Instructions for Use

Read carefully before use!

Cementless Femoral Hip Stems

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CE 0482

PRODUCTS AND MATERIALS

This information concerns:

- **Actinia® hip stems cementless; Actinia® hip stems coxa vara cementless; Actinia® hip stems coxa vara with collar cementless; Actinia® hip stems with collar cementless; Actinia® hip stems prox.mod. cementless** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® HA; HA acc. to ISO 13779-2)*
- **Aida® hip stems** *(Material: implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® Duo cpTi-coating and HA-coating acc. to ISO 13779-2)*
- **AJS® hip stems cementless** *(Material: implatan® $TiAl_6V_4$ alloy acc. to ISO 5832-3; Coating: implaFix® HA; HA acc. to ISO 13779-2)*
- **BethaLoc® stems** *(Material: implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® HA; HA acc. to ISO 13779-2)*
- **Ceraco® hip stems** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating and TCP-coating)*
- **DiaLoc® hip stems** *(Material: implatan® $TiAl_6Nb_7$ alloy acc. ISO 5832-11)*
- **DiaLoc® RS revision stems** *(Material: implatan® $TiAl_6Nb_7$ alloy acc. ISO 5832-11)*
- **DiaLoc® GIS® hip stems** *(Material: implatan® $TiAl_6Nb_7$ alloy acc. ISO 5832-11)*
- **EcoFit® hip stems cementless cpTi; EcoFit® hip stems 133° cementless cpTi; EcoFit® hip stems coxa vara cementless cpTi** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **EcoFit® hip stems cementless HA; EcoFit® hip stems 133° cementless HA; EcoFit® hip stems coxa vara cementless HA;** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® Duo cpTi-coating and HA-coating acc. to ISO 13779-2)*
- **EcoFit® hip stems cementless T-HA** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® Duo cpTi-coating and HA-coating acc. to ISO 13779-2, implaFix® HA; HA-coating acc. to ISO 13779-2)*
- **EcoFit® short stems cementless cpTi** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **EcoFit® short stems cementless cpTi+HA** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® Duo cpTi-coating and HA-coating acc. to ISO 13779-2)*

The chemical compositions of the individual materials used are available on our website under the following link.

https://www.implantcast.de/en/company/technology/

The CE mark is applicable only if it is also shown on the product label.

INTENDED USE AND PRODUCT DESCRIPTION

The following hip stems are femoral stems for total or hemi hip arthroplasty. They are intended for press-fit cementless meta-diaphyseal fixation.

- **Actinia®**
- **DiaLoc®**
- **EcoFit® T-HA**

The following hip stems are femoral stems for total- or hemi hip arthroplasty. They are intended for press-fit cementless metaphyseal fixation.

- **Aida®**
- **AJS®**
- **Ceraco®**
- **BethaLoc®**
- **EcoFit® HA**
- **EcoFit® cpTi**
- **EcoFit® Coxa Vara**
- **EcoFit® 133°**

The **EcoFit® short stems** are femoral stems for total hip arthroplasty or hemi hip arthroplasty. These bone conserving prostheses are intended for a press-fit cementless metaphyseal fixation and to better address minimally invasive techniques.

The **DiaLoc® RS revision stems** are femoral revision stems for revision hip arthroplasty. They are intended for press-fit cementless meta-diaphyseal fixation.

CLINICAL INFORMATION

Benefits

If all conservative or otherwise available therapeutic measures for the treatment of the present disease do not achieve the desired success or are exhausted, the hip joint replacement can be used.

The use of the hip joint replacement makes it possible to treat the underlying disease, to achieve freedom from pain, to restore the functionality of the affected limb or mobility and thus the independence in work and everyday life as far as possible. The improvement of the quality of life is the highest priority.

The aim of a revision surgery is the restoration of the stability, infection treatment, treating damage to nerves or blood vessels, pain reduction or eradication, or the restoration of mobility. The spotlight is on issues of social medicine, such as maintaining independence or reintegration into working life.

The hip joint replacement should only be revised if it is medically necessary, i.e., is indicated. If a revision diagnosis remains untreated, patients face the possibility of severely detrimental consequences for their health.

Target Group

The target group is patients that meet the indications given in these instructions for use and for whom the implantation of the hip joint replacement 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.

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 than artificial joint replacement.

Risk of postoperative 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 hip joint replacement is generally only indicated in patients whose skeleton is fully grown.

The necessary preoperative examinations should be performed by the attending medical doctor before intervention. The examinations depend on the patient's medical history.

