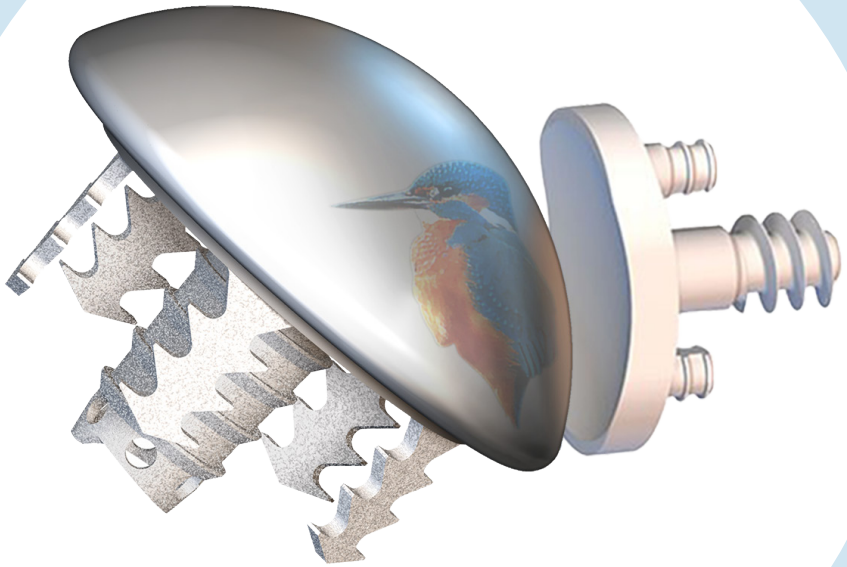
EASYTECH®

Stemless Primary Anatomical

SURGICAL TECHNIQUE

THE FIRST-AND-ONLY PRIMARY STEMLESS
WITH PERIPHERAL FIXATION



Stemless
Primary Anatomical

Shoulder Solutions

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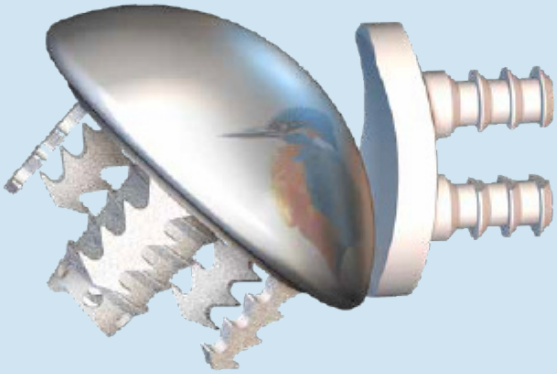
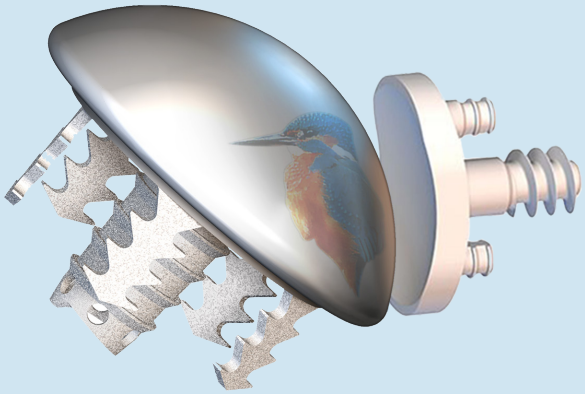
DEVICE DESCRIPTION

The EASYTECH® ANATOMICAL Shoulder Prosthesis consists of an anchor base, double taper connector or spacer (optional), humeral head, and glenoid component. Only the devices described in the surgical techniques are permitted for combined use in the U.S. market. Any combination of prosthetic components and/or instruments, other than those delivered by the manufacturer and/or distributor, is strictly prohibited.

The device can only be implanted after the surgeon has familiarized himself with the surgical technique. The surgery should be planned on the basis of a detailed evaluation of the patient's x-rays, since these provide important information on the choice of device (adaptation of dimensions to the individual case). Preoperative tracings and the surgical technique are available from the distributor or manufacturer.



EASYTECH® ANATOMICAL WITH 2 PEGS CEMENTED GLENOID

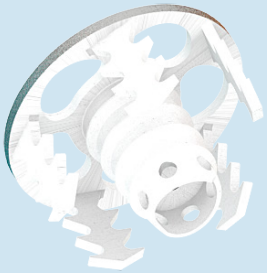


EASYTECH® ANATOMICAL WITH 3-4 PEGS CEMENTED GLENOID

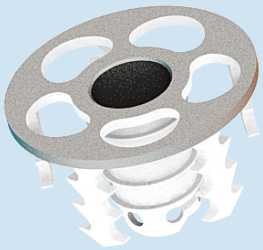
DEVICE DESCRIPTION

ANCHOR BASE

Unique-to-Market peripheral fixation anchor base with bone sparing plasma-sprayed hydroxyapatite coating (HA) on Ti6Al4V ELI (conforming to ISO 5832-3).

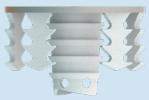


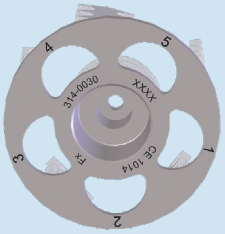
EASYTECH ANCHOR BASE



ANCHOR BASE SIZES

30mm
34mm
38mm
42mm

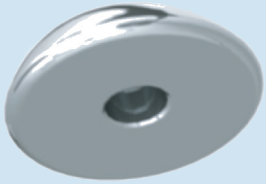




HUMERAL HEADS, TAPERS, AND SPACERS

The humeral heads are available in diameters of 39-50mm in centered and offset styles in CoCr and TiN* in 42 possible humeral head size and height options.

The straight double taper connector and centered spacers allow the offset of the humeral head to be increased from +0 to +3 or +5 mm. The straight double taper connector and centered spacers are compatible with all sizes of anchor bases and humeral heads as listed in this technique.

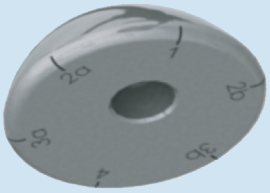


CoCr
CONCENTRIC HEADS

CONCENTRIC HEADS

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

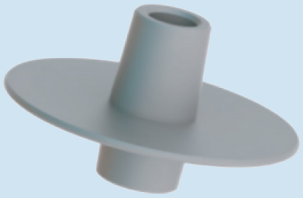
DOUBLE TAPER



CoCr
ECCENTRIC HEADS

ECCENTRIC HEADS

39x15
41x16
43x17
46x18
48x19
50x20



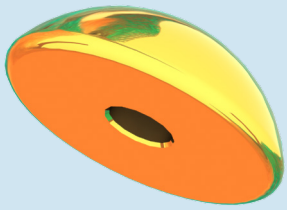
+3/+5MM
SPACER TAPER

TIN (TITANIUM NITRIDE) COATED HUMERAL HEADS**

NEXT GENERATION COATING TECHNOLOGY

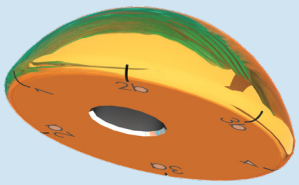
FIRST & ONLY TiN COATED HUMERAL HEADS AND GLENOSPHERES IN THE U.S. MARKET AS AN ALTERNATE BEARING FOR TOTAL SHOULDER ARTHROPLASTY

- **HARD, THIN SMOOTH COATING**
- **APPROXIMATELY 2300Hv**
- **WORST CASE LOAD & ENVIRONMENT**
- **EXCELLENT WEAR RESISTANCE*****
- **SINGLE LAYER**
- **BIOCOMPATIBLE TiN COATING OVER CoCr*****
- **SURFACE ROUGHNESS**
- **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

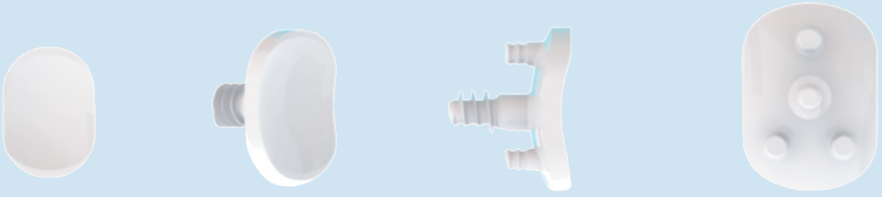
DEVICE DESCRIPTION

2 PEGS GLENOID

The 2 pegs cemented glenoid component is available in sizes XS, S, M, and L. 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 PEGS GLENOID

The 3-4 pegs cemented glenoid component is available in sizes XS, S, M, and L. Sizes XS and S have three fixation pegs. Sizes M and L 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.



Indications

The EASYTECH® ANATOMICAL Shoulder System is indicated for use in total shoulder replacement to treat a severely painful and/or disabled joint resulting from osteoarthritis.

The humeral stemless component of the EASYTECH® ANATOMICAL Shoulder is intended for cementless use only.

The glenoid components of the EASYTECH® ANATOMICAL Shoulder System are intended for cemented use only.

