

E v o l u t i s

C R E A T E U R F A B R I C A N T

www.evolutisfrance.com

UNIC®
ANATOMIC



SURGICAL
TECHNIQUE

TABLE OF CONTENTS

INDICATIONS	.p.3
PRE OPERATIVE PLANNING	.p.4
PATIENT INSTALLATION	.p.5
SURGICAL APPROACHES	.p.6
SURGICAL STEPS	
Humeral steps	
Reaming of the diaphysis	.p.7
Resection of the humeral head	.p.8
Humeral broaching	.p.10
Glenoid Steps	
Preparation of the glenoid	.p.11
Reaming of the glenoid	.p.12
Drilling of the peg holes	.p.12
Trials	.p.13
Definitive Implants	.p.14
Hemi prosthesis and CTA head	
Preparation and trials	.p.16
Definitive implants	.p.16
POST-OPERATIVE CARE	.p.17
IMPLANTS REFERENCE LIST	.p.18
SNAPSHOT OF THE INSTRUMENTATION SET	.p.19

Disclaimer

This document is intended to be read only by experienced orthopaedic surgeons and staff familiar with the application of shoulder arthroplasty, and by individuals related to or acknowledged by Evolutis company.

This publication is intended as the recommended procedure for using the Evolutis UNIC Shoulder System. It offers guidance only. Evolutis is the manufacturer of the device. As such and claiming no medical skill, Evolutis does not recommend a specific use of a product or a technique.

Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

For any additional information related to the products, the indications and contra indications, the warnings and precautions of use, and the adverse effects, please refer to the INSTRUCTION FOR USE leaflet included in the packaging of the implants. For further advice please contact your local representative.

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.



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 retroversion and adduction. Ideally the whole of the area of the shoulder and scapula should be unrestricted.



SURGICAL APPROACHES

Total shoulder arthroplasties 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.

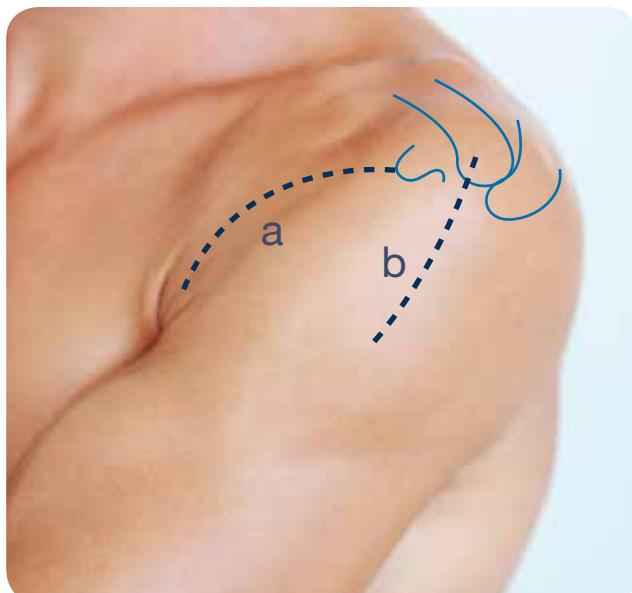
SUPERO LATERAL

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 reclin ed if it is intact. Extending the incision in case of necessity can be difficult.

The choice between a delto pectoral or supero lateral approach is usually made by the need or difficulty of access to the glenoid, as well as the condition of the rotator cuff.

