

FUJIFILM

Endoscope

EN-580T

OPERATION MANUAL

(Preparation and Operation)

Thank you for purchasing our product. Read this manual carefully before use to avoid unexpected accidents and to take full advantage of the product's capabilities.



CE 0123

Important Safety Information

1. Intended Use

This product is a medical endoscope intended for observation, diagnosis and endoscopic treatment of the esophagus, stomach, duodenum, small intestine and large intestine in medical facilities under management of physicians. Do not use this product for any other purpose.

2. Safety

Read and understand this manual carefully before use. Use the endoscope by following the provided instructions. Items important for the safe use of the endoscope are summarized in Chapter 1 “Safety.”

Safety precautions associated with individual operations or procedures are provided separately, indicated “**▲ WARNING**” or “**▲ CAUTION**.”

3. Warning

Items that must be observed for safety when performing endoscopy or electrosurgery are identified by “**▲ WARNING**” or “**▲ CAUTION**.” Perform procedures correctly by reading and understanding the warning information carefully.

▲WARNING
Read and understand this manual carefully before operating the equipment.
Improper use or operation of the equipment may injure patients, physicians, or people in the vicinity.

Improper operations that will damage the equipment only are identified by “**CAUTION**.”

4. Clinical Procedures

This manual assumes that the product will be used by medical specialists who have received proper training in endoscopic procedures. When performing observation, diagnosis and endoscopic treatment of small intestine, refer to general contraindications to upper gastrointestinal tract endoscopy and colonoscopy. In addition, if the general condition of the patient is extremely critical, or if there are any risks involved in performing the endoscopic examination of ileus, gastrointestinal perforation, respiratory disease, cardiovascular disease, Crohn's disease, acquired hemophilia, stenosis, large ulcer, tumor, etc., perform endoscopy only when the benefits outweigh the risks. This manual does not provide information about clinical procedures. Regarding clinical procedures, use proper clinical judgment.

5. When Using the Endoscope for the First Time

This product has not been sterilized. When using it for the first time, use the level of disinfection or sterilization suitable to the application, in accordance with Chapter 7 "Cleaning," Chapter 8 "Chemical Disinfection," and Chapter 9 "Gas Sterilization."

6. Single Patient Use Only

The Over-tube, balloon, setting tool ST-05B and forceps valve are intended for single patient use. To prevent infection, do not reuse them.

7. Treatment with Electrosurgical Instruments

Before electrosurgery, basic in vitro experiments must be performed to learn how to tighten the snare properly and how repeated use affects the cutting quality of endotherapy devices.

8. Use of Over-tube and Balloon

When the balloon is swollen too much, the enteric canal might be hurt. When using the Over-tube and balloon, the operator should conduct sufficient basic experiments outside the body and learn the degree of inflation of the balloon before using it.

9. Latex Allergy

!WARNING

<p>Do not use Over-tubes and balloons on patients allergic to latex. There is a risk of an anaphylactic reaction/shock.</p>

This product is used with a product that contains natural rubber as a material. Natural rubber may rarely cause allergy symptoms, such as itching, reddening, hives, swelling, fever, dyspnea, asthma-like symptoms, drop of blood pressure and shock. If such symptoms are observed, stop use immediately and take appropriate measures.

10. Use of Personal Protective Equipment

Patient's body fluids adhering to endoscopic accessories such as balloons used in combination with this product may splash, resulting in infection to the operator or assistant. Wear appropriate personal protective equipment when attaching or removing endoscopic accessories.

11. If Any Abnormality Occurs During Clinical Procedure

If any abnormality occurs with the equipment, refer to "Troubleshooting." In particular, continuing to use this product even after it displays abnormal images may cause overheating of the distal end, resulting in burns or other injury.

12. Loss of Function

During an examination, if the endoscopic image disappears, a live image is not displayed after freeze mode has been cancelled, or the endoscopic image is discolored, reset the processor and light source.

During treatment, if the endoscopic image disappears, a live image is not displayed after freeze mode has been cancelled, or the endoscopic image is discolored, stop treatment immediately, remove the endotherapy device from the endoscope, and then reset the processor and light source.

If an appropriate image does not appear even after resetting the processor and light source, turn them off, straighten the bending portion to unlock, release the angle knobs, and then withdraw the endoscope slowly from the patient.

Should the endoscopic image disappear during an examination or treatment, and if the processor and light source are not turned off, it may cause overheating of the distal end of the endoscope, possibly resulting in mucosal burns or other injury.

[Note] Reset: Turn off the processor and the light source, and wait for at least 5 seconds. Turn on the processor and the light source again, and then light the lamp by pressing the Lamp button.

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[Note] As for the table of contents details of “Cleaning, Disinfection and Storage” and “Electrosurgical Instruments”, refer to each operation manual.

Preface

This manual describes how to use endoscope EN-580T.

For how to use the peripherals used in combination with this product, refer to the respective operation manuals.

Conventions Used in This Manual

This manual uses the following conventions for easier understanding.

■ General conventions

Convention	Description
	Indicates a potential danger that may cause harm to people.
 WARNING	Explains dangerous situations that may cause death or serious injury if not avoided.
 CAUTION	Explains situations that may cause injury if not avoided.
CAUTION	Explains situations that may cause damage to equipment if not avoided.
(1), (2), (3), ...	Indicates consecutive numbers in operating procedures for the order in which successive steps in the procedure should be taken.
[Note]	Indicates a comment or supplementary information.
→	Indicates a reference.

Chapter 1 Safety

This chapter summarizes the information necessary for safe use of this product.

Chapter 1 Safety

1. Precautions in Using Endoscope

1) Applicable processor and light source

This product is used in combination with processor VP-4450HD and light source XL-4450.

2) Preparation and inspection before use

Prior to using this product, prepare a spare one to avoid unexpected accidents such as equipment failure. If a replacement is not available, you may not be able to continue endoscopic procedures.

Have this product inspected by medical specialists who have received proper training in endoscopic procedures before use according to the procedures provided in this manual, to avoid unexpected accidents, and take full advantage of the equipment's capabilities.

If the inspection result shows any abnormality, do not use the same equipment.

3) Combination of equipment

The endoscope may be used in combination with peripherals. To avoid an electric shock accident, use only the peripherals that are described in this operation manual.

Read also the attached document and operation manual of the peripherals used in combination with this product.

4) Prohibition of reuse

The Over-tube, balloon, setting tool ST-05B and forceps valve are intended for single patient use. To prevent infection, do not reuse them.

5) Expiration date for use

Do not use Over-tube, balloon, setting tool ST-05B or forceps valve after its expiration date has passed.

6) Preparation before use

Use diathermic treatment equipment or an endoscope which can be used with diathermic treatment equipment to provide proper emergency treatment, in cases of bleeding.

7) Abnormality in use

If any abnormality is found during its use, perform safety checks and immediately stop using this product.

8) Maintenance

The equipment will wear out and degrade after repeated use for a long period. In particular, resin and rubber parts wear out over time or due to the chemicals used. Have it checked by specialists once every six months or once every 100 cases. Also have it checked if there is anything wrong with the equipment.

Do not disassemble or modify the equipment.

9) Operation of Endoscope

Endoscope is a precision instrument. Excessive force or impact on the insertion portion, flexible portion, or distal end may injure the patient's body cavity as well as damage the instrument. If any resistance is sensed during the operation, do not continue operating it forcibly, but insert it slowly. Do not insert or bend the endoscope without checking the image on the monitor.

10) Handling of Endoscope

When holding endoscope, hold it by the control portion. Holding it up by the insertion portion or LG flexible portion is difficult to hold and may exert an excessive force, resulting in failure.

Do not apply any impact to the distal end of endoscope, especially to the lenses. It may result in abnormal endoscopic images or insufficient airtightness of the endoscope.

When carrying the endoscope, keep the endoscope clean. In addition, put the endoscope into a clean carrying case to avoid hitting against other objects.

Wear personal protective equipment when handling an endoscope to prevent infection and electrostatic discharge.

11) Temperature at distal end

When the endoscope projects light at high brightness for an extended time, the temperature may exceed 41°C at the distal end. Turn off the lamp when you hang the endoscope on the cart hanger.

12) Electromagnetic interference

This equipment has been tested and found to comply with the limits for medical devices defined in EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, it is possible that it may cause harmful interference to other devices in the vicinity, if it is installed and used in accordance with the instructions. Also, there is no guarantee that interference will not occur in a particular installation. Therefore, if this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Change the orientation or position of any affected device.
- Increase the spacing between devices.
- Consult the manufacturer or dealer of the device.

Noise may appear on the monitor of this equipment due to the effect of electromagnetic waves. In this case, turn off the device emitting the electromagnetic waves or move the device away from this equipment.

2. Cleaning and Disinfection/Sterilization

Perform cleaning, disinfection and sterilization of the endoscope according to respective guidelines. Clean and disinfect the endoscope after understanding the latest guidelines.

This product has not been sterilized. When using it for the first time, perform cleaning, disinfection and sterilization suitable for the application.

After using it, clean and disinfect/sterilize it according to the procedures in the manual (Cleaning, Disinfection and Storage). Inadequate cleaning may result in infection. Carefully clean the insertion portion and all the channels including the balloon air feed channel especially.

Wear personal protective equipment during chemical washing and disinfection to protect your skin and to prevent infection.

When using this product for a patient with Creutzfeldt-Jakob disease (especially variant Creutzfeldt-Jakob disease), use it exclusively for a patient with the same disease, or properly discard this product after use. Since the cleaning, disinfection and sterilization methods described in the manual (Cleaning, Disinfection and Storage) of this product cannot eliminate the causal agents of Creutzfeldt-Jakob disease, the product could be a source of infection. For the treatment of Creutzfeldt-Jakob disease, refer to the guidelines for it available.

3. Disposal

This product has heavy metal parts. When disposing of this product, comply with local laws and regulations in your area. Determine whether or not the product is to be treated as a biohazard, then handle and dispose of accordingly.

Before disposing of this product or an endoscopic accessory, perform cleaning and disinfection (or sterilization) according to the procedure described in the operation manual. There is a risk of being a source of infection.

4. Repair or Inspection

Contact your local FUJIFILM dealer when this product is returned for repair or inspection. In addition, be sure to clean and disinfect (or sterilize) this product before returning for repair or inspection. A returned product which is not cleaned and disinfected (or sterilized) may increase infection control risks.

5. Indication symbol

This symbol, developed by Eucomed^[Note], indicates that this specific type of medical device contains dibutyl phthalate (DBP). Its amount is so minuscule that it has little effect on patients' health.

[Note] The URL of Eucomed is as follows; <http://www.eucomed.be/>

6. “▲ WARNING” and “▲ CAUTION” Messages Appearing in Individual Chapters

Chapter 5 Preparation for Use of Endoscope

Insert the AC plug into a hospital grade receptacle. When carrying or connecting the endoscope, take care to keep it clean. Not doing so may cause an electric shock.

If an inspection result shows any abnormality, do not use the same product. Store the endoscope under the storage conditions described in Appendix. Use the endoscope under the operating conditions described in Appendix. The use of abnormal equipment will cause wrong diagnosis or injury.

5.2.2 Attaching Forceps Valve

Ensure that an appropriately reprocessed forceps valve is properly attached to the forceps inlet. If not attached, body fluid may flow back and it could be a source of infection.

Be sure to inspect the forceps valve before attachment. If any abnormality is found during inspection, do not use the product. It could be a source of infection.

5.3 Connecting Endoscope

Do not touch the LG connector tip until it cools down (approximately 5 minutes). Touching the LG connector with hands immediately after use of the endoscope may cause a burn injury.

Set a suction pressure at 53 kPa or less. Endoscope may be adhered to mucous membrane, resulting in damage to the mucous membrane.

5.4.4 Inspecting Distal End

Turn off the light before inspecting the lens. Viewing the light of light guide directly may damage your eyes.

5.7 Attaching and Inspecting Over-tube and Balloon

Use a sterilized balloon installation tool. Do not use the balloon or Over-tube after its expiration date has elapsed. There is a risk of infection.

Do not use Over-tubes and balloons on patients allergic to latex. There is a risk of an anaphylactic reaction/shock.

5.7.3 Attaching Hood (Only When Necessary)

Do not press the hood against the digestive tract wall with undue force. It may damage mucous membrane.

Fix the hood securely to the endoscope before use. Otherwise, the hood may drop.

5.9 Connecting Balloon Controller

Connect the endoscope and the Over-tube to the balloon controller properly. Before insertion, make sure that the balloon operates as intended. Otherwise, it may cause an injury.

Chapter 6 Method of Use

Wear personal protective equipment when using the endoscope. There is a risk of infection.

Be sure to attach a balloon and Over-tube when using the endoscope. If not attached, body fluid may flow back and it could be a source of infection.

Wear personal protective equipment when removing Over-tubes, balloons or hoods. There is a risk of infection.

Do not use Over-tubes and balloons on patients allergic to latex. There is a risk of an anaphylactic reaction/shock.

Do not supply excessive amount of air or gas during the procedure. It may result in perforation or rupture of digestive tract wall.

Do not supply an excessive amount of air or gas during electrosurgery. It could cause an embolism.

6.2 Insertion and Observation

Do not bend the endoscope quickly. There is a risk of damaging the inside of the body cavity.

Do not inflate the balloon in the pharynx or esophagus. There is a risk of suffocation.

Insert and withdraw the endoscope or Over-tube slowly. Do not press the endoscope or Over-tube strongly onto the walls of the digestive tract. Do not insert or withdraw the endoscope or Over-tube with the balloon inflated. Make sure water never enters the air feed inlet (clear tube) of the Over-tube. It may damage to the walls of the digestive tract, causing perforation.

Use of devices such as endoscopic/enteroscopy overtubes may be associated with potential complications including but not limited to mucosal trauma, pancreatitis and/or hyperamylasemia. Users are encouraged to closely monitor patients for such complications during and after procedures and to appropriately treat patients as required.

Do not allow the distal end to touch the same part for 5 minutes or more. Heat from the light may cause a burn.

Do not look at the light emitted from the light guide directly. There is a risk of damaging eyes.

If parts fall into a body cavity due to the malfunction of the device, immediately stop the examination and retrieve the parts by following appropriate measures. There is a risk of damaging the inside of the body cavity.

6.3 Biopsy

Do not insert an endotherapy device if you cannot see the forceps outlet on the endoscopic image. There is a risk of perforation and bleeding.

Slowly insert an endotherapy device straight into the forceps inlet of the endoscope. Also, when withdrawing it, slowly pull straight out. In addition, slowly attach or remove a syringe, etc. straight to/from the forceps inlet. If inserted or pulled out obliquely to the forceps inlet, the frictional resistance will increase and body fluid may be splattered around due to breakage or accidental detachment of the forceps valve, leading to infection.

Do not strongly press an endotherapy device against the digestive tract wall. There is a risk of perforation and bleeding.

6.4.1 Removing Hood (Only When Used)

Wear personal protective equipment when removing the balloon or hood. There is a risk of infection.

6.5.5 Removing Endoscope from Processor

Do not touch the LG connector tip until it cools down (approximately 5 minutes). Touching the LG connector with hands immediately after use of the endoscope may cause a burn injury.

6.5.6 Detaching Forceps Valve

Discard the forceps valve after use. It could be a source of infection.

Chapter 7 Cleaning

7.4 Manual Cleaning (Cleaning in Sink)

In case the cleaning brush is damaged during a cleaning process, remove any residue from inside the tube. A damaged cleaning brush could be a source of infection.

7.4.11 Cleaning Entire Endoscope

After cleaning, rinse off any remaining chemical with water. Cleaning fluid might flow into a patient's body.

After cleaning, rinse off any remaining cleaning fluid with water. If cleaning fluid remains, the chemical disinfection to be performed at the next step will lose its effectiveness.

7.9 Cleaning and/or Disinfection Using an Automated Endoscope Reprocessor (AER)

Some legally marketed automated endoscope reprocessors (AERs) may be able to clean and/or disinfect the endoscope. However, endusers should check with each AER manufacturer to confirm they have validation data to support their reprocessing claims for the endoscope and removable endoscope components, such as valve mechanisms. Inadequate device-specific instructions and/or non-validated AER recommendations could result in unsuccessful cleaning and/or disinfection which may increase risks to patient safety.

Chapter 8 Chemical Disinfection

8.3 Chemical Disinfection of Endoscope

When immersing the endoscope and the cleaning adapter in disinfectant solution, remove bubbles completely from the endoscope and the cleaning adapter. If any bubbles remain, effective disinfection cannot be achieved.

Immerse the entire endoscope and cleaning adapter in disinfectant solution. If any portion of the endoscope or cleaning adapter protrudes from disinfectant solution, insufficient chemical disinfection will result.

8.4.1 Injecting Sterile Water

After immersing in the disinfectant solution, rinse off remaining disinfectant solution with sterile water. Disinfecting liquid might flow into a patient's body.

Chapter 9 Gas Sterilization

Proceed gas sterilization after vaporizing water out of endoscope. Applying gas sterilization to wet parts presents incomplete sterilization.

Proceed aeration after gas sterilization. Gas remaining in endoscope after gas sterilization is harmful to human body.

Chapter 10 Storage

Do not store endoscope in a carrying case. Storage of endoscope in a carrying case may cause infection.

Chapter 11 Treatment with Electrosurgical Instruments

11.1 Preparing and Inspecting Equipment and Materials

Always keep pacemaker users away from electrosurgical instruments. The operation of the pacemaker will be malfunctioned by the electrosurgical instruments.

Replace any flammable gas in body cavities with non-flammable gas before using the electrosurgical instruments. Never use the electrosurgical instruments in atmosphere of flammable gas. Ignition and explosion may occur.

Do not apply the current when the electrode of diathermic treatment equipment and the metal part at the distal end of the endoscope are in contact with each other. Burns may occur.

11.1.3 Connecting Electrosurgical Instruments

Connect surgical instruments correctly in accordance with the operation manual. Wrong connection will cause electric shock accident and burns.

Do not use peripherals other than those described in the operation manual. If the endoscope is used in combination with the endoscopic accessories that have been connected to other medical devices, patient leakage current may increase.

11.1.4 Setting the Conditions of Surgery

Operate the instruments within specified output range. Leakage current may cause burns.

11.2 Polypectomy

Replace any flammable gas in body cavities with non-flammable gas before using the electrosurgical instruments. Ignition and explosion may occur.

Prevent patient's body from touching electric conductor such as metal part of bed. Physicians and assistants should wear rubber gloves. Leakage current may cause burns.

Do not apply the current when the electrode of diathermic treatment equipment and the metal part at the distal end of the endoscope are in contact with each other. Burns may occur.

11.3 Papillotomy

Replace any flammable gas in body cavities with non-flammable gas before using the electrosurgical instruments. Ignition and explosion may occur.

Prevent patient's body from touching electric conductor such as metal part of bed. Physicians and assistants should wear rubber gloves. Leakage current may cause burns.

Do not apply the current when the electrode of diathermic treatment equipment and the metal part at the distal end of the endoscope are in contact with each other. Burns may occur.

Chapter 2 Composition of Set and System Configuration

This chapter describes the composition of set and system configuration.

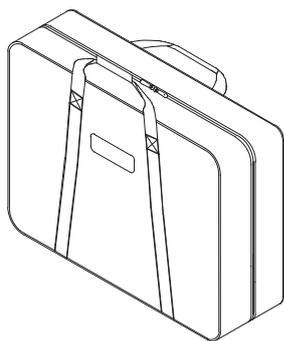
2.1 Composition of Set.....	2-2
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Chapter 2 Composition of Set and System Configuration

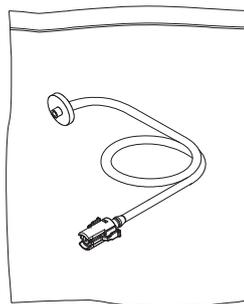
2.1 Composition of Set

The endoscope set is provided in a carrying case. The set consists of the following items.

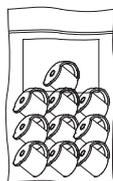
[Note] Figures in parentheses indicate quantities.



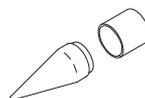
Carrying Case (1)



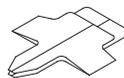
Tube Kit
TY-06S (1)



Forceps Valve
FOV-DV7 (10)



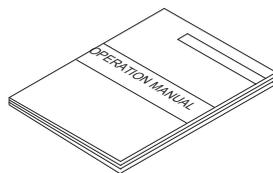
Setting Tool
ST-01B (1)



Setting Tool
ST-05B (20)



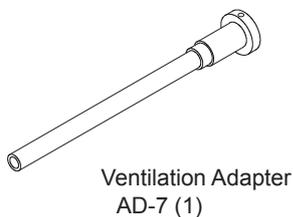
Cleaning Brush
WB4324FW2 (1)



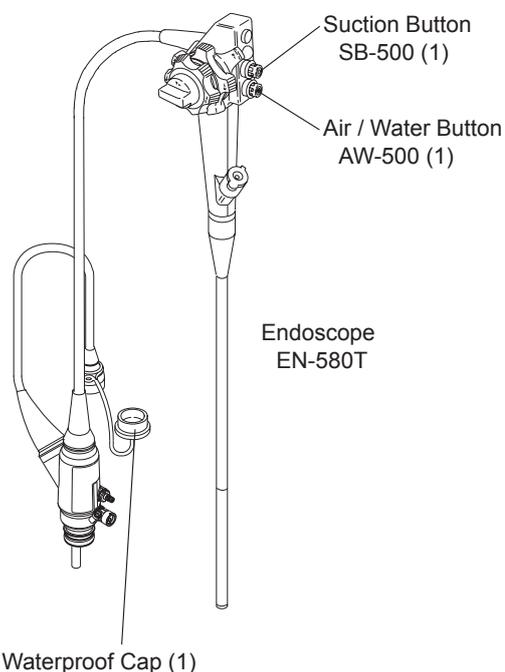
Operation Manual
Preparation and Operation (1)
Cleaning, Disinfection and Storage (1)
Electrosurgical Instruments (1)



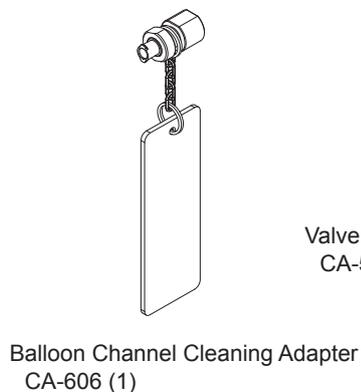
Valve Cleaning Brush
WB11002FW2 (1)



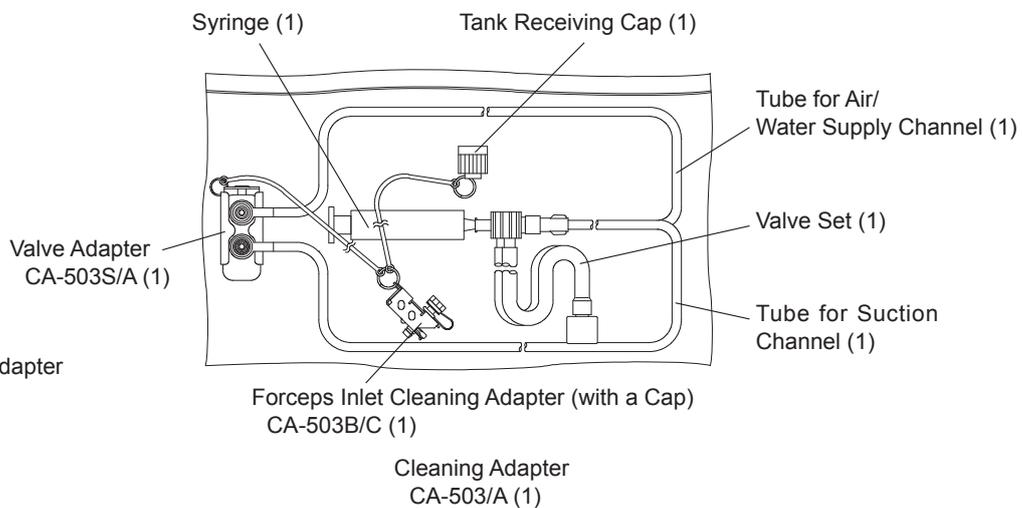
Ventilation Adapter
AD-7 (1)



