en **Instructions for Use**

Denssiflo® PTBD Catheter Set

BLUENEEM®
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Device Description

PTBD Catheters are self-shape retained catheters Administered in liver for biliary drainage, PTBD catheters were placed into the bile ducts up to duodenum so that through the holes present on the catheter bile will drain externally as well as internally.
For product specifications refer to the label.

Size (Fr)	Length (cm)	Model
6, 7, 8, 8.5, 9, 10, 12, 14 & 16	30, 35, 40, 45, 50, 55 & 60	All variants are available with and without locking mechanism

Denssiflo® PTBD Catheter Set package includes (set components may vary):

Denssiflo® PTBD Catheter Set-Standard	Denssiflo® PTBD Catheter Set-Micro puncture
• Radiopaque self-retention catheter with radiopaque position marker (with or without locking mechanism) • Plastic/metal cannulated stiffener • Plastic peel away sheath • Fascial dilators • Amplatz Ultra Stiff Guidewire • Chiba needle • Catheter fixing disc • Scalpel blade • Drainage bag connector	• Percutaneous introducer sheath • 0.018-inch cope mandril wire • Radiopaque self-retention catheter with radiopaque position marker (with or without locking mechanism) • Plastic/metal cannulated stiffener • Plastic peel away sheath • Fascial dilators • Amplatz Ultra stiff Guidewire • Chiba needle 21 G & 18 G • Catheter fixing disc • Scalpel blade • Drainage bag connector

Intended Purpose & Duration

PTBD Catheters is used for percutaneous placement of a catheter in bile duct up to the duodenum for biliary drainage up to a period of 30 days.

Indications For Use & Contraindications

When diagnosed to place drainage catheter percutaneously through the bile duct up to the duodenum for biliary 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, Mechanical catheter damage and pain.

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 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 Xray or ultrasound or fluoroscopic guidance.
- Retain the plastic/metal cannulated straightener to straighten the catheter loop to remove the catheter.
- 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.

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.

Standard Set

Catheter without locking mechanism

- Use fluoroscopic guidance/Ultrasound/ Computed Tomography (CT) Scan to locate the site of catheter insertion and collection system to be drained.
- Then identify and mark the skin site overlaying the collection system. Anesthetize the marked site.
- With the help of scalpel, make a small incision.
- Under fluoroscopic guidance, introduce the Chiba needle provided along with device package, on the skin at the marked and nicked site and introduce into the bile duct. After achieving placement, remove the inner part of the needle. Confirm placement via flow of bile.
- On confirmation, pass the guidewire through the needle cannula.
- On reaching duodenum, remove the outer cannula of the needle and maintain guidewire position.
- To facilitate passage of the catheter, dilate the musculofascial track using Fascial dilators in sequence from smallest to the largest.
- Use the peel away plastic sheath provided on the catheter to straight the pigtail of the catheter and then insert the plastic or metal straightener/Stiffener provided and twist the hub to lock after that remove the peel away plastic sheath.
- Then pass the pigtail end of the catheter over the external end of the guidewire. Gradually advance the pigtail end well into the collecting system up to the duodenum and remove the straightener/stiffener. Confirm the pigtail position using fluoroscopic guidance.
- Holding the shaft of the catheter securely in position remove the guidewire carefully.
- Tape or suture the catheter fixing disc to the skin.
- Secure the catheter to the catheter fixing disc.
- Using the Drainage bag connector, connect the catheter to the collection bag.

