

EXACTECH | EXTREMITIES

Operative Technique



equinox[®]

Preserve Stem



TABLE OF CONTENTS

INTRODUCTION.....	1
DETAILED OPERATIVE TECHNIQUE	2
PREOPERATIVE PLANNING/PATIENT POSITIONING	2
Patient Positioning.....	2
Surgical Approach	3
Humeral Head Resection	4
Anatomic Cutting Guide	4
Evaluate Resected Head Size	5
Humeral Preparation	6
Reaming the Humeral Shaft	6
Broaching the Humeral Shaft	6
Utilizing the Humeral Stem Trial.....	8
Humeral Stem Insertion.....	9
Inserting the Final Implants	10
Cementing the Press-Fit Prosthesis	12
IMPLANT AND INSTRUMENT LISTING	13
INDICATIONS FOR USE.....	15
CONTRAINDICATIONS FOR USE.....	15



INTRODUCTION

Since 2004, Exactech has been committed to providing clinical solutions that address the most challenging situations in shoulder arthroplasty. Our flagship product, the Equinox® shoulder system, has provided surgeons with a comprehensive system that uniquely focuses on all solutions in shoulder arthroplasty.

The new Equinox Preserve stem is our next generation platform stem. Created through the collaborative efforts of engineering research and global surgeon thought leaders, the Preserve stem allows intraoperative flexibility for the surgeon to choose between anatomic and reverse procedures.

Thank you for considering the Preserve stem.

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DETAILED OPERATIVE TECHNIQUE

PREOPERATIVE PLANNING/PATIENT POSITIONING

This document presents an addendum to Equinoxe® platform shoulder system operative technique (718-01-30) for the addition of Equinoxe Preserve stem.

The Preserve stem is implanted using similar steps as the primary, press-fit Equinoxe humeral stem devices, however this addendum specifically addresses the steps for using the Preserve stem and its related instrumentation.

Bone quality must be considered prior to implantation to ensure that the prostheses do not subside, tilt or migrate. Bone quality is an important factor that may prevent optimal fixation.

Please refer to the Equinoxe platform shoulder system operative technique (718-01-30) for additional information related to the preparation of the glenoid and humerus as well as implantation of the additional humeral components.

PREOPERATIVE PLANNING/PATIENT POSITIONING

After a careful history and physical examination, radiographs should be obtained to assess glenohumeral joint space narrowing, osseous deformities and glenoid wear. A CT scan is helpful to assist in the evaluation of the quality of bone stock and to further evaluate bone deformities that may be present. The following three radiographic views should be obtained: a true A/P view of the glenohumeral joint (30 degrees external oblique), a scapular lateral view and an axillary view. An MRI may be obtained if further evaluation of the soft tissues is determined to be helpful. To aid in preoperative planning, radiographic templates are available for the humeral components and glenoid components to approximate the required size and alignment of the implants.

PATIENT POSITIONING

The patient should be placed on an operating table in a supine position. The head of the operating table should be elevated approximately 30 degrees in a modified beach chair position. A small bolster should be placed laterally behind the involved shoulder. The patient should be moved to the side of the table, so that the upper extremity can be placed into maximum extension without obstruction by the operating table. Alternatively, a Captain's chair or similar positioning device can be used for proper patient positioning. The patient should be secured to the operating table to minimize any changes in position intraoperatively.

Once the patient is secure, the extremity is examined to assess the range of motion, with particular attention to external rotation with the arm at the side. If external rotation is restricted (i.e. internal rotation contracture), the need for more extensive subscapularis mobilization or lengthening procedures may be necessary. The entire upper extremity should be prepped and draped to allow complete access to the operative area and full mobility during the procedure.

