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Materialise aMace

Case Report

aMace Acetabular Revision System

Case ID: XXX

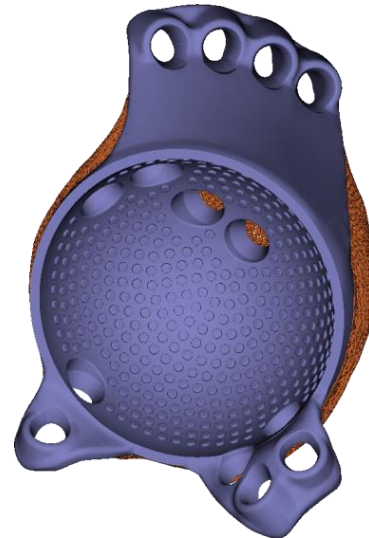
Side to treat: Left

Surgeon: Dr. XXX

Hospital: XXX

Scan date: XX/XX/2016

Surgery Date: XX/XX/2016



Case No: XXX
Surgeon: Dr. XXX
Hospital: XXX

PRIVACY STATEMENT

Materialise addresses great importance to the full protection of privacy and personal health information. Personal information is anonymized via a unique patient number and/or case number. Accordingly, patient data can be consulted by the surgeon by use of the prescription form. This report contains confidential information and is meant for the operating surgeon only.

IMPORTANT INFORMATION

This report contains the final custom-made case instructions and should be used in conjunction with the general instructions for use and surgical technique.

Case No: XXX
Surgeon: Dr. XXX
Hospital: XXX

MEDICAL PRESCRIPTION

Prescription delivered by:

Dr. XXX

Hospital XXX

Address

Device name: aMace Acetabular Revision System

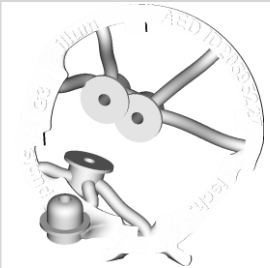
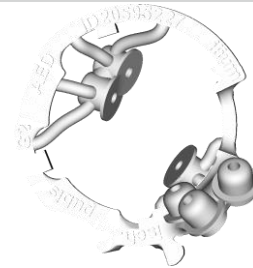
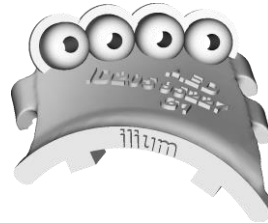
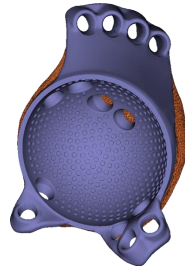
for the creation of:

A custom-made acetabular implant made of titanium alloy and designed to match the anatomical geometry of the patient's left hemi-pelvis, based on CT data.

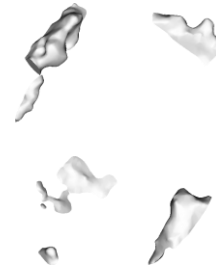
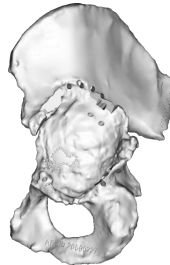
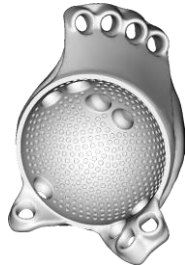
Case No: XXX
Surgeon: Dr. XXX
Hospital: XXX

OVERVIEW

Patient-specific components



Unique part ID	Case ID-A1	Case ID-G1	Case ID-G2	Case ID-G3
Reference Number	MOB-AR-13	MOB-200	MOB-200	MOB-200
Description	aMace Integrated (Non-Sterile)	Drill Guide (Non-Sterile)	Drill Guide (Non-Sterile)	Drill Guide (Non-Sterile)



