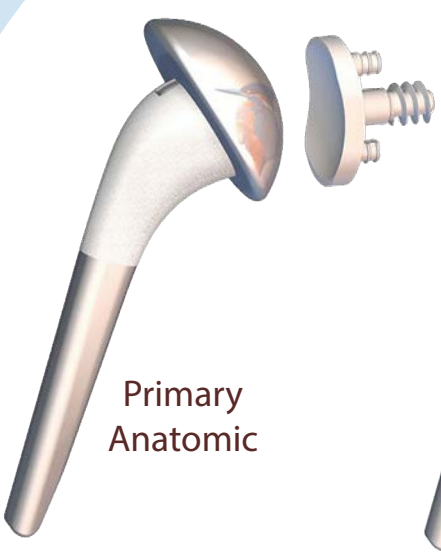
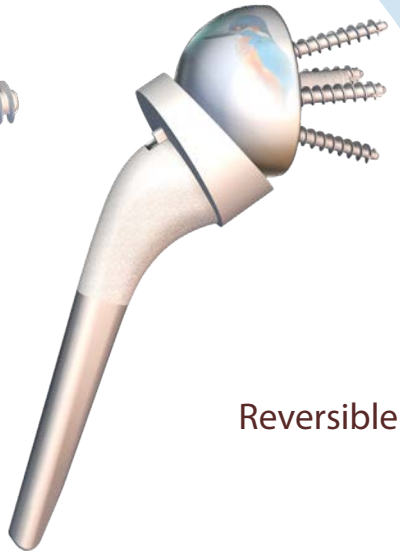
HUMERIS®

Cementless Primary Anatomic & Reversible

SURGICAL TECHNIQUES
Hemi, Total, Reversible



Primary
Anatomic



Reversible

Shoulder Solutions

Thank You

FX Shoulder USA, Inc. would like to thank with gratitude the surgeons listed here for their input on instrument design.

Wayne Z. Burkhead, M.D. | WB Carrell Clinic, Dallas, TX, USA
Travis Burns, M.D. | Ortho San Antonio, San Antonio, TX, USA
Alfred Cook, M.D. | The Villages, Leesburg, FL, USA
John Costouros, M.D. | Stanford University, Redwood City, CA, USA
Mark D'Onofrio, M.D. | Lancaster, OH, USA
David Glaser, M.D. | University of Pennsylvania, Philadelphia, PA, USA
Howard W. Harris, M.D. | TX Ortho, Dallas, TX, USA
Russell Huffman, M.D. | University of Pennsylvania, Philadelphia, PA, USA
Stanley Kupiszewski, M.D. | Orlando, FL, USA
Todd Moen, M.D. | WB Carrell Clinic, Dallas, TX, USA
Frederick Song, M.D. | Princeton, NJ, USA
Umasuthan Srikumaran, M.D. | Columbia, MD, USA

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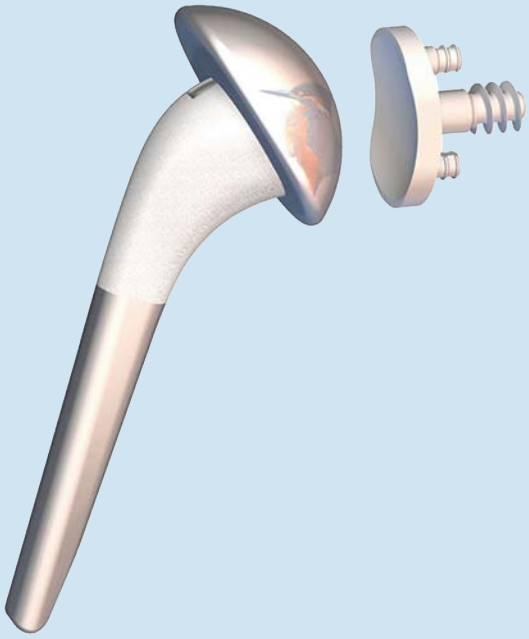
DEVICE DESCRIPTION

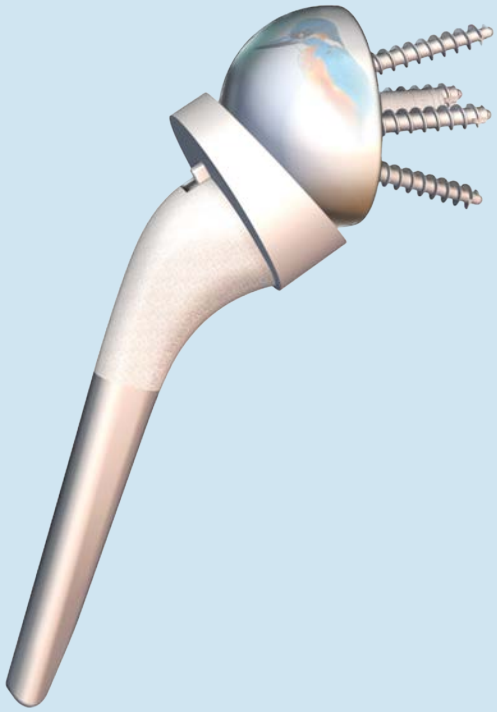
The Humeris® Cementless Humeral Stem is manufactured from Ti6Al4V ELI (conforming to ISO 5832-3) and is available in diameters from 8mm-20mm and has a length of 100mm. The distal end of the humeral stem is trapezoidal with a polished surface. The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP Ti) and hydroxyapatite (HA) coating. The humeral stem incorporates a female taper for attachment of a compatible component.

The Humeris® humeral stems can be used with a double taper or a centered spacer. A centered or offset humeral head and a 2-peg or 3-4-peg cemented glenoid can be used in an anatomical shoulder configuration.

The Humeris® humeral stems can also be used with a humeral cup (135°/145°), a reverse adapter (+9mm), a centered or eccentric glenosphere, a glenoid baseplate, post extensions, and standard (compression) or locking bone screws for use in a reverse shoulder configuration.



Anatomical



Reversible

DEVICE DESCRIPTION

HUMERAL STEMS

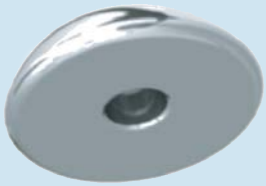
"Onlay" design at 135° (anatomic) with proximal plasma-sprayed hydroxyapatite coating (HA) on Ti6Al4V ELI (conforming to ISO 5832-3). Dual geometry proximally resist rotation.

STEM SIZES

8mm
9mm
10mm
11mm
12mm
13mm
14mm
15mm
16mm
18mm
20mm

HUMERAL HEADS

0°, double taper cone, connects the stem and the humeral head to match 135° inclination 0°, double morse taper cone with +3 and +5mm spacers allow for variable head heights in all diameter heads (42 possible combinations).

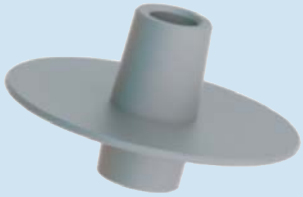


CoCr
CONCENTRIC HEADS

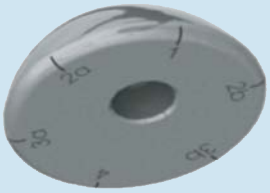
CONCENTRIC HEADS

39x14
41x15
43x16
46x17
48x18
50x19

DOUBLE TAPER



+3/+5MM
SPACER TAPER



CoCr
ECCENTRIC HEADS

ECCENTRIC HEADS

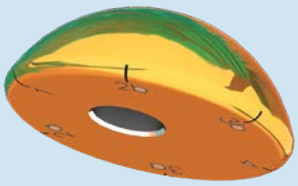
39x15
41x16
43x17
46x18
48x19
50x20
52x21 - Hemi Only**
54x21 - Hemi Only**

TIN (TITANIUM NITRIDE) COATED HUMERAL HEADS**

NEXT GENERATION COATING TECHNOLOGY

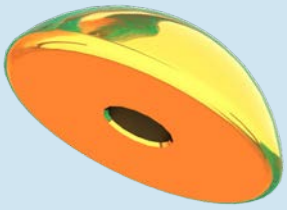
FIRST & ONLY TiN HUMERAL HEADS AND GLENOSPHERS IN THE U.S. MARKET AS AN ALTERNATE BEARING FOR TOTAL SHOULDER ARTHROPLASTY

- **HARD, THIN SMOOTH COATING**
- **APPROXIMATELY 2300Hv**
- **WORST CASE LOAD & ENVIRONMENT**
- **EXCELLENT WEAR RESISTANCE*****
- **SINGLE LAYER**
- **BIOCOMPATIBLE TiN COATING OVER CoCr*****
- **WORST CASE LOAD & ENVIRONMENT**
- **SURFACE ROUGHNES**
- **PARTICLE ANALYSIS**
- **1-6 MICRONS THICK**



TiN* COATED
CONCENTRIC HEADS

CAUTION



TiN* COATED
ECCENTRIC HEADS

*FX MAKES NO CLAIM ABOUT THE USE OF TIN FOR NICKEL ALLERGY PATIENTS
**THE TiN COATED HUMERAL HEADS ARE NOT INDICATED FOR SHOULDER HEMI-ARTHROPLASTY
***DATA ON FILE AT FX SHOULDER USA, INC. & FX SOLUTIONS S.A.S

DEVICE DESCRIPTION

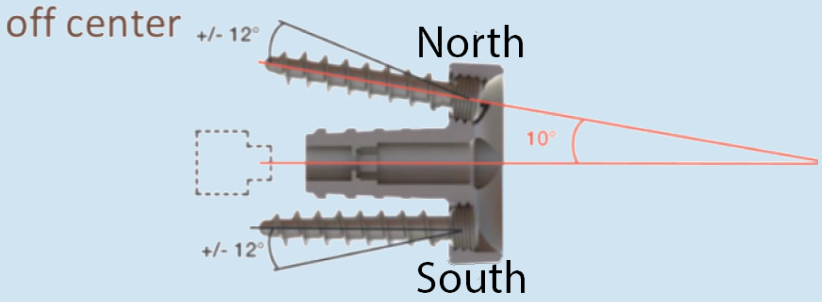
2-PEG GLENOID

The 2-peg cemented glenoid component is available in sizes extra small, small, medium and large. They feature two pegs for cemented fixation to the glenoid bone. It is manufactured from ultra-high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. Each peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.

3-4 PEG GLENOID

The 3-4 peg cemented glenoid component is available in sizes extra small, small, medium and large. Sizes extra small and small have three fixation pegs. Sizes medium and large have four fixation pegs. It is manufactured from ultra-high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. The central peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.

DEVICE DESCRIPTION



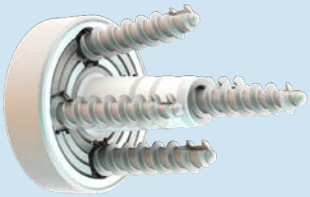
BASEPLATE (24mm)

The Ti6Al4V ELI 24mm size and cannulation allows for optimal placement in the inferior glenoid. 17mm post that tapers from 7.5mm proximally to 6.5mm distally with the option for an additional +6mm and +10mm extension posts. Preoriented 10° superiorly at the 12 o'clock position with 12° of variability off center.

A glenoid baseplate with a central screw is also available with central screw sizes from 8mm-20mm.

Baseplate with Central Post

Baseplate with Central Screw



DEVICE DESCRIPTION

GLENOSPHERES

The Humelock Reversed® Glenosphere is available in 32, 36 and 40mm diameter sizes in centered and eccentric styles. The eccentric glenospheres are designed to be offset from the center of the glenoid baseplate. All glenospheres are slightly lateralized of 3.5mm corresponding to 10° of tilt. The curvature of the glenosphere extends 10° beyond the equator of a hemisphere. This additional articular surface lateralizes the center of rotation to help reduce the potential for scapular notching by the humeral cup.

DIAMETERS

32mm, 36mm, 40mm

SIZES AND STYLES

Centered or Eccentric
Size 32 = 1mm of Eccentricty
Size 36 = 3mm of Eccentricty
Size 40 = 1mm of Eccentricty
Lateralization = 3.5mm

TIN COATED GLENOSPHERES*

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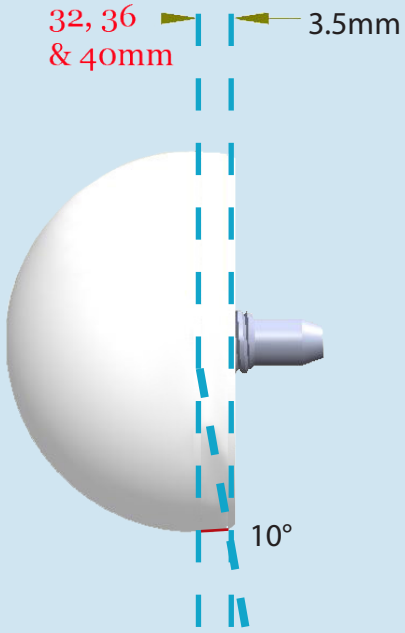
- **SURFACE ROUGHNES**
- **PARTICLE ANALYSIS**
- **1-6 MICRONS THICK**

TiN (TITANIUM NITRIDE)
ECCENTRIC AND CENTERED
GLENOSPHERE
Ø32/36/40MM

CAUTION



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DEVICE DESCRIPTION

HUMERAL CUP THICKNESS

The humeral cups (Figure A) are a one-piece construct consisting of net-shape molded UHMWPE (polyethylene) inserts onto Ti6Al4V alloy shells. A 10mm diameter male taper post allows attachment of the humeral cup into the stem.

DIAMETERS

32mm, 36mm, 40mm

THICKNESS

+3mm, +6mm, +9mm

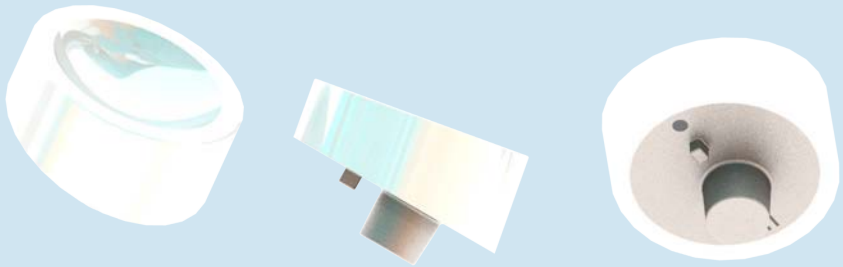


Figure A
135°/145°
HUMERAL CUP

OPTIONAL REVERSE ADAPTER

A reverse adapter (Figure B) 135°/145° can be used to add +9mm of height when combined with the Standard Reversed Humeral Cups to build up to +12mm, +15mm, or +18mm.
(Figure B)

+9MM
REVERSED
ADAPTER

Figure B

STANDARD
REVERSED
HUMERAL CUP

STABILITY CUP-OPTION

In extreme cases of instability, the stability variant of the humeral cups can provide added constraint by capturing more of the glenosphere with a deeper dish of the humeral cup without adding to the joint space. The stability variant may also reduce the potential range of motion that can be achieved. (Figure C)

Figure C
STABILITY
HUMERAL CUP

135/145° HUMERAL STABILITY CUP		
	STANDARD CUP	STABILITY CUP
DEPTH OF SPHERE	7MM	9MM

CAUTION

If BMI is equal to or greater than 40, it is recommended that a stability humeral cup is used.

