



Strada Regina

CH – 6874 Castel san Pietro - Switzerland

Phone: +41 91 696 60 60 Fax +41 91 696 60 66

Info@medacta.ch - www.medacta.com

US toll free phone number: 800-901-7836

Manufactured by:

Medacta International SA

CH-6874 Castel San Pietro - Switzerland

IFU MectaFlip

CAUTION

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

ENGLISH MectaFlip - INSTRUCTIONS FOR USE

Important notice: the device(s) can be prescribed and utilized only by a medical doctor legally authorized to perform this type of surgery.

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.

PRODUCT DESCRIPTION

Medacta MectaFlip is provided sterile and contains sterile single-use disposable instruments.

Medacta MectaFlip products:

Ref. No.	Description	Materials
05.09.10.0001	MectaFlip 80mm	AISI 630, Propylux
05.09.10.0002	MectaFlip 120mm	AISI 630, Propylux
05.09.10.0003	MectaFlip 150mm	AISI 630, Propylux

INTENDED USE:

Medacta MectaFlip is a disposable instrument for hip arthroscopy soft tissue management designed to retract the hip joint capsule and to increase the visibility in the intra-operative space during hip arthroscopic procedures.

CONTRAINDICATIONS:

The general contraindications for Medacta MectaFlip, are the following:

- MectaFlip instruments should not be used for anything other than their intended use, as defined in the instructions for use of the device
- MectaFlip instruments should not be used in cases involving active sepsis, infection, or poor quality of tissues involved
- MectaFlip instruments should not be used in cases involving foreign body sensitivity, known or suspected allergies to the device materials

POTENTIAL SIDE EFFECTS

- Infections, both deep and superficial
- Hematomas

WARNING

Check the expiration date prior to use. MectaFlip is meant to be single use. Reutilizing it is strictly forbidden and would lead to unpredictable outcomes. MectaFlip contains components 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 they did not experience any mechanical damage which may cause release of particles in the human body. Any non-functional instrument should be immediately returned to Medacta along with its label. The type of malfunction should be reported.

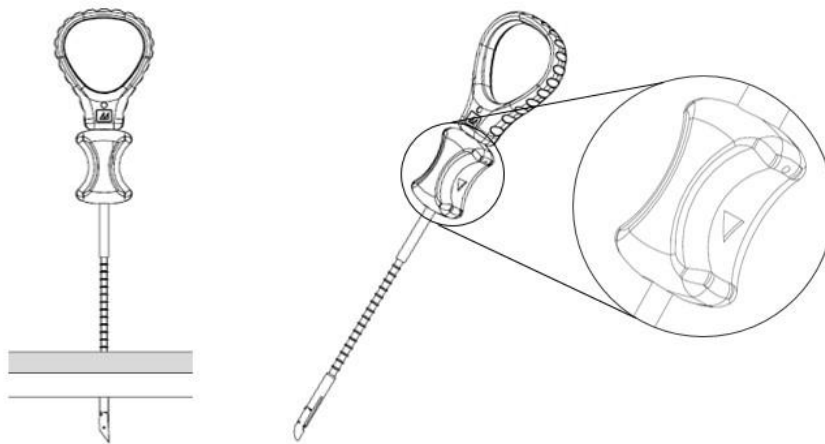
PRECAUTIONS

MectaFlip is designed for use by surgeons experienced in the appropriate specialized procedures. It is responsibility of the surgeon to become familiar with the proper technique. Refer to Medacta Mectaflip Surgical Technique (Ref. 99.111SMH.12) or the instructions here below to verify the appropriate surgical technique.

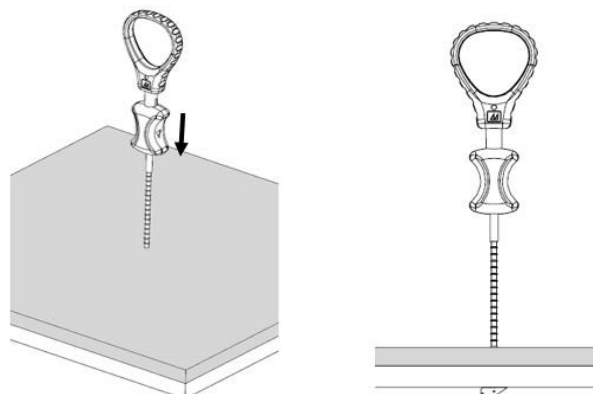
INSTRUCTIONS FOR USE

Remove items form the sterile package using aseptic technique.

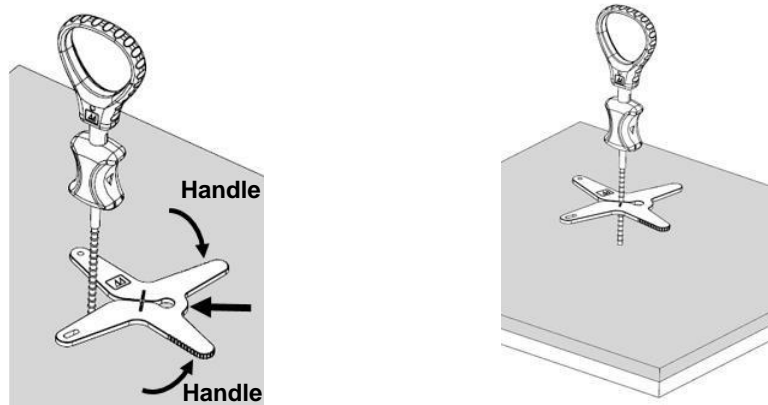
Insert the main body of the MectaFlip through the skin until the desired position is reached, paying attention to keep the distal tip in a straight configuration. Please check the arrow on the barrel to control the direction of the sharp tip of the MectaFlip.



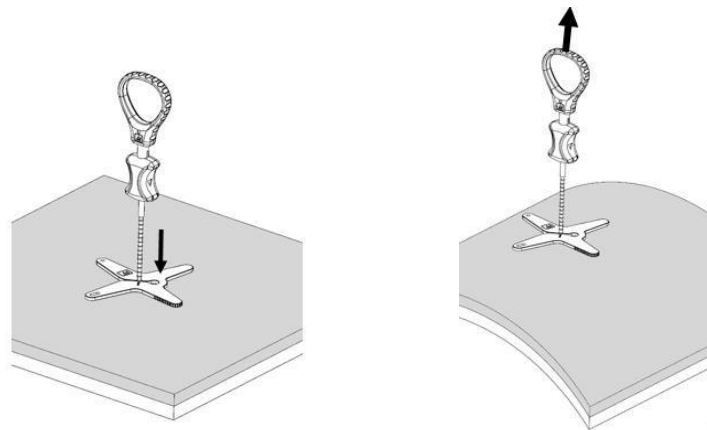
Flip the distal tip by moving the plastic barrel until the final position is reached.



Couple the star counter plate over the main body pressing the star handles, ensuring the Medacta logo is visible (upright as indicated) during the action.



Press the counter plate towards the skin while pulling the ring handle with the other hand in order to compress and raise the soft tissues.



Multiple devices can be used at the same time if more visibility is needed.

To remove the MectaFlip please follow the previous steps in reverse. Properly discard the MectaFlip after use following facility guidelines.

PACKAGING

The Medacta MectaFlip is 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.

STORAGE AND HANDLING

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

TRADEMARKS

Medacta is a 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 using irradiation

Date: 06/2019

Distributed by Medacta USA, Inc. 3973 Delp Street, Memphis, TN 38118 (800) 901-7836

