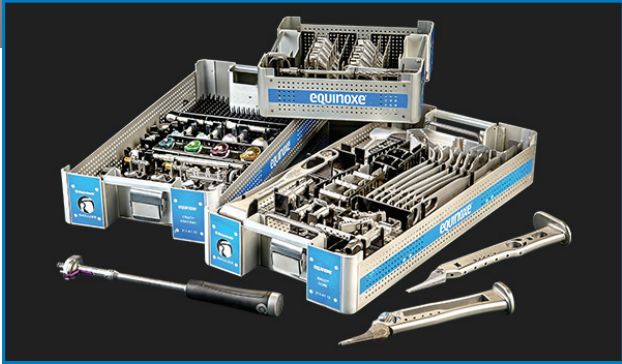


EXACTECH | EXTREMITIES

Operative Technique



equinox®

Stemless Shoulder-Laser Printed Operative
Technique with Ergo® Instruments





TABLE OF CONTENTS

INTRODUCTION	1
DETAILED OPERATIVE TECHNIQUE	5
Patient Positioning	5
Surgical Approach	6
Humeral Head Resection	7
Sizing Guide and Pin Placement	8
Calcar Planing	10
Central Reaming	10
Central Punching	11
Glenoid Preparation	12
Trialing/Range of Motion Assessment	12
Implant Insertion	13
Closure	14
Post-Operative Rehabilitation	14
Implant Removal/Revision	15
IMPLANT LISTING	16
INSTRUMENT LISTING	17
INDICATIONS FOR USE	19
REFERENCES	20

INTRODUCTION

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

The Equinoxe Stemless Shoulder was designed as a bone conserving and canal sparing implant for anatomic total shoulder arthroplasty. This specific technique outlines how to implant the Stemless Shoulder with Ergo Instruments. Designed through the collaborative efforts of engineering research and global surgeon thought leaders, this prosthesis incorporates a 3D-printed structure with optimized pore size, porosity and count. The unique laser 3D-printed bone cage is designed for bone through-growth to enhance the probability of biologic fixation.

The Stemless Shoulder was developed in conjunction with:

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OPERATIVE TECHNIQUE OVERVIEW - LASER PRINTED WITH ERGO INSTRUMENTS

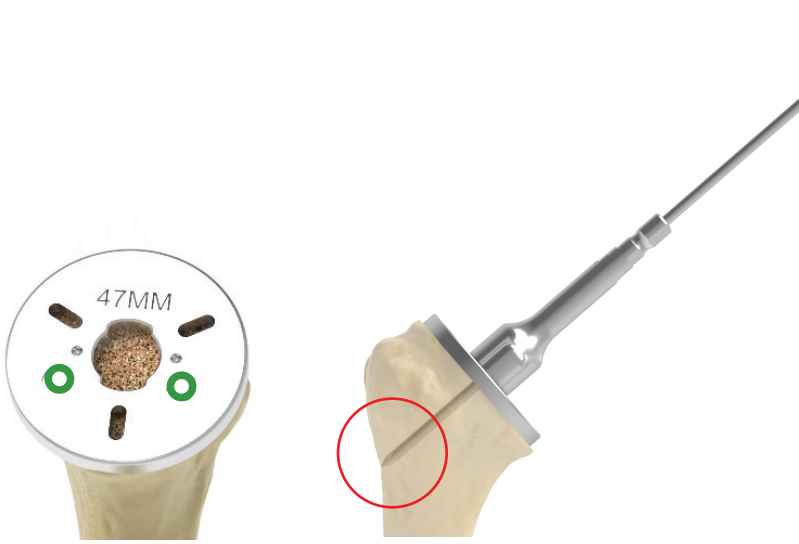


Figure A

Size the Resected Humerus and Place the Steinmann Pin

Note: Once the size has been picked, drive the Steinmann Pin deeper into the lateral cortex for pin stability.



Figure B

Plane the Resected Humerus

Note: Do not remove the Steinmann Pin.



Figure C

Ream Over the Steinmann Pin

Note: Do not remove the Steinmann Pin.



