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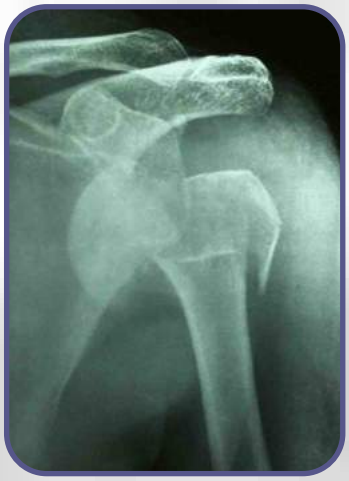
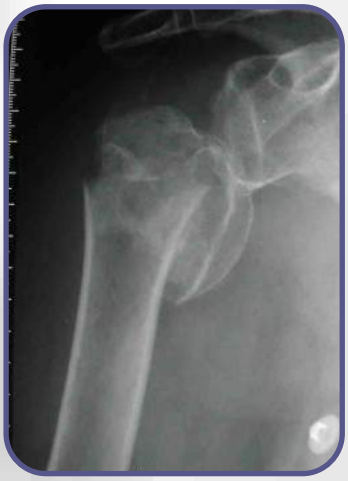




UNIC® Trauma

Surgical Technique

Evolutis
MOTION INSIDE

Table of contents

Disclaimer

Indications

The UNIC Trauma humeral stem is designed to treat fractures around the shoulder joint, especially displaced 3 or 4 part fractures of the proximal humerus, comminutive fractures, humeral head and neck fractures.
The UNIC trauma stem is specially designed with slender metaphyseal volume & non-slip macrotexture. The suture holes are conveniently positioned for easy access & allowing consolidation of the tuberosities to the stem.

The UNIC stem is truly modular in every sense. It allows for intraoperative corrections of preoperative diagnosis of the patient or intraoperative complications.
The Unic Trauma stem can be used for a hemiarthroplasty or anatomic total if the rotator cuff is in good condition, reverse prosthesis if the cuff is deficient or CTA arthroplasty if the glenoid bone stock does not allow for implant fixation and the cuff is also deficient.

The UNIC Trauma stem is designed for metaphyseal fixation without cement. The proximal HA coating enhances osteointegration of the shaft inside the humerus, and for tuberosity integration on the macrostructures.

In case of pronounced instability of the humeral implant, the distal part is mirror polished to allow for cement use and obtain immediate primary fixation stability.

Pre-operative planning

Pre-operative planning is often usefull since intra operative landmarks can be vague and sometimes difficult to find.
It is advised to dispose of calibrated bi-lateral x-rays (with size reference, measurement ruler or known sphere diameter).

- Calculate the true height of the humerus by using the contra lateral x-ray. *(illustration 1)*
- Establish where the summit of the humeral head was before the fracture, on the fractured side. *(illustration 2a)*
- Estimate the diameter of the humeral head. *(illustration 2a)*

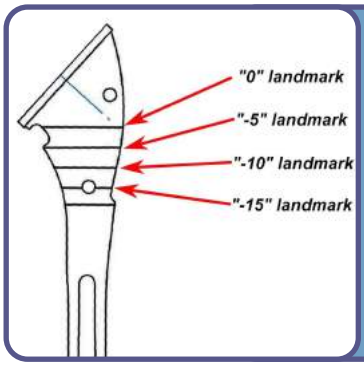
- Place the template of the estimated diameter over the mark made in the previous step. *(illustration 2b)*

- Position template of the stem (size 0) beneath the head template
- Select a bone landmark which can be found intra-operatively, such as the medial summit of humeral fracture *(illustration 2c)*
- Note which horizontal depth marker corresponds to the bone landmark chosen
  - The most proximal marker corresponds to a depth of "0" when aligned with the medial edge of the humeral head
  - The next markers going distally are 5mm apart, from -5 to -20mm
  - The position of the depth marker is reproduced with the rasps and the definitive stem

- The templates used to find the best depth of implantation are also used to determine the best size of implant for metaphyseal fixation *(illustration 2d)*

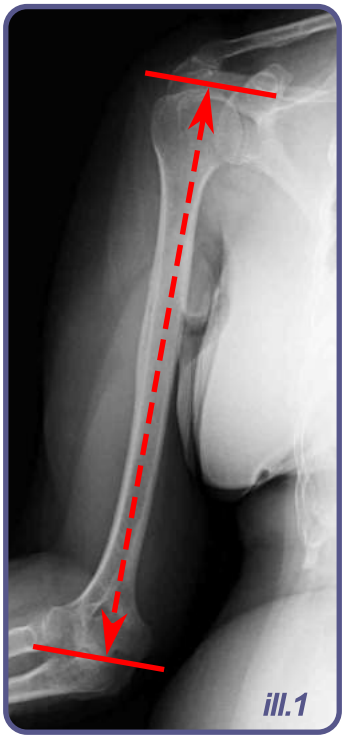
The use of templates to determine the position and size of anatomic implants can also be used for a **reverse prosthesis** since this method of planning is especially of use for positioning the humeral implant at the best anatomical height to recreate the space necessary to re-attach the tuberosities

