EXACTECH | SHOULDER

Operative Technique

equinoxe®

Resurfacing Humeral Head

Exactech® *Surgeon focused. Patient driven.™*

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INTRODUCTION

The Equinoxe® Shoulder System redefines "anatomical." The design goal of the resurfacing humeral head is to offer a bone preserving treatment option for the skeletally mature patient with early-stage arthritis. The platform primary stem is designed to allow independent adjustability of all four anatomic parameters *in situ*. The reverse shoulder is an optimized design that is designed to minimize both scapular notching and torque on the glenoid while seamlessly integrating with the primary and platform fracture stems. The platform fracture stem's offset anterior-lateral fin and asymmetric tuberosity beds define the next generation in complex fracture reconstruction. The platform nature of the Equinoxe primary and fracture stem allows the surgeon to have intra-operative flexibility to choose between a surface replacement, humeral hemiarthroplasty, primary total shoulder or reverse total shoulder, with seamless conversion to a reverse should a revision become necessary.

Thank you for considering the Equinoxe Shoulder System. We began the Equinoxe product development process by identifying concerns our team had with current shoulder replacement systems. Our goal was to develop solutions to those concerns, and we sought the following improvements:

RESURFACING HUMERAL HEAD

- Modularity: Facilitates implantation through a cuff-preserving approach (if desired), leaving the subscapularis essentially intact.
- Anatomic Sizing: Prevents overstuffing of the joint and aids in restoring the patient's own unique humeral head anatomy with anatomic sized implants.
- Low Profile Instrumentation: Cannulated system facilitates a seamless transition between surgical steps.

We hope that you come to agree, based on your experiences with the Equinoxe Shoulder System in the O.R., that we have accomplished our goals.

Finally, while we have taken a comprehensive approach to this operative technique, we would be remiss if we failed to make it clear that shoulder replacements are challenging procedures and should be performed by surgeons with significant experience. If you are new to shoulder arthroplasty, please consider observing a shoulder specialist, watching a shoulder surgical DVD, performing a sawbone and/or implanting in a cadaver to ensure you are comfortable with the surgical technique. We would be happy to facilitate any aspect of this training to ensure "A Great Day in the O.R." for the surgeon and the staff.

Respectfully,

Pierre-Henri Flurin, MDCurt Noel, MD

Felix "Buddy" Savoie, MD

Ryan Simovitch, MD

Thomas W. Wright, MD

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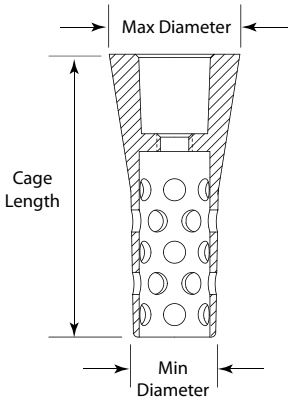
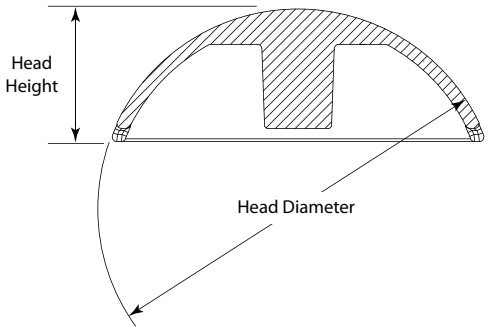
SYSTEM SPECIFICATIONS

Cage Length	Min. Diameter	Max. Diameter
25mm	9.5mm	14.8mm
30mm	9.3mm	14.8mm

Resurfacing Head	Head Diameter	Head Height
38	38mm	14mm
41	41mm	14mm
44	44mm	15mm
47	47mm	16mm
50	50mm	17mm
53	53mm	18mm





DETAILED OPERATIVE TECHNIQUE

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. Inadequate or poor quality bone stock could result in disassociation of the modular components, aseptic loosening, or implant migration. It is recommended that bone quality be assessed via CT or other equivalent means.

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.

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 tied off or cauterized, and the interval is developed distal to proximal to expose the clavipectoral fascia. In cases where the cephalic vein is not easily identified distally, it may be more easily identified by exposing the coracoid proximally.