Figure D

Insert Punch with Impactor Handle

OPERATIVE TECHNIQUE OVERVIEW - LASER PRINTED WITH ERGO INSTRUMENTS



Figure E
Place the Humeral Protector



Figure F
Trial the Humeral Head With the Punch
Note: *Trialing can be performed at the trial stage with the humeral component punch or once the final stemless cage component has been implanted.*

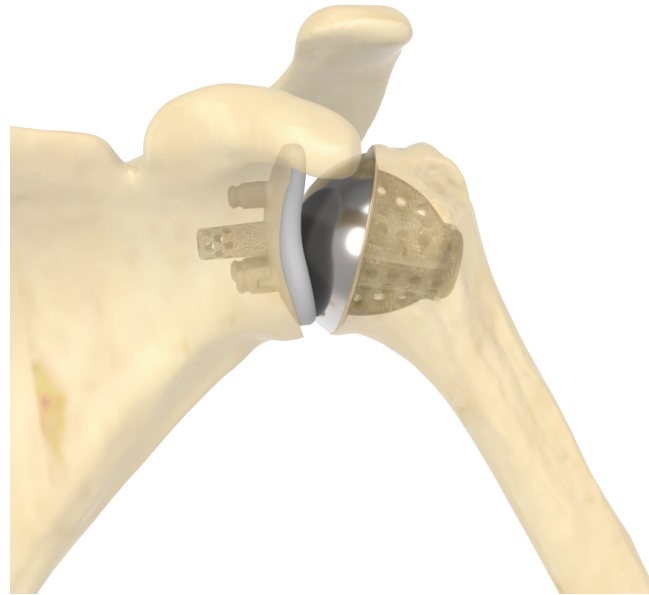


Figure G
Insert the Final Stemless Humeral Cage



Figure H
Impact the Final Stemless Humeral Head Implant





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: a true A/P view of the glenohumeral joint (30 degrees external oblique), a scapular lateral view, and 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.

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.

DETAILED OPERATIVE TECHNIQUE - LASER PRINTED WITH ERGO INSTRUMENTS

SURGICAL APPROACH

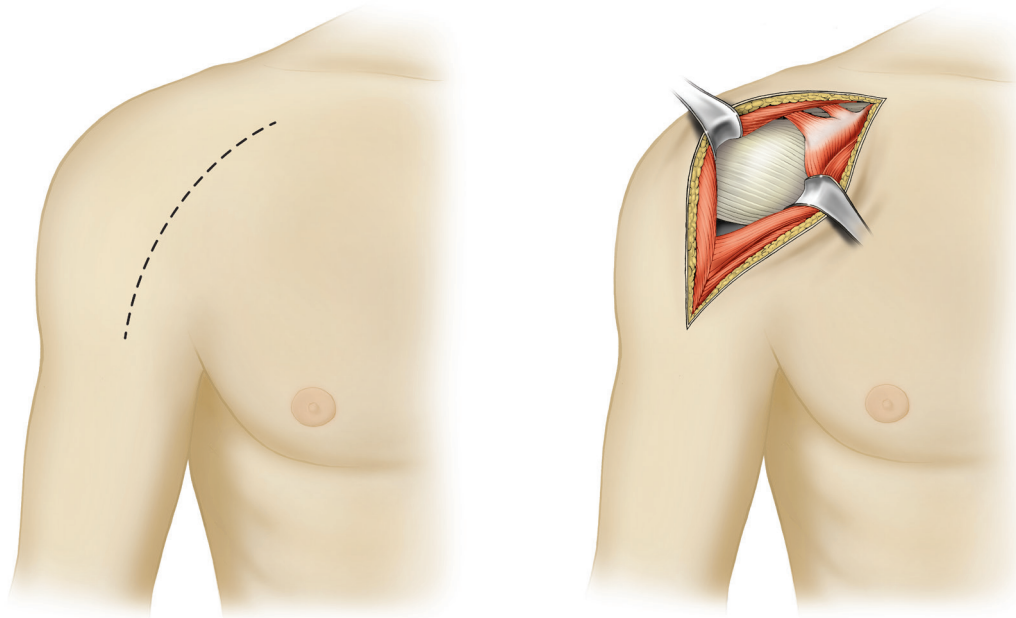


Figure 1
Surgical Approach

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 (*Figure 1*). 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 conjoint tendon is mobilized. A self-retaining retractor is placed with care to avoid excessive traction on the conjoint tendon. The coracoacromial ligament is identified and the subacromial

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

An alternative approach is to elevate the subscapularis directly off of the bone or elevate its insertion with a thin wafer of bone (1-2mm thick) using an osteotome. The choice is based primarily on surgeon preference; however, a lesser tuberosity osteotomy could compromise fixation, and a complete osteotomy is not advised.

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.



Figure 2
Fixed Angle Cutting Guide

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.

Several resection options are available and should be selected based upon surgeon preference.

