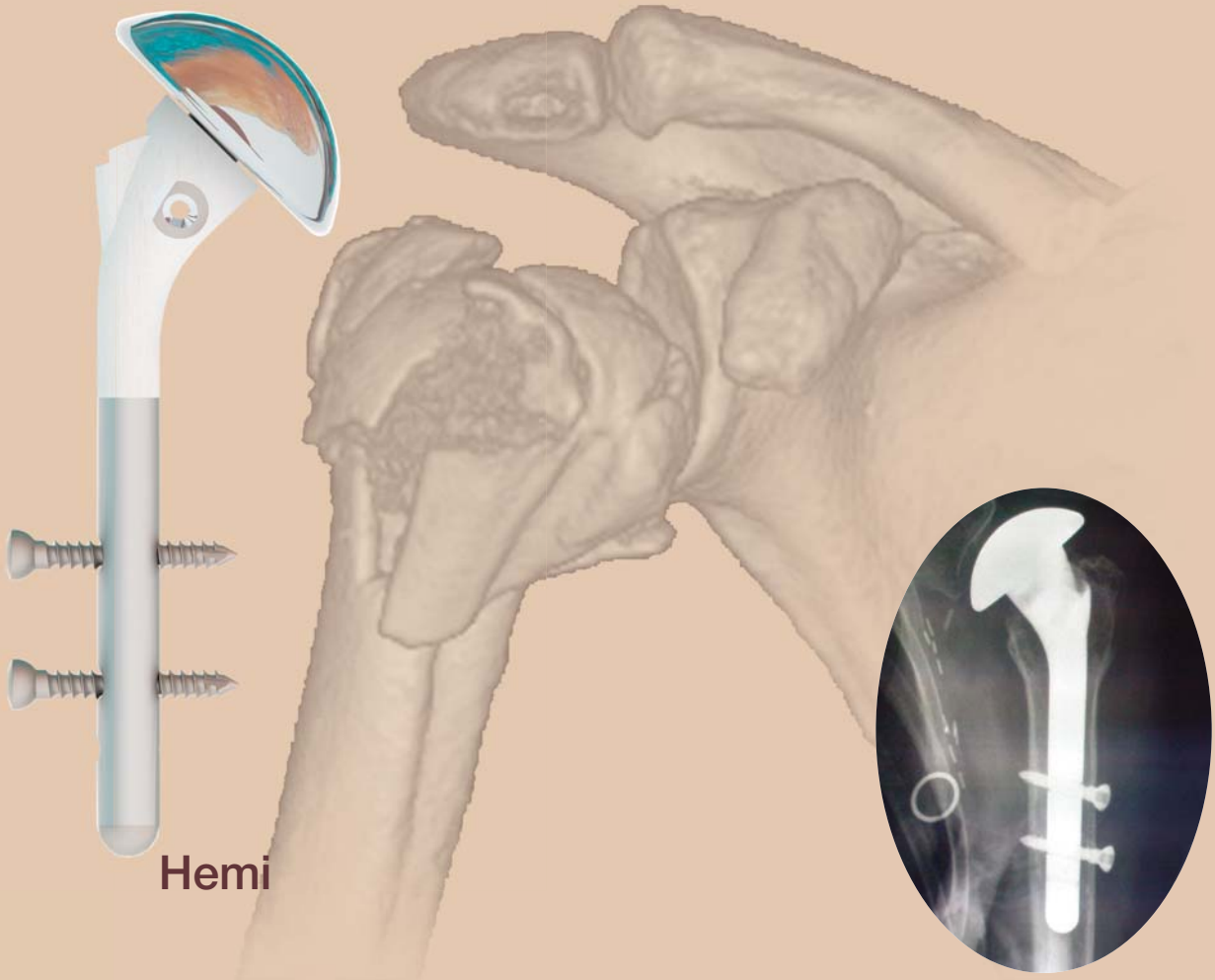
HUMELOCK™ II

Cementless



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 Cementless Humeral Stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and is available in diameters of 8-15mm. The distal end of the humeral stem is cylindrical with a grit blasted surface and two unthreaded screw holes oriented 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 humeral stem incorporates a female taper for attachment of compatible components.
The Humelock II Cementless Humeral Stems can be used with the following components for use in an anatomical shoulder configuration.
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.

