ASTER MEDISPRO PRIVATE LIMITED

CE 2803

Instruction for Use
Re-Entry Malecot Catheter

Device Description

The Re-entry Malecot Catheters are provided for use in Urology procedures. The device is delivered with Flexible stylet and Urine Bag Connector. Sterile medical device intended for single use. Duration of Contact with the body is short term. The configurations available include:

Family	Accessories	Proximal (Fr.)	Distal (Fr.)	Proximal (cm)	Distal (cm)	Catalogue Number	Colors
Re-Entry Malecot Catheter (REMC)	Straightener, Urine Bag Connector	10 12 14 16 18	/5 /6 /7 /8	26 30	15 24 26	AMPLCT010	Blue

Intended Purpose

Re-entry Malecot Catheters is used to gain access to the upper urinary tract & the ureter to perform external drainage of the urine from the renal pelvis and internal drainage into the bladder.

Performance Characteristics of the Device

Long Re-entry tip facilitates guidewire placement down the ureter for follow-up procedures. The malecot wings aids in securing the catheter position. The smooth surface aids in ease of introduction of the catheter and the device is radiopaque for better visualization.

Indications

- Used in patients during nephrostomy, abscess drainage and with gastrostomy tubes.
- External drainage of urine from the renal pelvis and internal drainage into the bladder
- Drainage of body Fluids such as Urine, bile and Pus.
- Perinephric drain in post nephrectomy patients.

Contraindications

- Bleeding Diathesis, most commonly uncontrollable coagulopathy.
- Severe hyperkalemia
- Uncooperative patient.

Precautions & Warnings

Carefully read all instructions for use and product labeling. Do not use this product without reading and understanding the complete instructions enclosed herein.

The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Re-entry Malecot Catheter/Nephrostomy Catheter at a temperature between 12-35^{0}C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- Flexible catheter stylet should be reserved for straightening the re–entry malecot catheter prior to the removal at a later date.

Warnings:

- All components of the Re-entry Malecot Catheters are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

The device is intended for use in patients of all age groups.

Shelf-life and storage condition of the Product

The shelf life of the Re-entry Malecot Catheter is 3 years (Indicated on product label with the following use-by date symbol).

Sterility – This product is Sterile unless the package has been opened or damaged

- The Re-entry Malecot Catheters have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- The Re-entry Malecot Catheters are packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

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Open the package from the Chevron Side ('V' Notch) of the pouch. Suggested instructions for using Re-entry Malecot Catheters:

- Perform the standard techniques for establishing a nephrostomy tract utilizing fluoroscopic control, leaving a 150cm guide wire in the collecting system. Ensure fluoroscopically that the guide wire travels the length of the ureter and is well into the bladder.
- To facilitate passage of the nephrostomy catheter, dilate the musculofascial tract by progressing from the smallest to the largest dilator. If replacing a re-entry malecot catheter for another, skip this step proceed with step number 3.
- Place the flexible stylet inside the catheter and secure its position with luer lock to straighten the malecot wings.
- Pass the stent end of the catheter over the external end of the guide wire, gradually advance the catheter end well into the collecting system and place the stent segment into the ureter the desired length. Confirm the position fluoroscopically. After releasing the luer lock in order to open the malecot wings, carefully remove the flexible stylet. Care must be exercised to avoid withdrawal of the guide wire.
- While the shaft of the catheter is held securely in position with open hand, the guide wire is withdrawn with the other. When the appropriate position of the catheter is assured by fluoroscopic visualization, remove the guide wire.
- Use the urine bag connector to connect the catheter to a drainage bag or leg bag.

Removal Instructions

- Retrieve cystoscopically by gently pulling on Catheter or retrieval line with grasping forceps or equivalent.
- If resistance is encountered during removal of the Catheter, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
REF	Catalogue Number	CE 2803	CE Mark	2 STERILIZE	Do not Re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	UDI	Unique Device Identifier
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35°C 12°C	Temperature Limit		Do Not Use if Package is Damaged	EC REP	Authorized Representative in the European community
75% 30%	Humidity Limit								

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EC REP

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Bibliography

- Contraindications: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312169/
- Single Use Medical Device: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.