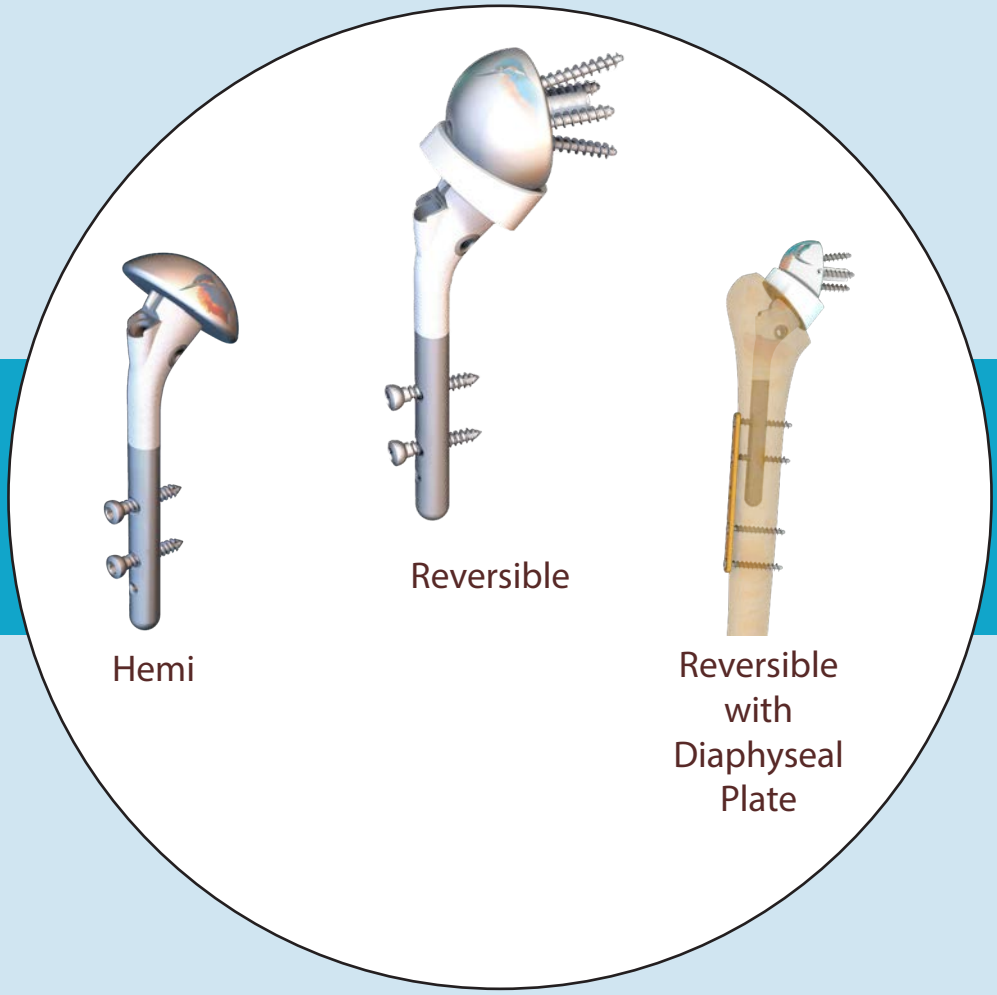
HUMELOCK II®

Cementless

SURGICAL TECHNIQUES
Hemi and 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.

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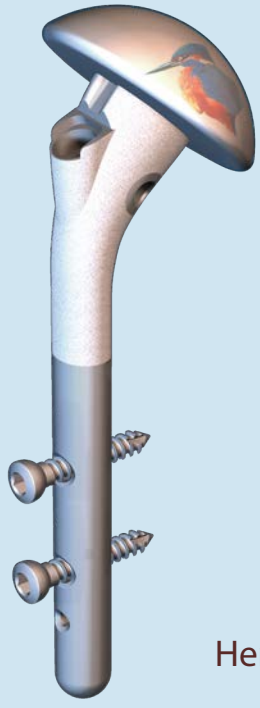
Russell Huffman, M.D. | University of Pennsylvania, Philadelphia, PA, USA
Stanley Kupiszewski, M.D. | Orlando, FL, USA
Todd Moen, M.D. | WB Carrell Clinic, Dallas, TX, USA
Frederick Song, M.D. | Princeton, NJ, USA
Umasuthan Srikumaran, M.D. | Columbia, MD, USA

TABLE OF CONTENTS

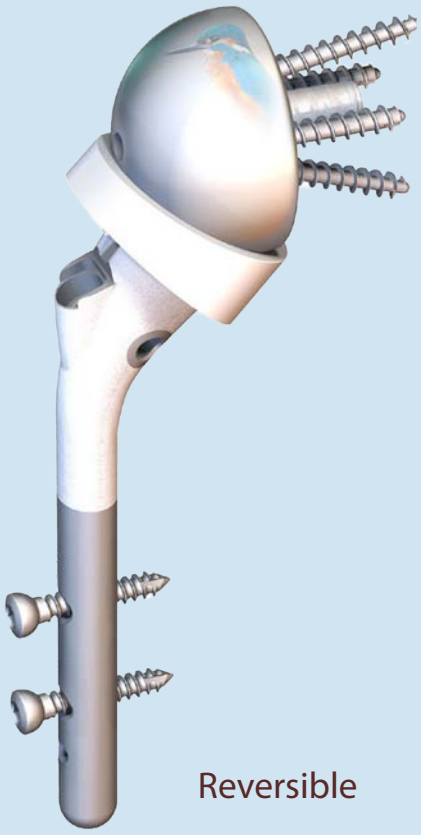
DEVICE DESCRIPTION

The Humelock II® Cementless Humeral Stem is manufactured from Ti-6AI-4V alloy conforming to ISO 5832-3 and is available in diameters of 8-14mm (2mm increments). The distal end of the humeral stem is cylindrical with a grit blasted surface and two unthreaded screw holes in the anterior / posterior direction for fixation using bone screws. The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP Ti) and Hydroxyapatite (HA) coating.

The Humelock® glenoid baseplate is available in two options: a 24mm round baseplate with a central cannulated post or a 24mm round baseplate with a central screw (with seven 4.5mm central screw lengths from 8-20mm in 2mm increments) and four peripheral polyaxially (12°) oriented 4.5mm screw holes for each type of baseplate. The outer edges of the baseplate are tapered to lock with the glenosphere component. 4.5mm non-locking and locking screws in lengths from 15-50mm (5mm increments) are used to secure the baseplate. The screw holes have 12° of polyaxial orientation with the superior hole pre-oriented to 10° allowing for up to 22° of angulation to reach the coracoid process. There are optional post extensions available to extend the central post of the baseplate from 17mm to provide additional anchoring in cases with poor bone quality. The post extensions are available in +6mm and +10mm lengths. When used, the post extensions screw into the baseplate post.

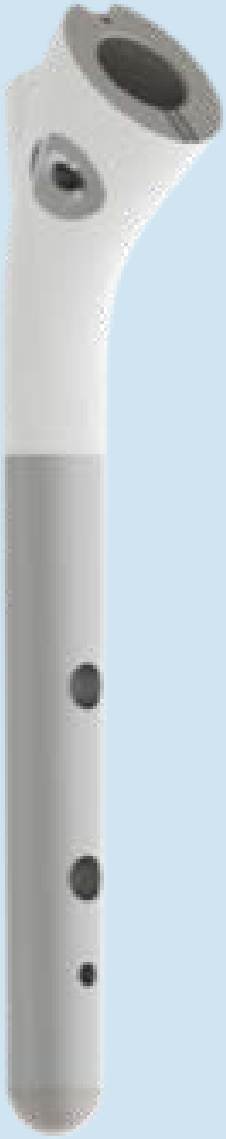


Hemi



Reversible

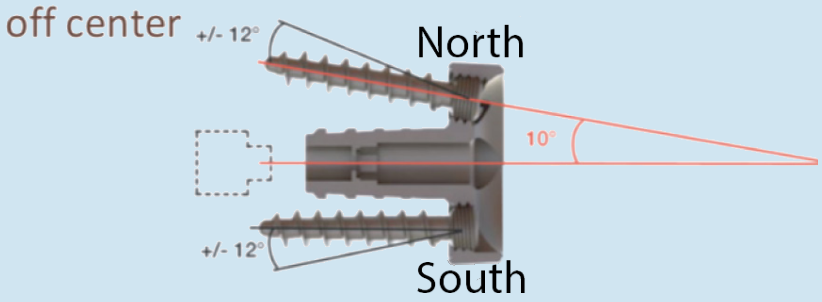
DEVICE DESCRIPTION



HUMERAL STEMS

"Onlay" design at 135°. The Humelock II Cementless Humeral Stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and is available in diameters of 8-14mm. The distal end of the humeral stem is cylindrical with a grit blasted surface and two unthreaded screw holes in the anterior / posterior direction for fixation using bone screws. The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP Ti) and Hydroxyapatite (HA) coating.

HUMELOCK II HUMERAL STEMS		
120MM CEMENTLESS	120 MM CEMENTED	200MM (LONG) CEMENTED
8MM	6MM	8MM
10MM	8MM	10MM
12MM	10MM	12MM
14MM	12MM	



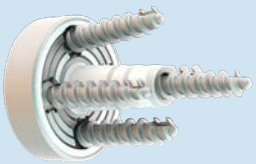
BASEPLATE (24mm)

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

The glenoid baseplate with a central screw has a 17mm post that tapers from 7.5mm proximally to 6.5mm distally with 7 different central screws sizes from 8mm-20mm in 2mm increments.

Baseplate with Central Post

Baseplate with Central Screw



DEVICE DESCRIPTION

GLENOSPHERES

The Humelock II® 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 of 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

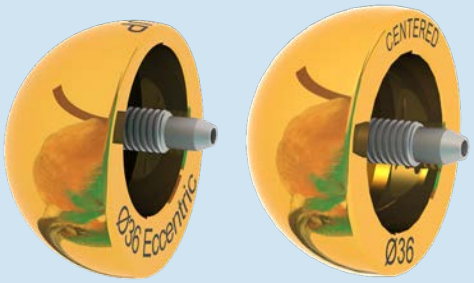
Centered or Eccentric
Size 32 = 1mm of Eccentricty
Size 36 = 3mm of Eccentricty
Size 40 = 1mm of Eccentricty
Lateralization = 3.5mm

TIN (TITANIUM NITRIDE) COATED GLENOSPHERES*

NEXT GENERATION COATING TECHNOLOGY

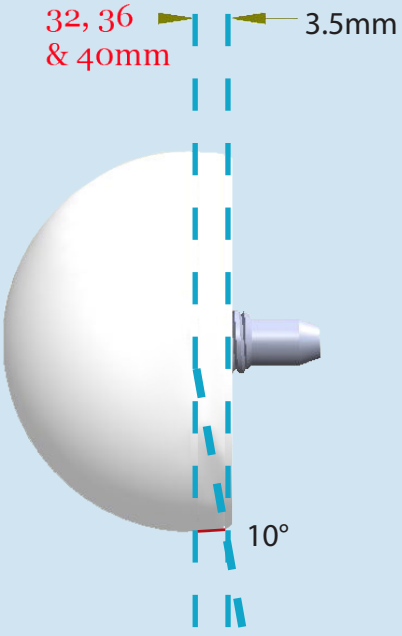
FIRST & ONLY TiN HUMERAL HEADS AND GLENOSPHERS IN THE U.S. MARKET AS AN ALTERNATE BEARING FOR TOTAL SHOULDER ARTHROPLASTY

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

CAUTION



*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

HUMERAL CUP THICKNESS

The 135°/145° 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.

