

MEDACTA LIGAMENT STAPLE



Surgical Technique

Joint

Spine

Sports Med

NOTE

This document describes the surgical technique for collateral ligaments (MCL and LCL) reconstruction using the Medacta Ligament Staple.

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1. INTRODUCTION

This document describes the surgical technique for collateral ligaments (MCL and LCL) reconstruction using Medacta Ligament Staple.

CAUTION

Federal law (USA) restricts these devices to sale distribution and use by or on the order of a physician.

1.1 INDICATION OF USE

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.

1.2 CONTRAINDICATIONS

- 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

2. IMPLANT OVERVIEW

2.1 MEDACTA LIGAMENT STAPLE

The Medacta Ligament Staple is a single size (Ø11mm) extra cortical fixation implant, to be impacted on the MCL or on the LCL for soft tissue refixation. The implant consists of four titanium serrated legs and a PEEK inlay for pressing the graft on the bone, minimizing the risk of ligament displacement.



The narrow structure of the central body ensures the titanium staple is flush against the PEEK inlay, reducing the amount of metal in contact with soft tissue and minimizing tissue irritation.



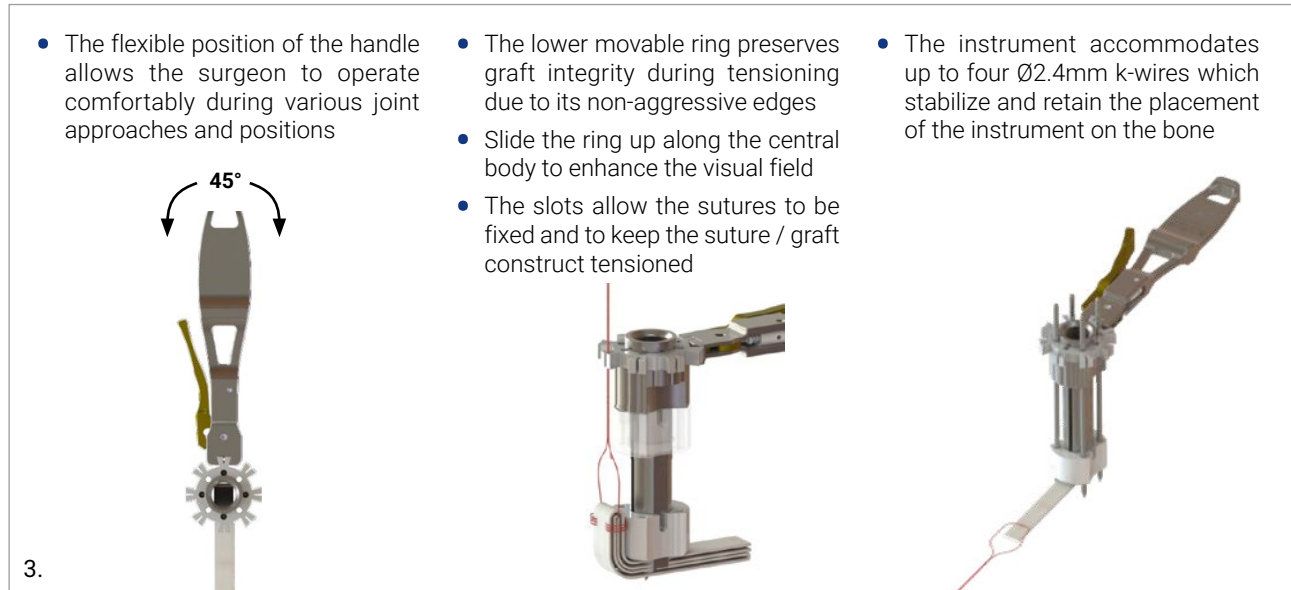
The PEEK inlay features a spiked undersurface which increases the soft tissue fixation and retention due to its increased surface area.

3. INSTRUMENTS OVERVIEW

3.1 LIGAMENT TENSIONER

The instrument allows the tensioning of the ligament (with respect to the anatomical direction of the ligament fibres), and guides the implant during the cortical impaction phase.

- The flexible position of the handle allows the surgeon to operate comfortably during various joint approaches and positions
- The lower movable ring preserves graft integrity during tensioning due to its non-aggressive edges
- Slide the ring up along the central body to enhance the visual field
- The slots allow the sutures to be fixed and to keep the suture / graft construct tensioned
- The instrument accommodates up to four Ø2.4mm k-wires which stabilize and retain the placement of the instrument on the bone

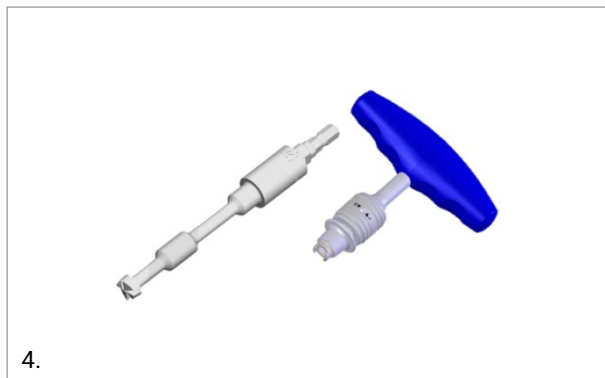


3.

