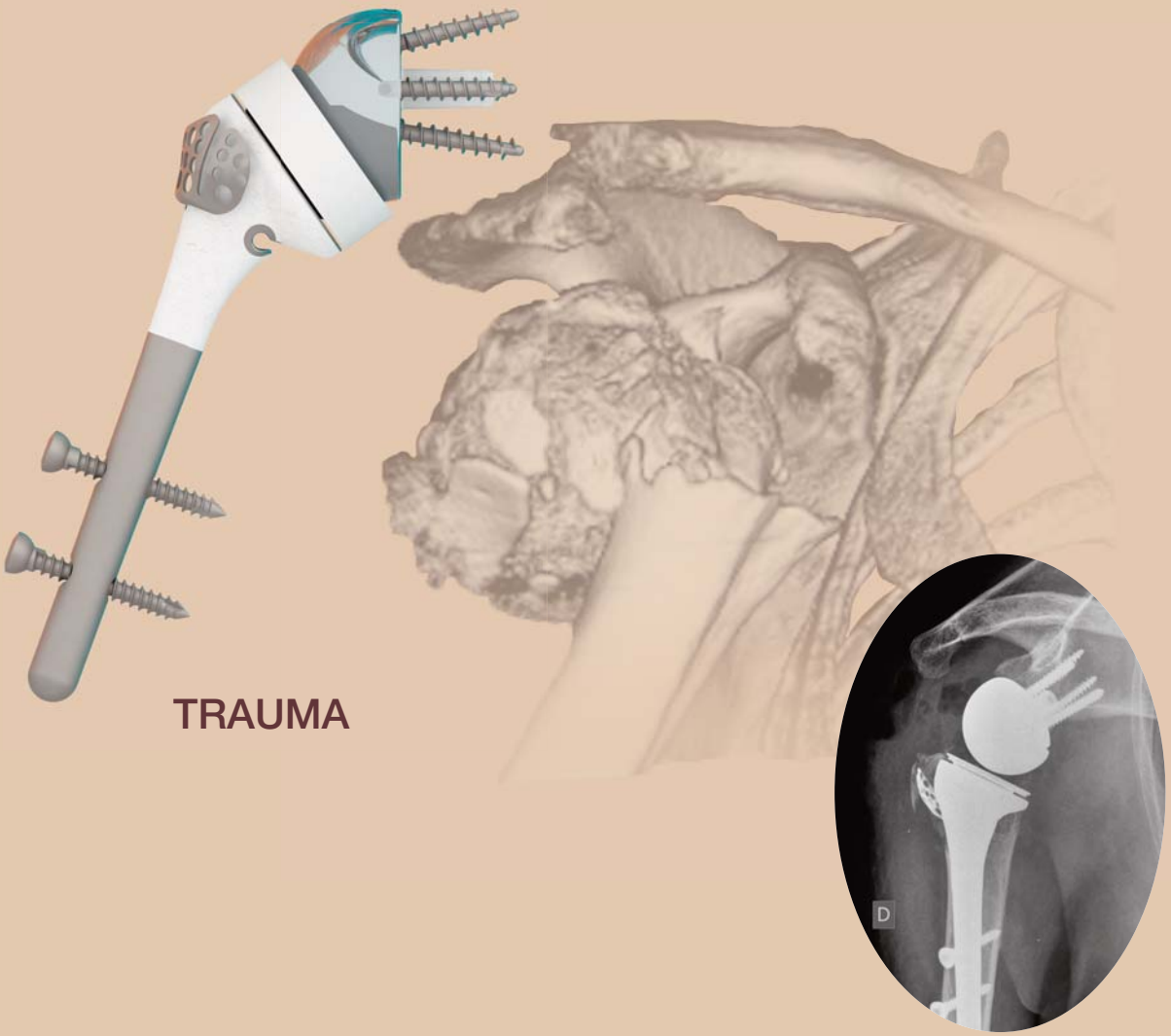
HUMELOCK™
REVERSED



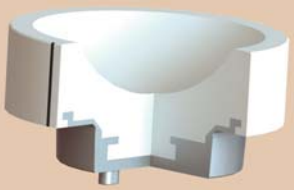
TRAUMA

SURGICAL TECHNIQUE

FX SOLUTIONS

CHARACTERISTICS, TIPS AND TRICKS

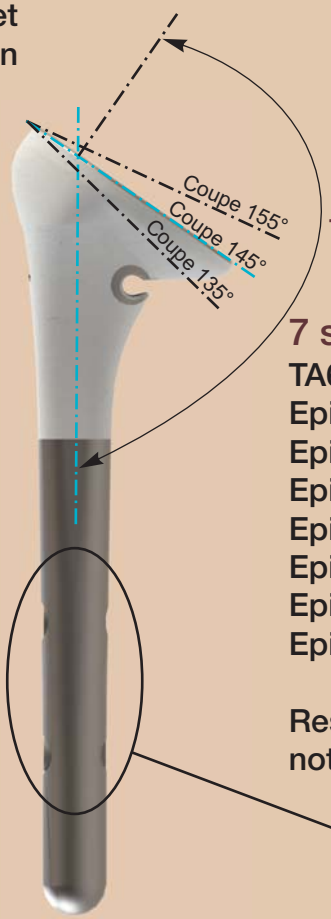
Index for offset of humeral cup = adaptation to posterior offset or in case of epiphyseal malunion (revision).



