equinoxe®
SHOULDER SYSTEM

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A Great Day in the O.R.™

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EQUINOXE SHOULDER SYSTEM DESIGN TEAM

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The Equinoxe® Shoulder System redefines "anatomical." The primary stem allows independent adjustability of all four anatomic parameters *in situ*. The reverse shoulder is an optimized design that minimizes both scapular notching and torque on the glenoid while seamlessly integrating with the primary stem. The fracture stem's offset anterior-lateral fin and asymmetric tuberosity beds define the next generation in complex fracture reconstruction.

INTRODUCTION

Throughout the development process, our team has collaborated on every facet of the Equinoxe Shoulder System including this surgical technique. We decided to take a comprehensive approach to the technique, discussing the surgery from pre-operative planning to post-operative rehabilitation, since many shoulder replacements are performed by surgeons who may only do two to three per year. Obviously, there are myriad approaches to each step of a total shoulder replacement and the surgeon should feel free to employ those with which he is most comfortable. The Equinoxe-specific techniques, though, should be respected to help ensure a safe and successful surgery.

We began the product development process by identifying concerns our team had with shoulder replacement. Our goal was to develop solutions to those concerns and we believe the Equinoxe System significantly improves the surgeon's ability to precisely replicate the patient's anatomy. The primary shoulder component utilizes an important design feature, which has been referred to as the "replicator plate". This plate is interposed between the humeral stem and the modular head and allows the neck inclination to be adjusted over a range of 15 degrees and the version to be adjusted over the same range. Additionally, two eccentricities (plate and head) provide what we consider the simplest and most precise way to reproduce the anatomy. The polyethylene glenoid is designed as both pegged and keeled components. There are two radii of curvature for the glenoid components, which allow the components to be paired with any size humeral head while maintaining the optimal radial mismatch.

We've decided to offer the surgical technique in two different formats. The first is a high level overview intended as a refresher before surgery or as a guide for the surgeon's support staff. The detailed, narrative version is intended for an in-depth understanding of the step-by-step approach that our team has endorsed and should be read at least once before using the Equinoxe Shoulder System.

We hope that our work, both the technique and the Equinoxe Shoulder System, will facilitate "A Great Day in the OR" for the surgeon and the staff.

Respectfully,

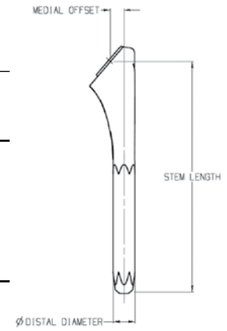
Pierre-Henri Flurin, M.D.
Thomas W. Wright, M.D.
Joseph D. Zuckerman, M.D.

SYSTEM SPECIFICATIONS

Press-Fit Stem

Distal Diameter	Length*	Inherent Medial Offset	Material	Surface Finish		Geometry	
				Proximal	Distal	Proximal	Distal
7	100	7.5	Ti-6Al-4V	16 grade grit blast	Hi-Brite Polish	Trapezoidal	Cylindrical with flutes
9	105						
11	110	8.5					
13	115	9.5					
15	120						
17	125						

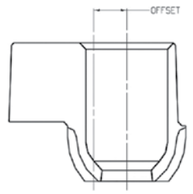
**Measured from distal tip to center of proximal spherical bore*



Replicator Plates

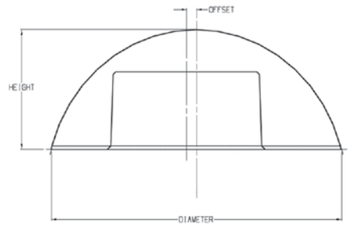
Offset	Material	Offset Ranges*		Angle Ranges (°)	
		Med/Lat	Ant/Post	Inclination	Version
1.5	Ti-6Al-4V	0 - 14	0 - 6	125 - 140	+/- 7.5
4.5					

**Includes effect of head offsets*



Humeral Heads

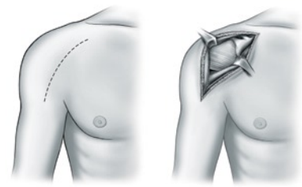
Diameter	Height			Glenoid		
	Short	Tall	Expanded	Offset	Mate	Material
38	16	19		0	Alpha	Co-Cr
41	16	20		0		
44	17	21		1.5		
47	18	22	26	1.5	Beta	
50	19	23	27	1.5		
53	20	24	28	1.5		



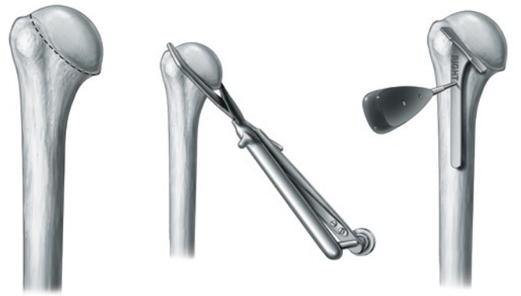
Glenoids

Sizes	Fixation	Material	Minimum Thickness	Curvature	Radial Mismatch	Shape
Small	Peg or Keel	Compression Molded UHMWPE	5mm	Alpha or Beta	Mean: 5.5	Anatomic (Pear)
Medium						
Large						

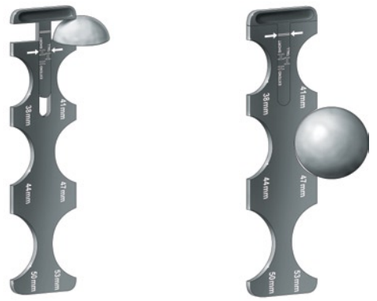
OVERVIEW TECHNIQUE



A Incision and exposure



B Resecting the humeral head



C Evaluating height and diameter of resected head

D Reaming the humeral shaft

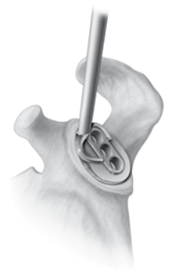
E Broaching the humeral shaft

F Inserting the press-fit stem

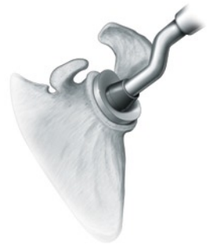
G Inserting stem protector

1. Fully mobilize subdeltoid space
2. Release inferior capsule completely off the humerus by externally rotating humerus
3. Release anterior capsule and subscapularis from glenoid
4. Excise labrum and release anterior and inferior capsule (protect axillary nerve)
5. Resect adequate amount of humerus
6. Stretch posterior capsule with humeral head retractor pushing humerus posterior to the glenoid
7. Biceps release with excision of superior labrum will also assist with glenoid exposure (surgeon preference)
8. If exposure still not adequate after steps 1-7, release posterior inferior capsule and triceps origin (must isolate and retract axillary nerve for this procedure)
9. If still poor exposure (very rare), then a posterior capsule release should be performed

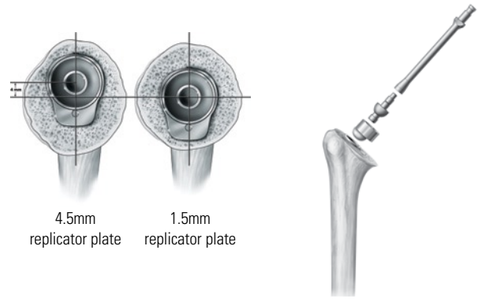
H Key steps to glenoid exposure



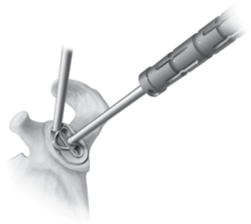
I Sizing the glenoid (with keel guide)



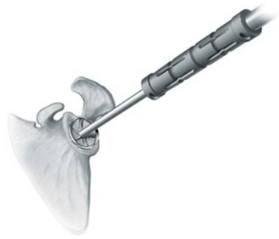
O Cementing and impacting final glenoid



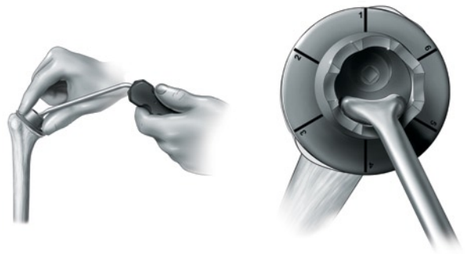
P Selecting and attaching the replicator plate (usually 4.5mm offset)



