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Manufactured by:

Medacta International SA

CH-6874 Castel San Pietro - Switzerland

**IFU Hip Access Kit****CAUTION**

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

**ENGLISH Hip Access Kit - 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**

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. The user should also take all necessary precautions to avoid accidents (gloves, protective glasses, etc.).

**PRODUCT DESCRIPTION**

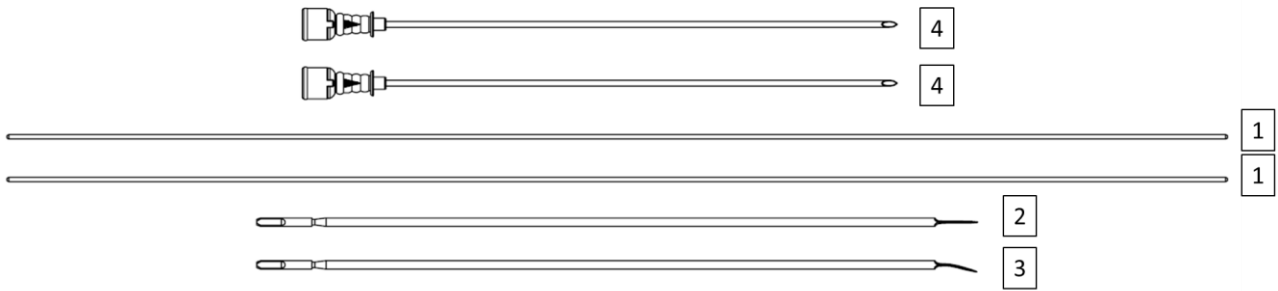
Medacta Hip Access Kit is provided sterile and contains sterile single-use disposable instruments.

The intended performance of each component of Medacta Hip Access Kit is listed below:

- Guidewire: ensures the arthroscopic portals remain open, after removing the needle
- Blades: enlarge the access into the hip capsule by cutting the tissue
- Access Needle: punctures the skin and tissues of the patient at the surgical site

**Medacta Hip Access Kit (Ref. 05.11.10.0041) instruments:**

Item	Ref. No.	Description	Qty	Materials
1	66.10.078	AK Nitinol Guidewire	2	Nitinol
2	66.10.079	AK Blade Straight	1	AISI630
3	66.10.080	AK Blade Curved	1	
4	66.10.081	AK Access Needle	2	AISI304, ABS, Polycarbonate



**INTENDED USE:**

Medacta Hip Access Kit is designed to provide the surgeon with all the main instruments to gain access to the surgical site during arthroscopy procedures.

**POSSIBLE ADVERSE EFFECTS:**

- Nerve damage
- Infection following the procedure
- Introduction of foreign materials can result in an inflammatory response or allergic reaction

**WARNING**

Check the expiration date prior to use. Hip Access Kit instruments are meant to be single use. Reutilizing them is strictly forbidden and would lead to unpredictable outcomes.

Proper hip position and distraction should be confirmed prior to advancement of distension needle, guidewires, switching stick and cannulae. Neurovascular structures must be avoided when advancing distension needle, guidewires, switching stick and cannulae.

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 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.

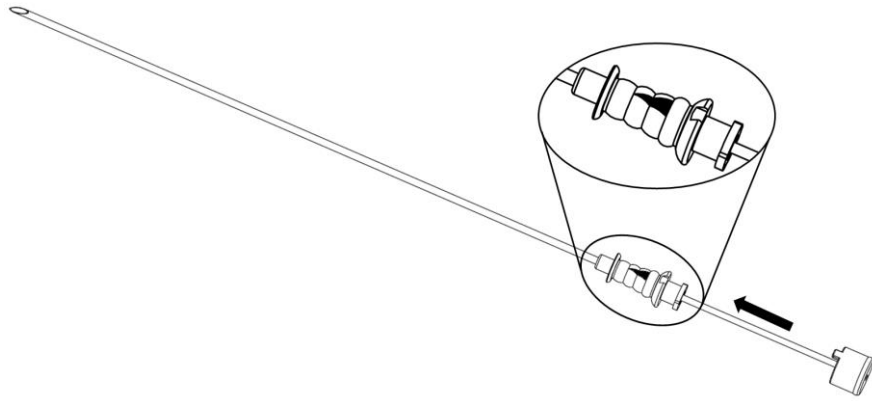
**PRECAUTIONS**

The instruments in this kit are designed for use by surgeons experienced in the appropriate specialized procedures. It is responsibility of the surgeon to become familiar with the proper technique.