Indications

In an anatomic configuration, the Humeris® shoulder is indicated for primary total or hemi-shoulder arthroplasty to treat:

- A severely painful and/or disabled joint resulting from osteoarthritis or rheumatoid arthritis
- Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (i.e. revision of a previously implanted primary component, a humeral plate, or a humeral nail).

In a reverse configuration, the Humeris® shoulder is indicated for primary 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 stem of the Humeris® cementless shoulder prosthesis is intended for cementless use only. The humeral stem of the Humeris® cemented shoulder prosthesis is intended for cemented use only.

Rehabilitation
(RECOMMENDATION ONLY)

Short-term immobilization (according to the surgeon's assessment) in the neutral position to promote recovery of external rotation. Promote pool therapy and specialist rehabilitation, without counter resistance work, for six weeks (depending on the age and objectives noted in the "patient contract").

Warnings

CONTRAINDICATIONS

- Non-displaced or slightly displaced fractures
- Dislocation fractures in elderly subjects
- Acute, chronic, local, or systemic infections
- Severe muscular, neurological or vascular impairment affecting the joint in question
- Bone destruction or poor bone quality that could compromise the stability of the joint
- Excessive alcohol consumption or other dependency disorders
- Allergy to the materials of the prosthesis
- Any concomitant Illness that could compromise the function of the devicess that could compromise the function of the device

WARNINGS AND PRECAUTIONS

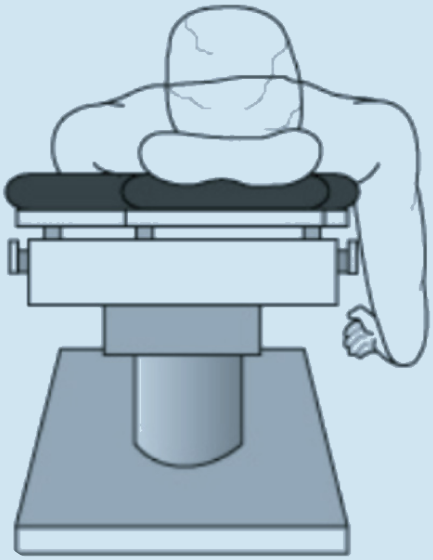
Unless otherwise indicated, instrument sets are provided non-sterile and must be completely cleaned and sterilized before use. Instruments must not undergo accelerated autoclave sterilization inside the instrument box. Accelerated autoclave sterilization of the instruments has not been validated by the manufacturer. Please consult the instrument package insert for validated sterilization instructions and the implant package insert of a complete list of warnings, precautions, contraindications and adverse events.

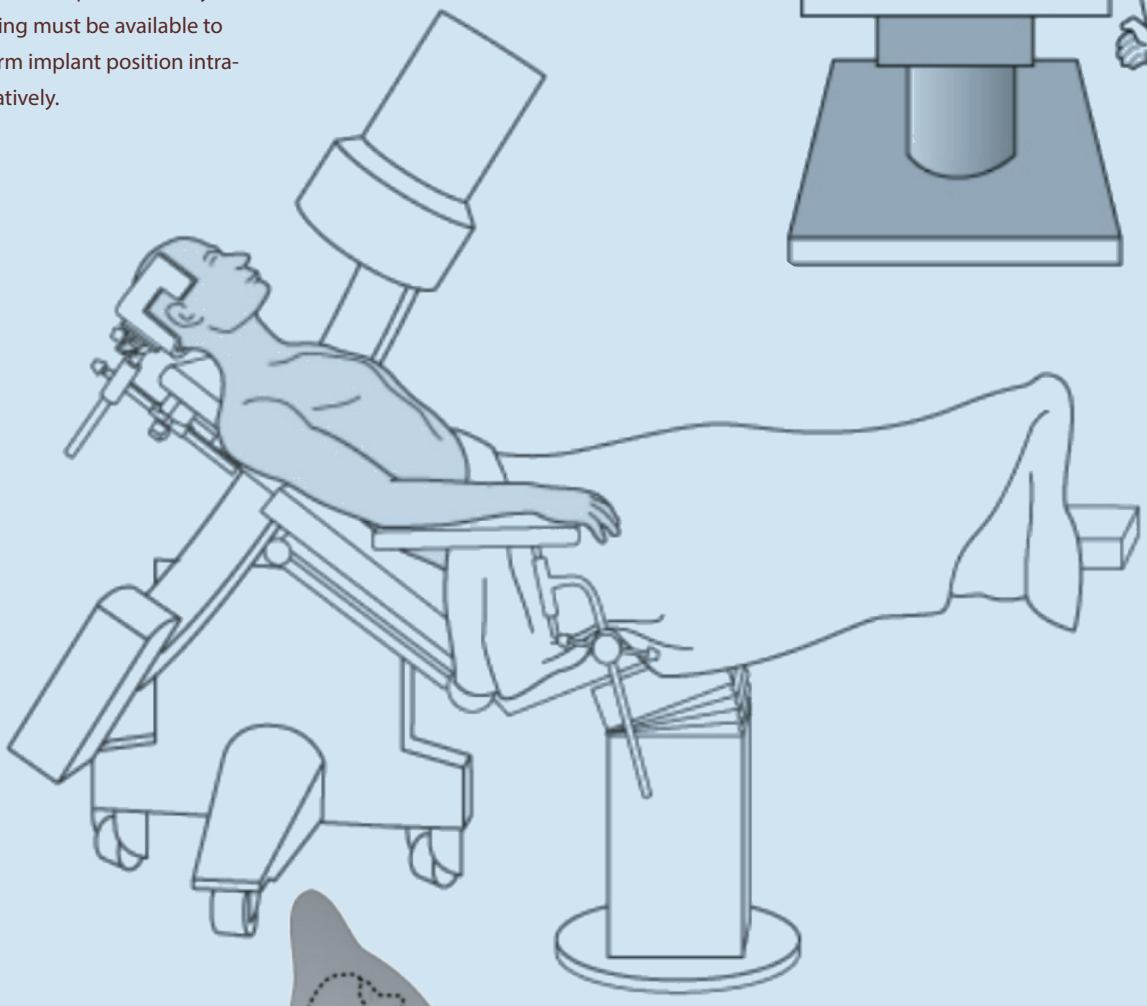
CAUTION

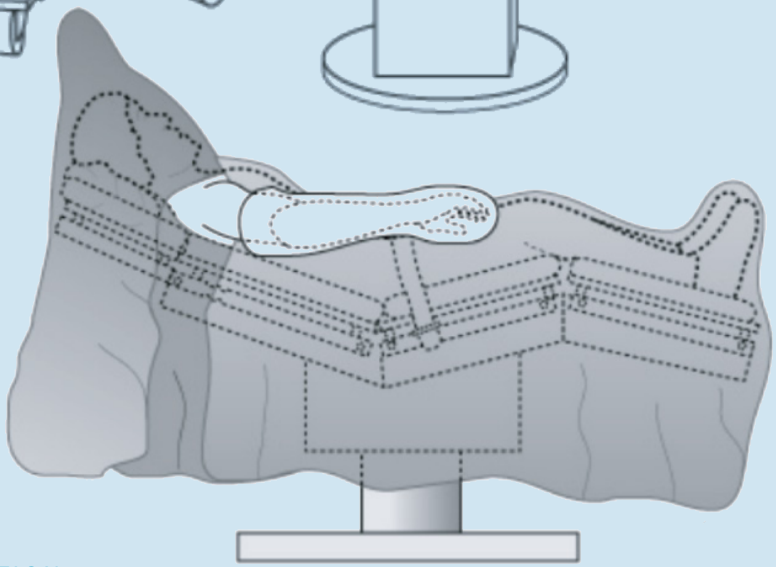
If BMI is equal to or greater than 40, it is recommended that a stability humeral cup is used.

Patient Positioning

The recommended patient positioning is a beach chair with the operative shoulder free to allow full range of motion in the operating area and the head fixed in position. X-ray imaging must be available to confirm implant position intra-operatively.





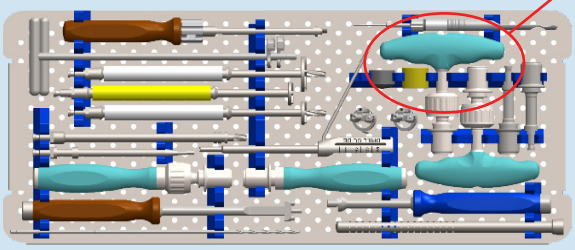


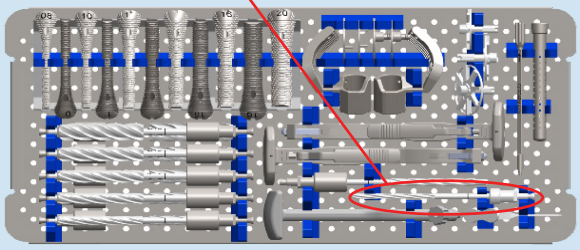
HUMERAL PREPARATION

STEP 1:
PREPARATION OF THE HUMERAL SHAFT (Figure 1)

Locate and perforate the top of the humeral head in the medullary canal axis using the 6mm awl tip starting reamer. Use the reamers in increasing size with the ratcheting T-Handle. Increase in reamer size diameter until the diameter of the reamer meets the diameter of the humeral canal.

Figure 1





HUMERAL PREPARATION

STEP 2: MOUNTING & PLACING THE INTRAMEDULLARY DELTO-PECTORAL 135° CUTTING GUIDE (Figure 2)

Slide the cutting guide over the remaining reamer from 8mm-20mm. Screw the forearm axis into one of the five positions according to the desired version for the patient (0°, 10°, 20°, 30°, or 40°). The cutting guide will be secured to the reamer when the forearm axis is screwed in completely and tightened to the reamer. (Figure 3)

Place a pin into each hole A1 and A2 (A1+A2). Remove the version rod and reamer.

Slide the cutting guide along the pins closer to the humeral head. Drill in the 3rd pin into the B hole.

Resect the humeral head.

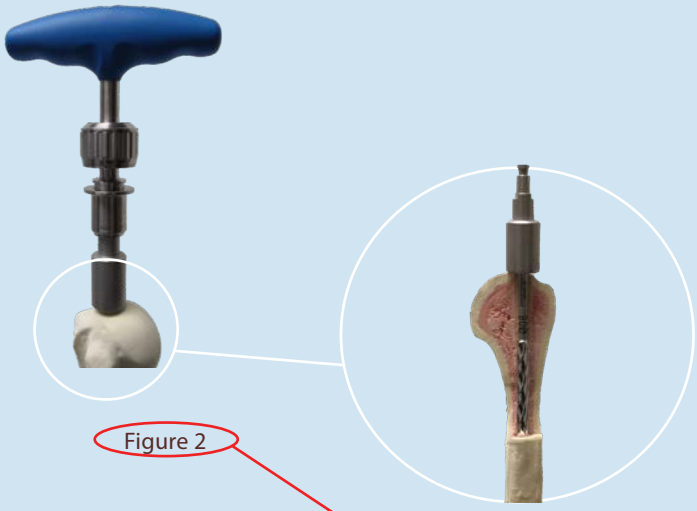


Figure 2

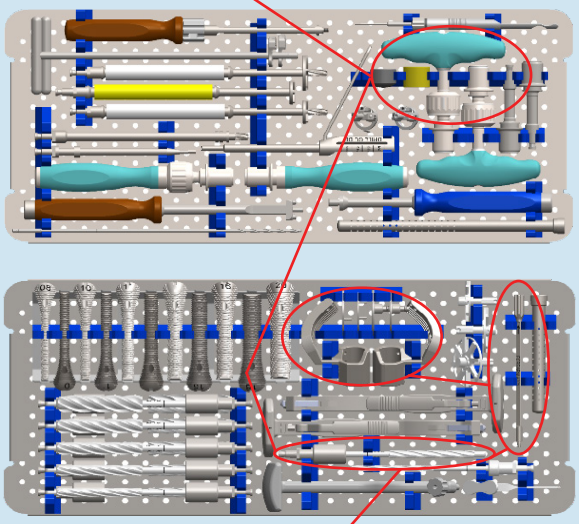
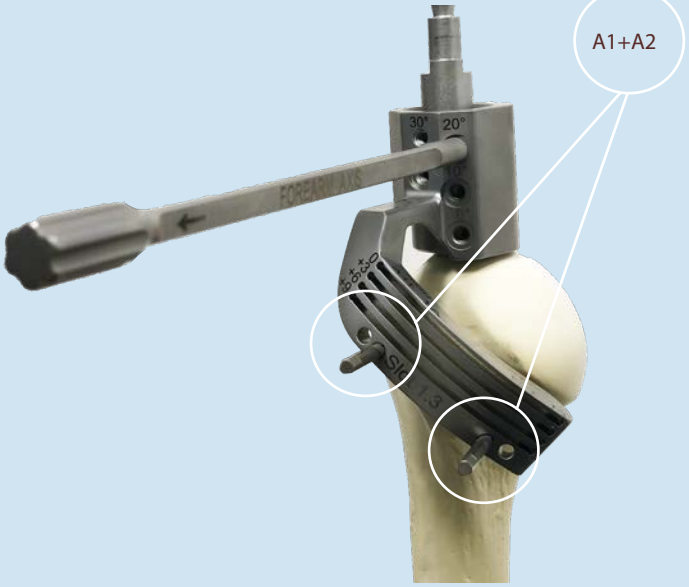
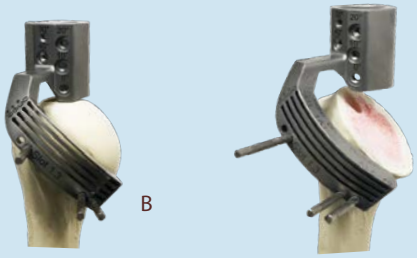


Figure 3





HUMERAL PREPARATION

STEP 2: OPTION
USING THE 135° EXTRAMEDULLARY CUTTING GUIDE

(Figure 4)

Insert the forearm axis by screwing it in according to the patients version (0°, 10°, 20°, 30° or 40°). Align the guide with the long axis of the humeral shaft, position the cutting guide at the anatomical neck and resect the humeral head.