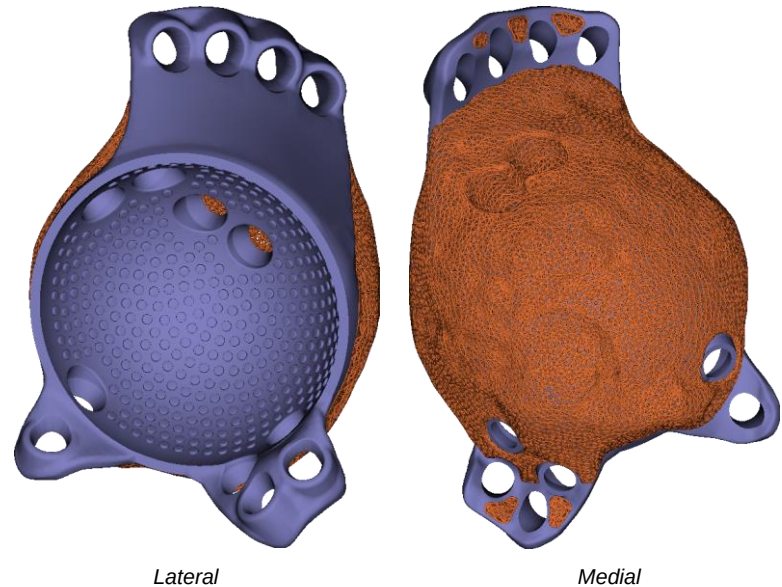
Unique part ID	Case ID-I1	Case ID-B1	Case ID-B2	
Reference Number	MOB-300	MOB-100	MOB-100	
Description	Implant trial (Non-Sterile)	Bone Model (Non-Sterile)	Bone Model (Non-Sterile)	

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DEVICE SPECIFICATIONS

Custom-made implant

- Implant Material: **Ti-6Al-4V ELI**
- Implant inner diameter: **61mm**
compatible with a **Cemented Acetabular Liner** with **outer diameter of 57mm**
- The implant contains screw holes for **titanium spongiosa** (6.5 mm diameter) & **cortical screws** (4.5 mm diameter): **maximal head height 4.8mm** and **head diameter** between 7.6 mm and 8mm.



Implant composition:

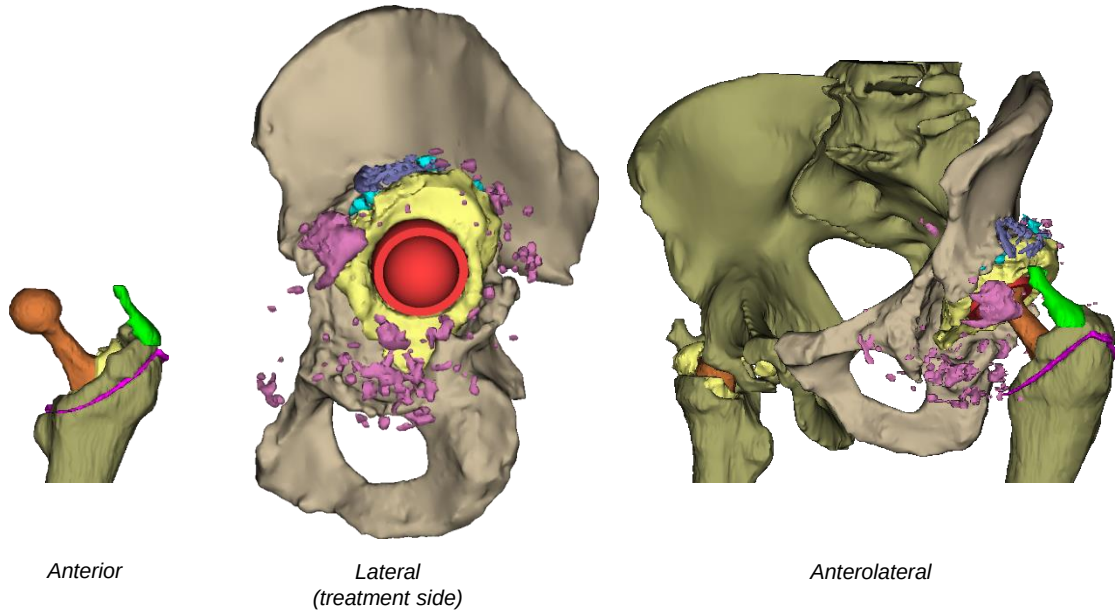
-  Solid plate
-  Integrated porous structures

