

SEVIIN[®]

Primary & Reverse
Shoulder System



Ingen
Orthopedics, LLC

One Set of Implants

One Set of Instruments

Seven Shoulder Solutions



I SEVIIN® Surface Replacement



II SEVIIN® Primary Fracture



III SEVIIN® Reverse Fracture



IV SEVIIN® Primary Hemi



V SEVIIN® Primary Keeled



VI SEVIIN® Primary Pegged



VII SEVIIN® Primary Reverse

Ingen *SEVIIN*[®] Shoulder System

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DESCRIPTION

The Ingen SEVIIN Primary Shoulder System includes an individually packaged humeral stem, a metal head and a glenoid component manufactured from ultra-high molecular weight polyethylene. A hemi-shoulder includes the humeral stem and metal head.

The Ingen SEVIIN Reverse Shoulder includes an individually packaged metal humeral cup and a poly inlay manufactured from ultra-high molecular weight polyethylene on the humeral side. The glenoid components include a Titanium Plasma Spray (TPS) coated metaglene plate, a metal glenosphere and reverse bone screws. These components are intended for use with the SEVIIN Humeral Primary Stems.

INDICATIONS

Total shoulder or hemi-shoulder replacement is indicated for a severely painful and disabled joint due to osteoarthritis, traumatic or rheumatoid arthritis. The device may also be used for fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from blood supply or where experience indicates that alternative treatment is unsatisfactory. Hemi-shoulder replacement is indicated for un-united or malunited humeral head fractures or avascular necrosis of the humeral head.

Reverse shoulder replacement is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral component is intended for cemented use and the TPS coated metaglene component is intended for cementless use with the addition of screws for fixation.

WARNINGS

A number of pre-existing conditions can affect the outcome of shoulder arthroplasty. These include: tumors in the operative area, osteoporosis (see contraindications), a history of allergic reactions to cobalt, chromium, nickel or molybdenum, previous tissue reactions to UHMW polyethylene or metallic debris, severe bony deformities which may lead to improper fixation or positioning of the implants, metabolic diseases (i.e., diabetes), prolonged immunosuppressive or steroid therapy, and a history of generalized or local infections.

It is critical that implants from different manufacturers are not used together in an arthroplasty procedure. Specifications are not the same and there is no assurance of a proper fit or tolerances between components.

Implants should never be reused. Previous use may lead to stress risers or other imperfections which would jeopardize performance of the device and its longevity.

The surgeon should use provisional prostheses for trials to avoid damaging the device intended for final implantation. Proper handling of all implantable components is critical to the success of total joint replacement.

CONTRAINDICATIONS

Shoulder arthroplasty is contraindicated in patients with active localized or systemic infections, inadequate bone stock in the operative area which would preclude a successful result, or where poor bone quality would compromise the overall success and result in migration of the components or fracture of the humerus or glenoid. Other relative contraindications relate to absent, irreparable, or nonfunctional rotator cuff or other essential muscles.

PRECAUTIONS

Preoperative planning and the surgical technique are based on principles that provide for sound surgical handling. Complete familiarity with the surgical technique is essential in reverse shoulder arthroplasty. The use of specific surgical instruments is recommended for each operation.

A number of patient conditions could affect the long-term success of shoulder arthroplasty, and the surgeon should consider them carefully. They include: active sports participation, the type of labor performed by the patient, alcohol or drug addiction, and the patient's ability to understand and participate in the post-surgical regimen.

Patients should be advised about the limitations and precautions related to shoulder replacement surgery, written instructions should be considered. It may be advisable to restrict certain activities to preclude dislocation or loosening of the prostheses. Patients should be told to report any unusual changes in the operated arm as soon as practical. Regular follow-up visits are advised.

ADVERSE EFFECTS

Premature device failure related to excessive physical activity or trauma has been reported. The most frequently reported adverse effects are as follows, some may not be device-related: early or late loosening of components, infection, device subsidence or subluxation, decreased range of motion, absence of external shoulder rotation, damage of the prosthetic components or surrounding tissues, hematoma or delayed wound healing, venous thrombosis, cardiopulmonary problems, and continued pain.

STERILITY

The implantable components are provided presterile by gamma irradiation. The device is intended for single use. The instrument set and individual instruments are available nonsterile and must be sterilized prior to clinical use. Steam sterilization is recommended for the instrument case.

MRI INFORMATION

The Ingen SEVIIN Shoulder System has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

Rx-Only

Ingen SEVIIN® Shoulder System

Primary Shoulder System

Stems

Titanium 6Al-4V alloy

On-Growth Surface: carborundum-blast surface on proximal end of the stem

Reverse Morse Taper: designed to mate with humeral heads and humeral cup

Lateral, Anterior and Posterior Fins: provide for soft tissue attachment

Smooth Distal Stem: to minimize stress shielding of the humerus

Anatomical Medial Curve: improves fit of the stem to proximal humerus

Distal Flutes: increase stem flexibility; allows for medullary revascularization

Reduced Collar Size: increases visibility of the stem/bone interface

Sizes

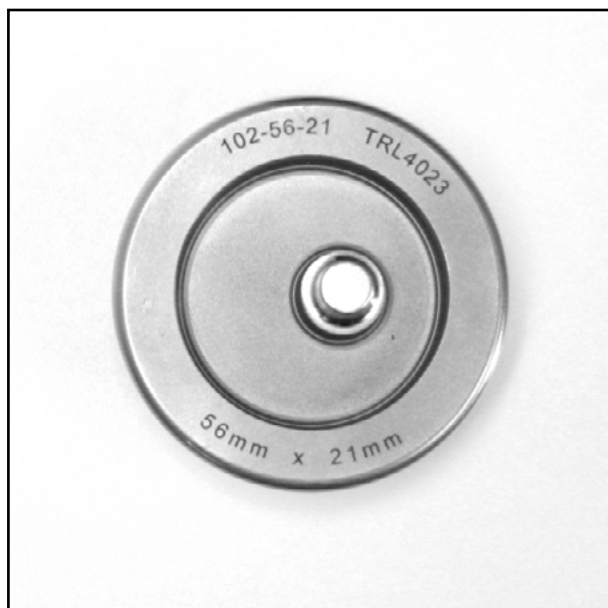
Size 1: 6mm x 100mm

Size 2: 8mm x 110mm

Size 3: 10mm x 120mm

Size 4: 12mm x 120mm

Size 5: 14mm x 125mm



Heads

Co-Cr Alloy

Morse Taper Trunion: designed to mate with the humeral stems

Low Profile Design: optimizes articulating surface area

4mm Offset: accommodates anatomical variations

Sizes

Standard

Diameter: 40, 44, 48, 52, 56mm

Height: 15, 18, 21mm

Offset

Diameter: 44, 48, 52, 56mm

Height: 18, 21mm

Glenoids

UHMWP

Pear-Shaped Frontal Profile: provides for anatomical fit and helps prevent soft tissue impingement

Articulating Surface: radius is oversized to provide translation and accommodate multiple humeral heads

Peg Design: 3 linear pegs, designed to avoid punch-through of thin cortical walls of glenoid periphery

Keel Design: allows for easy intra-operative conversion from Pegged to Keeled Glenoid

Sizes

X-Small
Small
Medium
Large



Ingen SEVIIN® Shoulder System

Reverse Shoulder System

PE-Inlay

UHMWP

Two Cup Depths: Centered and Retentive

Retentive Option: 2.4mm deeper cup to provide additional joint stability, if needed

Anti-rotational Design

Snap-Fit Mechanism: laboratory tested

Sizes

Centered & Retentive

Diameter: 36mm & 40mm

Thicknesses: 0, +3mm, +6mm

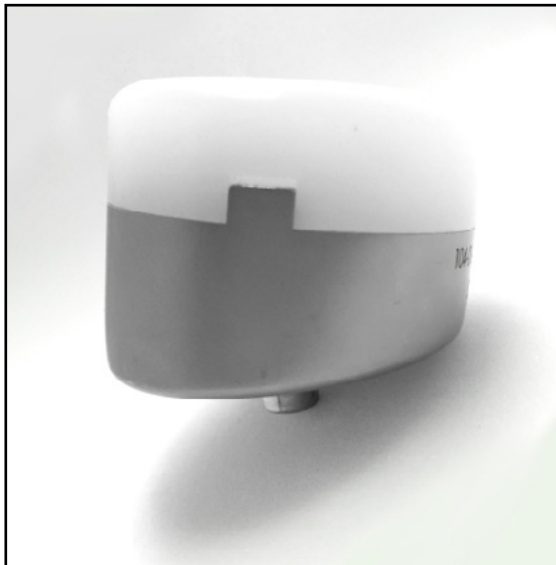
Humeral Cup

Co-Cr Alloy

Morse Taper Fixation: designed to mate with the humeral stems

+9mm Option: available to provide for lengthening the prosthesis

12° Angle: to make the scapular neck-humeral shaft angle 147°



Screws

Titanium Alloy: self-tapping 4.5mm bone screws

Sizes

15, 20, 25, 30, 35, 40mm

Metaglène Plate

Titanium 6Al-4V Alloy

9mm Cannulated Central Screw: to provide for primary fixation

Morse Taper Trunion: designed to mate with the reverse glenosphere

Titanium Plasma Spray Coated

4 Holes: for peripheral screw fixation

Sizes

25mm & 29mm



Glenosphere

Co-Cr Alloy

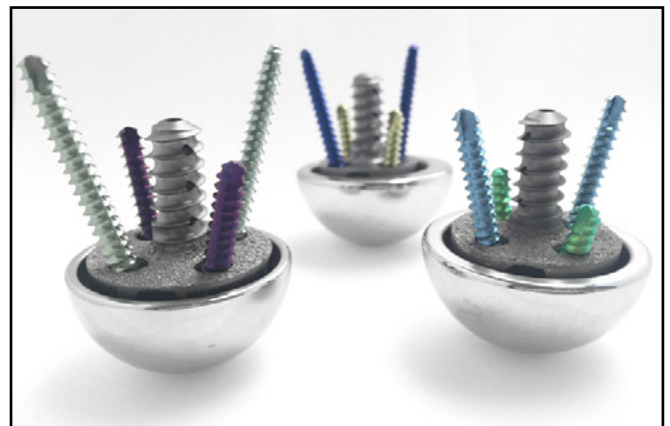
Reverse Morse Taper: fixation to the metaglène plate

Recessed Glenosphere Screw: for added security of fixation

1mm Clearance Gap: between the glenosphere and bottom of the metaglène plate

Sizes

Standard, +4mm, & Eccentric
Diameter: 36mm & 40mm



Ingen *SEVIIN*[®] Shoulder System

Humerus Preparation

Humeral Head Resection

The head of the humerus is resected exactly at the level of the anatomical neck of the humerus. Above and to the upper anterior aspect, the anatomical neck of the humerus corresponds to the tendon insertions of the rotator cuff. In the region of the infraspinatus muscle and the teres minor muscle, there is a bare area without cartilage and without tendon insertions. The osteotomy should be made here, directly on the edge of the cartilage. The cartilage-free area is not restricted.

Free Hand Technique

Place the appropriate Osteotomy Guide and adjust it to the appropriate level for the head resection. Using an oscillating saw, cut parallel to the Osteotomy Guide until the humeral head is resected.

Sizing the Humeral Head

Using the resected humeral head, assess the height and diameter with the Humeral Head Gauge.



Humeral Head Resection

Using a high-speed burr, bore a pilot hole through the humeral head along the axis of the humeral shaft. Starting with the 6mm hand reamer, begin reaming and continue to ream using successively larger reamers as required (8, 10, 12, 14mm).

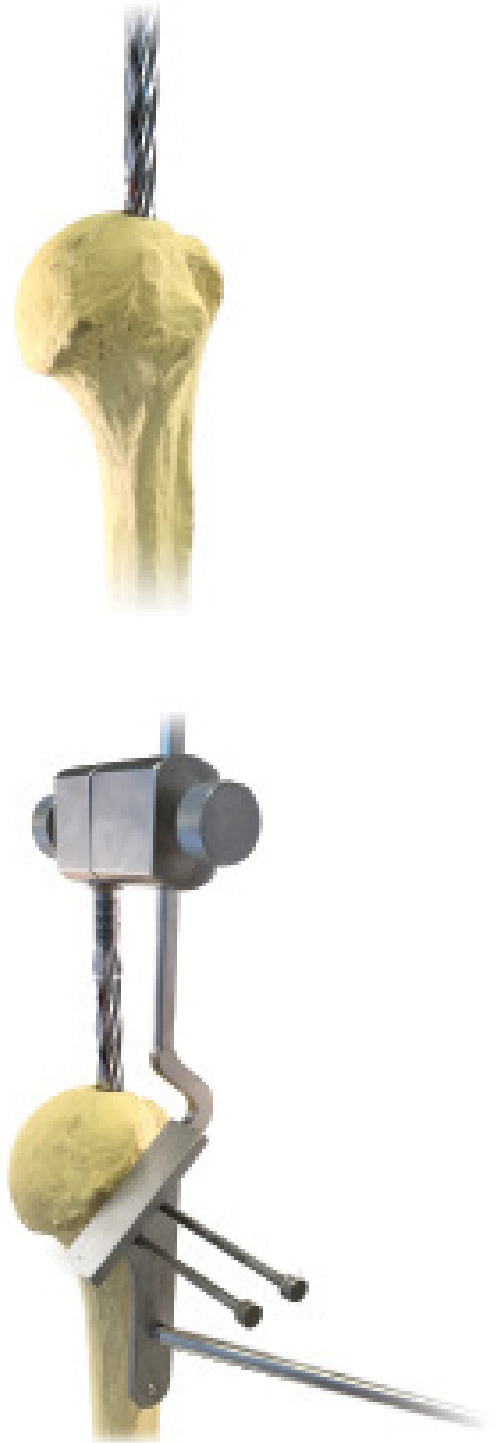
Each Humeral Reamer has two grooves to indicate depth. The lower, distal groove indicates the depth of reaming for standard size stems; the upper, proximal groove indicates the depth for long stems.

Intramedullary Resection Technique

Place the Cutting Guide Holder on the top of the Humeral Reamer and lock it into place. Slide the appropriate Cutting Guide (Left or Right) into the Cutting Guide Holder and adjust it to the required resection level.

Humeral retroversion is determined by using the forearm as a reference point to the bicondylar axis of the humerus. Align the retroversion Alignment Rod parallel to the forearm to recreate a preferred humeral neck resection. The Alignment Rod is angled at 30 degrees.

Using an oscillating saw, make the initial cut parallel to the Cutting Guide. After the initial cut is made, remove the Cutting Guide and Reamer and complete the cut by using freehand technique or by holding the Cutting Guide next to the humeral head until it is fully resected.



Ingen SEVIIN® Shoulder System

Humerus Preparation

Humeral Canal Reaming

Proceeding stepwise, the medullary cavity is reamed, starting with the 6mm hand reamer and using successively larger reamers as required (8, 10, 12, 14mm).

Each Humeral Reamer has two grooves to indicate depth. The lower, distal groove indicates the depth of reaming for standard size stems; the upper, proximal groove indicates the depth for long stems.

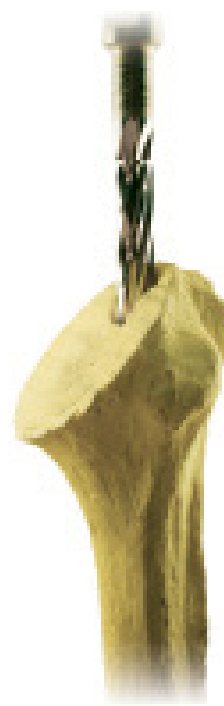
Humeral Canal Rasping

The proximal portion of the humerus is prepared proceeding stepwise, starting with the body-sizing Rasp corresponding to the largest reamer previously used.

Reamers and body-sizing rasps correspond as follows:

Reamer Body	Sizing Rasp
6mm	#1
8mm	#2
10mm	#3
12mm	#4
14mm	#5

Care must be taken to ensure that the Rasps are introduced completely, until the collar rests on the cut surface of the humerus. Do not drive the collar into the cancellous bone. If the top of the body-sizing Rasp penetrates below the level of the osteotomy of the head, an uncemented, or press-fit, stem of this size may not be used.



Humeral Canal Rasping

As a guide for proper alignment and retroversion, attach the Alignment Rod to the right or left hole in the Rasp Handle. Externally rotate the forearm, and align the Rod parallel to the forearm maintaining approximately 30 degrees of humeral retroversion.

The correct stem size is determined by reaming and rasping with the Body-Sizing Rasps.

Starting with the Body-Sizing Rasp having the same diameter as the largest Reamer previously used, rasp the proximal humerus with successively larger Rasps until cortical bone is reached.

To help ensure a correct press-fit, the final humeral prosthesis is designed to be 1 mm larger than the corresponding Rasp size.

With the Rasp in place, remove any osteophytes that might extend from the cut surface of the neck of the humerus, using an osteotome or rongeur.

Leaving the Body-Sizing Rasp in the humerus while preparing the glenoid is recommended. This protects the proximal humerus from compression fracture or deformation by the retractor.



Ingen *SEVIIN*[®] Shoulder System

Glenoid Preparation

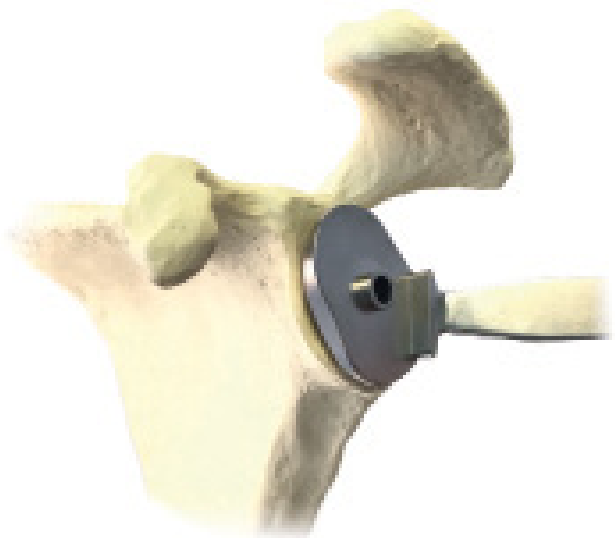
Glenoid Templating

A set of four Glenoid Templates (X-Small, Small, Medium, Large) are provided to help determine the proper size glenoid to select.



Glenoid Preparation

To create the central hole in the glenoid, use the appropriate Center Hole Drill Guide (X-Small, Small, Medium, Large). Advance the Glenoid Drill until the bit bottoms out on the guide. This will result in proper placement of the Glenoid Reamer.



