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CREATEUR FABRICANT

Horus® TMC

Surgical Technique

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MOTION INSIDE

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Horus® TMC

Warning:
This document is intended only for the use of trained orthopaedic specialists who have been trained in the implantation of articular orthopaedic implants and people approved to represent the EVOLUTIS company.
The operative technique manual is the recommended procedure for implanting the HORUS TMC trapezo metacarpal implant.
Evolutis is the manufacturer of this implant. As such Evolutis does not act within a medical capacity, the company does not recommend which surgical procedure or implants should be used.
Consequently it is up to the surgeon to decide which technique and implant is applicable to the patient, and which technique to choose for each individual patient.
For additional information on the product: indications, contra-indications, alerts, precautions, and side effects, please read the instructions for use which are supplied with each implant. For further information, please ask your local Evolutis representative.

Indications

The HORUS TMC prosthesis is indicated for arthritic trapezo-metacarpal lesions
(Dell 3 or Dell 4 stage of primary rizarthrosis or post-trauma arthritis of the basal thumb joint)
in patients not having a heavy manual use of the thumb joint either in professional, leisure or sports practices.
The trapezium should be large enough to support the implantation of the trapezium cup without damaging the cortical walls ;
a trapezium which is less than 8 mm in depth is a contra indication for an HORUS TMC prosthesis.

Positioning

The patient is positioned in a supine position.
A table or arm is also placed perpendicular to the patient.
The C-arm screen is best placed alongside the patients' hip so that images can be taken by simply extending the arm in the field of imagery of the amplifier.
The screen should be draped over its lower edge.

Approach and exposure

Use a dorsal curved incision over the trapezo metacarpal articulation (fig.1).
Undertake a subcutaneous dissection taking care not to damage the branches of the radial nerve.

Identify and retract the:
- Abductor policis longus tendon
- Extensor brevis tendon
- Extensor longus tendon

In order to avoid iatrogenic complications of the sensitive radial nerve branches it is best not to retract them but leave them in the body fat.

Undertake an arthrotomy between the tendons taking care of the insertion of the abductor longus at the base of the 1st metacarpal.
Continue with a horizontal capsulectomy flap and retraction of the extensor brevis from one side to the other.
A proximal base periosted flap gives good access to the articulation and avoids the need to identify the radial artery.
The periosted flap will not need to be re-attached at the end of the operation since the prosthesis is autostable.
The lateral edges of the metacarpal should be cleared of tissue to improve access to the trapezium.

Inspect the intra-articular space and proceed to a synovectomy if necessary.

Once the capsule is opened place a Hohman retractor under the tip of the metacarpus to lift and expose it (fig.2).


Fig.1


Fig.2

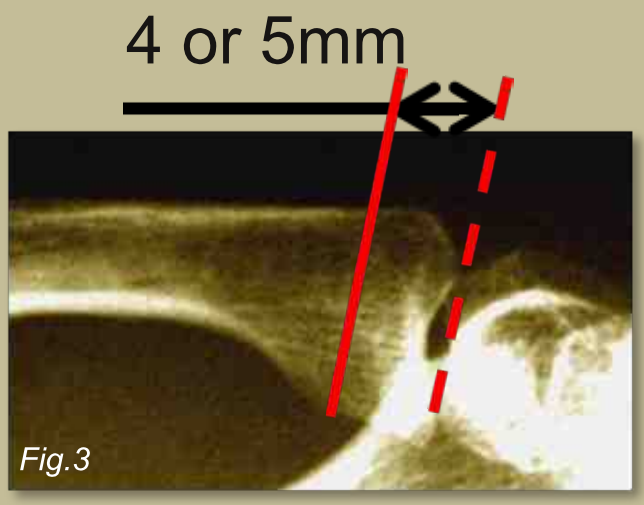


Fig.3


Fig.4

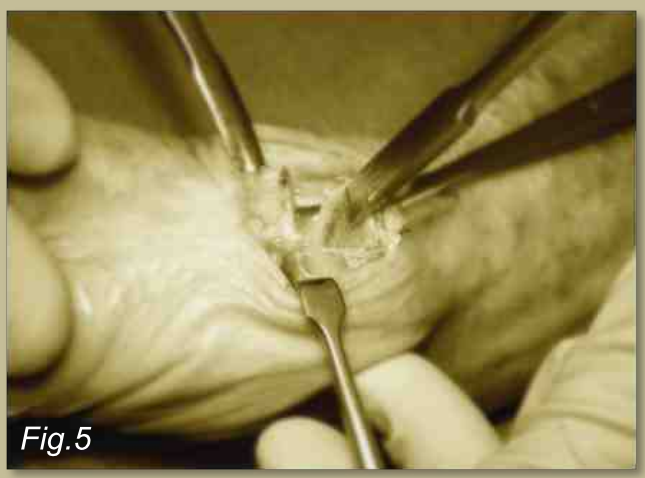


Fig.5

Metacarpal steps

Resection of the metacarpal base

Undertake the resection of 4 or 5mm (max.) at the base of the metacarpal (fig.3) with an oscillating saw (fig.4).

This should:
- be perpendicular to the axis of the metacarpus,
- remove the palmar “beak” using a slightly oblique cut.

