HIP PROSTHESIS: AMIStem

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

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 surgical literature and perform the necessary cross-references. It is recommended that this device is used on patients who are not obese. Overweight patients, or unsuitable functional requirements may generate excessive stresses and reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

PRODUCT DESCRIPTION
The AMIStem product range is composed of:

- AMIStem-H: cementless femoral stem made of Titanium-Niobium alloy, coated with HA over the endosteal part of the shaft.
- AMIStem-H collared: cementless collared femoral stem made of Titanium-Niobium alloy coated with HA over the endosteal part of the shaft.
- AMIStem-H Proximal Coated: cementless femoral stem made of Titanium-Niobium alloy coated with Titanium plasma spray on the proximal area and with HA over the endosteal part of the shaft.
- AMIStem-P: cementless femoral stem made of Titanium-Niobium alloy coated with Titanium plasma spray over the proximal area and with HA over the endosteal part of the shaft.
- AMIStem-C: cemented stem in high nitrogen stainless steel.

CoCr heads can be coupled with a CoCr femoral stem, an Endo Head, the MecaCo BIOLUX® femur or the MecaCo BIOLUX® delta femoral head. Refer to the CoCr head package leaflet for more information about these femoral heads.

INDICATIONS
The hip prosthesis AMIStem-H, AMIStem-H collared, AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P collared are designed for cementless use in total or partial hip arthroplasty, for primary or revision surgery. The hip prosthesis AMIStem-C is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severe painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis or congenital hip dysplasia.
- Vascular damage (iliac, obturator and femoral arteries);
- Neuropathies. Subclinical lesion of a nerve, due to surgical trauma;
- Severe muscular, neurological, or vascular deficiency, or other pathologies of the affected limb that may compromise the function of the implant.
- Bone condition that may compromise the stability of the implant in any way.
- Chronic infection.
- Other handicaps which could compromise the outcome of the operation.
- Probability of falling.
- Trauma, strenuous activity, improper alignment, abnormal wear can cause abnormal and unpredictable stresses on the prosthetic components which may result in loss of fixation, intraprosthetic disassembly or prosthetic component fracture.
- 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 correct selection of the implant is extremely important. The appropriate type and size should be selected according to anatomical and biomechanical factors such as patient age, activity level, weight, bone and muscle condition, any prior surgery and anticipated future surgeries.

The trial instrumentation must be confirmed to choose the type and size of the implant. The label can indicate the size of the taper and/or any limitations. The surgeon should take this information into consideration before implantation and check the stem-head fit before assembly.

Malpositioning may reduce implant fixation and, finally, may cause the implant to fail. Any ceramic liner must be used with a ceramic head.

- Patient's change in posture during the life of the prosthetic implant might result in a variation in the relative interaction of the components and potentially cause abnormal wear, reduced stability of the joint or interaction with other structures.

CONTRAINDICATIONS
Contraindications for use of the AMIStem stems are the standard contraindications for total or partial hip arthroplasty:

- Acute, systemic or chronic infection
- Skeletal immaturity
- Severe musculoskeletal, neurologic, or vascular deficiency, or other pathologies of the affected limb that may compromise the function of the implant.
- Bone condition that may compromise the stability 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.

POSTOPERATIVE CARE AND FOLLOW-UP
The surgeon should be 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 hip prosthesis AMIStem-H, AMIStem-H collared, AMIStem-H Proximal Coated, AMIStem-P and AMIStem-P collared are designed for cementless use in total or partial hip arthroplasty, for primary or revision surgery. The hip prosthesis AMIStem-C is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.

The surgeon should caution the patient to control their level of activity and avoid excessive loads on the replaced joint.

The surgeon should make the patient aware of the precautions to be taken during exercise, treatment, limitations on activities and medications reported on the label, as well as exposure to magnetic fields. The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

In case of cementless components, an osteointegration process is required in order to reach a reliable secondary fixation of the device. Hence, in the early postoperative period, controlled physical activity is recommended for an average of 6 weeks with the aim to avoid excessive stress loading on the prosthesis that may cause micromotions. The level of activity can be increased gradually.

ADVERSE EFFECTS AND COMPLICATIONS
One or more of the following situations might result in implant failure and lead to revision surgery.

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;
- Wear or ion release of the metallic bearing surfaces, often related to the above-mentioned factors.
- Early or late infection.
- Neupathies. Subclinical lesion of a nerve, due to surgical trauma;
- Tissue reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose ceramic particles.
- Unusual complications.
- Pain.

PERIOPERATIVE
- Dissection or removal of the prosthesis.
- Femoral diaphysis perforation, or fracture that may require internal fixation;
- Trochanter fracture;
- Vascular damage (fem, obturator and femoral arteries);
- Temporary or permanent nerve damage (femoral, obturator, or sciotic nerve);
- Subluxation or dislocation of the hip joint due to wrong size selection or wrong prosthesis configuration, malpositioning of the prosthesis and resultant lack of the coverage 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 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, perioperative 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.
- Failure of porous coating

PACKAGING
All the implant components for 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
- Use by
- Consult instructions for use
- Reference number
- Do not expose to sunlight
- Sterilized with ethylene oxide
- Store in a dry place
- Sterilized by irradiation
- MR Unsafe

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