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ANATOMIC SIZING AND DESIGN FEATURES

Anatomic Sizing

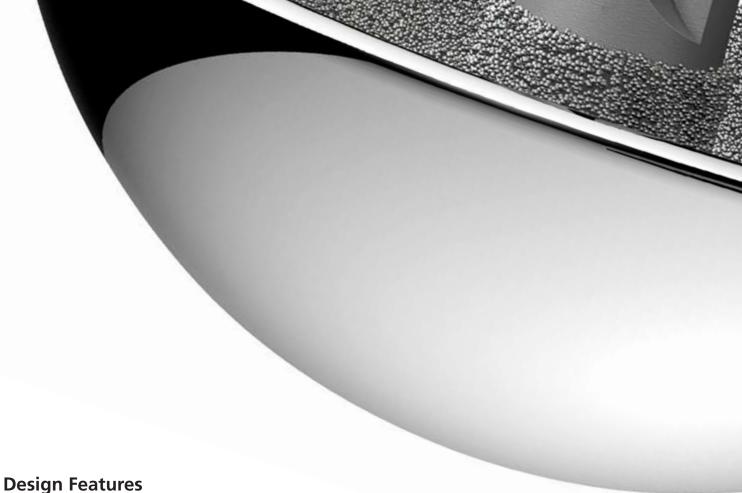
The sizing of the Global C.A.P.TM implant is based upon the observed variability in humeral head size in normal shoulders¹

- Normal shoulders exhibit a range of humeral head diameters and humeral head heights
 - Head height correlates with humeral head diameter

The variable sizing options of the Global C.A.P. system permit superior anatomic reconstruction of the humeral head

Head Diameters (mm)

(mm)		40	44	48	52	56
ghts	15					
Head Heights (mm)	18					
Head	21					



Secure implant design with cruciate stem.

Unique undersurface design that offers rotational stability.

Apical flat on undersurface of implant allows for better fit and intimate contact.

Variable stem lengths for corresponding head heights:

15 mm head height – 30 mm stem

18 mm head height – 35 mm stem

21 mm head height – 40 mm stem

Undersurface of the head and the proximal portion of the central stem are surface-treated either in Porocoat® Porous Coating or DuoFix® Hydroxyapatite on Porous Coating.

Instrumentation

The Global C.A.P. instruments are designed to be user-friendly and offer precise implant preparation.

- Reamers accurately reshape humeral head wear typically seen in arthritic patients with flattened humeral heads.
- Cannulated instrumentation (head sizers, reamers, trials and stem punch) allows the surgeon to move from one step to the next.
- Centering technique allows the surgeon to position the implant accurately.





Triple Step Reamers

Because bone preparation is an essential step, the humeral head reamers are sharp, accurate and offer optimal implant seating in one easy step. This design helps in reshaping the proximal humerus to ensure maximum contact area between the native humerus and the implant. The reamers shape the humeral head in three ways:

- Central portion of the reamer fashions a distally tapering hole.
- Peripheral portion of the reamer shapes the humeral head.
- Deepest portion of the reamer shapes the flat superior portion of the humeral head.



Indications

The Global C.A.P.™ implant has the same indications as general shoulder arthroplasty. They include loss of articular cartilage, joint incongruity, stiffness, loss of function and pain unresponsive to nonoperative measures. Indications specific to the Global C.A.P. include:

- Patients disabled by either non-inflammatory or inflammatory arthritis (i.e., rheumatoid arthritis, osteoarthritis and avascular necrosis).
- Mild or moderate humeral head deformity and/or limited motion.
- Post-traumatic arthritis.
- Malunions of the humeral head.
- Patients with an intact or reparable rotator cuff.

The Global C.A.P. implant is intended for cementless use only.

Contraindications

The following are contraindications for the Global C.A.P. implant:

- Active local or systemic infection.
- Inadequate bone stock in the proximal humerus



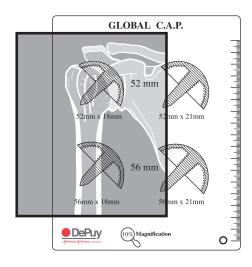


Figure 1
Preoperative radiograph and template used to verify appropriate head size

Humeral Preparation

Preoperative templating of radiographs is important for predicting the humeral head size that will be needed during surgery. The head size can be further verified intraoperatively by measuring the head after osteophyte removal. Begin preparation of the humerus by approximating the template (appropriate head size) over the preoperative radiograph (Figure 1).

