力発生室１２の長さＬ２に収まるように形成されている。つまり、上記長手方向における開口部５ａの両端はいずれも、圧力発生室１２の両端よりも内側に在る。そのため、上記長手方向における圧力発生室１２の両端には圧電体層５が重なることとなり、結果、圧力発生室１２の当該両端近傍における圧電素子３の剛性が高まる。これにより、圧電素子３における、能動部と非能動部との境界や当該両端近傍の領域への歪みの集中が緩和され、上記クラック等の不良発生の抑制効果がより高まる。

【００３０】

３．製造方法

次に、本実施形態にかかる記録ヘッド１の製造方法の一例を説明する。

図５Ａ，Ｂ，Ｃおよび図６Ａ，Ｂ，Ｃは、記録ヘッド１を構成する圧電素子３が製造される過程を順に示している。これら図５，６では、図２と同様の視点による上記長手方向に平行な面での垂直断面図と、図中のＤ－Ｄ´線による垂直断面図との組合せにより、各工程による変化を示している。ただし図５，６では、圧電素子３の構成要素以外の基板１０等は適宜省略している。まず、基板１０の素材となるシリコン単結晶基板（不図示）上に、二酸化シリコン（SiO_2）からなる弾性膜５１および酸化ジルコニウム（ZrO_2）からなる絶縁体膜５２を形成（特開２００５－８４１号公報等参照）する。そして、例えば、スパッタ法等により白金とイリジウムとを絶縁体膜５２上に積層することにより下電極膜を成膜後、下電極膜上に、例えばゾルーゲル法等を用いて圧電体層を薄く形成する。ここで言う、薄く形成するとは、少なくとも最終的に完成する圧電素子３において必要とされる圧電体層５の膜厚よりも薄く形成するという意味である。

【００３１】

このように形成された下電極膜および圧電体層に対して、フォトエッチングを施すことにより、各圧力発生室１２が形成される予定の各位置に対応する所定形状に下電極膜および圧電体層をパターニングする。図５Ａでは、このパターニングにより形成された下電極膜２および下電極膜２上の圧電体層５００を示している。次に、図５Ａに示した状態に対し、さらにゾルーゲル法等を用いて圧電体層を上記圧電素子３において最終的に必要とされる膜厚となるまで形成し、当該圧電体層上に、例えばイリジウムからなる上電極膜をスパッタ法等により薄く形成する。ここで言う、薄く形成するとは、少なくとも最終的に完成する圧電素子３において必要とされる上電極膜４の膜厚よりも薄く形成するという意味である。図５Ｂでは、ここまでの工程により形成された圧電体層５０１および圧電体層５０１上の上電極膜４００を示している。

【００３２】

次に、図５Ｂに示した状態において、上電極膜４００および圧電体層５０１に対してフォトエッチングを施すことにより、下電極膜２を覆う所定膜厚分の圧電体層およびその上の上電極膜が残るようにパターニングする。つまり、開口部５ａに相当する凹部を形成する。本実施形態ではこのような開口部５ａを形成するための圧電体層のエッチングを、適宜“圧電体層の第１エッチング工程”と呼ぶ。図５Ｃでは、ここまでの工程により形成された圧電体層５０２および圧電体層５０２上の上電極膜４０１を示している。

【００３３】

次に、図５Ｃに示した状態において、上電極膜４０１および圧電体層５０２に対してフォトエッチングを施すことにより、下電極膜２の一部を露出させるスルーホール５ｂを形成する。本実施形態ではスルーホール５ｂを形成するための圧電体層のエッチングを、適宜“圧電体層の第２エッチング工程”と呼ぶ。図６Ａでは、ここまでの工程により形成さ

れた圧電体層５および圧電体層５上の上電極膜４０２を示している。図６Ａに示すように、圧電体層５および上電極膜４０２には、スルーホール５ｂが貫通している。このように本実施形態では、図５Ｂに示した状態以後において、開口部５ａを形成するための圧電体層のエッチングと、スルーホール５ｂを形成するための圧電体層のエッチングとを分けて行なっている。その理由については後述する。

【００３４】

次に、図６Ａに示した状態に対し、さらにスパッタ法等により上電極膜を上記圧電素子３において最終的に必要とされる膜厚となるまで形成し、その上で、上電極膜に対してフォトエッチングを施すことにより、各圧力発生室１２が形成される予定の各位置に対応する所定形状およびスルーホールの範囲を含む所定形状（図３参照）に上電極膜をパターニングする。図６Ｂでは、このパターニングにより形成された上電極膜４を示している。次に、図６Ｂに示した状態に対し、リード電極６０，６１の素材となる金属層（例えば、金ＡｕおよびニクロムＮｉＣｒを含む金属層）をスパッタ法等により形成し、かつ当該金属層に対するフォトエッチングを行なうことにより、リード電極６０，６１を形成する。リード電極６０は上電極膜４に接続している。一方、リード電極６１は、スルーホール５ｂおよびスルーホール５ｂの表面に成膜された上電極膜４（図６Ｂ）を介して下電極膜２に接続している。なお、スルーホール５ｂの表面に成膜された上電極膜４（図６Ｂ）は、上記駆動回路１２０と個別電極（下電極膜２）とを接続する配線の一部として機能する。

【００３５】

図６Ｃでは、ここまでの工程により形成された構成を示している。図６Ｃに示した構成は、図２や図３に示した圧電素子３の構成と一致している。その後は、圧電素子３側への保護基板３０の接合、基板１０のエッチングによる圧力発生室１２やインク供給路１４等の形成、基板１０へのノズルプレート２０の接合、保護基板３０上へのコンプライアンス基板４０の接合といった各工程を経て、記録ヘッド１が完成する。なお、上述した記録ヘッド１の製造方法は、あくまで一例であり、種々の変更が可能である。上述した圧電体層の成膜方法も限定されず、スパッタ法で形成してもよい。また、圧電体層の材料としては、チタン酸ジルコン酸鉛系の材料やチタン酸バリウム等に代表される非鉛（鉛を使用しない。）のペロブスカイト型酸化物等、種々の材料を採用可能である。

【００３６】

上記製造方法において、圧電体層の第１エッチング工程と圧電体層の第２エッチング工程とをそれぞれ設けた理由について説明する。図５Ｂに示したように、下電極膜２および下電極膜２周囲の絶縁体膜５５を覆うように圧電体層５０１を成膜した場合、製造の精度上、絶縁体膜５５上の圧電体層５０１の膜厚と、下電極膜２上の圧電体層５０１の膜厚とを同じにすることは必ずしも容易ではない。特に、ゾル・ゲル法に代表されるように液体を用いて圧電体層を形成した場合に、このような膜厚の不均一性が顕著である。そのため、絶縁体膜５５を露出させるため（開口部５ａを形成するため）に最適な圧電体層５０１のエッチング量と下電極膜２を露出させるため（スルーホール５ｂを形成するため）に最適な圧電体層５０１へのエッチング量も同じではない。このような状況において、絶縁体膜５５を露出させるためのエッチングと下電極膜２を露出させるためのエッチングを同時に実行すると、場所毎のエッチング量の正確なコントロールは困難であるため、絶縁体膜５５と下電極膜２の一方に対してはオーバーエッチング（削り過ぎの状態）となったり、他方に対してはアンダーエッチング（削り足りない状態）となったりし得る。

【００３７】

例えば、絶縁体膜５５上の圧電体層５０１の膜厚＞下電極膜２上の圧電体層５０１の膜厚である場合、これらのエッチングを同時に行なうと、絶縁体膜５５上の圧電体層５０１を除去しようとする際に下電極膜２に対しオーバーエッチングとなり、下電極膜２の断線の可能性が生じる。また、下電極膜２のオーバーエッチングを避けようとすると、絶縁体膜５５を露出させられないことがある。あるいは、絶縁体膜５５上の圧電体層５０１の膜厚＜下電極膜２上の圧電体層５０１の膜厚である場合、これらのエッチングを同時に行なうと、下電極膜２上の圧電体層５０１を除去しようとする際に絶縁体膜５５に対しオーバ

ーエッチングとなる。すると、開口部５ａにおける膜厚が必要以上に薄くなり、必要な剛性が得られず開口部５ａにクラック等が発生する可能性がある。また、絶縁体膜５５のオーバーエッチングを避けようとすると、下電極膜２を露出させられないことがある。

【００３８】

そこで上述したように、本実施形態では、圧電体層の第１エッチング工程と圧電体層の第２エッチング工程とをそれぞれ設け、それぞれの工程にて処理対象とする範囲の圧電体層の膜厚に最適なエッチング量を設定する。これにより、開口部５ａを形成するために最適な圧電体層５０１のエッチングと、スルーホール５ｂを形成するために最適な圧電体層５０１のエッチングとを実現し、上述したようなオーバーエッチングやアンダーエッチングの発生を回避することができる。なお、圧電体層の第１エッチング工程と圧電体層の第２エッチング工程の実行順序は、上記説明と逆であってもよい。

【００３９】

４．変形例

本発明は上述の実施形態に限られるものではなく、その要旨を逸脱しない範囲において種々の態様において実施することが可能であり、例えば以下に述べるような変形例も可能である。各実施形態や変形例を適宜組み合わせた内容も、本発明の開示範囲である。

以下では、上述の実施形態と異なる点について説明し、上述の実施形態と共通する構成や作用は説明を適宜省略する。

【００４０】

図７は、一つの変形例にかかる基板１０上の一部領域についての平面図であって、図３と同様に一つの圧力発生室１２に対応する圧電素子３が形成された領域を示している。図７と図３の構成を比較した場合、開口部５ａの上記長手方向の長さが両構成間で異なる。具体的には、図７に示した開口部５ａのほが長く、当該開口部５ａは、上記長手方向において圧力発生室１２の両端よりも外側まで形成されている。つまり、図７においては、上記長手方向の開口部５ａの長さＬ３は、圧力発生室１２の長さＬ２を含むように形成されている。かかる構成によれば、上記長手方向における圧力発生室１２の両端近傍における圧電素子３の剛性が低下し、圧力発生室１２の両端付近における圧電素子３の変位量が向上する。

【００４１】

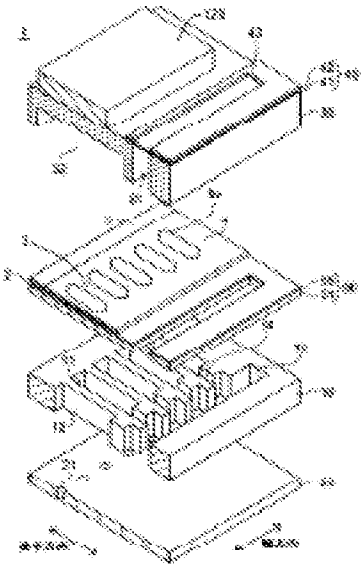
図８は、当該変形例による効果を説明するための図である。図８では、上記長手方向における圧力発生室１２と、圧力発生室１２の上側を閉じる弾性膜５１との位置関係をごく簡単に例示している。圧力発生室１２に対応して形成された圧電素子３に電圧が印加されて能動部が駆動すると、能動部の変位と共に弾性膜５１が圧力発生室１２内へ撓む。この撓む前の位置（図８において実線で示した弾性膜５１の位置）と撓んだ状態の位置との上下方向における差が変位量Δｈである。また、図８では、撓んだ状態の弾性膜５１の位置を、細線、２点鎖線のそれぞれで例示している。細線で示した位置は、開口部５ａの長さＬ３が圧力発生室１２の長さＬ２に収まるように形成された構成を採用した場合の位置を例示し、２点鎖線で示した位置は、開口部５ａの長さＬ３が圧力発生室１２の長さＬ２を含むように形成された構成（図７の構成）を採用した場合の位置を例示している。

【００４２】

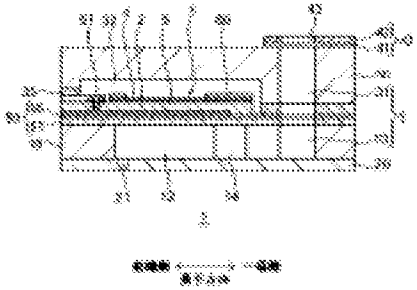
図８から判るように、上記長手方向における圧力発生室１２の中央部での変位量Δｈは、開口部５ａの長さＬ３の上記違いによらずほぼ同じである。しかし、圧力発生室１２の端付近では、開口部５ａの長さＬ３が長い構成の方が、変位量Δｈが増えている。このように圧力発生室１２の端付近で変位量Δｈが増加することで、圧電素子３の撓みによって吐出される液体量が増加する。すなわち図７に示した変形例によれば、当該吐出される液体量をより増加させることで、記録ヘッド１の性能を向上させることができる。なお図７に示した構成においては、Ｂ－Ｂ´線による垂直断面図は、図４Ｂに示したものと同様となる。また、Ａ－Ａ´線による垂直断面図およびＣ－Ｃ´線による垂直断面図にも、Ｂ－Ｂ´線による垂直断面図と同様に開口部５ａが出現し、開口部５ａへは上電極膜４およびリード電極６０が露出される。

【００４３】
その他；
上述した記録ヘッド１は、インクカートリッジ等と連通するインク流路を備える記録ヘッドユニットの一部を構成して、液体噴射装置としてのインクジェット式記録装置に搭載される。図９は、そのインクジェット式記録装置の一例を示す概略図である。図９に示すように、記録ヘッドを有する記録ヘッドユニット１Ａ，１Ｂは、インク供給手段を構成するカートリッジ２Ａ，２Ｂが着脱可能に設けられ、この記録ヘッドユニット１Ａ，１Ｂを搭載したキャリッジ１６は、装置本体１７に取り付けられたキャリッジ軸１８に軸方向移動自在に設けられている。この記録ヘッドユニット１Ａ，１Ｂは、例えば、それぞれブラックインク組成物及びカラーインク組成物を吐出するものとしている。そして、駆動モータ１９の駆動力が図示しない複数の歯車及びタイミングベルト７を介してキャリッジ１６に伝達されることで、記録ヘッドユニット１Ａ，１Ｂを搭載したキャリッジ１６はキャリッジ軸１８に沿って移動される。一方、装置本体１７には、キャリッジ軸１８に沿ってプラテン８が設けられており、図示しない給紙ローラなどによって給紙された紙等の記録媒体である記録シート５がプラテン８上を搬送されるようになっている。
【００４４】
なお、上記においては、本発明の液体噴射ヘッドの一例としてインクジェット式記録ヘッドを説明したが、液体噴射ヘッドは、上述したものに限定されるものではない。本発明は、広く液体噴射ヘッドの全般を対象としたものであり、インク以外の液体を噴射するものにも勿論適用することができる。その他の液体噴射ヘッドとしては、例えば、プリンター等の画像記録装置に用いられる各種の記録ヘッド、液晶ディスプレー等のカラーフィルタの製造に用いられる色材噴射ヘッド、有機ＥＬディスプレー、ＦＥＤ（電界放出ディスプレー）等の電極形成に用いられる電極材料噴射ヘッド、バイオｃｈｉｐ製造に用いられる生体有機物噴射ヘッド等が挙げられる。
【００４５】
また、本発明にかかる圧電素子は、液体噴射ヘッドに用いられる圧電素子に限定されず、その他のデバイスにも用いることができる。その他のデバイスとしては、例えば、超音波発信器等の超音波デバイス、超音波モータ、温度－電気変換器、圧力－電気変換器、強誘電体トランジスター、圧電トランス、赤外線等の有害光線の遮断フィルター、量子ドット形成によるフォトニック結晶効果を利用した光学フィルター、薄膜の光干渉を利用した光学フィルター等のフィルターなどが挙げられる。
また、センサーとして用いられる圧電素子、強誘電体メモリーとして用いられる圧電素子にも本発明は適用可能である。圧電素子が用いられるセンサーとしては、例えば、赤外線センサー、超音波センサー、感熱センサー、圧力センサー、焦電センサー、及びジャイロセンサー（角速度センサー）等が挙げられる。
【符号の説明】
【００４６】
１…記録ヘッド、１Ａ，１Ｂ…記録ヘッドユニット、２Ａ，２Ｂ…カートリッジ、２…下電極膜、３…圧電素子、４…上電極膜、５…圧電体層、５ａ…開口部、５ｂ…スルーホール、７…タイミングベルト、８…プラテン、９…リザーバ、１０…基板、１１…隔壁、１２…圧力発生室、１３…連通部、１４…インク供給路、１６…キャリッジ、１７…装置本体、１８…キャリッジ軸、１９…駆動モータ、２０…ノズルプレート、２１…ノズル開口、３０…保護基板、３１…リザーバ部、３２…圧電素子保持部、４０…コンプライアンス基板、４１…封止膜、４２…固定板、４３…開口部、５０…振動板、５１…弾性膜、５５…絶縁体膜、６０，６１…リード電極

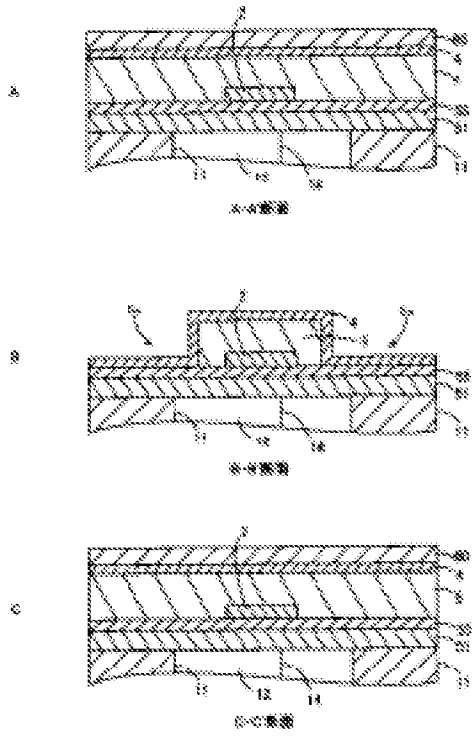
【図１】



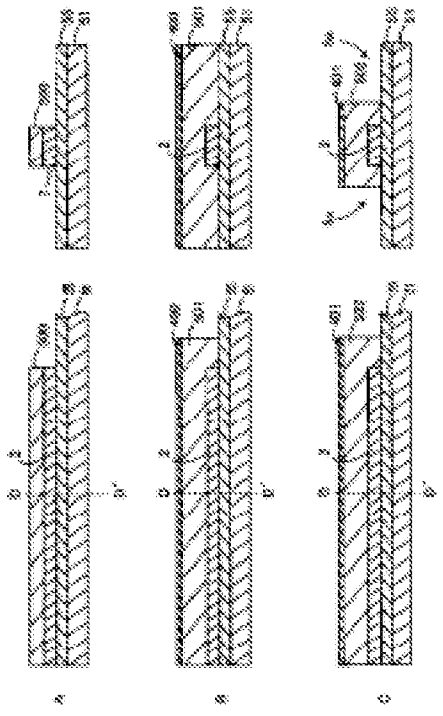
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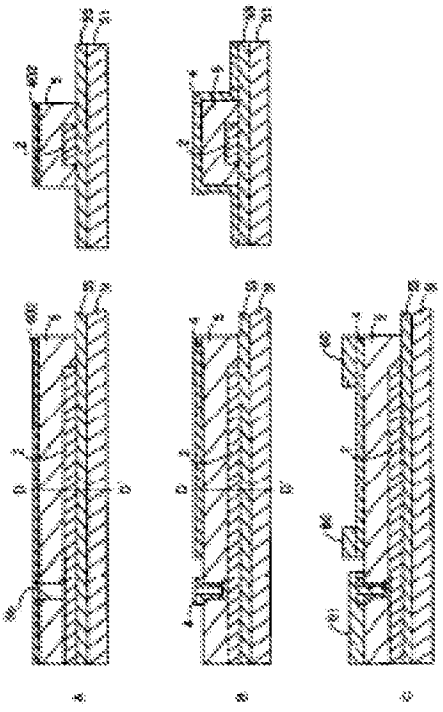
【図４】



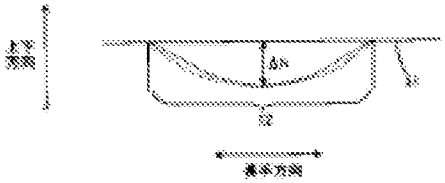
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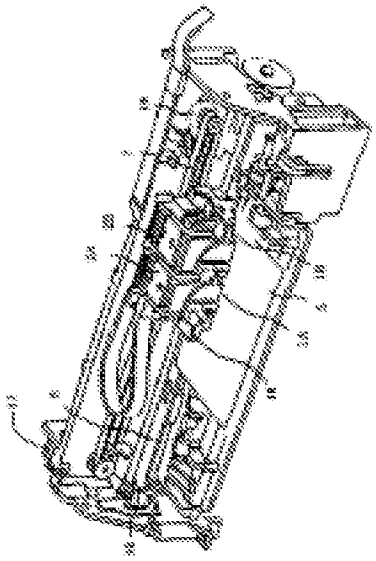
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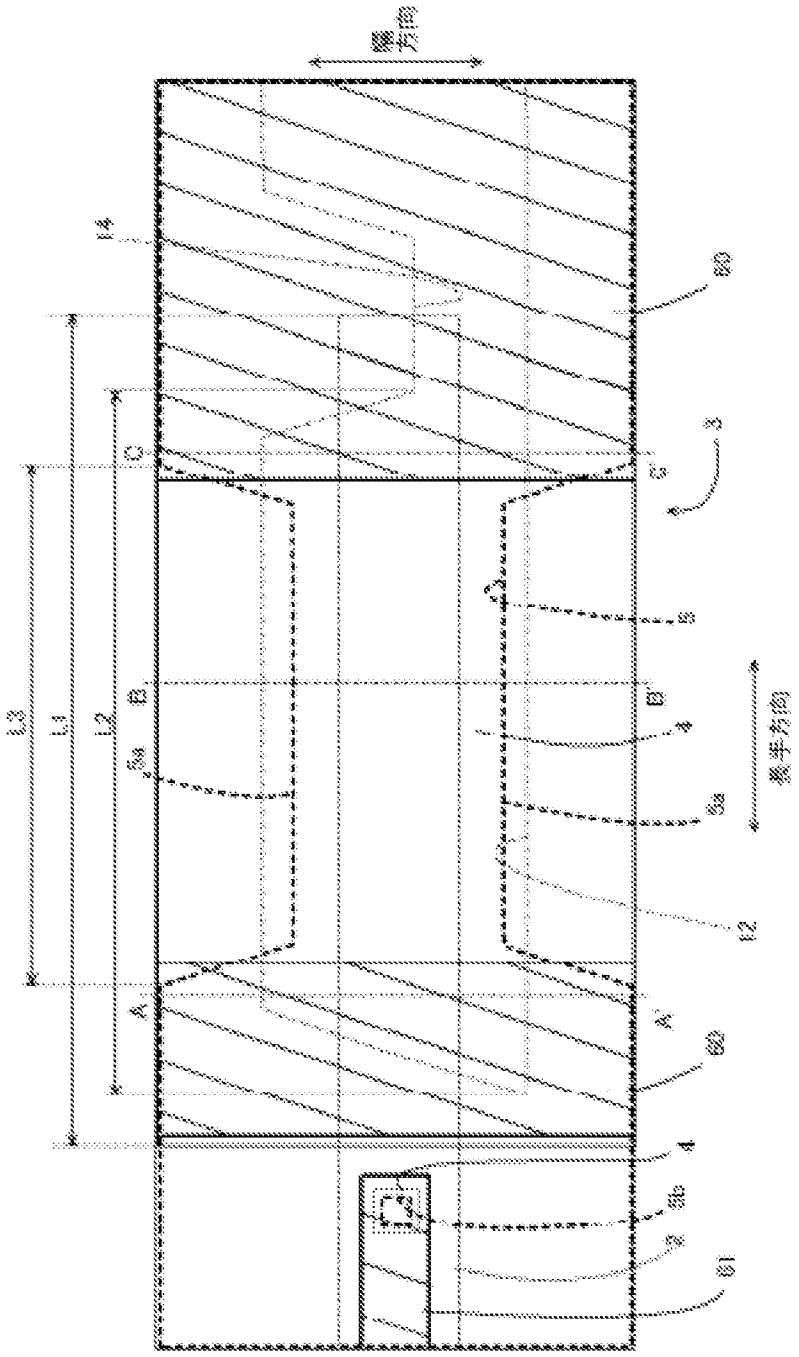
【図８】



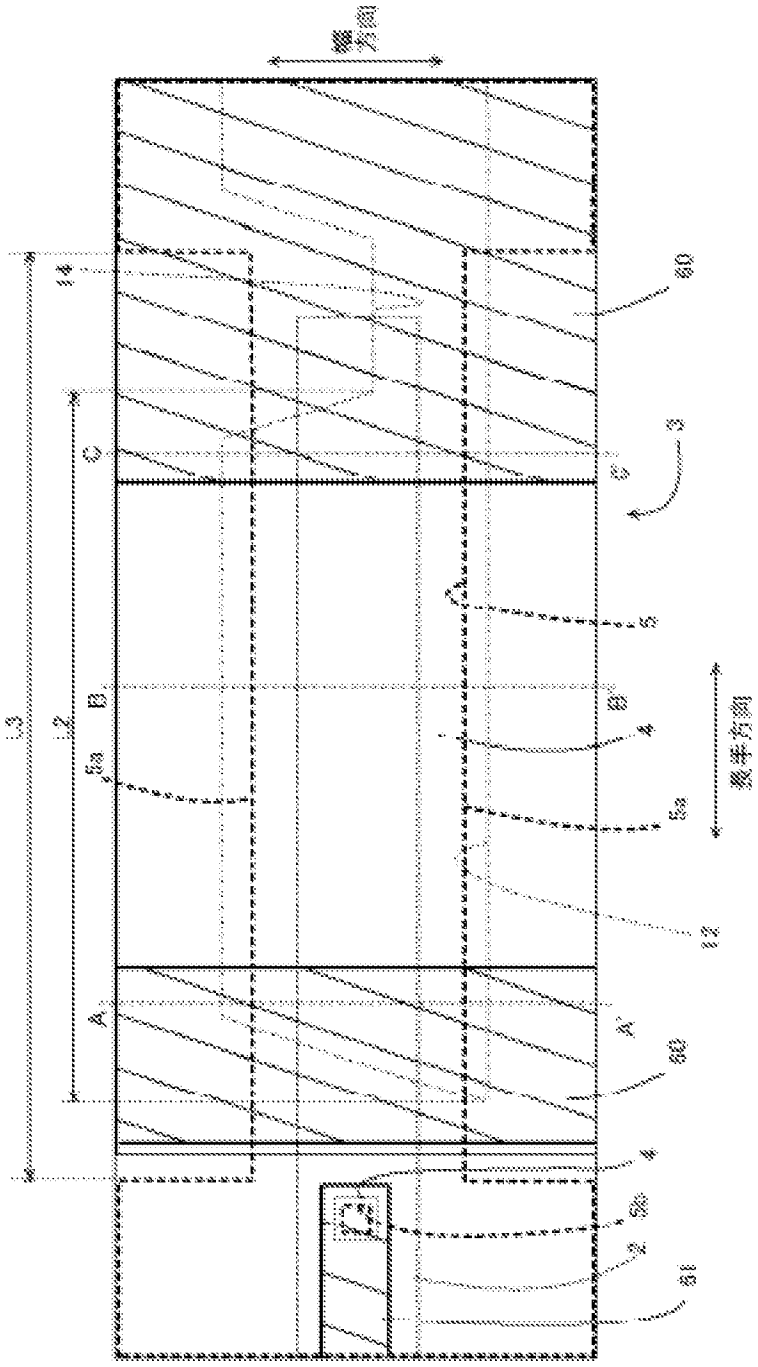
【図９】



【図３】



【図７】



フロントページの続き

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(54) Title: TOTAL SHOULDER PROSTHESIS HAVING INSET GLENOID IMPLANT CONVERTIBLE FROM ANATOMIC TO REVERSE

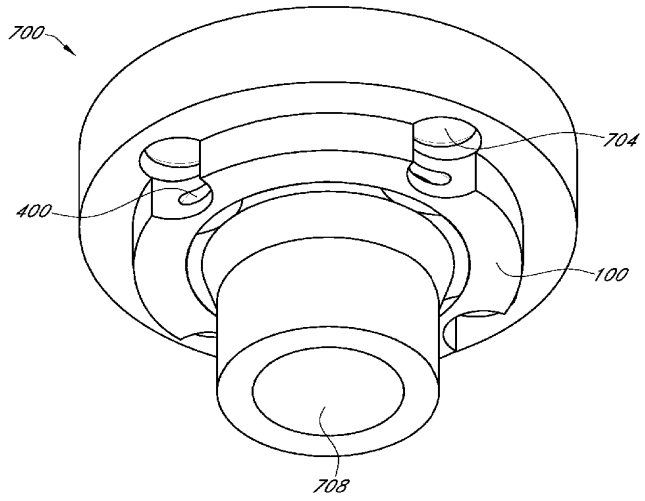


FIG. 8

(57) Abstract: Disclosed are prosthesis systems and methods that provide ways by which the articulating surfaces of the implant can be exchanged such that the anatomic surfaces can be converted to reverse surfaces, while not exchanging the fixation components. Also disclosed herein are methods by which the surgeon can implant an inset anatomic articulating glenoid implant whereby at a later date, can remove the anatomic articulating surface and replace it with a reverse articulating surface such that the primary means of fixation remains well fixed in the glenoid fossa at the moment of articular exchange.

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MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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TOTAL SHOULDER PROSTHESIS HAVING INSET GLENOID IMPLANT CONVERTIBLE FROM ANATOMIC TO REVERSE

[0001] This application claims the benefit under 35 U.S.C. § 119(e) as a nonprovisional of U.S. Prov. App. No. 62/485839 filed on April 14, 2017, which is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] Shoulder Replacement is a commonly performed medical procedure for treatment of osteoarthritis, rheumatoid arthritis, as well as for treatment of certain deformities related to oncological indications as well as trauma. There are two primary types of articulations available to surgeons for treatment: anatomic and reverse. With anatomic, the surgeon replaces the articular surfaces with industrial materials such that the articulating surfaces are substantially the same shape as the natural anatomy. A stem can be commonly fixed inside the canal of the humerus, a metallic articular head can be rigidly fixed to the proximal aspect of the same, the articular head having a convex articular surface adapted to articulate with the glenoid implant. The glenoid implant can include on its back side (medial side) certain pegs or posts or fins adapted to be rigidly fixed within the glenoid fossa of the scapula and on its front side a concave or flat articular surface adapted to articulate with the humeral head of the humeral implant.

[0003] When a reverse prosthesis is used, the articular surface is reversed in that the metallic ball is rigidly fixed to the glenoid fossa of the scapula, and the concave articular surface is rigidly fixed to the humeral bone, thereby reversing the fashion of articulation of the prosthesis.

[0004] The surgeon chooses between the two types of prostheses by assessing a number of conditions of the patient including level of pain, patient activity level, deformity or severity of the boney degradation, the strength of surrounding soft tissues, and present or absence of prior surgery, and particularly the health and strength of the rotator cuff muscle and tendon. Disease of the rotator cuff is common among patients with arthritis of the shoulder. In this circumstance, it is commonly observed that the absence of insufficiency of

the rotator cuff leads to a condition where the anatomic shoulder replacement prosthesis is not sufficiently stabilized by surrounding soft tissue. In this case, a reverse shoulder replacement prosthesis can be preferred in some cases due to the higher inherent stability of the articulation. In addition, the reverse prosthesis can advantageously utilize the remaining muscles in a way they can be more effective in the absence of the other soft tissue structures by adjusting the position of the articular surfaces within the joint.

[0005] It is not uncommon that a surgeon selects to use an anatomic prosthesis and is provides effective treatment to the patient though the shoulder replacement operation. However, over time and during use of the prosthesis, the patient's rotator cuff complex can become insufficient, tear, or generally be diseased such that it can no longer perform its function associated with normal joint kinematics. In this case, the surgeon can elect to perform a second operation to remove the anatomic prosthesis, and replace the anatomic prosthesis with a reverse prosthesis.

[0006] Several attempts have been made to attempt to address the need of conversion of the articular surface without interruption of the fixation. Primarily, these are created using a two (or more) system, where there is a metallic fixation component which is rigidly fixed to the glenoid fossa, and a polyethylene (PE) articular component which is secondarily fixed to the metallic component, and provides the concave articular surface adapted to articular with the humeral prosthesis. While referred to herein as a PE component, some embodiments do not require the use of polyethylene and can be made of other biocompatible materials depending on the desired clinical result. The PE component is commonly fixed to the metallic fixation component by conventional industrial techniques such as snap fit mechanisms, snap rings, compression pins, overmolding of the PE and other such means.

[0007] A challenge of this particular articulation in some cases is that the glenoid fossa is relatively small, and commonly there is much reduced presence of bone in patients with arthritis. In this context, the surgeon has limited positioning and bone to work with in order to fit within the patient. In addition, the surgeon must be careful not to overstuff the joint, meaning implant components that move the new articulating surface far from its original position such that the soft tissues is unnaturally tensioned, which can lead to

instability, accelerated where, soft tissue failure, pain, reduced range of motion, or fracture of the prosthesis and surrounding bone. Facing these conditions, the prosthesis typically needs to be designed to remain relatively thin (commonly, 1 piece, where PE glenoid implants typically have a 4mm thick articular surface). In order to design these modular components, there can be little additional packaging space provided into which to fit the attachment mechanisms necessary for use without adversely affecting the performance of the overall joint replacement procedure. Thus, typically, these designs lead to "over-optimization" of the fixation and articular portions in order to provide sufficient attachment mechanisms such that either: the PE is too thin to be sufficiently strong, the metallic components are too small to provide sufficient fixation, or the overall mechanism is insufficiently rigid causing there to be secondary wear surfaces, and generation of wear particles leading to PE disease.

[0008] A problem that can exist is that in the case where the surgeon wants to change the prosthesis type, the anatomic prosthesis is commonly well fixed and adapted to the patient's body such that removal of the prosthesis can be very destructive, and leave natural bone remaining that is perhaps insufficient to support the fixation of the reverse prosthesis. What is needed is a prosthesis system that provides a means by which the articulating surfaces of the implant can be exchanged such that the anatomic surfaces can be converted to reverse surfaces, while not exchanging the fixation components.

[0009] What is also needed is a simple means by which the surgeon can implant an inset anatomic articulating glenoid implant whereby at a later date, can remove the anatomic articulating surface and replace it with a reverse articulating surface such that the primary means of fixation remains well fixed in the glenoid fossa at the moment of articular exchange.

SUMMARY

[0010] In some embodiments, disclosed herein is a method of performing a reversible anatomic shoulder replacement procedure. The method can include any number of: reaming a cavity into the glenoid; and inserting an anatomic glenoid articular implant into the glenoid cavity, the glenoid anatomic articular implant comprising a medial surface configured

to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached to a snap ring attached to a fixation ring, the snap ring and the fixation ring at least partially implanted within the glenoid cavity. The anatomic glenoid articular implant can be partially or fully inset into the glenoid cavity. The cavity could be circular, oval, or another shape.

[0011] Also disclosed herein is a method of converting an anatomic to a reverse shoulder prosthesis, including any number of: identifying a patient with an anatomic glenoid articular implant within a glenoid cavity, the anatomic articular implant comprising a medial surface mated with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface articulating with a humeral component; and a central component between the lateral surface and the medial surface, the central component having an outer diameter reversibly attached to a snap ring and a fixation ring, the snap ring and the fixation ring at least partially implanted within the glenoid cavity; inserting a implant removal tool through the lateral articulating surface of the anatomic glenoid articular implant sufficient to collapse the snap ring; removing the anatomic glenoid articular implant while leaving the fixation ring in place within the glenoid cavity; and inserting a reverse shoulder implant into the glenoid cavity sufficient to actuate the snap ring such that the reverse shoulder implanted is reversibly fixed to the fixation ring. Inserting the removal tool can include driving pins, a drill bit, or another tool of the removal tool through the lateral articulating surface of the anatomic glenoid articular implant.

[0012] In some embodiments, also disclosed herein is a reversible anatomic shoulder replacement system, that can include any number of: a fixation ring configured to be positioned within the glenoid cavity, the fixation ring comprising a peripheral edge comprising an outer diameter and a plurality of spaced-apart radially inward indents in the peripheral edge, the fixation ring comprising a groove configured to house a snap ring therein; a snap ring comprising an expanded configuration and a collapsed configuration; and an anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface

configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached to the snap ring and the fixation ring, the snap ring and the fixation ring configured to be at least partially implanted within the glenoid cavity. The groove can include anti-rotation tabs. The peripheral edge of the fixation ring can be configured to facilitate bone ingrowth, e.g., via an osteoinductive or osteoconductive surface. The groove can be a circumferential groove. The lateral surface can include any appropriate material, such as polyethylene.

[0013] Also disclosed herein is a reverse shoulder replacement kit for an anatomic shoulder replacement system, that can include any number of: an implant removal tool configured to bore through a medial surface of the anatomic glenoid articular implant sufficient to collapse a snap ring; and remove an anatomic glenoid articular implant while leaving a fixation ring in place within the glenoid cavity; and a reverse shoulder implant configured to be implanted into the glenoid cavity, the reverse shoulder implant comprising a generally cylindrical component comprising a medial surface configured to mate with the glenoid cavity, a central receptacle for housing an articular post therethrough, and a plurality of peripheral screw holes; a lateral surface, and a central post extending away from the lateral surface, wherein the reverse shoulder implant is configured to reversibly mate with the snap ring and fixation ring embedded in the glenoid cavity to anchor the reverse shoulder implant.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 illustrates a lower perspective view of an embodiment of a fixation support which can be an annular fixation ring in some embodiments that can be fixed at least partially within a prepared glenoid cavity.

[0015] FIG. 2 illustrates an upper perspective view of an embodiment of a support, e.g., an annular ring 100.

[0016] FIGS. 3 and 4 illustrate an embodiment of an anatomic articular component 200 for a glenoid cavity which can be made of polyethylene or another appropriate material.

[0017] FIGS. 5 and 6 illustrate different perspective views of an embodiment of a reversible anatomic articular assembly 300 including the anatomic articular component 200, fixation ring 100, and location for placement of a snap ring 400.

[0018] FIG. 7 illustrates a perspective view of an embodiment of a reverse fixation disc 700 including a central fixation post 706 that can include a longitudinal axis aligned along the center of the reverse fixation disc as shown.

[0019] FIGS. 8 and 9 illustrate perspective views of a reverse fixation disc 700 including peripheral screw holes 704, fixation ring 100 and snap ring 400, the snap ring 400 which can have the same mechanism as the anatomic assembly described herein.

[0020] FIGS. 10A-C illustrate part of a method of implanting an anatomic prosthesis into a reamed glenoid cavity, according to some embodiments of the invention.

[0021] FIGS. 11A-D and 12A-B illustrate a method of removing an anatomic prosthesis while leaving a fixation ring in place embedded in the glenoid cavity, as well as embodiments of components for use in the method, according to some embodiments.

[0022] FIGS. 13A-13B, illustrates a method of implanting a replacement reverse prosthesis in the glenoid cavity, and mating the prosthesis with the implanted fixation ring.

DETAILED DESCRIPTION

[0023] In particular, some embodiments of the invention are focused on advantageously exchanging the articular surface of the glenoid from a concave shape to a convex shape, without removing the components or interface having to do with fixation of the implant into the glenoid fossa.

[0024] In some embodiments, embodiments of the invention can be used or modified with use with particular advantages of using inset glenoid fixation technology in anatomic shoulder arthroplasty, such as described, for example, in U.S. Pat. Nos. 8,007,538 and/or 8,778,028 to Gunther, which are hereby incorporated by reference in their entireties.

[0025] What is further described are methods by which the surgeon can achieve the use of the inset glenoid technology with an anatomic articulation, while after having the ability to convert the technology to a reverse articulation, without requiring removal the rigid fixation between the inset fixation and the scapula bone (in other words, allowing the rigid

fixation support between the inset fixation and the scapula bone to remain in place during conversion from an anatomic to a reverse prosthesis).

[0026] Some embodiments of the invention can utilize an inset glenoid articulation implant described by Gunther et al. including in U.S. Pat. No. 8,007,538 or 8,778,028. However, some embodiments of the invention can also utilize onlay glenoid articulation implants. The peripheral rim of the implant can in some cases have an important role in the fixation stability of the implant and its resistance to motion relative to the glenoid bone during articulation. In addition, it is recognized that a known "rule of thumb" in the industry is that the bearing component of the glenoid implant, such as the polyethylene (PE) component, should be at least about 3mm thick at its thinnest position in order to achieve a sufficient material strength to minimize risk of accelerated implant failure. Of course, this rule is only a guide, but has proven helpful in assessing longevity of implant designs. With these points in mind, it is recognized that in some embodiments the design of the implant (which can be inset in some embodiments) might be improved upon by providing a step in the outer diameter of the inset glenoid implant at its most medial aspect while being able to maintain a minimum PE thickness of about or at least about 2mm, 2.5mm, 3mm, 3.5mm, 4mm, or ranges incorporating any of the aforementioned values. In the space that this step provides is placement of an annular ring which can be rigidly fixed on the outer diameter of the articular implant such that the outer diameter of the inset glenoid implant remains a contiguous surface, albeit in some embodiments made a plurality of materials: the lateral aspect being part of the PE articulation, the medial aspect being the outer diameter of the annular ring, which can be metallic in some cases. The annular ring and the PE articular component can be attached to one another through the use of a snap ring mechanism or other ways, some of which are described elsewhere herein.

[0027] The annular ring can be configured such that its outer diameter presents a surface to the surrounding bone which can be adapted to be biologically attractive for the growth of surrounding bone tissue. This technology can be achieved by several means such as, for example, various coatings or secondary manufacturing operations, mechanical modification through machining operations, creation of an adapted surface using 3D printing manufacturing, or other means. One advantage of the surface on the outer diameter is such

that over the course of the healing process following surgery, bone grows and adapts itself to this annular ring so as to provide rigid attachment of surrounding bone to the annular ring. Thus, at the moment of articular component exchange, the ring is well fixed to bone, and following removal of the PE articulation component, the ring remains well fixed within the glenoid bone, and can be useful as a support surface in attachment of a new reverse articulating surface to the bone.

[0028] FIG. 1 illustrates a lower perspective view of an embodiment of a fixation support which can be an annular fixation ring in some embodiments that can be fixed at least partially within a prepared glenoid cavity. The annular ring 100 can include a central cavity 106 and a plurality of radially inward indents 102 in the outer circumference of the peripheral edge 104 of the annular ring 100 as shown and be sized and configured for fixation screw clearance. The ring 100 could have any number of indents 102 such as 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more, or ranges including at least two of the aforementioned values. The indents 102 could be regularly or irregularly spaced apart along the circumference in some embodiments, and have a curved shape as shown or other shapes. As shown, the peripheral edge 104 can include a coating or other surface, e.g., osteoinductive or osteoconductive surface to facilitate bone ingrowth and fixation into the cavity. The surface could include, for example, cortical bone, cancellous bone, particulate matter, a powder form, granules, chips, a synthetic bone substitute, growth factors and/or bone growth promoting proteins, or combinations thereof. The annular ring 100 can also include a groove or slot 108 that can be oriented along the outer circumference of the central cavity 106 (e.g., inner diameter of the ring) and configured to house a snap ring therein (not shown).

[0029] FIG. 2 illustrates an upper perspective view of an embodiment of a support, e.g., an annular ring 100, showing the indents 102 as previously described. Also shown is the groove or slot 108 configured to house a snap ring as well as radially-inward extending anti-rotation tabs 112. The outer diameter of the peripheral edge 104 of the annular ring 100 can match that of a bearing, e.g., polyethylene component in some embodiments.

[0030] FIGS. 3 and 4 illustrate an embodiment of an anatomic articular component 200 for a glenoid cavity which can be made of polyethylene or another appropriate material. The anatomic articular component 200 can include a concave

articulating surface 202 as shown, as well as a central fixation post or peg 204, which can be only a single post or peg in some cases, and be aligned coaxially with the center of the implant. The peripheral edge of the implant could have a generally cylindrical shape in some embodiments, and/or have a circular, oval, or other cross-section. The articular component 200 can also include a feature configured to mate with the fixation support, such as a cylindrical component 206 lateral to the articular surface 202 that can have an outer diameter that corresponds to the inner diameter of the fixation support (not shown) as well as a slot or groove (not shown) configured to house a snap ring (not shown). The outer diameter of the component 206 can be in some cases less than, such as about or at least about 5%, 10%, 20%, 30%, 40%, 50%, or more less than that of the outer diameter of the articulating surface 202 of the anatomic articular component 200, or ranges including any two of the aforementioned values.

[0031] FIGS. 5 and 6 illustrate different perspective views of an embodiment of a reversible anatomic articular assembly 300 including the anatomic articular component 200, fixation ring 100, and location for placement of a snap ring 400 as previously described and illustrated.

[0032] FIG. 7 illustrates a perspective view of an embodiment of a reverse fixation implant, e.g., disc 700 including a central fixation post 706 that can include a longitudinal axis aligned along the center of the reverse fixation disc as shown. The medial surface 702 of the disc can include a central receptacle 708 for an articular post, as well as a plurality, e.g., 2, 3, 4, or more screw holes 704 oriented more peripherally with respect to the peripheral edge 706 of the disc, which can be generally cylindrical as shown, or another suitable geometry.

[0033] FIGS. 8 and 9 illustrate perspective views of a reverse fixation disc 700 including peripheral screw holes 704, fixation ring 100 and snap ring 400, the snap ring 400 which can have the same mechanism as the anatomic assembly described herein. Also shown is the other end of the receptacle 708 for the articular post that can extend through the implant. The apertures 704 (e.g., screw holes) can be axially aligned and configured to correspond with each of the indents 102 of the fixation ring 100 with the indents 102 as previously described, to house fixation screws therethrough.

[0034] FIGS. 10A-10C illustrates part of a method of implanting an anatomic prosthesis into a reamed glenoid cavity, according to some embodiments of the invention. A pocket P can be prepared, such as by reaming, in the glenoid G (shown in FIG. 10A), which can be an appropriate shape, such as circular as shown, ovoid, or other geometries, with a central distal extending hole H for a central peg in some embodiments, as shown in FIG. 10C. The anatomic implant, one embodiment of which is shown in FIG. 10B along with the fixation ring and snap ring, can be implanted into the cavity, shown schematically in FIG. 10C such as in a partially or completely inset manner, with about or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 100% of the thickness of the peripheral edge of the implant inset below the prepared glenoid surface, or ranges including any two of the aforementioned values. The attachment of the ring to the PE implant can be preferably achieved in a reversible fashion using techniques and tools available to a surgeon such that the operation can be performed in situ, or in place within the patient. In order to accomplish this, a snap ring mechanism can be utilized such that another component, such as an angular metallic ring is positioned between the bearing component, e.g., PE component and the snap ring and/or metallic ring.

[0035] FIG. 11A schematically illustrates an anatomic articular implant 300 inserted into bone, such as the glenoid cavity. FIG. 11B schematically illustrates a side view, and FIG. 11C a top view, of an implant that can be as previously described. As shown in FIGS. 11A-D and 12 in some embodiments, at the moment the surgeon seeks to remove the PE component from the annular ring, the snap ring 400 (shown in phantom in FIG. 11C) can be collapsed in order to eliminate its interference fit between the annular ring and the PE component. This can be performed through the use of a guide 600 shown in FIG. 11D which can be placed over the surface of the PE component which can be in situ. In some embodiments, the guide 600 can have an elongate shaft 601 and a distal end 604 including an annular sidewall 606 defining a cavity 608 and an open distal end configured to have an inner diameter that can match, substantially match, or be the same size or larger than the outer diameter of the peripheral edge of the bearing component of the implant, such that the annular sidewall 606 and cavity 608 is placed over the glenoid implant. Release pins 602, a

drill, or other tool can be axially advanced into apertures 607 of the guide 600 to facilitate release of the snap ring from the glenoid implant.

[0036] The guide 600 provides positioning of a plurality of holes, e.g., about or at least about two, three, four, five, or more holes positioning around the periphery of the PE implanted such that which a drill or pin 602 is mechanically driven into the guide holes 607, they are aligned to force the snap ring 400 in an radially inward fashion to allow for release of the snap ring. FIG. 12A schematically illustrates the guide 600 being advanced toward the glenoid implant 300 in situ in the glenoid G, along with pins 602 that can be placed in apertures 607 of the guide 600. Once a number of pins 602, e.g., three pins are driven through the guide and PE component, the snap ring is collapsed, and the PE component and snap ring can be removed from the annular fixation ring as an assembly, as shown in FIG. 12B. At this point, what remains is the annular fixation ring well fixed within the glenoid fossa. In some embodiments, the fixation ring may not be fully counter-sunk, and be partially rather than fully inset, within the glenoid surface, and/or stand proud of the glenoid surface. With time, the fixation ring can have some bony ingrowth.

[0037] As shown in FIG. 13A, in some embodiments, an implant such as a disc, e.g., a metallic disc (e.g., as shown in FIGS. 7-9 for example) can then be placed into the previously implanted fixation ring 100 including a groove 108 configured to fit a new snap ring 400 as previously described. The implant 1300 can include a glenosphere 1302 with an offset peg 1303 configured to fit with baseplate 1304 with shaft 1306 (schematically shown in section view), and snap ring 400. The baseplate can have a longitudinal axis A2 that is offset from the longitudinal axis of the glenosphere A1 in some embodiments. FIG. 13B illustrates the reverse implant assembled and deployed within the glenoid cavity. Methods as disclosed herein can have several non-limiting potential advantages, including the following:

1. an outer diameter adapted to provide for a snap ring fit between the disc and annular ring in the same manner as the PE component and the annular ring;
2. a peg, pin, screw or other fixation means which is adapted to fit deeper into the central portion of the glenoid fossa to provide additional fixation means,
3. a central tapered hole into which a reverse ball articulating component can be placed and rigidly fixed; and

4. several peripheral holes through which screws can be driven to further increase the rigidity of fixation between the fixation disc and bone.

[0038] Following the removal of the anatomic, e.g., PE component, the surgeon can further prepare the glenoid fossa for the reverse fixation disc by drilling a centrally positioned hole. The hole can be adapted to receive a pin, post, screw, or other feature which is integrally attached to the medial aspect of the fixation disc. As the fixation disc can be positioned within the annular ring, the central fixation protrusion can be positioned within this hole in the glenoid bone such that further fixation rigidity is obtained.

[0039] Following the placement of the fixation disc in the annular ring, the surgeon can drill additional holes in the glenoid bone through peripheral holes in the fixation disc, which provides the ability to drive fixation screws through the fixation disc into the glenoid bone, even further improving rigidity, in addition to providing rotational stability. Due to the size constrains of the components, it can be advantageous to design the annular ring in a fashion that provides sufficient clearance through which these fixation screws can pass. To this end, the annular ring can be designed such that at on its periphery are several (four) indents of circular shape that provides clearance for passing of the peripheral screws.

[0040] Once the fixation disc is well fixed to the glenoid bone, the spherical articular component is introduced to the fixation disc. On its medial aspect, the articular component can have a cone-shaped protrusion which can be adapted to fit rigidly into a cone shaped hole centrally located within the fixation disc. This can provide a rigid fixation means by which the articular component is fixed to the fixation components using a technique and mechanism well known in the art.

[0041] Some embodiments of the modular, convertible shoulder system as disclosed for example herein can include several unique advantages not considered elsewhere, including but not limited to one or more of the following:

- The use of an annular fixation ring can further improve the fixation potential of inset glenoid technology as described herein. The ring can increase the rigidity of the overall PE glenoid construct, reducing its deflection under load, and improves fixation rigidly.

- The outer aspect of the annular ring can provide a surface which adheres to bone biologically and mechanically which provides further improvement of the rigidity of the fixation over time and in response to load in consideration of Wolf's law.
- This improved rigidity and fixation can be provided with no sacrifice of the 3mm minimum material thickness of the PE component, so that joint mechanics can be maintained with no change in the overall stack height of the anatomic prosthesis.
- The attachment mechanism between the PE articular and annular ring can be reversible in situ, meaning the PE component can be removed from the annular ring which the ring remains in the bone, and can be performed in a manner which is nondestructive to the ring or the surrounding bone.
- The annular ring can be shaped so as to provide a receptacle into which a reverse articulation can be inserted and rigidly fixed.
- The ring can provide clearance so that further rigidity can be obtained by passing screws through the reverse fixation disc, annular ring, and bone.
- The fixation disc can provide a female receptacle into which the articular sphere's attachment post can be positioned. Providing a female receptacle is shown in some cases to be an easy surgical technique and very robust attachment mechanism.

[0042] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form

varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "insetting an implant into a glenoid cavity" includes "instructing the insetting of an implant into the glenoid cavity." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least," "greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

WHAT IS CLAIMED IS:

1. A method of performing a reversible anatomic shoulder replacement procedure, comprising:

reaming a cavity into the glenoid; and

inserting an anatomic glenoid articular implant into the glenoid cavity, the glenoid anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached to a snap ring attached to a fixation ring, the snap ring and the fixation ring at least partially implanted within the glenoid cavity.

2. The method of Claim 1, wherein the anatomic glenoid articular implant is partially inset into the glenoid cavity.

3. The method of Claim 1, wherein the anatomic glenoid articular implant is fully inset into the glenoid cavity.

4. The method of Claim 1, wherein the cavity comprises a circular cavity.

5. The method of Claim 1, wherein the cavity comprises an oval cavity.

6. A method of converting an anatomic to a reverse shoulder prosthesis, comprising:

identifying a patient with an anatomic glenoid articular implant within a glenoid cavity, the anatomic articular implant comprising a medial surface mated with the glenoid cavity, a central peg extending medially from the medial surface, a lateral

surface articulating with a humeral component; and a central component between the lateral surface and the medial surface, the central component having an outer diameter reversibly attached to a snap ring and a fixation ring, the snap ring and the fixation ring at least partially implanted within the glenoid cavity;

inserting a implant removal tool through the lateral articulating surface of the anatomic glenoid articular implant sufficient to collapse the snap ring;

removing the anatomic glenoid articular implant while leaving the fixation ring in place within the glenoid cavity; and

inserting a reverse shoulder implant into the glenoid cavity sufficient to actuate the snap ring such that the reverse shoulder implanted is reversibly fixed to the fixation ring.

7. The method of Claim 6, wherein inserting the removal tool comprises driving pins of the removal tool through the lateral articulating surface of the anatomic glenoid articular implant.

8. A reversible anatomic shoulder replacement system, comprising:

a fixation ring configured to be positioned within the glenoid cavity, the fixation ring comprising a peripheral edge comprising an outer diameter and a plurality of spaced-apart radially inward indents in the peripheral edge, the fixation ring comprising a groove configured to house a snap ring therein;

a snap ring comprising an expanded configuration and a collapsed configuration; and

an anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached to the snap ring and the fixation ring, the snap ring and the fixation ring configured to be at least partially implanted within the glenoid cavity.

9. The system of Claim 8, wherein the groove comprises anti-rotation tabs.

10. The system of Claim 8, wherein the peripheral edge of the fixation ring is configured to facilitate bone ingrowth.

11. The system of Claim 10, wherein the peripheral edge of the fixation ring comprises an osteoinductive or osteoconductive surface.

12. The system of Claim 8, wherein the groove is a circumferential groove.

13. The system of Claim 8, wherein the lateral surface comprises polyethylene.

14. A reverse shoulder replacement kit for an anatomic shoulder replacement system, comprising:

an implant removal tool configured to bore through a medial surface of the anatomic glenoid articular implant sufficient to collapse a snap ring; and remove an anatomic glenoid articular implant while leaving a fixation ring in place within the glenoid cavity; and

a reverse shoulder implant configured to be implanted into the glenoid cavity, the reverse shoulder implant comprising a generally cylindrical component comprising a medial surface configured to mate with the glenoid cavity, a central receptacle for housing an articular post therethrough, and a plurality of peripheral screw holes; a lateral surface, and a central post extending away from the lateral surface,

wherein the reverse shoulder implant is configured to reversibly mate with the snap ring and fixation ring embedded in the glenoid cavity to anchor the reverse shoulder implant.

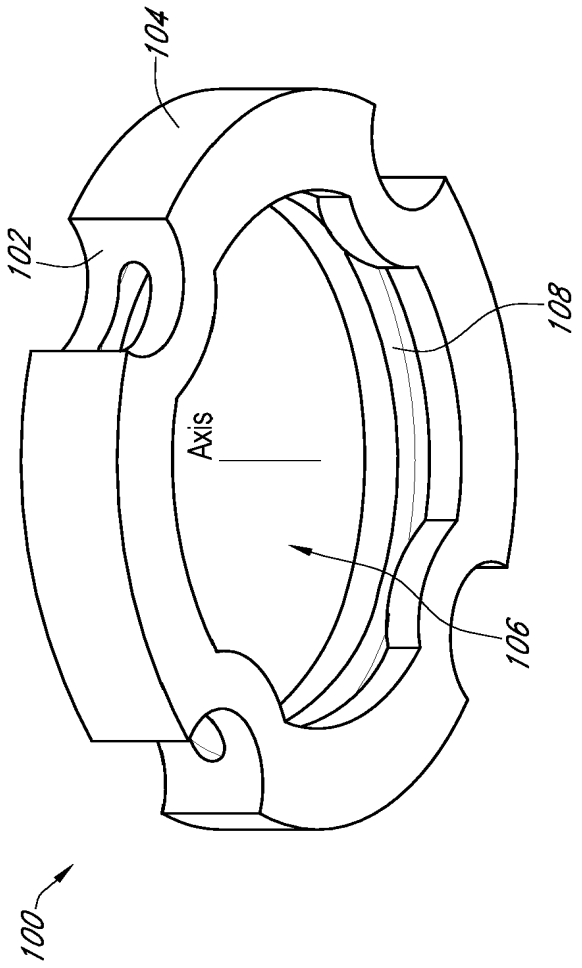


FIG. 1

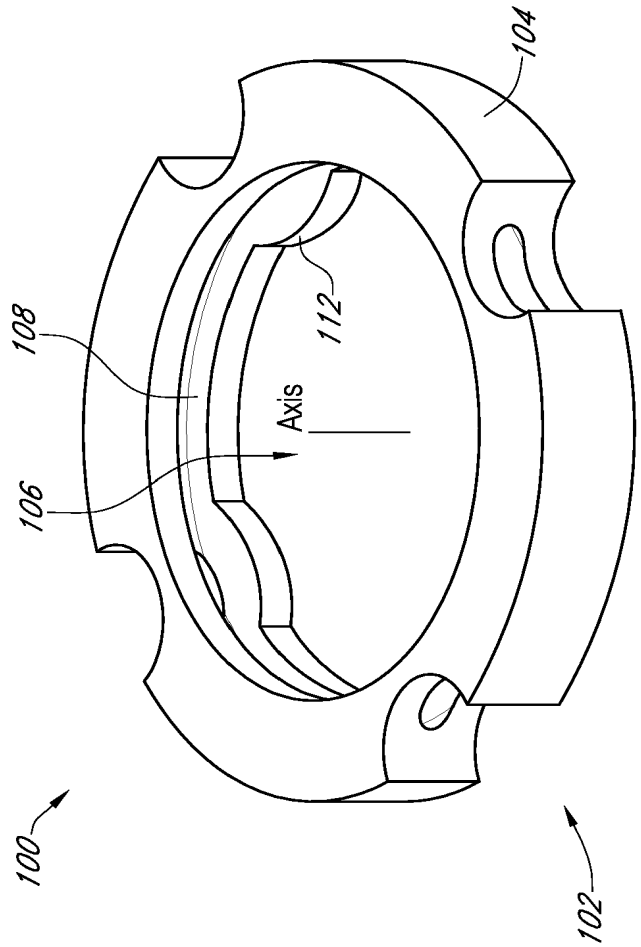


FIG. 2

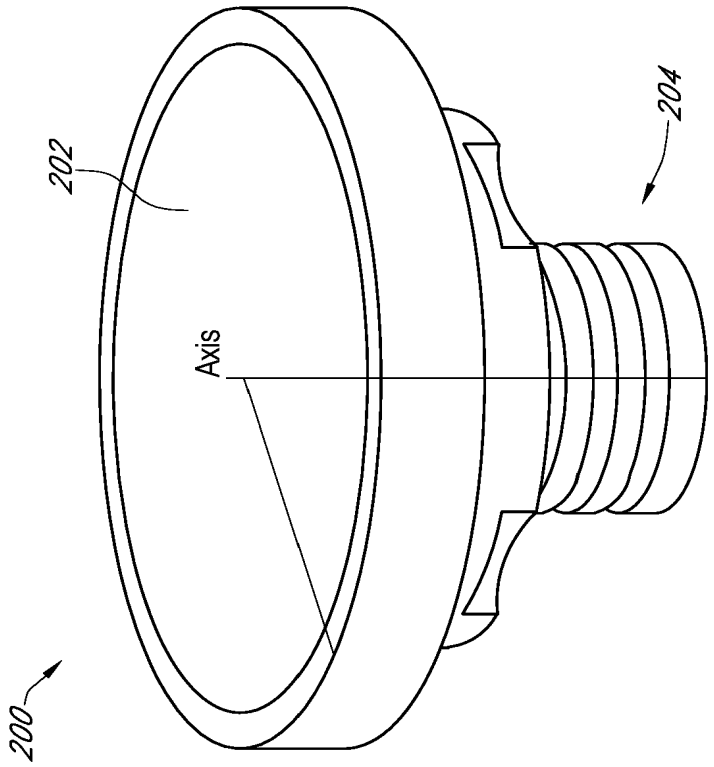


FIG. 3

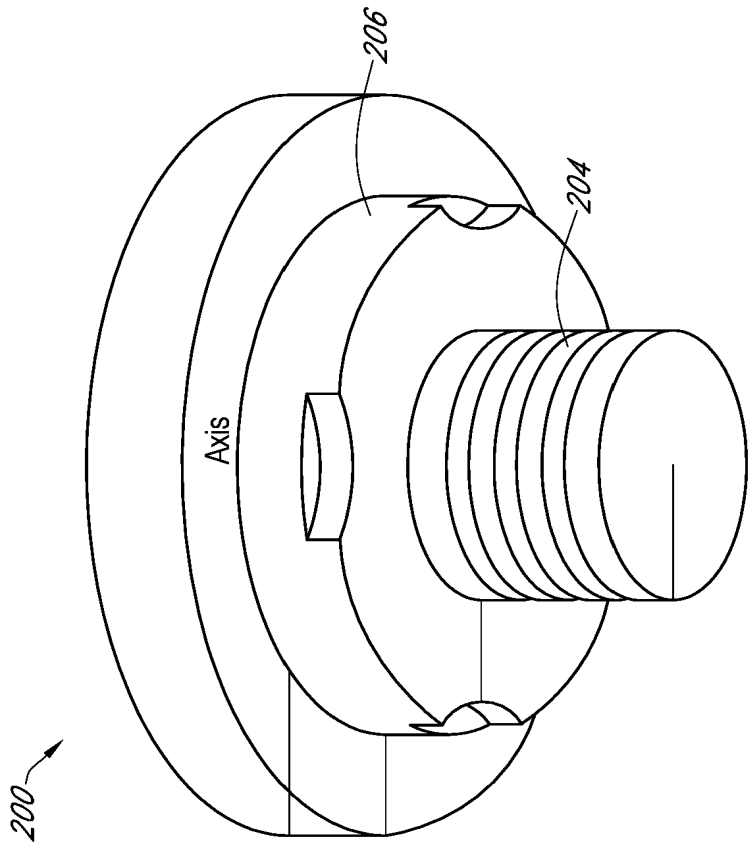


FIG. 4

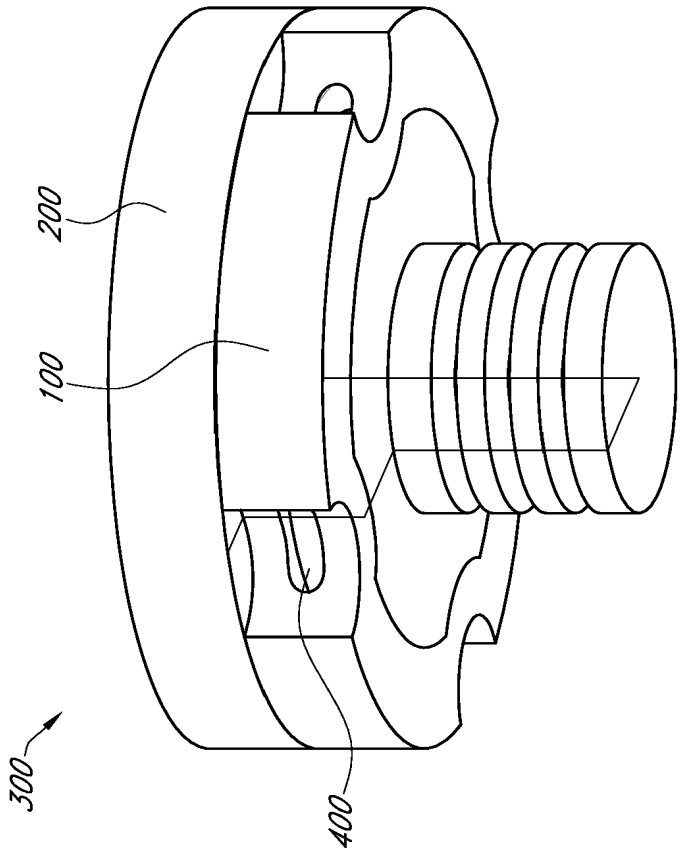


FIG. 5

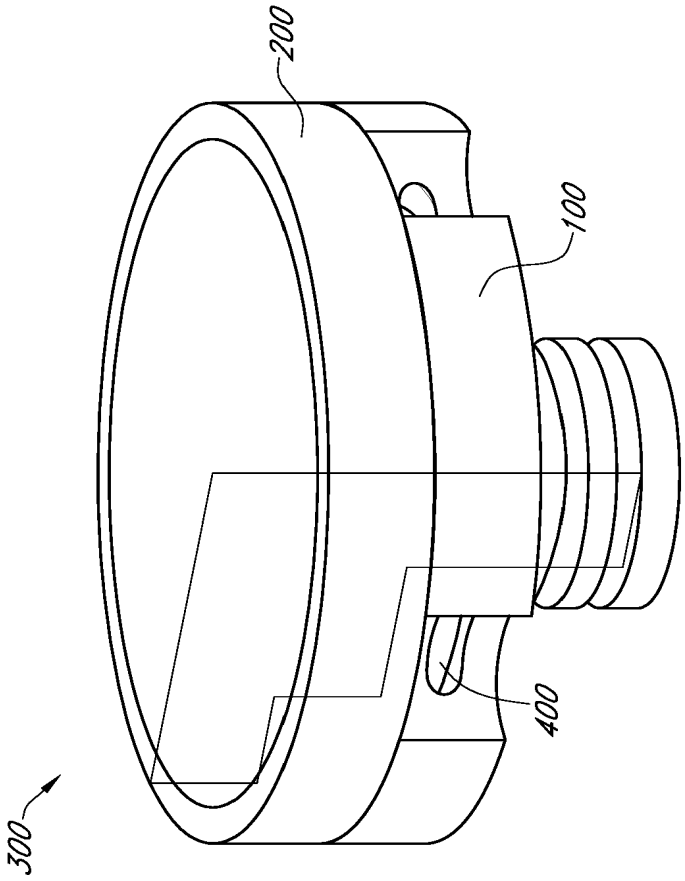


FIG. 6

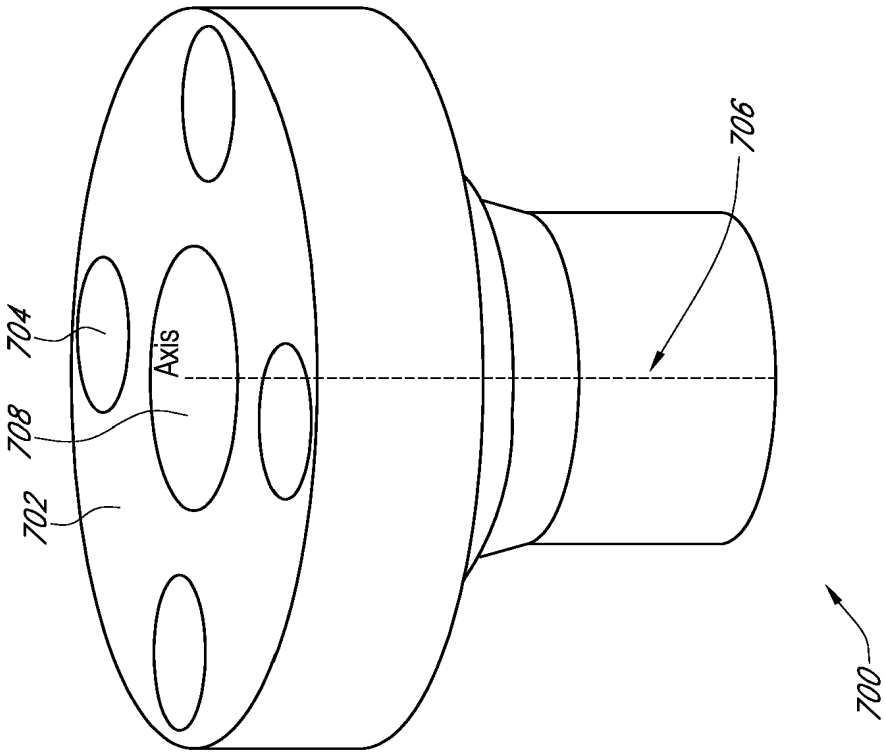


FIG. 7

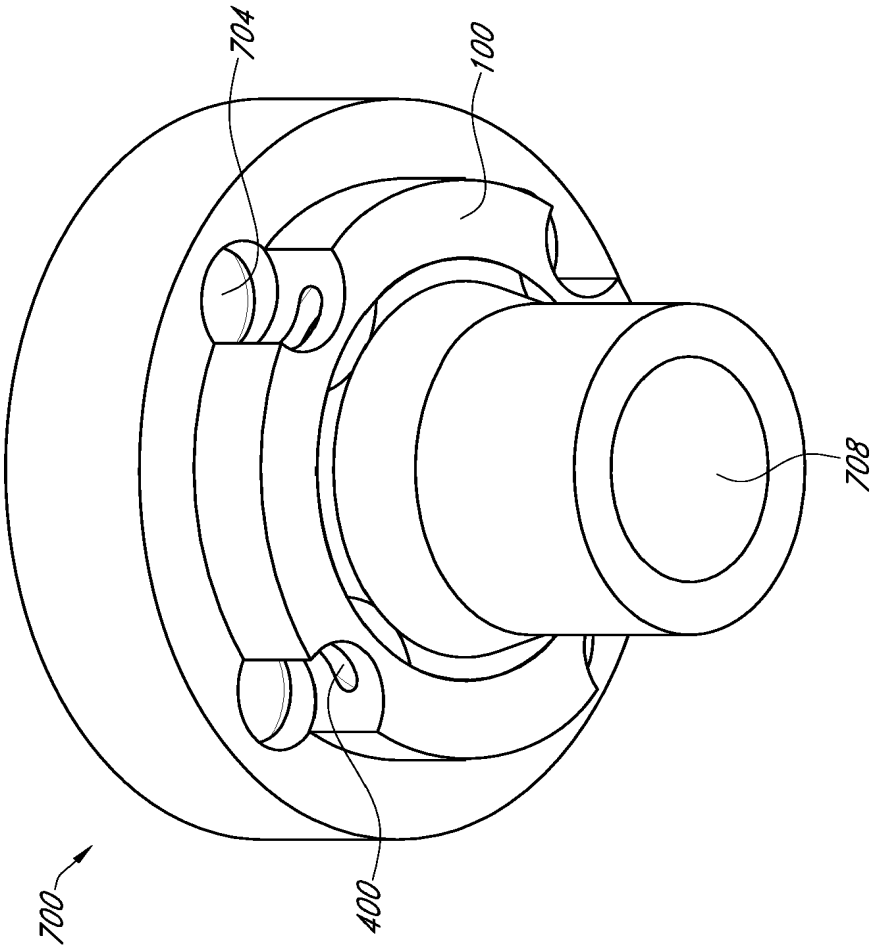


FIG. 8

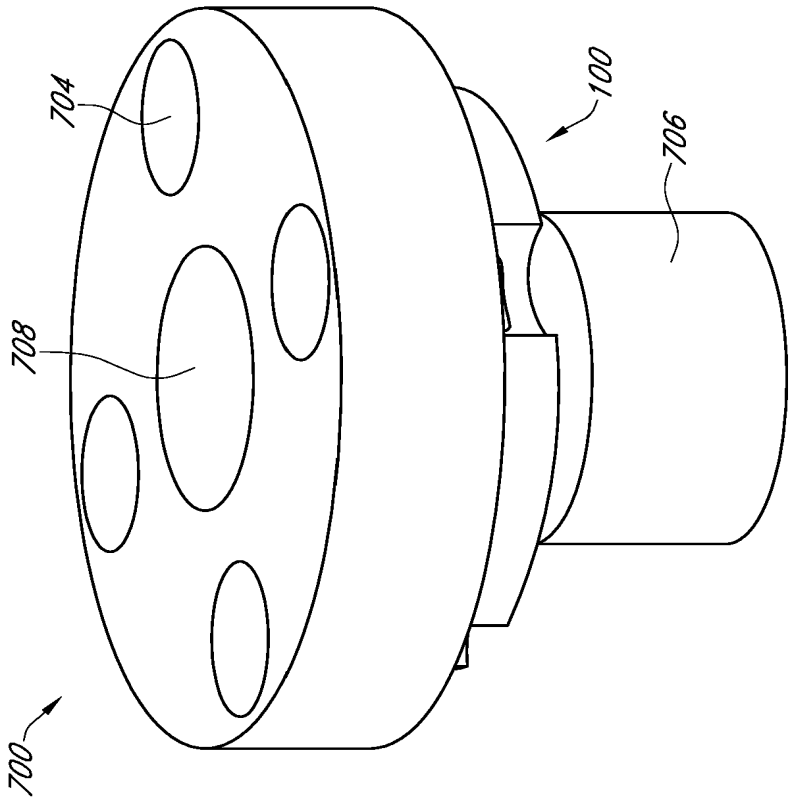


FIG. 9

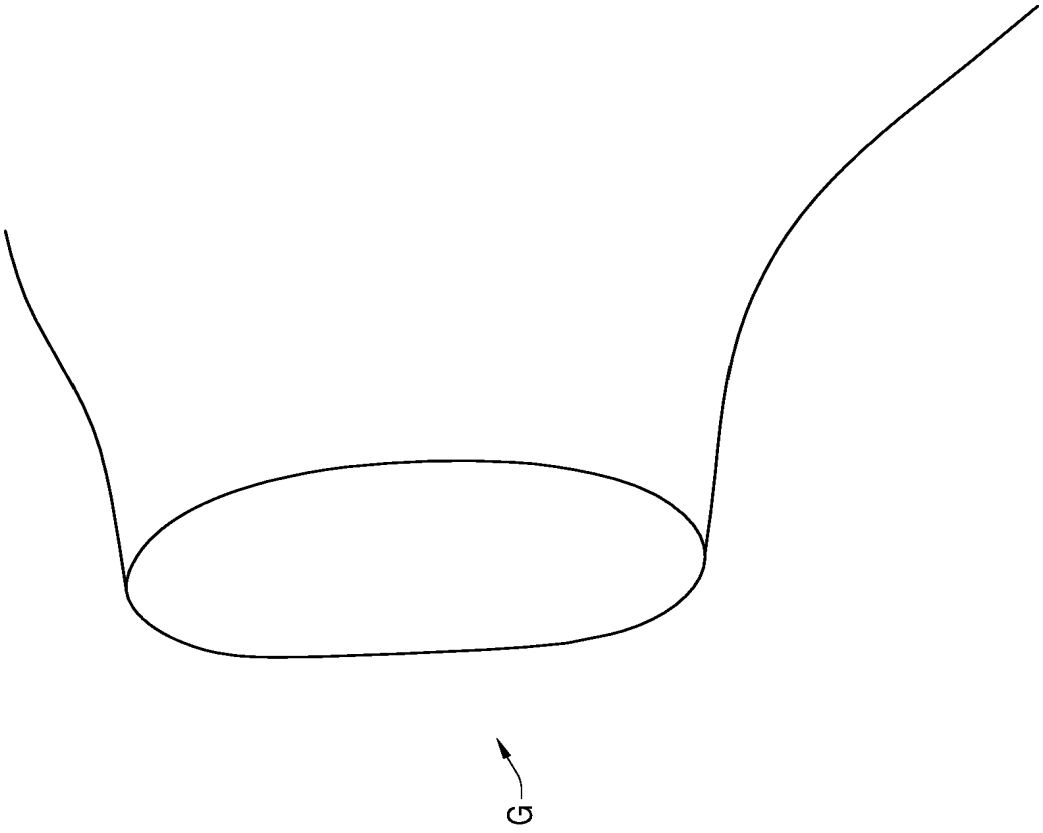


FIG. 10A

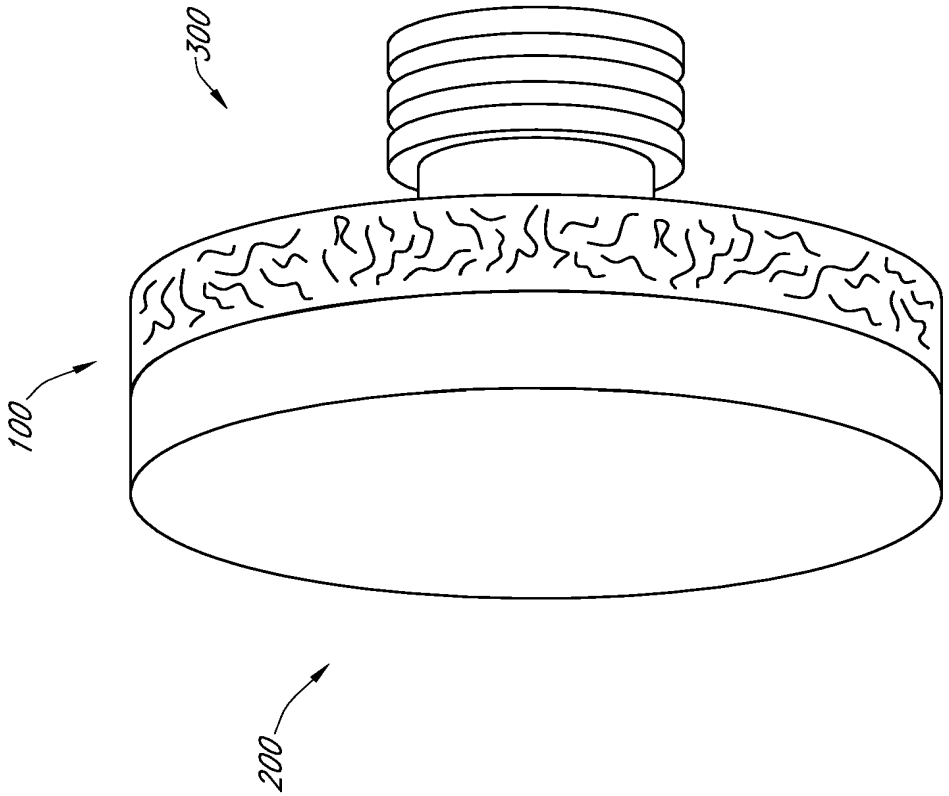


FIG. 10B

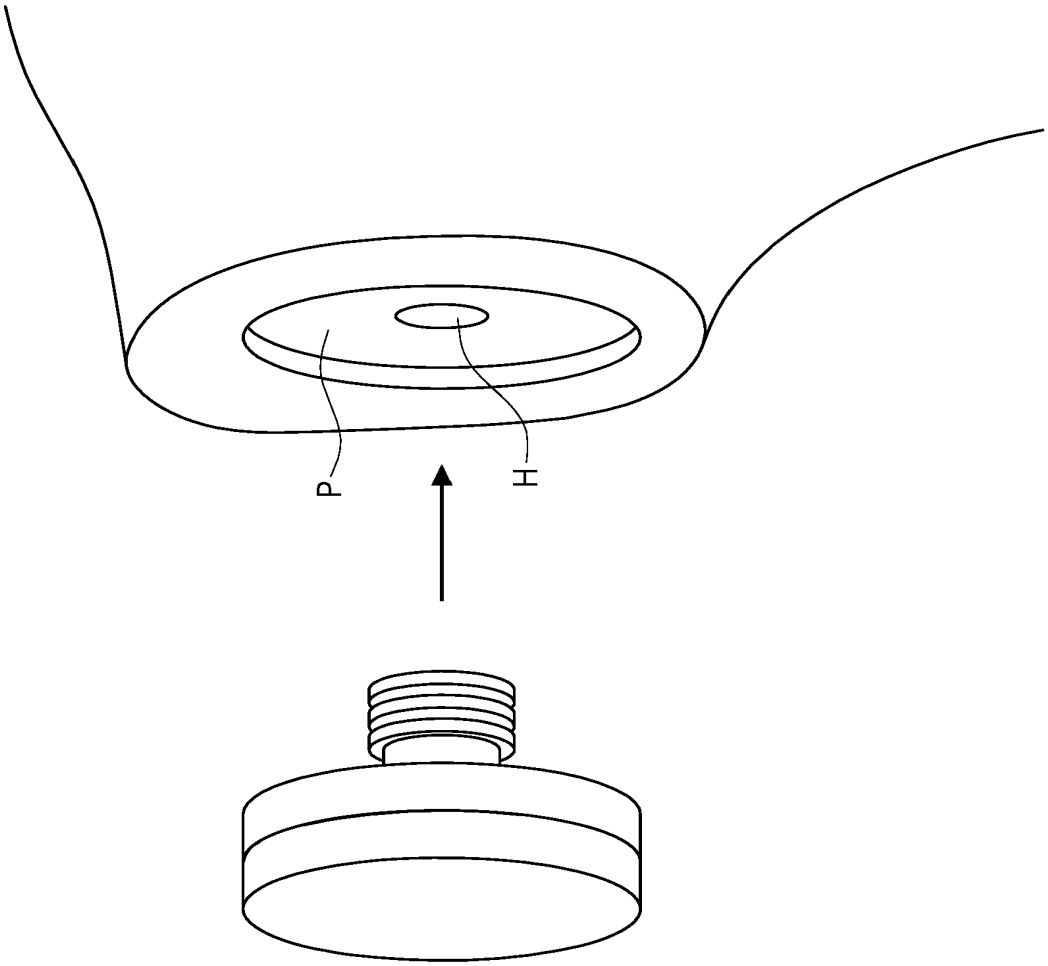


FIG. 10C

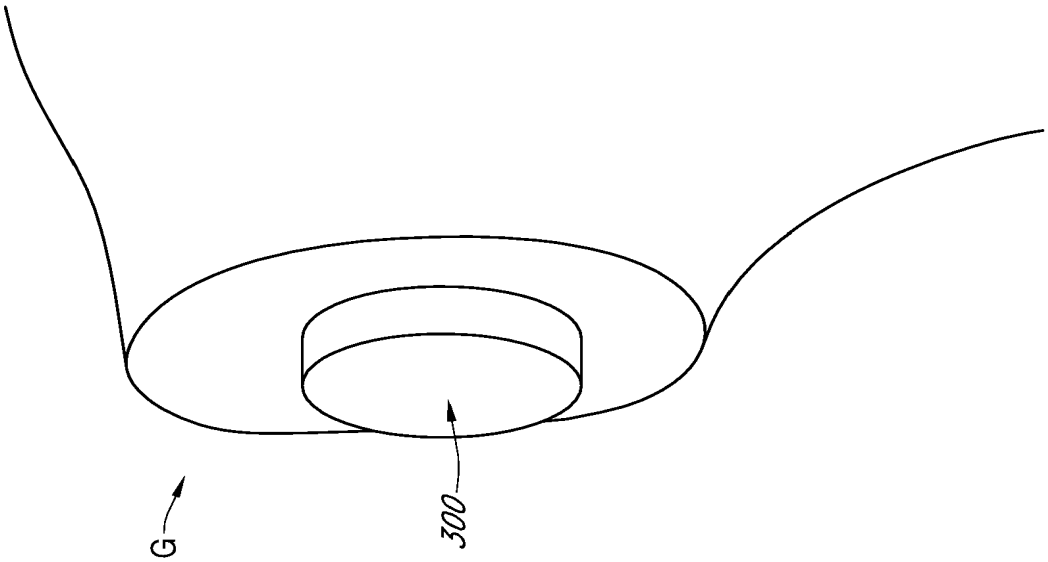


FIG. 11A

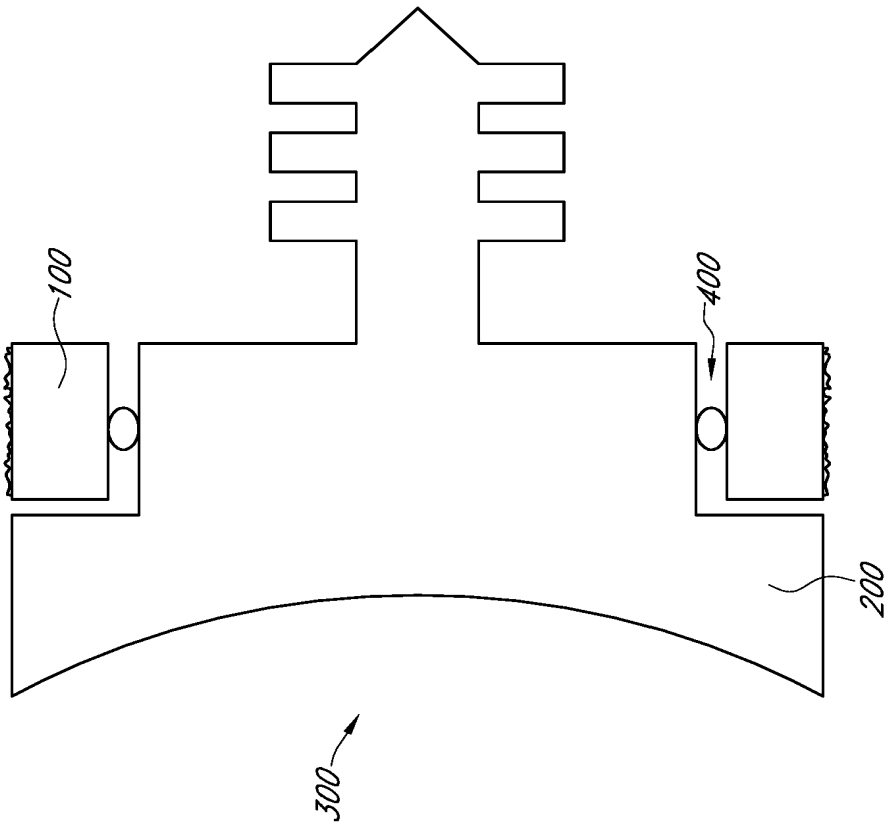


FIG. 11B

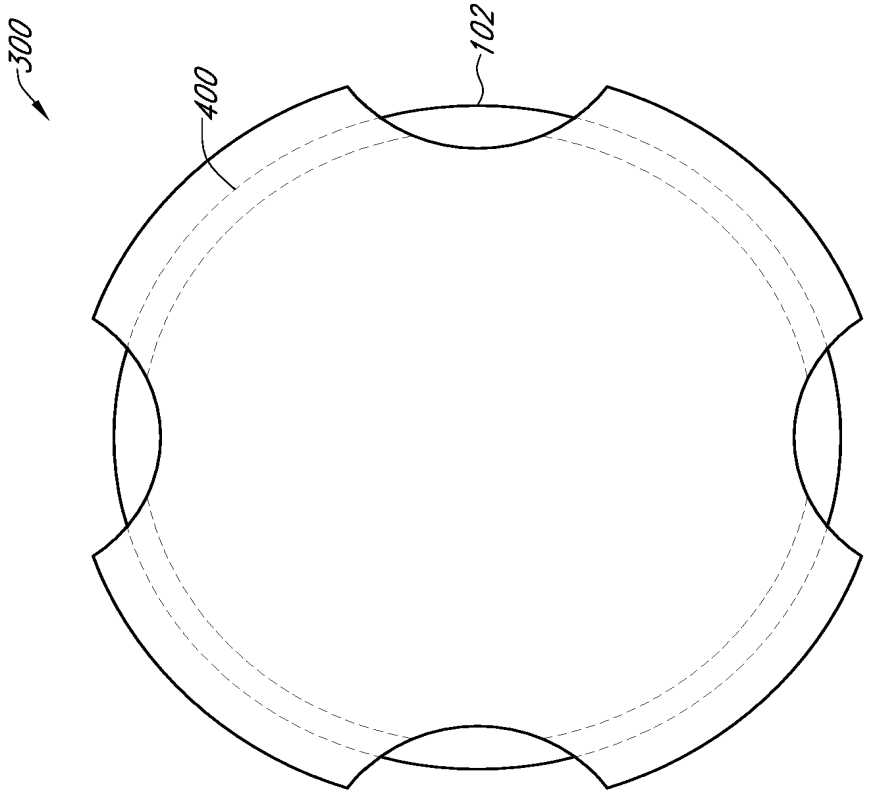


FIG. 11C

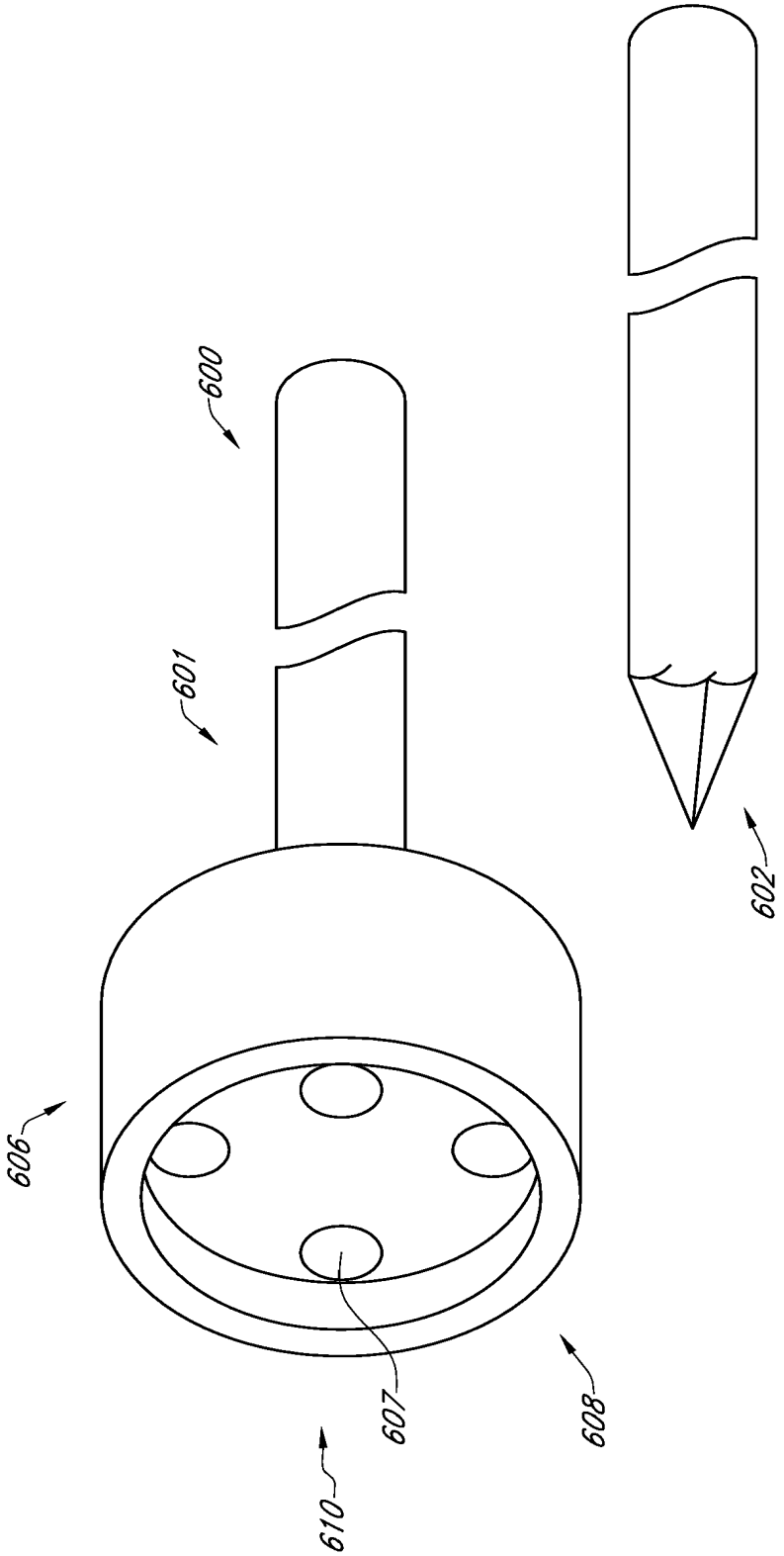


FIG. 11D

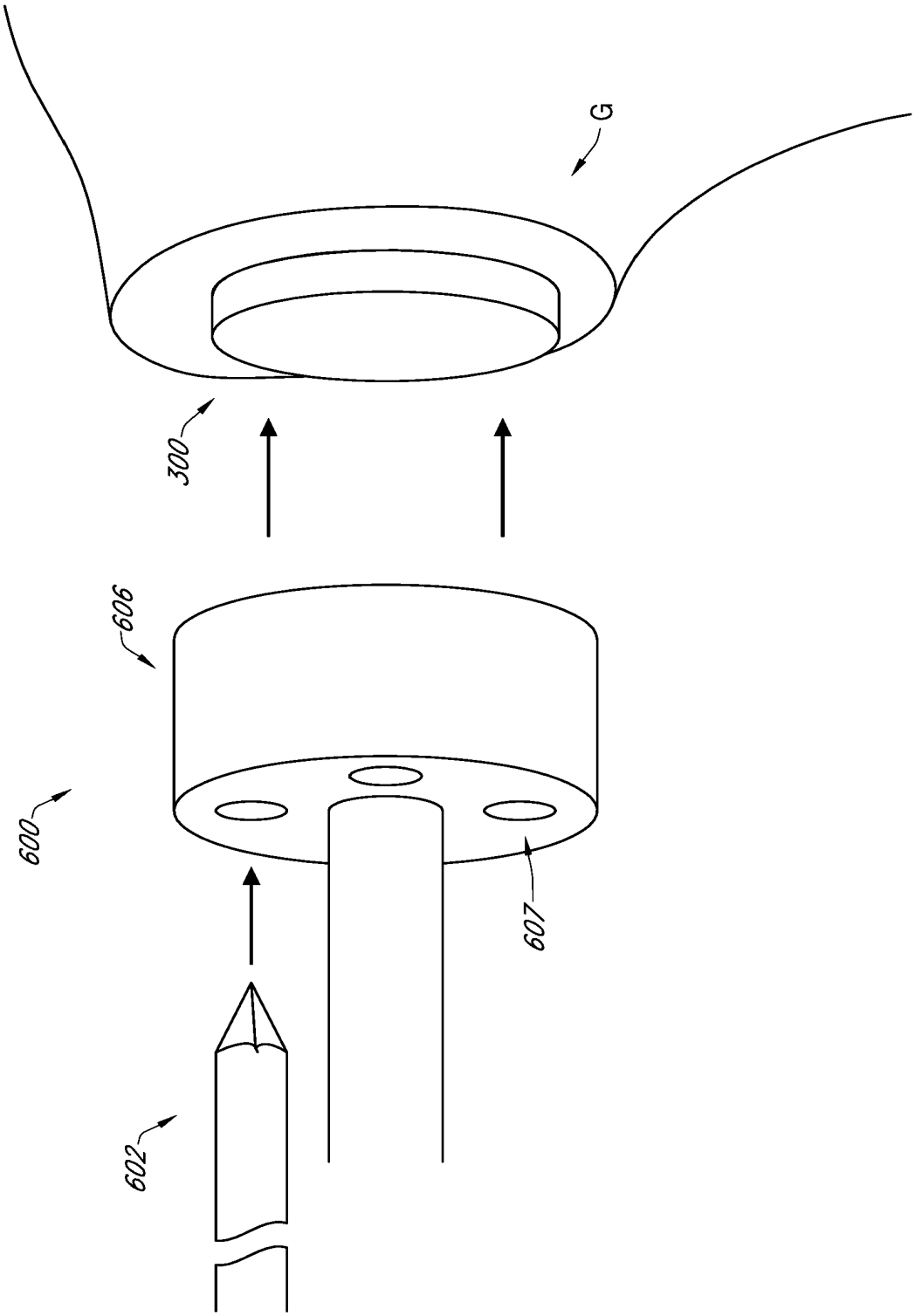


FIG. 12A

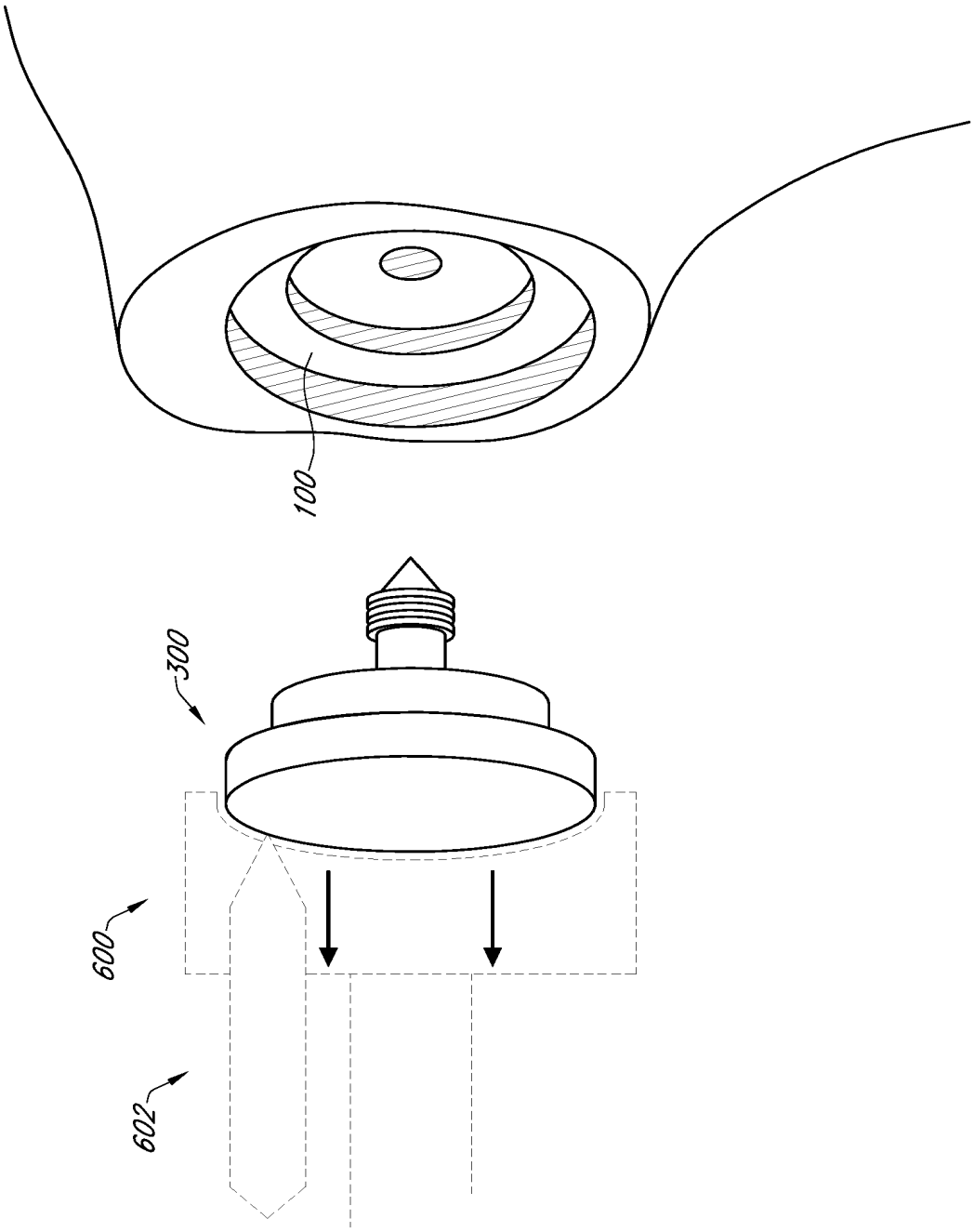


FIG. 12B

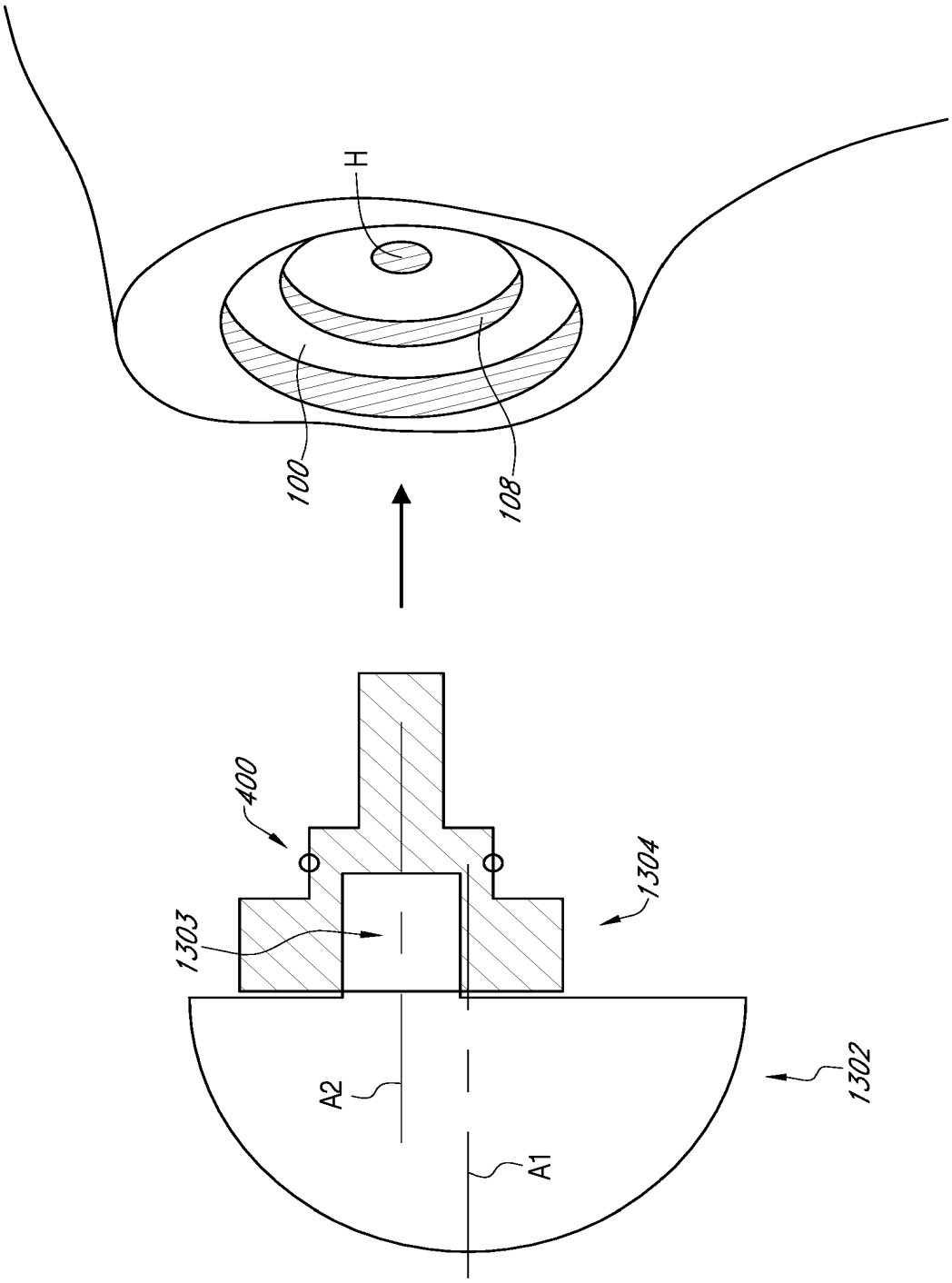


FIG. 13A

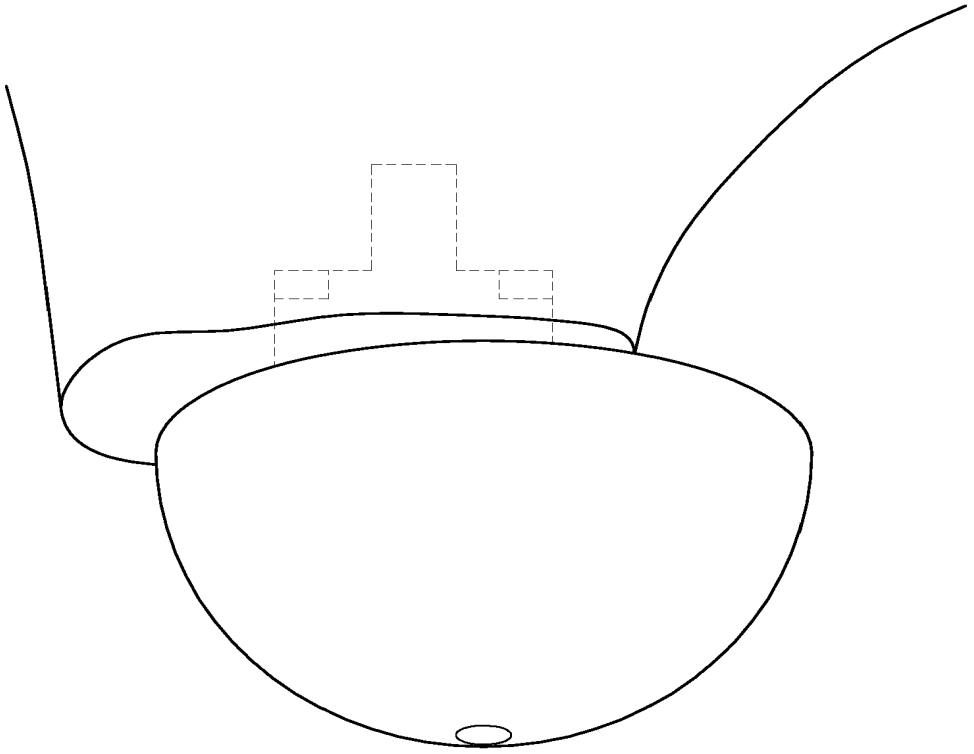


FIG. 13B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/027172

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/40(2006.01)i, A61F 2/46(2006.01)i, A61B 17/56(2006.01)i, A61F 2/30(2006.01)i

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)
A61F 2/40; A61F 2/46; A61B 17/56; A61F 2/30

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: shoulder prosthesis, reverse, fix, replace, remove

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2015-0105861 A1 (SHOULDER INNOVATIONS, LLC.) 16 April 2015 See paragraphs [0008]-[0018], [0091]-[0113].	8-14
Y	US 2013-0197651 A1 (BIOMET MANUFACTURING CORP.) 01 August 2013 See paragraphs [0027]-[0034] and figures 3-8.	8-14
Y	US 2015-0265411 A1 (TORNIER ORTHOPEDICS IRELAND LTD.) 24 September 2015 See paragraphs [0031]-[0052], [0121]-[0137] and figure 1.	9,12
A	US 2012-0209392 A1 (LAURENT ANGIBAUD et al.) 16 August 2012 See paragraphs [0033]-[0050] and figures 10A-10C.	8-14
A	JP 2014-515651 A (ZIMMER GMBH) 03 July 2014 See figure 7 and claim 1.	8-14

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

☒ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2018 (22.08.2018)	**22 August 2018 (22.08.2018)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer
HAN, Inho
Telephone No. +82-42-481-3362

Form PCT/ISA/210 (second sheet) (January 2015)

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2015-0105861 A1	16/04/2015	CA 2598659 A1	08/09/2006
		CA 2598659 C	30/05/2017
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		EP 2502606 B1	17/09/2014
		EP 2663263 A1	20/11/2013

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/027172

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-7
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-7 pertain to a method for treatment of the human body by surgery and thus relate to a subject matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 2663263 B1	21/05/2014
		JP 05647373 B2	24/12/2014
		US 2012-0265315 A1	18/10/2012
		US 2012-0296435 A1	22/11/2012
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		WO 2012-130524 A1	04/10/2012

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 September 2019 (19.09.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/178104 A1

(51) International Patent Classification:
A61F 2/40 (2006.01) *A61F 2/46* (2006.01)
A61F 2/30 (2006.01)

(21) International Application Number:
PCT/US2019/021859

(22) International Filing Date:
12 March 2019 (12.03.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/641,990 12 March 2018 (12.03.2018) US

(71) Applicant: **SHOULDER INNOVATIONS, LLC** [US/US]; 13827 Port Sheldon Street, Holland, Michigan 49424 (US).

(72) Inventors: **BALL, Robert, J.**; 13827 Port Sheldon Street, Holland, Michigan 49424 (US). **RUNNING, Donald, E.**; 13827 Port Sheldon Street, Holland, Michigan 49424 (US).

(74) Agent: **CHRISTENSEN, Michael, R.**; Knobbe, Martens, Olson & Bear, LLP , 2040 Main Street , 14th Floor, Irvine, California 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) Title: CONVERTIBLE TOTAL SHOULDER PROSTHESIS

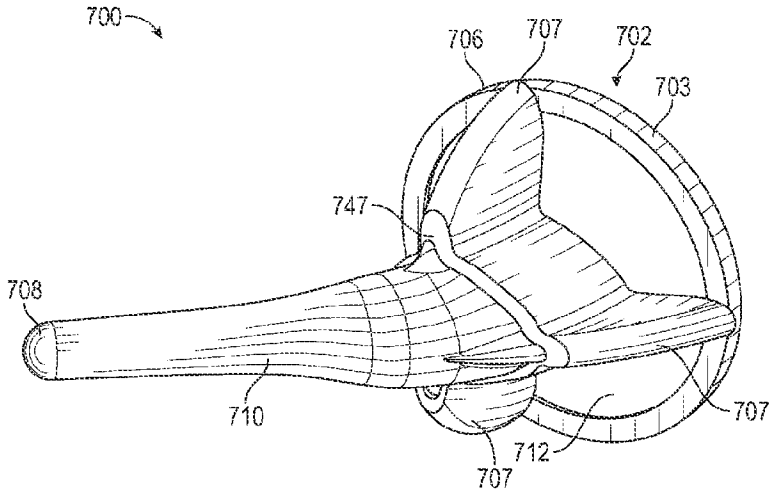


FIG. 7A

(57) Abstract: In some embodiments, disclosed is a glenohumeral implant with improved joint mobility. The implant can include a backing component; a neutral non-inclined bearing component on a concave side of the backing component, the bearing component made from a different material than the backing component and configured to touch a glenosphere having a center of rotation.

WO 2019/178104 A1

SURGICAL TECHNIQUE

Copeland™ Humeral Resurfacing Head

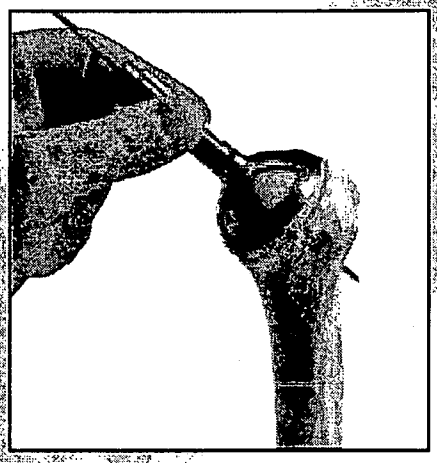
The surgical technique for the Copeland™ Humeral Resurfacing Head has been enhanced with the recently released instrument sets made in the USA. The new instruments include the new "Medium +" size to bring the size offering up to 5 sizes.

Please refer to the current technique (Y-BMT-725) noting the following enhancements:



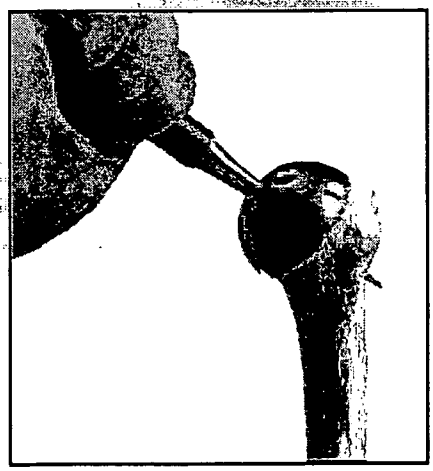
Step 1

Use the drill guide to locate the center of the humeral head.



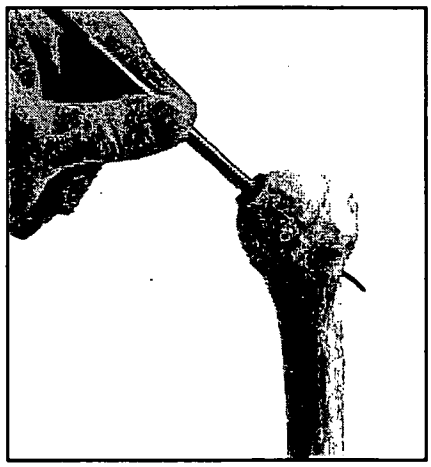
Step 2

Place a Steinmann Pin through the guide to mark the location of the center of the head.



Step 3

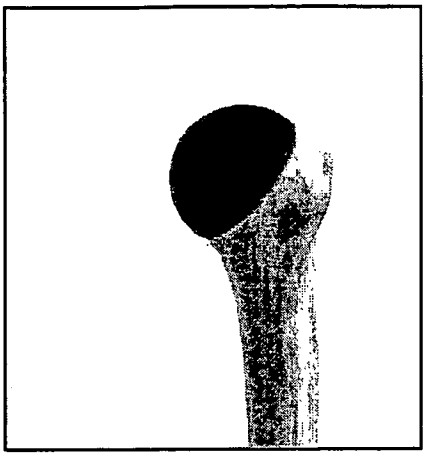
Place the Surface Cutter over the Steinmann Pin and ream until there is bone coming out of the top holes.



Step 4

Place the Spade Bit over the Steinmann Pin and drill until the stop-ledge touches the humeral head.

Copeland™ Humeral Resurfacing Head



Step 5

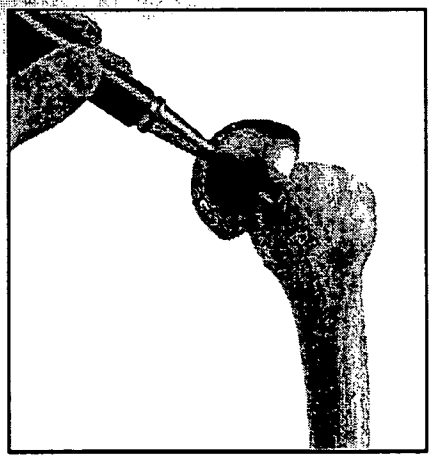
Remove both the Spade Bit and the Steinmann Pin. Place the Trial Head onto the resurfaced bone and go through a full range-of-motion to check for correct soft tissue tensioning.