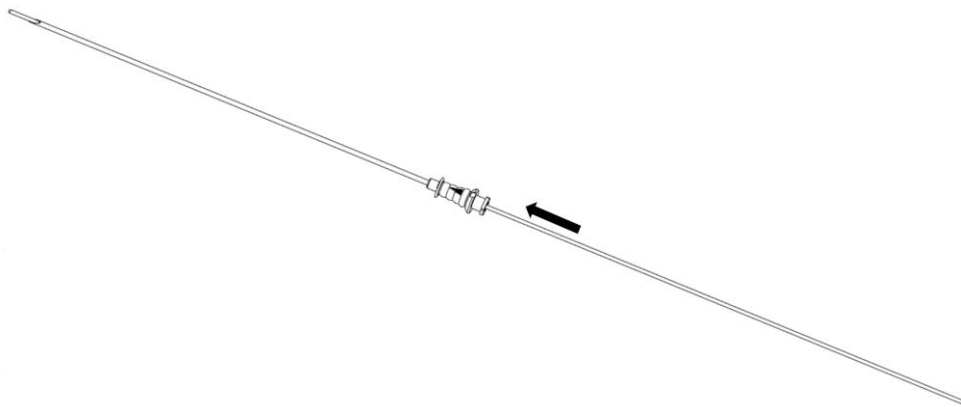
**INSTRUCTIONS FOR USE**

- Remove items from the sterile package using aseptic technique.
- Access needle: designed with a cannulation suitable to receive a 1.5Ø mm guidewire and with a working length of 180 mm. Access needle is used to get entrance to the joint according to the desired/preferred portal position.

**WARNING:** To reduce the risk of damage to the femoral head during the insertion phase, an arrow is marked on the plastic connection indicating the opening face of the needle.

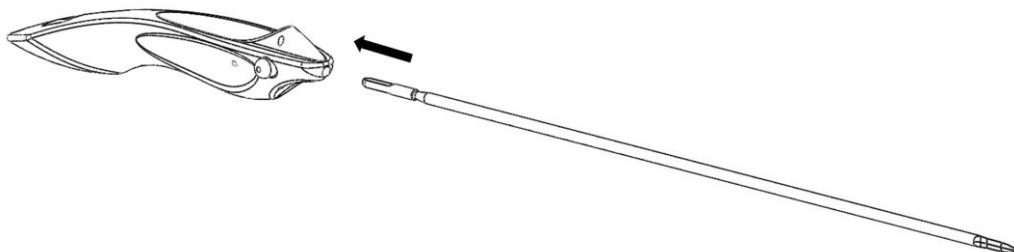


- Guidewire: flexible wire to be sled into the Access needle (after the removal of its stylet) to gain access to the joint and guide, after the removal of the access needle, the insertion of other instruments (like switching stick and cannulae) with a working length of 430 mm.



- Blades: designed with two different cutting edges (straight, curved), they are used to enlarge the access through the capsule's fibers. They have a special back-end to be connected with the reusable ergonomic handle (see below).

Ref. No.	Description	Materials
05.11.10.0040	Hip Arthro - Blade reusable handle	AISI 630, AISI 302-303, PROPYLUX (blue)



Properly discard the Hip Access Kit after use following facility guidelines.

## **PACKAGING**

The Medacta Hip Access Kit instruments 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.












## **STORAGE AND HANDLING**

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

## **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 using irradiation

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