Apact® SYSTEM

HEMISPHERICAL CEMENTLESS CUPS

EVOLVING SAFETY

Surgical Technique

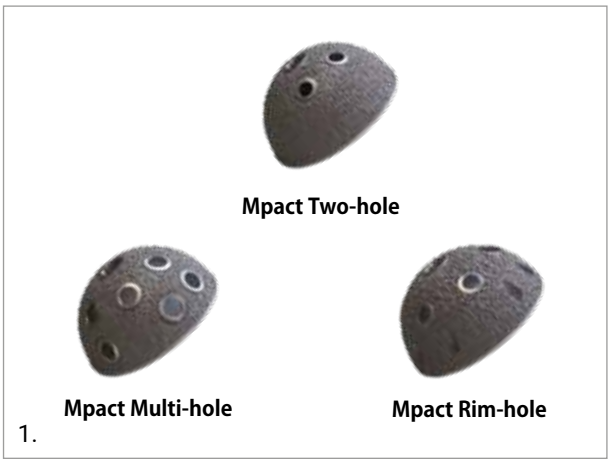
Joint | Spine | Sports Med

Medacta International

INDEX

1. INTRODUCTION

The Mpact Multi-hole and the Mpact Rim-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 Multi-hole and Mpact Rim-hole cups to be used with dome and/or rim screws to enhance the primary fixation.

The Mpact Multi-hole shell is available in 16 sizes, from 46 to 76 mm; the Mpact Rim-hole shell is available in 11 sizes, from 56 to 76 mm. Both shells can be coupled with UHMWPE liners.

For more details about other Mpact System acetabular shells please see the dedicated Surgical Techniques.

Please read carefully the instructions for use. Should 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 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.

1.2 CONTRAINDICATIONS

Total 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 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 of cup placement.

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 a conventional approach. Specific instrumentation for the anterior approach is available under request (for further information see the AMIS dedicated surgical technique).

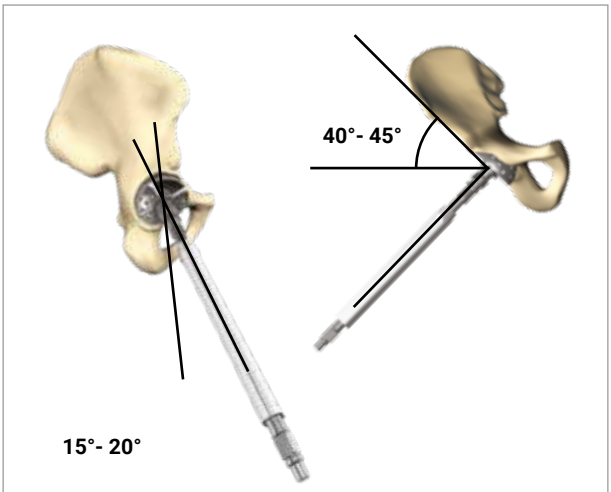
2. REAMING

Following the osteotomy of the femoral neck or dislocation of the existing femoral component, expose and prepare the acetabular cavity and remove osteophytes.

Start reaming with 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 as this may make the prepared bed oval and 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 bone quality: the denser the bone, the less press-fit required. In average conditions, an under-reaming of 1 mm should provide an appropriate pressfit of the Mpact acetabular shell.

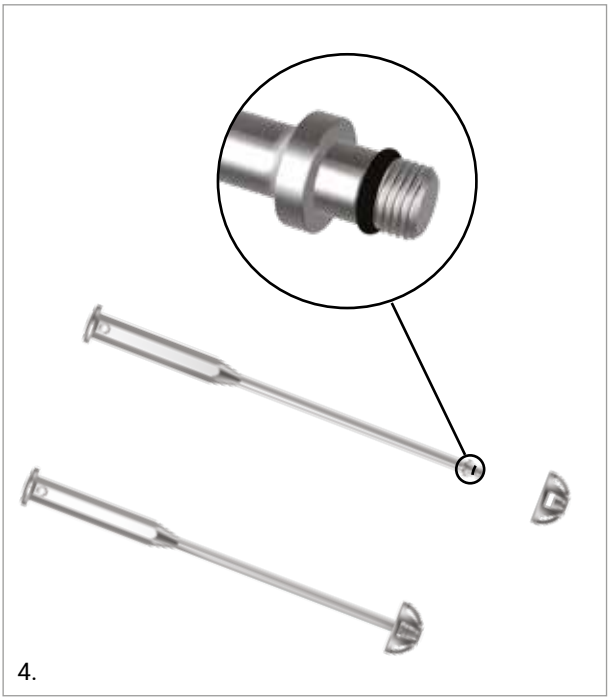
As a general rule the correct final reamed diameter corresponds to 4 or 6 mm more than the femoral head diameter size. Take care to retain, as much as possible, the bone stock to the level of anterior and posterior columns.