The operator then needs to adapt the virtual humeral resection level by positionning the humeral stem 3 to 5mm lower than for an anatomic shoulder, and further note which horizontal depth marker corresponds to the bone landmark chosen

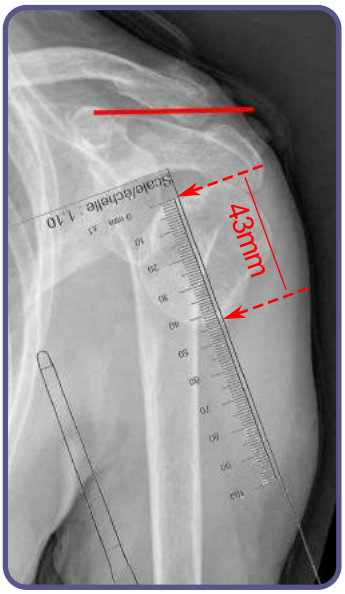


Note

*The **UNIC trauma rasps and implants** have the same depth markers which are designed to help planning, preparation and implantation of the implant is such a way as to conserve efficient articular space and soft tissue balance*

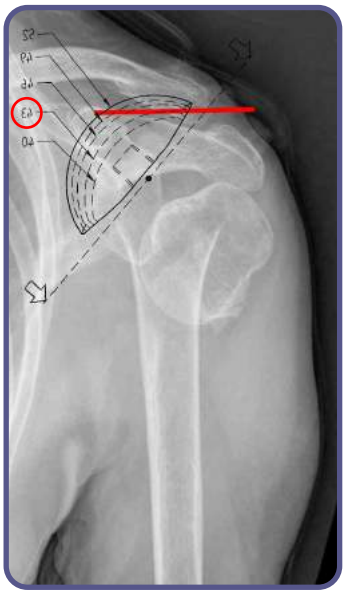


ill.1



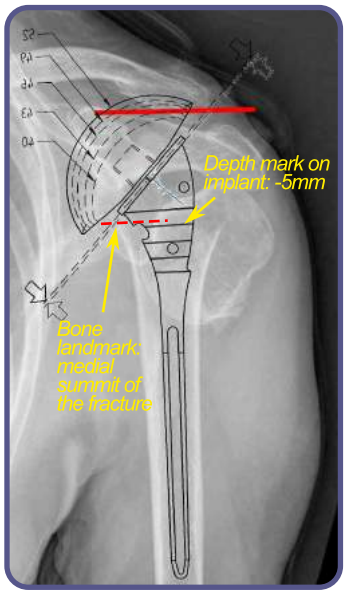
ill.2a

• Indicator of the summit of the humeral head (red line)
• Template of the diameter of the humeral head (in this case 43mm)



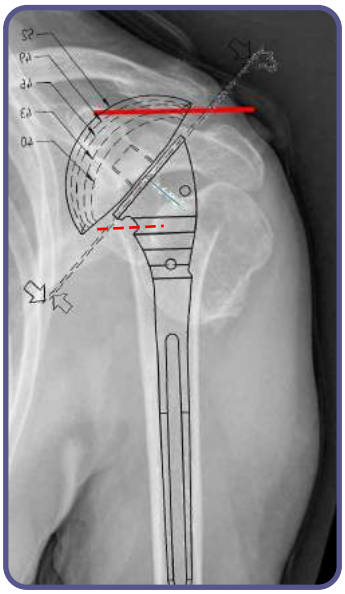
ill.2b

• Positioning the 43mm template at the theoretical summit of the humeral head (red line)



ill.2c

• Positioning of the humeral template size 0
• Identification of the bone landmark easily identifiable intra-operatively (medial summit of fracture)
• Identification of the depth marker which corresponds to the bone landmark (-5mm in this case)



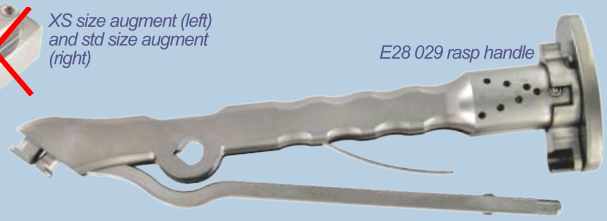
ill.2d

• Determination of the size of the humeral stem, by increasing in size (in this case size 2), at the same depth level

