EXACTECH | **SHOULDER**

Operative Technique
Addendum

equinoxe®

Platform Shoulder System

Equinoxe® Glenospheres and Extended Locking Caps

Exactech®

TABLE OF CONTENTS

INTRODUCTION

The Equinoxe® Shoulder System redefines "anatomical." The platform primary stem is designed to allow independent adjustability of all four anatomic parameters in situ. The reverse shoulder is designed to minimize both scapular notching and torque on the glenoid while seamlessly integrating with the primary and platform fracture stems. The platform nature of the Equinoxe primary and fracture stem allows the surgeon to have intra-operative flexibility to choose between a hemiarthroplasty, primary total shoulder or reverse total shoulder and seamlessly convert to a reverse should a revision become necessary. And with the latest addition of the intuitive and streamlined Ergo® instrumentation, we're enhancing the surgical experience. From our first pioneering idea to dozens of solutions for the continuum of care, Equinoxe is a story of teamwork that drives innovation, research and customer focus.

Figure A
Insert Compression Screws

DOLPHIN GLENOSPHERE INSERTER

KLIMO GLENOSPHERE INSERTER

PILOT GLENOSPHERE INSERTER

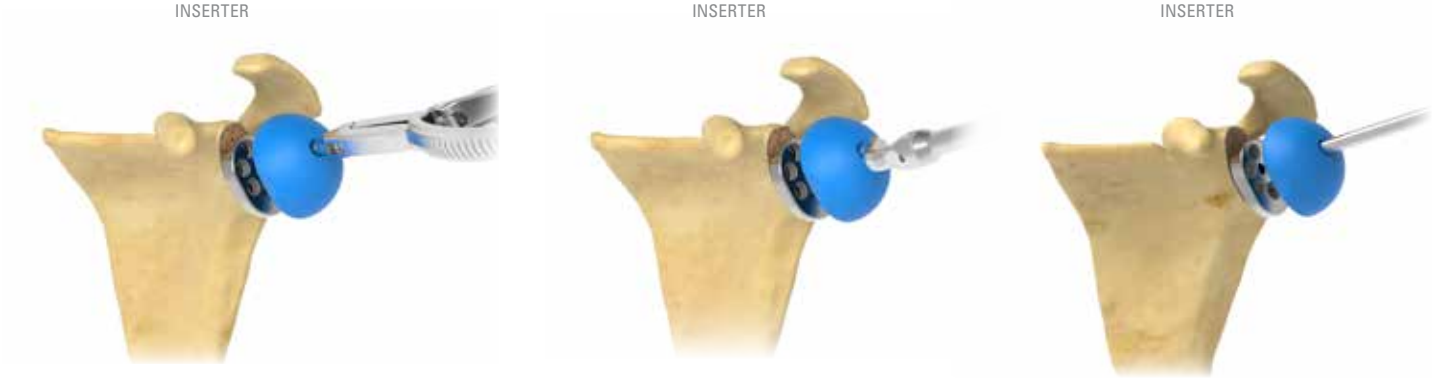


Figure B
Insert Glenosphere Trial

Figure C
Insert Humeral Tray Trial and Liner Trial

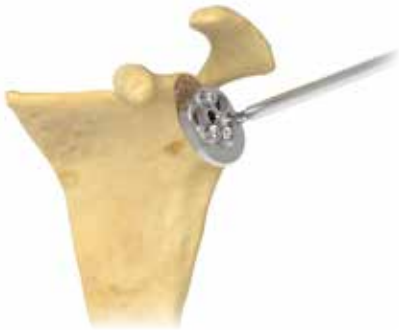


Figure D
Tighten Locking Caps

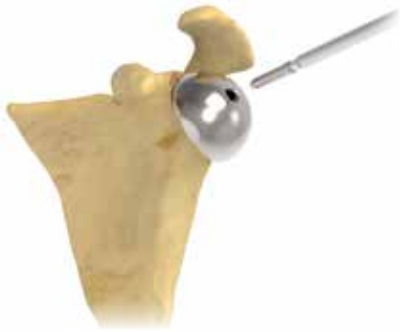


Figure E
Insert Definitive Glenosphere and Locking Screw

Figure 1
Insert Compression Screws

INSERT COMPRESSION SCREWS

Insert Compression Screws and tighten by hand, as deemed appropriate by the surgeon *(Figure 1)*.

