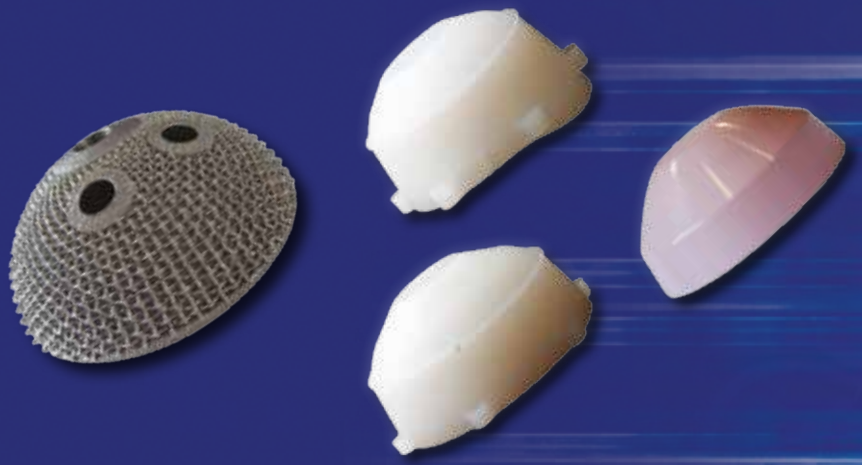
Apact 3D METAL™ TWO-HOLE

HEMISPHERICAL CEMENTLESS CUP SYSTEM

EVOLVING SAFETY



Surgical Technique

Hip | Knee | Spine | Navigation

Medacta International

PREFACE

The Mpact 3D Metal™ Two-hole is part of the Mpact product family, an acetabular shell system offering different shell and liner options, ranging from primary to complex revision solutions.

Mpact 3D Metal™ Two-hole

This document describes the Surgical Technique for the Mpact 3D Metal™ Two-hole.
The Mpact is a modular cementless hemispherical acetabular shell allowing the choice between different shell sizes, liner shapes and materials.
Mpact's hemispherical geometry and its firm press-fit provide an adequate primary stability which could be strengthened, if necessary, by adding screws.

The Mpact 3D Metal™ Two-hole is realized using the EBM (Electron Beam Melting) powder technology. This production method offers a high friction and scratch-fit feel for the initial stability, without the need of any additional coating. Moreover, the high porosity of the 3D Metal™ structure creates a favourable environment for bone thus providing secondary fixation.

Please read carefully the instructions for use. Should you have any questions concerning product compatibility please contact your local Medacta representative.

INDEX

1 INDICATIONS

The Mpact acetabular shell is designed to be used in total hip arthroplasty, for primary or revision surgery.

Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia.
- 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, partial hip arthroplasty, hip resurfacing replacement, or total hip arthroplasty.

2 CONTRAINDICATIONS

The Mpact acetabular shell contraindications are the standard contraindications for total hip replacement:

- Acute, systemic or chronic infection.
- Skeletal immaturity.
- Severe muscular, neurological, vascular deficiency or other pathologies of the affected limb that may compromise the function of the implant.
- Bone condition that may compromise the stability of the implant.

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 PRE-OPERATIVE PLANNING

The goal is to determine the optimum acetabular implant size. Using the X-ray templates to the scale of 1.15:1 (with an X-ray of the same magnification) it will be possible to determine:

- The implant size.
- The ideal position for optimal coverage of the metal back.

NOTICE: The final implant will be selected intra-operatively, because of possible discrepancies between actual conditions and templating. The choice will be determined by the size of the reamer used last and the trial cup tests.

4 SURGICAL APPROACH

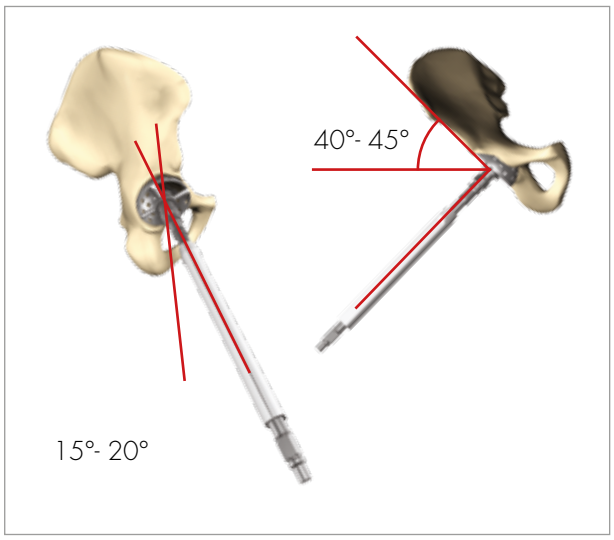
The surgical approach is up to the surgeon. The instrumentation has been developed for a posterior approach. Specific instrumentation for the anterior approach is available on request (for further information see the AMIS dedicated surgical technique).

