www.evolutisfrance.com

Evolutis

CREATEUR FABRICANT

UNIC®
STEMLESS

Surgical technique

Evolutis
MOTION INSIDE

Table of contents

Disclaimer

Indications

The UNIC STEMLESS implantable device is designed to treat osteoarthritis and osteonecrosis of the humeral joint when associated with an efficient rotator cuff for active patients.
The UNIC STEMLESS implantable device is specially designed for fixation in the cancellous bone of the proximal humerus. It can be used as an hemi-arthroplasty of the shoulder joint, or associated with a glenoid anatomic resurfacing with the anatomic glenoid components of the conventional UNIC system.

The UNIC STEMLESS humeral component is designed for cancellous fixation without cement. The humeral component is made out of additive printing technology and results in nano-structured porous and interconnected trabeculaes intended to favour in-depth osseo-integration. The additional proximal HA coating enhances the secondary fixation process.

Should the UNIC STEMLESS be revised, the implant has been designed to facilitate the introduction of bone chisels along the 4 intra-osseous flanges, leaving the humeral bone near-genuine for the implantation of a conventional stemmed primary humeral implant.

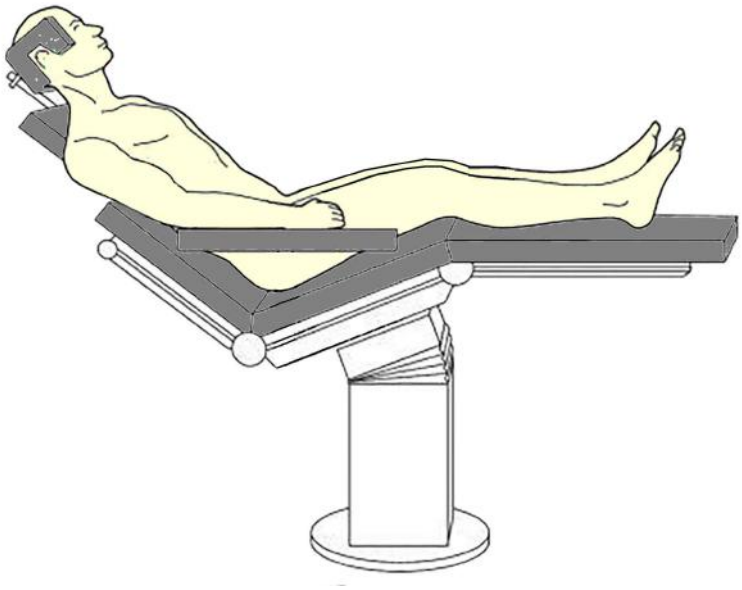
Patient positioning

The patient should be positioned in a beach chair position

The body of the patient on the table must allow for the operated arm to be free of the table edge and to be manipulated freely in extension and adduction without hindrance

Ideally the whole shoulder should be free and not hindered

A lateral support could be installed to support the arm alongside the body

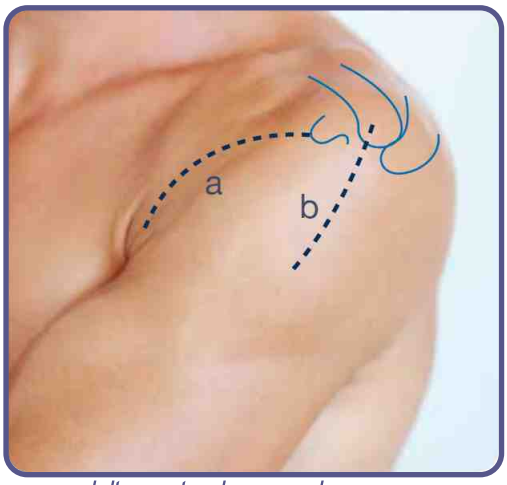


Surgical approaches

The selection of the surgical approach to the shoulder joint is left to the surgeon's preferences.
In cases of hemi-arthroplasty of the shoulder or in cases of total anatomic shoulder, the most commonly used approach is the delto-pectoral approach.

The delto-pectoral approach offers generally:

+ familiarity, hence most common approach
+ respect of the deltoid muscle and of the supra-spinatus
+ exposure of the axillary nerve possible
+ humeral preparation
- subscapularis cut & repaired: increased risk of subscap rupture
- exposure of the glenoid may be compromised



a : delto-pectoral approach
b : deltoid split (McKenzie) approach

Course of action regarding the subscapularis: tenotomy or osteotomy?