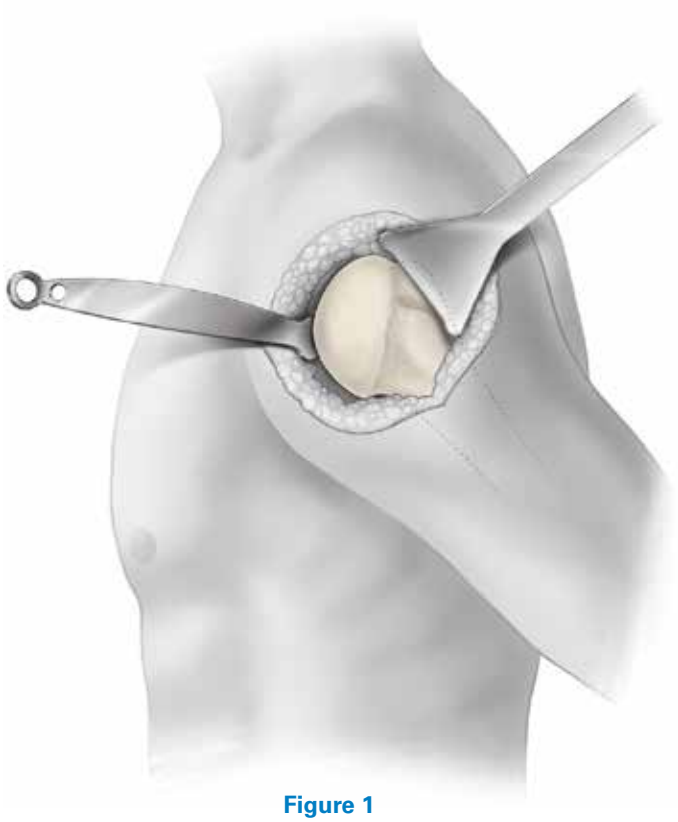


Figure 1
Use of the Chandler Anterior Humeral Head Retractor

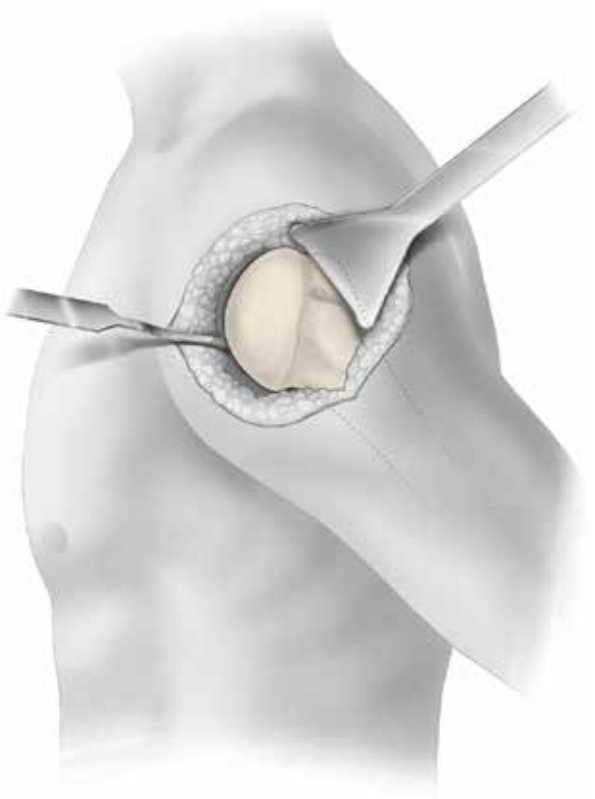


Figure 2
Use of the Small Darrach Anterior Humeral Head Retractor

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 retractors as they crosses the superior aspect of the interval.

The subdeltoid space is mobilized with a blunt elevator or curved Mayo scissors. Progressive internal rotation of the arm will allow further posterior release. The clavipectoral fascia is incised longitudinally up to the coracoacromial ligament and the conjoined tendon is mobilized. A self-retaining retractor is placed with care to avoid excessive traction on the conjoined tendon and musculocutaneous nerve. The coracoacromial ligament is identified and the subacromial space is mobilized with a blunt elevator or curved Mayo scissors. The coracoacromial ligament can be released based on pathology, surgeon preference or need for additional exposure. Releases of the subdeltoid and subacromial space must extend posteriorly to allow adequate visualization, especially of the glenoid. 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 or tied off, 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. One 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. 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 and the humeral head can be sized. Anterior humeral head retractors and a Browne deltoid retractor are supplied with the system to facilitate this exposure *(Figures 1 and 2).*

Another alternative approach is to retain the superior portion of the subscapularis and only reflect the bottom third to half. A full-thickness L-shaped incision is made in the inferior half of the subscapularis with the shoulder held in full external rotation. This incision should be made through both the subscapularis and the underlying joint capsule and extended laterally to within 1 cm of the bicipital groove. The vertical limb of the incision is then extended inferiorly parallel to the biceps tendon past the inferior edge of the subscapularis tendon insertion and is stopped at the pectoralis major insertion. The L-shaped flap of subscapularis and capsule is then completed and elevated with increasing shoulder external rotation until adequate visualization is obtained. The superior 50% of the subscapularis insertion is left intact. *(Figures 3 and 4)*. Once this flap is completely developed, the humeral head is then delivered through the capsulotomy underneath the subscapularis *(Figure 5)*. The head passes inferior to the remaining intact subscapularis tendon. After dislocation, the humeral head can be sized *(Figure 6)*.

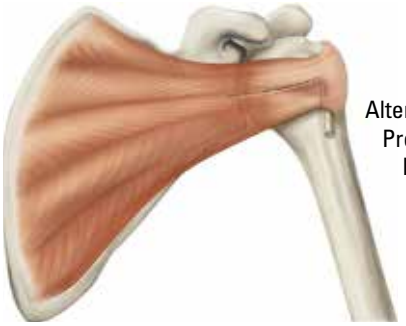


Figure 3
Alternative Subscapularis Preserving Technique: L-Shaped Incision

Figure 4
Alternative Subscapularis Preserving Technique: Elevation of the L-shaped Flap

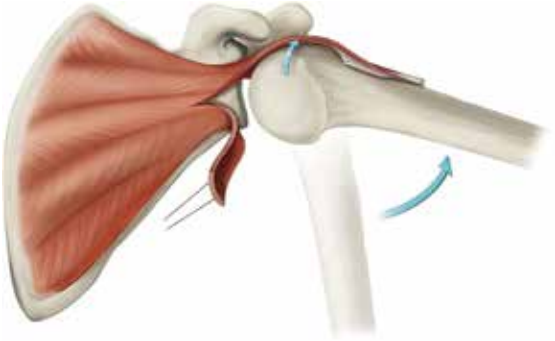


Figure 5
Alternative Subscapularis Preserving Technique: Humeral Head Dislocation Under Upper Portion of the Subscapularis