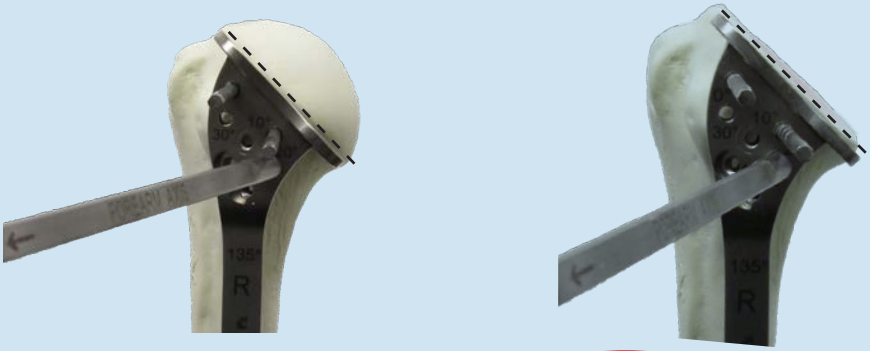
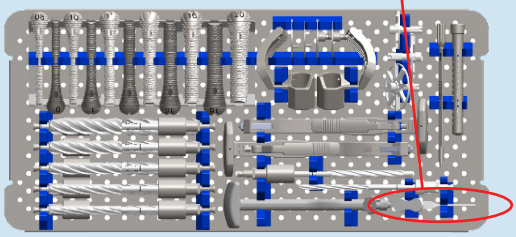


Figure 4



STEP 3: HUMERUS PROTECTION

(Figure 5)

Option 1:
Impact the selected spiked protector cap on the resected humeral surface. Humeral protectors are available in two diameters (Ø41 and Ø46).

Screw in Protector

Spiked Protector

** To use the screw in protector, proceed to Step 6 on page 14.

STEP 4:
BROACHING (Figure 6)

Attach the Forearm axis into the same angled version holes (0°, 10°, 20°, 30°, 40°) utilized for the head resection. The implant size is determined by the broach used.

Note: It is advisable to sequentially broach using a broach size two – three sizes smaller than the reamer size. In cases when a larger broach is required to fill the metaphysis, the corresponding reamer and broach to be impacted should be passed down the canal.

Figure 5

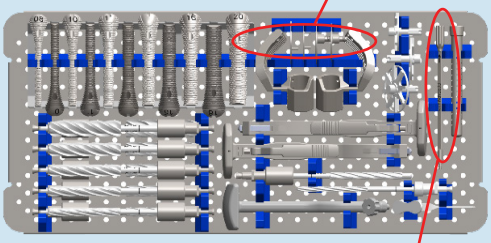


Figure 6

HUMERAL PREPARATION

STEP 5: CALCAR CLEANING (Figure 7)

Select the calcar reamer that best covers the resected surface, (Ø41, Ø46, Ø51mm) onto Blue driver shaft. Insert the reamer into the remaining broach and ream the existing surface to ensure a smooth resected surface.

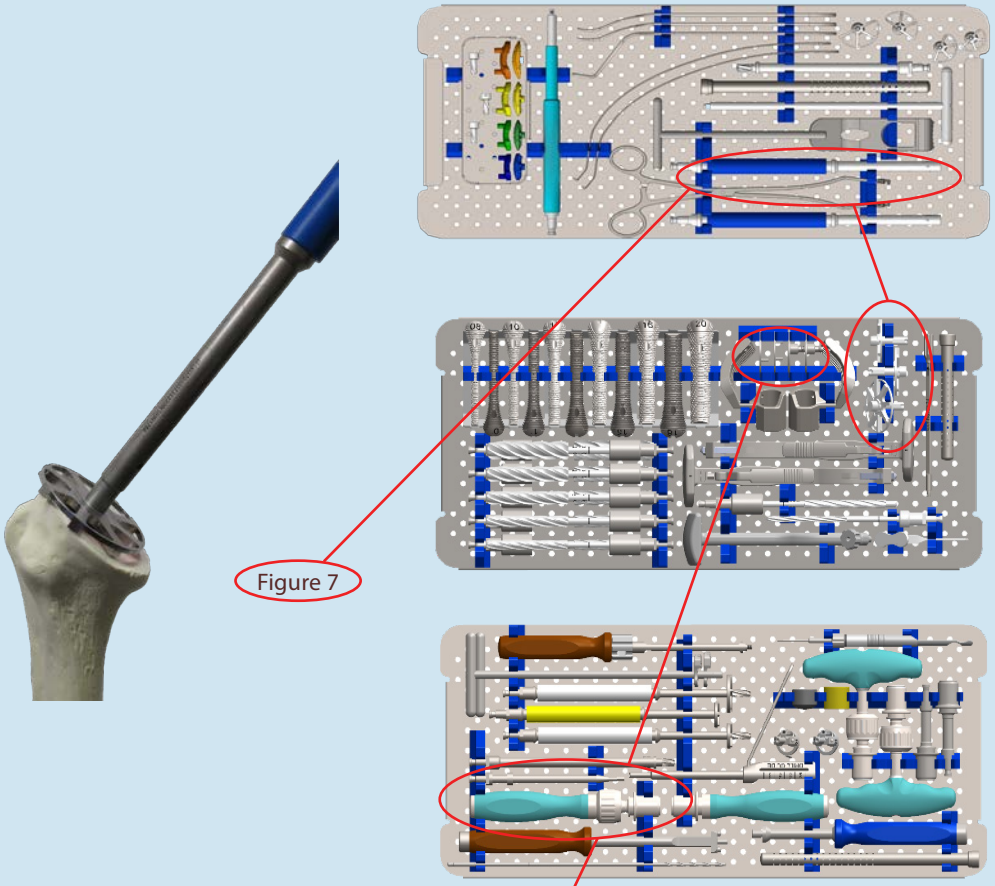


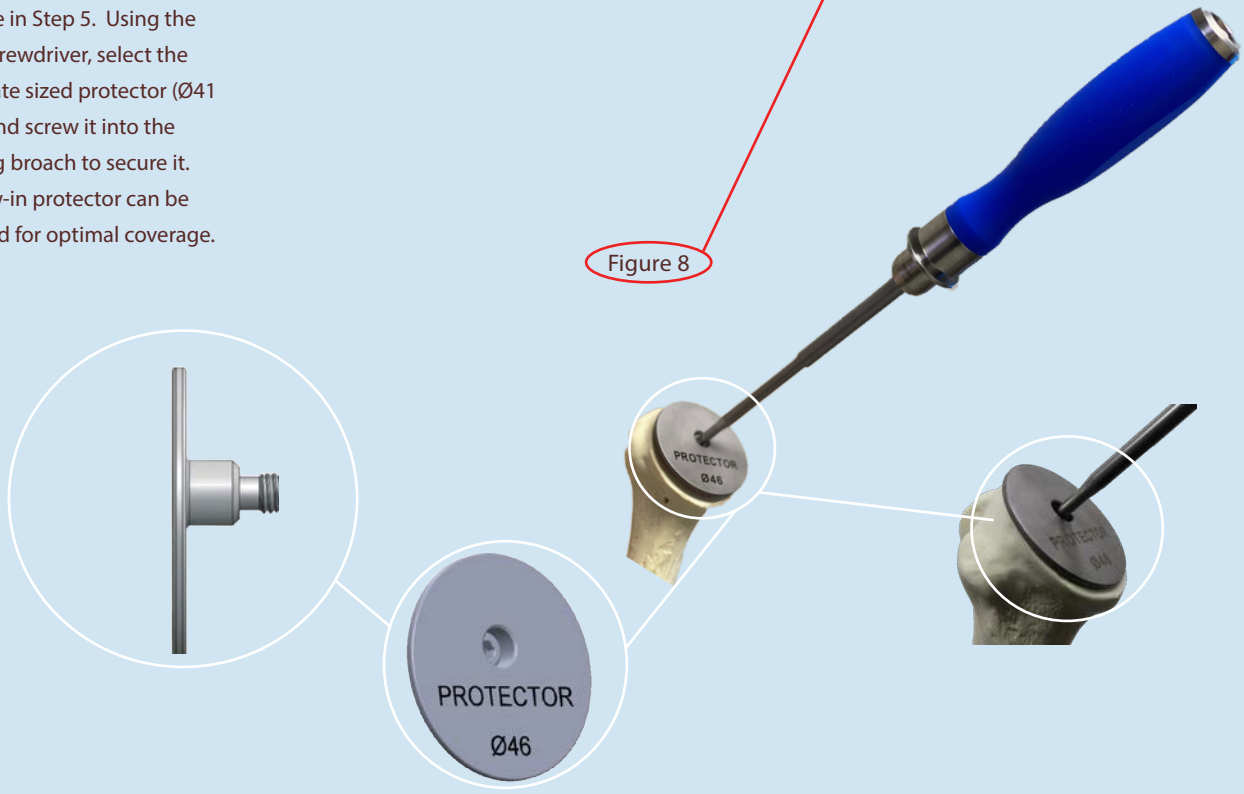
Figure 7

STEP 6: OPTION HUMERUS PROTECTION

(Figure 8)

Complete the broaching technique in Step 5. Using the 3.5mm screwdriver, select the appropriate sized protector (Ø41 or Ø46) and screw it into the remaining broach to secure it. The screw-in protector can be positioned for optimal coverage.

Figure 8



STEP 7: GLENOID EXPOSURE (Figure 9)

Expose the glenoid fully using four types of retractors:

- Anterior Retractor - 1
- Posterior Retractor - 2
- Inferior Retractor - 3
- Superior Retractor - 4

Remove the glenoid labrum.

Remove any potential osteophytes to expose the full bone anatomy.

Figure 9

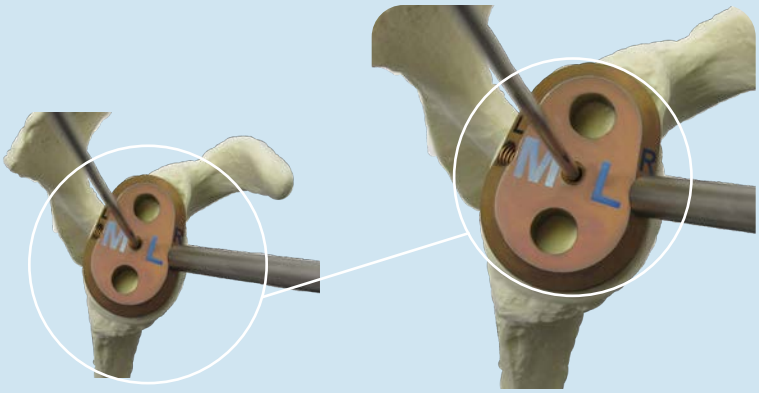
STEP 8: PLACING THE K-WIRE

(Figure 10)

Select a Glenoid Template that best covers the glenoid face. Visualize the position of the peg holes. The peg holes need to be postioned to prevent breakout of the glenoid rim.

The Glenoid Template should be centered to the antero-posterior plane. The angular orientation of the 2.5mm K-wire determines the inclination of the glenoid. This position is determined from the patient's anatomy and planned according to the pre-operative x-rays.

Small Template (Green) = Implant XS or S
Large Template (Orange) = Implant M or L



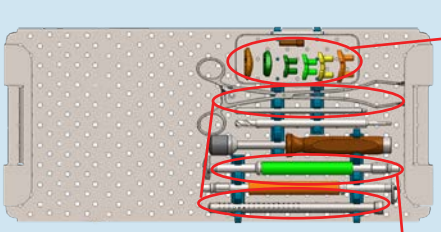
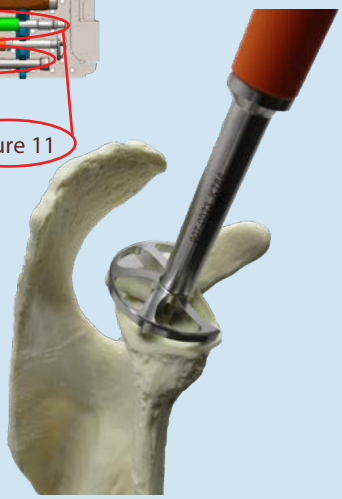


Figure 10

Figure 11



STEP 9: GLENOID REAMING

(Figure 11)

Assemble the Drill and ream the Glenoid by placing it over the K-wire (as a guide). Drill the post first and then switch to ream.
Ream until subchondral bone is reached (RECOMMENDATION).

Green Reamer = Implant XS or S
Orange Reamer = Implant M or L

2 PEG GLENOID

STEP 10: DRILLING GLENOID PEG HOLES

(Figure 12)

Insert the trial template over the 2.5mm K-wire. Drill the first hole until it stops. Remove the drill and put the brown peg in the hole of the trial template to prevent rotation or motion. Repeat the same thing with the second hole.

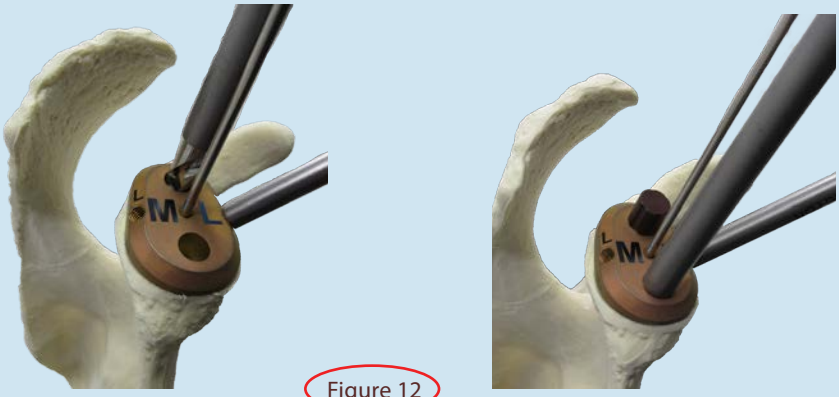
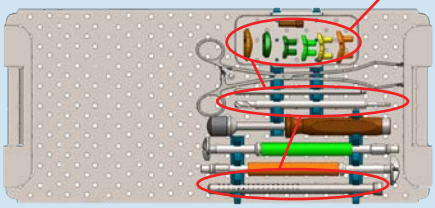
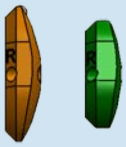


Figure 12





2 PEG DRILLING GUIDES

STEP 11: TRIAL IMPLANT (Figure 13)

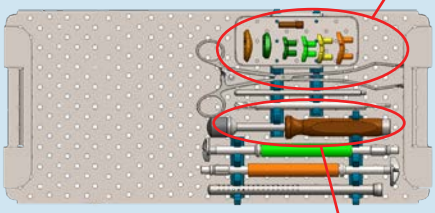
Insert the trial implant by using the glenoid holder clamp.

