VERSAFITCUP DM

ELLIPTICAL DOUBLE MOBILITY PRESS FIT CUP

ENHANCE YOUR OPTIONS

Surgical Technique

Joint | Spine | Sports Med

Medacta International

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1. INTRODUCTION

The Versafitcup Double Mobility is based on the original Dual Mobility design developed by Prof. Bousquet and the Medical School of St. Etienne, France, back in 1976.

The Versafitcup DM and the Versafitcup CC Trio Family constitute the Versafitcup System: a unique concept, which offers a complete product range for any requirement.

1.

This document describes the Surgical Technique for the Versafitcup DM.

Versafitcup DM can be considered a valid alternative to hard/hard big head articulation. The introduction of the Highcross (cross-linked polyethylene by Medacta) Double Mobility liner drastically reduces the wear rate, avoiding the risk of liner fractures and squeaking observed with Ceramic-on-Ceramic bearings and to avoid the risk of metal ions release observed with Metal-on-Metal[1].

For more details about Versafitcup CC Trio please see the dedicated Surgical Technique.

Carefully read the instructions for use and if you have any questions concerning product compatibility please contact your Medacta representative.

1.1 INDICATIONS

The hip prosthesis is designed for cementless use in total hip arthroplasty in primary or revision surgery. The patient should be skeletally mature.

The patient's condition should be due to one or more of:

- Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic arthritis, congenital hip dysplasia, ankylosing spondylitis.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.
- Dislocation risks.

1.2 CONTRAINDICATIONS

Total or partial hip replacement is contraindicated in the following cases:

- Acute, systemic or chronic infection.
- Muscular, neurological or vascular deficiency of the affected limb.
- Bone destruction, or loss of bone characteristics that may compromise the stability of the implant.
- Pathologies that may compromise the functionality of the implant in any way.

Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications.

It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

1.3 PREOPERATIVE PLANNING

Preoperative planning should be used to determine the optimum acetabular implant size. The following should be determined using a set of Versafitcup© DM X-ray templates on the patient's X-Ray (1.15:1 ratio):

- The implant size.
- The ideal position of the acetabular shell for optimum coverage.

WARNING

The final implant should be determined during surgery due to possible discrepancies between actual conditions and templating. The choice should be made based on final reamer size and trial cup.

1.4 SURGICAL APPROACH

The choice of surgical approach is up to the surgeon.

[1] M. Bernardoni, F. Siccardi, I. Quagliana, E. Spadini; Analysis of Versafitcup Double Mobility wear rates. M.O.R.E. Journal - May 2011, Vol 01, 99.99JOURNAL01-12 rev.00

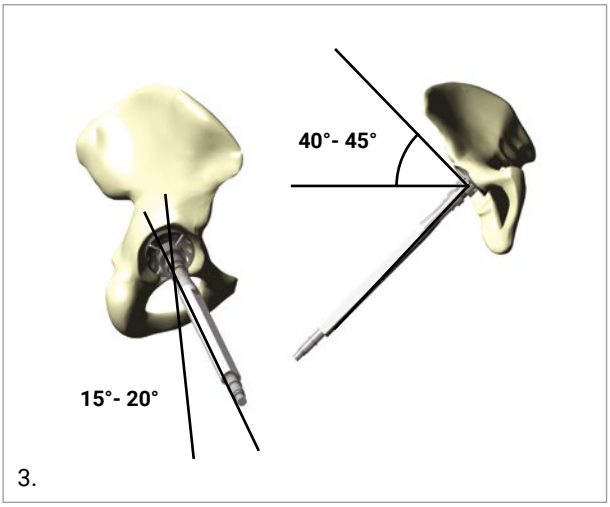
2. REAMING

After arthrotomy and osteotomy of the femoral neck, expose and prepare the acetabular cavity and remove any osteophytes.

Start reaming with acetabular reamers.

2.

The ideal reaming axis has an inclination of 40°/45° and an anteversion of 15°/20° (Anteversion recommended for posterior approaches).