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

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

- All proximal humerus 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 device.
- Excessive alcohol consumption or other dependency disorders.
- Allergy to the material.
- Any concomitant illness that could compromise the function of the device
- Any fracture and any revision surgery

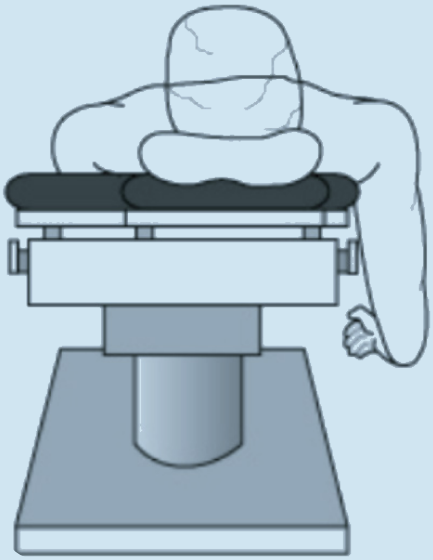
The EASYTECH® ANATOMICAL Shoulder System is contraindicated for use in revision and to treat other difficult clinical problems such as a revision of a previously implanted primary component, a humeral plate or a humeral nail.

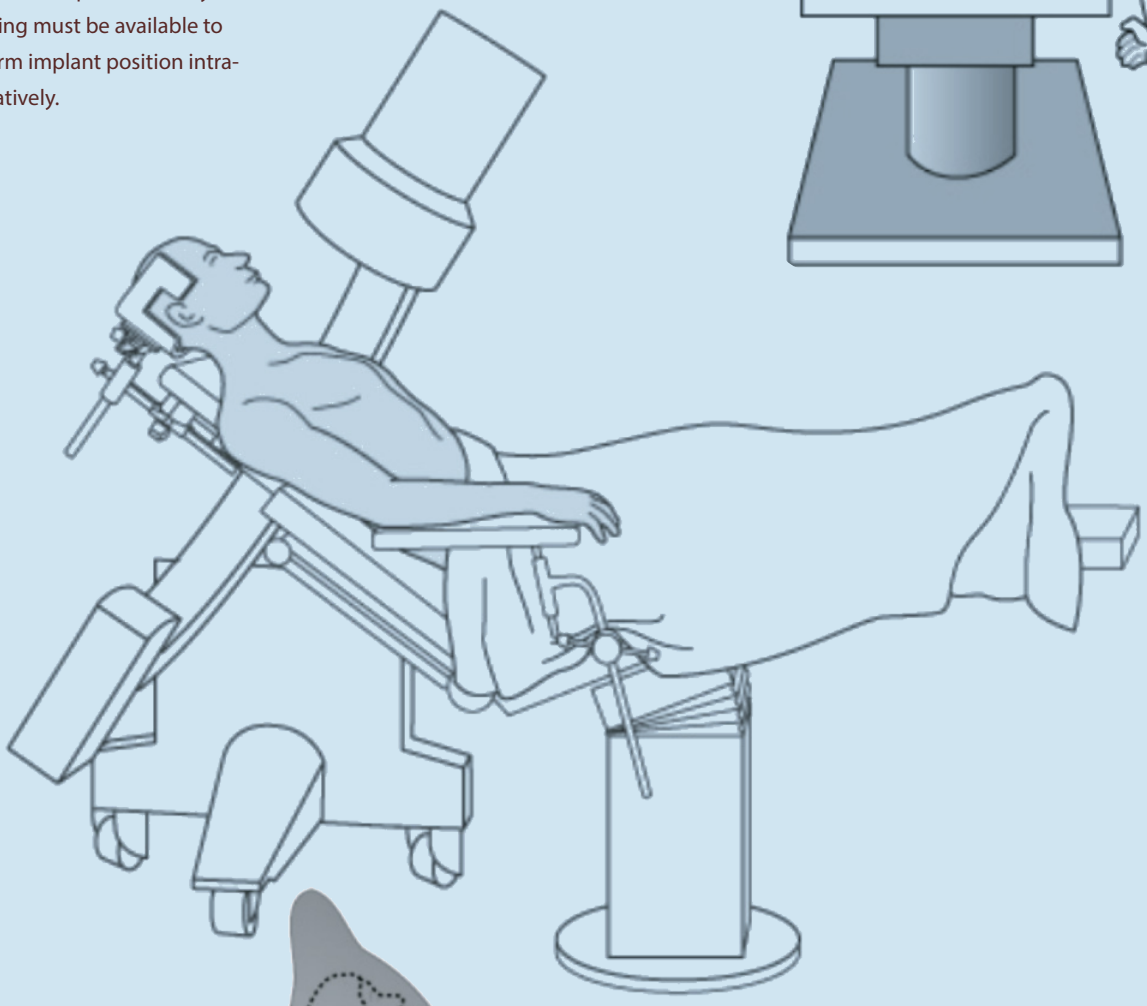
WARNINGS AND PRECAUTIONS

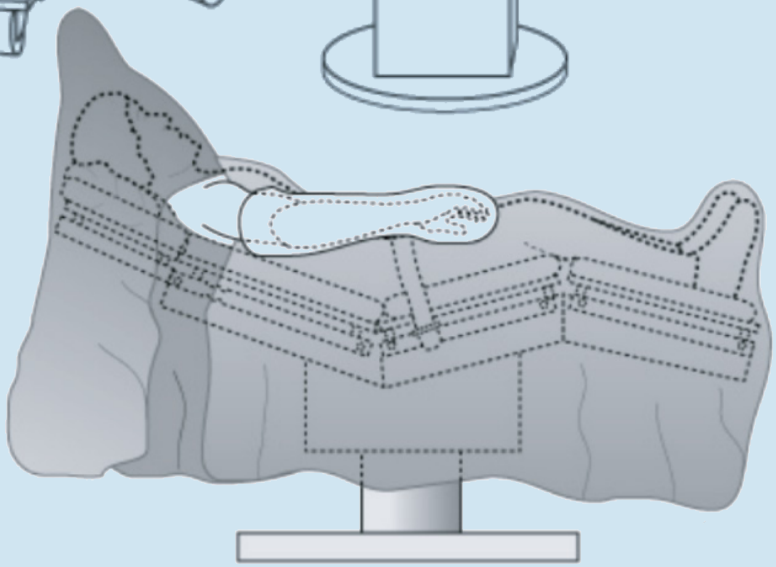
The surgeon must inform the patient that the safety and durability of the implant depends on the patient's weight and behavior, particularly the level of physical activity.
In cases where the surgeon considers that the patient needs this device, and the latter has one or more of the factors mentioned above, the surgeon must inform the patient of the effect that the factor(s) can have on the success of the procedure.
An implanted patient must always indicate that he has had an implant before embarking on any new treatment at a later date.
The Ø52 and Ø54mm humeral heads are not intended for use with Easytech Anatomical total shoulder replacement. Do not use trials as implants. Do not alter or modify the implant.
Potentially increased failures in patients with certain glenoid morphologies (Walch B2 and C).

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 and insert the intramedullary rod into the humeral canal until the spikes are seated into the humeral head. Remove the t-handle.

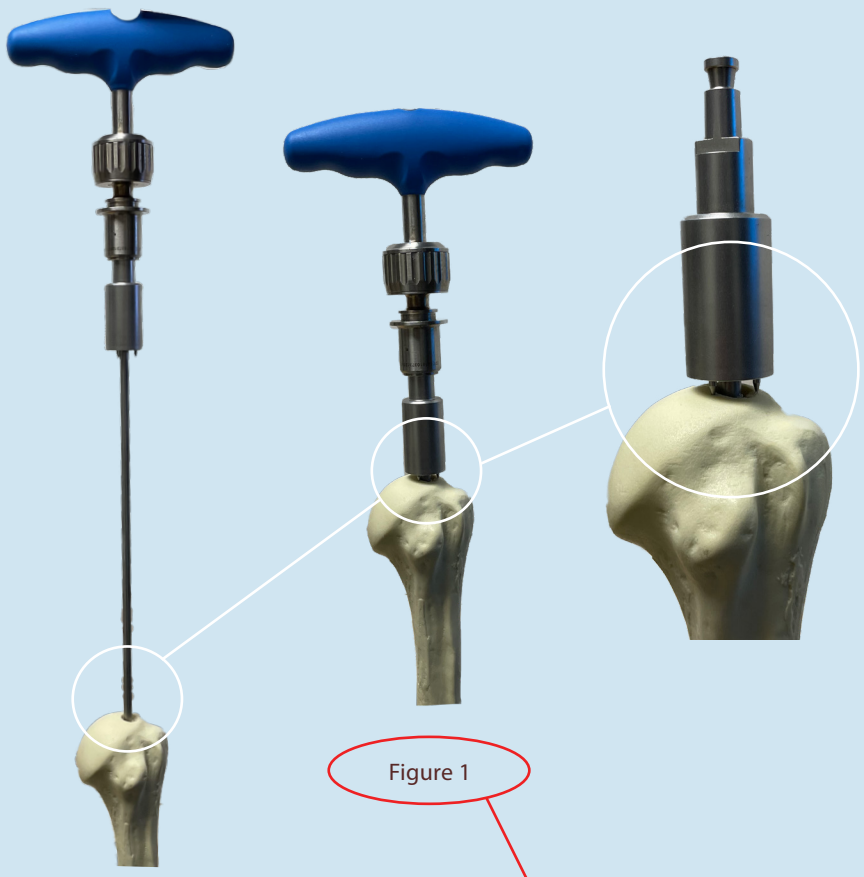
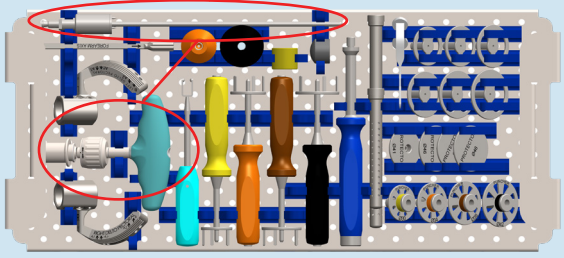


Figure 1



HUMERAL PREPARATION

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

(Figure 2)

Slide the cutting guide over the remaining intramedullary rod (IM rod). 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 IM rod when the forearm axis is screwed in completely and tightened to the IM rod.

