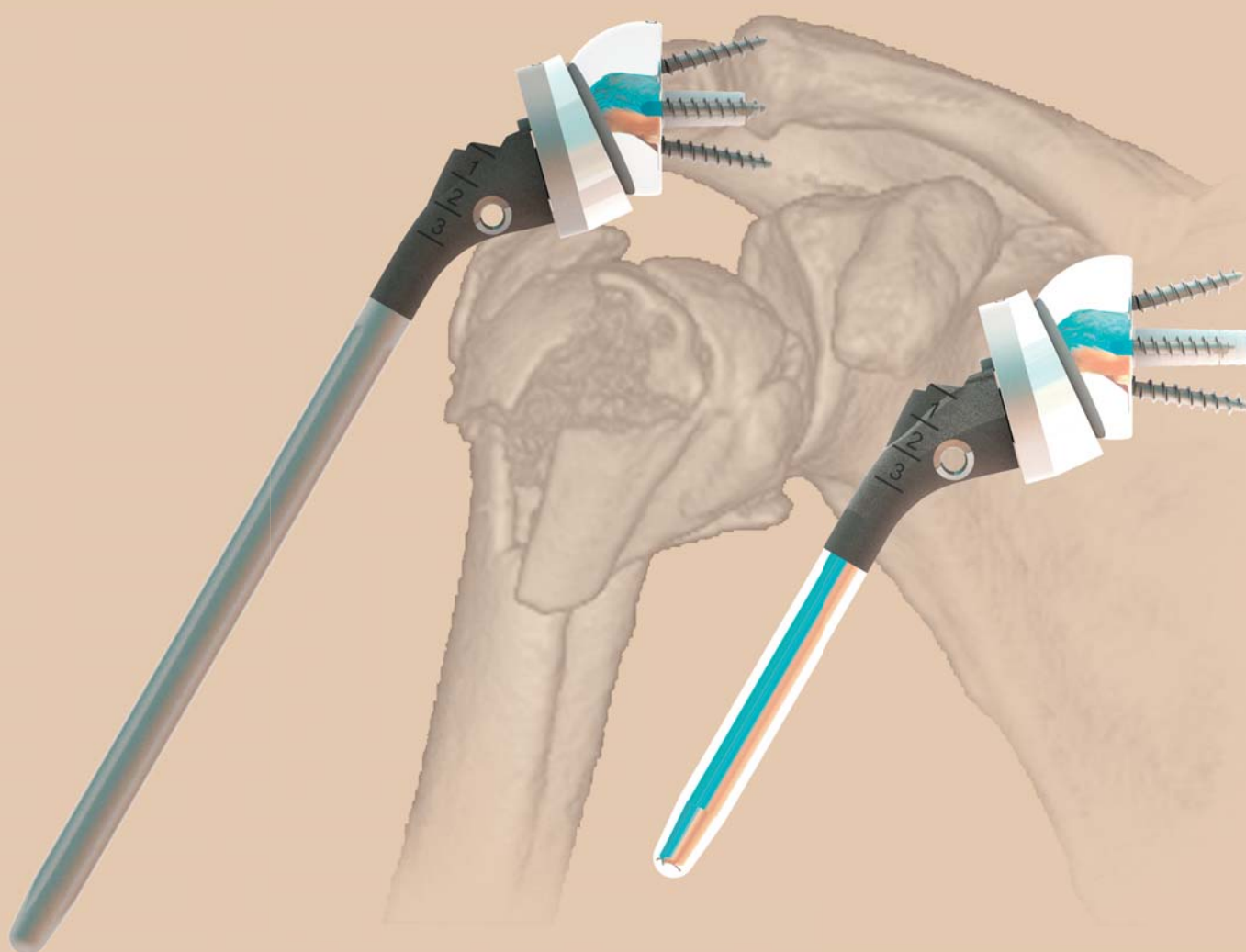




HUMELock™ II CEMENTED REVERSIBLE



SURGICAL TECHNIQUE

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PROPERTIES

HUMELOCK™ II cemented is a new-generation of modular implant designed for the efficacious treatment of fractures of the proximal humerus.

