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**Manufactured by:**  
**Medacta International SA**  
**CH-6874 Castel San Pietro – Switzerland**

## IFU MectaLock PEEK Suture Anchors

### **CAUTION**

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

## **ENGLISH** MectaLock PEEK 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 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	Compatible Reusable Drill Bit Catalogue Number
05.11.001	MectaLock PEEK Ø2.4 – Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 – Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 – Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 – Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 – Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 – Short driver	05.10.10.0017

Medacta MectaLock PEEK (Knotless) is manufactured in PolyEtherEtherKeton (PEEK). The MectaLock Suture Anchors are provided with sutures placed directly into the final packaging (MectaLock PEEK).

Catalog Number	Anchor family	Included sutures
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		

## **Material Specifications**

Anchors: PolyEtherEtherKeton (PEEK) [MectaLock PEEK]

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)

## **INTENDED USE**

The **MectaLock PEEK Suture anchors** is intended to treat the hip and shoulder instability by means of the refixation of the acetabular or glenoidal labrum to the bone.

## **Indications**

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

- Hip: acetabular labral repair; and
- Shoulder: glenoid labrum repair

## **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 the MectaLock Suture Anchors
- Physical condition that would eliminate, or tend to eliminate, adequate implant support or retard healing
- 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. 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**

Ensure the MectaLock 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 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 Suture Anchor to minimize possible breakage of the anchor.

Breakage of the MectaLock Suture Anchor can occur if:

- the pilot hole, where expected, is not drilled to the proper depth;
- the MectaLock Suture Anchor is not properly aligned with the pilot hole, where expected;
- any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor;
- the MectaLock 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 PEEK 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 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 or electrocautery, can have an influence on the endurance of the device and can lead to failure.

Medacta MectaLock 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.

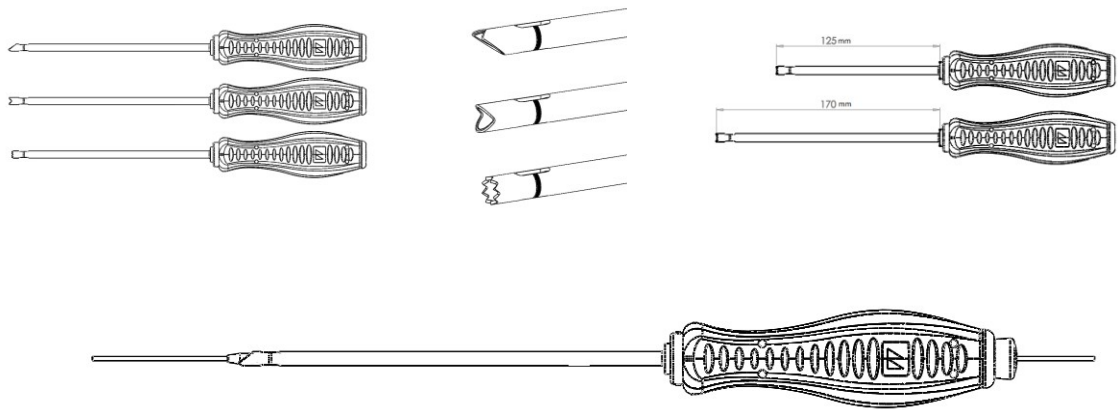
The implants should be kept in their undamaged packages.

### **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.

- Pass the USP#2/EP#5 HS Fiber 39" UHMWPE suture through soft tissue with surgeon's preferred suture-passing technique; let the two strands of the suture come out from the patient through the arthroscopic portal.

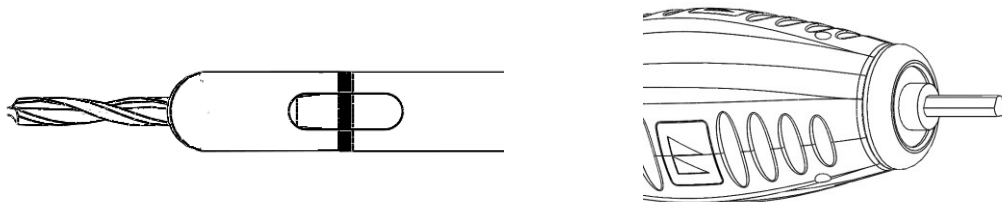
- Find the desired location for the placement of the MectaLock PEEK anchor; insert a percutaneous guidewire (max Ø1.5mm) through the proper arthroscopic portal to reach the desired location.
- A dedicated aimer can be used as a drill guide and to aid in pointing the location of the pilot hole in the bone. Insert the Medacta Arthroscopic Aimer coupled with a cannulated obturator over the guidewire; the surgeon can choose between different aimer's tip according to his preference and the anatomical structures to be treated. Aimers and obturators are provided in two different lengths:



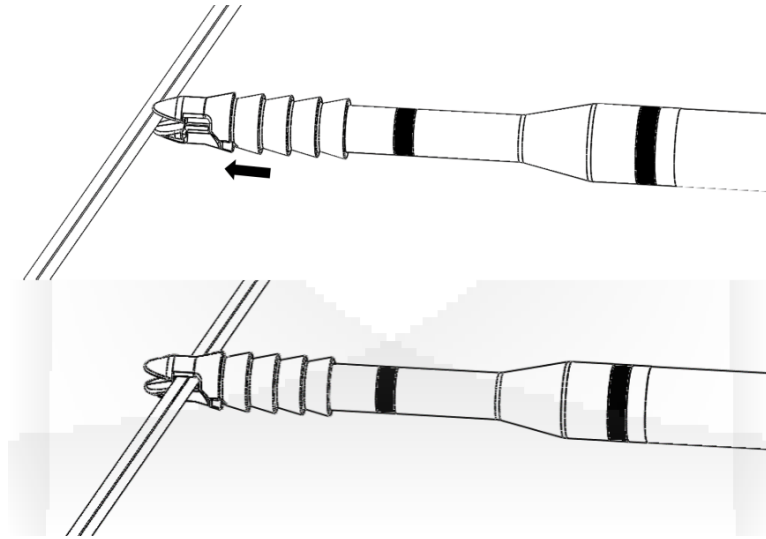
Aimers/obturators and drills can be coupled according to the following table:

Aimer		Obturator		Reusable Drill Bit	
Catalog no.	Description	Catalog no.	Description	Catalog no.	Description
05.11.10.0030	Crown tip – Long	05.11.10.0033	Obturator – Long	05.11.10.0035	Drill Ø2.4 - Long
05.11.10.0031	Fishmouth tip – Long			05.11.10.0036	Drill Ø2.9 - Long
05.11.10.0032	Fork tip – Long			05.11.10.0037	Drill Ø3.4 - Long
05.10.10.0010	Crown tip – Short	05.10.10.0013	Obturator – Short	05.10.10.0015	Drill Ø2.4 - Short
05.10.10.0011	Fish mouth tip – Short			05.10.10.0016	Drill Ø2.9 - Short
05.10.10.0012	Fork tip – Short			05.10.10.0017	Drill Ø3.4 - Short

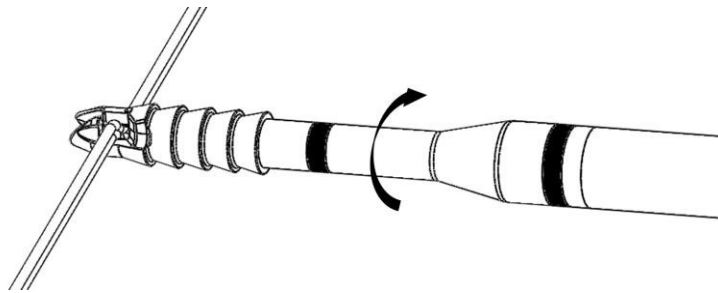
- Using the corresponding compatible reusable drill bit, create a hole in the bone in the desired location for the placement of the MectaLock PEEK anchor.
- Make sure to drill until the distal depth mark of the drill is aligned with the distal depth mark of the aimer or until the drill is mechanically blocked against the aimer:



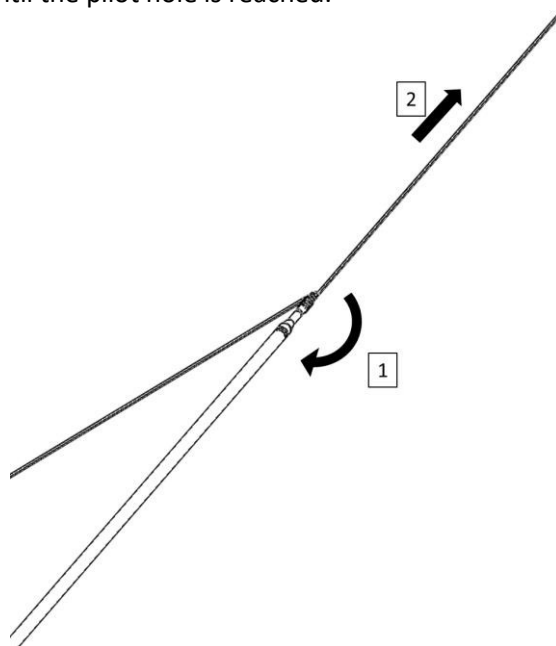
- Load the MectaLock PEEK anchor with the sutures coming out of the portal: while firmly holding the two strands of the suture with one hand, align them with the slot of the anchor's tip. Gently push the anchor against the suture to let it clip into the tip's eyelet.



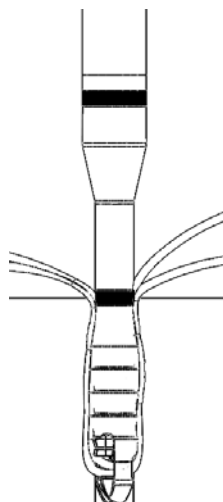
- Rotate the anchor clockwise by 90°:



- Align the main axis of the driver with the suture (1) and then, while still holding the suture gently tensioned, slide the anchor over the suture (2) towards the patient through the arthroscopic portal, until the pilot hole is reached:



- Once reaching the pilot hole, regulate the suture tension according to the surgeon's preference and tap the plastic handle of the driver until the MectaLock PEEK anchor is correctly placed. The correct depth is achieved when the distal laser marking is flush with the bone surface.



- Unscrew the disposable driver.
- Palpate the repaired soft tissue using an arthroscopic probe to ensure that the repair is secure.
- Cut and remove 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. The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

Periodic follow-up 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.

## **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](http://www.medacta.com).

## **PACKAGING**

The MectaLock PEEK 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

The reference text is the English text.

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