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

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

Resect the humeral head.

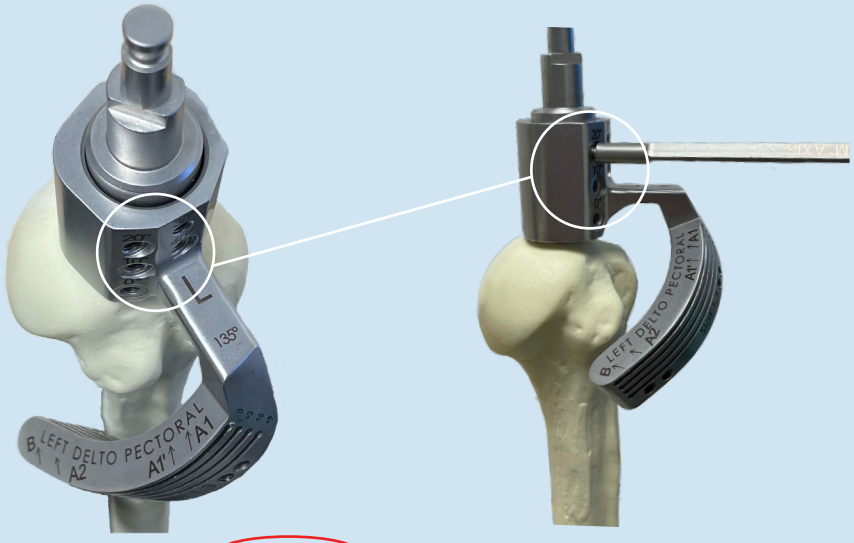


Figure 2

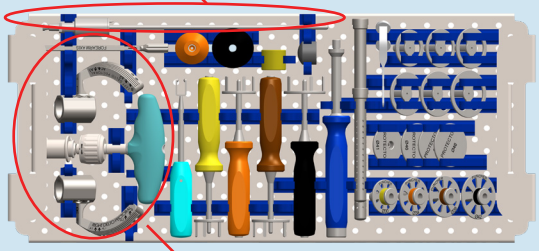
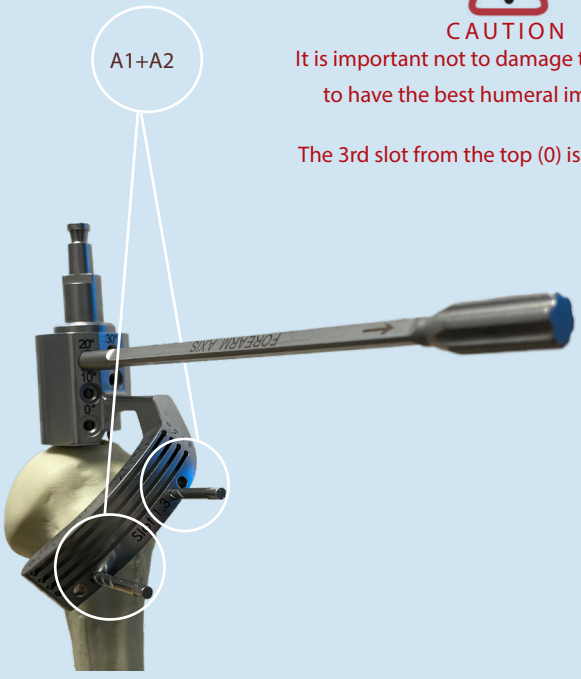


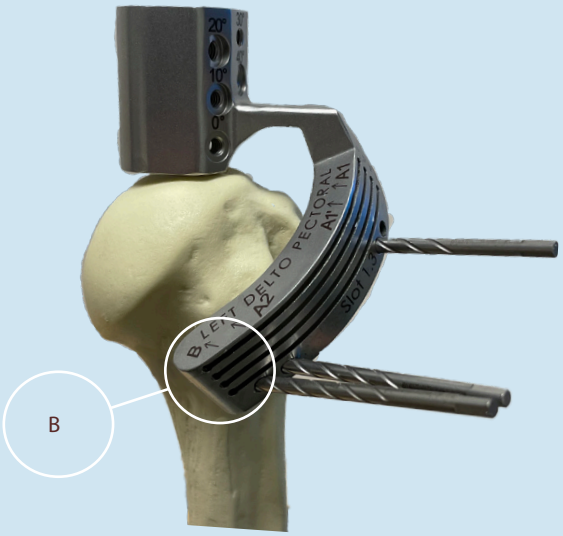
Figure 3

CAUTION

It is important not to damage the calcar in order to have the best humeral implant stability.

The 3rd slot from the top (0) is the ideal cutting.





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, drill the two holes with the pins to fix it, and resect the humeral head.

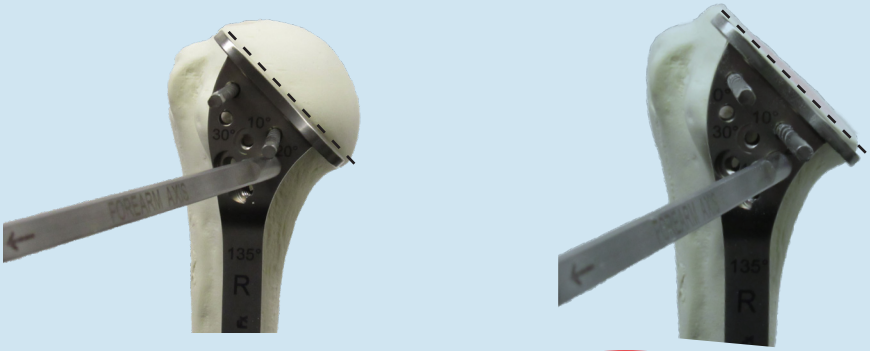
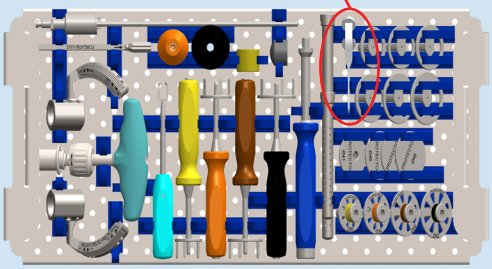


Figure 4

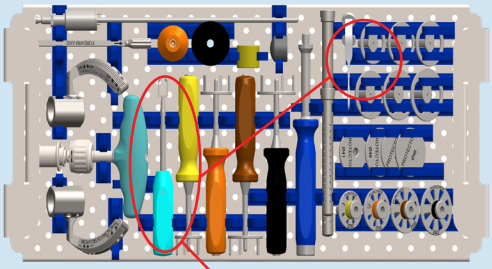


CAUTION

BONE TEST:

Put your thumb on the resected surface and push on it.

- *If your thumb does not sink in the humerus bone, there is sufficient bone quality*
- *If your thumb does sink in the humerus bone without much resistance, there may be insufficient bone quality (soft/weak) and a HUMERIS® stemmed prosthesis is recommened.*



STEP 3: PLACING THE K-WIRE (Figure 5)

Place the K-wire guide by centering it on the cut surface. Insert the threaded K-wire through the guide. Do not go further than the cortex. The pins have to be on average 5mm inside the cortex They do not contact the cortex.

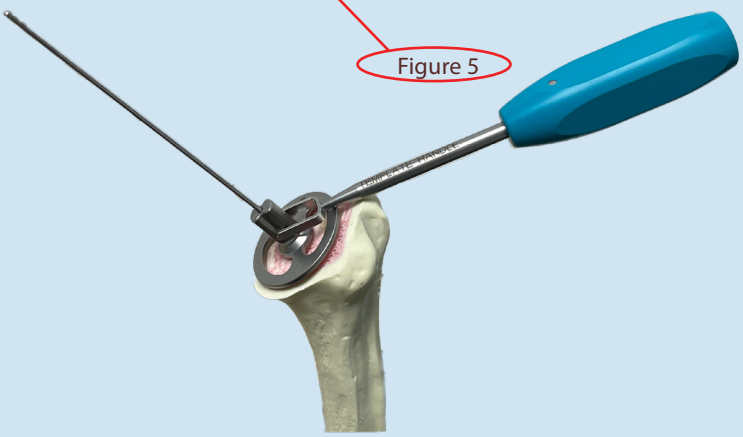


Figure 5

CAUTION

BONE TEST:

- If the K-Wire is unstable in the humerus, this may indicate that the bone is soft/weak and a HUMERIS® stemmed prosthesis is recommended*.

