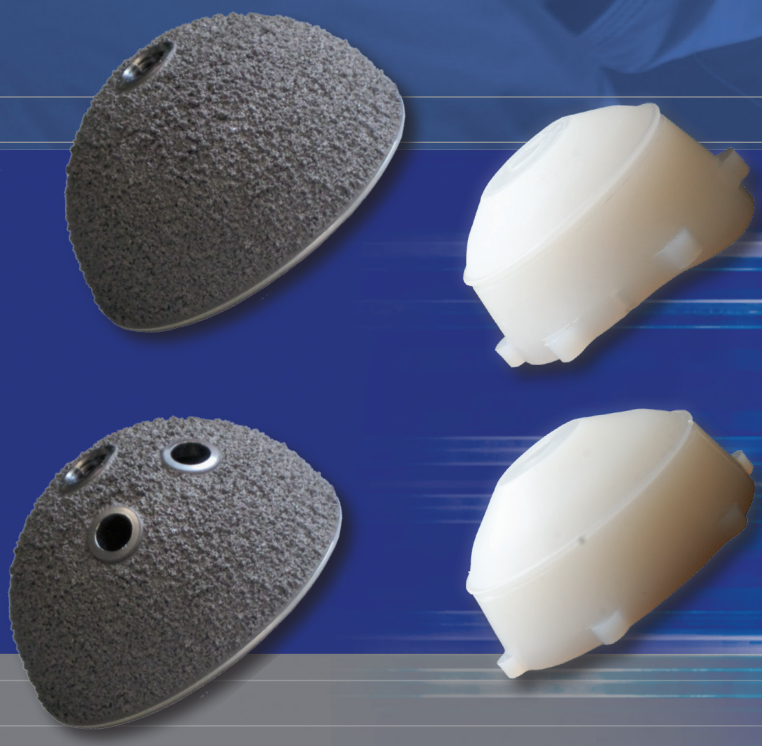
Apact® SYSTEM

HEMISPHERICAL CEMENTLESS CUPS

EVOLVING SAFETY



Surgical Technique

Joint | Spine | Sports Med

Medacta International

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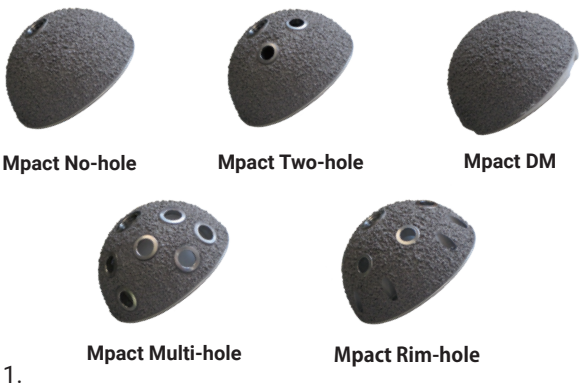
1. INTRODUCTION

The Mpact No-hole and the Mpact Two-hole are part of the Mpact product family, an acetabular shell system offering different shell and liner options, ranging from primary to complex revision solutions.



1.

This document describes the Surgical Technique for the Mpact No-hole and Two-hole.

The Mpact System 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 excellent primary stability which could be enhanced, if necessary, by adding screws (Mpact Two-hole, Multi-hole and Rim-hole).

For more details regarding other Mpact System acetabular shells please see the dedicated Surgical Technique.

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

CAUTION
Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.

1.1 INDICATIONS

The Mpact implants are 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.

1.2 CONTRAINDICATIONS

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

- 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 allergies to the materials used.

1.3 PRE-OPERATIVE PLANNING

The goal is to determine the optimum acetabular implant size and optimum component orientation. Using the set of 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 of the implant to achieve desired position for optimal coverage

WARNING
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 final reamer used and the trial cup evaluations.

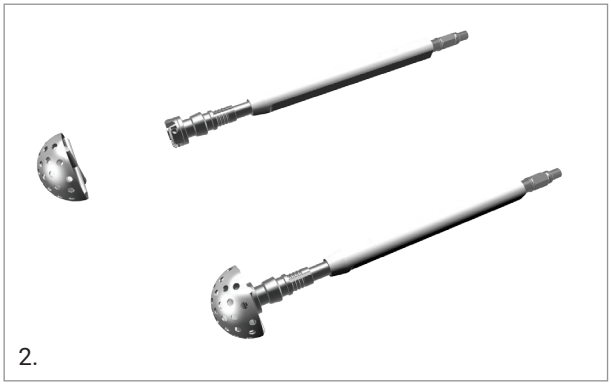
1.4 SURGICAL APPROACH

The surgical approach is at the discretion of the surgeon. The instrumentation has been developed for standard approach. Specific instrumentation for the anterior approach is available under request (for further information see the AMIS dedicated surgical technique).

