EXACTECH | **EXTREMITIES**

Operative Technique Addendum

equinoxe®

Preserve Stem

For Use in Australia

exactech

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INTRODUCTION

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

The new Equinoxe 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.

The Preserve stem was developed in conjunction with:

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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) or Equinoxe platform shoulder system with Ergo Instruments operative technique (00-0000121) 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.

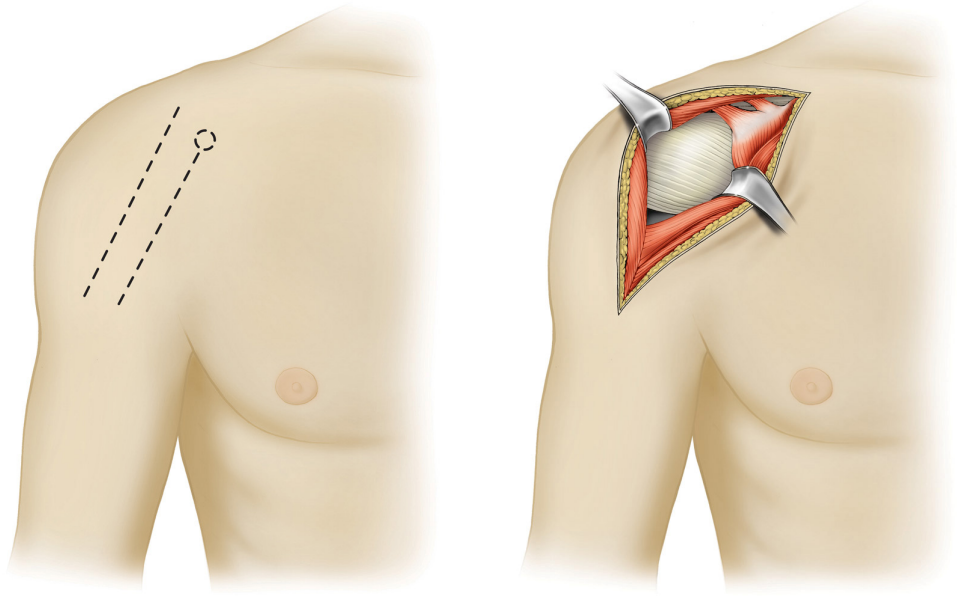


Figure 1
Surgical Approach

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)*.

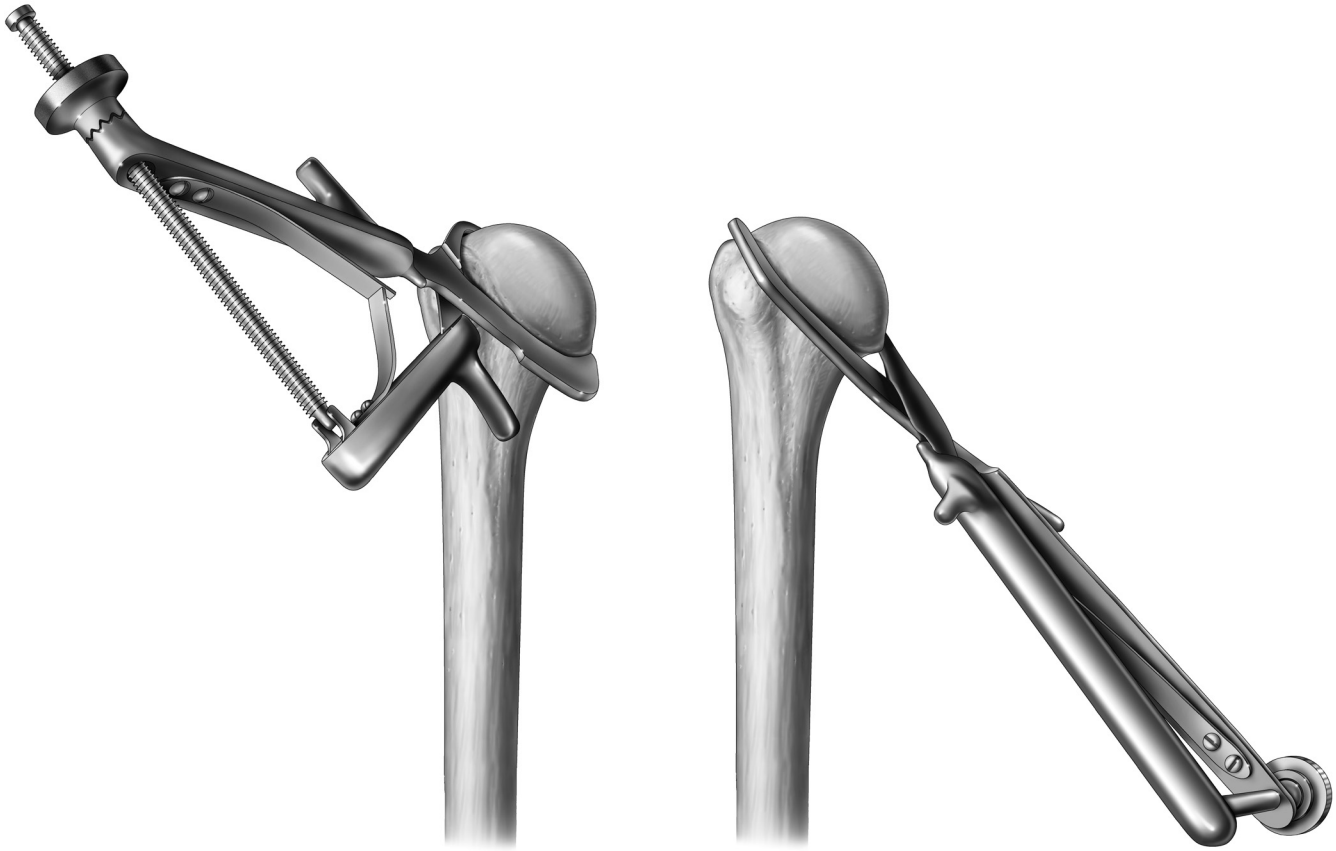
A thin fat stripe is usually located over the cephalic vein. The interval is usually developed medial to the cephalic vein, but it can also be developed laterally depending on the surgeon's preference. Branches of the cephalic vein on the approach side are cauterized, and the interval is developed inferior 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 conjoined tendon is mobilized. A self-retaining retractor is placed with care to avoid excessive traction on the conjoined 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.



