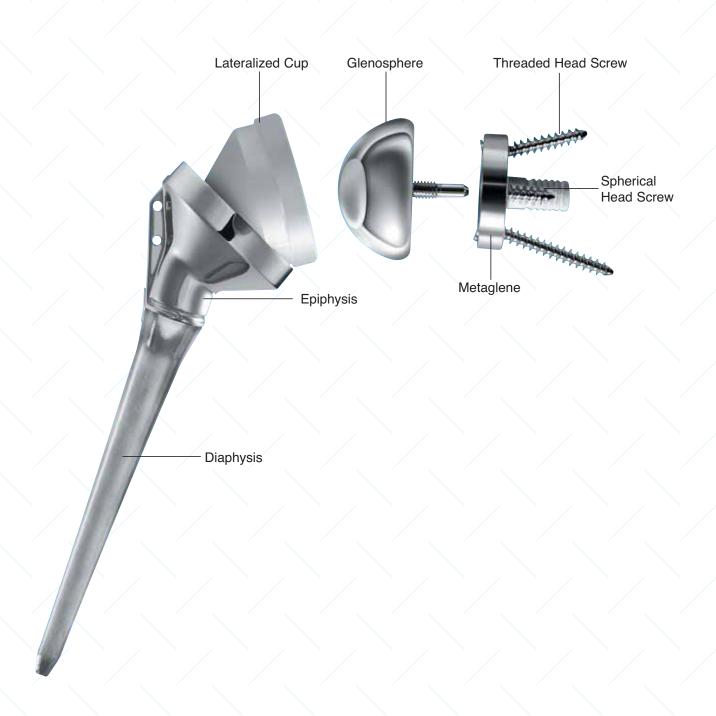


SURGICAL TECHNIQUE
REHABILITATING FUNCTION







Contents

Surgical Steps – At a Glance
Introduction
Preoperative Planning
Surgical Approach and Patient Positioning
Superior Lateral Approach
Humeral Head Resection
Humeral Reaming
Distal Humeral Reaming (Revision Surgery)
Proximal Reamer Guide Assembly
Proximal Humeral Reaming
Trial Humeral Implantation
Glenoid Exposure
Glenoid Preparation
Metaglene Insertion
Trial Reduction
Glenosphere Placement
Humeral Implant Insertion20
Closure
Postoperative Management
Ordering Information

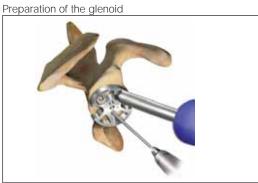
Surgical Steps - At a Glance

Superior lateral approach



Diaphyseal preparation

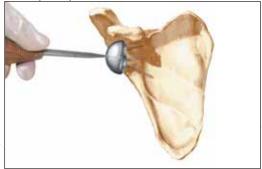




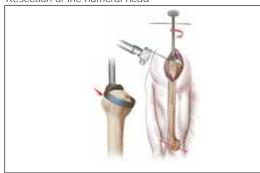
Preparation of the glenoid



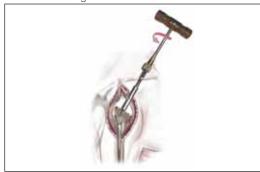
Glenosphere placement



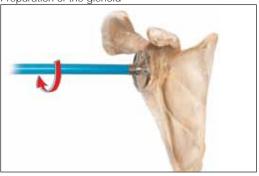
Resection of the humeral head



Proximal reaming of the humerus



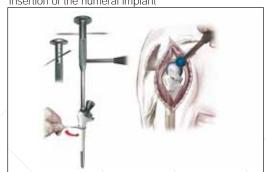
Preparation of the glenoid



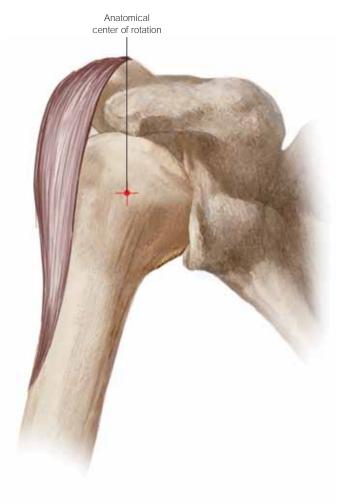
Insertion of the metaglene



Insertion of the humeral implant



Introduction



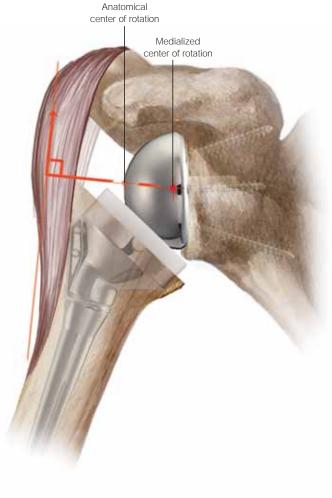


Figure 1 Figure 2

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.



