[23] When (DEHP) is found on the label, it means the product doesn't contain DEHP in the contact part with body fluid and drug solution.

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

< Defects >

[1] Burst of the cuff

(Burst due to the following reasons)

- Damage due to improper handling when inserting the product (damage by tweezers, forceps, scissors, knives, or other devices)
- Excessive infusion volume (overexpansion)
- Infusion of incorrect substance for balloon inflation (Substances liable to cause coagulation of components such as physiological saline and contrast medium)
- Abrupt load due to self-(accidental) removal, etc.
- Other multiple causes due to the above-mentioned events

[2] Blockage of catheter

(Adhesion of intestinal contents, contrast medium, etc. to the catheter lumen may lead to blockage.)

[3] Inability of removal of catheter

(Coagulation of components due to using saline or contrast medium for balloon expansion and excessive bending of the catheter tube may cause blocking and unremovable from the balloon lumen.)

[4] Disconnection of tube

(Disconnection due to the following reasons)

- Damage with tweezers, forceps, scissors, scalpels, or other instruments.
- Abrupt load on the product due to self-(accidental) removal.
- Other multiple causes due to the above-mentioned events.

[5] Bending, bending, damage, cutting of the guide wire.

(Breaking, bending, damage, or cutting due to the following reasons.)

- Impossible insertion, removal, excessive torque operation, etc.
- Use for kinked tubes.
- Other multiple causes due to the above-mentioned events.

[6] Inability of removal of guide wires

(Inability of removal due to the following)

- Bending, bending, damage, cutting of the guide wire.
- Decrease in lubricity.
- Use for kinked tubes.
- Other multiple causes due to the above-mentioned events

< Adverse events >

[1] Adverse events which may be associated with the use of the product include:

- During insertion :
  Intraperitoneal infection caused by bleeding, intestinal perforation, perforation.
- During depressurization :
  Intestinal necrosis, ulcer due to intestinal compression or intestinal perforation.

[2] The use of guide wires may cause the following adverse events.

- Damage (perforation, etc.)
- Bleeding

[3] Remains in the body due to the cutting tube.

[Storage Conditions and Expiration Date, etc.]

< Storage Conditions >

The product should be stored in a clean and dry place away from direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal light.

< Duration of Use >

This product is designed to be "used for 29 days or less." Avoid using the product for more than 30 days.

< Expiration date >

- See the expiration date indicated on each package for the products stored in an appropriate storage conditions.
- Store the product with sufficient care and do not use after the expiration date.

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DC61894 (MDR 1st Edition) Prepared on January 7, 2021

CLINY

Transanal Ileus Decompression Tube Set

Transanal Ileus Decompression Tube Set
Transanal Decompression Tube

Do Not Reuse (For Single Patient Use Only)

[Warning]

- When using this product, make sure to perform the procedure while able to directly visualize the product via the endoscope, as well as under fluoroscopic guidance.
- As the following events may occur during deployment of silicone balloons, always control the extent of balloon expansion. (Balloon deflation due to lots of spontaneous leakage compared with the latex balloon.)

[Contraindications / Prohibitions]

- Do not reuse this product (for single use only).
  (This product is disposable for single use, and of which the quality and performance are not guaranteed after use.
  In addition, reuse of the product may carry the risk of contamination (infection) on patients. Contamination of the product may result in injury, disease, or death of patients.)
- Do not reprocess or resterilize this product.
  (Reprocessing of this product may cause the product to malfunction. In addition, it may result in injury, disease, or death of patients.)
- Do not use for cases which cannot tolerate large intestine endoscopy, multiple stenosis cases, cases with peritonitis.
- Do not use other than sterilized distilled water for balloon expansion.
  (When physiological saline solution, contrast medium, etc. are used, there is a possibility that sodium chloride will appear after drying and it cannot be drained.)

[Form, Structure]

・This product is sterilized with ethylene oxide gas.

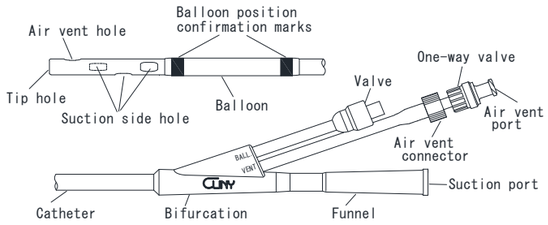
・This product (guide wire) uses metal.