J Drilling center hole

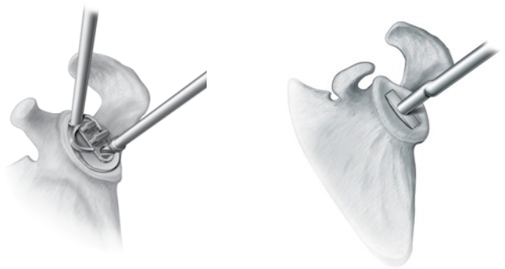


K Reaming the glenoid



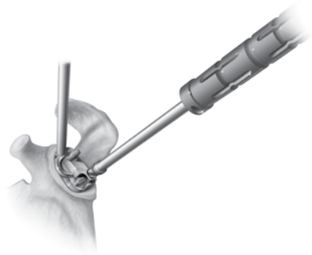
Q Covering resected surface with dual offsets

R Assessing range of motion

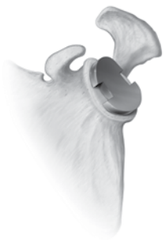


L1 Preparing keeled glenoid

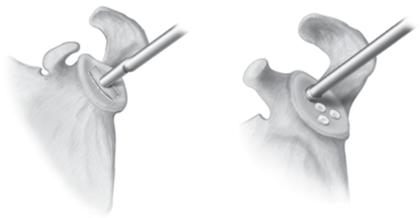
or



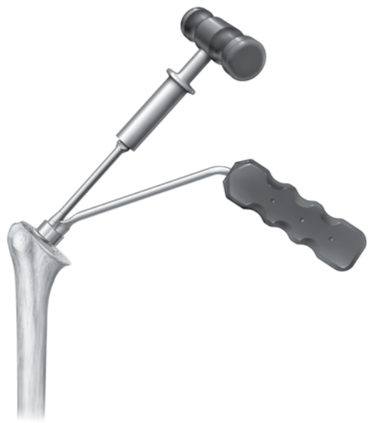
L2 Preparing pegged glenoid



M Implanting the trial glenoid



N Pressurizing the cement



S Disengaging superior portion of screw

T Impacting final humeral head

DETAILED OPERATIVE TECHNIQUE

INDICATIONS

The Equinoxe Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemiarthroplasty is determined by the surgeon to be the preferred method of treatment.

In general, primary shoulder arthroplasty is indicated for treatment of glenohumeral arthritis whether it be inflammatory, degenerative, or traumatic in origin or secondary to osteonecrosis of the humeral head. Primary shoulder arthroplasty is contraindicated in the presence of active infection, neuromuscular disorders which do not allow control of the joint and a non-functional deltoid muscle. For a more detailed description of the indications and contraindications, please refer to the package insert.

PRE-OPERATIVE EVALUATION

After a careful history and physical examination, radiographs should be obtained to assess glenohumeral joint space narrowing, osseous deformities and glenoid wear. The following three radiographic views should be obtained: 1) a true A/P view of the glenohumeral joint (30 degrees external oblique), 2) a scapular lateral view and 3) an axillary view.

In patients with osteoarthritis, varying amounts of posterior glenoid wear (with posterior subluxation of the humeral head) are common. If significant glenoid wear is a concern, a CT scan may be helpful to further define the bony anatomy.

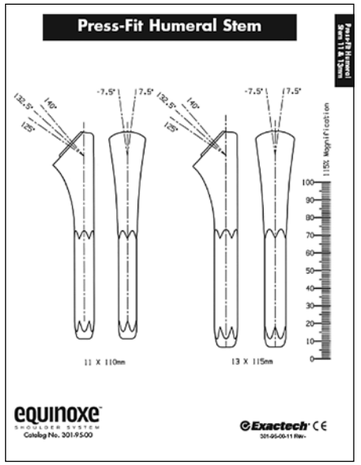
Rotator cuff tears are relatively uncommon in patients with osteoarthritis. The status of the rotator cuff can be determined at the time of surgery. For this reason, MRI or ultrasonography imaging is not routinely performed, though the decision is based upon surgeon preference.

To aid in pre-operative planning, radiographic templates are available for the humeral stems, humeral heads and glenoids to approximate the required sizes.

Step 1: 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 intra-operatively.

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.



Step 2: 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.

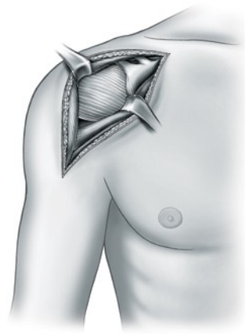
A thin fat stripe is usually located over the cephalic vein. The interval is usually developed medial to the cephalic vein; the interval can also be developed laterally depending on the surgeon's preference. Branches of the cephalic vein on the approach side are cauterized, and the interval is developed 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 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. Care is necessary to avoid injury to the biceps tendon. 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 degress of external rotation. The self-retaining retractor is then repositioned to retract the subscapularis. At this point, the humeral head can be dislocated.



Step 3: Humeral Preparation

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; 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.

Anatomic Cutting Guide:

The Equinoxe **Anatomic Cutting Guide** enables the surgeon to accurately resect the humeral head along the anatomic neck without the use of any complicated intramedullary or extramedullary fixturing devices *(Figure 1)*. The jaws encircle the humeral head along the anatomic neck, acting as a cutting surface.

Cutting from the inferior to superior *(Figure 1a)*, 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 *(Figure 1b)* approach 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.

Free Hand: Identify the anatomic neck and resect the head using a microsaggital 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 2)*. 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 or 3) use the cutting surface to mark the resection line with a bovie and then use the free hand 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.

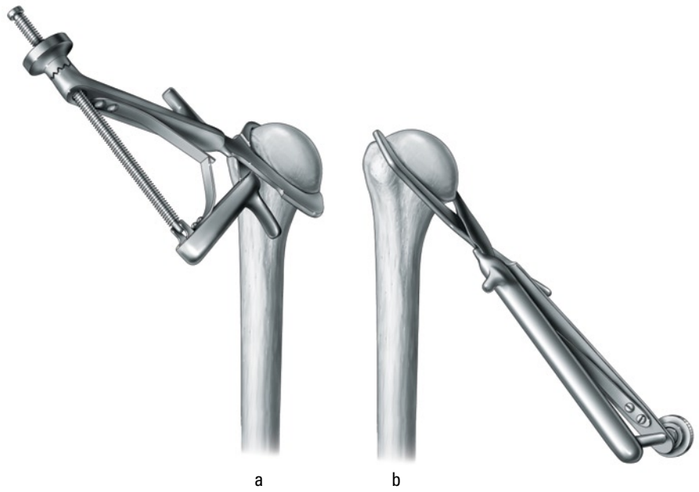


Figure 1
Anatomic Cutting Guide

Figure 2
Fixed Angle Cutting Guide

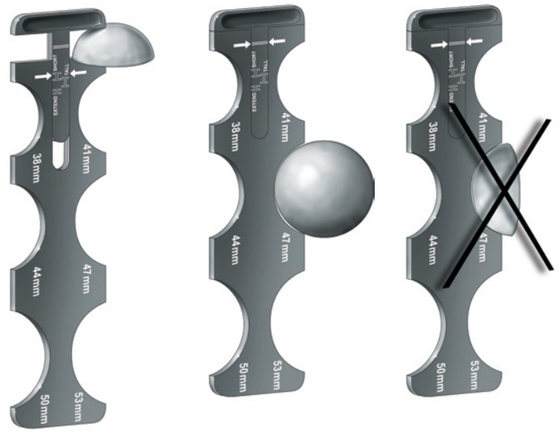


Figure 3
Humeral Head Sizer

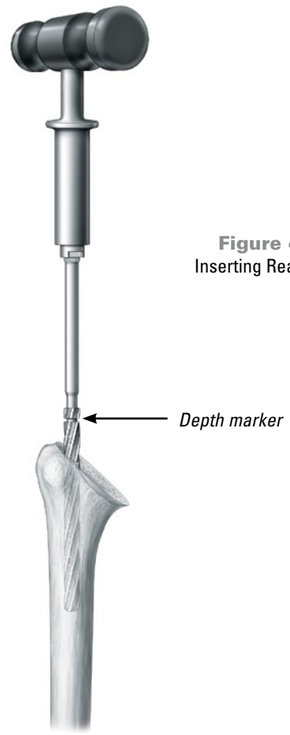


Figure 4
Inserting Reamer

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 3)*. **The head diameter will determine whether an alpha or beta glenoid will be used (for TSA), as described in *Table 1*.**