Endoscope
EN-580T



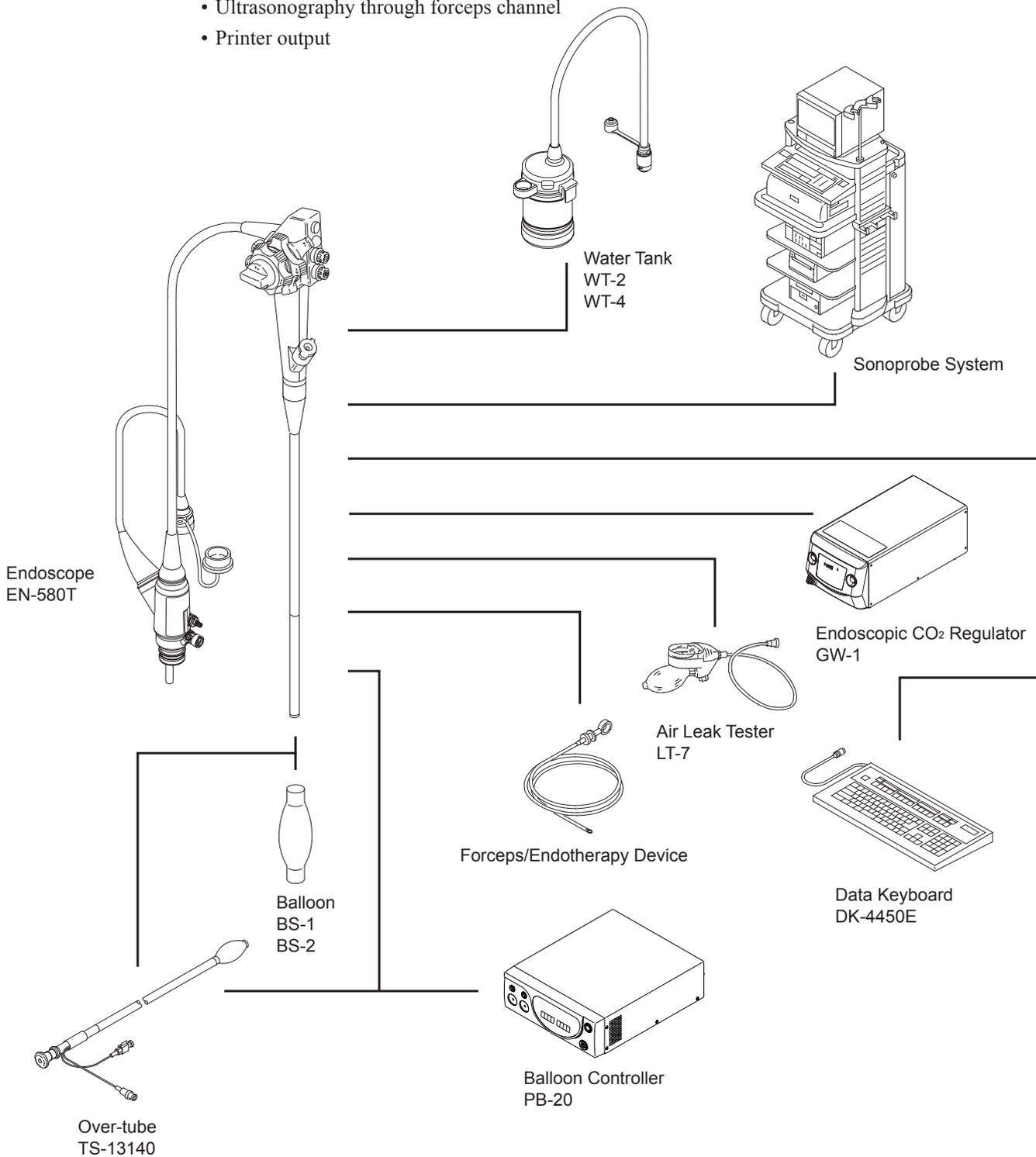
Balloon Channel Cleaning Adapter
CA-606 (1)



2.2 System Configuration

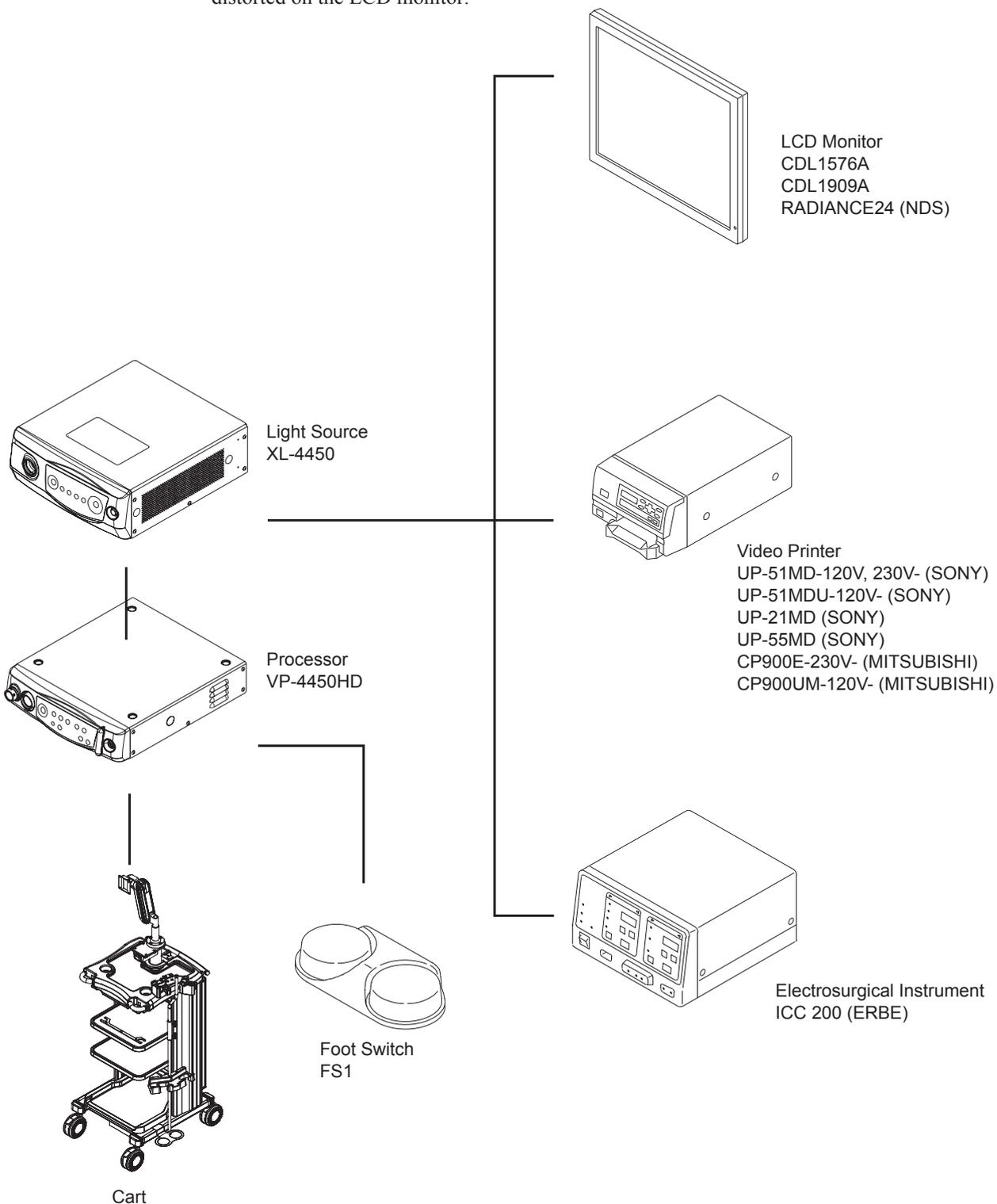
You may use this product with various peripherals attached to it. These peripherals are available separately. Extension makes the following possible.

- Endoscopic treatment
- Ultrasonography through forceps channel
- Printer output



[Note] For details on the connections of peripherals other than those listed here, contact your local FUJIFILM dealer.

[Note] When using a high-frequency power supply, connect CDL1904A and VP-4450HD via a DVI signal. If they are connected via an S-video signal, the image may be distorted on the LCD monitor.



Chapter 3 Names and Functions of Parts

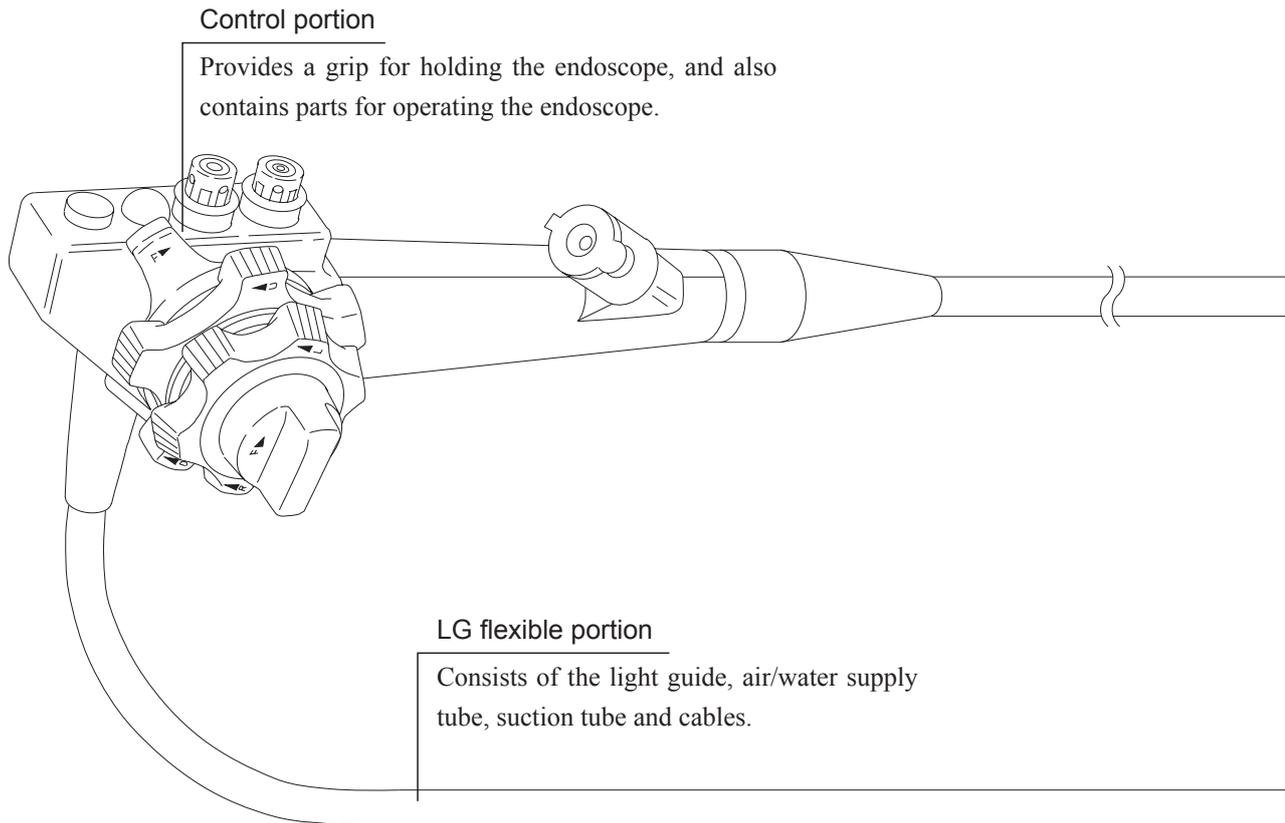
This chapter describes the names and functions of endoscope parts and the composition of the main unit.

3.1 Endoscope	3-2
3.2 Symbols	3-4

Chapter 3 Names and Functions of Parts

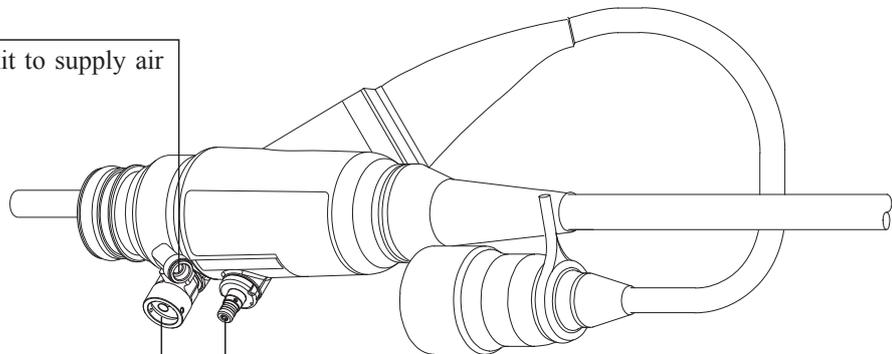
3.1 Endoscope

The endoscope consists of the following parts.



Balloon air feed inlet

Connects a syringe or tube kit to supply air to the balloon air feed outlet.



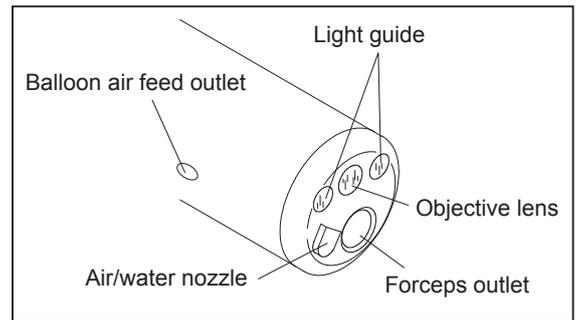
Feed water connector

Connects the water tank.

Ventilation connector

Connects the air leak tester or ventilation adapter.

Enlarged view of distal end



*** Insertion portion (applied part)**

This portion is inserted into body cavities and consists of the distal end, bending portion and flexible portion.

Distal end *

Consists of the objective lens, air/water nozzle, and forceps outlet. Air/water supply and suction are operated by the buttons on the control portion.

Flexible portion *

Connects bending portion and control portion. The endoscope can be inserted into the body cavity up to this portion.

Bending portion *

Bends when inserted. This portion bends by operating the lever on the control portion.

Waterproof cap

Prevents water from getting on electrical contacts.

LG connector

This connector connects to the scope socket on the light source.

Suction connector

Accepts tube from suction unit.

Video connector

Connected to the video connector socket of the processor.

S connector

Accepts S-cord when using electro-surgical instrument (electric cautery).

3.2 Symbols

Symbol	Location	Description
	LG connector	Serial number
	LG connector	Date of manufacture
	This manual	Manufacturer
	This manual	Authorised representative in the European Community
	LG connector	CE marking
IPX7	LG connector	Degree of waterproof
	LG connector	Type BF applied part
	LG connector	WEEE marking ^[Note]
	LG connector	Phthalates marking
	Control portion	Super CCD model

[Note] This product shall not be treated as household waste.

Chapter 4 Control Portion

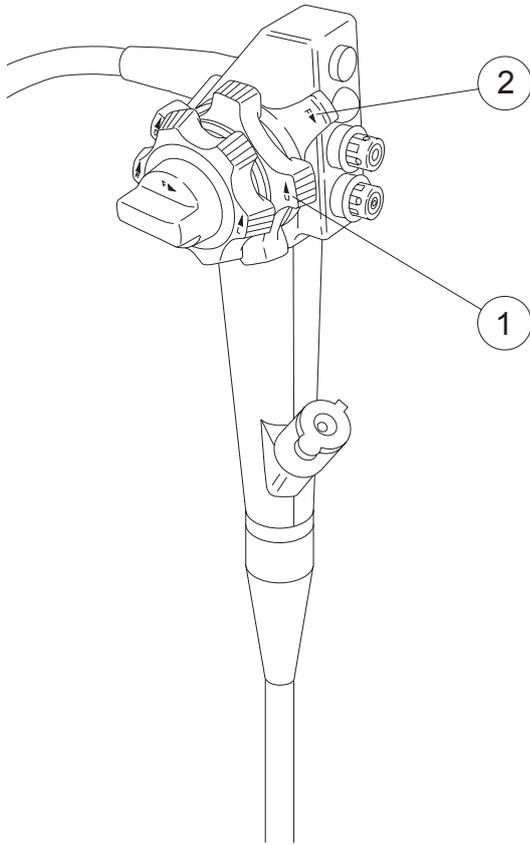
The control portion contains the angle knobs for operating the bending mechanism and valves for air/water supply and suction, etc.

This chapter describes the operations and functions of these parts.

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Chapter 4 Control Portion

4.1 Operating Bending Mechanism



① Up-down angle knob

Used to bend the bending portion upward and downward.

<When the up-down locking lever is slanted toward F ▶>

Turn the up-down angle knob in the direction of U ▶ to bend the bending portion upward. Turn it in the direction of D ▶ to bend the bending portion downward.

When the finger is released from the up-down angle knob, the bending portion slightly unbends. The bending portion is unlocked.

<When the up-down locking lever is slanted in the direction opposite to F ▶>

The bending portion retains the position even when the finger is released from the up-down angle knob. The bending portion is locked.

② Up-down locking lever

Used to retain the bent state of the bending portion. It switches between Lock and Unlock.

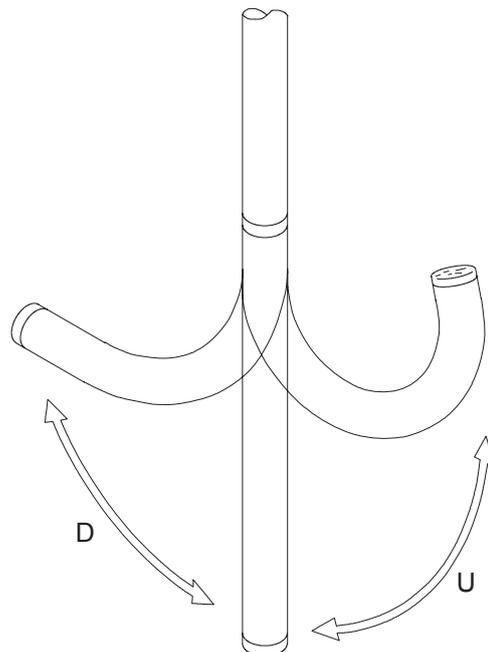
Slant this lever in the direction opposite to F ▶ to lock the bending portion. Slant it in the direction of F ▶ to unlock the bending portion.

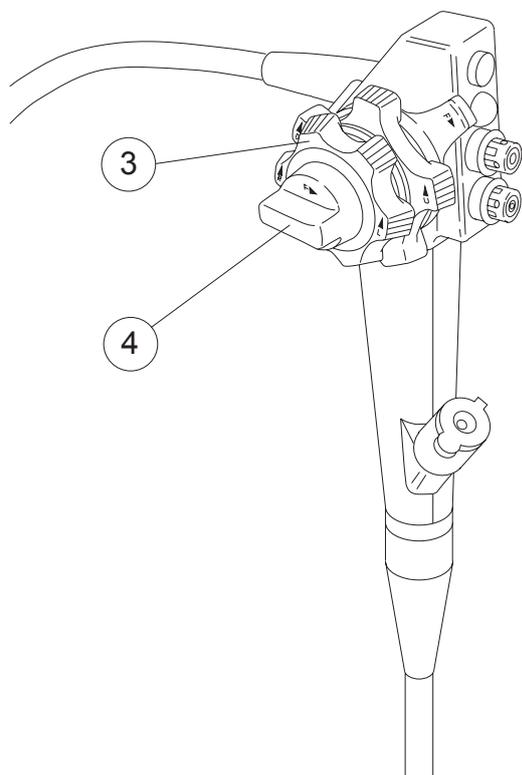
Operate this lever either before or after operating the up-down angle knob.

[Note]

Lock : retains bent state of bending portion.

Unlock : allows external force to bend bending portion freely.





③ Left-right angle knob

Used to bend the bending portion right or left.

<When the left-right locking knob is turned forward F ▶>

Turn the left-right angle knob in the direction of L ▶ to bend the bending portion to the left. Turn it in the direction of R ▶ to bend the bending portion to the right. When the finger is released from the left-right angle knob, the bending portion slightly unbends. The bending portion is unlocked.

<When the left-right locking knob is turned
in the direction opposite to F ▶>

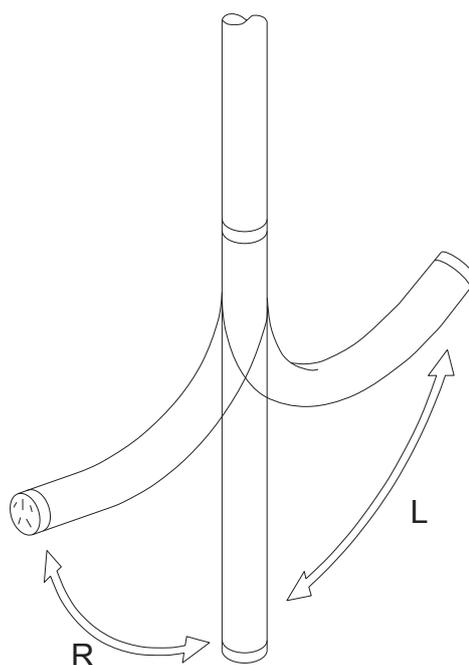
The bending portion retains the position even when the finger is released from the left-right angle knob. The bending portion is locked.

④ Left-right locking knob

Used to retain the bent state of the bending portion. It switches between Lock and Unlock.

Turn this knob in the direction opposite to F ▶ locks the bending portion. Turning it in the direction of F ▶ unlocks the bending portion.

Operate this knob either before or after operating the left-right angle knob.



4.2 Valve Control Buttons

⑤ Suction button

Allows suction through forceps channel (port) in distal end.

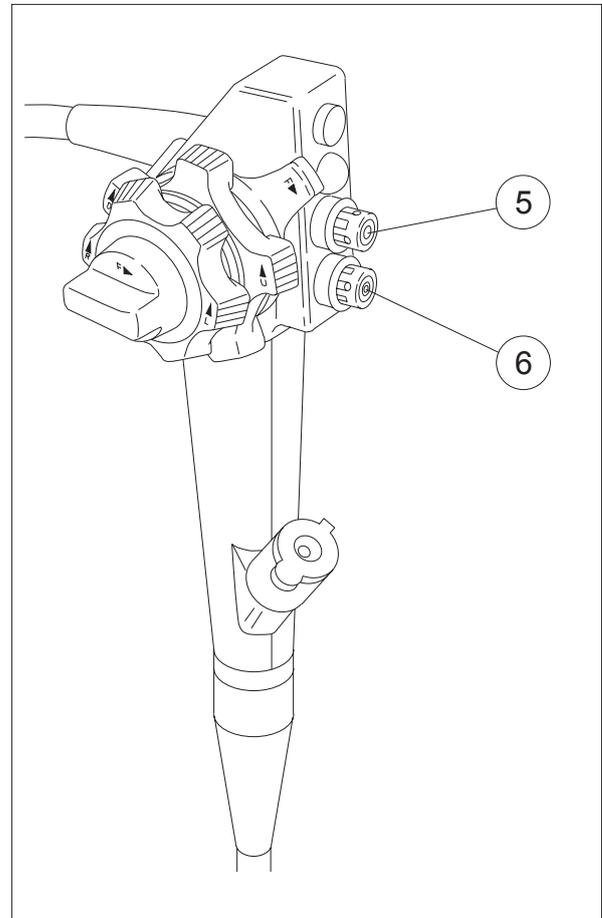
Suction is activated while this button is depressed.

