
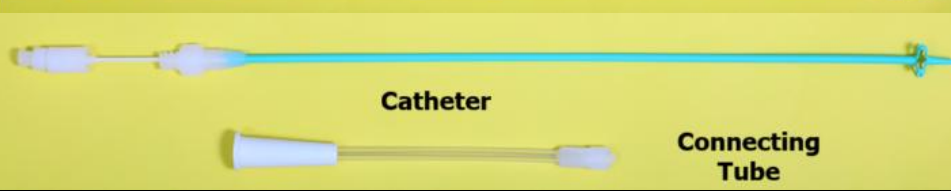
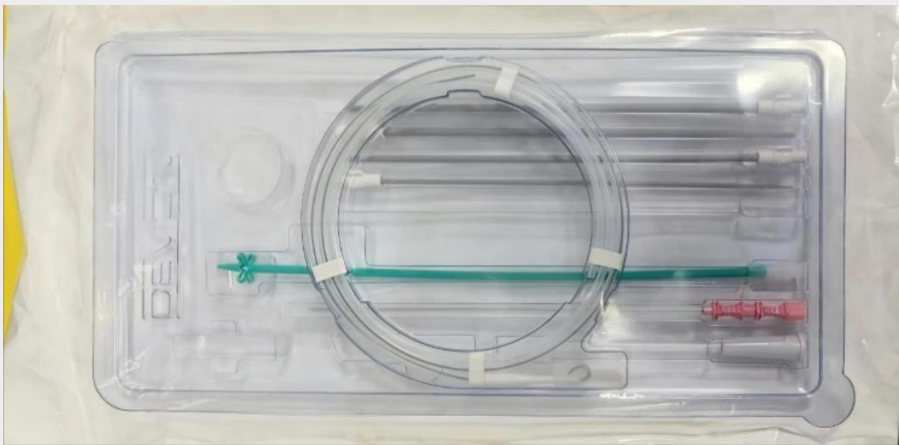
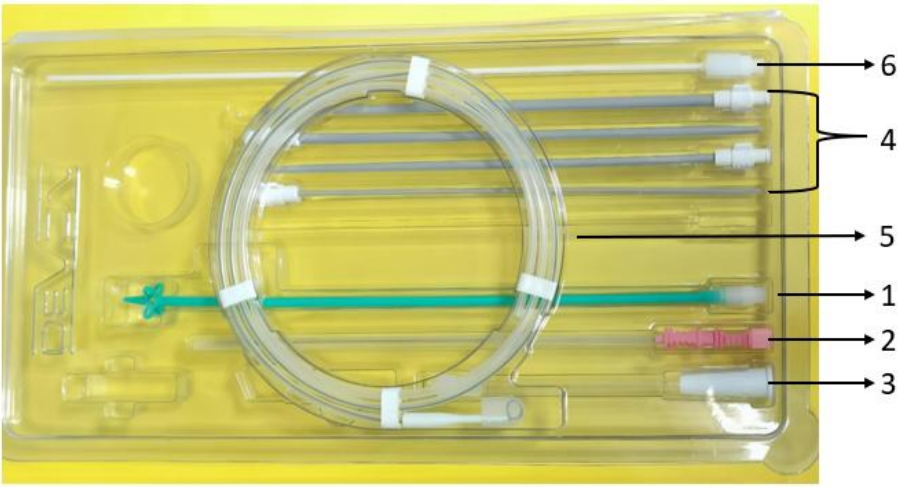




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BANGALORE

Percutaneous Nephrostomy Catheter/set with/without Hydrophilic coated

VARIANTS:

Product Name	Packin g	Image
Malecot Catheter	With Packing	
	Withou t Packing	 <p>Catheter</p> <p>Connecting Tube</p>
Percutaneous Malecot Catheter Set	With Packing	
	Withou t Packing	 <p>6</p> <p>4</p> <p>5</p> <p>1</p> <p>2</p> <p>3</p>



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Product Name	Packing	Image
		1 - Catheter 2 - IP Needle 3 - Connecting Tube 4 - Dilator Set 5 - Guidewire 6 – Flexible Stylet
Re-entry Malecot Catheter	With Packing	
	Without Packing	<p align="center">Catheter</p> <p align="center">Connecting Tube</p>
Malecot catheter with Needle (Suprapubic Cystostomy catheter)	With Packing	
	Without Packing	<p align="center">Catheter</p> <p align="center">Connecting Tube</p>
Suprapubic Cystostomy Catheter Set	With Packing	
	Without Packing	<p align="center">Catheter</p> <p align="center">Connecting Tube</p>



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INTENDED PURPOSE:

Used for nephrostomy drainage in the renal pelvis. The Malecot / Suprapubic cystostomy Catheter is placed percutaneously through an existing nephrostomy tract. The Radiopaque catheter allows fluoroscopic visualization of the catheter position. In case of Hydrophilic coated, it is to improve the ease of insertion.

