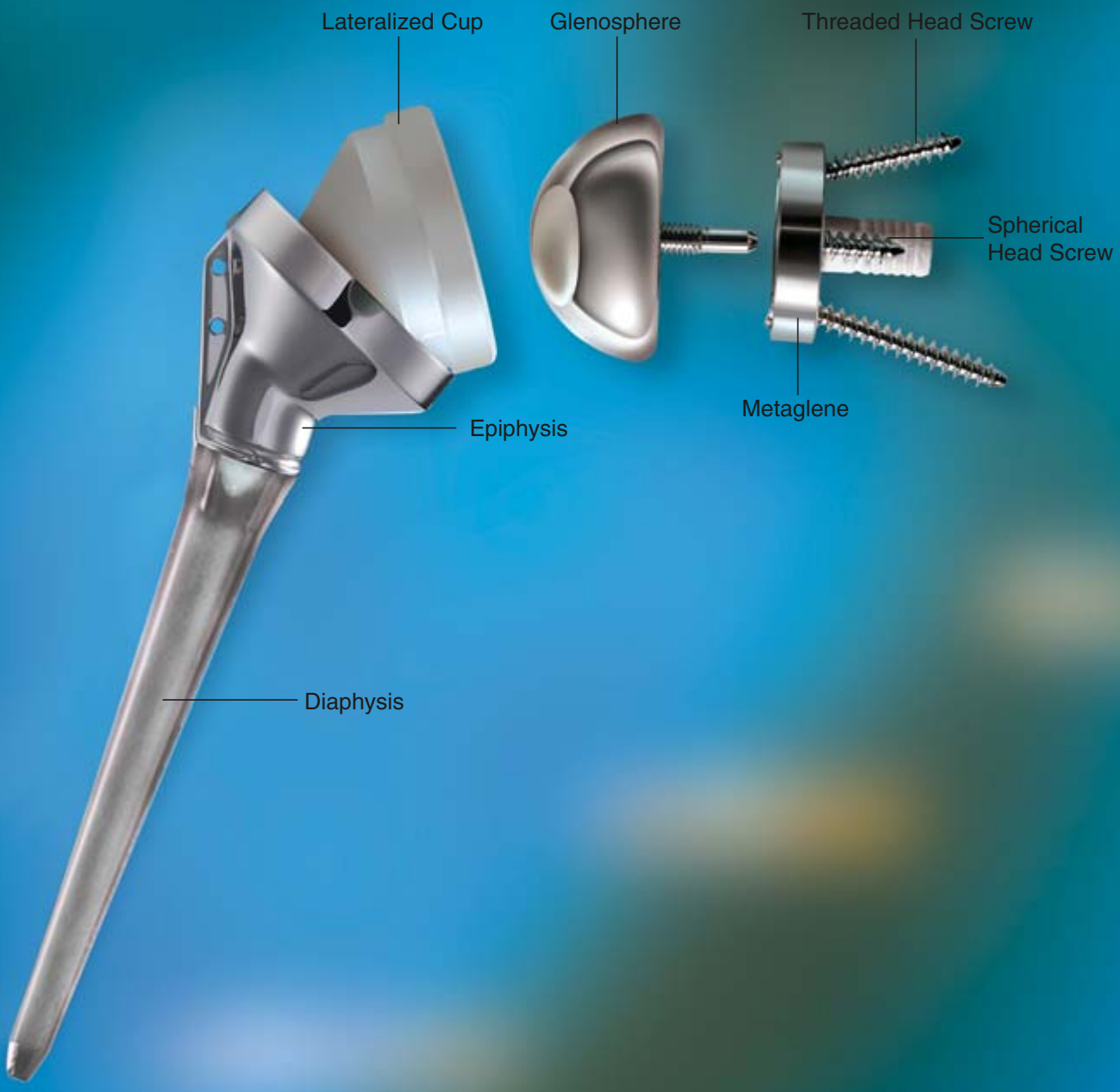
SURGICAL TECHNIQUE

DELTA CTA™

REVERSE SHOULDER SYSTEM

DePuy
a Johnson & Johnson company

DELTA CTA™


Lateralized Cup
Glenosphere
Threaded Head Screw
Spherical Head Screw
Metaglene
Epiphysis
Diaphysis

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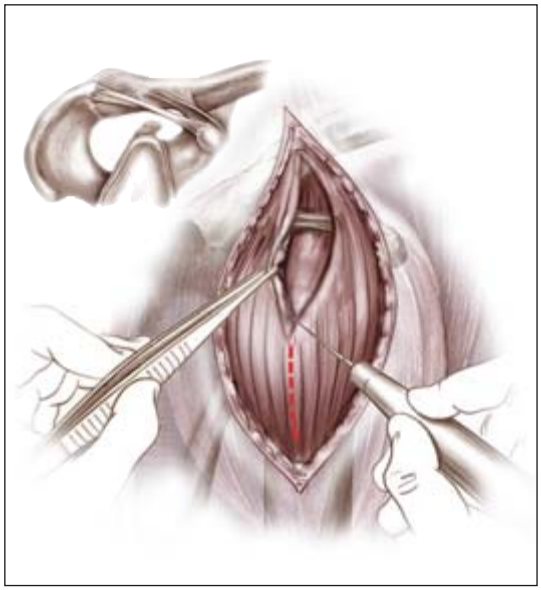
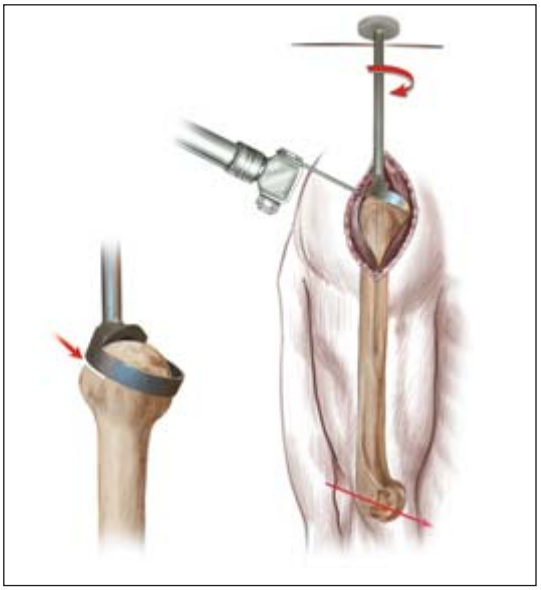
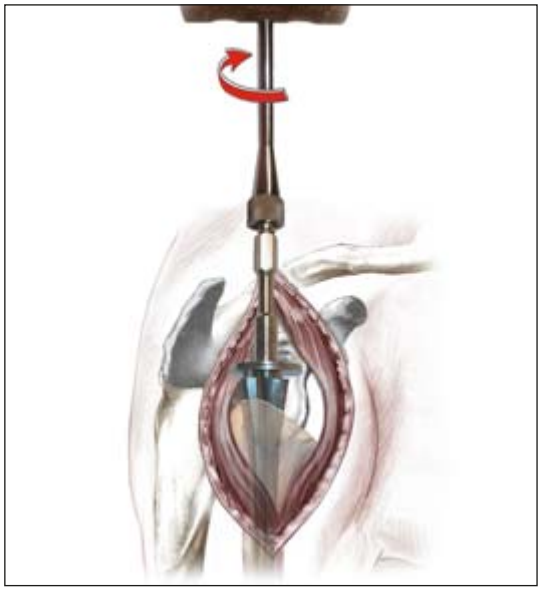