Step 6

Place the final prosthesis onto the bone and impact into place.





When choosing to drill the peg hole before resurfacing the outside of the head, the Surface Cutter Guide must be used to guide the cutter!

This brochure describes the surgical technique used by Steven A. Copeland, F.R.C.S. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be used for an individual patient.

The Copeland™ Surface Replacement Arthroplasty (CSRA) of the shoulder was developed by Steven A. Copeland, F.R.C.S., Consultant Orthopaedic Surgeon at the Royal Berkshire Hospital, Reading, England, U.K.

This device is intended to be used in the United States as described in the product labeling.

Copeland™ and MacroBond® are trademarks of Biomet, Inc.

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THE JOURNAL OF BONE & JOINT SURGERY (BR)

Cementless surface replacement arthroplasty of the shoulder

5- TO 10-YEAR RESULTS WITH THE COPELAND MARK-2 PROSTHESIS

O. Levy, S. A. Copeland

From the Royal Berkshire Hospital, Reading, England

Cementless surface replacement arthroplasty of the shoulder is designed to replace the damaged joint surfaces and restore normal anatomy with minimal resection of bone. We have used the Copeland shoulder arthroplasty for 14 years. Between 1986 and 2000, 285 surface replacement arthroplasties were implanted in our unit. The prosthesis has evolved during this time, but the principle of minimal bone resection has remained the same. Between 1990 and 1994, 103 Mark-2 prostheses were inserted into 94 patients (9 bilateral). The operations were carried out for the treatment of osteoarthritis, rheumatoid arthritis, avascular necrosis, instability arthropathy, post-traumatic arthropathy and cuff arthropathy. The mean follow-up was for 6.8 years (5 to 10).

The best results were achieved in primary osteoarthritis, with Constant scores of 93.7% for total shoulder replacement and 73.5% for hemiarthroplasty. The poorest results were seen in patients with cuff arthropathy and post-traumatic arthropathy with adjusted Constant scores of 61.3% and 62.7%, respectively. Most patients (93.9%) considered their shoulder to be much better or better than before the operation. Of the 88 humeral implants available for radiological review, 61 (69.3%) showed no evidence of radiolucency, nor did 21 (35.6%) of the 59 glenoid prostheses. Three were definitely loose, and eight shoulders required revision (7.7%), two (1.9%) for primary loosening. The results of this series are comparable with those for stemmed prostheses with a similar follow-up and case mix. The cementless surface replacement arthroplasty diminishes the risk of complications involving the humeral shaft and periprosthetic fractures. Revision or arthrodesis can be undertaken easily since the bone stock has been maintained with no loss of length.

J Bone Joint Surg [Br] 2001;83-B:213-21.
Received 6 April 2000; Accepted 28 June 2000

Early attempts at shoulder arthroplasty in Europe involved constrained prostheses in order to deal with the considerable loss of bone and soft tissues secondary to infection and tumour.[1] In the USA, Neer[2] developed a stemmed unconstrained humeral prosthesis specifically for the treatment of four-part fractures. His design was successful in providing a scaffold around which the proximal humerus could be rebuilt. Later this was this used for arthritis and a glenoid component developed.[3] Neither of these prostheses was specifically designed for use in arthritis of the shoulder. In the early 1980s came the idea of developing an arthroplasty using a surface replacement for use in the degenerative shoulder which was less worn.[4-7] Neer[2] had shown that the prosthetic shoulder joint did not need to be mechanically constrained. This was certainly true in the presence of an intact rotator cuff and arguably so even if it was damaged. The design of Neer's stemmed humeral component was very similar to that widely used for hip replacement. However, it seemed unnecessary to use a stem if the tuberosities were intact.

Patients and Methods

Design concept. The intention was to mimic the normal anatomy as closely as possible, replacing the damaged surfaces of the joint with minimal interference. We used 20 cadaver shoulders and 20 dry bone specimens together with 200 radiographs of normal shoulders to assess the normal anatomical variation. These measurements were subsequently confirmed by Boileau and Walch,[8] and three sizes of prosthesis were developed (Fig. 1).

All patients presenting for possible shoulder arthroplasty were considered for surface replacement. Only those with severe bone loss with no surface to replace or with acute fractures and nonunion of fractures were judged to require stemmed prostheses. Of the 320 primary shoulder arthroplasties, including acute fractures and nonunions, undertaken between 1986 and 2000, the Copeland surface replacement system was used in 285 (89%).

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0301-620X/01/211238 $2.00

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PAGE 452

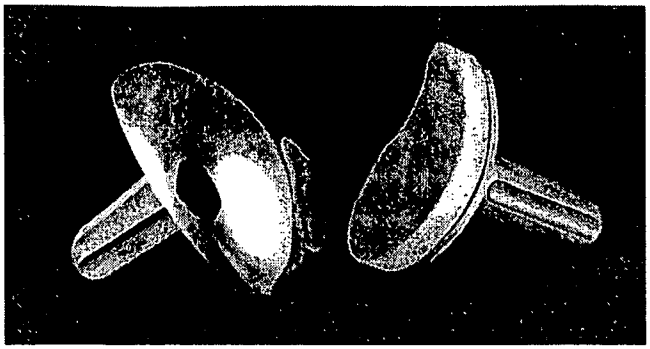


Fig. 1

Photograph of the Copeland Mark-2 cementless surface replacement; humeral and glenoid components.

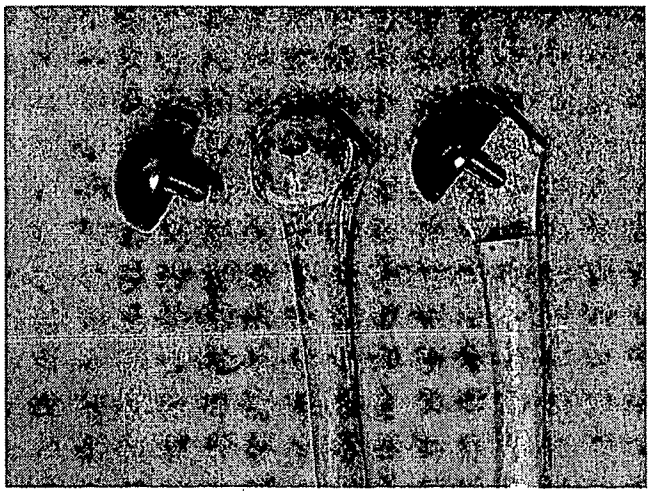


Fig. 2

Photograph of a cementless surface replacement arthroplasty on a dry bone model with minimal bone removal. The bone removed from the pilot hole is used for grafting defects in the head of humerus.

We have held to the principle that bone stock should be preserved whenever possible. The experience of replacement arthroplasty at both the hip and the knee indicates that, no matter how successful the prosthesis, a small number will fail and require revision. Loss of bone stock necessitates the use of larger prostheses and more cement, but if the uncemented surface replacement were to fail, only the amount of bone that lies immediately beneath the humeral cap would be lost. This is what is normally removed when inserting a standard stemmed humeral prosthesis (Fig. 2).

The use of cement in hip and knee replacement has been questioned and many cementless designs have been developed. Even with improved cementing techniques there will be considerable bone loss should infection or loosening occur. A simple grooved impact-fit taper peg was introduced for fixation.

Although most shoulder replacements are carried out in specialised centres, many are undertaken by surgeons who undertake only a few each year. Complicated instrumentation may not be available. We have therefore developed simple instruments to shape the joint surfaces and to guide positioning of the prosthesis.

There is little variation in the size of the glenoid and the head of the humerus, but anatomical version and inclination may vary greatly.[8] An important geometrical variation is the posterior offset.[9,10] The head of the humerus is not centred on the shaft, but offset posteriorly and medially by approximately 5 mm. If a stemmed prosthesis lies central in the shaft the head will not lie in an anatomical position unless it is specifically made for a left or right shoulder. More recent designs have allowed for this variation by modular design. If a surface replacement is used no instrumentation is required to calculate angles of version, inclination or offset. The offset is automatic and the varus angulation is determined from the original anatomical neck. Even in the presence of severe erosion of the head of the humerus, the anatomical neck can be visualised after removal of osteophytes and the drill guide jig for the head sited correctly.

Erosion caused by arthritis distorts the anatomy. It may be asymmetrical, anteriorly or posteriorly, and be more on the humeral or the glenoid side, but the net effect is to medialise the centre of rotation. This has a secondary effect of relative lengthening of both the rotator cuff and the deltoid. One of the aims of shoulder replacement is to restore the geometry by placing the centre of rotation more laterally. This may be an unrealistic goal since if the medial shift is gross and longstanding, relocation laterally will make the contracted soft tissues too tight. The surgical approach is usually anterior, dividing subscapularis. Even with lengthening of its tendon there may be difficulty in closure with the possibility of some internal rotation. This must be avoided and some external rotation allowed. If there is a fixed internal rotation deformity posterior translation will occur leading to posterior subluxation. A modular prosthesis may have many available sizes, but few are required. Different thicknesses of glenoid component are available if further lateralisation is deemed necessary, but these are also only needed rarely.

Evolution of the design. The first 19 implants (Mark I prosthesis) had a central pegged humeral component, which was secured initially with a screw from the lateral side of the proximal humerus, combined with a polyethylene glenoid element stabilised by a cementless finned peg.[11,12]

It was soon seen that the screw was unnecessary. Some became loose and had to be removed. In vitro testing suggested that it did not contribute to fixation. In 1990 the Mark-2 prosthesis was introduced which added metal backing to the glenoid component and a fluted taper fit peg to both constituents. In the Mark-3 model hydroxyapatite coating was added and this has been in use since 1993. The results in this article pertain to the Mark-2 prosthesis only.

Patients. Between 1990 and 1994, we implanted 103 consecutive Copeland surface replacement cementless pros-

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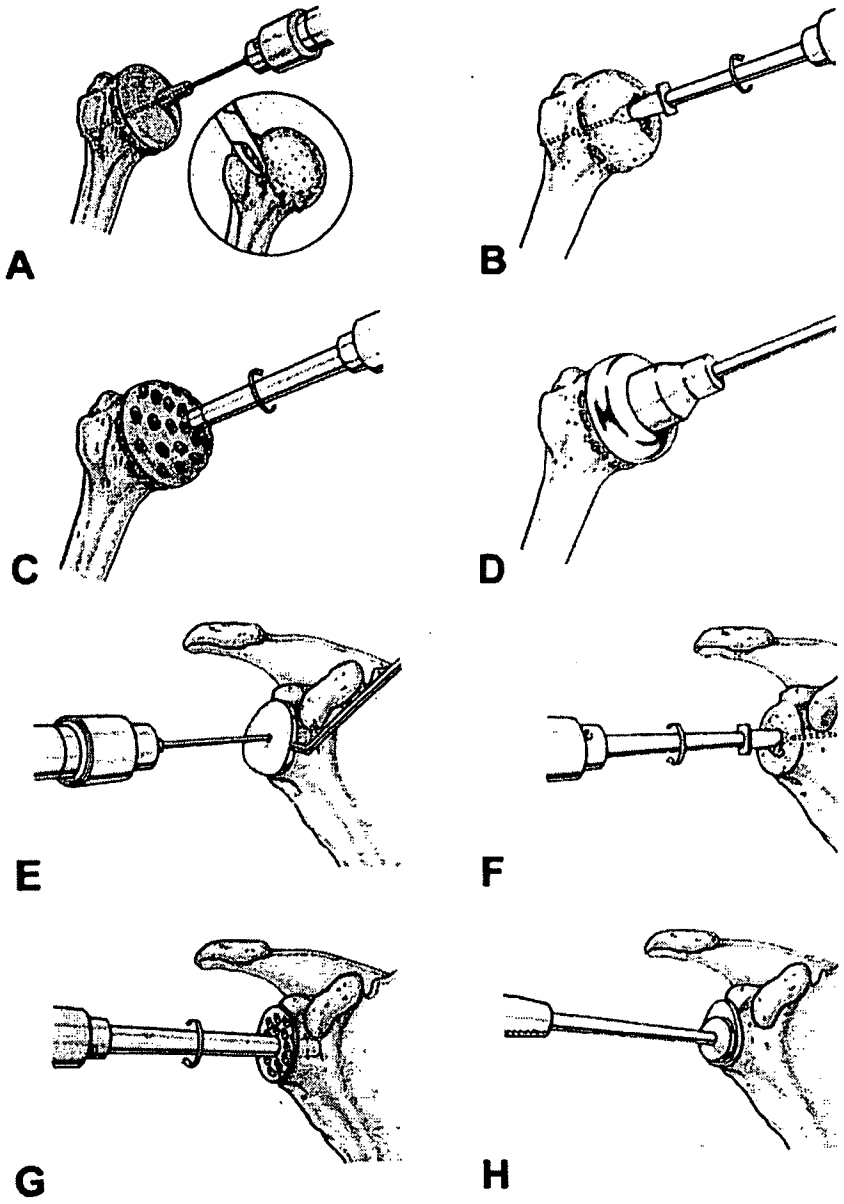


Fig. 3

Details of the stages of the surgical technique (see text).

theses into 94 patients (9 bilateral). The underlying aetiology was primary osteoarthritis in 41 shoulders, rheumatoid arthritis in 41, cuff tear arthropathy in eight, avascular necrosis in four, instability arthropathy in five, arthropathy secondary to septic arthritis in two, and other diagnoses in two. The indication for surgery was pain associated with limitation of function. Preoperative evaluation was undertaken using the Constant and Murley score.[13] Early in the series this score was not in common use, but ranges of pain, activity and movement were noted and used in the statistical evaluation of the results.[13] The outcome was recorded using the Constant score, the range of movement and a patient satisfaction score (Neer classification).[14] Data were analysed using the chi-squared test and analysis of variance to compare preoperative and postoperative results within the different groups.

There were 73 women and 21 men with a mean age at the time of surgery of 64.3 years (22 to 88). The women were slightly older than the men (66.4 *v* 57.8 years). Total shoulder replacement (TSR) was used in 68 shoulders and a hemiarthroplasty in 35.

Operative technique (Fig. 3). We used the standard deltopectoral approach before 1993 and the anterosuperior approach as described by Mackenzie[15] after September 1993. The prosthesis is suitable for insertion by either route. The advantages of the anterosuperior approach are a smaller scar, a shorter postoperative recovery, easier access by the rotator interval to the glenoid, and to the posterior and superior rotator cuff for reconstruction. It also allows for excision arthroplasty of the acromioclavicular joint and acromioplasty if these are required.

If the rotator cuff is intact or repairable an anterior acromioplasty is undertaken with partial resection of the coracoacromial ligament. The coracoacromial arch is left

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undisturbed if the rotator cuff is extensively torn. If preoperative radiographs show degenerative changes of the acromioclavicular joint and symptoms suggest that this is a site of pain, an excision arthroplasty can be done at this stage and improves the exposure. The rotator interval is identified and incised longitudinally along the line of the long head of biceps to define the insertion of subscapularis which is then detached and the shoulder dislocated anteriorly. If the long head of biceps is intact it is displaced posteriorly over the humeral head. The anatomical neck of the humerus is defined and the neck-shaft angle identified. Removal of all osteophytes is essential to define the anatomical neck and the humeral shaper may then be applied to the centre of the head. As shown in Figure 3A the humeral drill guide is positioned over the head with its free edge parallel to the anatomical neck; it is then positioned in the centre of the head and parallel to the neck, thus adjusting automatically for retroversion and inclination. The degree of retroversion may vary between 5° and 55°. All morsellised bone generated by making the drill hole (Fig. 3B) is saved for later grafting. Further details of the operative technique have previously been described (Figs 3C and 3D).[16] If a hemiarthroplasty only is to be done, the stability of the humeral component is tested and the range of movement confirmed.

The trial humeral cap is left in situ so that the prepared head is not damaged by subsequent retraction. An extensive capsulotomy must be made, sparing only the superior aspect and providing adequate exposure of the glenoid. The glenoid drill guide is inserted at the exact centre of the glenoid (Figs 3E and 3F). Asymmetrical erosion may have occurred and needs to be assessed. Reference to preoperative imaging with an axillary view is helpful at this stage. The glenoid articular surface is prepared with the cutter placed in the pilot hole (Figs 3G and 3H). If there is severe erosion of the bone, graft may be added anteriorly or posteriorly, but this is rarely needed.

In primary and secondary osteoarthritis, as much of the sclerotic surface of the bone is retained as possible to provide a firm foundation for the prosthesis. Each component is impacted flush with the surface of the prepared bone, the joint is reduced and stability ensured. Since the centre of rotation may have been lateralised, an attempt is made to gain relative length in subscapularis either with a stepwise incision in the tendon or by medial transfer of its insertion to the free edge of the prosthesis. The rotator interval is closed. Any deficiency of the rotator cuff is repaired at this stage if possible.

Passive movement only is allowed for the first 48 hours and passive assisted movement for five days. Active movements begin at one week as determined by comfort and the sling may be discarded at three weeks.

Radiological assessment. Anteroposterior views in internal and external rotation, and axillary views (Fig. 4) were taken postoperatively, at three and six months, at one year, then annually and at the final review. This protocol was followed in 89% of patients. An assessment was made of lucent lines (Fig. 5) and their width in relation to time. Definite loosening was defined as a change in position of a component, and probable loosening when the position was unchanged, but progressive radiolucencies greater than 2 mm wide involved all or part of the component.

Results

All the operations were carried out by the same surgeon (SAC) and the independent assessment was by the other author (OL).

Six patients died, and for these the latest follow-up review was recorded. One patient died less than 24 months after shoulder replacement and was excluded. Four were lost to follow-up. The seven patients who were not able to attend were elderly and living at a great distance. They were assessed using a questionnaire based on a Constant

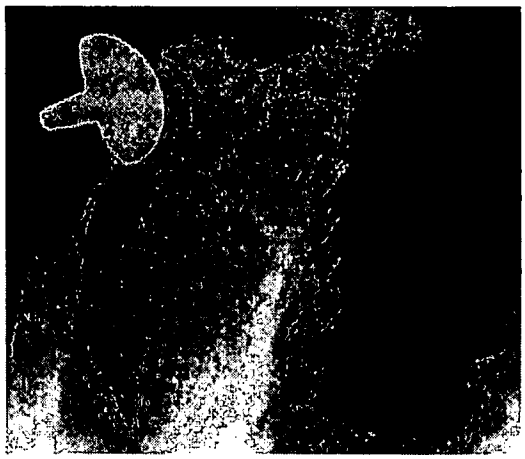


Fig. 4a



Fig. 4b

Anteroposterior (a) and axillary radiographs (b) of the Copeland cementless surface replacement hemiarthroplasty at ten years.

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Fig. 5

Radiograph of a Copeland Mark-2 total shoulder arthroplasty at nine years showing a glenoid lucent line (non-progressive).

score equivalent.[17] They also sent recent radiographs taken at a local hospital. Thus there were 98 shoulders available for review.

The mean follow-up was for 6.8 years (5 to 10). The preoperative average Constant scores were 1.8 of 15 points for pain, 4.0 of 20 points for daily activity, 8.2 of 40 for range of movement and 1.3 of 25 for strength. The total mean Constant score was 15.4 points or 24% after adjustments for age and gender. Table I shows the preoperative values with respect to the different aetiologies. The results after implantation of the Mark-1 prosthesis have been reported previously.[12]

Integrity of the rotator cuff. The rotator cuff was intact in 46 shoulders and in 18 it was thin and atrophic but in continuity. In 33 shoulders a full-thickness tear was found. In six the integrity of the cuff was not recorded. In 11 shoulders the rotator cuff was not repairable and in ten this was attempted but was incomplete. In 75 shoulders the rotator cuff was repaired and in seven repair was not recorded. The deltopectoral approach was used in 74 shoulders and the Mackenzie approach in 29.

Functional results. The results at follow-up are shown in Table II; they are related to diagnosis and include the basic information and the final Constant score. The best results were achieved in primary osteoarthritis with Constant scores of 93.7% for TSR and 73.5% for hemiarthroplasty. Early in the series TSR was almost invariably undertaken. Hemiarthroplasty was only carried out when a glenoid component could not be placed. The poorest results were encountered in patients with arthropathy of the cuff, instability arthropathy and other causes such as arthropathy secondary to septic arthritis, with adjusted Constant scores of 61.3%, 62.7% and 58.7%, respectively.

Active elevation improved by a mean of 69° to a mean of 133° for osteoarthritis and avascular necrosis, to a mean of 105° for rheumatoid arthritis, and for instability arthropathy and cuff arthropathy to a mean of 97° and 73°, respectively (Table II). Preoperative and postoperative differences were statistically significant for all disease groups ($p < 0.001$).

Patients' subjective assessment. Of those assessed, 68 patients (69.4%) considered that their shoulder was much better and 24 (24.5%) that it was better (93.9% much better or better). Six patients were disappointed and considered the shoulder to be unchanged by surgery, usually because of limited movement, but they were satisfied with the relief of pain (Table II).

Radiological results. Radiographs were available for 88 shoulders In 61 (69.3%), no lucencies were seen around the humeral component. In 25 shoulders (28.4%), a lucent line less than 1 mm wide was seen and in two a progressive lucent line more than 2 mm wide was encountered.

Of the 59 glenoid implants available for radiological review, no lucencies were seen around the implant in 21 (35.6%). In 35 (59.3%) there was a partial lucent line less than 1 mm wide. In three shoulders (5.1%) we observed a progressive lucent line of more than 2 mm, with definite signs of loosening.

In five shoulders some degree of mild subsidence of the humeral prosthesis was found, with no effect on the outcome. The degree of subsidence was measured by the migration of the central peg of the humeral cap towards the lateral cortex. Subsidence of less than 2 mm was defined as mild; greater than 2 mm, but not as lateral as the lateral cortex, as moderate; and up to the lateral cortex of the proximal humerus and beyond as severe. In all the shoulders with mild subsidence, this was noticed early after surgery and the prosthesis settled in the new position with no progression.

There was no subluxation of the humeral head in 58 shoulders. There was mild superior subluxation in 15, moderate superior migration in seven and severe superior subluxation with obliteration of the acromiohumeral interval in eight. All of the last eight had massive tears of the rotator cuff and six underwent arthroplasty for cuff arthropathy as a 'limited goal' procedure. In six the cuff was not repairable, and in one the repair was incomplete.

Complications. One patient developed marked myositis ossificans with almost complete ankylosis. His presenting diagnosis was arthropathy following septic arthritis and he had undergone extensive previous surgery. One patient suffered a spontaneous pneumothorax, postoperatively. One shoulder was left with a hemiarthroplasty since the glenoid could not be exposed adequately; the original diagnosis was multiple epiphyseal dysplasia. During insertion of the glenoid component a minor part of the rim was fractured in six patients. This was noted at the time of operation, but was not associated with later loosening. Two superficial wound infections, treated by antibiotics, settled uneventfully.

Three patients required arthroscopy for unexplained

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Table I. Preoperative details of the 94 patients (103 shoulders) who underwent cementless surface replacement arthroplasty

Diagnosis	Number of shoulders	Constant score values				Active flexion in degrees	Active abduction in degrees	External rotation in degrees	Internal rotation	Total points (Constant score)	Age-adjusted Constant score (%)
		Pain	Activity	Movement	Power						
Primary osteoarthritis									Buttock	25.3	*40.0*
Hemiarthroplasty	7	3.9	6.8	12.2	2.4	72	52	12			
TSR	34	2.1	5.2	9.6	3.1	62	49	13	Buttock	20	*33.8*
Rheumatoid arthritis									Buttock	11.8	*19.6*
Hemiarthroplasty	14	1.6	4.4	5.8	0	50	35	5			
TSR	27	0	1	5	0	47	37	6	Buttock*	6	*9.0*
Cuff arthropathy									Buttock	12.5	*18.8*
Hemiarthroplasty	7	2.7	3	6	0.8	37	38	13			
TSR	1										
Avascular necrosis									Buttock	9.25	*11.0*
Hemiarthroplasty	4	0	2.25	7	0	63	49	-3			
Instability arthropathy									Thigh-buttock*	14	*18.5*
Hemiarthroplasty	41	1	3	10	0	57	40	1			
TSR											
Other	2	*	*	*	*	65	40	8	Thigh*	*	*
Hemiarthroplasty (1 for septic arthritis)	2										
TSR (1 for septic arthritis)											
Global average		1.8	4.0	8.2	1.3	56	33	8	Buttock	15.4	*24.0*

* Constant scores were available for only some of the patients; however, it was recorded in all these patients' notes that they were very painful and severely limited in function

Table II. Follow-up results for the 94 patients (98 shoulders)

Diagnosis	Number of shoulders	Constant score values				Active flexion in degrees	Active abduction in degrees	External rotation in degrees	Internal Rotation	Patient assessment				Total points (Constant score)	Age-adjusted Constant score (%)
		Pain	Activity	Movement	Power					Much better	Better	Same	Worse		
Primary osteoarthritis															
Hemiarthroplasty	5	13.7	15	25.3	3.7	130	90	47	L2	1	3	1	0	57.7	*73.5*
TSR	33	14.1	17.5	27.4	5.2	133	113	55	L2	27	3	3	0	64.2	*93.7*
Rheumatoid arthritis															
Hemiarthroplasty	14	11.5	13.3	20.1	3.5	106	88	45	L4	12	2	0	0	48.4	*72.1*
TSR	27	12	13.5	21.1	6	104	80	44	L4	17	9	1	0	52.7	*71.8*
Cuff arthropathy	8	10.6	11.1	16.3	0.6	73	64	47	L4	5	3	0	0	38.6	*61.3*
Avascular necrosis	4	11.7	11	31.3	3.7	133	118	81	L1	3	1	0	0	57.7	*74.0*
Instability arthropathy	3	14.3	12.7	17.3	1.3	97	87	43	L5	2	1	0	0	45.7	*62.7*
Other	4	9.7	8	18	7.3	115	110	45	L4	1	2	1	0	43	*58.7*
Global average		12.1	13.9	22.2	4.2	110	90	48	L4	68	24	6	0	52.4	*75.2*

Table III. Details of the eight patients who underwent revision surgery

Case	Age (yr)	Gender	Preoperative diagnosis	Operation	Time to revision (years)	Indication(s) for revision	Surgical procedure	Notes
1	68	F	Osteoarthritis	TSR	1.5	Glenoid component loosening after heavy fall from a bike	Removal of glenoid component. Revision to Copeland stemmed hemiarthroplasty	Humeral cap was not loose, but technically had to be revised to provide glenoid exposure
2	48	F	Avascular necrosis	Hemiarthroplasty	1.75	Acute trauma Subcapital fracture at the distal edge of prosthesis	Revision to Neer stemmed TSR	Very easy revision. Humeral cut was along the line of the fracture
3	72	F	Rheumatoid arthritis Massive cuff tear - limited goal procedure	TSR	2.75	Glenoid and humeral loosening	Removal of glenoid component. Revision to Neer stemmed hemiarthroplasty	Massive cuff tear - limited goal procedure
4	77	F	Osteoarthritis	TSR	4.0	Glenoid loosening	Removal of glenoid component. Revision to Neer stemmed hemiarthroplasty	Humeral cap was not loose, but technically had to be revised to provide glenoid exposure
5	72	F	Osteoarthritis	TSR	0.83	Malpositioning (excessive anteversion) of the glenoid component	Revision of glenoid component	Poor rotator cuff CSRA* used
6	69	F	Osteoarthritis	TSR	4.4	Dissociation of polyethylene from the metal back. No loosening of both components	Revision to Copeland stemmed TSR	Humeral cap was not loose, but technically had to be revised to provide glenoid exposure
7	46	M	Instability arthropathy Stabilisation operation for Bankart repair with staples	TSR	1.7	Severe instability	Shoulder arthrodesis	Bald head Non-repairable massive rotator-cuff tear
8	37	M	Instability arthropathy Missed posterior fracture-dislocation. Stabilisation operation with bone block	TSR	1 week	Infection	Shoulder arthrodesis	Poor quality rotator cuff Unstable shoulder

* cementless surface replacement arthroplasty

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Table IV. Results of active movement (degrees) in our series compared with these using stemmed shoulder prosthesis

	Postoperative active elevation	Gain in active elevation	Postoperative external rotation	Gain in external rotation
Neer et al[14]		+77		+51
Cofield[27]	141	+55	49	+35
Barrett et al[24]	117	+73		+33
Cofield and Daly[28]	154	+47	61	+49
Boileau and Walch[8]	127	+48	41	+55
Torchia et al[26]	117	+40	48	+19
Gartsman et al[29]	129	+47	55	+39
Our series (average-all study group)	110	+54	54	+42
Our series (osteoarthritis)	133	+68	48	+40

pain. Two had a tear of the rotator cuff after a fall which required repair. One developed subacromial fibrosis with no loosening after being injured in a road-traffic accident.

Revision surgery. Two patients required arthrodesis after removal of the implant. Both underwent TSR for instability arthropathy with multiple previous operations. One developed deep infection and in the other stability could not be achieved (Table III). The prosthesis was revised in six patients (Table III). One had a fall sustaining a fracture of the head of the humerus at the margin of the humeral cap. The revision operation was easily achieved by removing the prosthesis with the bony fragments and inserting a standard stemmed prosthesis. In one patient, revision was required because of disassociation of the polyethylene from the metal-backed glenoid component. The latter was revised with revision of the humeral component in order to gain access to the glenoid. This complication has been obviated by a design change in the glenoid component. One patient required revision because of continuing pain. The version of the glenoid was altered which relieved her symptoms. One patient had loosening of the glenoid component after a fall. Arthroscopy was carried out and the glenoid component was noted to be loose; a revision procedure was undertaken using a stemmed humeral component. Two patients had primary loosening (1.9%). One involved both components and one the glenoid only. In four of six revision procedures, revision of the humeral cap was undertaken although it was not loose in order to gain access to the glenoid; all four were converted to stemmed prostheses.

Discussion

Cementless surface replacement arthroplasty of the shoulder differs in many aspects from a non-constrained stemmed shoulder prosthesis, but the results are similar to those published for the latter design including the new generation of modular prostheses (Table IV). In our series, 93.9% of the patients considered their shoulder to be much better or better after surgery. Because this is a different design of prosthesis some of the complications differ from those of other models. Those which we have observed have been more easily dealt with due to the preservation of bone stock. Removal of the humeral surface component was easily and speedily effected since no cement or stem had to be exposed and removed. Removal of a cemented stemmed prosthesis is associated with loss of bone stock with a risk of perforation and fracture of the humeral shaft. Thus, in the patient who presented with a fractured anatomical neck, the line of bone resection was determined by the injury, and revision to a cemented stemmed prosthesis was easily accomplished. The patient with previous infection and the one with uncontrollable instability were also easily revised to an arthrodesis since bone stock had been preserved with no loss of length. Union of the arthrodesis was achieved rapidly. The incidence of periprosthetic fractures has been quoted as 3% and accounts for approximately 20% of all complications associated with total shoulder arthroplasty both during surgery and later.[18-23]

At the time of operation no major complications were encountered; in particular there was no fracture or perforation of the shaft of the humerus since no preparation of it had been required. Stemmed prostheses create a stress riser effect at the tip of the stem in the midshaft of the humerus.[19,20,22-24] The key to correct anatomical alignment of the humeral component is the identification of the anatomical neck. Previous reports of cemented prostheses have also noted a high incidence of lucency around the components. There is a similar incidence in this prosthesis (Marks 1 and 2). Since we started to use hydroxyapatite-coated implants (Mark 3), no lucent lines have been observed. The relevance of the radiolucent line is uncertain, but seems unrelated to the outcome. Further major surgery, either revision arthroplasty or arthrodesis, was required in eight patients (7.7%) which is comparable with the published results for stemmed prostheses with a similar period of follow-up.[23,25,26]

During the period of the study the design of the prosthesis has evolved, but the basic concept of surface replacement with minimal removal of bone and cementless

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fixation has remained. The indications and surgical technique have been refined. The results of hemiarthroplasty should not be compared with those of TSR. The indications are different. Early in the series a total replacement was attempted in all patients. The glenoid component was omitted only if it was thought that adequate fixation could not be achieved. Later in the study a hemiarthroplasty was chosen for preference. A glenoid component was added only if the rotator cuff was intact and the bony glenoid non-concentric.

This is a mid-term report with a maximum follow-up of ten years. The early results with the hydroxyapatite-coated prosthesis (Mark 3) are encouraging. We have demonstrated results at least equal to those of conventional stemmed prostheses, suggesting that the humeral component does not need a stem or cement for fixation. We believe that the only indications for the use of a stemmed prosthesis are in four-part fractures and in those patients with severe destruction of the humeral head such that no surface remains to be replaced.

One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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Biomechanical evaluation of a novel glenoid design in total shoulder arthroplasty

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The amount of articular curvature mismatch providing optimal performance in total shoulder arthroplasty (TSA) is unknown. The objectives of this study were to quantify glenohumeral joint mechanics before and after TSA and to compare the performance of 3 glenoid components: (1) nonconforming, (2) conforming, and (3) a novel design featuring a conforming center extending into a nonconforming periphery. Six fresh-frozen cadaveric shoulders (mean age, 43 years) were mechanically tested on a custom apparatus by use of simulated muscle forces and a coordinate-measuring machine to determine joint kinematics. B-spline models of the natural and prosthetic articular surfaces were generated, and joint contact was computed by use of a proximity criterion. During both centered ($P = .02$) and eccentric ($P = .05$) loading protocols, glenoid contact migrated posteriorly in conforming implants. No statistical differences in kinematics and contact were found among the nonconforming design, the new design, and the natural joint. Therefore, adding a central region of conformity does not compromise the ability of nonconforming TSA components to reduce rim loading. (J Shoulder Elbow Surg 2005;14: 129S-140S.)

Prosthetic replacement of the glenohumeral joint (GHJ) articular surfaces is a highly successful surgical technique performed for pain relief and restoration of normal joint function, with greater than 90% of total shoulder arthroplasty (TSA) procedures providing satisfactory results with a relatively low revision rate.[5,6,11,14,25,26,30,38,42] Common indications for arthroplasty include osteoarthritis (primary or secondary), rheumatoid arthritis, trauma, avascular necrosis, and cuff tear arthropathy.[39] Neer's conforming prosthesis enjoyed widespread popularity and success upon its introduction in the mid 1970s and featured a humeral head and glenoid component with equal radii of curvature.[39] In retrospective studies of patients fitted with conforming implants, loosening of the glenoid component, though rare, is the most common complication of TSA, with studies suggesting a mean incidence of 5% for a mean follow-up time of 3 to 5 years.[12,40,53]

The prevalence of nonconforming GHJ implants has risen dramatically as surgeons seek to reduce the incidence of glenoid loosening and joint instability; indeed, fully nonconforming glenohumeral prosthetic components (in which the radius of curvature of the humeral head is smaller than that of the glenoid)[9,10] have become the preferred choice among many orthopaedic surgeons today. Still, major controversy exists with regard to selection of the optimal degree of glenohumeral mismatch in TSA. A conforming design ideally minimizes humeral head translations and provides maximal contact area with the glenoid. However, in extreme arm positions. such as hyperextension or flexion or with pathologic conditions such as rotator cuff tears,[15,19,43] subluxation of the humeral head may lead to rim loading of the glenoid and produce an undesired mechanical moment—the so-called rocking-horse effect.[5,20,32,34,44] In contrast, a nonconforming joint theoretically allows for some humeral head subluxation without rim loading; however, the relative contact area is decreased, and consequently, a higher contact stress is transmitted to the glenoid component. This increase in stress can lead to greater polyethylene deformation and wear or even catastrophic failure of the component.[18] To integrate the perceived advantages of both the conforming and nonconforming designs, 2 of us (L.U.B. and E.L.F.) recently developed a novel glenoid, the Bigliani-Flatow (BF) design,[54] a hybrid design featuring an articular surface with 2 distinct radii of curvature: an inner, perfectly congruent region extending

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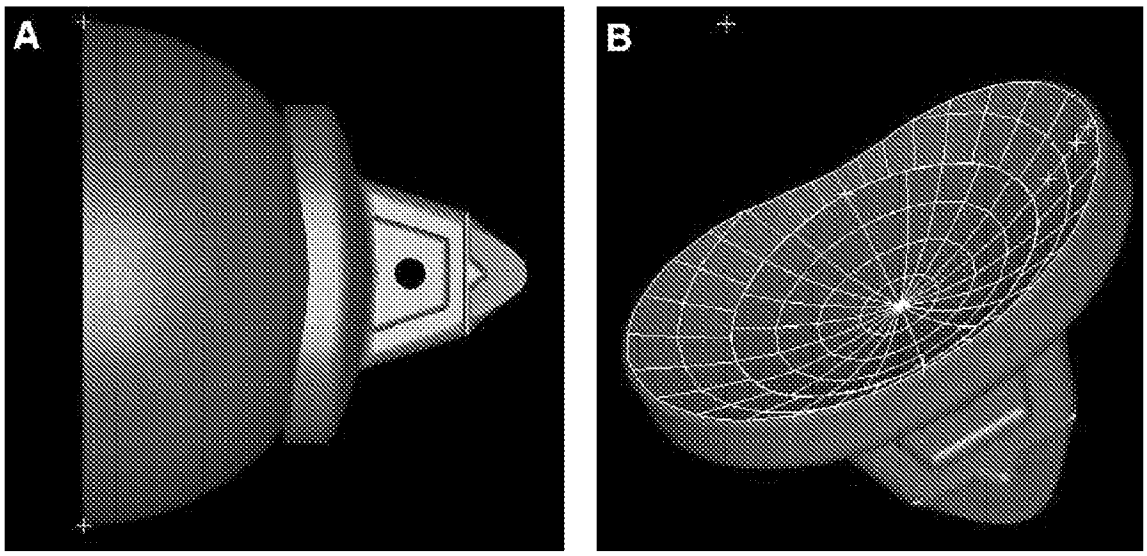


Figure 1 Computer representations of BF glenoid. Note the glenoid's central region of conformity and peripheral region of nonconformity in both the side (**A**) and articular (**B**) views.

into an outer, incongruent region or "translation zone" (Figure 1).

Previous experimental investigations of shoulder arthroplasty biomechanics have studied the role of component conformity on joint stability. Friedman[22] observed posterior humeral migration during flexion-extension movements in patients with conforming glenohumeral prostheses. Karduna et al[33] reported that dislocation forces were significantly affected by component conformity, although the differences were small (3%). This study implied that the wall length was the most important factor in determining joint stability. The same authors found that, on average, prosthetic components of less conformity tended to better replicate the kinematic patterns of the natural joint.[32] Karduna et al[34] and Anglin et al[1] conducted analyses on the load-deformation response of GHJ implants of varying conformity and showed favorable agreement between their experimental results and theoretic predictions from rigid-body mechanics. Whereas the effects of component size, conformity, and constraint on glenohumeral stability have been separately studied in numerous cadaveric models,[1,8,27,32-34,45,49] few, if any, experimental studies have examined changes in prosthetic articular contact patterns associated with varying component conformity. As small humeral head translations can dramatically affect the location and size of the corresponding glenoid contact area,[17] studying contact patterns after TSA may facilitate the localization of glenoid edge loading. Moreover, by simultaneously studying the kinematics, glenoid contact areas, and resultant GHJ forces after TSA, the consequences of altering component conformity may be more fully understood.

In previous unpublished finite-element studies, we examined the peak von Mises stresses for conforming and nonconforming glenohumeral components, as well as for the new BF design, under conditions of both centered loading (750 N) and prescribed posterior humeral head subluxation. When the head was centered in the glenoid, the nonconforming components (ie, 3-mm radius of curvature mismatch) experienced elevated peak stresses (10 MPa) compared with the conforming (approximately 1 MPa) and BF (1.3 MPa) designs. After an imposed humeral posterior subluxation of 1.0 mm, the peak von Mises stresses for the BF design (30.8 MPa) were found to be intermediate to those of the nonconforming (11.5 MPa) and conforming (43.2 MPa) designs. These finite-element analyses assumed a linear stress-strain response for ultrahigh–molecular weight polyethylene (Young's modulus, $E_Y = 930$ MPa; Poisson's ratio, $\nu = 0.46$) and did not account for stress yielding or creep. To supplement these data in a more clinically relevant fashion, we expanded our studies to a cadaveric shoulder model using muscle forces to position the humeral head on the glenoid so that the resulting kinematics and contact patterns could be determined experimentally.

The objective of the present study is to quantify and compare normal GHJ mechanics with that after TSA with 3 separate glenoid components: a perfectly conforming glenoid, a nonconforming glenoid, and the BF design. The specific aims of this investigation are to quantify the kinematics of the humeral head, the articular contact of the humeral head on the glenoid, and the resultant joint forces associated with both natural and prosthetic joints and to evaluate the effect

of articular-surface conformity on joint stability under conditions of both centered and eccentric joint loading. We hypothesized that elevation in the scapular plane, representing a mode of centered joint loading, would produce minimal translations of the humeral head and centered contact on the glenoid. For eccentric positions outside of the scapular plane, we hypothesized that contact would occur closer to the glenoid rim in conforming joints in comparison to nonconforming joints, with the BF design exhibiting an intermediate response.

MATERIALS AND METHODS

The experimental model used in this study is based on that developed by Soslowsky et al[47] for glenohumeral contact studies and adapted by Kelkar et al[36] for kinematic studies.

Specimen preparation

Six fresh-frozen cadaveric shoulders (mean age, 43 ± 12 years; range, 22-54 years) were tested in this study. All shoulders underwent radiography and were examined for evidence of fractures, osteoarthrosis, or bony abnormalities, which would otherwise render them inadequate for inclusion in the study. Furthermore, any specimen found to have soft-tissue pathology (ie, rotator cuff tear or evidence of prior surgery) or that demonstrated an abnormal limited range of motion at the time of dissection was also excluded.

After a 12-hour thawing process, each shoulder was dissected down to the GHJ, removing all soft tissue except for the subacromial bursa, coracohumeral and coracoacromial ligaments, and deltoid and rotator cuff muscles. During dissection, preparation, and testing, the joint was regularly moistened with a physiologic saline solution to retard specimen degradation. The muscle bellies of the supraspinatus, infraspinatus, teres minor, and subscapularis were dissected off the scapula and upon careful inspection of their muscle fiber directions, an eye screw was placed at the approximate centroid of each muscle origin near the medial border of the scapula. Dissection of rotator cuffs proceeded laterally, and their tendons were carefully separated from the underlying and confluent joint capsule by use of sharp dissection, with care taken to preserve their insertions on the proximal humeral tuberosities. Each rotator cuff muscle was then transected 3 to 4 mm medial to its musculotendinous junction, and a woven Dacron strip was sutured to the medial tendon edge. Because of their similar lines of action and adjacent insertion sites, the infraspinatus and teres minor were modeled as a single, summed musculotendinous unit. To simulate the rotator cuff lines of action, small triangular clamps were first looped through the Dacron strips to provide uniform loading across the tendon width. Flexible cables were then secured to each clamp, threaded through the eye screws on the scapula, and redirected over pulleys to worm gear mechanisms in series with calibrated spring scales. The precise tensile force applied to each tendon in all testing positions was recorded from the spring scales (resolution, 0.6 N) for subsequent calculation of resultant joint forces.

The 3 muscle bellies of the deltoid (anterior, middle, and posterior) were identified and traced to their origins along the distal clavicle, acromion, and scapular spine. The centroid of each of the 3 origins was marked on the bone and the origin of the entire deltoid resected. Each third of the deltoid was sharply dissected off its insertion on the distal humerus while the distally extending footprint of the insertion was marked with India ink as it was resected. Then a cortical bone screw was drilled through the humerus at the centroid of the 3 distal-most tendon insertions. To simulate the anatomic lines of action of the deltoid, flexible cables affixed to the cortical screws at the deltoid insertions were routed through eyebolts positioned at the approximate anatomic origin of each head of the deltoid and redirected over pulleys to worm gear mechanisms in series with calibrated spring scales.

A lightweight alignment plate was attached to the distal humerus to facilitate measurement of the angle of humeral rotation. The glenohumeral abduction angle was measured during experimentation with a goniometer centered behind the humeral head. The lower third of the scapula was potted in polymethyl methacrylate (PMMA) cement with the plane of the scapula tilted anteriorly by 20° and its medial border vertical, to simulate its in vivo orientation with the arm at the side.[36,47] The joint was then mounted onto a custom joint-testing rig[24] that facilitated the experimental modeling and measurement of GHJ motion.[35]

Both the scapula and humerus were instrumented with 2 rigid triads for geometric and kinematic analyses.[35,51] On the scapula, triads were placed in the scapular spine near the acromion as well as in the anterior coracoid; to accommodate the length of the stem used for the humeral prosthesis, the more proximal of the 2 humeral triads was typically inserted 140 mm from the articular margin of the humeral head. Each triad consisted of three 6.35-mm-diameter precision metallic spheres (Industrial Tectonics, Inc, Dexter, MI).

On the basis of anthropometric data for a 68.2-kg human being (representing a mean weight of male and female subjects), a 3.1-kg mass simulating the weight of the entire arm was attached at its center of gravity, 25.7 cm from the proximal end of the humerus.[52] As the scapula remained stationary during testing, scapulothoracic motion was simulated by adjusting the line of action of the arm weight vector originating from the distal humerus at each position of elevation.[36,47] Glenohumeral abduction angles were converted to total arm elevations in accordance with previous reports.[16,21,43]

Muscle loading

For each shoulder, the natural joint was actively positioned in each of 7 orientations (described below) by use of coordinated muscle force application. The patterns of muscle loading incorporated during testing were based on reported electromyographic data and muscle lever arms.[37,41] The joint capsule was vented in each shoulder to eliminate the effect of loss of intraarticular pressure that occurs at higher elevations.

As the principal objective of this investigation was to quantify the differences in GHJ mechanics associated solely with changes in articular geometry, the applied muscle loads used for the natural joint configuration were consistently maintained across all testing configurations in a

Table I Mean applied muscle forces at each test position (n = 6 specimens)

Test position	Subscapularis (N)	Supraspinatus (N)	Infraspinatus (N)	Anterior deltoid (N)	Middle deltoid (N)	Posterior deltoid (N)
SSR at 30°	15.8 ± 2.3	32.6 ± 5.6	14.7 ± 3.8	28.5 ± 6.4	30.7 ± 6.1	22.8 ± 6.5
SSR at 90°	13.7 ± 2.6	61.2 ± 11.5	18.2 ± 3.5	54.9 ± 16.4	54.4 ± 7.4	22.1 ± 11.9
SSR at 120°	14.2 ± 5.3	48.1 ± 10.5	19.3 ± 3.1	54.0 ± 19.1	48.5 ± 5.3	20.8 ± 10.9
SSR at 150°	13.6 ± 4.0	45.3 ± 19.6	22.7 ± 8.8	59.5 ± 19.5	46.2 ± 12.7	17.0 ± 6.7
ESR at 90°	17.9 ± 6.5	58.3 ± 14.1	27.5 ± 6.8	29.9 ± 10.0	58.1 ± 7.0	46.4 ± 8.3
SIR at 90°	42.8 ± 5.3	56.4 ± 14.6	16.8 ± 4.8	34.3 ± 12.0	59.7 ± 9.2	34.9 ± 3.3
FIR at 90°	45.3 ± 8.6	52.7 ± 13.9	17.2 ± 6.1	62.6 ± 13.5	48.5 ± 11.8	22.3 ± 9.6

Labels for test positions indicate humeral orientation and arm elevation angle.

particular specimen. The mean muscle forces for each test position are listed in Table I. After testing of the natural joint, a passive-assisted active loading protocol was implemented, whereby the shoulder was manually (ie, passively) positioned while muscle forces were adjusted toward their targeted values. For a given test position, adjustments to within 10% of the standard force for a particular tendon were permitted to maintain the desired elevation and rotation. With the exception of 1 test position for the conforming prosthesis of specimen 1, the standard load criterion was uniformly satisfied.

Joint loading and kinematic measurement

A coordinate-measuring machine (CMM) (No. CX-652-D2; Mitutoyo, Paramus, NJ) with a rated accuracy of 50 μm per axis was used to identify the precise location and orientation of both the humerus and the scapula throughout testing.[35,51] The CMM axes were visually aligned with the anatomic axes of the scapula before testing. At each test position, the 3 spheres on each humeral and scapular triad were digitized for post-experimental kinematic and joint contact analyses. During digitization, the coordinates of the sphere centers were automatically computed and written to a data file on a personal computer interfaced with the CMM.

A 6–degree-of-freedom load transducer (JR3, Inc, Woodland, CA) with repeatability better than 3 N (load) and 20 N-cm (torque) per axis was secured to the specimen-mounting pipe, offset medially from the scapula, to measure the resultant force and moment vector components resulting from external loads applied to the specimen-mounting pipe during testing. Very good agreement was found between the measured and calculated resultant force vector components for each anatomic axis, thus providing confidence in the resultant joint force computations. The equations of the linear regressions relating computed (y) to measured (x) forces were as follows: $y = 0.99x + 6.51$ ($R^2 = 0.98$, $P < .001$) (medial-lateral [M-L]), $y = 0.99x + 3.85$ ($R^2 = 0.93$, $P < .001$) (superior-inferior [S-I]), and $y = 0.96x + 1.69$ ($R^2 = 0.95$, $P < .001$) (anterior-posterior [A-P]). The resultant joint force data reported in this investigation are those after adjustment to measured values in accordance with the regression equations.

Resultant joint force calculation

The GHJ reaction force was calculated for each test position based on a free-body diagram analysis of the humerus in its experimental configuration. To satisfy static equilibrium (ie, sum of vector forces = 0), the joint reaction force must counteract the resultant force due to (1) the vector sum of the 3 rotator cuff forces, (2) the vector sum of the 3 deltoid forces, and (3) the force resulting from the weight of the arm acting at the distal humerus. Post-experimentally, after joint disarticulation, muscle origins and insertions were digitized together with their associated triads such that the calculated centroids could be transformed to their in situ coordinates. For each test position, force vectors for each individual muscle were computed from the 3-dimensional coordinates of its insertion and origin and by multiplying the unit vector by the magnitude of the applied force. Vectors representing the forces resulting from the weight of the arm were calculated by use of data recorded from digitization of the arm weight cable at each kinematic position during experimentation. Forces due to capsular tension or impingement of the rotator cuff tendons beneath the acromion were neither measured nor modeled. However, on the basis of the above equations demonstrating close agreement between measured and computed joint forces, we believe that the potential contributions of capsular and impingement forces were small.

Test protocol

On the basis of our laboratory and clinical experience, as well as the literature on GHJ kinematics,[7,28,29,31,36,51] a total of 7 test positions were selected for the experimental protocol. To test our hypotheses for concentric loading, 30°, 90°, 120°, and 150° of scapular-plane arm elevation were chosen on the basis of our previous kinematic studies,[36,51] which demonstrated minimal translation of the humeral head center of curvature. These arm elevations were performed in starting rotation (SR),[36,47] which is the amount of external humeral rotation allowing maximal abduction in the scapular plane. An at-risk elevation angle for patients with instability, 90° arm elevation, was selected for the following 3 eccentric loading positions: horizontal extension in starting rotation (ESR), internal rotation in the scapular plane (SIR), and forward flexion with internal rotation (FIR). Flexion and extension were oriented approximately 30° anterior and posterior from the scapular plane, respectively. These 3 test positions were expected to translate the humeral head along the anterior-posterior axis of the joint[28,29,51] to produce loading near or at the glenoid rim.

To accommodate the study design, which featured biomechanical testing of 3 prosthetic glenoids per specimen, the joint capsule was incised and immediately repaired.

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Suture loops were sewn along the incised edges of the capsule and then secured to eye screws inserted in the scapular neck; the length of each loop was adjusted such that the approximate tension of the intact capsule was restored for each test configuration. The extent to which the capsular repair restored the distribution of tension within the capsule was not evaluated quantitatively. Rather, a qualitative comparison was performed to verify that the passive range of rotation and elevation were preserved after capsular release and repair. In all experiments we could not detect an alteration of capsular tension throughout the duration of the entire testing protocol. The capsular repair allowed the replacement of multiple glenoid prostheses and facilitated the restoration of capsular tension for all test positions. After capsular repair, the natural joint was tested first, and the kinematics and force transducer readings were recorded for the 7 test positions described above. Stereophotogrammetry (SPG) was then performed on the glenoid and humeral head cartilage surfaces[2,46] to quantify their articular-surface topographies for joint contact and kinematic analyses.[3,36,47] During SPG, the joint remained rigidly mounted to the testing rig to preserve the orientation of the simulated muscle forces.

TSA

After SPG, GHJ replacement was performed by use of standard arthroplasty techniques, as detailed by Zimmer, Inc (Warsaw, IN).[54] For each specimen, a standard-sized cobalt-chromium-alloy humeral head component of either 18 or 21 mm in thickness with a radius of curvature of 23 or 26 mm was selected. Keeled, ultrahigh–molecular weight polyethylene glenoid components were used, with uniform radii of curvature of 23, 26, or 29 mm (representing conforming and nonconforming articulations with the humeral head components), whereas the available BF glenoids exhibited a central region radius of curvature of 23 or 26 mm. Uniform curvature glenoid components were custom made by Zimmer, Inc and shared the same keel design as the BF. In this study, for a humeral head component with radius of curvature R_H, the corresponding radii of mating conforming and nonconforming glenoids were defined as R_H and $R_H + 3$, respectively. Among the 6 specimens tested, 3 were fitted with humeral components measuring 21 × 46 mm (head height and head diameter, respectively), 2 were 18 × 46 mm, and 1 was 21 × 52 mm.

To prepare the specimens for prosthetic implantation, each GHJ was disarticulated and the incised capsule was reflected laterally and secured with sutures beneath the margins of the humeral articular surface. A custom alignment guide[54] was inserted onto the humeral reamer to facilitate anatomic resection of the native humeral head at a head-shaft angle of 135° while maintaining 30° of humeral retroversion. Immediately after selection of the prosthetic head, 3 glenoids—conforming, nonconforming, and BF—were randomly assigned the generic labels A, B, and C by a single investigator. A different investigator, blinded to the identities of glenoids A, B, and C, then selected the testing sequence (eg, C-A-B) for these components. After removal of the native glenoid articular cartilage and reaming of the glenoid fossa to a uniform radius of curvature matching that of the back of the glenoid component, the first keeled glenoid was cemented into place. The technique of cementing, removing, and recementing multiple glenoids was refined during our pilot experiments. When the first 2 glenoids were implanted in each specimen, a conservative amount of cement was used for fixation. A 90-minute period was allocated for curing of the bone cement before kinematic testing of each glenoid component. Our PMMA preparation resulted in minimal bone loss, and therefore, subsequent components could be consistently implanted within the bony vault. No visual glenoid loosening was detected during any of the experiments.

Surface registration of implants

After the 7 kinematic positions were tested in the first TSA preparation, the joint capsule was reopened and the humerus reflected superiorly to expose the glenoid surface. The CMM was used to digitize points on the articular and side surfaces of each glenoid component, as well as the coordinates of the spheres fixed to the scapular triads, for subsequent surface registration. After digitizing, the glenoid was removed, and the glenoid vault was prepared for implantation of the second glenoid component, which was tested by use of the identical protocol as the natural joint and first implant; this procedure was again repeated for the final glenoid. At the conclusion of testing, the capsule was fully resected, the joint was disarticulated, and the prosthetic humeral head was digitized along with its reference triads. Typically, prosthetic surface registration required digitizing a minimum of 150 and 80 points on each humeral head and glenoid, respectively.

Calculation of joint kinematics and contact areas

Natural joint surfaces. For the natural joint configuration, the relative positions of the glenoid and humeral head articular surfaces during experimentation were determined by use of the methodology described by Kelkar et al.[36] From SPG analysis, 3-dimensional geometric models of the glenoid and humeral head were obtained with their associated humeral and scapular triad coordinates. By use of a least squares optimization procedure, the spatial orientation of both the humeral head and glenoid cartilage surfaces, as well as the coordinates of their centers of curvature, was determined for each respective test position.[36,47] In situ joint contact areas were calculated by use of the proximity criterion described previously.[4]

Prosthetic components. To conduct kinematic and contact analyses of the implants, accurate geometric models of the GHJ prosthetic components were first created before their use in experiments. After articular curvature measurements were recorded from a CMM with a rated accuracy of 5 μm per axis (MicroVal 343; Brown and Sharpe, North Kingstown, RI), models were constructed by use of I-DEAS Master Series 7.0 solid modeling software (Electronic Data Systems, Plano, TX).

A series of sequential surface alignment procedures was performed to align the glenoid and humeral component surfaces into each of their respective in situ testing positions. In each test configuration, to obtain the orientation (and center of curvature) of the glenoid and humeral head components relative to their scapular and humeral reference triads, respectively, a least squares optimization technique was used to align their corresponding I-DEAS model to the points obtained from direct digitization of these prosthetic

components. To provide a common reference frame for the purpose of reporting results, all prosthetic and natural joint surfaces were aligned to the 90° scapular-plane SR position in the natural joint configuration.

Kinematic reference points. Reference points for kinematic calculations were obtained after alignment of the SPG or I-DEAS model of each glenoid to its experimental in situ position. The anatomic axes for the natural joint configuration were taken to be those of the CMM, as it was not possible to select a nonarbitrary set of coordinate axes for the SPG surfaces (which are portions of spheres). In contrast, anatomic axes were easily assigned to the computer models of the prosthetic glenoid components because of the geometry of these designs (ie, lengths > widths).

In the natural joint, the reference point for reporting translations of the humeral head on a stationary glenoid was computed from the following formulas (valid for left shoulders):

$$c_{ML} = a_{ML} + (R_G - R_H)\cos\alpha$$

$$c_{SI} = a_{SI}$$

$$c_{AP} = a_{AP} - (R_G - R_H)\sin\alpha$$

in which c_{ML}, c_{SI}, and c_{AP} are the M-L, S-I, and A-P coordinates of the reference point, respectively, and a_{ML}, a_{SI}, and a_{AP} are the coordinates of the glenoid center of curvature. R_G and R_H are the radii of curvature of the glenoid and humeral head articular surfaces, respectively, and α is the glenoid retroversion.

The reference point for the conforming prosthetic glenoid and the BF (whose central region is congruent with the humeral head) was the center of curvature of the glenoid component. For nonconforming implants, the reference point c_{gi} was adjusted by an amount proportional to the radial mismatch by use of the following formula (valid for left shoulders):

$$(c_{g_i})_m = (c_{g_c})_m + (R_G - R_H)n_m$$

in which c_{gc} is the center of curvature of a congruent glenoid, and n is the unit normal of the (nonconforming) glenoid surface. The subscript m denotes the anatomic directions (M-L, S-I, and A-P) for each implanted glenoid. The results from right shoulders were converted to left-shoulder equivalents for comparison purposes.

Statistical analysis

A generalized linear model analysis of variance with repeated measures was performed by use of SAS for Windows (version 8.0; SAS Institute, Cary, NC). The statistical factors were test configuration (natural joint and 3 glenoid types) and arm position (30°, 90°, 120°, and 150° for centered loading and ESR, SIR, and FIR for eccentric loading), whereas the dependent variables included the component resultant joint forces, humeral head translations, and glenoid contact area centroids. When significant differences were detected by use of the generalized linear model, a Student-Newman-Keuls multiple-range comparison was used to detect differences among levels of a factor. Group means for the 3 implant configurations were computed for statistical comparisons (ie, paired *t* tests) between natural and prosthetic joints. Statistical significance was assumed for $P < .05$.

RESULTS

Resultant joint forces

For the concentric loading positions, no significant differences ($P > .4$) were found among test configurations for the total resultant force magnitude or for the M-L, S-I, or A-P resultant force components. Similarly, no significant differences could be detected among total resultant forces ($P = .35$) or the M-L ($P = .45$) and S-I ($P = .28$) force components when eccentric loading positions were analyzed. However, A-P forces demonstrated significant differences in the FIR position, as nonconforming implants experienced more posteriorly directed forces (52 ± 23 N) when compared with the natural joints (35 ± 18 N) ($P = .037$). Across all test configurations, the mean total resultant force magnitude ranged from a minimum value of 81 ± 12 N (30°, nonconforming implant) to a maximum value of 194 ± 16 N (flexion with internal rotation, conforming implant).

Humeral head translation

During centered loading, the kinematics of the center of curvature of the humeral head was similar among natural and prosthetic glenoids, with the exception of the conforming prosthesis, which tracked significantly posteriorly ($P = .005$), particularly in the mid-range elevations (Figure 2, *A*). For all glenoids, the humeral head tended to migrate anteroinferiorly with elevation in the scapular plane (Figure 2). The mean position of the humeral head center was more superior with prosthetic glenoids in comparison to the natural joint (3.7 ± 3.8 mm vs 2.2 ± 2.6 mm, $P = .017$). Though not statistically significant, natural joints tended to track more anteriorly compared with implants (1.5 ± 3.0 mm vs 0.8 ± 2.0 mm, $P = .09$).

During eccentric loading, all 3 glenoid designs promoted similar kinematics to that of the natural joint (Figure 3). For all glenoids, characteristic trends were observed in the A-P direction, with progressive ($P < .02$) posterior translation observed as the humerus was moved from extension into flexion (Figure 3, *A*). Contrary to our hypothesis, A-P translations for the conforming glenoid were similar to the BF, nonconforming, and natural joint ($P = .27$). Similar to the centered loading mode, implants translated more superiorly than the natural joint (4.1 ± 4.0 mm vs 1.6 ± 2.9 mm, $P = .001$) under conditions of eccentric loading. However, A-P translations were very similar

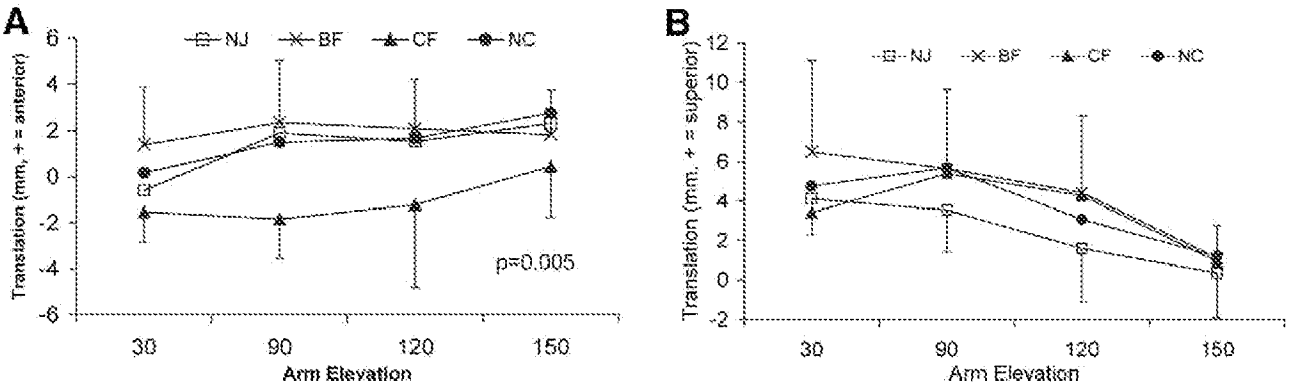


Figure 2 Mean A-P (**A**) and S-I (**B**) translation of the center of curvature of the humeral head during concentric loading. *Error bars* represent SDs. *NJ*, Natural joint; *CF*, conforming; *NC*, nonconforming.

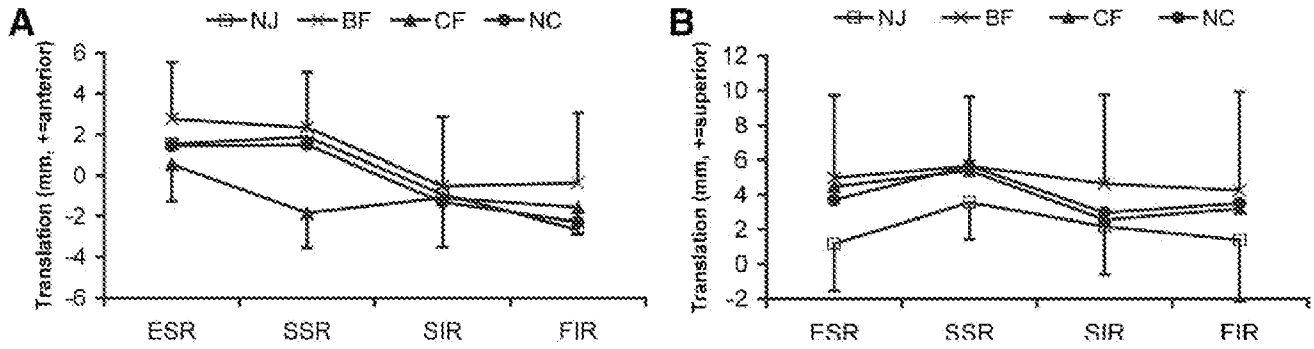


Figure 3 Mean A-P (**A**) and S-I (**B**) translation of the center of curvature of the humeral head during eccentric loading. *Error bars* represent SDs. *NJ*, Natural joint; *CF*, conforming; *NC*, nonconforming.

($P > .9$) between prosthetic and natural joints (mean posterior translation, 0.5 mm).

Glenoid contact centroids

Centroids for the prosthetic glenoid contact areas are presented in the anatomic coordinate system of their I-DEAS models. For consistency, the contact centroids in the natural joint were likewise expressed in this coordinate system. During concentric loading, the contact area centroid behaved similarly to the motion of the center of the humeral head. For the nonconforming, BF, and natural joints, the contact centroid remained centered or slightly anterior as well as superior to the joint center (Figure 4). However, the conforming glenoid demonstrated statistically significant ($P = .02$) posterior contact (Figure 4, *A*), consistent with the kinematic findings. S-I centroid translations were not influenced by glenoid type ($P > .3$) (Figure 4, *B*). Glenoid contact in implants was significantly more posterior than in the natural joints (-1.2 ± 4.4 mm vs 1.6 ± 3.8 mm, $P = .001$), whereas S-I centroids were approximately the same ($P > .8$; mean superior location, 8.8 mm).

Movement of the humerus from extension to flexion caused the centroid to migrate posteriorly ($P = .0006$) and inferiorly ($P = .003$) for all glenoid configurations (Figure 5). The conforming glenoid produced significantly ($P = .05$) more posterior contact than the natural joint, particularly in the position of flexion with internal rotation, where the contact occurred closer to the rim (Figures 5, *A* and 6). Interestingly, in all cases joint contact was predominantly in the superior region of the glenoid component (Figure 5, *B*). Prosthetic joint contact centroids were more superior (8.3 ± 5.3 mm vs 4.8 ± 6.2 mm, $P = .069$) and significantly more posterior (-3.2 ± 4.9 mm vs -0.4 ± 5.6 mm, $P = .0038$) than for natural joints.

DISCUSSION

Foremost among the objectives of total shoulder replacement are to restore motion and strength and to eliminate pain. Over the past 3 decades, modern TSA has been highly successful in the treatment of GHJ degeneration. However, there remains considerable controversy in determining the amount of component conformity that optimizes implant performance in

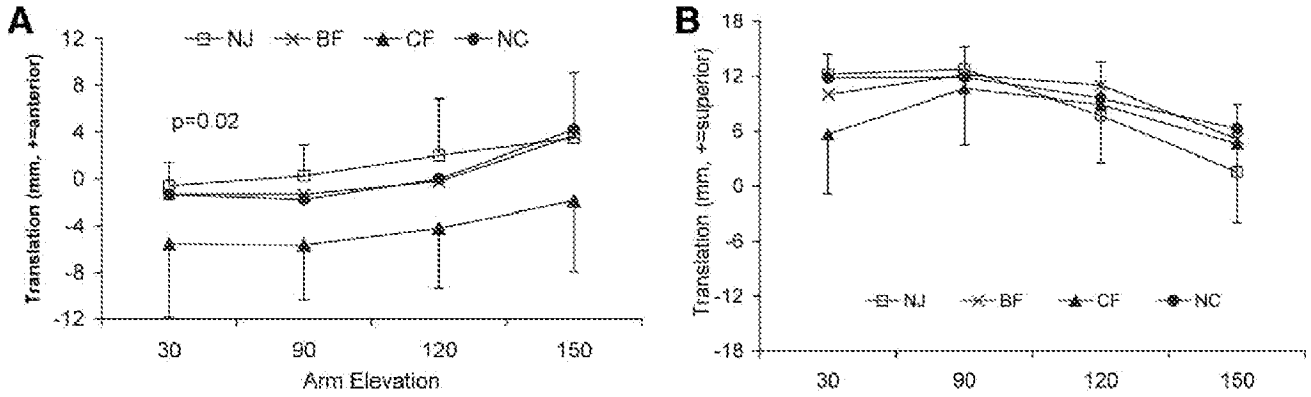


Figure 4 Mean A-P (**A**) and S-I (**B**) translation of glenoid contact centroid during concentric loading. In these lines graphs, the *y-axes* correspond to the typical 24-mm A-P width or 36-mm S-I length of the prosthetic glenoids, with 0 mm of translation indicating the glenoid center for each axis. *Error bars* represent SDs. *NJ*, Natural joint; *CF*, conforming; *NC*, nonconforming.

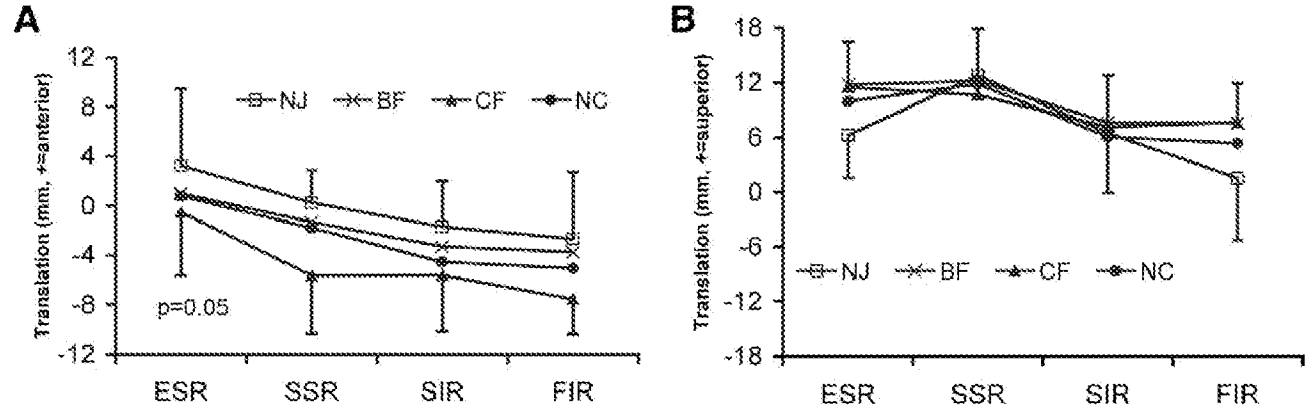


Figure 5 Mean A-P (**A**) and S-I (**B**) translation of glenoid contact centroid during eccentric loading. *Error bars* represent SDs. *NJ*, Natural joint; *CF*, conforming; *NC*, nonconforming.

vivo. Neer's original unconstrained TSA design featuring conforming glenohumeral components has long been considered the standard for GHJ replacement because of its clinical efficacy and durability.[11,38,48] Today, long-term follow-up studies continue to cite glenoid component loosening as the most frequent indication for revision surgery.[13,53] These results may be responsible for shoulder surgeons' increasing preference for nonconforming components (which, by design, are less likely to produce glenoid rim loading) despite the risk of increased contact stresses during centered loading. Recently, the innovative BF glenoid design (Zimmer, Inc) was introduced, featuring a conforming central geometry and nonconforming peripheral region, in contrast to other designs that are either fully conforming or fully nonconforming. The present study is among the first reports assessing ex vivo joint biomechanics after shoulder arthroplasty with the BF system.

The experimental protocol developed for this study included test positions (30°-150° arm elevation) in the scapular plane that we hypothesized would produce minimal translations and centered joint contact with no significant differences among glenoid implants. Throughout elevation in the scapular plane, the contact centroid for the conforming glenoid was displaced posteriorly ($P = .017$) by 3 mm or more relative to the natural joint, the BF, and the nonconforming glenoids, which demonstrated centered contact over these same elevations (Figure 4, *A*). An equally surprising finding was that conforming joints exhibited a marked and significant ($P = .005$) (Figure 2, *A*) posterior translation during concentric loading. S-I translations, meanwhile, demonstrated similar kinematic patterns among the implants, particularly above 30°, with a trend ($P = .1$) for native humeral heads to be closer to the joint midline (Figure 2, *B*). In light of these findings, we reject the hypothesis that concentric motion is achieved with all glenoids during scapular-plane elevation.

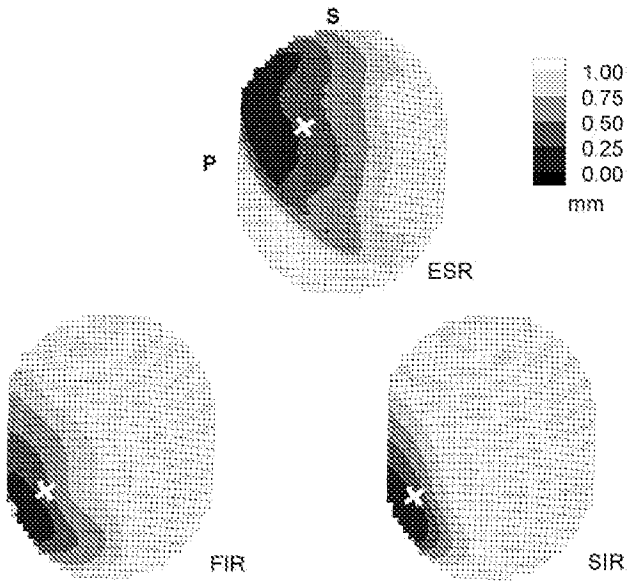


Figure 6 Representative contact map for conforming glenoid in eccentric loading positions. *White crosshairs* denote contact centroid. *S*, Superior; *P*, posterior.

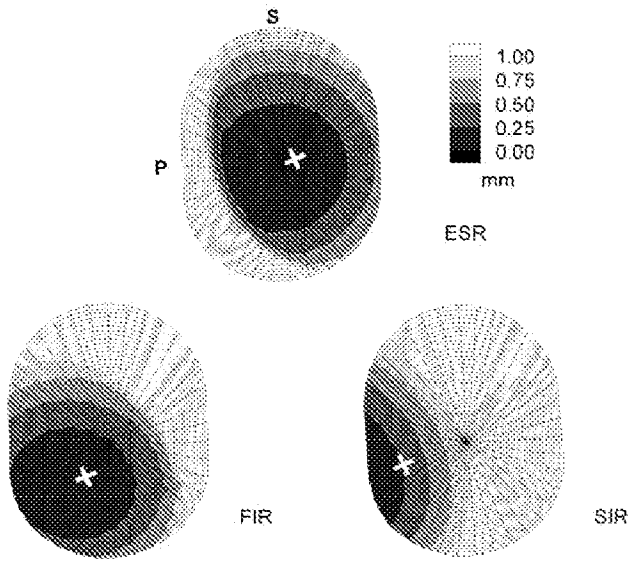


Figure 7 Representative contact map for nonconforming glenoid in eccentric loading positions. *White crosshairs* denote contact centroid. *S*, Superior; *P*, posterior.

Three additional loading positions (flexion, extension, and scapular-plane internal rotation) were selected to promote humeral head contact on or near the anterior-posterior glenoid rim. In response to these eccentric applied loads, the BF's ability to "contain" rim loading, given its hybrid design, was expected to be intermediate to that of the perfectly congruent and incongruent glenoids. As GHJs were progressively loaded from extension into flexion, despite the lack of statistically significant differences in humeral head kinematics, conforming joint contact centroids migrated closer to the posterior glenoid rim (Figure 5, *A*). Posterior translation has previously been shown in normal cadaveric joints in which simulated muscle forces were used to achieve flexion.[7] We believe that the combined effects of muscle forces (Table I) and glenoid component geometry led to the observed patterns of posterior humeral translation in our study. The BF, natural joint, and nonconforming glenoids appeared to control rim loading under these eccentric loads when compared with the conforming glenoid ($P = .05$) (Figures 5, *A*, 6, 7, and 8). The similarity in contact patterns between the BF and nonconforming glenoids suggests that, under the experimental loading conditions, contact typically occurred in the outer, nonconforming portion of the BF (Figures 7 and 8). Interestingly, all glenoids exhibited contact primarily superior to the component center, although these centroids were no closer than 5 mm from the superior glenoid rim (Figure 5, *B*). We, therefore, confirm the hypothesis that eccentric loading of conforming implants produces contact near the glenoid edge. With

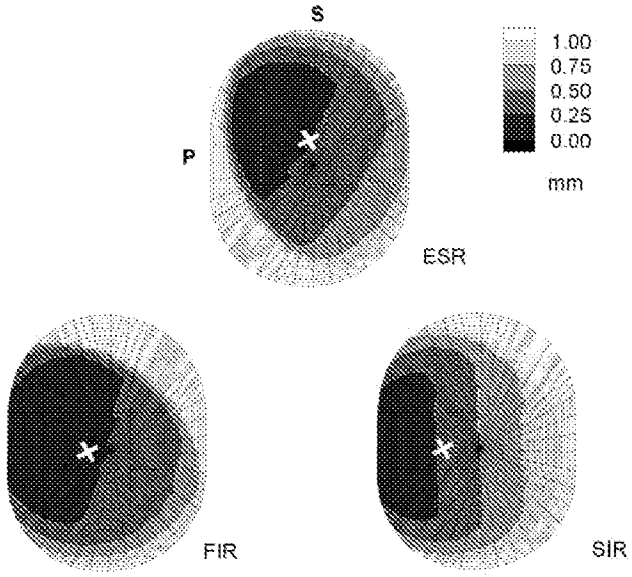


Figure 8 Representative contact map for variable conforming (ie, BF) glenoid in eccentric loading positions. *White crosshairs* denote contact centroid. *S*, Superior; *P*, posterior.

the numbers available, no significant differences in glenohumeral motion and contact could be detected among the BF and nonconforming designs as well as the natural joint.

Under conditions of uniformly applied muscle forces across the 4 test configurations, statistically significant differences in calculated resultant applied forces were found only with forward flexion, where the nonconforming design experienced greater pos-

terior loads than the natural joint ($P = .037$). The mean magnitude of the maximum resultant joint forces to which the implants were subjected in this study was 194 N (less than one-third body weight for a 76-kg individual). During independent experiments in our laboratory, a prosthetic humeral head was statically loaded (200 N) onto a mating glenoid by use of a servohydraulic testing system, and minimal (<0.15 mm) creep deformation of the polyethylene glenoids was noted. Therefore, it was not likely that ultrahigh–molecular weight polyethylene creep influenced the biomechanical results of the present study.

Care was taken to minimize confounding experimental variables during testing. We used a blinded and randomized testing approach for the prosthetic glenoids, and we could not attribute our results to testing sequence, as there did not exist meaningful disparities among glenoids. In each specimen, positioning of successive glenoid implants was consistent as a result of the minimal loss of bone associated with our recementing techniques. Hence, we do not believe that our results are attributable to glenoid malposition. The capsular release and repair, which were necessitated by our articular-surface registration techniques, were performed before any kinematic testing. A tight or lax capsule would be expected to alter joint motion with all glenoids, whereas in this study statistically significant posterior humeral migration was found only for the conforming glenoid. Additional pilot studies were conducted to investigate the influence of muscle forces on joint stability for the 7 test positions examined. We observed that incremental muscle force loading afforded a proprioceptive ability, in the sense that loads could be manually adjusted and balanced to prevent joint dislocation, particularly for eccentric loading positions. However, the capability to "sense" how well the humeral head was seated in the glenoid not only constituted a potential bias in experimentation but also resulted in substantial disparities in the magnitude of applied resultant force vectors across test configurations. Hence, we used a passive-assisted active muscle loading approach to maintain similar muscle force balancing throughout the course of testing of each shoulder specimen. At the same time, we recognize the possibility that a single combination of muscle forces may not have been conducive to stability for all implants. Indeed, this may have been the case for the conforming prosthetic joints, in which posterior kinematic and contact patterns were consistently noted across all experiments.

Few laboratory studies have examined the effect of component conformity on glenohumeral kinematics and contact patterns, although several investigations have reported subluxation or dislocation forces as measures of joint stability.[1,23,33,45] Karduna et al[32] used a human cadaveric model of TSA to quantify translations in glenohumeral components whose radial mismatches varied from 0 through 5 mm. Under conditions of active loading, both S-I and A-P translations increased significantly with radial mismatch. The authors found that approximately 4 mm of mismatch on average best replicated normal joint translations. Meanwhile, a recent clinical study by Walch et al[50] reported that glenoid radiolucent lines (a potential indicator of component loosening) were less prevalent in joints with a radial mismatch greater than 5.5 mm but less than 10 mm. However, in this radiographic study, all implanted glenoids were flat-backed and thus more prone to edge loading. In our study, nonconforming glenoids (whose radii of curvature were 3 mm greater than those of the humeral head) exhibited no statistically significant differences, aside from the resultant joint force in flexion, compared with natural joints.

Our results suggest that glenohumeral stability is greater in natural joints compared with prosthetic joints. When the group mean of the 3 implants is considered, the center of curvature of the native humeral heads was significantly closer to the joint midline during scapular-plane elevation on the basis of S-I kinematics ($P = .017$) and A-P contact ($P = .0015$); under eccentric loading, similar trends were evident ($P = .0015$ and $P = .0038$, respectively). In contrast, when data only for radial mismatches up to 3 mm are examined, it is apparent that the A-P and S-I joint translations reported by Karduna et al[32] were smaller for implants compared with natural joints. However, one must consider several key differences between our study and that of Karduna et al. The latter investigation focused on the positions of full internal to external humeral rotation at 90° arm elevation, used a surgical technique that preserved the integrity of the capsule, and found no significant differences in kinematics between natural joints and prosthetic joints whose radial mismatches ranged from 0 to 5 mm. The biomechanical differences between natural and prosthetic joints are likely attributable to the greater compliance of articular cartilage and labrum in comparison to polyethylene. For the native glenohumeral cartilage surfaces of the specimens evaluated in this investigation, the radial mismatch as determined from SPG analysis ranged from 0.7 to 2.4 mm, with a mean value of 1.4 ± 0.6 mm. In a natural glenohumeral articulation with a slight mismatch in humeral head and glenoid curvatures, deformation of cartilage during joint loading may actually increase the congruity of the joint and improve stability. This mechanism may explain the findings that joint contact centroids tended to be closer to the joint midline in natural relative to prosthetic joints.

In summary, despite clinical speculation that component conformity in TSA strongly influences implant performance and survival, in this investigation few

statistically significant ($P < .05$) differences were detected among 3 prosthetic glenoid designs under the imposed test conditions. The glenoid designs featuring some degree of mismatch behaved similarly to the natural joint, with no statistical differences in joint kinematics or contact patterns detected among these 3 test configurations. However, the conforming design led to posterior translation and contact near the glenoid rim. With regard to glenoid component complications, the 2 major mechanisms of clinical concern are elevated contact stresses producing polyethylene wear and edge loading leading to component loosening. Our finite-element studies previously demonstrated considerably increased contact stresses in fully nonconforming relative to fully conforming glenoids, as well as a benefit (ie, lowered stresses) to adding a partial region of conformity to a fully nonconforming glenoid. Our kinematic and contact data further suggest that adding a peripheral zone of translation to a fully conforming glenoid reduces the likelihood of rim loading, thereby increasing joint stability.

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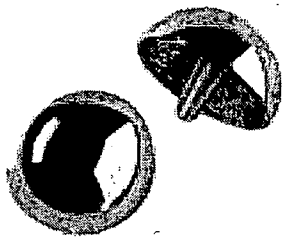
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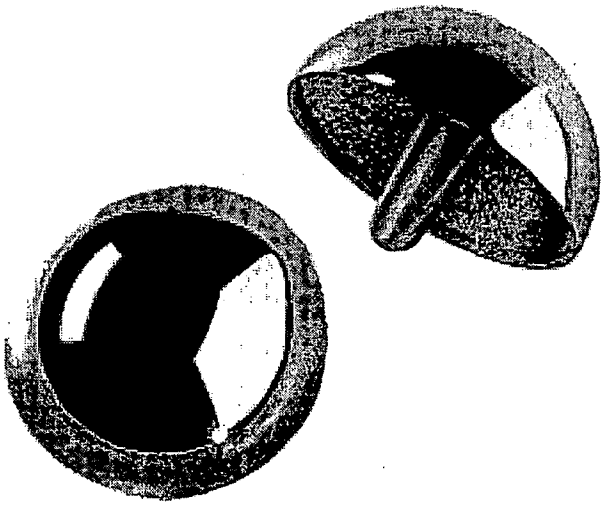
MACROBOND™ IMPLANT INFORMATION

Copeland™
Humeral Resurfacing Head

Copeland™ Humeral Surface Replacement Arthroplasty System

Product Photo	Part Number	Description	Size
	114621 114622 114627 114623 114624	Copeland™ Macrobond™ HRS Copeland™ Macrobond™ HRS Copeland™ Macrobond™ HRS Copeland™ Macrobond™ HRS Copeland™ Macrobond™ HRS	Small Medium Medium + Large X-Large

The Copeland™ Humeral Resurfacing Head is offered with a titanium plasma sprayed coating applied over the cobalt chrome alloy substrate. This coating, called MacroBond,™ looks very similar to our porous coating, but lacks the pores. It is designed for bone "ongrowth" instead of "ingrowth."



The Copeland™ Surface Replacement Arthroplasty (CSRA) of the shoulder was developed by Steven A. Copeland, F.R.C.S., Consultant Orthopaedic Surgeon at the Royal Berkshire Hospital, Reading, England, U.K.

This device is intended to be used in the United States as described in the product labeling.

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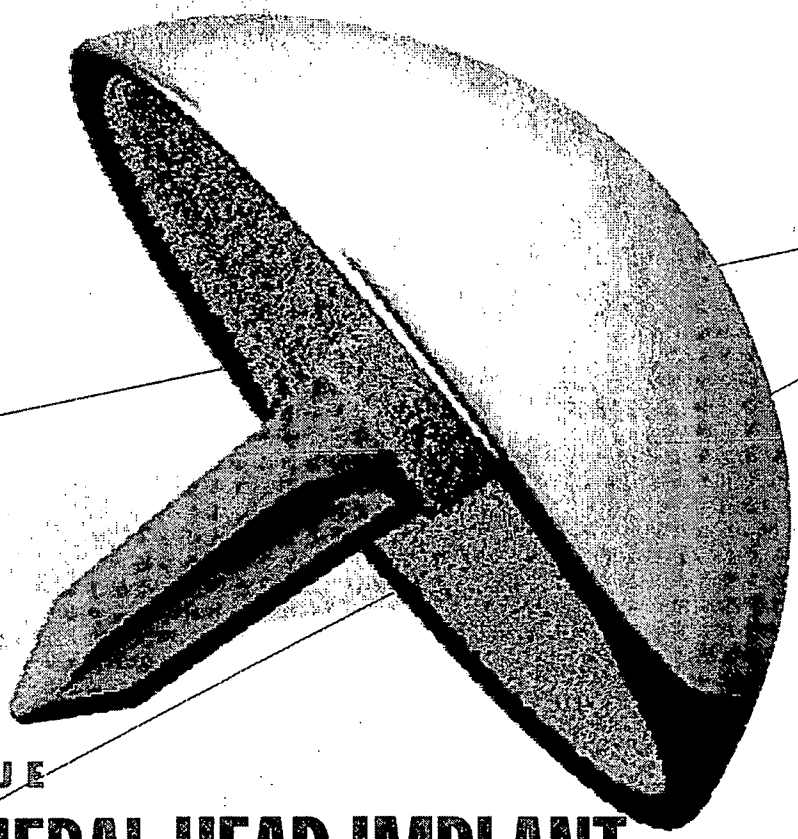
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GLOBAL C.A.P.™

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SURGICAL TECHNIQUE

RESURFACING HUMERAL HEAD IMPLANT

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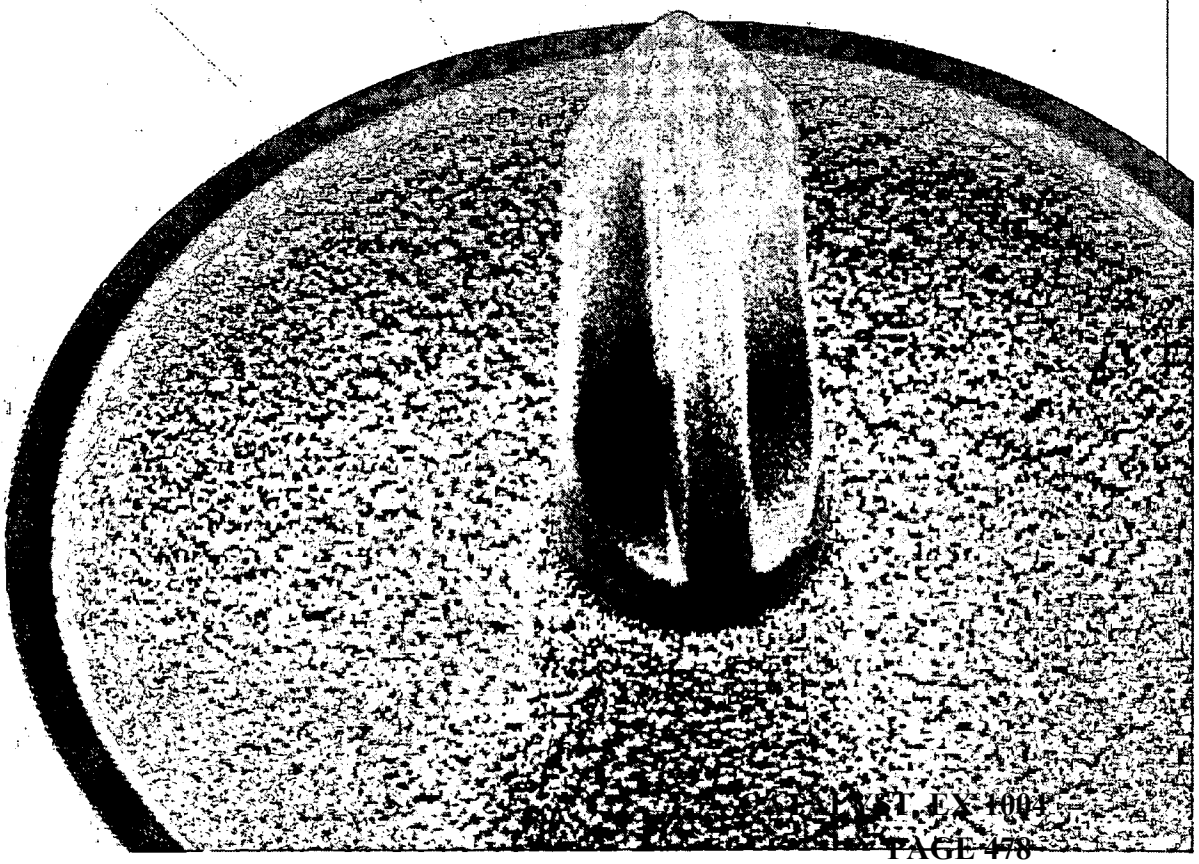
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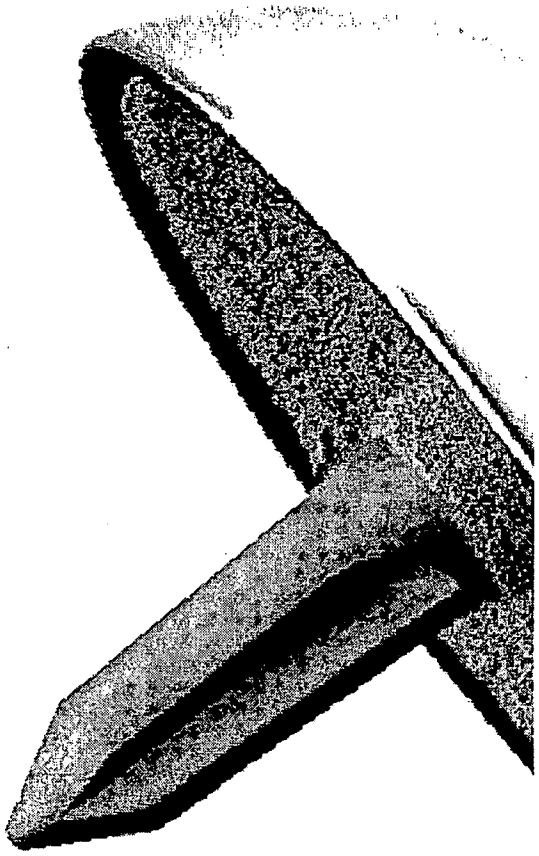
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The Global C.A.P.™ Resurfacing Humeral Head Implant from DePuy is well suited for younger osteoarthritic or rheumatoid arthritic patients in need of a bone-preserving implant. Complementing DePuy's existing Global™ shoulder portfolio, this implant is designed to articulate either with a glenoid component from the Global Advantage® system (total arthroplasty) or without a glenoid (hemiarthroplasty).

The Global C.A.P.™ design draws upon advanced research and design philosophies of the Global Advantage® system. These design philosophies were derived from detailed investigations of the structure and mechanics of normal and prosthetic glenohumeral joints, conducted at the University of Texas at San Antonio, University of Washington, The Cleveland Clinic Foundation, University of Pennsylvania and DePuy Orthopaedics, Inc., Warsaw, Indiana.[1]



ANATOMIC SIZING AND DESIGN FEATURES



Anatomic Sizing

The sizing of the Global C.A.P.™ implant is based upon the observed variability in humeral head size in normal shoulders[1] and the Global™ Advantage® system.

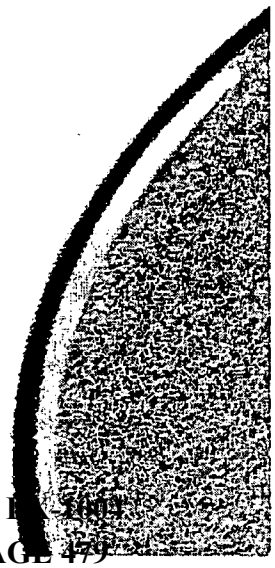
- Normal shoulders exhibit a range of humeral head diameters and humeral head heights.
- Head height correlates with humeral head diameter.

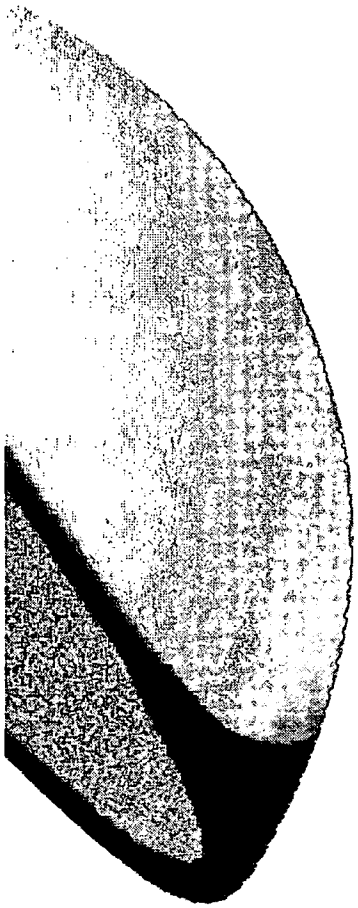
The variable sizing options of the Global C.A.P.™ system permit enhanced anatomic reconstruction of the humeral head.

ANATOMIC SIZING	Head Diameters (mm)				
Head Heights (mm)	40	44	48	52	56
15	X	X			
18	X	X	X	X	X
21			X	X	X

Design Features

- Secure implant design with cruciate stem.
- Unique undersurface design providing rotational stability.
- Apical flat on undersurface of implant allows for better fit and intimate contact.
- Variable stem lengths for corresponding head heights:
  - 15 mm head height — 30 mm stem
  - 18 mm head height — 35 mm stem
  - 21 mm head height — 40 mm stem





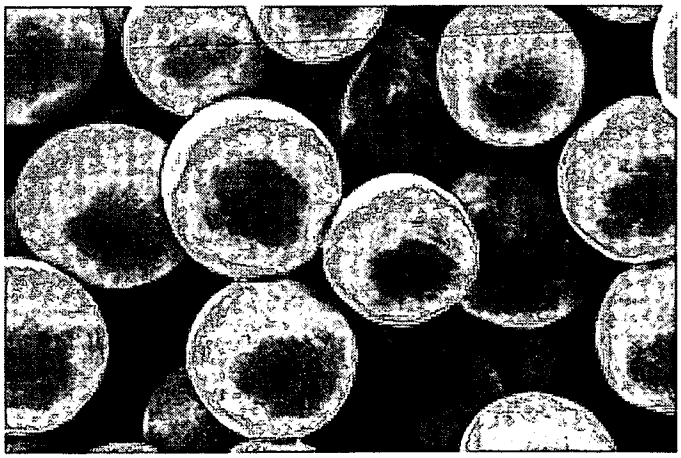
PROVEN FIXATION

The undersurface of the Global C.A.P.™ implant and the proximal portion of the cruciate stem are surface-treated either in Porocoat® Porous Coating or DuoFix® HA.

Porocoat® Porous Coating

The Porocoat® Porous Coating process results in a strong bond of proud, randomly arranged beads that form interconnecting pores for ingrowth. Porocoat® Porous Coating exhibits a pore size in the optimal range for bony ingrowth, resulting in a more efficient and uniform transmission of stresses.[2,3]

The clinical performance of the Porocoat® Porous Coating has been tracked for more than 25 years. Studies continue to provide definitive evidence that the porous surface comprised of progressively sized beads gives early stability in healthy bone and assures long-term biological fixation as ingrowth takes place.[4-6]

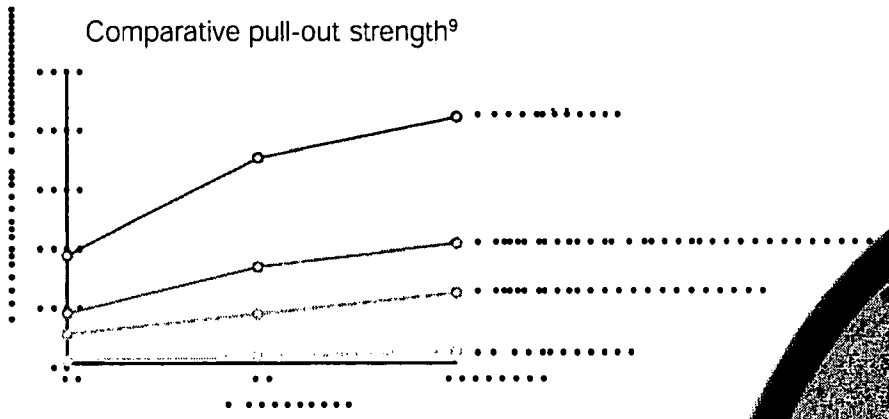


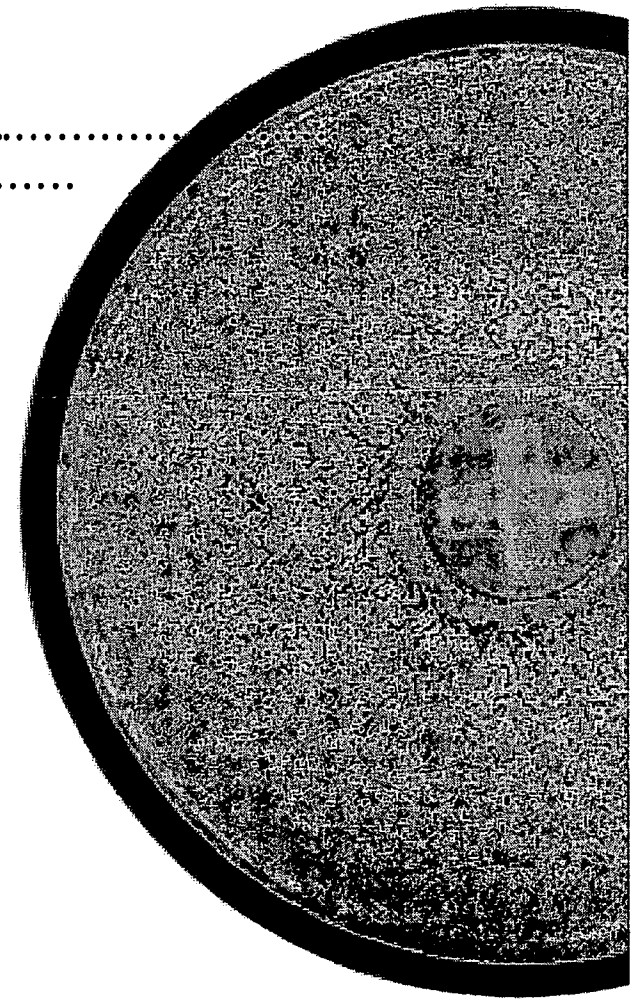


PROVEN FIXATION

DuoFix™ HA

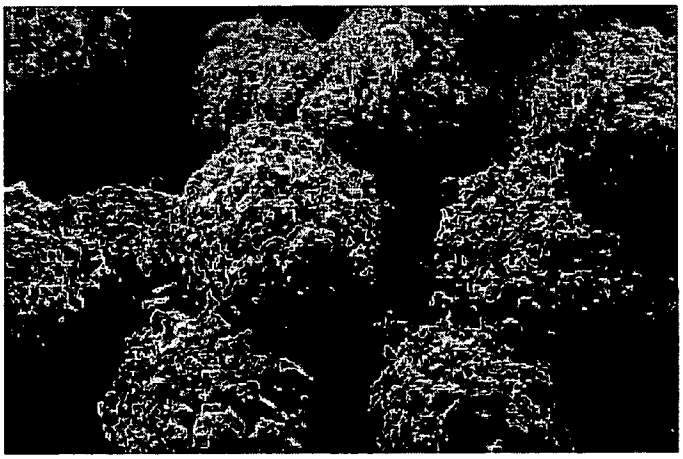
The Global C.A.P.™ implant is also available with DuoFix™ HA coating, which combines the clinically proven fixation of Porocoat® Porous Coating with the potential benefits of hydroxyapatite (HA) coating.[2,3,7]





The HA interface provides an ideal coating for stable implant fixation. Duofix™ HA is the application of plasma-sprayed HA over Porocoat® Porous Coating. The precision controlled, 35 micron application ensures the HA does not occlude the pores in Porocoat® Porous Coating.[8]

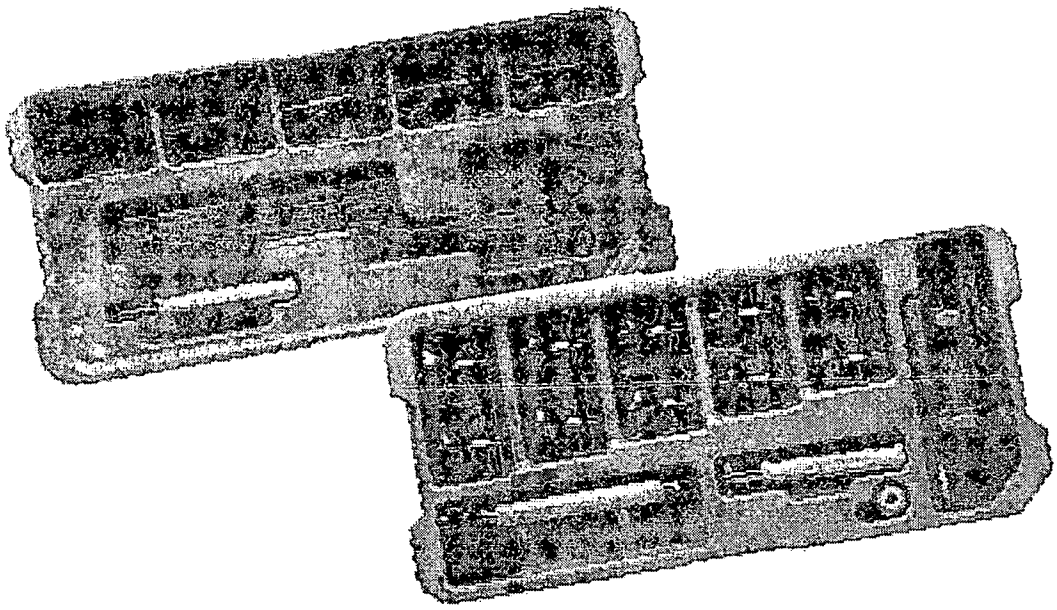
This bioactive material formulation, with a composition similar to that of natural bone, acts as a catalyst for ongrowth, bridging gaps at the interface of up to 2 mm.[3,14,15]



INSTRUMENTATION

The Global C.A.P.™ instruments are designed to be user-friendly and offer precise implant preparation.

- Reamers accurately reshape humeral head wear typically seen in arthritic patients with flattened humeral heads.
- Cannulated instrumentation (head sizers, reamers, trials and stem punch) allows the surgeon to move from one step to the next.
- Centring technique allows the surgeon to position the implant accurately.



TRIPLE STEP REAMERS



Humeral bone preparation is an essential step therefore the humeral head reamers are sharp, accurate and offer optimal implant seating in one easy step. This design helps in reshaping the proximal humerus to ensure maximum contact area between the native humerus and the implant. The reamers shape the humeral head in three ways:

- Central portion of the reamer fashions a distally tapering hole.
- Peripheral portion of the reamer shapes the humeral head.
- Deepest portion of the reamer shapes the flat superior portion of the humeral head.

INDICATIONS

The Global C.A.P.™ implant has the same indications as general shoulder arthroplasty. They include loss of articular cartilage, joint incongruity, stiffness, loss of function and pain unresponsive to nonoperative measures. Indications specific to the Global C.A.P.™ implant include:

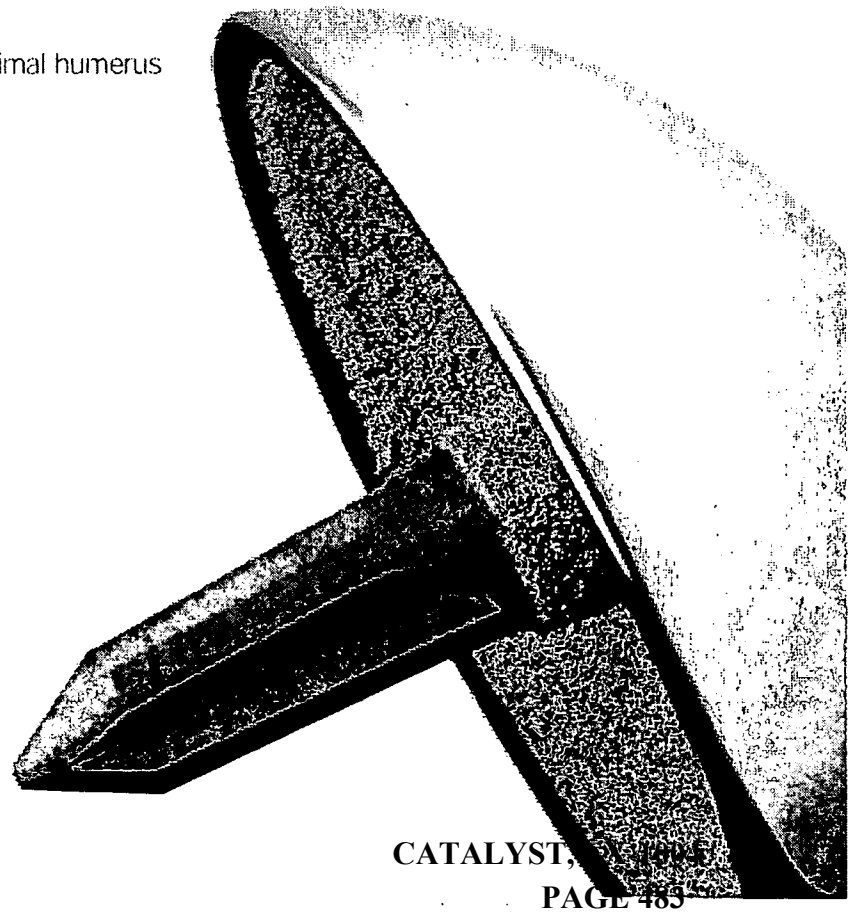
- Patients disabled by either non-inflammatory or inflammatory arthritis (i.e. rheumatoid arthritis, osteoarthritis and avascular necrosis).
- Mild or moderate humeral head deformity and/or limited motion.
- Post-traumatic arthritis.
- Malunions of the humeral head.
- Patients with an intact or reparable rotator cuff.

The Global C.A.P.™ implant is intended for cementless use only.

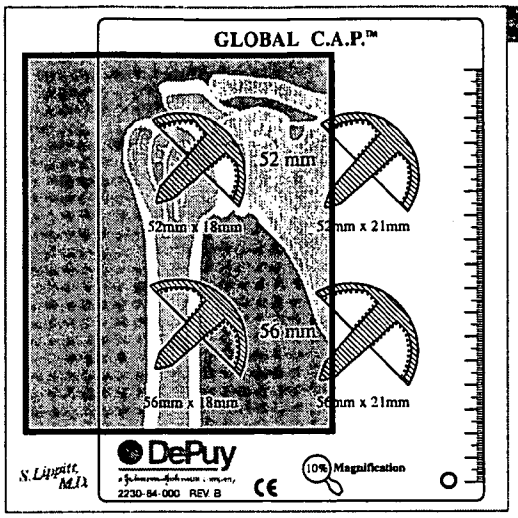
CONTRAINDICATIONS

The following are contraindications for the Global C.A.P.™ implant:

- Active local or systemic infection.
- Inadequate bone stock in the proximal humerus (humeral head).



SURGICAL TECHNIQUE



Preoperative radiograph and template used to verify appropriate head size

fig. 1

Humeral Preparation

Preoperative templating of radiographs is important for predicting the humeral head size that will be needed during surgery. The head size can be further verified intraoperatively by measuring the head after osteophyte removal. Begin preparation of the humerus by approximating the template (appropriate head size) over the preoperative radiograph (fig. 1).

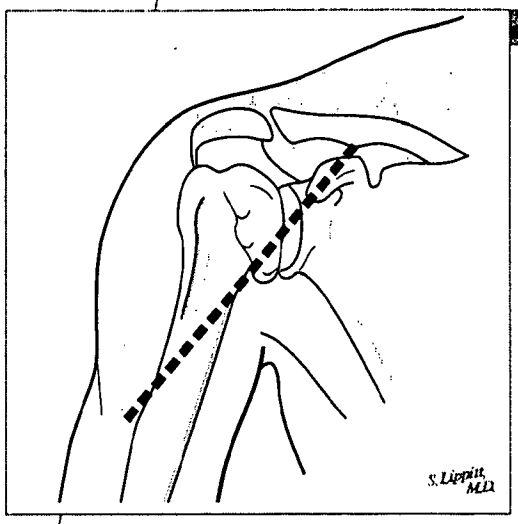
Depending on surgeon preference, either the Deltopectoral or the Superior Approach (commonly known as McKenzie's) can be used. The advantages of the Deltopectoral Approach include preservation of the deltoid origin and insertion, utilisation of an internervous plane (extensile), and facilitation of subscapularis lengthening. The Superior Approach may be preferred since it offers retention of the subscapularis. Since the Deltopectoral Approach is the most typical approach for this procedure, the surgical technique will highlight this approach only.

Anaesthesia and Patient Positioning

Proximal humeral replacement using the Global C.A.P.™ implant can be performed using general anaesthesia, regional anaesthesia (i.e., interscalene block), or a combination of general anaesthesia and regional anaesthesia. Place the patient in a supine position, with the hips flexed approximately 30 degrees, knees bent approximately 30 degrees and back elevated approximately 30 degrees (i.e., the beach chair position). Complete access to the top and back of the shoulder can be achieved through the use of specialised headrests or operating tables with break-away side panels.

Exposure - Deltopectoral Approach

Obtain exposure through a deltopectoral incision extending 10-15 cm inferolaterally from approximately the mid-shaft of the clavicle toward the deltoid insertion. Identify the cephalic vein within the deltopectoral groove. Dissect it away from the pectoralis major, and mobilise it laterally with the deltoid. The superior 1.0-1.5 cm of the pectoralis major insertion may be released from the humerus to improve exposure of the inferior aspect of the joint. Place a self-retaining retractor to retract the deltoid and cephalic vein laterally and the pectoralis major medially.



Deltopectoral incision

fig. 2 **Deltopectoral Incision**

Identify the conjoined tendon of the coracobrachialis and short head of the biceps. Make an incision in the clavipectoral fascia at the lateral-most extent of the conjoined tendon. Carry this incision superiorly to the coracoacromial ligament (fig. 2). Adequate exposure is usually obtained without sacrifice of any portion of the coracoacromial ligament. Therefore, preservation of the coracoacromial ligament may be performed in all arthroplasty cases, especially those with poor quality rotator cuff tissue (i.e., rheumatoid arthritis).

The axillary and musculocutaneous nerves may be injured in any deltopectoral approach. Thus, care should be taken to identify and protect them whenever possible. Routinely identify the axillary nerve at the inferior aspect of the glenohumeral joint, either by digital palpation or direct visualisation. The musculocutaneous nerve has a more variable course, particularly with reference to the distance from the tip of the coracoid to its passage into the posterior surface of the conjoined tendon. Because of this variability, it may not always be easily palpable within the surgical field. However, an attempt should always be made to palpate it. This will help ensure that the nerve can be protected throughout the procedure.

Deep Dissection

With the conjoined tendon retracted medially and the deltoid retracted laterally, the subscapularis muscle and tendon and the anterior humeral circumflex vessels can be easily identified. Clamp and coagulate or ligate the anterior circumflex vessels to prevent excessive bleeding throughout the procedure. Identify the superior and inferior extents of the subscapularis. Superiorly, the subscapularis forms a well-defined tendon that inserts into the lesser tuberosity. Inferiorly, the subscapularis consists of laterally extending muscle fibres with a less well-demarcated tendon that inserts directly into the humerus. Place stay sutures within the tendon in anticipation of its later release.

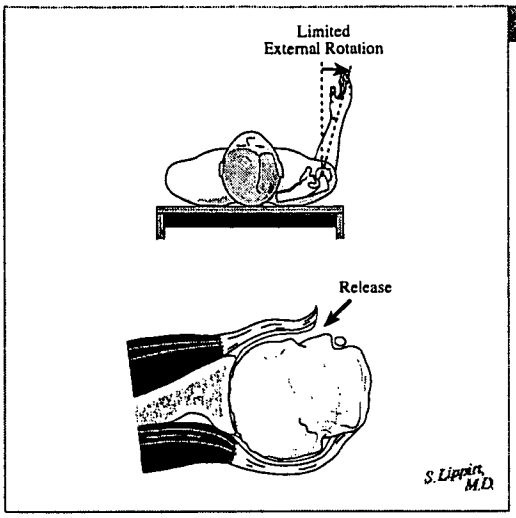


fig. 3 The method of subscapularis release and repair is dependent on the degree of external rotation loss (fig. 3). In patients with 20 degrees or more of preoperative external rotation, incise the subscapularis intratendinously and repair anatomically at the completion of the procedure. If preoperative external rotation is less than 20 degrees, but greater than negative 30 degrees, release the subscapularis from the lesser tuberosity as far laterally as possible and repair to bone at the bone-prosthesis junction, thereby advancing it medially to gain length. On very rare occasions where external rotation is less than negative 30 degrees, perform a z-lengthening of the subscapularis and anterior capsule.