The **delto pectoral approach is generally preferred for Anatomic TSA, and supero lateral for Reverse TSA.**

a : Delto pectoral approach
b : Supero lateral approach

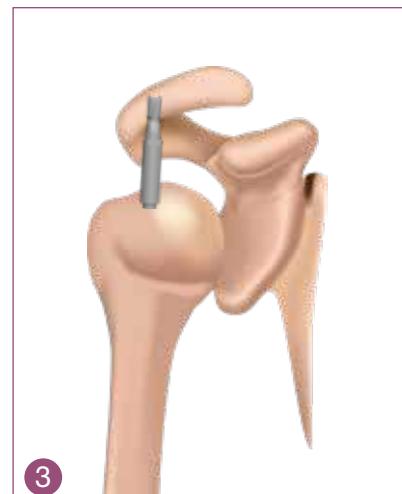
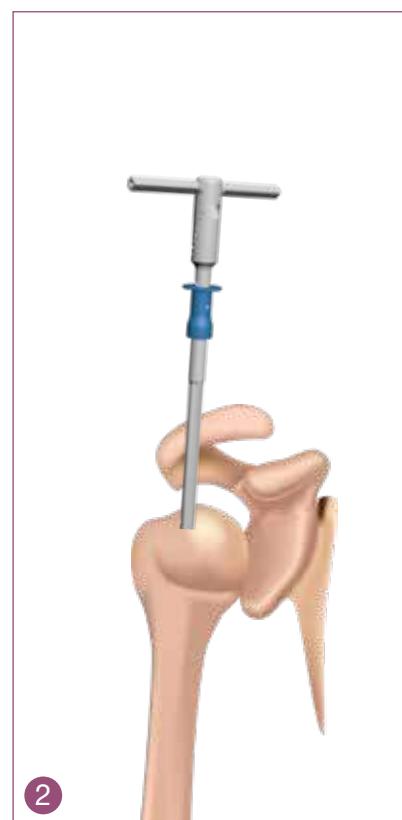


Reaming of the diaphysis

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

1. Assemble the **T handle** on **reamer size 0** which is sharp, and perforate the entry point. ②

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



INFO



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 ③.

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

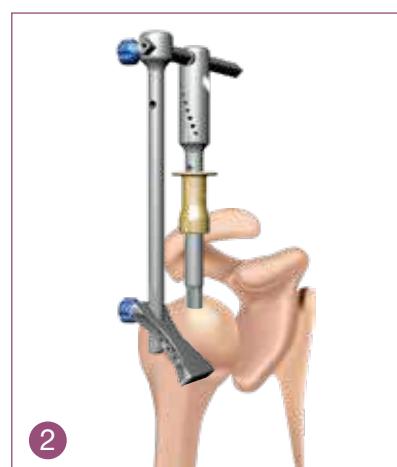
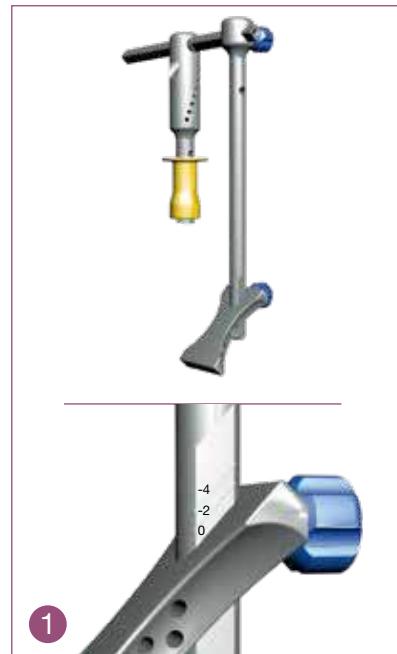
* : on special request.

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** ①.

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
T handle	E28 009
Orientation guide	E28 007
Hexagonal 3,5mm screwdriver	S01 037
2,5mm, 100mm long pin	E28 102
Humeral cut stylus	E28 156
	x2



INFO



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 ②.