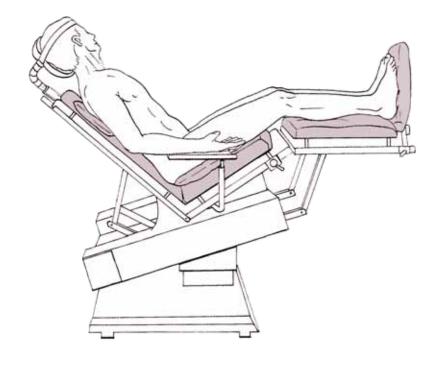


Figure 3
Preoperative Planning

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).

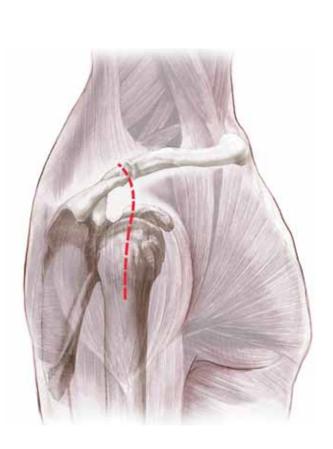
The Delta CTA Reverse Shoulder System may be implanted using either a transacromial or transdeltoid approach. Preoperative planning should take into account the quality of the acromion.

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



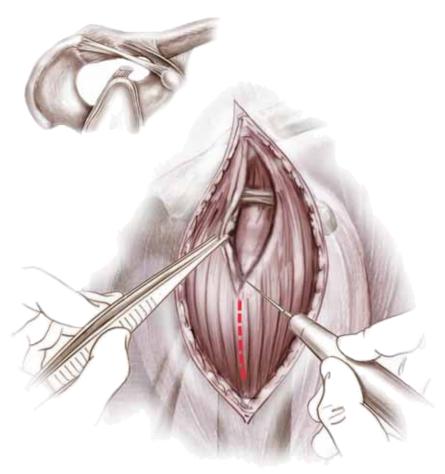


Figure 5 Superior Lateral Approach

Figure 6 Superior Lateral Incision

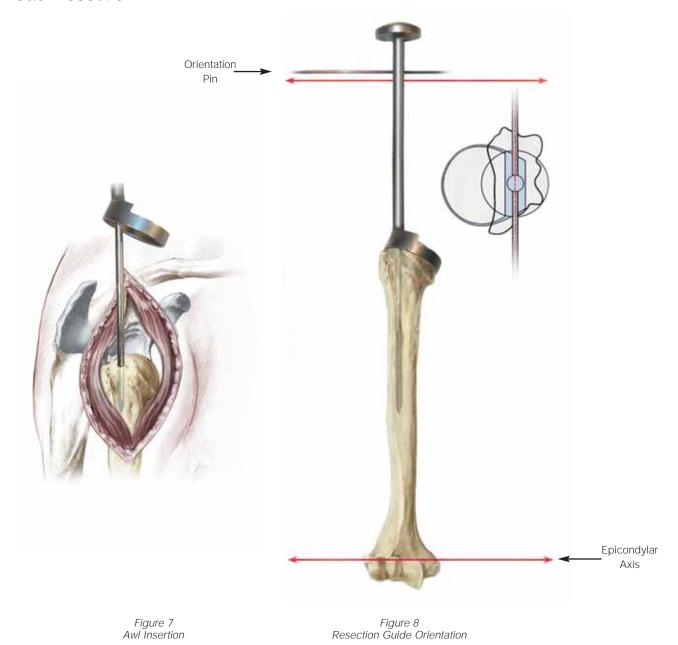
The surgical approach – superior lateral *(Figure 5)* or delto-pectoral – depends mainly on surgeon preference and clinical parameters. Revision surgery, for instance, usually dictates a delto-pectoral approach as it allows for a longer humeral incision when faced with a difficult removal of the humeral stem.

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 subcutaneous 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 resection guide. If the biceps is still present, tenodese in the bicipital groove. Retain the teres minor and infraspinatus when present.

Humeral Head Resection

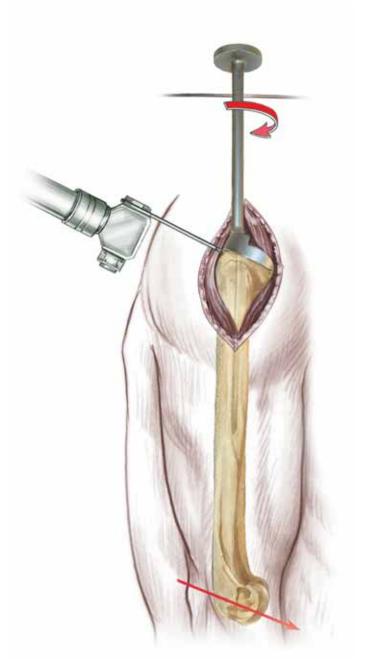


Humeral Head Resection

Remove any osteophytes, then 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 8). 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 8).