2. REAMING

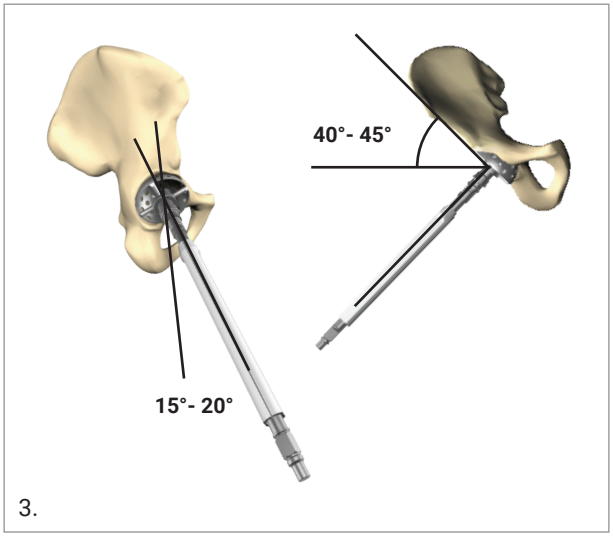
Following the osteotomy of the femoral neck, expose and prepare the acetabular cavity and remove osteophytes.

Start reaming using the 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.

Start reaming the acetabulum progressively increasing the reamer size until a hemispherical cavity has been obtained and there is presence of bleeding subchondral bone. The preoperative plan can also be used as a reference.

WARNING

During final reaming, avoid changing the reamer axis, in order to prevent 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 "52 mm shell" contains a shell with an outer diameter of 52 mm (including Mectagrip coating).

The press-fit should be determined intra-operatively depending on bone quality: the denser the bone, the less press-fit required. In average conditions, an under-reaming of 1 mm should provide an appropriate press-fit of the Mpact acetabular shell.

As a general rule the correct final reamed diameter corresponds to 4 or 6 mm more than the femoral head diameter size. Take care to retain, as much as possible, the bone stock to in the anterior and posterior columns.

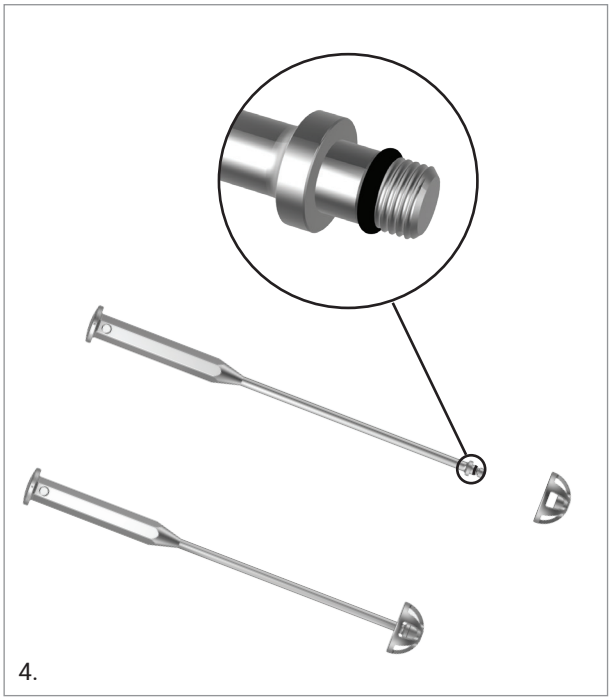
Reamed bone may be used to fill the void between the implant and the acetabulum.

3. TRIALS

Trial cups should be used to assess shape and orientation of the cavity.

A trial cup of the same diameter of the last reamer (or 1 mm smaller in case of odd-size reaming) should be used.

Place the trial cup chosen onto the multifunction handle.



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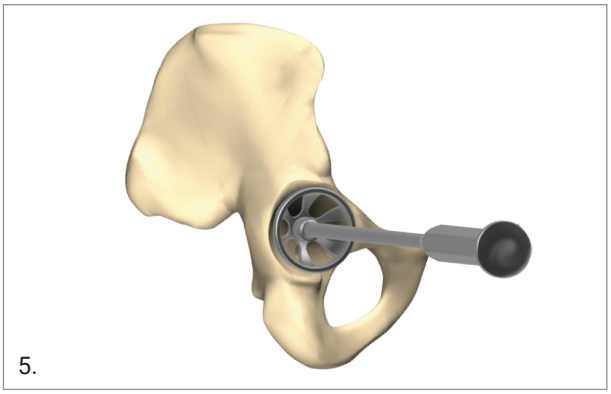


5.

Trial cups:

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

TIP

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.

