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Manufactured by:

Medacta International SA

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IFU - MectaLock All-Suture Anchors

CAUTION

For U.S. specific instructions for use, please go to www.medacta.com or call toll free 800-901-7836.

ENGLISH MectaLock All-Suture Anchors - 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 a reduction of 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.

MectaLock All-Suture Anchor		Medacta Reusable compatible drills	
Ref. nr.	Description	Ref. nr.	Description
05.11.010	Soft anchor Size1 - Short driver - 2x USP#2	05.11.10.0045	All-Suture Anchor drill Ø1.8 - Short
05.11.011	Soft anchor Size1 - Long driver - 2x USP#2	05.11.10.0047	All-Suture Anchor drill Ø1.8 - Long
05.11.012	Soft anchor Size1 - Short driver - USP#2 / Tape	05.11.10.0045	All-Suture Anchor drill Ø1.8 - Short
05.11.013	Soft anchor Size1 - Long driver - USP#2 / Tape	05.10.10.0047	All-Suture Anchor drill Ø1.8 - Long
05.11.014	Soft anchor Size2 - Short driver - 2x USP#2	05.10.10.0046	All-Suture Anchor drill Ø2.4 - Short
05.11.015	Soft anchor Size2 - Short driver - USP#2 / Tape	05.10.10.0046	All-Suture Anchor drill Ø2.4 - Short

Medacta MectaLock All-Suture Anchors are fully manufactured in Ultra High Molecular Weight Polyethylene (UHMWPE). The MectaLock All-Suture Anchors are provided preloaded with sutures in different configurations. HS Fiber® is a non-absorbable braided surgical suture prepared from fibers of ultra high molecular weight, long-chain linear polyethylene; it is provided with a solid blue color or in an alternate pattern of white and black fibers. HS SutureTape® is an HS Fiber® ultra high molecular weight polyethylene (UHMWPE) non-absorbable suture offered in a tape configuration provided with a solid blue color.

MectaLock All-Suture Anchor	
Ref. Nr.	Preloaded Sutures
05.11.010	1x HS Fiber® UHMWPE white/black USP#2/EP#5 1x HS Fiber® UHMWPE blue USP#2/EP#5
05.11.011	
05.11.012	1x HS Fiber® UHMWPE white/black USP#2/EP#5 1x HS SutureTape® UHMWPE blue 1.4mm USP#2/EP#5
05.11.013	
05.11.014	1x HS Fiber® UHMWPE white/black USP#2/EP#5 1x HS Fiber® UHMWPE blue USP#2/EP#5
05.11.015	1x HS Fiber® UHMWPE white/black USP#2/EP#5 1x HS SutureTape® UHMWPE blue 1.4mm USP#2/EP#5

Material Specifications

Anchor: non-absorbable HS Fiber® 48" white UHMWPE

Driver shaft: Stainless steel

Driver handle: Polycarbonate medical grade

Sutures: non-absorbable white/black or solid blue HS Fiber® 40" UHMWPE; non-absorbable solid blue HS SutureTape® 40" UHMWPE

Suture colorants: additive D&C Blue No. 6; Logwood extract

INTENDED USE

The **MectaLock All-Suture Anchor Size 1** is intended to treat the hip and shoulder instability by means of the refixation of the acetabular or glenoidal labrum.

The **MectaLock All-Suture Anchor Size 2** is intended to treat the shoulder joint by means of the soft tissue refixation (i.e.: cuff rotator repair, biceps tenodesis).

Indications

The MectaLock All-Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of suture (soft tissue) to bone in the hip and shoulder in the following procedures:

- Hip: acetabular labral repair
- Shoulder: glenoid labrum repair; cuff rotator repair

Contraindications

- Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation
- Pathological conditions of bone which may adversely affect the stability of the MectaLock Suture Anchor
- Physical condition that would eliminate, or tend to eliminate, adequate implant support
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period
- 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 specially designed for that range of implants. Surgeons must choose the proper implant size based on the specific procedure and patient data. 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.

One Medacta label for each device must be properly applied to the Medacta Implant Card provided, and delivered to the patient.

PRECAUTIONS

Ensure the MectaLock All-Suture Anchors are used with the corresponding compatible reusable drill bit. Use the corresponding compatible reusable drill bit to create the pilot hole. Maintain proper alignment during insertion of the Anchor and prevent disengagement from the driver.

The risk of MectaLock All-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 the MectaLock All-Suture Anchor to minimize possible breakage of the anchor.