The z-lengthening is accomplished by releasing the subscapularis from the lesser tuberosity as far laterally as possible while preserving the humeral capsular attachment. A small amount of the deep portion of the subscapularis can be left with the anterior capsule for reinforcement. The capsule is released from the glenoid and incised in a medial-lateral direction at the inferior portion of the glenohumeral joint. This creates a laterally based capsular flap and a medially based subscapularis flap with which to perform a z-lengthening.

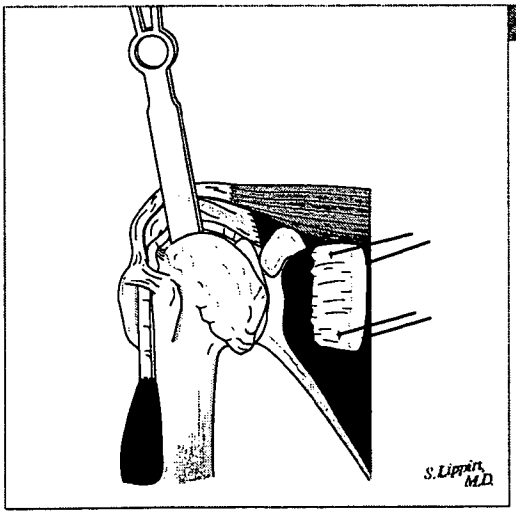


fig. 4 After the subscapularis and capsule have been released by the method that is appropriate for the degree of contracture present, deliver the humerus out of the wound using simultaneous adduction, external rotation and extension of the arm. This requires a complete inferior capsular release from the humeral neck to its posterior inferior attachment (fig. 4).

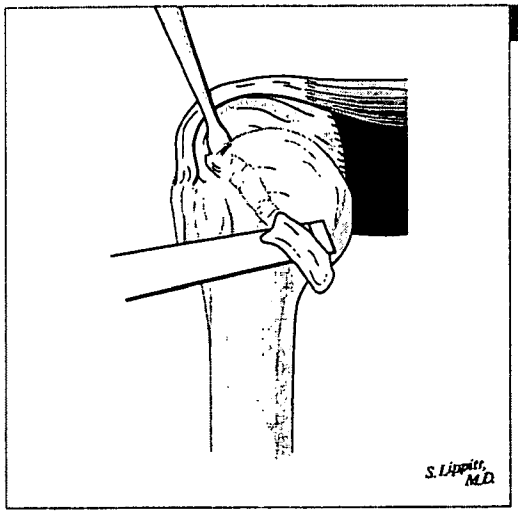


fig. 5 With the humeral head delivered out of the wound, remove all humeral osteophytes (fig. 5). This is a particularly important step, since the anatomic neck must be visualised to guide humeral preparation. Place a curved Crego or reverse Hohmann retractor along the anatomic neck superiorly to protect and retract the long head of the biceps and posterosuperior rotator cuff.

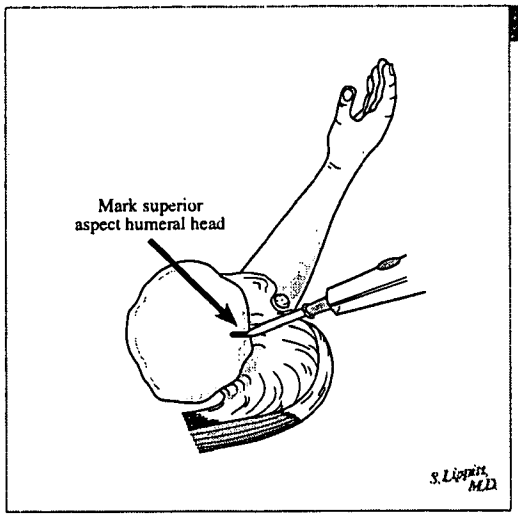


fig. 6 Mark the most superior point of the articular margin or anatomic neck with electrocautery or marking pen (fig. 6).

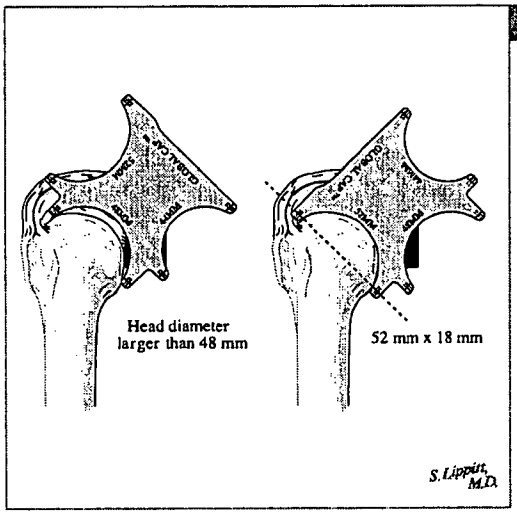


fig. 7 **Head Sizing**

Head sizing is confirmed intraoperatively using the humeral head sizers or humeral head gauge (fig. 7 and fig. 8).

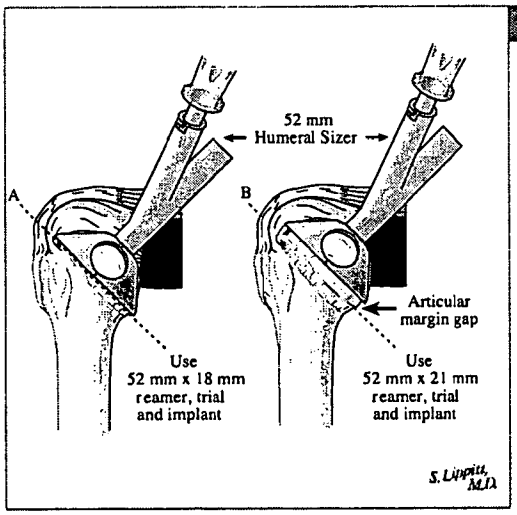


fig. 8 Assemble the appropriate humeral head sizer to the sizer/drill guide handle. Place the sizer over the humeral articular surface, such that its superior mark is aligned with the previously placed mark on the humeral head and the plane of the head sizer rim is parallel with the plane of the anatomic neck of the native humerus.

The appropriate head sizer is determined by identifying the articular margin of the humerus in relation to the inferior edge of the sizer. If the inferior margin is 3 mm below the inferior edge of the sizer, a deeper head height is necessary (fig. 8). Also, note that the interior of the sizer represents the outermost diameter of the definitive implant. If the sizer looks too small or too large, a smaller or larger head sizer can be used.

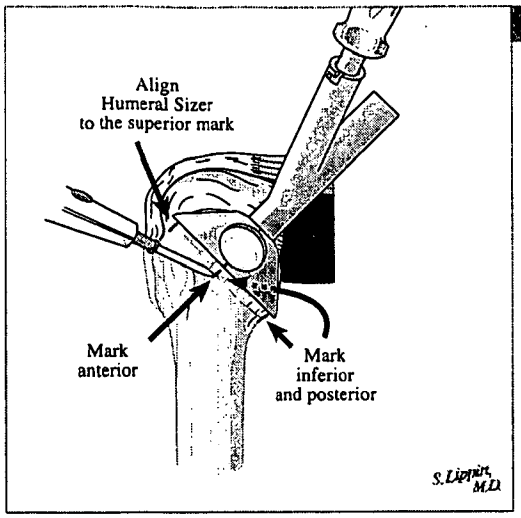


fig. 8a **Identifying Centre of Humeral Head**

Further mark the humerus at the most anterior, posterior and inferior aspects of the sizer (fig. 8a).

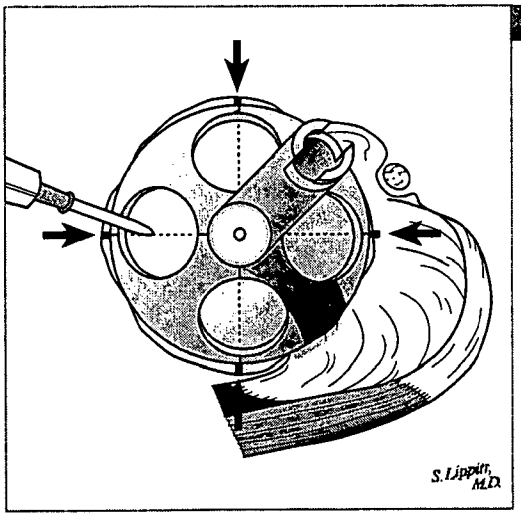


fig. 9 Next, mark the surface of the humeral head along the determined superior-inferior and anterior-posterior axes using electrocautery or marking pen through the round fenestrations in the sizer (fig. 9).

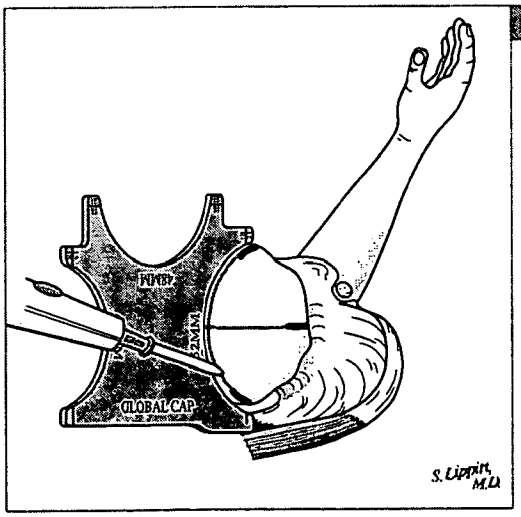


fig. 10 Remove the sizer and visualise the marked surface of the humeral head. **Note: It is important to check that the centre of the sizer/intersecting marks on the corresponding humeral head identify the centre of the humeral head. Identification of the centre will ensure proper guide pin and definitive implant placement.** Complete the interrupted superior-inferior and anterior-posterior lines using the humeral head gauge as a template (fig. 10). If the lines do not intersect at what appears to be the centre of the humeral head, repeat the previous steps until the centre of the humeral head has correctly been identified.

Using the head gauge, confirm the humeral head diameter and thickness.

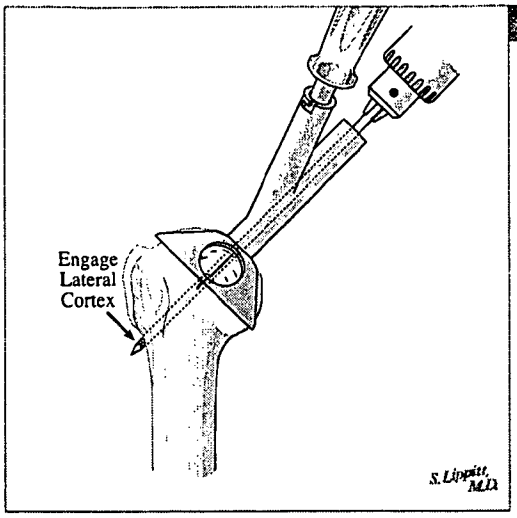


fig. 11 Replace the humeral sizer over the humeral head in the previously determined centre position. Drill the threaded guide pin through the centre of the cannulated sizer, the centre of the humeral articular surface and into the humeral head (fig. 11). The tip of the guide wire should penetrate the lateral cortex of the humerus. **Note: Full penetration of lateral cortex will prevent guide pin from migrating in cancellous bone.** Remove the humeral sizer.

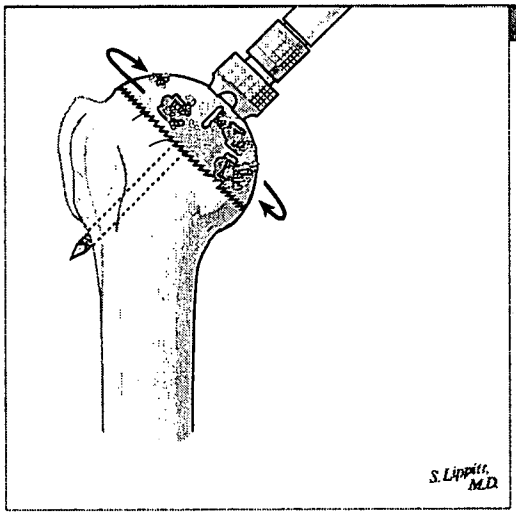


fig. 12 **Humeral Head Shaping**

Based on previously determined head size, perform humeral shaping with the appropriate size reamer (fig. 12).

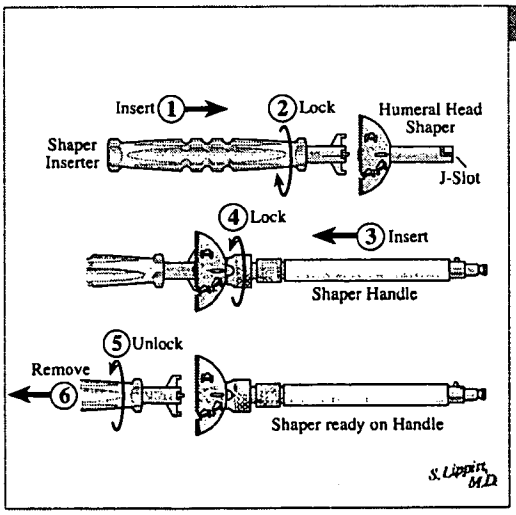


fig. 13 Assemble the appropriate reamer to the shaper/drill guide handle and tighten using the assembling tool (fig. 13). **Note: When inserting the reamer to the humeral head shaper handle, the J-slot of the reamer must be engaged with the shaper handle before the neck can be locked. Turn the neck counterclockwise to lock handle.**

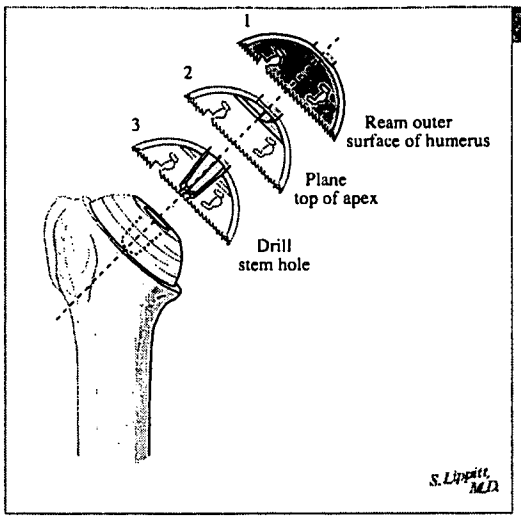


fig. 14 Connect the reamer to power. Pass the assembled reamer over the guide wire onto the humeral head. Ream until bone chips are seen to exit from the most superior holes in the peripheral surface of the reamer (fig. 14). Reaming depth can also be checked by observing the distance between the advancing reamer and the rotator cuff attachment site. **Note: Reaming should cease before the sharp-toothed edge of the reamer damages the rotator cuff attachment.** There may be some apparent cancellous bone at the superior shelf of the reamed humeral head. The humeral bone fragments generated from the reaming process can be saved for bone graft between the implant and humerus if needed. The reaming process creates a shelf, equal in width to the thickness of the eventual implant at the base of the humeral head in the anatomic neck region. Any attached fragments of bone that might interfere with complete seating of the trial or implant should be excised with a rongeur. Remove all remaining osteophytes so that the implant forms a smooth transition to the peripheral rim of the humeral head.

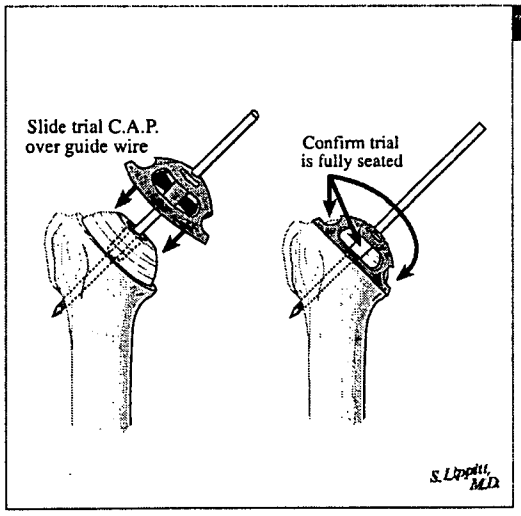


fig. 15 **Implant Trialing**

Use the trial to assess final implant size and fit (fig. 15). Pass the appropriate cannulated trial implant over the guide wire onto the reamed humeral surface. If the trial is the appropriate size and reaming has been adequately performed, the trial should seat completely so that the edge of the trial rests on the shelf created at the anatomic neck region. **Note: Check to ensure there is uniform contact between the undersurface of the trial and the bone.** The trials have large viewing windows to aid in this visualisation. Remove the trial using the trial grasping tool.

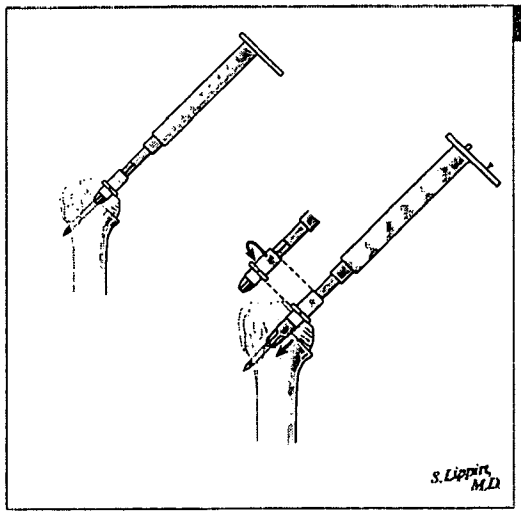


fig. 16 **Central Stem Preparation**

The shape of the definitive implant's stem is a cruciform. This shape improves implant rotational stability. The cannulated cruciform stem punch is used to create a path for the implant stem in the unreamed cancellous bone in the base of the central hole and ensure correct stem seating of the implant (fig. 16). Pass the stem punch over the guide pin and into the central hole in the humeral head. Place the centring sleeve into the locked position by turning it clockwise one-quarter turn. Advance the stem punch shaft into the reamed central hole. Rotate the centring sleeve one counter-clockwise turn to unlock the punch and then impact the stem punch with a mallet into the cancellous bone of the humerus. The depth of penetration is controlled by the centring sleeve. Remove the central guide pin. **Note: When impacting the stem punch, avoid impacting the mallet over drill pin hole to avoid striking the pin.**

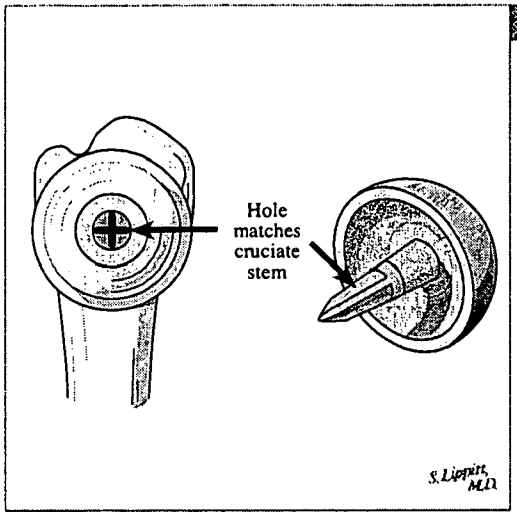


fig. 17 The stem punch ensures that the axes of the punch and the eventual implant stem are co-linear (fig. 17). If these two axes are divergent, the implant may not be completely seated.

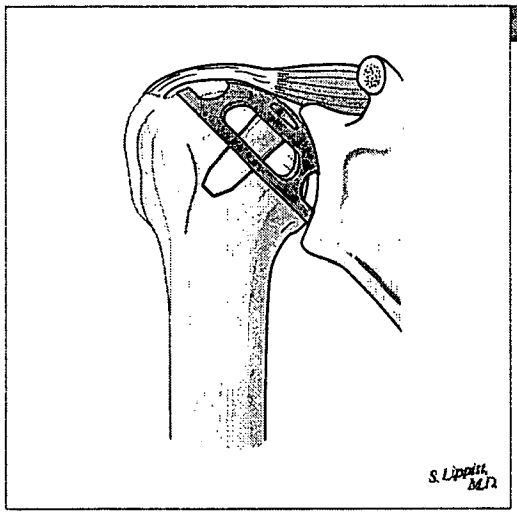


fig. 18

Soft-tissue Releases

Regardless of whether or not a glenoid component will be used in combination with this implant, soft-tissue releases are required to maximise postoperative range of motion. A ring retractor may be used to retract the humeral head posteriorly. However, extreme care must be observed so that the retractor does not damage the reamed humeral surface. The humeral head trial may be re-inserted to aid in protection of the reamed bone (fig. 18). Circumferential release of the glenohumeral joint capsule may then be accomplished. In cases where the anteroinferior capsule is pathologically thickened, it can be excised. Glenoid preparation may also be performed if necessary.

After appropriate soft-tissue releases have been performed, evaluate soft-tissue tension. Re-insert the humeral head trial and reduce the humerus into the glenoid fossa. As a general rule, with the humerus in neutral rotation and the arm in 0-20 degrees of scapular plane abduction, a posteriorly directed subluxating force should cause posterior translation of 50 percent of the humeral head (fig. 18). In addition, the subscapularis should be long enough to reattach to its insertion site, allowing the arm to go to at least 30 degrees of external rotation.

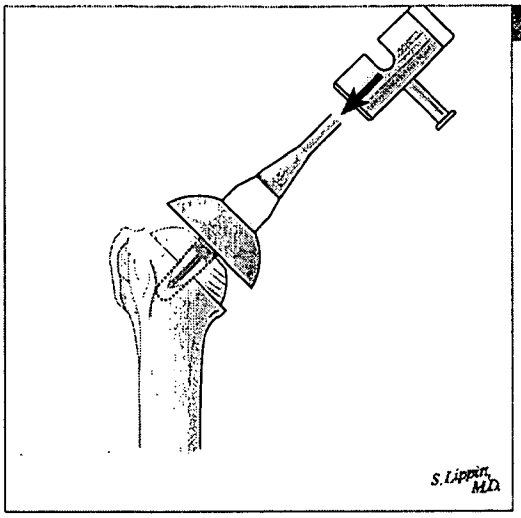


fig. 19 **Implant Placement**

Expose the humeral head so that the entire prepared surface of the humerus can be seen. Remove the humeral trial. Place the stem of the humeral head implant into the central hole with the cruciform flanges aligned in the appropriate cruciate path. Use the head impactor tool to completely seat the implant with a mallet (fig. 19).

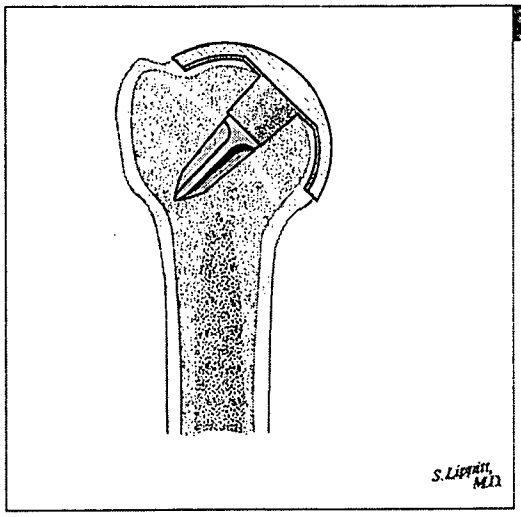


fig. 20 Verify that the implant has been fully seated. There should be no gap from the periphery of the implant and reamed margin of the humerus. Reduce the humerus into the glenoid fossa (fig. 20).

Cross-section of humeral head with Global C.A.P.™ implant

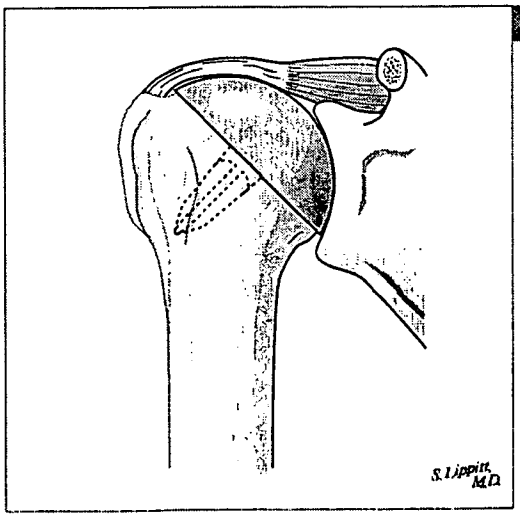


fig. 21 After joint reduction, verify that the shoulder has the desired amount of laxity (fig. 21).

Definitive Global C.A.P.™ implant

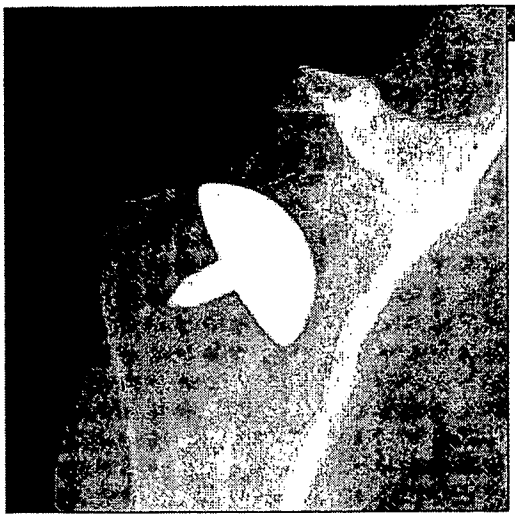


fig. 22

Closure

Repair the subscapularis according to the method of detachment. If the subscapularis was released intratendinously, repair it anatomically, tendon-to-tendon. If it was released from the lesser tuberosity with maximum length, it is most often advanced medially to the implant-bone junction and repaired to bone. On rare occasions, a z-lengthening is performed using the medially based subscapularis tendon and the laterally based anterior capsule. Following subscapularis closure, passive external rotation with the arm at the side should be at least 30 degrees. Close the deltopectoral interval. In a routine fashion, close the subcutaneous tissue and skin. Radiographs should be taken to verify implant positioning and seating (fig. 22).

Aftercare

Begin pendulum exercises and passive range of motion within 24 hours of surgery. There are no limits to the passive range of motion performed, except that external rotation should not exceed the safe zone of rotation observed at surgery after subscapularis closure. A sling may be used for comfort and protection. An overhead pulley is added at four to six weeks. Passive stretching and strengthening exercises of the rotator cuff, deltoid and scapular muscles should commence at six weeks postoperatively. These exercises are progressed as tolerated over the next three to six months. Complete recovery from surgery occurs at 9-12 months.

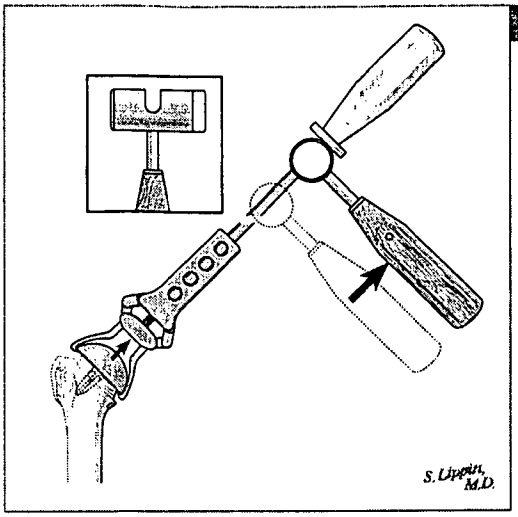


fig. 23 **Extraction of the Implant**

Indications for revision may include infection, glenoid wear, implant loosening or dislocation. Additionally, in rare cases, removal of the implant may be required during revision surgery. Attain exposure as described previously. Attach the extractor tool to the implant that is to be removed (fig. 23). This may require removal of a small amount of bone at the edge of the implant to allow the extraction tool to be attached to the edge of the implant. Extract the implant using a slotted mallet. If the implant is well-fixed, a saw can be used to cut the periphery of the humerus at the bone-implant junction. The implant and the contained humeral bone can then be removed together. The surface of the remaining humerus can then be prepared for conversion to a Global™ Advantage® stem (Global™ Advantage® Surgical Technique Cat. No. 0601-69-050).

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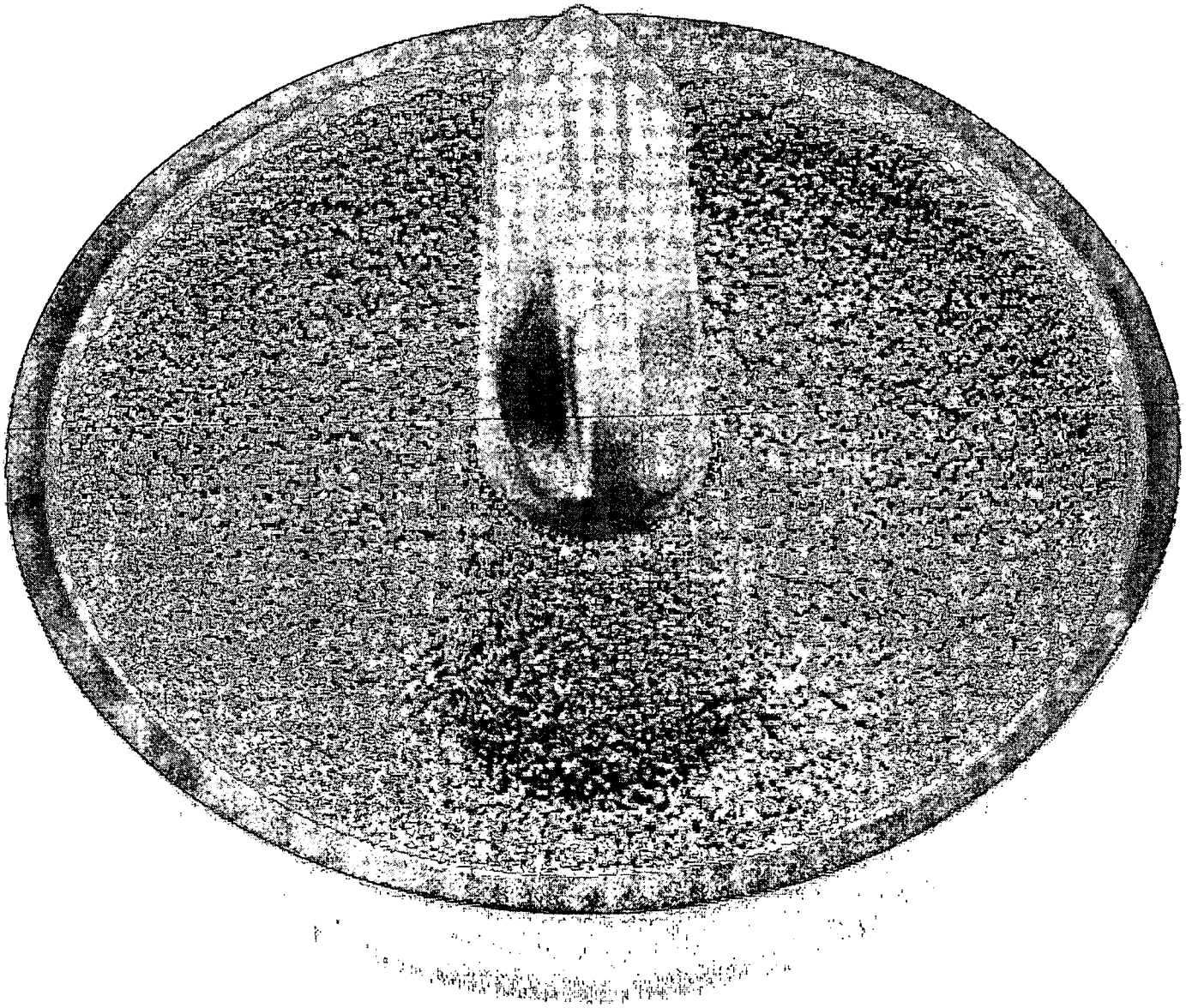
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1230-48-010	Global C.A.P.™ Head Porocoat® Porous Coated 48 x 18
1230-48-020	Global C.A.P.™ Head Porocoat® Porous Coated 48 x 21
1230-52-010	Global C.A.P.™ Head Porocoat® Porous Coated 52 x 18
1230-52-020	Global C.A.P.™ Head Porocoat® Porous Coated 52 x 21
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1230-56-020	Global C.A.P.™ Head Porocoat® Porous Coated 56 x 21

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1230-44-015	Global C.A.P.™ Head DuoFix™ HA 44 x 18
1230-48-015	Global C.A.P.™ Head DuoFix™ HA 48 x 18
1230-48-025	Global C.A.P.™ Head DuoFix™ HA 48 x 21
1230-52-015	Global C.A.P.™ Head DuoFix™ HA 52 x 18
1230-52-025	Global C.A.P.™ Head DuoFix™ HA 52 x 21
1230-56-015	Global C.A.P.™ Head DuoFix™ HA 56 x 18
1230-56-025	Global C.A.P.™ Head DuoFix™ HA 56 x 21

INSTRUMENTATION

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2001-66-000	Impactor Tip
2128-61-017	Glenoid Graspers
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2230-52-020	Global C.A.P.™ Humeral Head Trial 52 x 21
2230-56-010	Global C.A.P.™ Humeral Head Trial 56 x 18
2230-56-020	Global C.A.P.™ Humeral Head Trial 56 x 21
2230-80-010	Global C.A.P.™ Humeral Head Sizer/Drill Guide 40
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2230-80-030	Global C.A.P.™ Humeral Head Sizer/Drill Guide 48
2230-80-040	Global C.A.P.™ Humeral Head Sizer/Drill Guide 52
2230-80-050	Global C.A.P.™ Humeral Head Sizer/Drill Guide 56
2230-80-060	Global C.A.P.™ Humeral Head Sizer/Drill Guide Handle
2230-81-010	Global C.A.P.™ Humeral Head Shaper 40 x 15
2230-81-020	Global C.A.P.™ Humeral Head Shaper 40 x 18
2230-81-030	Global C.A.P.™ Humeral Head Shaper 44 x 15
2230-81-040	Global C.A.P.™ Humeral Head Shaper 44 x 18
2230-81-050	Global C.A.P.™ Humeral Head Shaper 48 x 18
2230-81-060	Global C.A.P.™ Humeral Head Shaper 48 x 21
2230-81-070	Global C.A.P.™ Humeral Head Shaper 52 x 18
2230-81-080	Global C.A.P.™ Humeral Head Shaper 52 x 21
2230-81-090	Global C.A.P.™ Humeral Head Shaper 56 x 18
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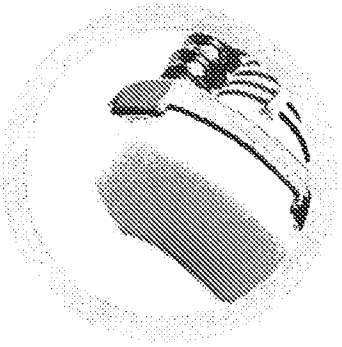
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	Glenoidi cementati (TiAl6V4PE)	Cemented Glenoids (TiAl6V4PE)
7560.50.005	SMALL	SMALL
7560.50.010	STANDARD	STANDARD
7560.50.030*	MINIGLENOIDE	MINIGLENOID
	* su richiesta	on Request

	Glenoidi non cementati (TiAl4V) e inserti (UHMWPE)	Uncemented Glenoids (TiAl4V) and Liners (UHMWPE)
	componente metal back	Metal Back Component
7570.20.005	riv. HA, S	HA Coated - S
7570.20.010	riv. HA, STD	HA Coated - STD

	Inserto per glenoide metal back	Liner for Metal Back Glenoid
7565.50.005	S	S
7565.50.010	STD	STD

	Viti di fissaggio (TiAl4V)	Bone Screws (TiAl4V)
	dia. 6.5 mm	dia. 6.5 mm
8420.15.010	h. 20 mm	h. 20 mm
8420.15.020	h. 25 mm	h. 25 mm
8420.15.030	h. 30 mm	h. 30 mm

	Strumentario	Instrument Set
9075.50.000	set	Set

	Set comune per viti	General Set for Bone Screws
9084.20.000	set	Set

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Glenohumeral Joint Translations before and after Total Shoulder Arthroplasty. A Study in Cadavera

ANDREW R. KARDUNA, GERALD R. WILLIAMS, JOHN L. WILLIAMS and JOSEPH P. IANNOTTI

J Bone Joint Surg Am. 1997;79:1166-74.

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Glenohumeral Joint Translations before and after Total Shoulder Arthroplasty

A Study in Cadavera*

BY ANDREW R. KARDUNA, PH.D.†, GERALD R. WILLIAMS, M.D.‡, JOHN L. WILLIAMS, PH.D.§, AND JOSEPH P. IANNOTTI, M.D., PH.D.‡, PHILADELPHIA, PENNSYLVANIA

Investigation performed at the Departments of Orthopaedic Surgery and Bioengineering, University of Pennsylvania, Philadelphia

ABSTRACT: The purpose of the present study was to examine the motions of natural and prosthetically reconstructed glenohumeral joints without capsular contracture in the laboratory to obtain a better understanding of joint motion as it may relate to failure of the implant. Seven joints from fresh-frozen human cadavera were instrumented with a six-degrees-of-freedom magnetic tracking device to study patterns of translation and rotation with and without the application of simulated muscle forces (active and passive models). The specimens were tested before and after reconstruction of the joint with use of modified operative techniques and implants that had from zero to five millimeters of radial mismatch between the humeral head and glenoid components.

The natural and reconstructed joints had similar patterns of translation, with larger rotations and translations observed in the passive model. On the average, the active translations of the natural joints were best reproduced by the reconstructed joints with less conforming articulations. The mean active translation in the natural joints was 1.5 millimeters along the anterior-posterior axis and 1.1 millimeters along the superior-inferior axis. The active translations in the reconstructed joints were observed to increase consistently as the conformity of the components decreased: the mean active anterior-posterior translations ranged from 0.3 millimeter for conforming components to 1.7 millimeters for components with a five-millimeter radial mismatch, and the mean active superior-inferior translations ranged from 0.4 to 1.1 millimeters. The patterns of translation during passive motions were less consistent, presumably because of the influence of capsular ligaments and because the translations were large enough for the articular surface of the humeral head to lose contact with the articular surface of the glenoid component.

CLINICAL RELEVANCE: Glenohumeral translations during active motions were found to depend on articular conformity, which indicates that the choice of implants may have important consequences for normal motions. Totally conforming designs may impose a degree of restraint to translations that is higher than that in the natural joint. The patterns of translation may influence the longevity of the joint replacement with respect to stability, loosening of the glenoid component, and wear of the components.

Although less common than total hip or knee arthroplasty, total shoulder arthroplasty is performed on a regular basis and is the preferred operative treatment for end-stage glenohumeral arthritis. Total shoulder arthroplasty involves resurfacing of the articular surface of both the glenoid cavity and the humeral head as well as balancing of the rotator cuff and capsular ligaments. These changes have important implications with regard to joint motions because of their effect on articular geometry, the lines of action of muscles, and soft-tissue tensions. Of particular interest are glenohumeral translations, which are related to the stability of the joint and the patterns of joint-loading[7,21]. Translations also may lead to loosening of the glenoid component by altering the stresses developed at the site of fixation of the implant. Although there has been a myriad of published reports on natural glenohumeral translations, few studies have addressed glenohumeral translations after shoulder arthroplasty[5,9,11].

Currently, the most commonly used implant is the so-called unconstrained design, in which the height of the glenohumeral wall is minimum[6,24]. Some recently designed unconstrained systems include a glenoid component that has a radius of curvature that is greater than that of the humeral head component[6]. Although these types of implants are widely used, the effects of varying

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articular conformity on glenohumeral motions are currently unknown. There also is a lack of understanding of how varying the conformity of the components alters joint motions compared with those of natural (unreconstructed) joints.

Friedman used routine radiographs to measure *in vivo* translations during active motions in the horizontal plane; despite the use of conforming components, a mean of four millimeters of anterior-posterior translation was observed. Harryman et al. used a passive cadaveric model to compare the translations associated with conforming and non-conforming components[11]. They found no significant differences ($p > 0.05$) with regard to laxity of the joint, ranges of motion, and glenohumeral translations when shoulders were moved through various passive ranges of motion. However, they observed greater translations during passive motions than Friedman found during active motions.

A previous study in our laboratory showed that, when positioned actively, natural joints displayed different patterns of translation depending on whether the articulation was conforming or non-conforming[16]. We hypothesized that this response is simply a subset of a more general relationship between articular conformity and translation and could be extended to prosthetic glenohumeral joints. Therefore, the primary purpose of the present investigation was to study the influence of articular conformity on translations in glenohumeral prostheses. The effects of muscle forces and ligamentous constraints on translations also were investigated. Finally, we compared the glenohumeral translations before and after total shoulder arthroplasty.

Materials and Methods

Preparation of the Specimens

Glenohumeral joints were obtained from fresh-frozen cadavera. Each shoulder was dissected to the level of the rotator cuff, with preservation of the distal humeral condyles and the site of insertion of the deltoid muscle. Shoulders that were found to be abnormal, on either radiographic or physical examination, were eliminated from the study. Seven specimens from the cadavera of individuals who were a mean of seventy-three years old (range, fifty-four to eighty-seven years old) at the time of death were used. Each joint was vented to eliminate any effects of intra-articular pressure. The joints were stored frozen, thawed at room temperature before testing, and kept moist with a protease-inhibitor solution during experimentation.

Simulated deltoid muscle forces were applied with strands of low-stretch braided Dacron, which were attached to the site of insertion of the deltoid on the humerus by a transosseous bolt. The strands of Dacron were placed through three eyelets on the scapula that corresponded approximately to the mid-points of the anatomical origins of the anterior, middle, and posterior portions of the deltoid muscle (the tip of the coracoid and the anterior and posterior portions of the acromion, respectively).

For simulation of the rotator-cuff muscles, Dacron cord was sewn, in a Bunnell suture pattern, directly into the tendinous insertion of the subscapularis, the supraspinatus, and the combined infraspinatus-teres minor complex. The infraspinatus and subscapularis fossae were cleaned of all soft tissue, and the muscle centroids were marked. Pulleys were placed on the potting base so that the lines of action of the rotator cuff were aligned with the centroids marked on the muscles.

As the entire protocol was performed at 90 degrees of humeral elevation, the scapula was potted in Bondo (Dynatron/Bondo, Atlanta, Georgia) with its medial border aligned at 30 degrees of scapular elevation in order to achieve a 2:1 ratio of glenohumeral-to-scapulothoracic motion. To ensure proper alignment, the scapula was held in its desired position with alignment bolts and the Bondo was injected into the base with Monoject catheter-tip syringes (Sherwood Medical, St. Louis, Missouri). Muscle forces were simulated with a hand-crank system that has been described elsewhere[16].

Technique for Arthroplasty

Each shoulder-implant system (DePuy, Warsaw, Indiana) consisted of a humeral stem, a humeral head, and a glenoid component. A titanium-alloy humeral stem of appropriate size (eight or ten millimeters in diameter) with a reverse locking taper fitting at its neck was chosen for each specimen. Six cobalt-chromium-alloy humeral head components, with a nominal radius of curvature ranging from twenty to twenty-five millimeters in one-millimeter increments, were used in each specimen. In order to maintain consistent capsular tensioning, all of the humeral head components had the same neck length, so that the distance from the resected surface of the humerus to the most proximal point of the head was constant. Keeled glenoid components were made of ultra-high molecular weight polyethylene, and the articular surface had a nominal radius of curvature of twenty-five millimeters. The glenoid component was combined with each of the six humeral head components, yielding six articulations with zero, one, two, three, four, or five millimeters of mismatch between the radii of curvature of the glenoid and humeral head components. The actual curvature of each humeral head and glenoid component was measured with a custom-made profilometer on an MTS mechanical testing machine (Minneapolis, Minnesota)[16].

With the standard technique for clinical prosthetic implantation, the subscapularis tendon is incised and repaired and the anterior-inferior capsular ligament complex often is excised[8,20]. Healing of the tendon and the ligament is necessary for a functional structure after the operation. Because we wanted to minimize operative alterations of the length of the normal capsular ligament tissue during implantation in this cadaver model, an alternative procedure was developed to minimize soft-tissue damage.

An incision was made through the capsular interval between the subscapularis and supraspinatus tendons (the rotator-interval region of the capsule). The entire humerus, including the head, was split longitudinally through this incision to the distal part of the humerus with use of a power sagittal saw. The shaft was opened like a book so that the inside of the joint could be viewed, and a humeral osteotomy template was used to score both halves of the head. The sagittal saw was used to resect each half of the humeral head by starting at the score and proceeding to the edge of the articular surface in both halves. This ensured that the plane of resection approximated the anatomical retroversion of the humeral head. With removal of the head, the glenoid was easily accessible, with little operative alteration of the joint capsule. The glenoid surface was reamed so that its curvature matched that of the back of the glenoid component, and a keeled glenoid component was fixed in place with polymethylmethacrylate (Zimmer, Warsaw, Indiana) and standard cementing techniques[8,20].

Marrow was removed from the medullary canal of the humerus, and polymethylmethacrylate was inserted into both halves of the shaft. The humeral stem was positioned so that the lateral fin came to rest approximately three to five millimeters posterior to the bicipital groove. The two halves of the shaft were brought together and held in place with plastic cable ties, producing a rigid and anatomical configuration.

After this procedure, the joint capsule was intact, except for a longitudinal incision in the rotator interval. A humeral head component was inserted into the joint through this incision, and the interval was anatomically closed with sutures. Once testing with a particular humeral head had been completed, the rotator interval was reopened

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by removing the sutures. The head was extracted, another was inserted, and the interval was again closed with sutures. This procedure was repeated for all six of the humeral head components for each specimen. Before insertion, each head was coated with K-Y lubricating jelly (Johnson and Johnson, New Brunswick, New Jersey) to reduce friction between the metal and plastic components.

Motion Analysis

Coordinate System

Joint motions were monitored with a six-degrees-of-freedom magnetic tracking device (3Space Fastrak System; Polhemus, Colchester, Vermont)[1,19]. The transmitter of the device was fixed to the scapula, and a scapular axis was defined on the basis of the plane of the scapula (two points on the medial border and one at the center of the glenoid curvature)[16]. The receiver of the device was fixed to the humerus, and a humeral axis was defined so that it was aligned with the scapular axis when the humerus was in its neutral position — that is, with the center of the humeral head coinciding with the center of the glenoid, the extremity at the side, and the humeral condyles parallel to the plane of the scapula. Translations were recorded along the superior-inferior, medial-lateral, and anterior-posterior axes. Euler angles were used to represent three sequence-dependent rotations: the plane of elevation, the degree of elevation, and internal-external rotation, as described by An et al.[2].

This procedure was used to collect the data for both natural and reconstructed joints. Arthroplasty did not alter the alignment of the medial border of the scapula or the neutral orientation of the humerus; it did, however, alter the centers of the glenoid and the humeral head. Therefore, it was necessary to define different coordinate systems for each reconstructed joint. This was done once the entire experimental protocol had been completed, as it required complete excision of the joint capsule. Thus, all data were saved in an uncalibrated format and subsequently were calibrated with the appropriate axis system.

Center of the Glenoid Component

Once the entire experimental protocol had been completed, the capsule was excised. In order to find the center of the implanted glenoid component, the conforming humeral head (the component with a twenty-five-millimeter radius of curvature) was placed on the humeral stem, and the humerus was rotated through a central range of motion (one in which the ligaments were not taut), with the head centered in the glenoid component. The point that moved the least in the scapular reference frame was defined as the center of the glenoid component. As the same glenoid component was used for all of the experiments performed after the arthroplasties, this center was used for the coordinate-axis system for all of the implants.

Center of the Humeral Head Component

To determine the center of the humeral head component, it was necessary to articulate the head with a conforming glenoid component. Because only one of the humeral heads had a radius of curvature (twenty-five millimeters) that conformed with that of the glenoid component, additional glenoid components were machined to fit snugly over the implanted component. Each of these so-called calibration glenoid components matched the radius of curvature of one of the six heads. In turn, each head was rotated passively on its matching calibration glenoid component, and the point that moved the least in the humeral reference frame was defined as the center of that humeral head component.

Subtraction of Systematic Errors

As the magnetic tracking device is susceptible to error when it is in the vicinity of a metal object[10,12], we attempted to increase its accuracy by subtracting systematic errors. This involved articulating the humeral head under conditions of no translation. Therefore, the passive experimental protocol was repeated for each humeral head by articulating it with its corresponding calibration glenoid component after the entire capsule had been excised. The translations that were recorded during these motions then were subtracted from the translations that were recorded during the actual experiment.

Errors in Measurement

Although the accuracy of the magnetic tracking device for these experiments in the absence of metal was found to be approximately 0.4 millimeter at the 95 per cent confidence level[16], the effect of metal in the environment was assessed in the present study. After the capsule had been excised, the passive experimental protocol was repeated with the conforming (twenty-five-millimeter) humeral head on the original, implanted glenoid component. Because there should be no translation during this so-called zero translation motion, translations that were recorded after subtraction of systematic errors were considered an indication of random error.

Experimental Protocol

The glenohumeral joint was positioned in maximum internal rotation and then externally rotated in 10-degree increments until maximum external rotation was achieved. This protocol was chosen because both internal and external rotation are positions in which the capsular ligaments are presumed to be tight. A previous study of the motions of the natural glenohumeral joint demonstrated that the patterns of translations during active and passive internal-to-external rotation motions were similar for various planes and elevations[16]. Therefore, only one position was used for testing in the present study: 90 degrees of total elevation (60 degrees of glenohumeral elevation and 30 degrees of scapulothoracic elevation) in the plane of the scapula.

At each increment of external rotation, the elevation and the plane were maintained within 5 degrees of the desired values, and the rotation was maintained within 1 degree of the target value. Experiments were conducted first on the natural joint, after which the arthroplasty was performed and testing was repeated with each of the six humeral head components in place, in a random order.

Active and passive motions were performed in a random order on the natural joint and each implant. Active motions were achieved by applying forces to the sites of the insertions of the muscles with use of the hand cranks and spring scales. A 2.3-kilogram mass was hung on the distal end of the humerus to approximate the weight of the upper extremity. Maximum rotation during active motions was set with a sixty-newton force on either the infraspinatus-teres minor complex or the subscapularis.

For passive motions, the medially applied centering load was achieved by the application of a ten-newton force to each of the simulated rotator-cuff muscles with use of hanging weights and pulleys. Maximum rotation during passive motions was set by the application of torque through a torque wrench attached to the end of the humeral shaft. In order to approximately reproduce the torque that had been achieved actively (a sixty-newton force multiplied by a twenty-five-millimeter moment arm), a maximum torque of 1.5 newton-meters was set for both internal and external rotation.

On completion of the experimental protocol, the anterior and posterior bands of the inferior glenohumeral ligament were identified by palpation. By following along the length of these bands, we were able to identify their sites of osseous origin and insertion, and these were digitized with the stylus of the magnetic tracking device. After the location of the origin in the scapular axis and the insertion in the humeral axis had been determined, the distance between these two points was calculated from the data collected with the tracking device during experimentation. This method allowed us to determine the lengths of the bands for each experimental position[13].

The range of motion for a given experiment was defined as the

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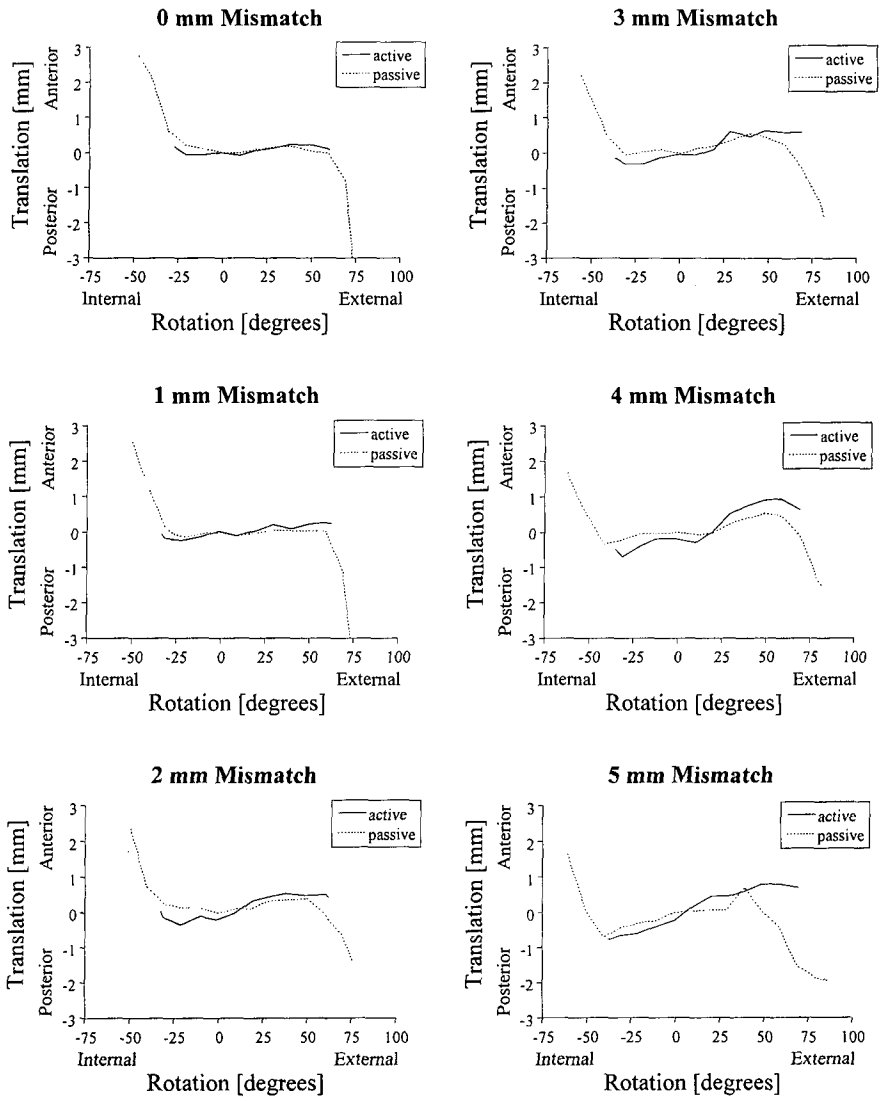


FIG. 1

Plots of the active and passive anterior-posterior translations in a representative specimen tested with the six different sizes of humeral head component. Zero translation was set arbitrarily at neutral rotation for the passive model.

angle between the points of maximum internal and external rotations. The net anterior-posterior and superior-inferior translations were defined as the maximum translations over the range of motion for that experiment.

Statistical Analysis

SYSTAT (Version 5.2 for the Macintosh computer; Systat, Evanston, Illinois) was used for statistical analysis. A repeated-measures analysis of variance was performed for each dependent variable with two within-subject factors: model (active and passive) and experiment (the natural joint and the six implants). A Bonferroni correction factor was used to account for the fact that a total of five analysis-of-variance tests were performed (range of motion, anterior-posterior translation, superior-inferior translation, and the lengths of the anterior and posterior bands of the inferior glenohumeral ligament). *A priori* comparisons (or contrasts) between group means were planned before the experimentation. Unlike *post hoc* tests, which essentially make all possible comparisons, contrasts allow for fewer comparisons among means[22]. To determine the effects of arthroplasty, contrasts were made between the value for the natural joints and the group mean for the reconstructed joints. To determine the effects of alteration of the articular conformity, polynomial contrasts were used to test for linear trends among the implants. Because the contrasts used in the present study were orthogonal, or independent, a Bonferroni correction factor was not used[18,22]. The acceptable rate for a type-I error was chosen as 5 per cent ($p = 0.05$) for all tests.

Results

Accuracy of Measurements

Translation

The net anterior-posterior and superior-inferior translations for the so-called zero translation motion (articulation of the humeral head component with a conforming glenoid component after capsular excision) were calculated for each specimen. The range of motion used was set at the maximum active and passive range of motion for that specimen. After subtraction of systematic errors, translation errors (at the 95 per cent confidence level) were 0.5 millimeter for passive motions and 0.3 millimeter for active motions.

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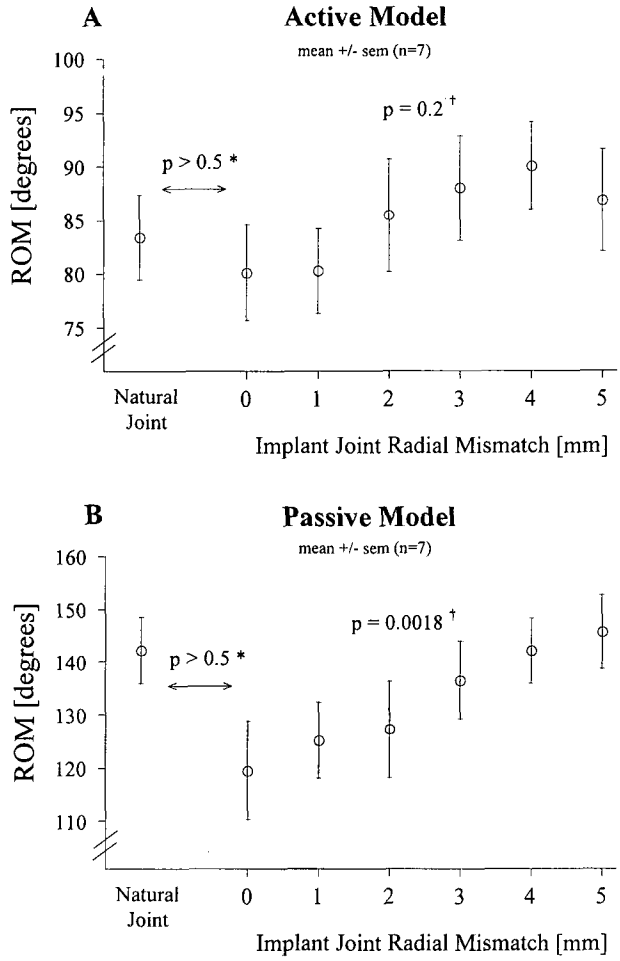


FIG. 2

Graphs showing the ranges of motion (ROM) of the natural and reconstructed joints in the active and passive models. (Note that the axes for the range of motion are not the same for the two plots.) The p value indicated by the asterisk was derived with a contrast between the mean value for the natural joints and the group mean value for all of the reconstructed joints. The p value indicated by the dagger was derived with a linear polynomial contrast among the reconstructed joints. SEM = standard error of the mean.

Radius of Curvature

Measurements of articular geometry were made for all of the glenoid and humeral head components used in the present study. The mean difference between the measured and nominal values for the radius of curvature for both components was less than 2 per cent. Therefore, the nominal values were used in all of the analyses of the data.

Arthroplasty Procedure

Because all of the humeral components had a neck of the same length, each reconstructed joint was moved laterally by approximately the same amount (mean, seven millimeters; range, three to twelve millimeters) at 60 degrees of glenohumeral elevation in the scapular plane and the upper extremity in neutral rotation. Although the length of the neck was kept constant, the width of the neck and the centers of the articular surfaces varied as a result of changes in the radii of curvature. The humeral components were found to have a mean retroversion angle of 26 degrees (range, 10 to 42 degrees) and a mean neck-shaft angle of 41 degrees (range, 34 to 48 degrees).

Comparison of Active and Passive Models

The mean range of motion of the glenohumeral joint was found to be greater ($p = 0.0005$) during passive motions than during active motions (134 compared with 85 degrees). In fact, the passive range of motion exceeded the active range of motion in all experiments on every specimen. Along the anterior-posterior axis, the mean translations were also greater ($p = 0.05$) in the passive model (6.3 millimeters) than in the active model (1.1 millimeters). As with the data for range of motion, the passive translations exceeded the active translations in all experiments on every specimen. In both the natural and the reconstructed joints, these larger passive anterior-posterior translations occurred at the extremes of internal and external rotation — regions of motion that are not achievable actively. Anterior translation occurred at the extreme of internal rotation, and posterior translation occurred at the extreme of external rotation (Fig. 1). Although the mean superior-inferior translations also were greater in the passive model (2.5 millimeters) than in the active model (0.9 millimeter), these results were not found to be significantly different ($p = 0.075$), with the numbers available. In addition, the patterns of superior-inferior translation at the extremes of motion were not as consistent as the anterior-posterior translations.

Active Model

Comparison of Natural and Reconstructed Joints

In general, the data for active translation and the range of motion were similar for the natural and reconstructed joints. With the numbers available, we could detect no significant difference ($p > 0.5$) between the mean active range of motion before the arthroplasty (83 degrees) and that after the arthroplasty (85 degrees) (Fig. 2). In addition, no significant difference ($p > 0.5$) was detected between the mean superior-inferior translations before (1.1 millimeters) and after (0.8 millimeter) the arthroplasty (Fig. 3) or between the mean anterior-posterior translations before (1.5 millimeters) and after (1.0 millimeter) the arthroplasty (Fig. 4).

Effects of Articular Conformity

Changes in the active range of motion could not be accounted for by increases in the radial mismatch between the components of the prosthetically reconstructed joints ($p = 0.2$) (Fig. 2). Significant linear increases, however, were observed in both superior-inferior ($p = 0.01$) and anterior-posterior ($p = 0.0015$) translations (Figs. 3 and 4); the relative increases were 175 per cent (from 0.4 to 1.1 millimeters) and 467 per

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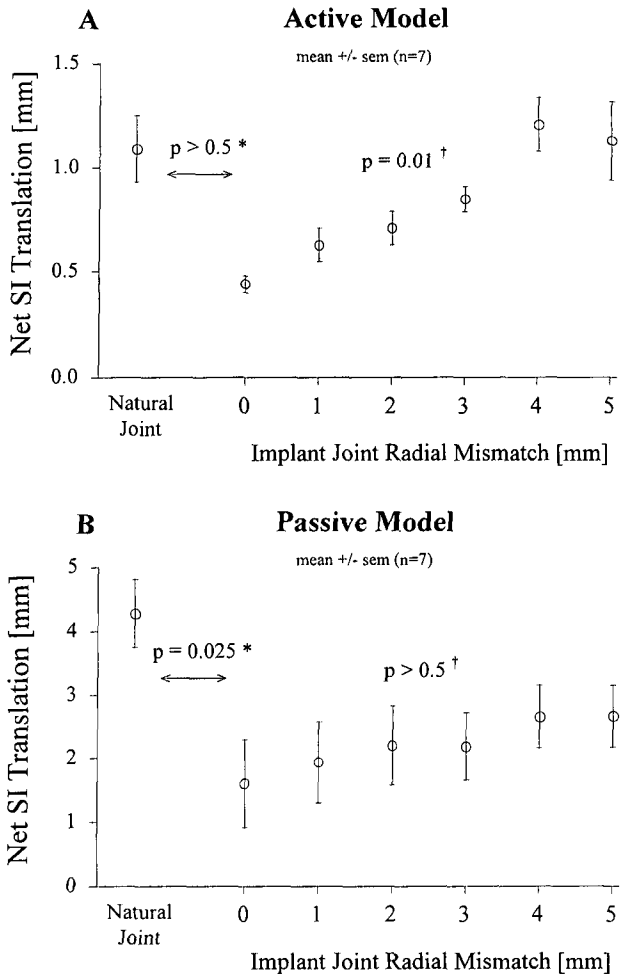


FIG. 3

Graphs showing the net superior-inferior (SI) translations of the natural and reconstructed joints in the active and passive models. (Note that the axes for translation are not the same for the two plots.) The p value indicated by the asterisk was derived with a contrast between the mean value for the natural joints and the group mean value for all of the reconstructed joints. The p value indicated by the dagger was derived with a linear polynomial contrast among the reconstructed joints. SEM = standard error of the mean.

cent (from 0.3 to 1.7 millimeters), respectively. Along the anterior-posterior axis, the progressive increase in active translation with increasing radial mismatch was due to the tendency of the humeral head to progressively translate anteriorly with increased external rotation over the full active range of motion (Fig. 1). This pattern was observed in all specimens.

Passive Model

Comparison of Natural and Reconstructed Joints

There were variations between the natural and reconstructed joints during passive motions. With the numbers available, we could detect no significant difference ($p > 0.5$) between the mean range of motion of the natural joints and that of the reconstructed joints in the passive model (142 compared with 133 degrees) (Fig. 2). The mean passive superior-inferior translation was reduced, significantly ($p = 0.025$), from 4.3 millimeters before the arthroplasty to 2.2 millimeters after it (Fig. 3). The mean passive anterior-posterior translation was also reduced, from 9.3 millimeters before the arthroplasty to 5.8 millimeters after it, but this reduction was not found to be significant ($p = 0.3$) (Fig. 4).

Effects of Articular Conformity

A linear increase ($p = 0.0018$) in the range of motion was found with increasing radial mismatch in the passive model (Fig. 2). This increase (from 120 to 146 degrees) was more than twice that seen in the active model. With the numbers available, we could detect no significant change in either superior-inferior ($p > 0.5$) or anterior-posterior ($p = 0.2$) translations with increasing radial mismatch in this model (Figs. 3 and 4). The patterns of both superior-inferior and anterior-posterior translations varied among the specimens, with the trans-

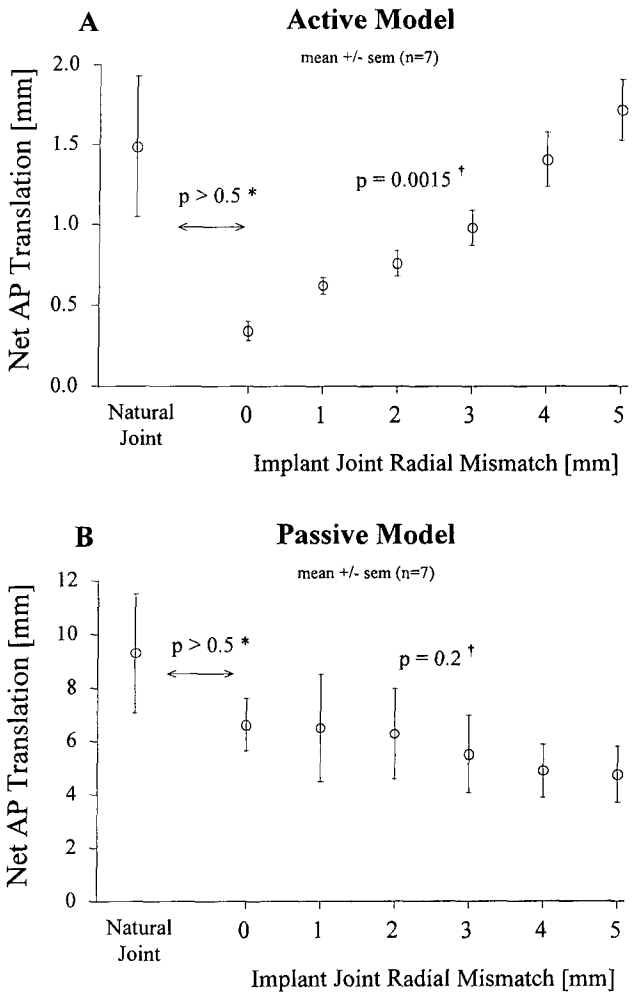


FIG. 4

Graphs showing the net anterior-posterior (AP) translations of the natural and reconstructed joints in the active and passive models. (Note that the axes for translation are not the same for the two plots.) The p value indicated by the asterisk was derived with a contrast between the mean value for the natural joints and the group mean value for all of the reconstructed joints. The p value indicated by the dagger was derived with a linear polynomial contrast among the reconstructed joints. SEM = standard error of the mean.

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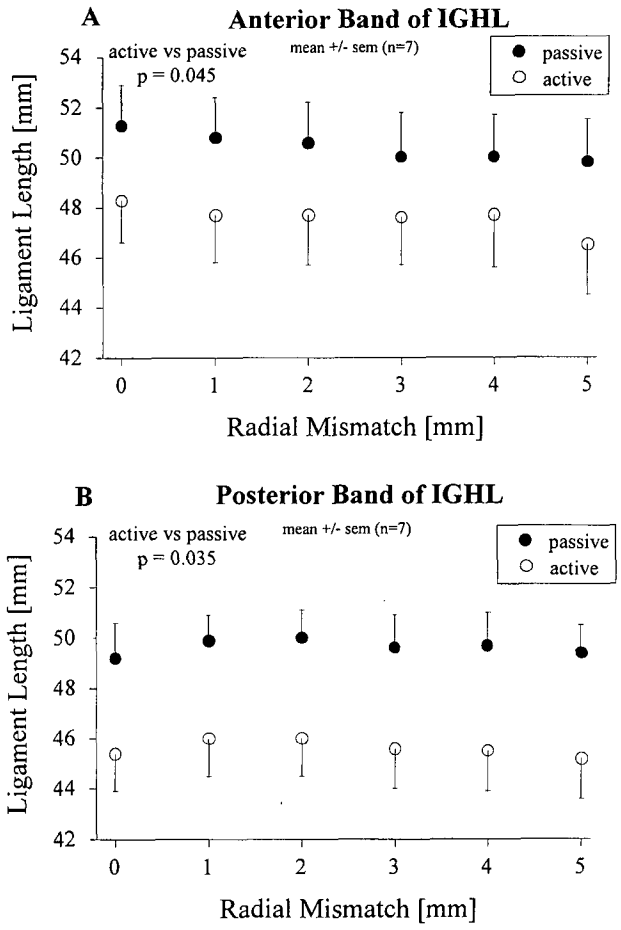


FIG. 5

Graphs showing the lengths of the anterior and posterior bands of the inferior glenohumeral ligament (IGHL) at the extremes of the range of motion according to the degree of radial mismatch. The length of the anterior band was determined at maximum external rotation and the length of the posterior band was determined at maximum internal rotation in both the active and the passive model. SEM = standard error of the mean.

lation increasing in some specimens and decreasing in others as articular conformity was decreased.

Ligamentous Constraints

The length of the anterior and posterior bands of the inferior glenohumeral ligament was calculated as the shortest distance between the sites of origin and insertion. The anterior band lengthened with external rotation and the posterior band lengthened with internal rotation in all specimens.

The length of the anterior band at maximum external rotation was significantly greater ($p = 0.045$) during passive motions than during active motions (Fig. 5). There was a slight but significant decrease (less than 4 per cent) in the length of this band with increasing radial mismatch during both active ($p = 0.04$) and passive ($p = 0.025$) motions.

Similarly, the length of the posterior band at maximum internal rotation was significantly greater ($p = 0.035$) during passive motions than during active motions (Fig. 5). However, with the numbers available, we could not find a significant effect of radial mismatch on the length of the posterior band during either active or passive motions ($p > 0.5$ for both comparisons).

Discussion

The relationship between radial mismatch — that is, articular non-conformity — and glenohumeral translation during active positioning of the joint after prosthetic arthroplasty was found to be similar to the relationship demonstrated in the natural, unreconstructed joint[16,17]. Articular conformity appears to be the predominant factor controlling translations during these motions. Relative increases in active superior-inferior and anterior-posterior translations of 175 and 467 per cent, respectively, were observed when the radial mismatch of the glenohumeral components increased from zero to five millimeters. Although decreasing articular conformity led to increased active translations, the mean active translation was less than two millimeters with the least conforming components. On the basis of theoretical calculations[15], it appears that these translations are less than what is required to achieve contact between the humeral head and the glenoid rim. The muscle forces required for active positioning of the joint, therefore, acted to limit glenohumeral translations to an amount that prevented loading of the glenoid rim.

Glenohumeral translations after prosthetic arthroplasty were larger during passive positioning of the joint than during active positioning. Also, translations varied more among specimens during passive positioning than during active positioning, as evidenced by the larger standard errors of the mean for both superior-inferior and anterior-posterior translations (Figs. 3 and 4). Active translations tended to occur over the entire range of motion, during which the head was in contact with the glenoid surface, whereas passive translations were observed primarily during ranges of motion that were not achievable during active range of motion. Consequently, no significant relationship was found between passive translations and articular conformity, with the numbers available. However, increased passive translations were associated with increased length of the inferior glenohumeral ligament, with the increased translation occurring in the direction opposite to that of the elongating ligament. For example, internal rotation during passive motions produced lengthening of the posterior band of the inferior glenohumeral ligament, which was associated with an increase in anterior translations.

The patterns of translation were similar for the natural and reconstructed joints, with the only significant difference being a decrease in the net passive superior-inferior translation after arthroplasty. There were large specimen-to-specimen variations in the active translations of the natural joint. This variability probably was due to differences in glenohumeral conformity among

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the specimens, as was documented in a previous study of natural joints[16]. Because of this variability and the small number of specimens used in the present study, it is difficult to predict the amount of conformity of the glenohumeral components that is needed to reproduce the translations of a natural joint most accurately. For example, to reproduce the patterns of anterior-posterior translation of the natural joints on an individual basis, the amount of articular congruence would range from perfectly conforming to a radial mismatch of more than five millimeters. On the average, however, active translations of the natural joint were most similar to those of the reconstructed joints that had a radial mismatch of approximately four millimeters (Figs. 3 and 4).

During simulated active motions, the articular surface of the humeral head presumably was in contact with the articular surface of the glenoid; this explains the influence of articular conformity on translations. To accommodate the larger passive translations, however, either the humeral head was not in contact with the glenoid or its edge or beveled portion was in contact with the glenoid, as was discussed by Ballmer et al. In these cases, the capsular structures had a more important role in the control of translations, as the anterior and posterior bands of the inferior glenohumeral ligament were longer at maximum rotation during passive motions than during active motions.

Few investigators have addressed the effects of articular conformity on forces and translations after total shoulder arthroplasty. Severt et al. studied specimens that had been excised from cadavera and found that, when articular conformity and constraint were reduced, joint subluxation forces also were reduced. Harryman et al. found that articular conformity did not have a significant influence on glenohumeral translations in a passive cadaveric model[11]. However, those authors did not examine the effects of maintaining a compressive load on the joint. The results of the present study indicate that articular conformity plays a greater role in the control of translations when muscle forces are present.

Although the technique for arthroplasty that was used in the present study is clinically unconventional, it maintains the integrity of the capsular ligaments; therefore, it was appropriate for this experimental model. The mean 26-degree retroversion angle for the humeral shaft in the present study is only slightly smaller than the 30 to 35-degree angle that has been typically recommended for this procedure[20]. Similarly, the mean neck-shaft angle of 41 degrees in the present study is very close to the 45-degree angle that has been reported for the natural joint[14]. The movement of the humerus laterally due to reconstruction of the joint also occurs in the clinical situation and is primarily a result of the thickness of the glenoid component and the position of the humeral stem.

In the clinical environment, prosthetic replacement often is performed in a shoulder with capsular contracture and rotator-cuff disease. Operative soft-tissue balancing and rotator-cuff repair are attempts to restore these tissues to a more natural condition. Clearly, however, re-establishing normal soft-tissue balance and rotator-cuff function is a goal that is rarely, if ever, achieved. Because each of the cadaveric specimens in the present study had intact rotator-cuff muscles and normal capsular tissues, it was desirable to avoid alteration or damage of these tissues so that different patterns of motion could be attributed to changes in the characteristics of the implant rather than to deficient soft tissue. This was accomplished with the modified technique for arthroplasty.

The specimens used in the present study showed no signs of injury of the rotator cuff or capsular contracture. This often is not the case for patients who have a shoulder arthroplasty. Depending on the type of arthritis, there may be substantial capsular contracture or rotator-cuff injury. Although these conditions often are improved through capsular release and repair of the cuff with the standard technique for total shoulder arthroplasty, it is unlikely that the soft tissues are returned to their normal condition. Previous studies of cadavera have demonstrated that capsular contracture (or capsular imbrication) increases translations of the humeral head during both active and passive positioning of the joint[4,10]. A similar study also showed increased translations due to rotator-cuff injury in an active model[23]. Because our study was designed to characterize the relationship between glenohumeral motions and conformity of the components, independent of problems with the capsule and the rotator cuff, we believed that simulating these conditions would only weaken the study.

The limitations of the current study include those that have been discussed previously, such as the somewhat arbitrary selection of muscle forces, the difficulty in interpreting data on the length of the ligament, and the venting of the joint capsule[16]. With regard to the accuracy of measuring translation, the magnetic tracking device (the 3Space Fastrak), because of its pattern of systematic errors, was found to be as accurate in measuring translations of a reconstructed joint as it is in measuring translations of a natural joint, even in the presence of metal. Although clinical knowledge and electromyography were used to determine the forces in the present study, other combinations of muscle forces may have produced the same motions. The lengths of the ligament that are reported in the present study are reflections of the straight-line distance between the sites of origin and insertion and do not account for wrapping of the ligament around the articular surface of the humeral head. Finally, it was not possible to perform the arthroplasty without venting of the joint.

In conclusion, articular conformity was found to

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play a vital role in the control of glenohumeral translations during active positioning of the joint. This is an important starting point for improving the understanding of the biomechanics of shoulder arthroplasty systems. The consequences of these translations, however, still need to be investigated.

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EARLY EXPERIENCE IN THE USE OF A NEW GLENOID RESURFACING TECHNIQUE

Mark Ross and Phillip Duke

Introduction Glenoid replacement remains controversial in shoulder arthroplasty. Advocates of hemiarthroplasty point to increased complications and compromised revision options with glenoid replacement. Advocates of glenoid replacement point to increased pain due to native glenoid wear and medialisation. In some circumstances in may not be possible to implant a normal glenoid due to structural inadequacy of the glenoid or it may be less desirable due to young patient age and high functional load. We report on the early experience with a new technique utilising an unusual mini-glenoid implant originally designed for juvenile rheumatoid cases or very small individuals.

Method We have utilised this technique in young high demand cases where we were concerned regarding standard glenoid replacement but reluctant just to perform hemiarthroplasty. We have also used it as an adjunct to the "ream and run "technique where standard glenoid replacement was not feasible. The technique involves using an all poly 20 mm diameter circular glenoid with a single 8mm x 10 mm central peg. It is implanted within the central portion of the glenoid, flush with the remaining articular cartilage , and cemented in place. If the articular surface has an even concavity it is not reamed. The normal capsular releases are performed on the humeral side but the labrum is not resected. A standard humeral head replacement is performed.

Results 6 cases have been performed since 2001.Average age was 54 years (51 – 60). All implants remain in situ and all patients are satisfied with both pain relief and range of motion.There has been no radiographic loosening.

Discussion This technique provides an intermediary solution between full glenoid replacement and hemiarthroplasty. Our early results are encouraging but further investigation is required. We postulate that by fully recessing the prosthesis and if possible preserving peripheral cartilage and labrum, there is both load sharing in more extreme functional positions and a medial resistance to wear of the native glenoid. Furthermore, in the event that revision is required there has been little compromise of existing bone stock, although we have not had to perform revision as yet. We plan to enhance the ease and efficacy of this technique by attempting to expand the available implants to include 2 different diameters and 3 different concavities to better match native glenoid size and curvature. Although we have been very particular in selecting patients for this, as yet, experimental technique , we believe it may present another potential option in managing the young , high demand osteoarthritic patient. It may also offer improved outcome where hemiarthroplasty is performed because a routine glenoid replacement is not possible or is contraindicated.

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(54) **Title**: METHODS AND DEVICES FOR LESS INVASIVE GLENOID REPLACEMENT

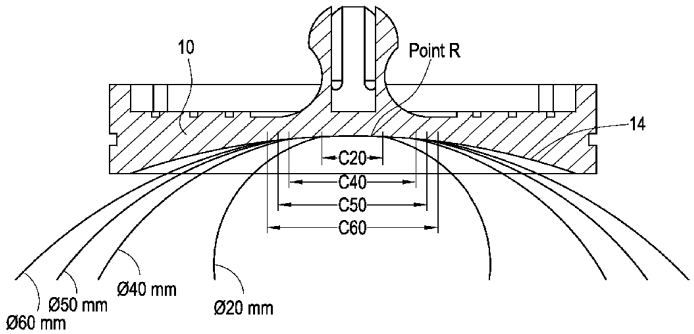


FIG. 43

(57) **Abstract**: The invention relates to a glenoid (shoulder socket) implant prosthesis (10), a humeral implant prosthesis, devices for implanting glenoid and humeral implant prostheses, and less invasive methods of their use for the treatment of an injured or damaged shoulder.

WO 2011/112425 A1

METHODS AND DEVICES FOR LESS INVASIVE GLENOID REPLACEMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation-in-part application of U.S. Patent Application No. 11/066,978 filed on February 25, 2005, the entirety of which is hereby incorporated by reference herein and made a part of the present specification.

Field of the Invention

[0002] The present invention relates to the field of glenoid surface replacement.

BACKGROUND OF THE INVENTION

[0003] The invention provides a glenoid shoulder implant, a humeral implant, and devices for preparing the glenoid and humeral head for joint replacement.

[0004] Shoulder replacement surgery is currently used to treat patients suffering from disabling pain due to worn or damaged shoulder joints, which can be caused by, e.g., arthritis or injury. The humeral implants currently in use are typically made from metal, and the implants are affixed to the bone using bone cement (e.g., polymethylmethacrylate) or by press fitting the implant into the bone using a roughened outer surface coating on the metal for bony integration. Most glenoid (shoulder socket) implants are made completely from polyethylene and affixed to the cortical bone using bone cement. Some glenoid implants have a rigid base plate made of metal, ceramic or rigid polymer with a polyethylene insert. The polyethylene material is suitable as a low friction articulating surface for engaging the humeral component. Current glenoid implants are intended to sit on a prepared surface of a glenoid bone. The surface is typically prepared by removing any remaining cartilage, reaming a smooth bony surface and by drilling receiving pockets for anchoring features or devices within the natural glenoid area. Current implant designs use either a keel or multiple elongated pegs on the back (medial surface) of the prosthetic glenoid implant as anchoring features to secure the glenoid implant inside the glenoid vault.

[0005] Glenoid implants with keeled or elongated peg anchors suffer from several disadvantages, which limit their lifespan once implanted and reduce the number of indications for which they can be used. For example, these glenoid implants can loosen due to poor fixation to the bone, and are prone to wear and fatigue failure of the polyethylene due to adhesion, abrasion, and shear stress. Because of these deficiencies,

surgeons hesitate to perform glenoid replacement surgery on young or middle aged patients with glenoid articular cartilage injuries or damage due to early arthritis for fear that the implant may not last more than 10-15 years in the body, thus subjecting the patient to the possibility of two or more surgeries during the lifetime of the patient to preserve the function and pain-free state of the joint. Finally, current glenoid implants with a long keel or an elongated anchor peg are sometimes contraindicated in patients with significant glenoid bone loss. As arthritis progresses, the humeral head can wear medially and destroy the foundation of glenoid bone. In these cases, the glenoid vault can be significantly reduced in volume and depth. Thus, a typical keel or peg design can penetrate through the glenoid vault and injure the suprascapular nerve along the suprascapular notch or spinoglenoid notch with resultant denervation injury to the rotator cuff muscles. Penetrating through the bone of the glenoid vault can also fracture the body of the scapula and cause early implant loosening.

[0006] There are also several disadvantages associated with current glenoid replacement surgical techniques. Current techniques require extensive shoulder exposure with capsular releases in order to fully expose the glenoid surface circumferentially. Since the axillary nerve is located within 1 cm of the inferior capsule, there is potential risk of axillary nerve injury with resultant denervation injury to the deltoid muscle when these releases are performed. Use of the current glenoid implants with keels or elongated anchor pegs requires this extensive glenoid exposure for proper fitting and placement of the prostheses. Current glenoid replacement surgery also requires a long skin incision, typically 150mm to 200mm in length, and extensive soft tissue stripping in order to fully expose the glenoid circumferentially, which increases the risk of tissue damage and produces a cosmetically unappealing scar. Finally, current glenoid replacement surgical techniques require advanced surgical training and expertise within the specialty of shoulder surgery, yet the majority of shoulder implants performed in the U.S. every year are performed by orthopedic surgeons who do not have advanced training in the subspecialty of shoulder surgery. Therefore, many surgeons have difficulty preparing the glenoid site for a total shoulder replacement using the current techniques.

[0007] As a consequence of the limitations of the currently available designs and surgical techniques some patients forego surgery and incur a risk of continued pain and disability. Patients who elect a surgical solution incur the risk of neurovascular injuries, glenoid and scapula fractures, and failed shoulder prostheses requiring revision

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surgery. Thus, there remains a need for an improved glenoid implant and improved methods for performing replacement shoulder surgery.

SUMMARY OF THE INVENTION

[0008] There is provided in accordance with one aspect of the present invention, a method of treating a patient. The method comprises the steps of identifying a patient having a glenoid surface, and reaming a cavity into the glenoid surface. A glenoid implant is inserted into the cavity, such that at least a portion of a peripheral edge of the implant resides below the adjacent glenoid surface, and the portion residing below the adjacent glenoid surface is circumferentially surrounded by the cortical bone of the glenoid.

[0009] The reaming a cavity step comprises reaming a circular cavity so as to create a mating surface for the prosthetic glenoid implant, said surface being below the native glenoid bone surface and being circumferentially surrounded by native glenoid bone. The inserting a glenoid implant step may comprise fitting a glenoid implant having a circular portion into the cavity, said circular portion having a diameter complimentary to that of the cavity reamed in the glenoid bone

[0010] The method may additionally comprise the step of securing the implant within the cavity using bone cement or mechanical engagement such as can be achieved using a press-fit interference or bone screws. The implant has a medial surface disposed to engage the prepared surface within the reamed cavity. Various configurations of this medial surface are presented, these surface geometries being configured to receive bone cement and improve adhesion of the implant to, and retention within, the reamed bone cavity.

[0011] The method may additionally comprise the step of stabilizing the implant within the cavity using a central peg extending from a medial surface of the implant, said peg being located within a prepared receiving hole in the glenoid bone Various geometric configurations of this peg are presented.

[0012] The method may additionally comprise the step of accessing the glenoid via a deltopectoral approach. Alternatively, the method may comprise the step of accessing the glenoid via an anterolateral approach.

[0013] In certain implementations of the invention, the reaming a cavity step comprises reaming a cavity completely within the boundary of the native glenoid cavity, without destroying the peripheral margin of the glenoid surface. This step may be accomplished while leaving the majority of the inferior capsule intact. The reaming a

cavity step may comprise reaming a cavity while leaving the peripheral cortex intact. The method may include the step of accessing the glenoid surface via an incision having a length of no more than about 9 cm.

[0014] In the patients having more extensive deficiency of glenoid bone there is often a need to reconstruct the natural geometry of the shoulder so as to restore the natural orientation and engagement of the humerus to glenoid interface. This is often currently achieved by grafting bone tissue or otherwise reconstructing the bony geometry of the glenoid structure. In one aspect of the glenoid prosthesis invention disclosed herein there is a circular prosthesis configuration presented whereon the plane of the articulating surface is offset from the plane of the medial, bone engaging, surface of the implant. The combination of a circular implant and included angles between the medial and articulating surfaces of the implant device allows for in-situ positioning of the implant by rotating the circular implant around the central axis of the medial surface in order to restore the natural plane of the glenoid value.

[0015] In certain patients there is extreme bone deficiency or there exists an atypical bone wear pattern, in these case there may remain insufficient bone in which to create a reamed cavity which completely surrounds the perimeter of the glenoid implant. In one implementation the invented glenoid implant device has an annular ring disposed around the circumference of the medial surface. During the cavity reaming step of the surgical procedure a perimeter groove is cut into the glenoid bone structure around the circumference of the reamed cavity so as to create a receiving channel around the perimeter of the reamed cavity in the bone, this groove receives within it a corresponding annular ring of the glenoid implant device thereby creating full circumferential engagement of the implant within the bone in order to increase the retention and stability of said implant.

[0016] There is further presented a geometry for the articulating surface of the device which permits a semi-constrained relationship between the glenoid implant device and the humeral head.

[0017] In accordance with a further aspect of the present invention, there is provided a glenoid implant. The implant comprises a circular body, having a medial surface, an articulating surface, a peripheral edge and central axis. A post is provided on the medial surface, disposed concentrically on the central axis. At least one axially extending flange extends from the medial surface at the peripheral edge of the circular body.

[0018] Preferably, the at least one flange extends around at least about 75% of the peripheral edge of the circular body. The flange may extend at least about 85% or 95% of the way around the peripheral edge of the circular body, and may be discontinuous or continuous.

[0019] The circular body has a first thickness measured in the axial direction at a first point on the peripheral edge, and a second thickness measured in the axial direction at a second point on the peripheral edge which is spaced apart from the first point by 180°. In one implementation of the invention, the first thickness is substantially equal to the second thickness. Alternatively, the first thickness may be at least about 125% of the of the second thickness, at least about 150% of the second thickness, or at least about 200% of the second thickness to provide an angled, rotationally adjustable implant.

[0020] In accordance with a further aspect of the present invention, there is provided a glenoid implant. The implant comprises a circular body, having a medial surface, an articulating surface, a peripheral edge and a central axis. A post is provided on the medial surface, disposed concentrically on the central axis. The body comprises a first thickness measured in the axial direction at a first point on the peripheral edge, and a second thickness measured in the axial direction at a second point on the peripheral edge, spaced apart from the first point by 180°. The first thickness is at least about 125% of the second thickness. The implant may additionally comprise at least one projection extending axially from the body at the peripheral edge. The projection may comprise an annular flange, which may be continuous or discontinuous. The implant may additionally comprise at least one bone cement flow channel on the medial surface.

[0021] In accordance with a further aspect of the present invention, there is provided a method of treating a patient. The method comprises the steps of exposing a glenoid surface, and reaming a circular depression in the glenoid surface. A glenoid implant is provided, having a circular peripheral edge and a non-spherical concavity with an articulating surface, the concavity having an axis of rotation which is angularly offset from an axis of the circular peripheral edge. The implant is positioned such that the circular peripheral edge at least partially resides within the circular depression. The implant is thereafter rotated, to direct the axis of rotation of the articulating surface to a desired position.

[0022] In accordance with a further aspect of the present invention, there is provided a method of treating a patient. The method comprises the steps of making a skin

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incision, and exposing a glenoid surface through the incision. A reamer is introduced through the incision, and a circular depression is reamed within the glenoid surface. The glenoid implant is introduced through the incision, and positioned at least partially within the depression. The incision is preferably no more than about 100mm in length.

[0023] In accordance with a further aspect of the present invention, there is provided a cement construct, for retaining an implant within a cavity in a bone. The construct comprises a cement shell, having a concave side corresponding to the configuration of an implant and a convex side corresponding to the configuration of a prepared cavity in a bone. The concave side has an axis of rotational symmetry. A first tubular wall section is concentrically disposed about the axis, and a substantially planar section extends radially outwardly from an end of the first tubular wall section and transverse to the axis.

[0024] A second tubular wall section is concentrically disposed about the axis, and extends axially from a peripheral edge of the planar section. The second tubular wall section extends at least about 180°, preferably at least about 270°, and in certain implementations completely around the axis.

[0025] In accordance with another aspect of the present invention, there is provided a method of preparing a glenoid surface for implantation of a glenoid implant. The method comprises the steps of reaming a circular depression in the glenoid surface, to produce a reduced glenoid surface having an axis of rotation. A bore is reamed coincident with the axis, and below the level of the reduced surface. An annular channel is reamed concentrically about the axis, and below the level of the reduced surface.

[0026] Further features and advantages of the present invention will become apparent to those of skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1A is an anterior surface view of the circular glenoid implant of the invention.

[0028] FIG. 1B is an anterior surface view of the oval glenoid implant of the invention.

[0029] FIG. 1C is a backside view of the circular glenoid implant of FIG. 1A

[0030] FIG. 2A is an anterior surface view of the circular glenoid implant of the invention that includes a single short backside peg.

[0031] FIG. 2B is a backside view of the circular glenoid implant of FIG. 2B.

[0032] FIG. 3 is an anterior (frontal) view of a typical prior art glenoid implant with a keel design situated in the glenoid.

[0033] FIG. 4 is an anterior (frontal) view of a scapula containing a typical prior art glenoid implant with a multiple peg design situated in the glenoid.

[0034] FIG. 5 is a backside view of a scapula containing a typical prior art pegged glenoid implant which was removed from a patient.

[0035] FIG. 6 is a lateral view of the prior art pegged glenoid implant of FIG. 5.

[0036] FIG. 7 is an anterior (frontal) view of a scapula containing an inset glenoid implant of the invention situated in the glenoid.

[0037] FIG. 8A is an anterior surface view of a typical prior art glenoid implant.

[0038] FIG. 8B is an anterior surface view of the circular glenoid of the invention.

[0039] FIG. 9A is a backside view of a typical prior art keeled glenoid trial implant.

[0040] FIG. 9B is a backside view of the circular glenoid of the invention showing a short backside peg.

[0041] FIG. 10A is a surface view of the glenoid bone with an inset circular glenoid implant of the invention.

[0042] FIG. 10B is a surface view of the glenoid bone with an inset oval glenoid implant of the invention.

[0043] FIG. 11 is a surface view of the glenoid bone with a typical prior art onlay glenoid implant, which does not sit inset to the glenoid bone.

[0044] FIG. 12 is a photograph of a model depicting the glenoid (G), scapula (S), clavicle (C), Acromio-Clavicular Joint (AC), and Coracoid (Co). The glenoid is shaded to designate the placement surface for the glenoid implant of the invention.

[0045] FIG. 13 is a view showing the use of a straight drill of the prior art for preparing the glenoid for implantation.

[0046] FIG. 14 is a view of the 90° drill of the invention.

[0047] FIG. 15 is an anterior (frontal) view of the scapula showing the use of the 90° drill of the invention.

[0048] FIG. 16 is a view of the reamer of the invention.

[0049] FIG. 17 is frontal view of the humeral cutting jig of the invention

[0050] FIG. 18 is side view of the humeral cutting jig of FIG. 17 placed in position on a humerus. The cutting jig can be secured by K-wires (shown), pins, or screws.

[0051] FIG. 19 is a view of the humerus and humeral cutting jig of FIG. 18 after resection of humeral head along the axis of the cutting jig.

[0052] FIG. 20A is an anterior (frontal) view of the humeral implant of the invention.

[0053] FIG. 20B is a lateral view of the humeral implant of the invention.

[0054] FIG. 20C is an anterior (frontal) view of the humeral implant of the invention with a collar.

[0055] FIG. 20D is a lateral view of the humeral implant of the invention with a collar.

[0056] FIGS. 21, 22, and 23 are photographs showing the inset circular glenoid implant of the invention implanted in the glenoid of a patient.

[0057] FIG. 24 is a photograph showing the 15 cm incision from a typical prior art total shoulder replacement surgery.

[0058] FIG. 25 is a photograph showing the 9 cm incision from the "mini-incision" total shoulder replacement surgery of the invention.

[0059] FIG. 26A is a view showing a right angle drill attachment for use in preparing a glenoid for implantation of a glenoid implant.

[0060] FIG. 26B is a view showing a drill with the right angle drill attachment and drill bits for use in preparing a glenoid for implantation of a glenoid implant.

[0061] FIG. 27 is perspective view of the medial aspect of a circular glenoid implant, showing a geometry of the medial and perimeter surfaces of the device configured to receive and distribute bone cement.

[0062] FIG. 27A is a partial cross sectional view of a circular glenoid implant taken along the line 27A-27A in FIG. 27.

[0063] FIG. 27B is a cross sectional view of a circular glenoid implant located within a reamed receiving cavity in bone tissue and being encased and anchored therein by bone cement.

[0064] FIG. 28 is a cross sectional perspective view of a glenoid implant, illustrating the interconnected bone cement receiving geometry of the medial and circumferential surfaces.

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[0065] FIG. 29 is a bottom plan view of the medial surface of a glenoid implant, illustrating the interconnected bone cement receiving geometry of the medial and circumferential surfaces.

[0066] FIG. 30 is a perspective view of a reamed native glenoid bone, showing a reamed cavity within the bone

[0067] FIG. 31 is a perspective view of a reamed cavity in glenoid bone, the glenoid structure exhibiting bone deficiency.

[0068] FIG. 32 is a perspective view of the medial aspect of a circular glenoid repair device.

[0069] FIG. 33 is a perspective view of a reamed cavity in glenoid bone, the glenoid structure exhibiting bone deficiency. FIG. 33 further illustrates the reamed cavity having an annular recess at the circumference to receive a corresponding protruding feature of a prosthetic glenoid device.

[0070] FIG. 34 is a cross sectional view of reamed glenoid bone, showing the view 34-34 of FIG. 33.

[0071] FIG. 35 is a perspective view of an alternate embodiment of the medial aspect of a circular glenoid repair device, having localized protrusions at a radius corresponding to that of the reamed circumferential groove of FIG. 33.

[0072] FIG. 36 is a cross sectional view of a circular glenoid implant showing an articulating surface which is offset from the medial surface by an included angle.

[0073] FIG. 37 is a perspective view of a circular glenoid implant showing an articulating surface which is offset from the medial surface by an included angle.

[0074] FIG. 37A is a perspective cross sectional view of a circular glenoid implant having an articulating surface which is offset from the medial surface by an included angle, the articulating surfaces having a visible indicator to identify the apex of the articulating surface of the device.

[0075] FIG. 37B is a perspective view of a circular glenoid implant having an articulating surface which is offset from the medial surface by an included angle, the articulating surfaces having visible graduated indicia to identify the apex of the articulating surface of the device and to aid in angular positioning of the implant device.

[0076] FIG. 38 is an elevational cross sectional view of a circular glenoid implant having offset medial and articulating surfaces and further illustrating an axis of rotation for positioning the implant device within the reamed receiving cavity in the glenoid bone.

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[0077] FIG. 39 is an elevational cross sectional view of a circular glenoid implant having offset medial and articulating surfaces, the articulating surface being generated by an arc of constant radius with an origin offset from the axis of revolution, and further illustrating an axis of rotation for positioning the implant device within the reamed receiving cavity in the glenoid bone.

[0078] FIG. 40 is an elevational cross sectional view showing the articulating surface resulting from a constant radius arc with an origin offset from the axis of rotation being rotated about the axis of rotation.

[0079] FIG. 41 is an illustration of an exemplary embodiment of an offset surface design.

[0080] FIG. 42 is a cross sectional perspective view of a glenoid repair device having the plane of the articulating surface angularly offset from the plane of the medial surface, the articulating surface being a non-spherical surface of revolution of a constant radius arc.

[0081] FIG. 43 is a cross sectional view of a glenoid repair device having a non-spherical surface of constant radius, engaging various humeral head configurations.

[0082] FIG. 43A is a cross section view of a glenoid repair device having a non-spherical surface, the articulating surface having a fixation port between the articulating surface and the medial surface and a mechanical fastener inserted there through into native bone.

[0083] FIG. 43B is a cross sectional view of a glenoid repair device having a non-spherical articulating surface, and a fixation port between the articulating surface and the medial surface, the medial surface including an expandable anchor post with a locking element being inserted into the fixation post through the articulating surface to laterally expand the anchor post elements on the medial surface.

[0084] FIG. 44 is a cross sectional view as in FIG. 43, further illustrating the engagement of various humeral head configurations.

[0085] FIG. 45 is a perspective view of the medial aspect of a circular glenoid repair device, showing an alternate implementation of the central anchor peg.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0086] The invention features an inset glenoid implant prosthesis, a humeral implant prosthesis, and methods and devices for preparing the surgical site for implantation of the implant prostheses.

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[0087] In one aspect, the invention features an inset glenoid shoulder implant that is implanted within the glenoid vault, thereby allowing circumferential cortical support along the rim of the prosthesis, which improves fixation strength in comparison to current glenoid implants. Another advantage of the glenoid implant is that it requires only a minimal amount of bone removal for implantation.

[0088] The glenoid implant itself includes a (1) body portion having (i) a smooth concave lateral articulating surface facing away from the scapula, which is adapted to be engaged by a convex surface of a humeral component, and (ii) an opposing surface on the medial side intended to be positioned within a cavity reamed in the glenoid. In a preferred embodiment, the glenoid implant also includes (2) a short peg on the medial side extending centrally outward along an axis from a convex or flat backside (medial) surface of the glenoid implant. In a preferred embodiment, the short peg of the glenoid implant is less than about 10 mm long, more preferably about 8 mm or less in length, even more preferably about 5 mm or less in length. Alternatively, the glenoid implant has multiple pegs, each of which can be the same length or different lengths, e.g., less than about 8 mm or less in length, more preferably about 5 mm or less in length. In another embodiment, at least one of the pegs is between about 5 mm and about 8 mm in length and the remaining pegs are less than about 8 mm in length.

[0089] In another preferred embodiment, the body portion extends to an edge having a circular configuration while, in a second embodiment, the body portion has an edge defining a non-circular configuration, such as an oval, an elongated configuration, or a configuration which may be characterized as rectangular with slightly rounded ends. In another preferred embodiment, the glenoid implant is implanted in a prepared cavity of the glenoid which conforms generally to the backside (medial) surface only and sits inset slightly within the glenoid vault. In another preferred embodiment, the glenoid implant is implanted in a prepared cavity of the glenoid which conforms generally to the single short peg or multiple short pegs, if present, and the backside (medial) surface of the glenoid implant.

[0090] In another preferred embodiment, the glenoid implant of the invention is manufactured using polyethylene, metal, or ceramic, or combinations thereof, e.g., a combination of metal and polyethylene or ceramic and polyethylene.

[0091] In another preferred embodiment, the glenoid implant of the invention is secured to the glenoid using cement fixation or press fit technique. In yet another

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preferred embodiment, the glenoid implant is further secured to the glenoid using screws, e.g., in press fit designs.

[0092] In another preferred embodiment, the glenoid implant can be customized during the surgical procedure, as is required based on the condition of the patient. In another embodiment, the glenoid implant is sterilized prior to implantation. In yet another embodiment, the glenoid implant is provided in sterile packaging.

[0093] In the method of implanting the glenoid component, the first step after exposing the glenoid cavity is to determine the appropriate size of component to be used. This is done by placing a series of circular sizers having varying diameters over the glenoid cavity to determine the proper diameter to which the scapula should be reamed at the surface defining the glenoid cavity and the proper size of glenoid component. Using a combined sizer/guide having a central hole and passageway formed therein to determine the correct location and attitude, a hole is drilled a few millimeters into the scapula through the glenoid surface using a combined guide wire/drill. The guide wire/drill is calibrated in order to readily determine the depth of drilling and is attached to a chuck if a power drill is used or a T-handle or the like if the drilling is manual. The guide wire/drill should be drilled into the scapula substantially perpendicular to the anatomic axis of the glenoid surface. Thereafter, the combined sizer/guide is removed and a reamer is positioned to ream the scapula to the proper shape and depth forming a cavity having a circular cross-sectional configuration for a circular implant or an oval configuration for an oval implant in a plane normal to the axis defined by the guide wire.

[0094] In another aspect of the invention, the glenoid implant can be used in patients with deficient glenoid bone due to fracture or severe arthritis. In preferred embodiments, the glenoid implant has none, one, two, or three or more short backside pegs that do not extend beyond about 10 mm outwardly from the backside (medial) surface of the glenoid implant. In a preferred embodiment, the peg or pegs do not extend beyond about 8 mm from the backside (medial) surface of the glenoid implant. Because the glenoid implant lacks a long backside extension, it can be safely placed inside a glenoid vault with minimal depth. This minimizes the risk of fracturing the body of the scapula or injuring the suprascapular nerve or rotator cuff.

[0095] Another aspect of the invention features a humeral implant for use in a total shoulder replacement procedure. The humeral implant of the present invention is less than 70 mm in length, preferably about 60 mm in length, and is less than 40 mm wide anterior to posterior (preferably 20 to 30 mm wide). In an embodiment, the humeral

implant includes a collar, which prevents the humeral implant from embedding too deeply in the humerus. In other embodiment, the humeral implant includes a flange (fin), which provides fixation of the humeral implant in the medial to lateral plane and rotational control. Alternatively, the humeral implant can contain 3 flanges (fins) with 1 lateral, 1 anterior, and 1 posterior. The stem of the humeral implant defines a longitudinal axis and the planar surface extends from between about 45° to about 60° to the axis of the stem. The proximal end of the stem includes a bore that extends downward from the planar surface and is adapted to be engaged by an artificial humeral head by means of a morse taper. In other embodiments, the humeral implant is fixed using a bone cement, such as polymethylmethacrylate (PMMA) or a compatible fixation material, or it is press-fit without bone cement. The humeral implant can be customized during the surgical procedure, as is required based on the condition of the patient. In another embodiment, the humeral implant is sterilized prior to implantation. In another embodiment, the humeral implant is provided in sterile packaging. In another preferred embodiment, the humeral implant of the invention is manufactured using polyethylene, metal, or ceramic, or combinations thereof, e.g., a combination of metal and polyethylene or ceramic and polyethylene.

[0096] Another aspect of the invention features a cutting jig for preparing a humerus for replacement by a humeral implant. The humeral head cutting jig is a simple, low profile humeral cutting jig that can be a fill circle or part thereof. The cutting jig is placed along the anatomic neck of the humerus in the appropriate version (angle of the cut) as determined by the surgeon. The cutting jig can be secured along the anatomic neck of the proximal humerus using K-wires, pins, or screws and is removed after completion of humeral head resection. In an embodiment, the cutting jig includes a handle portion.

[0097] Another aspect of the invention features a method for providing a shoulder implant which can be performed through a minimal incision technique ("mini-incision"). Instead of an extensive deltopectoral approach involving extensive soft tissue stripping, capsular releases, and circumferential glenoid exposure, this inset implant can be performed through a more limited mini-incision technique. A mini-deltopectoral incision is utilized. The skin incision is shorter, and the pectoralis tendon is left intact. The majority of the inferior capsule is also left intact. In a preferred embodiment, the glenoid labrum can be left intact if this is preferred by the surgeon. The central portion of the glenoid bone is then reamed while leaving the peripheral cortex intact. There are three major consequences of this mini-incision technique:

[0098] 1 - Shortening the length of the incision and exposure provides a more cosmetic incision for the patient.

[0099] 2 - Avoiding an extensive inferior capule incision increases the safety of the procedure by reducing the risk of injury to the axillary nerve.

[0100] 3 - Providing an implant that can be placed in the glenoid without extensive, circumferential glenoid exposure would allow general orthopedists to perform a shoulder replacement with less difficulty and potentially fewer complications.

[0101] The present invention is also directed to a method for implanting such glenoid implant for precise placement in the scapula and precise drilling and reaming of the scapula. The method is performed using a specialized power drill having a lateral drilling attachment and a short drill bit incorporated into the attachment, which is used to drill a central hole in the glenoid surface. The bone is then reamed with a reamer bit attached to the drill. The lateral drilling attachment inclines the axis of the drill relative to the axis of the access pathway by an angle within the range of from about 45° to about 110°, often within the range of from about 50° to about 90°, and, in one implementation about 60°.

[0102] Another aspect of the invention features a slim design power drill for preparing a glenoid for implantation of a glenoid implant, in which the power drill includes a right angle drilling attachment having an extension rod with a length of at least 10 cm, more preferably at least 12, 15, or 18 cm long, the end of which is includes a collet or chuck that is positioned at a 90° angle relative to the extension rod and which is adapted to receive a short drill bit; the power drill being prepared for use in the surgical field by sterilization. In a preferred embodiment, the drill and accessories are sterilized and provided in a sterile container. In other preferred embodiments, the drill bit is 10 mm long, more preferably 12, 14, 16, 18, or 20 mm long, and most preferably 25, 35, 45, 55, 65, or 75 mm long. In other preferred embodiments, the drill bit has the following diameters: 1.5 mm, 2.5 mm, 3.0 mm, 3.2 mm, 4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5 mm, 7.0 mm, 8.0 mm, 9.0 mm, or 10.0 mm. The power drill is designed to allow drilling in spaces as tight as 50 mm. In other preferred embodiments, the overall length of the right angle drilling attachment is 18 cm, more preferably 20 cm, most preferably 22 cm. The head width and extension rod diameter are preferably less than 25 mm, more preferably less than 22 mm, and most preferably less than 20 mm. The head length is preferably less than 30 mm, more preferably less than 28 mm, and most preferably less than 25 mm. In other preferred embodiments, the right angle drilling attachment is

designed to be attached to any power drill, the use of which is acceptable in a surgical field, and is designed to be lightweight, e.g., less than about 200 grams, more preferably less than about 180 grams, and most preferably less than about 150 grams. The power drill can be powered using a battery supply (cordless) or it can be powered using an electrical cord powered from a standard electrical outlet. See, e.g., U.S. Pat. No. 6,037,724, incorporated herein by reference.

[0103] The design of the glenoid implant of the invention provides increased implant fixation strength to glenoid bone and therefore decreases the rate of glenoid implant loosening. This implant is also designed for use in cases of deficient glenoid bone which would preclude the use of a current glenoid implant since they require adequate bone in the glenoid vault to support multiple long pegs or a keel.

[0104] The invention also features a humeral implant, which is less than 70 mm in length, preferably about 60 mm in length, and is less than 40 mm wide from anterior to posterior (preferably 20-30 mm). The humeral implant of the invention is significantly shorter and thinner (in the anterior to posterior dimension) than most current stems, which are about 70-115 mm in length and bulkier in the proximal (metaphyseal) area than distally both in the anterior to posterior dimension and medial to lateral dimension. Because the humeral implant of the invention is shorter, it can be implanted in a narrower metaphyseal area and does not require the removal of a significant amount of bone. Fixation of the present humeral implant depends upon good interference fixation in the medial-lateral plane when press fit (similar to some current total hips). The humeral implant can be fixed using a bone cement, such as polymethylmethacrylate (PMMA) or a compatible fixation material. Alternatively, the humeral implant can be press-fit.

[0105] The invention also features a minimal incision shoulder arthroplasty technique that allows replacement of the glenoid surface and humeral head with only a small incision and less extensive soft tissue stripping. The "mini-incision" procedure also leaves the pectoralis tendon and the majority of the inferior capsule intact. The glenoid labrum can also be left intact. The central portion of the glenoid bone is then reamed while leaving the peripheral cortex intact. The advantages of this "mini-incision" procedure include a shorter incision with less scarring, increased safety, and a more simple exposure of the glenoid, thus allowing general orthopedists to perform a shoulder replacement with less difficulty and potentially fewer complications.

[0106] The glenoid implant of the invention lacks a keel and multiple long pegs, which are typically present in the prior art glenoid implants. Instead, the glenoid

implant of the invention optionally includes one or more pegs or flanges disposed radially symmetrically about a central axis of the implant, such as only a single short (less than about 8 mm), central backside peg which stabilizes the glenoid implant. The glenoid implant of the invention does not require a long extended keel or long pegs because the majority of the fixation strength is concentrated on the rim of the embedded implant. This obviates the need for significant backside fixation. The fixation, with either cement or press fit techniques, offers circumferential cortical bone fixation around the prosthesis. The shear stresses placed on the implant are therefore supported by a circumferential buttress of bone, which is more mechanically sound than an onlay prosthesis with an extended backside keel or multiple long pegs.

[0107] An object of the invention is to minimize the common complications of glenoid implant loosening and fatigue failure that exist with current glenoid implants. All previous glenoid implants sit on the surface of a reamed articular surface and utilize a keel or multiple pegs to secure the implant inside the glenoid vault (see, e.g., FIGS. 3-6). This invention features a glenoid implant (which can be polyethylene, metal, ceramic, or combinations thereof) that is not designed to be placed on the surface of the reamed glenoid articular cartilage. Rather, the present implant is designed to be inset partially (e.g. at least about 1mm or 2mm or 3mm or 4mm or more below the native adjacent surface of the bone at at least one point around the circumference of the implant) or fully within the glenoid vault (see FIG. 7). The implant may be press fit or cemented in the reamed cavity within the glenoid bone.

[0108] Patients who can benefit from the use of the glenoid implant of the invention and the improved methods for performing a total shoulder arthoplasty include young, middle, and older patients with arthritis (typical total shoulder replacement (TSR) patients) or damage or injury to the shoulder. This new inset glenoid implant allows TSR surgery for new, previously contraindicated applications, including applications in which the patient presents with bone defects on the glenoid. The glenoid implant of the invention can also be utilized in revision surgeries.

[0109] Referring now to FIGS. 1A, 1B, and 1C, there is provided glenoid implant 10, which is intended to be implanted in the glenoid as part of a TSR arthroplasty. Glenoid implant 10 replaces the natural glenoid cavity (see G of FIG. 15) and provides a bearing surface against which the head of a humerus or humeral component may articulate. Glenoid implant 10 includes concave articulating surface 14 and convex or flat backside surface 16, which can, optionally, include roughened or textured surface 18.

Glenoid implant 10 can be provided as a circular design (FIG. 1A and 1C) or as an oblong, oval design (FIG. 1B).

[0110] Referring now to FIGS. 2A and 2B, glenoid implant 10 can include short, backside peg 12 on the medial, convex or flat backside surface 16 of glenoid implant 10. Short, backside peg 12 is situated centrally on the medial (back) side of glenoid implant 10 and is preferably a cylindrical peg shape that extends outwardly from glenoid implant 10 away from the back of the implant 16.

[0111] Glenoid implant 10, including or excluding short, backside peg 12, is adapted to be implanted in a prepared cavity of the glenoid (see, e.g., FIG. 12), such that it is partially or fully inset to the cortical bone of the glenoid, and is retained with bone cement or using press-fit techniques. Glenoid implant 10 can be further secured to the glenoid using one or more screws.

[0112] Glenoid component 10 of the present invention includes concave lateral articulating surface 14 against which the head of a humerus or humeral component moves. Glenoid implant 10 is manufactured using a suitable material, for example, polyethylene, metal, ceramic, or combinations thereof, with lateral articulating surface 14 being smoothly contoured. The radius of curvature of the articulating glenoid surface can match the humeral head surface or it can be slightly larger than the radius of curvature of the humeral head implant.

[0113] In preferred embodiments, glenoid implant 10 has a lateral articulating surface 14 having a concave circular or oval surface encircled by circular edge 20. The implant at the circular edge 20 has a thickness in an axial direction in the range of about 3-6 mm, preferably about 3 mm. The peripheral edge will have a greater axial dimension in embodiments such as illustrated in FIG. 32 which includes an additional axially extending annular flange.

[0114] The medial, back side of glenoid implant 10 is preferably roughened or textured. For example, glenoid implant 10 can include a series of elongated groves 18 in multiple locations for receiving bone cement to assist in the cement augmentation and retention of glenoid implant 10.

[0115] In preparing the glenoid to receive glenoid implant 10, the glenoid (G; see, e.g., FIG. 12) is reamed to receive all or a portion of glenoid implant 10 so that glenoid implant 10 is circumferentially surrounded by cortical bone of the glenoid (G), which aids in the stabilization and security of glenoid implant 10.

[0116] Referring now to FIGS. 13-16, there will be described a method for preparing a cavity in the glenoid for receiving a glenoid implant of the present invention and apparatus to be used therewith.

[0117] In preparing the cavity in the glenoid (G) to receive glenoid implant 10, the surgeon will initially determine the position of the drill site using a guide known in the art (see, e.g., U.S. Pat. Nos. 6,712,823; 6,364,910; 5,030,219; and 5,489,310; all of which are incorporated in their entireties by reference herein).