MEDICAL INDICATIONS:

Malecot Catheter/Re-entry Malecot Catheter:

Nephrolithiasis (Kidney Stone)

Malecot catheter with Needle (Suprapubic Cystostomy catheter):

- Urethral injuries.
- Urethral obstruction.
- Bladder neck masses.
- Benign prostatic hypertrophy (BPH)
- Prostate cancer.

TARGET PATIENT POPULATION:

Adult

INTENDED USERS:

Urologist

CLINICAL BENEFITS:

A. Malecot catheter

- Percutaneous nephrostomy is a gentle procedure associated with high technical success
- Low morbidity
- PCN is a relatively safe and effective procedure with low risk
- Safe method of treating urinary obstruction
- Minimally invasive procedure
- Minimizes the risk of sepsis

B. Re-entry Malecot catheter

- Lower cost
- Improved post operative patient comfort
- Improved tract recovery
- Shorter hospital stay
- No bladder irritation
- Minimize bleeding

C. Malecot catheter with needle

- Safe
- Reduced post-operative urethral stricture








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- Improved patient comfort
- Less complications
- Reduced Urinary tract infections
- Less trauma to urethra
- Reduced urethral stricture rate


PERCUTANEOUS NEPHROSTOMY CATHETER SET COMPONENTS:

The following accessories are supplied only along with Percutaneous Nephrostomy Catheter Set.

#	Accessory Name	Variant Name	Image	Intended Use
1.	Guide wire	Straight/ J-tip		Guidewires facilitate the delivery of wide variety of Catheters and Stents to a Medical procedure site within the body. In case of Hydrophilic coated, it is to improve the ease of insertion.
				
		Zebra crossing Nitinol (Straight /J-tip)		
				
2.	Dilator set- Fascial	--		Used for fascial dilation or dilation of the ureter prior to ureteroscopy and/or stone manipulation. In case of Hydrophilic coated, it is to improve the ease of insertion.



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#	Accessory Name	Variant Name	Image	Intended Use
3.	IP needle	--		Used to puncture deep tissue for all percutaneous applications

SPECIFICATION:

Malecot Catheter:

Parameters	Specifications
Shelf Life	3,5 years
Size	8F,10F,12F,14F,16F,18F,20F,22F,24F,26F,28F and 30F
Length	20cm, 30cm
Supplied with connecting tube	14F,16F,18F, 22F, 24F

Re-entry Malecot catheter:

Parameters	Specifications
Shelf Life	3 years
Size	10/5F,10/6F,12/6F,14/6F,14/7F,16/7F,16/8F,18/8F,20/8F
Length (cm)	22/26, 24/26, 26 /26, 30/17
Supplied with connecting tube	14F,16F,18F, 22F, 24F
Supplied with connecting tube	14F,16F,18F, 22F, 24F

Malecot catheter with Needle (Suprapubic Cystostomy catheter):

Parameters	Specifications
Shelf Life	3 years
Size	8F, 10F, 12F, 14F, 16F
Catheter Length	20cm
Trocar Needle Length	22.5cm
Needle Size	15G, 17G, 18G
Supplied with connecting tube	14F,16F,18F, 22F, 24F

RESIDUAL RISKS:

1. Urinary tract infection
2. Catheter dislodgement and migration
3. Urethral inflammation
4. Toxic to Environment

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CONTRAINDICATIONS:

- Uncorrected coagulopathy or bleeding disorders where the risk of bleeding is high and cannot be medically managed.
- Untreated urinary tract infection (UTI)

PRECAUTIONS:

- Carefully read all instructions for use and product labeling. 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.
- All Health care professionals is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Do not use the catheter if the packaging is damaged or if the catheter appears bent, broken, or contaminated.

CAUTIONS:

- The sale of this device is restricted by or on the order of a Urologist.

WARNING:

- Percutaneous Nephrostomy Catheter/set are for single use only.
- Do not use device if there is any indication that the sterility of the device has been compromised.
- If the catheter becomes blocked, kinked, leaks, or is accidentally removed, check its position and function using fluoroscopy. Replace or reposition the catheter as needed.
- If the patient has fever, pain, reduced urine drainage, or blood in urine, this may mean the catheter is not working properly or an infection is present. Get medical help immediately.
- If the catheter has a hydrophilic coating, make sure it is properly wetted before insertion to make placement easier. Do not use if the coating looks dry or damaged.
- **Duration of Use**
 - Short term only, not for permanent use
- **Adverse effects:**
 - Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- **Reuse**
 - Reusing single-use catheters can lead to urinary tract infections in patients.

