



# SHOULDER

INNOVATIONS

Strong Glenoid Fixation

Simple Surgical Technique

Published Results

**SURGICAL  
TECHNIQUE**

## SHOULDER INNOVATIONS TOTAL SHOULDER SYSTEM

The Shoulder Innovations Primary Total Shoulder System was initially designed to provide improved glenoid implant fixation in deficient glenoid bone. The inset glenoid design addresses the two most significant challenges in shoulder arthroplasty surgery- glenoid bone loss and glenoid implant loosening<sup>1,2,3,4,5,6,7</sup>.

In order to maximize glenoid fixation strength in both bone deficiency cases and standard shoulder arthritis cases, an inset glenoid design was developed, tested, and enhanced<sup>9,10</sup>. The inset technique includes placing the glenoid implant down in to a shallow pocket below the articular surface with a strong, circumferential cortical bone periphery. Supplemental fixation is also provided utilizing a scalloped central post, peripheral pegs, and peripheral cement channels.

### ARTICULAR SURFACE DESIGN

The glenoid articulating surface maximizes glenoid to head compatibility while optimizing contact area between the humeral head and the articulating surface of the glenoid. This allows for more compatibility between glenoid and humeral head sizes. This novel articular surface also diminishes the risk of polyethylene surface wear.

### HUMERAL IMPLANTS

The cobalt chrome humeral stem prosthesis incorporates a proximal press fit, with a blast finish, while offering additional component options to aid with rotational stability.

### FIXATION

The inset glenoid design offers a number of key advantages to the current on-lay designs. Since loosening of the glenoid component has been a continued reason for shoulder replacement failure, this new inset design offers a strategic advantage over classic glenoid designs. The circumferential strong, cortical support of the implant around the perimeter shields the implant from rocking horse loosening forces during daily shoulder motion activities. The flat back design, pegs, and cement channels also potentiate the increased fixation strength that decrease the risk of implant loosening<sup>9,10</sup>.

## System Design Rationale

The first advantage pertains to the elimination of a rocking glenoid. This is accomplished with the backside design and surgical preparation. The back of the glenoid is flat. This design offers stable fixation that is intended to decrease the potential for the rocking horse effect often seen with curved back designs. (Fig. 1)

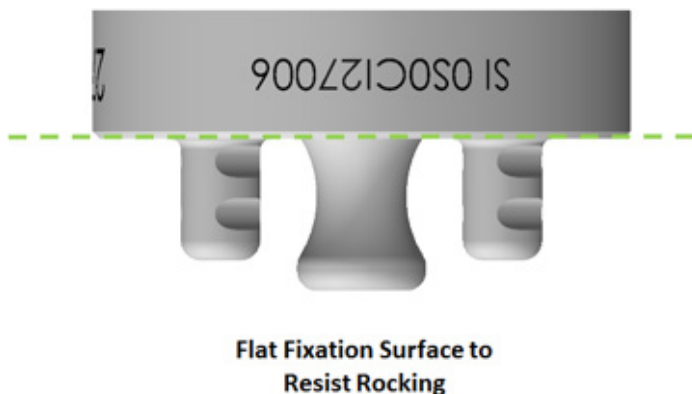


Fig. 1

## Circumferential Bone Support

The second advantage relates to the reaming and preparation of the bone bed in which the inset glenoid will be placed.

This preparation results in the capture of the glenoid implant by the surrounding bone. This circumferential rim of bone offers up to 40x increased implant stability as compared to an on-lay design<sup>8</sup>. (Fig. 2 & 3)

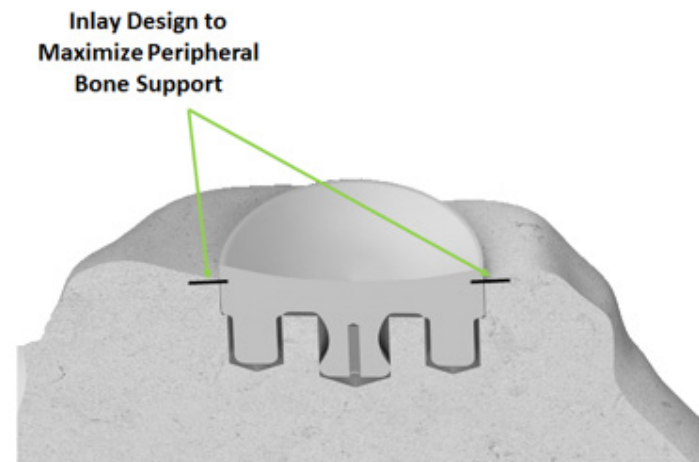


Fig. 2



Fig. 3

## Glenoid Sizes

Components are available in diameters of 22, 24, 27 and 30 mm. (Fig. 4)

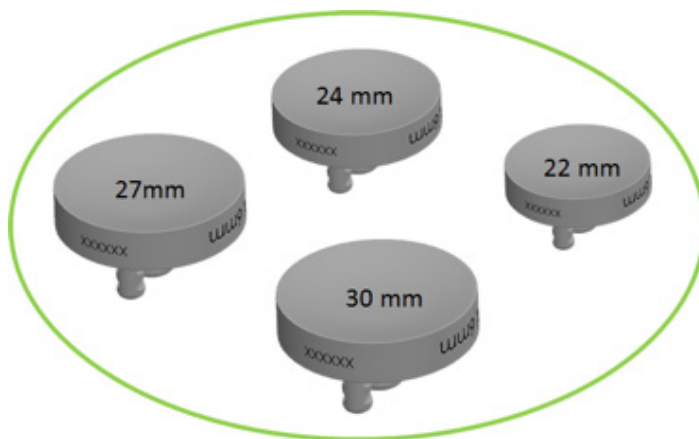


Fig. 4

The components are offered in 6 mm and 8 mm thicknesses, which offer intraoperative flexibility in addressing a variety of patient anatomies. The central peg of the implant is 8 mm in length and 6.5 mm in diameter, while the peripheral pegs are 6 mm in length and 4 mm in diameter.

## Glenoid Fixation Surface

Fixation is obtained by combining the backside macro geometry of the glenoid with the use of bone cement. The design incorporates captured cement channels, a parabolic shaped central post and two peripheral pegs. (Fig. 5)

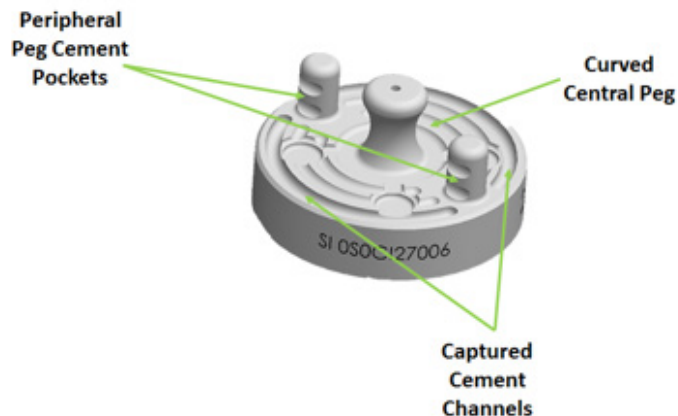


Fig. 5

The central 6.5 mm central peg design, 4.0 mm peripheral superior and inferior pegs and cement channels work in conjunction with bone cement to optimize short and long term implant fixation.

## Glenoid Articulating Surface

The articulating surface of the glenoid has 3 major advantages over conventional articular surface designs.

1. This surface geometry allows complete interchangeability with a variety of humeral head sizes. (Fig. 6)
2. A large contact area provides reduced stress on the polyethylene.

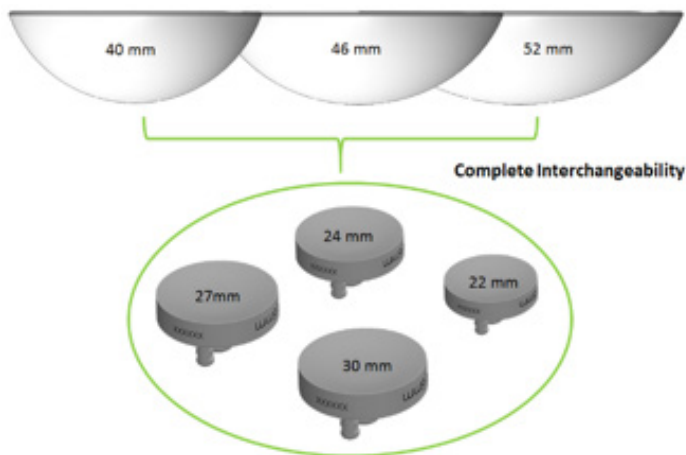


Fig. 6

3. With the inset fixation, this system offers the greatest tested resistance to the rocking horse effect. The result is a total shoulder system that offers intraoperative flexibility, low wear, and stable long-term fixation.<sup>10</sup>

## Humeral Stem Component

The cobalt chrome humeral stem component of the Shoulder Innovations system is available in 5 sizes in 2 mm increments (6, 8, 10, 12, 14mm).

STEM OPTIONS
6 x 130 mm
8 x 130 mm
10 x 130 mm
12 x 130 mm
14 x 130 mm

This bone preserving design incorporates a collar, proximal cylinder, proximal fins, 1mm diaphyseal taper, fluted distal stem and a blasted surface for optimal fixation. (Fig. 7)

This design is cleared for use with and without bone cement. The 2 mm increments enable the surgeon to match the stem closely to the patient's anatomy while optimizing the metaphyseal and diaphyseal fit.