For a STEMLESS humeral component, prefer tenotomy to osteotomy as the tenotomy will preserve the bone stock at the anterior part of the cephalic border. The tenotomy will spare the bicipital groove and the lesser tuberosity.

The tenotomy should be made 1cm away from the lesser tuberosity in the tendinous structure as it will facilitate a solid repair with a few stitches at the end of the surgery.

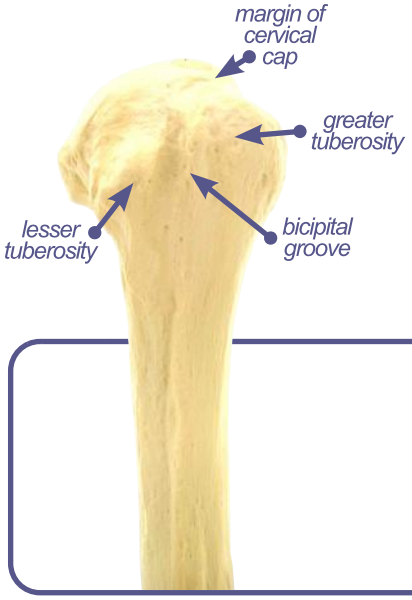
In case the osteotomy of the lesser tuberosity is prefered, the bone resection should remain superficial in order not to fragilize the bone stock.

In both cases, the suture or osteosynthesis of the subscapularis should thoroughly be realized.

Positioning of the humeral jig

The instruments used in this chapter are

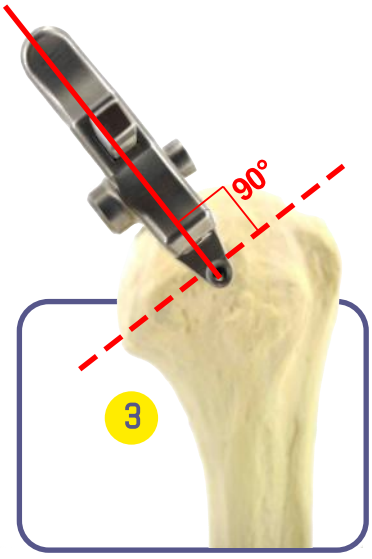
Humeral jig E38 006

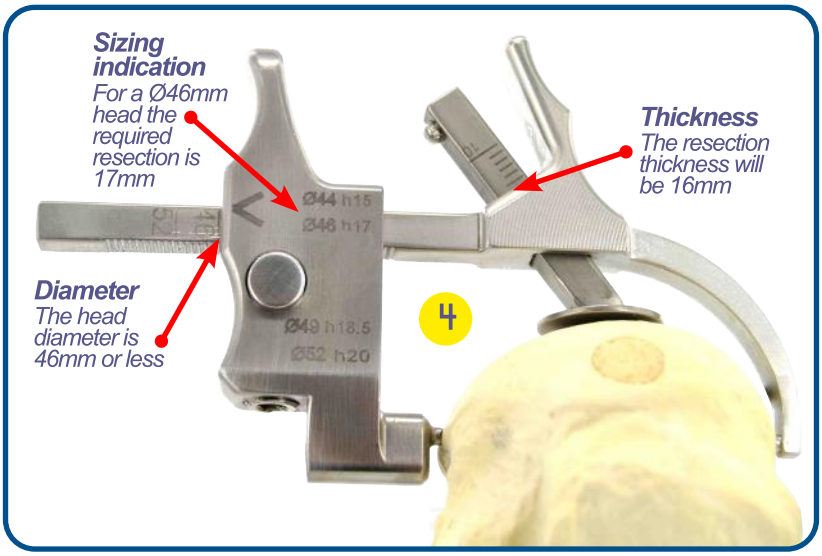


Place the humeral jig on the proximal humerus.
Check for the positioning of both anterior (1) and posterior (2) teeth of the humeral jig at the margins of the cervical cap and at the limits of the cuff and the cartilage.

Lock the humeral jig in this position.

Turn humeral jig perpendicular to the cervical neck line (3) and read resection values (4) on the jig. Check that resection height is consistant with the A/P value.