Locate the tip of the resection 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 8 and 9).



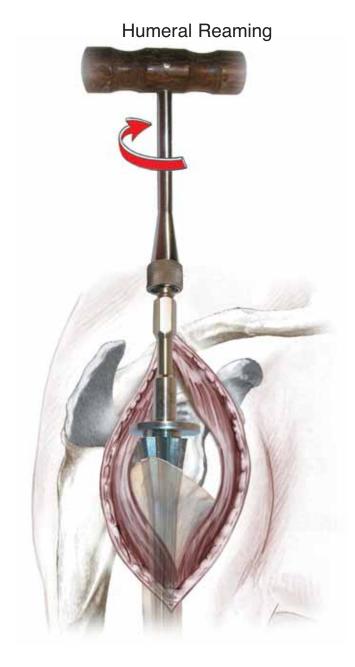


Figure 9 Head Resection

Initiate humeral head resection in line with the inferior aspect of the humeral resection guide. Remove the humeral resection 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.

Figure 10 Humeral Reaming

Note: Some surgeons may prefer to next proceed to glenoid preparation before completing humeral preparation.

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.

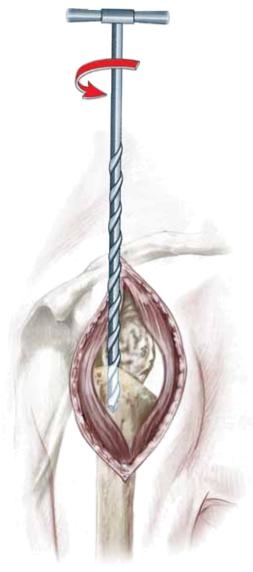


Figure 11 Reaming – Revision Surgery

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)	7.5 mm diameter (ref. ALR 075)
Size 1, length 180 mm (ref. DHC118B) Size 2, length 150 mm (ref. DHC215B)	0 li
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)



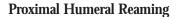
Proximal Reamer Guide Assembly

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).

Proximal Humeral Reaming



Figure 13 Determining Depth



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*).



Figure 14
Proximal Reaming

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 less 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.



Figure 15 Implant Trial Assembly



Figure 16 Glenoid Exposure

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 and verify humeral version.

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

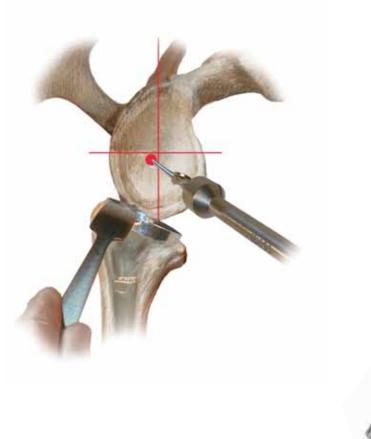




Figure 17a

Figure 17b

Positioning of the metaglene is important to achieve a good, stable range of motion. However, the position must allow the locked superior and inferior screws to be secured in bone.

The metaglene positioner allows the metaglene plate position to be trialed and screw angle checked by passing a K-wire.

The standard position for the metaglene central peg is posterior and inferior to the intersection of the glenoid axes (Figure 17a).

However, Radiograph and CT images, combined with X-rays templates can lead to choosing a different position according to the glenoid osseous state.

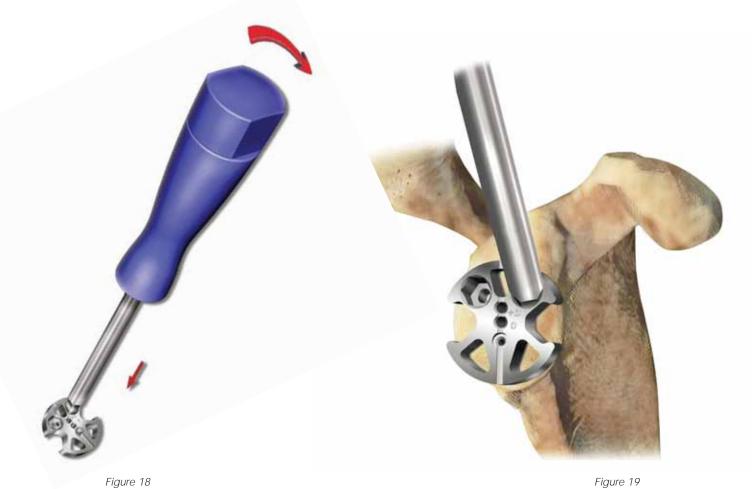
When the bone stock is sufficient, it is recommended to place the

metaglene as inferior as possible on the glenoid bone in order to limit impingement.

In order to define the optimal metaglene position, the metaglene positioner will be used as described below.

Assemble the positioner by inserting the internal rod into the positioner handle (*Figure 17b*).