Compatibility of component and instruments

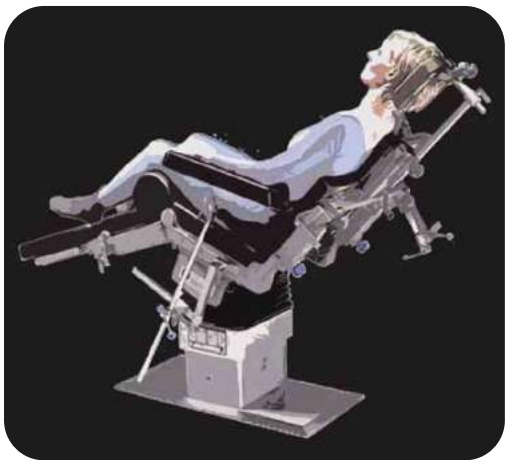
The UNIC trauma humeral stem implants are compatible with:
- Reverse humeral cups and inserts, standard and XS sizes
- Reverse glenoid implants, standard, XS and revision sizes
- Heads and modules of Anatomic heads
- CTA heads
- +10mm augment ONLY of XS size (NOT standard +10mm augment)
  However both augments accept all reverse, anatomic and CTA head possibilities

XS size augment (left) and std size augment (right)



E28 029 rasp handle

The UNIC Trama humeral stem requires the use of the UNIC general instrumentation tray E28 9105 when associated with a reverse component, and the use of the UNIC complementary instrumentation tray E28 9106 when associated with an antomic or CTA component
The E28 9105 has to be equiped with the E28 029 "rasp handle" with a 2 positions locking ring. If your instrumentation does not include the E28 029 rasp handle, please do not proceed to the surgery.



Patient positioning

The patient should be positioned in a half upright position

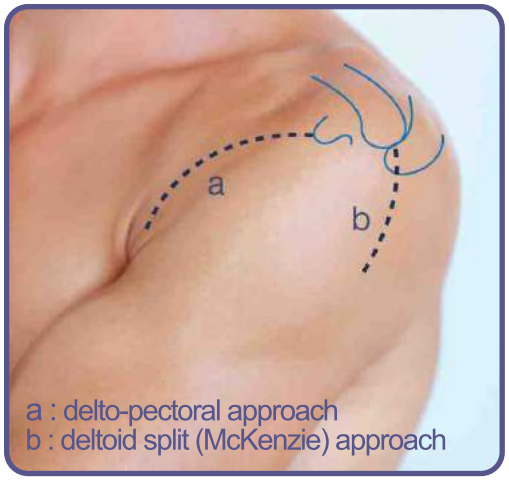
The body of the patient on the table must allow for the operated arm to be free of the table edge and to be manipulated freely in extension and adduction without hindrance

Ideally the whole shoulder should be free and not hindered

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

Technical introduction

In the presence of complex 4 part fragment fractures, the lesser tuberosity is pulled forward and medially by sub-scapularis retraction, whilst the greater tuberosity is pulled proximally and backwards by the combined effects of the supra spinatus, infra spinatus and the teres minor
The humeral head generally loses all vascular attachments and is found lateral and distal to its anatomic position
It can be useful to preserve the humeral head in order to take cancellous bone graft for use between the implant and tuberosities



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

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

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.

Surgical steps

After exposing the fracture, cleaning away the haematoma and removing the humeral head, the surgeon must evaluate regarding the following features
- The rotator cuff
- The glenoid
- The position and quality of bone fragments

Then confirm the indication and tenodese the tendon of the long head of the biceps muscle
The surgeon can then decide the type of prosthesis and extent of tuberosity / rotator cuff repair

For glenoid preparation and trials please refer to the UNIC op tech (ref EN_UNIC STC E28)

Preparation of the humerus

Assemble the T handle (ref E28 009) onto humeral rasp size 0 (ref E28 084) *(Illustration 3)*

Calibrate the humeral diaphysis diameter WITHOUT REAMING, as far as the stop *(Illustration 4)*

Progressively increase the reamer diameters until obtaining scraping cortical contact, but not tight. This step is to calibrate the distal diameter of the diaphysis and help choose the correct size of trauma stem and make sure it does not jam inside the humerus. Do not use a larger stem


ill.3


ill.4

Important notice

UNIC trauma implants are only compatible with rasp holder E28 029. Before operating ensure that this is the rasp/implant holder in the instrument kit

Assemble rasp size 0 (ref E28 000) onto the rasp handle (ref E28 029), and lock it by turning the locking ring beneath the strike plate *(Illustration 5)*


ill.5

Note

The locking ring of E28 029 handle has 2 positions:
- All rasps except the XS (00) size lock into the second notch (Illustration 6a and 6b)
- The UNIC trauma stems lock into the first notch (Illustration 6c and 6d)


ill.6a


ill.6b

6a and 6b: locking of the humeral rasp
- *6a Tightening the locking arm*
- *6b Locking the locking arm in the second notch*


ill.6c


ill.6d

6c and 6d: Locking the UNIC trauma stem
- *6c Tightening the locking arm*
- *6d locking the locking arm in the first notch*

ill.7

Place the orientation guide (ref E28 007) in the hole in the handle corresponding to the chosen retroversion *(Illustration 7)*