<Product components>

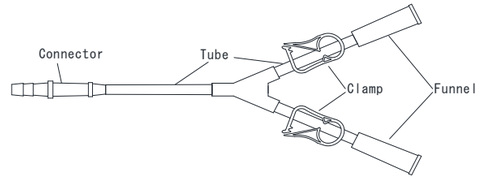
	Component	QTY
Transanal Ileus Decompression Tube Set	Transanal Decompression Tube	1
	2-channel connector	1
	Guide wire	1
	Dilator designed for the opened forceps	1
	Dilator for dilating stenosis	1
Transanal Decompression Tube	Transanal Decompression Tube	1
	2-channel connector	1

<Shape>

- Transanal Decompression Tube



- 2-channel connector



- Guide wire

- Dilator designed for the opened forceps

- Dilator for dilating stenosis

< Raw materials >

- Transanal Decompression Tube :
  Silicone rubber, polyester or Polycarbonate, polypropylene
- 2-channel connector : PVC, Polycarbonate, polypropylene
- Guide wire : Stainless steel, Polytetrafluoroethylene
- Dilator designed for the opened forceps : Polyethylene
- Dilator for dilating stenosis : PVC

<Shape>

- Transanal Decompression Tube

Size designation	O.D.	Total length	Maximum balloon capacity	Tip hole / Side hole
22Fr	7.3mm	500 to 2000mm	30mL	Open tip 4 to 6 side holes

- Guidewire

Designation	O.D.	Total length	Specification
G/W.052"3000T	1.32 mm (0.052")	3000mm	Fixed straight (Soft tip type) Teflon coating

- Dilator designed for the opened forceps

Size designation	O.D.	Total length	Specification
8Fr	2.7mm	2000～4000mm	All radiopaque

- Dilator for dilating stenosis

Size designation	O.D.	Total length	Specification
26Fr	8.6mm	1000mm	Radiopaque with tapered rear end

<Principle>

Insert the product from the anus into the intestine and inflate the balloon to secure the probe in the desired location.

Perform the decompression of intestinal gas, aspiration of intestinal contents and injection of a water soluble contrast agent/medium for upper GI series like gastrografin.

[Intended use]

This product is inserted transanally and used for the intestinal decompression, aspiration of intestinal contents and injection of medicinal solution.

The dilators are used for facilitating the catheter insertion or dilating the stenotic part.

[Efficacy or Effect]

Intestinal gas can be depressurized, intestinal contents can be aspirated, and drug solution can be injected.

[Specifications and performance]

- Secure the level of sterility assurance (SAL) 10^{-6}.
- Sterilization residue: Conforms to ISO10993-7.
- Does not contain materials of biological origin and is biocompatible with biological safety.
- Can withstand 29 days of continuous use.
- To be stable and durable for 5 years.
- Balloon maximum capacity 30 mL
- Tensile strength

  This product does not tear when both ends of the product are exposed to the following forces in a longitudinal direction.

  Transanal Decompression Tube 20N

  2-channel connector 30N

[Operating or using method]

The following method of use is a typical usage.

< What to prepare >

- Colonoscope
- Contrast agent

  It is used to grasp the condition of the stenotic region after inserting the colon endoscope. Water-soluble gastrointestinal contrast medium is suitable.
- Olive oil

  It is used for smooth operation of this product.
- Syringe

  It is used for balloon expansion. A general slip type syringe of 20 to 50 mL is required.

  A catheter tip type syringe is required for washing intestinal contents.
- Sterile distilled water

  Prepare for balloon water injection.
- Low pressure continuous suction machine

  It is used for decompression in the intestinal tract.
- Lukewarm water

  It is used for washing the inside of the intestinal tract after placing the decompression tube.

< Usage >

1) Preparation before the procedure

[1] Insert the dilator designed for the opened forceps to near the distal end of the guide wire.

[2] The both inner lumens of the dilator for dilating stenosis and the decompression tube must be filled with approximately 5mL of olive oil for smoother insertion over the dilator designed for the opened forceps up to behind the stenosis/stenose. (hereinafter referred to as "decompression tube").

