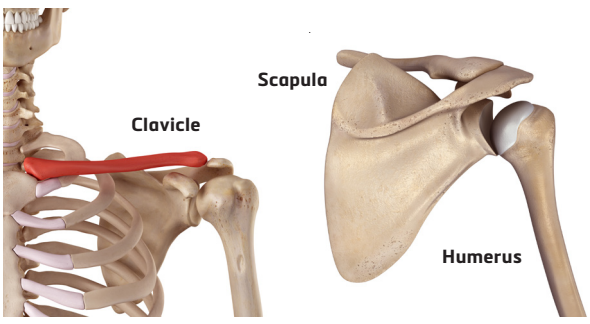
Glenius Shoulder Implant
Patient Information Leaflet

Product

Product Category	36259 Prosthesis, shoulder glenoid component	
Brand name	Glenius Glenoid Reconstruction System	
Model codes	MOB-GR-11 Glenoid Reconstruction System 36mm MOBGR-000 Glenius baseplate component MOBGR-051 Glenius glenosphere component 36mm MOB-GR-12 Glenoid Reconstruction System 38mm MOBGR-000 Glenius baseplate component MOBGR-052 Glenius glenosphere component 38mm MOB-GR-13 Glenoid Reconstruction System 42mm MOBGR-000 Glenius baseplate component MOBGR-053 Glenius glenosphere component 42mm	
Material	Titanium alloy (baseplate) CoCr alloy (glenosphere) Note that the Glenius Glenoid Reconstruction System is containing Cobalt which is a hazardous substance, but scientific evidence supports that medical devices manufactured from cobalt alloys do not cause an increased risk of cancer or adverse reproductive effects.	
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 Glenius Glenoid Reconstruction System?

The shoulder is a complex joint formed by three bones: the humerus (upper arm bone), the scapula (shoulder blade), and the clavicle (collar bone). The spherical, upper part of the humerus forms a ball-and-socket joint with part of the scapula, the glenoid (shoulder socket). A shoulder replacement surgery is a procedure in which the shoulder joint is replaced by an artificial joint often made from metal and plastic components. In a reverse shoulder replacement, the structure of the



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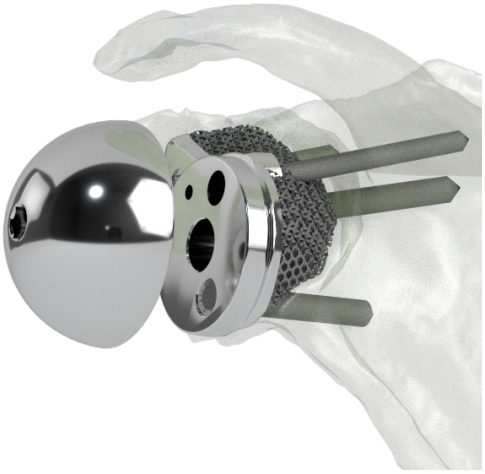
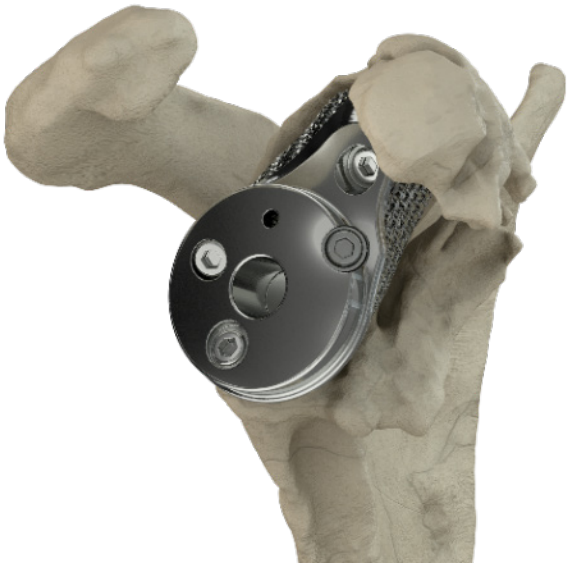
shoulder joint is reversed and the position of ball and socket are swapped. The upper part of the humerus is replaced with a cup-shaped implant, and the glenoid is reconstructed into a ball-type shape, using a baseplate and a hemispherical implant (the glenosphere).