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

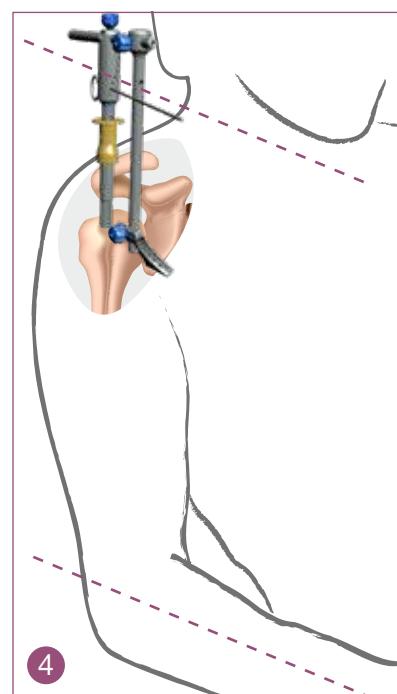
- Introduce the **orientation guide** through the appropriate eyelet hole in the **T handle** to give the desired degree of retroversion, on the chosen side ③.
- Align the orientation guide with the forearm ④.
- Maintain the instruments in this axis.

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.



Cut height adjustment :

- Slightly loosen the M6 locknut of the cutting guide
- Adjust the superior plane of the cutting guide so as to be flush with the anatomical neck (the lower limit of the cartilaginous section)
- The inferior landmark for the capital neck is the visible transition between the cartilage and the bone
- The superior landmark for the capital neck is the proximal insertion of the subscapularis and the insertion of the supraspinatus
- When aligned on the anatomical neck, tighten the M6 locknut with the screwdriver

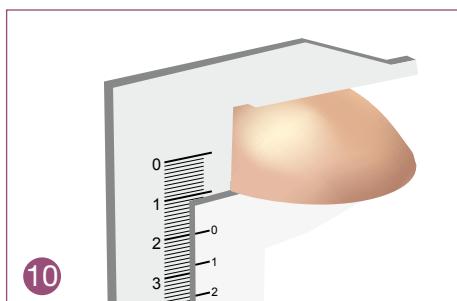
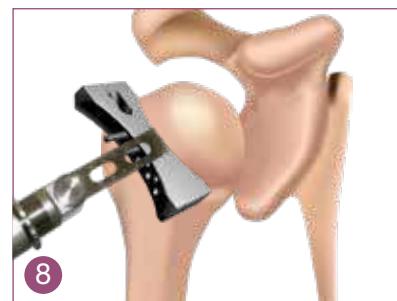
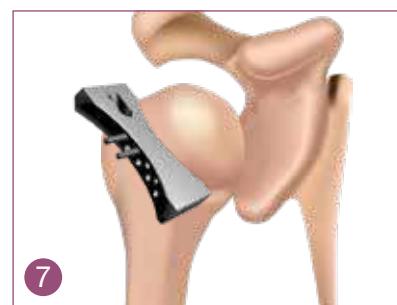


Humeral head cut :

- 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. **6**
- 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. **7**
- Cut the head with an oscillating saw. **8** **9**

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. **10**

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”. **11**



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

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

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.

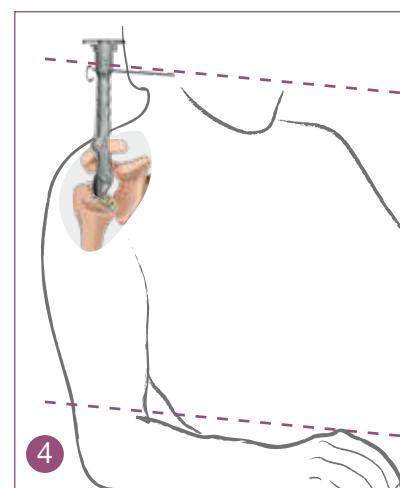
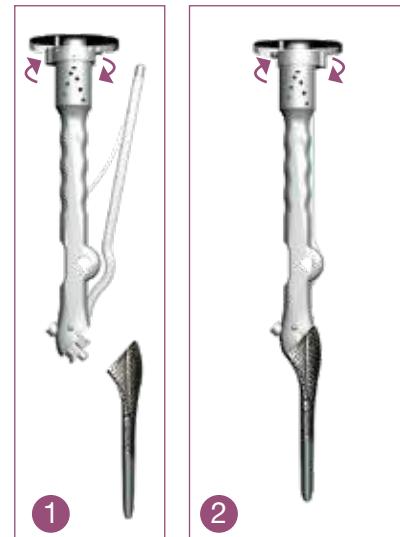
Check the stability of the broach in rotation and axial subsidence.