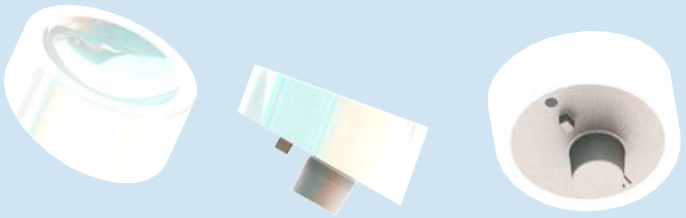


Figure A

135°/145° HUMERAL CUP

DIAMETERS

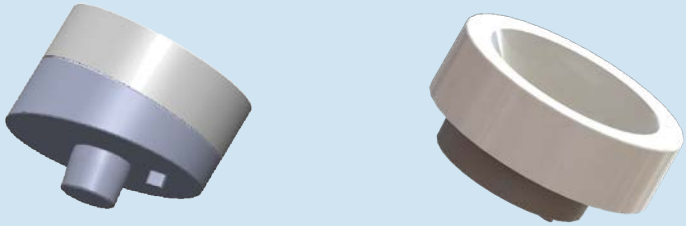
32mm, 36mm, 40mm

THICKNESS

+3mm, +6mm, +9mm

OPTIONAL REVERSE ADAPTER

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



+9MM REVERSE ADAPTER

Figure B

STANDARD REVERSE HUMERAL CUP

STABILITY CUP-OPTION

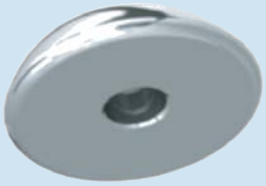
In extreme cases of instability, the stability variant of the humeral cups can provide added constraint by capturing more of the glenosphere with a deeper dish of the humeral cup without adding to the joint space. The stability variant may also potentially reduce the range of motion that can be achieved.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

STABILITY HUMERAL CUP

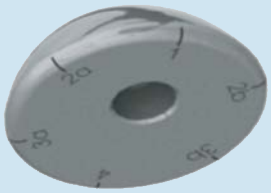
Figure C

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

DEVICE DESCRIPTION



CoCr CONCENTRIC HEADS



CoCr ECCENTRIC HEADS

HUMERAL HEADS

0°, double taper cone, connects the stem and the humeral head to match 135° inclination.

CONCENTRIC HEADS

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

DOUBLE TAPER

ECCENTRIC HEADS

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

TIN COATED HUMERAL HEADS**

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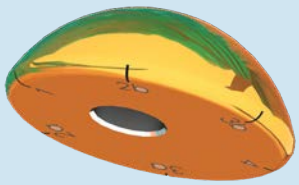
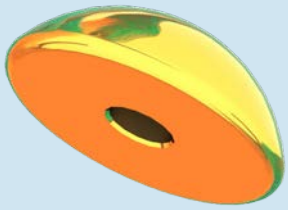


TiN* COATED CONCENTRIC HEADS



TiN* COATED ECCENTRIC HEADS

CAUTION

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***DATA ON FILE AT FX SHOULDER USA, INC. & FX SOLUTIONS S.A.S

Indications

In an anatomical shoulder configuration, the Humelock II® Cementless Shoulder System is indicated for use in a hemi-shoulder arthroplasty for fractures of the proximal humerus.

In a reversible shoulder confirguration, the HumelockII® Cementless is indicated for fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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 components are intended for cementless use. The baseplate component is intended for cementless use with the addition of screws for fixation.

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 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.

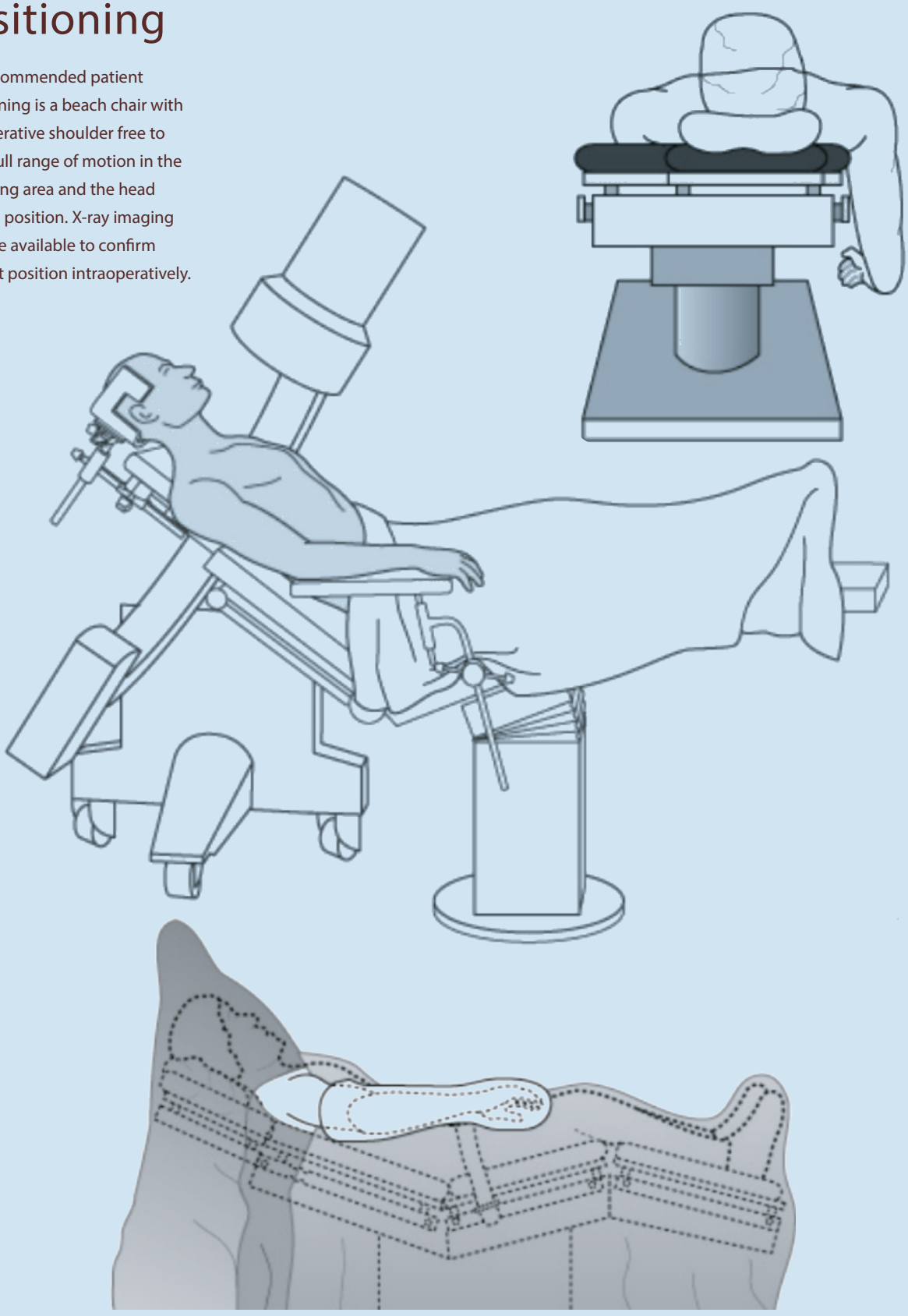
Please note that two cortical screws are intended for use with the Humelock II® Cementless Humeral Stem

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 intraoperatively.



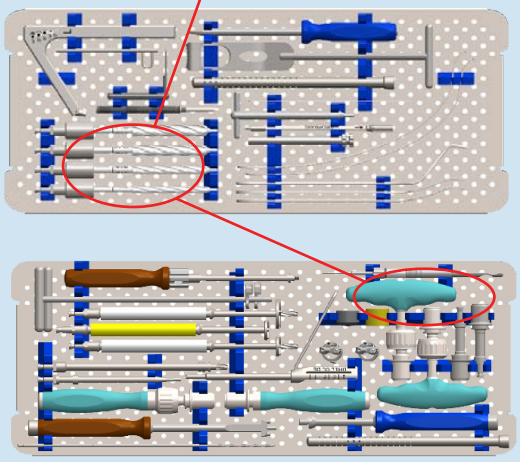
HUMERAL PREPARATION

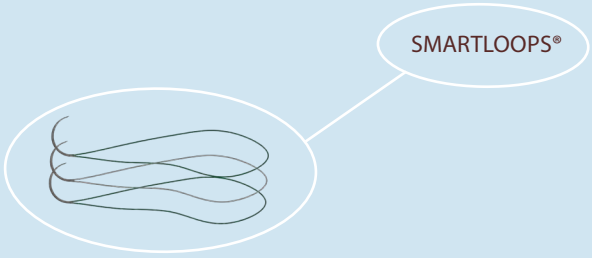
STEP 1: PREPARATION OF THE HUMERAL SHAFT (Figure 1)

Prepare the humeral shaft using the reamers from the smallest (8mm to the biggest size (14mm) to until the reamer diameter fits to the humeral intramedullary canal (8 , 10, 12, or 14mm for cementless stems). The reamer must be introduced into the canal until it stops.
(Size of the Reamer = Size of the Stem)

POSITIONING THE SMARTLOOPS®: (OPTION) (RECOMMENDATION)

Make two holes in the diaphysis before inserting the stem into the humeral shaft using the same 3.2mm drill that is provided for the interlocking screws. Introduce the loop from the outside to the inside, then through the second hole from the inside to the outside. Introduce Smartloops® into both tuberosties as well.





HUMERAL PREPARATION

STEP 2: FITTING THE STEM (Figure 2)

1. Set-up the aiming guide onto the implant without tightening the screw.
2. Place the stability jig (A) into the distal locking hole of the guide of the stem. Do not lean on the stability jig in order to avoid stress on the stem.
3. Tighten the screw to secure the implant (B) to the aiming guide.
4. Remove the stability jig.
5. Verify the proper alignment of the locking holes with the aiming guide and k-wire or drill..