Glenoid Reaming

Attach the appropriately sized Glenoid Reamer (X-Small, Small, Medium, Large) to the power drill. With the Reamer engaged, insert the central peg into the pilot hole in the glenoid and apply gentle pressure to the reamer.

Gradually increase pressure on the Reamer.

Ream only until the surface of the glenoid fossa is smooth.

The open-backed Ingen Glenoid Reamers provide for excellent visualization of the glenoid surface.

Pegged Glenoid Preparation

Following the glenoid reaming, place the post of the Peg Drill Guide into the central hole in the glenoid. Drill the superior hole first and place the anti-rotation peg to prevent any rotation of the guide while the other hole is being drilled. Drill the inferior hole in the same fashion. This will result in proper alignment of the peg holes.



Ingen SEVIIN® Shoulder System

Glenoid Preparation

Pegged Glenoid Preparation

Insert the previously selected Trial Pegged Glenoid and keep it in place during sizing of the Trial Humeral Head. The pegs of the Trial Glenoid prostheses are a little larger than the pegs on the final prosthesis.

The Ingen Glenoid diametric curvature is larger than the Humeral Head to allow for up to 6mm of diametric mismatch between the Humeral Head and Glenoid.

Size	Trial Color	"Mismatch"
X-Small	Red	40, 44mm
Small	Brown	40, 44mm
Medium	Purple	48, 52mm
Large	Gray	52, 56mm



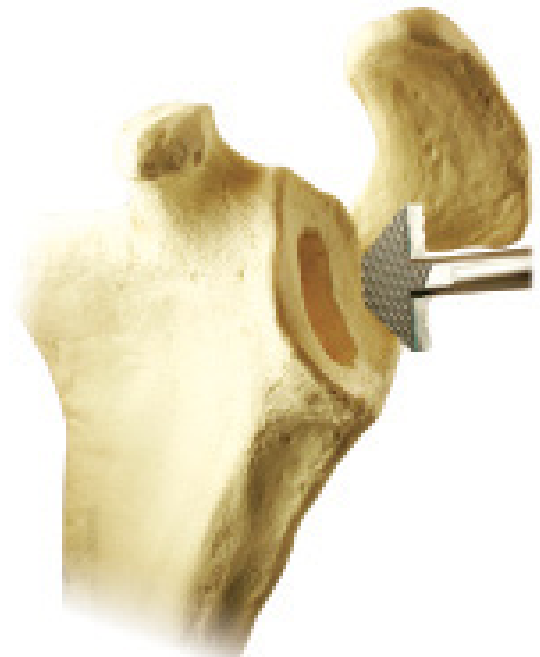
Keeled Glenoid Preparation

If using a Keeled Glenoid, prepare the glenoid fossa as previously described (see preceding sections, Glenoid Preparation and Pegged Glenoid Preparation).

Using a power burr, rongeur or curette, connect the holes for the keel of the prosthesis. Use the Keel Punch (rasp) for accurate sizing and fitting.

Insert the appropriate Keeled Glenoid Trial prosthesis.

Keep the trial prosthesis in place during sizing of the Trial Humeral Head.



Ingen SEVIIN® Shoulder System

Humeral Head Selection

Trial Humeral Head Selection

Select the Trial Head that matches the height and diameter of the measured resected head (see pg 15). Place the Trial Head in the Rasp that has been left in the Humerus.

For Offset Head Trials, rotate the head into the desired position and use the tightening screw to hold it in place during trial reduction.

Standard Trials for Rasps

Diameter	Color	Height
40mm	Red	15, 18, 21mm
44mm	Yellow	15, 18, 21mm
48mm	Green	15, 18, 21mm
52mm	Blue	15, 18, 21mm
56mm	Black	15, 18, 21mm

Offset Trials for Rasps

Diameter	Color	Height
44mm	Yellow	18, 21mm
48mm	Green	18, 21mm
52mm	Blue	18, 21mm
56mm	Black	18, 21mm

Offset Trials with Tapers, for Stems

Diameter	Color	Height
44mm	Red	18, 21mm
48mm	Brown	18, 21mm
52mm	Purple	18, 21mm
56mm	Gray	18, 21mm

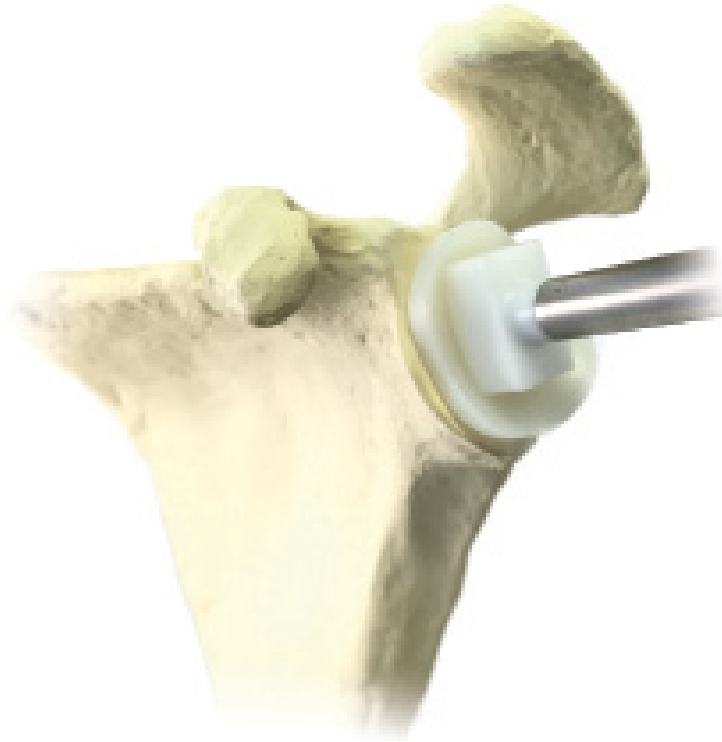


Inserting the Glenoid

The surface of the glenoid and the anchoring holes or keel slot are now carefully cleaned and dried.

The anchoring holes or keel slot are filled with bone cement, and the cement is pressed into the bone with a clean sponge.

Insert the Ingen Glenoid and hold it in place with the Glenoid Pusher until the cement is cured.



Ingen *SEVIIN*® Shoulder System

Inserting the Stem and Head

Inserting the Stem

The final prosthesis is 1mm larger than the Body-Sizing Rasp to facilitate, whenever possible, a firm press-fit.

If the Body-Sizing Rasp is loose after humeral canal preparation, use autogenous bone graft from the resected humeral head, or cement, to achieve good fixation of the final prosthesis. For this purpose, it is recommended that all of the cancellous bone in the humeral head be removed and saved on the back table. If bone graft is used, place the cancellous bone in the medullary canal, particularly into the inter-tuberosity region, and compact it by repeated insertion of the Body-Sizing Rasp. Do not advance the rasp or prosthesis beyond the humeral osteotomy plane.

The decision to use cement or a press-fit technique is the individual surgeon's prerogative.

If cement is used for fixation of the prosthesis, a humeral stem of a smaller size than the Rasp should be implanted to allow an appropriate cement mantle to be created. In certain circumstances, such as previous surgical procedures, fractures, osteoporosis or a degenerative cyst in the humerus, it may be necessary to use cement.

Inserting the Head

Use the Humeral Head Impactor to tap the appropriately sized head onto the stem to achieve a tight Morse taper fit.



Ingen, as a manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to use on each individual patient.

Primary



Reverse



Ingen *SEVIIN*[®] Shoulder System

Humeral Head Selection

The Humeral Stem for the Ingen Primary TSA and Ingen Reverse TSA is the same. See the Ingen Primary TSA Procedure Guide for instructions on preparing the humerus and implanting the Humeral Stem.

Resect the Humeral Head



Ream the Humeral Canal



Rasp the Humeral Canal



Glenoid Preparation

After exposure of the glenoid is obtained, use a drill and the Central Hole Drill Guide to insert the 2.4mm Guide Pin into the glenoid where the Metaglene Plate is to be placed.

Next, attach the cannulated, 29mm Glenoid Resurfacing Reamer to a drill or the T-Handle, depending on the preferred method of reaming.

Place the 29mm Glenoid Resurfacing Reamer over the 2.4mm guide pin and ream the glenoid until the surface of the glenoid is smooth and flat.

If necessary to remove osteophytes and other tissue from a wider diameter area, repeat the process with the 40mm Glenoid Peripheral Reamer.

The open design of the Ingen Glenoid Resurfacing Reamers provides for excellent visualization of the glenoid surface during the reaming process.

Leave the 2.4mm Guide Pin in place in the glenoid.



Ingen SEVIIN® Shoulder System

Inserting the Metaglène Plate

Inserting the Metaglène Plate

Primary objectives of placing the Metaglène Plate:

- Maximum contact area with the glenoid
- Secure placement of peripheral screws

The Metaglène Plate should be placed inferiorly, centered on the lower circle of the glenoid. Osteophytes, cartilage and soft tissue that might prevent contact between the glenoid bone and the Metaglène Plate must be removed prior to implantation.

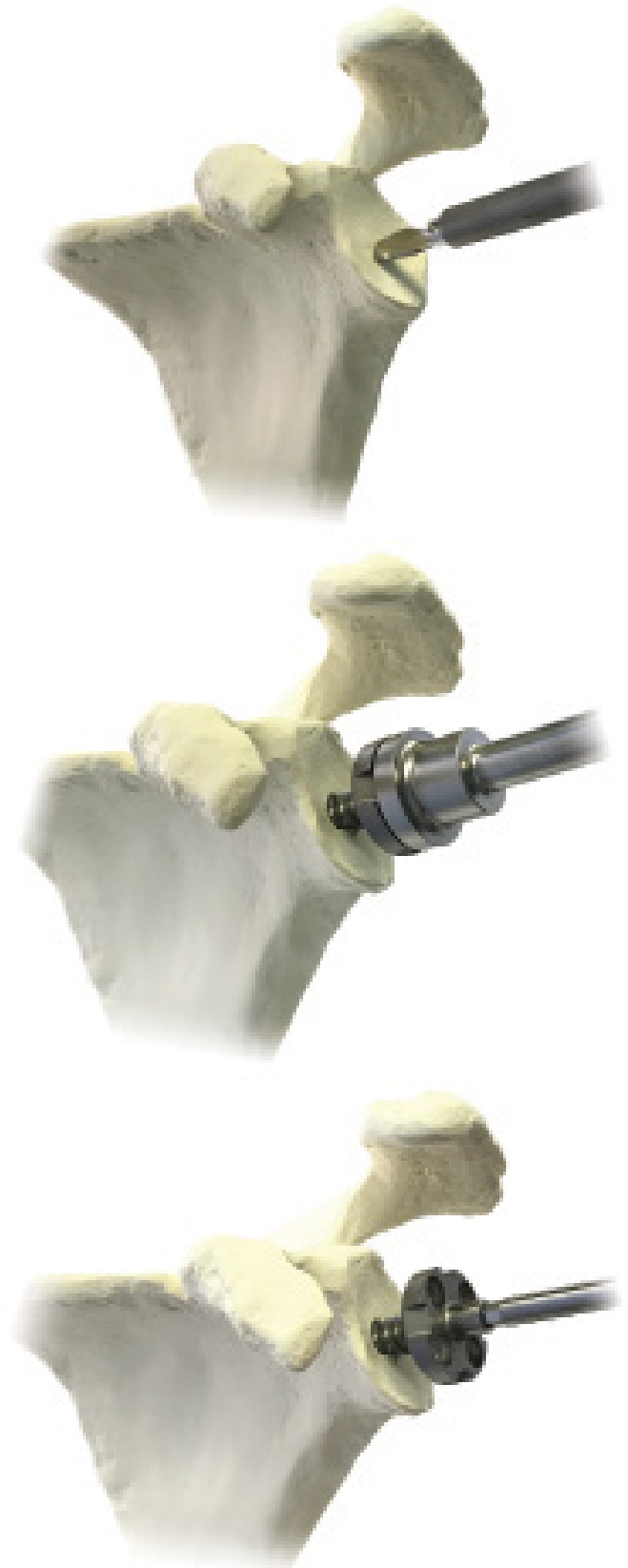
After the glenoid surface is prepared, place the cannulated, 6.8mm Drill Bit into a drill and place it over the 2.4mm Guide Pin.

Drill until the 6.8mm Drill Bit bottoms out (until the wider edge of the drill is flush with the glenoid surface). This will provide the proper depth for the threaded, central post of the Metaglène Plate.

Remove the 2.4mm Guide Pin.

Place the Metaglène Plate onto the Metaglène Plate Inserter/Extractor and use the Inserter to insert the Metaglène Plate into the 6.8mm hole until it is fully seated against the reamed glenoid surface and the superior and inferior Peripheral Screw holes in the Metaglène Plate are properly oriented in the glenoid for placement of the superior and inferior screws.

If greater visualization of the Metaglène Plate is desired for insertion, the 4.5mm Hex Screwdriver can be used instead of the Metaglène Plate Inserter/Extractor to insert the Metaglène Plate.



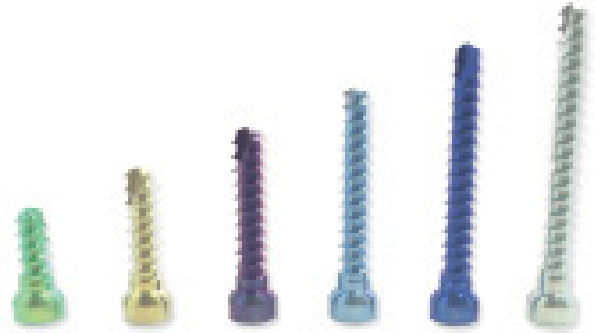
Inserting the Peripheral Screws

- Peripheral screws are self-tapping 4.5mm bone screws, 15-40mm in length, in 5mm increments.

The Metaglene Plate has four screw holes to accommodate the placement of up to four self-tapping 4.5mm Peripheral Bone Screws to provide additional fixation of the Metaglene Plate.

The non-locking design of the Peripheral Bone Screws in the Metaglene Plate provides for placement of the Peripheral Bone Screws at any angle within a 12-degree arc.

Using the Angled Drill Guide and the 3mm Drill Bit, drill the holes for placement of the Peripheral Bone Screws.



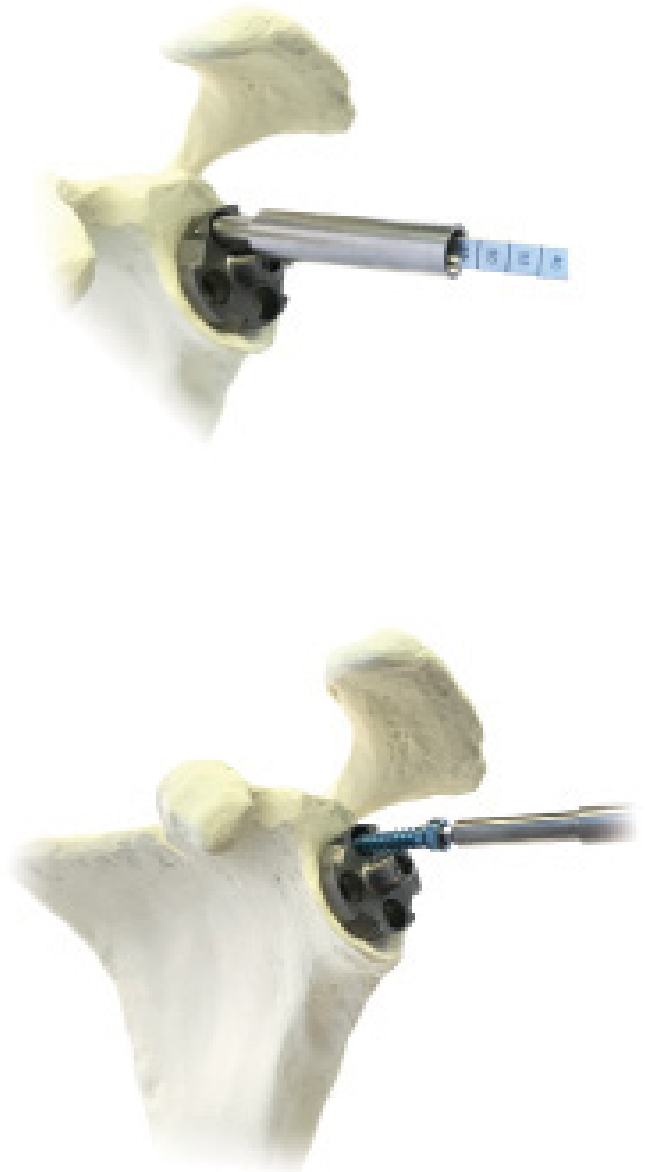
Ingen *SEVIIN*[®] Shoulder System Inserting the Peripheral Screws

Inserting the Peripheral Screws

Depth of the screw holes can be measured using the 10mm-increment depth markings on the drill bit or the standard Depth Gauge provided.

Using the Angled Drill Guide, the superior and inferior screws should be placed first, followed by the anterior and posterior screws.

Fully tighten all peripheral screws so that the heads of the screws do not interfere with the seating of the glenosphere.



Reverse Glensphere Trial

The Reverse Glensphere Implants are available in two diameters, 36mm and 40mm, and come in a standard, +4mm, and eccentric option.

Fit the appropriate Trial Glensphere to the Metaglene Plate and lock it into place using the Morse taper.

For the Eccentric Trial Glenspheres, a trial screw is provided to hold the Trial Glensphere securely in place during the trial reduction.

Size	Option	Color
36mm	Standard	Green
36mm	+4mm	Blue
36mm	Eccentric	Gray
40mm	Standard	Yellow
40mm	+4mm	Purple
40mm	Eccentric	Brown



Ingen SEVIIN® Shoulder System Trial Reduction

Humeral Cup/PE-Inlay Trial

Select the appropriate one-piece Trial Humeral Cup/PE-Inlay. Note the “SUPERIOR” markings on the trial. Place the Trial Humeral Cup/PE-Inlay into the Rasp that has been left in the Humerus.

Use the tightening screw to hold the Trial Humeral Cup/PE-Inlay in place during the trial reduction.

There are two PE-Inlay options, Centered and Retentive. Each option is available in both 36mm and 40mm Diameters and each is offered in 3 different thicknesses: +0mm, +3mm, and +6mm.

The Standard Humeral Cup is typically used; however a +9mm option is available if greater height is needed to increase joint stability.

Size	Option	Humeral Cup
36mm	Centered	Standard
36mm	Centered	+9mm
40mm	Centered	Standard
40mm	Centered	Standard
36mm	Retentive	+9mm
36mm	Retentive	Standard
40mm	Retentive	+9mm
40mm	Retentive	Standard



Inserting the Glenosphere

After the Metaglene Plate is in place, insert the 1.6mm Guide Pin into the cannulated trunnion (central hole) of the Metaglene Plate.

