

Evolutis

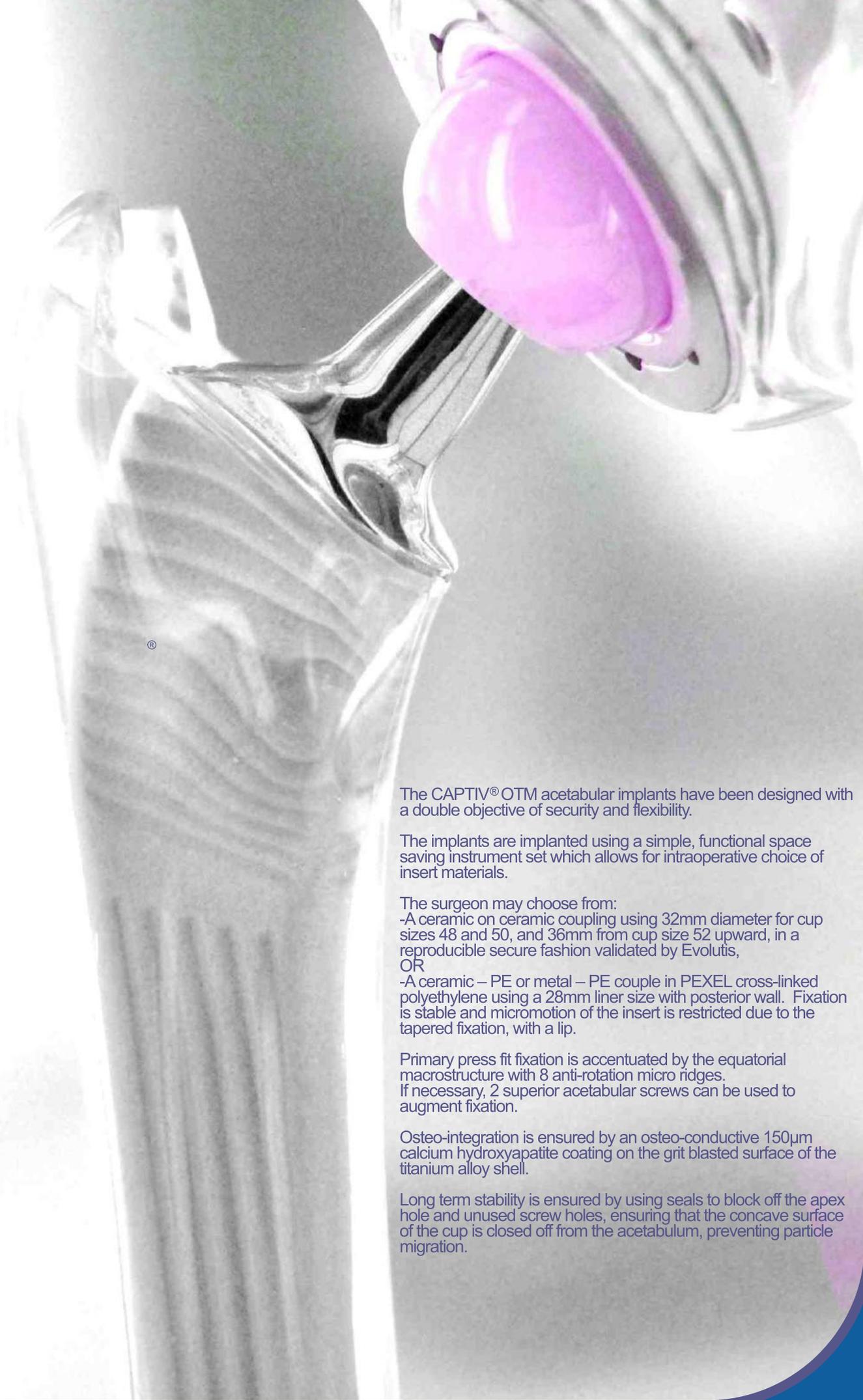
CREATEUR FABRICANT



Captiv[®] OTM

*Surgical
Technique*

Evolutis
MOTION INSIDE



®

The CAPTIV® OTM acetabular implants have been designed with a double objective of security and flexibility.

The implants are implanted using a simple, functional space saving instrument set which allows for intraoperative choice of insert materials.