[0118] A reamer of appropriate size is then chosen based on the size of the sizer guide previously chosen. The reamer has a symmetrical head with a plurality of cutting blades and may have a peripheral stop surface. The previously drilled hole is used as a center guide for the reamer. The reamer is used to create a cavity in the glenoid surface of the scapula in which the prosthetic glenoid component will be installed. The reamed cavity is a receiving cavity for the glenoid repair device and is of a geometry that is generally complimentary to the geometry of the medial and peripheral aspects of the glenoid repair implant After the cavity has been created, the glenoid repair device is installed within the reamed bone cavity, with or without the use of bone cement. Insertion may be achieved by manually placing the repair device through the incision into the cavity within the bone or by means of an elongated insertion device so as to permit easy location, guidance and manipulation of the repair device through the incision and into and within the reamed bone cavity.

[0119] A method for implanting glenoid implant 10 will now be described with reference to FIGS. 13-16. Initially, if a total shoulder arthroplasty is performed, a humeral implant having a head portion, discussed below, and a glenoid implant are implanted. Prior to implantation of the humeral component into the humerus, glenoid preparation begins. With the glenoid cavity (G) of the scapula (S) exposed, an alignment or pilot hole is first drilled substantially in the center of the glenoid cavity (G) using, e.g., the drill shown in FIGS. 14, 15, and 26. Once the pilot hole is drilled, the glenoid cavity (G) is reamed using a glenoid surface rasp (see bit attached to the drill depicted in FIG. 16) attached to a reamer shaft with a driver having a laterally directed (e.g. 90°) distal end (see FIG. 26). The glenoid surface rasp may include a guide pin and a roughened cutting surface to create a trough for the glenoid component. The 90° angle of the shaft of the driver permits drilling in tight glenoid cavities. Thus, the procedure can be performed in a minimally invasive manner because it does not require full circumferential exposure of the glenoid, nor does it require a complete capsular release. The 90° shaft of the drill

includes a quick-connect attachment which receives the quick-connect drill bit. The reamer is rotated by suitable power means or by hand to ream the glenoid cavity. Following such reaming, the reamer and the guide wire/drill are removed leaving a cavity which is wholly contained within the glenoid cavity (G).

[0120] Once the holes have been drilled and the glenoid reamed, a confirmation step is performed in which a provisional or surrogate glenoid implant (often called "a trial") may be used prior to cementing the final glenoid implant to verify placement, range of motion, and glenoid size, and to verify that the glenoid implant is sufficiently inset within the bone. Several iterations of this step may occur, in which various surrogate implant devices are tested in-vivo in order to select a preferred implant geometry. After the preferred glenoid implant has been selected, the surrogate implant is removed. In instances where the surgeon elects to insert the implant within the reamed bone cavity a suitable bone cement, such as polymethylmethacrylate (PMMA) or other compatible material, is placed in the reamed bone cavity of the glenoid vault and may also be applied to the medial (back) surface of glenoid implant 10. Glenoid implant 10 is then positioned within the prepared cavity. If a cemented construct has been chosen, the glenoid implant 10 is then held in place until the cement hardens to assure strong fixation of glenoid implant 10 in the scapula. The head portion of the humerus or humeral component may then engage the concave articulating surface of the glenoid implant 14.

[0121] As can be appreciated, the reaming is contained completely within the boundary of the glenoid cavity (G) and therefore does not destroy the peripheral margin of the glenoid surface. Additionally, as can be seen in FIG. 7, there is preferably a slight overhang of glenoid implant 10 beyond the margin of the natural glenoid cavity.

[0122] This method can be performed using a deltopectoral or anterolateral surgical approach. For most cases, a limited deltopectoral incision will be adequate to allow exposure to all involved structures. Use of glenoid implant 10 in the shoulder arthroplasty procedure allows the surgeon to use a "mini-incision technique," similar to techniques utilized for total knee surgery and total hip surgery. Typical incision sizes for current Glenoid repair procedures are in the range of 150mm to 200mm, use of the methods and devices disclosed herein permits a typical incision size in the range of 70mm to 100mm to be used. Further, the use of the glenoid implant 10 reduces the number of surgical steps, entries into the wound and has other surgical benefits as outlined in Table 1. Thus, the glenoid reaming and insertion of the glenoid trial and/or final glenoid implant as described herein may be accomplished via an incision of no more

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than about 100mm, preferably no more than about 90mm and in some embodiments of the invention, no more than about 80mm.

	Standard surgical approach	Less Invasive Glenoid approach,
Incision size	15-20 cm	7-10 cm
Deltopectoral incision	Yes	Yes
Subscap incision	Yes	Yes
Capsule wide excision	Yes	No (only incision of capsule)
Labral incision	Yes	No
Biceps release	Yes	Only if needed
Full inferior capsule incision	Yes	No - partial
Axillary nerve dissection-mobilization	Yes	No

Table 1: Comparison of surgical procedures for Current and Less Invasive Glenoid Replacement

[0123] Referring to FIGS. 27, 27A, 27B, 28 and 29 , the medial aspect of a glenoid implant device 10 is shown. The device is substantially circular in design, having a radius in the range of about 22 to about 46mm. Shown also is a central anchor peg 12, the peg having a diameter range of 5mm to 12mm and an overall length of less than about 8mm. The central anchor peg shown has a concave surface 51 disposed to receive a volume of bone cement so as to enhance adhesion and retention of the implant. Alternate configurations of this concave feature may include a plurality of annular ridges or grooves or other negative impressions in the exterior surface of the peg.

[0124] In this embodiment the medial surface 16 of the implant device has been configured to facilitate the flow of bone cement across and around the medial and circumferential aspects of said device so as to attain enhanced adhesion and stability of the glenoid implant after insertion into the reamed cavity in the glenoid bone. The medial surface 16 has therein a plurality of concentric grooves 18, and a plurality of radial flow channels 120 disposed to interconnect the concentric grooves forming a continuous flow path between each of the concentric grooves. The interconnecting channels 120 on the medial surface are further connected to one or more circumferentially disposed channels

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102 via the radial flow channels 120, thereby forming an open continuous flow pathway from the central anchoring peg 12, across the medial surface of the device 16 to and around the perimeter wall 20 of the glenoid implant device. This interconnected system of concentric grooves 18, radial flow channels 120 and circumferential channel 102 is designed to accommodate the flow of bone cement across the medial surface and around the circumference of the glenoid implant device so as to assure enhanced adhesion of the implant device to and within the reamed glenoid cavity in the bone.

[0125] Further illustrated are bone cement wells 100 on the medial aspect of the implant device 16. These wells 100 may be used in conjunction with the interconnected system of grooves 18 and radial flow channels 120 to accommodate and accept any excess bone cement material which may migrate while the glenoid implant device is being compressively inserted into the reamed cavity in the glenoid bone.

[0126] While the cross sectional geometry of the flow channel system shown is generally rectilinear in nature it will be understood that various other geometries can be used to further enhance performance, including but not limited to those with negative tapers. FIG. 27A illustrates flow channels with such a negative taper geometry. As illustrated in FIG. 27A, the width of the channel at an opening 104 is less than the width at the bottom of the channel 106. This enables the strength of the bond between the bone cement and the implant to be a function of both the adhesive bonding capabilities of the cement as well as the mechanical interlocking provided by the negative taper.

[0127] As illustrated in FIG. 27B, the bone cement 700 following implantation of the glenoid implant 10 will assume a concave configuration in which a first surface corresponds to the medial surface of the implant 10, and a second surface will assume the configuration of the reamed glenoid cavity. The bone cement shell will typically have a first layer 108 extending across the distal end of the central anchoring peg 12. The first layer 108 is connected via tubular wall 112 to a second layer 111. The radially inwardly facing surface of tubular wall 112 will preferably be provided with at least one interlocking engagement structure such as a radially inwardly extending annular ridge (as illustrated) which interlocks with the complementary annular concavity 51 illustrated in FIG. 27. The second layer 111 generally comprises at least one surface structure 114 such as an annular ridge having a complementary configuration to the at least one annular concentric groove 18.

[0128] The outer periphery of the second layer 111 is substantially circular in configuration, and carries an outer peripheral annular flange 116. Outer peripheral flange

116 may be provided with at least one radially inwardly directed projection or ridge 118, such as an annular ridge having a complementary configuration to one or more radially inwardly extending annular channels 102 on the perimeter surface 20 of the glenoid implant device.

[0129] The hardened cement thus takes on the configuration of a concave shell, which corresponds to the mismatch in size and configuration between the surface of the implant and the complementary reamed surface of the glenoid bone. The thickness of the cement shell may vary, potentially down to zero in spots, depending upon placement and size of the implant relative to its corresponding reamed cavity in the glenoid bone.

[0130] Fig 27B is an illustration demonstrating the adhesion and encapsulation of the glenoid repair implant device 10 within the reamed bone cavity, further illustrated is the bone cement 700, the bone cement adhering to or encapsulating the anchor peg 16, the medial surface of the implant device 16 and the perimeter groove 102.

[0131] In certain patients arthritis or other degenerative conditions may have caused substantial wear and degeneration of the glenoid bone structure, resulting in a substantial deficiency of native bone and/or a loss of the natural concave structure of the glenoid joint. As a consequence there may be insufficient native bone remaining to completely engage the circumference of the glenoid implant device using the surgical methods previously described herein.

[0132] FIG. 30 illustrates a cavity reamed within glenoid bone, having a reamed surface 203 for engaging the medial aspect of a glenoid repair implant and a perimeter wall 201 completely surrounding the reamed surface 203 for the purposes of circumferentially engaging the complimentary perimeter aspect of said repair implant, thereby encircling and constraining the implant in the reamed bone cavity. FIG. 31 illustrates such a cavity reamed into the glenoid structure of a patient having worn, degenerated or otherwise deficient bone. In this instance there may be insufficient native bone to create a fully enclosed cavity within the bone tissue. As a consequence the reamed surface 203 may not be completely surrounded by the perimeter wall 201. As a result, there may be insufficient native boney structure to assure positive location or fixation of the glenoid repair implant within the reamed bone cavity.

[0133] Referring now to FIG. 32, an alternate embodiment of the medial aspect of a glenoid implant device is shown. In this embodiment the medial surface of the device 16 has thereon an axially extending bone engagement structure 110. This structure

may be a continuous annular construct such as an axially extending circumferential flange or may be an interrupted or castellated construct as shown. Preferably, the engagement structure 110 will be symmetrically disposed about the circumference of the implant 10 so that the implant may be positioned without regard for its rotational orientation within the bore. Alternatively, the axially extending bone engagement structure 110 may be provided around less than the entire circumference, such as no more than about 270°, or no more than about 180° of the circumference of the implant. Measured in a direction parallel to the longitudinal axis of the post 12, the axial length of the sidewall which includes both engagement structure 110 and the thickness of the implant at the peripheral edge will generally be at least about 3.5mm, generally no more than about 18mm and typically within the range of from about 4.5mm to about 12mm.

[0134] The illustrated engagement structure 110 is positioned at the peripheral edge of the implant 10. However, the bone engagement structure 110 may be spaced radially inwardly from the outer peripheral edge of the implant 110. In general, the engagement structure 110 will comprise either a single annular ridge, or a plurality of projections. See, *e.g.*, FIG. 35. In either event, the engagement structure will generally reside in a concentric circular orientation having a constant radius of curvature from the longitudinal axis of the implant. This permits convenient installation of the implant within a recess formed by a reaming tool having a rotational axis of symmetry. A second or a third or additional axially extending bone engagement structures 110 may also be provided, spaced radially inwardly from the illustrated annular flange.

[0135] To accommodate the embodiment of implant device of FIG. 32 an alternate geometry of the reamed bone cavity may be created. Referring now to FIG. 33 and FIG. 34, this complementary surface structure geometry is illustrated and described in connection with an implant having a single peripheral annular flange bone engagement structure. In this embodiment the reamed bone cavity has a reamed surface 203 disposed to engage the medial surface of the glenoid repair implant. This surface is further provided with a receiving groove 204 reamed below the plane of the surface 203 to receive the peripheral anchor 110 of the glenoid repair implant (see Fig 32). The groove within and below the surface of the bone tissue may be produced by reaming, either by means of a reamer tool having a complimentary cutting profile which simultaneously produces the surfaces 203, 205, 206 and 207 or by means of 2 reamers, one which produces surface 203, and another which subsequently produces surfaces 205, 206 and 207. The engagement of the perimeter construct 110 of the glenoid repair implant (FIG.

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32) with the receiving bone groove 204 within the glenoid bone structure enables complete circumferential engagement of the implant repair device within the glenoid bone structure to assure positive location and engagement of the implant device with and within the native bone tissue. The glenoid repair implant may be fixed to and within the reamed cavity by means of bone cement or other fixation means.

[0136] Significant posterior wear and bone loss is common in patients with osteoarthritis, and significant medial wear and bone loss is common in patients with inflammatory arthritis. Combinations of different wear patterns further complicate surgical decision making. Since all current models of glenoid implants lay on the surface of the disfigured, erratic joint surface, it is often impossible to provide secure fixation with current implants that can withstand the stresses of a rotating, elevating, translating humeral head throughout a full array of shoulder motions. Therefore, surgeons often abandon placement of a glenoid implant in deficient bone. In other instances, the surgeon may elect to create a bone graft by cutting out part of the humeral head or resecting hip bone in order to provide a wedge of bone to be secured onto the glenoid bone tissue with screws or other means of fixation. Thereafter, a glenoid implant can be placed through the graft wedge. This procedure is extremely difficult to perform, even by highly skilled surgeon, there is a high degree of subjectivity and the rate of complications is high. Complications may include implant loosening, screw breakage or loosening, graft resorption, neurovascular injury and death..

[0137] Further, in patients with substantial bone wear, degradation, or deficiency there may be a need to restore the natural angulation of the articulating surface so as to recreate the natural geometry of the glenoid to humeral interface so as to restore normal mobility and range of motion to the joint. Current practices include the use of a bone graft material in conjunction with prosthetic implant devices, the bone graft material being implanted between the prosthetic and native bone tissue in an attempt to reconstruct the volume and angulation of the bony structure to receive and support the prostheses.

[0138] Proposed herein is an alternate embodiment of a glenoid implant device which can be implanted in a minimally invasive manner into bone deficient patients which allows for the restoration of natural angulation and geometry at the humerus to glenoid interface, does not require the use of bone graft material and does not require the use of a long keel or anchor peg system.

[0139] Referring now to FIG. 36 and FIG. 37 a glenoid repair implant device is described, the implant device 300 having a generally cylindrical perimeter

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concentrically disposed about a central axis which is coincident with centerline CL. A medial surface 16 is configured to contact a reamed surface within glenoid bone and a concave articulating surface 14 is configured to contact the articulating surface of a humeral bone, or humeral bone prosthesis. The 'plane' of the articulating surface 14 is offset from the plane of the medial surface 16 by an include angle A, resulting in a wedge shaped cylindrical form. Angle A represents the corrective angle necessary to restore the functional angulation of the concave glenoid articulating 14 surface with respect to the reamed surface of the cavity within the bone tissue (203) of FIG. 30 . Angle A is generally within the range of 5 degrees to 30 degrees.

[0140] The position of the neutral or resting position of the humeral to glenoid interface, Point R, may be adjusted by varying the nominal thickness of the implant device, d3 This thickness is typically in a range of 3mm to 15mm, depending upon the extent of the deficiency of native bone and the corrective angle necessary to restore functional angulation to the glenoid joint.

[0141] Referring specifically now to FIG. 36, shown is a center section view of through a circular glenoid implant. The section view shows the maximum height of the implant Dmax and the minimum height of the implant Dmin, both measured from a common reference such as the medial surface of the implant device 16. The medial surface 16 is perpendicular to the centerline of the implant device CL. The 'plane' of the articulating surface 301 is offset from the plane of the medial surface 14 by the corrective angle A. The offset angle of the plane of the articulating surface, angleA, is defined as the maximum angle created by the intersection of a perpendicular 302 to the centerline of the device CL and the chord line 304 produced by connecting point P and point Q. Points P and Q are the respective maximum and minimum thickness dimension of the implant, measured in an axial direction, at their respective maximum radial distances from the device centerline CL, as measured from a constant reference such as the medial surface of the implant device 16.

[0142] The combination of a circular implant device with this offset angular surface construction enables the surgeon to accurately orient the primary axis of the articulating surface within the wound by rotating the implant device about the centerline of the device CL while it is in-situ in the reamed cavity of the glenoid bone. Referring to FIG. 37A, it is evident that point P can be positioned at any radial location by rotating the implant device about the centerline CL, thereby providing infinite planar orientation of

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the articulating surface 14 and enabling the surgeon to orient the plane of the glenoid implant so as to optimally restore the functional angulation of the glenoid joint structure.

[0143] As an aid to the surgeon, one or more indicator marks can be included on the device, this indicator being visible when the device is implanted within the reamed cavity in the glenoid bone. Figures 37A and 37B illustrate alternate embodiments of indicator markings. FIG. 37A illustrates a single indicator mark on the articulating surface and/or the peripheral edge of the implant, which indicates the apex of the articulating surface, point P. FIG. 37B illustrates a plurality of indicia radially orientated around the perimeter of the device, allowing for metered in-vivo rotational adjustment of the device to orient the apex of the implant at the optimal position within the reamed glenoid cavity. Indicia markings may be manufactured by many processes which produce a positive or negative feature on the device or which produce a graphic on or within the device , including but not limited to, laser marking, printing, injection molding and machining.

[0144] Referring now to the embodiment of FIG. 38, the articulating surface 14 is defined as a surface of revolution created by rotating an arc of constant radius R1 about an axis of rotation 400, this axis of rotation being offset from the centerline of the device CL by angle A and intersecting the centerline of the device CL at a prescribed distance from the medial surface D3. In the embodiment of FIG. 38 the radius of the arc of rotation has an origin (0) located on the axis of rotation, thereby producing a spherical articulating surface.

[0145] In the foregoing illustration, a line drawn perpendicular to the axis of rotation 400 at the articulating surface 14 (e.g., a tangent) will be angularly inclined relative to the centerline by an Angle A. Angle A may be at least about 5°, 10°, 15°, or 20° or more, depending upon the desired clinical performance.

[0146] In an alternate embodiment, shown in FIG. 39, the origin O of the constant radius arc is offset contra-laterally from the axis of rotation 400 of the concave surface. In this embodiment the articulating surface is defined as a surface of revolution, created by sweeping an arc of constant radius (R1) about the axis of rotation 400 to produce a non spherical articulating surface of constant radius R1. FIG. 40 is a side elevational cross sectional view of the articulating surface created by the geometrical construct of FIG. 39, illustrating that the surface construct has an apex at point R. FIG. 41 is a specific embodiment of this construct for a glenoid implant having a cylindrical diameter of 31mm, the radius of the arc of revolution being 90mm and being offset

contra-laterally from the axis of rotation by 7.78mm to produce a concave articulating surface with a depth of 3mm at the device centerline.

[0147] In general, glenoid implants in accordance with the present invention will often have a lateral offset distance within the range of from about 2mm to about 18mm, and a radius for the arc of revolution within the range of from about 30mm to about 200mm and have a circular diameter of 20mm to 55mm.

[0148] FIG. 42 is a perspective view showing a cross section through an articulating surface generated by the specific geometry of FIG. 41, the plane of the articulating surface 14 being offset from the plane of the medial surface 16. FIG. 42 further shows the articulating surface generated by the specific construct of FIG. 41 and identifying the axis of rotation (400), the device centerline CL, the articulating surface of constant radius (R1) created by revolving this arc 360 degrees about the axis of rotation (400) and the resultant apex of the articulating surface, occurring at Point R.

[0149] There remains ongoing debate as to the relative benefits of a constrained or non-constrained shoulder replacement system. A constrained system is a specific combination on a prosthetic humeral head and glenoid implant pair, wherein there is a precise and constrained fit between the humeral head and the glenoid implant device, limiting relative motion of the two components to pure spherical articulation. In non-constrained systems the spherical diameters of the humeral head prosthesis and that of the glenoid implant device are deliberately mismatched, the glenoid implant having a larger diameter than the humeral head. In this construct the humeral head can articulate spherically and can translate across the surface of the glenoid implant in an unconstrained manner.

[0150] Published literature discusses various biomechanical benefits and limitations of both systems. Both systems offer significant benefits and limitations and several attempts have been made to develop hybrid systems. US patent 5,928,285 to Bigliani et Al. discloses a system wherein the glenoid surface is defined by 2 or more tangentially intersecting radii, with the central radius being matched to that of the humeral head and the lateral radii of the glenoid being larger than that of the humeral head. The cited benefit being that in the central neutral position the pair acted as a constrained pair and when the humeral head translated laterally onto a glenoid surface of larger radius size than the head, the system mimicked the characteristics of an un-constrained system. In this construct it is necessary to match the humeral head radius to that of the glenoid, thereby requiring that matched pairs be implanted within the patient. US patent

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application 6,875,234 to Lipman et al. discloses a system wherein the glenoid articulating surface is comprised of 2 non tangential radii, the radius in the central neutral zone being larger than that of the humeral head and the glenoid radius lateral to the neutral zone being of a smaller size and being non-tangential to the radius of the neutral zone. In this configuration the humeral head is free to articulate and translate within the central neutral zone and becomes more constrained as the humeral head translates laterally across the glenoid surface.

[0151] Of further note is that fact that in unconstrained systems the contact between the humeral head and the articulating glenoid surface is essentially a point contact. This increases load transfer within and through the glenoid implant and has been shown to negatively impact wear and permits loosening of the glenoid repair implant over time.

[0152] Referring now to FIG. 43, there is illustrated an enlarged cross sectional view of the articulating surface of the glenoid repair implant construct shown in FIG. 41. FIG. 43 further illustrates a representation of various diameter humeral heads, ranging in size from 20mm to 60mm engaging the articulating surface 14 of the glenoid repair implant device 10. Humeral heads in current use range from 36mm to 60mm. FIG. 43 illustrates that the geometry of the articulating surface resulting by generating a surface of revolution in a manner described by FIG. 41 can accommodate a humeral head of any size. Further, this offset surface geometry construct results in full circumferential contact between the humeral head and the glenoid articulating surface while in the neutral position. FIG. 43 illustrates the chords C20, C40, C50 and C60 which are the diameters of the circumference of contact between the articulating surface of the glenoid repair device and the corresponding humeral heads having diameters measuring 20mm, 40mm, 50mm and 60mm respectively. This circumferential contact: 1) increases the surface area of contact between the glenoid surface and humeral head implants significantly, as compared to an unconstrained system with a single point of contact; 2) results in a uniform circular distribution of loads within and through the glenoid implant; 3) distributes loads more uniformly around the central anchor peg so as to minimize offset loads which can loosen the implant; and 4) induces the humeral head to return to the neutral position after any translational movement across the articulating surface 14, resulting in an implant system with self centering characteristics.

[0153] In FIG. 43, the geometry of the articulating surface 14 clearly demonstrates an apex of non-contact at Point R. As a consequence of the offset surface

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geometry construct there is never contact between the humeral head or the glenoid articulating surface 14 in an area of the surface surrounding point R, thereby creating a zone of non-contact having a diameter approximately equal to the chord length discussed above which depends upon the curvature of the humeral head. With this offset surface construct it is therefore conceivable that the articulated surface of the glenoid implant could be discontinuous in this region, allowing for the inclusion of a port or hole passing through the Glenoid articulating surface into the central anchor peg to accommodate secondary fastening or securement of the implant device in the final in-vivo location. Such fasteners could include bone screws, staples, expanding pegs or other axially or rotationally adjustable devices which induce mechanical engagement to the native bone. This construct offers substantial advantage over current devices in which there is contact between the humeral head and any discontinuity in the articulating surface.

[0154] FIG. 43A and 43B illustrate exemplary embodiments of one such construct. In both embodiments there is an open lumen or channel between the offset articulating surface 14 and the medial surface 16, the opening on the articulating surface being located in the zone of non-contact.

[0155] The exemplary embodiment of FIG. 43A illustrates a glenoid repair device which does not have an integral central anchor peg. In this specific embodiment the peg is replaced by a removable mechanical fastener 600 such as a bone screw, barbed peg, staple or other device which is inserted through the central access channel into the native glenoid bone passing from the articulating surface 14 through the medial surface 16 and into the native bone structure after the repair implant has been inserted into the reamed receiving cavity in the bone.

[0156] Referring once again to FIG. 32, an exemplary embodiment of the medial aspect of a glenoid repair implant device is shown. In the configuration shown a segmented central anchor peg is shown, having an annular construct with a hollow core 132 and the annular aspect being divided into a plurality such as two or three or four or more discrete axially extending finger elements 130. In this embodiment the external diameter of the anchor peg (E) is larger than the internal diameter of the corresponding receiving hole drilled in the native glenoid bone. Upon insertion of the anchor peg into the receiving hole the finger elements 130 flex elastically radially inwardly into the hollow core 132 producing a radially outwardly directed compression force to be exerted in the native bone tissue. Such a segmented construct can be mechanically enhanced and

complimented by a mechanical feature which engages the finger elements or native bone within or through the hollow core 132.

[0157] Referring now to FIG. 43B in combination with FIG. 32, the exemplary embodiment illustrated in Fig 43b has an open access channel 600 between the articulating surface 14 and the medial surface 16 of the device and further passing axially through the segmented central anchor peg, the segmented anchor peg being of a construct similar to that illustrated in Fig 32. A mechanical fastener 601 is inserted in an axial direction through the opening of the central access channel 600 at the articulating surface of the implant device 14, engaging the internal surfaces of the anchor peg segments 610. As the fastener progresses axially into the channel, the anchor peg segments 130 are induced to flex radially outwards causing the external surfaces of the anchor peg segments 620 to impinge into the native cancellous bone of the glenoid structure below the cortical bone surface. This impingement anchors the implant within the native bone of the glenoid structure. The radially outwardly facing surfaces of the segments 620 may be provided with any of a variety of barbs, ridges, roughened surface textures or other bone engagement feature.

[0158] The mechanical fastener illustrated in Fig 43b is a threaded device, having an external thread 630 which mates with an internal thread 640 within the glenoid implant device. Various embodiments of the mechanical fastener 601 may be used, including but not limited to, screws, barbed rods and split pegs.

[0159] The mechanical fastener 601 includes a proximally facing surface 650, which, following installation, will face the humeral ball. Surface 650 is preferably recessed beneath the adjacent articulating surface 14. This may be accomplished by providing a recess 652 into the articulating surface 14 to receive a head on which the surface 650 resides. Alternatively, the mechanical fastener 601 may comprise a threaded body having a relatively constant outside diameter throughout its axial length, such that it can be axially advanced into the access channel 600 until the proximally facing surface 650 is beneath the level of articulating surface 14.

[0160] In an embodiment in which mechanical fastener 601 is rotated into engagement with segments 610, the proximal surface 650 is provided with a mechanical interfit coupling, for removably cooperating with a driver tool. The coupling may comprise a recess such as slot or polygon such as a triangle, square, pentagon or hexagon. Implants in accordance with this aspect of the invention may be provided in a kit which includes a driver tool, such as an Allen wrench, or other specialized screwdriver to

rotationally engage the mechanical fastener 601. The driver tool may comprise an elongate tubular body, having a lateral bend such as a 90° bend at its distal end. A rotatable tip is carried by the distal end, and configured to complement the geometry of the engagement structure on mechanical fastener 601. The rotatable tip is connected via the central lumen to a proximal control, which may be rotated by the clinician to rotate the mechanical fastener 601 into place. Mechanical connection between the proximal control and the distal rotatable tip may comprise a flexible cable extending through the central lumen, or a torque rod which may be provided with suitable gears at the point of the bend to translate rotational force from the longitudinal axis of the tool to the transverse axis of the rotatable tip.

[0161] In general, any of a variety of structures may be utilized to convert axial proximal or distal movement, or rotational movement of an active engagement mechanism, to produce a radially outwardly directed advance of one or more bone engaging components carried by the post 12 , to facilitate bone engagement.

[0162] Referring now to FIG. 45, an alternate embodiment of the medial aspect of a glenoid repair implant device 16 is shown having yet another exemplary embodiment of a segmented central anchor peg construct. In this embodiment the central anchor peg has an external diameter F, within the range of from about 10mm to 20mm. The relatively wide anchor peg is intended to isolate and distribute the forces transmitted to the glenoid implant device by the humeral head while articulating within the normal neutral region of the shoulder joint.

[0163] The segmented anchor peg of this embodiment may further be provided with a hollow core 132, capable of accepting and retaining supplemental bone graft material so as to promote osteointegration of the glenoid repair implant within the native bone. Radially outwardly actuatable barbs, spikes or other bone engagement structures may also be provided as discussed above.

[0164] Referring now to FIG. 43 and 45 in combination, a specific embodiment of a glenoid repair device is described, the device having an offset articulating surface construction of FIG. 43 combined with the large diameter anchor peg construct of FIG. 45. In this embodiment, diameter F of the glenoid repair implant (FIG. 45) is larger than the maximum chord of contact which can occur for the corresponding humeral implant thereby assuring an optimal distribution of forces within the glenoid repair implant as a result of the circumferential line of contact and optimal transfer of

loads through the glenoid repair implant into the native bone structure through the structure of the central anchor peg .

Humeral Head Cutting Jig

[0165] Referring now to FIGS. 17-19, humeral head cutting jig 26 according to the present invention is a simple, low profile humeral cutting jig that can be a full circle or part thereof. Cutting jig 26 can be secured to the humeral head using K-wires, pins, or screws 27 and is removed after completion of humeral head resection. Cutting jig 26 includes handle portion 28.

[0166] The cutting jig should be placed along the anatomic neck of the humeral head. Osteophytes which obscure the junction of the humeral head and humeral shaft should be removed in order to accurately mark the level of the anatomic neck circumferentially from anterior to inferior to posterior. The cutting jig can be fixed to the humerus using wires, pins, or screws at the appropriate angle and version as determined by the surgeon. The rotator cuff should be carefully protected with retractors, and then the humeral cut is performed using an oscillating saw or osteotome along the surface of the cutting jig.

[0167] The cutting jig can be manufactured using metal.

Humeral Implant

[0168] Referring now to FIGS. 20A-D, humeral implant prosthesis 38 according to the present invention includes stem 40 having elongated portion 42 optionally including collar 44, which prevents humeral implant prosthesis 38 from embedding too deeply in the humerus. Humeral implant 38 also includes flange (fin) 46, which aids in the fixation of the stem in the humerus and prevents rotation of humeral implant in the humerus. There may be just one lateral flange (fin), or there may be two or three flanges (fins), e.g., with one lateral, one anterior, and one posterior. The stem length is preferably less than about 70 mm, and the stem width is preferably less than about 40 mm (preferably about 30 mm).

[0169] At the distal end of the stem, there is rounded portion 48 and at the proximal end of the stem is a support surface extending radially from the stem. The support surface has an upper planar surface 50 that includes bore (hole with morse taper) 52 extending inwardly from the top plane thereof, and which is adapted to be engaged by a humeral head implant with a morse taper extension. Modular humeral head implants (both concentric and eccentric) are known in the art (see, e.g., U.S. Pat. Nos. 4,865,605; 5,314,479; 5,462,563, and 5,489,309, and U.S. Patent Application Nos. 2004/0167629,

2004/0064187; each of which is incorporated herein by reference). The plane of upper planar surface 50 is preferably between about 45 degrees and about 60 degrees to the axis of the stem.

[0170] The entire stem portion, or a portion thereof, is preferably coated with a porous material for aiding in the fixation of the humeral implant in the humerus for a press fit stem. The implants made for cement fixation can have a smooth surface or a roughened, textured surface.

[0171] Humeral implant 38 can be rectangular or rounded edges, but is significantly thinner anterior to posterior than medial to lateral. It will have a morse taper for securing a standard humeral head implant.

[0172] An advantage of the humeral implant of the present invention over current humeral implant stems is that the humeral implant of the invention is significantly shorter than most current stems, which are about 70-115 mm in length. Because the humeral implant is shorter, it saves bone because of the narrow metaphyseal area required for implantation. The present humeral implant is less than 70 mm in length, preferably about 60 mm in length, and less than 40 mm anterior-posterior width (preferably about 30 mm). Fixation of the present humeral implant depends upon good interference fixation in the medial-lateral plane when press fit (similar to some current total hips). The humeral implant can be fixed using a bone cement, such as polymethylmethacrylate (PMMA) or a compatible fixation material, or it can be press-fit.

[0173] The invention will now be described by the following examples. The following examples are meant to illustrate the invention. They are not meant to limit the invention in any way.

EXAMPLES

Example 1

[0174] A 62 year old woman presented with progressive, debilitating shoulder pain from osteoarthritis, which she had experienced for approximately 15 years. She had constant pain (rated 9/10) and difficulty washing her hair, fastening her bra, lifting a cup of coffee, and performing other daily activities. The preoperative radiographs and CT scan showed severe shoulder arthritis and glenoid bone loss that would preclude the use of a keeled or pegged glenoid implant. There was concern that a hemiarthroplasty procedure (replacement of the humeral ball, which would leave the arthritic glenoid socket bare) would not relieve the patient's pain.

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[0175] A total shoulder replacement using an inset glenoid implant of the invention and a standard humeral implant was performed. The smaller size and circumferential fixation of the inset glenoid implant allowed safe placement of the prosthesis within the confines of the patient's deficient glenoid cavity.

[0176] The deficient glenoid vault was not fractured and the fixation was very stable. The patient had 100% relief of pain only 1 week after surgery. Her own assessment of shoulder function 4 weeks after surgery was 56% of normal (American Shoulder and Elbow Society validated outcome score [ASES score]) was 56 compared to 16% of normal before the surgery (ASES score 16).

[0177] This surgery was performed through the "mini-incision total shoulder technique" described above. FIG. 25 shows the surgical incision 4 weeks post-operatively. FIG. 24, which shows a more typical total shoulder incision, clearly demonstrates the improved cosmetic appearance and reduced incision size achieved using the "mini-incision total shoulder technique" described above. FIGS. 21-23 are intraoperative pictures of the implanted inset glenoid prosthesis in this patient.

Example 2

[0178] An 81 year old woman presented with severe shoulder pain and stiffness. She had severe shoulder arthritis with medial wear causing glenoid bone loss. Her own assessment of shoulder function was 25% of normal (American Shoulder and Elbow Society validated outcome score [ASES score] was 25).

[0179] A total shoulder replacement using an inset glenoid implant prosthesis was performed. Two months after her surgery, the patient had no pain and exhibited improved function. Her own assessment of shoulder function was 70% of normal (American Shoulder and Elbow Society validated outcome score [ASES score] was 70).

[0180] While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modifications and this application is intended to cover any variations, uses, or adaptations of the invention following, in general, the principles of the invention and including such departures from the present disclosure that come within known or customary practice within the art to which the invention pertains and may be applied to the essential features hereinbefore set forth.

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WHAT IS CLAIMED IS:

1. A method of treating a patient, comprising the steps of:

identifying a patient having a glenoid surface;

surgically exposing the glenoid surface,

reaming a circular cavity into the glenoid surface; and

inserting a glenoid implant into the cavity, the medial aspect of the implant having a circular geometry complimentary to that of the reamed bone cavity, such that at least a portion of a circular peripheral edge of the implant resides below the adjacent glenoid surface and the portion residing below the adjacent glenoid surface is circumferentially surrounded by cortical bone of the glenoid.

2. A method of treating a patient as in Claim 1, wherein cortical bone surrounds the entire circular edge of the implant, for at least a portion of the height of the circular edge.

3. A method of treating a patient as in Claim 1, additionally comprising the step of securing the implant within the cavity using bone cement.

4. A method of treating a patient as in Claim 1, additionally comprising the step of securing the implant within the cavity by interference fit.

5. A method of treating a patient as in Claim 1, additionally comprising the step of securing the implant within the cavity using a mechanical fastener.

6. A method of treating a patient as in Claim 1, additionally comprising the step of stabilizing the implant within the cavity using a central peg extending from a medial surface of the implant.

7. A method of treating a patient as in Claim 1, additionally comprising the step of accessing the glenoid via a deltopectoral approach.

8. A method of treating a patient as in Claim 1, additionally comprising the step of accessing the glenoid via an anterolateral approach.

9. A method of treating a patient as in Claim 1, wherein the reaming a cavity step comprises reaming a cavity completely within the boundary of the native glenoid cavity without destroying the peripheral margin of the glenoid surface.

10. A method of treating a patient as in Claim 1, additionally comprising the step of accessing the glenoid via an incision no more than about 9 cm in length.

11. A method of treating a patient as in Claim 1, wherein the reaming a cavity step is accomplished while leaving the majority of the inferior capsule intact.

12. A method of treating a patient as in Claim 1, wherein the reaming a cavity step is accomplished while leaving the peripheral cortex intact.

13. A method of treating a patient as in Claim 1, wherein the reaming a cavity step is accomplished using a power drill having a 90 degree bend.

14. A glenoid implant, comprising:

a circular body, having a medial surface, an articulating surface, a peripheral edge, and a central axis;

a post on the medial surface, disposed concentrically on the central axis; and

at least one axially extending flange extending from the medial surface at the peripheral edge of the circular body.

15. A glenoid implant as in Claim 14, wherein the at least one flange extends around at least about 75% of the peripheral edge of the circular body.

16. A glenoid implant as in Claim 14, wherein the circular body has a first thickness measured in the axial direction at a first point on the peripheral edge, and a second thickness measured in the axial direction at a second point on the peripheral edge spaced apart from the first point by 180 degrees, and the first thickness is substantially equal to the second thickness.

17. A glenoid implant as in Claim 16, wherein the first thickness is at least about 125% of the second thickness.

18. A glenoid implant as in Claim 16, wherein the first thickness is at least about 150% of the second thickness.

19. A glenoid implant as in Claim 16, wherein the first thickness is at least about 200% of the second thickness.

20. A glenoid implant, comprising:

a circular body, having a medial surface, an articulating surface, a peripheral edge, and a central axis;

a post on the medial surface, disposed concentrically on the central axis; and

a first thickness measured in the axial direction at a first point on the peripheral edge, and a second thickness measured in the axial direction at a second point on the peripheral edge spaced apart from the first point by 180 degrees;

wherein the first thickness is at least about 125% of the second thickness.

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21. A glenoid implant as in Claim 20, further comprising at least one projection extending axially from the body at the peripheral edge.

22. A glenoid implant as in Claim 21, wherein the projection comprises an annular flange.

23. A glenoid implant as in Claim 22, wherein the annular flange is discontinuous.

24. A glenoid implant as in Claim 20 further comprising at least one bone cement flow channel on the medial surface.

25. A method of treating a patient, comprising the steps of:

exposing a glenoid surface;

reaming a circular depression in the glenoid surface;

providing a glenoid implant having a circular peripheral edge and a nonspherical concavity with an articulating surface, the concavity having an axis of rotation which is angularly offset from an axis of the circular peripheral edge;

positioning the circular peripheral edge at least partially within the circular depression; and

rotating the implant to direct the axis of rotation to a desired position.

26. A method of treating a patient, comprising the steps of:

making a skin incision;

exposing a glenoid surface through the incision;

introducing a reamer through the incision and reaming a circular depression in the glenoid surface; and

introducing a glenoid implant through the incision and positioning the glenoid implant at least partially within the depression;

wherein the incision is no more than about 100 mm in length.

27. A cement construct for retaining an implant within a cavity in bone, comprising:

a cement shell, having a concave side corresponding to the configuration of an implant and a convex side corresponding to the configuration of a prepared cavity in a bone, the concave side having an axis of rotational symmetry;

a first tubular wall section concentrically disposed about the axis,

a substantially planar section extending radially outwardly from an end of the first tubular wall section and transverse to the axis; and

a second tubular wall section concentrically disposed about the axis and extending axially from a peripheral edge of the planar section;

wherein the second tubular wall section extends at least about 180 degrees around the axis.

28. A cement construct as in Claim 27, wherein the second tubular wall section extends at least about 270 degrees around the axis.

29. A method of preparing a glenoid surface for implantation of a glenoid implant, comprising the steps of:

reaming a circular depression in the glenoid surface, to produce a reduced glenoid surface having an axis of rotation;

reaming a bore coincident with the axis and below the level of the reduced surface; and

reaming an annular channel, concentrically positioned about the axis and below the level of the reduced surface.

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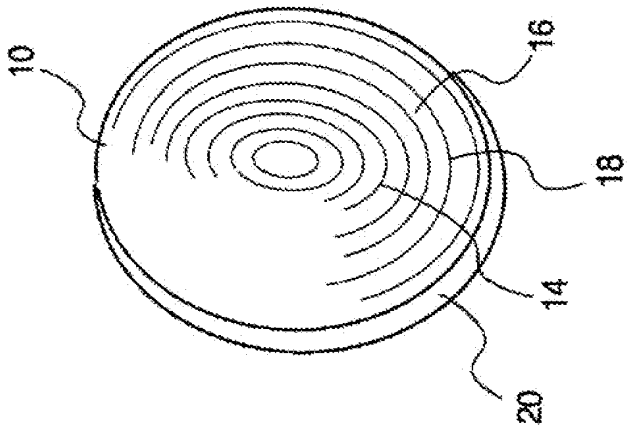