5 REAMING

Following the osteotomy of the femoral neck, expose and prepare the acetabular cavity and remove osteophytes.

Start reaming using the acetabular reamers.

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



Begin reaming the acetabulum using the smallest reamer and increase the reamer size until a perfectly formed hemispherical cavity has been obtained, in the presence of bleeding subchondral bone.

WARNING

During final reaming, avoid changing the reamer axis, in order to avoid making the prepared bed oval, which may affect or prevent the primary seating of the implant.

The size shown on the implant box is the outer diameter of the Mpact shell. For example, a box displaying "52mm shell" contains a shell with an outer diameter of 52mm.

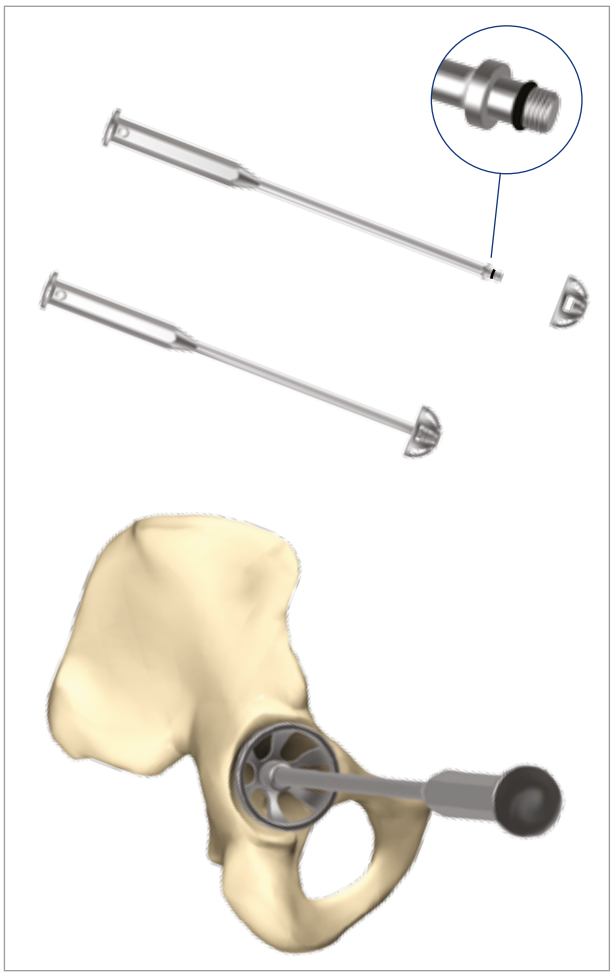
The press-fit should be determined intra-operatively depending on the quality of the bone. However, an under-reaming of 2 mm should provide an appropriate press-fit of the Mpact acetabular shell.

As a general rule, the final reamed diameter should correspond to 4-6 mm more than the diameter of the femoral head. Retain as much bone stock as possible up to the level of the anterior and posterior columns.

If desired, reamed bone can be saved to fill the void between the implant and the acetabulum.

6 TRIALS

Place the trial cup (with the same diameter as the final reamer) onto the multifunction handle.
Insert the trial cup into the reamed cavity in order to establish the depth of the acetabular component.



Trial cups:

- Are smooth and have the same dimensions as the reamers to avoid damaging the socket.
- Are the exact size specified.
- Have several openings to permit a direct visualization of the underlying acetabular surface.

TRICK

As a general rule, soft bone is suitable for a greater press-fit than dense sclerotic bone. Moreover, the bigger the size of the acetabulum, the greater the suitable press-fit.
Depending on the quality of the bone, reaming between sizes is possible as an option.

