PATIENT LEAFLET

ARTHRODESIS IMPLANTS

VALID FOR: AUSTRALIA

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REVISION: 0

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1. IDENTIFICATIONS

1.1. IDENTIFICATION OF THE MANUFACTURER

MANUFACTURER NAME	implantcast GmbH
ADDRESS	Lueneburger Schanze 26 21614 Buxtehude Germany
TELEPHONE NUMBER	+49 4161 744-0
FAX NUMBER	+49 4161 744-200
WEBSITE	www.implantcast.de

1.2. IDENTIFICATION OF THE SPONSOR (IMPORTER)

SPONSOR NAME	Lifehealthcare Distribution Pty Ltd
ADDRESS	Level 8/15 Talavera Road North Ryde NSW 2113 Australia
TELEPHONE NUMBER	+61 1800 060 168
WEBSITE	www.lifehealthcare.com.au

1.3. IDENTIFICATION OF THE DEVICE

This patient leaflet is applicable for the following components:

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® RS arthrodesis implant femoral component	$TiAl_6V_4$ acc. to ISO 5832-3	67700011; 67700021	
MUTARS® RS arthrodesis implant femoral component silver	$TiAl_6V_4$ acc. to ISO 5832-3, silver coated	67700011S; 67700021S	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® RS arthrodesis implant tibial component	$TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2	67700031	
MUTARS® RS arthrodesis implant tibial component silver	$TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2, silver coated	67700031S	
MUTARS® arthrodesis	$TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2	57300162	
MUTARS® arthrodesis silver	$TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2, silver coated	57300162S	
MUTARS® tibial plate	CoCrMo acc. to ISO 5832-4, TiN coated	57300164N	
MUTARS® arthrodesis screws	$TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2	57300163	

No known manufacturing residuals that could pose any health hazard are on the listed devices.

2. INTENDED PURPOSE

The MUTARS® Arthrodesis is a non-articulating replacement for the knee joint intended to be implanted after failed knee arthroplasty and which functions as a bridge between the resected metaphysis of the femur and tibia.

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The MUTARS® Silver products are silver-coated endoprostheses. The silver-coated surface forms a long-term prophylaxis against colonization with human pathogenic bacteria.

3. INDICATIONS

The decision for replacement of the joint should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising.

Danger of post-operative complications can be limited by careful evaluation of the individual anatomical and load conditions, the condition of the soft tissues and the condition of the bone bed for the implants.

The provision of the Arthrodesis Implants is generally indicated only in patients whose skeleton is fully grown.

Before intervention, preoperative examinations should be performed. The examinations depend on the patient's medical history.

To re-establish the full anatomical skeletal function, it may be necessary to readjust any traumatized or diseased bone segment, attach it to present fragments or substitute in by implant components.

Under consideration of these conditions the Arthrodesis Implants applies to the following indications:

- massive bone loss with insufficient skin and soft tissue coverage because of tumors, revisions, fractures or Morbus Gorham,
- a deficit extensor mechanism.

In case of primary tumours an extensive resection, as described by Enneking, into the non-diseased area should be possible to ensure adequate surgical treatment of the disease. If this is not possible other treatment options, such as amputation should be considered. The application of an arthrodesis implant should not lead to intralasional or marginal and therefore inadequate therapy.

In case of bone metastasis, the indication is related to the physical condition of the patient. If a resected part of the skeleton cannot take the normal anatomical loading and if simple osteosyntheses will not provide sufficient stability, the implantation of a tumour system may help to re-establish the function quickly and to improve the quality of life of the patient. In case of a multiple osseous affection the indication for the use of an arthrodesis implant should be limited if a mobilisation of the patient cannot be expected.

In benign diseases the resection of the bone should be limited, and the prosthesis should be seen as a place holder only.

The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

SILVER COATING:

The indication for the implantation of a silver coated orthopaedic implant should be made carefully. Patients with a weakened immune system caused by bone marrow suppression after chemotherapy or radiotherapy, generally weakened immune system and chronic inflammation and infection may present an increased risk when implanting an orthopaedic implant.

The MUTARS® Silver is for single use only. The MUTARS® Silver is for cementless and cemented use.

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4. CONTRAINDICATIONS (CONDITIONS IN WHICH THE IMPLANTS SHOULD NOT BE USED)

The longevity of an orthopaedic implant can be reduced by biological aspects, material characteristics and biomechanical factors. Therefore, a careful examination of the indications is recommended in overweight patients, in patients with very high joint loads due to high physical activity as well as in patients younger than 60 years.

