VERSAFITCUP®

CAUTION

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

VERSAFITCUP® - 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 or unsalvageable tissues and joints and the hip implant. The warnings must be heeded, and the instructions for use must be strictly followed.

PRODUCT DESCRIPTION

A hip prosthesis consists of a femoral stem made from metal, a modular femoral head made of metal or ceramic compound and acetabular components. The acetabular components consist of a metal cup, and a liner that is made of ultra-high molecular weight polyethylene (UHMWPE) or Highcross highly crosslinked ultra-high molecular weight polyethylene (XLH-MWP). The auxiliary components of the prosthesis are supplied in single-use individual packages.

INTENDED USE / INDICATIONS

The hip prosthesis is designed for cementless use in total hip arthroplasty in primary or revision surgery. The patient should be skeletally mature. The patient’s condition should not preclude:

• Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriatic 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.
• Dislocation risks.

CONTRAINDICATIONS

Total or partial hip replacement is contraindicated in the following cases:

• Acute, systemic or chronic infection.
• Musculoskeletal 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.

The surgeon’s responsibility to ensure that the patient has no allergy to the materials used.

WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the implant and implantation technique and awareness of all contraindications. The final acetabular implant should be press fit into the prepared acetabulum without threading.

X-rays, is essential. X-ray templates are available for most implants.

The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical technique (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. Note that the final acetabular implant should be press fit into the prepared acetabulum without threading.

SURGICAL TECHNIQUE

The surgeon should be familiar with the surgical technique. Supplementary information about the surgical technique (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 must caution the patient to control their level of activity and avoid excessive loads on the replaced joint, and make 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 prosthesis 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.
• Fatigue failure of the femoral stem, often related to the above-mentioned risk factors.
• Wear of the polyethylene component or fracture of the liner head, often related to the above-mentioned risk factors.
• Early or late infection.
• Neuropathies. Infradiscal lesion of a nerve, due to surgical trauma.
• Tussular reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose cement particles.

PEROPERATIVE

• Cup perforation.
• Femur diaphysis perforation, crack or fracture that may require internal fixation.
• Trochanter fracture.
• Vascular damage (iliac, obturator and femoral arteries).
• 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.
• Haematoma and/or delayed healing.
• Pneumonia and/or atelectasis.
• Subluxation or dislocation.

LATE POSTOPERATIVE

• Avulsion of the trochanter resulting from excessive muscle tension or overloading.
• 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, periprosthetic 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 hip joint, due to the position of the limb during the operation.
• Subluxation or dislocation.

PACKAGING

All the implant components of a total part hip prosthesis are supplied in single-use individual packages.

For correction or preventive nerve damage (femoral, obturator or sciatic nerve).

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 haematoma.

STORAGE

The packages must be stored in a cool, dry place, away from light. Recommended cleaning, decontamination and sterilization instructions are provided on www.medacta.com.

SYMBOLES

Do not use

Caution, read the accompanying documents

Do not expose to sunlight

Store in a dry place

Lot number

Use by

Trade name

Stabilized with ethylene oxide

Sterilized by irradiation

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