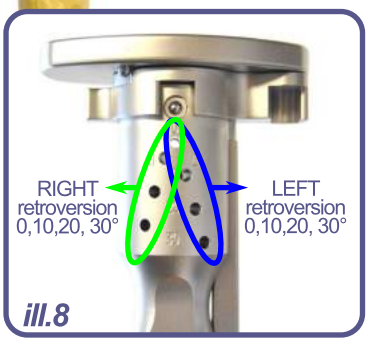
Use the DROIT (RIGHT) holes for a right shoulder and GAUCHE (LEFT) for a left shoulder *(Illustration 8)*

For a reverse shoulder the retoversion is generally included inside the 10 to 20° range
For an anatomic prosthesis it is usually included inside the 20 to 30° range

Place the 0 rasp inside the humerus taking care not to go beyond the preoperative planning mark chosen: for example in the pre-operative planning (Page 3) align the -5mm mark with the medial summit of the fracture

Remove the rasp size 0 from the humerus and remove the handle by turning the locking ring, replace the rasp with size 1 and place it in the humerus
Check its depth with the depth landmark selected pre-operatively

Incrementally increase the rasp size (ref E28 000 to E28 004) until good primary stability is achieved axially and rotationally, with the depth landmark being at the level selected pre-operatively



ill.8

ill.9

Disassemble the rasp holder leaving the rasp in the humerus

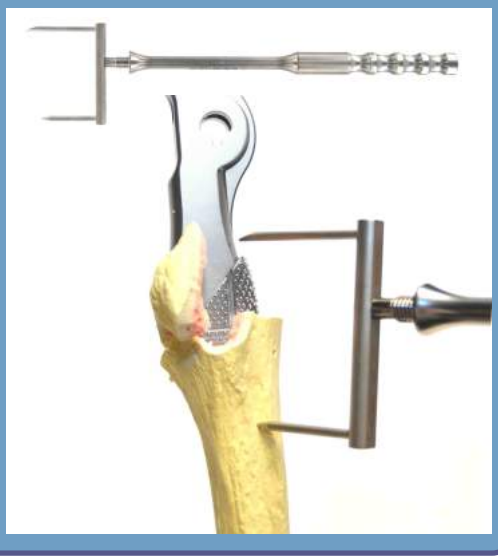
If necessary remove any bone fragments or spurs with a rongeur or saw *(Illustration 9)*

Option

A depth calibrator (ref E28 260) which should be aligned on the superior edge of the tendon of the pectoralis major is available as an option in the instrumentation

*It can **only** be used with a delto – pectoral approach*

How to use:
- *Identify the humeral insertion of the pectoralis major muscle*
- *Place the short arm of the calibration device in line with the superior edge of the tendon*
- *The longer arm of the calibrator shows the theoretical summit of the humeral head at 56mm of the proximal fibres of the tendon insertion (according to Murachowski)*
- *Dependent on the type or size of the patient, up to 5mm can be added between the calibrator branch and the summit of the humeral head*
- *Note the depth mark of the rasp in relation to the planified landmark (in relation to pre-operative planning)*
- *Should the rasp be too deeply impacted, try the next size up rasp and check its depth*



Glenoid Preparation

See the UNIC operative technique (ref EN_UNIC STC E28) for glenoid preparation:
- Reverse prosthesis pages 13 to 17

Trial Reductions

The trials allow for verification that the depth of the humeral implant defined by the pre-operative planning and confirmed by use of the rasp correspond to the anatomical situation of the operated shoulder
The intra-prosthetic stability must be sufficient: at this step the articulation must be stable even **without** fixation and suture of the tuberosities

However the trials will only be of any value if the rasp is stable within the humerus
If stability cannot be achieved with the rasp because of the condition of the bone being too fragile to undertake trials, then it is preferable to undertake the trials on the definitive prosthesis

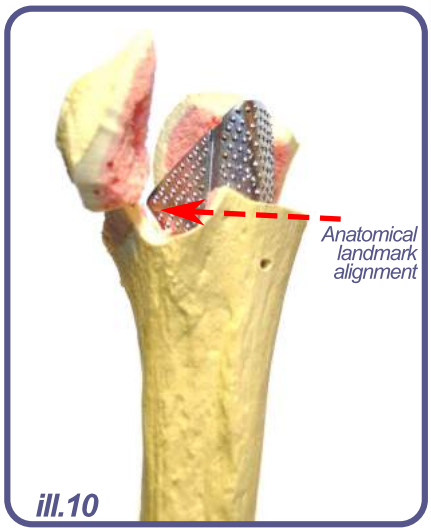
Refer to the UNIC operative technique (ref EN_UNIC STC E28) for trials
- Trials for reverse prosthesis page 18
- Trials for anatomic prosthesis page 23

