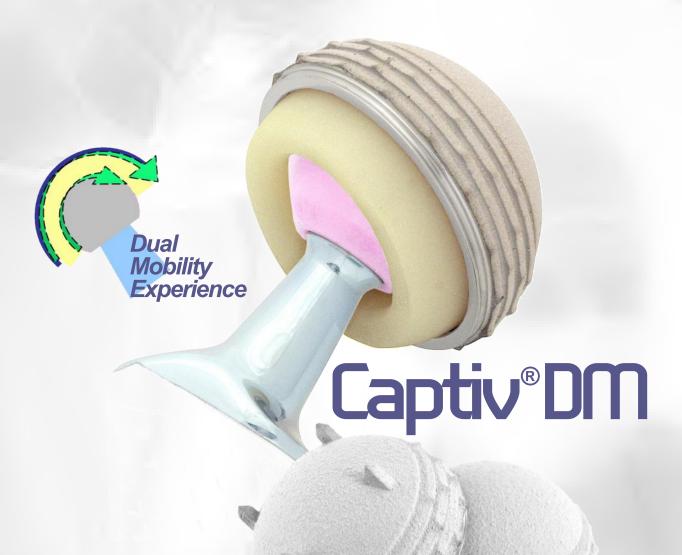
E V O L U T I S
CREATEUR FABRICANT

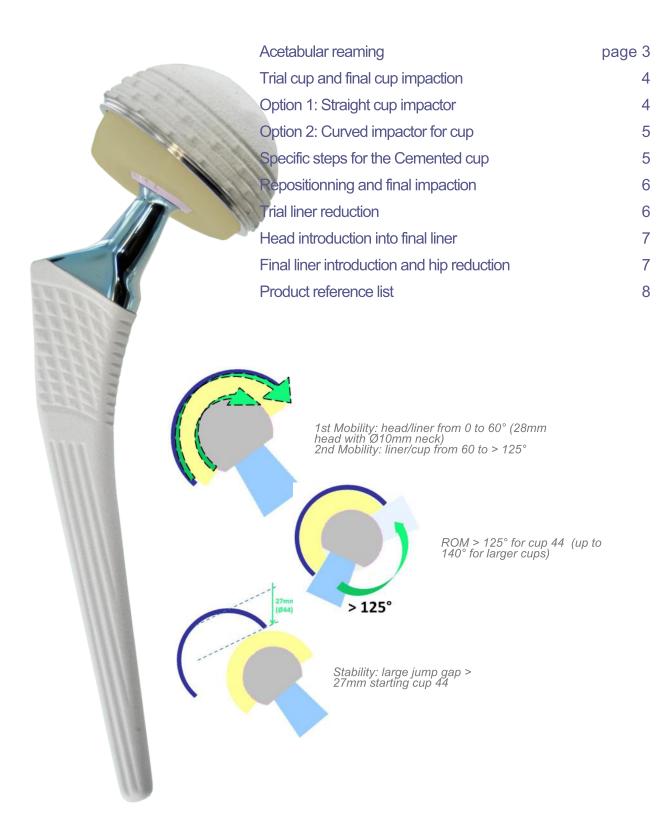


Pexel®

Evolutis MOTION INSIDE Surgical Technique

Pexel®-E

TABLE OF CONTENTS



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 Dual Mobility 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

schnique.

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

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

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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) should 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,

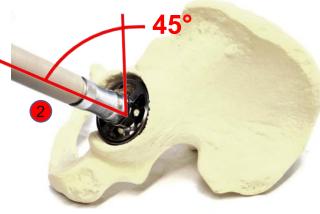
Select the reamer 1 size under the diameter of the retreived femoral head. Introduce the reamer with the reamer shaft at 45° of vertical axis, and with anatomic anteversion (2).

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



Cup impactor screw

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,

Cup impactor

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



45° orientation guide



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

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



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 tip on 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:

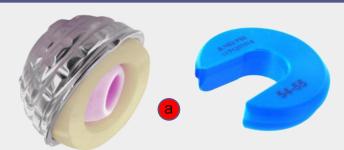
- select the cup impaction tip (option 1: straight impaction shaft) or the expanding holding disc (option 2: curved impaction handle) of the size corresponding to the diameter of the cup to be implanted, and attach to the impaction handle. Example: for a \varnothing 50 cup, select the \varnothing 50 impaction tip or disc (a).



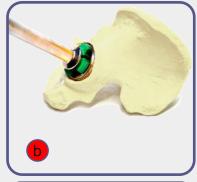
- place the impaction set inside the cup and expand moderately the tip or disc (screw action for a straight handle, pull the trigger for a curved handle).
- introduce a dose of cement into a clean and dry acetabulum.
- introduce the handle/cup assembly into the acetabulum, set the correct orientation 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.

