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CREATEUR FABRICANT

Captiv Freeliner®

Surgical Technique
Conventional Set

Evolutis
MOTION INSIDE

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Indications and contra-indications

Hemi and total hip arthroplasties are indicated for the treatment of symptomatic pain and/or functional problems of the hip in patients whose skeleton is mature and only when pain killer medication and correctly followed conservative treatment have failed. For the patient, his anatomy and the structure of his articulation will need to be adapted to receive the selected implant(s).
The indications for total or partial hip arthroplasty are:
- Degenerative non inflammatory hip disease (coxarthrosis, arthritis of the hip).
- Inflammatory hip disease (rheumatoid arthritis, post traumatic arthritis).
- Metabolic hip disease (chondrocalcinosis).
- Post Traumatic degenerative arthritis.
- Avascular necrosis.
- Congenital dysplasia of the hip.
- Functional repair of a recent trauma (fracture, dislocation)
- Revision of a failed conservative surgery, osteosynthesis, partial or total arthroplasty.
- Tumoral surgery when affecting the hip joint.

In primary surgery of the hip joint, and even more in revision or tumoral surgery, the quality of the bone stock and the bone defects due to the ablation of any previously implanted material can compromise the primary fixation of the implantable device and thus limit its indications. Depending on the location and the extension of the bone defect, a longer cemented or cementless femoral component including a variety of complementary fixation means or an acetabular component including peripheral flanges and hooks can be considered.

Arthroplasty of the hip can be contra-indicated in cases of local or systemic infection, mental deficiency, neuromuscular afflictions, neurologic or vascular affections, patients addicted to alcohol or psychotropic drugs, excessive medication, excessive functional use (sport with prevalent risk of fall or with excessive functional expectations beyond the limits of the mechanical resistance of the prosthesis), overweight, insufficient bone stock, weak demineralized bone impeding a good prosthetic fixation, or severe extra articular deformation.

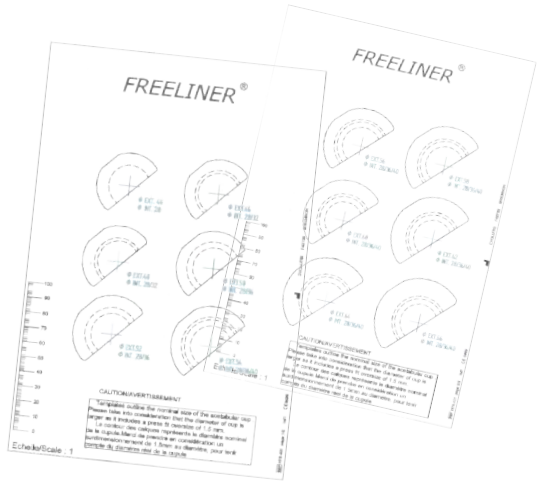
The implantation of a hip implant can entail the following complications: bruise, thrombosis, pulmonary embolism, cardiovascular disorders, nervous, tendinous or venous affliction, peri-prosthetic ossifications, allergenic reaction to the material(s), tissular reaction to the wear particles (metallosis), pain, bone split, fracture of a component of the implant, an bone resorbtion, wear of a component of the implant, articular squeaking, Limb length disrepancy, dislocation, loosening, infection.

Preoperative templating

A set of Captiv FREELINER® templates is available with the instrument set. The set contains two templates:

- Template n°1 for sizes 44 to 54
- Template n°2 for sizes 56 to 66

(Please note that sizes 44 and 66 are only available on special request.)



The aim of the pre-operative planning is to predetermine the diameter of the cup best suited for the acetabular cavity and to quantify the relative position of the cup in respect to the femoral component.

Important prerequisite:
The true magnification ratio of the preoperative images need to be checked with the radiologist, and the theater staff should make sure that the templates of the corresponding magnification is available for the surgery. The radiological protocol must be strictly established and known by all the manipulators of the medical imaging department.

The templating steps are:

- On a frontal x-ray for which the scale has been predetermined trace a horizontal line linking the radiological U in order to check any length discrepancy or abnomaly which should be taken into account (fig A)

- Trace a 45° line from the U joining the supero-lateral edge to the acetabular rim (fig B)

- Position the most size suited template to the acetabular in order to (fig C):
  - stay parallel to the traced 45°
  - adapt the circumference of the cup to the geometry of the acetabulum
  - place the bottom of the cup on the quadrilateral blade

- Trace the rotation center of the cup implant and evaluate in terms of shortening and medialization in respect to the center of the anatomic acetabulum

- Template the femoral side juxta positioning the center of the head implant with the center of the cup implant

- Record the sizes of the templated implants of the most favorable offset and length.

