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## HIP PROSTHESIS: MEDACTA® BIPOLAR HEAD

### CAUTION

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

### ENGLISH MEDACTA® BIPOLAR HEAD - HIP PROSTHESIS - 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 product literature and operative technique and must carefully read these instructions for use. Patient selection is as important as implant placement or positioning. Over-weight patients, 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

A hip prosthesis for hemiarthroplasty consists of a femoral stem made of metal, a modular femoral head made of metal or ceramic, and a bipolar head designed to articulate directly in the patient acetabulum. The bipolar head has an inner ultra-high molecular weight polyethylene (UHMWPE) surface and an outer metal surface which is assembled in the factory.

All the auxiliary components of the prosthesis are supplied in single-use individual packages.

The MEDACTA® Bipolar Head stems can be combined with the CoCr ball heads or with the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta femoral heads. Refer to the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta femoral heads package insert for more information about the ceramic ball heads.

### INTENDED USE / INDICATIONS

The Medacta® Bipolar Head is intended for use in combination with Medacta® Hip Prosthesis System and Mectacer femoral heads for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur.
- Osteonecrosis of the femoral head.
- Revision procedures where other devices or treatments for these indications have failed.

### CONTRAINDICATIONS

Hemiarthroplasty is contraindicated in the following cases:

- Acute, systemic or chronic infection.
- Muscular, neurological or vascular deficiency of the affected limb.
- 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.

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

It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

### WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the instrumentation supplied and specially designed for that range of implants. The trial instrumentation must be used to confirm the choice of sizes and verify the functionality of the joint. The label shows the size of the taper cone. The surgeon should check the stem-head fit before assembly.

The Medacta® BIPOLAR HEAD has not been evaluated for safety and compatibility in the MR environment. The Medacta® BIPOLAR HEAD has not been tested for heating or migration in the MR environment.

### MEDACTA® INTERNATIONAL IMPLANTS

Under no circumstances should a Medacta® International modular implant component be used in combination with a component from another manufacturer, unless otherwise specified by Medacta® International.

Only authorized Medacta® combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Medacta® sales representative or visit the Medacta® website: [www.medacta.com](http://www.medacta.com). The components of a hip prosthesis should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure.

Always use a trial prosthesis for trial purposes only. Trial prostheses should not be assembled with components intended for permanent placement. Never adapt or alter trial prostheses.

When changing a prosthetic head on a femoral stem in place, it is essential to use a metal head.

PE implants should be stored for at least three hours at 20°C (+/- 3°C) before the operation.

### RISK FACTORS

The following conditions, individually or together, may cause excessive loading of the affected limb, exposing the patient to greater risk of a hemiarthroplasty failure:

- Obesity or overweight of the patient, depending on the type of implant.
  - Hard manual work.
  - Intensive sporting activity.
  - High level of activity.
  - Probability of falling.
  - Alcoholism or drug addiction.
  - Other handicaps which could compromise the outcome of the operation.
- The following conditions, individually or together, will make fixation of the hip prosthesis challenging:
- Advanced osteoporosis or insufficient bone stock.
  - Metabolic disorders or systemic medications leading to gradual loss of bone support for the prosthesis (e.g. diabetes mellitus, treatment by steroids, immunosuppressives, etc.).
  - History of disseminated systemic or local infection.
  - Significant deformations preventing correct fixation or placement of the prosthesis.
  - Tumours of the supporting bone structures.
  - Allergic reactions to the prosthesis materials (e.g. cement, metal, polyethylene).
  - Tissue reaction to implant corrosion or wear debris.
  - Functional incapacity of the other joints.

### INSTRUCTIONS FOR USE

#### PREOPERATIVE PHASE

The surgeon should discuss with the patient their physical and mental limitations, as well as all the details of the procedure and prosthesis. The discussion should consider the limitations of the procedure and the constraints imposed by the selected implant. The factors which could limit the performance and stability of the implant, e.g. level of activity, patient's weight, should be set out to improve the patient's chances to avoid complications. 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 surgery.

### 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 until needed for use.

Do not use implants from opened packages, that are damaged, or that are beyond their expiration date.

### SURGICAL TECHNIQUE

The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical techniques (brochure and video) and products are available on request. Careful preoperative planning, documented by X-rays, is essential. X-ray templates are available for most implants.

### 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, and make them aware of the precautions to be taken with regards to exercise, treatments and limitations on activities, as well as avoiding exposure to magnetic fields.

Periodic follow-up and X-rays are recommended to make comparisons with the immediate postoperative condition and identify implant displacement, loosening, etc. Excessive physical activity, and operated limb traumas may cause early failure of the arthroplasty through implant displacement, fracture and/or wear. If the case occurs, it is necessary to place the patient under supervision, evaluate the possible progression of the deterioration, and weigh the benefit of early revision.

### ADVERSE EFFECTS AND COMPLICATIONS

#### GENERAL

- Prosthesis dislocation, often related to the above-mentioned risk factors.
- Early or late loosening of the prosthetic components, often related to the above-mentioned risk factors.
- Fatigue failure of the femoral stem, often related to the above-mentioned factors.
- Wear of the polyethylene component or fracture of the liner or head, often related to the above-mentioned risk factors.
- Early or late infection.
- Neuropathies. Intra-operative lesion of a nerve, due to surgical trauma.
- Tissue reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose cement particles.

#### INTRA-OPERATIVE

- Femur diaphysis perforation, crack or fracture that may require internal fixation.
- Trochanter fracture.
- Vascular damage (iliac, obturator and femoral arteries).
- Temporary or permanent nerve damage (femoral, obturator or sciatic nerve).
- Subluxation or dislocation of the hip joint due to wrong size selection or wrong prosthesis configuration, malposition of the components and/or laxity of the muscles and connective tissue.
- Lengthening or shortening of the operative side.

#### IMMEDIATE POSTOPERATIVE

- Cardiovascular disorders, including vein thrombosis, embolism, and myocardial infarction.
- Hematoma and/or delayed healing.
- Pneumonia and/or atelectasis.
- Subluxation or dislocation.

#### LATE POSTOPERATIVE

- Avulsion of the trochanter resulting from excessive muscle tension or overloading.
  - Aggravation of the problems with the knee and ankle of the ipsilateral or contralateral limb caused by difference in leg length, femur displacement and/or muscular deficiency.
  - Fracture of the femur or acetabulum resulting from trauma or overloading, especially because of poor bone stock resulting from severe osteoporosis, bone defects resulting from previous surgery, intra-operative reaming or bone resection.
  - Bone resorption which may damage the fixation or result in implant loosening.
  - Periarthral calcification or ossification which may reduce mobility and the articular range of motion.
  - Traumatic arthritis of the ipsilateral knee, due to the position of the limb during the operation.
  - Subluxation or dislocation.
- The incidence and severity of the complications related to hip replacement are usually higher with revision surgery than with primary surgery. Common problems during revision surgery may include the difficulty of finding where to make the incision, the resection of sequestra and old bone cement, the placement and fixation of the components and/or on the search for adequate bone support. During revision surgery, there is an increased risk of longer operative times, blood losses and higher incidence of infection, embolism and hematoma.

### PACKAGING

All the implant components of a hip prosthesis are supplied in single-use individual packages.

For components delivered sterile, 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 package is damaged, 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](http://www.medacta.com).

### STORAGE

The packages must be stored in a cool, dry place, away from light.

### SYMBOLS

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

Date: 11/2011