Reaming the Humeral Shaft

The smallest **Reamer** (7mm) has a sharp tip to facilitate the initial entry into the IM canal *(Figure 4)*. The entry point is made just posterior to the bicipital groove and at the junction of the middle and upper thirds of the resected humeral surface. The canal should be sequentially reamed until endosteal cortical contact is obtained. It is imperative that the Reamer be inserted into the canal to the appropriate depth as indicated by the depth markers; **reaming prepares the canal for the distal diameter of the stem and determines the final diameter of the definitive stem.** There is no need for forceful reaming. If there is difficulty fully inserting a reamer, the broach and implant selected should be the size of the last reamer that was completely seated. If there is any concern about the size of the implant to use, the smaller alternative should be selected since the stem will be cemented in place.

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

Note: Since the Reamer is the only instrument that prepares the distal canal, do not attempt to implant a stem that is larger than the largest reamer fully seated.

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

Table 1
Relationship between Humeral Head Diameter and Glenoid Curvature

Broaching the Humeral Shaft

After the canal has been reamed, attach the smallest **Broach** (7mm) to the **Modular Broach Handle** as illustrated *(Figure 5)*. The Broach should be inserted into the canal at a version consistent with that of the cut surface (i.e. the broach collar should be flush with the resected surface). The canal should be sequentially broached until the size of the broach matches that of the final reamer. Each Broach should be impacted until contact is made between the resected bone surface and the broach collar. The Broach should not be countersunk and only the strike surface should be used for impaction.

As a visual check to assess version, the **Retroversion Handle** can be attached to the broach handle ("L" and "R" indicate appropriate side) and lined up with the patient's forearm (assuming the patient has a stable elbow). The Retroversion Handle indicates 20 degrees retroversion when aligned with the forearm.

Note: The Broach is undersized distally because the reamer prepares the distal canal. This enables the surgeon to create a cement mantle by upsizing the Broach in cases where a proximal cement mantle is desired.

Humeral Stem Insertion

One unique advantage of the Equinoxe primary shoulder system is that it does not require stem trialing. Once the humeral canal is prepared, the implant is ready to be inserted into the canal. The implant **(having the same distal diameter as that of the final reamer)** is threaded to the **Primary Stem Inserter** *(Figure 6)*. Be sure to align the dimple on the inserter with the divot in the stem.

The broaches are undersized by 0.5mm proximally (to ensure adequate press-fit); therefore, impaction is necessary to insert the stem into the canal. 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. Do not attempt to countersink the prosthesis (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 above.

Note: Prior to humeral stem insertion, prepare the drill holes in the proximal humerus to facilitate the subscapularis repair, if a tendon-to-bone repair is utilized.

Figure 5
Inserting Broach

Figure 6
Inserting Humeral Stem

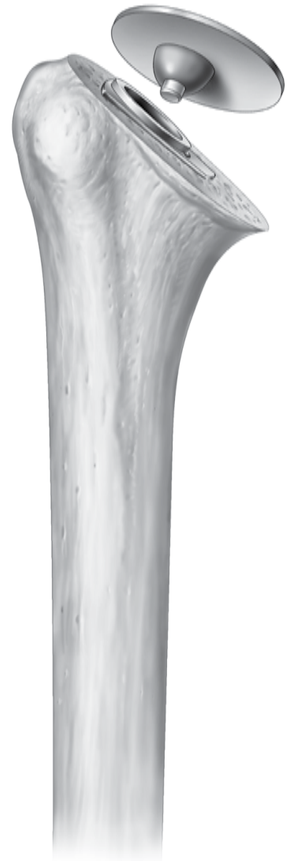


Figure 7
Stem Protector

Cementing the Press-Fit Prosthesis

The press-fit Equinoxe 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 1.5mm 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 and, for example, an 11mm stem is cemented in a humerus that has been reamed to an 11 and broached to an 11. Alternatively, in this same scenario, the surgeon could broach to a 13 to create room for a more robust proximal cement mantle and then cement the 11mm stem.

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.

Humeral Stem Protector

If the procedure requires a glenoid implant, place the humeral **Stem Protector** into the proximal portion of the implanted stem to protect the resected surface during glenoid preparation *(Figure 7)*. If a glenoid is not being implanted, Step 4 is omitted.

Note: The Stem Protector is offset so it can be rotated to ensure the best possible coverage. It is important for it to reach cortical bone so the cancellous bone is not damaged during glenoid exposure. A smaller option is also included.

Step 4: Preparing the Glenoid

Glenoid Exposure

Retractors are provided to aid in glenoid exposure. A **Posterior Glenoid Retractor** should be used to displace the proximal humerus posteriorly. The **Single Point Glenoid Retractor** is then placed anteriorly along the glenoid neck. **Hohmann Retractors** are placed superiorly and inferiorly around the glenoid.

The glenoid labrum is excised and an anterior and inferior capsular release is performed both for exposure and soft tissue mobilization. A formal posterior capsular release is only performed if adequate glenoid exposure cannot be obtained or if limitation of internal rotation is identified as a significant problem.

Some surgeons prefer to resect the biceps insertion and perform a biceps tenodesis (depending on the state of the biceps, particularly if significant degenerative changes are present). Biceps release and tenodesis will also enhance glenoid exposure. At this point, the degree and location of glenoid erosion can be visualized.

Assessing Glenoid Version

Glenoid wear requires special consideration. With increasing posterior erosion, posterior humeral head subluxation occurs with secondary stretching of the posterior capsule. Options to treat this asymmetric wear include, most commonly, reaming eccentrically to lower the high (nonwear) side; or, in very severe cases, bone grafting to elevate the low (worn) side. In Step 5, the surgeon will have the opportunity to modify humeral head version by up to 7.5 degrees if additional stability is required.

Occasionally, there may be significant symmetric (central) wear, which is more common in inflammatory arthritis. In these cases, the remaining glenoid vault should be assessed for its capacity to support a glenoid component. A **Keeled Glenoid** component can be inserted in the majority of cases of moderate central wear. If a **Pegged Glenoid** component is used, perforation by one or more of the pegs may occur. Although generally acceptable, it should be avoided when possible.

If the glenoid bone is inadequate (an uncommon occurrence), hemiarthroplasty should be performed with glenoid shaping to provide a concave surface for the humeral head.

Choosing the Glenoid

The Equinoxe System provides both Keeled and Pegged Glenoid options *(Figure 8)*. With this system, any size glenoid component (small, medium or large) can be matched with any size humeral head component (38mm - 53mm) while at the same time obtaining an optimal radial mismatch (average: 5.5mm). This is accomplished by choosing an alpha or beta glenoid based upon the humeral head diameter.