The surgeon may choose from:

-A ceramic on ceramic coupling using 32mm diameter for cup sizes 48 and 50, and 36mm from cup size 52 upward, in a reproducible secure fashion validated by Evolutis,
OR

-A ceramic – PE or metal – PE couple in PEXEL cross-linked polyethylene using a 28mm liner size with posterior wall. Fixation is stable and micromotion of the insert is restricted due to the tapered fixation, with a lip.

Primary press fit fixation is accentuated by the equatorial macrostructure with 8 anti-rotation micro ridges. If necessary, 2 superior acetabular screws can be used to augment fixation.

Osteo-integration is ensured by an osteo-conductive 150µm calcium hydroxyapatite coating on the grit blasted surface of the titanium alloy shell.

Long term stability is ensured by using seals to block off the apex hole and unused screw holes, ensuring that the concave surface of the cup is closed off from the acetabulum, preventing particle migration.

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Disclaimer

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

This publication is intended as the recommended procedure for using the Evolutis Captiv OTM Acetabular Implants. It offers guidance only.

Evolutis is the manufacturer of the device. As such and claiming no medical skill, Evolutis does not recommend a specific use of a product or a technique.

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

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

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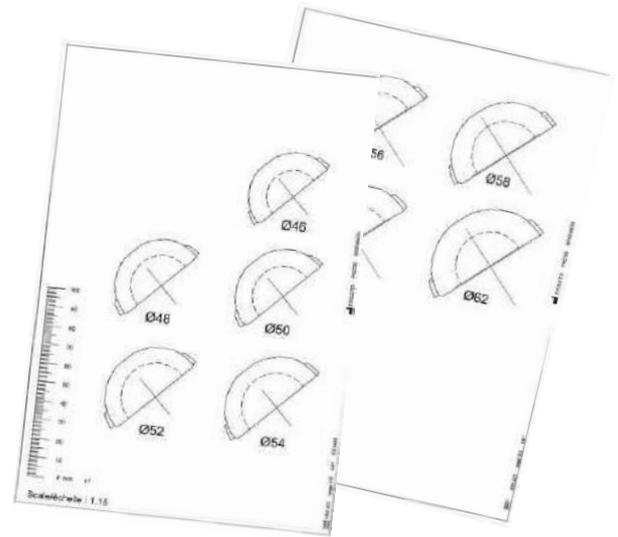
TEMPLATING

A set of CAPTIV ©™ templates is available for each set of instruments.

There are 2 pages

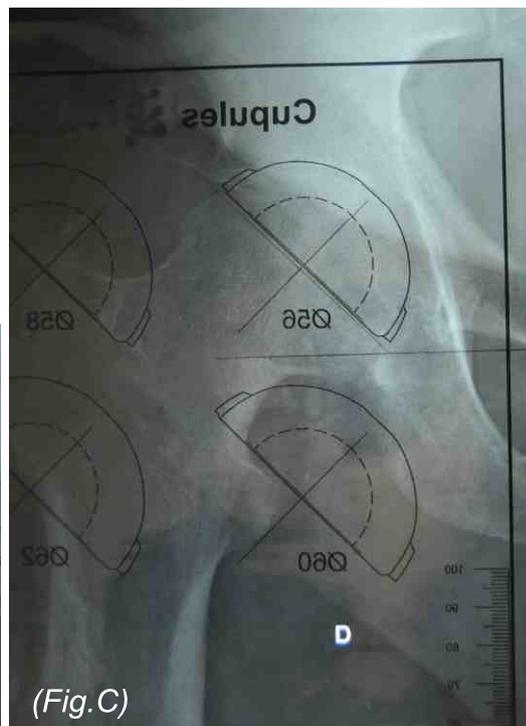
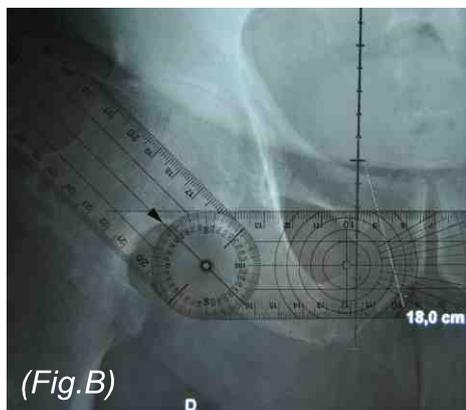
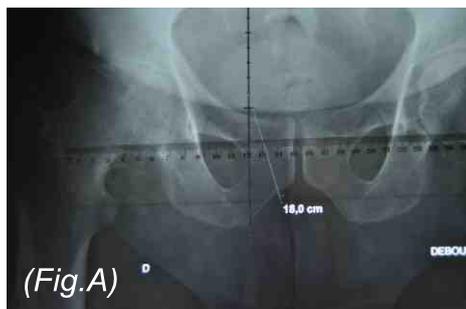
- Page 1 for sizes 46 to 54
- Page 2 for sizes 56 to 62