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-cut 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 (deltoid-pectoral approach) ①.

CAREFUL



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

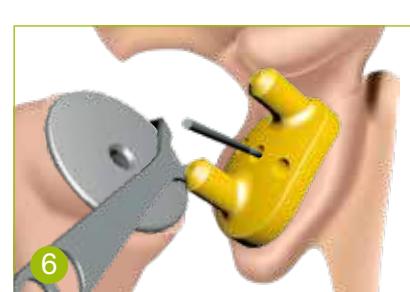
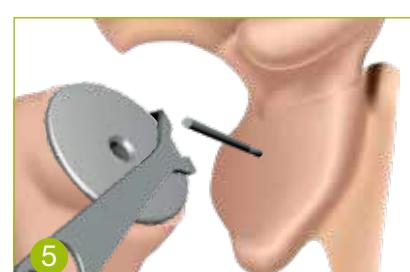
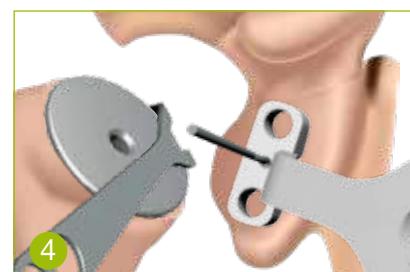
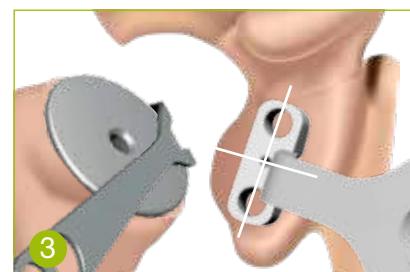
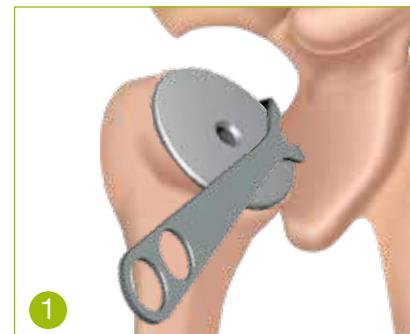
Remove the joint capsule with a diathermy knife whilst maintaining contact with the glenoid in order to avoid damage to the inferior part of the axillary nerve. Remove osteophytes in order to establish the true margins of the glenoid and its orientation.

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

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



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.

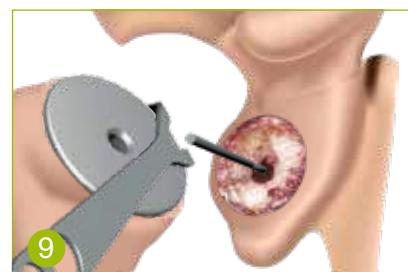
Start reaming by hand in order to remove any prominent hard bone and also avoid fracturing the glenoid if the torque on a powertool is too powerful.

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.

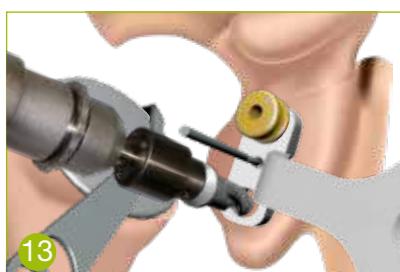
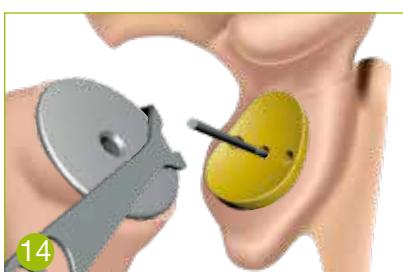
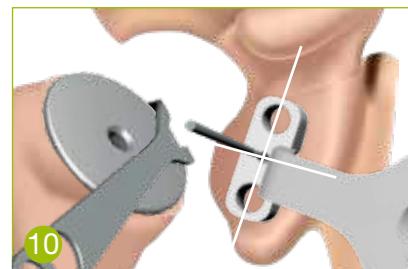
Maintain the guide in position and drill the superior hole with the **8.5mm stop drill length 30mm** 11.