Key Steps to Adequate Glenoid Exposure:

1. Fully mobilize subdeltoid space
2. Release inferior capsule completely off the humerus by externally rotating humerus
3. Release anterior capsule and subscapularis from glenoid
4. Excise labrum and release anterior and inferior capsule (protect axillary nerve)
5. Resect adequate amount of humerus
6. Stretch posterior capsule with humeral head retractor pushing humerus posterior to the glenoid
7. Biceps release with excision of superior labrum will also assist with glenoid exposure (surgeon preference)
8. If exposure still not adequate after steps 1-7, release posterior inferior capsule and triceps origin (must isolate and retract axillary nerve for this procedure)
9. If still poor exposure (very rare), then a posterior capsule release should be performed

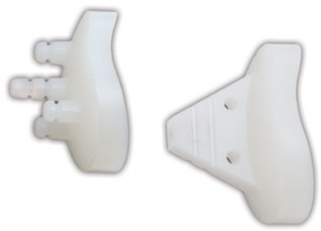


Figure 8
Equinoxe Keeled and Pegged Glenoids

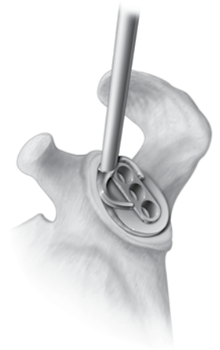


Figure 9
Sizing the glenoid

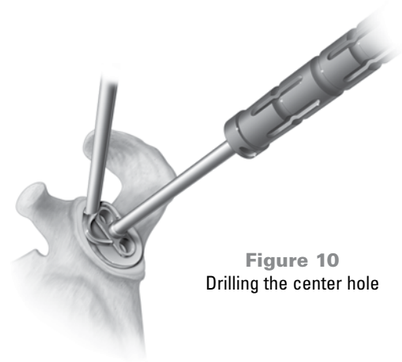


Figure 10
Drilling the center hole

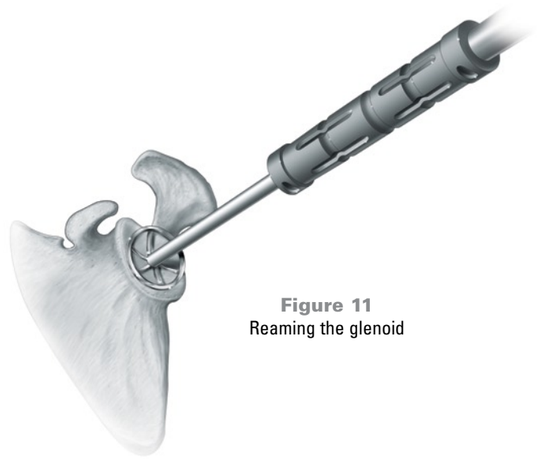


Figure 11
Reaming the glenoid

Summary

Step 1: Decide on Pegged and Keeled Glenoid based on surgeon preference and patient's anatomy.

Step 2: Based on the anticipated humeral head size (evaluate resected head size by placing anticipated trial head over resected surface of proximal humerus), refer to Table 1 to determine whether the patient should receive an alpha or beta glenoid (two different radii of curvature).

Step 3: Determine appropriate glenoid size *(Figure 9)* and drill the center hole *(Figure 10)* using the **Keeled Drill Guides** at the point where the superior/inferior axis and anterior/posterior axis intersect.

Note: The quick-connect handle always attaches to the anterior side of the glenoid drill and the narrow part of the glenoid is always superior.

Note: Ensure the glenoid osteophytes have been removed so the true center of the glenoid fossa is acccurately identified.

Reaming the Glenoid

Sequentially ream the glenoid up to the desired size *(Figure 11)*. While the Reamer can be connected to a powered drill, hand reaming is recommended to conserve bone stock. An extra small glenoid reamer is provided to aid the surgeon in the initial preparation.

Implanting the Glenoid

Keeled Glenoid: Connect the appropriately sized Keel Drill Guide to the **Drill Guide Handle**. Align its center hole with the center of the glenoid and redrill the center hole to ensure the proper depth before inserting the T-shaped **Holding Pin** into the drilled hole. Next, use the **Short Keel Drill** to drill the superior hole and insert an L-shaped Holding Pin *(Figure 12)* into the drilled hole.

Drill the third hole and use a rongeur or a burr to remove the cortical bone between the holes. Sequentially impact the keel broach (starting with the small size) to finalize the trough for the keel *(Figure 13)*. Do not attempt to countersink the keel broach and ensure the broach only impacts cancellous bone.

Finally, ensure proper seating and sizing by inserting the trial glenoid.

Note: The medium and large glenoids have the same size keel so there are only two keel broaches.

Note: The Holding Pins were designed to fit conveniently in Allis clamps for easy insertion.

Pegged Glenoid: Connect the **Pegged Drill Guide** to the Drill Guide Handle *(Figure 14)*. The integral central peg of the Pegged Drill Guide should be inserted into the central hole. Next, the superior hole is drilled with the **Center Keel/Peg Drill** and the T-shaped Holding Pin is placed into that hole through the Pegged Drill Guide. Then, the two inferior holes can be drilled through the Pegged Drill Guide.

Note: The Holding Pins were designed to fit conveniently in Allis clamps for easy insertion.

Finally, ensure proper seating and sizing by inserting the trial glenoid *(Figure 15)*. Since the peg spacing is the same on all sizes, the surgeon may easily upsize or downsize the pegged glenoid to achieve the best coverage.

Note: Drill the center and superior holes first for the peg; once the inferior holes are drilled, it becomes more difficult to switch to a Keeled Glenoid.

Note: The glenoid curvature (alpha or beta) is determined by the head diameter so there is only one set of trials for the Pegged and Keeled Glenoid.

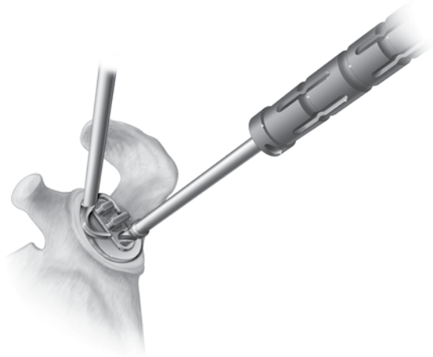


Figure 12
Drilling the keeled glenoid

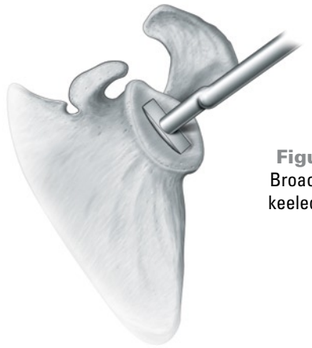


Figure 13
Broaching the keeled glenoid

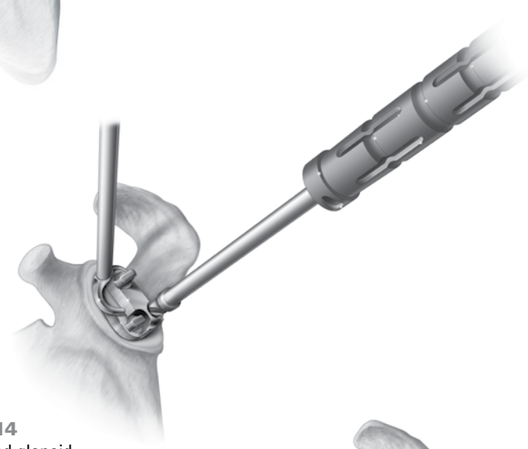


Figure 14
Drilling the pegged glenoid

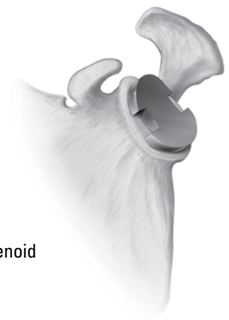
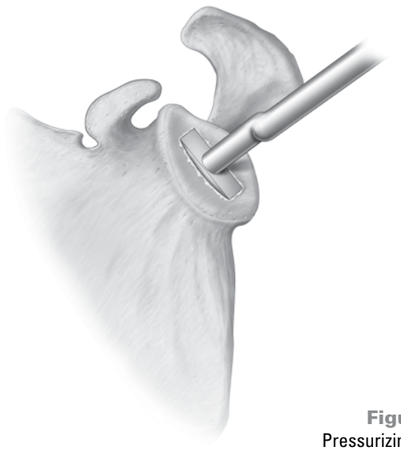


