PATIENT LEAFLET

ECOFIT® ACETABULAR CUPS 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	PICTURE
EcoFit® cup cementless	implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating	02200046; 02200048; 02200050; 02200052; 02200054; 02200056; 02200058; 02200060; 02200062; 02200064; 02200066; 02200068	
EcoFit® cup HA cementless	implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® Duo; cpTi-coating and HA-coating acc. to ISO 13779-2	02200346; 02200348; 02200350; 02200352; 02200354; 02200356; 02200358; 02200360; 02200362; 02200364; 02200366; 02200368	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
implacross® PE insert 0°	implacross®; crosslinked UHMW-PE	02232839; 02232844; 02232848; 02232852; 02233239; 02233244; 02233248; 02233252; 02233644; 02233648; 02233652	
implacross® PE insert 10º	implacross®; crosslinked UHMW-PE	02242839; 02242844; 02242848; 02242852; 02243239; 02243244; 02243248, 02243252; 02243644; 02243648; 02243652	
BIOLOX® delta cup insert	Al_2O_3 and ZrO_2 acc. to ISO 6474-2	02203239; 02203244; 02203248; 02203252; 02203644; 02203648; 02203652; 02204048; 02204052	

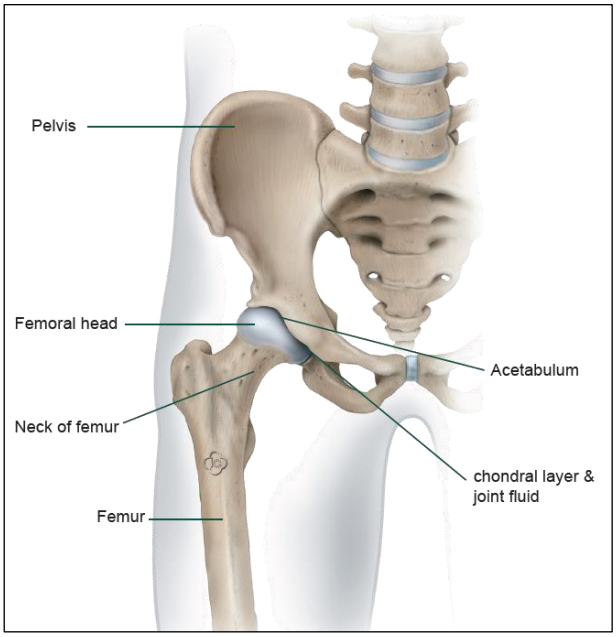
No known manufacturing residuals that could pose any health hazard are on the listed devices.

2. INTENDED PURPOSE

The EcoFit® cups are acetabular components intended to be used in combination with an acetabular insert to replace the natural acetabulum in total hip arthroplasty.

The EcoFit® cups are intended for cementless, press-fit fixation.

The implacross® PE insert 0° and implacross® PE insert 10° are acetabular cup inserts intended to articulate with a femoral head prosthesis. The BIOLOX® delta cup insert is an acetabular cup insert intended to articulate with ic-heads BIOLOX®.



Hip Joint

3. INDICATIONS

The decision for joint replacement 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 an endoprosthesis is generally only indicated 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,
- Treatment of fractures that are unmanageable using other surgical techniques,
- Rheumatoid arthritis.

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

The longevity of orthopaedic implants 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.

Hip joint replacement is 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.
- Severe neuromuscular diseases that strongly impair the affected limb.

In case of insufficient quantity and quality of bone stock, an alternative prosthetic treatment allowing for sufficient bony fixation should be considered.

- Using a BIOLOX® delta insert in combination with an acetabular shell left in situ in a revision surgery is contraindicated. In this case, a polyethylene insert may be used.
- In the event of the fracture of a ceramic component, a combination of metal (ball head) with plastic (insert) as well as metal with metal is contraindicated in a revision.

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5. TARGET POPULATIONS

Patients that meet the indications given in the associated Instructions for Use and for whom the implantation of the hip joint replacement 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

	
EcoFit® cup	**EcoFit® cup HA**

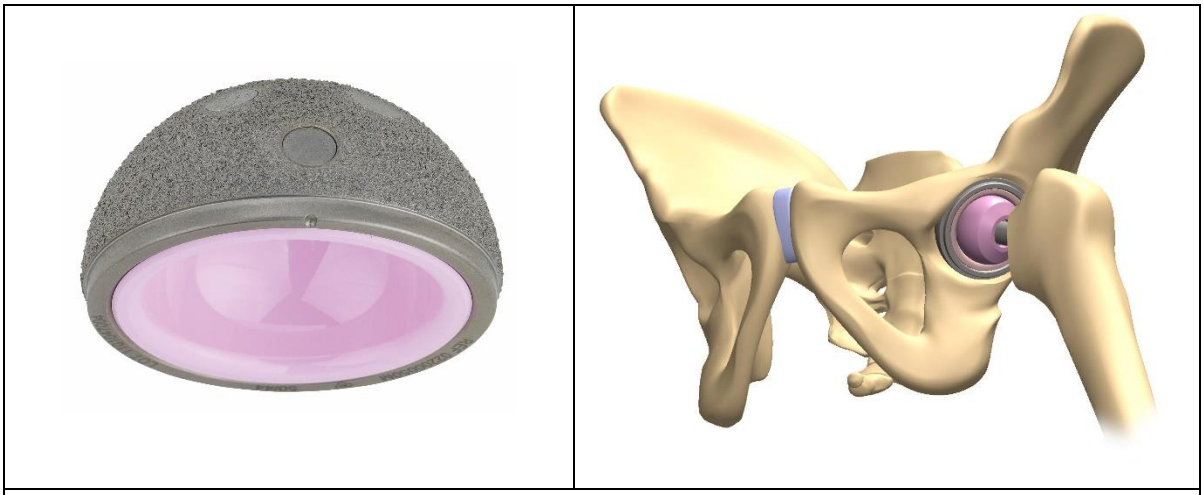
The EcoFit® cups are hemispherical acetabular cups designed to be coupled with polyethylene inserts as well as with BIOLOX® delta cup inserts. The cups incorporate a porous coating on their bone-facing side for the bone ingrowth.

