English

FUJIFILM

Ultrasonic Endoscope

EG-580UR

OPERATION MANUAL

This Operation Manual describes details on how to operate the ultrasonic endoscope and cautions to be observed when operating it. Please read this manual thoroughly before actually operating the ultrasonic endoscope.
After reading this manual, store it nearby the ultrasonic endoscope so that you can see it whenever necessary.

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Introduction

Ultrasonic Endoscope EG-580UR is an upper gastrointestinal endoscope intended for the observation and diagnosis of the esophagus, stomach and duodenum, and for the observation, diagnosis and endoscopic treatment of submucosal and peripheral organs at medical facilities under the management of physicians.
This product is not intended for use on children and infants.

This manual provides necessary information for using the ultrasonic endoscope, such as the equipment overview, operation procedures and precautions to observe.

The Reprocessing Manual describes precautions and the cleaning, disinfection and storage methods for the ultrasonic endoscope.

If you are a first-time user of this product, be sure to read this manual before actual operation. Also, after reading this manual, store it close to this product for future reference to keep the ultrasonic endoscope in optimum working condition.

⚠CAUTION

1 No part or all of this manual may be reproduced in any form without prior permission.
2 The information contained in this manual may be subject to change without prior notice.
3 FUJIFILM Corporation shall not be liable for malfunctions and damages caused by installation, relocation, remodeling, maintenance, and repair performed by dealers other than those specified by FUJIFILM Corporation.
4 FUJIFILM Corporation shall not be liable for malfunctions and damages of FUJIFILM Corporation products due to products of other manufacturers not supplied by FUJIFILM Corporation.
5 FUJIFILM Corporation shall not be liable for malfunctions and damages caused by remodeling, maintenance, and repair using repair parts other than those specified by FUJIFILM Corporation.
6 FUJIFILM Corporation shall not be liable for malfunctions and damages resulting from negligence of the precautions and operating methods contained in this manual.
7 FUJIFILM Corporation shall not be liable for malfunctions and damages resulting from use under environment conditions outside the range specified for this product, such as the power supply, installation environment, etc., as described in this manual.
8 FUJIFILM Corporation shall not be liable for malfunctions and damages resulting from natural disasters, such as fires, earthquakes, floods, lightning, etc.

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 Reprocessing Manual. There is a risk of being a source of infection.

Endoscope Manuals

Manage and store the Operation Manual and Reprocessing Manual of this product as a set.

Ultrasonic Endoscope EG-580UR Operation Manual

This manual provides necessary information for using the ultrasonic endoscope such as the equipment overview, operation procedures and precautions to observe.

Ultrasonic Endoscopes EG-580UT and EG-580UR Reprocessing Manual

This manual describes the cleaning, disinfection, sterilization and storage methods of the ultrasonic endoscope.

[Note] In this manual, the Ultrasonic Endoscope EG-580UR Operation Manual is referred to as “this manual”, and the Ultrasonic Endoscopes EG-580UT and EG-580UR Reprocessing Manual as “Reprocessing Manual”.

How to Read This Manual

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.

Contents at a Glance

Contents

Chapter 1 Precautions

1.1 For Safe Operation

Before using this product, read this section carefully so that you can operate it correctly. Whenever you operate this product, be sure to observe those precautions. Failure to do so may cause you to subject to injuries or property damage to occur.

The institution is responsible for the use and maintenance of this product.
In addition, this product should not be used by persons other than doctors or suitably trained staff.

Be sure to prepare a spare endoscope against unexpected accidents such as the failure of this product. Otherwise, you may not be able to continue the endoscopic procedure. If the spare endoscope is not available, prepare other alternative means such as abdominal surgery.
This product is intended for use by medical professionals 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 or any aspects of endoscopic techniques.

Do not modify this product or its components, and do not disassemble, repair or in any other way reverse-engineer these products. Even if you find a defect, do not attempt to repair these products yourself. FUJIFILM Corporation shall not be liable for any defects or device failures caused by such modifications, disassembly, repairs or reverse-engineering.

1.2 Classification

<Classification of Medical Electrical Equipment>

1. Type of protection against electric shock	: Class I equipment (power supply: protected ground fault receptacle)
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.
4. Degree of waterproof	: IEC 60529 IPX7 (with US waterproof cap attached)

[Note] Use in combination with the VP-4450HD processor, XL-4450 light source and SU-1 ultrasonic processor.

1.3 Safety

Read the following precautions before using this product to ensure proper handling.

