Patient information Metal Augments

EPORE® augments (EPORE® acetabular spacer 8 mm, EPORE® buttress and shim augment, MUTARS® PRS, MUTARS® PRS reinforcement cage, ic restrictor acetabulum)

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: **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 strong mechanical loading on the affected limb, for example due to accidents, falls, sports, or strenuous activities, will have negative effects. Depending on the situation (e.g., a fall), the use of a device with electric drive, such as an e-scooter, can cause the strong mechanical loading/overloading of the affected limb described above. After an overload of this kind, implants can break or fail in some other way. Low-impact activities, such as 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.

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 an endoprosthesis, 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.

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 anchorage or the exact positioning, or the function of the implant
- → Therapies that degrade bone quality
- → Muscle insufficiency
- → 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
- → Nicotine and/or drug abuse
- → Alcoholism
- → Previous surgeries on the affected limb
- → Diabetes
- → Psoriasis
- → Previous intra-articular injection of corticosteroids
- → Status post infection

Survival rate of the revision hip arthroplasty (first revision) [in %] depending on the anchorage of the primary arthroplasty (95% confidence interval)

Years since first revision	Cemented (cemented cup + cemented stem)	reverse hybrid (cemented cup + cementless stem)
1	94,10 (93,61, 94,55)	93,96 (92,16, 95,35)
3	90,54 (89,91, 91,13)	90,18 (87,91, 92,05)
5	88,73 (88,03, 89,40)	*85,01 (80,86, 88,32)*
10	84,97 (83,95, 85,93)	*85,01 (80,86, 88,32)*

Years since first revision	Cemented (cementless cup + cementless stem)	Hybrid (cementless cup + cemented stem)
1	94,59 (94,25, 94,91)	93,09 (92,46, 93,67)
3	90,42 (89,96, 90,85)	89,03 (88,23, 89,79)
5	88,33 (87,83, 88,82)	*86,85 (85,93, 87,71)*
10	84,7 (84,05, 85,33)	*83,09 (81,08, 84,29)*

.**The survival rates are based on the revision rate data from the 2021 annual report of the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR).
***95% CI: A 95% confidence interval (CI) means that there is a 95% probability that the survival rate lies within the specified range.

Information regarding medical tests

Before undergoing magnetic resonance imaging (MRI), for example, or any other medical tests, please inform your physician about your endoprosthesis. 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 harm 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

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:

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
31	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.

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Manufactured in Germany.

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