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CREATEUR FABRICANT

EBAUCHE

UNIC®
STEMLESS

Surgical technique

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MOTION INSIDE

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Disclaimer

Indications

The UNIC STEMLESS implantable device is designed to treat centered omarthrosis pathologies at the shoulder joint of physically young and 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 trabeculaesintended 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 half upright 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 should be installed to support the arm alongside the body

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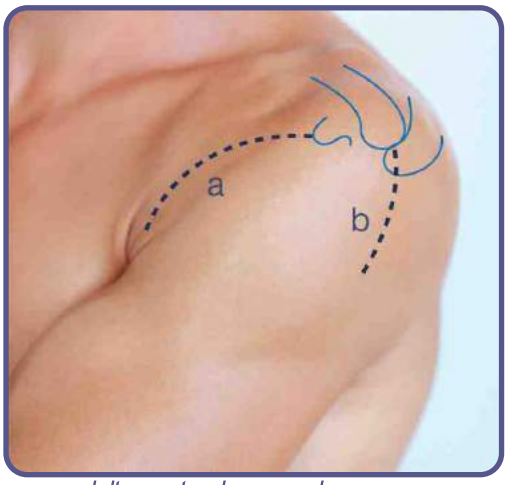
Surgical approaches

The two most common approaches for prosthetic shoulder surgery are the Delto-pectoral and the deltoid split approaches
Both approaches present advantages, the main difference between the two approaches is the exposure of the Glenoid

- deltoid split
  - \+ simplicity
  - \+ easier exposure to the glenoid
  - \+ tuberosity repair is easier
  - \+ sub-scapularis preserving approach
  - \- cut through the deltoid muscle
  - \- if the cuff is intact, the exposure is compromised
- delto-pectoral
  - \+ 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

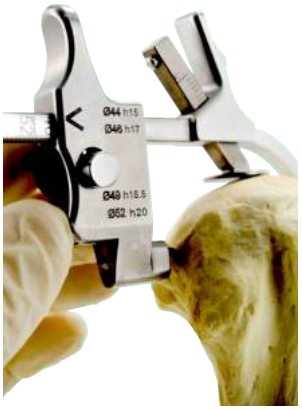
The preference between delto-pectoral and deltoid split approach is usually related to the necessity of porperly exposing the glenoid bone.
In general the delto-pectoral approach will be preferred for a total anatomic shoulder prosthesis, while the deltoid split will be preferred for a total reverse shoulder prosthesis.

Positionning of the humeral jig

The instruments used in this chapter are

Humeral jig	E38 006

Check for positionning of both anterior and posterior teeth at the margins of the cervical neck (calotte céphalique).
Lock the humeral jig in this position.
Turn humeral jig perpendicular to the cervical neck line and read resection values 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.
Introduce the pin into the humeral jig.
Press the lateral knob on the humeral jig, and pull the humeral jig out of the pin.

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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 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 and lateral levels of resection.
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 thrid Ø2.5 L.70mm pin introduced in the more lateral and convergent hole of the resection guide.
Resect the humeral cap.

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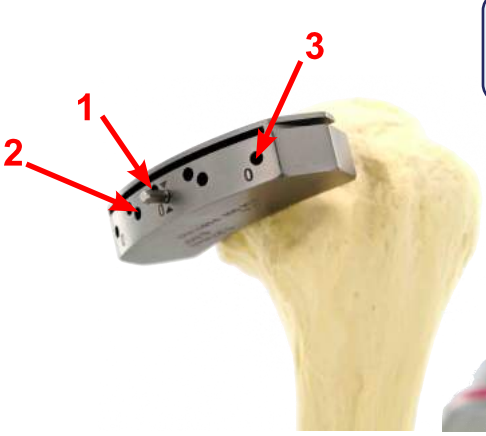


The instruments used in this chapter are

Vernier caliper	E38 036

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

According to the measures read on the humeral jig (page y), the humeral head will be less than 46mm. The minimal corresponding thickness is therefore between 15mm (head size 44) and 17mm (head size 46).

In the case the head size 46 is confirmed at the following steps, a correction of the resection level may be necessary to approximate a thickness value of 17mm.
To acheive an additionnal 2mm resection, remove the lateral convergent pin, an re-position the resection guide on the 2 remaining pins an in the holes of the resection guide marked "2".
Resect the excess of bone.