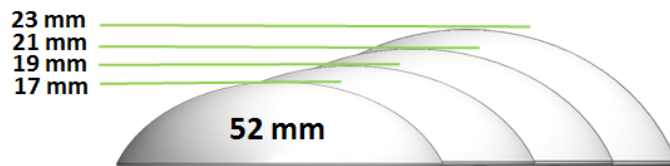
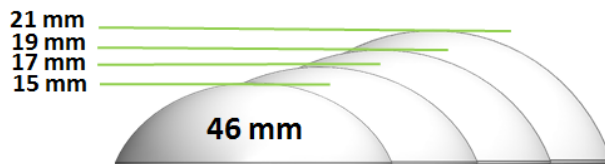
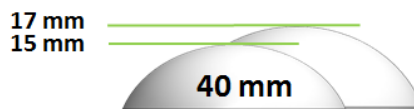


Fig. 7

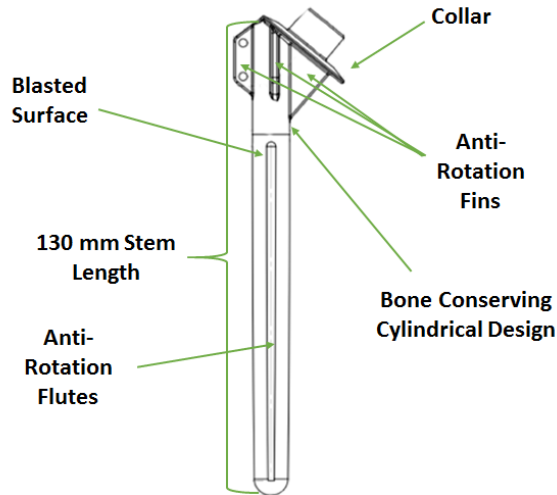


Fig. 8

The 40 - degree fixed neck angle, proximal cylinder and 1mm taper allow for a reproducible surgical approach. (Fig. 8)

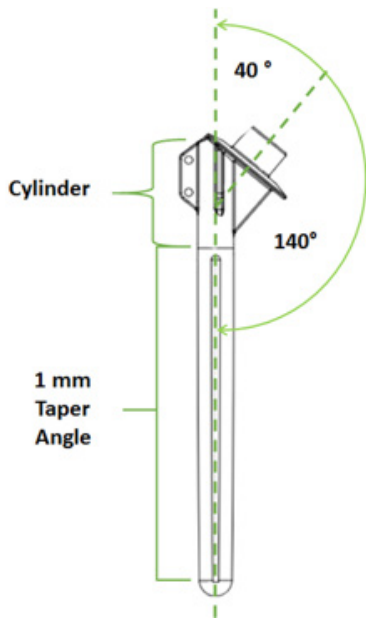


Fig. 9

## Humeral Heads

The CoCr humeral heads are available in the following diameters and head heights: (Fig. 9)

DIAMETER (mm)	HEIGHT (mm)
40	15
40	17
46	15
46	17
46	19
46	21
52	17
52	19
52	21
52	23

All humeral heads incorporate a 3 mm offset allowing for an infinite number of head positions. (Fig. 10)

Head options are designed to offer maximum humeral coverage and optimization of joint stability.

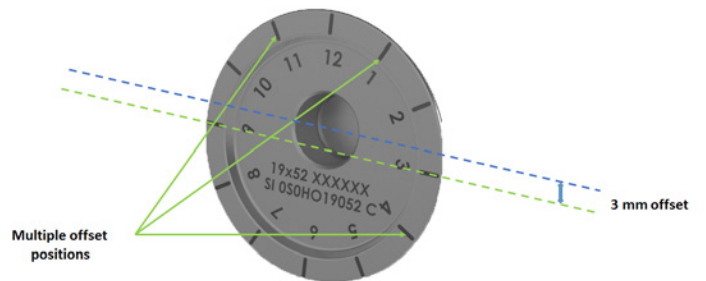
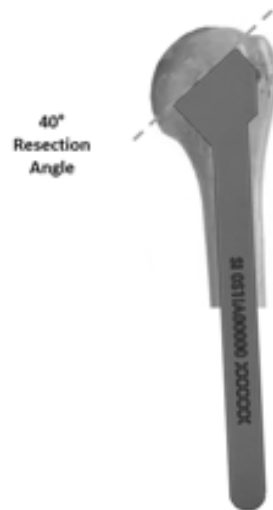


Fig. 10

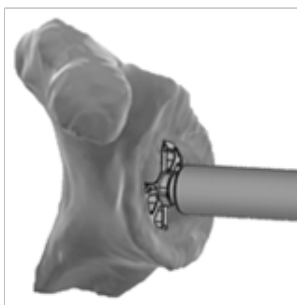
## SHOULDER INNOVATIONS SURGICAL TECHNIQUE OVERVIEW



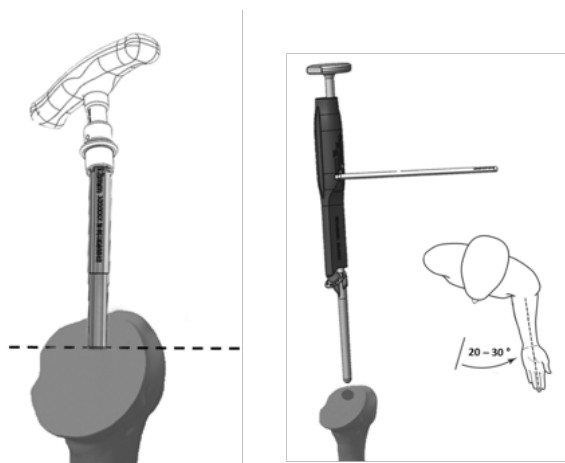
1. Surgical Approach



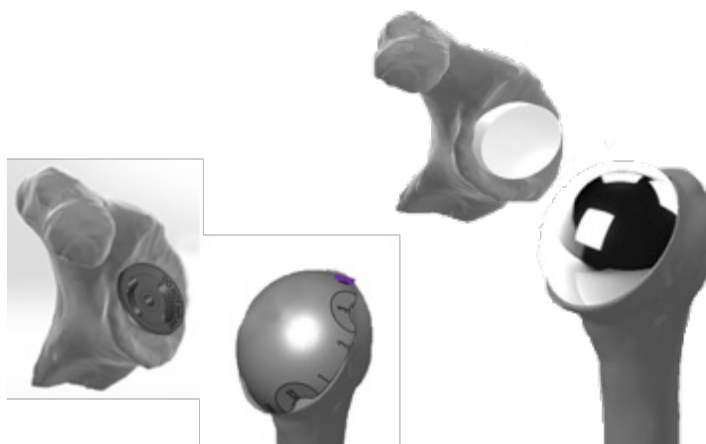
2. Humeral Head Resection



3. Three-Step Glenoid Preparation



4. Humeral Preparation



5. Trial and Final Implantation



## Patient Positioning and Surgical Exposure

Place the patient in a semi-beach chair position. Use a head rest that allows for the superior part of the table to be removed.

Place a towel under the medial border of the scapula to raise the affected side.

Raise the head of the table at least 30 degrees to reduce venous pressure. (Fig. 11)

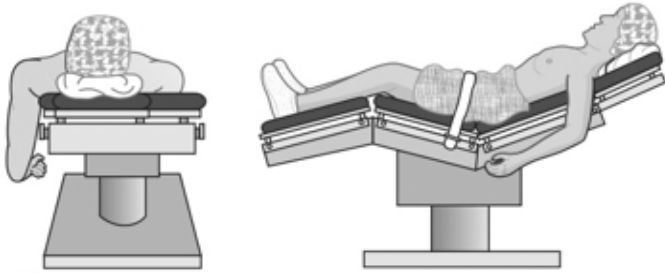


Fig. 11

## Exposure

Mark a line beginning just superior to the coracoid process. (Fig. 12)



Fig. 12

Extend the line along the deltopectoral groove 8-15cm distally, as required for adequate exposure.

Complete the skin incision along this line. Undermine the skin flaps to improve exposure. Dissect subcutaneous tissue from the deltoid fascia, and expose the deltoid and pectoralis major muscles. Develop the deltopectoral interval (indicated by the line), retracting the pectoralis major medially and the deltoid laterally.

Identify and dissect the interval between the pectoralis major muscle and the cephalic vein.

Retract the cephalic vein either medially or laterally out of the field of vision.

## Deep Exposure

Release the upper 1 - 2cm of the insertion of the pectoralis major tendon if necessary for exposure, being careful to avoid the long head of the biceps tendon.

In very tight shoulders, it may become necessary to completely release the pectoralis.

Tag the pectoralis major muscle with a suture to allow for easy identification during the reattachment, later in the procedure.

Release any adhesions between the deltoid and conjoined tendon (coracobrachialis and short head of biceps) and gently retract the conjoined tendon medially.

Avoid constant pressure on the conjoined tendon distally as this may cause injury to the musculocutaneous nerve.

## Subscapularis Release

With the humerus in a neutral position, expose the superior portion of the sub-acromial space by resecting the leading edge of the coracoacromial ligament.

Identify the superior and inferior margins of the subscapularis tendon.

Divide the tendon just medial to the bicipital groove and elevate it from the lesser tuberosity.

Retract the subscapularis medially, exposing the articular surface of the humeral head while taking care to avoid the axillary nerve, inferiorly.

The approach to the subscapularis can be completed using a variety of techniques, which should be left up to the discretion of the surgeon. (Fig. 13)



Fig. 13

**Note:** It is important to maintain as much length of the subscapularis muscle as possible.

Remove the capsule and subscapularis tendon, as a unit, laterally from the humerus while protecting the axillary nerve by externally rotating the humerus.

**Note:** If a large inferior osteophyte is present on the humeral head, it is important to dissect the capsule off the neck of the humerus laterally and rotate the humeral head away from the axillary nerve, in order to safely remove the osteophyte.

Medially, the capsule and labrum can be separated from the subscapularis in order to mobilize the tendon.

## Humeral Head Resection: Cutting Template Positioning

With the humerus in 20- 30 degrees of external rotation, place the humeral head resection guide template over the humerus such that the cutting surface is at the level of the anatomic neck and the long arm of the template overlays the humeral shaft. (Fig. 14)

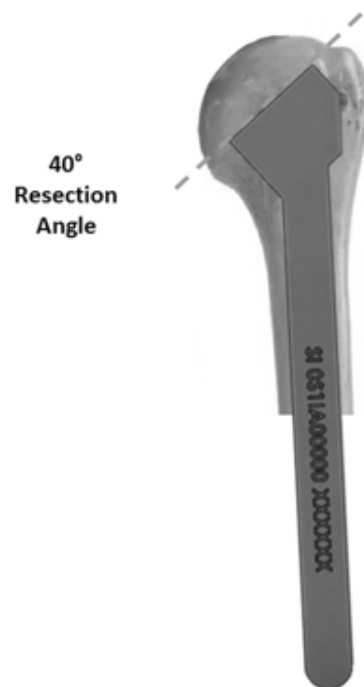


Fig. 14



# SURGICAL TECHNIQUE

The resection guide is designed with a 40-degree angle, which matches the neck/shaft angle of the humeral stem implant.

Using a cautery or surgical skin marker, draw a line along the top of the template.

The humeral head can be resected with a fine tooth oscillating sawblade or with the use of a wide osteotome.

Prior to resection, palpate the anterior and posterior aspect of the humeral head at the resection line to ensure a cut along the anatomic neck.

Place retractors around humeral head and take care not to extend the sawblade past the medial or posterior aspect of the humeral head.

**Note: Assess resection and confirm appropriate version. The humeral cut should point directly towards the glenoid surface with the arm in neutral rotation.**

## Glenoid Preparation

Axillary radiographs and CT scans are very helpful in the preoperative preparation to assess glenoid wear, asymmetry, and the depth of the glenoid vault.

It is important to identify the center of the glenoid vault as this landmark will be used in placement of the guide pin and subsequent preparation steps. (Fig. 15 & 15a)

To accomplish this, retract the soft tissues both anteriorly and posteriorly to expose the glenoid.

Place a Fukuda retractor, or a bent glenoid retractor posteriorly, to facilitate the subluxation of the humerus posteriorly and inferiorly.