Catheter with locking mechanism

- Use fluoroscopic guidance/Ultrasound/ Computed Tomography (CT) Scan to locate the site of catheter insertion and collection system to be drained.
- Then identify and mark the skin site overlaying the collection system. Anesthetize the marked site.
- With the help of scalpel, make a small incision.
- Under fluoroscopic guidance, introduce the Chiba needle provided along with device package, on the skin at the marked and nicked site and introduce into the bile duct. After achieving placement, remove the inner part of the needle. Confirm placement via flow of bile.
- On confirmation, pass the guidewire through the needle cannula.
- On reaching duodenum, remove the outer cannula of the needle and maintain guidewire position.
- To facilitate passage of the catheter, dilate the musculofascial track using Fascial dilators in sequence from smallest to the largest.
- The catheter is supplied in ready to use state.
- Use the peel away plastic sheath provided with the catheter to straight the pigtail of the catheter.
- Then insert the plastic/metal straightener/stiffener provided into the catheter and twist to lock with catheter hub.
- Remove the Peel away plastic Sheath on the catheter. When inserting the Straightener into the catheter with locking mechanism, hold the string during Straightener insertion to avoid bunching or tangling of suture. Luer lock should not be tighten along with Straightener, to do so may cause kinking of catheter
- Then pass the pigtail end of the catheter over the external end of the guidewire.
- Gradually advance the pigtail end well into the collecting system and remove the Straightener.
- Confirm the pigtail position using fluoroscopic guidance.
- Holding the shaft of the catheter securely in position remove the guidewire carefully.
- On confirmation, remove the straightener. The catheter will now acquire pigtail shape.
- After that pull the locking string as shown in image A.
- After pulling the string, wind the string firmly around the locking hub as shown in image B.
- Then lock the red clip to the locking hub, therefore the pigtail locks firmly inside the body as shown in image C.
- 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.
- Using the Drainage bag connector, connect the catheter to the collection bag.

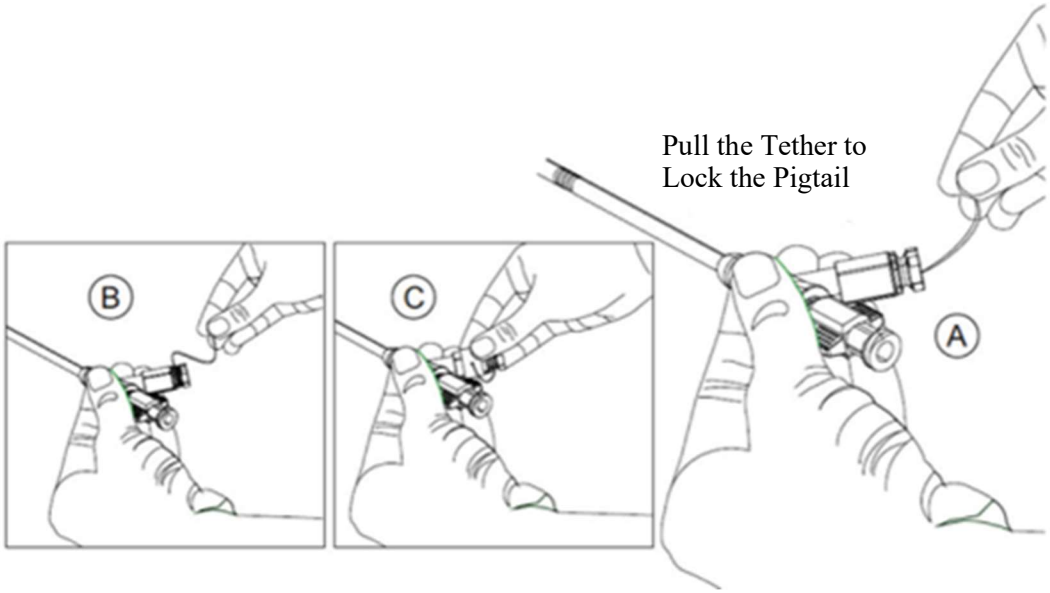
Micro puncture type Kit:

Catheter without locking mechanism

- After patient preparation, use fluoroscopic guidance/Ultrasound/ Computed Tomography (CT) Scan to locate the site of catheter insertion and collection system to be drained.
- Then identify and mark the skin site overlaying the collection system. Anesthetize the marked site.
- With the help of scalpel, make a small incision and through this nick introduce 21g Chiba needle into the small bile duct.
- Then remove the needle inner part and introduce 0.018-inch wire through the needle and push the wire into small bile duct. Then remove the needle outer cannula maintaining the wire in position. Activate the hydrophilic coating over the introducer sheath surface by using sterile water or saline or similar isotonic solution and introduce the 6fr introducer sheath along with obturator over the 0.018-inch guidewire.
- Once the sheath is in place, remove the metal stiffener and advance the introducer sheath up to main biliary duct. Then remove plastic obturator of the sheath leaving 0.018-inch wire in place. This wire act as safety wire to maintain tract up to main biliary duct. After removal of safety wire now introduce 0.035-inch guidewire through the lumen of 6fr introducer sheath, manipulate it and advance up to duodenum.
- Then remove the 6fr introducer sheath and perform musculofascial dilation by using fascial dilators in sequence of smallest to largest dilator size.
- Follow the standard procedure of catheter placement as described in instructions for use of Standard set-catheter with out locking mechanism.