This will avoid the possibilities of a bone-to-bone cam effect. The bigger the cut the easier the access to the trapezium, but also the risk of needing to use a long neck to preserve stability of the thumb.
The constraint design of the articulation allows for a certain amount of piston whilst avoiding intra articular dislocation.

Osteophyte removal should be undertaken as necessary.

Rasping of the metacarpal base

The entry point of the metacarpal with the bone awl should be more or less central in order to avoid damaging the dorsal cortex.
Progressive rasping will bring the horizontal part of the rasps beneath the dorsal cortex, thereby ensuring an optimal dorsal position of the future implant.
Introduce the starter bone awl so that the curve is in line with metacarpal anatomy (fig.6).
Select a centered entry point as the successive rasps will have a tendancy to migrate dorsally.

Starter bone awl (E32 M000)

Pre op planning will enable the identification of any intra-metacarpal cysts which might interfere with the best entry point.

Assemble rasp T1 on the holder-impactor, impact it by hand in the same axis as the metacarpal up until it is flush with the level of the basal cut.
The flat dorsal surface of the rasp, should be dorsal (fig.7).

Holder impactor for rasps and implants : shaft (E32 024) and screw (E32 025).

Successively increase the rasp sizes, and terminate the impaction of the last rasp with a small hammer whilst the assistant firmly holds the thumb.
Be careful not to crack the metacarpal.
Should the fit not feel secure, examine with a C-arm image.

Impact up until secure fit and contact with the metacarpal (fig.8), remove the holder impactor (fig.9) and leave the rasp in place (fig.10).

Metacarpal rasps : 5 sizes, cementless (E36 M001 to E36 M005)

Fig.6

Fig.7

Fig.8

Fig.9

Fig.10

Trapezium steps

Before preparation of the trapezium it is important to determine the size of trapezium implant which can be used in correlation with the depth, volume and shape of the trapezium.

Trapezo Metacarpal implants are contra indicated when the trapezium's depth is less than 8mm.

Important:

The trapezium must be at least 8mm deep.

The depth should be determined pre operativlely by scanner or x ray and intra operatively through a Kapandji view with a C-arm.

The height and width dimensions of the trapezium can be evaluated intra operatively.

Fig.11

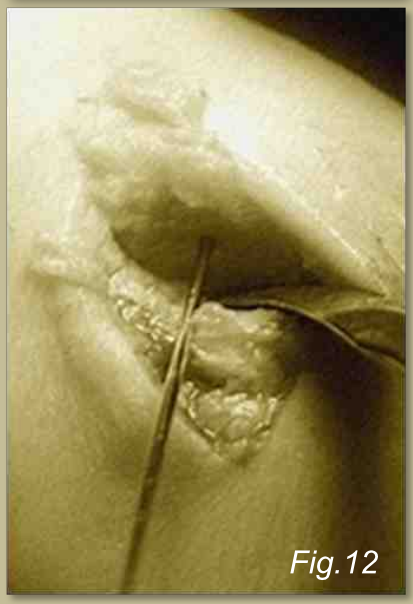


Fig.12

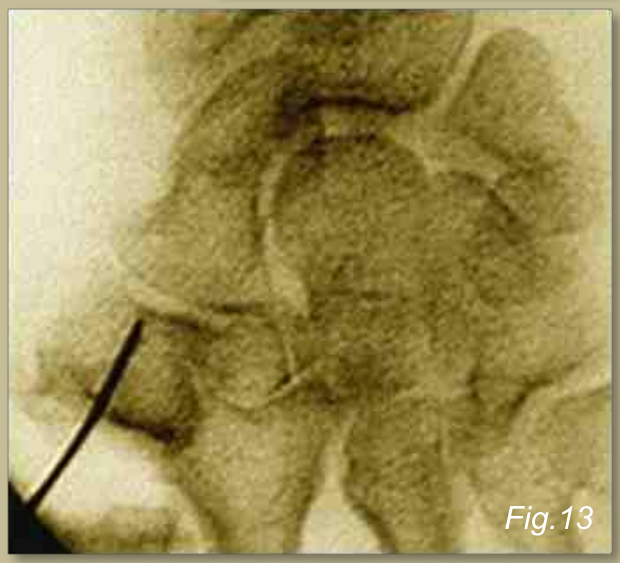


Fig.13

Trapezium preparation

Expose the trapezium and its attachments using a retractor, then evaluate its shape and orientation.

Prepare trapezium plan by resecting the bony horns so that the guide wire will be centred on a flat surface. The use of the successive reamers on a deep concave surface may increase the risk of fracture.
Resecting the bony horns also reduces the incidence of a bone-to-bone cam effect.

When the planning reveals the presence of osteophytes, often situated on the ulnar side, remove them (fig.11).

Introduce the guide wire (diameter: 1.25mm, length: 100mm / E36 008) into the centre of the trapezium with a power tool (fig.12).
Introduce the guide wire at minimum down to the black mark (on the guide wire) which corresponds to a depth of 8mm.

Ø 1.25mm Guide wire (E36 008)

Check that the guide wire is properly positioned and centred -both planes- with the help of a C-arm image (fig.13).

The surgeon should be able to push downwards the base of the metacarpal -using the trapezium retractor- in order to facilitate the introduction of the guide wire. Avoid the natural tendency to position the guide wire too vertical.