Breakage of the MectaLock All-Suture Anchor can occur if:

- The pilot hole is not drilled to the proper depth
- The MectaLock All-Suture Anchor is not properly aligned with the pilot hole
- Any lateral loading is applied on the anchor/insertor while inserting the MectaLock All-Suture Anchor
- The MectaLock All-Suture Anchor driver is used for prying

Do not use any other suture other than non-absorbable USP#2/EP#5 UHMWPE suture.

MRI Compatibility

The MectaLock All-Suture Anchors have been evaluated for safety and compatibility in the MR environment, and this device is not likely to result in patient harm during MR scanning.

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 a use.

The MectaLock All-Suture Anchors 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, can have an influence on the endurance of the device and can lead to failure.

Medacta MectaLock All-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

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

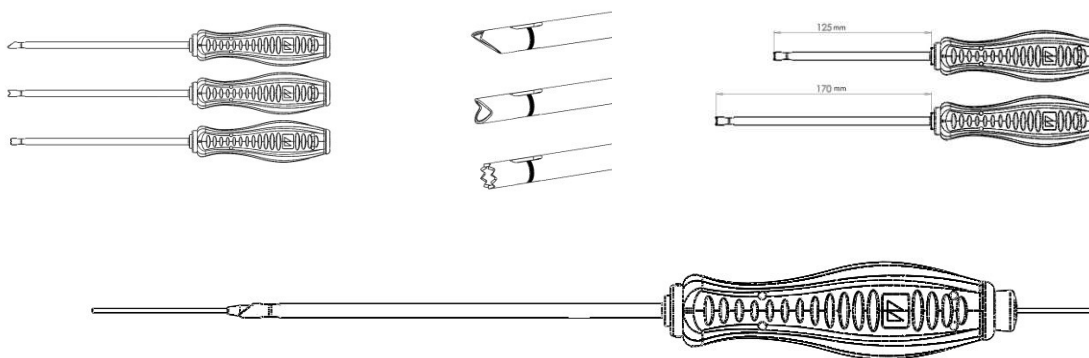
To avoid scratching or damaging the implants, these should be handled with the utmost care by qualified personnel and in an environment where conditions of hygiene are controlled. The implants should be kept in their undamaged packages.

Surgical 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.

- Find the desired location for the placement of the MectaLock All-suture Anchor; insert a percutaneous guidewire (max Ø1.5mm) through the proper arthroscopic portal to reach the desired location.

- A dedicated aimer can be used as a drill guide and to aid in pointing the location of the pilot hole in the bone. Insert the Medacta Aimer coupled with a cannulated obturator over the guidewire; the surgeon can choose between different aimer tips based on preference and the anatomical structures to be treated. Aimers and obturators are provided in two different lengths:



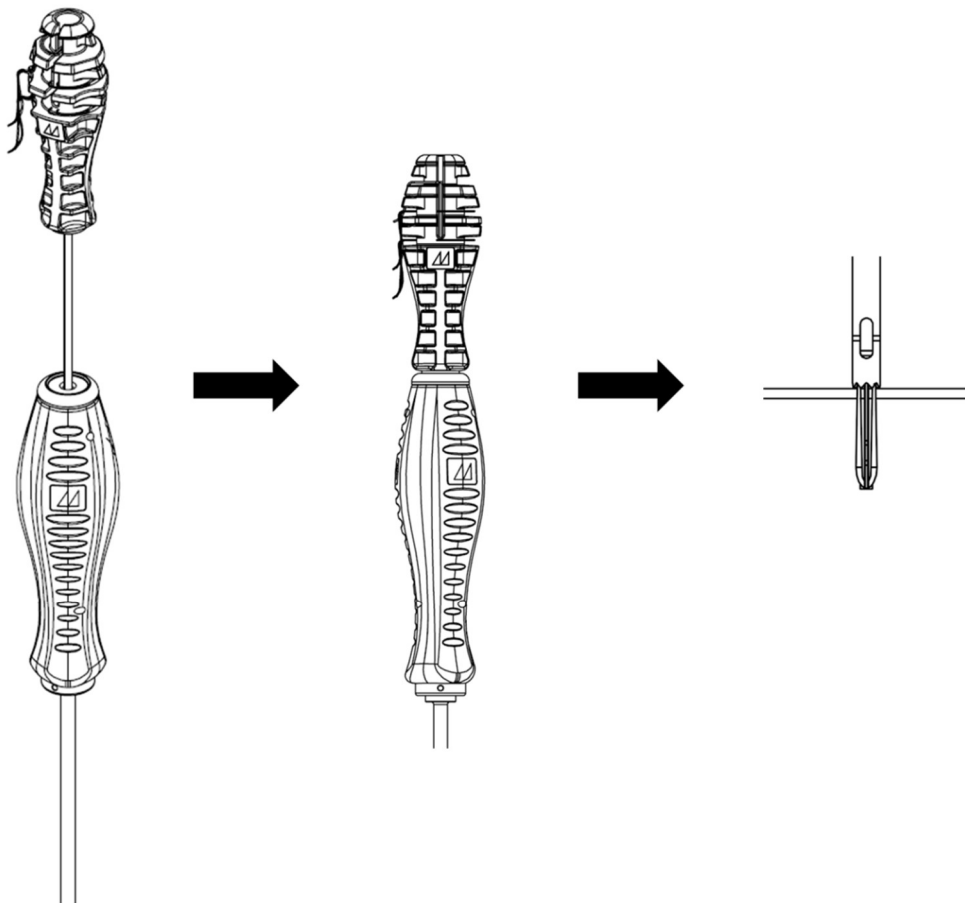
Aimers/obturators and drills can be coupled according to the following table:

Medacta Aimer		Medacta Obturator		Reusable Drill Bit	
Ref. Nr.	Description	Catalog no.	Description	Catalog no.	Description
05.11.10.0030	Crown tip - Long	05.11.10.0033	Obturator Long	05.11.10.0047	All-Suture Anchor Drill Ø1.8 Long
05.11.10.0031	Fish mouth tip - Long				
05.11.10.0032	Fork tip - Long				
05.10.10.0010	Crown tip - Short	05.10.10.0013	Obturator Short	05.11.10.0045	All-Suture Anchor Drill Ø1.8 Short
05.10.10.0011	Fish mouth tip - Short				
05.10.10.0012	Fork tip - Short				
				05.11.10.0046	All-Suture Anchor Drill Ø2.4 Short

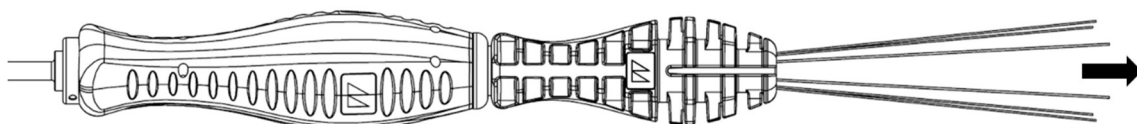
- Using the corresponding compatible reusable drill bit, create a hole in the bone in the desired location for the placement of the MectaLock All-Suture Anchor.
- Make sure to drill until the distal depth mark of the drill is aligned with the distal depth mark of the aimer or until the drill's hard stop is mechanically in contact against the aimer.



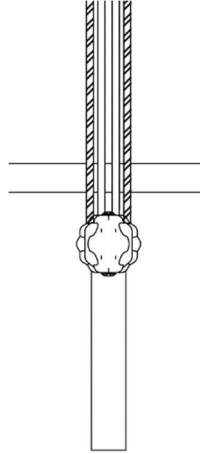
- Keeping the aimer in position, insert the MectaLock All-Suture Anchor's driver into the aimer to place the anchor within the pilot hole. Push it manually or with the help of a mallet until the plastic handle of the driver reaches a hard stop.



- Once the inserter has been fully seated into the pilot hole, release the sutures from the plastic handle.
- Keeping and holding the driver in place, gently pull back the **full white suture only** (deployment suture) to let the anchor start its deployment.



- Gently remove the driver out through the arthroscopic portal.
- Gently remove the Medacta aimer out through the arthroscopic portal.
- Pull back firmly the **full white suture only** (deployment suture) until resistance from anchor engagement is felt. This denotes that the anchor is correctly deployed under the cortical layer.



- Manage the HS Fiber® UHMWPE white/black or solid blue **functional sutures** (or HS SutureTape®) through soft tissues 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 the deployment suture and the functional sutures 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.

Periodic follow-up is 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
 - Allergic reactions, 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

INSTRUMENTS

Instruments are supplied non-sterile and must be cleaned and sterilized prior to use. Recommended cleaning, decontamination and sterilization instructions are provided on www.medacta.com.

PACKAGING

The MectaLock All-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 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 with ethylene oxide



MR safe



Manufacturer

The reference text is the English text.

Last update: October 2019