Note: *There is an increased risk of varus placement when using a stemless device compared to a stemmed. An excessively varus cut cannot be corrected. The osteotomy can be confirmed with fluoroscopy prior to proceeding with stemless preparation.*

FIXED ANGLE (132.5 DEGREES) OSTEOTOMY GUIDE

Though this method is not based upon the patient's anatomy, we have provided a **Fixed Angle Cutting Guide (311-11-13)** for surgeons who prefer this method (*Figure 2*). The surgeon may attach a **Version Rod (301-05-20)** to the guide that will align the forearm at 0, 10, 20, 30, and 40 degrees of retroversion. Three options are available for the guide:

- 1) Use the cutting surface to make a free hand resection.
- 2) Use the two **3.2mm Short Threaded K-wire (321-52-10)** to secure it to the bone.
- 3) Use the cutting surface to mark the resection line with a bovie and then use the free hand method.

FREE HAND

Identify the anatomic neck and resect the head using a saw.

DETAILED OPERATIVE TECHNIQUE - LASER PRINTED WITH ERGO INSTRUMENTS

SIZING GUIDE / PIN PLACEMENT



Figure 3a

Determine the Humeral Head Diameter Size with the Sizing Guide

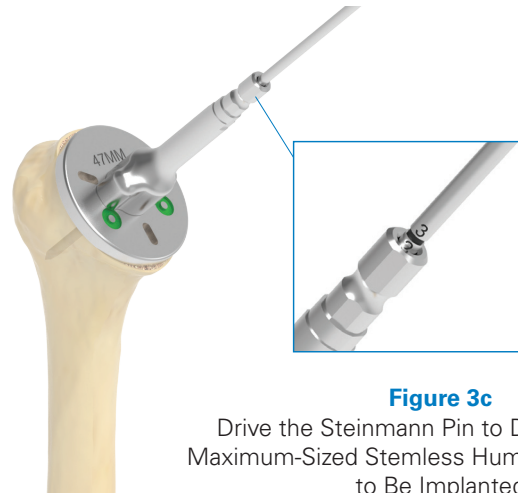


Figure 3c

Drive the Steinmann Pin to Determine the Maximum-Sized Stemless Humeral Component to Be Implanted



Figure 3b

Connect the Sizing Guide Handle to the Chosen Sizing Guide, Turn and Lock

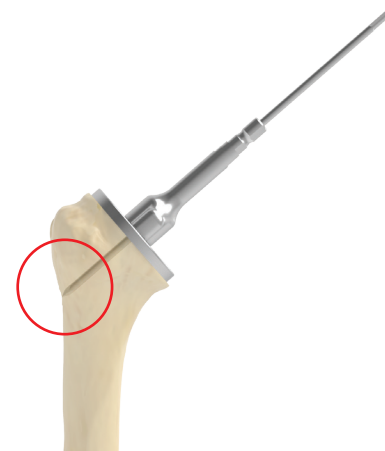


Figure 3d

Once the Size of the Humeral Component Has Been Determined, Continue Driving the Steinmann Pin

SIZING GUIDE AND PIN PLACEMENT

It is recommended that the surgeon evaluate the metaphyseal bone to confirm that there is sufficient bone stock for a stemless device. As an example, the surgeon can apply thumb pressure to the cancellous bone to make this assessment. It is highly recommended that a stemmed option be available as a back-up if stemless arthroplasty must be abandoned. It should be noted that as many as 33 percent of patients will not have adequate bone stock for stemless component fixation.¹

Utilize the **Sizing Guides (319-00-38, 41, 44, 47, 50, 53)** to determine the diameter size of the humeral resection. The Sizing Guides are offered in sizes that match the outer diameter of the humeral heads and therefore the guide that best covers the entire resected surface should be chosen (*Figure 3a*). The **Guide Handle (319-00-30)** should then be connected to the chosen Sizing Guide by inserting and turning to lock (*Figure 3b*).

With the Sizing Guide centered and flush on the humeral cut, insert the 3.2mm **Steinmann Pin (319-01-32)** through the central hole of the Guide Handle and drive the pin until initial contact with the lateral cortex is made. Use the markings on the Steinmann Pin (1,2,3) to determine the maximum-sized Stemless Humeral Component that can be implanted while avoiding contact with the lateral cortex (*Figure 3c*).

In the example shown in *Figure 3c*, the Size 2 Stemless Humeral Component would be the recommended size since that is the largest implant that could be inserted without violating the far cortex. Note that if between markings on the 3.2mm Steinmann Pin, always downsize. See page 16 for the Stemless Humerus Cage Dimensions chart and diagram.

Important: Once the size has been recorded, continue driving the Steinmann Pin into the lateral cortex for pin stabilization (*Figure 3d*).



