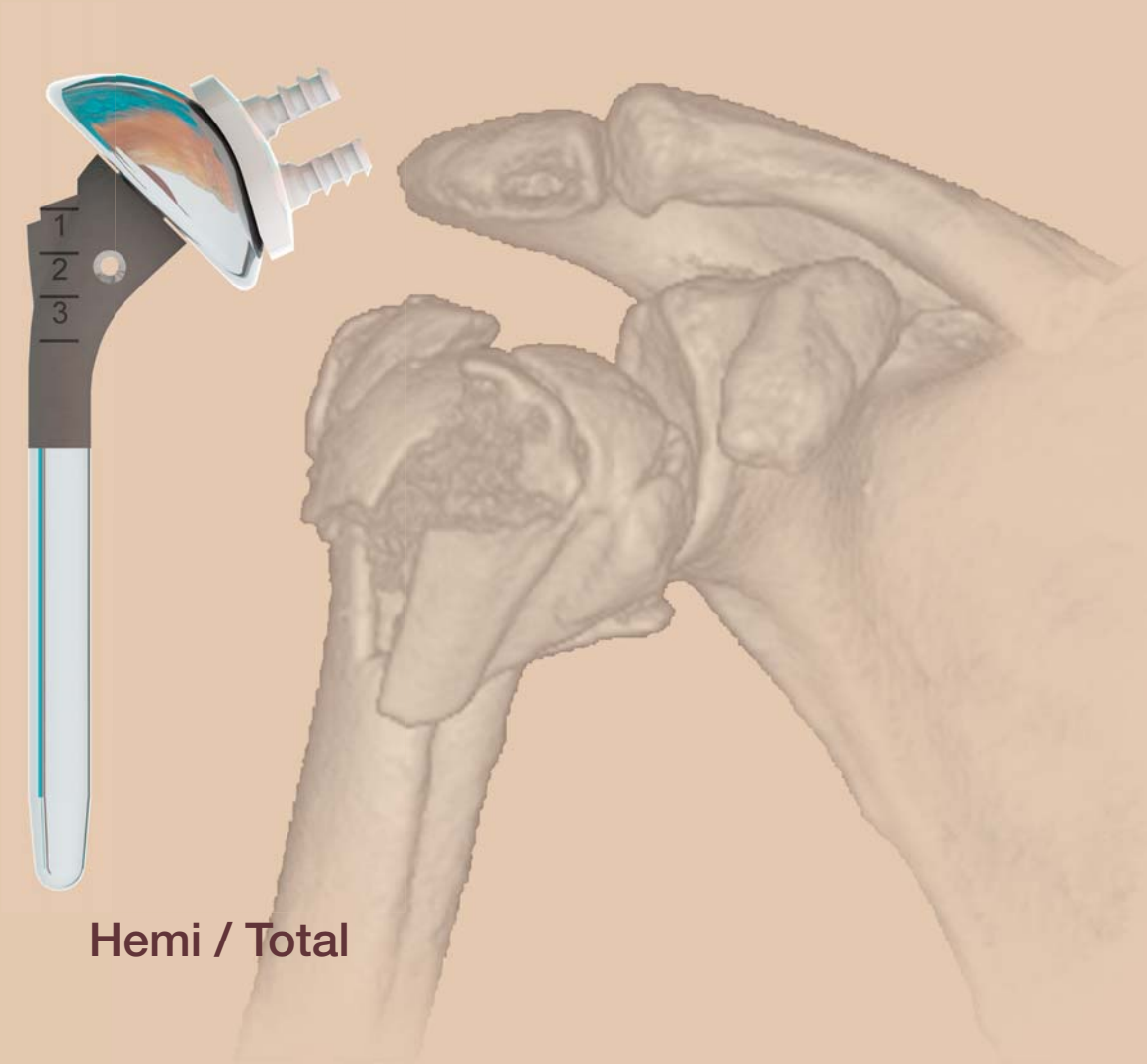
HUMELOCK™ II

Cemented



Hemi / Total

SURGICAL TECHNIQUE

FX SOLUTIONS

CONTENTS

PROPERTIES

HUMELOCK™ II is a new-generation modular implant designed for the efficacious treatment of fractures of the proximal humerus.
HUMELOCK™ II is a solution which takes account of the latest scientific developments in the treatment of cephalotuberosity fractures and is well suited to the treatment of complex shoulder fractures.