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 1mm smaller in case of odd-size reaming) should be used.

Place the trial cup chosen onto the multifunction handle.



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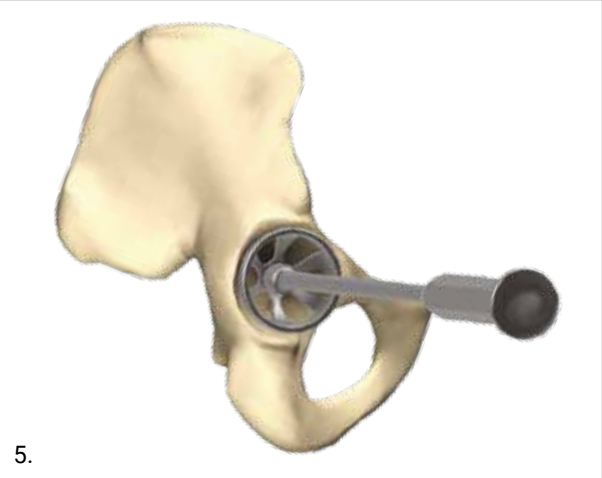


5.

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

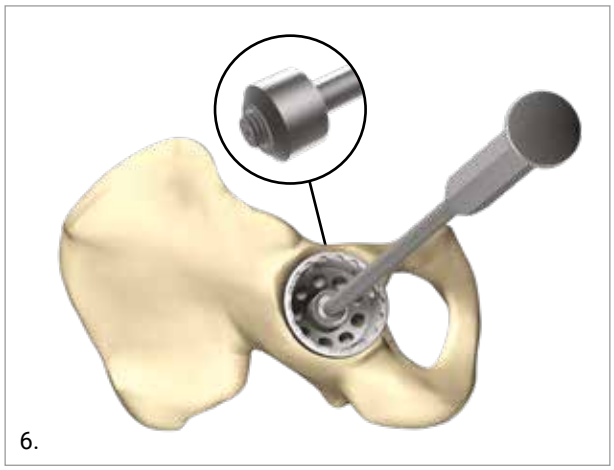
As a general rule, soft bone is suitable for a greater press-fit than dense sclerotic bone. Moreover, the bigger the size of the acetabulum, the greater the suitable press-fit.

4. IMPACTION OF THE ACETABULAR SHELL

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

Assemble the impactor handle (Ref. 01.32.10.0183) with the acetabular shell until it is completely locked in order not to damage the impactor screw thread during the impaction (for detailed instructions see chapter 10 - INSTRUMENT DETAILS).

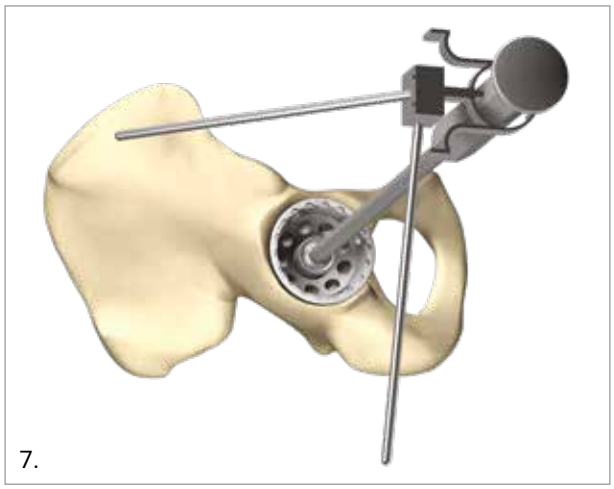
NOTICE: do not impact on the central rod, but always impact on the anvil.



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 (for detailed instructions see chapter 10 - INSTRUMENT DETAILS).



