MECTACER BIOLÖX® OPTION System

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

IMPORTANT INFORMATION FOR THE DOCTOR

ALLORED COMBINATION OF PROSTHETIC COMPONENTS
Medacta International is not responsible for the use of implant components in combination with a component from another manufacturer (unless otherwise specified by Medacta International in the surgical instruction). Therefore, we advice against such use. The possible combination of Medacta International implant components is given in the surgical technique of the selected stem. The thread-on-horn combination consists of two total surfaces with a precisely fitted geometry and a precise defined linear. The surgeon always should make sure that the components selected according to these instructions for use match each other (especially Medacta International BIOLÖX® OPTION prosthesis femoral heads are available in combination with Polyethylene liners).

MektacBIOLÖX® OPTION ceramic femoral heads only with QuadraS, QuadraTi, Quadra4, AML+HLM, femoral stems specifically labeled for use with these ball heads.

FEMORAL HEAD FIXATION TO THE STEM TAPER
The standard Medacta BIOLÖX® OPTION stem system prevents any tilting motion. It also has the advantage of uniformly distributing stress over the stem length. The Medacta BIOLÖX® OPTION system should perfectly fit into the corresponding part of the stem.

The following recommendations must be kept in mind:
• The Medacta BIOLÖX® OPTION system must be used only with prosthesis which have -with the specified taper- matching taper system. The taper size is shown on the product label and, when possible, on the implant label.
• The Medacta BIOLÖX® OPTION system is delivered as disposable components (ceramic femoral head, sleeve). Each component (ceramic femoral head, sleeve) is delivered in an individual package. The Medacta BIOLÖX® OPTION femoral head and sleeve must be implanted together.

The ceramice femoral head is placed on the sleeve and pressure is applied until resistance is felt. It should be ensured that the ceramic femoral head is not placed or carried on an edge on the sleeve.

Before fitting the Medacta BIOLÖX® OPTION system to the stem:
• Thoroughly clean the stem taper with water.
• Dry the stem taper carefully using a clean cloth.
• Temporarily impact the stem taper and femoral head taper, and remove any foreign material, such as dust particles, bone fragments or cement.
• Place the Medacta BIOLÖX® OPTION system on the stem taper by locking lightly and using axial manual pressure until it feels as if a real joint is being placed on the Medacta BIOLÖX® OPTION system on the stem taper. Pressure should be enough to seat the Medacta BIOLÖX® OPTION system, the system must not be used.
• Place the plastic head implant on the poles of the femoral head and with moderate load on the hammer in an axial direction. Ensure that it is fully impacted. It is possible to use more than one modafix taper to fix the Medacta BIOLÖX® OPTION femoral head and sleeve on the stem taper. The surface structure of the metal taper becomes distorted plastically by the impacting of the taper, thereby preventing an optimal pressure distribution and a transaxial-resistant fixation. The assemble of the acetabular head fixation must be tested by an attempt to remove it by head.

Caution: A metal hammer must never be used on the Medacta BIOLÖX® OPTION femoral head. Use only the plastic head implant provided for the purpose must be used.

INSTRUCTIONS WITH DRUGS
No interactions with any drugs have been reported to data.

RECAPITULATION AND REVIEW
Medacta BIOLÖX® OPTION System components that have already been used, have a risk of complications invisible to the naked eye. Since any time of osteolysis could indicate a loosening, its functionality and/or stability, a safe use cannot be guaranteed. For the reason, only used and unattached components possess in their original packaging may be implanted.

Use only new components removed from their original package. A component which has been left to the ground must not be reimplanted. The same ceramic component or sleeve must never be used again. This means, for example, that a BIOLÖX® OPTION system component that has been placed once on a stem and then removed must not be placed on the same stem a second time. A component with any kind of damage must be discarded. In the event of fractures of the ceramic head with a polyethylene liner, then remove the polyethylene liner because ceramic particles could damage the new femoral head, which would lead to a necrosis of the polyethylene (see warning). In case of perforative fractures of the ceramic component, remove all ceramic particles.

WARNING
Ceramic implants must only be applied by qualified operating surgeons who possess in-depth knowledge and experience in the field of head joint replacement. In emergency cases, in vitro fracture of the ceramic component may occur. To minimize this risk, before delivery each part is pretested to determine parts that may pose a risk. The reasons for head fracture may be:
• Excess load on the prosthetic sleeve, for example through misplaced placement of the femoral head on the stem taper or on an incorrect or insufficient taper between the femoral head and stem taper.
• Mandated ceramic taper and stem taper.
• Use of prosthetic components not allowed by the prosthesis supplier.

