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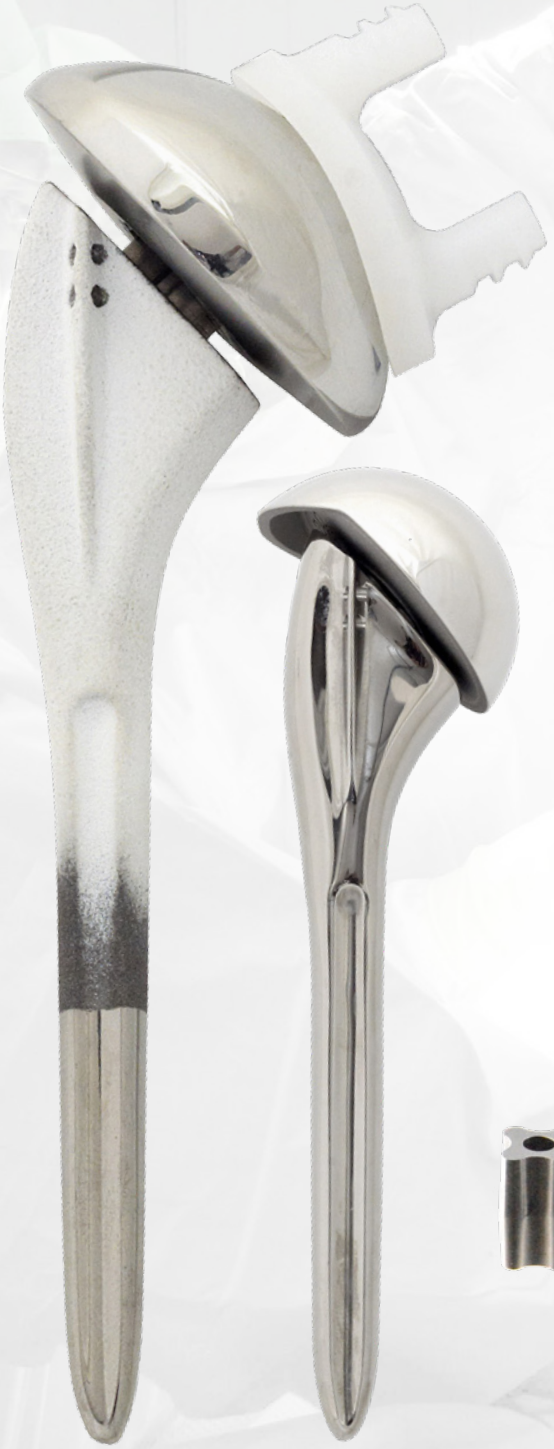
UNIC®
Anatomic

Surgical Technique



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INDICATIONS

Today, total shoulder replacement is an everyday operation when undertaken by trained surgeons. The objectives are to relieve pain due to degenerative lesions or trauma of the gleno-humeral joint, and to restore functional movement of the upper limb.

Hemi and total anatomic shoulder arthroplasty are indicated for the treatment of symptomatic pain and/or functional problems of the shoulder in patients whose skeleton is mature and only when pain killers and conservative treatment used correctly have failed. The anatomy and structure of the patient's articulation will need to be adapted to receive the selected implant(s).

Indications of total anatomic or partial (hemi) anatomic shoulder arthroplasty

- Degenerative non-inflammatory arthropathy: centered shoulder arthritis, osteonecrosis of the humeral head.
- Inflammatory arthropathy such as rheumatoid arthritis, or post traumatic arthritis.
- Post Traumatic degenerative arthritis.
- Functional repair of recent complex proximal humeral fractures at the elderly.
- Revision of a previous failed partial or total arthroplasty.

Whatever is the pathology the presence of a functional or repairable rotator cuff is absolutely necessary for the establishment of an indication of partial or total anatomic shoulder arthroplasty.

Contra-indications

Absolute contra-indications of partial or total anatomic shoulder arthroplasty are: presence of a deficient or unrepairable rotator cuff, local or systemic infection, mental deficiency, neuromuscular disease, neurological or vascular problems, and patients addicted to alcohol or psychotropic drugs.

Relative contra indications of partial or total anatomic shoulder arthroplasty are: excessive functional demands (sport with risk of falls, or with excessive functional demands beyond the limits of the prosthesis resistance) overweight, insufficient bone stock or demineralization of the bone which would compromise prosthetic fixation, severe humerus deformity, and pre-existing periarticular oncological pathology.

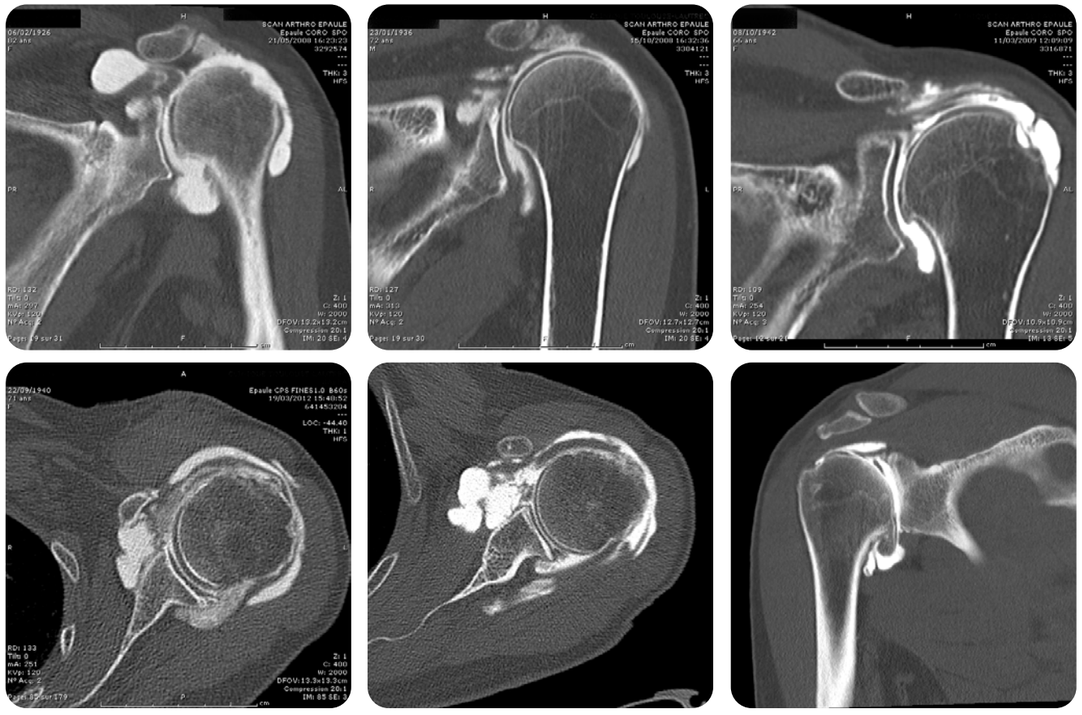
PRE OPERATIVE PLANNING

Essential pre-operative imagery planning elements should be interpreted by using a scanner or an MRI examination which is especially of interest in glenoid resurfacing in total arthroplasties.