7 IMPACTION OF THE ACETABULAR SHELL

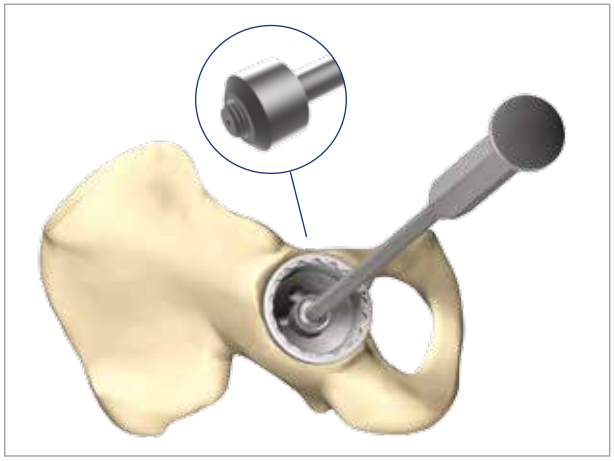
After a satisfactory trial the final acetabular shell can be positioned.

Assemble the impactor handle (Ref. 01.31.10.0066) onto the acetabular shell and ensure it is completely locked to avoid damaging the impactor screw thread during impaction.

OPTION

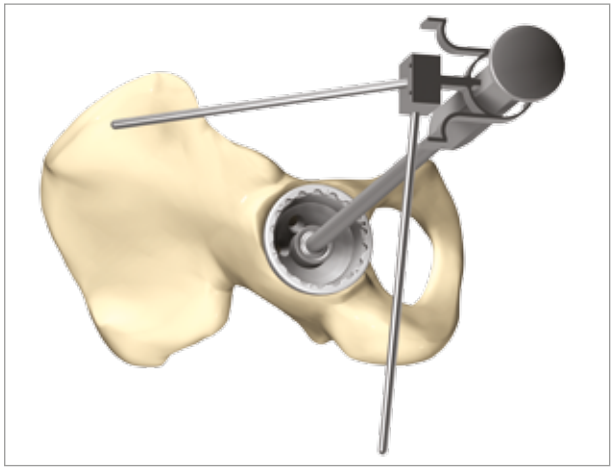
The impactor handle (Ref. 01.32.10.0183) is available upon request. For detailed instructions see chapter 11 – INSTRUMENTS DETAILS.

Impact the implant, at the desired angle of orientation, into the prepared acetabulum.



OPTION

An orientation guide is available to aid in the positioning of the acetabular shell and to establish satisfactory orientation as tested during trials: the orientation guide should be positioned on the top of the impactor handle - the inclination of the anteversion rods is 20° and the inclination rod is 45°.

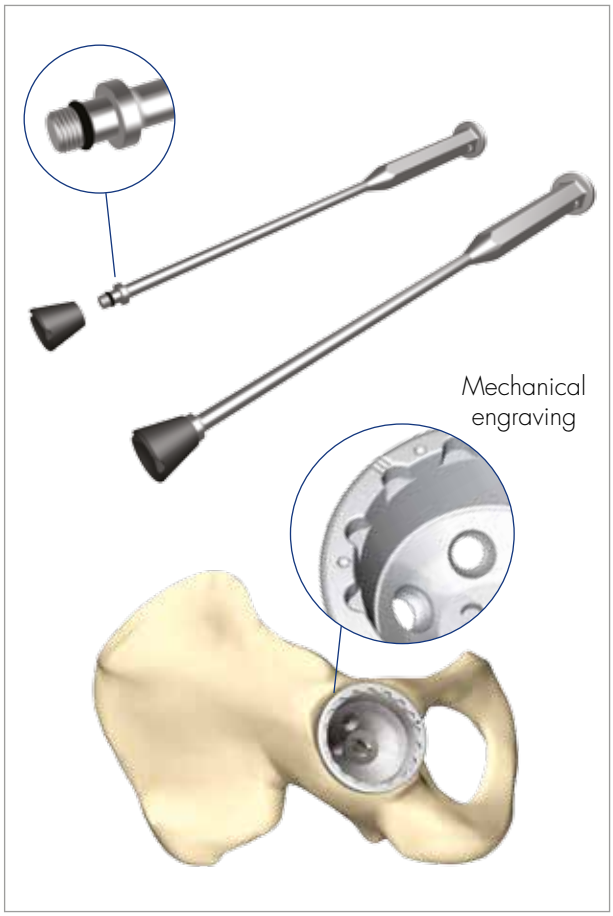


A mechanical engraving on the rim of the acetabular shell is designed to aid in identifying the screw holes for desired implant position.

Impact the acetabular shell with the aid of a hammer, until it is completely stable.

Following impaction never use the impactor handle to reposition or rotate the acetabular shell as this may damage the threads. If required, use only the acetabular shell correction impactor, assembled with the multifunction handle.

Remove the handle.