2) Techniques for emergency depressurization

[1] Insert the endoscope up to the narrowing of the colon.

A contrast agent (25 to 100 mL) is injected from the forceps port of the colonoscope and grasp the state of the narrowed part under X-ray fluoroscopy. When the contrast agent does not enter the stenosis, there are cases where the stenosis can be imaged by pushing the contrast agent in the air (double contrast method).

[2] Insert the guide wire slowly and carefully into the lumen of the narrowed part, after passing through the stenotic part, send it to the deep part (30 to 40 cm or more) together with the dilator designed for the opened forceps.

[3] While leaving the guide wire and the dilator designed for the opened forceps in the intestinal tract, while pushing slightly, remove only the endoscope.

[4] Insert the dilator for dilating stenosis slowly and carefully along the dilator designed for the opened forceps and let it pass through the stricture.

[5] Remove the dilator for dilating stenosis while leaving the guide wire and the dilator designed for the opened forceps in the intestinal tract.

[6] Insert the decompression tube slowly and carefully along the dilator designed for the opened forceps and insert until the balloon portion passes through the stenotic site.

[7] Inject 30 mL of sterilized distilled water into the balloon.

[8] Confirm that the balloon is expanded and securely caught in the stenosis (decompression tube does not come off). (Check the balloon part with two "balloon position confirmation marks".)

[9] Aspirate and inject 100 to 300 mL of lukewarm water from the suction port repeatedly as much as possible to reduce the pressure in the dilated intestinal tract. (At this time, occasionally, posture transformation or manual compression of the abdomen is used together.)

[10] Insert the balloon slowly and carefully so that the balloon portion is about 10cm deeper than the narrowed portion, place it. In this case to place the tip of the decompression tube at a position that does not hit the intestinal wall. Also, make sure not to catch the balloon on the stenosis.

[11] After applying the two clamps of the 2-channel connector, connect the 2-channel connector to the suction port of the decompression tube.

[12] Put a syringe for washing to one of the funnels, release the clamp and inject 200 to 300 mL of lukewarm water in the intestinal tract.

[13] Clamp after injection and leave it for a while.

[14] Release the clamp of the other funnel, connect the low pressure continuous suction device or drainage bag and drain. Or place a drainage container and drain.

3) After indwelling, treatment after the second day

For the treatment on the second day after indwelling, wash the intestinal tract thoroughly with 2) "Emergency depressurization procedure [12] to [14]" mentioned above repeatedly with a total of 2000 to 3000 mL lukewarm water. During indwelling of this product, wash at least once a day until ileus improves. Wash once a day after improvement. (If cleaning operation is omitted, the tube may clog.)

4) During surgery

Remove decompression tube when performing intestinal resection. At this time, contract the balloon immediately before resection of the intestinal tract, pull out the decompression tube slightly to the anus side from the narrowed part, expand the balloon again with 30 mL of sterilized distilled water, and remove the decompression tube after removing the intestinal tract on the anal side.

＜Concomitant devices＞

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

Name	Specification
Endoscope	・Channel diameter：2.8 mm or more ・Total length：Not more than 1700 mm ・Specification：For use in colon
Syringe	・Slip type ・Capacity：20 - 50mL
Syringe	Catheter tip type
Sterilized distilled water	—
Low pressure continuous suction machine	End shape： Catheter tip shape or bamboo shoot shape ・Suction pressure： −980～−2450Pa (−10～−25cmH_2O)
Drainage bag	End shape： Catheter tip shape or bamboo shoot shape
Lukewarm water	—

[2] Medical drug compatible to this product

Products name	Nonproprietary name
Gastrografin	Amidotrizoic Acid
Olive oil	Olive oil
Xylocaine-jelly	Lidocaine

Do not use other medical drug.

＜Precautions for use related with the using procedure＞

[1] Before using this product, make sure that the balloon surely expands and contracts.

[2] To spread a balloon, use a general slip type disposable syringe.
(In the lock type syringe, it cannot be surely inserted in the depth of valve. Also, if the taper does not match, the valve will be damaged.)

[3] When expanding or contracting the balloon, make sure that the tip of the syringe is inserted deeply into the valve and operate.
(Insufficient insertion of the tip of the syringe in the valve, the valve does not operate and the balloon cannot be operated in some cases.)

