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IFU M-ARS ACL Pull Suture Plate (PSP)

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

ENGLISH M-ARS ACL Pull Suture Plate (PSP)– 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 products described here below.

Medacta's product description
Medacta Pull Suture Plate is an extra-cortical fixation device which is impacted in correspondence of the tibia tunnel using a specifically designed impactor.

INTENDED USE
The Pull Suture Plate is used for the tibial fixation of the implanted cruciate ligament replacement graft during the reconstructive treatment of cruciate ligament ruptures.

Indications
Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of autologous grafts.

Contraindications
- Osteoporosis and osteomalacia
- Degenerative osteopathies
- Osteomata in the area in which the fixation button is to be placed
- Deformities of the bone, or general conditions of the bone, which preclude the implantation of the fixation button in the opinion of a physician
- Systemic diseases and metabolic disorders that may compromise the outcome of the surgery

WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the dedicated instruments specially designed for that range of implants.

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

MRI Compatibility
Medacta implants have not been tested for heating, migration, or to determine the specifications for conditional status in the MR (magnetic resonance) environment. The safety of the implants in the MR environment is unknown, and scanning of patients who have the implant may result in patient injuries.

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 M-ARS ACL Pull Suture Plate 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.

Medacta M-ARS ACL products are non-pyrogenic.

Caution
The following risk factors, individually or together, may result in poor clinical outcomes:
- Inadequate bone quality, (e.g. osteoporosis, previous cruciate ligament operation)
- Systemic diseases or metabolic disorders
- History of infections or recurrent falls
- Drug dependence and abuse of alcohol and medicaments
- Mental incapacity of patient to understand the instructions of the physician and to comply with them
- local bone tumors

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 implant. 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.

Postoperative care and follow-up
The surgeon should caution the patients to control their level of activity and avoid excessive loads on the operated limb. 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 related complications. Excessive physical activity, and operated limb traumas may cause early failure of the implant. 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 reconstructive treatment of ligament ruptures include:
- Infection, both deep and superficial
- Allergies, mild inflammatory and foreign body reactions to implant material

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 M-ARS ACL Pull Suture Plate 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 by irradiation

 MR Unsafe

TRADEMARKS

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

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