ref: 75.09.039AUS rev. 02

Strada Regina
CH – 6874 Castel san Pietro – Switzerland
Phone: +41 91 696 60 60 Fax +41 91 696 60 66
Info@medacta.ch – www.medacta.com
US toll free phone number: 800-901-7836

Manufactured by:
Medacta International SA
CH-6874 Castel San Pietro – Switzerland

MEDACTA SHOULDER SYSTEM

CAUTION
Federal law (USA) restricts this device to sale distribution and used by or on the order of physician.

ENGLISH MEDACTA SHOULDER SYSTEM – INSTRUCTION FOR USE

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

GENERAL
Before any surgery, the surgeon must be familiar with the product literature and operative technique and must read carefully these instructions for use. Patient selection is as important as implant placement or positioning. Unsuitable functional requirements may contribute to reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

PRODUCT DESCRIPTION
These instructions for use are intended for all of the products described here below.

Medacta's product description - Anatomical
Medacta shoulder products used in anatomical configuration are:
- Humeral diaphysis (cementless and cemented) to be used in total shoulder arthroplasty, for primary or revision surgery
- Humeral diaphysis Short (cementless) to be used in primary total shoulder arthroplasty
- Humeral anatomical metaphysis (cementless and cemented) to be used in total shoulder arthroplasty, for primary or revision surgery
- Humeral stem screw to be used in total shoulder arthroplasty, for primary or revision surgery
- Double eccenter to be used in total shoulder arthroplasty, for primary or revision surgery
- Metal humeral head to be used in total shoulder arthroplasty, for primary or revision surgery
- Cemented glenoid component to be used in total shoulder arthroplasty, for primary or revision surgery
- Double eccenter/reverse metaphysis screw to be used in total shoulder arthroplasty, for primary or revision surgery

Total Shoulder Arthroplasty - Anatomical
A shoulder prosthesis designed for use in total shoulder arthroplasty in anatomical configuration consists of: a metallic humeral diaphysis, a metallic humeral anatomical metaphysis, a humeral stem screw, a double eccenter, a metal humeral head and a cemented glenoid component.

INTENDED USE

Indications - Anatomical

The Medacta Anatomic Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement.
The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.
The glenoid component is intended for cemented application.

Short Humeral Diaphysis

The Medacta Anatomic Shoulder Prosthesis – Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy.
The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.
The glenoid component is intended for cemented application.

Contraindications

Total joint replacement is contraindicated where there is:
- Local or systemic infection or sepsis;
- Insufficient bone quality which may affect the stability of the implant;
- Muscular, neurological, or vascular deficiencies, which compromise the affected extremity;
- Any concomitant disease and dependence that might affect the implanted prosthesis;
- Materials (metals, etc.) sensitivity or allergy;
- Loss of ligamentous structures that will prevent stabilisation and/or function of the device in vivo;
- Non-functional deltoid muscle.

WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the dedicated instruments and specially designed for that range of implants.
The trial instrumentation must be used to confirm the choice of sizes and verify the functionality of the joint.

Malpositioning may reduce implant longevity and lead to early implant failure.

MRI Compatibility

The Medacta Shoulder System 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 the Medacta Shoulder system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

HA coated implants

HA-coated surfaces must not be implanted in contact with cement.

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

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 a use.
The components of a shoulder prosthesis should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure.
The operating surgeon must 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 the device and can lead to fracture.
Always use a trial prosthesis for trial purposes. Never adapt or alter trial prostheses.

UHMWPE implants should be stored for at least three hours at 20°C (+/- 3°C) before the operation.
The surfaces of the articulated components must be cleaned and dried before reduction. A reliable seating is only possible when both surfaces are completely intact.

Caution
The following risk factors, individually or together, may result in poor clinical outcomes:
• strenuous physical activities (active sports, heavy physical work);
• fretting of modular junctions;
• incorrect implant positioning;
• muscle deficiencies;
• multiple joint disabilities;
• refusal to modify postoperative physical activities;
• patient history of infections or falls;
• systemic diseases and metabolic disorders;
• local or disseminated neoplastic diseases;
• drug therapies that adversely affect bone quality, healing, or resistance to infection;
• drug use or alcoholism;
• marked osteoporosis or osteomalacia;
• patient's resistance to disease generally weakened (HIV, tumor, infections);
• severe deformity leading to impaired anchorage or improper positioning of implants;

INSTRUCTIONS FOR USE

Preoperative phase
The surgeon should verify possible patient physical limitations and mental deficiencies and he should also discuss with the patient 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, 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 must 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.

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. Moreover the surgeon should make the patients aware of the precautions to be taken in terms of exercises, 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

Adverse effects that can occur in shoulder arthroplasty include:

- loosening of the prosthetic components;
- prosthesis dislocation and instability;
- damage to the prosthetic implant;
- instability of the system because of inadequate soft tissue balancing;
- dissociation due to incorrect coupling of the devices;
- infection;
- local hypersensitivity;
- local pain;
- periprosthetic fractures;
- temporary or permanent nerve damage;
- fractures of the devices;
- excessive wear of UHMWPE components due to damaged articular surfaces or the presence of particles;
- additional surgery.

Some adverse effects can ultimately lead to death.

General complications include:

- venous thrombosis with/without pulmonary embolism;
- cardiovascular or pulmonary disturbances;
- haematomas;
- systemic allergic reactions;
- systemic pain.

PACKAGING

The components of all Medacta shoulder 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.

STORAGE

The packages must be stored in a cool, dry place, away from light.

PICTOGRAMS

 Do not reuse

 Do not resterilize

 Caution, read the accompanying documents

 Consult instructions for use

 Do not expose to sunlight

 Store in a dry place

 Do not use if package is damaged

 Use by

 Lot number

 Reference number

 Sterilized with ethylene oxide

 Sterilized by irradiation

TRADEMARKS

Medacta® is registered trademark of Medacta International SA, Castel San Pietro, Switzerland.

Date: 03/2018

Distributed by Medacta USA, Inc. 3973 Delp Street, Memphis, TN 38118
(800) 901-7836