This helps to assess:
- The condition of the rotator cuff.
- The degree, area and amount of wear of the glenoid.
- The bone quality of the glenoid, volume, shape, and density of the glenoid.

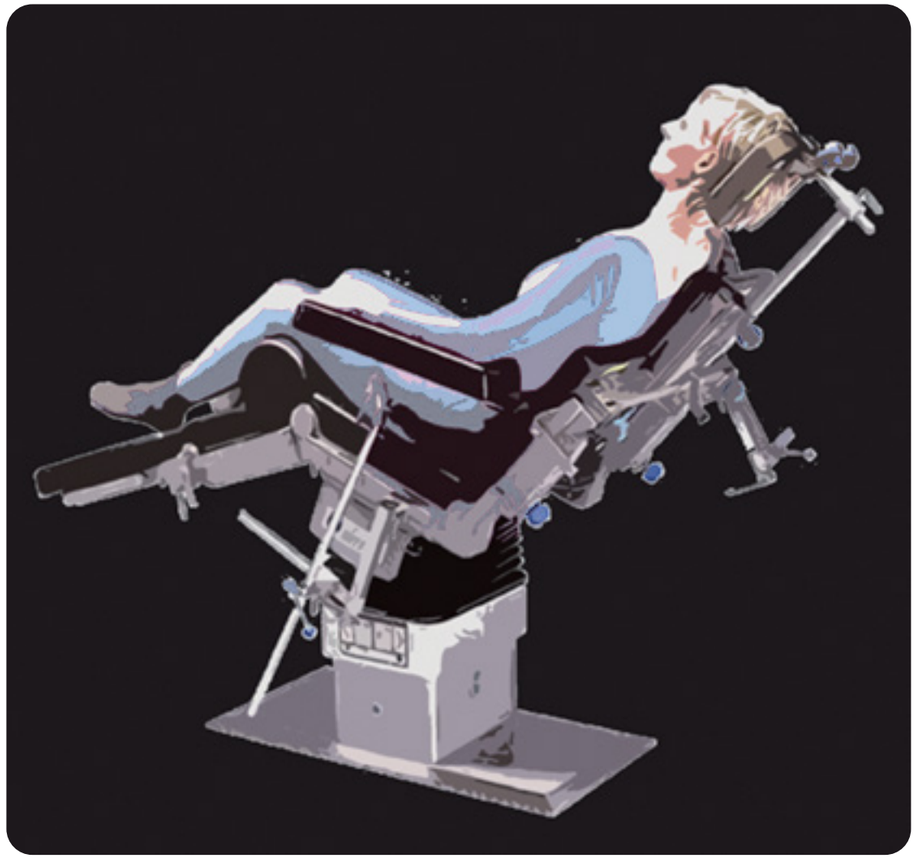
By analysing these elements the surgeon can determine the best theoretical position of the glenoid in 3 planes:
- Antero-posterior position
- High, medium or low position
- Anteversion, neutral, retroversion
- Tilt

These elements will determine the position of the guide wire for glenoid preparation.



PATIENT INSTALLATION

The patient should be installed in a half seating position at an angle of about 30°, (beach chair).
The arm to be operated on should initially be placed on the lateral removable support and should be free to move within the operative field in retroplusion and adduction. Ideally the whole of the area of the shoulder and scapula should be unrestricted.



Total shoulder arthroplasies are generally implanted by either delto pectoral or supero lateral approaches.

The UNIC shoulder prosthesis can be used in different surgical indications of shoulder arthroplasty, principally anatomic and reverse shoulders. It is up to the surgeon to choose the approach best adapted to the indication based on his experience, objectives, the anatomy and condition of the patient.

DELTO PECTORAL

The **delto pectoral** approach which follows the delto pectoral groove is the most widely used because it follows natural landmarks. Humeral exposure is good, preserves the deltoid, is easily reproducible, and is not aggressive for the blood vessels or nerves except for the axillary nerve which must be identified. Furthermore, if access is difficult the incision can be extended quite easily. However the sub scapularis must be cut and the glenoid access is not good.

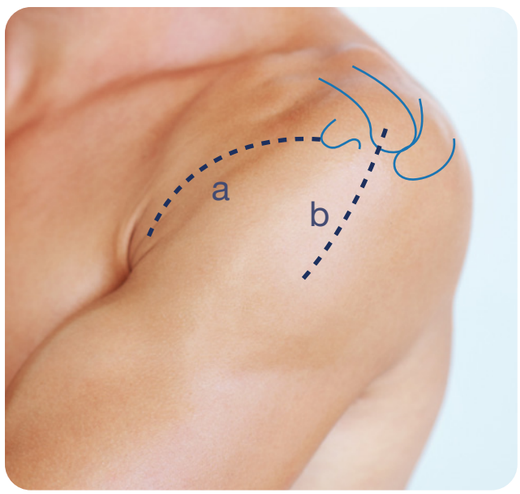
SUPERO LATERAL

The **supero lateral** approach starts at the anterior edge of the acromion without overstepping the acromio clavicular junction, and descends by about 3 or 4cm. This approach is generally indicated in complex glenoid surgeries where due to excellent visibility glenoid access is important. It can be used where rotator cuff repair is associated with arthroplasties or revisions of prostheses. This approach also gives good access to the axis of the humerus which allows for good control of retroversion and anterior- posterior position. The sub scapularis is untouched, but deltoid must be incised and the rotator cuff reclined if it is intact. Extending the incision in case of necessity can be difficult.

The choice between a delto pectoral (DP) or supero lateral (SL) approach is mainly a matter of surgical preference, but the DP approach could be preferred in cases of anticipated difficulty to access the glenoid side of the joint.

The DP approach is generally preferred for Anatomic TSA.

For a Reverse TSA procedure, both SL approach and DP approach are equivalent.

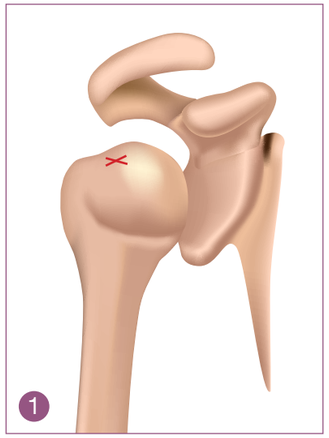


a : Delto pectoral approach
b : Supero lateral approach

Reaming of the diaphysis

After exposing the head and proximal humerus by external rotation or dislocation (depending on the approach) the entry point of the humerus is identified (generally about 5 to 10mm medial and posterior to the bicipital groove between the tuberosities ❶. Assemble the T handle on reamer size 0 which is sharp, and perforate the entry point. ❷

T handle	E28 009
Humeral Reamer size 00*	E28 083
Humeral Reamer size 0	E28 084
Humeral Reamer size 1	E28 085
Humeral Reamer size 2	E28 100
Humeral Reamer size 3	E28 115
Humeral Reamer size 4	E28 130



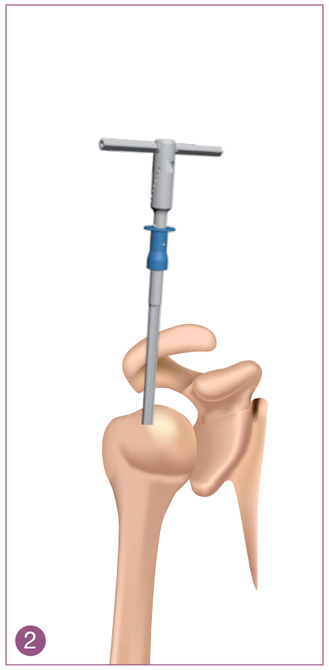
INFOS

Humeral preparation requires the E28 9105 “UNIC Reverse Shoulder instrument set”.