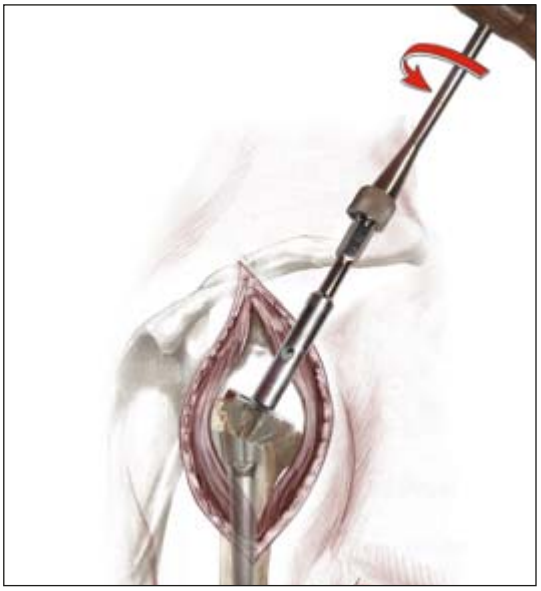
1. Superior lateral approach



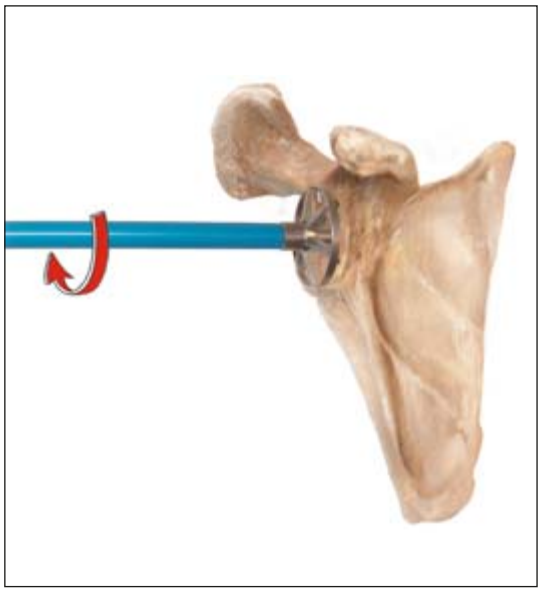
2. Humeral head resection



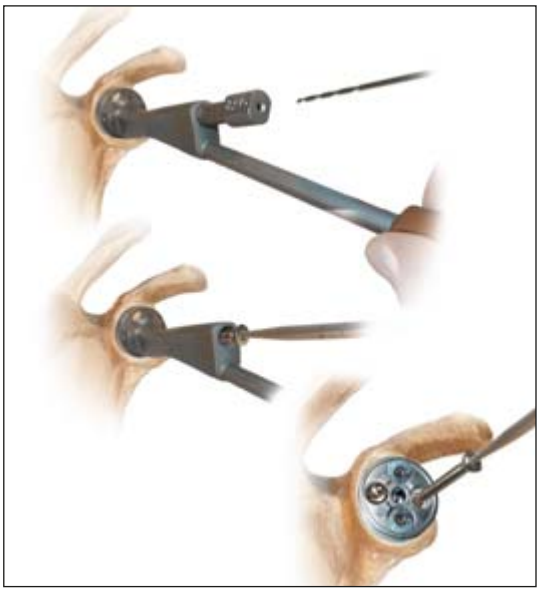
3. Diaphyseal preparation



4. Proximal reaming of the humerus



5. Glenoid preparation



6. Metaglene insertion

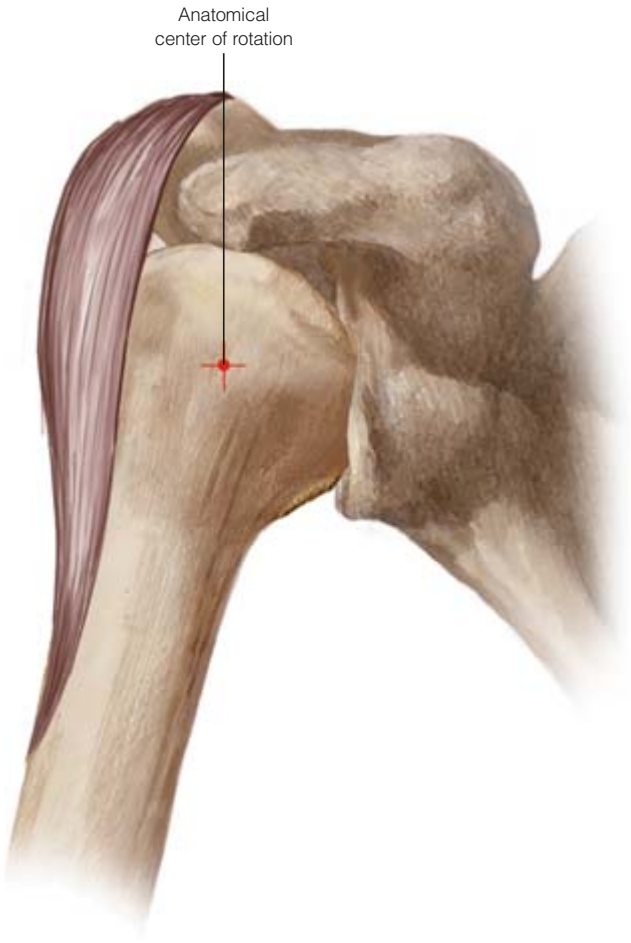


Figure 1

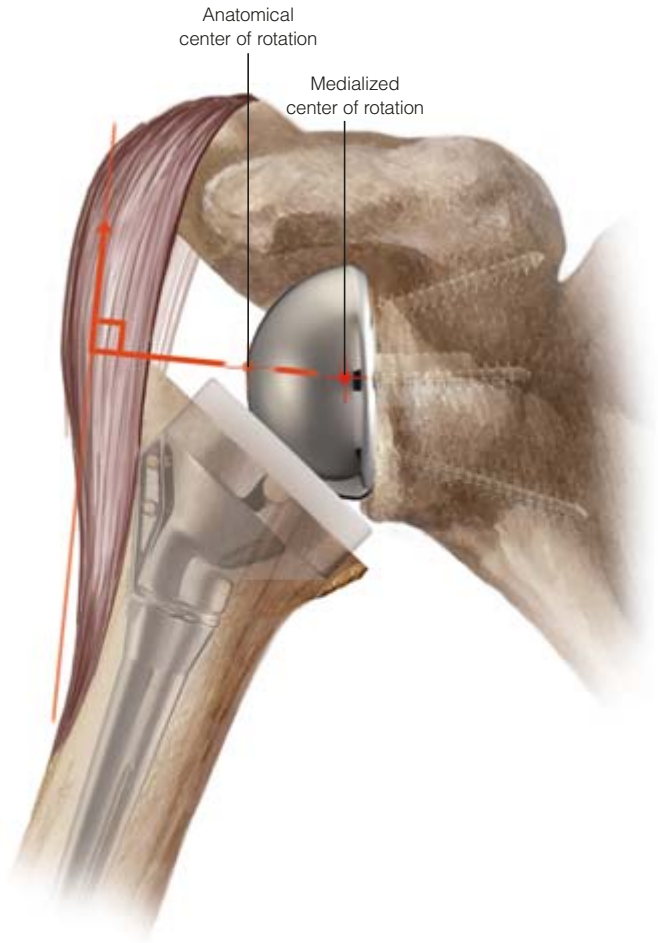


Figure 2

Introduction

The Delta CTA™ Reverse Shoulder System is indicated for the treatment of glenohumeral arthritis when it is associated with irreparable rotator cuff damage and where conventional total shoulder arthroplasty may not be fully effective in restoring joint stability with an adequate range of movement. The design avoids high shear forces associated with unstable conventional or hemiarthroplasty, that can cause the implant to wear and loosen.

The Delta CTA prosthetic geometry reverses the normal relationship between scapular and humeral components, moving the center of rotation medially and distally to increase the lever arm length of the deltoid muscle *(Figures 1 and 2)*.

This allows the three muscles in the deltoid group to compensate for rotator cuff deficiency, drawing the articulating surfaces together to stabilize the joint to allow as near normal function as possible.

Figure 3
Preoperative Planning

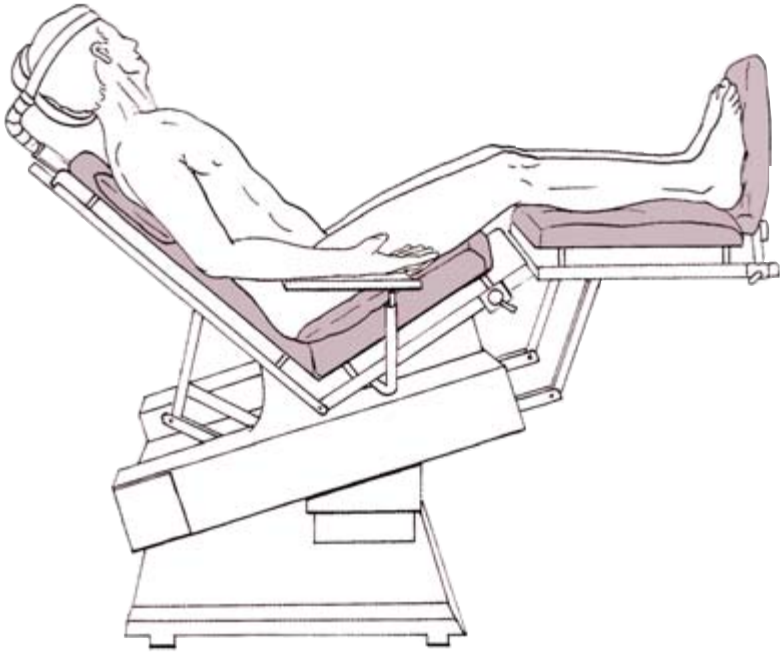


Figure 4
Patient Positioning

Preoperative Planning: Surgical Approach and Patient Positioning

Make an initial assessment of the bone in the superior and inferior aspects of the glenoid, using radiographic and CT imaging in order to determine the suitability of the patient for treatment. And, if appropriate, establish the location of the four metaglene screws for optimum implant stability.
Carry out preoperative planning using AP and lateral shoulder radiographs of known magnification and the template to confirm the size and alignment of the implant *(Figure 3)*.

The Delta CTA Reverse Shoulder System may be implanted using either a transacromial or transdeltoid approach. Preoperative planning should take into account the quality of the acromion.

If the acromion is small or has been weakened by previous acromioplasties, or in cases of severe osteoarthritis where there may be erosion on the inferior aspect, the transacromial approach will not be suitable.

A lateral deltoid splitting approach provides excellent visualization of the glenoid cavity during implantation.

Place the patient in the deck chair position, with the affected arm completely free and resting on a support *(Figure 4)*.

Superior Lateral Approach

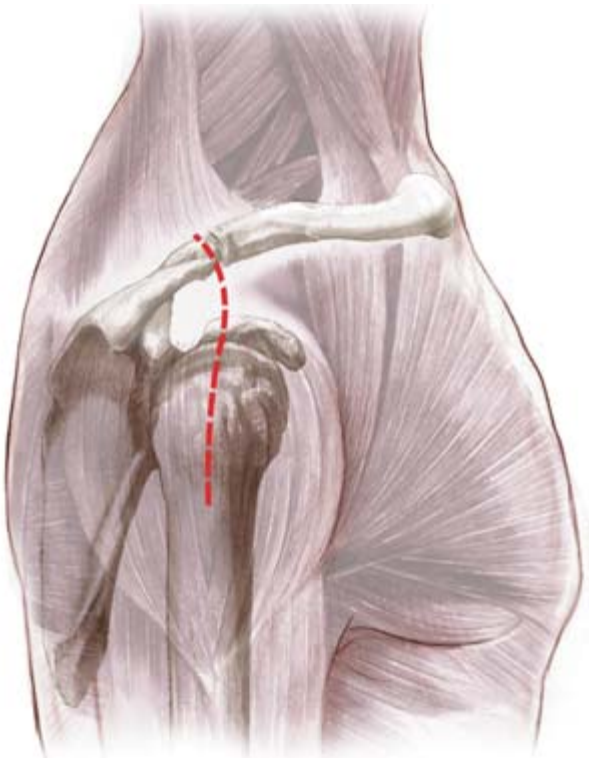


Figure 5
Superior Lateral Approach

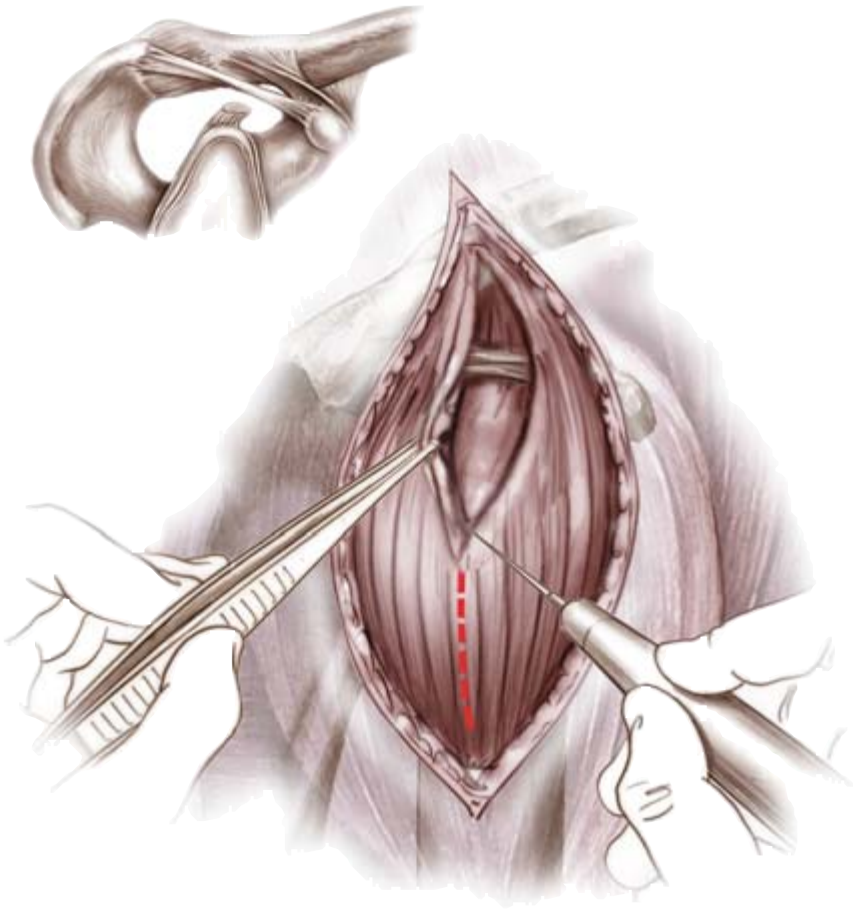


Figure 6
Superior Lateral Incision

The surgical approach – superior lateral *(Figure 5)* or delto-pectoral – depends mainly on surgeon preference and clinical parameters. Revision surgery, for instance, usually dictates a delto-pectoral approach as it allows for a longer humeral incision when faced with a difficult removal of the humeral stem. When used for classic rotator cuff repairs, the delto-pectoral approach allows clear visualization of the glenoid and therefore facilitates the implantation of the glenoid components of the prosthesis.

Superior Lateral Approach

Start the incision at the level of the acromioclavicular (AC) joint. Follow the anterior aspect of the acromion and finish vertically downwards for 4 cm *(Figure 6).* Following sub-cutaneous dissection, separate the anterior and middle deltoid muscle bundles opposite the lateral margin of the acromion, using blunt dissection. **The dissection should not extend beyond 4 cm from the external aspect of the acromion in order to preserve the axillary nerve.** When the subacromial bursa is visible, gentle longitudinal traction in line with the limb will allow a retractor to be placed in the subacromial space.

Release the anterior deltoid subperiosteally from its acromial insertion up to the AC joint. The humeral head is then visible at the anterior edge of the acromion. Remove the subacromial bursa. If necessary, exposure may be improved by dividing the AC ligament and performing acromioplasty. Then, externally rotate the limb and dislocate the head anterosuperiorly to facilitate positioning of the cutting guide. If the biceps is still present, tenodese in the bicipital groove. Retain the teres minor and infraspinatus when present.