3.2 STAPLE REAMER

The Medacta Staple Reamer allows to create a 1.5mm deep indentation in the cortical bone for implant seating.

- Compatible with a T-handle connector for manual reaming of the cortical bone (not included in the set)
- Used with the dedicated Ø2.4mm disposable k-wires



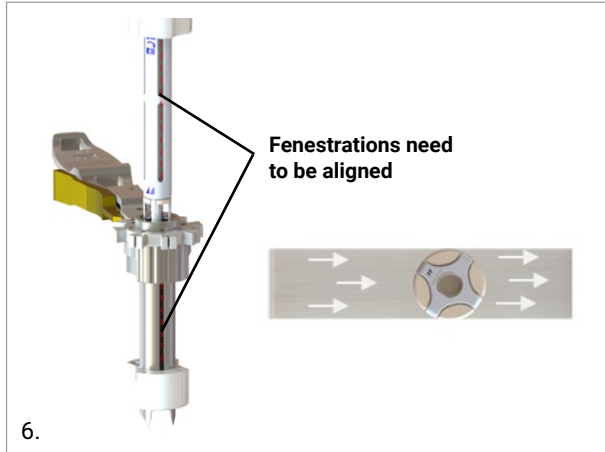
3.3 STAPLE IMPACTOR

The Staple Impactor is used to insert the Medacta Ligament Staple implant.

The instrument can be disassembled to facilitate the cleaning process.



The instrument is equipped with fenestrations for fast implant orientation. To ensure an optimal result make sure that the fenestrations of the Staple Impactor and the Ligament Tensioner are aligned (see image 6).



3.4 STAPLE FORK AND STAPLE LIFTER

The Staple Fork and Staple Lifter can be used alternately to remove the implant in case of implant malpositioning or later removal.

The crowbar tip design of the Staple Fork is used to initially lift the implant from the bone.



The Staple Lifter can be connected with the T-handle connector (not included in set). The Staple Lifter minimizes the risk of bone damage during implant removal.



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.

3.5 Ø2.4MM K-WIRE KIT FOR LIGAMENT STAPLE L105MM

The k-wire kit is used to target the insertion site, and to guide the positioning of the Ligament Tensioner. The kit includes five sterile k-wires. Kit available on demand.



3.6 ANVIL

The Anvil is used in preparation for the circular indentation, to impact the Ligament Tensioner flush to the bone maintaining the central k-wire in place.



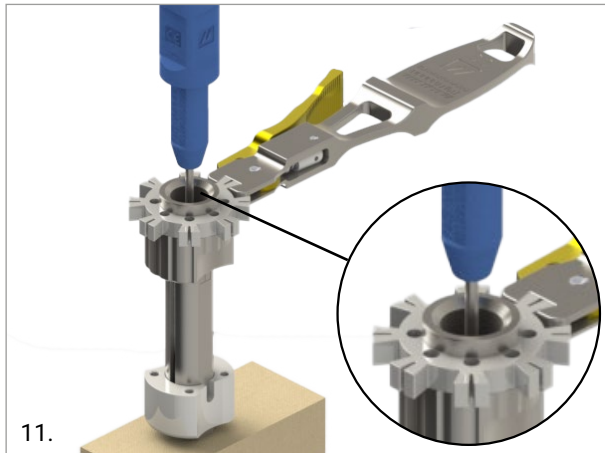
4. SURGICAL TECHNIQUE

4.1 LIGAMENT & BONE PREPARATION

Suture the ligament with preferred technique.

Target the insertion site using a Ø2.4mm k-wire from the k-wire kit.

Slide the Ligament Tensioner over the k-wire and insert the Cannulated Anvil (see image 11).



11.

Anticipate the foreseen anatomical graft orientation and align the slotted gates of the Ligament Tensioner accordingly. In a later surgical step, the ligament needs to pass the Ligament staple gate (see image 15).