⑥ Air/Water button

Used to blow air or water onto the surface of objective lens from the nozzle in distal end.

To supply air, stop the hole in the center of this button with a finger.

To supply water, depress this button.



4.3 Switches for Images and Recording

⑦ RC switch

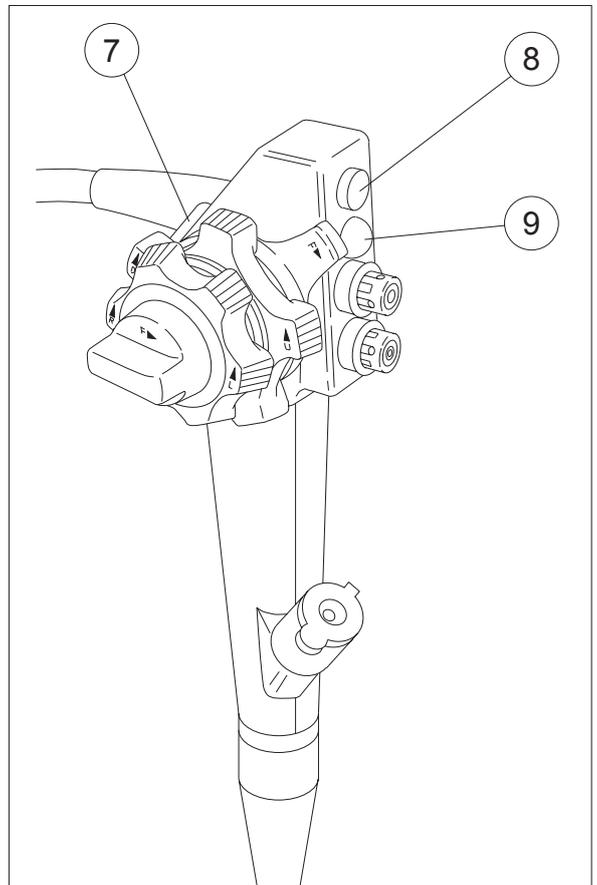
This is the switch that starts and stops VCR recording. Pushing it once starts the recording. Pushing it again stops the recording.

⑧ MM switch

This switch electronically enlarges the image. The image is enlarged to 1.5x when this switch is pushed. The field of view then narrows by the amount of enlargement. The image returns to the normal size when the switch is pushed again.

⑨ FR switch

This is the remote switch for still image and the capture. The screen image is frozen while this button is being pushed. Image freezing is canceled a few seconds after it is released. If the switch is pushed again while the image is still frozen, a trigger signal is output to the device connected to the hard copy terminal.



4.4 Forceps Valve/Forceps Inlet

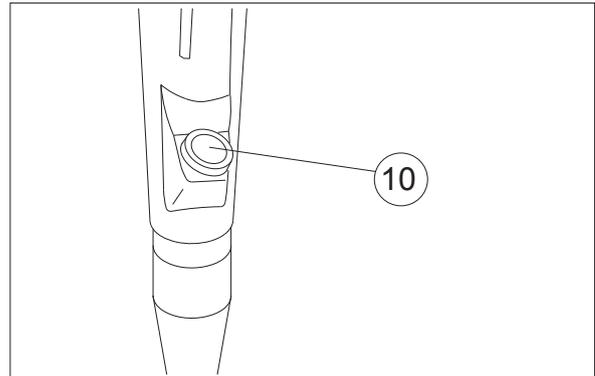
The forceps valve consists of a valve body and a lid. It performs the function of preventing the leak or flowback of air. By opening and closing this valve, you can change the frictional resistance of an endotherapy device by two levels as it is being inserted.

⑩ Forceps inlet

Inlet for passing an endotherapy device, etc.

Normally, the forceps valve is attached.

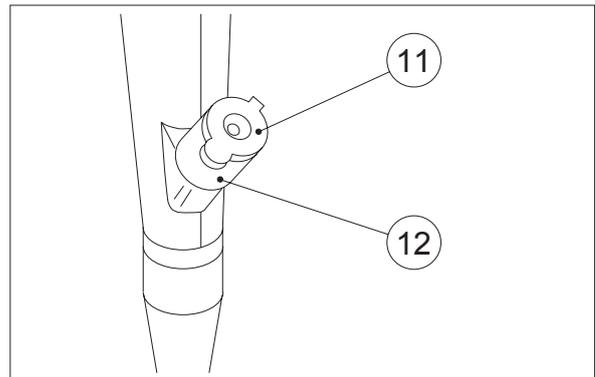
A syringe can also be attached to the forceps valve to supply water or fluid.



⑪ Lid

The lid functions as a valve for preventing the leak or backflow of air. It should normally be kept closed. Closing this lid increases the backflow preventive effect, although it makes the frictional resistance of an endotherapy device larger when it is inserted.

When attaching a syringe to supply water or fluid, remove this lid.

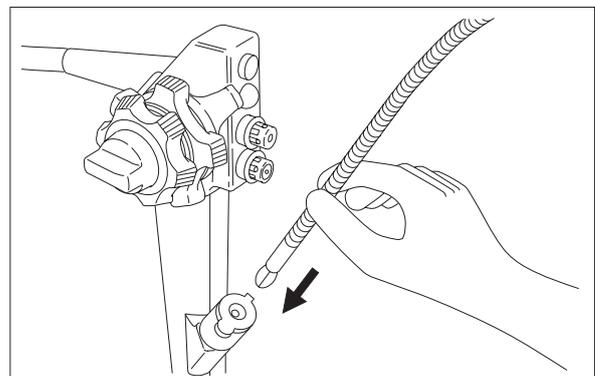


[Note]

When neither an endotherapy device nor a syringe is used, keep this lid closed.

⑫ Valve body

The valve body is a part that reduces the leakage or backflow of air when an endotherapy device is used. It is mounted on the opening of the forceps inlet where a forceps is manipulated. Opening the lid of this valve body lowers the frictional resistance of an endotherapy device when it is inserted and weakens the backflow preventive effect.



Chapter 5 Preparation for Use of Endoscope

This chapter describes the system necessary for endoscopy.

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Chapter 5 Preparation for Use of Endoscope

⚠ WARNING

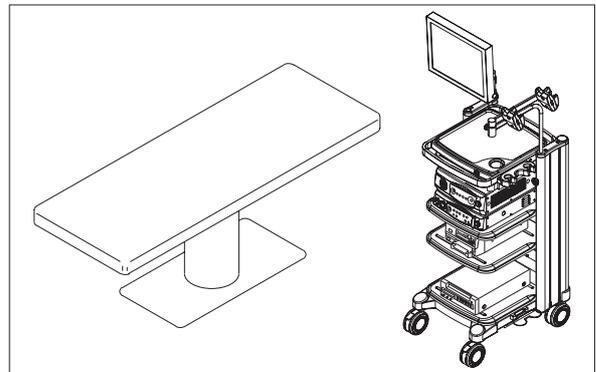
Insert the AC plug into a hospital grade receptacle. When carrying or connecting the endoscope, take care to keep it clean. Not doing so may cause an electric shock.

⚠ CAUTION

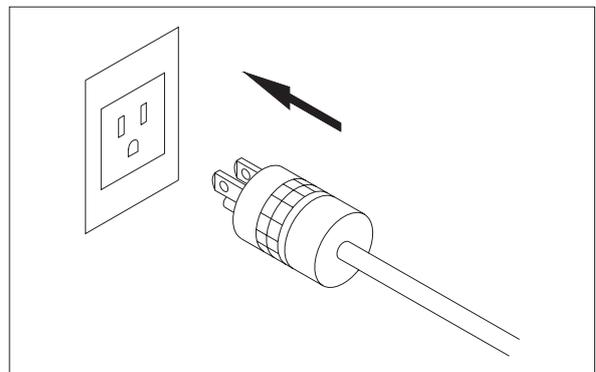
If an inspection result shows any abnormality, do not use the same product. Store the endoscope under the storage conditions described in Appendix. Use the endoscope under the operating conditions described in Appendix. The use of abnormal equipment will cause wrong diagnosis or injury.

5.1 Preparing Equipment

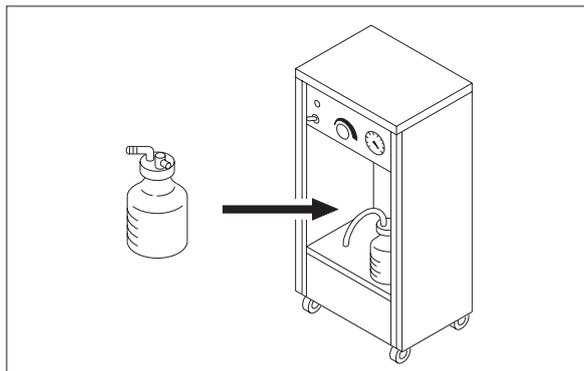
- (1) Move the cart with the processor to the place where the endoscope is to be used.



- (2) Turn OFF the cart, plug the power cord from the cart into a hospital grade receptacle.



- (3) Mount the collection bottle for liquid on the suction unit.



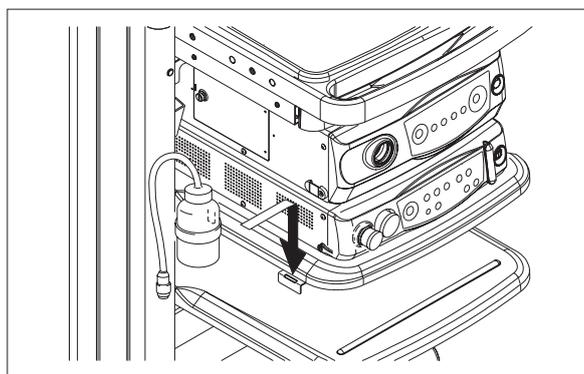
- (4) Mount the water tank, 80% filled with water, on the processor.

[Note]

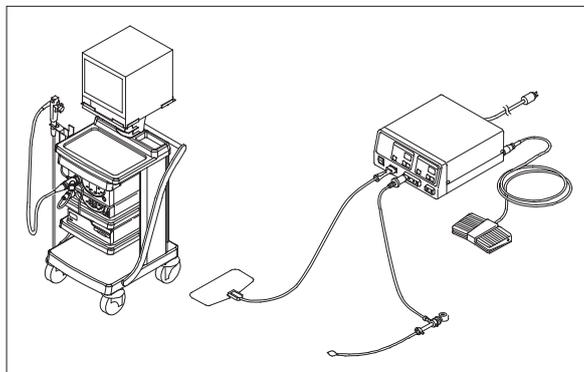
The water in the water tank should be changed every day using sterile water.

[Note]

For details on how to use and clean the water tank, refer to the operation manual of the water tank.



- (5) Prepare diathermic treatment equipment and the applicable endoscope for unexpected bleeding.



5.2 Preparing Forceps Valve and Button

For operational methods of the ultrasonic cleaning unit/autoclaving unit, follow the instructions described in each operation manual for the respective units.

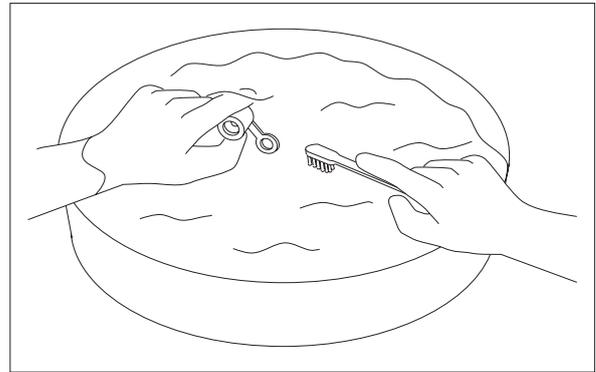
[Note] Do not use the forceps valve after its expiration date has elapsed.

5.2.1 Method of Cleaning, Disinfecting and Sterilizing Forceps Valve

The forceps valve is a single-use product. Prepare a new forceps valve before use. The forceps valve has not been sterilized. Perform cleaning and disinfection or sterilization before use according to the following procedure.

(1) Wipe the surface of the parts with gauze soaked in cleaning fluid.

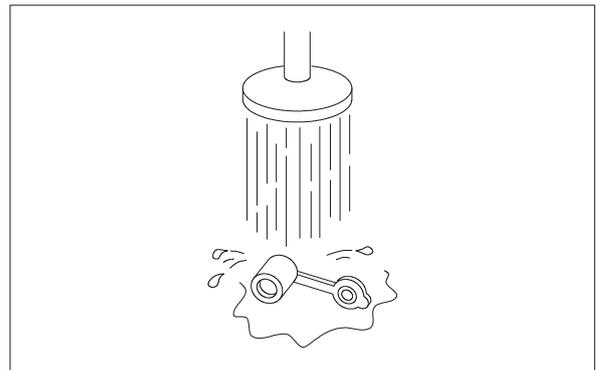
(2) Brush the entire forceps valve in the cleaning fluid using a soft toothbrush.



(3) Clean the forceps valve using the ultrasonic cleaning unit.

(4) Pull out the forceps valve from the cleaning fluid and rinse off with running water (clean water).

(5) Wipe off the remaining water on the parts with dry sterile gauze.



<Autoclave sterilization>

- (1) Seal the forceps valve in a sterile pack.
- (2) Carry out an autoclaving operation in accordance with the operation manual of the autoclaving unit.

Recommended steam sterilization (autoclaving) conditions

Sterilization temperature (°C)	Operation time
121	Max 20 minutes Min 15 minutes
126	Max 15 minutes Min 10 minutes
134	Max 8 minutes Min 5 minutes

For France and Switzerland only:

Sterilization for the minimum of 18 minutes at temperature 134°C

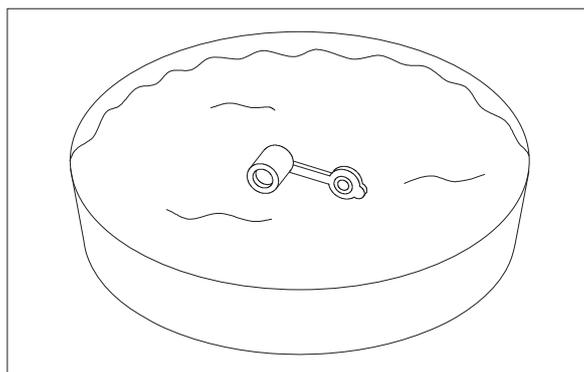
Steam Sterilizer Class B according EN 13060

<Chemical disinfection>

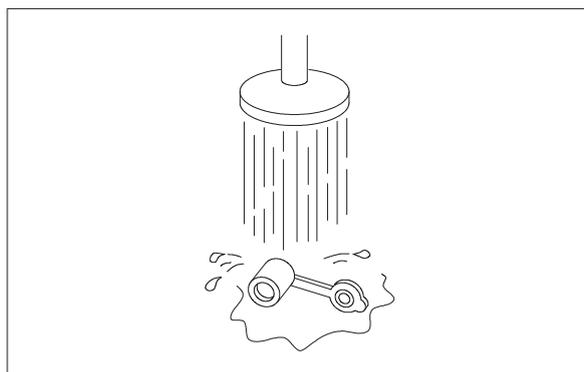
- (1) Immerse the forceps valve in disinfectant and disinfect.

[Note]

When performing disinfection using chemicals, follow the conditions indicated in “Chemicals and Conditions” in Appendix of Operation Manual (Cleaning, Disinfection and Storage).



- (2) Pull out the forceps valve from the disinfectant and rinse it with running water (sterile water).
- (3) Wipe off the remaining water on the forceps valve with sterile gauze.



5.2.2 Attaching Forceps Valve

! WARNING

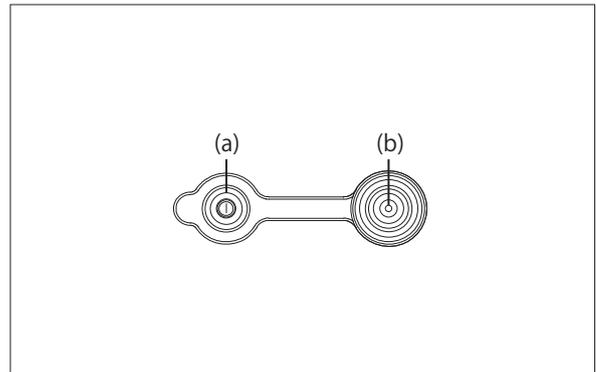
Ensure that an appropriately reprocessed forceps valve is properly attached to the forceps inlet.

If not attached, body fluid may flow back and it could be a source of infection.

Be sure to inspect the forceps valve before attachment. If any abnormality is found during inspection, do not use the product.

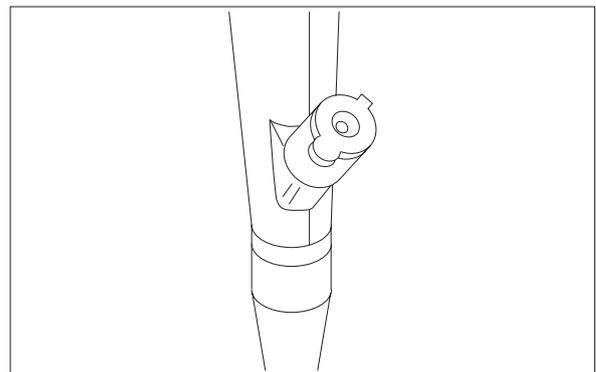
It could be a source of infection.

- (1) Visually check that the slits (a) on the lid and circular hole (b) of the forceps valve are free from abnormalities such as tears, cracks, deformation, discoloration and so on.



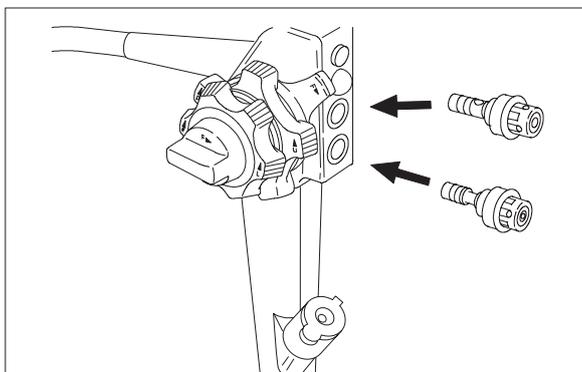
- (2) Attach the forceps valve to the forceps inlet of the endoscope.

- (3) Close the lid of the forceps valve.



5.2.3 Attaching Air/Water Button and Suction Button

- (1) Attach the air/water button and suction button to the control portion of the endoscope.



5.3 Connecting Endoscope

! CAUTION

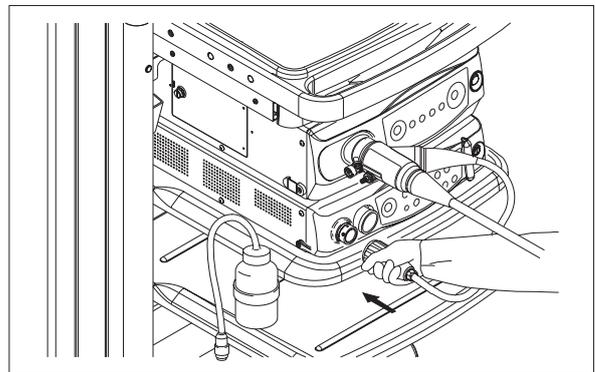
Do not touch the LG connector tip until it cools down (approximately 5 minutes).

Touching the LG connector with hands immediately after use of the endoscope may cause a burn injury.

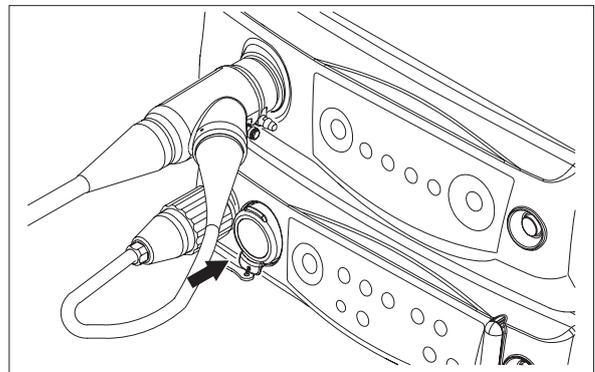
- (1) Insert the LG connector of the endoscope into the endoscope socket on the light source.
- (2) Insert the video connector of the endoscope into the video connector socket on the processor.

[Note]

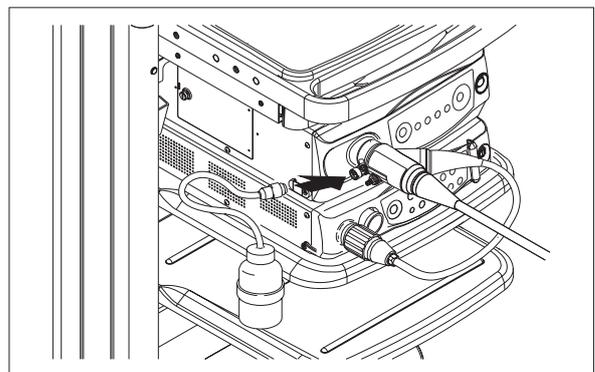
Place the waterproof cap on the edge of the tray.



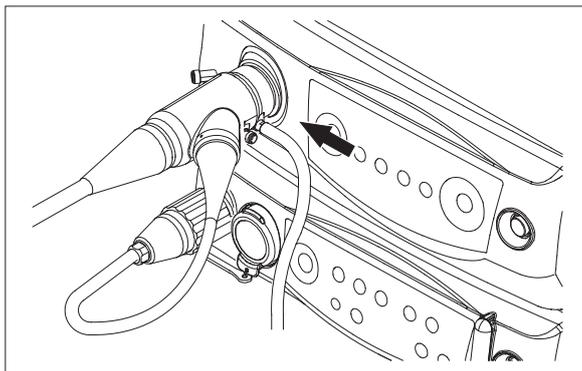
- (3) Connect the dedicated connector cap to the connector socket not in use.



- (4) Insert the connector of the water tank into the feed water connector on the endoscope.



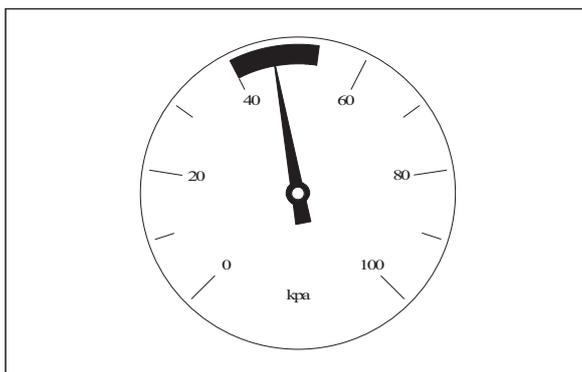
- (5) Connect the suction unit and suction connector of the endoscope with the suction tube.



⚠ CAUTION

Set a suction pressure at 53 kPa or less.
Endoscope may be adhered to mucous membrane, resulting in damage to the mucous membrane.