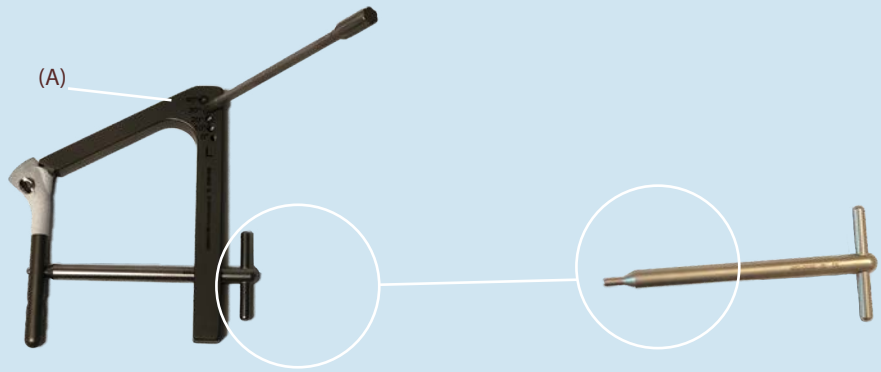
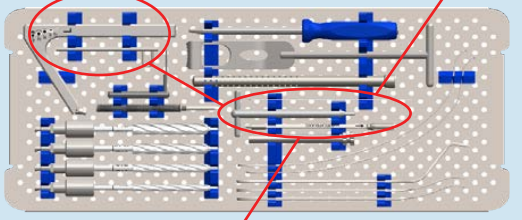
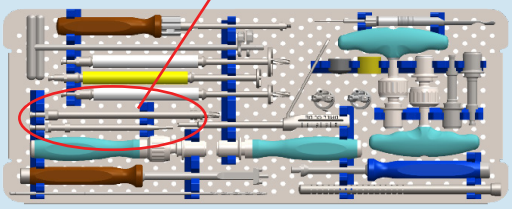


Figure 2





HUMELOCK II® CEMENTLESS STEM SIZES

8mm, 10mm, 12mm, 14mm

Refer to Humeral Stem description on Page 4

The size of the stem is determined by the size of the last reamer.

Note: If a trial stem (C) is preferred to ensure the definitive stem size will be accurate, follow the same steps as above to fasten the blue stem trial to the aiming guide and proceed as follows in the remaining steps. A 2.0mm K-Wire cannot be used to set provisional height and version with the blue stem trial.

HUMERAL PREPARATION

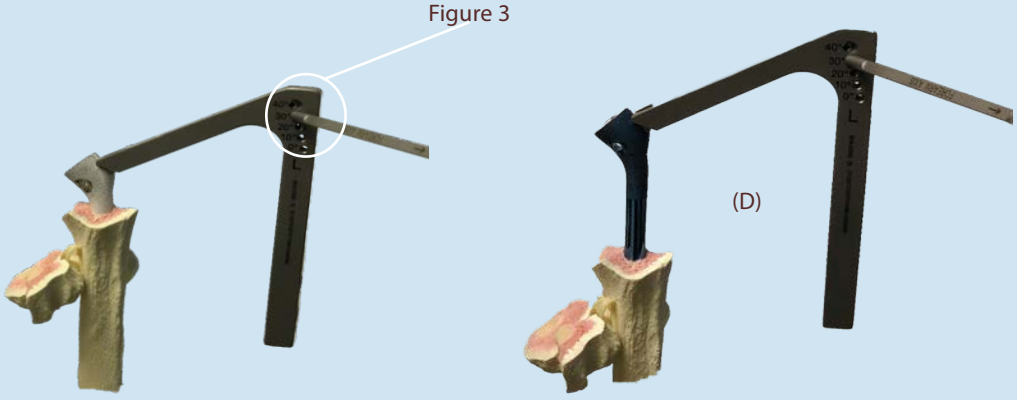
STEP 3: HUMERAL STEM IMPACTION

(Figure 3)

Insert the forearm axis by screwing it into the preferred version (0°, 10°, 20°, 30° or 40°) on the aiming guide to match the side of the patients procedure (Left or Right).

A trial reduction can be performed directly off the definitive stem. If you wish to use a trial stem (D) you may do so and attach it as described in Step 2.

Figure 3



STEP 4: SETTING HEIGHT AND VERSION (Figure 4)

Screw the version rod (Forearm Axis) into one of the (5) positions according to the patients version: 0°, 10°, 20°, 30°, or 40°.

a) DELTO-PECTORAL APPROACH:

Use Murachovsky's* criteria. Position the trocar level with the point from the top of the head to the insertion of the pectoralis major. (Figure 5) The face of the top plate indicates the position for the top of the humeral head.

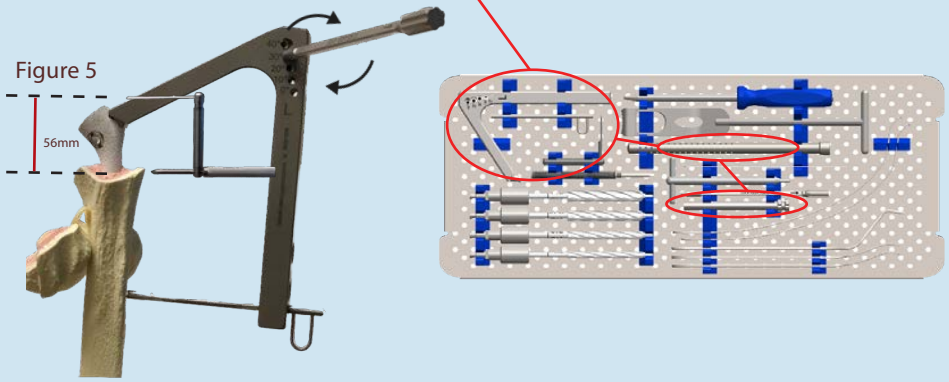
b) SUPERO-LATERAL APPOACH:

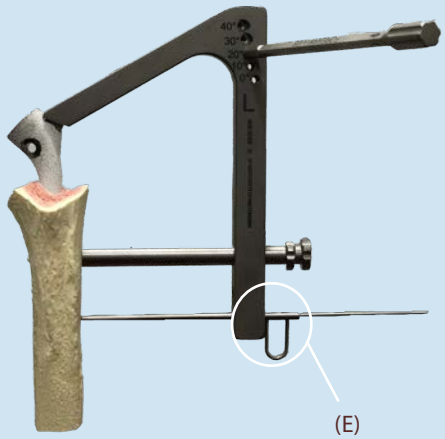
This criteria applies when there is continuity between the diaphysis and the greater tuberosity. Position the trocar at the top of the greater tuberosity. The face of the top plate indicates the position for the top of the humeral head. This position is best assessed by perioperative x-ray. The best criteria is the anatomical reduction of the tuberosities (if the fracture is not too comminuted).

*Murachovsky J et al. JSES 06; Torrens et al. JSES 06; Hasan SA et al. Orthopedics 09

Figure 4

Figure 5





STEP 5: STABILIZING HEIGHT AND VERSION

Insert the 2.0mm k-wire through the 2.2mm guide to make contact with the second cortex. (E)

Visually check the height, version, and position of the stem by x-ray before locking the stem with two screws.

HUMERAL PREPARATION

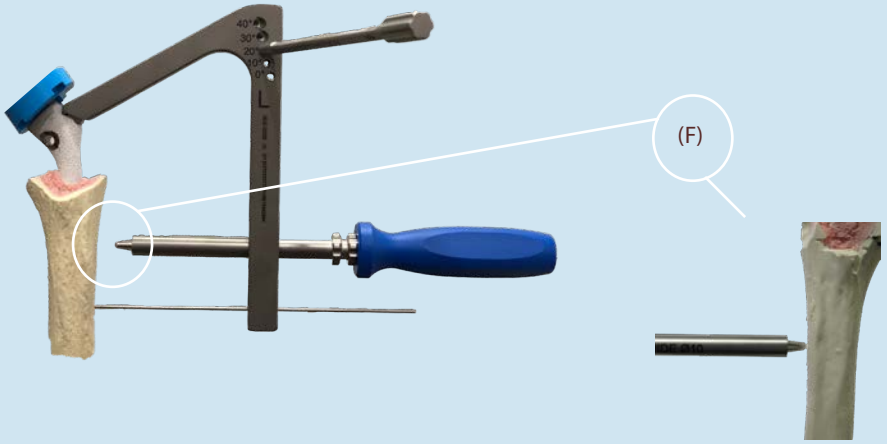
STEP 6: PROXIMAL AND DISTAL INTERLOCKING SCREWS

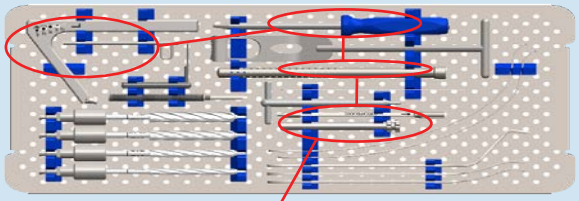
(Figure 6)

Insert the drill guide into the proximal hole of the Trauma Aiming Guide. Identify the incision point for the Drill Guide Sleeve with blunt dissection. Using forceps, expose the soft tissue to bone. After having carefully dissected the soft tissue, insert the 10mm guide into the proximal hole of the aimer until contact is made with the cortex using the soft-tissue holder.

(F) Insert the 4.5mm guide into the 10mm guide.

Leave the distal K-Wire in place.





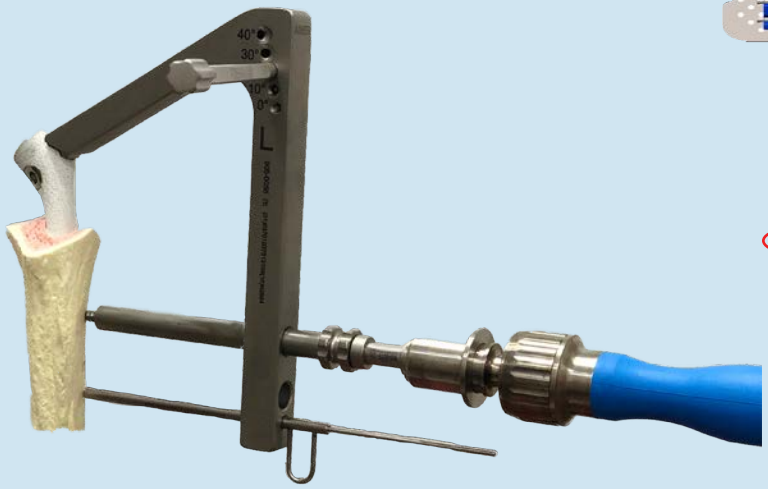
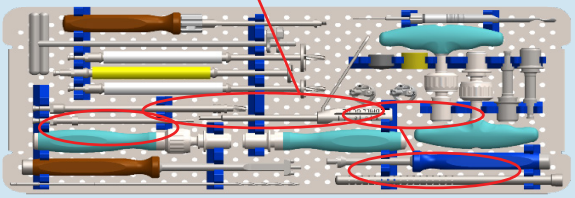
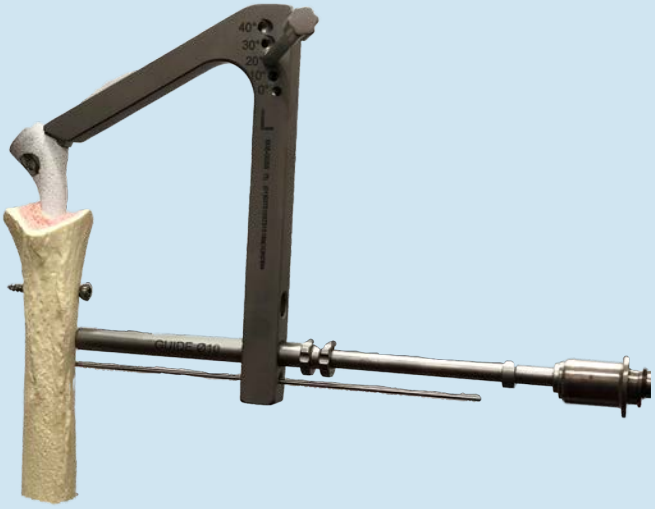


Figure 6





HUMERAL PREPARATION

STEP 7: CORTICAL SCREW LENGTHS

(Figure 7)

The calibrated 3.2mm x 270mm Drill Bit is drilled through the first cortex, stop at the second cortex and measure. Read the length directly on the Drill Guide/Depth gauge ruler. Add +4mm to the measurement (Figure 8)

(Example: If the 3.2mm drill bit laser-etched mark indicates 20mm at the opposite cortex, the definitive screw is 24mm).