Pre-operative planning helps define the best diameter cup to use as determined by the acetabular cavity and to quantify the amount of reaming necessary to implant the cup with the femoral implant.



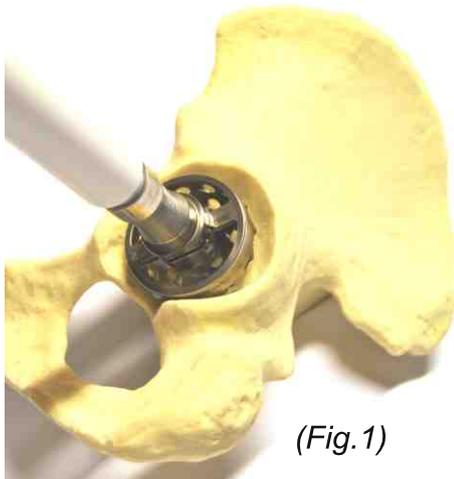
Planning steps are as follows:

- On a frontal x ray the magnification of which must be known, draw a horizontal line between the bottom of both radiological U's (teardrop) in order to determine if there is any limb length discrepancy or anomaly which should be taken into account (fig. A).
- Draw a line at 45° to this line, going through the supero – lateral edge of the acetabulum (fig. B)
- Place the template of the best adapted size of cup (fig. C) trying to
 - stay parallel to the 45° line
 - placing the bottom of the cup on the true base of the acetabulum
- Mark the centre of rotation: of the cup and evaluate the shortening and medialisation with respect to the anatomic centre.
- Template the femoral side, and try to place the centre of the head at the same position as the centre of the cup.
- Note down or remember the size and orientation of implants template with the best configuration in terms of lateralisation/medialisation and limb length.



SURGICAL STEPS

Preparation of the acetabulum

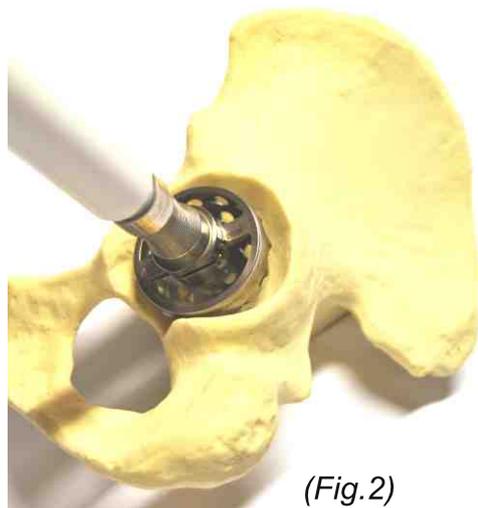


(Fig.1)

Assemble the 44mm reamer onto the reamer shaft and power tool.

Ream the acetabulum to identify the true base by removing the osteophyte and capitis femoris ligament (fig. 1).

Ream incrementally in size until the acetabular space is filled but without reaming the anterior and posterior acetabular walls (fig. 2).

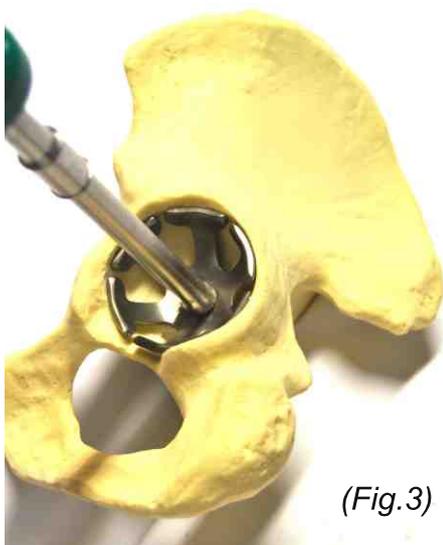


(Fig.2)

Use of the trial cup

Assemble the trial cup the same size as the last reamer using the M10 handle.