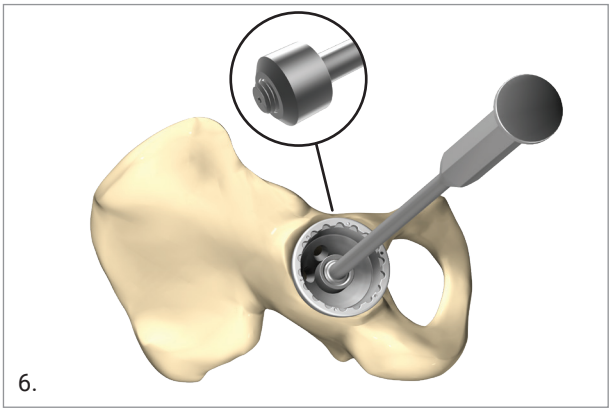
4. IMPACTION OF THE ACETABULAR SHELL

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

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

For detailed instructions of the impaction handle see chapter 10 - INSTRUMENTS DETAILS.

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



6.

OPTION

An orientation guide is available to aid in the positioning of the acetabular shell and to establish the required orientation as tested during trials: the orientation guide will be assembled in the dedicated socket onto the impactor handle. The inclination of the anteversion rods is 20° and the inclination rod is 45°.

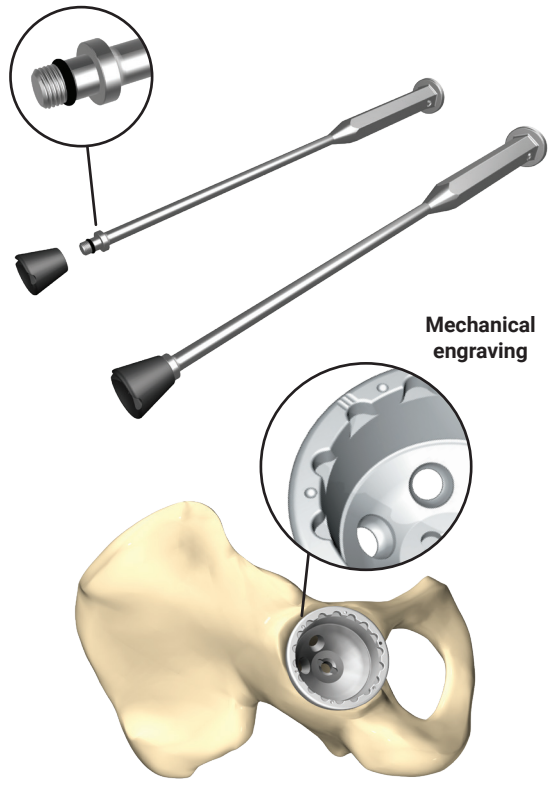
If present, a mechanical engraving on the rim of the acetabular shell (introduced February 2015) is designed to aid in identifying the screw holes for desired implant position.

Impact the acetabular shell with the aid of a mallet until desired stability has been archieved.

CAUTION

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.



7.

CAUTION

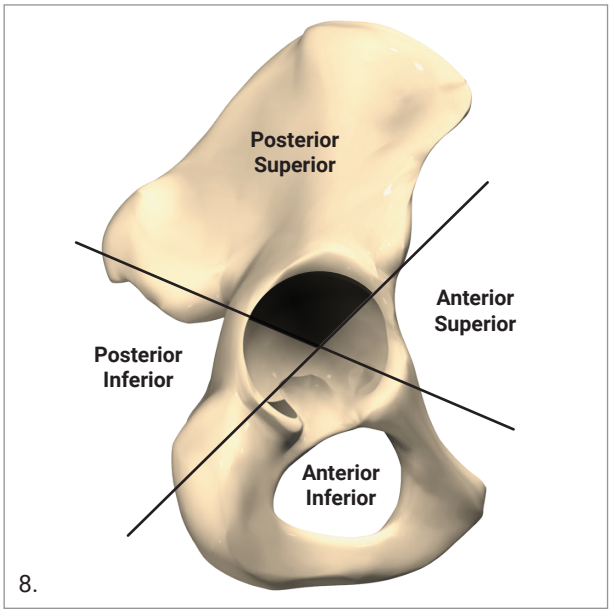
After impaction of the acetabular shell, ensure osteophytes have been properly removed in order to avoid any impingement.

TIP

In order to ensure the correct depth of the definitive acetabular shell use the shell hole to see the bed of the acetabulum.

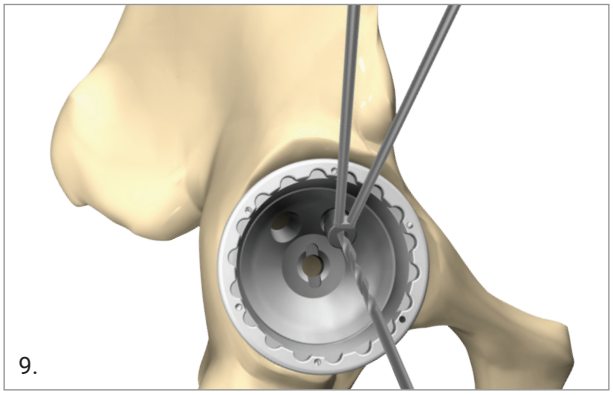
5. PLUG AND SCREW FIXATION (OPTIONS)

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



8.