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.

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



INFO

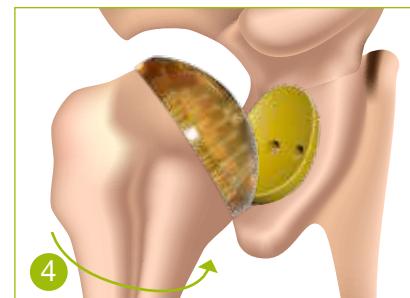


The humeral heads are not circular but oval in order to respect anatomy.

WARNING



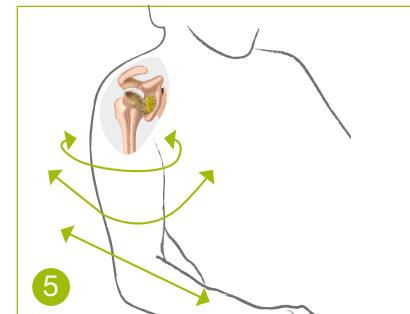
Adjustments on the stem are vertical and those on the head are horizontal, which allows the surgeon to select amongst combinations of positions in both planes, proximal/distal and anterior/posterior ③.



INFO



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



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.

Trial reductions :

Reduce the articulation with the trial implants in place ④.

Test passive motion, stability and muscle tension ⑤.

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

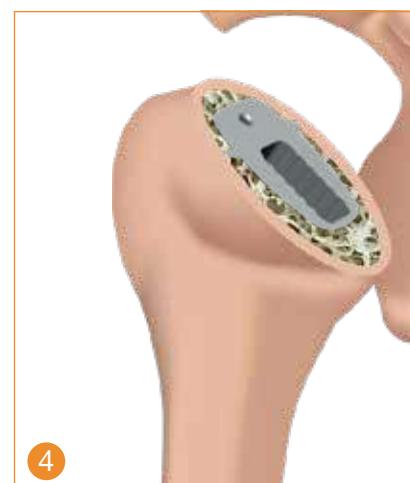
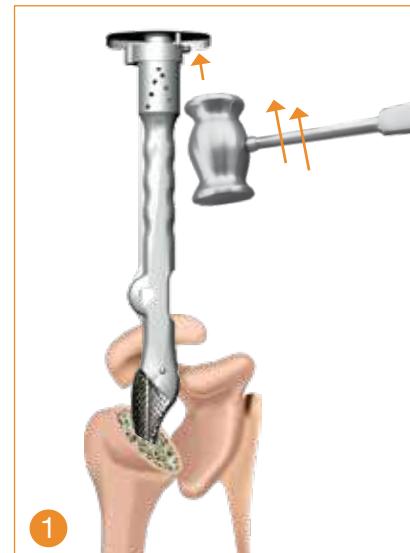
Humeral implants:

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.

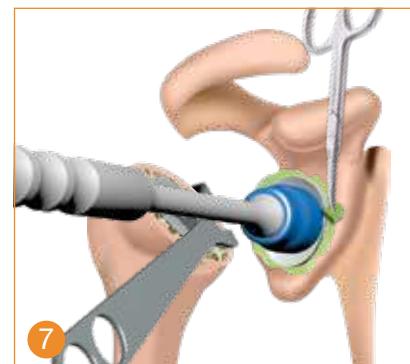
Glenoid implant :

