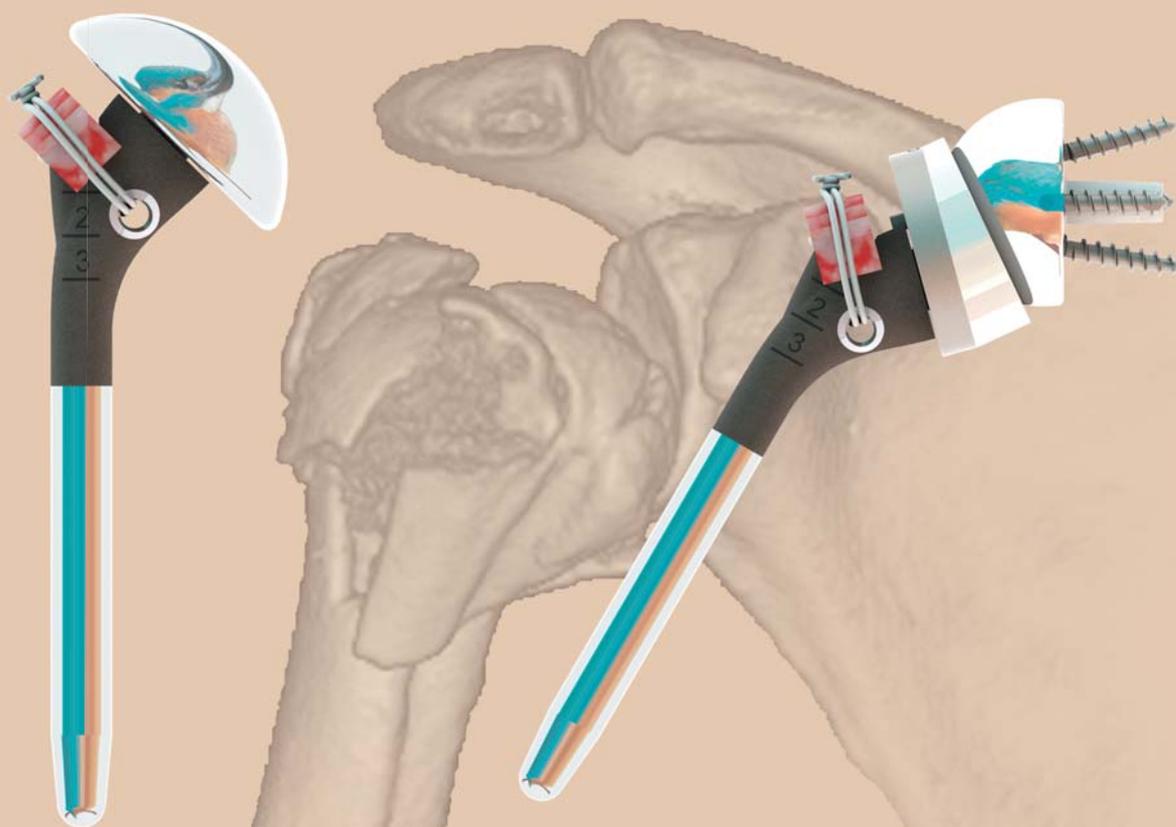




TM

HUMELock II

Cemented + Graft
ANATOMICAL and REVERSIBLE if REVISION



SURGICAL TECHNIQUE

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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 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.

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.

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. Glenspheres 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 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.

Bone graft cutting and manipulating instruments and graft trials may be used to cut bone graft from the humeral head and position it around the humeral stem. The bone graft can be used to help position and consolidate the tuberosities in cases with proximal bone loss.



INTENDED USE / INDICATIONS

In an anatomical shoulder configuration, 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.

In a reversible shoulder configuration, the Humelock II Cemented 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 stem is intended for cemented use only. The metaglene 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

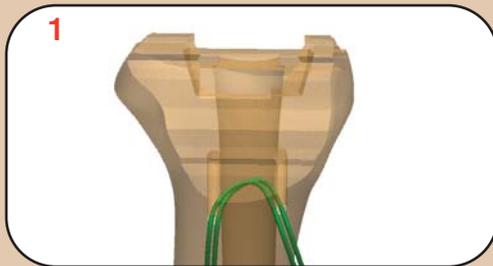
Unless otherwise indicated, instrument sets are sold non-sterile and must be completely cleaned and sterilized before use.

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.