Humeral cup:

Thermocompressed poly UHMWPE in titanium shell
3 available heights (+3, 6, +9mm) + spacer (+9mm)

Stem designed with an anatomical shape giving intrinsic stability:
Fluted in diaphysis,
Belled in metaphysis,
Filling in epiphysis.

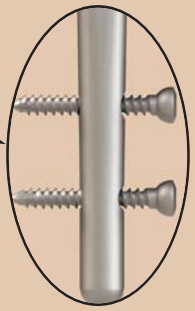


7 sizes of humeral stems*:

TA6V ELI / Ti + HA coated
Epiphysis Ø32 mm - diaphysis Ø08 mm
Epiphysis Ø32 mm - diaphysis Ø10 mm
Epiphysis Ø32 mm - diaphysis Ø12 mm
Epiphysis Ø36 mm - diaphysis Ø10 mm
Epiphysis Ø36 mm - diaphysis Ø12 mm
Epiphysis Ø36 mm - diaphysis Ø14 mm
Epiphysis Ø40 mm - diaphysis Ø12 mm

Resection at 145° = protection of scapula notching.

T40 cage* allowing molding to fit epiphysis.
3 sizes: 32/36 mm, 36/40 mm and 40/44 mm.

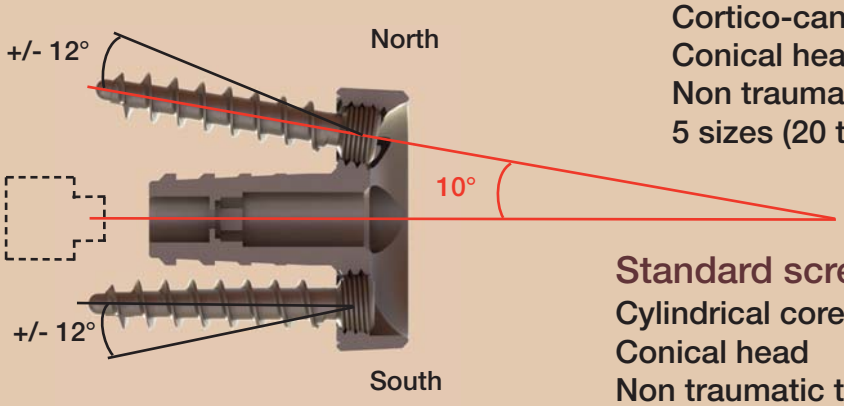


Self-stable stem (pressfit) but cementable or lockable in the event of instability.

Modularity of the prosthesis:

Humeral stem (Ø32, 36, 40) →
- Standard cup Ø36 or 40 +3 mm
- Standard cup Ø36 or 40 +6 mm
- Standard cup Ø36 or 40 +9 mm

→ Glenosphere Ø36 / Glenosphere Ø40 ⟹ 42 options due to different sizes of humeral stems: see above



Locking screw Ø4.5 TA6V ELI :

Cortico-cancellous (conical core)
Conical head
Non traumatic tip
5 sizes (20 to 40 mm)

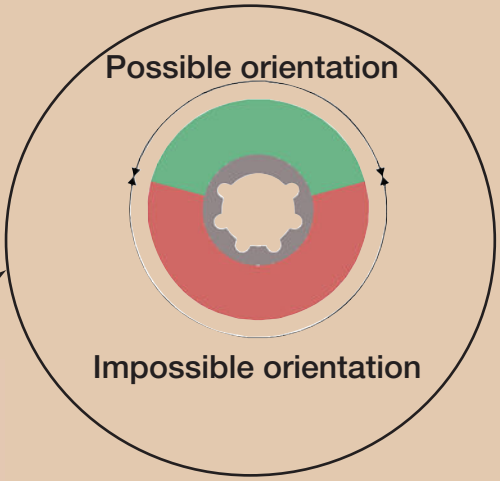
Standard screw Ø4.5 TA6V ELI :

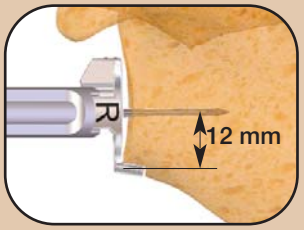
Cylindrical core
Conical head
Non traumatic tip
5 sizes (20 to 40 mm)

Baseplate Ø24 mm :

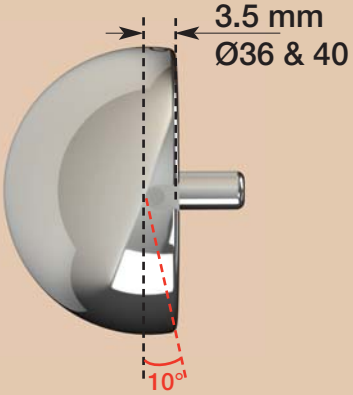
Fits all anatomies
TA6V ELI / Ti + HA coated
Conical assembly
4 cylindrical threaded holes
2 extensions of +6 and +10 mm for lateralization and revisions.

Directive locking & variable angle screw system*





Implantation at 12 mm from inferior edge of the scapula



Tilt = 10°

CoCr glenosphere*:

2 sizes: Ø36, Ø40 mm
Centered or eccentric (3 mm)
Impacted with or without screw
Conical grooved impaction.