Drill through the acetabular shell hole using a Ø 3.2 mm drill bit with the help of a drill guide. If appropriate, a flexible shaft bit driver is available in order to facilitate the drilling procedure.

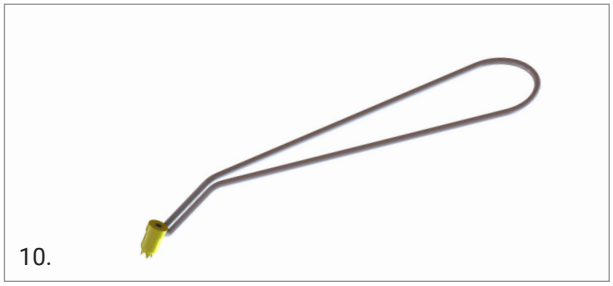

9.

Two different screw versions are available:

- Cancellous Bone Screw Flat Head Ø 6.5 (01.32.6515 01.32.6570) offering a wider angular range.
- Cancellous Bone Screw Ø 6.5 (01.43.0015 - 01.43.0070) offering higher mechanical resistance.

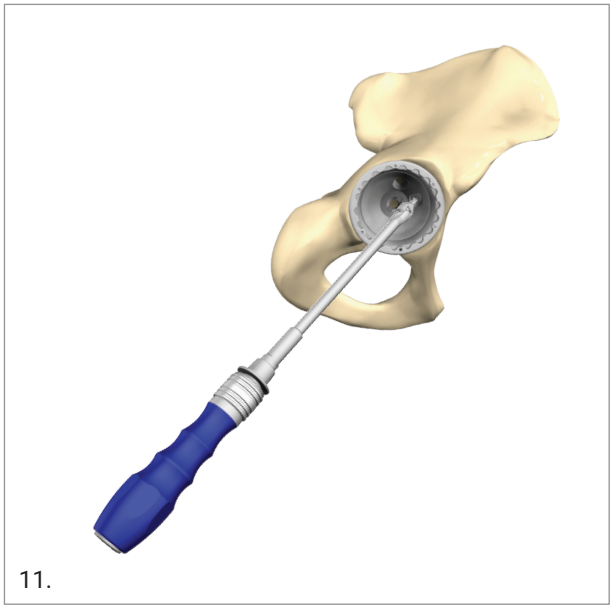
CAUTION

The Cancellous Bone Screw Ø 6.5 (01.43.0015 – 01.43.0070) requires a dedicated drill guide (01.10.10.372). Color coding has been introduced for easier identification. The dedicated drill guide has a gold colored tip and a gold colored band is present on the screw label.


10.

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

Use a hex-head screwdriver to insert the screws.

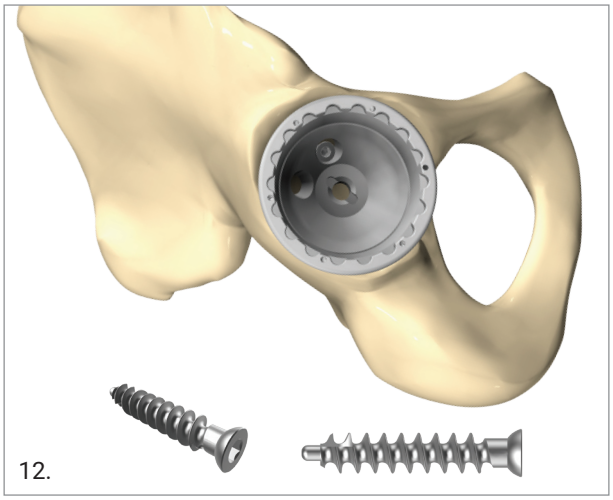

11.

OPTION

The cardan flexible screwdriver (Ref. 01.32.10.0290) is available upon request.

CAUTION

Always use Medacta flat head screws (listed at page 15) and check that the screws are fully seated (ensure that the screw heads do not protrude from the inner surface of the acetabular shell).

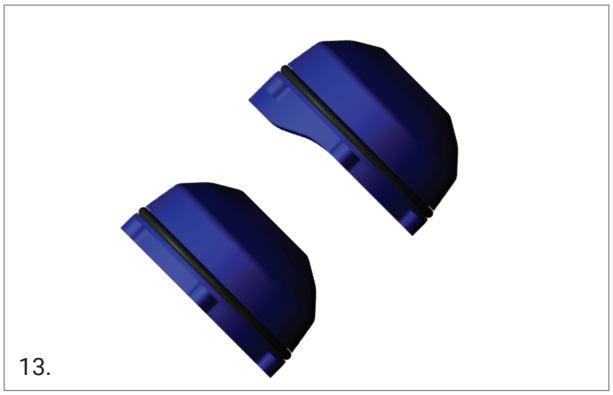


12.

