PATIENT LEAFLET

MUTARS® RS REVISION SYSTEM

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	
MUTARS® RS proximal component incl. safety screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	67101527; 67101535; 67101627; 67101635	

MUTARS® RS proximal component silver incl. safety screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	67101527S; 67101535S; 67101627S; 67101635S	
MUTARS® RS metaphyseal component	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	67304021; 67304321; 67305021; 67305321	
MUTARS® RS metaphyseal component HA	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3 with implaFix® HA; HA coating acc. to ISO 13779-2	67304121; 67304221; 67305121; 67305221	
MUTARS® RS stem cementless HA	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3 with implaFix® HA; HA coating acc. to ISO 13779-2	67621512; 67621514; 67621516; 67621518; 67621520; 67622012; 67622014; 67622516	

MUTARS® RS stem cementless HA with locking screw holes	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3 with implaFix® HA; HA coating acc. to ISO 13779-2	67622016; 67622018; 67622020; 67622022; 67622518; 67622520; 67622522	
MUTARS® RS stem cemented TiN	CoCrMo acc. to ISO 5832-4 with TiN coating	67601212N; 67601412N; 67601612N; 67601812N; 67601215N 67601415N; 67601615N; 67601815N; 67611220N; 67611420N; 67611620N; 67611820N	
MUTARS® RS extension piece HA	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3 with implaFix® HA; HA coating acc. to ISO 13779-2	67300125	
MUTARS® RS screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	67201008; 67201158; 67201258; 67204008; 67205008; 67206508; 67207508; 67209008	

MUTARS® RS coupling device	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57720030	
MUTARS® RS coupling device silver	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57720030S	
MUTARS® screw for RS coupling device	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57920060 57920080 57920100 57920120 57920140	
MUTARS® intramed. connecting module for GenuX® femur	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57215180 57215200 57215220 57215240 57215260 57215280 57215300 57215320 57215340 57215360 57215380 57215400 57215420 57215440	

MUTARS® intramed. connecting module for KRI	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57205100 57205120 57205140 57205160 57205180 57205200 57205220 57205240 57205260 57205280 57205300 57205320 57205340 57205360	
cortical screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57924525 57924530 57924540 57924542 57924545 57924550 57924555 57924560	

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

2. INTENDED PURPOSE

The MUTARS® RS Revision System is a modular femoral hip system for primary and revision hip arthroplasty in patients with severe femoral bone deficiencies whose bone stock is inadequate for other more conservative methods of treatment.

MUTARS® RS proximal component is a femoral component intended to replace the proximal part of the femur in proximal or total femur replacement.

MUTARS® RS metaphyseal component and MUTARS® RS metaphyseal component HA are femoral components intended to be placed in the metaphyseal part of the proximal femur. It connects proximally to the MUTARS® RS proximal component. They are intended for cementless application.

MUTARS® RS extension piece HA is intended for intraosseous length adjustment in the area of the proximal and diaphyseal femur. It is intended for cementless application.

MUTARS® RS stems cemented TiN are stems for cemented fixation intended for a diaphyseal anchorage in the femur and in the tibia respectively.

MUTARS® RS stems cementless HA and MUTARS® RS stem cementless HA with locking screw holes are stems for cementless fixation intended for a diaphyseal anchorage in the femur and in the tibia respectively.

MUTARS® RS screws are intended to join components of the MUTARS® RS Hip System.

MUTARS® RS coupling device is intended to provide coupling of a component with the MUTARS® male taper connection to a component with the MUTARS® female cylindrical fit connection.

MUTARS® screw for RS coupling device is intended to join components with the MUTARS® male taper connection with components with the MUTARS® cylindrical fit connection.

MUTARS® intramed. connecting module for KRI and MUTARS® intramed. connecting module for GenuX® femur are placed intramedullary in the diaphyseal part of the femur and connect the proximal and distal femoral components in cases of intramedullary total femur replacement. The MUTARS® intramedullary connecting modules are intended for cementless application.

Bone Screws are intended for screwing into the bone for primary and/or permanent stable anchorage of an implant in case of inadequate primary stability.