* Patented

		Ø36	Ø40
Impacted	Centered	X	X
	Eccentric	X	X
With screw	Centered	X	X
	Eccentric	X	X

CONTENTS

INTRODUCTION

Humelock™ Reversed is a new generation of reversed prosthesis, designed for numerous shoulder pathologies: ranging from offset arthritis to a complex cephalotuberosity fracture in a subject over 70 years. The technical characteristics of this implant have been designed based on computer simulations, correlated to results previously published in medical journals, in order to avoid the disadvantages of traditional reverse prostheses.

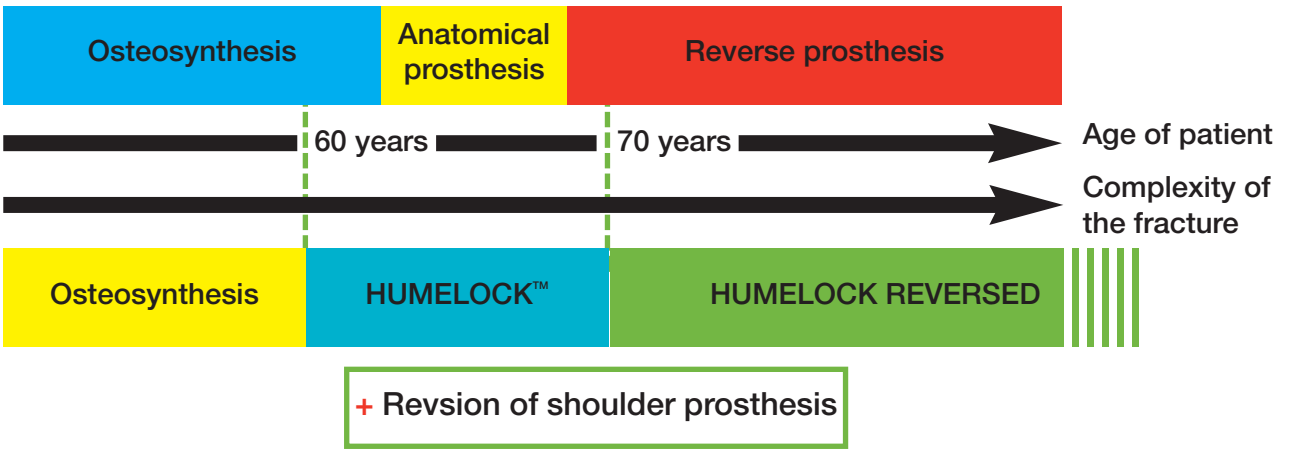
A centric or eccentric glenosphere, tilted at 10°, centered on a variable length baseplate post (compatible with positioning techniques), the position of which is guided by an intuitive adaptive instrumentation.
A 145° prosthetic epiphysis allows the pillar of the scapula to be protected while maintaining optimum stability.

The humeral implant is positioned naturally in the center of the epiphysis, preserving the remaining bone as much as possible. However, the options of locking or cementing will allow the surgeon to position the prosthetic stem at the required height, according to the patient's indication and anatomy.

Humelock™ Reversed is a totally modern implant, designed to adapt to the new lifestyles of older, increasingly active, patients for a longer timeframe.

INDICATIONS

Classical indications for anatomical prostheses in cephalotuberosity fractures:



PATIENT POSITIONING

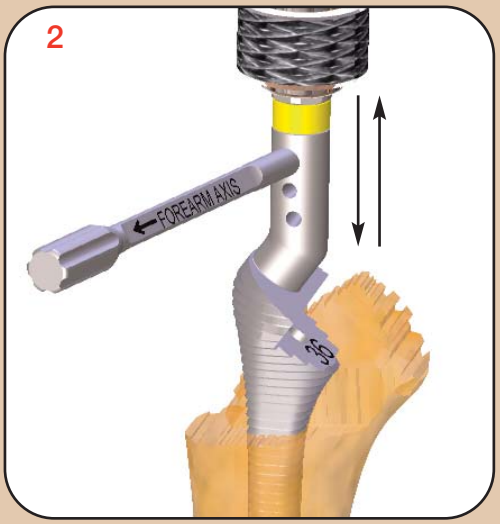
The recommended patient positioning is a beach chair with a member free in the operating area and the head fixed in position.

X-ray imaging must be available to confirm implants position intraoperatively.

SURGICAL TECHNIQUE - HUMERUS

Preparation of the humeral shaft:

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 stem choice is made depending on the last reamer size used:
Ø08 mm --> Stem with an epiphysis of Ø32 mm;
Ø10 mm --> Stem with an epiphysis of Ø32 or 36 mm;
Ø12 mm --> Stem with an epiphysis of Ø32, 36 or 40 mm;
Ø14 mm --> Stem with an epiphysis of Ø36 mm.



Metaphyseal preparation (OPTION):

Use the metaphyseal rasps in order of increasing size while also checking the retroversion.
The size of the metaphysis is determined by the size of the last reamer used.
Ø08 mm --> Stem with an epiphysis of Ø32 mm;
Ø10 mm --> Stem with an epiphysis of Ø32 or 36 mm;
Ø12 mm --> Stem with an epiphysis of Ø32, 36 or 40 mm;
Ø14 mm --> Stem with an epiphysis of Ø40 mm;
Connect the rasp to the T handle.
Screw the retroversion stem onto the rasp.
Impact the rasp until it is flush with the height of the resected bone surface.
The rasps have to be used as templates and no as rasps.