3.

Reaming of the acetabulum starts with the smallest reamer and increases in increments of 2 mm, until a perfectly regular hemispherical cavity has been obtained, in the presence of bleeding subchondral bone.

WARNING

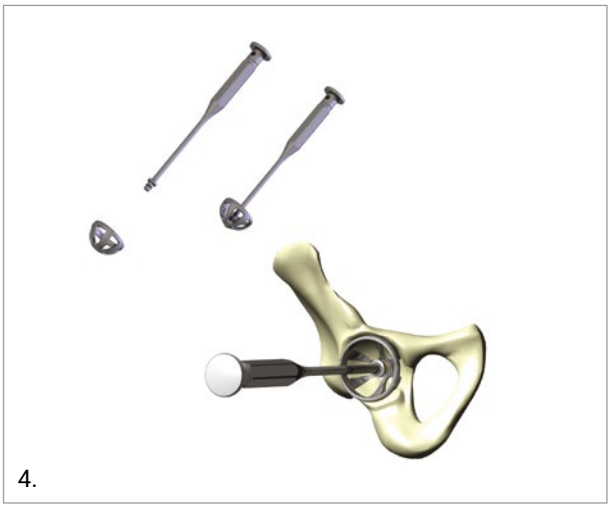
During final reaming, avoid changing the reamer axis, in order not to make the reaming oval, which may affect or prevent primary seating.

As a general rule, the correct diameter corresponds to 4 or 6 mm greater than the femoral head diameter size. Take care to preserve, as far as possible, the bone stock up to the level of anterior and posterior columns. Reamings may be saved for filling any void between the implant and the acetabulum.

3. TRIALING

Using the multifunction handle, insert the trial cup (matching the size of the last reamer) into the reamed acetabulum in order to estimate the depth and the orientation of the acetabular component.

Insert the trial cup into the reamed cavity in order to estimate the depth and the orientation of the acetabular component.



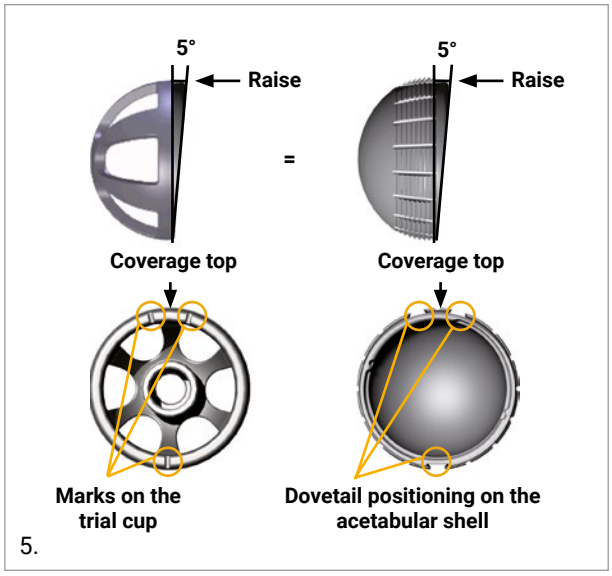
4.

Trial cups:

- are smooth and have the same dimensions as the reamers to avoid damaging the socket.
- are slightly undersized compared to the implant to allow maximum press-fit effect with the definitive implant.
- have several openings to permit a direct view of the underlying acetabular surface.

Both the reamers and trial cups are hemispherical, whereas the implants are elliptical and equatorially expanded, to facilitate an effective immediate press-fit.

Both the trial and implant cups have a 5° raise, indicated by marks on the trial and a dovetail on the implant (see image).



5.

OPTION

An electrocautery tool may be used to mark the coverage top of the trial in order to be correctly matched with the final implant. An orientation guide is available to aid in the positioning.

TIP

If the trial cup is not stable or primary stability is doubtful, especially in the presence of poor bone quality, it is possible to choose a larger cup size, either with or without additional acetabular reaming.