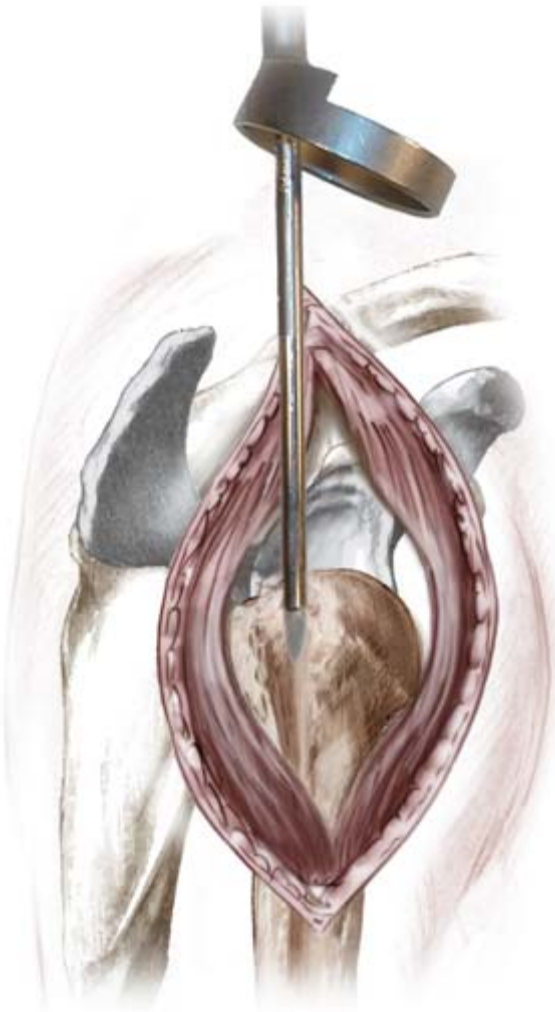


Figure 7
Awl Insertion

Figure 8a
Resection Guide Orientation

Figure 8b
Orientation

Humeral Head Resection

Make an initial entry hole in the proximal humerus using an awl. Center the awl tip over and in line with the long axis of the humerus, at the junction of the intratubercular groove and the articulating surface of the humeral head *(Figure 7).*

Pass the orientation pin through the hole in the resection guide corresponding to the desired retroversion *(Figure 8a).* Zero degrees of retroversion is preferred since excessive retroversion will restrict joint rotation, especially in external rotation. Retroversion is calculated with reference to the axis of the humeral epicondyles *(Figure 8b).*

Locate the tip of the cutting guide in the entry hole and pass the guide down the humeral canal until it rests on the humeral head. With the humeral resection guide rim located on the humeral head, align the orientation pin with the transcondylar axis *(Figures 8b and 9).*

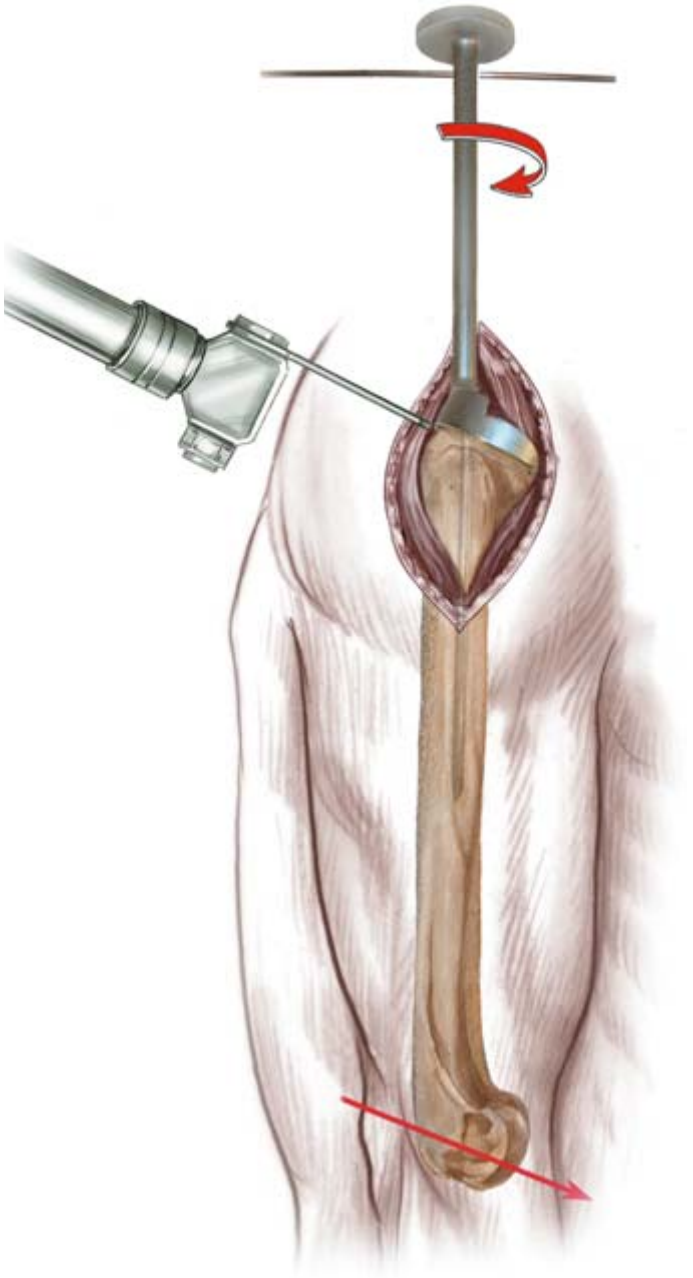


Figure 9
Head Resection

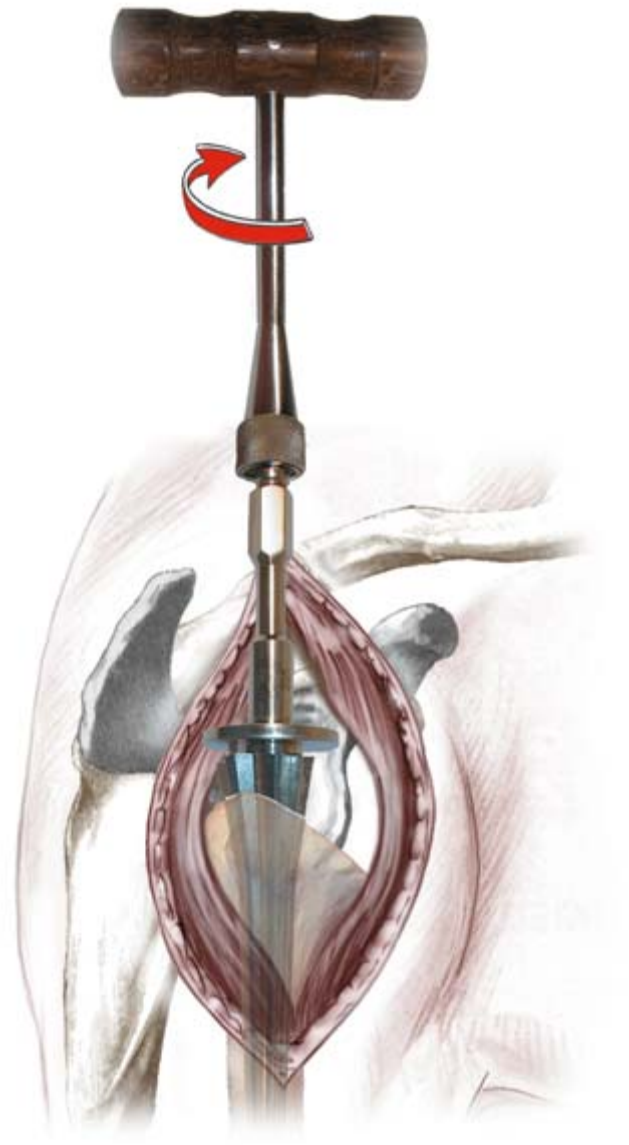


Figure 10
Humeral Reaming

Initiate humeral head resection in line with the inferior aspect of the humeral cutting guide. Remove the humeral cutting guide and complete the resection *(Figure 9).* The initial resection removes a minimal amount of bone. More bone may be removed if necessary.

Pass a forked retractor under the scapula to lower the humerus. If this provides clear visualization of the glenoid surface, the resection level is correct. If not, further resection may be carried out.

Humeral Reaming

Humeral Reaming

Starting with the smallest diameter distal reamer attached to the T-handle, ream the distal humeral canal in line with the long axis of the humerus *(Figure 10).* The final reamer should not exceed the templated proximal diameter (up to size 4). Stop reaming when the flange of the reamer is level with the lateral resection. **Power reaming should not be used to ream the humerus.**

Distal Humeral Reaming (Revision Surgery)

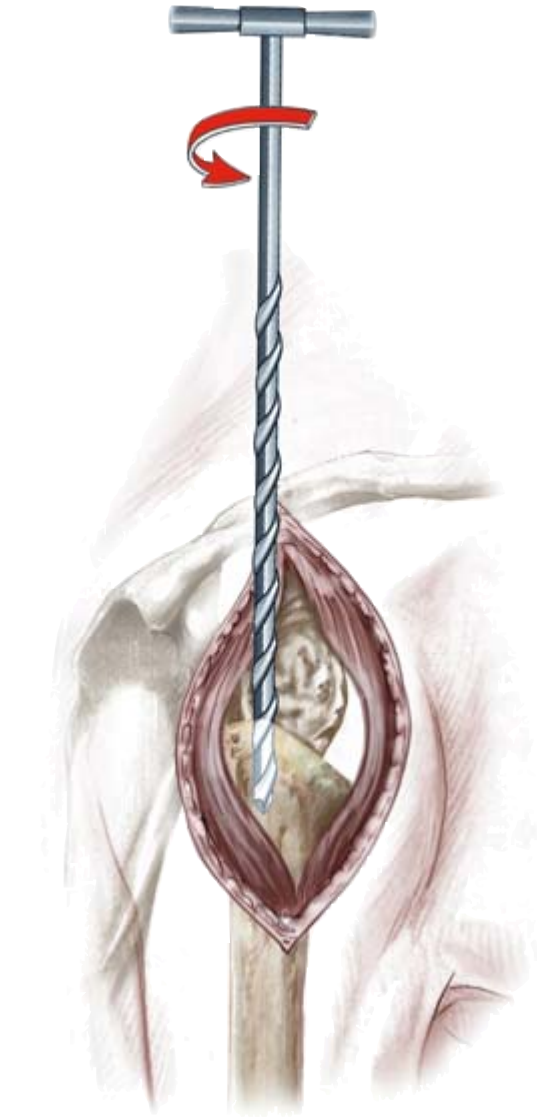


Figure 11
Reaming – Revision Surgery

Distal Humeral Reaming (Revision Surgery)

If a long stem is to be implanted, 150 mm and 180 mm diaphyseal revision reamers should be used in conjunction with the rigid reamers that are included within the Delta CTA revision instrumentation *(Figure 11).*

In addition to the reamers in the accompanying table, 5 mm and 6 mm diameter reamers are provided as start-up reamers.

