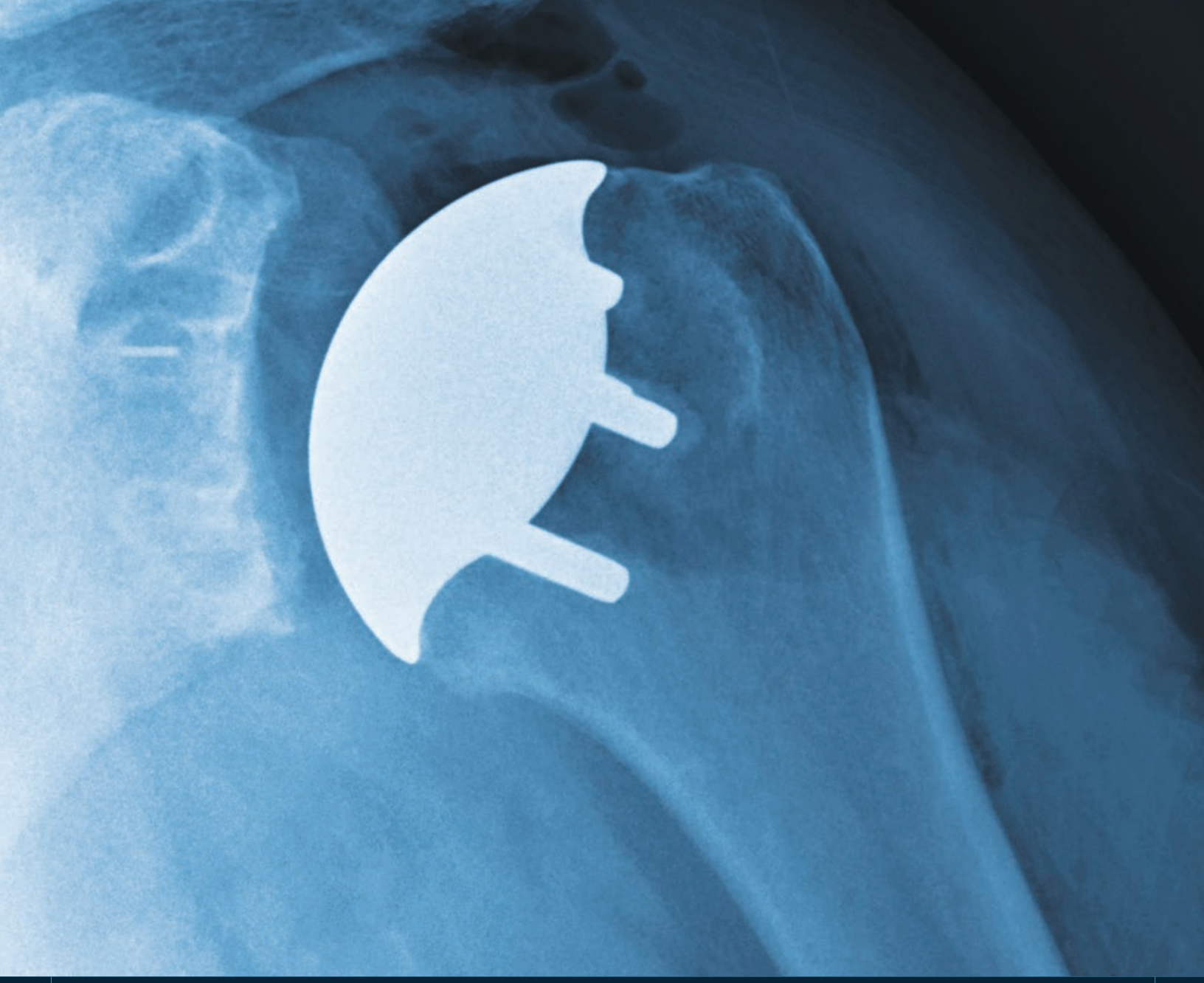


CATALYST CSR™

TOTAL SHOULDER ARTHROPLASTY

3-PEG GLENOID SURGICAL TECHNIQUE GUIDE

CATALYST

ORTHOSCIENCE®

INTRODUCTION

At Catalyst OrthoScience, our goal is to develop innovative products that make orthopedic surgery less invasive and more efficient for both surgeons and patients. Catalyst OrthoScience continues to provide solutions and advances in medical technology that change lives for the better.

THE RESULT OF AN EXHAUSTIVE ANALYSIS OF OVER 300 PUBLISHED ARTICLES, THE CATALYST CSR SYSTEM IS THE COMBINATION OF THE BEST EVIDENCE-SUPPORTED ATTRIBUTES OF SHOULDER IMPLANT DESIGN INTO ONE SYSTEM ENGINEERED TO IMPROVE PATIENT OUTCOMES.

HISTORY

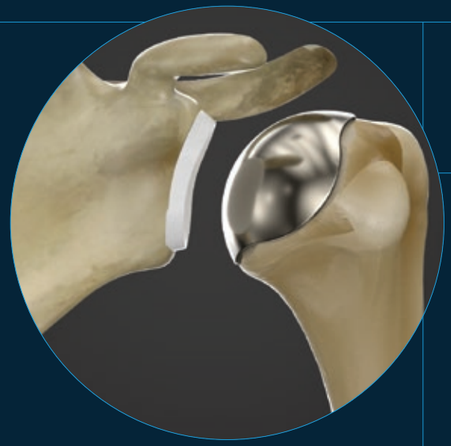
Catalyst OrthoScience was founded by a board-certified orthopedic surgeon who was looking to improve the lives of his patients. It is comprised of a team of biomedical industry professionals with more than 150 years of combined medical device experience, and every member of this team is committed to the goal of returning patients to their active lifestyles. Catalyst provides only the highest level of quality, safety and customer satisfaction to our patients. Catalyst was founded in 2014 and is headquartered in Naples, Florida.

CATALYST CSR™ TOTAL SHOULDER SYSTEM

Catalyst OrthoScience developed and commercialized the Catalyst CSR Total Shoulder System to address a significant need in the marketplace for a bone preserving, simple and consistent shoulder arthroplasty operation. The result of an exhaustive analysis of more than 300 published articles, the Catalyst CSR system is the combination of the best evidence-supported attributes of shoulder implant design into one system engineered to improve patient outcomes.