Trapezium retractor (E32 023)

Fig.14

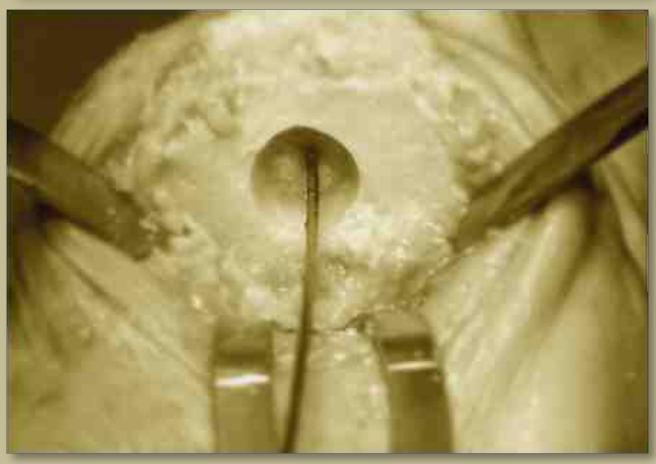
Adapt the Starter reamer on a small AO connection power tool.
Introduce the Starter reamer on the guide guide wire and ream the trapezium until the collar of the Starter reamer comes flush with the bone (fig.14).

From top: Starter reamer (E36 010), Medium reamer (E36 020), Large reamer (E36 030)

Fig.15

Ream incrementally with the trapezium reamers (fig.15) starting with the MEDIUM reamer and finishing if indicated with the LARGE reamer.

Trapezium cup range:
Cemented Medium and Large, Cementless Medium and Large



In cases where only the Medium reamer could be used, then the MEDIUM cemented or MEDIUM cementless cups should be implanted.
In cases where the Large reamer was used, then the LARGE cemented or LARGE cementless cups should be implanted.

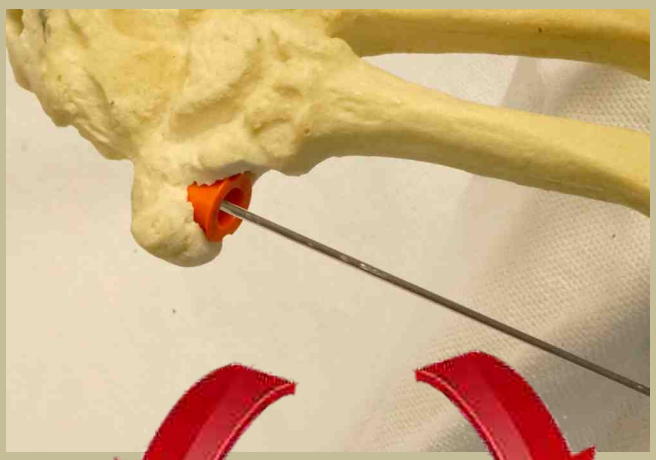


Fig.16

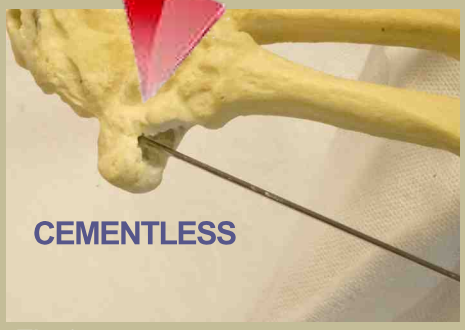


Fig.17a

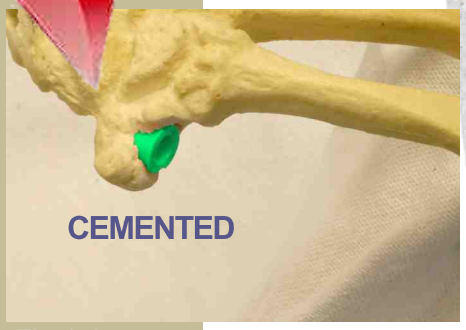


Fig.17b

Assessment of cup fixation

Keeping the guide wire into position, introduce the trial cup of size and fixation choice corresponding to the preparation, 4 options:

Trial cups:
Red and Green (cemented)
sizes M (E36 T020) and L (E36 T030),
Orange and Yellow (cementless)
sizes M (E36 T120) and L (E36 T130)

The trial cup should come flush with the bone and demonstrate good bone coverage and stability (fig.16).

CAUTION
Following assessment of the coverage and stability of the trial cup:

- In case of implantation of a **cementless cup** remove the trial cup and keep the guide wire into position (fig.17a).

- In case of implantation of a **cemented cup** remove the guide wire and keep the trial cup into position (fig.17b).

The E36 009 clip is intended to hold the trial cups and inserts after the surgery and during the decontamination and cleaning phases:
- Open the clip
- Thread the trial cups and inserts onto the clip
- Close the clip
- Place in the decontamination bath

After cleaning, the trial cups and inserts must be returned to their place in the instrumentation tray.

Implanting the cementless final cup

Fig.1

Leaving the guide wire into position, introduce the final cementless cup with the screw-wrench corresponding to the size of the selected cementless cup.