Diaphyseal references	Reamer references
Size 1, length 150 mm (ref. DHC115B) Size 1, length 180 mm (ref. DHC118B)	7.5 mm diameter (ref. ALR 075)
Size 2, length 150 mm (ref. DHC215B) Size 2, length 180 mm (ref. DHC218B)	8 mm diameter (ref. ALR 008)
Size 3, length 150 mm (ref. DHR315B) Size 3, length 180 mm (ref. DHR318B)	9 mm diameter (ref. ALR 009)

Proximal Reamer Guide Assembly

Figure 12
Guide Assembly

Proximal Reamer Guide Assembly

Referring to the templated epiphysis size, screw the 36 mm or 42 mm proximal reaming guide to the trial diaphyseal stem that matches the distal reamer diameter. Mount the assembly on the humeral stem impactor and introduce in line with the long axis of the humerus *(Figure 12).*

Figure 13
Determining Depth

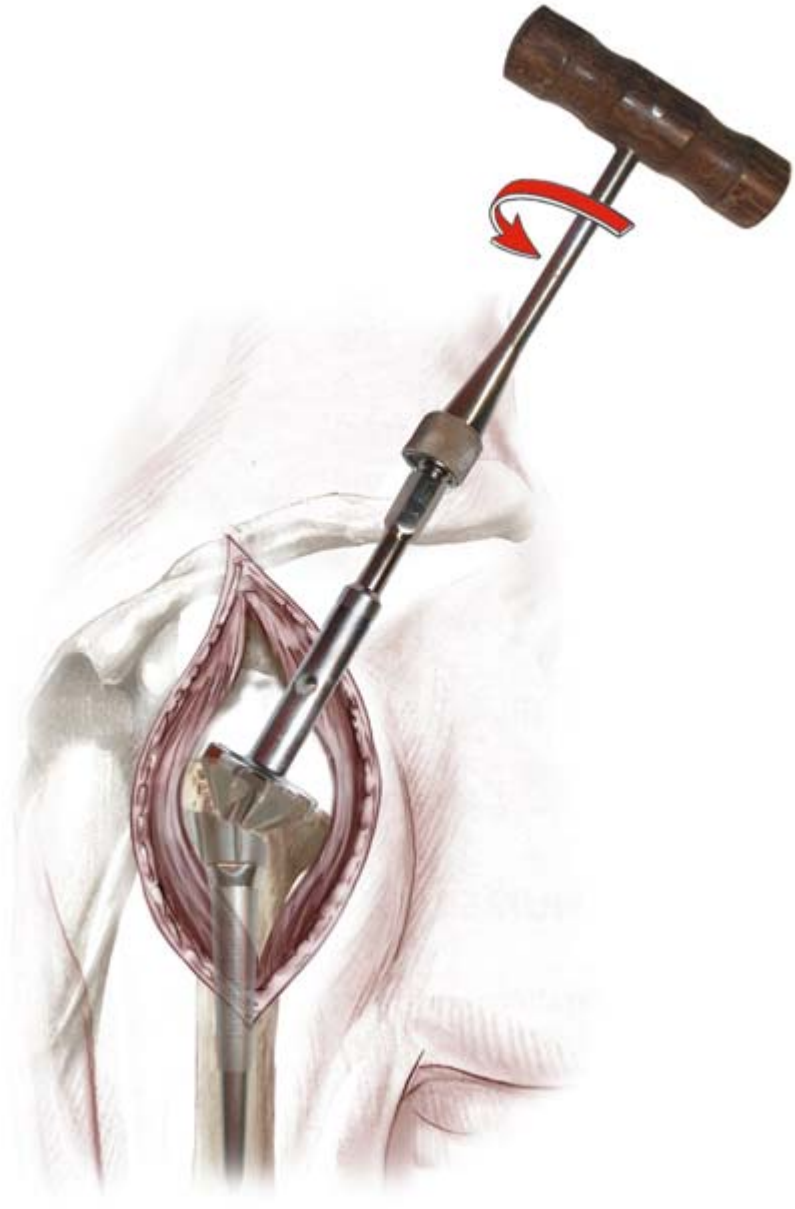


Figure 14
Proximal Reaming

Proximal Humeral Reaming

Pass the orientation pin through the hole in the impactor handle and check the previously selected version angle. Impact the assembly into the humeral canal until the appropriate mark (36 mm or 42 mm) on the impactor reaches the level of the resection *(Figure 13)*.

Check retroversion again and remove the impactor, leaving the reaming guide in place. Mount the appropriate size proximal humeral reamer, (36.1, 36.2 or 42.2) on the T-handle. The 36 size 1 reamer removes more bone than the 36 size 2 reamer, as shown in the Delta templates. Ream the humerus until the flange of the reamer is level with the osteotomy, and contact is made with cortical bone *(Figure 14)*.

If necessary, insert the reaming guide more deeply to ensure that the proximal reamer reaches the level of osteotomy. Reaming is now complete. Extract the reamer, reamer guide and trial stem from the humerus.

Trial Humeral Implantation

Figure 15
Implant Trial Assembly

Trial Humeral Implantation

Attach the trial epiphyseal component to the trial diaphyseal stem, and mount the assembly onto the humeral stem impactor *(Figure 15).* It may be necessary to remove a wedge of cortical bone to accommodate the lateral fin on the epiphyseal component. Impact the assembly into the humeral canal, ensuring the diaphyseal fin does not impinge upon the lateral cortex of the humerus. Remove the humeral stem impactor.

Glenoid Exposure

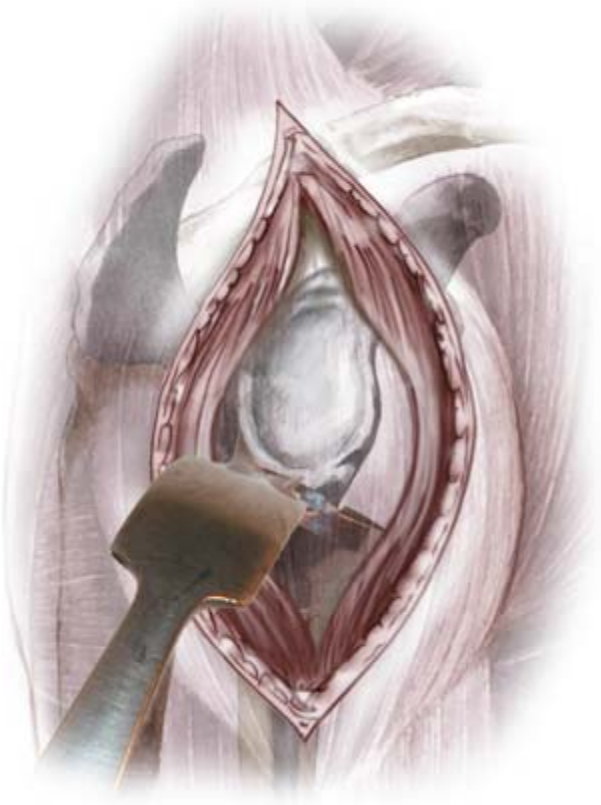


Figure 16
Glenoid Exposure

Glenoid Exposure

Position an anterior glenoid neck retractor (Cat. Nos. 2810-16-000 and 2810-17-000) on the axillary margin of the scapula, under the inferior glenoid labrum, to reflect the humerus down or backward, depending on the approach taken. Excise the labrum and perform an extensive periglenoid capsulotomy. Any peripheral osteophytes should be removed to restore the natural anatomic shape of the glenoid *(Figure 16).*

Glenoid Preparation

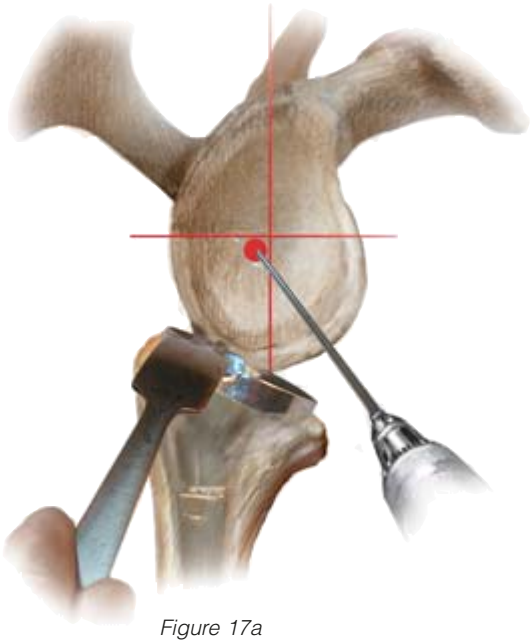
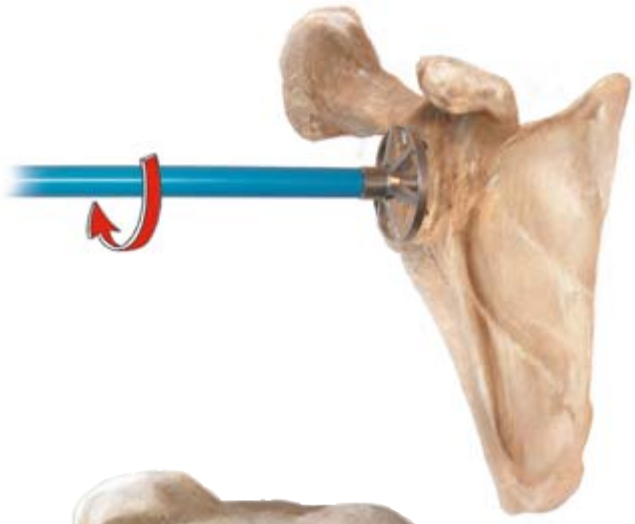


Figure 17a
Guide Pin Placement



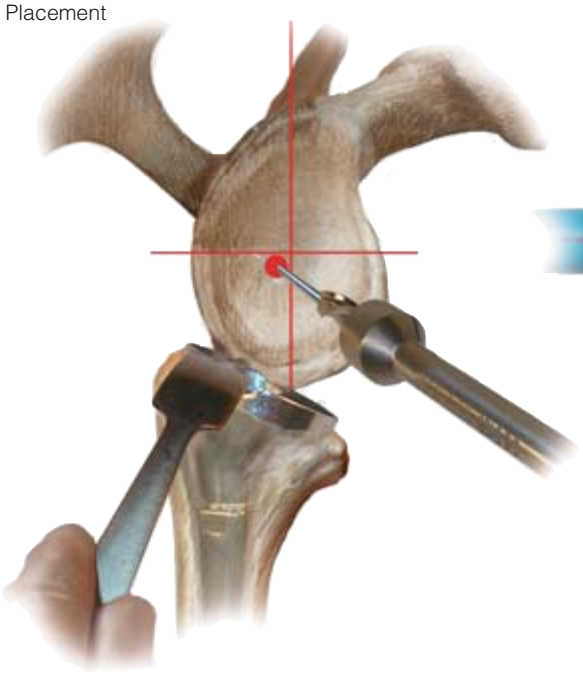


Figure 17b
Glenoid Centering Hole

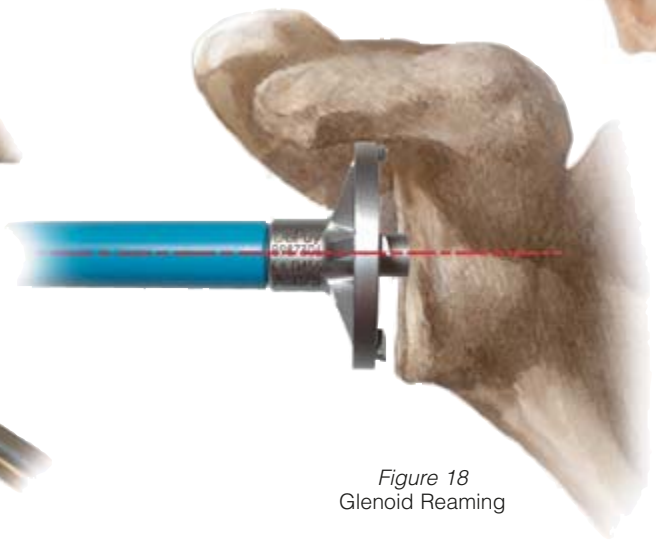


Figure 18
Glenoid Reaming

Glenoid Preparation

Mark the major and minor axes of the glenoid using diathermy. Attach the 1.5 mm guide pin to the power tool and create an entry point just posterior and inferior to the intersection of the axes *(Figure 17a).* The location for this entry point may be checked using CT imaging.
It should be as inferior as possible, while ensuring that sufficient space is available to place the entire length of the inferior screw in cancellous bone.

Attach the cannulated stop drill to the power source and complete the glenoid centering hole over the guide pin *(Figure 17b).* Attach the glenoid reamer to the power source and introduce the reamer pilot shaft into the glenoid centering hole. In cases of osteoporotic bone, hand reaming should be used. **Ensure that the reamer is not in contact with bone before applying power since this may damage the glenoid.**

Ream the glenoid until a smooth platform, devoid of cartilage, is created for the metaglene, with sufficient depth to accommodate its peripheral rim *(Figure 18).* Check the depth before implantation of the prosthesis. If sufficient peripheral depth is not achieved, the glenosphere will not fully engage with the taper on the metaglene, and further reaming should be carried out until the tray is fully seated.