DESIGN RATIONALE

The Catalyst CSR system has been designed to meet the demands of orthopedic surgeons for a bone preserving, simple and consistently reproducible shoulder arthroplasty operation. The technique and instrumentation were evaluated in a cadaver study and shown to replicate the anatomy with high accuracy and precision. [REF 1]



- The implant is engineered to accurately replace the elliptical shape of the patient's native non-spherical humeral head.
- The instruments and implants are designed to precisely restore the joint line using a simple, reproducible, and streamlined surgical procedure.

CATALYST HUMERUS COMPONENT

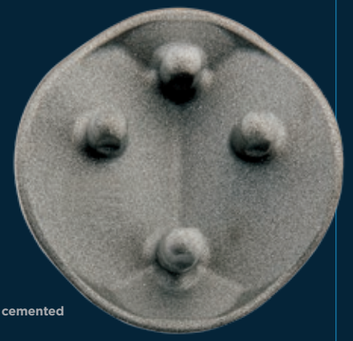
The Catalyst CSR humeral components are elliptical with a reduced width and are designed to accurately replicate the natural non-spherical anatomy of the humeral head [REF 2]. Laboratory studies have shown that non-spherical humeral heads can improve shoulder motion and kinematics [REF 3]. The position and depth of the anchoring components of the Catalyst CSR system have been designed to facilitate either anchor or bone tunnel repair when utilizing a variety of subscapularis take-down methods such as Lesser Tuberosity Osteotomy, Tenotomy, or Peel-Off techniques.

The Catalyst CSR surgical instruments are engineered to consistently restore the original size, shape and height of the humerus while minimizing inconsistent bone resection. The specialized, patented instrumentation removes a specified thickness of humeral head articular surface that is equal to the implant size. This provides an advantage over traditional resurfacing arthroplasty techniques which are often associated with overstuffing the joint. [REF 4]

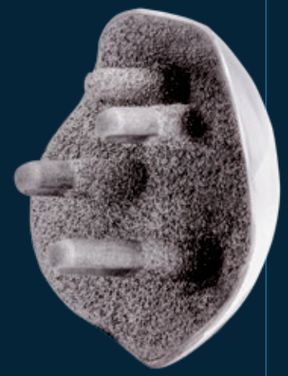
The cutting guides create a unique four-plane geometry for the implant which resists rotational forces and preserves subchondral bone. By preserving the dense subchondral bone of the humeral head, fixation may be achieved without a large stemmed implant, preserving both the metaphysis and the diaphysis for later revision surgery if needed.

Other factors were also considered to respect soft tissue and improve anatomic restoration. The humerus technique is designed to prevent the incidence of iatrogenic rotator cuff injury by having the superior saw cut remain 3-4mm medial to the insertion of the supraspinatus, rather than right at the insertion as many other systems do.

The Catalyst CSR humeral component comes in both a standard cemented and a Press Fit cementless option for speed and convenience.



Standard cemented



Press Fit cementless

CATALYST GLENOID COMPONENT

The glenoid components are designed to allow both surgical preparation and implant insertion to be performed at an angle, in the same orientation as the surgeon's exposure. This reduces the forceful retraction of soft tissues and as well as bone and soft tissue trauma usually required to insert standard glenoid components.

The backside anchoring elements consist of three obliquely positioned pegs to facilitate insertion. These pegs are oriented to match the triangular shape of the glenoid vault and position the implant near the dense cortical and subchondral bone. The three pegs are slightly offset and have small anchoring prominences, which work together to provide a slight three-point-mold interference fit upon insertion to reduce micromotion forces while the cement is hardening. The perimeter of the implant contains a bevel, which is designed to minimize unwanted notching impact forces of the humerus against the glenoid component [REF 5] and to potentially reduce edge loading and the cantilever effect experienced by standard glenoid component designs according to the literature.

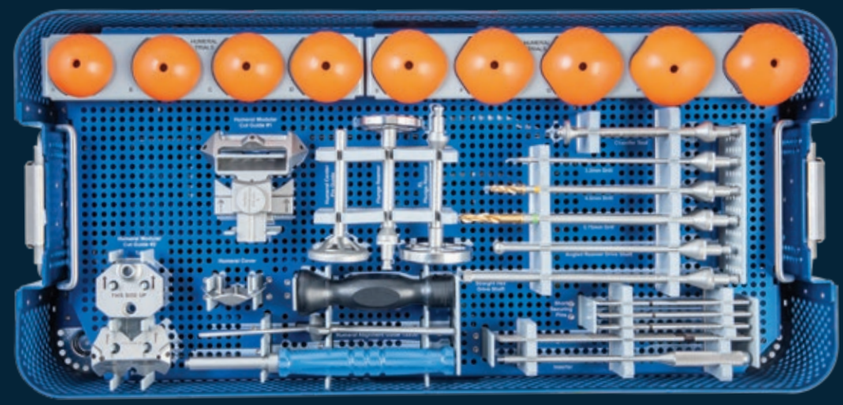
All sizes of the Catalyst CSR 3-Peg Glenoid are available in an augmented version which have a bone-sparing full wedge design with 10° of posterior correction. The Catalyst CSR Augmented 3-Peg Glenoid is designed to provide version correction while simplifying the surgical procedure by not requiring any deviation from the standard technique, additional instruments, or surgical planning software. The CSR Augmented 3-Peg Glenoid permits interoperative decision-making between either a standard or augmented implant design, even after having trialed for both.