If the preference is to drill through both cortices an alternative AO type depth gauge is available.

Drill through the second cortex. Place the definitive screw on the screwdriver (blue handle) and through the guide to screw through and fixate the humerus and stem.

The optional depth gauge is available to measure screw length if desired. Drill up to the second cortex and use screw size based on the length measured + 2mm.

FOR REVERSIBLE GO TO STEP 11 ON PAGE 17.

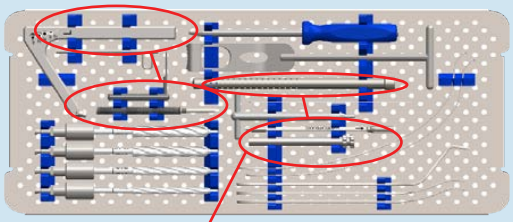
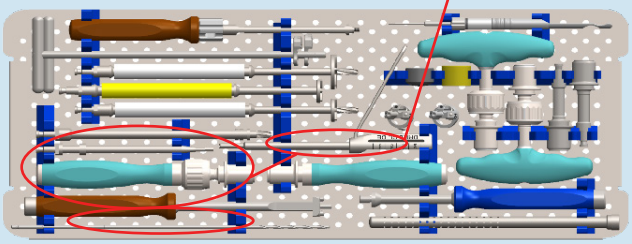


Figure 7

Figure 8



CAUTION

For Trauma Indications, use both interlocking screws to ensure stability of the prosthesis

STEP 8: IMPACTION OF THE DEFINITIVE DOUBLE TAPER

(Figure 9)

Insert the double cone taper into the female taper of the stem so that the index of the taper adapter and the stem are correctly aligned. Check to ensure that nothing is impeding the taper adapter and impact it. Impact INTO THE STEM (not the head) using the impactor

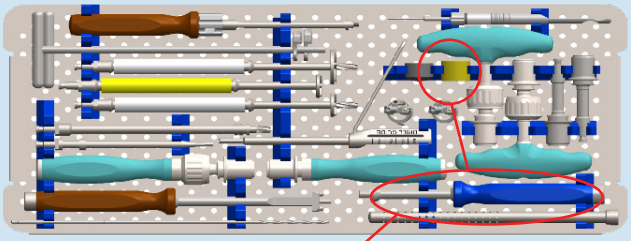


Figure 9

STEP 9: OFFSET HEAD TRIAL SELECTION (6 CENTERED / 8 OFFSET)

(Figure 10)

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

If an offset head is used, mark its position.

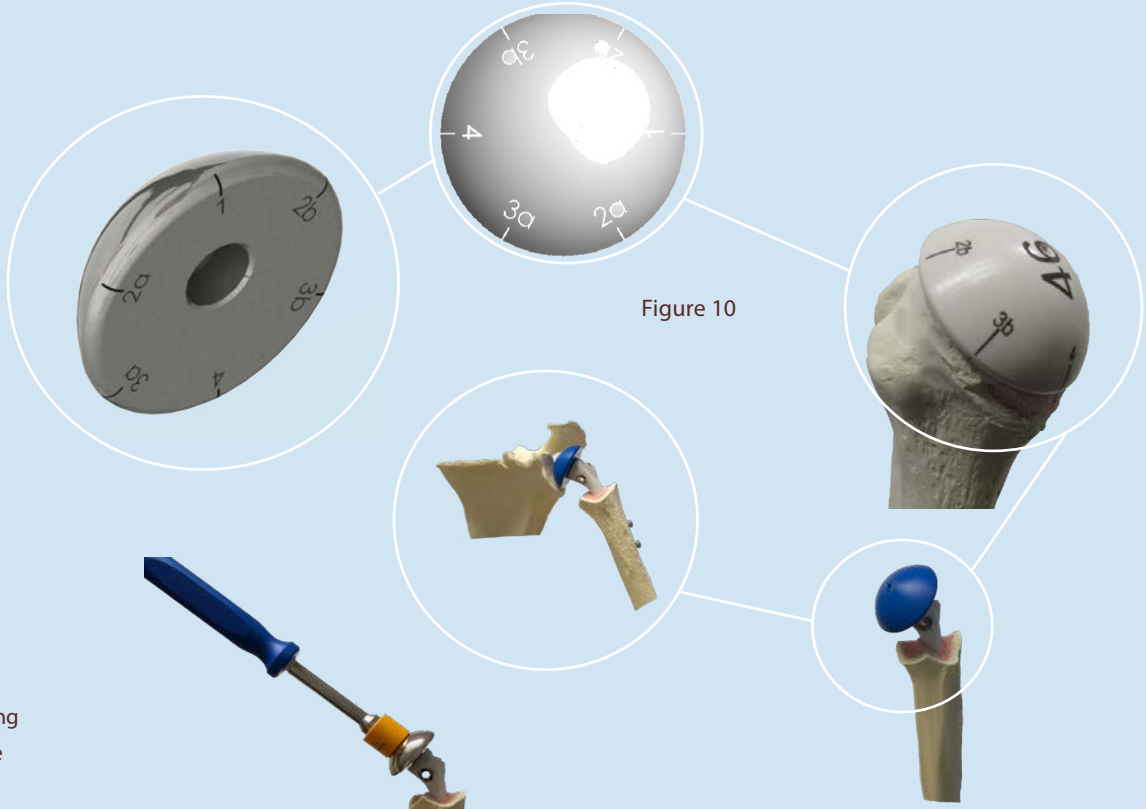


Figure 10

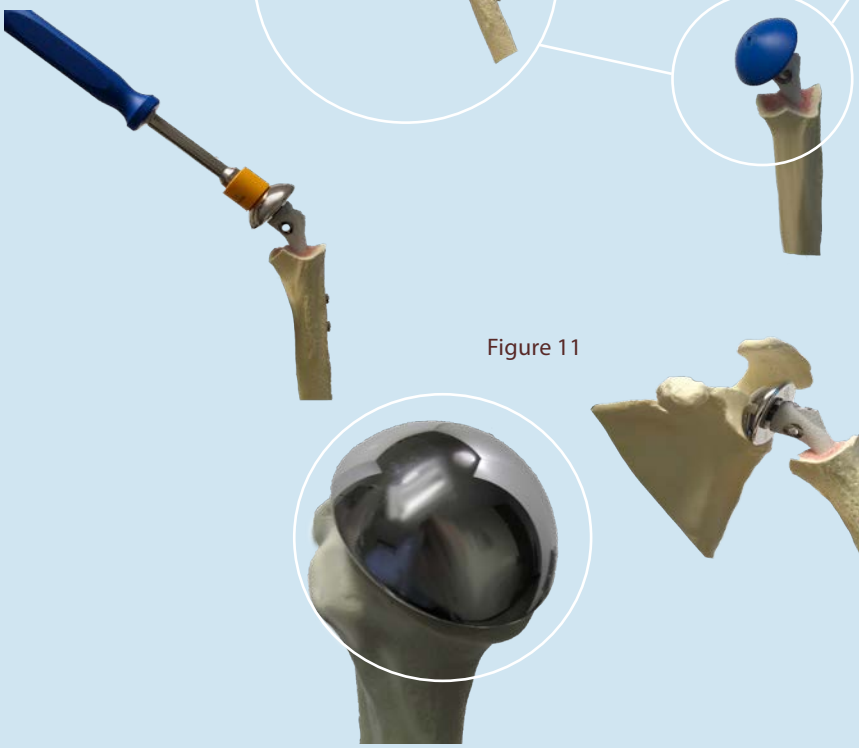


Figure 11

STEP 10: IMPACTION OF THE DEFINITIVE HEAD

(Figure 11)

Take appropriate implant and insert it on the taper in the same position as the trial. Impact the head using the impactor.

HEMI-PROSTHESIS CONVERSION

HUMERAL HEAD REMOVAL

(Figure 12)

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

FOR REVISION TO A REVERSIBLE PROSTHESIS GO TO STEP 11 ON PAGE 17.

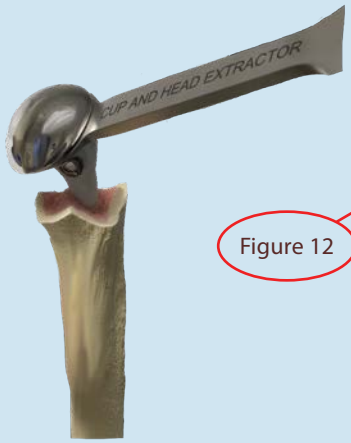
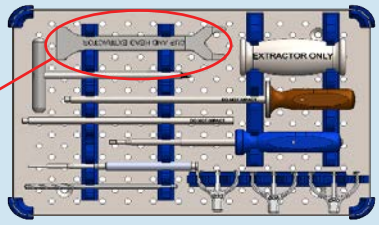


Figure 12



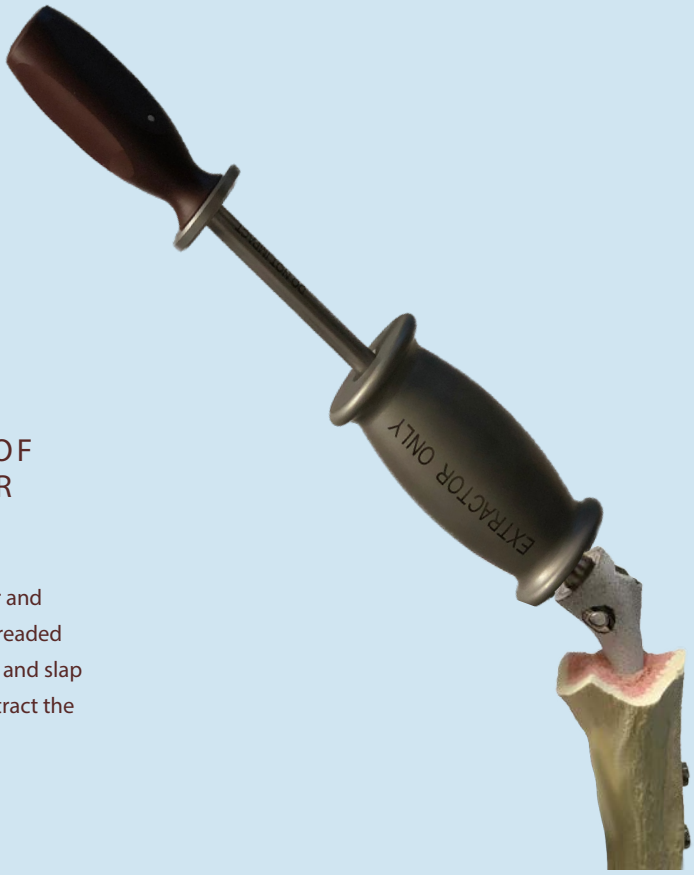
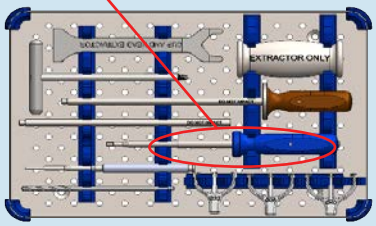


Figure 13



EXTRACTION OF DOUBLE TAPER

(Figure 13)

Insert the stem extractor and slap hammer into the threaded hole of the double taper and slap toward the handle to extract the double taper..