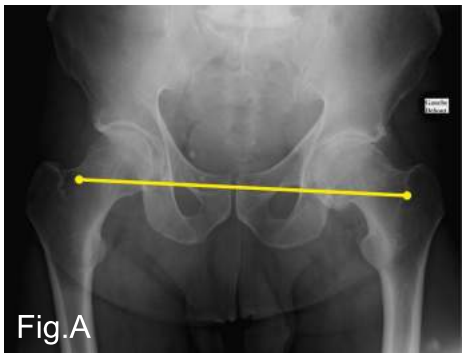


Fig.A

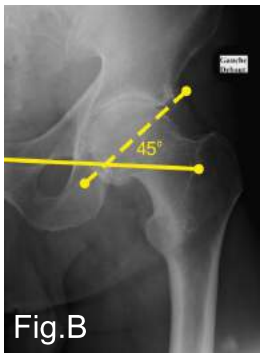


Fig.B

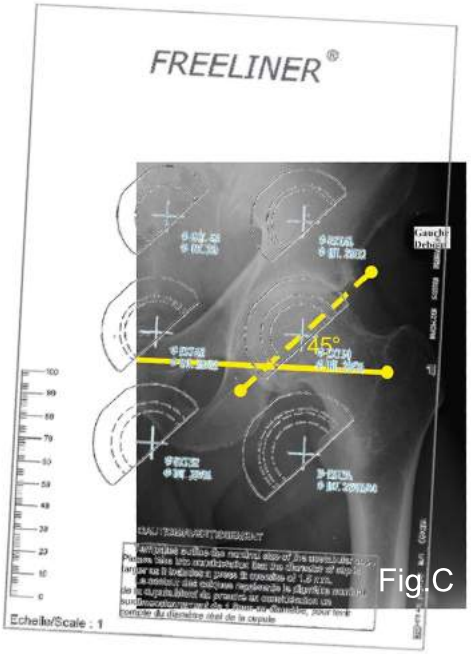
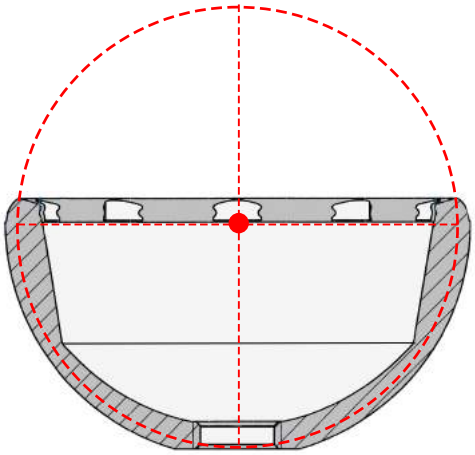


Fig.C

Digital Templating

Digital templates for the Captiv FREELINER® cup can also be available on the following platforms:

- MediCAD® (www.hectec.de/content/index.php/en/)
- TraumaCad® (www.traumacad.com/)
- Sectra (www.sectra.com/medical/orthopaedics/)
- OrthoView (www.orthoview.com/)



Dimensional correspondence of the cup

Note concerning sizes:

The Captiv FREELINER® cup external geometry is a coated hemisphere. The primary stability of the cup is ensured by the rugosity of the macro-porous coating and by the peripheral oversize of the cup in comparison to its nominal diameter.

The total oversize is of 1.66mm in the diameter
(1.26mm for the cup Ø44, and 1.46mm for the cup Ø46).

Nominal Ø Cup: *d* → True Ø cup: *d* + 1.66mm

Reamer Ød

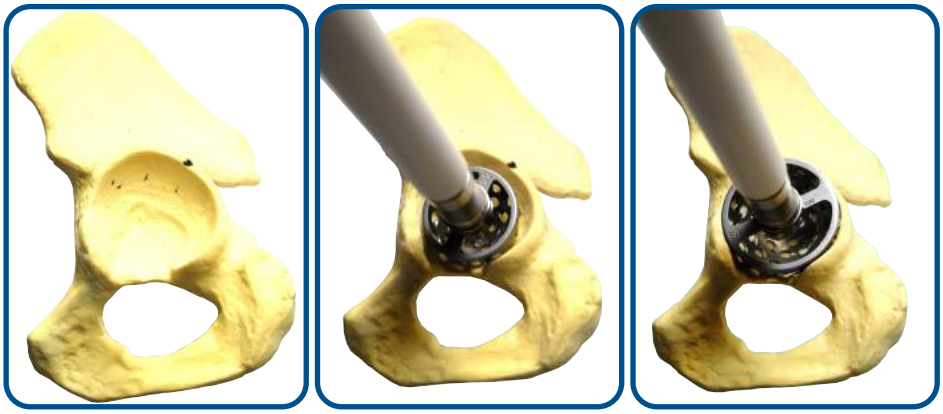
=

Cup Ød

Correspondence between the reamer and the cup size:
The true diameter of the cup must always be larger than the diameter of the last acetabular reamer introduced in order to ensure a good primary fixation and stability of the implant.
This difference in diameter has been taken into account in the cup sizing and description of the Captiv FREELINER®. For most indications, after reaming the acetabular to a given diameter *d*, the cup size to be selected will also correspond to *d* (size for size).

Special cases:
In sclerotic bone, after reaming of the acetabulum to a diameter of *d*, the Captiv FREELINER® cup could be difficult to position or may seat imperfectly into the acetabulum. In such cases the cup should be removed and either:
- if the anterior and posterior walls of the acetabulum still have enough thickness, introduce an acetabular reamer of diameter *d+2mm* only at the entry of the acetabulum and ream the acetabular rim only, or
- if the bone stock allows, deepen the acetabulum with the last reamer introduced without increasing the reaming diameter, and then re-introduce and impact the cup.

Reaming of the acetabulum



After exposure of the coxo-femoral joint, dislocation of the femoral head, resection of the femoral head, and excision of the labrum and of the residues of the ligamentum teres, begin the reaming of the acetabulum with the smallest size reamer available.

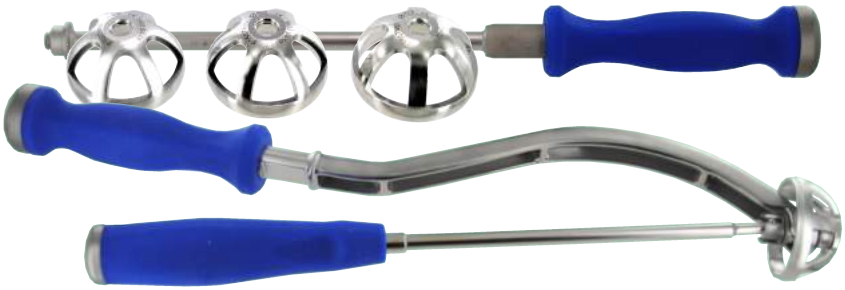
Increment the sizes of reamer down to the sub-chondral bone while avoiding reducing the thickness of the anterior and posterior walls of the acetabulum.

Checking the reaming of the acetabulum with the trial cup

Select a trial cup *(ref H03 0446 to H03 0464)* corresponding to the size of the last reamer used.

Reamer Ø*d* = Trial cup Ø*d*

Screw the trial cup on the straight impaction handle *(H76 009)* or on the curved impaction handle *(H76 001, H76 002 and H76 003)* according to the version of your instrumentation set.



Introduce and hammer the setup in the acetabulum in order to evaluate:
- the correct cup size,
- the depth of the reamed cavity,
- the primary stability of the final cup.