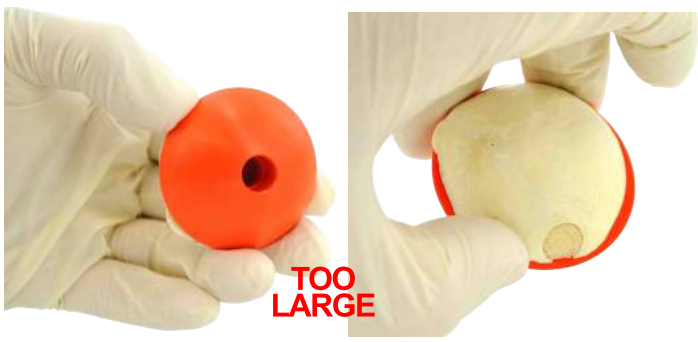
Size selection of the humeral head

The instruments used in this chapter are

Humeral head trials	E38 020 to E38 032

Select the humeral head trials corresponding to the initial measures (in our example 44 and 46), 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.



Preparation of the humeral epiphysis

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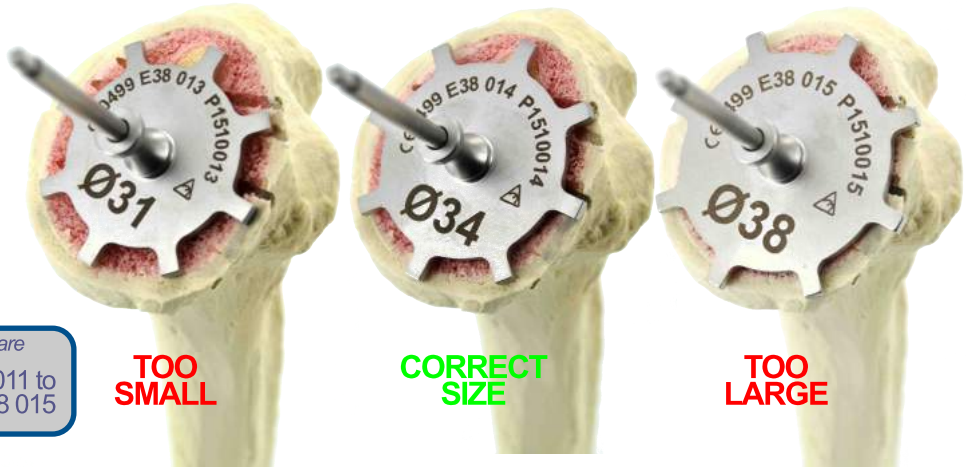
The instruments used in this chapter are

Humeral head trials	E38 020 to E38 032
Head centering sleeve	E38 019
AO quick connect for pin	E38 037
Ø3.5 L.70mm pin	E38 009

Introduce a head centering sleeve into the selected humeral head trial.
Place the humeral head trial at best on the humeral epiphysis.
Adjust the AO quick connect for pin on the power tool.
Introduce one pin (Ø3.5 L.70mm) on the AO quick connect.
Drill into the centering sleeve untill contact with the lateral cortex of the humerus.
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 anchorage

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
Modular trial taper	E38 007

Adapt the cannulated drill to the power tool (small AO connect.) and drill the center imprint up to the hilt of the reamer.
Remove the drill.
Select the conformator of the sizes selected at the previous sizing of the component step.
Assemble the conformator with the impaction handle.

Introduce the conformator on the guiding pin and check for orientation of the flanges: orientate the flanges (shown with the "X" marks on the conformator) away fro the most fragile regions of the cortex such as the quadricipital groove. In general, an orthogonal positionning of the flanges (in the A/P and M/L orientations) will be acceptable.
Impact firmly untill the conformator comes in contact with the humeral cut.

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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.
Position the trial humeral head on the taper.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

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.
Open the sterile pack and leave the STEMLESS implant in the packaging foam.
Screw the impaction handle directly on the STEMLESS implant.
Position the implant on the humeral epiphysis and check for the proper orientation of the flanges.
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.

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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.
Position the implant directly on the taper of the STEMLESS implant.
Assemble the head pusher tip on the impaction handle.

Impact the head on the taper.
Impact firmly until the lower edge of the head comes in contact with the humeral edge.

