Instructions for Use

Read carefully before use!

Cementless Acetabular Cups

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CE 0482

1. Materials used, product information

This information concerns:

- **Ceraco® ROM cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: cpTi acc. to ISO 5832-2 and TCP)*
- **Ceraco® Dysplasia and Revision cups** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: cpTi acc. to ISO 5832-2 and TCP)*
- **EcoFit® cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **ST-Fit cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **Cupola® Cup 3 holes** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **EcoFit® HA cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi coating and hydroxyapatite coating acc. to ISO 13779-2)*
- **EcoFit® NH cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **ST-Fit NH cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **Cupola® Cup closed** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: implaFix® cpTi-coating)*
- **EcoFit® NH HA cup** (*Material: implatan® $TiAl_6V_4$ acc. To ISO 5832-3; Coating: implaFix® cpTi coating and hydroxyapatite coating acc. to ISO 13779-2)*
- **EcoFit® cup EPORE®** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3)*
- **EcoFit® cup EPORE® NH** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3)*
- **EcoFit® cup EPORE® Multi-Hole** *(Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3)*
- **EcoFit® cup EPORE®/TCP** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: TCP)*
- **EcoFit® cup EPORE®/TCP NH** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: TCP)*
- **EcoFit® cup EPORE®/TCP Multi-Hole** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3; Coating: TCP)*
- **EcoFit® SC cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3)*
- **DiaLoc® SC cup** (*Material: implatan® $TiAl_6V_4$ acc. to ISO 5832-3)*
- Polyethylene cup inserts:
  - **PE - cup inserts** (*Material: UHMW-PE acc. to ISO 5834-2; X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
  - **ST-Fit PE-Inlay** *(Material: UHMW-PE acc. to ISO 5834-2; X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
  - **Cupola® Inlays UHMWPE** *(Material: UHMW-PE acc. to ISO 5834-2; X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
  - **implacross® PE inserts** (*Material: UHMW-PE acc. to ISO 5834-1, crosslinked (gamma radiation (75±5 kGy)); X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
  - **Cupola® Inlay XLPE** (*Material: UHMW-PE acc. to ISO 5834-1, cross-linked (gamma radiation (75±5 kGy)); X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
  - **ST-Fit PE-Inlay implacross®** (*Material: UHMW-PE acc. to ISO 5834-1, crosslinked (gamma radiation (75±5 kGy)); X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
  - **implacross® E PE inserts** (*Material: UHMW-PE acc. to ISO 5834-1, crosslinked (gamma radiation (75kGy±10%)) and doped with vitamin E (1000 ppm); X-ray wire from $TiAl_6V_4$ acc. to ISO 5832-3)*
- BIOLOX® delta inserts:
  - **BIOLOX® delta cup inserts** (*Material: Al_2O_3 and ZrO_2 acc. to ISO 6474-2)*
  - **Cupola® Inlays Biolox® Delta** (*Material: Al_2O_3 and ZrO_2 acc. to ISO 6474-2)*
  - **ST-Fit Ceramic inserts BIOLOX® delta** (*Material: Al_2O_3 and ZrO_2 acc. to ISO 6474-2)*

The cementless press-fit acetabular cups are supplied including fixation screws with flat heads from $TiAl_6V_4$-alloy (acc. to ISO 5832-3). These can be used to provide additional, initial stability of the metal shell within the acetabulum.

Product description, size, product code and lot / batch number can be found on the outside product label and on the labels within the packaging.

For reasons of traceability, the batch and item numbers of the products have to be documented. We recommend that the included labels are attached to the patient's status and/or operation report.

2. Preliminary Remarks

It is important to carefully read the instructions for use and the respective surgical technique before using the implants mentioned in 1. A list of the associated surgical techniques is provided at the end of this instruction for use.

To obtain the best possible results, it is important to pay careful attention to the indications, contraindications, warnings, precautions and directions described in the instructions for use and surgical technique.

The use of this implant is restricted to persons who, based on their education, knowledge and practical experience, are capable of proper handling and use of the device.