Definitive stem

Identify the horizontal depth marker selected on the rasp using the same anatomical landmark *(Illustration 10)*
Re-mount the rasp handle (E28 028) on the rasp left in situ and remove it from the humerus

Take the corresponding definitive UNIC humeral stem (Ref E27 030 to E27 034) and mount it on the rasp handle (E28 028)

Lock into place on the first notch of the rasp handle *(Illustration 11)*



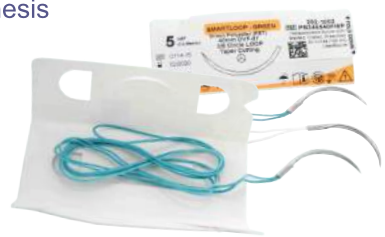
ill.10

ill.11

Preparation of the suture loops

The synthesis of a 4 fragments fracture requires the use of 5 or 6 suture loops :
• 1 or 2 loops for the tension banding
• 2 loops to re-attach the greater tuberosity to the prosthesis
• 2 loops to re-attach both greater and lesser tuberosity together

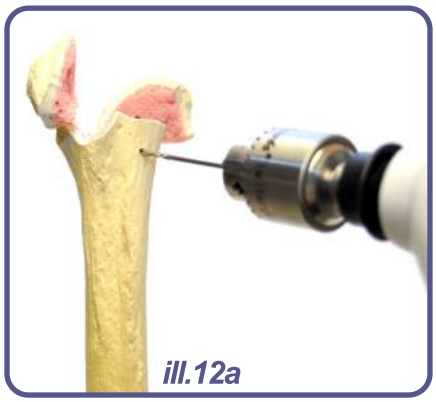
All loops have to be placed on the humerus before introducing the final implant



1) Tension banding loop(s)
- drill 2 holes (Ø2.0mm) through the lateral cortex on both sides, 1cm below the fracture and 1cm apart *(illustration12a)*
- introduce the loop from outside-in and then inside-out *(illustration12b & c)*
- grip both ends of the loop with a pair of artery forceps *(illustration12d)*

or

- introduce 1 loop from outside-in in each hole
- grip both ends of each loop separately with a pair of artery forceps


ill.12a


ill.12b


ill.12c

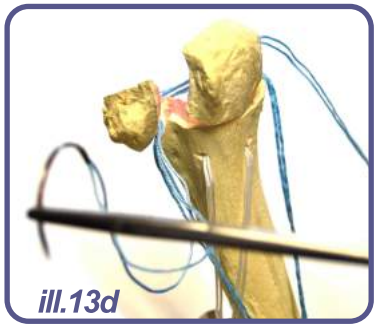

ill.12d

2) Greater tuberosity to the prosthesis re-attachment loops
- introduce a first loop through the lower supra-spinatus fibers medially to the greater tuberosity *(illustration13a & b)*
- introduce a second loop through the higher supra-spinatus fibers medially to the greater tuberosity *(illustration 13c & d)*
- wrap the suture loops around the medial edge of the humerus for the loops, so as not to interfere with the humeral of stem during its introduction
- grip both anterior and posterior ends of each loop separately with a pair of forceps


ill.13a

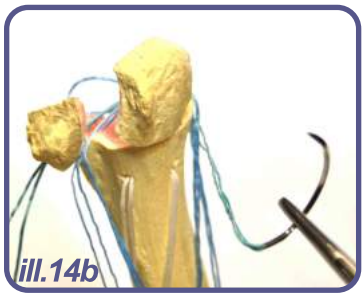

ill.13b

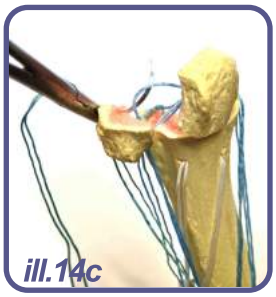

ill.13c

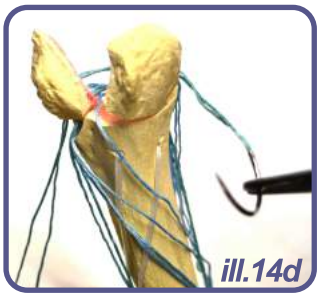

ill.13d


ill.14a

3) Re-attachment of greater and lesser tuberosity together loops
- introduce a first loop outside-in through the lower sub-scapularis fibers medially to the lesser tuberosity *(illustration14a)*
- introduce the first loop inside-out through the lower supra-spinatus fibers medially to the greater tuberosity *(illustration14b)*
- introduce a second loop outside-in through the higher sub-scapularis fibers medially to the lesser tuberosity *(illustration14c)*
- introduce the second loop inside-out through the higher supra-spinatus fibers medially to the greater tuberosity *(illustration14d)*
- wrap the suture loops around the medial edge of the humerus for the loops not to be in the way when introducing the stem
- grip both anterior and posterior ends of each loop separately with a pair of forceps *(illustration14e)*