Glenoid Preparation Cont'd

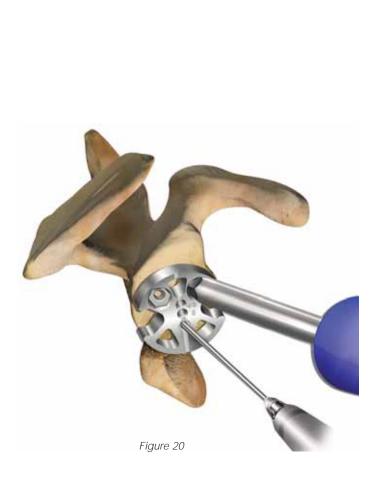


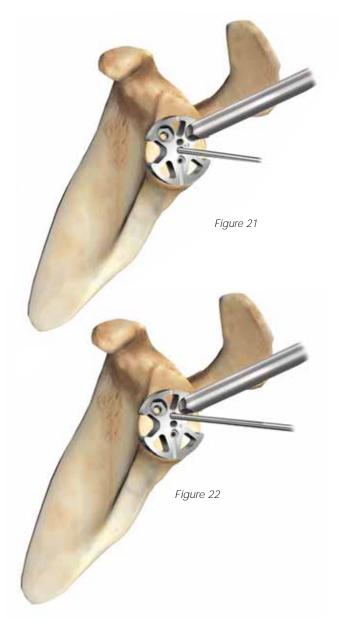
Then insert the hex head tip of the handle into the plate corresponding hole (right or left according to the operated shoulder) and lock the assembly by screwing tightly the internal rod (Figure 18).

Note: The handle is angulated by 20° relative to the plate, for optimal visibility.

Position the plate as low as possible on the glenoid bone. Align the vertical mark with the scapular neck (Figure 19).

Glenoid Preparation Cont'd

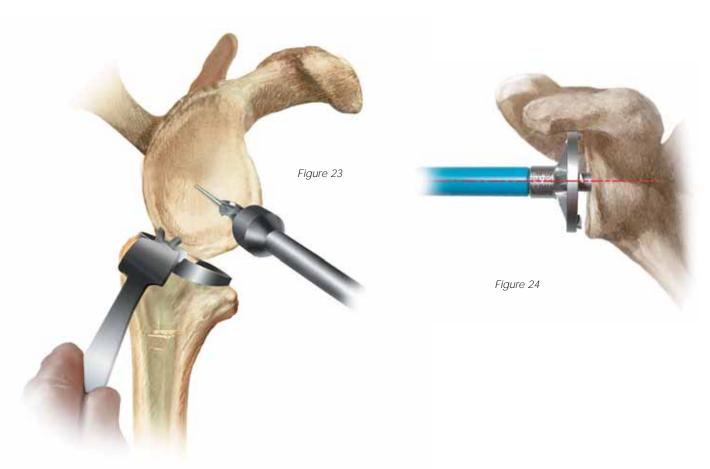




To ensure that the inferior metaglene screw will be fixed in good cancellous bone, introduce the 1.5 mm K-wire (Cat. No. 9375-15-150) into the plate inferior hole, using a power tool. The K-wire is directed at 17° angulation such as the inferior metaglene screw (*Figure 20*).

If the K-wire stays within bone all along its way, remove it and place the $2.5~\mathrm{mm}$ guide pin into the plate central hole etched +0, using power tool (Figure 21).

If the K-wire emerges from the scapular pilar, place the 2.5 mm guide pin into the upper hole etched +3 (*Figure 22*). This will move the inferior screw superiorly to keep it within bone.



Leave the guide pin in place and remove the metaglene positioner. Attach the cannulated stop drill to the power tool and drill the glenoid central hole over the guide pin (Figure 23).

The glenoid reamer is attached to the power tool and the reamer pilot shaft is introduced into the glenoid centering hole. In cases of osteoporotic bone, hand reaming should be used.

Ensure that the reamer is not in contact with the bone before applying power since this may damage the glenoid.

The glenoid is then reamed until a smooth platform devoid of cartilage is created for the metaglene and

glenosphere, with sufficient depth to accommodate its peripheral rim (Figure 24). The depth should be checked 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

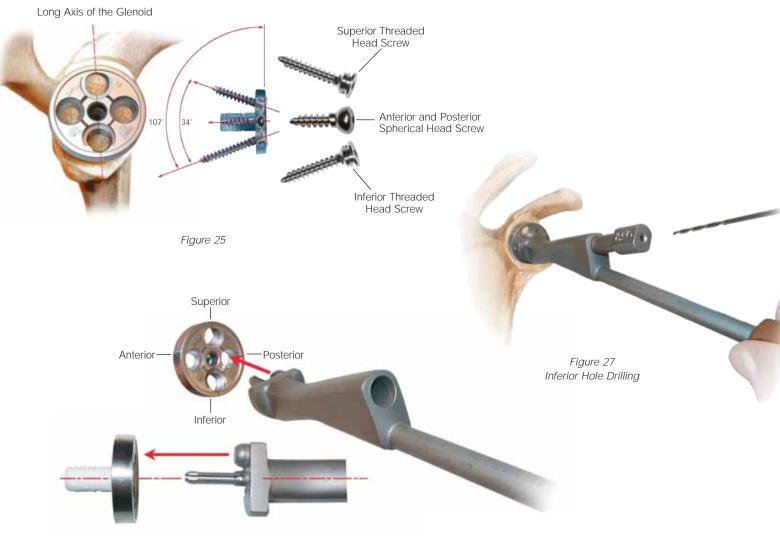


Figure 26 Drill Guide Orientation

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 25). 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 *(Figure 26)*. 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 34-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 27)*.