DEVICE DESCRIPTION

The Humelock II Cemented Shoulder System is a total and hemi-shoulder prosthesis consisting of a humeral stem, a humeral head, a double taper connector and, when used for total shoulder replacement, a glenoid component.
The humeral stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and is available in diameters of 6-15mm. The distal end of the humeral stem is cylindrical with a polished surface. The proximal portion of the humeral stem has a grit blasted surface.
The humeral stem incorporates a female taper for attachment of the double taper connector, which connects to the humeral head.
The double taper connector is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. One size is available and is compatible with all sizes of humeral stems and humeral heads. The double taper connector has a male taper on each end and is used to connect the humeral head to the humeral stem. An impactor / extractor hole is incorporated into the proximal end of the taper.
The humeral head is manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and is available in diameters of 39 – 50mm in centered and offset styles. The offset of the taper allows the head to be rotated relative to the cut surface of the humerus to provide optimal coverage of the bone. A female taper allows attachment to the double taper connector, which connects to the humeral stem.
The glenoid component is manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. It is available in sizes extra small, small, medium and large. The glenoid component features two pegs for cemented fixation to the glenoid bone. Each peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.

INTENDED USE / INDICATIONS

The Humelock II Cemented Shoulder System is indicated for use in total and hemi-shoulder replacement to treat:
- Proximal humeral fractures
- A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
- Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a previously implanted primary component, a humeral plate or a humeral nail).

The humeral stem and glenoid components of the Humelock II Cemented Shoulder System are intended for cemented use only.

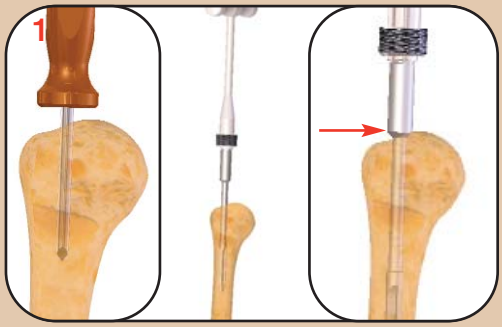
Contraindications
-Non-displaced or slightly displaced fractures.
- Dislocation fractures in elderly subjects.
- Acute, chronic, local or systemic infections.
- Severe muscular, neurological or vascular impairment affecting the joint in question.
- Bone destruction or poor bone quality that could compromise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

WARNINGS AND PRECAUTIONS

Unless otherwise indicated, instrument sets are sold 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 individual instruments has not been validated by the manufacturer.

Please consult the instrument package insert for validated sterilization instructions and the implant package insert for a complete list of warnings, precautions, contraindications and adverse events.

SURG. TECH. HUMERUS: DEGENERATIVE

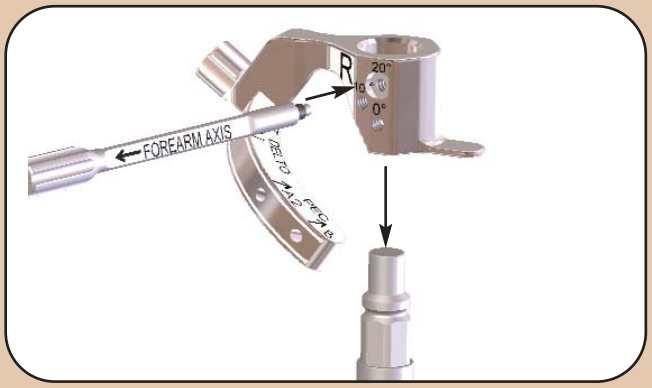


Preparation of the humeral shaft:

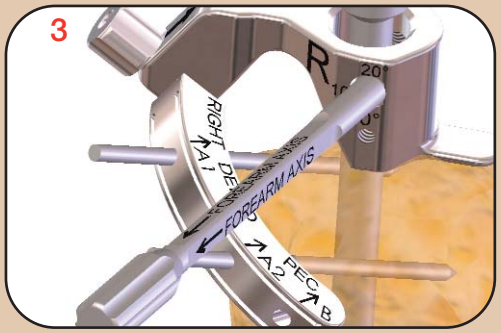
Locate and perforate the top of the humeral head in the medullary canal axis using a triangular awl.
Use the reamers in increasing size order on the T handle.
Go from one size to the next until the diameter of the reamer meets the diameter of the shaft.
The reamer should enter the humeral shaft up to the guard (⟶).
The stem choice is made depending on the last reamer size used:
Ø08 mm --> Stem Ø06 mm
Ø10 mm --> Stem Ø08 mm
Ø12 mm --> Stem Ø10 mm
Ø14 mm --> Stem Ø12 mm

Mounting the delto-pectoral cutting guide:

Place the delto-pectoral cutting guide on the operating side of the guide holder.
Fasten the guide with the knurled screw (1).



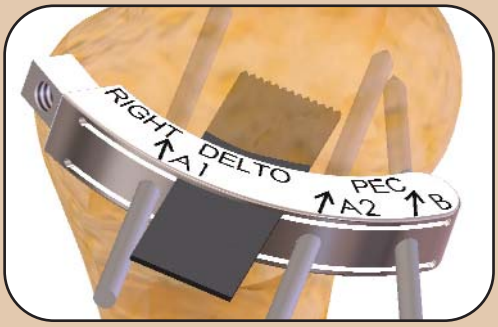
Slide the assembly onto the remaining reamer.
Screw the retroversion stem into one of the three positions according to the required angle: 0°, 10, 20°.



Placing the 135°cutting guide:

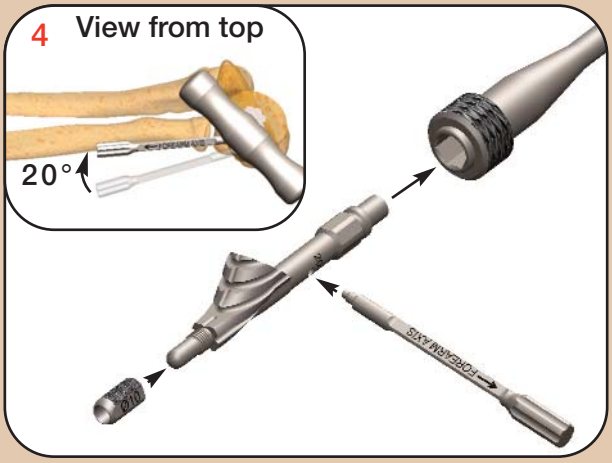
The probe stops at the top of the head and determines the incision height.
The retroversion is determined by screwing the stem into one of 3 positions (0, 10, 20°) and aligning it with the forearm axis. Fastening the retroversion stem sets the position for the cutting guide.
Place two pins (A1+A2) by drilling if necessary, using the Ø3.2 mm bit.

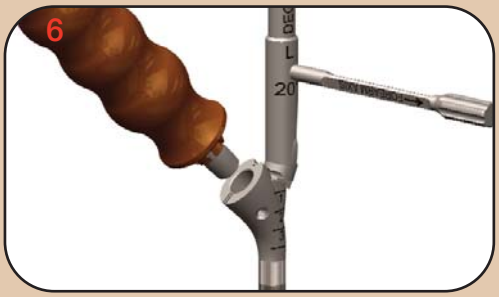
Remove the retroversion stem and the guide holder as well as the reamer.
Slide the cutting guide along the pins.
Stabilize the mounting using a 3rd oblique pin (B).
Make the incision across the slot with a saw blade of a maximum 0.9 mm thickness.

