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Evolutis

CREATEUR FABRICANT

Capitole®

Evolutis
MOTION INSIDE

Surgical Technique

TABLE OF CONTENTS

Important notice:

SELECTION OF THE FEMORAL STEM SUITABLE FOR DUAL MOBILITY ARTICULATION

The surgeon should select a femoral component with a neck design adapted to the kinematics of the dual-mobility liners.
The prosthetic femoral neck should:

- (1) be 12mm or less in diameter -measured at its narrowest section- to allow a minimum clearance in the "first" articulation of 45°,
- (2) have a round or rounded section, and free of any sharp edge -the rounded section should run on a minimum length of 12mm (corresponding to the range of head sizes from -4 to +8mm), where the inner lip of the liner can impinge with the prosthetic neck-,
- (3) hould have an overall length of minimum 25mm to avoid impingement of the liner with any other section but the prosthetic rounded neck of the femoral implant,
- (4) should have the portion of connecting taper fully covered by the femoral head and for all available lengths of femoral heads,
- (5) should be free from holes, threads, and laser etchings,
- (6) be fully shiny polished.

Any neck divergent in design from this recommendation, including sand-blasted neck or portion of neck, rectangular section neck, sharp edges, less than 12mm of smooth portion of neck, overall length of less than 25mm, neck larger than 12mm diameter at its narrowest section, neck showing a portion of the Morse taper below the femoral head or showing a loss of surface continuity with hole, thread or laser etching, **is not recommended for use with a dual mobility liner** and cup.

Acetabular reaming

After having resected the femoral head, measure its diameter with a caliper,

Remove osteophytes, chondral and fibrous tissues to perfectly expose the rim of the acetabulum,

Engage smallest diameter reamer on the reaming shaft and begin reaming the acetabular fossa holding the power tool in a vertical position **(1)**,

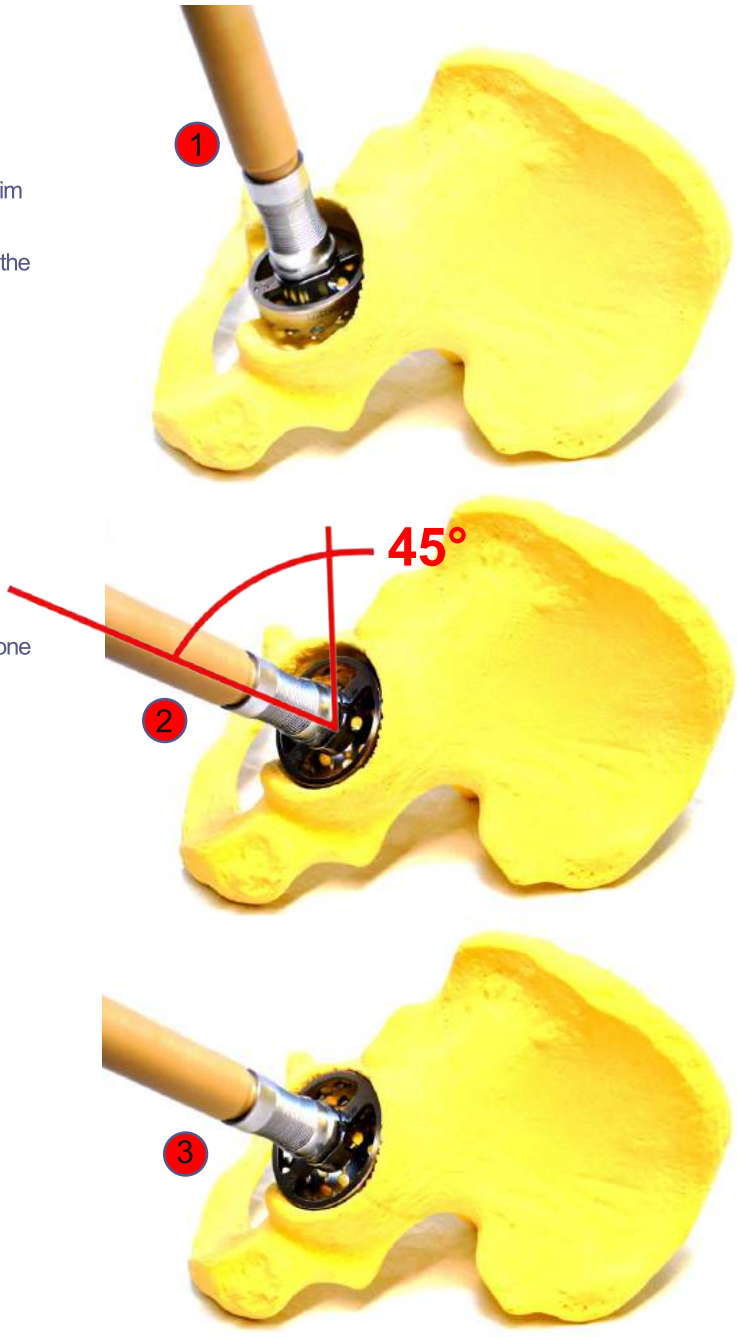
Ream through the cartilage down to the true base of the acetabulum,
Stop reaming when reamer reaches slightly bleeding hard bone,