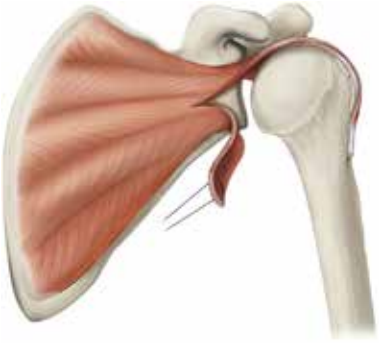


Figure 6
Alternative Subscapularis Preserving Technique: Humeral Head Exposure

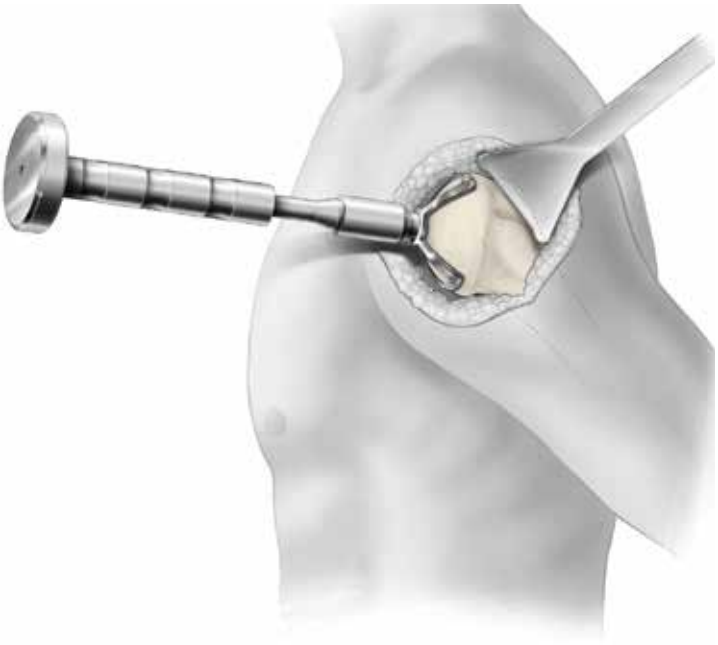


Figure 7
Sizing the Humeral Head

SIZING THE HUMERUS FOR A RESURFACING IMPLANT

The Resurfacing Humeral Head Sizer is placed onto the Impactor Handle. The Sizer is used to find the center of the humeral head and to determine the proper Resurfacing Humeral Head size *(Figure 7)*. If there are osteophytes present around the humeral head, it is important to remove with a rongeur or osteotome, as they could lead to placing the Sizer incorrectly. The tendency is to place the Sizer in varus which must be avoided. The anatomic neck and rotator cuff should be used for reference of native anatomy. Each sizer is color coded to streamline measurement and selection of each instrument *(Table 1)*.

Once the Sizer is positioned properly, the 3mm x 250mm K-wire is placed through the cannulation in the handle and inserted into the humerus until the far cortex is penetrated *(Figure 8)*. Penetration of the far cortex will ensure pin retention throughout the remaining steps of preparation and implant insertion. It is important not to plunge with the pin to avoid Axillary nerve trauma.

Note: *The K-wire should be positioned in the center of the humeral head to ensure concentric reaming. If the K-wire is not positioned in the center of the humeral head, eccentric reaming could result in removal of an insufficient amount of bone.*

Table 1
Colors are used to streamline selecting the surgical instruments

Size	Color
38mm	Black
41mm	Blue
44mm	Brown
47mm	Green
50mm	Orange
53mm	Purple

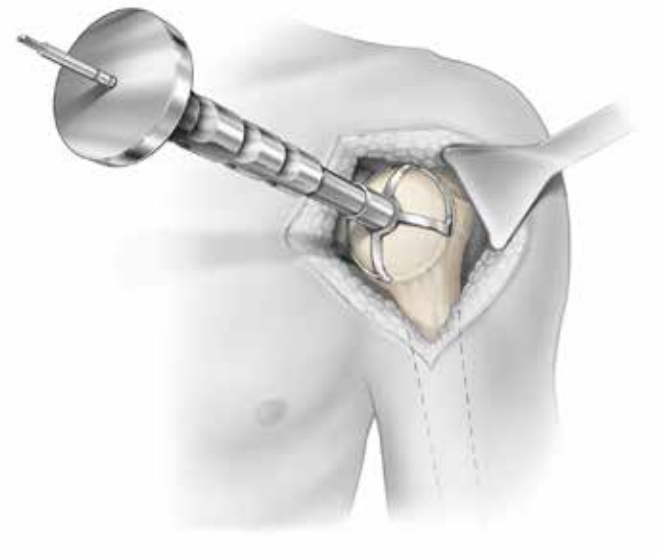


Figure 8
Placing K-Wire Through the Cannulated Handle

K-WIRE

The remaining steps of the humeral preparation are performed over the K-wire. Selection of the Humeral Cage Implant length can be done by preoperative templating or determined intra-operatively.

Note: *The K-wire should be inserted to the depth of the lateral cortex but not penetrated.*

REAMING THE HUMERUS

The handle is pulled off the K-wire leaving the K-wire in the humeral head *(Figure 9)*. The initial Sizer chosen will dictate the Resurfacing Reamer size that is to be used. The Reamer is placed onto the Modular Reamer Handle and a powered handpiece is used to facilitate reaming *(Figure 10)*. Reaming is done to remove the articular cartilage of the humeral head in preparation for the Resurfacing Humeral Head Implant. There is a stop on the Reamer body to help avoid excessive reaming. However, care must be exercised with soft bone, collapsed bone or in cases of significant head deformity not to over ream. Subchondral bone should be preserved.

Note: *The humeral head should be reamed fully as determined by complete seating of the reamer on the bone surface. Failure to fully ream the humeral head could result in incorrect implant placement, instability, bone fracture and excessive joint tissue tensioning.*

There are two laser marked lines on the K-wire. If the first line is below the surface of the Impactor Handle, then the K-wire has been positioned deep enough to prepare for the 25mm Humeral Cage. If both lines are below the surface of the Impactor Handle, then the K-wire has been positioned deep enough to prepare for the 30mm Humeral Cage.