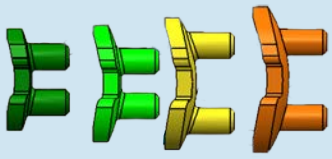
Dark and Light Green Templates = Trial Implants XS or S

Yellow and Orange Templates = Trial Implants M or L

RECOMMENDATION:
Put some cement into the holes to ensure full stability

Figure 13





2 PEG TRIALS

STEP 12: DEFINITIVE IMPLANT (Figure 14)

Take the implant of the same size as the trial and impact it with impactor.

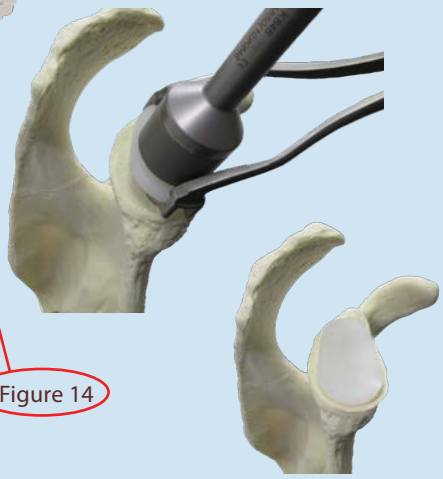


Figure 14

Humeral Head and Glenoid Component Association				
GLENOID SIZE	XS	S	M	L
HEAD SIZE	39	39	X	X
	41	41	41	X
	43	43	43	43
	X	X	46	46
	X	X	48	48
	X	X	50	50

3-4 PEG GLENOID

STEP 13: GLENOID EXPOSURE (Figure 15)

Expose the glenoid fully using four types of retractors:

- Anterior Retractor - 1
- Posterior Retractor - 2
- Inferior Retractor - 3
- Superior Retractor - 4

Remove the glenoid labrum.

Remove any potential osteophytes to expose the full bone anatomy.

Anterior - 1

Posterior - 2

Inferior - 3

Superior - 4

Figure 15

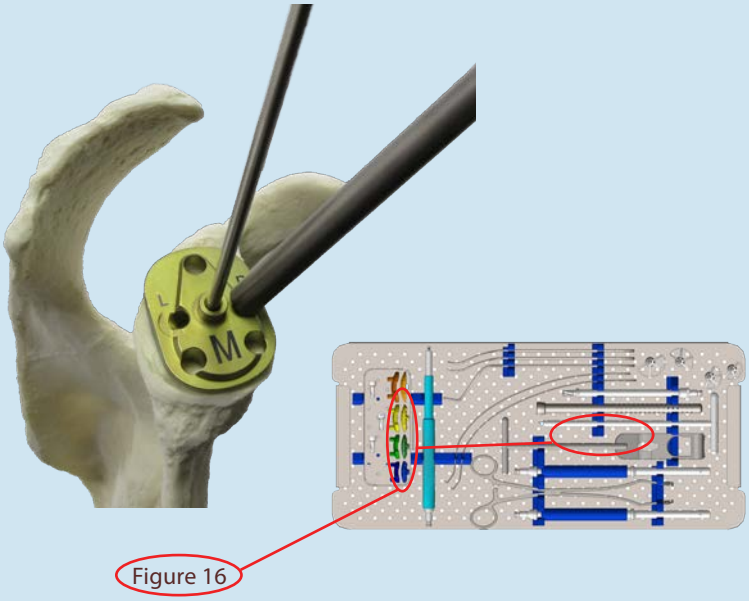
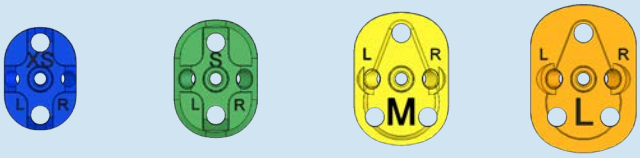


Figure 16



3-4 PEG DRILLING GUIDES

STEP 14: PLACING THE K-WIRE

(Figure 16)

Determine the desired Glenoid size, attach K-wire Guide T-Handle to the Trial Glenoid. Insert the handle into the appropriate left or right (L or R) threaded holes.

Insert the 3.0mm K-wire guide and template for the symmetrical glenoid (XS, S, M, or L).

The K-wire should be centered to the antero-posterior plane. The orientation of the 3.0mm K-wire will determine the inclination of the glenoid.

The position should be adapted to the patient's anatomy and planned according to the pre-operative x-rays.

3-4 PEG GLENOID

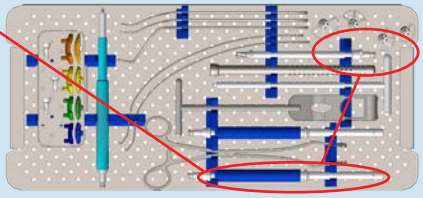
STEP 15: GLENOID REAMING

(Figure 17)

Ream the glenoid by placing it over the K-wire (as a guide). Ream until subchondral bone is reached (RECOMMENDATION).

It is preferable to begin this reaming by hand with the ratcheting T-handle in order to avoid osteophytes and also in cases when the glenoid is osteoporotic.

Figure 17



3-4 PEG DRILLING GUIDES

STEP 16: DRILLING STABILIZATION HOLES 3-4 PEG

(Figure 18)

Drill the first stabilization hole and leave the drill in to prevent the drill guide from moving or rotating. Repeat for the second hole on a 3-peg glenoid and the remaining two holes for the 4-peg drill guide. Once all the stabilization holes have been drilled, remove the drill heads from the drill guide. Slide the drill guide backward off of the k-wire and prepare to drill the central peg hole.

For the 4-peg glenoid, after drilling the superior stabilization hole, replace the drill shaft to drill the posterior hole and repeat the process for to drill the anterior stabilization hole. Once all the stabilization holes have been drilled, remove the drill heads from the drill guide. Slide the drill guide backward off of the k-wire and prepare to drill the central peg hole.

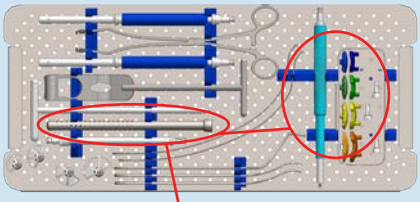
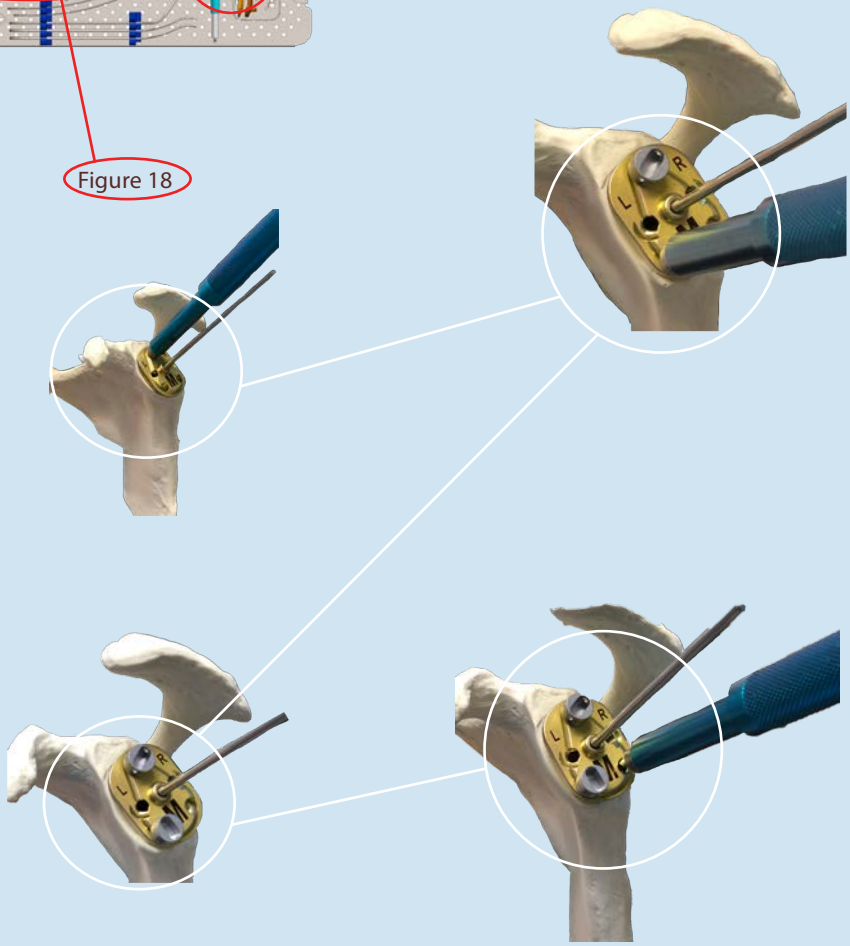


Figure 18

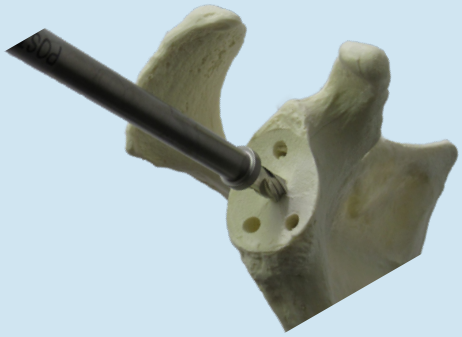


3-4 PEG GLENOID

STEP 17: DRILLING THE CENTRAL PEG HOLE

(Figure 19)

Remove the drill bits and Glenoid drill template and leave the K-wire. Place the cannulated stop drill over the K-wire and drill the central hole until it stops.



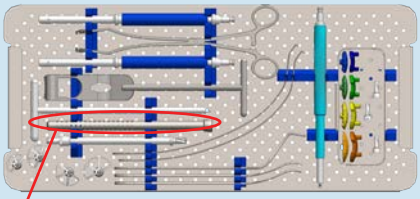


Figure 19

STEP 18: TRIAL IMPLANT (Figure 20)

Select the appropriate trail and insert it into the glenoid with the clamp.

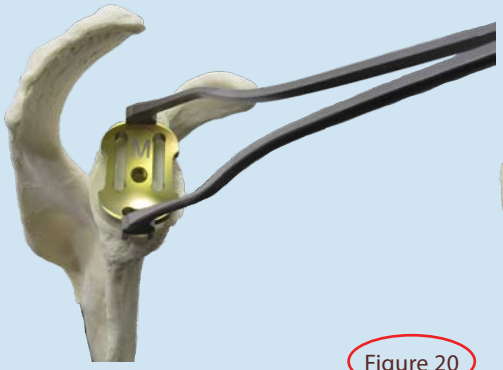
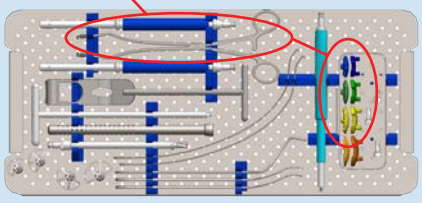
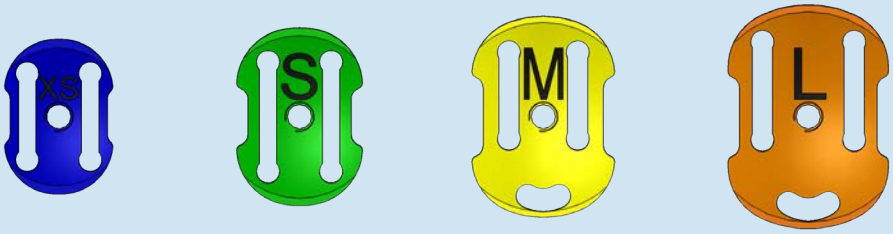


Figure 20





3-4 PEG TRIALS

3-4 PEG GLENOID

STEP 19: DEFINITIVE IMPLANT – GLENOID (Figure 21)

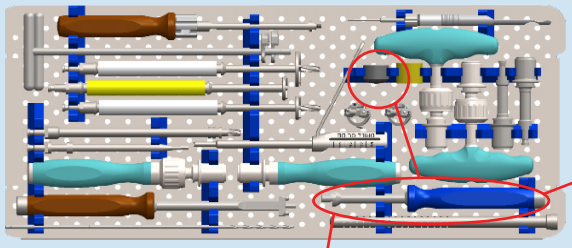
Select the Glenoid implant of the same size as the Glenoid trial.

Wash and dry the peg holes and bony surface in the usual manner. Apply cement to the prepared bony surface.

Insert the implant with the glenoid holder clamp.

Impact and maintain the pressure with the glenoid impactor.

Note: 52mm and 54mm humeral heads are available in the offset option only



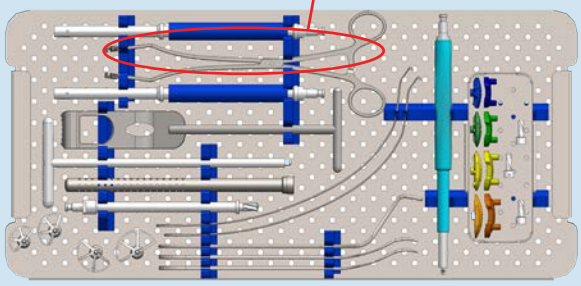


Figure 21

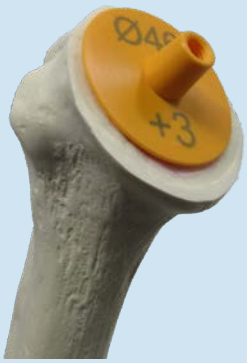
Humeral Head and Glenoid Component Association				
GLENOID SIZE	XS	S	M	L
HEAD SIZE	39	39	X	X
	41	41	41	X
	43	43	43	43
	X	X	46	46
	X	X	48	48
	X	X	50	50

HUMERAL HEAD TRIAL

STEP 20: SELECT THE HUMERAL HEAD TRIAL (Figure 22)

Compare the resected humeral head to the closest humeral head trial.

Use a smaller prosthetic head than the measurement taken for the native head.