Depending on surgeon preference, either the Deltopectoral or the Superior Approach (commonly known as McKenzie's) can be used. The advantages of the Deltopectoral Approach include preservation of the deltoid origin and insertion, utilization of an internervous plane (extensile),

and facilitation of subscapularis lengthening. The Superior Approach may be preferred since it offers retention of the subscapularis. Since the Deltopectoral Approach is the most typical approach for this procedure, the surgical technique will highlight this approach only.

Anesthesia and Patient Positioning

Proximal humeral replacement using the Global C.A.P. implant can be performed using general anesthesia, regional anesthesia (i.e., interscalene block), or a combination of general anesthesia and regional anesthesia. Place the patient in a supine position, with the hips flexed approximately 30 degrees, knees bent approximately 30 degrees and back elevated approximately 30 degrees (i.e., the beach chair position). Complete access to the top and back of the shoulder can be achieved through the use of specialized headrests or operating tables with break-away side panels.

Exposure - Deltopectoral Approach

Obtain exposure through a deltopectoral incision extending 10-15 cm inferolaterally from approximately the mid-shaft of the clavicle toward the deltoid insertion. Identify the cephalic vein within the deltopectoral groove. Dissect it away from the pectoralis major, and mobilize it laterally with the deltoid. The superior 1.0-1.5 cm of the pectoralis major insertion may be released from the humerus to improve exposure of the inferior aspect of the joint. Place a self-retaining retractor to retract the deltoid and cephalic vein laterally and the pectoralis major medially.

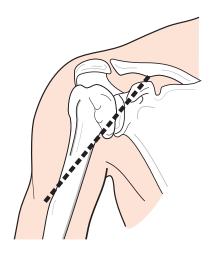


Figure 2 Deltopectoral incision

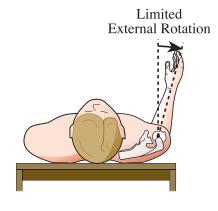
Deltopectoral Incision

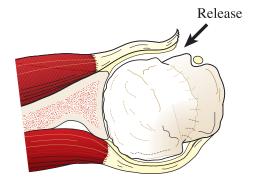
Identify the conjoined tendon of the coracobrachialis and short head of the biceps. Make an incision in the clavipectoral fascia at the lateral-most extent of the conjoined tendon. Carry this incision superiorly to the coracoacromial ligament (Figure 2). Adequate exposure is usually obtained without sacrifice of any portion of the coracoacromial ligament. Therefore, preservation of the coracoacromial ligament may be performed in all arthroplasty cases, especially those with poor quality rotator cuff tissue (i.e., rheumatoid arthritis).

The axillary and musculocutaneous nerves may be injured in any deltopectoral approach. Thus, care should be taken to identify and protect them whenever possible. Routinely identify the axillary nerve at the inferior aspect of the glenohumeral joint, either by digital palpation or direct visualization. The musculocutaneous nerve has a more variable course, particularly with reference to the distance from the tip of the coracoid to its passage into the posterior surface of the conjoined tendon. Because of this variability, it may not always be easily palpable within the surgical field. However, an attempt should always be made to palpate it. This will help ensure that the nerve can be protected throughout the procedure.

Deep Dissection

With the conjoined tendon retracted medially and the deltoid retracted laterally, the subscapularis muscle and tendon and the anterior humeral circumflex vessels can be easily identified. Clamp and coagulate or ligate the anterior circumflex vessels to prevent excessive bleeding throughout the procedure. Identify the superior and inferior extents of the subscapularis. Superiorly, the subscapularis forms a well-defined tendon that inserts into the lesser tuberosity. Inferiorly, the subscapularis consists of laterally extending muscle fibers with a less well-demarcated tendon that inserts directly into the humerus. Place stay sutures within the tendon in anticipation of its later release.