1.3.1 Infection

⚠WARNING

This product has not been cleaned or disinfected (or sterilized). It must be cleaned and disinfected (or sterilized) for the first time prior to use and after any subsequent use as per instructions provided in the Reprocessing Manual. Prior to reuse, this product must be pre-cleaned, cleaned and disinfected (or sterilized) according to the procedures given in the Reprocessing Manual. Inadequate cleaning may compromise successful disinfection or sterilization, increasing the risk of infection.

Meticulously clean the ultrasonic endoscope's all surfaces including channels as per provided reprocessing instructions.

Wear personal protective equipment during a procedure as well as during cleaning and disinfection (or sterilization) to protect your eye and 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 Reprocessing Manual 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 local guidelines.

Ensure that the forceps valve is properly attached to the instrument channel inlet. If this product is used without the forceps valve attached, body fluid may flow back and it could be a source of infection.

Attach a properly disinfected (or sterilized) forceps valve. If the forceps valve is not cleaned or disinfected (or sterilized) properly, it can create a risk of infection to patients and/or end-users.

⚠WARNING

The forceps valve must be completely immersed in a disinfectant solution. Remove air bubbles completely. If any air bubbles remain, effective disinfection cannot be achieved and an inadequately cleaned and disinfected (or sterilized) forceps valve may increase a risk 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.

The lid of the forceps valve must be closed when using the ultrasonic endoscope. Not doing so may cause backflow of body fluids and increase a risk of infection.

Use a disinfected (or sterilized) balloon attachment tool. There is a risk of infection.

During ultrasonic procedures in which a balloon is not used, do not fully depress the suction valve and do not attempt to aspirate patient material into/through the balloon evacuation channel. Doing so can result in partial or complete clog of the narrow balloon evacuation channel, especially if the ultrasonic endoscope is not cleaned immediately after each procedure and if not reprocessed as per FUJIFILM recommendations. Once the balloon evacuation channel is clogged, it cannot be cleaned, disinfected or sterilized properly and can be a source of infection.

If the lid of the forceps valve needs to be open during a procedure, put sterile gauze around the forceps valve before opening the lid. If sterile gauze is not applied, body fluid may be splattered, leading to infection.

⚠WARNING

Slowly insert an endotherapy device (e.g. forceps) or syringe straight into the ultrasonic endoscope. Also, when withdrawing it, slowly pull straight out. If it is inserted or withdrawn quickly, body fluid may be splattered around due to breakage or accidental detachment of the instrument, leading to infection.

Do not perform procedures with an endotherapy device hung over the forceps valve. Doing so may cause backflow of body fluids and increase a risk of infection.

The forceps valve and balloon are intended for single use. To prevent infection, do not reuse them.

Discard the forceps valve and balloon after use. Used forceps valve and balloon could be a source of infection.

Use a cleaned and disinfected (or sterilized) air/water valve and suction valve. An inadequately cleaned and disinfected (or sterilized) valve may pose an infection risk.

Use a cleaned and disinfected (or sterilized) endotherapy device. An inadequately cleaned and disinfected (or sterilized) endotherapy device may pose an infection risk.

When supplying water, use sterile water. If sterile water is not used, it can create a risk of infection.

Carry a cleaned and disinfected (or sterilized) ultrasonic endoscope at a clean state. If personal protective equipment such as gloves is contaminated, the contaminants adhere to the ultrasonic endoscope and it can be a source of infection.

When removing the balloon, wear personal protective equipment and slowly remove the balloon. There is a risk of infection.

1.3.2 Preventing Electrical Shock

⚠WARNING

Insert the AC plug into a hospital grade receptacle. Not doing so may cause an electric shock accident.

Use an electrosurgical instrument conforming to EN 60601-2-2. Refer to the manual of the electrosurgical instrument for how to operate the electrosurgical instrument.

Connect the electrosurgical instruments and electrosurgical generators in accordance with each operation manual. Incorrect connection may cause electric shock and/or burns.

⚠CAUTION

The ultrasonic endoscope may be used in combination with peripherals. To avoid an electric shock accident, do not use any peripherals than the ones specified in this manual.

1.3.3 Treatment with Electrosurgical Instruments

⚠WARNING

This product is not intended to stop bleeding with diathermic treatment equipment. Prepare an endoscope and diathermic treatment equipment that can be used with it, so as to take necessary actions in emergencies such as bleeding.

Do not use an electrosurgical instrument when supplying flammable gas. There is a risk of ignition. If necessary, use non-flammable gas such as carbon dioxide. Do not use excessive non-flammable gas.

