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IFU MectaScrew PEEK

CAUTION

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

ENGLISH

MectaScrew PEEK– 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 MectaScrew PEEK interference screws have been developed to provide interference between a ligament graft and a bone tunnel in the ligament reconstruction surgery.

INTENDED USE

The purpose of the MectaScrew PEEK interference screws is to provide a suitable and secure intra-tunnel graft fixation in ligamentoplasty surgery.

Indications

Reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of auto- and allo-grafts.

Contraindications

- Osteoporosis and osteomalacia
- Degenerative osteopathies
- Adiposity or patient overweight, leading to excessive strain on the fixation
- 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

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.

PRECAUTIONS

Ensure Medacta MectaScrew PEEK interference screws are used with the special screwdriver designed for this purpose. The screwdriver must be inserted into the screw as far as it will go in order to prevent damage to the screw and its head during insertion.

MRI Compatibility

The Medacta MectaScrew PEEK interference screws are MR Safe.

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 MectaScrew PEEK interference screw 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 electrocautery, can have an influence on the endurance of the device and can lead to fracture.

Medacta MectaScrew PEEK interference screw 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 (and/or computer tomography (CT) or magnetic resonance imaging (MRI) scans), 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.

Periodic follow-up and X-rays (and/or computer tomography (CT) or magnetic resonance imaging (MRI) scans) 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 MectaScrew PEEK interference screw 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.

TRADEMARKS

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

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 using irradiation



MR safe

The reference text is the English text.

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