Figure 4

Plane the Resected Humerus With the Calcar Planer Blade

REAMER SIZES

Size	Color
1	Bronze
2	Gold
3	Black

Table 1



Figure 5

Ream Over Steinmann Pin with the Humeral Component Drill

Note: This illustration is shown with size 2.

Note: If stable fixation of the pin cannot be achieved, it is strongly recommended that stemless arthroplasty be abandoned and stemmed preparation be conducted.

The Sizing Guide and Guide Handle should be removed from the joint, but the Steinmann Pin will remain in place.

CALCAR PLANING

Calcar Planer Blades (319-09-44, 50, 56) may be used to even out the humeral resection if desired. The Calcar Planer Blade is connected to the Sizing Guide Handle and driven over the Pin under power (Figure 4). Remove the planer and leave the Steinmann Pin in position for reaming.

Note: Care should be taken to ensure that the planer is driven perpendicular to the cut as there is a tendency for the weight of the power hand piece to tilt the hand into varus.

Note: If a significant amount of bone is removed, the implant sizing step should be repeated using the Sizing Guide and Guide Handle.

CENTRAL REAMING

Once the appropriately-sized **Stemless Humeral Component Drill (319-00-01, 02, 03)** has been selected from the Steinmann Pin laser mark size, select the correlating reamer size (Table 1). The reamer should be placed over the Steinmann Pin and driven, under power, perpendicular to the cut until the bottom of the collar of the reamer sits flush with the humeral cut (Figure 5). The reamer is then removed, leaving the Steinmann Pin in position for the **Stemless Punch Inserter (319-01-00)**.

DETAILED OPERATIVE TECHNIQUE - LASER PRINTED WITH ERGO INSTRUMENTS

CENTRAL PUNCHING



Figure 6a

Stemless Punch Inserter - How to Open and Close the Punch Handle

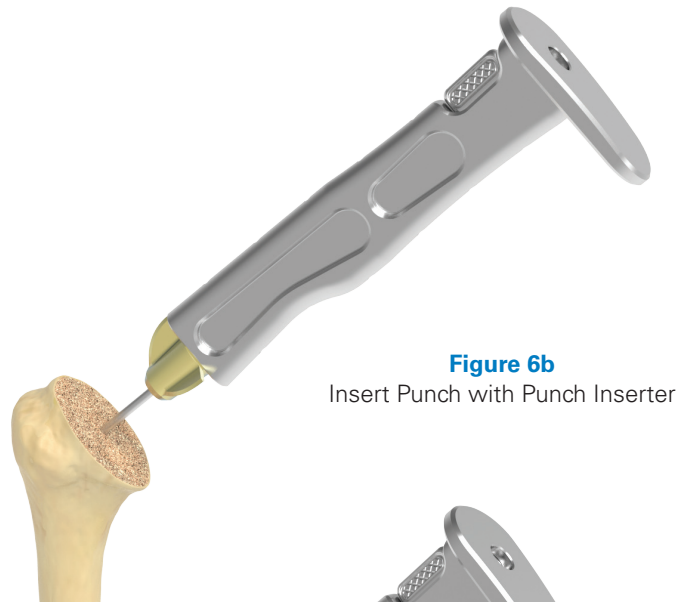


Figure 6b

Insert Punch with Punch Inserter

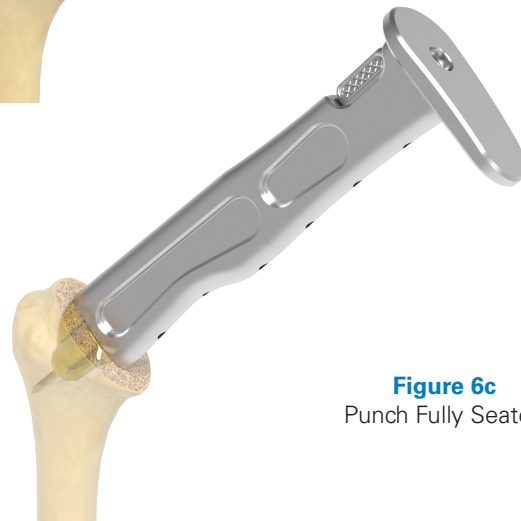


Figure 6c

Punch Fully Seated

CENTRAL PUNCHING

In order to insert the punch, please note how the Stemless Punch Inserter lever locks and unlocks (*Figure 6a*). The matching-sized punch should then be attached to the Punch Inserter and the assembly placed over the Steinmann Pin (*Figure 6b*). With one of the fins aligned at approximately the 12 o'clock position, a mallet should be used to impact the strike plate of the Punch Inserter until the base of the Punch Inserter is flush with the resection (*Figure 6c*). Care should be taken to ensure the punch is impacted perpendicular to the cut surface.

