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SUTURE PASSER: FastShuttle Suture Passer System

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 / ΕΙΚΟΝΟΣΥΜΒΟΛΑ

APPLICABLE TO THE NEEDLE :



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



Do not resterilize / Non risterilizzare / Niet resteriliseren / Bitte nicht re-sterilisieren / No reesterilize / Não reesterilizar / Ne pas restériliser / Να μην αποστειρωθεί ξανά



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



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

APPLICABLE TO SUTURE PASSERS:



Non sterile / Non sterile / niet-steriel/ unsteril / no estéril/ não estéril/ non stérile/ Μην αποστειρωμένο

APPLICABLE TO ALL DEVICES:



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

LOT

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

REF

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



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

R ONLY

RX Only/ Solo prescrizione medica/RX Enkel/RX Only/Sólo RX/Somente RX/Sur prescription seulement/RX μόνον

FastShuttle Suture Passer System - 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 musculoskeletal system. The instrumentation can be used only by a qualified surgeon who practices arthroscopic surgical techniques with awareness of current advances in science. The user should ensure that the instruments are undamaged and in good working order before use. Surgeons should choose an operating method that is the best for their patient's comfort and safety. No undesirable side effects are known if these instructions for use are respected.

2. PRODUCT DESCRIPTION

The Medacta FastShuttle System combines single use sterile Nitinol needles and a reusable grasper provided in two configurations for shoulder and in one configuration for hip to aid in passing the suture through soft tissue.



REFERENCE NO..	DESCRIPTION	IMAGE
05.15.10.0015	Suture Passer and Retriever Shoulder WL 170 mm	
05.15.10.0016	Suture Passer Shoulder WL 170 mm	
05.15.10.0017	Nitinol Needle Shoulder	
05.11.10.0050	Suture Passer for Hip Capsular Closure WL 220 mm	
05.11.10.0051	Nitinol Needle Hip	

FastShuttle Suture Passer System - INSTRUCTIONS FOR USE

The intended performance of the Medacta FastShuttle System is listed below.

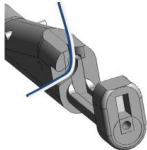
Shoulder Hand Instrument Grasper

Holds the rotator cuff soft tissue and advances the Nitinol needle through the tissues for suture passing. The device is available in two configurations defined by the upper grasping jaws design.

CONFIGURATION	DESCRIPTION	IMAGE
Suture Passer Shoulder	Allows the suture to be disengaged from the grasping jaw and to retrieve it from an additional arthroscopic portal	
Suture Passer And Retriever Shoulder	Allows to pull out the suture from the same arthroscopic portal previously used to insert the instrument	



Hip Hand Instrument Grasper

Holds the hip capsule soft tissue and advances the Nitinol needle through the tissues for suture passing. The device is available in one configuration.

CONFIGURATION	DESCRIPTION	IMAGE
Suture Passer Hip	The tip of the needle has a hook-shape design to engage the suture and guide it through the soft tissue once the handle is squeezed	

Nitinol Needle

Engages the preloaded suture, guiding it through soft tissue

JOINT	DESCRIPTION	IMAGE
Nitinol Needle Shoulder	The tip of the needle has a hook-shape design to engage the suture and guide it through the soft tissue once the handle is squeezed	
Nitinol Needle Hip		
Nitinol Needle Hip	Straight Tip	

FastShuttle Suture Passer System - INSTRUCTIONS FOR USE

3. INTENDED USE / INDICATIONS

Medacta FastShuttle System is intended to:

FastShuttle Shoulder

In arthroscopic shoulder procedures for rotator cuff repair to pass and retrieve sutures through soft tissue.

FastShuttle Hip Capsular Closure

Closure of hip capsulotomies performed during arthroscopic procedures

4. CONTRAINDICATIONS, ADVERSE EFFECTS AND COMPLICATIONS

FastShuttle System instruments are not to be used on bone or similar hard tissues.

Potential adverse effects include breakage of the needle in presence of:

- Thick tendon
- High tendinosis
- Delaminated tears

5. WARNINGS AND PRECAUTIONS

Check the expiration date prior to use of the sterile Nitinol needle.

The FastShuttle System needles are for single-patient use only. Reutilizing them is strictly forbidden and would lead to unpredictable outcomes. Do not clean or re-sterilize the needle. Do not touch sharp areas with fingers. Injury may result. Dispose according to hospital guidelines pertaining to sharp disposable instruments. The graspers are reusable instruments delivered non-sterile and should be steam sterilized according to recommended cleaning, decontamination and sterilization instructions provided on www.medacta.com. Do not overstuff the jaw with tissue. Do not force the upper jaw into open or closed position. Do not force the device into tight joint spaces.