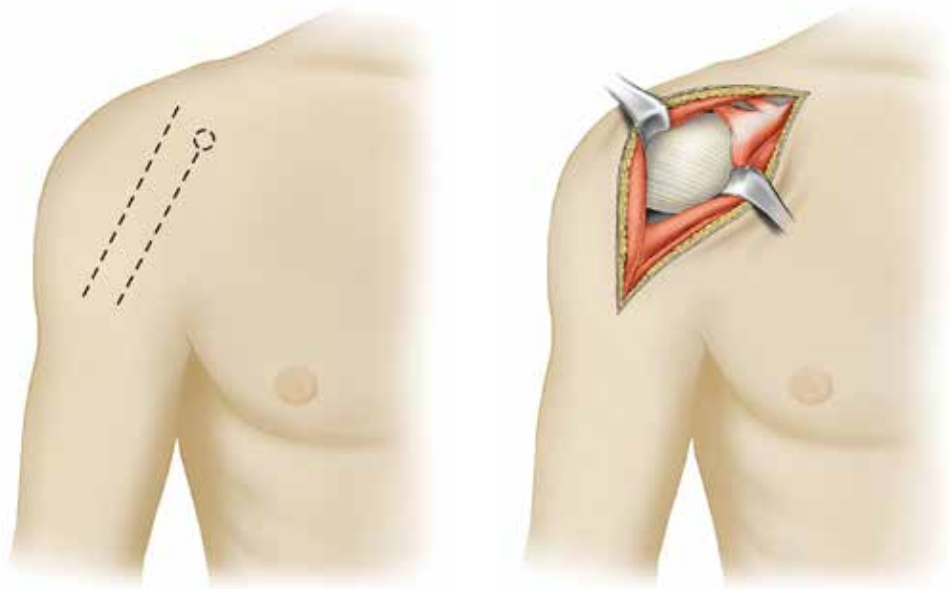


Figure 1
Surgical Approach

SURGICAL APPROACH

An anterior deltopectoral incision is made beginning inferior to the clavicle and passing over the coracoid process and extending distally toward the deltoid insertion. Medial and lateral subcutaneous flaps are created, and the deltopectoral interval is identified (*Figure 1*).

A thin fat stripe is usually located over the cephalic vein. The interval is usually developed medial to the cephalic vein, but it can also be developed laterally depending on the surgeon's preference. Branches of the cephalic vein on the approach side are cauterized, and the interval is developed inferior to superior to expose the clavipectoral fascia.

The advantage of retracting the cephalic vein with the deltoid is that the majority of the branches come from the deltoid. The disadvantage is the vein is more exposed to injury from the retractor as it crosses the superior aspect of the interval.

The subdeltoid space is mobilized with a blunt elevator. The clavipectoral fascia is incised longitudinally up to the coracoacromial ligament (which is spared), and the conjoint tendon is mobilized. A self-retaining retractor is placed with care to avoid excessive traction on the conjoint tendon. The