Figures 2a and 2b*
Anatomic Cutting Guide

**Available in legacy Equinoxe set (part number 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. It is recommended that the surgeon evaluate the metaphyseal bone to confirm that there is sufficient bone stock for a short stem. As an example, the surgeon can apply thumb pressure to the cancellous bone to make this assessment. It is highly recommended that a longer stemmed option be available as a back-up if a short stem must be abandoned.*

Anatomic Cutting Guide:

The **Anatomic Cutting Guide** (311-01-01) 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.

Figure 3*
Fixed Angle Cutting Guide

**Available in legacy Equinoxe set (part number 311-01-10) or Ergo set (part number 311-11-10)*

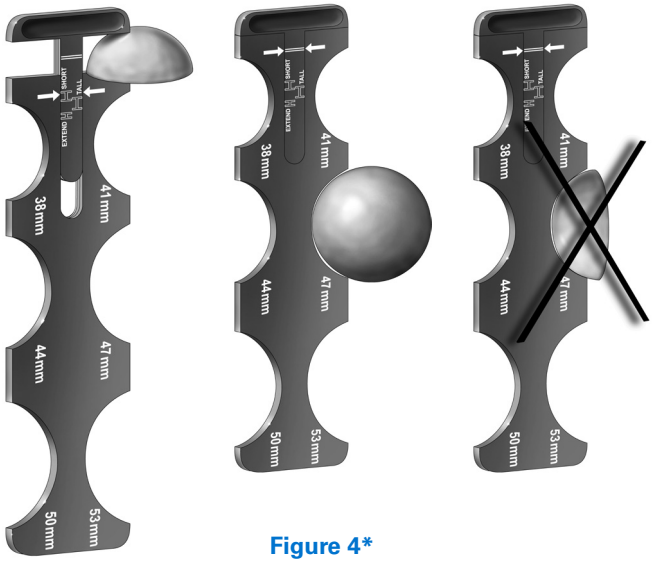


Figure 4*
Humeral Head Sizer

**Available in legacy Equinoxe set (part number 311-01-20)*

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

Table 1
Relationship Between Humeral Head Diameter and Glenoid Curvature

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.*

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

Fixed Angle (132.5 degrees) Guide (311-01-10 in the legacy Equinoxe set or 311-11-10 in the Ergo set): 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.

Note: *Refer to the reverse section of the Ergo operative technique (00-0000121) for the intermedullary humeral head cutting guide, utilizing the Ergo-Compatible Starter Reamer with the Ergo IM Cutting Guide.*

Evaluate Resected Head Size

After resecting the humeral head, use the **Humeral Head Sizer** (311-01-20) 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

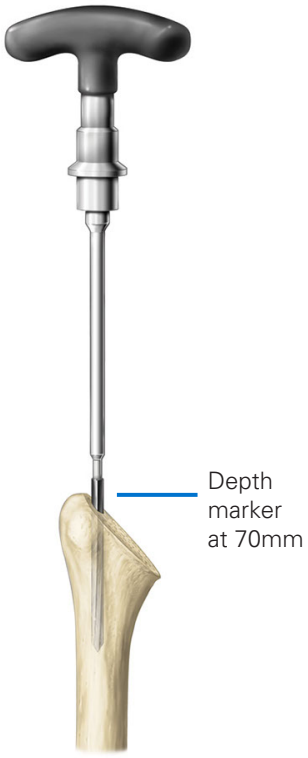


Figure 5*
Starter Reamer

(301-15-06 for Legacy handle and 301-18-06 for Ergo-compatible handle)