INSERT THE GLENOSPHERE TRIAL

Attaining adequate glenoid exposure is critical for this step—especially posterior glenoid exposure. The **Posterior Glenoid Retractor** included in the set can help provide the posterior clearance necessary to implant the **Glenosphere Trial**.

The appropriately sized Glenosphere trial is defined by implanting the largest one that can be inserted based upon exposure and the coracoacromial arch anatomy (ensuring that it was reamed up to that size during the glenoid reaming step). Note that unlike circular baseplates, the anatomical shape of the Equinoxe Glenoid Plate mandates that the Glenosphere trial can only fit in one specific orientation (i.e. the superior/inferior axis of the glenoid).

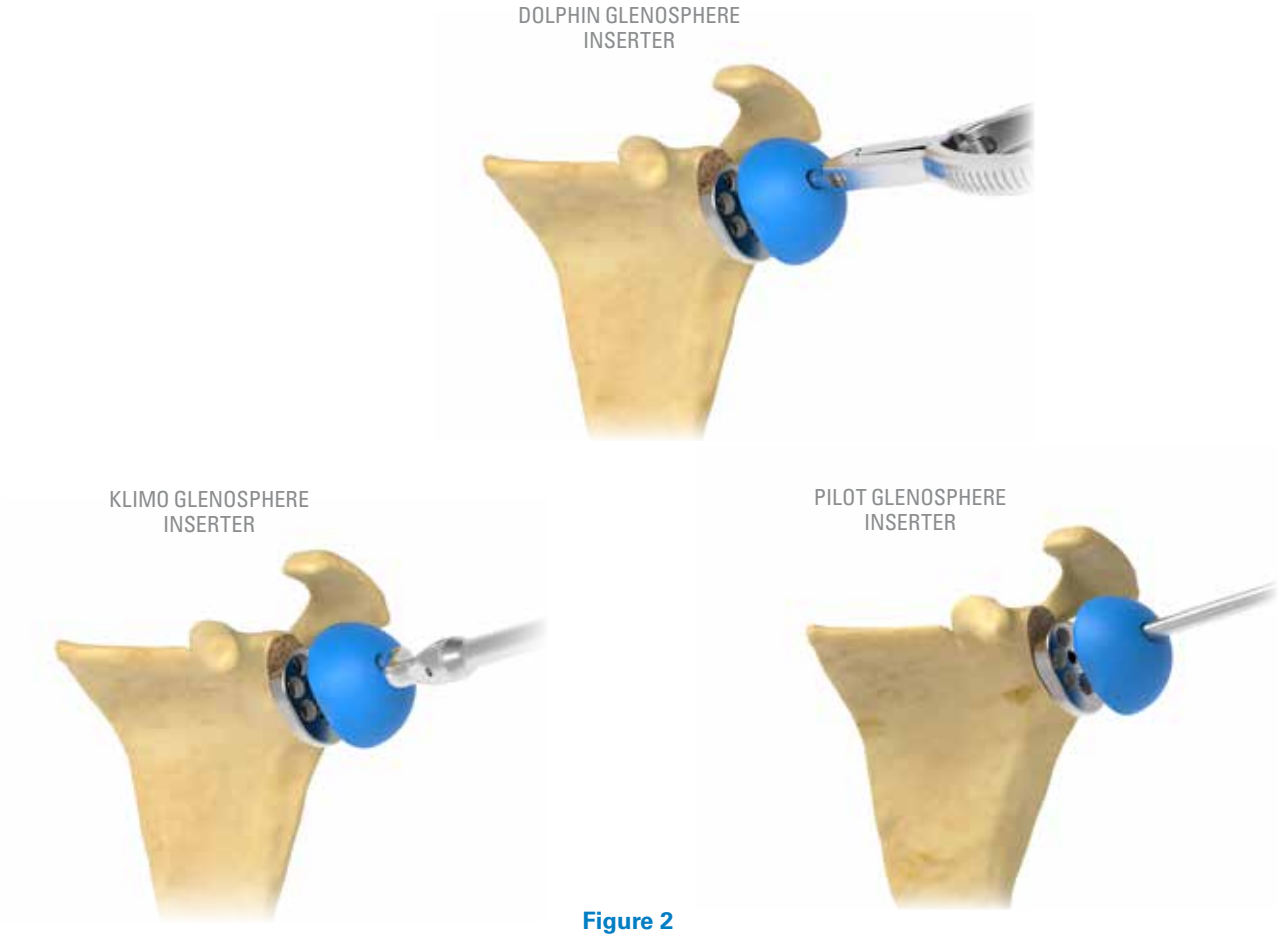


Figure 2
Insert Glenosphere Trial

The glenosphere trial can be inserted with the **Dolphin Glenosphere Inserter**, **Klimo Inserter** or **Pilot Inserter** *(Figure 2)*.

Note: *The Pilot Glenosphere Inserter (321-01-26) is not intended to be used with the 46mm Expanded Glenosphere (320-08-46).*

The Glenosphere Trial is connected to the **Glenoid Plate** with the **Glenosphere Locking Screw** to prevent the Glenosphere from disengaging during trial reductions.

If additional stability is required based upon the trial reduction, constrained liner options are provided in the same offset as the standard liners. While constrained liners will provide better stability, it is important to note they will also reduce the potential range of motion that can be achieved. If tension is inadequate, additional offset can be added up to 17.5mm. If trial components are changed, additional closed reductions and assessments should be performed to confirm that the desired stability has been obtained. In the unusual situation in which the +0mm liner is too tight, the humeral component should be removed and additional bone should be resected using the methods described.

Note: *Because Extended Locking Caps are packaged with the definitive Glenosphere, they cannot be used during trialing.*

Note: *The Pilot Glenosphere Inserter Slide (321-01-27), Glenosphere Inserter Spring Handle (321-01-28) and Universal Glenosphere Inserter (321-01-29) found in KIT-321B are not intended to be used with these glenospheres. The Glenosphere Inserter Clamps (321-02-38/42) are also not intended to be used with these glenospheres.*