Wear electrically insulating gloves when using an electrosurgical instrument or accessory. If not worn, there is a risk of thermal injury or electric shock.

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

When using diathermic treatment equipment, suck mucus adhered to the tissues in the body cavity first and then energize the instrument. If the equipment is energized when in contact with mucus, it may cause thermal injury.

Before electrosurgery, basic in vitro experiments must be performed to learn how repeated use affects the cutting quality of therapeutic accessories.

⚠CAUTION

We recommend use of only those peripheral products specified in this manual to avoid adverse outcomes such as electric shock when this product is used in combination with other devices.

Prevent patient's body from touching electric conductor such as metal part of bed while using an electrosurgical instrument and an accessory instrument. Not doing so could cause thermal injury to a patient.

Do not energize the electrosurgical instruments when the electrically active portion of diathermic treatment equipment and the metal part at the distal end of the ultrasonic endoscope are in contact with each other. Thermal injury or scope damage may occur.

Do not apply the current under the circumstance that patient's clothing is wet when using electrosurgical instruments. Doing so may cause thermal injury.

Operate the instruments within specified output range as per the device's operating instructions. Leakage current may cause thermal injury.

Perform electrosurgical procedures as per instructions provided in the operation manual for an electrosurgical instrument.

When using diathermic treatment equipment, maintain enough distance between the distal end of the ultrasonic endoscope and the tip of the treatment equipment. Energize the high-frequency power supply after bringing the tip of the treatment equipment into the field of view. Set the output power of the high-frequency power supply and treatment equipment below the rated output. Also, set the output power to the minimum within the required range. If the output power is inappropriate, it may cause damage to tissues in the body cavity, thermal injury, bleeding or perforation.

1.3.4 Direct Harm to Human Body

⚠WARNING

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 in blood pressure and shock. If such symptoms are observed, stop the use of this product immediately and take appropriate measures.

Do not use this product with an endoscopic CO_2 regulator. If used, air bubbles may be generated in the sterile water inside the water tank and enter the balloon channel. This could prevent water discharge from the balloon and disable deflation of the balloon.

Do not use a balloon on patients allergic to latex. There is a risk of an anaphylactic reaction.

Do not supply an excessive amount of air or gas during the procedure as doing so could cause an embolism. Do not overinsufflate during any clinical procedure to minimize the potential for pneumatic perforation.

To avoid the potential for patient injury including perforation, do not apply excessive force of the ultrasonic endoscope or endotherapy device against mucosal surfaces. Only advance the endotherapy device while viewing the endoscopic image.

Use the air/water channel cleaning adapter CA-609 only for cleaning the air/water channel. If it is used during a procedure, continuous air supply may occur and cause patient injury.

⚠CAUTION

Take extreme care when inserting the ultrasonic endoscope into the oral cavity. Otherwise, it may cause pain to the patient.

Do not forcibly advance or withdraw the ultrasonic endoscope into/from the patient. It may cause damage to the body lumen, bleeding or perforation.

Do not angulate the bending section forcibly or operate it quickly. It may cause damage to the body lumen, bleeding or perforation.

During an observation, do not perform close observation for an extended period of time. Use the ultrasonic endoscope with a minimum necessary amount of brightness and time while maintaining an appropriate distance. When the shutter speed is set to “HIGH”, take care not to set the brightness level too high. Thermal energy created by illumination may cause burn injury. For details on the settings, refer to the operation manual of the light source and processor in use.

If the brightness level is high, the temperature at the distal end may exceed 41°C. Do not allow the distal end to remain in contact with the same site for an extended period of time. It may cause burn injury.

⚠CAUTION

When the ultrasonic endoscope projects light at high brightness and transmission of ultrasonic waves for a long time, the temperature may exceed 41°C at the distal end. Turn off the lamp and stop transmission of ultrasonic waves (Freeze the ultrasonic processor) when you hang the ultrasonic endoscope on the cart hanger.

Immediately after removing the LG connector from the light source, do not touch the light guide rod with hands since it is extremely hot. There is a risk of burn injury.

Set the suction pressure between 40 and 53 kPa. If the suction pressure is too high, the ultrasonic endoscope may adhere to mucous membrane, resulting in damage to the mucous membrane.

Do not look directly into the light coming from the light guide at the distal end of the ultrasonic endoscope. Turn off the lamp before inspecting the objective lens. Viewing the light from the light guide directly may damage your eyes.

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

1.4 Electromagnetic Compatibility (EMC)

To avoid electromagnetic interference in the operational environment, read the following precautions and properly handle this product and other devices in the vicinity.

