

CAUTION

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



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1. INTRODUCTION

Femoral neck fracture and femoral head necrosis are surgical cases in which hemiarthroplasty is recommended as it seems inappropriate to replace an healthy acetabulum, that might result in subsequent bone loss and additional revision problems.

Furthermore, compared to the total hip replacement, hemiarthroplasty procedures involve shorter surgical times and lower medical and prosthesis costs.

The Medacta Bipolar Head is a product suitable to perform hemiarthroplasty on any hip joint whose acetabular conditions are satisfactory.

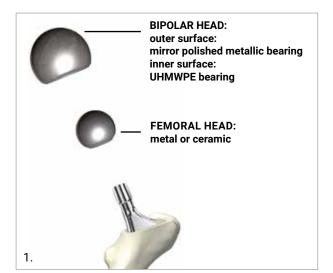
This document describes the concept and the surgical technique for the Medacta Bipolar Head implant. Carefully read the instructions for use and if you have any questions concerning product compatibility please contact your Medacta representative.

1.1 CONCEPT

The Medacta Bipolar Head includes an outer shell made of stainless steel, designed to articulate directly in the patient's acetabulum with an inner Ultra High Molecular Weight Polyethylene (UHMWPE) bearing surface, in which articulates the prosthetic femoral head.

The locking of the femoral head inside the bipolar head is easily achieved and assured thanks to an elastic internal retaining ring.

It is possible the change into a Total Primary Arthroplasty, without any damage to the head and the taper, simply by removing the Medacta Bipolar Head (see section 6).



1.2 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.

1.3 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.

1.4 PREOPERATIVE PLANNING

Careful preoperative planning is essential.

A set of X-ray templates to the scale of 1.15:1 (with an X-ray of the same magnification) will help the surgeon to preselect the implant details in order to restore an architecture corresponding to the patient's anatomy.

WARNING

The final implant will be selected intra-operatively, because of possible discrepancies between actual conditions and templating.

1.5 SURGICAL APPROACHES

The choice of the surgical approach is up to the surgeon.



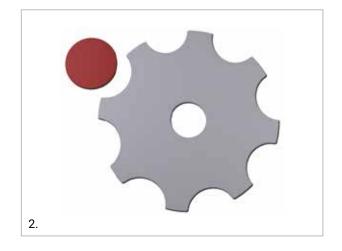
2. FEMORAL HEAD SIZE

The bipolar head diameter depends on the smaller resected femoral head diameter and can be evaluated with the aid of the femoral head sizer. This preliminary choice will be confirmed by the trial reduction.

CAUTION

The head diameter must be checked in different positions as it is not spherical.

NOTE: Not all the sizes indicated in the sizers are available for both Medacta Bipolar Head size Ø 22 mm and Ø 28 mm. Take care to check for the implant size available.



3. TRIAL REDUCTION

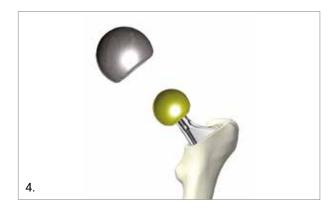
Mount the adapter for trial bipolar head on the multifunction handle and screw the assembly into the trial bipolar head of the diameter chosen preliminary.

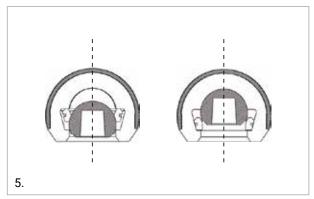
Test the correct diameter dimension placing the trial bipolar head directly into the acetabulum.

Unscrew the assembly "multifunction handle-adapter" from the trial bipolar head.



Place the trial bipolar head on the trial head positioned on the trial or final stem and proceed with the trial reduction in order to test mobility, joint stability, range of motion and leg length.



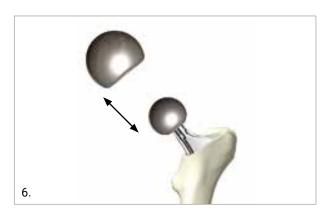


4. FINAL SETTING

After final head positioning, place the Medacta Bipolar Head on it.

The head retention into the bipolar head is guaranteed by the elastic internal retaining ring.

Verify the correct functioning of the retentive mechanism.



Use the impactor adaptor for multifunction handle screwed on the multifunction handle for final implant impaction.



Proceed with the final reduction.

5. BIPOLAR HEAD REMOVAL

If the bipolar head has to be removed (e.g. change of neck length, change to a total hip arthroplasty) a special key is supplied. This key frees the retaining ring in order to unlock the bipolar head from the head.

NOTE: When the key is positioned under the Medacta Bipolar Head it is essential to pull ONLY the bipolar head and not the key, otherwise it will be impossible to disassemble.





6. IMPLANTS NOMENCLATURE

MEDACTA BIPOLAR HEAD (Ø 28 MM)

Ref.	Internal / External Diameter
25060.2844	Ø 28x44 mm
25060.2845	Ø 28x45 mm
25060.2846	Ø 28x46 mm
25060.2847	Ø 28x47 mm
25060.2848	Ø 28x48 mm
25060.2849	Ø 28x49 mm
25060.2850	Ø 28x50 mm
25060.2851	Ø 28x51 mm
25060.2852	Ø 28x52 mm
25060.2853	Ø 28x53 mm
25060.2854	Ø 28x54 mm
25060.2855	Ø 28x55 mm
25060.2856	Ø 28x56 mm
25060.2857	Ø 28x57 mm
25060.2858	Ø 28x58 mm
25060.2859	Ø 28x59 mm
25060.2860	Ø 28x60 mm

MEDACTA BIPOLAR HEAD (Ø 22 MM)

Ref.	Internal / External Diameter
25060.2240	Ø 22x40 mm
25060.2241	Ø 22x41 mm
25060.2242	Ø 22x42 mm
25060.2243	Ø 22x43 mm
25060.2244	Ø 22x44 mm
25060.2245	Ø 22x45 mm
25060.2246	Ø 22x46 mm
25060.2247	Ø 22x47 mm
25060.2248	Ø 22x48 mm
25060.2249	Ø 22x49 mm
25060.2250	Ø 22x50 mm
25060.2251	Ø 22x51 mm
25060.2252	Ø 22x52 mm

Part numbers subject to change.

NOTE FOR STERILIZATION

Manual instruments supplied non-sterile. Instruments must be cleaned and sterilized prior to use.

Refer to www.medacta.com for instructions on cleaning, decontamination and sterilization of reusable manual instruments.

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Medacta International SA

Strada Regina - 6874 Castel San Pietro - Switzerland Phone +41 91 696 60 60 - Fax +41 91 696 60 66 info@medacta.ch

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Bipolar Head Surgical Technique

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