DETAILED OPERATIVE TECHNIQUE

INSERT THE GLENOSPHERE TRIAL

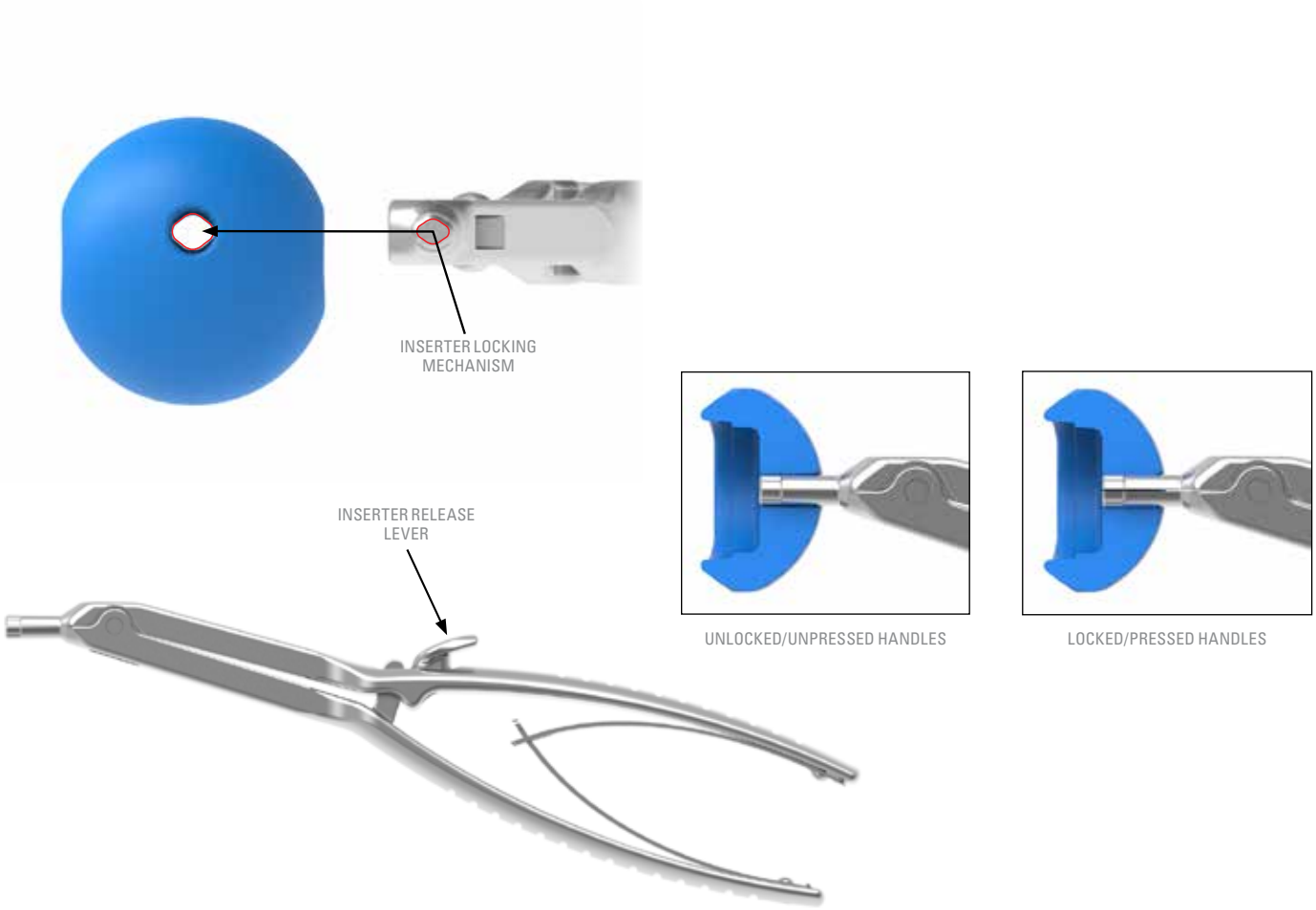


Figure 3
Insert the Dolphin Glenosphere Inserter:
How to Unlock and Lock

Dolphin Glenosphere Inserter

The tip of the Glenosphere Inserter is inserted in (into) the central hole of the Glenosphere Trial *(Figure 3)*. The clocking features must be aligned to maintain rotational stability. The handle is angled relative to the tip, which allows for slight angulation out of the joint. Once inserted onto the central hole, squeeze the handles to lock the Glenosphere onto the inserter. Maintain a firm grip on the handles of the Glenosphere Inserter to allow for the best control. Once fully seated on the Glenosphere, release the locking mechanism to remove the inserter from the seated Glenosphere.

Klimo Glenosphere Inserter

Attach the Klimo Inserter to the impactor handle. The curved axis (elbow) of the inserter should be aligned at the three o'clock position for a right shoulder or the nine o'clock position for a left shoulder. The Klimo Inserter helps to keep the Glenosphere aligned with the long axis of the Glenoid Plate during insertion. Do not attempt to impact the Klimo Inserter once the Glenosphere is seated.

Pilot Glenosphere Inserter

Attach the T-Handle to the inserter. Align the T-Handle in the north/south axis of the glenosphere to ensure that it is properly oriented with the Glenoid Plate. Except for the 46mm Expanded Glenosphere (320-08-46), the pilot tip fits into the baseplate to aid in orienting the glenosphere onto the baseplate. Do not attempt to impact the Pilot Inserter once the Glenosphere is seated.

Note: *Once the Glenosphere is seated on the baseplate, apply digital pressure to ensure the glenosphere stays on the baseplate and remove the inserter.*