Select the reamer 1 size under the diameter of thr retreived femoral head.
Introduce the reamer with the reamer shaft at 45° of vertical axis, and with anatomic anteversion **(2)**.

Ream untill the reamer reaches the same sub chondral bone level as 1st reamer,

Sequentially increase reamer size untill the last size perfectly adapts to the acetabular margins **(3)**,

Increment sizes cautiously in order never to reduce anterior and posterior bone margin thicknesses.



Trial cup and final cup impaction

Select a trial cup the same diameter as the last reamer used,

Screw the trial cup on the cup impactor screw (threaded inner shaft),

Introduce the trial cup into the acetabulum **(4)**,

Assess cup dimension and position in the acetabulum,
The flexible trial cup is designed to assess bone contact and sphericity of reaming, it is not designed for stability testing, do not evaluate cup stability according to this test.

Option 1: Straight cup impactor

Introduce the cup impactor screw into the cup impactor body up to the stop,

Select the cup impactor tip of the same diameter as the final cup,

Screw the cup impactor tip on the cup impactor thread until it just touches the conical end piece, not tight

Open the sterile pack of the final cup and leave the cup into the foam packaging,

Position the cup impactor assembly and the impaction tip into the final cup **(5)**,

Hold the outer body tight and screw the inner shaft firmly, which will tighten the impactor into the cup,

Important: if using a Capitol T cup, at this step bend the screw plate with the plate iron tool to match the acetabular roof morphology (generally 45°).

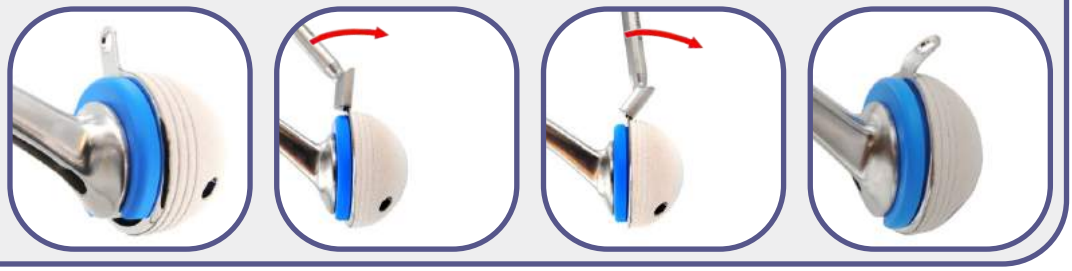
Snap the 45° orientation guide on the cup impactor body **(6)**.

Bending the screw plate of a Capitole T

While the cup is held on the impactor, hold the cup firmly an use the bending iron (H52 018) to bend the screw plate.

The bending angle is adapted to the morphology of the acetabular roof.

An angle of 45° is an average.



Introduce the final cup into the acetabulum **(7)**,
Orientate the cup to avoid verticalizing it in the acetabulum, and check the anteversion of the cup with respect to the acetabulum's anterior wall: the cup should not protrude from the anterior wall. **This attention during implant placement is of upmost importance to reduce the friction of the psoas tendon with the edge of the cup.**

Hammer the cup into position, and test for stability,

Unscrew the inner impactor screw a little until the tip is loose in the cup, but still attached to the shaft,

Remove the cup impactor tip out from the final cup.