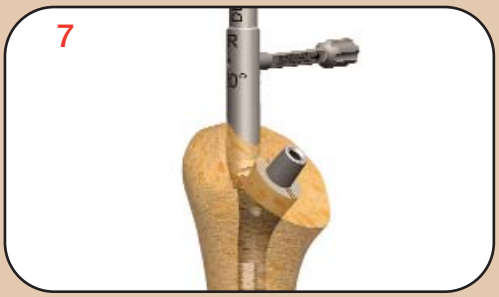


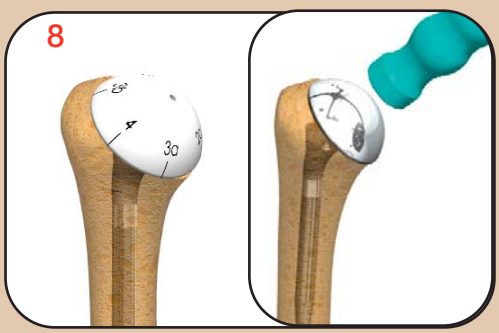
Puncher + retroversion adjustment:

Mount the retroversion rod from the right- or left-hand side.
The size of the sleeve is determined by the size of the last reamer.
Plug the puncher on the T handle.
Place the rod parallel to forearm to achieve 20° retroversion.
Impact the puncher until the resected bone surface.









Fitting the impactor:

Mount the impactor onto the implant with the 3.5 mm screwdriver
Tighten the screw of the «implant + impactor» assembly.

Impaction of the definitive taper:

Put the stem into the stem holder before impacting the double taper in it.

Check carefully that there are no splinters on the top of the humeral 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.

Cementing:

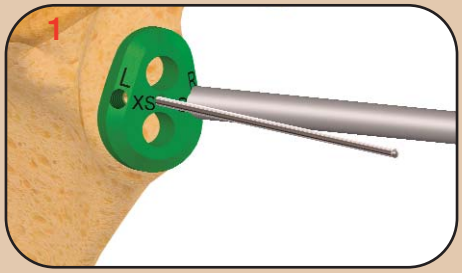
Insert the stem in the humeral shaft keeping good retroversion.
Stem is in place when at the humeral cut
Position a plug, 1 cm under the end of the stem (L=120 mm).

Do not apply too much cement in the proximal position, in order to optimize the osteogenic environment around the tuberosities.
Remove the impactor.

Once the trial head has been selected, (4 centered, 4 offset):

Insert the head onto the taper of the stem.
If an offset head is used (white), turn it to find the best position, i.e., the position that is closest to the anatomical structure.
Record the details so that this position can be used again for the definitive implant.

SURGICAL TECHNIQUE: GLENOID



Placing the K-wire:

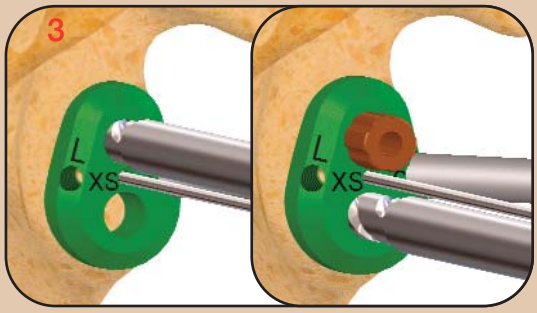
Apply one of the two templates of the glenoid cavity and visualize the fixing pegs.
Small template (green) = implant XS or S
Large template (orange) = implant M or L

Define the positioning of template and insert central K-wire.

Glenoid reaming:

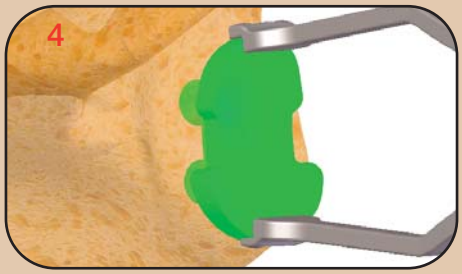
Drill and ream the glenoid using the K-wire guide.
Ream until the subchondral bone is reached.

Green reamer = implant XS or S
Orange reamer = implant M or L



Drilling peg' holes:

Insert the template over the K-wire.
Drill the first hole until it stops.
Stabilize the assembly with the peg.
Drill the second hole.