Figure 6
Extended Broach

Figure 7
Extended Broach Orientation

HUMERAL PREPARATION

Reaming the Humeral Shaft

The Preserve stem **Starter Reamer** (301-15-06 for Legacy handle and 301-18-06 for Ergo-compatible handle) 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.**

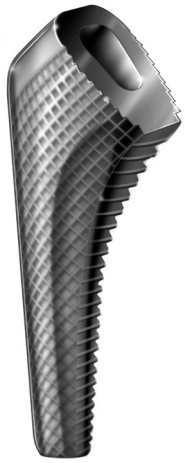


Figure 8
Stem Broach

Figure 9
Broach Insertion With Modular Broach Handle and Retroversion Handle

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).*

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: *It is important to maintain cancellous bone. If cancellous bone cannot be maintained, then switch to a longer platform stem.* ***We recommend using the smallest-sized broach necessary to obtain adequate fixation in order to determine rotational stability and avoid cortical contact.*** *In cases of conversion to a stemmed implant, the humerus is prepared following pages 11 through 13 of the Equinoxe Primary/Reverse Operative Technique (718-01-30).*

As a visual check to assess version, the **Retroversion Handle** can be attached to the Equinoxe 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.

Figure 10
Tray Trial Placed on Broach

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.*

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

REVERSE TRIAL PROCEDURE

Utilizing the Humeral Stem Trial

The final broach can also be utilized as a trial humeral stem. The broach/trial is 1mm 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.

Note: *If using Ergo-compatible instrumentation, refer to the reverse trialing humeral adapter tray and liner section of the Ergo technique (00-0000121) for an alternative trialing approach using the Ergo-Compatible Broaches and Ergo Tray Trials.*

Figure 11
Implant Insertion

FINALIZE aTSA WITH THE PRESERVE STEM

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** and be sure to align the dimple on the inserter with the divot on the stem *(Figure 11)*.

Note: *Only use finger tightening to assemble the Stem Inserter with the stem. The 3.5mm Hex Driver may be used to loosen the Stem Inserter after impaction. Excessive tightening can lead to device deformation causing instrument to bind with implant.*

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. After the humeral stem insertion step, complete the primary shoulder procedure by following the Equinoxe Platform Shoulder System with Ergo Instruments Operative Technique (00-0000121), starting at the humeral protector step of the primary shoulder operative technique section.

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.

FINALIZE rTSA WITH THE PRESERVE STEM

Reverse Trial Procedure

Utilizing the Broach as a Stem Trial

The final broach can also be utilized as a trial humeral stem. The **Reverse Tray Broach Adapter** *(Figure 12)* is to be placed in the broach and trialed as denoted in the Platform Shoulder System operating technique.

Trialing The Humeral Adapter Tray & Liner

As an alternative to the Reverse Tray Broach Adapter, the Humeral Tray Trial can be used. The +0mm **Humeral Tray Trial** is attached to the Humeral Broach and secured by threading the captured screw into the threads of the broach *(Figure 13)*. This is an Ergo-specific instrument.

SURGICAL NOTES

It is critical that the Humeral Adapter Tray be oriented such that the line on the adapter tray aligns with the lateral fin of the humeral stem.

For larger offsets, **+5mm EQ Humeral Tray Trial** Spacer to add 5mm of offset *(Figure 13)*. If more offset is needed, remove the +0mm and +5mm tray trials and attach the **+10mm EQ Humeral Tray Trial**. Combinations of trays and liners can achieve the following offsets: +0, +2.5, +5.0, +7.5, +10.0, +12.5mm, +15mm, and +17.5mm.

It is important to note that the assembled humeral component will have a humeral neck angle of 145 degrees because the liner adds 12.5 degrees to the stem's 132.5 degree neck angle.

Note: *Avoid using a sliding motion when separating Tray Trials and Liner Trials.*

INSERTING THE FINAL IMPLANT

To insert the **Humeral Liner Trial** *(Figure 14)* into the Trial Tray, the underside asymmetric-connecting feature should be appropriately aligned, and the liner/tray trials should be pressed together until they engage. To disengage the trials, the tip of the **Humeral Liner Removal Tool** is inserted into the recessed region of the trial tray and the instrument is turned like a key until the Humeral Liner Trials and plate trials are disengaged, thereby freeing the liner.