UNDESIRABLE SIDE EFFECTS:

They are bladder spasms, blood in your urine, and infections

DIRECTIONS FOR USE:

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Open the package carefully to avoid damaging the catheter. Incorrect removal of the catheter from the package may lead to contamination or product deterioration.

a) Malecot Catheter:

- Perform the standard techniques for establishing a nephrostomy tract utilizing fluoroscopic control, leaving the guidewire (included only with the stent set) in the collecting system.
- To facilitate passage of the nephrostomy catheter, dilate the musculofascial tract by progressing from the smallest to the largest dilator (included only with the stent set).
- Place the stylet into the Malecot catheter and secure its position with the lock to Straighten Malecot wings.
- Pass the Malecot end of the catheter over the external end of the guidewire; gradually advance the catheter well into the collecting system. Confirm the position fluoroscopically. After releasing the lock in order to open the Malecot wings, carefully remove the stylet.
- While the shaft of the Malecot catheter is held securely with one hand, the guidewire is withdrawn with the other. When the appropriate position of the Malecot is assured by fluoroscopic visualization, remove the guidewire.
- Secure the catheter to the skin with retention disc. Tape or suture the retention disc to the skin; secure the catheter to the disc with the pull tie. A dressing may be applied. Use the connecting tube to connect the Malecot catheter to a drainage bag or leg bag.

b) Re-entry Malecot catheter:

- Perform the standard techniques for establishing a nephrostomy tract utilizing fluoroscopic control, leaving the guidewire (included only with the stent set) in the collecting system.
- To facilitate passage of the nephrostomy catheter, dilate the musculofascial tract by progressing from the smallest to the largest dilator (included only with the stent set).
- Place the stylet into the Malecot catheter and secure its position with the lock to straighten Malecot wings.
- Pass the Stent end of the Malecot catheter over the external end of the guidewire; gradually advance the catheter well into the collecting system and place the Stent segment into the ureter to the desired length. Confirm the position fluoroscopically. After releasing the lock in order to open the Malecot wings, carefully remove the stylet.
- While the shaft of the Malecot catheter is held securely with one hand, the guidewire is withdrawn with the other. When the appropriate position of the Malecot is assured by fluoroscopic visualization, remove the guidewire.
- Secure the catheter to the skin with retention disc. Tape or suture the retention disc to the skin; secure the catheter to the disc with the pull tie. A dressing may be applied. Use the connecting tube to connect the Malecot catheter to a drainage bag or leg bag.

c) Malecot catheter with Needle (Suprapubic Cystostomy catheter):

- Straighten the Malecot catheter and guide the needle obturator into the catheter tip. Secure its position with the lock to close the Malecot wings.
- Fill the bladder



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- Make a small 2mm incision in the skin approximately 1-2 inches above the symphysis pubis.
- Insert the catheter vertically into the bladder on patients without previous pelvic surgery or at a 30° angle toward the symphysis pubis on patients with previous pelvic surgery. Gradually advance the catheter 4-5 cm beyond the first sign of the bladder fluid.
- If the bladder pressure is low and the urine fails to flow spontaneously through the hollow obturator, withdraw urine to ascertain that the catheter is within the bladder.
- After releasing the lock in order to open the Malecot wings, carefully remove the hollow needle obturator.
- Use the connecting tube to connect the Malecot catheter to the drainage bag.
- Allow the bladder to empty.
- Withdraw the Malecot catheter until the Malecot wings meet the resistance of the bladder dome. Advance the catheter approximately 2cm back into the bladder to allow for movement.
- With the catheter held up in vertical position, begin at the skin level place a tape vertically against the catheter tube.
- Wrap the tape completely around the catheter tube forming a 1cm adhesive land to allow for a catheter movement, lay the tape flat on the abdomen.
- Apply a second piece of tape in the same fashion just above the first.
- Using a tape secure the connecting tube to the abdomen in a gentle curve

STERILITY:

These catheters are supplied in a package which is sterilized by using Ethylene Oxide. Do not use the catheter if the package is damaged. If used it leads to Urinary tract infection.

STORAGE CONDITION:

Keep in cool and dry place. store the catheter at temperatures between 5°C to 40°C. Do not expose to direct sun light.

DISPOSITION:













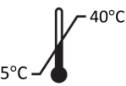





The product shall be disposed as per medical device disposal regulation.

NOTE:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;



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SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	MANUFACTURER		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE		USE-BY DATE
	BATCH CODE		COUNTRY OF MANUFACTURE
	STERILIZED USING ETHYLENE OXIDE		DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED		SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING INSIDE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	TEMPERATURE LIMIT		DO NOT RE-USE
	CONSULT INSTRUCTIONS FOR USE		CAUTION
	MEDICAL DEVICE		UNIQUE DEVICE IDENTIFIER

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REVISION HISTORY:

Doc. No.	Revision Number	Revision Date	Description
CRP 7.2 F (9)	00	08.08.2025	INSTRUCTIONS FOR USE(IFU)

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