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CREATEUR FABRICANT

Captiv Freeliner®

Surgical Technique

Pre-Set Impaction

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.

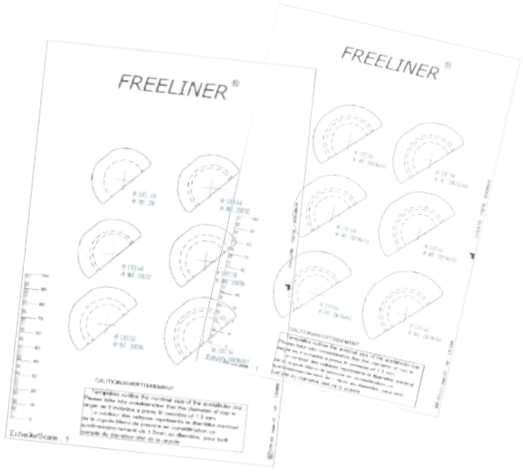
The implantation of a hip implant can entail the following complications: bruise, thrombosis, pulmonary embolism, cardiovascular disorders, nervous, tendinous or venous affliction, peri-prosthetic ossifications, allergenic reaction to the material(s), tissular reaction to the wear particles (metallosis), 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.

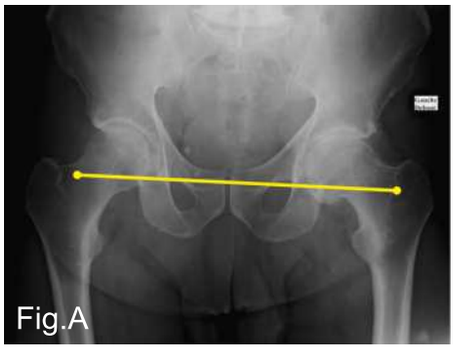


Fig.A

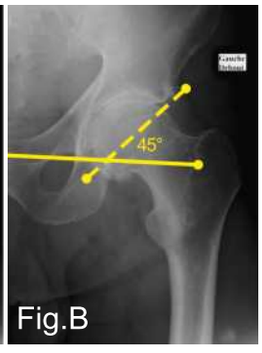


Fig.B

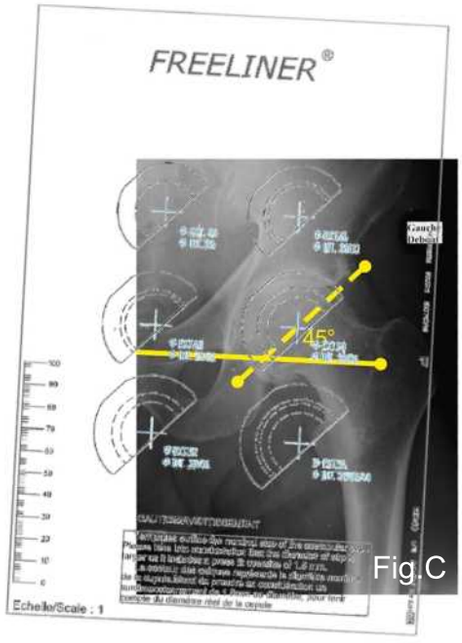
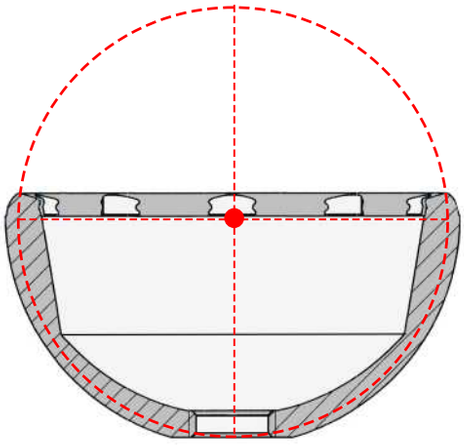


Fig.C

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/)
- EOS (www.eos-imaging.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