Instrumentation SNAPSHOT

Ref : E38 9100

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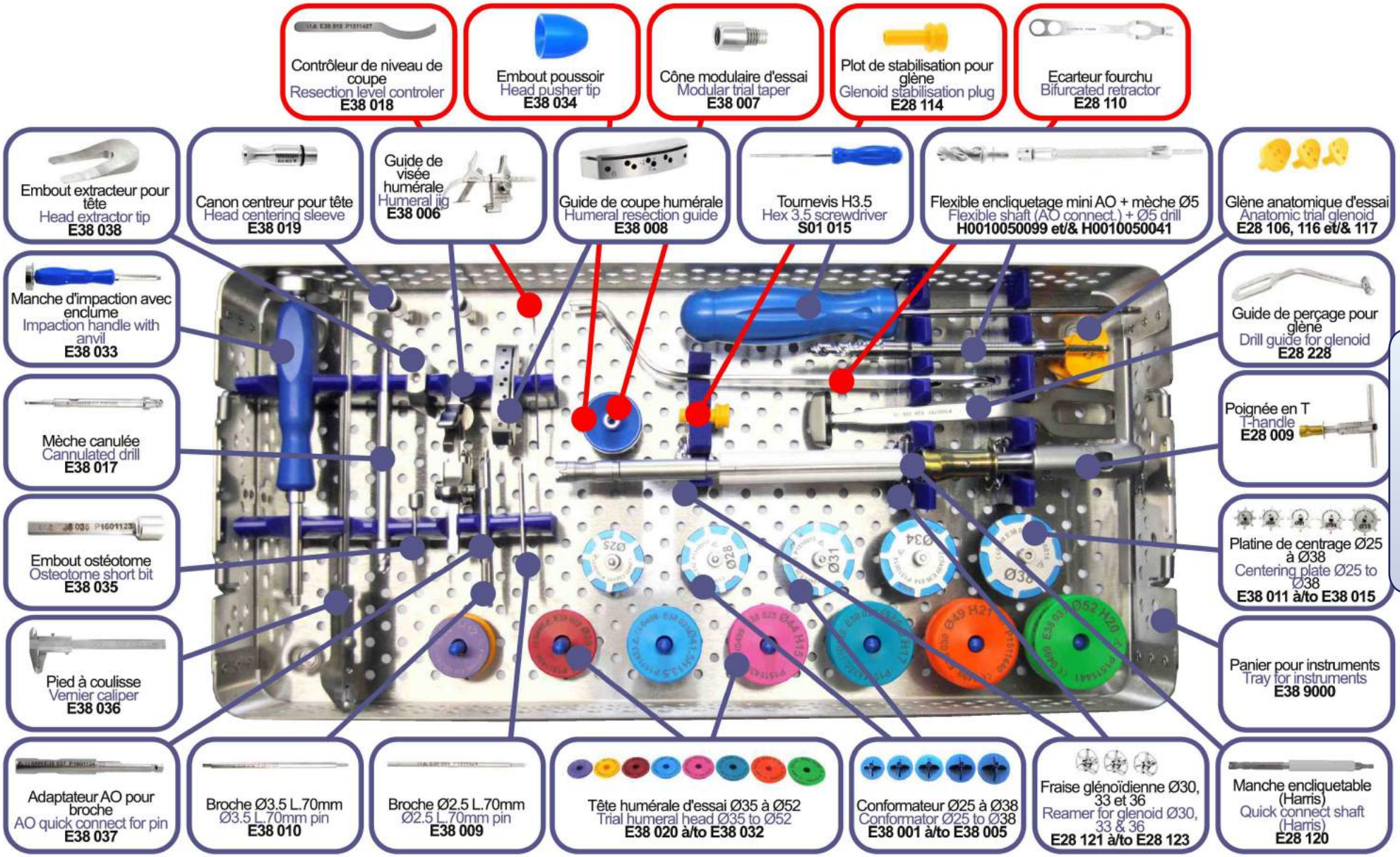

Contrôleur de niveau de coupe
Resection level controler
E38 018

Embout poussoir
Head pusher tip
E38 034

Cône modulaire d'essai
Modular trial taper
E38 007

Plot de stabilisation pour glène
Glenoid stabilisation plug
E28 114

Ecarteur fourchu
Bifurcated retractor
E28 110

Embout extracteur pour tête
Head extractor tip
E38 038

Canon centreur pour tête
Head centering sleeve
E38 019

Guide de visée humérale
Humeral jig
E38 006

Guide de coupe humérale
Humeral resection guide
E38 008

Tournevis H3.5
Hex 3.5 screwdriver
S01 015

Flexible encliquetage mini AO + mèche Ø5
Flexible shaft (AO connect.) + Ø5 drill
H0010050099 et/& H0010050041