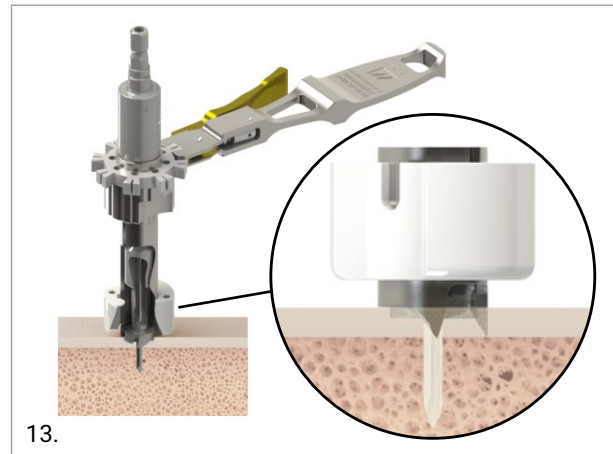
Keeping the K-wire in place, use the anvil as interface to impact the Ligament Tensioner in the bone, checking that the two spikes on the tube are completely inserted and the instrument's lower base is flush with the bone.



12.

Using the Cannulated Reamer, create a 1.5mm deep implant indentation cavity.

Drill until a hard stop is reached.

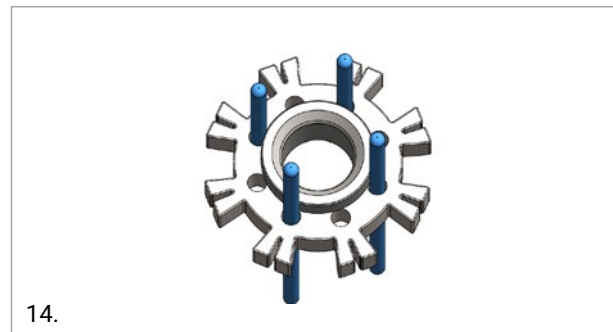


13.

CAUTION

Before reaming, make sure that the two spikes of the Ligament Tensioner are completely inserted into bone and the instrument's lower base is flush to the bone.

NOTE: Insert up to four Ø2.4mm k-wires through the surrounding external holes to increase instrument stability. Keeping the k-wires in place helps to maintain correct instrument positioning.



14.

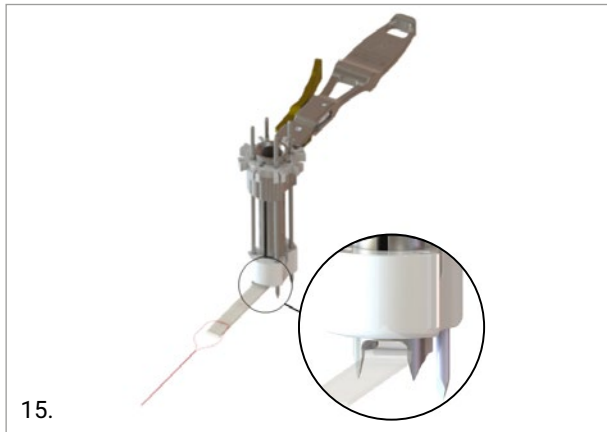
OPTION

The reamer can be used manually with a Hall-Jacobs T-Handle connector.

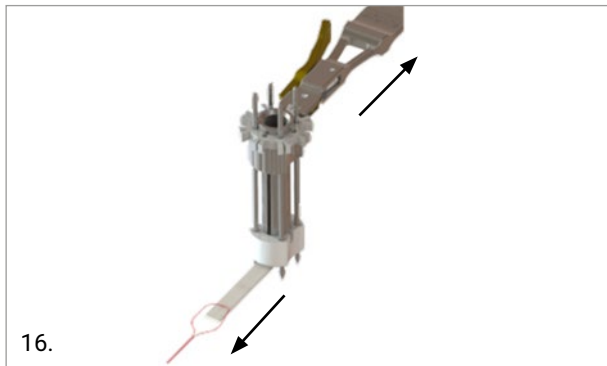
4.2 LIGAMENT TENSIONING

Orient the sutured ligament with respect to the previously planned anatomic position (see paragraph 4.1).

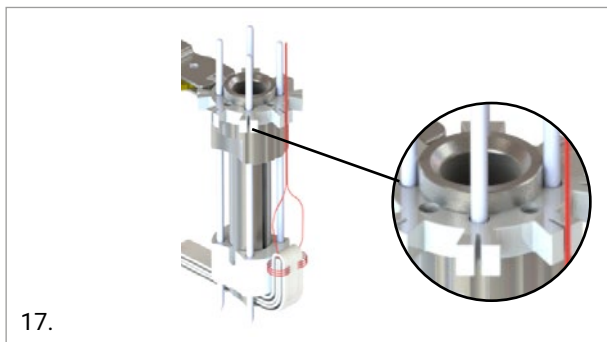
Hold the ligament in place and reposition the Ligament Tensioner in the previous position over the k-wires. Make sure the ligament is passed through the slotted gates (see image 15).



Engage the handle along the running direction axis of the ligament to facilitate tensioning (see image 16).



To maintain optimal ligament tensioning secure sutures ideally in multiple dedicated slots of the Ligament Tensioner (see image 17).