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

6. STABILITY TEST

During stability tests, the choice between a flat and a hooded liner can be made according to the surgeon's choice. Offset and Face-changing liners are also availble upon request (see chapter 9 - MPACT POLYETHYLENE LINER OPTIONS).



13.

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 indentations 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.

TIP

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

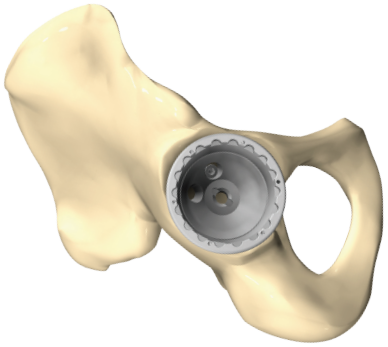
WARNING

Stability tests must be performed with trial heads and not with final 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.

7. POSITIONING OF DEFINITIVE LINER

The external diameter of the liner will be the same as the internal diameter of the acetabular shell implanted. This is noted with the letter code. The internal diameter of the liner will be the same as the outer diameter of the chosen head.

Before inserting the liner, thoroughly clean and dry the interior surface of the Mpact acetabular shell, carefully remove any bone debris and tissue residue to avoid damaging the mechanical coupling.



14.

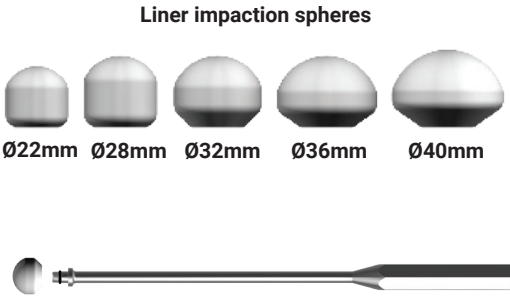
7.1 POSITIONING OF THE DEFINITIVE UHMWPE LINER

Place carefully by hand the UHMWPE liner in the acetabular shell along its axis taking care to align the anti-rotation tabs with the indentations 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 head size) onto the multifunction straight impactor.

It is recommended, to facilitate proper assembly of the liner, to choose the largest fitting impaction sphere.



15.

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

WARNING

Impaction should follow the "axis" of the cup, i.e. should be in a direction perpendicular to the plane of equator. In order to do so, the offset AMIS impactor may facilitate negotiating soft tissues when an AMIS approach is being performed.

TIP

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 or flush, with the outside rim of the liner with the tabs in the corresponding indentations.

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.

8. REMOVAL AND REVISION PROCEDURE

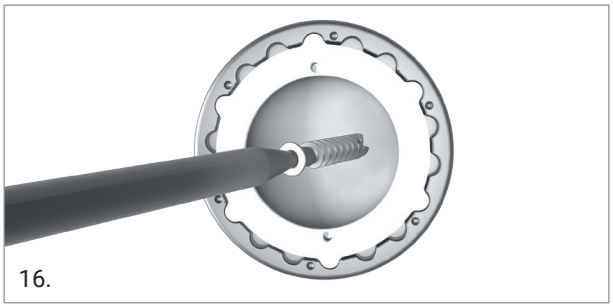
This chapter provides some options if the removal of the Mpact components is needed.

8.1 LINER REMOVAL

If a liner must be removed from the Mpact shell we recommend using the Bone screw method:

- Locate the 3.2 mm drill bit and drill a hole into the dome of the liner avoiding the areas of the holes of the shell
- Use a cancellous bone screw and insert it inside the hole. Drive the screw by hand until the liner is lifted out of the shell

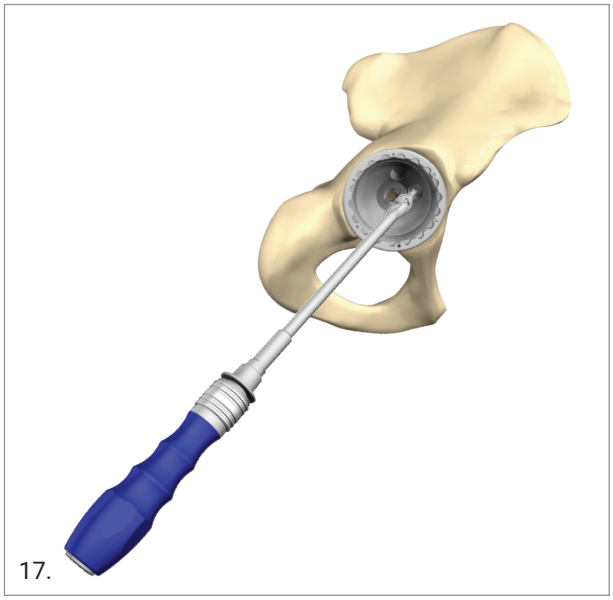
WARNING
While removing the liner, care should be taken to avoid damaging the shell taper or its locking mechanism.