Place the central hole of the Glenosphere over the Guide Pin and guide it onto the trunnion of the Metaglene Plate.

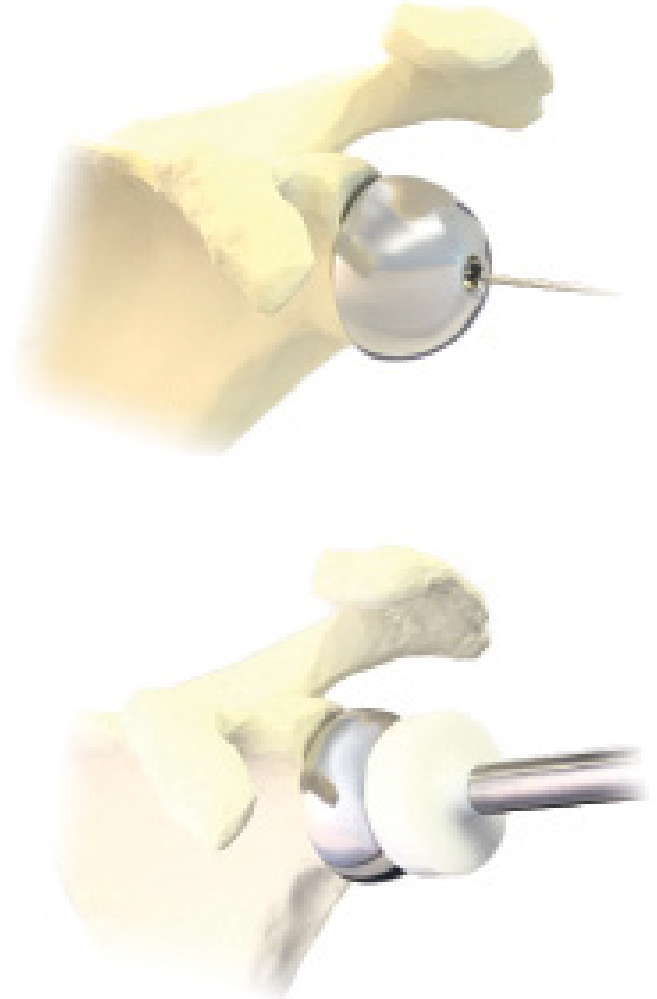
Complete the assembly of the Glenosphere and Metaglene Plate by placing the cannulated Glenosphere Impactor over the 1.6mm Guide Pin and locking the Morse taper with a mallet.

Once the Morse taper is set, remove the 1.6mm Guide Pin.

Insert the Glenosphere Screw through the center hole in the Glenosphere and into the trunnion of the Metaglene Plate.

Using the 2.5 mm Hex Screwdriver Bit and the Torque-Limiting screwdriver handle, tighten the Glenosphere Screw into the Metaglene Plate.

When the Glenosphere is fully seated, a 1mm clearance, or gap, will remain between the bottom of the Glenosphere and the bottom of the Metaglene Plate.



Ingen *SEVIIN*[®] Shoulder System Inserting the Stem

The Humeral Stem for the Ingen Primary TSA and Ingen Reverse TSA is the same. See the Ingen Primary TSA Procedure Guide for instructions on preparing the humerus and implanting the Humeral Stem.



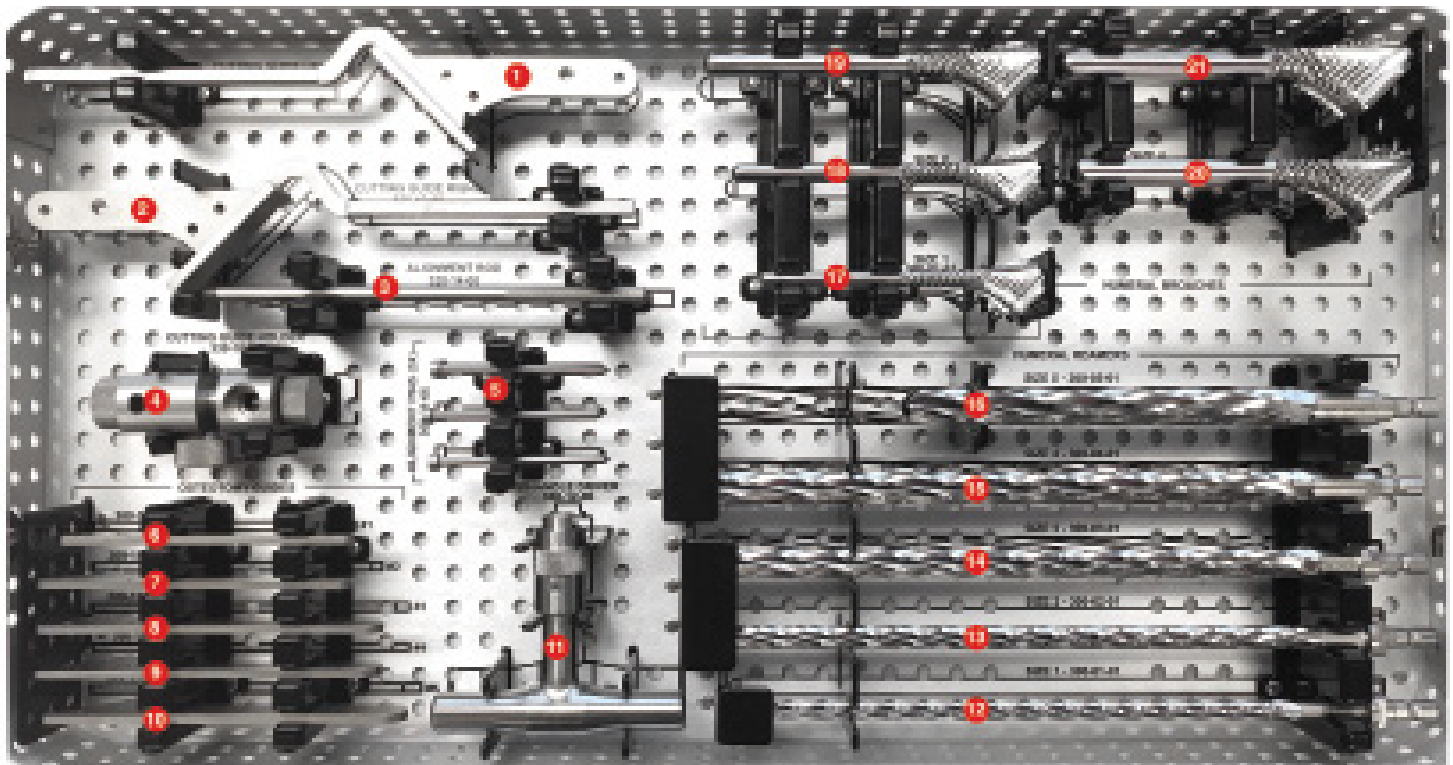
Humeral Cup & PE-Inlay Assembly

After selecting the appropriate Humeral Cup and PE-Inlay, use the assembly disc and PE-Inlay Impactor to snap lock the PE-Inlay into the Humeral Cup. An audible “CLICK” will be heard when the parts are fully engaged.

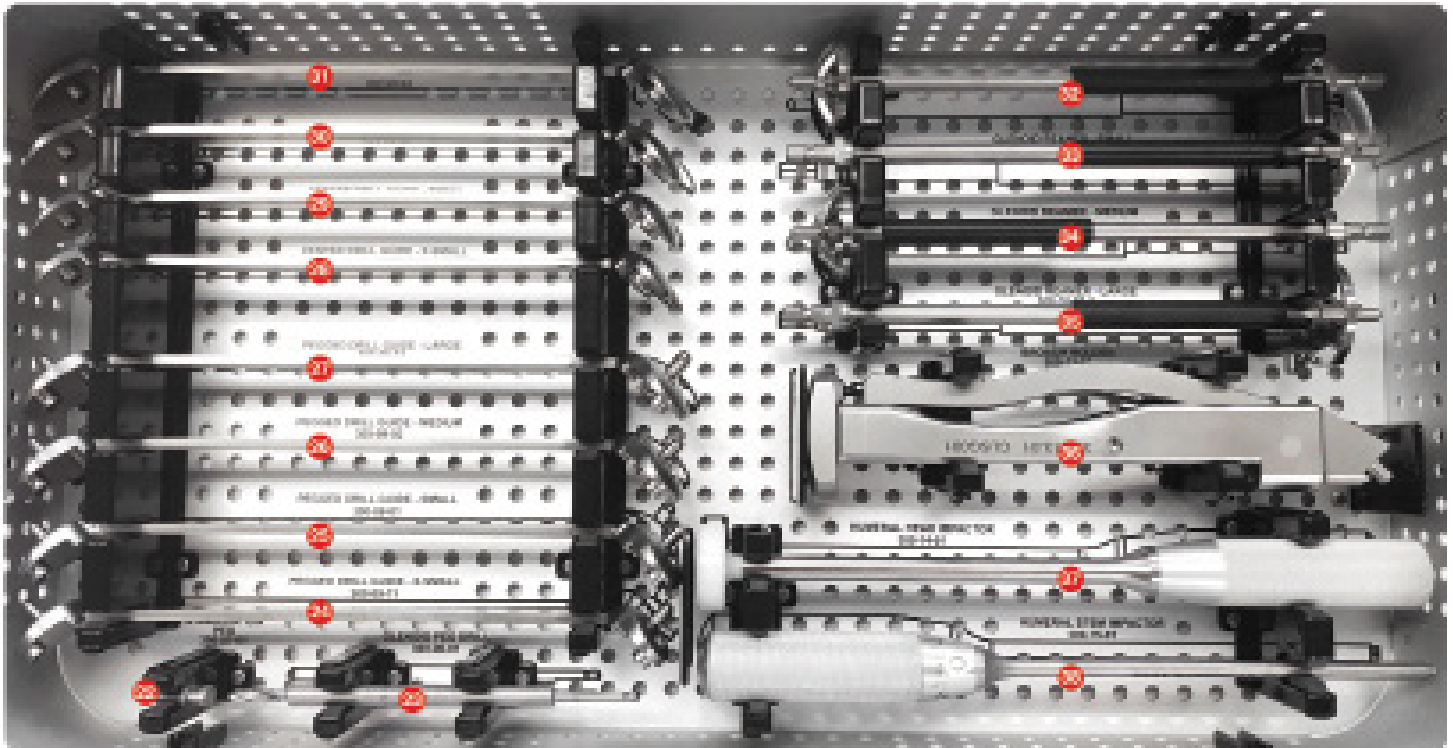
With two firm strikes of the PE-Inlay Impactor, Impact the assembled Humeral Cup and PE-Inlay into the Primary Stem. The Humeral Cup is marked “SUPERIOR” to aid in positioning the Humeral Cup and PE-Inlay with respect to the Stem.



Ingen *SEVIIN*® Shoulder System
Humeral Instruments: *Top Tray*



- | | | |
|--------------------------|------------------------|-----------------------|
| 1. Cutting Guide – Left | 8. Osteotomy Guide #3 | 15. Humeral Reamer #4 |
| 2. Cutting Guide – Right | 9. Osteotomy Guide #4 | 16. Humeral Reamer #5 |
| 3. Alignment Rod | 10. Osteotomy Guide #5 | 17. Humeral Rasp #1 |
| 4. Cutting Guide Holder | 11. T-Handle Driver | 18. Humeral Rasp #2 |
| 5. Alignment Pins (3x) | 12. Humeral Reamer #1 | 19. Humeral Rasp #3 |
| 6. Osteotomy Guide #1 | 13. Humeral Reamer #2 | 20. Humeral Rasp #4 |
| 7. Osteotomy Guide #2 | 14. Humeral Reamer #3 | 21. Humeral Rasp #5 |



- | | | |
|-------------------------------|----------------------------------|-----------------------------|
| 22. Stabilization Peg | 28. Center Drill Guide (X-SMALL) | 34. Glenoid Reamer (MEDIUM) |
| 23. Glenoid Peg Drill | 29. Center Drill Guide (SMALL) | 35. Glenoid Reamer (LARGE) |
| 24. Peg Drill Guide (X-SMALL) | 30. Center Drill Guide (MEDIUM) | 36. Broach Holder |
| 25. Peg Drill Guide (SMALL) | 31. Center Drill Guide (LARGE) | 37. Head Impactor |
| 26. Peg Drill Guide (MEDIUM) | 32. Glenoid Reamer (X-SMALL) | 38. Stem Impactor |
| 27. Peg Drill Guide (LARGE) | 33. Glenoid Reamer (SMALL) | |

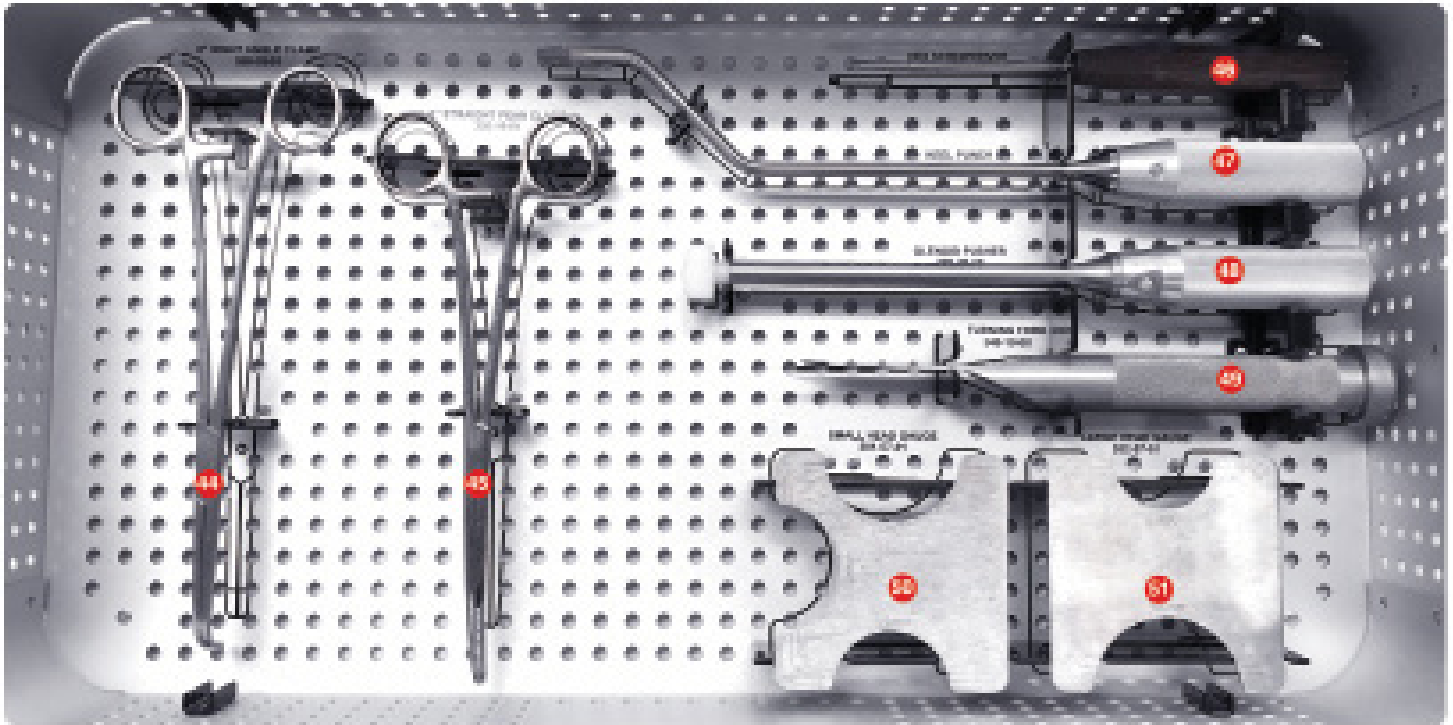
Ingen SEVIIN® Shoulder System
 Primary Trials: *Top Tray*



1. Offset 44 x 18
2. Offset 44 x 21
3. Offset 48 x 18
4. Offset 48 x 21
5. Offset 52 x 18
6. Offset 52 x 21
7. Offset 56 x 18
8. Offset 56 x 21
9. Standard 40 x 15
10. Standard 40 x 18
11. Standard 40 x 21
12. Standard 44 x 15
13. Standard 44 x 18
14. Standard 44 x 21
15. Standard 48 x 15

16. Standard 48 x 18
17. Standard 48 x 21
18. Standard 52 x 15
19. Standard 52 x 18
20. Standard 52 x 21
21. Standard 56 x 15
22. Standard 56 x 18
23. Standard 56 x 21
24. Offset Tapered 44 x 18
25. Offset Tapered 44 x 21
26. Offset Tapered 48 x 18
27. Offset Tapered 48 x 21
28. Offset Tapered 52 x 18
29. Offset Tapered 52 x 21
30. Offset Tapered 56 x 18