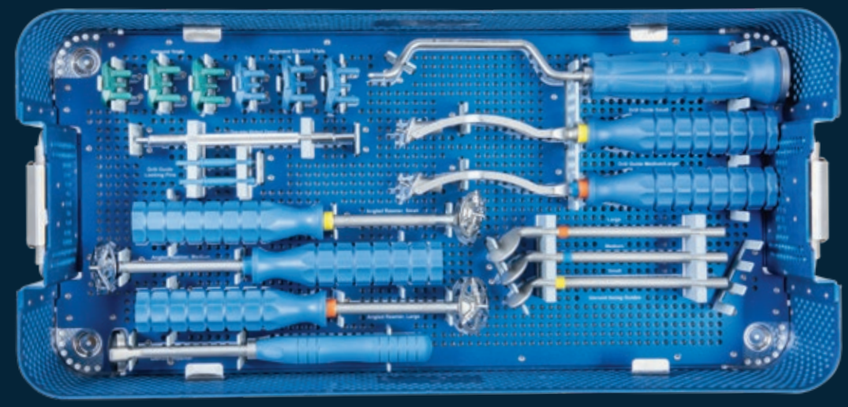
3-Peg Glenoid

Augmented 3-Peg Glenoid

ONE INSTRUMENT TRAY

The surgeon-designed instrument set minimizes the number of steps required by both surgeon and surgical assistant to result in a more streamlined operation.* The reduced number of instruments allows for rapid turnover of equipment at the end of the procedure, potentially improving operating room efficiency and reducing cost. Finally, the instrument tray has been uniquely designed to facilitate both outpatient and inpatient shoulder replacements. A significant number of Catalyst CSR system shoulder replacements have been successfully completed as an outpatient procedure.





*As compared to total shoulder systems utilizing multiple instrument trays.

INDICATIONS FOR USE

The Catalyst CSR system is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where hemi- or total shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment. The Catalyst CSR system is intended for use in patients with the following conditions where the humeral head, neck and glenoid vault are of sufficient bone stock and the rotator cuff is intact or reconstructable.

- **OSTEOARTHRITIS**
- **AVASCULAR NECROSIS**
- **RHEUMATOID ARTHRITIS**
- **POST-TRAUMATIC ARTHRITIS**
- **CORRECTION OF FUNCTIONAL DEFORMITY**

The Catalyst CSR humeral and glenoid implants are intended for cemented use. The Catalyst CSR Press Fit humeral implants are intended for uncemented or cemented use.

RECOMMENDED COMBINATIONS OF IMPLANTS

The recommended combinations of humeral and glenoid components are provided in Table 1 below. The radial mismatches (in mm) for each combination are provided as the difference in bearing surface radii between the humeral and glenoid components. Since the humeral component is non-spherical, the radial mismatch was calculated using the average radii in the superior-inferior (SI) and medial-lateral (ML) planes as most in vivo motion occurs somewhere in between the true SI and ML planes.

TABLE 1: Radial Mismatches for Catalyst CSR Non-Spherical Humeral Components (mm)

COMPONENT	SMALL GLENOID	MEDIUM GLENOID	LARGE GLENOID
Humeral, Size A	8.1	9.6	11.1
Humeral, Size B	7.0	8.5	10.0
Humeral, Size C	6.0	7.5	9.0
Humeral, Size D	4.8	6.3	7.8
Humeral, Size E	3.7	5.2	6.7
Humeral, Size F	2.7	4.2	5.7
Humeral, Size G	1.6	3.1	4.6
Humeral, Size H	Not Recommended	1.9	3.4
Humeral, Size I	Not Recommended	Not Recommended	2.3

RECOMMENDED

ACCEPTABLE IF CLINICALLY INDICATED

NOT RECOMMENDED

PREOPERATIVE PLANNING

It is recommended prior to surgery that the surgeon use available imaging studies to ensure patient compatibility with the Catalyst CSR system. The Catalyst humeral implants range in diameter from 44-58mm in the coronal (superior-inferior) plane.

SURGICAL TECHNIQUE

PREOPERATIVE POSITIONING

The patient is placed into a semi-reclined beach chair position on the operating table, with the patient's head secured in a headrest. In this surgeon's experience, a small folded towel is placed behind the medial border of the scapula of the operative side, which has the effect of improving the position of the glenoid intra-operatively. Standard sterile skin preparation and draping are done to isolate the sterile field. The operative arm may either be placed freely on a padded mayo stand or alternatively secured to an arm holder.

INCISION AND HUMERUS EXPOSURE

A standard deltopectoral incision is made beginning just above the coracoid process, extending inferolaterally to the anterior arm, just below the level of the axillary fold. The surgeon dissects the interval between the pectoralis major medially and the deltoid laterally, usually taking the cephalic vein laterally with the deltoid. A narrow yellow fat stripe in line with the muscle fibers serves as a landmark to identify the location of the cephalic vein and deltopectoral interval. A Richardson retractor is used to retract the pectoralis medially and a deltoid retractor is used to retract the deltoid and cephalic veil laterally.

The surgeon dissects through the clavipectoral fascia and repositions the Richardson retractor beneath the strap muscles, exposing the subscapularis tendon. After ligating or coagulating the anterior circumflex vessels at the inferior portion of the subscapularis, the surgeon then releases the subscapularis to expose the glenohumeral joint. In this surgeon's opinion the subscapularis is best cut vertically 1cm medial to its insertion onto the lesser tuberosity, which provides ample soft tissue for an excellent tendon-to-tendon repair with suture at the end of the procedure. Alternatively, the surgeon can perform a subscapularis peel or a lesser tuberosity osteotomy, if preferred.

Once the glenohumeral joint is exposed, the surgeon delivers the humeral head anteriorly. One preferred method is to place a Darrach retractor between the humeral head and glenoid, and a cobra or second Darrach behind the superolateral humeral head, superficial to the supraspinatus tendon. By simultaneously pressing on both retractors and externally rotating the patient's arm, the humeral head is delivered anteriorly. Osteophytes on the anterior and inferior edge of the humeral head are removed at this time using a rongeur.

The surgeon is now ready to prepare the humeral head.

SIMPLIFIED OVERVIEW OF SURGICAL STEPS:

HUMERUS BONE PREPARATION

After all osteophytes have been removed, utilizing a standard flexible ruler, locate the central point of the humeral articular surface by measuring the Anterior-Posterior articular distance and Superior-Inferior distance. Position the Humeral Center Pin Guide at the previously marked center point and visually confirm that the circumferential edge of the guide is equidistant to the surrounding articular surface **[FIG 1]**. *Note: The Humeral 135/30 Alignment Guide provides a 135 degree inclination and 30 degree retroversion reference with the pin and handle respectively* **[FIG 2]**.