The Arthrodesis Implants are contraindicated in cases of:

- Allergy to one of the implant materials. (The label on the secondary packaging of the respective component indicates the materials used. It is strongly recommended to perform an allergy test.)
- Ongoing infections
- Physiological or anatomic conditions, which preclude or are not expected to maintain an adequate bony support of the implant or do not allow the implantation of a sufficiently large prosthesis
- Bone tumors in the implant fixation area
- Untreated vascular diseases which limit blood supply to the affected limb
- Metabolic disorders that may impair bone formation

  In case of insufficient quantity and quality of bone stock, an alternative prosthetic treatment allowing for sufficient bony fixation should be considered
- Contralateral knee amputation
- Ipsilateral hip arthrodesis
- Ipsilateral degenerative hip or ankle as well as spine changes
- Endoprosthesis or arthrodesis of the contralateral extremity

SILVER COATING:

MUTARS® components with silver coating should not be used in patients who are sensitive or allergic to silver.

A silver coated implant should not be implanted during pregnancy or planned pregnancy, as the risks for the unborn child were not tested in conjunction with the silver coating. Same applies to patients with impaired blood-brain barrier, since the interactions of the silver ions with nerve tissue are not sufficiently known.

Neurological diseases (such as MS or epilepsy) as well as limited liver and kidney functions are also a contraindication for the implantation of silver-coated implants.

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5. TARGET POPULATIONS

Patients, that meet the indications given in this instruction for use and for whom the implantation of Arthrodesis Implants is a suitable therapy. The treating surgeon decides whether and which version of the implant is suitable for each patient. This decision depends on several factors, such as the patient's age and weight, bone quality, shape of the bone and deformation of the joint.

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6. PRODUCT DESCRIPTION

The MUTARS® Arthrodesis component serves for bridging the knee joint and form a knee arthrodesis prosthetically. The arthrodesis component consists of three parts: dorsal component, ventral component, axis. The two parts are connected to each other with the MUTARS® Arthrodesis Screws. The Axis serves for interlocking with screws.
The MUTARS® Tibial Plate component serves as the bearing Surface for the MUTARS® Arthrodesis component if needed. For fixation with the tibia two pins are incorporated on the backside.

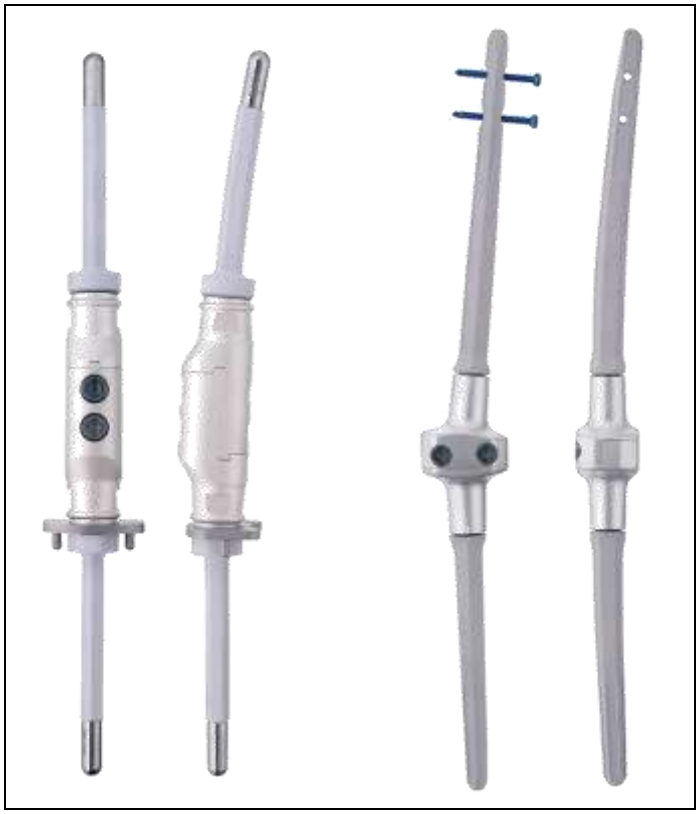

Figure 1: MUTARS® Arthrodesis System (Left) and MUTARS® RS Arthrodesis System (Right)

The materials used for implants are not as resilient as the natural bone structures and joints. They have a limited lifetime. The expected lifetime of the implant generally depends on several factors that can shorten or lengthen it. Some of these factors are the patient's health, activity level and exact implantation of the product.
Subsequently, minor surgically invasive procedures, such as the replacement of individual components, may be necessary or the implantation of a completely new implant may be necessary. This depends on the reason for the revision.

7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

The following risk factors may affect the success of the Arthrodesis Implants:

- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Severe deformities which lead to an impairment of bone fixation or the exact positioning or the function of the implant
- Therapies that may affect bone quality
- Muscle insufficiency

- Neuromuscular disease of 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

The following procedure-related complications (side-effects) can be associated with orthopaedic surgeries:

- Wound hematoma and delayed or impaired wound healing
- Cardiovascular disturbances, venous thrombosis, pulmonary embolism, stroke
- Renal (kidney), urinary, hepatic (liver) or gastrointestinal complications
- Respiratory disorders
- Blood loss requiring transfusions

As with all surgical interventions side effects (negative effects) and complications can occur with the implantation of the Arthrodesis Implants.

In the following the most frequent side effects and complications are listed, which can occur in connection with the implantation of Arthrodesis Implants.