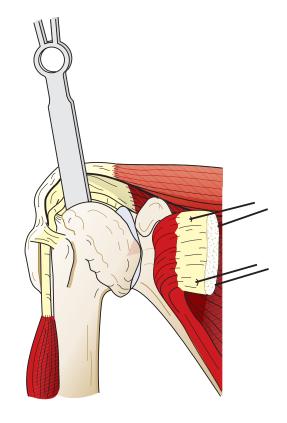
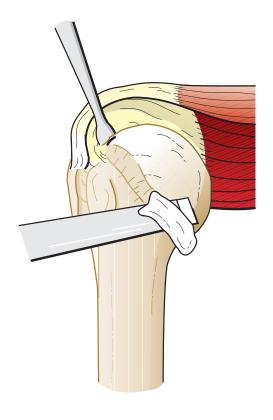


Figure 4

The method of subscapularis release and repair is dependent on the degree of external rotation loss (Figure 3). In patients with 20 degrees or more of preoperative external rotation, incise the subscapularis intratendinously and repair anatomically at the completion of the procedure. If preoperative external rotation is less than 20 degrees, but greater than negative 30 degrees, release the subscapularis from the lesser tuberosity as far laterally as possible and repair to bone at the bone-prosthesis junction, thereby advancing it medially to gain length. On very rare occasions where external rotation is less than negative 30 degrees, perform a z-lengthening of the subscapularis and anterior capsule.

The z-lengthening is accomplished by releasing the subscapularis from the lesser tuberosity as far laterally as possible while preserving the humeral capsular attachment. A small amount of the deep portion of the subscapularis can be left with the anterior capsule for reinforcement. The capsule is released from the glenoid and incised in a medial-lateral direction at the inferior portion of the glenohumeral joint. This creates a laterally based capsular flap and a medially based subscapularis flap with which to perform a z-lengthening.

After the subscapularis and capsule have been released by the method that is appropriate for the degree of contracture present, deliver the humerus out of the wound using simultaneous adduction, external rotation and extension of the arm. This requires a complete inferior capsular release from the humeral neck to its posterior inferior attachment (Figure 4).





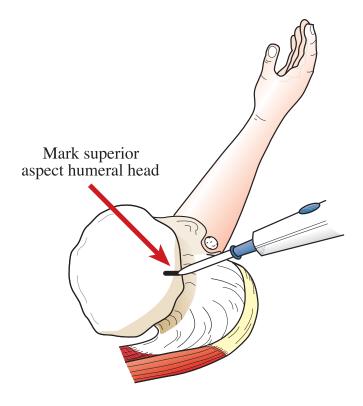
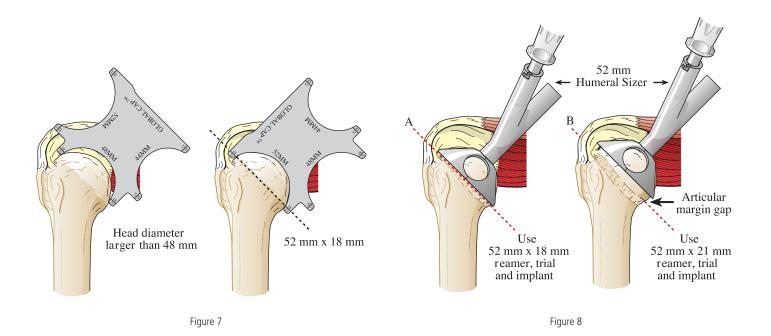


Figure 6

With the humeral head delivered out of the wound, remove all humeral osteophytes (Figure 5). This is a particularly important step, since the anatomic neck must be visualized to guide humeral preparation. Place a curved Crego or reverse Hohmann retractor along the anatomic neck superiorly to protect and retract the long head of the biceps and posterosuperior rotator cuff.

Mark the most superior point of the articular margin or anatomic neck with electrocautery or marking pen (Figure 6).