Case No: XXX
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ACETABULAR PREPARATION

Pre-operative situation – overview

-  Hip stem (cemented)
-  Cement
-  Bone fragments
-  Cerclage wire
-  Screws
-  Liner
-  Unknown tissue fragments
-  Metal mesh

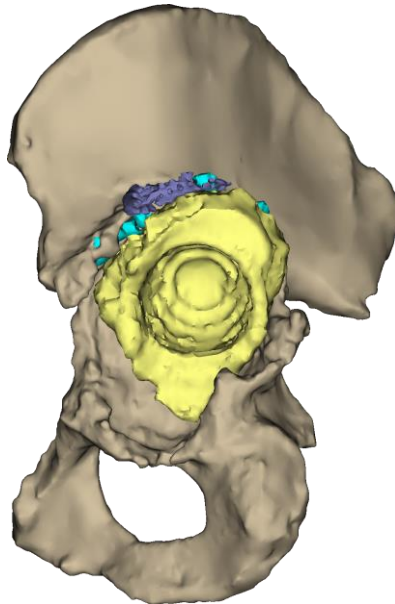


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Hospital: XXX

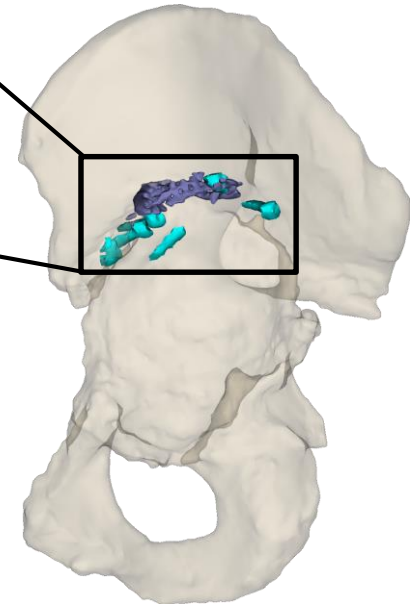
ACETABULAR PREPARATION

Pre-operative situation – component removal

-  Screws
-  Cement
-  Metal mesh



All components are assumed to be removed prior to implant insertion.



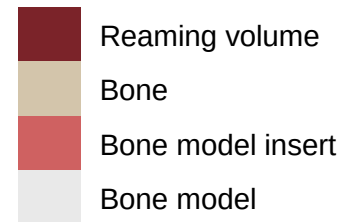
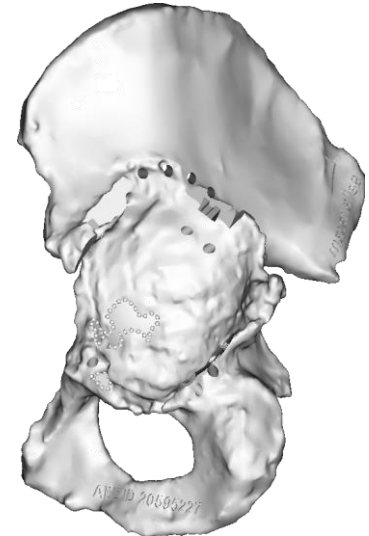
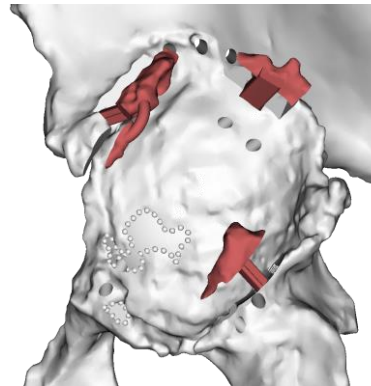
- 1 screw is fixating the metal mesh (no. 5).
- 1 screw is loose (no. 6).
- 4 screws are partially embedded in the bone (no. 1 to 4) .