Note: Ensure lever remains in the lock position from initial engagement with Inserter until impaction into the humerus.

Note: If the punch is unstable due to poor bone quality or inadequate bone stock, then switching to a stemmed prosthesis is advised.

Leaving only the punch in place, the Punch Inserter should then be separated from the punch and removed. The Steinmann Pin should also be removed.

DETAILED OPERATIVE TECHNIQUE - LASER PRINTED WITH ERGO INSTRUMENTS

GLENOID PREPARATION/TRIALING / RANGE OF MOTION ASSESSMENT

Table 2

TRIAL STEMLESS HUMERAL HEAD SIZES

		Head Coverage Diameter						
		36	38	41	44	47	50	53
Height (mm)	Extra-Short	13	13	13	14	15	16	
	Short		16	16	17	18	19	20
		ALPHA				BETA		
		Glenoid Curvature						



Figure 7

Place Humeral Protector



Figure 8

Insert Stemless Humeral Head Trial

A **Stem Protector (301-08-20, 40, 60)** can then be placed onto the cut surface to protect the prepared humerus if so desired (*Figure 7*).

GLENOID PREPARATION

Prepare the glenoid as described in the Equinox Primary/Reverse Operative Technique (718-01-30) or the Equinox Ergo Primary Reverse Operative Technique (00-0000121).

TRIALING/RANGE OF MOTION ASSESSMENT

Trialing can be performed at the trial stage with the Humeral Component Punch or once the final Stemless Humeral Cage Component has been implanted.

Place the desired **Stemless Humeral Head Trial (319-11-38,**

41, 44, 47, 50, 53 or 319-12-36, 38, 41, 44, 47, 50) onto the punch (*Figure 8, Table 2*) and reduce the joint.

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.

