Instructions for Use

Read carefully before use!

Bone Screws

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CE 0482

PRODUCTS AND MATERIALS

This information concerns:

- **cortical screw** (Material: $TiAl_6V_4$ acc. ISO 5832-3)
- **cancellous screw** (Material: $TiAl_6V_4$ acc. ISO 5832-3)
- **cancellous screw angle stable** (Material: $TiAl_6V_4$ acc. ISO 5832-3)
- **spongiosa screw flat head** (Material: $TiAl_6V_4$ acc. ISO 5832-3)
- **Shim for EPORE® acetabular spacer sz. 8 mm** (*Material:* $TiAl_6V_4$ acc. to ISO 5832-3)
- **Shim for cancellous screw Ø 6.5 mm** (*Material:* $TiAl_6V_4$ acc. to ISO 5832-3)

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.

ATTENTION: The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The instructions for use of the implants used with bone screws or shims are to be considered primarily while the instructions for use for bone screws and shims are to be considered in addition.

INTENDED USE AND PRODUCT DESCRIPTION

Bone Screws* are intended for screwing into the bone for primary and/or support of a stable anchorage of an implant in case of inadequate primary stability.

*: *All bone screws which are listed under "Product Identification and Materials"*

The shim is a flat washer that is placed between a compatible screw and a corresponding hole in an implant, to provide an optimized bearing area of the screw and/or to allow the usage of a screw with smaller diameter.

CLINICAL INFORMATION

Benefits

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The benefits of the implants used with bone screws or shims are to be considered primarily while the benefits for bone screws and shims are to be considered in addition.*

PRIMARY ENDOPROSTHETICS: 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 appropriate implants with bone screws can be used.

The use of the appropriate implants with bone screws 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.

REVISION ENDOPROSTHETICS: 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 endoprotheses 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.

TUMOR ENDOPROSTHETICS: The use of tumor endoprostheses currently represents the state of the art in bone tumor therapy. Amputation is often the only alternative for the patients affected. This leads to an impairment in the quality of life, loss of mobility (and possibly independence) as well as potential psycho-social problems. The limb affected can be preserved with the assistance of a tumor endoprosthesis and the joint function for the most part restored. As a result, this enables the mostly young patients to take an active part in life. Compared to primary endoprostheses, tumor endoprostheses are associated with increased complications, which, due to the in some cases very long lifetime of the implants, are associated with several revision operations. However, their benefits are clear as a result of the limbs being saved by the tumor endoprostheses and thus also the preservation of mobility. When evaluating the benefits of tumor endoprostheses, sociomedical aspects in particular, such as the preservation of independence or reintegration in working life, should be in the foreground.

Indications and Target Group

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The indications of the implants used with bone screws or shims are to be considered primarily while the indications for bone screws and shims are to be considered in addition.*

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 endoprostheses 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.

The target group is patients that meet the indications given in these instructions for use and for whom the implantation of the appropriate implants with bone screws 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.

Contraindications

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The contraindications of the implants used with bone screws or shims are to be considered primarily while the contraindications for bone screws and shims are to be considered in addition.*

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 contraindications are:

- 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)
- Current 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
- Persistent severe axis deviation
- Severe neuromuscular diseases that strongly influence the affected limb

Risk Factors

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The risk factors of the implants used with bone screws or shims are to be considered primarily while the risk factors for bone screws and shims are to be considered in addition.*

The following risk factors may affect the success of the bone screws and shims:

- 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
- Previous 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, apoplexy, venous thrombosis, pulmonary embolism
- Renal (kidney), urinary, hepatic (liver) or gastrointestinal complications
- Respiratory disorders
- Blood loss requiring transfusions
- Delirium

Implant-specific Complications

(Negative Effects / Side-effects)

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As with all surgical interventions, side-effects (negative effects) and complications can occur with the implantation of the bone screws. In the following, the most frequent side-effects and complications are listed, which can occur in connection with the implantation of bone screws and shims:

- Movement restrictions in the affected joint
- 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 (Myositis ossificans)
- Injury of surrounding blood vessels, soft tissue (such as quadriceps atrophy, tibial tendon dysfunction, PCL rupture) or nerves with temporary or ongoing malfunctions**
  **: *also possible as operation-specific complication without relation to the implant*
- 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), tendonitis
- Adverse local tissue reaction (ALTR) to foreign bodies or abrasion particles
- Allergic reactions to the implant materials
- Implant deformities or breakage
- MRP (metal-related pathology) due to corrosion and/or fretting
- Fretting and/or corrosion of the modular connections
- Pain

Expected Lifetime and Necessary Follow-up

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The expected lifetime of the implants used with bone screws or shims are to be considered primarily while the expected lifetime for bone screws and shims are to be considered in addition.*

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 implant systems used in combination with bone screws. The following values are given in various international publications concerning implant systems that are used in combination with bone screws.