Progressively ream the humerus up to the stop of the reamer starting with size 0 and incrementally increasing size step by step, until cortical contact is achieved. The standard sizes available are 0 to 4.

The last size reamer which reached the stop and had good cortical contact indicates the MAXIMUM size humeral stem to use. Remember the size for the following steps.

Leave the reamer in place and remove the T handle ❸.

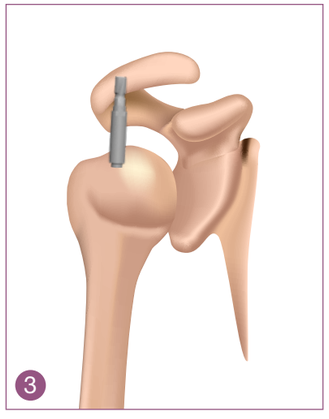


NOTE

Each reamer size corresponds to the length and diameter of the diaphysis of the same size implant. For reamer size “n” the implant used is most often size “n” or sometimes “n-1”

Size of implant	Reamer diameter	Reamer reference
Size 0	Ø7mm	E28 084
Size 1	Ø8.5mm	E28 085
Size 2	Ø10mm	E28 100
Size 3	Ø11.5mm	E28 115
Size 4	Ø13mm	E28 130

* : on special request.

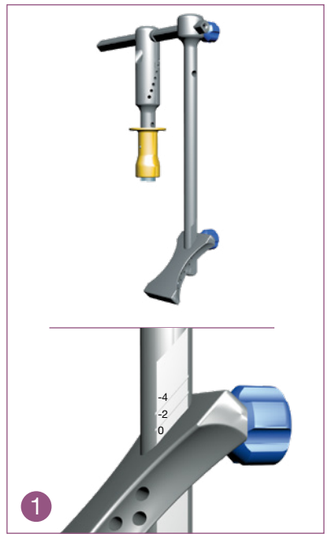


Resection of the humeral head

Assemble the delto pectoral cutting guide on the delto pectoral support arm, and fix it at “0” with an M6 locknut. This can be tightened with the 3,5mm hexagonal screwdriver ❶.

Mount the arm with guide onto the selected side of the T handle, and attach with an M6 locknut.

Delto pectoral cutting guide	E28 010	
Delto pectoral cutting guide arm	E28 089	
M6 locknut	S01 024	x2
T handle	E28 009	
Orientation guide	E28 007	
Hexagonal 3,5mm screwdriver	S01 037	
2,5mm, 100mm long pin	E28 102	x2
Humeral cut stylus	E28 156	

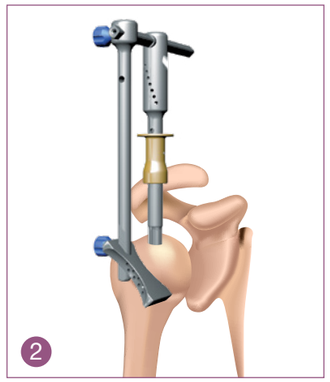


1

INFOS

The Delto pectoral approach requires the E28 9105 “UNIC Reverse Shoulder instrument set” and the E28 9106 “UNIC Anatomic complementary instrument set”.

Attach the assembly onto the reamer previously left in situ ❷.


2

Retroversion adjustments are made in 10° increments as selected by the surgeon (0° to 30° possible):

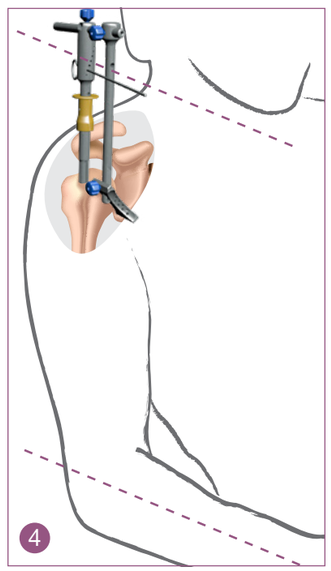
- Introduce the orientation guide through the appropriate eyelet hole in the T handle to give the desired degree of retroversion, on the chosen side ❸.
- Align the orientation guide with the forearm ❹.
- Maintain the instruments in this axis.

TIP

Humeral retroversion should be adapted as a function of the type of implant.

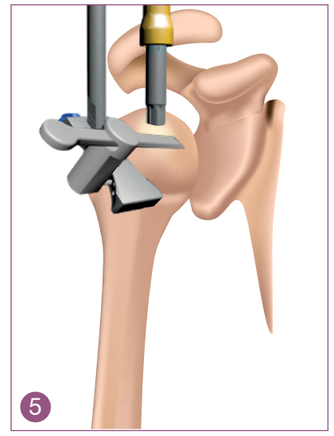
- Copied on the orientation of the anatomic epiphysis for the anatomical prosthesis.
- 0° to 10° for a reverse prosthesis.

3


4

Cut height adjustment :

- Slightly loosen the M6 locknut of the cutting guide
- Slide the Humeral Cut Stylus in any pair of holes marked “0” on the cutting guide
- Adjust the tip of the stylus above the upper section of the humeral head, and lock the locknut. This tuning determines a thickness resection of 22mm ❺.
- In cases of bulky humeral head, prefer the holes marked “-3” on the cutting guide, and adjust the stylus in this position. This tuning will determine a new thickness resection of 25mm.
- Secure the locking of the M6 locknut between the Cutting Guide Arm and the Cutting Guide with the H.3.5 screwdriver.
- Remove the Humeral Cut Stylus.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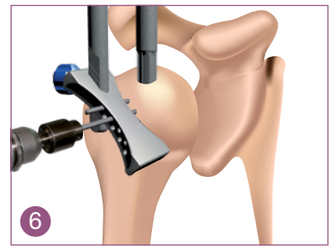
Humeral head cut :