Metaglene Insertion

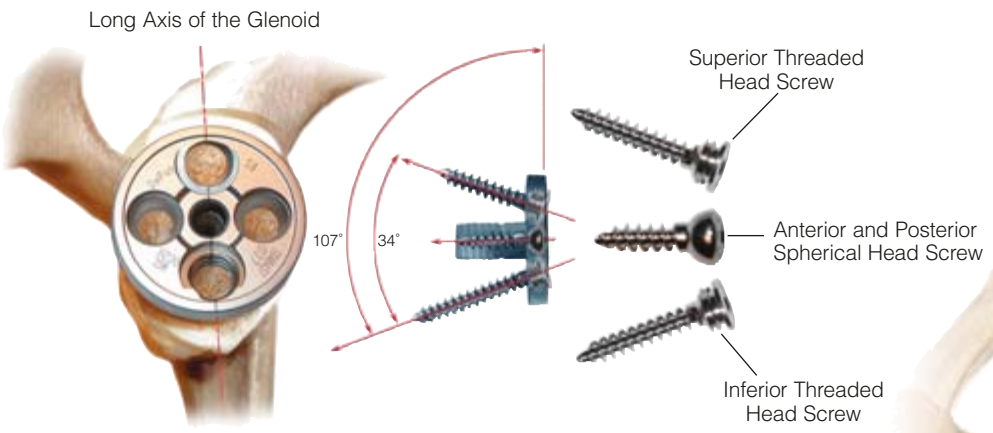


Figure 19

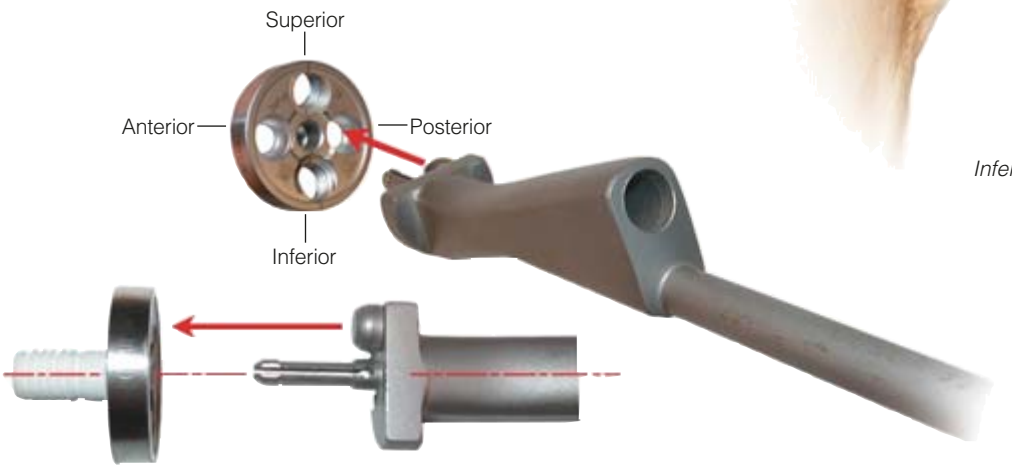


Figure 20
Drill Guide Orientation

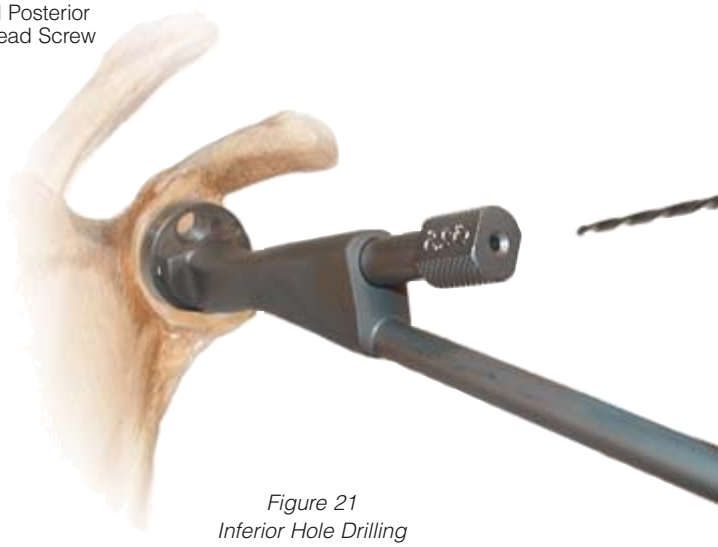


Figure 21
Inferior Hole Drilling

Metaglene Insertion

The metaglene is available in one size for both 36 mm and 42 mm glenospheres and is implanted without cement. Initial, primary mechanical stability is provided by the 4.5 mm diameter screws. When correctly positioned, the angled, threaded screw holes in the metaglene should be aligned superiorly and inferiorly on the glenoid *(Figure 19).* After determining there is sufficient bone to support the metaglene and provide screw fixation, attach the definitive metaglene to the holder, with the drill guide covering the inferior threaded screw hole on the implant. Insert the assembly into the prepared glenoid with the superior and inferior holes aligned with the long axis of the glenoid.

Caution: It is imperative to use the metaglene holder to insert the inferior and superior screws. The 80-degree angle between these two screws is fixed and cannot be altered.

Once the metaglene has been manually aligned, tap the holder firmly so that the tray is impacted flat onto the prepared surface of the glenoid. **It is important to ensure that the metaglene is fully seated, flat on the prepared glenoid, before it is screwed into position.**

Then, insert a drill bush 2 or 2.5 mm in diameter, depending on the quality of bone, into the drill guide. Select the corresponding drill, pass through the bush, and drill the inferior fixation hole *(Figure 21).*

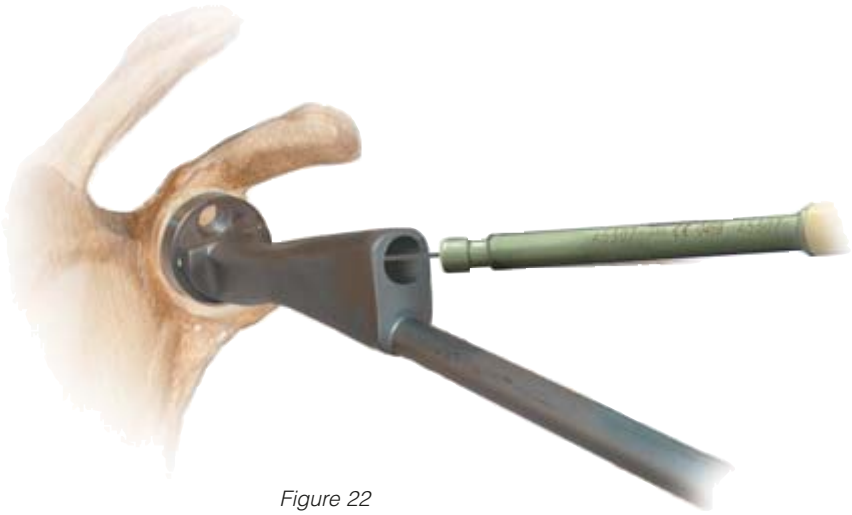


Figure 22
Depth Measurement

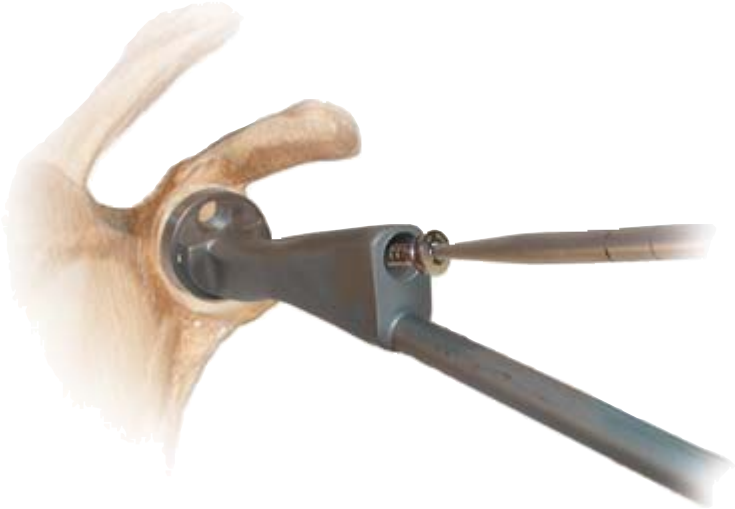


Figure 23
Screw Placement

Figure 24
Superior Hole Drilling

Remove the drill bush and check the depth of the screw hole by using the depth gauge provided *(Figure 22).* Threaded head screws must be used for the inferior and superior holes. The spherical head screws are designed for use only with anterior and posterior holes.

A threaded head screw of corresponding length to the measured depth is passed through the drill guide and screwed into the inferior fixation hole. **The screw should be fully tightened at this stage *(Figure 23).***

Gently detach the metaglene holder from the bearing tray and turn 180 degrees to prepare the superior fixation hole in the same way as the inferior hole.

Measure its depth and screw the appropriate threaded head screw into position *(Figure 24),* again ensure it is fully tightened.

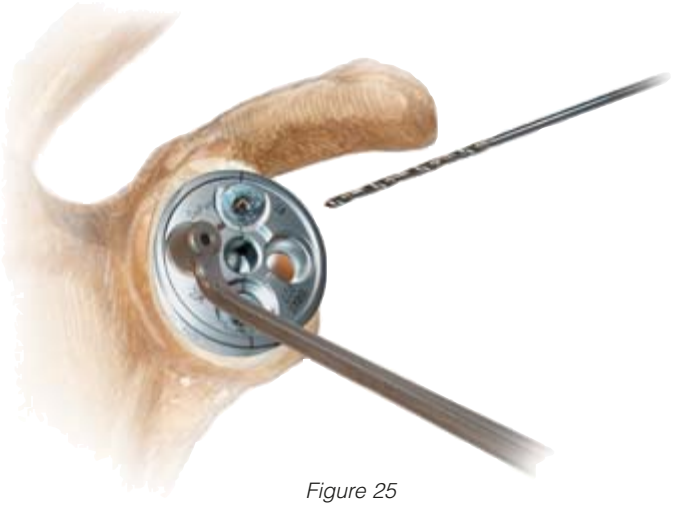


Figure 25
Anterior Hole Drilling

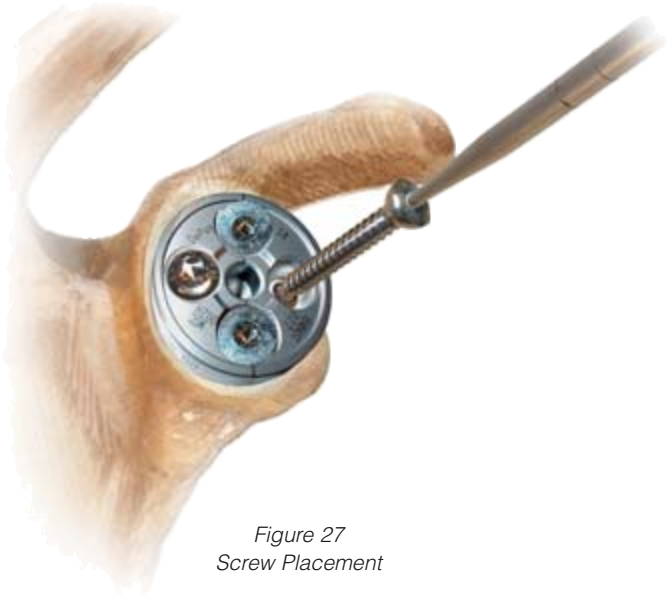


Figure 27
Screw Placement

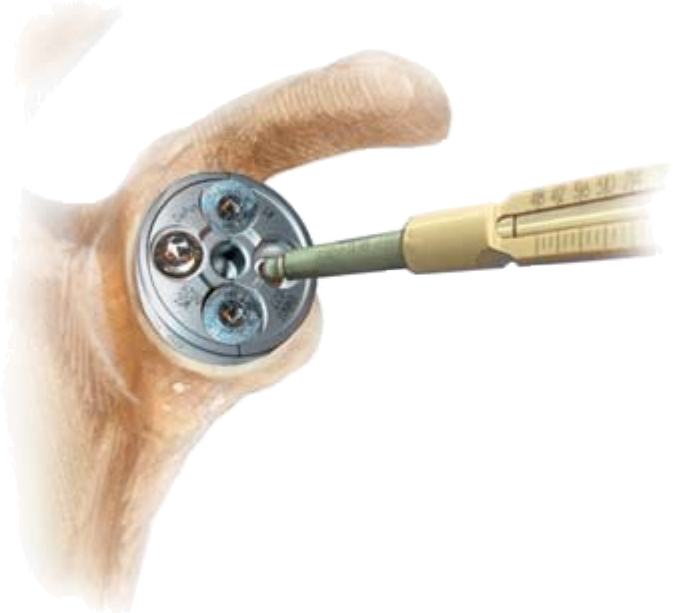


Figure 26
Depth Measurement

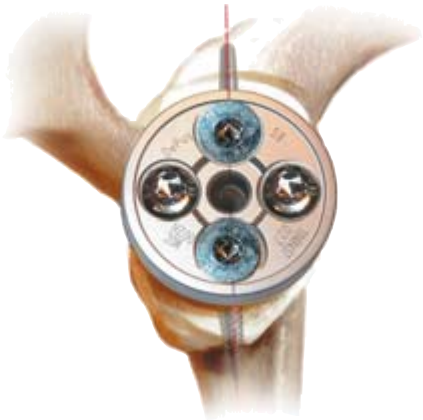


Figure 28
Final Screw Tightening

Remove the metaglene holder and locate the free hand drill guide of appropriate size, 2.0 or 2.5 mm, in the anterior fixation hole. Both anterior and posterior screw positions allow angulation of ± 20 degrees. Use the drill guide to set the most appropriate angle to ensure that each screw is located in reliable bone stock *(Figure 25).*

Preferential position is usually chosen by palpating the anterior and posterior aspects of the scapula as well as examining the X-rays and CT scans.