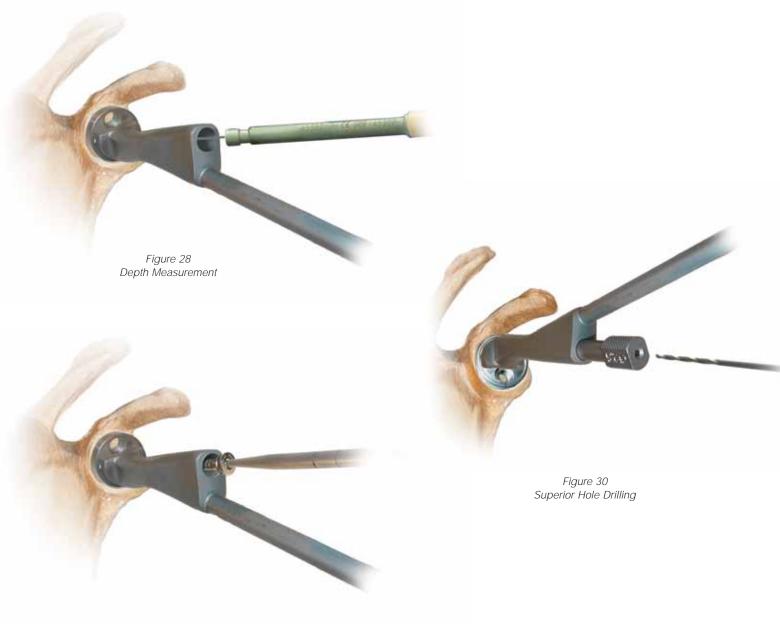


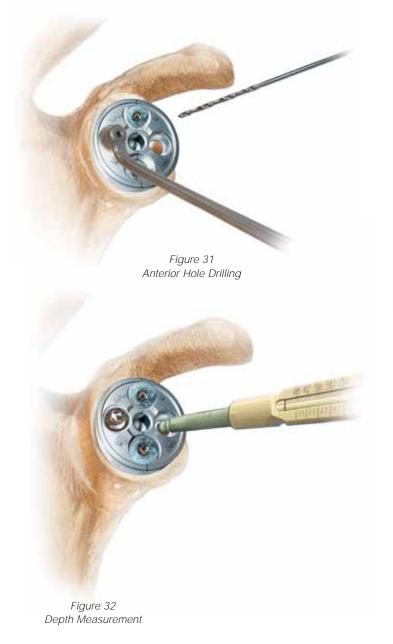
Figure 29 Screw Placement

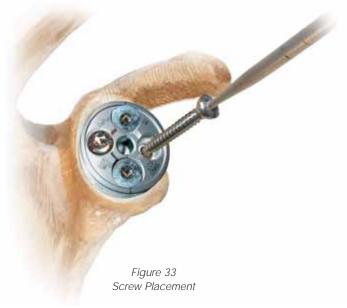
Remove the drill bush and check the depth of the screw hole by using the depth gauge provided (Figure 28). Threaded head screws must be used for the inferior and superior holes. The spherical head screws are designed for use only with anterior and posterior holes.

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 29).

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 30)*. Again ensure it is fully tightened.