- Loosen the M6 locknut on top of the T-handle.
- Slide the arm along the horizontal arm of the T handle until the cutting guide is in contact with the humerus.
- Check that the cut is at the desired level.
- Lock the M6 locknut of the arm on the T handle firmly.
- Place by power tool two 2,5mm threaded pins, length 100mm, through the cutting guide in the “0” position, to fix it onto the humerus. ❻
- Unscrew the M6 locknut of the cutting guide and the one of the support arm.
- Remove the entire reamer, T handle and arm assembly, leaving the cutting guide in place fixed by the 2 pins. ❼
- Cut the head with an oscillating saw. ❽ ❾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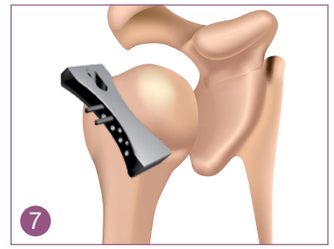
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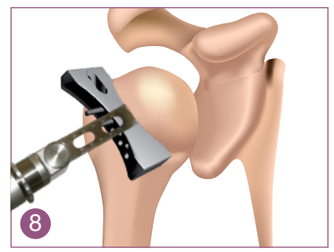
Verify the thickness of the humeral head cut with a micrometer or ruler to assess the thickness and size of humeral head implant to be used. ❿

Should the cut appear too thin, a re-cut of 3mm can be undertaken by repositioning the cutting guide over the pins via the holes marked “-3”. ⓫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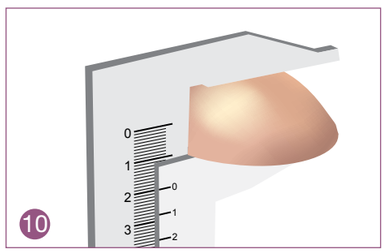

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9

Humeral broaching

Preparation of the humeral canal:

Assemble the size 0 broach on the broach-implant handle as follows:

- Unlock the handle by turning the ring beneath the strike plate 1.
- Place the handle over the end of the broach.
- Close the handle 2.
- Lock the system by turning the ring beneath the strike plate until it clicks into place.

Place the broach into the humeral canal 3.

Place the orientation guide in the selected index hole (0° to 30°) of the appropriate side of the broach and implant handle.

Check that the orientation of the broach is correct by aligning the orientation guide with the forearm, adjust retroversion 4.

Impact the 0 size rasp up until it is level with the humeral cut.

Broach in one size increments up until the size of the last reamer selected (step 1). It sometimes occurs that the last broach will be one size under the last size reamer.

Size 0 humeral broach	E28 000
Size 1 humeral broach	E28 001
Size 2 humeral broach	E28 002
Size 3 humeral broach	E28 003
Size 4 humeral broach	E28 004
Broach and implant handle	E28 029
Orientation guide	E28 007
Protection plate	E28 118
Wing Chisel endpiece	E28 127
M6 Impaction shaft	S01 026

Check the stability of the broach in rotation and axial subsidence.

Remove the handle and leave the broach in situ in the humerus. 5

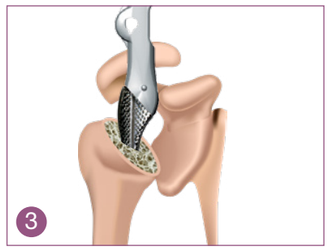
If necessary, re-cut the humerus around the edge of the broach to remove any prominent bone.

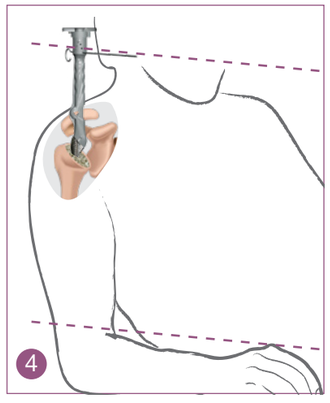
In cases of hard or sclerotic bone, use the wing chisel to prepare grooves for the wings on the prosthesis so as to avoid splitting the humerus 6.

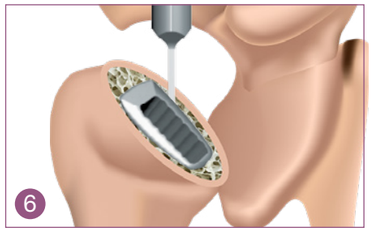
Place the protection plate over the top of the broach (optional) 7.

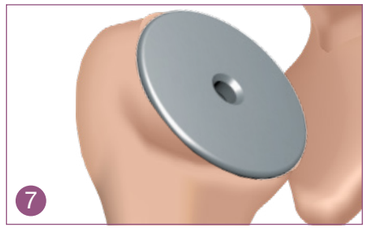
TIP

The broach should either be flush with the cut or just proud of it.
If it is below the level of the cut, the humerus must be re-cutted flush with the upper plane of the broach, otherwise the impaction of the humeral head may be compromised.









Preparation of the glenoid

Place the protection plate (optional) over the cut end of the humerus

Retract the proximal humerus by using the Two-pronged retractor (or the optional « Favard » retractor ref. E28 132) which should be placed posterior to the glenoid (delto-pectoral approach) 1.

CAREFUL

Place the retractor prongs under the glenoid rim and slightly posterior.

Remove the joint capsule with a diathermy knife whilst maintaining contact with the glenoid in order to avoid damage to the inferior part of the axillary nerve. Remove osteophytes in order to establish the true margins of the glenoid and its orientation.

If necessary draw the axes of the glenoid with the diathermy 2.

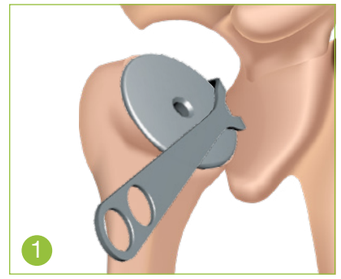
Place the glenoid guide wire guide over the glenoid surface with the 2 large holes vertical 3.

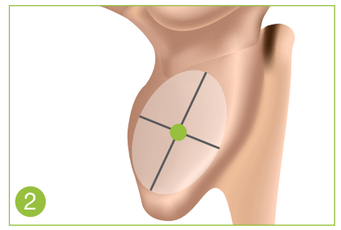
Once the position of the anatomic glenoid is selected, fix the orientation with a 2.5mm guide wire 150mm length, with a powertool through the hole in the centre of the guide. Be careful not to go beyond the 30mm mark 4.

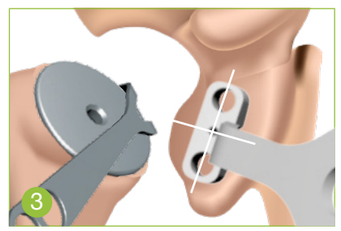
2 pronged retractor	E28 110
Glenoid guide wire guide	E28 228
2.5mm guide wire 150mm length	E28 150
36mm trial glenoid	E28 106
33mm trial glenoid	E28 116
30mm trial glenoid	E28 117
30mm glenoid reamer	E28 121
33mm glenoid reamer	E28 122
36mm glenoid reamer	E28 123
Reamer shaft	E28 120
T handle	E28 009
8.5mm stop drill length 30mm	E28 105
Stabiliser plug	E28 114

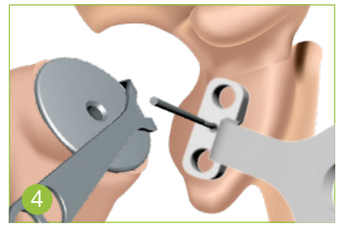
Remove the drill guide and leave the guide wire in place 5.