4. IMPACTION OF THE ACETABULAR SHELL

4.1 USE OF THE IMPACTING RING

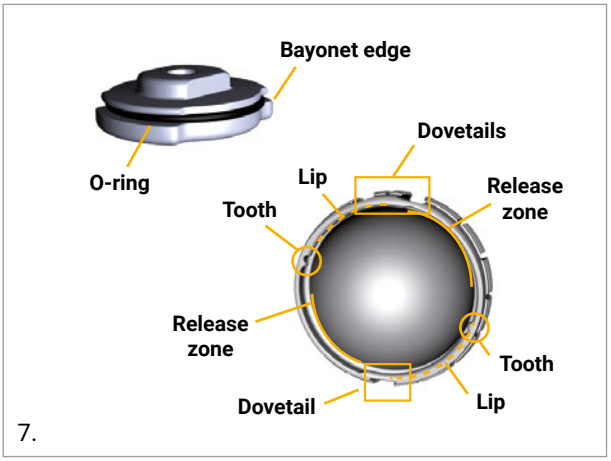
After a satisfactory trial the final acetabular shell can be positioned.

The definitive acetabular shell size will be the same as the final reamer size.

Step 1: Screw the impacting ring of the same size of the chosen implant onto the multifunction handle and tighten it using the release key for impaction washer.

6.

Step 2: Identify the teeth or the dovetails on the shell.



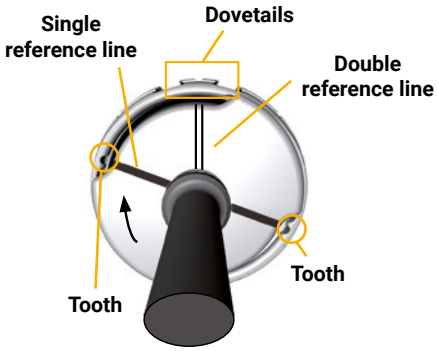
7.

Step 3: Position the impacting ring into the shell in the unlocked position (bayonets in the release zones), in order to have:

1. the single reference line aligned to the teeth,

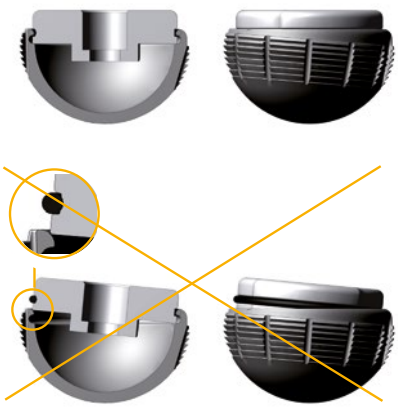
OR

2. the double reference line pointing at the space between the two dovetails and at the single dovetail.



8.

Step 4: Correctly couple the two bayonet edges of the impacting ring with the two acetabular shell lips.



9.

Take care to not damage the inner mirror polished surface of the shell.

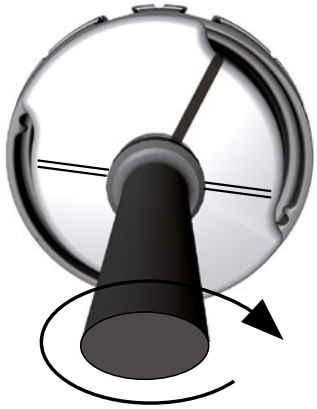
WARNING

If the acetabular shell is already in situ, take the uppermost care in screwing the impacting ring into the shell avoiding any contact with the inner mirror polished surface of the shell. Presence of scratches may lead to increased PE wear.

Step 5: The impacting ring must engage freely with the shell. Make a trial before impacting: engage the impacting ring; turn clockwise till disengagement; then disengage the impacting ring.

If the impacting ring engages freely with the shell:

- reposition in the correct way the impacting ring into the shell;
- turn about 90° clockwise to get the proper final position of the impacting ring;
- perform the impaction.



10.