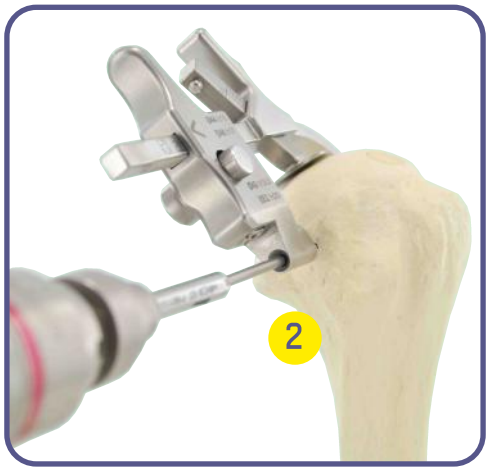


Introduction of central pin for fixation of the resection guide

The instruments used in this chapter are

AO quick connect for pin	E38 037
Ø2.5 L.70mm pin	E38 009

Place the AO quick connect for pin on the power tool.
Introduce one pin (Ø2.5 L.70mm) on the AO quick connect (1).
Introduce the pin into the humeral jig (2).
Press the lateral knob on the humeral jig, and pull the humeral jig out of the pin (3).

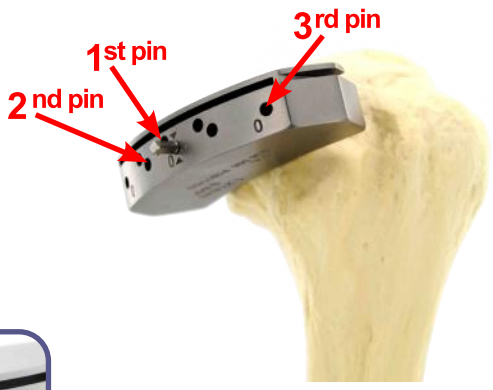


Resection of the humeral cap

The instruments used in this chapter are

Humeral resection guide	E38 008
Resection level controller	E38 018
AO quick connect for pin	E38 037
Ø2.5 L.70mm pin	E38 009

Introduce the humeral resection guide on the center pin (1) in the center hole marked "0".
Hold manually the humeral guide parallel to the humeral neck line.
Introduce the resection level controller into the slot of the resection guide and check for the medial (2) and lateral (3) levels of resection.
The level of resection must be flush with with the medial border of the footprint *(junction between the cartilage and the supra-spinatus tendon)*.
If required, modify the orientation of the resection guide.
Once the guide is in the correct "anatomic" position, introduce a second Ø2.5 L.70mm pin into the more medial "0" hole of the resection guide and drill into the humerus.
Lock the position of the resection guide with a third Ø2.5 L.70mm pin introduced in the more lateral and convergent hole of the resection guide.
Resect the humeral cap (4).



Correction of the resection level

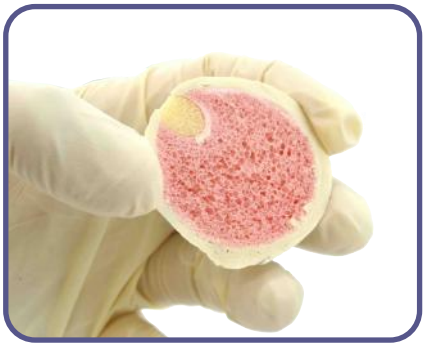
In case a correction of the resection level is necessary to match the thickness of the prosthetic humeral head, it is possible to acheive an additionnal 2mm resection.
Remove the lateral convergent pin, an re-position the resection guide on the 2 remaining pins and in the holes of the resection guide marked "2".
Place a convergent pin to stabilize the cutting guide.
Resect an additional 2mm of bone.

Size selection of the humeral head

The instruments used in this chapter are

Vernier caliper E38 036

Humeral head trials E38 020 to E38 032



Select the humeral head trials corresponding to the initial measures (in our example 44 and 46.5), and position the humeral head trial on the resected humeral cap and/or on the resected humeral epiphysis. The humeral epiphysis will usually show a larger size than the humeral cap.
Taking into consideration that the humeral cap may not be spherical, the surgeon needs to assess the best overall size adaptation, but **a sligthly smaller head is to be preferred to a slightly larger head**.

In our example, the size 46.5 (blue trial) appears to have a better adaptation to both the cap and the epiphysis than the size 44 (pink trial).
The larger size 49 (orange trial) is obviously too large and overhangs around the cap too much.

Head size selection

If there is any doubt between 2 sizes **always prefer the smaller one**.

Control the thickness of the resected humeral cap with the Vernier caliper.

For the real value of the resection, use the sum of the value read on the Vernier caliper plus the thickness of the saw blade (1.3mm).
In illustration (1) the real resection value is: 13.3mm (caliper) + 1.3mm (saw blade) = 14.6mm

The thickness of the humeral head of size 46.5 is 17mm. If the size 46.5 is finally selected than a correction of the humeral cut may be necessary *(see page 6: Correction of the resection level)*.