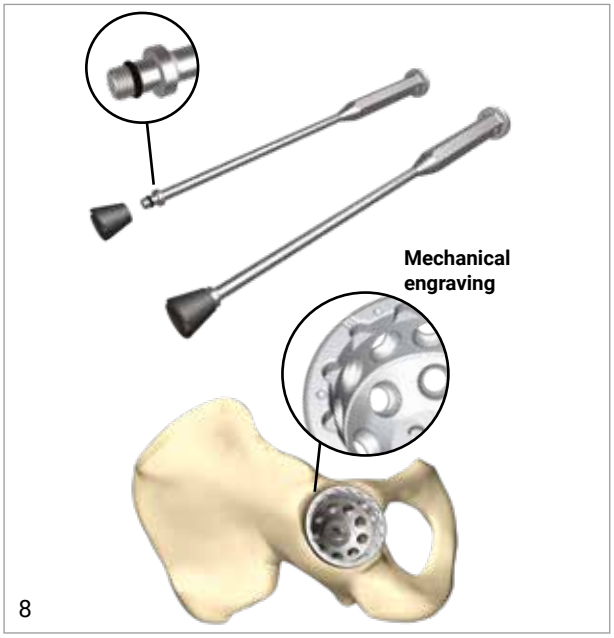
7.

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. The correct position of the acetabular shell is achieved by positioning the mechanical engraving in the posterior superior quadrant of the acetabulum, in the direction of the center of the ilium.

Impact the acetabular shell with the aid of a mallet, at the desired angle of orientation, 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 (for detailed instructions see chapter 10 - INSTRUMENT DETAILS).



8

CAUTION

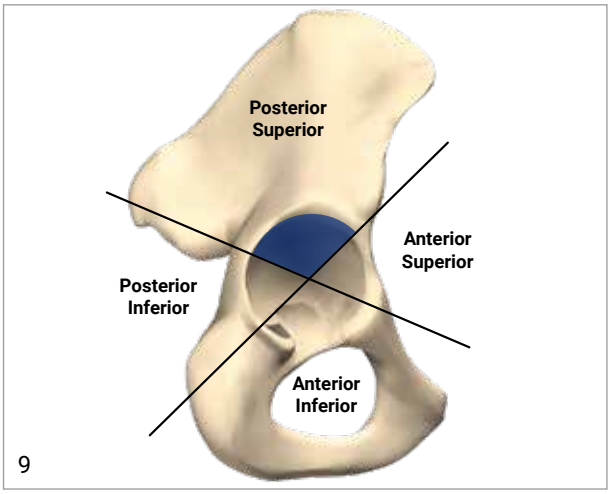
After impaction of the acetabular shell, ensure osteophytes have been properly removed in order to avoid any impingement.

TIP

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

5. PLUG AND ACETABULAR SCREW INSERTION

The Mpact Multi-hole and the Mpact Rim-hole allow the surgeon to use bone screws to provide additional fixation. Screw holes should be located in the Posterior-Superior acetabular quadrant to minimize the potential for neurologic and vascular injury. Additional screw holes may be located in the other acetabular quadrants to increase fixation, if necessary. Screw placement is at the discretion of the surgeon.



9

The Mpact Multi-hole allows the surgeon to use cancellous bone screws (with flat head and Ø 6.5 mm), to be placed on the dome of the shell.

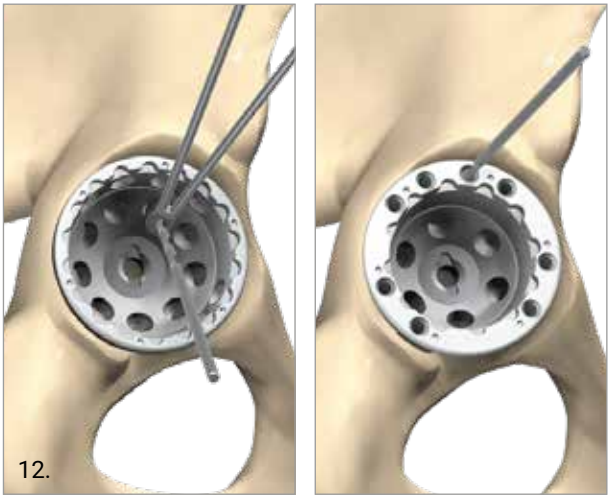

10.

The Mpact Rim-hole allows the surgeon to use both cancellous bone screws (to be placed on the dome of the shell) and cortical bone screws (with flat head and Ø 4.0 mm), to be placed on the rim of the shell.