Next, place a Bankart retractor or other similar retractor anteriorly along the glenoid neck.

Strip the capsule from the articular margin of the glenoid.

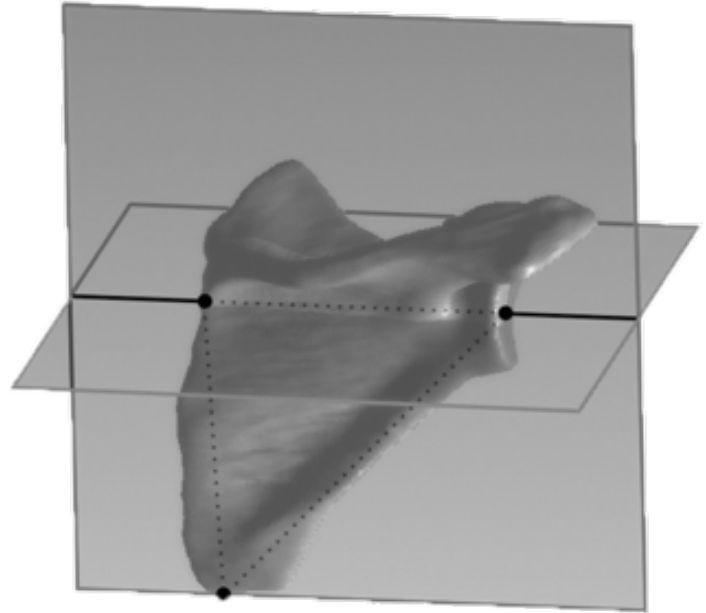


Fig. 15

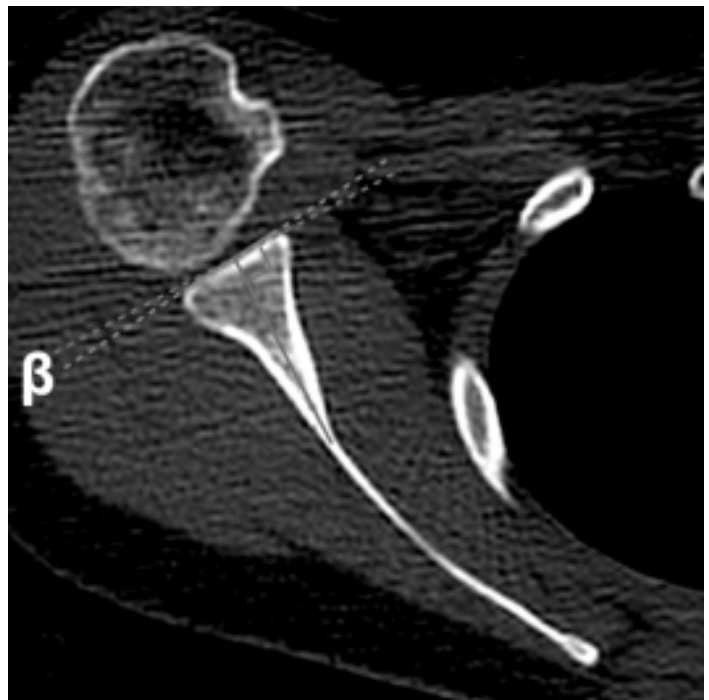


Fig. 15a

Next, place a finger along the anterior glenoid neck to allow for a tactile confirmation of the glenoid surface version.

**Note:** In tight shoulders, it may be necessary to release the capsule and labrum along the inferior margin of the glenoid. Care should be taken to avoid injury to the axillary nerve by pushing the nerve inferiorly.

**Note:** In rare cases of extremely tight shoulders some posterior release may be helpful, however this must be individualized and should be performed with caution.

Remove any remaining cartilage or soft tissue from the glenoid using a Cobb elevator.

## Glenoid sizing

Begin by selecting the glenoid sizer from the instrument tray. Each guide is available in a double-ended configuration. (Fig. 16)

Position the sizing guide flat against the face of the glenoid. (Fig. 17)

Placement of the guide and subsequent guide wire is determined by pre-op planning and intraoperative assessment. The surgeon may palpate the anterior and posterior walls of the glenoid vault for additional reference.

Approximately 2 to 3 mm of the bone should be visible outside of the guide to ensure adequate peripheral bone coverage and support.

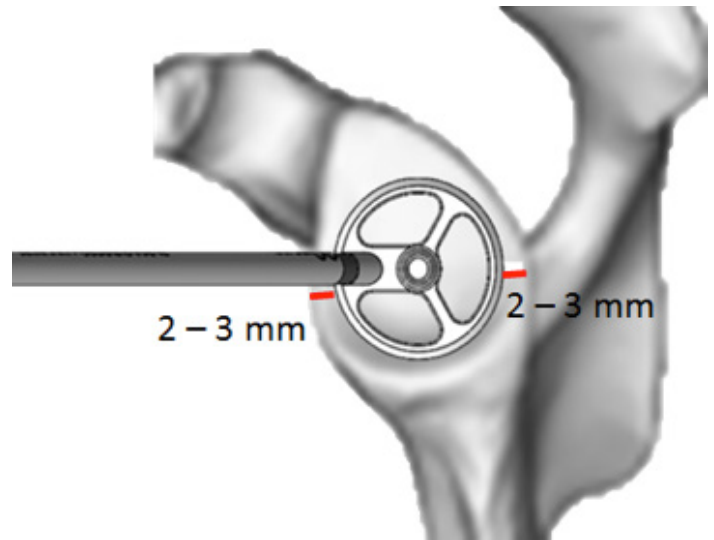


Fig. 17



Fig. 16

## Guide Pin Insertion

The SI Shoulder System utilizes a cannulated approach to the preparation of the glenoid.



Fig. 18

The 2.4 mm guide pin is inserted 10 – 15 mm, or a depth determined during pre-operative planning, in to the glenoid at an angle perpendicular to the glenoid face. (Fig. 18)

The guide pin may also be placed at a slight angle to the articular surface in certain cases in order to realign altered version in arthritic bone in order to slightly inset more on the “high side”, as determined by preoperative templating.



The result should be a stable pin. (Fig 18a)

Fig. 18a

## Central Guide Hole and Reaming Preparation

The next step of the procedure is to drill the central guide hole and ream the glenoid pocket. The reamer is designed to accomplish the central hole preparation and glenoid reaming in one step. (Fig. 19)

Select the glenoid reamer corresponding to the size determined during sizing.

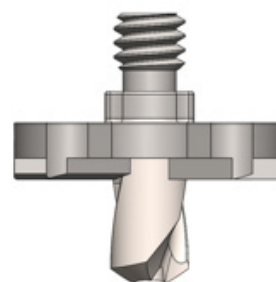


Fig. 19

The glenoid reamers are 5 mm thick. The glenoid trials and implants are 6 mm and 8mm thick. These offerings allow for flexibility in reaming and subsequent selection of the glenoid trial and implant. (Fig. 20)

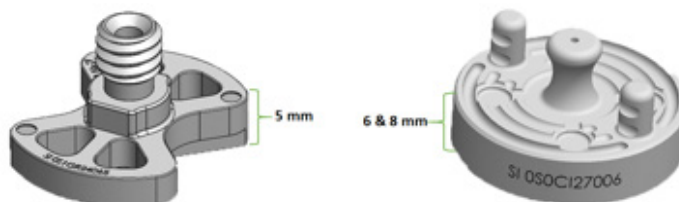


Fig. 20

Assemble the reamer to the reamer guide and tighten by turning the wrench in a clockwise direction, as shown. (Fig. 21)



Fig. 21

Slide the glenoid reamer over the guide pin and initiate the reamer prior to engaging the glenoid to minimize the risk of glenoid fracture. (Fig. 22)



Fig. 22

Advance the reamer into the glenoid to the desired depth. The goal is to have a glenoid that is circumferentially supported by bone and sits above the most prominent bony surface. This will be assessed during trialing. (Fig. 23 & 23a)

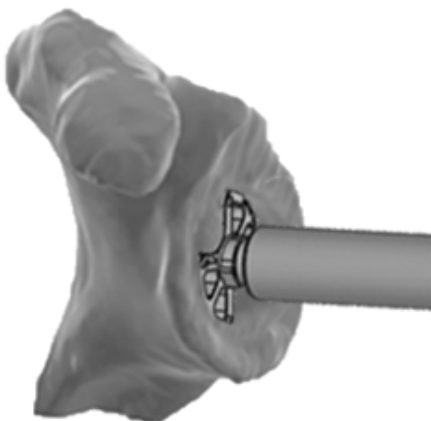


Fig. 23

**Note:** The Glenoids of the SI system are available in 6 and 8 mm thicknesses to allow for adjustments of the glenoid height. Avoid reaming through the strong, sclerotic subchondral bone.

**Note:** Defects in the Glenoid topography must be assessed prior to reaming to ensure that an adequate amount of circumferential bone will be present upon the completion of the reaming step. Inadequate circumferential bone support may lead to loosening of the glenoid component.

Remove the reamer from the guide wire upon the completion of reaming. (Fig. 24)

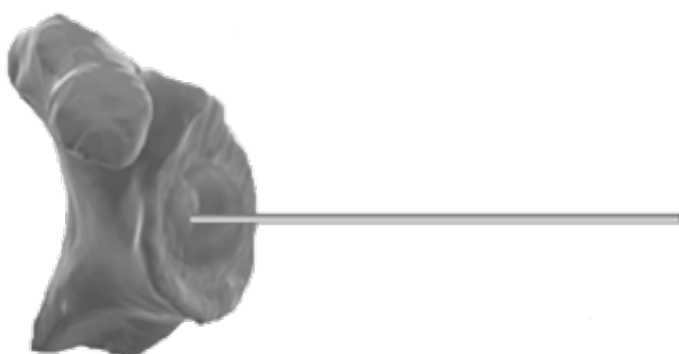


Fig. 24

Leave the guide wire in place.

**Inlay Design to Maximize Peripheral Bone Support**

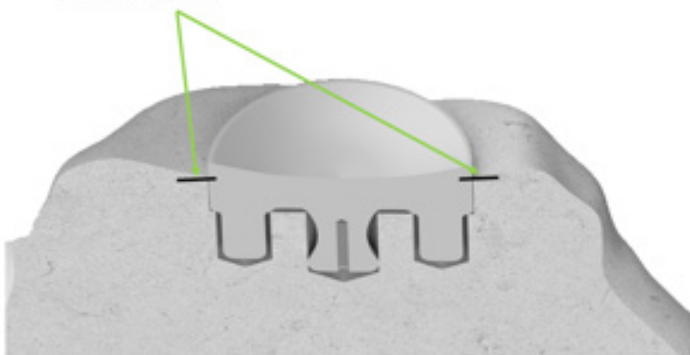


Fig. 23a

## Peripheral Peg Preparation

Select the drill guide that corresponds to the size of the glenoid reamer. The drill allows for the preparation of the superior and inferior pegs of the glenoid. The guide incorporates 2 levels indicating the 6mm and 8mm glenoid thicknesses. The central stabilizing peg of the guide, in conjunction with the guide wire, allows for accurate positioning and stabilization during use.