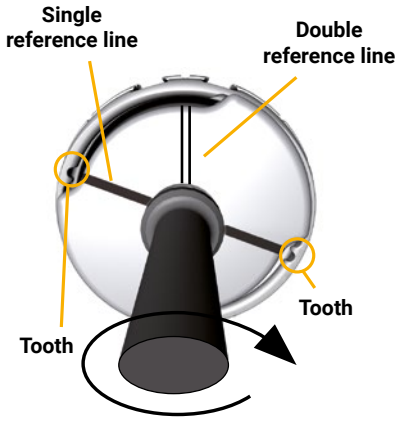
CAUTION

Don't force the impacting ring engagement with the shell. If the turning seems too difficult use a minimal engagement or no engagement for impaction. In this case if you want to disengage the impacting ring from the shell before the impaction: slightly pull the multifunction handle when turning counterclockwise.

OPTION

An orientation guide is available to aid in the acetabular shell positioning: the orientation guide will be positioned on the top of the multifunction handle. The two rods are inclined at 45° and 20° to the handle.

Step 6: After impaction, disengage the impacting ring by turning clockwise 90° until it is in the unlocked position and can be removed.



11.

CAUTION

If the shell has been impacted with a minimal engagement: disengage the impacting ring slightly pulling when turning counterclockwise till the unlocked position of the impacting ring and take it away.

Step 7: Disassemble the impacting ring from the handle by using the release key for impaction washer (01.26.10.0150).

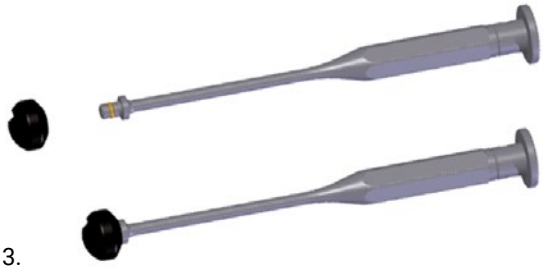
12.

CAUTION

After impaction of the definitive acetabular shell, make sure osteophytes have been properly removed in order to avoid any impingement.

OPTION

In order to perform a final impaction use the multifunction handle assembled with the correct impaction sphere for acetabular shell.



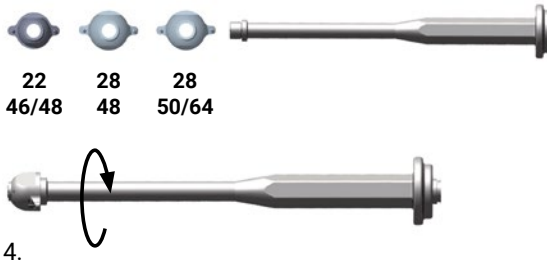
13.

4.2 USE OF THE TRIAL FIXED LINER

After a satisfactory trial the final acetabular shell can be positioned. The definitive acetabular shell size will be the same as the final reamer size.

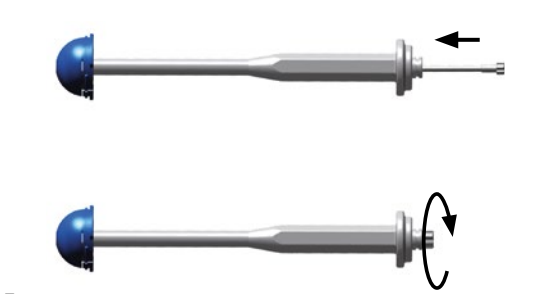
Step 1: Screw onto impactor handle's extremity the impaction washer corresponding to the chosen implant size.

NOTICE: Always use one of the three impaction washers adapted to the right size (please refer to the marks on the washers: 22/46-48; 28/48; 28/50-64).



