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Mpact® 3D Metal™ Implants and Augments 3D Metal™

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

ENGLISH – Mpact 3D Metal Implants and Augments 3D Metal – INSTRUCTION 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 read carefully these instructions for use. Patient selection is as important as implant placement or positioning. Overweight 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 Augments 3D Metal are porous metal augments designed to act as defect filling implants in case of severe bone loss in the acetabulum to help maximize the stability of the acetabular component.
The Augments 3D Metal are intended for cemented use in combination with the Mpact 3D Metal Multi-hole acetabular cup, to address bone defects in complex acetabular surgery and to provide the surgeon with a prosthetic alternative to structural allograft in cases of segmental deficiencies.

INTENDED USE / INDICATIONS

Mpact 3D Metal Implants

The Mpact 3D Metal Implants is designed to be used in total hip arthroplasty, for primary or revision surgery.
The patient should be skeletally mature.
Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic arthritis, congenital hip dysplasia, ankylosing spondylitis.
- 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 where sufficient bone stock is present.

Augments 3D Metal

The Augments 3D Metal are intended to be used in combination with the Mpact 3D Metal Multi-hole acetabular cup in hip replacement surgeries.

The Augments 3D Metal are indicated in cases of:

- Congenital dysplasia
- Acetabular fractures
- Revision of previous implants in presence of insufficient bone quality or seriously altered bone structures

CONTRAINDICATIONS

Mpact 3D Metal Implants

The Mpact 3D Metal Implants contraindications are the standard contraindications for total hip replacement:

- Acute, systemic or chronic infection.
- Skeletal immaturity.
- Severe muscular, neurological, 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.

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.

Augments 3D Metal

Augments 3D Metal are contraindicated when it is not deemed necessary by the surgeon to provide additional stability to the cup.
The contraindications reported in the surgical technique of the chosen cup have to be followed.
It is the surgeon's responsibility to ensure that the patient has no known allergy or hyper-sensitivity to the materials used [Titanium Alloy Ti-6Al-4V (ASTM F2924)]

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.

MRI Compatibility

The MPACT 3D Metal Implants and Augments 3D Metal have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of the MPACT 3D Metal Implants and Augments 3D Metal in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

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, can have an influence on the endurance of implant.
Always use a trial prosthesis for trial purposes only. Never adapt or alter trial prostheses.

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
- 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
- Tumors 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

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, implants 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 patients 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, treatments and 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.

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 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 displacement, often related to the above-mentioned factors
- Early or late loosening of the prosthetic components, often related to the above-mentioned factors
- Fatigue failure of the femoral stem, often related to the above-mentioned factors
- Wear of the polyethylene component or fracture of the ceramic liner or head, often related to the above-mentioned factors
- Wear or ion release of the metallic bearing surfaces, often related to the above-mentioned factors
- Early or late infection
- Neuropathies, including infraclinical 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

Intra-operative

- Cup perforation
- 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

Immediate postoperative

- Cardiovascular disorders, including vein thrombosis, embolism, and myocardial infarction
- Haematoma and/or delayed healing
- Pneumonia and/or atalectasis
- 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
- Traumatic arthritis of the ipsilateral knee, due to the position of the limb during the operation
- Subluxation or dislocation

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 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 haematoma.
During revision surgery, when implanting the Augments 3D Metal always replace the cup with a new one.

PACKAGING

The components of all Medacta hip systems are supplied in single-use packages.
For components delivered sterile, the sterilization method is indicated on the label. The expiration date must be checked on the label as well as the package integrity to ensure that sterility of the contents has not been compromised. If the package is damaged or has been previously opened, do not use the component. Do not resterilize.

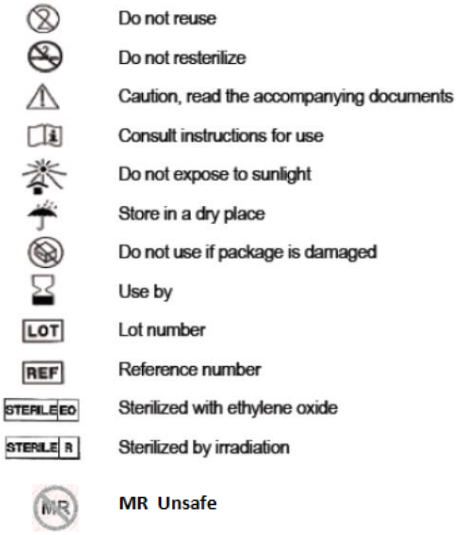
INSTRUMENTS

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.

PICTOGRAMS



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