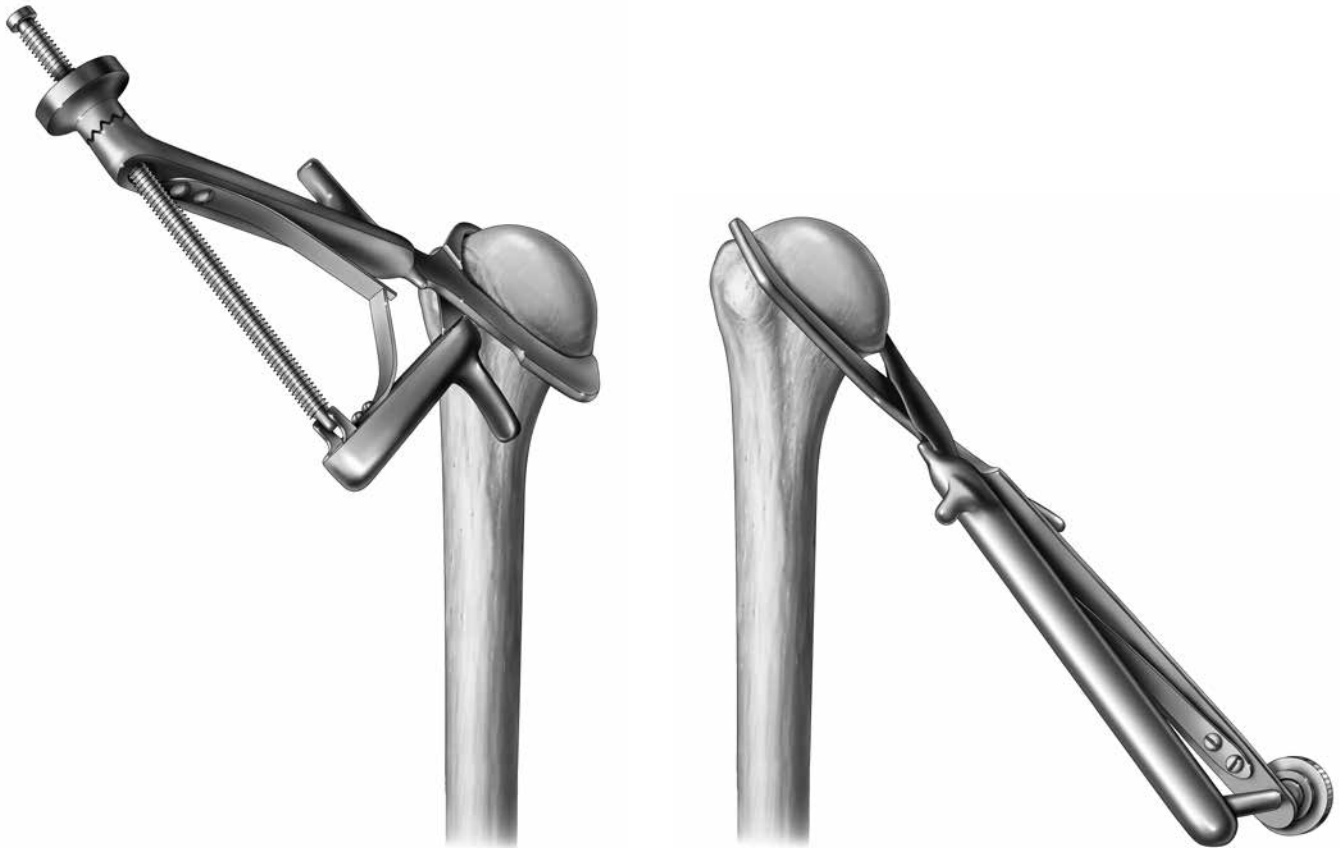
coracoacromial ligament is identified and the subacromial space is mobilized with a blunt elevator. The subscapularis tendon insertion on the lesser tuberosity is identified along with the rotator interval. The anterior humeral circumflex vessels along the inferior border of the subscapularis muscle, the "three sisters," are cauterized extensively, and the biceps tendon is palpated in its groove. The subscapularis tendon and the capsule are tenotomized 1cm medial to the lesser tuberosity and tagged with #1 sutures.

An alternative approach is to elevate the subscapularis directly off of the bone or elevate its insertion with a thin wafer of bone (1-2mm thick) using an osteotome. The choice is based primarily on surgeon preference.

The rotator interval is divided in a lateral to medial direction up to the superior glenoid rim. With the humerus extended, adducted and externally rotated, the capsule is carefully dissected off the inferior humeral neck, protecting the axillary nerve inferiorly with a small blunt retractor placed just inferior to the capsule. The capsular releases should be performed to allow 90 degrees of external rotation. The self-retaining retractor is then repositioned to retract the subscapularis. At this point, the humeral head can be dislocated.

DETAILED OPERATIVE TECHNIQUE

HUMERAL HEAD RESECTION



Figures 2a and 2b*
Anatomic Cutting Guide

* Part of the standard Equinox set, 311-01-01

HUMERAL HEAD RESECTION

Prior to the humeral head resection, all osteophytes should be removed using a rongeur. Doing so will properly expose the anatomic humeral neck, and anatomic replication is facilitated by an accurate resection along the anatomic neck. Three resection options are available and should be selected based upon surgeon preference.

Note: Bone quality must be considered to ensure proper proximal press-fit conditions and adequate stability.

Anatomic Cutting Guide

The **Anatomic Cutting Guide** enables the surgeon to accurately resect the humeral head along the anatomic neck without the use of intramedullary or extramedullary fixturing devices (Figures 2a and 2b). The jaws encircle the humeral

head along the anatomic neck, acting as a cutting surface. Cutting from the inferior to superior (Figure 2a), the thin jaw of the Anatomic Cutting Guide should slide between the bone and the superior cuff. The wide jaw should be in direct contact with the medial portion of the anatomic neck. Alternatively, an anterior-posterior cutting approach (Figure 2b) can be used with the thin jaw encircling the posterior side of the anatomic neck and the cutting jaw positioned on the anterior side. Once the guide is in position, it is secured using the threaded knob. To ensure the device does not move, hold the handle while performing the osteotomy. To protect the rotator cuff, the saw blade should not pass superior or posterior to the thin jaw.