The guide contains a threaded side hole that accepts the stabilizing handle. (Fig. 25)

Assemble the multipurpose handle by threading it into the side hole of the drill guide in a clockwise direction. The guide is universal for left or right procedures. (Fig. 26)

Place the guide over the guide wire and into the prepared central hole and glenoid bed. Fully seat the guide with the superior and inferior holes of the guide in a vertical position to the glenoid vault. (Fig 27)

Visualization slots are designed into the guide to enable the surgeon to confirm the guide is fully seated.

**Note: The guide must be fully seated and flush with the glenoid bed to ensure that the correct depth and alignment angle are achieved during preparation of the peripheral pegs.**

**Note the level at which the guide sits within the bed for reference of desired glenoid implant thickness: 6 or 8 mm.**

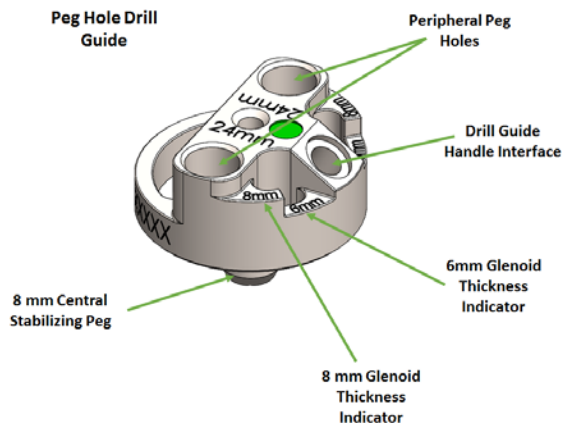


Fig. 25



Fig. 26



Fig. 27

# SURGICAL TECHNIQUE

Select the drill driver, sleeve, 5mm peripheral drill bit and wrench. Insert the sleeve over the driver, thread the drill bit on to the end of driver and gently tighten in a clockwise direction, as shown. (Fig. 28)

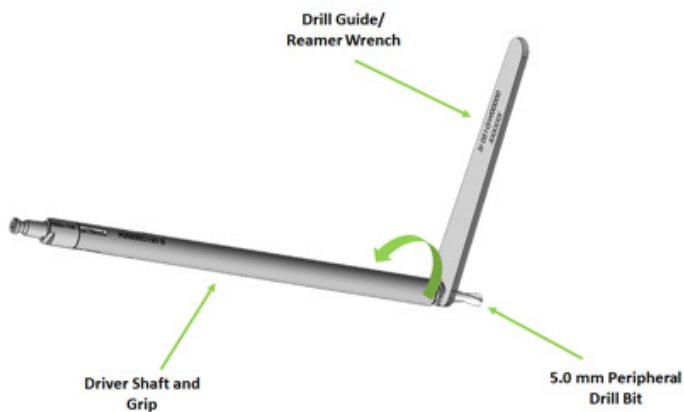


Fig. 28

The instrumentation contains anti-rotation pegs. Insert a peg into the prepared superior peg hole. (Fig 29a)

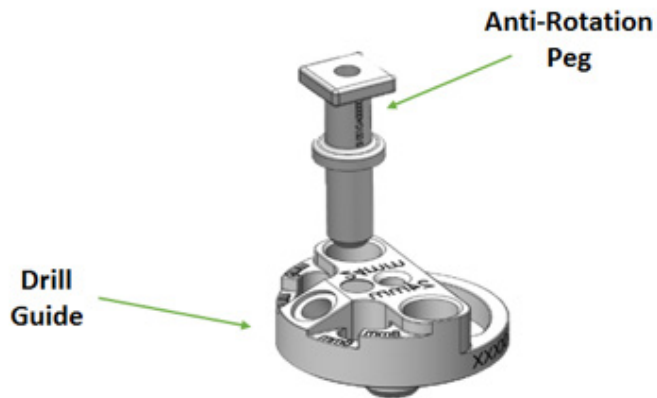


Fig. 29a

The guide is equipped with a drill stop to prevent over drilling. Begin with the superior hole.

Advance the drill until the collar of the drill bit contacts the drill guide. (Fig. 29)

Complete preparation of the inferior hole. Remove the anti-rotation peg and guide. (Fig. 29b)



Fig. 29



Fig. 29b



# SURGICAL TECHNIQUE

Select the 6mm thick glenoid trial corresponding to the reamed glenoid size. (Fig. 30)

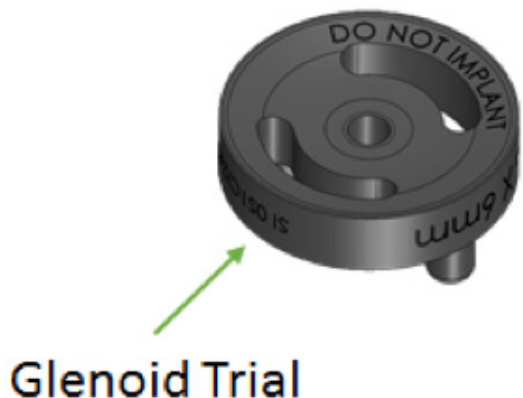


Fig. 30

Insert the glenoid trial. Ensure that all pegs are aligned and that the trial sits flush with the prepared glenoid bed. (Fig. 30a & 30b)

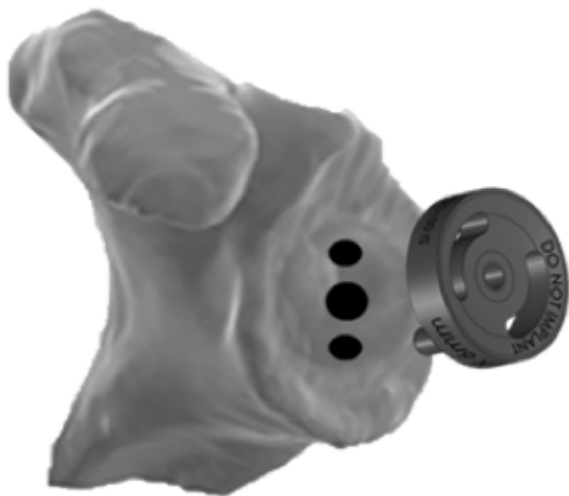


Fig. 30a

**Note:** If you are unable to fully seat the trial component due to interference with pegs, replace the drill guide, ensure that the guide is sitting flush, and redrill the central and peripheral pegs.

Assess depth and circumferential bony coverage.

The articular surface of the trial should protrude above the surface of the glenoid, at its deepest point. If the trial is below the surface the 8 mm trial can be inserted and assessed for proper clearance of the circumferential bone.



Fig. 30b

**Note:** The trial should be covered circumferentially by bone and should protrude above the surface of the bony structure. This will ensure adequate bony support while allowing for articulation with the humeral head without bony impingement.

**Note:** Loosening or excessive wear may occur if the glenoid component lacks sufficient bony support.

The trial may be left in place or removed during the preparation of the humerus.

Surgeons may choose to implant the final glenoid implant at this time.

**(Refer to the instructions for cementing of the glenoid component on page 25).**

## Humeral Preparation: Reaming

Place a Darrach or another similar retractor between the humerus and the glenoid.

Remove any remaining osteophytes along the peripheral rim of the humerus with a curved osteotome or Rongeur.

Select the 6mm starter reamer and t-handle. Load the reamer into the t-handle by pulling back on the sleeve. (Fig. 31)



Fig. 31

The reamers are marked with a black line that corresponds to the length of the trials and implants. (Fig. 32)

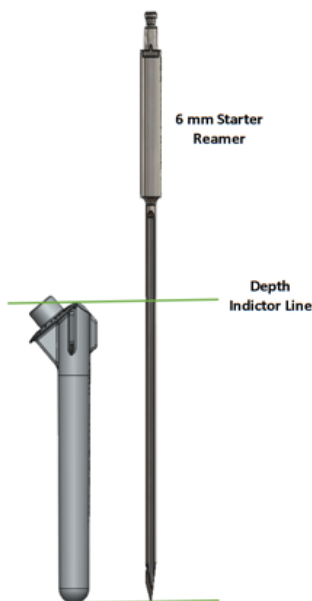


Fig. 32

Insert the starter reamer approximately 1 cm posterior and 1cm medial to the top of the bicipital groove to enter the anatomic humeral canal center and initiate reaming 11. The starter reamer has a trocar tip to allow for easy access to the canal. (Fig. 33)



Fig. 33

**Note: Do not power ream the humerus as this may result in removal of excess bone or a humeral fracture.**

Advance the reamer until the black line is level with resected humeral surface. (Fig. 33a)

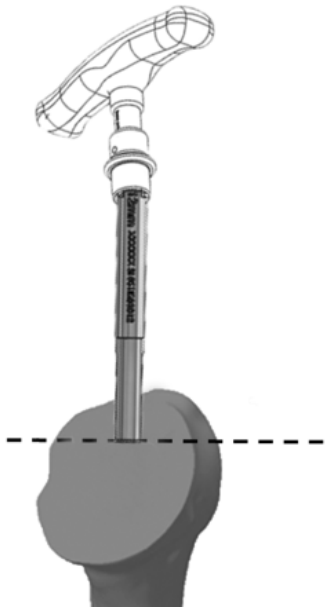


Fig. 33a

Progressively ream by 2mm increments to the depth line until mild resistance is felt from cortical contact in the canal. Reamer sizes 8 through 14 mm utilize a blunt tip and side cutting teeth. (Fig. 34)

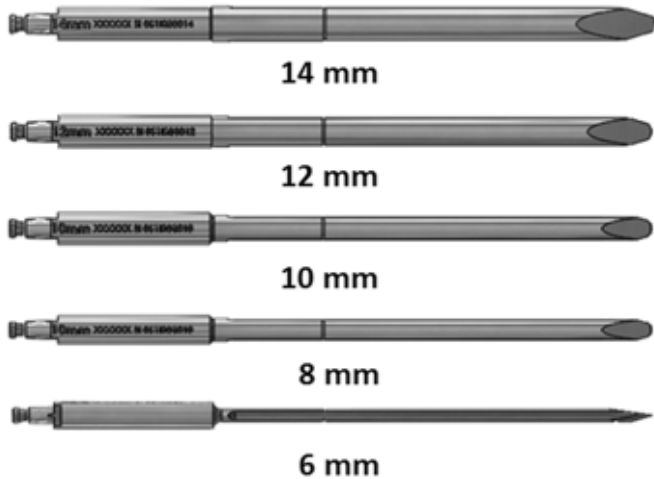


Fig. 34

**NOTE:** Obtaining cortical chatter is not recommended as this may increase the risk of humeral fracture.

## Humeral Preparation: Trial Insertion

Select the multipurpose impactor handle, version control sleeve, version rod and drill guide handle. The drill guide handle functions as a version rod during this step.

