

- BT-PDL0, BT-PDL1 (DIRECT ACCESS)
- BT-PDL2, BT-PDLS, PDL3, PDL4 (SELDINGER)

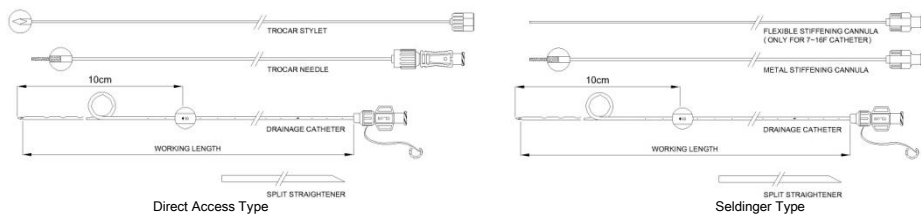
INSTRUCTIONS FOR USE

ENGLISH

DEVICE DESCRIPTION

The Percutaneous Drainage Catheter with hydrophilic coating ,BT-PDL0, BT-PDL1/ BT-PDL2, BT-PDLS, BT-PDL3, BT-PDL4, is used for drainage of abscess and fluid collections. The catheter is made from a soft, biocompatible radiopaque polyurethane (TPU). The distal end of catheter contains a "J" or a pigtail and drainage holes.

The catheter comes with a variety of operational accessories. Accessories include: scalpel, stopcock, connecting tube, drainage bag, catheter securement device, contrasting needle, retention disk, fixing needle. The connecting tube and drainage bag are made of PVC contain DEHP.



INDICATIONS FOR USE

The catheter is designed for percutaneous drainage of abscesses applied in gastroenterological system, urological system and other applicable drainage abscesses.

The operator can use different drainage sets according to the type of accumulated fluid and place of accumulation. These kits are classified according to the catheter size (5F~16F pertaining to various fluid viscosity) and according to the position of the accumulation. The operator can choose either BT-PDL0/ BT-PDL1 (Direct Access) or BT-PDL2/ BT-PDLS/ BT-PDL3/ BT-PDL4 (Seldinger Type), depending on the method used to provide access.

PRIOR TO USE

The Percutaneous Drainage Catheter is supplied sterile in a sealed pouch. Prior to use, inspect both the sterile seal and device for any damage. If there is a breach to the seal or if the product is damaged, DO NOT USE! Immediately return defective package/product to BIOTEQUE for replacement.

WARNINGS

- Do not use catheters for feeding tube/ gastrostomy procedures. Exposure to gastric juices may damage the catheter.
- Do not allow alcohol to contact with the catheter. Exposing the catheter to alcohol may damage the coating and the catheter.

PRECAUTIONS

- The device is restricted to be sold on the order of a physician by Federal law (USA).
- The device is intended for single use only.
- Carefully read all instructions prior to use of this device. Observe all warnings and precautions. Failure to do so may result in complications.
- If abnormalities are noted discontinue the use immediately and take appropriate action.
- Do not use continuously for more than 90 days. The catheter should be evaluated by the physician on or before 90 days post-placement periodically.
- The effective period of this product is 3 years when stored appropriately.
- Store catheters in a cool, dry area. Do not expose to organic solvents, ionizing radiation or ultra violet light.
- Rotate inventory so that catheters are used prior to the sterilization expiration date on package label.
- Handle the device carefully and avoid forceful stretching etc.
- Use the device immediately after opening the package. After use, deposit it in a safe manner.

STERILE EO CE 0434

PVDF DEHP
Connecting Tube
Drainage Bag



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CONTRAINDICATIONS

Only qualified personnel who are familiar with the technique should apply the device. During insertion avoid contact with bone, cartilage and scar tissue which may damage the catheter tip.

The kit must not be applied where percutaneous catheterization is unacceptable.

Echinococcus cyst, multiple chamber accumulation of fluids or accumulations known as phlegmonic accumulations can mostly not be satisfactorily treated using the percutaneous drainage technique.

POTENTIAL COMPLICATIONS

- Catheter Occlusion
- Catheter Dislodgement
- Haemorrhage
- Sepsis and Urinoma/Biloma
- Perforation
- Peritonitis
- Pneumothorax
- Skin Infection

RECOMMENDED PROCEDURE - USING DIRECT ACCESS TECHNIQUE:



CAUTION :

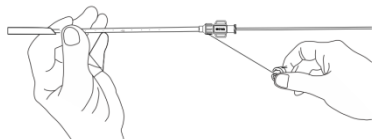
The application of the direct access method is recommended for those cavities only which are not covered by any organ or intestine.

