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MECTACER BIOLOX® OPTION System

CAUTION
Federal law (USA) restricts this device to sale distribution and use by or on the order of physician.

ENGLISH MectaCer BIOLOX® OPTION System – INSTRUCTIONS FOR USE

Important notice: the device(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

GENERAL
Before any surgery, the surgeon must be familiar with the sales literature and operative technique and must read carefully these instructions for use and also the instruction for use of the associated hip implants selected by the surgeon. Patient selection is as important as implant placement or positioning. The patient's weight or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

PRODUCT DESCRIPTION
These instruction for use are intended for the MectaCer BIOLOX® OPTION System that consist of:
- a metal sleeve made of titanium alloy TiAl6V4 according to ISO 5832-3 and ASTM F136 with an inner 12/14 taper;
- a MectaCer BIOLOX® OPTION ceramic femoral head (made of BIOLOX® delta ceramic) with a conical bore which matches with the external taper of the sleeve.

PROPERTIES AND ADVANTAGES OF MectaCer COMPONENTS FOR HIP PROSTHESES
The MectaCer BIOLOX® OPTION femoral heads are made of high-purity aluminium oxide ceramic compound according to ISO 6474-2. These components are bioinert, biocompatible, biostable, mechanically stable, corrosion-resistant and they avoid allergic reactions. They exhibit excellent fatigue strength, high shock and tensile strength, excellent breaking strength, and extreme hardness.

INDICATIONS
The MectaCer BIOLOX® OPTION femoral heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for total or partial hip arthroplasty in primary or revision surgery. The patient should be skeletally mature. The patient's condition should be due to one or more of the following:
- Severely painful and/or disabled joint as a result of osteoarthritis, post- traumatic arthritis, rheumatoid arthritis, or psoriatic arthritis.
- Congenital hip dysplasia.
- Ankylosing spondylitis.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement where sufficient bone stock is present.

CONTRAINDICATIONS
- Acute, systematic or chronic infection.
- Muscular, neurological or vascular deficiency of the affected limb making the operation unjustifiable.
- Bone destruction, or loss of bone characteristics that may compromise the stability of the implant.
- Pathologies that may compromise the functionality of the implant in any way.
- Known allergies to materials used.

Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of post-operative complications.

IMPORTANT INFORMATION FOR THE SURGEON

ALLOWED COMBINATIONS OF PROSTHETIC COMPONENTS
Medacta® International is not responsible for the use of its implant components in combination with a component from another manufacturer (unless otherwise specified by Medacta® International in the surgical technique), therefore we advise against such a use. The possible combination of Medacta® International implant components is given in the surgical technique of the selected stem. The hard-on-hard combination consists of two articular surfaces with a precisely defined geometry, and a precisely defined material. The surgeon should always make sure that the components selected according to these instructions for use match one another geometrically. MectaCer BIOLOX® OPTION ceramic femoral heads are allowed in combinations with Polyethylene liners.
Use MectaCer BIOLOX® OPTION ceramic femoral heads only with Quadra®-S, Quadra®-H, Quadra®-R, AMIStem-H, femoral stems specifically labelled for use with these ball heads.

FEMORAL HEAD FIXATION TO THE STEM TAPER
The taper fixation of MectaCer BIOLOX® OPTION system prevents any twisting motion. It also has the advantage of uniformly distributing stresses over the stem. The MectaCer BIOLOX® OPTION system should perfectly fit into the corresponding part of the stem.
The following precautions must be taken:
The MectaCer BIOLOX® OPTION system must be used only with prostheses which have - within the specified tolerances - matching taper sizes. The taper size is shown on the product label and, when possible, on the implant itself.

The MectaCer BIOLOX® OPTION system is delivered as separate components (ceramic femoral head, sleeve). Each component (ceramic femoral head and sleeve) is delivered in an individual package. The MectaCer BIOLOX® OPTION femoral head and sleeve must be implanted together.

The ceramic femoral head is placed on the sleeve and pressure is applied until resistance can be felt. It should be ensured that the ceramic femoral head is not canted or placed at an angle on the sleeve.