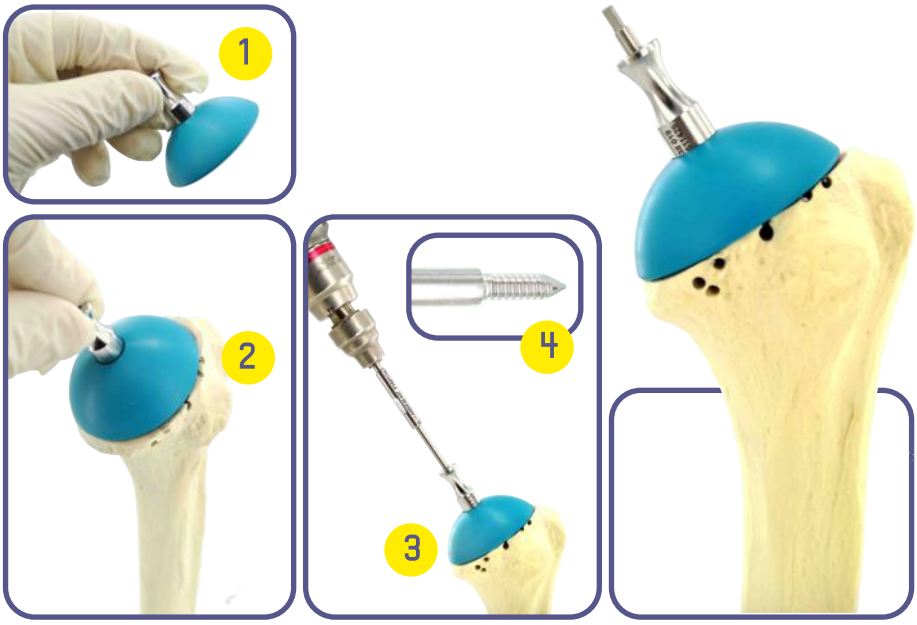
Important : Head Resection Measure

In addition to the physical thickness of the resected head, the surgeon needs to take into consideration the cartilage wear in arthritis, or the bone defect in osteonecrosis, and estimate the total resected thickness of the humeral head.

Preparation of the humeral epiphysis

The instruments used in this chapter are

Humeral head trials	E38 020 to E38 032
Head centering sleeve	E38 019
AO quick connect for pin	E38 037
Ø3.5 L.88mm pin	E38 010



Introduce a head centering sleeve into the selected humeral head trial (1).

Place the humeral head trial at best on the humeral epiphysis (2).

Adjust the AO quick connect for pin on the power tool.
Introduce the specific *(dual diameter Ø3.5/2.5 L.88mm)* guiding pin on the AO quick connect.
Drill into the centering sleeve until contact with the lateral cortex of the humerus (3). The guiding pin has a smaller diameter tip *(Ø2.5mm)* which creates an hilt immediately below the threads (4). The smaller diameter tip should be drilled down to the lateral cortex, the hilt will protect the drill from piercing through the cortex. Important: at this step pay additional attention in cases of osteoporotic bone.

Remove the centering sleeve and the humeral head trial.