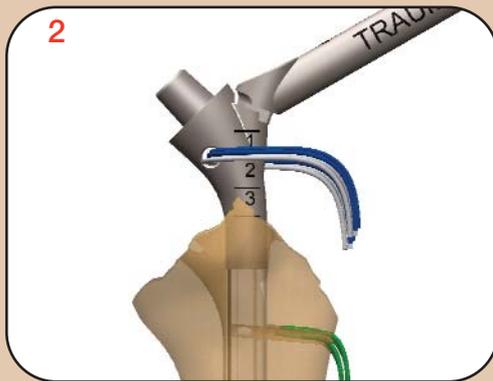
USING THE BONE GRAFT SYSTEM



Positioning one loop:

Make two holes in the diaphysis before inserting the stem into the humeral shaft.

Introduce a loop (green) from the outside to the inside, then through the second hole from the inside to the outside.



Suturing:

Pass two loops through the stem hole before inserting the prosthesis into the humeral shaft to attach the graft.

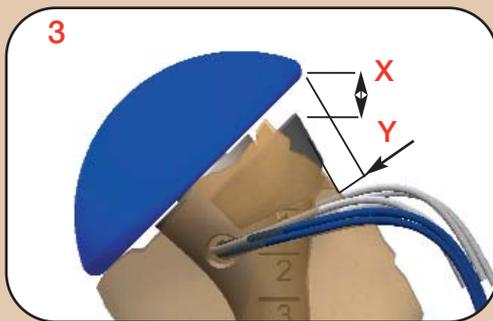
One (blue) to gather tuberosities.

One (white) to tighten the bone graft.

Cementing - stem insertion:

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.



Selecting the graft size: (5 sizes)

Use graft trials increasing size by size.

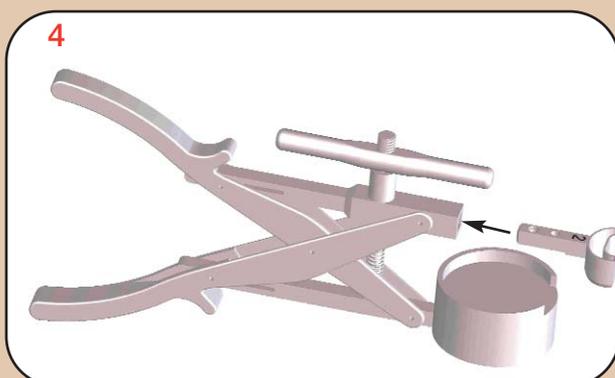
Change from one size to another until the diameter of the trial allows correct filling of the epiphyseal space.

From the front view, the trial must be lower than (X) and inside (Y) the top edge of the prosthetic head.



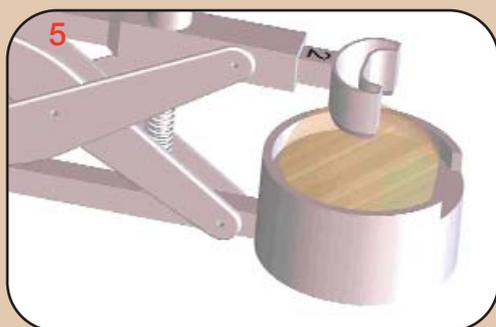
The size selected depends on the anatomy of the tuberosities.

The volume of the trial graft corresponds to the volume of the graft.



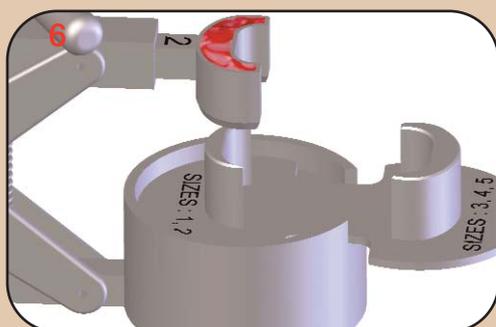
Setting the graft clamp: (5 sizes)

Insert size of the graft cutter identical to the graft trial in the clamp.



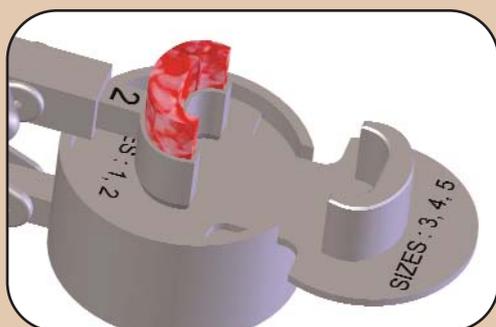
Setting the graft:

Put the native head in the graft clamp.
Close the graft clamp by screwing the handle.

