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 prognosis. 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 trauma may cause early failure of the arthroplasty through implant displacement, fracture and/or wear. If the case occurs 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 risk 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.
• Tissue 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 (iac, 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

• Vascular injury (iliac, femoral, obturator, sciatic nerve).
• Fracture of the femur or acetabular cup occurring from trauma or overload, especially because of poor bone stock resulting from severe osteoporosis, bone defects resulting from previous surgery, periprosthetic reaming or bone resorption.
• Bone resorption which may damage the fixation or result in implant loosening.
• Proliferative calcification or ossification which may reduce mobility and the articular range of motion.
• Arthritis of the pelvic girdle.
• 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 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.

REFERENCES

Do not reuse
Do not resterilize
Use by
Cautions, read the accompanying documents
Consult instructions for use
Store in a dry place

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Femoral Component for Hip Prosthesis: MiniMAX™

CAUTION

Important note: the device(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

MEDACTA INTERNATIONAL IMPLANTS

Do not use if package is damaged
Sterilized with ethylene oxide
Use by
Sterilized by irradiation

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