



INDEX

1.	INTRODUCTION	4
	1.1 Concept	4
	1.2 Indications of use	4
	1.3 Contraindications	4
	1.4 Preoperative planning	4
	1.5 Surgical approach	4
2.	FEMORAL HEAD SIZE	5
3.	TRIAL REDUCTION	5
4.	FINAL SETTING	6
<u>5.</u>	BIPOLAR HEAD REMOVAL	6
6.	IMPLANT POSSIBLE COMBINATIONS	6
7.	IMPLANTS NOMENCLATURE	7

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.

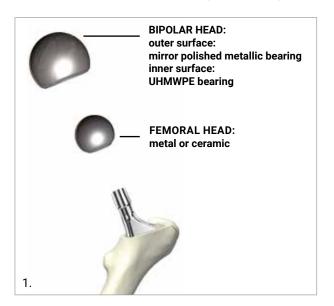
This document describes the concept and the surgical technique for the Medacta Bipolar Head implant. Carefully read the instructions for use and if you have any questions concerning product compatibility please contact your Medacta representative.

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 OF USE

Partial hip arthroplasty is indicated in the following cases:

- Acute traumatic fracture of the femoral head or neck
- Non-union of femoral neck fracture
- Avascular necrosis of the femoral head
- Primary pathology involving the femoral head but with a non deformed acetabulum

1.3 CONTRAINDICATIONS

The Medacta Bipolar Head controindications are the standard contraindications for total and partial hip arthroplasty:

- Acute, systemic or chronic infection
- Skeletal immaturity
- Severe muscular, neurological, or vascular deficiency, or other pathologies of the affected limb that may compromise the functionality of the implant
- Bone condition that may compromise the stability of the implant

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 APPROACH

The choice of surgical approach is up to the surgeon.



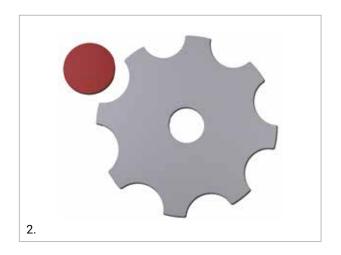
2. FEMORAL HEAD SIZE

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

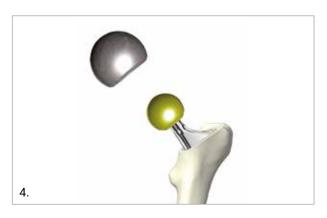
Mount the adapter for trial bipolar head on the multifunction handle and screw the assembly into the trial bipolar head of the diameter chosen preliminary.

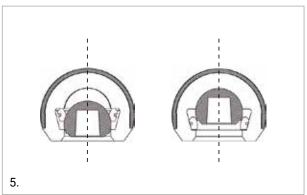
Test the correct diameter dimension placing the trial bipolar head directly into the acetabulum.

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.



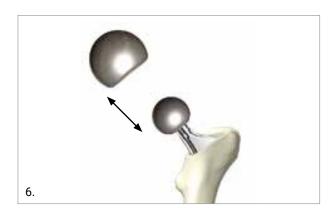


4. FINAL SETTING

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. IMPLANT POSSIBLE COMBINATIONS

All Medacta implants possible combinations are represented in the table "Medacta hip product compatibility" (ref. 99.99.COM), available at www.medacta.com.



7. IMPLANTS NOMENCLATURE

MEDACTA BIPOLAR HEAD (Ø 28 MM)

Internal / External Diameter			
Ø 28x42 mm			
Ø 28x43 mm			
Ø 28x44 mm			
Ø 28x45 mm			
Ø 28x46 mm			
Ø 28x47 mm			
Ø 28x48 mm			
Ø 28x49 mm			
Ø 28x50 mm			
Ø 28x51 mm			
Ø 28x52 mm			
Ø 28x53 mm			
Ø 28x54 mm			
Ø 28x55 mm			
Ø 28x56 mm			
Ø 28x57 mm			
Ø 28x58 mm			
Ø 28x59 mm			
Ø 28x60 mm			

MEDACTA BIPOLAR HEAD (Ø 22 MM)

Ref.	Internal / External Diameter	
25060.2239"	Ø 22x39 mm	
25060.2240"	Ø 22x40 mm	
25060.2241 ^{III}	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	

 $^{^{\}mbox{\tiny III}}$ Bipolar Heads for femoral heads Ø 22 mm are available under specific request.

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave in accordance with the regulations of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer.

For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.



MEDACTA.COM



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

Find your local dealer at: medacta.com/locations

All trademarks and registered trademarks are the property of their respective owners. This document is not intended for the US market. Please verify approval of the devices described in this document with your local Medacta representative.

Bipolar Head Surgical Technique

ref: 99.19.12 rev. 06

Last update: September 2018 **C € 0476**