Select the components:

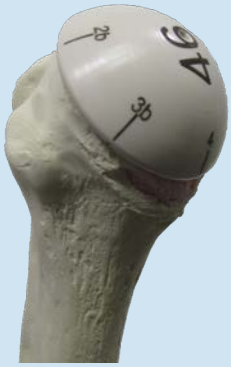
DOUBLE-TAPER (+0mm)
OR
SPACER (+3, +5mm)

Figure 22

CENTERED OR OFFSET TRIAL HEAD

The humeral head should cover the cortical bone in an appropriate manner while being 5 to 8mm above the greater tuberosity.

The flat side of the head should be parallel to the incision. If an offset head is used, mark its position.



DEFINITIVE IMPLANTS

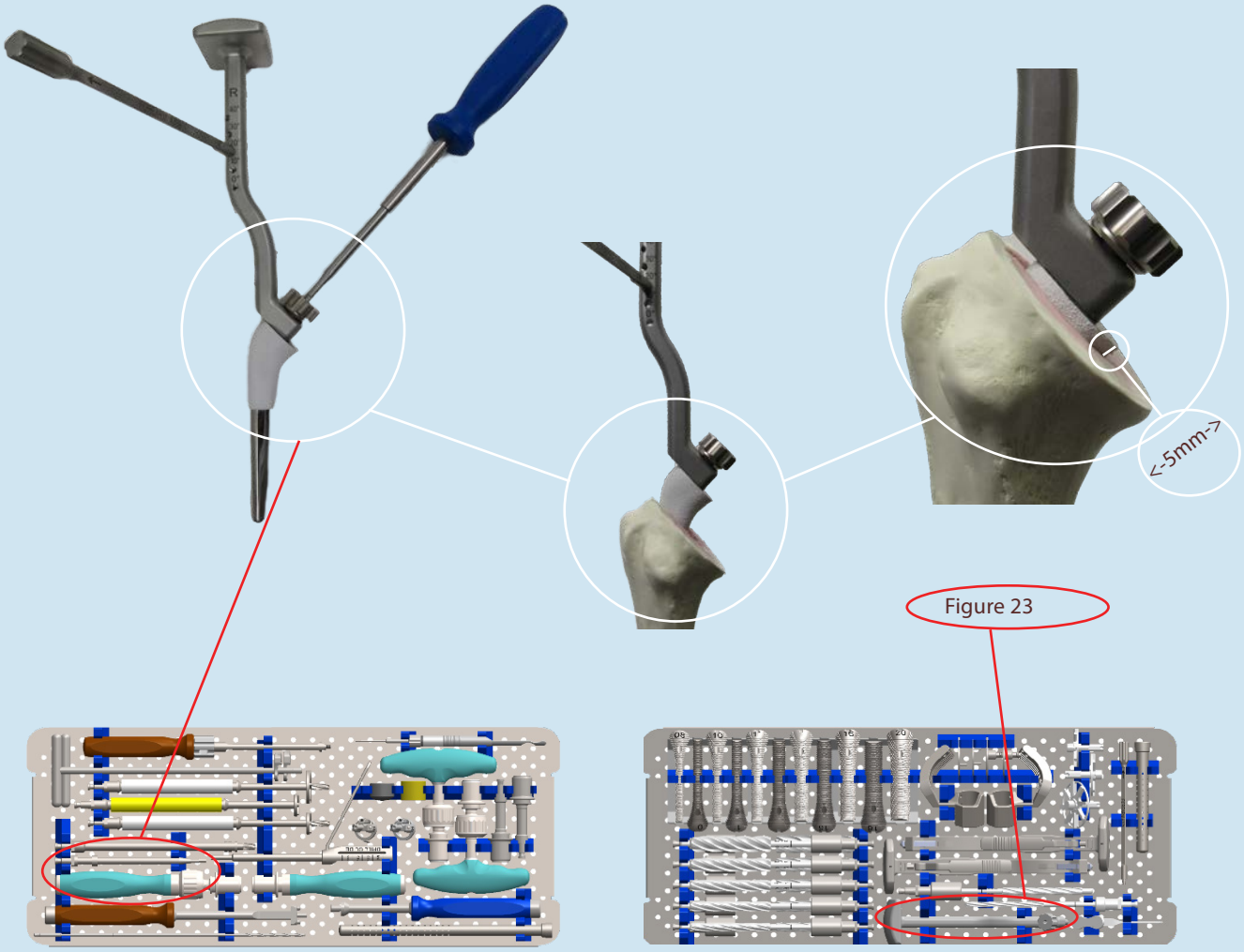
STEP 21:
DEFINITIVE STEM

(Figure 23)

Screw the definitive stem based on the last broach size selected onto the broach handle.

Screw in the forearm axis according to the patients version (0°, 10°, 20°, 30°, or 40°)

Impact the stem until it is 5mm proud over the humeral resection. Then, impact the final implants (humeral stem, double cone taper or spacer, and humeral head) together until the stem is flush with the resection.



DEFINITIVE IMPLANTS

STEP 22:
DEFINITIVE TAPER AND HEAD

(Figure 24)

Be sure to check that there are no splinters on the upper extremity of the humerus metaphysis hindering impaction of the morse taper.

Take the definitive double taper and impact it INTO THE STEM (not to the head) using the impactor to start with.

Select the appropriate final head and impact it onto the taper. If using an offset head, insert it onto the double taper with the same position as determined by the trial.

Finalize impaction of the stem while impacting the head onto the taper.

CAUTION

IMPACT THE TAPER INTO THE STEM NOT THE HEAD

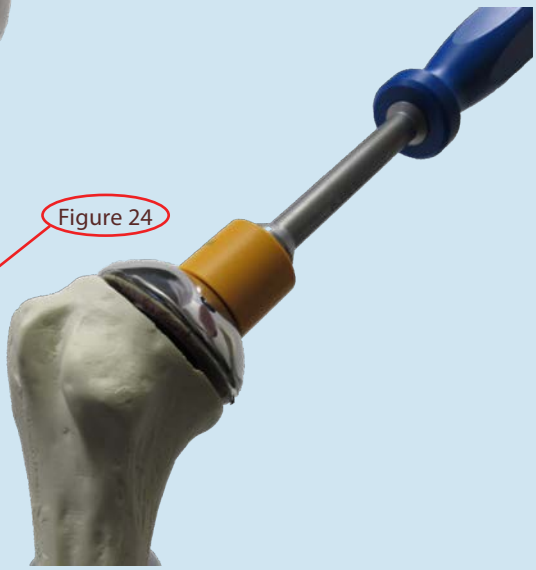
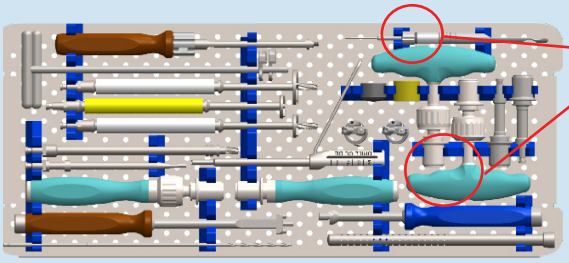


Figure 24



STEP 23:
DEFINITIVE REDUCTION

((Figure 25)

Reduce and make sure the joint is stable by pushing back the humerus. It needs to come back of 50% (RECOMMENDATION) to have a stable joint.

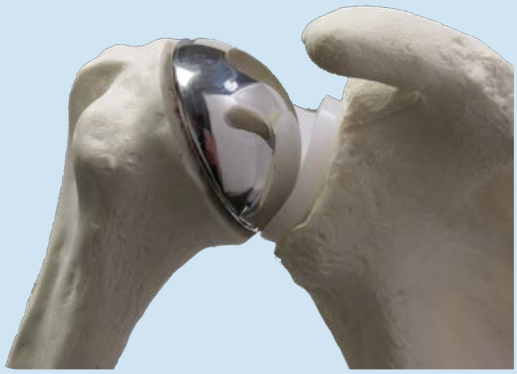


Figure 25

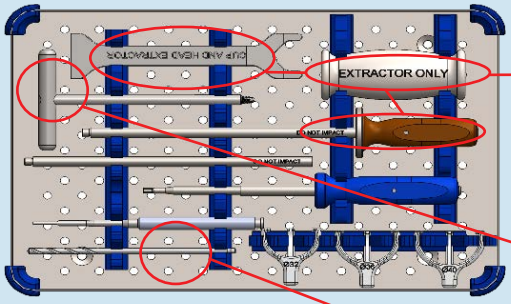
REVERSIBILITY

ANATOMICAL IMPLANT REMOVAL

(Figure 26)

Remove the head by sliding a small fork between the head and the stem.

Remove the double taper by screwing in and tightening the slap hammer extractor and backing it out.



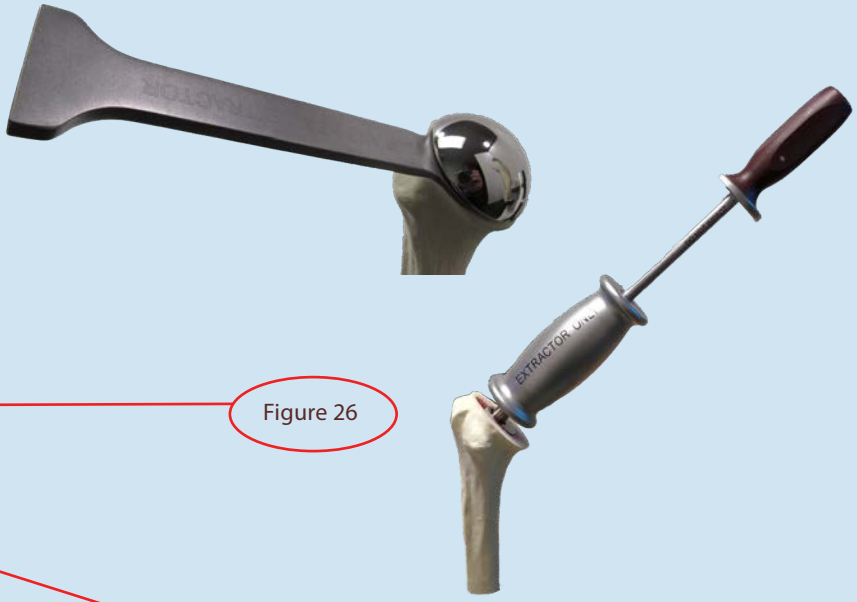


Figure 26

GLENOID EXTRACTION

(Figure 27)

Using the drill bit provided in the extraction kit, drill through the central hole for an insertion point for the T-handle extractor. Screw in the T-handle extractor into the pre-drilled hole and pull to extract the glenoid. If required, carefully saw the back side of the glenoid to remove it from the stablization and central peg. Using a forceps, hold the glenoid antero-posteriorly and unscrew the glenoid.

**This step only applies to the 3-4 peg glenoid.

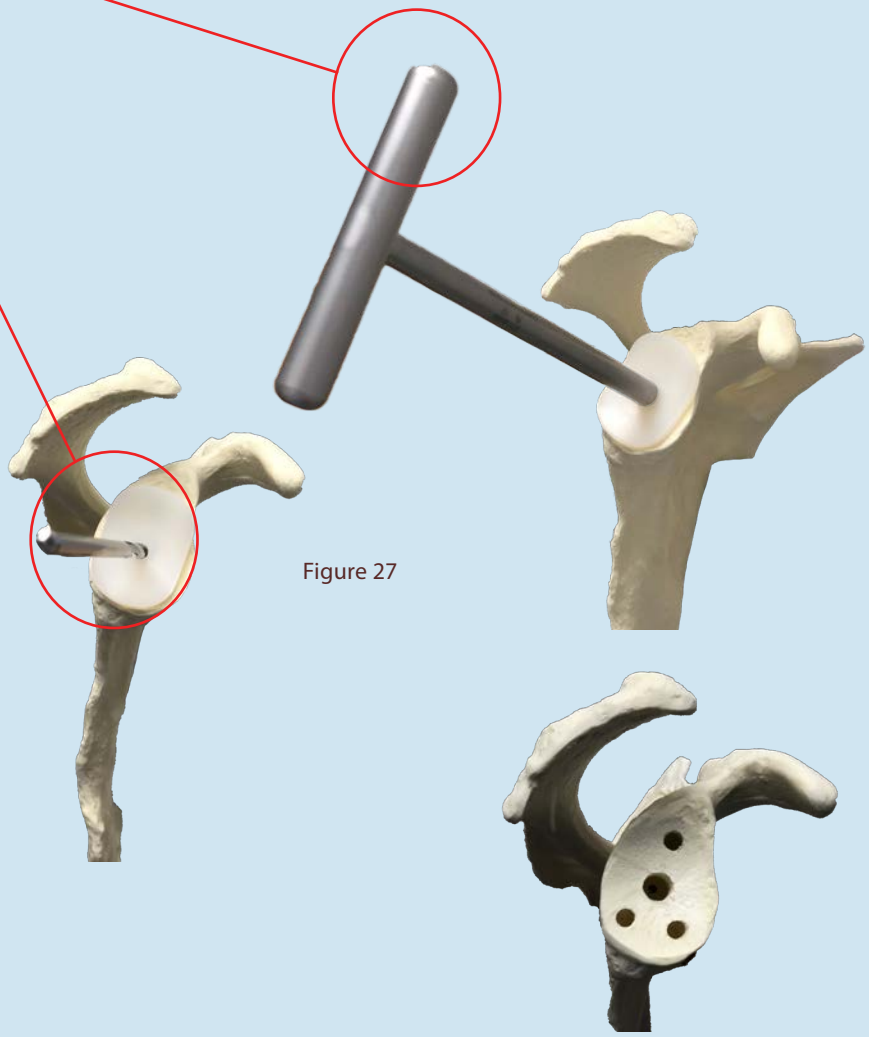


Figure 27

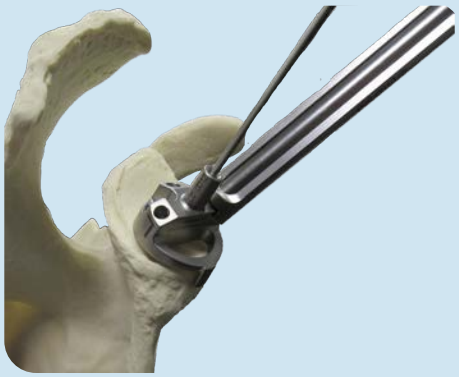
CAUTION

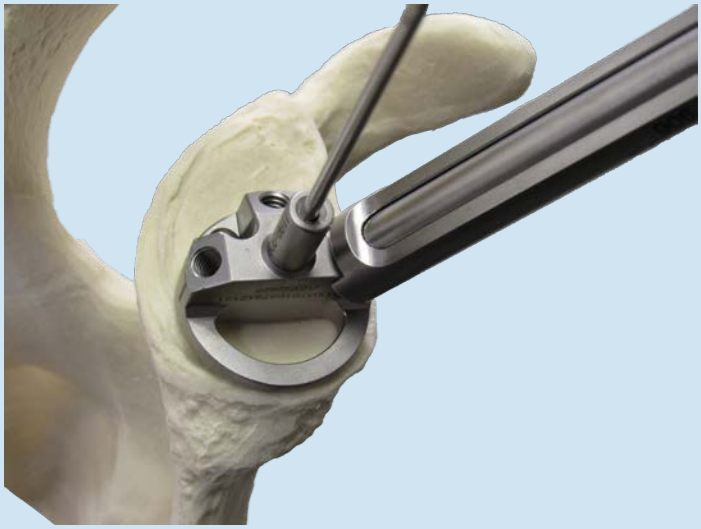
GLENOID PREPARATION

STEP 24: PLACING THE 2.0mm K-WIRE**

(Figure 28)

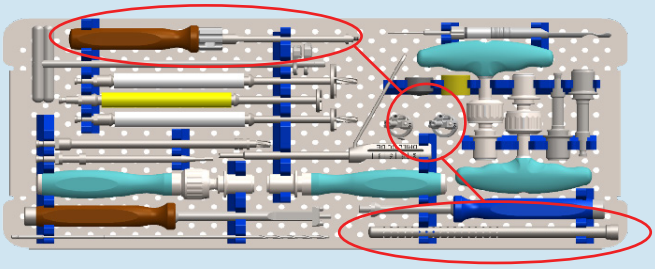
The (3) different positions for the guide are left (L), right (R) for delto-pectoral approach and the (S) is for the superior-lateral approach. Positioning should fit the anatomy of the patient and planned according to the pre-operative x-ray.