The Medacta BIOLÖX® OPTION system components may only be combined with prosthetic components that are released by Medacta® for the Medacta® BIOLÖX® OPTION system components. The sleeve and the ceramic head component are the ceramic counterparts of the Medacta® BIOLÖX® OPTION system. Only unused sleeves must be used. Any re-use and re-sterilization of these components is not permitted. The operating surgeon must feel the stem taper of the stem which remains installed in the hip for at least 12 months before the first upper taper angle of the sleeve. If there is any doubt concerning the taper angle, the stem component must be customised. In case a ceramic component breaks, a pairing of metal (ball) with polyethylene (neck) and medical metal must not be used for this purpose. Misaligning may result in impaired longevity and lead to early implant failure.

INSTRUCTIONS FOR USE

PREOPERATIVE PHASE
The surgeon must make the patient aware of the fact that artificial joints cannot realize natural joint function. Any form of competitive sport, or any sport involving jumping and sudden movements of the prosthesis joint, is contraindicated for ceramic implants. The patient must be informed about possible postoperative complications, and those must be customary for modern medical science. There is increased risk in patients with osteoarthritis, patients with fragile bones, or patients who are usually very active, or have unrealistic expectations of the artificial joint. Mentally overloading in a fall or accident may cause failure of the implant, sometimes long after the event. The necessity to follow the conservative instructions given by the surgeon should be fully understood by the patient. A stock of sterile implants of suitable size should be available and checked by the operator before the surgery. Planning of the operation is based on the information available. Especially for the stability of the stem and which has remained in an already existing prosthesis in case of preoperative planning. The taper angle of the sleeve must fit the stem taper, Technical Information can be requested from the manufacturer of the prosthesis system. The Medacta BIOLÖX® OPTION system and the associated metallic prosthesis components (femoral stems and acetabular shell) have not been evaluated for safety and compatibility in the MRI environment. The Medacta BIOLÖX® OPTION system and their associated metallic prosthesis components have not been tested for healing in an in vivo and in vitro environment.

INTRAOPERATIVE PROCEDURE
HEAD REMOVAL AND INSERTION OF THE USED STEM TAPER
In case of removal of the head, the surface of the stem which has remained in situ should be treated using a suitable extraction instrument, to avoid unnecessary damage to the stem taper and to the polished rough of the sleeve.

After extraction, the remaining taper must be visually inspected and only in case the taper is the undercut the Medacta® BIOLÖX® OPTION system can be used with the taper. If the stem taper is damaged, the Medacta® BIOLÖX® OPTION system cannot be used. The taper 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 free of any foreign material (e.g. tissue paper, bone 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 structural rest can have an influence to the endurance of the stem and can lead to an early failure of the stem neck.

HANDLING
For avoiding damaging 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 control the patient to control the load of activity and avoid excessive loads on the replaced joint. Moreover the surgeon should make the patients aware of the procedures 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) and magnetic resonance imaging (MRI) scan.

STERILIZATION
Medacta® BIOLÖX® OPTION system components implants are sterilized by gamma irradiation at 25 kGy, which can be seen from the designation on the packaging and the sterilization indicator. Sterility of the entire suture must be guaranteed. The use of any preirradiation packaging or preirradiation packaging or the packaging has been opened, do not use the component. A Medacta® BIOLÖX® OPTION system must be sterilized.

PACKAGING
Femoral heads and sleeves are supplied in single-use individual packages. For components delivered sterile, the sterilization method is indicated on the sere. The expiration data must be checked on the label as well as the package integrity to ensure that it is not contaminated. In case of damage of the packaging, the package can not be used. Any damage to the packaging may compromise sterility. When this information is removed from the package and during the entire manipulation, the ability of sterilization must be observed.

INSTRUMENTS
Instruments are supplied non-sterile and must be sterilized and stored 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 packages. The Medacta® BIOLÖX® OPTION ceramic femoral head are susceptible to damage. Small scratches or impact points can cause wear and tear or fracture and lead to complications. Extraneous surface hardening is therefore recommended.

SYMBOLS

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<th>Symbol</th>
<th>Description</th>
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<tr>
<td>Dornot reuse</td>
<td>Use by</td>
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<tr>
<td>Dornot resealize</td>
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<tr>
<td>Caution</td>
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<tr>
<td>Read the accompanying documents</td>
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<td>Consult instructions for use</td>
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<td>Dornot expose to sunlight</td>
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TRENDS
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Medacta International’s registered trademark of Medacta International SA, Castel San Pietro, Switzerland.

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(303) 361-3030