PATIENT LEAFLET

IC - HEADS

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	PICTURE
ic-head CoCrMo taper 12/14mm	CoCrMo acc. to ISO 5832-12	23122200; 23122205; 23122210; 23872800; 23872805; 23872810; 23872815; 23872820; 23872825; 23873200; 23873205; 23873210; 23873215; 23873220; 23873225; 23873600; 23873605; 23873610; 23873615; 23873620; 23873625	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ic-head Biolox® delta taper 12/14mm	Al_2O_3 and ZrO_2 acc. to ISO 6474-2	25862800; 25862805; 25862810; 25863200; 25863205; 25863210; 25863600; 25863605; 25863610; 25863615; 25864000; 25864005; 25864010; 25864015	
ic-head titanium taper 12/14mm	$TiAl_6V_4$ acc. to ISO 5832-3; *coating*: TiN	27872800; 27872805; 27872810; 27872815; 27872820; 27872825; 27873200; 27873205; 27873210; 27873215; 27873220; 27873225; 27873600; 27873605; 27873610; 27873615; 27873620; 27873625	
ic-bipolar head CoCrMo	Outer Shell: CoCrMo acc. to ISO 5832-4; Inner shell and retain-ment ring UHMW-PE acc. ISO 5834-2	21512238; 21512239; 21512240; 21512241; 21510042; 21510043; 21510044; 21510045; 21510046; 21510047; 21510048; 21510050; 21510052; 21510054; 21510056; 21510058; 21510060; 21510062	

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

2. INTENDED PURPOSE

The **ic-Heads** [(1)] are femoral heads intended for articulation with polyethylene-acetabular cups, polyethylene-acetabular cup inserts or tripolar polyethylene-components as part of a total hip arthroplasty or with ic- bipolar heads CoCrMo as part of a hemi hip arthroplasty. They are connected modularly with hip stems.

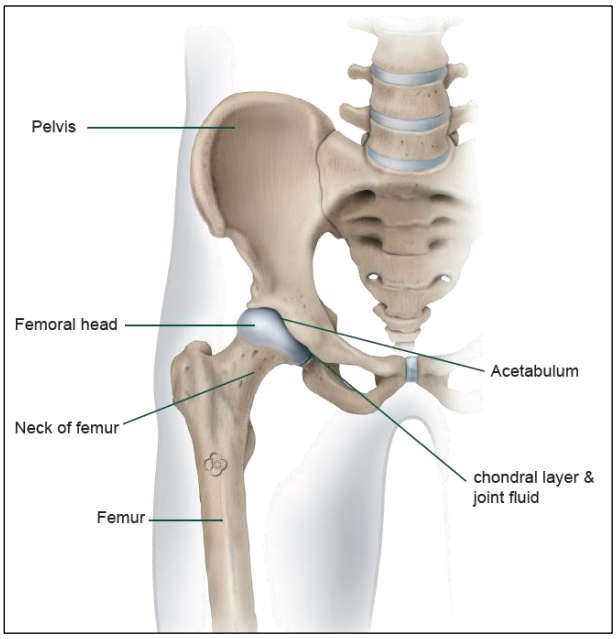
(1) ic- head CoCrMo, ic- head titanium

The **ic- Heads BIOLOX®** [(2)] are ceramic femoral heads intended for articulation with BIOLOX® delta cup inserts, polyethylene-acetabular cups, polyethylene-acetabular cup inserts or tripolar polyethylene-components as part of a total hip arthroplasty or with ic- bipolar heads CoCrMo as part of a hemi hip arthroplasty. They are connected modularly with hip stems.

(2) ic- head BIOLOX® delta

The **ic- Bipolar Head** is a femoral head for the hemi hip arthroplasty. The ic-Bipolar Head is intended to articulate freely with the natural acetabulum on its outer surface, and interface with an ic-head on its inner surface where it allows free rotation of the ic-head.

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 medical 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,
- Femoral neck fracture,

- Rheumatoid arthritis.

Indications for the application of hip heads:

- Primary total hip arthroplasty of the hip joint affected by arthrosis,
- Revision hip arthroplasty.

The area of application for the ic-head BIOLOX® delta comprises:

1. Primary surgeries in combination with new prosthesis stems
2. Revisions (= endoprosthesis removals), i.e. re-operations in combination with new prosthesis stems

The following applies to ic- heads BIOLOX® delta:

Reoperation and revision in the event of a ceramic component fracture

In the extremely rare event of the fracture of a ceramic component, a synovectomy has to be performed whenever appropriate. In this case, a combination of metal (hip head) with polyethylene (insert) as well as metal with metal is contraindicated in a revision. When a polyethylene (plastic) insert is present, it must also be removed and replaced, even if it is well fixed.