Note: Removing the osteophytes is imperative in order to visualize the anatomic neck, but it also improves the bite obtained by the teeth on the cutting guide.



Figure 3*

Fixed Angle Cutting Guide

* Part of the standard Equinox set, 311-01-01

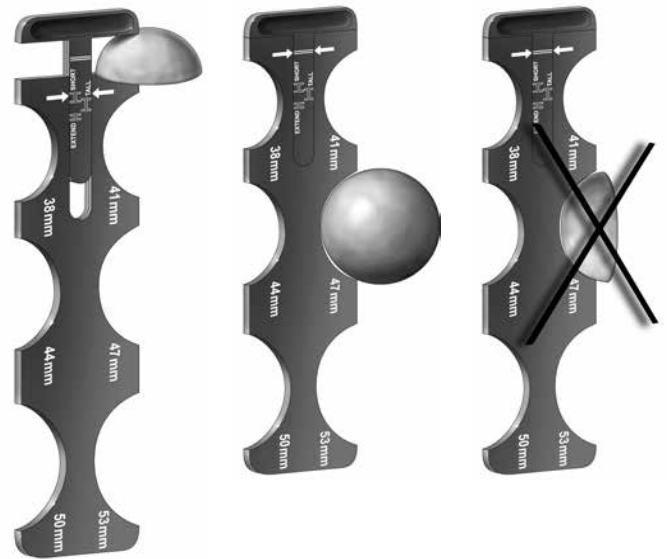


Figure 4*

Humeral Head Sizer

* Part of the standard Equinox set, 311-01-01

Head Size (mm)	38	41	44	47	50	53
Glenoid Curvature	Alpha			Beta		

Table 1

Relationship Between Humeral Head Diameter and Glenoid Curvature

Freehand: Identify the anatomic neck and resect the head using a microsagittal saw.

Fixed Angle (132.5 degrees) Guide: Though this method is not based upon the patient's anatomy, we have provided a Fixed Angle Cutting Guide for surgeons who prefer this method (Figure 3). Three options are available for the guide:

1. The surgeon may attach the guide to a handle, which aligns with the forearm for 20 degrees of retroversion.
2. Use .062 K-wires to secure it to the bone.
3. Use the cutting surface to mark the resection line with a bovie and then use the freehand method.

With this method, the superior portion of the resection should be just medial to the rotator cuff insertion. The amount of retroversion (usually 20-40 degrees) should be determined by positioning the humerus in external rotation before the resection is made.

Evaluate Resected Head Size

After resecting the humeral head, use the **Humeral Head Sizer** to estimate both the head's diameter (circumferentially) and height in order to determine the probable size of the modular humeral head (Figure 4). The head diameter will determine what size glenoid will be used for TSA as described in Table 1.

DETAILED OPERATIVE TECHNIQUE

HUMERAL PREPARATION

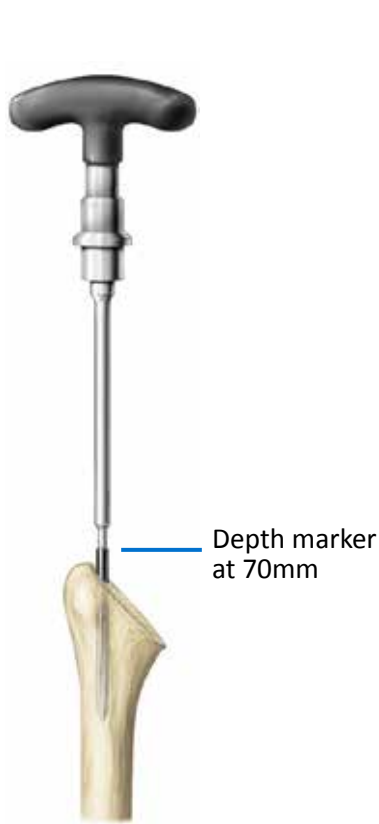


Figure 5
Starter Reamer



Figure 6
Extended Broach



Figure 7
Extended Broach Orientation

HUMERAL PREPARATION

Reaming the Humeral Shaft

The Preserve stem **Starter Reamer** has a pointed tip to facilitate the initial entry into the IM canal. The entry point is made just posterior to the bicipital groove and at the junction of the middle and upper third of the resected humeral surface. It is imperative that the reamer be inserted into the canal to the appropriate depth as indicated by the depth markers (*Figure 5*).