**There is a choice of a K-wire guide with a foot or without for surgeons preference

Figure 28



GLENOID PREPARATION

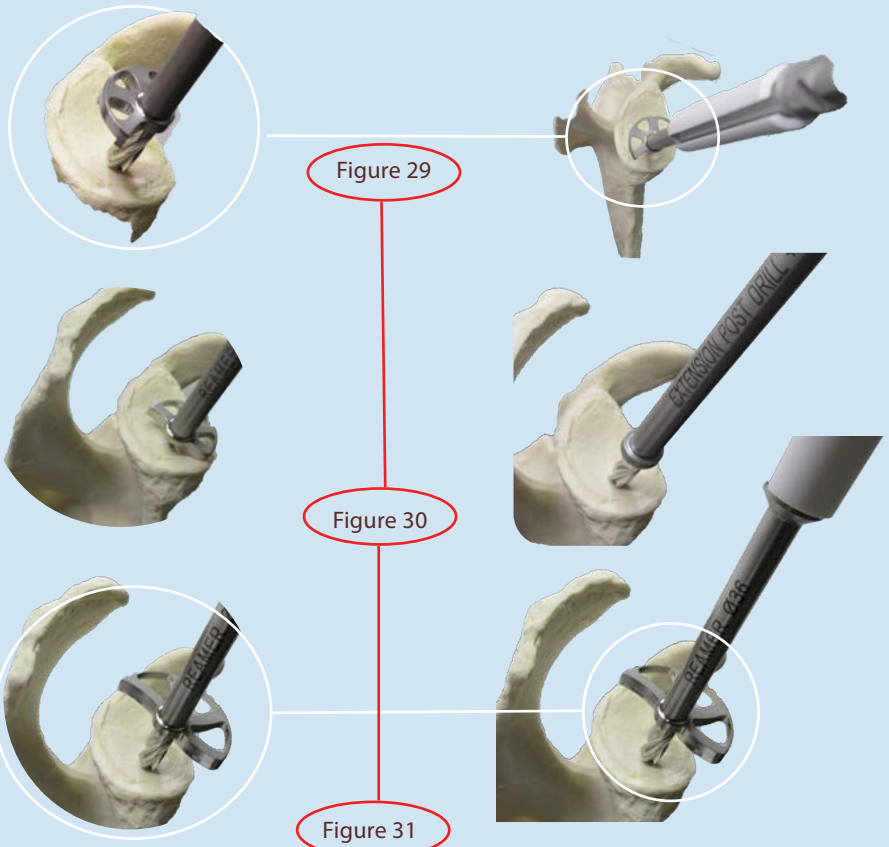
STEP 25: GLENOID REAMING

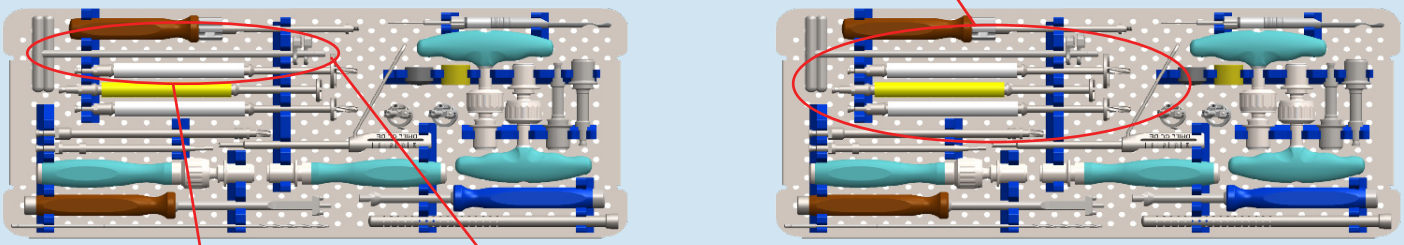
This step can be performed with three different options: Ream to bleeding subchondral bone for all options. (RECOMMENDATION ONLY)

OPT 1: GLENOID RESURFACING REAMER Ø24MM WITH DRILL / HUDSON
Over the 2.0mm K-wire, drill central peg and switch to ream to prepare the glenoid surface. (Figure 29)

OPT 2: Ø24MM GLENOID RESURFACING WITHOUT DRILL
Ream over the 2.0mm K-wire, remove reamer and drill the central peg using the Ø7mm cannulated drill. (Figure 30)

OPT 3: GLENOID RESURFACING REAMER Ø36MM WITH DRILL
Place over the 2.0mm K-wire. Drill and ream. (Figure 31)





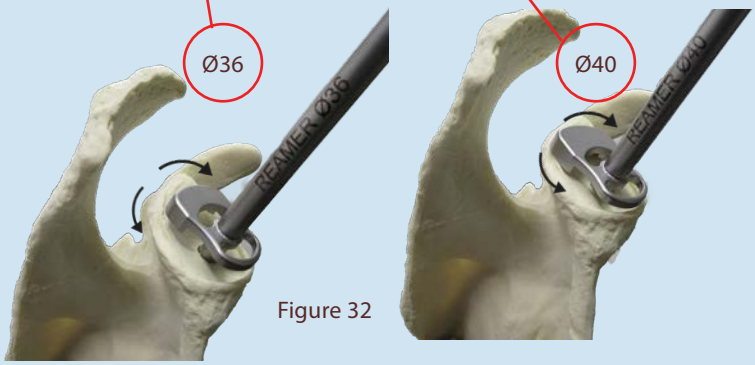


Figure 32

CAUTION

INSPECT TO MAKE SURE ALL OF THE BONE AND SOFT TISSUE HAVE BEEN REMOVED DURING THE GLENOID CLEARANCE BY SWEEPING YOUR FINGER AROUND THE IMPACTED BASEPLATE TO ENSURE YOU WILL HAVE A PROPER IMPACTION AND SEATING OF THE GLENOSPHERE

STEP 26: GLENOID CLEARANCE

Use the GLENOID MANUAL REAMER 36mm OR 40mm. *Must be performed after OPT 1 and OPT 2 (or with the 40mm T-handle if selecting a 40mm glenosphere).* To avoid an interference between the definitive glenosphere and the scapula, ream the glenoid using the Ø36mm or Ø40mm T-handle reamers if needed. (Figure 32)

GLENOID PREPARATION

STEP 27: OPTION 1
BASEPLATE WITH A POST

(Figure 33)

For the Glenoid Baseplate with a Central Screw Proceed to Step 31 on page 29. Connect the baseplate impactor to the definitive baseplate implant. The baseplate impactor is positioned in the anterior and posterior baseplate holes with the "UP" in the superior position. Impact the baseplate so that there is pressure on the whole surface. (RECOMMENDATION ONLY)

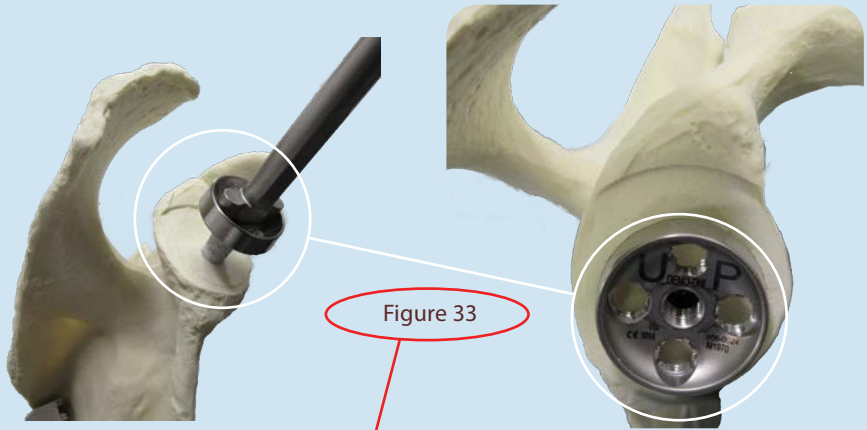
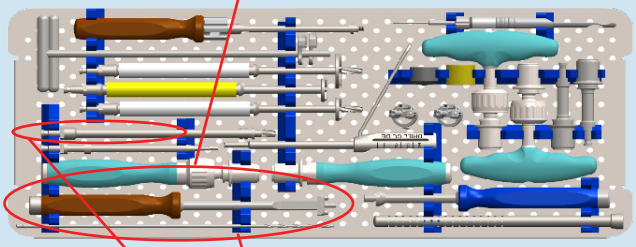


Figure 33



BASEPLATE WITH EXTENSION POST

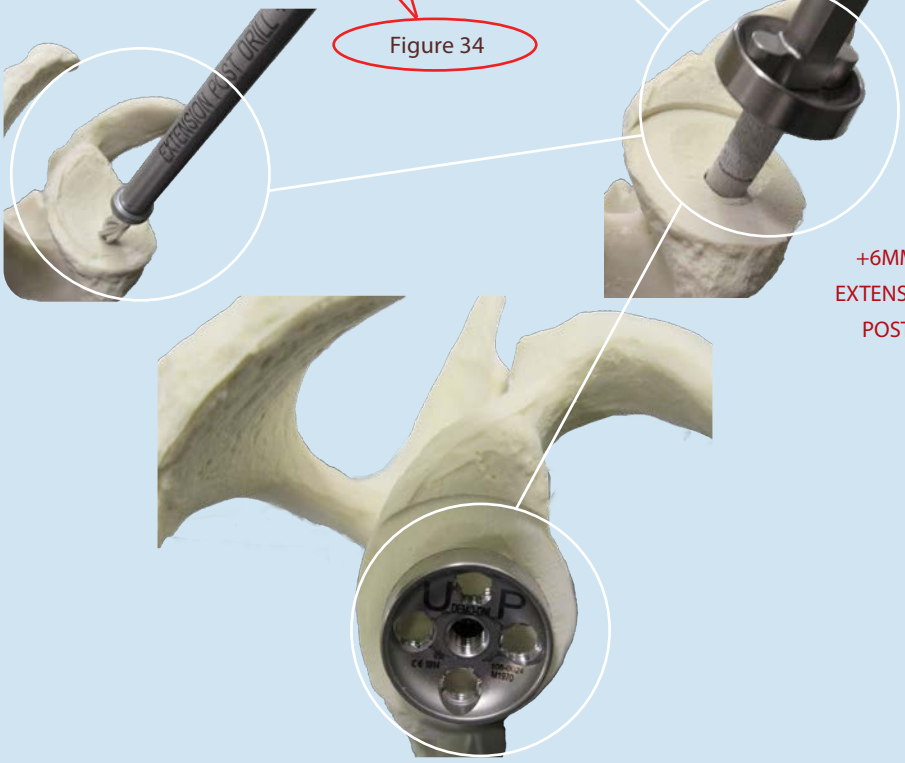
Figure 34

STEP 28: EXTENSION POST (OPTIONAL)

(Figure 34)

In cases of poor bone quality, a medialized glenoid, or in revision cases, a bone graft could be used between the glenoid baseplate and the native glenoid, the baseplate post can be extended by +6mm or +10mm as required. It is important to check that the tip of the extension post is properly implanted into the native glenoid.

Drill the post again with stop drill bit either +6mm or +10mm as required.



+6MM EXTENSION POST

GLENOID PREPARATION

STEP 29: LENGTH OF SCREWS

(Figure 35)

An adapted guide allows drilling and measuring the screws with a 3.2mm drill bit.

Be sure the drill guide is flush within the screw hole. Measure the length of the screws directly from the drill guide.