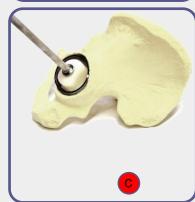


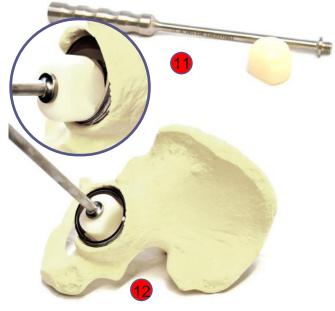
- attach the white cup impaction tip to the M10 impaction shaft.
- introduce the white cup impaction tip into the cup, and apply manual pressure to the cup until the cement is set (c).



cup Ø50 = impaction tip Ø50







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 reorientate the cup to the final position (11).

Finalize cup impaction with the same tool (12).



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 (13),

In cases of 22.2mm ball head, place the grey Ø22.2mm trial head adaptor inside the Ø28mm blue trial liner (14).





Assemble the cup impaction tip to the M10 impaction shaft,



Reduce hip joint (15),

Undertake mobility and stability tests, select definitive head length (16).



Introduction of the head in the final liner

Prepare the liner press:

- screw the liner press screw on the liner press body (17),
- 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 (18).

Position and hold final liner on the concave liner pusher tip, liner opening facing upwards (19),

Position and hold final femoral head on top of the final liner, openings facing upwards (20),

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 (21),

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,

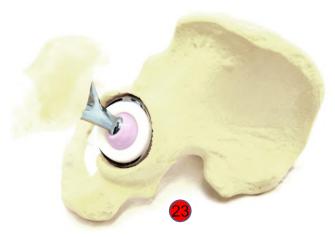


Impact the final liner and final head assembly with the cup impaction tip,

Relocate the hip joint while pushing the liner into the cup with the impaction tip (22),

Undertake final mobility and stability tests (23).





Cupules CAPTIV® Acetabular cups									
Description	ø	Réf. Cat N°	Description	Ø	Réf. Cat N°				
HA ss ciment Press-Fit / C.less HA Press-Fit	44	H29 DM044	HA ss. ciment av. picots / C.less HA with spikes	44	H29 DM144				
HA ss ciment Press-Fit / C.less HA Press-Fit	46	H29 DM046	HA ss. ciment av. picots / C.less HA with spikes	46	H29 DM146				
HA ss ciment Press-Fit / C.less HA Press-Fit	48	H29 DM048	HA ss. ciment av. picots / C.less HA with spikes	48	H29 DM148				
HA ss ciment Press-Fit / C.less HA Press-Fit	50	H29 DM050	HA ss. ciment av. picots / C.less HA with spikes	50	H29 DM150				
HA ss ciment Press-Fit / C.less HA Press-Fit	52	H29 DM052	HA ss. ciment av. picots / C.less HA with spikes	52	H29 DM152				
HA ss ciment Press-Fit / C.less HA Press-Fit	54	H29 DM054	HA ss. ciment av. picots / Cless HA with spikes	54	H29 DM154				
HA ss ciment Press-Fit / C.less HA Press-Fit	56	H29 DM056	HA ss. ciment av. picots / C.less HA with spikes	56	H29 DM156				
HA ss ciment Press-Fit / C.less HA Press-Fit	58	H29 DM058	HA ss. ciment av. picots / C.less HA with spikes	58	H29 DM158				
HA ss ciment Press-Fit / C.less HA Press-Fit	60	H29 DM060	HA ss. ciment av. picots / C.less HA with spikes	60	H29 DM160				
HA ss ciment Press-Fit / C.less HA Press-Fit	62	H29 DM062	HA ss. ciment av. picots / C.less HA with spikes	62	H29 DM162				
HA ss ciment Press-Fit / C.less HA Press-Fit	64	H29 DM064							

Inserts DM CAPTIV® DM Liners							
			PEXEL® UHMWPE		PEXEL®-E(1) UHMWPE		
Ø de cupule Ø of cup	Descri	ption	Tête / <i>Head</i> Ø 22.2	Tête / <i>Head</i> Ø 28	Tête / <i>Head</i> Ø 22.2	Tête / Head Ø 28	
44	Insert UHMWPE	UHMWPE liner	H51 M2245		H51 ME2245(1)	H51 ME2845(1)	
46	Insert UHMWPE	UHMWPE liner	H51 M2247	H51 M2847	H51 ME2247(1)	H51 ME2847(1)	
48	Insert UHMWPE	UHMWPE liner	H51 M2249	H51 M2849	H51 ME2249(1)	H51 ME2849(1)	
50	Insert UHMWPE	UHMWPE liner	H51 M2251	H51 M2851	H51 ME2251(1)	H51 ME2851(1)	
52	Insert UHMWPE	UHMWPE liner	H51 M2253	H51 M2853	H51 ME2253(1)	H51 ME2853(1)	
54	Insert UHMWPE	UHMWPE liner	H51 M2255	H51 M2855	H51 ME2255(1)	H51 ME2855(1)	
56	Insert UHMWPE	UHMWPE liner	H51 M2257	H51 M2857	H51 ME2257(1)	H51 ME2857(1)	
58	Insert UHMWPE	UHMWPE liner	H51 M2259	H51 M2859	H51 ME2259(1)	H51 ME2859(1)	
60	Insert UHMWPE	UHMWPE liner	H51 M2261	H51 M2861	H51 ME2261(1)	H51 ME2861(1)	
62	Insert UHMWPE	UHMWPE liner	H51 M2263	H51 M2863	H51 ME2263(1)	H51 ME2863(1)	
64	Insert UHMWPE	UHMWPE liner	H51 M2265	H51 M2865	H51 ME2265(1)	H51 ME2865(1)	