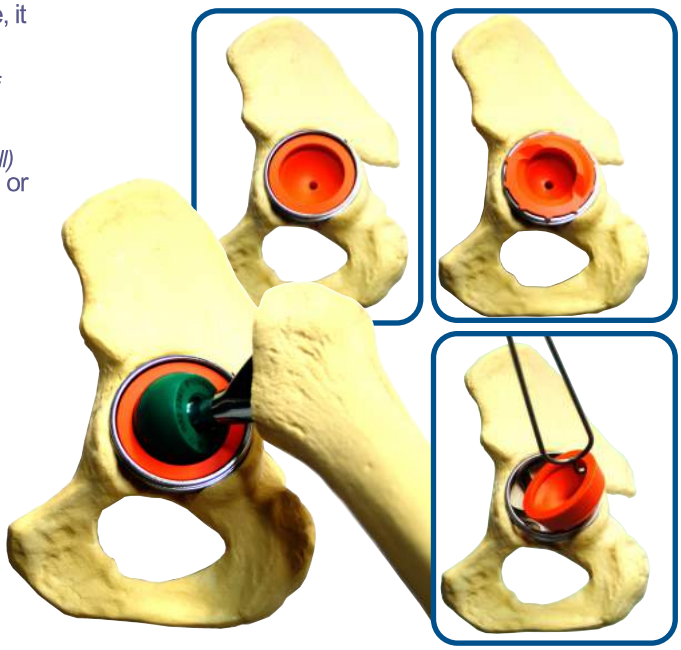
Reduction and trials in the trial cup

If the femoral preparation step has already been made, it is possible at this step to proceed to a trial.

Unscrew the impaction handle *(straight or curved)* out of the trial cup.

Select the trial insert *(choice of flat rim or with posterior wall)* normally stored with the trial cup in the instrument tray, or that of the same color.

The trial inserts Ø28mm (with posterior wall), Ø32mm and Ø36mm (flat rim) are supplied in standard in the Captiv FREELINER® instrumentation set. The trial liners Ø40mm (flat rim) are not supplied in standard and should be requested to your local distributor when necessary.



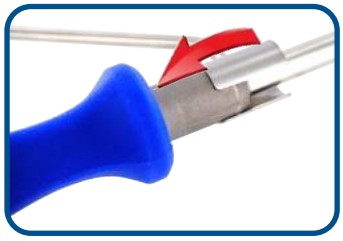
Place the trial liner by hand into the trial cup.

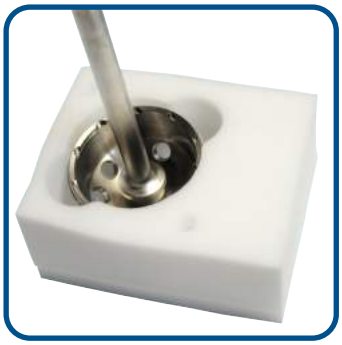
Make sure that the diameter of the trial head is of the same diameter as that of the trial liner. Reduce the hip joint and check for stability and limb length.

After the trials, remove the trial liner with the "hook" side of the drilling guide *(H76 010)*.

H76 010

Positioning of the definitive cup
With the straight impaction handle



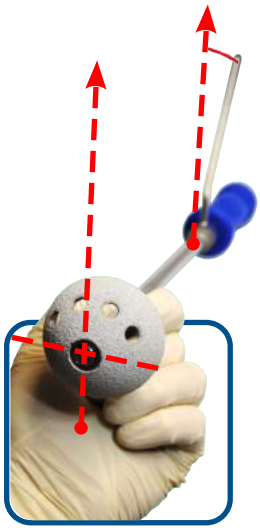


Prepare the 45° version axis *(H76 019)* with the straight impaction handle *(H76 009)*:

- introduce the ring of the 45° axis on the long and narrow cylindrical segment of the impaction handle,
- check that the tip of the 45° is oriented towards the blue grip,
- pull the 45° axis towards the blue grip until it is tightly fixed on the cylindrical and rough segment of the impaction handle.

Open the sterile packaging of the cup, remove the pouches, and leave the cup in the white foam pack.

Introduce the tip of the straight impaction handle into the cup, then screw the impaction handle into the threaded apex hole of the cup.
Lock firmly.



Turn the 45° version axis up so that it is aligned with the superior quadrant of the cup and the 4 screw holes.

Position the cup into the acetabulum.

Check that the 45° version axis is perfectly vertical, and that the impaction handle is orientated with an angle of 15 to 20° from the longitudinal side of the table.

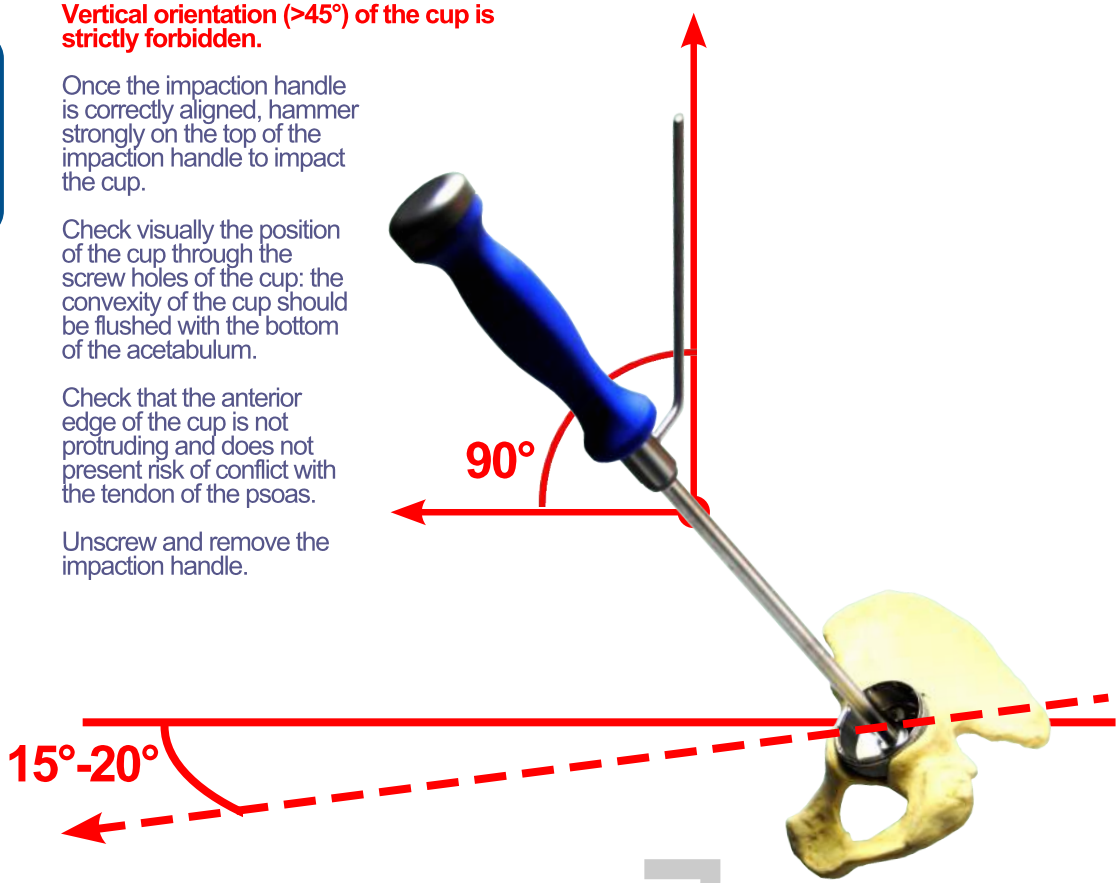
Vertical orientation (>45°) of the cup is strictly forbidden.