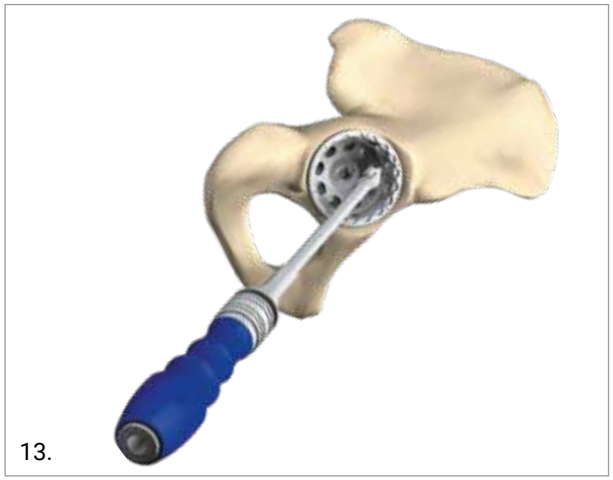

11.

A depth gauge is available in order to measure the drilling depth and select a self-tapping screw of appropriate length.

To insert cancellous bone screws on the dome of the shell, drill through the acetabular shell holes using a Ø 3.2 mm drill bit with the help of a drill guide.


12.

Screwing is performed with the aid of a 3.5 mm hex-head screwdriver.


13.

To insert cortical bone screws on the rim of the shell, drill through the acetabular shell rim holes using a Ø 3.0 mm drill bit.

For cortical bone screws placement, screwing is performed with the aid of a 2.5 mm hex-head screwdriver.

CAUTION
Always use Medacta flat head screws (see chapter 11 - IMPLANTS NOMENCLATURE) 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 titanium plug if desired. The titanium plug (ref 01.31.55TP) is packaged separately from the acetabular shells.

6. STABILITY TEST

During stability tests, the choice between a flat and a hooded liner can be made according to the surgeon's preference. Offset and Face-changing liners are also availble.


14.

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 into 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.

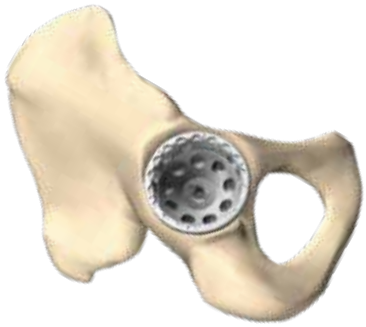
TIP
If using a hooded trial liner, use electrocautery to mark the satisfactory position of the hood.

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 THE 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 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.

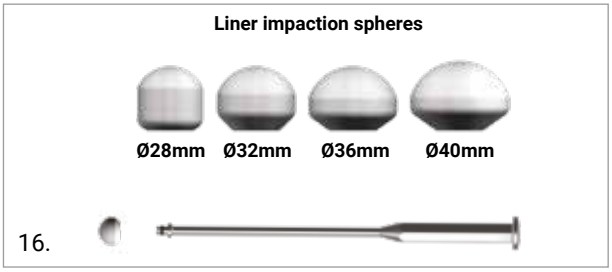


15.

Carefully and manually, place the UHMWPE liner in the acetabular shell along its axis taking care to align the anti-rotation tabs with the indentions on the shell.
Be careful to position the hooded liner in the correct location as determined by the trial.

Check that the liner has been positioned correctly.

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 impaction sphere (of the correct liner) with the multifunction straight impactor.



16.

Insert the sphere into the UHMWPE liner and impact it using a mallet, until completely seated.
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 under request to be used with the multifunction handle. Also under request, a washer release key is available to unlock the impaction washer from the multifunction handle.

8. REMOVAL AND REVISION PROCEDURE

This chapter provides some options if removal of the Mpact component is required.

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.

17.

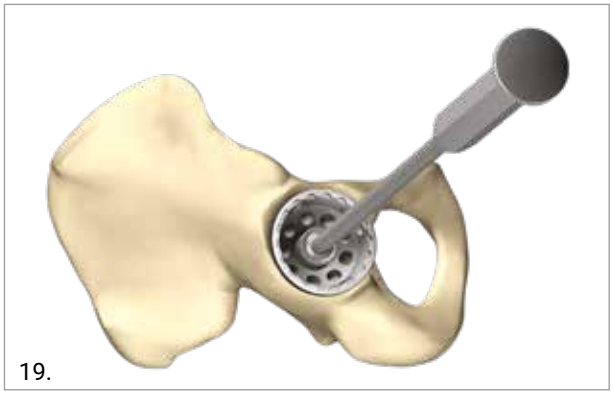
8.2 SHELL AND SCREWS REMOVAL

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

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

18.

