**HIP PROSTHESIS: QUADRA-P**

**CAUTION**

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

**PRODUCT DESCRIPTION**

The QUADRA-P is a cementless femoral stem made of Titanium-Nobium alloy coated with Titanium plasma spray over the proximal area and with HA over the entire endosteal part of the shaft.

The QUADRA-P stem is made with a CoCr ball head, Endo Head, the MedActa BIOLOX® forte or the MedActa BIOLOX® delta femoral head. Refer to the MedActa BIOLOX® forte or MedActa BIOLOX® delta package leaflet and the CoCr head package leaflet for more information about these femoral heads.

**INDICATIONS**

The hip prosthesis QUADRA-P is designed for cementless use in total or partial hip arthroplasty, for primary or revision surgery.

**WARNINGS AND PRECAUTIONS**

- The success of the operation depends on compliance with the operative technique supplied, as well as the proper use of the implantation 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 conditions.
- 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 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.
- Painful 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 components.
- 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.

**ADVERSE EFFECTS AND COMPLICATIONS**

- The surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

**PRODUCT SAFETY INFORMATION**

The QUADRA-P has not been evaluated for safety and compatibility in the MR environment. It has not been tested for MRI compatibility. The QUADRA-P has not been evaluated for safety and compatibility in the MR environment. It has not been tested for MRI compatibility.

**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.
- Manual hand 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 prostheses challenging:

- Advanced osteoporosis or insufficient bone stock.
- Metabolic disorders or systemic medications leading to gradual loss of bone support for the prostheses (e.g. diabetes mellitus, treatment by steroids, immunosuppressives, etc.).
- History of disseminated or local infection.
- Significant deformations preventing correct fixation or placement of the prostheses.
- 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 difficult finding where to make the incision, resection of old bone cement, placement and fixation of the component 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 Biocer® 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 the 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 limited expectable 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.

**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 patient 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 imagining (MRI) scans.

In case of ceramic components, an osteolitisation 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 must be kept in their undamaged packages. 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 loosening.

The patient under supervision, evaluate the possible progression of the deterioration, and weigh the benefit of early revision.

**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.

Progressive branching of the femoral bone must be carried out with the utmost care to avoid femoral fractures. Constantly check broach orientation and observe strategy consistent with the quality of the bone. Forcing an oversized broach over the stem head will cause a metal cylinder to form in bone fracture. An under-sized stem may not achieve sufficient primary stability and develop a fibrous tissue layer that may result in radiological sign of loosening and reduced implant fixation.

**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 infection 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.
- Loose fit of the metallic bearing surfaces, often related to the above-mentioned factors.
- Early or late infection.
- Neuphotonic. 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);
- Femoral component diaphysis perforation, or fracture that may require internal fixation;
- Pain.
- Neuropathies. Subclinical lesion of a nerve, due to surgical trauma;
- Fatigue failure of the femoral stem, often related to the above-mentioned factors;
- Early or late infection;
- Neuphotonic. 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.
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;
• Arthritis of the hip;
• 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
- Do not expose to sunlight
- Store in a dry place
- Sterilized with ethylene oxide
- Sterilized by irradiation
- MR Unsafe

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