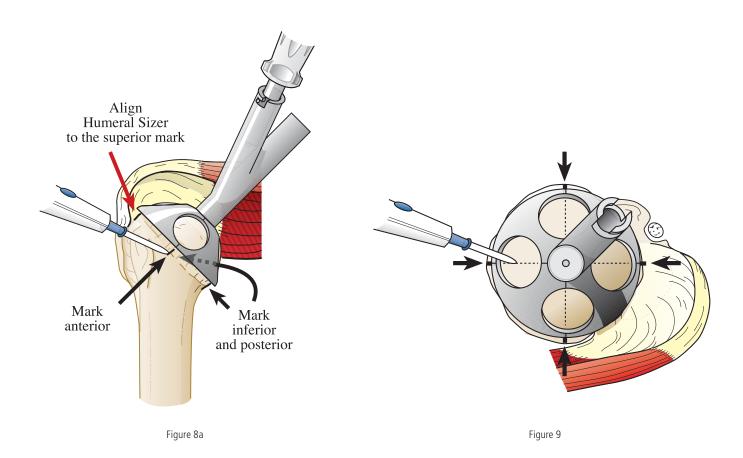


Head Sizing

Head sizing is confirmed intraoperatively using the humeral head sizers or humeral head gauge (Figure 7 and Figure 8).

Assemble the appropriate humeral head sizer to the sizer/drill guide handle. Place the sizer over the humeral articular surface, such that its superior mark is aligned with the previously placed mark on the humeral head and the plane of the head sizer rim is parallel with the plane of the anatomic neck of the native humerus.

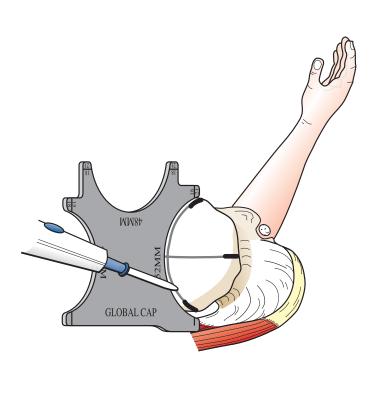
The appropriate head sizer is determined by identifying the articular margin of the humerus in relation to the inferior edge of the sizer. If the inferior margin is 3 mm below the inferior edge of the sizer, a deeper head height is necessary (Figure 8). Also, note that the interior of the sizer represents the outermost diameter of the definitive implant. If the sizer looks too small or too large, a smaller or larger head sizer can be used.



Identifying Center of Humeral Head

Further mark the humerus at the most anterior, posterior and inferior aspects of the sizer (Figure 8a).

Next, mark the surface of the humeral head along the determined superior-inferior and anterior-posterior axes using electrocautery or marking pen through the round fenestrations in the sizer (Figure 9).





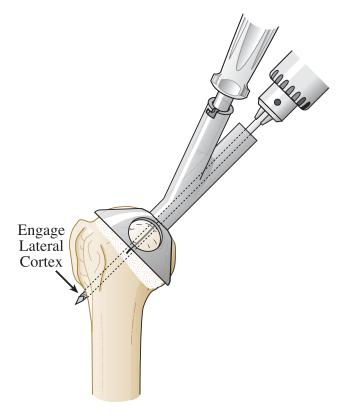


Figure 11

Remove the sizer and visualize the marked surface of the humeral head.

Note: It is important to check that the center of the sizer/intersecting marks on the corresponding humeral head identify the center of the humeral head. Identification of the center will ensure proper guide pin and definitive implant placement.

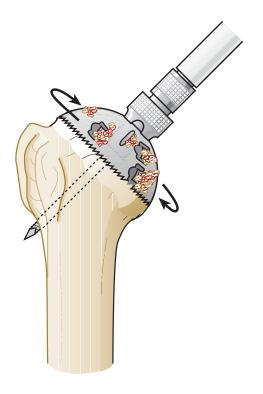
Complete the interrupted superior-inferior and anterior-posterior lines using the humeral head gauge as a template (Figure 10). If the lines do not intersect at what appears to be the center of the humeral head, repeat the previous steps until the center of the humeral head has correctly been identified.

Using the head gauge, confirm the humeral head diameter and thickness.

Replace the humeral sizer over the humeral head in the previously determined center position. Drill the threaded guide pin through the center of the cannulated sizer, the center of the humeral articular surface and into the humeral head (Figure 11). The tip of the guide wire should penetrate the lateral cortex of the humerus.

Note: Full penetration of lateral cortex will prevent guide pin from migrating in cancellous bone.

Remove the humeral sizer.