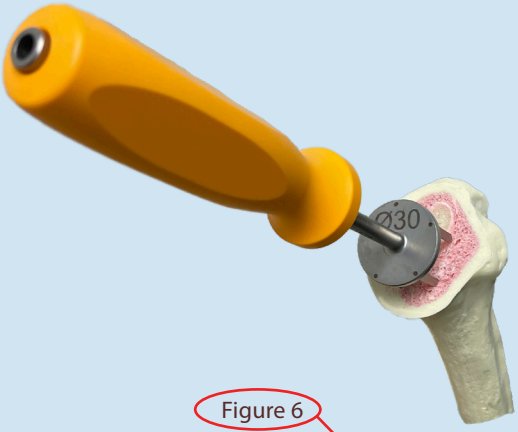
*For the HUMERIS® surgical technique visit www.fxshoulder.com

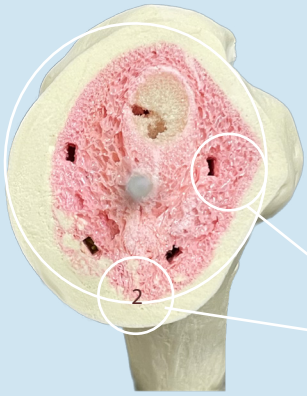
HUMERAL PREPARATION

STEP 4: SIZING ANCHOR BASE

(Figure 6)

Choose the largest anchor base size possible in order to have peripheral primary fixation. The peripheral pegs do NOT contact the cortex (A) and need to be inside the cancellous bone.





(A)

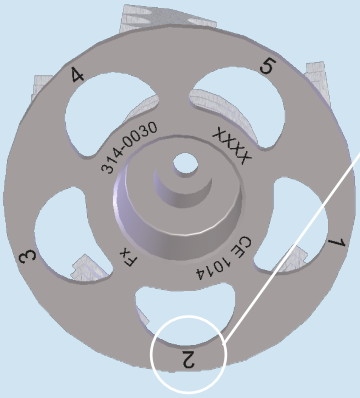
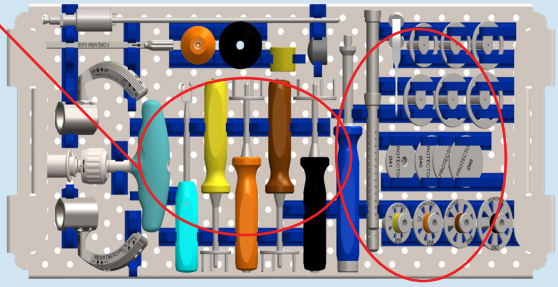
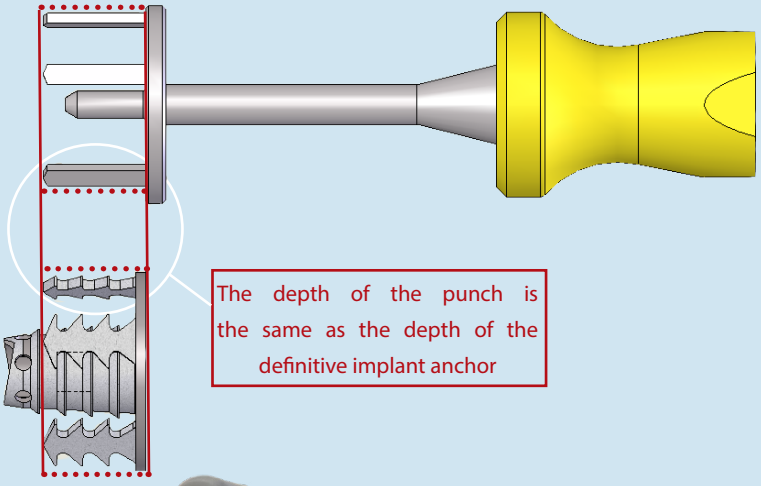


Figure 6





The depth of the punch is the same as the depth of the definitive implant anchor

STEP 5: HUMERAL PUNCHER

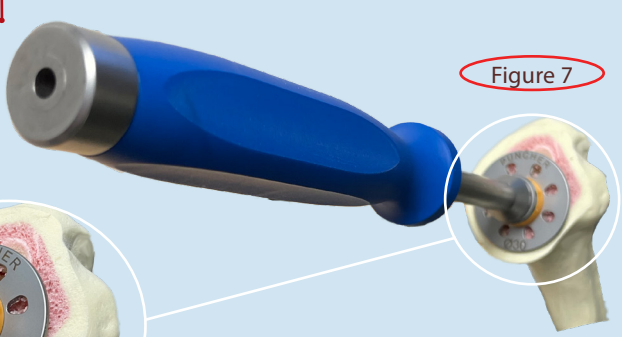
(Figure 7)

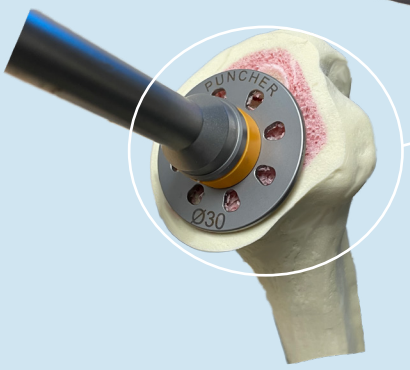
Make a central guide-mark for the anchoring base using the cannulated puncher with the same diameter as the anchorbase. Use the same color puncher as from the previous step:

Ø30 = YELLOW
Ø34 = ORANGE
Ø38 = MAROON
Ø42 = BLACK

Turn the puncher clockwise until the planer portion is flush to the resection.

Figure 7





BONE TEST:

- if the anchoring base is unstable in the humerus, then this may indicate that the bone is soft / weak. Use a HUMERIS® stemmed prothesis.

HUMERAL PREPARATION

STEP 6: IMPACT ANCHOR BASE

(Figure 8)

Seat the appropriate final anchor base using the cannulated impactor. The flat side of the anchor base should be flush to the resected proximal humerus surface.

The K-wire must be at a right angle to the anchor base.