16.

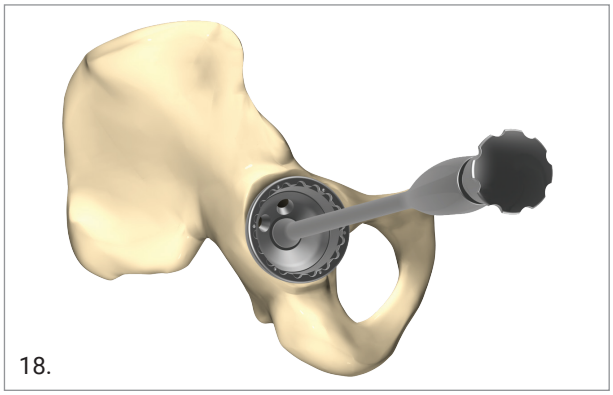
8.2 SHELL AND SCREWS REMOVAL

The Mpact existing instruments can be used in case of removal of the acetabular shell and of the screws.

To remove the cancellous bone screws you can use the ratchet handle together with the screwdriver to unscrew them.


17.

If the acetabular shell is loose you might use the impactor handle to remove it.

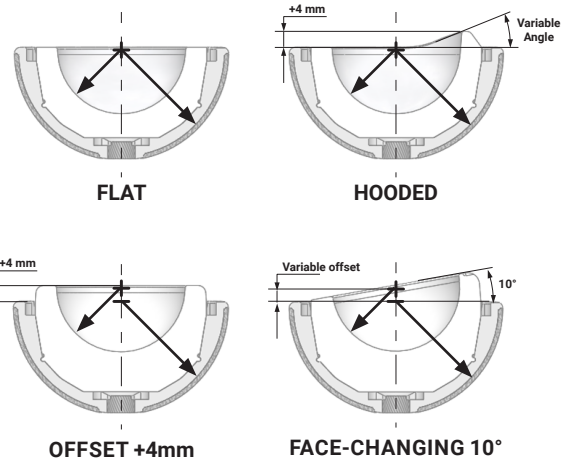

18.

For well fixed acetabular shells you should use specific revision instrumentation, available on request.

9. MPACT POLYETHYLENE LINER OPTIONS

Within the MPACT Acetabular System, a variety of liner designs are available:

- Flat liners offer concentric inner and outer spheres and maximum ROM
- Hooded liners offer additional head coverage in a specific, limited area
- + 4mm Offset liners lateralize and distalize the center of rotation by 4 mm along the cup axis
- + 10° Face-changing liners modify anteversion and inclination. The preferred anteversion and inclination can be achieved by rotating the liner in the shell taking care to align the antirotation tabs with the indentations on the shell. The center of rotation is lateralized and distalized along the cup axis by the distance shown in the table below



19.

For the hooded liners, the hood makes an angle which is size dependant:

LINER SIZE	HEAD	ANGLE
B	22	16
	28	20
C	22	16
	28	20
	32	20
D	22	16
	28	19
	32	20
E	22	16
	28	20
	32	20
	36	20
F	22	16
	28	20
	32	20
	36	20
G	22	16
	28	20
	32	20
	36	20

In the face changing liners, the position of the center of rotation is offset from the neutral position by the distance listed below (size dependant):

FACE-CHANGING LINER SIZE	OFFSET (mm)
B	4
C	4
D	4
E	4.5
F	4.5
G	5

Each design has specific benefits. The choice of the correct liner is at the discretion of the surgeon.

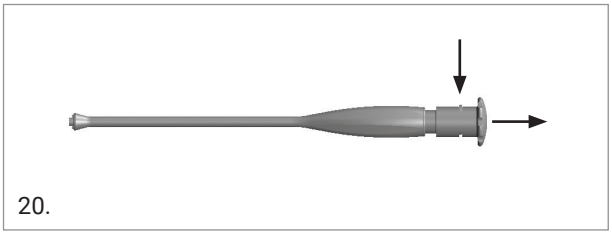
For each design, dedicated trial liners are available to properly perform the stability test.

The implantation of the definitive liners is the same for all designs. In the face changing liners, the multifunction handle must be aligned with the cup axis.