CAUTION

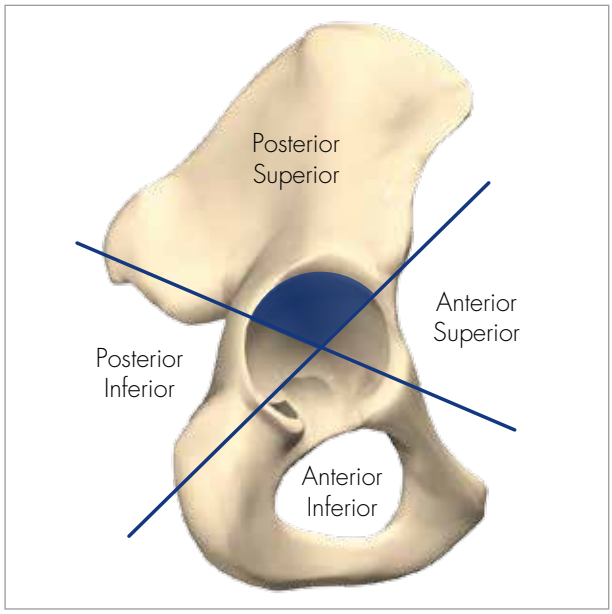
After impaction of the acetabular shell, ensure osteophytes have been properly removed in order to avoid any impingement.

TRICK

In order to ensure the correct depth of the definitive acetabular shell use the shell holes to see the acetabulum floor.

8 PLUG AND SCREW FIXATION (OPTIONS)

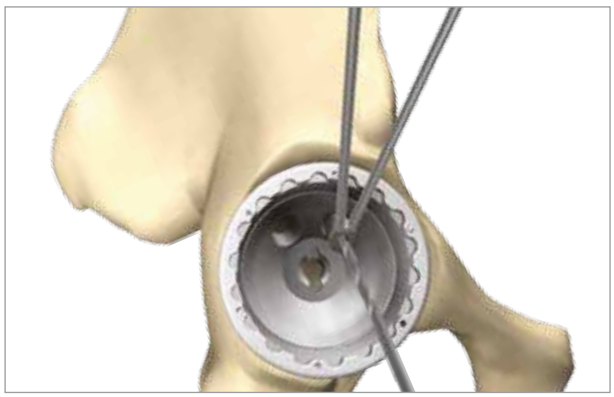
The Mpact 3D Metal acetabular shell Two-hole allows the surgeon to use cancellous bone screws to provide additional fixation. These two screw holes should be positioned in the Posterior-Superior acetabular quadrant once final impaction is done, to minimize the potential for neurologic and vascular injury.

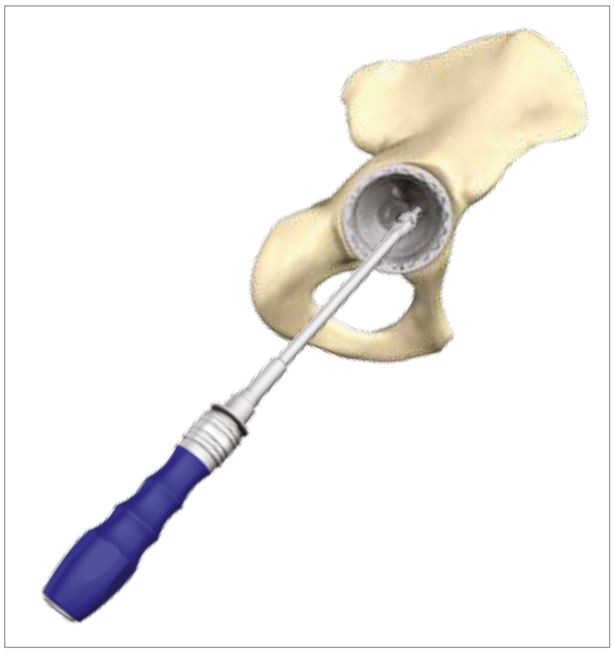


Drill through the acetabular shell holes using a ∅ 3.2 mm drill bit with the help of a drill guide.

Use the depth gauge in order to measure the drilling depth and select a self-tapping screw of appropriate length (with flat head and ∅ 6.5 mm).