ill.14b

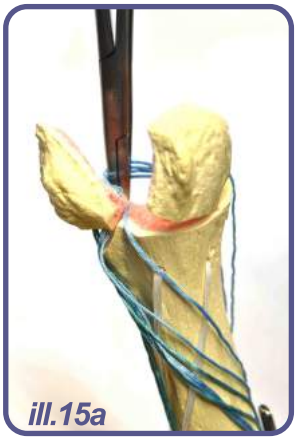

ill.14c


ill.14d

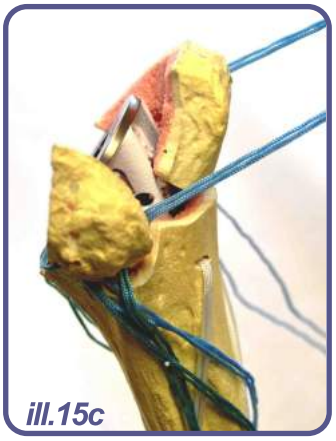

ill.14e

Final implantation

Precautions when implanting the definite stem
- Wrap the sutures around the medial edge of the humeral bone *(illustration15a)*
- Introduce the humeral stem without impaction *(illustration15b)*
- Pull on all the blue and green loops so that all sutures engage in the medial hook of the stem *(illustration15c & d)*
- Finalize the impaction of the stem


ill.15a


ill.15b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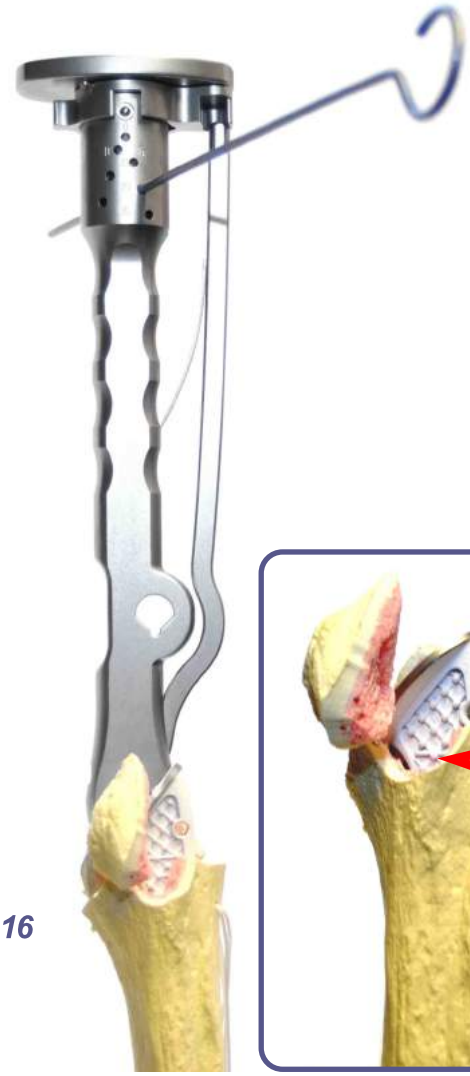

ill.16

The UNIC trauma stem has been designed for cementless fixation. The proximal third is HA coated.
However, if the bone is osteoporotic or of poor quality and so primary stability is difficult to achieve or that there is a risk of peri-prosthetic fracture, it is possible to cement the distal portion of the stem over 8 to 10cm depending on the implant size.

Cementless fixation:

- Place the implant in the diaphysis attached to the handle
- Introduce the orientation rod (E28 007) into the hole indicating the desired retroversion
- Push down the assembly by hand maintaining the retroversion *(Illustration 16)*
- Finish impaction with a hammer up to the horizontal depth indicator pre-selected to align with the chosen landmark *(Illustration 17)*

ill.17

Cemented distal fixation:

- Put into place the cement restrictor adapted to the humeral diameter (See humeral preparation: page 5)
- Prepare the cement, and fill the canal with retrograde cementing technique using a cement syringe
- Make sure the cement remains distal: use a quantity relative to implant/reamer calibre
- Insert the stem up to the depth landmark as for a cementless stem

Implantation of anatomic heads, CTA heads humeral, reverse cups and glenoid implants