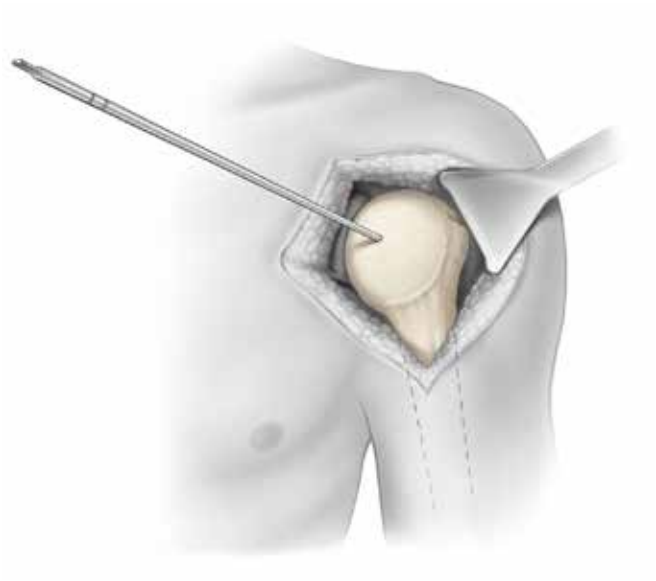


Figure 9
K-wire Placement in the Humeral Head

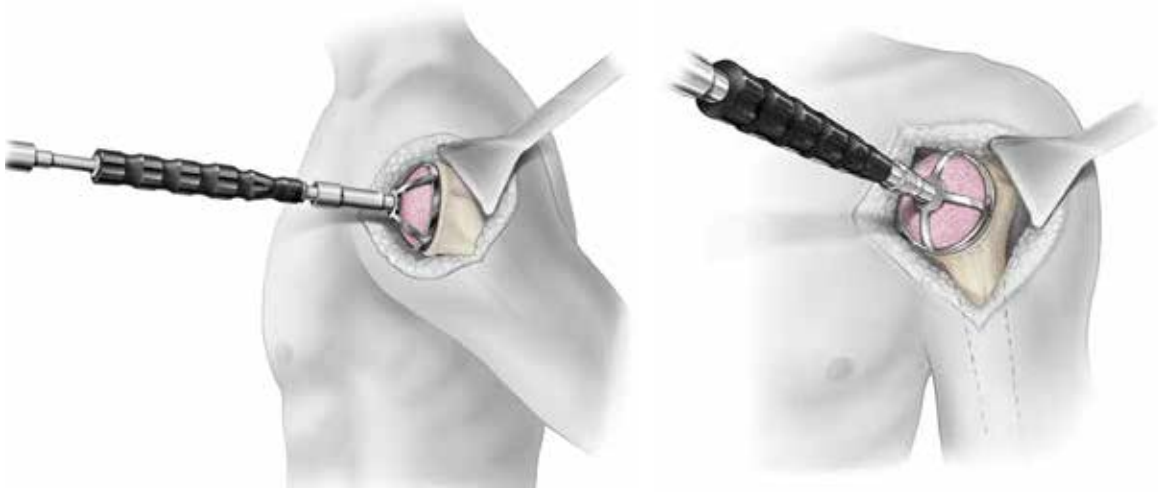


Figure 10
Reaming the Humeral Head Over the K-wire

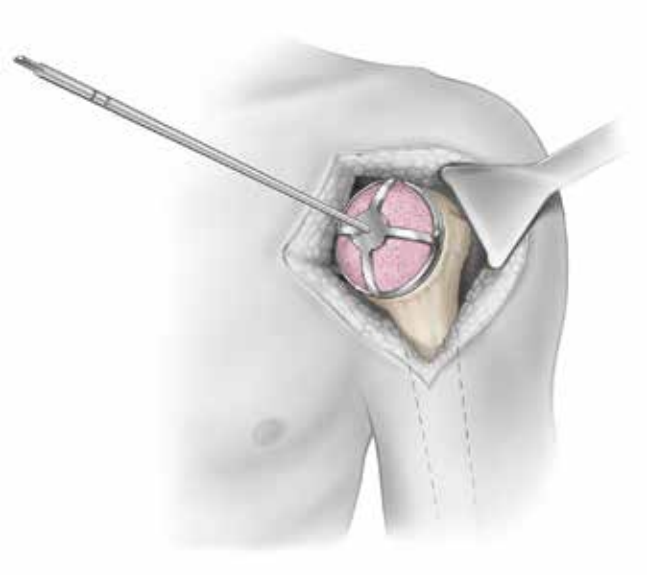


Figure 11
Trialing the Resurfacing Humeral Head

IMPLANTATION OF GLENOID

After reaming, if a prosthetic glenoid component will be implanted, refer to the Equinoxe Platform Shoulder System Surgical Technique or the Equinoxe Posterior Augment Glenoid Surgical Technique Addendum. Glenoid exposure is the challenging portion of shoulder resurfacing. Generally, it is easier to accomplish in patients with smaller body habitus and who maintain a good degree of their shoulder motion pre-operatively. Exposure depends on adequate osteophyte resection and soft tissue release during the initial exposure. Care must be exercised not to compress the humeral head with retractors while exposing the glenoid because this bone is necessary to support the humeral head prosthesis. During the initial approach as described above, an aggressive subscapularis mobilization was done. This should have included release of the inferior capsule (protect axillary nerve) and coracohumeral ligament. To provide additional exposure the upper 1/3 to 1/2 of the Pectoralis Major tendon can be released (repaired at completion of the case). Next, to release the posterior and superior capsule, a laminar spreader is inserted and used to distract the humeral head and glenoid. With the forearm in neutral rotation, the capsule is released just off of the glenoid rim until the muscles of the posterior and superior rotator cuff are visualized. Release of this capsule creates a pocket in which to displace the humeral head. A 360 degree release of the labrum is done to help with exposure. A Fukuda retractor or other humeral head retractor can be used to retract the humeral head posteriorly and inferiorly. It is important to make sure the bed or arm positioner is not preventing displacement of the humeral head posteriorly.

TRIALING

After humeral head reaming, the Trial is placed over the K-wire to verify that adequate reaming has occurred for placement of the Resurfacing Head *(Figure 11)*. The windows of the Trial provide visibility of the reamed bone. The crown (most proximal) portion of the trial should be resting on the prepared bone surface.

DRILLING FOR THE HUMERAL CAGE

After trialing, the appropriately sized Cannulated Drill is then attached to the Modular Reamer Handle and placed over the K-wire *(Figure 12).* The 25mm Drill is used to prepare for the 25mm Humeral Cage, and the 30mm Drill is used to prepare for the 30mm Humeral Cage. The drill has a stop to prevent over/under drilling.

TAMPING FOR THE HUMERAL CAGE

The Tamp is used to prepare the humerus for the fin pattern of the Humeral Cage Peg. The Tamp should be connected to the Impactor Handle and Impacted with a mallet. To enable axial control, the impactor handle has a retention feature: by twisting the tamp on the inserter handle, the tamp may be axially extracted during/after impaction. Additionally, the tamp has a stop to prevent over/under tamping *(Figure 13)*. This step should be done over the K-wire.