Catheter with locking mechanism

- After patient preparation, use fluoroscopic guidance/Ultrasound/ Computed Tomography (CT) Scan to locate the site of catheter insertion and collection system to be drained.
- Then identify and mark the skin site overlaying the collection system. Anesthetize the marked site.
- With the help of scalpel, make a small incision and through this nick introduce 21g Chiba needle into the small bile duct.
- Then remove the needle inner part and introduce 0.018-inch wire through the needle and push the wire into small bile duct. Then remove the needle outer cannula maintaining the wire in position. Activate the hydrophilic coating over the introducer sheath surface by using sterile water or saline or similar isotonic solution and introduce the 6fr introducer sheath along with obturator over the 0.018-inch guidewire.
- Once the sheath is in place, remove the metal stiffener and advance the introducer sheath up to main biliary duct. Then remove plastic obturator of the sheath leaving 0.018-inch wire in place. This wire act as safety wire to maintain tract up to main biliary duct. After removal of safety wire Now introduce 0.035-inch guidewire through the lumen of 6fr introducer sheath, manipulate it and advance up to duodenum.
- Then remove the 6fr introducer sheath and perform musculofascial dilation by using fascial dilators in sequence of smallest to largest dilator size.
- The catheter is supplied in ready to use state.
- Follow the standard procedure of catheter placement as described in instructions for use of Standard set-catheter with locking mechanism.



NOTE: Retain the plastic straightener/stiffener provided in the set for straightening the pigtail catheter at a later date for removal.

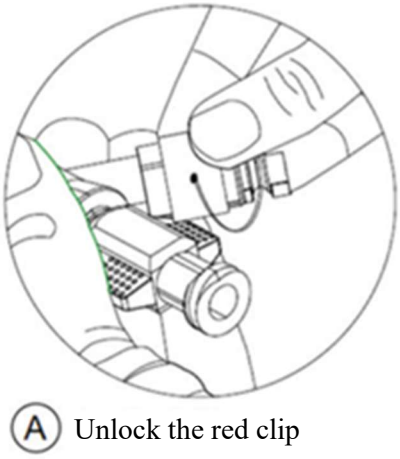
Catheter Removal Procedure

Catheter removal for standard type

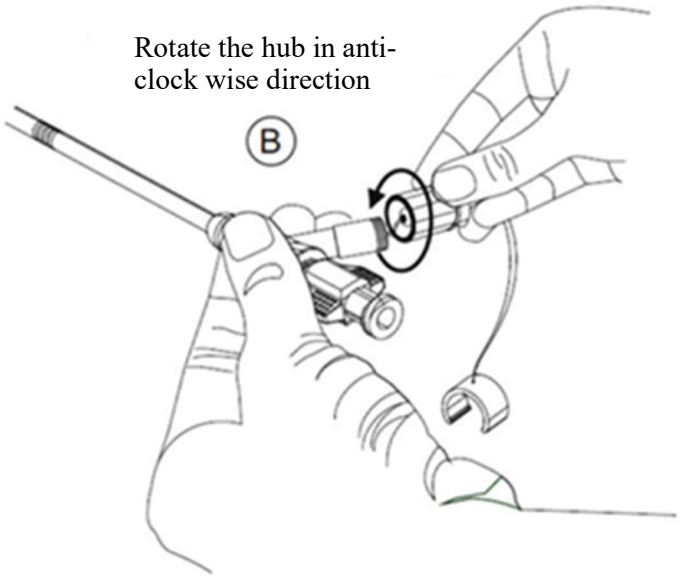
Detach the catheter from catheter fixing disc or skin.
- Using the plastic stiffener supplied along with the catheter make the pigtail of catheter straight and remove from body carefully.
- If necessary, place a guidewire, into the collecting system to maintain access while removing the catheter.
- Remove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



Supply and Storage

The device is packed in such a way that, catheter and all accessories primarily assembled in plastic 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

Adult Male and Female patients who require catheter placement for drainage of bile.

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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