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IFU MectaLock TI Suture Anchors

CAUTION

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

ENGLISH MectaLock TI – 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

Catalog Number	Anchor Description	Included Sutures
05.10.011	MectaLock TI Ø5.0	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012	MectaLock TI Ø6.5	

MectaLock TI Suture Anchors are manufactured in Titanium alloy.

MectaLock TI Suture Anchors are provided with sutures directly preloaded into the implant.

Material Specifications

Anchors: Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Driver shaft/body: Stainless steel

Driver Handle: Polycarbonate medical grade

Suture: non-absorbable USP#2/EP#5 HS Fiber 39" Ultra-High molecular weight polyethylene (average diameter: 0.500-0.599mm).

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

INTENDED USE

The MectaLock TI Suture Anchors are intended to be used for soft tissue refixation within the shoulder joint.

Indications

The MectaLock TI Suture Anchors are intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in shoulder in the following procedure:

- Shoulder: cuff rotator repair and biceps tenodesis

Contraindications

- Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation.
- Pathological conditions of bone which adversely affect stability of the MectaLock TI Suture Anchors.
- Attachment of artificial ligament or other implants.
- Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials.

WARNINGS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the dedicated instruments especially designed for that range of implants. Surgeon must choose proper implant size based on specific procedure and patient history. Malpositioning may reduce implant longevity and lead to early implant failure. The disposable driver is single use and must be disposed of according to hospital policy and procedure.

PRECAUTIONS

The risk of MectaLock TI Suture Anchor breakage during implantation is reduced by following the specified instructions for use listed below. Proper selection and placement of the implant are important considerations in the successful utilization of this device. Proper orientation and alignment of instruments is important during implantation of MectaLock TI Suture Anchors to minimize the risk of breakage of the anchor. Breakage of MectaLock TI Suture Anchors can occur if:

- any bending or shear load is applied on the anchor/insertor while inserting the MectaLock TI anchor;
- MectaLock TI Suture Anchor driver is used for prying.

Do not disengage the sutures from the disposable driver while inserting the MectaLock TI Suture Anchor before the final positioning depth is reached. Do not use any other suture other than non-absorbable USP#2/EP#5 UHMWPE suture.

MRI Compatibility

MectaLock TI Suture Anchor is MR Unsafe.

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 steps), therefore we advise against such practice. MectaLock TI Suture Anchors should never be re-implanted. 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 failure.

Medacta MectaLock TI Suture Anchors are non-pyrogenic.

Caution

The following risk factors, individually or together, may result in poor clinical outcomes:

- Inadequate bone quality, (e.g. osteoporosis, osteopenia)
- 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
- Physical condition that would eliminate, or tend to eliminate, adequate implant support or impede healing.
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.

INSTRUCTIONS FOR USE

Preoperative phase

The surgeon should verify possible patient physical limitations and mental deficiencies. The surgeon 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

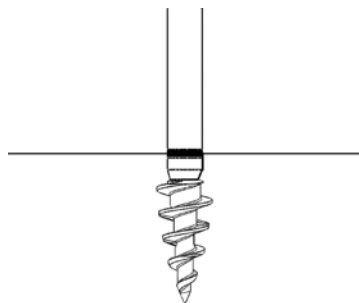
To avoid scratching or damaging the implants, these must be handled with the utmost care by qualified personnel. Sterile implants must be opened with the use of sterile technique in a controlled environment. The implants must be kept in their undamaged packages.

Surgical steps

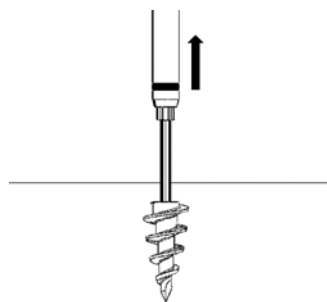
The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical techniques (brochure and video) and products are available on request. Careful preoperative planning is essential.

MectaLock TI Suture Anchor:

- Find the desired location for the placement of the MectaLock TI anchor; insert the preloaded driver with the MectaLock TI anchor through the proper arthroscopic portal to reach the desired location;
- Gently tap on the back handle of the disposable driver to let the MectaLock TI anchor's tip pierce the bone in the chosen spot; while keeping a gentle axial force on the disposable driver, screw the MectaLock TI anchor into the bone until the distal laser marking on the driver is flush with the bone surface.



- Unlock the sutures from the plastic handle and gently disengage the driver's tip from the MectaLock TI anchor, pulling the driver out through the arthroscopic portal;



- Manage the 2x USP#2/EP#5 HS Fiber 39" UHMWPE sutures through soft tissue with surgeon's preferred suture-passing and knotting technique;
- Palpate the repaired soft tissue using an arthroscopic probe to ensure that the repair is secure;
- Cut and remove suture in excess.

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 visits 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 the reattachment of soft tissue to bone in orthopedic surgical procedures:

- 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

MectaLock TI Suture Anchors 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 re-sterilize.

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 restenilize
	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 with ethylene oxide
	MR Unsafe

The reference text is the English text.

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