(RECOMMENDATION ONLY)
DO NOT REMOVE OSTEOPHYTES BEFORE FULLY SEATING THE ANCHOR BASE

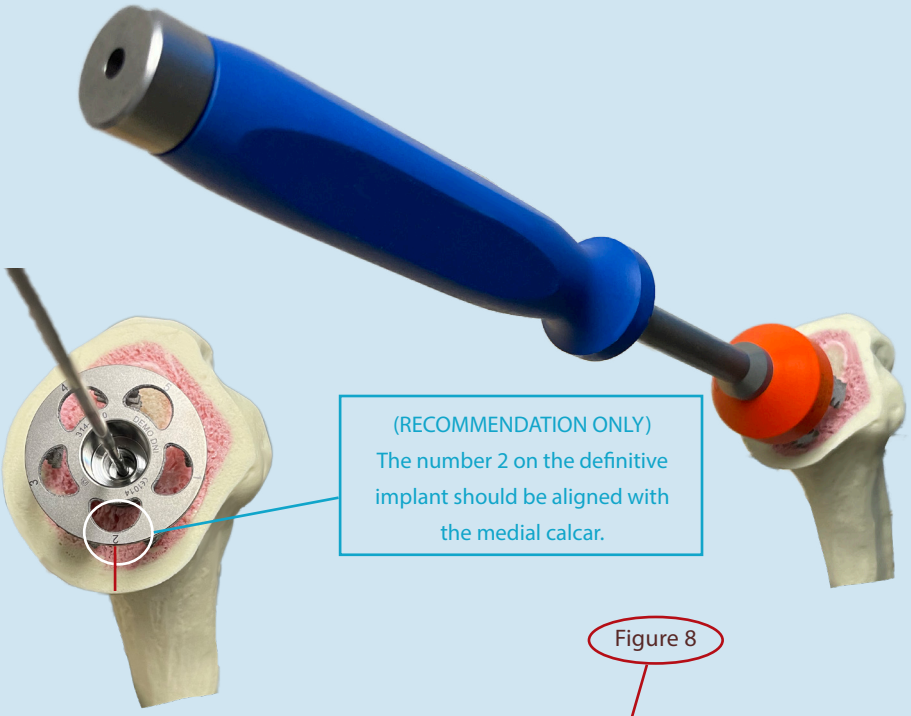


Figure 8

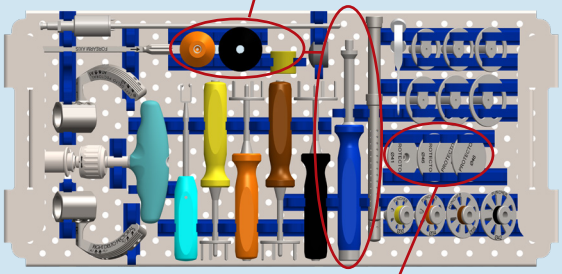
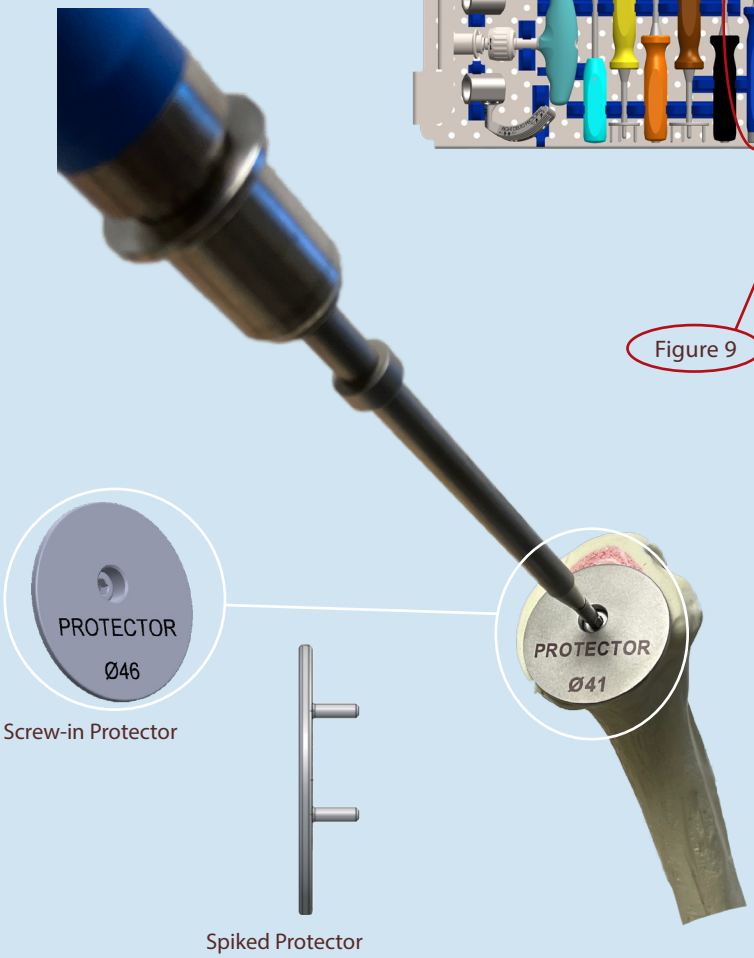


Figure 9

STEP 7: HUMERUS PROTECTION

(Figure 9)

Protect the humerus by using a protector cap. There are two humeral protectors: a spiked protector (A) that can be impacted or a screw-in protector (B). Both are available in two diameters (Ø41 and Ø46).



Screw-in Protector

Spiked Protector

2 PEGS GLENOID

STEP 8: GLENOID EXPOSURE (Figure 10)

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 10

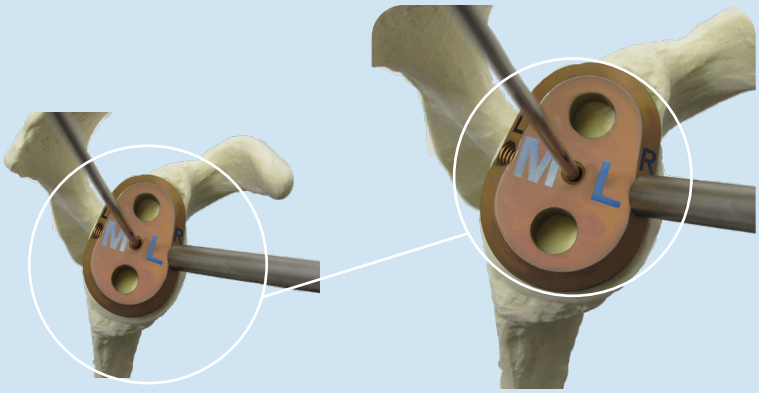
STEP 9: PLACING THE K-WIRE

(Figure 11)

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



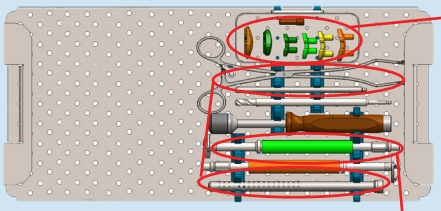


Figure 11

Figure 12

STEP 10: GLENOID REAMING

(Figure 12)

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 ONLY).

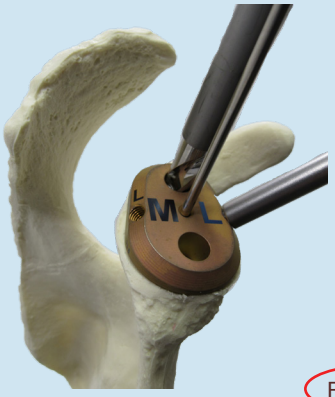
Green Reamer = Implant XS or S
Orange Reamer = Implant M or L

2 PEGS GLENOID

STEP 11: DRILLING GLENOID PEG HOLES

(Figure 13)

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.



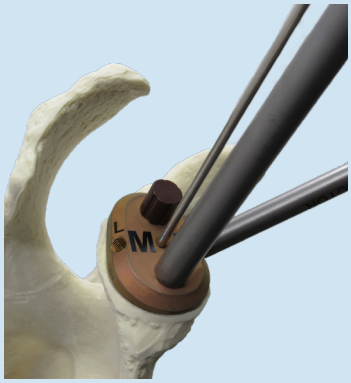
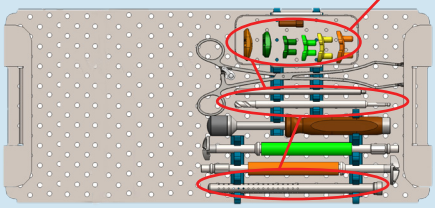
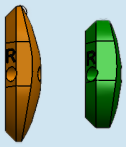


Figure 13





2 PEGS DRILLING GUIDES

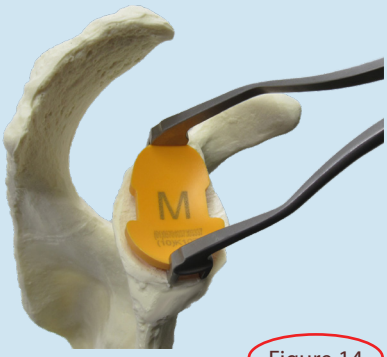
STEP 12: TRIAL IMPLANT (Figure 14)

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



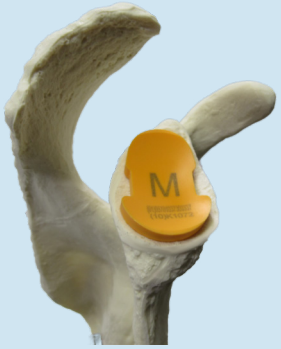
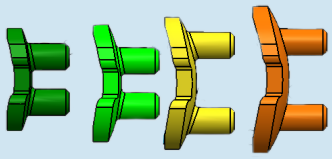
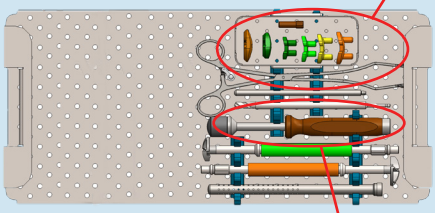


Figure 14



2 PEGS TRIALS



STEP 13: DEFINITIVE IMPLANT (Figure 15)

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

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

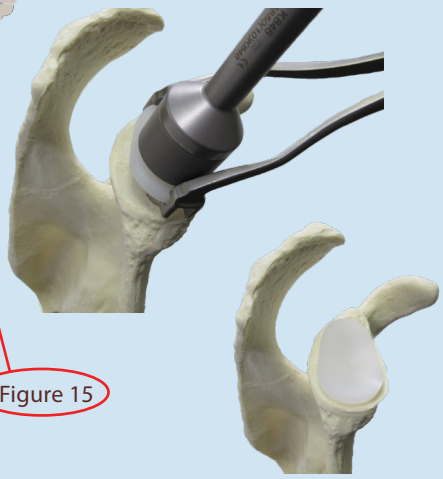


Figure 15

3-4 PEGS GLENOID

STEP 14: GLENOID EXPOSURE (Figure 16)

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 16

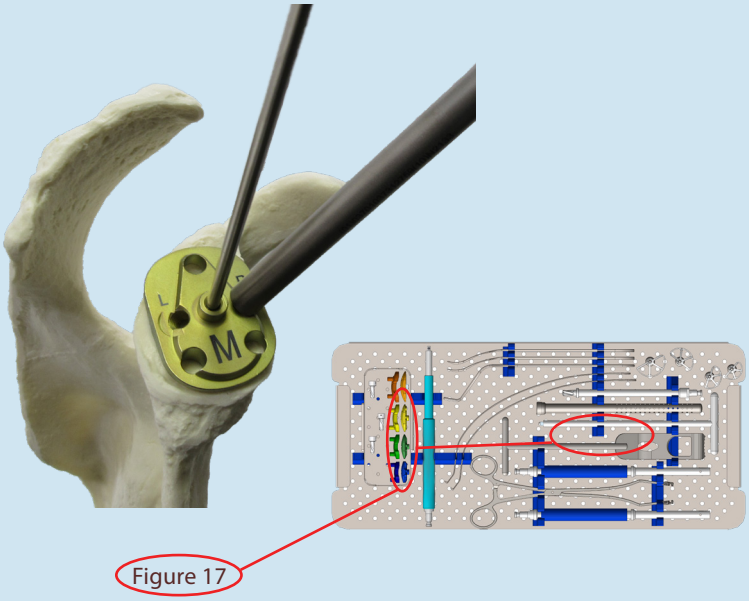
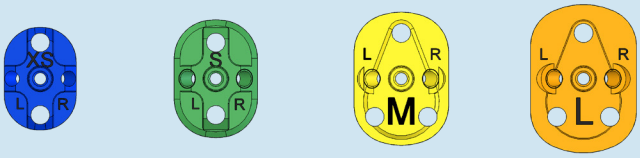


Figure 17



3-4 PEGS DRILLING GUIDES

STEP 15: PLACING THE K-WIRE

(Figure 17)

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 PEGS GLENOID

STEP 16: GLENOID REAMING

(Figure 18)

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.

