PATIENT LEAFLET

MUTARS® ACETABULAR CUP SYSTEMS

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® LUMiC® cup incl. safety screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57110050; 57110054; 57110160	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® LUMiC® cup silver incl. safety screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57110060S	
MUTARS® LUMiC® stem cementless HA	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3 with implaFix® HA; HA coating acc. to ISO 13779-2	57111065; 57111075; 57111085; 57111865; 57111875; 57111885	
MUTARS® LUMiC® stem cemented	implavit®; CoCrMo acc. to ISO 5832-4	57112865; 57112875; 57112885	
MUTARS® LUMiC® screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57111002	
MUTARS® RS cup	$TiAl_6V_4$ with EPORE®	57120546; 57120550; 57120554; 57120558; 57120562; 57120046; 57120050; 57120054; 57120058; 57120062	
implacross® PE insert 15° neutral 0mm	implacross®, crosslinked UHMW-PE	02273239; 02273644; 02273648; 02273652	
implacross® PE insert 15° offset 4mm	implacross®, crosslinked UHMW-PE	02283239; 02283644; 02283648; 02283652	

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

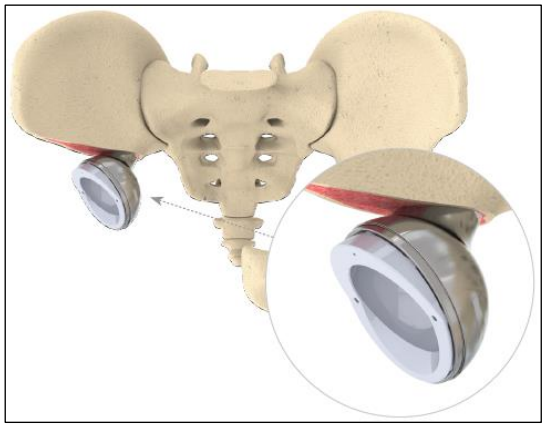
2. INTENDED PURPOSE

MUTARS® LUMiC® cups are acetabular components of the MUTARS® LUMiC® cup system. The MUTARS® LUMiC® cup system is a modular acetabular reconstruction system, which restores hip function after massive acetabular bone loss (hemipelvectomy) or severe acetabular defects.

MUTARS® LUMiC® stem cemented is a stem for cemented fixation intended for anchorage of the MUTARS® LUMiC® cup in the Os ilium. MUTARS® LUMiC® stem cementless HA is a stem for cementless fixation intended for anchorage of the MUTARS® LUMiC® cup in the Os ilium.

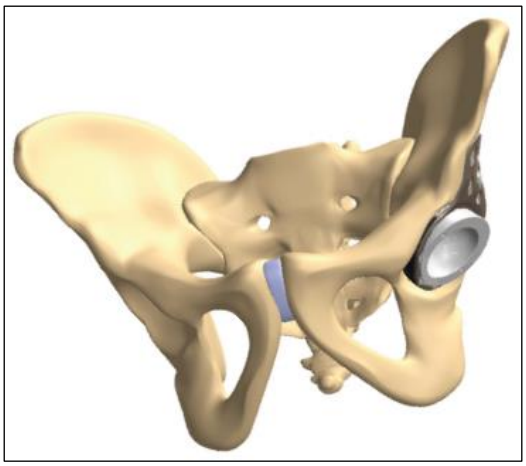
MUTARS® LUMiC® screw is intended to connect MUTARS® LUMiC® cup to a MUTARS® LUMiC® stem.

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



MUTARS® RS cup is an acetabular cup, which is used in cases of large acetabular bone defects. The cup bridges the defect zone of the damaged acetabulum and allows for stabilization of the hip joint area. The MUTARS® RS cup is intended for cementless application.

Implacross® PE insert 15° neutral 0mm and implacross® PE insert 15° offset 4mm are acetabular cup inserts intended to articulate with a femoral head prosthesis.



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.

The MUTARS® LUMiC® acetabular cup system is a modular acetabular reconstruction system, which restores hip function after massive acetabular bone loss (hemipelvectomy) or severe acetabular defects. 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.

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 should be considered. The application of the MUTARS® LUMiC® system 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 osteosynthesis 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 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.

Under consideration of these conditions the hip joint replacement with MUTARS® LUMiC® acetabular cup system applies to the following indications:

- type II pelvectomy according to Enneking.

For the hip joint replacement with the MUTARS® RS cup applies to the following indications:

- large cavitary or segmental acetabular defects (up to type IIIa/IIIb of Paprosky classification)
- Non- inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Post-traumatic osteoarthritis,
- Fractures,
- Rheumatoid arthritis.

For the reconstruction of the bone defects the application of allogenic bone grafts may be required when using the MUTARS® RS cup.

