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HIP PROSTHESIS: AMIStem

CAUTION

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

ENGLISH AMIStem - 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

The AMIStem product range is composed of:

- AMIStem-H: cementless femoral stem made of Titanium-Niobium alloy, coated with HA over the entire endosteal part of the shaft.
 - AMIStem-H collared: cementless collared femoral stem made of Titanium-Niobium alloy coated with HA over the entire endosteal part of the shaft.
 - AMIStem- H Proximal Coating: cementless femoral stem made of Titanium-Niobium alloy coated with Titanium plasma spray and HA over the proximal 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 entire endosteal part of the shaft.
 - AMIStem-P collared: cementless collared femoral stem made of Titanium-Niobium alloy coated with Titanium plasma spray over the proximal area and with HA over the entire endosteal part of the shaft.
 - AMIStem-C: cemented stem in high nitrogen stainless steel.
- The AMIStem stems can be combined with a CoCr ball head, Endo Head, the MectaCer BIOLOX® forte or the MectaCer BIOLOX® delta femoral head. Refer to the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta package leaflet and 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:

- 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, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty

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 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 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 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 used to confirm the choice of size and verify the functionality of the joint. 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 longevity and lead to early implant failure.
- 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.
- HA-coated implants must not be implanted with cement.
- HA coating is subject to metabolic activity and will be processed by the host organism causing its partial or total disappearance from the device surface. The disappearance of the coating should not be regarded as an adverse event and does not, in itself, hinder device fixation.
- Cemented implants: It is essential to follow carefully the instructions for use provided by the cement manufacturer because cement handling may influence the effectiveness of implant fixation. The use of Medacta® bone cement is strongly recommended.
- After inserting a cemented implant, cement excess must be carefully removed making sure that no cement debris is loose or trapped in the articulating surfaces where it could cause abnormal wear or component failure.
- Medacta® International is not responsible for the use of its implant components in combination with a component from another manufacturer (unless otherwise specified by Medacta® International in the surgical technique), therefore we advise against such use. The possible combination of Medacta® International implant components is detailed in the surgical technique.
- 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 very small superficial damage, caused for instance by a sharp tool or electrocautery, 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. Never adapt or alter trial prostheses.
- Acetabular screws not fully inserted in their seating, presence of debris or fluids in the taper connections, presence of debris between articulating surfaces may cause abnormal wear, component failure, pain or loss of function.
- Ceramic heads are sensitive to shock. Never use a part that has been subject to shock. In case of failure of a ceramic head, the UHMWPE cup or liner must also be changed. Any ceramic liner must be used with a ceramic head.
- The surfaces of the articulating or modular components must be cleaned and dried before reduction or assembly. A reliable seating is only possible when both surfaces are completely intact.
- When assembling modular components, such as acetabular inserts or femoral heads, utmost care should be taken that nothing may hinder perfect coupling of the components.
- Avoid repeated assembly and disassembly of the modular components.
- When the connection between modular components is ensured by screws or other auxiliary devices, make sure that the components are secured per the applicable Surgical Technique.
- Under no circumstances should the porous surfaces come into contact with any cloth or material which can release fibres.

- Trauma, strenuous activity, improper alignment, abnormal wear can cause abnormal and unpredictable stresses on the prosthetic components which may result in loss of fixation, intraoperative disassembly or prosthetic component fracture.

- It is the surgeon's responsibility to ensure that the patient has no known allergy or hyper-sensitivity to the materials used.

- Prosthetic implants are designed to interact with bone tissue. In some cases, interaction with soft tissue can occur potentially causing pain, functional limitations and damage the anatomical structures and/or the prosthetic components.

MRI SAFETY INFORMATION

The AMIStem 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 AMIStem in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

RISK FACTORS

The following conditions, individually or together, may cause excessive loading of the affected limb, exposing the patient to greater risk of hip arthroplasty failure:

- Obesity or overweight of the patient.
 - Hard manual work.
 - Intensive 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 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).
 - Tissue reaction to implant corrosion or wear debris.
 - Functional incapacity of the other joints.

- The incidence and severity of the complications related to hip arthroplasty are usually higher with revision surgery than with primary surgery. Common problems during revision surgery may include difficulty finding where to make the incision, resection of old bone cement, placement and fixation of the components and/or identifying areas for adequate bone support. During revision surgery, there is an increased risk of longer operative times, blood loss and a higher incidence of infection, embolism and hematoma.

- During revision surgery, fixation and expected longevity of components left in place should be thoroughly assessed.
- When changing a prosthetic head on a femoral stem in place, it is essential to use a metallic head or Biolox® Option head, depending on the liner material. However, in case of re-intervention upon fractured ceramic component, metal heads are contra-indicated.

INSTRUCTIONS FOR USE

PREOPERATIVE PHASE

The surgeon should verify possible patient physical limitations and mental deficiencies and they should also discuss with the patient the details of the procedure and prosthesis. The discussion should consider the limitations of the procedure and constraints imposed by the selected implant. The patient should be warned that the device does not replace normal healthy bone and that the implant can break or be damaged as a result of strenuous activity or trauma. The patient should be warned that the implant has a finite expected service life and may need to be replaced in the future. 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 of avoiding 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.

Care should be taken that all devices have been stored at room temperature for at least 2 hours before surgery.

The implants should be kept in their undamaged packages. Do not use implants from opened packages, that are damaged, or that are beyond their expiration date.

PERIOPERATIVE PHASE

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. The surgeon should make the patient aware of the precautions to be taken during exercise, treatment, limitations on activities, any limitations 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.

Periodic follow-up and X-rays are recommended to make comparisons with the immediate postoperative condition and anticipate implant displacement, loosening, etc. Excessive physical activity, and operated limb trauma may cause early failure of the arthroplasty through implant displacement, fracture and/or wear. If this 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

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;
- Neuropathies. 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 cement particles.
- Urological complications.
- Pain.

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 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
	Do not resterilize		Use by
	Caution, read the accompanying documents		Lot number
	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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