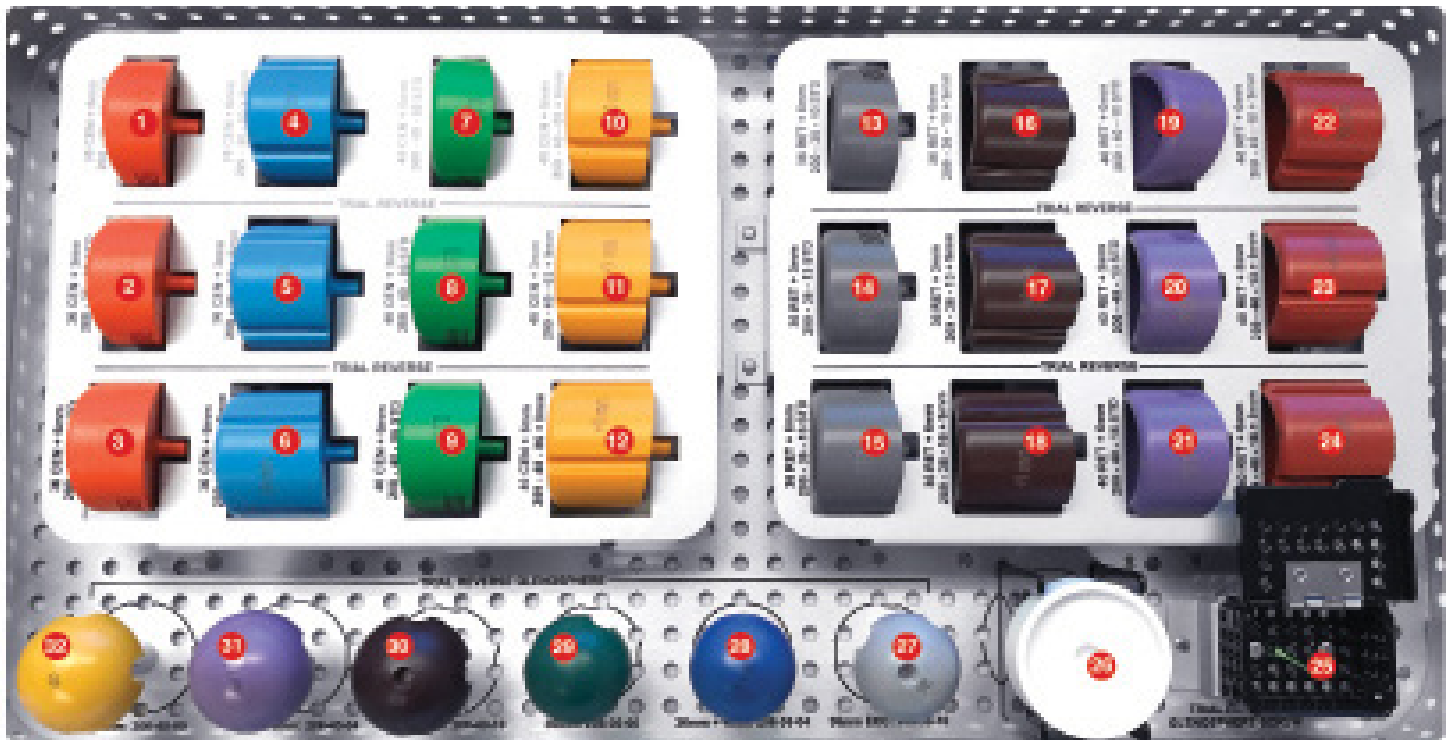
31. Offset Tapered 56 x 21
32. Keeled X-SMALL
33. Keeled SMALL
34. Keeled MEDIUM
35. Keeled LARGE
36. Glenoid Template X-SMALL
37. Glenoid Template SMALL
38. Glenoid Template MEDIUM
39. Glenoid Template LARGE
40. Pegged X-SMALL
41. Pegged SMALL
42. Pegged MEDIUM
43. Pegged LARGE



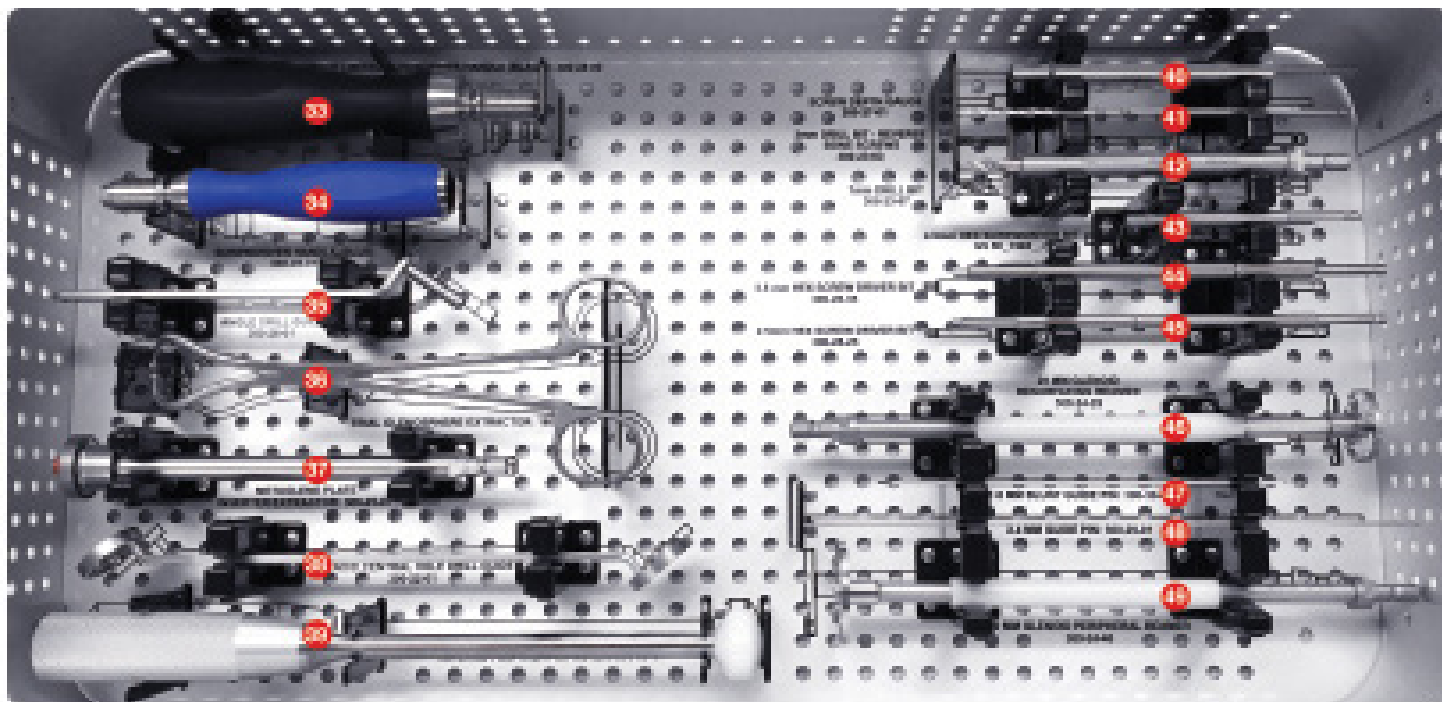
- 44. Right Angle Clamp
- 45. Straight Pean Clamp
- 46. 2.5mm Hex Screwdriver
- 47. Keel Punch

- 48. Glenoid Pusher
- 49. Turning Fork
- 50. Small Head Gauge
- 51. Large Head Gauge

Ingen *SEVIIN*® Shoulder System
Reverse Instruments: *Top Tray*



- | | |
|--|--|
| 1. Centered 36mm +0 (STD Humeral Cup) | 17. Retentive 36mm +3 (+9mm Humeral Cup) |
| 2. Centered 36mm +3 (STD Humeral Cup) | 18. Retentive 36mm +6 (+9mm Humeral Cup) |
| 3. Centered 36mm +6 (STD Humeral Cup) | 19. Retentive 40mm +0 (STD Humeral Cup) |
| 4. Centered 36mm +0 (+9mm Humeral Cup) | 20. Retentive 40mm +3 (STD Humeral Cup) |
| 5. Centered 36mm +3 (+9mm Humeral Cup) | 21. Retentive 40mm +6 (STD Humeral Cup) |
| 6. Centered 36mm +6 (+9mm Humeral Cup) | 22. Retentive 40mm +0 (+9mm Humeral Cup) |
| 7. Centered 40mm +0 (STD Humeral Cup) | 23. Retentive 40mm +0 (+9mm Humeral Cup) |
| 8. Centered 40mm +3 (STD Humeral Cup) | 24. Retentive 40mm +0 (+9mm Humeral Cup) |
| 9. Centered 40mm +6 (STD Humeral Cup) | 25. Trial Glenosphere Screw |
| 10. Centered 40mm +0 (+9mm Humeral Cup) | 26. Assembly Disc |
| 11. Centered 40mm +3 (+9mm Humeral Cup) | 27. 36mm Glenosphere ECCENTRIC |
| 12. Centered 40mm +6 (+9mm Humeral Cup) | 28. 36mm Glenosphere +4MM |
| 13. Retentive 36mm +0 (STD Humeral Cup) | 29. 36mm Glenosphere STANDARD |
| 14. Retentive 36mm +3 (STD Humeral Cup) | 30. 40mm Glenosphere ECCENTRIC |
| 15. Retentive 36mm +6 (STD Humeral Cup) | 31. 40mm Glenosphere +4MM |
| 16. Retentive 36mm +0 (+9mm Humeral Cup) | 32. 40mm Glenosphere STANDARD |



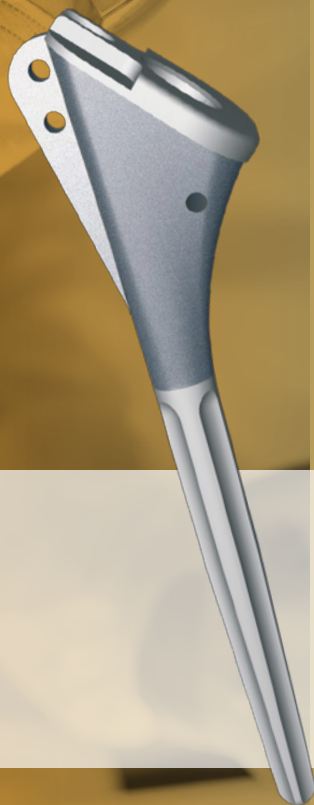
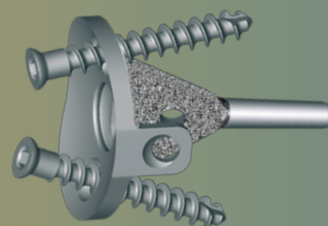
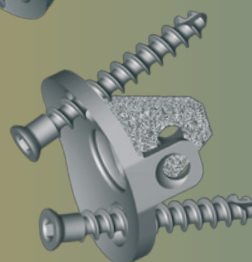
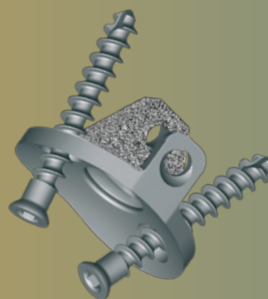
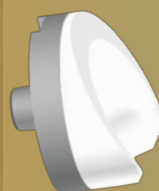
- 33. Torque Limited Handle
- 34. Screwdriver Handle
- 35. Angle Drill Guide
- 36. Trial Glenosphere Extractor
- 37. Metaglene Inserter/Extractor
- 38. Center Hole Drill Guide
- 39. PE-Inlay Impactor

- 40. Screw Depth Gauge
- 41. 3mm Bone Screw Drill Bit
- 42. 7mm Drill Bit
- 43. 4.5mm Hex Bit
- 44. 3.5mm Hex Bit
- 45. 2.5mm Hex Bit
- 46. 29mm Glenoid Reamer
- 47. 1.6mm Guide Pin
- 48. 2.4mm Guide Pin
- 49. 40mm Glenoid Peripheral Reamer



Ingen Orthopedics, LLC
2650 US Highway 130
Cranbury, NJ 08512

DUAL
PLATFORM
SHOULDER
SYSTEM



ARROW[®]
PRIME



FH ORTHO[™]
www.FHortho.com



DUAL
PLATFORM
SYSTEM

ARROW[®] PRIME has been designed to reproduce patient anatomy and reestablish soft-tissue equilibrium. Featuring a wide-range of humeral stem and head options, the ARROW[®] PRIME is well-suited to address various morphologies.

The ARROW[®] PRIME Dual-Platform System addresses the continuum of shoulder arthroplasty indications in an efficient, four-tray instrument layout.

- 12 years of successful clinical history
- Humeral and glenoid platforms offer convertibility options
- Proven, universal metal-back glenoid baseplate
- Lateralized system optimizes motion and minimizes scapular notching



- Titanium stem features corundum-blasted metaphyseal surface to optimize fixation.
- Fixed neck-angle of 135 degrees.
- Stability provided by metaphyseal volume and lateral fin.
- Humeral stem can be implanted with or without cement.
- Stem diameters of 6, 8, 10, 12, 14 and 16 mm.
- Proportional stem length limits varus or valgus malpositioning.
- Female morse-taper facilitates glenoid exposure and visualization.
- The lateral fin suture holes support tuberosity reduction and fixation for fracture reconstruction.



ECCENTRIC HEAD



CONCENTRIC HEAD

HUMERAL HEADS

- CoCr humeral head.
- Concentric and eccentric heads are available to optimize medial and posterior offsets.
- Diameters of 40 to 54mm available to achieve ideal humeral coverage.
- Multiple head-heights available to restore soft-tissue tensioning.

ANATOMIC

CEMENTED GLENOID



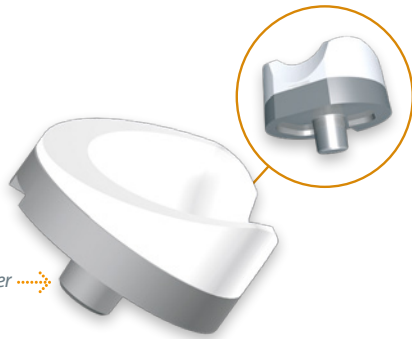
- Pegged, curved-back polyethylene implant conserves bone and maximizes stability.
- A 4mm "mismatch" allows for proper humeral head translation and reduces the risk of glenoid loosening.



GLENOID INSERT

- Consistent 4mm thick polyethylene insert reduces contact stress and improves wear properties.
- Secure, single-step locking of insert to porous glenoid baseplate.

REVERSE



Morse taper

HUMERAL INSERT

- Patented medial cut-out minimizes scapular notching.
- Increased congruency to optimize stability.
- Pre-assembled humeral insert prevents dissociation.



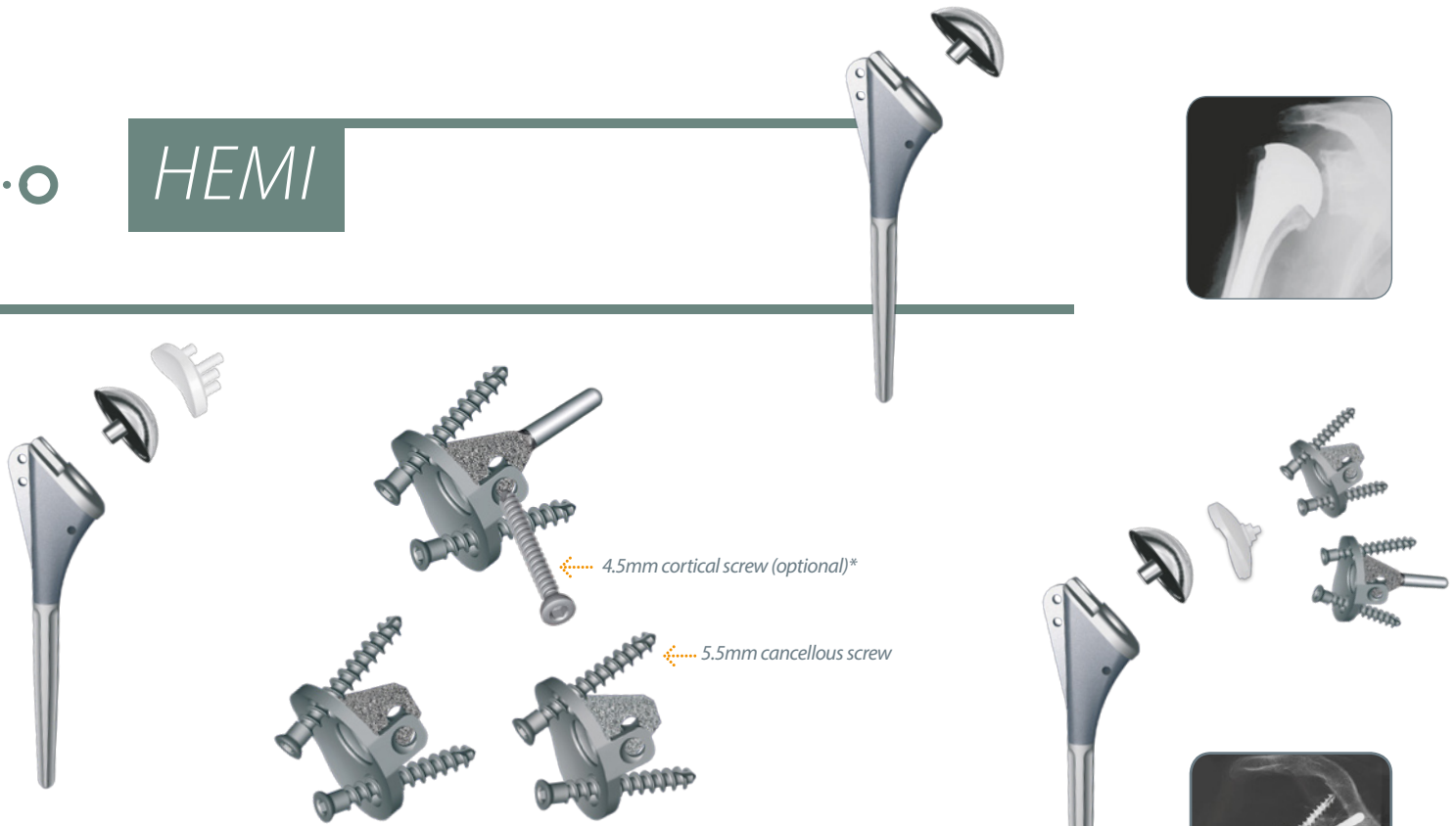
Morse taper

Capscrew

GLENSPHERE

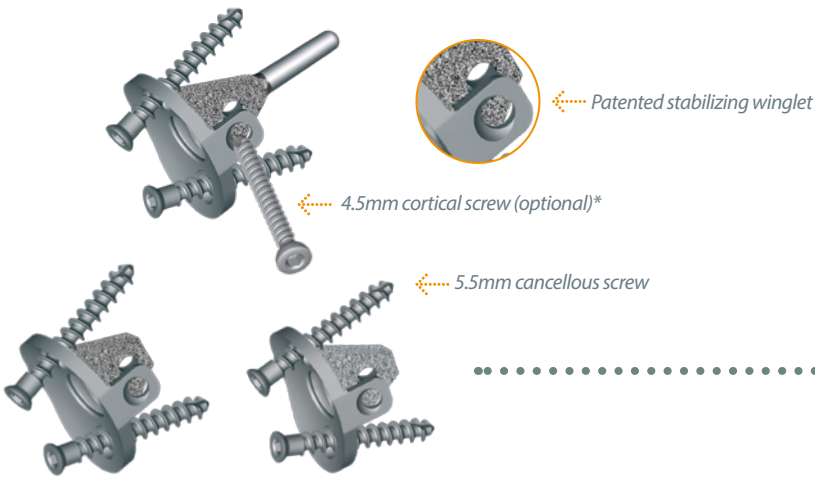
- Three diameters available (36, 39, and 42mm).
- Morse taper couples glenosphere to baseplate.
- Capscrew secures glenosphere to the baseplate, preventing dissociation.