INTENDED USE / INDICATIONS

The Humelock II Cementless Shoulder System is indicated for use in hemi-shoulder replacement for fractures of the proximal humerus.
The Humelock II Cementless Humeral Stem is intended for use with two cortical screws.

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

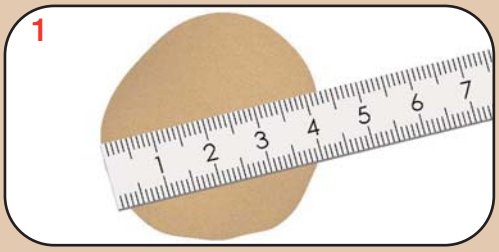
Unless otherwise indicated, instrument sets are sold non-sterile and must be completely cleaned and sterilized before use.
Instruments must not undergo accelerated autoclave sterilization inside the instrument box.
Accelerated autoclave sterilization of individual instruments has not been validated by 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.

SURGICAL TECHNIQUE

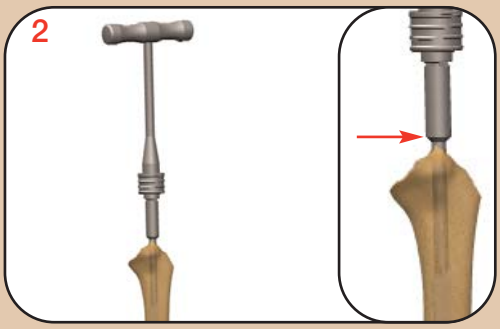
Patient positioning:

Position the patient so that the extremity is completely clear with his/her head in a slightly bent position (NEVER HYPEREXTENDED).
Plan on having an image intensifier outside of the operative field, on the anaesthesiologist side, so that you can check the procedure each time.



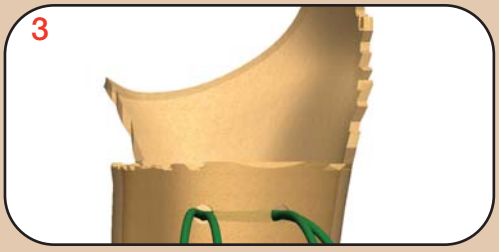
Extraction of the humeral head:

Measure the head using the metallic ruler.
Use a smaller prosthetic head than the size measured.
Example: Measurement = 46 mm => trial 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 (Ø08, 10, 12 mm for cementless stems).
The reamer must be introduced into the canal until it stops (→).
(Size of the reamer = Size of the stem).



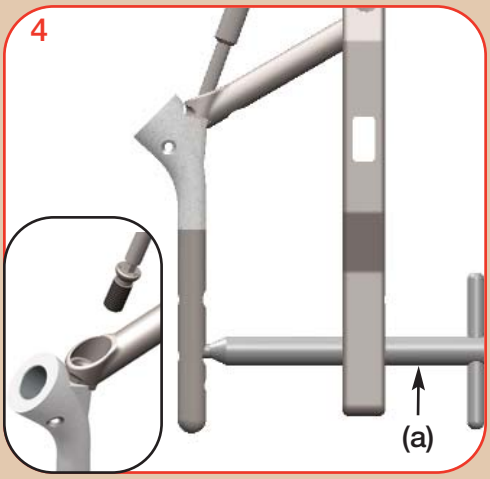
Positioning one loop:

Make two holes in the diaphysis before inserting the stem into the humeral shaft using the same drill (Ø3.2 mm) as for interlocking screws.
Introduce the loop from the outside to the inside, then through the second hole from the inside to the outside.

Fitting the stem:

WARNING

1- Mount the aiming guide onto the implant without tightening the screw.
2- Place the stability pin (a) into the distal locking hole of the guide and the stem.
Do not lean on the stability pin, in order to avoid stress on the stem.
3- Tighten the screw of the «implant + guide» assembly.
4- Remove the stability pin.
5- Verify the proper alignment of locking holes with the aimer.