Epiphyseal preparation (OPTION):

Use the same size epiphyseal rasp as the metaphyseal rasp. The metaphyseal and epiphyseal rasps are color coded.

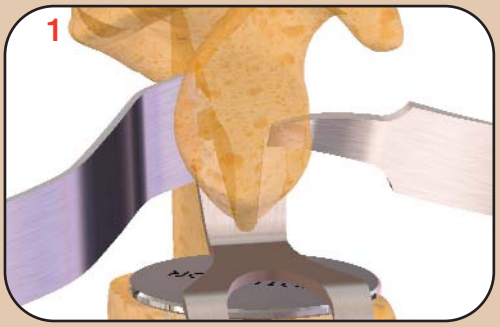
Unfasten the inside part of the rasp and fit the epiphyseal rasp in the designated hole.

Maintain the metaphyseal rasp using the special wrench.
Shape the epiphysis up to the height of the metaphyseal rasp.

Humerus protection:

Insert the protector into the prepared humerus during the glenoid preparation.

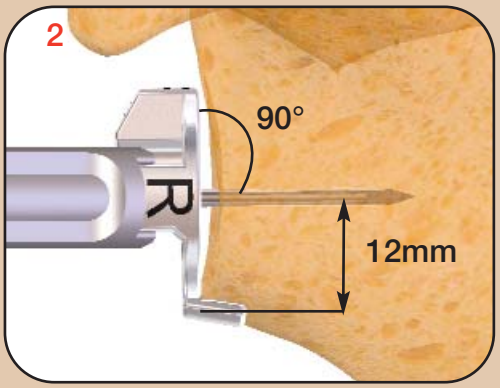
SURGICAL TECHNIQUE - GLENOID

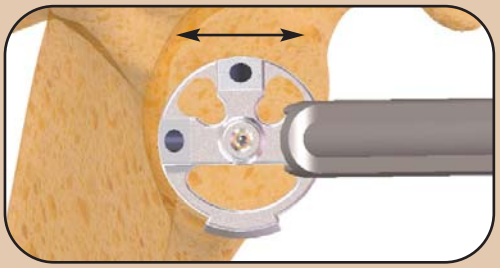


Glenoid exposure :

Expose the glenoid fully using the three types of retractors.
- Anterior retractor,
- Superior retractor,
- Inferior retractor.

Remove the glenoid labrum.
Remove any potential osteophytes to expose the full bone anatomy.

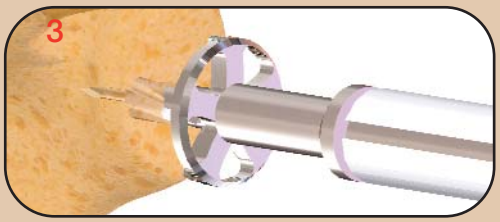




Placing the K-wire:

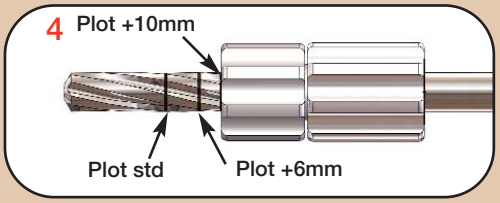
Three different positions for the guide: Left (L), Right (R) for a deltopectoral approach and Superior lateral (S).
Position the K-wire guide on the inferior part of the glenoid to determine the correct height.
The K-wire is 12 mm above the lower edge, according to Kelly[2] and must be centered in the antero-posterior plane.
The K-wire guide orientation is important for the glenoid tilt and must be done at 90°. (see picture #2).
The glenospheres are tilted (lower lip) by 10°.
Positioning should be to fit the anatomy of the patient and planned according to the pre-operative X rays.
This element must be decided in pre-operative planning. By default, the base plate is perpendicular to the mid plane of the glenoid.
Insert the K-wire using a power tool.

(2) Kelly JD, Humphrey CS, Norris TR. Optimizing glenosphere position and fixation in reverse shoulder arthroplasty, Part One: the twelve-mm rule. J Shoulder Elbow Surg 2008;17:589-94



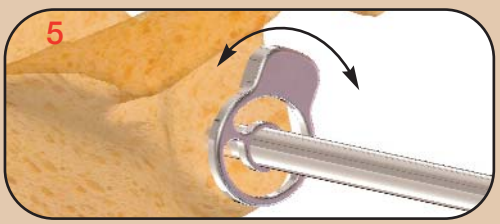
Glenoid reaming:

Drill and ream the glenoid using the K-wire guide.
Ream until the subchondral bone is reached.
This step can be done by power or by hand if the glenoid is porotic.



Extension post:

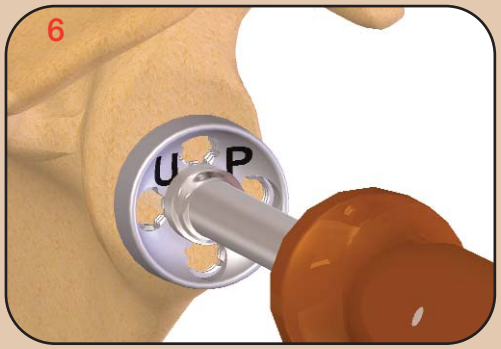
In the case of revision or lateralisation of the center of rotation with a graft from the pillar of the scapula, it is possible to extend the post by 6 or 10 mm.
Tighten the block-stop in the correct position by screwing it onto the drill to either 6 mm or 10 mm, as required.
Drill the post again with block stop in position.