Figure 15
Inserting the trial glenoid



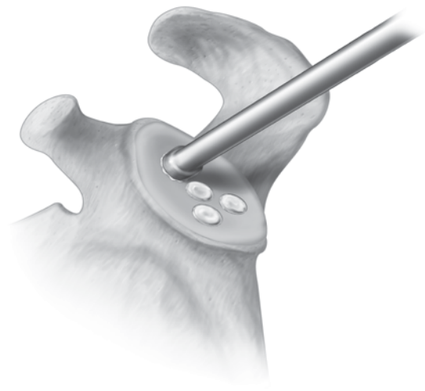


Figure 16
Pressurizing the cement

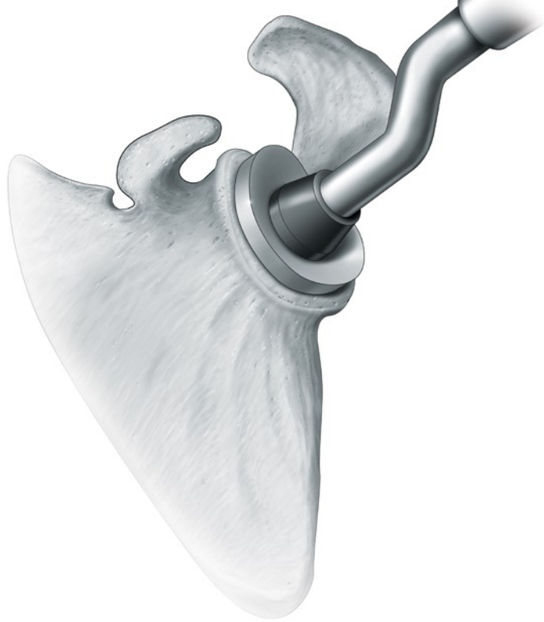


Figure 17
Impactor with glenoid tip

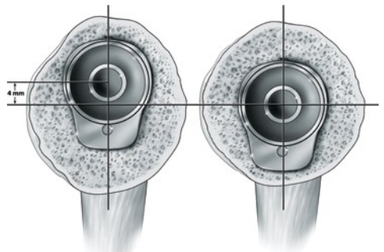
Whether using a Keeled and Pegged Glenoid, prepare the glenoid by first copiously irrigating the holes to clear any debris. Place thrombin-soaked surgigel, or a similar hemostatic agent, in the keel or peg holes. Cement should be impacted using the appropriate **Cement Pressurizer** *(Figure 16)*. A second injection of cement with thumb pressurization is then completed. The glenoid component is then seated using the glenoid impactor. Ensure the glenoid tip is fully threaded to the **Impactor** before striking *(Figure 17)*.

Apply firm, steady pressure on the glenoid with either the **Glenoid Impactor** or with digital pressure until polymerization is complete. Run a small elevator around the edge of the glenoid component to ensure there is no interposed soft tissue. Excess cement around the edges of the glenoid implant is removed before the cement polymerizes.

Step 5: Humeral Head Positioning

Replicator Plate Selection

Remove the humeral stem protector and assess the position of the stem's spherical bore in relation to the resected surface of the proximal humerus. In the majority of cases, the stem will be offset from the center of the resected surface (in any direction) by more than 3mm. In this situation, a **4.5mm Replicator Plate** should be used. If this is not the case (i.e. the head is not offset), a **1.5mm replicator plate** should be used.



4.5mm Replicator Plate

1.5mm Replicator Plate

Attaching the Replicator Plate

Attach the Replicator Plate to the stem by hand tightening the **Torque Defining Screw** with the **Torque Defining Screw Drive** *(Figure 18)*. Once the Torque Defining Screw meets resistance, loosen it one half turn (this will provide adjustability to the Replicator Plate so the desired head position can be obtained).

*Note: The concentric **T-handle** can be used for the initial tightening.*

Dialing in the Head Position

Place the appropriately sized **Plate Dial** (diameter matches the options for head implant diameters) on the Replicator Plate and insert the **Replicator Plate Handle** into the two holes on the Replicator Plate *(Figure 19)*.

The surgeon now has the ability to adjust four independent variables to ensure the prosthesis reproduces the patient's original anatomy: medial offset, posterior offset, inclination and version. When the head resection matches the anatomical neck, the surgeon can replicate the patient's anatomy by simply covering the resected humeral surface.

Note: Both the Replicator Handle and the Plate Dial rotate independently to provide dual eccentricities.

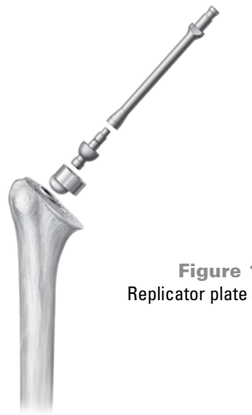


Figure 18
Replicator plate assembly

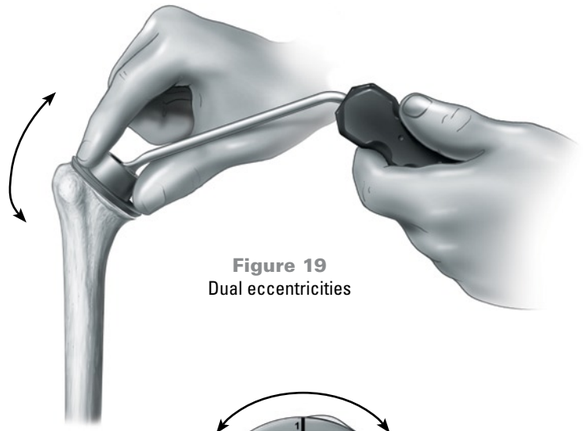
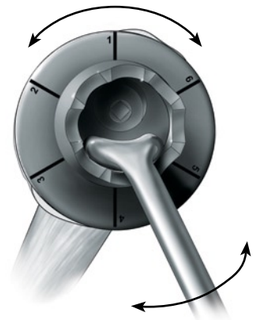


Figure 19
Dual eccentricities



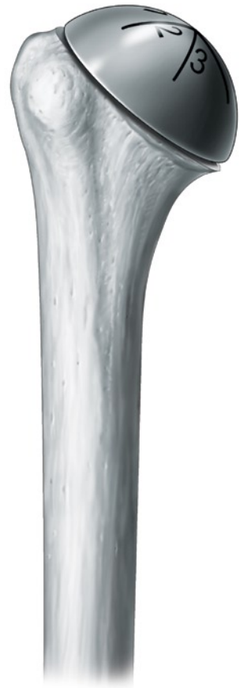


Figure 20
Humeral Head Trial

Head Diameter (mm)

Height		38	41	44	47	50	53
	Short	16	16	17	18	19	20
	Tall	19	20	21	22	23	24
	Expanded				26	27	28

Table 2
Humeral Head Scope

The Equinoxe System provides eccentricity on two components: in the humeral head and in the Replicator Plate. These two eccentricities enable the surgeon to reproduce both the medial and posterior offset independently by turning the plate dial and the replicator plate separately. If the surgeon desires to compensate for a less than perfect humeral resection, the system provides +/- 7.5 degrees to adjust the neck angle (inclination) and the version for a total range of 15 degrees for each parameter.

If the surgeon is pleased with the humeral head resection, begin the trialing process with the trial ring parallel to the resection (i.e., neck angle and retroversion match the cut). Cover the resected surface by rotating the trial ring with your fingers and the Replicator Plate with the Replicator Plate Handle. Angulation (neck angle and retroversion) adjustments should be assessed during the trial reduction (i.e., if posteriorly unstable, consider reducing the retroversion by loosening the screw and tilting the Replicator Plate.)

Note: In rare cases, the patient's body may obstruct the perfect positioning of the Replicator Plate Handle. In this case, a smaller version of the Replicator Plate Handle may be used.

Once the Plate Dial is perfectly positioned, tighten the Torque Defining Screw. (This is an interim tightening. The screw is not completely torqued until after assessing the range of motion). Using the numbers on the Plate Dial, take note of the head position or make an identifying mark in order to place the **Head Trial** on the Replicator Plate with the exact same orientation. Replace the Plate Dial with the same size Head Trial (color-coded) and assess the range of motion as described below *(Figure 20)*.

