CAUTION

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

The MiniMAX is a cementless anatomic stem available in 9 right sizes and 9 left sizes.

The anatomical design results in a 9° anteversion of the neck and a 5° curvature on the distal tip to follow the contours of the femoral canal. Size by size the head center and the volume of the prosthesis are designed to restore anatomy and provide optimal fit and fill.

Carefully read the instructions for use and if you have any questions concerning product compatibility please contact your Medacta representative.

1.1 INDICATIONS OF USE

- The MiniMAX stem is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery.
- Hip Replacement is indicated in the following cases:
  - Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis or 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.

1.2 CONTRAINDICATIONS

Total or partial hip replacement is contraindicated in the following cases:

- Acute, systemic or chronic infection;
- Skeletal immaturity;
- Muscular, neurological or vascular deficiency of the affected limb;
- Bone condition 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.

1.3 SPECIAL CONSIDERATIONS

The quality of the cancellous bone and the integrity of the cortical bone in the metaphyseal femur have to be considered for a successful implantation of the stem. Since MiniMAX stems are designed to reproduce the anatomical anteversion of the natural femur, it is important to take into account this aspect (especially with dysplastic hips) to ensure that correct reconstruction is possible.

1.4 PREOPERATIVE PLANNING

Careful preoperative planning is essential. It will help the surgeon to pre-select the femoral implant size in order to restore an architecture corresponding to the operated patient’s anatomy. In addition, using the set of X-ray templates to the scale of 1.15:1 (with an X-ray of the same magnification), it may be possible to determine:

- The implant size, that must ensure the best metaphyseal fill with the shoulder resting on the infero-lateral part of the greater trochanter;
- The level of the neck resection, at about 60° with respect to the femoral axis;
- The neck length;
- Appropriate femoral head center.

NOTICE: 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 at discretion of the surgeon.

The instrumentation has been developed for any approach. A specific instrumentation for the anterior approach is available upon request (for further information see the AMIS dedicated surgical technique).
2. FEMORAL NECK OSTEOTOMY

The level of the neck cut is determined during preoperative planning using the X-Ray templates. The femoral neck resection should be planned in accordance with the anatomy of the patient. The suggested resection angle for this implant is 60° to the diaphyseal axis of the femur.

The resection is performed with an oscillating saw, taking care to maintain the planned neck resection.

The femoral head is removed using an extractor.
3.  FEMORAL PREPARATION

To access to the medullary canal, the thigh is held in the position providing the best exposure of the diaphyseal axis, depending on the selected approach.

Create access to the femoral canal using the smallest broach or with the chisel. Remove the bone so that the spongiosa of the greater trochanter does not interfere with the broaches.

Both left and right broaches are available. Make sure the correct one is used.

Femoral anatomies vary with individual parameters. However, a frequently chosen and normally valid entry point is the piriformis fossa. Aim the individual instrument toward the femoral axis, starting from the piriformis fossa and carefully follow the canal without applying excessive stress on the femoral bone during the preparation.

The MiniMAX is an anatomical stem that will find its way naturally in the femur reproducing the natural anteversion of the femur. The chisel should not determine the antetorsion. A neck anteversion of 9° should be taken into account during the positioning of the cup. Pronounced cup anteversion may result in a less stable artificial joint.

For an anterior approach, do not use the chisel because of the possibility of entering the femur with a curved path. Use a curette from bottom to top to clear the lateral proximal metaphysis.

**NOTICE:** in varus hips, correct entry point to the medullary canal and reproduction of the longitudinal axis of the femur can be adequately obtained by reaming the medial part of the greater trochanter.

Use the smallest broach to begin broaching of the proximal femur.

Assemble the broach on the manual broach handle.

2. The MiniMAX implant has a neck length that increases with the size. To allow a correct trial reduction, all broaches are endowed with a toothless raise, such that when the trial neck is assembled, the correct neck length is reproduced. The raise is different for each size and must be above the femoral cut. The broaches must be inserted at optimum level determined by the neck cut being flush with the level of the last tooth.

**WARNING**

Never force impaction when the broach is blocked in the diaphysis.

3. Broaches of increasing size are introduced until optimal metaphyseal filling is achieved. Ensure proper alignment and antetorsion are achieved.

The final broach should be rotationally stable to assure perfect stability of the implant.
4. TRIALING

Once the femoral broach shows a satisfactory rotational stability, position a trial neck, left or right depending on the side being operated on.

After placement of the trial or final acetabular component, the trial reduction is performed with the help of the head impactor.

To lock the trial necks to the broach press onto the socket; to unlock pull the neck.

**NOTICE:** the head impactor must be used only for head impaction and reduction and not for the correction of the acetabular shell position.

To remove a trial head, simply pull it.

**TRICK**
If the trial head is difficult to remove from the trial neck, moisten the trial head - trial neck assembly. Twist and gently pull the trial head to extract it.

TRICK
If the broach is difficult to remove, first screw the broach extractor to the broach. Depending on the selected approach, assemble the screwed stem extractor M8 to the broach extractor. Pull out the broach.

**TRICK**

To make head insertion easier wet the head before insertion.

**Anterior approach**

**Posterior approach**

Trial heads of different diameters and sizes are available to perform the trial reductions.

A trial head is fitted to the trial neck by pushing it onto the taper.
5. FINAL IMPLANTS

Insert the final prosthesis into place. The final prosthesis corresponds to the size of the last trial broach and to the side (left or right) corresponding to the operated leg.

**WARNING**
Take care not to damage the neck's micro-thread while placing the final implant.

The stem is moved down to the limit corresponding to the test and matching the end of the macrostructures.
Carefully perform final impaction using the dedicated impactor.

**CAUTION**
Under no circumstances should the implant anteversion be changed at this stage.

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**CAUTION**
The metal head sizes XL (for Ø 28 mm and Ø 32 mm) and XXL (for Ø 28 mm, Ø 32 mm and Ø 36 mm) have a collar. This may decrease the Range of Motion in comparison to smaller sizes. Always perform trial reduction with the chosen head.

The stem taper must be thoroughly cleaned before impacting the prosthetic head.
Place the final head of the chosen size in position and secure it using the head impactor.

**WARNING**
Never force impaction when the stem is blocked in the diaphysis.
A further trial reduction can then be performed to determine the final head size.

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

**NOTICE:** for further details about ceramic femoral heads, please refer to the instructions for use for ceramic femoral heads.

**OPTION**
After impaction, if the final stem needs to be repositioned, a stem repositioner is available. This repositioner can be used with any hip approach, including the AMIS technique.
Assemble the stem repositioner by unscrewing the screw with the 3.5mm screwdriver to open the plastic clamps. Then, assemble it to the implanted stem until this is firmly seated between the plastic clamps and re-tighten the screw. The metal body should be positioned on the medial side of the stem.

Depending on the selected approach, screw the threaded stem extractor M8 onto the stem repositioner (30° hole is suggested for the AMIS approach). Pull out the stem.
6. IMPLANT NOMENCLATURE

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* On demand

**Anteversion:** 9°

**Distal curvature:** 5°

**CCD angle:** 127°
### FEMORAL HEADS

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<sup>1</sup> On demand
<sup>11</sup> Specific for revision cases

### MECTACER BIOLOX OPTION SYSTEM<sup>11</sup>

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</table>

<sup>11</sup> Specific for revision cases

Part numbers subject to change.

### NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable, and following the manufactures instructions for use of the autoclave. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.