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

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

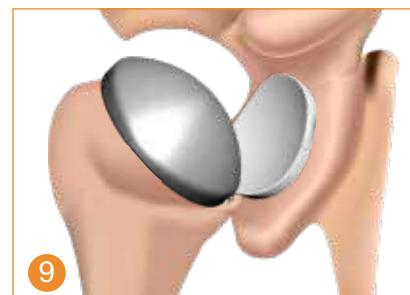
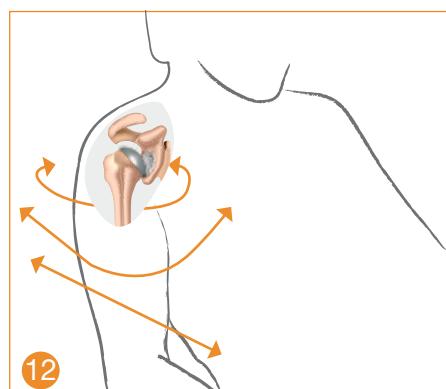
- Place the 2 pegs over the two peg holes, and progressively push them into place using the **glenoid impactor endpiece** on the **M6 impaction shaft** ⑥.

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



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.

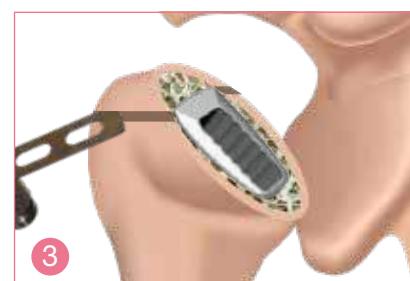
CTA cutting guide	E28 301
42mm CTA trial head	E28 342
46mm CTA trial head	E28 346
50mm CTA trial head	E28 350
54mm CTA trial head	E28 354
head impactor endpiece	E28 108
M6 impaction shaft	S01 026



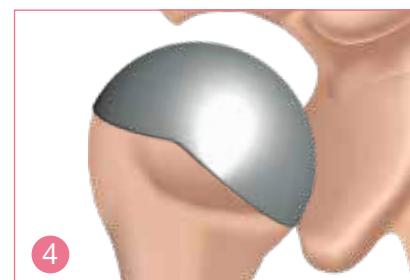
1



2



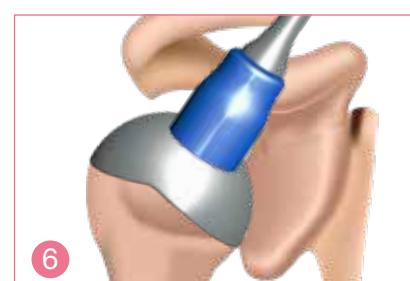
3



4



5



6

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 advise immobilization in a scarf and anterior and pendular mobilization for the first 30 days post-operatively. With lateral elevation reduction for the first 30 days postoperatively. With this immobilization secondary bone ingrowth into the implants can commence and allows for compression rather than shear forces.

After one month immobilization, active physiotherapy is unrestricted and within the limits of the patients' pain.



ANATOMIC SHOULDER			
Humeral stem			
Size	Cemented	L. (mm)	Cementless
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

Humeral Module	
Description	Reference
Straight	E27 100
6° Angle	E27 106

10mm Humeral Augment	
Description	Reference
For Trauma and XS stem	E27 110
For S.0 to S.4 stem	E27 110

Humeral Head		
Ø (mm)	Thickness	Reference
40	13	E27 140
43	16	E27 143
46	19	E27 146
49	21	E27 149
52	23	E27 152

Cemented Anatomic Glenoid	
Ø (mm)	Reference
30/22	E27 130
33/24	E27 133
36/36	E27 136