See the UNIC operative technique (Ref EN_UNIC STC E28) for the following stages
- Glenoid base and sphere on reverse implant (Page 17)
- Humeral cup on reverse implant (Pages 18 to 20)
- Preparation and implantation of a CTA head (Page 26)

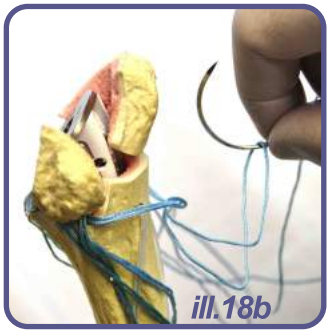
Fixation and suture attachment of the tuberosities

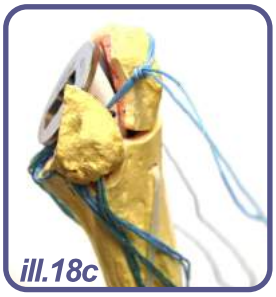
Place the arm in external rotation and at 25° of abduction

Re-attachment of the greater tuberosity

- grab the 2 ends of the proximal blue loop
- adjust the loop until there is only between 5 and 10cm of loop remaining outside of the greater tuberosity
- tie a flat knot *(illustration18a)*
- pass the needle in the loop extremity *(illustration18b)*
- thighten the knot by pulling on the 2 threads together *(illustration18c)*
- repeat the same procedure with the distal loop *(illustration 18d & e)*


ill.18a


ill.18b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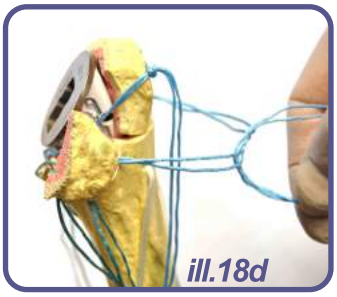
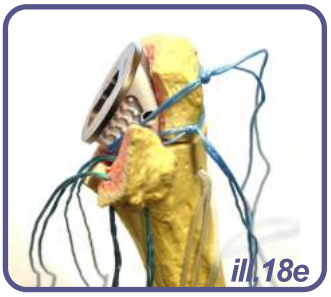

ill.18d


ill.18e

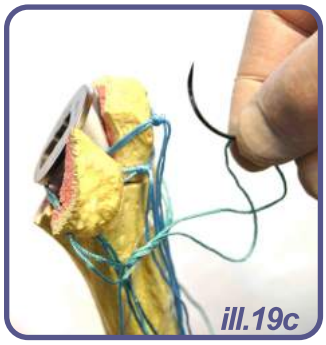
Synthesis of the greater and the lesser tuberosity together

- grab the 2 ends of the proximal loop *(Illustration 19a)*
- adjust the loop until there is only between 5 and 10cm of loop remaining outside of the lesser tuberosity
- tie a flat knot *(illustration19a)*
- pass the needle in the loop extremity *(illustration19c)*
- thighten the knot by pulling on the 2 threads together
- repeat the same procedure with the distal loop *(illustration 19d & e)*

- tighten firmly all 4 loops *(illustration19f)* by pulling on the 2 threads of each loop, begining with the loops

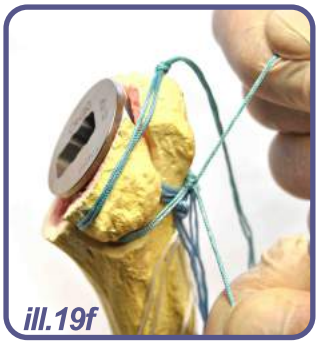

ill.19a


ill.19b


ill.19c


ill.19d


ill.19e


ill.19f

Tension banding finalisation


ill.20a

The basic principle of the tension banding is to cross the 2 threads of the loop (or the 2 loops) between the 2 distal holes in the humerus and the greater and lesser tuberosities: the thread tensioning on the greater tuberosity will be anchored to the anterior hole, while the thread tensioning on the lesser tuberosity will be anchored to the posterior hole.

Use of a single loop:
- grap the needle on the loop out of the anterior hole (see page 8)
- adjust the loop until there is only beetween 5 and 10cm of thread out of the posterior hole
- pass the needle through the greater tuberosity insertion of the supra-spinatus and from bottom to top *(illustration 20a)*


ill.20b


ill.20c

- pass the needle through the lesser tuberosity insertion of the sub-scapularis and from top to bottom *(illustration 20b)*
- pull on the loop until it is applied on the rotator cuff
- grap the second end of the loop out of the posterior hole
- tie a flat knot *(illustration 20c)*
- pass the needle in the loop extremity *(illustration20d)*
- thighten the knot by pulling on the 2 threads together *(illustration20e)*


ill.20d


ill.20e

Use of 2 loops:
Alternative allowing the surgeon to adjust separately the tension on either tubersosity, and a stronger more resistant synthesis.

