PTCD Kit

Do not reuse

[WARNINGS]

< Usage >

[1] During placement, always manage the patient's condition and the condition of the catheter and keep patient at rest.
[The catheter may be damaged. Catheter displacement may cause bile leakage and peritonitis.]

[2] When using the fixing needle and the ultrasonic puncture needle, be careful not to puncture the portal vein.
[It may lead to intrabiliary and intraabdominal bleeding.]

[3] 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.]

< Usage >

Do not pull out the guide wire from the ultrasonic puncture needle.
[The guide wire may be caught by the tip of the ultrasonic puncture needle and become impossible to remove. The guide wire may also break and remain in the bile duct.]

[SHAPE, STRUCTURE AND PRINCIPLE]

- The product has been sterilized with ethylene oxide gas.
- Metals are used in this product (fixing needle, ultrasonic puncture needle, guide wire, dilating catheter with needle).

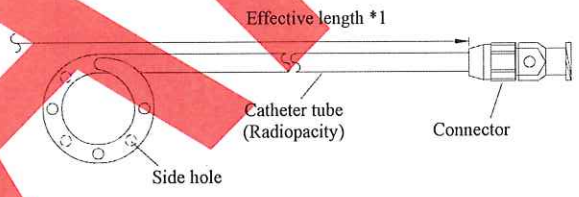
< Components >

Type	Component	Quantity	Specification
ONE STEP TYPE	Catheter	1	Size: 7 Fr Outer diameter: 2.3 mm, Inner diameter: 1.4 mm Effective length: 350 mm
	Fixing needle	1	Outer diameter: 1.83 mm (15 G), Inner diameter: 1.63 mm Effective length: 75 mm
	Ultrasonic puncture needle	1	Outer diameter: 1.26 mm (18 G), Inner diameter: 1.07 mm Effective length: 200 mm, pink
	Guide wire	1	Outer diameter: 0.89 mm (0.035"), total length: 800 mm 3 mm J fixed, Teflon coating
	Dilator	1	Outer diameter: 2.3 mm (7 Fr), Effective length: 203 mm
	Stabilizer	1	Type C, No. 1

Type	Component	Quantity	Specification
TWO STEP TYPE	Catheter	1	Size: 7 Fr Outer diameter: 2.3 mm, Inner diameter: 1.4 mm Effective length: 350 mm
	Fixing needle	1	Outer diameter: 1.26 mm (18 G), Inner diameter: 1.07 mm Effective length: 75 mm
	Ultrasonic puncture needle	1	Outer diameter: 0.81 mm (21 G), Inner diameter: 0.54 mm Effective length: 200 mm, green
	Guide wire	2	Outer diameter: 0.46 mm (0.018"), total length: 800 mm 3 mm J fixed
			Outer diameter: 0.89 mm (0.035"), total length: 800 mm 3 mm J fixed, Teflon coating
	Dilating catheter with needle	1	Inner needle Outer diameter: 1.09 mm (19 G), total length: 300 mm
			Dilating catheter Outer diameter: 1.7 mm (5 Fr), total length: 280 mm
	Dilator	1	Outer diameter: 2.3 mm (7 Fr), Effective length: 203 mm
	Stabilizer	1	Type C, No. 1

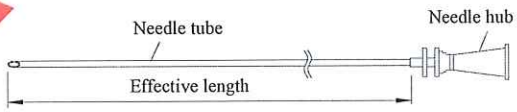
< Shape >

- Catheter

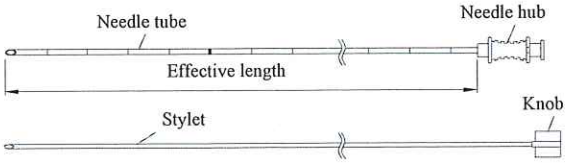


*1 The tip end of the effective length is the position when the loop is extended.