- Subluxation, dislocation or instability
- Implant subsidence or early loosening
- Periprosthetic fractures. Bone fractures can occur intraoperatively or due to implant loosening, overload as well as one-sided joint load
- Heterotopic ossification
- Injury of surrounding blood vessels, soft tissue or nerves with temporary or continuing nerve malfunctions
- Infection (such as acute postoperative wound infections, deep infections with possibility of sepsis, cellulitis (bacterial infection of the skin and tissues underneath the skin))
- Inflammation, such as synovitis, bursitis, adhesive capsulitis (adhesion)
- Adverse local tissue reaction (ALTR) to foreign body or abrasion particles

- Allergic reactions to the implant materials
- Separation of modular components
- Deformities or breakage of an implant
- MRP (metal-related pathology) due to corrosion and/or fretting
- Fretting and/or corrosion of the modular connections
- Lengthening or shortening of the affected extremity
- Pain
- Increased pelvic tilt
- Foot drop

SILVER COATING:

The risk factors which can adversely affect the success of the silver coating include loss of efficiency due to incorrect application (e.g. flushing with an antiseptic that contains iodine). Therefore, observance of intra-operative instructions is of particular importance.

Possible adverse effects include allergic reactions and argyria. Argyria is a complication where a too high silver concentration causes silver ions to be deposited in tissues; this can cause an irreversible grey-blue discoloration of the skin. Circulatory disturbances may increase the risk of argyria.

Argyria is not dangerous to health and not linked with tissue damage or functional disorders. However, the discoloration of the skin can cause severe psychological stress for the person affected.

The manufacturer or its representative should be notified of any complication or adverse event that may have been caused by or contributed to by the silver coated implants.

Complications and / or any unsatisfactory or negative results can also be attributed to an incorrect indication for use, improper patient selection, errors in surgical technique, improper selection of components, and / or concomitant medical conditions. The treatment thereof is the responsibility of the surgeon and neither the manufacturer nor its distributor and/or agent can be held liable for this.

Warnings:

	*"Single use only"*		*"Attention"*
	*"Do not re-sterilise"*		*"Read the instructions for use"*

	*"Do not use in case of damaged packaging"*		*"Use before date"*
	*"Contains hazardous substances"*		

8. MAGNETIC RESONANCE COMPATIBILITY

The Arthrodesis Implants have not been evaluated for safety and compatibility in the MR environment. Please tell your doctor or inform healthcare staff if you are asked to undergo any sort of MRI scan, that you have this implant. Scanning a patient who has this device may result in patient injury.

9. POST-OPERATIVE INFORMATION

Post-operative patient care, patient instructions and warnings are of the utmost importance.

The use of an external support of the operated extremity for a limited period is recommended.

Active and passive movements of the operated extremity should be monitored.

The post-operative regime should be aimed at the prevention of overloading of the operated extremity and stimulation of the healing process.

Regular monitoring of the position and condition of the prosthetic components and the surrounding bone is recommended.

10. PATIENT INFORMATION

The treating surgeon must inform the patient before surgery about any alternative surgical treatments and about all aspects of the surgery and the implant, including known complications and side effects and their consequences.

Additionally, the treating surgeon must inform about the post-operative limitations. Patients should be informed by their surgeon that the results and durability of their implant are related to patient compliance, patient weight and the physical activities.

The patient should be made aware of post-operative limitations including the consequences of over-loading of the joint by excessive weight, strong mechanical load on the affected extremity, high levels of physical activities and that the patient should adapt his / her lifestyle to these limitations. The patient should be instructed how to adapt the activities accordingly.

The patient should be told that any kind of high-loading sports should be avoided with the operated joint and that implants can break after such excessive loads or otherwise fail.

Depending on the situation (e.g. fall), the use of a device with electric drive, such as an e-scooter, can cause the strong mechanical load / overloading of the affected extremity described above.

The patient should be informed that the instructions of the treating physician for the time after the operation must be strictly followed.

The patient should be noted to immediately inform his doctor if he notices unusual changes in the surgical area.

All information provided to the patient should be documented in writing by the operating physician.

Information to be supplied to the patient with an implanted device is available on our homepage under the following link:

https://www.implantcast.de/en/for-patients/

11. INCIDENT REPORTING

In case of unusual changes in the surgical area your treating physician should be informed.

If you experience any serious problem, incident or malfunction related to your implant, please report this information to the manufacturer or its Australian sponsor via:

Contact information	Manufacturer	Sponsor
Address	implantcast GmbH Lueneburger Schanze 26 21614 Buxtehude Germany	Life Healthcare Pty Ltd Level 8, 15 Talavera Road, North Ryde, NSW 2113
E-Mail	MDVS@implantcast.de	quality@lifehealthcare.com.au
FAX	+49 4161 744 201	+61 2 8114 1599

And also report to the Therapeutic Goods Administration at http://www.tga.gov.au/reporting-problems.

Address:
TGA
GPO Box 100
Woden ACT 2606

For product complaints:
Phone: 1800 809 361

E-mail: iris@health.gov.au