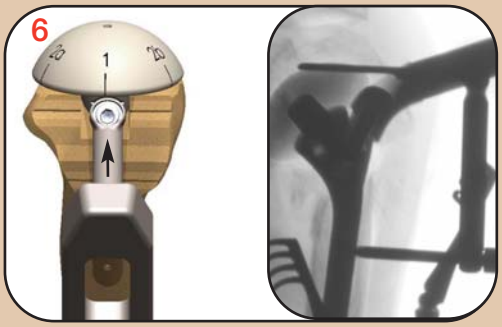


Impaction of the definitive taper:

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

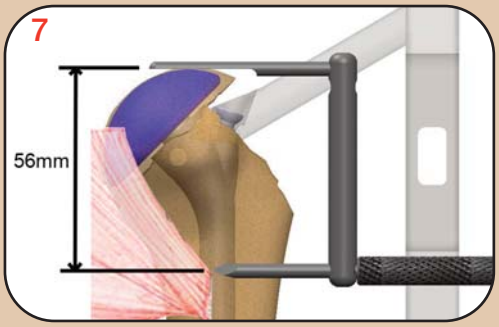
Check carefully that there are no splinters on the top of the humeral metaphysis hindering impaction of the morse taper.

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):

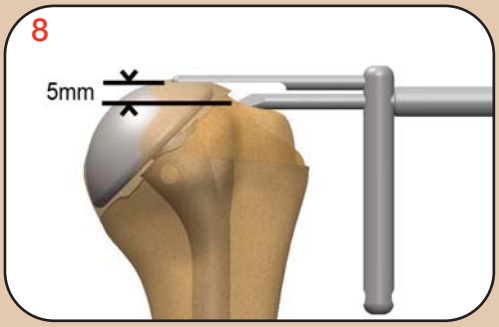
Insert the head onto the taper of the stem.
If an offset head is used (white), turn it to find the best position, i.e., the position that is closest to the anatomical structure.
Record the details so that this position can be used again for the definitive implant.



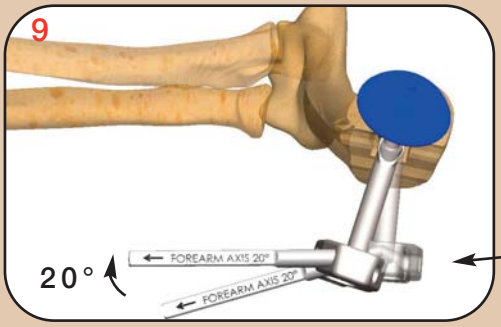
Height adjustment (height gauge):

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



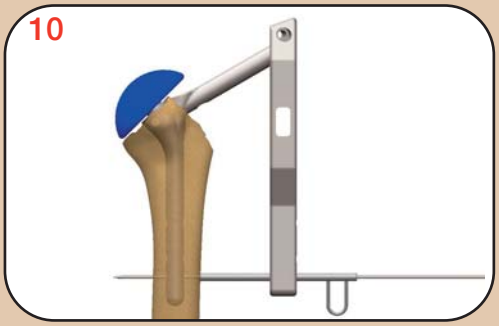
b) SUPERO-EXTERNAL APPROACH
This criteria applies when there is continuity between the diaphysis and the greater tuberosity.
Position the trocar at the top of the greater tuberosity.
The face of the top plate indicates the position for the top of the humeral head.
This position is best assessed by perioperative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



Retroversion adjustment:

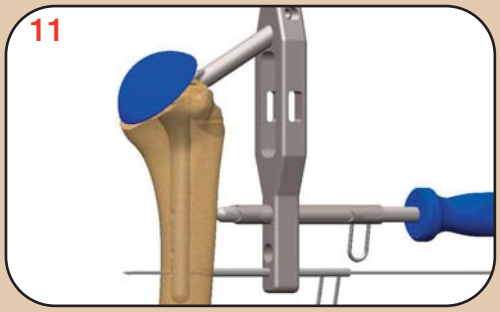
Mount the retroversion rod onto the aimer from the right- or left-hand side.
Position this rod parallel to the forearm to achieve 20° retroversion.

View from top: upper left limb.



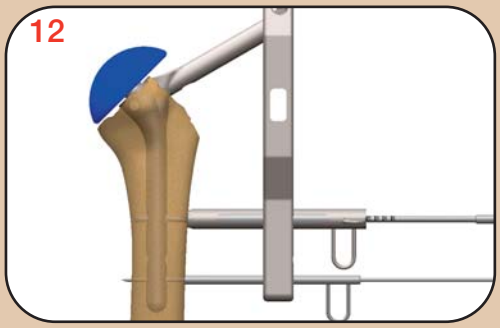
Stabilizing of height and retroversion:

Insert the Ø2.0 mm K-wire through the Ø2.2 mm guide to make contact with the second cortex.
Visually check the height and position of the stem by X-ray before interlocking with two screws.



