VERSAFITCUP® DM

DOUBLE MOBILITY LINER

Surgical Technique

<table>
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<tr>
<th>Hip</th>
<th>Knee</th>
<th>Spine</th>
<th>Navigation</th>
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</thead>
</table>

VersaFitCup® DM Double Mobility Liner

Medacta International
DOUBLE MOBILITY PRESS-FIT CUP

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.

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.

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

PREAMBLE

This document describes the Surgical Technique for the Versafitcup® DM.

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.

CAUTION

Caution: Federal law (USA) restricts this device to sale by or on the order of physician.

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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 psoriatic 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.

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.

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.

NOTICE: 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.

4 SURGICAL APPROACH

The choice of surgical approach is up to the surgeon.
After arthrotomy and osteotomy of the femoral neck, expose and prepare the acetabular cavity and remove any osteophytes. Start reaming with acetabular reamers.

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.

**NOTICE:** 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.

The ideal reaming axis has an inclination of 40°/45° and an anteversion of 15°/20° (Anteversion recommended for posterior approaches).
6 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.

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).

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.

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.

NOTICE: 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.
7 IMPACTION OF THE ACETABULAR SHELL

7.1 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.

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

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.

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

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

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.

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

NOTICE: After impaction of the definitive acetabular shell, make sure osteophytes have been properly removed in order to avoid any impingement.
7.2 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).

**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.

**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.

**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.

OPTION

In order to perform a final impaction use the multifunction handle assembled with the correct impaction sphere for acetabular shell.
Note that the final acetabulum shell is press fit, not threaded into the acetabulum.

**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.

**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.

**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.

**NOTICE:** After impaction of the final acetabular shell, make sure osteophytes have been properly removed in order to avoid any impingement.
8 STABILITY TEST

8.1 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.

<table>
<thead>
<tr>
<th>Trial Adapter</th>
<th>Modular Trial Mobile Liner</th>
</tr>
</thead>
<tbody>
<tr>
<td>S, M</td>
<td>XL, XXL</td>
</tr>
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</table>

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.

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

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.

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.
8.2 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.

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.

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.
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.

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

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.

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.
ACETABULAR SHELL VERSAFITCUP® DM

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<th>Diameter (mm)</th>
<th>Ref.</th>
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DOUBLE MOBILITY LINER

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<th>Acetabular shell size (mm)</th>
<th>Heads (mm)</th>
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On request

Part numbers subject to change.

NOTE FOR STERILIZATION

Note for sterilization: the instruments are 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.


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