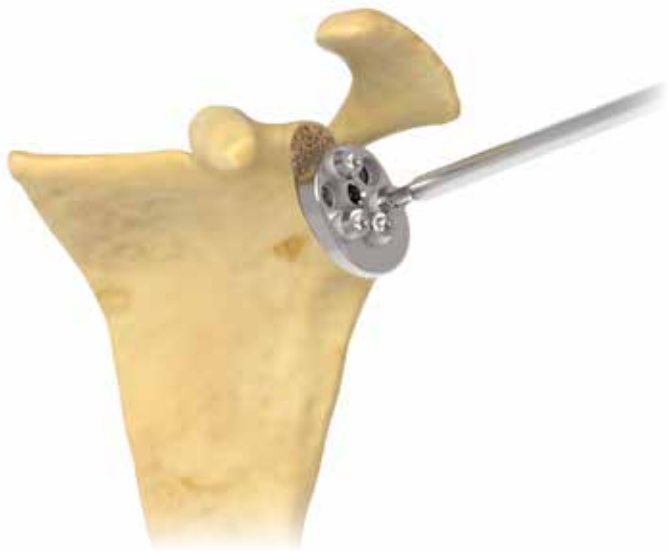


Figure 4
Tighten Locking Cap

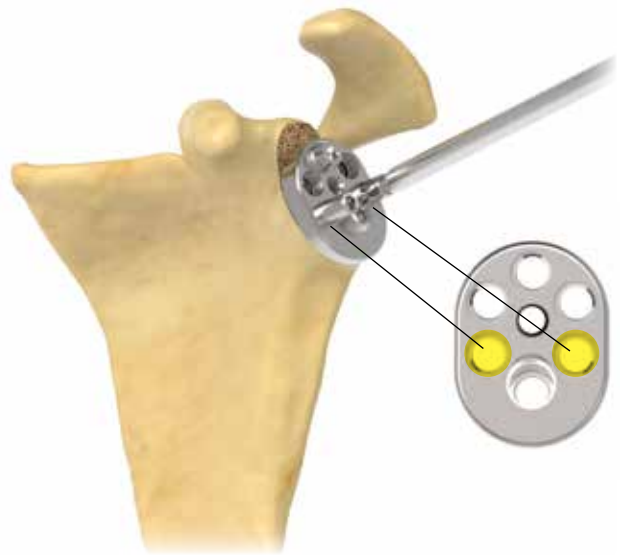


Figure 5
Extended Locking Cap Alternative

INSERT LOCKING CAPS

After all **Compression Screws** are tightened by hand, as deemed appropriate by the orthopaedic surgeon, the surgeon must insert the **Locking Caps** into each screw hole. This will lock each Compression Screw and prevent the screws from backing out. Each Locking Cap is inserted perpendicular to the plate with the exception of the inferior one, which must be threaded at a 15-degree superior tilt *(Figure 4)*.

Alternatively, the Extended Locking Caps may be used in this step, on the inferior-anterior and inferior-posterior holes only *(Figure 5)*.

Although two Extended Locking Caps are provided, the surgeon may choose to use two, one or none, according to preference. If no extended locking caps are used, standard locking caps must be used.

The Extended Locking Caps are designed to aid with Glenosphere insertion by positioning the Glenosphere on the correct axis of insertion.