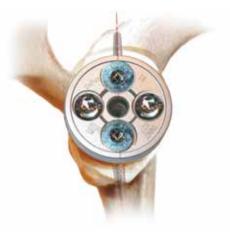


Figure 34
Final Screw Tightening

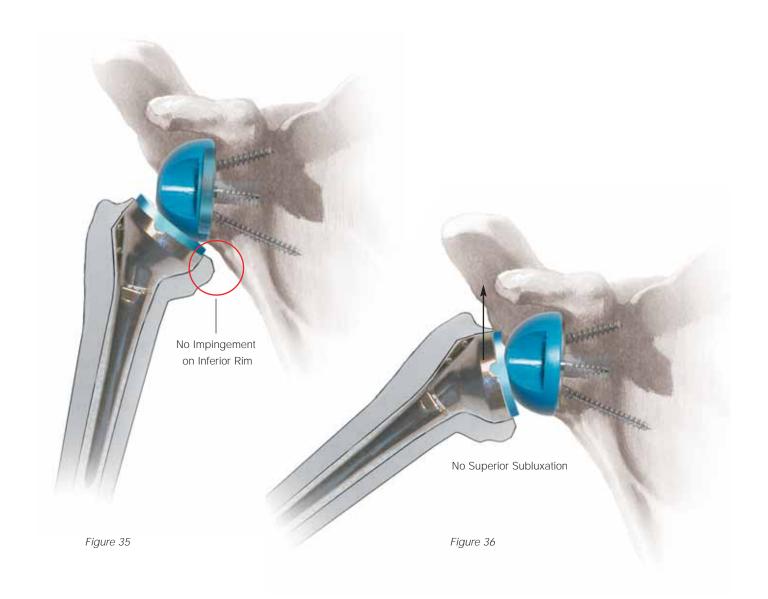
Remove the metaglene holder and locate the free hand drill guide of appropriate size, 2.0 or 2.5 mm, in the anterior fixation hole. Both anterior and posterior screw positions allow angulation of \pm 20 degrees. Use the drill guide to set the most appropriate angle to ensure that each screw is located in reliable bone stock (*Figure 31*).

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 32).*

Introduce a spherical head screw and partially tighten (*Figure 33*). Follow the same procedure for the posterior screw. Alternately tighten both screws until fully tightened (*Figure 34*).

Trial Reduction



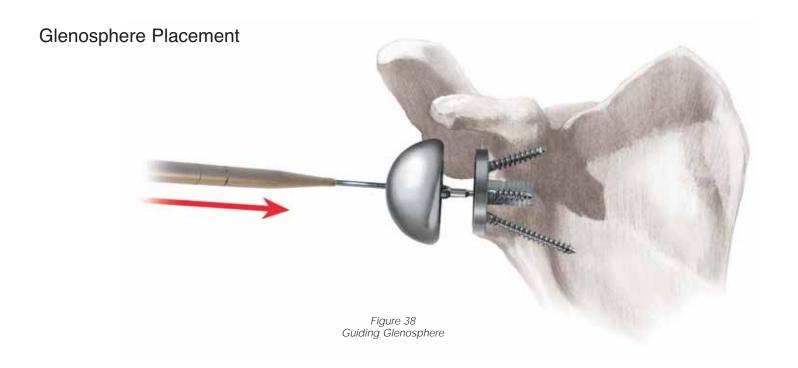
Trial Reduction

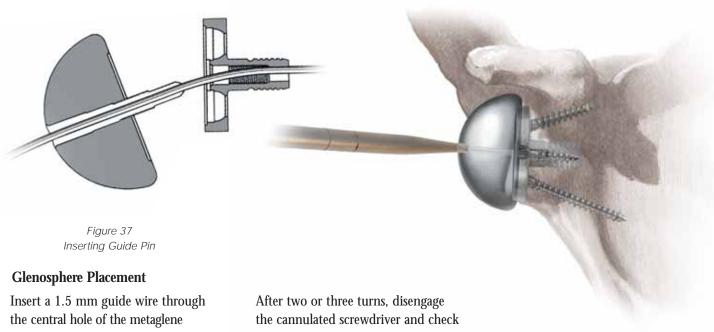
Attach the appropriate trial glenosphere (36 mm or 42 mm) to the metaglene. Insert the corresponding lateralized humeral cup trial (36+6 or 42+6) into the humeral trial assembly. Reduce the shoulder and assess for a full range of movement. If soft tissue tension is correct, the glenoid bearing will not impinge on the inferior rim of the resected humeral head (*Figure 35*). 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 36). Additional joint stability may be achieved by introducing a retentive, more constrained cup. If less or more soft tissue tension is required a +3 mm or +9 mm cup can be inserted. If even further tensioning is required, a +9 mm metal humeral spacer with any combination of +3, +6 or +9 polyethylene cup can be used.

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 +3, +6 or +9 mm will be sufficient in the majority of cases.





Insert a 1.5 mm guide wire through the central hole of the metaglene (*Figures 37 and 38*). Engage the 3.5 mm cannulated screwdriver in the definitive glenosphere and guide over the 1.5 mm guide wire.

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 (Figure 39). Ensure that the glenoid bearing is fully locked onto the bearing tray (Figure 36). It is critical that you use the guidepin in this step or the glenosphere may not screw down correctly.

Figure 39 Engaging Glenosphere



Humeral Implant Insertion

Extract the trial humeral assembly from the humerus. Attach the corresponding definitive humeral epiphyseal component to the impactor (Figure 40). Screw the definitive diaphyseal component to the epiphyseal component. Lock the two components using the wrench and driver (Figure 41).

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. Fully tighten the humeral spacer.

