



2011-01

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Connecting Tube

used with

Flexima™ Biliary Catheter System Kit

VTC™ Nephrostomy Catheter System Kit

Flexima™ APD™ Drainage Catheter System Kit

Flexima™ APDL Drainage Catheter System Kit

Flexima™ Nephrostomy Catheter System Kit

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Connecting Tubes used with the Drainage Catheter System Kits are inserted using percutaneous access and used for drainage of abscesses and fluid collections. The catheter is manufactured of a biocompatible material which is intended to resist encrustation and degradation. The catheter is designed to be radiopaque and easily visualized using ultrasonography, computed tomography or fluoroscopy.

The distal end of the catheter contains drainage holes with a J shaped tip or locking pigtail to prevent migration during use. The proximal end of the catheter with the locking pigtail is provided with a locking hub. The luer of the locking hub allows for connection of medical apparatus' with a conical fitting, including a drainage tube. When in the locked position, the suture is captured in the locking hub, retaining the pigtail in the desired shape, while leaving the lumen open for flushing and draining.

Select drainage catheters are supplied with Glidex™ Hydrogel Coating for the reduction of surface friction during placement.

Select drainage catheters are available with a TempTip™ Hydrophilic Dissolving Tip. This dissolvable tip facilitates tracking over a guidewire for percutaneous placement and dissolves within 24 hours of placement to provide a larger drainage lumen.

Select Biliary Radiopaque Marker catheters include a radiopaque marker band to aid in proper placement of the catheter. This marker band is located approximately 5 mm proximal to the most proximal drainage hole and serves as a landmark to denote that all drainage holes are distal to the marker band.

Contents

APD or APDL Catheter System Kit

- (1) Dressing
- (1) Flexima Catheter
- (1) Metal Stiffening Cannula
- (1) Flexible Stiffening Cannula
- (1) Percufix™ Catheter Cuff
- (1) Connecting Tube with Stopcock
- (1) Introducer Needle with Stylet
- (1) Dilators
- (1) Stainless Steel Guidewire with J-Tip
- (1) Accustick II Introducer Set
- (1) Stainless Steel Guidewire with Floppy Tip
- (2) Cable Ties

Biliary and Nephrostomy Catheter System Kits

- (1) Percuflex™ or Flexima Catheter
- (1) Metal Stiffening Cannula
- (1) Flexible Stiffening Cannula
- (1) Accustick II Introducer Set
- (1) Introducer Needle with Stylet
- (1) Stainless Steel Guidewire with Floppy Tip
- (1) Stainless Steel Guidewire with J-Tip or Straight Tip
- (1) Percufix Catheter Cuff
- (1) Dressing
- (1) Connecting Tube with Stopcock
- (1) Fascial Dilators
- (2) Cable Ties

Note: Contents vary depending upon device model.

INTENDED USE/INDICATIONS FOR USE

Catheter System Kit	Intended Use/Indications For Use
Drainage Catheter System Kit	To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.
Biliary Catheter System Kit	To provide external and internal percutaneous drainage of the biliary system.
Nephrostomy Catheter System Kit	To provide external drainage of the urinary tract.

CONTRAINDICATIONS

Where percutaneous drainage catheterization is unacceptable.

WARNINGS

Do not use catheter for feeding tube/gastrostomy procedures. Exposure to gastric juices may damage the catheter.

PRECAUTIONS

These recommendations are meant to serve only as a basic guide to the utilization of this catheter. The performance of percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collections should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure.

Do not allow alcohol to contact the catheter. Exposing the catheter to alcohol may damage the coating and catheter.

For units with Glidex Hydrogel Coating:

- Use a wet gauze pad to handle the catheter during placement, if necessary.
- Do not wipe catheter with dry gauze or any solvents as it may damage coating.
- Keep the catheter wet during placement.

Where long-term use is indicated, it is recommended that indwelling time not exceed 90 days. This catheter should be evaluated by the physician on or before 90 days post-placement.