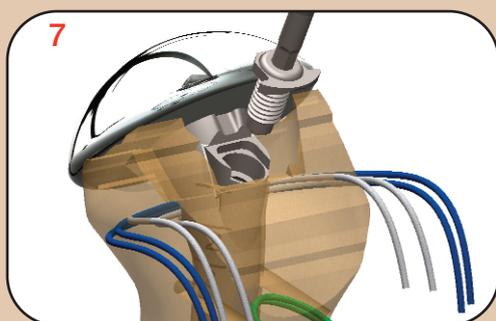


Ejecting the graft:

Open the graft clamp.
Insert the graft pusher checking the size of the graft cutter.

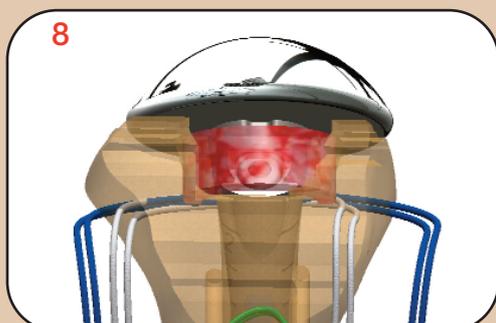


Close the graft clamp to eject the bone graft.
Remove any cortical bone from the cancelous bone with a rongeur.



Set up the protector + screw:

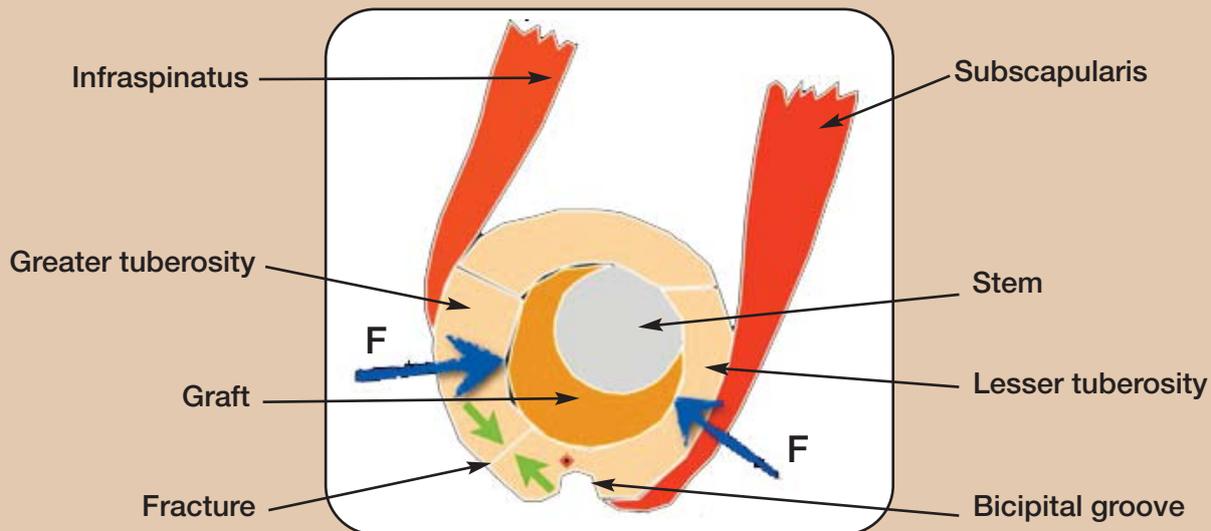
Insert the protector with screw in the M6 thread of the stem by means of the 3.5 mm hex screwdriver.



Positioning the graft:

For axial and rotational stability of the bone graft, position it around the posterior part of the stem, resting on the square or on the protector.

Graft can be adapted (5 sizes) to get a better configuration of the tuberosities and preserve the bone stock.

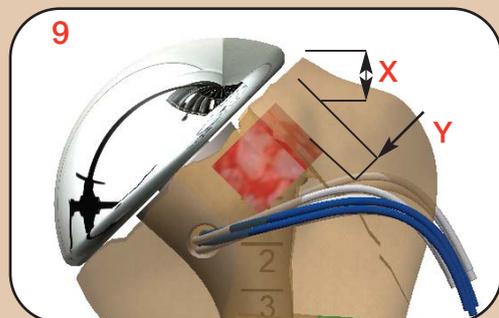


Adjusting the graft:

The purpose of a custom graft taken from the humeral head is to restore the volume of the fractured tuberosity cancellous bone.