Once the Humeral Pin Guide location is confirmed, drill the Long 3.2mm Guidewire Pin into the center of the articular surface until the cortex is felt or the black laser line is at the level of the proximal opening of the cannulated shaft of the Pin Guide **[FIG 3]**. Remove the Pin Guide, leaving the Pin in the center of the humerus **[FIG 4]**.

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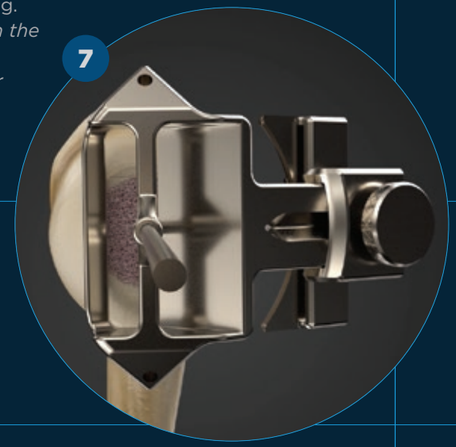
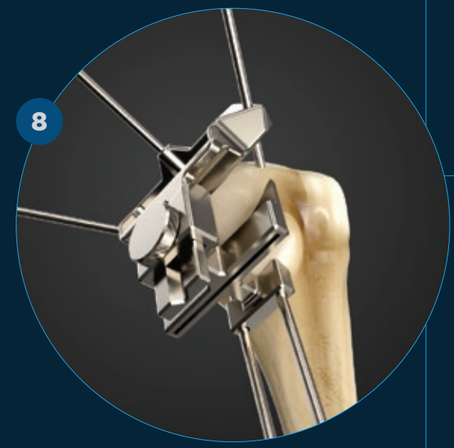
HUMERUS BONE PREPARATION

Advance the Plunge Reamer over the Long Guidewire Pin and ream a small portion of humeral head subchondral bone until it is visibly and audibly apparent that the Plunge Reamer is no longer removing bone **[FIG 5]**. *Note: The patented Plunge Reamer design removes only the precise amount of bone necessary for the humeral implant to restore the patient's anatomy. The surgeon knows that the reamer has achieved its desired depth when it is no longer creating new bone shavings and the surgeon is able to hear and feel that the reamer is spinning but no longer cutting.*

After confirmation that the Plunge Reamer is no longer cutting, remove the Plunge Reamer and leave the Long Guidewire Pin in place **[FIG 6]**.

Advance the Modular Humeral Cut Guide #1 over the Long Guidewire Pin. Rotate the guide so that the superior and inferior tips of the guide are oriented towards the 12:00 and 6:00 positions on the humeral head. **[FIG 7]**. ***Note: It is important to confirm that Guide #1 sits flush against the flat reamed surface of the humerus.*** Insert the four short Guidewire Pins **[FIG 8]** and remove the Long Guidewire Pin prior to cutting.
Note: Do not place the pin in the guide under power. Instead, attach the orthopedic power drill/reamer to the pin only after having first placed the pin manually in the guide.



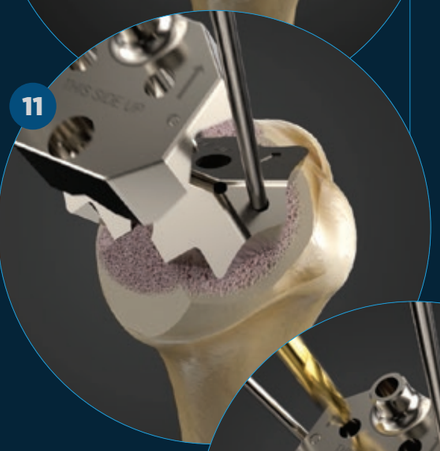


Utilizing an oscillating saw, create the posterior and anterior facets through the saw captures in the Cut Guide #1. *Note: An approximate equivalent to the the Stryker 2108-182-000 saw blade with a thickness that is less than 1.27mm is required.* Once the anterior and posterior cuts have been made, remove the four Short Guidewire Pins and Modular Cut Guide #1 **[FIG 9]**.

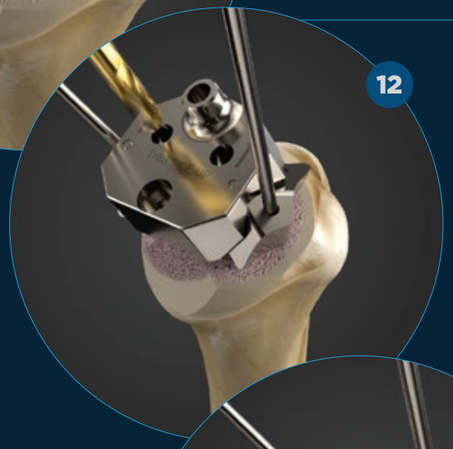
HUMERUS
BONE PREPARATION

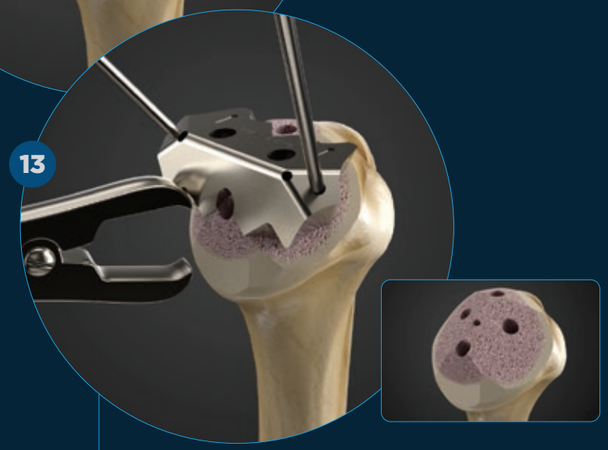
The Humeral Cut Guide has two portions, a top and a bottom. The bottom portion guides the final chamfer cuts, and the top portion guides the drilling of the lug holes.