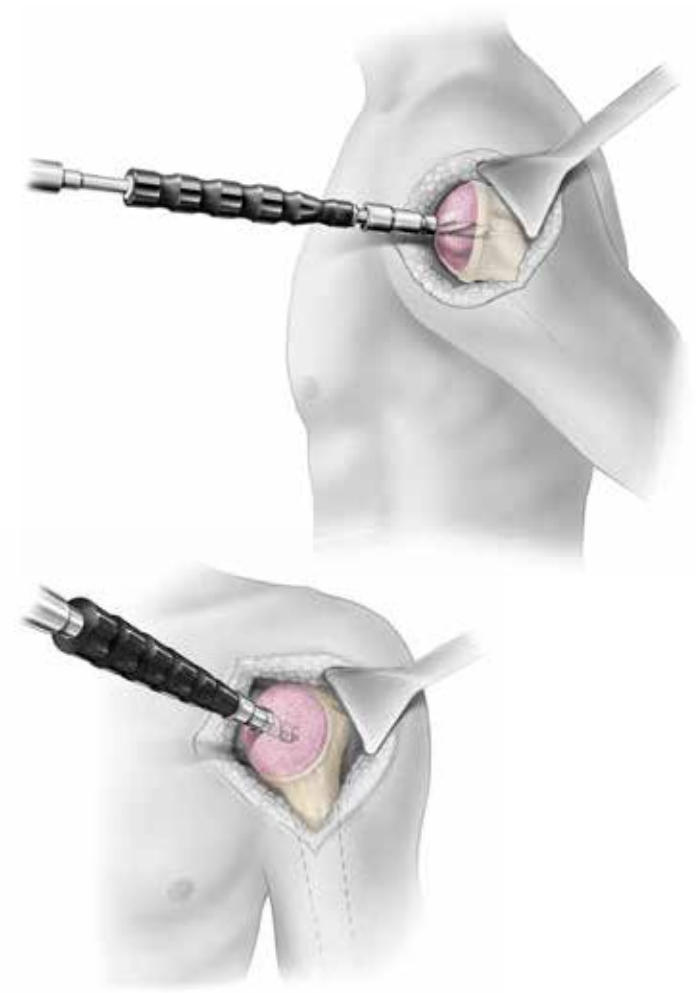


Figure 12
Drilling the Humeral Cage Peg

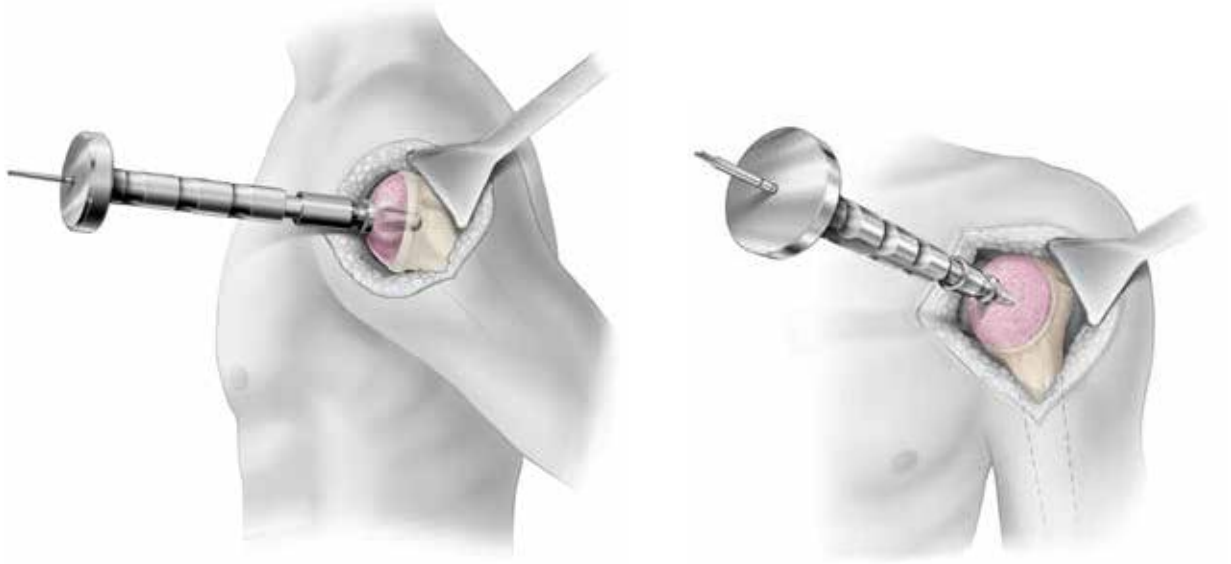


Figure 13
Tamping the Humeral Cage Peg

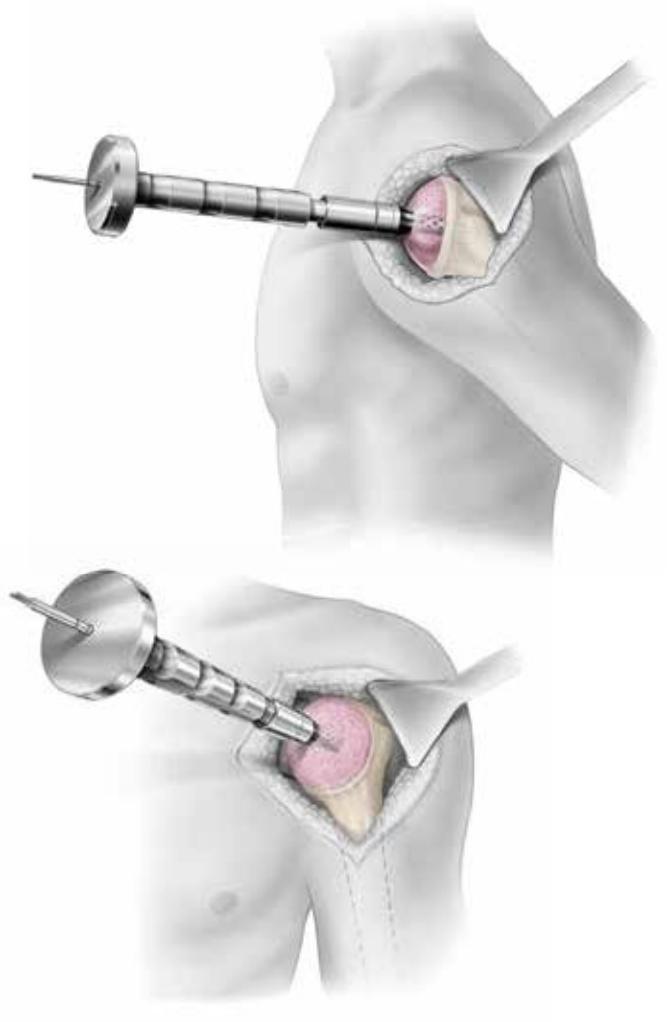


Figure 14
Inserting the Humeral Cage Peg Over K-wire

IMPLANTING THE HUMERAL CAGE

The Cage Impactor Tip is placed onto the Impactor Handle, and is used to impact the Humeral Cage into the humerus. Insertion of the humeral cage may be performed over the K-wire *(Figure 14)*. Note that the fins of the Humeral Cage will be held in place with a press-fit on the Impactor Tip. The Impactor Handle with the connected Impactor Tip is then impacted with a mallet *(Figure 15)*. The Impactor Tip has a positive stop so that the Humeral Cage is left approximately 1mm proud after Impaction *(Figure 16)*. This is done to ensure that the Resurfacing Head taper engages the female taper of the Humeral Cage.

Note: *Care should be taken to ensure that the fins of the Humeral Cage are properly aligned.*

Note: *If the bone is soft and the surgeon is concerned about the ability to engage the morse taper between the humeral head and cage in-situ, a back table assembly can be done. (See following section.)*

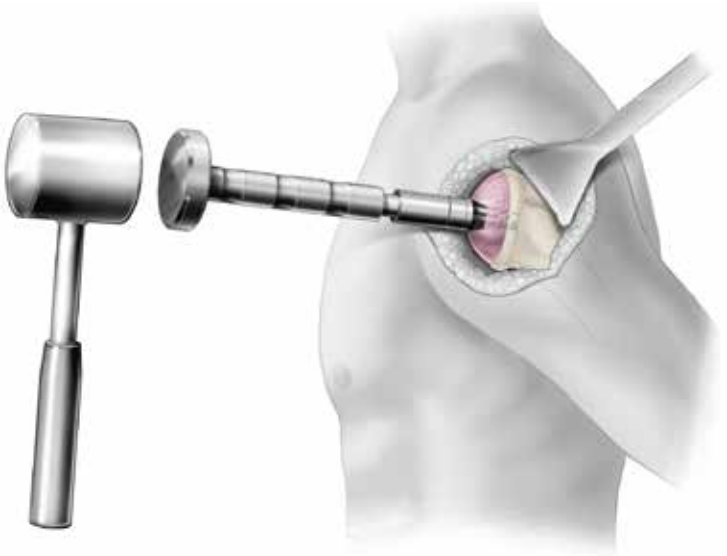


Figure 15
Impacting the Humeral Cage Peg

Figure 16
Humeral Cage Peg Left Approximately 1mm Proud After Impaction

IMPLANTING THE RESURFACING HUMERAL HEAD

The Head Impactor is placed onto the Impactor Handle, and is used to impact the Resurfacing Humeral Head onto the Humeral Cage. The first impaction will engage the tapers of the implants. Subsequent impaction will fully seat the cage and the humeral component *(Figure 17)*. Care should be taken to leave a gap of approximately 1mm between the inferior reamed surface of the humerus and the bottom rim of the Resurfacing Humeral Head to prevent stress shielding. If there is no gap, a rongeur can be used to create it.

BACK TABLE ASSEMBLY (OPTIONAL)

Depending on surgeon preference, the Humeral Cage and Resurfacing Head can be assembled on the back table prior to implantation. Care should be taken to align the notches of the Resurfacing Head with fins of the Humeral Cage. The Back Table Assembly device is marked for visualization of the fins. Proper alignment at back-table assembly will ensure that the fins of the Humeral Cage can be visualized while implanting in the humerus, which will be necessary if the Tamp was used to prepare the humerus. Once the Resurfacing Head is aligned, use the Impactor Handle and Resurfacing Head Impactor to assemble the devices together *(Figure 18)*.