Case No: XXX
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ACETABULAR PREPARATION

Bone removal

- Planned **bone removal volume** requires careful removal: **4.2 ml**
- Bone removal volumes** are represented by the bone model **insert(s)**, when possible. Thin volumes are indicated on the bone model **by a contour**.
- A reamer can be used for spherical reaming, diameter: **71 mm**
- Compare** the intra-operative situation with the **plastic bone model** to ensure accurate bone removal.

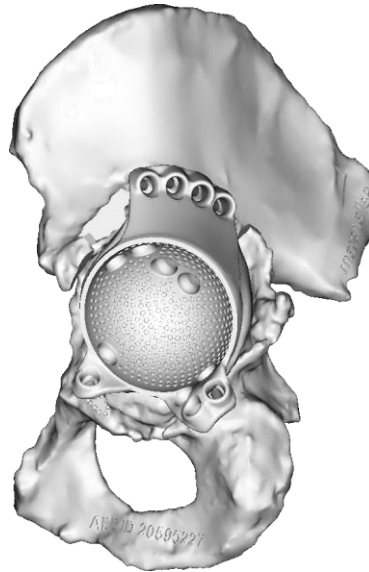


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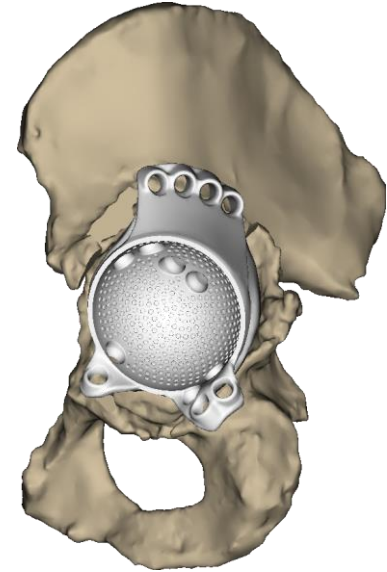
ACETABULAR PREPARATION

Implant trial fitting

- Use the bone model and implant trial to verify the fit.
- The planned position is obtained when the trial fits to the patient bone as it fits to the model



Implant trial
on bone model



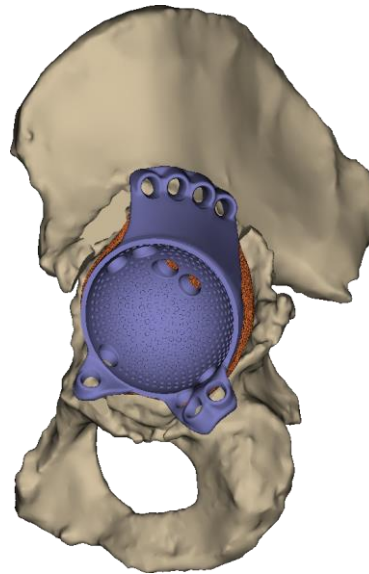
Implant trial at planned fit
on patient bone

Case No: XXX
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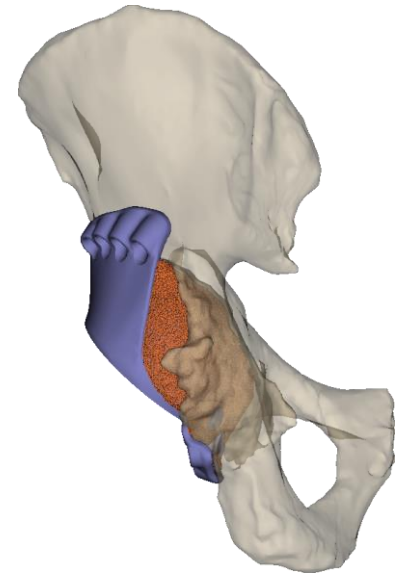
IMPLANT FIT