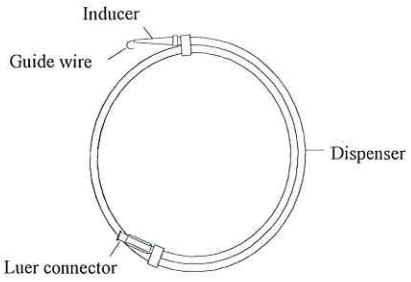
- Fixing needle



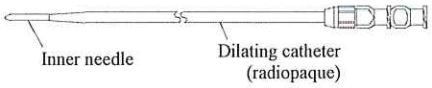
- Ultrasonic puncture needle



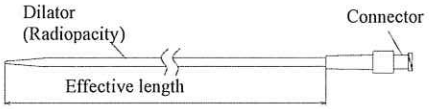
- Guide wire



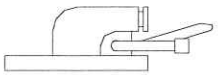
- Dilating catheter with needle



- Dilator



- Stabilizer



< Raw materials >

- Catheter: Polyurethane, polypropylene
- Fixing needle: Stainless steel, polycarbonate
- Ultrasonic puncture needle: Stainless steel, polycarbonate, polypropylene
- Guide wire (0.46mm [0.018"]): Stainless steel
- Guide wire (0.89mm [0.035"]): Stainless steel, polytetrafluoroethylene
- Inducer: Polypropylene
- Luer connector: Polypropylene
- Dilating catheter with needle (inner needle): Stainless steel, brass-nickel-chromium-plated
- Dilating catheter with needle (dilating catheter): Polypropylene, polyethylene
- Dilator: Polyethylene
- Stabilizer: Silicone rubber, polyamide

< 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 a force of 10N.

  The guide wire shall not break when both ends are pulled with a force of 2.45N.

  When a load of 69N is applied to both ends of the needle, the needle tube shall not come off from the needle hub.
- 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.

The usage differs by the type of the product. Refer to the table below.

Catheter type	Usage
ONE STEP TYPE	a
TWO STEP TYPE	b

< Usage a >

[1] Take the product out of the package and check that all components are provided as specified in the < Components >.
[2] Disinfect the skin around the puncture site.
[3] 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 insertion site.
[4] Puncture the ultrasonic puncture needle into the target site (intrahepatic bile duct) through the fixing needle. If bleeding a lot, take appropriate hemostatic measures.
[5] 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).
[6] Insert the guide wire from the lumen of the ultrasonic puncture needle into the bile duct and place it there.
[7] Remove the ultrasonic puncture needle and advance the dilator along the guide wire to dilate the puncture site.
[8] Remove the dilator and insert the catheter into the bile duct along the guide wire for placement.
[9] After confirming the placement position, remove the guide wire.
[10] Fix the catheter to the skin with the stabilizer, etc.
[11] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.

< Usage b >

[1] Take the product out of the package and check that all components are provided as specified in the < Components >.
[2] Disinfect the skin around the puncture site.
[3] Attach the fixing needle to the ultrasound probe, check the puncture site under ultrasound imaging, and then puncture the needle under the skin. If necessary, make a small incision on the skin at the insertion site.
[4] Puncture the ultrasonic puncture needle into the target site (intrahepatic bile duct) through the fixing needle. If bleeding a lot, take appropriate hemostatic measures.
[5] 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).

[6] Insert the 0.46mm (0.018") guide wire and place it in the bile duct from the lumen of the ultrasonic puncture needle.
[7] Remove the ultrasonic puncture needle, and insert the dilating catheter with needle along the 0.46mm (0.018") guide wire.
[8] When the tip of the dilating catheter with needle enters the bile duct, remove the inner needle, and then insert the dilating catheter to the placement position.
[9] While fixing the dilating catheter with fingers to prevent it from coming out, remove the 0.46mm (0.018") guide wire and replace it with the 0.89mm (0.035") guide wire.
[10] Remove the dilating catheter and advance the dilator along the 0.89mm (0.035") guide wire to dilate the insertion site.
[11] Remove the dilator and insert the catheter into the bile duct along the 0.89mm (0.035") guide wire for placement.
[12] After confirming the placement position, remove the 0.89mm (0.035") guide wire.
[13] Fix the catheter to the skin with the stabilizer, etc.
[14] Connect a syringe or a drainage bag, etc. to the connector at the proximal end of the catheter to drain bile juice.