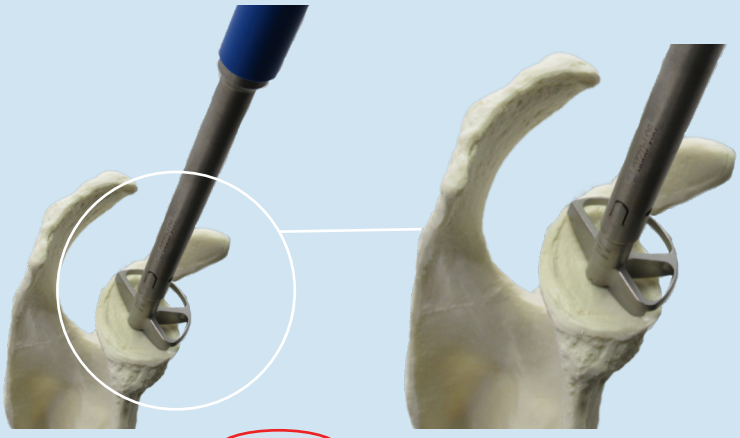
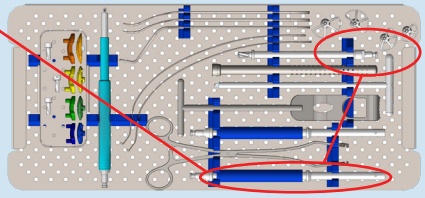
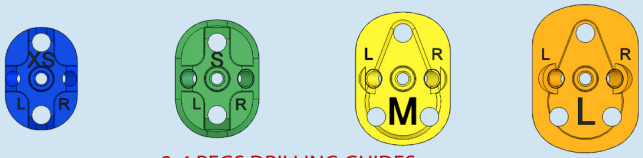


Figure 18





3-4 PEGS DRILLING GUIDES

STEP 17: DRILLING STABILIZATION HOLES FOR 3-4 PEG (Figure 19)

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-pegs glenoid and the remaining two holes for the 4-pegs 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-pegs glenoid, after drilling the superior stabilization hole, replace the drill shaft to drill the posterior hole and repeat the process 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.

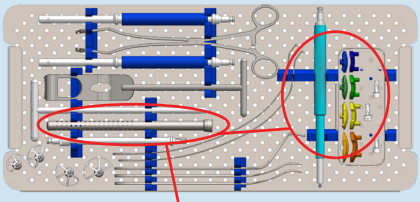
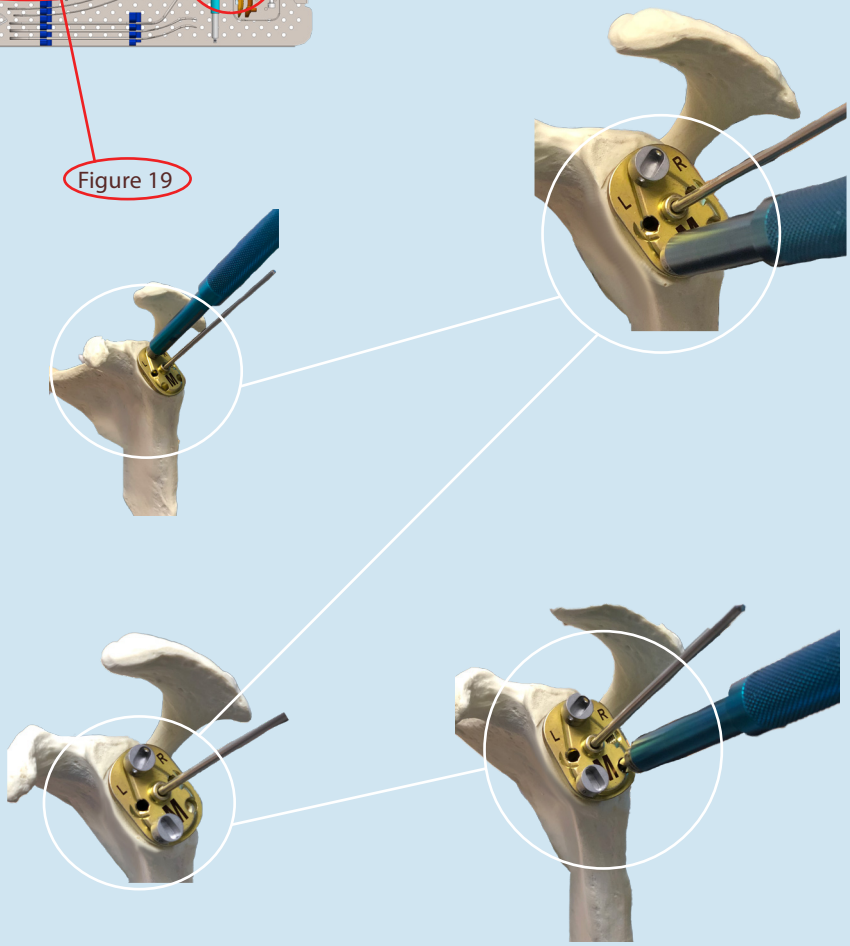


Figure 19

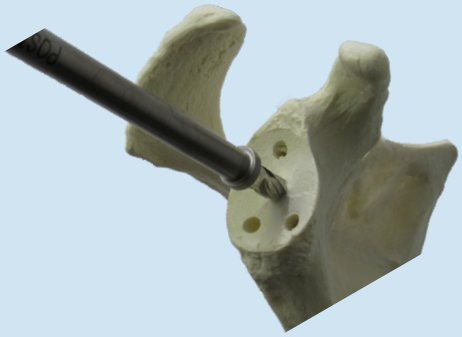


3-4 PEGS GLENOID

STEP 18: DRILLING THE CENTRAL PEG HOLE

(Figure 20)

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.



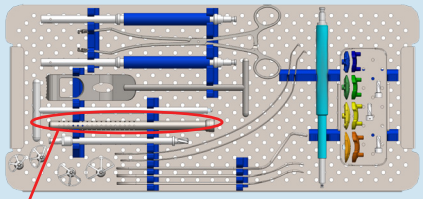
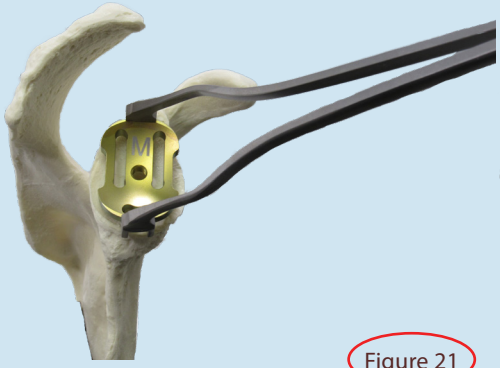


Figure 20

STEP 19: TRIAL IMPLANT (Figure 21)

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



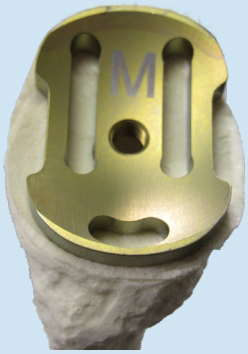
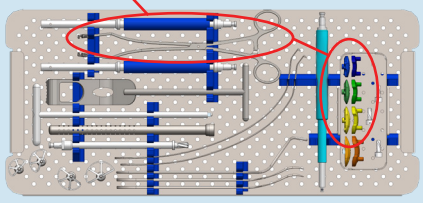
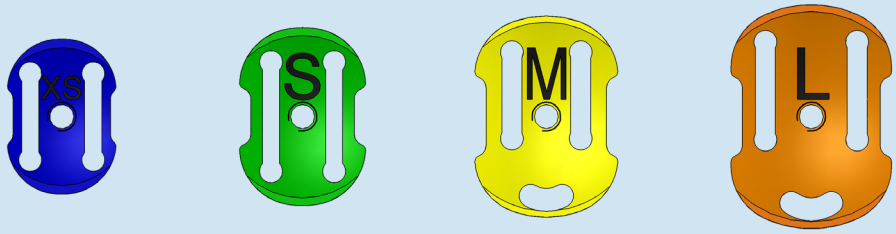


Figure 21





3-4 PEGS TRIALS

3-4 PEGS GLENOID

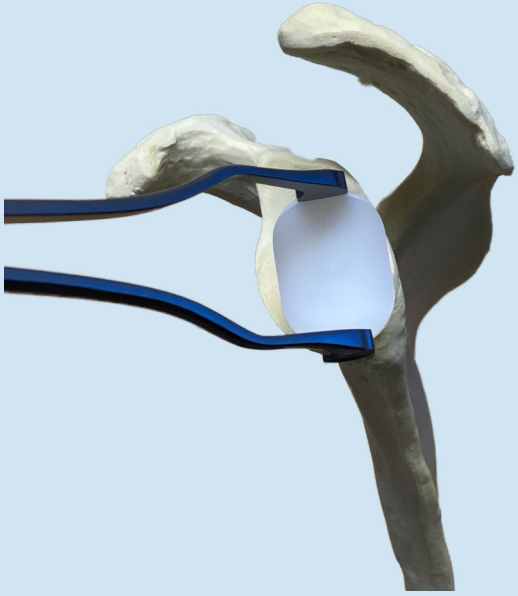
STEP 20: DEFINITIVE IMPLANT – GLENOID (Figure 22)

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.