Trial implant:

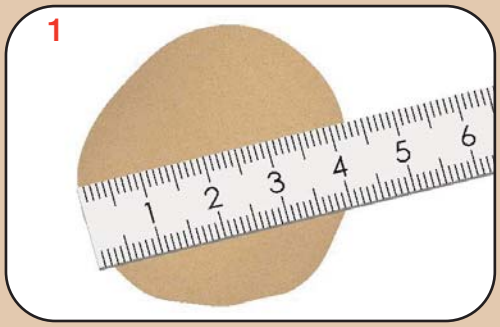
Insert trial implant by using the glenoid holder clamp.
Green template = trial implants XS or S.
Orange template = trial implants M or L.

Test the mobility with trial glenoid.
Trials are identical to final implants.

Definitive implant:

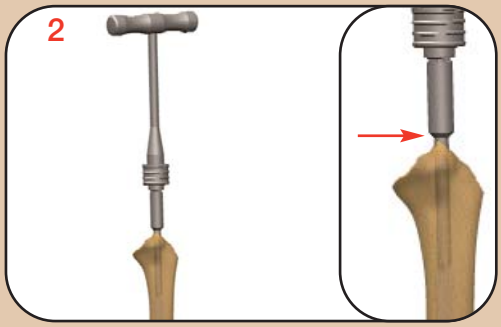
Take the implant of the same size as trial.
The pegs must be carefully cleaned, then dried with gauze stuffed in the peg holes while the cement is being prepared.
Remove the gauze and fully cement the glenoid.
Insert the implant with the glenoid holder clamp.
Maintain the pressure with the glenoid impactor.

Allowable combinations humeral heads / glenoid components				
Glenoid size	XS	S	M	L
Head Ø (centered & offset)	Ø39 Ø41 Ø43	Ø39 Ø41 Ø43	Ø43 Ø46 Ø48	Ø46 Ø48 Ø50



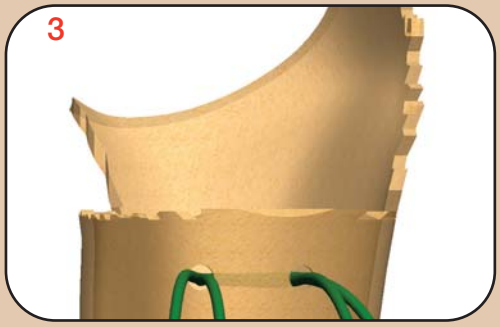
Extraction of the humeral head:

Measure the head using the metallic ruler.
Use a smaller prosthetic head than the size measured.
Example: Measurement = 46 mm => prosthetic head = Ø43 mm.



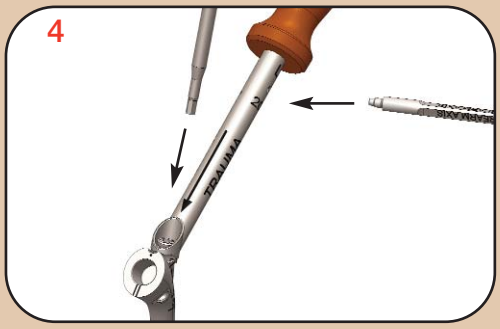
Preparation of the humeral shaft:

Prepare the humeral shaft using the reamers from the smallest to the biggest size.
Use one size then the other until the reamer diameter fits to the humeral intramedullary canal.
The reamer must be introduced into the canal until it stops (→).
Size of the stem is defined by the size of the reamers : size of the stem (Ø06, 08, 10, 12) a reamer below the last one used (Ø08, 10, 12, 14).



Positioning one loop:

Make two holes in the diaphysis before inserting the stem into the humeral shaft.
Introduce the loop from the outside to the inside, then through the second hole from the inside to the outside.



Fitting the impactor:

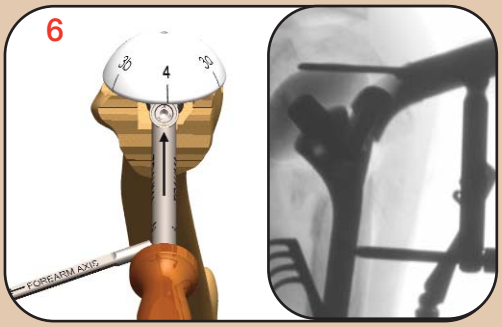
Mount the impactor onto the implant with the 3.5 mm screwdriver
Tighten the screw of the «implant + impactor» assembly.