Slide the multipurpose impactor through the hole in the version handle until the rod exits the distal end of the handle. (Fig. 35)

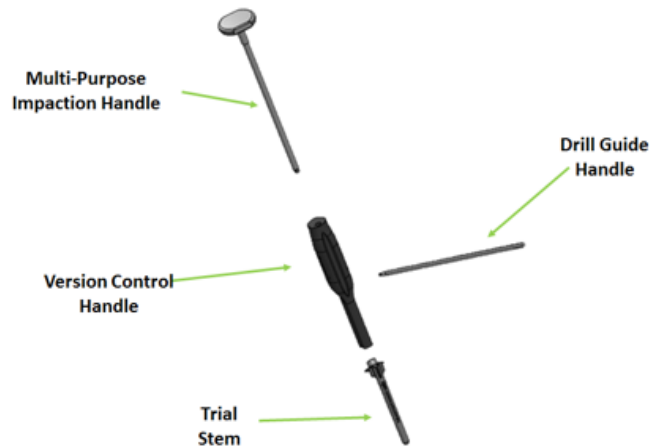


Fig. 35

Select the stem trial size matching the last reamer. (Fig. 36)



Fig. 36

# SURGICAL TECHNIQUE

Place the assembled version control handle guide onto the trial stem, as shown in **figure 37**. Tighten the version guide and impactor handle by turning the multipurpose handle in a clockwise direction.

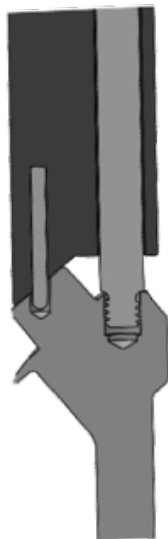


Fig. 37

The version handle accommodates version angles of 20, 30 and 40 degrees. (Fig 38)

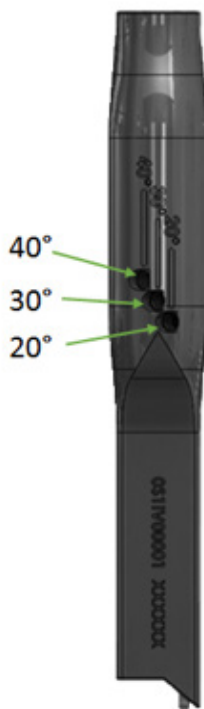


Fig. 38

Screw the version rod into the hole indicating the desired amount of version. (Fig. 38a)



Fig. 38a

Align the version rod perpendicular to the condyles of the elbow with the arm in 20- 30 degrees of external rotation. Position the trial in the canal and insert it until the anterior and posterior fins contact the resected surface. (Fig. 39)

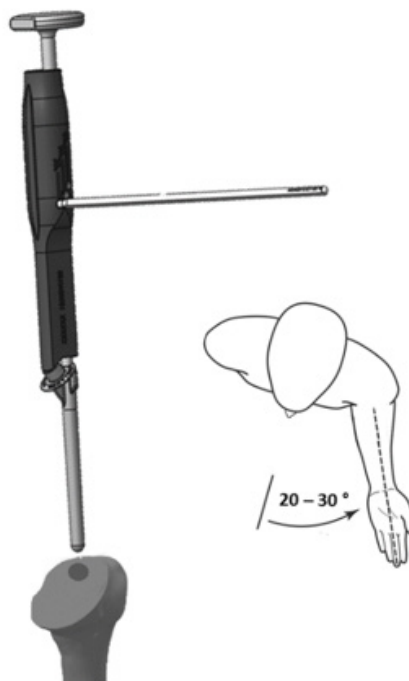


Fig. 39

## Humeral Stem Trial

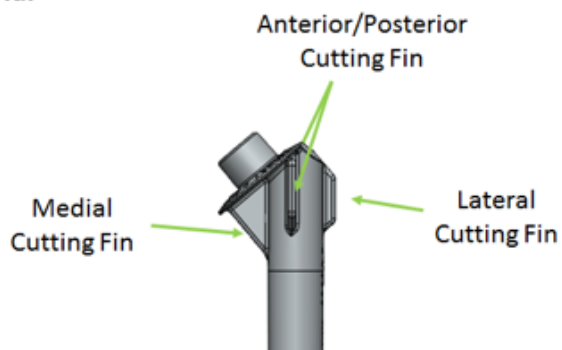


Fig. 40

**Note:** Confirm anatomic version prior to completing the final impaction of the trial stem. The fins on the Humeral Stem Trial are self-cutting and will prepare for the final implant fins once fully impacted. (Fig 40)

Fully impact the Humeral Stem Trial into the humeral canal until the collar rest flush on the resected humerus. (Fig 40a)



Fig. 40a

Leave the trial stem in place and proceed to the selection of the humeral head. Using a skin marker or cautery, make a mark on the bone aligning with the lateral fin of the implant trial. This will be used in subsequent steps to align the head/stem final construct.

## Humeral Trial Head Selection

Select the humeral head sizing guide from the instrument tray. (Fig 41)

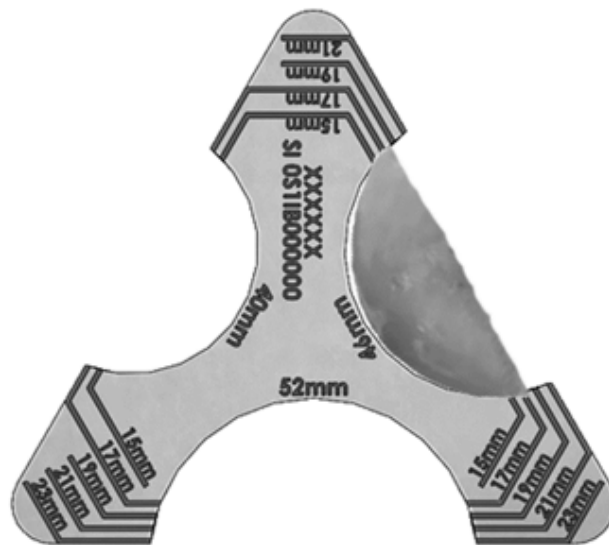


Fig. 41

**Note:** The resected humeral head can be used as an initial reference for humeral head sizing.

Insert the resected head into the sizing triangle as shown. The guide allows for assessment of both diameter and height.

Select the humeral head trial size determined in the previous step. (Fig 41a)

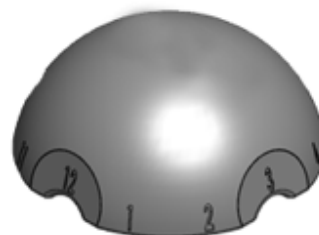


Fig. 41a

# SURGICAL TECHNIQUE

The heads of the SI system incorporate 3 mm of offset to allow for an infinite number of rotational positions for achieving optimal coverage and joint stability. (Fig 42)

Place the Humeral Head trial on to the Humeral Stem trial. Assess height of trial relative to the supraspinatus insertion. Also confirm that the humeral head trial reaches or slightly overhangs the calcar medially. (Fig 43)

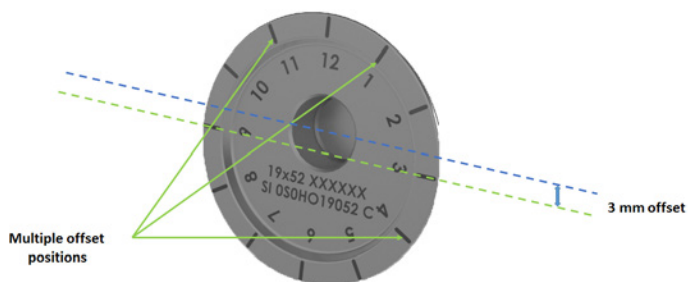


Fig. 42

Each trial is etched with markings to assist in relaying rotational position from trial to final implantation. (Fig 42a)

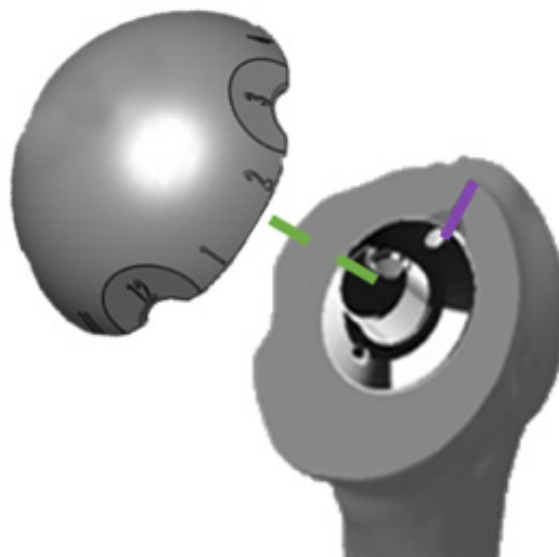


Fig. 43

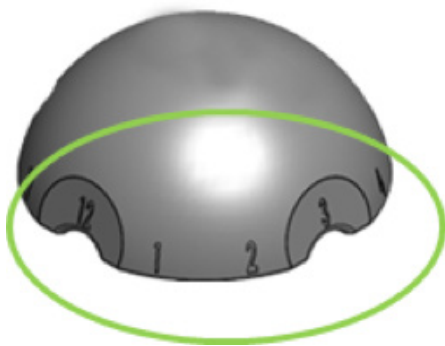


Fig. 42a

Once in place, rotate the humeral head to a position that best matches the circumference of the resected humerus. (Fig 43a)

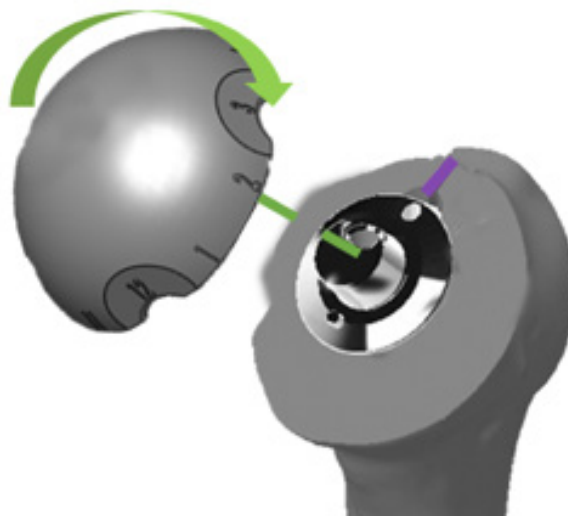


Fig. 43a



## Trial Range of Motion

When head placement is confirmed, complete a trial range of motion to assess the joint motion, stability, and lack of soft tissue or bony impingement.

**Note:** Adjustments to motion, stability, or impingement should be addressed by eliminating any remaining osteophytes (especially along the posterior inferior humeral neck), performing appropriate soft tissue tensioning, or utilizing an alternate head size.

