U-Flex Ureteral Access Sheath

Description:
U-Flex Ureteral Access Sheath

Configuration:
See brochure

Intended use:
Used to establish continuous working channel thereby reducing ureteral trauma during multiple instrument exchange.

Contraindications:
This device is contraindicated in patients who do not tolerate retrograde urological procedure.

Complications:
Complications may include but are not limited to mucosal irritation, inflammation and perforation of the urethra, bladder, or ureter.

Caution:
Federal (USA) law restricts this device to sale by or on the order of a physician.

Warning/ Precaution:

- Do not use if package is opened or damaged.
- Only experienced surgeon should use this device.
- This device is supplied sterile and intended for single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Dispose in accordance with recognized medical practice and under observance of applicable law & regulation.
- Storage temperature between 5ºC to 30ºC.

Instruction for Use:

1. Using the standard procedure a compatible guidewire is placed into the urinary tract.
2. Activate the hydrophilic coating by placing sheath and dilator in the saline water / saline for 30 sec.
3. Insert the dilator into sheath and secure engagement.
4. Advance the dilator sheath assembly to the desired location over the guidewire.
5. After confirming proper placement via fluoroscopy, remove the dilator gently, while maintaining sheath position.
6. Under no circumstance should the sheath be advanced without the dilator in it.
7. If required, the sheath may be secured using the holes on the sheath funnel.
8. Instrumentation can be used in the established channel, through the sheath, as required.
9. To remove the sheath, withdraw gently. Discard in accordance to hospital procedure.

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only — Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | STERILE EO — Sterilized using ethylene oxide

EC REP

CMC Medical Devices & Drugs S. L.
C/Horacio Lengo N' 18, CP 29006, Malaga, Spain
Tel.: +34 951 214 054
E-mail : info@cmcmedicaldevices.com

CE 0123

Temperature Limit

Allwin Medical Devices, Inc.
3305 E. Miraloma Ave., Suite 176 Anaheim, CA 92806 (USA)
Tel. : +1 714-572-1709
E-mail : info@allwinmedical.com | www.allwinmedical.com