Glenoid clearance:

Remove the K-wire.
To avoid any interference between the glenosphere and the scapula, ream the glenoid using the Ø40 mm hand reamer.

Pay attention to avoid ovalizing the post hole.
360° clearance = succesfull impaction of the glenosphere.



Positioning the baseplate :

Connect the holder / impactor to the baseplate. Impact the baseplate so that there is pressure over the whole surface.
The impactor allows for the upper and lower holes to be placed so that a screw can be positioned in the base of the coracoid and in the pillar of the scapula.

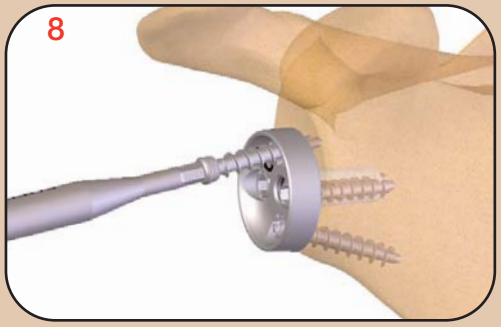
The sign (UP) must be on top under the coracoid basis.

Remove the K-wire.

Length of screws (5 sizes from 20 to 40 mm) :

An adapted guide allows for the holes to be drilled and the length of the screws measured with the Ø 3.2 mm drill bit. The length of the screws are measured directly.

The screw length is measured from under the head.
Two types of screws are available, locking or standard.



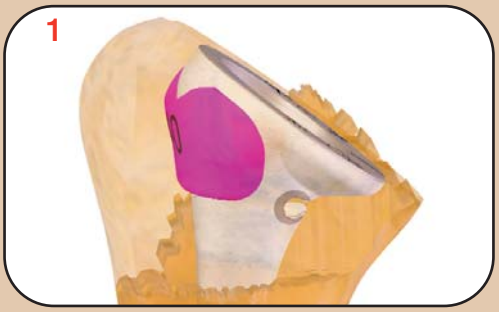
Fixation of the baseplate:

Standard screws allow the baseplate to be lagged to the bone, and locking screws fix the mounting.
Each screw allows an angulation of +/-12° around the axial hole.
The upper hole for the first screw is pre-oriented by 10° to optimise its positioning in the base of the coracoid.

Recommendations:

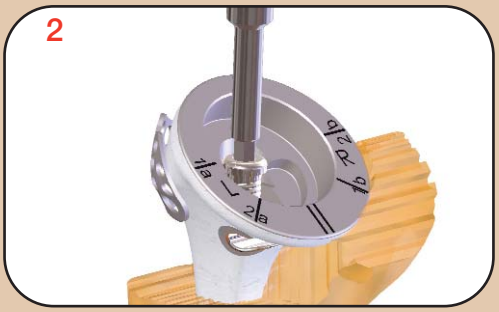
2 compression screws (std) for anterior and posterior holes.
2 locking screws for superior and inferior holes.

OPTION: CAGE AND/OR LOCKING



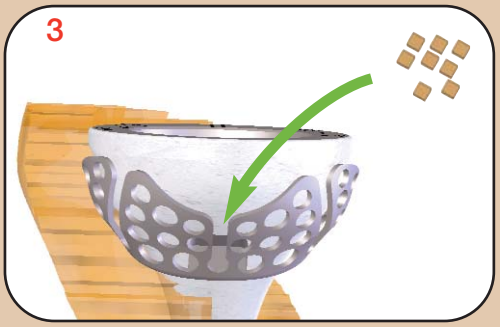
Choice of the cage size:

Use the trials in order of increasing sizes.
The cage allows for the metaphysis to be increased at the anterio-posterior and lateral level.
It therefore allows for a homogeneous epiphyseal mass to be reconstructed.



Fitting of the definitive cage:

Fit the appropriate implant to the stem.
Secure using the screw provided with the Hex 3.5 mm screwdriver.



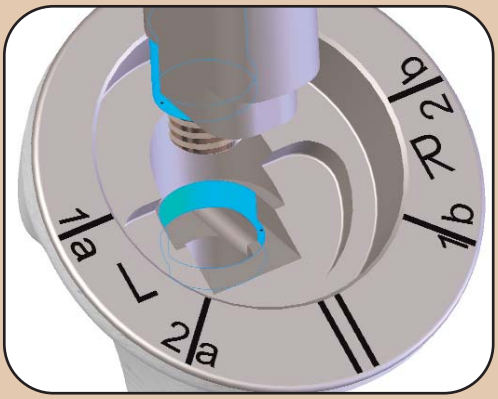
Filling the cage:

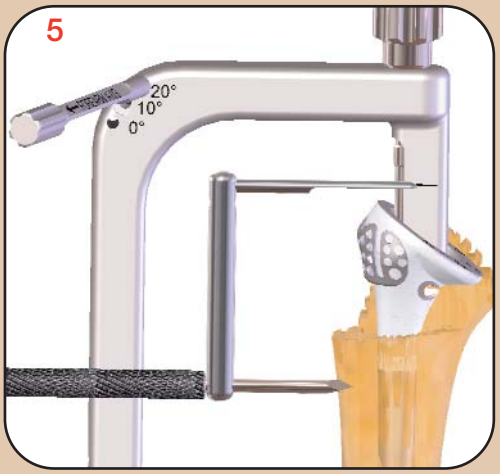
Use small autograft cubes (5mm) taken from the native head to fill the cage.
The cage, made of T40 titanium, allows for optimized epiphyseal filling in patients with osteoporosis.
For these patients one may not wish to cement the stem but preserve maximum bone contact.