**Note:** Record the number of the humeral head trial that corresponds to the mark on the lateral humerus. This number will be used as a secondary check during final implantation. (Fig 44)

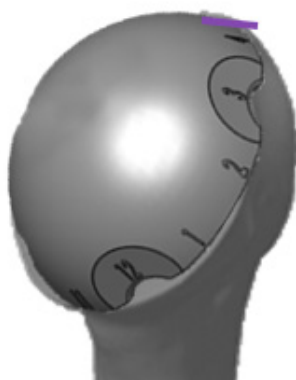


Fig. 44

Once the final position of the head is confirmed, extract the trial stem and head construct together using the removal tool. (Fig 45)

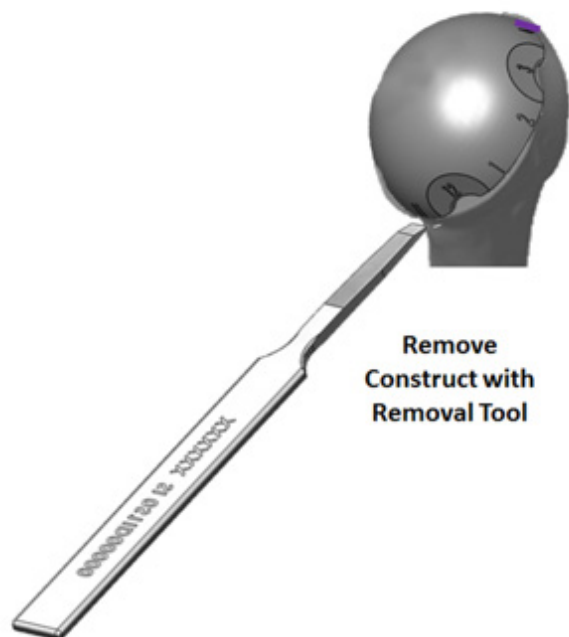


Fig. 45

**Note:** Note the number location on the head that most directly lines up with the lateral fin of the stem trial. This relationship will be reproduced during the impaction of the humeral head implant on to the stem implant. (Fig 45a)



Fig. 45a

## Final Glenoid Implantation

Remove the Glenoid Trial and irrigate the glenoid vault.

Apply epinephrine soaked sponges to the glenoid vault. Suction the vault and completely dry the glenoid with dry sponges.

Introduce bone cement into the drilled cavity using a 60cc syringe.

Cement should be introduced early in the working time to facilitate pressurization into the cancellous bone bed. Push the cement in to the drilled holes with a sterile glove.

Apply a layer of bone cement to the backside of the glenoid component, filling the channels. (Fig 46)

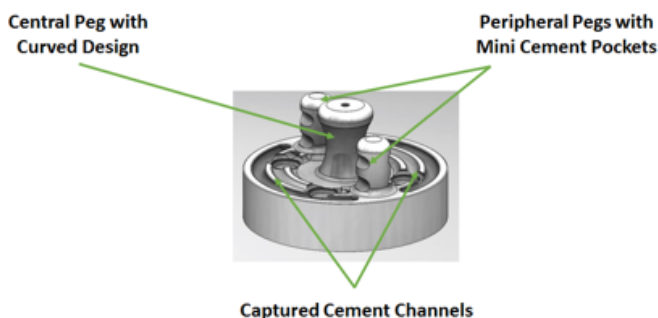


Fig. 46

**Note: Do not place bone cement on the pegs. Apply gentle manual pressure to the cement to eliminate any air pockets.**

Use the Glenoid Inserter to place the glenoid component in to the reamed glenoid pocket and drilled holes. Ensure alignment of central and peripheral pegs, and then fully impact the glenoid implant.

The Glenoid Impactor handle and mallet are used for final seating of the component. (Fig 47)



Fig. 47

Ensure the component is fully seated against the prepared surface and in contact with the perimeter of the glenoid bone. (Fig 48)

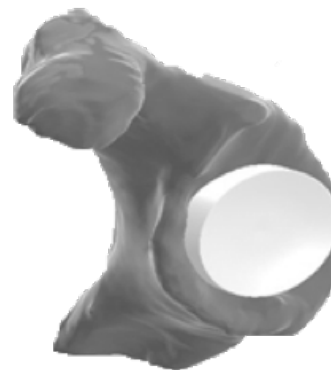


Fig. 48

Maintain pressure on the glenoid with the pusher or thumb until the cement has hardened. Ensure that the pressure remains centralized within the glenoid so that eccentric pressure is not applied during cement hardening. Using a curette or freer retractor to remove the excess cement carefully.

## Final Implantation: Head/Stem Construct: Cemented Technique

Select the final stem and humeral head implants. The system contains an impaction block that enables the final head and stem components to be impacted in the position reproducing the positioning noted during trialing.

(Fig 49)

### Implant Assembly Block

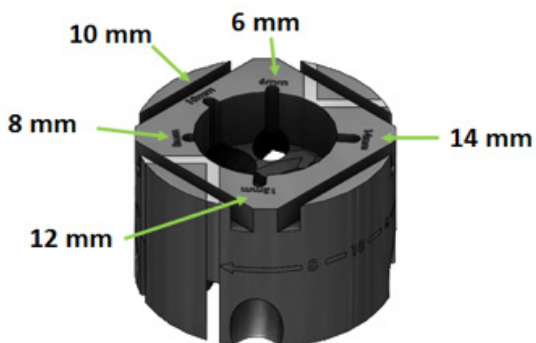


Fig. 49

**Note:** Prior to impaction, ensure that the male taper of the stem and female taper of the humeral head are clean and dry.

Place the humeral head implant on to the final stem implant.

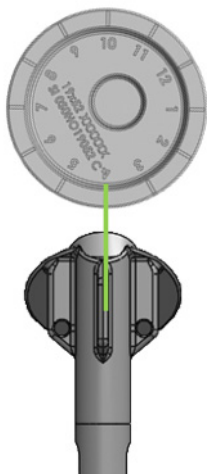


Fig. 49a

Position the offset head to correspond to the numbers noted during the trial reduction. (Fig 49a)

Set the stem and head into the channel of the impaction block that corresponds to the stem size.

The block can be placed on the side of the case or used directly on the back table. Using the multi-purpose impactor handle and head impactors, set the tapers with 2 – 4 taps of a mallet. (Fig 50)

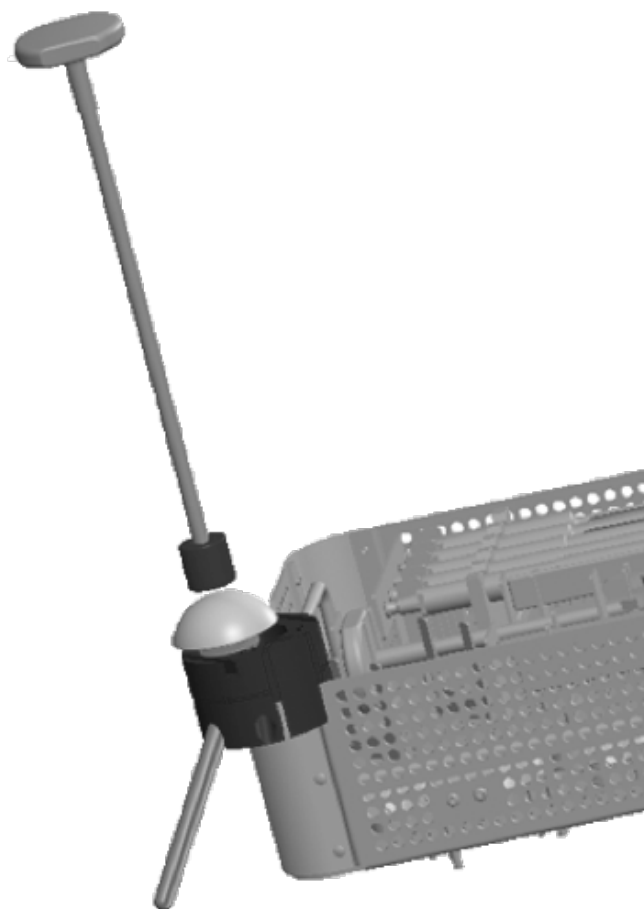


Fig. 50

**Note: Use of a bone cement restrictor is recommended if full cement fixation is desired. A Proximal only cement technique is another viable option.**

Method for full cement technique:

- To size for a restrictor, select the insert canal sizes from a disposable cement kit.
- Advance the sizer into the canal and assess fit and size.
- Using the restrictor plug application tool, insert the restrictor into the canal at a distance one centimeter greater than the length of the stem.
- Clean and dry the canal. Using a cement gun, retro fill the humeral canal.
- Use a finger to thoroughly pack the cement
- Remove the stem and humeral head construct from the impaction block.
- Apply a thin layer of bone cement to the proximal surface of the stem.
- Insert the stem into the prepared stem envelope. Ensure that the fins are aligned. (The fin slot may be marked with a surgical marker or bovie to enable easier identification).

Impact the components with the mallet and impactor handle. Be sure that the collar of the component is seated flush on the cut surface of the humerus. Make sure that the head is firmly attached. (Fig 51)

Remove any excess bone cement.

Reduce the joint and reassess stability for the final time.



Fig. 51

## Press-Fit Technique: Stem First Implantation

Select the final stem implant size that corresponds to the final trial.

Insert the stem into the humeral canal with the stem impaction handle and version control guide, ensuring the fins align with the prepared stem envelope. (Fig 52)



Fig. 52

**Note: Use of the version rod is optional at this point as stem envelope with fins is prepared.**

Advance with hand pressure until fins are aligned and engaged.

A mallet is used for the final impaction of the stem.

Ensure that the collar of the stem rests flush to the resected surface. (Fig 52a)



Fig. 52a

Select the final Humeral Head implant and position it onto the taper of the stem.

**Note: Be sure to dry taper of stem and female taper on head prior to assembly.**

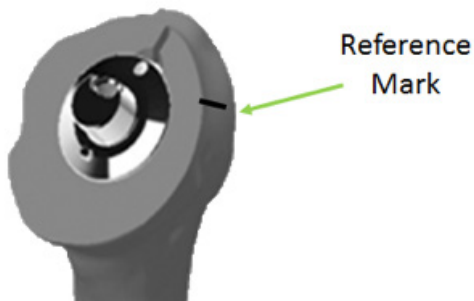


Fig. 53

Position the head matching the number on the back of the head implant with the mark previously made on the humerus. (Fig 53 & 53a)



Correlates to number on trial head.