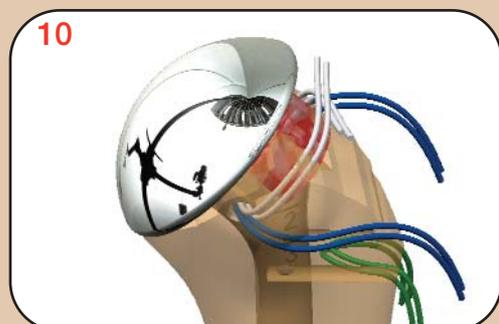
This graft, fixed on the stem by means of a conventional suture technique, provides biological and mechanical elements promoting consolidation.

The fact that the graft is interposed between the stem and the tuberosities promotes stability of the whole assembly because the forces *F* acting on the stem when tightening the sutures are concentric.



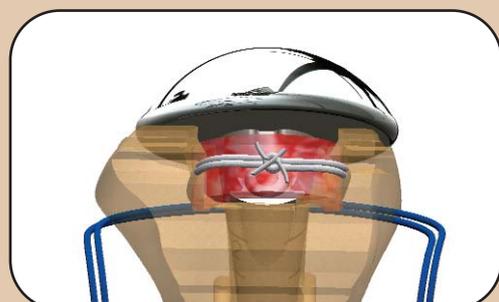
The height of the graft is adjusted to ensure continuity between the head and the greater tuberosity.

From the front view, the implant must be lower than (X) and inside (Y) the top edge of the prosthetic head.



Fixation of the graft:

With suture already in place through the stem enclose the bone graft to fix it to the prosthesis and tighten the suture until the bone graft is stable in all directions.



Once the bone graft is stable make a knot to fix it definitely.



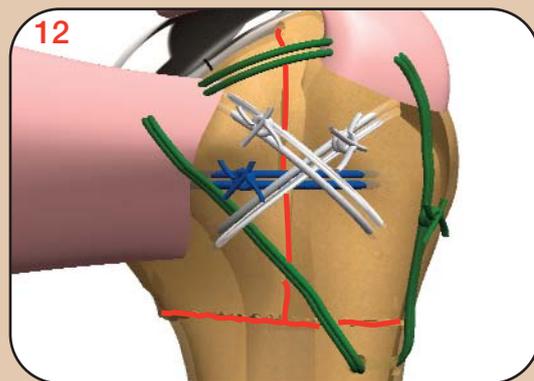
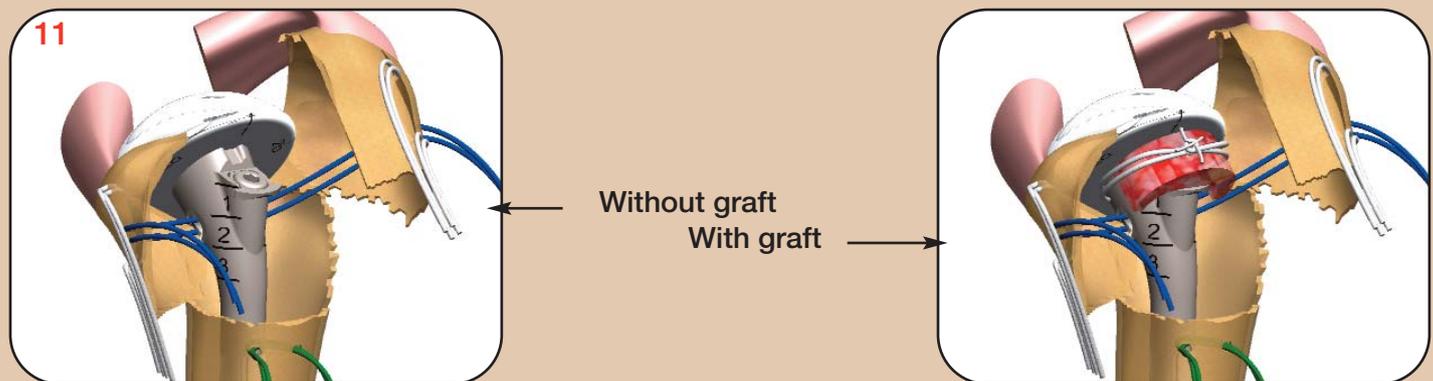
Tuberosity attachment:

Introduce one loop (white) through the lesser tuberosity and/or subscapularis from the outside to the inside, in order to provide two free ends.

