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LIGAMENT STAPLE: Medacta Ligament Staple

CAUTION

Federal (USA) Law restricts this device to sale, distribution and use by or on the order of a physician.

SYMBOLS

	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
	Non-sterile
	Manufacturer
	RX Only
	MR Conditional
	Double sterile barrier system

ENGLISH – Medacta Ligament Staple - INSTRUCTIONS 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.

1. GENERAL

Before any surgery, the surgeon must be familiar with the product literature and surgical 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.

Implant components material:

Ligament Staple: Ti6Al4V ELI

Staple Inlay: PEEK

2. PRODUCT DESCRIPTION

Medacta Ligament Staple is a single size (ø11 mm) extra cortical fixation device which is impacted on the Medial Collateral Ligament (MCL) or on the Lateral Collateral Ligament (LCL) for soft tissue to bone refixation by means of a dedicated impactor. The device consists of (1) a titanium circular plate with protruding tapered serrated legs and (2) a PEEK staple inlay for pressing the graft down to the bone, featuring a lower spike patterned surface for increasing soft tissue fixation.

Medacta Ligament Staple is provided with a complete set of dedicated reusable instruments.

REFERENCE NO.	PRODUCT	INTENDED PERFORMANCE	IMAGE	STERILITY STATUS
05.12.001	Ligament Staple	Treatment of torn or ruptured MCL and LCL		Sterilized by irradiation
05.12.10.0006	Ø2.4 k-wire KIT for Ligament Staple L105mm	Positioning of implant on bone		Sterilized by irradiation
05.12.10.0001	Staple Impactor	Implant insertion into the bone		Not-sterile
05.12.10.0002	Staple Extractor	Staple removal from the surgical site		Not-sterile
05.12.10.0003	Ligament Tensioner	Preparation for ligament positioning		Not-sterile
05.12.10.0004	Reamer ø11 mm	Cortical bone countersink preparation for implant seat		Not-sterile

05.12.10.0005	Staple Lifter	Staple lifting from the bone		Not-sterile
05.12.10.0007	Anvil	Cortical bone countersink preparation for implant seat		Not-sterile

NOTE: Sterilization of non-sterile and reusable instruments: The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave in accordance with the regulations of the country, US directives where applicable and following the instructions for use of the autoclave manufacturer. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta International orthopaedic devices" available at www.medacta.com.

3. INTENDED USE / INDICATIONS

The Medacta Ligament Staple is intended for use in medial collateral ligament (MCL) and lateral collateral ligament (LCL) reconstruction.

Reconstructive treatment of ruptured or damaged MCL and LCL.

4. CONTRAINDICATIONS, ADVERSE EVENTS AND COMPLICATIONS

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

Adverse events 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

General complications include:

- Venous thrombosis with/without pulmonary embolism
- Cardiovascular or pulmonary disturbances
- Haematomas
- Systemic allergic reactions
- Systemic pain

5. RISK FACTORS

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 medications
- Mental incapacity of patient to understand the instructions of the physician and to comply with them
- Local bone tumors

6. WARNINGS AND PRECAUTIONS

The components of Medacta Ligament Staple should never be reimplanted. While an implant may appear undamaged, microscopic damage may occur and cause implant failure. The operating surgeon must be aware that even very small superficial damage can lead to fracture.

The success of the surgical procedure depends on compliance with the surgical technique supplied, and the proper use of the dedicated instruments specially designed for Medacta Ligament Staple. Malposition may reduce implant longevity and can lead to early implant failure.

7. MRI Compatibility

Non-clinical testing has demonstrated titanium implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions. Static magnetic field of 1.5 Tesla and 3 Tesla, with:

- Maximum spatial field gradient of 7,732 G/cm (77,32 T/m)

Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, titanium implants expected to produce a maximum temperature rise of less than:

- 3.0°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ≈2.3°C (2W/kg, 3 Tesla)

after 15 minutes of continuous scanning.

The presence of this implant may produce an image artifact.

8. 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 Medacta Ligament Stape 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.

INSTRUCTIONS FOR USE

9. PREOPERATIVE PHASE

The surgeon should verify possible patient physical limitations and mental deficiencies and she/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 must be available and checked by the operator before surgery.

10. 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.

11. SURGICAL TECHNIQUE

The surgeon should be fully familiar with the surgical technique (Ref. 99.117SMK.12US). Supplementary information about the surgical technique (brochure and video) and products are available on request. Careful preoperative planning, documented by X-rays, is essential.

12. POSTOPERATIVE CARE AND FOLLOW-UP

The surgeon should caution the patients to control their level of activity and to follow postoperative recommendations given by their physician. 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.

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.

13. PACKAGING

The components of Medacta Ligament Staple 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.

14. STORAGE

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

15. TRADEMARKS

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

This document is intended for the US market.

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