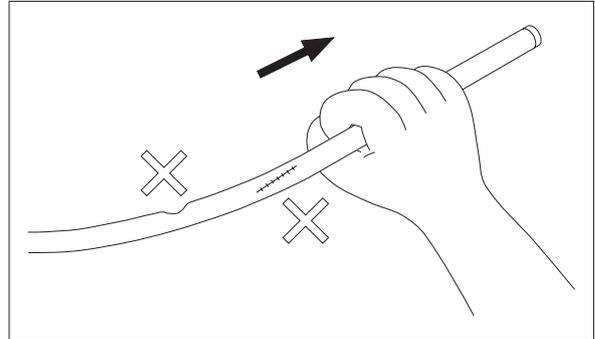
- (6) Set the suction pressure to 40 to 53 kPa.



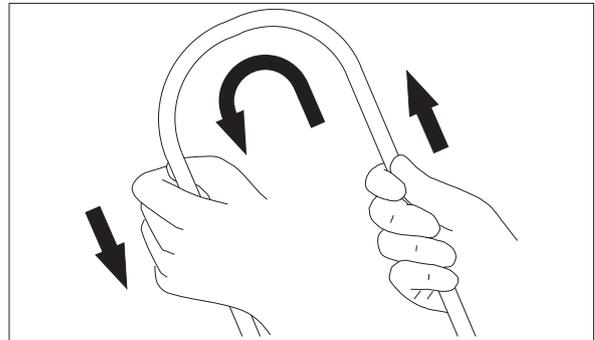
5.4 Inspecting Endoscope

5.4.1 Inspecting Insertion Portion

- (1) Visually check the insertion portion (distal end, bending portion and flexible portion) for abnormalities such as flaws or dents and for sharp edges or protrusions that may injure the patient.

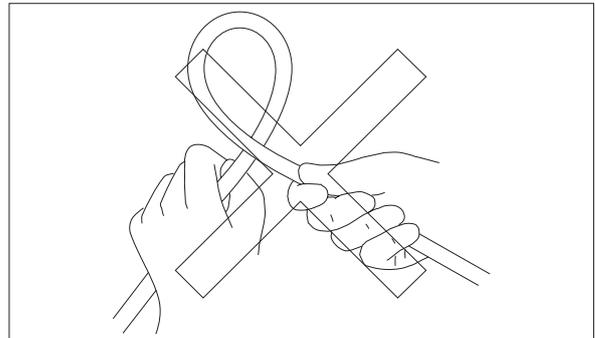


- (2) Hold the flexible portion with both hands and allow it to go over its total length in such a way that the apex of the semicircle with a diameter of about 200 mm gradually begins to slide. Check that the portion bends fully and there is no local difficulty in bending it.



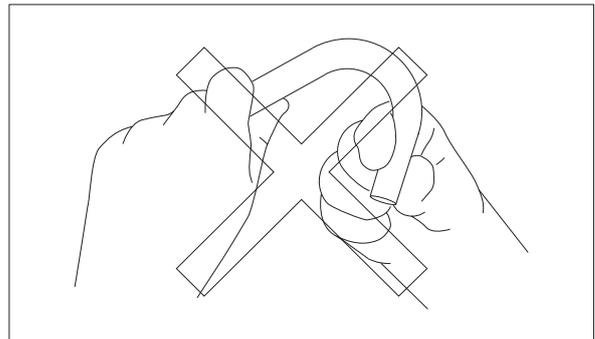
[Note]

Do not forcibly twist or bend too sharply the flexible portion by hand. It may cause a failure.



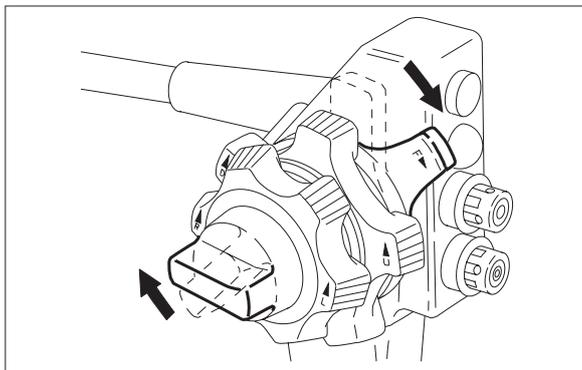
[Note]

Do not forcibly twist or bend too sharply the bending portion by hand. It may cause a failure.



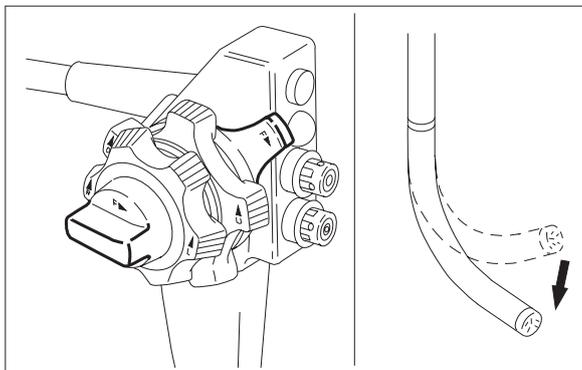
5.4.2 Inspecting Bending Mechanism

- (1) Unlock the up-down locking lever and left-right locking knob by turning them in the direction of F ►.

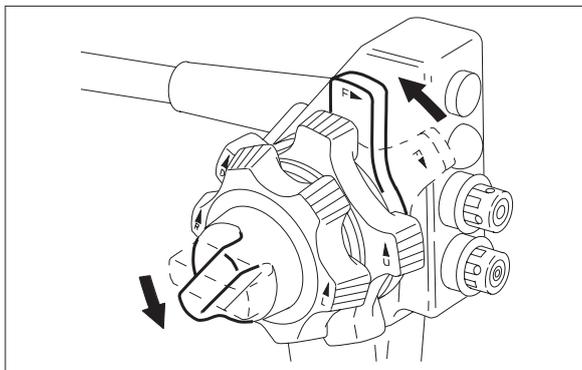


- (2) Turn the up-down angle knob and left-right angle knob in the U, D, L and R directions until they stop. Check that the bending portion turns smoothly.

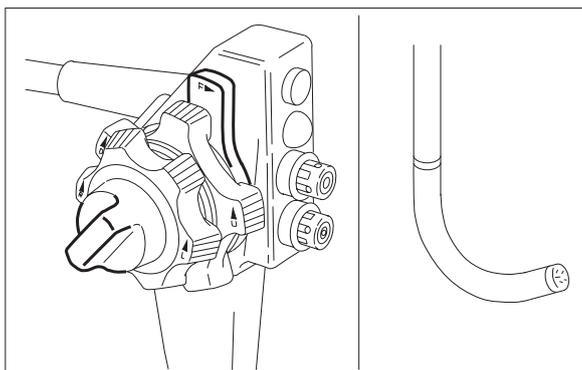
Check that releasing the knobs unbends the bending portion a little.



- (3) Turn the up-down locking lever and left-right locking knob in the direction opposite to F ►, and then lock them.

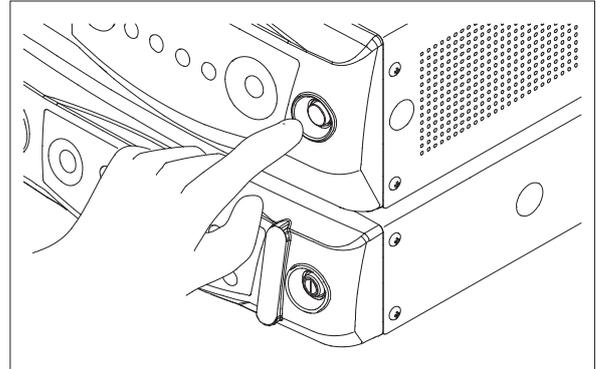


- (4) Turn the angle knobs in similar manner as in step (2), and check how the bending portion bends. Here, the angle knobs should feel a little heavier than in step (2). Check that bending portion retains its bent state after the angle knobs are released.



5.4.3 Inspecting Air/Water Supply Channel, Suction Channel, Forceps Channel and Balloon Air feed Inlet

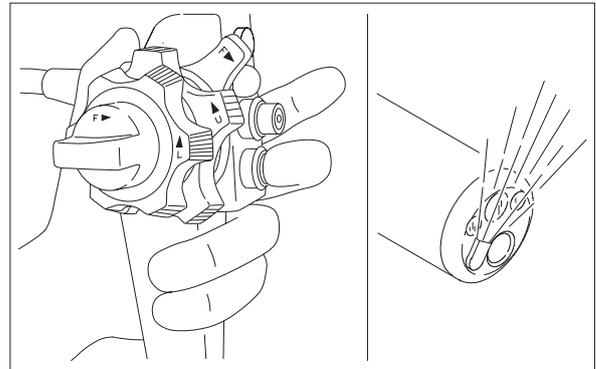
- (1) Turn on the power of the suction unit, cart and processor.
Keep the lamp off.
- (2) Prepare a cup of sterile water.



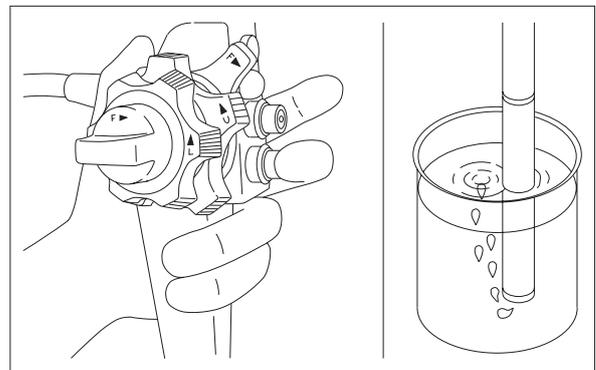
- (3) With the distal end of the endoscope held in the air, press the air/water button completely. Check that water is discharged from the balloon water port.

[Note]

Note that the direction that water comes out.



- (4) Immerse the distal end of the endoscope in water, cover the hole at the center of the air/water button with your finger, and then check that air comes out of the nozzle. Release the finger from the hole and check that air does not leak from the nozzle.



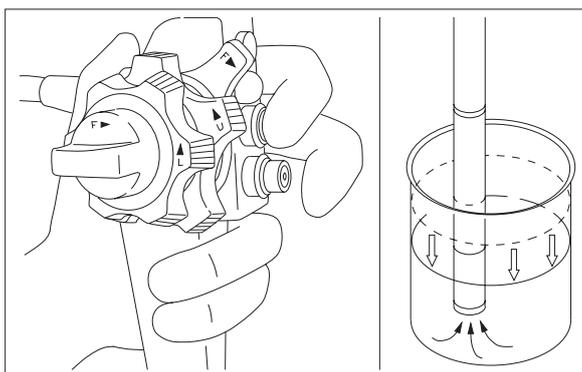
- (5) While immersing the distal end of the endoscope in water, check that the water is sucked in when the suction button is pressed and the suction stops when the finger is released from the button.

[Note]

Visually check that the forceps valve has been properly attached to the forceps inlet of the endoscope.

[Note]

Do not use the forceps valve after its expiration date has elapsed.



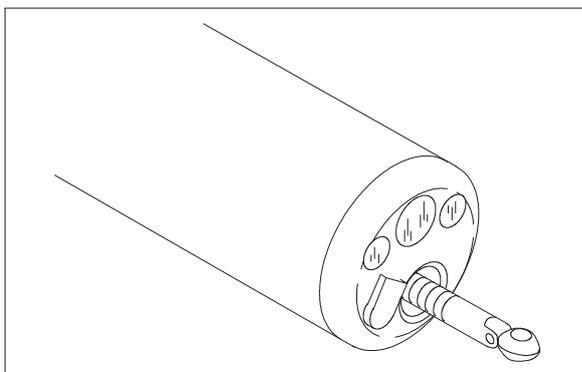
- (6) Insert an endotherapy device from the forceps inlet and check that the tip of the endotherapy device projects smoothly from the forceps channel of the distal end.

[Note]

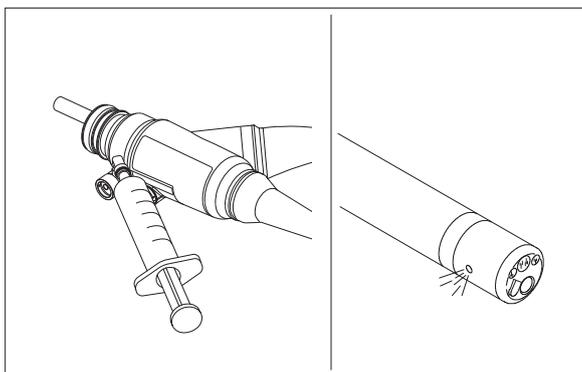
Visually check that the forceps valve has been properly attached to the forceps inlet of the endoscope.

[Note]

Do not use the forceps valve after its expiration date has elapsed.



- (7) Feed air from the balloon air inlet using a syringe, and make sure that air comes out from the balloon air feed outlet.



5.4.4 Inspecting Distal End

! CAUTION

Turn off the light before inspecting the lens.
Viewing the light of light guide directly may damage your eyes.

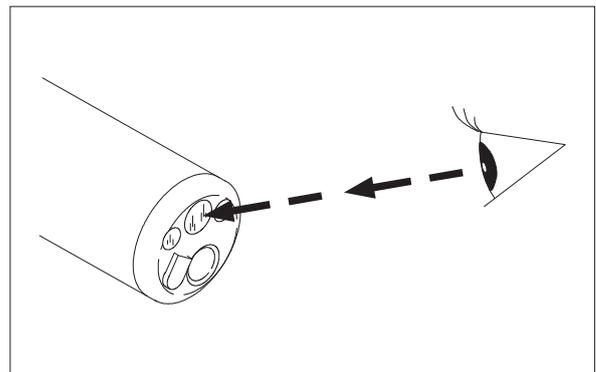
- (1) Turn OFF the lamp.

Look at the distal end of the endoscope at an angle and check that the objective lens and light guide are free of dirt or foreign matter.

[Note]

Check that the objective lens and its surrounding area are free from cracks. In addition, check the following points.

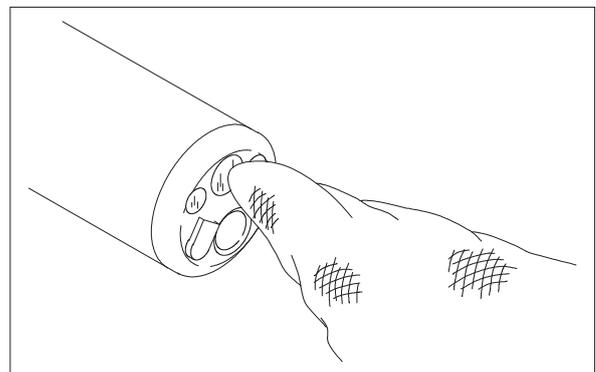
- The side surface of the distal end is free from scratches, peeling and abnormal bulging.
- The light guides are free from cracks, and are securely fixed.
- The air/water nozzle is free from cracks, and is securely fixed.



- (2) If any dirt or foreign matter adheres to the lens, clean it off.

[Note]

To clean the lens, wipe it lightly with gauze or similarly soft cloth soaked with lens cleaner or ethanol.



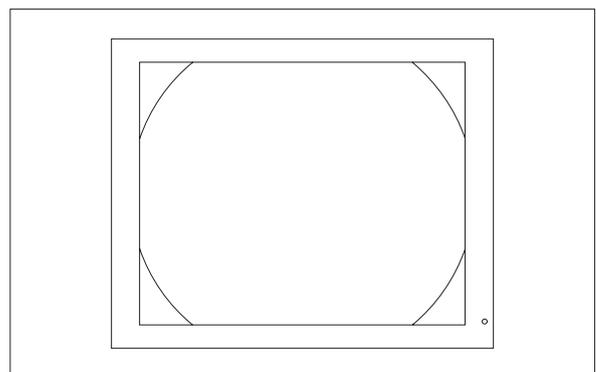
- (3) To clean the lens, wipe it lightly with gauze or similarly soft cloth soaked with lens cleaner or ethanol.

[Note]

If the objective lens is still fogged even after wiping with gauze, the air leak of the endoscope is insufficient.

Run an air leak test with an air leak tester LT-7.

→ “7.4.2 Air Tightness Test” in Operation Manual (Cleaning, Disinfection and Storage)



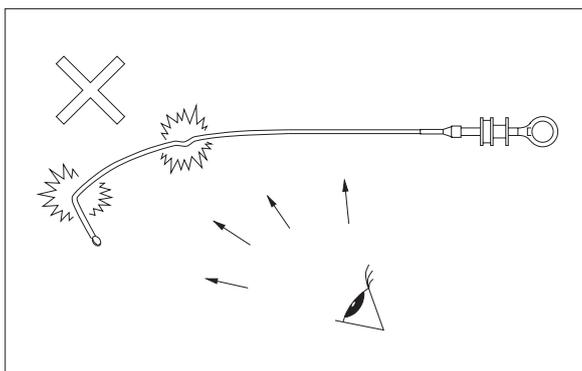
5.5 Inspecting Forceps

CAUTION

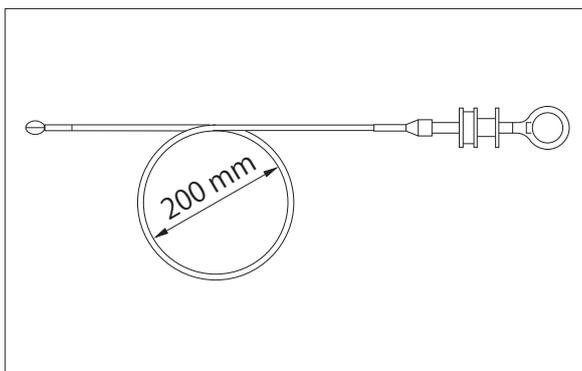
Do not bend forceps with a curvature radius of 10 mm or less.
Bending forceps with a small curvature may break it.

- (1) Inspect the operation of the forceps.

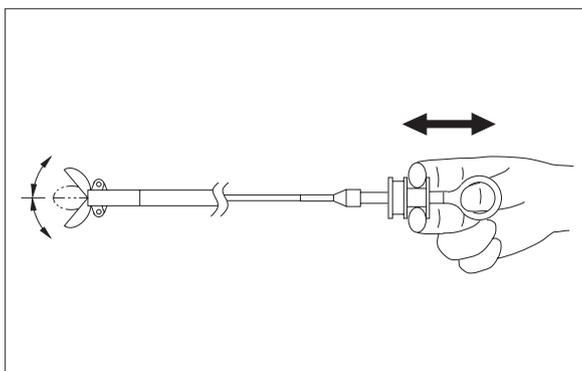
Visually check the forceps for breakage or significant bends, and for sharp edges on protrusions that may injure the patient.



- (2) Form the spring of the forceps into a double ring approximately 200 mm in diameter, as shown in the figure.



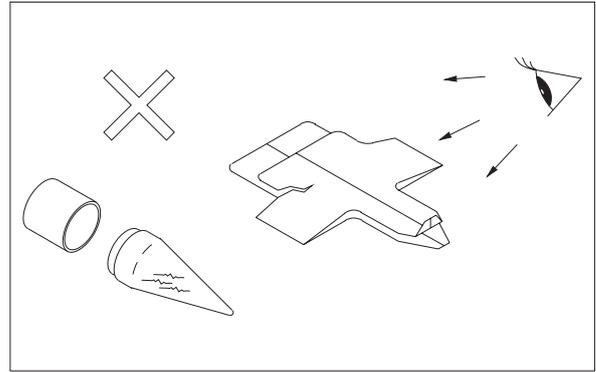
- (3) Operate the handle of the forceps and check that their tips open and close.



5.6 Inspecting Setting Tools ST-01B and ST-05B

Do not use the setting tools (ST-01B and ST-05B) for purposes other than mounting the balloon.

Check that the exterior of the setting tools (ST-01B and ST-05B) is free from defects such as damage and folding.



5.7 Attaching and Inspecting Over-tube and Balloon

⚠ WARNING

Use a sterilized balloon installation tool. Do not use the balloon or Over-tube after its expiration date has elapsed.

There is a risk of infection.

Do not use Over-tubes and balloons on patients allergic to latex.

There is a risk of an anaphylactic reaction/shock.

CAUTION

When attaching a balloon, take care not to apply excessive force to the endoscope.

The endoscope may be damaged.

[Note] Make sure water never enters the air feed inlet (clear tube) of the Over-tube. If water enters the air feed inlet, deflate the balloon using a syringe, and then slowly pull out the Over-tube along with the endoscope.

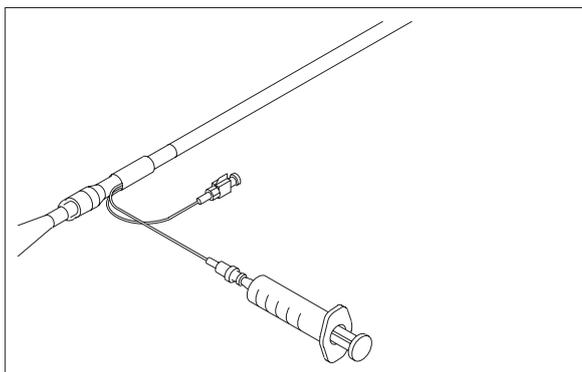
5.7.1 Attaching Over-tube

[Note] Use the Over-tube (TS-13140) applicable to this product.

- (1) Moisten the inside of Over-tube by injecting sterile water into the water feed inlet (blue tube) using a syringe.
- (2) Insert the endoscope from the endoscope insertion inlet of the Over-tube to the proximal end of the flexible portion.

[Note]

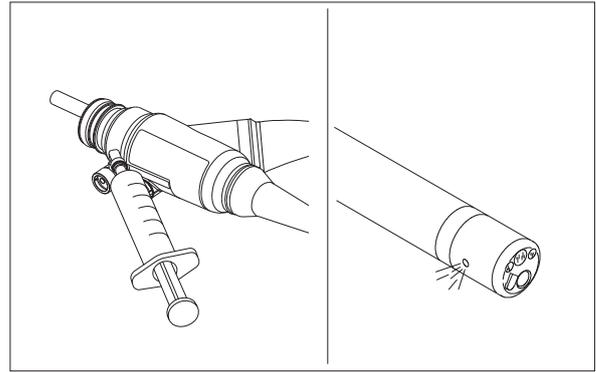
If the endoscope and Over-tube do not slide smoothly, inject sterile water into the water feed inlet using a syringe.



- (3) Feed air from the balloon air feed inlet several times and let air come out from the balloon air feed outlet.

[Note]

Discharge water completely to remove moisture from inside the channel.



5.7.2 Mounting Endoscope Balloon

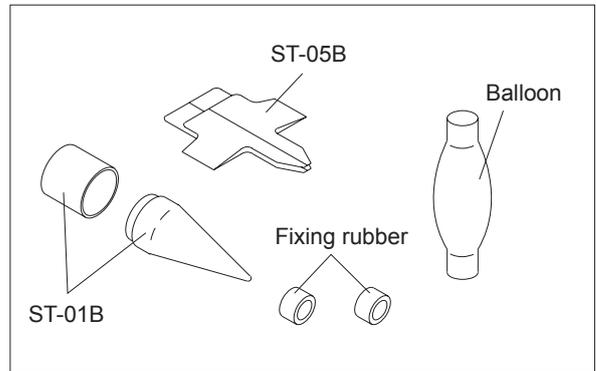
[Note]

Use the balloon (BS-1 or BS-2) applicable to this product.

- (1) Prepare the balloon, setting tools (ST-01B and ST-05B) and fixing rubber.