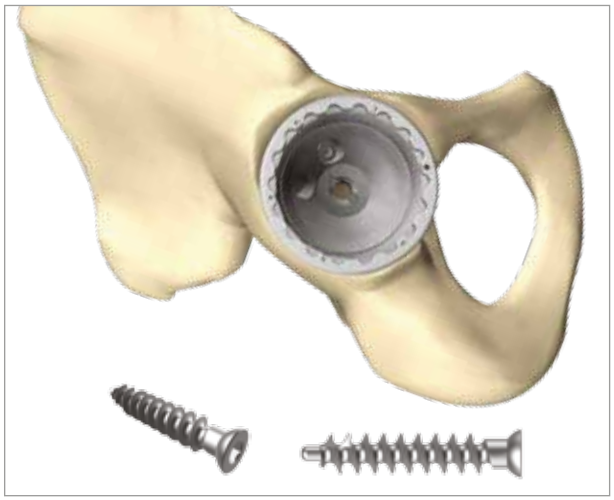
Use a hex-head screwdriver to insert the screws.





CAUTION

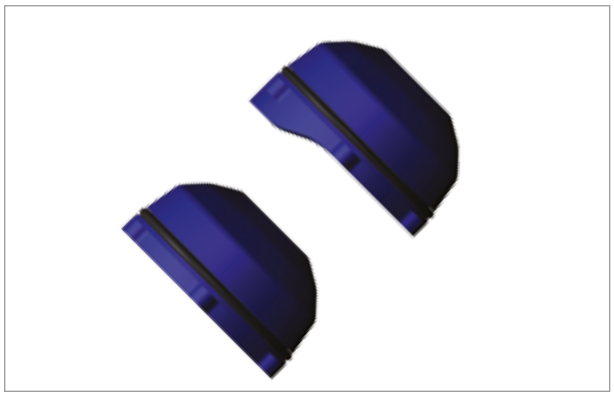
Always use flat head screws (listed at page 14) and check that the screws are fully seated (ensure that the screw heads do not protrude from the inner surface of the acetabular shell).



NOTICE: The central impaction threaded hole may be closed with a metallic plug if desired.
For the Mpact 3D Metal acetabular shell Two-hole version, the acetabular shell is packaged separately from the metallic plug (ref 01.31.55TP).

9 STABILITY TEST

During stability tests, the choice between a flat and a hooded liner can be made according to the surgeon's choice (check the available hooded liners material and size).



Clean the interior surface of the acetabular shell.
Assemble the multifunction handle with the trial liner corresponding to the acetabular shell size and femoral head diameter.

Position the assembly gently in the acetabular shell at the desired rotational position taking care to align the anti-rotation tabs with the indentions on the shell.

Unscrew the multifunction handle and reduce the hip in order to test the joint stability and limb length.
After checking and testing mobility, joint stability and lower limb length, remove the trial liner with the aid of the multifunction handle.

TRICK

If using a hooded trial liner, use electrocautery to mark the satisfactory position of the hood.

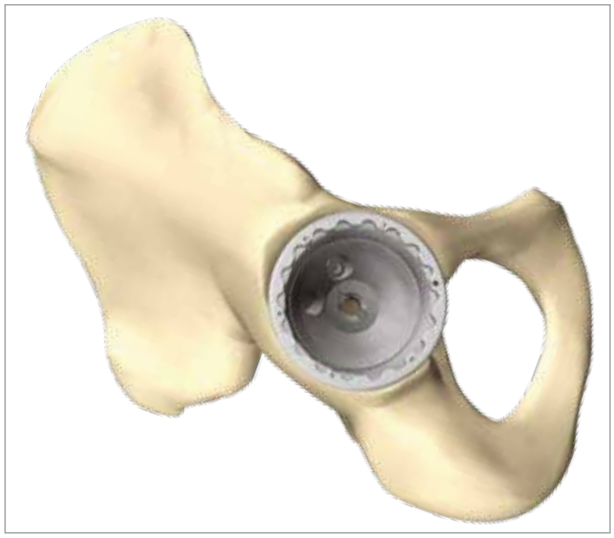
WARNING

Stability tests must be performed with trial heads and not with definitive heads. The head sizes XL (for Ø28 mm, Ø32 mm) and XXL (for Ø28 mm, Ø32 mm, Ø36 mm, Ø40 mm) have a collar which may decrease the Range of Motion in comparison to smaller sizes. Always perform trial reduction with the chosen head size.

10 POSITIONING OF THE DEFINITIVE LINER

The external diameter of the liner will be the same as the internal diameter of the acetabular shell implanted following the letter code; the internal diameter of the liner will be the same as the head chosen.

Before inserting the liner, clean the interior surface of the acetabular shell, carefully remove any bone debris and tissue residues to avoid damaging the mechanical bearing.

