Internal External Drainage Catheter for PTCD

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] The product should not be used in patients with acute suppurative cholangitis without administrating antibiotics.
[Catheter infection may occur.]

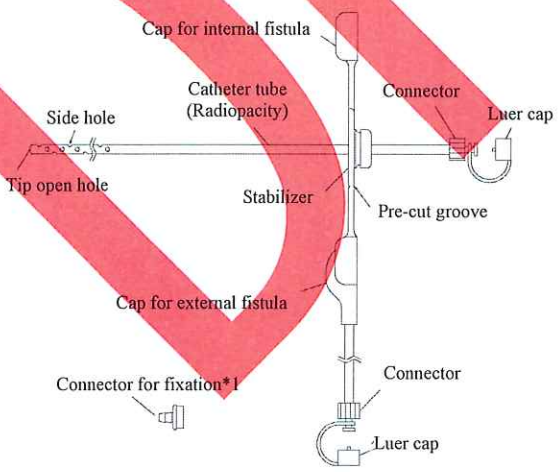
[SHAPE, STRUCTURE AND PRINCIPLE]

This product has been sterilized with ethylene oxide gas.

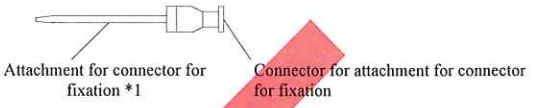
< Shape >

- Stylet

- Catheter



- Attachment for connector for fixation



*1 The connector for fixation is attached to the attachment for connector for fixation in advance when it is opened.

Size	Outer diameter	Inner diameter	Total length	Tip hole Side hole	Depth mark
8 Fr 10 holes	2.7mm	1.5mm	400mm	Open tip 10 side holes (10 holes at 10 to 100mm from the tip)	10mm intervals at 100 to 300mm from the tip
10 Fr 10 holes	3.3mm	1.8mm			
12 Fr 10 holes	4.0mm	2.2mm			
14 Fr 10 holes	4.7mm	2.5mm			
16 Fr 10 holes	5.3mm	3.0mm			
18 Fr 10 holes	6.0mm	3.4mm			
8 Fr 15 holes	2.7mm	1.5mm		Open tip, 15 side holes (15 holes at 10 to 150mm from the tip)	10mm intervals at 150 to 300mm from the tip
10 Fr 15 holes	3.3mm	1.8mm			
12 Fr 15 holes	4.0mm	2.2mm			
14 Fr 15 holes	4.7mm	2.5mm			
16 Fr 15 holes	5.3mm	3.0mm			
18 Fr 15 holes	6.0mm	3.4mm			
8 Fr 20 holes	2.7mm	1.5mm		Open tip, 20 side holes (20 holes at 20 to 200mm from the tip)	10 mm intervals at 200 to 300mm from the tip
10 Fr 20 holes	3.3mm	1.8mm			
12 Fr 20 holes	4.0mm	2.2mm			
14 Fr 20 holes	4.7mm	2.5mm			
16 Fr 20 holes	5.3mm	3.0mm			
18 Fr 20 holes	6.0mm	3.4mm			

< Raw materials >

- Catheter: Silicone rubber, polypropylene, polyacetal
- Stylet: Polypropylene, polycarbonate, polyethylene
  (*Polyethylene: Used for the stylet for 8 Fr)
- Attachment for connector for fixation: Polypropylene, polyethylene, polycarbonate

< Principle >

After PTCD, the catheter is percutaneously and transhepatically inserted into the biliary tract and fixed. The catheter can be placed for internal or external fistula. Bile juice is drained to the distal end through the catheter lumen or the proximal end through the catheter lumen. When it is drained to the proximal end, a drainage bag, etc. can be connected 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. 2～4 mm: 10N or more
  O.D. >4 mm: 20N or more
- Fitting
  The connector is fitted with a syringe compatible with a male connector conforming to ISO 80369-7.