Introduce the cup snapped on the screw-wrench on the guide wire and into the trapezium bone (fig.18).

Screw-wrench for cementless trapezium cup:
Yellow ribbon = MEDIUM (E36 120),
Orange ribbon = LARGE (E36 130)

Screw firmly the cup into final position.
Should the screwing feel tight or difficult, the surgeon should go in back and forth steps of un-screwing screwing until the final position is reached.

The final cup should come flush with the bone and demonstrate good bone coverage and stability.

Once the cup is fully secured, remove the guide wire (fig.19).

Fig.18

Fig.19

Trials with the cementless final cup

Fig.20

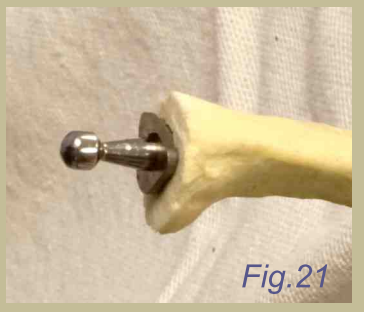


Fig.21

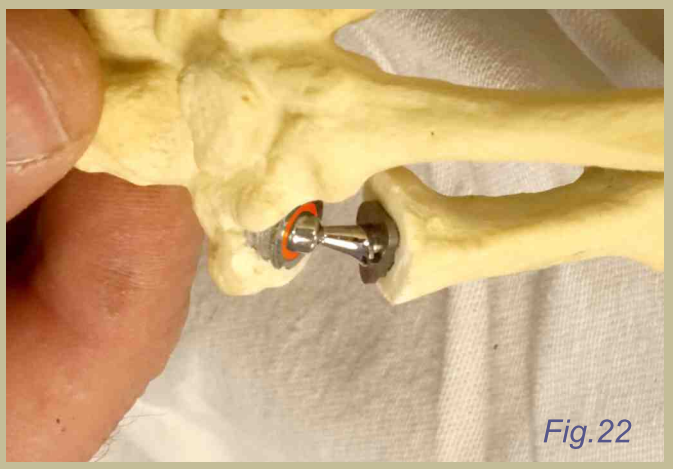


Fig.22

When implanting a cementless trapezium cup, the trials for neck length and offset can be made either with:

- a trial liner and a trial neck into the final cementless cup and with the trial or the final metacarpal implant.

- the final liner into the final cementless cup and a trial neck and with the trial or the final metacarpal implant.

Surgical steps for a trial liner and a trial neck into the final cementless cup and with the trial metacarpal implant.

Select the trial insert of the same size as the cup (MEDIUM or LARGE).

Introduce the trial insert into the cup using the Pusher for trial trapezium cup and liner (E32 016) (fig.20).

Pusher for trial trapezium cup and liner (E32 016)

Begin trial with a straight 6mm trial neck first (fig.21).

Range of trial necks: straight or offset at 15° in lengths of 6 or 8mm (E32 M006 and 008, and 32 M156 and 158)

Reduce the trapezo-metacarpal articulation (fig.22).

Unlike the final liners, the trial liners are not constrained and so there is no need to force the impaction into the liner.

Test the stability and mobility of the articulation, pull gently on the thumb and check for any cam contacts and for dislocation of the head out of the liner.
When pulling on the thumb, if the head dislocates for more than half of its diameter, change for a longer 8mm neck length.

The offset necks are indicated when -at rest position of the thumb- the metacarpal head is not aligned with the trapezium.

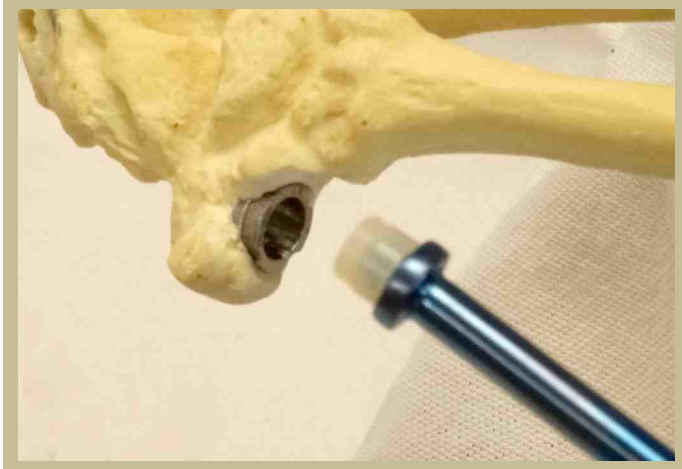
Implanting the final liner

Remove the trial neck and the trial liner with the E32 025 screw (part of impactor for rasp and implant).

Position the final liner into the cup (fig.23) with the Pusher for trial trapezium cup and liner (E32 016) and push strongly for final impaction.

Pusher for trial trapezium cup and liner (E32 016)

The operator should feel a "clicking" step and the final liner should come flush with the edge of the final cup (fig.24).