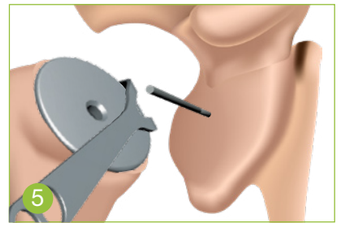
At this stage it is still possible to adjust the size, centring and position of the selected anatomic glenoid implant by placing the trial glenoid over the guide wire with the pegs facing out 6.

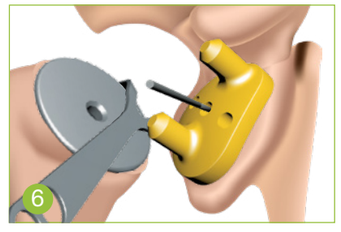












Reaming of the glenoid

Assemble the glenoid reamer of the selected size, 30, 33 or 36mm on the reamer shaft and T handle.

Place this over the guide wire 7.

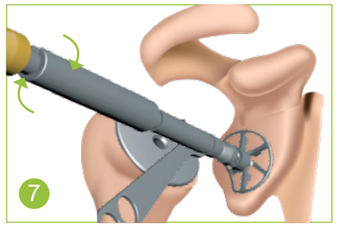
The cutout in the reamer is there to facilitate its introduction into the glenoid space over retractor and on the guide wire.

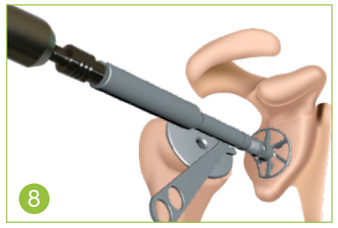
Start reaming by hand in order to remove any prominent hard bone and also avoid fracturing the glenoid if the torque on a powertool is too powerfull.

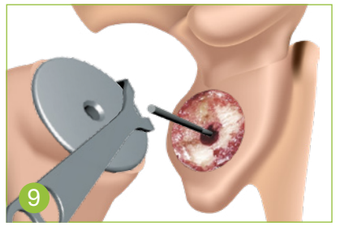
The T handle can be removed and a powertool snapped onto the shaft with a Hudson type adaptor. 8

Reaming should be continued until bleeding subchondral bone is reached. 9

Remove the reamer still leaving the guide wire in place.







Drilling of the peg holes

Place the Glenoid guide wire guide over the guide wire 10.

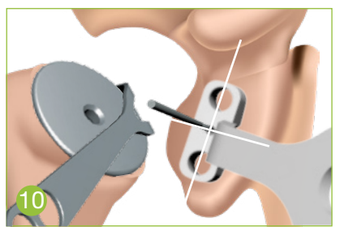
Maintain the guide in position and drill the superior hole with the 8.5mm stop drill length 30mm 11.

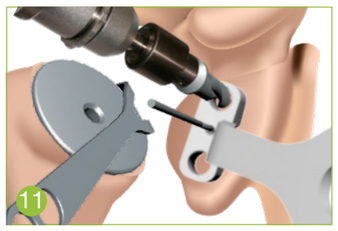
Remove the drill and place the stabiliser plug into the hole 12.

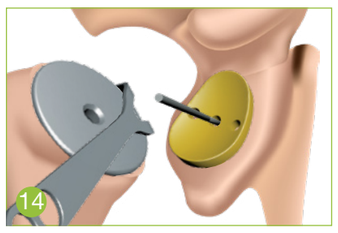
Repeat the drilling process in the inferior hole 13.

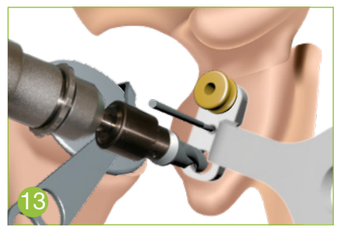
Remove the drill guide and handle.

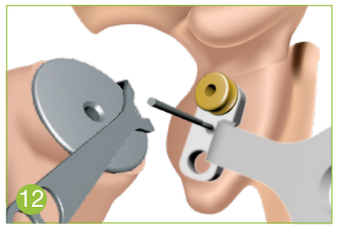
Place an anatomic trial glenoid over the guide wire and check the degree of bone cover and version, select the best size 14.











Trials

Trials, adjustment and choice of anatomic head:

Remove the humeral protection plate (if it was used).

Place a 0° (straight) trial module into the most lateral position of the humeral broach in situ 1.

Select the humeral trial head which best corresponds to the previously cut humeral head in diameter and thickness 2.

Select the best position in terms of bone coverage by moving the trial head and module in the head into different positions on the broach.

The retroversion or varus tilt may be adjusted by +/- 6° by using the offset module.

0° (straight) trial module	E28 011
6° (offset) trial module	E28 012
40mm Humeral trial head	E28 140
43mm Humeral trial head	E28 143
46mm Humeral trial head	E28 146
49mm Humeral trial head	E28 149
52mm Humeral trial head	E28 152

Trial humeral modules

6° offset 0°

INFOS

The humeral heads are not circular but oval in order to respect anatomy.

In cases where the surgeon must choose between 2 positions, it is best to use the lower of the two in order to avoid possible conflict with the rotator cuff.

WARNING

Adjustments on the stem are vertical and those on the head are horizontal, which allows the surgeon to select amongst combinations of positions in both planes, proximal/distal and anterior/posterior 3.

Trial reductions :

Reduce the articulation with the trial implants in place 4.

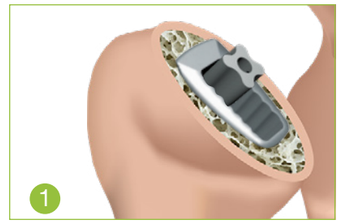
Test passive motion, stability and muscle tension 5.

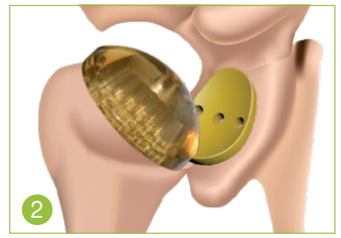
Memorize the positioning of the trial humeral module in the humeral head AND in the humeral broach. This positioning will be reproduced during the placement of the definitive implants.

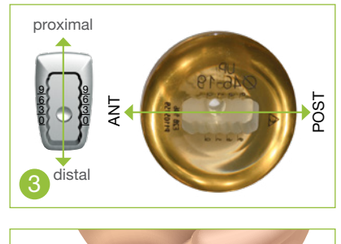
Retrieve the trial implants.