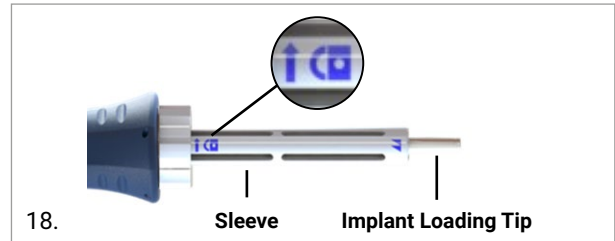


Check the knee range of motion.

4.3 IMPLANT LOADING

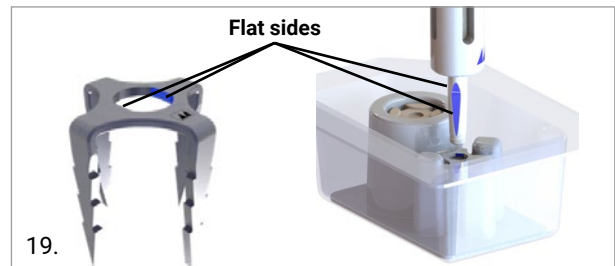
Assemble the Ligament Impactor.

Prior to load the implant, expose the implant loading tip and lock the sleeve in place (see image 18).



Align the flat sides of the loading tip with the corresponding flat sides of the implant hole.

Press until it stops against the impactor sleeve (see image 19).



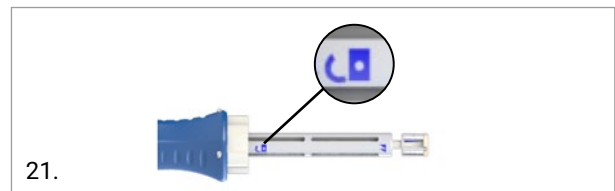
With the Titanium Staple loaded press the loading tip in the PEEK inlay. The loading interference between the implant component and the impactor tip prevents accidental dropping of the implant.



CAUTION

Pay attention to correctly align the PEEK inlay slots with the staple legs to ensure correct matching of the two components (see image 20).

With the implant loaded, carefully unlock the sleeve. Hold the sleeve in place to prevent accidental sliding of sleeve and implant loss.



4.4 IMPLANT INSERTION

Remove residual k-wires.

Impact the Medacta Ligament Staple into bone.



Remove the impactor, release sutures from the Ligament Tensioner and remove tensioner.

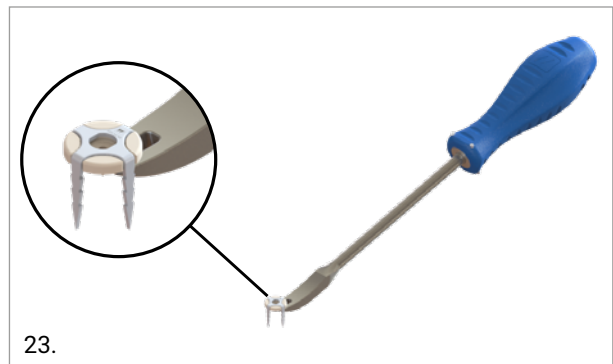
Check the range of motion, cut any excessive sutures and close the surgical site.

4.5 IMPLANT REMOVAL

In case of accidental implant malpositioning or desired removal, use either the Staple Fork or alternatively the Staple Lifter.

Position the Staple Fork tip between the staple and the PEEK inlay.

Gently hammer the protruding surface of the implant, to lift it and remove it from the bone, repeating on different sides of the implant.



Alternatively, screw the tip of the Staple Lifter into the implant and extract the implant.



5. IMPLANT AND INSTRUMENTS NOMENCLATURE

| REF. NO. | DESCRIPTION | PICTURE |
|---------------|---|---|
| 05.12.001 | Ligament Staple Ø11mm |  |
| 05.12.10.0001 | Staple Impactor |  |
| 05.12.10.0002 | Ligament Staple Lifter |  |
| 05.12.10.0003 | Ligament Tensioner |  |
| 05.12.10.0004 | Ligament Staple Reamer |  |
| 05.12.10.0005 | Ligament Staple Fork |  |
| 05.12.10.0006 | Ø2.4 k-wire KIT for Ligament Staple L105mm Qty 5x (sterile) |  |
| 05.12.10.0007 | Anvil |  |
| 05.12.10.9001 | Ligament Staple Tray |  |
| 01.10.10.202 | Short T-handle - Zimmer all connection (On Demand) |  |

Part numbers subject to change.

NOTE FOR STERILIZATION

Please check on the product label if product is sterile or non sterile. The non sterile instrumentation 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.



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MEDACTA.COM



Medacta International SA
Strada Regina - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
info@medacta.ch

Find your local dealer at: [medacta.com/locations](https://www.medacta.com/locations)

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Surgical Technique

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