PTC Drainage Tube

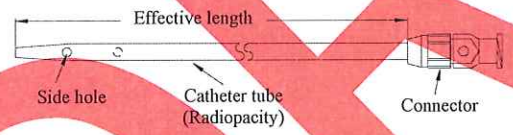
Do not reuse

[WARNINGS]
< Usage >
[1] During placement, always manage the patient's condition and the condition of the catheter, and keep the patient at rest.
[The catheter may be damaged. Catheter displacement may cause bile leakage and peritonitis.]
[2] Contrast medium should be injected slowly in small increments not to increase intrabiliary pressure.
[Cholangitis may occur.]

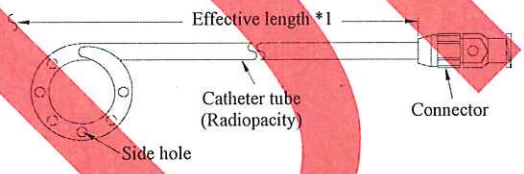
[CONTRAINDICATIONS, PROHIBITIONS]
[1] Do not reuse the product (single use for one case).
[The product is single use only and disposable, and its quality or performance after one use is not guaranteed. Further, reuse carries the possible risk of contamination (infection) to patients. Contamination of the product may lead to patient injury, illness or death.]
[2] Prohibition of reprocessing, re-sterilization.
[Reprocessing of the product may lead to defects. It may also cause patient injury, illness or death.]
< Target patients >
[1] Do not use the product in patients with blood coagulation disorder.
[It may lead to adverse events such as haemorrhagic shock.]
[2] Do not use the product in patients with panperitonitis.
[This is because an emergency surgery is indicated.]
[3] Do not use the product in patients with massive ascites.
[Fistula may not be formed and peritonitis, etc. may occur.]
[4] The product should not be used in patients with acute suppurative cholangitis without administrating antibiotics.
[Catheter infection may occur.]

[SHAPE, STRUCTURE AND PRINCIPLE]
The product is sterilized with ethylene oxide gas.

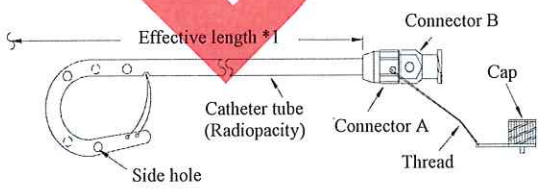
< Shape >
- Catheter (Straight Type)



- Catheter (Pigtail Type)



- Catheter (ρ Type with thread)



*1 The tip end of the effective length of the Pigtail Type and ρ Type with thread is the position when the loop is extended.

Type	Size	Outer diameter	Inner diameter	Effective length
Straight Type	6Fr	2.0mm	1.2mm	350mm
	7Fr	2.3mm	1.4mm	
	8Fr	2.7mm	1.6mm	
	9Fr	3.0mm	1.8mm	
	10Fr	3.3mm	2.0mm	
Pigtail Type	7Fr	2.3mm	1.4mm	
	8Fr	2.7mm	1.6mm	
	9Fr	3.0mm	1.8mm	
	10Fr	3.3mm	2.0mm	
ρ Type with thread	7.2Fr	2.3mm	1.4mm	

< Raw materials >
- Catheter (Straight Type): Polyurethane, polypropylene
- Catheter (Pigtail Type): Polyurethane, polypropylene
- Catheter (ρ Type with thread): Polyurethane, polypropylene, polyester

< Principle >
The catheter is percutaneously and transhepatically inserted into and placed in the biliary tract and gallbladder. Bile juice passes through the catheter lumen and is drained to the proximal end. Connect a drainage bag, etc. to the proximal end to collect bile juice.

[INTENDED USE]
It is placed in the bile duct or gallbladder to drain bile juice.

[EFFICACY OR EFFECT]
- Bile juice can be drained from the body.
- Connect a drainage bag, etc. to the connector at the proximal end of the catheter to collect bile juice.

[PERFORMANCE]
- Secure the sterility assurance level (SAL) 10^{-6}.
- Sterile residues: Shall conform to ISO10993-7.
- Shall not contain biological substance and conform to biological safety requirements.
- Shall be durable for 29 days continuous use.
- Shall maintain the stability and durability for 5 years.
- Tensile strength
  The catheter tube shall not break when both ends are pulled with the following force.
  O.D. < 2mm: 5N or more
  O.D. 2～4mm: 10N or more
  O.D. > 4mm: 20N or more
- Fitting
  The connector is fitted with a syringe compatible with a male connector conforming to ISO 80369-7.