ST-01B : Fixing rubber setting tool

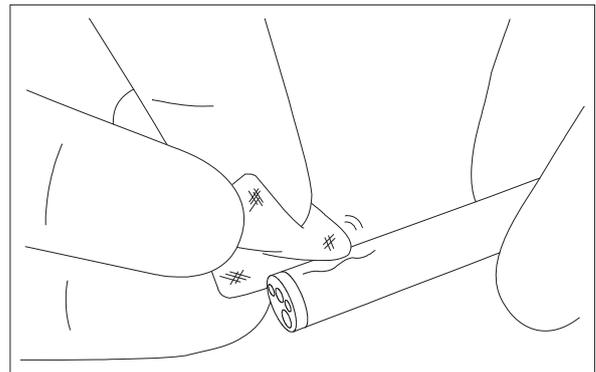
ST-05B : Balloon setting tool



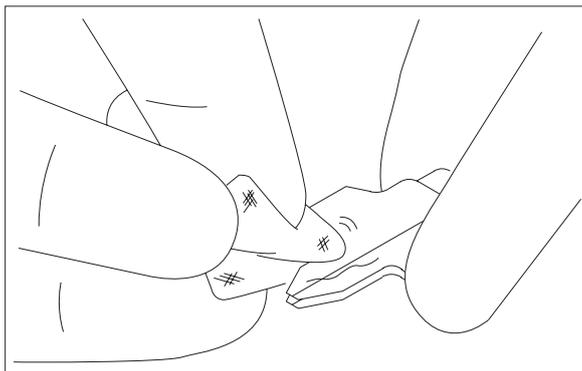
[Note]

Do not use the balloon after its expiration date has elapsed.

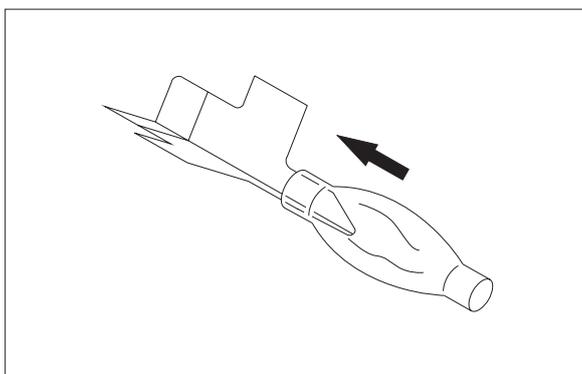
- (2) Check that the tip of the endoscope is free of dirt.
Apply a small amount of 70% ethanol solution to the tip of the endoscope.



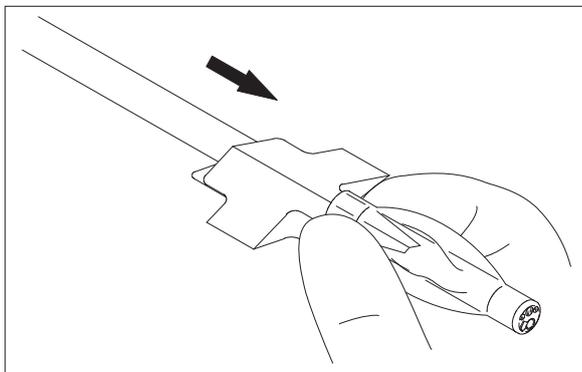
- (3) Apply a small amount of 70% ethanol solution to the outside of the setting tool (ST-05B).



- (4) Put the balloon on the setting tool (ST-05B).



- (5) Insert the distal end of the endoscope into the setting tool (ST-05B) and form the balloon so as not to be twisted.

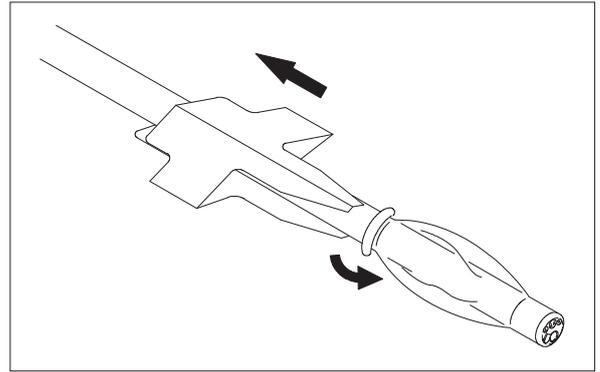


- (6) Roll up the edge of the balloon, and slide the setting tool (ST-05B) toward the control portion of the endoscope to mount the balloon on the endoscope.

Return the edge of the balloon to the original form.

[Note]

Make the ethanol inside the balloon evaporate by widening the end of the balloon.



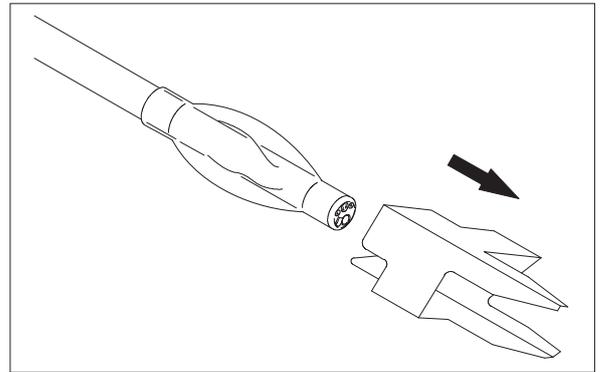
[Note]

Handle the setting tool (ST-05B) without applying an excessive force to it.

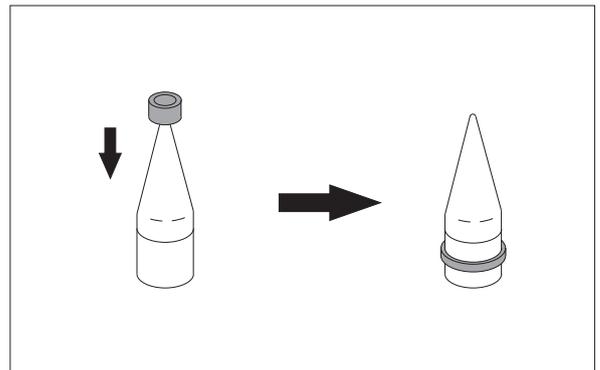
- (7) Extract the air in the balloon and remove the setting tool (ST-05B).

[Note]

Dispose of the setting tool (ST-05B) after use.



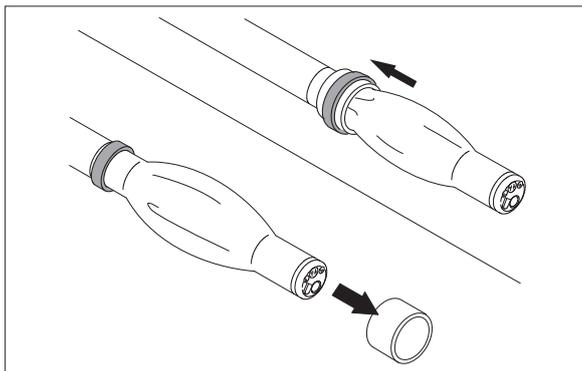
- (8) Press the fixing rubber into the mounting fixture (ST-01B).



- (9) Slide the fixing rubber down from the mounting fixture (ST-01B) to the end of the balloon on the curved section side.

When using a hood, attach a hood by following the procedure described in “5.7.3 Attaching Hood.”

→ “5.7.3 Attaching Hood”

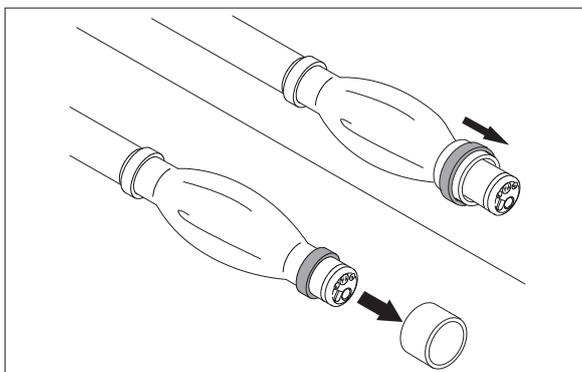


<When a hood is not used>

- (10) Slide the fixing rubber to the end of the balloon as in step (9).

[Note]

Carefully attach the fixing rubber so as not to cover the balloon air feed outlet.



5.7.3 Attaching Hood (Only When Necessary)

Attach a hood to hold the endoscope in an appropriate position for close-up observation during an examination.

! CAUTION

Do not press the hood against the digestive tract wall with undue force.
It may damage mucous membrane.

Fix the hood securely to the endoscope before use.
Otherwise, the hood may drop.

CAUTION

Do not grasp the bending portion forcefully when attaching or removing the hood.
It may damage the endoscope.

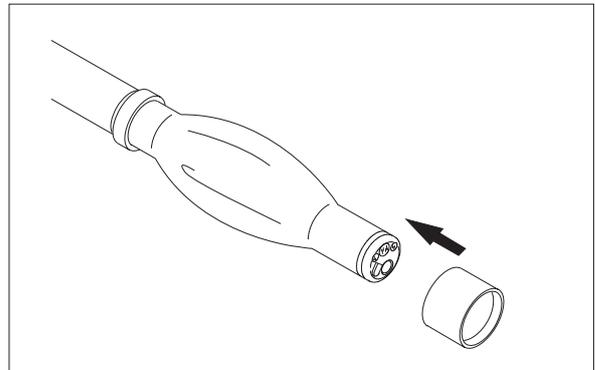
(1) Attach the balloon by following steps (1) to (9) in “5.7.2 Mounting Endoscope Balloon.”

(2) Attach a hood (DH-17EN) onto the distal end of endoscope.

Insert the endoscope until it reaches the end of the hood.

[Note]

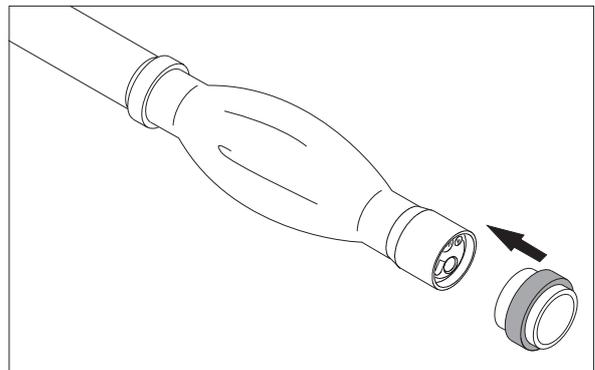
Attach a hood onto the dry distal end of endoscope.



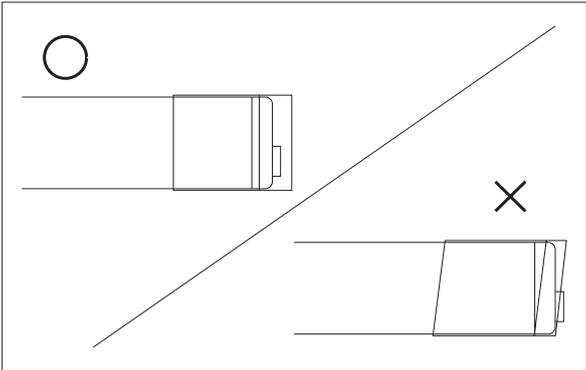
(3) Attach the fixing rubber onto the hood using the setting tool (ST-01B).

[Note]

Carefully attach the fixing rubber so as not to cover the balloon air feed outlet.

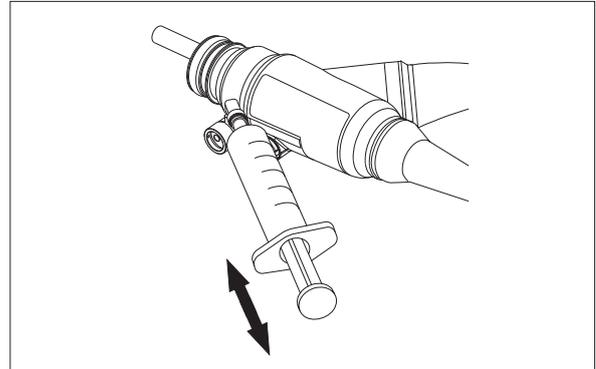


(4) Make sure the hood is fixed correctly.

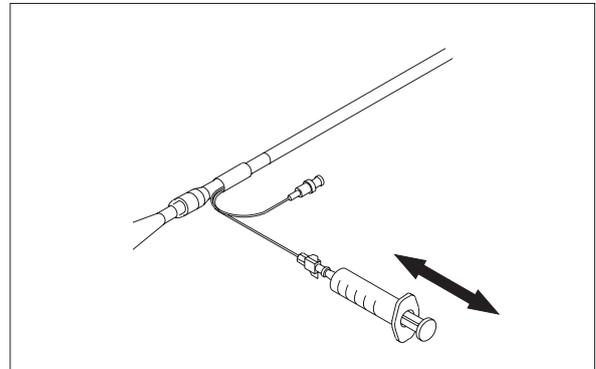


5.8 Inspecting Balloon

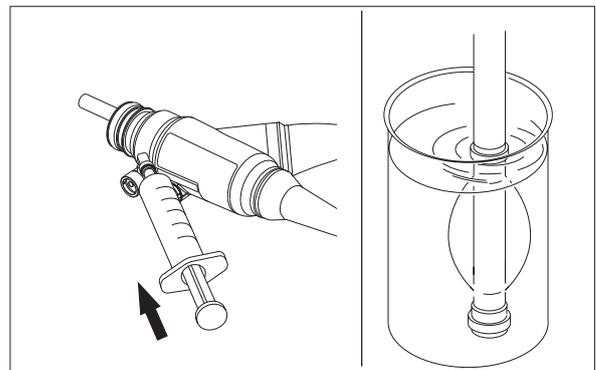
- (1) Supply air into the balloon air feed inlet to make sure that the balloon attached to the endoscope inflates.
- (2) Remove air from the balloon air feed inlet to make sure that the balloon deflates.



- (3) Supply air into the air feed inlet of the Over-tube to make sure that the balloon attached to the distal end of Over-tube inflates.
- (4) Remove air from the air feed inlet of the Over-tube to make sure that the balloon deflates.



- (5) Immerse the distal end of the endoscope into water and, by feeding air from the balloon air feed inlet using a syringe, make sure that there is no air leakage.
- (6) Immerse the tip of the Over-tube into water and, by feeding air from the air feed inlet of the Over-tube to make sure that there is no air leakage.



5.9 Connecting Balloon Controller

⚠ CAUTION

Connect the endoscope and the Over-tube to the balloon controller properly. Before insertion, make sure that the balloon operates as intended.

Otherwise, it may cause an injury.

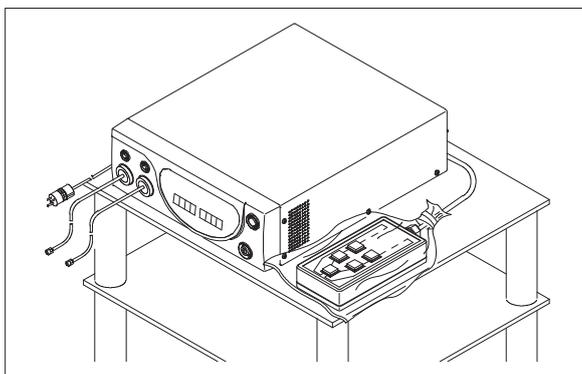
[Note] This endoscope cannot be connected to the balloon controller PB-10.

5.9.1 Connecting Balloon Controller

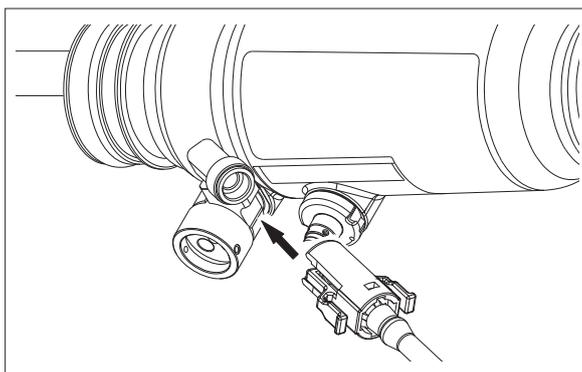
- (1) Install the balloon controller referring to the operation manual of the balloon controller.

Connect the tube kit as follows.

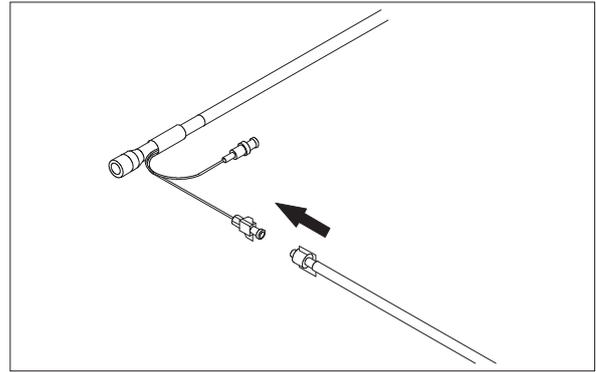
Balloon controller	Applicable tube
Tube connector 2 (endoscope side)	Attached tube kit TY-06S
Tube connector 1 (Over-tube side)	Tube 1 (white tube) of tube kit TY-04



- (2) Securely insert the endoscope-side connector of the tube kit (TY-06S) into the balloon air feed inlet of the endoscope.

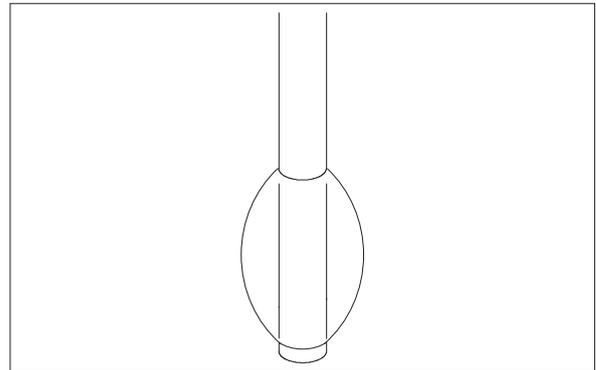


- (3) Connect the tube 1 (white tube) of the balloon controller to the air feed inlet (clear tube) of the Over-tube.



5.9.2 Inspecting Balloon (Balloon Controller)

- (1) Make sure that the "SCOPE" side connector of the balloon controller is connected to the balloon air feed inlet of the endoscope, and the "OVERTUBE" side connector of the balloon controller is connected to the air feed inlet of the Over-tube.
- (2) Press the endoscope-side switch on the balloon controller, and then make sure that the balloon attached to the distal end of endoscope inflates.



- (3) Press the switch again, and then make sure that the balloon deflates.
- (4) Press the Over-tube-side switch on the balloon controller, and then make sure that the balloon attached to the distal end of Over-tube inflates.
- (5) Press the switch again, and then make sure that the balloon deflates.

Chapter 6 Method of Use

This chapter outlines how to operate of the equipment, according to the general procedures.

Regarding clinical procedures, use proper clinical judgment.

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Chapter 6 Method of Use

WARNING

Wear personal protective equipment when using the endoscope.
There is a risk of infection.

Be sure to attach a balloon and Over-tube when using the endoscope.
If not attached, body fluid may flow back and it could be a source of infection.

Wear personal protective equipment when removing Over-tubes, balloons or hoods.
There is a risk of infection.

Do not use Over-tubes and balloons on patients allergic to latex.
There is a risk of an anaphylactic reaction/shock.

Do not supply excessive amount of air or gas during the procedure.
It may result in perforation or rupture of digestive tract wall.

Do not supply an excessive amount of air or gas during electrosurgery.
It could cause an embolism.

[Note] Always observe the patient closely. If the patient has symptoms suggestive of an embolism, discontinue the endoscopic procedure immediately and give proper treatment to him/her.

CAUTION

Do not bend the insertion portion near the control portion in a small radius.
It may cause the endoscope to malfunction.

When inserting the endoscope into or withdrawing it from the body, deflate the balloon in advance.
The balloon may burst.

When removing a balloon, take care not to apply excessive force to the endoscope.
It may damage the endoscope.

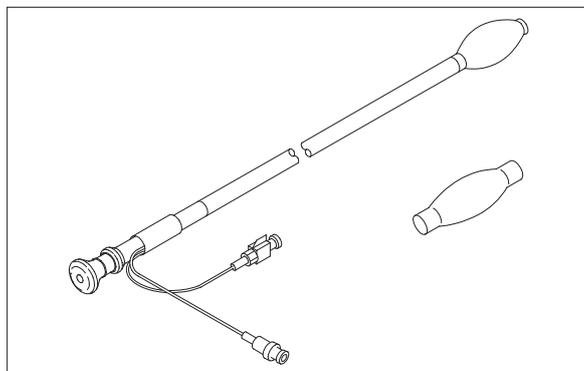
[Note] Check the status of the balloon by fluoroscopy.

[Note] Use the FUJIFILM-specified balloon controller to operate balloons.

6.1 Preparation

6.1.1 Preparing Necessary Equipment

Prepare the accessories, endotherapy devices, etc. to be used.



6.1.2 Pre-treatment of Patient

Use pretreatment that suits the purpose of examination.

6.2 Insertion and Observation

WARNING

Do not bend the endoscope quickly.
There is a risk of damaging the inside of the body cavity.

Do not inflate the balloon in the pharynx or esophagus.
There is a risk of suffocation.

Insert and withdraw the endoscope or Over-tube slowly. Do not press the endoscope or Over-tube strongly onto the walls of the digestive tract. Do not insert or withdraw the endoscope or Over-tube with the balloon inflated. Make sure water never enters the air feed inlet (clear tube) of the Over-tube.

It may damage to the walls of the digestive tract, causing perforation.

Use of devices such as endoscopic/enteroscopy overtubes may be associated with potential complications including but not limited to mucosal trauma, pancreatitis and/or hyperamylasemia. Users are encouraged to closely monitor patients for such complications during and after procedures and to appropriately treat patients as required.

[Note] If any resistance is felt, stop use immediately.

When using this product, check the status of the balloon, Over-tube and endoscope by fluoroscopy.

[Note] If water enters the air feed inlet of the Over-tube, deflate the balloon using a syringe, and then slowly withdraw the Over-tube along with the endoscope.

CAUTION

Do not allow the distal end to touch the same part for 5 minutes or more.

Heat from the light may cause a burn.

Do not look at the light emitted from the light guide directly.
There is a risk of damaging eyes.

If parts fall into a body cavity due to the malfunction of the device, immediately stop the examination and retrieve the parts by following appropriate measures.

There is a risk of damaging the inside of the body cavity.

[Note] Do not inflate the balloon around the duodenal papilla. It may trigger complications.

[Note] In cases where the amount of bleeding is large, patient's blood may adhere to the light guide and clot. In such cases, use the light save function of light source. For details on how to use the light save function, refer to the operation manual of the light source.

CAUTION

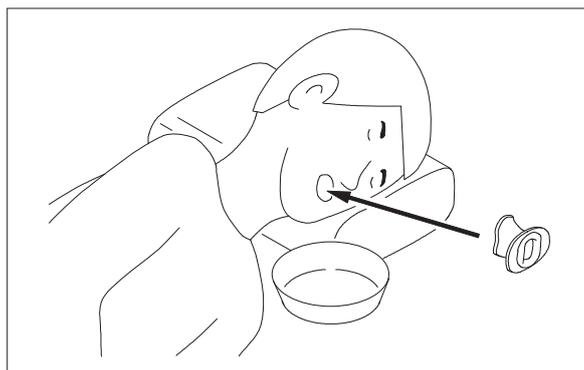
Do not directly apply Xylocaine spray to the insertion portion.
It may cause deterioration of the outer surface.