1.4.1 Electromagnetic Compatibility (EMC) Related Standard

This product has been tested and confirmed 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 electromagnetic interference in a typical installation at medical facilities.
However, there is a possibility that this product may cause harmful electromagnetic interference to other devices in the vicinity, even if it is used according to the processor instructions. Also, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful electromagnetic interference to other devices, that can be determined by turning the processor off and on, we recommend that you may 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 other devices.

If the problem cannot be solved with the above measures, stop using this product and consult the manufacturer or your local FUJIFILM dealer for help.

⚠WARNING

Do not place any objects that emit strong electromagnetic waves near this product. Otherwise, malfunction of this product may occur.

CAUTION

Noise may appear on the monitor of this product 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 product.

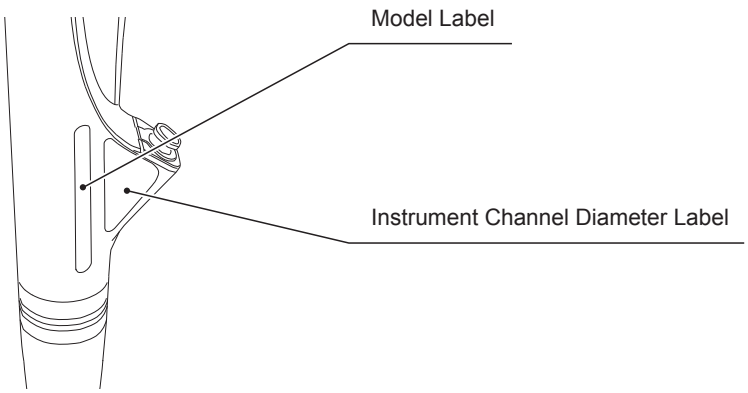
Use the cable specified in the Installation Manual of the processor for this product. Use of other cables may cause an increase in electromagnetic emission or decrease in electromagnetic immunity of this product.

1.5 Location of Each Label

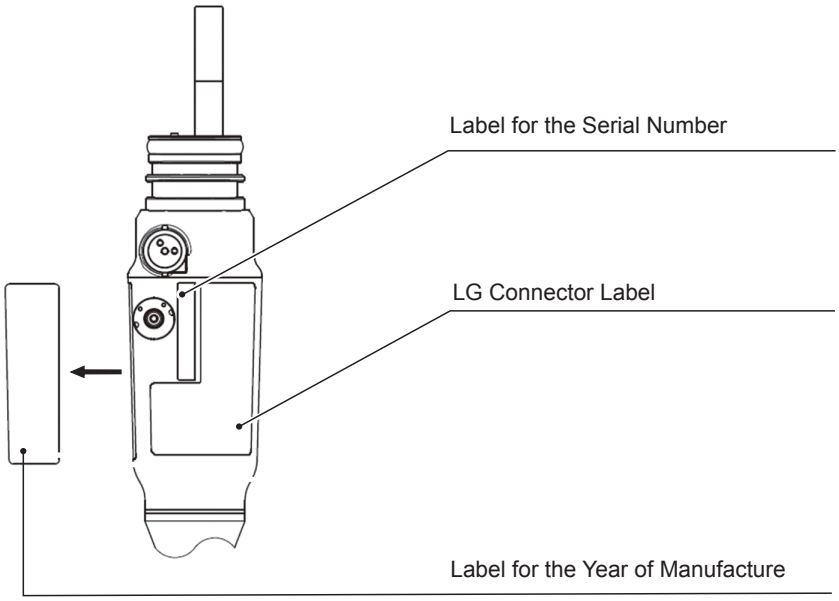
The positions where the labels are affixed on this product are shown below. The relevant safety signs are also described.