DETAILED OPERATIVE TECHNIQUE - LASER PRINTED WITH ERGO INSTRUMENTS

IMPLANT INSERTION

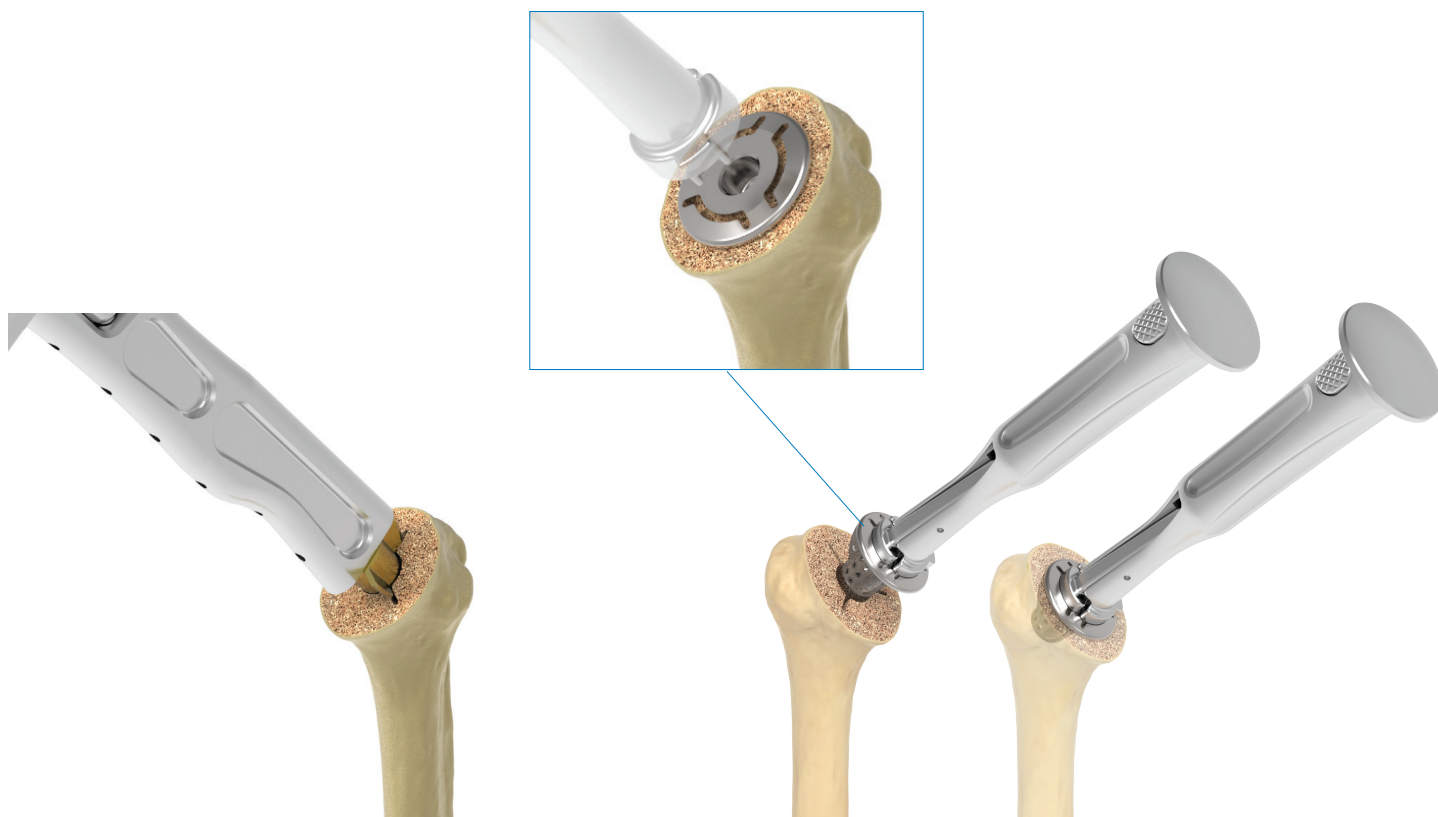


Figure 9
Punch Removal with
Stemless Punch Inserter

Figure 10
Insert Stemless Component

Varying the thickness of the Humeral Head provides the ability to optimize joint stability and range of motion. 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.

Note: Ensure that the chosen head trial sits evenly on the resection. Additional calcar planing may be necessary if there are any bony prominences that prevent full seating.

Remove the Stemless Head Trial, then remove the punch (Figure 9). To remove the punch, set the lever of the Punch

Inserter to the "open" position, insert it into the punch, flip the lever to the "closed" position (Figure 6a). Next retrograde impact the underside of the strike plate with a mallet.

IMPLANT INSERTION

The final Stemless component is then attached to the **Stemless Inserter (319-00-10)**. With the fins aligned to the slots prepared by the punch, the **Stemless Component (300-60-01, 02, 03)** is implanted into the humerus (Figure 10). Care should be taken to ensure the Stemless Component is inserted perpendicular to the cut surface. Once the collar of the Stemless Component is flush with the resection, the Stemless Inserter is released from the Stemless Component by pressing the textured button and removed from the joint.



Figure 11
Impact Final Stemless Humeral Head

After cleaning and drying the Stemless Component taper, the final **Stemless Humeral Head (310-61-38, 41, 44, 47, 50, 53 or 310-62-36, 38, 41, 44, 47, 50)** implant is then placed onto the Stemless Component. Using the **Modular Impactor Handle (321-09-05)** or **Impactor Handle (321-07-05)** and the **Humeral Head Impactor Tip (311-09-07)** and a mallet, strike the head directly in line with the taper to ensure proper engagement of the Morse taper (*Figure 11*).

WARNING: Don't assemble or disassemble devices in the surgical field.

Note: Ensure that the gap between the humeral head and resection is even prior to impaction. Additional calcar planing may be necessary if there are any bony prominences that could prevent full seating.

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.