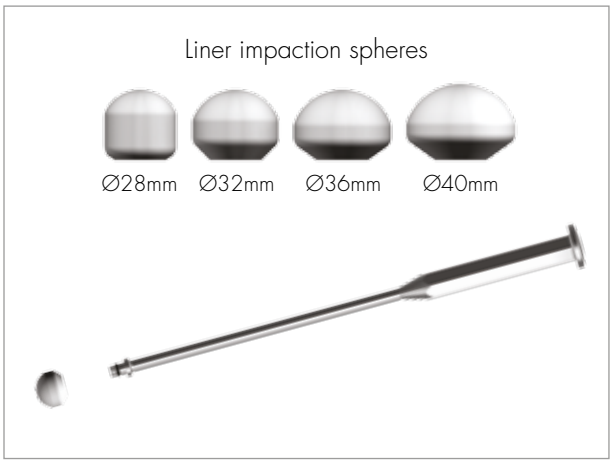


10.1 Positioning of the definitive UHMWPE liner

Place carefully by hand the UHMWPE liner in the acetabular shell along its axis taking care to align the anti-rotation tabs with the indentions on the shell.
Ensure the hooded liner is positioned in the correct location, as determined by the trial.

Check that the liner has been positioned correctly.

Once the liner is in the correct position, secure it by pushing it in with your thumb.
To perform the final impaction, assemble the impaction sphere (of the correct liner) onto the multifunction straight impactor.



Insert the sphere into the UHMWPE liner and impact it using a hammer, until completely fixed. Remove the multifunction hammer with the liner impaction sphere.

TRICK

In order to ensure the correct placement of flat liners and the flat part of the hooded liner check that the outside rim of the acetabular shell is exactly aligned with the outside rim of the liner with the tabs in the corresponding indentions.

Position the definitive head and reduce the hip.

OPTION

Metallic impaction washers (for each liner size), to impact the UHMWPE liners, are available upon request for use with the multifunction handle. Also available upon request is a washer release key to unlock the impaction washer from the multifunction handle.

10.2 Positioning of the definitive ceramic liner

Carefully, manually place the ceramic liner in the acetabular shell along its axis. A suction cap is available to manipulate ceramic liners without touching them.

Check that the liner has been positioned correctly.

TRICK

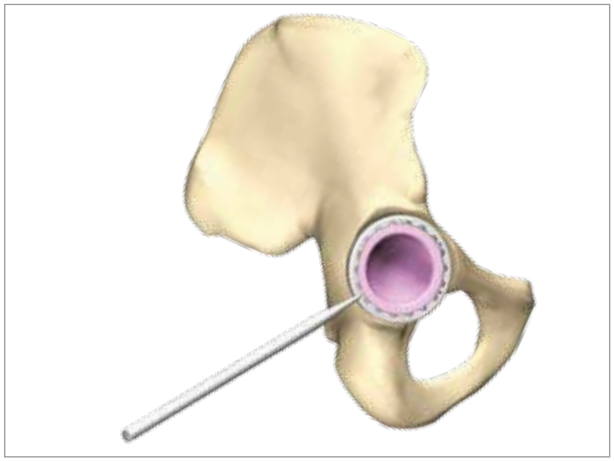
In order to ensure the correct placement of the ceramic liners press the liner with your finger to be sure that it is seated correctly and that the outside rim of the acetabular shell is exactly aligned with the outside rim of the liner.

CAUTION

It is not advised to implant a ceramic liner if the cup placement is too vertical, e.g. if the inclination is greater than 45°.

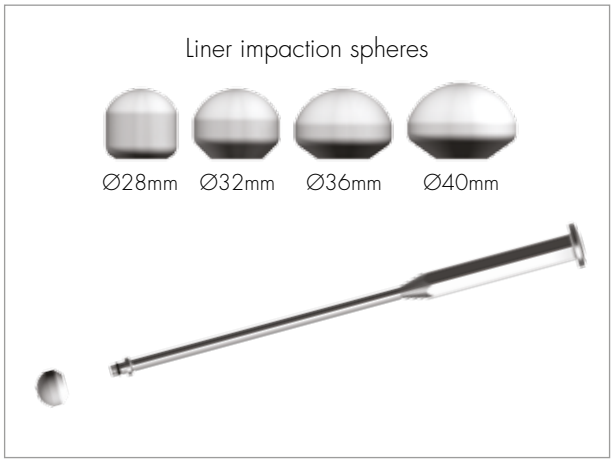
CAUTION

In case of incorrect positioning of the ceramic liner, remove the liner with the blue suction cap and reposition it accordingly. The ceramic liner removal tool is useful to tap on the rim of the shell causing sufficient vibration to facilitate the removal of the liner.