1.5.1 Location of Labels

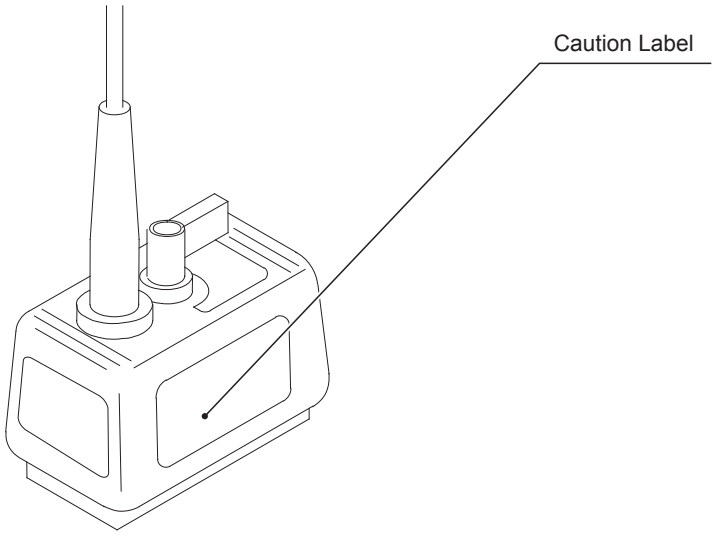
<Control Portion>



<LG Connector>



<US Connector>



1.5.2 Symbols

Symbol	Description
	Do not re-use / Single patient use only
	Use by date / Expiration date of use
	Lot number
	Serial number
	Date of manufacture
	Manufacturer
	Authorised representative in the European Community
	Consult instructions for use
	Temperature limitation
	Keep dry
	Non-sterile
	CE marking
	Degree of waterproof
	Type BF applied part
	WEEE marking [Note 1]
	Phthalates marking [Note 2]
	Humidity limitation

Symbol	Description
	Atmospheric pressure limitation
	Super CCD model
	Minimum diameter of the instrument channel: 2.8 mm
AUTOCLAVABLE	Applicable for autoclave

[Note 1] This product shall not be treated as household waste.

[Note 2] This symbol indicates that this specific type of medical device contains dibutyl phthalate (DBP).
But the device has little impact on patients' health because of its trace constituent.

1.6 Possible Combinations for Use

1.6.1 Accessories

Use this product in combination with the accessories described in “Main Specification”.

⚠WARNING

Do not use the ultrasonic endoscope in combination with accessories other than those described in this manual. Otherwise, it is unable to ensure its functionality, and creates a risk of patient injury or equipment damage.

[Note] For details on how to use accessories, refer to each operation manual of accessories.

1.6.2 Compatible Processor, Light Source and Ultrasonic Processor

This product is used in combination with the VP-4450HD processor, XL-4450 light source and SU-1 ultrasonic processor.
Do not use this product in combination with the processors or light sources other than above.

1.6.3 Peripheral Devices

⚠WARNING

We recommend use of only those peripheral products specified in this manual. Read the operation manuals of the peripheral devices used in combination with this product.

1.7 Cautions/Warnings

Observe the following cautions when handling this product. Also, there are same cautions in each chapter.

⚠CAUTION

Do not use the ultrasonic endoscope if it has failed its pre-inspection check. Doing so can negatively affect the functionality of the instrument or increase risks to patient safety.

Ultrasonic endoscope is a precision instrument. Unnatural force or impact on the insertion portion, bending section, control portion or connector may injure the inside of the patient as well as damage the instrument. If you encounter any resistance, insert it slowly. Do not force it in. Do not insert or bend the ultrasonic endoscope without securing the view on the monitor. Not doing so may cause damage to both the ultrasonic endoscope and body cavities of the patient.

Wear personal protective equipment when handling an ultrasonic endoscope to prevent infection and static charges. When holding ultrasonic endoscope, hold it by the control portion. Handling it up by the insertion portion or LG flexible portion is difficult to hold and may exert an unnatural force, resulting in instrument failure.

1.7.1 Abnormalities during Use of This Product

⚠WARNING

If any abnormality is noticed during use, carry out safety checks and discontinue use immediately.

If any abnormality occurs with this product, refer to “Chapter 5 Troubleshooting”. Should any questions arise regarding information contained in the operation manuals or any safety concerns, contact your local FUJIFILM dealer.

1.7.2 Transportation and Storage

⚠WARNING

Contact your local FUJIFILM dealer when this product is returned for repair. Be sure to clean and disinfect (or sterilize) this product before returning for repair. A returned product which is not cleaned and disinfected (or sterilized) may increase infection control risks to users, service personnel or other persons in contact with it.

⚠CAUTION

Store the ultrasonic endoscope under the storage conditions described in “Main Specification.”

CAUTION

Store the ultrasonic endoscope in an exclusive carrying case when transporting the ultrasonic endoscope. Not doing so may cause a failure.

1.7.3 Storage and Management

⚠WARNING

Ultrasonic endoscopes are reusable devices subject to routine wear and tear. Many factors can contribute to the reuse life of any instrument. Besides clinical use, routine handling as well as repeated cleaning and disinfection (or sterilization) can affect the durability of parts and materials. Periodic inspections should be performed to check the integrity of all external ultrasonic endoscope surfaces as well as components. Abnormalities and/or material changes including but not limited to cracking, flaking, pitting, corrosion, etc. which can create sharp edges, compromise sealed surfaces and/or negatively affect device functionality are indications for returning an instrument for evaluation or repair. Have this product checked by service personnel once every six months or once every 100 cases. Do not disassemble or modify this product.