DETAILED OPERATIVE TECHNIQUE - LASER PRINTED WITH ERGO INSTRUMENTS

POST-OPERATIVE REHABILITATION / IMPLANT REMOVAL / REVISION



Figure 12

Use Stemless Revision Punch and Central Peg Extractor for Revisions

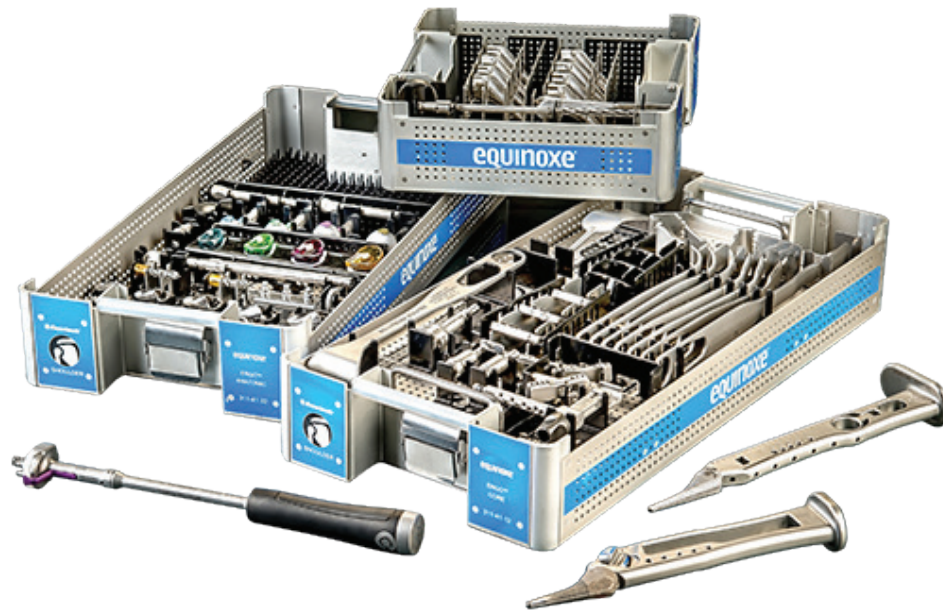
POST-OPERATIVE REHABILITATION

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.

IMPLANT REMOVAL/REVISION

Using a thin osteotome, lever the head off the Stemless Humeral Component. Once the head has been removed, align the blades of the **Revision Punch (319-00-11)** with the slots in the collar of the Stemless Component (*Figure 12*). Using a mallet, slowly impact the Revision Punch into the humerus. After removing the Revision Punch, use a thin osteotome to clear bone beneath the underside of the collar. The Stemless Component can then be carefully extracted from the humerus using the **Modular Central Peg Extractor (315-57-17)** and a slap hammer.



Note: *The Stemless Inserter should not be used for implant removal as it is not designed for retrograde impaction.*

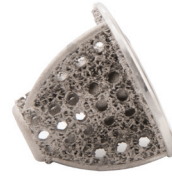
In cases of conversion to a stemmed implant, the humerus is prepared by following the instructions in the Equinox Primary/Reverse Operative Technique (718-01-30), the Equinox Ergo Primary Reverse Operative Technique (00-0000121), or the Preserve Stem Operative Technique (00-0001103).

IMPLANT LISTING

STEMLESS SHOULDER IMPLANT KIT - KIT-318US

CATALOG NUMBER DESCRIPTION

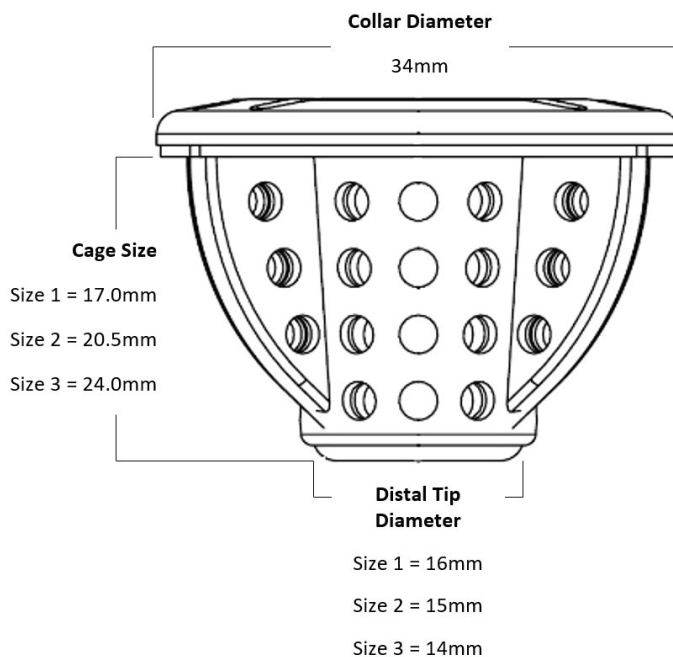
300-60-01	Equinox Stemless Humerus, Cage, Size 1, Laser
300-60-02	Equinox Stemless Humerus, Cage, Size 2, Laser
300-60-03	Equinox Stemless Humerus, Cage, Size 3, Laser



310-61-38	Stemless Humeral Head, 38mm, x 16mm x Alpha
310-61-41	Stemless Humeral Head, 41mm, x 16mm x Alpha
310-61-44	Stemless Humeral Head, 44mm, x 17mm x Alpha
310-61-47	Stemless Humeral Head, 47mm, x 18mm x Beta
310-61-50	Stemless Humeral Head, 50mm, x 19mm x Beta
310-61-53	Stemless Humeral Head, 53mm, x 20mm x Beta
310-62-36	Stemless Humeral Head, 36mm x 13mm x Alpha
310-62-38	Stemless Humeral Head, 38mm x 13mm x Alpha
310-62-41	Stemless Humeral Head, 41mm x 13mm x Alpha
310-62-44	Stemless Humeral Head, 44mm x 14mm x Beta
310-62-47	Stemless Humeral Head, 47mm x 15mm x Beta
310-62-50	Stemless Humeral Head, 50mm x 16mm x Beta
