< Removal method >
[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).

< Medical devices to be used in combination >
When using the product, use it in combination with the following devices.

Name	Specification
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] When inserting the ultrasonic puncture needle into the intrahepatic bile duct, be careful not to penetrate the bile duct.
[The bile duct and gallbladder may be perforated and tissue may be damaged.]
[3] Insert the dilator carefully. If the dilator cannot be inserted smoothly, do not push it more than necessary.
[The tip of the dilator may be curled if the insertion site is bent, or if the dilator comes in contact with a hard part. If the dilator is pushed forcibly in this state, the product or the tissue may be damaged.]
[4] Before inserting the guide wire into the lumen of the ultrasonic puncture needle, turn the blade of the ultrasonic puncture needle toward the direction of guide wire insertion.
[5] If the guide wire cannot be inserted smoothly in the hub of the ultrasonic puncture needle, do not manipulate it forcibly. Advance the guide wire by pulling and pushing it little by little or rotating it slowly. (It is desirable to use the inducer at the time of insertion, by pushing it deep into the hub and then inserting the guide wire.)
[Forcible operation may damage the guide wire or the tissue.]
[6] If the guide wire is caught during the removal of the ultrasonic puncture needle, do not manipulate forcibly, and remove the ultrasonic puncture needle by pulling and pushing it little by little.
[If the guide wire is caught by the tip of the ultrasonic puncture needle, it may be damaged.]
[7] Do not insert the guide wire from the hard proximal end.
[8] After catheter 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.
[9] 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.
[10] 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.]
[11] 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] When using the product, confirm that the pigtail part is not formed excessively in the bile duct.
[It is because some knot may be formed at the pigtail part during placement or removal.]
[2] If any resistance is felt during removal, confirm the reason for the resistance by using X-ray fluoroscopy etc. and take appropriate measures.
[If it is removed forcibly, the bile duct, etc. may be damaged.]
[3] Be careful as cracking may occur when the fixing needle (needle hub) or the ultrasonic puncture needle (needle hub) comes in contact with surfactant, alcohol, etc.
[4] 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 (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.]
[5] 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.]
[6] Do not grip the product strongly with forceps, etc.
[Tube cut, lumen occlusion and balloon breakage may occur.]
[7] Confirm that the needle hubs of outer and inner needles of the ultrasonic puncture needle are set correctly before use.
[Puncture performance may be decreased.]
[8] Do not retract the guide wire with the guide wire sticking out from the edge of the ultrasonic puncture needle.
[The guide wire may be damaged or broken.]
[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] Do not perform MRI (Magnetic Resonance Imaging) while using the fixing needle, the ultrasonic puncture needle, the guide wire, or the inner needle of dilating catheter.
[In MRI, the metal parts of these may be heated by high-frequency electromagnetic fields, leading to an injury in the patient.]

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

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

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

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

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

[18] Do not modify the product.
[If side holes, etc. are added, the tube may be cut.]

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

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

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

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

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

[24] 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, or cutting of the guide wire.
[Breaking, bending, damage, or cutting may occur because of the following causes.]
- Forcible insertion, removal, excessive torque operation, etc.
- Use for kinked catheter.
- Friction with ultrasonic puncture needle, etc.
- Other complex causes due to factors such as the above events.

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

[5] Curling, breaking, bending, damage, or cutting of the dilator.
[Curling, breaking, bending, damage, or cutting may occur because of the following causes.]
- Forcible insertion, removal, excessive torque operation.
- Insertion into a curved or hard part.
- Other complex causes due to factors such as the above events.

[6] Breaking or bending of the ultrasonic puncture needle.

Serious adverse events

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

Other adverse events

[1] Contact of the catheter tip during placement may cause perforation or damage.

[2] Bleeding, perforation, etc. caused by the fixing needle and the ultrasonic puncture needle.

[3] The use of guide wire and dilator may cause the following adverse events.
- Damage (perforation, etc.)
- Bleeding

[4] Remains in the body due to the cutting tube and stylet.

[5] 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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