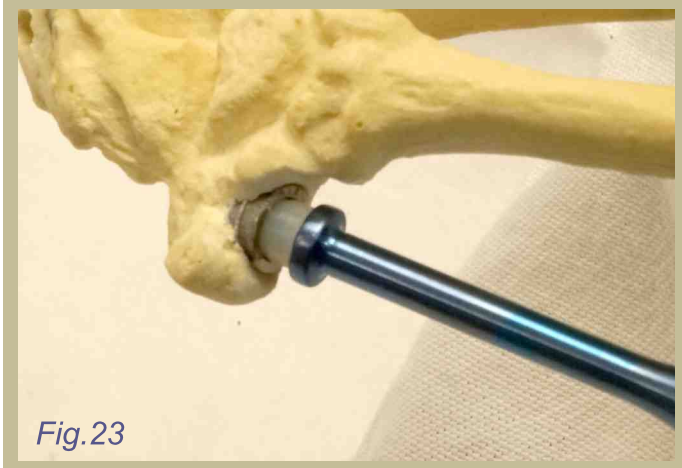


Fig.23

Fig.24

Trials with the cementless trial cup

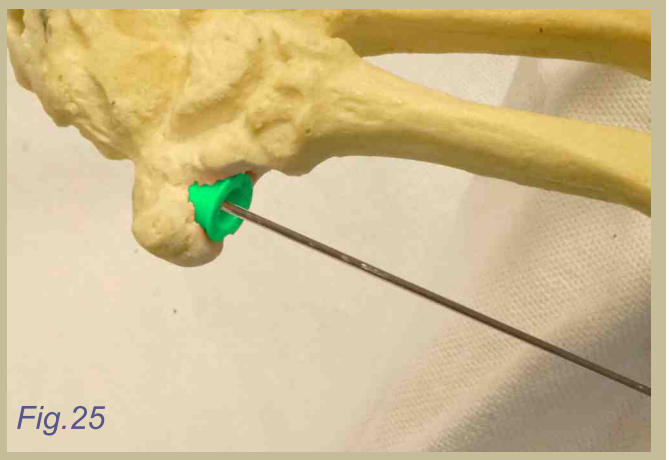


Fig.25

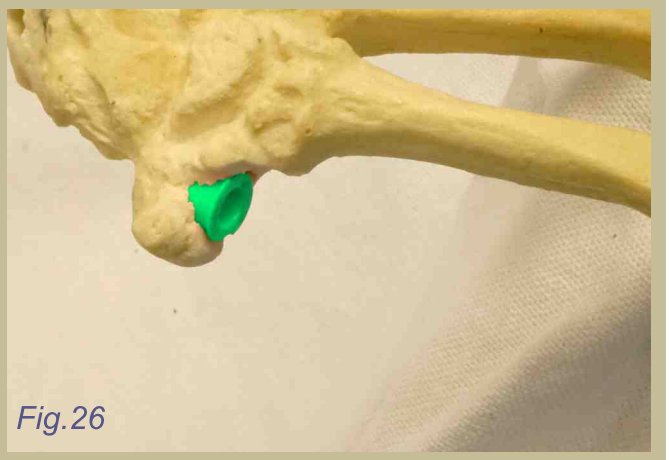


Fig.26

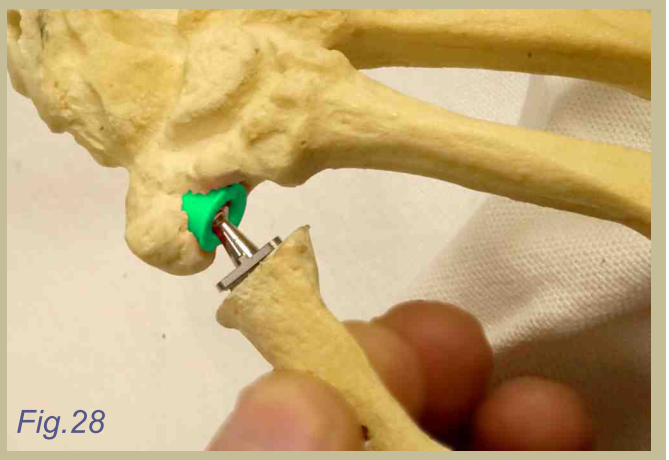


Fig.28

Following placement of the trial cementless cup (red = M size cup, Green = L size cup) (fig.25), remove the guide wire (fig.26).

Range of trial necks: straight or offset at 15° in lengths of 6 or 8mm (E32 M006 and 008, and 32 M156 and 158)

Fig.27

Use a straight 6mm trial neck first (fig.27).

The offset necks are indicated when -at rest position of the thumb- the metacarpal head is not aligned with the trapezium.

Reduce the trapezo-metacarpal articulation.

Unlike the definitive implants, the trial implants are not constrained and so there is no need to force the impaction into the liner.

Test the stability and mobility of the articulation, pull gently on the thumb and check for any cam contacts and for dislocation of the head out of the liner (fig.28).

When pulling on the thumb, if the head dislocates for more than half of its diameter, change for a longer 8mm neck length.