Once the impaction handle is correctly aligned, hammer strongly on the top of the impaction handle to impact the cup.

Check visually the position of the cup through the screw holes of the cup: the convexity of the cup should be flushed with the bottom of the acetabulum.

Check that the anterior edge of the cup is not protruding and does not present risk of conflict with the tendon of the psoas.

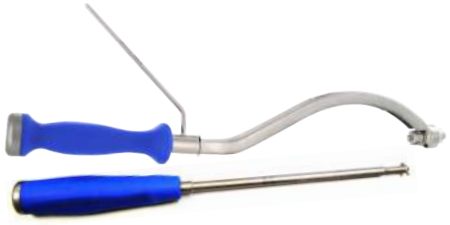
Unscrew and remove the impaction handle.

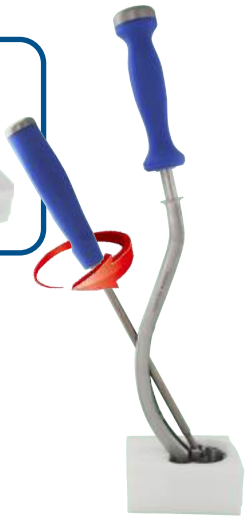


Positioning of the definitive cup
With the curved impaction handle

Prepare the screw for curved impaction handle *(H76 002)* together with its washer, at the extremity of the curved impaction handle *(H76 001)*.
Introduce the screw until its threaded extremity is freed out of the impaction handle.

Introduce the 45° version axis *(H76 019)* on its dedicated rectangular section on the curved impaction handle, close to the lower part of the blue grip:
- first introduce the ring tip of the 45° version axis on the thinner side of the quadrangular section,
- push the ring tip entirely on the quadrangular section,
- rotate the 45° axis through a quarter turn (90°) until locked on the curved impaction handle.





Introduce the screwdriver with nipples *(H76 003)* into the upper opening of the curved impaction handle, and then into the head of the screw *(H76 002)*.

Open the sterile packaging of the cup, remove the pouches, and leave the cup in the white foam pack.

Place the tip of the curved impaction handle into the cup, then thighten the screw *(H76 002)* into the threaded apex hole of the cup.
Lock firmly.

Turn the 45° version axis up so that it is aligned with the superior quadrant of the cup and with the 4 screw holes.

Introduce the cup into the acetabulum.

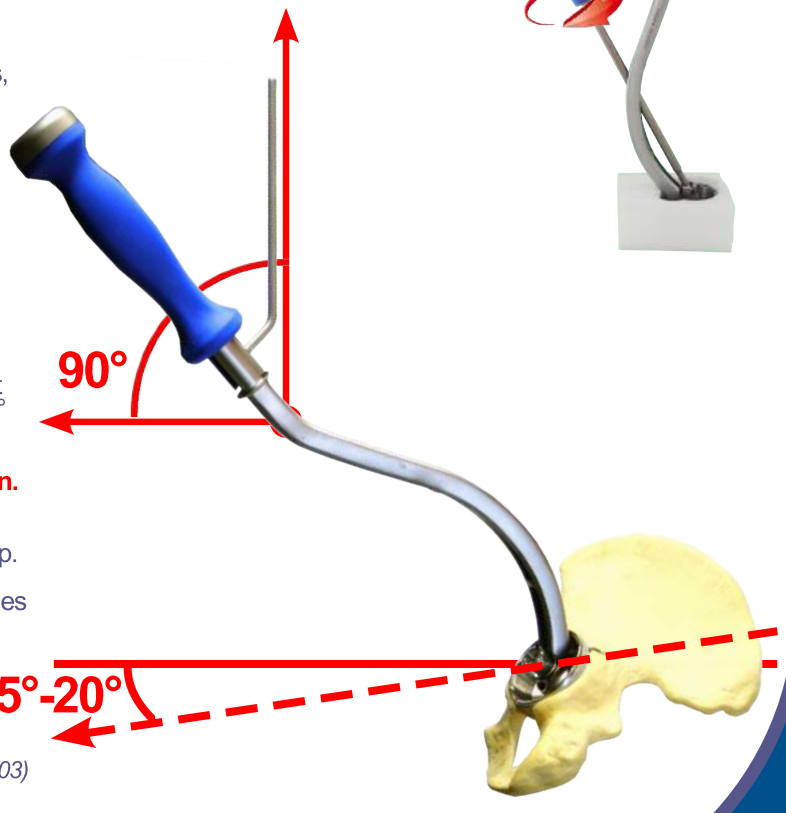
Check that the 45° version axis is perfectly vertical, and that the impaction handle is orientated with an angle of 15 to 20° from the longitudinal side of the table.

Vertical orientation (>45°) of the cup is strictly forbidden.

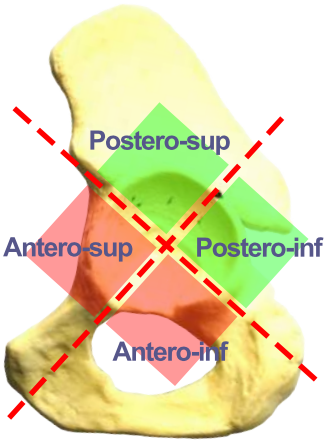
Once the impaction handle is correctly aligned, hammer strongly on the top of the impaction handle to impact the cup.