The stability of the implant is assessed during a trial reduction. The shoulder should be placed through a range of motion to assess the stability of the construct. While each surgeon may have their own system to assess stability, we approach the trial reduction as follows:

Figure 12
Trial the Reverse Tray Broach Adapter

Figure 13
Humeral Tray Trial

Figure 14
Humeral Tray Trial with Liner

1) With reduction and arm by the side, the lateral deltoid and conjoined tendon should be under tension. The expectation is that the reduction should require more distraction to achieve than reduction of non-constrained implants.

2) Forward elevation and abduction should be assessed to determine that the construct is stable and the components do not impinge on bony structures.

3) Internal and external rotation should be assessed with the humerus at 0 and 90 degrees to assess stability. Although maximal ranges of external rotation may produce some impingement posteriorly, it should not result in instability.

4) With the arm at the side, there should be no evidence of impingement that results in distraction of the implants.

Note: *The Tray Trial or Liner Trial may become disengaged in tight shoulders or during impingement.*

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 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 liner trial can pop out from the tray trial. The humeral component should then be removed and additional bone should be resected using the methods described.

The final Humeral Adapter Tray is attached to the Humeral Stem *(Figure 15)* using the Reverse Torque Defining Screw.

Alternatively, the stem, tray and liner can be assembled using the **Back Table Assembly Stand** *(Figure 16)* 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.

Note: *Verify that the stem is in the correct hole and in the correct orientation before impaction. The hole size and the stem should both face the same direction. Improper use can lead to the stem becoming stuck in the insert.*

Figure 15
Implant Insertion

Figure 16
Back Table Assembly to Lock Torque Defining Screw

Size	Color of Impactor Tip
36	Green
38	Blue
40	Purple
42	Yellow

Table 2
Impactor Tips

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 or reverse total arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total 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
- 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.

CONTRAINDICATIONS FOR USE

Use of the Equinoxe Preserve stems are contraindicated in the following situations:

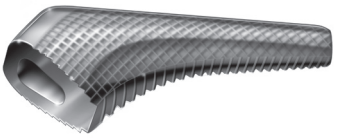
- Osteomyelitis of the proximal humerus or scapula; if a systemic infection or a secondary remote infection is suspected or confirmed, implantation should be delayed until infection is resolved.
- Inadequate or malformed bone that precludes adequate support or fixation of the prosthesis.
- Neuromuscular 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).

IMPLANT LISTING

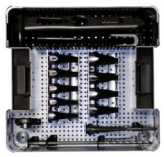
CATALOG NUMBER	PART DESCRIPTION
Implant Listing	
300-30-06	Equinoxe, Preserve Stem, Size 6mm
300-30-07	Equinoxe, Preserve Stem, Size 7mm
300-30-08	Equinoxe, Preserve Stem, Size 8mm
300-30-09	Equinoxe, Preserve Stem, Size 9mm
300-30-10	Equinoxe, Preserve Stem, Size 10mm
300-30-11	Equinoxe, Preserve Stem, Size 11mm
300-30-12	Equinoxe, Preserve Stem, Size 12mm
300-30-13	Equinoxe, Preserve Stem, Size 13mm
300-30-14	Equinoxe, Preserve Stem, Size 14mm

INSTRUMENT LISTING

301-05-03	Equinoxe Broach Collar
301-05-02	Equinoxe Broach Handle
301-05-20	Retroversion Bar
301-15-06	Starter Reamer
301-18-06	Ergo-Compatible Starter Reamer
301-30-06	Preserve Stem Broach, Size 6mm
301-30-07	Preserve Stem Broach, Size 7mm
301-30-08	Preserve Stem Broach, Size 8mm
301-30-09	Preserve Stem Broach, Size 9mm
301-30-10	Preserve Stem Broach, Size 10mm
301-30-11	Preserve Stem Broach, Size 11mm
301-30-12	Preserve Stem Broach, Size 12mm
301-30-13	Preserve Stem Broach, Size 13mm
301-30-14	Preserve Stem Broach, Size 14mm



CATALOG NUMBER	PART DESCRIPTION
301-32-06	Ergo-Compatible Broach, Size 6mm
301-32-07	Ergo-Compatible Broach, Size 7mm
301-32-08	Ergo-Compatible Broach, Size 8mm
301-32-09	Ergo-Compatible Broach, Size 9mm
301-32-10	Ergo-Compatible Broach, Size 10mm
301-32-11	Ergo-Compatible Broach, Size 11mm
301-32-12	Ergo-Compatible Broach, Size 12mm
301-32-13	Ergo-Compatible Broach, Size 13mm
301-32-14	Ergo-Compatible Broach, Size 14mm
303-30-06	Preserve Stem Extended Broach, Size 6mm
303-32-06	Ergo-Compatible Extended Broach, Size 6mm
321-05-21	Reverse Tray Trial Broach Adapter
301-51-01	Equinoxe, Preserve Stem, Instrument Case



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.

 OPTECH-000045 Rev. B 0625

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