GLENOID PREPARATION

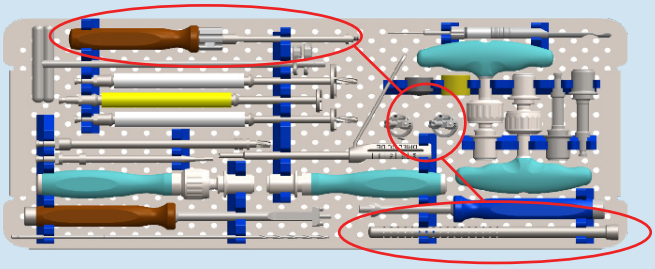
STEP 11: PLACING THE 2.0mm K-WIRE**

(Figure 14)

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 14



GLENOID PREPARATION

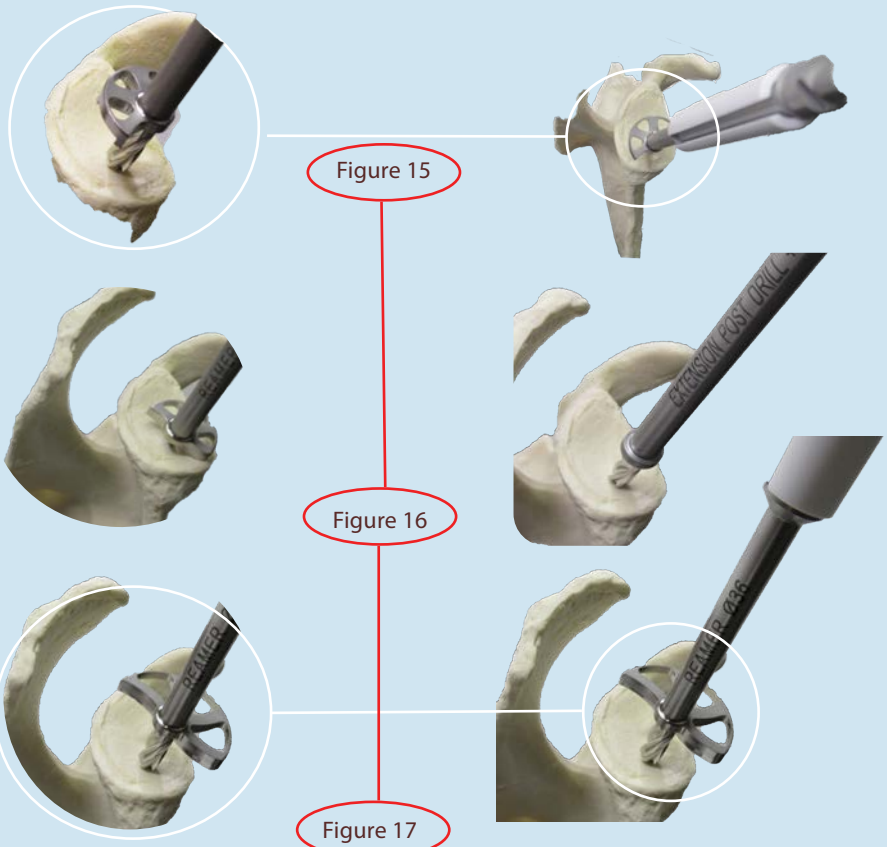
STEP 12: GLENOID REAMING

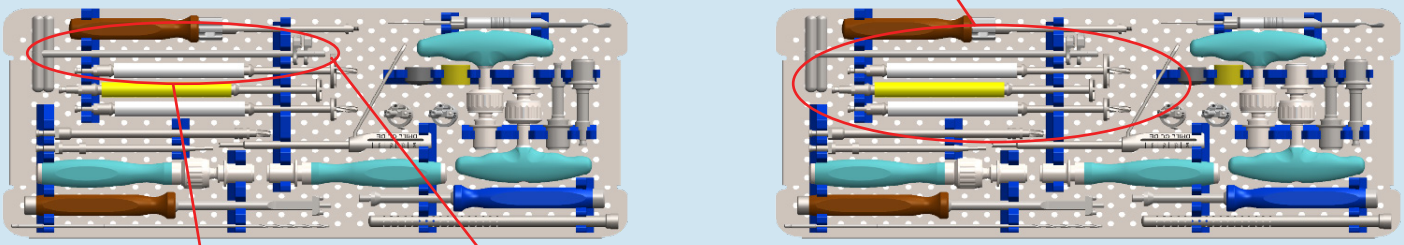
This step can be performed with three different options: Ream to bleeding subchondral bone for all options. (RECOMMENDATION ONLY)

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 15)

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 16)

OPT 3: GLENOID RESURFACING REAMER Ø36MM WITH DRILL
Place over the 2.0mm K-wire. Drill and ream. (Figure 17)





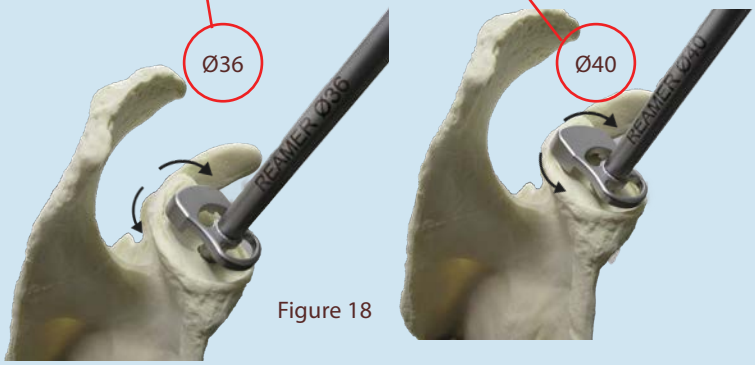


Figure 18

STEP 13: 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 18)

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

GLENOID PREPARATION

STEP 14: OPTION 1
BASEPLATE WITH A POST (Figure 19)

For the Glenoid Baseplate with a Central Screw Proceed to Step 18 on page 21. 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)

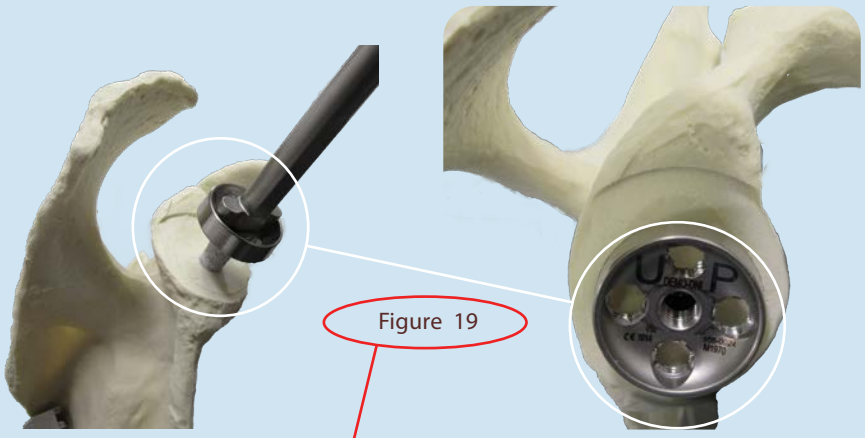


Figure 19

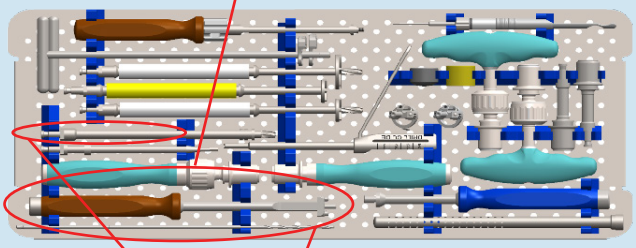


Figure 20

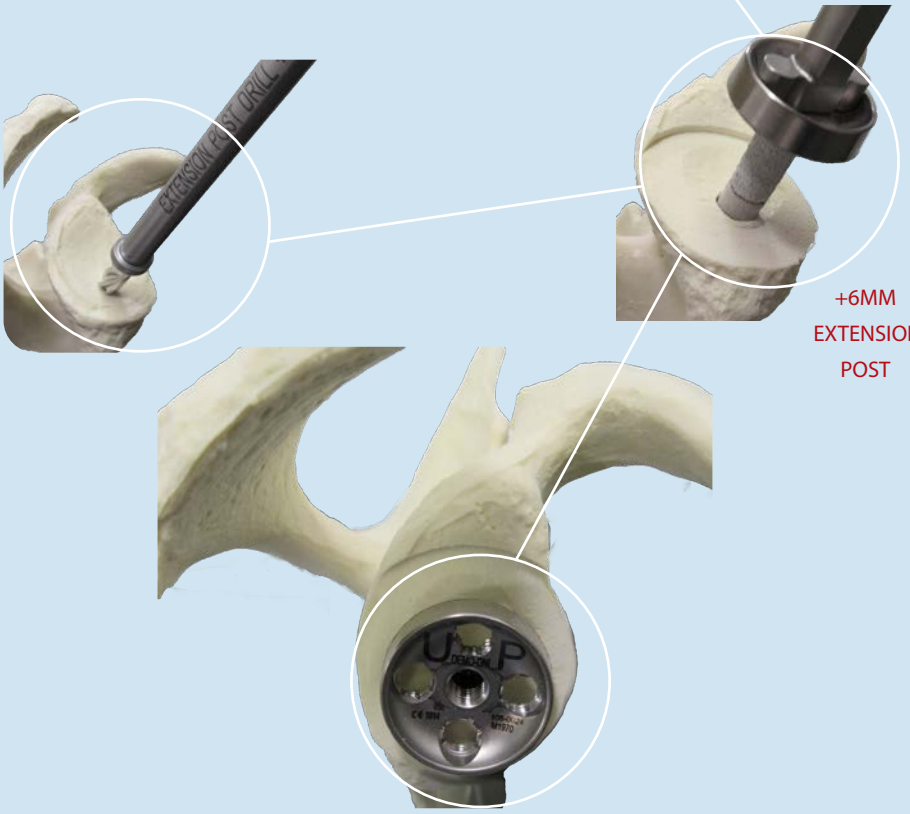
BASEPLATE WITH EXTENSION POST

STEP 15: EXTENSION POST (OPTIONAL)

(Figure 20)

In cases of poor bone quality, a medializied 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 16: LENGTH OF SCREWS

(Figure 21)