Option: The 45° orientation rod can be put on the impactor.



(Fig.3)

Place the trial cup inside the acetabulum and impact with a hammer, keeping the orientation rod vertical (fig. 3).

Check that:

- The cup is well covered by bone
- Anteversion and tilt
- That the reamed acetabular concavity is good for optimal bone contact.

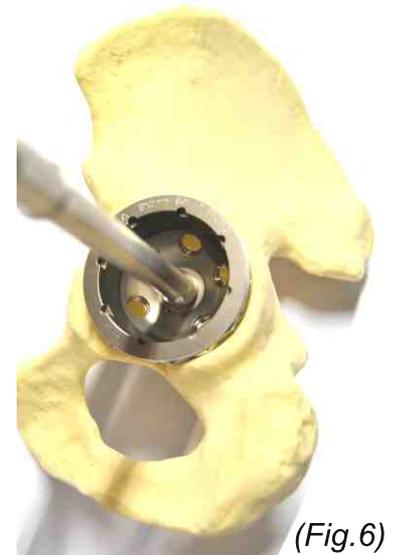
The stability of the trial cup will be less than the definitive cup due to the press fit and equatorial ridges of the definitive cup.

Trial reductions are undertaken in the definitive cup.

SURGICAL STEPS

Definitive cup impaction

Screw the cup of chosen size, same as the trial, onto the M10 impaction handle (fig. 4).
Option: The 45° orientation rod can be put on the impactor.



Orientate the cup so that the screw holes are superior and the rounded rim inferior (fig. 5)

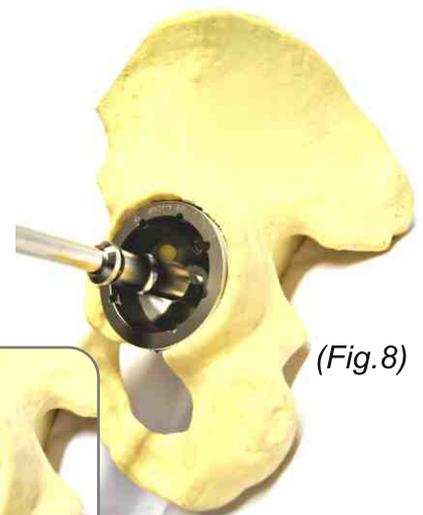


Place the cup in the acetabulum, and impact slightly with a hammer keeping the orientation rod vertical and the cup at about 15° of anteversion (fig. 6).

Check that the inferior part of the cup is not proud of the bone, especially the anterior, inferior rim.
If necessary re-orientate the cup before final impaction. Terminate impaction, check the stability of the cup.

Remove the M10 shaft (fig. 7).

Screw the apex hole seal into place (fig. 8 and 9).



(Fig.9)

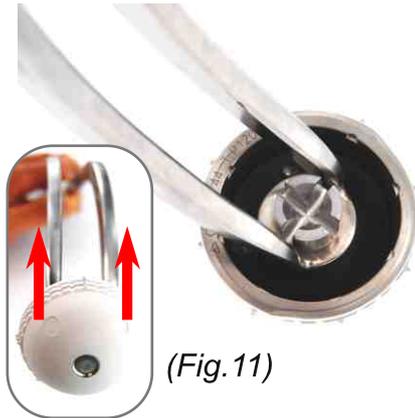
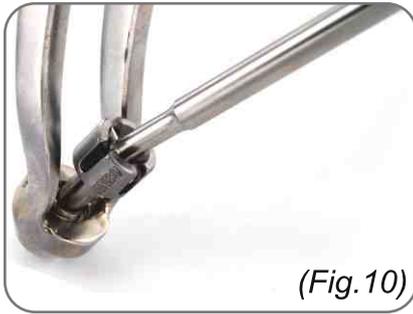
SURGICAL STEPS

Option: use of the curved cup impactor

A curved cup impactor is available on special request for small and anterior incisions.

The handle is composed of 3 parts

- The curved shaft (H30 025)
- The threaded nut to fasten the cup holder onto the shaft (H30 024)
- The T shaped screw driver to fasten the nut (H62 003)



Place the nut into the handle until it turns freely (fig. 10).