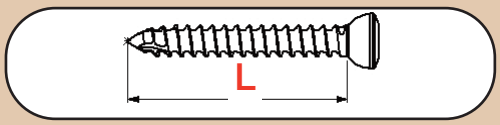
Proximal interlocking screw:

After having carefully dissected the soft tissue using Halstead forceps, insert the Ø10 mm guide into the top hole of the aimer until contact is made with the cortex using the soft-tissue holder.
Insert the Ø4.5 mm guide into the Ø10 mm guide.
Leave the distal K-wire in place.



Length of screws:

a) 1st method without a gauge:
Drill the 1st cortex with the measurer drill.
When in contact with the 2nd cortex, read the measurement and use screw size L + 4 mm.
Drill to the 2nd cortex.
b) 2nd method with gauge:
Drill up to and including the 2nd cortex.
Use the gauge to measure the screw length.
Use screw size L + 2 mm.



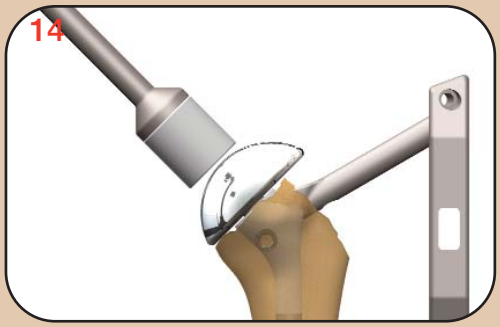
Screw length is measured from under the head.

Distal interlocking screw:

Proceed in the same way as for proximal interlocking screw leaving the K-wire in place.

Positioning of the definitive head:

Record the position of the offset head in relation to the arrow on the aimer.
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.



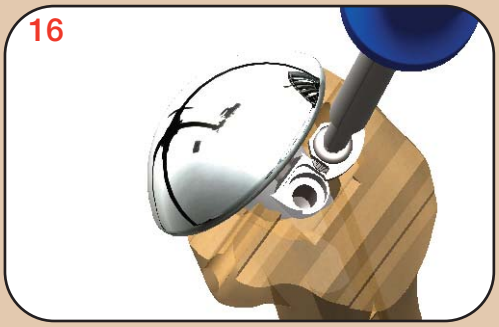
Impaction of the head:

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

Removal of the aimer:

Remove the aimer locking screw.
Remove the aimer.

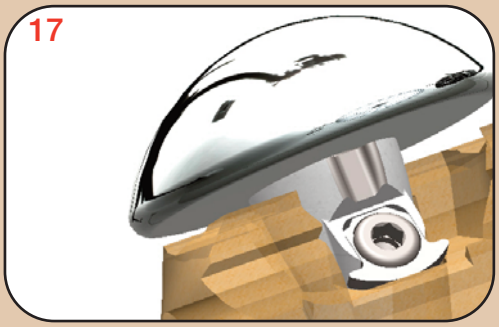
16



Set up the protector + screw:

Insert the screw with protector in the M6 thread of the stem by means of the 3.5 mm hex screwdriver.

17

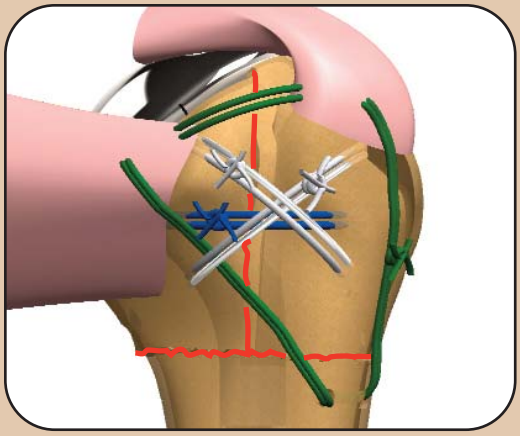


Insert the protector in the square of the stem.
Tighten the screw with the 3.5 mm hex screwdriver.

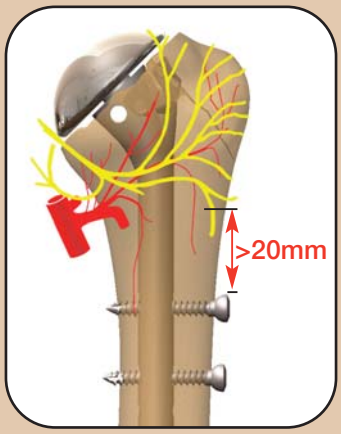
18

Humerus with prosthesis and tuberosities in place.