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

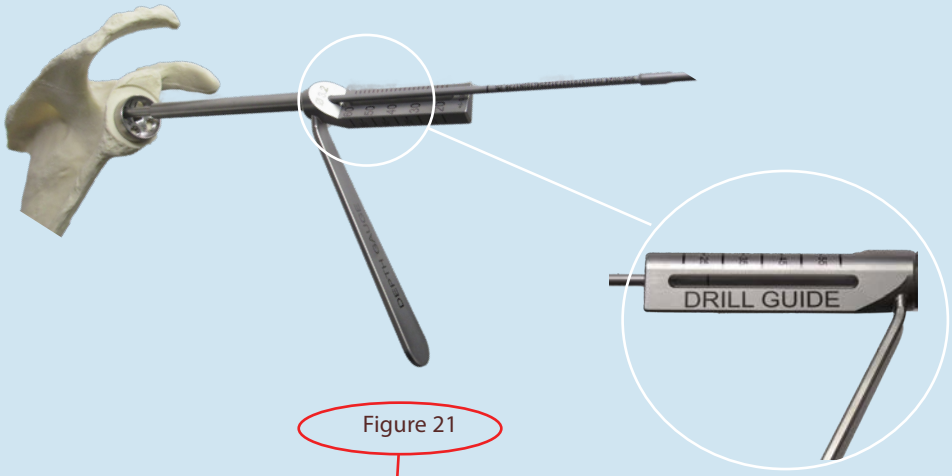
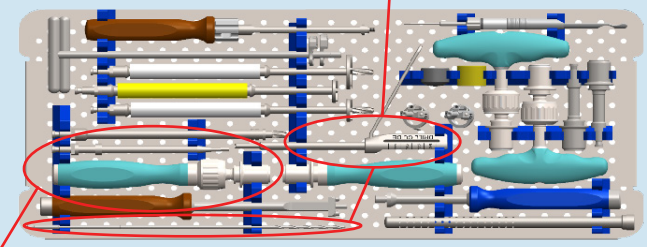


Figure 21



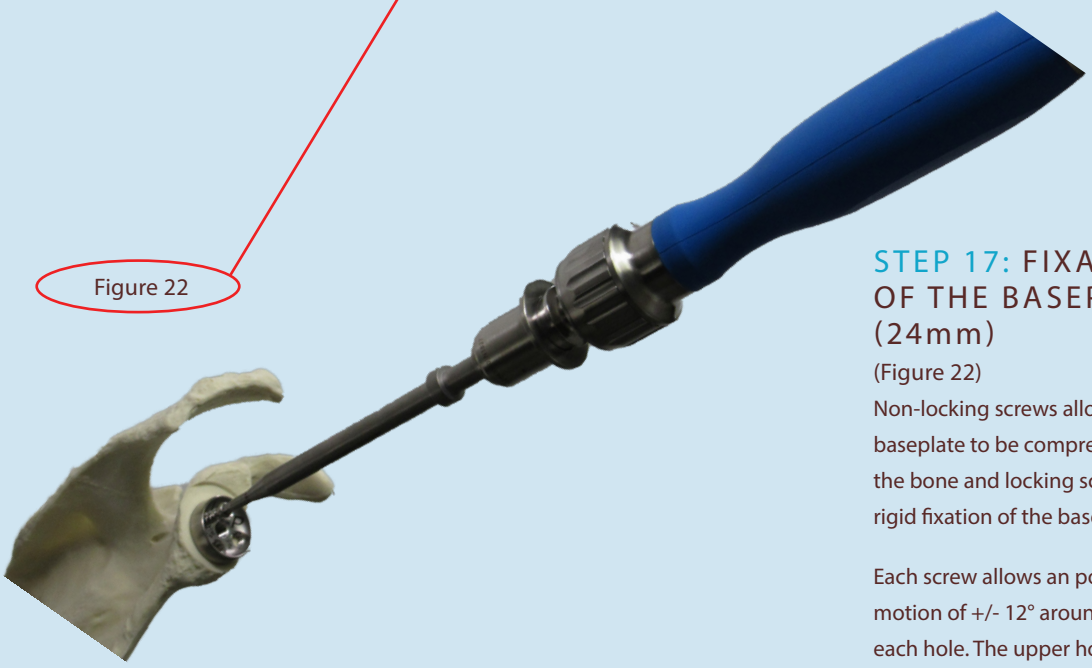


Figure 22

STEP 17: FIXATION OF THE BASEPLATE (24mm)

(Figure 22)

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.

GLENOID PREPARATION

STEP 18: OPTION 2 BASEPLATE WITH CENTRAL SCREW

(Figure 23)

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 24) after drilling to measure or ensure an accurate screw length is measured.

Figure 23

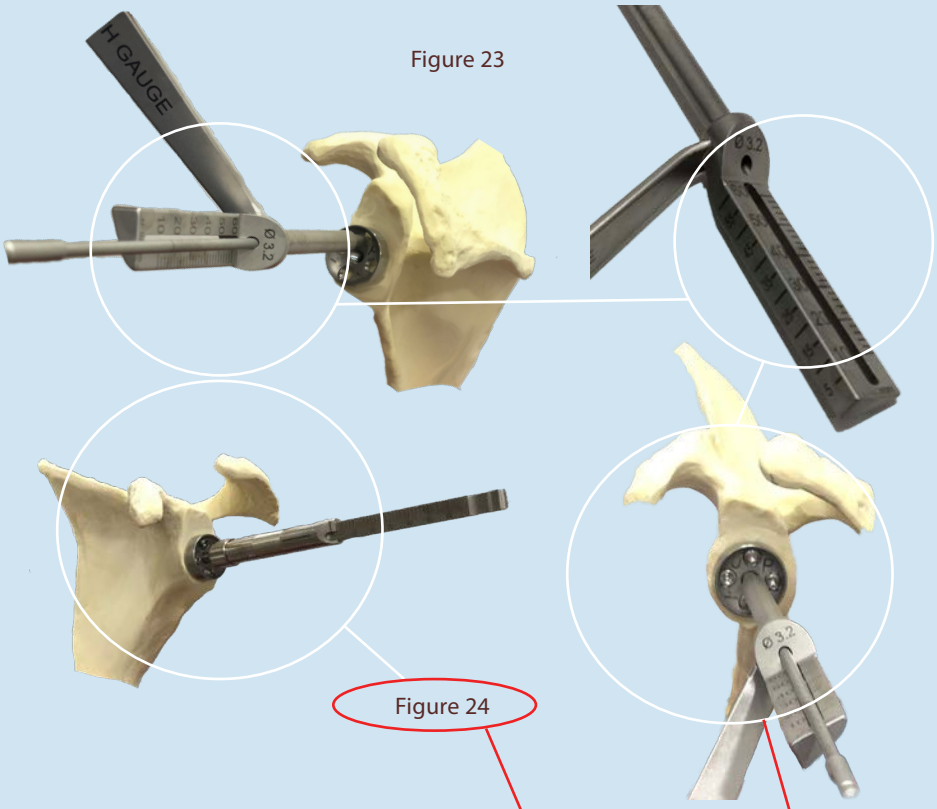
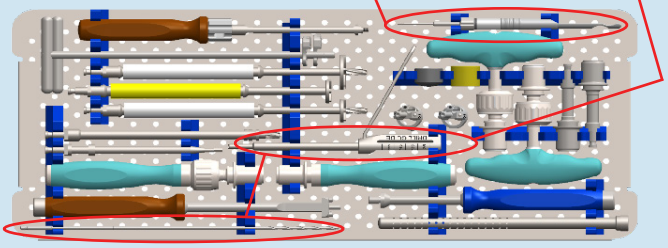


Figure 24



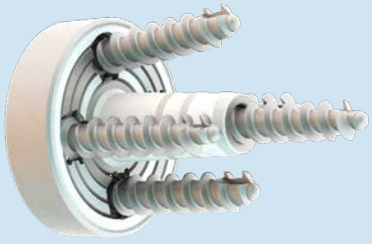
STEP 18 (A): LENGTH OF SCREWS

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.



BASEPLATE WITH CENTRAL SCREW

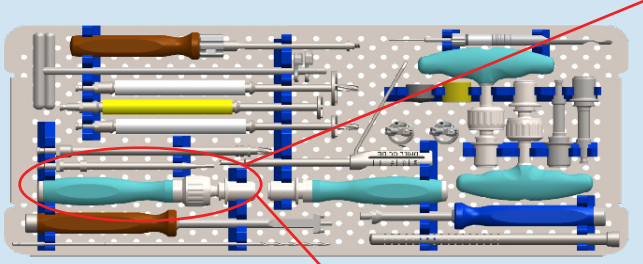
STEP 18 (B): FIXATION OF THE BASEPLATE (24mm)

(Figure 25)

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 26) 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.



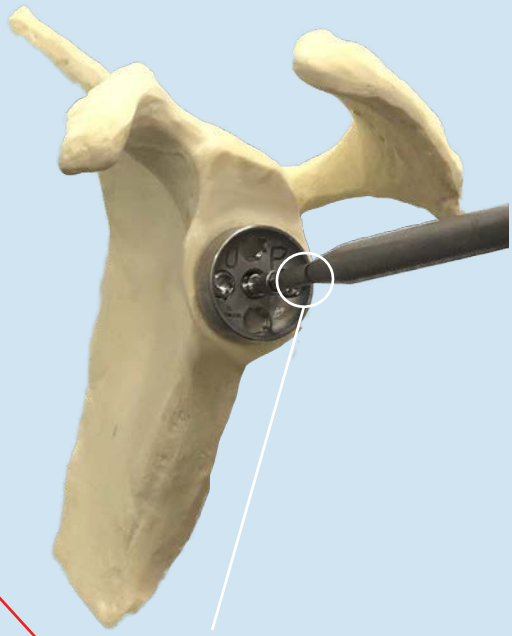


Figure 25

Figure 26

GLENOSPHERE - TRIAL AND DEFINITIVE

Figure 27

GLENOSPHERE TRIALS Ø32/36/40MM

STEP 19: TRIAL IMPLANTS - GLENOSPHERE

(Figure 27)

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 20: DEFINITIVE GLENOSPHERE

(Figure 28)

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

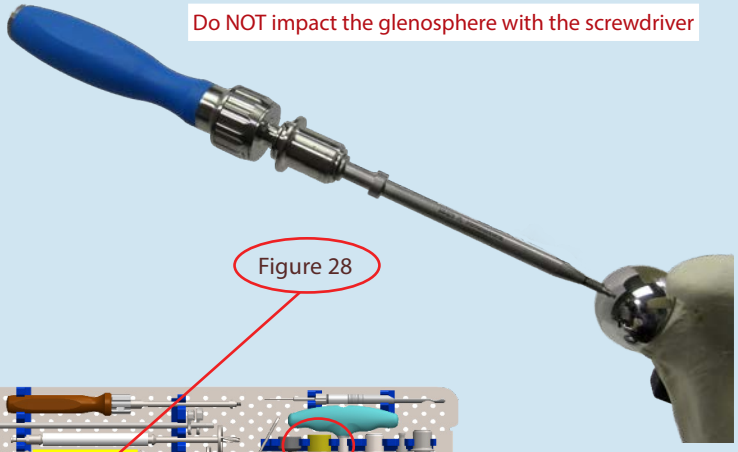
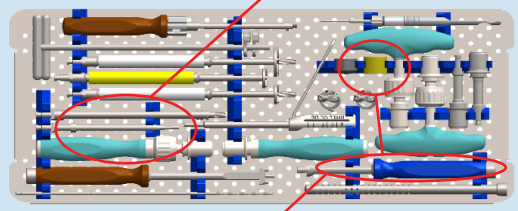
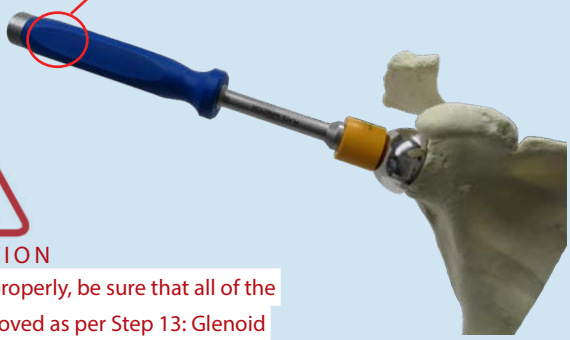


Figure 28





CAUTION

To ensure the morse taper engages properly, be sure that all of the bone and soft tissue have been removed as per Step 13: Glenoid Clearance on page 18

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.