Fig. 53a

A mark corresponding to the number on the backside of the trial may be made on the articulating surface of the head, with use of a skin marker, for easy reference. Position the head onto the stem, aligning the marks. (Fig 53b)

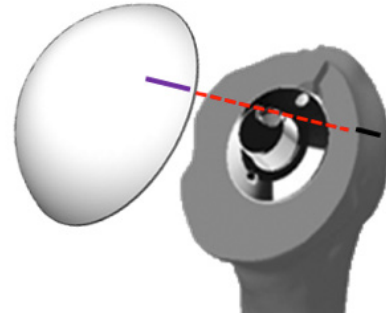


Fig. 53b

Select the humeral head impactor and impact the head to the stem with 2-4 light taps of a mallet. (Fig 54)



Fig. 54

Assess head to ensure it is firmly attached.

Reduce the joint and reassess stability for the final time.

### Subscapularis Repair

Complete the reattachment of the subscapularis.

### Final Assessment

Reduce the joint and complete a final assessment of joint stability and motion.

## **Closure**

Irrigate the wound and then reattach the subscapularis muscle-tendon unit using multiple non-absorbable #2 sutures.

Some surgeons, including the author, also place a #5 suture (through anterior drill holes in the proximal shaft and around the implant stem) for added pull out strength when repairing the subscapularis tendon. Close the deltoid and the subcutaneous layers. Then, close the skin.

## **Postoperative Management**

On the first postoperative day, the patient typically begins passive and assisted range of motion.

This should include pendulum exercises in the erect position, assisted forward elevation exercises in the erect and supine positions, and external rotation exercises to neutral version.

The patient is typically discharged 1 to 2 days after surgery. Further exercises are continued after discharge with supervision by the surgeon or physical therapist.



## Addendum A: Non-Cannulated Glenoid Preparation

### Glenoid Sizing

Begin by selecting the sizing guide from the instrument tray. Each guide is equipped with dual sizing options. (Fig A1)



Fig. A1

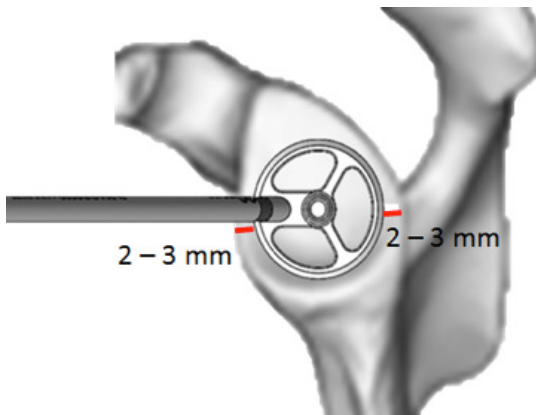


Fig. A2

Position the sizing guide flat against the face of the glenoid. The guide is equipped with short fixation pegs for added stability. (Fig A2)

Placement of the guide is determined by pre-op planning and intraoperative assessment.

The surgeon may palpate the anterior and posterior walls of the glenoid vault for additional reference.

Approximately 2 to 3 mm of the bone should be visible outside of the guide to ensure adequate peripheral bone coverage and support.

Select a 2.0 to 2.5 mm drill bit. Drill through sizing guide to prepare a starter hole for the 6.5 mm central peg drill.

### Central Peg Hole Preparation

The next step of the procedure is to drill the central peg hole. The central hole matches the tip of the glenoid reamer, drill guide, trial and final implant.

Select the drill driver and sleeve, non-cannulated 6.5 mm drill bit and wrench. Assemble the bit to the drill guide and tighten by moving the wrench in a clockwise direction.

(Fig A3)

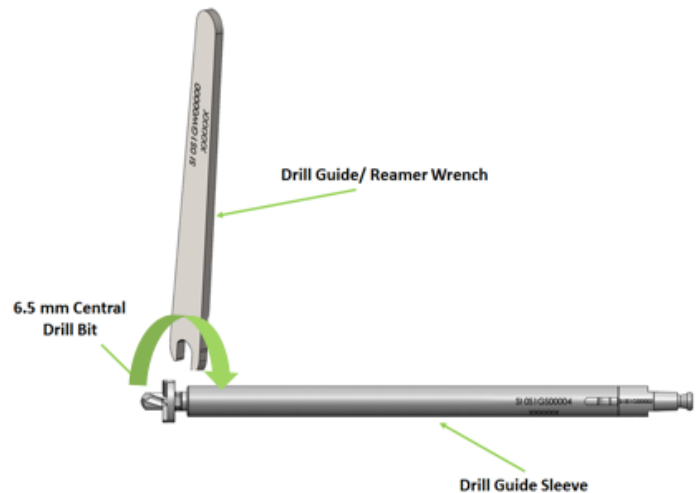


Fig. A3

# SURGICAL TECHNIQUE

Place the 6.5 drill bit into the prepared starter hole and advance the drill until the collar of the drill bit engages the face of the glenoid. (Fig A4)



Fig. A4

## Glenoid Reaming

The next step of the procedure is to drill the central guide hole and ream the glenoid pocket. The reamer is designed to fit into the prepared 6.5 mm hole and complete reaming process.

Select the glenoid reamer corresponding to the size determined during sizing. (Fig A5)

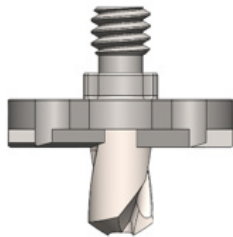


Fig. A5

The glenoid reamers are 5 mm thick. The glenoid trials and implants are 6 mm and 8mm thick. These offerings allow for flexibility in reaming and subsequent selection of the glenoid trial and implant.

Assemble the reamer to the reamer guide and tighten by turning the wrench in a clockwise direction, as shown. (Fig A6)



Fig. A6

Insert the tip of the reamer into the prepared hole and initiate the reamer prior to engaging the glenoid to minimize the risk of glenoid fracture. (Fig A7)

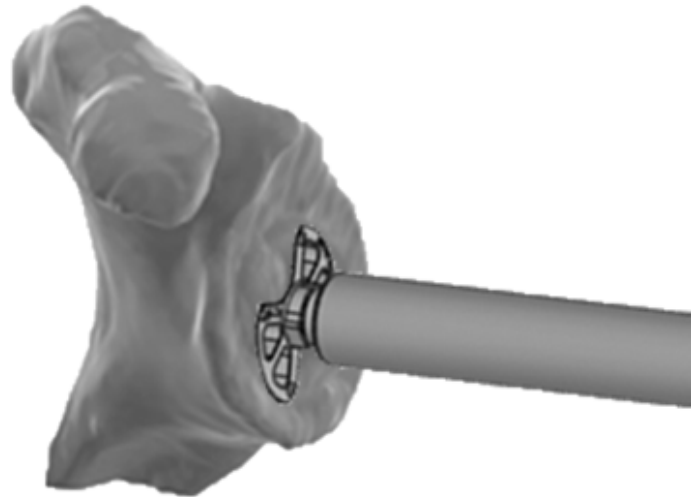


Fig. A7

Advance the reamer into the glenoid to the desired depth. The goal is to have a glenoid that is circumferentially supported by bone and sits above the most prominent bony surface. This will be assessed during trialing.

**Note: The Glenoids of the SI system are available in 6 and 8 mm thicknesses to allow for adjustments of the glenoid height. Avoid reaming through the strong, sclerotic subchondral bone. (Fig A8)**

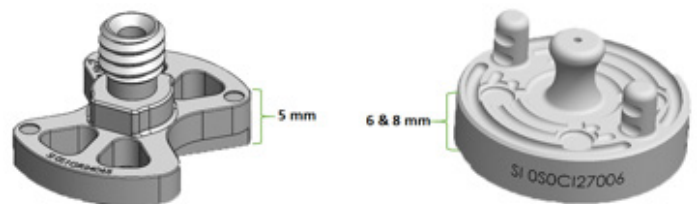


Fig. A8

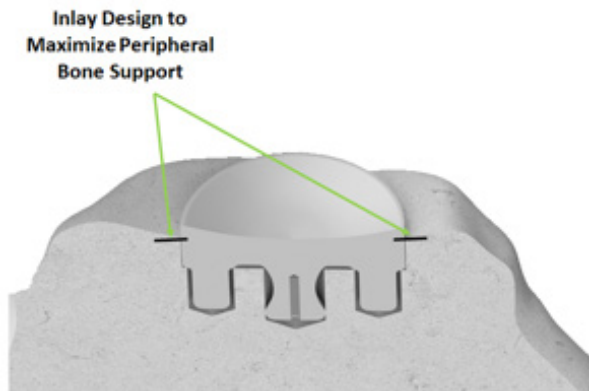


Fig. A9

**Note:** Defects in the Glenoid topography must be assessed prior to reaming to ensure that an adequate amount of circumferential bone will be present upon the completion of the reaming step. Inadequate circumferential bone support may lead to loosening of the glenoid component.

### Peripheral Peg Preparation

Select the drill guide that corresponds to the size of the glenoid reamer. The guide incorporates two levels indicating the 6mm and 8 mm glenoid thicknesses. The central stabilizing peg of the guide allows for accurate positioning and stabilization during use. The guide contains a threaded side hole that accepts the stabilizing handle. (Fig A10)

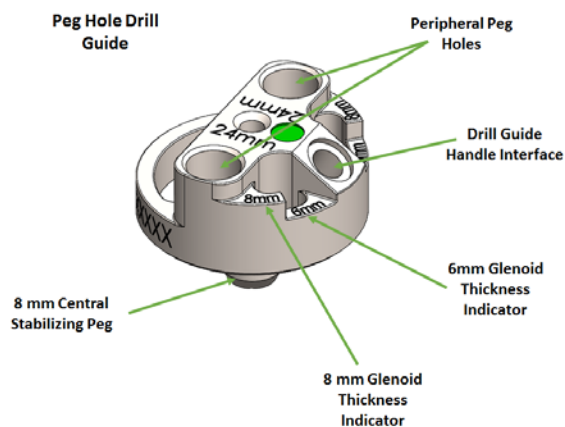


Fig. A10

Assemble the multipurpose handle by threading it into the side hole of the drill guide in a clockwise direction. The guide is universal for left or right procedures. (Fig A11)



Fig. A11

Select the drill driver, sleeve, 5mm peripheral drill bit and wrench. Insert the sleeve over the driver, thread the drill bit on to the end of driver and gently tighten in a clockwise direction, as shown. (Fig A12)

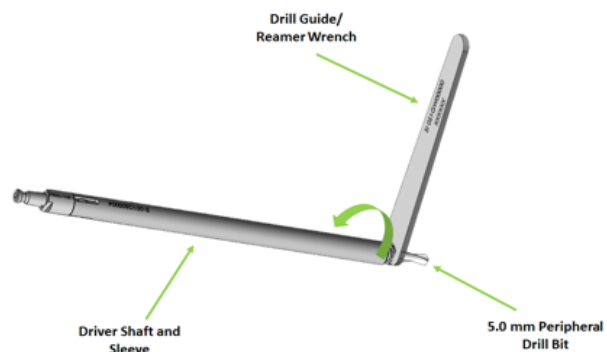


Fig. A12

Place the drill guide into the prepared glenoid pocket. The guide is equipped with a drill stop to prevent over drilling. Begin with the superior hole. (Fig A13)



Fig. A13

# SURGICAL TECHNIQUE

Advance the drill until the collar of the drill bit contacts the drill guide.