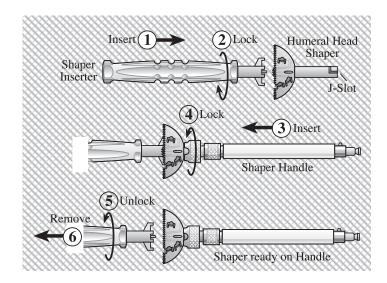


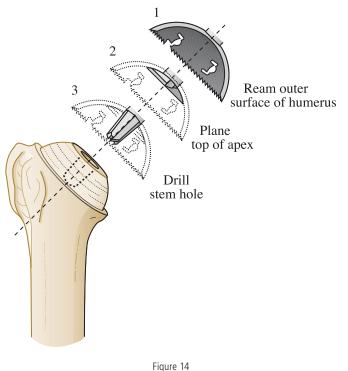
Figure 13

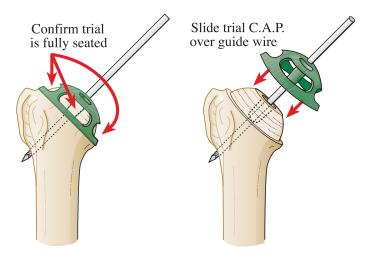
Humeral Head Shaping

Based on previously determined head size, perform humeral shaping with the appropriate size reamer (Figure 12).

Assemble the appropriate reamer to the shaper/drill guide handle and tighten using the assembling tool (Figure 13).

Note: When inserting the reamer to the humeral head shaper handle, the J-slot of the reamer must be engaged with the shaper handle before the neck can be locked. Turn the neck counterclockwise to lock handle.





Connect the reamer to power. Pass the assembled reamer over the guide wire onto the humeral head. Ream until bone chips are seen to exit from the most superior holes in the peripheral surface of the reamer (Figure 14). Reaming depth can also be checked by observing the distance between the advancing reamer and the rotator cuff attachment site.

Note: Reaming should cease before the sharp-toothed edge of the reamer damages the rotator cuff attachment.

There may be some apparent cancellous bone at the superior shelf of the reamed humeral head. The humeral bone fragments generated from the reaming process can be saved for bone graft between the implant and humerus if needed. The reaming process creates a shelf, equal in width to the thickness of the eventual implant at the base of the humeral head in the anatomic neck region. Any attached fragments of bone that might

interfere with complete seating of the trial or implant should be excised with a rongeur. Remove all remaining osteophytes so that the implant forms a smooth transition to the peripheral rim of the humeral head.

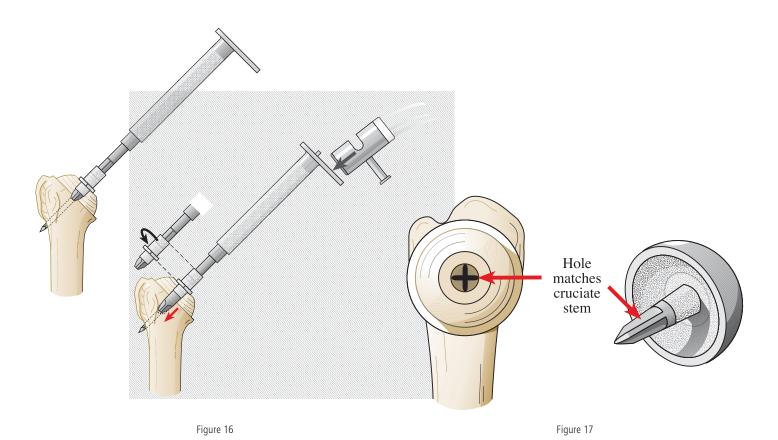
Figure 15

Implant Trialing

Use the trial to assess final implant size and fit (Figure 15). Pass the appropriate cannulated trial implant over the guide wire onto the reamed humeral surface. If the trial is the appropriate size and reaming has been adequately performed, the trial should seat completely so that the edge of the trial rests on the shelf created at the anatomic neck region.

Note: Check to ensure there is uniform contact between the undersurface of the trial and the bone.

The trials have large viewing windows to aid in this visualization. Remove the trial using the trial grasping tool.