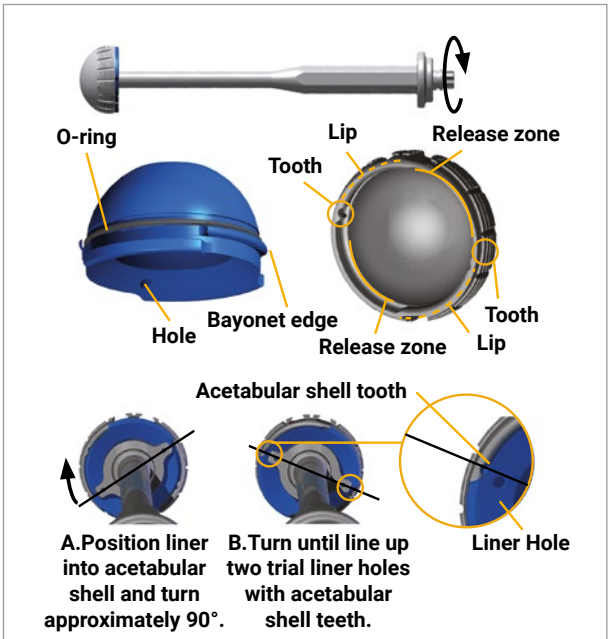
14.

Step 2: Assemble the impaction washer with trial fixed liner; introduce and screw the central rod to the last thread in order to stabilize the assembly impactor handle - central rod - trial fixed liner.



15.

Step 3: The assembly is positioned in the acetabular shell by putting two trial liner bayonets in the two release zones and achieving close contact. Lock the assembly into the acetabular shell Versafitcup by turning the impactor handle about 90° clockwise until the two trial liner holes are lined up with the acetabular shell teeth. In the correct position the fixed liner bayonets are completely covered by acetabular shell lips.

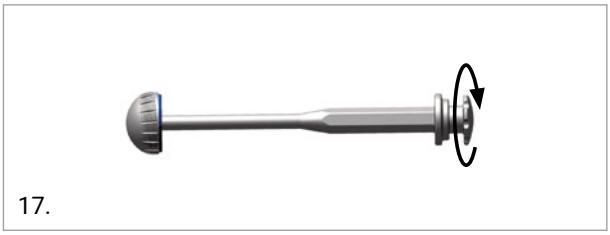


16.

Step 4: Cover the impactor handle with the anvil.

Set the implant in the acetabulum axis and position it at the desired angle of orientation into prepared acetabulum. Impact the acetabular shell with the aid of a hammer, until fully seated and stabilized.

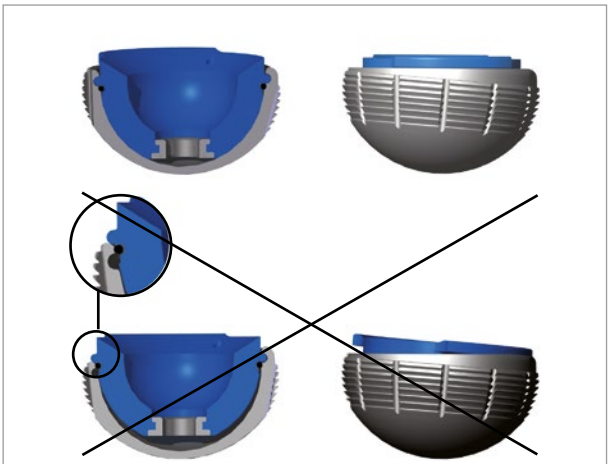
Note that the final acetabulum shell is press fit, not threaded into the acetabulum.



17.

NOTICE: Do not impact on the central rod, but always impact on the anvil.

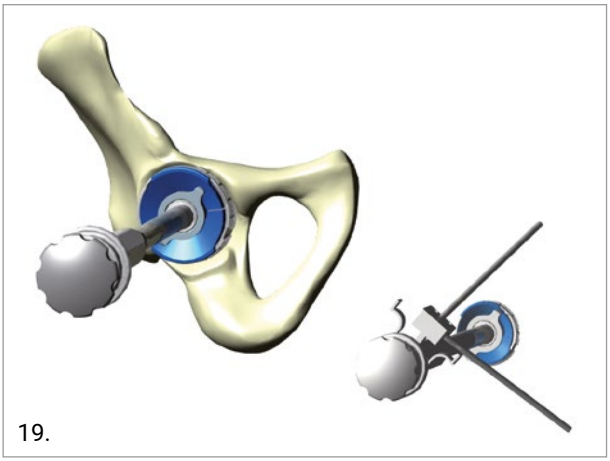
NOTICE: Correctly couple the two bayonet edges of the trial fixed liner with the two acetabular shell lips. Remove the liner's O-ring if you have problem to lock acetabular shell with trial liner.



