

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 EXCHANGING THE CATHETER PROCEDURE:

You can replace the catheter in case of clogging of the previously introduced catheter.

1. 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.
 - ▶ Hold the thread stretched, if present, while inserting the stiffening cannula to avoid tangles.
 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, you can 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 a drainage bag with connecting tube.
10. Check the position of the catheter using fluoroscopy .
11. A flush regimen may be designed for the circumstances of each patient and protocol of the physician.
12. 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 REMOVAL OF CATHETER PROCEDURE:

1. Disconnect the drainage bag connecting tube from catheter.
2. 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.
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 be made aware of the catheter removal process.



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



Do not use if package is damaged

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MADE IN TAIWAN

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Instruction For Use 4

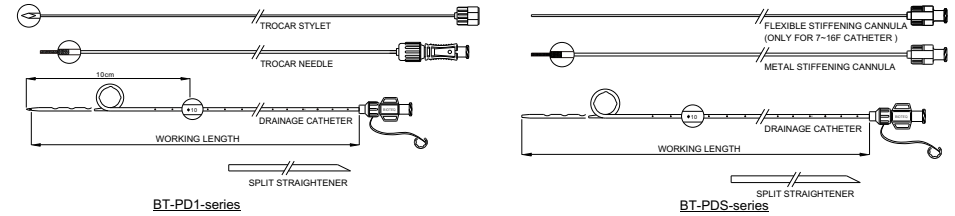
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INSTRUCTIONS FOR USE

ENGLISH

DEVICE DESCRIPTION

The BT-PD1/ BT-PDS/ BT-PD4 Percutaneous Drainage Catheter with hydrophilic coating is a percutaneous drainage catheter used for drainage of abscess and fluid collections. The catheter is made from a soft, biocompatible plastic, a material that is radiopaque for X-rays. The distal end of catheter contains a "J" or a pigtail and drainage holes.



INDICATIONS FOR USE

The catheter is designed for percutaneous drainage of abdominal abscesses, cholecystostomy, liver abscess (or cyst), nephrostomy, pancreatic, pleural effusion and pneumothorax. The intended patients include neonates, infants, children, adolescents and adults. 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 the BT-PD1/BT-PD0 (Direct Access) or BT-PDS/BT-PD2/BT-PD4 (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 (something that makes you understand there is a possible danger or problem, especially one in the future)

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

PRECAUTIONS (an action that is done to prevent something unpleasant or dangerous happening)

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- This 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 30 days.
- 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 product carefully and avoid forceful stretching etc.
- Use this product immediately after opening the package. After use, deposit it in a safe manner.

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CONTRAINDICATIONS

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

The kit should not be used 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 organs or intestines.

1. Select the patient for suitability of 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 .
 - ▶ Hold the thread stretched, if present, while inserting the stiffening cannula and trocar to avoid tangles.Remove the splittable straightener.
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, you can first of all unlock trocar stylet from the cannula hub and remove it. 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)



Fig. 1

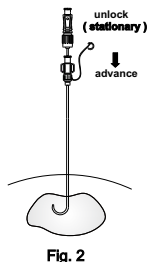


Fig. 2

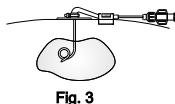


Fig. 3

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 designed for the circumstances of each patient and protocol of the physician.
12. 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. (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. In such case, you should replace drainage catheter.

RECOMMENDED PROCEDURE - USING SELDINGER (GUIDE WIRE) TECHNIQUE:

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

1. Select the patient for suitability of percutaneous drainage.
2. Localize the accumulated fluid under CT or ultrasound guidance.
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.
 - ▶ Hold the thread stretched, if present, while inserting the stiffening cannula to avoid tangles.Remove the splittable straightener.
4. Disinfect the entrance site and perform local anesthesia.
5. Puncture the puncture site area with the puncture needle 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 back over the guide wire, which remains in the cavity.
8. The puncture channel can be gradually extended 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. At this time, fluid frequently starts flowing out from the catheter. (Fig.5 ; Fig.6)

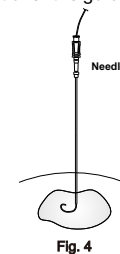


Fig. 4

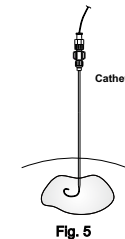


Fig. 5

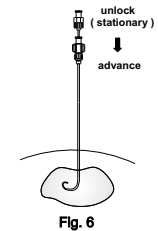


Fig. 6

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.

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Instruction For Use 2

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Instruction For Use 3

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-  Caution
-  Catalogue number
-  Batch code
-  Date of manufacture
-  Use-by date
-  Manufacturer
-  Do not re-use
-  Authorized representative in the European community
-  Sterilized using ethylene oxide
-  Consult instructions for use
-  Do not use if package is damaged
-  Keep away from sunlight
-  Keep dry
-  Temperature limit
-  CE mark
-  Fragile, handle with care
-  Do not re-sterilize

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Instruction For Use 5

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