Assessing Range of Motion

Assessment of stability is performed in a step-wise sequence. First, the articulation is assessed with the arm at the side. The arm is rotated internally and externally; rotation should be smooth and the humeral head should maintain a reduced position on the glenoid component. Second, with the arm at the side, anterior, posterior and inferior translation should be assessed. Up to 50 percent posterior and inferior translation is acceptable; up to 25 percent anterior translation is acceptable. Third, range of motion is assessed. The arm should internally rotate to the chest wall without limitation. At 90 degrees of abduction, the shoulder should internally rotate 70 degrees.

Varying the thickness of the modular Humeral Head provides the ability to optimize stability and range of motion *(Table 2)*. If soft-tissue laxity is excessive, a taller Humeral Head may be necessary. Conversely, if soft-tissue tension is excessive, a shorter Humeral Head may be necessary.

In general, the thinnest Humeral Head that provides adequate stability should be used to avoid overstuffing the joint.

If the surgeon desires to further adjust the positioning of the head, simply loosen the screw one-half rotation and repeat the previous steps.

Torque Defining Screw

Once the surgeon is satisfied with the position of the Replicator Plate and the size of the trial Humeral Head, remove the Head Trial and insert the Replicator Plate Handle into the holes located on the surface of the plate. Impact the T-handle with a Mallet to ensure the drive is fully engaged in the screw. The plate is now ready to be locked into position.

With one hand, use the T-handle to tighten the screw until the superior portion disengages *(Figure 21),* which will occur at an applied torque of 11 Nm. To prevent the stem from rotating within the canal, a countertorque must be simultaneously applied using the Replicator Plate Handle.

The portion of the screw that remains in the implant will have a square head that the surgeon can use to loosen the screw using the **Torque Defining Screw Removal Instrument** should the Replicator Plate ever need to be removed (e.g. revision of hemi to a TSA or reverse).

Impacting the Humeral Head

Clean and dry the visible portion of the Replicator Plate and place the final Humeral Head implant on the Replicator Plate **using the numbers on the bottom of the implant** to replicate the Head Trial orientation. Using the Head Impactor and a Mallet, strike the head directly in line with the taper to ensure proper engagement of the morse taper *(Figure 22)*. Ensure the **Head Impactor Tip** is fully threaded to the Impactor before striking. Hand-test to ensure proper seating.

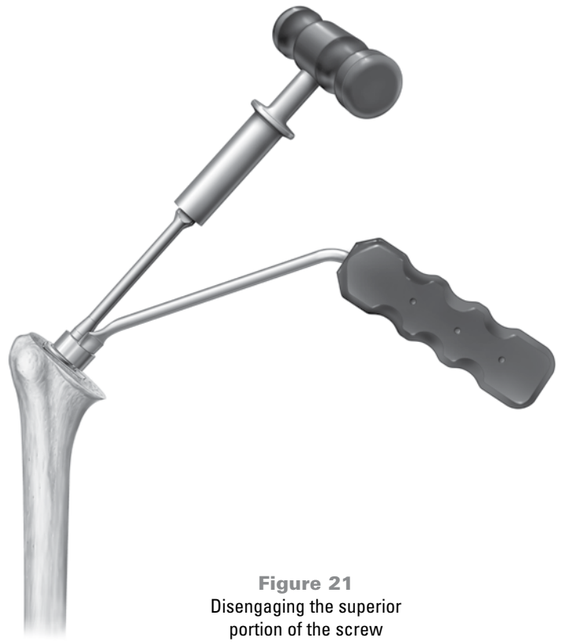


Figure 21
Disengaging the superior portion of the screw

Figure 22
Impacting the Humeral Head

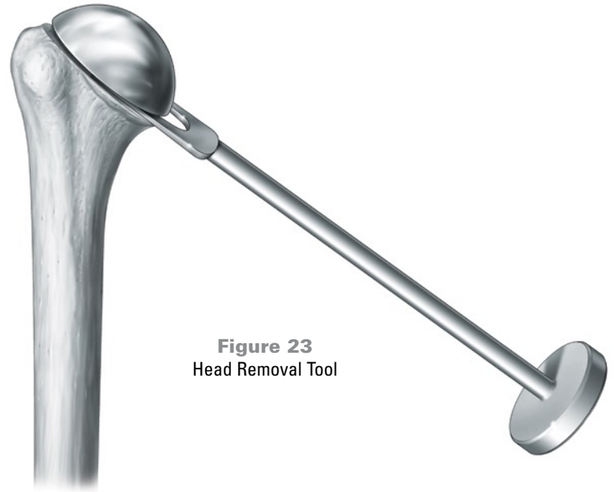


Figure 23
Head Removal Tool

Revising a Hemi to a TSA

Gaining exposure to the glenoid after a hemiarthroplasty, while rarely easy, is facilitated with the Equinoxe System's removable Replicator Plate. Using the **Head Removal Tool**, lever the head off the Replicator Plate *(Figure 23)*.

When the Torque Defining Screw was initially torqued, the portion that snapped off left a square that can be used to remove the screw. Attach the Torque Defining Screw Removal Instrument to the asymmetric T-handle and loosen the screw *(Figure 24)*.

The Replicator Plate can now be removed and discarded. Protect the resected humeral surface and humeral stem with the Humeral Stem Protector while the glenoid is prepared. A new Replicator Plate, screw and head should be used to ensure proper engagement of the morse taper.

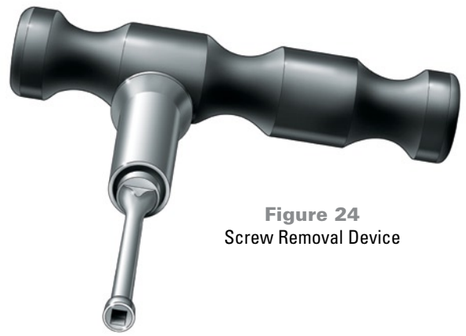


Figure 24
Screw Removal Device

Step 6: Closure

Closure is performed beginning with the subscapularis. The repair of the subscapularis will depend on the type of exposure used: tenotomy, elevation off bone or elevation with a wafer of bone. In general, #2 non-absorbable braided suture, or its equivalent, is used for either a tendon-to-tendon, tendon-to-bone or bone-to-bone repair. The rotator interval is then closed, though it may be left partially open medially to avoid excessive tension of the closure. External rotation is checked at this point to define the parameters for post-operative rehabilitation. A drain may be used, placing it deep into the deltopectoral interval. The deltopectoral interval is closed followed by closure of the subcutaneous tissue and the skin. The upper extremity is then placed in a sling and swathe.

Step 7: Post-Operative Rehabilitation

It is recommended to initiate the rehabilitation program on the same day as surgery and certainly by post-operative day one. All patients begin active range of motion of the elbow, wrist and hand. Range of motion of the shoulder consists of passive forward elevation, external rotation based on the assessment following subscapularis repair and internal rotation to the chest wall (if there is concern about the security of the subscapularis repair, external rotation should be limited to 0 degrees). Isometric deltoid strengthening can also be performed.

Patients should be instructed to perform these exercises five to six times per day for short periods of up to 10 minutes each session. The sling is discontinued after four weeks. A longer period of sling use should be used if there is concern about the soft tissue repair. When the sling is discontinued, active range of motion should begin. Internal rotation behind the back can also be started at this time. Isometric internal and external rotation is added at six weeks and gentle resistive strengthening of the deltoid and rotator cuff begins 10-12 weeks post-operatively. When the sling is removed, the patient is instructed to increase use of the upper extremity for activities of daily living. More vigorous strengthening can be initiated 12 weeks after surgery.

