en **Instructions for Use**

Denssicath® Multipurpose Drainage Catheter-Pigtail

BLUENEEM®
Clinicians Trust. Patients Wellbeing

Device Description

The Multi-Purpose Drainage Catheter Pigtail 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 pigtail shape for retention. The device is available in various sizes and lengths, standard and With Locking Mechanism variants will be introduced into the anatomies using Seldinger technique. For product specifications refer to the label. Multipurpose Drainage Catheters package includes (package components may vary):

Multipurpose Drainage Catheters (Standard) package includes (set components may vary)

- Radiopaque pigtail catheter
- Plastic/metal cannulae
- Plastic sheath
- Drainage bag connector
- Scalpel blade

Multipurpose Drainage Catheters with locking mechanism package includes (set components may vary)

- Radiopaque pigtail catheter with locking mechanism
- Plastic/ metal cannulae
- Plastic sheath
- Drainage bag connector
- Scalpel blade

Size (Fr)	Length (cm)	Model
6, 7, 8, 9, 10, 12, 14 & 16	22, 25, 30 & 35	Multipurpose Drainage Catheter (with or without Locking Mechanism).

Intended Purpose & Duration

Multipurpose Drainage Catheter is used for percutaneous drainage in drainage applications of nephrostomy, biliary, abscess, pleural and peritoneal cavities by seldinger technique for a period of up to 30 days.

Indications For Use & Contraindications

When diagnosed to place drainage catheter percutaneously in liver for biliary drainage / in the abdominal or thoracic cavity for drainage of clear or infected fluid collection / abscess / in kidney for renal drainage. Contraindications include 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 and pain, Bile leak.

Warnings And Precautions

- If a catheter has become malpositioned or if drainage ceases, the catheter should be promptly exchanged or removed.
- The split away Plastic Sheath, if retained, is not be used as introducer sheath for any purpose.
- 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 re-sterilization of the device is strictly prohibited.

Catheter Placement Procedure

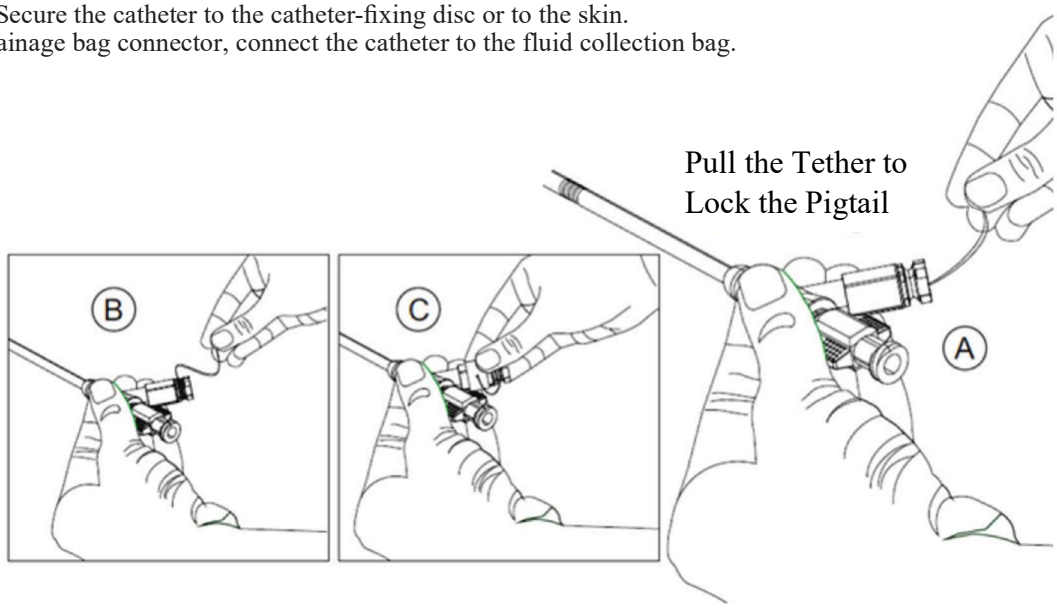
Note: Activate the hydrophilic coating, by wetting the catheter with sterile water or saline. For best results, keep catheter surface wet during placement.