For locked stem option:

Remove the cage screw. It will be replaced after locking is finished.
Screw the aimer (jig) into the threaded hole of the stem.
Check if the pin is correctly located in its housing within the stem.

Tighten the screw of the mounting «implant + aimer (jig)».

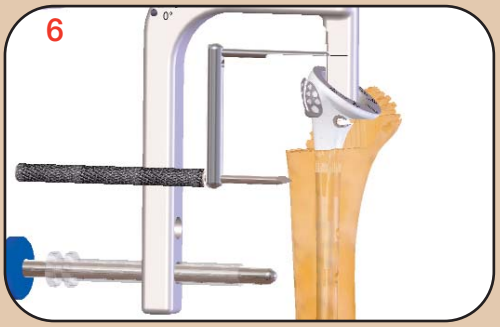




The retroversion is determined by screwing the rod into one of 3 positions (0, 10, 20°) and aligning it with the arm.
Use the Muraschosky[1] criteria to set the height of the implant.

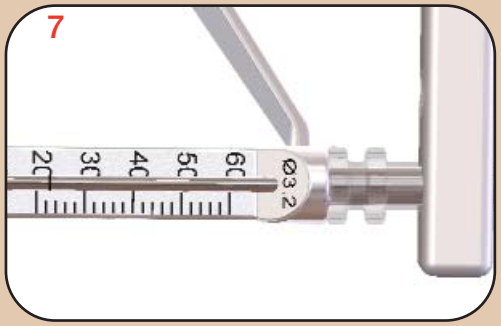
(1) Murachowsky J et al. JSES 06; Torrens C et al. JSES 08; Hasan SA et al. Orthopedics 09

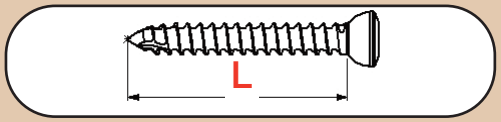
If epiphysis and/or metaphysis is totally damaged, it is better to use a cemented stem not to have all weight bearing on screws.



Proximal interlocking:

Carefully dissect the soft tissue using Halstead forceps.
Insert the Ø10mm guide into the top hole of the aimer (jig), using the soft tissue protector, until contact is made with the cortex.
Insert the Ø4.5mm guide into the Ø10mm guide.





Screws length (10 sizes):

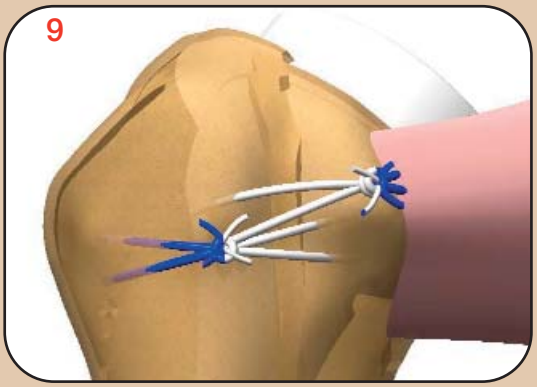
Without gauge, drill through first cortex using marked drill bit.
Stop at second cortex, measure and use a screw size 4 mm longer, ie L + 4 mm.
Drill through the second cortex.

Screw length is measured from under the head.

Distal interlocking:

Use the same method as proximal interlocking.

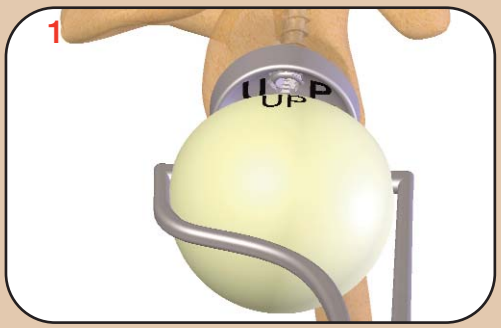
Remove aimer (jig) and replace cage screw.



Fitting of Smartloop sutures:

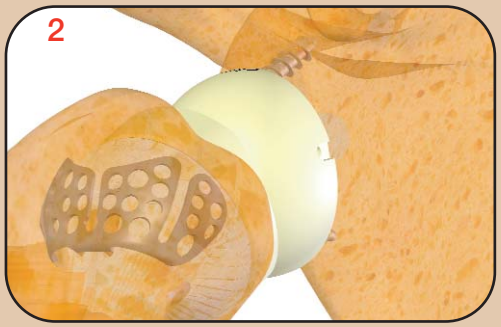
- 2 traction loops (white)
- 2 plating loops (blue)

TRIAL IMPLANTS



Glenosphere trial (10° tilt):

There are two diameters of glenospheres: Ø36 and 40mm.
All glenospheres are centered or eccentric with or without a screw.
The choice of glenosphere does not depend on the size of the humeral stem.
All glenospheres are tilted downwards by 10°.
For slim patients (BMI (W/S2)≤21) (Body Mass Index (weight / size²)), use of the Ø 40 mm glenosphere is recommended, where possible, particularly if the subject is male.
Position the glenosphere with the special clamp allowing the humerus to be circumvented by the delto-pectoral approach.