HUMELOCK™ II cemented 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 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 compatible components. The Humelock II Cemented Humeral Stems can be used with the following components for use in a reversible shoulder configuration.

The humeral cup and 135/145 humeral cup are manufactured from UHMWPE conforming to ISO 5834-2 and Ti-6Al-4V alloy conforming to ISO 5832-3. There are two sizes (Ø36 and 40 mm). If the humeral cup is used, it must be used with a 135/145 adaptor.

Each size is available in two versions. Each version is available in three heights (+3, +6, +9 mm) and is compatible with all sizes of humeral stems. A male taper allows attachment of the 135/145 cup to the humeral stem or the humeral cup to the 135/145 adaptor.

The glenosphere component is manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and is available in diameters of 36 and 40mm in centered and eccentric versions. A female taper allows attachment to the baseplate. The glenosphere component is also available with a screw which can be used for additional security in attaching the glenosphere to the baseplate. The glenosphere screw is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. Glenospheres with screws are also available in diameters of 36 and 40 mm in centered and eccentric versions.

A female taper allows attachment to the baseplate.

The baseplate component is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. The undersurface has a plasma sprayed commercially pure Titanium (CP Ti) and a hydroxyapatite (HA) coating. The baseplate has four threaded screw holes for adjunctive fixation using bone screws. One size is available (24 mm) and is compatible with all sizes and styles of glenosphere.

Bone screws are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and are available in two versions: Standard screws (compression) and Locking screws. Each version is available in lengths from 20 to 50 mm in 2 mm increments.



INTENDED USE / INDICATIONS

The Humelock II Reversible Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

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

The humeral component is intended for cemented use only. The metaglène baseplate component is intended for cementless use with the addition of screws for fixation.

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.

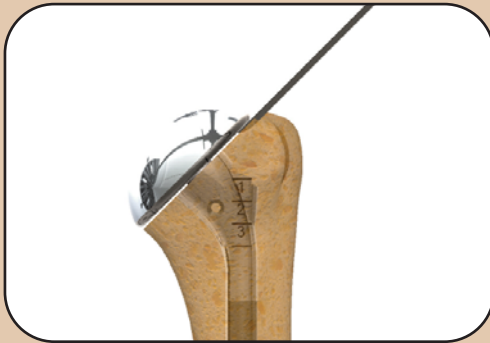
Instruments must not undergo accelerated autoclave sterilization inside the instrument box.

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

IF REVISION:



Anatomical implant removal:

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

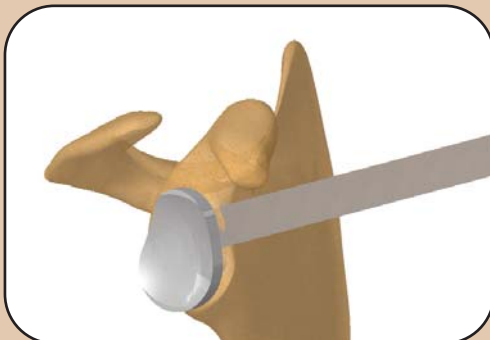
Remove the double taper by screwing the extractor in and backing the extractor out with a hammer.

Remove the glenoid by sliding a Powells blade between the implant and bone.



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IF PRIMARY:

Refer to surgical technique (TP51) of Humelock II cemented.

Follow steps 1 to 7 of TP51 without impacting the double taper (pages 3 and 4).

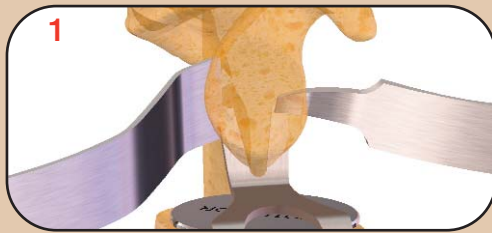
Then begin at step 1 (page 5) and follow this surgical technique (TP55).