Drill the anterior hole, remove the drill guide and measure the hole depth using the depth gauge *(Figure 26).*

Introduce a spherical head screw and partially tighten *(Figure 27).* Follow the same procedure for the posterior screw. Alternately tighten both screws until fully tightened *(Figure 28).*

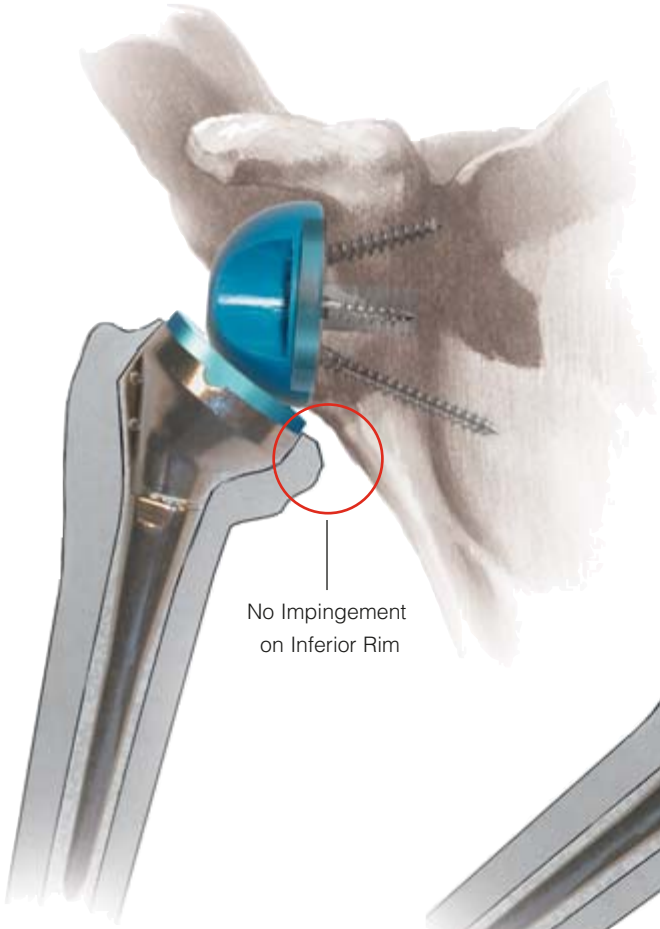


Figure 29

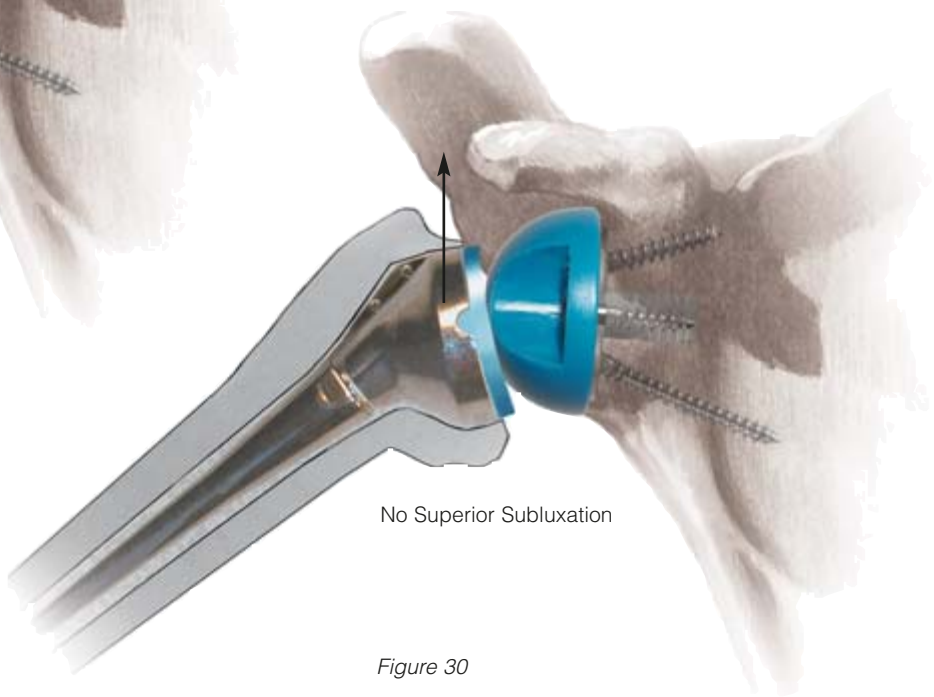


Figure 30

Trial Reduction

Attach the appropriate trial glenosphere (36 mm or 42 mm) to the metaglene. Insert the corresponding lateralized humeral cup trial into the humeral trial assembly. Reduce the shoulder and assess for a full range of movement. If soft tissue tension is correct, the glenoid bearing will not impinge on the inferior rim of the resected humeral head *(Figure 29).* When the arm is pulled down and outward, approximately 5 mm of humeral-glenoid component separation may be expected.

The joint should remain stable when the arm is abducted, with no indication of superior subluxation *(Figure 30).* Additional joint stability may be achieved by introducing a retentive, more constrained cup. If further soft tissue tension is required, a +9 mm humeral spacer may be attached to the trial epiphyseal component, using the hexagonal head screwdriver.

A retentive cup should only be used in revision cases or to correct extreme instability. If the humeral cut is adequate, a lateralized cup will be sufficient in the majority of cases.

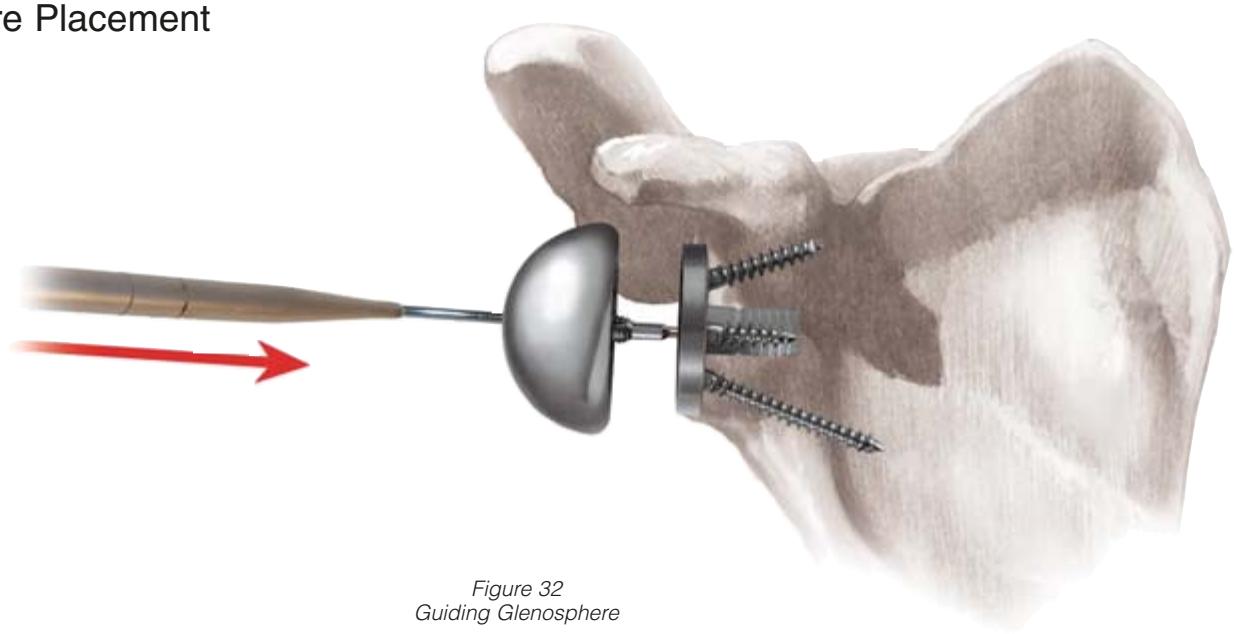


Figure 32
Guiding Glenosphere

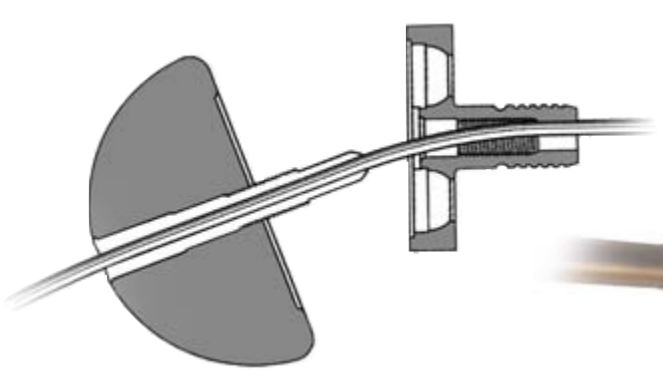


Figure 31
Inserting Guide Pin

Glenosphere Placement

Insert a 1.5 mm guide pin through the central hole of the metaglene *(Figures 31 and 32).* Engage the 3.5 mm cannulated screwdriver in the definitive glenosphere and guide over the 1.5 mm guide pin.

After two or three turns, disengage the cannulated screwdriver and check the glenoid bearing to ensure proper alignment. Then re-engage the cannulated screwdriver and tighten the captive screw until the glenoid bearing closes on the taper of the bearing tray. Ensure that the glenoid bearing is fully locked onto the bearing tray *(Figure 33).*