Place the bottom portion of Modular Humeral Cut Guide #2 over the chamfered proximal humerus by inserting the spike at the base of the guide into the previously drilled central guide pin hole. *Note: the arrows must be oriented superiorly.* Secure the guide with two Short Guidewire Pins. Create the superior and inferior cuts along the surfaces of the guide using the oscillating saw. **[Fig 10]** Note: Both cuts made with the Modular Humeral Cut Guide #2 remove substantially less bone than Modular Humeral Cut Guide #1.



Place the top portion of Modular Humeral Cut Guide #2 over the bottom portion. Note: the arrows must be oriented superiorly and the pegs must be inserted into the corresponding holes of the bottom portion **[FIG 11]**. Using the 6mm Drill, create the four lug holes by drilling to the positive drill stop **[FIG 12]**. Remove the top portion of the cut guide. Contour the edges of the four corners using a small rongeur **[FIG 13]**. Remove the two short Guidewire Pins and the bottom portion of Modular Humeral Cut Guide #2.





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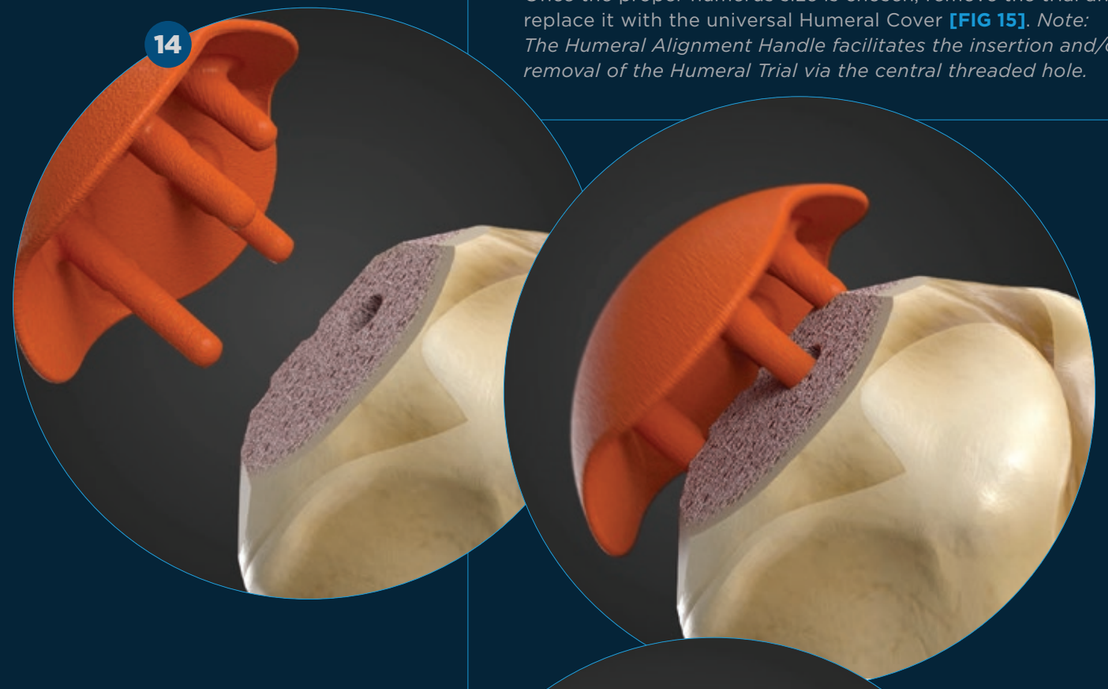
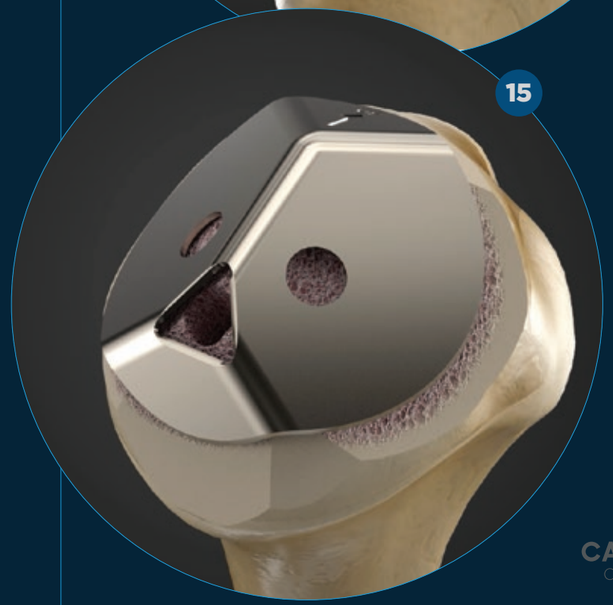
HUMERUS
TRIAL SELECTION

At this point, use the humeral trials to determine the correct humeral implant size by correctly matching the periphery of the implant with the cortex of the humerus **[FIG 14]**. *Note: The asymmetric peg pattern of the trial allows the implant to fit onto the humerus in only one orientation with the longest peg oriented inferiorly.*

Once the proper humerus size is chosen, remove the trial and replace it with the universal Humeral Cover **[FIG 15]**. *Note: The Humeral Alignment Handle facilitates the insertion and/or removal of the Humeral Trial via the central threaded hole.*





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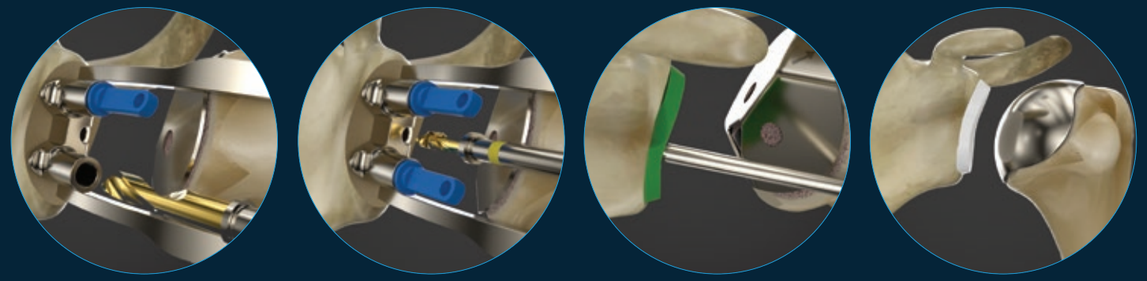
SURGICAL TECHNIQUE