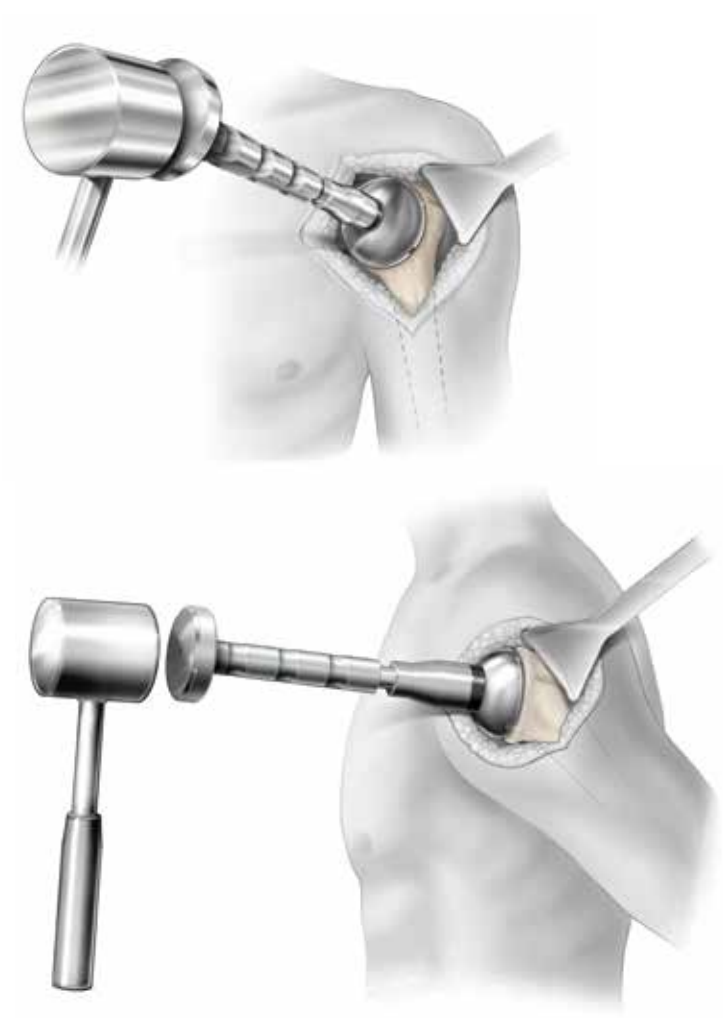


Figure 17
Impaction of the Resurfacing Humeral Head

Figure 18
Back-Table Assembly of the Humeral Head and Cage Peg

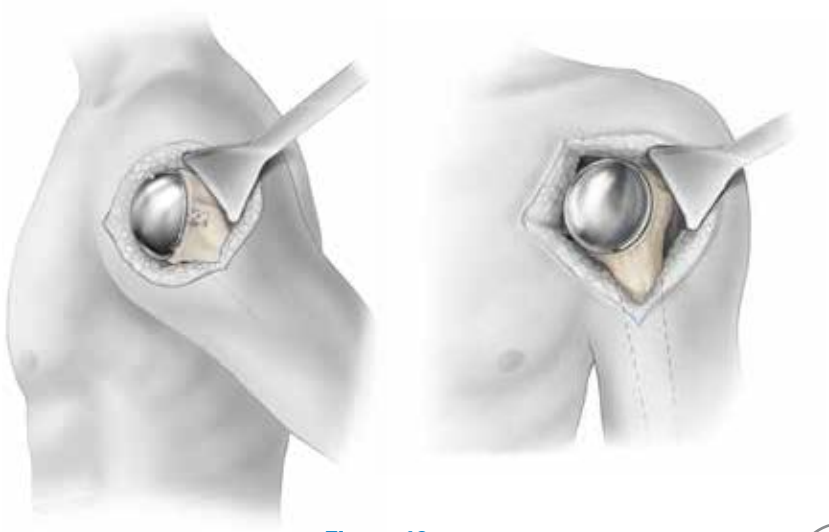


Figure 19
Final Resurfacing Humeral Head

The final assembled resurfacing humeral head is implanted into the humerus as depicted in Figure 19.

EXPLANTING THE DEVICES

Two extractors are provided to assist in removing the Resurfacing Humeral Head and Resurfacing Humeral Cage. The Humeral Head Extractor is placed along the notches of the Resurfacing Humeral Head while the thumb screw tightens the jaws of the device. A Slap Hammer may be attached for more leverage to extract the implant *(Figure 20)*.

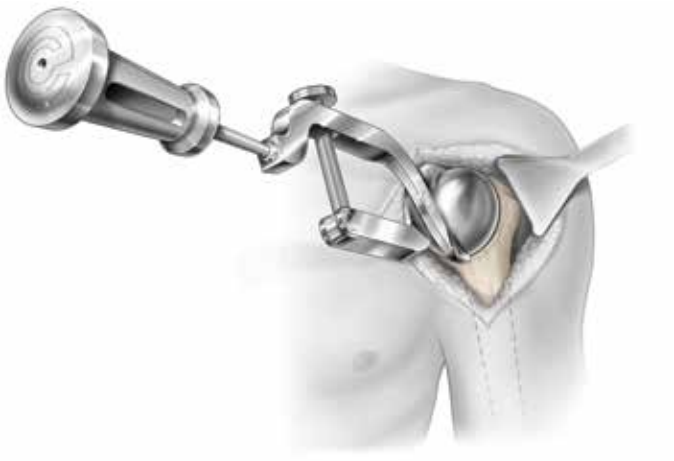


Figure 20
Extracting the Humeral Head

Prior to removing the Humeral Cage, a 3.2mm drill (321-20-00) may be used to drill through the cage to remove any bony in-growth. A small flexible osteotome can be passed around the proximal portion of the cage to release any bone ongrowth if necessary. The Humeral Cage Extractor is threaded to the Humeral Cage and a Slap Hammer may be attached to assist in removing the implant *(Figure 21)*.

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.

After the implantation of the resurfacing humeral head prosthesis, if the subscapularis preserving technique was used then the humeral head is then reduced with internal rotation and flexion of the shoulder. The subscapularis capsule flap is repaired anatomically using a double-row suture anchor technique and a reinforcing stitch. One suture anchor is placed along the medial aspect of the subscapularis insertion into the lesser tuberosity at the apex of the flap. Two full-thickness mattress sutures are then placed through the subscapularis capsule flap to reduce the medial aspect of the flap to its