The main indications for the insertion of a hemi arthroplasty implant (Bipolar head):

- femoral neck fractures,
- femoral head necrosis.

Hemi-arthroplasty of the hip is indicated for femoral fractures in the vicinity of the hip joint, when femoral head retaining procedures cannot be followed. Hemi-arthroplasty after femoral neck fracture is the procedure of choice in patients over 65. In case of existing arthritis total hip arthroplasty with replacement of the acetabulum is indicated.

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.

The indications of the corresponding endoprosthesis system used must also be considered.

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 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

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

Further contraindication for the insertion of a hemi arthroplasty implant (Bipolar head) is:

- Osteoarthritis

Using an ic-head BIOLOX® delta in combination with a prosthesis stem left in situ in a revision surgery is contraindicated.

The section "Reoperation and revision in the event of a ceramic component fracture " (under “indication”) must be taken into account whenever appropriate.

The contraindications of the corresponding endoprosthesis system used must also be considered.

---

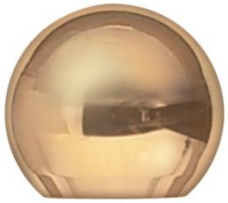
5. TARGET POPULATIONS

Patients, that meet the indications given in the associated instructions for use and for whom the implantation of 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.

6. PRODUCT DESCRIPTION

The ic-heads are spherical modular femoral heads for the connection with the hip stems of the company implantcast. The heads are available in various sizes and neck lengths to match the individual patients' anatomy. Below, variations of the ic- heads are shown.

	IC- HEAD CoCrMo taper 12/14 mm
	IC- HEAD TITANIUM Taper 12/14 mm
	IC- HEAD BIOLOX® DELTA

The ic- bipolar heads CoCrMo are hemi-endoprostheses replacing only the femoral part of the hip joint. The acetabular part is maintained. The ic-bipolar heads articulate directly with the natural (non-replaced) acetabulum on the outer side and with a (artificial) femoral ball head (ic - head) on the inner side.

The ic- bipolar head consists of three components: the metal outer shell, the PE-insert and the PE-retaining ring. Below, ic-bipolar head CoCrMo is shown.

IC-BIPOLAR HEAD CoCrMo

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.

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

Under normal conditions the following survival rates (lifetime) are expected for hemiarthroplasty of the hip with bipolar component. The following values are given in Australian Orthopaedic Association National Joint Replacement Registry (Annual Report 2019).

BIPOLAR *	
YEARS	SURVIVAL RATE IN % (95% CONFIDENCE INTERVAL**)
1	97,6 (97,9-97,5)
5	95,6 (96-95,3)
10	93,8 (94,4-93,2)
(*): Primary diagnosis; fractured Neck of Femur (**): "95% confidence interval" means that the survival rate is in the given range with the 95 % probability.	

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

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 the bone fixation or the exact positioning or the function of the implant
- Therapies that may affect bone quality
- Muscle insufficiency
- Neuromuscular diseases 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
- Intra-articular injection of corticosteroids

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 hip endo-prosthesis.

- 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
- Excessive wear of articulating components
- Deformities or breakage of an implant
- MPR (=metal related pathologies) due to corrosion/Fretting
- Lengthening or shortening of the leg
- Pain
- secondary sign of wear can occur on articulation surface of the joint after implantation of a hemiprosthesis.
- Squeaking and/or clicking noises from the hip (in case of ceramics).

WARNINGS: Noise generated during movement after an ic-head BIOLOX® delta system 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.

Warnings:

Hazardous Substances: *(Applicable for ic-head CoCrMo taper 12/14mm, ic-bipolar head CoCrMo)*

One or more components of this device contains the following substance(s) defined as CMR 1A and/or CMR 1B and/or endocrine disrupting substances in a concentration above 0.1% weight by weight:

- Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

This device contains the following material or substance that could result in sensitisation or an allergic reaction by the patient or user:

- Nickel; CAS No. 7440-02-0; EC No. 231-111-4

WARNINGS: In extremely rare cases, a fracture of the ic-head BIOLOX® delta may occur. In order to minimize this risk as much as possible, the ball heads made of BIOLOX® delta have been individually examined before delivery. One reason a fracture can occur, among others, is due to an incorrect placement of the ic-head BIOLOX® delta on the stem taper or an incorrect or missing fit between the ic-head BIOLOX® delta and the stem taper. The use of prosthesis components which are not released by implantcast GmbH for combination with an ic-head BIOLOX® delta can also lead to a fracture of the ic-head BIOLOX® delta. In the extremely rare case of a fracture of a ceramic hip head, there is a risk of injury caused by sharp edges of ceramic or metal fragments during a revision.

For the ic-heads BIOLOX® delta, 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 in the context of 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 ball head made of BIOLOX® delta or in harm to the patient.

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

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.

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.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