18.

OPTION

An orientation guide is available to aid in the acetabular shell positioning: the orientation guide will be positioned on the top of the impaction handle. The two rods are inclined at 45° and 20° to the handle.



19.

CAUTION

After impaction of the final acetabular shell, make sure osteophytes have been properly removed in order to avoid any impingement.

OPTION

It is possible to use the release key for impaction washer in order to unlock the impaction washer from impactor handle.

OPTION

In order to perform a final impaction use the multifunction handle assembled with the correction impaction sphere for acetabular shell.

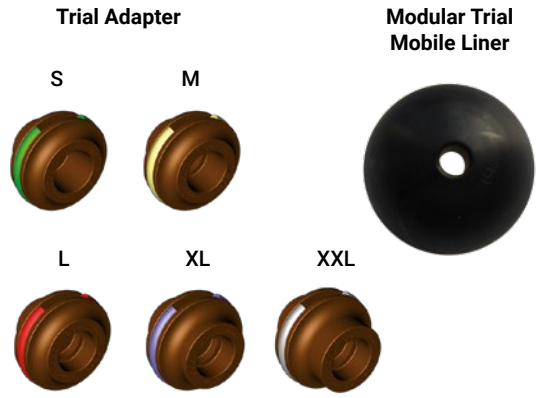
20.

5. STABILITY TEST

5.1 STABILITY TEST: MODULAR TRIAL MOBILE LINER

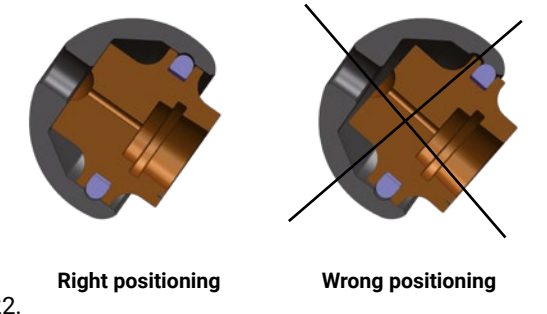
After the impaction of the final acetabular shell:

Step 1: Choose the trial adapter corresponding to the head size (S, M, L, XL, XXL) selected in the preoperative planning.



21.

Step 2: Assemble the trial adapter with the modular trial mobile liner of the same size of the implanted Versafitcup®. The trial adapter must be inserted straight along the axis of the modular trial mobile liner.



22.

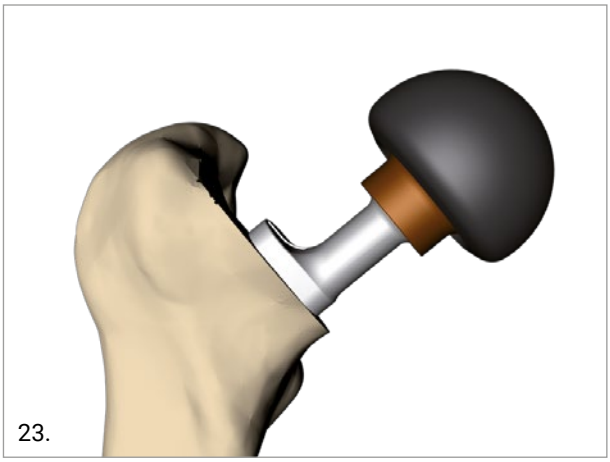
NOTICE: The side marked with references of the trial adaptor must stay in the external part of the trial mobile liner.

If the trial adaptor is free to rotate inside the trial mobile liner the assembly is correctly coupled. If not, reposition the trial adapter until the right position is reached.