FIG. 1C

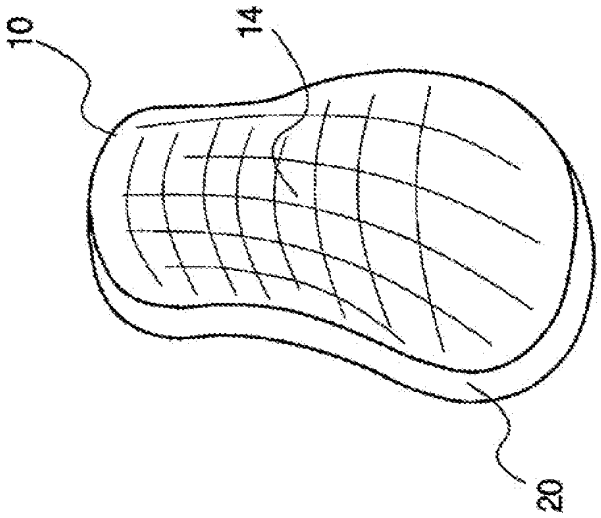


FIG. 1B

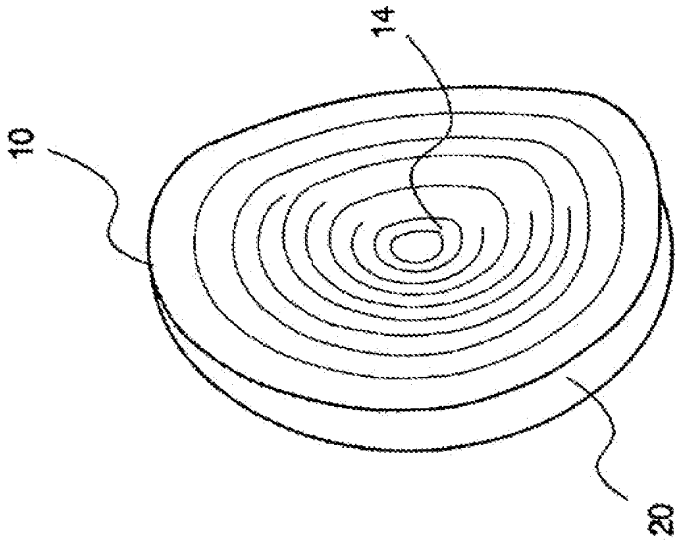


FIG. 1A

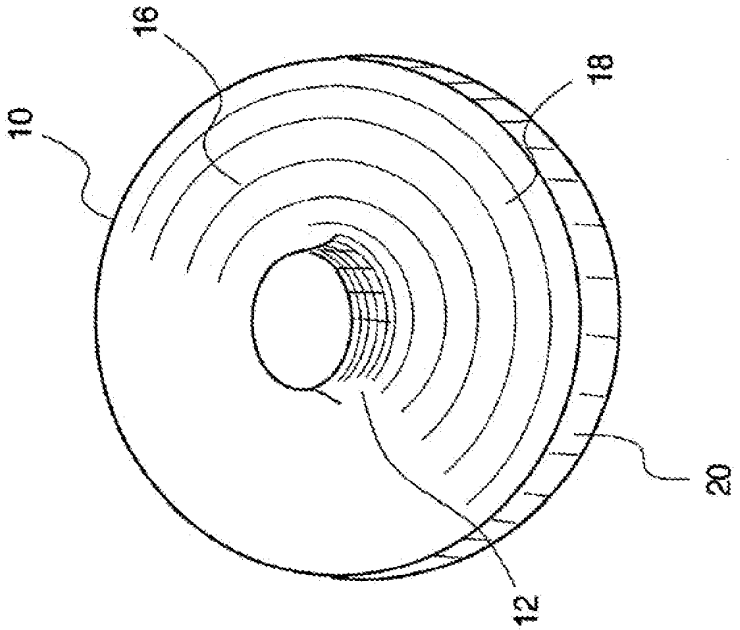


FIG. 2B

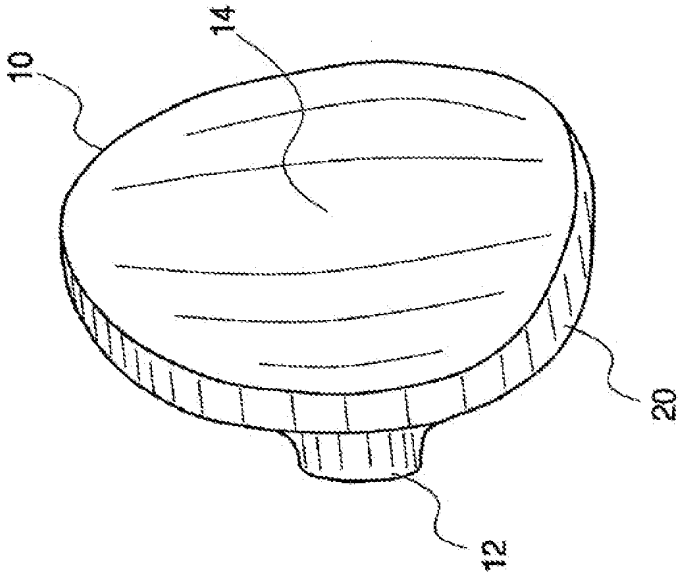


FIG. 2A

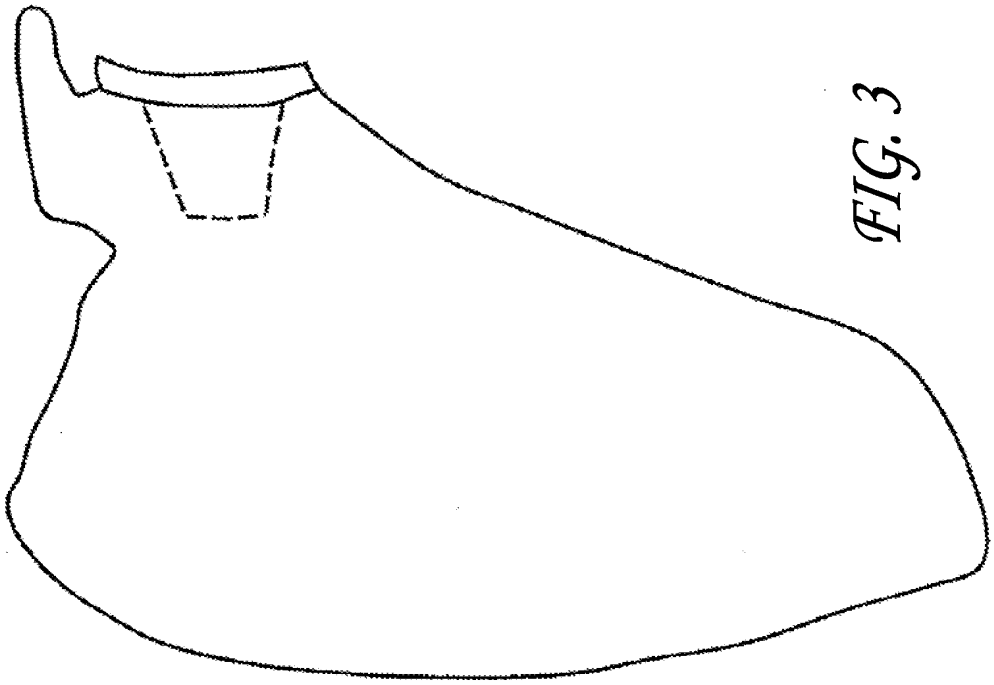


FIG. 3

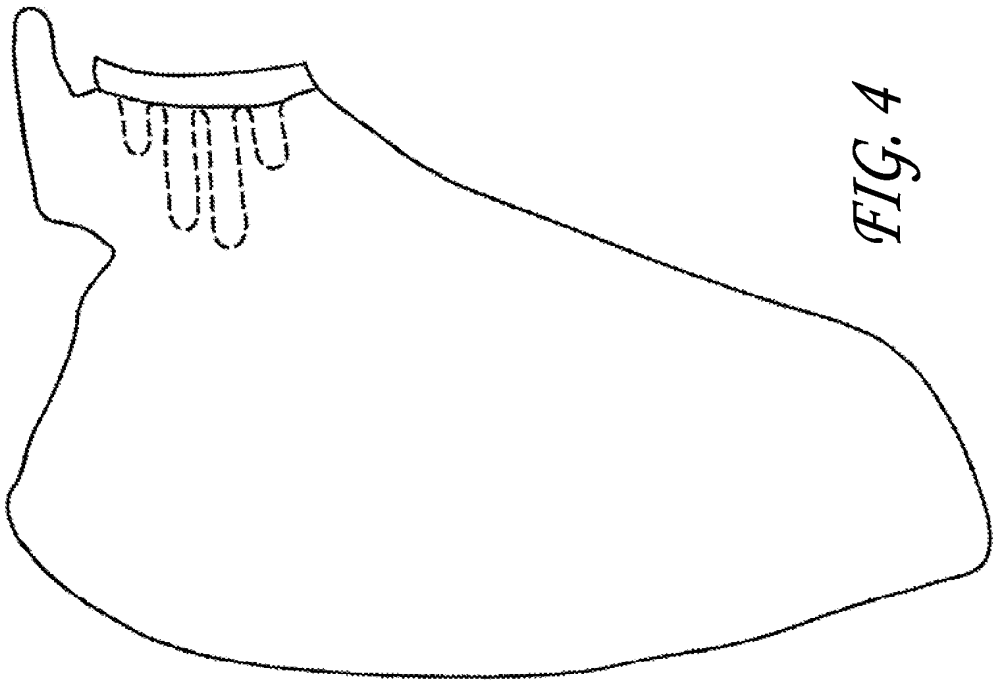


FIG. 4

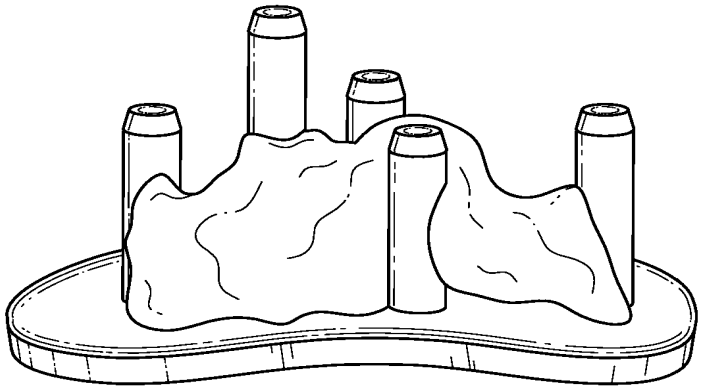


FIG. 5

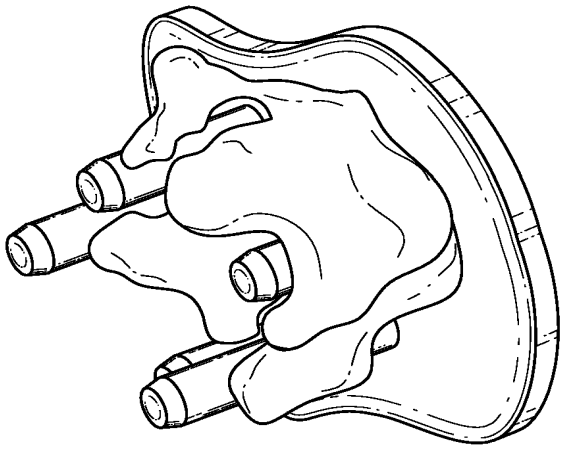


FIG. 6

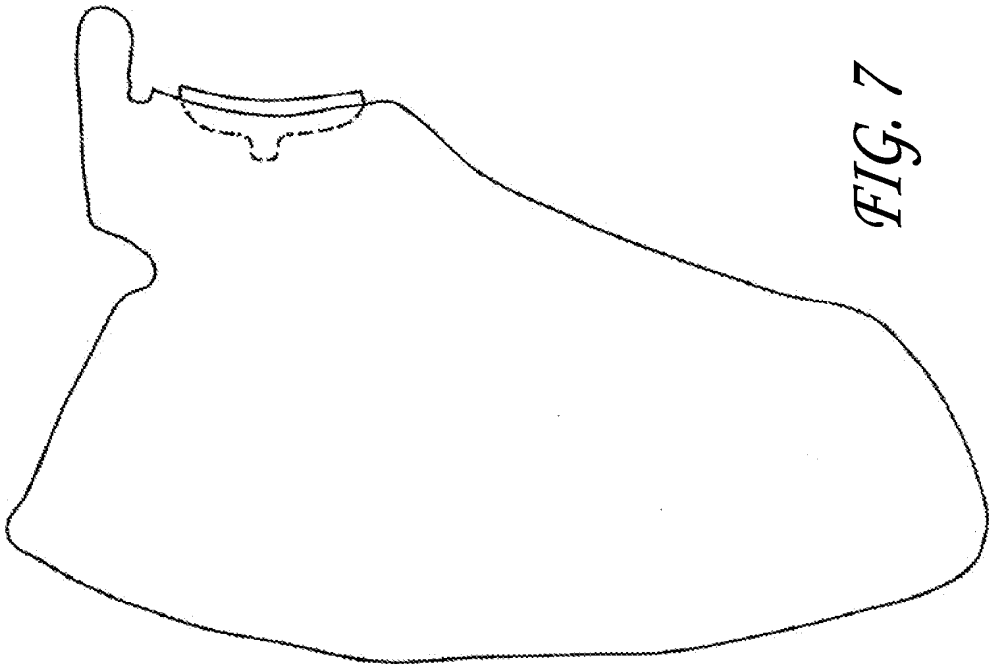


FIG. 7

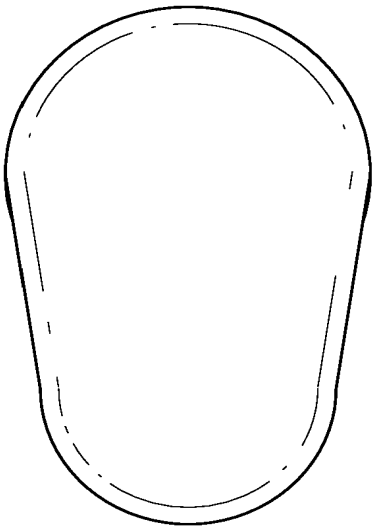


FIG. 8A

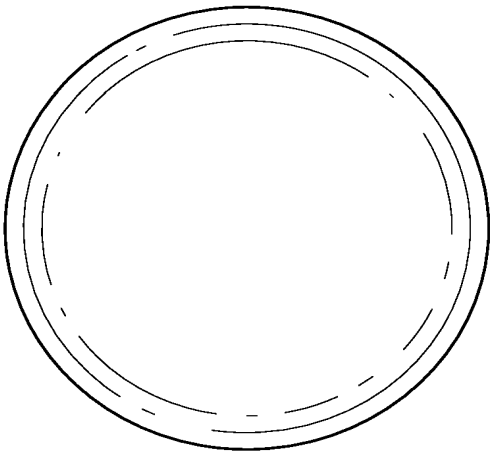


FIG. 8B

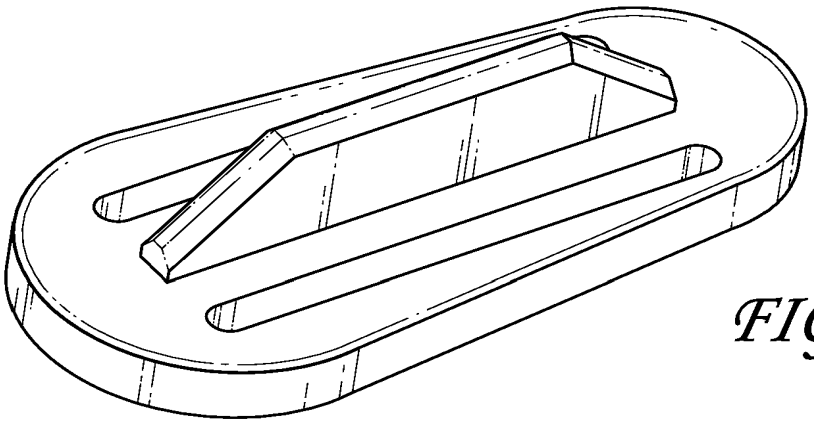


FIG. 9A

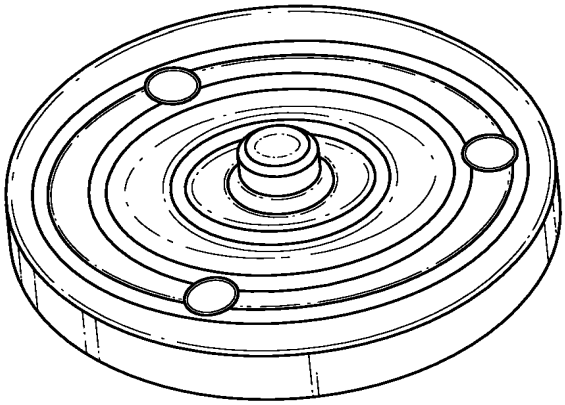


FIG. 9B

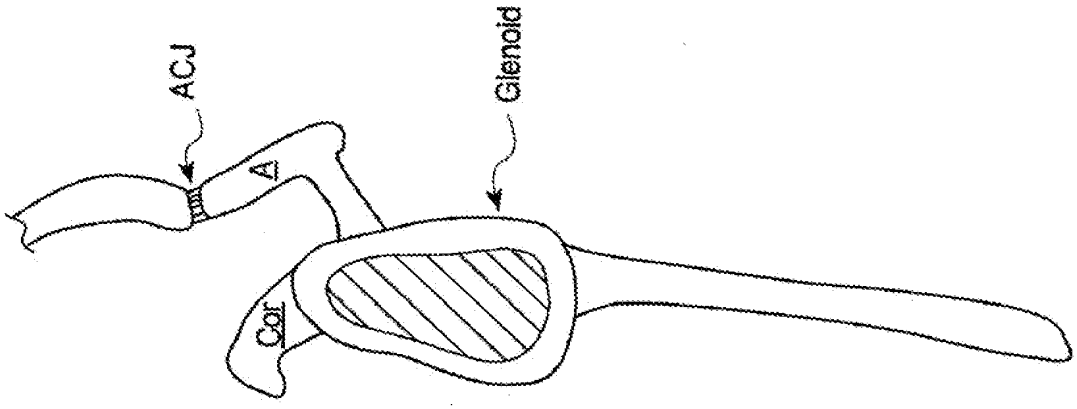


FIG. 10B

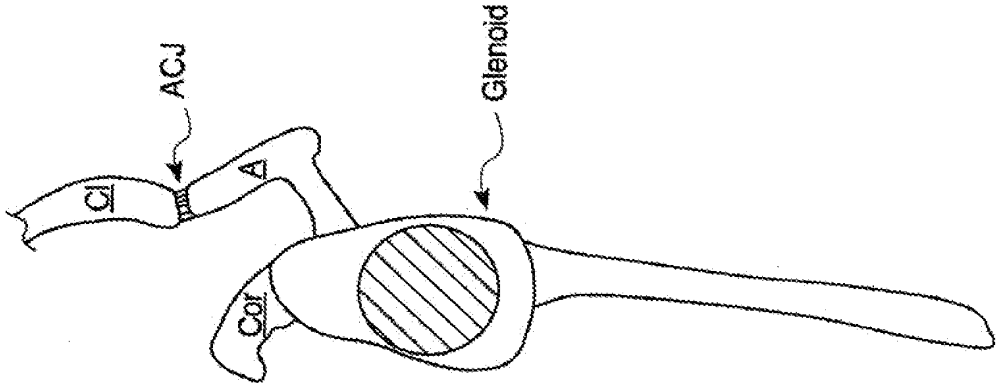


FIG. 10A

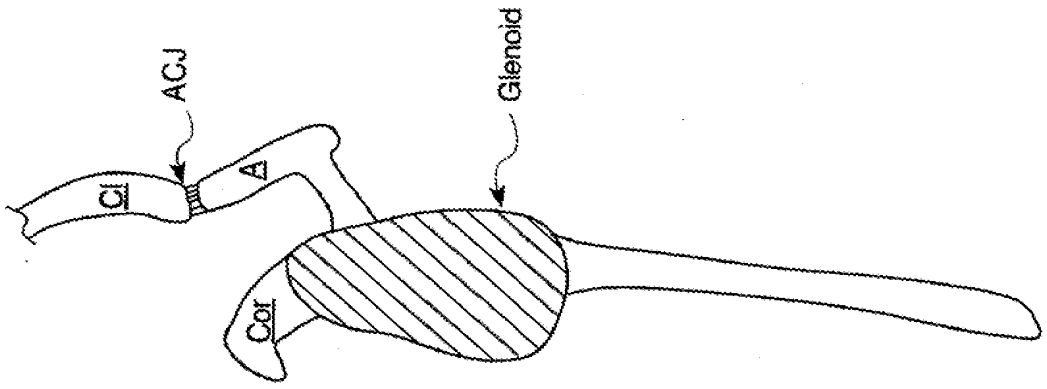


FIG. 11

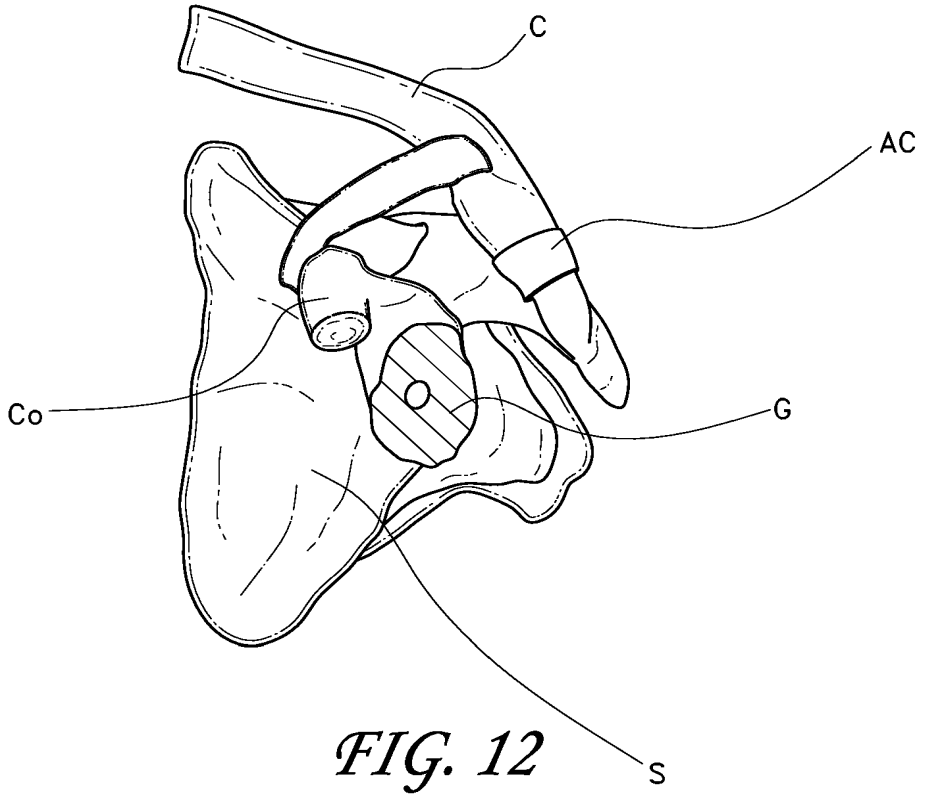


FIG. 12

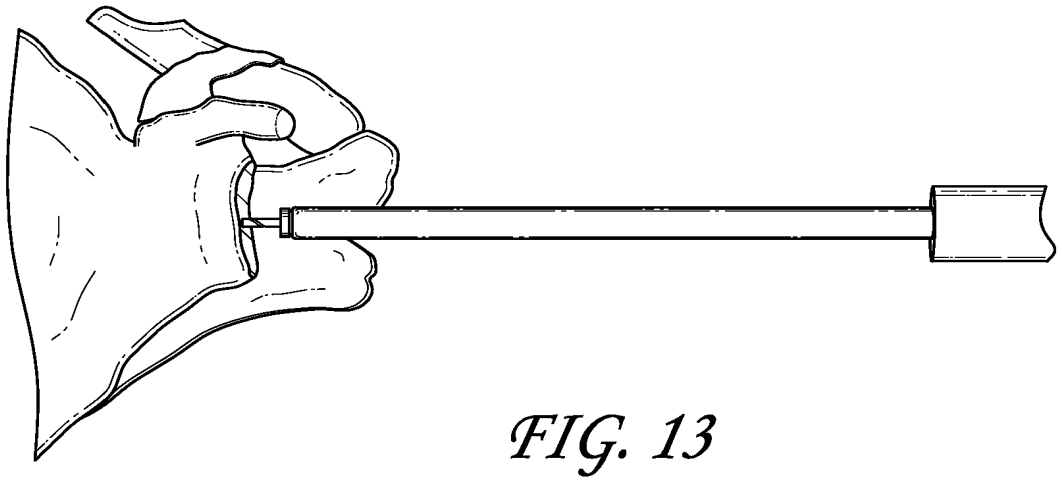


FIG. 13

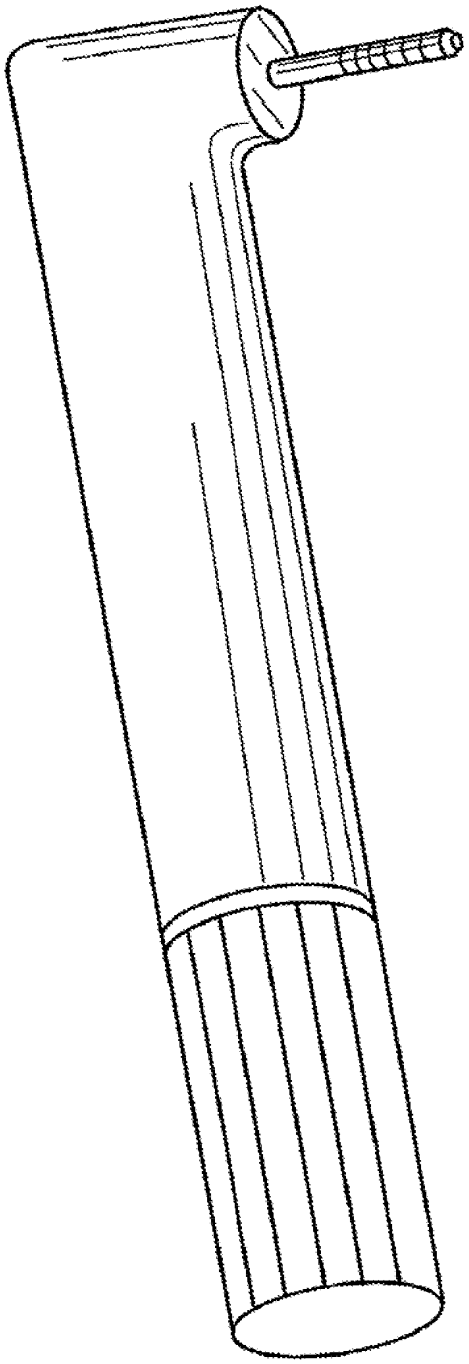


FIG. 14

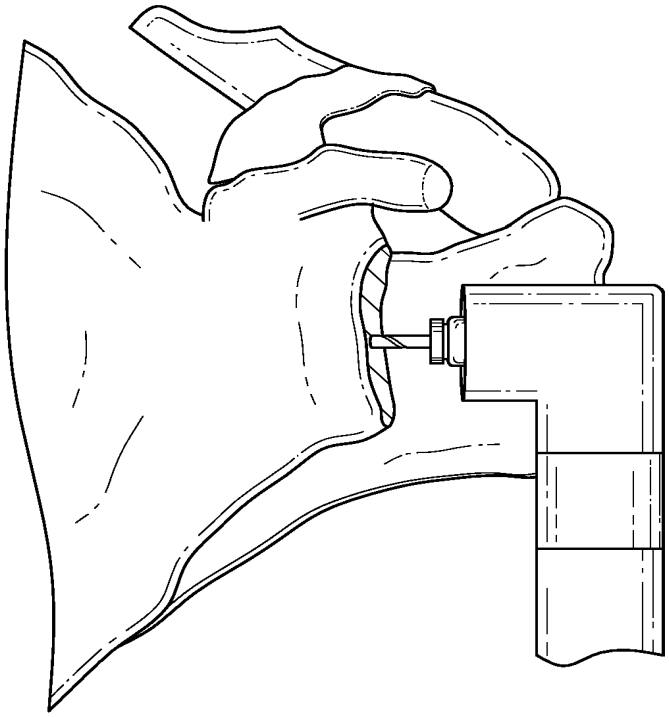


FIG. 15

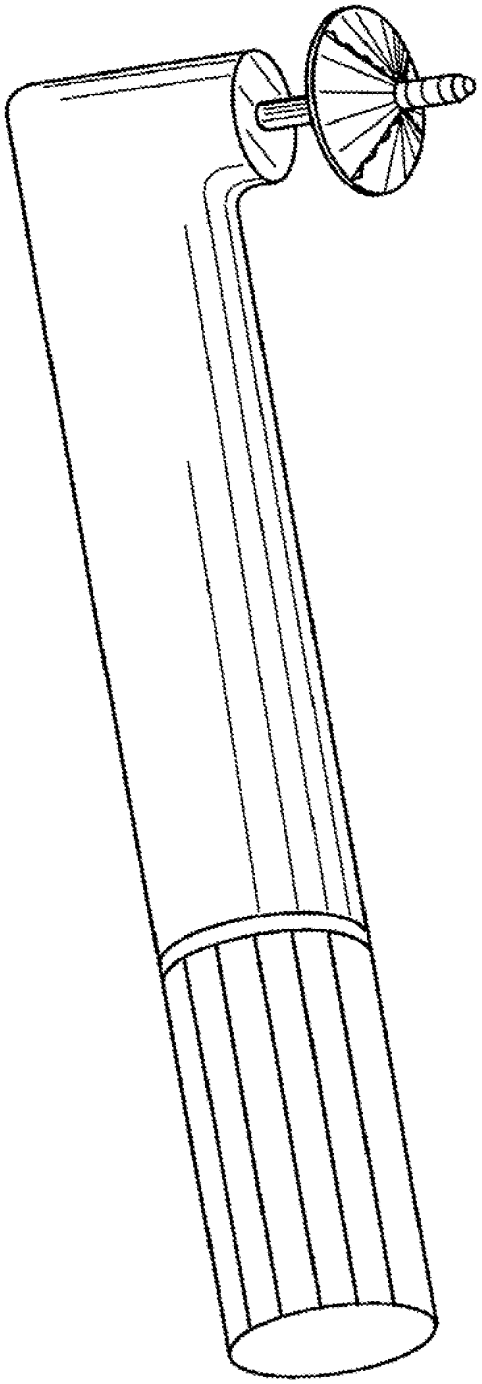


FIG. 16

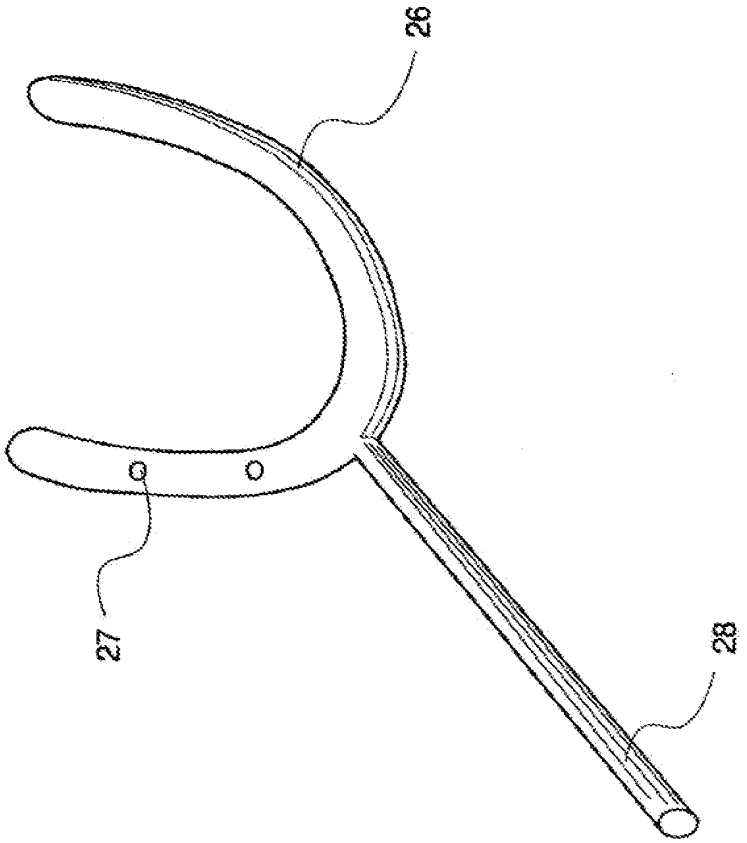


FIG. 17

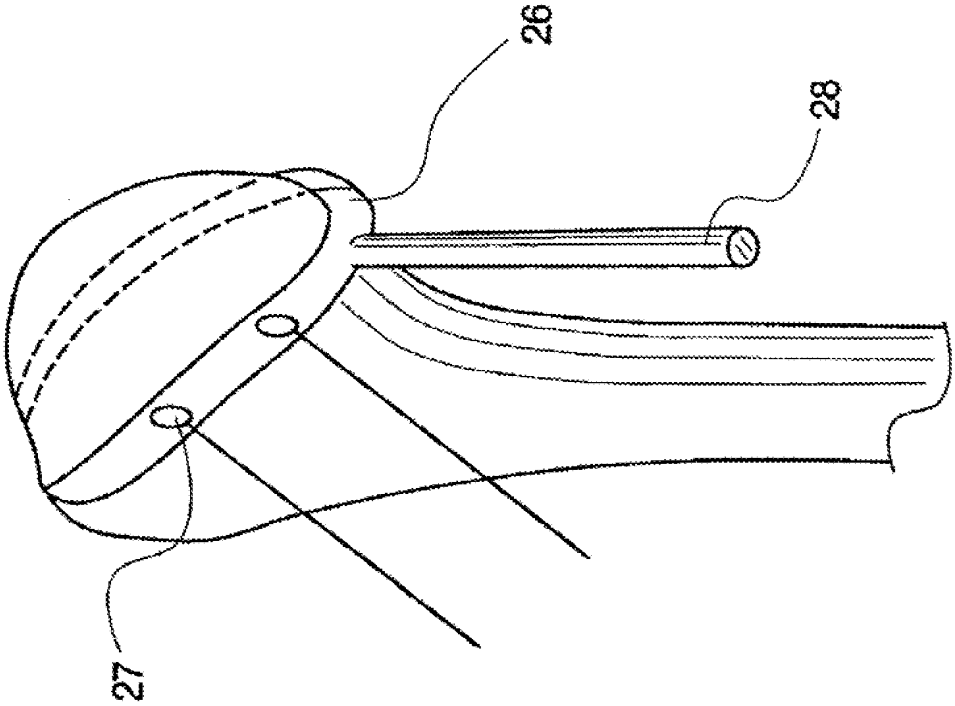


FIG. 18

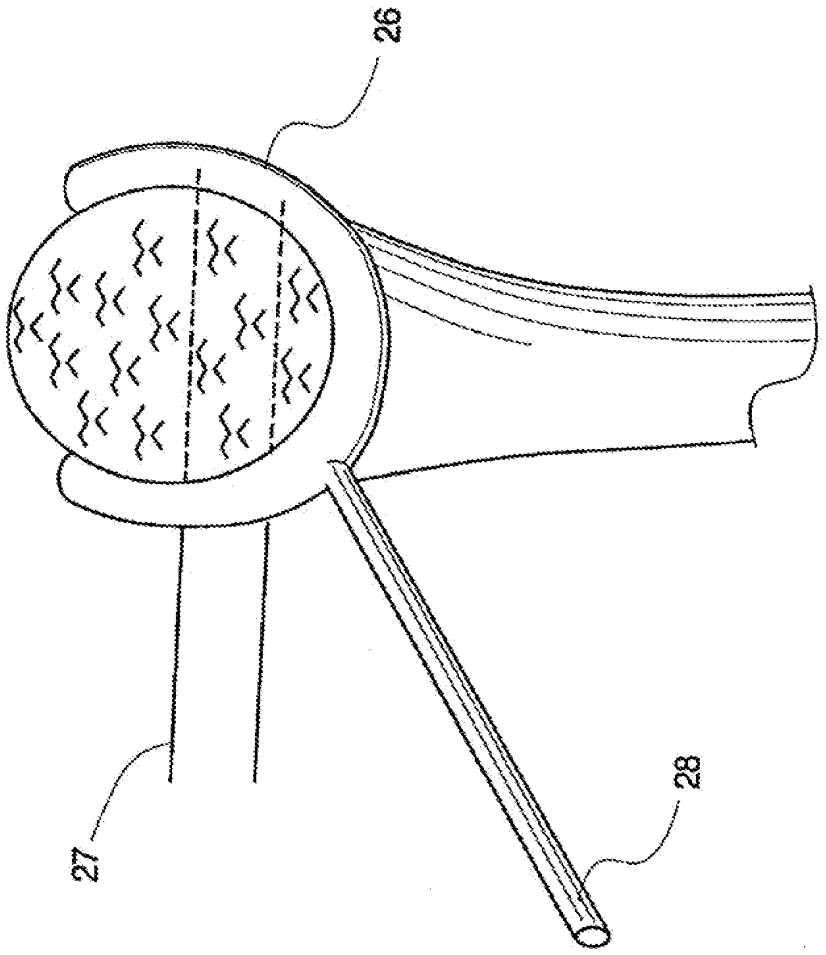


FIG. 19

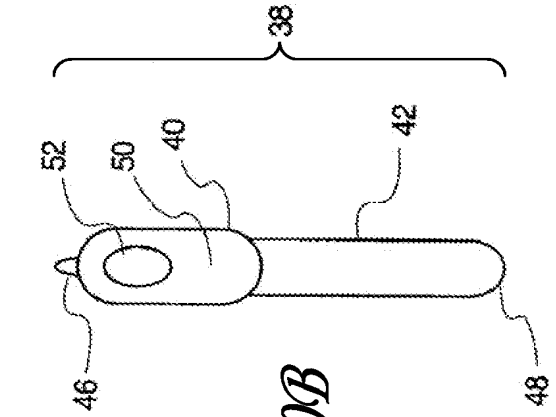


FIG. 20B

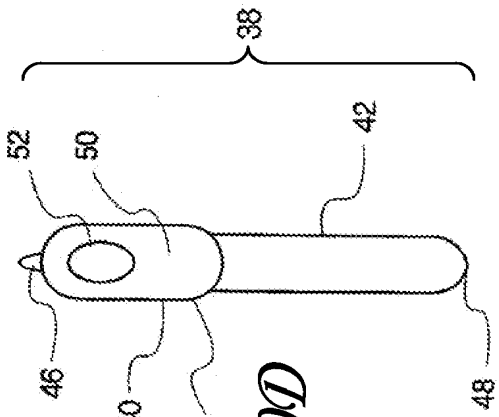


FIG. 20D

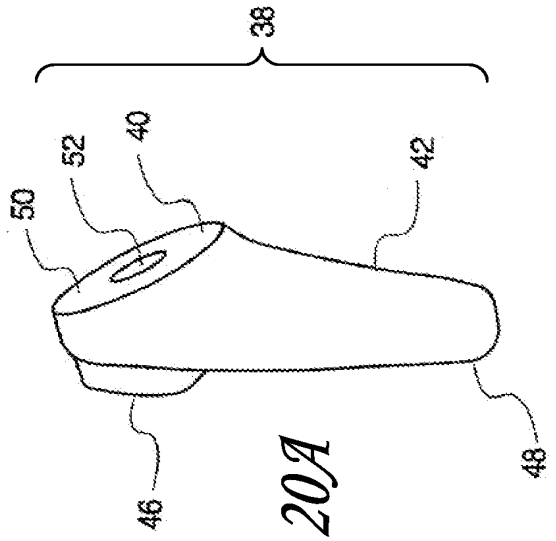


FIG. 20A

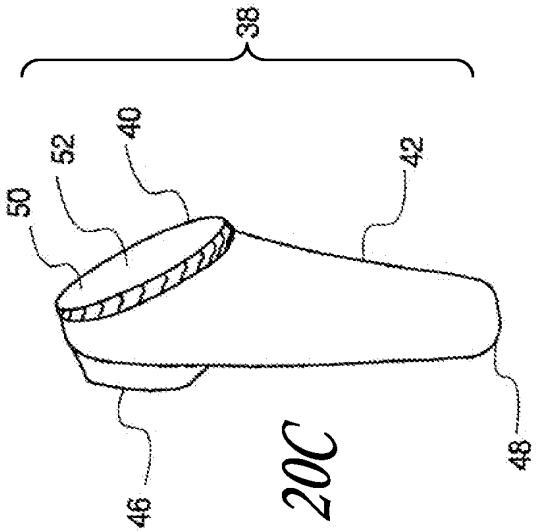


FIG. 20C

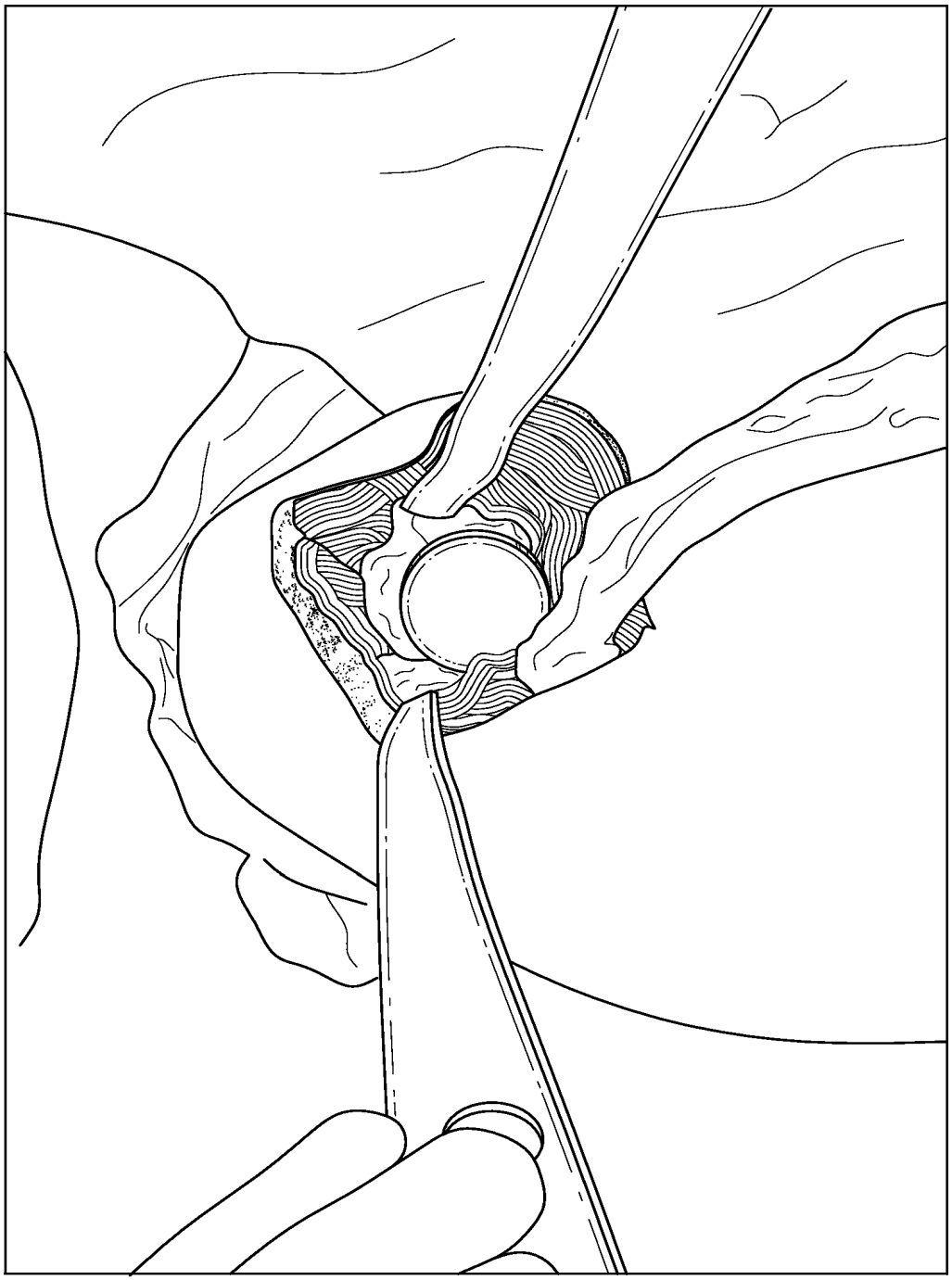


FIG. 21

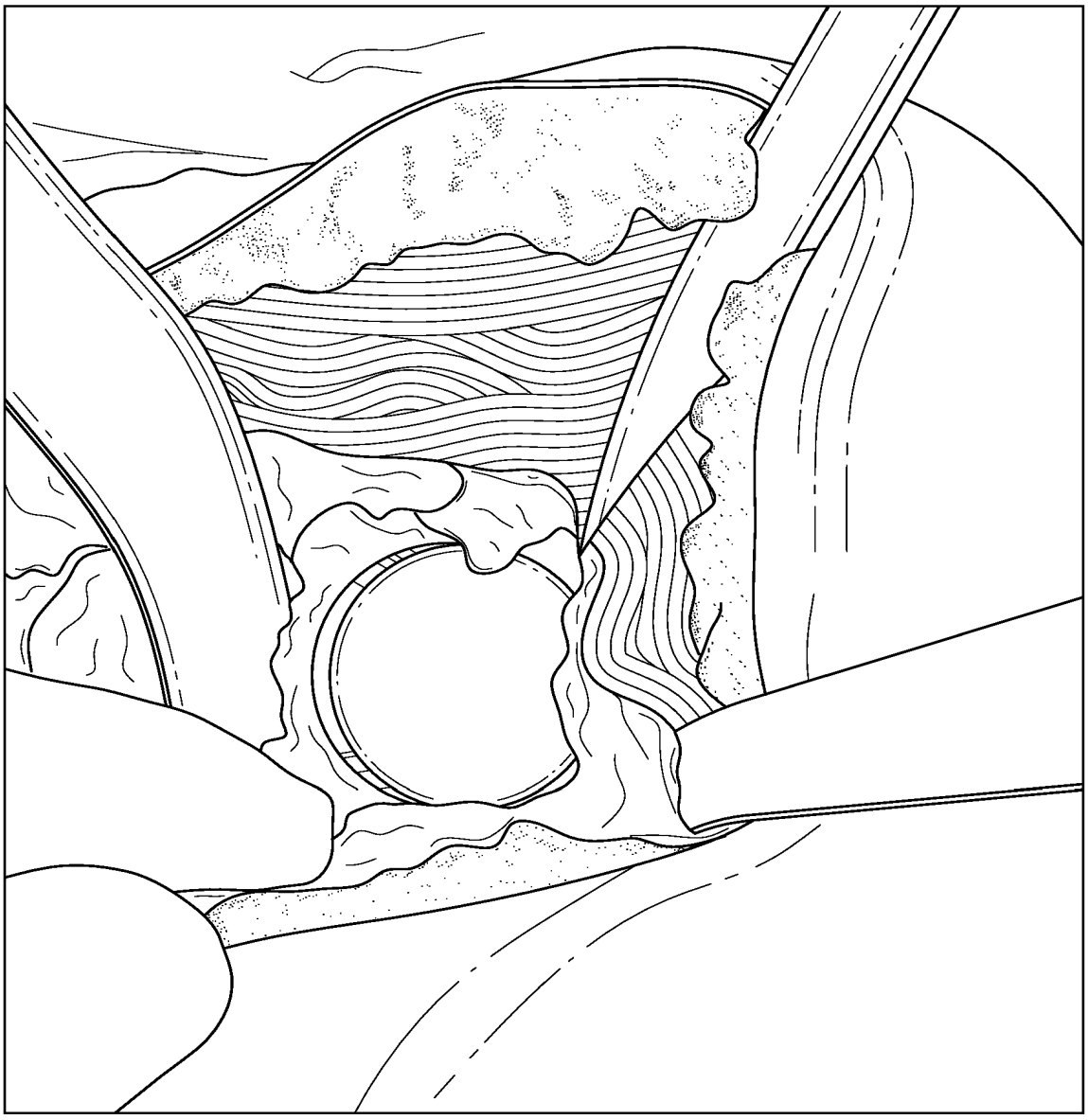


FIG. 22



FIG. 23

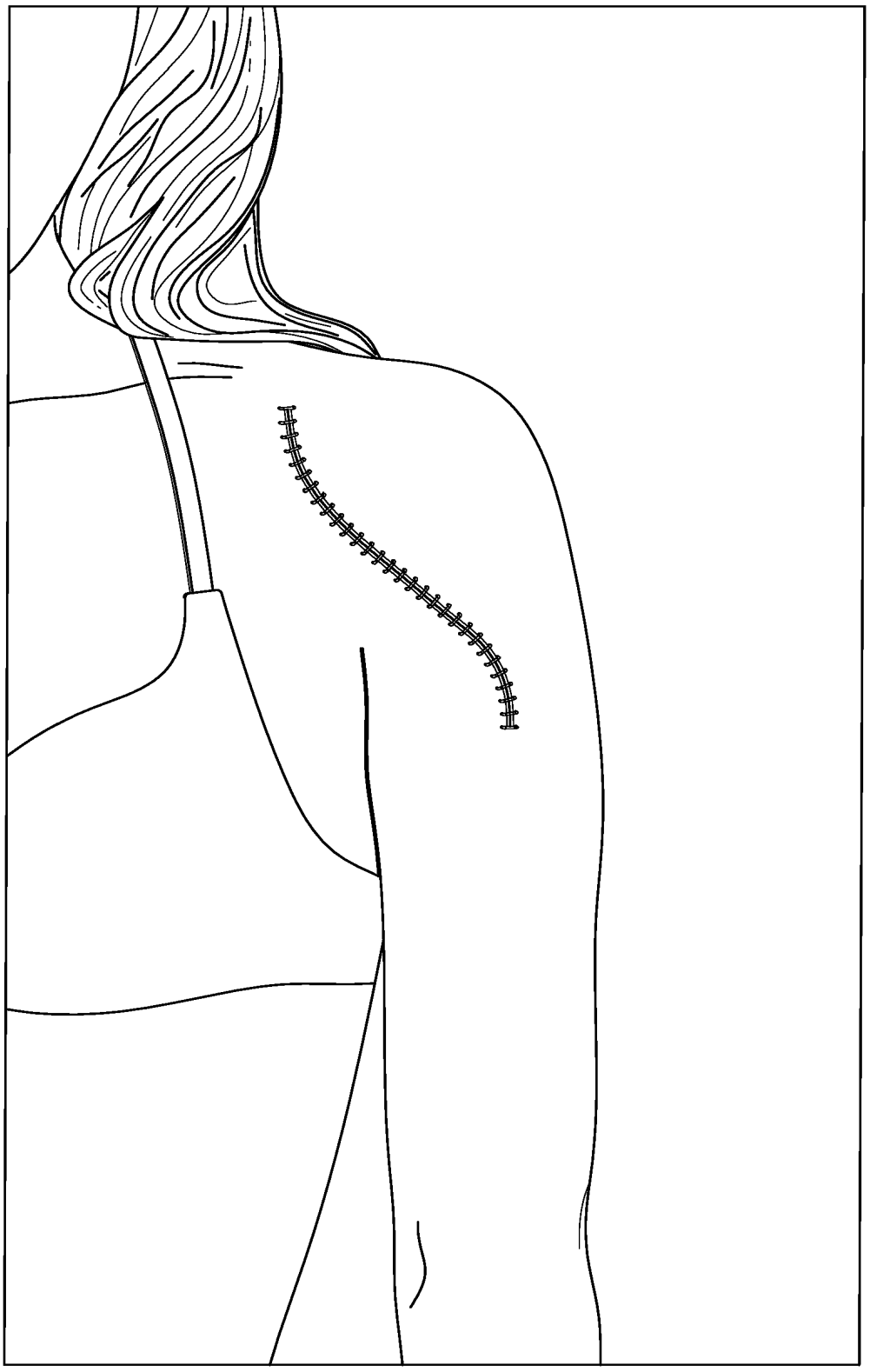


FIG. 24

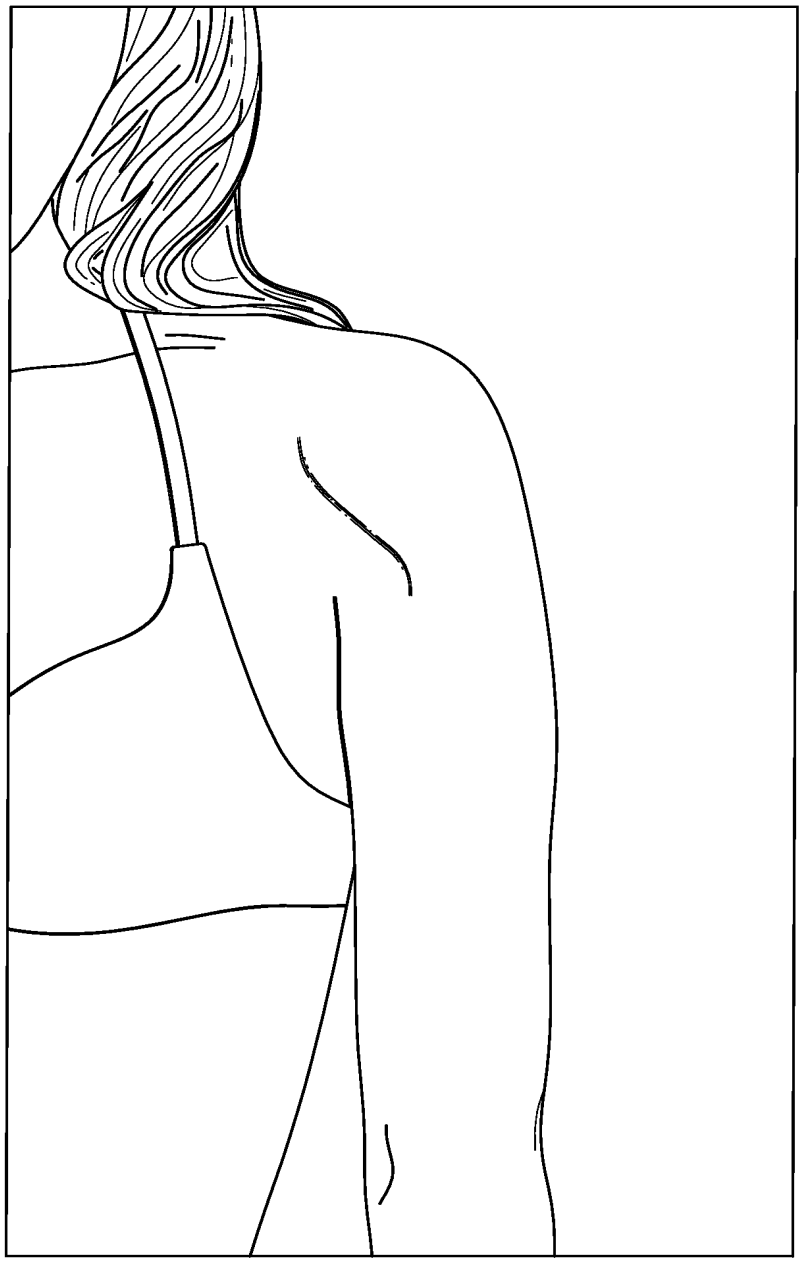


FIG. 25

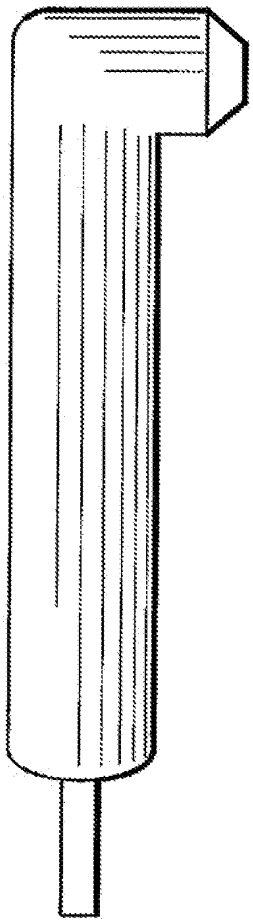


FIG. 26A

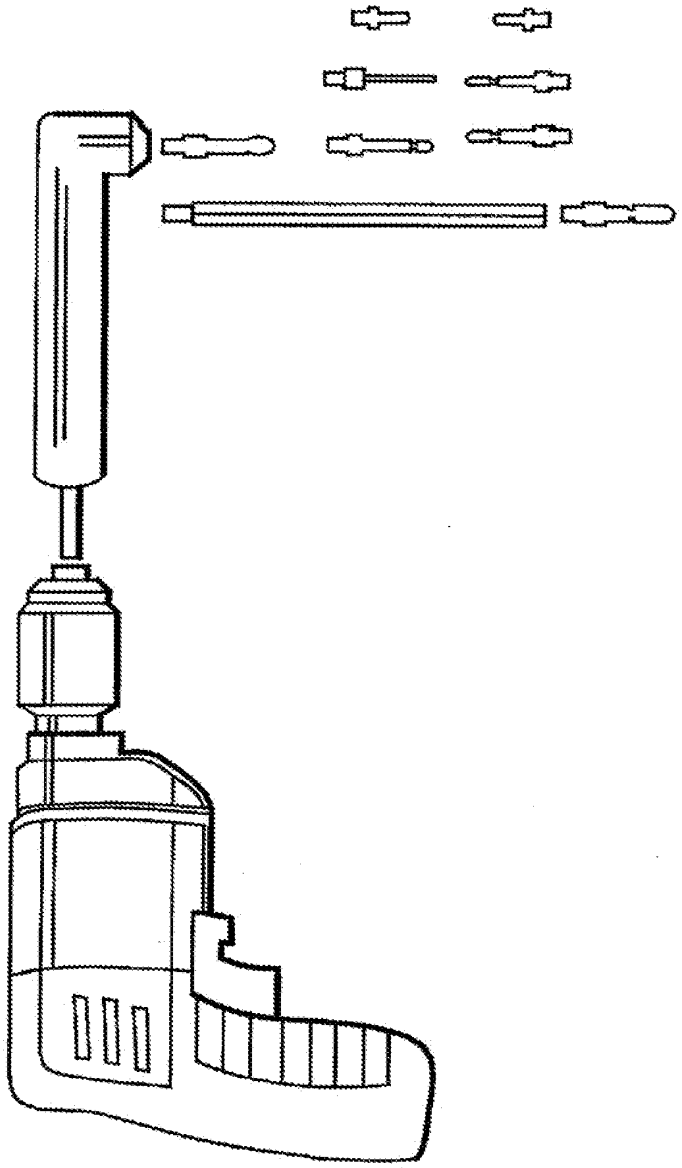


FIG. 26B

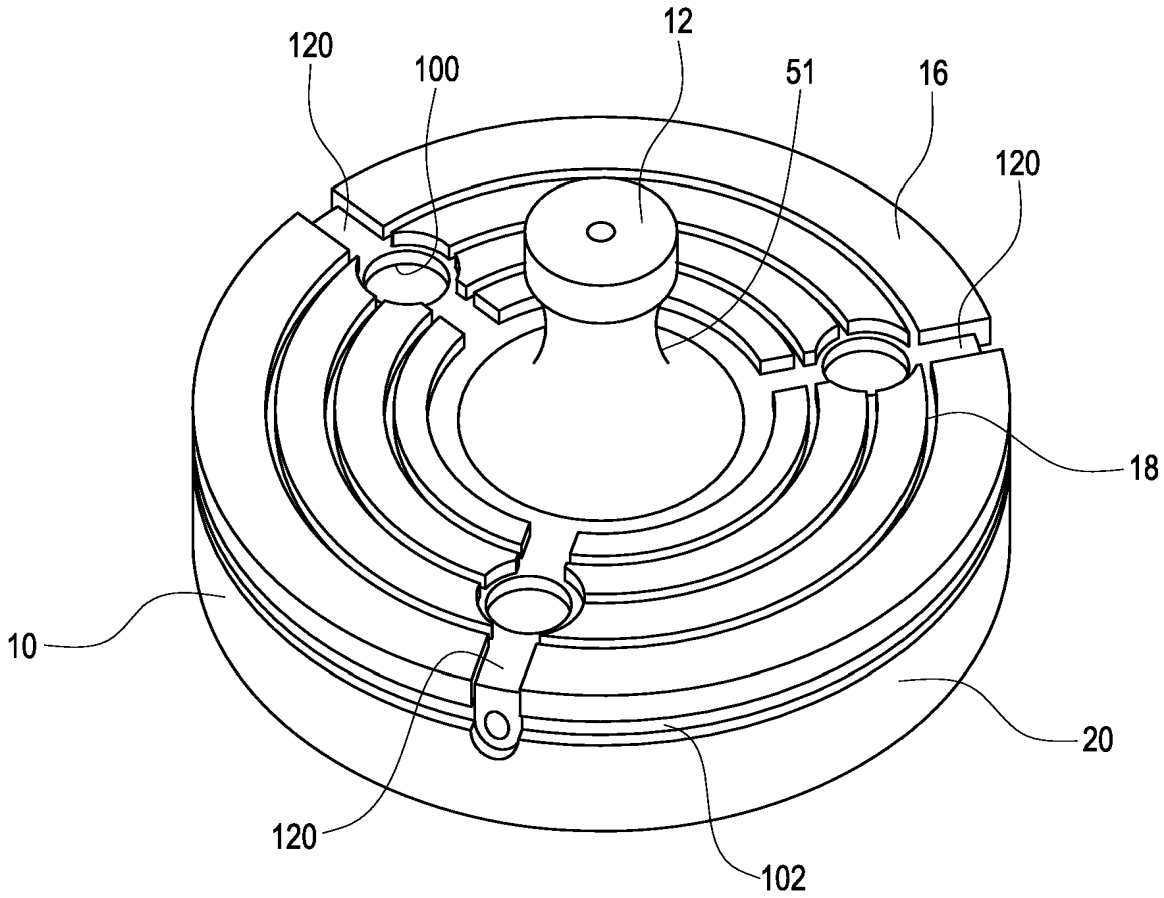


FIG. 27

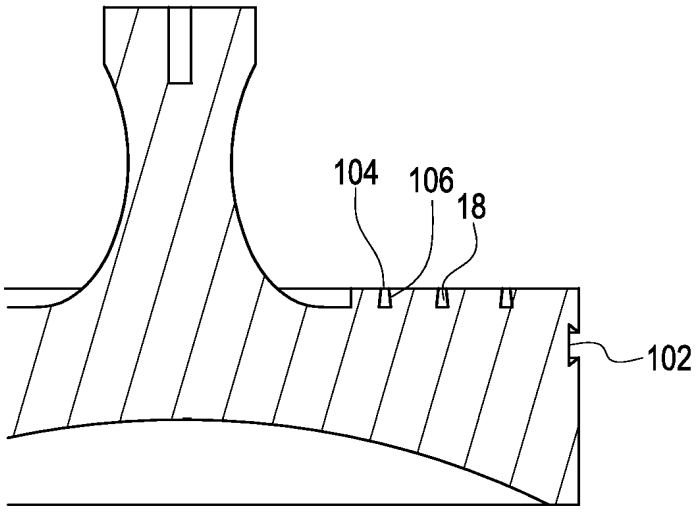


FIG. 27A

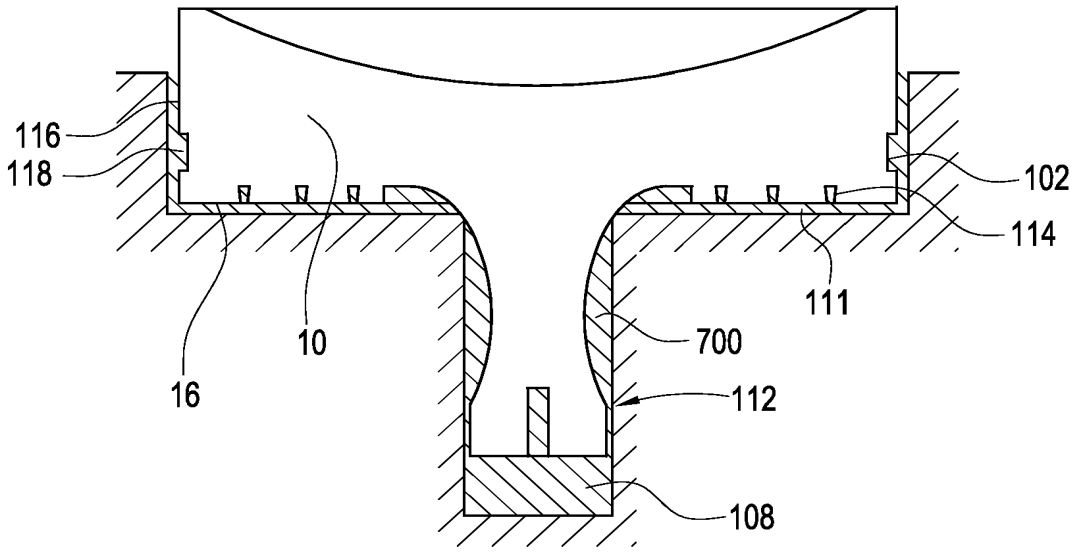


FIG. 27B

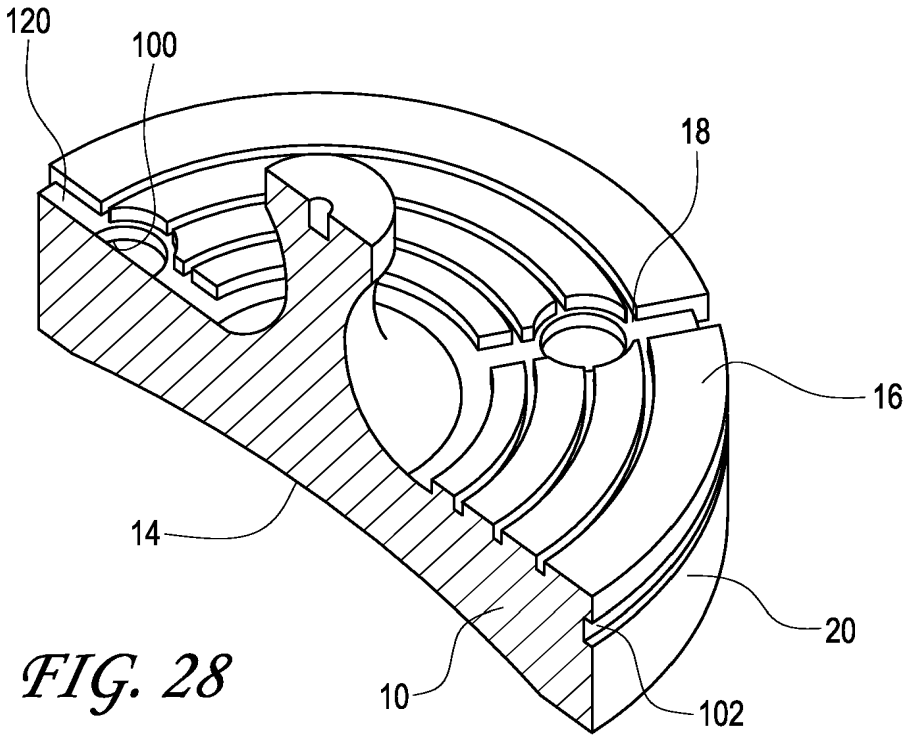


FIG. 28

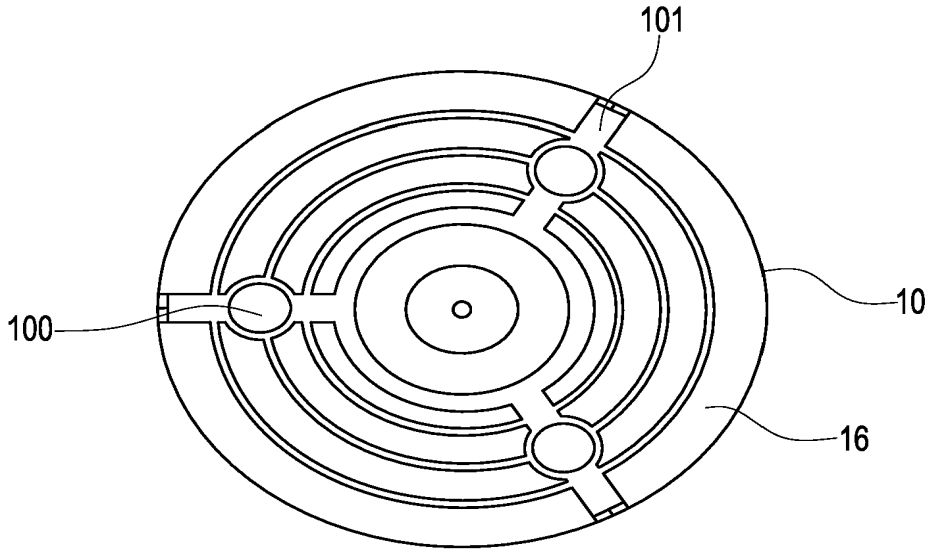


FIG. 29

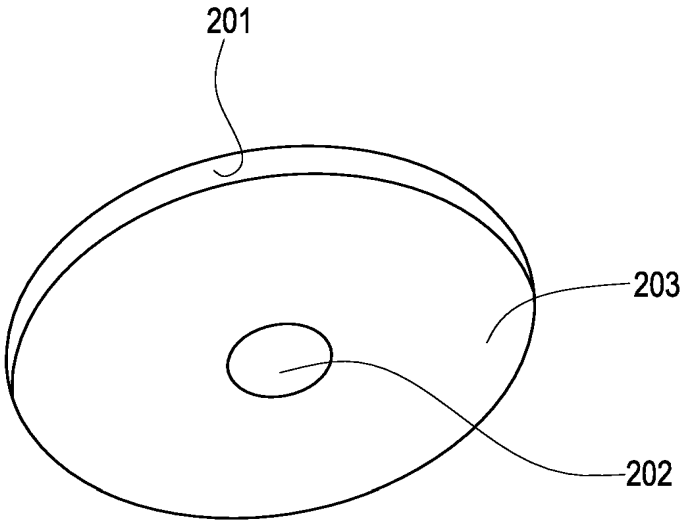


FIG. 30

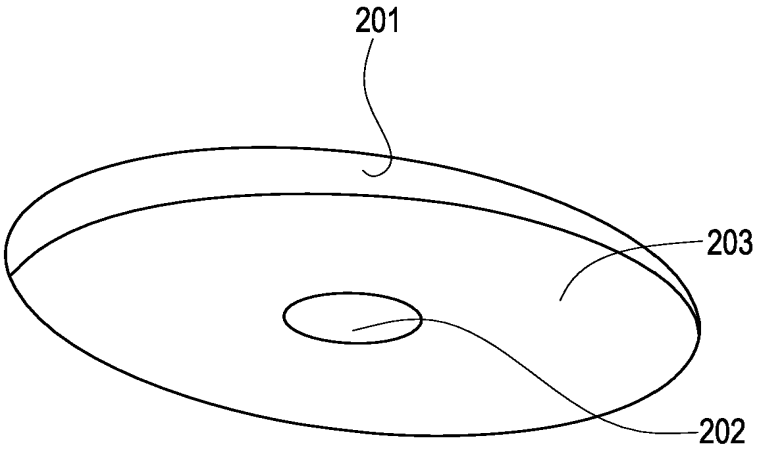


FIG. 31

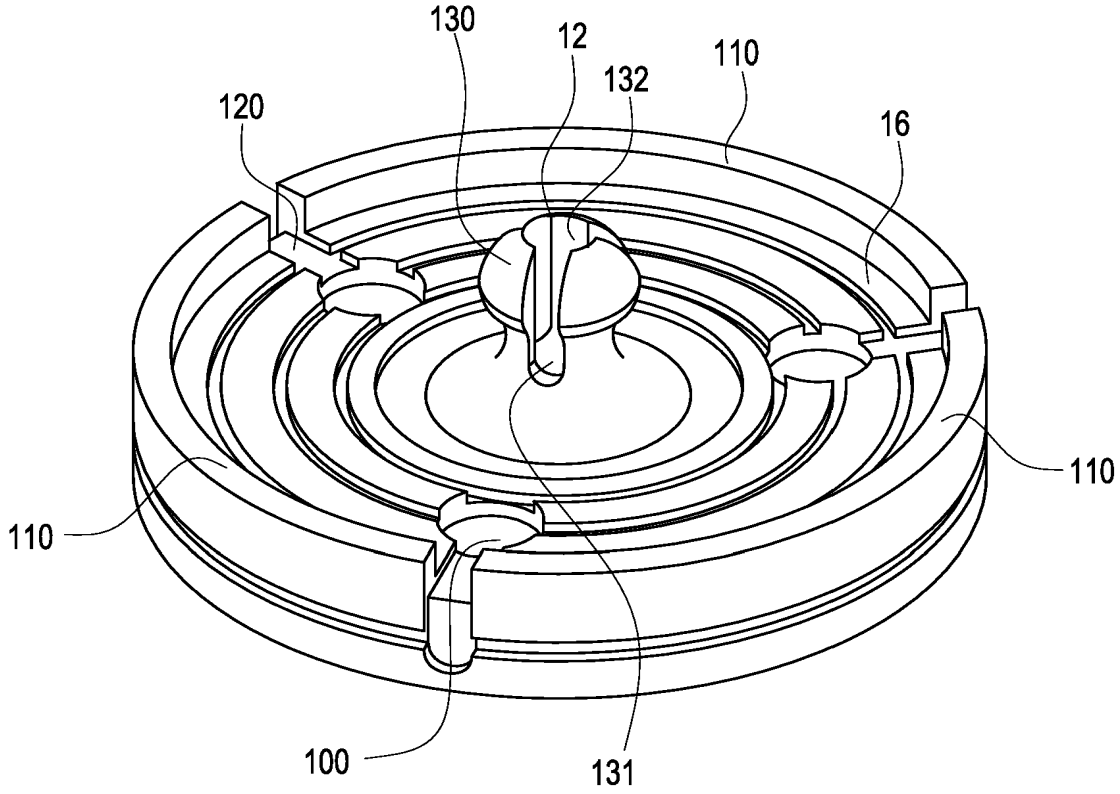


FIG. 32

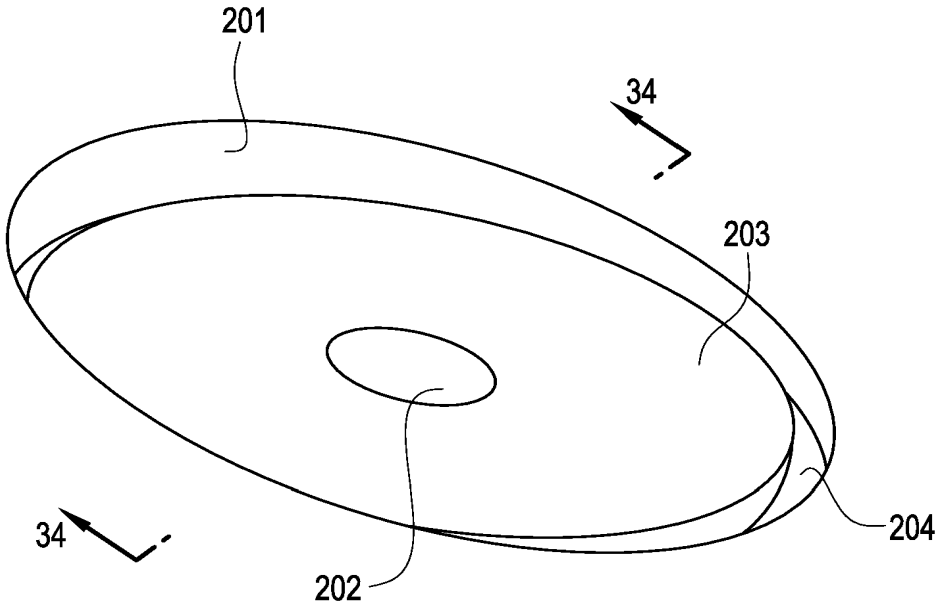


FIG. 33

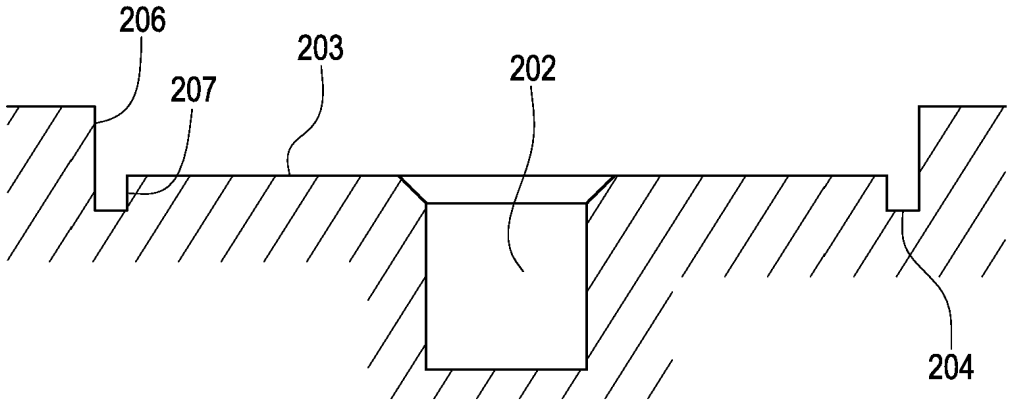


FIG. 34

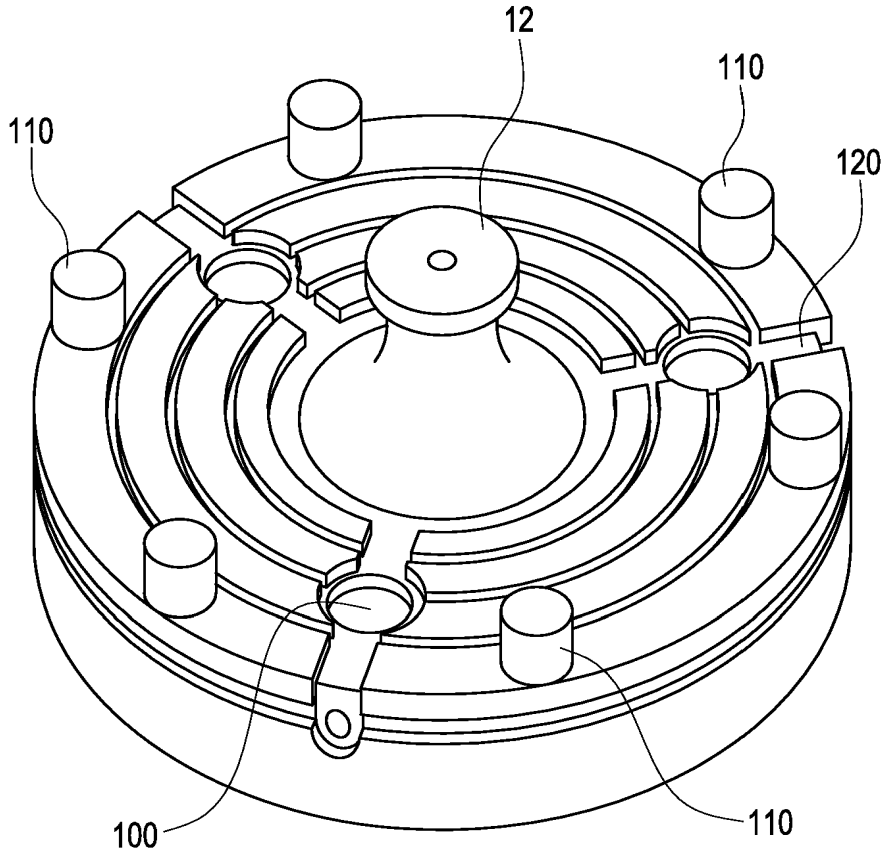

12
110
110
120
100
110

FIG. 35

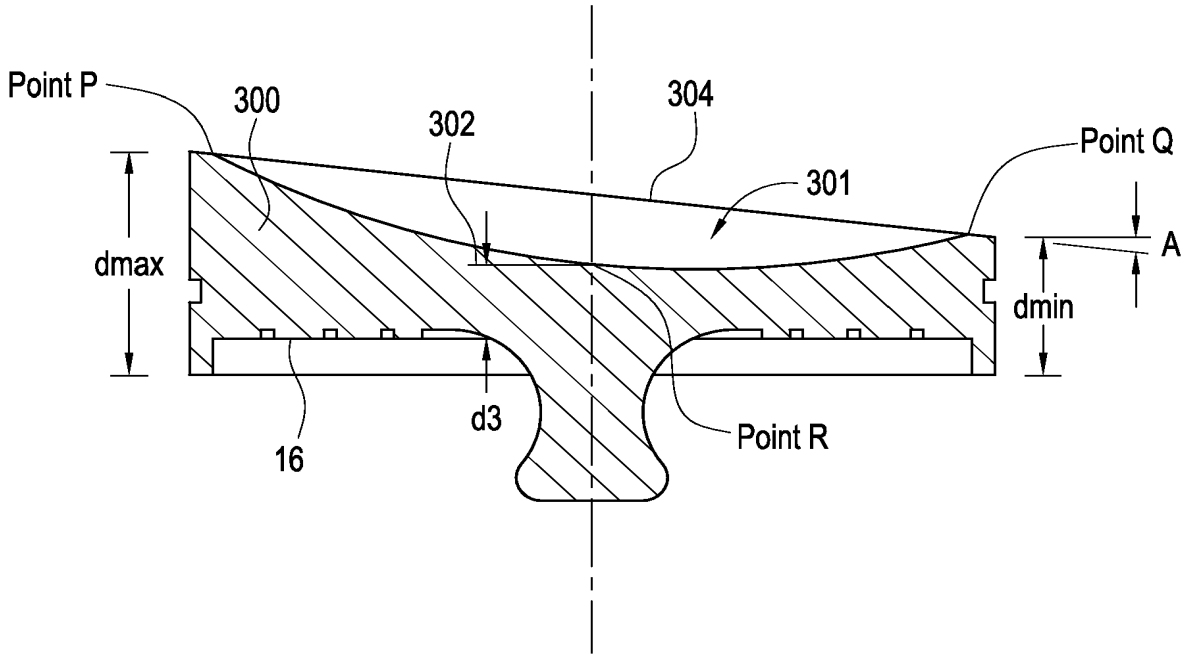

Point P
300
302
304
301
Point Q
dmax
A
dmin
d3
16
Point R

FIG. 36

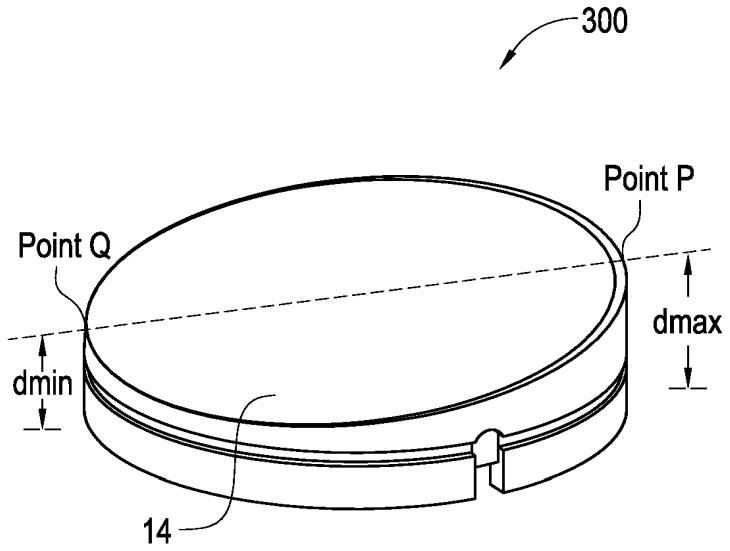


FIG. 37

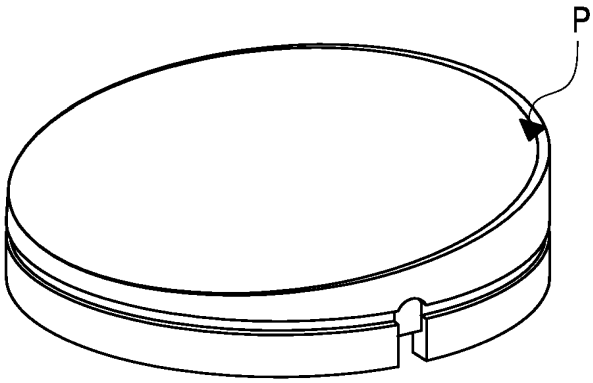


FIG. 37A

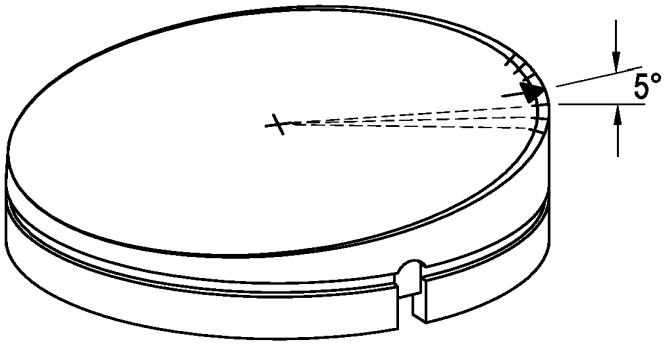


FIG. 37B

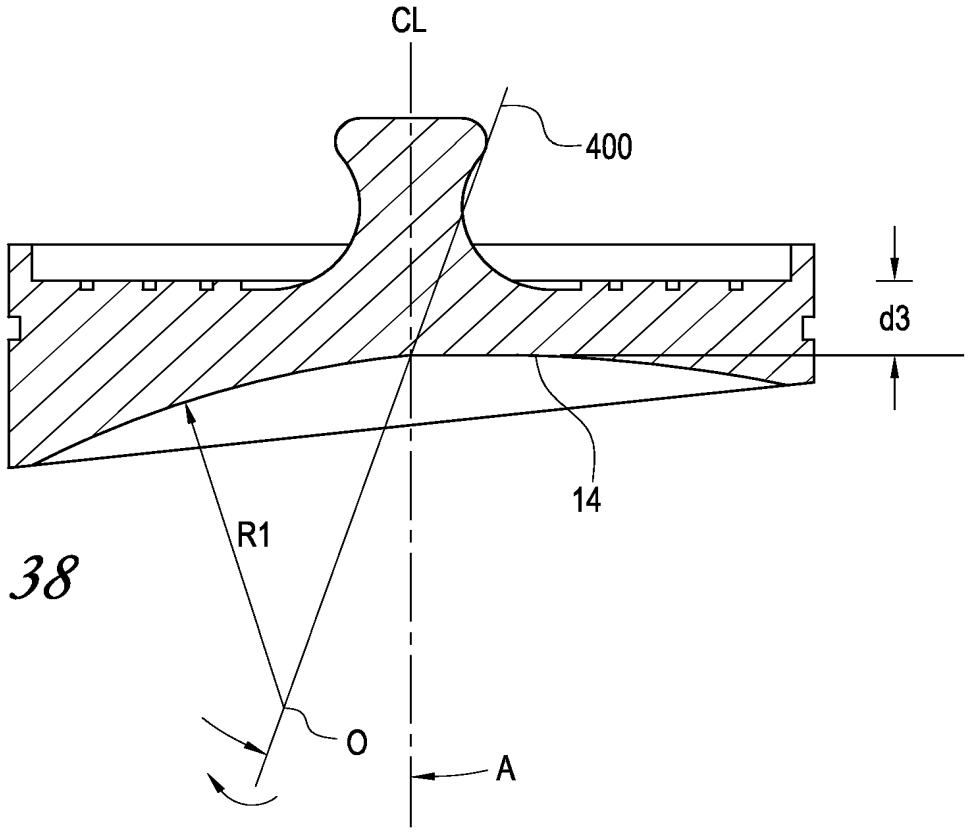


FIG. 38

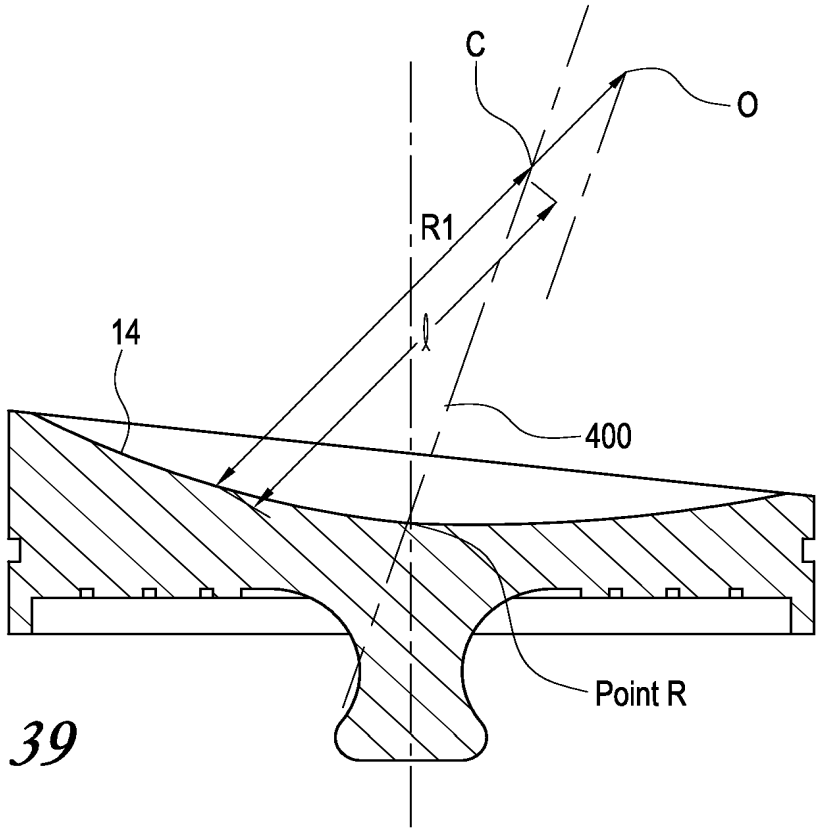


FIG. 39

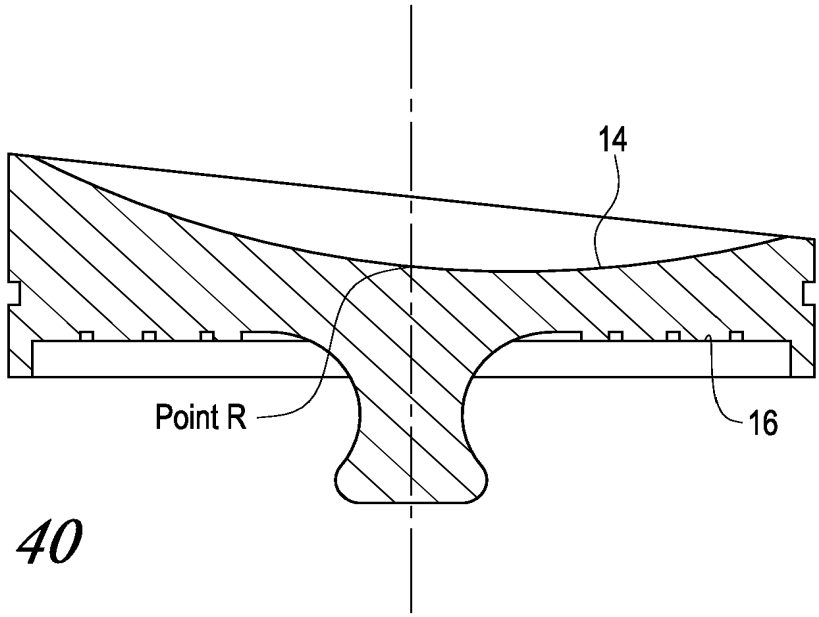


FIG. 40

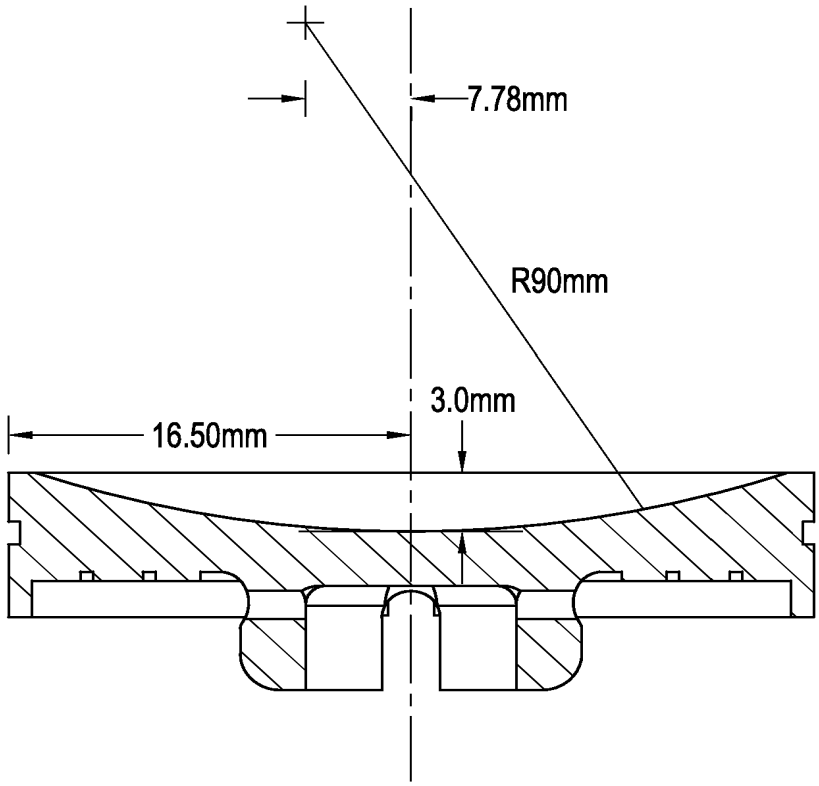


FIG. 41

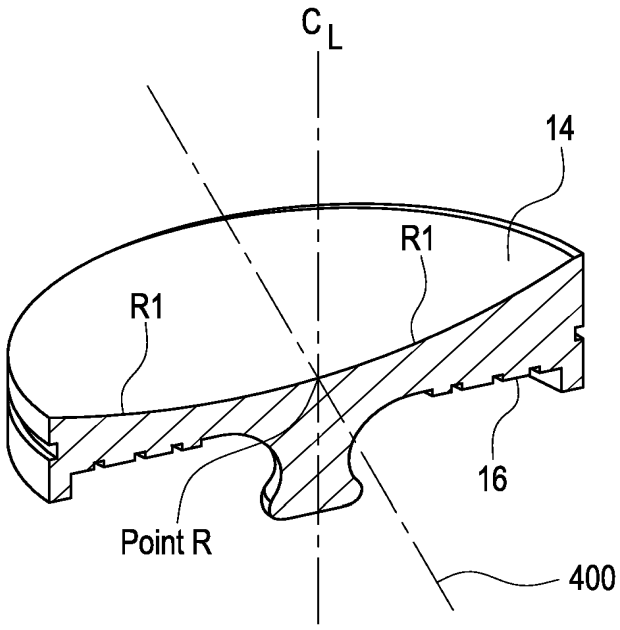

C L
14
R1
R1
16
Point R
400

FIG. 42

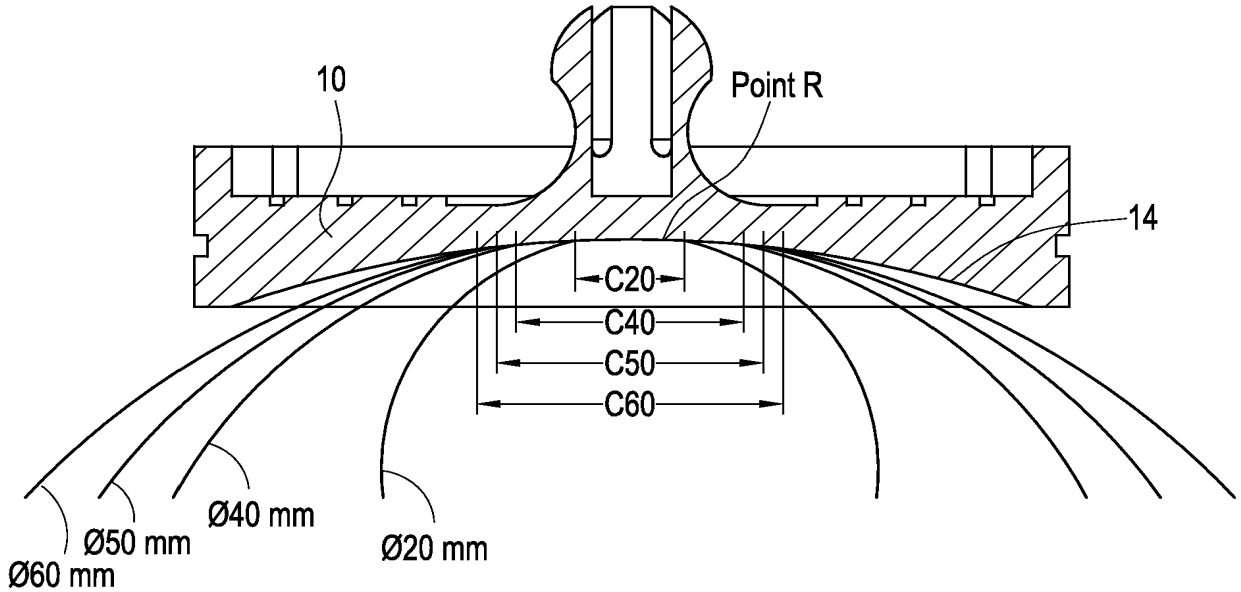

10
Point R
14
C20
C40
C50
C60
Ø40 mm
Ø50 mm
Ø60 mm
Ø20 mm

FIG. 43

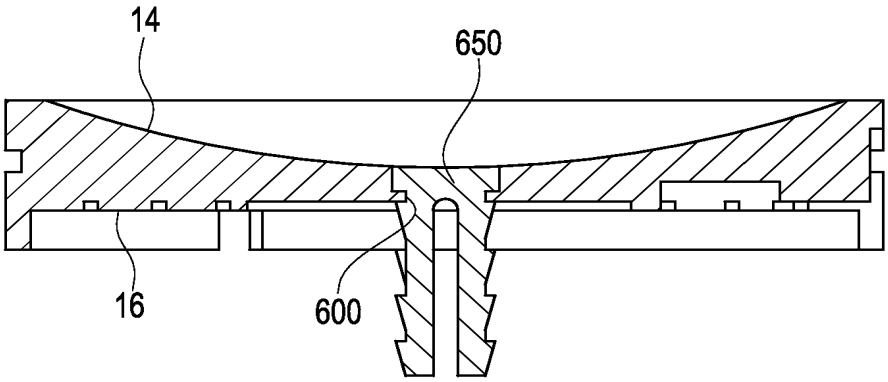


FIG. 43A

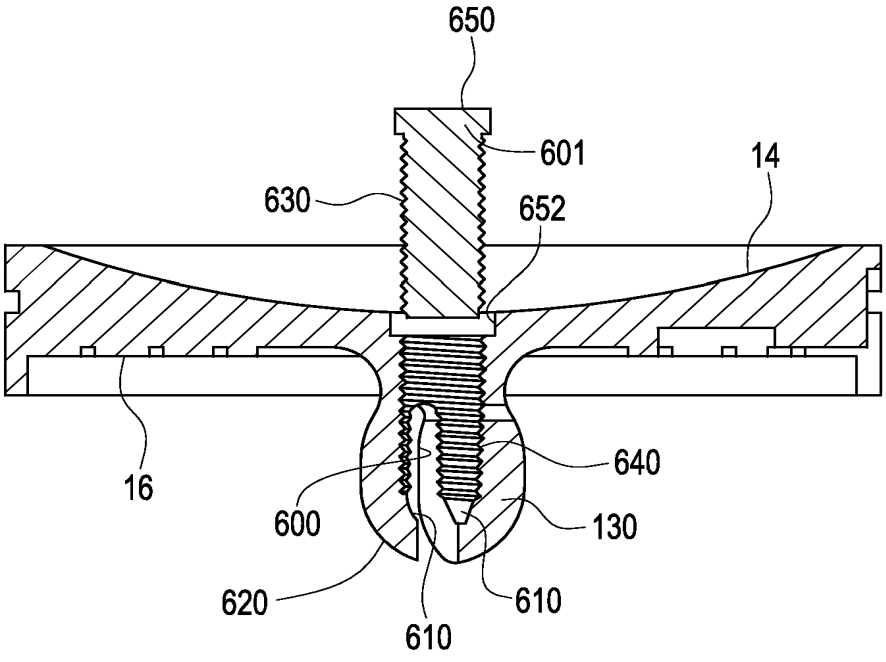


FIG. 43B

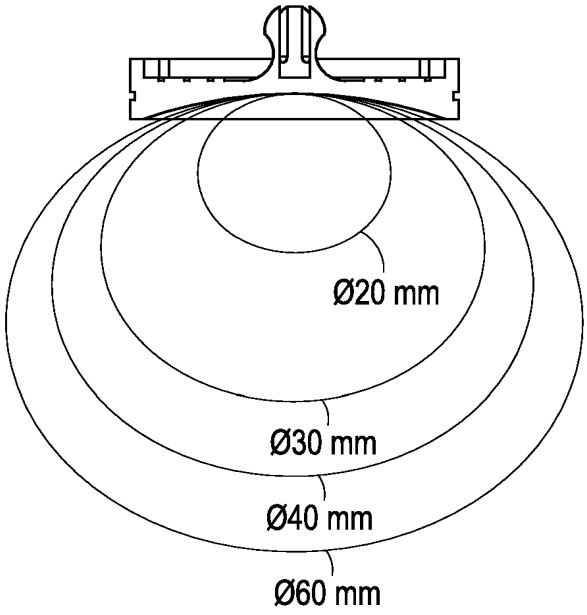


FIG. 44

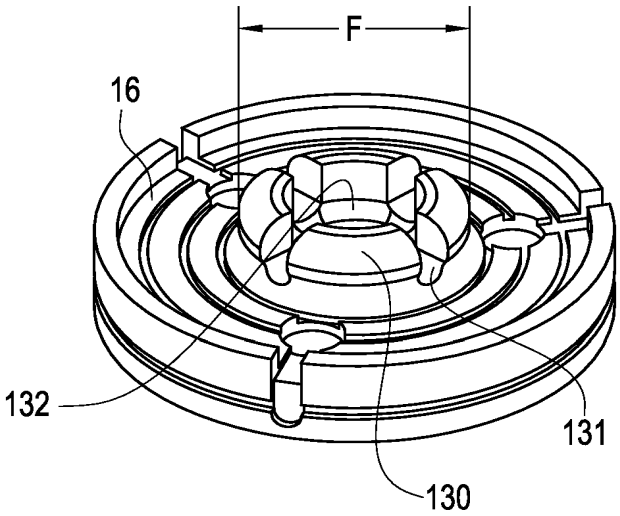


FIG. 45

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/027082

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/40 (2011.01)
USPC - 623/19.13
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/56; A61F 2/40 (2011.01)
USPC - 606/86R; 623/19.11, 19.13

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2006/0195194 A1 (GUNTHER) 31 August 2006 (31.08.2006) entire document	1-13, 26 --- 14-25, 29
Y	US 4,550,450 A (KINNETT) 05 November 1985 (05.11.1985) entire document	14-19, 21-23, 29
Y	US 5,080,673 A (BURKHEAD et al) 14 January 1992 (14.01.1992) entire document	16-25
Y	US 2009/0228112 A1 (CLARK et al) 10 September 2009 (10.09.2009) entire document	24
Y	WO 2009/071940 A1 (BISHOP et al) 11 June 2009 (11.06.2009) entire document	25
A, P	US 2010/0087876 A1 (GUNTHER) 08 April 2010 (08.04.2010) entire document	1-26, 29

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
20 June 2011	30 JUN 2011
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: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/027082

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-26 and 29

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/027082

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-26 and 29 are drawn to a method of treating a patient and an implant.

Group II, claims 27 and 28 are drawn to a cement construct for retaining an implant in bone.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I, a glenoid surface; a glenoid implant; implant having a medial circular body/edge/surface, are not present in Group II; and the special technical features of Group II, a cement shell; a first tubular wall section; a second tubular wall section, are not present in Group I.

Since none of the special technical features of the Groups I and II inventions is found in more than one of the inventions, unity is lacking.

SHOULDER PROSTHESIS DESIGN EVOLUTION

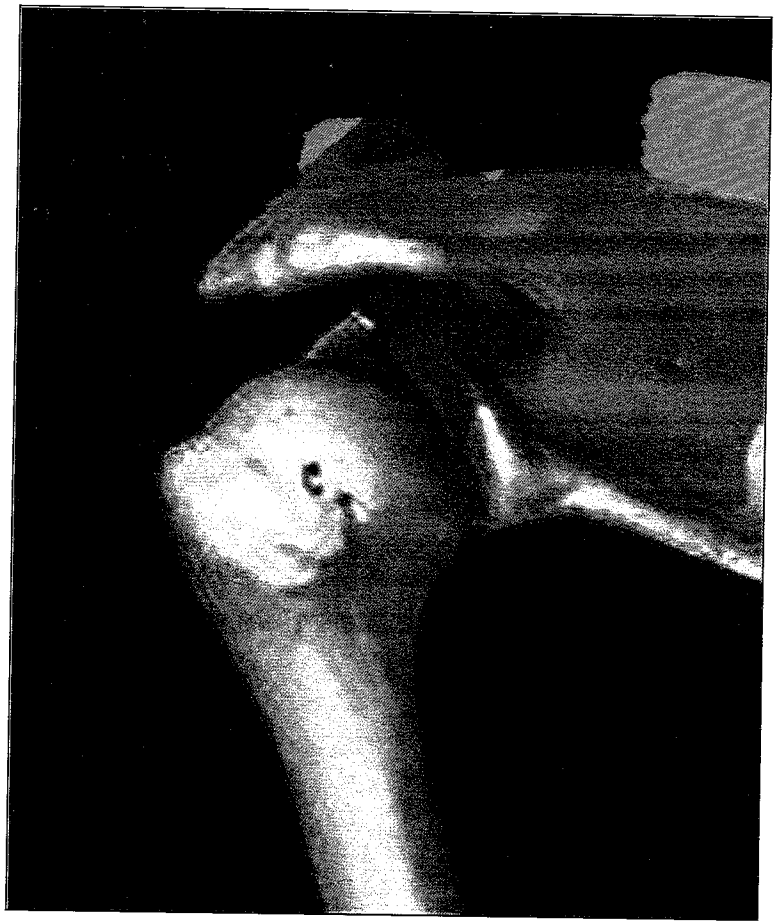
Paolo Dalla Pria

Lima-Lto (San Daniele - UD)

University of Trieste

Orthopedics and Traumatology Faculty

GLENO-HUMERAL JOINT
LOW CONGRUENCY DIARTHROSIS



JOINT MOTION

- THE WIDE R.O.M. IS ALLOWED BY THE LOW STABILITY OF THE HEAD IN THE GLENOID CAVITY
- IT IS POSSIBLE ONLY IF ALL THE CUFF MUSCLES ARE ACTIVE

- GLENOID AND HEAD ARE DIFFERENT DIAMETERS (average ratio 0,7)
- GLENOID EXTENSION:
  - 76° ON THE CORONAL PLANE
  - 62° ON THE TRANSVERSAL PLANE

25-30% ONLY OF THE GLENOID COVERS THE HEAD

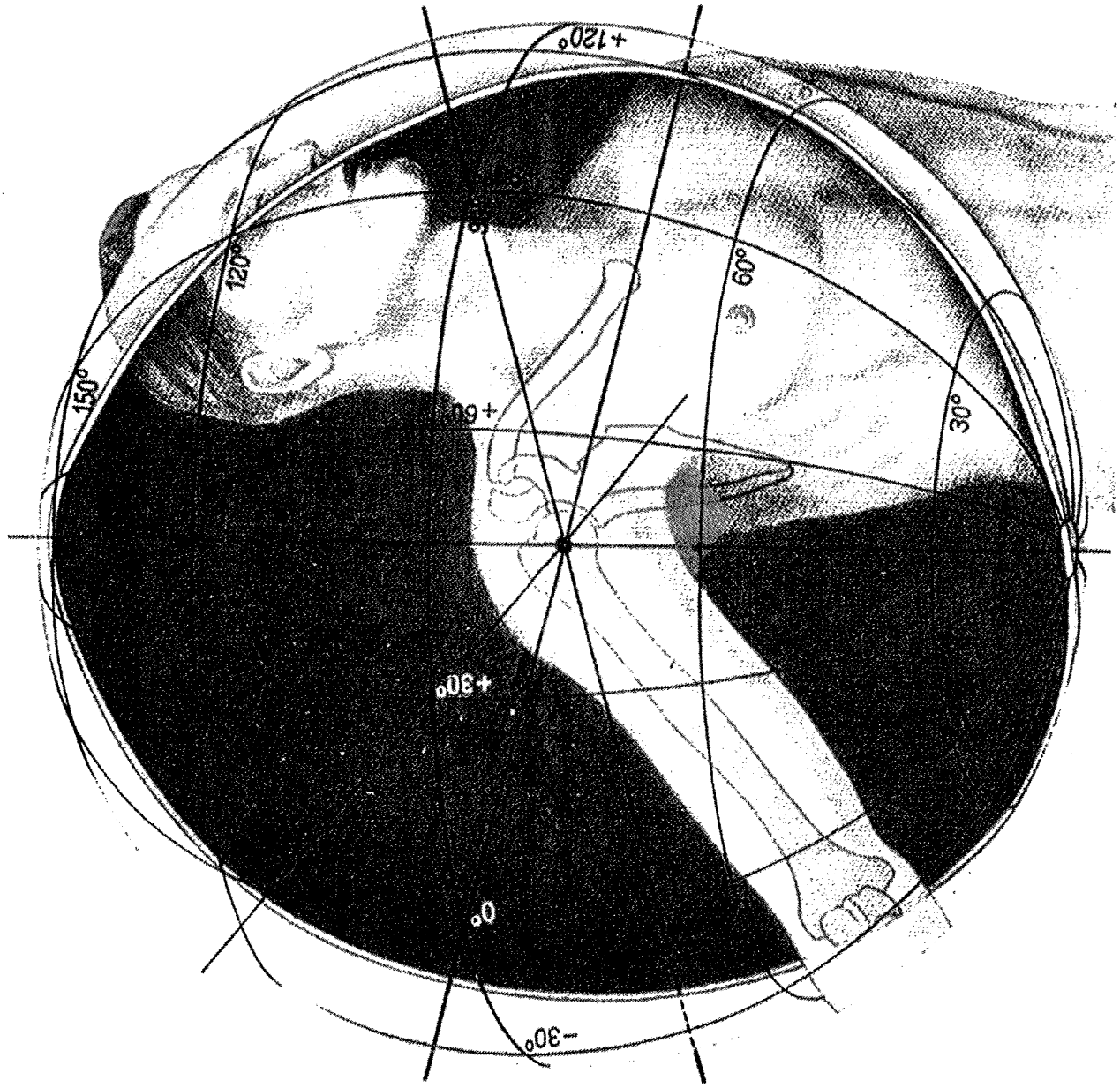
35°
62°

76°
4.7°
155°
47°
79°
angle of excursion
center of humerus

STABILISATION

- PASSIVE OR STATIC
  - CAPSULE + LIGAMENTOUS REINFORCEMENT
  - LABRUM
  - ELASTICITY OF THE CUFF TISSUES
  - INTRA-ARTICULAR NEGATIVE PRESSURE
- ACTIVE OR DYNAMIC
  - CUFF ROTATOR MUSCLES

CATALYST, EX-1004
PAGE 597


+120°
120°
60°
150°
+60°
30°
+30°
0°
-30°

PROSTHESIS AIMS

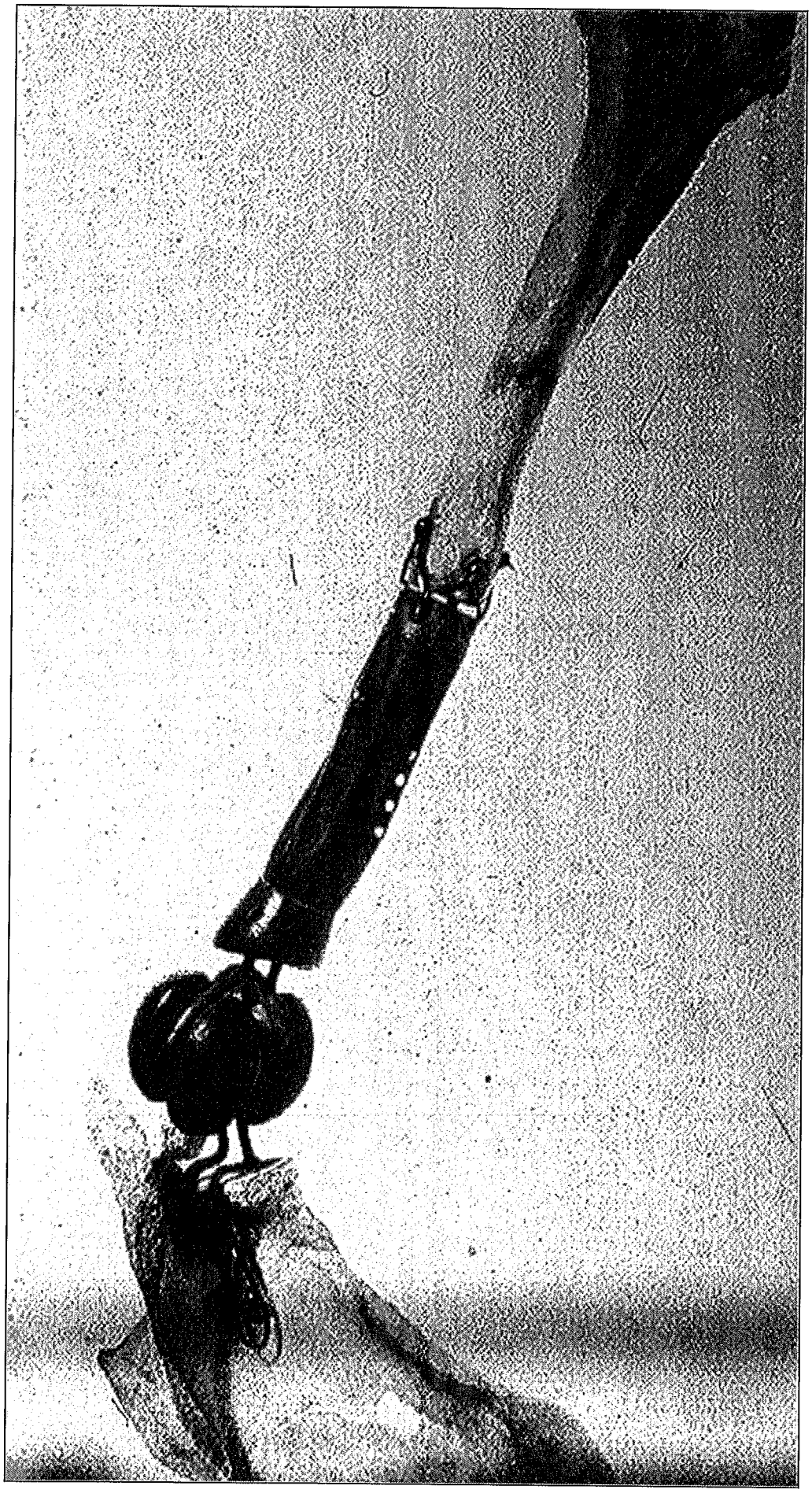
- PAIN RELIEF
- ACTIVE FUNCTION RESTORATION

ANATOMICAL CONDITIONS RESTORATION

VERY DIFFICULT!

WHAT DOES IT MEAN 'RESTORATION OF THE ANATOMICAL CONDITIONS'?

- REPRODUCING THE NORMAL BONE MORPHOLOGY (Epiphisis and Glenoid)
- RESTORING THE CAPSULAR TENSION (Retractions and Releases)
- RESTORING THE MUSCULAR ACTIVITY (Trophism and lever arms)



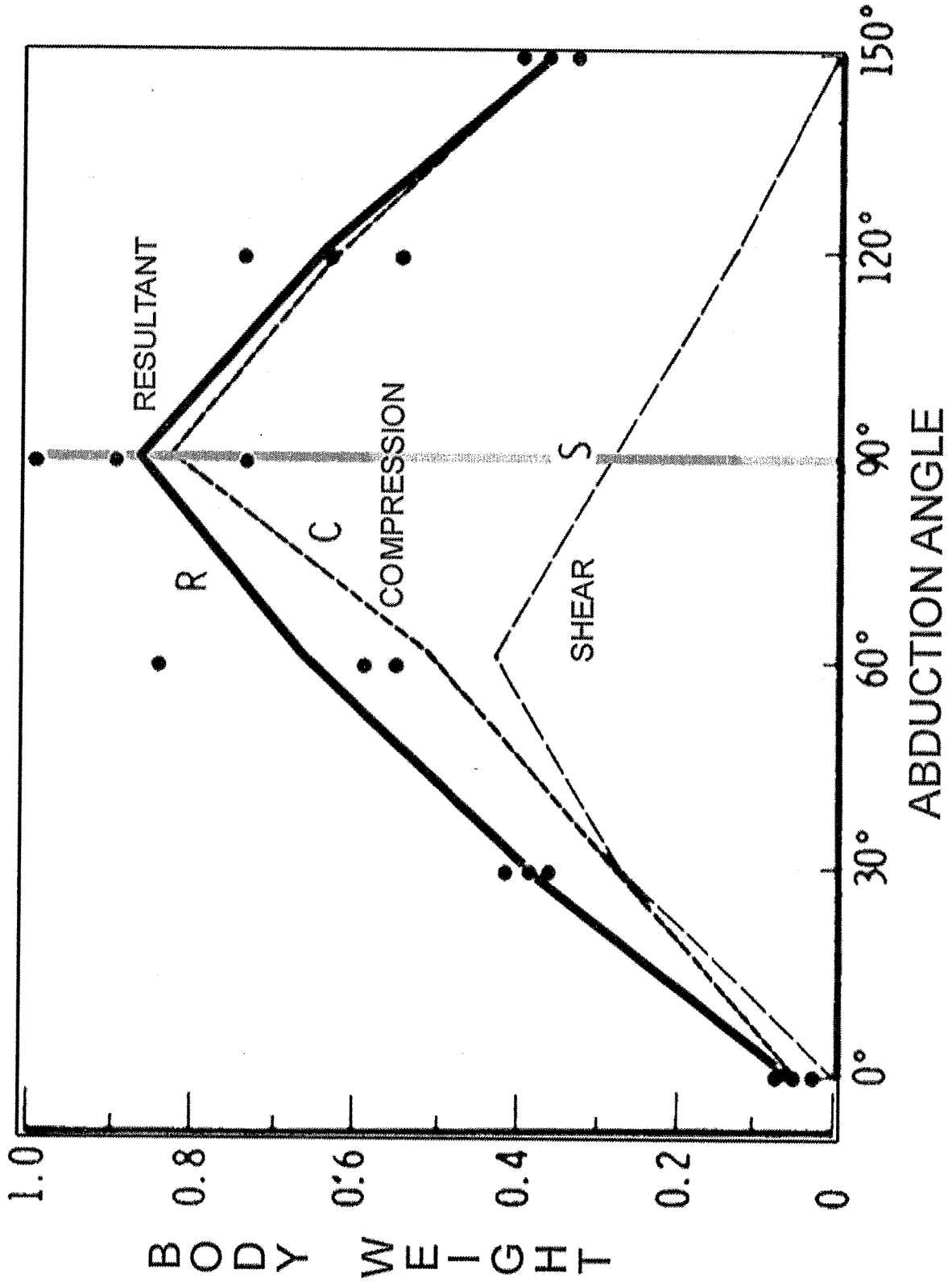
J. PEAN, 1891

SHOULDER PROSTHESIS TYPES

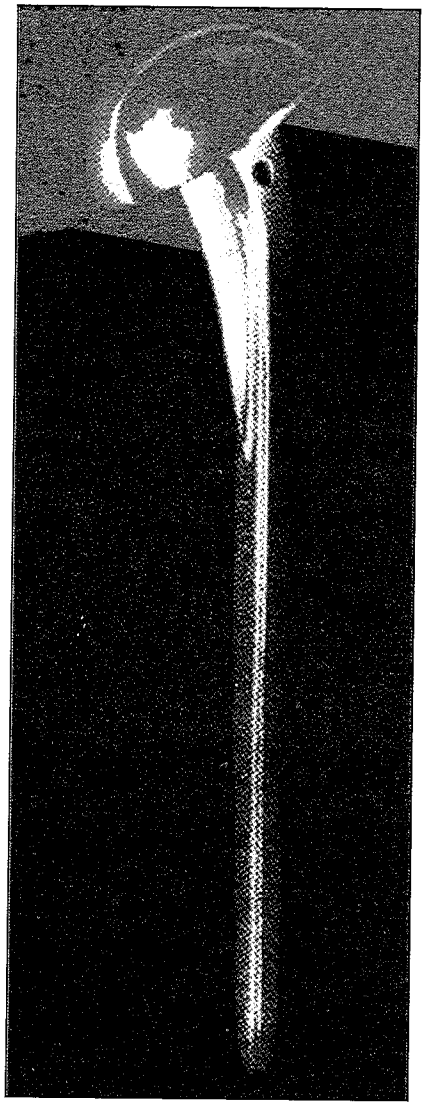
- CONSTRAINED
- SEMI- CONSTRAINED
- RESURFACING

JOINT FORCES

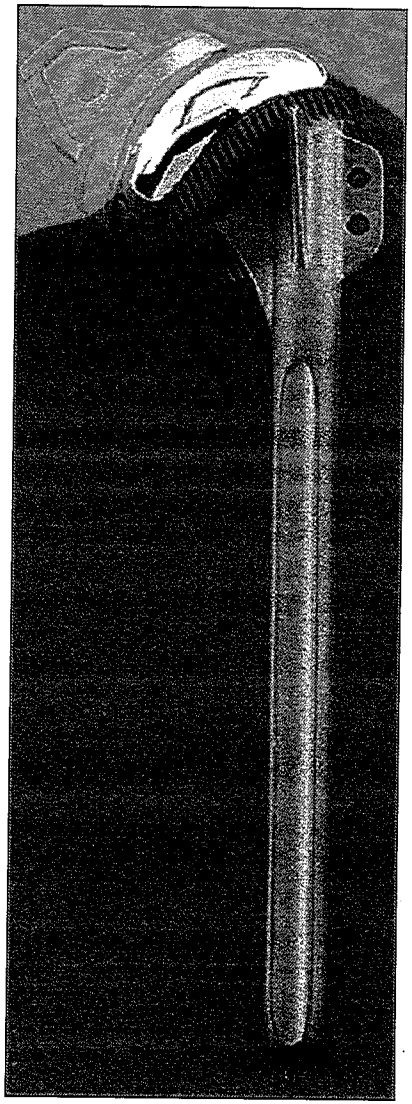
- DIFFICULT TO BE VECTORIALLY DEFINED
- HARMFUL IN ABSENCE OF DYNAMIC EQUILIBRUM
- AT 90° ABDUCTION THE JOINT REACTION IS ABOUT 1XBW
- LIFTING A 5 kg WEIGHT THE JOINT REACTION IS ABOUT 2.5XBW.

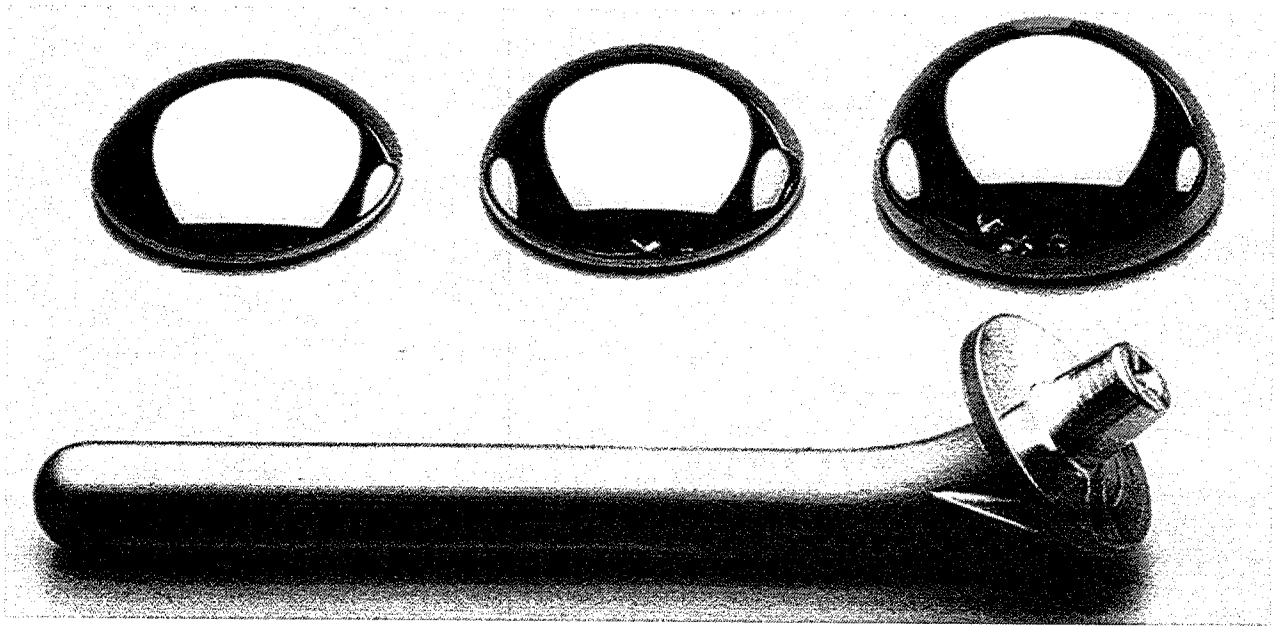

BODY WEIGHT
1.0
0.8
0.6
0.4
0.2
0
0°
30°
60°
90°
120°
150°
ABDUCTION ANGLE
RESULTANT
R
C
COMPRESSION
S
SHEAR

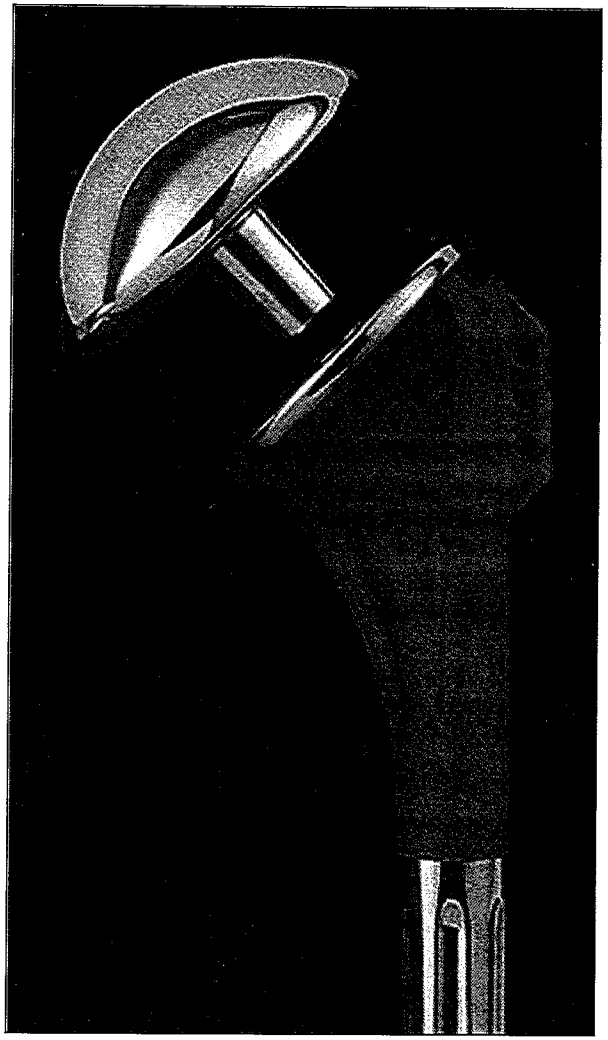
FIRST GENERATION



NEER, 1953







SECOND GENERATION

VARIABILES TO BE CHECKED ON THE CORONAL PLANE

- IMPLANT HEIGHT
- HEAD DIEMNSION
- LEVER ARM BETWEEN THE HEAD CENTER AND THE TUBOEROSITIES

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PAGE 607

VARIABILES TO BE CHECKED ON THE ANTERO-POSTERIOR PLANE

- HEAD RETROVERSION
- GLENOID ANETEVERSION
- TUBEROSITIES POSITIONING

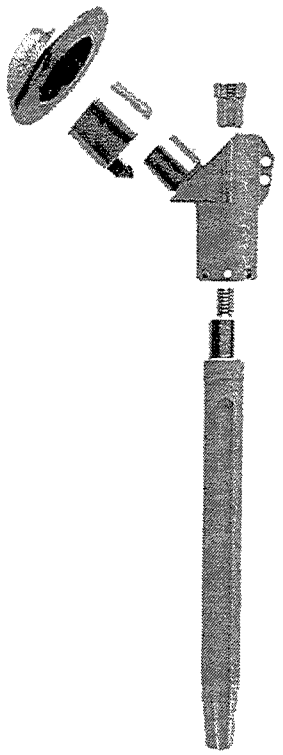
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GEOMETRICAL PARAMETERS

- CCD ANGLE
- HEAD DIAMETER AND HEIGHT
- CLEARANCE BETWEEN TOP OF THE HEAD AND TROCHITE
- HEAD RETROVERSION
- HEAD MEDIAL *OFFSET*
- HEAD POSTERIOR *OFFSET*
- HEAD-ACROMIOMCLEARANCE
- IMPLANT HEIGHT

RESTORATION OF ALL GEOMETRICAL PARAMETERS ALLOWS THE ANATOMICAL CONDITIONS RESTORATION AND THEN THE FUNCTIONAL OUTCOME

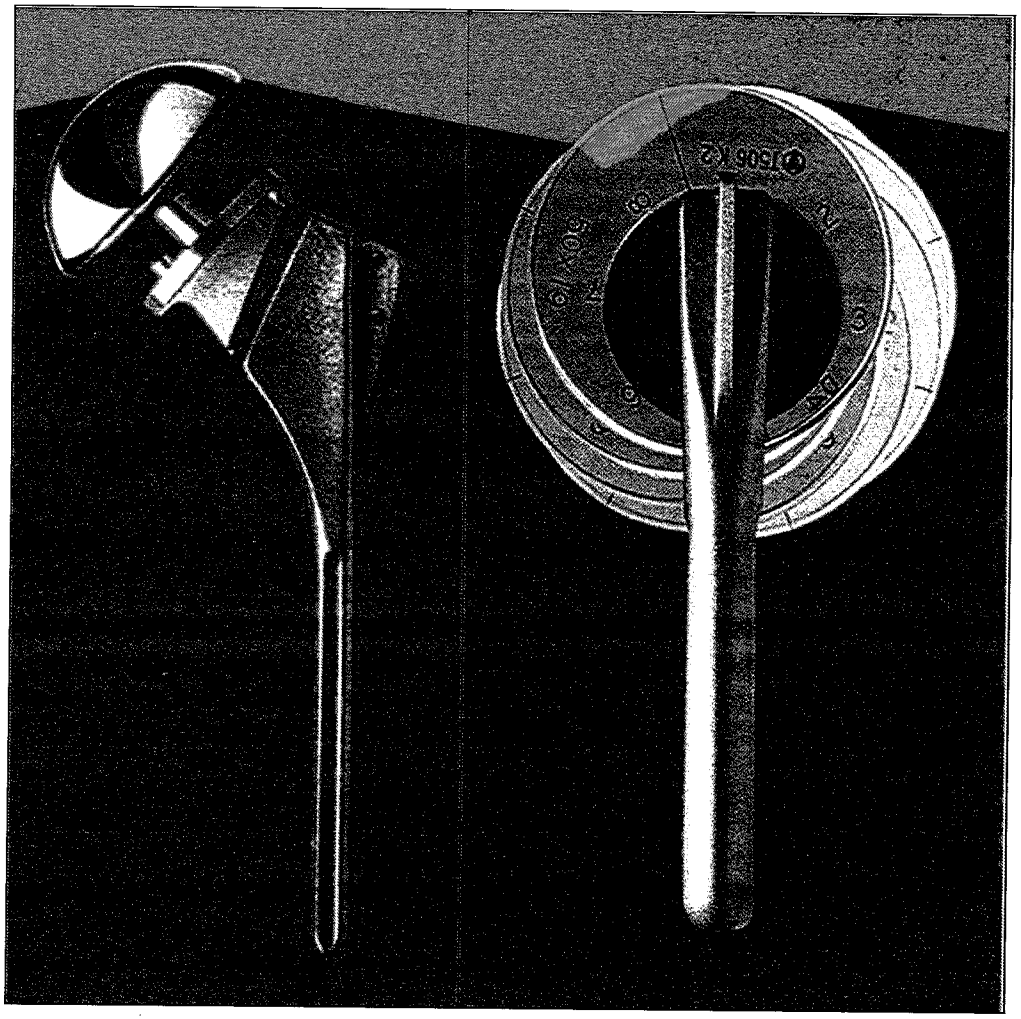
UNFORTUNATELY THESE ARE NOT INDEPENDENT AND TO MANAGE THEM IN THE BEST WAY A WIDE MODULARITY PROSTHESIS IS NECESSARY



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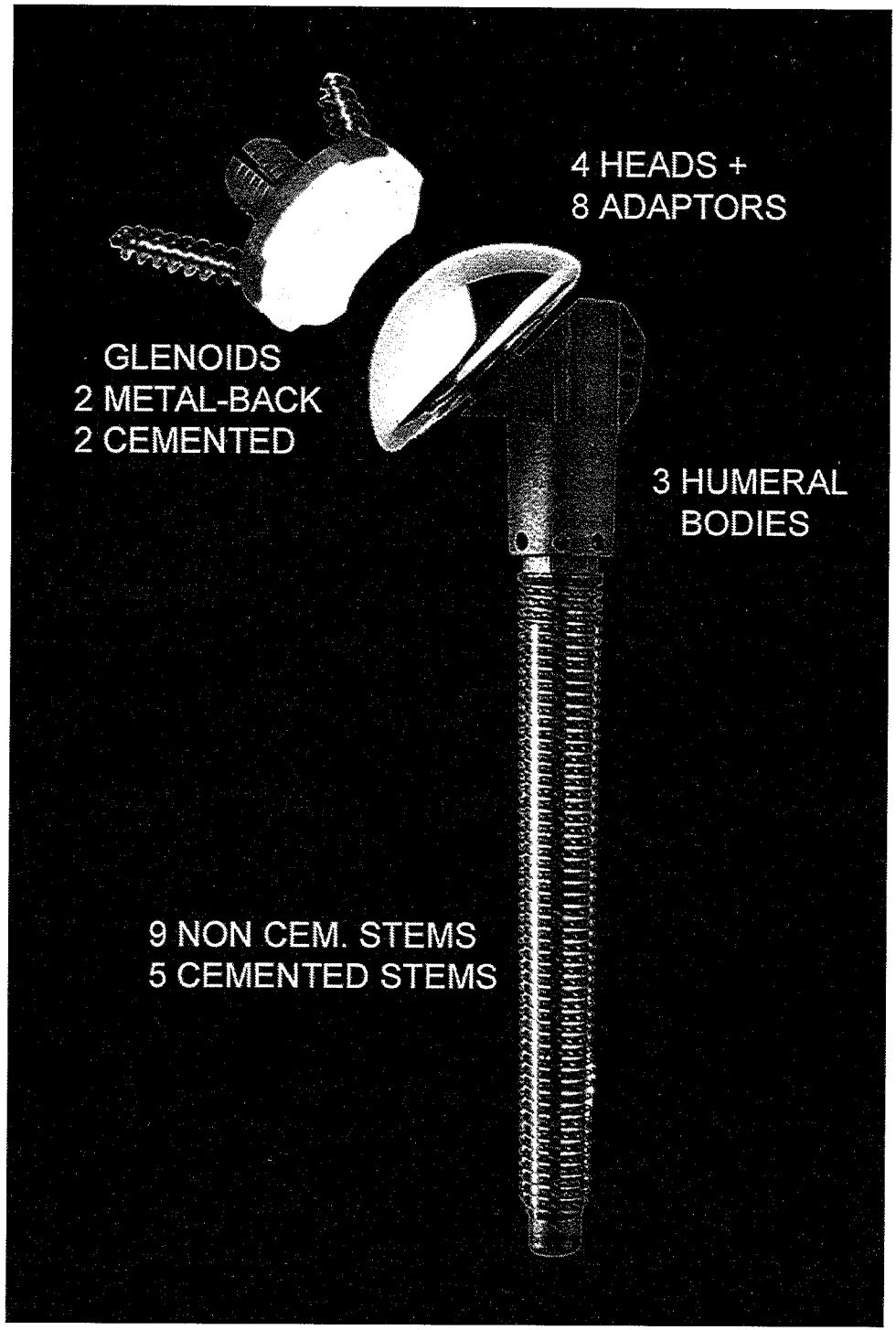
ODELLA



WALSCH

THIRD GENERATION

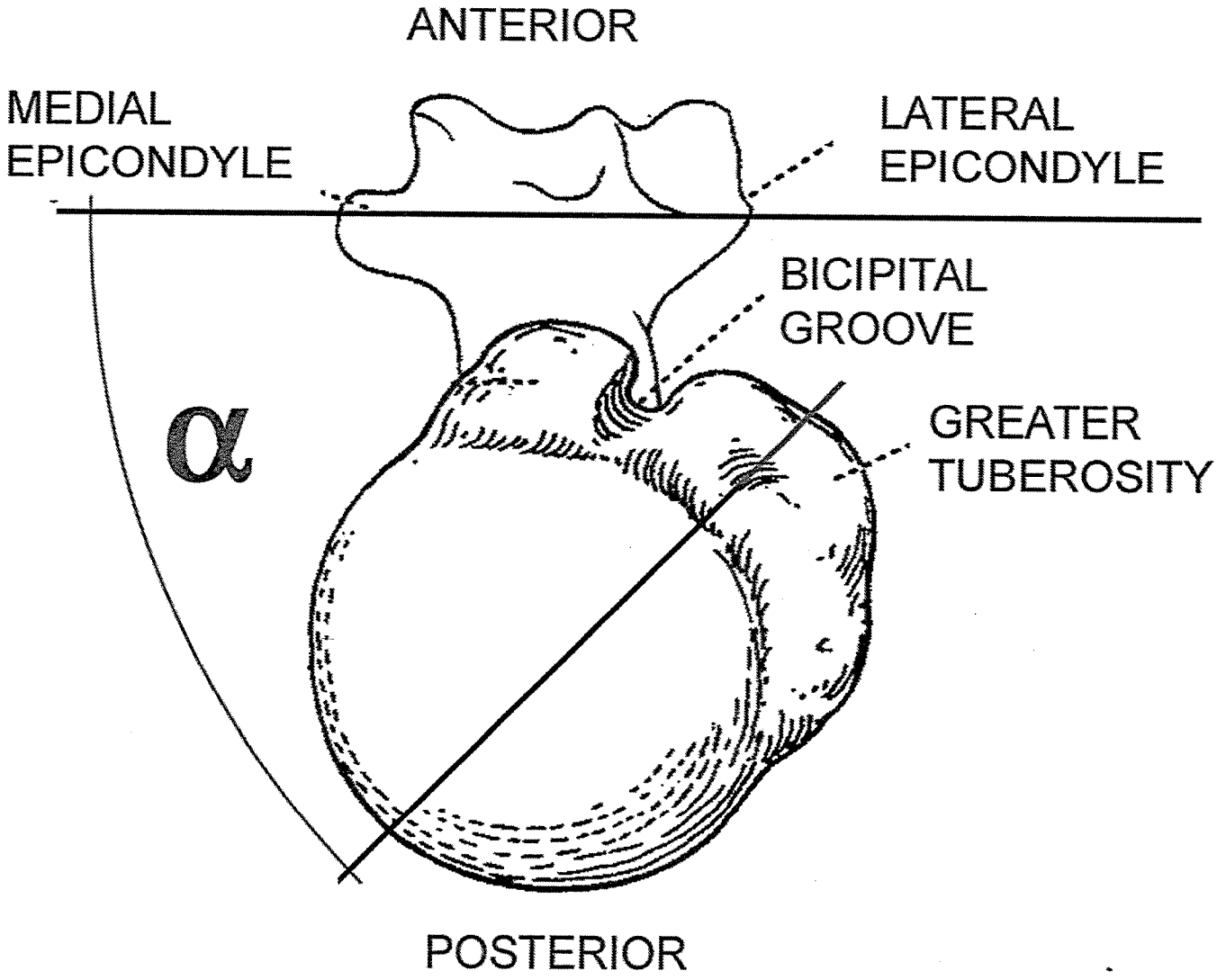
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4 HEADS +
8 ADAPTORS
GLENOIDS
2 METAL-BACK
2 CEMENTED
3 HUMERAL
BODIES
9 NON CEM. STEMS
5 CEMENTED STEMS

RETROVERSION

- NORMALLY = 30°
- IT VARIES FROM 0° UP TO 60°
- IF UNSUFFICIENT CAUSES BREAKAGE OR CONFLICT WITH THE SUBSCAPULARIS TENDON
- IF EXCESSIVE CAUSES THE POSTERIOR DISLCOTAION OF THE HEAD
- IN BOTH THE CASES THE LEVER ARMS ARE CHANGED

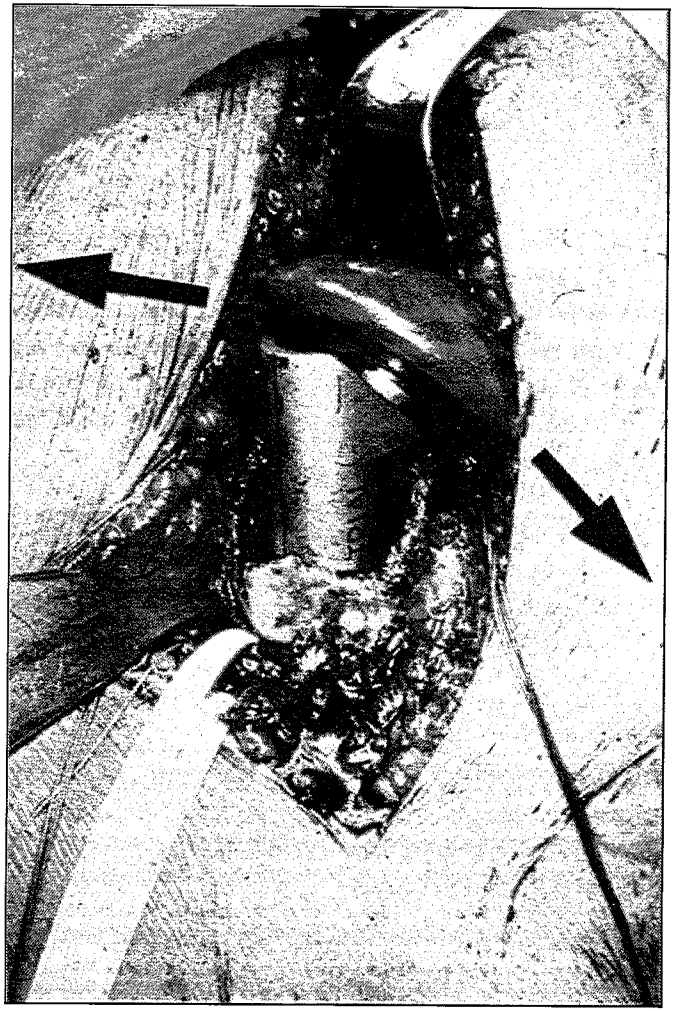
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ANTERIOR
MEDIAL
EPICONDYLE
LATERAL
EPICONDYLE
BICIPITAL
GROOVE
α
GREATER
TUBEROSITY
POSTERIOR

RETROVERSION

THE SYSTEM MUST:

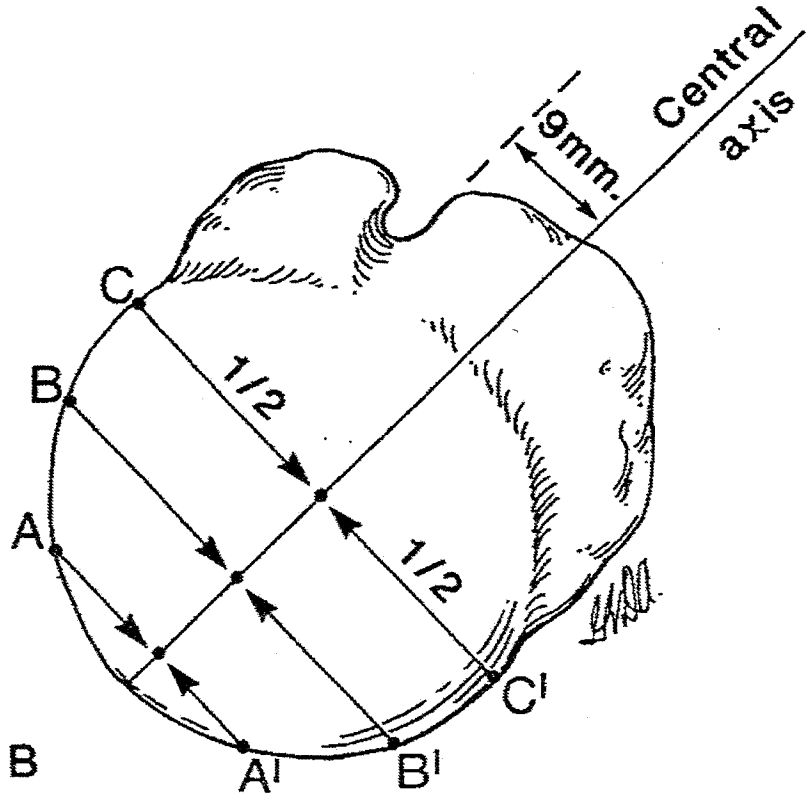
- LET THE FREE CHOICE
- LET CHANGE THE TRIAL AND THE DEFINITIVE COMPONENTS POSITION



RETROVERSION

THE PLANE OF SYMMETRY OF THE HEAD IS LOCATED 9 mm POSTERIOR TO THE BICIPITAL GROOVE

THE RANDELLI SYSTEM ALLOWS THE REAL RETROVERSION FOR EACH PATIENT



Tillett, 1993

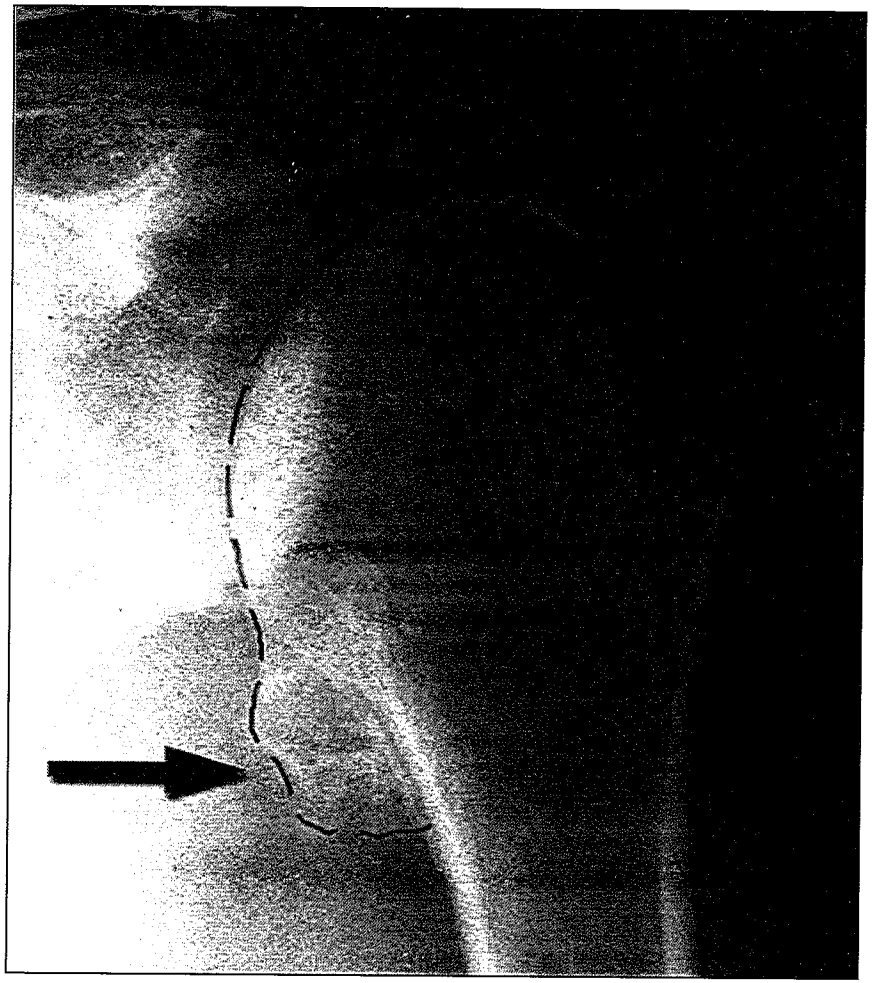
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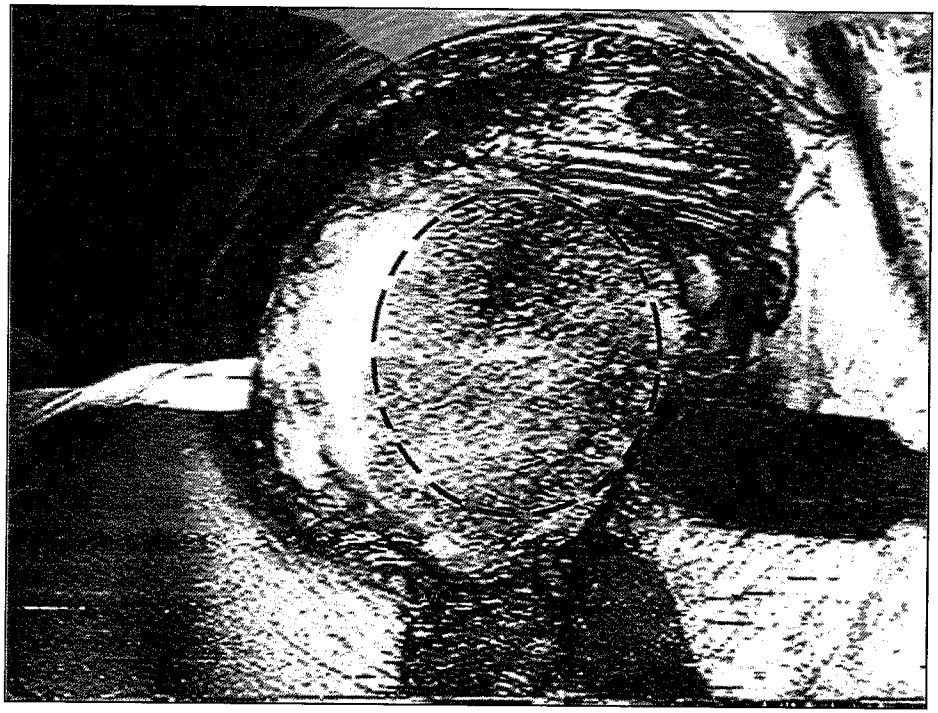
HEAD DIAMETER

- AVERAGE DIAMETER = 46 mm (FROM 38 TO 58 mm)
- DIFFICULT TO KNOW IN DEGENERATIVE PATHOLOGIES
- A TOO BIG DIAMETER STIFFS THE JOINT
- A TOO LITTLE DIAMETER CAUSES INSTABILITY AND REDUCES THE MUSCOLAR POWER

IN ACUTE TRAUMAS
THE HEAD
DIAMETER IS EASILY
MEASURED BY A
PROPER GAUGE







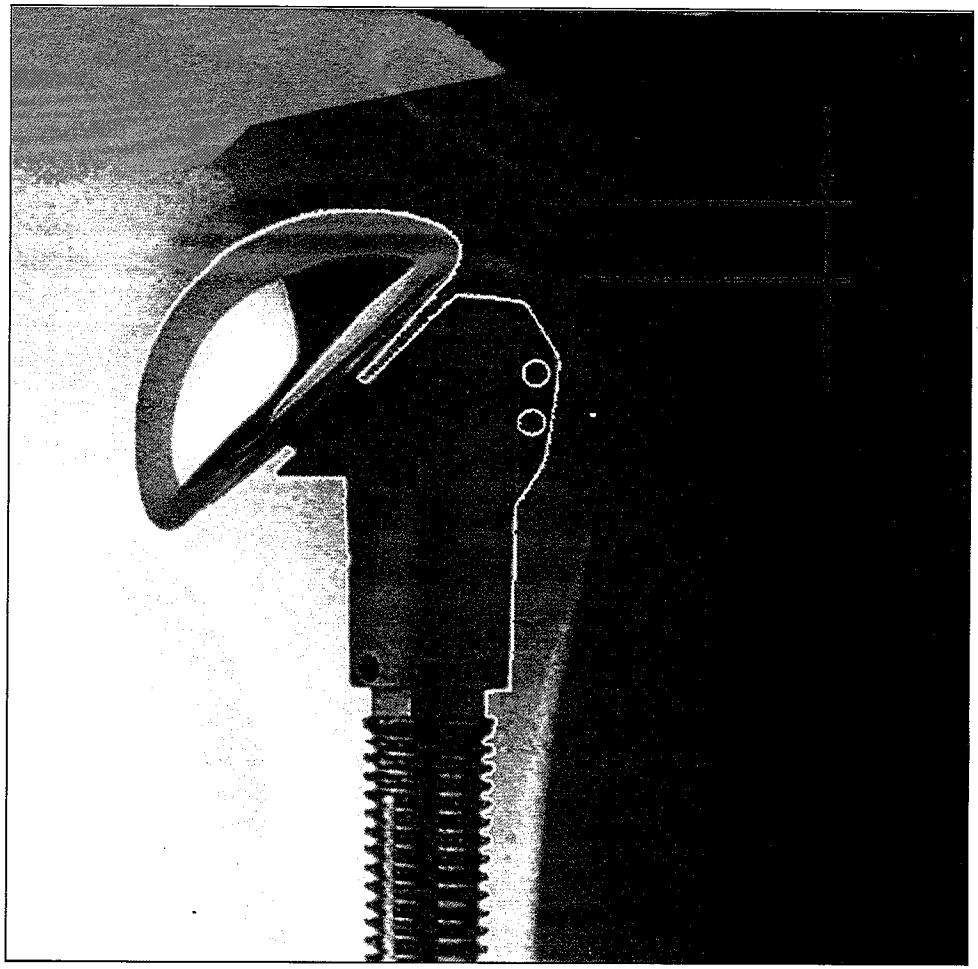
IN THE DEGENERATIVE PATHOLOGIES IT IS DIFFICULT TO KNOW THE HEAD DIAMETER

IF IN DOUBT A SMALLER DIAMETER IS BETTER

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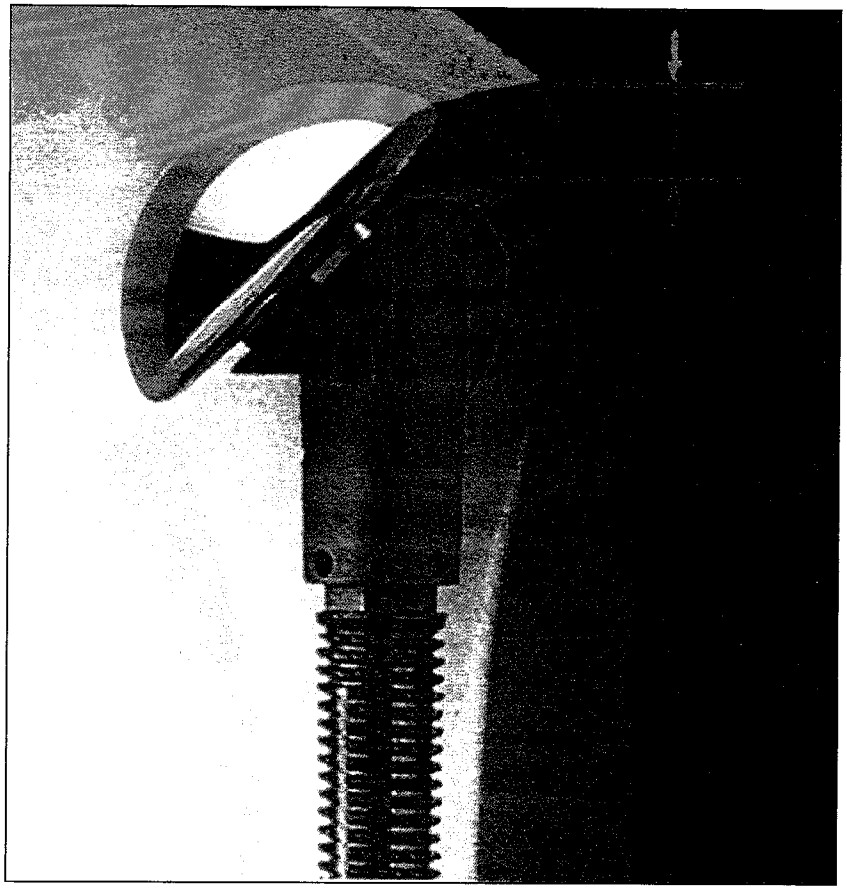
THE HEAD MUST BE OF THE RIGHT DIAMETER AND SOME MILLIMETERS ABOVE THE TROCHITE





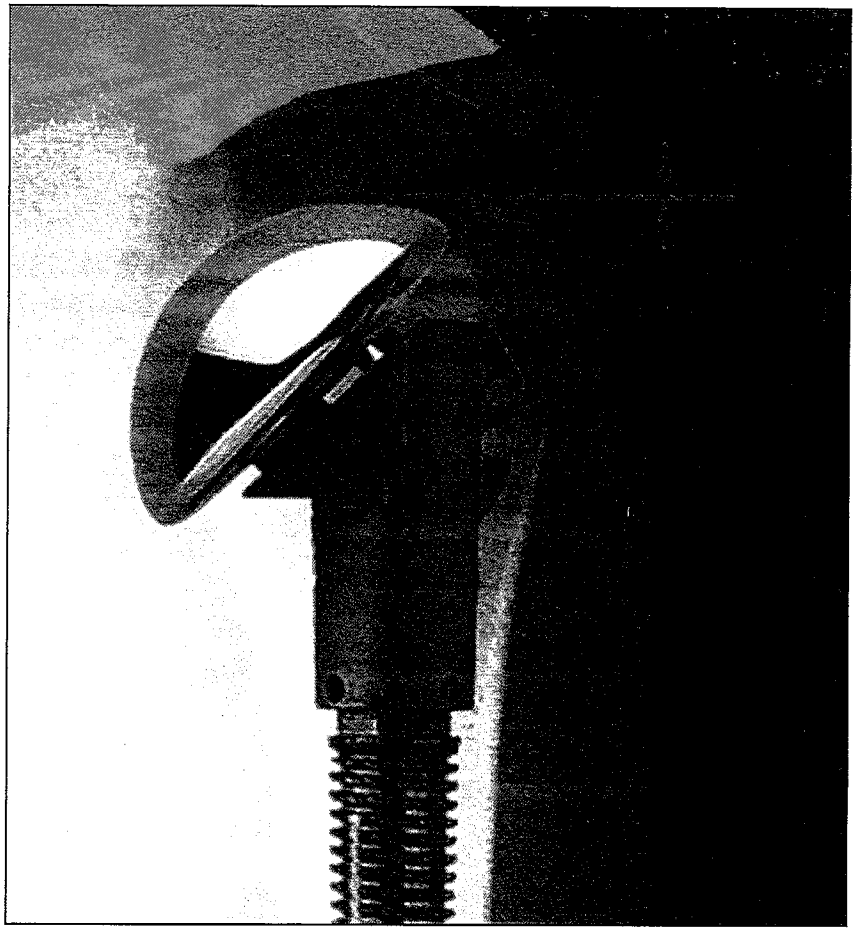
IF THE HEAD IS TOO HIGH

- INCREASE OF CAPSULO-LIGAMENTOUS TISSUES IN ELEVATION
- SUB-ACROMIAL CONFLICT OF THE HEAD
- BIG TROUBLES IF CUFF DEFICIENCY



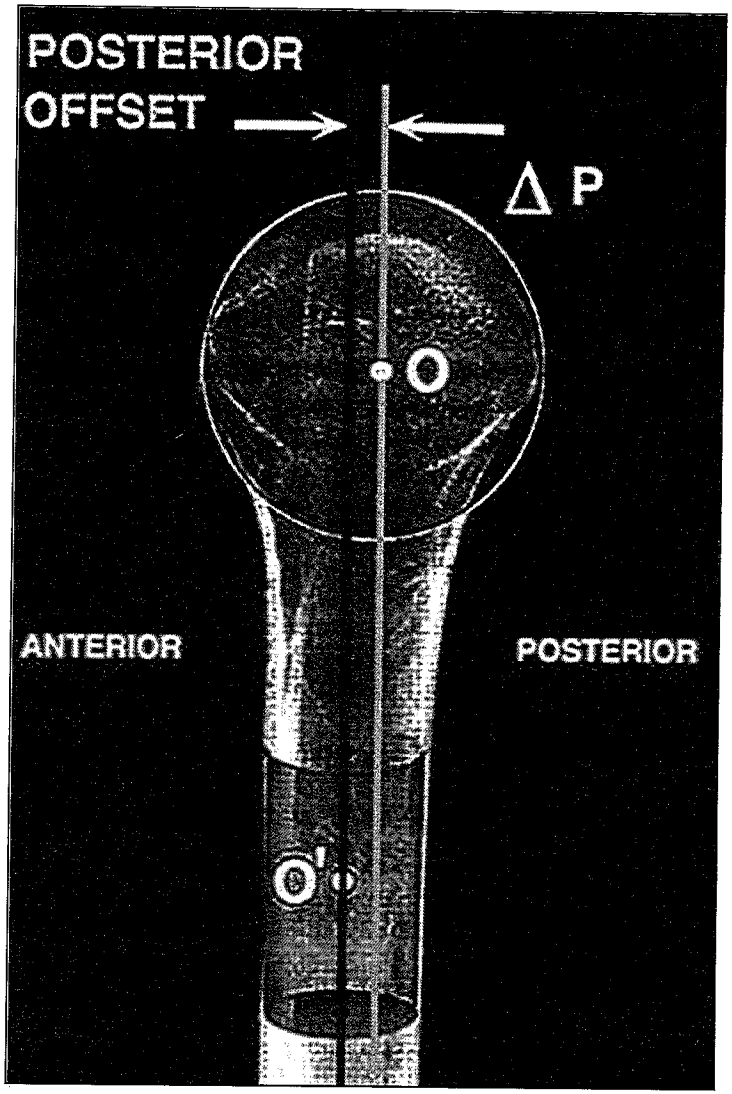
IF THE HEAD IS TOO LOW

- LOWER OF THE CENTER OF ROTATION
- LESS HEAD DEPRESSION
- INCREASE OF TENSION IN ABDUCTION
- GREATER TUBEROSITY SUB-ACROMIAL CONFLICT IN ELEVATION



POSTERIOR *OFFSET*

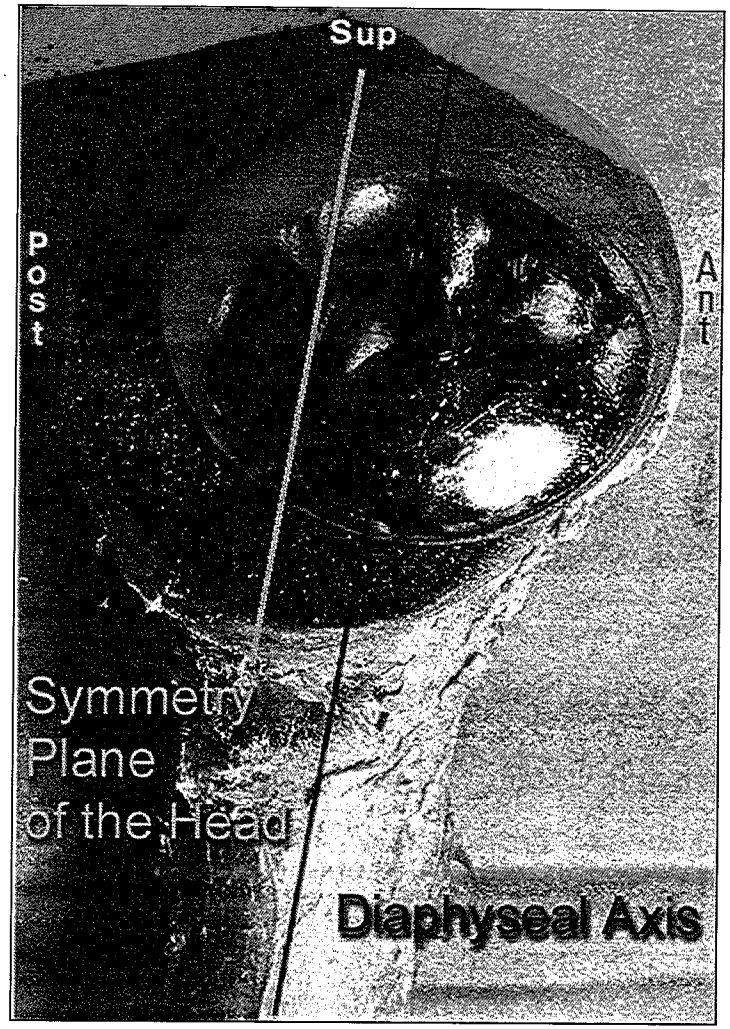
- THE HUMERAL HEAD IS PLACED POSTERIORLY TO THE DYAPHYSEAL AXIS
- ABOUT 4 mm (0-10 mm)
- DIFFICULT TO SEE IN ACUTE AND OLD TRAUMAS



POSTERIOR *OFFSET*

IF IT IS NOT CONSIDERED THE CENTER OF ROTATION IS ANTERIORLY SHIFTED

- CHANGE OF LEVER ARMS
- ABNORMAL CONTACT WITH THE GLENOID
- CORACOID *IMPINGMENT*
- SUBSCAPULARIS PRESSURE



OFFSET A-P

standard
+ 2 mm
+4 mm
+6 mm
NEUTRAL
CRANIAL
CAUDAL

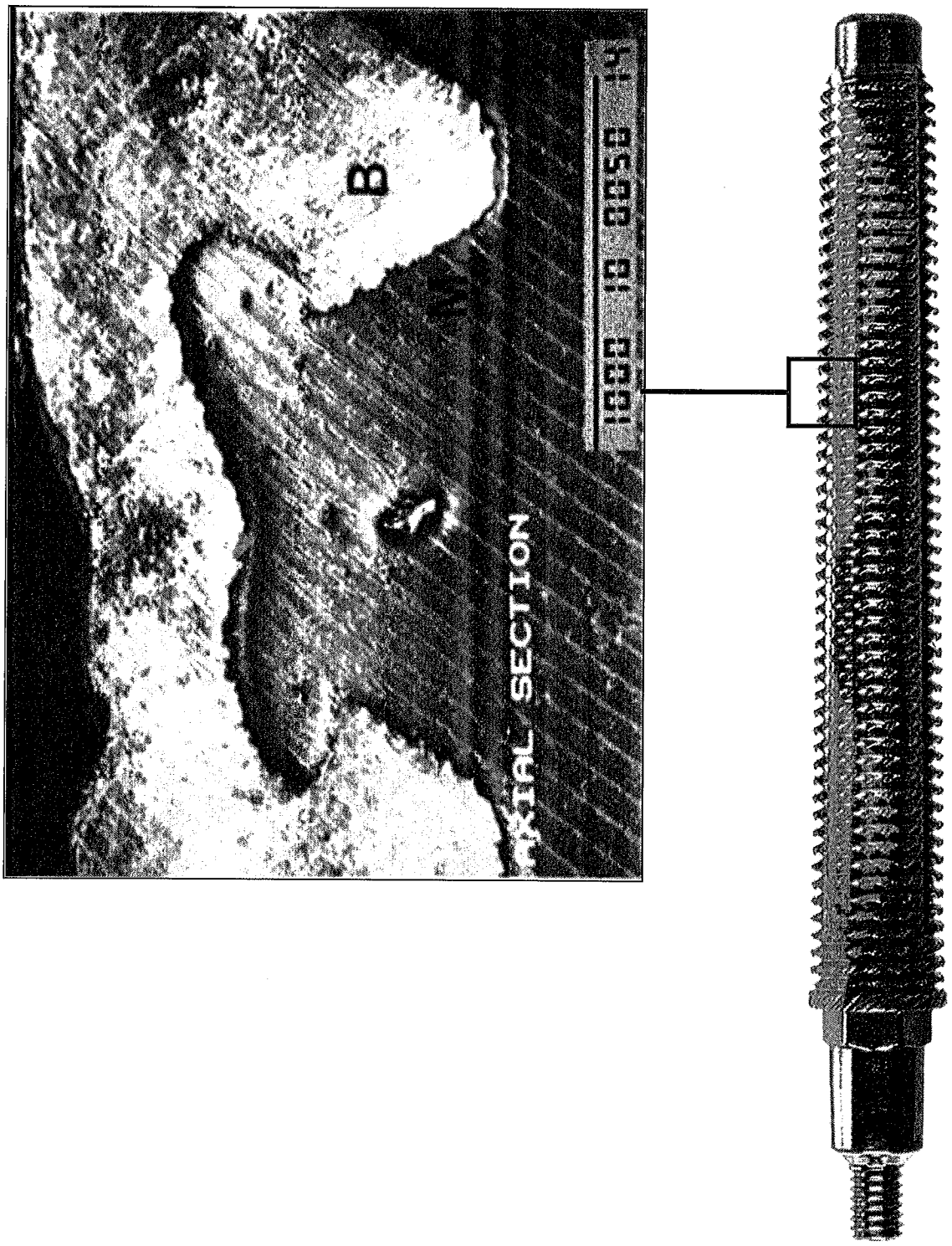
FUTURE DEVELOPEMENTS

FOURTH GENERATION PROSTHESES

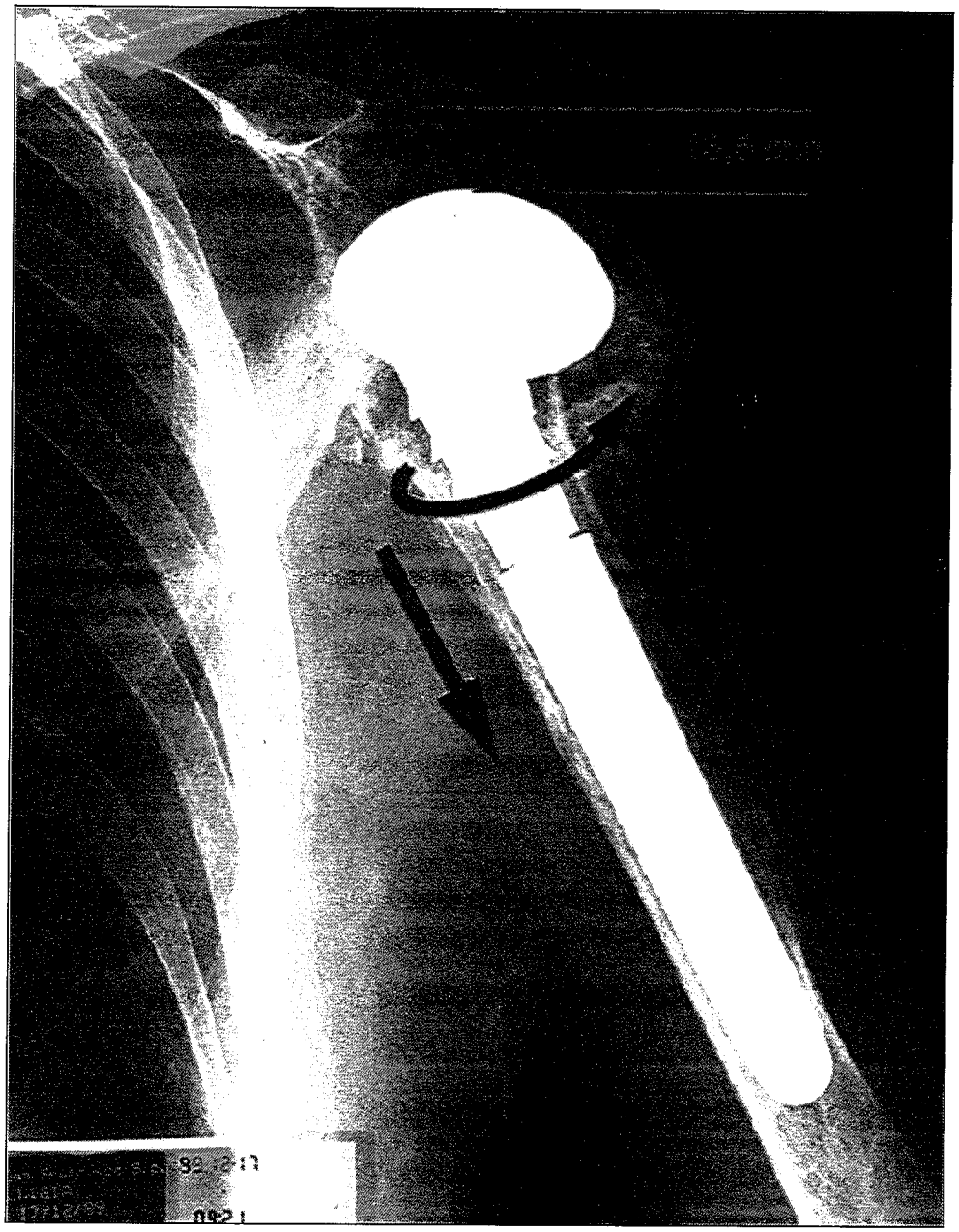
REQUIREMENTS

- CUSTOM SET-UP
- SEVERAL TYPES ACCORDING TO AGE AND PATHOLOGY
- REVISION EVEN PARTIAL
- SOLUTION OF THE 'GLENOID' PROBLEM

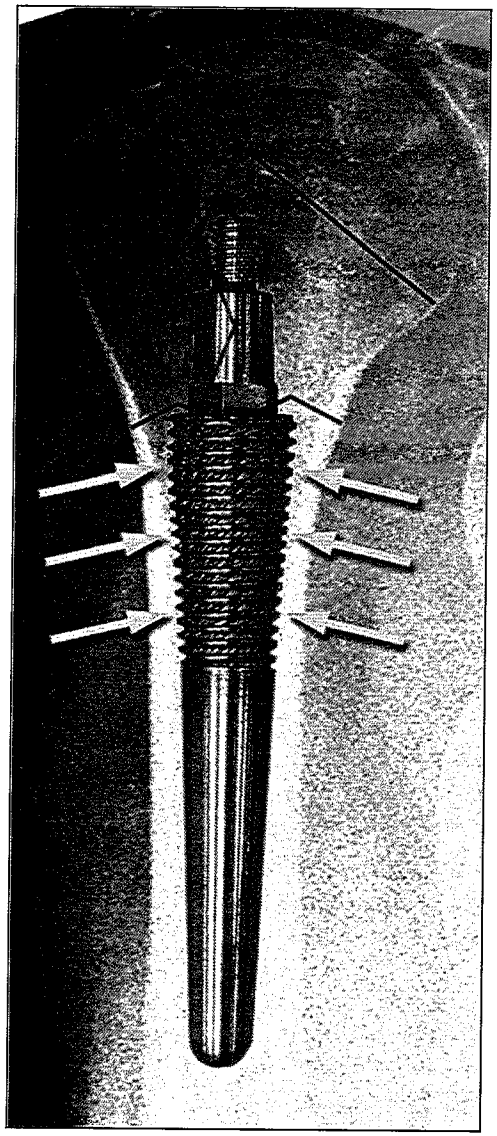
NON CEMENTED STEMS MUST GUARANTEE AN EXCELLENT PRIMARY FIXATION ESPECIALLY IN ACUTE TRAUMAS

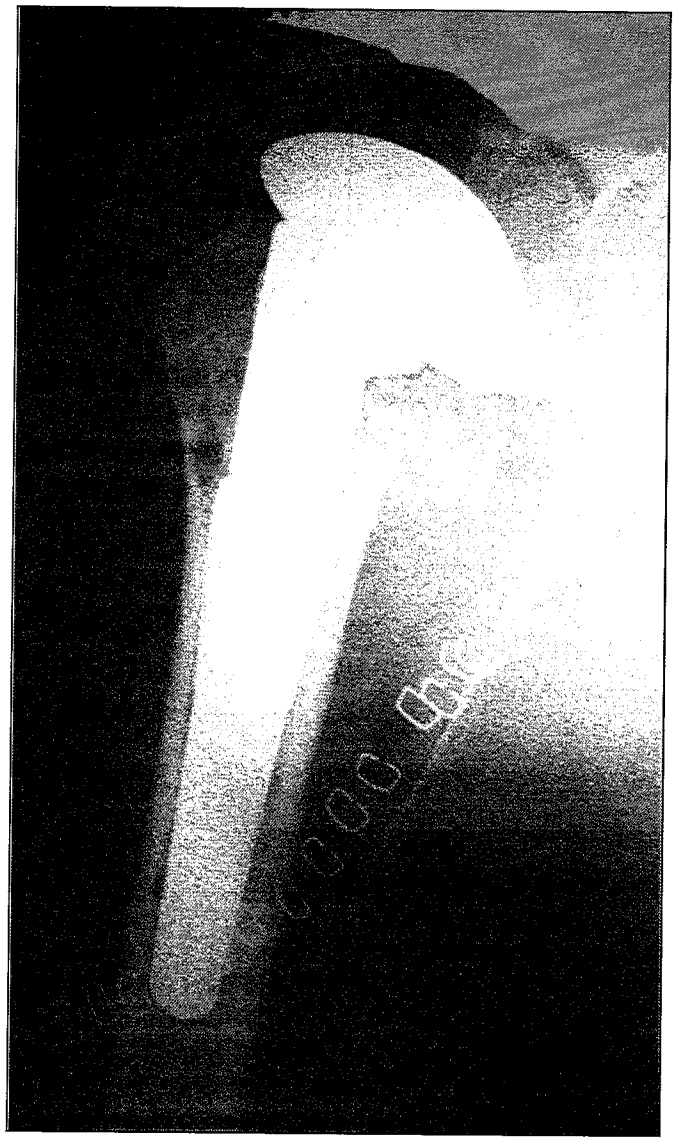

B
AXIAL SECTION

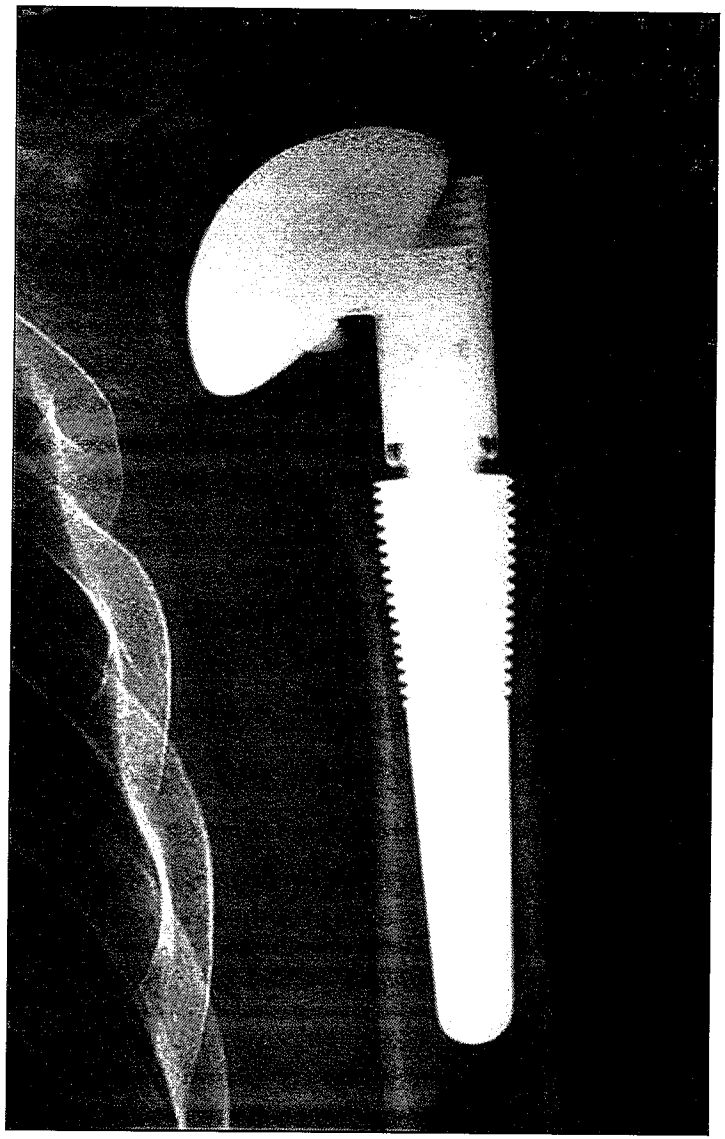
STEM LOOSENING OF A (BAD) COPY OF THE RANDELLI SYSTEM



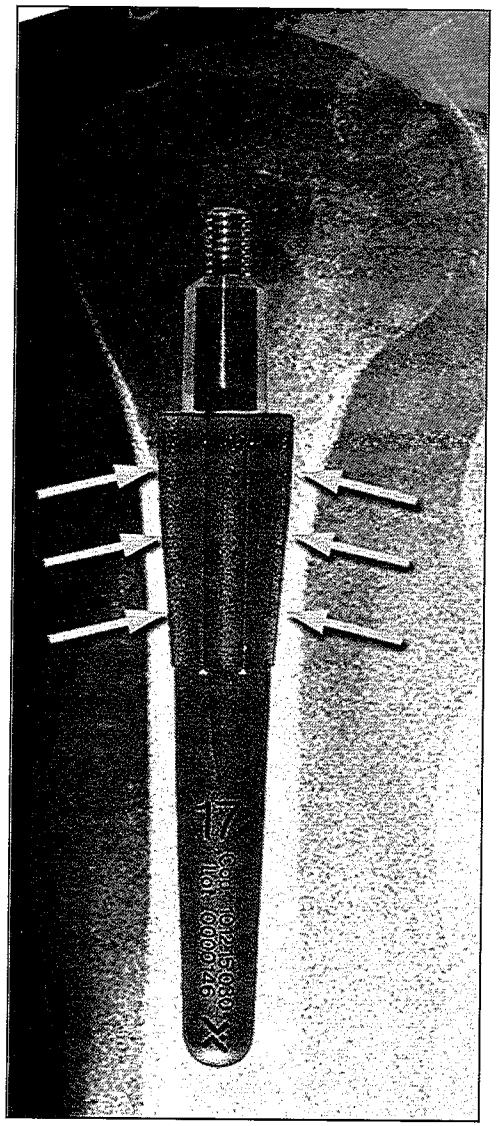
PARTIALLY KNURLED
(ACUTE TRAUMAS)

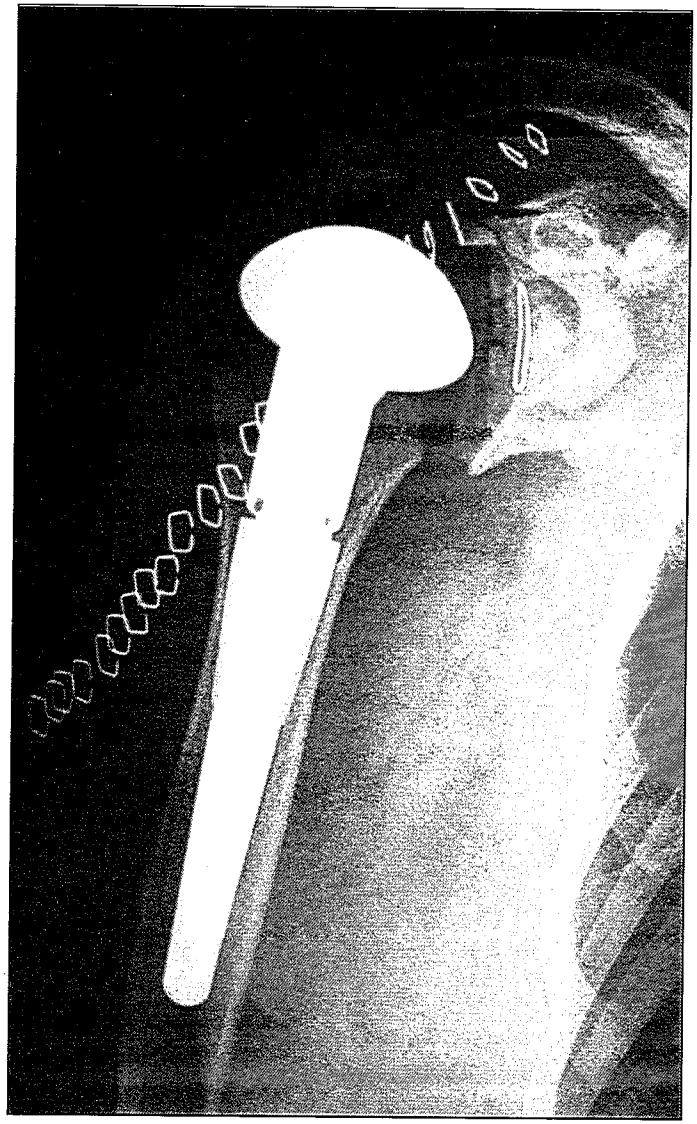


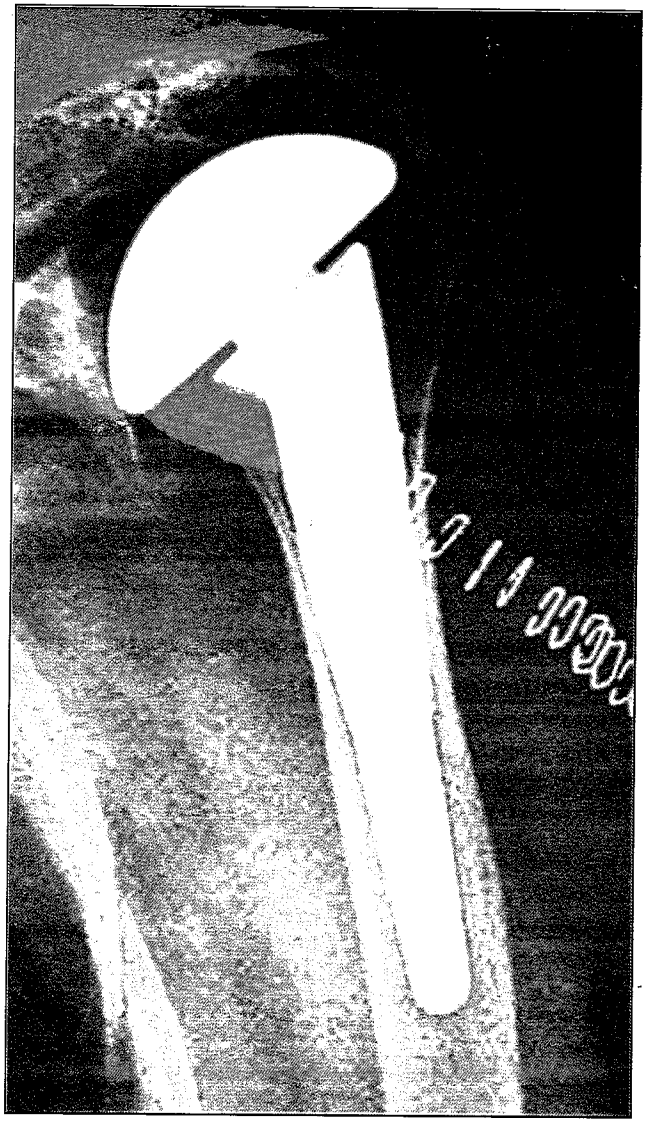




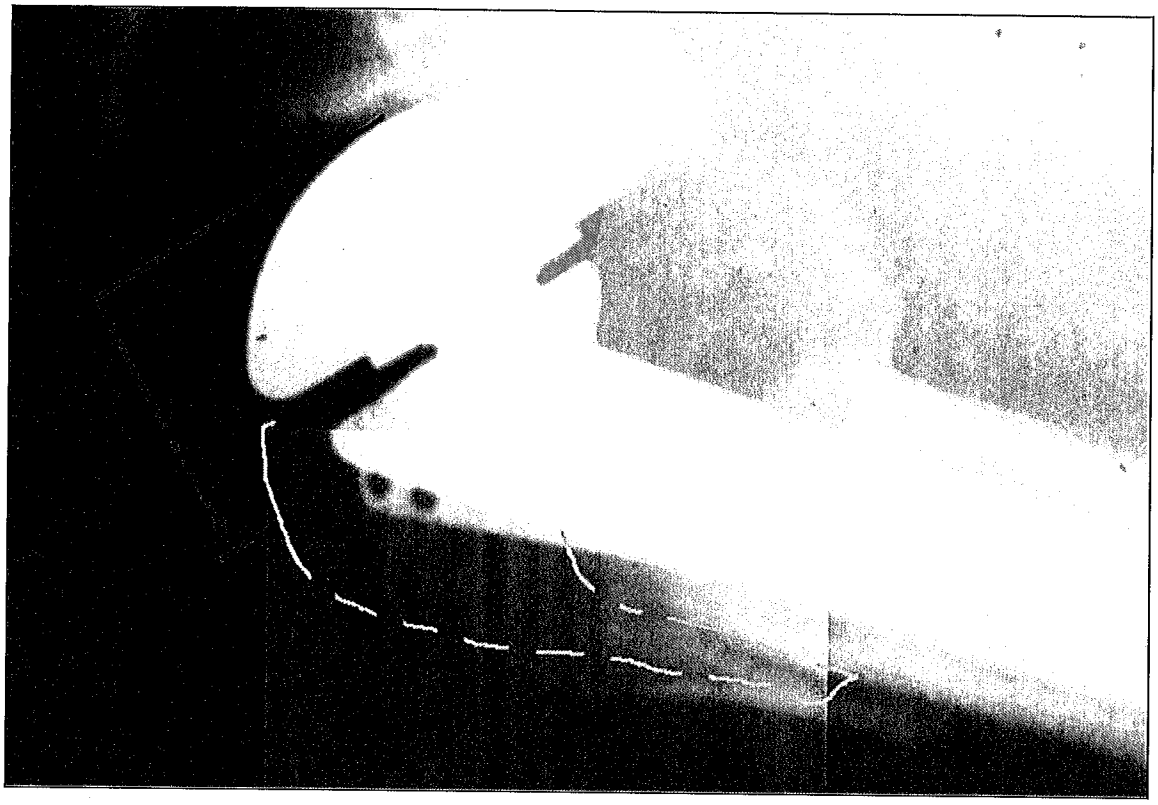
FINNED
(DEGENERATIVE PATHOLOGIES)

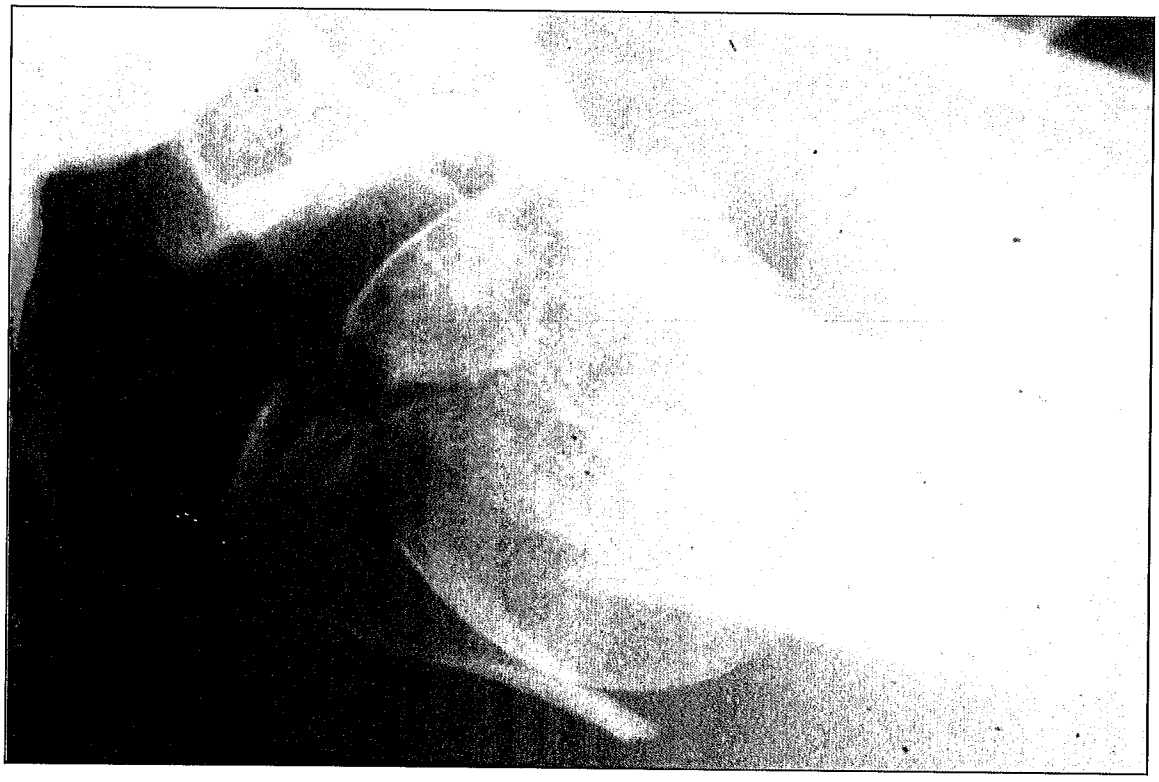


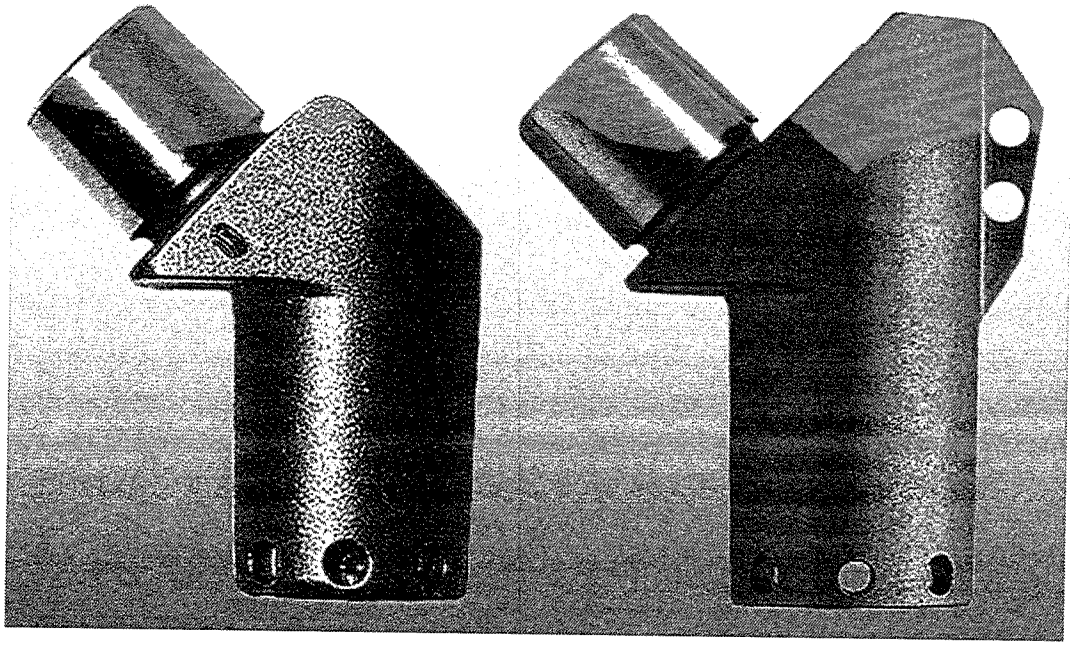




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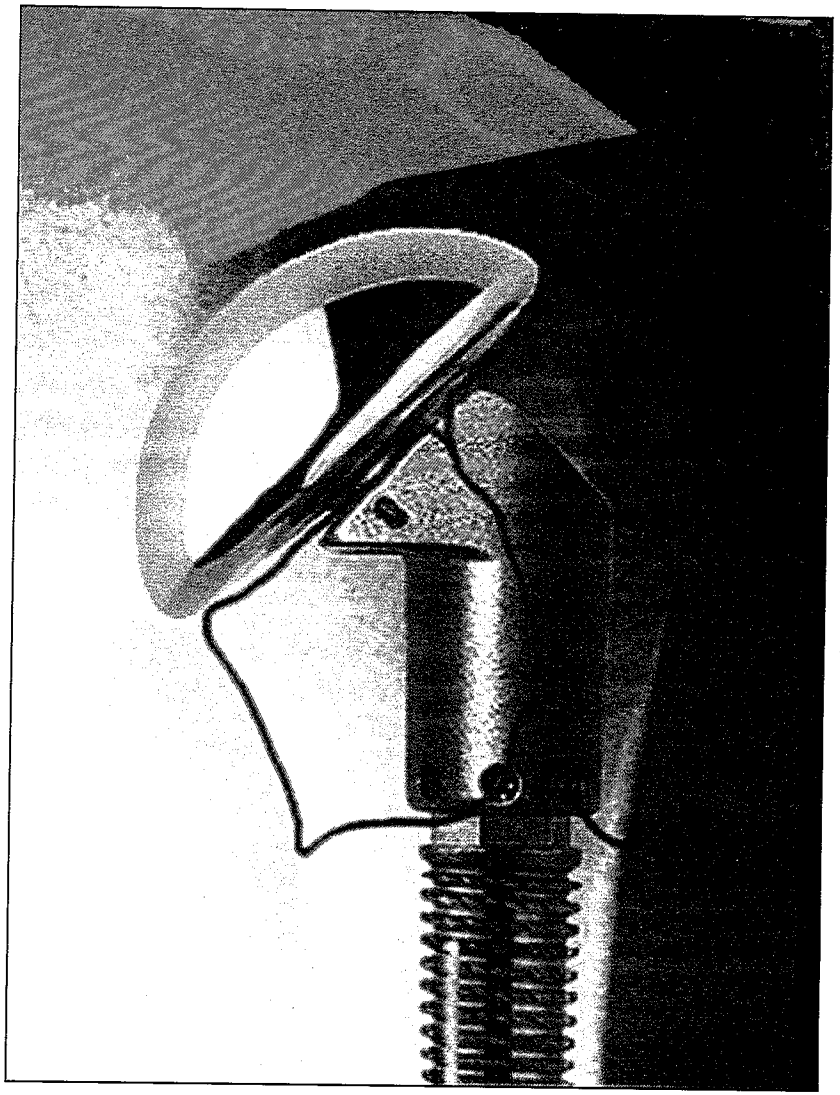




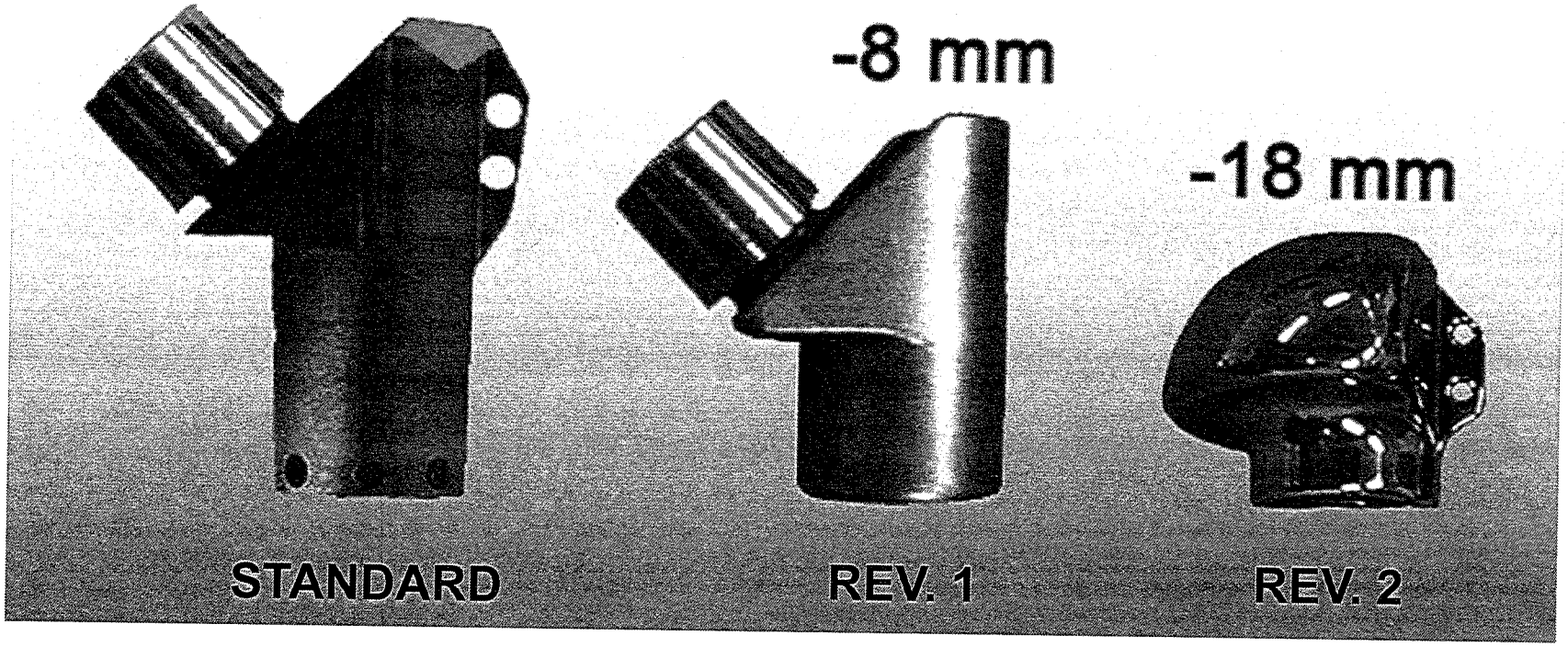


CORPO TRAUMA

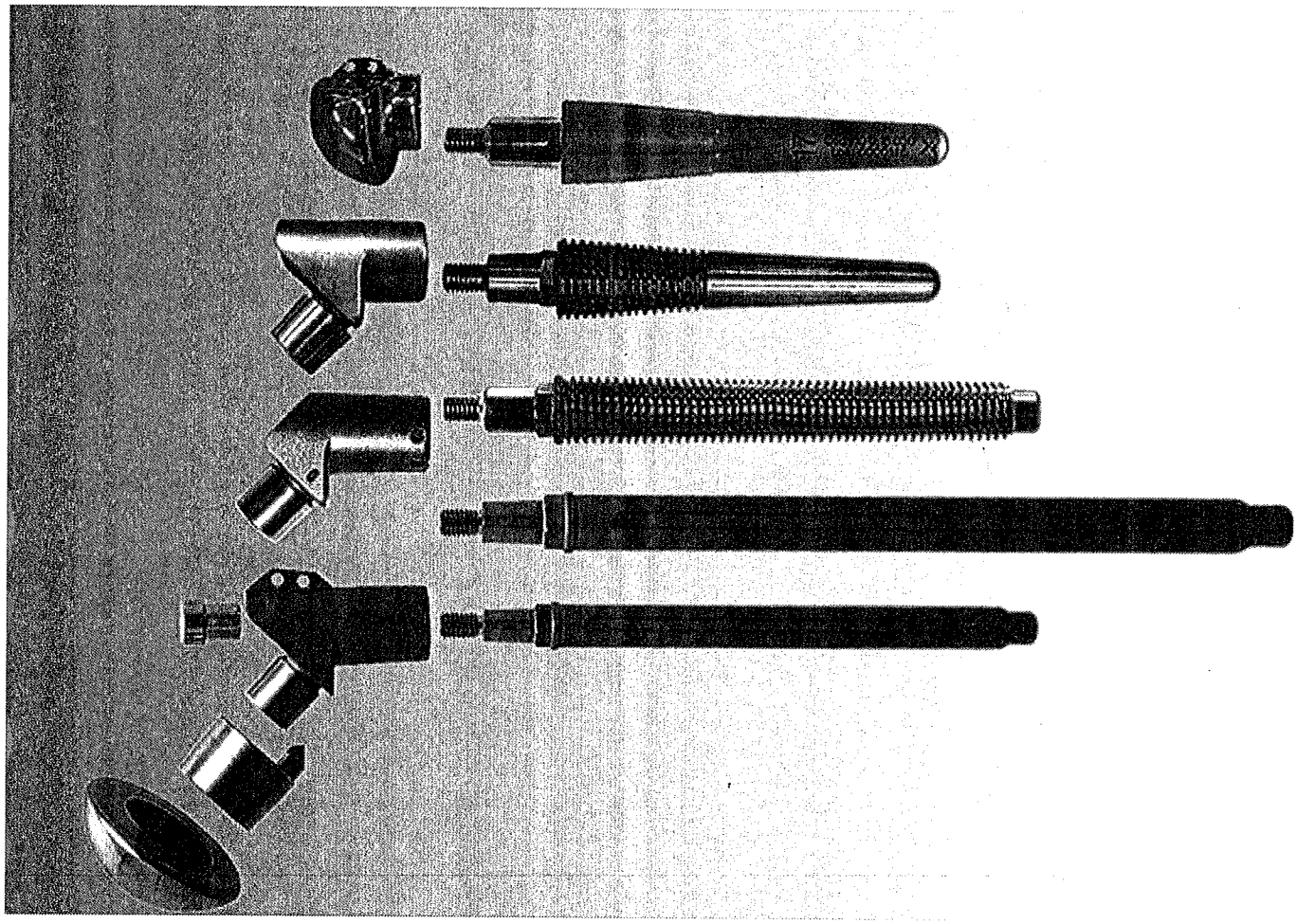
CORPO ELEZIONE



REVISION HUMERAL BODIES



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TO GLENOID OR NOT TO GLENOID?