[4] When removing the syringe, always hold the valve and remove the syringe while turning it.
(In rare cases, the valve may be misaligned, sometimes disengaged.)

[5] Use sterilized distilled water for balloon expansion, inject it slowly and carefully.
(Rapid injection may result in dislocation or removal of the valve in rare occasions due to its pressure.)

[6] Do not inject sterilized distilled water more than the maximum capacity in the balloon.
(Excessive infusion causes a burden on the balloon, which causes bursting.)

[7] Do not use other than the included guide wire.

[8] Be careful that it is a danger of piercing the intestinal tract with the distal end of guide wire, the dilator designed for the opened forceps and the dilator for dilating stenosis.

[9] When indwelling the decompression tube, when washing the tube lumen and intestinal tract, be careful not to catch the balloon portion on the stenosis.

[10] Make sure to clamp the 2-channel connector and fit with each part securely.
(It causes liquid leakage.)

[11] Withdraw the decompression tube after aspirating the sterilized distilled water completely from the balloon.

[12] Do not inject contrast agent and chemicals with possibility of crystallization from the air vent port.
(It causes clogging and decompression and suction efficiency decrease.)

[13] When connecting a low-pressure continuous suction machine, etc. to the end tube, select the one fits perfect. After starting to use, make sure that no leaks or looseness in the connection part, and use in a securely connected state.

[14] When using the endoscope etc, make sure to refer to the package insert etc. of each product.

[Precautions]

< Important Precautions >

[1] Using oily components such as castor oil, surfactants, alcohol, etc. may cause cracks to the 2-channel connector.

[2] Insert the 2-channel connector, etc. straight along the funnel cavity when connecting a 2-channel connector, etc. to the funnel. Do not apply a load such as bending, twisting, or pinching the funnel in this state.
[Damaging the funnel cavity to the tip of a 2-channel connector, etc. may causes cracks or breaks in the funnel.]

[3] During indwelling, take a photograph of abdominal X-rays regularly, and confirm that decompression of the intestinal tract is performed surely.
Confirm that the tube is not dislodged by contrast, and whether the tip is pressing the intestinal tract if necessary. (When the lumen is clogged, wash the lumen of the tube with lukewarm water.)

[4] Do not force suction.
(There is a risk of damaging tissue.)

[5] Do not intentionally block air vents during decompression therapy.
(Decompression / suction may not be operate.)

[6] Remove all of the sterilized distilled water in the balloon as a guide once a week and inject sterile distilled water of the recommended capacity again.

[7] Be careful when use X-rays to a pregnant patient or a patient with the pregnant possibility.
(Concerned about the effects on the embryo by X-rays.)

[8] Before using the product, make sure that each component works properly.

[9] Do not insert forcedly. If insertion is difficult, stop using the tube andt ake appropriate measures.
(It may cause damage on the tissue.)

[10] Do not insert or remove forcedly. Operate the product with a caution.
(It may cause damage on the product.)

[11] If any problem is found, stop using the product as soon as possible and take appropriate measures.

[12] Do not pull or bend the product forcedly. Handle the product carefully and gently.

[13] Do not modify the product.
(Modification such as making additional side holes may cause disconnection of tube.)

[14] Do not hold the product forcefully with forceps.
(It may cause disconnection of the tube, obstruction of the lumen, or damage on the cuff.)

[15] Do not use the product if the package is broken or the product is damaged.

[16] Use the product soon after the package is opened and dispose the used product in a secure manner for each country.

[17] When using this product and injecting the drug solution in the body, select the proper drug solution under the responsibility of the doctor. Also, refer to the package insert of the chemical.

[18] During placement, keep the device under full control to prevent its operation by an untrained person.

[19] This product uses polyvinyl chloride (plasticizer: phthalate (2-ethylhexyl) = DEHP).
DEHP is included in the dilator for dilating stenosis.
DEHP is included in 2-channel connector.

[20] When 

is found on the label, it means the product contains DEHP.

[21] When using this product for pregnant women and lactating women who are likely to be affected in addition to newborns and babies who are considered highly susceptible, to fully explain the risks from DEHP and obtain consent. It harms to liver and kidney.

[22] When  is found on the label, it means that the product should not be used if the package has been damaged or opened.