Before fitting the MectaCer BIOLOX® OPTION system to the stem:
- Thoroughly clean the stem taper with water.
- Dry the stem taper carefully using a clean cloth.
- Scrupulously inspect the stem taper and femoral head taper, and remove any foreign matter, such as tissue particles, bone fragments or cement residues.
- Place the MectaCer BIOLOX® OPTION system on the stem taper by twisting lightly and using axial manual pressure until it locks. As a rule, it should be easy to place the MectaCer BIOLOX® OPTION system on the stem taper. Should pressure be necessary to seat the MectaCer BIOLOX® OPTION system, the system must not be used.
- Place the plastic head impactor on the pole of the femoral head and with one moderate tap on the hammer in an axial direction, firmly and definitively fix it on the stem taper. It is possible to use more than one moderate tap to fix the MectaCer BIOLOX® OPTION femoral head and sleeve on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, thus providing an optimal pressure distribution and a torsion-resistant fixation. The successful assembly of the head fixation must be tested by an attempt to remove the head by hand.

Caution: A metal hammer must never be used on the MectaCer BIOLOX® OPTION femoral head. Use only the plastic head impactor provided for this purpose must be used.

INTERACTIONS WITH DRUGS
No interactions with any drugs have been reported to date.

REOPERATION AND REUSE
Mectacer BIOLOX® OPTION System components that have already been used, have a risk of damages invisible to the naked eye. Since any kind of damage can adversely affect the ceramic's functionality and/or stability, a safe use cannot be guaranteed. For this reason, only unused and undamaged components packaged in their original packaging may be implanted.
Use only new components removed from their original package. A component which has suffered an impact (such as fall to the ground) must not be implanted. The same ceramic component or sleeve must never be used again. This means, for example, that a BIOLOX® OPTION system component that has been placed once on a stem and then removed must not be placed on the stem a second time. A component with any kind of damage must be discarded. In the event of fracture of the ceramic head with a polyethylene liner: remove the polyethylene liner because ceramic particles could damage the new femoral head, which would result in increased friction wear of the polyethylene (see "Warnings"). In case of peroperative fracture of the ceramic component, remove all ceramic particles.

WARNINGS
Ceramic implants must only be applied by qualified operating surgeons who possess in-depth knowledge and experience in the field of hip joint replacement. In extremely rare cases, in vivo fracture of the ceramic component may occur. To minimize this risk, before delivery each part is proof-tested to eliminate parts that may pose such a risk. The reasons for head fracture may be:
- Excess load on the prosthesis due, for example through incorrect placement of the femoral ball head on the stem taper or an incorrect or miss fit between the femoral ball head and the stem taper.
- Mismatched ceramic head and stem tapers.
- Use of prosthetic components not allowed by the prosthesis supplier.

The MectaCer BIOLOX® OPTION system components may only be combined with prosthesis components that are released by Medacta® for MectaCer BIOLOX® OPTION system components.
The sleeve and the ceramic femoral head are components of the MectaCer BIOLOX® OPTION system. Only unused sleeves must be used. Any reuse and resterilization of these components is not permitted. The operating surgeon must test the stem taper of the stem which has remained in situ for compatibility with the inner taper angle of the sleeve. If there is any doubt concerning the taper angle, the stem manufacturer must be contacted. In case a ceramic component breaks, a pairing of metal (ball head) with polyethylene (insert) and of metal with metal must not be used for revision. Malpositioning may reduce implant longevity and lead to early implant failure.

