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MECTAQTH

CAUTION

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

SYMBOLS / SIMBOLI / PICTOGRAMMES / PIKTOGRAMME / PICTOGRAMAS / PICTOGRAMAS / PICTOGRAMMES / EIKONOΣYΜΒΟΛΑ



Do not reuse / Non riutilizzare / Niet hergebruiken / Nicht wiederverwenden / No reutilizable / Não reutilizar / Ne pas réutiliser / Μην επαναχρησιμοποιείτε



Do not re-sterilize / Non risterilizzare / Niet re-steriliseren / Bitte nicht re-sterilisieren / No re-sterilize / Não re-sterilizar / Ne pas restériliser / Να μην αποστειρωθεί ξανά



Caution, read the accompanying documents / Attenzione, consultare i documenti di accompagnamento / Opgelet, raadpleeg de bijgeleverde documenten / Achtung, Begleitdokumente beachten / Atención, consulte los documentos que se acompañan / Atenção, consultar os documentos de acompanhamento / Attention, consulter les documents d'accompagnement / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα



Consult instructions for use / Consultare le istruzioni di utilizzo / Gebruiksaanwijzing / Bitte lesen Sie die Gebrauchsanweisung / Consulte las Instrucciones antes de su uso / Consulte as instruções de uso / Consultez les instructions d'utilisation / Οδηγίες χρήσης



Do not expose to sunlight / Non esporre alla luce del sole / Niet blootstellen aan zonlicht / Vor Sonnenlicht schützen / No exponer a la luz solar / Não expor à luz solar / Ne pas exposer à la lumière du soleil / Μην εκθέτετε σε ηλιακό φως



Store in a dry place / Conservare in luogo asciutto / Droog bewaren / Trocken aufbewahren / Conservar en lugar seco / Conservar em local seco / Conserver au sec / Φυλάσσετε σε ξηρό χώρο



Do not use if package is damaged / Non utilizzare se la confezione è danneggiata / Niet gebruiken als verpakking beschadigd is / Bitte nicht verwenden, falls Verpackung beschädigt ist / No utilize si el envoltorio está dañado / Não utilizar se a embalagem estiver violada / Ne pas utiliser si l'emballage est abîmé / Να μην χρησιμοποιηθεί εάν η συσκευασία είναι κατεστραμμένη



Use by / Utilizzare entro il / Te gebruiken voor / Zu verwenden bis / Utilizar antes de / A utilizar antes de / A utiliser avant / Ημερομηνία λήξης



Lot number / Numero di lotto / Nummer van de partij / Waren-Lot-Nummer / Número de lote / Número de lote / Numéro de lot / Αριθμός παρτίδας



Reference number / Riferimento commerciale / Handelsreferentie / Referenznummer / Numero de Referencia / Referência comercial / Référence commerciale / Νούμερο παραπομπής



Sterilized by irradiation / Sterilizzato mediante irradiazione / Gesteriliseerd door doorstraling / Sterilisiert durch Bestrahlung / Esterilizado por irradiación / Esterilizado por irradiação / Stérilisé par irradiation / Αποστειρωμένο με ακτινοβολία



Manufacturer / Produttore / Fabrikant / Hersteller / Fabricante / Fabricante / Fabricant / Κατασκευαστής

ENGLISH - MECTAQTH - 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

Use of the instrumentation requires knowledge of the anatomy, biomechanics and reconstructive surgery of the locomotive system. The instrumentation can be used only by a qualified surgeon who practices with an awareness of current advances in science and surgical techniques. The user should ensure that the instruments are undamaged and in good working order before use.

2. PRODUCT DESCRIPTION

Medacta MectaQTH Vertical and Horizontal Cutters are provided sterile.

REF NO.	DESCRIPTION	MATERIAL
05.05.10.0094	Vertical Cutter - 8x5	AISI 420c
05.05.10.0095	Vertical Cutter - 8x7	
05.05.10.0096	Vertical Cutter - 9x5	
05.05.10.0097	Vertical Cutter - 9x7	
05.05.10.0098	Vertical Cutter - 10x5	
05.05.10.0099	Vertical Cutter - 10x7	
05.05.10.0100	Vertical Cutter - 12x5	
05.05.10.0101	Vertical Cutter - 12x7	
05.05.10.0102	Vertical Cutter - 14x5	
05.05.10.0103	Vertical Cutter - 14x7	
05.05.10.0104	Vertical Cutter - MARS ACL SMALL	
05.05.10.0105	Vertical Cutter - MARS ACL MEDIUM	
05.05.10.0106	Vertical Cutter - MARS ACL LARGE	
05.05.10.0107	Horizontal Cutter - 10x4	
05.05.10.0108	Horizontal Cutter - 15x3	
05.05.10.0109	Horizontal Cutter - 15x5	
05.05.10.0110	Horizontal Cutter - 15x6	
05.05.10.0111	Horizontal Cutter - MARS ACL SMALL	
05.05.10.0112	Horizontal Cutter - MARS ACL MEDIUM	
05.05.10.0113	Horizontal Cutter - MARS ACL LARGE	

