The MectaCer BIOLOX® forte femoral heads and the MectaCer BIOLOX® delta femoral heads are made of high-purity aluminium oxide ceramic component. These components are 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 extremely hardness.

**INDICATIONS**

The MectaCer BIOLOX® forte femoral heads and the MectaCer BIOLOX® delta femoral heads are intended for mechanical fixation to a matching 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:
- Severe painful and/or disabled joint as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or juvenile arthritis.
- Congenital hip dysplasia.
- 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, systemic 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 neuropsychiatric disorders may create an unacceptable risk to the patient and can be a cause 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.

**STORAGE**

Packaging materials are sterilized by gamma irradiation at 25 kGy. Aluminium oxide ceramics may change colour after gamma irradiation. This has no effect on their properties.

**Stereilization**

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.

**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.

**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 prosthetic joint, 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.

**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.

**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 prosthetic joint, 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.

**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.

**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 prosthetic joint, 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.

**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.

**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 prosthetic joint, 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.

**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.

**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 prosthetic joint, 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.

**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 adversel