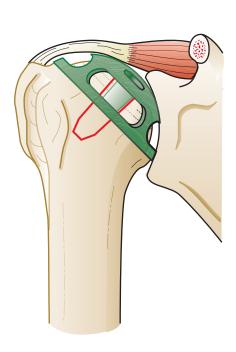
Central Stem Preparation

The shape of the definitive implant's stem is a cruciform. This shape improves implant rotational stability. The cannulated cruciform stem punch is used to create a path for the implant stem in the unreamed cancellous bone in the base of the central hole and ensure correct stem seating of the implant (Figure 16). Pass the stem punch over the guide pin and into the central hole in the humeral head. Place the centering sleeve into the locked position by turning it clockwise one-quarter turn. Advance the stem punch shaft into the reamed central hole. Rotate the centering sleeve one counter-

clockwise turn to unlock the punch and then impact the stem punch with a mallet into the cancellous bone of the humerus. The depth of penetration is controlled by the centering sleeve. Remove the central guide pin.

Note: When impacting the stem punch, avoid impacting the mallet over drill pin hole to avoid striking the pin.

The stem punch ensures that the axes of the punch and the eventual implant stem are collinear (Figure 17). If these two axes are divergent, the implant may not be completely seated.





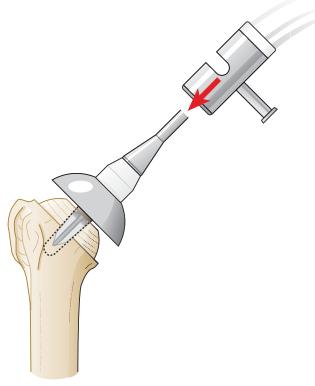


Figure 19

Soft-tissue Releases

Regardless of whether or not a glenoid component will be used in combination with this implant, soft-tissue releases are required to maximize postoperative range of motion. A ring retractor may be used to retract the humeral head posteriorly. However, extreme care must be observed so that the retractor does not damage the reamed humeral surface. The humeral head trial may be re-inserted to aid in protection of the reamed bone (Figure 18). Circumferential release of the glenohumeral joint capsule may then be accomplished. In cases where the anteroinferior capsule is pathologically thickened, it can be excised. Glenoid preparation may also be performed if necessary.

After appropriate soft-tissue releases have been performed, evaluate soft-tissue tension. Re-insert the humeral head trial and reduce the humerus into the

glenoid fossa. As a general rule, with the humerus in neutral rotation and the arm in 0-20 degrees of scapular plane abduction, a posteriorly directed subluxating force should cause posterior translation of 50 percent of the humeral head (Figure 18). In addition, the subscapularis should be long enough to reattach to its insertion site, allowing the arm to go to at least 30 degrees of external rotation.

Implant Placement

Expose the humeral head so that the entire prepared surface of the humerus can be seen. Remove the humeral trial. Place the stem of the humeral head implant into the central hole with the cruciform flanges aligned in the appropriate cruciate path. Use the head impactor tool to completely seat the implant with a mallet (Figure 19).

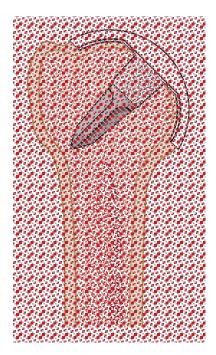


Figure 20 Cross-section of humeral head with Global C.A.P. implant

Verify that the implant has been fully seated. There should be no gap from the periphery of the implant and reamed margin of the humerus. Reduce the humerus into the glenoid fossa (Figure 20).

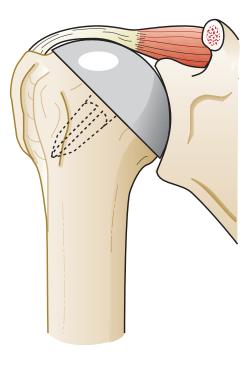


Figure 21 Definitive Global C.A.P. implant

After joint reduction, verify that the shoulder has the desired amount of laxity (Figure 21).