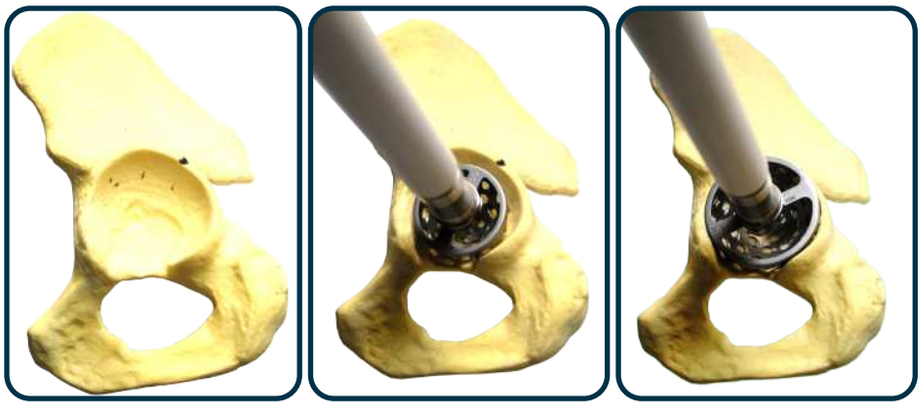
Reamer Ød
=

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 0463)* corresponding to the size of the last reamer used.

Reamer Ø*d* = Trial cup Ø*d*

Select the Expanding cup holder endpiece *(H52 P47 to H52 P65)* corresponding to the diameter of the trial cup.

Pull the "arming lever" to open the impaction handle *(H52 036)*.

Engage the Expanding cup holder endpiece on the extremity of the impaction handle.
Caution: *there is only one possible orientation where the opening of the baseplate is turned downwards and the flat side of the cup holder is facing the impaction handle.*

Position the impaction handle with the Expanding cup holder endpiece on the trial cup.
Close the "arming lever" to lock the cup on the impaction handle set.
Place 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.

Release the impaction handle out of the trial cup.

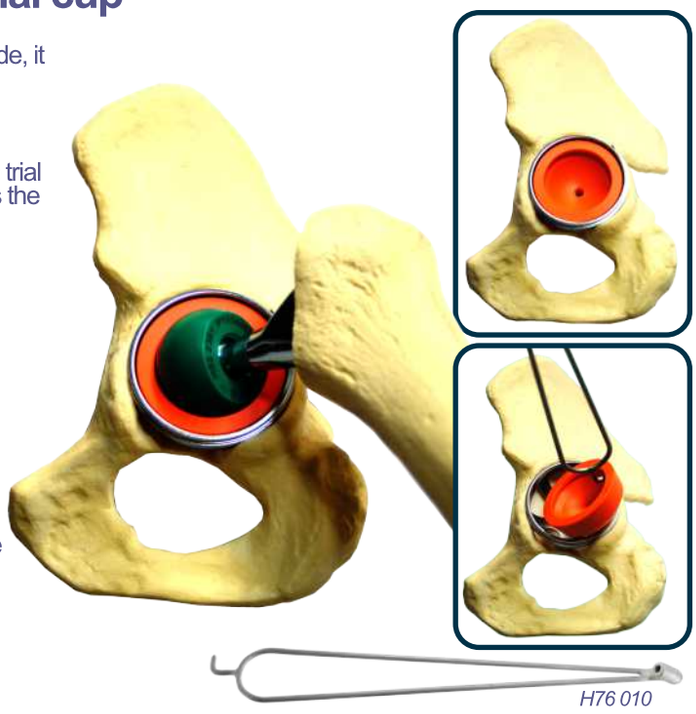
Select the trial insert *(flat rim)* normally stored with the trial cup in the instrument tray, and of the same colour as the impaction baseplate used previously.

The trial inserts Ø32mm and Ø36mm are supplied in standard in the Captiv FREELINER® instrumentation set.