Place the cup onto the part of the thread which pokes out beyond the handle.

Screw the cup onto the thread.

Orientate the cup so that the handle curve is in the same plane as the 2 optional blocked screw holes (fig. 11).

Tighten the locknut using the T screw driver.

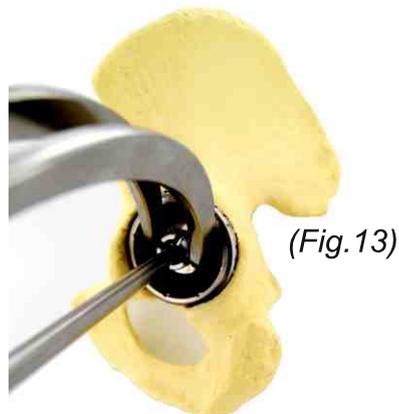
Present the cup to the acetabulum (fig. 12).

Check the orientation and anteversion of the cup with the screw holes in the postero – superior quarter of the acetabulum.

Firmly impact the cup.

Check the stability of the cup.

Release the handle using the T screwdriver (fig. 13).



SURGICAL STEPS

Optional screw fixation

In case of doubt about primary fixation of the cup, it is possible to augment the fixation by using one or two cancellous screws:

- Remove the seal using the 3,5mm hexagonal screwdriver.



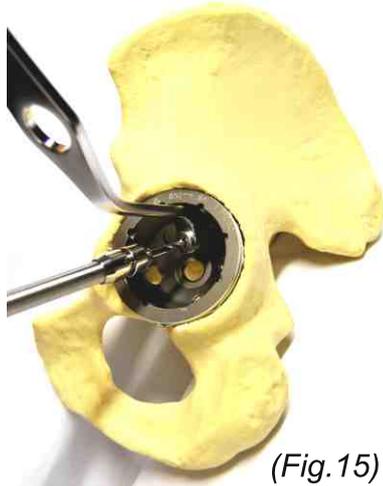
(Fig. 14)

- Mount the 3,2mm drill onto the flexible drill shaft (mini AO) and onto the powertool. Place the drill through the drill guide.



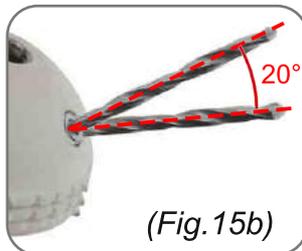
- Place the drill guide into the cup hole at the desired angle (fig. 14).

- Drill and then remove the drill from the guide (fig. 15).

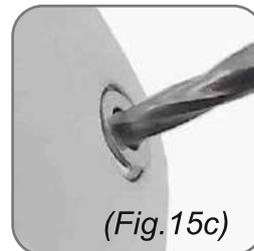


(Fig. 15)

Caution : the drill guide is designed for angular limitation (max clearance 20°) in order to avoid any belching of the screws into the housing of the ceramic liner. In order to drill within these angular limits it is important to firmly maintain the drill guide into the drill hole (Fig. 15b et 15c).

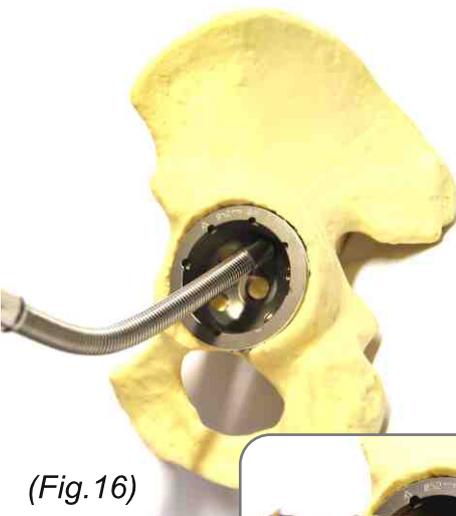


(Fig. 15b)



(Fig. 15c)

- Measure the screw length with the gauge (fig. 16).



(Fig. 16)

- Mount the screw onto the angled screwdriver and screw into place (fig. 17).



(Fig. 17)

- If necessary do the same with a second screw

- Re tighten the first screw after having tightened the second one.

