

Denssicath[®] Multipurpose Drainage Catheter-Malecot

Device Description

The Multipurpose Drainage Catheter Malecot is flexible tube made of polyurethane, intended for percutaneous introduction into two or more abdominothoracic anatomies (nephrostomy, biliary, abscess, pleural, peritoneal, mediastinal) [i.e., multi-purpose] for intermittent or long-term drainage. The tip of the device has a wing shaped configuration with petals which enhances retention

For product specifications refer to the label.

Malecot Catheters package includes (package components may vary):

- Radiopaque Malecot catheter
- Plastic/metal cannulated stiffener
- Drainage bag connector
- Scalpel blade

Size (Fr)	Length (cm)
8, 10, 12, 14, 16 & 18	20, 25, 30 & 35

Intended Purpose & Duration

Malecot catheter is intended to be used for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary and abscess) by Seldinger access or direct stick technique for a period of up to 30 days.

Indications For Use & Contraindications

When diagnosed to place drainage catheter percutaneously in kidney for renal drainage. No known contraindications. Device should not be used in the conditions of Bleeding Diathesis and uncontrolled hypertension, Anticoagulant use.

Potential Complications

Bleeding (including chronic hematuria, post-procedural, intraprocedural, puncture site), Catheter dislocation/dislodgement, Catheter malposition/transcolonic catheter placement, Catheter occlusion/obstruction, Damage to adjacent organs, Urinary tract infection, Mechanical catheter damage, pain and bile leak

Warnings And Precautions

- If a catheter has become malpositioned or if drainage ceases, the catheter should be promptly exchanged or removed.
- Do not use if product is damaged or expired and do not reuse the device.
- Use only accessories supplied along with package and do not resterilize.
- Manipulation of the product needs ultrasound or fluoroscopic guidance.
- Dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
- This device is intended for use by physicians trained and experienced in diagnostic and interventional techniques, standard techniques for placement of percutaneous drainage catheters should be employed.
- Periodic evaluation of the catheter is advised; catheter should not remain indwelled for more than 30 days after deployment.

Catheter Placement Procedure [Seldinger Technique]

Note: Activate the hydrophilic coating, by wetting the catheter with sterile water or saline. For best results, keep catheter surface wet during placement.

1. Localise the site of catheter insertion and mark the skin site overlying the collecting system. Then Anesthetize the marked skin site.
2. Perform procedure using standard procedures of puncture, compatible guidewire placement and dilatation (Seldinger technique).
3. As required, Use the Plastic or Metal Stiffener provided to close the Malecot wings and twist the hub to lock. Then pass the closed wings end of the catheter over the external end of the guidewire.
4. Gradually advance the closed winged end well into the collecting system.
5. Confirm the position using fluoroscopic guidance.
6. Unlock the Stiffener with a gentle twist and remove the Straightener from the catheter to open the Malecot wings.
7. Using the drainage bag connector, connect the catheter to the drainage collection bag.

Catheter Placement Procedure [Direct Stick Technique]

Note: Activate the hydrophilic coating, by wetting the catheter with sterile water or saline. For best results, keep catheter surface wet during placement.

1. Localise the site of catheter insertion and mark the skin site overlying the collecting system. Then Anesthetize the marked skin site.
2. Perform initial nick by using scalpel blade.
3. As required, Use the Plastic or Metal Stiffener provided to close the Malecot wings and twist the hub to lock. Then insert the trocar needle through the metal stiffener and twist to lock with metal stiffener hub.
4. Gradually advance the closed winged end well into the collecting system under fluoroscopic guidance.
5. Confirm the position using fluoroscopic guidance and aspiration or free backflow of fluid.
6. After confirmed placement unlock the Stiffener with a gentle twist and remove the Straightener from the catheter to open the Malecot wings.
7. Using the drainage bag connector, connect the catheter to the drainage collection bag.

Catheter Removal Procedure

- Detach the catheter from catheter fixing disc or skin.
- Gently pull the catheter carefully to remove.
- If necessary, place a guidewire, into the collecting system to maintain access. Gently withdraw the catheter carefully.

Product Recommendations

Stent Size (Fr)	Accepted Guidewire (inch)
8	0.035
10, 12, 14, 16, 18, 20 & 22	0.038

Supply and Storage

The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

Target Population Group

In patients who have, or might have, obstruction due to various reasons, an external drainage tube called a 'catheter' is commonly placed in the target site in order to prevent or to temporarily relieve the obstruction.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



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