HUMELOCK II

Cemented

Primary / Trauma

SURGICAL TECHNIQUE
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 not sterilised and must be completely cleaned and sterilized before use.

Instruments must not undergo accelerated autoclave sterilisation inside the instrument box. Accelerated autoclave sterilisation of individual instruments has not been validated by the manufacturer.
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

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

Place 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 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.

**Cementing:**

Insert the stem in the humeral shaft keeping the good retroversion.
Stem is in place when at the humeral cut
Position a plug, 1 cm under the end of the stem (L=150mm).
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.
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
Big 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 pegs’ holes:
Insert the template through 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 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.

<table>
<thead>
<tr>
<th>Allowable combinations humeral heads / glenoid components</th>
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<tbody>
<tr>
<td>Glenoid size</td>
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<tr>
<td>Head Ø (centered &amp; offset)</td>
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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 intermedullary 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) a reamer below the last one used (Ø08, 10, 12).

Fitting of a tension suture:
Make two holes in the diaphysis before inserting the stem into the humeral shaft.
Introduce the suture 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 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.
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 per-operative 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 of 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=150mm).
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.

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**IMPLANTS 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 8 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.