Impaction of the definitive taper:

Put the stem into the stem holder before impacting the double taper in it.

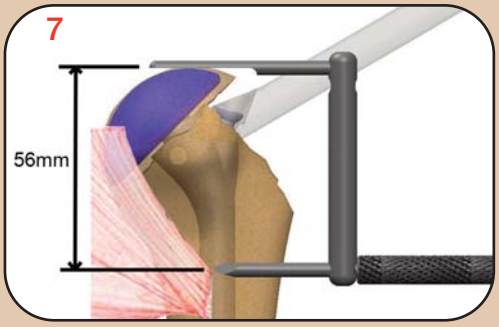
Check carefully that there are no splinters on the top of the humeral metaphysis hindering impaction of the morse taper.

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



Once the trial head has been selected, (4 centered, 4 offset):

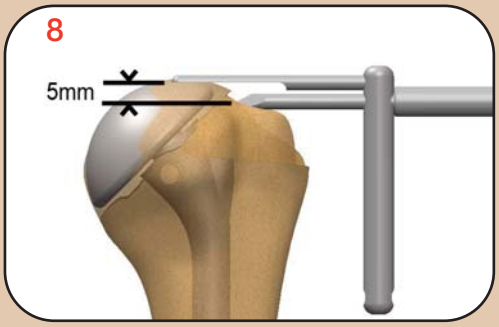
Insert the head onto the taper of the stem.
If an offset head is used (white), turn it to find the best position, i.e., the position that is closest to the anatomical structure.
Record the details so that this position can be used again for the definitive implant.



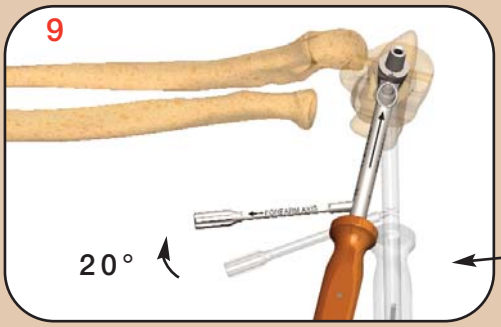
Height adjustment (height gauge):

a) DELTO-PECTORAL APPROACH
Use Murachovsky's criteria (1).
Position the trocar level with the point of insertion of the clavicular fascicle of the pectoralis major muscle.
The face of the top plate indicates the position for the top of the humeral head.

(1) Murachowsky J et al. JSES 06; Torrens C et al. JSES 08; Hasan SA et al. Orthopedics 09



b) SUPERO-EXTERNAL APPROACH
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.



Retroversion adjustment:

Mount the retroversion rod onto the impactor from the right- or left-hand side.
Position this rod parallel to the forearm to achieve 20° retroversion.

View from top: upper left limb.

Checking of the stem position in regard to the tuberosities and glenoid:

Locate the horizontal reference point for any remarkable elements of the metaphysis that you will use to cement the stem at a good height (scalpel line, for example).

Impaction of the head:

Record the position of the offset head in relation to the arrow on the impactor.
Take the appropriate implant and insert it on the taper of the stem in the same way.
Check carefully that there are no splinters on the top of the humeral metaphysis hindering impaction of the morse taper.

Cementing

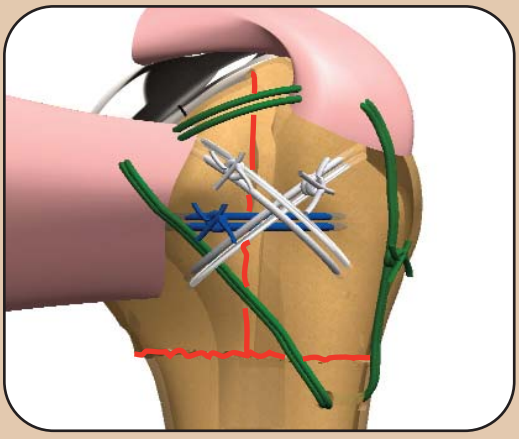
Position a plug, 1 cm under the end of the stem (L=120 mm).