The surgeon should hand over a prosthesis passport to the patient, which should be kept by the patient.

An implant may under no circumstances be re-used. Each component is manufactured for single use only!

Although not visibly apparent, damage may be present which can affect the functioning or life of the implant.

3. Packaging

The implants are individually packed in sealed triple peel pouches or double blister packaging and then packed in a sealed carton. The outer packaging serves as protective packaging. Only implants provided in their original intact packaging with the original label should be used.

4. Sterilisation

The implant components are sterilised and supplied sterile by the implantcast GmbH.

The components that are manufactured from metal alloys or ceramic are sterilised by gamma radiation with a minimal dose of 25 kGy. All polyethylene components are sterilised by ethylene oxide. A corresponding icon of the sterilisation method can be found on the product label.

The product is sterile unless the packaging is damaged or opened and the "Use before" date has not expired.

Please observe the "Use before" date on the product label. If the date has expired, sterility can no longer be guaranteed and the product should not be used.

5. Resterilisation

Re-sterilisation of any implant of the implantcast GmbH is not permitted!

The manufacturer is only liable for implants that have been implanted immediately after removal from the original packaging; re-sterilisation is not permitted and is beyond implantcast's responsibility and liability.

6. Storage

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

7. Handling

Before surgery the implant should be visually inspected for any damage. The product is sterile unless the packaging is damaged or opened and the use before date has not been expired.

The implant should not be used if the sterile packaging is damaged or was previously opened. Please return any affected packages to implantcast GmbH.

Before using, the implant should be checked to ensure that the product code lot numbers and size corresponds with the data on the labelling (Product description, LOT-No., REF-No. and size).

Use appropriate aseptic technique when removing the implant from the packaging. Implants should be implanted immediately after removal from the original packaging.

The surfaces of the implants are extremely sensitive; implants should not be allowed to come into contact with objects that could damage the surfaces. Coated implants must be treated with special care to avoid damaging the coating.

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

The implant should not be modified in any way – modifications to the implant may lead to impairment of its function or early failure. The manufacturer assumes no liability for modified products. In case of changes or manipulation the regulatory responsibility is transferred to the person changing or manipulating the components. The manufacturer no longer guarantees the product.

When acrylic bone cement is used the instruction for use from the cement manufacturer should be followed.

Bone cement should not be allowed to come or remain in contact with the articulating surfaces of the implant during or after the surgery. Bone cement residues that could dislodge over time and get between the articulation surfaces must be removed. Bone cement fragments and residues may lead to increased wear and damage of the implant components.

A reliable taper fit between the stem and the modular head is only possible when the entire taper contact surfaces are clean and undamaged. The taper of the stem must be cleaned and dried before being connected to the taper of the head. The inner taper of the head and the outer taper of the stem should be of matching compatible tapers.

In cementless application it is important that at the point of insertion there is good initial stability. Cementless components should be in firm contact with the prepared bone by press fit. Meticulous preparation of the bone with the special instruments available is required.

Prior to wound closure is recommended to clean the surfaces of the implant articulation of bone fragments and / or residual bone cement.

8. Combinability

The acetabular cups of the implantcast GmbH are only allowed to be used in combination with cup inserts approved by the implantcast GmbH for use with them. Only approved combinations will provide a reliable connection between the metal shell and the insert. The approved combinations are to be taken from the addendum to this package insert.

❖ cf. Annex I – IFU – Cementless acetabular cups / Item Number: 09300041GB / Issued: 15/02/2016

Whether the selected insert can be combined with the metal shell of choice should be checked before insertion. The matching of the components is additionally shown by colour coding.

The diameter of the head of the selected implant must match the internal diameter of the selected cup insert. The diameter of the femoral head to be used is indicated on the label of the product.

Cup inserts from *BIOLOX® delta* may only be combined with acetabular shells approved by the manufacturer for use with them. The surgeon should make sure that the selected acetabular shell, the *BIOLOX® delta* insert and the selected femoral head are matching.