[OPERATING AND USING METHOD]
The general operational procedure is described below.

< Usage in PTCD (in the case of Straight Type and Pigtail Type) >
[1] Disinfect the skin around the puncture site.
[2] Attach the fixing needle to the ultrasound probe, check the puncture site under ultrasound image, and then puncture the needle

under the skin. If necessary, make a small incision on the skin at the puncture site.

[3] Puncture the ultrasonic puncture needle into the target site (intrahepatic bile duct) through the fixing needle. If bleeding a lot, take appropriate hemostatic measures.

[4] After confirming that the needle was inserted into the target site, remove the inner needle of the ultrasonic puncture needle and check the outflow of bile juice. If the placement position is unclear, perform percutaneous transhepatic cholangiography (PTC).

[5] Insert the guide wire from the lumen of the ultrasonic puncture needle into the bile duct and place it there (refer to < **Medical devices to be used in combination** > for the compatible guide wire of the product).

[6] Remove the ultrasonic puncture needle and advance the dilator along the guide wire to dilate the puncture site.

[7] Remove the dilator and insert the catheter into the bile duct along the guide wire for placement.

[8] After confirming the placement position, remove the guide wire.

[9] Fix the catheter to the skin with the stabilizer, etc.

[10] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.

< Removal method (in the case of Straight Type and Pigtail Type) >

[1] If a drainage bag, etc. are connected to the connector at the proximal end of the catheter, disconnect them.

[2] Detach the catheter from the skin.

[3] Insert the guide wire into the bile duct along the catheter under fluoroscopy (select the guide wire of the same specification as the guide wire used during placement. If the catheter is to be replaced subsequently, select the guide wire corresponding to the product and the catheter that replaces it).

[4] Remove the catheter gently.

[5] Remove the guide wire (if the catheter is being replaced subsequently, leave the guide wire).

< Usage upon the catheter replacement (in the case of Straight Type and Pigtail Type) >

[1] Remove the placed catheter according to the procedures [1] to [4] in the above < **Removal method (for Straight Type and Pigtail Type)** >. If the placed catheter is not Straight or Pigtail Type, remove it in accordance with the procedures for each removal method.

[2] Disinfect the skin around the fistula.

[3] Insert the product into the bile duct along the guide wire and place it there.

[4] After confirming the placement position, remove the guide wire.

[5] Fix the catheter to the skin with the stabilizer, etc.

[6] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.

< Usage in PTCD (in the case of ρ Type with thread) >

Follow [1] to [6] in < **Usage in PTCD (in the case of Straight Type and Pigtail Type)** >.

[7] Remove the dilator, insert the catheter along the guide wire, and place the tip sufficiently in the bile duct.

[8] After confirming the placement position, pull back the guide wire to the middle of the catheter and loosen the connectors A and B at the proximal end of the catheter by at least one rotation (Figure 1).

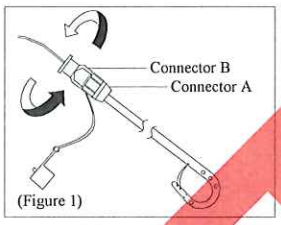
[9] While holding the connector by hand, pull the thread gradually to form a loop (Figure 2).

[10] After confirming the loop formation, completely tighten the connectors A and B to fix the thread (Figure 3).

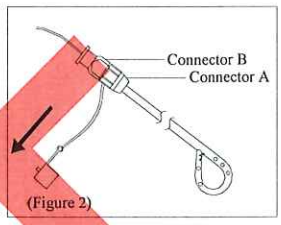
[11] Remove the guide wire and check the outflow of bile juice (Figure 4). To stop the flow of bile temporarily, attach the cap to connector B.

[12] Fix the catheter to the skin with the stabilizer, etc.

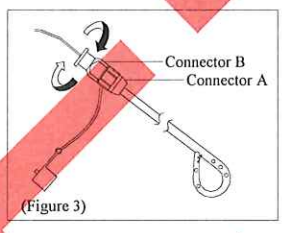
[13] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.