SURGICAL STEPS

Trials

The Captiv OTM acetabular cup has been designed to take different inserts, either metal or ceramic heads on 28 PE liners or ceramic liners of 32 or 36mm internal diameter for ceramic on ceramic coupling. The instrumentation allows for trials with all the configurations, and in an effort to keep all the instruments in one tray, they are modular. 36mm femoral head trials are included in the instruments because they are specific to ceramic on ceramic articulations. The heads are adapted to Evolutis morse tapers. Should a femoral stem from another source be used, then the surgeon must check the compatibility between manufacturers so that the definitive implants reproduces what is found with the trials.

Ceramic on ceramic trial

The ceramic on ceramic insert trials can be fitted into cups of different sizes. The smallest is for 32mm head diameter. The three others are for 36mm head diameters.

Select the trial appropriate to the shell size (see table on last page), and position it inside the shell (fig. 18).

Place the corresponding head trial on the rasp or definitive stem. Reduce the articulation using the head reducer (fig.19).

Undertake range of motion and stability testing, avoiding excessive limb lengthening.

If necessary use different head length trials to find the best compromise.

Dislocate the articulation and remove the trials.



(Fig.18)

Polyethylene liner trials

In this case use a 28mm adaptor inside a ceramic insert trial. (fig. 20).

Select the ceramic on ceramic trial insert corresponding to the cup size.

Choose either of the two adaptors adapted to the inner diameter of the ceramic trial insert: either 32 or 36mm. (fig. 21).

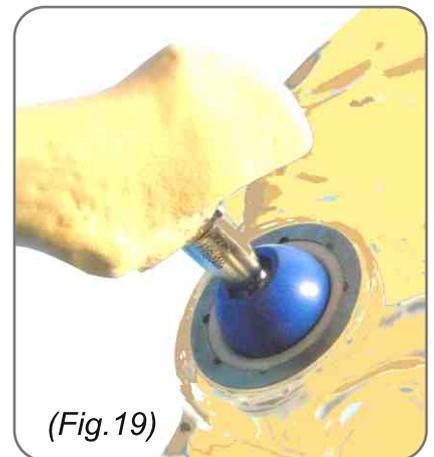
Place the adaptor inside the trial and then the assembly inside the cup, and in the correct orientation of the raised posterior wall.

Place the corresponding 28mm head trial on the rasp or definitive stem. Reduce the articulation using the head reducer.

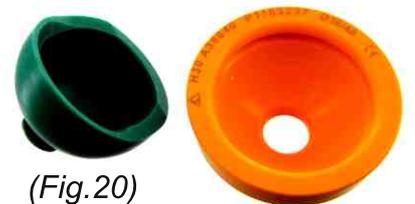
Undertake range of motion and stability testing, avoiding excessive limb lengthening.

If necessary use different head length trials to find the best compromise.

Dislocate the articulation and remove the trials.



(Fig.19)



(Fig.20)



(Fig.21)

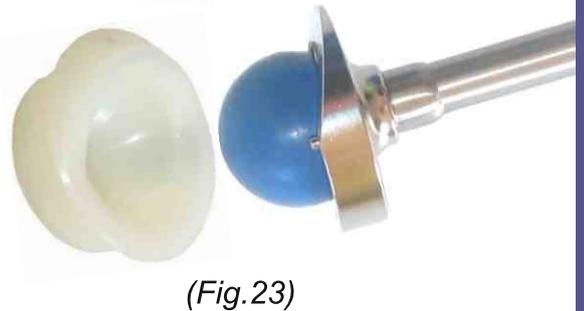
SURGICAL STEPS

Definitive Polyethylene insert implantation

Screw the posterior wall liner plate onto the M10 impaction handle. (fig. 22).



Prepare the definitive polyethylene insert by removing it from the sterile packaging; leave it in the foam protection, with the concave opening facing up. Place the 2 pegs on the liner plate over the corresponding holes of the insert and press down firmly (fig. 23).



Place the insert now mounted on the handle into the cup (fig. 24). Position the posterior wall insert in the postero –superior quarter of the acetabulum. It can be rotated in 45° increments.

Firmly impact the insert (fig. 25).

Test its stability in the shell, further impaction can be undertaken using the 28mm sphere on the M10 handle (fig. 26).