Cup trial:

The cup diameter matches the glenosphere diameter.
Three heights are available (+3, +6, +9 mm). If required a spacer (+9 mm) is available to add to the cup.

Take care to respect index marks on the stem and cup.

Test for stability and mobility.
Trials are identical to the final implants.

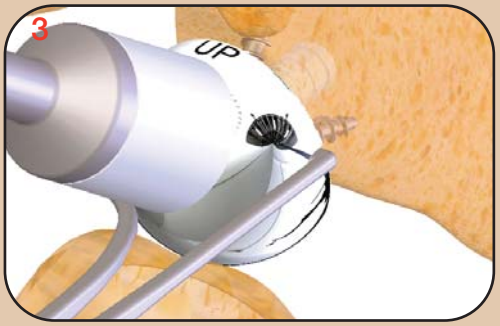
DEFINITIVE IMPLANTS

Handling of the definitive glenosphere:
Impacted glenosphere

Insert the glenosphere implant holder into the definitive implant. On the specially designed clamp, there are notches on the jaws which should be positioned to coincide with those on the middle of the glenosphere implant.

Handling of the definitive glenosphere w/screw:
Impacted glenosphere w/screw

Insert the 3.5mm hex screwdriver in the screw of the glenosphere.



Fitting of the definitive implants:
Impacted glenosphere

When positioning the glenosphere, pay attention to the "UP" marking, if an eccentric glenosphere is used.
First introduce the guiding post, then the female taper of the glenosphere into the male taper of the baseplate.
Be sure to check that the baseplate is clean and free of any bone or tissue particles that could hinder impaction of the morse taper.

Impact the glenosphere and check it before closure.

Fitting of the definitive implants:
Impacted glenosphere w/screw

Insert the glenosphere paying attention to the «UP» marking, if an eccentric glenosphere is used.
Introduce the screw of the glenosphere in the post of the baseplate.

Be sure to check that the baseplate is clean and free of any bone or tissue particles that could hinder impaction of the morse taper.

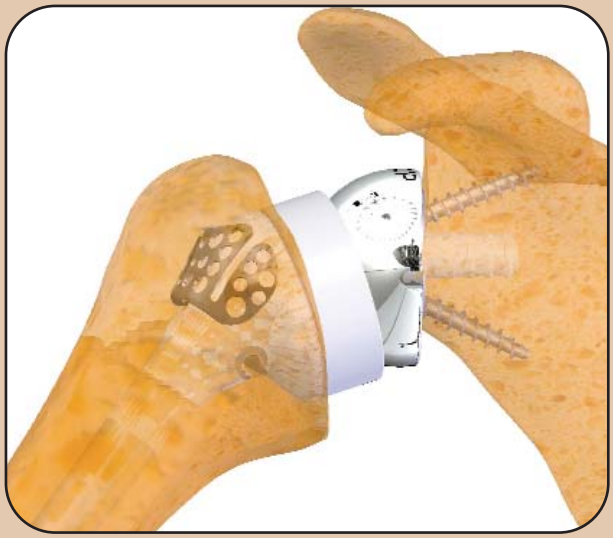
1- Begin to screw the glenosphere w/screw.
2- Impact the glenosphere with the impactor.
3- Finish screwing

Do not impact the glenosphere with the screwdriver.

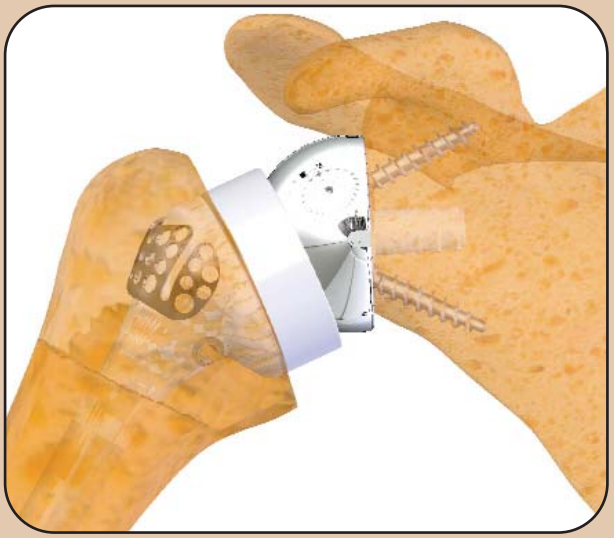
Index of the definitive reversed cup:

Find the index marks on both the definitive cup and the stem.
Position the cup so that the index matches the index on the stem.

Insert the cup into the taper of the stem so that indices of the cup and stem are correctly aligned.
Check there is nothing impeding impaction of the cup and impact it.



If the neck of the scapula is short, it is recommended to use an offset 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.