Visualizations

- ▶ Please note that, due to component removal the effectively obtained clearance between the porous structure and the bone can vary.
- ▶ Gaps can be filled with morselized bone graft.
- ▶ If morselized bone graft is applied, please verify that the implant position is still according to plan.



Lateral



Posterior

Case No: XXX
Surgeon: Dr. XXX
Hospital: XXX

IMPLANT POSITION

Measurements

▪ Cup orientation

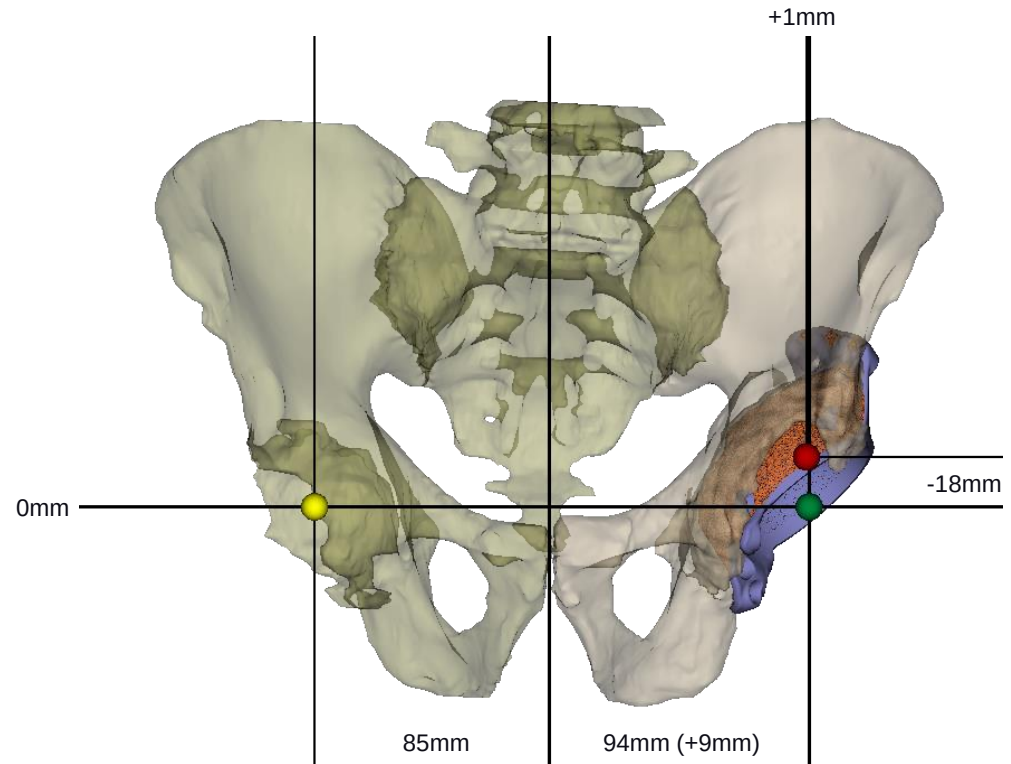
Inclination 40°
AV angle 20°

▪ Cup diameter

Implant inner diameter: **61mm**
Liner outer diameter: **57mm**

▪ Center of rotation

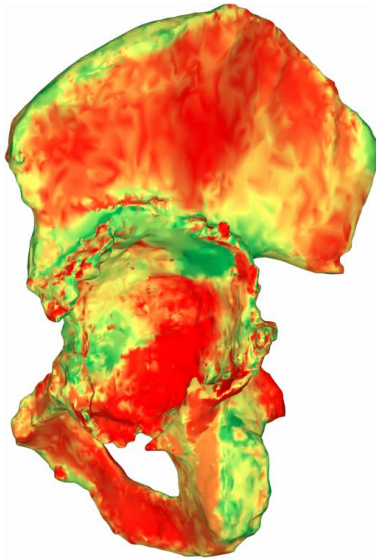
- Pre-operative
- Proposed
- Contralateral