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 and impaction of the ceramic insert in the definitive cup

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

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

Introduce the insert into the cup.
Check that the insert is correctly orientated in the taper of the cup.
Slightly and gently impact on the extremity of the sucker.

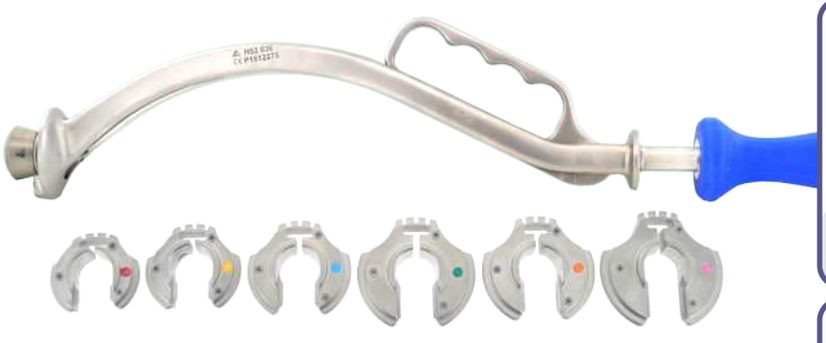
Release the sucker in the insert by pulling on the trigger freeing the vacuum.

Depending of the inner diameter of the ceramic insert, place the ceramic insert impactor alone *(H76 020)* or fitted with the Ø36mm reducer *(H76 021)* in the ceramic insert.
Hammer firmly on the impactor for the ceramic insert to be fixed into the cup.

Impactor for Ø32 inserts

Impactor with reducer for Ø36mm insert

Impaction of the definitive cup



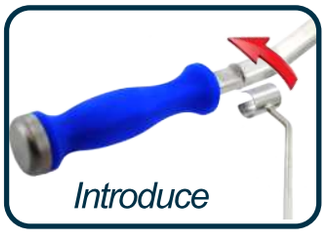
Select the impaction baseplate *(H76 012 à H76 017)* of the same diameter as that of the definitive cup, or refer to the color pellet on the baseplate for correspondance to the color code on the packaging of the cup.

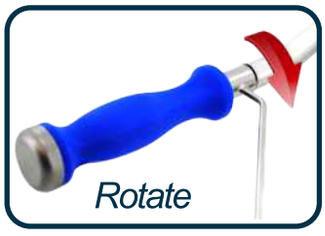
Pull the "arming lever" to open the impaction handle *(H52 036)*.
Engage the impaction baseplate on the extremity of the impaction handle.
Caution: *there is only one possible orientation where the opening of the baseplate is turned downwards and the flat side of the baseplate is facing the impaction handle.*

Position the impaction handle with the impaction baseplate in the cup while taking care to align the curvature of the impaction handle towards the upper quadrant of the cup and the middle of the 4 screw holes.

Close the "arming lever" to lock the cup and insert on 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.