GLENOID PROCEDURE

The anterior capsule is removed from the undersurface of the subscapularis, which also helps with subscapularis mobilization. The anterior labrum is subsequently removed, and a spiked Darrach retractor is placed along the anterior glenoid neck. This exposes the anterior side of the glenoid. Forward flexion of the humerus to approximately 20 degrees with 30 degrees abduction and 45 degrees external rotation typically optimizes glenoid visualization. A posterior retractor such as a Fukuda or Darrach is inserted on the posterior aspect of the glenoid and is used to displace the humeral head to increase glenoid exposure. The inferior labrum and other soft tissue that may interfere with reaming or glenoid implant seating is then removed.

SIMPLIFIED OVERVIEW OF SURGICAL STEPS:



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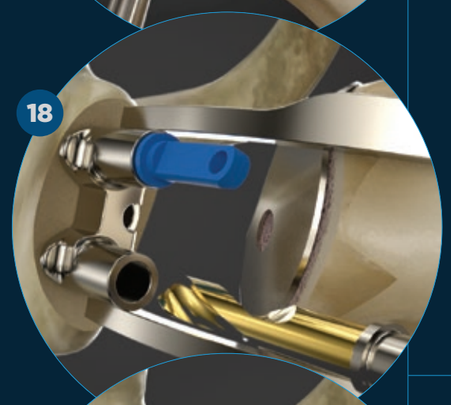

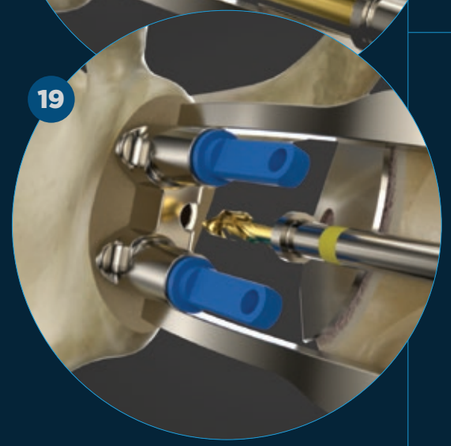

GLENOID PREPARATION

Use the Glenoid Sizing Guide to select the correct glenoid implant size. Create a pilot hole in the center of the glenoid fossa using the Center Point Awl through the sizing guide **[FIG 16]**. *Note: It is important to reinsert the Center Point Awl to deepen the pilot hole after the sizing guide has been removed. Alternatively, this pilot hole may be created using the 3.2mm Drill.*

Select the Angled Reamer (S/M/L) that corresponds to the previously sized glenoid implant. Insert the pilot tip of the Angled Reamer into the pilot hole of the glenoid to prevent reamer migration. Position the Angled Reamer Drive Shaft inside the drive nut of the Reamer **[FIG 17]** and commence reaming of the glenoid. *Note: Best results are obtained when the surgeon holds the Angled Reamer tool gently, applying greater pressure to the Drive Shaft.*

It is strongly recommended to preserve as much dense cortical bone on the glenoid surface as possible.

Next the glenoid Drill Guide is inserted by placing the instrument's pilot tip into the pilot hole in the glenoid. The surgeon chooses the appropriate size of the drill guide based on the Sizing Guide selection. Once the corresponding drill guide is chosen and the surgeon confirms that the instrument is sitting flush against the reamed surface of the glenoid, the 6 mm Drill is used to drill the first two glenoid holes, while applying an axial load to the drill guide against the glenoid bone **[FIG 18]**. After each hole is drilled, the surgeon inserts a Locking Peg into each hole. The third hole is drilled using the 4.5 mm Drill making sure the Drill seats fully **[FIG 19]**. Remove any sharp bone corners and displaced fragments with a small curette. The glenoid bone preparation is now complete.

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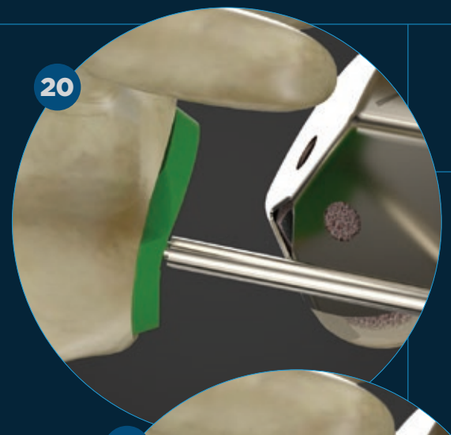
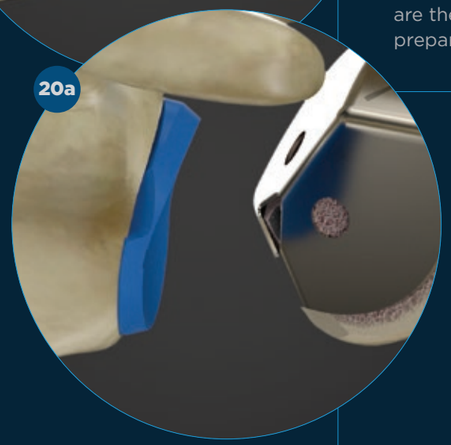
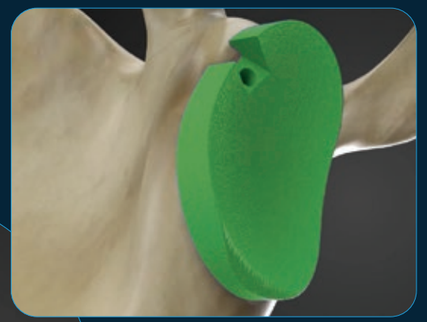
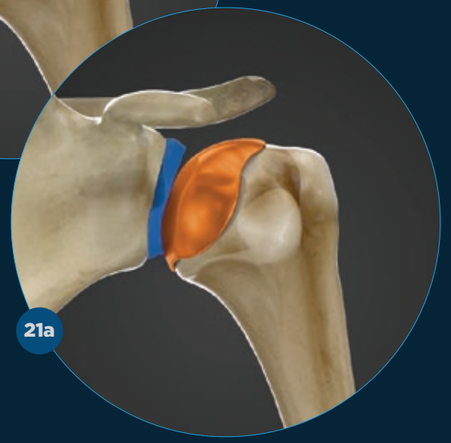