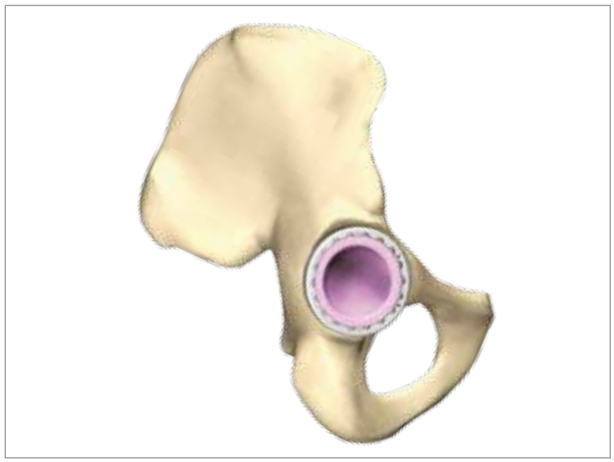


Once the liner is positioned correctly secure it into place by pushing it in with your thumb.

In order to perform a final impaction, assemble the ceramic liner impaction sphere (of the correct liner) with the multifunction straight impactor.



Insert the sphere into the liner and fix the liner with a slight hammer stroke in the axial direction.



CAUTION

Never bring a metal hammer into contact with a ceramic liner.

Position the final ceramic head and reduce the hip.

11 INSTRUMENT DETAILS

11.1 Assembling the cup with the cup impactor (ref. 01.32.10.0183)

Step 1

Remove the anvil from the handle by pushing the button.

Step 2

Position the tip of the cup impactor in the acetabular shell taking care to align the teeth of the impactor with the dedicated sockets near the central hole of the acetabular shell.
Screw the central hole of the cup impactor by hand until fully tightened.

Step 3

Assemble the anvil and screw it until fully tightened.

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

11.2 Disassembling the cup with the cup impactor (ref. 01.32.10.0183)

Unscrew the anvil from the impactor handle to release.

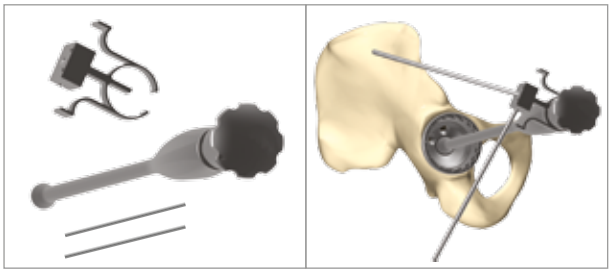
11.3 Assembling the alignment guide (ref. 33.22.0066 and 01.32.10.0072) with cup impactor (ref. 01.32.10.0183)

Step 1

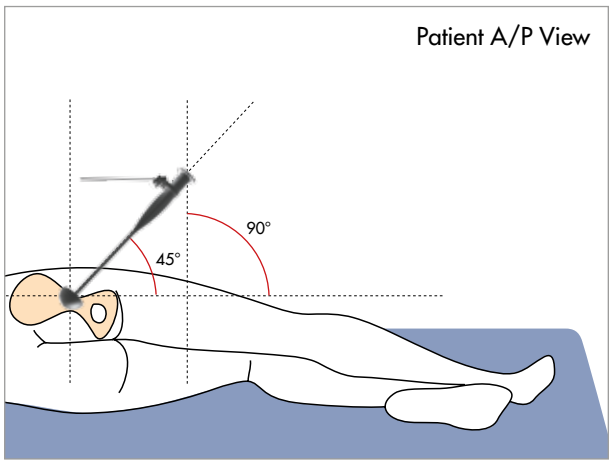
Screw the inclination rod and the anteversion rod onto the alignment guide.

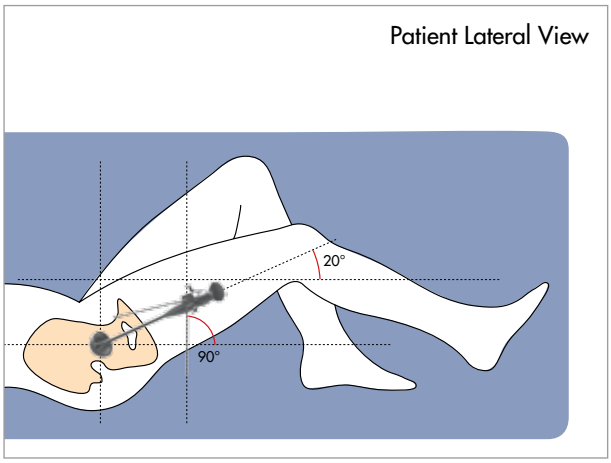
Step 2

Assemble the alignment guide onto the cup impactor.