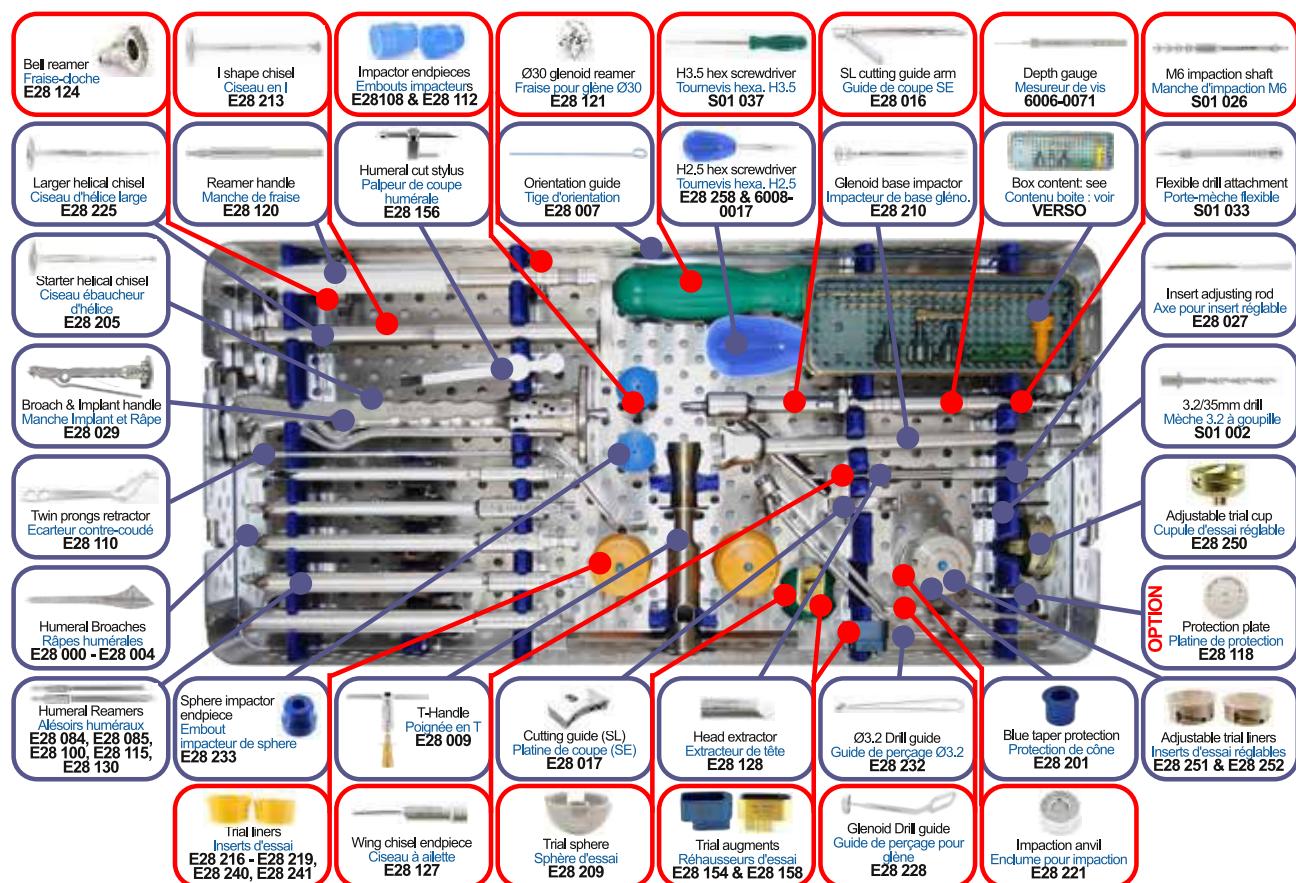
CTA Head		
Ø (mm)	Thickness	Reference
40	17	E27 342
46	21	E27 346
50	23	E27 350
54	25	E27 354



