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Strada Regina
CH - 6874 Castel San Pietro - Switzerland
Phone : + 41 91 696 60 60 Fax +41 91 696 60 66
Info@medacta.ch – www.medacta.com
US toll free phone number : 800-901-7836

Manufactured by:
Medacta International SA
CH-6874 Castel San Pietro - Switzerland

Femoral Component for Hip Prosthesis: MiniMAX™

CAUTION
Federal law (USA) restricts this device to sale, by or on the order of a physician.

ENGLISH **MiniMAX - 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. Overweight 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 total hip replacement consists of:
- A femoral stem made of metal.
- A modular femoral head made of metal or ceramic.
- An acetabular component.

A hip prosthesis for partial hip replacement consists of:
- A femoral stem made of metal.
- A femoral head that can be:
  - The Medacta Endo Head.
  - A modular femoral head made of metal or ceramic coupled with Medacta Bipolar head.

The MiniMAX femoral stem is made out of Titanium alloy (Titanium Aluminum Niobium, Ti-6Al-7Nb) coated with Titanium plasma spray in the proximal 2/3 of the shaft and extensively coated with Hydroxyapatite along the entire length of the shaft.
The cementless acetabular components consist of a metal cup and a liner (either fixed or mobile, depending on cup type) that is made of Highcross highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE).
Acetabular components that may be associated with the MiniMAX stem are: Versafitcup CC Trio, Versafitcup DM, Mpact system, Mpact DM.
All the components of the prosthesis are supplied in single-use individual packages.
The MiniMAX stem can be combined with the CoCr ball heads, Endo Head or with the MectaCer BIOLOX® *forte*, MectaCer BIOLOX® *delta* or MectaCer BIOLOX® *Option* femoral heads. Please refer to the MectaCer BIOLOX® *forte* or MectaCer BIOLOX® *delta* or MectaCer BIOLOX® *Option* package insert and to CoCr heads package insert for more information about ball heads.

INTENDED USE / INDICATIONS
The hip prosthesis MiniMAX 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 arthritis, 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.

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 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 as well as the proper use of the instrumentation specially designed and supplied 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 MiniMAX has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of MiniMAX in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.
The components of a hip prosthesis should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure.
The operating surgeon has to be aware that even a very small superficial damage, caused for instance by a sharp tool or electrocautering, particularly on the stem neck, can have an influence on the endurance of the stem and can lead to fracture.
Always use a trial prosthesis for trial purposes only. 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.

RISK FACTORS
The following conditions, individually or together, may cause excessive loading of the affected limb, exposing the patient to greater risk of a hip arthroplasty failure:
- Obesity.
- Hard physical labor.
- Intense 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).
- Tissular reaction to implant corrosion or wear debris.
- Functional incapacity of the other jointss.

INSTRUCTIONS FOR USE

PREOPERATIVE PHASE
The surgeon should discuss with the patients 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. Subclinical lesion of a nerve, due to surgical trauma.
- Tissular reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris or loose cement particles.

PERIOPERATIVE
- Cup penetration into the pelvis.
- Femoral component diaphysis perforation, 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 acetabular cup resulting from trauma or overloading, especially because of poor bone stock resulting from severe osteoporosis, bone defects resulting from previous surgery, peroperative reaming or bone resorption.
- Bone resorption which may damage the fixation or result in implant loosening.
- Periarticular calcification or ossification which may reduce mobility and the articular range of motion.
- Arthritis of the ipsilateral knee.
- 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 total or partial 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.

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

SYMBOLS

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

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Distributed by Medacta® USA, Inc. 3873 Delp St. - Memphis, TN 38118
+1 312 878 2381