EQUINOXE IMPLANT SCOPE

Press-Fit Humeral Stems*

300-01-07	Equinoxe, humeral stem, primary, press-fit, 7mm
300-01-09	Equinoxe, humeral stem, primary, press-fit, 9mm
300-01-11	Equinoxe, humeral stem, primary, press-fit, 11mm
300-01-13	Equinoxe, humeral stem, primary, press-fit, 13mm
300-01-15	Equinoxe, humeral stem, primary, press-fit, 15mm
300-01-17	Equinoxe, humeral stem, primary, press-fit, 17mm

Revision Humeral Stems

306-01-08	Equinoxe, humeral stem, revision, 8 x 175mm
306-02-08	Equinoxe, humeral stem, revision, 8 x 215mm
306-02-10	Equinoxe, humeral stem, revision, 10 x 200mm (special order)
306-02-12	Equinoxe, humeral stem, revision, 12 x 200mm (special order)

Anatomic Replicator Plate

300-10-15	Equinoxe, Anatomic Replicator Plate, 1.5mm o/s
300-10-45	Equinoxe, Anatomic Replicator Plate, 4.5mm o/s

Torque Defining Screw Kit

300-11-00	Equinoxe, torque defining screw kit

Short Heads

310-01-38	Equinoxe, humeral head, short, 38mm
310-01-41	Equinoxe, humeral head, short, 41mm
310-01-44	Equinoxe, humeral head, short, 44mm
310-01-47	Equinoxe, humeral head, short, 47mm
310-01-50	Equinoxe, humeral head, short, 50mm
310-01-53	Equinoxe, humeral head, short, 53mm

Tall Heads

310-02-38	Equinoxe, humeral head, tall, 38mm
310-02-41	Equinoxe, humeral head, tall, 41mm
310-02-44	Equinoxe, humeral head, tall, 44mm
310-02-47	Equinoxe, humeral head, tall, 47mm
310-02-50	Equinoxe, humeral head, tall, 50mm
310-02-53	Equinoxe, humeral head, tall, 53mm

Expanded Heads

310-03-47	Equinoxe, humeral head, expanded, 47mm
310-03-50	Equinoxe, humeral head, expanded, 50mm
310-03-53	Equinoxe, humeral head, expanded, 53mm

Keeled Glenoids

314-01-02	Equinoxe, glenoid, keeled, alpha, small
314-01-03	Equinoxe, glenoid, keeled, alpha, medium
314-01-04	Equinoxe, glenoid, keeled, alpha, large
314-01-12	Equinoxe, glenoid, keeled, beta, small
314-01-13	Equinoxe, glenoid, keeled, beta, medium
314-01-14	Equinoxe, glenoid, keeled, beta, large

Pegged Glenoids

314-02-02	Equinoxe, glenoid, pegged, alpha, small
314-02-03	Equinoxe, glenoid, pegged, alpha, medium
314-02-04	Equinoxe, glenoid, pegged, alpha, large
314-02-12	Equinoxe, glenoid, pegged, beta, small
314-02-13	Equinoxe, glenoid, pegged, beta, medium
314-02-14	Equinoxe, glenoid, pegged, beta, large

* Can be cemented

EQUINOXE INSTRUMENT SCOPE

Anatomic Cutting Guide
311-01-01

132.5-Degree Osteotomy Guide
311-01-10

Straight Reamer
Multiple sizes

Mallet
301-07-01

Broach
Multiple sizes

Modular Broach Handle
301-03-01

Retroversion Handle
301-03-10

Primary Stem Inserter/Extractor
301-07-10

Stem Protector
301-07-20

Small Stem Protector
301-07-60

T-Handle
301-07-30

Short T-Handle
301-07-70

Torque Defining Screw Removal Instrument
301-10-10

Replicator Handle
301-10-30

Short Replicator Handle
301-10-40

Plate Dial
Multiple sizes

Humeral Head Sizer
311-01-20

Short Head Trial
Multiple sizes

Tall Head Trial
Multiple sizes

Expanded Head Trial
Multiple sizes

Head Removal Tool
311-05-01

Impactor
311-07-05

Humeral Head Impactor Tip
311-07-07

Center Keel/Peg Drill
315-07-60

Short Keel Drill
315-07-61

Glenoid Reamer
Multiple sizes

Glenoid Impactor Tip
311-07-06

Keel Trial
Multiple sizes

Peg Trial
Multiple sizes

Keel Drill Guide
Multiple sizes

Peg Drill Guide
315-07-10

Drill Guide Handle
315-17-20

132.5-Degree Osteotomy Guide Handle
315-07-20

Central Peg Holding Pin
315-07-30

Holding Pin
315-07-40

Keeled Cement Pressurizer
315-09-05

Pegged Cement Pressurizer
315-09-06

Keel Broach
Multiple sizes

Darrach Retractor
317-01-03

Hohmann Retractor
317-01-06

Humeral Head Retractor
317-01-02

Dual Point Glenoid Retractor
317-01-04

Single Point Glenoid Retractor
317-01-05

Periosteal Elevator
317-01-07

Wolfe Retractor
317-01-08

equinoxe®

SHOULDER SYSTEM

DESCRIPTION

The Equinoxe® Shoulder System comprises both cemented and press-fit semi-constrained glenohumeral prostheses for use in hemi-shoulder and total-shoulder joint replacement procedures, a cemented semi-constrained glenohumeral fracture prosthesis for use in fractures of the proximal humerus, and a reverse semi-constrained prosthesis for use in total-shoulder joint replacement procedures in conjunction with an irreparable or nonfunctional rotator cuff. The system includes various sizes and types of modular humeral stems, humeral heads, humeral liners, glenoid components, humeral replicator plates/adapter trays, and screws for use in primary, revision, fracture, and reverse applications.

The cemented primary humeral stem, long/revision stem, fracture stem, and both the pegged and keeled glenoids are intended for cemented fixation only. The press-fit humeral stems are intended for press-fit applications but may be used with bone cement if deemed appropriate by the surgeon. The long/revision stem is advised when the distal bone quality is insufficient to adequately anchor the primary stems (typically as a result of mid-humeral fractures). The fracture stems are intended for three and four part fractures of the proximal humerus. 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. The reverse shoulder system is designed to function with the Equinoxe primary press-fit, primary cemented, and long/revision humeral stems; this system is not designed to function with the Equinoxe fracture humeral stems. All components are supplied sterile.

A complete instrumentation and trial system is available to assist in the implantation of each component. For a more detailed description of the implants, instruments and their utilization, please refer to the surgical technique, or contact your Exactech sales representative.

Description	Material	Component Sizes (mm)
Press-Fit Primary Humeral Stems	Titanium Alloy (Ti-6Al-4V, E.L.I.) per ASTM F136 and ASTM F620	7 x 100, 9 x 105, 11 x 110, 13 x 115, 15 x 120 & 17 x 125
Cemented Primary Humeral Stems		6 x 95, 8 x 100, 10 x 105, & 12 x 110
Cemented Revision Humeral Long Stems		8 x 175, 8 x 215, 10 x 200 & 12 x 200
Cemented Fracture Humeral Stems	Titanium Alloy (Ti-6Al-4V) per ASTM F1472 and SAE AMS 4928	7 x 140, 7 x 200, 9.5 x 140, & 12 x 140 (Left & Right)
Humeral Heads	Cobalt Chromium Alloy (Co-28Cr-6Mo) per ASTM F1537	Short: 38 x 16, 41 x 16, 44 x 17, 47 x 18, 50 x 19, & 53 x 20 Tall: 38 x 19, 41 x 20, 44 x 21, 47 x 22, 50 x 23, & 53 x 24 Expanded: 47 x 26, 50 x 27, & 53 x 28
Glenospheres	Cobalt Chromium Alloy (Co-28Cr-6Mo) per ASTM F1537	3 Sizes: 38 x 20, 42 x 22, & 46 x 24
Cemented Glenoid Components	Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM F648 & Stainless Steel Radiographic Wire per ASTM F138	Keeled: Small, Medium, & Large (2 different articular curvatures: α and β) Pegged: Small, Medium, & Large (2 different articular curvatures: α and β)
Reverse Humeral Liners	Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM F648	Standard: 3 Diameters (38, 42, & 46) & 2 Offsets (+0 & +2.5) Constrained: 3 Diameters (38, 42, & 46) & 2 Offsets (+0 & +2.5)
Replicator Plates	Titanium Alloy (Ti-6Al-4V, E.L.I.) per ASTM F136	2 Offsets: 1.5 & 4.5
Reverse Humeral Adapter Trays		3 Offsets: +0, +5, & +10
Reverse Glenoid Plate		1 Size
Primary and Reverse Torque-Defining Screws	Titanium Alloy (Ti-6Al-4V) per ASTM F1472 and Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM F648	1 size for each application
Reverse Compression Screws	Titanium Alloy (Ti-6Al-4V, E.L.I.) per ASTM F136	8 Sizes: 4.5 x 18, 4.5 x 22, 4.5 x 26, 4.5 x 30, 4.5 x 34, 4.5 x 38, 4.5 x 42, & 4.5 x 46
Reverse Locking Cap	Titanium Alloy (Ti-6Al-4V) per ASTM F1472	1 Size
Glenosphere Locking Screw		1 Size