REHABILITATION

Short-term immobilisation (on the surgeon's assesment) with mobilization in neutral rotation to promote recovery of the external rotation.

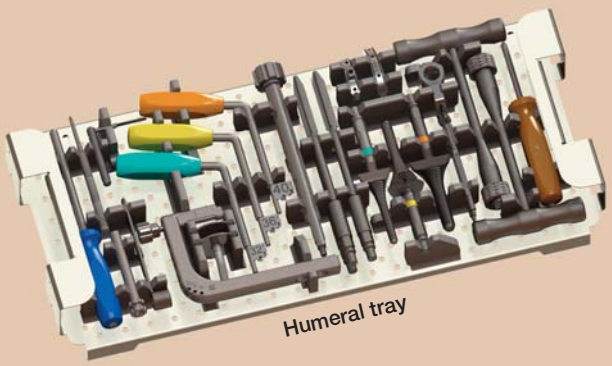
Promote balneotherapy and specialist rehabilitation, without counter-resistance work until the sixth week, depending on the age and objectives noted in the "patient contract".

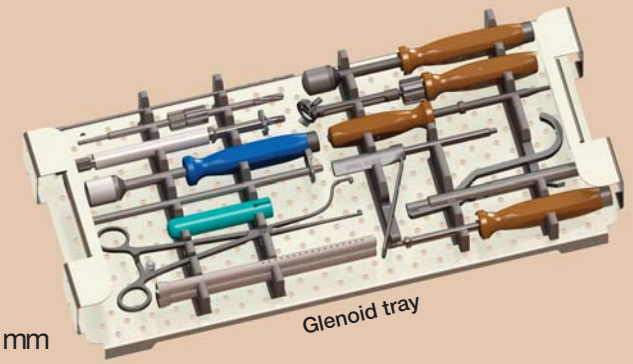
IMPLANTS

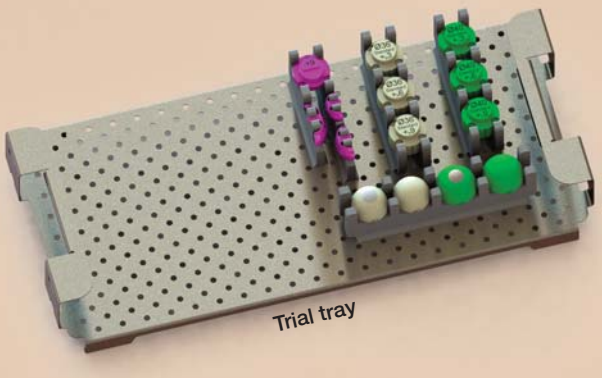
101-0000	Hex. 3.5 screw for OMS / cage
103-0007	Humeral spacer TA6V +9 mm
103-0803	Humeral cup std PE/TA6V Ø36/+3
103-0806	Humeral cup std PE/TA6V Ø36/+6
103-0809	Humeral cup std PE/TA6V Ø36/+9
104-0803	Humeral cup std PE/TA6V Ø40/+3
104-0806	Humeral cup std PE/TA6V Ø40/+6
104-0809	Humeral cup std PE/TA6V Ø40/+9
105-0006	Post extension TA6V +6 mm
105-0010	Post extension TA6V +10 mm
105-0024	Glenoid baseplate TA6V Ti/HA Ø24 mm
105-3600 *	Centered glenosphere CoCr 10° tilt Ø36 mm
105-3603	Eccentric glenosphere CoCr 10° tilt Ø36 mm
105-4000	Centered glenosphere CoCr 10° tilt Ø40 mm
105-4001	Eccentric glenosphere CoCr 10° tilt Ø40 mm
105-3610	Centered glenosphere w/ screw CoCr/TA6V 10° tilt Ø36 mm
105-3613	Eccentric glenosphere w/ screw CoCr/TA6V 10° tilt Ø36 mm
105-4010	Centered glenosphere w/ screw CoCr/TA6V 10° tilt Ø40 mm
105-4011	Eccentric glenosphere w/ screw CoCr/TA6V 10° tilt Ø40 mm
107-4518/4536	Corticale screw TA6V Ø4.5 mm L.18 to 36 mm inc. 2 mm
108-4520/4540	Polyaxial locking screw TA6V Ø4.5 mm L. 20 to 40 mm inc. 5 mm
109-4520/4540	Polyaxial standard screw TA6V Ø4.5 mm L.20 to 40 mm inc. 5 mm
108-3632	Cage T40 R36/Ø32 mm
108-4036	Cage T40 R40/Ø36 mm
108-4440	Cage T40 R44/Ø40 mm
312-3208	Stem TA6V cementless Ø32/08 Ti/HA
312-3210	Stem TA6V cementless Ø32/10 Ti/HA
312-3212	Stem TA6V cementless Ø32/12 Ti/HA
312-3610	Stem TA6V cementless Ø36/10 Ti/HA
312-3612	Stem TA6V cementless Ø36/12 Ti/HA
312-3614	Stem TA6V cementless Ø36/14 Ti/HA
312-4012	Stem TA6V cementless Ø40/12 Ti/HA

* Glenospheres are also available in CoCr / TiN coated.

INSTRUMENTS


Humeral tray


Glenoid tray


Trial tray

FX SOLUTIONS

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

TP09-EN-17/05/16