Check visually the position of the cup through the screw holes of the cup: the convexity of the cup should be flushed with the bottom of the acetabulum.
Check that the anterior edge of the cup is not protruding and does not present risk of conflict with the tendon of the psoas.

Unscrew the screw with the screwdriver with nipples *(H76 003)* and remove the curved impaction handle.



Complementary fixation with acetabular screws



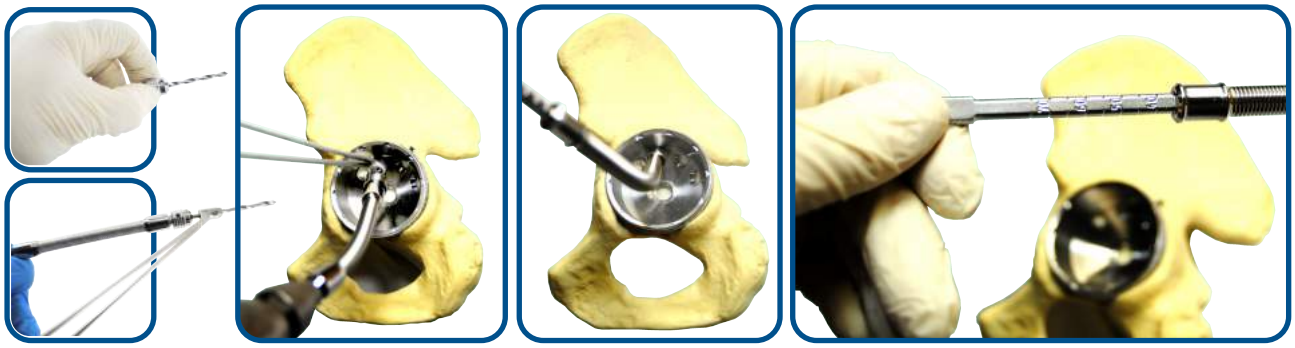
If the primary fixation of the cup does not appear to be satisfactory after impaction, a complementary fixation with up to 4 cancellous screws is possible.

The complementary fixation screws should only be positionned in the posterior quadrants of the acetabulum. The anterior quadrants of the acetabulum should be avoided in standard primary THA cases.

Prepare each screw with the L.25mm *(S01 010)* or L.45mm *(S01 003)* drill bit fitted on the flexible shaft for drill *(H0010050099)*, and with the drill guide *(H76 010)*.

Note : *The lengths of the drill bits are calculated to include the length of the drill guide. In cases where the drill bit is not long enough for a bi-cortical drilling, and once the first oriented drill hole has been made, remove the drill guide and continue drilling directly with the drill bit alone. This allows for an additional drilling of 15mm.*

Measure the length of the screw with the screw gauge *(H03 004)*.



Introduce each screw with the H3.5 screwdriver *(S01 005)* and with the forceps for screws *(H03 003)*.

Check with the finger that the head of the screw is flush with the concavity of the cup and will not interfere with the seating of the insert. Any such interference could jeopardize the fixation of the ceramic liner and its integrity. In such cases the screw should be tightened again or removed and introduced in another angular direction.

Trials in the definitive cup

Select the trial insert corresponding to the size of the implanted cup.

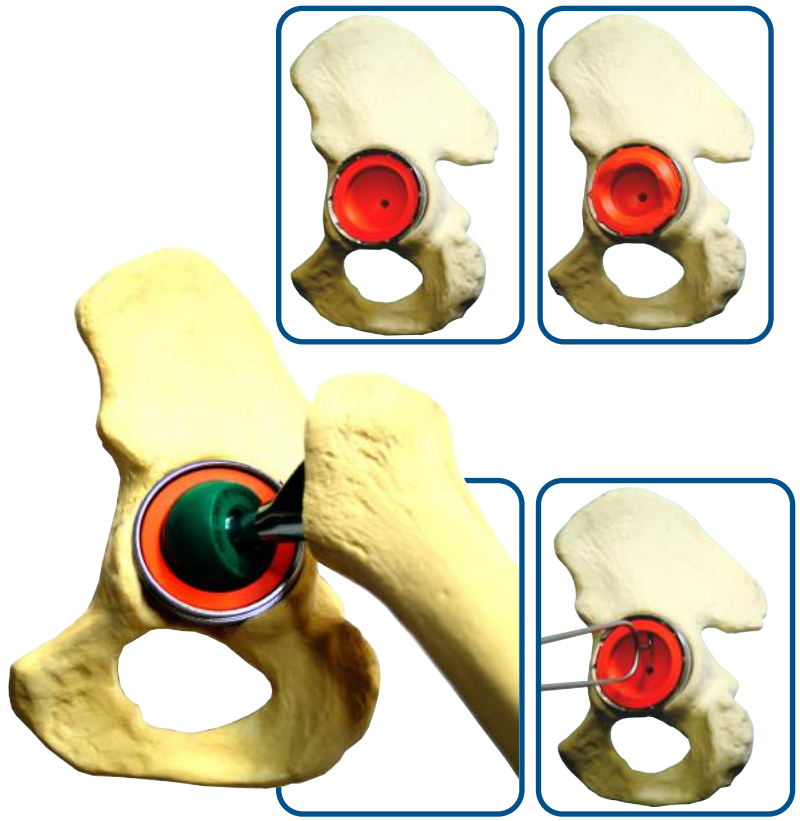
The posterior wall trial inserts for Ø28mm femoral head and the flat rim trial inserts for Ø32mm & Ø36mm femoral head are delivered in standard with the Captiv FREELINER® instrument sets.
The flat rim trial inserts for Ø40mm femoral head are available on option. Please refer to your local retailer.

Captiv FREELINER® cups and instrumentation are color coded in order to facilitate and secure the choice of the trial components and the selection of the definitive implants.

Example: if the cup implanted is a size 52, high-lighted **blue** on the packaging label, the corresponding trial insert will also be **blue** and so will be the highlight on the cup packaging label.

The trial inserts Ø28mm (with posterior wall), Ø32mm and Ø36mm (flat rim) are supplied in standard in the Captiv FREELINER® instrumentation set.
The trial liners Ø40mm (flat rim) are not supplied in standard and should be requested to your local distributor when necessary.