[OPERATING OR USING METHOD]

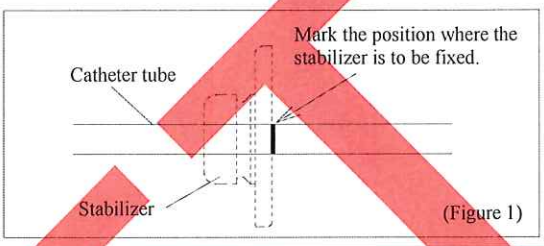
The general operational procedure is described below.

< Usage for internal/external fistula, when the cap for external fistula is not used >

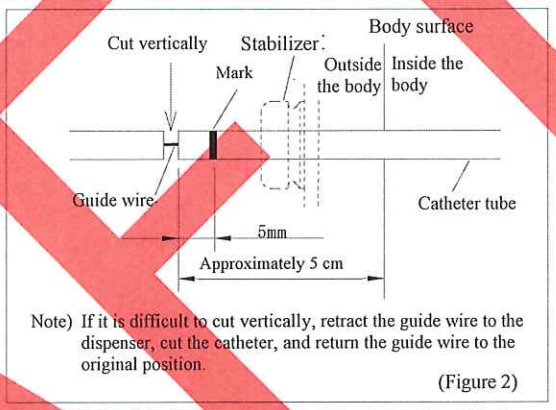
[1] Perform PTCD (percutaneous transhepatic cholangial drainage). After fistula formation, insert a guide wire along the placed catheter under X-ray fluoroscopy, and pass the guide wire through the obstruction site. Advance and place the guide wire as far as possible. (Select the guide wire corresponding to the placed catheter and the product. Regarding the guide wires for the product, refer to < Medical devices to be used in combination >.)
[2] Remove the catheter gently.
[3] Disinfect the skin around the puncture site.
[4] Dilate with a dilator, etc. as needed to ensure passage through the stenotic site.
[5] Insert the product along the guide wire after flushing the lumen of the catheter of the product with physiological saline, attaching the stylet, and locking the connector.
[6] Once the tip of the product has passed through the stenotic site, unlock the connector and insert only the catheter to the target site while holding the stylet in place.
[7] Remove the stylet.
[8] Remove the guide wire.
[9] Confirm that the side holes of the catheter are positioned in front and behind the stenotic site by using X-ray fluoroscopy.
[10] Fix the catheter to the skin with the stabilizer, etc. separately prepared.
[11] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.
[12] When removing the product, detach a drainage bag, etc. After that, remove the fixation to the skin, and gently pull out of the fistula.

< Usage for internal/external fistula, when the cap for external fistula is used >

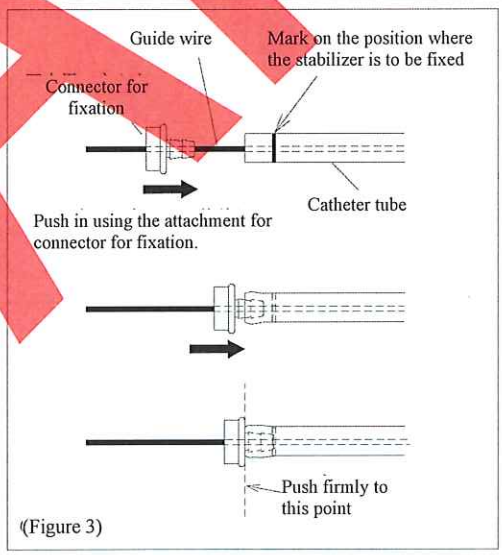
[1] Insert the catheter according to the procedures [1] to [7] in the above **< Usage for internal/external fistula, when the cap for external fistula is not used >**.
[2] Mark the position where the stabilizer of the catheter is to be fixed (Figure 1). Pull out the catheter so that it can be held with fingers along the guide wire (up to 50mm) and slide the stabilizer from the mark position to the distal end of the catheter.
[3] Cut the catheter vertically at a position 5mm from the mark on the connector side of the catheter (Figure 2), and remove the proximal end of the cut catheter from the guide wire.
[4] Insert the attachment for the connector for fixation with the connector for fixation along the guide wire.
[5] Attach the connector for fixation to the catheter. When attaching the connector, hold the connector part of the attachment for connector for fixation and screw it into the catheter. At this time, hold, with the hand on the side of the catheter, further toward the distal end of the catheter than the part where the connector for fixation is to be attached, and firmly press it until the uneven part of the connection part of the connector for fixation is firmly pushed into the catheter. After attaching, make sure that the connector for fixation is firmly attached to the catheter (Figure 3).