Example of use in decubitus lateralis





12 IMPLANTS NOMENCLATURE

Mpact 3D Metal acetabular shell Two-hole

Diameter (mm)	Ref.	Liner Size
46	01.38.046DH	B
48	01.38.048DH	C
50	01.38.050DH	D
52	01.38.052DH	E
54	01.38.054DH	E
56	01.38.056DH	F
58	01.38.058DH	F
60	01.38.060DH	G
62	01.38.062DH	G
64	01.38.064DH	G
66	01.38.066DH	G

Mpact acetabular shell central screw plug

Description	Ref.
Plug	01.31.55TP

Cancellous bone screws (flat head - ø 6.5mm)

Length (mm)	Ref.
15	01.32.6515
20	01.32.6520
25	01.32.6525
30	01.32.6530
35	01.32.6535
40	01.32.6540
45	01.32.6545
50	01.32.6550'
55	01.32.6555'
60	01.32.6560'
65	01.32.6565'
70	01.32.6570'

' On demand

Ceramic liner (BIOLOX *delta*)

Liner size	Head Ø 28 mm	Head Ø 32 mm	Head Ø 36 mm	Head Ø 40 mm
B	38.49.7188.575.20	-	-	-
C	38.49.7188.765.20	38.49.7188.525.20	-	-
D	38.49.7188.775.20	38.49.7188.535.20	-	-
E	38.49.7188.785.20	38.49.7188.845.20	38.49.7188.545.20	-
F	38.49.7188.795.20'	38.49.7188.855.20	38.49.7188.555.20	38.49.7188.585.20
G	38.49.7188.805.20'	38.49.7188.865.20	38.49.7188.565.20	38.49.7188.595.20

UHMWPE HC flat liner (Highcross)

Liner size	Head Ø 22 mm	Head Ø 28 mm	Head Ø 32 mm	Head Ø 36 mm	Head Ø 40 mm
B	01.32.2237HCT'	01.32.2837HCT	-	-	-
C	01.32.2239HCT'	01.32.2839HCT	01.32.3239HCT	-	-
D	01.32.2241HCT'	01.32.2841HCT	01.32.3241HCT	-	-
E	01.32.2244HCT'	01.32.2844HCT	01.32.3244HCT	01.32.3644HCT	-
F	01.32.2248HCT'	01.32.2848HCT'	01.32.3248HCT	01.32.3648HCT	01.32.4048HCT
G	01.32.2252HCT'	01.32.2852HCT'	01.32.3252HCT	01.32.3652HCT	01.32.4052HCT

UHMWPE HC hooded liner (Highcross)

Liner size	Head Ø 22 mm	Head Ø 28 mm	Head Ø 32 mm	Head Ø 36 mm
B	01.32.2237HCAT'	01.32.2837HCAT	-	-
C	01.32.2239HCAT'	01.32.2839HCAT	01.32.3239HCAT	-
D	01.32.2241HCAT'	01.32.2841HCAT	01.32.3241HCAT	-
E	01.32.2244HCAT'	01.32.2844HCAT	01.32.3244HCAT	01.32.3644HCAT
F	01.32.2248HCAT'	01.32.2848HCAT'	01.32.3248HCAT	01.32.3648HCAT
G	01.32.2252HCAT'	01.32.2852HCAT'	01.32.3252HCAT	01.32.3652HCAT

' On demand

13 POSSIBLE IMPLANT COMBINATIONS

All Medacta implant combinations are represented in the table "Medacta Hip product compatibility" (ref. 99.99.COMC), contact your Medacta representative to receive a copy.

NOTICE: in the case of a ceramic-on-ceramic bearing it is compulsory to use compatible ceramic femoral heads and liners.

NOTES

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the regulations of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta International reusable orthopedic devices" available at www.medacta.com.

All trademarks and registered trademarks are the property of their respective owners.

REDEFINING BETTER
IN ORTHOPAEDICS
AND NEUROSURGERY

MEDACTA.COM

Medacta
International

Medacta International SA
Strada Regina - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
info@medacta.ch

Find your local dealer at: medacta.com/locations

All trademarks and registered trademarks are the property of their respective owners.

Mpact 3D Metal™ Two-hole
Surgical Technique

ref: 99.703D.12
rev. 01

Last update: November 2016
CE 0476