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 SmartSet® MV (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

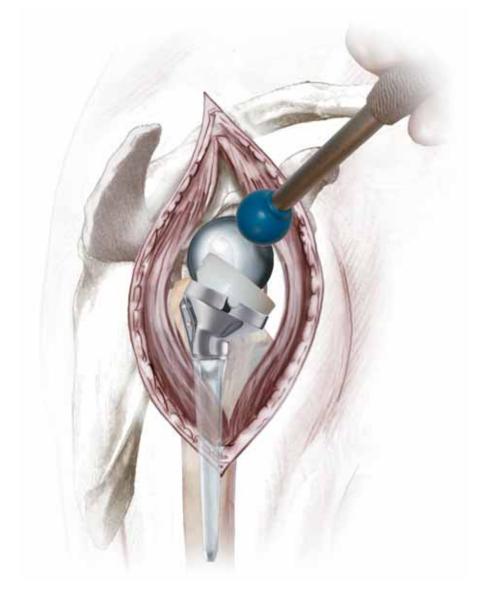


Figure 42 Impacting Humeral Cup

After the implant is fully seated, trial for soft tissue tensioning again before selecting the final humeral component. Using the cup impactor, impact the definitive humeral cup. Ensure it is fully seated and secure into the snap fit (Figure 42). Reduce the joint and make a final assessment of joint stability and range of motion.

Closure

Postoperative Management

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.

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. EHC361B EHC362B EHC422B	Description Cemented Humeral Epiphysis, 36.1 mm Cemented Humeral Epiphysis, 36.2 mm Cemented Humeral Epiphysis, 42.2 mm
DHC010B DHC110B DHC210B DHC310B DHC410B	Cemented Humeral Diaphysis, Size 0, 85 mm Cemented Humeral Diaphysis, Size 1, 86 mm Cemented Humeral Diaphysis, Size 2, 88 mm Cemented Humeral Diaphysis, Size 3, 89 mm Cemented Humeral Diaphysis, Size 4, 94 mm
DHC115B DHC215B DHC315B DHC118B DHC218B DHC318B	Revision Cemented Humeral Diaphysis Size 1 (150 mm) Revision Cemented Humeral Diaphysis Size 2 (150 mm) Revision Cemented Humeral Diaphysis Size 3 (150 mm) Revision Cemented Humeral Diaphysis Size 1 (180 mm) Revision Cemented Humeral Diaphysis Size 2 (180 mm) Revision Cemented Humeral Diaphysis Size 3 (180 mm)
4CHS036R 4CHS042R	$\begin{array}{c} Medialized\ Retentive\ Humeral\ Cup,\ 36\ mm\ diameter+0\ mm\\ Medialized\ Retentive\ Humeral\ Cup,\ 42\ mm\ diameter+0\ mm \end{array}$
4CHL336 4CHL342 4CHL636 4CHL636R 4CHL642 4CHL642R 4CHL936 4CHL942	Lateralized Humeral Cup, 36 mm diameter + 3 mm Lateralized Humeral Cup, 42 mm diameter + 3 mm Lateralized Humeral Cup, 36 mm diameter + 6 mm Lateralized Retentive Humeral Cup, 36 mm diameter + 6 mm Lateralized Humeral Cup, 42 mm diameter + 6 mm Lateralized Retentive Humeral Cup, 42 mm diameter + 6 mm Lateralized Humeral Cup, 36 mm diameter + 9 mm Lateralized Humeral Cup, 42 mm diameter + 9 mm
RTH236 RTH242	Humeral Spacer, 36 mm + 9 Humeral Spacer, 42 mm + 9
MGC002H	Standard Metaglene
GSC236 GSC242	Glenosphere 36 mm Glenosphere 42 mm
VFM4524 VFM4530 VFM4536 VFM4542 VFM4548 VSM4518 VSM4524 VSM4530 VSM4536 VSM4536	Metaglene Screws, Dia. 4.5 x 24 mm (Threaded Head) Metaglene Screws, Dia. 4.5 x 30 mm (Threaded Head) Metaglene Screws, Dia. 4.5 x 36 mm (Threaded Head) Metaglene Screws, Dia. 4.5 x 42 mm (Threaded Head) Metaglene Screws, Dia. 4.5 x 48 mm (Threaded Head) Metaglene Screws, Dia. 4.5 x 18 mm (Spherical Head) Metaglene Screws, Dia. 4.5 x 24 mm (Spherical Head) Metaglene Screws, Dia. 4.5 x 30 mm (Spherical Head) Metaglene Screws, Dia. 4.5 x 36 mm (Spherical Head) Metaglene Screws, Dia. 4.5 x 42 mm (Spherical Head) Metaglene Screws, Dia. 4.5 x 42 mm (Spherical Head)