Since an exact fit of *BIOLOX® delta* insert and acetabular shell must be guaranteed, only new and unused components may be combined.

Cup inserts from *BIOLOX® delta* are only allowed to articulate with *BIOLOX® forte* or *BIOLOX® delta* femoral heads. Coupling with a different femoral head or with a ceramic ball from other manufacturers is not allowed.

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

The implants mentioned in 1 may not be used or combined with other systems and components of other manufacturers. If nevertheless it is required, to combine the implants of the implantcast GmbH with implants from other manufacturers and distributors, the verification of possible combinations can be examined by the implantcast GmbH on request.

9. The positioning of the prosthesis components

The positioning of the prosthesis components has a direct influence on the range of movement and thus represents a potential risk of impingement, luxation or subluxation. For acetabular shells which are too steep, surface pressure on the acetabular edge increases. This can lead to increased wear and tear. The cup position complies with the safety zone according to Lewinnek.

Before a decision is made on implanting a ceramic cup insert, a synthetic test inlay is inserted into the cup and the stem component is implanted. Ensure that the test inlay is removed. Freedom of joint movement and joint stability are tested using test femoral heads of the intended diameter. Ensure that the test femoral head is removed. The joint may not luxate during movement or subluxate through impingement of the implant components or of soft tissue.

The inclination of the cup components should not significantly exceed or fall below a value of 40-45°. The anteversion of the cup components should not significantly exceed or fall below a value of 10-20°. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the femoral head from the *BIOLOX® delta* insert.

For a cup position which lies outside the above-mentioned values, a *BIOLOX® delta* insert must not be used. (Exceptions can be made for specifically designed systems with luxation-free elements, such as asymmetric inserts or ones twisted out of position). For acetabular shells in retroversion, a *BIOLOX® delta* insert must not be used. Possible consequences are an increase in the surface pressure on the cup edge with grain break-out from the *BIOLOX® delta* insert associated with increased ceramic debris. Excessive ceramic debris can lead to adverse tissue reactions, loosening of the prosthesis and in extreme cases ceramic breakage.

Ensure adequate joint tension is achieved on implantation, as luxation can also lead to the adverse results listed above.

10. Fixation of the *BIOLOX® delta* insert in the acetabular shell

Aim: A perfect fit of the *BIOLOX® delta* insert

Make sure you remove any foreign matter from the prosthesis components, such as tissue particles, bone or cement particles from the surface of the shell before positioning the *BIOLOX® delta* insert in the shell.

Fix the *BIOLOX® delta* insert centrally in place in the acetabular shell with the greatest of care – if necessary using an insert aid offered by the manufacturer or prosthesis company – following the diagrams provided for this purpose.

On Fig. 1: After having inserted the acetabular shell in the acetabulum, make sure the position of the acetabular cup and its function, i.e. movement of the joint is thoroughly checked using a test implant. It is important to make sure that the screws are completely countersunk.

On Fig. 2: Remove the test implant after having checked both the position of the cup and the function of the joint and be sure to rinse and dry the acetabular shell. Ensure that there are no bone or tissue residues left in the fixation area.

On Fig. 3: Insert the *BIOLOX® delta* insert by hand as described in the diagram: pick up the *BIOLOX® delta* insert with two fingers and introduce it into the acetabular shell. The *BIOLOX® delta* insert will slide into the shell automatically as soon as the fingertips contact the rim of the acetabular shell.

On Fig. 4: Check whether the *BIOLOX® delta* insert been positioned correctly by feeling the rim of the cup with your fingers, and correct, if necessary. The rims of the metal shell and of the ceramic insert must be flush and on the same plane!

On Fig. 5: If the *BIOLOX® delta* insert is positioned correctly, fix in position by pushing it in with your thumb. For the final fitting of the *BIOLOX® delta* insert an impactor suitable for ceramic *BIOLOX® delta* inserts and recommended by the prosthesis company is used to firmly position it with a slight hammer stroke in the axial direction.