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 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.

Further absolute contraindications are infections.

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

SILVER COATING

MUTARS® components with silver coating should not be used in patients who are sensitive or aller-gic 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 POPULATION

The target group is patients that meet the indications given in the associated Instructions for Use and for whom the implantation of the MUTARS® LUMiC® Cup System or the MUTARS® RS Cup 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

MUTARS® LUMiC® Cup System

The MUTARS® LUMiC® Cup System is a modular system for acetabular reconstruction that is indicated in revision cases when severe acetabular defects are present. Additionally, the MUTARS® LUMiC® Cup System can be used for the reconstruction of bone defects after tumor resection.

The MUTARS® LUMiC® Cup System consists of:

- MUTARS® LUMiC® cup and MUTARS® LUMiC® safety screw

- MUTARS® LUMiC® stems
- MUTARS® LUMiC® screw
- implacross® PE inserts 15° neutral 0mm, implacross® PE inserts 15° offset 4mm.

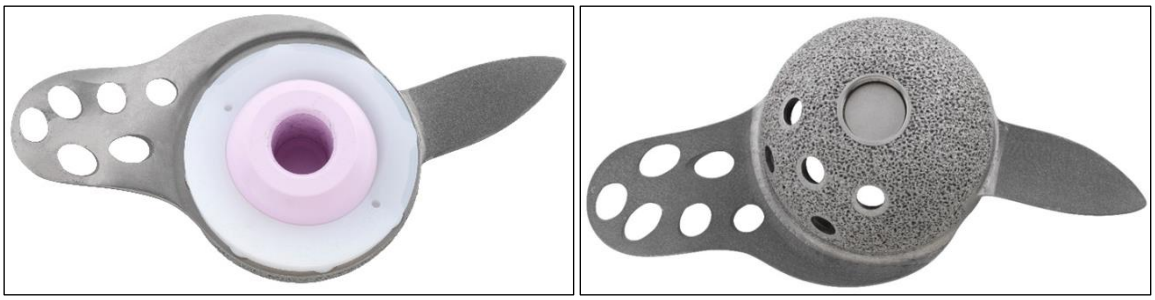
The MUTARS® LUMiC® cup is a hemi-spherical metal shell incorporating a socket with an inner thread for the MUTARS® LUMiC® screw und safety screw. The MUTARS® LUMiC® stem and MUTARS® LUMiC® cup are connected by means of the MUTARS® cylindrical fit and serration connection and a connecting screw (MUTARS® LUMiC® screw). The MUTARS® cylindrical fit and serration connection is provided by a precise male cylindrical fit and a serration of interdigitating teeth. The MUTARS® LU-MiC® screw is axially applied across the connection during component assembly to connect and secure the MUTARS® cylindrical fit connection.

MUTARS® LUMiC® stem cementless HA, MUTARS® LUMiC® Cup with implacross® PE insert 15° and ic-head BIOLOX® delta

MUTARS® RS Cup System

The MUTARS® RS Cups have a spherical design and are flattened at the pole. Their bone facing surface incorporates a highly porous EPORE® structure to enhance bony ingrowth into the implant surface. The MUTARS® RS Cups are intended for cementless application. The MUTARS® RS Cups are to be used in conjunction with the implacross® PE inserts 15° neutral 0mm or implacross® PE inserts 15° offset 4mm.

The MUTARS® RS Cup has two anatomically shaped flanges which allow for fixation of the cup in the vital portion of the os coxae. The cranial flange is attached to the os ilium by means of screws. The caudal flange is anchored (inserted) in the ischium. The MUTARS ® RS cup incorporates a cluster of five cranial screw holes for additional screw fixation if required to support the initial fixation.



MUTARS® RS Cup with implacross® PE insert 15° (on the left); Bone facing side with its porous EPORE® structure (on the right)

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® acetabular cup system.

In the following the most frequent side effects and complications are listed, which can occur in connection with the implantation of the MUTARS® acetabular cup 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
- Lengthening or shortening of the leg.

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 indi-cation for use, improper patient selection, errors in surgical technique, improper selection of compo-nents, 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.

SILBER COATING

The risk factors which can adversely affect the success of the silver coating include loss of efficien-cy due to incorrect application (e.g., flushing with an antiseptic that contains iodine). Therefore, ob-serv-ance 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. Howev-er, 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 indi-cation for use, improper patient selection, errors in surgical technique, improper selection of compo-nents, 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® Acetabular Cup System has not been evaluated for safety and compatibility in the MR environment. The MUTARS® Acetabular Cup System has not been tested for heating, migration, or image artefact in the MR environment. The safety of the MUTARS® Acetabular Cup 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.

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/

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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