The EcoFit® cups incorporate a cluster of three peripheral screw holes for adjunctive screw fixation. The screw holes are covered with screw-hole plugs, which can be removed intraoperatively if additional screw fixation is required to support the primary fixation.

The implacross® PE inserts are available in two versions: neutral and lipped. The lipped insert version incorporates a 10° lateral lip to provide greater coverage of the femoral head to help prevent dislocation in cases of greater risk of dislocation. The two versions are shown in the figures below.

	
implacross® PE inserts 10°	**implacross® PE inserts 0°**

EcoFit® cup HA with implacross® PE inserts 10°



EcoFit® cup with BIOLOX® delta insert

Expected Lifetime

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.

Under normal conditions the following survival rates (lifetime) are expected for cementless primary total hip arthroplasty (THA) with metal-on-polyethylene (MoP) bearing or with ceramic-on-polyethylene (CoP) bearing. The values are given in the Annual Report (2019) of the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man.

CEMENTLESS PRIMARY THA (MoP)		CEMENTLESS PRIMARY THA (CoP)	
YEARS	SURVIVAL RATE IN % (95% CONFIDENCE INTERVALL)	YEARS	SURVIVAL RATE IN % (95% CONFIDENCE INTERVALL)
3	98,3 (98,2-98,3)	3	98,6 (98,2-98,7)
5	97,8 (97,7-97,9)	5	98,1 (98,0-98,2)
10	96,0 (95,9-96,2)	10	96,8 (96,6-97,0)
15	93,5 (92,9-94,0)	15	93,9 (93,1-94,8)

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.

The expected application period of the endoprosthesis system is not reduced by using the BIOLOX® delta insert.

7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

Risk factors

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

- 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,
- Conditions after infection,
- Diabetes,
- Psoriasis.

Operation Specific Complications (Negative Effects / Side-Effects)

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

Implant Specific Complications (Negative Effects / Side-Effects)

As with all surgical interventions, side effects (negative effects) and complications can occur with the implantation of the hip endoprosthesis.

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

- 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,
- Adverse local tissue reaction (ALTR) to foreign body or abrasion particles,
- Allergic reactions to the implant materials,
- Separation of modular components,
- Excessive wear of articulating components,
- Deformities or breakage of an implant,
- MRP due to fretting and/or corrosion of modular connections,
- Lengthening or shortening of the affected extremity,
- Pain,
- Squeaking and/or clicking noises from the hip (in case of BIOLOX® delta inserts).
  Noise generated during movement after a BIOLOX® delta insert has been implanted is not sufficient to indicate a malfunction or change in the performance of the endoprosthesis system. However, it is recommended to check the integrity of the endoprosthesis system.
- In the case of pathologically altered bone tissue of the operated patient (e.g., Osteosclerosis), there is a risk during impacting of the EcoFit® cup into the bone that the plugs may come loose from the cup.

WARNINGS: In very rare cases, a fracture of the BIOLOX® delta insert may occur. In order to minimize this risk as much as possible, the BIOLOX® delta insert has been individually examined before delivery. One reason a fracture can occur, among others, is due to an incorrect fixation of the BIOLOX® delta insert in the acetabular shell or an incorrect or missing fit between the BIOLOX® delta insert and the acetabular shell. The use of prosthesis components which are not approved by implantcast GmbH for combination with a BIOLOX® delta insert can also lead to a fracture of the BIOLOX® delta insert. The same applies for the non-compliance of the recommended positioning of the acetabular shell. In the very rare case of a fracture of a ceramic insert, there is a risk of injury caused by sharp edges of ceramic fragments during a revision.
For the BIOLOX® delta insert, the risk of fracture (intra-operative or post-operative) was identified as a residual risk specific to the ceramic material. This residual risk was assessed within the risk management system and classified as acceptable within the framework of the overall residual risk.

Short, extreme overloading such as a trauma, an accident or excessive load for example due to extreme sport can result in a fracture of the BIOLOX® delta insert or in harm to the patient

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"*

8. INFLUENCE OF IMAGING TECHNIQUES

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.
The safety and the performance of the implant-components made of polyethylene are unknown after the radiation associated with diagnostic or therapeutic procedures.

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 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:	**For product complaints:**
TGA GPO Box 100 Woden ACT 2606	Phone: 1800 809 361 E-mail: iris@health.gov.au