IF TRAUMA:

Refer to surgical technique (TP51) of Humelock II cemented or (TP59) of Humelock II cemented + graft, if a graft is needed.

Follow steps 1 to 4 (page 6) of TP51 or steps 1 to 12 of TP59 without impacting the double taper or humeral head.

Then begin at step 1 (page 5) and follow this surgical technique (TP55).



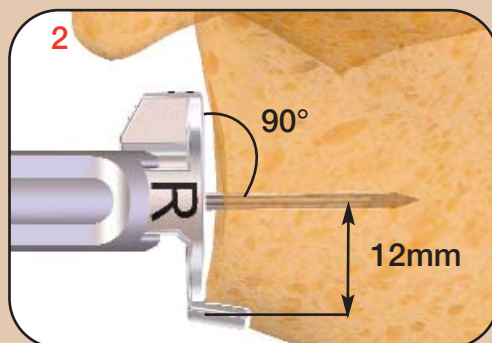
Glenoid exposure :

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 Kelly¹ and must be centered in the antero-posterior plane.

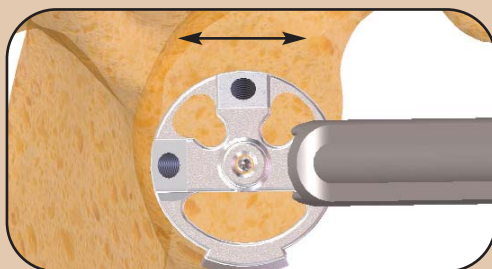
The K-wire guide orientation is important for the glenoid tilt and must be done at 90°. (see picture #2).

The glenospheres are tilted (lower lip) by 10°.

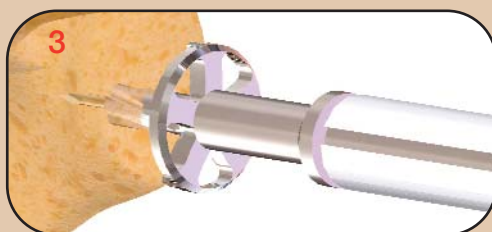
Positioning should be to fit the anatomy of the patient and planned according to the pre-operative X rays.

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.



(1) 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

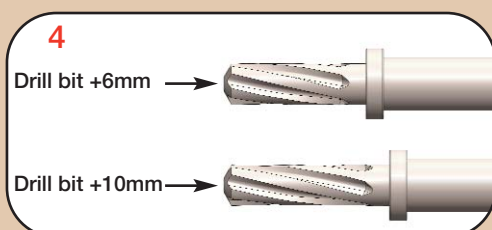


Glenoid reaming:

Drill and ream the glenoid using the K-wire guide.

Ream until the subchondral bone is reached.

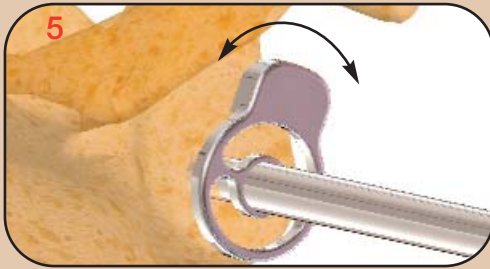
This step can be done by power or by hand if the glenoid is porotic.



Extension post:

In case of revision or lateralization of the center of rotation with a graft from the pillar of the scapula, it is possible to extend the baseplate post by 6 or 10 mm.

Drill the post again with the stop drill bit either +6 mm or +10 mm as required.



Glenoid clearance:

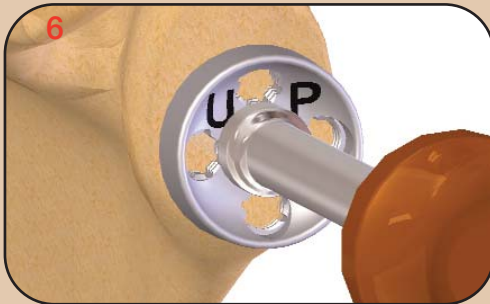
Remove the K-wire.