To suture the tuberosities, consult surgical technique TP07.



TIPS AND TRICKS



Interlocking screws:

For obese patients, you can attach an absorbable suture to the screw head in order not to lose the screw in the fatty tissue.

Interlocking screws in relation to the axillary nerve and the circumflex artery:

The interlocking screws of a correctly positioned prosthesis are at a distance from the axillary nerve.

If your soft tissue pusher is at the inflexion point of the trochiterian curve, the implant height is probably incorrect.

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.

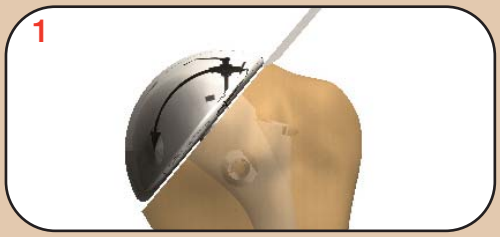
Anti-inflammatories may be taken for one week for relief of pain due to the removal of adhesions.

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).

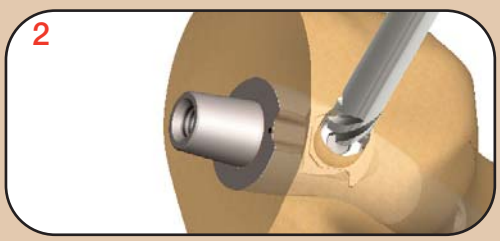
The optimal functional result is generally only acquired after the 6th post-operative month.

IMPLANT REMOVAL



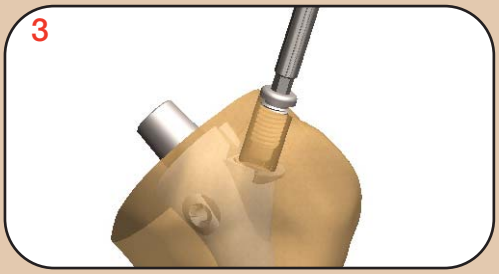
Humeral head removal:

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



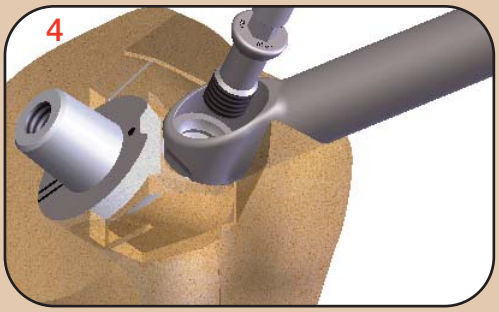
Release M6 thread:

Free the 3.5 mm hex screw from the bone and / or bone graft with Ø 4.5 mm drill.



Screw removal:

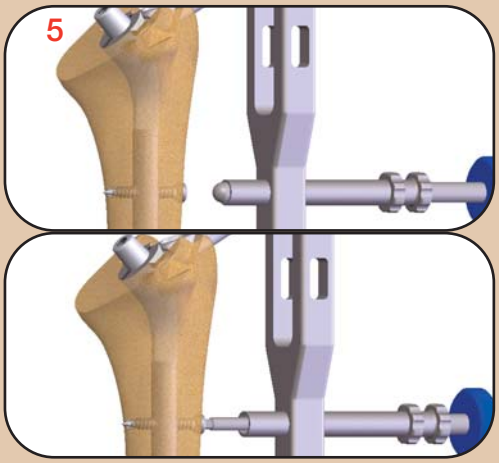
Remove the screw with the 3.5 mm hex screwdriver.



Mounting the aimer (option):

Screw the aimer 908-0056 + 107-0056 onto the implant and tighten the «implant + aimer» mount if it is a Humelock.

Check that the central peg is correctly seated at the center of the stem.



Extraction of the locking screws (option):

After having carefully dissected the soft tissue using Halsted forceps, insert the Ø 10 mm guide into the top hole of the aimer until contact is made with the cortex using the soft-tissue holder.

Insert the screwdriver into Ø 10 mm guide and remove the screw.

Repeat the procedure for the distal hole.

Extraction of the stem:

Screw the extractor with hammer into the threaded hole of the stem.
Remove the stem.
If it does not remove easily, make a vertical corticotomy and loosen the complete circumference of the stem from the cut bone.

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