Recommendations:

(2) Standard 4.5mm screws (compression) for anterior and posterior holes

(2) Locking 4.5mm screws for superior and inferior holes

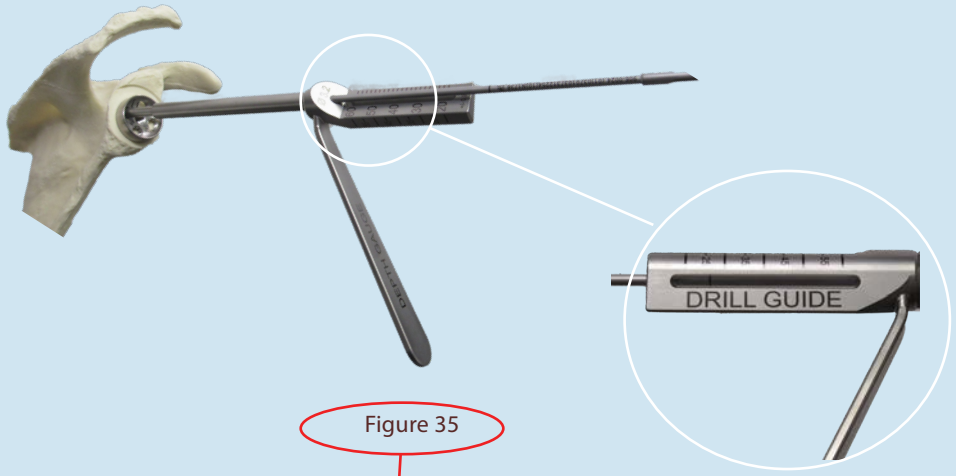


Figure 35

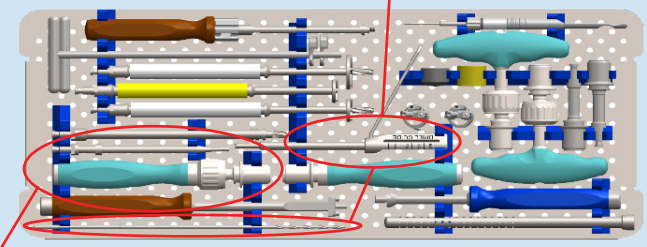
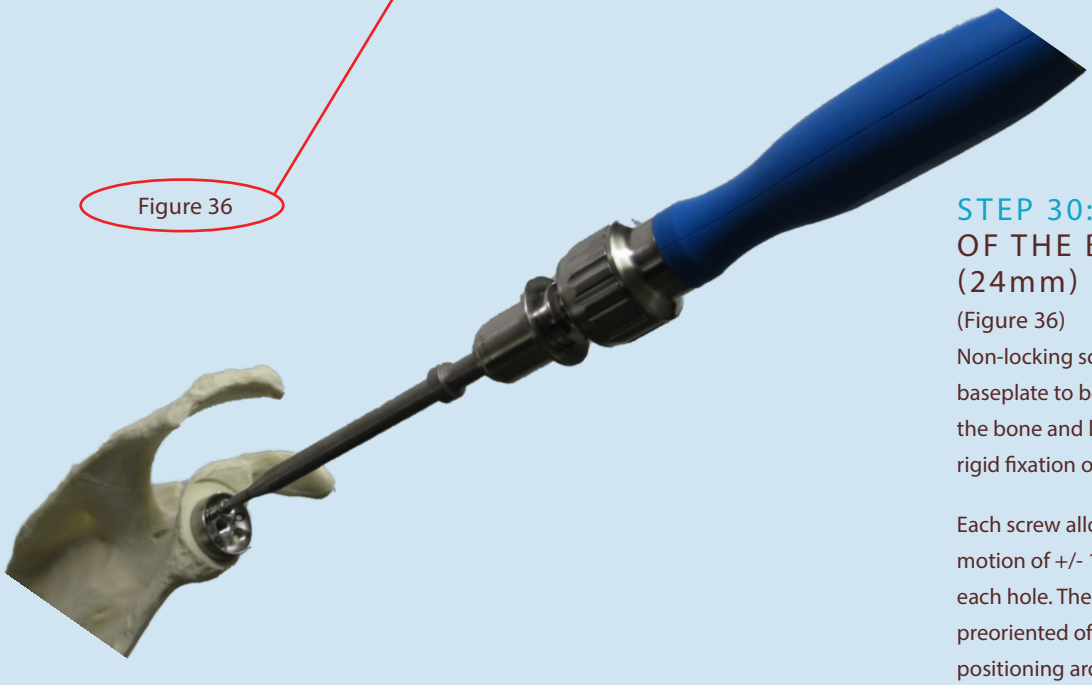


Figure 36



STEP 30: FIXATION OF THE BASEPLATE (24mm)

(Figure 36)

Non-locking screws allow the baseplate to be compressed to the bone and locking screws for rigid fixation of the baseplate.

Each screw allows an polyaxial motion of +/- 12° around the each hole. The upper hole is preoriented of 10° to optimize its positioning around the base of the coracoid process.

GLENOID PREPARATION

STEP 31: OPTION 2
BASEPLATE WITH CENTRAL SCREW

(Figure 37)

Insert the drill guide depth gauge in the central hole of the baseplate. Drill until the cortex.

The length of the screw is measured directly off of the laser etching on the 3.2mm drill at the marking on the drill guide.

Option: Use the depth guage (Figure 38) after drilling to measure or ensure an accurate screw length is measured.

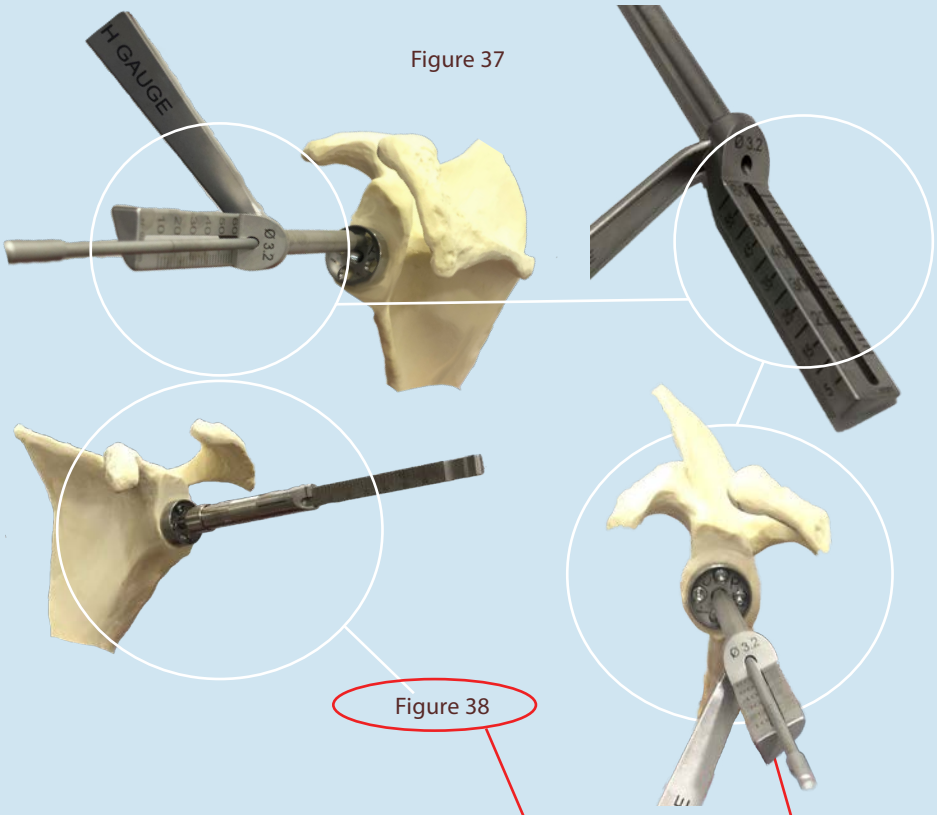
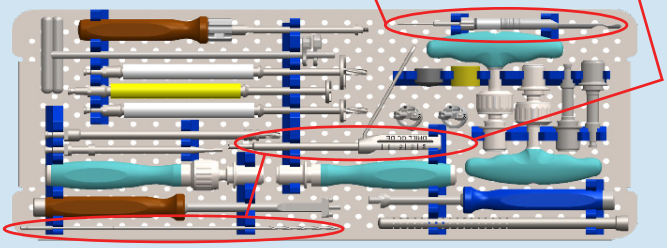


Figure 37

Figure 38



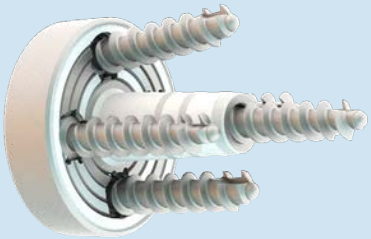
STEP 32 (A):
LENGTH OF SCREWS

There are (7) central screw lengths from 8mm to 20mm (2mm increments).

Recommendations:
(2) Standard 4.5mm screws (compression) for anterior and posterior holes
(2) Locking 4.5mm screws for superior and inferior holes

Standard screws allow the baseplate to be compressed to the bone and locking screws for rigid fixation of the baseplate.

Each screw allows an polyaxial motion of +/- 12° around the each hole. The upper hole is preoriented of 10° to allow up to 22° orientation to reach the base of the coracoid process.



BASEPLATE
WITH
CENTRAL SCREW

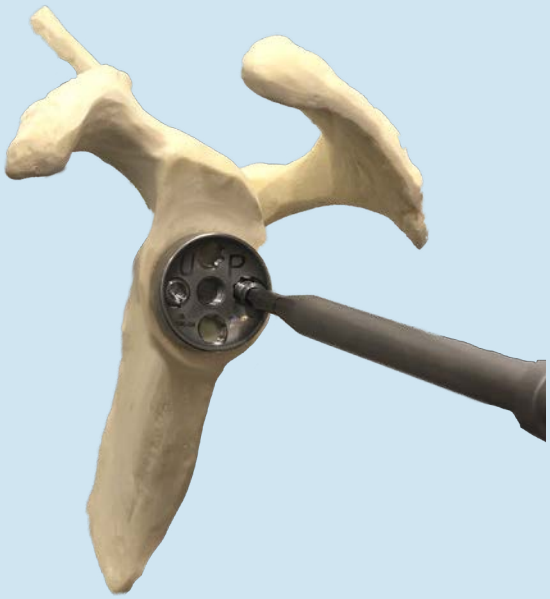
STEP 32 (B): FIXATION OF THE BASEPLATE (24mm)

(Figure 39)

It is recommended to screw the anterior and posterior screws first. Then screw the central screw with the 3.5mm hex screwdriver. The central screw will engage the threads of the baseplate post first before the glenoid bone.

The central screw is correctly tightened when the laser etching on the screwdriver (Figure 40) is not visible anymore and the screw cannot be tightened any further through the main post.

Follow and finish the fixation of the baseplate by inserting two locking screws to complete the fixation of the baseplate.



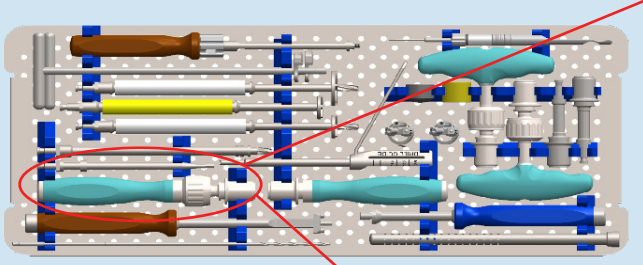


Figure 39

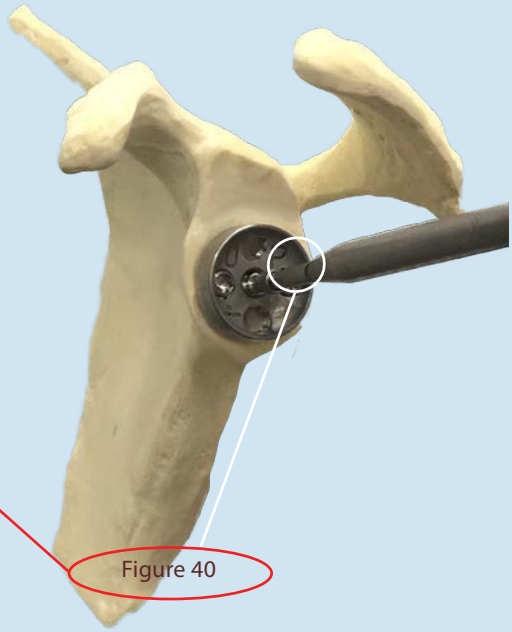


Figure 40

GLENOSPHERE - TRIAL AND DEFINITIVE

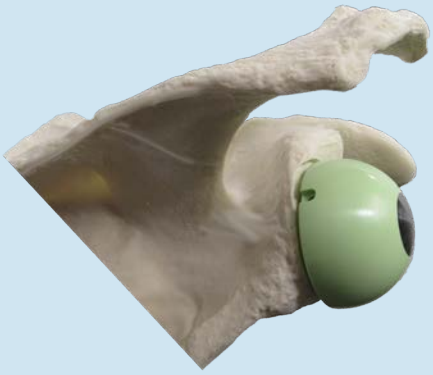


Figure 41

GLENOSPHERE TRIALS Ø32/36/40MM

STEP 33: TRIAL IMPLANTS - GLENOSPHERE

(Figure 41)

There are (3) diameters of glenospheres: 32mm, 36mm and 40mm.

The choice of glenosphere does not depend on the size of the humeral stem.

STEP 34: DEFINITIVE GLENOSPHERE

(Figure 42)

Visualize the glenoid baseplate taper surfaces, clean and dry the surfaces to enable the tapered surfaces to be securely engaged. All definitive glenospheres are centered or eccentric with a screw taper. Insert the 3.5mm hexagonal screwdriver into the screw hole of the glenosphere.

If the 2.0 K-wire is still in place, guide the glenosphere over the K-wire to seat it onto the baseplate.

Once the screw of the glenosphere is inserted into the post of the baseplate, tighten the screw one full turn to align the tapers and then tighten the screw until the screw has fully engaged. Impact the glenosphere with the impactor. Hand tighten to finish securing the baseplate.

If using an eccentric glenosphere, be sure that the glenosphere "UP" marking is in the superior and "UP" position. Use the glenoid impactor head attached to the blue sleeved handle for impaction.

CAUTION

Do NOT impact the glenosphere with the screwdriver

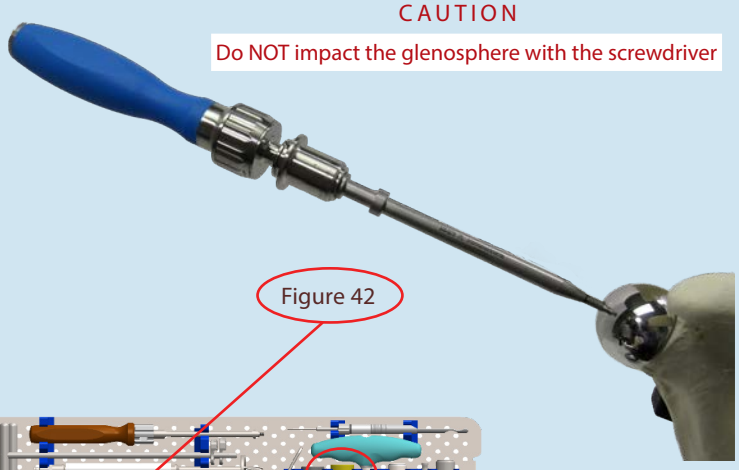
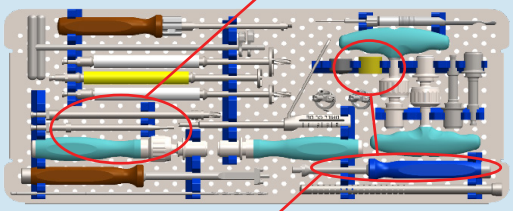


Figure 42



CAUTION

To ensure the morse taper engages properly, be sure that all of the bone and soft tissue have been removed as per Step 26: Glenoid Clearance on page 26

RECOMMENDATION:

If the neck of the scapula is short, it is recommended to use an eccentric glenosphere to reduce the risk of notching.