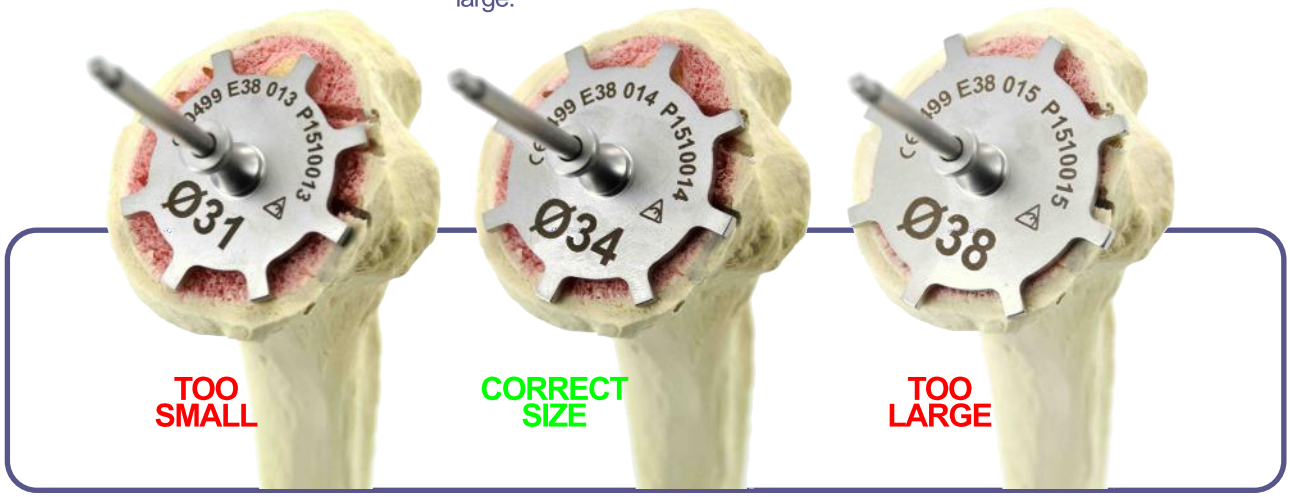
Sizing of the STEMLESS component

The instruments used in this chapter are

Centering plates	E38 011 to E38 015

Select a centering plate of diameter 10 to 12mm less than the selected humeral head.
Introduce the centering plate on the Ø3.5 L.70mm pin.

The centering plate is crenelled to show 2 dimensions:
- the inner diameter (bottom of crenels) of the centering plate shows the overall diameter of the final implant. This dimension should remain at distance of the cortical bone.
- the outer diameter (top of crenels) of the centering plate provides an information regarding the necessary distance between the implant and the cortex : if one of the top sides of the crenels overhangs outside the humeral cortex, than the size is too large.



Preparation of the humeral fixation

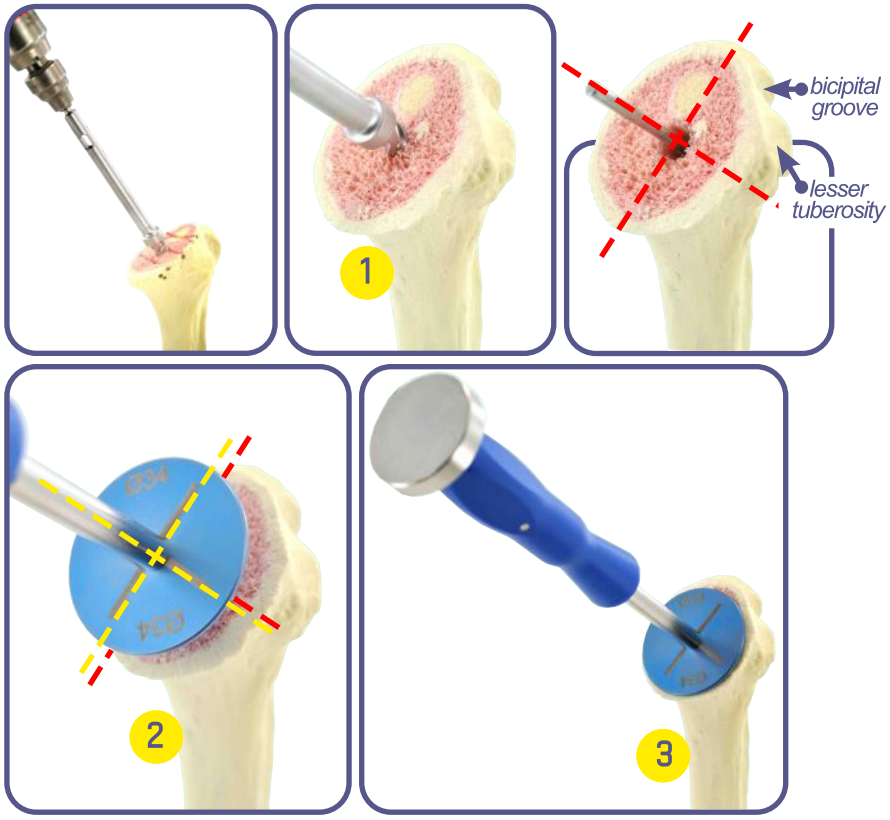
The instruments used in this chapter are

Cannulated drill	E38 017
Conformators Ø25 to Ø38	E38 001 to E38 005
Impaction handle with anvil	E38 033

Adapt the cannulated drill to the power tool *(small AO connect.)* and drill the center imprint (1) up to the hilt of the reamer.
Remove the drill.
Select the conformator of the size selected at the previous step.

Assemble the conformator with the impaction handle.