1. Select an appropriate patient for direct access insertion drainage.
2. Using the splittable straightener, straighten the whole catheters out (before advance stiffening cannula and trocar). Advance the stiffening cannula and trocar into the catheter, fully straightening distal tip, and lock cannula in place. Remove the splittable straightener. (Step 1-3)
 - ▶ Hold the thread stretched, if present, while inserting the stiffening cannula and trocar to avoid tangles. (Step 2)Remove the splittable straightener from Catheter. (Step 4)
Remove the Septum Paper from the Trocar Needle. (Step 5)
Advance the Trocar Stylet and lock to the Hub of Needle. (Step 6)
Verify the tip of the Trocar Stylet protrudes through the tip of the Catheter.

Step 1 : Straighten Catheter Loop.



Step 2 : Pull the String stretched.



Step 3 : Lock Cannula.



Step 4 : Remove Straightener and Fully Seat Catheter onto Cannula Tip.



Step 5 : Remove Septum Paper.



Step 6 : Lock Stylet.



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PH7/DEHP
Connecting Tube
Drainage Bag



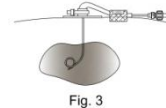
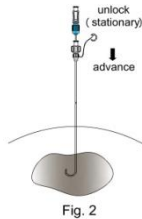
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3. Disinfect the entrance site and perform skin incision under local anesthesia.
4. Insert the prepared catheter into the entrance site and advance it in the direction towards the accumulated fluid under using fluoroscopy, CT or ultrasound guidance.
5. Once you pass the wall of the cavity, unlock and remove trocar stylet from the cannula hub first. Aspirate fluid from accumulated fluid, with a syringe, to determine correct catheter placement. If the catheter is located in the target area, fluid should start flowing out from the catheter. (Fig.1)
6. After the catheter is positioned, unlock the cannula from the Catheter. (A guide wire may be inserted at this point to aid in placement, if desired)
7. Holding the cannula stationary, advance the catheter to the desired location ensuring that the pigtail/"J" tip is within the cavity. (Fig.2)



8. To lock the pigtail in its position: (Only for Locking Pigtail)
 - (1) Pull the thread gently.
 - (2) Keep thread stretched and attach and **tighten the female/male adapter onto the catheter to activate the valve** in the catheter.
 - (3) Wind the thread around the slot and press the clip onto the slot.
9. Connect the catheter to a drainage bag with connecting tube.
10. Check the position of the catheter using fluoroscopy.
11. A flush regimen may be used depending upon condition of each patient and the physician's diagnosis.
12. The catheter must be secured on the skin so the patient can easily cleanse the entrance site without adjusting the position of the catheter.. (Fig.3)



CAUTION :

It is not possible to exclude the possibility that the lumen of the catheter will clog, and therefore perfect drainage can no longer be guaranteed. It is suggested to replace the drainage catheter in such case.

RECOMMENDED SELDINGER (GUIDE WIRE) TECHNIQUE PROCEDURE:

The guide wire method according to Seldinger is suitable for the treating deep or inaccessible positions. In addition, the use of this method is suitable if the fluid accumulation is covered by any organ or with intestines.

1. Select an appropriate patient for percutaneous drainage.
2. Locate the accumulated fluid under CT or ultrasound guidance.
 - ▶ Hold the thread stretched, if present, while inserting the stiffening cannula to avoid tangles. (Step 2) Remove the splittable straightener.
3. Using the splittable straightener, straighten the whole catheters out (before advance stiffening cannula). Advance the stiffening cannula into the catheter, fully straightening distal tip, and lock cannula in place. Remove the splittable straightener.
4. Disinfect the entrance site and perform local anesthesia.
5. Use puncture needle to Puncture the puncture site area and remove the stylet.
6. A guide wire is introduced and bends in the cavity to the shape of the loop. Inspect using proper type of imaging. A heavy duty type guide wire (0.035") is recommended. (Fig.4)
7. Remove the puncture needle from the guide wire. The guidewire still remains in the cavity.