Note: To ensure adequate depth is achieved, ream until the depth marker is no longer visible.

Broaching the Humeral Shaft

Note: Bone quality must be considered to ensure proper proximal press-fit conditions and adequate stability.

The **Extended Broach** can be used to facilitate the initial entry into the IM canal (*Figure 6*). The entry point is made

just posterior to the bicipital groove and at the junction of the middle and upper third of the resected humeral surface.

It is imperative that the Extended Broach be inserted into the canal to the appropriate depth dictated by the **Broach Handle** and **Broach Collar**. The Extended Broach should be impacted until contact is made between the tip of the Broach Handle and the resected bone surface.

The Broach Collar can be chosen to allow for the broach to be flush with that of the cut surface, utilizing the 0mm option.

The Broach Collar can also be chosen to utilize a -2mm feature, which will countersink the broach 2mm below the cut surface.

Note: Only the strike surface of the Broach Handle should be used for impaction. The use of the Extended Broach aids in orientation of the implant with the IM canal (*Figure 7*).

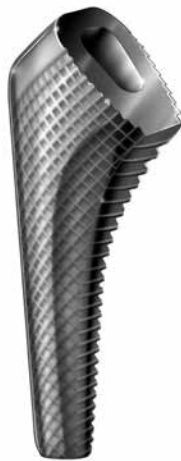


Figure 8
Stem Broach



Figure 9
Broach Insertion With Modular Broach Handle
and Retroversion Handle

If the surgeon does not feel the Extended Broach provides adequate stability, then attach the next sized broach (*Figure 8*) to the **Modular Broach Handle**, as illustrated in *Figures 8 and 9*, respectively.

The **Preserve Stem Broach** should be inserted into the proximal humerus at a version consistent with that of the cut surface. The proximal humerus should be sequentially broached until sufficient stability of the broach is reached.

Note: We recommend using the smallest-sized broach necessary to obtain adequate fixation in order to determine rotational stability and avoid cortical contact.

Only the strike surface of the handle should be used for impaction.

As a visual check to assess version, the **Retroversion Handle** can be attached to the Equinox Broach Handle ("L" and "R" indicate appropriate side), as shown in *Figure 9* and lined up with the patient's forearm. The Retroversion Handle can be placed in 20, 30 or 40 degrees of retroversion based on surgeon preference.

Note: The broaches are undersized by 1mm (total diametrical press-fit 0.5mm per side) to ensure adequate press-fit, therefore impaction is necessary to insert the stem.

DETAILED OPERATIVE TECHNIQUE

REVERSE TRIAL PROCEDURE



Figure 10

Trial the Reverse Tray Broach Adapter

REVERSE TRIAL PROCEDURE

Utilizing the Humeral Stem Trial

The final broach can also be utilized as a trial humeral stem. The broach/trial is 1 mm diametrically undersized in the proximal region and line-to-line distally with respect to the final implant. The Reverse Tray Broach Adapter (*Figure 10*) is to be placed in the broach and trialed as denoted in the Platform Shoulder System operating technique.



Figure 11
Implant Insertion

HUMERAL STEM INSERTION

Once the proximal humerus is prepared, the implant is ready to be inserted. The definitive implant will match the last broach size used. Attach the definitive implant to the **Stem Inserter** (Figure 11), and be sure to align the dimple on the inserter with the divot on the stem.

For this reason, it is important that the stem be completely threaded to the Stem Inserter prior to impaction to prevent damage to the threads. Use the mallet to impact the Stem Inserter until the superior face of the stem is at the level of the resected surface. Only the strike surface should be used for impaction.

As a visual check to assess version, the Retroversion Handle can be attached to the Stem Inserter in the same manner described previously.

SURGICAL NOTES

- If a tendon-to-bone repair is utilized, prepare the drill holes in the proximal humerus to facilitate the subscapularis repair prior to humeral stem insertion.
- If cement is desired, it is recommended to use an implant one size less than the last used broach.

DETAILED OPERATIVE TECHNIQUE

INSERTING THE FINAL IMPLANT



Figure 12
Implant Insertion

INSERTING THE FINAL IMPLANTS

The final Humeral Adapter Tray is attached to the Humeral Stem (*Figure 12*) using the Reverse Torque Defining Screw.