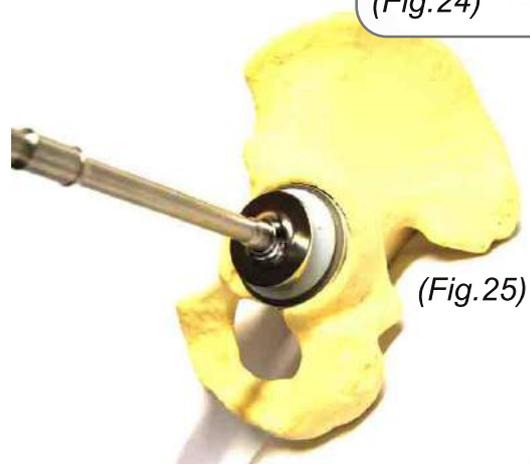


Impact the definitive head on the femoral stem.

Reduce the articulation.

Test for mobility and stability.

Close the wound.



SURGICAL STEPS

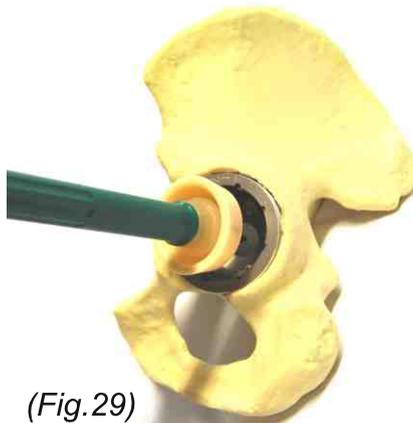
Definitive Ceramic insert implantation



The definitive ceramic insert is positioned inside the shell by using the special vacuum holder (fig. 27).

Place the vacuum holder in the centre of the ceramic insert (fig. 28). Press it down into the insert to expel the air and create the vacuum.

Carefully place the insert (now held onto the shaft by vacuum) into the shell so that it is centred and in the correct axis. (fig. 29). Press down gently checking that the conical taper seats inside the shell properly.



Release the vacuum by pulling on the trigger and remove the shaft (fig.30).

Check the edge of the insert and shell with a finger so that the insert is flush.

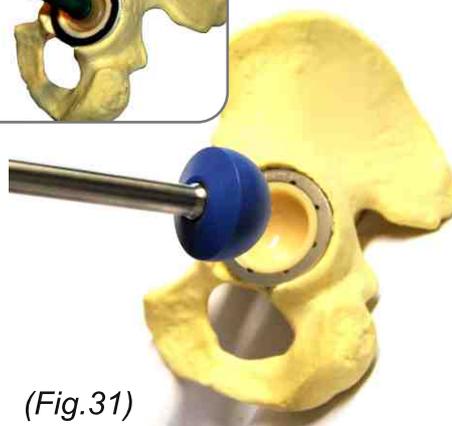
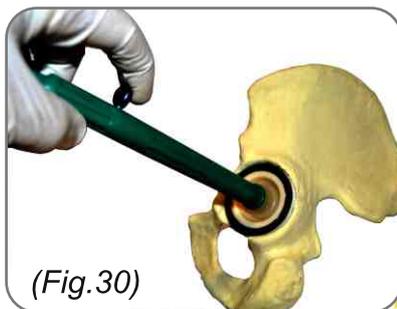
Finish off impaction of the insert with the spherical impactor of the chosen size (32 or 36mm) mounted on the M10 shaft (fig. 31).

Impact the definitive head on the femoral stem.

Reduce the articulation.

Test for mobility and stability.

Close the wound.



REFERENCES IMPLANTS & INSTRUMENTS

Implants CAPTIV OTM

Description	Ø	Cat. N°	Liner post. wall Insert à débord UHMWPE	Liner Alumina Insert Alumine	Liner Composite Ceram Insert Céram composite
Cup. CAPTIV OTM*	Ø44	H29 OT044*	H29 OT22010*		
Cup. CAPTIV OTM*	Ø46	H29 OT046*			
Cup. CAPTIV OTM	Ø48	H29 OT048	H29 OT28020	H29 A32020	H29 C32020
Cup. CAPTIV OTM	Ø50	H29 OT050			
Cup. CAPTIV OTM	Ø52	H29 OT052	H29 OT28030	H29 A36030	H29 C36030
Cup. CAPTIV OTM	Ø54	H29 OT054			
Cup. CAPTIV OTM	Ø56	H29 OT056			
Cup. CAPTIV OTM	Ø58	H29 OT058	H29 OT28040	H29 A36040	H29 C36040
Cup. CAPTIV OTM	Ø60	H29 OT060			
Cup. CAPTIV OTM	Ø62	H29 OT062			
Cup. CAPTIV OTM*	Ø64	H29 OT064*	H29 OT28050	H29 A36050	H29 C36050
Cup. CAPTIV OTM*	Ø66	H29 OT066*			