Step 3: Place the assembly on the taper of the femoral stem or the trial neck already in place.

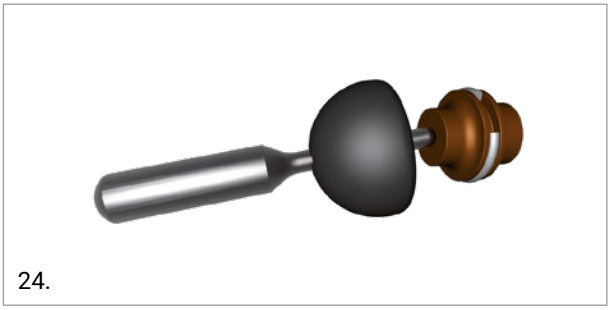
Proceed with the trial reduction.

The mobility, joint stability, range of motion and leg length is tested to confirm the final implant diameter.



23.

Step 4: After stability test, remove the assembly from the taper of the femoral stem or the trial neck. To release the trial adaptor from the trial liner socket you can use the dedicated trial extractor (ref. 01.25.10.005) pushing the adaptor through the central hole of the trial mobile liner.



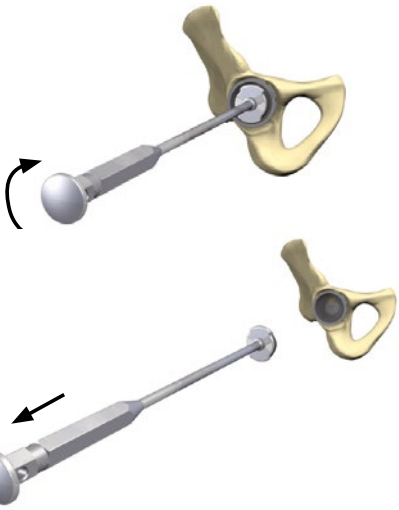
24.

5.2 STABILITY TEST: TRIAL DOUBLE MOBILITY LINER

After the impaction of the final acetabular shell:

Step 1: Turn the handle 90° clockwise in order to unlock the trial fixed liner or the impacting ring used for impaction from the acetabular shell groove.

Step 2: Remove the impactor handle.



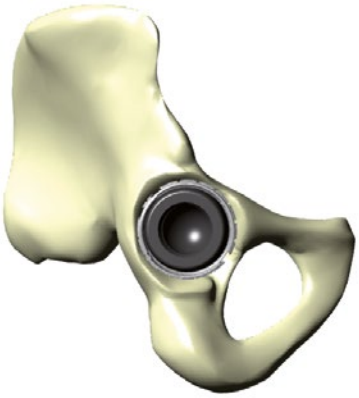
25.

Test with the double mobility liner is carried out at this stage. Clean the interior surface of the acetabular shell. Position the trial double mobility liner corresponding to the expected diameter.

Trial Double Mobility Liner

(to be used with trial heads)

26.



27.

Stability tests are performed after having positioned the trial or final stem and the trial head.

Reduce the hip in order to test the joint stability and limb length.

CAUTION

Test of stability must be performed with trial heads and not with final heads.The head sizes XL and XXL (for Ø 28 mm) have a skirt. This may decrease the Range of Motion and may cause an impingement risk with the double mobility liner.

OPTION

Leg length test can be performed also by keeping the trial fixed liner in situ.

6. POSITIONING OF THE FINAL LINER

Clean the interior surface of the acetabular shell. The external diameter of the liner will be the same as the internal diameter of the acetabular shell implanted following the letter and the colour code; the internal diameter of the liner will be the same as the head chosen. Make the reduction of the final double mobility liner on the prosthetic femoral head using the double mobility liner inserter with cups adaptor and verify the correct head mobility in the liner. Proceed to install the assembly on the taper of the femoral stem in place.