Introduce another loop (white) through the greater tuberosity and/or supraspinatus tendon from the outside to the inside, in order to provide two free ends.



If the bone of the tuberosities is too hard, use a Ø3.2 mm drill to make a hole, paying attention not to drill the bone graft.



Knot together:

- 1- the superior loop (white) of the lesser tuberosity to the inferior loop of the greater tuberosity,
- 2- the inferior loop (white) of the lesser tuberosity to the superior loop of the greater tuberosity,
- 3- one end of loop (blue) from lesser tuberosity and other end of loop (blue) from greater tuberosity.
- 4- both ends of loop (green) already in place going into the subscapularis from outside to the inside and then going back out from the inside to the outside in the supraspinatus.

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).

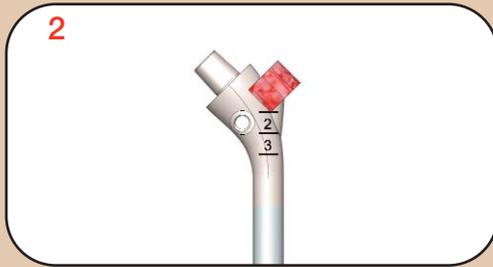
The optimal functional result is generally only acquired after the 6th post-operative month.

ANATOMICAL IMPLANT REMOVAL



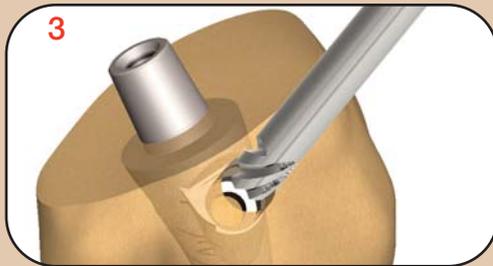
Humeral head removal:

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



Remove the sutures:

Remove the suture of the graft by cutting it with a cutter.
Remove the suture of tuberosities by cutting it with a cutter.



Removing bone:

Remove bone and/or bone graft with Ø 4.5 mm drill in order to access the 3.5 mm hex of screw.



Screw removal:

Remove the screw with the 3.5 mm hex screwdriver.



Stem removal:

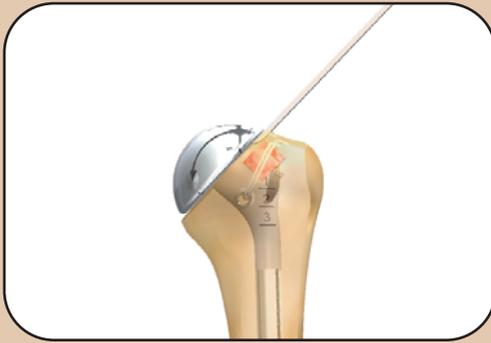
Screw the stem extractor into the stem, then use the hammer to remove the stem.



REVISION TO REVERSIBLE PROSTHESIS

Anatomical implant removal:

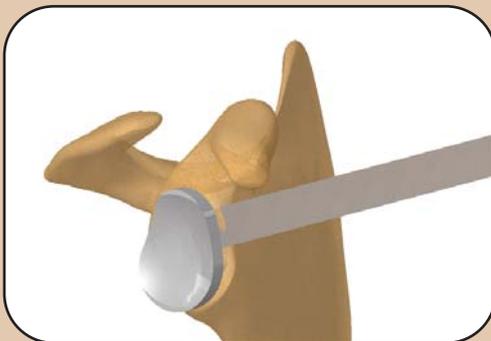
Remove the head by sliding a blade between the head and the stem.

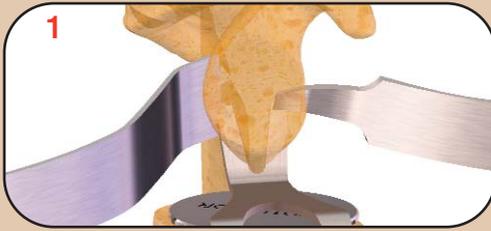


Remove the double taper by screwing the extractor in and backing the extractor out with a hammer.