Catheter (without locking mechanism)

1. Under fluoroscopic guidance, perform procedure using standard procedures of puncture, compatible guidewire placement and dilatation.
2. Use the peel away plastic sheath provided on the catheter to straight the pigtail of the catheter and then insert the plastic or metal cannulated stiffener provided and twist the hub to lock. Then remove the peel away plastic sheath.
3. Load the pigtail end of the catheter over the guidewire.
4. Gradually advance the pigtail end well into the collecting system and remove the stiffener.
5. Confirm the pigtail position under fluoroscopic control.
6. Holding the shaft of the catheter securely in position remove the guidewire carefully.
7. Secure the catheter to the catheter-fixing disc or to the skin.
8. Using the drainage bag connector, connect the catheter to the drainage collection bag.

Catheter (with locking mechanism)

1. Under fluoroscopic guidance, perform procedure using standard procedures of puncture, compatible guidewire placement and dilatation.
2. Use the peel away plastic sheath provided with the catheter to straighten the pigtail of the catheter.
3. Then insert the stiffener provided into the catheter and twist to lock with catheter hub.
4. Remove the Peel away plastic Sheath on the catheter. When inserting the stiffener into the catheter with locking mechanism, hold the string during stiffener insertion to avoid bunching or tangling of suture. Luer lock should not be tighten along with stiffener, to do so may cause kinking of catheter.
5. Then pass the pigtail end of the catheter over the external end of the guidewire.
6. Gradually advance the pigtail end well into the collecting system and remove the stiffener.
7. Confirm the pigtail position using fluoroscopic guidance.
8. Holding the shaft of the catheter securely in position remove the guidewire carefully, confirm placement via free flow of fluid. On confirmation, remove the stiffener. The catheter will now acquire pigtail shape.
9. After that pull the locking string as shown in image A.
10. After pulling the string, wind the string firmly around the locking hub as shown in image B.
11. Then lock the red clip to the locking hub, therefore the pigtail locks firmly inside the body as shown in image C.
12. Traction on the locking string, if present, should be sufficient to ensure adequate retention of the tip, but should not be overly tight. Secure the catheter to the catheter-fixing disc or to the skin.
13. Using the Drainage bag connector, connect the catheter to the fluid collection bag.

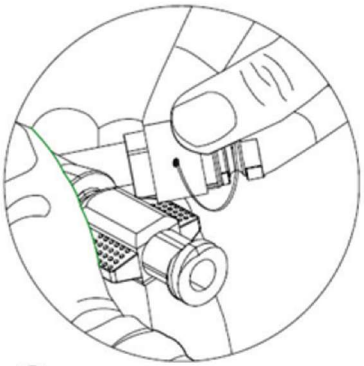


Catheter Removal For Standard Type

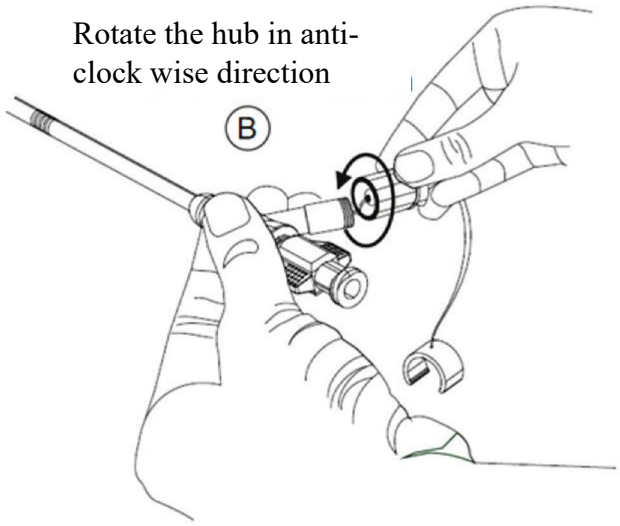
- Detach the catheter from catheter fixing disc or skin.
- Using the plastic stiffener supplied along with the catheter make the pigtail of catheter straight and remove from body carefully.
- If necessary, place a guidewire, into the collecting system to maintain access while removing the catheter.
- Remove the catheter gently and carefully.

Catheter Removal For Locking Mechanism Type

- For removal of Catheter from the body unlock the red clip from the locking hub of the catheter.
- Unwind the string in anti-clockwise, after that turn the locking hub in anti-clockwise direction to release the locking of the string.
- Using the plastic stiffener supplied along with the catheter make the pigtail of catheter straight and remove from body carefully.
- If necessary, place a guidewire, into the collecting system to maintain access while removing the catheter.



(A) Unlock the red clip



Product Recommendations

Stent Size (Fr)	Accepted Guidewire (inch)
6 7, 8, 9, 10, 12, 14 & 16	0.025 0.035

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^{o}C to 40^{o}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 in various multiple drainage applications.

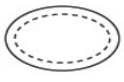
Report Any Serious Incident

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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