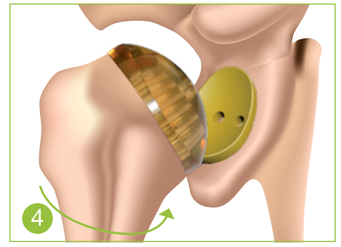
INFOS

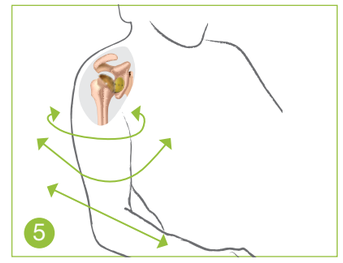
In passive mobilisation, the posterior subluxation of the head relative to the glenoid should not exceed 50% of the head volume.











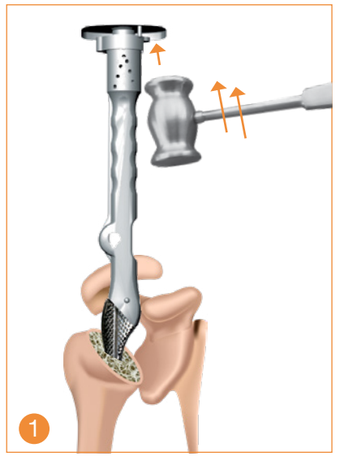
Humeral implants:

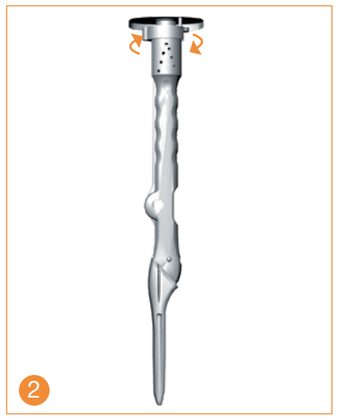
Unic implants are available either in versions to be cemented or with a dual coating of porous Ti + HA for cementless fixation.

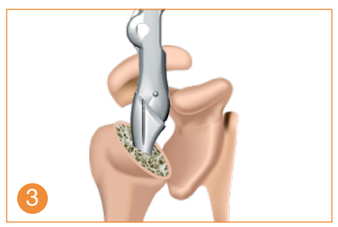
For cementless use, the stem size must be the same as the last size rasp which was seated in the humerus.

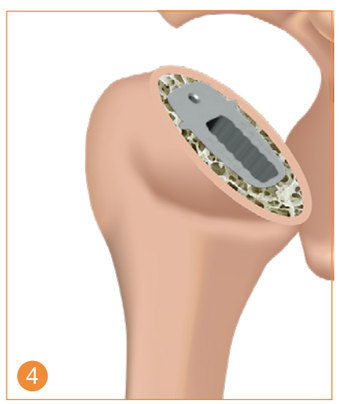
Broach and implant handle	E28 029
Orientation guide	E28 007
Wing Chisel endpiece	E28 127
M6 Impaction shaft	S01 026

For cemented use, cement mantle thickness choice is up to the surgeon. Cement preparation should be in line with best cementation practice.









Remove the humeral broach from the humerus by attaching the broach handle to it and striking upwards on the strike plate with a hammer 1.

Attach the definitive implant onto the same holder as follows :

- Unlock the handle
- Place the implant on the end of the holder
- Close the handle
- Lock by turning the locking ring beneath the strike plate 2 :

Place the implant inside the humeral canal and impact until it is stable. 3

Retroversion can be checked with the retroversion guide.

The proximal part of the stem should be flush with the humeral cut. 4

If not then :

- If the prosthesis is too suspended, re-impact it. If the bone is sclerotic, it is best to have used the wing chisel (page 10) to avoid fracturing the humerus;
- If the prosthesis is sunk below the level of the cut, re-cut the proximal humerus so that the cut is flush with stem; it may be necessary to repeat the head trials with the definitive humeral implant.

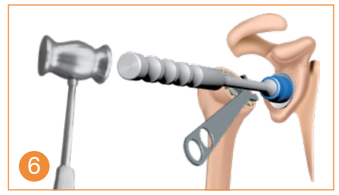
Glenoid implant :

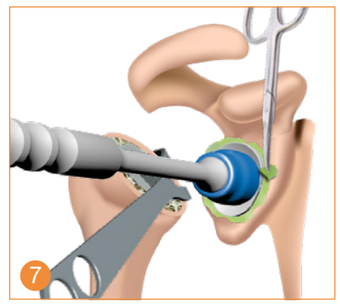
The glenoid implant is only available in an all cemented PE version. Preparation and cementation as per best practices.

Glenoid impactor endpiece	E28 112
M6 impaction shaft	S01 026
Head impaction endpiece	E28 108

Choose the prosthesis size indicated by the trials. Present the glenoid implant to the glenoid when the cement is in place 5 :

- Place the 2 pegs over the two peg holes, and progressively push them into place using the glenoid impactor endpiece on the M6 impaction shaft 6.
- Remove the excess of cement. 7
- Maintain in place under pressure until polymerisation is complete.



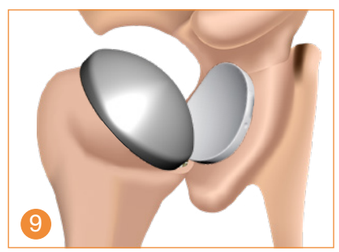


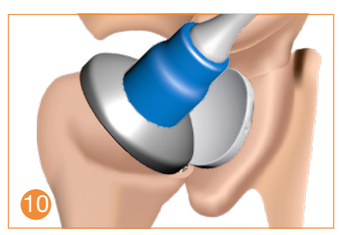
Humeral head positioning :

Assemble the humeral module into the head in the selected position on the operating table. Impact firmly 8.

Present the head and module assembly over the selected position in the humeral implant and ensuring that the positions are perpendicular to each other 9.

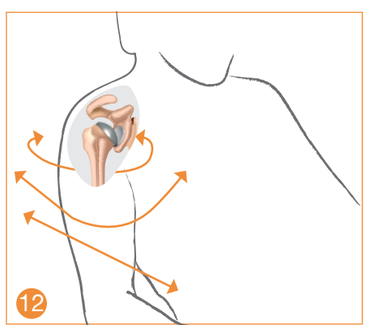
Impact the head firmly using the head impaction endpiece and the M6 impaction shaft, and check manually for stability 10.

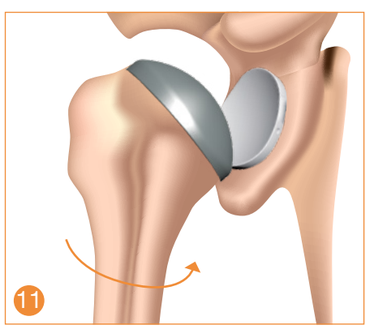




Reducing the articulation :

Reduce the articulation 11 and before closure check mobility and stability 12.