HEMI



CEMENTLESS POROUS GLENOID BASE

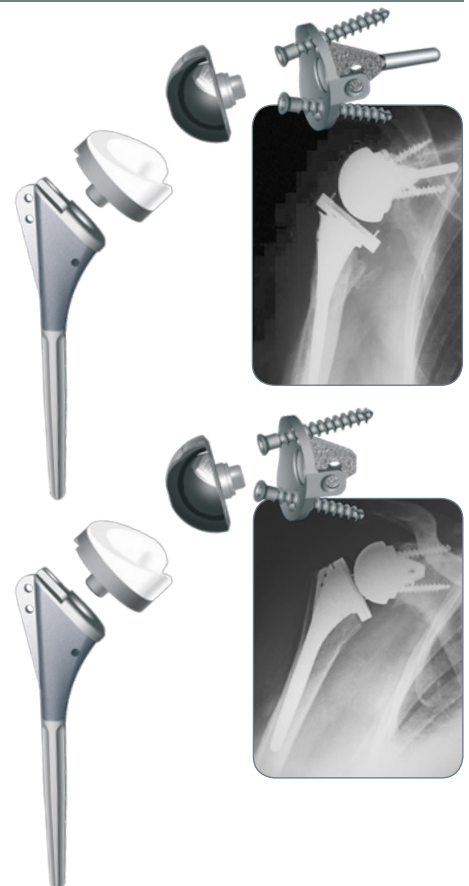
- Titanium porous coating.
- Multiple sizes available to accommodate variable anatomy.



CEMENTLESS POROUS GLENOID BASE

- Divergent 5.5mm cancellous bone screws.
- Multiple sizes available to accommodate variable anatomy.
- Curved-back design improves stability and force transfer.

* OPTIONAL
Cortical bone screw for compromised glenoid bone and for fractures of the glenoid



REFERENCE NUMBERS



HUMERAL STEM

REFERENCE	DIAMETER	HEIGHT
267 360	Ø 06 (CEMENTED ONLY)	100
265 102	Ø 08	120
265 103	Ø 08	170
265 104	Ø 10	125
265 105	Ø 12	130
265 106	Ø 14	135
267 361	Ø 16	140

CONCENTRIC HUMERAL HEAD



REFERENCE	DIAMETER	HEIGHT
265 107	Ø 40	15
265 108	Ø 40	17
265 109	Ø 44	16
265 110	Ø 44	18
265 111	Ø 46	16
265 112	Ø 46	18
265 113	Ø 46	21
265 114	Ø 48	16
265 115	Ø 48	18
265 116	Ø 48	21
265 117	Ø 50	17
265 118	Ø 50	19
265 119	Ø 50	21
265 120	Ø 52	19
265 121	Ø 52	21
265 122	Ø 54	19
265 123	Ø 54	21

ECCENTRIC HUMERAL HEAD



REFERENCE	DIAMETER	HEIGHT
265 124	Ø 44	16
265 125	Ø 44	18
265 126	Ø 46	16
265 127	Ø 46	18
265 128	Ø 46	21
265 129	Ø 48	16
265 130	Ø 48	18
265 131	Ø 48	21
265 132	Ø 50	17
265 133	Ø 50	19
265 134	Ø 50	21
265 135	Ø 52	19
265 136	Ø 52	21

CEMENTED GLENOID



REFERENCE	SIZE
265 137	44
265 138	46
265 139	48
265 140	50



POROUS GLENOID IMPLANT

REFERENCE	SIZE
267 702	44S
267 701	44
267 704	46
267 705	48
268 698	44S-LP*
267 703	44-LP*
268 699	46-LP*

* LONG POST

GLENOID INSERT



REFERENCE	SIZE
265 157	44
265 158	46
265 159	48

GLENSPHERE



REFERENCE	DIAMETER
265 150	Ø 36
265 151	Ø 39
265 152	Ø 42

HUMERAL INSERT



REFERENCE	DIAMETER	HEIGHT
265 141	Ø 36	00
265 142	Ø 36	05
265 143	Ø 36	10
265 144	Ø 39	00
265 145	Ø 39	05
265 146	Ø 39	10
265 147	Ø 42	00
265 148	Ø 42	05
265 149	Ø 42	10

special sizes for larger anatomies, trauma or revision cases



CANCELLOUS BONE SCREW - sterile -

REFERENCE	DIAMETER	LENGTH
265161	Ø 5.5	24
265162	Ø 5.5	28
265163	Ø 5.5	32
265164	Ø 5.5	36
265165	Ø 5.5	40
265166	Ø 5.5	45
265167	Ø 5.5	50

CORTICAL BONE SCREW - sterile -



REFERENCE	DIAMETER	LENGTH
265 168	Ø 4.5	32
265 169	Ø 4.5	34
265 170	Ø 4.5	36
265 171	Ø 4.5	38
265 172	Ø 4.5	40

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Valenti P, Sauzières P, Katz D, Kalouche I, Kilinc AS. Clin Orthop Relat Res. (2011) Mar 15. - DOI 10.1007/s11999-011-1844-8
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Kalouche I, Sevivas N, Wahegaonker A, Sauzières P, Katz D, Valenti P. - Acta Orthop Belg. 2009 Apr;75(2):158-66.
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SURGICAL TECHNIQUE
DUAL-PLATFORM SHOULDER ARTHROPLASTY

ARROW[®]
PRIME




REFERENCE NUMBERS

HUMERAL STEMS




REFERENCE	DIAMETER	HEIGHT
267 360	Ø 06	100
265 102	Ø 08	120
265 103	Ø 08	170
265 104	Ø 10	125
265 105	Ø 12	130
265 106	Ø 14	135
267 361	Ø 16	140

POROUS GLENOID IMPLANT




REFERENCE	SIZE
267 702	44S
267 701	44
267 704	46
267 705	48
268 698	44S-LP*
267 703	44-LP*
268 699	46-LP*

GLENOSPHERES



REFERENCE	DIAMETER
265 150	Ø 36
265 151	Ø 39
265 152	Ø 42


STD HUMERAL INSERTS



REFERENCE	DIAMETER	HEIGHT
265 141	Ø 36	00
265 142	Ø 36	05
265 143	Ø 36	10
265 144	Ø 39	00
265 145	Ø 39	05
265 146	Ø 39	10
265 147	Ø 42	00
265 148	Ø 42	05
265 149	Ø 42	10


special sizes for larger anatomies, trauma or revision cases

GLENOID INSERT




REFERENCE	SIZE
265 157	44
265 158	46
265 159	48

CANCELLOUS BONE SCREW - steriles -




REFERENCE	DIAMETER	LENGTH
265161	Ø 5.5	24
265162	Ø 5.5	28
265163	Ø 5.5	32
265164	Ø 5.5	36
265165	Ø 5.5	40
265166	Ø 5.5	45
265167	Ø 5.5	50

CORTICAL BONE SCREW - steriles -




REFERENCE	DIAMETER	LENGTH
265 168	Ø 4.5	32
265 169	Ø 4.5	34
265 170	Ø 4.5	36
265 171	Ø 4.5	38
265 172	Ø 4.5	40

CONCENTRIC HUMERAL HEAD

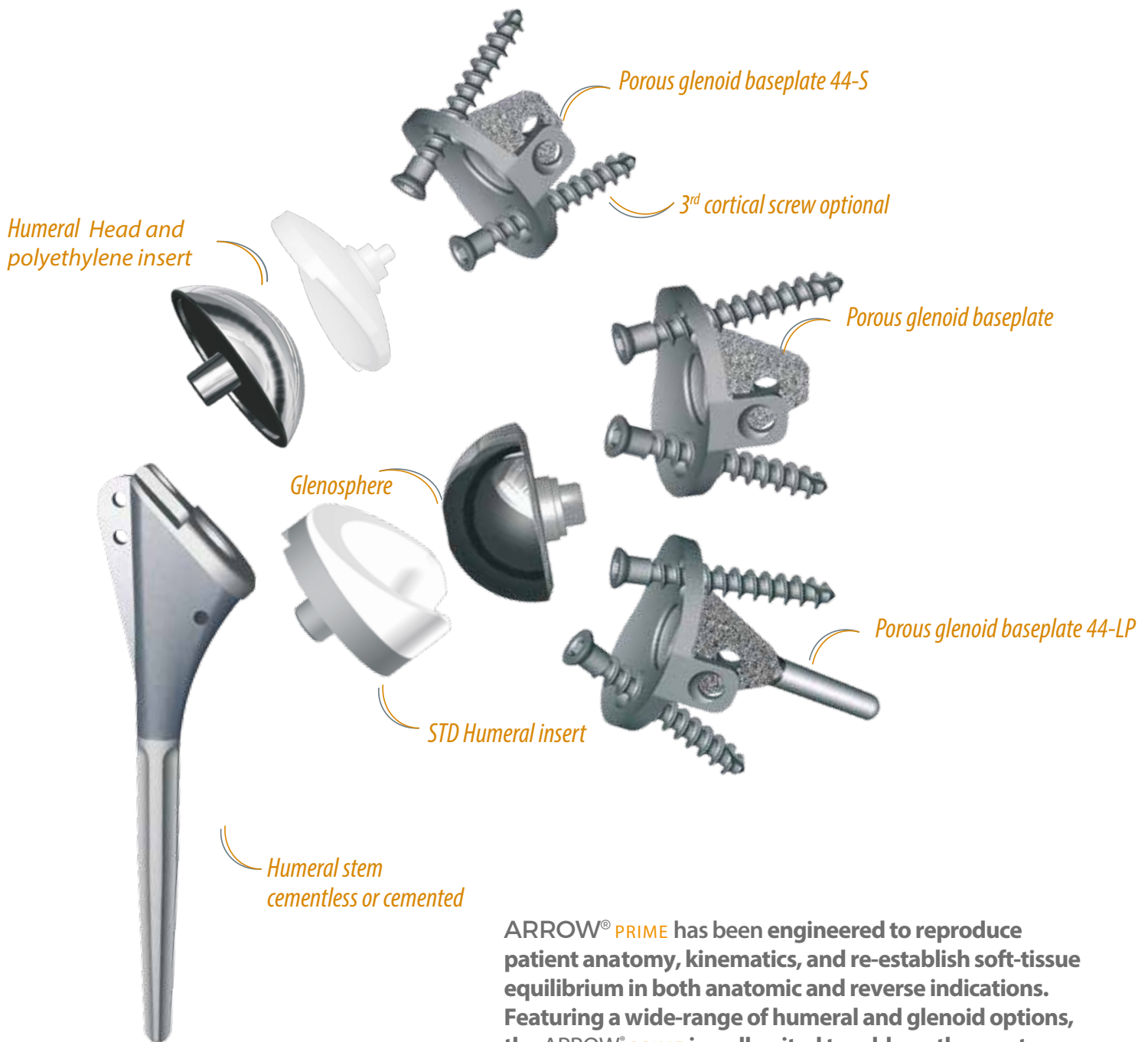


REFERENCE	DIAMETER	HEIGHT
265 107	Ø 40	15
265 108	Ø 40	17
265 109	Ø 44	16
265 110	Ø 44	18
265 111	Ø 46	16
265 112	Ø 46	18
265 113	Ø 46	21
265 114	Ø 48	16
265 115	Ø 48	18
265 116	Ø 48	21
265 117	Ø 50	17
265 118	Ø 50	19
265 119	Ø 50	21
265 120	Ø 52	19
265 121	Ø 52	21
265 122	Ø 54	19
265 123	Ø 54	21

ECCENTRIC HUMERAL HEAD



REFERENCE	DIAMETER	HEIGHT
265 124	Ø 44	16
265 125	Ø 44	18
265 126	Ø 46	16
265 127	Ø 46	18
265 128	Ø 46	21
265 129	Ø 48	16
265 130	Ø 48	18
265 131	Ø 48	21
265 132	Ø 50	17
265 133	Ø 50	19
265 134	Ø 50	21
265 135	Ø 52	19
265 136	Ø 52	21



ARROW[®] PRIME has been engineered to reproduce patient anatomy, kinematics, and re-establish soft-tissue equilibrium in both anatomic and reverse indications. Featuring a wide-range of humeral and glenoid options, the ARROW[®] PRIME is well-suited to address the most complicated of patient presentations.

The ARROW[®] PRIME Dual-Platform System addresses the continuum of shoulder arthroplasty indications in an efficient, four-tray instrument layout, providing the surgeon with a true, convertible, cementless anatomic glenoid option.

1 - ARROW PRIME SYSTEM OVERVIEW

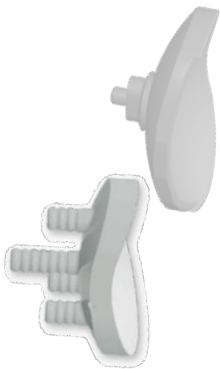
Anatomic Configuration

The humeral platform features a fixed 135° neck angle, a female morse taper that enhances glenoid visualization, and six sizes to optimize humeral fit and stability.



Concentric and eccentric heads are available to respect medial and posterior offset and are offered in 40 to 52 mm with variable height options.

The porous-coated glenoid platform is indicated for cementless anatomic TSA. It features divergent screw fixation, a universal flange, and is available in multiple sizes to accommodate patient anatomy.



Cemented, pegged glenoid implants are available in multiple sizes as well as modular inserts for use with the porous-coated glenoid platform.



Arrow®Prime Anatomic

Reversed Configuration

Humeral inserts are available in multiple thicknesses to optimize stability and feature a patented medial cut-out to minimize impingement with the scapular pillar. The inserts articulate at 155° with the glenosphere.



Glenospheres are available in 36, 39 and 42 mm and feature a central capscrew that eliminates dissociation.



The porous-coated glenoid platform is indicated for reversed arthroplasty. It features divergent screw fixation, a universal flange, and is available in multiple sizes to accommodate patient anatomy.



The extended-post platform provides enhanced stability in challenging glenoid anatomy. A universal flange supports additional screw fixation and/or structural bone graft for either anterior or posterior glenoid augmentation when indicated.



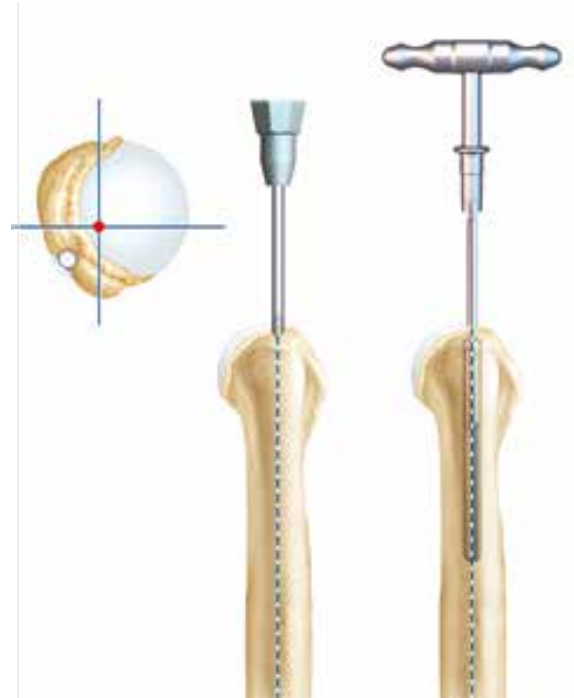
Arrow®Prime Reverse

2 - HUMERAL PREPARATION

2.1 - HUMERAL REAMING

Using the starter awl (*ref. 264868*), create a pilot hole at the highest point, or hinge point, of the humerus, typically-located approximately 1 cm posteromedial to the bicipital groove. Insert the awl to create a proximal portal for humeral canal entry, using a mallet as necessary.




Connect the T-handle (*ref. 261054*) to the 6 mm humeral reamer and insert until the laser-etched line is at the level of the humeral head. Repeat with sequentially larger reamers, ensuring the “step” of the reamer is at the level of the bone, until a stable fit is achieved. Remove the T-handle and leave the final reamer in the humerus to guide subsequent humeral resection.



➤ Should a long-stem humeral component be indicated, use the appropriate 8 x 200 mm reamer (*ref. 268108*). The long-stem implant is indicated for cemented use only.

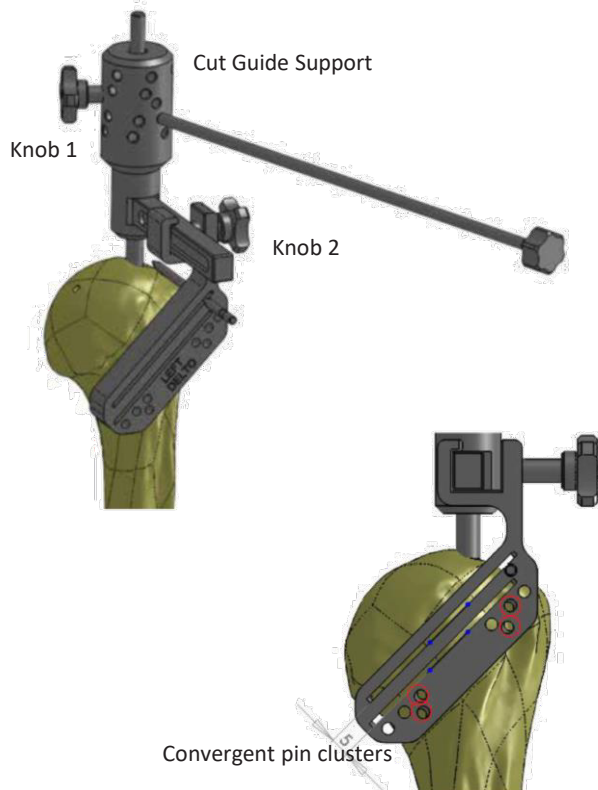
➤ Do NOT oversize the reamer during this step. If excessive cortical “chatter” is realized, defer to the next SMALLEST reamer.

➤ Implant sizing is ultimately determined during broaching, as the Arrow humeral component achieves its fixation proximally.

Starter Awl <i>(ref. 264868)</i>	T-Handle <i>(ref. 261054)</i>	Humeral Reamers <i>(ref. 267605-610)</i>
		

2 - HUMERAL PREPARATION

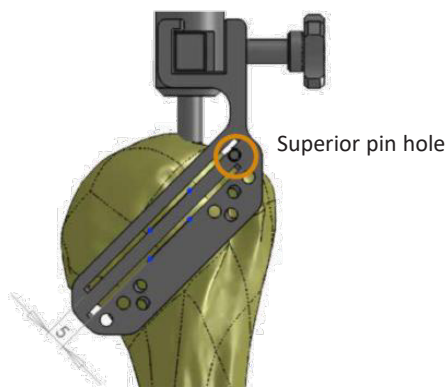
2.1 - HUMERAL RESECTION GUIDE ASSEMBLY AND POSITIONING



The approach-specific resection block should be selected (ref. 267611 or 267612) and assembled to the intramedullary reamer as shown. Knob 1 (ref. 267613) secures the cut guide support (ref. 267610) to the intramedullary reamer, while Knob 2 (ref. 267613) secures the resection block to the cut guide support. Knob 2 controls translation of the resection block along the arm of the cut guide support. A retroversion rod (ref. 261053) is threaded into the tower at the desired angle and aligned with the patient's forearm in neutral rotation. The guide provides retroversion options of 0 to 30 degrees.