Figure 22

Closure

Repair the subscapularis according to the method of detachment. If the subscapularis was released intratendinously, repair it anatomically, tendon-to-tendon. If it was released from the lesser tuberosity with maximum length, it is most often advanced medially to the implant-bone junction and repaired to bone. On rare occasions, a z-lengthening is performed using the medially based subscapularis tendon and the laterally based anterior capsule. Following subscapularis closure, passive external rotation with the arm at the side should be at least 30 degrees. Close the deltopectoral interval. In a routine fashion, close the subcutaneous tissue and skin. Radiographs should be taken to verify implant positioning and seating (Figure 22).

Aftercare

Begin pendulum exercises and passive range of motion within 24 hours of surgery. There are no limits to the passive range of motion performed, except that external rotation should not exceed the safe zone of rotation observed at surgery after subscapularis closure. A sling may be used for comfort and protection. An overhead pulley is added at four to six weeks. Passive stretching and strengthening exercises of the rotator cuff, deltoid and scapular muscles should commence at six weeks postoperatively. These exercises are progressed as tolerated over the next three to six months. Complete recovery from surgery occurs at 9-12 months.

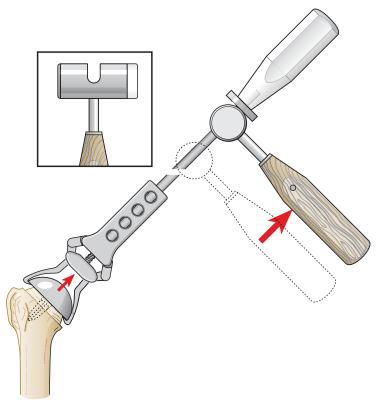


Figure 39

Extraction of the Implant

Indications for revision may include infection, glenoid wear, implant loosening or dislocation. Additionally, in rare cases, removal of the implant may be required during revision surgery. Attain exposure as described above. Attach the extractor tool to the implant that is to be removed (Figure 39). This may require removal of a small amount of bone at the edge of the implant

to allow the extraction tool to be attached to the edge of the implant. Extract the implant using a slotted mallet. If the implant is well-fixed, a saw can be used to cut the periphery of the humerus at the bone-implant junction. The implant and the contained humeral bone can then be removed together. The surface of the remaining humerus can then be prepared for conversion to a Global Advantage stem (Global Advantage Surgical Technique, Cat. No. 0601-69-050).

Implants

Porocoat porous coated

Catalog No.	Description
1230-40-000	Global C.A.P. Head Porocoat Porous Coated 40 x 15
1230-40-010	Global C.A.P. Head Porocoat Porous Coated 40 x 18
1230-44-000	Global C.A.P. Head Porocoat Porous Coated 44 x 15
1230-44-010	Global C.A.P. Head Porocoat Porous Coated 44 x 18
1230-48-010	Global C.A.P. Head Porocoat Porous Coated 48 x 18
1230-48-020	Global C.A.P. Head Porocoat Porous Coated 48 x 21
1230-52-010	Global C.A.P. Head Porocoat Porous Coated 52 x 18
1230-52-020	Global C.A.P. Head Porocoat Porous Coated 52 x 21
1230-56-010	Global C.A.P. Head Porocoat Porous Coated 56 x 18
1230-56-020	Global C.A.P. Head Porocoat Porous Coated 56 x 21

Duofix HA on porous coating

Catalog No.	Description
1230-40-005	Global C.A.P. Head DuoFix HA 40 x 15
1230-40-015	Global C.A.P. Head DuoFix HA 40 x 18
1230-44-005	Global C.A.P. Head DuoFix HA 44 x 15
1230-44-015	Global C.A.P. Head DuoFix HA 44 x 18
1230-48-015	Global C.A.P. Head DuoFix HA 48 x 18
1230-48-025	Global C.A.P. Head DuoFix HA 48 x 21
1230-52-015	Global C.A.P. Head DuoFix HA 52 x 18
1230-52-025	Global C.A.P. Head DuoFix HA 52 x 21
1230-56-015	Global C.A.P. Head DuoFix HA 56 x 18
1230-56-025	Global C.A.P. Head DuoFix HA 56 x 21