INSERT THE FINAL IMPLANTS

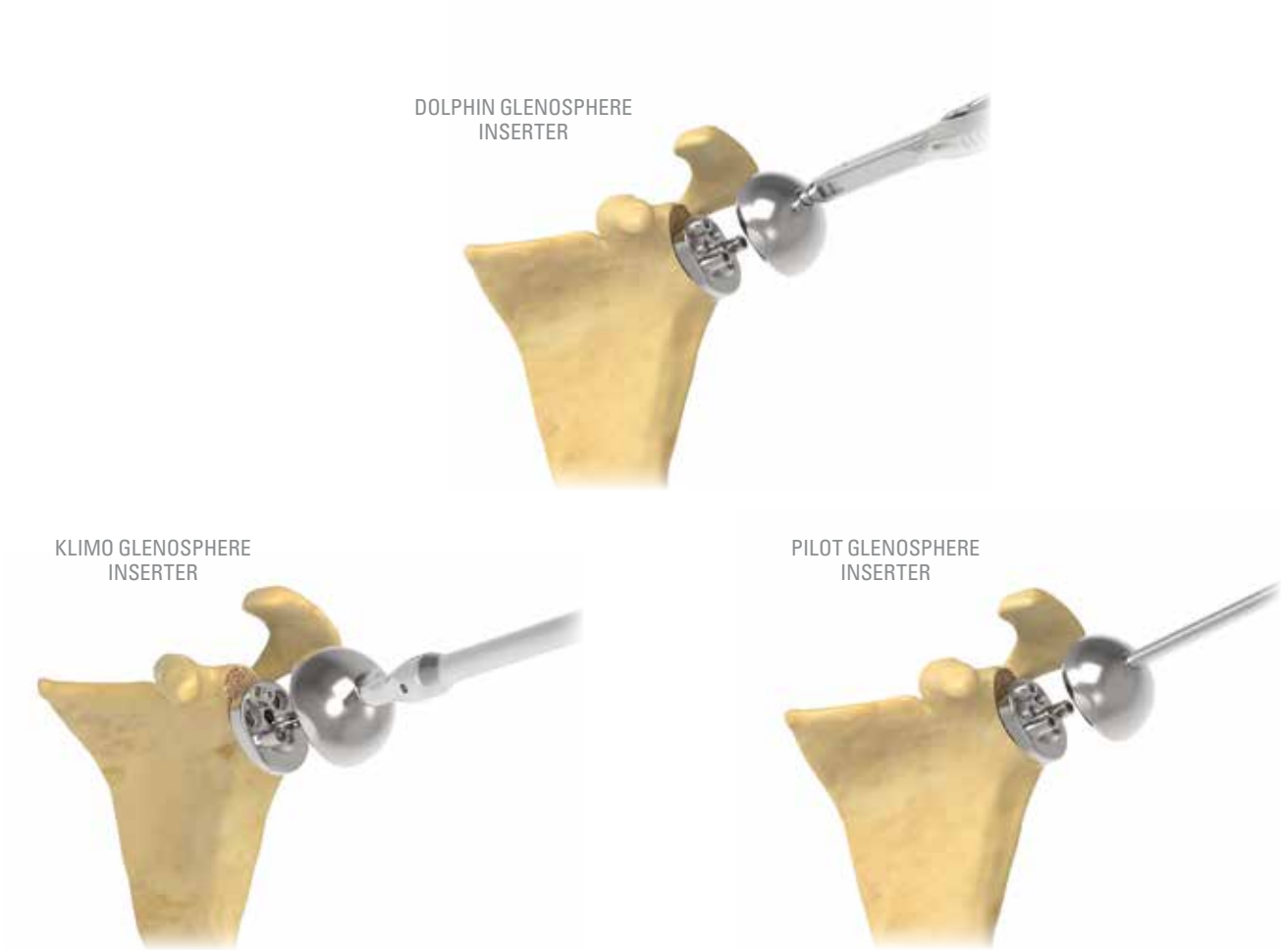


Figure 6
Attach the Definitive Glenosphere Implant

INSERT THE FINAL IMPLANTS

The final Glenosphere is implanted in the same manner used with the Glenosphere Trial. The Glenosphere is not a morse taper and should not be impacted. The Glenosphere is secured with the Glenosphere Locking Screw.

Attach the definitive glenosphere implant using either the Klimo Inserter, Dolphin Inserter or Pilot Glenosphere Inserter (except for the 46mm Expanded Glenosphere, 320-08-46) per *(Figure 6)*.