INSTRUCTIONS FOR USE

PREOPERATIVE PHASE
The surgeon should make the patient aware of the fact that artificial joints cannot replicate natural joint function. Any form of competitive sport, or any sport involving jerky and sudden movements of the prosthetic joint, is contraindicated for ceramic implants. The patient must be informed about possible postoperative complications, and these must conform to the current medical science. There is increased risk in patients with overweight, patients with fragile bones, or patients who are physically very active, or have unrealistic expectations of the artificial joint. Momentary overloading in a fall or accident may cause failure of the implant, sometimes long after the event. The necessity to follow the postoperative instructions given by the surgeon should be fully understood by the patient. A stock of sterile implants of suitable sizes should be available and checked by the operator before the surgery. Planning of the operation is based on the information available. Basically the determination of the stem which has remained in situ and of the stem taper is of prime importance during the pre-operative planning. The inner taper of the sleeve must fit the stem taper. Technical information can be requested from the manufacturer of the prosthesis system.
The MectaCer BIOLOX® OPTION system and their associated metallic prosthetic components (femoral stems and acetabular shells) have not been evaluated for safety and compatibility in the MR environment. The MectaCer BIOLOX® OPTION system and their associated metallic prosthetic components have not been tested for heating or migration in the MR environment.

INTRASURGICAL PROCEDURE

HEAD REMOVAL AND INSPECTION OF THE USED STEM TAPER
In case of revision surgery, extracting the femoral head that has remained in situ should be done using a suitable extraction instrument, to avoid unnecessary damage to the stem taper and/or to the polished neck of the stem.
After extraction, the remaining stem taper must be visually inspected and only in case the taper is undamaged the MectaCer BIOLOX® OPTION system can be used with the taper. If the stem taper is damaged the MectaCer BIOLOX® OPTION system cannot be used.
Trial heads must be used to determine the neck length and to check the tissue balance and the range of motion.

FINAL SETTING ON THE STEM
The stem taper, sleeve and ceramic femoral head must be dry and free of any foreign matter (e.g. tissue parts, bone or cement particles) before their final setting in order to guarantee a safe coupling between the components. The operating surgeon has to be aware that a scratched neck can have an influence to the endurance of the stem and can lead to an early fracture of the stem neck.

HANDLING
To avoid scratching or damaging the implants, these should be handled with the utmost care by qualified personnel and in an environment where conditions of hygiene are controlled. The implants should be kept in their undamaged packages.

POSTOPERATIVE CARE AND FOLLOW-UP
The surgeon should caution the patient to control their level of activity and avoid excessive loads on the replaced joint. Moreover the surgeon should make the patients aware of the precautions to be taken as regards exercises, treatments and limitations on activities, as well as exposure to magnetic fields. The patient must be told that metallic implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI scans).

STERILIZATION
MectaCer BIOLOX® OPTION system components implants are sterilized by gamma irradiation at 25 kGy, which can be seen from the designation on the packaging and the coloured sterilization indicator. Aluminium oxide ceramics may change colour after gamma irradiation; this has no effect on their properties. Sterilized devices must be kept in their sealed original package until opened for use. The expiration date (shown on the label) and package integrity must be checked. Any damage to the package may compromise sterility. When the implant is removed from the package and during the entire implantation, the rules of asepsis must be observed.

PACKAGING
Femoral heads and sleeves are supplied in single-use individual packages. For components delivered sterile, the sterilization method is indicated on the label. The expiration date must be checked on the label as well as the package integrity to ensure that sterility of the contents has not been compromised. If the sterilization expiry date has passed or there is any damage to the protective packaging or the package has been opened, do not use the component. A MectaCer BIOLOX® OPTION system must not be resterilized.

INSTRUMENTS
Instruments are supplied non-sterile and must be cleaned and sterilized prior to use.
Recommended cleaning, decontamination and sterilization instructions are provided on www.medacta.com.

STORAGE
The packages must be stored in a cool, dry place, away from light. Observe the indications, as well as the pictograms, shown on the package. The MectaCer BIOLOX® OPTION ceramic femoral head are extremely sensitive to damage. Even small scratches or impact points can cause wear and tear or fracture and lead to complications. Extremely careful handling is therefore required.

SYMBOLS

	Do not reuse		Do not use if package is damaged
	Do not resterilize		Use by
	Caution, read the accompanying documents	LOT	Lot number
	Consult instructions for use	REF	Reference number
	Do not expose to sunlight	STERILE EO	Sterilized with ethylene oxide
	Store in a dry place	STERILE R	Sterilized by irradiation

TRADEMARKS
BIOLOX® is a registered trademarks of CeramTec GmbH.
Medacta® is registered trademark of Medacta International SA, Castel San Pietro, Switzerland.

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