

# allDrain Re - Entry Malecot Catheter

**Description:**

allDrain Re-Entry Malecot Catheter

**Configuration:**

See brochure

**Intended use:**

Used for internal as well as external drainage with combination of nephrostomy catheter with stent.

**Contraindications:**

- Bleeding tendency
- Hypertonia
- Intake of anticoagulants

**Complications:**

- Hemorrhage
- Subcapsular Renal Hematoma
- Bleeding from iatrogenic arteriovenous-caliceal fistulas
- Edema
- Extravasation
- Loss of renal function
- Sepsis

**Caution:**

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

**Warning/ Precaution:**

- Periodic evaluation of drainage catheter is recommended.
- Do not force the catheter against any resistance without having previously determined its cause under fluoroscopy
- Fluoroscopic evaluation of placements is recommended.
- 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.
- Do not use if package is opened or damaged
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Only experienced surgeons should place this device.
- Storage temperature between 5°C to 30°C.

**Instruction for Use:**

- Puncture the renal cavity using initial puncture needle.
- After ascertaining its tip position, remove the stylet and inner cannula.
- Place the flexible guidewire through the cannula and secure into the cavity till the bladder, remove the outer cannula.
- Dilate the percutaneous tract using dilators over the guidewire, sequentially till desired dilation is achieved.
- Place the drainage catheter over guide wire and confirm its position fluoroscopically ensuring ureteral stenting and malecot position in the renal pelvis.
- Remove the guidewire.
- Attach the drainage catheter to flexible connecting tube, which can be attached to collection device.

**Storage:**

The device should be stored in a clean, dry area. Do not expose to organic solvents, ionizing radiation or ultraviolet light. The devices must be used prior to the sterilization expiration date on package.

**Do not reuse, reprocess & resterilize:**

Reuse, Reprocessing & reesterilization 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.

Catalogue Number  
 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**  
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CE 0123  
 Temperature Limit

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