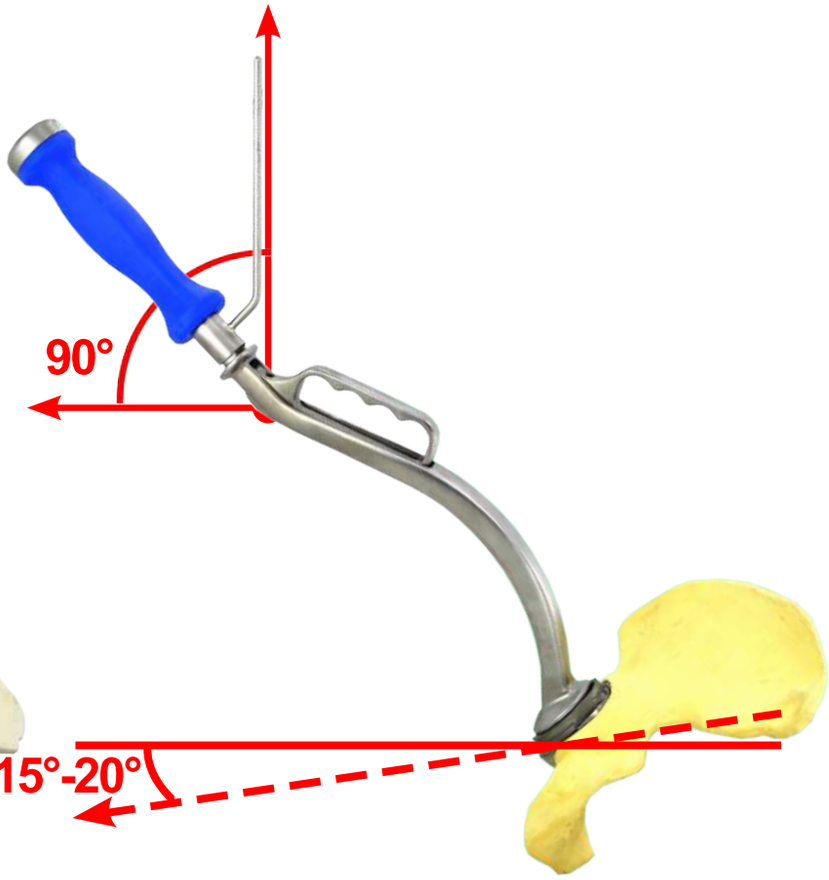


Turn the 45° version axis up so that it is aligned with the superior quadrant of the cup and the 4 screw holes.

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.

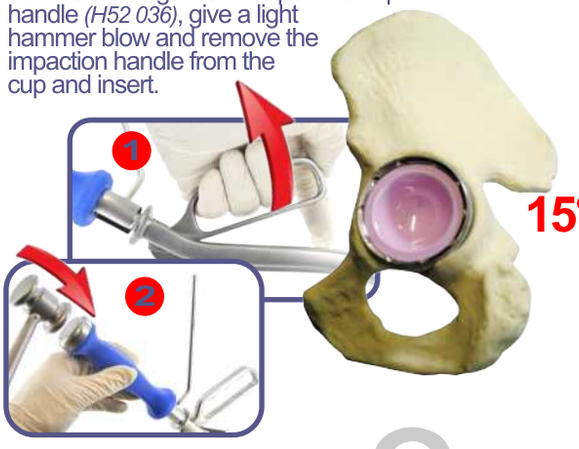
Vertical orientation (>45°) of the cup is strictly forbidden.



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

Check visually the orientation *(verticalization and anteversion)* and that the anterior edge of the cup is notprotruding and does not present risk of conflict with the tendon of the psoas.

Pull the "arming lever" to open the impaction handle *(H52 036)*, give a light hammer blow and remove the impaction handle from the cup and insert.



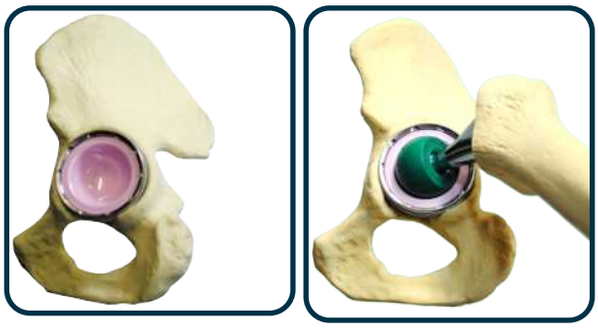
Femoral head length trials on definitive implants

After positioning of the definitive femoral stem, proceed to 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.

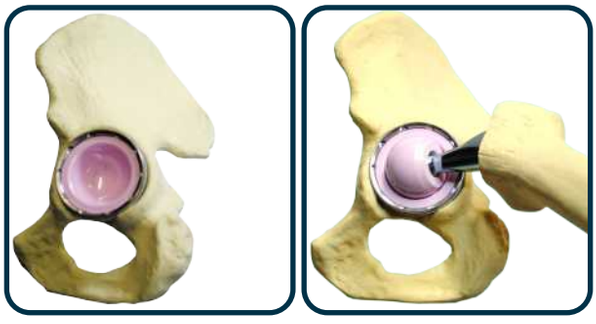
Position the definitive femoral head of the length and diameter corresponding to the best femoral head trial used.