Preparation and trials

CTA shoulder hemiarthroplasties are indicated when there is marked deterioration of the rotator cuff muscles associated with poor bone quality of the glenoid which would not allow fixation of a reverse glenoid baseplate. The CTA head in these situations allows for the prosthetic head to articulate in the acromio clavicular arch.

CTA cutting guide	E28 301
42mm CTA trail head	E28 342
46mm CTA trail head	E28 346
50mm CTA trail head	E28 350
54mm CTA trail head	E28 354
head impactor endpiece	E28 108
M6 impaction shaft	S01 026

Preparation and trials :

Place the CTA cutting guide on the humeral broach in situ in the highest position 1.

With an oscillating saw placed on the surface of the cutting guide, cut the anterior and posterior supero lateral bone of the humerus 2.

Remove the cutting guide and finish the cut by hand 3.

Select the most appropriate CTA trial head which best fits the humeral cut and place it in the highest broach position 4.

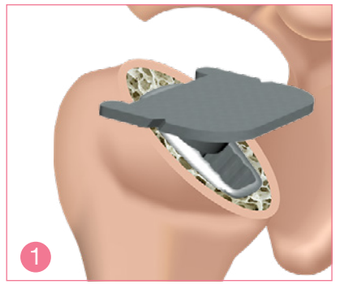
Reduce the articulation and test for stability and range of motion 5.

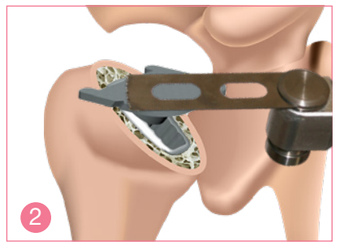
Definitive implants

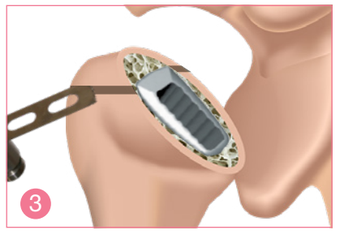
After the definitive humeral stem has been implanted as outlined in the protocol on page 14, select the CTA head chosen during the trials.

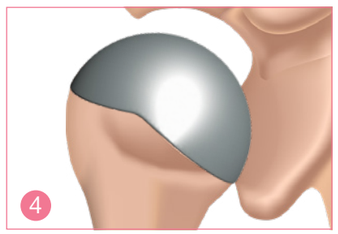
Position the head over the highest recess in the stem and firmly impact using the head impactor on the M6 impaction shaft.6

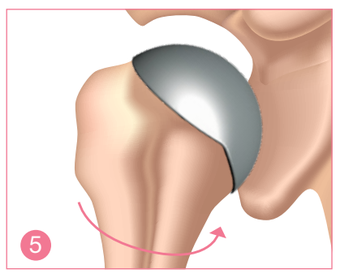
Reduce test and close.

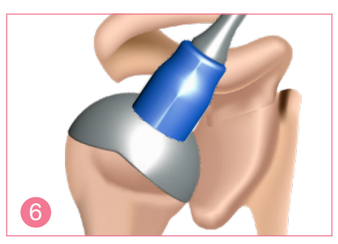












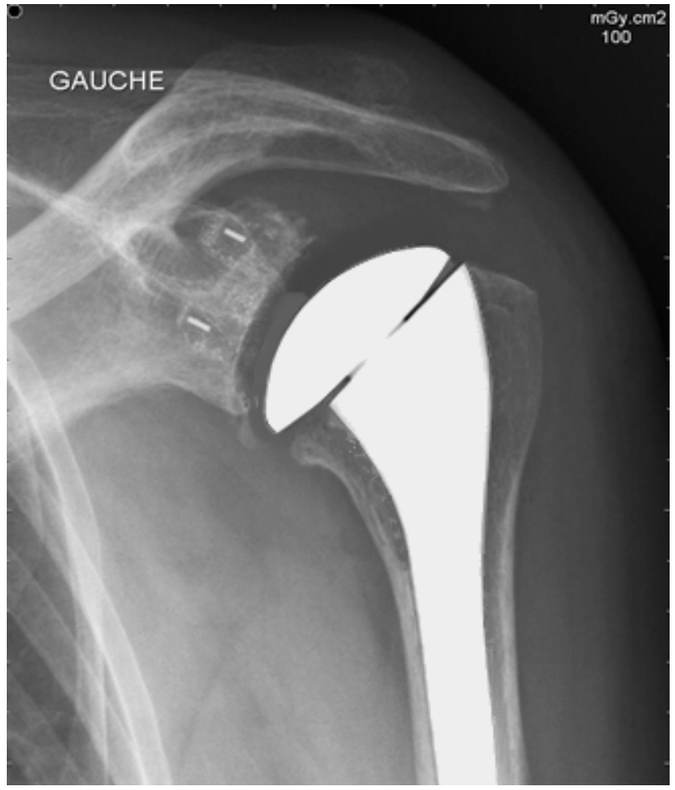
Physiotherapy protocol varies from one surgeon to another.

We recommend an immobilization using an IGLOO splint with abduction cushion, which allows a limitation of the lateral elevation during the first 30 post-operative days.

The IGLOO splint system allows completion of the usual follow-up post-operative care with a pain treatment by cryotherapy.

This immobilization, during the secondary integration of the implants period avoids submitting shear stresses to the implants, and favors compressive stress.

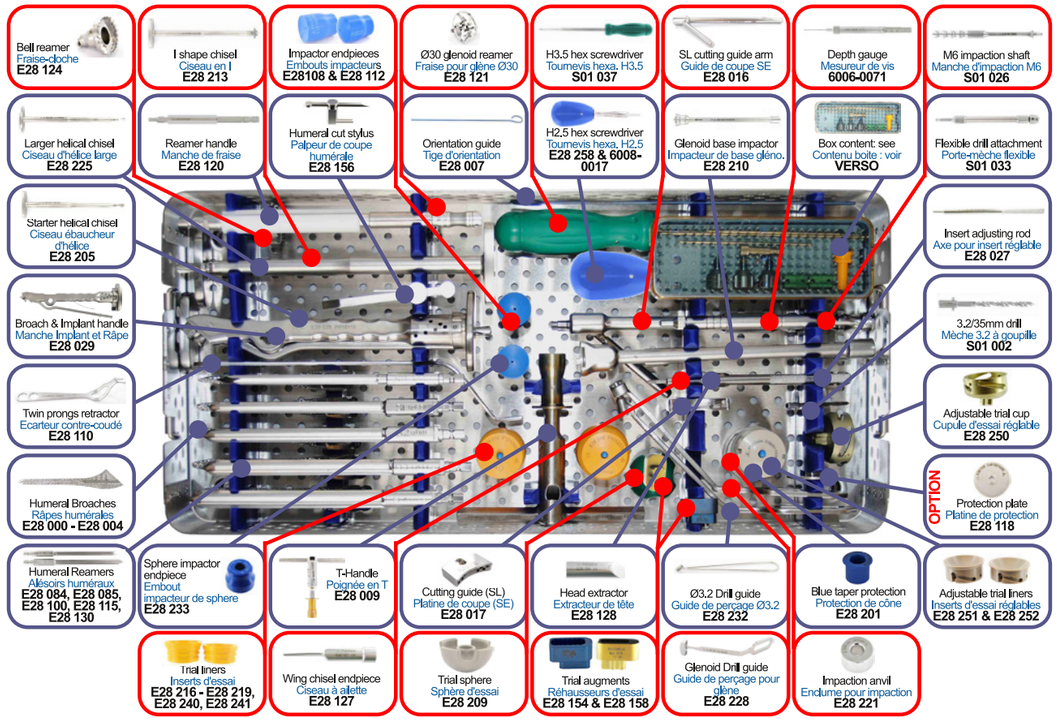
An active and pendulum mobilization can be practiced daily.