Option 2: Curved impactor for cup

Select the cup holding disc of the same diameter as the final cup,

Set the trigger of the curved impactor for cup in the "open" position **(8)**,

Slide and snap the curved impactor cup tipon the bottom end of the curved impactor **(9)**,

Open the sterile pack of the final cup and leave the cup into the foam packaging, Position the curved impactor and cup tip assembly into the final cup, check the orthogonality of the tip and the cup.

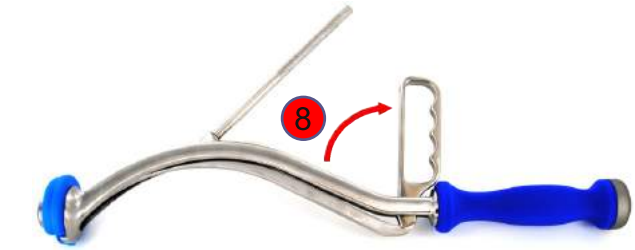
Lock tight the trigger of the curved impactor in the "closed" position **(10)**,

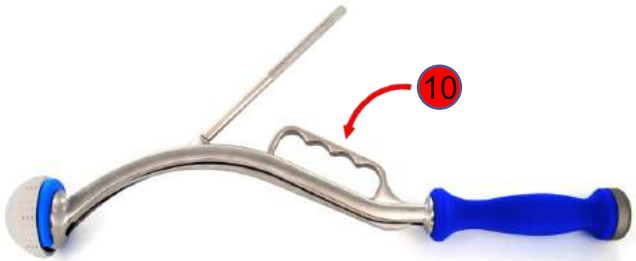
Screw the 45° orientation guide on the cup impactor body,

Introduce the final cup into the acetabulum,
Orientate the cup to avoid verticalizing it in the acetabulum, and check the anteversion of the cup with respect to the acetabulum's anterior wall: the cup should not protrude from the anterior wall. **This attention during implant placement is of upmost importance to reduce the friction of the psoas tendon with the edge of the cup.**

Hammer the cup into position, and test for stability,

Set the trigger of the curved impactor for cup in the "open" position,
Remove the cup impactor tip out from the final cup.





Specific steps for the Cemented cup

Whenever implanting a Cemented version of the DM cup, it is MANDATORY to proceed according to the following instructions:

- select the cup impaction tip (option 1: straight impaction shaft) or the expanding holding disc (option 2: curved impaction handle) of the size corresponding to the diameter of the cup to be implanted, and attach to the impaction handle. Example: for a Ø50 cup, select the Ø50 impaction tip or disc **(a)**.

cup Ø50 = impaction tip Ø50

- place the impaction set inside the cup and expand moderately the tip or disc (screw action for a straight handle, pull the trigger for a curved handle).

- introduce a dose of cement into a clean and dry acetabulum.

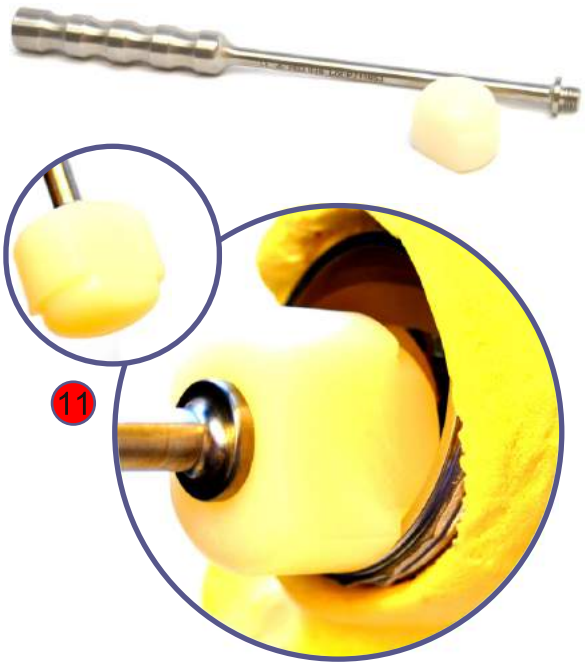
- introduce the handle/cup assembly into the acetabulum, set the correct orientation plans (tilt and anteversion) with reference to the 45° orientation rod.
Orientate the cup to avoid verticalizing it in the acetabulum, and check the anteversion of the cup with respect to the acetabulum's anterior wall: the cup should not protrude from the anterior wall. **This attention during implant placement is of upmost importance to reduce the friction of the psoas tendon with the edge of the cup.**

- hammer the cup in its final position **(b)**.