Catheters attached to suction should follow normal clinical practices in selecting a static vacuum level. Testing has demonstrated the catheters can withstand a negative pressure of 200 mm Hg (26.7 kPa).

ADVERSE EVENTS

- Catheter Occlusion and/or Dislodgment
- Dysuria and Frequency/Urgency
- Encrustation
- Fistula
- Hemorrhage/Hematoma
- Infection/Sepsis
- Jaundice
- Pain
- Pancreatitis
- Perforation
- Peritonitis
- Pneumothorax

HOW SUPPLIED

Contents are supplied in a sterile pouch.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Do not expose to organic solvents, ionizing radiation or ultraviolet light.

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Prior to Placement

Prior to use, all devices to be used for the procedure should be carefully examined to verify the sterile barrier, proper function, and integrity.

For units with TempTip Hydrophilic Dissolving Tip and Glidex Hydrogel Coating:

- To activate the coating, soak the catheter in sterile water or saline for at least 30 seconds.
- Keep the TempTip Dissolving Tip protector in place while activating coating.

- Immediately prior to insertion, wet catheter with sterile saline by spraying with a syringe or wiping with a wet gauze. Do not soak tip as it may start to dissolve, and may compromise the catheter's ease of insertion.
- Remove TempTip™ Dissolving Tip protector prior to placement.

For units with Glidex™ Hydrogel Coating:

- Use a wet gauze pad to handle the catheter during placement.
- Do not wipe catheter with dry gauze or any solvents as it may damage coating.
- Keep the catheter wet during placement.

Caution: DO NOT ALLOW ALCOHOL TO COME IN CONTACT WITH THE CATHETER. Exposing the catheter to alcohol may damage the coating and the catheter.

Placement Techniques

The Drainage catheter is prepared for two introduction techniques.

Option I: Guidewire Exchange (Using Stiffening Cannula)

Option II: Direct Puncture (Using Trocar Stylet)

Note: The direct puncture method is applicable to the APD™ Catheter only and is intended for use in cases of superficial collections, i.e., cavities not more than 3 cm - 5 cm below the skin surface, with no intervening bowel or organ. For procedures using the guidewire exchange method, remove the trocar from the catheter prior to use, leaving the stiffening cannula in place.

Note: Withdrawal of guidewires should be smooth and without resistance. If resistance is felt, carefully remove guidewire(s) and system as a unit.

Option I

Guidewire Exchange (Using Stiffening Cannula)

1. Use conventional methods of opacifying and visualizing the collecting system. Using local anesthesia and Seldinger Techniques, place a guidewire within the collecting system. It is recommended that a 0.038 in (0.97 mm) diameter guidewire be used.

Note: When placing a 6F catheter, refer to product label for recommended guidewire size.

2. If dilation is necessary, dilate tract to one French size larger than catheter. This will ease introduction of the catheter.
3. Straighten the distal tip before advancing stiffening cannula into the catheter. Advance the stiffening cannula, fully straightening distal tip, and lock cannula in place.
4. Wet the Hydrogel coated catheter to activate the coating (see "Prior To Placement").
5. The catheter/cannula (without trocar stylet) is advanced over the guidewire into the superficial part of the cavity, at which point the cannula is unlocked and held stationary while the catheter is fully advanced ensuring all holes are within the cavity. The cannula is then removed.
6. Verify drainage hole position using contrast.
7. For those catheters with locking pigtails, follow the instructions below "To Lock the Pigtail Catheter Tip."
8. Fix the catheter in place with adhesive pads. Be careful not to kink the shaft when securing the catheter. If using the catheter cuff, see note in "Percufix™ Catheter Cuff" section below.
9. Fluid is drained by syringe, gentle suction, or gravity.

Option II

Direct Puncture (Using Trocar Stylet)

Note: Use caution to prevent bending the trocar or stiffening cannula during use. Use ultrasound guidance when puncturing bile duct and confirm the position of the guidewire using fluoroscopy.