Implanting the final cemented cup

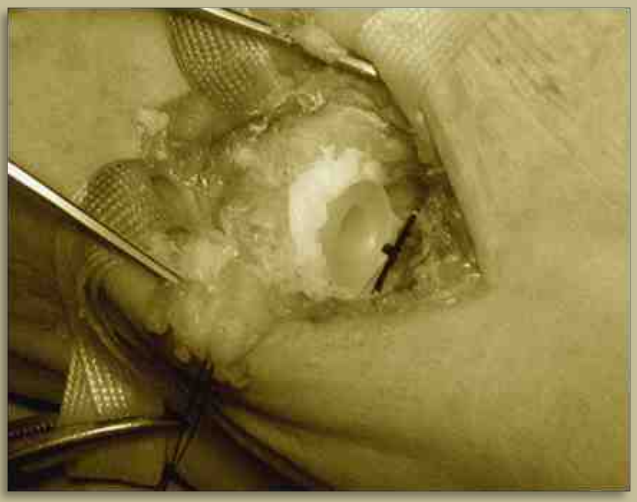
Remove the trial neck and the trial cup.

After cleaning and drying the reamed trapezium, inject PMMA bone cement with a syringe into the cavity. Apply pressure.

Place the definitive cup in the trapezium and push it into place using the offset cup impactor.

Offset cemented cup impactor (E32 002)

Maintain the pressure and the orientation until the cement has cured.



Implanting the final metacarpal implant

Remove the last size rasp left in situ using the Impactor for metacarpal rasp and implant (fig.29).

Mount the final metacarpal implant onto the Impactor for metacarpal rasp and implant (fig.30).

Impactor for rasps and implants ; shaft (E32 024) and screw (E32 025).

Place the implant in the correct orientation inside the metacarpal, and impact gently until it reaches the same seating position as the last rasp.

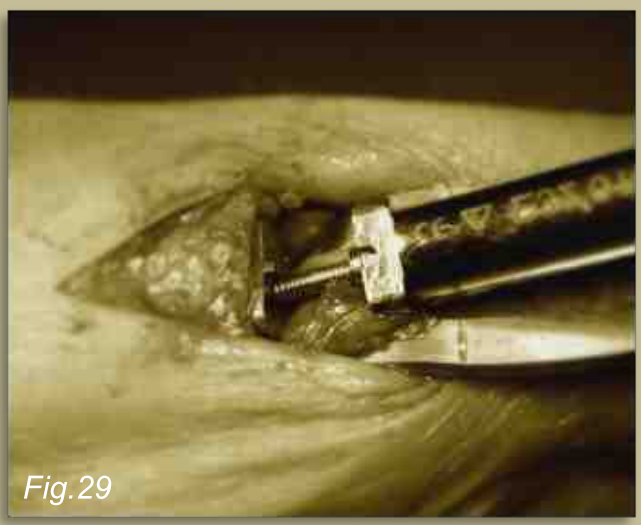


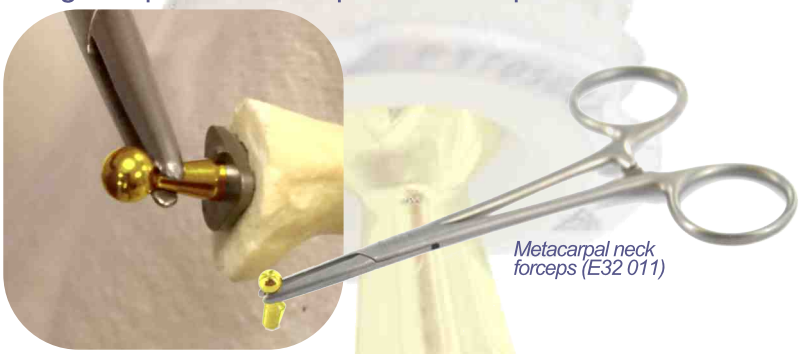
Fig.29

Fig.30

Fig.28

Fig.29

Place the final neck of the selected length and angle using the specific metacarpal neck forceps.



Metacarpal neck forceps (E32 011)

Impact the neck with a firm tap using the neck impactor (fig.28).

Metacarpal neck impactor (E32 016)

Reduce the articulation by snapping the head into the constrained liner (fig 29).

Confirm the stability and mobility of the thumb.

Wound closure and brace

Suture the flap which was retained.

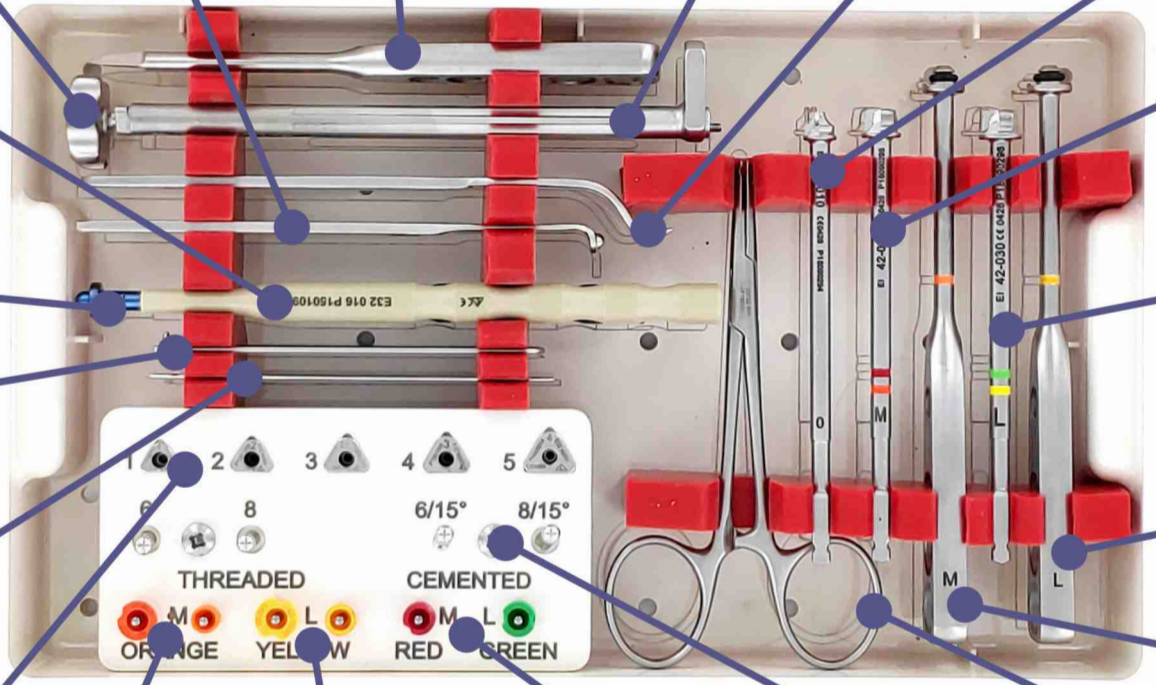
Close using a vacuum drain.