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



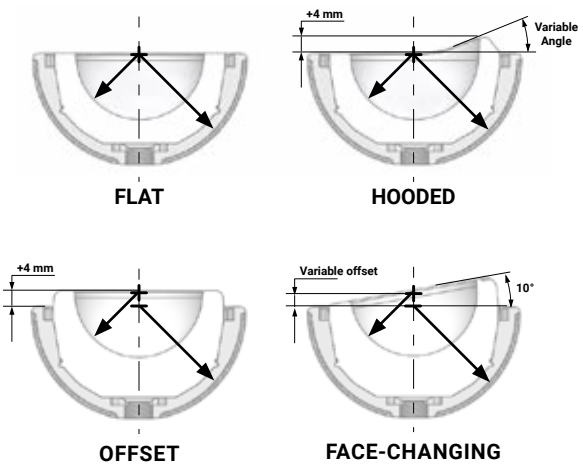
19.

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 centre 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 centre of rotation is lateralized and distalized along the cup axis by the distance shown in the table below



20.

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
J	22	16
	28	20
	32	20
	36	20
K	22	20
	28	20
	32	20
	36	20

In the face changing liners, the position of the centre 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
J	5.5
K	6

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.

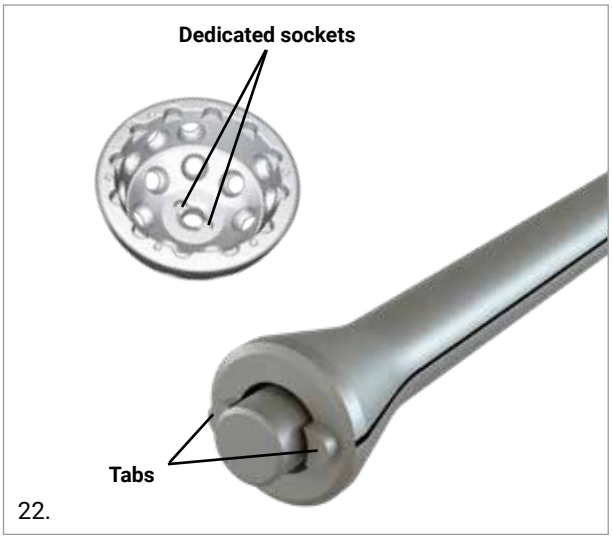
10. INSTRUMENT DETAILS

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

Step 1: Remove the anvil (impaction plate) from the handle by pushing the button.

21.

Step 2: Insert the tip of the cup impactor in the acetabular shell taking care to align the two tabs of the impactor with the matching grooves near the central hole of the acetabular shell. Screw the cup impactor into the central hole until fully tightened.



22.

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.

23.

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

24.

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

Unscrew the anvil from the impactor handle to release.

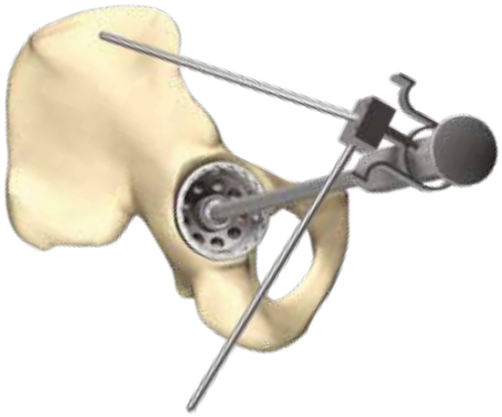
25.

10.3 ASSEMBLING THE ALIGNMENT GUIDE (REF. 33.22.0066 AND 01.32.10.0072) WITH THE CUP IMPACTOR (REF. 01.32.10.0183)

Step 1: Screw the inclination rod and the anteversion rod onto the alignment guide.

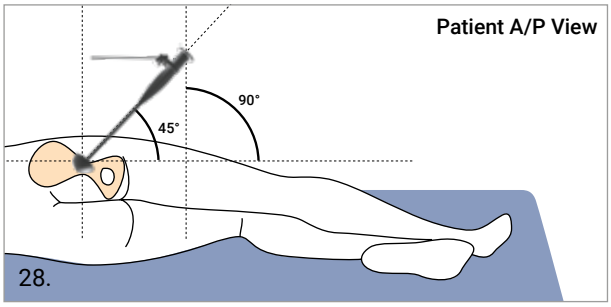
26.

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



27.