Screws Vis

Dimension	Cat. N°
Ø6.0 lg.20mm	H15 SA6020
Ø6.0 lg.25mm	H15 SA6025
Ø6.0 lg.30mm	H15 SA6030
Ø6.0 lg.35mm	H15 SA6035
Ø6.0 lg.40mm	H15 SA6040
Ø6.0 lg.45mm	H15 SA6045
Ø6.0 lg.50mm	H15 SA6050

* Implants available on special request / implants sur demande spéciale

Instrument Set CAPTIV OTM H30 9103 Instrumentation

Description	Cat. N°	Description	Cat. N°
Tray with lid <i>Panier avec couvercle</i>	H30 9003	Cup impaction handle <i>Manche impacteur cup.</i>	H03 026
Ceram liner extractor <i>Extracteur insert céram</i>	H30 001	Trial cup Ø48 <i>Cotyle d'essai</i>	H03 0248
Ceram liner holder <i>Préhenseur insert céram</i>	H30 002	Trial cup Ø50 <i>Cotyle d'essai</i>	H03 0250
Post. wall liner plate <i>Platine d'insert à débord</i>	H30 027	Trial cup Ø52 <i>Cotyle d'essai</i>	H03 0252
Drilling Guide <i>Guide de perçage</i>	H30 028	Trial cup Ø54 <i>Cotyle d'essai</i>	H03 0254
32/28 Head Ø reducer <i>Réducteur de Ø tête</i>	H30 3228	Trial cup Ø56 <i>Cotyle d'essai</i>	H03 0256
36/28 Head Ø reducer <i>Réducteur de Ø tête</i>	H30 3628	Trial cup Ø58 <i>Cotyle d'essai</i>	H03 0258
Trial liner Ø32/48-50 <i>Insert d'essai</i>	H30 A32020	Trial cup Ø60 <i>Cotyle d'essai</i>	H03 0260
Trial liner Ø36/52-54 <i>Insert d'essai</i>	H30 A36030	Trial cup Ø62 <i>Cotyle d'essai</i>	H03 0262
Trial liner Ø36/56-60 <i>Insert d'essai</i>	H30 A36040	Hex-screwdriver H3.5 <i>Tournevis hexagonal</i>	S01 005
Trial liner Ø36/62-66 <i>Insert d'essai</i>	H30 A36050	Drill bit Ø3.2 Lg 25 <i>Mèche</i>	S01 010
Depth Gauge <i>Mesureur de vis</i>	H03 004	Flex drilling tip Ø8mm Mini AO <i>Embout flexible</i>	S01 033
Orientation rod <i>Tige d'orientation</i>	H03 007		
Ø28 Liner impactor <i>Impacteur d'insert</i>	H03 024		
Ø32 Liner impactor <i>Impacteur d'insert</i>	H03 025		
Ø36 Liner impactor <i>Impacteur d'insert</i>	H03 029		
Trial head Ø36 -4mm 12/14 <i>Tête d'essai</i>	H02 2360		
Trial head Ø36 +0mm 12/14 <i>Tête d'essai</i>	H02 2361		
Trial head Ø36 +4mm 12/14 <i>Tête d'essai</i>	H02 2362		

Options	Cat. N°
Curved cup impactor <i>Impacteur cup. courbe</i>	H30 025
Screw for curved imp. <i>Vis d'impacteur courbe</i>	H30 024
Wrench for curved imp. <i>Clé pour imp. courbe</i>	H62 003
Trial cup Ø44 <i>Cotyle d'essai</i>	H03 0244
Trial cup Ø46 <i>Cotyle d'essai</i>	H03 0246
Head pusher tip Ø22.2 <i>Embout pousse tête</i>	H03 023



Instrumentation
H30 9103



Captiv® OTM



Designed and
Manufactured in
France

www.evolutisfrance.com