

# PATIENT LEAFLET

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## DiaLoc® Hip Stems

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**VALID FOR: AUSTRALIA**

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**REVISION: 0**

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### 1. IDENTIFICATIONS

#### 1.1. IDENTIFICATION OF THE MANUFACTURER


<b>MANUFACTURER NAME</b>	implantcast GmbH
<b>ADDRESS</b>	Lueneburger Schanze 26 21614 Buxtehude Germany
<b>TELEPHONE NUMBER</b>	+49 4161 744-0
<b>FAX NUMBER</b>	+49 4161 744-200
<b>WEBSITE</b>	www.implantcast.de


#### 1.2. IDENTIFICATION OF THE SPONSOR (IMPORTER)

<b>SPONSOR NAME</b>	Lifehealthcare Distribution Pty Ltd
<b>ADDRESS</b>	Level 8/15 Talavera Road North Ryde NSW 2113 Australia
<b>TELEPHONE NUMBER</b>	+61 1800 060 168
<b>WEBSITE</b>	www.lifehealthcare.com.au

#### 1.3. IDENTIFICATION OF THE DEVICE

This patient leaflet is applicable for the following components:

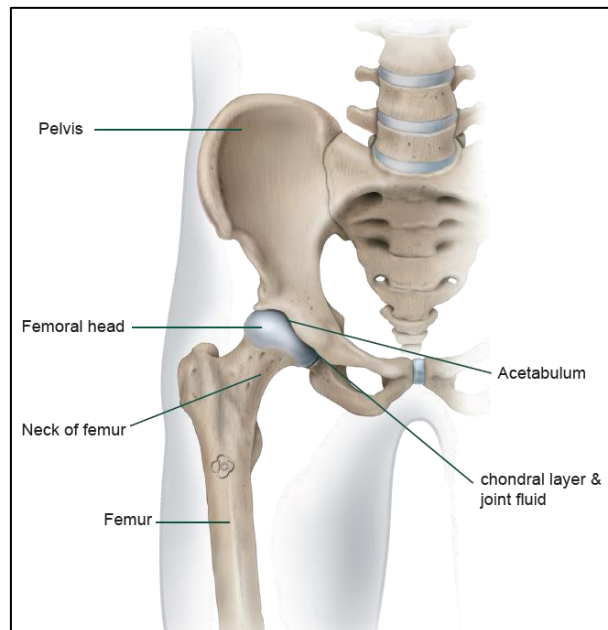
COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
DiaLoc® hip stem cementless lateralized	implatan® TiAl <sub>6</sub> Nb <sub>7</sub> alloy acc. to ISO 5832-11	85000103; 85000104; 85000105; 85000106; 85000107; 85000108; 85000109	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
DiaLoc® hip stem cementless standard	implatan® TiAl <sub>6</sub> Nb <sub>7</sub> alloy acc. ISO 5832-11	850000-1; 85000000; 85000001; 85000002; 85000003; 85000004; 85000005; 85000006; 85000007; 85000008; 85000009; 85000010	

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

## 2. INTENDED PURPOSE

The DiaLoc® hip stems are femoral stems for total hip arthroplasty or hemi hip arthroplasty. They are intended for cementless meta-diaphyseal press-fit 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 an endoprosthesis 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 hip joint replacement applies to the following indications:

- ⊕ Non- inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- ⊕ Post-traumatic osteoarthritis,
- ⊕ Femoral head and femoral neck fractures,
- ⊕ Rheumatoid arthritis.

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#### 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.

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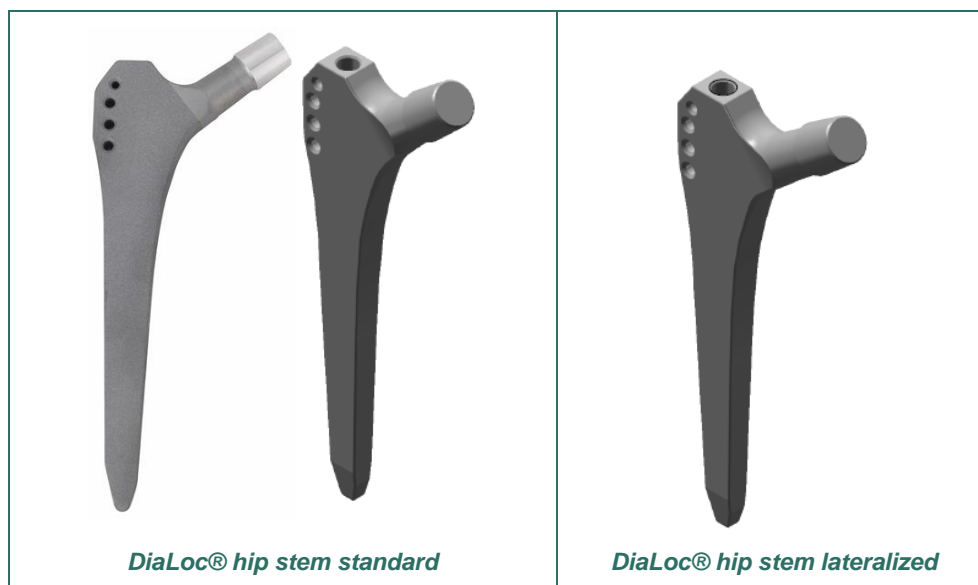
#### 5. TARGET POPULATIONS

Patients, that meet the indications given in the associated Instructions for Use and for whom the implantation of a cementless hip stem 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 DiaLoc® hip stem is available in standard and lateralized versions with stem-neck angle (CCD angle) of 131° and 127°, respectively. The DiaLoc® hip stem is a collarless, straight stem with a rectangular cross-sectional geometry to provide rotational stability.



#### 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 cement-less 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.

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### 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 a hip endoprosthesis.

In the following the most frequent side effects and complications are listed, which can occur in connection with the implantation of a 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 (metal-related pathology) due to fretting and/or corrosion,
- ⊕ Lengthening or shortening of the affected extremity,
- ⊕ Pain.

### Warnings:

	<p><i>“Do not re-use“</i></p>		<p><i>„Caution“</i></p>
	<p><i>“Do not resterilize“</i></p>		<p><i>„Read the instructions for use“</i></p>
	<p><i>„Do not use if package is damaged and consult instructions for use“</i></p>		<p><i>„ Use-by date“</i></p>



#### 8. MAGNETIC RESONANCE COMPATIBILITY

The DiaLoc® hip stems have not been evaluated for safety and compatibility in the MR environment. The DiaLoc® hip stems have not been tested for heating, migration, or image artefact in the MR environment. The safety of the DiaLoc® hip stems in the MR environment is unknown. Scanning a patient who has this device implanted may result in patient injury.

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#### 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.

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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](mailto:iris@health.gov.au)