The resection block is fixed to the proximal humerus with as many as four, 3.0 x 90 mm threaded pins (ref. 268016). Once fixed, the cutting guide support is removed by releasing knob 1 and knob 2. The T-handle (ref. 261054) is then reattached to the intramedullary humeral reamer, which is removed, leaving only the resection block in place (See Section 2.1(a) below).

→ The cut-block has a number of stabilization holes to utilize with the 3.0 x 90 mm threaded pins (ref. 268016). Note that there are convergent AND parallel pin holes that can be selected.



→ To guide placement of the cutting block, place a pin in the most superior pin hole and align with the top of the greater tuberosity at the top of the supraspinatus insertion.

Cut Guide Support <i>(ref. 267610)</i>	Humeral Cut Block <i>(ref. 267611)</i>	Connecting Screw <i>(ref. 267613)</i>
Retroversion Rod <i>(ref. 261053)</i>	Fixation Pins <i>(ref. 268016)</i>	AO Pin Driver <i>(ref. 269239)</i>

2.2 - PROXIMAL HUMERAL OSTEOTOMY

With the block stabilized on the proximal humerus, resection is made with an oscillating saw, through either of the available resection slots. The two resection slots are separated by 5 mm, offering the opportunity for a controlled secondary resection if desired.

- The most proximal slot is typically sufficient for an anatomic cut and the distal slot is generally recommended for a reverse cut.

Once the resection is complete, the stabilization pins can be removed with a pin driver. The resected humeral head can then be sized using the humeral head trials or the included sizing templates (ref. 261041/42).

- Residual osteophytes may bias towards an oversized prosthetic head.





2.3 - HUMERAL BROACHING

Attach the broach handle (ref. 267614) to the 6 mm broach (ref. 266222). Replicate the retroversion established during humeral resection by threading a retroversion rod (ref. 261053) into the appropriate hole on the broach handle. Sequentially broach the humeral canal by impacting until the collar of the broach is flush with the resected humeral surface. Once the final broach has been determined and seated, the cut-cover (ref. 261845) can be placed to protect the proximal humerus from retraction injury during glenoid exposure.

- Continue broaching until solid fixation is achieved and the broach doesn't toggle or rotate. The broach ultimately determines the size of prosthesis to be implanted.
- Although the broach and reamer sizes typically coincide, it is possible for a "mismatch".

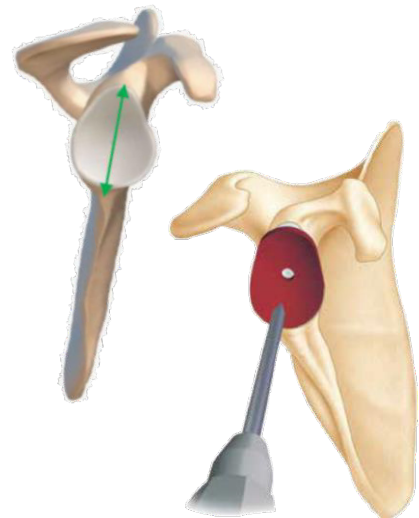


Retroversion Rod <i>(ref. 261053)</i>	Broach Handle <i>(ref. 267614)</i>	Humeral Broaches <i>(ref. 264447 - 50)</i>
		

3 - PREPARATION OF THE GLENOID

3.1 - GLENOID SIZE

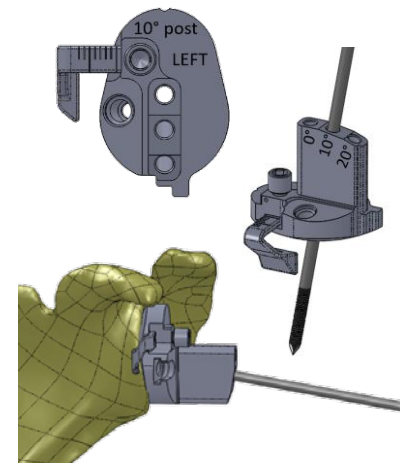
Once sufficient glenoid exposure has been achieved, mark the coracoscapular axis with electrocautery. Apply the glenoid templates (ref. 261077/78/79) to estimate the size of the glenoid baseplate required. The center of the glenoid can be marked with electrocautery or the starter awl (ref. 264868). The appropriate size is that which provides the most complete coverage of the glenoid.



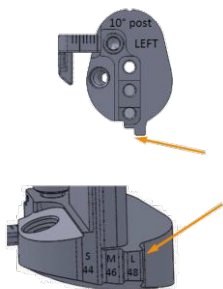
- The central hole in the glenoid template should only to be used for identifying the center of the glenoid. It is NOT to be drilled.

3.2 - GLENOID PIN POSITIONING

Select the side-specific pin-setting guide (ref. 269086 - 091) that coincides with the degree of posterior correction desired (0, 10, or 20 degrees). Thread the jig handle (ref. 261844) into the threaded hole of the pin-setting guide and confirm a tight connection. If desired, set the optional anterior stylus at the appropriate distance determined preoperatively. With the guide appropriately aligned, advance the 3.0 x 170 mm threaded-pin (ref. 269138) through the most proximal guide hole (0 degrees of inferior tilt), until the laser-marked line of the guide pin is at the level of the tower.



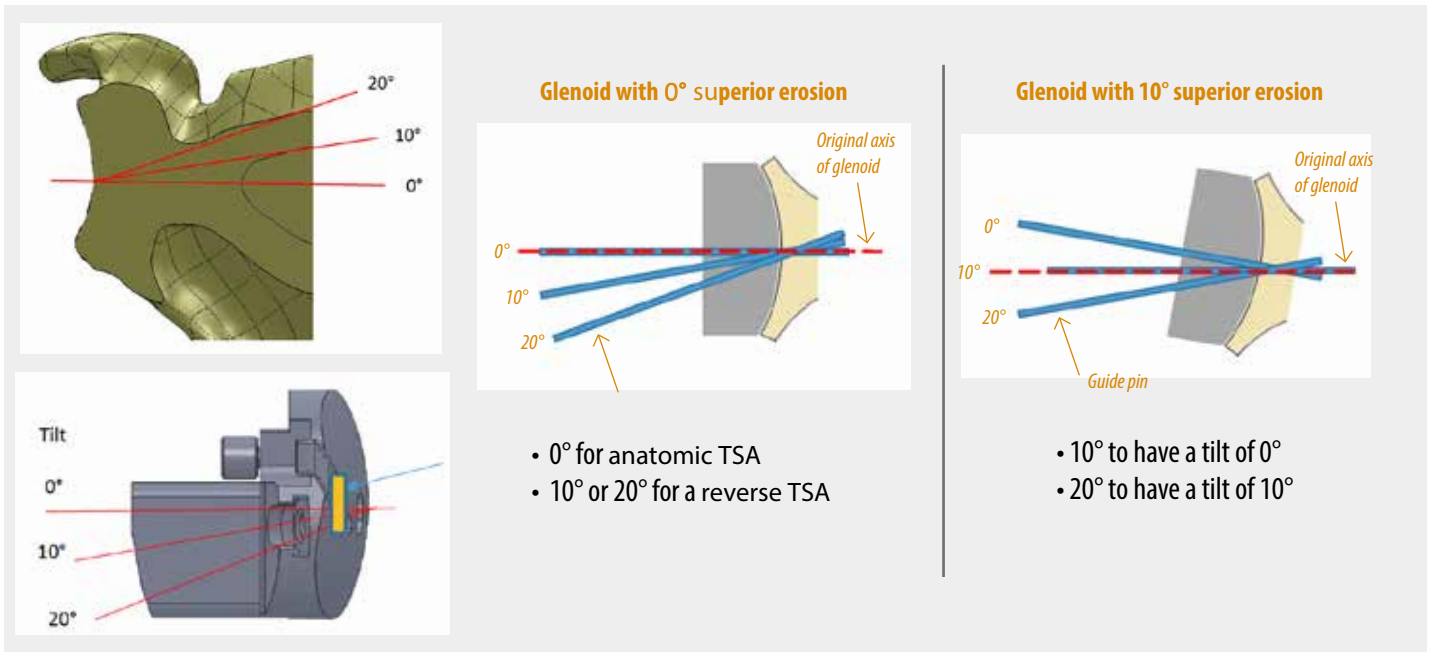
- The 3.0 x 170 mm threaded-pin has two laser marks that guide depth. When the pin-setting guide is used, the most proximal laser mark should be at the level of the tower. When the pin-setting guide is NOT used, the most distal laser mark should be at the level of the glenoid bone.



The profile of the guide is that of a size 44 baseplate. There are a series of “notches” inferiorly on the guide that correspond to available glenoid baseplate sizes. Align the appropriate “notch”, from the size determined previously, with the inferior glenoid rim.

Jig Handle (ref. 261844)	Glenoid Guides (ref. 269086 - 091)	3.0 x 170mm Pin (ref. 269138)

3.2(a) - ADDRESSING GLENOID TILT



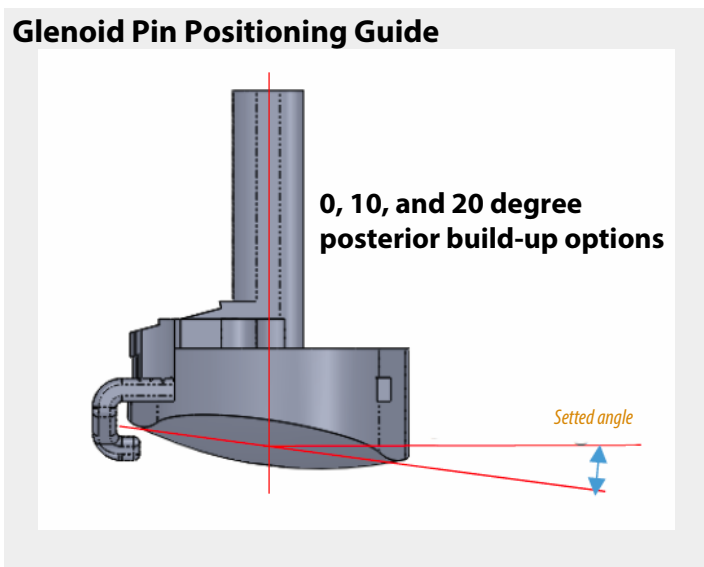
→ The universal glenoid pin positioning guide provides guidance for pin placement with several inclination options of 0, 10, and 20 degrees. For most anatomic indications, the pin should be placed through the 0 degree hole, which is most superior of the three. In reversed indications, should inclination be desired, either the 10 or 20 degree options should be selected and should consider the degree of superior wear present. For example, significant superior wear should be addressed via the 20 degree hole.

3.2(b) - ADDRESSING POSTERIOR WEAR

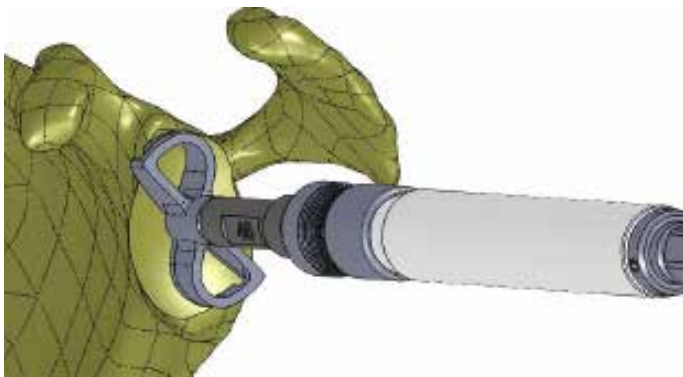
→ One of the biggest challenges facing the shoulder surgeon is placing a central guide pin in a glenoid with significant posterior wear.

The Arrow Prime glenoid preparation instruments provide the surgeon options to correct 0, 10, and 20 degrees of posterior wear via the pin positioning guide.

These guides have posterior "build-ups" that modify the "setted angle" of the guide itself that adds precision to glenoid guide pin placement in the face of posterior wear.





3.3 - GLENOID REAMING



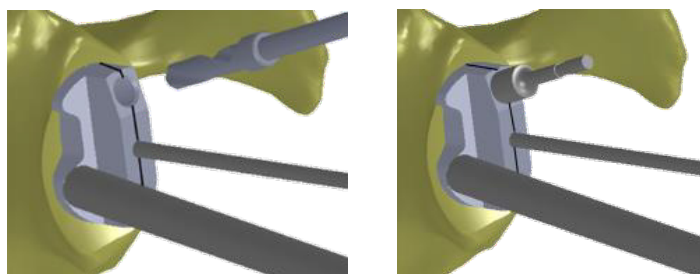
Select the appropriate cannulated reamer (ref. 267650/51/52) that corresponds to the previously determined baseplate size and connect to the reamer drive shaft (ref. 269147). Position the reamer over the 3.0 x 170 mm guide pin (ref. 269138) and begin reaming. Reaming should be carried out until proper concavity has been achieved and glenoid cartilage has been removed.

- The glenoid reamer should be started prior to engaging the glenoid bone to minimize likelihood of a glenoid fracture.
- Over-reaming will both decrease the surface area of the glenoid face and reduce the depth of the glenoid vault. Excessive reaming should be avoided.
- Should a remnant of bone remain around the guide pin following reaming, remove with a rongeur. If retained, this remnant may prevent full-seating of the keel drill guide in the subsequent step.

Reamer Drive Shaft <i>(ref. 269147)</i>	Glenoid Reamer <i>(ref. 267650 - 52)</i>
	

3.4 - KEEL PREPARATION

3.4(a) - SUPERIOR/INFERIOR KEEL



Select the appropriate keel drill guide.

Drill guides	Baseplate sizes
Metal-Back drill guide 44S <i>ref. 268 470</i>	44S & 44S-LP
Metal-Back drill guide 44/46/48 <i>ref. 268 471</i>	44/46/48
	44-LP/46-LP

Select the appropriate keel drill guide (ref. 268470/71) and attach the guide handle (ref. 267667). Slide keel drill guide over the central guide pin and align the laser mark with the previously drawn coracoscapular axis. Drill the superior hole with the 5.0 mm stopped drill bit (ref. 267114) until the "stop" engages and insert a stability peg (ref. 267112) to prevent rotation and loss of desired alignment. Drill the inferior hole in the same fashion then remove the guide assembly.



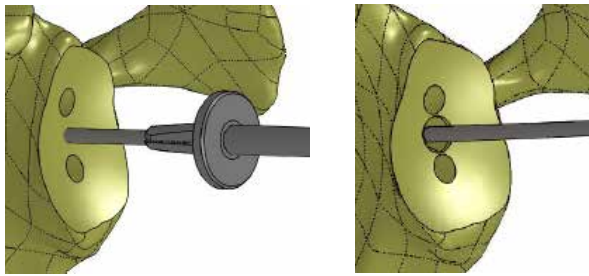
USING "LEAVE-BEHIND" DRILL BITS

Engage a 5 mm modular drill bit (ref. 269240) into the quick-release peripheral drill shaft (ref. 269242), drill the superior hole of the keel drill guide, then disengage drill bit *in situ* to provide stability for subsequent inferior hole drilling. The keel drill guide assembly can then be removed.



Quick release peripheral drill shaft ref. 269 242

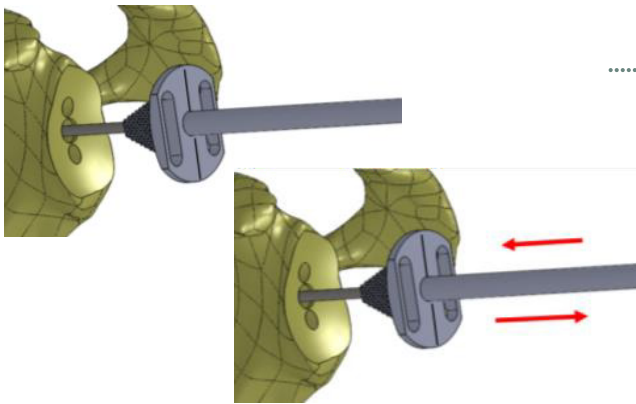
3.4(b) - CENTRAL KEEL PREPARATION



Position the cannulated tapered reamer (ref. 269132) over the central guide pin, reaming until the mechanical “stop” is reached.



Should bone bridges remain following central reaming, carefully remove with a rongeur.



Select the cannulated glenoid vault broach that corresponds to the previously determined glenoid size (ref. 269133/34/35/36) and position over the central guide pin, aligning the laser mark with the coracoscavular axis. Using a mallet, impact the punch until the broach platform is flush with the reamed surface of the glenoid.



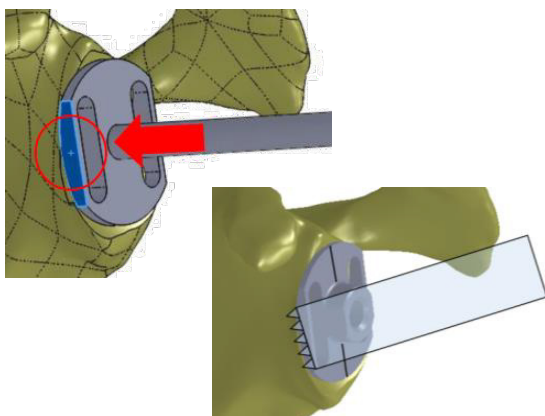
Repeat progressive back and forth impactions, until the punch platform is in contact with the glenoid bone surface.

Instrument Compatability Table

ref. 269 133	Cannulated glenoid punch 44S	MB 44S & 44S-LP
ref. 269 134	Cannulated glenoid punch 44	MB 44 & 44-LP
ref. 269 135	Cannulated glenoid punch 46	MB 46 & 46-LP
ref. 269 136	Cannulated glenoid punch 48	MB 48

Tapered Reamer (ref. 269132)	Glenoid Punch (ref. 269133 - 36)
	

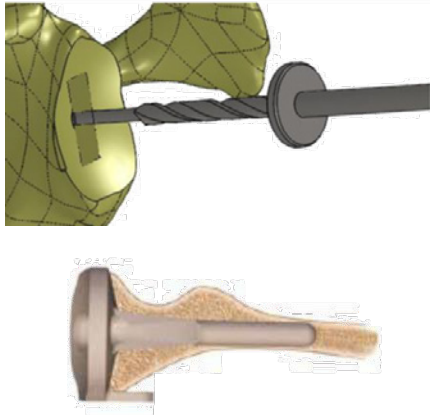
3.5 - ANTERIOR RESECTION



With the keel broach fully-seated, make a controlled anterior cut, using the anterior rim of the broach platform as a resection guide.