Labels for a Captiv FREELINER® cup and liners in Ø52



Place a trial insert in the cup.
Reduce the articulation and check the limb length and the stability.

H76 010

Remove the trial insert use the 'hook' side of the drill guide *(H76 010)*.

Positioning of the definitive insert
Steps for a ceramic insert

Select the definitive insert by means of the color code on the packaging label.
The color code must be the same that the one on the packaging of the cup.

Open the sterile packaging keeping the insert in the packaging foam.

Position the insert sucker *(H30 002)* in the ceramic insert.

H30 002

Push the sucker in order to achieve a vacuum fixing it to the insert.

Handle the setup with care in order to avoid the sucker coming off releasing the ceramic insert and falling off.

Carefully clean and dry the inside of the cup.

Introduce the insert into the cup.
Check visually and by fingering that the insert is correctly orientated in the taper of the cup. Any misdirection of the insert in the cup during its introduction can jeopardize its fixation into the cup and compromise the resistance of the ceramic at the impaction step or during the functional loading in the post-operative use.
In the cases where the insert is badly orientated, refer to the removal procedure described in page 13 *(Removal of the ceramic insert)*.

Slightly and gently impact on the extremity of the sucker.

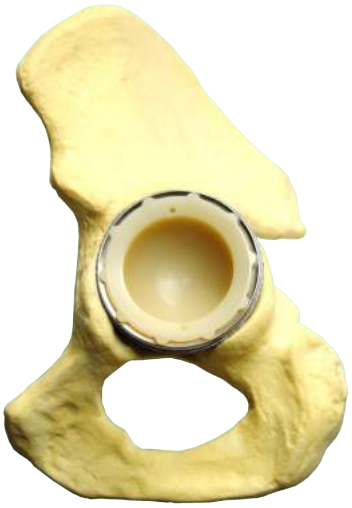
Release the sucker in the insert by pulling on the trigger freeing the vacuum.

H76 009

H76 004 à H76 007

Affix the corresponding spherical impaction nozzle *(H76 004 à H76 007)* of the same diameter as the insert *(Ø28, Ø32 or Ø36 if standard, Ø40 on option)* on the straight impaction handle *(H76 009)* or on the curved impaction handle *(H76 001, H76 002 and H76 003)* according to your instrument set, and **drive home the ceramic insert with a sharp hammer blow on the impaction handle.**

Steps for a PEXEL-E insert
Ø32 or 36 with flat rim



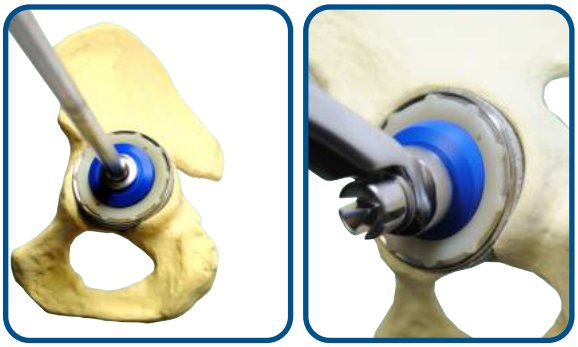
Select the definitive highly crosslinked with E vitamin insert by means of the color code on the packaging label.
The color code should be identical to that of the cup.

Open the sterile packaging keeping the insert in the packaging foam.

Carefully clean and dry the inside of the cup.

Introduce by hand the insert into the cup checking that the spigots on the insert are correctly aligned with the indentations on the cup.
The PEXEL-E inserts are only available with flat rim. The insertion of the insert require no specific orientation.

Affix the corresponding spherical impaction nozzle *(H76 004 à H76 007)* of the same diameter as the insert *(Ø28, Ø32 & Ø36 standard, Ø40 on option)* on the straight impaction handle *(H76 009)* or on the curved impaction handle *(H76 001, H76 002 and H76 003)* according to your instrument set.



Position the insert into the cup and check that the spigots of the insert are correctly aligned with the indentations on the cup.

Check visually that the insert is correctly aligned with the peripheral edge of the cup, **then position the impactor into the PEXEL-E insert and finalize the impaction of the insert with a sharp hammer blow.**
Check visually the correct positioning of the spigots into the indentations of the cup, and that there is no micro-mobility between the insert and the cup.

Steps for a PEXEL insert
Ø28 with posterior wall

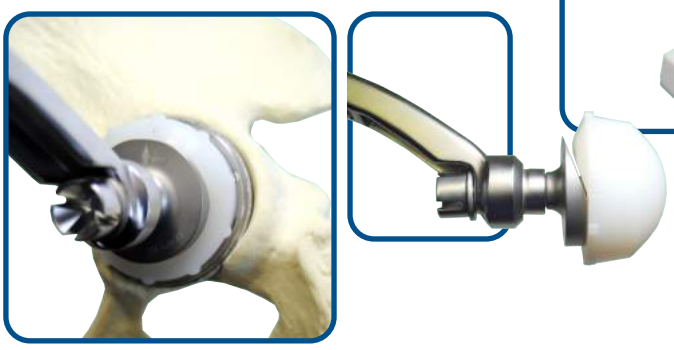
Select the definitive UHMWPE insert by means of the color code on the packaging label.
The color code must be the same that the one on the packaging of the cup.

Open the sterile packaging keeping the insert in the packaging foam.

Carefully clean and dry the inside of the cup.

Prepare the impaction plate for Ø28 insert *(H76 028)* and the spherical Ø28mm impaction nozzle *(H76 004)* on the straight impaction handle *(H76 009)* or on the curved impaction handle *(H76 001, H76 002 and H76 003)* according to your instrument set, and then position the plate and tip directly on the Ø28 posterior wall insert.
Make sure that the 2 spurs of the impaction plate are correctly aligned with the 2 holes on the insert. The beveled plan of the impaction plate should match the posterior wall profile of the insert.

Position the insert into the cup and check that the posterior wall of the insert is orientated in the postero-superior quadrant of the acetabulum, and that the spigots on the insert are correctly aligned with the indentations on the cup.



Check visually that the insert is correctly aligned with the peripheral edge of the cup, **then finalize the impaction of the PEXEL liner with a sharp hammer blow.**
Check visually the correct positioning of the spigots into the indentations of the cup, and that there is no micro-mobility between the insert and the cup.