Under consideration of these conditions, the following indications apply for the hip joint replacement:

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

The main indication for **DiaLoc® RS revision stem** is:

- Revision hip arthroplasty (Paprosky Type I to IIIa)

For **Aida® hip stem, BethaLoc® stem** and **EcoFit® short stem** applies:

- Short stem hip prostheses are indicated for younger patients (< 70 years) with good bone quality.

The surgeon decides which version of prosthesis is to be used for the individual 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.

Contraindications

The durability of an implant can be limited by biological, material, 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, and patients under the age of 60.

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 that an allergy test be performed)
- Active 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 of the affected limb
- Metabolic disorders that may impair bone formation
- Severe neuromuscular diseases that strongly influence the affected limb
- For revision stems: one-stage revision surgery of the infected hip

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

Risk Factors

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

- Excessive loading of the joint operated on by heavy 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
- Diabetes
- Psoriasis
- Intra-articular injection of corticosteroids
- State after infection

Operation-specific Complications

(Negative Effects / Side-effects)

The following procedure-related complications (side-effects) can be associated with orthopedic surgeries:

- Wound hematoma and delayed wound healing
- Cardiovascular disturbances, venous thrombosis, pulmonary embolism
- 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 a hip endoprosthesis:

- Movement restrictions in the affected joint (such as arthrofibrosis, joint stiffness)
- Subluxation, dislocation or instability
- Implant subsidence or early loosening
- Periprosthetic fractures (bone fractures can occur intraoperatively as well as due to implant loosening or implant overload)
- Heterotopic ossification
- Injury of surrounding blood vessels, soft tissue or nerves with temporary or ongoing 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 bodies or abrasion particles
- Allergic reactions to the implant materials
- Separation of modular components
- Excessive wear of articulating components
- Implant deformities or breakage
- MRP (metal-related pathology) due to corrosion and/or fretting
- Fretting and/or corrosion of the modular connections
- Lengthening or shortening of the affected limb
- Pain
- Squeaking/noises

Expected Lifetime and Necessary Follow-up

The materials used for implants are not as resilient as the natural bone structures and joints. They have a limited lifetime that generally depends on several factors. Some of these factors are the patient's health, activity level and exact implantation of the product according to the established surgical technique for the product.

Under normal conditions, the following survival rates (lifetimes) are expected for (primary) elective total hip arthroplasty with uncemented stems. These values were calculated from the cumulative revision rates given in the annual report (2021) of the German Arthroplasty Registry (EPRD).

(PRIMARY) ELECTIVE TOTAL HIP ARTHROPLASTY WITH CEMENTLESS STEMS	
Years	Survival rate in % (95% confidence interval)
1	97.3 (97.2, 97.4)
2	96.9 (96.8, 96.9)
3	96.6 (96.5, 96.7)
4	96.4 (96.3, 96.5)
5	96.3 (96.2, 96.3)
	96.1 (96.0, 96.2)

The underlined (italics) entry is the number of arthroplasties being followed up is less than 750 at only one time. (If the number is less than 50, the results are not reported.)

Under normal conditions, the following survival rates are expected for revision hip arthroplasty (first revision). These values were calculated from the cumulative re-revision rates given in the Annual Report (2021) of the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man.

/	SURVIVAL RATE OF THE REVISION HIP ARTHROPLASTY (FIRST REVISION) [IN %] BY FIXATION AND BEARING USED IN PRIMARY HIP REPLACEMENT (95% CONFIDENCE INTERVALL)		
YEARS	BEARING	UNCEMENTED	REVERSE HYBRID (cemented cup + uncemented stem)
1	MoP CoP CoC	94.61 (93.91, 95.23) 93.93 (92.80, 94.88) 94.51 (93.73, 95.20)	94.12 (91.59, 95.90) Not specified Not specified
3	MoP CoP CoC	90.11 (89.15, 90.98) 89.10 (87.58, 90.45) 90.28 (89.25, 91.22)	90.79 (87.67, 93.15) Not specified Not specified
5	MoP	88.63 (87.58, 89.60)	*90.02 (86.7, 92.55)*

	CoP	87.34 (85.63, 88.85)	Not specified
	CoC	87.85 (86.67, 88.93)	Not specified
7	MoP	86.05 (84.76, 87.25)	*87.06 (82.68, 90.40)*
	CoP	86.42 (84.55, 88.07)	Not specified
	CoC	86.06 (84.73, 87.28)	Not specified
10	MoP	84.18 (82.55, 85.68)	*83.48 (76.17, 88.72)*
	CoP	*84.43 (81.92, 86.61)*	Not specified
	CoC	83.95 (82.29, 85.47)	Not specified
The underlined italics signify that fewer than 250 cases remained at risk at these time points.			
MoP: Metal on Polyethylene, CoP: Ceramic on Polyethylene CoC: Ceramic on Ceramic			

Following the implantation, further surgically invasive procedures (re-operations) such as the replacement of individual components or even the replacement of the entire endoprosthesis may be necessary.