Humeral Preparation Instruments

Humeral	Preparation Instruments	
Cat. No. GSH002	Description Humeral Resection Guide	
ARR001	Orientation Pin	
FPH361 FPH362 FPH422	Proximal Humeral Reamer, 36.1 Proximal Humeral Reamer, 36.2 Proximal Humeral Reamer, 42.2	
FDH036N FDH136 FDH236 FDH336 FDH436 FDH142 FDH242 FDH342 FDH342 FDH442	Distal Humeral Reamer, Size 0, Dia. 36 mm Distal Humeral Reamer, Size 1, Dia. 36 mm Distal Humeral Reamer, Size 2, Dia. 36 mm Distal Humeral Reamer, Size 3, Dia. 36 mm Distal Humeral Reamer, Size 4, Dia. 36 mm Distal Humeral Reamer, Size 1, Dia. 42 mm Distal Humeral Reamer, Size 2, Dia. 42 mm Distal Humeral Reamer, Size 3, Dia. 42 mm Distal Humeral Reamer, Size 4, Dia. 42 mm	
ITH003	Humeral Stem Impactor/Extractor	0
EHF001	Forked Retractor	*
EHF002	U-forked Retractor	> 00
GFP136 GFP142	Proximal Reamer Guide, Dia. 36 Proximal Reamer Guide, Dia. 42	
IGF004	Reamer Guide Impactor/Extractor	
CLE014	Diaphyseal Stem Locking Wrench	>
DHF010N DHF110 DHF210 DHF310 DHF410	Humeral Diaphysis Trial, Size 0 Humeral Diaphysis Trial, Size 1 Humeral Diaphysis Trial, Size 2 Humeral Diaphysis Trial, Size 3 Humeral Diaphysis Trial, Size 4	
EHF361 EHF362 EHF422	Humeral Epiphysis Trial, 36.1 Humeral Epiphysis Trial, 36.2 Humeral Epiphysis Trial, 42.2	
REH236 REH242	Humeral Spacer Trial, Dia. 36 Humeral Spacer Trial, Dia. 42	
A5265 A5264 A5263 A5262 A5261 A5260	Medialized Retentive Humeral Cup Trial, Dia. 36 mm Lateralized Humeral Cup Trial, Dia. 36 mm Lateralized Retentive Humeral Cup Trial, Dia. 36 mm Medialized Retentive Humeral Cup Trial, Dia. 42 mm Lateralized Humeral Cup Trial, Dia. 42 mm Lateralized Retentive Humeral Cup Trial, Dia. 42 mm	
TEH036 TEH042 TEH436 TEH442	Humeral Head Trial Dia. 36 mm Humeral Head Trial Dia. 42 mm Humeral Head Trial Dia. 36 mm + 4 Humeral Head Trial Dia. 42 mm + 4	

Glenoid Preparation Instruments

Cat. No. A5267	Description Cannulated Stop Drill	~)———
A5075 A5076	Glenoid Surfacing Rasp, Dia. 36 Glenoid Surfacing Rasp, Dia. 42	
PAM001	T-handle	0
A5271 A5272	Drill Bush, Dia. 2.0 Drill Bush, Dia. 2.5	
GPM020 GPM025	Drill Guide, Dia. 2.0 Drill Guide, Dia. 2.5	
A5326 A5327	S/I Drill Bit, Dia. 2.0 (170 mm Length) S/I Drill Bit, Dia. 2.5 (170 mm Length)	
MPG020 MPG025	A/P Drill Bit, Dia. 2.0 (100 mm Length) A/P Drill Bit, Dia. 2.5 (100 mm Length)	Walls
A5273 A5274	Glenosphere Trial, Dia. 36 Glenosphere Trial, Dia. 42	1
9E03011 A5307	3.5 mm Hex. Head Screwdriver, Cannulated Screw Depth Gauge	
PRT001	Standard Impactor Holder	
EPT001 EPC032	Humeral Head Impactor Humeral Cup Impactor	
A5268 A5470 A5471 A5472	Metaglene Holder Delta Metaglene Positioner Plate Delta Metaglene Positioner Handle Delta Pin for Metaglene Positioner	
Guide Pins and Cat. No. A5266 A5074 9375-15-150	Guide Wires Description Guide Pin 1.5 mm Guide Wire Kirschner K-Wire Dia. 1.5 mm Lg. 150 mm	

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irays	
Cat. No.	Description
A5807	Glenoid Tray Base
A5831	Upper Glenoid Tray
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
A5819	Tray insert for Cups
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Delta Revision

Instruments	
Cat. No.	Description
ETH001	Standard Humeral Prosthesis Extractor
MDE001	Extraction Rod
MAI001	Slap Hammer
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

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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.

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:

- Active local or systemic infection;
 Poor bone quality and/or inadequate bone stock to appropriately support the prosthesis;
- Severe deformity;
- Muscle, nerve or vascular disease;
 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:

- The following conditions tend to adversely attect 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 deformitties 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 ioints.

- 8. Disabilities of other joints.

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;

- Larly or late infection;
 Early or late loosening of the prosthetic component(s), often related to factors listed in WARNING AND PRECAUTIONS;
 Temporary inferior subluxation. Condition generally disappears as muscle tone is regained;
 Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction;
 Hematoma and/or delayed wound healing;
 Pneumonia and/or atelectasis;

- 8. Subluxation or dislocation of the replaced joint.

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