(Figure 1)



Note) If it is difficult to cut vertically, retract the guide wire to the dispenser, cut the catheter, and return the guide wire to the original position.
(Figure 2)



(Figure 3)

[6] Attach the stabilizer to the connector for fixation, and position the stabilizer on the body surface.
[7] Remove the attachment for connector for fixation from the guide wire. Remove the guide wire.
[8] Check the position of the catheter tip by ultrasound image or X-ray fluoroscopy. Attach the cap for external fistula and fix it to the epidermis using the fixture (adhesive tape, gauze, etc.).
[9] Connect a syringe or a drainage bag, etc. to the connector of the cap for external fistula to drain bile juice.
[10] When removing, remove a drainage bag, etc. After that, remove the fixation to the skin, and gently pull it out of the fistula.

< When re-attaching the connector for fixation >

[1] Re-attach the connector for fixation to the attachment for connector for fixation.

[2] Retract the catheter so that the connector for fixation can be attached. At this time, retract it to some extent that the side holes of the catheter are properly positioned against the stenotic site. Do not pull out 50mm or more.

[3] After retracting the catheter, cut it again vertically at a position 5mm on the connector side of the catheter, and remove the proximal end of the cut catheter from the guide wire.

[4] Insert the attachment for the connector for fixation with the connector for fixation along the guide wire.

[5] Attach the connector for fixation to the catheter. When attaching the connector, hold the connector part of the attachment for connector for fixation and screw it into the catheter. At this time, hold, with the hand on the side of the catheter, further toward the distal end of the catheter than the part where the connector for fixation is to be attached, and firmly press it until the uneven part of the connection part of the connector for fixation is firmly pushed into the catheter. After attaching, make sure that the connector for fixation is firmly attached to the catheter (Figure 3).

[6] Complete the procedure according to [6] to [10] in the above **< Usage for internal/external fistula, when the cap for external fistula is used >**.

< Usage for internal fistula >

[1] Insert and place a catheter according to the procedures [1] to [8] in the above **< Usage for internal/external fistula, when the cap for external fistula is used >**.

[2] Check the position of the catheter tip by ultrasound image or X-ray fluoroscopy. Attach the cap for internal fistula to form an internal fistula. Fix it to the epidermis using the fixture (adhesive tape, gauze, etc.). When the cap for external fistula is not used, cut it along the pre-cut groove. For internal fistula, if external fistula is formed or imaging is performed periodically for the purpose of observation, etc., the cap for external fistula should be attached.

[3] When removing the product, remove the fixation to the skin and gently pull it out of the fistula.

< Medical devices to be used in combination >

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

Size of the product	Outer diameter of corresponding guide wire
8 Fr 10 holes	0.64mm (0.025") or less
10 Fr 10 holes	0.89mm (0.035") or less
12 Fr 10 holes	
14 Fr 10 holes	
16 Fr 10 holes	0.97mm (0.038") or less
18 Fr 10 holes	
8 Fr 15 holes	0.64mm (0.025") or less
10 Fr 15 holes	0.89mm (0.035") or less
12 Fr 15 holes	
14 Fr 15 holes	
16 Fr 15 holes	0.97mm (0.038") or less
18 Fr 15 holes	
8 Fr 20 holes	0.64mm (0.025") or less
10 Fr 20 holes	0.89mm (0.035") or less
12 Fr 20 holes	
14 Fr 20 holes	
16 Fr 20 holes	0.97mm (0.038") or less
18 Fr 20 holes	

Name	Specification
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] When cutting the catheter to attach the connector for fixation, cut it vertically to the catheter. Do not cut the guide wire.
[If the cut surface of the catheter is not vertical, the connector for fixation may come off and the catheter may be cut, split, etc.]