To avoid any interference between the glenosphere and the scapula, ream the superior and inferior parts of the glenoid using the Ø40 mm hand reamer.



Pay attention to avoid ovalizing the post hole.

360° clearance = successful impaction of the glenosphere.



Positioning the baseplate: (Ø24 mm)

Connect the holder/impactor to the baseplate.

Impact the baseplate so that there is pressure on 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 UP marking must be on top under the coracoid basis.



Length of screws (16 sizes from 20 to 50 mm) :

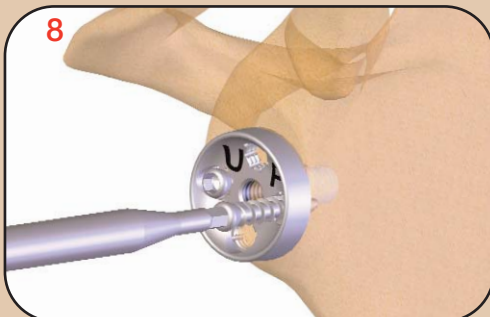
An adapted guide allows for the holes to be drilled and the length of the screws measured with the Ø 3.2 mm drill bit.

The length of the screws is measured directly.

It is possible to drill up to the 2nd cortex and use the gauge to measure the screw length.

The screw length is measured from under the head.

Two types of screws are available, locking or standard (compression).

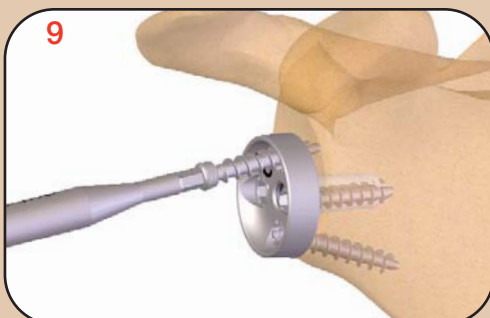


Fixation of the baseplate: (Ø24 mm)

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 optimize its positioning in the base of the coracoid.



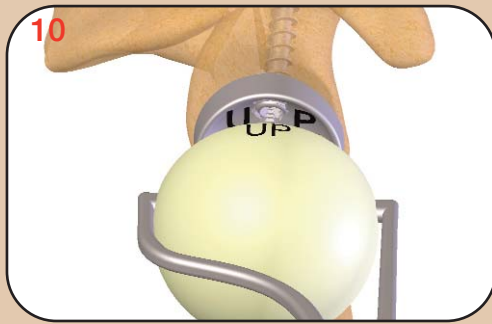
Recommendations:

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

2 locking screws for superior and inferior holes.



TRIAL IMPLANTS



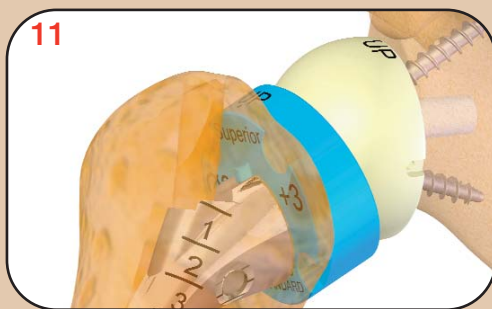
Glenosphere trial (10° tilt):

There are two diameters of glenospheres: Ø36 and 40 mm. 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.



135/145° cup trial:

The cup diameter matches the glenosphere diameter.

Three heights are available (+3, +6, +9 mm).

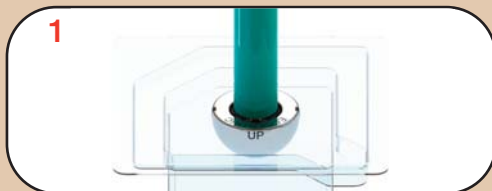


Take care to respect index marks on the stem and cup.

Test for stability and mobility.

Trials are identical to final implants.