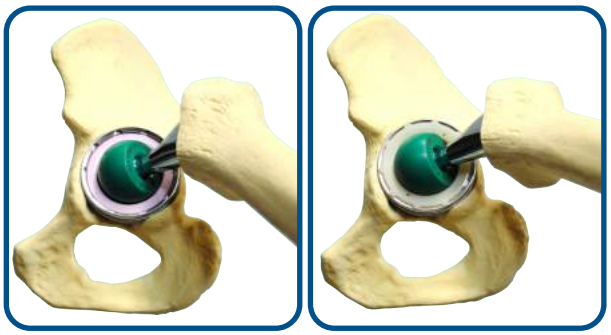
Femoral head length trials on definitive implants

After positioning of the definitive femoral stem, achieve a final femoral head trials:
Place a femoral head trial *(instrumentation of the femoral implant)* corresponding to the inner diameter of the Captiv FREELINER® insert.

Reduce the joint and test for stability and limb length.
If necessary change the length of the femoral head trial until the proper stability and length is achieved.

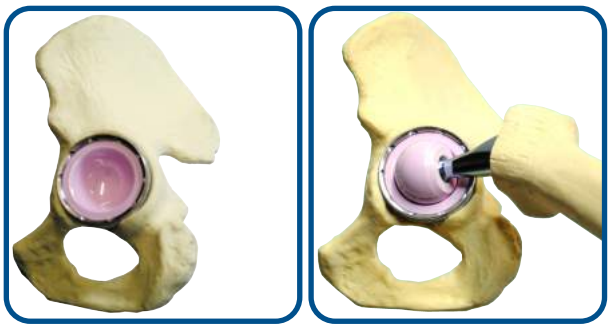
Position the definitive femoral head of the length and diameter corresponding to the best femoral head trial used.

Note: the PEXEL & PEXEL-E inserts can be used in association either with a metal *(stainless steel or cobalt-chromium)* **or a ceramic femoral head. The ceramic inserts can only be used in association with a ceramic femoral head.**



Reduction and wound closure

Reduce the articulation.
Clean the wound extensively.
Close and suture the capsule.
Suture the muscle, subcutaneous and dermal layers.



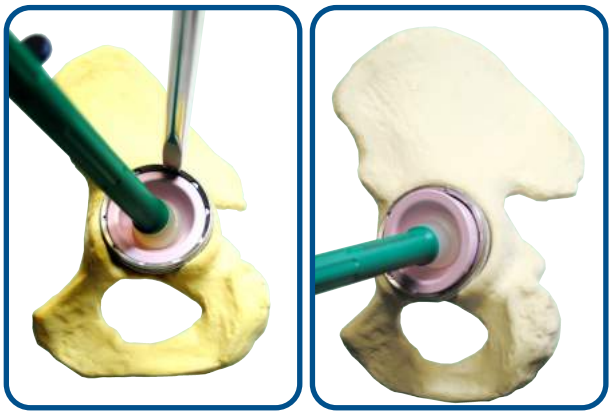
Removal of the ceramic insert

In the case of a cup revision the first thing to do is to remove the ceramic insert before being able to unscrew any complementary fixation screw and introduce an impaction handle in the apex hole of the cup.

Clean and dry the ceramic insert.
Place the sucker in the ceramic insert.
Press down the sucker so as to create a vacuum.

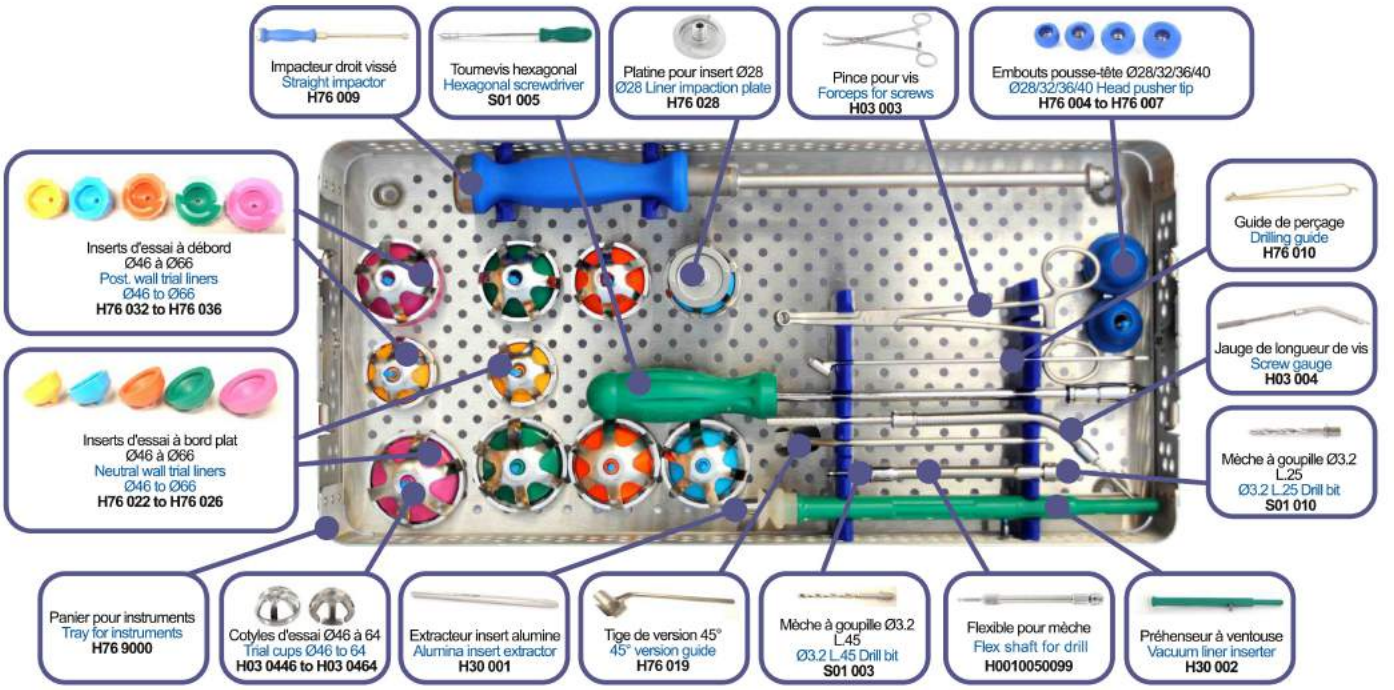
Use the insert extractor *(H30 001)* and place it on the external rim of the cup.
While maintaining traction on the sucker handle give a sharp hammer blow on the insert extractor.
If necessary repeat the operation until the insert is freed.