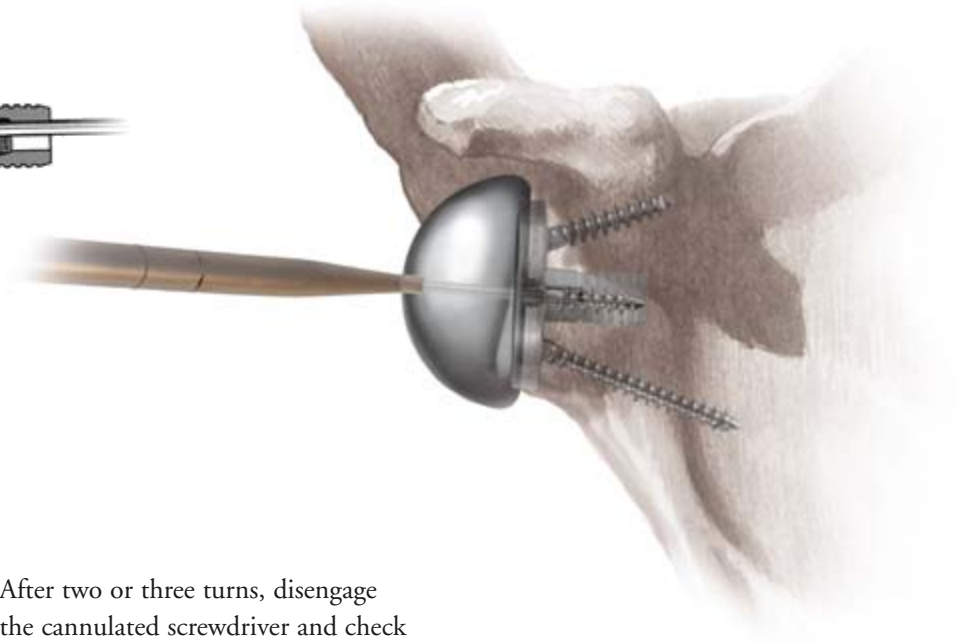


Figure 33
Engaging Glenosphere

Humeral Implant Insertion

Figure 34
Attaching Epiphyseal Component

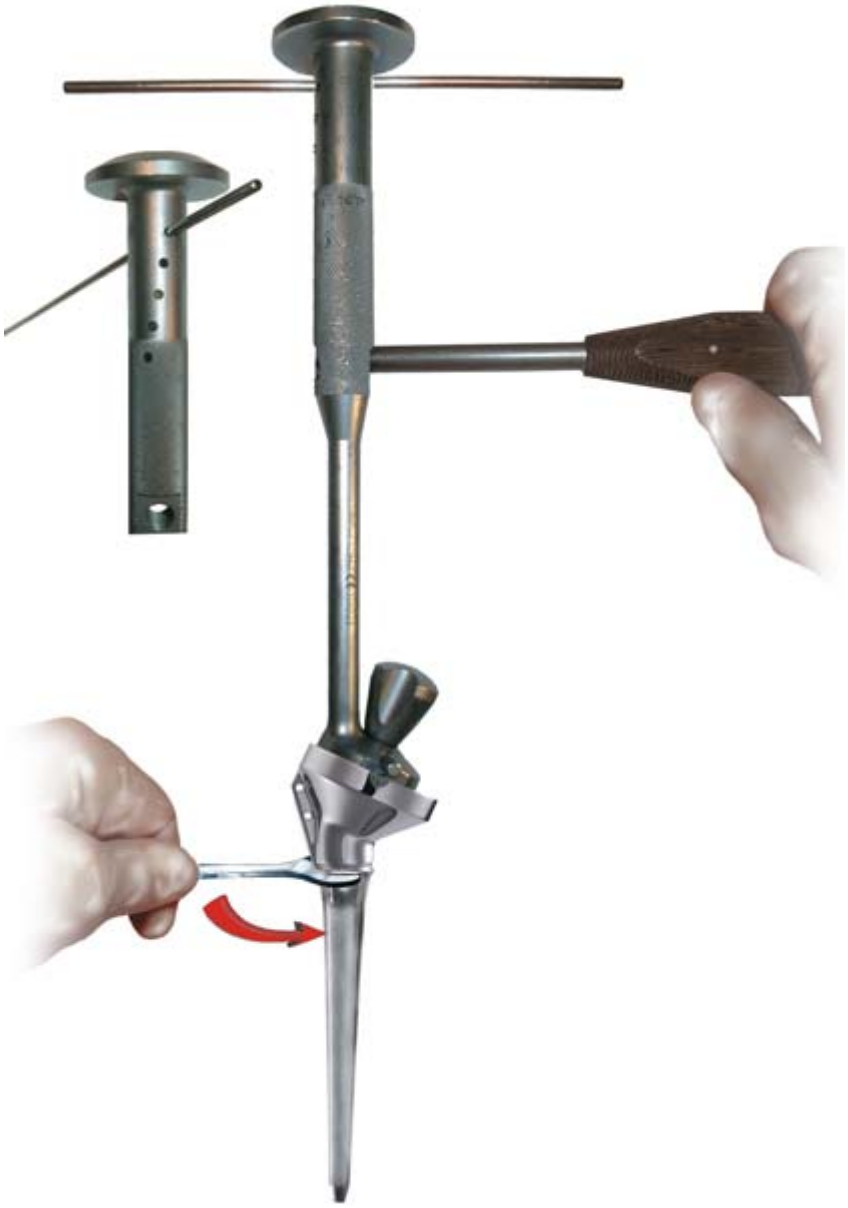


Figure 35
Attaching Diaphyseal Component

Humeral Implant Insertion

Extract the trial humeral assembly from the humerus. Attach the corresponding definitive humeral epiphyseal component to the impactor *(Figure 34).* Screw the definitive diaphyseal component to the epiphyseal component. Lock the two components using the wrench and driver *(Figure 35).*

If it was determined during trial reduction that a humeral spacer is needed, attach the humeral spacer to the epiphyseal component using the hex driver and wrench.

Introduce a cement restrictor, such as BIOSTOP® G or a bone plug, into the distal humeral canal to restrict the passage of cement. Introduce cement, such as SmartSet® HV or DePuy 1 (high viscosity bone cements) or Endurance® (medium viscosity bone cement), into the humeral canal and, when the cement is at its appropriate viscosity, introduce the implant assembly in line with the long axis of the humerus and in the chosen version angle. Maintain pressure on the introducer until the cement is fully polymerized.

Humeral Implant Insertion

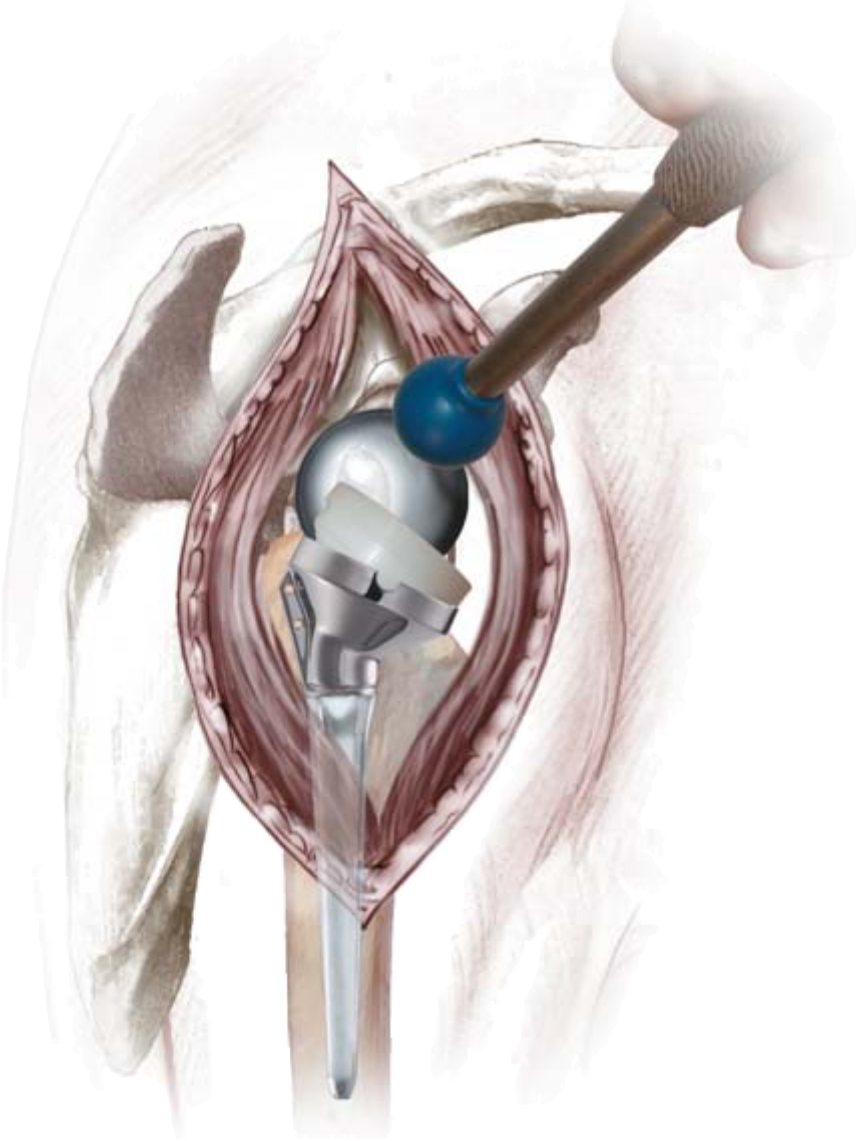


Figure 36
Impacting Humeral Cup

Using the cup impactor, impact the definitive humeral cup. Ensure it is fully seated and secure into the snap fit *(Figure 36).* Reduce the joint and make a final assessment of joint stability and range of motion.

Closure

Once the joint space is irrigated and cleared of debris, firmly suture the anterior deltoid at the fibrous acromial perimeter or use transosseous stitches. A drain may be left in place. Layered closure of the soft tissues normally leads to an adequate range of motion, without instability.

Postoperative Management

Appropriate postoperative physiotherapy is an important factor in the outcome of this procedure, since stability and mobility now depend on the deltoid alone. The physiotherapy program, which should be planned to suit the individual patient, consists of two phases: early (6 weeks) and late. Two days after the operation the patient can be mobile. This early phase is dedicated to gentle and gradual recovery of the passive range of shoulder motion: abduction of the scapula, anterior elevation and medial and lateral rotation. An abduction cushion may be used to relieve pressure on the deltoid.

Physiotherapy is mainly performed with the patient supine, passive and with both hands holding a bar that is manipulated by the contralateral hand, as described by Neer.

The patient is encouraged to use the affected arm to eat and write but should not raise the arm. In conjunction with these exercises for scapulohumeral recovery, it is important to strengthen muscle connection with the scapula in order to facilitate muscle and implant function. Passive exercise in the swimming pool is recommended as soon as scars begin to form.
After the sixth or seventh week, active strengthening movements may be gradually added to the program. These exercises, which closely follow everyday activities, are performed in a sitting or standing position, using conventional methods, with isometric exercises and resistance movements becoming increasingly important.

A series of exercises for rhythmic stabilization of the upper arm as well as eccentric working on lowering the arms complete the strengthening of the muscles. Physiotherapy should be performed over a period of at least six months.

Ordering Information

Implant Cat. No.	Description
EHC361B	Cemented Humeral Epiphysis, 36.1 mm
EHC362B	Cemented Humeral Epiphysis, 36.2 mm
EHC422B	Cemented Humeral Epiphysis, 42.2 mm
DHC010B	Cemented Humeral Diaphysis, Size 0
DHC110B	Cemented Humeral Diaphysis, Size 1
DHC210B	Cemented Humeral Diaphysis, Size 2
DHC310B	Cemented Humeral Diaphysis, Size 3
DHC410B	Cemented Humeral Diaphysis, Size 4
4CHS036R	Retentive Humeral Cup, 36 mm
4CHL636	Lateralized Humeral Cup, 36 mm + 6
4CHL636R	Lateralized Retention Humeral Cup, 36 mm + 6
4CHS042R	Retentive Humeral Cup, 42 mm
4CHL642	Lateralized Humeral Cup, 42 mm + 6
4CHL642R	Lateralized Retention Humeral Cup, 42 mm + 6
RTH236	Humeral Spacer, 36 mm + 9
RTH242	Humeral Spacer, 42 mm + 9
MGC002H	Standard Metaglene
GSC236	Glenosphere 36 mm
GSC242	Glenosphere 42 mm
VFM4524	Metaglene Screws, Dia. 4.5 x 24 mm (Threaded Head)
VFM4530	Metaglene Screws, Dia. 4.5 x 30 mm (Threaded Head)
VFM4536	Metaglene Screws, Dia. 4.5 x 36 mm (Threaded Head)
VFM4542	Metaglene Screws, Dia. 4.5 x 42 mm (Threaded Head)
VFM4548	Metaglene Screws, Dia. 4.5 x 48 mm (Threaded Head)
VSM4518	Metaglene Screws, Dia. 4.5 x 18 mm (Spherical Head)
VSM4524	Metaglene Screws, Dia. 4.5 x 24 mm (Spherical Head)
VSM4530	Metaglene Screws, Dia. 4.5 x 30 mm (Spherical Head)
VSM4536	Metaglene Screws, Dia. 4.5 x 36 mm (Spherical Head)
VSM4542	Metaglene Screws, Dia. 4.5 x 42 mm (Spherical Head)