Introduce the conformator on the guiding pin and search for proper orientation of the flanges: the flanges *("X" marks on the conformator)* are to be oriented away from the bicipital groove and the lesser tuberosity (2).
Impact firmly untill the conformator comes in contact with the humeral cut (3).



Trial and reduction with trial implants

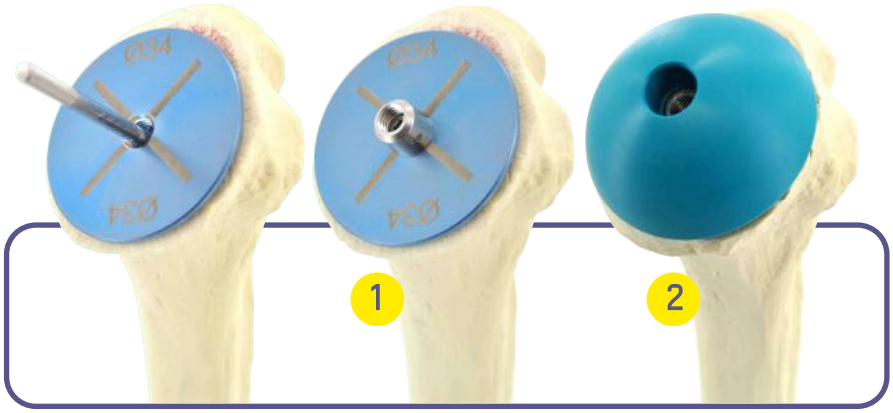
The instruments used in this chapter are

Modular trial taper	E38 007
Humeral head trials	E38 020 to E38 032

Remove the impaction handle and the centering pin.

Note: if total shoulder arthroplasty, leave the conformator on the humerus and proceed to the glenoid preparation.

Adapt the modular trial taper on the conformator (1).
Position the trial humeral head on the taper (2).
Reduce the shoulder joint and assess the mobility and stability.
In case of joint laxity, from humeral head of size 44, 2 thicknesses are available.



Implantation of the final implant

The instruments used in this chapter are

Impaction handle with anvil E38 033

Adapt the impaction handle on the trial taper and remove both the taper and the conformator.
Ask for the final STEMLESS implant to be given and thoroughly check the size before opening (1).
Open the sterile pack and leave the STEMLESS implant in the packaging foam.

Screw the impaction handle directly on the STEMLESS implant (2).

Position the implant on the humeral epiphysis and check for the proper orientation of the flanges (3).
Impact the STEMLESS implant untill the proximal ring of the implant comes in contact with the cut.
At this stage, do not impact the ring below the level of the cut (4).

Implantation of the final humeral head

The instruments used in this chapter are

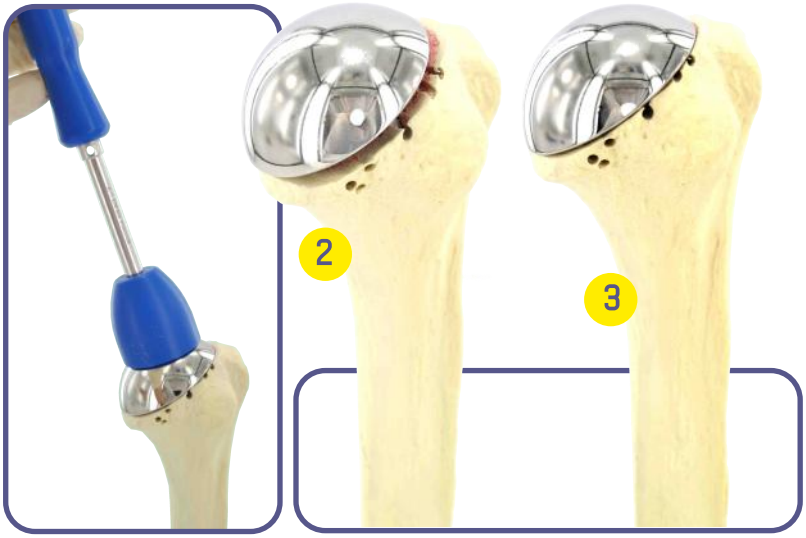
Impaction handle with anvil E38 033
Head pusher tip E38 034

Ask for the final humeral head implant to be given and thoroughly check the size before opening.
Open the sterile pack and seize the implant by hand (1).

Position the implant directly on the taper of the STEMLESS implant.

Assemble the head pusher tip on the impaction handle.