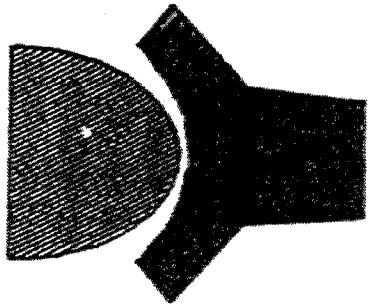
THIS IS THE QUESTION



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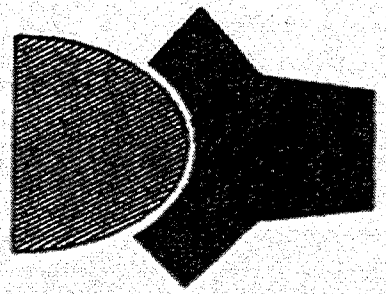
EFFETTO 'ROCKING HORSE'

LOW CONSTRAINT (CSI)



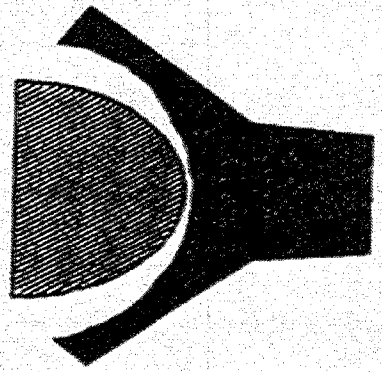
LOW CONFORMITY (CFI)

LOW CONSTRAINT (CSI)



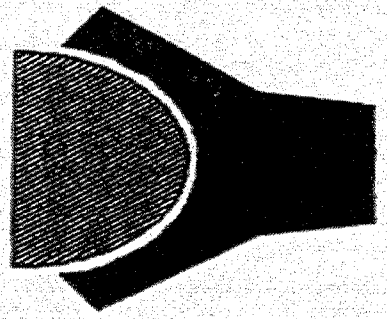
HIGH CONFORMITY (CFI)

HIGH CONSTRAINT (CSI)

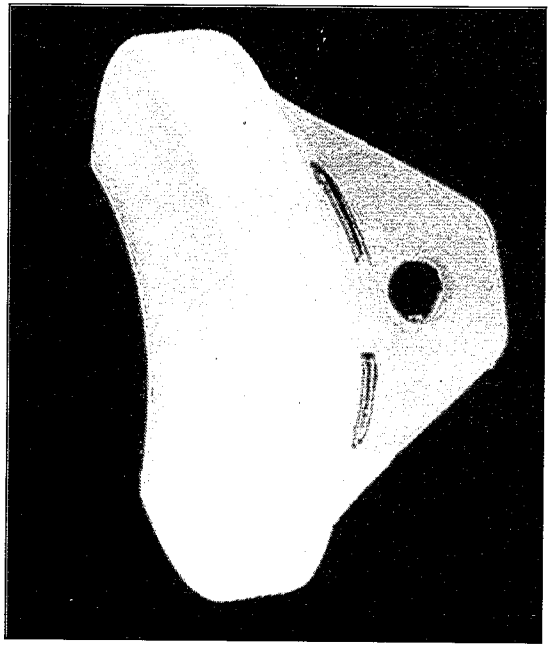


LOW CONFORMITY (CFI)

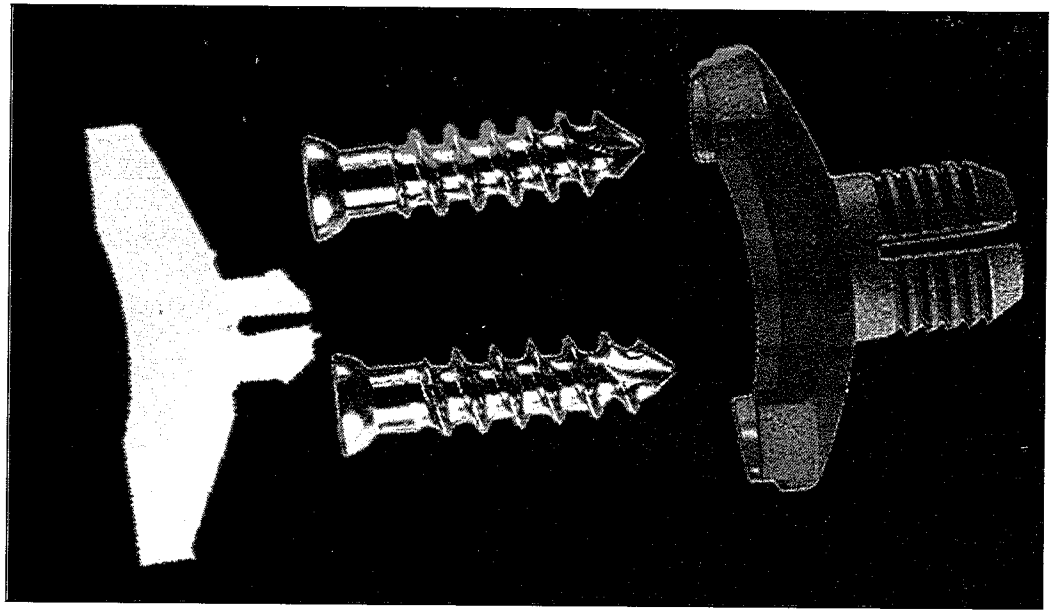
HIGH CONSTRAINT (CSI)

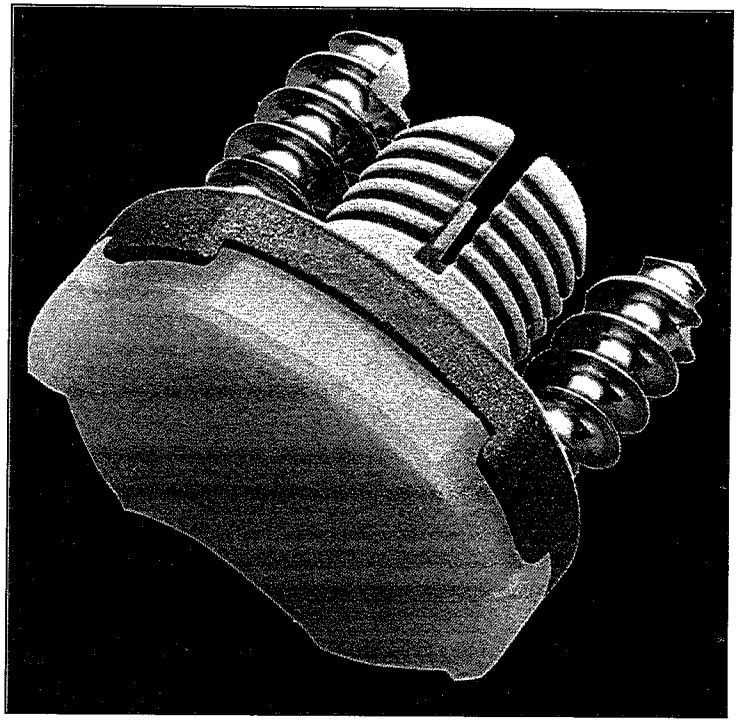


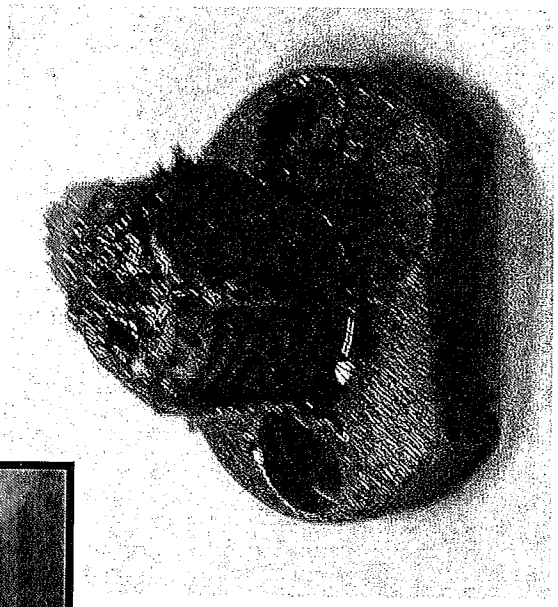
HIGH CONFORMITY (CFI)

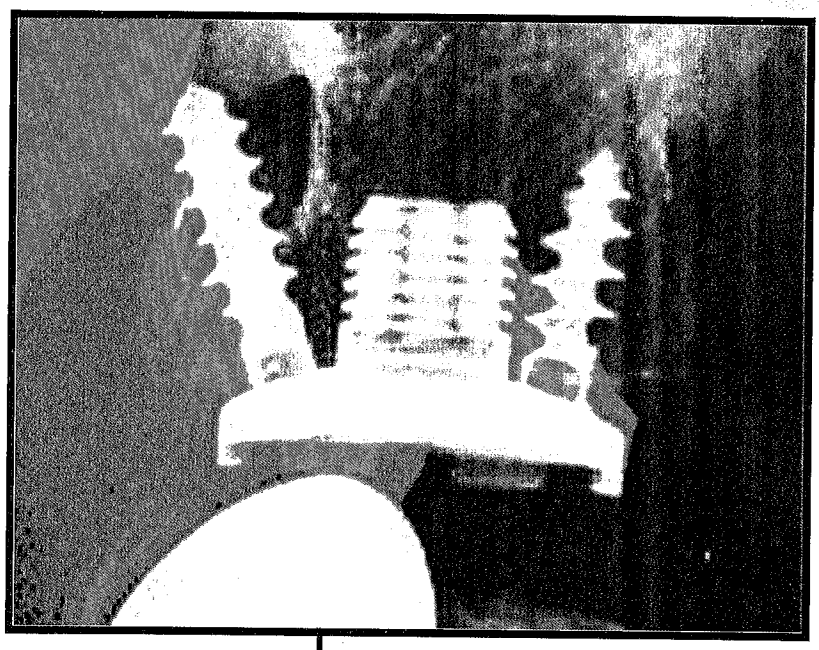


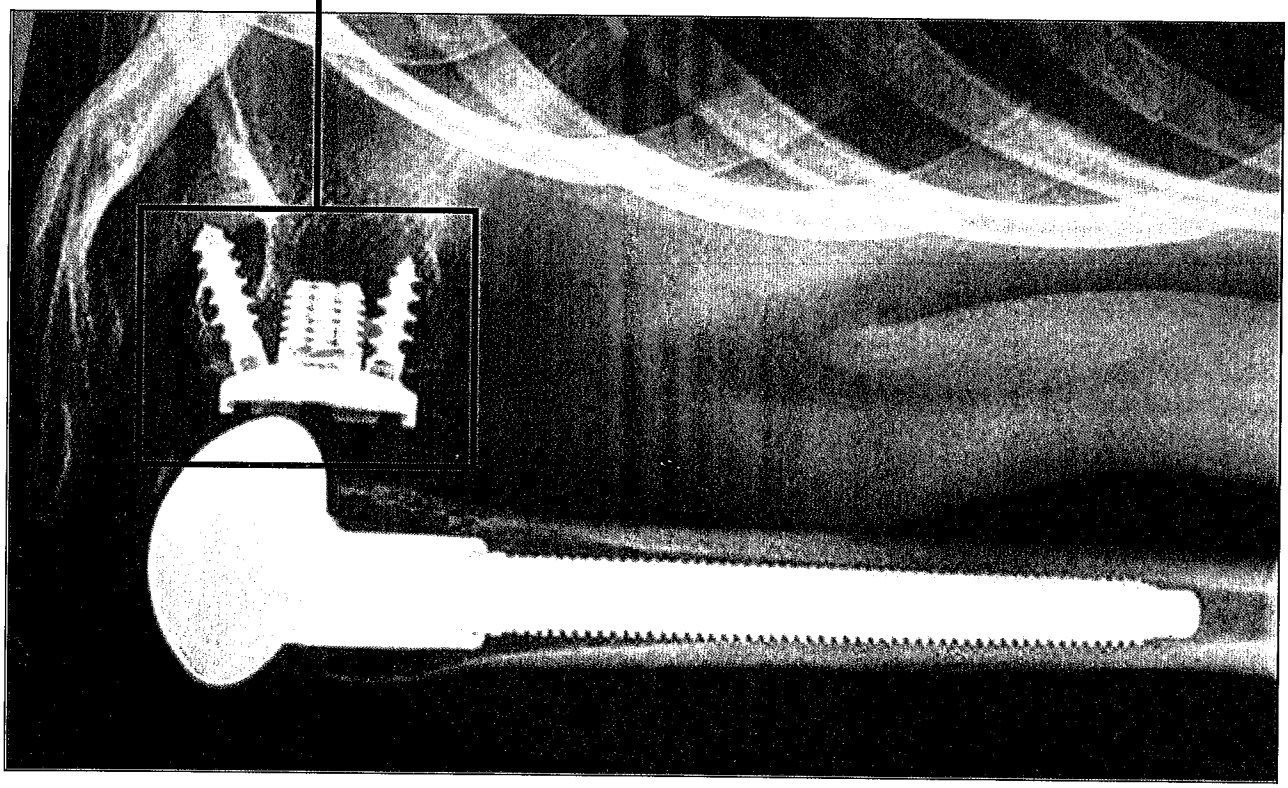
EITHER CEMENTED OR PRESS-FIT THE GLENOID HAS TO BE LOW CONSTRAINT AND LOW CONFORMITY

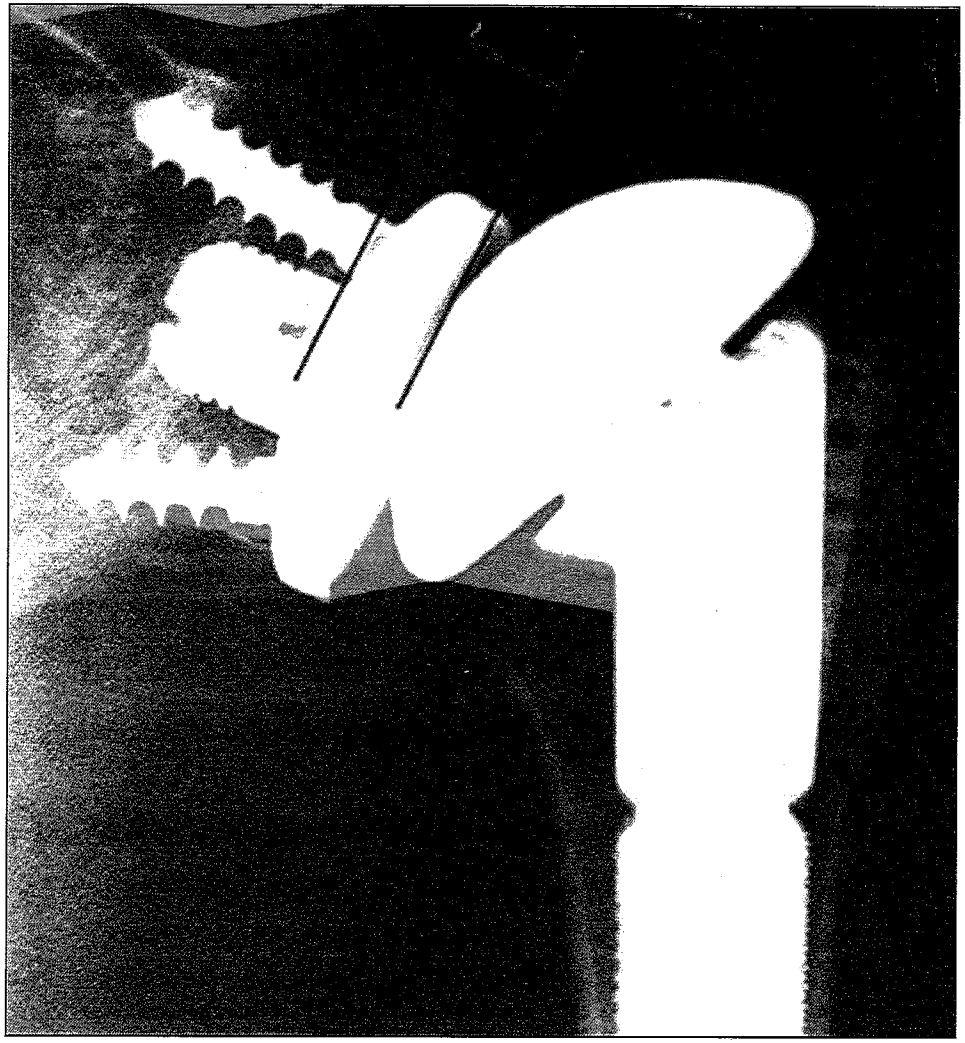






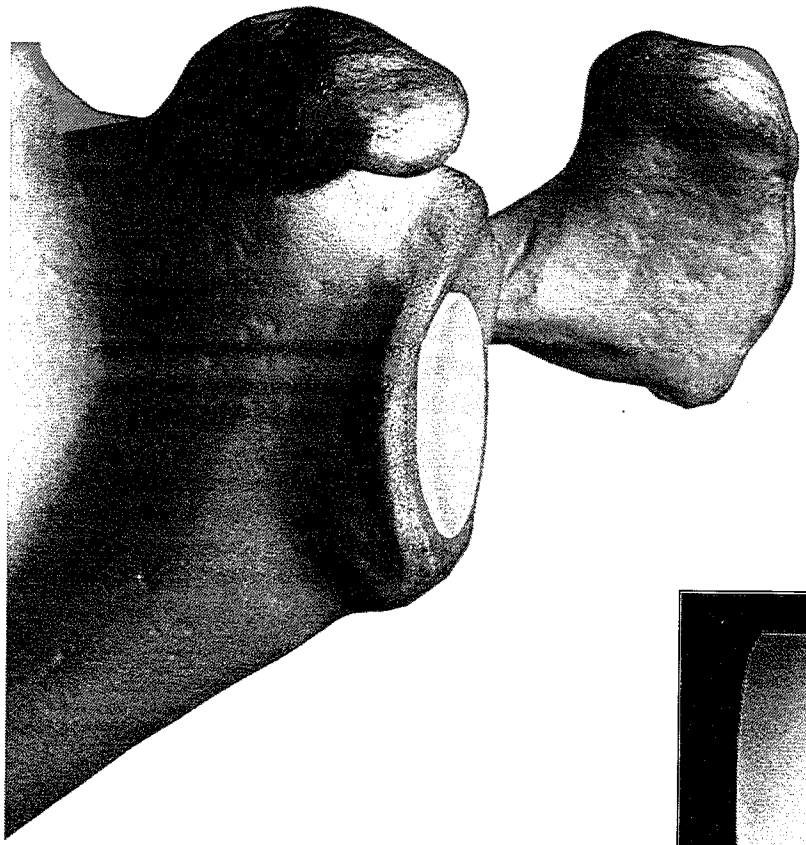


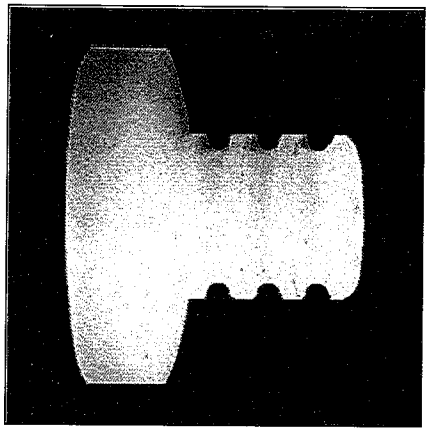


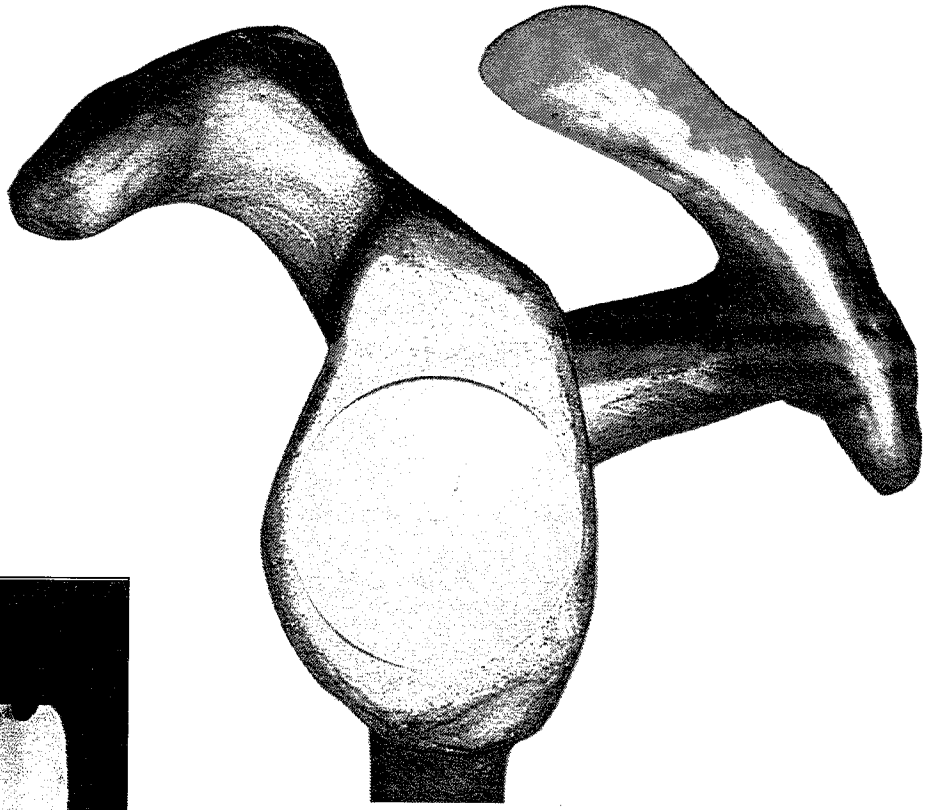


EVEN WELL POSITIONED, THE GLENOID CHANGES THE JOINT CENTER OF ROTATION AND IT IS COUNTERPRODUCTING WHEN TEHRE IS NO CUFF BALANCE (DISLOCATION)

BUTTON GLENOID







CONCLUSIONS

- SHOULDER ARTHROPLASTY IS DIFFICULT AND THE OUTCOMES ARE OFTEN UNCERTAIN
- A GOOD AND COMPLETE PROSTHETIC SYSTEM DOES NOT SUBSTITUTE THE SURGEON'S EXPERIENCE BUT IT HELPS TO FACE THE VARIABILITY OF THE CASES

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TECHNIQUE

Enhancement of Glenoid Prosthesis Anchorage Using Burying Technique

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ABSTRACT

Seventy unconstrained total shoulder prostheses were evaluated with a mean follow-up of 42 months (range, 24–96 months). A flat polyethylene cemented glenoid device with 2 fixation points was always used. It was a slightly undersized device to facilitate insertion. Glenoid modifications were assessed on anteroposterior (AP) views (3 rotations) and with a modified axillary lateral view using Bernageau technique. We noted the thickness of the radiolucent lines, whether they were complete or incomplete, and how they had evolved over 12 months. On coronal x-rays, only 7 devices had no radiolucent line at 12 months, 42 had a partial radiolucent line, and 20 a complete radiolucent line, including 2 with a radiolucent line greater than 2 mm that seemed to be loose. One device had migrated secondary to an anterior dislocation. Radiolucent lines were clear in 90% of cases and had evolved in 27% of cases. Radiographically, the loosening rate was 28%. Comparison of the clear radiographic radiolucent lines, clinical parameters (constant score), and the position of the implants did not demonstrate any predictive factor for evolution of the periglenoid radiolucent lines. Age- and sex-weighted constant score at 42 months was 87.7 %. The technique was developed to spare the glenoid bone, which is often deteriorated by the degenerative process, and to obtain stable primary fixation on the subchondral bone. The clear radiolucent lines noted immediately postoperatively led us to improve our technique by making small perforations in the subchondral bone and by performing cementing in 2 stages. Although no revision surgery was performed, the bone preservation observed suggests that this would be possible in good conditions.

Keywords: shoulder prosthesis, biomechanics, loosening, constant score, radiolucent line, arthroplasty

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Clinical results obtained in unconstrained total shoulder prostheses are excellent or good on the Neer and Cofield scale in 80% to 90% of cases.[1–4] The rate of clear radiographic radiolucent lines at the bone-cement-glenoid implant interface after cementing of an unconstrained device ranges from 30% for Neer et al[1] to 96% for Broström et al.[5] However, analyzing radiolucent lines remains difficult. O'Driscoll et al[6] demonstrated how some assessments may lack objectivity or reproducibility. Indeed, a standardized radiographic technique is required.[7–9] The most widely used glenoid technique is cementing with polyethylene implants.[10–13] To decrease the rate of radiolucent lines and glenoid loosening, we tested a new glenoid with 2 plugs to limit the bone resection required when using keel devices.[1] To improve the anchorage, we decided to undersize the glenoid implant as in the patellar resurfacing used in total knee prostheses. This burying technique has never been described before. We then assessed the efficacy of

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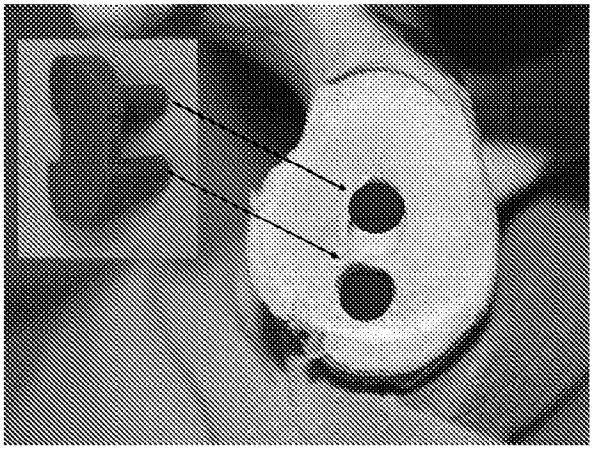


FIGURE 1. Fixation orifices in the glenoid and the glenoid trial implant.

both technical points clinically and analyzed the periglenoid radiolucent lines on plain films taken under videoscopic control.

MATERIALS AND METHODS

Patients

This was a prospective study conducted in a consecutive series of 78 patients receiving a total shoulder arthroplasty between June 1992 and March 2000 performed by the same surgeon (J.C.L.H.). Sixty-four (82%) patients were seen again with a minimum follow-up of 24 months (24–96 months). Because 6 patients received a bilateral shoulder replacement, the study was conducted in 70 cases. Eleven patients (14%) were lost to follow-up, and 3 (4%) died of causes unrelated to the intervention. In 43 cases, there was a primary degenerative pathologic finding, including 6 who received bilateral arthroplasty. Nine patients had rheumatoid polyarthritis, 6 had avascular osteonecrosis, 7 had fracture sequelae, and there were 5 cases of arthritis. In total, the study concerned 70 shoulder prostheses. There were 17 men and 47 women. Mean age at intervention was 66 years (range, 33–80 years). Intervention concerned the right shoulder in 48 cases and the left in 22. The dominant limb was operated in 47 cases.

Preoperative Clinical and Radiologic Work-up

All patients were assessed clinically with a total constant score and an age- and sex-weighted score.[15] Three frontal views were taken: in the neutral position and with external and internal rotation. A lateral view was also taken. On the neutral straight view, we measured the height of the acromiohumeral space. A computed tomographic scan was performed in 39 patients, whereas magnetic resonance imaging was performed in 28. These data allowed us to assess the state of the rotator cuffs (continence, trophicity, and fat degeneration),[16] type of glenoid wear,[17] and the bone remaining on the glenoid side.

Operative Technique

The same Aequalis total shoulder device (Tornier, St-Ismier, France) was used in all patients. All humeral and glenoid implants were cemented. The approach was deltopectoral without disinsertion of the anterior bundle of the deltoid. The rotator cuffs were intact in 61 cases. In 9 cases, the supraspinatus tendon was sutured (5 partial tears and 4 full-thickness ruptures). Twenty-one tenodeses of the long head of the brachial biceps tendon were performed. The glenoid implant was made of high-density polyethylene. It was flat and had 2 cylindrical parallel fixation points situated on the both sides of the center.

The glenoid was prepared with a suitable tool. The bone was planed with drills to adapt the posterior face of the implant to the subchondral bone. The 2 fixation orifices were made with a guided drill (Fig. 1). Several peripheral perforations were then made in the subchondral bone so that the cement would penetrate under the plate of the device. We always used a device smaller than the glenoid bone. A periglenoid bone edge can therefore be used to protect the device, which is buried in the peripheral glenoid bone (Fig. 2). We used the Neer 2-step cementing technique. The bone surface was washed and dried, then liquid cement was pressure-injected into the 2 orifices. Cement was also applied to the posterior surface of the implant before insertion.

Postoperative Clinical and Radiographic Evaluation

Evaluation was performed by an independent specialist (F.P.). All patients were examined and received a constant score. Postoperative radiographic assessment was

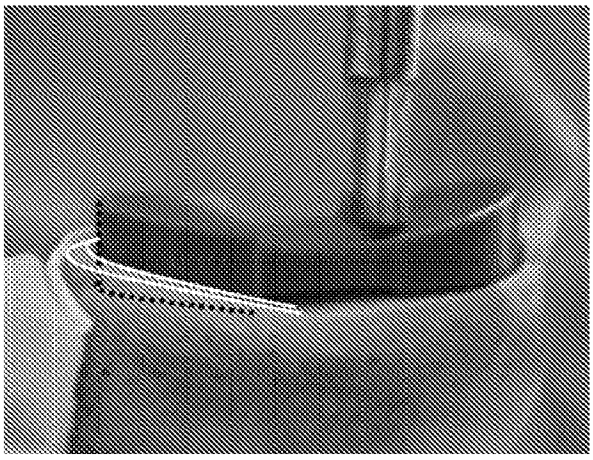


FIGURE 2. Periglenoid bone edge used to protect the glenoid implant.

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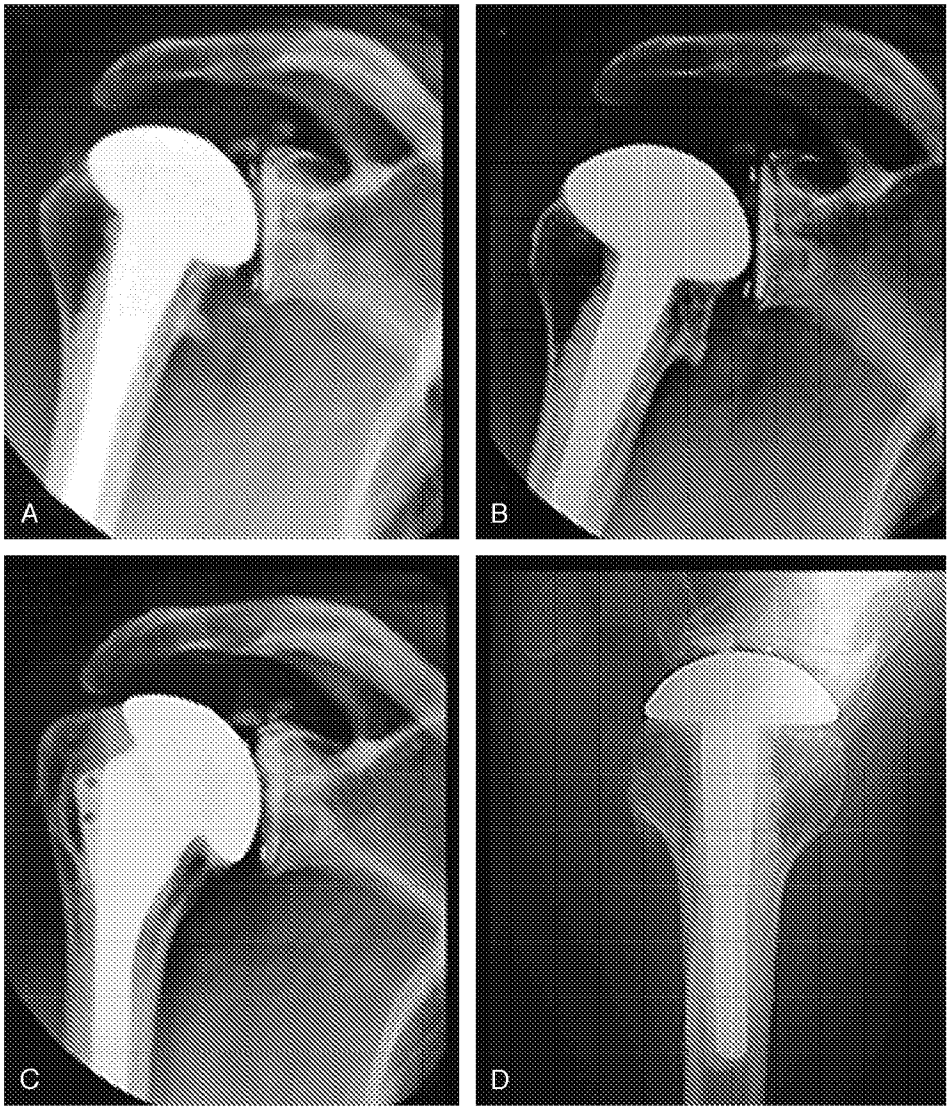


FIGURE 3. Postoperative x-rays of the prosthesis. A, Neutral rotation; B, internal rotation; C, external rotation; D, Bernageau lateral view.

performed using plane x-rays of the shoulder in neutral, internal, and external rotation, and in a modified axillary profile using Bernageau technique (Fig. 3). Digital views were obtained on the same table. Radioscopy was always used to obtain clear views of the bone-cement-device interface. Radiographic follow-up was performed postoperatively, at 3 and 6 months, then yearly. The following parameters were assessed: acromiohumeral space and height of implant with regard to glenoid bone. We also assessed the centering of the device by AP and lateral views and noted whether it was in the center, dislocated, or subluxated. Periglenoid radiolucent lines were analyzed with the following criteria: thickness (<1, between 1 and 2, and >2 mm), distribution per area (including 5 areas on the frontal view and 3 on the lateral view), extension (complete or incomplete), and evolution between the last 2 assessments at 12 months' interval (Fig. 4).

Statistical Methods

All data were put in an Excel (Microsoft Office SR-1 Premium-USA; Redmond, Wash) spreadsheet and analyzed with STATA (version 6.0; STATA Corp, College Station, Tex). Quantitative variables were analyzed as follows. The Student *t* test was used whenever there was a normal distribution between 2 groups. Otherwise, the Mann-Whitney nonparametric test was used. For 3 groups or more, an analysis of variance was performed for normal distribution and equal variance. Otherwise, the Kruskall-Wallis nonparametric test was used. To determine the correlation between 2 quantitative variables,

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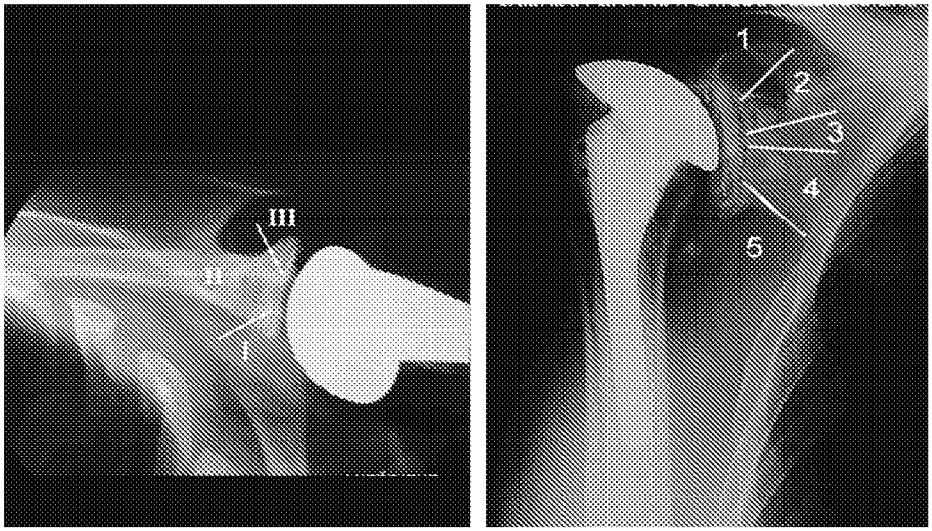


FIGURE 4. Analysis of the glenoid radiolucent line according to the different areas on the AP and Bernageau views: 5 areas on the AP view, 3 areas on the lateral (Bernageau) view.

the correlation coefficient was calculated and tested at zero. A simple linear regression model was also used. Qualitative variables were compared with the χ^2 test for groups exceeding 5 subjects. Otherwise, Fisher exact test was used.

RESULTS

Sixty-four patients were examined with a mean follow-up of 42 months (range, 24–96 months).

Clinical Results

Mean postoperative pain was rated 12.4 points (range, 5–15 points). The difference compared with preoperative pain (2.9 points) was significant ($P < 0.001$). That is a gain of 9.5 points. Active joint range of motion with anterior elevation and external rotation of the elbow was significantly improved, with gains of 41 and 28 degrees, respectively. Mean gain with internal rotation was 4 points. Total and weighted postoperative constant score were 64.1% (range, 31–84%) and 88%, with a gain of 34.9 points and 49% ($P < 0.0001$).

Radiographic Data

Mean preoperative and postoperative acromiohumeral space was 9.3 (±3.8) and 9.6 mm (±4.3). On the AP view, slight superior shift of the device occurred in 37%, and on the lateral view, 81.4 % were correctly centered. In fact, 84% were correctly centered, and 16% were too inferior. In the latter, there were 8 (73%) cases of superior subluxation of the device in which the mean acromiohumeral space was 9.7 mm due to the device being too inferior. Clear periglenoid radiolucent lines were present immediately postoperatively in

TABLE 1. *Distribution of the Glenoid Radiolucent Lines on the AP View, Evolutivity, and Sclerotic Radiolucent Line on the AP View*

Radiolucent Line	*n*	*%*	*Evolutivity, n (%)*	*Sclerotic radiolucent line*
Absent	7	10		
<1 mm				
Incomplete	14	20	7 (50)	1
Complete	17	24.4	1 (5.8)	1
1–2 mm				
Incomplete	12	17.2	1 (8.3)	1
Complete	1	1.4		1
>2 mm				
Incomplete	16	22.8	7 (43.7)	4
Complete	2	2.8	1 (50)	
Migration of implant	1	1.4		
Total series	70		17 (27)	8

TABLE 2. *Distribution of the Glenoid Radiolucent Lines on the Lateral (Bernageau) View*

Radiolucent Line	*n*	*%*
Absent	20	28.5
<1 mm		
Incomplete	16	22.9
Complete	23	32.8
1–2 mm		
Incomplete	5	7.3
Complete	2	2.8
>2 mm		
Incomplete	3	4.3
Complete	0	0
Migration of implant	1	1.4
Total series	70	100

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TABLE 3. *Distribution of the Glenoid Radiolucent Lines on the AP and Lateral View According to the Different Areas at Latest Follow-up (Mean, 42 mo)*

Areas/Radiolucent Lines	<1 mm	1–2 mm	>2 mm
AP view			
1	45	11	4
2	38	12	10
3	46	9	5
4	31	16	13
5	37	9	14
Lateral			
I	33	3	1
II	25	5	1
III	33	5	1

39 cases (56%). In 11, the radiolucent line was complete and measured less than 1 mm while it was incomplete and also measured less than 1 mm in 28. At the latest follow-up, 90% of the devices had a radiolucent line (Tables 1 and 2). We considered radiolucent lines to be evolving whenever they shifted 1 radiographic zone in a 12-month period. There were 17 such cases (27%). In 2 cases, the radiolucent line was complete, nonevolving, and measured greater than 2 mm (Fig. 4). In 1 patient with a history of recurrent luxation, the device had migrated to a subacromial position. In several cases, the radiolucent lines had evolved for 24 months and then become stable. At 42 months, 28% of patients showed evidence of laxity, corresponding to 17 evolving radiolucent lines, 2 complete radiolucent lines, and 1 case of migration. Zones 4 and 5 were the most frequently involved when the radiolucent lines measured greater than 2 mm (Table 3).

DISCUSSION

These findings confirm previous clinical results obtained with modular devices.[6] At 41 months' follow-up, Gartsman et al[18] found a 47-degree gain in active anterior elevation and a 39-degree gain in external rotation, whereas Fenlin et al[19] reported a gain of 4 vertebral levels in active internal rotation at 54 months. In the present study, we found gains of 41 and 28 degrees and 4 vertebral levels for these parameters, respectively.

Because there is no standardized radiological method for analyzing radiolucent lines, their assessment is difficult.[8,7,20] In an in vitro study, Havig et al[9] showed that radiolucent lines cannot be precisely analyzed unless the view is taken 10 degrees of angulation in relation to the neutral position, so they recommend using fluororadioscopy. The frequency of radiolucent lines in our series is comparable to that found by O'Driscoll et al[6] with 90% and 91.3% at 42 and 49 months, respectively. The latter author group is the only one other than us to have used a standardized radiological method for analyzing radiolucent lines.

Apprehension concerning the outcome of shoulder replacements is legitimate in view of the increase in laxity with time (Table 4). Radiographic signs of laxity are as follows: a complete or evolving radiolucent line greater than 2 mm and migration of the implant or cement fracturing.[3,21,22] The rate of laxity at 42 months was 10% and 15 % in the studies by Barrett et al[3] and Boileau et al,[23] respectively, and was 30.9% at 49 months in the study by O'Driscoll et al.[6] We found 28% laxity at 42 months with a protocol similar to that of O'Driscoll et al.[6]

Long-term radiological findings demonstrate a higher level of laxity, Sneppen et al[22] reporting 40% at 7.8 years and Torchia et al[24] reporting 44% at 12.2 years. However, the rate of revision surgery remains low and was 6%, 5%, 7%, and 5.6% in the series of Barrett et al,[3] Boileau et al,[23] Sneppen et al,[22] and Torchia,[24] respectively. We performed 1 revision for a case of glenoid migration. Torchia et al[24] assessed the probability that the implant would still be functional as being 93% at 10 years and 87% after 15

TABLE 4. *Review of the Literature: Glenoid Radiolucent Lines After Cemented Glenohumeral Prostheses (Neer Modular Device; Gartsman et al[18] [60])*

Series	No. cases	Follow-up (yr)	Radiological Radiolucent Lines, n (%)		Clinical Loosening: Revision, n (%)
Neer et al[1] (170)	194	3.1	59 (30)	0	0
Cofield[2] (114)	73	3.8	60 (82)	8 (11%)	3 (4)
Barrett et al[3] (108)	50	3.5	37 (74)	5 (10)	3 (6)
Figgie et al[8] (105)	50	5	—	18 (36)	0
Brenner (97)	28	5.1	16 (57)	6 (22)	1 (3.6)
Boileau et al[23] (216)	71	3.5	64 (78)	11 (15)	4 (5)
Kelly (182)	36	9.5	24 (67)	9 (25)	2 (5.5)
Sneppen et al[22] (181)	62	7.8	38 (61)	25 (40)	5 (7)
Norris and Lachiewicz[33] (64)	38	5	20 (63)	16 (42)	1 (2.6)
Torchia et al[24] (58)	89	12.2	75 (84)	39 (44)	5 (5.6)
O'Driscoll et al[6] (217)	81	4.1	74 (91.3)	25 (30.9)	3 (3.7)
Gartsman et al[18] (60)	25*	4.2	62 (62)		1 (1)

*Series of 100 prostheses; only 25 glenoids were analyzed.

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years. They found a statistical relation between laxity and sex (more frequent in men), but there was no relation with age of patient, initial cause, or with rotator cuff status. In the series by Cofield,[2] the surgical revision rate increased from 4% to 5.6%, and there was a very significant relation between the onset of pain and radiographic evidence of laxity. We have not yet demonstrated such a relation owing to our shorter follow-up (42 months).

In a prospective multicenter study of 146 shoulder devices with keel (Aequalis), Molé et al[25] used an overall score to rate evolution of radiolucent lines. He found 31% of evolving radiolucent lines at 20 months' follow-up: 9% were considered loose (full radiolucent line >2 mm), and 51% measured less than 2 mm. There was no relation between scores and preoperative, intraoperative, or postoperative status. On the other hand, evolution was correlated with decreased functional score. Like Boyd et al[26] and Sneppen et al,[22] we did not find the same outcome.

Molé et al[25] demonstrated a relation between superior subluxation of the humeral implant on the glenoid implant and the presence of a complete radiolucent line or glenoid laxity. We did not find any relation between superior glenohumeral migration and evolution of the radiolucent line. Sneppen et al[22] reported superior subluxation of the humeral implant on the glenoid implant in 51% of his polyarthritic patients at 7 years and considered it responsible for 40% of glenoid loosening. We did not find any relation between superior subluxation and loosening of the glenoid implant. Moreover, superior subluxation rates are perhaps underestimated in the literature because plain films do not show abnormal kinematics of the prosthesis. The scapulohumeral motion may be highly disturbed.[27]

The latest generation of shoulder implants resembles natural anatomy much more closely than the Neer device because the radius curve is different between the glenoid and the prosthetic humeral head. This difference is a testimony to the nonconformity of a device.[28] According to Severt et al,[29] use of such models should reduce the risk of glenoid loosening by reducing the translation and shear forces transmitted to the glenoid during movement. The off-center constraints are the most harmful to implants. If the cuff is no longer able to act as a shock absorber, there occurs a superior subluxation of the prosthetic humeral head under the action of the deltoid. It then projects upward over the glenoid implant and behaves like a rocking chair, thereby inducing loosening of the glenoid anchoring,[30] as likely attested by our case of migration of the glenoid implant occurring in a patient with recurrent anterior dislocation (Fig. 5).

Greater stability is theoretically obtained by using a device fixed at 2 points to a flat subchondral bone surface. Moreover, the bone stock is spared because there

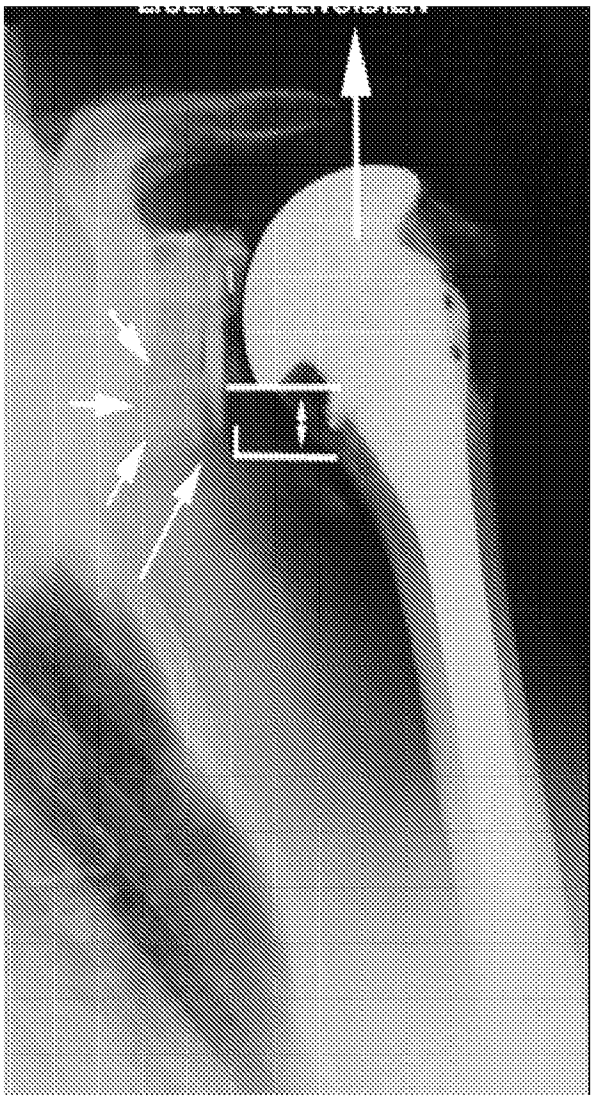


FIGURE 5. Phenomenon of the "rocking chair", explaining the occurrence of a glenoid radiolucent line, according to Matsen and Franklin (106) in the AP view, neutral rotation, superior shifting of the humeral head.

is no central keel. The rocking chair phenomenon is thus limited to the frontal plane[30,31] but does not preclude its occurrence in the sagittal plane because the 2 fixation points are superposed. Our findings are similar to those obtained with devices using a glenoid with keel and a convex base.[4,6,25] However, in case of revision surgery, the preservation of the central bone is an advantage in our series.

The immediate postoperative presence of a radiolucent line is closely related to the manner in which the glenoid was prepared and to the cementing technique. Brems[21] demonstrated the presence of a radiolucent line in the recovery room in 70% of patients, and the defect has been clearly linked to inadequate cementing.[33,34]

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Both Neer and Kirby[35] and Brems[21] reported a higher incidence of radiolucent lines at the beginning of their experience that they attributed to the learning curve required for correct implant positioning. Our cementing technique also seems to require improvement because we found 56% of immediate postoperative radiolucent lines.

CONCLUSIONS

Our functional results obtained using a flat glenoid device with 2 fixation plugs and a burying technique are equivalent to those reported by others using a keel and a convex base. The frequency of radiolucent lines and loosening was 90% and 28%, respectively. Although 56% of patients presented an immediate postoperative radiolucent line due to cementing difficulties, this does not call into question the rationale of this operative technique. The radiolucent lines evolved in 27% of patients so they should be monitored carefully over time. Although no correlation was found between loosening and decreased shoulder function, some patients will likely need revision surgery in the future. Further research involving long-term follow-up is required to assess the value of flat glenoid implants and burying technique.

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PAGE 654
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(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
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PARIS

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(12) DEMANDE DE BREVET D'INVENTION A1

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

(71) **Demandeur(s) :** *SOCIETE DE FABRICATION D'ETUDE ET DE REALISATION D'IMPLANTS - SFERI - (S.A.)* — FR.

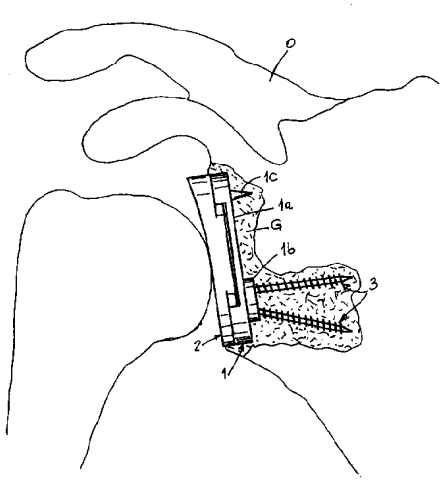
(72) **Inventeur(s) :** Landanger Joël.

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

(74) **Mandataire :** Cabinet Laurent & Charras.

(54) Implant glénoïdien.

(57) L'implant comprend une embase métallique (1) recevant un plateau polyéthylène (2), caractérisé en ce que l'embase (1) est d'épaisseur très réduite et présente, en débordement de sa face de dessous, des agencements (1b) aptes à permettre l'intégration de moyens de fixation (3) coopérant notamment avec le spongieux de la glène.



FR 2 695 313 - A1

Implant glénoïdien.

L'invention concerne plus particulièrement des implants orthopédiques, notamment pour les prothèses d'épaule.

On connaît différentes formes de réalisation de prothèse pour le traitement des épaules détruites. Le problème posé est de pouvoir reproduire la surface anatomique de l'articulation de l'épaule.

Généralement, ces prothèses présentent un élément huméral constitué par une tête sphérique destinée à remplacer la tête de l'humérus. Cette tête, solidaire d'une tige fixée dans le canal médullaire de l'humérus, coopère en appui soit directement avec la glène, lorsqu'elle est en bon état ou bien, avec un implant glénoïdien dans le cas contraire.

L'invention concerne plus particulièrement un implant glénoïdien destiné à être fixé sur la glène de l'omoplate.

Certains types d'implants connus sont constitués par un élément en polyéthylène cimenté au niveau de la glène. Des problèmes de fixation apparaissent.

On connaît également des implants comportant une embase métallique recevant un plateau en polyéthylène.

Cependant, ce type d'implant est très peu utilisé car, compte-tenu de l'articulation à restaurer, l'implant doit être d'épaisseur la plus réduite possible, ce qui, en l'espèce, n'est pas le cas, compte-tenu de la présence de l'embase métallique qui génère une surépaisseur. En effet, l'embase doit être assez épaisse pour permettre l'intégration notamment des têtes de vis de fixation coopérant avec la glène au niveau du spongieux. A titre indicatif, dans les implants connus, l'épaisseur de

l'embase est très sensiblement de l'ordre de 11 à 13 mm.

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 de réduire au minimum l'épaisseur de l'embase métallique.

Pour résoudre un tel problème, il a été conçu et mis au point un implant glénoïdien du type de ceux comprenant une embase métallique recevant un plateau en polyéthylène, remarquable en ce que l'embase est d'épaisseur très réduite et présente en débordement de sa face de dessous, des agencements aptes à permettre l'intégration de moyens de fixation coopérant notamment avec le spongieux de la glène.

Compte-tenu de ces dispositions, il est possible de réaliser un implant dont l'embase peut présenter une épaisseur réduire de l'ordre de 3 à 4 mm.

Le problème posé est avantageusement résolu en ce que les agencements sont constitués par au moins un bossage établi selon l'axe longitudinal de l'embase en étant décalé transversalement pour coopérer avec le spongieux de la glène.

Ce bossage assure une préstabilisation de l'implant glénoïdien par rapport à la glène qui a été usinée en conséquence.

Le bossage présente des évidements pour le logement et l'intégration de têtes de vis, qui constituent les moyens de fixation. Les évidements sont constitués par des trous débouchants évasés et orientés pour faire varier à volonté l'angulation des vis, en fonction du spongieux.

Pour améliorer la stabilisation de l'implant au niveau de la glène, la face de dessous de l'embase présente, selon son axe longitudinal, en alignement avec le bossage, un picot d'ancrage.

L'embase à une forme très sensiblement ovoïde et présente à chacune de ses extrémités arrondies coaxialement opposées, des agencements aptes à assurer la fixation du plateau.

Le problème posé d'assurer la fixation du plateau sur l'embase tibiale est résolu en ce que les agencements sont constitués par des rebords d'appui présentant chacun une nervure de clipsage coopérant avec des formes complémentaires du plateau.

Le plateau présente une surface d'appui profilée dans le plan longitudinal et dans le plan transversal, pour correspondre au mouvement d'articulation de la tête humérale sur la glène.

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 éléments de l'implant selon l'invention.

La figure 2 est une vue en coupe longitudinal de l'implant.

La figure 3 est une vue de dessous de l'implant.

La figure 4 est une vue montrant l'impaction de l'implant au niveau de la glène.

L'implant glénoïdien comprend une embase métallique (1) et un plateau en polyéthylène (2).

D'une manière connue, l'embase est destinée à être fixée sur la glène (G) de l'omoplate (O), tandis que le plateau (2) constitue une surface d'appui et d'articulationn, soit directement à la tête humérale de l'humérus, soit à une tête sphérique que présente un implant huméral.

Selon une caractéristique à la base de l'invention, l'embase (1) est d'épaisseur très réduite. Compte-tenu de cette très faible épaisseur, l'embase (1) présente en débordement de sa face de dessous, des agencements (1b) pour l'intégration de vis (3) en vue de sa fixation au niveau du spongieux de la glène (G).

Comme le montre la figure 1, les agencements sont constitués par au moins un bossage (1b) de forme circulaire. Ce bossage (1b) est établi selon l'axe longitudinal de l'embase (1) en étant décalé transversalement pour faire office d'organe stabilisateur en coopérant avec le spongieux. Ce bossage (1b) présente des évidements débouchants (1b1) pour le logement et l'intégration des têtes de vis (3a). Ces évidements (1b1) sont constitués par des trous évasés et orientés (figure 2), permettant ainsi de diriger angulairement les vis (3) pour leur vissage dans le spongieux (figure 4).

En alignement avec le bossage (1b), la face de dessous de l'embase (1) présente, selon son axe longitudinal, un picot d'ancrage (1c).

L'embase (1) est de forme générale ovoïde et présente à chacune de ses extrémités arrondies et coaxialement opposées, des rebords d'appui (1d-1e). Chacun des rebords présente une nervure (1d1-1e1) pour le clipsage du plateau en polyéthylène (2) au moyen de formes

complémentaires (2a-2b).

D'une manière connue, le plateau (2) présente un profil longitudinal et transversal courbes pour tenir compte du développement de l'articulation de la tête humérale.

Les avantages ressortent bien de la description.

REVENDICATIONS

-1- Implant glénoïdien comprenant une embase métallique (1) recevant un plateau polyéthylène (2), caractérisé en ce que l'embase (1) est d'épaisseur très réduite et présente, en débordement de sa face de dessous, des agencements (1b) aptes à permettre l'intégration de moyens de fixation (3) coopérant notamment avec le spongieux de la glène.

-2- Implant selon la revendication 1, caractérisé en ce que les agencements (1b) sont constitués par au moins un bossage établi selon l'axe longitudinal de l'embase (1) en étant décalé transversalement pour coopérer avec le spongieux de la glène.

-3- Implant selon l'une quelconque des revendications 1 et 2, caractérisé en ce que le bossage (1b) présente des évidements (1b1) pour le logement et l'intégration de têtes de vis (3a), qui constituent les moyens de fixation (3).

-4- Implant selon la revendication 3, caractérisé en ce que les évidements (1b1) sont constitués par des trous débouchants évasés et orientés pour faire varier à volonté l'angulation des vis (3), en fonction du spongieux.

-5- Implant selon la revendication 2, caractérisé en ce que la face de dessous de l'embase (1) présente, selon son axe longitudinal, en alignement avec le bossage, un picot d'ancrage (1c).

-6- Implant selon la revendication 1, caractérisé en ce que l'embase (1) à une forme très sensiblement ovoïde et présente à chacune de ses extrémités arrondies coaxialement opposées, des agencements aptes à assurer la fixation du plateau (2).

-7- Implant selon la revendication 6, caractérisé en ce que les agencements sont constitués par des rebords d'appui (1d-1e) présentant chacun une nervure de clipsage coopérant avec des formes complémentaires du plateau (2).

-8- Implant selon la revendication 1, caractérisé en ce que le plateau (2) présente une surface d'appui profilée dans le plan longitudinal et dans le plan transversal, pour correspondre au mouvement d'articulation de la tête humérale sur la glène.

-9- Implant selon la revendication 2, caractérisé en ce que le bossage (1b) est de forme circulaire.

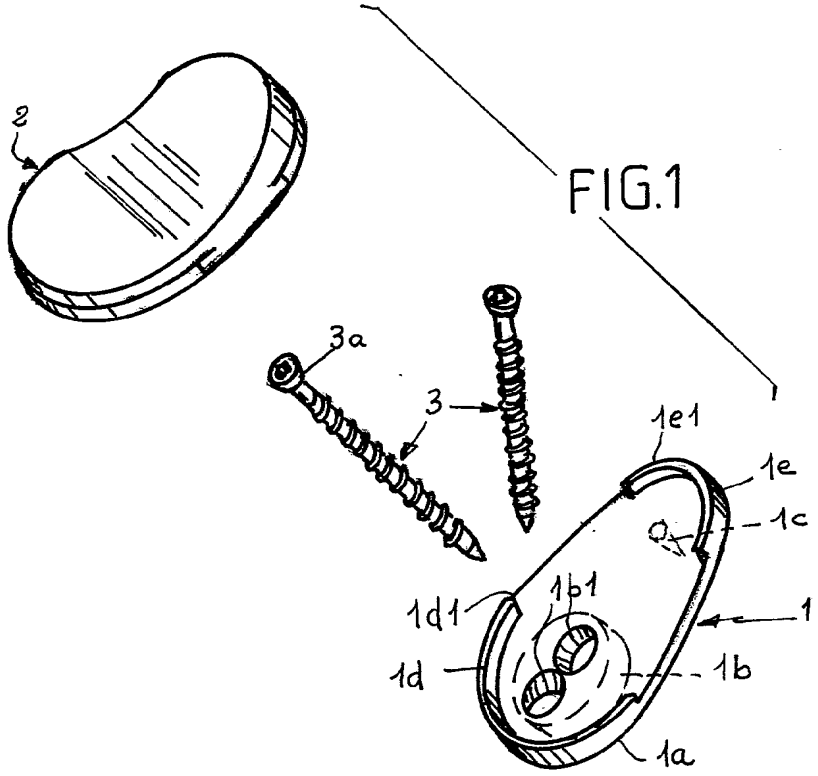

2
3a
3
1e1
1e
1c
1d1
1b1
1
1d
1b
1a

FIG.1

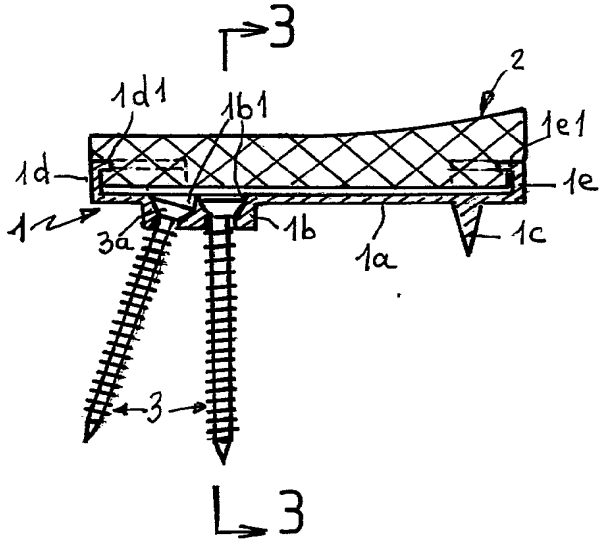

3
1d1
1b1
2
1e1
1d
1e
1
3a
1b
1a
1c
3
3

FIG.2

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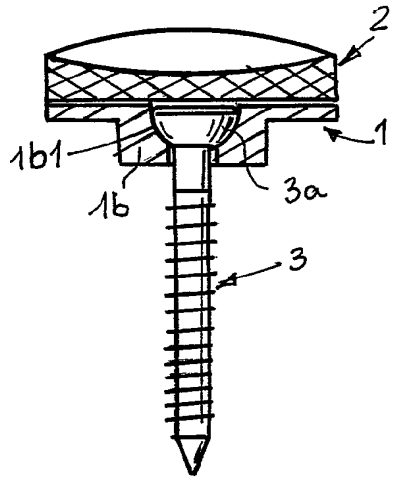


FIG.3

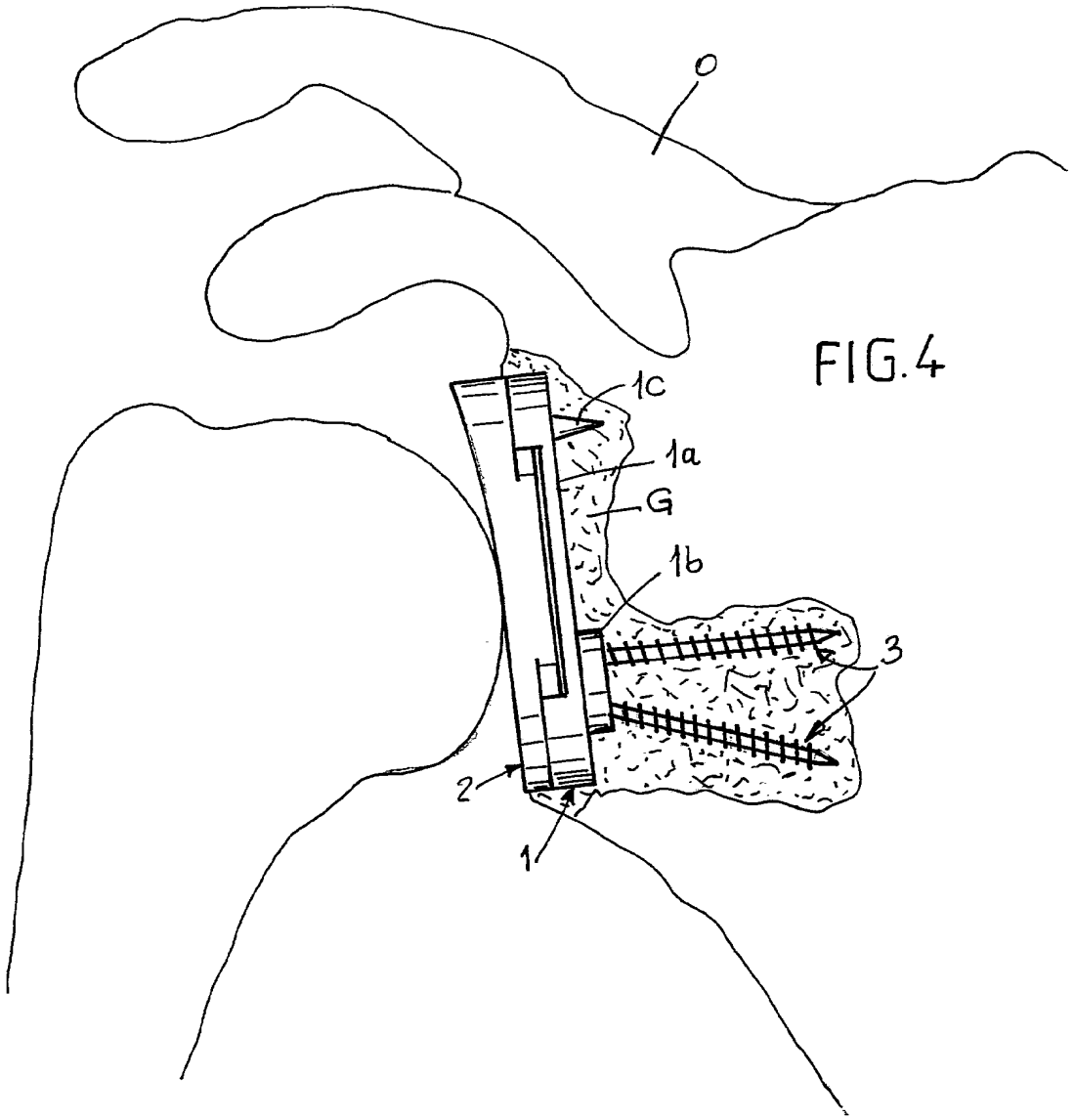


FIG.4

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RAPPORT DE RECHERCHE

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

2695313
N° d'enregistrement national

FR 9211000
FA 475619

DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	Revendications concernées de la demande examinée
X	US-A-4 964 865 (BURKHEAD ET AL.) * colonne 7, ligne 15 - ligne 26 * * colonne 7, ligne 57 - ligne 59 * * colonne 8, ligne 58 - ligne 62; figures 1,10,12,16-19 *	1,2,5,8, 9
Y	---	3,4,6,7
Y	US-A-4 808 185 (PENENBERG ET AL.) * colonne 6, ligne 42 - ligne 50 * * colonne 8, ligne 14 - ligne 16; figures 4,7,8 *	3,4
Y	---	6,7
	FR-A-2 653 992 (BERAKASSA ET AL.) * page 7, ligne 10 * * page 7, ligne 25 - ligne 27 * * page 9, ligne 13 - ligne 17; figures 5,6 *	
A		3,4

DOMAINES TECHNIQUES RECHERCHES (Int. Cl.5)

A61F

Date d'achèvement de la recherche	Examinateur
24 MAI 1993	SEDY R.

CATEGORIE DES DOCUMENTS CITES

- X : particulièrement pertinent à lui seul
- Y : particulièrement pertinent en combinaison avec un autre document de la même catégorie
- A : pertinent à l'encontre d'au moins une revendication ou arrière-plan technologique général
- O : divulgation non-écrite
- P : document intercalaire
- T : théorie ou principe à la base de l'invention
- E : document de brevet bénéficiant d'une date antérieure à la date de dépôt et qui n'a été publié qu'à cette date de dépôt ou qu'à une date postérieure.
- D : cité dans la demande
- L : cité pour d'autres raisons

& : membre de la même famille, document correspondant

1

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(71) Applicant and
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(74) Agent: **CLARK, Paul, T.**; CLARK & ELBING LLP, 101 Federal Street, Boston, Massachusetts 02110 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: 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.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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).

Published:
— *with international search report*

(88) Date of publication of the international search report:
9 April 2009

(15) Information about Correction:
Previous Correction:
see Notice of 1 November 2007

(54) Title: SHOULDER IMPLANT FOR GLENOID REPLACEMENT AND METHODS OF USE THEREOF

FIG. 2A

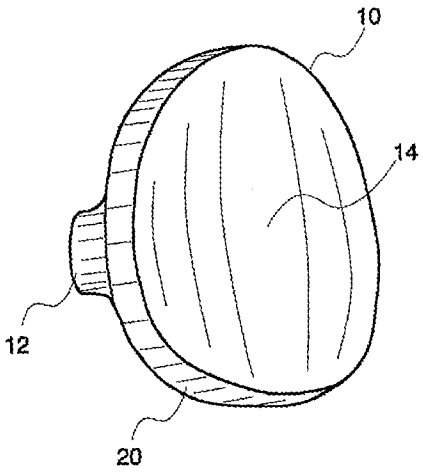
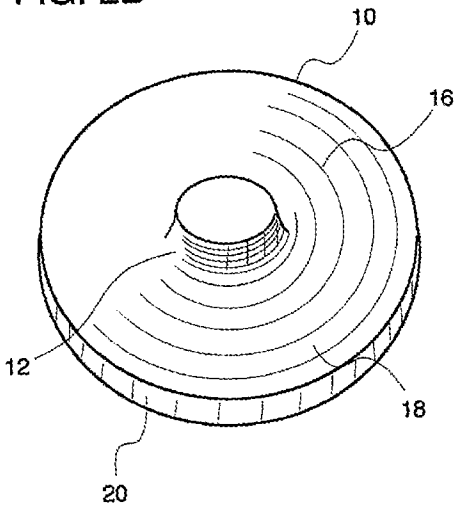


FIG. 2B



(57) Abstract: The invention features a glenoid (shoulder socket) implant prosthesis, a humeral implant prosthesis, devices for implanting glenoid and humeral implant prostheses, and methods of their use for the treatment an injured or damaged shoulder.

WO 2006/093763 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 06/06330

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 5/00; A61B 17/00; A61F 2/40 (2007.10)
USPC - 623/19.13; 606/80; 606/87
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)
IPC8 : A61F 5/00; A61B 17/00; A61F 2/40 (2007.10)
USPC : 623/19.13, 606/80, 606/87

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC8 : A61F 2/30; A61B 17/56 (2007.10)
USPC : 623/16.11, 623/18.11, 623/19.11, 623/19.14;

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,EPAB,JPAB), Google Scholar
Search terms : surround, circumference, concave, convex, peg, stem, fin, humerus, shoulder, set, deep, depth, cortical, inset, inlaid, inlay, recess, glenoid

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2004/0220674 A1 (PRIA) 4 November 2004 (04.11.2004) see especially para [0024], [0028] -[0031], fig 1	1-7 --- 14-24
Y	US 4,865,605 A (DINES et al) 12 September 1989 (12.09.1989) see especially col 2, ln 8-34	8-11 and 16-24
Y	US 5,282,865 A (DONG) 1 February 1994 (01.02.1994) see especially col 3, ln 5-15	8-11 and 16-24
Y	US 2005/0043805 A1 (CHUDNIK) 24 February 2005 (24.02.2005) see especially para [0013]-[0022], [0101], [0107]	14-24

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"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
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Date of the actual completion of the international search	Date of mailing of the international search report
20 November 2007 (20.11.2007)	24 JAN 2008
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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 06/06330

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-11 and 14-24 are directed to a glenoid and humeral implant for the shoulder.
Group II: claims 12-13 and 25-32 are directed to a surgical drill for use in shoulder implants.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

Group II does not include the inventive concept of a glenoid and humeral implant of Group I.
Group I does not include the inventive concept of a surgical drill of Group II.

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

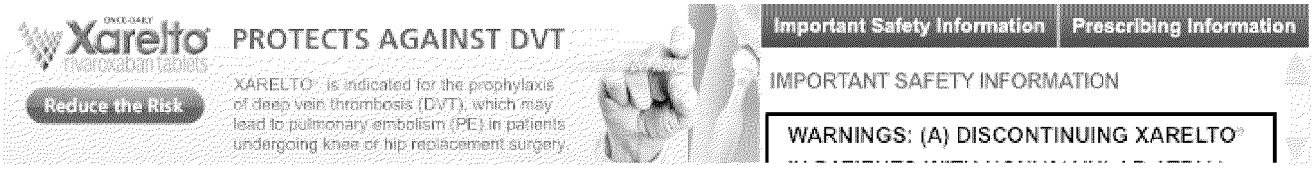
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-11, 14-24

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.



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Modular Short-stem Prosthesis in Total Hip Arthroplasty: Implant Positioning and the Influence of Navigation

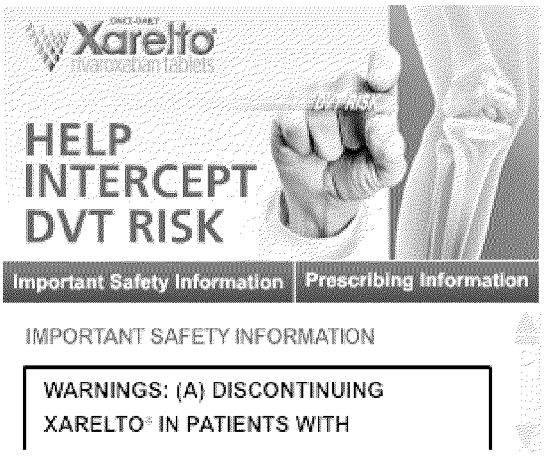
By Arnim Braun, MD; Djordje Lazovic, MD; Rasmus Zigan, MD

Abstract

Successful total hip arthroplasty with the Metha short-stem prosthesis (B. Braun Aesculap; Tuttlingen, Germany) depends on the correct indication and an accurate preoperative measurement of the femoral bone shape. Intraoperatively, bone quality, osteotomy, and implant position are of particular importance. Navigation assists with the selection of modular neck adapters for optimal free range of motion. The selection of adapters differs significantly depending on whether navigation is used during surgery. The positioning of the osteotomy depends on the surgeon's experience and judgment as well as the local anatomical circumstances. The osteotomy can be checked intraoperatively by the positioning of the rasp. Correct positioning of the osteotomy and correct dorsolateral contact of the short stem determine the optimal implant position. Implant depth should be adjusted in relation to the lateral circumference of the femoral neck rather than in relation to the calcar osteotomy. Valgus positioning with loss of the lateral support must be avoided. Use of a double osteotomy and routine radiographic controls make it easy to implant the short-stem prosthesis in this less invasive manner. The use of navigation influences the choice of neck position toward reduced anteversion compared with non-navigated selection.

Short hip stem implants are designed for cementless fixation in the proximal femur.[1] A number of these types of implants have been developed recently.[2] The Metha short-stem prosthesis (B. Braun Aesculap; Tuttlingen, Germany) has a modular neck[3] and is suitable for navigated implantation.[4]

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A correct indication is a prerequisite for successful implantation of a short-stem prosthesis. In particular, the quality and shape of the bone must be considered. The use of kinematic navigation technology supports the selection of modular implant components to optimize joint reconstruction and range of motion (ROM).

This article describes the indications and contraindications for the Metha modular short-stem prosthesis (Figure 1) as well as the implantation procedure with a focus on the optimal alignment of the femoral osteotomy and the benefit of navigation for the selection of modular implant components.

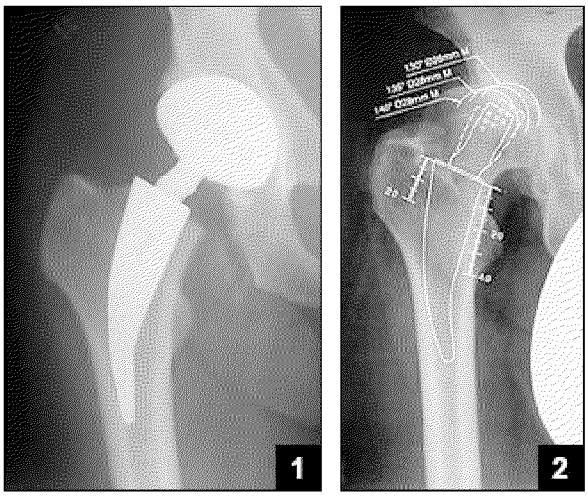


Figure 1: Postoperative radiograph shows optimal Metha stem implant placement in a 54-year-old man. Figure 2: Preoperative radiograph showing dysplasia with coxa valga and a short, wide femoral neck in a 51-year-old man. In this patient, the Metha stem could only be placed in an extreme valgus position, causing the tip of the prosthesis to move in a medial direction. Although use of the Metha prosthesis may be possible in such a case, implanting the Metha prosthesis in an extreme valgus position is not recommended.

Preoperative Planning

Short-stem prostheses can be implanted using a minimally invasive technique and are particularly useful in younger, active patients. Short-stem prostheses also may be useful in older patients who are interested in a less invasive procedure. However, patients must meet the necessary criteria in terms of soft tissue and body mass index (BMI), and both bone quality and bone shape must be suitable for a short-stem prosthesis. Poor bone quality or bone shapes that are not amenable to a proximal fixation of the implant are contraindications for a short-stem prosthesis in patients of all ages.

Unsuitable bone shapes include dysplastic coxarthrosis with extreme coxa valga (Figure 2) or a short, wide femoral neck and coxa vara (Figure 3). Severe antetorsion of the femoral neck also may lead to problems during implantation (Figure 4), even with a short-stem implant if the lateral radiograph projection is not considered preoperatively.

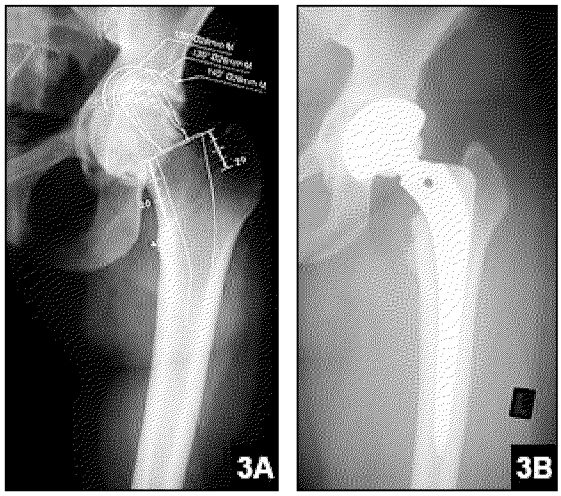


Figure 3: Preoperative radiograph showing protrusion coxarthrosis in a 44-year-old woman with coxa vara (A). Implantation of a Metha prosthesis was not possible without lengthening the leg. Postoperative radiograph shows a straight stem was used instead with a low osteotomy and correctly adapted leg length (B).

A wide femoral neck (Figure 2) is a special condition to be aware of during preoperative planning, particularly when there are additional uncertainties regarding the osteotomy or the correct implant size. In such cases, an undersized implant would lead to reduced stability.

Therefore, the planning template is important in the preoperative phase. We prefer a standard prosthesis whenever a complicated reconstruction of the acetabulum is necessary because the higher osteotomy needed for the short-stem prosthesis may obstruct access to the acetabulum.

We inform our patients that our experience with the newly introduced short-stem prosthesis is still limited and that medium- and long-term results are not available. We also respect a patient's wish to be treated with an established standard cementless implant.

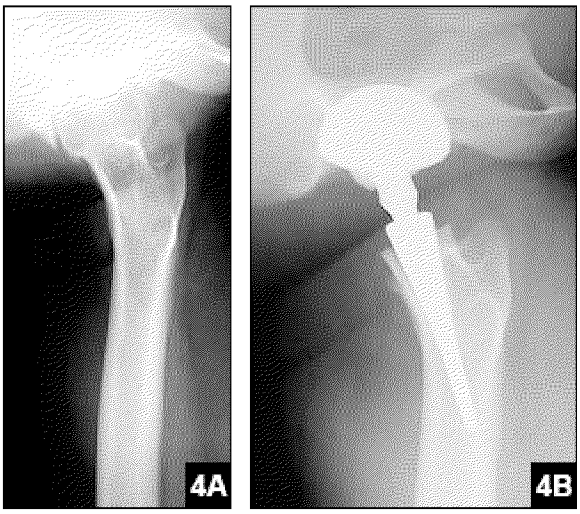


Figure 4: Preoperative radiographs showing obvious antetorsion of the femoral neck (A). Postoperative radiographs showing the tip of the Metha stem contacts the dorsolateral cortex (B).

Intraoperative Management

For implanting the Metha short-stem prosthesis, the anterolateral approach as described by Watson-Jones[5] is particularly suitable because the muscles can be preserved. This approach is suitable with both navigated and non-navigated procedures.

As opposed to the implantation of straight stems, it is possible to drape both legs for the implantation of a short-stem prosthesis (Figure 5A), which allows the operative leg to be positioned under the contralateral leg in a “figure of four” configuration. This position aids in evaluating leg length. Because of the extreme external rotation in this position, the femoral neck will turn into the muscle compartment between the tensor fascia lata and the gluteus medius.

The navigation procedure with the OrthoPilot system (B. Braun Aesculap; Tuttlingen, Germany) supports cup and stem implantation, and allows a dedicated selection of modular neck adapters to optimize free ROM after manual implantation of the modular Metha stem. However, the femoral osteotomy and preparation with rasps is not supported by the navigation technology.

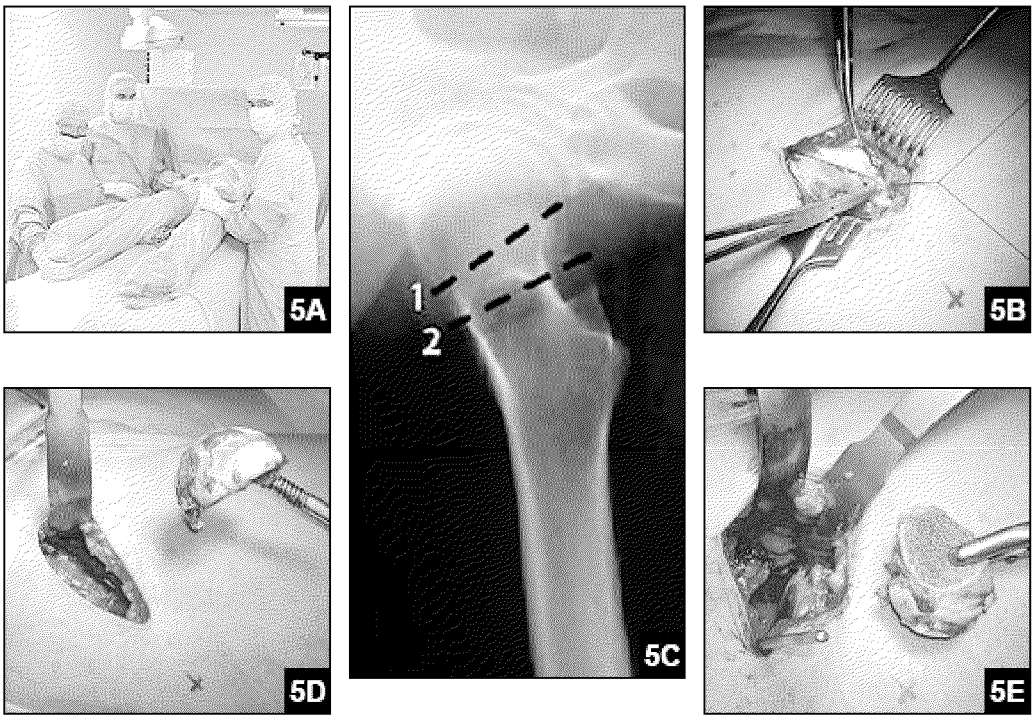


Figure 5: Photographs showing leg position (A) and operative approach (B). Radiograph showing alignment of the two osteotomies for implanting a short-stem prosthesis (nonnavigated procedure) (C). First osteotomy: removal of femoral head (D). Second osteotomy, removal of femoral neck (E).

Implantation Technique (Non-navigated)

A 7- to 9-cm incision is made in the central third between the anterosuperior iliac spine and the greater trochanter. The incision can easily be moved in a distal or proximal direction.

The incision in the fascia is basically analogous to the skin cut. If necessary, a transverse blood vessel on the anterior margin of the gluteus medius muscle can be tied (Figure 5B). After the capsule is located and the femoral head is palpated, three Hohmann retractors are placed and the capsule is almost completely removed.

For optimal positioning of the final osteotomy, it is helpful to perform two consecutive osteotomies (Figures 5C-E). The first subcapital osteotomy (Figure 5C, line 1) is performed in situ. The femoral head is removed either immediately or after the second osteotomy.

The second osteotomy (Figure 5C, line 2) is performed with the leg slightly rotated and adducted externally. The exact position of this line depends on the planned implantation depth of the stem. This second osteotomy should be slightly trapezoid in shape, with the removed

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bone thicker in the back than in the front. This reduces the danger of increased antetorsion of the prosthesis and makes it easier to introduce the rasps.

One important requirement for the osteotomy is that it should be closed on the lateral neck. In addition, there must be a sufficiently strong bone lamella.

After cup implantation, the leg is positioned under the contralateral leg in a “figure of four” configuration, which places the femoral neck in the optimal direction for femoral rasp preparation and stem implantation. A special Hohmann retractor supports the greater trochanter and another holds the femur to the lateral side. The femur is then opened with a small, blunt awl, which is placed in a neutral position on the osteotomy (Figure 6A). There should be no antetorsion.

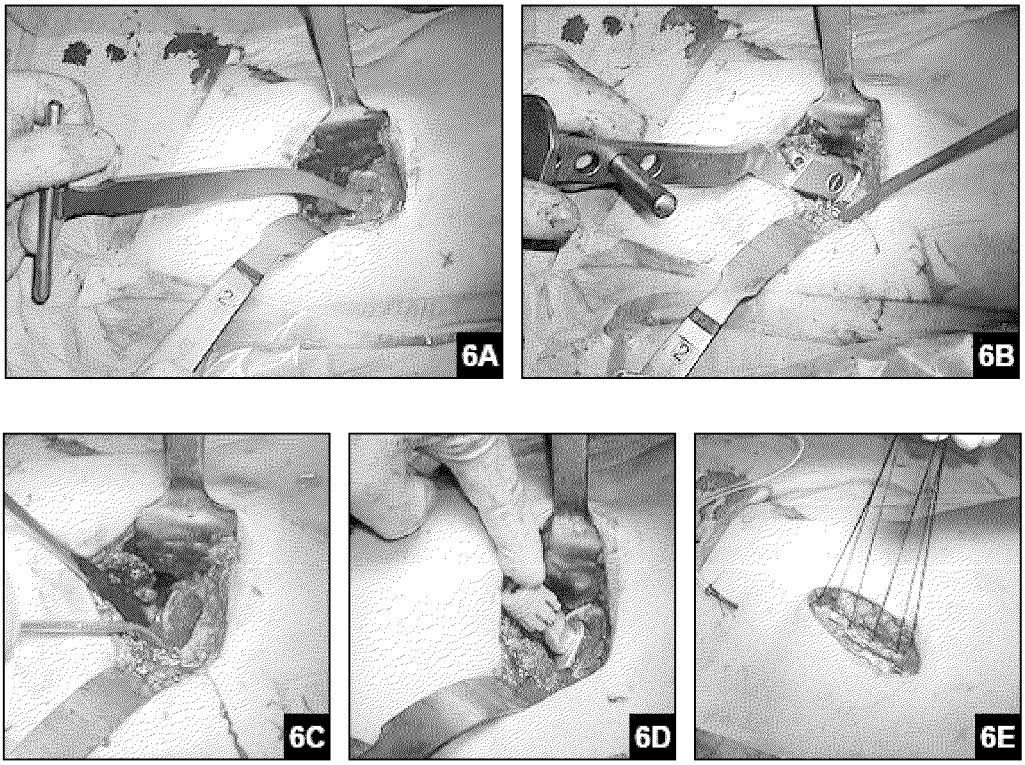


Figure 6: Photographs demonstrating implantation of the short-stem prosthesis (nonnavigated procedure). Opening of the medullary cavity (A). Femur preparation using a forming rasp (B). Preserved ring of cortex around the neck of the femur (C). Inserting the stem (D). Closure (E).

The awl is pressed into the bone marrow space by hand by slightly rotating the handle. This instrument is not designed to be used in combination with a hammer; the use of the hammer in the beginning of the procedure is sometimes helpful, but not once the awl has clearly penetrated the osteotomy plane.

The awl should make contact with the lateral cortex. This is easily achieved and can be checked again when the awl is removed. One also can introduce the same awl again, thus getting a good feeling for the direction of implantation. If necessary, a second awl with twice the width can be used. This compresses the bone and offers a guide for the subsequent use of the rasps.

When using rasps of increasing size, a slight varus pressure may help to control the tendency of the instruments toward valgus. Even with the first rasp, the alignment of the osteotomy can be checked again (Figure 6B). In cases in which further resection is needed, the lateral part of the osteotomy should never be removed (Figure 6C). Proper preparation of the lateral femoral neck is necessary for assessment. The short-stem prosthesis is best implanted with a flat osteotomy (Figure 7A). A steep osteotomy can result in poor medial bone support (Figure 7B). However, if a too-low calcar osteotomy is used for orientation when implanting the stem, the stem also may placed too low, with no lateral support and a tendency to valgus (Figure 7C).

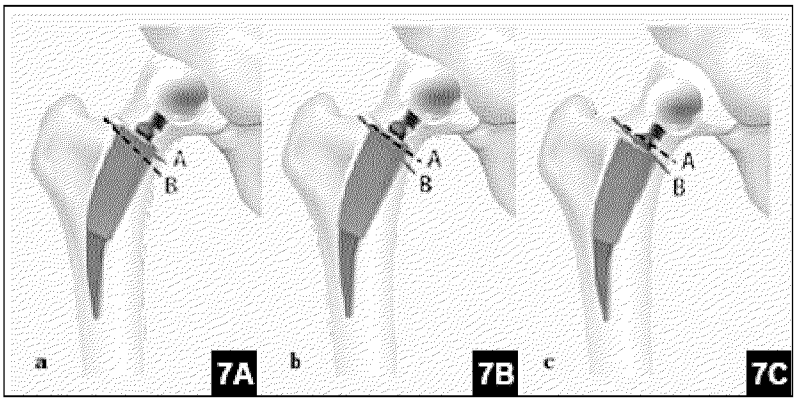


Figure 7: Drawings showing a correct osteotomy and ideal positioning of the stem (A), a steeply angled osteotomy (B) with the stem in the ideal position, and a steeply angled osteotomy with the stem positioned too deep (C).

During the rasping process and implantation, stem placement can easily divert from a 50° osteotomy. In addition, the shape of the bone may cause more valgus positioning of the implant. Therefore, as a rule, we exclude extreme cases of dysplastic osteoarthritis from short-stem THA.

Generally, curved short-stem rasps react differently than straight rasps. With increasing rasp size, valgus positioning may occur because the tip of the stem is guided along the dorsolateral inner side of the cortex and may shift with increasing size. Therefore, care should be taken not to lateralize the rasp during insertion.

During the rasping process, the body of the rasp should never be inserted lower than the level of the osteotomy, which would promote valgus positioning of the rasp as well. Under load, the stem could then sink below the level of the lateral resection. To avoid this problem, several extra millimeters should be left during rasping (Figure 6D). A routine check by fluoroscopy is recommended for rasp position with a trial head in situ.

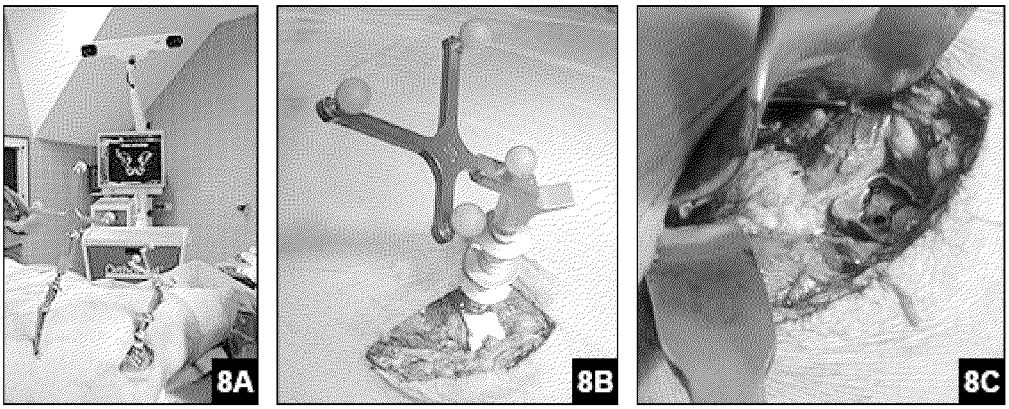


Figure 8: Photographs showing set-up for the navigated implantation of the short-stem prosthesis. OrthoPilot set up with rigid bodies (A), femoral sensor (B), c-clamp fixed to the greater trochanter (C).

Navigated Implantation

For navigated implantation of the Metha short-stem prosthesis (Figure 8A), the femoral sensor (Figure 8B) can be removed (Figure 8C) and reattached on a femoral c-clamp that is firmly fixed to the greater trochanter. Trial repositioning with appropriate modular cone adapters easily allows for corrections, such as a relative antetorsion or retrotorsion of the implanted stem. This process is supported by the navigation system.

A lower centre-collum-diaphysis angle results in an effective offset increase without lengthening the leg. This is why the Metha short-stem prosthesis has some limitations in treating pronounced varus deformities.

The choice of modular trial adapters and trial head leads to an improved free ROM. The Table compares navigated and non-navigated selection of the modular neck adapter (Table and Figure 8).

The use of navigation influences the choice of neck position toward reduced anteversion. However, it should be noted the retroverted modular Metha adapters do not lead to an absolutely retroverted neck position; instead, they reduce the amount of anteversion relative to a given implant position.

Table

Distribution of Modular Adapters in Manual and Navigated Selection

	Modular Adapter Chosen (%)			
	140°	135°	130°	Total
Manual selection				
-7.5° retroversion	0	26	19	45
Neutral position	3	26	26	55
7.5° anteversion	0	0	0	0
Total	3	52	45	100
Navigated selection				
-7.5° retroversion	18	19	27	64
Neutral position	4	11	8	23
7.5° anteversion	0	10	3	13
Total	22	40	38	100

Conclusion

Successful use of a short-stem hip prosthesis such as the Metha implant depends on the correct preoperative indication and bone shape. Intraoperatively, bone quality is of particular importance, and the osteotomy is dependent on the surgeon's experience as well as the patient's anatomy. Implant depth should never be adjusted in relation to the femoral osteotomy but rather in relation to the lateral cortex of the femoral neck. A valgus position with loss of the lateral cortical support must be avoided under all circumstances. Navigation supports the exact reconstruction of leg length, femoral offset, and ROM by improved selection of modular neck adapters.

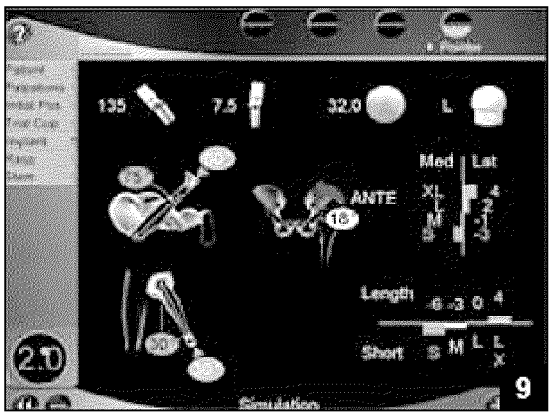


Figure 9: Screen display of the OrthoPilot shows navigated selection of modular Metha neck adapters.

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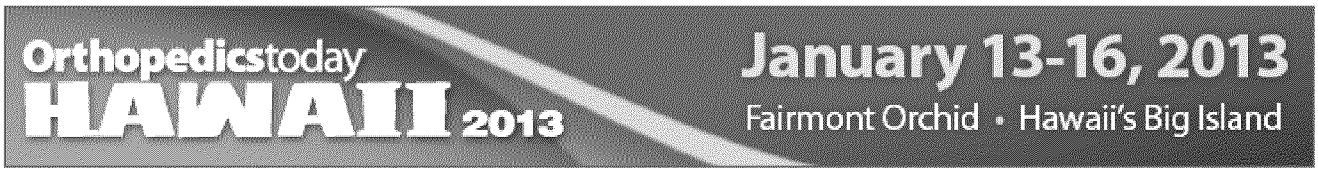
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Drs Braun is a member of the B. Braun Aesculap speaker's bureau. Dr Lazovic is a consultant for B. Braun Aesculap. Dr Zigan has not provided financial disclosure information.



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Espacenet

DE4220217A1 Endoprosthesis for shoulder joint head replacement - has metal cap, whose inner surface has open cell or pore structure and has conical shaft tapering towards full end and forming sleeve

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Classifications:

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CPC **A61F2/30907 (EP); A61F2/4003 (EP);** A61F2/30749 (EP); A61F2/3603 (EP); A61F2002/30011 (EP); A61F2002/3021 (EP); A61F2002/30878 (EP); A61F2002/3092 (EP); A61F2002/4007 (EP); A61F2220/0008 (EP); A61F2230/0067 (EP); A61F2250/0023 (EP); A61F2310/00011 (EP); A61F2310/00395 (EP);

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Endoprosthesis for shoulder joint head replacement - has metal cap, whose inner surface has open cell or pore structure and has conical shaft tapering towards full end and forming sleeve

Abstract

The metal cap (2) has a rotation symmetrical outer, dished surface, while its inner surface (10, 12) has a structure (16) with open cells on faces. Inside (8) of the cap is pref. formed a central shaft (14) conically tapering towards its full end, forming a sleeve. The shaft is also formed of an open cell or porous metal structure. Alternately it may have a solid metal core and an open cell or pore surface structure. It typically protrudes from the cap inside by a first length. The cap inner surface has a specified configuration. ADVANTAGE - Improved anchorage in adjacent bone tissue.