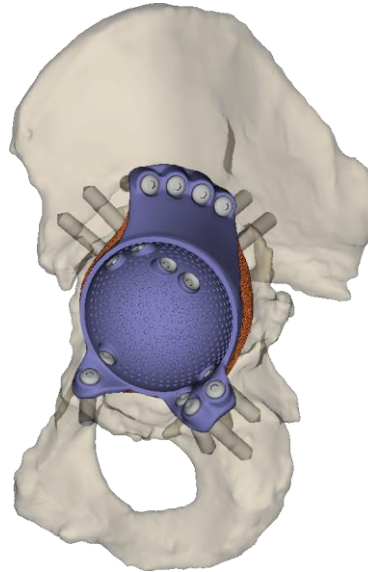
Case No: XXX
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IMPLANT FIXATION

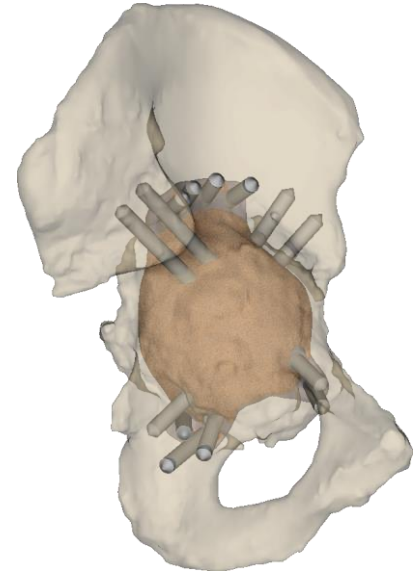
Bone quality for screw planning



Lateral



Lateral



Medial

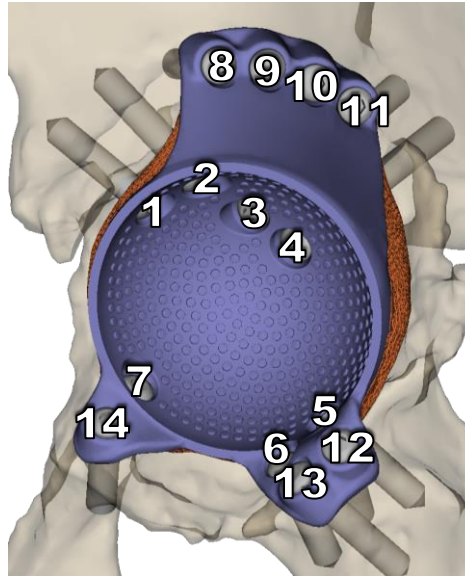
Case No: XXX
 Surgeon: Dr. XXX
 Hospital: XXX

IMPLANT FIXATION

Screw planning

- Maximum occupancy of screw holes is recommended.
- Intra-operative measurement of the screw lengths should be performed before application of the screws.

Screw planning



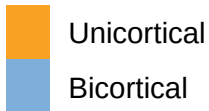
Screw	Length (mm)
1	31
2	36
3	60
4	60
5	30
6	30
7	27
8	28
9	26
10	27
11	32
12	36
13	40
14	31

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GUIDE USE

- The guides are compatible with a drill bit diameter of 3.2 mm.
- A flexible drill bit is advised for drilling the screw trajectories in the bone (cup screws).