We recommend immobilization with an IGLOO commisural brace maintaining the thumb opened in antepulsion.
The IGLOO splints allow to complete the post-operative phisiotherapy with a compressive and analgesic cryotherapy treatment.

Keep the brace for 8 to 10 days.

Instrumentation SNAPSHOT

Ref : E36 9100 HORUS TMC



E32 025
Metacarpal rasp and implant impactor (screw)
Impacteur de râpe et implant métacarpien (vis)

E32 002
Offset pusher for cemented trapezium cup
Poussoir décalé de trapèze à cimenter

E32 M000
Starter awl
Trocart de démarrage

E32 024
Metacarpal rasp and implant impactor (body)
Impacteur de râpe et implant métacarpien (corps)

E32 023
Retractor for trapezium
Ecarteur fourchu pour trapèze

E36 010
Starter reamer for trapezium
Fraise d'ébauche trapézienne

E32 016
Metacarpal neck impactor
Impacteur de tête métacarpienne

E36 020
MEDIUM reamer for trapezium
Fraise de trapèze MEDIUM

E32 018
Pusher for trial trapezium cup and liner
Poussoir pour cup trapèze d'essai et insert

E36 030
LARGE reamer for trapezium
Fraise de trapèze LARGE

E36 009
Clip for trial cups
Agrafe pour cupules d'essai

E36 130
Screw-wrench for LARGE trapezium cup
Clé pour cupule trapézienne LARGE

E36 008
Guide wire Ø1.25 L.100mm (x2)
Broche guide Ø1,25 L.100mm (x2)

E36 120
Screw-wrench for MEDIUM trapezium cup
Clé pour cupule trapézienne MEDIUM

E36 9000
Tray with lid
Panier avec couvercle

E36 M001 to/à M005
Metacarpium rasps size 1 to 5
Râpes métacarpiennes tailles 1 à 5

E36 T020 & E36 I020
Cementless MEDIUM trial cup and liner
Cupule et insert d'essai MEDIUM sans ciment

E36 T030 & E36 I030
Cementless LARGE trial cup and liner
Cupule et insert d'essai LARGE sans ciment

E36 T120 & E36 T130
Cemented trial cup MEDIUM & LARGE
Cupule d'essai à cimenter MEDIUM & LARGE

E32 M006 & 8, E32 M156 & 8
Metacarpal trial neck Ø5mm: straight and 15° offset
Tête d'essai métacarpienne Ø5mm: droite et 15°

E32 011
Metacarpal neck forceps
Préhenseur de tête métacarpienne

Jan 2022 / Ref: BI_HORUS TMC SNP E36 *(E36 9100)*

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Metacarpal Implant
Implant Métacarpien

Ref.	*Description*		
E35 M010	Metacarpal stem Size 1	*Tige métacarpienne Taille 1*	Cementless / *Sans ciment*
E35 M020	Metacarpal stem Size 2	*Tige métacarpienne Taille 2*	Cementless / *Sans ciment*
E35 M030	Metacarpal stem Size 3	*Tige métacarpienne Taille 3*	Cementless / *Sans ciment*
E35 M040	Metacarpal stem Size 4	*Tige métacarpienne Taille 4*	Cementless / *Sans ciment*
E35 M050	Metacarpal stem Size 5	*Tige métacarpienne Taille 5*	Cementless / *Sans ciment*

Modular neck
Col modulaire

Ref.	*Description*		
E35 H006	Metacarpal head straight neck	*Tête métacarp. col droit*	Ø 5mm L.6mm
E35 H008	Metacarpal head straight neck	*Tête métacarp. col droit*	Ø 5mm L.8mm
E35 H156	Metacarpal head offset neck	*Tête métacarp. col décalé*	Ø 5mm L.6mm 15°
E35 H158	Metacarpal head offset neck	*Tête métacarp. col décalé*	Ø 5mm L.8mm 15°