8. The puncture channel can be gradually expanded using the standard method with the dilators.
9. Advance the catheter, under fluoroscopic control, over the heavy duty guide wire into the target area. At the point of entry into the cavity, the cannula is unlocked and held stationary, while the catheter is further advanced into the patient over the guide wire. (Fig.5 ; Fig.6)



Fig. 4



Fig. 5

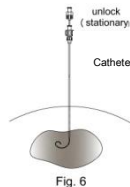


Fig. 6

10. The catheter must be introduced far ahead to a position so that all the perforations of the catheter are located inside the cavity. In order to form the pigtail/"J" tip, slowly remove the guide wire while rotating the catheter counter-clockwise. This movement observed with fluoroscopy will cause the catheter to reform the pigtail/"J" tip in the cavity.
11. After verifying the proper positioning of the catheter inside the cavity, remove the guide wire and wash/drain off the secretion. The proper positioning of the catheter can be verified after administration of the contrast medium through the catheter itself. The position can be corrected with the repeated introduction of the guide wire or reinforcement cannula.
12. Once the catheter has been placed successfully (all side perforations of the catheter are located inside the cavity), remove the reinforcement cannula from the catheter.
13. To lock the pigtail in its position: (Only for Locking Pigtail)
 - (1) Pull the thread gently.
 - (2) Keep thread stretched and attach and **tighten the female/male adapter onto the catheter to activate the valve** in the catheter.
 - (3) Wind the thread around the slot and press the clip onto the slot.
14. Connect the catheter to a drainage bag with connecting tube.
15. Check the position of the catheter using fluoroscopy.
16. A flush regimen may be designed for the circumstances of each patient and protocol of the physician.
17. It is essential to fix the catheter securely at the skin so that the entrance site can be easily maintained by the patient without disturbing the position of the catheter.

RECOMMENDED CATHETER EXCHANGE PROCEDURE:

The catheter can be replaced in case of clogging of the present catheter.

1. Use splittable straightener to straighten the whole catheters out (before advance stiffening cannula). Advance the stiffening cannula into the catheter, fully straightening distal tip, and lock cannula in place. Remove the splittable straightener.
2. Disconnect the drainage bag connecting tube from catheter.
3. To unlock the pigtail in its position: (Only for Locking Pigtail)
 - (1) Remove the clip and unwind the suture if any.
 - (2) Loosen the female/male adaptor from the standard luer hub at the catheter to deactivate the valve.
 - (3) Check that both threads are loose and cut one thread in order to loosen the pigtail.
4. Insert the 0.035" guide wire through the catheter introduced into the patient to the relevant cavity.
5. Remove the catheter carefully from the puncture drain over the guide wire.
6. Now, introduce the replacement catheter into the relevant cavity over this guide wire.
7. Once the catheter has been placed successfully (all side perforations of the catheter are located inside the cavity), remove the reinforcement cannula from the catheter and then the guide wire.
8. To lock the pigtail in its position: (Only for Locking Pigtail)
 - (1) Pull the thread gently.
 - (2) Keep thread stretched and attach and **tighten the female/male adapter onto the catheter to activate the valve** in the catheter.

- (3) Wind the thread around the slot and press the clip onto the slot.
9. Connect the catheter to the drainage bag with connecting tube.
10. Use the fluoroscopy to check the location and of the catheter..
11. A flush regimen may be used depending upon condition of each patient and the physician's diagnosis. 12. The catheter must be secured on the skin so the patient can easily cleanse the entrance site without adjusting the position of the catheter.

RECOMMENDED REMOVAL OF CATHETER PROCEDURE:

1. Disconnect the drainage bag connecting tube from catheter.
 2. To unlock the pigtail from its position: (Only for Locking Pigtail)
 - (1) Remove the clip and unwind the suture.
 - (2) Loosen the female/male adaptor from the standard luer hub at the catheter to deactivate the valve.
 - (3) Check that both threads are loose and cut one thread in order to loosen the pigtail.
 3. Pull the catheter out gently. If access is to be maintained, a straight floppy tip guide wire passed through the catheter will facilitate removal while maintaining access.
- Note : It is recommended that all personnel are trained of the catheter removal process.



The product is for single use. By several time use patient increases the risk of infection.

The product is for single use. The reprocessing and reuse of single-use products pose the risk of bacterial growth, contamination, patient injuries and could lead to death. Faulty cleansing, re-sterilization and tests may allow the transmission of infectious disease between patients; may alter device's mechanical properties and thus risk product failure. It is the end user's responsibility to read and understand the important warnings and to ensure the single use of medical devices.



Connecting Tube and Drainage Bag contain Phthalates(DEHP).

This medical device is made of material PVC, and it includes the plasticizer DEHP, so called Bis (2-ethylhexyl) phthalate. DEHP's effect to pregnant women and children is bigger than adult.

When using this device, please pay attention to the risk result in the following possible complications, but are not limited to:

Pregnant women : Miscarriage and the deformity to embryo.

Children : The effects to the reproductive system including the decrease of the reproductive rate, the quantity of the sperm and the damage to the testis.

Contact the trained doctor and nurses in advance to prevent the complications.



Do not use if package is damaged



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MADE IN TAIWAN

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