Stemless Humerus Cage Dimensions



STEMLESS SHOULDER INSTRUMENT KIT - KIT-319ST







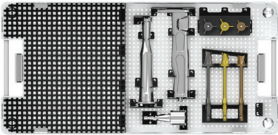
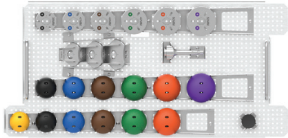

CATALOG NUMBER DESCRIPTION

301-08-20	Spiked Humeral Stem Cover, Small	
301-08-40	Spiked Humeral Stem Cover, Medium	
301-08-60	Spiked Humeral Stem Cover, Large	
319-00-01	Stemless Humeral Component Drill, Size 1	
319-00-02	Stemless Humeral Component Drill, Size 2	
319-00-03	Stemless Humeral Component Drill, Size 3	
319-00-10	Stemless Spring Inserter	
319-00-11	Stemless Revision Punch	
319-00-30	Stemless Sizing Guide Handle	
319-00-38	Stemless Sizing Guide, 38mm	
319-00-41	Stemless Sizing Guide, 41mm	
319-00-44	Stemless Sizing Guide, 44mm	
319-00-47	Stemless Sizing Guide, 47mm	
319-00-50	Stemless Sizing Guide, 50mm	
319-00-53	Stemless Sizing Guide, 53mm	

INSTRUMENT LISTING

STEMLESS SHOULDER INSTRUMENT KIT - KIT-319ST

CATALOG NUMBER DESCRIPTION

319-01-00	Stemless Punch Inserter	
319-01-01	Stemless Humeral Component Punch, Size 1	
319-01-02	Stemless Humeral Component Punch, Size 2	
319-01-03	Stemless Humeral Component Punch, Size 3	
319-09-44	Stemless Calcar Planer Blade, 44mm	
319-09-50	Stemless Calcar Planer Blade, 50mm	
319-09-56	Stemless Calcar Planer Blade, 56mm	
319-11-38	Stemless Humeral Head Trial, 38mm, x 16mm x Alpha	
319-11-41	Stemless Humeral Head Trial, 41mm, x 16mm x Alpha	
319-11-44	Stemless Humeral Head Trial, 44mm, x 17mm x Alpha	
319-11-47	Stemless Humeral Head Trial, 47mm, x 18mm x Beta	
319-11-50	Stemless Humeral Head Trial, 50mm, x 19mm x Beta	
319-11-53	Stemless Humeral Head Trial, 53mm, x 20mm x Beta	
319-12-36	Stemless Humeral Head Trial, 36mm x 13mm x Alpha	
319-12-38	Stemless Humeral Head Trial, 38mm x 13mm x Alpha	
319-12-41	Stemless Humeral Head Trial, 41mm x 13mm x Alpha	
319-12-44	Stemless Humeral Head Trial, 44mm x 14mm x Beta	
319-12-47	Stemless Humeral Head Trial, 47mm x 15mm x Beta	
319-12-50	Stemless Humeral Head Trial, 50mm X 16mm x Beta	
319-41-10	Equinox Stemless Instrument Tray, Lower, KIT-319ST	
319-41-11	Equinox Stemless Instrument Tray, Upper, KIT-319ST	
319-01-32	Steinmann Pin, Sterile, 3.2mm x 178mm, OPT-319	

INDICATIONS FOR USE

The Equinoxe Stemless Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total shoulder arthroplasty are as follows:

- Osteoarthritis, osteonecrosis or post-traumatic degenerative problems
- Congenital abnormalities in the skeletally mature
- Primary and secondary necrosis of the humeral head.
- Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
- To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Stemless Shoulder humeral components are indicated for press-fit, uncemented use.

The Equinoxe Stemless Shoulder System is intended to be used with the cemented Equinoxe glenoid components.

CONTRAINDICATIONS FOR USE

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

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

REFERENCES

1. Churchill R. Stemless shoulder arthroplasty: current status. J Bone Surg. 2014(23); 9:1409-1414. <https://doi.org/10.1016/j.jse.2014.05.005>
2. 00-0000121 Platform Shoulder System with Ergo Instruments Operative Technique.

ADDITIONAL RESOURCES

1. 718-01-30 Platform Shoulder System Operative Technique
2. 718-10-31 Equinox Stemless Operative Technique Legacy Instrumentation

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

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

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

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