If the neck of the scapula is long, depending on the deltoid tension and the stability of the mounting, a centered glenosphere can be implanted.

STEP 35:
BROACHING

(Figure 43)

Remove the spiked protector cap. Attach the Forearm axis into the same angled retroversion holes 0°, 10°, 20°, 30°, 40° utilized for the head resection. The implant size is determined by the broach used.

Note: It is advisable to sequentially broach using a broach size two – three sizes smaller than the reamer. In cases when a larger broach is required to fill the metaphysis, the corresponding reamer and broach to be impacted should be passed down the canal.

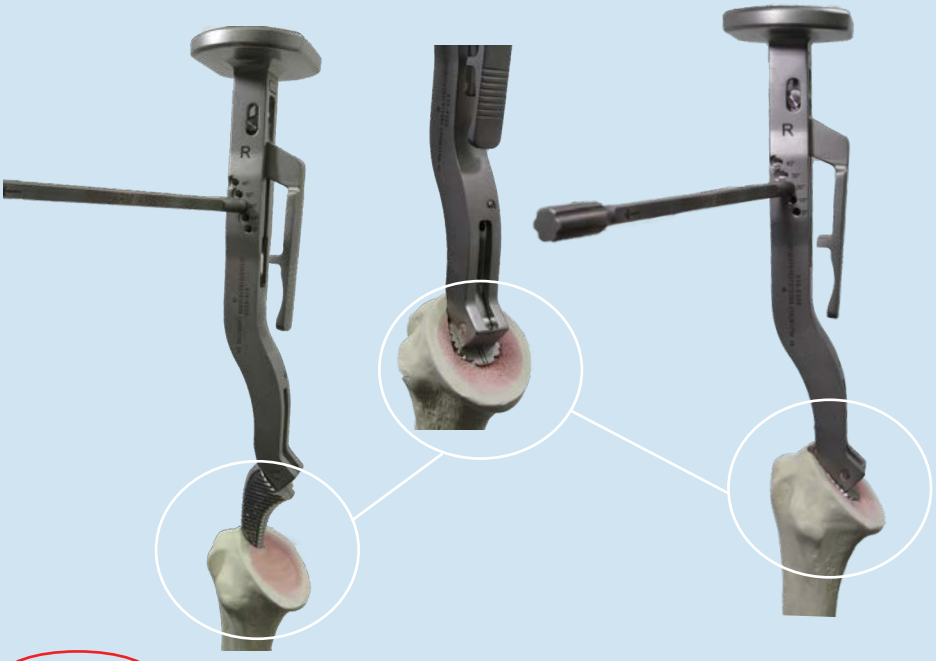
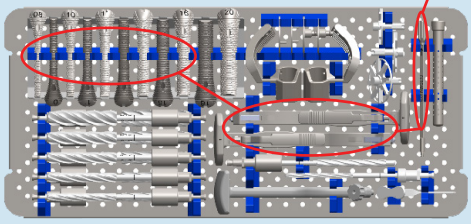


Figure 43



HUMERAL CUP - TRIAL AND DEFINITIVE

STEP 36: HUMERAL CUP TRIAL (Figure 44)

The cup diameter matches the glenosphere diameter.
Three heights are available (+3, +6, +9mm).

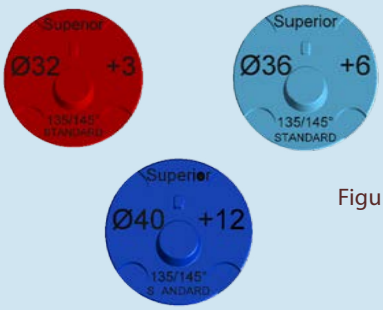


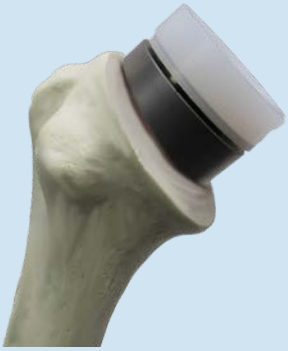
Figure 44

135°/145° HUMERAL CUP TRIALS Ø32/36/40MM

STEP 37: HUMERAL CUP CHOICE

(Figure 45)
The choice of the 135°/145° humeral cup or the 135°/145° adaptor plus the standard reverse humeral cup is based on the height needed for the humeral side of the joint reconstruction. Humeral cup choices are available in +3, +6 and +9 thickness. A reverse adapter can be used to add +9mm of thickness to build up to +12, +15, or +18. You can trial directly off of the broach or the definitive stem.

Figure 45



REVERSE ADAPTER (+9MM) + STANDARD REVERSE HUMERAL CUP

STEP 38: DEFINITIVE CUP

(Figure 46)
Find the index marks on both the definitive cup and the stem. Position the cup so that the index matches the index on the stem.

Insert the cup into the taper of the stem so that indices of the cup and stem are correctly aligned. Be sure to check that there are no impediments and impact the cup. Also, be sure to check that the shoulder is stable and there are no impingements.

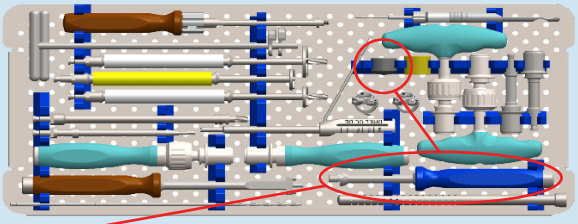


Figure 46

IMPLANT REMOVAL

HUMERAL CUP REMOVAL

(Figure 47)

Remove the cup by sliding a small fork between the cup and the stem.

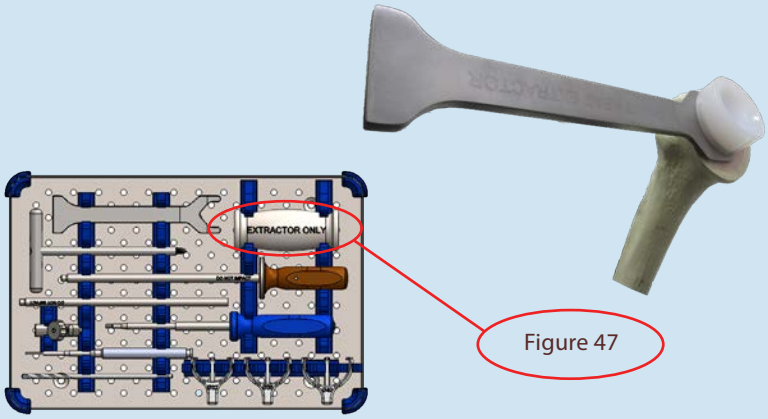


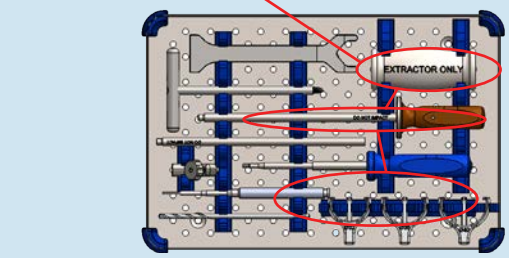
Figure 47

GLENOSPHERE REMOVAL

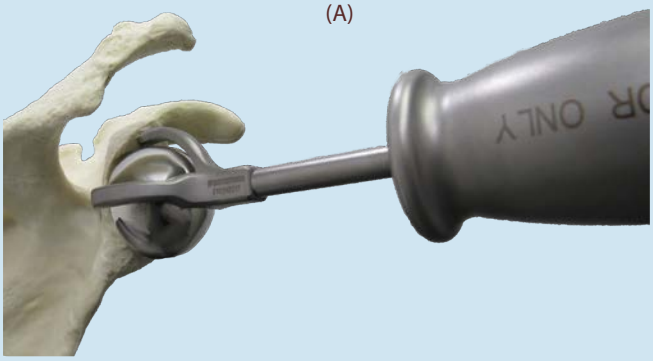
(Figure 48)

Completely loosen and untighten the glenosphere using the 3.5mm hexagonal screwdriver. Select and attach the corresponding size 32, 36, or 40mm arch to the extractor. Slide the arch spurs onto the equator face of the glenosphere rim. Separate the glenosphere from the baseplate using the slap hammer. (A)

Figure 48



(A)



IMPLANT REMOVAL

BASEPLATE REMOVAL

(Figure 49)

Unscrew the baseplate screws with the 3.5mm hex screwdriver.

Screw the extractor into the baseplate post and remove it.

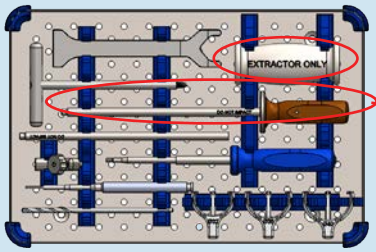


Figure 49

EXTRACTION OF THE STEM

(Figure 50)

First slide the slap hammer over the shaft of the brown handled extractor. If additional length is required, an additional segment in the extraction tray may be screwed on to the brown handle extractor. Screw the adaptor head onto the brown handle extractor shaft. Tighten the adaptor portion into the definitive stem with the blue screw driver and extract using the slap hammer..

If, after this step, removal of the stem is still difficult, the surgeon can make a vertical corticotomy and loosen the stem from the cut bone.

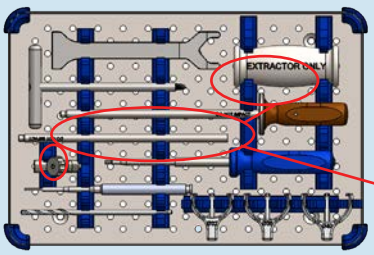
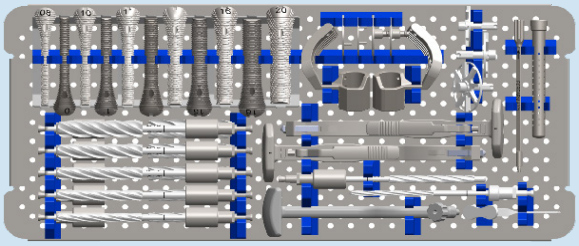
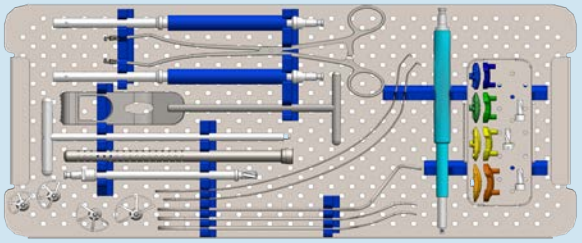
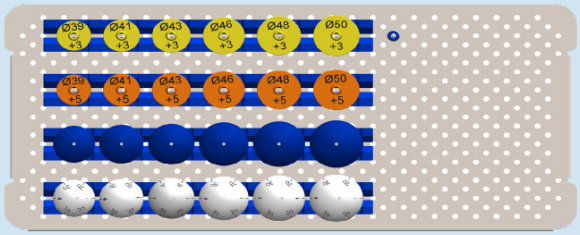
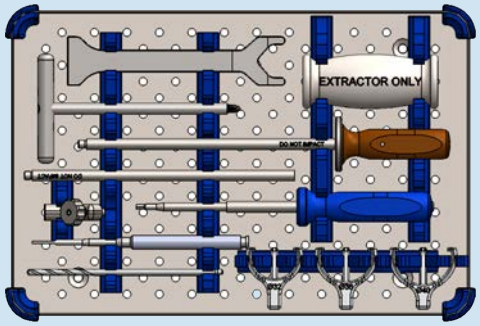
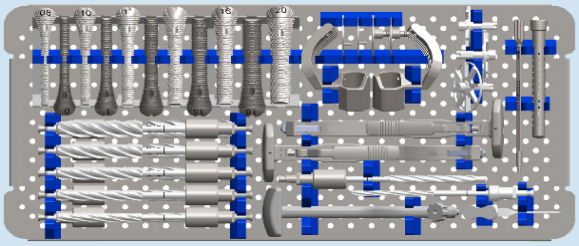
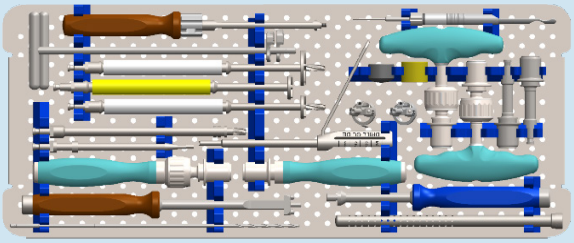
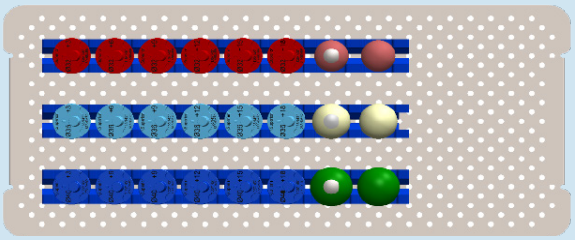
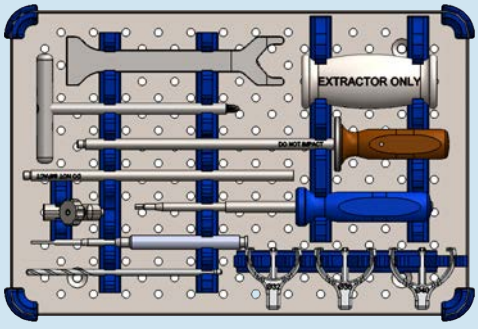


Figure 50

ANATOMICAL INSTRUMENTATION

REFERENCE NUMBER	DESCRIPTION	INSTRUMENTATION
606-0050	HUMERIS HUMERAL TRAY	
606-0051	HUMERIS GLENOID TRAY	
606-0042	HUMERIS TRIAL TRAY	
606-0010	EXTRACTION TRAY	

REVERSIBLE INSTRUMENTATION

REFERENCE NUMBER	DESCRIPTION	INSTRUMENTATION
606-0050	HUMERIS HUMERAL TRAY	
606-0008	REVERSED GLENOID TRAY	
606-0044	HUMERIS TRIAL TRAY	
606-0010	EXTRACTION TRAY	

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