GLENOID AND HUMERAL TRIAL INSERTION

The surgeon then inserts a trial glenoid component of the chosen size **[FIG 20]**, along with the chosen humeral trial, and the shoulder is checked for stability and range of motion **[FIG 21]**. The surgeon may use an augmented glenoid component if necessary. **[FIG 20a** and **FIG 21a]**. *Note: The Glenoid Trial Inserter may be threaded onto the Trial for ease of insertion and removal.* Both trial components are then removed, the retractors are re-inserted and the cement is prepared for insertion of the final implants.







PROSTHESIS IMPLANTATION

Fill the glenoid anchor holes with cement. *Note: The Cement Tamp may be used to pressurize the cement.*

Insert the glenoid implant by hand, and then impact it using the angled Glenoid Implant Impactor. Remove any excess cement posterior to the fully seated implant. Apply pressure to the glenoid implant using a thumb or the Glenoid Implant Impactor until the cement has hardened.

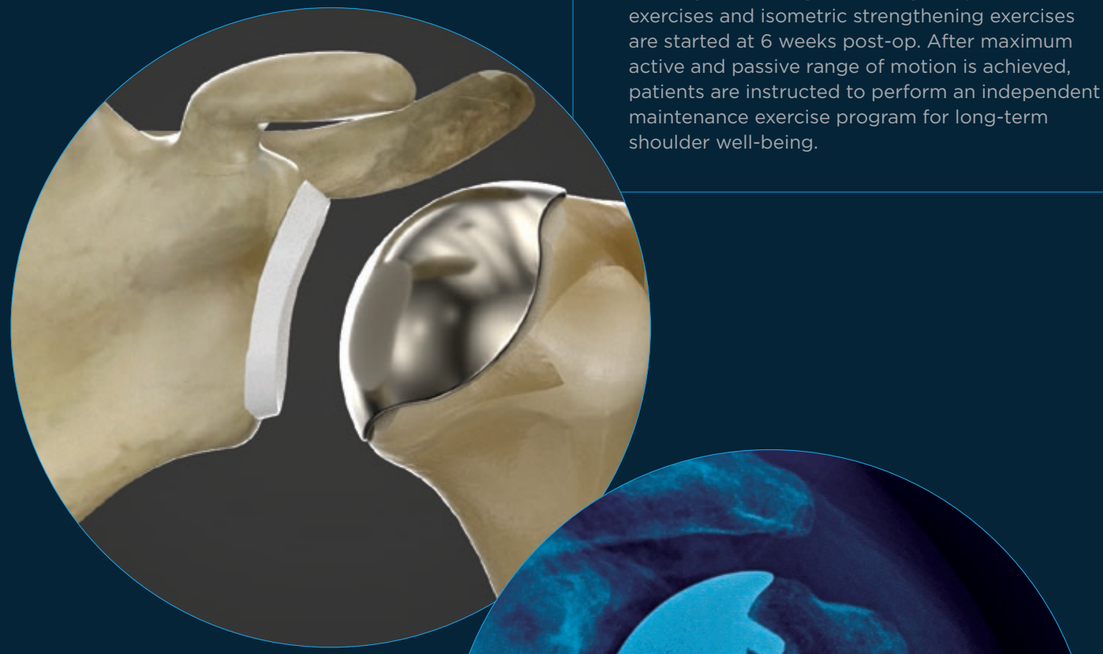
The humerus is then delivered anteriorly. *Note: If the surgeon is repairing the subscapularis through bone tunnels, sutures should be placed at this time, prior to humeral implant insertion. Suture anchors may also be utilized after humeral implant insertion.*

After washing and drying the proximal humerus, apply a layer of cement over the holes and the cut surface along with a small portion of cement to the undersurface of the humeral implant. If using a Press Fit humeral implant, no cement is necessary. Insert the implant by hand and utilize the Humeral Implant Inserter to ensure the implant has been fully seated. *Note: As with the glenoid, excess cement may need to be removed just posterior to the implant.*

If humeral cement has been used, proceed once it has hardened. Otherwise, proceed directly to irrigate the glenohumeral joint, reduce the shoulder, and begin closure with subscapularis repair. Approximate the deltopectoral interval with nonabsorbable suture. Perform subcutaneous and skin closure according to the surgeon's preference.

POSTOPERATIVE REHABILITATION

The arm is placed into a sling after surgery and worn for 4-6 weeks. Pendulum exercises are started immediately postoperatively four times daily along with active hand, wrist and elbow exercises. After the first postoperative checkup, outpatient therapy is begun consisting of passive exercises for 4-6 weeks, with the limit of no external rotation of the arm beyond 20 degrees during this period. Active exercises and isometric strengthening exercises are started at 6 weeks post-op. After maximum active and passive range of motion is achieved, patients are instructed to perform an independent maintenance exercise program for long-term shoulder well-being.



REMOVAL OF IMPLANTS

HUMERUS

If removal of the humeral prosthesis is desired, the surgeon places a small osteotome between the underside of the prosthesis and the humerus bone, and gently works the osteotome under the implant with a mallet. Once the osteotome has been inserted fully the osteotome is removed and the process is repeated adjacent to the area just completed. It is important to undermine the implant under all four underside flat surfaces with the osteotome before trying to remove the implant. The surgeon continues undermining the implant circumferentially around the border of the implant until it is loosened from the proximal humerus bone.