Excessive pushing and twisting may cause breakage. Whether used arthroscopically or open surgery, the devices must be used under direct visualization. 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 for sterile parts). The type of malfunction should be reported.

The Medacta FastShuttle System instruments 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.

INSTRUCTIONS FOR USE

6. PREOPERATIVE PHASE

NOTE: carefully read the following instructions prior to surgical use.

The surgeon should verify possible patient physical limitations and mental deficiencies and she/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 must be available and checked by the operator before surgery.

FastShuttle Shoulder System

Needle loading:

- Locate the cannulated shaft on the proximal end of the FastShuttle Grasper handle.
- Insert the needle through the cannulated shaft. To ensure the proper positioning of the needle, check that the needle plastic flag fits the slots on the grasper back handle.

Suture loading:

- Insert 2/5 cm of a standard USP#2 suture with its short, free end down into the lower jaw suture slot keeping the free end downwards and maintaining tension on both ends of the suture.

Suture introduction and passing:

- The diameter of the proximal jaw is compatible with a Ø 6.1 mm Medacta Shoulder Cannula or larger cannula arthroscopic portal.
- Push the anterior lever (grasping jaw locking lever) to grab soft tissue in the jaws.
- Maintaining the jaws in closed position, gently squeeze the needle actuator (needle advancement handle) to slightly advance the needle until the suture loads into the needle eyelet.
- Continue to apply pressure to advance the loaded needle forward and pass it through soft tissue.
- If the suture passer configuration is used, retract the needle by removing palm pressure from the needle actuator, release the forward lever to open the upper jaw and disengage the suture from the grasping jaw. Retrieve the suture from the desired arthroscopic portal.
- If the suture passer and retriever configuration is used, retract the needle by removing palm pressure from the needle actuator. The suture remains secured in the "trap door" of the upper jaw. Keeping the upper jaw closed, pull the suture back through the same arthroscopic portal. Release the forward lever to open the upper jaw and disengage the suture from the trap door by gently pulling the instrument.
- Knot the suture as per standard technique.
- Repeat the above steps to place as many stitches as desired.

FastShuttle Suture Passer System - INSTRUCTIONS FOR USE

FastShuttle Hip Capsular Closure System

Needle loading:

- Locate the cannulated shaft on the proximal end of the FastShuttle Grasper handle.
- Insert the needle through the cannulated shaft until it fits the slot located into the grasper lower jaw. To ensure the proper positioning of the needle, check that the needle plastic flag fits the slots on the grasper back handle.

Suture loading:

- Insert a standard USP#2 suture into the fixed proximal jaw slot located in the superior portion of the grasper tip keeping the free end downwards and maintaining tension on both ends of the suture.

Suture introduction and passing:

- The diameter of the proximal jaw is compatible with a Ø 8.5 mm Medacta Hip Cannula or larger cannula arthroscopic portal.
- Push the forward lever (grasping jaw locking lever) to compress soft tissue between the movable and the fixed jaws.
- Maintaining the jaws in the closed position, gently squeeze the needle actuator (needle advancement handle) to slightly advance the needle until the suture loads into the needle slot.
- Continue to apply pressure to advance the loaded needle forward and pass it through soft tissue.
- Retract the needle by removing palm pressure from the needle actuator. The suture remains secured in the movable jaw flap. Pull the suture back through the same arthroscopic portal. Release the forward lever to open the movable jaw and disengage the suture from the flap by gently pulling the sutures.

For further details regarding the surgical steps, refer to the surgical technique.

7. SURGICAL TECHNIQUE

The surgeon should be fully familiar with the surgical technique. Supplementary information about the product (brochure and video) is available on request. Careful preoperative planning, documented by X-rays, is essential.

8. POSTOPERATIVE CARE AND FOLLOW-UP

The surgeon should caution the patients to control their level of activity and to follow postoperative recommendations given by their physician. 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.

9. PACKAGING

Sterile Instrument Packaging

The Medacta FastShuttle Needle is provided disposable and sterile. It is single-packaged and supplied in boxes of 1 unit each for FastShuttle and 5 units each for FastShuttle CC. 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.

Sterile Instrument Packaging

The Medacta FastShuttle Graspers are supplied in single packages and must be cleaned before use and sterilized in an autoclave. The grasper features a cleaning mechanism on the back handle that allows access to the inner surfaces of the cannulated shaft. Washing process must be performed in accordance to Medacta's Instruction for Use "Recommendations for Decontamination and Sterilization of Medacta International SA Orthopaedic Devices" (ref. 75.09.050 and 75.09.050US).

10. STORAGE

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

11. TRADEMARKS

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

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