- IMMEDIATELY unscrew (straight handle) or release the trigger (curved handle) and retrieve the impaction handle and the impaction tip out of the cup.

- attach the white cup impaction tip to the M10 impaction shaft.

- introduce the white cup impaction tip into the cup, and apply manual pressure to the cup until the cement is set **(c)**.



Re-positionning and final impaction

In case the cup is misaligned in the acetabulum, but not firmly impacted, assemble the impaction spherical tip to the M10 impaction shaft,

Position one of the stepped edges on the edge of the cup and tap to re-orientate the cup to the final position **(11)**.

Finalize cup impaction with the same tool **(12)**.

Tripode fixation for Capitole T

The Capitole T is an evolution of the original Tripode dual mobility cup. The initial press-fit stability is completed by 2 anchoring pegs in the pubic and the ischiatic bone, and one bi-cortical screw in the acetabulum roof.

The two anchoring pegs are provided with the packaging of the cup.

Once the cup shell is fully seated in the acetabulum,

Drill through each ischiatic and pubic peg hole using the drill guide and special flexible drill **(13)**.

Impact the ischiatic peg with the staight impactor **(14)**, and the pubic peg with the curved impactor **(15)**.

Do not impact loudly, but control that both pegs are properly seated, not proud inside the shell.

Once the superior iliac flange has been contoured with the bending iron (see cup impaction step), drill with the 3,2mm drill through the guide with a 45° orientation and down to the posterior cortex **(16)**.

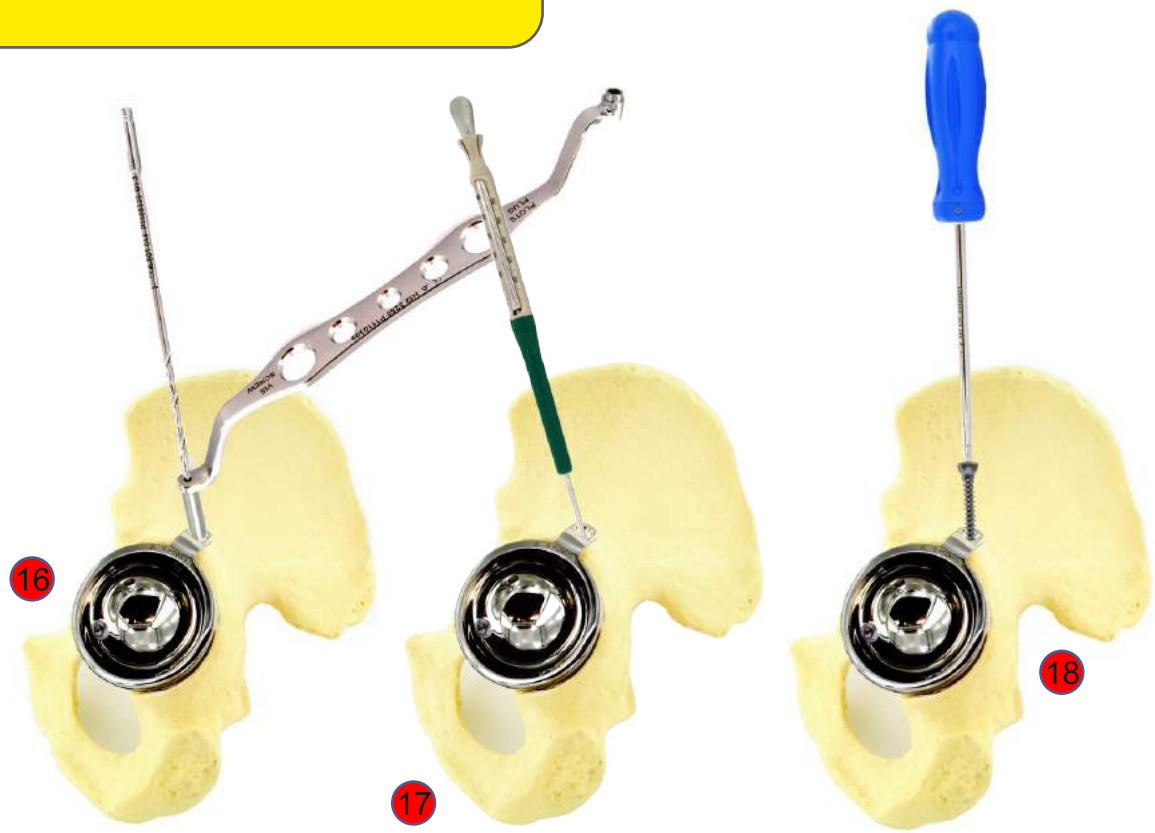
Measure the screw lenght with the gauge **(17)**, and screw in a Ø5mm screw bi-cortically **(18)**.