Glène anatomique d'essai
Anatomic trial glenoid
E28 106, 116 et/& 117

Manche d'impaction avec enclume
Impaction handle with anvil
E38 033

Mèche canulée
Cannulated drill
E38 017

Embout ostéotome
Osteotome short bit
E38 035

Pied à coulisse
Vernier caliper
E38 036

Guide de perçage pour glène
Drill guide for glenoid
E28 228

Poignée en T
T-handle
E28 009

Platine de centrage Ø25 à Ø38
Centering plate Ø25 to Ø38
E38 011 à/to E38 015

Panier pour instruments
Tray for instruments
E38 9000

Adaptateur AO pour broche
AO quick connect for pin
E38 037

Broche Ø3.5 L.70mm
Ø3.5 L.70mm pin
E38 010

Broche Ø2.5 L.70mm
Ø2.5 L.70mm pin
E38 009

Tête humérale d'essai Ø35 à Ø52
Trial humeral head Ø35 to Ø52
E38 020 à/to E38 032

Conformateur Ø25 à Ø38
Conformator Ø25 to Ø38
E38 001 à/to E38 005

Fraise glénoïdienne Ø30, 33 et 36
Reamer for glenoid Ø30, 33 & 36
E28 121 à/to E28 123

Manche encliquetable (Harris)
Quick connect shaft (Harris)
E28 120

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Avril 2016 / Ref: BI_UNIC STEMLESS SNP E38 9100

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References

Ref.code	Description		Ø	H. (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
E37 M3712	Humeral head S.37/12	*Tête humérale T.37/12*	Ø37	H.12
E37 M3912	Humeral head S.39/12	*Tête humérale T.39/12*	Ø39	H.12
E37 M4113	Humeral head S.41/13	*Tête humérale T.41/13*	Ø41	H.13
E37 M4116	Humeral head S.41/16	*Tête humérale T.41/16*	Ø41	H.16
E37 M4415	Humeral head S.44/15	*Tête humérale T.44/15*	Ø44	H.15
E37 M4418	Humeral head S.44/18	*Tête humérale T.44/18*	Ø44	H.18
E37 M4617	Humeral head S.46/17	*Tête humérale T.46/17*	Ø46	H.17
E37 M4620	Humeral head S.46/20	*Tête humérale T.46/20*	Ø46	H.20
E37 M4918	Humeral head S.49/18	*Tête humérale T.49/18*	Ø49	H.18
E37 M4921	Humeral head S.49/21	*Tête humérale T.49/21*	Ø49	H.21
E37 M5220	Humeral head S.52/20	*Tête humérale T.52/20*	Ø52	H.20
E37 M5223	Humeral head S.52/23	*Tête humérale T.52/23*	Ø52	H.23
E27 130	Cemented anatomic glenoid S.1	*Glène anatomique cimentée T.1*	Ø30/22	
E27 133	Cemented anatomic glenoid S.2	*Glène anatomique cimentée T.2*	Ø33/24	
E27 136	Cemented anatomic glenoid S.3	*Glène anatomique cimentée T.3*	Ø36/26	

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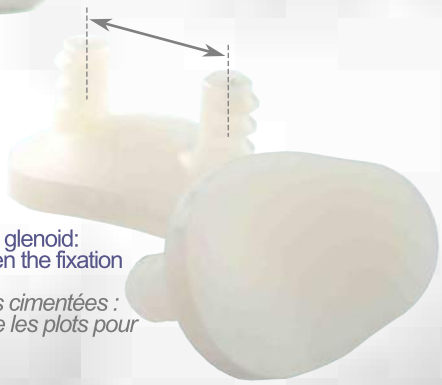
Dimensions of anatomic head:
choice of 2 heights from Ø 41 to 52
Dimensions des têtes anatomiques :
choix de 2 hauteurs du Ø 41 au 52



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

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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
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
Tête humérale : Alliage de chrome-cobalt selon ISO 5832-12
Conditionnement : Stérilisé sous rayonnement Gamma, conditionnement VacUpac

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