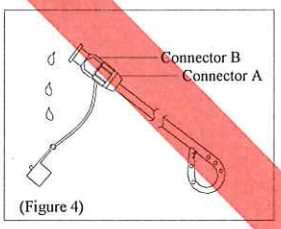
(Figure 1)



(Figure 2)



(Figure 3)



(Figure 4)

< Removal method (in the case of ρ Type with thread) >

[1] If a drainage bag, etc. are connected to the connector at the proximal end of the catheter, disconnect them.

[2] Detach the catheter from the skin.

[3] Insert the guide wire to the position immediately before the loop in the catheter under fluoroscopy (select the guide wire of the same specification as the guide wire used during placement. If the catheter is to be replaced subsequently, select the guide wire corresponding to the product and the catheter that replaces it).

[4] Loosen the connectors A and B at the proximal end of the catheter by at least one rotation.

[5] Remove the catheter gently while advancing the guide wire and extending the loop.

[6] Remove the guide wire (if the catheter is being replaced subsequently, leave the guide wire).

< Usage upon the catheter replacement (in the case of ρ Type with thread) >

[1] Remove the placed catheter according to the procedures [1] to [5] in the above < **Removal method (in the case of ρ Type with thread)** >. If the placed catheter is not ρ Type with thread, remove it in accordance with the procedures for each removal method.

[2] Disinfect the skin around the fistula.

[3] Insert the product along the guide wire and place the tip sufficiently in the bile duct.

[4] After confirming the placement position, pull back the guide wire to the middle of the catheter and loosen the connectors A and B at the proximal end of the catheter by at least one rotation (Figure 1).

[5] While holding the connector by hand, pull the thread gradually to form a loop (Figure 2).

[6] After confirming the loop formation, completely tighten the connectors A and B to fix the thread (Figure 3).

[7] Remove the guide wire and check the outflow of bile juice (Figure 4). To stop the flow of bile juice temporarily, attach the cap to connector B.

[8] Fix the catheter to the skin with the stabilizer, etc.

[9] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.

< Medical devices to be used in combination >

When using the product, use it in combination with the following devices.

Name	Specification
Guide wire	• When using Straight Type 6Fr, 7Fr, Pigtail Type 7Fr, or ρ Type with thread 7.2Fr O.D.: 0.89mm (0.035") or less • When using Straight Type 8Fr, 9Fr, 10Fr, or Pigtail Type 8Fr, 9Fr, 10Fr O.D.: 0.97mm (0.038") or less
Fixing needle	O.D.: 1.83mm (15G), I.D.: 1.63mm Effective length: 75mm
Ultrasonic needle	O.D.: 1.26mm (18G), I.D.: 1.07mm Effective length: 200mm, pink
Dilator	O.D.: 2.3mm (7Fr), Effective length: 203mm
Stabilizer	Stabilizer compatible with catheter outer diameter
Ultrasound probe	Attach the needle guide for the ultrasound probe compatible with the outer diameter of the fixing needle.
Syringe	Tip shape: Male connector conforming to ISO 80369-7
Drainage bag	Tip shape: Male connector conforming to ISO 80369-7

＜Precautions in use related with the method of use＞

[1] When using the product, perform the procedure under X-ray fluoroscopy or combination of X-ray fluoroscopy and ultrasound image.
[The bile duct and gallbladder may be perforated and tissue damage may occur.]

[2] If Pigtail Type is used, after placement, confirm a formation of the loop under X-ray fluoroscopy during confirmation of the placement position. If the loop is not formed, move it to a position where it can be formed.

[3] When using the ρ Type with thread, please note the following.
1) Before using, check if the loop can be formed once.
2) When pulling the thread to form the loop, be sure to loosen the connectors A and B by at least one rotation. If loop formation is unsuccessful or the thread is cut, gradually advance the guide wire to extend the loop and remove the catheter, then replace the catheter.
3) If the loop does not extend and the guide wire cannot be inserted when removing, remove the connector B, cut the thread, pull out the thread, insert the guide wire, and remove the catheter while gradually extending the loop.

[4] When connecting a syringe, drainage bag, etc. to the connector at the proximal end of the catheter, select the one that fits surely. During use, check the connection for leakage or loosening as appropriate, and use it in a state where it is securely connected.

[5] When fixing the catheter to the skin, use the stabilizer, etc. and do not directly fix the catheter with a thread.
[Obstruction or rupture may occur.]

[6] If the catheter is fixed with an adhesive tape, etc., remove them slowly and carefully when removing the fixation.
[If adhesive tapes, etc. with strong adhesion are used for a small diameter catheter, an excessive load may be applied to the catheter when it is removed, and the catheter may be cut.]