The instrumentation contains anti-rotation pegs. Insert a peg into the superior peg hole. (Fig A14)

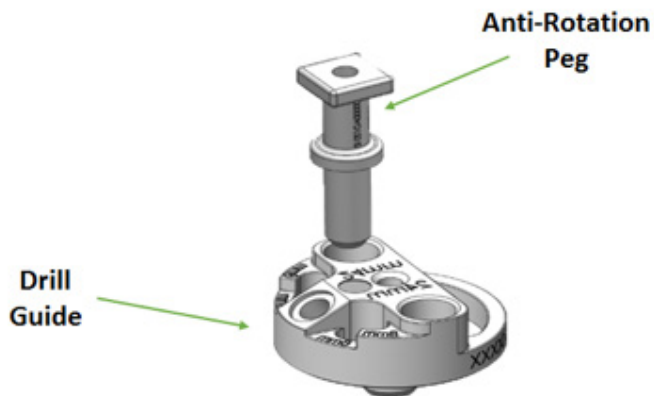


Fig. A14

Complete preparation of the inferior hole. Remove the anti-rotation peg and guide. (Fig A15)



Fig. A15

Conduct the glenoid trial per the cannulated approach highlighted earlier in this technique.

## SHOULDER INNOVATIONS TOTAL SHOULDER SYSTEM









<b>GLENOID IMPLANT</b>	<b>UNIT</b>	<b>SIZE</b>	<b>PART No.</b>
Circular Glenoid w/ In-Line Peripheral Pegs	1	22 mm x 6 mm	0S0CI22006
Circular Glenoid w/ In-Line Peripheral Pegs	1	24 mm x 6 mm	0S0CI24006
Circular Glenoid w/ In-Line Peripheral Pegs	1	27 mm x 6 mm	0S0CI27006
Circular Glenoid w/ In-Line Peripheral Pegs	1	30 mm x 6 mm	0S0CI30006
Circular Glenoid w/ In-Line Peripheral Pegs	1	22 mm x 8mm	0S0CI22008
Circular Glenoid w/ In-Line Peripheral Pegs	1	24 mm x 8 mm	0S0CI24008
Circular Glenoid w/ In-Line Peripheral Pegs	1	27 mm x 8 mm	0S0CI27008
Circular Glenoid w/ In-Line Peripheral Pegs	1	30 mm x 8 mm	0S0CI30008










<b>HUMERAL IMPLANT</b>	<b>UNIT</b>	<b>SIZE</b>	<b>PART No.</b>
Humeral Head w/ Offset Taper	1	15 mm x 40 mm	0S0HO15040
Humeral Head w/ Offset Taper	1	15 mm x 46 mm	0S0HO15046
Humeral Head w/ Offset Taper	1	17 mm x 40 mm	0S0HO17040
Humeral Head w/ Offset Taper	1	17 mm x 46 mm	0S0HO17046
Humeral Head w/ Offset Taper	1	17 mm x 52 mm	0S0HO17052
Humeral Head w/ Offset Taper	1	19 mm x 46 mm	0S0HO19046
Humeral Head w/ Offset Taper	1	19 mm x 52 mm	0S0HO19052
Humeral Head w/ Offset Taper	1	21 mm x 46 mm	0S0HO21046
Humeral Head w/ Offset Taper	1	21 mm x 52 mm	0S0HO21052
Humeral Head w/ Offset Taper	1	23 mm x 52 mm	0S0HO23052

<b>HUMERAL STEM IMPLANT</b>	<b>UNIT</b>	<b>SIZE</b>	<b>PART No.</b>
Humeral Stem CoCr	1	6 mm x 130 mm	0S0HO15040
Humeral Stem CoCr	1	8 mm x 130 mm	0S0HO15046
Humeral Stem CoCr	1	10 mm x 130 mm	0S0HO17040
Humeral Stem CoCr	1	12 mm x 130 mm	0S0HO17046
Humeral Stem CoCr	1	14 mm x 130 mm	0S0HO17052

<b>GLENOID INSTRUMENT</b>	<b>UNIT</b>	<b>SIZE</b>	<b>PART No.</b>
K Wire	2	9 in x 2.4 mm	0S1GK00002

# SURGICAL TECHNIQUE

Description Case & Upper & Lower Tray	Quantity per set		Part Number																				
	Full Kit w/ Instrumentation	1																					
	Case and Trays	1	5952-100-100																				
Humeral Instruments																							
Multi-Use Tool		1	0S1IT00000																				
Impaction Head		1	0S1IH00000																				
Sizing Star		1	0S1IB00000																				
Trial Stem		5	<table border="1"> <tr><td>6mm x 130mm</td><td>0S1SS06130</td></tr> <tr><td>8mm x 130mm</td><td>0S1SS08130</td></tr> <tr><td>10mm x 130mm</td><td>0S1SS10130</td></tr> <tr><td>12mm x 130mm</td><td>0S1SS12130</td></tr> <tr><td>14mm x 130mm</td><td>0S1SS14130</td></tr> </table>	6mm x 130mm	0S1SS06130	8mm x 130mm	0S1SS08130	10mm x 130mm	0S1SS10130	12mm x 130mm	0S1SS12130	14mm x 130mm	0S1SS14130										
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14mm x 130mm	0S1SS14130																						
Head Distractor		1	0S1ID00000																				
Cut Guide		1	0S1IA00000																				
Impaction Block		1	0S1II00000																				
Version Control Handle		1	0S1IV00000																				
Canal Reamers		5	<table border="1"> <tr><td>0S1IR00006</td></tr> <tr><td>0S1IR00008</td></tr> <tr><td>0S1IR00010</td></tr> <tr><td>0S1IR00012</td></tr> <tr><td>0S1IR00014</td></tr> </table>	0S1IR00006	0S1IR00008	0S1IR00010	0S1IR00012	0S1IR00014															
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Trial Heads		10	<table border="1"> <tr><td>15mm x 40mm</td><td>0S1HO15040</td></tr> <tr><td>15mm x 46mm</td><td>0S1HO15046</td></tr> <tr><td>17mm x 40mm</td><td>0S1HO17040</td></tr> <tr><td>17mm x 46mm</td><td>0S1HO17046</td></tr> <tr><td>17mm x 52mm</td><td>0S1HO17052</td></tr> <tr><td>19mm x 46mm</td><td>0S1HO19046</td></tr> <tr><td>19mm x 52mm</td><td>0S1HO19052</td></tr> <tr><td>21mm x 46mm</td><td>0S1HO21046</td></tr> <tr><td>21mm x 52mm</td><td>0S1HO21052</td></tr> <tr><td>23mm x 52mm</td><td>0S1HO23052</td></tr> </table>	15mm x 40mm	0S1HO15040	15mm x 46mm	0S1HO15046	17mm x 40mm	0S1HO17040	17mm x 46mm	0S1HO17046	17mm x 52mm	0S1HO17052	19mm x 46mm	0S1HO19046	19mm x 52mm	0S1HO19052	21mm x 46mm	0S1HO21046	21mm x 52mm	0S1HO21052	23mm x 52mm	0S1HO23052
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21mm x 46mm	0S1HO21046																						
21mm x 52mm	0S1HO21052																						
23mm x 52mm	0S1HO23052																						

Glenoid Instruments				
Guide Wires		2	0S1GK0002	
Impaction Head		1	0S1GB00000	
Driver Shaft		2	0S1GS00002	
Driver Grip		2	0S1GS00004	
Reamer Wrench		2	0S1GW00000	
Glenoid Trials		8	22mm x 6mm	0S1CI22006
			24mm x 6mm	0S1CI24006
			27mm x 6mm	0S1CI27006
			30mm x 6mm	0S1CI30006
			22mm x 8mm	0S1CI22008
			24mm x 8mm	0S1CI24008
			27mm x 8mm	0S1CI27008
			30mm x 8mm	0S1CI30008
Drill Guide		4	22mm	0S1GG00022
			24mm	0S1GG00024
			27mm	0S1GG00027
			30mm	0S1GG00030
Drill Guide Handle		1		
Glenoid Sizer		2	Sizer Disk - 22 + 24	0S1GD22024
			Sizer Disk - 27 + 30	0S1GD27030
Anti Rotation Peg		2	0S1GA00000	
Glenoid Grasper		1	0S1GT00000	
Glenoid Reamers		4	22mm	0S1GR22065
			24mm	0S1GR24065
			27mm	0S1GR27065
			30mm	0S1GR30065
6.5 mm Can Drill Bit		2	0S1GC00001	
6.5 mm Non - Can Drill Bit		2	0S1GC00002	
5.0 mm Non - Can Peripheral Drill Bit		2	0S1GP00005	

# SURGICAL TECHNIQUE

## Indications

The Shoulder Innovations Total Shoulder System is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following:

1. significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint
2. united humeral head fractures of long duration
3. irreducible 3- and 4-part proximal humeral fractures
4. avascular necrosis of the humeral head

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty.

The Total Shoulder System components are intended for single use only. The glenoid component is intended for cemented fixation only; the humeral stem may be implanted by press-fit or cement fixation.

## Contraindications

Absolute contraindications include infection, sepsis, and osteomyelitis. Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram 7) Lack of quality bone to seat and support the implant, including that resulting from skeletal immaturity 8) metal allergies or sensitivity -Infection at or near the site of implantation 9) glenohumeral instability.

A relative contraindication is rotator cuff insufficiency (subscapularis, supraspinatus, or infraspinatus).

## Possible Adverse Events

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative, infection, and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, or while inserting the device.
4. Loosening or migration of the implant can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Accelerated wear of glenoid articular cartilage.
13. Intraoperative or postoperative bone fracture and/or postoperative pain

## Warnings

The functional life expectancy has not been determined for this device.

## CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction of the service life of the implants. Mis-alignment of the component or inaccurate implantation can lead to excessive wear and/or failure of the implants or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

The Shoulder Innovations Total Shoulder System provides the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight and excessive weight bearing have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

The Shoulder Innovations' Total Shoulder System Implants have not been evaluated for safety and compatibility in the MR environment. The Shoulder Innovations' Total Shoulder System Implants have not been tested for heating or migration in the MR environment.

## Precautions:

Specialized instruments are designed for Shoulder Innovations Total Shoulder System to aid in the accurate implantation of the implants. The use of instruments from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments have been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Shoulder Innovations recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. Implants are single use only. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant.

Do not treat patients with implants that have been, even momentarily, placed in a different patient.

Do not implant trials.

Do not modify the implant.

Do not use any implant from a previously opened or damaged package.

Do not use implants after expiration date or use by date.

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