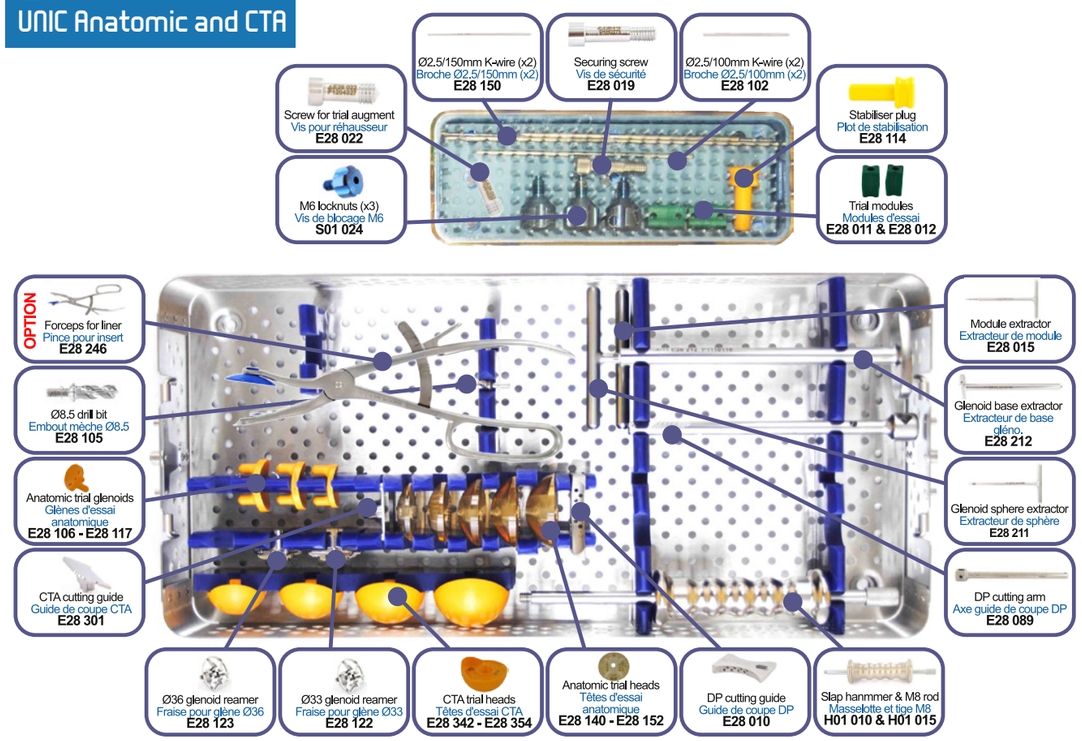
NOTES

SNAPSHOT OF THE INSTRUMENTATION SET

E28 9105 UNIC Reverse



E28 9106
UNIC Anatomic and CTA



IMPLANTS REFERENCE LIST

Humeral stem / Tige humérale

Primary Stem / Tige de Première Intention

Size / Taille	*Cemented* Cimentée	*L. (mm)*	*Cementless* Sans ciment
S.00	E27 020XS*	110	E27 000XS*
S.0	E27 020	115	E27 000
S.1	E27 021	120	E27 001
S.2	E27 022	125	E27 002
S.3	E27 023	130	E27 003
S.4	E27 024	135	E27 004

Anatomic shoulder / Epaule anatomique

Connection modulus / Module de connexion

Description	*Reference*
0° (straight)	E27 100
6° (offset)	E27 106

Humeral augment / Réhausseur huméral

Description	*Reference*
Standard sizes	E27 110
XS & Trauma sizes	E27 112

Humeral head / Tête humérale

Ø (mm)	*H. (mm)*	*Reference*
40	13	E27 140
43	16	E27 143
46	19	E27 146
49	21	E27 149
52	23	E27 152

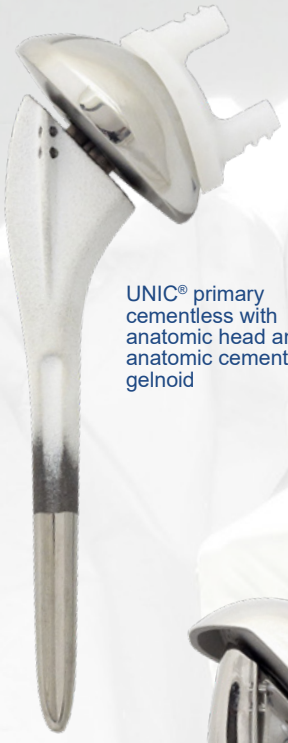
Anatomic glenoid / Glène anatomique

Description	*Reference*
30/22	E27 130
33/24	E27 133
36/36	E27 136

CTA head / Tête CTA

Ø (mm)	*H. (mm)*	*Reference*
40	17	E27 342
46	21	E27 346
50	23	E27 350
54	25	E27 354

* Product available only on request. Not provided in standard.



UNIC® primary cementless with anatomic head and anatomic cemented gelnoid

UNIC® primary cimented with CTA

Important Notice:
The UNIC Anatomic implants belong to the class III implantable medical device classification. The UNIC Anatomic implants are indicated in hemi or total anatomic arthroplasty procedures.
The surgeon is required to read the instructions for use (IFU) S12 0314 (Total Anatomic Arthroplasty) included in the packaging of the implant or available for download from the www.evolutis-group.com website, as well as the surgical technique manual E28 491 (UNIC Anatomic) or E28 454 (UNIC Trauma) initially delivered with the instrument set, or equally available for download from the www.evolutis-group .com website.

Materials:
Humeral stem: Titanium alloy (TA6V) according ISO 5832-3, with T40 and calcium hydroxyapatite coatings (cementless) or Shiny polished titanium alloy according ISO 5832-3 (cemented) 32-3
Humeral head and CTA head: high Nitrogen content stainless steel according ISO 5832-9
Glenoid implant: UHMWPE according ISO 5834-1&2, radiolucent ring in 316L Stainless Steel according ISO 5832-1
Packaging: Sterilized under Gamma irradiation, VacUpac packaging

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Evolutis GROUP

July 2024 / EN_UNIC ANATOMIC STC E28 (E28 491)