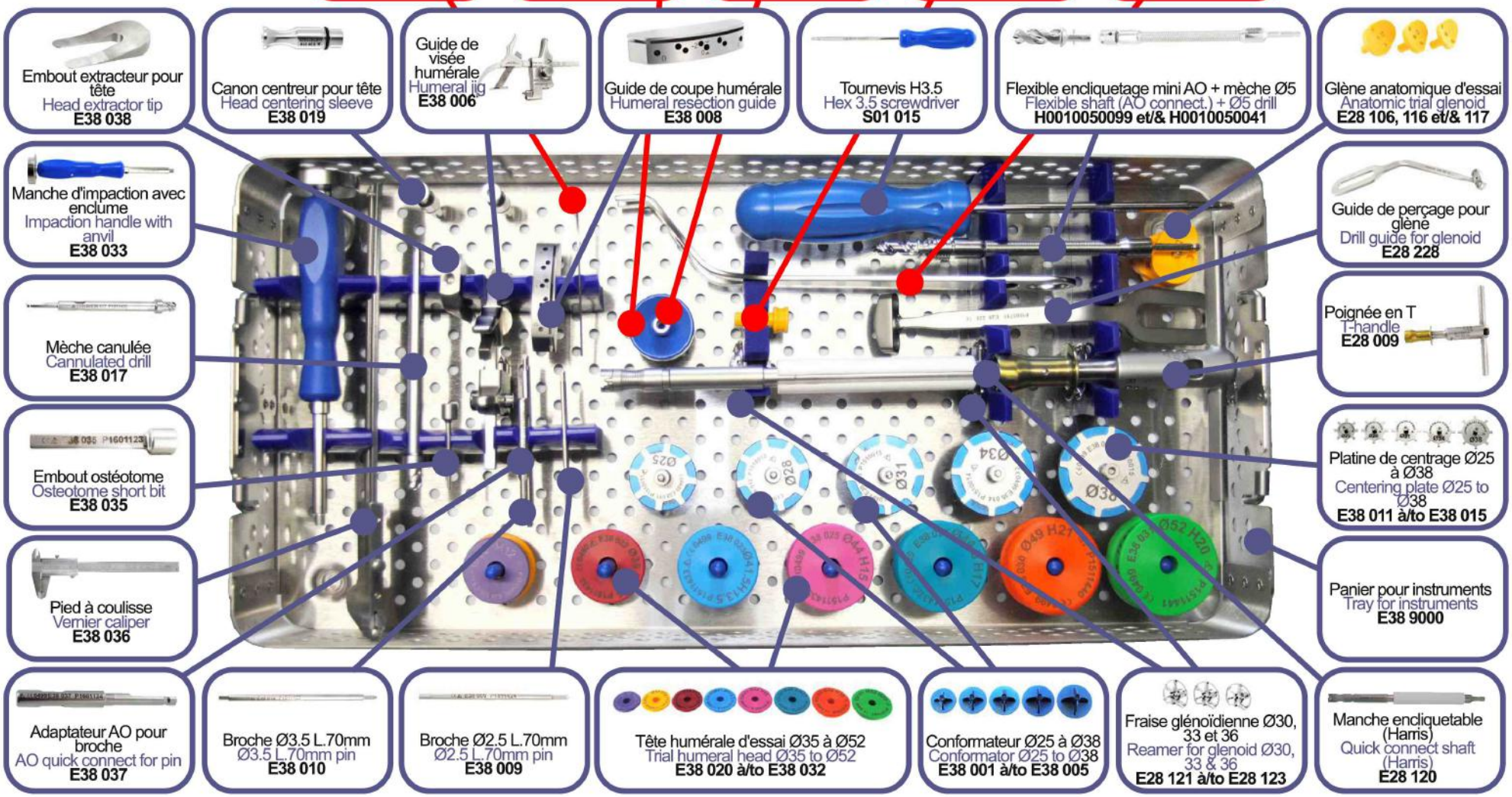
Impact the humeral head (2).
Impact firmly until the lower edge of the head comes in contact with the humerus bone (3).