Figure 13

Back Table Assembly to Lock Torque Defining Screw

Size of Preserve Implant	Space on Back Table Assembly to be Used
6mm	7mm
8mm	9mm
10mm	11mm
12mm	13mm
14mm	15mm

TABLE 2

Back Table Compatibility with Preserve Stem

The stem tray and liner can be assembled using the **Back Table Assembly** (*Figure 13*) first and then placed as a unit into the humerus. The disadvantage of this technique is that further implant trialing is not possible, so it should only be used when the surgeon is confident about the thickness of the tray and liners based on the previous trialing.

The Preserve stem sizing is different from the labels on the Back Table Assembly, use *Table 2* for clarification.

DETAILED OPERATIVE TECHNIQUE

CEMENTING THE PRESS-FIT PROSTHESIS



Figure 14
Preserve Stem

CEMENTING THE PRESS-FIT PROSTHESIS

The press-fit **Preserve Stem** (Figure 14) was designed with several features that optimize a cementless application. However, the stem has features that enable it to be cemented if desired. In this situation, a stem one size smaller in diameter than the broach size would provide a minimum 1mm cement mantle proximally and a minimum 2mm distally.

In cases where an adequate press-fit was not achieved, the surgeon has two options. A minimized cement technique could be employed, whereby a small amount of cement is placed in the proximal canal. For example, whatever size stem is cemented in a humerus, it has to be broached to the same size.

Alternatively, in this same scenario, the surgeon could broach up a larger size to create room for a more robust proximal cement mantle and then cement a stem one size smaller than what was broached.

The use of a cement restrictor is based on personal preference, however an appropriately-sized cement restrictor will improve distribution. Formal cement pressurization is avoided to decrease the possibility of humeral shaft fracture. The intramedullary canal should then be packed with a sponge to obtain adequate drying before cementing. Once the canal is prepared, the cement is mixed and injected into the canal.

IMPLANT AND INSTRUMENT LISTING

CATALOG NUMBER PART DESCRIPTION

Implant Listing

300-30-06	Equinox, Preserve Stem, Size 6mm
300-30-08	Equinox, Preserve Stem, Size 8mm
300-30-10	Equinox, Preserve Stem, Size 10mm
300-30-12	Equinox, Preserve Stem, Size 12mm
300-30-14	Equinox, Preserve Stem, Size 14mm



Instrument Listing

301-03-10 Retroversion Handle



301-05-00 Equinox Broach Collar



301-05-01 Equinox Broach Handle



301-05-10 Retroversion Bar



301-15-06 Starter Reamer



301-07-10 Primary Stem Inserter/Extractor



311-01-10 132.5 Degree Osteotomy Guide



315-07-20 Drill Guide (132.5 Retroversion Handle)



INSTRUMENT LISTING

CATALOG NUMBER	PART DESCRIPTION
301-30-06	Preserve Stem Broach, Size 6mm
301-30-08	Preserve Stem Broach, Size 8mm
301-30-10	Preserve Stem Broach, Size 10mm
301-30-12	Preserve Stem Broach, Size 12mm
301-30-14	Preserve Stem Broach, Size 14mm
303-30-06	Preserve Stem Extended Broach, Size 6mm
321-05-21	Reverse Tray Trial Broach Adapter
321-10-05	Humeral Adapter Tray Trial Assembly, +5
321-10-10	Humeral Adapter Tray Trial Assembly, +10



INDICATIONS FOR USE

The Equinoxe Preserve stems are indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total arthroplasty, anatomic hemi-arthroplasty, or reverse total arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total arthroplasty and anatomic hemi-arthroplasty are as follows:

- Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
- Congenital abnormalities in the skeletally mature
- Primary and secondary necrosis of the humeral head
- 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)
- To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Preserve stems are additionally indicated for use in reverse total arthroplasty in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff or a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Equinoxe Preserve stems are intended for press-fit applications but may be used with bone cement at the discretion of the surgeon.

CONTRAINDICATIONS FOR USE

Use of the Equinoxe Preserve stems are 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 that 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.
- Acute fracture of the proximal humerus and displacement of the tuberosities, displaced three- and four-part fractures of the proximal humerus (hemi-arthroplasty) or acute fracture of the proximal humerus with failure of the glenohumeral joint (total anatomic shoulder arthroplasty).
- Acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty).

Exactech, Inc. 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 Preserve Stem 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.

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