Note: the 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.



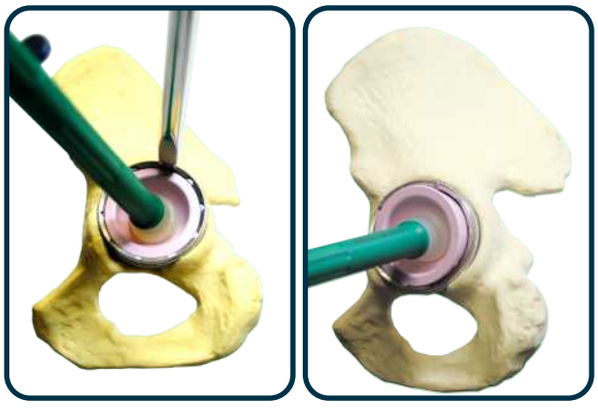
Removal of the ceramic insert

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.

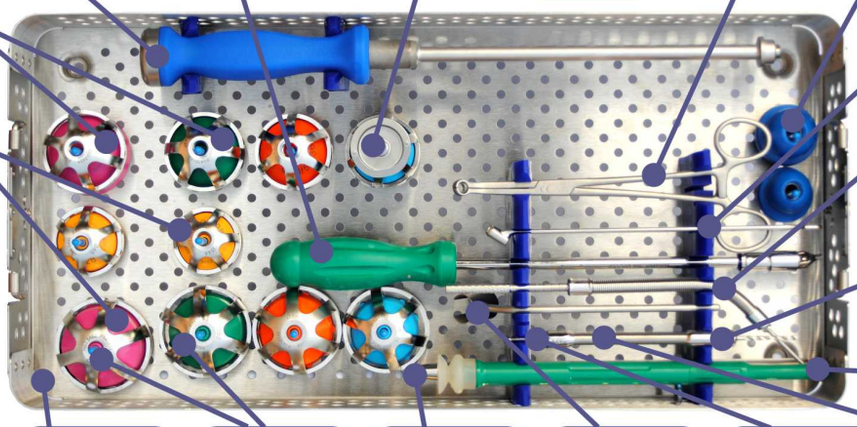
Use the insert extractor *(H30 001)* and place it on the external rim of the cup.
While maintaining traction on the sucker handle give a sharp hammer blow on the insert extractor.
If necessary repeat the operation until the insert is freed.

Remove the ceramic insert.



Instrumentation SNAPSHOT

Ref : H76 9100 FREELINER manche droit / straight



OPTION
Inserts d'essai à débord
Ø46 à Ø66/28
Post. wall trial liners
Ø46 to Ø66/28
H76 032 to H76 036
OPTION
Ø44/28
H76 031

Inserts d'essai à bord plat
Ø46 et Ø48/32
Ø50 à Ø66/36
Neutral wall trial liners
Ø46 & Ø48/32
Ø50 to Ø66/36
H76 022 to H76 026

OPTION
Inserts d'essai à bord plat
Ø50 à Ø66/32
Neutral wall trial liners
Ø50 to Ø66/32
H76 042 to H76 045