ATTENTION! Never bring a metal hammer into contact with a *BIOLOX® delta insert*!

11. 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 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,
- Fractures,
- Rheumatoid arthritis.

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 main indication for the implantation of a **Ceraco® Dysplasia** cup is dysplastic coxarthrosis.

The main indication for the implantation of a **Ceraco® Revision** cup is the revision arthroplasty of the hip joint.

12. Contraindications

The longevity of an orthopaedic joint replacement device can be reduced by biological aspects, material characteristics and biomechanical factors. Patient selection and indication should be carefully monitored especially in patients who are overweight, patients with high physical activity levels and patients younger than 60 years of age.

An absolute contraindication is a known allergy to any of the implant materials used. The label on the secondary packaging of each component specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.

Further absolute contraindications are infections.

The relative contraindications include:

1) 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.
    - Insufficient quantity and quality of bone stock, e.g. as a result of osteoporosis or osteomalacia
    - Vascular disease of the affected limb
2) Metabolic disorders that can affect a stable anchorage of the implant
3) Bone tumors in the implant fixation area
4) Neuromuscular diseases that can impair the affected limb
5) Lack of patient compliance
6) Mental or neurological conditions that affect the ability of patients to comply with medical instructions, especially during the healing phase
7) Obesity

13. Risk factors

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

- Nicotine and/or drug abuse
- Alcoholism
- Severe deformities, which lead to an impairment of the anchorage, the exact positioning or function of the implant
- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Therapies that may affect bone quality

14. Complications

As with all medical interferences, 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 a hip endoprosthesis implantation.

- Dislocation and loosening of the prosthesis
- Tissue reactions to allergies or foreign body reactions to abrasion particles
- Injury of nerves and vessels with temporary or continuing nerve malfunctions
- wound hematoma and delayed wound healing
- Cardiovascular disturbances, venous thrombosis and pulmonary embolism
- Acute postoperative wound infections and late infections with possibility of sepsis
- Subluxation or luxation of the implant. This may cause severe pain and an abnormal positioning.
- Lengthening or shortening of the leg
- Instability
- Periprosthetic fractures. Bone fractures can occur intraoperatively and as a consequence of an implant loosening or due to overload as well as one-sided joint load.
- Separation of modular components
- Wear of articulating components
- Deformities or breakage of an implant
- Fretting and/or corrosion of modular connections
- Heterotopic ossification.

WARNINGS On rare occasions, in vivo fracturing of the *BIOLOX® delta* insert may occur. In order to minimize this risk, the *BIOLOX® delta* insert was individually examined before delivery. One cause of failure can be the incorrect fixation of the *BIOLOX® delta* insert with the metal acetabular shell. The use of prosthesis components which are not released by the prosthesis company for combination with a *BIOLOX® delta* insert can also lead to the fracture of the *BIOLOX® delta* insert. The same applies if the recommended position of the *BIOLOX® delta* insert (inclination/anteversion) is not observed. In case a ceramic component breaks, a pairing of metal (ball head) with polyethylene (insert) and of metal with metal is contraindicated in a revision.

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 and / or any unsatisfactory or negative results can also be attributed to an incorrect indication for use, improper patient selection, errors in surgical technique, improper selection of components, and / or concomitant medical conditions. The treatment thereof are the responsibility of the surgeon and neither the manufacturer nor its distributor and/or agent can be held liable for this

15. Magnetic Resonance Compatibility

The implantcast GmbH does not warrant the implants for MRI or NMRI imaging techniques. The treating physician should evaluate the risks and benefits and decide whether other imaging techniques could provide similar data and information.

16. Pre-operative Instructions

The implantation must be carried out according to the established surgical technique which is available from the implantcast GmbH. A list of the associated surgical techniques is provided at the end of this instruction for use.

Pre-operative planning and precise surgical techniques are mandatory for optimal results. The instructions and operative procedure provided in the surgical technique available from the manufacturer should be followed.