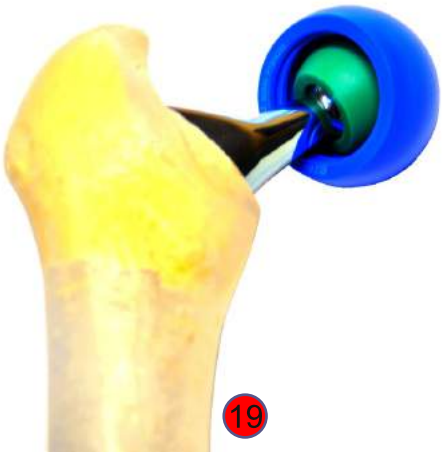
Impaction of pegs : Important Notice

In the cases where a CAPITOL T cup (with pegs) should be revised, it will be advisable beforehand to remove the screw of fixation and the 2 pegs. The ablation of the pegs by means of a threaded extractor (H52 012) can be compromised by the difficult access, the fibrous filling of the threaded holes, and the osseous integration of the pegs.
In these cases, the recommended technique will be to chase away the 2 pegs by impacting on them through the cup.

To achieve this, the conical fixation of the pegs was calibrated to get a sufficient resistance during the implantation, and to allow the pegs to pass through the cup during a more pronounced impaction.

As a consequence, during the implantation of the pegs, **it is recommended to apply a strength of impaction similar to that used for the implantation of a metallic head on the taper of a femoral stem.**
A more important impaction could pull the passage of the pegs through the cup.





Trial liner reduction

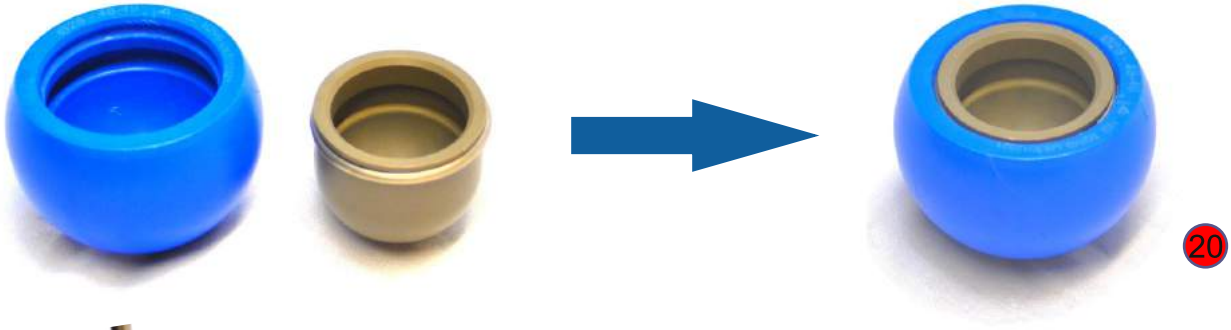
Select a trial liner of the same diameter as the final cup,

Standard liner is for Ø28mm trial head, and trial liner is non retentive.

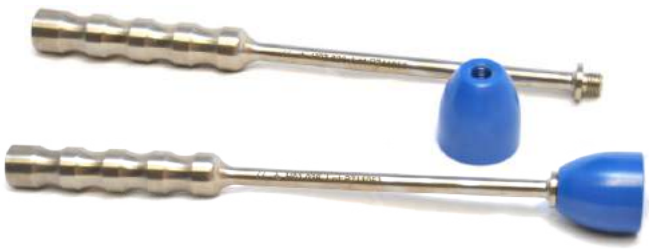
Position the trial head on the trial or final femoral stem,

Position the trial liner over the trial femoral head **(19)**,

In cases of 22.2mm ball head, place the grey Ø22.2mm trial head adaptor inside the Ø28mm blue trial liner **(20)**.