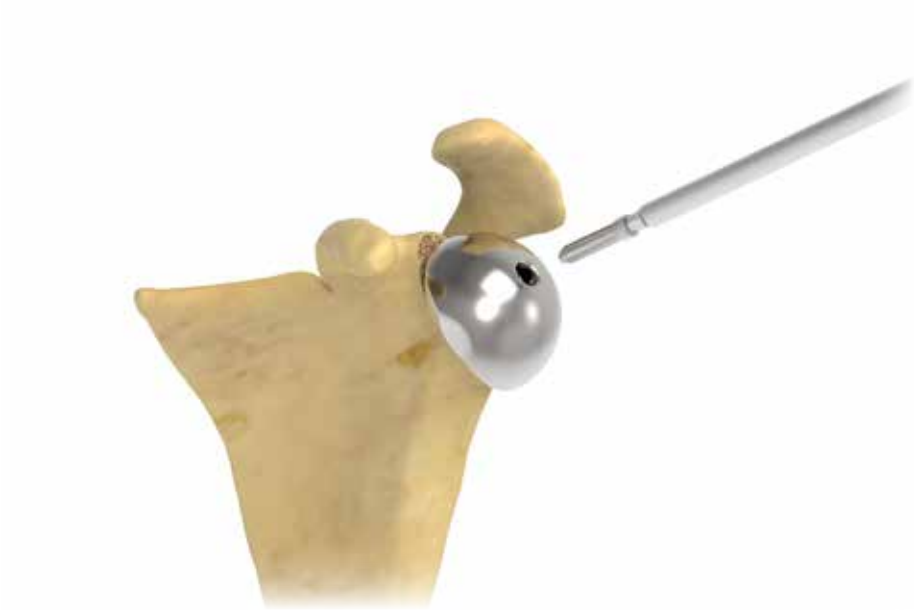


Figure 7
Glenosphere Locking Screw

INSERT THE GLENOSPHERE LOCKING SCREW

The Glenosphere Locking Screw is placed perpendicular to the hole within the Glenosphere and the Glenoid Baseplate, which are aligned with one another *(Figure 7)*. Note that the outer periphery of the apical hole of the Glenosphere is curved because of the intersection of the articular curvature on the superior surface of the device. The Glenosphere Locking Screw should not be inserted perpendicular to this articular curvature but instead be inserted perpendicular to the Baseplate and hole within the Glenosphere.

SURGICAL TIP

If you hear the Glenosphere Locking Screw "squeaking" prior to the screw head being recessed in the Glenosphere apical hole, STOP. The Glenosphere is not seated on the baseplate correctly. Run an instrument along the back side of the Glenosphere to feel for the plate. You should not feel any of the plate if the Glenosphere is seated properly. You can also visually assess this anteriorly.

IMPLANT LISTING

CATALOG NO.	PART DESCRIPTION
320-06-38	38mm Glenosphere/Extended Locking Cap Kit
320-06-42	42mm Glenosphere/Extended Locking Cap Kit
320-06-46	46mm Glenosphere/Extended Locking Cap Kit*
320-08-38	38mm Expanded Glenosphere/Extended Locking Cap Kit*
320-08-42	42mm Expanded Glenosphere/Extended Locking Cap Kit*
320-08-46	46mm Expanded Glenosphere/Extended Locking Cap Kit*
320-10-46	46mm Inset Glenosphere/Extended Locking Cap Kit*

INSTRUMENT LISTING

CATALOG NO.	PART DESCRIPTION
LEGACY	
301-07-70	T-Handle, short
321-07-05	Impactor Handle
321-01-26	Pilot Glenosphere Inserter
321-01-31	Klimo Glenosphere Inserter
321-01-38	Glenosphere Trial, 38mm
321-01-42	Glenosphere Trial, 42mm
321-01-46	Glenosphere Trial, 46mm*
321-04-38	Expanded Glenosphere Trial, 38mm*
321-04-42	Expanded Glenosphere Trial, 42mm*
321-12-46	Inset Glenosphere Trial, 46mm*

ERGO	
301-09-30	T-Handle
321-09-05	Modular Impactor Handle

** Special order*

CATALOG NO.	PART DESCRIPTION
321-01-52	Dolphin Inserter
321-01-51	Klimo Glenosphere Inserter
321-06-38	Glenosphere Trial, 38mm
321-06-42	Glenosphere Trial, 42mm
321-06-46	Glenosphere Trial, 46mm*
321-08-38	Expanded Glenosphere Trial, 38mm*
321-08-42	Expanded Glenosphere Trial, 42mm*
321-08-46	Expanded Glenosphere Trial, 46mm*
321-10-46	Inset Glenosphere Trial, 46mm*

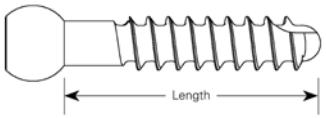
** Special order*

SYSTEM SPECIFICATIONS

(ALL DIMENSIONS IN MILLIMETERS)