- grab the anterior loop needle and pass it through the greater tuberosity insertion of the supra-spinatus and from bottom to top
- grab the other end of the same loop
- tie a flat knot
- pass the needle in the loop extremity
- thighten the knot by pulling on the 2 threads together

- repeat the same procedure through the lesser tuberosity insertion of the sub-scapularis and from bottom to top with the posterior loop

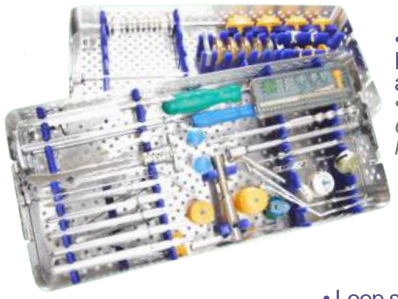
Post-operative care

- The arm should be immobilised with the elbow against the body in a Dujarier type brace
- If necessary a small abduction cushion or rotational control can be used
- The dressing should be changed at 48 hours at the same time as drain removal

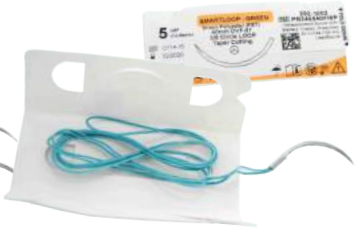
UNIC® Trauma stem

Mars 2016 / Ref: EN_UNIC TRAUMA STC E28 (E28 454)

• Compatibility with all components of the UNIC range
• *Compatibilité avec l'ensemble des composants de la gamme UNIC*



• Instrumentation set E28 9105 & E28 9106 suits all primary indications
• *Instrumentation E28 9105 et E28 9106 couvre toutes les indications primaires*



• Loop sutures -2 coulours- for reliable suture of the tuberosities
• *Boucles de suture -2 couleurs- pour réaliser la suture des tubérosités*

• "Clover" connection: full compatibility with the UNIC system
• *Connexion "trèfle" : compatibilité totale au système UNIC*

• Large collar to limit secondary migration
• *Collerette large pour limiter la migration secondaire*

• Medial hook & holes for suture threads and cerclages
• *Crochet interne et trous pour sutures et cerclages*

• Narrow and bone preserving metaphysis - one of the narrowest amongst available stems
• *Métaphyse étroite et conservatrice en stock osseux*

• Hollowed out anterior, posterior, and lateral surfaces: correct positioning of tuberosities
• *Evidement A/P et externe: repositionnement des tubérosités*

• 3D macrostructure to enchance fragment mechanical stability
• *Macrostructure 3D : ancrage mécanique des fragments*

• Fluted shiny-polished distal tip can be cemented
• *Quille cylindro-conique polie-brillante cimentable*

References

Description	Size	Cat. N°	Désignation	Taille
Humeral Trauma Stem	Size 0	**E27 030**	Tige Humérale Trauma	Taille 0
Humeral Trauma Stem	Size 1	**E27 031**	Tige Humérale Trauma	Taille 1
Humeral Trauma Stem	Size 2	**E27 032**	Tige Humérale Trauma	Taille 2
Humeral Trauma Stem	Size 3	**E27 033**	Tige Humérale Trauma	Taille 3
Humeral Trauma Stem	Size 4	**E27 034**	Tige Humérale Trauma	Taille 4
1 loop suture white		**292-1001**	Suture 1 boucle blanche	
1 loop suture green		**292-1003**	Suture 1 boucle verte	
Humeral Augment XS		**E27 112**	Réhausseur huméral XS	

Important Notice:
The UNIC TRAUMA implants belong to the class III implantable medical device classification. The UNIC TRAUMA implants are indicated in hemi arthroplasty or total arthroplasty anatomic or reverse procedures of the proximal shoulder joint in post-trauma situations.
The surgeon is required to read the instructions for use (IFU) included in the packaging of the implant, as well as the surgical technique manual initially delivered with the instrument set, or available for download on the www.evolutisfrance.com website.

Materials:
Stem: Titanium alloy TA6V according ISO 5832-3. Double coating porous titanium + calcium hydroxyapatite.Vacuum packed & double wrapped. Gamma ray sterilised.
Loop sutures: Thread Ethylene Polyterephtalate (PET) Ø0.7mm - Needle 40mm.
Matériaux *:*
Tige : Alliage de titane TA6V selon ISO 5832-3. Double revêtement titane poreux et hydroxyapatite de calcium.
Conditionnement sous vide double sachet. Stérilisation rayons gamma.
Sutures : Fil Ethylène Polytéréphtalate (PET) Ø0.7mm - Aiguille 40mm.

CE 0499 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