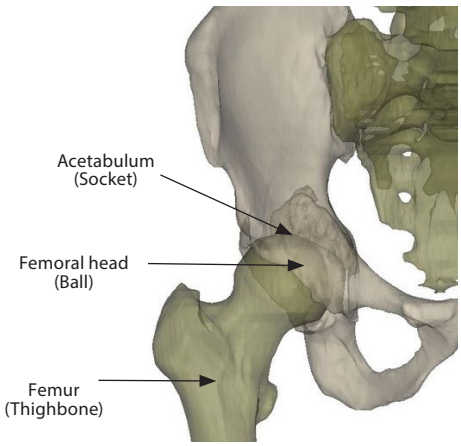
Materialise aMace Onco
Patient Information Leaflet

Product

Product Category	60516 Metallic acetabulum prosthesis	
Brand name	Materialise aMace Onco	
Model codes	MOBAT2-000	
Material	Titanium alloy	
Legal Manufacturer	materialise innovators you can count on	Materialise N.V. Technologielaan 15 3001 Leuven Belgium www.materialise.com/en/medical/patient-information

What is the Materialise aMace Onco tumor reconstruction system?

The Materialise aMace Onco tumor reconstruction system is used in hip reconstruction surgery after tumor resection, a procedure in which the patient's hip joint is replaced by an artificial joint after resection of a tumor at the hip joint. The hip joint is composed of two parts: the hip socket, or acetabulum — a cup-shaped structure in the pelvis, and the ball-shaped head of the thigh bone called the femur head.



The Materialise aMace Onco tumor reconstruction system is a patient-specific implant solution intended for use in reconstruction surgery for adult patients with severe acetabular bone deficiencies due to tumor resection. The aMace Onco implant is an acetabular component designed to match the exact anatomy of the patient. Each aMace Onco implant is made exclusively for a particular patient, so no two implants are alike. The aMace Onco implant design is based on a preoperative plan generated from a computed tomography (CT) scan.

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What do you need to know?

Safety

For safe use of the aMace Onco implant, patients must carefully follow the instructions provided by their healthcare practitioner as the level of care required differs with each case. In general, avoid excessive stress or heavy use of the implant while healing to avoid loosening, breakage, or wear of the implant. Please discuss with your healthcare practitioner when you can resume exercise or other physically-demanding activities.

Testing done on the implant has shown that residuals from the manufacturing process do not pose a risk to the patient. Additionally, the implant goes through a sterilization process before coming in contact with patients.

Medical examinations

There is a possibility that the acetabular implant can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

The implant's impact on safety in the CT or MRI environment is currently unknown, so patients must inform their healthcare practitioner when CT or MRI scans are needed in case patient harm is possible.

Medical procedures

Please inform your healthcare practitioner that you have a hip implant when you require another medical procedure, including small dental procedures.

What are the possible side effects?

As with all surgeries, there are possible side effects including pain, swelling, bruising, bleeding, infection, and reduction of mobility.

Other risks include:

- Insufficient bone reconstruction (osteolysis, osteomyelitis, osteoporosis), inhibited vascularization (the process of blood vessels forming properly), or infection that may result in failure of the reconstruction site.
- Sensitivity or allergic reactions to the material used, reaction of the immune system to a foreign body, and infections. When suspected, material sensitivity tests are made prior to the implantation.
- Damage to soft tissue and avulsion (the wearing down of soft tissue in the bone).

- Pain, discomfort, and abnormal sensation related to the implant. This usually resolves itself, but it can take weeks or months. Some people have a permanent change in sensation of the area surrounding the implant.
- Soft tissue damage caused by the loosening or migration of the implant due to trauma or loosened fixation devices that keep the implant in place.
- Perforation or fracture of the pelvic (hip) bone during or after surgery caused by trauma.
- Reduction of mobility due to incorrect placement of the implant or its components, damage to the bone, or osteophyte formation (abnormal bone growth).
- Morphological change or shortening/lengthening of the leg, unequal length of limbs, or traumatic arthrosis of the knee joint.
- Cardiovascular diseases such as venous thrombosis (blood clot in limbs), pulmonary embolism (blood clot in lungs), or myocardial infarction (heart attack).
- Total or partial dislocation of the joint due to improper placement of the implant's parts. Weak muscles and fibrous tissue can also play a role here.

When should you contact your healthcare practitioner?

Preventive monitoring of the device itself is not required. Please consult your healthcare practitioner for guidelines in terms of medical examinations or follow-ups after the procedure.

Please consult your healthcare practitioner in case one or more of the following events occur:

- Acute pain or swelling at the implantation site.
- Skin redness, inflammation, or infection at the implantation site.

What is the expected lifetime of your medical device?

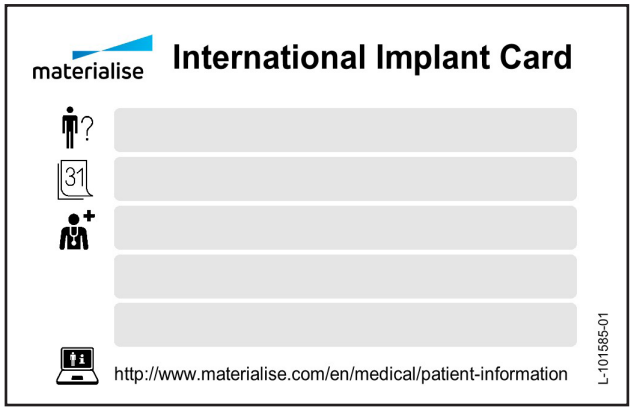
There are no expected effects of aging on the acetabular implant. The implant has been mechanically tested to withstand a minimum of ten years of average use.

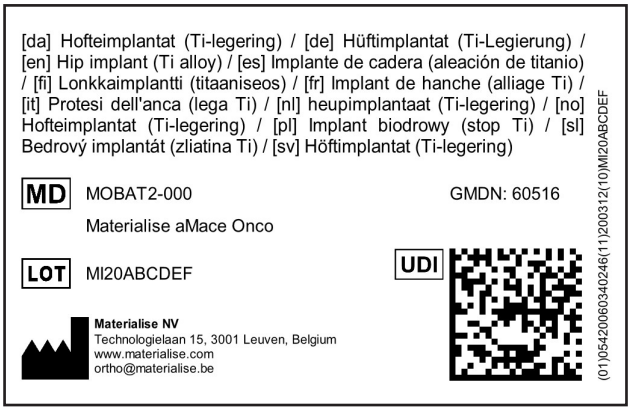
To prolong the lifetime of your device, do not put heavy stress on the implant until it has adequately healed and properly settled in the correct location. Consult your healthcare practitioner for your specific guidelines.

Identifiable information for your implanted device

In order to save the identifiable details of your particular implanted device, you will receive an "International Implant Card". Your surgeon will complete it with information specific to your surgery.

It will allow you to contact your surgeon and to find information on the device readily available online.





This card is representative, and information may differ according to the country in which the implant was purchased.

SYMBOL	DESCRIPTION OF SYMBOL
	Full name of the patient
	The date the implant was placed
	The name and address of the health care centre or doctor who performed the implantation
	Website where a patient can obtain additional information on the implant
MD	Name of the implant (MD = Medical Device)
LOT	Lot number of the implant
UDI	Reference number of the implant (UDI = Unique Device Identifier)
	Name and address of the legal manufacturer of the implant

This is version 1 of this document, issued in April 2021.

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