PATIENT LEAFLET

IC-RECONSTRUCTION SYSTEM

VALID FOR: AUSTRALIA

DATE: 03.02.2022

REVISION: 0

implantcast GmbH · Lüneburger Schanze 26 · 21614 Buxtehude · Germany
Tel.: +49 4161 744-0 · Fax: +49 4161 744-200
E-mail: info@implantcast.de · Internet: www.implantcast.de

TABLE OF CONTENTS

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	
ic acetabular ring	pure titanium (cpTi) acc. to ISO 5832-2; Grade 1	70001242; 70001244; 70001246; 70001248; 70001250; 70001252; 70001254; 70001256; 70001258	

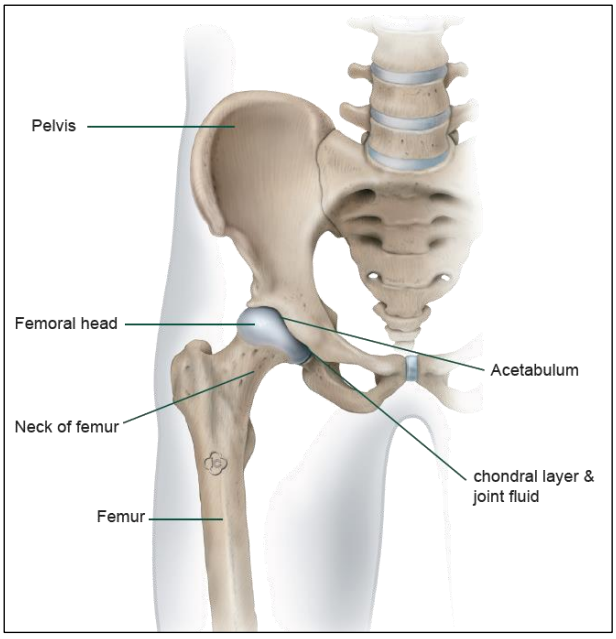
COMPONENT	MATERIAL	MODEL NUMBERS	
ic reinforcement cage	pure titanium (cpTi) acc. to ISO 5832-2; Grade 1	70000244: 70000250; 70000256; 70000262; 70010244; 70010250; 70010256; 70010262	

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

2. INTENDED PURPOSE

The ic-Acetabular Ring and the ic-Reinforcement Cage are intended for reconstruction of the acetabular roof in primary and secondary revision cases to bridge acetabular defects with the use of screws. They are intended for bone-side cementless and implant-side cemented fixation.

Hip Joint



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.

Under consideration of these conditions the hip joint replacement applies to the following indications:

- 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 bone grafts can be required

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.

---

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 compo-nent specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.

Further absolute contraindications are infection and osteomyelitis.

The relative contraindications include:

1) Anatomic conditions, which preclude or are not expected to main-tain 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 osteo-malacia
    - Vascular disease of the affected limb
2) Metabolic disorders that can affect a stable anchorage of the implant
3) Bone tumors in the implant fixation area
4) Neuromuscular diseases that can impair the affected limb
5) Lack of patient compliance
6) Mental or neurological conditions that affect the ability or willing-ness of patients to comply with medical instructions, especially during the healing phase
7) Obesity

5. TARGET POPULATIONS

The target population corresponds to the population likely to benefit from the product in indication for joint replacement. Finally, the surgeon decides whether and which version of prosthesis for the individual patient is suitable. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone, patient's physical activity levels and deformation of the joint. The pro-vision of prostheses is generally indicated only in patients whose skeleton is fully grown.

6. PRODUCT DESCRIPTION

The ic-acetabular ring and the ic-reinforcement cage serve for reconstruction of the acetabular roof for both primary and secondary revision cases. They also help to bridge acetabular defects. An all-poly acetabular cup (“PE- cup Mueller II”) or an “EcoFit® 2M hip cup cemented” is placed into the ic-acetab-ular ring or into the ic-reinforcement cage by the means of bone cement. The acetabular cup serves as the articulating partner for the femoral head.

IC-ACETABULAR RING

IC REINFORCEMENT CAGE

7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

Risk factors

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

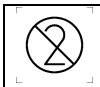
Complications

As with all medical interferences, side effects (negative effects) and complications can occur with the implantation of the reconstruction implants.

In the following the most frequent side effects and complications are listed, which can occur in connection with a reconstruction implants implantation.

- 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

	*“Single use only“*		*„Attention "*
	*“Do not re-sterilise“*		*„Read the instructions for use "*
	*„Do not use in case of damaged packaging "*		*„Use before date"*

8. MAGNETIC RESONANCE COMPATIBILITY

The implants referred to in Section 1.3. "IDENTIFICATION OF THE DEVICE" have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating, migration, or image artefact in the MR environment. The safety of these implants in the MR environment is unknown. Scanning a patient who has this device implanted 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 the position and condition of the prosthetic compo-nents 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.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