[7] Do not use a guide wire with a hydrophilic coating when using a puncture needle for the procedure.
[There is a risk of peeling of the hydrophilic coating layer, peeling of the covering tube, breakage and cutting of the covering tube.]

[PRECAUTIONS IN USE]

< Important basic precautions >

[1] When using the product, confirm that the pigtail part and loop part are not formed excessively in the bile duct. Also consider using types with other tip shapes depending on the risk.
[It is because some knot may be formed at the pigtail part or loop part during placement or removal.]
(When using Pigtail Type and ρ Type with thread.)

[2] If any resistance is felt during removal, confirm the reason for the resistance by using X-ray fluoroscopy etc. and take appropriate measures.
[In case removing forcibly, the bile duct etc. may be damaged.]

[3] During placement of the catheter, the catheter should be securely fixed with a stabilizer, etc., and the status of placement of the catheter should be properly managed. If necessary, confirm the position of the catheter (in the case of Pigtail type and ρ Type with thread, including the loop formation status) by using X-ray fluoroscopy, etc.
[A load may be applied to the catheter due to patient's body movement, movement due to breathing, etc., and the catheter may be damaged.]

[4] During catheter placement, lumen irrigation should be performed as necessary.
[Reflux of bile juice or obstruction of the lumen may occur due to clogging of bile juice in the catheter lumen.]

[5] Do not grip the product strongly with forceps, etc.
[Tube cut, lumen occlusion and balloon breakage may occur.]

[6] Do not place the side holes of the catheter in the liver parenchymal tissue.
[Intermittent bleeding from hepatic veins may occur.]

[7] When the catheter is fixed on the body surface, it should be fixed with appropriate force to avoid narrowing of the lumen of the product.
[Narrowing of catheter lumen may result in drainage failure.]

[8] Do not press the catheter tip with forcible power against the bile duct.
[Perforation, bleeding, mucosal injury, etc. may occur.]

[9] Before using the product, check whether there is any abnormality in each part.

[10] Do not insert forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Tissue may be damaged.]

[11] Do not insert or remove the product forcibly. Operate the product with great care.
[The product may be damaged.]

[12] If any abnormality is observed, discontinue the use of the product immediately and take appropriate measures.

[13] Do not pull or bend the product forcibly during use. Handle it carefully.

[14] Do not modify the product.
[If a side hole, etc. is added, the tube may be cut.]

[15] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.

[16] Use immediately after opening and dispose in a safe manner for each country after use.

[17] During placement, keep the product under full control to prevent its handling by an untrained person.

[18]  printed on the label means that the product does not contain phthalic acid in the contact part of the body fluid/drug solution.

[19]  printed on the label means that the product should not be used if the package is damaged or opened.

[20] Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

< Defects and adverse events >

Other defects

[1] Obstruction of the tube.
[The lumen of the catheter may be obstructed by bile juice.]

[2] Cut of the tube.
[Cut due to the following causes.]
- Lack of strength due to addition of a side hole, etc.
- Damage caused by tweezers, forceps, scissors, scalpel, or other instruments.
- Damage due to a calculus in the patient.
- Sudden load on the product due to self (accidental) removal, etc.
- Excessive load on the product when an adhesive tape, etc. are removed rapidly.
- Other complex causes due to factors such as the above events.

Serious adverse events
Catheter dislodgement during placement may cause bile juice leakage and peritonitis.

Other adverse events
[1] During placement, contact of the catheter tip may cause perforation or damage.
[2] Remains in the body due to the cutting tube and stylet.
[3] Infection, bacteraemia, sepsis, inflammation, necrosis, oedema, pyrexia, pain, bile juice leakage, shock, hepatic abscess, pneumothorax, cholangitis, bile cyst, pleurisy

< Use during pregnancy, delivery, or lactation and pediatric use >
Be careful when using X-ray to the patient who is pregnant or has some possibility of pregnancy.
[The influence of X-ray to the fetus is concerned.]

[STORAGE METHOD AND DURATION OF USE]
< Storage method >
Store the product cleanly. Avoid wetting, direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal lamp, etc.

< Duration of use >
The product has been developed for "use within 29 days".
[Based on self-certification (our company data).]

< Expiration date >
When the proper storage method has been maintained, refer to the expiration date on the individual package.
[Based on self-certification (our company data).]

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