Impacteur droit vissé
Straight impactor
H76 009

Tournevis hexagonal
Hexagonal screwdriver
S01 005

Platine pour insert Ø28
Ø28 Liner impaction plate
H76 028

OPTION
Platine pour insert Ø32
Ø32 Liner impaction plates
H76 051

Pince pour vis
Forceps for screws
H03 003

Embouts pousse-tête Ø28/32/36
Ø28/32/36 Head pusher tip
H76 004 to H76 006

Guide de perçage
Drilling guide
H76 010

Jauge de longueur de vis
Screw gauge
H03 004

Mèche à goupille Ø3.2 L.25
Ø3.2 L.25 Drill bit
S01 010

Préhenseur à ventouse
Vacuum liner inserter
H30 002

Panier pour instruments
Tray for instruments
H76 9000

Cotyles d'essai Ø46 à 64
Trial cups Ø46 to 64
H03 0446 to H03 0464

Extracteur insert alumine
Alumina insert extractor
H30 001

Tige de version 45°
45° version guide
H76 019

Mèche à goupille Ø3.2 L.45
Ø3.2 L.45 Drill bit
S01 003

Flexible pour mèche
Flex shaft for drill
H0010050099

Cotyles d'essai
Ø44 & 66
Trial cups
Ø44 & 66
H03 0444 & H03 0466
OPTION

Mar 2023 / Ref: BI_FREELINER Straight SNP H76 9100

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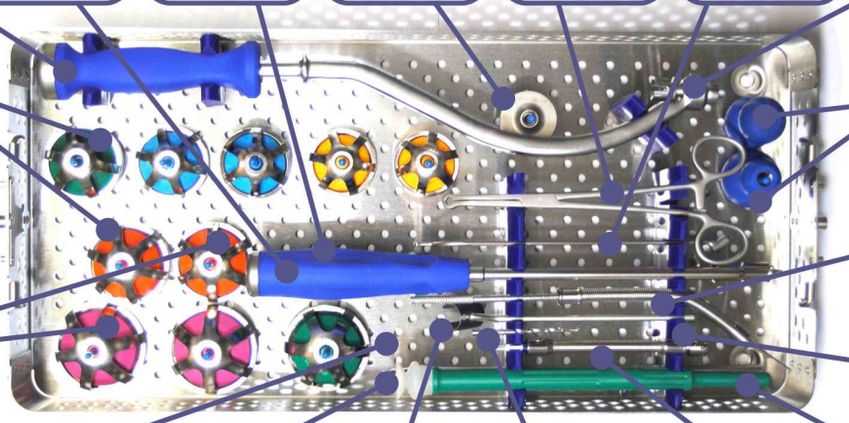
Instrumentation SNAPSHOT

Ref: H76 9101 FREELINER manche courbe / curved



OPTION
Platine pour insert Ø32
Ø32 Liner impaction plates
H76 051

Impacteur courbe vissé
Curved impactor handle
H76 001

Clé à ergot
Handle for screw
H76 003

Tournevis hexagonal
Hexagonal screwdriver
S01 005

Platine pour insert Ø28
Ø28 Liner impaction plate
H76 028

Pince pour vis
Forceps for screws
H03 003

Guide de perçage
Drilling guide
H76 010

Vis pour impacteur courbe
Screw curved impactor
H76 002

OPTION
serts d'essai à débord
Ø46 à Ø66/28
Post. wall trial liners
Ø46 to Ø66/28
H76 032 to H76 036
Ø44/28
H76 031

Inserts d'essai à bord plat
Ø46 et Ø48/32
Ø50 à Ø66/36
Neutral wall trial liners
Ø46 & Ø48/32
Ø50 to Ø66/36
H76 022 to H76 026

OPTION
Inserts d'essai à bord plat
Ø50 à Ø66/32
Neutral wall trial liners
Ø50 to Ø66/32
H76 042 to H76 045