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(54) Endoprothese

(57) Es wird eine Endoprothese aus Metall, insbesondere zum Ersatz des Schultergelenkkopfes angegeben, die eine Kappe mit einer rotationssymmetrischen, kalottenförmigen Außenfläche aufweist. Um die Verankerung der Endoprothese im Knochengewebe zu verbessern, ist die Innenfläche der Kappe und ggf. der Schaft mit einer offenzelligen oder offenporigen Oberflächenstruktur aus Metall versehen.

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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Beschreibung

Die Erfindung betrifft eine Endoprothese zum Ersatz des Gelenkkopfes eines menschlichen Knochens, insbesondere des Schultergelenkkopfes, mit einer eine rotationssymmetrische, kalottenförmige Außenfläche aufweisenden Kappe aus Metall.

Eine derartige Endoprothese ist beispielsweise aus der DE-OS 30 06 178 bekannt, die einen Teil des Gelenkkopfes des menschlichen Femurknochens ersetzen soll und zur Verankerung einen hülsenförmigen Schaft aufweist, der aus dem Innenraum der Kappe in den Femurhals hineinragt, wobei der Schaft Bohrungen aufweist, durch welche das Knochengewebe hindurchwachsen soll. Durch das vergleichsweise geringe Knochenvolumen, welches im Bereich eines Gelenkkopfes insbesondere in Richtung der Rotationsachse zur Verfügung steht, besteht bei derartigen bekannten Endoprothesen die Gefahr, daß die mechanische, formschlüssige Verankerung nur durch einen Schaft nicht ausreicht, um die Endoprothese auch langzeitig sicher zu verankern.

Aus der DE-PS 39 23 154 ist es bekannt, eine derartige Endoprothese für den Ersatz eines natürlichen Gelenkkopfes so auszubilden, daß der in Rotationsachsenrichtung verlaufende hohle oder massive Schaft zusätzlich noch ein Außengewinde zur verbesserten Verankerung trägt.

Aufgabe der Erfindung ist es, eine Endoprothese der eingangs genannten Art derart weiterzubilden, daß eine verbesserte Verankerung der Endoprothese im angrenzenden Knochengewebe erzielt wird.

Diese Aufgabe wird bei der Endoprothese der eingangs genannten Art erfindungsgemäß dadurch gelöst, daß die Innenfläche der Kappe eine offenzellige oder offenporige Oberflächenstruktur aufweist.

Die Vorteile der Erfindung liegen insbesondere darin, daß die dem natürlichen Knochengewebe zugewandte Innenfläche der Kappe eine offenzellige oder offenporige Oberflächenstruktur aufweist, in welche das angrenzende Knochengewebe einwachsen kann. Dadurch wird ein großflächiger Formschlußverbund auf der gesamten Kontaktfläche zwischen Knochen und der Innenfläche der Prothese verwirklicht. Die erfindungsgemäßen Merkmale ermöglichen es insbesondere auch, die Endoprothese für den Ersatz des Schultergelenkkopfes vorzusehen, wo für die Verankerung — aufgrund der dort vorliegenden natürlichen Gegebenheiten — ein besonders geringes Knochenvolumen vorliegt. Besonders bevorzugt ist im Innenraum der Kappe zentral ein Schaft angeordnet, der bevorzugt als Kegelabschnitt ausgebildet ist, der sich zu seinem freien Ende hin verjüngt. Alternativ läßt sich der Schaft auch als Hülse ausbilden, in welche — ggfs. auch durch Hülsenbohrungen hindurch — Knochengewebe einwachsen kann, um auf diese Weise die Verankerung von Knochengewebe und Prothese weiter zu verbessern.

Gemäß einer besonders bevorzugten Ausführungsform der Erfindung ist der Schaft durchgängig aus offenporigem oder offenzelligem Material ausgebildet, so daß das gesamte Schaftvolumen formschlüssig mit Knochengewebe durchsetzt und auf diese Weise die Verankerung noch verbessert werden kann.

Alternativ läßt sich der Schaft auch mit einem massiven metallischen Kern versehen, die offenporige Oberflächenstruktur umgibt dann den Schaftkern in einer vorgegebenen Dicke.

Besonders bevorzugt ragt der Schaft eine vorgegebene Länge aus dem Innenraum der Kappe heraus. Die

Innenfläche der Kappe besitzt bevorzugt vom Kappenrand einen sich nach innen verjüngenden Konusabschnitt und daran anschließend einen Basisabschnitt, der senkrecht zur Rotationsachse verläuft und zentral in den nach außen gerichteten Schaft übergeht. Durch diese Ausgestaltung des Innenraums der Kappe wird eine einfache Resektion der zu entfernenden Knochenteile ermöglicht, weil die verbleibenden, in den Kappenraum hineinragenden Knochenbereiche durch Kegelflächen bzw. eine ebene Basisfläche definierbar sind.

Falls eine vorgegebene Primärstabilität des Implantats unmittelbar nach der Operation gewünscht ist, läßt sich der Schaft und/oder der Konusabschnitt der Kappeninnenfläche mit einem Gewinde versehen.

Vorteilhafte Weiterbildungen der Erfindung sind durch die Merkmale der Unteransprüche gekennzeichnet.

Im folgenden wird ein Ausführungsbeispiel der Erfindung anhand der Zeichnung näher erläutert.

Die Figur zeigt eine Endoprothese 1 aus Metall, die zum Ersatz des Gelenkkopfes eines menschlichen Knochens, insbesondere des Schultergelenkkopfes dient und eine Kappe 2 mit einer rotationssymmetrischen, kalottenförmigen Außenfläche 4 aufweist. Im Innenraum 8 der Kappe 2 sitzt zentrisch ein Schaft 14, der sich in Richtung der Rotationsachse 3 nach außen ein vorgegebenes Maß über den Kappenrand 6 hinauserstreckt und sich dabei konisch verjüngt. Kappe 2 und Schaft 14 bestehen aus Metall, der Schaft 14 besitzt einen Kern aus massivem Material.

Die Innenfläche 10, 12 der Kappe 2 und der Schaft 14 besitzen an ihrer Oberfläche eine offenzellige oder offenporige Metallstruktur, die eine vorgegebene Tiefe und eine Verteilung unterschiedlicher Porengrößen aufweist und dazu dient, daß das angrenzende Knochengewebe in die Poren oder Zellen einwachsen und einen großflächigen Formschlußverbund zwischen Knochengewebe und Implantat realisieren kann.

Die Innenfläche 10, 12 der Kappe 2 besitzt einen vom Kappenrand 6 ausgehenden Konusabschnitt 10, dessen Radius zur Rotationsachse 3 hin nach innen kleiner wird. Der Konusabschnitt 10 geht im Inneren der Kappe 2 in einen Basisabschnitt 12 über, der senkrecht zur Rotationsachse 3 verläuft. An den Basisabschnitt 12 schließt zentral der Schaft 14 an, der nach außen gerichtet mit seinem freien Ende 15 aus dem Innenraum 8 der Kappe 2 herausragt. Die Innenfläche 10, 12 und der Schaft 14 sind durchgängig mit der offenporigen oder offenzelligen Oberflächenstruktur 16 versehen.

Die Kappe 2 besitzt im wesentlichen die Form eines Kugelabschnitts, der zum Kappenrand 6 hin anatomisch adaptiert, und damit von der Kugelform abweichend gestaltet sein kann.

Patentansprüche

1. Endoprothese zum Ersatz des Gelenkkopfes eines menschlichen Knochens, insbesondere des Schultergelenkkopfes, mit einer eine rotationssymmetrische, kalottenförmige Außenfläche aufweisenden Kappe aus Metall, **dadurch gekennzeichnet**, daß die Innenfläche (10, 12) der Kappe (2) eine offenzellige oder offenporige Oberflächenstruktur (16) aufweist.
2. Endoprothese nach Anspruch 1, dadurch gekennzeichnet, daß im Innenraum (8) an die Kappe zentral ein Schaft (14) angeformt ist.
3. Endoprothese nach Anspruch 2, dadurch gekenn-

zeichnet, daß der Schaft (14) zu seinem freien Ende (15) hin sich kegelförmig verjüngt.

4. Endoprothese nach Anspruch 2, dadurch gekennzeichnet, daß der Schaft als Hülse ausgebildet ist.

5. Endoprothese nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß der Schaft durchgängig aus einer offenporigen oder offenzelligen Metallstruktur besteht.

6. Endoprothese nach einem der Ansprüche 2 bis 4, dadurch gekennzeichnet, daß der Schaft (14) einen massiven Kern aus Metall und eine offenporige oder offenzellige Oberflächenstruktur aus Metall enthält.

7. Endoprothese nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß der Schaft (14) eine vorgegebene Länge aus dem Innenraum (8) der Kappe (2) herausragt.

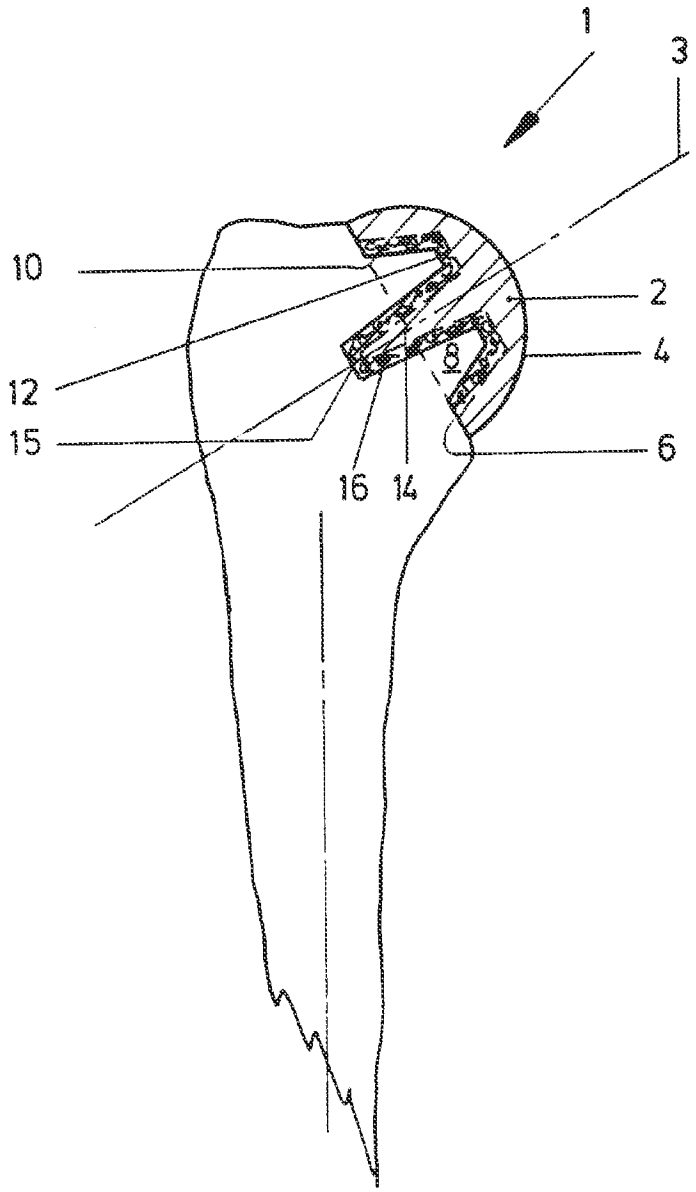
8. Endoprothese nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die Innenfläche (10, 12) der Kappe (2) vom Kappenrand (6) ausgehend einen sich nach innen verjüngenden Konusabschnitt (10) und anschließend eine zur Rotationsachse (3) senkrechte Basisfläche besitzt, die zur Rotationsachse hin in den Schaft (14) übergeht.

9. Endoprothese nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß der Schaft (14) und/oder Teile der Innenfläche (10, 12) ein Gewinde aufweisen.

10. Endoprothese nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die Achse des Schafts (14) mit der Rotationsachse (3) fluchtet.

Hierzu 1 Seite(n) Zeichnungen

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(54) **SHOULDER PROSTHESIS**

SCHULTERPROTHESE

PROTHÈSE D'ÉPAULE

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Description

[0001] This invention relates to a shoulder prosthesis and particularly but not exclusively relates to a bearing component for use with a humeral prosthesis.

BACKGROUND

[0002] In the field of reconstructive joint surgery, it is known to replace a deficient shoulder joint with a total shoulder prosthesis. In cases of severe damage to the rotator cuff, it is known to employ a "reverse" type shoulder prosthesis, in which the anatomy of a healthy shoulder is reversed, with a spherical ball component being implanted in the glenoid cavity of the scapula, and a cup component being implanted in a proximal end of the humerus. The design of the reverse shoulder prosthesis enables the upward force provided by the deltoid muscle to be employed for the purposes of rotation, thus compensating, at least in part, for a deficient rotator cuff and restoring some measure of abduction to a patient's arm. In order to recruit as many deltoid fibres as possible for the purposes of abduction, and to reduce torque at the point of fixation of the glenoid component, the centre of rotation of the prosthetic joint is designed to be in a more medial position than that of a normal, healthy joint. This medialisation of the centre of rotation is achieved through the design of the glenoid component, which is a large diameter partial sphere having no neck. Medialisation of the centre of rotation, and consequently of the humerus, leads to detensioning of the deltoid. To address this, and to improve the power of the deltoid, the humeral cup is oriented with a non anatomic inclination of approximately 155°, thus lowering the humerus and over tensioning the deltoid muscle.

[0003] Medialisation of the centre of rotation of the joint and lowering of the humerus are essential biomechanical features of a reverse shoulder prosthesis. However, the inevitable consequence of these features is impingement of the medial aspect of the humeral cup on the inferior scapular neck with the arm in an adducted position (as illustrated in Figure 1). This impingement damages the humeral cup and causes scapular notching, which can be an initiating factor for osteolysis. Further bone degradation may be triggered by wear particles from the humeral cup. Osteolysis in this region can result in loosening of the glenoid component. In addition, impingement of the humeral cup on the inferior scapular neck can cause superior (asymmetric) decoaptation, where a superior portion of the humeral cup loses contact with the glenoid component. Such decoaptation reduces prosthetic stability.

[0004] US 3 978 528 A discloses a humeral component of a reverse shoulder prosthesis comprising a cup with a rim, a split pair of insert liners and a lock ring to be attached to the rim, whereby both, the rim and the lock ring, have a uniform thickness about their circumference.

SUMMARY OF THE INVENTION

[0005] According to the present invention, there is provided a bearing component for use in a humeral prosthesis, the bearing component comprising a concave bearing surface that terminates at a continuous substantially circular rim, the rim defining a first plane; a convex engaging surface, that is on an opposite side of the bearing component to the bearing surface and terminates in an annular shoulder, the shoulder defining a second plane; and a connecting region which extends between the first and second planes, wherein the first and second planes are not parallel, wherein the bearing component together with a stem is configured to form a humeral part of a reverse shoulder prosthesis. In an embodiment of the invention, the rim of the bearing component is angled with respect to the base of the bearing component, causing the thickness of the bearing component to vary about its circumference. Such variation in thickness can be employed to advantage when the bearing component is implanted in a patient. For example, the bearing component may be implanted with the area of least thickness in an inferior, medial position. In this orientation, projection of the bearing component towards the inferior scapular neck is reduced, thus reducing the occurrence of scapular impingement and notching.

[0006] The concave bearing surface may comprise less than a hemisphere. It is an advantage of the invention that the reduced area of the bearing surface affords a greater range of motion to a prosthetic joint in which the bearing component of the present invention is employed, thus assisting to reduce the occurrence of scapular impingement and notching. It has been discovered that the reduction in contact area between the bearing component and the prosthesis component against which it articulates need not lead to a lessening of the stability of the joint.

[0007] An angle between the first and second planes of the bearing component may be between 5 and 20 degrees but is preferably approximately 10 degrees. The angle may be selected to provide the optimum variation in thickness about the circumference of the bearing component.

[0008] The connecting region may comprise a connecting wall, which may be substantially in the shape of a truncated cylinder.

[0009] The annular shoulder of the convex engaging surface may define an annular bearing surface. The annular shoulder may comprise at least one recess.

[0010] The bearing component may be formed from a polymeric material. The polymeric material may be ultra high molecular weight polyethylene. Alternatively, the polymeric material may be any suitable biologically compatible polymeric material.

[0011] The bearing component may further comprise a lining component. The lining component may comprise a metallic shell that lines the concave bearing surface of the bearing component. In this manner, the bearing com-

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ponent of the present invention may be employed in a metal-on-metal articulation.

[0012] According to another aspect of the present invention, there is provided a humeral prosthesis comprising a bearing component as disclosed above, and a stem.

[0013] The engaging surface of the bearing component may be received within the stem such that the annular bearing surface of the bearing component engages a corresponding annular bearing surface on the stem.

[0014] The annular bearing surface of the stem may comprise at least one projecting lug, adapted to be received within the recess on the annular shoulder of the bearing component.

[0015] The annular shoulder of the bearing component may comprise a plurality of recesses arranged circumferentially around the bearing component. Similarly, the annular bearing surface of the stem may comprise a plurality of projecting lugs, adapted to be received within the plurality of recesses on the annular shoulder of the bearing component.

[0016] The corresponding recesses and lugs therefore form an indexing system. It is an advantage of the humeral prosthesis of the present invention that the bearing component may be securely inserted into the stem at any desired rotational orientation. Further, the relative rotational orientation of the two components may be altered simply and easily. For example, when implanting the prosthesis into a patient, the surgeon may orientate the bearing component such that the portion having the least thickness is placed at the position where the anatomy of the patient dictates scapular impingement is most likely to occur. If a trial reduction suggests the bearing component has not been inserted at the optimal position, this may be corrected, simply by repositioning the bearing component.

[0017] According to another aspect of the present invention, there is provided a shoulder prosthesis comprising a humeral prosthesis as claimed in any one of claims 10 to 14 and a glenoid prosthesis. The glenoid prosthesis may comprise a glenoid screw (metaglene) and a glenoid head (glenosphere).

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Figure 1 is a side view illustrating scapular notching in a reverse shoulder prosthesis,

Figure 2 is a side view of a humeral bearing component,

Figure 3 is a perspective view of a humeral stem and bearing component,

Figure 4 is a side view of an assembled reverse shoulder prosthesis

Figure 5 is an illustrative view of an implanted reverse shoulder prosthesis.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0019] With reference to Figures 2 and 3, a humeral bearing component 2 comprises a substantially cup shaped body 1, having a concave bearing surface 4, a convex engaging surface 6 and a connecting region 8. The bearing surface 4 is substantially spherical and terminates at a substantially circular rim 10, that defines a first plane 12. The engaging surface 6 comprises a cylindrical part 13 and a spherical part 16 and is designed to form one half of a standard taper connection. The engaging surface 6 terminates at a second plane 14. The connecting region 8 extends from the first plane 12 to the second plane 14 and terminates at the second plane 14 in an annular shoulder 18 that forms an annular bearing surface 20. The first and second planes 12 and 14 intersect at an angle α such that the depth d of the connecting region 8 varies about the circumference of the bearing component 2. The angle α may be between 5 and 20 degrees but is preferably approximately 10 degrees.

[0020] The connecting region 8 is in the form of a substantially cylindrical wall 22. The wall 22 includes a plurality of recesses 24 that extend into the wall 22 from the annular bearing surface 20. Those recesses 24 that are located at the part of the wall 22 having the least depth d may extend through the entire depth d of the wall 22.

[0021] With reference also to Figure 4, the humeral bearing component 2 is suitable for use with a humeral stem 30. The stem 30 comprises a flange in the form of a fin 32 and a socket portion 34. The socket portion 34 is connected to the fin 32 by a web 33 that imparts rotational stability to the stem 30. The socket portion 34 is shaped to receive the engaging surface 6 of the bearing component 2 and includes an annular bearing surface 36. When the bearing component 2 is received within the stem 30, the annular bearing surface 20 of the bearing component 2 is in contact with the annular bearing surface 36 of the stem 30. The socket portion 34 of the stem 30 includes a plurality of lugs 38 that protrude from the annular bearing surface 36 on the stem 30. The lugs 38 are shaped to be received within the recesses 24 on the bearing component 2. The lugs 38 and recesses 24 form an indexing system, preventing relative rotational movement between the bearing component 2 and the stem 30 when assembled, but permitting the bearing component 2 to be received within the stem 30 at a plurality of rotational orientations.

[0022] The bearing component 2 is formed from a polymeric material which may be polyethylene, ultra high molecular weight polyethylene (UHMWPE) or any other suitable, biocompatible polymeric material. The bearing

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component 2 may also include a metallic liner (not shown). The liner may cover substantially the entire bearing surface 4 so as to provide a metallic bearing surface, if required. The stem 30 is made from a metallic material which may be titanium, cobalt chrome or any other suitable biocompatible metallic material including stainless steel and tantalum. The stem is preferably made from cobalt chrome. The stem may be coated with a porous metal, with Hydroxyapatite, or with any other material suitable for supporting bone ingrowth.

[0023] Referring to Figures 4 and 5, the humeral bearing 2 and stem 30 together form the humeral part of a reverse shoulder prosthesis 50. The glenoid part 40 of the prosthesis 50 comprises a metal plate, or glenoid screw (metaglene) 42, having a threaded protrusion 44 extending from a bone engaging face 46 thereof, and a glenoid head (glenosphere) 48. The glenoid head (glenosphere) 48 comprises at least a portion of a sphere and is mounted on the glenoid screw (metaglene) 42. When assembled, the glenoid and humeral parts of the prosthesis 50 articulate, with at least a portion of the glenoid head (glenosphere) 48 being received within the bearing component 2.

[0024] In use, the prosthesis 50 is implanted within a patient's shoulder and a trial reduction is performed to asses the range of motion afforded by the prosthesis. The limiting feature in adduction is, as explained above, impingement of the inferior medial aspect of the humeral bearing component 2 on the inferior scapular neck. By orienting the bearing component 2 such that the thinnest section of the bearing component is in the inferior medial position, the range of motion that can be achieved before impingement occurs is increased. In some patents, impingement may occur in a slightly more anterior or more posterior position than is usual. In such cases, the indexing system of the humeral prosthesis enables the bearing component to be rotated, so as to ensure that the thinnest section of the bearing component 2 is positioned at the point of impingement, thus gaining the greatest increase in range of motion from the design of the bearing component.

Claims

1. A bearing component (2) for use in a humeral prosthesis, the bearing component comprising
a concave bearing surface (4) that terminates at a continuous substantially circular rim (10), the rim defining a first plane (12);
a convex engaging surface (6), that is on an opposite side of the bearing component to the bearing surface and terminates in an annular shoulder (18), the shoulder defining a second plane (14); and
a connecting region (8) which extends between the first and second planes, wherein the first and second planes are not parallel,
wherein the bearing component together with a stem (30) is configured to form a humeral part of a reverse shoulder prosthesis.

2. A bearing component (2) as claimed in claim 1 wherein the concave bearing surface (4) comprises less than a hemisphere.

3. A bearing component (2) as claimed in claim 1 or 2, wherein an angle between the first and second planes is between 5 and 20 degrees.

4. A bearing component (2) as claimed in any of the preceding claims, wherein the connecting region (8) comprises a connecting wall (22), substantially in the shape of a truncated cylinder.

5. A bearing component (2) as claimed in any one of the preceding claims, wherein the annular shoulder (18) defines an annular bearing surface (20).

6. A bearing component as claimed in any one of the preceding claims, wherein the annular shoulder comprises at least one recess.

7. A bearing component (2) as claimed in any one of the preceding claims, wherein the bearing component is formed from a polymeric material.

8. A bearing component (2) as claimed in claim 7, wherein the polymeric material is ultra high molecular weight polyethylene.

9. A bearing component (2) as claimed in any one of the preceding claims, further comprising a lining component.

10. A bearing component (2) as claimed in claim 9, wherein the lining component comprises a metallic shell that lines the concave bearing surface (4) of the bearing component.

11. A humeral prosthesis comprising a bearing component (2) as claimed in any one of the proceeding claims and a stem (30).

12. A humeral prosthesis as claimed in claim 11, wherein the engaging surface (6) of the bearing component (2) is received within the stem (30) such that the annular bearing surface (20) of the bearing component engages a corresponding annular bearing surface (36) on the stem.

13. A humeral prosthesis as claimed in claim 11 or 12, wherein the annular bearing surface (36) of the stem (30) comprises at least one projecting lug (38), adapted to be received within the recesses (24) on the annular shoulder (18) of the bearing component (2).

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14. A humeral prosthesis as claimed in any one of claims 11 to 13, wherein the annular shoulder of the bearing component comprises a plurality of recesses arranged circumferentially around the bearing component.

15. A humeral prosthesis as claimed in claim 14, wherein the annular bearing surface (36) of the stem (30) comprises a plurality of projecting lugs (38), adapted to be received within the plurality of recesses (24) on the annular shoulder (18) of the bearing component (2).

16. A shoulder prosthesis (50) comprising a humeral prosthesis as claimed in any one of claims 11 to 15 and a glenoid prosthesis (40).

17. A shoulder prosthesis (50) as claimed in claim 16, wherein the glenoid prosthesis (40) comprises a glenoid screw (42) and a glenoid head (48).

Patentansprüche

1. Tragelement (2) zur Verwendung in einer Humerusprothese, wobei das Tragelement (2) umfasst:

   Eine konkave Tragoberfläche (4), die an einem durchgehenden, im Wesentlichen kreisförmigen Kranz (10) endet, wobei der Kranz eine erste Fläche (12) definiert,
   eine konvexe Eingriffoberfläche (6), die an dem Trageelement gegenständig der Tragoberfläche angeordnet ist und in einer ringförmigen Schulter (18) endet, wobei die Schulter eine zweite Fläche (14) definiert, und
   einen Verbindungsbereich (8), der sich zwischen der ersten und der zweiten Fläche erstreckt, wobei die erste und die zweite Fläche nicht parallel zueinander liegen,
   wobei das Tragelement zusammen mit einem Schaft (30) angepasst ist, den humeralen Teil einer inversen Schulterprothese zu bilden.

2. Tragelement (2) nach Anspruch 1, wobei die konkave Tragoberfläche (4) weniger umfasst als eine Halbkugel.

3. Tragelement (2) nach Anspruch 1 oder 2, wobei der Winkel zwischen der ersten und der zweiten Fläche zwischen 5 und 20° beträgt.

4. Tragelement (2) nach einem der vorstehenden Ansprüche, wobei der Verbindungsbereich (8) eine Verbindungswand (22) umfasst, die im Wesentlichen die Form eines verkürzten Zylinders aufweist.

5. Tragelement (2) nach einem der vorstehenden Ansprüche, wobei die ringförmige Schulter (18) eine ringförmige Tragoberfläche (20) definiert.

6. Tragelement (2) nach einem der vorstehenden Ansprüche, wobei die ringförmige Schulter wenigstens eine Vertiefung umfasst.

7. Tragelement (2) nach einem der vorstehenden Ansprüche, wobei das Tragelement aus einem polymeren Material gefertigt ist.

8. Tragelement (2) nach Anspruch 7, wobei das polymere Material ein ultrahochmolekulargewichtiges Polyethylen ist.

9. Tragelement (2) nach einem der vorstehenden Ansprüche, ferner umfassend eine Auskleidungskomponente.

10. Tragelement (2) nach Anspruch 9, wobei die Auskleidungskomponente eine metallene Hülle umfasst, die die konkave Tragoberfläche (4) des Tragelements auskleidet.

11. Humeralprothese, umfassend ein Tragelement (2) nach einem der vorstehenden Ansprüche und einen Schaft (30).

12. Humeralprothese nach Anspruch 11, wobei die Eingriffoberfläche (6) des Tragelements (2) in dem Schaft (30) derart ausgenommen ist, dass die ringförmige Tragoberfläche (20) des Tragelements in Eingriff mit einer entsprechenden ringförmigen Tragoberfläche (36) auf dem Schaft (30) kommt.

13. Humeralprothese nach Anspruch 11 oder 12, wobei die ringförmige Tragoberfläche (36) des Schafts (30) wenigstens einen vorstehenden Ansatz (38) umfasst, der angepasst ist, in der Vertiefung (24) der ringförmigen Schulter (18) des Tragelements (2) aufgenommen zu werden.

14. Humeralprothese nach Anspruch 11 bis 13, wobei die ringförmige Schulter des Tragelements mehrere Vertiefungen umfasst, die umlaufend um das Tragelement angeordnet sind.

15. Humeralprothese nach Anspruch 14, wobei die ringförmige Tragoberfläche (36) des Schafts (30) mehrere vorstehende Ansätze (38) umfasst, die angepasst sind, in den mehreren Vertiefungen (24) der ringförmigen Schulter (18) des Tragelements (2) aufgenommen zu werden.

16. Schulterprothese (50) umfassend eine Humeralprothese nach einem der Ansprüche 11-15 und eine Glenoidprothese (40).

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17. Schulterprothese (50) nach Anspruch 16, wobei die Glenoidprothese (40) eine Glenoidschraube (42) und einen Glenoidkopf (48) umfasst.

Revendications

1. Composant d'appui (2) destiné à être utilisé dans une prothèse humérale, le composant d'appui comprenant
une surface d'appui concave (4) qui se termine au niveau d'un rebord continu sensiblement circulaire (10), le rebord définissant un premier plan (12) ;
une surface de mise en prise convexe (6), qui se trouve sur un côté opposé du composant d'appui par rapport à la surface d'appui et se termine en un épaulement annulaire (18), l'épaulement définissant un second plan (14) ; et
une région de liaison (8) qui s'étend entre les premier et second plans, dans lequel les premier et second plans ne sont pas parallèles,
dans lequel le composant d'appui conjointement avec une tige (30) est conçu pour former une partie humérale d'une prothèse d'épaule inverse.

2. Composant d'appui (2) selon la revendication 1, dans lequel la surface d'appui concave (4) comprend moins d'un hémisphère.

3. Composant d'appui (2) selon la revendication 1 ou 2, dans lequel un angle entre les premier et second plans est compris entre 5 et 20 degrés.

4. Composant d'appui (2) selon l'une quelconque des revendications précédentes, dans lequel la région de liaison (8) comprend une paroi de liaison (22), sensiblement sous la forme d'un cylindre tronqué.

5. Composant d'appui (2) selon l'une quelconque des revendications précédentes, dans lequel l'épaulement annulaire (18) définit une surface d'appui annulaire (20).

6. Composant d'appui selon l'une quelconque des revendications précédentes, dans lequel l'épaulement annulaire comprend au moins un évidement.

7. Composant d'appui (2) selon l'une quelconque des revendications précédentes, où le composant d'appui est formé d'un matériau polymère.

8. Composant d'appui (2) selon la revendication 7, dans lequel le matériau polymère est du polyéthylène à masse moléculaire ultra-élevée.

9. Composant d'appui (2) selon l'une quelconque des revendications précédentes, comprenant en outre un composant de revêtement.

10. Composant d'appui (2) selon la revendication 9, dans lequel le composant de revêtement comprend une enveloppe métallique qui revêt la surface d'appui concave (4) du composant d'appui.

11. Prothèse humérale comprenant un composant d'appui (2) selon l'une quelconque des revendications précédentes et une tige (30).

12. Prothèse humérale selon la revendication 11, dans laquelle la surface de mise en prise (6) du composant d'appui (2) est reçue à l'intérieur de la tige (30) de telle sorte que la surface d'appui annulaire (20) du composant d'appui vient en prise avec une surface d'appui annulaire correspondante (36) sur la tige.

13. Prothèse humérale selon la revendication 11 ou 12, dans laquelle la surface d'appui annulaire (36) de la tige (30) comprend au moins un ergot faisant saillie (38), adapté pour être reçu à l'intérieur des évidements (24) sur l'épaulement annulaire (18) du composant d'appui (2).

14. Prothèse humérale selon l'une quelconque des revendications 11 à 13, dans laquelle l'épaulement annulaire du composant d'appui comprend une pluralité d'évidements disposés de façon circonférentielle autour du composant d'appui.

15. Prothèse humérale selon la revendication 14, dans laquelle la surface d'appui annulaire (36) de la tige (30) comprend une pluralité d'ergots faisant saillie (38), adaptés pour être reçus à l'intérieur de la pluralité d'évidements (24) sur l'épaulement annulaire (18) du composant d'appui (2).

16. Prothèse d'épaule (50) comprenant une prothèse humérale selon l'une quelconque des revendications 11 à 15 et une prothèse glénoïdienne (40).

17. Prothèse d'épaule (50) selon la revendication 16, dans laquelle la prothèse glénoïdienne (40) comprend une vis glénoïdienne (42) et une tête glénoïdienne (48).

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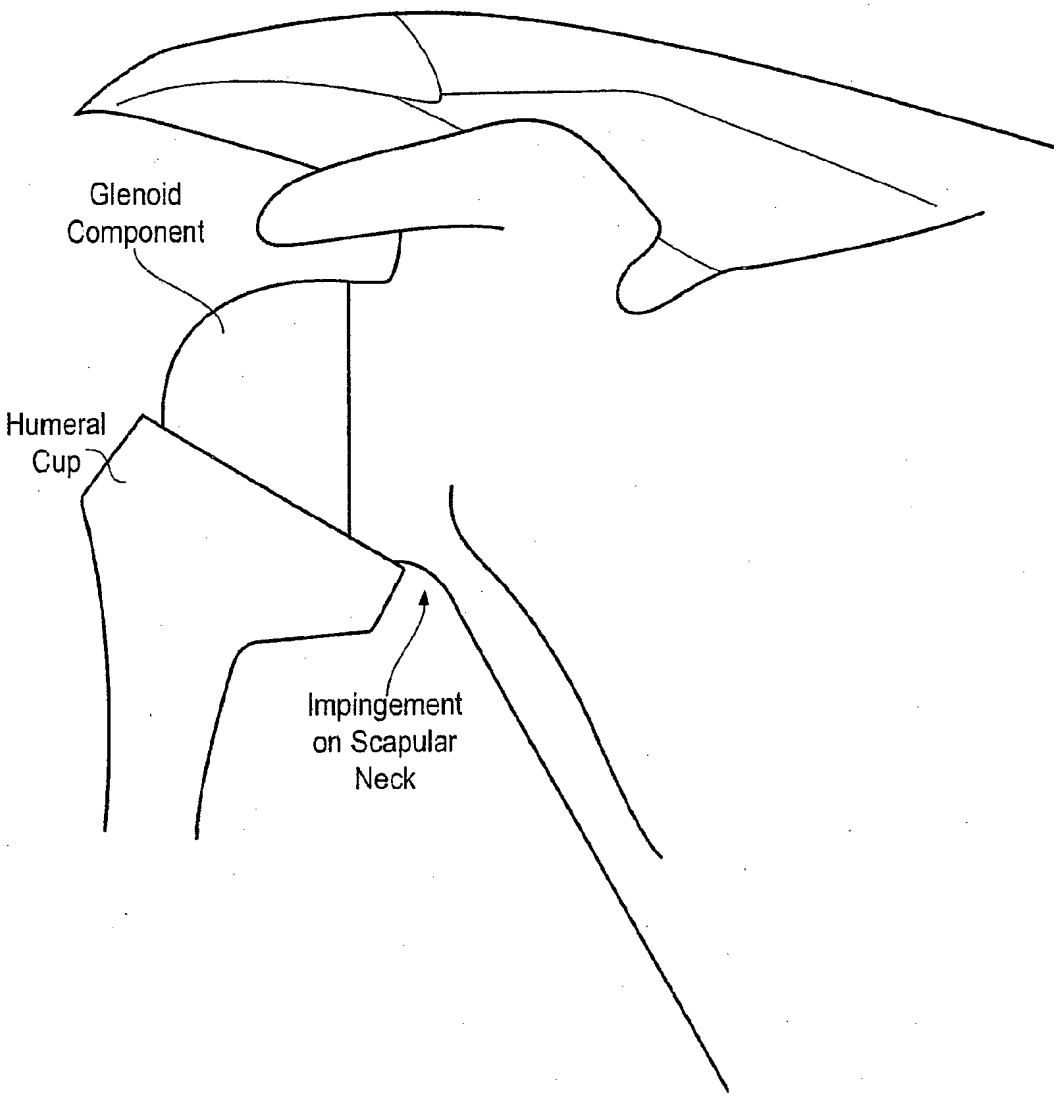


Fig. 1

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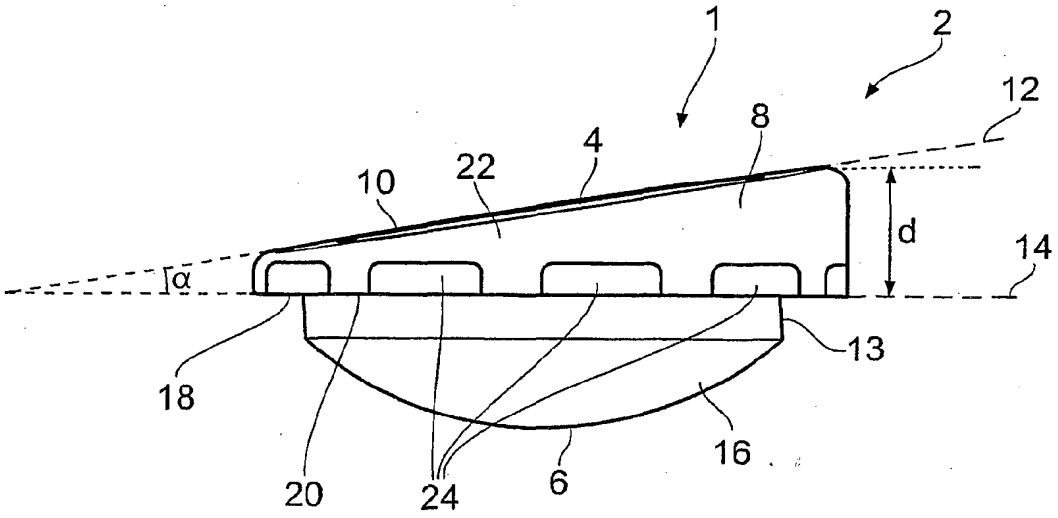


Fig. 2

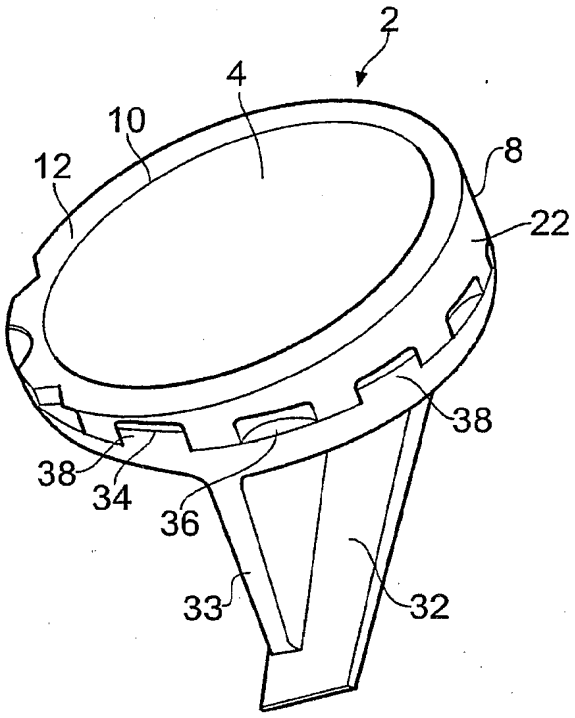


Fig. 3

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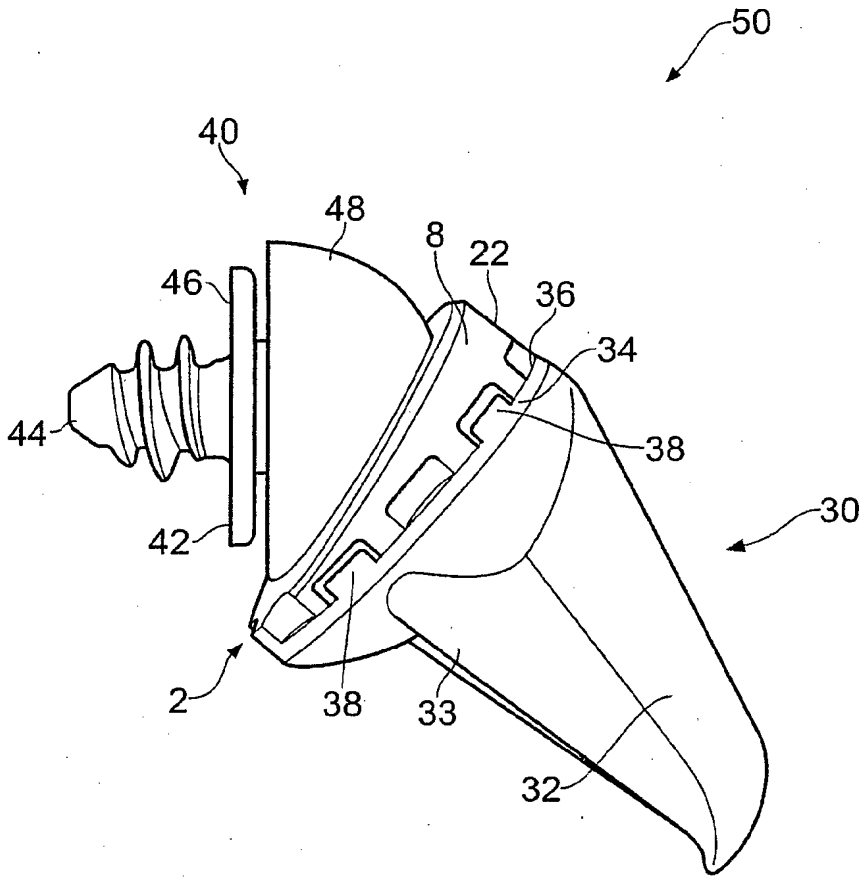


Fig. 4

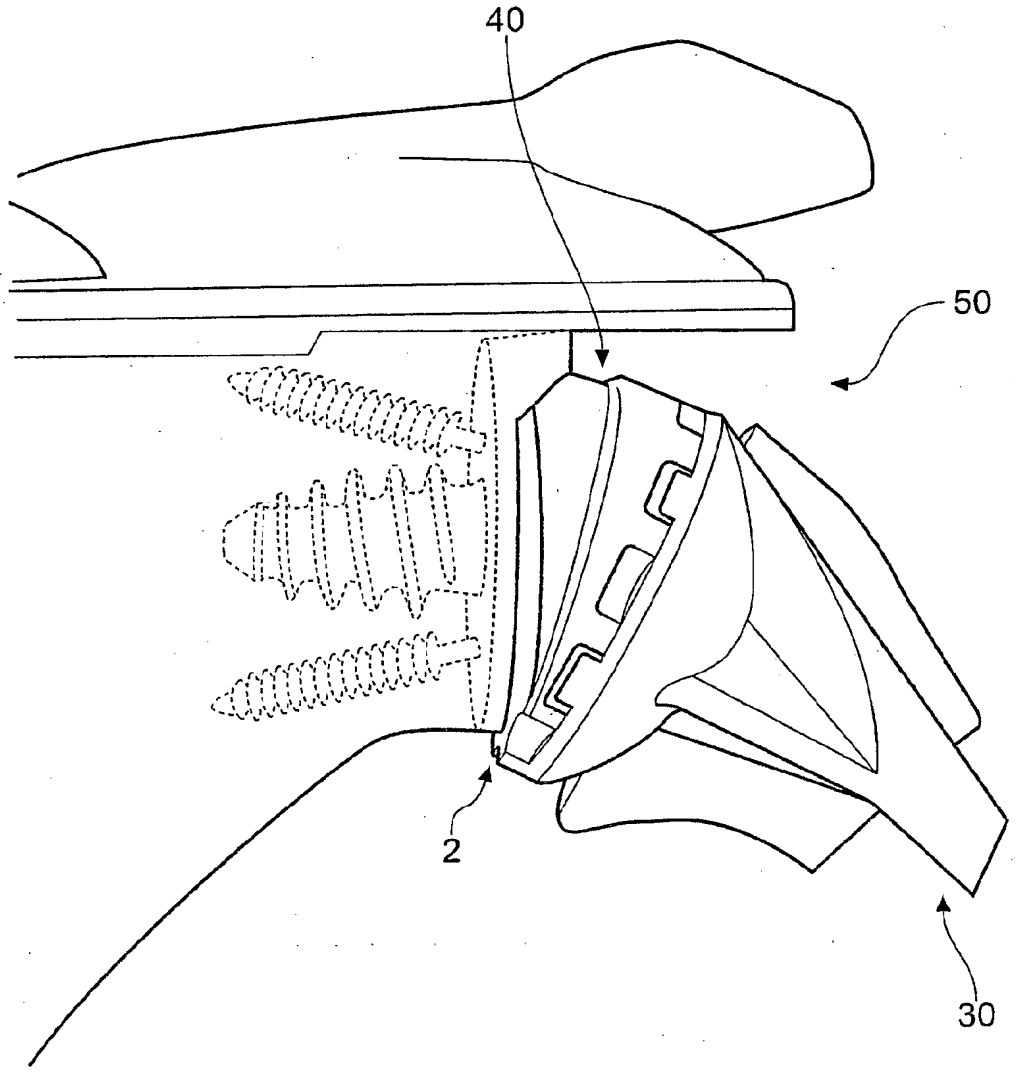


Fig. 5

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REFERENCES CITED IN THE DESCRIPTION

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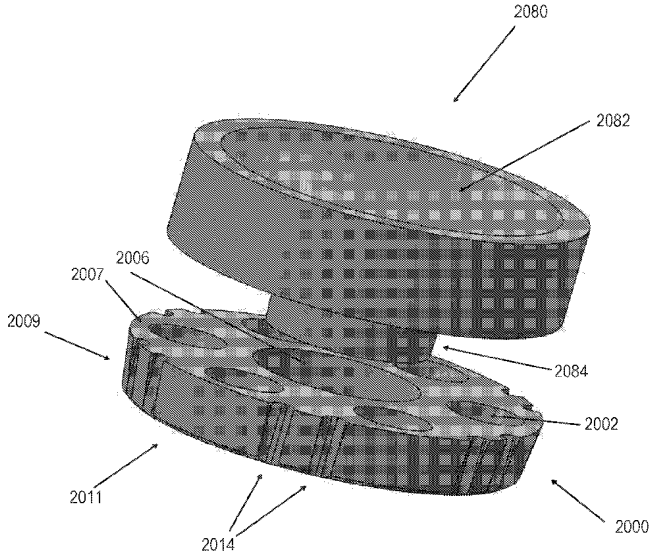


FIG. 23A

(57) Abstract: Disclosed are prosthesis systems and methods that provide porous fixation rings by which the articulating surfaces of the implant can be exchanged such that the anatomic surfaces can be converted to reverse surfaces, while not exchanging the fixation components. Also disclosed herein are methods by which the surgeon can implant an inset anatomic articulating glenoid implant whereby at a later date, can remove the anatomic articulating surface and replace it with a reverse articulating surface such that the primary means of fixation remains well fixed in the glenoid fossa at the moment of articular exchange.

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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INSET/ONLAY GLENOID, POROUS COATED CONVERTIBLE GLENOID, AND HUMERAL HEADS WITH TEXTURED UNDERSIDES

[0001] This application claims the benefit under 35 U.S.C. § 119(e) as a nonprovisional of U.S. Prov. App. No. 62/664,909 filed on April 30, 2018, which is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] Shoulder Replacement is a commonly performed medical procedure for treatment of osteoarthritis, rheumatoid arthritis, as well as for treatment of certain deformities related to oncological indications as well as trauma. There are two primary types of articulations available to surgeons for treatment: anatomic and reverse. With anatomic, the surgeon replaces the articular surfaces with industrial materials such that the articulating surfaces are substantially the same shape as the natural anatomy. A stem can be commonly fixed inside the canal of the humerus, a metallic articular head can be rigidly fixed to the proximal aspect of the same, the articular head having a convex articular surface adapted to articulate with the glenoid implant. The glenoid implant can include on its back side (medial side) certain pegs or posts or fins adapted to be rigidly fixed within the glenoid fossa of the scapula and on its front side a concave or flat articular surface adapted to articulate with the humeral head of the humeral implant.

[0003] When a reverse prosthesis is used, the articular surface is reversed in that the metallic ball is rigidly fixed to the glenoid fossa of the scapula, and the concave articular surface is rigidly fixed to the humeral bone, thereby reversing the fashion of articulation of the prosthesis.

[0004] The surgeon chooses between the two types of prostheses by assessing a number of conditions of the patient including level of pain, patient activity level, deformity or severity of the boney degradation, the strength of surrounding soft tissues, and present or absence of prior surgery, and particularly the health and strength of the rotator cuff muscle and tendon. Disease of the rotator cuff is common among patients with arthritis of the

shoulder. In this circumstance, it is commonly observed that the absence of insufficiency of the rotator cuff leads to a condition where the anatomic shoulder replacement prosthesis is not sufficiently stabilized by surrounding soft tissue. In this case, a reverse shoulder replacement prosthesis can be preferred in some cases due to the higher inherent stability of the articulation. In addition, the reverse prosthesis can advantageously utilize the remaining muscles in a way they can be more effective in the absence of the other soft tissue structures by adjusting the position of the articular surfaces within the joint.

[0005] It is not uncommon that a surgeon selects to use an anatomic prosthesis and is provides effective treatment to the patient though the shoulder replacement operation. However, over time and during use of the prosthesis, the patient's rotator cuff complex can become insufficient, tear, or generally be diseased such that it can no longer perform its function associated with normal joint kinematics. In this case, the surgeon can elect to perform a second operation to remove the anatomic prosthesis, and replace the anatomic prosthesis with a reverse prosthesis.

[0006] Several attempts have been made to attempt to address the need of conversion of the articular surface without interruption of the fixation. Primarily, these are created using a two (or more) system, where there is a metallic fixation component which is rigidly fixed to the glenoid fossa, and a polyethylene (PE) articular component which is secondarily fixed to the metallic component, and provides the concave articular surface adapted to articular with the humeral prosthesis. While referred to herein as a PE component, some embodiments do not require the use of polyethylene and can be made of other biocompatible materials depending on the desired clinical result. The PE component is commonly fixed to the metallic fixation component by conventional industrial techniques such as snap fit mechanisms, snap rings, compression pins, overmolding of the PE and other such means.

[0007] A challenge of this particular articulation in some cases is that the glenoid fossa is relatively small, and commonly there is much reduced presence of bone in patients with arthritis. In this context, the surgeon has limited positioning and bone to work with in order to fit within the patient. In addition, the surgeon must be careful not to overstuff the joint, meaning implant components that move the new articulating surface far from its

original position such that the soft tissues is unnaturally tensioned, which can lead to instability, accelerated where, soft tissue failure, pain, reduced range of motion, or fracture of the prosthesis and surrounding bone. Facing these conditions, the prosthesis typically needs to be designed to remain relatively thin (commonly, 1 piece, where PE glenoid implants typically have a 4mm thick articular surface). In order to design these modular components, there can be little additional packaging space provided into which to fit the attachment mechanisms necessary for use without adversely affecting the performance of the overall joint replacement procedure. Thus, typically, these designs lead to "over-optimization" of the fixation and articular portions in order to provide sufficient attachment mechanisms such that either: the PE is too thin to be sufficiently strong, the metallic components are too small to provide sufficient fixation, or the overall mechanism is insufficiently rigid causing there to be secondary wear surfaces, and generation of wear particles leading to PE disease.

[0008] A problem that can exist is that in the case where the surgeon wants to change the prosthesis type, the anatomic prosthesis is commonly well fixed and adapted to the patient's body such that removal of the prosthesis can be very destructive, and leave natural bone remaining that is perhaps insufficient to support the fixation of the reverse prosthesis. What is needed is a prosthesis system that provides a means by which the articulating surfaces of the implant can be exchanged such that the anatomic surfaces can be converted to reverse surfaces, while not exchanging the fixation components.

[0009] What is also needed is a simple means by which the surgeon can implant an inset anatomic articulating glenoid implant whereby at a later date, can remove the anatomic articulating surface and replace it with a reverse articulating surface such that the primary means of fixation remains well fixed in the glenoid fossa at the moment of articular exchange.

[0010] In some embodiments, disclosed herein is a method of performing a reversible anatomic shoulder replacement procedure. The method can include any number of: reaming a cavity into the glenoid; and inserting an anatomic glenoid articular implant into the glenoid cavity, the glenoid anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate

component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached to a snap ring attached to a fixation ring, the snap ring and the fixation ring at least partially implanted within the glenoid cavity. The anatomic glenoid articular implant can be partially or fully inset into the glenoid cavity. The cavity could be circular, oval, or another shape.

[0011] Also disclosed herein is a method of converting an anatomic to a reverse shoulder prosthesis, including any number of: identifying a patient with an anatomic glenoid articular implant within a glenoid cavity, the anatomic articular implant comprising a medial surface mated with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface articulating with a humeral component; and a central component between the lateral surface and the medial surface, the central component having an outer diameter reversibly attached to a snap ring and a fixation ring, the snap ring and the fixation ring at least partially implanted within the glenoid cavity; inserting a implant removal tool through the lateral articulating surface of the anatomic glenoid articular implant sufficient to collapse the snap ring; removing the anatomic glenoid articular implant while leaving the fixation ring in place within the glenoid cavity; and inserting a reverse shoulder implant into the glenoid cavity sufficient to actuate the snap ring such that the reverse shoulder implanted is reversibly fixed to the fixation ring. Inserting the removal tool can include driving pins, a drill bit, or another tool of the removal tool through the lateral articulating surface of the anatomic glenoid articular implant.

[0012] In some embodiments, also disclosed herein is a reversible anatomic shoulder replacement system, that can include any number of: a fixation ring configured to be positioned within the glenoid cavity, the fixation ring comprising a peripheral edge comprising an outer diameter and a plurality of spaced-apart radially inward indents in the peripheral edge, the fixation ring comprising a groove configured to house a snap ring therein; a snap ring comprising an expanded configuration and a collapsed configuration; and an anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer

diameter reversibly attached to the snap ring and the fixation ring, the snap ring and the fixation ring configured to be at least partially implanted within the glenoid cavity. The groove can include anti-rotation tabs. The peripheral edge of the fixation ring can be configured to facilitate bone ingrowth, e.g., via an osteoinductive or osteoconductive surface. The groove can be a circumferential groove. The lateral surface can include any appropriate material, such as polyethylene.

[0013] Also disclosed herein is a reverse shoulder replacement kit for an anatomic shoulder replacement system, that can include any number of: an implant removal tool configured to bore through a medial surface of the anatomic glenoid articular implant sufficient to collapse a snap ring; and remove an anatomic glenoid articular implant while leaving a fixation ring in place within the glenoid cavity; and a reverse shoulder implant configured to be implanted into the glenoid cavity, the reverse shoulder implant comprising a generally cylindrical component comprising a medial surface configured to mate with the glenoid cavity, a central receptacle for housing an articular post therethrough, and a plurality of peripheral screw holes; a lateral surface, and a central post extending away from the lateral surface, wherein the reverse shoulder implant is configured to reversibly mate with the snap ring and fixation ring embedded in the glenoid cavity to anchor the reverse shoulder implant.

[0014] In some configurations, disclosed herein is a method of performing a reversible anatomic shoulder replacement procedure, comprising reaming a cavity into the glenoid; and inserting an anatomic glenoid articular implant into the glenoid cavity, the glenoid anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached via press fitting to a fixation ring at least partially comprising a porous surface, the fixation ring at least partially implanted within the glenoid cavity.

[0015] In some configurations, the anatomic glenoid articular implant is partially or fully inset into the glenoid cavity. The cavity can be, for example, circular or oval.

[0016] In some configurations, disclosed herein is a reversible anatomic shoulder replacement system, comprising a fixation ring configured to be positioned within the glenoid

cavity, the fixation ring at least partially comprising a porous coating, the fixation ring also comprising a peripheral edge comprising an outer diameter; and an anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; a medial peripheral edge; and a lateral peripheral edge, the medial peripheral edge comprising a substantially constant diameter that is less than a substantially constant diameter of the lateral peripheral edge, the fixation ring comprising an inner diameter sized and configured to circumscribe the medial peripheral edge of the implant. The fixation ring can be configured to be at least partially implanted within the glenoid cavity. The fixation ring can include anti-rotation features on an outer diameter of the fixation ring. The peripheral edge of the fixation ring can be configured to facilitate bone ingrowth, e.g., an osteoinductive or osteoconductive surface. The inner diameter of the fixation ring can include barbs and/or threads, including self-tapping threads.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 illustrates a lower perspective view of an embodiment of a fixation support which can be an annular fixation ring in some embodiments that can be fixed at least partially within a prepared glenoid cavity.

[0018] FIG. 2 illustrates an upper perspective view of an embodiment of a support, e.g., an annular ring 100.

[0019] FIGS. 3 and 4 illustrate an embodiment of an anatomic articular component 200 for a glenoid cavity which can be made of polyethylene or another appropriate material.

[0020] FIGS. 5 and 6 illustrate different perspective views of an embodiment of a reversible anatomic articular assembly 300 including the anatomic articular component 200, fixation ring 100, and location for placement of a snap ring 400.

[0021] FIG. 7 illustrates a perspective view of an embodiment of a reverse fixation disc 700 including a central fixation post 706 that can include a longitudinal axis aligned along the center of the reverse fixation disc as shown.

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[0022] FIGS. 8 and 9 illustrate perspective views of a reverse fixation disc 700 including peripheral screw holes 704, fixation ring 100 and snap ring 400, the snap ring 400 which can have the same mechanism as the anatomic assembly described herein.

[0023] FIGS. 10A-C illustrate part of a method of implanting an anatomic prosthesis into a reamed glenoid cavity, according to some embodiments of the invention.

[0024] FIGS. 11A-D and 12A-B illustrate a method of removing an anatomic prosthesis while leaving a fixation ring in place embedded in the glenoid cavity, as well as embodiments of components for use in the method, according to some embodiments.

[0025] FIGS. 13A-13B, illustrates a method of implanting a replacement reverse prosthesis in the glenoid cavity, and mating the prosthesis with the implanted fixation ring.

[0026] FIGS. 14-16 illustrate views of a glenoid implant with both onlay and inset components, according to some embodiments of the invention.

[0027] FIGS. 17-18D illustrate views of a glenoid implant with a porous ring component, according to some embodiments of the invention.

[0028] FIGS. 19-20 illustrate views of a glenoid implant with a porous ring component and a porous coated stem, according to some embodiments of the invention.

[0029] FIGS. 21-22 illustrate embodiments of bottom views of humeral heads including non-planar underside surfaces such as concentric annular rings or elongated grooves, according to some embodiments of the invention.

[0030] FIGS. 23A-23C illustrate views of a porous fixation support configured to reversibly connect with various glenoid implants, according to some embodiments.

[0031] FIGS. 23D-23F schematically illustrates views of an anatomic glenoid implant configured to mate with a porous fixation ring.

[0032] FIGS. 23G-23H schematically illustrate views of a glenoid implant connectable with a porous fixation ring via barbed elements.

[0033] FIGS. 23I-23K schematically illustrate views of a glenoid implant connectable with a porous fixation ring via threaded elements.

DETAILED DESCRIPTION

[0034] In particular, some embodiments of the invention are focused on advantageously exchanging the articular surface of the glenoid from a concave shape to a convex shape, without removing the components or interface having to do with fixation of the implant into the glenoid fossa.

[0035] In some embodiments, embodiments of the invention can be used or modified with use with particular advantages of using inset glenoid fixation technology in anatomic shoulder arthroplasty, such as described, for example, in U.S. Pat. Nos. 8,007,538 and/or 8,778,028 to Gunther, which are hereby incorporated by reference in their entireties.

[0036] What is further described are methods by which the surgeon can achieve the use of the inset glenoid technology with an anatomic articulation, while after having the ability to convert the technology to a reverse articulation, without requiring removal the rigid fixation between the inset fixation and the scapula bone (in other words, allowing the rigid fixation support between the inset fixation and the scapula bone to remain in place during conversion from an anatomic to a reverse prosthesis).

[0037] Some embodiments of the invention can utilize an inset glenoid articulation implant described by Gunther et al. including in U.S. Pat. No. 8,007,538 or 8,778,028. However, some embodiments of the invention can also utilize onlay glenoid articulation implants. The peripheral rim of the implant can in some cases have an important role in the fixation stability of the implant and its resistance to motion relative to the glenoid bone during articulation. In addition, it is recognized that a known "rule of thumb" in the industry is that the bearing component of the glenoid implant, such as the polyethylene (PE) component, should be at least about 3mm thick at its thinnest position in order to achieve a sufficient material strength to minimize risk of accelerated implant failure. Of course, this rule is only a guide, but has proven helpful in assessing longevity of implant designs. With these points in mind, it is recognized that in some embodiments the design of the implant (which can be inset in some embodiments) might be improved upon by providing a step in the outer diameter of the inset glenoid implant at its most medial aspect while being able to maintain a minimum PE thickness of about or at least about 2mm, 2.5mm, 3mm, 3.5mm, 4mm, or ranges incorporating any of the aforementioned values. In the space that this step

provides is placement of an annular ring which can be rigidly fixed on the outer diameter of the articular implant such that the outer diameter of the inset glenoid implant remains a contiguous surface, albeit in some embodiments made a plurality of materials: the lateral aspect being part of the PE articulation, the medial aspect being the outer diameter of the annular ring, which can be metallic in some cases. The annular ring and the PE articular component can be attached to one another through the use of a snap ring mechanism or other ways, some of which are described elsewhere herein.

[0038] The annular ring can be configured such that its outer diameter presents a surface to the surrounding bone which can be adapted to be biologically attractive for the growth of surrounding bone tissue. This technology can be achieved by several means such as, for example, various coatings or secondary manufacturing operations, mechanical modification through machining operations, creation of an adapted surface using 3D printing manufacturing, or other means. One advantage of the surface on the outer diameter is such that over the course of the healing process following surgery, bone grows and adapts itself to this annular ring so as to provide rigid attachment of surrounding bone to the annular ring. Thus, at the moment of articular component exchange, the ring is well fixed to bone, and following removal of the PE articulation component, the ring remains well fixed within the glenoid bone, and can be useful as a support surface in attachment of a new reverse articulating surface to the bone.

[0039] FIG. 1 illustrates a lower perspective view of an embodiment of a fixation support which can be an annular fixation ring in some embodiments that can be fixed at least partially within a prepared glenoid cavity. The annular ring 100 can include a central cavity 106 and a plurality of radially inward indents 102 in the outer circumference of the peripheral edge 104 of the annular ring 100 as shown and be sized and configured for fixation screw clearance. The ring 100 could have any number of indents 102 such as 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more, or ranges including at least two of the aforementioned values. The indents 102 could be regularly or irregularly spaced apart along the circumference in some embodiments, and have a curved shape as shown or other shapes. As shown, the peripheral edge 104 can include a coating or other surface, e.g., osteoinductive or osteoconductive surface to facilitate bone ingrowth and fixation into the cavity. The surface could include, for example, cortical

bone, cancellous bone, particulate matter, a powder form, granules, chips, a synthetic bone substitute, growth factors and/or bone growth promoting proteins, or combinations thereof. The annular ring 100 can also include a groove or slot 108 that can be oriented along the outer circumference of the central cavity 106 (e.g., inner diameter of the ring) and configured to house a snap ring therein (not shown).

[0040] FIG. 2 illustrates an upper perspective view of an embodiment of a support, e.g., an annular ring 100, showing the indents 102 as previously described. Also shown is the groove or slot 108 configured to house a snap ring as well as radially-inward extending anti-rotation tabs 112. The outer diameter of the peripheral edge 104 of the annular ring 100 can match that of a bearing, e.g., polyethylene component in some embodiments.

[0041] FIGS. 3 and 4 illustrate an embodiment of an anatomic articular component 200 for a glenoid cavity which can be made of polyethylene or another appropriate material. The anatomic articular component 200 can include a concave articulating surface 202 as shown, as well as a central fixation post or peg 204, which can be only a single post or peg in some cases, and be aligned coaxially with the center of the implant. The peripheral edge of the implant could have a generally cylindrical shape in some embodiments, and/or have a circular, oval, or other cross-section. The articular component 200 can also include a feature configured to mate with the fixation support, such as a cylindrical component 206 lateral to the articular surface 202 that can have an outer diameter that corresponds to the inner diameter of the fixation support (not shown) as well as a slot or groove (not shown) configured to house a snap ring (not shown). The outer diameter of the component 206 can be in some cases less than, such as about or at least about 5%, 10%, 20%, 30%, 40%, 50%, or more less than that of the outer diameter of the articulating surface 202 of the anatomic articular component 200, or ranges including any two of the aforementioned values.

[0042] FIGS. 5 and 6 illustrate different perspective views of an embodiment of a reversible anatomic articular assembly 300 including the anatomic articular component 200, fixation ring 100, and location for placement of a snap ring 400 as previously described and illustrated.

[0043] FIG. 7 illustrates a perspective view of an embodiment of a reverse fixation implant, e.g., disc 700 including a central fixation post 706 that can include a longitudinal axis aligned along the center of the reverse fixation disc as shown. The medial surface 702 of the disc can include a central receptacle 708 for an articular post, as well as a plurality, e.g., 2, 3, 4, or more screw holes 704 oriented more peripherally with respect to the peripheral edge 706 of the disc, which can be generally cylindrical as shown, or another suitable geometry.

[0044] FIGS. 8 and 9 illustrate perspective views of a reverse fixation disc 700 including peripheral screw holes 704, fixation ring 100 and snap ring 400, the snap ring 400 which can have the same mechanism as the anatomic assembly described herein. Also shown is the other end of the receptacle 708 for the articular post that can extend through the implant. The apertures 704 (e.g., screw holes) can be axially aligned and configured to correspond with each of the indents 102 of the fixation ring 100 with the indents 102 as previously described, to house fixation screws therethrough.

[0045] FIGS. 10A-10C illustrates part of a method of implanting an anatomic prosthesis into a reamed glenoid cavity, according to some embodiments of the invention. A pocket P can be prepared, such as by reaming, in the glenoid G (shown in FIG. 10A), which can be an appropriate shape, such as circular as shown, ovoid, or other geometries, with a central distal extending hole H for a central peg in some embodiments, as shown in FIG. 10C. The anatomic implant, one embodiment of which is shown in FIG. 10B along with the fixation ring and snap ring, can be implanted into the cavity, shown schematically in FIG. 10C such as in a partially or completely inset manner, with about or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 100% of the thickness of the peripheral edge of the implant inset below the prepared glenoid surface, or ranges including any two of the aforementioned values. The attachment of the ring to the PE implant can be preferably achieved in a reversible fashion using techniques and tools available to a surgeon such that the operation can be performed in situ, or in place within the patient. In order to accomplish this, a snap ring mechanism can be utilized such that another component, such as an angular metallic ring is positioned between the bearing component, e.g., PE component and the snap ring and/or metallic ring.

[0046] FIG. 11A schematically illustrates an anatomic articular implant 300 inserted into bone, such as the glenoid cavity. FIG. 11B schematically illustrates a side view, and FIG. 11C a top view, of an implant that can be as previously described. As shown in FIGS. 11A-D and 12 in some embodiments, at the moment the surgeon seeks to remove the PE component from the annular ring, the snap ring 400 (shown in phantom in FIG. 11C) can be collapsed in order to eliminate its interference fit between the annular ring and the PE component. This can be performed through the use of a guide 600 shown in FIG. 11D which can be placed over the surface of the PE component which can be in situ. In some embodiments, the guide 600 can have an elongate shaft 601 and a distal end 604 including an annular sidewall 606 defining a cavity 608 and an open distal end configured to have an inner diameter that can match, substantially match, or be the same size or larger than the outer diameter of the peripheral edge of the bearing component of the implant, such that the annular sidewall 606 and cavity 608 is placed over the glenoid implant. Release pins 602, a drill, or other tool can be axially advanced into apertures 607 of the guide 600 to facilitate release of the snap ring from the glenoid implant.

[0047] The guide 600 provides positioning of a plurality of holes, e.g., about or at least about two, three, four, five, or more holes positioning around the periphery of the PE implanted such that which a drill or pin 602 is mechanically driven into the guide holes 607, they are aligned to force the snap ring 400 in an radially inward fashion to allow for release of the snap ring. FIG. 12A schematically illustrates the guide 600 being advanced toward the glenoid implant 300 in situ in the glenoid G, along with pins 602 that can be placed in apertures 607 of the guide 600. Once a number of pins 602, e.g., three pins are driven through the guide and PE component, the snap ring is collapsed, and the PE component and snap ring can be removed from the annular fixation ring as an assembly, as shown in FIG. 12B. At this point, what remains is the annular fixation ring well fixed within the glenoid fossa. In some embodiments, the fixation ring may not be fully counter-sunk, and be partially rather than fully inset, within the glenoid surface, and/or stand proud of the glenoid surface. With time, the fixation ring can have some bony ingrowth.

[0048] As shown in FIG. 13A, in some embodiments, an implant such as a disc, e.g., a metallic disc (e.g., as shown in FIGS. 7-9 for example) can then be placed into the

previously implanted fixation ring 100 including a groove 108 configured to fit a new snap ring 400 as previously described. The implant 1300 can include a glenosphere 1302 with an offset peg 1303 configured to fit with baseplate 1304 with shaft 1306 (schematically shown in section view), and snap ring 400. The baseplate can have a longitudinal axis A2 that is offset from the longitudinal axis of the glenosphere A1 in some embodiments. FIG. 13B illustrates the reverse implant assembled and deployed within the glenoid cavity. Methods as disclosed herein can have several non-limiting potential advantages, including the following:

1. an outer diameter adapted to provide for a snap ring fit between the disc and annular ring in the same manner as the PE component and the annular ring;
2. a peg, pin, screw or other fixation means which is adapted to fit deeper into the central portion of the glenoid fossa to provide additional fixation means,
3. a central tapered hole into which a reverse ball articulating component can be placed and rigidly fixed; and
4. several peripheral holes through which screws can be driven to further increase the rigidity of fixation between the fixation disc and bone.

[0049] Following the removal of the anatomic, e.g., PE component, the surgeon can further prepare the glenoid fossa for the reverse fixation disc by drilling a centrally positioned hole. The hole can be adapted to receive a pin, post, screw, or other feature which is integrally attached to the medial aspect of the fixation disc. As the fixation disc can be positioned within the annular ring, the central fixation protrusion can be positioned within this hole in the glenoid bone such that further fixation rigidity is obtained.

[0050] Following the placement of the fixation disc in the annular ring, the surgeon can drill additional holes in the glenoid bone through peripheral holes in the fixation disc, which provides the ability to drive fixation screws through the fixation disc into the glenoid bone, even further improving rigidity, in addition to providing rotational stability. Due to the size constrains of the components, it can be advantageous to design the annular ring in a fashion that provides sufficient clearance through which these fixation screws can pass. To this end, the annular ring can be designed such that at on its periphery are several (four) indents of circular shape that provides clearance for passing of the peripheral screws.

[0051] Once the fixation disc is well fixed to the glenoid bone, the spherical articular component is introduced to the fixation disc. On its medial aspect, the articular component can have a cone-shaped protrusion which can be adapted to fit rigidly into a cone shaped hole centrally located within the fixation disc. This can provide a rigid fixation means by which the articular component is fixed to the fixation components using a technique and mechanism well known in the art.

[0052] Some embodiments of the modular, convertible shoulder system as disclosed for example herein can include several unique advantages not considered elsewhere, including but not limited to one or more of the following:

- The use of an annular fixation ring can further improve the fixation potential of inset glenoid technology as described herein. The ring can increase the rigidity of the overall PE glenoid construct, reducing its deflection under load, and improves fixation rigidly.
- The outer aspect of the annular ring can provide a surface which adheres to bone biologically and mechanically which provides further improvement of the rigidity of the fixation over time and in response to load in consideration of Wolf's law.
- This improved rigidity and fixation can be provided with no sacrifice of the 3mm minimum material thickness of the PE component, so that joint mechanics can be maintained with no change in the overall stack height of the anatomic prosthesis.
- The attachment mechanism between the PE articular and annular ring can be reversible in situ, meaning the PE component can be removed from the annular ring which the ring remains in the bone, and can be performed in a manner which is nondestructive to the ring or the surrounding bone.
- The annular ring can be shaped so as to provide a receptacle into which a reverse articulation can be inserted and rigidly fixed.
- The ring can provide clearance so that further rigidity can be obtained by passing screws through the reverse fixation disc, annular ring, and bone.

- The fixation disc can provide a female receptacle into which the articular sphere's attachment post can be positioned. Providing a female receptacle is shown in some cases to be an easy surgical technique and very robust attachment mechanism.

Inset/Onlay Glenoid Implant

[0053] In some embodiments, an improved glenoid implant can be configured to lie both inset in a subchondral bone pocket in the glenoid, as well as on subchondral bone so that there is additional surface for the humeral head to articulate with in cases of perceived or real joint laxity.

[0054] The most common failure mechanism of glenoid implants is loosening due to a rocking horse motion which can be related to joint laxity. This joint laxity can sometimes allow the humeral head to undesirably articulate at the margins of a glenoid implant. This potential complication can occur with both inset glenoid implants as well as conventional onlay glenoid implants.

[0055] In some embodiments, such as for a circular inset glenoid, providing additional material for articulation can prevent subluxation while still providing enhanced inset fixation. This same fixation argument can be beneficial with respect to onlay glenoids which only provide fixation at small, discrete locations (e.g., peripheral and central pegs or keels).

[0056] Standard onlay glenoids use small, discrete fixation methods. Some designs include 1, 2 or more peripheral pegs which are small in diameter and allow for very small (<0.5mm) cement mantle fixation. Other designs may use porous coated peripheral pegs. Typically, the central peg of most glenoids use cementless fixation through fins packed with morcellized bone or porous coated cylindrical pegs. Each of these designs provide no fixation for the majority of the backside surface, thereby allow the plastic glenoid material to move up or down in relation to the loading of the humeral head.

[0057] By providing a large fixation surface covering the majority of the implant backside, any rocking horse motion is advantageously greatly minimized or even eliminated. Such embodiments can be used in a large number of total shoulder arthroplasty surgery

procedures. Further details of glenoid implants that can be used or modified for use with those as disclosed herein can be found, for example, in U.S. Pat. No. 8,778,028 to Gunther et al. and/or U.S. Pat. App. No. 15/952,063 to Ball, both of which is hereby incorporated by reference in its entirety. In some embodiments, an inset glenoid implant configured to reversibly connect with and press-fit into a partial or completely porous ring can be very clinically advantageous.

[0058] FIGS. 14-17 illustrate embodiments of a hybrid inset and onlay glenoid implant. FIG. 16 illustrates a side view of an embodiment of a glenoid implant 10 with a backside peg 12. The peg could be a single peg 12 situated centrally on the medial (back) side of glenoid implant 10 and in some cases can be a cylindrical peg shape that extends outwardly from glenoid implant 10 away from the back of the implant 16. The glenoid implant 10 can also include a lateral articulating surface 20 against which the head of a humerus or humeral component can move. Some embodiments include an extended onlay body portion 19 having a width or diameter than is greater than an inset body portion 17 having including the lateral articulating surface 20 and a medial surface 21 on the onlay body portion 19 that is meant to lay on the glenoid surface G. In some embodiments, the width or diameter is about or at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, or more greater than the width or diameter of the inset body portion 17, or ranges incorporating any two of the aforementioned values. The extended articular surface 20 can lie off axis with the medial surface 16 of the inset body portion 17 as shown in FIG. 16, or parallel in some embodiments, and be coaxial or non-coaxial. The periphery of the extended articular surface 20 and the medial surface 16 can be circular, non-circular such as an oval, or other shapes. FIG. 15 illustrates a top view illustrating the extended articular surface 20 of the onlay body portion 19, with the medial surface 21 (not shown) resting on top of the glenoid. FIG. 15 illustrates a completely inset glenoid implant with the extended articular surface 20 removed for clarity or not present, and the lateral surface 15 of the inset body portion 17 is shown. FIG. 16 illustrates a side view of the glenoid implant of FIG. 14.

[0059] In some embodiments, disclosed is a method of treating a patient, including identifying a patient having a glenoid surface; reaming a cavity into the glenoid surface; and inserting a glenoid implant having an inset body portion and a peg, the inset

body portion having a bearing surface on a peripheral edge thereof into the cavity, such that at least a portion of, or the entire peripheral edge of the inset body portion resides below the adjacent glenoid surface and the portion residing below the adjacent glenoid surface is circumferentially surrounded by cortical bone of the glenoid, while an onlay body portion having a diameter or width greater than the inset body portion has an extended lateral articulating surface for articulation with a humerus or a humeral component, and a medial surface that rests on top of the glenoid surface.

Porous Coated Convertible Glenoid Implant

[0060] In some embodiments, disclosed herein are implants that can use porous coating as a fixation method and optionally allow for conversion to a reverse shoulder arthroplasty during a revision surgery. The use of cement during a total shoulder arthroplasty procedure adds additional cost and time to the surgery. Any design that can effectively provide short and long term cementless fixation can advantageously simplify the procedure and reduce overall cost and risk to the patient. The porous coating could be, for example, poly-ether-ether-ketone (PEEK), a biostable and biocompatible thermoplastic polymer, hydroxyapatite (or other crystalline phases of HA), metals, or combinations thereof. Some embodiments can include HA coated PEEK implants, but can also include any polymer of the poly-aryl-ether-ketone family such as, but not limited to, poly-ether-ketone (PEK) and poly-ether-ketone-ether-ketone-ketone (PEKEKK), or others such as UHMWPE. In some embodiments, the coating can be applied via a plasma spray process. Prior to coating PEEK (or other similar polymers) with HA (or other crystalline phases of HA), the surface of the PEEK can be textured to provide a more suitable surface for HA deposition. Texturing of the surface further enhances the bond strength between the coating and the PEEK and also enhances fixation of the PEEK between the adjacent vertebrae, due to bony ingrowth, upon resorption of the coating. The surface of the porous coating may be textured into microstructured, macrostructured, microporous or macroporous morphologies. Texturing can be accomplished, for example, by grit blasting using a suitable media such as alumina, or by machined grooves or threads, or any other method that may allow for texturing of the surface. Alternatively, a metal porous coating, such as titanium or its alloys, stainless steel alloys,

cobalt-chromium (Co—Cr) alloys, tantalum alloys, zirconium alloys, nitinol, or other metals and/or metal alloys can be used. One example of a suitable titanium-based material is commercially pure (CP) titanium. Examples of different grades of CP titanium are specified in ASTM F67 as grades 1-4. One example of a suitable titanium alloy is a titanium-aluminum-vanadium (Ti—Al—V) alloy. In one embodiment, the Ti—Al—V alloy is Ti—Al6-V4, or Ti-6-4, which includes 6% aluminum and 4% vanadium and is sometimes referred to as grade 5 titanium alloy. In some embodiments, the porosity can be between about 20% and about 80%, such as about 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, or ranges including any two of the aforementioned values. In some embodiments, individual pore sizes may range from about 100 μm to about 1000 μm, and such as from about 200 μm to about 300 μm in some cases.

[0061] By adding one or more porous coated elements to the underside of a glenoid implant, short and long term fixation can be created. Conventional devices either created a modular implant with a plastic glenoid articular surface implant fitting in to a metal stem and metal underside with porous coating and/or a porous stem compression molded to a plastic glenoid articular surface.

[0062] The use of a modular, metal backed implant can be deficient in multiple areas. First, the addition of metal backing required a reduction in polyethylene thickness. This increased the contact stresses in the plastic leading to early failures. Second, the poor mechanical lock between the plastic and metal backing, along with a non-polished metal surface, created wear debris that led to glenoid bone osteolysis and implant failure.

[0063] The use of porous stem compression molded to the articular plastic only provides stem fixation of the implant. Any loading that occurred off the axis of the stem creates a bending moment about the metal/plastic compression molded interface leading to wear debris generation and implant failure.

[0064] Some embodiments include a metal/plastic modular glenoid implant using porous coating fixation. The porous structure, e.g., ring can be attached to the inferior periphery of the plastic glenoid implant as shown in FIGS. 17-20. As illustrated in FIG. 17 glenoid implant 498 can include a body 401 that can be made of metal or plastic for example, and include a large diameter lateral portion 403 and a smaller diameter medial portion 405

(shown in FIG. 19), lateral articulating surface 402, medial surface 404 (shown in FIG. 19), central peg 406, and a porous ring 408 directly adjacent to both the peripheral edge of the medial surface 405 of the metal or plastic component and the medial surface of the large diameter lateral portion 403 of the body 401. The ring 408 can include a central aperture circumscribing a portion of the central peg 406 and a peripheral edge that can generally mirror the peripheral edge of the metal or plastic component, and have a maximal outer diameter that is the same as or substantially the same as that of the metal or plastic component. In some embodiments, the porous ring 408 can include one, two, three, four, five, or more spaced-apart radially inward indentations 410 that can be utilized, for example, for fixation after later optional conversion to a reverse glenoid. FIG. 18 is a side view of the implant of FIG. 17.

[0065] FIG. 18A schematically shows a side sectional view of a porous coated ring 1802, with a snap ring 1804 that can be present for assembly to the implant 1800. One potential issue that could be encountered is if the bearing surface of the implant 1800 (e.g., polyethylene bearing surface) wears, it could produce a metal on metal interaction. As such, compared with FIG. 18A, the ring 1806 thickness could be asymmetrically reduced in the posterior glenoid relative to the anterior glenoid, as shown in FIG. 18B, wherein the anterior surface of the ring 1806 is angled, e.g., not parallel to the backside of the glenoid. In some embodiments, the thickness of the ring 1806 in the posterior of the glenoid is about or at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, or 90% less than the thickness of the ring 1806 in its anterior portion, or ranges including any two of the aforementioned values.

[0066] In some embodiments, the glenoid implants need not be convertible from anatomic to reverse. An implant could include a porous coated ring or band around the periphery of the implant body, partially or completely circumscribing the peripheral edge of the implant, somewhat similar to bands around a wine barrel. In some embodiments, the porous coating can be present in lieu of a metal backing component. In other words, a metal backing component can be absent in some embodiments and the porous ring forms the backside of the implant (other than the peg(s) or keel(s) in some cases).

[0067] In some embodiments, instead of a locking snap ring as shown in FIG. 18A, an interlocking assembly could be used to leverage the forces in the shoulder. FIG. 18C schematically illustrates a cross-section of an embodiment of a glenoid implant 1860 with a porous ring 1862. FIG. 18C schematically illustrates anatomic loads AL; outward forces (arrows at 1888) created by in-use loads; cement 1882 and forces 1884 present during cement cure; and an interlocking surface 1886 with can be present at an incline in some cases. The outward force can create more intimate contact with bone, potentially improving fixation and the bone response. The fixation ring 1890 can be split (e.g., having an incomplete ring defining a channel 1891) in some cases in order to assemble onto the implant, as illustrated in FIG. 18D.

[0068] The initial and long-term fixation of another embodiment of an implant 498' can also be enhanced by the optional use of a porous coated stem 499, as illustrated in FIGS. 19-20. In addition, if the glenoid implant ever needs to be revised/removed for a reverse shoulder arthroplasty, the metal ring can be disengaged from the plastic implant by removing the plastic, leaving the porous ring in the subchondral bone. This ring can then be engaged with a metal reverse shoulder arthroplasty baseplate, thus providing immediate strong fixation between the ring and the metal baseplate.

[0069] By using a porous coated metal structure, e.g., a ring on the underside of the plastic implant, any off-axis loads can be advantageously readily counter-acted by the large diameter ring fixed into the subchondral bone. The ring is in some embodiments only used on the periphery of the plastic, thus keeping the plastic (or plastic plus porous structure) at a minimum thickness of about 3mm which is the normal amount required for successful implant longevity, or at least about 2mm, 2.5mm, 3mm, 3.5mm, 4mm, or more.

[0070] The ring can be attached in multiple ways to the polyethylene including press-fit or compression molded (e.g., without any adhesive or cement) and has the ability to be removed after implantation and reattached to a metal reverse arthroplasty baseplate.

[0071] It can be a difficult procedure to convert a primary shoulder arthroplasty to a reverse shoulder implant during a revision surgery. Not only is the original plastic implant difficult to remove, but the initial fixation of the reverse metal baseplate must begin to form

at the completion of surgery. Having a component of the reverse implant already well-fixed enhances the overall integrity of the reverse shoulder construct immediately post-op.

Humeral Head with Textured Underside

[0072] Some embodiments can include texturing of the underside of a humeral head. FIGS. 21 and 22 illustrate embodiments of bottom views of humeral heads 800, 900. This can include both texturing along with the method of implanting a textured humeral head so that it contacts the resected humeral bone. The texturing can include a layer of porous material along a flat base head underside. It also, alternatively or in addition, could include creating non-planar surfaces such as concentric annular rings 802 which can have circumferential 804 and/or axially 806 oriented channels therebetween as shown in FIG. 21, sinusoidal waves, elongated grooves 902 as shown in FIG. 22, or other desired patterns.

[0073] In some embodiments, systems and methods involving a humeral head can advantageously include an underside with an enlarged surface area relative to a flat underside to contact the resected surface of the humeral head thereby distributing loads incurred during gleno-humeral articulation and allowing for bone in-growth into the humeral head underside. In some embodiments, the enlarged surface area is about or at least about 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95%, 100%, or more relative to a flat underside humeral head, or ranges incorporating any two of the aforementioned values.

[0074] Bone resorption tends to occur in the areas surrounding a humeral stem implant. This resorption occurs due to a lack of load transmission from the implant in to the bone. By purposefully engaging contact between a large portion of the humeral head and the resected bone surface, compressive and tensile load transfer can occur, thus eliminating the possibility of bone resorption around the implant.

[0075] Prior devices either ignored the possibility of bone resorption or included a collar of metal at the proximal aspect of the implant to distribute the loads. The collars used on other devices is typically either too small or too large. The majority of devices using a collar employ a small diameter configuration. The small diameter was used to allow for the use of skirts on concentric and eccentric humeral heads. The skirt is used to extend the

articular surface of the humeral head implant and to provide a more appropriate looking AP x-ray. These small collars are not large enough in diameter to appropriately transmit loads into the resected bone. The larger diameter collar design is also in use. This collar edge was exposed to the surrounding soft tissues which led to irritation as the tissues rubbed against the edges of the collar. In addition, the larger diameter collar did not allow for the humeral head articular region to extend below the collar.

[0076] By texturing the underside of the humeral implant and forcing contact with the resected bone at implant insertion, the head now can serve as the implant pseudo-collar, and an actual collar is not required. This allows for load transmission at the furthest margins without creating any sharp features. It also allows for the humeral head articular region to extend all the way down to the resected bone surface.

Additional Glenoid Embodiments

[0077] FIG. 23A illustrates a perspective view of an embodiment of a fixation support, e.g., a fixation ring 2000 that can be fixed at least partially or entirely within a prepared glenoid cavity as previously described. The fixation support 2000 can be generally annular and include a plurality of spaced apart indents or slots 2014 along the peripheral side edge 2009 of the support 2000. The indents 2014 can be configured to prevent or inhibit rotation of the support 2000 as well as be sized and configured to fit bone fragments or other debris within from the reaming process and during implantation of the support 2000 and assist in preventing fracturing of the reamed glenoid cavity. Also illustrated are apertures 2002 spaced proximate the peripheral edge 2009 of the support 2000 configured to house screws or other fixation elements. The support 2000 can also include one or more apertures, such as central aperture 2006 configured to house a peg or keel of the glenoid implant 2080, such as via press-fit. However, other ways to house the glenoid implant 2080 such as threaded surfaces, barbs, and the like can The fixation support 2000 could include upper surface 2007, lower surface 2011, and peripheral side edge 2009 as previously described. In some embodiments, upper surface 2007 can be a machined surface, and lower surface 2011 and peripheral side edge 2009 could be porous surfaces. The glenoid implant 2080 can removably interface with the support 2000 as schematically illustrated in FIG. 23B, and be

exchanged for a different implant, such as a reverse implant 2077 as schematically illustrated in FIG. 23C.

[0078] In some embodiments, the fixation support does not include a snap ring.

[0079] FIGS. 23D-23F schematically illustrates views of an anatomic glenoid implant 2100 configured to mate with a porous fixation ring (not shown). FIG. 23D is a side view, FIG. 23E is a close-up side view, and FIG. 23F is a perspective view. Glenoid implant 2100 can be partially or fully inset within a reamed glenoid cavity in some embodiments as described for example elsewhere herein. Glenoid implant 2100 can include a medial surface 2110 including one or more backside pegs, such as central peg 2102. Glenoid implant 2100 can also include a plurality of screws 2112 for additional fixation within the cavity. Glenoid implant can also include lateral articulating surface 2108, as well as a "two step" stepped thickness including first, lateral peripheral edge 2106 and second, medial peripheral edge 2104 with a surface 2105 that can include features such as barbs and/or threads for example, and be configured to reversibly mate with a fixation ring (not shown). Medial peripheral edge 2104 can have a diameter that is less than that of lateral peripheral edge 2106 in some embodiments such that the fixation ring can circumscribe the medial peripheral edge 2104 but not the lateral peripheral edge 2106. In some embodiments, the diameter of the medial peripheral edge 2104 can be between about 1mm and about 2mm less than about, or about 1.5mm less than about the diameter of the lateral peripheral edge 2106. In some embodiments, the diameters of each of the medial peripheral edge 2104 and the lateral peripheral edge 2106 can be constant or substantially constant (e.g., discrete steps). In some embodiments, the medial peripheral edge 2104 (and the corresponding fixation ring) can have a thickness/depth of about 3mm, such as between about 2mm and about 4mm, or between about 2.5mm and 3.5mm in some embodiments. In some embodiments, the outer diameter of the medial peripheral edge 2104 or the lateral peripheral edge 2106 can be from about 20mm to about 30mm, such as about 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30mm, or ranges including any of the foregoing values. In some embodiments, the thickness of the glenoid implant measured at a corner as shown in FIG. 23E by distance D can be between about 2mm and about 3.5mm, such as about 2.7mm in some embodiments. As illustrated in FIG. 23F,

glenoid implant 2100 can also include channels or grooves 2120 on the medial surface 2110 configured to house cement for additional fixation if desired.

[0080] FIGS. 23G-23H schematically illustrate a glenoid implant 2100 with smaller diameter medial peripheral edge 2104 and larger diameter lateral peripheral edge 2106 that can be as previously described, with a ledge 2121 extending between the medial peripheral edge 2104 and the lateral peripheral edge 2106 and configured to abut a lateral-facing surface of a fixation ring. The medial peripheral edge 2104 of the glenoid implant 2100 can include reverse barbs 2185 as illustrated. As shown in FIG. 23H, fixation ring 2190 can include barbs 2186 made of oversized metal or other elements and configured to reversibly press into the medial peripheral edge 2104 of the glenoid implant 2100 (either with or without reverse barbs). The lateral peripheral edge 2106 of the glenoid implant 2100 can be barb-less as illustrated. Fixation ring 2190, or portions thereof can be porous as previously described herein.

[0081] FIGS. 23I-23K schematically illustrate a glenoid implant 2100 with smaller diameter medial peripheral edge 2104 and larger diameter lateral peripheral edge 2106 that can be as previously described. The medial peripheral edge 2104 of the glenoid implant 2100 can include threads 2198. As shown in FIG. 23J, fixation ring 2190 can include threads 2199 configured to reversibly mate with the threads 2198 of the medial peripheral edge 2104 of the glenoid implant 2100. In some embodiments, the threads 2199 of the fixation ring 2190 can be self-tapping, in which the medial peripheral edge 2104 of the glenoid implant need not be threaded, as the self-tapping threads 2199 of the fixation ring 2190 can "bite" or otherwise transform the medial peripheral edge 2104 of the glenoid implant 2100. The lateral peripheral edge 2106 of the glenoid implant 2100 can be thread-less as illustrated. Fixation ring 2190, or portions thereof can be porous as previously described herein.

[0082] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above

may be made and still fall within one or more of the inventions. For example, some embodiments can include one, two, or more of a hybrid inset-onlay glenoid implant, a porous ring structure, and/or a textured underside humeral implant. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "reaming a glenoid implant" includes "instructing the reaming of a glenoid implant." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least," "greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

WHAT IS CLAIMED IS:

1. A method of performing a reversible anatomic shoulder replacement procedure, comprising:

reaming a cavity into the glenoid; and

inserting an anatomic glenoid articular implant into the glenoid cavity, the glenoid anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; and an intermediate component between the lateral surface and the medial surface, the intermediate component having an outer diameter reversibly attached via press fitting to a fixation ring at least partially comprising a porous surface, the fixation ring at least partially implanted within the glenoid cavity.

2. The method of Claim 1, wherein the anatomic glenoid articular implant is partially inset into the glenoid cavity.

3. The method of Claim 1, wherein the anatomic glenoid articular implant is fully inset into the glenoid cavity.

4. The method of Claim 1, wherein the cavity comprises a circular cavity.

5. The method of Claim 1, wherein the cavity comprises an oval cavity.

6. A reversible anatomic shoulder replacement system, comprising:

a fixation ring configured to be positioned within the glenoid cavity, the fixation ring at least partially comprising a porous coating, the fixation ring also comprising a peripheral edge comprising an outer diameter; and

an anatomic articular implant comprising a medial surface configured to mate with the glenoid cavity, a central peg extending medially from the medial surface, a lateral surface configured to articulate with a humeral component; a medial peripheral edge; and a lateral peripheral edge, the medial peripheral edge comprising a substantially constant diameter that is less than a substantially constant diameter of the lateral peripheral edge, the fixation ring comprising an inner diameter sized and configured to circumscribe the medial peripheral edge of the implant,

wherein the fixation ring is configured to be at least partially implanted within the glenoid cavity.

7. The system of Claim 6, wherein the fixation ring comprises anti-rotation features on an outer diameter of the fixation ring.

8. The system of Claim 6, wherein the peripheral edge of the fixation ring is configured to facilitate bone ingrowth.

9. The system of Claim 8, wherein the peripheral edge of the fixation ring comprises an osteoinductive or osteoconductive surface.