1.7.4 General Warnings

⚠WARNING

Make sure to inspect the equipment before use according to the procedures provided in this manual to avoid unexpected accidents and to take full advantage of the equipment's capabilities. If the inspection result shows any abnormality, do not use the same equipment.

This product is an ultrasonic endoscope for the upper digestive tract. It is intended for the observation and diagnosis of the esophagus, stomach and duodenum, and for the observation, diagnosis and endoscopic treatment of submucosal and peripheral organs. Never use this product for any other purposes. It may cause severe harm to patient and/or end-users.This product is not intended for use on children and infants.

Do not use this product outside the specified operating environment. Otherwise, it can cause malfunction or failure.

⚠CAUTION

Do not use this product using maximum light intensity from the light source. Using the ALC (Automatic Light Control) mode is recommended. Refer to the manual of the light source for the ALC mode. When this product projects light at the maximum brightness for 2-3 minutes, temperature at the distal end may exceed 41°C. If the surface temperature exceeds 41°C, thermal injury to the patient may occur.

Turn off the lamp and stop the transmission of ultrasonic waves (freeze the ultrasonic processor) except during a procedure, inspection, etc., when necessary. If the lamp is left on, the distal end may become hot, causing burn injury to the operator, assistant or patient. Turn on the lamp and transmit ultrasonic waves immediately before starting a procedure.

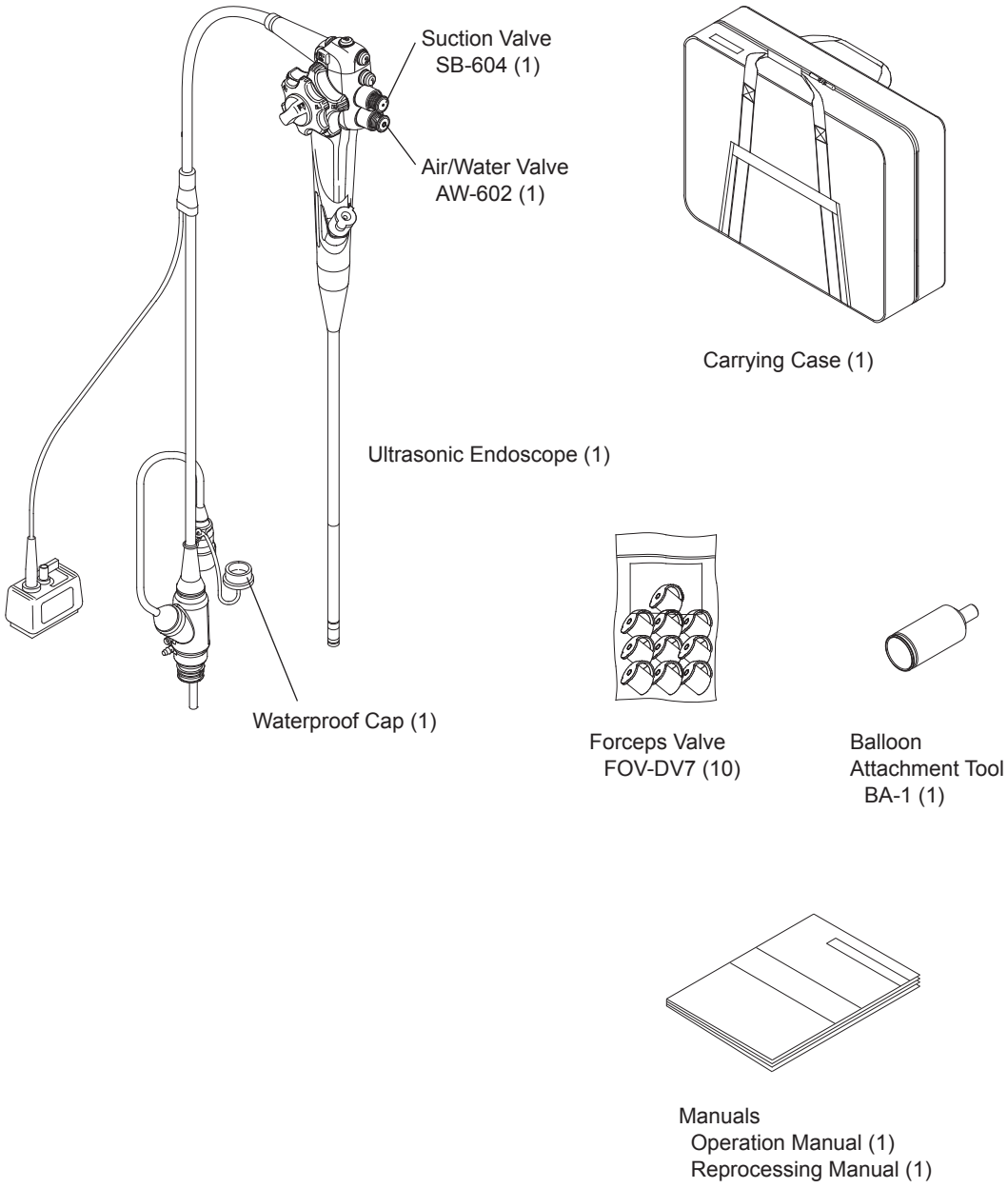
When turning off the processor, also turn off the light source. If the light source remains on after turning off the processor, the ALC (automatic light control) does not function and the maximum amount of light is emitted. As a result, the distal end of ultrasonic endoscope may become hot, causing burn injury to the operator, assistant or patient.