Embouts pousse-tête
Ø28/32/36
Ø28/32/36
Head pusher tip
H76 004 to H76 006

Jauge de longueur de vis
Screw gauge
H03 004

Mèche à goupille Ø3.2 L.25
Ø3.2 L.25 Drill bit
S01 010

Cotyles d'essai Ø46 à 64
Trial cups Ø46 to 64
H03 0446 to H03 0464

Extracteur insert alumine
Alumina insert extractor
H30 001

Tige de version 45°
45° version guide
H76 019

Mèche à goupille Ø3.2 L.45
Ø3.2 L.45 Drill bit
S01 003

Flexible pour mèche
Flex shaft for drill
H0010050099

Préhenseur à ventouse
Vacuum liner inserter
H30 002

Panier pour instruments
Tray for instruments
H76 9001

Cotyles d'essai
Ø44 & 66
Trial cups
Ø44 & 66
H03 0444 & H03 0466
OPTION

Mar 2023 / Ref: BI_FREELINER Curved SNP H76 9101

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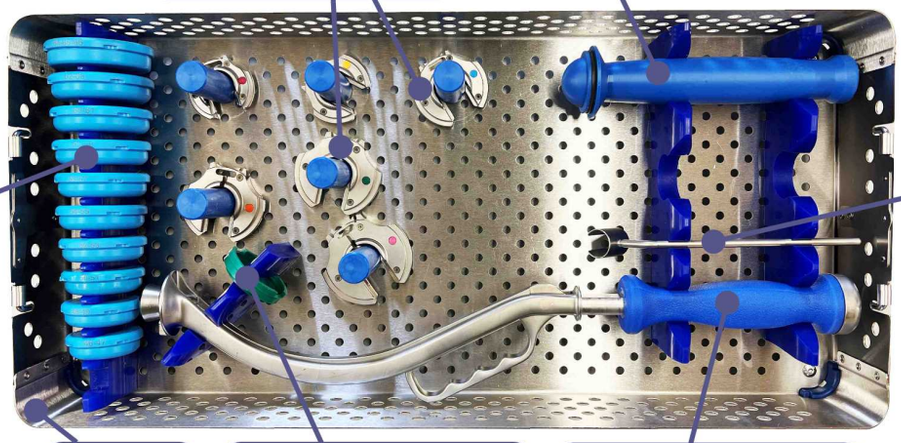
Instrumentation SNAPSHOT

Ref : H76 9102

FREELINER Impaction sur table / Pre-set impactor



Platine d'impaction pour cupule Ø44 à 66
Impaction baseplate for cup Ø44 to 66
H76 012 à/to H76 017

Impacteur pour insert céramique Ø32
Impactor for Ø32 ceramic liner
H76 020

Platine d'expansion préhenseur à cotyle Ø46 à 66
Expanding cup holder endpiece Ø46 to 66
H52 P47 à/to H52 P65

Tige de version 45°
45° version guide
H76 019

Panier pour instruments
Tray for instruments
H76 9002

Réducteur d'impaction pour insert Ø36mm
Impaction reducer for Ø36mm insert
H76 021

Manche d'impaction pour cupule
Cup impaction handle
H52 036

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Notes :

Captiv Freeliner®

Ref. Cup.	Ref. Liner Ø28 UHMWPE "PEXEL"	Ø32 XLPE "PEXEL-E"	Ø36 XLPE "PEXEL-E"	Ø32 CERAMIC	Ø36 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
Ø58 H75 5850 Ø60 H75 6050	H75 P5028	H75 XE5032(*)	H75 XE5036		H75 C5036
Ø62 H75 6254 Ø64 H75 6454 Ø66 (*) H75 6654(*)	H75 P5428	H75 XE5432(*)	H75 XE5436		H75 C5436

(*): 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&2 and stainless steel ISO 5832-1, or Composite Ceramic according ISO 6474-2
Packaging: vacuum packed and gamma ray sterilized

Important Notice:
The CAPTIV FREELINER implants belong to the class III implantable medical device classification. The CAPTIV FREELINER implants are indicated in total hip arthroplasty primary procedures (THR) for the acetabular component.
The surgeon is required to read the instructions for use (IFU) leaflet S12 0303 included in the packaging of the implant or available for download on the www.evolutisfrance.com website, as well as the surgical technique manual H76 452 (Standard Impaction) or H76 454 (Pre-set impaction) initially delivered with the instrument set, or equally available for download on the www.evolutisfrance.com website.

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