10. INSTRUMENT DETAILS

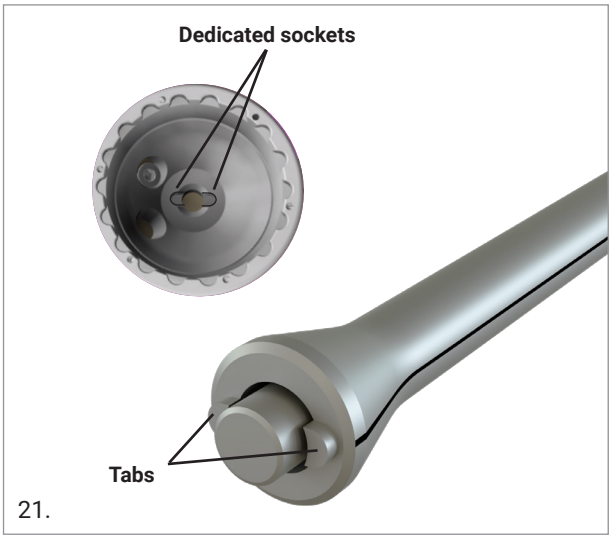
10.1 ASSEMBLING THE CUP WITH THE CUP IMPACTOR (REF. 01.32.10.0183)

Step 1: Remove the anvil from the handle by pushing the button.



20.

Step 2: Position the tip of the cup impactor in the acetabular shell taking care to align the tabs 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.

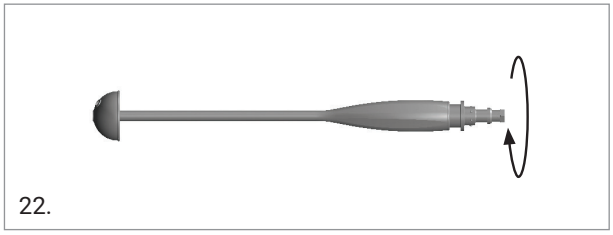


21.

TIP

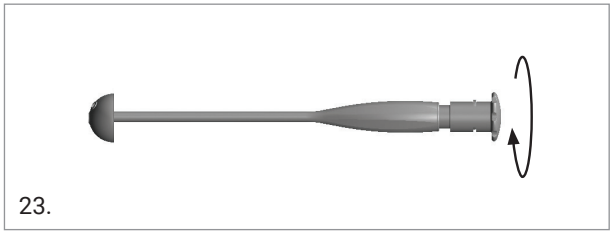
The black line on the distal shaft of the handle indicates the position of the tabs. Aligning the black line on the handle with the mechancical engravings on the shell will align the tabs to the socket.

NOTE: Do not over tighten.



22.

Step 3: Assemble the anvil and screw it until fully tightened.

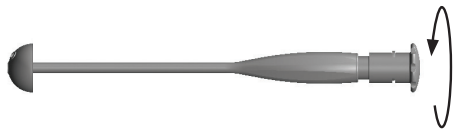


23.

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

10.2 DISASSEMBLING THE CUP WITH THE CUP IMPACTOR (REF. 01.32.10.0183)

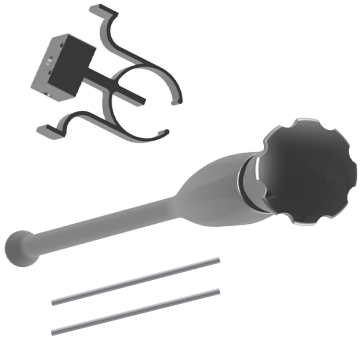
Unscrew the anvil from the impactor handle to release.



24.

10.3 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.



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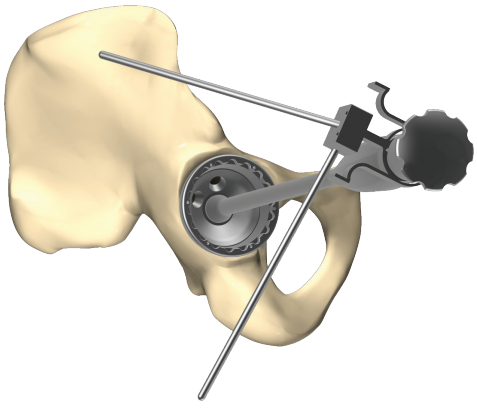
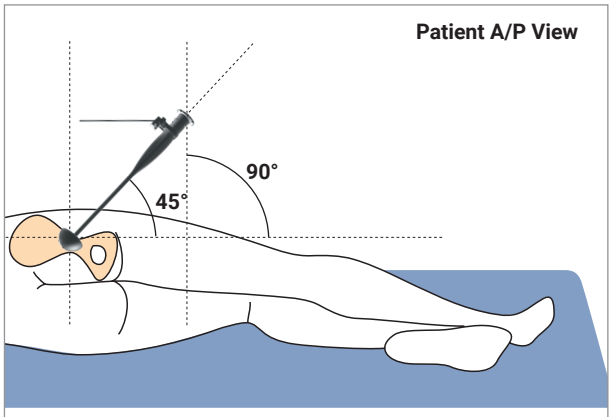


26.