Assemble the cup impaction tip to the M10 impaction shaft,



Reduce hip joint **(21)**,

Undertake mobility and stability tests, select definitive head length **(22)**.

Insertion of the femoral head in the final liner

Prepare the liner press:
- screw the liner press screw on the liner press body **(23)**,
- snap the femoral head centralizer on the liner press screw tip,
- snap the concave liner pusher tip onto the fork of the liner press body **(24)**.

Position and hold final liner on the concave liner pusher tip, liner opening facing upwards **(25)**,

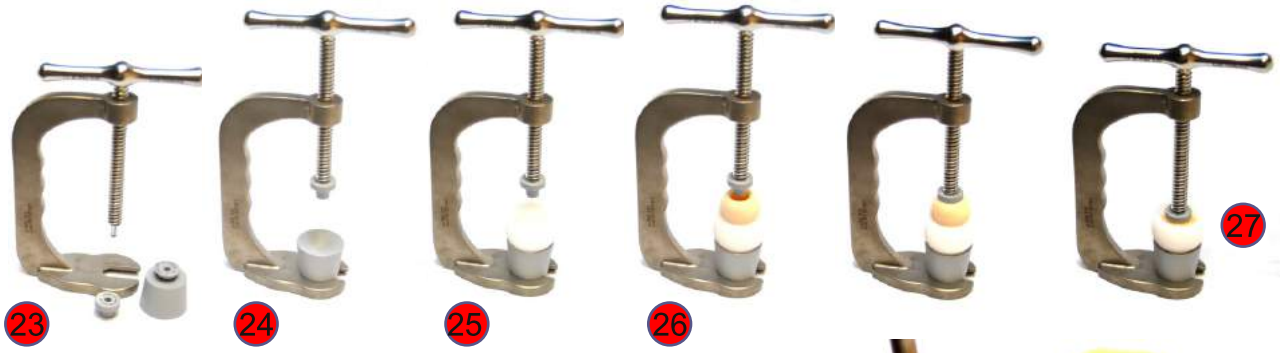
Position and hold final femoral head on top of the final liner, openings facing upwards **(26)**,

Turn the liner press screw clockwise until the centralizer fits into the femoral head,

Continue turning clockwise until the femoral head snaps into the final liner **(27)**,

The impaction is complete after the second "snap" sound (air escapes out of the liner).

Make sure the head is captured in the liner but free to move.



Introduction of the final liner and reduction of the hip

Position the final liner and head assembly on the femoral morse taper,

Important: control that the prosthetic femoral neck is compatible for association with a dual mobility cup. Please refer to the **Important notice** on page 3 of this document.

Assemble the cup impaction tip to the M10 impaction shaft,

Impact the final liner and final head assembly with the cup impaction tip,

Reduce the hip joint while pushing the liner into the cup with the impaction tip **(28)**,

Undertake final mobility and stability tests **(29)**.

Instrumentation
SNAPSHOT

Ref : H52 9100

CAPITOLE *Base* / Base

H52 020
Cup Impaction Tip
Embout d'Impaction Sphérique

H52 2228
Ø22 Adaptator for Ø28 liners
Adaptateur Ø22 pour Inserts Ø28

H52 M2847 *to*/à H52 M2865
Ø28 Trial Liners 46-47 to 64-65-66
Inserts d'essai Ø28/46-47 à 64-65-66

H52 M2245
Ø22/44-45 Trial Liner
Insert d'essai Ø22/44-45

H52 008
Impaction Rod for DM cup
Vis d'Impacteur pour cupule DM

H52 007
Impaction Shaft for DM cup
Corps d'Impacteur pour cupule DM

H03 013
Snap-on Orientation Rod Ø18
Tige d'Orientation à clip Ø18

H52 010
Cup Orientation tip
Embout Orienteur de cupule

H03 200212
Reamer Handle with AO connector
Porte-Fraise encliquetage AO

16-14-045 to/à 16-14-065
Acetabular Reamers Ø 45 to 65
Fraises à Cotyle Ø 45 à 65

