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Manufactured by:

Medacta International SA

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IFU MectaFix CL Fixation Button with Continuous Loop

CAUTION

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

ENGLISH MectaFix CL Fixation Button with Continuous Loop - 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

The MectaFix CL - Fixation button with continuous Loop is used for the extra-cortical femoral fixation of the (ACL) graft. The implant is preloaded with a suture loop available in various length options and with a pulling / flipping suture to pull the implant assembled with the graft through the prepared bone tunnel and to subsequently flip it after passing the femoral lateral cortex.

Catalog Number	Fixed Loop Length	Included Suture
05.05.0022	MectaFix Continuous Loop, 15 mm	1x USP#6/EP#8 HS Fiber 36" UHMWPE suture with stopper knot
05.05.0023	MectaFix Continuous Loop, 20 mm	
05.05.0024	MectaFix Continuous Loop, 25 mm	
05.05.0025	MectaFix Continuous Loop, 30 mm	
05.05.0026	MectaFix Continuous Loop, 35 mm	
05.05.0027	MectaFix Continuous Loop, 40 mm	
05.05.0028	MectaFix Continuous Loop, 45 mm	
05.05.0029	MectaFix Continuous Loop, 50 mm	
05.05.0030	MectaFix Continuous Loop, 55 mm	
05.05.0031	MectaFix Continuous Loop, 60 mm	

Material Specifications

Femoral Button: Ti6Al4V ELI ISO 5832-3

Continuous Loop: UHMWPE

Pulling/Flipping Suture: non-absorbable USP#6/EP#8 HS Fiber 36" Ultra-High molecular weight polyethylene (average diameter: 0.800-0.899mm)

Suture colorants: additive D&C Blue No. 6, 21CFR §74.3106

INTENDED USE

The MectaFix CL Fixation Button with Continuous Loop is indicated for use in reconstructive treatment and extra-cortical femoral fixation of an implanted anterior cruciate ligament reconstruction.

Contraindications

The Medacta MectaFix CL device is contraindicated in case of:

- Active infection
- Blood supply and previous infections which may tend to retard healing
- Known hypersensitivity to the implant material
- Insufficient quantity or quality of bone
- Conditions which tend to limit the patient's ability of willingness to restrict activities or follow directions during the healing period
- Foreign body sensitivity

ADVERSE EFFECTS

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
- Hematomas
- Systemic allergic reactions
- Systemic pain

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 the Medacta MectaFix CL Fixation Button 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.

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 dedicated 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 and that MRI may result in patient injuries. 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.

PACKAGING

The components of all MectaFix CL Fixation Button are supplied in single-use packages, 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.

SYMBOLS



Do not reuse



Do not resterilise



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



Manufacturer



RX Only



Sterilized using ethylene oxide

The reference text is the English text.

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