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





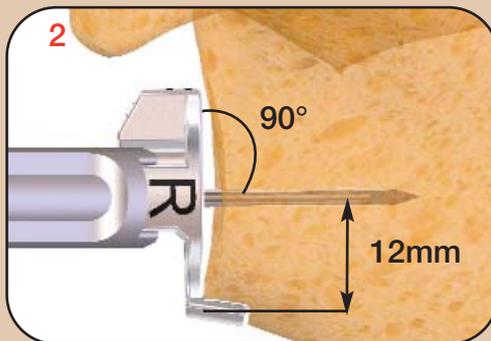
Glenoid exposure :

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 12mm above the lower edge, according to Kelly¹ and must be centered in the antero-posterior plane.

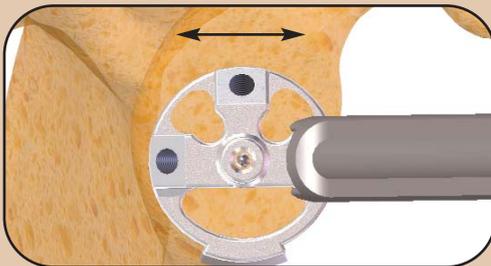
The K-wire guide orientation is important for the glenoid tilt and must be done at 90°. (see picture #2).

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

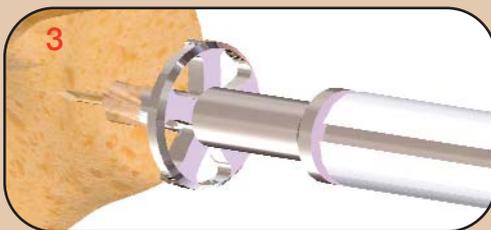
Positioning should be to fit the anatomy of the patient and planned according to the pre-operative X rays.

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

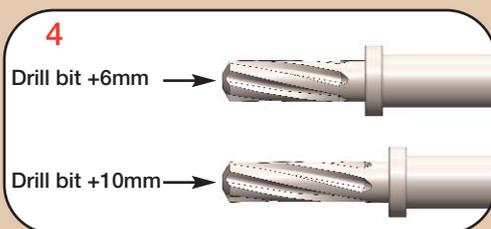


Glenoid reaming:

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

Ream until the subchondral bone is reached.

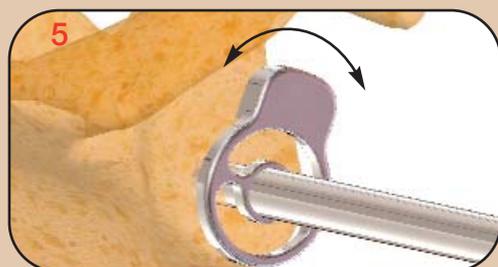
This step can be done by power or by hand if the glenoid is porotic.



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) :

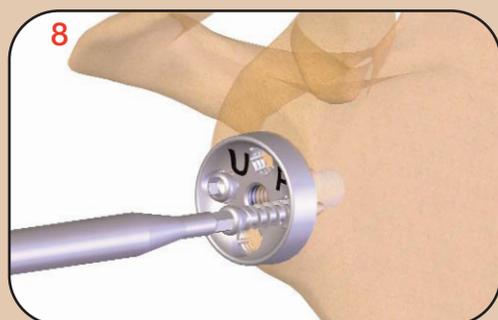
An adapted guide allows for the holes to be drilled and the length of the screws measured with the Ø 3.2 mm drill bit.

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).

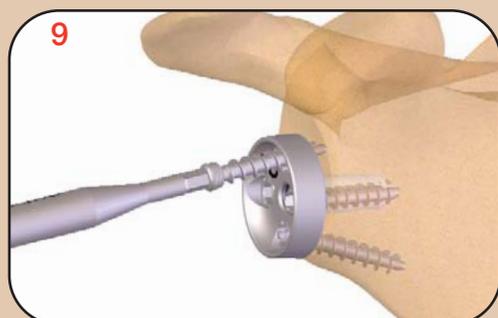


Fixation of the baseplate: (Ø24 mm)

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.

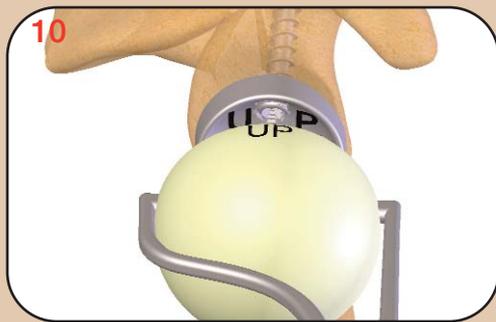


Recommendations:

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

2 locking screws for superior and inferior holes.