HUMERAL PREPARATION

STEP 24: SETTING HEIGHT AND VERSION (Figure 29)

Screw the forearm axis into one of the (5) positions according to the required angle: 0°, 10°, 20°, 30°, or 40° according to the patient's version.

a) DELTO-PECTORAL APPROACH:

Use Murachovsky's* criteria. Position the trocar level with the point from the top of the head to the insertion of the pectoralis major. (Figure 30) The face of the top plate indicates the position for the top of the humeral head.

b) SUPERO-LATERAL APPOACH:

This criteria applies when there is continuity between the diaphysis and the greater tuberosity. Position the trocar at the top of the greater tuberosity. The face of the top plate indicates the position for the top of the humeral head. This position is best assessed by perioperative x-ray. The best criteria is the anatomical reduction of the tuberosities (if the fracture is not too comminuted).

RECOMMENDATION:

Place the +3 humeral cup trial just below the center of the glenosphere (G) before placing the 2.0mm k-wire to set the height for a precise reduction of the tuberosities around the stem.

STEP 25: STABILIZING HEIGHT AND VERSION

Insert the 2.0mm k-wire through the 2.2mm guide to make contact with the second cortex. Visually check the height, version, and position of the stem by x-ray before locking the stem with two screws.

Figure 29

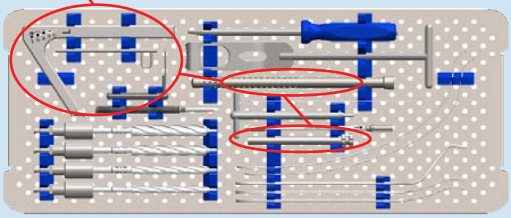
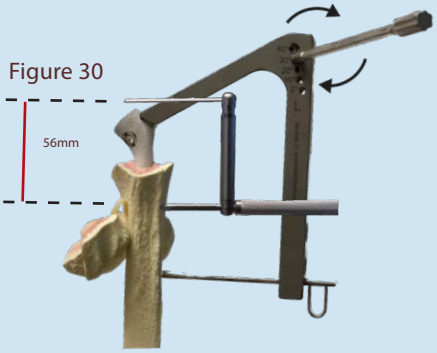
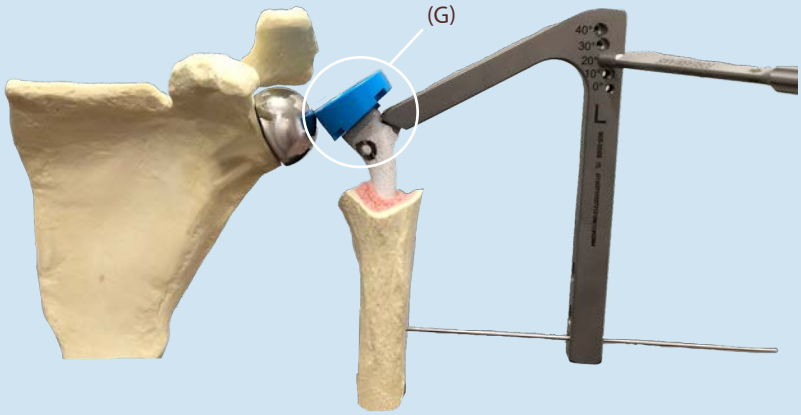
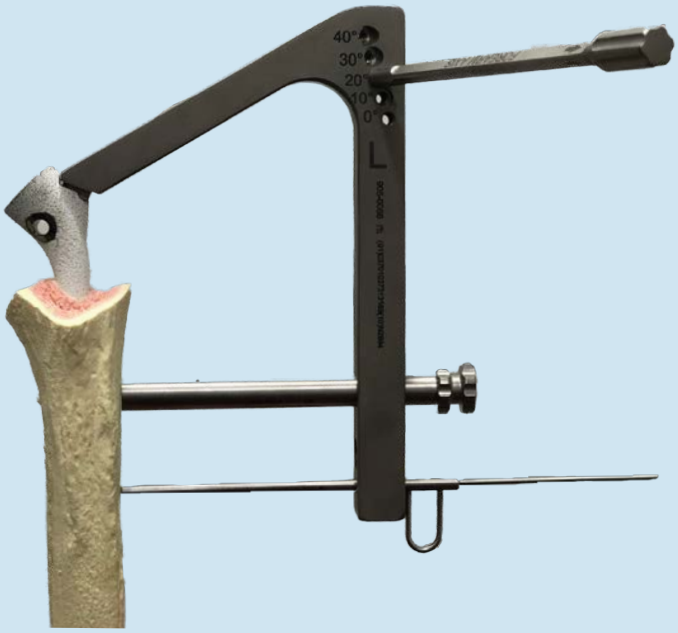


Figure 30







*Murachovsky J et al. JSES 06; Torrens et al. JSES 06; Hasan SA et al. Orthopedics 09

STEP 26: PROXIMAL AND DISTAL INTERLOCKING SCREWS

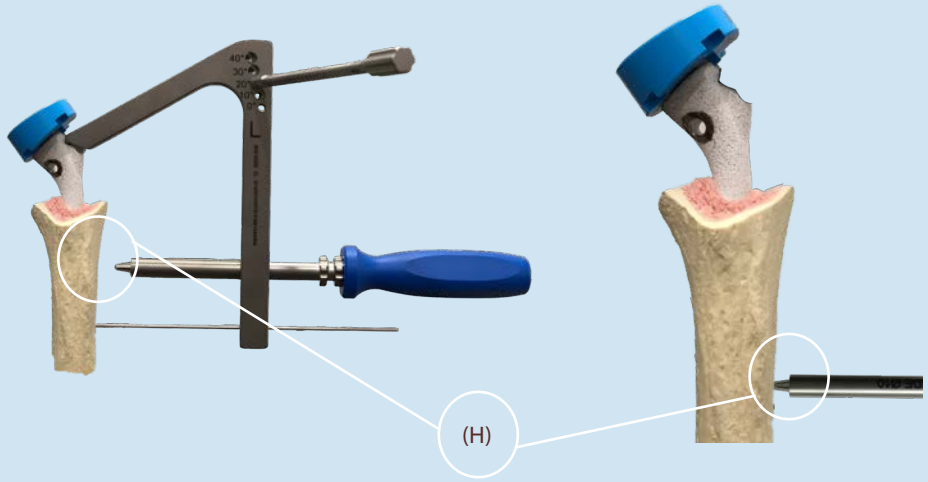
(Figure 31)

Insert the drill guide into the proximal hole of the Trauma Aiming Guide. Identify the incision point for the Drill Guide Sleeve, with blunt dissection using forceps expose the soft tissue to bone. After having carefully dissected the soft tissue, insert the 10mm guide into the proximal hole of the aimer until contact is made with the cortex using the soft-tissue holder.

(H) Insert the 4.5mm guide into the 10mm guide.

Recommendation:

Leave the k-wire in place for drilling the proximal screw to make sure the height and the version do not change



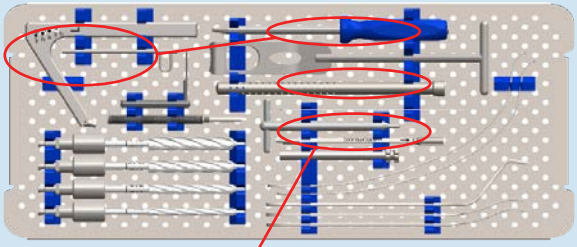


Figure 31

HUMERAL PREPARATION

STEP 28: CORTICAL SCREW LENGTHS

(Figure 32)

The calibrated 3.2mm x 270mm Drill Bit is drilled through the first cortex, stop at the second cortex and measure. Read the length directly on the Drill Guide/Depth gauge ruler. Add +4mm to the measurement (Figure 33)

(Example: If the 3.2mm drill bit laser-etched mark indicates 20mm at the opposite cortex, the definitive screw is 24mm).

If the preference is to drill through both cortices an alternative AO type depth gauge is available.

Drill through the second cortex. Place the definitive screw on the screwdriver (blue handle) and through the guide to screw through and fixate the humerus and stem.

The optional depth gauge is available to measure screw length if desired. Drill up to the second cortex and use screw size based on the length measured + 2mm.

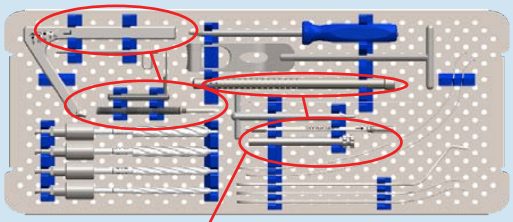


Figure 32

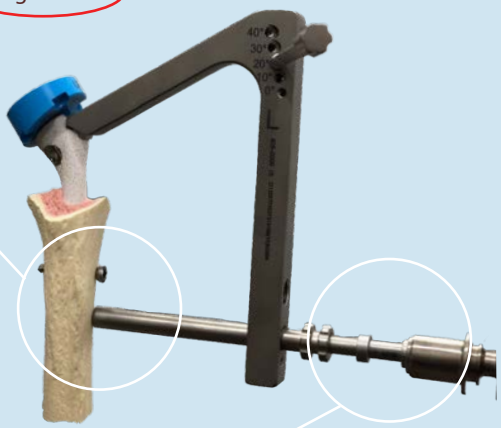
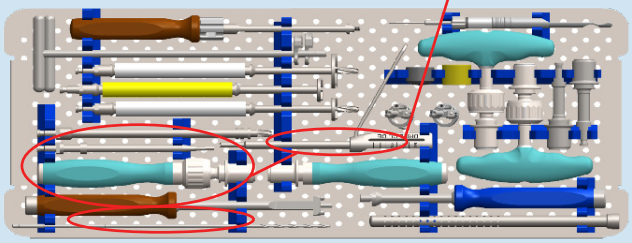
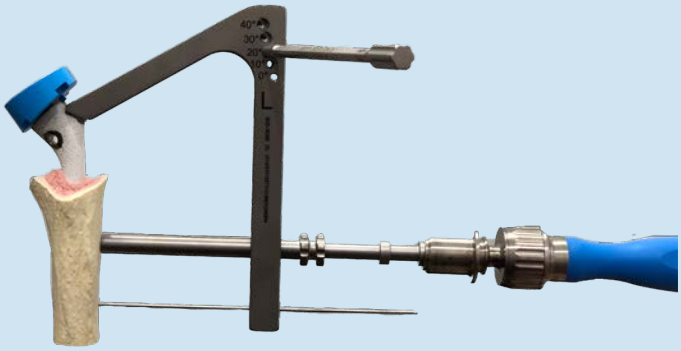


Figure 33





CAUTION

For Trauma Indications, use both interlocking screws to ensure stability of the prosthesis

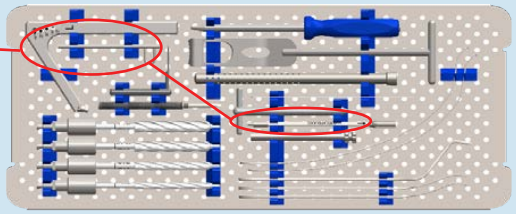
HUMERAL CUP - TRIAL AND DEFINITIVE

STEP 29: HUMERAL CUP CHOICE (Figure 34)

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 +18mm. You can trial directly off of the definitive stem.