INDICATIONS FOR USE

The Equinoxe Shoulder System is indicated to relieve pain and restore function 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 Equinoxe Shoulder System comprises PRIMARY (P), LONG/REVISION (L), FRACTURE (F), and REVERSE (R) components; each is indicated as follows:

P	L	F	R	Indications
√	√			Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
			√	Rheumatoid arthritis, osteoarthritis, osteonecrosis, or post-traumatic degenerative problems in conjunction with an irreparable or nonfunctional rotator cuff and/or a superiorly migrated humerus.
√	√			Congenital abnormalities in the skeletally mature
√				Primary and secondary necrosis of the humeral head.
√		√		Humeral head fracture with displacement of the tuberosities
√	√		√	Pathologies where arthodesis 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
√			√	Revision of failed previous reconstructions when distal anchorage is not required
√	√		√	To restore mobility from previous procedures (e.g. previous fusion)

CONTRAINDICATIONS FOR USE

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, implementation 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.

WARNINGS AND PRECAUTIONS

Only qualified surgeons knowledgeable in anatomy, biomechanics, and reconstructive surgery should utilize these devices. The surgeon must be fully knowledgeable about all aspects of the Equinoxe surgical technique and use these implants in accordance with the respective indications and contraindications summarized in this document. In addition, the surgeon should be fully knowledgeable about the compatibility of system components and use each device accordingly. Finally, the surgeon must be fully knowledgeable about the Equinoxe surgical technique, and he/she must be trained according to the proper use of the system instrumentation. For more information, contact your Exactech sales representative.

Pre-operatively:

As part of the pre-operative assessment, the surgeon must ensure that no biological, biomechanical, or other factors exist that might adversely affect the surgery and/or postoperative period. Bone quality must be considered to ensure that the prostheses does not subside, tilt, or migrate within the humeral canal; fracture of host bone should also be considered. Such events could result in adverse outcome. The expected useful life of the device may be compromised in very large or overweight individuals and in individuals who have a physically active lifestyle. It is recommended to use the largest possible humeral stem size that will achieve the desired anatomic and functional characteristics in such patients. The use of the Equinoxe prostheses outside of the specified weight limits may result in an adverse outcome (e.g. stem fracture).

Humeral Stem Diameter	Body Weight Limit
6 mm cemented stem	150 lbs
7 mm press-fit stem	230 lbs
7 mm fracture stem	280 lbs
8 mm cemented stems	340 lbs
9 mm press-fit stem	470 lbs
9.5 & 12 mm fracture stem; 10 & 12 mm cemented stem; 11, 13, 15 & 17 mm press-fit stem	No weight limit

Prior to surgery the patient must be informed of all potential risks and adverse effects contained in the present instructions for use.

Intra-operatively:

The entire prosthesis size range should be available at the time of the surgery; selecting the correct type of prosthesis with the correct size for each specific application is essential to the success of the procedure. For example, it has been documented in the literature that a radial mismatch between the humeral head and glenoid of 4-6 mm is associated with a diminished incidence of glenoid loosening, the most common failure mode in TSA. With this in mind, the Equinoxe has been designed to provide for an average radial mismatch of 5.5 mm (range: 3.4 – 7.7 mm). This has been accomplished by offering glenoids with two different articular curvatures: α and β; doing so enables any size glenoid to be used with any size humeral head provided the surgeon correctly mates the appropriate glenoid curvature with the appropriate humeral head diameter. As described in the following table, α glenoids should be used with humeral head diameters of 38, 41, and 44 mm and β glenoids should be used with humeral head diameters of 47, 50, and 53 mm.

Humeral Head Diameter	38 mm	41 mm	44 mm	47 mm	50 mm	53 mm
Glenoid Curvature	α	α	α	β	β	β

The surgeon must not allow damage to the polished bearing surfaces or damage and/or contamination of taper locking surfaces. Any alteration or damage to these surfaces will reduce the fatigue strength of the prostheses and may result in failure under load. Furthermore, the wear rate of each component is greatly accelerated if loose fragments of bone, bone cement, or other particulate debris become detached in the wound site; these debris can act as an abrasive in the articular or modular interfaces. Components should be handled with care to minimize contamination of the component surfaces with any material that would interfere with cement fixation. When using cement for fixation, the surgeon should ensure complete cement support on all parts of the prosthesis embedded in bone cement.

Exactech screw components are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Failure to adhere to these recommendations will result in increased probability of poor function, loosening, wear, fracture or premature failure.

Exactech components must not be used with those of another manufacturer since dimensional compatibility cannot be assured.

Post-operatively:

Post-operative counseling and care is important. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of component wear and loosening, and to consider the course of action to be taken if such events occur. A suitable rehabilitation program must be designed and implemented. All patients should be instructed on the limitations of the prosthesis and the possibility of subsequent surgery. Patients must be informed that their weight and activity level may affect the longevity of the implant.

Implants must not be reused. Any implant, once used, should be discarded even though it may appear undamaged.
Normal wear of the implant given the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or deterioration in the characteristics of the implant.

ADVERSE EFFECTS

The following serious adverse effects may be associated with the use of this device. Although some effects are not directly attributable to the device itself, the surgeon should be aware of these potential complications and be ready to treat the patient accordingly.

General Surgical Risks	Total Joint Surgery Risks	Device Specific Risks
venous thrombosis	damage to blood vessels	component loosening
transitory hypotension	nerve damage	device breakage
myocardial infarction	bone bed damage	difficulty removing the device
pulmonary embolism	arthrofibrosis	subluxation
arrhythmias	phlebitis, thrombophlebitis	dislocation
delayed wound healing	haematoma	iatrogenic fracture
extensive blood loss	wound healing problems	arm length discrepancy
infection		sensitivity reactions to implant materials adverse events associated with the use of bone cement

UTILIZATION AND IMPLANTATION

Component selection depends upon the judgment of the surgeon with relationship to the requirements of the patient. The surgeon shall become thoroughly familiar with the surgical technique of these prostheses by: 1) appropriate reading of the literature, 2) specific training in the operative skills and techniques required for the implant system, and 3) reviewing any other relevant information regarding the use of instrumentation designed for device implantation.

Use During Pregnancy:

Surgery should be avoided during pregnancy. This product is indicated for applications in pregnancy only when it is believed impossible to save the joint or preserve the patient's life through other forms of intervention.

Use in Children:

There are no tests that demonstrate the device is safe for use in children. The device should only be used in skeletally mature individuals.

HOW SUPPLIED

Implants are supplied sterile (gamma radiation) to a sterility assurance level (SAL) of 10^{-6} and are intended for single use only. Never resterilize an implant. Resterilization may adversely affect implant materials and result in premature failure.

STORAGE AND HANDLING

Implants should be stored in their original, sealed packaging in clean, dry conditions. This packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. In order to ensure sterility, implants must be used before the end of the expiration date indicated on the outer package label. Prior to use, inspect the packaging and labeling for seal integrity. If the device has been opened, damaged or adulterated in any way, it must not be used. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

INFORMATION

For further product information, please contact Customer Service, Exactech, Inc., Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

US Patent # **6,228,120,** additional patents pending.

European Patent # **DE69902971T**, additional patents pending.

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Some components may not be currently available. Please contact your Exactech representative for additional information.

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