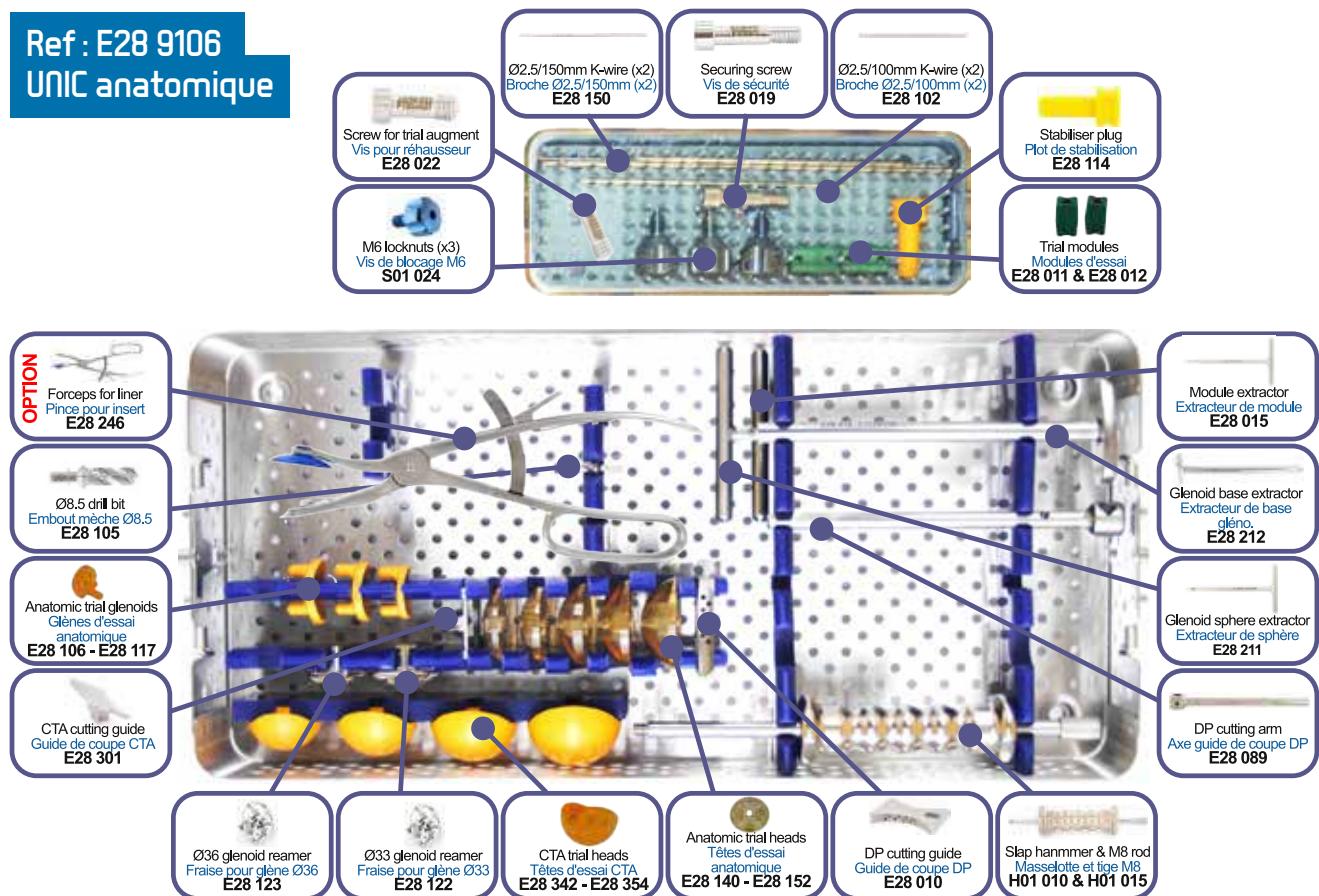
SNAPSHOT OF THE INSTRUMENTATION SET

19

Ref : E28 9105 - UNIC inversée



Ref : E28 9106
UNIC anatomique





www.evolutisfrance.com



EVOLUTIS

10 place des Tuiliers
42720 Briennon
FRANCE
Tél. +33 (0)4 77 60 79 99
Fax +33 (0)4 77 60 79 90
evolutis@evolutis42.com