Do not use olive oil as a lubricant for insertion.
It may cause swelling on the outer surface.

The method described in this operation manual is only an example. Regarding clinical procedures, use proper clinical judgment.

6.2.1 Peroral Insertion

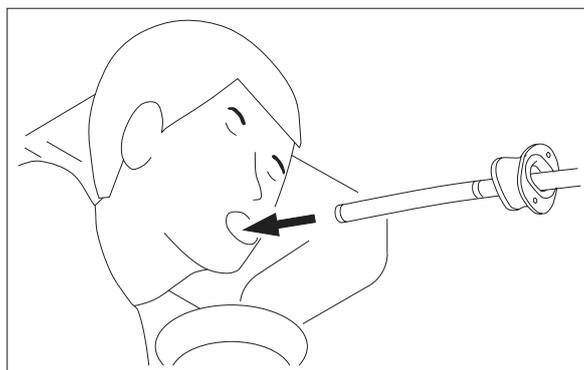
- (1) Instruct the patient to take an appropriate position for the insertion procedure.
- (2) Have the patient hold the mouthpiece in his/her mouth.



[Note]

If you choose to have the patient hold the mouthpiece after insertion, attach the mouthpiece to the insertion portion in advance.

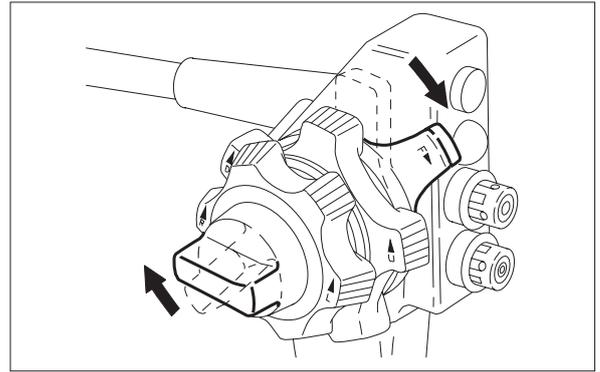
Have the patient hold it promptly after insertion.



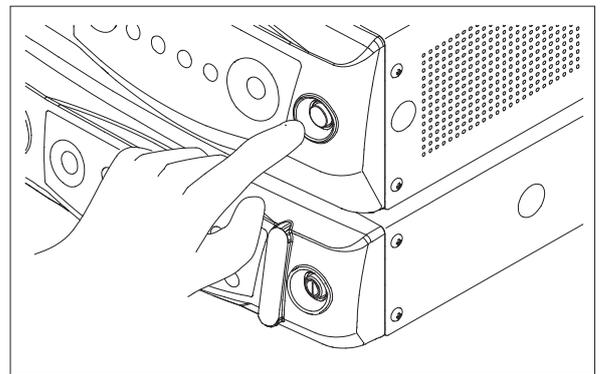
- (3) Unlock the bending portion by turning the up-down locking lever and the left-right locking knob in the direction of F ► until they stop.

[Note]

Another procedure is also available: you can insert the endoscope by locking the bending portion only in the left-right direction and unlocking it in the up-down direction.



- (4) Switch on the power to the processor and turn on the lamp.

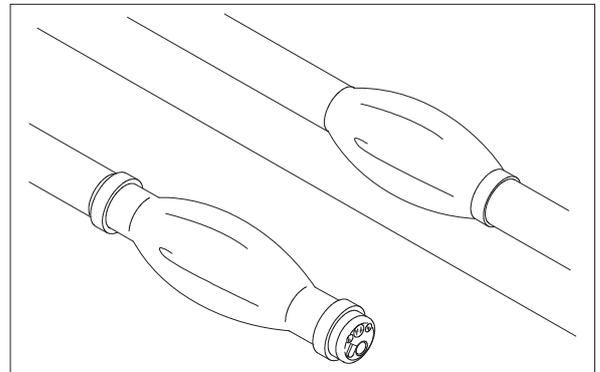


- (5) Deflate the balloon on the distal end of endoscope and the balloon on the Over-tube.

Apply clean lubricant (Xylocaine jelly or the like) to the insertion portion as required.

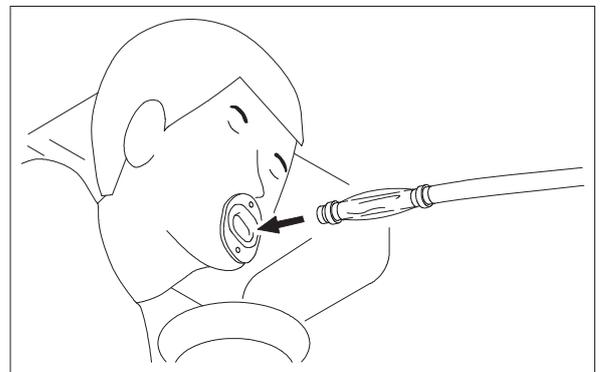
[Note]

Do not apply Xylocaine spray, olive oil or the like directly to the insertion portion.

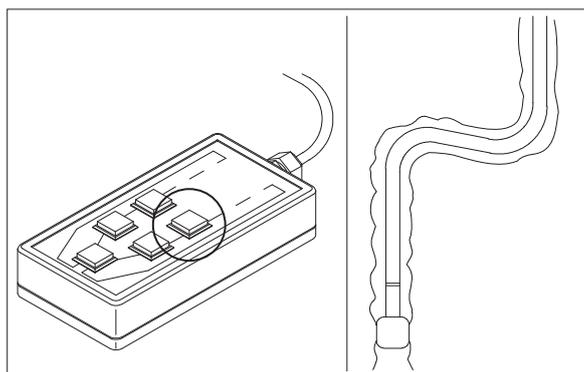


- (6) Insert the distal end of the endoscope from the oral cavity to the pharynx, while observing the process.

Adjust the brightness with the level button on the light source.



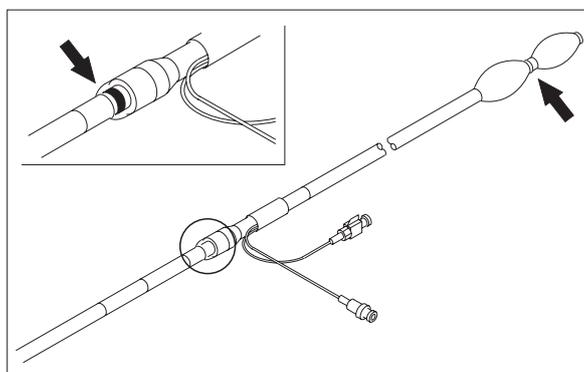
- (7) Feed air to inflate the balloon on the distal end of the endoscope, and stabilize it within the enteric canal.



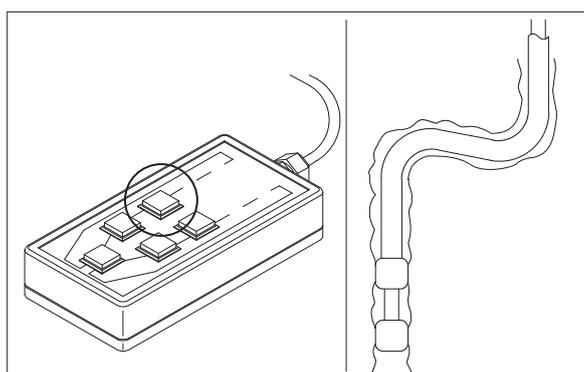
- (8) Insert the Over-tube into the body cavity along the endoscope to a point close to the balloon on the distal end of the endoscope.

[Note]

There is a thick line (indicator) on the insertion portion of the endoscope. When the Over-tube is inserted into the body or the endoscope is pulled out from this position, the tip of the Over-tube touches the balloon.

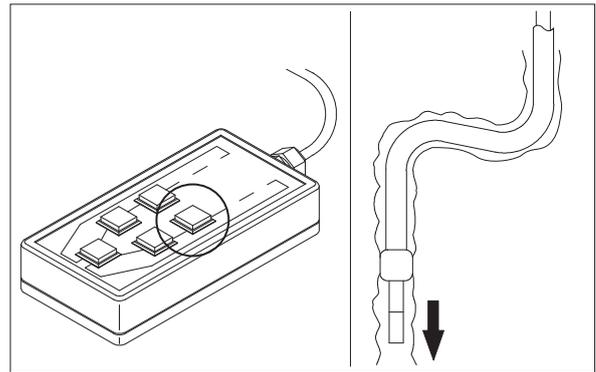


- (9) Feed air to inflate the balloon on the Over-tube, and stabilize it within the body cavity (small intestine).

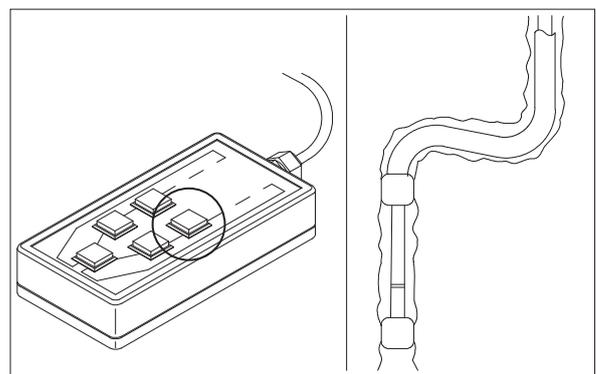


(10) Remove air to deflate the balloon on the distal end of the endoscope.

(11) Insert the endoscope.

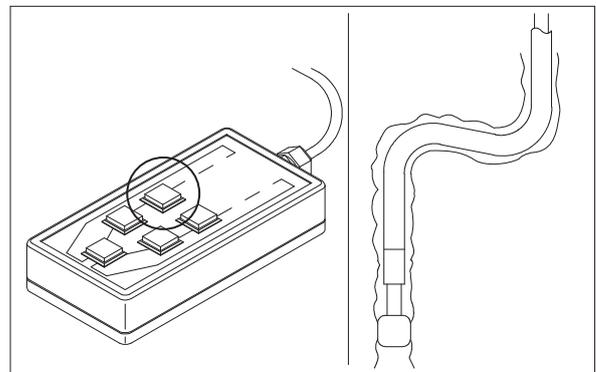


(12) Feed air to inflate the balloon on the distal end of the endoscope, and stabilize it within the body cavity.



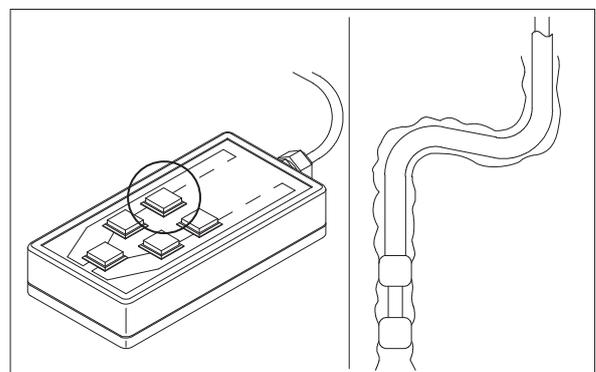
(13) Remove air to deflate the balloon on the Over-tube.

(14) Advance the Over-tube over the endoscope to a point close to the balloon on the distal end of the endoscope.

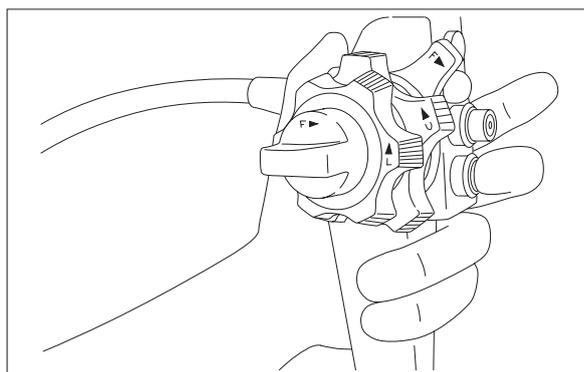


(15) Feed air to inflate the balloon on the Over-tube, and stabilize it within the body cavity.

(16) Repeat steps (10) through (15) to advance the endoscope.



- (17) Stop the center hole in the air/water button with a finger to supply air to the digestive tract.
The mucous membrane of the digestive tract will become clearly visible.



- (18) Steer the distal end of the endoscope to the region of interest by turning the up-down and left-right angle knobs.

[Note]

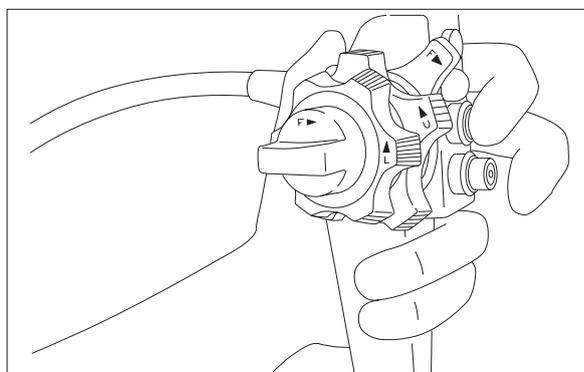
In case that the bending portion does not return or cannot be pulled out easily because it is inverted inside the narrow lumen, do not pull it out forcibly.

<When sucking mucus>

To suck mucus, insert the distal end of the endoscope in the mucous lake and press the suction button.

[Note]

Do not suck in solid or viscous materials with the endoscope. Such material may clog the suction pipe line or stick to the suction button preventing proper stopping of suction.

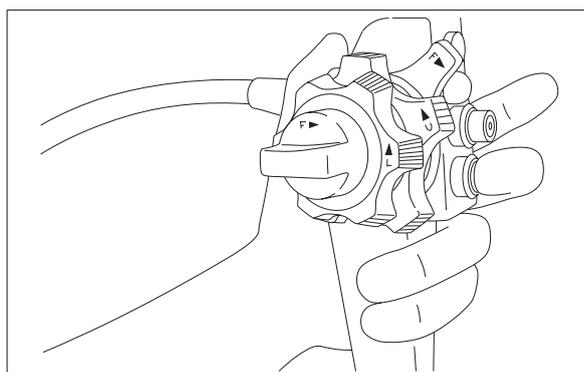


<If the surface of the lens is fogged with mucus or if the image is obscured>

Clean the lens surface by pressing the air/water button. After completing the cleaning, remove water from the lens surface by supplying air and sucking off the water.

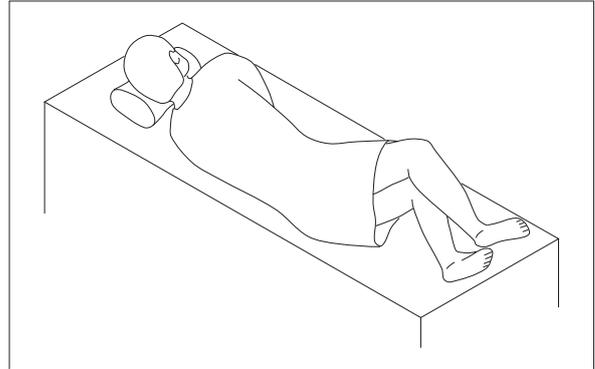
[Note]

If the image does not return to normal, repeat cleaning of the lens surface and removal of water from the lens surface.



6.2.2 Transanal Insertion

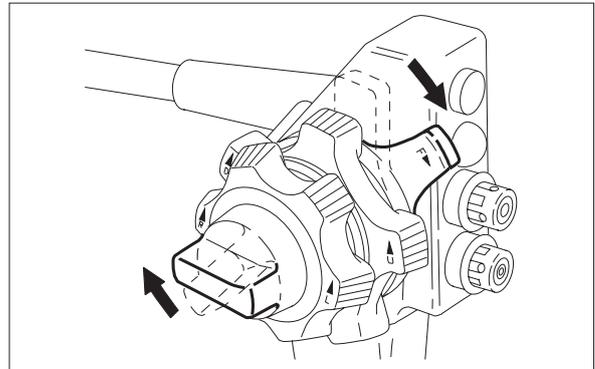
- (1) Instruct the patient to take an appropriate position for the insertion procedure.



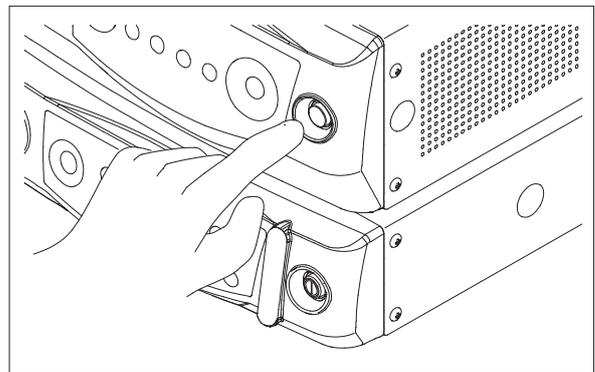
- (2) Unlock the bending portion by turning the up-down locking lever and the left-right locking knob in the direction of F ► until they stop.

[Note]

Another procedure is also available: you can insert the endoscope by locking the bending portion only in the left-right direction and unlocking it in the up-down direction.



- (3) Switch on the power to the processor and turn on the lamp.

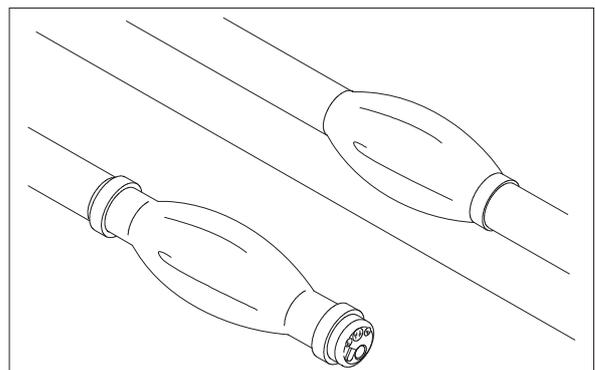


- (4) Remove air from the balloon on the distal end of the endoscope and the balloon on the overtube.

Apply clean lubricant (Xylocaine jelly or the like) to the insertion portion as required.

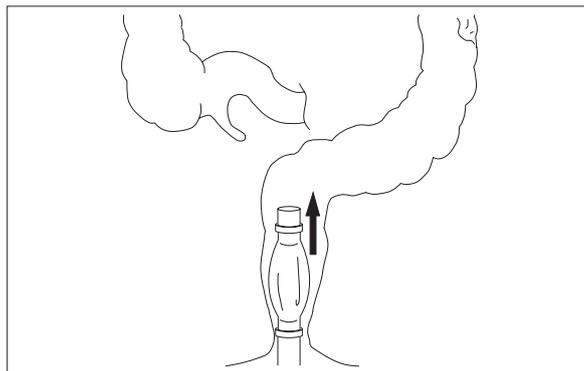
[Note]

Do not apply Xylocaine spray, olive oil or the like directly to the insertion portion.

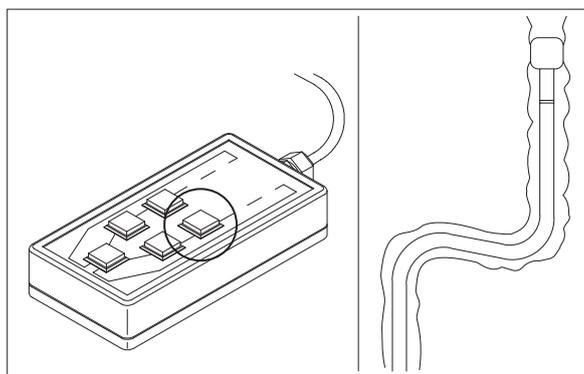


- (5) Insert the distal end of the endoscope from the anus to the rectum while observing them.

Adjust the brightness with the level button on the light source.



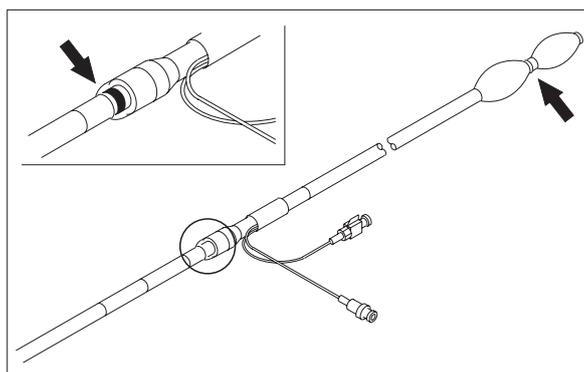
- (6) Feed air to inflate the balloon on the distal end of the endoscope, and stabilize it within the enteric canal.



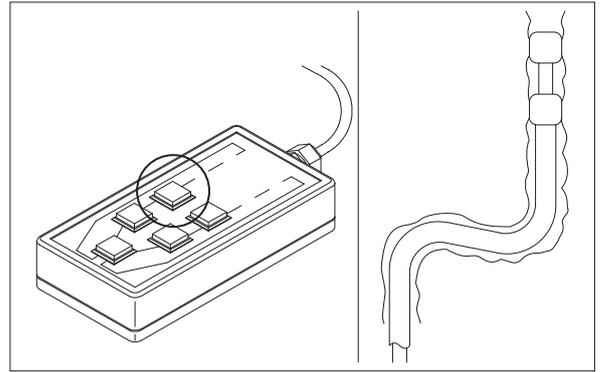
- (7) Insert the Over-tube into the body cavity along the endoscope to a point close to the balloon on the distal end of the endoscope.

[Note]

There is a thick line (indicator) on the insertion portion of the endoscope. When the Over-tube is inserted into the body or the endoscope is pulled out from this position, the tip of the Over-tube touches the balloon.

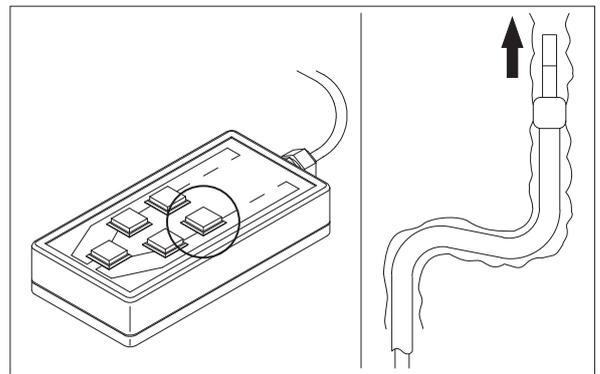


- (8) Feed air to inflate the balloon on the Over-tube, and stabilize it within the body cavity (small intestine).

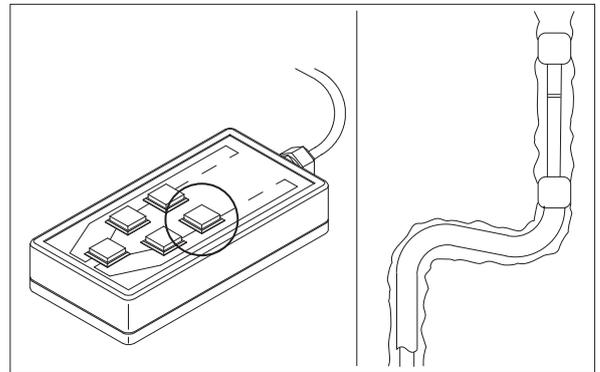


- (9) Remove air to deflate the balloon on the distal end of the endoscope.

- (10) Insert the endoscope.