Step 2: Assemble the alignment guide onto the cup impactor.

Example of use in decubitus lateralis.



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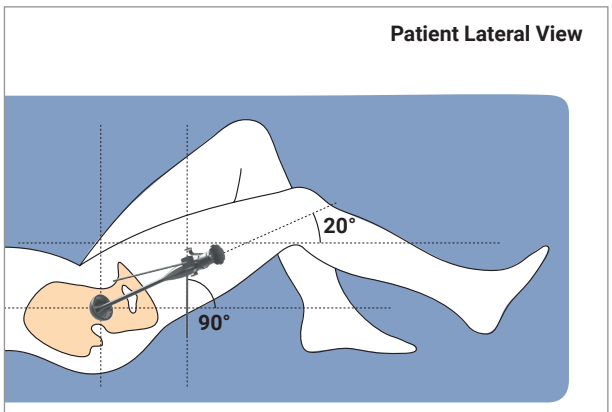

28.

11. IMPLANTS NOMENCLATURE

MPACT ACETABULAR SHELL NO-HOLE

DIAMETER (mm)	REF.	LINER SIZE
46	01.32.146SH	B
48	01.32.148SH	C
50	01.32.150SH	D
52	01.32.152SH	E
54	01.32.154SH	E
56	01.32.156SH	F
58	01.32.158SH	F
60	01.32.160SH	G
62	01.32.162SH	G
64	01.32.164SH	G
66	01.32.166SH	G

MPACT ACETABULAR SHELL TWO-HOLE

DIAMETER (mm)	REF.	LINER SIZE
46	01.32.146DH	B
48	01.32.148DH	C
50	01.32.150DH	D
52	01.32.152DH	E
54	01.32.154DH	E
56	01.32.156DH	F
58	01.32.158DH	F
60	01.32.160DH	G
62	01.32.162DH	G
64	01.32.164DH	G
66	01.32.166DH	G

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'

CANCELLOUS BONE SCREWS Ø 6.5MM*

LENGTH (mm)	REF.
15	01.43.0015
20	01.43.0020
25	01.43.0025
30	01.43.0030
35	01.43.0035
40	01.43.0040
45	01.43.0045
50	01.43.0050'
55	01.43.0055'
60	01.43.0060'
65	01.43.0065'
70	01.43.0070'

' On demand
* For further details, please see page 8

MPACT ACETABULAR SHELL CENTRAL SCREW PLUG

DESCRIPTION	REF.
Plug	01.31.55TP

HIGHCROSS UHMWPE FLAT LINER

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

HIGHCROSS UHMWPE HOODED LINER

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

HIGHCROSS UHMWPE 4 mm OFFSET LINERS - ON DEMAND

LINER SIZE	HEAD Ø 22 mm	HEAD Ø 28 mm	HEAD Ø 32 mm	HEAD Ø 36 mm	HEAD Ø 40 mm
B	01.32.2237HC4"	01.32.2837HC4	-	-	-
C	01.32.2239HC4"	01.32.2839HC4	01.32.3239HC4	-	-
D	01.32.2241HC4"	01.32.2841HC4"	01.32.3241HC4	01.32.3641HC4	-
E	01.32.2244HC4"	01.32.2844HC4"	01.32.3244HC4	01.32.3644HC4	-
F	01.32.2248HC4"	01.32.2848HC4"	01.32.3248HC4"	01.32.3648HC4	01.32.4048HC4
G	01.32.2252HC4"	01.32.2852HC4"	01.32.3252HC4"	01.32.3652HC4	01.32.4052HC4

HIGHCROSS UHMWPE FACE-CHANGING LINERS - ON DEMAND

LINER SIZE	HEAD Ø 22 mm	HEAD Ø 28 mm	HEAD Ø 32 mm	HEAD Ø 36 mm	HEAD Ø 40 mm
B	01.32.2237HC10A"	01.32.2837HC10A	-	-	-
C	01.32.2239HC10A"	01.32.2839HC10A	01.32.3239HC10A	-	-
D	01.32.2241HC10A"	01.32.2841HC10A	01.32.3241HC10A	-	-
E	01.32.2244HC10A"	01.32.2844HC10A"	01.32.3244HC10A	01.32.3644HC10A	-
F	01.32.2248HC10A"	01.32.2848HC10A"	01.32.3248HC10A"	01.32.3648HC10A	01.32.4048HC10A
G	01.32.2252HC10A"	01.32.2852HC10A"	01.32.3252HC10A"	01.32.3652HC10A	01.32.4052HC10A

" Availability upon approved special request only

Part numbers subject to change.

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. For detailed instructions please refer to the document “Recommendations for cleaning decontamination and sterilization of Medacta® International reusable orthopaedic devices” available at www.medacta.com.

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