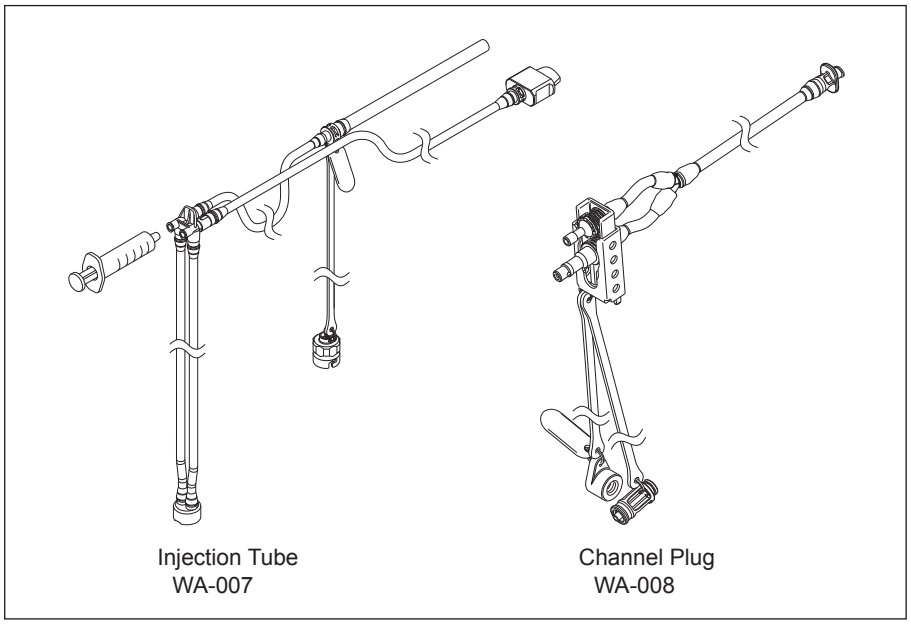
Chapter 2 Product Overview

2.1 Composition of Standard Set

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

[Note] Figures in parentheses indicate the number of articles.

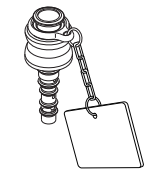




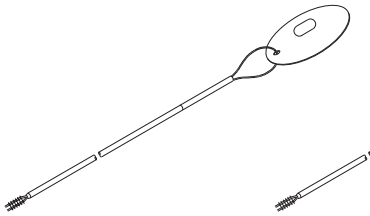
Injection Tube
WA-007

Channel Plug
WA-008

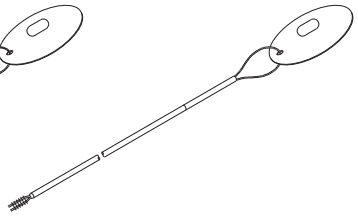
Cleaning Adapter
CA-608 (1)



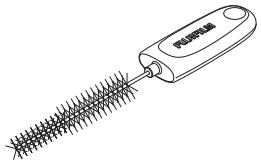
Air/Water Channel
Cleaning Adapter
CA-609 (1)



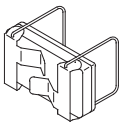
Cleaning Brush
WB7024FW (1)



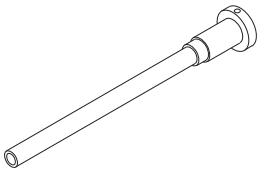
Cleaning Brush
WB2221FW2 (1)