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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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 prostheses 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 history.

To ensure firm anchorage and offer full weight bearing of the operated extremity, the implant is usually cemented in the case of elderly patients. In contrast, cementless fixation of the implant is applied in younger patients, who are able to move with partial weight bearing of the operated extremity after surgery.

Under consideration of these conditions the hip joint arthroplasty with the MUTARS® RS system is indicated, if

- severe joint destruction with significant impairment where other therapeutic measures are not more promising.
- severe joint pain due to degenerative or rheumatoid arthritis, joint fractures or bone necrosis. Deformations of the proximal femur due to fractures and osteotomy can be an indication for the MUTARS® RS system.
- post-operative conditions after previous surgery with or without the use of implants.
- Revision surgery in cases of femoral implant component loosening with extended calcar resorption of the proximal femur and enlargened medullary canal or with a large lytic area of the proximal femoral cortex,
- Revision surgery in cases of femoral implant component loosening due to peri/subprosthetic fractures,
- Revision cases of extensive comminuted fractures of the proximal femoral segment, concerning older patients with indicated prostheses but in which cases a sufficient fixation of a standard arthroplasty cannot be performed.

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.

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

The longevity of an orthopaedic joint replacement device can be reduced by biological aspects, material characteristics and biomechanical factors. Patient selection and indication should be carefully monitored especially in patients who are overweight, patients with high physical activity levels and patients younger than 60 years of age.

An absolute contraindication is a known allergy to any of the implant materials used. The label on the secondary packaging of each component specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.

Another absolute contraindication is infection.

The relative contraindications include:

- 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.
- Insufficient quantity and quality of bone stock, e.g., as a result of osteoporosis or osteomalacia
- Vascular disease of the affected limb
- Metabolic disorders that can affect a stable anchorage of the implant
- Bone tumors in the implant fixation area
- Neuromuscular diseases that can impair the affected limb
- Lack of patient compliance
- Mental or neurological conditions that affect the ability or willingness of patients to comply with medical instructions, especially during the healing phase
- Obesity
- severe arthropathy of the femoral diaphysis, that prevents a stable anchorage of the prothesis
- revision in septic environment
- an insufficient intact diaphysis which is needed for the preparation of the prosthesis bearing area.

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

The target group is patients that meet the indications given in the associated Instructions for Use and for whom the implantation of MUTARS® RS Revision System is a suitable therapy. The attending medical doctor decides if the product is suitable for the individual patient, and which implant is to be used. 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® RS System is a modular femoral hip system for primary and revision hip arthroplasty in patients with severe femoral bone deficiencies whose bone stock is inadequate for other more conservative methods of treatment. The MUTARS® RS System includes the following components:

- MUTARS® RS proximal component incl. safety screw,
- MUTARS® RS metaphyseal component,
- MUTARS® RS extension piece,
- MUTARS® RS screws,
- MUTARS® RS stems cemented and cementless,
- MUTARS® RS coupling device and MUTARS® screw for RS coupling device,
- MUTARS® intramed. connecting module for KRI and MUTARS® intramed. connecting module for GenuX® femur,
- cortical screws.

The individual components are connected by means of a cylindrical fit and serration connection and a Morse-type taper connection and connecting screws (MUTARS® RS screws).

The MUTARS® RS proximal component is a femoral component that replaces the proximal part of the femur including the femoral neck. It is an extraosseous component.

The MUTARS® RS metaphyseal component is available in two variants to better match the patients' individual anatomy: "standard" which combines a conical shape (cone) and an extended triangle (spout) and "small" with a conical shape.

The MUTARS® RS extension piece is an optional component that serves as an intraosseous length adjustment. The extension piece has a cylindrical cross-section.

The MUTARS® RS stem cementless has a collarless, curved, and tapered stem design. The proximal area of the stem has a hexagonal cross section while the distal area has longitudinal ribs, which provide a star-shaped cross section for additional rotational stability. Stems of lengths 200 and 250 mm and with diameters of 16 - 22 mm and 18 - 22 mm, respectively, have two distal interlocking screw holes for placement of cortical screws for additional fixation if required.