Instrumentation

Catalog No.	Description
14012-9	Threaded Guide Pin
2001-65-000	Head Impactor
2001-66-000	Impactor Tip
2128-61-017	Glenoid Graspers
2230-40-000	Global C.A.P. Humeral Head Trial 40 x 15
2230-40-010	Global C.A.P. Humeral Head Trial 40 x 18
2230-44-000	Global C.A.P. Humeral Head Trial 44 x 15
2230-44-010	Global C.A.P. Humeral Head Trial 44 x 18
2230-48-010	Global C.A.P. Humeral Head Trial 48 x 18
2230-48-020	Global C.A.P. Humeral Head Trial 48 x 21
2230-52-010	Global C.A.P. Humeral Head Trial 52 x 18
2230-52-020	Global C.A.P. Humeral Head Trial 52 x 21
2230-56-010	Global C.A.P. Humeral Head Trial 56 x 18
2230-56-020	Global C.A.P. Humeral Head Trial 56 x 21
2230-80-010	Global C.A.P. Humeral Head Sizer/Drill Guide 40
2230-80-020	Global C.A.P. Humeral Head Sizer/Drill Guide 44
2230-80-030	Global C.A.P. Humeral Head Sizer/Drill Guide 48
2230-80-040	Global C.A.P. Humeral Head Sizer/Drill Guide 52
2230-80-050	Global C.A.P. Humeral Head Sizer/Drill Guide 56
2230-80-060	Global C.A.P. Humeral Head Sizer/Drill Guide Handle
2230-81-010	Global C.A.P. Humeral Head Shaper 40 x 15
2230-81-020	Global C.A.P. Humeral Head Shaper 40 x 18
2230-81-030	Global C.A.P. Humeral Head Shaper 44 x 15
2230-81-040	Global C.A.P. Humeral Head Shaper 44 x 18
2230-81-050	Global C.A.P. Humeral Head Shaper 48 x 18
2230-81-060	Global C.A.P. Humeral Head Shaper 48 x 21
2230-81-070	Global C.A.P. Humeral Head Shaper 52 x 18
2230-81-080	Global C.A.P. Humeral Head Shaper 52 x 21
2230-81-090	Global C.A.P. Humeral Head Shaper 56 x 18
2230-81-100	Global C.A.P. Humeral Head Shaper 56 x 21
2230-81-110	Global C.A.P. Humeral Head Shaper Handle
2230-81-120	Global C.A.P. Humeral Head Shaper Inserter
2230-82-000	Global C.A.P. Implant Stem Punch
2230-83-000	Head Extractor
2230-84-000	Global C.A.P. Template
2230-84-010	Humeral Head Gauge 40, 56
2230-84-020	Humeral Head Gauge 44, 48, 52
2230-90-000	Global C.A.P. Instrument Case
2421-22-000	Slotted Mallet

Important:

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications:

Total shoulder or hemi-shoulder replacement is indicated for:

- 1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
- Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
- Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

- 1. Ununited humeral head fractures;
- 2. Avascular necrosis of the humeral head;
- 3. Rotator cuff tear arthropathy. Global C.A.P.™ is indicated for intact or repairable rotator cuff.
- 4. Deformity and/or limited motion.

Porocoat® Porous-Coated Components

Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue ingrowth into the porous coating.

Global C.A.P. is intended for cementless use only.

Cemented Components

Humeral stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

Press-fit or Cemented Components

Humeral stem prostheses without porous coating and labeled "for press fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

Contraindications

The following conditions are contraindications for total shoulder and hemi-shoulder arthroplasty.

- 1. Active local or systemic infection.
- 2. Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components.
- 3. Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid.

The following condition is a contraindication for total shoulder arthroplasty.

1. Absent, irreparable or nonfunctional rotator cuff or other essential muscles.

Warnings and Precautions:

The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non anatomic loading conditions. The following conditions tend to adversely affect shoulder replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events:

The following are the most frequent adverse events after shoulder arthroplasty: change in position of the components, loosening of components, dislocation, infection, hematoma, pneumonia, and cardiovascular disorders.

References

 lannotti, J.P.; Gabriel, J.P.; Schneck, S.L.; Evans, B.G.; and Misra, S. "The normal glenohumeral relationships. An anatomical study of one hundred and forty shoulders." Journal of Bone and Joint Surgery April 1992: 491-500.

Color illustrations by S. Lippitt, MD

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