10. The system of Claim 6, wherein the inner diameter of the fixation ring comprises barbs.

11. The system of Claim 6, wherein the inner diameter of the fixation ring comprises threads.

12. The system of Claim 11, wherein the threads are self-tapping threads.

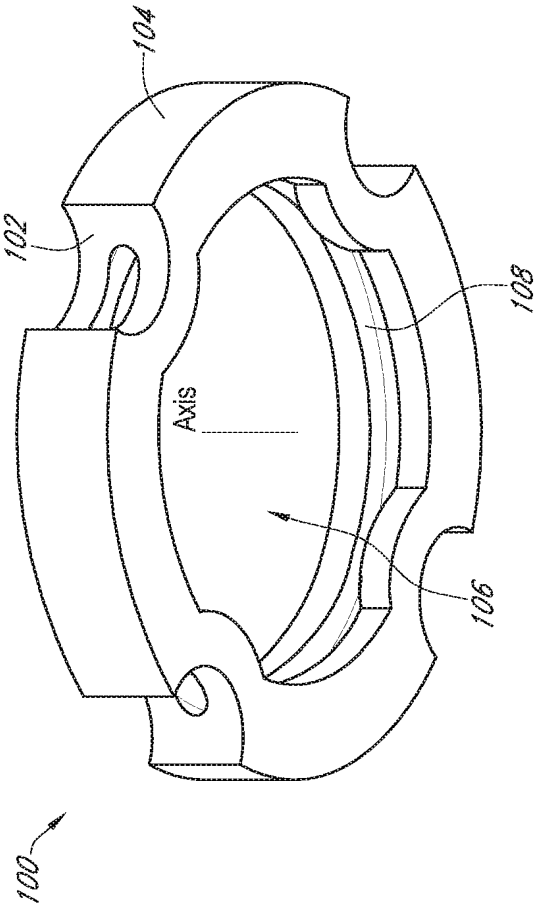


FIG. 1

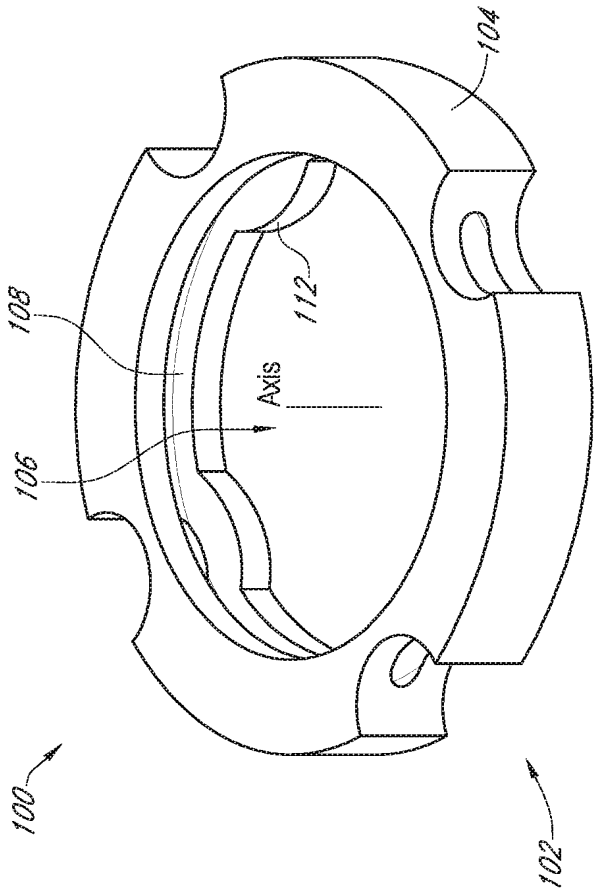


FIG. 2

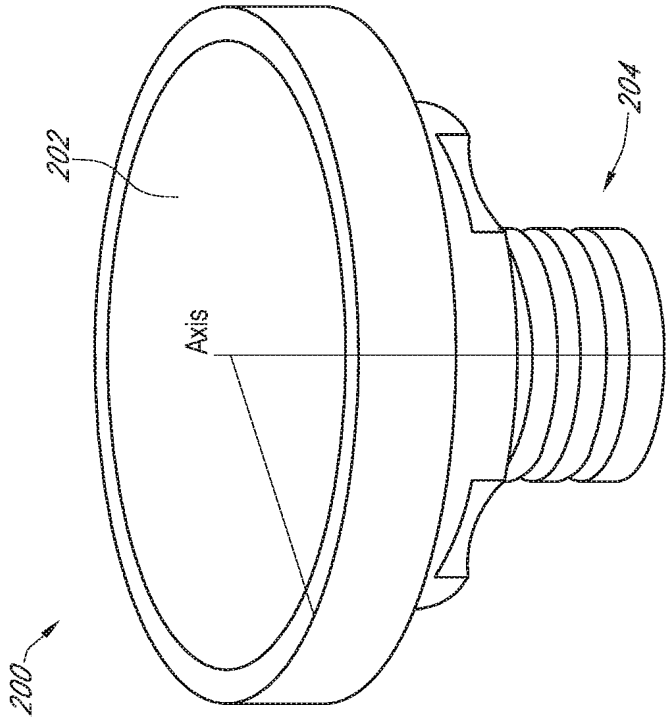


FIG. 3

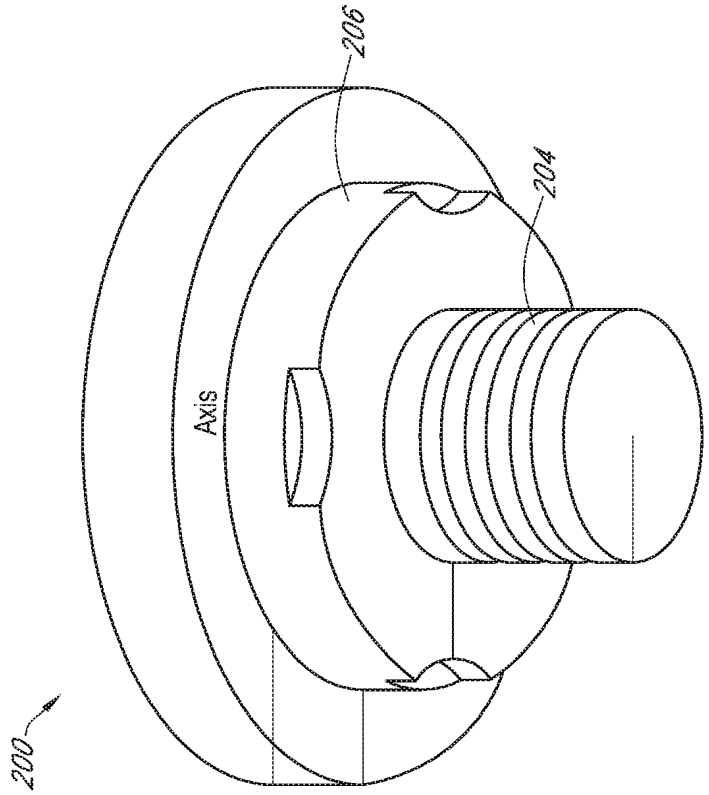


FIG. 4

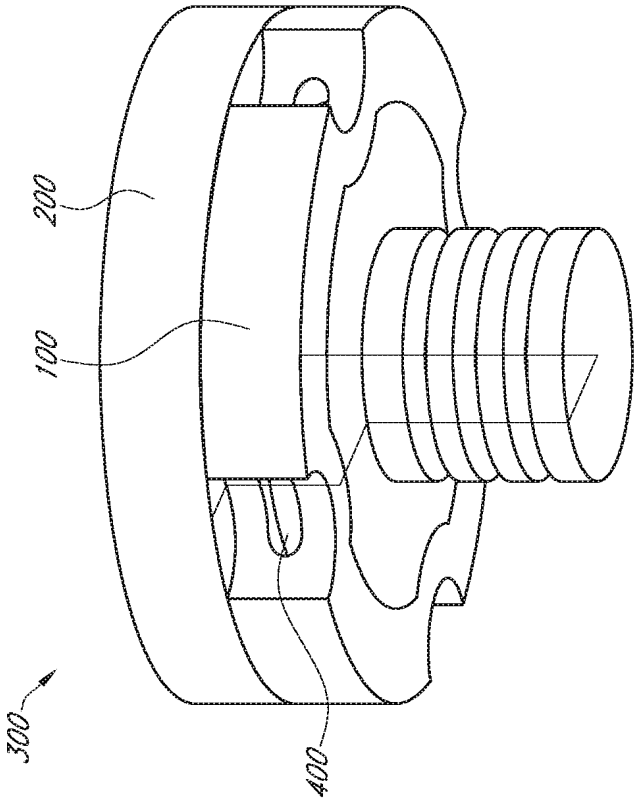


FIG. 5

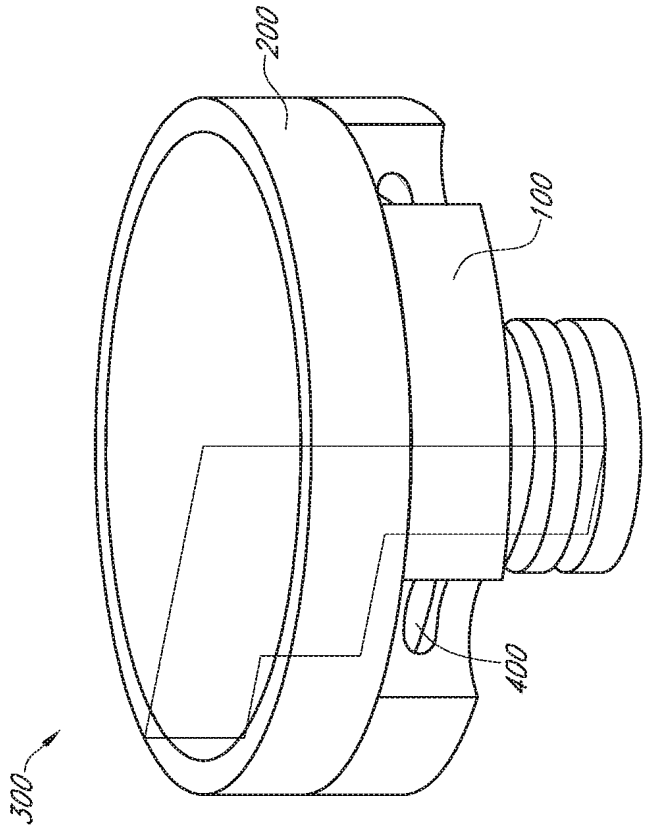


FIG. 6

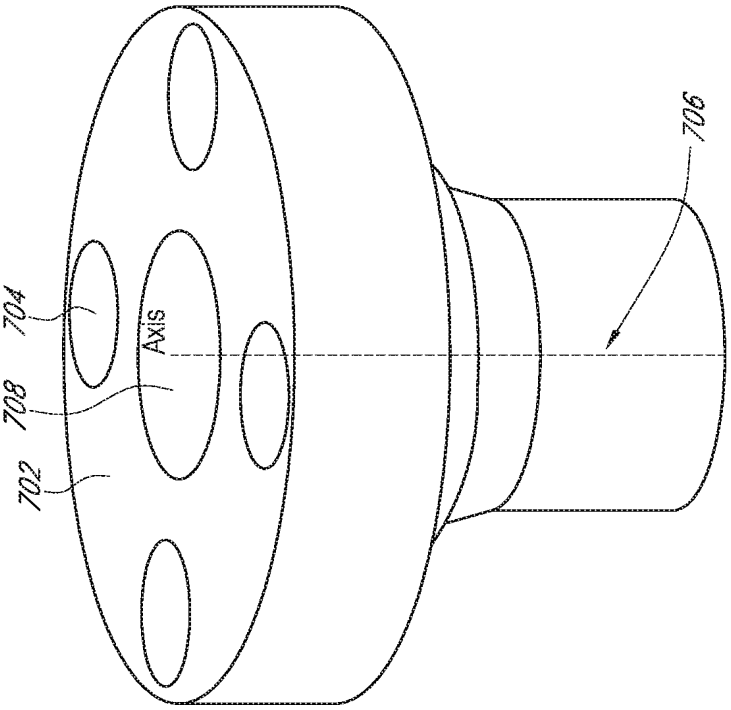


FIG. 7

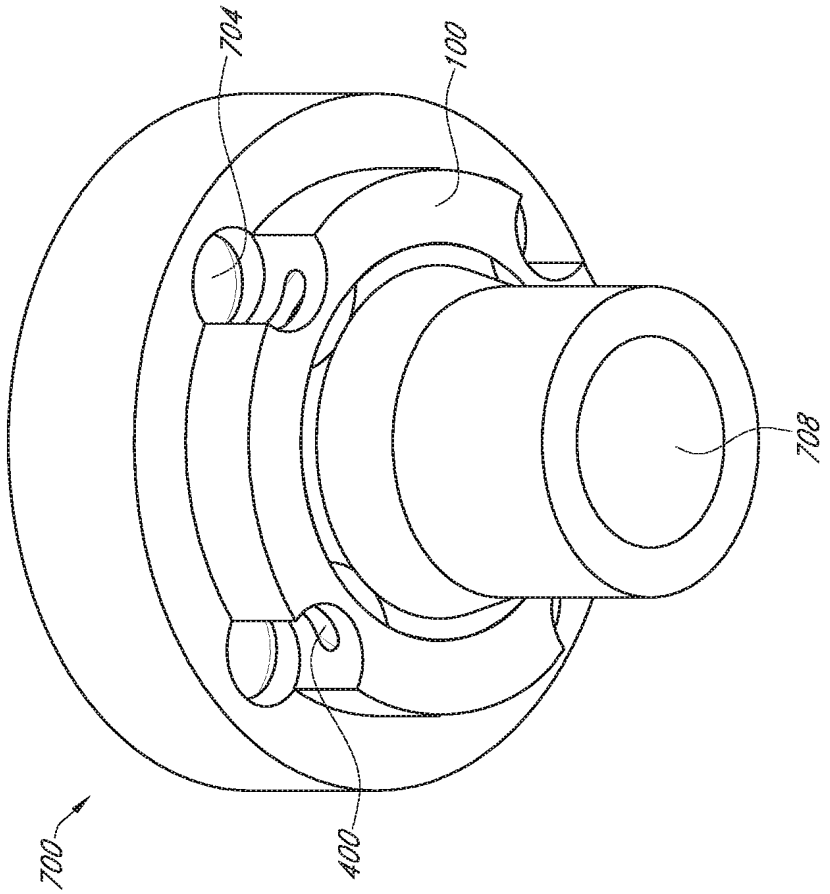


FIG. 8

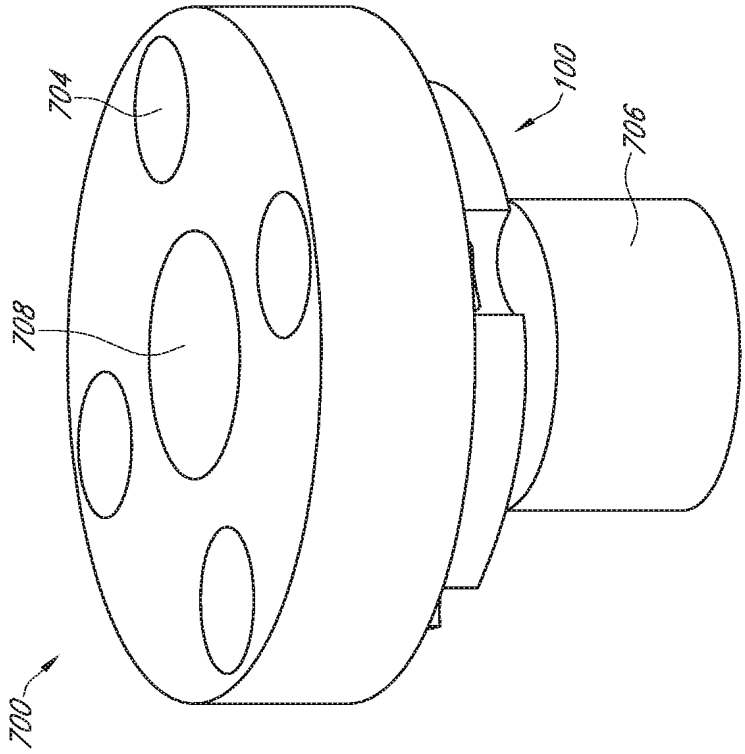


FIG. 9

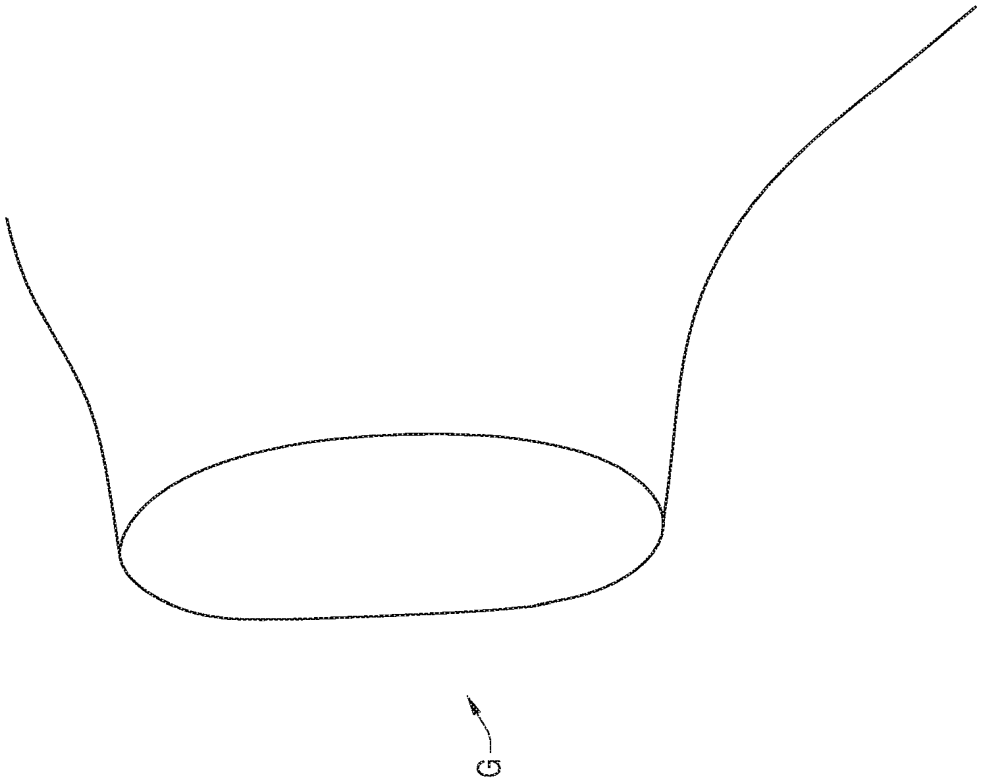


FIG. 10A

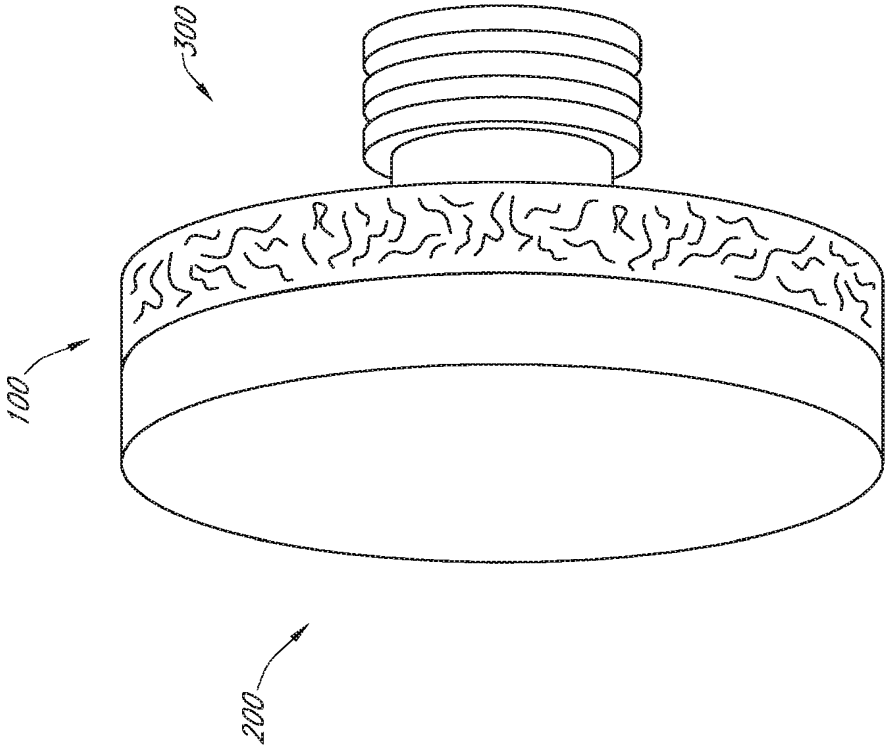


FIG. 10B

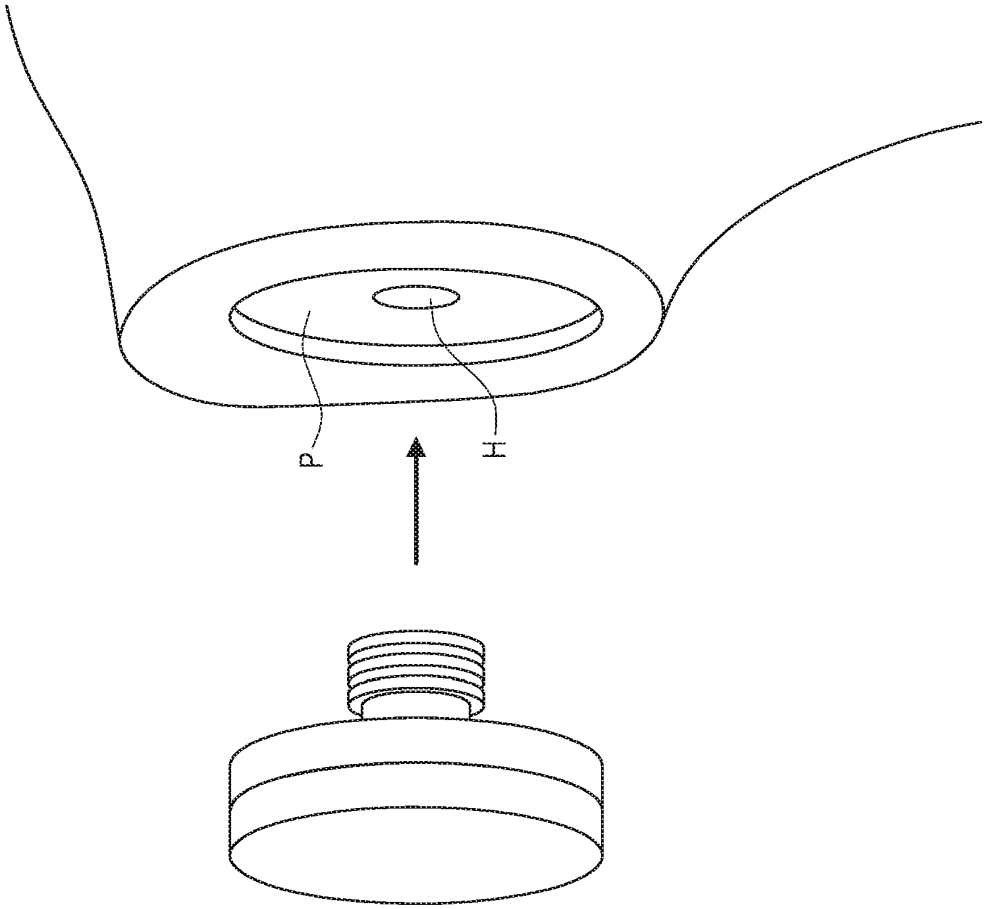


FIG. 10C

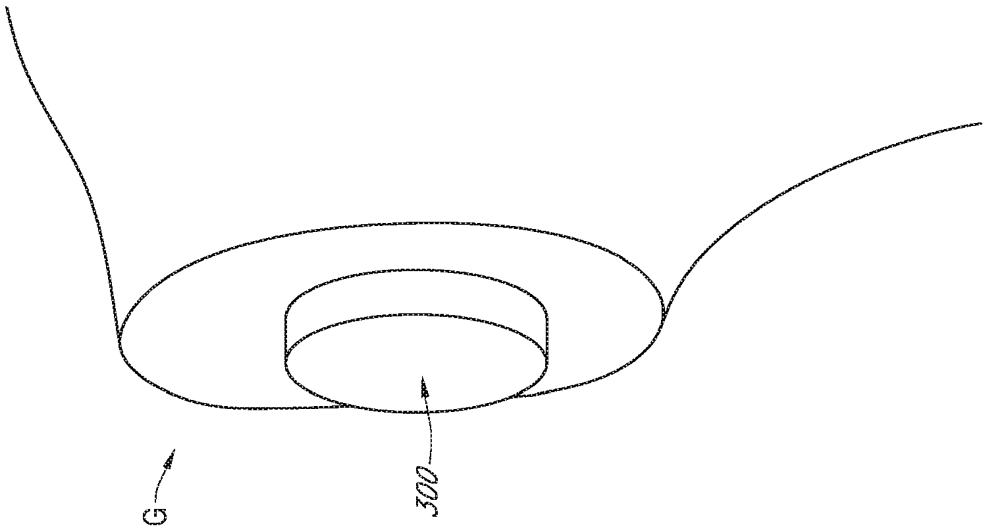


FIG. 11A

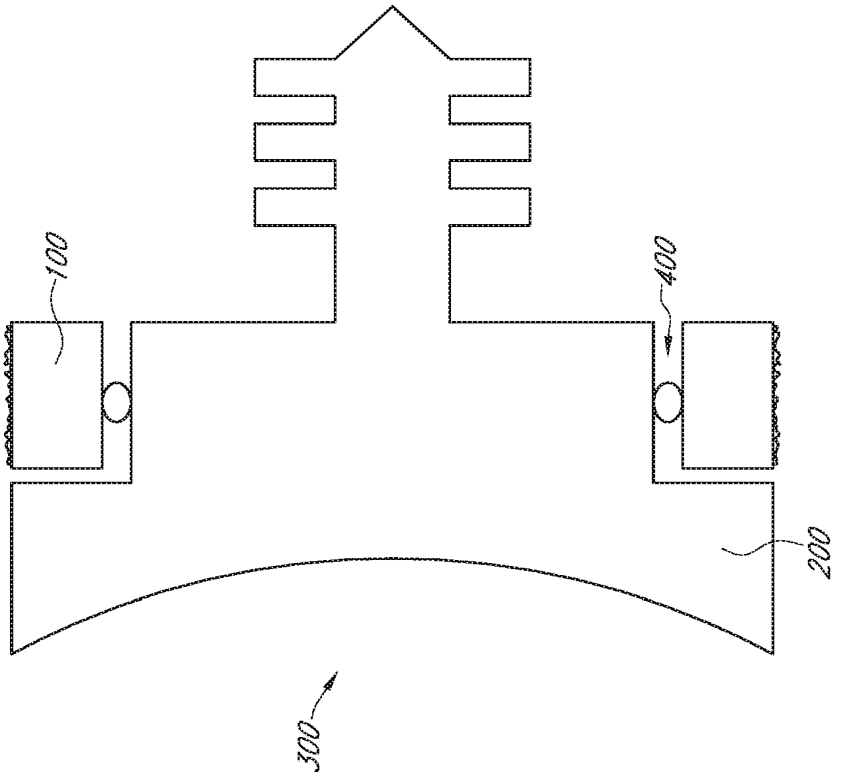


FIG. 11B

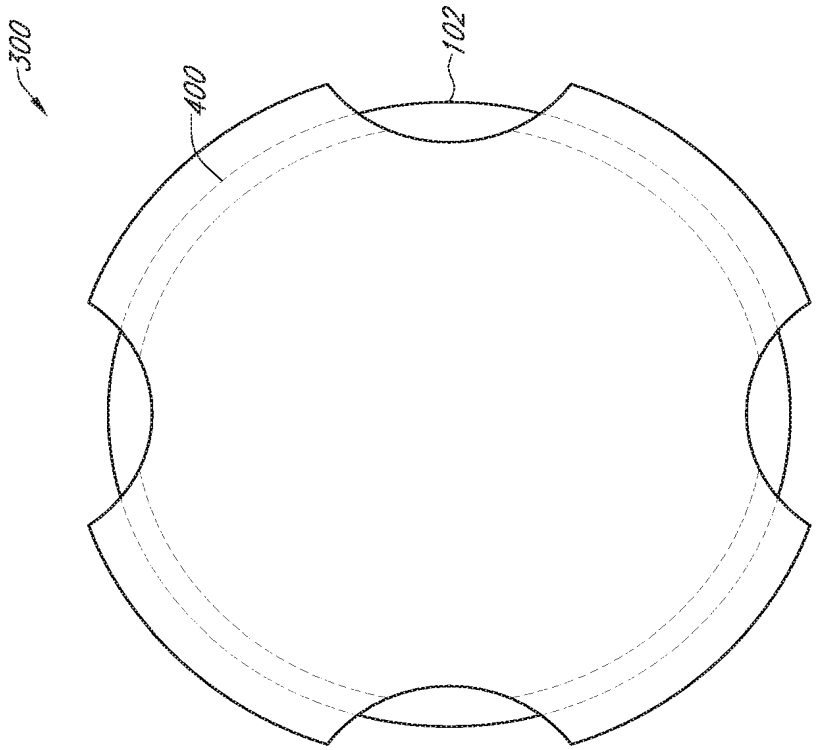


FIG. 11C

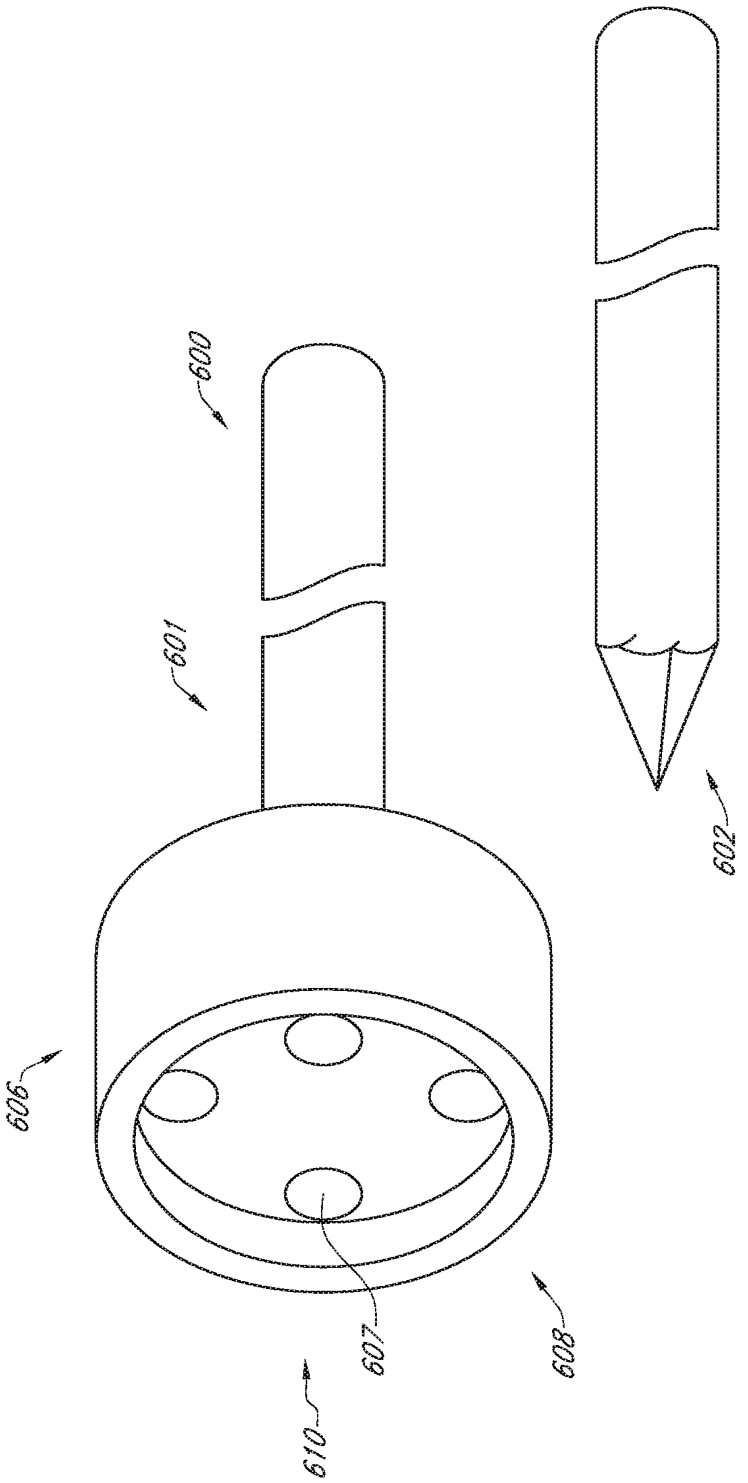


FIG. 11D

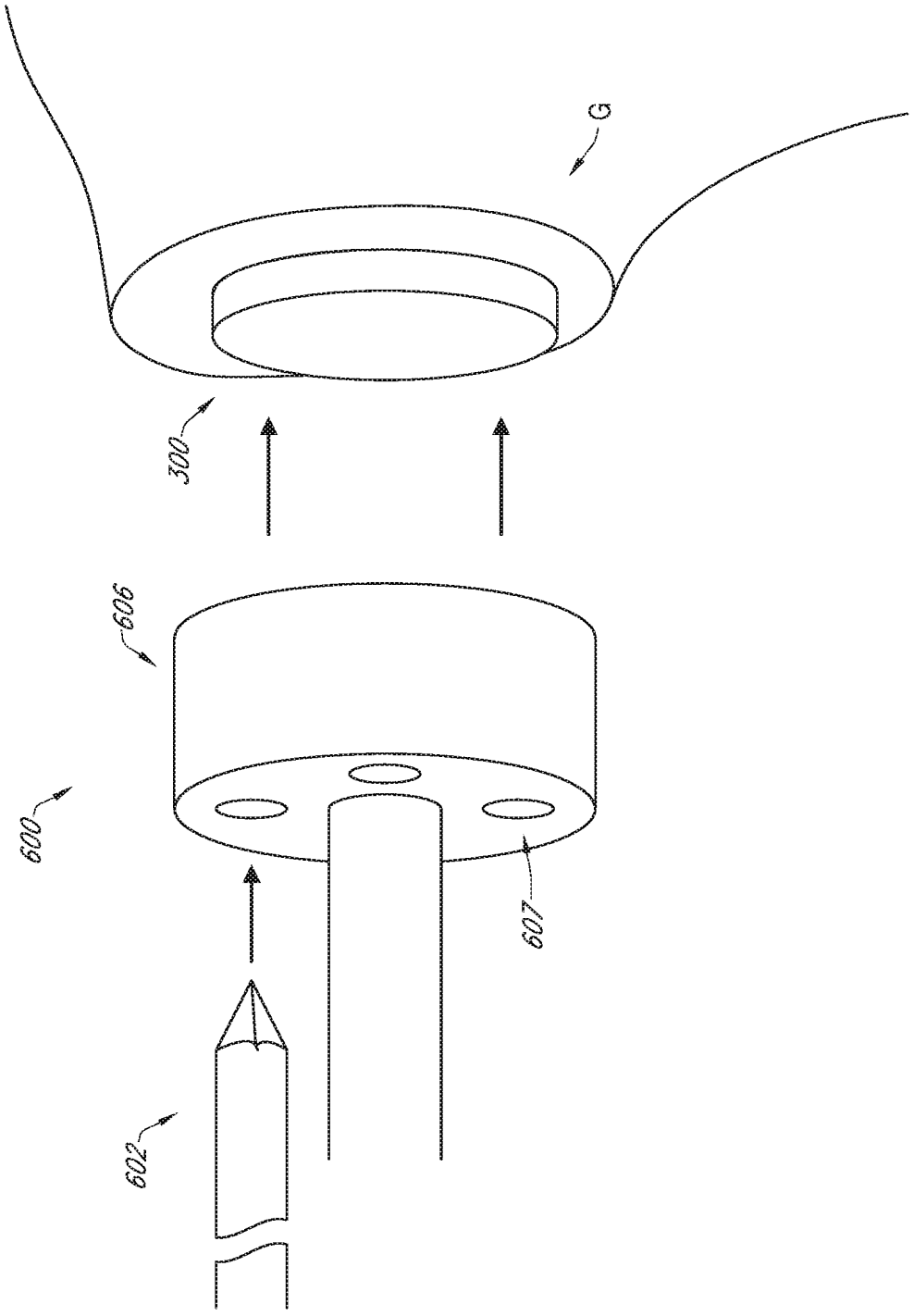


FIG. 12A

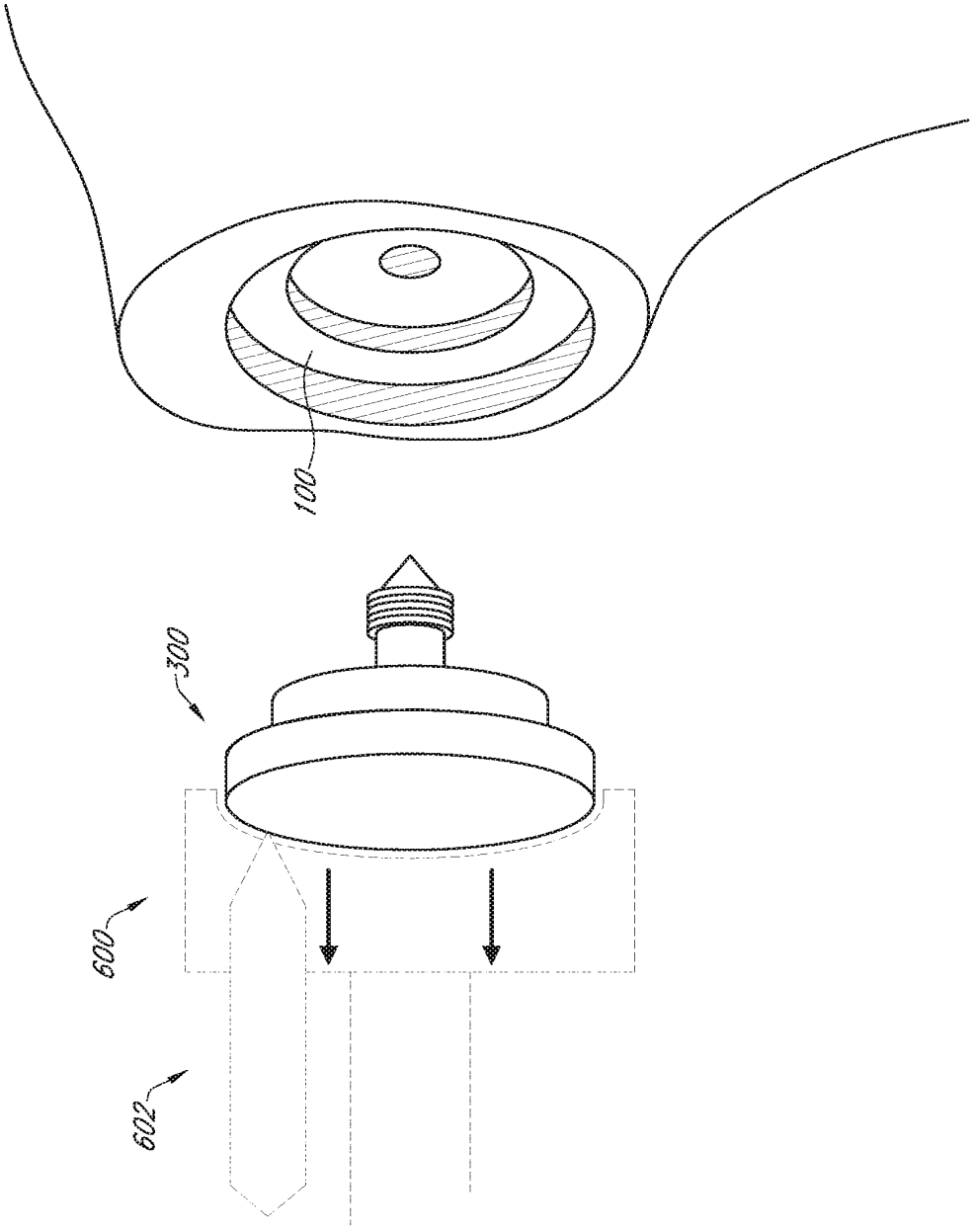


FIG. 12B

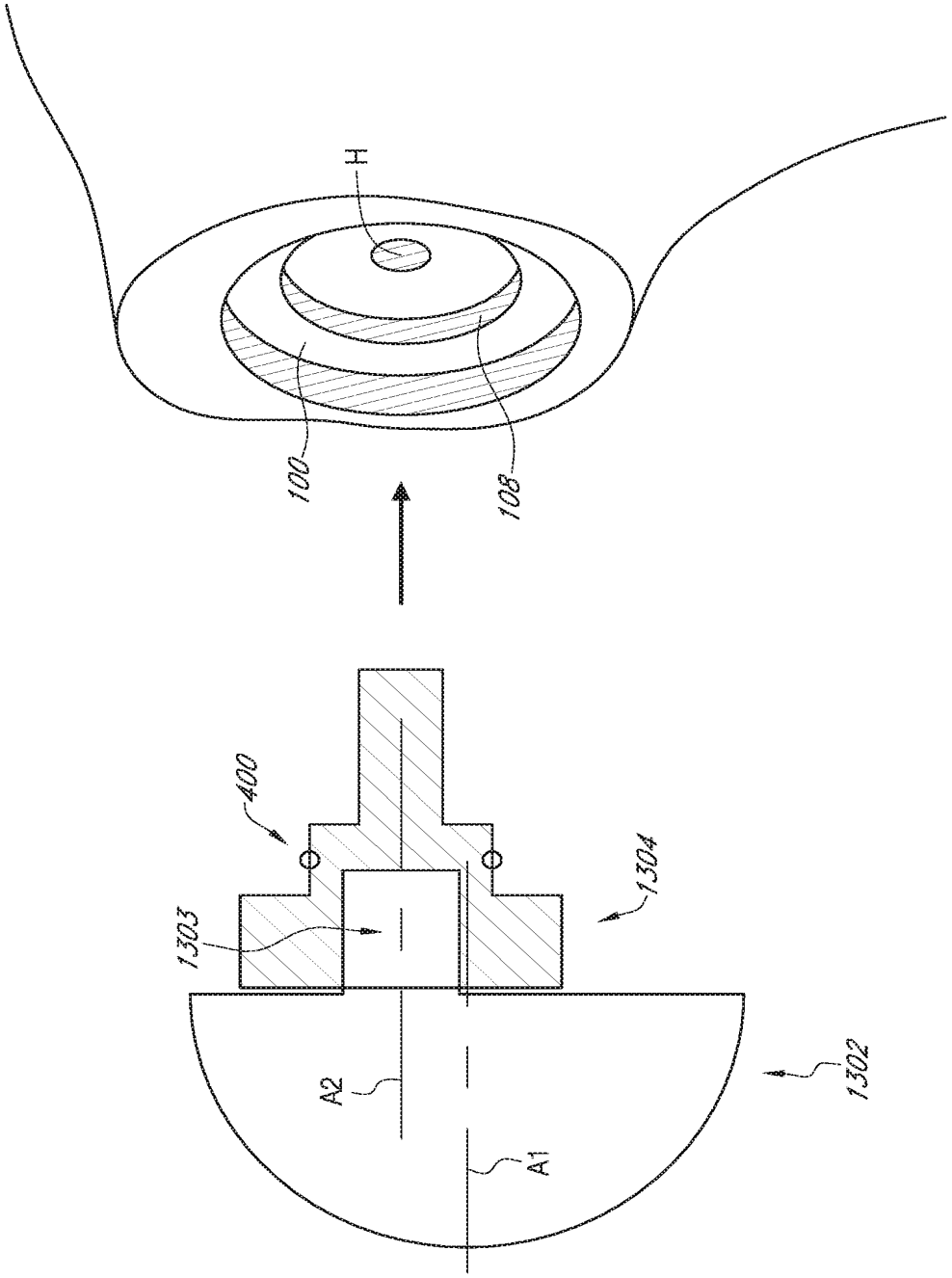


FIG. 13A

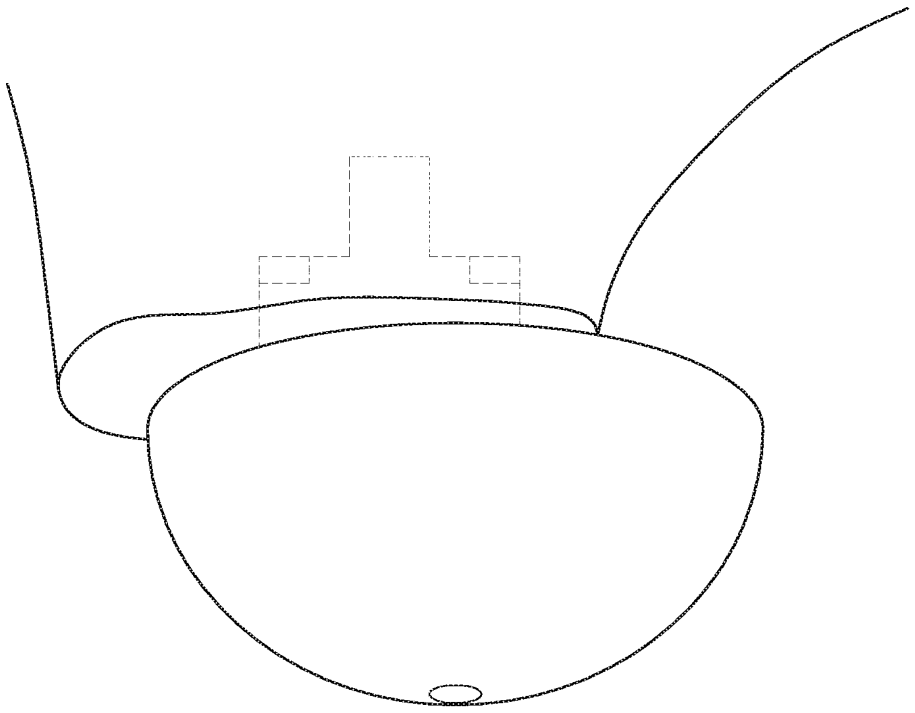


FIG. 13B

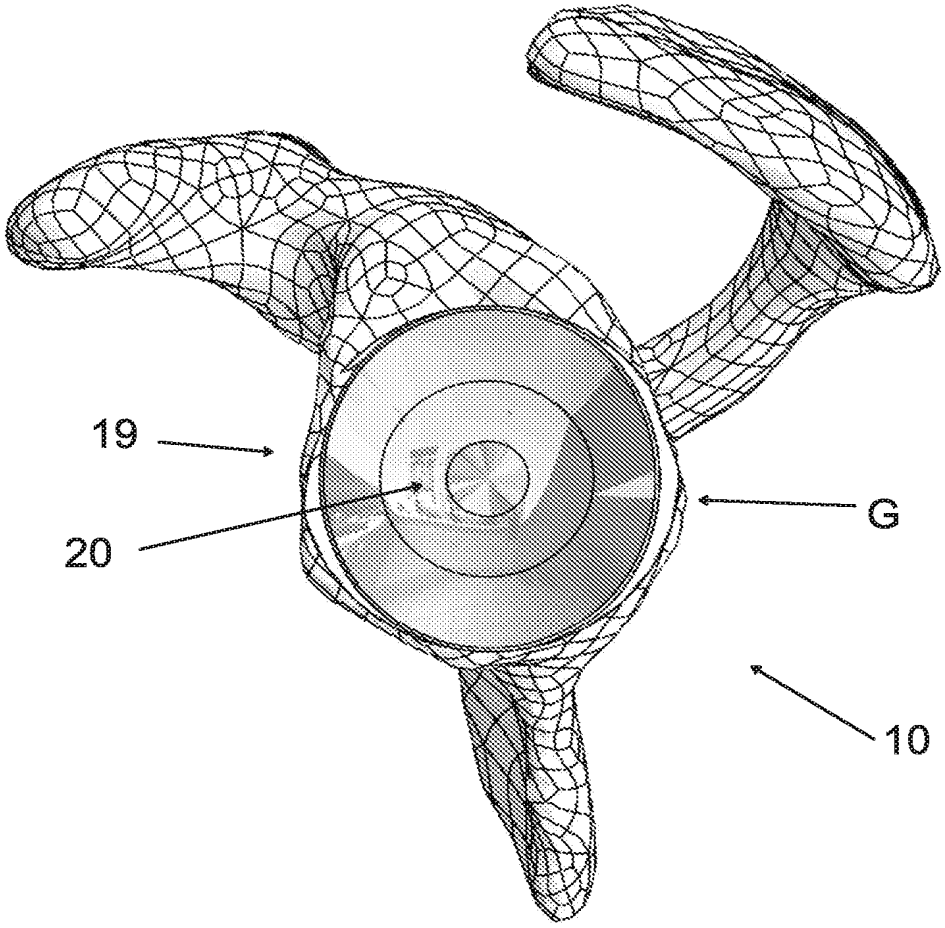


FIG. 14

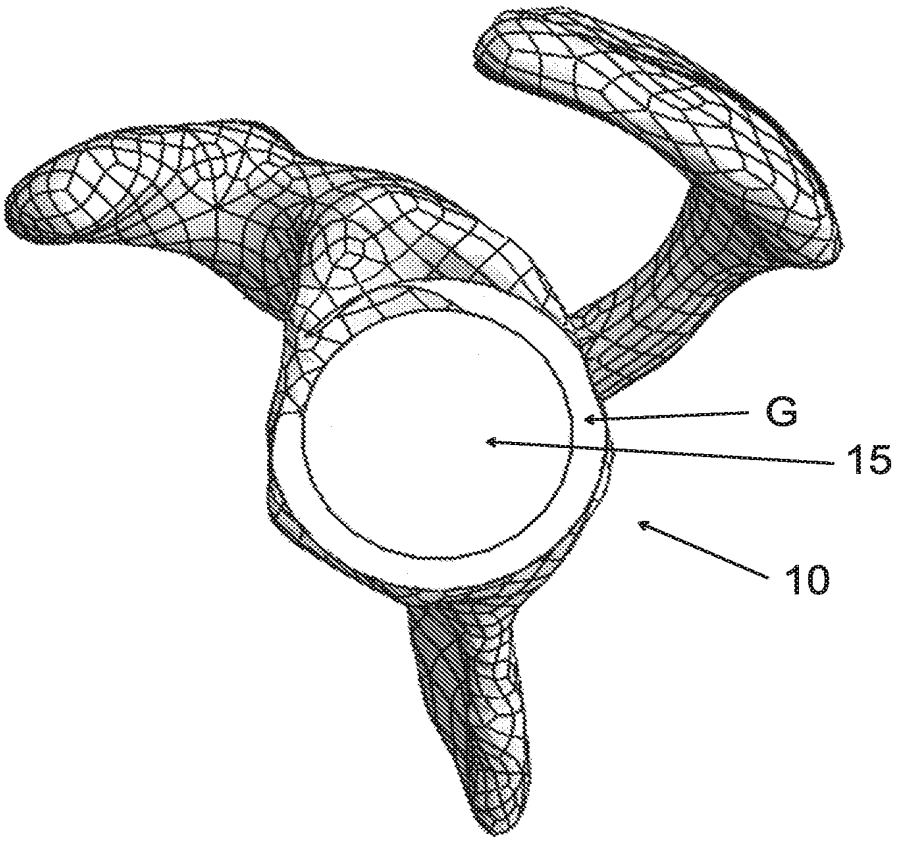


FIG. 15

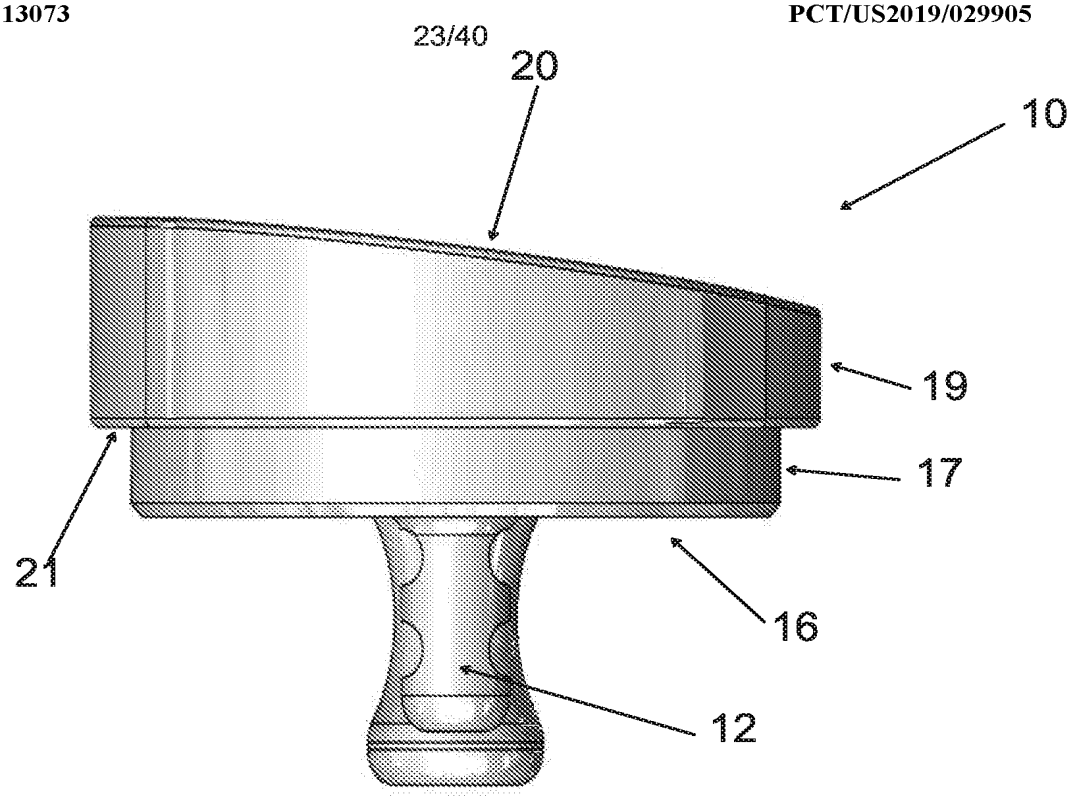


FIG. 16

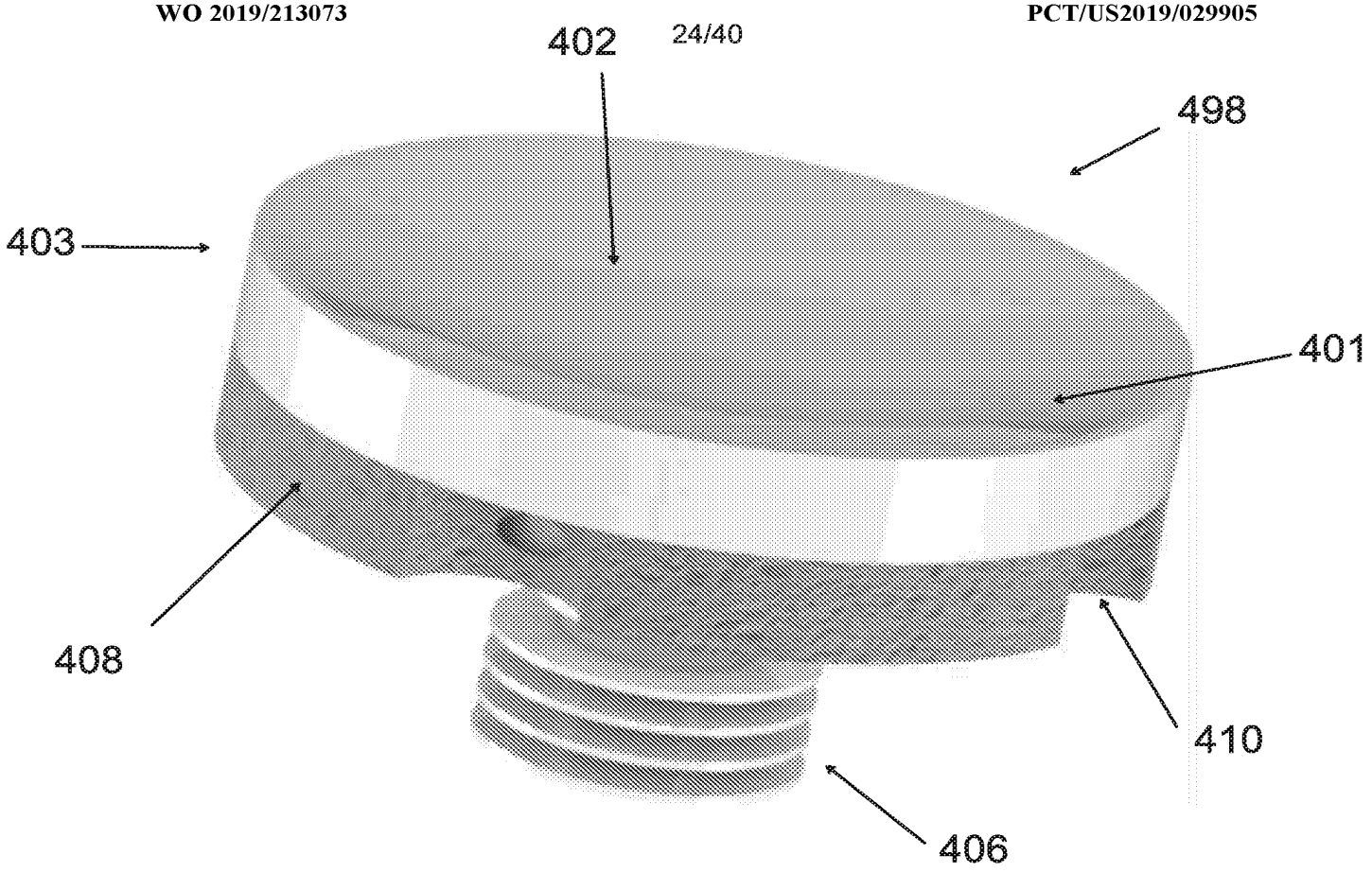


FIG. 17

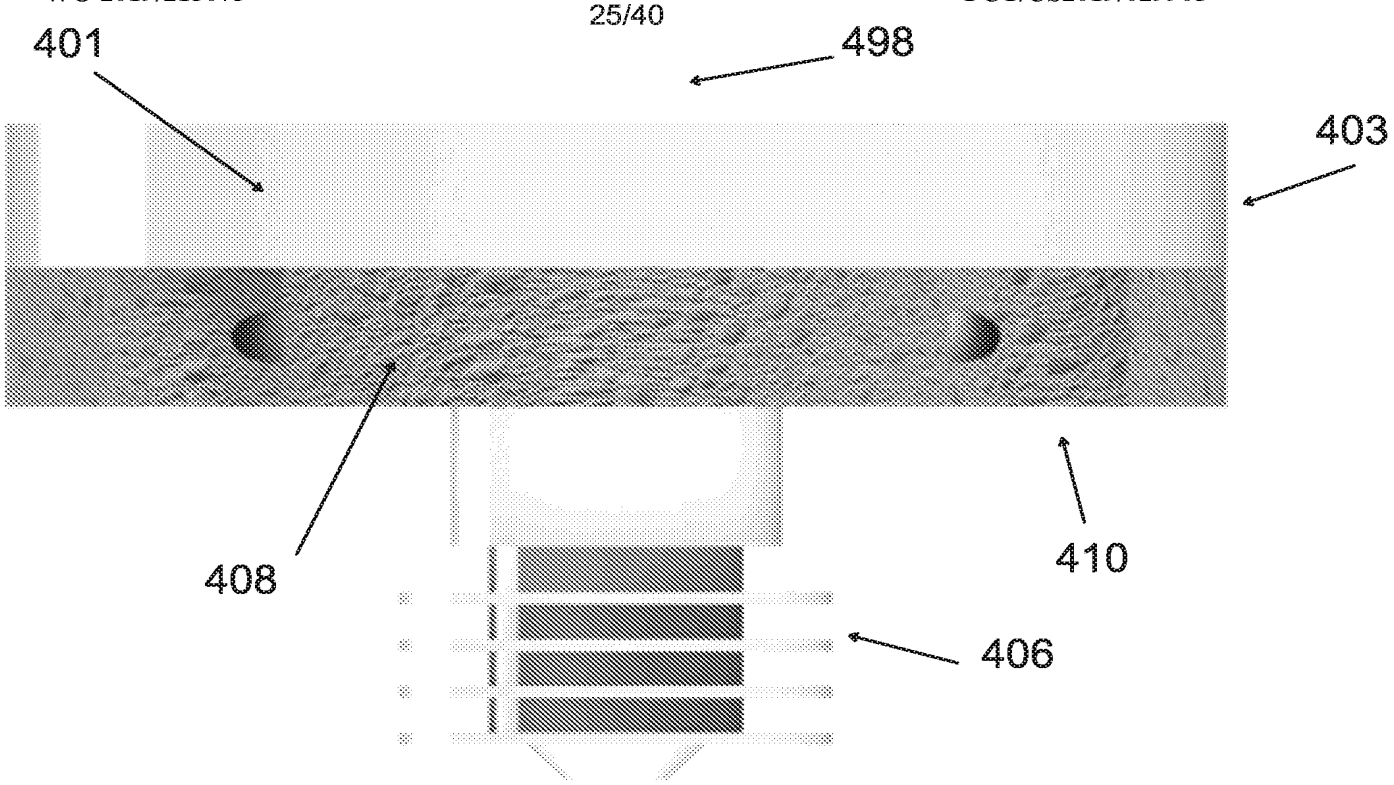


FIG. 18

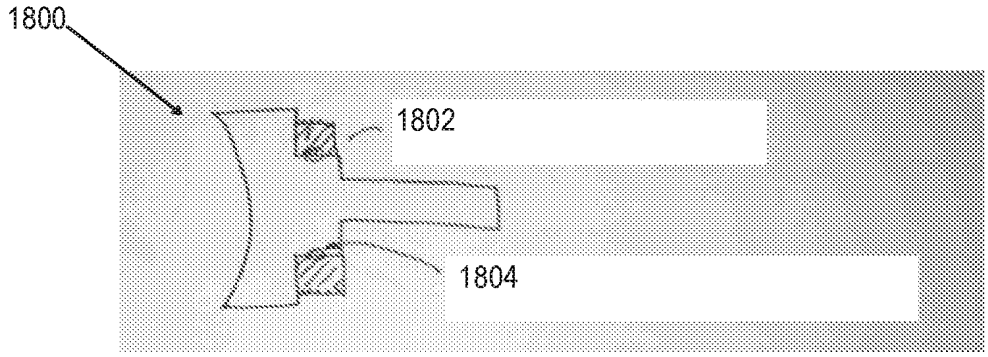


FIG. 18A

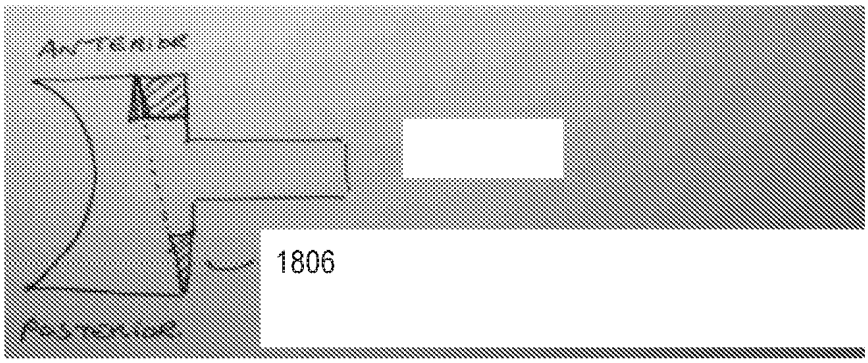


FIG. 18B

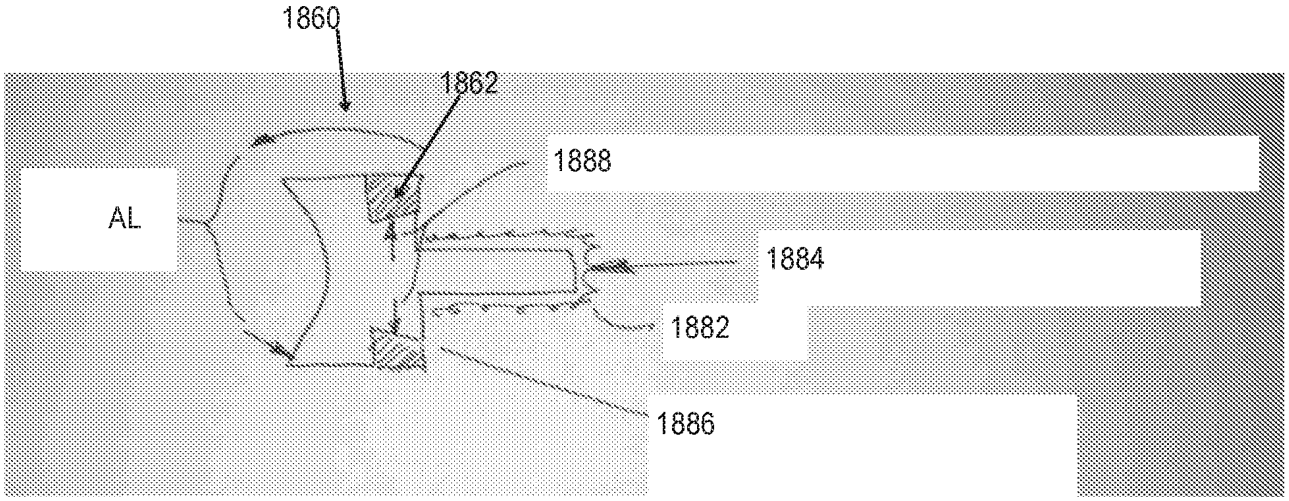


FIG. 18C

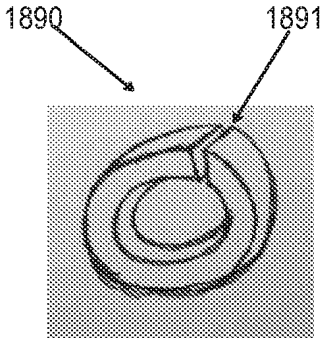


FIG. 18D

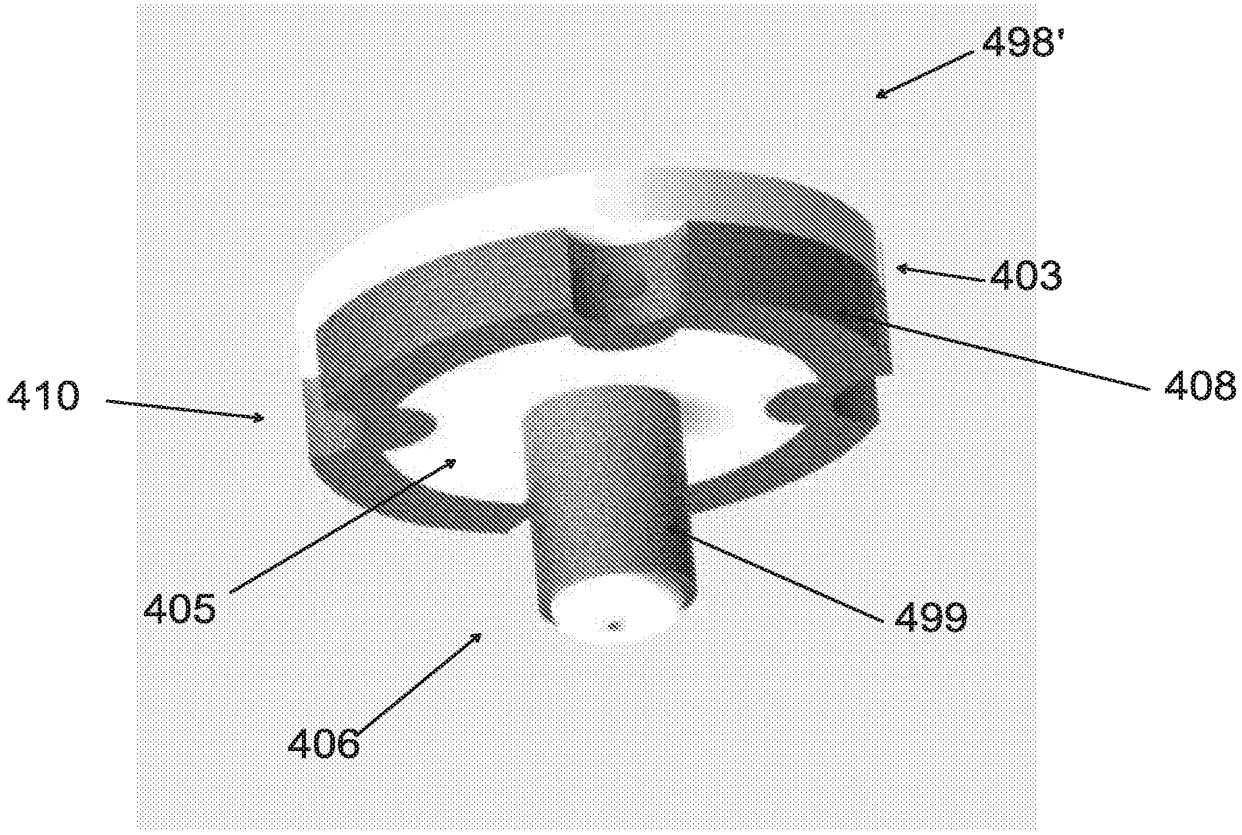


FIG. 19

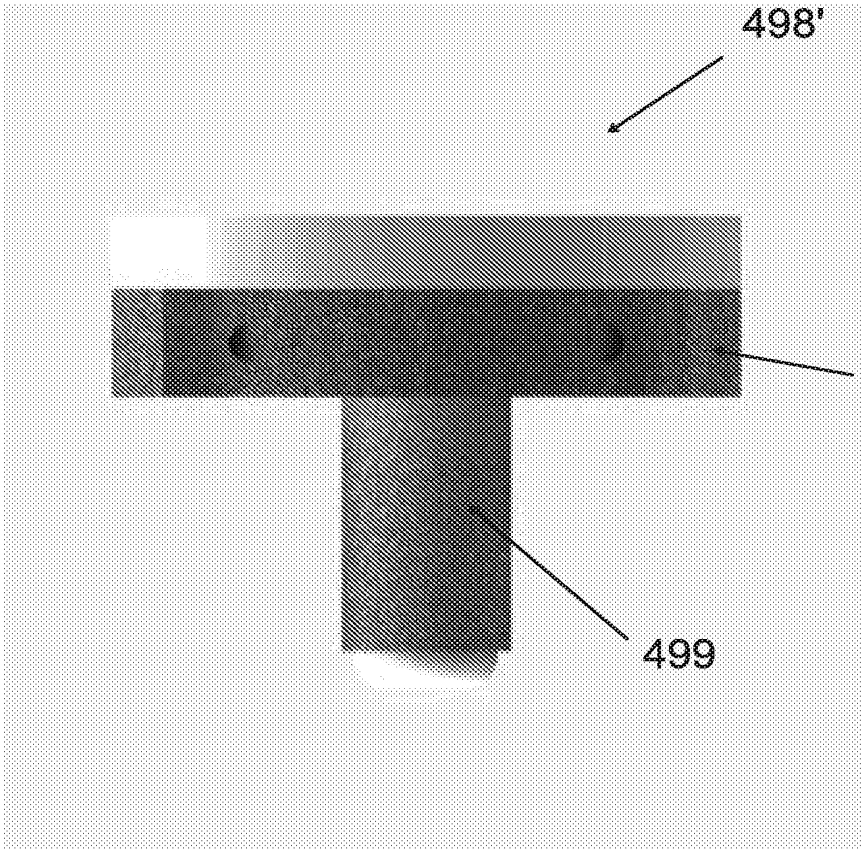


FIG. 20

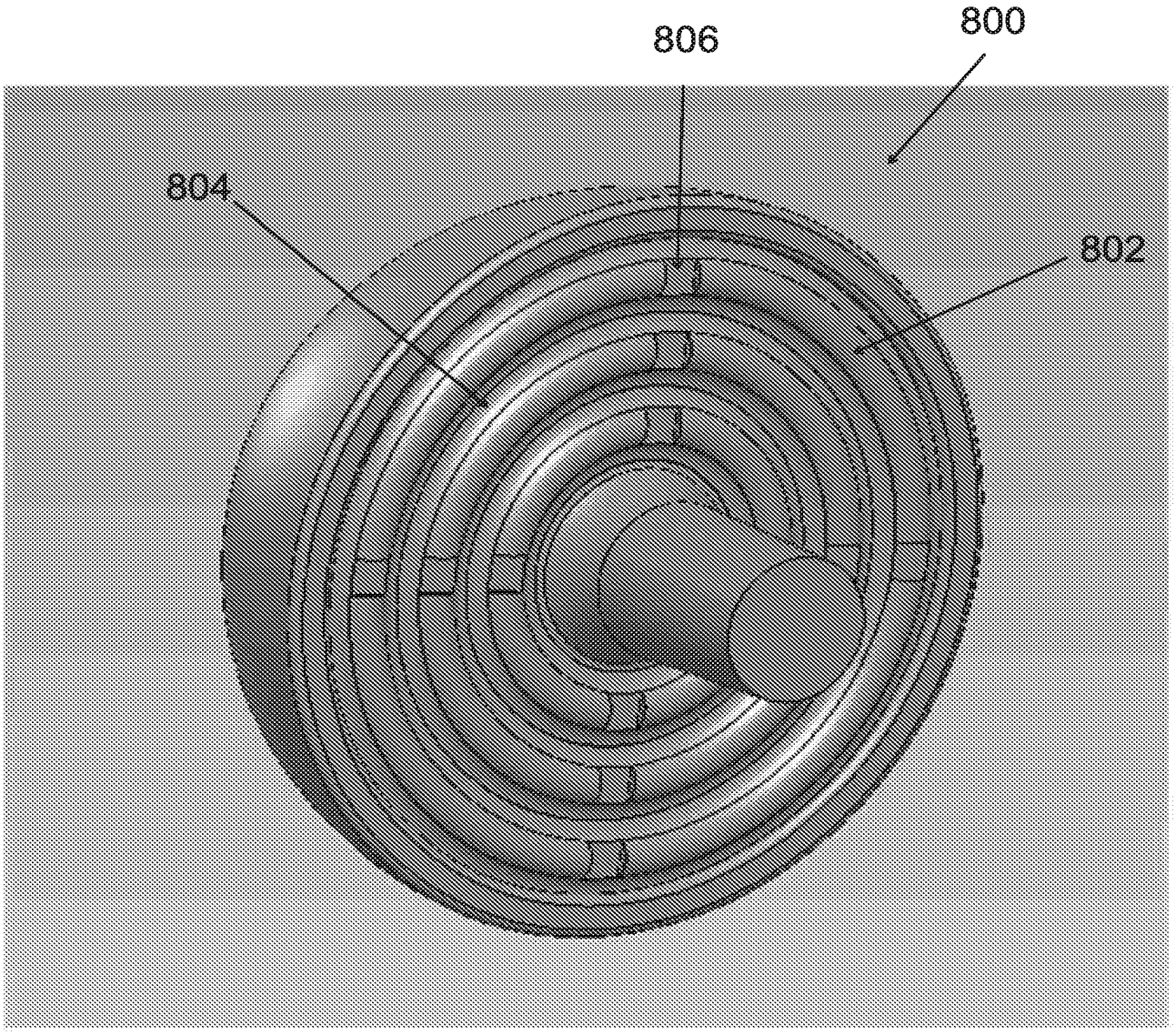


FIG. 21

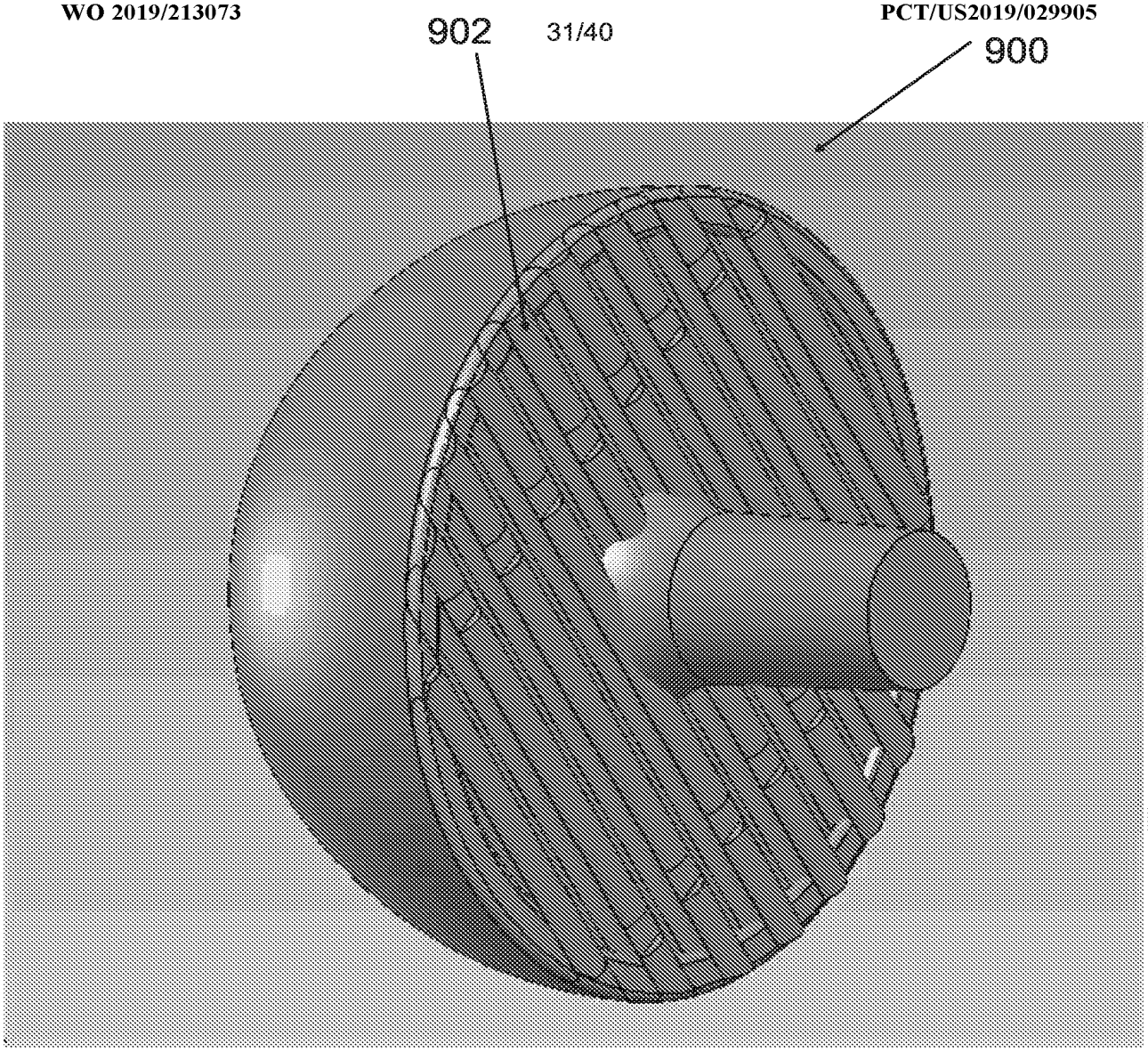


FIG. 22

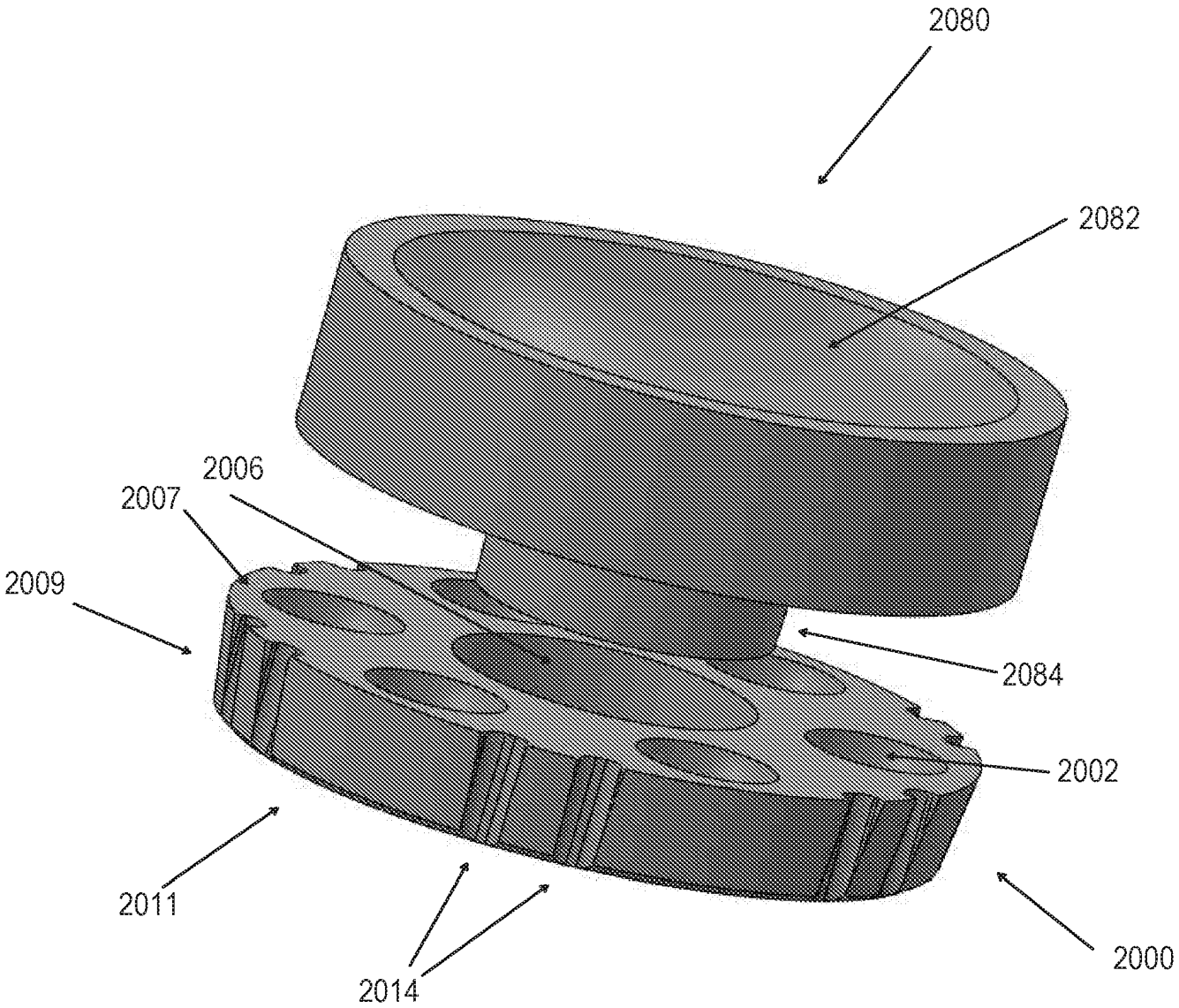


FIG. 23A

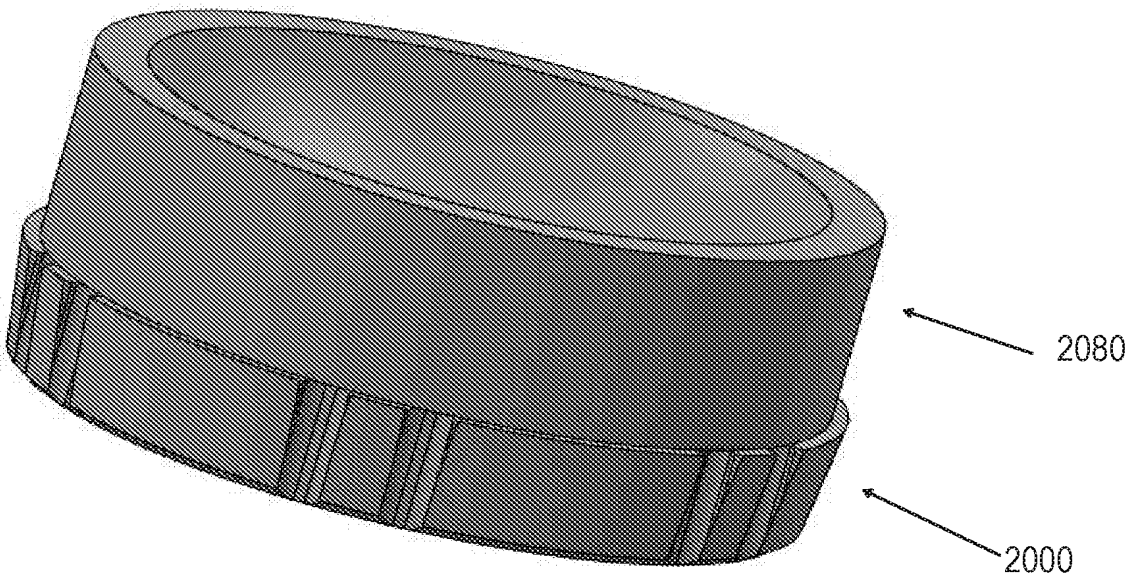


FIG. 23B

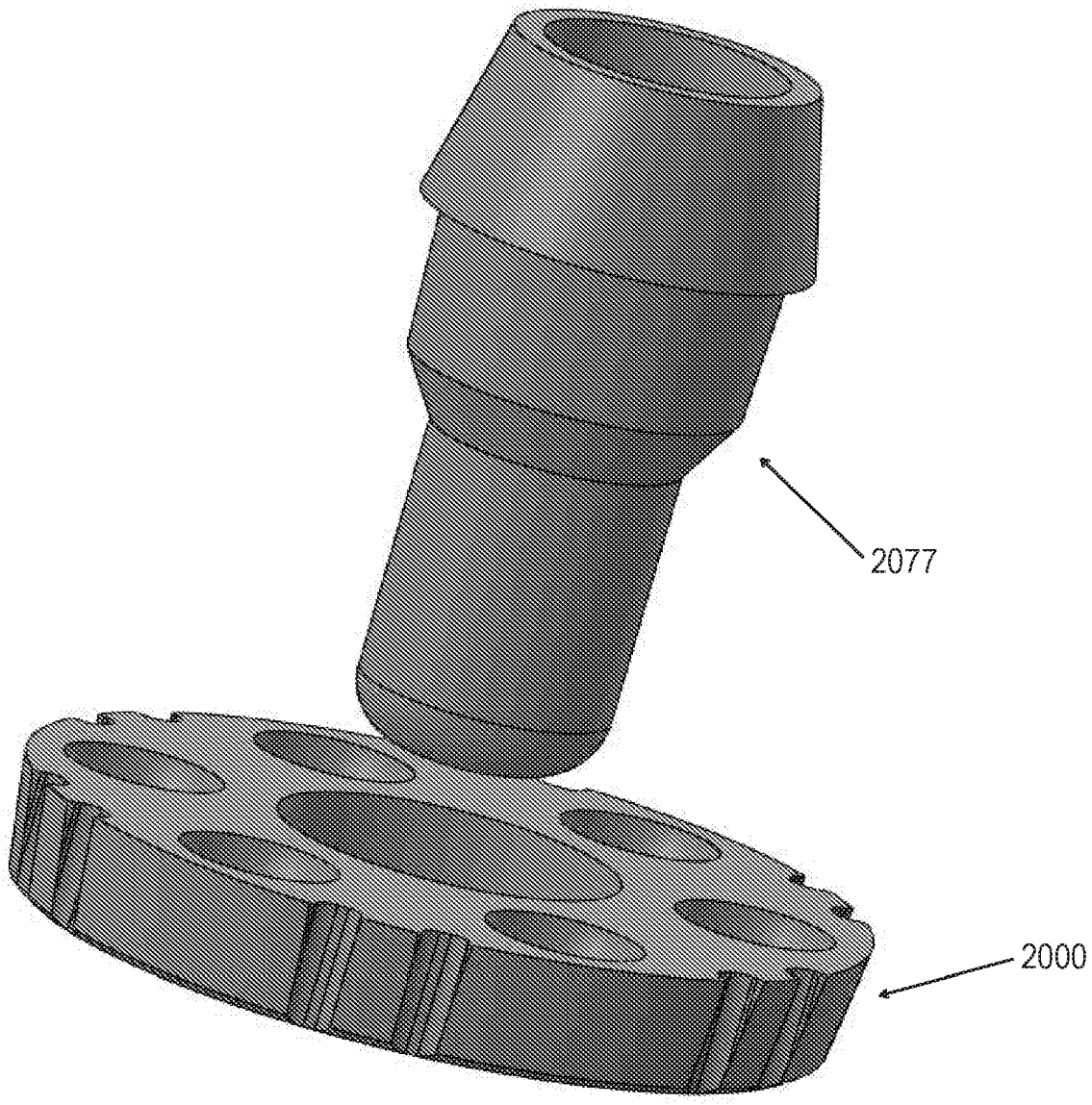


FIG. 23C

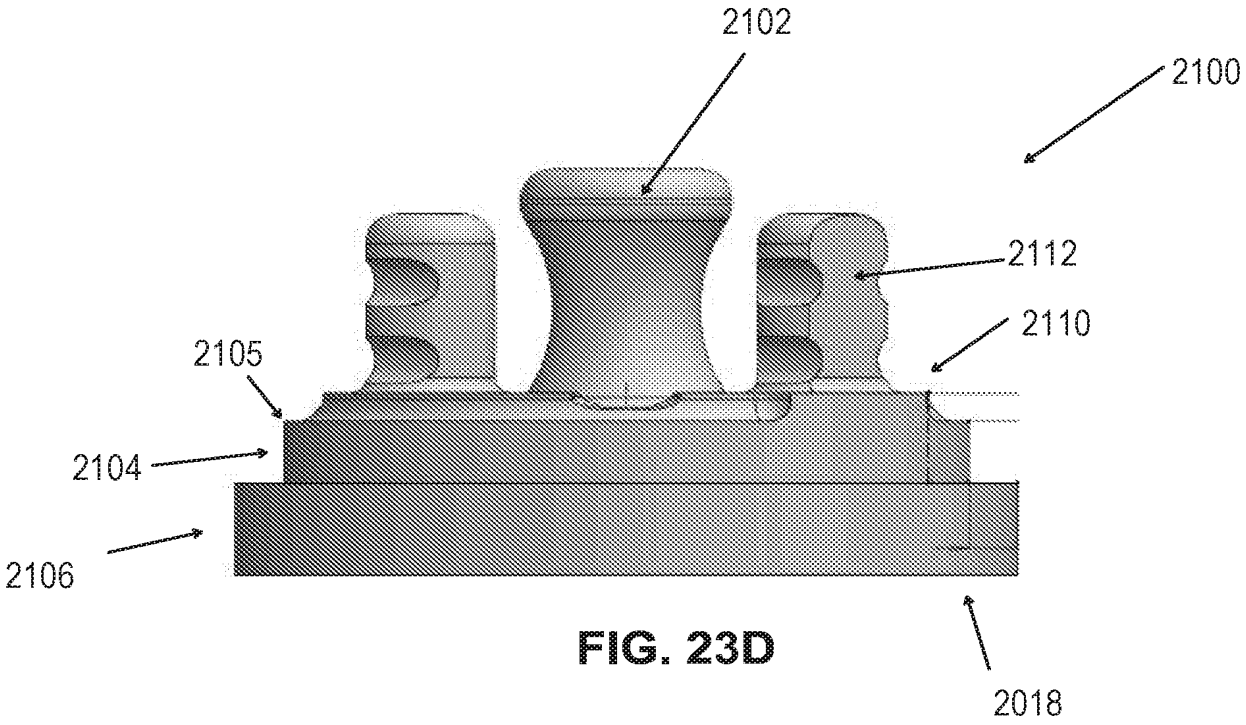


FIG. 23D

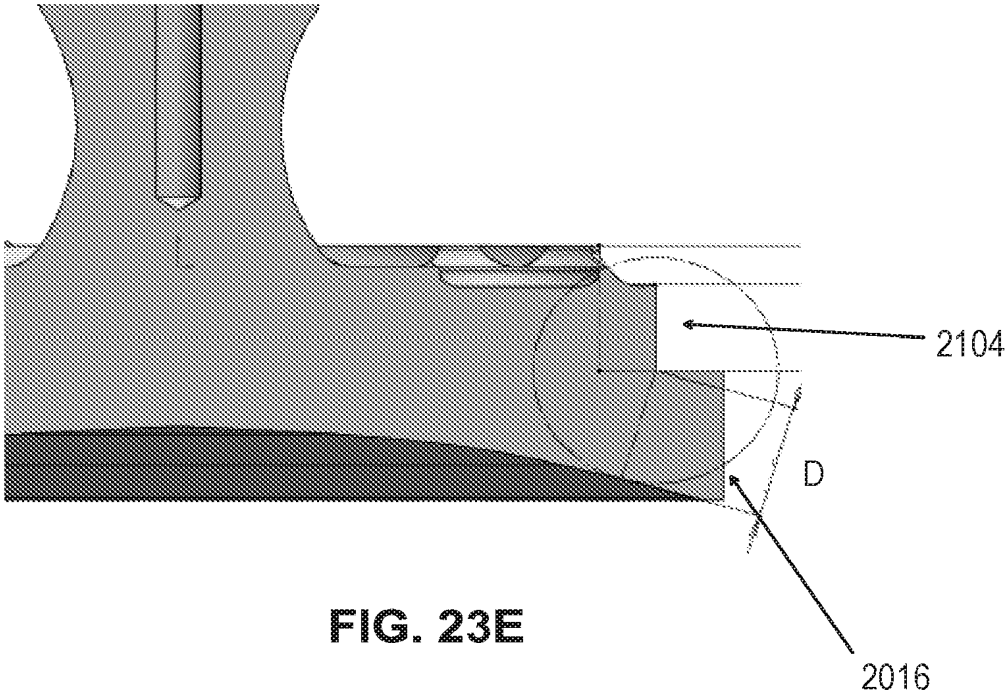


FIG. 23E

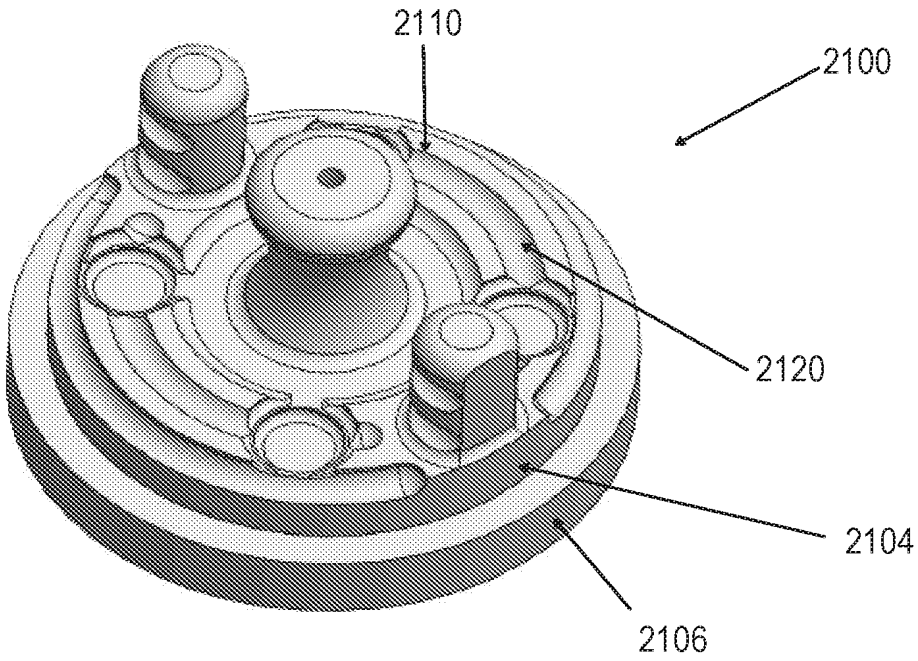


FIG. 23F

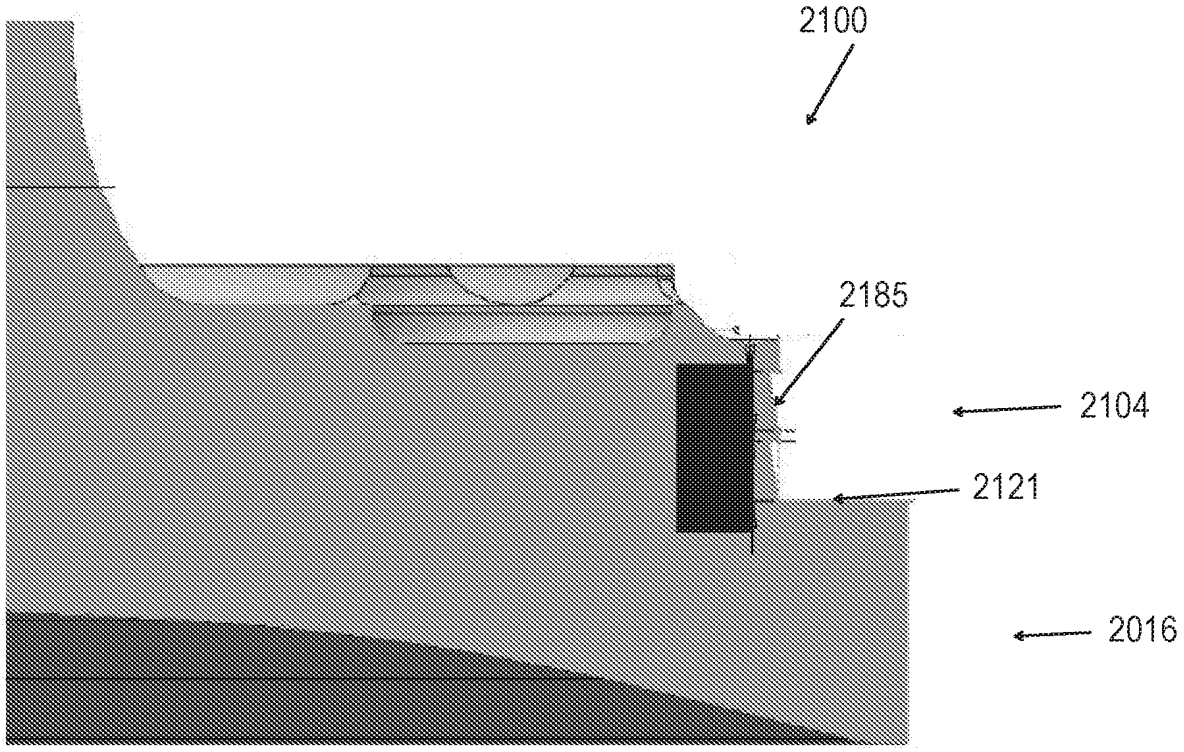


FIG. 23G

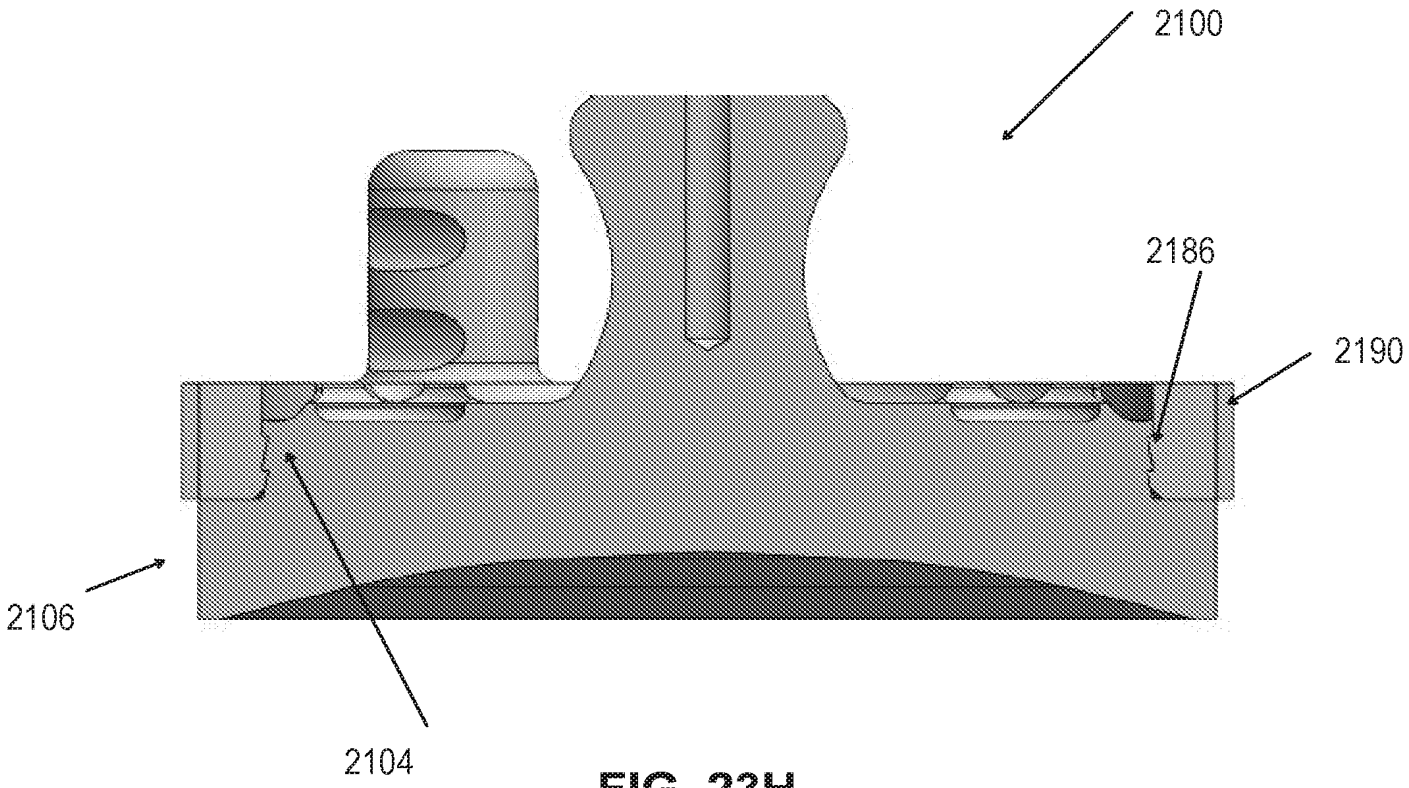


FIG. 23H

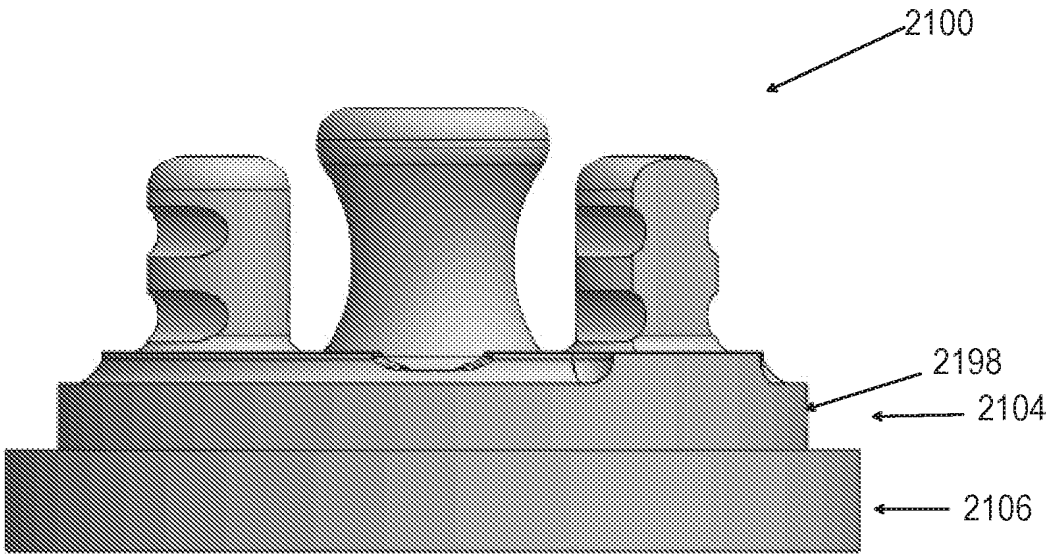


FIG. 23I

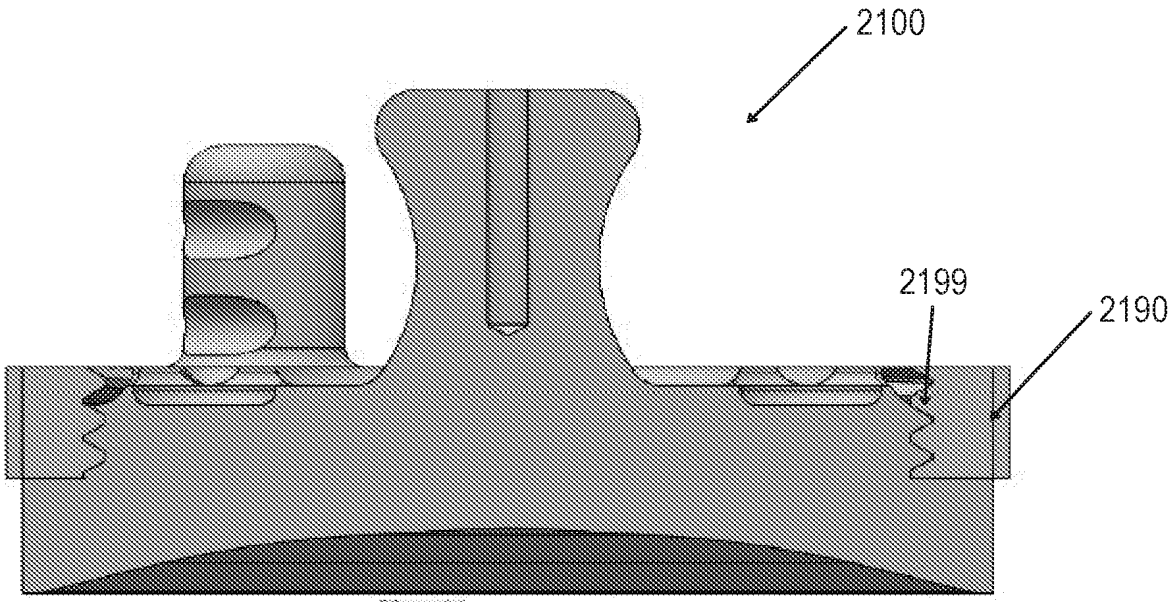


FIG. 23J

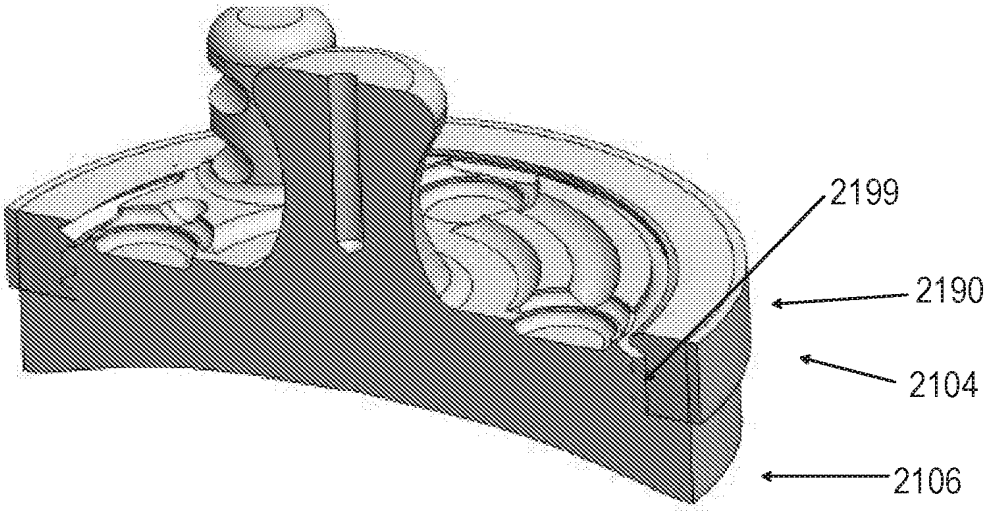


FIG. 23K

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/029905

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/40; A61F 2/30; A61F 2/46 (2019.01)
CPC - A61F 2/4081; A61F 2/40; A61F 2/4059 (2019.05)

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

B. FIELDS SEARCHED

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

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 623/19.11; 623/19.12; 623/19.13 (keyword delimited)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/0071749 A1 (DEPUY SYNTHES PRODUCTS INC) 16 March 2017 (16.03.2017) entire document	1-12
A	US 2009/0287309 A1 (WALCH et al) 19 November 2009 (19.11.2009) entire document	1-12
A	US 2014/0107794 A1 (DEPUY (IRELAND)) 17 April 2014 (17.04.2014) entire document	1-12

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

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 June 2019	18 JUL 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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1 December 2008 (01.12.2008)

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(71) Applicant *(for all designated States except US)*: **DePuy International Ltd** [GB/GB]; St Anthony's Road, Leeds, Yorkshire LS11 8DT (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BISHOP, Nick** [GB/DE]; c/o TUHH Hamburg University of Technology, Denickestrasse 15, 21073 Hamburg (DE). **MOORE, Gary** [GB/GB]; c/o DePuy International Ltd, St Anthony's Road, Leeds, Yorkshire LS11 8DT (GB). **MORLOCK, Michael** [DE/DE]; Bei der Johanniskirche 19, 22767 Hamburg (DE).

(74) Agent: **GOVER, Richard**; Urquhart-Dykes & Lord LLP, Tower North Central, Merrion Way, Leeds LS2 8PA (GB).

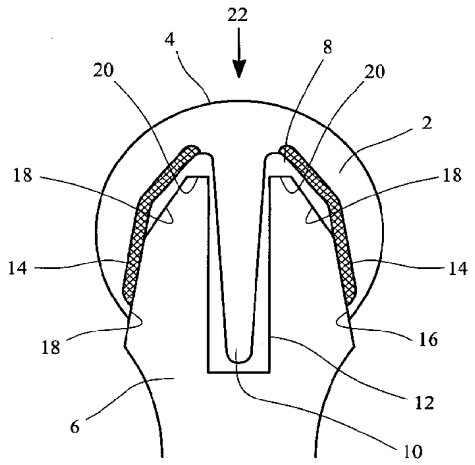
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) Title: IMPLANT ASSEMBLY

FIG. 1



(57) Abstract: An implant assembly comprising an implant forming one component of a joint prosthesis, the implant comprising an articulating surface and an axial cavity arranged to receive an end of a bone, the axial cavity being generally circular in cross section in a plane normal to the axis of the implant. The implant assembly further comprises a spacing element detachable from the implant. At least a portion of the interior surface of the cavity is roughened and is arranged to abrade bone when the end of the bone is received in the cavity. The spacing element is arranged to prevent the implant from fully seating on the end of the bone such that the implant and the end of the bone are in a predetermined spaced apart arrangement. A method of implanting such an implant is also disclosed. The method comprises receiving the end of a bone in the cavity; rotating the implant assembly while applying axial pressure to the implant in the direction of the bone such that bone is abraded by the roughened surface; removing the spacing element from the implant; and applying an axial impaction force to the implant until the implant is fully seated upon the end of the bone.

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Implant Assembly

The present invention relates to an implant assembly. In particular, but not exclusively, the present invention relates to an implant assembly for implanting a resurfacing implant to replace an articulating surface at the end of a bone which forms the ball component of a ball and socket joint. Certain embodiments of the present invention comprise an implant that is provided with a roughened bone engaging surface to prepare the bone surface so as to accurately shape the end of the bone to fit a cavity within the implant. Embodiments of the implant assembly further includes a spacer sleeve releasably coupled to the implant during the bone preparation in order to position the implant correctly relative to the bone.

Conventional orthopaedic joint prostheses for replacing ball and socket joints comprise an implanted socket prosthesis component and an implanted ball prosthesis component. Implantation of the ball prosthesis component typically involves removal of a large portion of the ball end of the bone, including all of the ball component and much or all of any neck at the end of the bone, in a process known as resection. The ball prosthesis component comprises a stem which is inserted into the open medullary canal of the resected bone. The stem terminates at a proximal end at a neck portion coupled to a head component formed as a partial sphere. The head component comprises a bearing surface which articulates within the implanted socket component.

It is known to replace only the articulating surface at the end of a bone in preference to removing and replacing a significant portion of the bone. In such a "resurfacing" joint prosthesis, the bone tissue that provides the ball component of a ball and socket joint (for example the humeral component of a shoulder joint or the femoral component of a hip joint) is prepared to receive a cap-like component having an outer bearing surface which can be received in the socket component of the joint prosthesis. Preparation of the bone involves shaping the bone tissue of the ball component of the natural joint so that its external shape is approximately the same as the shape of a cavity within the cap-like component. The cavity is rotationally symmetrical. Preparation further involves drilling a bore in the end of the bone in which a central locating implant pin of the cap-like component can be located. The resurfacing implant can then be implanted over the

prepared bone end and secured in position using an impaction force, to create a press fit, or using bone cement.

It is known to use a reamer tool to prepare a bone for implantation of a component of an orthopaedic joint prosthesis. A reamer includes cutting teeth which can be moved against the bone surface to cut the bone. The reamer can be moved reciprocally along an axis to cut the bone, when the cutting teeth are arranged so that they face along that axis. In such a case the cutting teeth may be provided on the end of a wall of a reamer body similar to the teeth provided on a saw. A reamer may also have cutting teeth defined by slits in the wall of a reamer body. The material of the reamer body is deformed out of the plane of the reamer wall at each slit to provide a cutting tooth (alternatively referred to as "slit-like cutting teeth").

In order to prepare the end of a bone to receive a resurfacing component of a joint prosthesis, it is known to use a reamer assembly to remove the articulating surface of the bone so that the bone can receive the cap-like component. The reamer may comprise a reamer guide and a reamer shell with a sleeve portion which is a sliding fit upon the reamer guide.

Such a reamer assembly for preparing the ball component of a natural ball and socket joint for a resurfacing joint prosthesis is described in EP-1549230B1 ("A Reamer Assembly", DePuy International Limited). The reamer assembly is described as being particularly suitable for preparing the ball component of a hip joint for resurfacing. The reamer guide comprises an elongate member which can be implanted within a bore cut into the end surface of the natural ball component of the joint along an axis defined by the sphere of the bearing surface. The reamer shell is arranged to cut bone around the reamer guide to a desired shape. The reamer guide comprises a sleeve portion at a proximal end which is arranged to slide over the reamer guide and a shell wall which extends distally from the sleeve in a generally cylindrical or conical fashion to a cutting edge at the distal end of the shell which engages and cuts the bone as the shell is rotated about the reamer guide. Slit like cutting teeth may also be provided in the shell wall to remove portions of the ball

component of the bone, in particular those portions of the bone at the existing bearing surface of the joint.

The resurfacing implant is then implanted over the prepared bone. The implant comprises an external convex bearing surface and an internal cavity. The cavity is generally cylindrical or conical and is sized to receive the prepared bone end. A central locating implant pin within the cavity is received within the bore in the end of the bone and assists in accurately aligning the implant. The resurfacing implant is then driven home over the bone end by an impaction force.

It is known to secure orthopaedic joint prostheses using an adhesive (also referred to as bone cement). Alternatively, it is known to secure joint prostheses using techniques that do not use cement. For instance, it is known that if the surface of the bone can be brought into close proximity to the implant then bone growth around and over the prosthesis can secure the prosthesis in position. Furthermore it is known that if at least the surface of the prosthesis comprises a porous structure then bone growth can be encouraged through the cavities of the porous structure firmly embedding the prosthesis within the bone. As the bone is embedded into the prosthesis, the interface between the bone and the prosthesis and the bone is merged increasing the joint strength.

Such a porous structure can be provided as a porous coating applied to the prosthesis. Alternatively, part or all of the prosthesis can be formed from a material that is itself a porous structure.

Various porous coatings have been found to be effective, for example a porous coating is described in US-3855638. One particularly effective coating is applied to prosthesis components available from DePuy Orthopaedics Inc under the trademark Porocoat. Porocoat is a porous coating that comprises a beaded coating that may, for instance, be sintered onto the underlying material of the prosthesis. The porous coating consists of a plurality of small discrete particles of a metallic material bonded together at their points of contact with each other to define a plurality of connected interstitial pores in the coating. Typically, the particles are formed of the same metallic material as the material from which

the substrate is formed. Bone regrowth through the interstitial pores fixes the implant in position.

A porous coating can be applied to inside of the cavity of a resurfacing implant in order to secure the resurfacing implant into position.

In order to securely fix a resurfacing implant to the end of the bone it is important to ensure that the end of the bone is accurately prepared such that it is a close fit for the cavity of the resurfacing implant. How securely the implant is seated is greatly affected by the degree of interference between the prepared bone and the cavity. For implants that are to be fixed into position without cement, using a porous structure, the amount of interference between the prepared bone end and the porous structure significantly affects the resulting strength of the implant. If the prepared bone is poorly sized for the implant cavity it may even be difficult to fully seat the implant to its final position at all.

Inaccurate preparation of the bone end can result in a range of problems. In addition to having difficulty in fully seating the implant, excess exposed cut bone may be left uncovered by the implant. It is desirable that as little bone is cut away as possible during implantation of a resurfacing prosthesis to preserve the integrity of the remaining bone and thereby increase its strength. Difficulty in seating the implant can result in excessive impaction forces being applied, risking further damage to the bone. This can occur if there is too much contact between the bone and the implant, that is if the fit is too tight. A poorly positioned implant may not transfer loads correctly to the bone, risking further damage to the bone later on. Conversely, if the implant fit is loose, its position may vary over time risking further damage when the joint is loaded. Furthermore, if the fit is too loose then bone in-growth into the porous structure is inhibited, resulting in a weaker joint.

It is an object of the present invention to obviate or mitigate one or more of the problems associated with the prior art, whether identified herein or elsewhere. In particular, it is an object of embodiments of the present invention to provide an implant assembly that ensures that a prepared end of a bone is correctly sized for a resurfacing implant such that the resurfacing implant is a close fit.

According to a first aspect of the present invention there is provided an implant assembly comprising: an implant forming one component of a joint prosthesis, the implant comprising an articulating surface and an axial cavity arranged to receive an end of a bone, the axial cavity being generally circular in cross section in a plane normal to the axis of the implant; and a spacing element detachable from the implant; wherein at least a portion of the interior surface of the cavity is roughened and is arranged to abrade bone when the end of the bone is received in the cavity, the spacing element being arranged to prevent the implant from fully seating on the end of the bone such that the implant and the end of the bone are in a predetermined spaced apart arrangement

An advantage of the first aspect of the present invention is that because the implant assembly includes the implant itself, when the implant assembly is used to prepare an end of a bone this ensures that the end of the bone will accurately match the implant cavity once the spacing element has been removed and the implant is fully seated on the bone using an impaction force. The implant assembly, with the spacing element attached to the implant is used to prepare the bone surface at the end of the bone by rotating the implant while axial pressure brings the roughened surface to bear against the bone. The spacing element prevents too much bone from being abraded such that with the spacing element removed the implant will form a tight compression fit. The spacing element prevents the implant from being fully seated upon the end of the bone by preserving the cavity at least partially open. This prevents excess bone from being abraded by limiting the extent to which the implant can travel along the axis of the bone.

Preferably, the implant further comprises an implant pin projecting axially from the closed end of the cavity.

Advantageously, the spacing element comprises a spacer sleeve having an axial bore arranged to releasably receive the implant pin and an outer surface arranged to be inserted into a bore provided in the end of the bone. The spacer sleeve serves to ensure that the implant remains correctly aligned with the bone. The exterior surface of the spacer sleeve forms a sliding fit within the cylindrical bore within the end of the bone.

The spacer sleeve may further comprise an annular collar arranged to space the closed end of the cavity away from the end of the bone. The collar may be less than 5mm thick in a direction parallel to the axis of the implant. Advantageously, the spacer sleeve collar spaces the implant away from the head of the bone by being impinged between the two.

Preferably, the interior surface of the cavity diverges from the axis of the implant towards its open end. More preferably, the angle between the interior surface of the cavity and the axis of the implant is less than 5°.

Preferably, the axial bore of the spacer sleeve tapers towards its closed end and the implant pin tapers towards its free end, the exterior surface of the spacer sleeve generally forming a cylinder.

The spacer sleeve may be formed from a plastics material and the implant may be formed substantially from a metallic material

Preferably, the roughened surface comprises a porous structure adapted to encourage bone ingrowth. The porous structure may comprise a porous coating applied to at least a portion of the interior surface of the cavity.

The implant may comprise a femoral resurfacing implant and the joint prosthesis comprises a hip joint prosthesis.

According to a second aspect of the present invention there is provided a method of implanting an implant forming one component of a joint prosthesis, the implant comprising an articulating surface and an axial cavity, the axial cavity being generally circular in cross section in a plane normal to the axis of the implant, at least a portion of the interior surface of the cavity being roughened, the implant being detachably coupled to a spacing element, the method comprising: receiving the end of a bone in the cavity, the spacer sleeve preventing the implant from fully seating on the end of the bone such that the implant and the end of the bone are in a predetermined spaced apart arrangement; rotating the implant assembly while applying axial pressure to the implant in the direction of the bone such that

bone is abraded by the roughened surface; removing the implant from the end of the bone; removing the spacing element from the implant; positioning the implant over the end of the bone such that the end of the bone is inserted into the cavity; and applying an axial impaction force to the implant until the implant is fully seated upon the end of the bone.

The method may further comprise drilling the bore into the end of the bone and forming the end of the bone to the approximate shape of the cavity prior to positioning the implant assembly over the end of the bone.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 schematically illustrates in cross section a conventional resurfacing joint prosthesis during implantation over a prepared end of a bone forming the ball component of a ball and socket joint; and

Figure 2 schematically illustrates an implant assembly comprising a resurfacing implant and a spacer sleeve in accordance with an embodiment of the present invention being used to prepare a ball component of a natural ball and socket joint before final implantation of the resurfacing implant.

Referring to figure 1, this schematically illustrates a conventional resurfacing implant 2 which forms part of a orthopaedic joint prosthesis. In particular, resurfacing implant 2 forms the femoral component of a hip joint prosthesis and provides a partially spherical articulating surface 4 that is received within an implanted acetabulum prosthesis (not shown). The resurfacing joint prosthesis 2 provides a hard wearing bearing surface 4 on the head of a femur 6

Figure 1 is illustrated in cross section, and further illustrates the prepared end of the femur 6. The prepared femur 6 is received within an axial cavity 8 formed within the resurfacing implant 2. The axial cavity 8 is generally cylindrical or conical about the axis of the

implant 2. Figure 1 illustrates the implant 2 not yet fully seated upon prepared femur 6, such that the cavity 8 is still partially open.

The resurfacing implant 2 further comprises an axial implant pin 10 which is received within an axial bore 12 within the prepared end of the femur 6. The bore may be cylindrical or may taper toward its closed end. The implant pin 10 serves to ensure that the resurfacing implant 2 is correctly aligned with the prepared end of the femur 6 before the implant 2 is implanted.

At least part of the interior surface of the cavity 8 is provided with a porous structure 14 such as a layer of porocoat. The porous structure 14 serves to secure the implant 2 into position as natural bone can grow through the pores to firmly bond the implant into position.

Conventionally, the preparation of the head of the femur 6 to receive the resurfacing implant 2 involves first forming a bore 12 along or at a desired angle to the axis of the femoral head to receive the implant pin 10. The external surface of the femur 6 is prepared by the formation of three rotationally symmetrical reamed surfaces 16, 18 and 20. A first surface 16 is generally aligned parallel or close to parallel to the axis of the bore 12. The second surface extends between the first surface and a third surface at about 135°. The third surface is generally formed as a plane normal to the axis of the bore 12. The surfaces 16-20 may be formed using a reamer as described above in the introduction.

Once the femoral head is prepared, the resurfacing implant 2 is positioned over the femoral head such that the implant pin 10 is aligned with the bore 12 and the implant 2 is driven onto the femur 6 using an impaction force provided along the axis of the implant pin, in the direction indicated by arrow 22. The resurfacing implant 2 is driven along the axis of the implant pin 10 until the implant 2 is fully seated upon the femur 6 (figure 1 illustrates an intermediate position in which the implant 2 has not yet been fully seated such that the axial cavity 8 is still partially open between the upper surface 20 of the femur 6 and the closed end of cavity 8).

However, as discussed above in the introduction, if the end of the femur 6 is not accurately matched to the axial cavity 8 of the implant 2 then problems can occur. If the end of the femur is too small then the implant may be loose, or become loose during normal use. This may be due to the presence of a gap between the femur and part or all of the porous structure 14, which inhibits bone in growth. Alternatively, if the femur is too large then it can be difficult to fully seat the implant 2 into its final position, such that either axial cavity 8 remains partially open, or excessive damaging force is required. Incorrect seating of the implant 2 can result in the implant not correctly transferring loads to the bone, resulting in increased wear of the implant and possible damage to the bone, which can result in the implant loosening.

Problems in sizing the prepared end of femur 6 are due in part to tolerance stack up between the reamer used to prepare the bone and the implant 2. This can result in there being too much or too little surface area contact between the bone and the implant. Furthermore, using a separate reamer to prepare the bone does not allow the fit between the implant and the bone to adjusted prior to the implant being attached using the axial impaction force. As the exact dimensions of implants can vary, using a separate reamer to prepare the bone does not allow for adjustment of the bone specific to a particular implant.

Figure 2 illustrates in cross section an implant assembly in accordance with an embodiment of the present invention. The implant assembly comprises a resurfacing implant 30 which forms part of an orthopaedic joint prosthesis. In particular, resurfacing implant 30 forms the femoral component of a hip joint prosthesis and provides a partially spherical articulating surface 32 that it received within an implanted acetabulum prosthesis (not shown). The resurfacing joint prosthesis 30 provides a hard wearing bearing surface 32 on the head of a femur 6.

Figure 2 further illustrates the prepared end of the femur 6. In accordance with embodiments of the present invention the femur 6 may be initially prepared using a reamer as described above in order to approximately size the femur 6 to be received within an axial cavity 34 within the implant 30. Figure 2 illustrates the implant assembly during an intermediate stage during which the implant assembly is used to accurately prepare the

approximately prepared femur 6. Because the implant assembly includes the resurfacing implant 30, the finally prepared femur 6 matches the axial cavity 34 more accurately than if the femur 6 was prepared only using a separate reamer.

The axial cavity 34 is generally cylindrical or conical about an axis of the implant 30 defined by the partial sphere of the articulating surface 32. The implant assembly further comprises a spacer sleeve 36. The spacer sleeve 36 is located about implant pin 38 which extends axially from the closed end of axial cavity 34. When the implant assembly is being used to finalise the preparation of the femur 6, the spacer sleeve 36 and the implant pin 38 are received within an axial bore 40 within the end of the femur 6. The implant pin 38 and the spacer sleeve 36 serve to ensure that the resurfacing implant 30 is correctly aligned with the prepared end of the femur 6 during final preparation of the exterior surfaces of the femur 6. Once the femur 6 has been fully prepared, the spacer sleeve 36 is removed before the implant 30 is fully seated upon the end of the femur.

At least part of the interior surface of the cavity 34 is provided with a porous structure 42 such as a layer of porocoat. The porous structure 42 serves to secure the implant 30 into position once the implant 30 is finally seated upon femur 6 as natural bone can grow through the pores to firmly bond the implant into position. Furthermore, during final preparation of the femur 6 using the implant assembly, the porous structure serves to abrade surface portions of the bone in order to ensure a close fit between the implant 30 and the femur 6.

The preparation of the head of the femur 6 to receive the resurfacing implant 30 involves first forming bore 40 along or at a desired angle to the axis of the femoral head to receive the implant pin 38 and the spacer sleeve 36. The external surface of the femur 6 is then approximately prepared by the formation of three rotationally symmetrical reamed surfaces 44, 46 and 48 A first surface 44 is generally aligned close to parallel to the axis of the bore 40, though at an angle of approximately 3° to the axis of the bore 40, as will be described in greater detail below. The second surface 46 extends between the first surface and a third surface at an angle of about 135°. The third surface 48 is generally formed as a plane

normal to the axis of the bore 40 The surfaces 44, 46, 48 may be formed using a reamer as described above.

The embodiment of the present invention illustrated in figure 2 comprises an implant assembly which comprises a resurfacing implant 30 and a spacer sleeve 36 that allows for a repeatable method of reducing the amount of interference between the prepared bone 6 and the inner surface of the axial cavity 34. Spacer sleeve 36 comprises a one piece sleeve having an interior bore that closely matches the tapering implant pin 38. The exterior surface of the spacer sleeve 36 comprises a cylinder having generally parallel sides that is arranged to form a close sliding fit within the bore 40 in the end of femur 6. That is, the spacer sleeve is thicker at its distal end than at its end proximal the closed end of cavity 34. The spacer sleeve 36 further comprises a flanged portion 50 that forms an axial collar about the end of implant pin 38 at the closed end of cavity 34. Flange 50 rests upon bone surface 48 and prevents the implant 30 from fully seating upon femur 6 during preparation of the femur 6.

As described above, the femur 6 is first approximately shaped using, for instance, a reamer as described above in the introduction. The end of the femur 6 is arranged to be slightly larger in circumference that the axial cavity 34. In order to finally prepare the femur 6 to exactly fit the axial cavity 34, the spacer sleeve 36 is placed over the implant pin 38 and the spacer sleeve is inserted into bore 40 in the end of femur 6. The implant 30 is pushed along the axis of bore 40 until the interior surfaces of axial cavity 34 contact the exterior surfaces of the femur 6. The implant assembly is then rotated in either direction as indicated by arrow 52 while axial pressure is applied forcing the implant assembly onto femur 6. Due to the porous structure 42 such as a layer of porocoat, the interior surfaces of cavity 34 are abrasive. As the implant assembly is rotated a small amount of bone is removed from at least portions of surfaces 44 and 46 providing an accurately controlled final preparation to bone 6 that is unique to the particular implant 30.

The rotation and axial pressure is continued until the flange 50 prevents further axial motion of the implant assembly by being trapped between bone surface 48 and the closed end of the cavity 34.

Once the femoral head is thus finally prepared, the spacer sleeve 36 is removed and the resurfacing implant 30 is positioned over the femoral head such that the implant pin 38 is aligned with the bore 40 and the implant 30 is driven on to the femur 6 using an impaction force provided along the axis of the implant pin 38 in the direction indicated by arrow 54. The resurfacing implant 30 is driven along the axis of the implant pin 38 until the implant 30 is fully seated upon the femur 6.

As the prepared bone and the axial cavity taper, that is narrow in cross section, towards the closed end of the cavity or the free end of the bone, forcing the implant 30 onto the femur 6 forms an interference fit that firmly locks the implant in position. As the femur 6 is finally prepared using the implant 30 itself, an accurate fit is ensured, such that the fit is close, without requiring an excessive impaction force. The prepared bone 6 slightly compresses as the implant 30 is driven onto it. This compression serves to secure the bone in position. Furthermore, accurately sizing the femur 6 using the implant 30 ensures that the bone is compressed correctly, that is not too much which could result in difficulty in fully seating the implant 30, and not too little, which could result in a loose fit for the implant 30.

In order to ensure a close interference fit between the femur 6 and the axial cavity 34 it is preferable that the taper of the axial cavity wall and the prepared femur relative to the axis of the implant pin 38 is less than 10°. More preferably, the taper is less than 5°, for instance about 3°.

The height of flange 50 along the axis of bore 40 also determines the degree of compression of the bone as the implant 30 is finally driven onto the prepared tapering bone. The height of the flange is preferably less than 10mm. More preferably, the height is less than 5mm. Most preferably the height of flange 50 is between about 2mm and about 3mm.

The degree of compression of the bone when the implant 30 is fully seated upon femur 6 is a key factor in determining how firmly the implant is attached. The smaller the angle of the walls of the cavity and the prepared femur to the axis of the implant pin, the tighter the

interference fit will be. Additionally, a tighter fit and more compression is achieved for a taller flange 50.

Spacer sleeve 36 may suitably be formed from a plastics material, for instance polyethylene. However, any suitable bio-compatible material may be used that can be releasably mounted upon implant pin 38.

In alternative embodiments of the present invention, the spacer sleeve may be truncated. That is, the spacer sleeve may not extend all of the way to the free end of the implant pin, and therefore be open ended. Separation between the end of the bone and the closed end of the implant cavity is still caused by the flange.

The spacer sleeve may be formed from two separate components: a sleeve component and spacing component (that is, a separate flange).

Embodiments of the present invention consistently refer to a spacer sleeve. However, it will be readily apparent to the appropriately skilled person that the primary purpose of the spacer sleeve is to space the implant apart from the end of the bone such that it cannot be fully seated on the end of the bone. This controls the amount of bone that is removed from the peripheral external surface of the end of the bone and thereby accurately controls the shape of the end of the bone and ensures an accurately controlled fit. Thus, the spacer sleeve may be replaced in alternative embodiments of the present invention by other spacing elements that achieve this effect. For instance, if the implant includes an implant pin, then a spacing element may be formed as a simple annular ring or collar about the implant that is seated upon the end surface of the bone. Alternatively, the spacing element could form a cap that fits only over the tip of the implant pin and thus prevents the implant pin from being fully inserted into the bore within the end of the bone (note, that such a spacing element requires that the depth of the bore is closely controlled). Further spacing elements may be formed not as initially separate components, but rather as a part of the implant that may be detached once the end of the bone is fully prepared. For instance, such a detachable spacing element could form one or more protrusion in the closed end of the cavity coupled to the remainder of the implant via a narrow section of material that may be

snapped off. Further alternative forms of spacing element will be readily apparent to the appropriately skilled person from the teaching herein, without departing from the scope of the appended claims.

In alternative embodiments, the implant pin need not taper: it could be cylindrical. In such an embodiment the spacer sleeve may be of constant thickness along its length. For an implant pin having parallel sides the spacing element may comprises a ring or a washer. The parallel sides of the implant pin reduce the risk of the ring falling off during preparation of the end of the bone, if the ring is a tight fit about the implant pin.

Advantageously, accurately sizing the prepared femur 6 using the resurfacing implant 30 itself as part of an implant assembly provides for a closely controlled fit between the bone and the implant obviating the problems identified above relating to a poor size match between the femur and the implant. In particular, as the implant 30 is fully seated, bone ingrowth into the porous structure is encouraged resulting in a stronger implant. As the implant is fully seated, the possibility of cut bone being left exposed is reduced. Bone ingrowth into the porous structure may be encouraged as during rotation of the implant assembly the porous structure may be impregnated with bone material.

While the present invention has been predominantly described herein in the context of the implantation of a resurfacing implant onto the head of a femur, it will be readily apparent the invention is not limited to this. The present invention may be readily applied to any situation in which as prosthesis is to be applied to the end of a bone, for instance a resurfacing humeral component of a prosthetic shoulder joint. Further advantages and applications of the present invention will be readily apparent to the appropriately skilled person without departing from the scope of the appended claims.

CLAIMS:

1. An implant assembly comprising:

an implant forming one component of a joint prosthesis, the implant comprising an articulating surface and an axial cavity arranged to receive an end of a bone, the axial cavity being generally circular in cross section in a plane normal to the axis of the implant; and

a spacing element detachable from the implant;

wherein at least a portion of the interior surface of the cavity is roughened and is arranged to abrade bone when the end of the bone is received in the cavity, the spacing element being arranged to prevent the implant from fully seating on the end of the bone such that the implant and the end of the bone are in a predetermined spaced apart arrangement.

2. An implant assembly according to claim 1, wherein the implant further comprises an implant pin projecting axially from the closed end of the cavity.

3. An implant assembly according to claim 2, wherein the spacing element comprises a spacer sleeve having an axial bore arranged to releasably receive the implant pin and an outer surface arranged to be inserted into a bore provided in the end of the bone.

4. An implant assembly according to claim 3, wherein the spacer sleeve further comprising an annular collar arranged to space the closed end of the cavity away from the end of the bone.

5. An implant assembly according to claim 1, wherein the interior surface of the cavity diverges from the axis of the implant towards its open end.

6 An implant assembly according to claim 5, wherein the angle between the interior surface of the cavity and the axis of the implant is less than 5°.