Summary of Safety and Clinical Performance (SSCP)

The summary of safety and clinical performance for the implants* listed in “Products and Materials” is available upon request*.

**: Currently it is only valid for Actinia® hip stems*

INFORMATION

Implant card

The product description, size, reference number (catalogue number) and lot/batch number, and the UDI can be found on the outside product label and patient labels provided within the packaging.

For traceability, the lot/batch number, the reference number (catalogue number), and the UDI of the products used must be documented. For this reason, the patient labels need to be attached to the implant card that is to be provided to the patient after the operation. We also recommend that the patient labels be attached to the applicable surgery report.

User and Training

The use of the implants listed in “Products and Materials” is restricted to persons who, based on their education, knowledge, and practical experience, are capable of proper handling and use of the device.

It is important to carefully read the instructions for use and the respective surgical technique before using the implants listed in “Products and Materials”. The implantation according to the established surgical technique and complying with the information described in these instructions for use are mandatory to achieve the best possible outcome. A list of the associated surgical techniques is provided at the end of these instructions for use.

Implantcast GmbH offers special user trainings to ensure an optimal preparation.

Packaging

The implants are individually packed in sealed triple-peel or double-blister packaging and then packed in a sealed carton. The outer peel package serves as protective packaging. Only implants provided in their original intact packaging with the original label may be accepted by hospitals and medical doctors.

Sterilization

The implants are provided packaged sterile by implantcast GmbH.

The cementless hip stems are sterilized by gamma radiation with a dose of at least 25 kGy. A corresponding icon of the sterilization method can be found on the product label.

Before surgery the implant packaging must be visually inspected for any damage. The product is sterile unless the packaging is damaged or opened or the “Use before” date is exceeded. Non-sterile products must not be used and must be returned to implantcast GmbH.

The implantcast GmbH instruments are supplied non-sterile and must be disinfected, cleaned, and sterilized before use. For the correct procedure, please refer to document RA_000_ROW_Instructions for processing of surgical instruments. If the instruments are not treated before use, there is a risk of infection.

Resterilization

Resterilization of any implant of implantcast GmbH is not permitted!

The manufacturer is only liable for implants that have been implanted immediately after removal from the original packaging. Resterilization is not permitted and is beyond implantcast’s responsibility and liability.

Storage

The implant should always be kept under controlled climatic conditions in the unopened original packaging in a storage repository suitable for sterile goods. It should be protected from excessive temperatures, humidity and direct sunlight.

Single-Use

An implant may under no circumstances be reused. Each implant is manufactured for single use only!

The mechanical and biological safety of the implant can no longer be guaranteed if it is reused inadmissibly. Even when no damage is visibly apparent, there can still be faults or damages which can affect the functioning and/or lifetime of the implant.

The hygienic safety of the implant can no longer be guaranteed if it is reused inadmissibly. There is a risk of infection.

For safe disposal of the product, the hospital guidelines and other applicable legal provisions must be followed accordingly. During disposal, microbiological and physical hazards, such as infections, potentially contaminated explants, and/or sharp edges of the product must be taken into account.

Combinability

ATTENTION: The cementless hip stems of implantcast GmbH are only allowed to be used in combination with femoral heads approved by implantcast GmbH for use with them. The approved combinations are to be taken from the Annex to these instructions for use.

cf. Annex I – IFU – Cementless Femoral Hip Stems

Item Number: 09300085GB

Combination with femoral heads and/or components from other manufacturers is not permitted.

The user must follow the instructions for combination provided in the respective surgical technique for the product. Additional information regarding the combinations can also be obtained directly from implantcast GmbH.

The cutting blocks and saw guides from implantcast GmbH are precisely aligned to the saw blades offered by implantcast GmbH so that only these products may be combined with each other.

Influence of Imaging Techniques and Active Invasive Surgical Procedures

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

Any contact between electrosurgical high-frequency instruments and metallic implants (e.g. during high-frequency electrocautery) must be avoided to prevent damage to the implants caused by flashover. An increased hazard exists in case of revision surgery.

When using water jet surgery, any contact with the implant should be avoided.