[3] When temporarily retracting the guide wire to the dispenser to cut the catheter vertically, hold the catheter on the body surface lightly with forceps (forceps covered by rubber, etc.), and retract the guide wire so that the catheter is not moved. When returning the guide wire after cutting the catheter, re-insert the guide wire slowly and carefully so as not to cause perforation, haemorrhage, mucosal injury, etc.

[4] When using, hold the connector for fixation with fingers, push it firmly into the attachment for connector for fixation, and keep holding the connector for fixation pushed into the attachment for connector for fixation until it is attached to the catheter.
[The product may come off, be lost, etc.]

[5] When attaching the connector for fixation to the catheter, use the attachment for connector for fixation and firmly screw it in. After attaching, make sure that the connector for fixation is firmly attached to the catheter.
[The product may come of, be damaged, etc.]
[If the connector for fixation is not firmly attached to the catheter, the connector for fixation may come off from the catheter.]

[6] Attach the cap for internal fistula, the cap for external fistula, and the luer cap securely.
[The cap for inner fistula, the cap for outer fistula, and the luer cap may come off, which may cause bile juice leakage.]

[7] 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.]

[8] 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.

[9] 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.]

[PRECAUTIONS IN USE]

< Important basic precautions >

[1] Thoroughly form external fistula until hepatic edema cures, then, start to form internal fistula.
[The fistula may shift and come off easily in the process of healing of hepatic edema.]

[2] Be careful as cracking may occur when the stylet comes in contract with surfactant, alcohol, etc.

[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 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.]
[If fixation with fixture (adhesive tape, gauze, etc.) is not performed securely, the cap may come off, causing bile juice leakage.]

[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] After the tip of the product has passed through the stenotic region, do not insert the stylet deeper.
[The stylet may become unremovable.]
[6] Do not pull the cap for internal fistula or the cap for external fistula.
[The stabilizer may be damaged.]
[7] In principle, do not re-attach the connector for fixation. If it needs to be re-attached, refer to the section of **[USAGE, ETC.] < When re-attaching the connector for fixation >**.
[The attachment strength of the connector for fixation and the catheter may be reduced.]
[8] When clamping this product using forceps, use forceps covered by rubber, etc.
[The catheter may be cut or the lumen may be occluded.]
[9] Do not place the side holes of the catheter in the liver parenchymal tissue.
[Intermittent bleeding from hepatic veins may occur.]
[10] 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.]
[11] Do not press the catheter tip with forcible power against the bile duct.
[Perforation, bleeding, mucosal injury, etc. may occur.]
[12] Before using the product, check whether there is any abnormality in each part.
[13] Do not insert it forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Tissues may be damaged.]
[14] Do not insert or remove the product forcibly. Operate the product with great care.
[The product may be damaged.]
[15] If any abnormality is observed, discontinue the use of the product immediately and take appropriate measures.
[16] Do not pull or bend the product forcibly during use. Handle it carefully.
[17] Do not modify the product.
[If a side hole, etc. is added, the tube may be cut.]
[18] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.
[19] Use immediately after opening and dispose in a safe manner for each country after use.
[20] During placement, keep the product under full control to prevent its handling by an untrained person.
[21] printed on the label means that the product should not be used if the package is damaged or opened.
[22] printed on the label means that the product does not contain phthalic acid in the contact part of the body fluid/drug solution.
[23] 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 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 abruptly.
- Other complex causes due to factors such as the above events.

[3] Breaking, bending, damage, cutting of the stylet.
[Breaking, bending, damage, or cutting may occur due to the following causes.]
- Forcible insertion, removal, excessive torque operation, etc.
- Damage caused by tweezers, forceps, scissors, scalpel, or other instruments.
- Other complex causes due to factors such as the above events.

[4] Impossibility of removal of the stylet.
[Impossibility of removal may occur due to the following causes.]
- Breaking, bending, damage, cutting of the stylet.
- Decrease in lubricity.
- Use for kinked tubes.
- Other complex causes due to factors such as the above events

[5] Catheter dropout
[Dropout due to the following.]
- Insufficient attachment of the connector for fixation to the catheter.
- Excessive load on the connection between the catheter and the connector for fixation caused by body movement.
- 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 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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