The Glenius Glenoid Reconstruction System is a patient-specific implant solution intended for patients with severe bone defects at the glenoid that require reconstruction of the shoulder joint. The Glenius Glenoid Reconstruction System comprises of two implants: a glenosphere and the baseplate, which forms the connection between the glenoid and the glenosphere and is designed to match each patient's individual anatomy. Adult primary or revision shoulder joint replacements are the device's intended use. The Glenius implant design is based on a preoperative plan generated from a computed tomography (CT) scan. Each Glenius implant is made exclusively for a particular patient, so no two Glenius implants are alike.



What do you need to know?

Safety



For safe use of the glenoid 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 on 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 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 glenoid 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 shoulder 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, and infection.

Other risks include:

- Insufficient bone reconstruction (osteolysis, osteomyelitis, osteoporosis), inhibited vascularization (the process of new blood vessels forming properly), or infection that may result in implant failure.
- Material sensitivity reactions — when suspected, material sensitivity tests are made prior to implantation.
- Hematoma (contusion or bruise).
- Pain, discomfort, and abnormal sensation related to the implant. This usually resolves itself but can take weeks or months. Some people have a permanent change in sensation of the area surrounding the implant.
- Loosening or migration of the implant due to trauma or loosened fixation devices that keep the implant in place.
- Perforation or fracture of the scapula (shoulder blade) during or after surgery caused by trauma.
- Reduction of mobility due to damage to the bone, calcification of joints, or incorrect placement of the implant or its components.
- 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:

- Pain or swelling at the implantation site.
- Skin redness, inflammation, or infection at the implantation site.
- Sudden inability to move your arm.

What is the expected lifetime of your medical device?

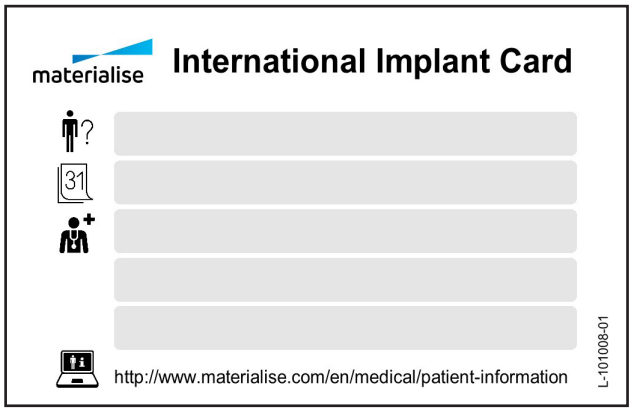
There are no expected effects of aging on the shoulder implant. The implant has been mechanically tested to withstand a minimum of ten years of average use.

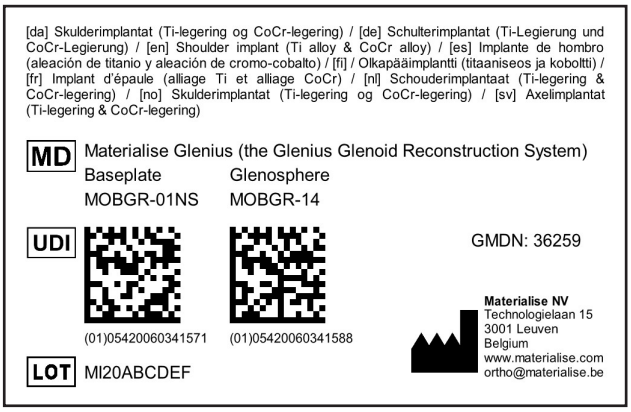
To prolong the lifetime of your device, do not put heavy stress on the implant, such as lifting, until it has adequately healed and properly settled in the correct location. Consult your healthcare practitioner for your specific guidelines.

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.

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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

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