Instrume	entati	on CA	PTIV® <i>Instrument Se</i> r	t		
Description	H30 9102 Droit/Straight	H30 9104 Courbe/Curved	Description	H30 9102 Droit/Straight	H30 9104 Courbe/Curved	
Plateau avec couvercle / Troy with Lid	H30 9002	H30 9004	Préhenseur de cotyle Ø46-47 cup impaction tip	H52 2247	H52 P47	
Corps d'impacteur / Cup impactor (body)	H52 007	7	Préhenseur de cotyle Ø48-49 cup impaction tip	H52 2249	H52 P49	
Vis d'impacteur / Cup impactor (Screw)	H52 008	2	Préhenseur de cotyle Ø50-51 cup impaction tip	H52 2251	H52 P51	
Manche impacteur courbe / Curved impaction handle		H52 036	Préhenseur de cotyle Ø52-53 cup impaction tip	H52 2253	H52 P53	
Tige d'orientation Ø18 Orientation axis	H03 013	H76 019	Préhenseur de cotyle Ø54-55 cup impaction tip	H52 2255	H53 P55	
Presse à insert / Liner press	H52 033		Préhenseur de cotyle Ø55-56 cup impaction tip	H52 2257	H52 P57	
Vis de presse à insert / Liner press screw	H52 030		Préhenseur de cotyle Ø57-58 cup impaction tip	H52 2259	H52 P59	
Centreur de tête / Femoral head centralizer	H52 031		Préhenseur de cotyle Ø59-60 cup impaction tip	H52 2261	H52 P61	
Embout poussoir d'insert / liner pusher tip	H52	2 035	Préhenseur de cotyle Ø62-63 cup impaction tip	H52 2263	H52 P63	
Réducteur d'essai Ø22.2 trial insert adaptor	H52 2228		Cotyle d'essai Ø44 trial cup	H03 0444		
Manche impacteur M10 Impaction shoft	H03 036		Cotyle d'essai Ø46 trial cup	H03 0446		
Embout poussoir de cupule / Cup impaction tip	H03 037		Cotyle d'essai Ø48 trial cup	H03 0448		
Sphère d'impaction / Impaction spherical tip	H62 005		Cotyle d'essai Ø50 trial cup	H03 0450		
Insert d'essaiØ 28/44-45 trial liner	H52 M2845		Cotyle d'essai Ø52 trial cup	H03 0452		
Insert d'essaiØ 28/46-47 trial liner	H52 M2847		Cotyle d'essai Ø54 trial cup	H03 0454		
Insert d'essai Ø28/48-49 trial liner	H52 M2849		Cotyle d'essai Ø56 trial cup	H03 0456		
Insert d'essai Ø28/50-51 trial liner	H52 M2851		Cotyle d'essai Ø58 trial cup	H03 0458		
Insert d'essai Ø28/52-53 trial liner	H52 M2853		Cotyle d'essai Ø60 trial cup	H03	H03 0460	
Insert d'essai Ø28/54-55 trial liner	H52 M2855		Cotyle d'essai Ø62 trial cup		0462	
Insert d'essai Ø28/56-57 trial liner	H52 I	M2857				
Insert d'essai Ø28/58-59 trial liner	H52 M2859 H52 M2861		Options		Réf.	
Insert d'essai Ø28/60-61 trial liner			- Options	Cat N°		
Insert d'essai Ø28/62-63 trial liner	H52 M2863		Instrum. fraises à cotyle / Grater Reamer set		H03 9100	
Préhenseur de cotyle Ø44-45 cup impaction tip	H52 2245	H52 P45				

(1) Not availble for sale in France and DROM COM

H30 9102



Materials:
Cups: High Nitrogen content Stainless Steel according ISO 5832-9 with T40 and calcium hydroxyapatite coatings
Polyethylene liners: UHMWPE according ISO 5834-1 & 2
Packaging: Sterilized under Gamma irradiation, VacUpac packaging

CE certification of implants covered by CE0483, CE certification of instruments covered by CE0426.