YEARS	SURVIVAL RATE IN %			
	CANCELLOUS		CORTICAL	
	PRIMARY	REVISION	PRIMARY	REVISION
1	89,3	--	--	--
2	80,1%	--	--	--
3	71,2%	--	--	--
5	70%	81,8	64,3	--
10	--	--	--	85,3

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. This depends on the reason for the revision.

Summary of Safety and Clinical Performance (SSCP)

The summary of safety and clinical performance for the bone screw is available upon request.]

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 bone screws and shims 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 bone screws. 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. Training is necessary before first use.

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 bone screws and shims that are manufactured from metal alloys 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 bone screws and shims may only be combined with the systems or implants of implantcast GmbH mentioned in the Annex. The respective combinations of the bone screws and shims are given in the Annex of these instructions for use.*

⇨ cf. Annex I Approved bone screw combinations

Item Number: 09300070GB

The bone screws are fully compatible with the systems of implantcast GmbH and may only be used or combined with these systems. Combination with 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.

Influence of Imaging Techniques and Active Invasive Surgical Procedures

The bone screws and shims have not been evaluated for safety and compatibility in the magnet resonance (MR) environment. The bone screws have not been tested for heating, migration, or image artefacts in the MR environment. The safety of the bone screws 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.

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

Hazardous Substances

The products listed under **PRODUCTS AND MATERIALS** do **not** contain 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.

The products do **not** contain the following material or substance that could result in sensitization or an allergic reaction in the patient or user:

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

Preoperative Instructions

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The preoperative instructions of the implants used with bone screws or shims are to be considered primarily while the preoperative instructions for bone screws and shims are to be considered in addition.*

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

ATTENTION: *The bone screws and shims are used as accessory in implantation of several implants (for combination of implant systems with bone screws and shims please refer to the annex of this instruction for use). The intraoperative instructions of the implants used with bone screws or shims are to be considered primarily while the intraoperative instructions for bone screws and shims are to be considered in addition.*

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.

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.de/en/for-patients/

When using the bone screws and shims, the information on the implants used in conjunction with the bone screws and shims must be considered, too.

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)

Before using the bone screws and shims in conjunction with implants, it is mandatory to consider the surgical techniques of the respective implants. An overview of the associated surgical techniques is provided at the end of the instructions for use of the respective implant or system.

Issued: 05.12.2023

Reference Number: 09300069GB

Symbols and Abbreviations Glossary

Symbol / Abbreviation	Standard	Reference number	Title	Description
CE	MDD 93/42 EEC MDR EU 2017/745	N/A	“CE marking”	The requirements for accreditation and market surveillance relating to the marketing of products
	ISO 15223-1:2021	5.1.1	“Manufacturer”	Indicates the medical device manufacturer
CH REP	N/A	N/A	“Authorized representative in Switzerland”	Indicates the authorized representative in Switzerland
	ISO 15223-1:2021	5.1.3	“Date of manufacture”	Indicates the date when the medical device was manufactured
	ISO 15223-1:2021	5.1.4	“Use by date”	Indicates the date after which the medical device is not to be used
LOT	ISO 15223-1:2021	5.1.5	“Batch code”	Indicates the manufacturer’s batch code so that the batch or lot can be identified
REF	ISO 15223-1:2021	5.1.6	“Catalogue number”	Indicates the manufacturer’s catalogue number so that the medical device can be identified
SN	ISO 15223-1:2021	5.1.7	“Serial number”	Indicates the manufacturer’s serial number so that a specific medical device can be identified
	ISO 15223-1:2021	5.1.8	“Importer”	Indicates the entity importing the medical device into the locale
	ISO 15223-1:2021	5.1.9	“Distributor”	Indicates the entity distributing the medical device into the locale
STERILE R	ISO 15223-1:2021	5.2.4	“Sterilized using irradiation”	Indicates a medical device that has been sterilized using irradiation
	ISO 15223-1:2021	5.2.6	“Do not resterilize”	Indicates a medical device that is not to be resterilized
	ISO 15223-1:2021	5.2.8	“Do not use if package is damaged and consult instructions for use”	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	ISO 15223-1:2021	5.2.12	“Double sterile barrier system”	Indicates two sterile barrier systems
	ISO 15223-1:2021	5.4.2	“Do not re-use”	Indicates a medical device that is intended for one single use only
	ISO 15223-1:2021	5.4.3	“Consult instructions for use”	Indicates the need for the user to consult the instructions for use
	ISO 15223-1:2021	5.4.4	“Caution”	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
MD	ISO 15223-1:2021	5.7.7	“Medical device”	Indicates the item is a medical device
UDI	ISO 15223-1:2021	5.7.10	“Unique device identifier”	Indicates a carrier that contains unique device identifier information
Qty.	N/A	N/A	“Quantity”	Abbreviation for “Quantity”. Quantity of products within the package.
Mat.	N/A	N/A	“Material”	Abbreviation for “Material”