The MUTARS® intramed. (intramedullary) connecting module for KRI is used in cases of intramedullary femur replacement in which the femoral diaphysis is preserved, and the proximal femur and knee joint are replaced by endoprostheses, which are then connected using this intramedullary rod.

The MUTARS® intramed. connecting module for GenuX® femur has the same design characteristics as the MUTARS® intramedullary connecting module for KRI. The only difference is that the MUTARS® intramed. connecting module for GenuX® femur is designed to be connected to the MUTARS® GenuX® Femur instead of the MUTARS® KRI.

LEFT: MUTARS® RS PROXIMAL COMPONENT WITH MUTARS® RS METAPHYSEAL COMPONENT HA, MUTARS® RS EXTENSION PIECE HA AND MUTARS® RS STEM CEMENTLESS HA WITH LOCKING SCREW HOLES

IN THE MIDDLE: MUTARS® RS PROXIMAL COMPONENT + MUTARS® RS METAPHYSEAL COMPONENT + MUTARS® RS EXTENTION PIECE WITH MUTARS® INTRAMED. CONNECTING MODULE FOR KRI AND MUTARS® KRI

RIGHT: MUTARS® RS PROXIMAL COMPONENT + MUTARS® RS METAPHYSEAL COMPONENT + MUTARS® RS EXTENTION PIECE WITH MUTARS® INTRAMED. CONNECTING MODULE FOR GENUX® FEMUR AND MUTARS® GENUX®

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7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

The following risk factors may affect the success of joint replacement:

- Nicotine and/or drug abuse
- Alcoholism
- Muscle insufficiency

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

As with all medical interferences, side effects (negative effects) and complications can occur with the implantation of the MUTARS® RS system. In the following the most frequent side effects and complications are listed, which can occur in connection with an implantation of the MUTARS® RS system.

- Dislocation and loosening of the prosthesis
- Tissue reactions to allergies or foreign body reactions to abrasion particles
- Injury of nerves and vessels with temporary or continuing nerve malfunctions
- wound hematoma and delayed wound healing
- Cardiovascular disturbances, venous thrombosis and pulmonary embolism
- Acute postoperative wound infections and late infections with possibility of sepsis
- Subluxation or luxation of the implant. This may cause severe pain and an abnormal positioning.
- Instability
- Periprosthetic fractures. Bone fractures can occur intraoperatively and as a consequence of an implant loosening or due to overload as well as one-sided joint load.
- Separation of modular components
- Wear of articulating components
- Deformities or breakage of an implant
- Fretting and/or corrosion of modular connections
- Heterotopic ossification
- secondary sign of wear can occur on articulation surface of the joint after implantation of a hemiprosthesis

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 implant or the instrumentation.

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.

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:

	*“Do not re-use“*		*„Caution"*
	*“Do not resterilize“*		*„Read the instructions for use"*
	*„Do not use if package is damaged and consult instructions for use"*		*„ Use-by date"*
	*“Contains hazardous substances”*		

8. MAGNETIC RESONANCE COMPATIBILITY

The MUTARS® RS Revision System has not been evaluated for safety and compatibility in the MR environment. The MUTARS® RS Revision System has not been tested for heating, migration, or image artefact in the MR environment. The safety of the MUTARS® RS Revision System in the MR environment is unknown. 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 limb for a limited period is recommended.

Active and passive movements of the patient should be monitored.

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

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

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10. PATIENT INFORMATION

The attending medical doctor 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 attending medical doctor must inform about the postoperative limitations. Patients must 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 must be made aware of postoperative limitations including the consequences of overloading of the joint by excessive weight, strong mechanical load on the affected limb, high levels of physical activity, and it must be pointed out to them that they should adapt their lifestyle to these limitations. The patient should be instructed how to adapt the activities accordingly.

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

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 loading/overloading of the affected limb described above.

The patient must be informed that the instructions of the medical doctor for the time after the operation must be strictly followed.

The patient should be told 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 medical doctor.

Information to be supplied to the patient with an implanted device is available on our website 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