Patient information MUTARS® Knee System

Knee system of the MUTARS® Tumor and Revision System (cementless and cemented)

Dear Patient,

You recently received an implant from the company implantcast GmbH. Below you will find some information regarding your implant. You can find more information in the patient section on our homepage: **https://www.implantcast.de/en/for-patients/**

Possible risks, complications, and service life

The materials used for implants are not as resilient as the natural bone structures and joints. They have a limited service life. The service life of an implant generally depends on multiple factors that can either shorten or extend its service life. In particular, body weight and heavy mechanical demands on the affected extremity, for example due to accidents, falls, sports or strenuous activities, will have negative effects. In addition, the use of devices with electric drive motors represents an increased risk of injury. After an overload of this kind, implants can break or fail in some other way. Smooth exertions, such as when cycling or swimming, are recommended. For a good chance of having a long-lived prosthesis, it is important to avoid all kinds of overload. This can require substantial changes in your lifestyle.

Factors associated with an increased likelihood of failure are:

- → Excessive strain on the operated joint due to strenuous physical labor and/or unsuitable sporting activities
- → Severe deformities which lead to an impairment of bone fixation or the exact positioning, or the function of the implant
- → Therapies that degrade bone quality
- → Muscular insufficiency
- → Untreated vascular diseases of the affected limb
- → Metabolic disorders that may impair bone formation
- → Neuromuscular diseases in the affected limb
- → Conditions that restrict the patient's ability or willingness to comply with medical instructions, especially during the healing process
- → Obesity
- → Smoking
- → Taking drugs
- → Alcoholism
- → Previous surgeries on the affected limb
- → Diabetes
- → Psoriasis
- → Status post infection
- → Injection of corticosteroids into the affected joint

Following the implantation, further surgically invasive procedures (reoperations) such as the replacement of individual components or even the replacement of the entire endoprosthesis may be necessary. This depends on the reason for the revision.

As with any medical application, negative side effects and complications may occur with the implantation of a joint replacement. All types of endoprosthesis can fail for a number of reasons, including accidents, infections, aseptic loosening, dislocation of components, or wear.

As the wearer of a prosthesis, you should seek early treatment for all infections (e.g. of the teeth or urinary tract). By using follow-up examinations as they are offered, you can detect potential complications at an early stage. Inform your physician immediately of any unusual changes in the area of the surgery.

Under normal conditions of use, the following survival rates* (service life) can be expected for the **MUTARS® Knee System**:

Years	MUTARS® Knee System
1	96,7 %
3	90,2 %
5	82,7 %
10	72,4 %

*All survival rates are based on the revision rate data from the 2020 annual report of the Finnish Arthroplasty Register (FAR)..

Silver coating

This medical device may contain a silver coating. If the patient desires to have children or is pregnant, implants with a silver coating must not be implanted, since the risks for unborn children with regard to silver-coated implants have not been studied. The possible undesirable side effects of silver-coated implants are allergic reactions and argyria. Argyria is a side effect that can occur when excessive silver is present in tissue as the result of deposits of silver ions. This is made visible by an irreversible gray-blue discoloration of the skin. Circulatory disorders can possibly increase the risk of argyria. Argyria is neither harmful to patient health nor connected to tissue damage or disorders. Nevertheless, the associated discoloration of the skin can possibly be a psychological burden.

Information regarding medical tests

Before undergoing magnetic resonance imaging (MRI), for example, or any other medical examinations, please inform your physician about your joint replacement. Your joint replacement has not been assessed for its safety and compatibility in an MRI environment. Its safety in an MRI environment is unknown. Therefore, it is not possible to rule out harms from MRI scans.

One or more components of this device contains the following substance(s) defined as CMR 1A and/or CMR 1B and/or endocrine-disrupting substances in a concentration above 0.1% weight by weight:

→ Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

According to current scientific evidence, medical devices made from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or have deleterious effects on reproductive ability.

This product contains the following material or substance that could cause sensitivity or an allergic reaction in the patient:

→ Nickel; CAS No. 7440-02-0; EC No. 231-111-4

There is the possibility of an increase in the metal ion concentration in breast milk and the blood of the fetus in nursing or pregnant patients.

Information about the implant card

Refer to your implant card for information that identifies all the components used in your endoprosthesis as well as each of the materials used. Always carry your implant card with you. It may be very helpful in case of any joint injuries or complications. You must also present this card at some security checkpoints, for example in airports.

For more information on each of the materials used, visit our homepage at the following link:

https://www.implantcast.de/en/company/technology/

The symbols used on your implant card are explained below:

	Patient name		Manufacturer
MD	Medical device	LOT	Lot designation
	Outpatient clinic or physician	SN	Serial number
	Date	UDI	Unique product identifier
	Internet page with patient information	UDI-DI	Product and manufacturer identification according to HRI format
Mat.	Material	REF	Catalog number
	Sales partner		

Best wishes from implantcast.

Manufactured in Germany.

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