en **Instructions for Use**

Denssicath® Multipurpose Drainage Catheter Set - Malecot

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Clinicians Trust. Patients Wellbeing

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.

Multipurpose Drainage Catheter Set - Malecot package includes (set components may vary):

- Radiopaque Malecot catheter
- Plastic/metal cannulated stiffener
- Fascial dilators
- Amplatz Ultrastiff Guidewire
- Chiba needle
- Catheter fixing disc
- Scalpel blade
- Drainage Bag Connector

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 haematuria, post-procedural, intraprocedural, puncture site), Catheter dislocation/dislodgement, Catheter malposition/trans colonic 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.
- 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.
- Do not forcefully advance any components during removal or placement of the catheter. Carefully remove the components if any resistance is occurred.
- Reuse and resterlization of the device is strictly prohibited.

Instructions For Use

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

- Under Ultrasound or CT scan, localize the collection system to be drained. Under fluoroscopic guidance, perform procedure using standard procedures of puncture, compatible guidewire placement and dilatation.
- After pyelogram, ultrasound or CT scan, Identify and mark the skin site overlaying the collection system. Anesthetize the marked skin site. Make a small incision, by using scalpel.
- Under fluoroscopic guidance, introduce the Chiba needle provided in the kit at right angles to the skin at the marked site exactly into the collection system. After achieving placement, remove the inner trocar of the needle. Confirm placement via aspiration.
- Then introduce guidewire through needle cannula. On reaching the desired position, remove the outer cannula of the needle while maintaining guidewire position.
- To facilitate passage of the catheter, dilate the musculofascial track using Fascial dilators in sequence from smallest to the largest.
- 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.
- Gradually advance the closed winged end well into the collecting system.
- Confirm the position using fluoroscopic guidance.
- Unlock the Stiffener with a gentle twist and remove the Straightener from the catheter to open the Malecot wings.
- Using the drainage bag connector, connect the catheter to the drainage collection bag.

Catheter Removal Procedure

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

Supply and Storage

The device is packed in such a way that, all the contents are assembled in tray 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^{O}C to 40^{O}C and away from direct sunlight.

Target Population Group

In patients who have, or might have, a urinary obstruction due to various reasons, an external drainage tube called a ‘catheter’ is commonly placed in the kidney 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 resterilize
	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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