GLENOID

If removal of the glenoid prosthesis is desired, the surgeon places a small osteotome between the underside of the prosthesis and the glenoid bone, and gently works the osteotome under the implant with a mallet. The surgeon gently levers the implant out from the glenoid vault. If the implant does not lever easily, the use of a fine oscillating saw with a short blade may be used beneath the backside of the glenoid implant to detach the bearing surface from the anchoring portion embedded in the glenoid vault.

PLEASE CONSULT THE PACKAGE INSERT FOR A COMPLETE LIST OF CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND POTENTIAL ADVERSE EVENTS.

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ORDERING INFORMATION

HUMERAL IMPLANTS

PART #	DESCRIPTION
1226-7200-001	Humeral Implant, Size A
1226-7200-002	Humeral Implant, Size B
1226-7200-003	Humeral Implant, Size C
1226-7200-004	Humeral Implant, Size D
1226-7200-005	Humeral Implant, Size E
1226-7200-006	Humeral Implant, Size F
1226-7200-007	Humeral Implant, Size G
1226-7200-008	Humeral Implant, Size H
1226-7200-009	Humeral Implant, Size I

PART #	DESCRIPTION
1228-7300-001	Press Fit Humeral Implant, Size A
1228-7300-002	Press Fit Humeral Implant, Size B
1228-7300-003	Press Fit Humeral Implant, Size C
1228-7300-004	Press Fit Humeral Implant, Size D
1228-7300-005	Press Fit Humeral Implant, Size E
1228-7300-006	Press Fit Humeral Implant, Size F
1228-7300-007	Press Fit Humeral Implant, Size G
1228-7300-008	Press Fit Humeral Implant Size H
1228-7300-009	Press Fit Humeral Implant Size I

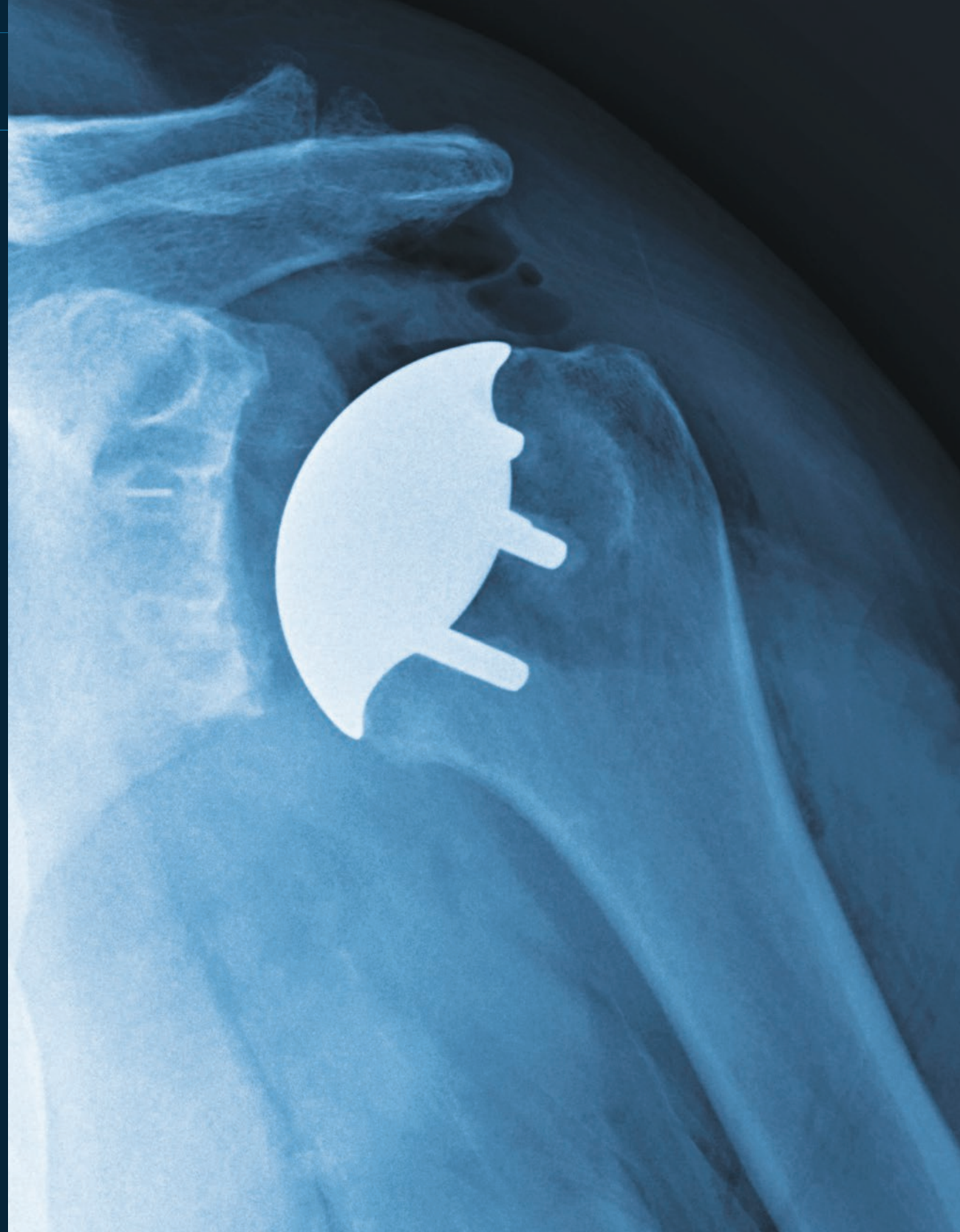
GLENOID IMPLANTS

PART #	DESCRIPTION
1227-7001-001	3-Peg Glenoid, SM
1227-7001-002	3-Peg Glenoid, M
1227-7001-003	3-Peg Glenoid, L

PART #	DESCRIPTION
1227-7003-001	Augmented 3-Peg Glenoid, SM
1227-7003-002	Augmented 3-Peg Glenoid, M
1227-7003-003	Augmented 3-Peg Glenoid, L

DISPOSABLES

PART #	DESCRIPTION
1226-4074-001	Short Securing Pin
1226-4074-002	Starting Guide Pin
1229-7430	Sterile Humeral Cut Guide Fixation Kit



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