Preoperative Instructions

A preoperative planning is mandatory for optimal results. Before surgery, a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, two kinds of implant templates are available:

Digital templates: Digital templates are included in the database of common planning tools. For desired templates that aren’t in the software, please contact the provider of the planning tool and request these templates.

Radiographic templates: Alternatively, radiographic templates are available in various scale factors, which can be obtained from your local representative.

In addition, before surgery it must be ensured that:

- All necessary components are available. An adequate number of all necessary implant sizes should be available during surgery.
- All instruments necessary are present for surgery. The insertion instruments must match the implant being used. Only instruments designed for use with the implant system by implantcast GmbH may be used. An exclusive exception are the standardized instruments used during surgery.
- The surgeon must ensure that instruments of a correct size are used during surgery to prevent damage to the implant.

Intraoperative Instructions

When removing the implant from the packaging, it must be checked if it matches the description on the packaging (REF, LOT and size).

When removing the implant from the packaging, the corresponding hygiene rules must be adhered to. The user undertakes full responsibility for this. Implants should be implanted immediately after removal from the original packaging.

The surfaces of the implants are extremely sensitive. Implants must not come into contact with objects that could damage the surfaces.

Before implantation, the implant must be visually inspected by the user for possible damage. Damaged implants must not be used.

The implant must not be modified in any way! Modifications to the implant may lead to impairment of its function and early failure of the prosthesis. In case of changes or manipulation, the regulatory responsibility is transferred to the person changing or manipulating the components and the manufacturer is no longer liable for the product.

In cementless applications, a firm fixation of the implant at the time of surgery is essential for the success of the implantation. The cementless components are to be seated in the bone by pressfit, which requires precise surgery and the use of the instruments provided for this purpose.

A reliable fit of taper connections is only possible with completely intact surfaces of the tapers. The taper of the stem must be cleaned and dried before being connected to the taper of the head. Both tapers must be of matching size.

Prior to wound closure, the surgical area including the articulation surfaces of the implant must be thoroughly cleaned to remove any foreign bodies such as bone splinters, bone cement residues and any remaining fragments of a previously revised component or instrument.

It is also recommended that an intraoperative X-ray image be taken and examined for remaining particles, and that they be removed before wound closure.

Postoperative Instructions

Postoperative patient care, patient instructions, and warnings from the attending medical doctor are of the utmost importance. The use of an external support of the limb operated on for a limited period is recommended.

Active and passive movements of the limb operated on must be exercised with great caution.

The postoperative therapy should be structured to prevent overloading of the limb operated on, and stimulate the healing process.

Regular monitoring of the position and condition of the prosthetic components and the surrounding bone is recommended.

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/

NOTIFIABLE INCIDENTS

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 or other negative effects that may result from an incorrect diagnosis, surgical technique or planning, as well as improper patient or implant selection, existing concomitant medical conditions, or non-compliance with hygiene regulations are the responsibility of the surgeon and cannot be attributed to either the manufacturer or the distributor.

Serious incidents can be reported by both the user and the patient.

Any serious incident that has occurred in relation to the device must be reported to implantcast GmbH (email address: MDVS@implantcast.de) and the national competent authority of the Member State in which the user and/or patient is established.

OVERVIEW OF THE RELATED SURGICAL TECHNIQUE(S)

REF NUMBER	DESCRIPTION
ACTINOPE	Actinia®
AIDASOPE	Aida® short stem hip system
AJSOPE	AJS® anatomical hip stem system
BETALOPE	BethaLoc®
CERACOPE	Ceraco® hip stem system
DIALOOPE	DiaLoc® hip stem system
DIGISOPE	DiaLoc® GIS® hip stem system
DIARSOPE	DiaLoc® RS Revision Stem
ECOSTOPE	EcoFit® hip stem system
ECOFIOPE	EcoFit® hip stem system (EcoFit® hip stem 133° / EcoFit® hip stem coxa vara)
ECOKUOPE	EcoFit® short stem system

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TITLE OF SYMBOLS	
	“Date of manufacture”
	“Use by date”
	“Batch code”
	“Catalogue number”
	“Serial number”
	“Distributor”
	“Sterilized using ethylene oxide”
	“Sterilized using irradiation”
	“Do not resterilize”
	“Do not use if package is damaged”

	“Double sterile barrier system”
	“Do not re-use”
	“Operating instructions”
	“Caution”
	“Contains a medical substance”
MD	“Medical device”
UDI	“Unique device identifier”
QTY	“Quantity of products within the package”
Mat.	“Material”
	“Contains hazardous substances”