Do not apply too much cement in the proximal position, in order to optimize the osteogenic environment around the consolidation zone of the tuberosities.

Removal of the impactor:

Remove the impactor's screw.
Remove the impactor.

To suture the tuberosities, please consult surgical technique TP07.



REHABILITATION

6 weeks of post-operative immobilization with a splint: mild abduction of approximately 15 degrees, in external rotation so that all rotation is prohibited.

1st week: Physical therapy + lymphatic drainage + passive mobilization of the elbow in the axis of the arm. No rotation.

2nd to 6th week: Small isometric muscular contraction exercises of the broadest muscle of the back (Latissimus dorsi) and the large pectoral muscle (Pectoralis major), as well as the stabilizers of the scapula (Serratus anterior). Free the elbow "under control" several times per day so as not to cause stiffness. No active engagement of the biceps, if tenodesis was performed.

3rd week: Light, passive flexion using a pool therapy program, or perform a series of 10 passive flexions, 3 times per day, assisted by the healthy extremity, in a dorsal decubitus position.

6th week: Remove the splint. Have the patient go to a rehabilitation center 3 times per week in order to recover passive joint amplitudes. Validate the continuation of the physiotherapy protocol using an X-ray exam. Encourage pool therapy, as well as specialized rehabilitation treatment.

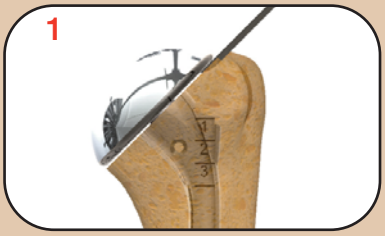
Anti-inflammatories may be taken for one week for relief of pain due to the removal of adhesions.

Starting from the 3rd month: Passive amplitudes must be acquired. Concentrate efforts on rehabilitating ER1 and ER2. Active flexion to 80 degrees is desirable.

Encourage the patient to swim, regardless of the stroke, on his/her back, in order to work on the ER amplitude. Beginning with the 4th month: Check-up visit with X-rays. (Order types: Frontal, neutral rotation of shoulder + Profile of shoulder cuff).

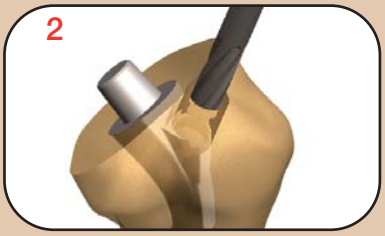
The optimal functional result is generally only acquired after the 6th post-operative month.

IMPLANT REMOVAL



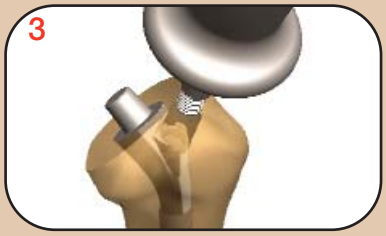
Humeral head removal:

Remove the head by sliding a Powels blade between the head and the stem.



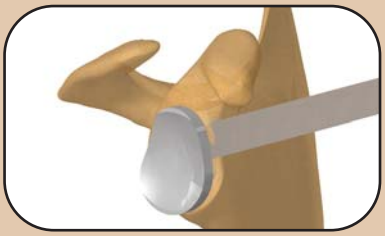
Release M6 thread:

Extract the bone over and around the screw with a 4.5 mm diameter drill.



Stem removal:

Screw the stem extractor in the stem, then use the hammer to remove the stem.



Glenoid removal:

Remove the glenoid by sliding a Powels blade between the glenoid and the bone.

1663, rue de Majornas - 01440 Viriat - France
Tél. : (33) Ø4 74 55 35 55 - Fax : (33) Ø4 74 52 44 01
E-mail: info@fxsolutions.fr - www.fxsolutions.fr

TP51-US-11/02/15