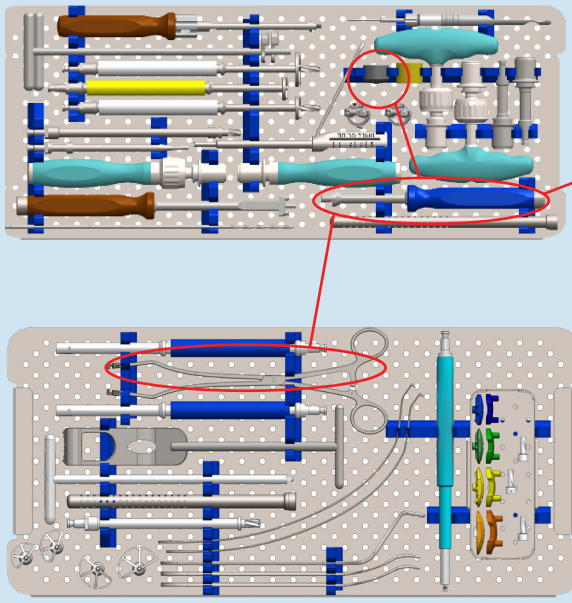
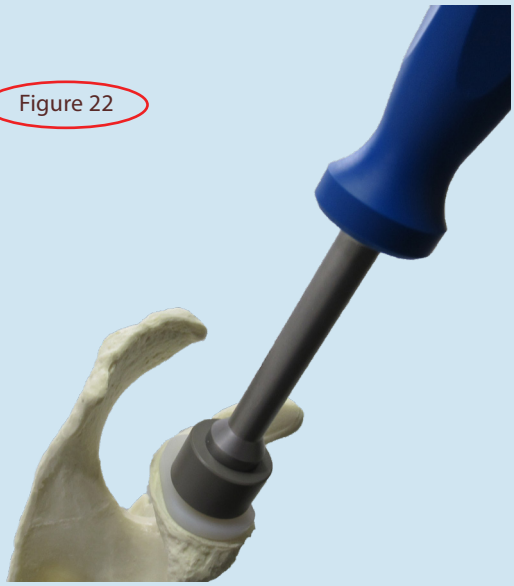


Figure 22



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

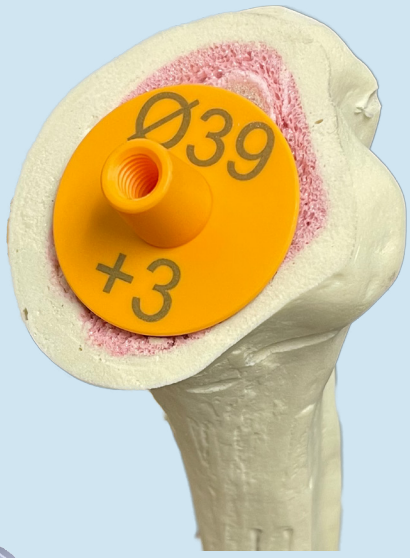
HUMERAL HEAD TRIAL

STEP 21: SELECT THE HUMERAL HEAD AND TAPER TRIAL (Figure 23)

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

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

A double taper OR a spacer +3mm OR a spacer +5mm may be used.



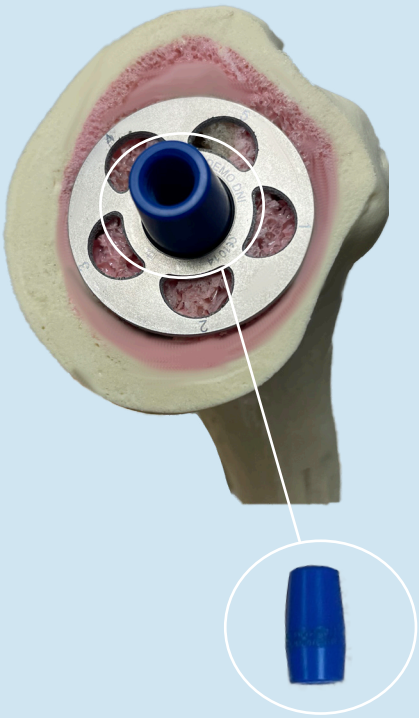


Figure 23

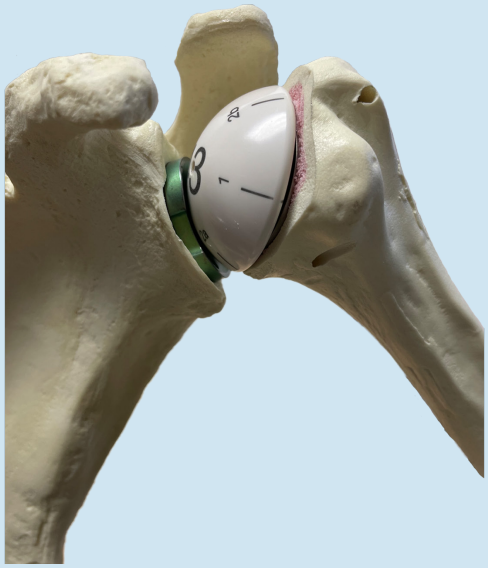
SPACERS
(+3mm / +5mm)

DOUBLE TAPER
(+0mm)

CENTERED OR OFFSET TRIAL HEAD

The humeral head should cover the cortical bone while being 5mm below the greater tuberosity.

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



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.

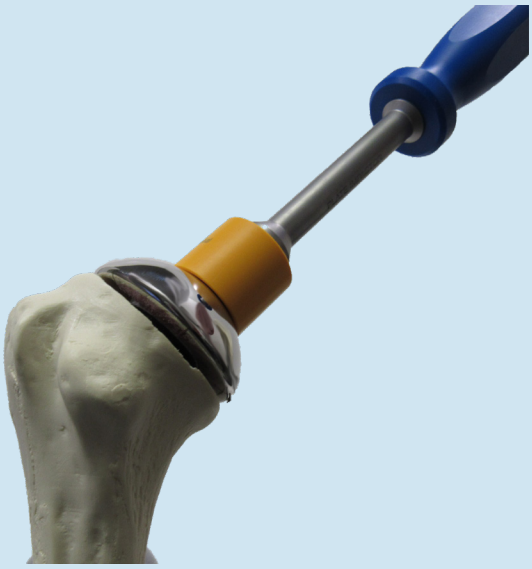
Take the definitive double taper and impact it INTO THE ANCHOR BASE (not to the head) using the impactor to start with.

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.

A definite +3mm or +5mm spacer may be used instead of the definitive double taper.

CAUTION

IMPACT THE TAPER INTO THE ANCHOR BASE NOT THE HEAD



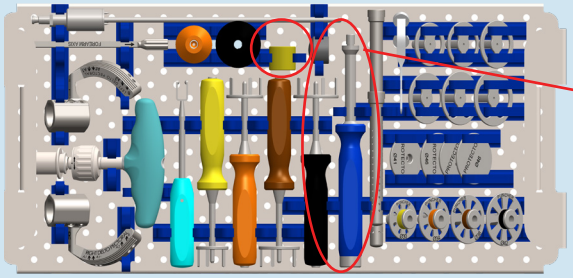


Figure 24

STEP 23:
DEFINITIVE REDUCTION

((Figure 25)

Reduce and make sure the joint is stable by pushing back the humerus.

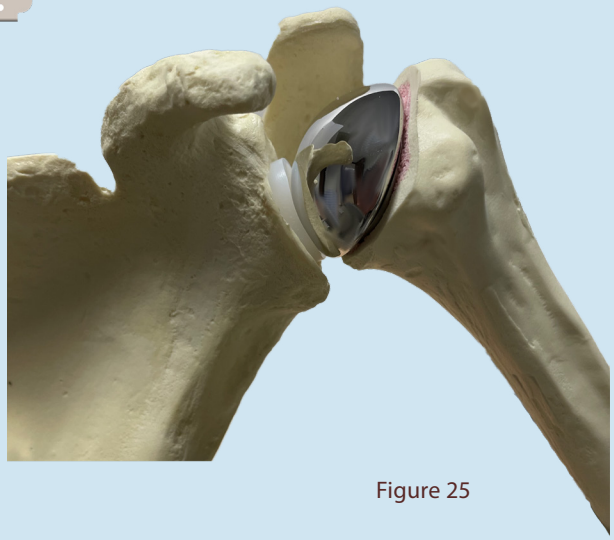


Figure 25

IMPLANT REMOVAL

ANATOMICAL IMPLANT REMOVAL

(Figure 26)

Remove the head by sliding a small fork between the head and the anchor base.