Humeral Preparation Instruments

Cat. No.	Description
GSH002	Humeral Resection Guide
ARR001	Orientation Pin
FPH361	Proximal Humeral Reamer, 36.1
FPH362	Proximal Humeral Reamer, 36.2
FPH422	Proximal Humeral Reamer, 42.2
FDH036N	Distal Humeral Reamer, Size 0, Dia. 36
FDH136	Distal Humeral Reamer, Size 1, Dia. 36
FDH236	Distal Humeral Reamer, Size 2, Dia. 36
FDH336	Distal Humeral Reamer, Size 3, Dia. 36
FDH436	Distal Humeral Reamer, Size 4, Dia. 36
FDH142	Distal Humeral Reamer, Size 1, Dia. 42
FDH242	Distal Humeral Reamer, Size 2, Dia. 42
FDH342	Distal Humeral Reamer, Size 3, Dia. 42
FDH442	Distal Humeral Reamer, Size 4, Dia. 42
ITH003	Humeral Stem Impactor
EHF001	Forked Retractor
EHF002	U-forked Retractor
GFP136	Proximal Reamer Guide, Dia. 36
GFP142	Proximal Reamer Guide, Dia. 42
IGF004	Reamer Guide Impactor/Extractor
CLE014	Diaphyseal Stem Locking Wrench
DHF010N	Humeral Diaphysis Trial, Size 0
DHF110	Humeral Diaphysis Trial, Size 1
DHF210	Humeral Diaphysis Trial, Size 2
DHF310	Humeral Diaphysis Trial, Size 3
DHF410	Humeral Diaphysis Trial, Size 4
EHF361	Humeral Epiphysis Trial, 36.1
EHF362	Humeral Epiphysis Trial, 36.2
EHF422	Humeral Epiphysis Trial, 42.2
REH236	Humeral Spacer Trial, Dia. 36
REH242	Humeral Spacer Trial, Dia. 42
A5265	Standard Humeral Retention Cup Trial, Dia. 36
A5264	Lateralized Humeral Cup Trial, Dia. 36
A5263	Lateralized Humeral Retention Cup Trial, Dia. 36
A5262	Standard Humeral Retention Cup Trial, Dia. 42
A5261	Lateralized Humeral Cup Trial, Dia. 42
A5260	Lateralized Humeral Retention Cup Trial, Dia. 42



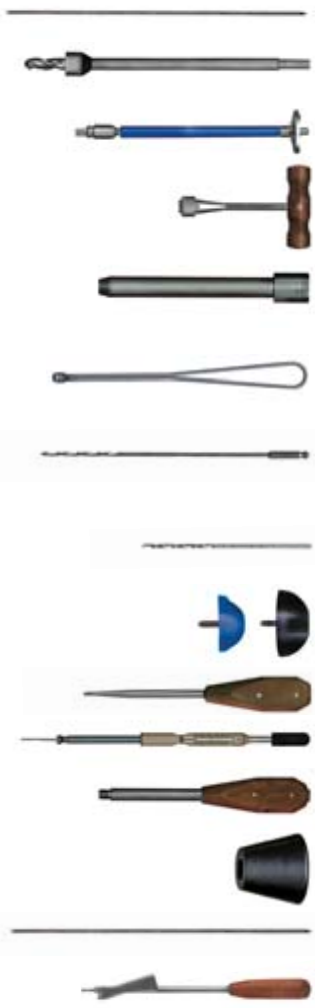






Glenoid Preparation Instruments

Cat. No.	Description
A5266	Guide Pin
A5267	Cannulated Stop Drill
A5075	Glenoid Surfacing Rasp, Dia. 36
A5076	Glenoid Surfacing Rasp, Dia. 42
PAM001	T-handle
A5271	Drill Bush, Dia. 2.0
A5272	Drill Bush, Dia. 2.5
GPM020	Drill Guide, Dia. 2.0
GPM025	Drill Guide, Dia. 2.5
A5326	S/I Drill Bit, Dia. 2.0 (170 mm Length)
A5327	S/I Drill Bit, Dia. 2.5 (170 mm Length)
MPG020	A/P Drill Bit, Dia. 2.0 (100 mm Length)
MPG025	A/P Drill Bit, Dia. 2.5 (100 mm Length)
A5273	Glenosphere Trial, Dia. 36
A5274	Glenosphere Trial, Dia. 42
9E03011	3.5 mm Hex. Head Screwdriver, Cannulated
A5307	Screw Depth Gauge
PRT001	Standard Impactor Holder
EPT001	Humeral Head Impactor
EPC032	Humeral Cup Impactor
A5074	1.5 mm Guide Wire
A5268	Metaglene Holder



Trays

Cat. No.	Description
A5807	Glenoid Tray Base
A5806	Glenoid Tray Insert
A5812	Glenoid Tray Lid
A5815	Glenoid Tray Screw Rack
A5809	Humeral Tray 1 Base
A5808	Humeral Tray 1 Insert
A5813	Humeral Tray 1 Lid
A5811	Humeral Tray 2 Base
A5810	Humeral Tray 2 Insert
A5814	Humeral Tray 2 Lid

Implant

Cat. No.	Description
DHC115B	Revision Cemented Humeral Diaphysis (150 mm), Size 1
DHC215B	Revision Cemented Humeral Diaphysis (150 mm), Size 2
DHC315B	Revision Cemented Humeral Diaphysis (150 mm), Size 3
DHC118B	Revision Cemented Humeral Diaphysis (180 mm), Size 1
DHC218B	Revision Cemented Humeral Diaphysis (180 mm), Size 2
DHC318B	Revision Cemented Humeral Diaphysis (180 mm), Size 3

Delta Revision

Instruments

Cat. No.	Description
ETH001	Standard Humeral Prosthesis Extractor
MDE001	Extraction Rod
MAI001	Slap Hammer
ITH003	Delta Stem Extractor
TEP035	3.5 mm Hex. Head Screwdriver
TEP025	2.5 mm Hex. Head Screwdriver
ALR005	Diaphyseal Reamer, Dia. 5 mm
ALR006	Diaphyseal Reamer, Dia. 6 mm
ALR075	Diaphyseal Reamer, Dia. 7.5 mm
ALR008	Diaphyseal Reamer, Dia. 8 mm
ALR009	Diaphyseal Reamer, Dia. 9 mm
DHF115	150 mm Long Humeral Diaphysis Trial, Size 1
DHF215	150 mm Long Humeral Diaphysis Trial, Size 2
DHF315	150 mm Long Humeral Diaphysis Trial, Size 3
DHF118	180 mm Long Humeral Diaphysis Trial, Size 1
DHF218	180 mm Long Humeral Diaphysis Trial, Size 2
DHF318	180 mm Long Humeral Diaphysis Trial, Size 3
A5288	Metaglene Extractor

Trays

Cat. No.	Description
A5280	Tray Base
A5281	Tray Insert
A5279	Lid
A5287	Label for Revision Tray Sterilization Container
A5194	Sterilization Container 550 x 265 x 167 mm
A5066	Bottom Plate 550 x 265 x 167 mm
A5054	Lid for Container 550 x 265 mm

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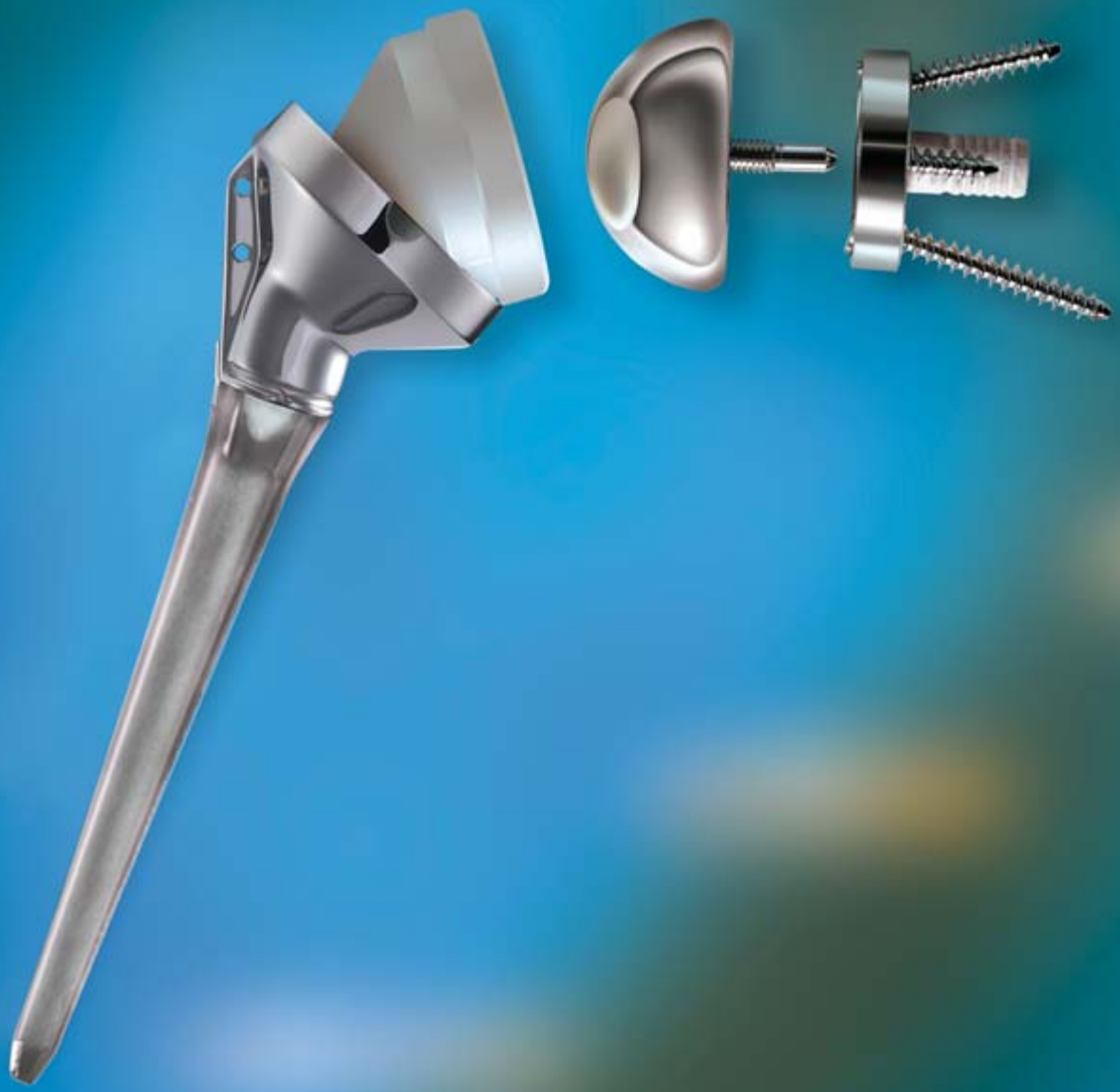

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IMPORTANT

This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS

Delta shoulder replacement is indicated for use in grossly rotator cuff deficient joints with severe arthropathy, or for use when a previous joint replacement has failed with a grossly rotator cuff deficient joint. A functional Deltoid muscle is needed for use of this device. Also, the patient's joint must be anatomically and structurally suited to receive the device.

The metaglene component is for cementless use only. All other components are intended for cemented use only.

CONTRAINDICATIONS

The following are contraindications for shoulder arthroplasty:
1. Active local or systemic infection;
2. Poor bone quality and/or inadequate bone stock to appropriately support the prosthesis;
3. Severe deformity;
4. Muscle, nerve or vascular disease;
5. Obesity, drug abuse, over activity or mental incapacity.

WARNINGS AND PRECAUTIONS

The following conditions tend to adversely affect the fixation of the shoulder replacement implants:
1. Marked osteoporosis or poor bone stock;
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.);
3. History of general or local infections;
4. Severe deformities leading to impaired fixation or improper positioning of the implant;
5. Tumors of the supporting bone structures;
6. Allergic reactions to implant materials (e.g. bone cement, metal, polyethylene);
7. Tissue reactions to implant corrosion or implant wear debris;
8. Disabilities of other joints.

ADVERSE EVENTS

The following are the most frequent adverse events encountered after total or hemi-shoulder arthroplasty:
1. Change in position of the prosthesis, often related to factors listed in WARNINGS AND PRECAUTIONS.
2. Early or late infection;
3. Early or late loosening of the prosthetic component(s), often related to factors listed in WARNING AND PRECAUTIONS;
4. Temporary inferior subluxation. Condition generally disappears as muscle tone is regained;
5. Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction;
6. Hematoma and/or delayed wound healing;
7. Pneumonia and/or atelectasis;
8. Subluxation or dislocation of the replaced joint.

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