Instruction for Use
Malecot Catheter

CE 2803

Device Description
The Malecot Catheters are provided for use in Urology procedures to provide drainage following open renal or bladder surgeries. It is a sterile, self-retaining, radiopaque catheter with a flower at the tip. Intended for single use. Duration of Contact with the body is not more than 30 days. The device consists of a Radiopaque Malecot Catheter, flexible stylet and an Urine Bag connector. The configurations available include:

Family	Accessories	Size (Fr.)	Length (Cm)	Catalogue Number	Color
Malecot Catheter (MC)	Straightener, Urine Bag Connector	10 12 14 16 18 20 22 24	30	AMPLCT007	Blue

Intended Purpose
This device is used for percutaneous placement of a Malecot catheter in the renal pelvis for nephrostomy drainage. It is used as a self-retaining tube in the drainage of different body fluids, e.g., urine, bile, pus.

Performance Characteristics of the Device
Malecot Catheter is used to provide drainage following an open renal or bladder surgery. Malecot wings are employed to provide enhanced drainage and promote catheter retention and prevents its accidental removal. Malecot Catheter provides maximum softness for enhanced patient comfort and provides a useful alternative to latex catheters.

Indications
- Nephrostomy Drainage of body Fluids such as Urine, bile and Pus.
- Perinephric drain in post nephrectomy patients
- Percutaneous nephrolithotomy
- Percutaneous resection and coagulation of urothelial tumors.

Contraindications
- Bleeding Diathesis (most commonly uncontrollable coagulopathy or pharmacological anticoagulation)
- Severe Hyperkalemia
- Severe metabolic acidosis
- 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 Malecot Catheter at a temperature between 12-35^{0}C and a Humidity range of 30-75%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:
- All components of the 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 possible 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
Intended for use in patients of all age groups.

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

Sterility – This product is Sterile unless the package has been opened or damaged
- The 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 Malecot Catheters are packed single. Product in each pack must be utilized immediately when opened.

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Directions for Use

Open the package from the Chevron Side ('V' Notch) of the pouch.

- By preliminary plain film, I.V.P, retrograde pyelogram, ultrasound or CT scan, localize the kidney to be drained. A prone or slightly oblique position is preferred. Prepare and drape the flank in the usual fashion. Under fluoroscopic control, identify and anesthetize the skin site overlying the collection system.
- Pass the 18-gauge needle vertically through a small incision in the skin (made with a scalpel blade) insert the needle into the appropriate part of the pyelocaliceal system. Free flow of fluid from the needle after removing the obturator confirms a satisfactory location for the tip of the needle cannula.
- Pass the flexible end of the J guide wire through the hub of the 18-gauge needle cannula, insert the guide wire three (3) more inches into the collecting system. Confirm the position fluoroscopically. Maintain the position of the guide wire as the needle cannula is withdrawn over it.
- Care must be exercised to avoid withdrawal of the guide wire itself.
- To facilitate passage of the Malecot catheter, dilate the musculofascial tract by progressing from the smallest to the largest dilator provided. Place the stylet inside the Malecot catheter and secure its position with the luer lock to straighten the malecot flower wings.
- Pass the Malecot end of the catheter over the external end of the guide wire, gradually advance the Malecot flower end well into the collecting system. Confirm the position fluoroscopically. After releasing the luer lock in order to open the malecot flower, carefully remove the stylet.
- While the shaft of the Malecot catheter is held securely in position with one hand, the guide wire is withdrawn with the other. When the appropriate position of the Malecot Catheter is assured by fluoroscopic visualization, remove the 18 -gauge needle.
- Use the urine bag connector to connect the Malecot 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.