Trapezium cup and liner
Cupule trapézienne et insert

Ref.	*Description*		
E35 T020	Trapezium cup MEDIUM	*Cupule trapézienne MEDIUM*	Cementless / *Sans ciment*
E35 T030	Trapezium cup LARGE	*Cupule trapézienne LARGE*	Cementless / *Sans ciment*
E35 T120	Trapezium cup PEXEL-E MEDIUM	*Cupule trapézienne PEXEL-E MEDIUM*	Cemented / *A cimenter*
E35 T130	Trapezium cup PEXEL-E LARGE	*Cupule trapézienne PEXEL-E LARGE*	Cemented / *A cimenter*
E35 I020	PEXEL-E liner MEDIUM	*Insert PEXEL-E MEDIUM*	
E35 I030	PEXEL-E liner LARGE	*Insert PEXEL-E LARGE*	

Instruments set E36 9100
Instrumentation E36 9100

Ref.	*Description*	
E36 9000	Base Instrument tray	*Panier ancillaire de base*
E32 002	Offset pusher for cemented trapezium cup	*Poussoir décalé de trapèze à cimenter*
E32 011	Metacarpal neck forceps	*Préhenseur de tête métacarpienne*
E32 016	Metacarpal neck impactor	*Impacteur de tête métacarpienne*
E32 018	Pusher for trial trapezium cup and liner	*Poussoir pour cup trapèze d'essai et insert*
E32 023	Retractor for trapezium	*Ecarteur fourchu pour trapèze*
E32 024	Metacarpal rasp & implant impactor (shaft)	*Impacteur de râpe et implant métacarpien (corps)*
E32 025	Metacarpal rasp & implant impactor (screw)	*Impacteur de râpe et implant métacarpien (vis)*
E32 M000	Starter awl	*Trocard de démarrage*
E32 M006	Metacarpal trial neck Ø5mm L.6mm Straight	*Tête d' essai métacarpienne Ø5mm L.6mm Droite*
E32 M008	Metacarpal trial neck Ø5mm L.8mm Straight	*Tête d' essai métacarpienne Ø5mm L.8mm Droite*
E32 M156	Metacarpal trial neck Ø5mm L.6mm Offset	*Tête d' essai métacarpienne Ø5mm L.6mm Décalée*
E32 M158	Metacarpal trial neck Ø5mm L.8mm Offset	*Tête d' essai métacarpienne Ø5mm L.6mm Décalée*
E36 008	Guide wire Ø1.25 L.100mm	*Broche guide Ø1,25 lg100mm*
E36 009	Clip for trial cups	*Epingle pour cupules d'essai*
E36 010	Starter reamer for trapezium	*Fraise d' ébauche trapézienne*
E36 020	MEDIUM reamer for trapezium	*Fraise de trapèze MEDIUM*
E36 030	LARGE reamer for trapezium	*Fraise de trapèze LARGE*
E36 120	Screw-wrench for MEDIUM trapezium cup	*Clé pour cupule trapézienne MEDIUM*
E36 130	Screw-wrench for LARGE trapezium cup	*Clé pour cupule trapézienne LARGE*
E32 M001	Metacarpal rasp S1	*Râpe métacarpienne T.1*
E32 M002	Metacarpal rasp S2	*Râpe métacarpienne T.2*
E36 M003	Metacarpal rasp S3	*Râpe métacarpienne T.3*
E36 M004	Metacarpal rasp S4	*Râpe métacarpienne T.4*
E36 M005	Metacarpal rasp S5	*Râpe métacarpienne T.5*
E36 T020	Cementless MEDIUM trial cup	*Cupule trapézienne d' essai sans ciment MEDIUM*
E36 T030	Cementless LARGE trial cup	*Cupule trapézienne d' essai sans ciment LARGE*
E36 I020	Trial liner for MEDIUM trapezium cup	*Insert d'essai pour cupule MEDIUM*
E36 I030	Trial liner for LARGE trapezium cup	*Insert d'essai pour cupule LARGE*
E36 T120	Cemented MEDIUM trial cup	*Cupule trapézienne d' essai cémentée MEDIUM*
E36 T130	Cemented LARGE trial cup	*Cupule trapézienne d' essai cimentée LARGE*

Important Notice:
The HORUS TMC implants belong to the class IIb implantable medical device classification. The HORUS TMC implants are indicated in Trapezometacarpal joint arthroplasty procedures (TMC).
The surgeon is required to read the instructions for use (IFU) leaflet IT11 0319 included in the packaging of the implant or available for download on the www.evolutisfrance.com website, as well as the surgical technique manual E36 451 initially delivered with the instrument set, or equally available for download on the www.evolutisfrance.com website.

Materials:
Metacarpal implant: titanium alloy TA6V according ISO 5832-3 coated with pure titanium.
Modular neck: cobalt-chromium alloy steel according ISO 5832-12 coated with TiN.
Cemented trapezium cup: UHMWPE according ISO 5834-1 and 2, ring in stainless steel according ISO 5832-1.
Coated trapezium cup: UHMWPE according ISO 5834-1 & 2, TA6V according ISO 5832-3 coated with pure titanium.
Liner for coated trapezium cup: UHMWPE according ISO 5834-1 and 2.
Gamma ray sterilised

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