Reusable, non-sterile instruments are provided, to be used in combination with MectaQTH Vertical and Horizontal sterile Cutters, as reported below:

REF NO.	DESCRIPTION	MATERIAL
05.05.10.0092	Subcutaneous Cutter Small	AISI 630; AISI 420 MOD; AISI 420a; AISI 316L; AISI 304; AISI 302-303; AISI 301; Ti6Al4V ISO 5832-3
05.05.10.0114	Subcutaneous Cutter Large	AISI 630; AISI 420 MOD; AISI 420a; AISI 316L; AISI 304; AISI 302-303; AISI 301; Ti6Al4V ISO 5832-3
05.05.10.0093	Small Screwdriver - Rotation Locking	AISI 630; AISI 301; AISI 302-303; PROPILUX BLUE

3. INTENDED USE / INDICATIONS

Medacta MectaQTH is designed to provide the surgeon with all the main instruments to subcutaneously harvest the quad tendon for various surgical indications (ACL, PCL or MPFL reconstruction). The general contraindications for Medacta MectaQTH, are the following:

- Prior quadriceps tendon surgery or injury
- Quadriceps tendinopathy
- Untreated coagulopathy

4. WARNINGS AND PRECAUTIONS

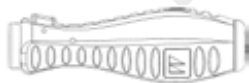
Check the expiration date prior to use. MectaQTH sterile instruments are meant to be single use. Reutilizing them is strictly forbidden and would lead to unpredictable outcomes. This kit contains instruments that are very sharp. Do not touch sharp areas with fingers. Injury may result. Dispose according to hospital guidelines pertaining to sharp disposable instruments. Visually inspect the instruments after use in order to verify that they did not experience any mechanical damage which may cause release of particles into the human body. Any non-functional instrument should be immediately returned to Medacta® along with its label. The type of malfunction should be reported.

The instruments in this kit are designed for use by surgeons experienced in the appropriate specialized procedures. It is the responsibility of the surgeon to become familiar with the proper technique. Refer to Medacta MectaQTH Surgical Technique (ref. 99.107SMK.12) or the instructions here below to verify the appropriate surgical procedure.

5. INSTRUCTIONS FOR USE

Remove items from the sterile package using aseptic technique.

- MectaQTH Vertical Cutters: used to create parallel subcutaneous incisions of the Quadriceps Tendon (QT) over a defined length for graft harvesting. The width (W) of the incision is variable while the depths (H) are defined to either 5 mm or 7 mm and combination of these dimensions create a portfolio of cutters that address the various surgical indications (ACL, PCL or MPFL reconstruction). Furthermore, dedicated configurations for the M-ARS ACL surgical technique are available.
- MectaQTH Horizontal Cutters: used to create horizontal subcutaneous incisions of the Quadriceps Tendon (QT) over a defined length for graft harvesting. The width (W) and depth (H) of the incisions are available in different configurations depending on the surgical indications (ACL, PCL or MPFL reconstruction). In addition, M-ARS ACL dedicated configurations are available. Medacta MectaQTH Vertical and Horizontal Cutters have a special back-end to be connected with a reusable ergonomic handle (see below).

REF NO.	DESCRIPTION	IMAGE
05.05.10.0093	Subcutaneous Cutter Small	

Properly discard the Medacta MectaQTH Vertical and Horizontal Cutters after use following facility guidelines.

6. ADVERSE EFFECTS AND COMPLICATIONS

- Infection, both deep and superficial
- Hematomas
- Increased effusion

7. PACKAGING

The Medacta MectaQTH Vertical and Horizontal Cutters are supplied sterile, in single use packages. The sterilization method is indicated on the label. The expiration date and package integrity must be checked to ensure the sterility of the contents has not been compromised. If the package is damaged, do not use the components and return it immediately to Medacta along with its label. Do not resterilize.

8. INSTRUMENTS

Subcutaneous Cutters and the Small Screwdriver 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.

9. STORAGE AND HANDLING

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

10. TRADEMARKS

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

The reference text is the English text.

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