Before surgery, planning of the sizes and dimensions of the prosthetic components to be used and positioning of the implant components in the bone should be carried out by the surgeon using the x-ray templates available from implantcast GmbH.

The surgeon should ensure that:

- An adequate number of all necessary implant components will be available during surgery.
- All instruments necessary will be present for surgery and that they match the implants being used. Only instruments designed for use with the implant system by implantcast GmbH should be used.
- The correct sized instruments are used during surgery to prevent damage to the implants.

The implantcast GmbH instruments are supplied non-sterile and must be disinfected, cleaned, and sterilized before use. Please refer to the cleaning statement RA_000_ISO17664 for the correct procedures. If the equipment is not treated before use, there is a risk of infection.

17. Post-operative Instructions

Post-operative patient care, patient instructions and warnings are of the utmost importance.

The use of an external support of the operated limb for a limited period is recommended.

Active and passive movements of the patient should be monitored.

The post-operative regime should be aimed at the prevention of overloading of the joint and stimulation of the healing process.

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

18. Patient Information

The surgeon should inform the patient about any alternative surgical treatments.

The surgeon should inform the patient before surgery about all known complications and side effects and their consequences.

The surgeon should inform the patient about all aspects of the surgery and the prosthesis, in particular about the limitations of joint replacement.

Patients should be informed by their surgeon that the results and durability of their implant are related to patient weight and the physical activities. The patient should be informed about the differences between an artificial joint and a natural, healthy joint.

The patient should be made aware of post-operative limitations, including the consequences of overloading of the joint by excessive weight and high levels of physical activities and that the patient should adapt his / her life style to these limitations.

The patient should be informed that the materials used for artificial joint replacement are not as resilient as a natural joint and have a limited life. The patient should be informed of the consequences of excessive exposure of body weight or demanding activities and instructed how to adjust activities.

The patient should be told that any kind of high-loading sports should be avoided with the operated joint and that implants can break after such excessive loads or otherwise fail.

The patient should be aware that he/she should follow the instructions of the treating physician precisely, in particular instructions about activity and weight.

The patient should be noted to immediately inform his doctor if he notices unusual changes in the surgical area.

All information provided to the patient should be documented.

19. Overview of the respective Surgical Technique/-s

Ref-Number	Item Description
CEREVOPE	Ceraco® dysplasia / revision cup surgical technique
ECOCUOPE	EcoFit® cup surgical technique
ECOSCOPE	EcoFit® SC screw cup surgical technique
ECOEPOPE	EcoFit® cup EPORE® surgical technique
DIASCOPE	DiaLoc® screw cup surgical technique

Issued: 15/11/2016

Item number: 09300038GB


"Single use only"

"Do not re-sterilise"


"Manufacturing date"


"Use before date"

"Product number"

"Lot number"

"Sterilised by Ethylene-oxide"

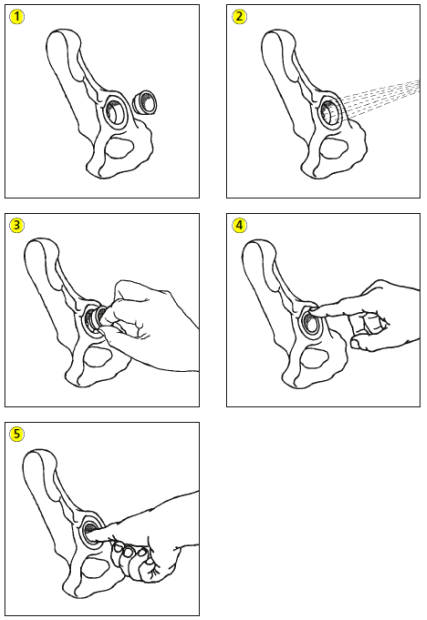
"Sterilised by Radiation"


"Attention"


"Read the instructions for use"


"Do not use in case of damaged packaging"

Fig. 1 to 5 Fixation of the *BIOLOX® delta* insert in the acetabular shell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