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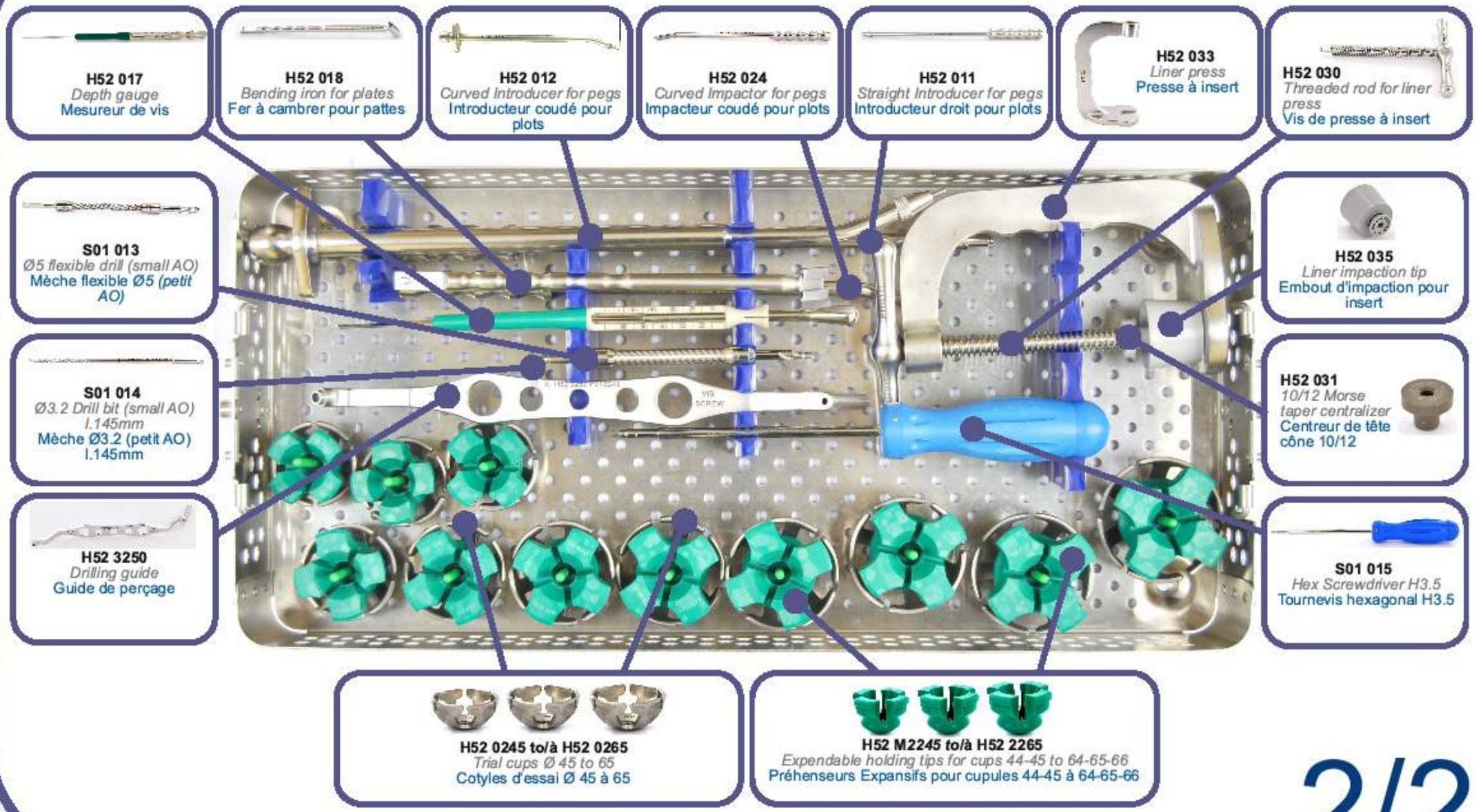
Instrumentation SNAPSHOT