Instrumentation SNAPSHOT

Ref : E38 9100

UNIC STEMLESS



Avril 2016 / Ref: BI_UNIC STEMLESS SNP E38 9100

www.evolutisfrance.com / Evolutis, Avenue de la Libération, 42720 Briennon, France. Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

References

Ref.code	Description		Ø	H. (mm)	Radius (mm)	Mismatch (mm)
E37 001	Short anatomic stem S.25	*Tige anatomique courte T.25*	Ø25			
E37 002	Short anatomic stem S.28	*Tige anatomique courte T.28*	Ø28			
E37 003	Short anatomic stem S.31	*Tige anatomique courte T.31*	Ø31			
E37 004	Short anatomic stem S.34	*Tige anatomique courte T.34*	Ø34			
E37 005	Short anatomic stem S.38	*Tige anatomique courte T.38*	Ø38			
E37 M3512	Humeral head S.35/12	*Tête humérale T.35/12*	Ø35	H.12	21	-7
E37 M3712	Humeral head S.37/12	*Tête humérale T.37/12*	Ø37	H.12	22	-6
E37 M3912	Humeral head S.39/12	*Tête humérale T.39/12*	Ø39	H.12	23	-5
E37 M4113	Humeral head S.41/13	*Tête humérale T.41/13*	Ø41	H.13	24	-4
E37 M4116	Humeral head S.41/16	*Tête humérale T.41/16*	Ø41	H.16	24	-4
E37 M4415	Humeral head S.44/15	*Tête humérale T.44/15*	Ø44	H.15	24.5	-3.5
E37 M4418	Humeral head S.44/18	*Tête humérale T.44/18*	Ø44	H.18	24.5	-3.5
E37 M4617	Humeral head S.46/17	*Tête humérale T.46/17*	Ø46	H.17	25	-3
E37 M4620	Humeral head S.46/20	*Tête humérale T.46/20*	Ø46	H.20	25	-3
E37 M4918	Humeral head S.49/18	*Tête humérale T.49/18*	Ø49	H.18	26	-2
E37 M4921	Humeral head S.49/21	*Tête humérale T.49/21*	Ø49	H.21	26	-2
E37 M5220	Humeral head S.52/20	*Tête humérale T.52/20*	Ø52	H.20	27.5	-0.5
E37 M5223	Humeral head S.52/23	*Tête humérale T.52/23*	Ø52	H.23	27.5	-0.5
E27 130	Cemented anatomic glenoid S.1	*Glène anatomique cimentée T.1*	Ø30/22		28	
E27 133	Cemented anatomic glenoid S.2	*Glène anatomique cimentée T.2*	Ø33/24		28	
E27 136	Cemented anatomic glenoid S.3	*Glène anatomique cimentée T.3*	Ø36/26		28	

Dimensions of anatomic head:
choice of 2 heights from Ø 41 to 52
Dimensions des têtes anatomiques :
choix de 2 hauteurs du Ø 41 au 52

Cemented anatomic glenoid:
constant gap between the fixation pegs for all 3 sizes
Glènes anatomiques cimentées :
écartement fixe entre les plots pour les 3 tailles

Humeral stem Ø 25 to 38,
humeral head Ø 35 to 52
Tige humérale Ø 25 à 38,
tête humérale Ø 35 à 52

Evolutis
MOTION INSIDE

Mentions légales :
Les implants articulaires d'épaule UNIC sont des dispositifs médicaux implantables de classe III indiqués pour les arthroplasties primaires partielles (Hémiarthroplastie) ou totales (PTE) de l'épaule.
Les implants UNIC sont pris en charge par l'assurance maladie.
Le chirurgien est expressément invité à lire attentivement les instructions mentionnées sur la notice d'utilisation incluse dans le conditionnement du DMI, ainsi que le manuel de technique opératoire délivré à la mise en place du produit ou disponible en téléchargement sur le site www.evolutisfrance.com.

***Materials* / Matériaux :**
Humeral stem: Titanium alloy according ISO 5832-3 and Calcium Hydroxyapatite coating
Cemented glenoid: UHMWPE according ISO 5834-1 & 2, and Stainless steel according ISO 5832-1 (radiolucent wire)
Humeral head: Cobalt-chromium alloy according ISO 5832-12
Packaging: Sterilized under Gamma irradiation, VacUpac packaging
Tige humérale : Alliage de titane selon ISO 5832-3 revêtue Hydroxyapatite de Calcium
Glène cimentée : UHMWPE selon ISO 5834-1 et 2, et Inox selon ISO 5832-1 (fil radio-repère)
Tête humérale : Alliage de chrome-cobalt selon ISO 5832-12
Conditionnement : Stérilisé sous rayonnement Gamma, conditionnement VacUpac

CE 0086 Evolutis
Avenue de la Libération, 42720 Briennon, France
Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Designed and Manufactured in France

www.evolutisfrance.com

Dec 2017 / Ref: EN_UNIC STEMLESS STC E38 (E38 451)