Screw planning

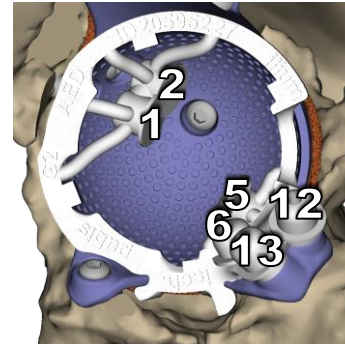


GUIDE 1



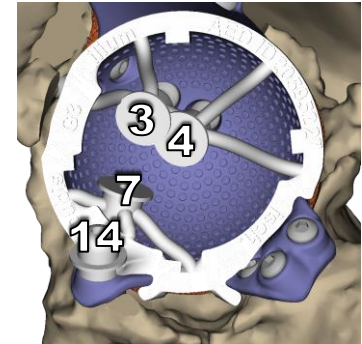
Screw	Length (mm)
8	28
9	26
10	27
11	32

GUIDE 2



Screw	Length (mm)
1	31
2	36
5	30
6	30
12	36
13	40

GUIDE 3

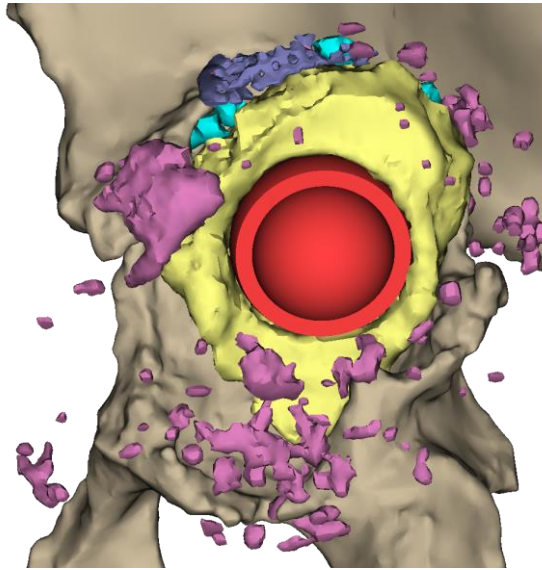


Screw	Length (mm)
3	60
4	60
7	27
14	31

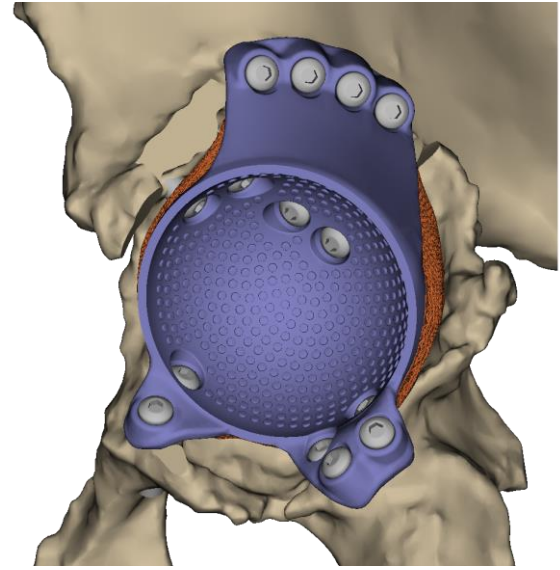
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ACETABULAR RECONSTRUCTION RESULT

Pre-operative and planned postoperative situation



Pre-operative
Lateral



Postoperative
Lateral

Case No: XXX
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Hospital: XXX

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- The custom-made acetabular implant is designed to the specific characteristics of the patient and fixed according to the situational bone structure to offer a stable reconstruction of the bone and support for the articulating joint components. Due to its custom-made character, experimental verification of the mechanical and clinical performance for each individual implant is impossible. A custom-made implant may not be expected to withstand the same activities and the same loads as normal healthy bone. A custom-made implant will not show the same reliable and durable mechanical behavior as natural human bone.
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Example of an aMace implant.

Materialise aMace

MANUFACTURER INFORMATION

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B-3001 Leuven
BELGIUM



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