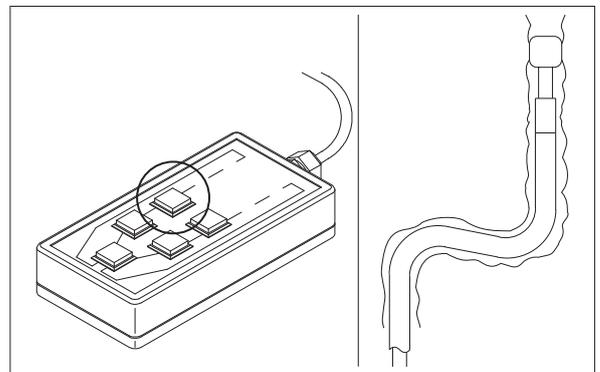


- (11) Feed air to inflate the balloon on the distal end of the endoscope, and stabilize it within the body cavity.



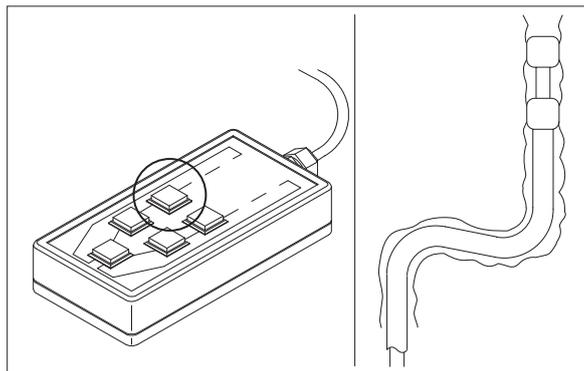
- (12) Remove air to deflate the balloon on the Over-tube.

- (13) Advance the Over-tube over the endoscope to a point close to the balloon on the distal end of the endoscope.



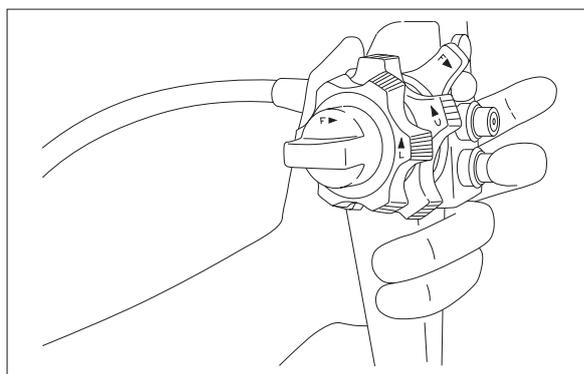
(14) Feed air to inflate the balloon on the Over-tube, and stabilize it within the body cavity.

(15) Repeat steps (9) through (14) to advance the endoscope.



(16) Stop the center hole in the air/water button with a finger to supply air to the digestive tract.

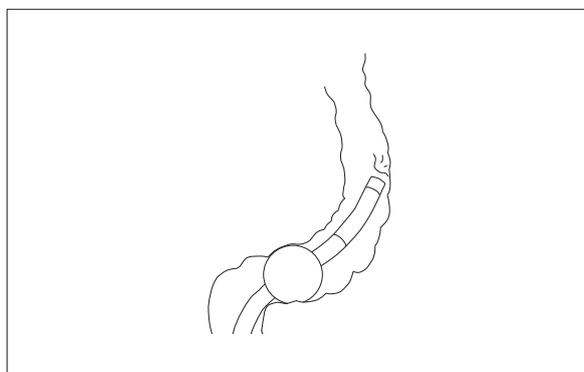
The mucous membrane of the digestive tract will become clearly visible.



(17) Steer the distal end of the endoscope to the region of interest by turning the up-down and left-right angle knobs.

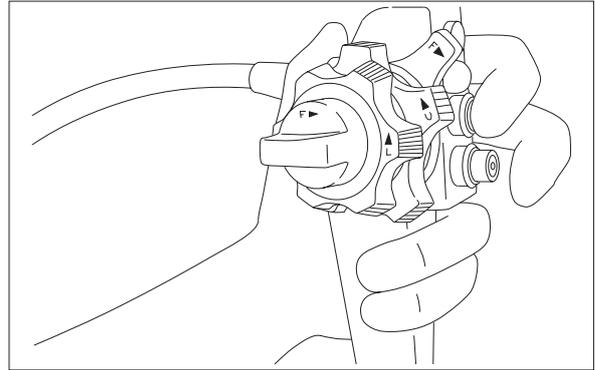
[Note]

In case that the bending portion does not return or cannot be pulled out easily because it is inverted inside the narrow lumen, do not pull it out forcibly.



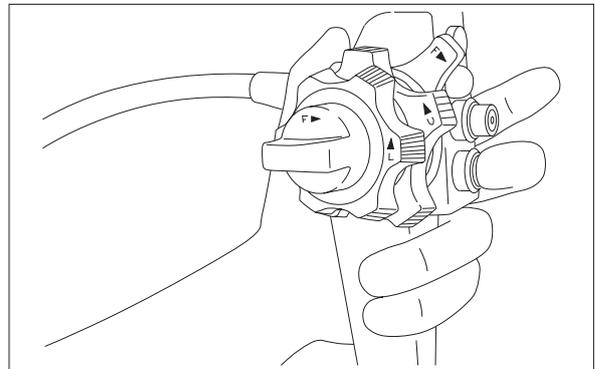
<When sucking mucus>

To suck mucus, insert the distal end of the endoscope in the mucous lake and press the suction button.



<If the surface of the lens is fogged with mucus or if the image is obscured>

Clean the lens surface by pressing the air/water button. After completing the cleaning, remove water from the lens surface by supplying air and sucking off the water.



6.3 Biopsy

! WARNING

Do not insert an endotherapy device if you cannot see the forceps outlet on the endoscopic image.

There is a risk of perforation and bleeding.

Slowly insert an endotherapy device straight into the forceps inlet of the endoscope. Also, when withdrawing it, slowly pull straight out. In addition, slowly attach or remove a syringe, etc. straight to/from the forceps inlet.

If inserted or pulled out obliquely to the forceps inlet, the frictional resistance will increase and body fluid may be splattered around due to breakage or accidental detachment of the forceps valve, leading to infection.

Do not strongly press an endotherapy device against the digestive tract wall.

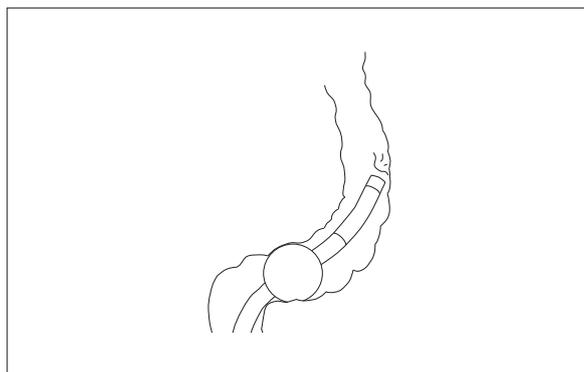
There is a risk of perforation and bleeding.

CAUTION

If resistance is encountered while advancing a forceps (or endotherapy device) within the forceps channel, stop and withdraw the forceps (or endotherapy device). Repeat again, but do not apply excessive force to avoid damaging the endoscope.

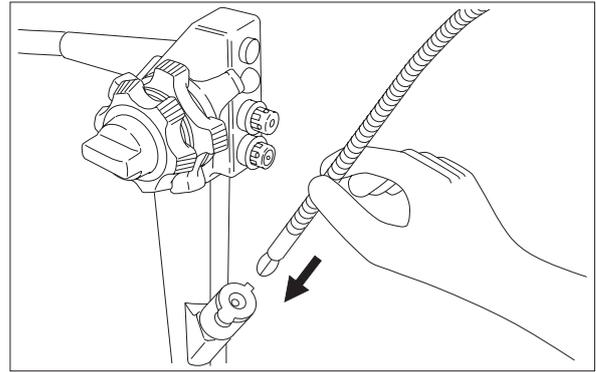
[Note] An endotherapy device may not pass through the bending portion smoothly. In such a case, slightly unbend the bending portion and try to insert it again.

- (1) Steer the distal end of the endoscope to the site.

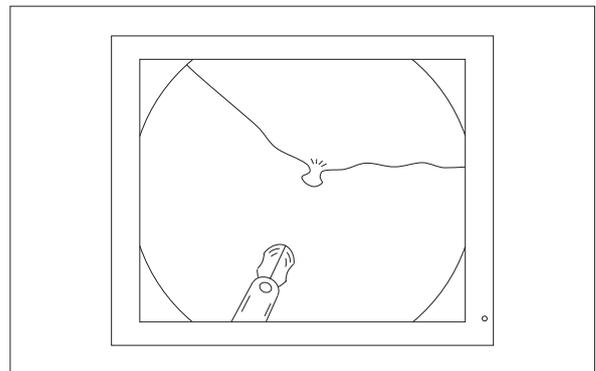


- (2) Check the opening and closing of the forceps.

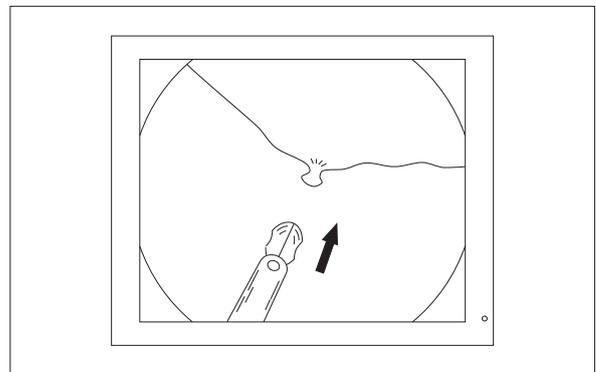
Slowly insert the forceps straight into the forceps inlet while observing the image.



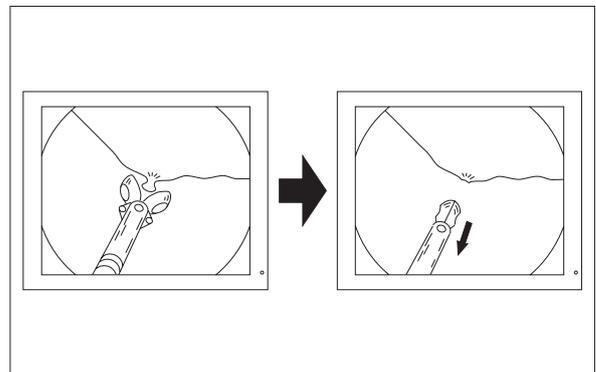
- (3) Stop the insertion of the forceps when its tip appears on the field of view.



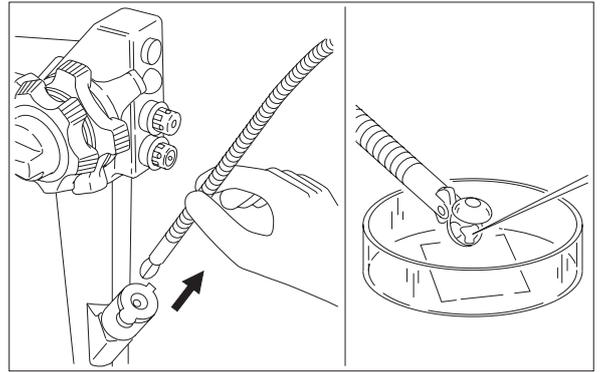
- (4) Slowly move the forceps to the site.



- (5) Perform a biopsy by controlling the forceps and the angle knobs.

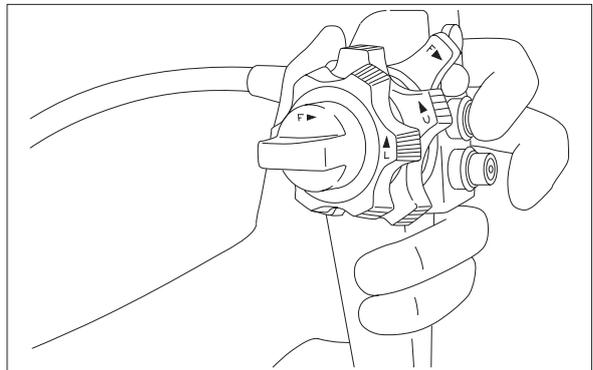


- (6) Slowly pull the forceps straight out of the forceps valve and take out the biopsy specimen.

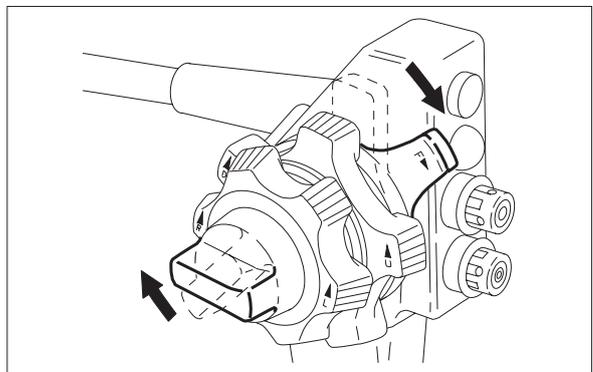


6.4 Withdrawal

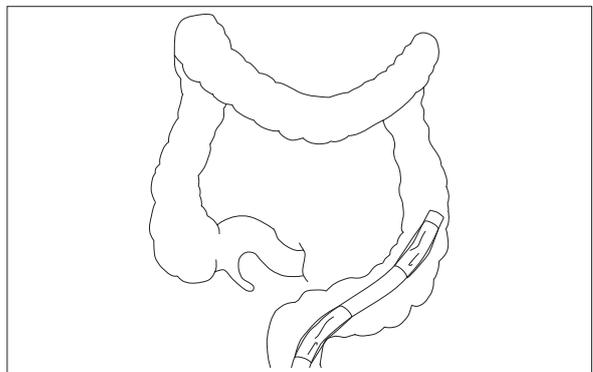
- (1) When the examination is over, remove any excessive air from the body cavity.



- (2) Unlock the up-down and left-right knobs.



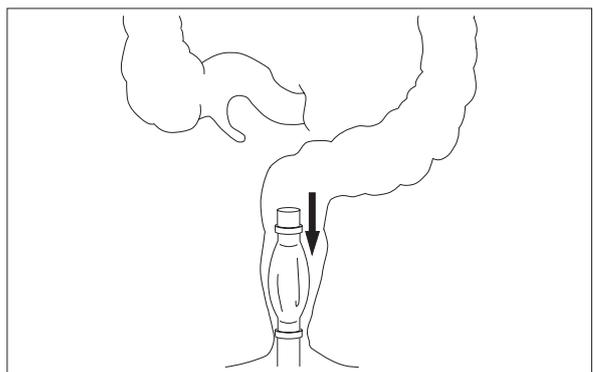
- (3) Unbend the bending portion until it is almost straight by operating the angle knobs.



- (4) Deflate the balloon, and then slowly withdraw the Over-tube along with the endoscope.

[Note]

Withdraw the balloon after the balloon is deflated completely.



6.4.1 Removing Hood (Only When Used)

⚠ WARNING

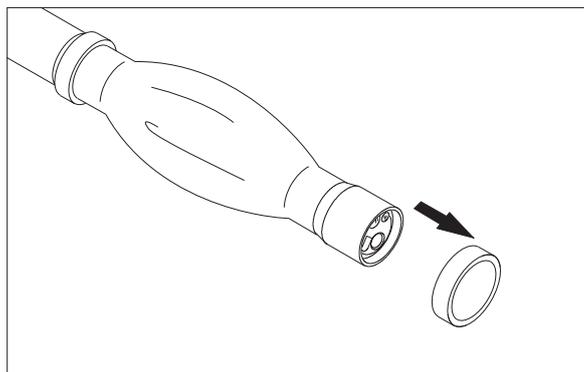
Wear personal protective equipment when removing the balloon or hood.
There is a risk of infection.

CAUTION

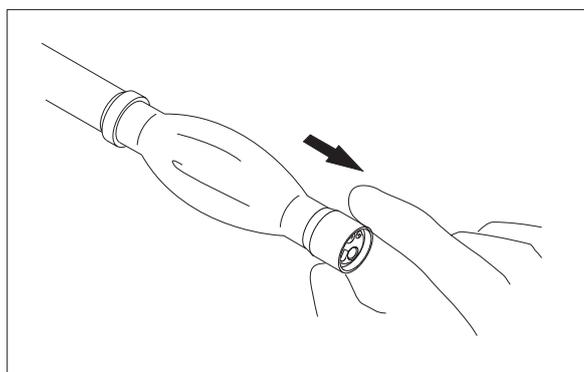
When removing the balloon or hood, take care not to apply excessive force to the endoscope.
It may damage the endoscope.

Remove the hood from the endoscope after withdrawal.

- (1) Remove the fixing rubber securing the hood.



- (2) Slowly remove the hood from the distal end of endoscope.
When it is difficult to remove the hood, do it after infiltrating cleaning fluid into the hood.



[Note]

Dispose of the removed hood.

6.4.2 Removing Balloon

- (1) Remove the fixing rubber securing the balloon.
- (2) Roll the balloon slowly toward the distal end of the endoscope to remove.

[Note]

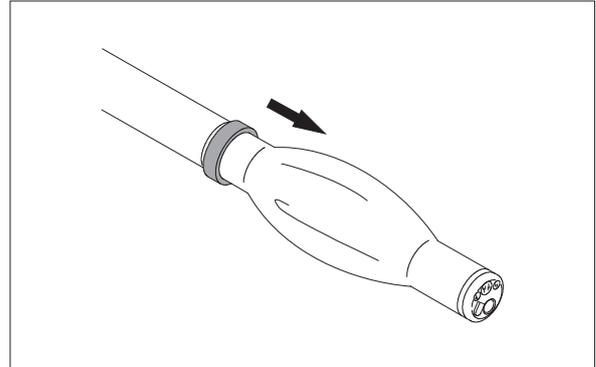
If the balloon is too slippery to be held, cover the balloon with gauze for easier removal.

[Note]

Dispose of the removed balloon.

[Note]

Make sure to remove the balloon before cleaning the endoscope.



6.4.3 Removing Over-tube

Remove the Over-tube from the endoscope.

[Note]

Dispose of the removed Over-tube.

[Note]

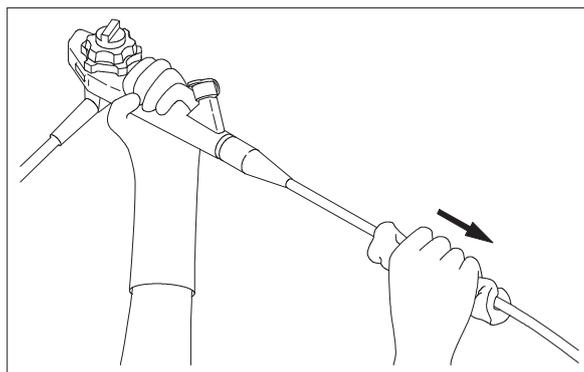
Make sure to remove the Over-tube before cleaning the endoscope.

6.5 Pre-cleaning (Primary Cleaning)

Pre-cleaning (primary cleaning) means cleaning performed at bedside immediately after use of endoscope.

6.5.1 Wiping off Endoscope

Wipe off any matter adhering to the outer surface of the insertion portion by using gauze or a paper towel.

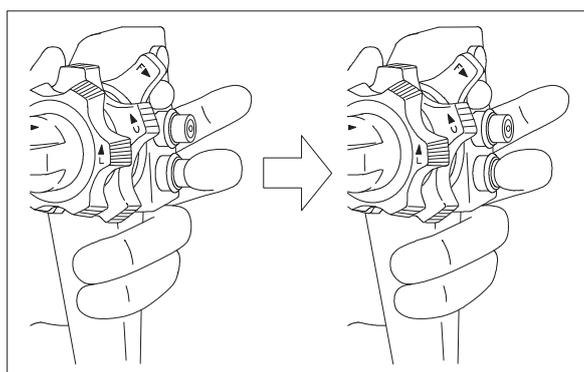


6.5.2 Purging Air/Water Supply Channel

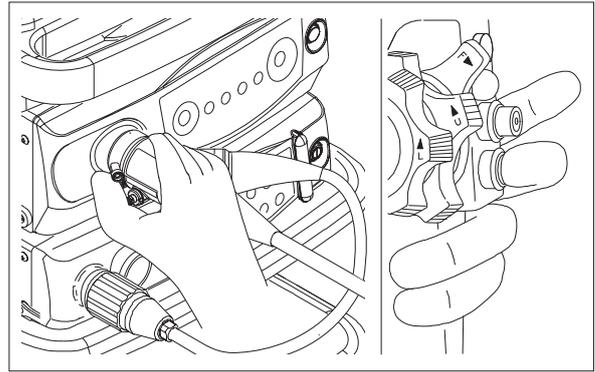
Remove mucosal fluids, blood, etc. from the air/water supply channel of the endoscope in accordance with the following procedure.

[Note] When CA-511N (optional item) is used, see “6.5.4 Cleaning Air/Water Supply Channel Using CA-511N.”

- (1) Supply air for 10 seconds by covering the air/water button with a finger.
- (2) Supply water for 10 seconds by depressing the air/water button.



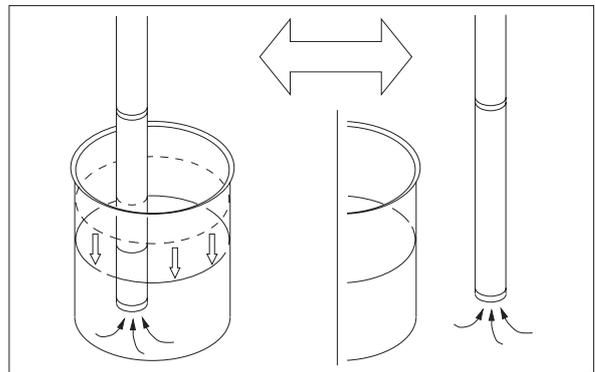
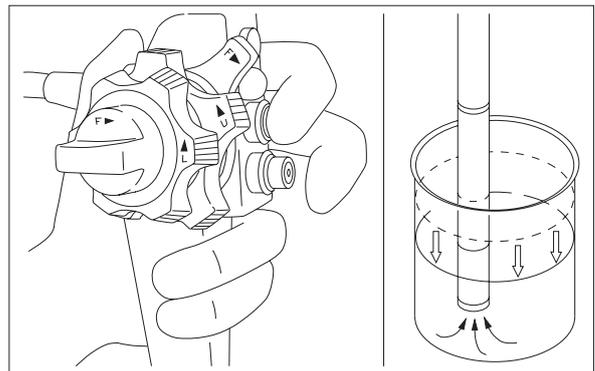
- (3) Turn the connector of water tank attached to the endoscope to remove it.
Then cover the feed water connector of the endoscope with a finger.
- (4) Continue depressing the air/water button until the water remaining in the channel is discharged completely.



6.5.3 Pre-cleaning Suction Channel

Remove body fluids from the suction channel of endoscope in accordance with the following procedure.

- (1) Immerse the distal end of endoscope in cleaning fluid, and depress suction button to suck cleaning fluid for 10 seconds.
- (2) Keeping suction button depressed, pull the distal end of endoscope out of cleaning fluid and suck in air.
- (3) Repeat steps (1) and (2) above 2 or 3 times to suck cleaning fluid and air alternately.
- (4) Finally, pull distal end of endoscope out of cleaning fluid and suck in air until cleaning fluid is completely drained from suction channel.

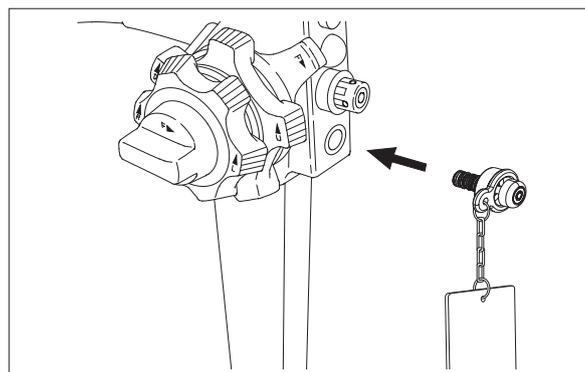


6.5.4 Cleaning Air/Water Supply Channel Using CA-511N

This section explains how to clean the air/water supply channel using the CA-511N (optional item).