This anterior glenoid resection creates sufficient clearance for the anterior winglet of the baseplate trial component (ref. 261088/89/90/101) and/or the definitive implant.

3.6 - LONG-POST BASEPLATE PREPARATION (OPTIONAL)



→ The long-post baseplate may be necessary for patients presenting with significant glenoid deformity or in the setting of revision surgery.

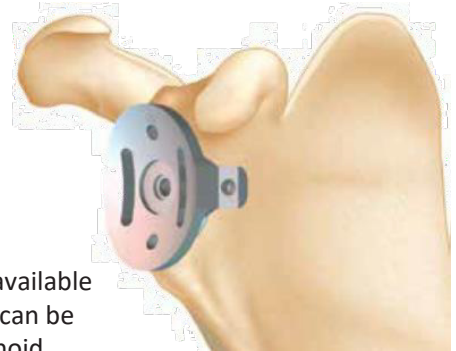
With the 3.0 x 170 mm guide pin still in place, pass the cannulated long-post drill (*ref. 269149*) until the “stop” engages the glenoid face.



The long-post of the baseplate is designed to traverse the medial cortical bone to achieve superior stability.

3.7 - BASEPLATE TRIALING (OPTIONAL)

Select the appropriate trial baseplate (*ref. 261088/89/90/101*) and attach to the impactor handle (*ref. 267667*). Impact into position with a mallet, confirming full-seating of the baseplate and anterior clearance of the baseplate winglet.



There are keeled, polyethylene trials (*ref. 266833/34/35/36*) available that replicate the combined offset of baseplate and poly that can be used to approximate lateralization of the final metal-back glenoid assembly.

3.8 - POROUS BASEPLATE IMPLANTATION

Thread the metal-back baseplate inserter handle (*ref. 261101*) into the center hole of the definitive baseplate.





The threads of the inserter handle are relatively fine, so over-tightening should be avoided to prevent stripping.

Once the baseplate is provisionally-seated, unthread the metal-back inserter handle and complete seating with the baseplate impactor assembly (*ref. 264459 and 267659*) until baseplate is flush with glenoid surface.

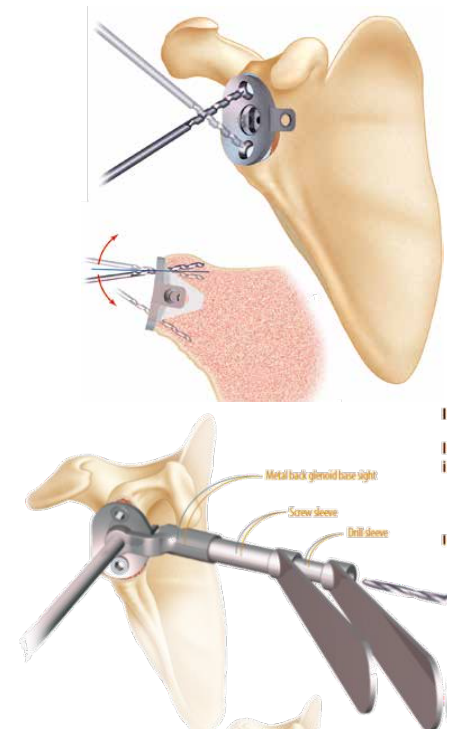


3.9 - PLACEMENT OF BASEPLATE SCREWS

Using the 3.2 mm drill bit (*ref. 267115*) and drill sleeve (*ref. 264479*), target the scapular pillar with the inferior screw. Determine the length of the screw required with the depth gauge (*ref. 269241*) and insert, but do not fully tighten, with the hex driver (*ref. 264683*). Repeat these steps for the superior screw, targeting the base of the coracoid, drilling bi-cortically.

-  Screw length may be measured off of the drill bit relative to the top of the drill sleeve.
-  Alternate tightening of the screws will prevent rocking of the definitive implant.

Should the optional anterior cortical screw be indicated, select the appropriate glenoid base jig (*ref. 261840/41/42*) and attach to the jig handle (*ref. 261844*). With base jig engaged in the oval well of the baseplate, insert the screw sleeve and drill guide through the anterior barrel of the base jig. Drill bi-cortically with the 3.2 mm drill bit. Determine screw length with the depth gauge or by adding 2 mm to the depth dictated by the drill bit and insert the 4.5 mm screw with the hex driver (*ref. 264683*).



Optional anterior cortical screw

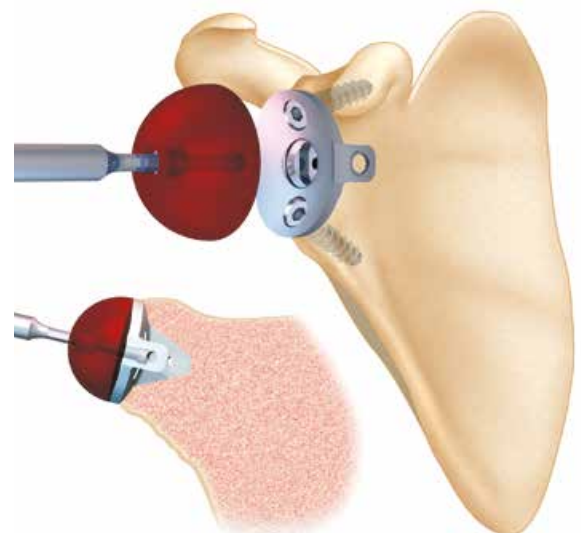
➔ For more information on the anterior cortical screw, see Appendix 1.

4 - TRIALING


4.1 - GLENOSPHERE TRIAL

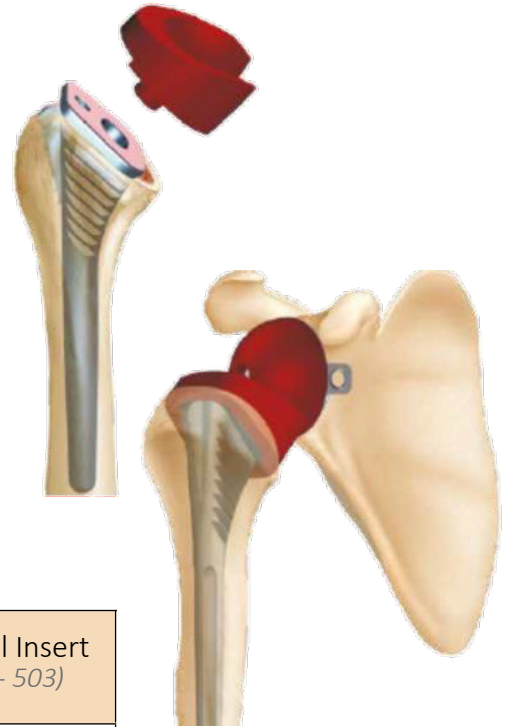
➔ Glenosphere trials (*ref. 261092/93/94*) are available when necessary. Remove the central set screw from the trial glenosphere and position into the the definitive porous baseplate using the glenosphere inserter handle (*ref. 261101*).

Once positioned, fix the trial glenosphere to the baseplate with the trial set screw that was removed previously. This set screw will ensure stability during the trialing process



4.2 - HUMERAL INSERT TRIAL

- Select the humeral trial insert (*ref. 264495 to 264503*) that corresponds to the diameter of the implanted glenosphere. Inserts are available in multiple heights to optimize tension and stability.
 - Beginning with the 0 mm trial insert, perform a trial reduction and assess shoulder stability by placing through a range of motion. If any decoaptation is observed, glenoid impingement should be considered. If tension is inadequate, a thicker trial insert (5 or 10 mm) should be trialed.
-  Light impaction with the humeral insert impactor (*ref. 264459 and 267696*) can be used to improve stability of the trial insert, if necessary.



Impactor Handle <i>(ref. 264459)</i>	Humeral Impactor Tip <i>(ref. 267696)</i>	Humeral Trial Insert <i>(ref. 264495 - 503)</i>
		

Compatibility table

POROUS GLENOID BASEPLATE	GLENSPHERE	HUMERAL INSERT
44S / 44 44S-LP / 44-LP	Ø36	36/00; 36/05; 36/10
	Ø39	39/00; 39/05; 39/10
46 / 46-LP	Ø39	39/00; 39/05; 39/10
	Ø42	42/00; 42/05; 42/10
48	Ø42	42/00; 42/05; 42/10

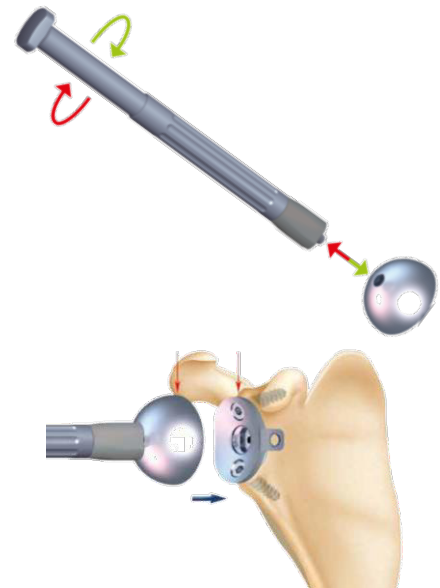
5 - DEFINITIVE GLENOID IMPLANTS

5.1 - GLENSPHERE INSERTION - REVERSED ONLY

- Rotate the proximal end of the glenosphere positioner/impactor (*ref. 269137*) counter-clockwise to retract the locking mechanism. Engage the positioner/impactor by aligning one of the arrows on the distal end of the impactor with the notch on the appropriate glenosphere (review compatibility table below). Rotate the proximal end of the impactor handle in a clockwise direction to secure the impactor to the glenosphere.

Position the taper of the glenosphere into the oval well of the baseplate and firmly impact into position. Once security has been confirmed, rotate the proximal end of the impactor handle counter-clockwise to release the impactor from the glenosphere. The humeral head impactor tip (*ref. 261043*) and impaction handle (*ref. 264459*) can be assembled and used for final impaction if desired.

METAL BACK GLENOID BASE	GLENSPHERE	HUMERAL INSERT
44 / 44S / 44R	Ø36	36/00; 36/05; 36/10
	Ø39	39/00; 39/05; 39/10
46	Ø39	39/00; 39/05; 39/10
	Ø42	42/00; 42/05; 42/10
48	Ø42	42/00; 42/05; 42/10



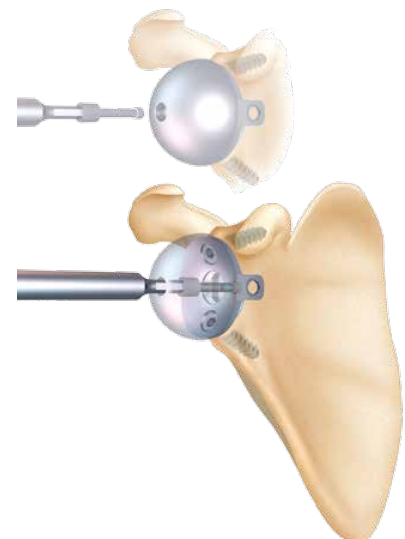
Glenosphere trials (*ref. 261093/93/94*) are available when necessary. A set screw threads into the baseplate to ensure secure trialing. See section 4.1 for more information.

- The glenosphere is then secured with a definitive “capscrew”, which locks the glenosphere to the glenoid baseplate, confirming proper alignment and minimizing the likelihood of a dissociation event.

Use the hex driver (*ref. 264683*) to thread the capscrew through the central hole of the glenosphere into the baseplate. The capscrew will bottom-out when fully-threaded.



Should the capscrew NOT engage and “bottom-out”, there is likely a problem with alignment. The glenosphere should be removed and realigned.



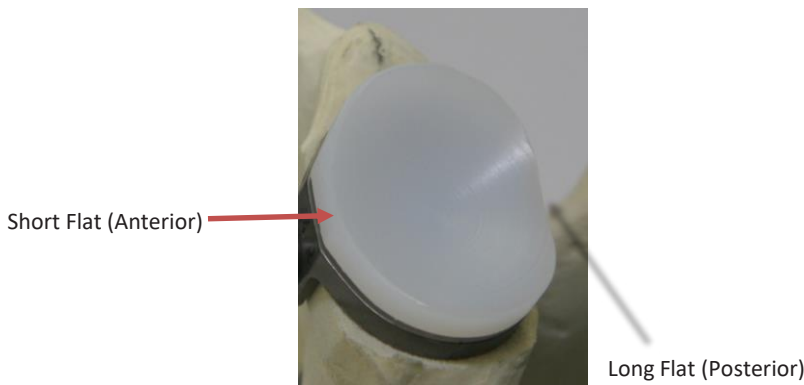
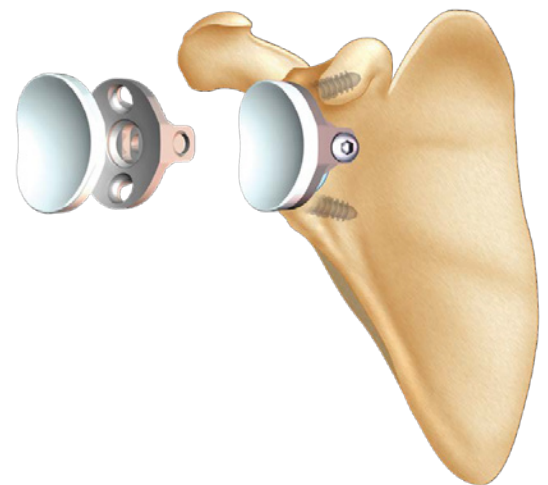
5.2 - MODULAR GLENOID INSERT - ANATOMIC ONLY

The proper insert matches the size of the baseplate implanted. For example, a size 46 baseplate requires a size 46 glenoid insert. When positioning the glenoid insert, notice that there are two “flats” on the insert, one long and one short. The short flat is to be aligned anteriorly, while the long flat should be aligned posteriorly.

Once orientation is confirmed, place the insert into the baseplate such that the oval peg on the insert sits in the oval well of the baseplate. To best achieve this, position the insert from a “straight-on” approach rather than obliquely. When provisionally-engaged, the insert can be definitively-seated with the baseplate impactor assembly (ref. 264459 and 267659). Ensure that the glenoid insert is flush with the baseplate and no gapping or asymmetries exist.



Alternate impactor tip



Mismatch table

MISMATCH	GLENOID	44	46	48	50
Head	Curvature radius	26	27	28	29
Ø40	20	6	7	8	9
Ø44	22	4	5	6	7
Ø46	23	3	4	5	6
Ø48	24	2	3	4	5
Ø50	25	1	2	3	4
Ø52	26	0	1	2	3
Ø54	27	-1	0	1	2

We recommend a mismatch between 2 and 4mm*



If there are issues with the seating of the glenoid insert, there is likely a problem with alignment.



Should the insert require removal because of a failure to seat, it is worthwhile to use a “fresh” implant as repeated impactions of a poorly-aligned insert can damage the structural integrity of the locking-mechanism.

5.3 - DEFINITIVE STEM AND INSERT - REVERSED ONLY



Engage the definitive humeral insert with the humeral stem by aligning the notch on the underside of the humeral insert with the superior tongue on the stem platform.

Once the humeral insert is provisionally-seated, use the humeral insert impactor assembly (ref. 264459 and 267696) to set the Morse taper.

Reduce the joint and perform a final assessment of stability and range of motion.

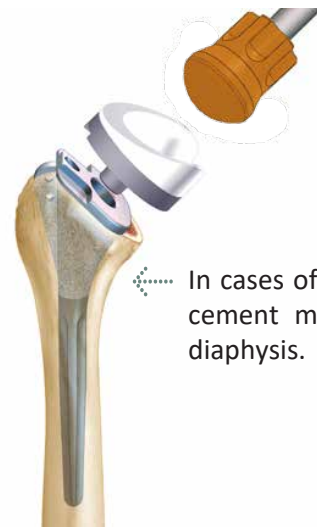
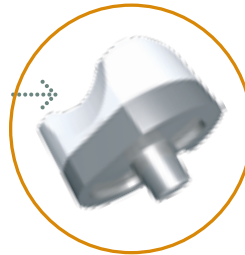


The standard humeral insert has a 155 degree angle and is specially designed to avoid glenoid notching.



The humeral insert also has a medial cut-out to minimize impingement with scapular pillar.

Patented medial cut-out



In cases of osteoporotic bone, cement may be used in the diaphysis.

5.4 - DEFINITIVE STEM AND HUMERAL HEAD - ANATOMIC ONLY

Place the definitive stem into the humerus by connecting it to the broach handle. The retroversion rod should be used to confirm desired rotation used throughout the procedure to this point. Ensure the collar of the stem is impacted until flush with the humeral resection.

Select the desired humeral head size and insert into the female Morse taper of the humeral stem. If an eccentric head was chosen, confirm the position of the eccentricity determined during the previous trial steps.

If necessary, a trial humeral head can be used with the definitive stem to reconfirm eccentric positioning as necessary.