1. Insert trocar into the stiffening cannula.
2. Straighten the distal tip and insert trocar/cannula assembly into the drainage catheter. Fully straighten the distal tip and lock the cannula in place.
3. Remove caution tag from trocar/cannula assembly and lock trocar to cannula. Ensure all hubs are properly engaged.

4. Wet the hydrogel coated catheter to activate the coating (see "Prior to Placement").
5. Introduce the catheter/cannula/trocar assembly percutaneously into the cavity.
6. Remove the trocar stylet. If desired, a guidewire can be inserted at this point to aid placement into cavity. Advance the guidewire using ultrasound imaging and to confirm the position of the guidewire using fluoroscopy.
7. The catheter/cannula (without trocar stylet) is advanced over the guidewire into the superficial part of the cavity, at which point the cannula is unlocked and held stationary while the catheter is fully advanced ensuring all holes are within the cavity.
8. Remove the cannula. Verify drainage hole position using contrast.
9. For those catheters with locking pigtails, follow the instructions below "To Lock the Pigtail Catheter Tip."
10. Fix the catheter in place with adhesive pads. Be careful not to kink the shaft when securing the catheter. If using the catheter cuff, see note in "Percufix Catheter Cuff" section below.
11. Fluid is drained by syringe, gentle suction, or gravity.

To Lock The Pigtail Catheter Tip

Note: Use caution when removing guidewire to prevent pigtail from being repositioned.

1. To form the locking pigtail, slowly remove the guidewire while rotating the catheter counterclockwise under fluoroscopy. This movement will cause the catheter to reform the pigtail.
2. To lock the pigtail in its position, gently pull the suture until resistance is felt. Holding the suture, insert the "key" into the slot of the locking hub and rotate the locking hub clockwise 180 degrees. The arrow will point to the "Locked" position. This position locks the pigtail in place but leaves the lumen open for flushing and draining. See Figure 1.

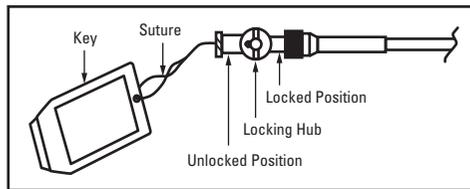


Figure 1. Suture Locking Mechanism

3. Cut suture flush with hub.
4. Connect drainage tube to the hub.

Two Methods For Pigtail Catheter Removal

Caution: Do not attempt to remove catheter prior to unlocking pigtail as outlined in methods below:

Note: Method 1 should be attempted in all cases. Only use Method 2 when Method 1 can not be applied.

Method 1

1. Disconnect drainage tube from the hub.
 2. Using the "key", or alternate items that fit in the slot of the locking hub, rotate the locking hub counterclockwise 180 degrees to the "unlocked" position.
- Note:** After rotating the locking hub clockwise 180 degrees to lock the pigtail during placement, you must rotate the locking hub counterclockwise 180 degrees to unlock the pigtail prior to catheter removal.
3. If access to the cavity is to be maintained, insert a 0.038 in (0.97 mm) floppy tip guidewire through the catheter and past the distal tip using fluoroscopic guidance.

Note: When removing a 6F catheter, refer to product label for recommended guidewire size.

4. Gently withdraw the catheter.

Method 2

1. Disconnect drainage tube from the hub.
2. If access to the cavity is to be maintained, advance a 0.038 in (0.97 mm) floppy tip guidewire through the catheter and past the distal tip using fluoroscopic guidance.

Note: When removing a 6F catheter, refer to product label for recommended guidewire size.

3. Carefully cut the full circumference of the catheter immediately distal of the locking hub and strain relief, being sure to sever the suture without damaging the guidewire. Remove the locking hub. Be aware that the suture is no longer secured to the catheter. Gently remove the catheter, taking care to remove both the suture and the catheter.

Caution: Be certain to remove both the suture and the catheter. Failure to do so could result in the suture being left behind in the patient. The suture is non-absorbable monofilament nylon.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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