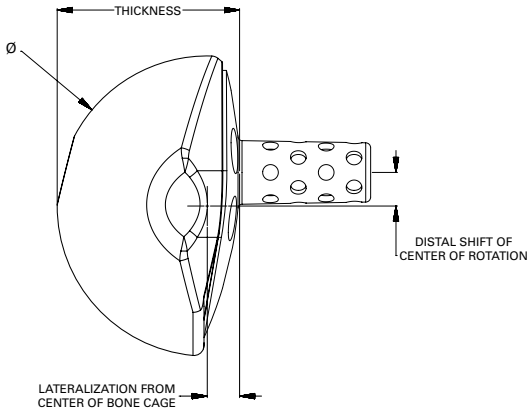
COMPRESSION SCREWS

Outer Diameter	Length	Color
4.5	18	White
	22	Black
	26	Orange
	30	Blue
	34	Red
	38	Green
	42	Yellow
	46	Purple

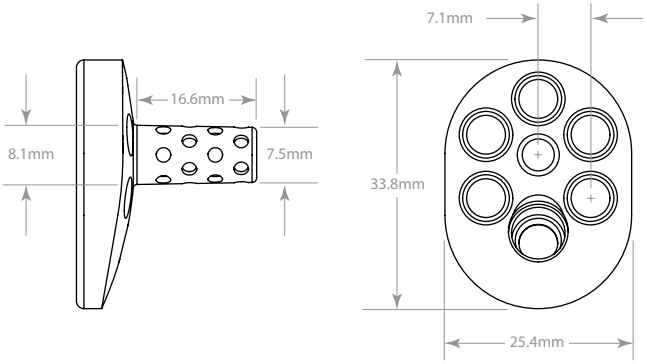


GLENOSPHERE/GLENOID PLATE

	Diameter	Thickness	Average Lateralization of Center of Rotation
38 Glenosphere	38	23.1	2.3
42 Glenosphere	42	25.1	2.3
46 Glenosphere	46	27.1	2.3
38mm Expanded Glenosphere	38	27.1	6.0
42mm Expanded Glenosphere	42	29.1	6.0
46mm Inset Glenosphere	46	23.0	2.1



All dimensions are in mm.



INDICATIONS

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion of the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L/R) and FRACTURE (F) humeral components are as follows:

P	L/R	F	Indications
√	√	√	Rheumatoid Arthritis, Osteoarthritis, Osteonecrosis Or Post-Traumatic Degenerative Problems
√	√		Congenital Abnormalities In The Skeletally Mature
√			Primary And Secondary Necrosis Of The Humeral Head
√		√	Humeral Head Fracture With Displacement Of The Tuberosities
√	√		Pathologies Where Arthrodesis Or Resectional Arthroplasty Of The Humeral Head Are Not Acceptable
√	√		Revisions Of Humeral Prostheses When Other Treatments Or Devices Have Failed (Where Adequate Fixation Can Be Achieved)
		√	Displaced Three-Part And Four-Part Upper Humeral Fractures
	√		Spiral And Other Fractures Of The Mid-Humerus (In Combination With Glenohumeral Degenerative Diseases)
	√		Revision Of Failed Previous Reconstructions When Distal Anchorage Is Required
√	√		To Restore Mobility From Previous Procedures (E.g. Previous Fusion)

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

CONTRAINDICATIONS

Use of the Equinoxe Shoulder System is contraindicated in the following situations:

- Osteomyelitis of the proximal humerus or scapula; if a systemic infection or a secondary remote infection is suspected or confirmed, implantation should be delayed until infection is resolved.
- Inadequate or malformed bone that precludes adequate support or fixation of the prosthesis.
- Neuromuscular disorders that do not allow control of the joint.
- Significant injury to the brachial plexus.
- Non-functional deltoid muscles.
- Patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.
- The patient is unwilling or unable to comply with the post-operative care instructions.
- Alcohol, drug, or other substance abuse.
- Any disease state that could adversely affect the function or longevity of the implant.

NOTES

NOTES

Exactech is proud to have offices and distributors around the globe. For more information about Exactech products available in your country, please visit www.exac.com

---

For additional device information, refer to the Exactech Shoulder System–Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

 00-0000634 Rev. C 0421

Exactech®

GLOBAL HEADQUARTERS:
2320 NW 66TH COURT
GAINESVILLE, FL 32653 USA

+1 352.377.1140
+1 800.EXACTECH
+1 352.378.2617 (FAX)
www.exac.com