Strada Regina
CH - 6874 Castel San Pietro - Switzerland
Phone : + 41 91 696 60 60 Fax +41 91 696 60 66
Info@medacta.ch – www.medacta.com
US toll free phone number : 800-901-7836

Manufactured by:
Medacta® International SA
CH-6874 Castel San Pietro - Switzerland

MectaCer BIOLOX® *forte*, MectaCer BIOLOX® *delta* – femoral heads

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

ENGLISH **MectaCer BIOLOX® *forte*, MectaCer BIOLOX® *delta* - femoral heads - INSTRUCTIONS FOR USE – USA only**
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 carefully read these instructions for use. 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.

PROPERTIES AND ADVANTAGES OF CERAMIC FEMORAL HEADS FOR HIP PROSTHESES
The MectaCer BIOLOX® *forte* femoral heads and the MectaCer BIOLOX® *delta* femoral heads are made of high-purity aluminium oxide ceramic compound.
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® *forte* femoral heads and the MectaCer BIOLOX® *delta* 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 advises against the use of their prosthetic components with implants offered by other companies unless explicitly recommended. Medacta® International will accept no responsibility for any malfunction if Medacta® implants are used with components offered by other companies not specifically recommended.
MectaCer BIOLOX® *forte* femoral heads and MectaCer BIOLOX® *delta* femoral heads may only be combined with prosthetic components released by Medacta® for use with MectaCer BIOLOX® *forte* femoral heads and MectaCer BIOLOX® *delta* femoral heads.

The surgeon should always make sure that the components selected according to these instructions for use match one another geometrically.
The MectaCer BIOLOX® forte femoral heads and the MectaCer BIOLOX® delta femoral heads are allowed in combination with Polyethylene liners.

Use MectaCer BIOLOX® *forte* femoral heads and MectaCer BIOLOX® *delta* femoral heads only with Quadra®-S, Quadra®-H, Quadra®-C, Quadra®-R, AMIStem-H, AMIStem-C femoral stems specifically labelled for use with these ball heads.

Femoral head fixation to the stem taper
The taper fixation of MectaCer BIOLOX® *forte* femoral heads and MectaCer BIOLOX® *delta* femoral heads prevents any twisting motion; it also has the advantage of uniformly distributing stresses over the stem. The femoral head should perfectly fit into the corresponding part of the stem.
The following precautions must be taken:
The MectaCer BIOLOX® *forte* femoral heads and the MectaCer BIOLOX® *delta* femoral heads should 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.
Use only new tapers, and do not ever use damaged tapers. It is important to make sure that the ceramic femoral head and stem tapers match perfectly.

For proper functioning of the prosthesis, it is essential to fit the femoral head to the stem taper with meticulous care.
Do not remove the plastic protective cap which protects the stem taper from damage, until immediately before the test ball head is put on.
Before fitting the femoral head to the stem:

- Thoroughly clean the stem taper with water.
- Dry the stem taper using a clean towelette.
- 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 femoral head on the stem taper by twisting lightly and using axial manual pressure until it sits firmly.
- Place the plastic head impactor on the pole of the femoral head and with a light tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, causing an optimal distribution of pressure and a torsion-resistant fixation.

Caution: Never strike the ceramic femoral head directly with a metal mallet or hammer. Use only the plastic head impactor provided for this purpose.

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

REOPERATION AND REUSE
With ceramic ball heads that have already been used, there is a risk that they could have 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 new ceramic ball heads packaged in their original packaging may be implanted.
A ceramic component which has suffered an impact (fall to the ground) must not be implanted.
A ceramic component with any kind of damage may not be used, but discarded instead.
A ceramic femoral head which has been fixed to the taper of a stem and then removed must not be reused.

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 preoperative fracture of the ceramic component, remove all ceramic particles.

If, during revision surgery, the stem can be left in place while the femoral head must be replaced, never use a MectaCer BIOLOX® *forte* or a MectaCer BIOLOX® *delta* ball head.

WARNINGS
The positioning of the prosthetic components has a direct influence on the range of motion and therefore poses a potential risk of jamming, dislocation, or subluxation.
Too vertical a cup will increase edge stresses, which will result in increased wear.
The angle of inclination of the acetabular components should not be smaller than 40 degrees or larger than 45 degrees.
Out-of-limit values may cause excessive range of motion resulting in femoral head subluxation and/or dislocation from the liner.

Ceramic wear from excessive friction may cause reactions in tissue, loosening of the prosthesis, and, in extreme cases, breakage of the ceramic.

Sufficient joint tension should be maintained because dislocation could have the above consequences.
In these cases, Medacta® International accepts no responsibility.

For other risks and side effects, the surgeon should refer to the instructions for use of the prosthetic system with which the head is used.

In extremely rare cases, fracture of the ceramic component may occur. To minimize this risk, 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 for example through incorrect placement of the femoral ball head on the stem taper or a wrong or missing fit between the femoral ball head and the stem taper.
- Mismatched ceramic head and stem tapers.
- Use of prosthetic parts not provided with the ceramic range.

The MectaCer BIOLOX® *forte* femoral ball heads or the MectaCer BIOLOX® *delta* femoral ball heads may only be combined with prosthesis components that are released by Medacta® for MectaCer BIOLOX® *forte* femoral ball heads or MectaCer BIOLOX® *delta* femoral ball heads.

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 physician 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 should be informed about possible postoperative complications, and these must conform to the current state of medical findings. 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 MectaCer BIOLOX® *forte* femoral heads and MectaCer BIOLOX® *delta* femoral heads 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® *forte* femoral heads and MectaCer BIOLOX® *delta* femoral heads and their associated metallic prosthetic components have not been tested for heating or migration in the MR environment.

STERILIZATION
All ceramic implants are sterilized by gamma irradiation at 25 kGy. 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. Do not use product past expiration date or if the package is damaged. When the implant is removed from the package and during the entire implantation the rules of asepsis must be observed.

PACKAGING
The MectaCer BIOLOX® *forte* femoral heads and the MectaCer BIOLOX® *delta* femoral heads are supplied in single-use individual packages.
The sterilization method is indicated on the label. The expiration date and package integrity must be checked to ensure that sterility of the contents has not been compromised. If the sterilization expiry date has expired or in any case of any damage to the protective packaging or if the package has been previously opened, do not use the component.
Do not resterilize.

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 warnings shown on the packages.

SYMBOLS


"Do not reuse"


"Do not resterilize"


"Caution, read the accompanying documents"


"Consult instruction for use"


"Do not expose to sunlight"


"Store in a dry place"

"Do not use if the package is damaged"


"Use by"

"Lot number"

"Reference number"

"Sterilized by irradiation"

Date:11/2011

Distributed by Medacta USA, Inc 4725 Calle Quetzal unit B Camarillo, CA 93012-9101 (800) 901-7836