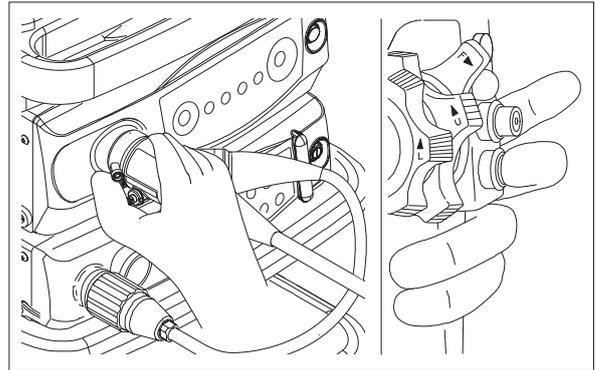
For details on how to use the CA-511N, refer to the operation manual of the CA-511N.

- (1) Perform pre-cleaning of items other than the air/water supply channel referring to 6.5.1 “Wiping off Endoscope” and 6.5.3 “Pre-cleaning Suction Channel”.
- (2) Immerse the distal end of endoscope in clean water.
- (3) Turn OFF the air supply pump of the light source.
- (4) Remove the air/water button (AW-500) from the endoscope and then immerse it in cleaning fluid.
- (5) Attach the cleaning adapter CA-511N to the air/water supply valve of the endoscope.



- (6) Turn ON the air supply pump of the light source.
- (7) Press the button on the cleaning adapter CA-511N to supply water for 30 seconds.
Make sure that water discharges from the distal end of endoscope while pressing the button.
- (8) Release the button to supply air for 10 seconds or longer until water in the air/water supply channel is completely discharged.

- (9) Disconnect the connector of the water tank and cover the feed water connector of the endoscope with your finger.
- (10) Press the button on the cleaning adapter CA-511N to supply air until water in the air/water supply channel is completely discharged.

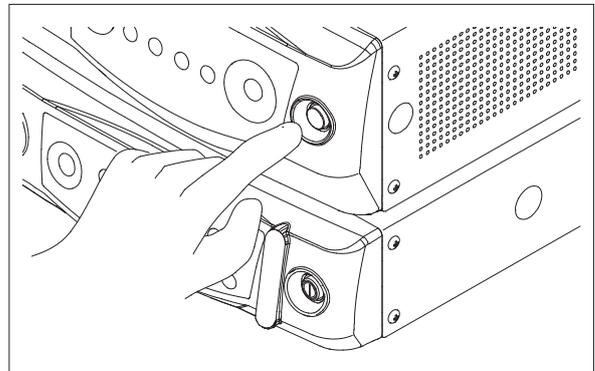


6.5.5 Removing Endoscope from Processor

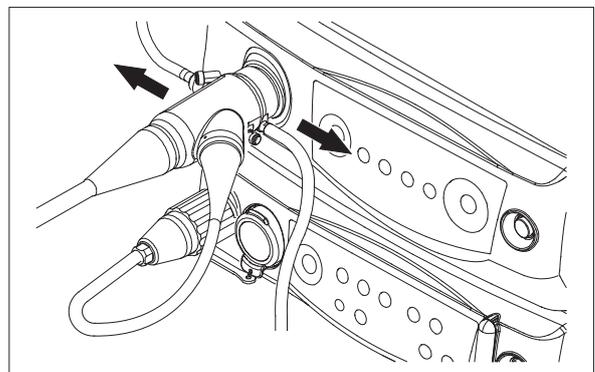
! CAUTION

Do not touch the LG connector tip until it cools down (approximately 5 minutes).
Touching the LG connector with hands immediately after use of the endoscope may cause a burn injury.

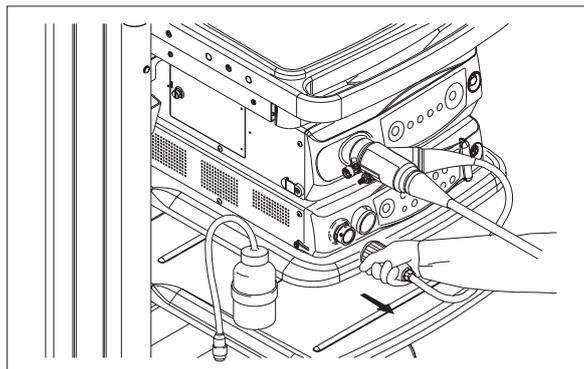
- (1) Turn OFF the power switch of the processor and the light source.



- (2) Remove the suction tube and water tank from the suction connector of the endoscope.



- (3) Remove the video connector from the processor.
- (4) Remove the LG connector from the light source.



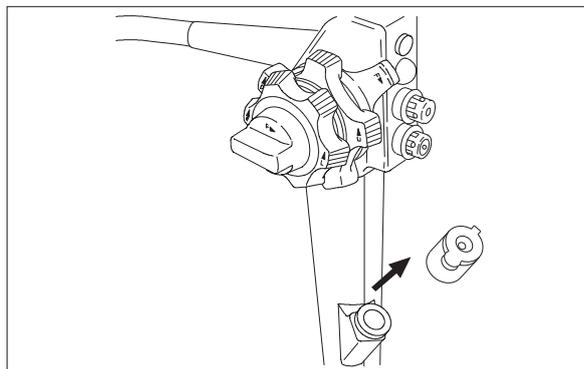
6.5.6 Detaching Forceps Valve

! WARNING

Discard the forceps valve after use.
It could be a source of infection.

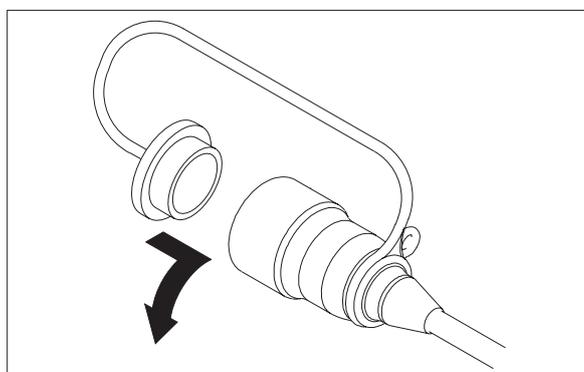
Detach the forceps valve from the endoscope.

Discard the detached forceps valve.



6.5.7 Protecting Video Connector from Water

If the video connector is used with water remaining on the electric contact, it may cause a failure of the video connector. Attach the waterproof cap to the video connector before cleaning.



6.5.8 Transporting Endoscope

Transport the endoscope to the room where the secondary cleaning (manual cleaning) is performed.

Place the endoscope in a transport container so as not to hit it against other objects or to splatter residual fluids in the endoscope.

Appendix

Main Specifications	Appendix-2
Troubleshooting	Appendix-8
After-Sales Service.....	Appendix-12
Disposal of Electric and Electronic Equipment ...	Appendix-13
Index	Appendix-14

Main Specifications

<Classification of Medical Electrical Equipment>

1. Type of protection against electric shock : Class I equipment
(power supply: protective earth plug)
2. Degree of protection against electric shock : Type BF applied part
3. Degree of explosion protection : Use is prohibited in an oxygen-rich environment or in a flammable gas atmosphere.

[Note] Use in combination with VP-4450HD and XL-4450.

<Applied Part>

Insertion portion

<Specifications>

Model	EN-580T
Optical system:	
Viewing direction	0° (Forward)
Field of view	140°
Observation range (mm)	2 to 100
Method of illumination	Light guide method
Image size	Super image
Distal end diameter (mm)	9.4
Flexible portion diameter (mm)	9.3
Forceps channel diameter (mm)	3.2 ^[Note 1]
Bending capability: Up/down	180° / 180°
Left/right	160° / 160°
Working length (mm)	2000 ^[Note 2]
Total length (mm)	2300
Insertion route	Peroral/Transanal

[Note 1] The compatibility of equipment chosen solely according to this forceps channel diameter is not guaranteed.

[Note 2] Use an endotherapy device with working length of 2300 mm or longer.

<Operating Environment>

Temperature	+10 to +40°C
Humidity	30 to 85%RH (no dew condensation)
Pressure	70 to 106 kPa (within range of atmospheric pressure)

<Transport and Storage Environment>

Temperature	+10 to +40°C
Humidity	30 to 85%RH (no dew condensation)
Pressure	70 to 106 kPa (within range of atmospheric pressure)

<Term of Validity/Period for Use (Durability)>

The term of validity (durability) is six years ^[Note] after beginning of use, if proper maintenance and inspection are performed. “Based on our company’s criteria”

[Note] Except for consumable supplies.

<Applicable Processor and Light Source>

Processor	VP-4450HD
Light source	XL-4450

<Accessories>

Name	Model
Biopsy forceps:	
Fenestrated	BF2424SF
Fenestrated with needle	BF2424FN
Long jaw	BF2424LN
Alligator jaw	BF2224A
Grasping forceps:	
Three prong	GF2325 -T-
V-shaped	GF2424V
Basket	GF2325 -B-
Cleaning brush	WB4324FW2
Valve cleaning brush	WB11002FW2
Cleaning tube	WT1726ST
Over-tube	TS-13140
Balloon	BS-1
	BS-2
Mouthpiece	MPC-ST
Hood	DH-17EN

<Consumable Supplies>

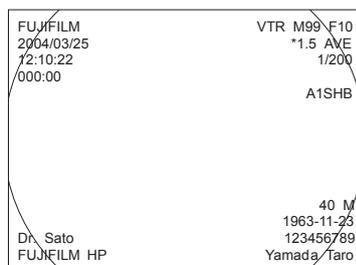
Name	Model
Forceps valve	FOV-DV7
Suction button	SB-500
Air/Water button	AW-500
Setting tool	ST-01B ST-05B
Tube kit	TY-06S
Cleaning brush	WB4324FW2
Valve cleaning brush	WB11002FW2
Cleaning adapter	CA-503/A
Balloon channel cleaning adapter	CA-606

[Note] If any abnormality is found in consumable supplies during inspection before use, replace them with new ones.

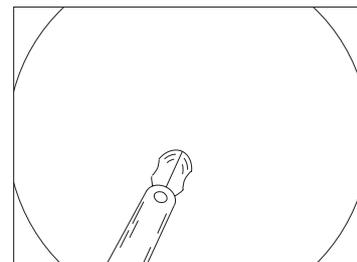
<Applicable Optional Supplies>

Name	Model
Air/Water supply channel cleaning adapter	CA-511N
Air leak tester	LT-7 LT-7F

<Image Size>



<Direction of Forceps>



<Medical Device Directive>

This product complies with the requirements of European Directive 93/42/EEC.
Classification : Class II a



<Electromagnetic Compatibility (EMC) Information>

This product is intended for use in the electromagnetic environments specified below.

The customer or the user of this product should assure that it is used in such an environment.

Electromagnetic emission compliance information and guidance

Emission standard	Compliance	Guidance
RF emissions CISPR 11	Group I	This product uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electric equipment.
Radiated emissions CISPR 11	Class A	This product is intended for use in medical facilities and commercial facilities.
Harmonic emissions EN 61000-3-2	Class A	If this product is used in domestic establishments, electromagnetic interference may occur on any equipments.
Voltage fluctuations/ flicker emissions EN 61000-3-3	Applicable	In this case, it is recommended to use this product according to Chapter 1 “Safety.”

[Note] Use in combination with VP-4450HD and XL-4450.

Electromagnetic immunity compliance information and guidance

Immunity test	EN 60601-1-2 Test level	Compliance level	Guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV: contact ± 8kV: air	Same as left	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2kV: for power supply lines ± 1kV: for input/output lines	Same as left	Main power quality should be that of a typical commercial or hospital.
Surge EN 61000-4-5	± 1kV: Line to line ± 2kV: Line to earth	Same as left	Main power quality should be that of a typical commercial or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 11.5V (> 218.5V dip) For 0.5 cycle 92V (138V dip) For 5 cycle 161V (69V dip) For 25 cycle < 11.5V (> 218.5V dip) For 5 sec	Same as left	Main power quality should be that of a typical commercial or hospital. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	Same as left	It is recommended to use this product by maintaining enough distance from any equipment that operates with high current.

Electromagnetic immunity compliance information and guidance

Immunity test	EN 60601-1-2 Test level	Compliance level	Guidance
Conducted RF EN 61000-4-6	3Vrms 150kHz to 80MHz	3V[V ₁]	<p>Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <p>Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m).</p> <p>This product complies with the requirements of EN 60601-1-2: 2007.</p> <p>However electromagnetic interference may occur on this product under electromagnetic environment that exceeds its noise level.</p> <p>Electromagnetic interference may occur in the vicinity of equipment marked with the following symbol.</p> 
Radiated RF EN 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m[E ₁]	

Electromagnetic immunity compliance information and guidance

The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and this product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter P (W)	Separation distance related to frequency of the transmitter (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80 to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Troubleshooting

If the endoscope should fail during use, follow these instructions to troubleshoot it.

Problem	Cause	Remedy
No images come out.	<ol style="list-style-type: none"> 1) The cart, monitor or processor is unplugged from the main outlet. 2) The cart, monitor or processor is off. 	<ol style="list-style-type: none"> 1) Plug the cart, monitor or processor into the main outlet. 2) Power on the cart, monitor or processor.
The image appears dark.	<ol style="list-style-type: none"> 1) The endoscope is not connected completely. 2) The brightness level is approaching the minimum level. 3) The iris mode is at "PEAK." 4) Dirt adheres to the lens of endoscope. 5) The shutter speed is "HIGH." 6) The maximum light amount is limited with the light save function. 7) Iris timer is activated. 	<ol style="list-style-type: none"> 1) Connect the endoscope correctly. → 5.3 "Connecting Endoscope" 2) Set the brightness level to approximately 0. → VP-4450HD 5.6 "Adjusting the Brightness" 3) Set the iris mode to "AVE." → VP-4450HD 5.12 "Switching the Iris Mode" 4) Supply water to the distal end of endoscope to remove dirt. 5) Set the shutter speed to "NORM." 6) Turn OFF the light save function of light source. 7) Release the timer by pressing the FR switch of endoscope. <p>[Note] If the image still appears dark even after performing 4) to 7), slowly pull out the endoscope and clean the distal end.</p>
Highlight area of images is too bright.	<ol style="list-style-type: none"> 1) The brightness level is approaching the maximum level. 2) The iris mode is at "AVE." 	<ol style="list-style-type: none"> 1) Set the brightness level to approximately 0. → VP-4450HD 5.6 "Adjusting the Brightness" 2) Set the iris mode to "PEAK." → VP-4450HD 5.12 "Switching the Iris Mode"
An image disappears during an examination.	<ol style="list-style-type: none"> 1) The endoscope connection is incomplete. 2) The system has malfunctioned due to such as static charges. 3) The video signal cable has shorted out or broken. 4) The imaging section is damaged. 	<ol style="list-style-type: none"> 1) Reconnect the endoscope. → 5.3 "Connecting Endoscope" 2) 3) 4) <p>Reset the processor and the light source. If the image is still not displayed, turn the processor and the light source off, and then straighten the bending portion to unlock and release the angle knobs. Pull out the endoscope slowly.</p>

[Note] Reset: Turn off the processor and the light source, and wait for at least 5 seconds. Turn on the processor and the light source again, and then light the lamp by pressing the Lamp button.

Problem	Cause	Remedy
A live image is not displayed after image freezing is cancelled during an examination.	The system has malfunctioned due to such as static charges.	Reset the processor and the light source. If the image is still not displayed, turn the processor and the light source off, and then straighten the bending portion to unlock and release the angle knobs. Pull out the endoscope slowly.
An image is suddenly discolored during an examination.	1) The system has malfunctioned due to such as static charges. 2) The video signal cable has shorted out or broken. 3) The imaging section is damaged.	1) 2) 3) Reset the processor and the light source. If the image is not recovered and it is impossible to continue the examination, turn the processor and the light source off, and then straighten the bending portion to unlock and release the angle knobs. Pull out the endoscope slowly.
An image appears distorted.	1) High-frequency interference 2) Not connected correctly 3) The video signal cable has shorted out or broken. 4) The imaging section is damaged.	1) Stop power supply to the diathermic treatment equipment to restore image output. The endoscope is working all right. 2) Connect properly. 3) 4) Reset the processor and the light source. If the image is not recovered, turn the processor and the light source off, and then straighten the bending portion to unlock and release the angle knobs. Pull out the endoscope slowly.
Air and/or water cannot be fed.	1) The pump is switched off. 2) The water tank cap is loose. 3) The water tank is filled with too much water. 4) The water tank is empty. 5) The water tank is not connected.	1) Switch on the pump. 2) Close the cap firmly. 3) Reduce the water level in the water tank to about 80% of its capacity. 4) Fill the water tank with water. 5) Connect the water tank.
Low air/water supply volume	1) Foreign matter adheres to the air/water supply channel. 2) The air/water supply channel is damaged.	1) Pull out the endoscope from the body cavity and clean the air/water supply channel referring to “6.5.1 Wiping off Endoscope” and “6.5.2 Purging Air/Water Supply Channel.” If the air/water supply volume is still low, replace the endoscope with a spare one. 2) Consult your local FUJIFILM dealer.

[Note] Reset: Turn off the processor and the light source, and wait for at least 5 seconds. Turn on the processor and the light source again, and then light the lamp by pressing the Lamp button.

Problem	Cause	Remedy
Air/Water button won't reset.	The air/water button has deteriorated.	Replace the air/water button with a new one.
Suction is disabled.	<ol style="list-style-type: none"> 1) The pump is switched off. 2) The pump is not connected. 3) No forceps valve is attached. 	<ol style="list-style-type: none"> 1) Switch on the pump. 2) Connect the pump. 3) Attach a forceps valve.
Low suction volume	<ol style="list-style-type: none"> 1) The suction button has been damaged. 2) The forceps valve has been degraded. 3) The suction tube is not attached properly. 4) The forceps valve is not attached properly. 5) The lid of the forceps valve is not closed. 	<ol style="list-style-type: none"> 1) Replace with a new suction button. 2) Replace with a new forceps valve. 3) Reattach the suction tube. 4) Reattach the forceps valve. 5) Close the lid of the forceps valve securely.
The suction button won't reset.	<ol style="list-style-type: none"> 1) Foreign matter or blood adhering to the button is coagulated. 2) The suction button is damaged. 	<ol style="list-style-type: none"> 1) Disconnect the suction tube. After diagnosis, remove the button and clean or replace it. 2) Replace with a new suction button.
An endotherapy device cannot be inserted.	<ol style="list-style-type: none"> 1) The endotherapy device is left open (such as biopsy forceps). 2) The handle of the endotherapy device is held firmly (such as biopsy forceps). 3) The endotherapy device has difficulty being inserted due to bending. 4) Non-applicable endotherapy device is used. 	<ol style="list-style-type: none"> 1) Close the endotherapy device for insertion. 2) Loosen the grip to insert the endotherapy device. 3) Return the bending portion slightly and then insert it. 4) Use applicable endotherapy device.
An endotherapy device cannot be withdrawn.	<ol style="list-style-type: none"> 1) The endotherapy device is left open (such as biopsy forceps). 2) The handle of the endotherapy device is held firmly (such as biopsy forceps). 3) The endotherapy device has difficulty being inserted due to bending. 4) An abnormality occurs in the endotherapy device. 5) Non-applicable endotherapy device is used. 	<ol style="list-style-type: none"> 1) Close the endotherapy device and pull it out. 2) Loosen the grip and pull out the endotherapy device. 3) Return the bending portion slightly and then pull out the endotherapy device. 4) Return the end of the endotherapy device to the forceps outlet of the endoscope, and then slowly pull out the endoscope and endotherapy device together. 5) Return the end of the endotherapy device to the forceps outlet of the endoscope, and then slowly pull out the endoscope and endotherapy device together. <p>[Note] Use applicable endotherapy device.</p>
Images cannot be captured in the image recorder.	<ol style="list-style-type: none"> 1) The image recorder is not connected. 2) The image recorder is not connected correctly. 	<ol style="list-style-type: none"> 1) Connect the image recorder. 2) Reconnect the image recorder to ensure correct connection.

Problem	Cause	Remedy
The bending portion cannot return to neutral position.	<ol style="list-style-type: none"> 1) The angle is locked. 2) The bending control mechanism is malfunctioning. 	<ol style="list-style-type: none"> 1) Use the angle lock knob to unlock the angle. 2) Discontinue use immediately, and contact your local FUJIFILM dealer or the nearest service center without forcing the bending portion out of position. Forcing the bending portion out of position could result in body cavity damage.
A balloon does not inflate.	<ol style="list-style-type: none"> 1) The balloon air feed channel is clogged. 2) The tube kit has been perforated. 3) The tube kit is crushed. 4) The fixing rubber covers the balloon air feed inlet. 5) The balloon or fixing rubber is attached improperly and air is leaking from the balloon. 6) The balloon has been perforated. 	<ol style="list-style-type: none"> 1) Replace the endoscope with a spare one. 2) Replace the tube kit with a spare one. 3) Eliminate crushing of the tube kit. 4) Shift the position of the fixing rubber. 5) Adjust the position of the balloon or fixing rubber again. 6) Replace the balloon with a spare one.
The balloon does not deflate.	Water has entered the channel from the balloon air feed inlet or the air feed inlet of the Over-tube (clear tube).	<p>Stop using the endoscope immediately, deflate the balloon using a syringe and then slowly withdraw the endoscope and Over-tube together.</p> <p>When the balloon does not deflate even if a syringe is used, take possible measures such as surgical operation.</p>

After-Sales Service

- 1) If the equipment does not work properly, check it first by reading this manual again and follow all instructions.
- 2) If the equipment is still not working well, contact your local FUJIFILM dealer.
- 3) Repairs during the warranty period

We will repair the endoscope free of charge according to the provisions of the warranty.

The warranty period of the endoscope is one year ^[Note] after date of purchase.

[Note] Except for consumable supplies.

We will replace the Over-tube or balloon with a new equivalent product if any quality problem due to a manufacturing defect is found within the warranty period.

The warranty period of the Over-tube-and balloon is from the date of purchase to the expiration date of the product.

For the warranty period of the balloon controller, refer to the operation manual of the balloon controller.

Note that the warranty is void in the following cases:

- a. Damage caused by fire or natural disaster such as storms or floods.
- b. Troubles caused by careless handling or misuse of the product on the part of the user.
- c. Troubles caused by repair or modification by an unauthorized person.

- 4) Repairs after the warranty period

We will make a paid repair at your request if the equipment is found possible to restore the normal function by repair. When contacting our service representative, provide the following information.

Model name :
Serial number :
Description of failure : as detailed as possible
Date of purchase :

Disposal of Electric and Electronic Equipment



Disposal of Used Electrical and Electronic Equipment (Applicable in the European Union and other European countries with separate collection systems)

This symbol on the product, or in the manual and/or on this packaging, indicates that this product shall not be treated as household waste.

Instead it should be taken to an applicable collection point for the recycling of electrical and electronic equipment.

By ensuring this product is disposed of correctly, you will help prevent potential negative consequences to the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

The recycling of materials will help to conserve natural resource. For more detailed information about recycling of this product, please contact your local dealer.

In Countries outside the EU: If you wish to discard this product, contact your local authorities and ask for the correct way of disposal.

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