Remove the ceramic insert.



Instrumentation SNAPSHOT

Ref : H76 9100 FREELINER manche droit / straight



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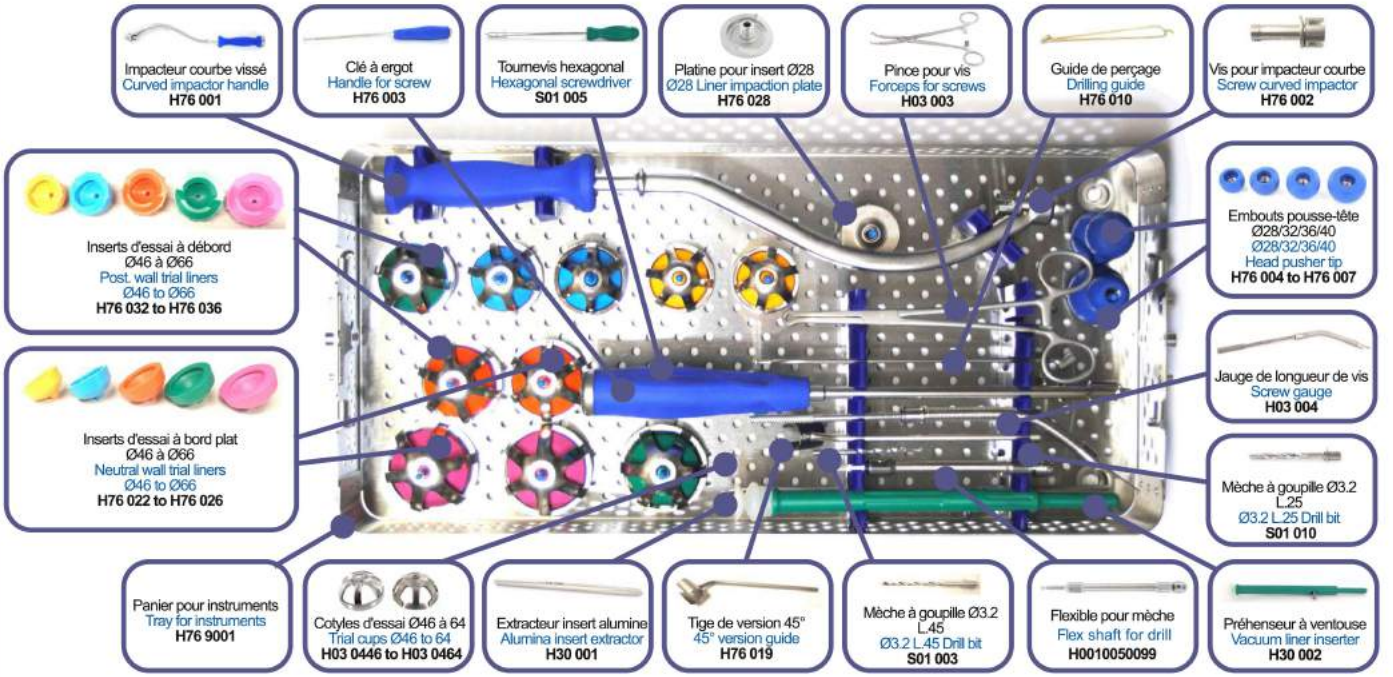
Dec 2015 / Ref: BI_FREELINER Straight SNP H76 9100

Instrumentation SNAPSHOT

Ref: H76 9101 FREELINER manche courbe / curved



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Dec 2015 / Ref: BI_FREELINER Curved SNP H76 9101

Notes :

Captiv Freeliner®

Ref. Cup.	Ref. Liner Ø28 UHMWPE "PEXEL"	Ø32 XLPE "PEXEL-E"	Ø36 XLPE "PEXEL-E"	Ø32 CERAMIC	Ø36 CERAMIC	Ø40 CERAMIC
Ø44 (*) H75 4438(*)	H75 P3828(*)					
Ø46 H75 4640 Ø48 H75 4840	H75 P4028	H75 XE4032		H75 C4032		
Ø50 H75 5044 Ø52 H75 5244	H75 P4428	H75 XE4432	H75 XE4436		H75 C4436	
Ø54 H75 5448 Ø56 H75 5648	H75 P4828	H75 XE4832	H75 XE4836		H75 C4836	H75 C4840
Ø58 H75 5850 Ø60 H75 6050	H75 P5028	H75 XE5032(*)	H75 XE5036		H75 C5036	H75 C5040
Ø62 H75 6254 Ø64 H75 6454 Ø66 (*) H75 6654(*)	H75 P5428	H75 XE5432(*)	H75 XE5436		H75 C5436	H75 C5440

(*): References available only on special request

A colour code (red, yellow, blue, orange, green, pink) facilitates the cup and liner size match. Example for a 58mm cup, the colour code is "green": once the material and the inner diameter are selected, choose the corresponding liner along the green line.

Acetabular screw / *vis à cotyle*

	Length *Longueur*	Ref.
Ø6.0 Screw/Vis	20 mm	H15 SB6020
Ø6.0 Screw/Vis	25 mm	H15 SB6025
Ø6.0 Screw/Vis	30 mm	H15 SB6030
Ø6.0 Screw/Vis	35 mm	H15 SB6035
Ø6.0 Screw/Vis	40 mm	H15 SB6040
Ø6.0 Screw/Vis	45 mm	H15 SB6045
Ø6.0 Screw/Vis	50 mm	H15 SB6050

Material
Cup: TA6V titanium alloy according ISO 5832-3. Porous titanium and Calcium hydroxyapatite coating
Screw: TA6V titanium alloy according ISO 5832-3
Liner: UHMWPE according ISO 5834-1 and 2, or Composite Ceramic according ISO 6474-2
Packaging: vacuum packed and gamma ray sterilized

Your EVOLUTIS distributor is:

Designed and Manufactured in France

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