TRIAL IMPLANTS



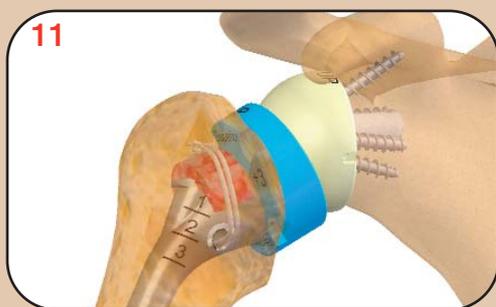
Glenosphere trial (10° tilt):

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 ($BMI (W/S^2) \leq 21$) (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.

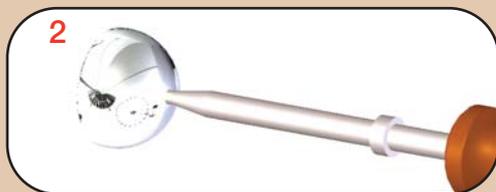
DEFINITIVE IMPLANTS



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

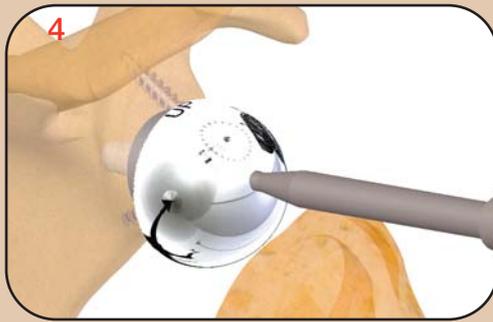
When positioning the glenosphere, pay attention to the "UP" marking, if an eccentric glenosphere is used.

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 glènosphère 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.

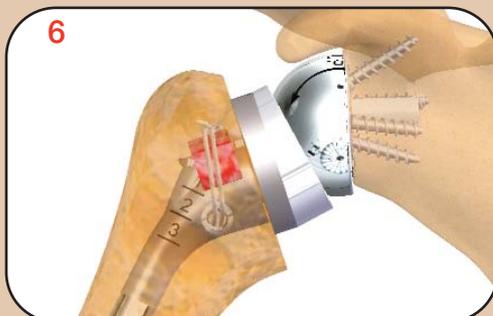
- 1- Begin to screw the glenosphere w/screw.
- 2- Impact the glenosphere with the impactor.
- 3- Finish screwing



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".

REVERSIBLE IMPLANT REMOVAL

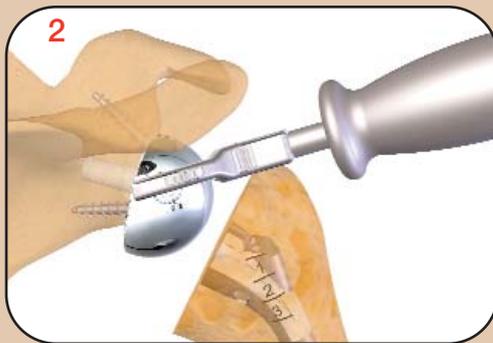


Humeral cup and sutures removal:

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

Remove the suture of the graft by cutting it with a cutter.

Remove the suture of tuberosities by cutting it with a cutter.



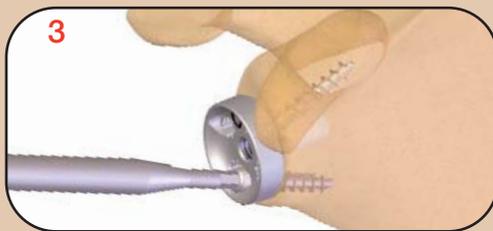
Glenosphere removal:

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

Screw the arch with the corresponding Ø to remove the glenosphere onto the extractor.

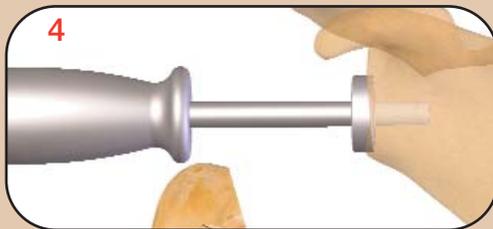
Pass the spurs onto the internal face of the glenosphere to fit them in the designed notches.

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.