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

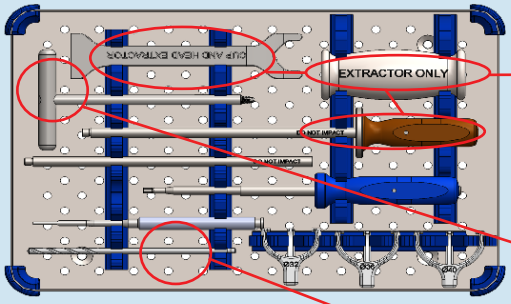


Figure 26

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 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 pegs glenoid.

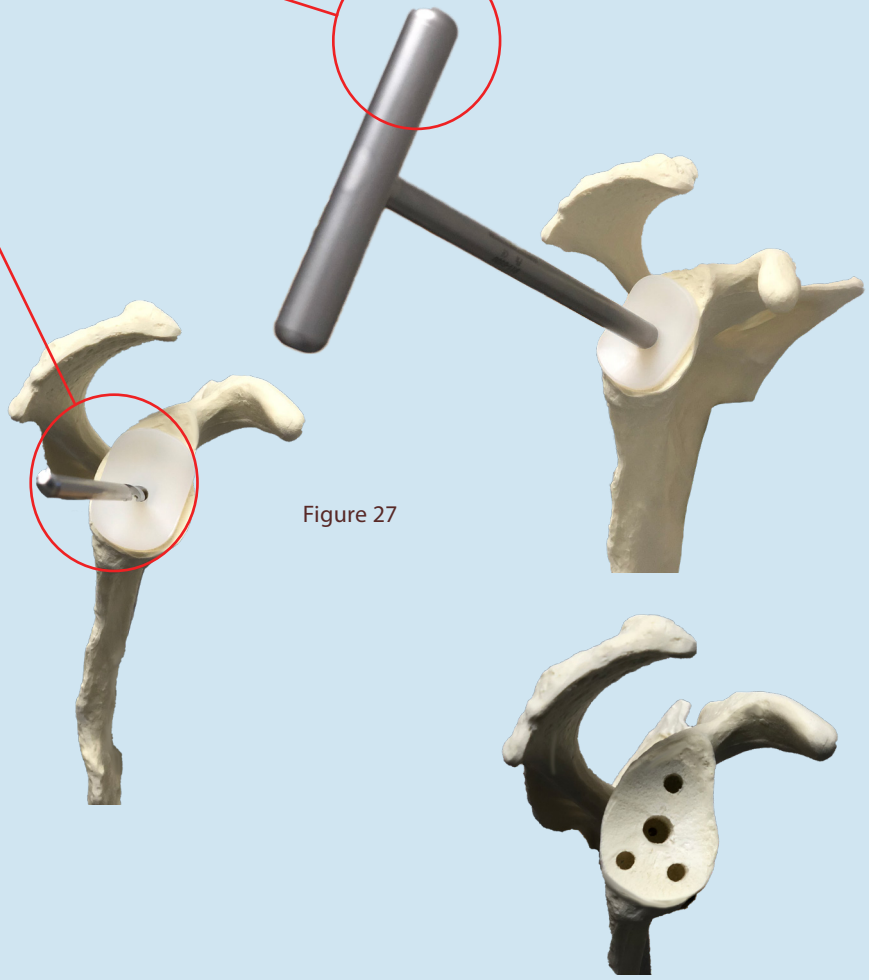


Figure 27

CAUTION

EXTRACTION OF ANCHOR BASE

(Figure 28)

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 slaphammer into the center of the anchor base taper and slap toward the brown handle to remove the anchor base. Use an osteotome to remove any bone stuck to the anchor base before extracting.

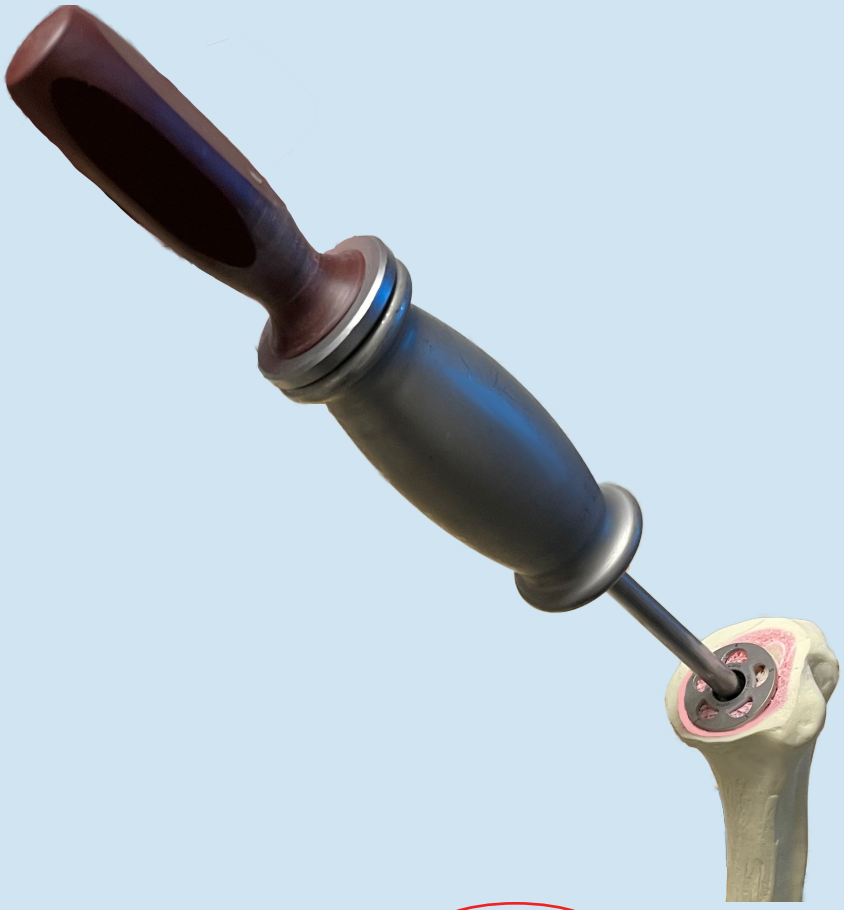
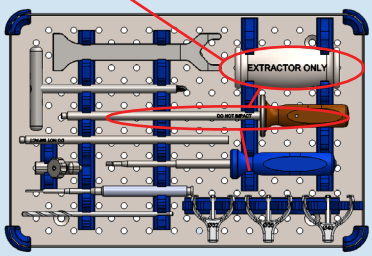
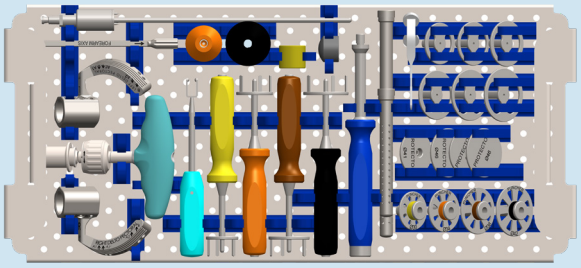
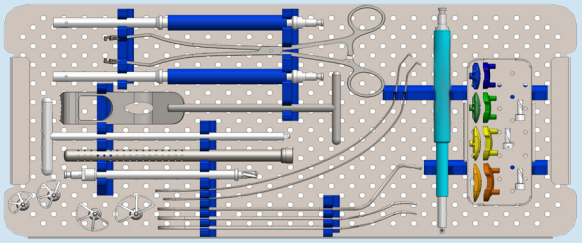
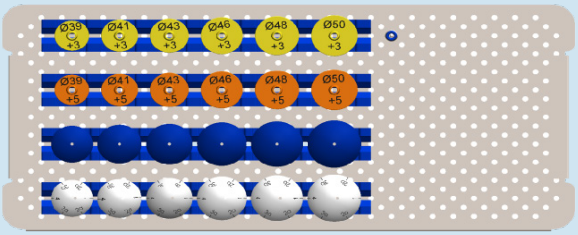
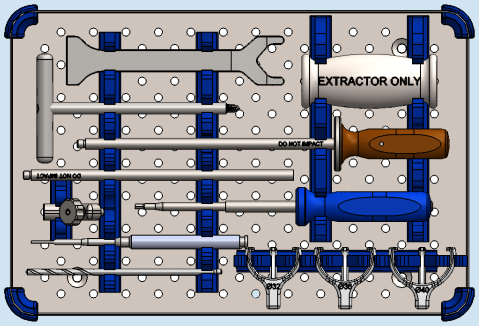


Figure 28



ANATOMICAL INSTRUMENTATION

REFERENCE NUMBER	DESCRIPTION	INSTRUMENTATION
606-0040	EASYTECH HUMERAL TRAY	
606-0051	HUMERIS GLENOID TRAY	
606-0042	HUMERIS TRIAL TRAY	
606-0010	EXTRACTION TRAY	

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