DEFINITIVE IMPLANTS



Handling of the definitive glenosphere:

Impacted glenosphere

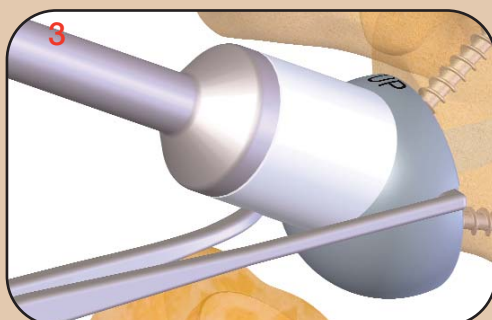
Insert the glenosphere implant holder into the definitive implant. On the specially designed clamp, there are notches on the jaws which should be positioned to coincide with those on the middle of the glenosphere implant.



Handling of the definitive glenosphere w/screw:

Impacted glenosphere w/screw

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



Fitting of the definitive implants:

Impacted glenosphere

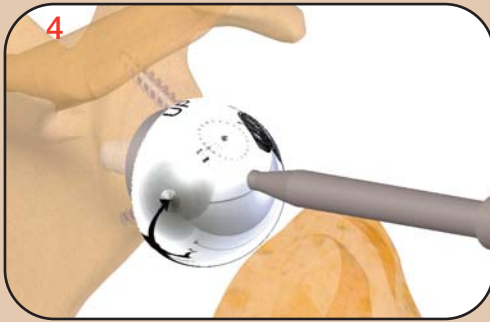
When positioning the glenosphere, pay attention to the "UP" marking, if an eccentric glenosphere is used.

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.

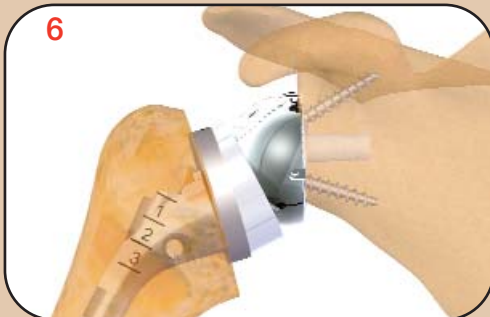
- 1- Begin to screw the glenosphere w/screw.
- 2- Impact the glenosphere with the impactor.
- 3- Finish screwing



Index of the definitive cup 135/145°:

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.



Definitive implants.

REHABILITATION

Short-term immobilization (according to the surgeon's assessment) with mobilization in neutral rotation 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".

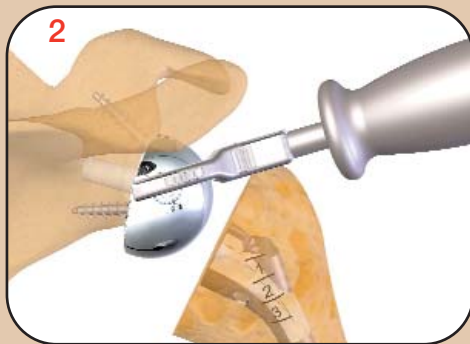


IMPLANT REMOVAL



Humeral cup removal:

Remove the cup by sliding a Powells blade between the cup and the stem.



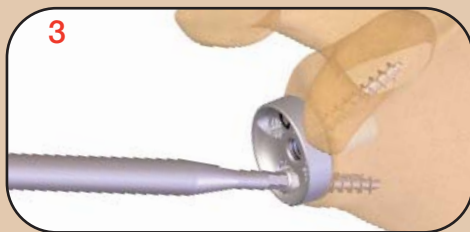
Glenosphere removal:

Unscrew the glenosphere screw, if there is one, with the 3.5 mm hex screwdriver.

Screw the arch with the corresponding \varnothing to remove the glenosphere onto the extractor.

Pass the spurs onto the internal face of the glenosphere to fit them in the designed notches.

Separate tapers with the sliding hammer.



Baseplate removal:

Unscrew the baseplate screws with the 3.5 mm hex screwdriver.



Screw the extractor into the baseplate post and remove it.



Release M6 thread:

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



Stem removal:

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