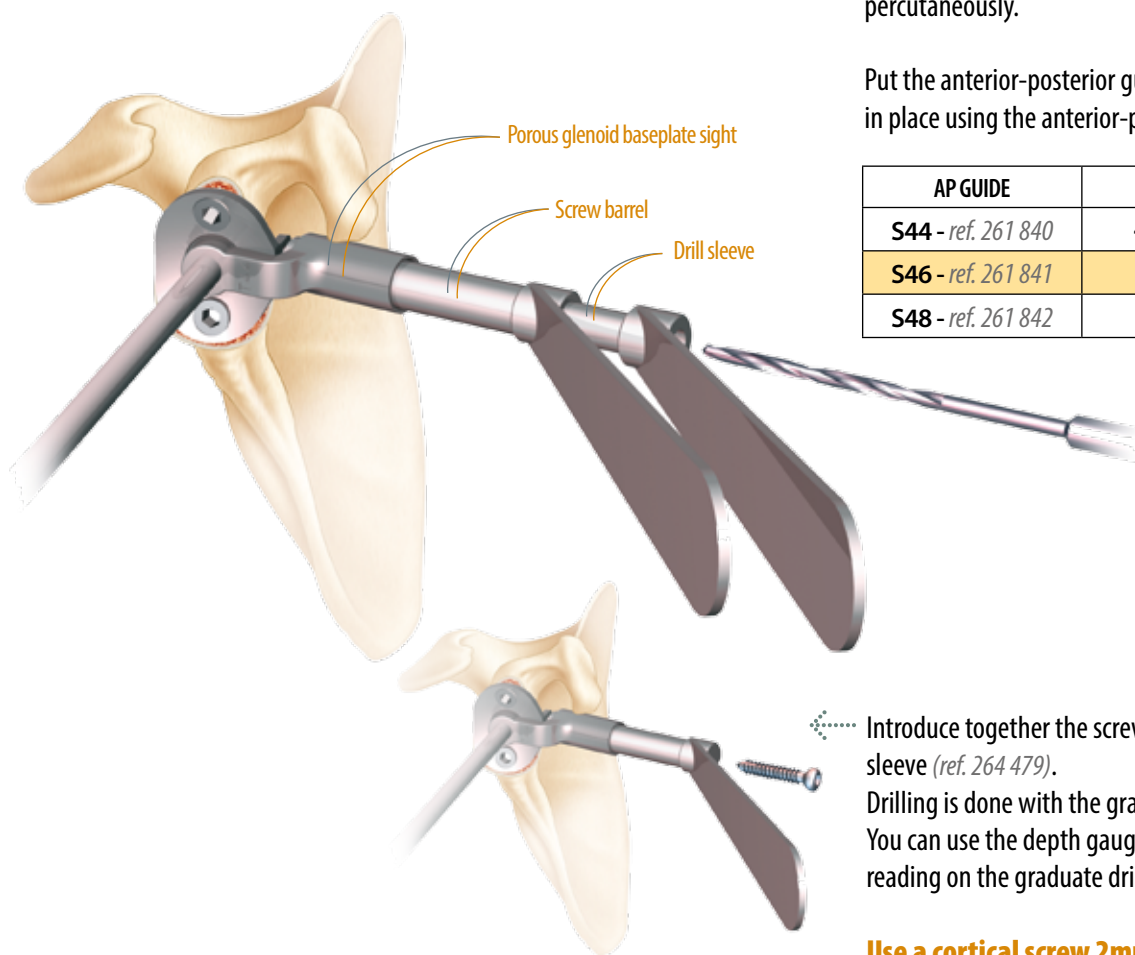


APPENDIX A

PREPARING AND PLACING THE ANTERIOR-POSTERIOR SCREW

This procedure is recommended for bone grafting, when an anterior glenoid fracture is present and when the bone quality is compromised. A deltopectoral approach makes it easier. In the case of a superior-lateral approach, it should be done percutaneously.

Put the anterior-posterior guide for the porous glenoid baseplate in place using the anterior-posterior guide handle (ref. 261 844).



AP GUIDE	POROUS GLENOID IMPLANT
S44 - ref. 261 840	44S / 44S-LP / 44 / 44-LP
S46 - ref. 261 841	46 / 46-LP
S48 - ref. 261 842	48

Introduce together the screw barrel (ref. 261 846) and the drill sleeve (ref. 264 479).

Drilling is done with the graduated drill bit (ref. 267 115).

You can use the depth gauge (ref. 269 241) or use the direct reading on the graduate drill (ref. 267 115).

Use a cortical screw 2mm longer than the graduation previously readen.

Remove the drill sleeve to introduce the cortical screw.

APPENDIX B

PROSTHESIS REMOVAL

HUMERAL INSERT REMOVAL

In the event of revision, the humeral insert can be removed with the extractor assembly. Thread the head extractor tip (Ref. 261014) on the impactor handle (Ref. 264459) and use as demonstrated in the diagram.

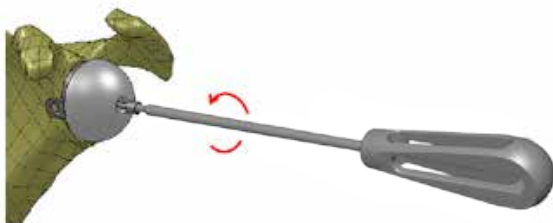
Several light impactions should be sufficient to uncouple the morse taper and permit removal of the humeral insert, leaving the humeral stem in place.



If initial impaction fails to disassemble the insert from the stem, impact in the same fashion, in multiple locations around the perimeter of the insert. This should be sufficient to disrupt the morse taper connection and permit removal of the humeral insert.

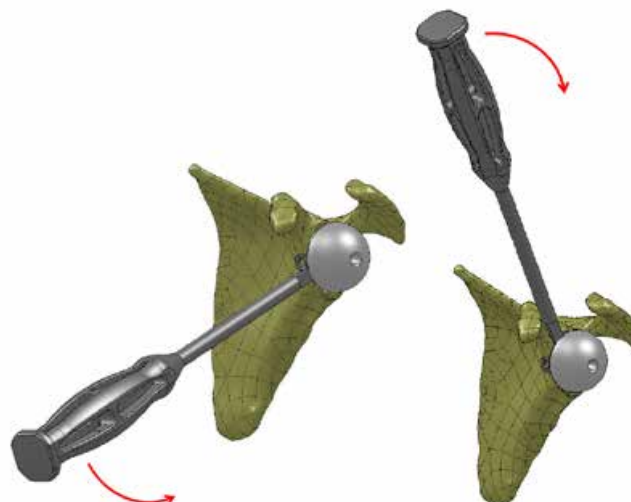


GLENOSPHERE REMOVAL



To remove the glenosphere, remove the connecting capscrew with the hex driver (ref. 264683).

Place the osteotome (ref. 261103) between the glenosphere and the baseplate and lever up. This should be sufficient to release the morse taper and the glenosphere can be extracted.



APPENDIX B (Continued)

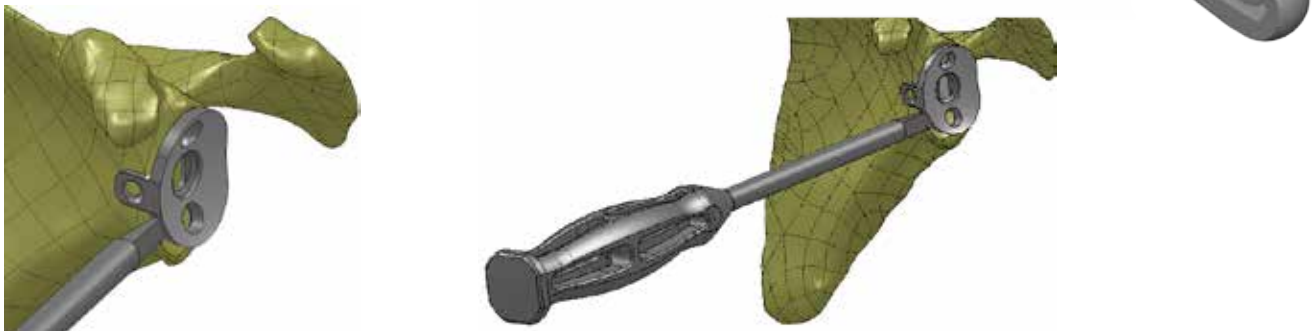
PROSTHESIS REMOVAL

POROUS GLENOID BASEPLATE REMOVAL

Once the glenosphere has been removed, use the hex driver (ref. 264683) to remove the superior and inferior cancellous screws as well as the cortical screw if present.

Position the osteotome (ref. 261103) between the baseplate and the face of the glenoid, working it around as much as possible to free the underside of the baseplate from any ongrown-bone.

Periodic, gentle "levering up" of the baseplate should be used to incrementally work the baseplate out of the bone.



HUMERAL STEM REMOVAL

Should the humeral stem need to be removed, attach the broach handle (ref. 267114) and use a mallet to extract.



If the stem is well-fixed, it may be helpful to use flexible osteotomes to work around the stem as distally as possible as well as underneath to collar.

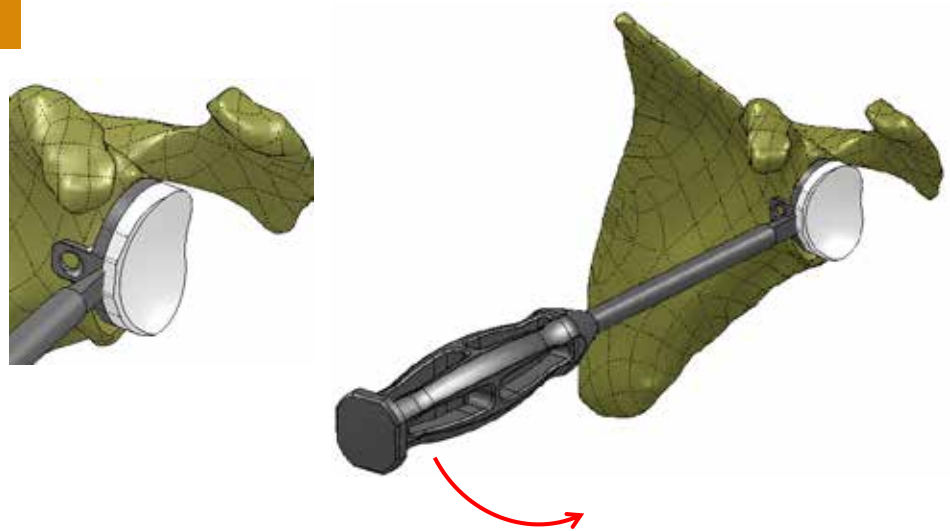


APPENDIX C

REMOVAL OF ANATOMIC GLENOID AND HUMERAL COMPONENTS

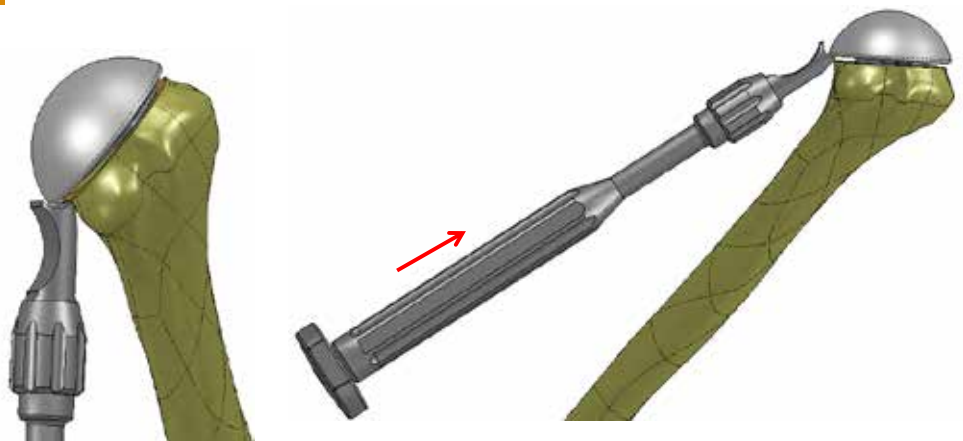
GLENOID INSERT

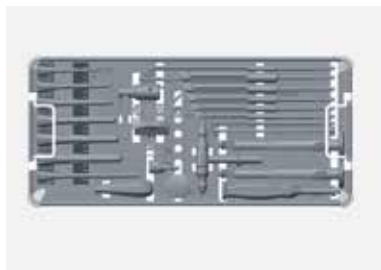
Put the osteotome (ref. 261 103) between glenoid insert and glenoid base and lever up to extract glenoid insert.













HUMERAL HEAD

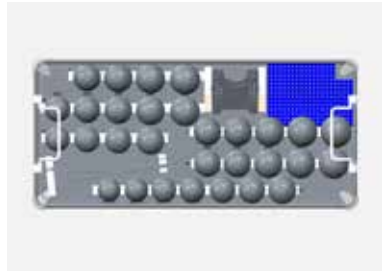
Remove the head using the extraction endpiece (ref 261 014) fitted to the handle (ref 261 009).



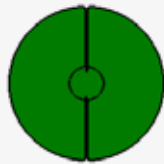


Ref.	Designation	
267841	Arrow tray - Humeral stem PRIME	
267802	Arrow Top	
264868	Square taper bone awl	
261054	Reamer handle	
267604	Reamer D6	
267605	Reamer D8	
268108	Long Reamer D8 lg 200	
267606	Reamer D10	
267607	Reamer D12	
267608	Reamer D14	
267609	Reamer D16	
267610	Cutting Guide Support	
267611	Deltopectoral approach cutting block	

Ref.	Designation	
267612	Superior-lateral approach cutting block	
267613	Cutting guide connecting screw	
261053	Retroversion rod	
269239	AO pin driver	
267614	Arrow Broach Handle	
266222	Arrow Humeral broach Ø6	
264447	Arrow Humeral broach Ø8	
268100	Arrow Humeral broach Ø8 L170	
264448	Arrow Humeral broach Ø10	
264449	Arrow Humeral broach Ø12	
264450	Arrow Humeral broach Ø14	
267357	Arrow Humeral broach Ø16	
264459	Impactor handle	
261043	Head impactor tip	
261014	Head extractor	
261845	Protector for stem	



Ref.	Designation	
267842	Arrow tray- humeral head PRIME	
267802	Arrow top	
261015	Off-centred humeral trail head Ø44 H16	
261016	Off-centred humeral trail head Ø44 H18	
261017	Off-centred humeral trail head Ø46 H16	
261018	Off-centred humeral trail head Ø46 H18	
261019	Off-centred humeral trail head Ø46 H21	
261020	Off-centred humeral trail head Ø48 H16	
261021	Off-centred humeral trail head Ø48 H18	
261022	Off-centred humeral trail head Ø48 H21	
261023	Off-centred humeral trail head Ø50 H17	
261024	Off-centred humeral trail head Ø50 H19	
261025	Off-centred humeral trail head Ø50 H21	
264090	Off-centred humeral trail head Ø52 H19	
264091	Off-centred humeral trail head Ø52 H21	



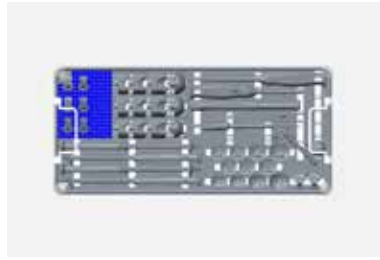
Ref.	Designation	
261026	Centered humeral trail head Ø40 H15	
261027	Centered humeral trail head Ø40 H17	
261028	Centered humeral trail head Ø44 H16	
261029	Centered humeral trail head Ø44 H18	
261030	Centered humeral trail head Ø46 H16	
261031	Centered humeral trail head Ø46 H18	
261032	Centered humeral trail head Ø46 H21	
261033	Centered humeral trail head Ø48 H16	
261034	Centered humeral trail head Ø48 H18	
261035	Centered humeral trail head Ø48H21	
261036	Centered humeral trail head Ø50 H17	
261037	Centered humeral trail head Ø50 H19	
261038	Centered humeral trail head Ø50 H21	
264092	Centered humeral trail head Ø52 H19	
264093	Centered humeral trail head Ø52 H21	
261039	Centered humeral trail head Ø54 H19	
261040	Centered humeral trail head Ø54 H21	
261041	Humeral head sizer Ø40, 44, 46	
261042	Humeral head sizer Ø48, 50, 52, 54	
261109	Head holder	




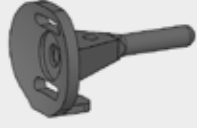




Ref.	Designation	
267843	Arrow tray - glenoid PRIME	
267802	Arrow top	
261059	Retractor	
267110	glenoid inserter	
261077	Glenoid template Ø44	
261078	Glenoid template Ø46	
261079	Glenoid template Ø48	
261080	Glenoid template Ø50	
269086	Glenoid guide 0° post wear - right	
269087	Glenoid guide 0° post wear - left	
269088	Glenoid guide -10° post wear - right	
269089	Glenoid guide -10° post wear - left	
269090	Glenoid guide -20° post wear - right	
269091	Glenoid guide -20° post wear - left	
269092	Glenoid guide stylus - right	
269093	Glenoid guide stylus - left	







Ref.	Designation	
267650	Cannulated reamer XS-S / 44	
267651	Cannulated reamer M / 46	
267652	Cannulated reamer L / 48	
267653	Cannulated reamer XL / 50	
269147	Drill Handle	
267654	Full PE Drilling Guide	
269242	Quick-Release Peripheral Drill Shaft	
261070	Cemented trial glenoid Ø44	
261071	Cemented trial glenoid Ø46	
261072	Cemented trial glenoid Ø48	
261073	Cemented trial glenoid Ø50	
264459	Impaction handle	
267659	Cemented/Metal-Back Glenoid Impactor tip	
261103	Chisel	
261844	Jig handle	
261840	Jig size 44 for glenoid base	
261841	Jig size 46 for glenoid base	
261842	Jig size 48 for glenoid base	
264683	screwdriver	



Ref.	Designation	
267844	Arrow tray - metalback glenoid PRIME	
267802	Arrow top	
267667	Trial MB Handle	
268470	metal-back drill guide 44S	
268471	metal-back drill guide 44-46-48	
269133	Cannulated glenoid punch 44S	
269134	Cannulated glenoid punch 44	
269135	Cannulated glenoid punch 46	
269136	Cannulated glenoid punch 48	
264101	trial metalback glenoid base 44S	
261088	Glenoid metal back trial size 44	
261089	Glenoid metal back trial size 46	
261090	Glenoid metal back trial size 48	
269056	trial metalback glenoid base size 44S-LP	
264951	trial metalback glenoid base size 44-LP	
268988	trial metalback glenoid base size 46-LP	

Ref.	Designation	
266833	trial cementless glenoid 44S	
266834	trial cementless glenoid 44	
266835	trial cementless glenoid 46	
266836	trial cementless glenoid 48	
261846	Screw barrel	
264479	Drill sleeve	
269241	Depth gauge	
261108	Screw holder	
261101	Metal-Back Baseplate handle	
264495	Humeral trial insert Ø36 H00	
264496	Humeral trial insert Ø36 H05	
264497	Humeral trial insert Ø36 H10	
264498	Humeral trial insert Ø39 H00	
264499	Humeral trial insert Ø39 H05	
264500	Humeral trial insert Ø39 H10	
264501	Humeral trial insert Ø42 H00	
264502	Humeral trial insert Ø42 H05	
264503	Humeral trial insert Ø42 H10	
267696	Humeral insert impactor tip	
261092	Glenosphere trial Ø36	
261093	Glenosphere trial Ø39	
261094	Glenosphere trial Ø42	
269137	Glenosphere positioner/impactor	

Single use unstruments - Sterile delivery

Ref.	Designation	
267115	Drill bit Ø3,2	
268016	Extended cutting guide pins (x4)	
269132	Cannulated tapered reamer	
269138	Threaded pin Ø3 L170	
269148	Cannulated drill bit Ø5	
269240	Quick-release peripheral drill Ø5 (x2)	
269149	Cannulated long drill bit Ø5	