Example of use with patient in lateral position



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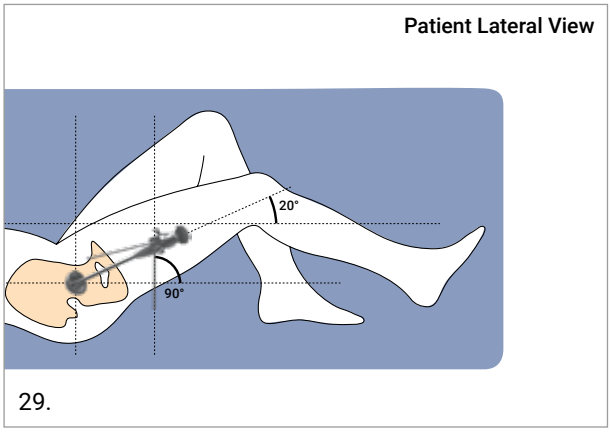


29.

11. IMPLANTS NOMENCLATURE

MPACT ACETABULAR SHELL MULTI-HOLE

DIAMETER (mm)	REF.	LINER SIZE
46	01.32.146MH'	B
48	01.32.148MH'	C
50	01.32.150MH	D
52	01.32.152MH	E
54	01.32.154MH	E
56	01.32.156MH	F
58	01.32.158MH	F
60	01.32.160MH	G
62	01.32.162MH	G
64	01.32.164MH	G
66	01.32.166MH	G
68	01.32.168MH	J
70	01.32.170MH	J
72	01.32.172MH'	K
74	01.32.174MH'	K
76	01.32.176MH'	K

MPACT ACETABULAR SHELL RIM-HOLE

DIAMETER (mm)	REF.	LINER SIZE
56	01.32.156RH	D
58	01.32.158RH	D
60	01.32.160RH	E
62	01.32.162RH	E
64	01.32.164RH	F
66	01.32.166RH	F
68	01.32.168RH	G
70	01.32.170RH	G
72	01.32.172RH'	J
74	01.32.174RH'	J
76	01.32.176RH'	J

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'

CORTICAL BONE SCREWS (FLAT HEAD - Ø 4.0mm)

LENGTH (mm)	REF.
25	01.32.4025
30	01.32.4030
35	01.32.4035
40	01.32.4040
45	01.32.4045
50	01.32.4050
55	01.32.4055

' On demand

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
J	01.32.2256HCT'	01.32.2856HCT'	01.32.3256HCT	01.32.3656HCT	01.32.4056HCT
K	01.32.2260HCT'	01.32.2860HCT'	01.32.3260HCT'	01.32.3660HCT'	01.32.4060HCT'

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
J	01.32.2256HCAT'	01.32.2856HCAT'	01.32.3256HCAT	01.32.3656HCAT
K	01.32.2260HCAT'	01.32.2860HCAT'	01.32.3260HCAT'	01.32.3660HCAT'

' On demand

HIGHCROSS UHMWPE OFFSET LINERS 4 mm - 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
J	01.32.2256HC4	01.32.2856HC4	01.32.3256HC4	01.32.3656HC4	01.32.4056HC4
K	01.32.2260HC4	01.32.2860HC4	01.32.3260HC4	01.32.3660HC4	01.32.4060HC4

HIGHCROSS UHMWPE FACE-CHANGING LINERS 10° - ON DEMAND

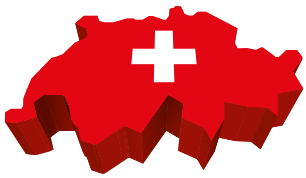
LINER SIZE	HEAD Ø 22 mm	HEAD Ø 28 mm	HEAD Ø 32 mm	HEAD Ø 36 mm	HEAD Ø 40 mm
B	01.32.2237HC10A	01.32.2837HC10A	-	-	-
C	01.32.2239HC10A	01.32.2839HC10A	01.32.3239HC10A	-	-
D	01.32.2241HC10A	01.32.2841HC10A	01.32.3241HC10A	-	-
E	01.32.2244HC10A	01.32.2844HC10A	01.32.3244HC10A	01.32.3644HC10A	-
F	01.32.2248HC10A	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
J	01.32.2256HC10A	01.32.2856HC10A	01.32.3256HC10A	01.32.3656HC10A	01.32.4056HC10A
K	01.32.2260HC10A	01.32.2860HC10A	01.32.3260HC10A	01.32.3660HC10A	01.32.4060HC10A

NOTES

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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Strada Regina - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
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ref: 99.70NR.12US
rev. 03

Last update: February 2019