Ref : H52 9100

CAPITOLE *Base* / Base



H52 017
Depth gauge
Mesureur de vis

H52 018
Bending iron for plates
Fer à cambrer pour pattes

H52 012
Curved Introducer for pegs
Introducteur coudé pour plots

H52 024
Curved Impactor for pegs
Impacteur coudé pour plots

H52 011
Straight Introducer for pegs
Introducteur droit pour plots

H52 033
Liner press
Presse à insert

H52 030
Threaded rod for liner press
Vis de presse à insert

S01 013
Ø5 flexible drill (small AO)
Mèche flexible *Ø5 (petit AO)*

S01 014
Ø3.2 Drill bit (small AO) l.145mm
Mèche Ø3.2 (petit AO) l.145mm

H52 3250
Drilling guide
Guide de perçage

H52 035
Liner impaction tip
Embout d'impaction pour insert

H52 031
10/12 Morse taper centralizer
Centreur de tête cône 10/12

S01 015
Hex Screwdriver H3.5
Tournevis hexagonal H3.5

H52 0245 to/à H52 0265
Trial cups Ø 45 to 65
Cotyles d'essai Ø 45 à 65

H52 M2245 to/à H52 2265
Expendable holding tips for cups 44-45 to 64-65-66
Préhenseurs Expansifs pour cupules 44-45 à 64-65-66

2/2

References

CAPITOLE dual mobility acetabular cup
Cupule acétabulaire à double mobilité CAPITOLE

Shell ø *Cupule*	Press-fit I	2 pegs T *2 plots T*	Cemented C *Cimenté C*	Revision R
ø45	**H51 I245**	**H51 T245**	**H51 C045**	-
ø47	**H51 I247**	**H51 T247**	**H51 C047**	**H51 R247**
ø49	**H51 I249**	**H51 T249**	**H51 C049**	**H51 R249**
ø51	**H51 I251**	**H51 T251**	**H51 C051**	**H51 R251**
ø53	**H51 I253**	**H51 T253**	**H51 C053**	**H51 R253**
ø55	**H51 I255**	**H51 T255**	**H51 C055**	**H51 R255**
ø57	**H51 I257**	**H51 T257**	**H51 C057**	**H51 R257**
ø59	**H51 I259**	**H51 T259**	**H51 C059**	**H51 R259**
ø61	**H51 I261**	**H51 T261**	**H51 C061**	**H51 R261**
ø63	**H51 I263**	**H51 T263**		**H51 R263**
ø65	-	-		**H51 R265**

CAPITOLE dual mobility liner
Insert à double mobilité CAPITOLE

Liner ø *Insert*	Inner ø *Interne* 22.2 PE	Inner ø *Interne* 28 PE
ø45	H51 M2245	-
ø47	H51 M2247	H51 M2847
ø49	H51 M2249	H51 M2849
ø51	H51 M2251	H51 M2851
ø53	H51 M2253	H51 M2853
ø55	H51 M2255	H51 M2855
ø57	H51 M2257	H51 M2857
ø59	H51 M2259	H51 M2859
ø61	H51 M2261	H51 M2861
ø63	H51 M2263	H51 M2863
ø65	H51 M2265	H51 M2865

Screws and Pegs
Vis et plots

Description	ø (mm)	L. (mm)	Cat N°
Cortical screw / *Vis corticale*	5	35	H16 S5035
Cortical screw / *Vis corticale*	5	40	H16 S5040
Cortical screw / *Vis corticale*	5	45	H16 S5045
Cortical screw / *Vis corticale*	5	50	H16 S5050
Cortical screw / *Vis corticale*	5	55	H16 S5055
Cortical screw / *Vis corticale*	5	60	H16 S5060
Tripode pegs (set of 2) *Plots Tripode (par 2)*	7	15	H51 P2715

Important Notice:
The CAPITOLE I/T/R acetabular implants belong to the class III implantable medical device classification. The CAPITOLE I/T/R acetabular implants are indicated in total hip arthroplasty procedures (THA) and total hip revision procedures (THR) for the acetabular component.
The surgeon is required to read the instructions for use (IFU) included in the packaging of the implant, as well as the surgical technique manual initially delivered with the instrument set, or available for download on the www.evolutisfrance.com website.

Materials:
Cups: I/T/R: High Nitrogen Content Stainless steel according ISO 5832-9 coated with porous T40 and Calcium Hydroxyapatite. C: Stainless steel according ISO 5832-1.
Liners: UHMWPE according ISO 5834-1 & 2
Screws: Stainless steel according ISO 5832-1
Pegs: titanium alloy (TA6V) according ISO 5832-3
Packaging: Sterilized under Gamma irradiation, VacUpac packaging

Designed and Manufactured in France

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