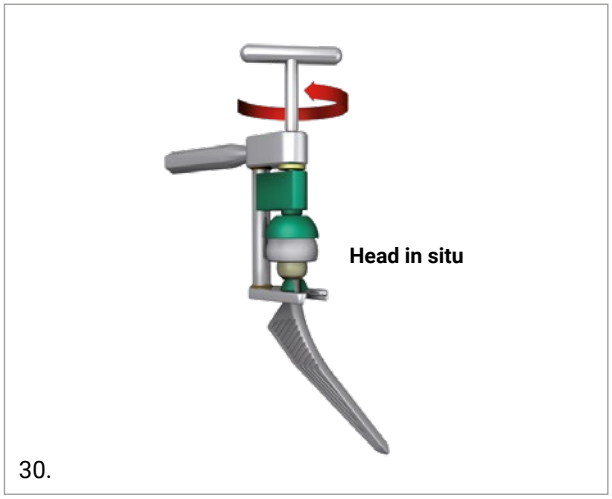
CAUTION
Metal heads sizes XL and XXL, for Ø 28 mm, have a skirt. This may cause an impingement risk with the double mobility liner.

28.

Impact lightly using the multifunction handle assembled with the acetabular shell correction impactor (in case of ceramic head manually impact).

29.

In case of stem with head in situ or monobloc stem: use specific double mobility liner adaptor and stem support with the double mobility liner inserter.



30.

Reduce the hip and verify the liner mobility in the acetabular shell Versafitcup.

CAUTION
During the final reduction with the final double mobility liner, take care not to damage its external spherical surface.

7. IMPLANT NOMENCLATURE

ACETABULAR SHELL VERSAFITCUP DM

Diameter (mm)	Ref.	Liner size	Colour code
46	01.26.46MB	DMC	
48	01.26.48MB	DMD	
50	01.26.50MB	DME	
52	01.26.52MB	DMF	
54	01.26.54MB	DMG	
56	01.26.56MB	DMH	
58	01.26.58MB	DMI	
60	01.26.60MB	DML	
62	01.26.62MB	DMM	
64	01.26.64MB	DMN	

DOUBLE MOBILITY LINER

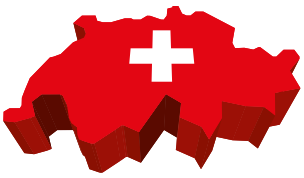
Acetabular shell size (mm)	Heads (mm)	Liner size	Colour code	Standard UHWMPE	Highcross
46	22.2	DMC		01.26.2246M	01.26.2246MHC
48	22.2	DMD		01.26.2248M	01.26.2248MHC
50	22.2	DME		01.26.2250M[I]	01.26.2250MHC[I]
52	22.2	DMF		01.26.2252M[I]	01.26.2252MHC[I]
54	22.2	DMG		01.26.2254M[I]	01.26.2254MHC[I]
56	22.2	DMH		01.26.2256M[I]	01.26.2256MHC[I]
58	22.2	DMI		01.26.2258M[I]	01.26.2258MHC[I]
60	22.2	DML		01.26.2260M[I]	01.26.2260MHC[I]
62	22.2	DMM		01.26.2262M[I]	01.26.2262MHC[I]
64	22.2	DMN		01.26.2264M[I]	01.26.2264MHC[I]
48	28	DMD		01.26.2848M	01.26.2848MHC
50	28	DME		01.26.2850M	01.26.2850MHC
52	28	DMF		01.26.2852M	01.26.2852MHC
54	28	DMG		01.26.2854M	01.26.2854MHC
56	28	DMH		01.26.2856M	01.26.2856MHC
58	28	DMI		01.26.2858M	01.26.2858MHC
60	28	DML		01.26.2860M	01.26.2860MHC
62	28	DMM		01.26.2862M	01.26.2862MHC
64	28	DMN		01.26.2864M	01.26.2864MHC

[I] On request

Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable, and following the manufactures instructions for use of the autoclave. For detailed instructions please refer to the document “Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices” available at www.medacta.com.



REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY

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Versafitcup DM
Surgical Technique

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rev. 09

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