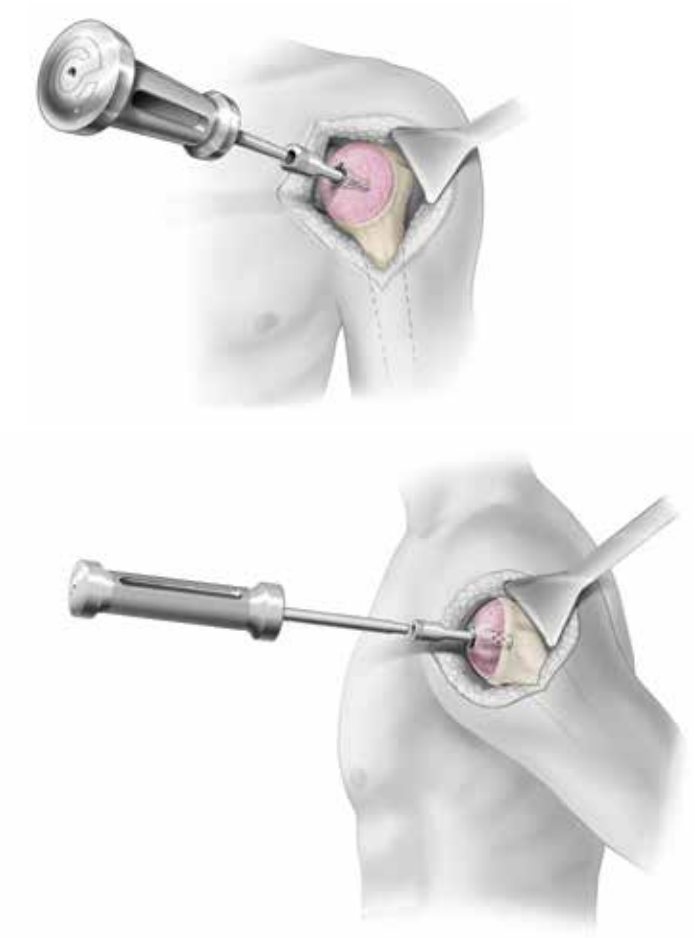


Figure 21
Extracting the Cage Peg

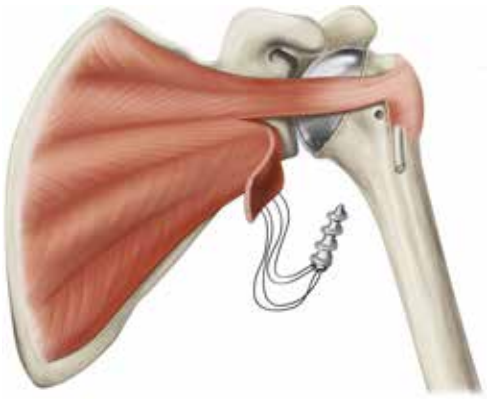


Figure 22
Alternative Subscapularis Preserving Technique Closing the Inferior Subscapularis L-shaped Flap

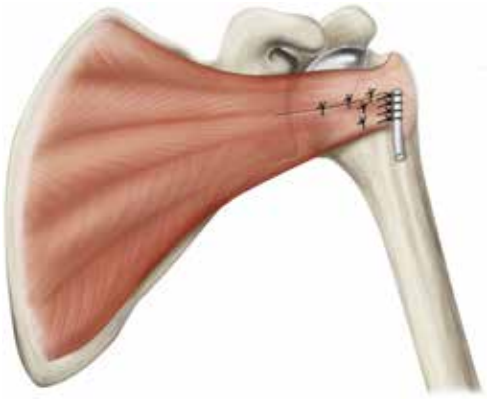


Figure 23
Alternative Subscapularis Preserving Technique: Complete Suture Repair of the Subscapularis

original footprint *(Figure 22)*. After tying, these sutures are left at full length and the remaining portion of the suture is used to reinforce the horizontal limb of the flap. Care is taken to avoid over-tightening of the tissues. The vertical limb is also oversewn with the extended length of the other suture. This vertical repair includes the biceps tendon to restore the lateral footprint. A final absorbable suture is used to reinforce and streamline the repair *(Figure 23)*. The arm is then externally rotated to ensure a good closure with no gapping of the repair.

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. External rotation should be limited for four weeks to the range without tension on the subscapularis repair as determined intra-operatively. If there is concern about the security of the subscapularis repair, external rotation should be limited to 0 degrees for four weeks. 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. The sling should be used longer, if there is a 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. Note that this document is a general guideline for postoperative rehabilitation but should not substitute for each surgeon's preference and experience.

IMPLANT SCOPE

Catalog Number	Part Description
312-01-01	Resurfacing Cage, 25mm
312-01-02	Resurfacing Cage, 30mm
312-01-38	Resurfacing Humeral Head, 38mm
312-01-41	Resurfacing Humeral Head, 41mm
312-01-44	Resurfacing Humeral Head, 44mm
312-01-47	Resurfacing Humeral Head, 47mm
312-01-50	Resurfacing Humeral Head, 50mm
312-01-53	Resurfacing Humeral Head, 53mm

INSTRUMENT SCOPE

Catalog Number	Part Description
313-01-10	Resurfacing Back Table Assembly
313-01-38	Resurfacing Head Trial, 38mm
313-01-41	Resurfacing Head Trial, 41mm
313-01-44	Resurfacing Head Trial, 44mm
313-01-47	Resurfacing Head Trial, 47mm
313-01-50	Resurfacing Head Trial, 50mm
313-01-53	Resurfacing Head Trial, 53mm
313-05-01	Resurfacing Cage Drill (short)
313-05-02	Resurfacing Cage Drill (long)
313-05-10	Cage Tamp
313-07-01	Resurfacing Head Extractor
313-07-02	Resurfacing Cage Extractor
313-07-03	Slap Hammer
313-07-05	Resurfacing Impactor Handle

INSTRUMENT SCOPE

313-07-07	Resurfacing Head Impactor Tip	
313-07-10	Resurfacing Cage Impactor Tip	
313-10-38	Resurfacing Head Sizer, 38mm	
313-10-41	Resurfacing Head Sizer, 41mm	
313-10-44	Resurfacing Head Sizer, 44mm	
313-10-47	Resurfacing Head Sizer, 47mm	
313-10-50	Resurfacing Head Sizer, 50mm	
313-10-53	Resurfacing Head Sizer, 53mm	
313-25-00	Reamer Handle	
313-25-38	Resurfacing Humeral Reamer, 38mm	
313-25-41	Resurfacing Humeral Reamer, 41mm	
313-25-44	Resurfacing Humeral Reamer, 44mm	
313-25-47	Resurfacing Humeral Reamer, 47mm	
313-25-50	Resurfacing Humeral Reamer, 50mm	
313-25-53	Resurfacing Humeral Reamer, 53mm	
313-35-00	3mm x 250mm K-Wire	
317-20-07	Chandler Retractor	
317-20-08	Small Darrach Retractor	
313-41-01	Resurfacing Humeral Head Instrument Tray	
313-41-02	Resurfacing Humeral Head Instrument Upper Tray	

NOTES

NOTES

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

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

 718-07-30 Rev. D 0402

CE 2797 CE Mark is not valid unless there is a CE Mark on the product label.

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