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

Figure 34



RECOMMENDATION: Use the Aiming Guide to help you reduce and dislocate while trialing the humeral cup

STEP 30: TRIAL REDUCTION

Assess joint stability and range of motion. The eccentric glenosphere trials and implants offset the glenosphere center of rotation inferiorly of 3mm. Proceed to the definitive humeral cup if the selected humeral cup trial is properly selected for the patient.

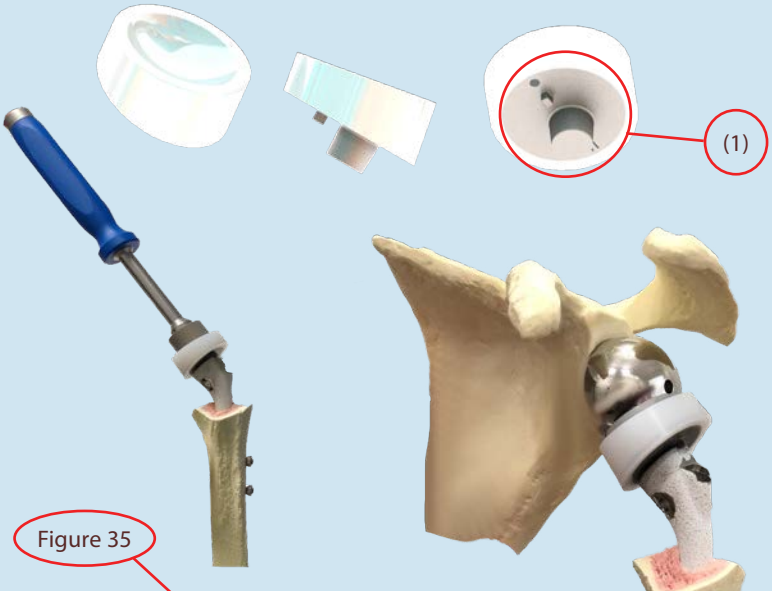
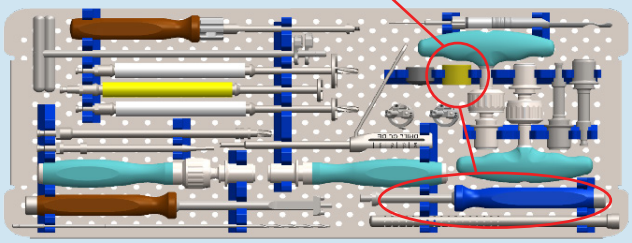


Figure 35



STEP 30: DEFINITIVE CUP

(Figure 35)

Find the index marks (1) 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.

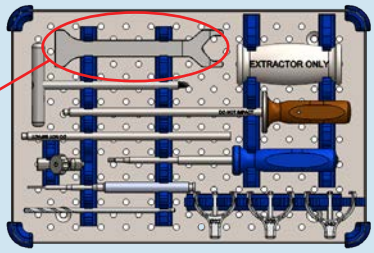
IMPLANT REMOVAL

HUMERAL CUP REMOVAL

(Figure 36)

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

Figure 36



GLENOSPHERE REMOVAL

(Figure 37)

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)

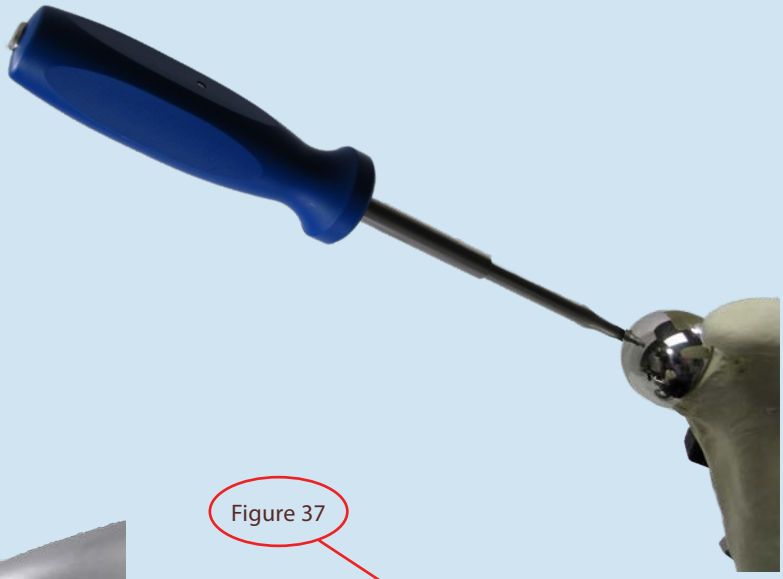
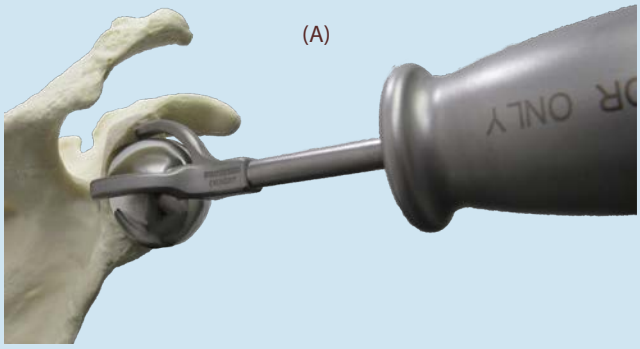
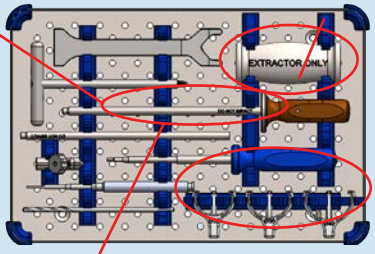


Figure 37

(A)





BASEPLATE REMOVAL

(Figure 38)

Unscrew the baseplate screws with the 3.5mm hexagonal screwdriver.

Screw the extractor and slap hammer into the baseplate post and remove it.

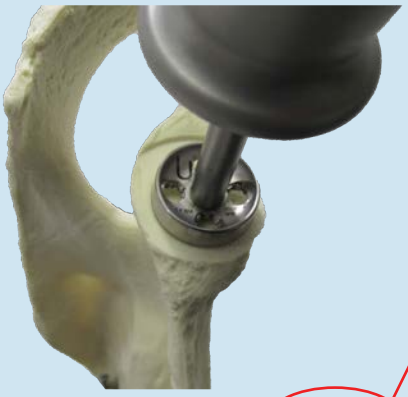


Figure 38

IMPLANT REMOVAL

EXTRACTION OF THE LOCKING SCREWS (OPTIONAL)

(Figure 39)

Insert the aiming guide first by screwing it in to the definitive humeral implant. After carefully dissecting the soft tissue, insert the 10mm guide into the proximal hole of the aiming jig until contact is made with the cortex using the soft tissue holder.

Insert the screwdriver into the guide and remove the cortical screw. Repeat for this procedure for the distal hole.

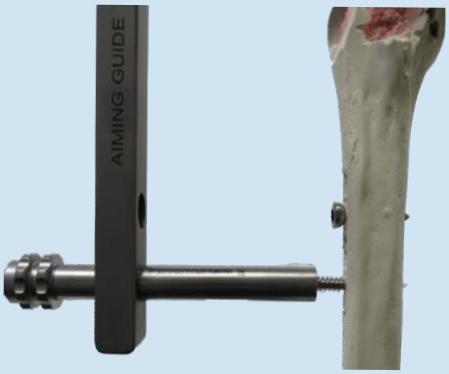
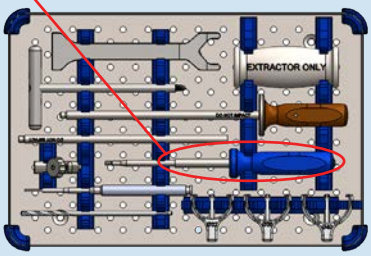


Figure 39



EXTRACTION OF THE STEM

(Figure 40)

Insert the stem extractor and slap hammer into the threaded hole of the proximal body. Use this to extract and pull out the stem.

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

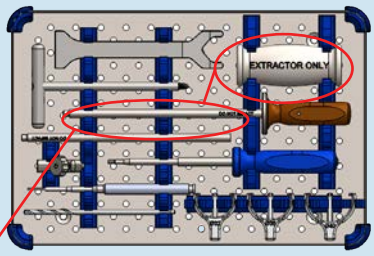
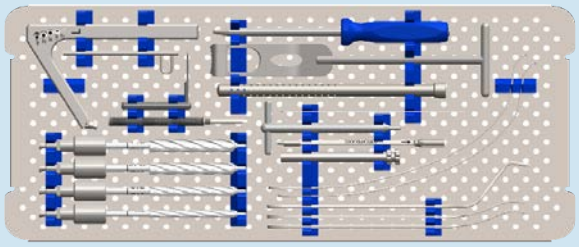
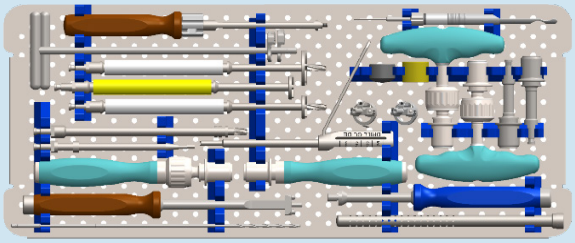
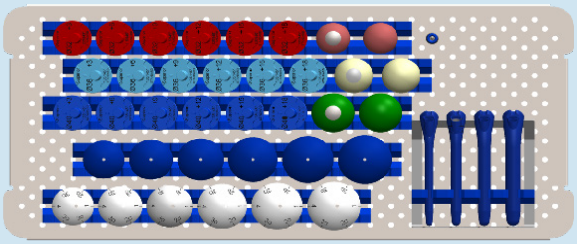
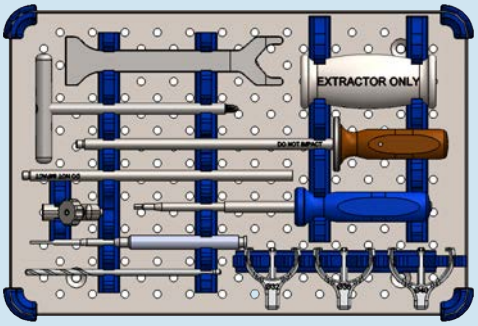


Figure 40

INSTRUMENTATION

REFERENCE NUMBER	DESCRIPTION	INSTRUMENTATION
606-0016	HUMELOCK II HUMERAL TRAY	
606-0008	HUMELOCK REVERSED GLENOID TRAY	
606-0032	HUMELOCK II TRIAL TRAY	
606-0010	EXTRACTION TRAY	

NOTES

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