Cleaning Brush
WB11003FW (1)



US Waterproof Cap
WA-7000 (1)

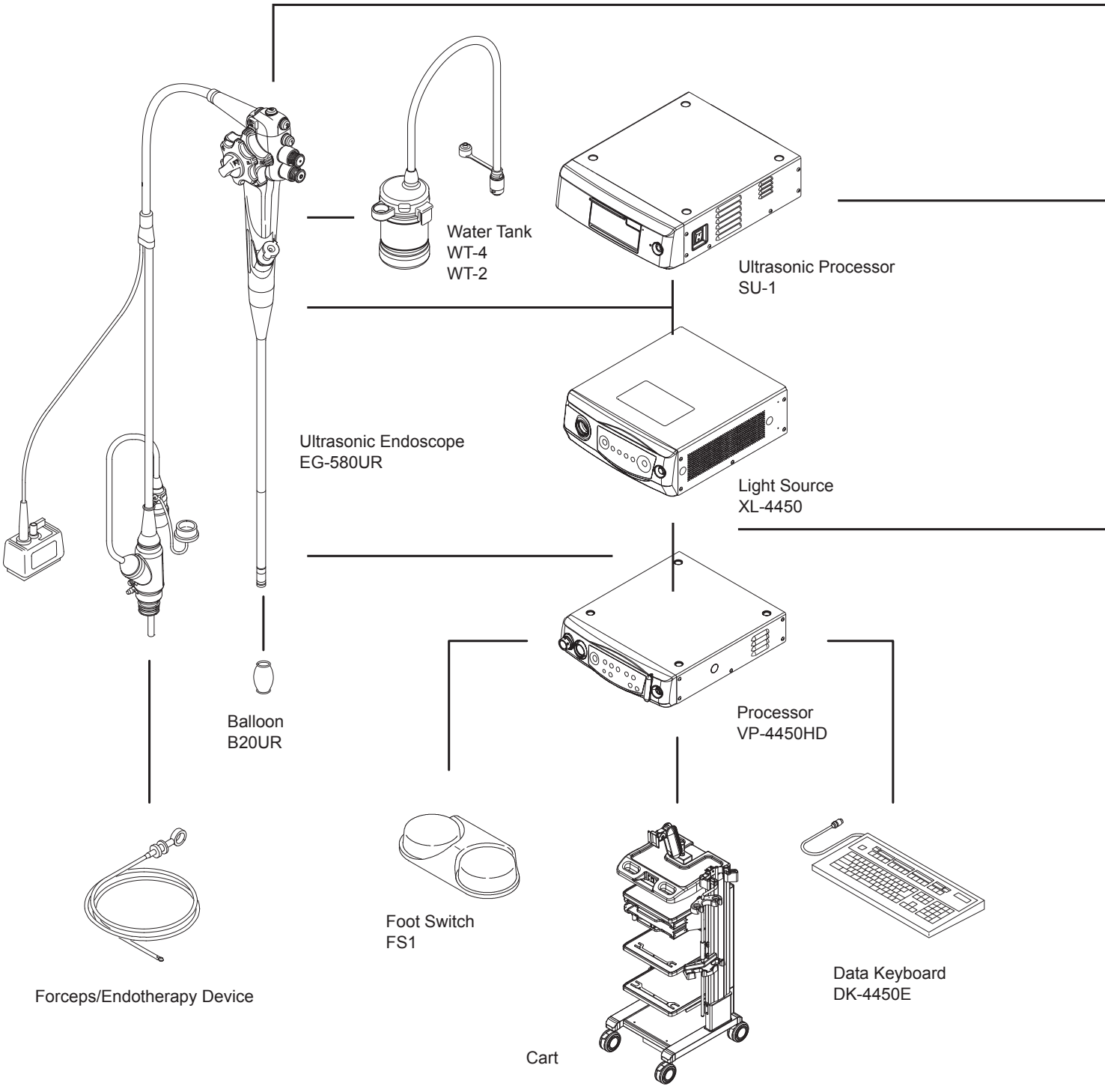


Ventilation Adapter
AD-7 (1)

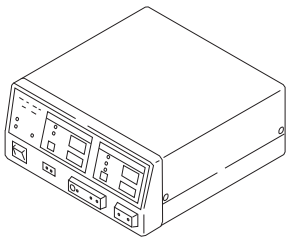
2.2 System Configuration

Optional peripheral devices including but not limited to the following various functions can be used with this product.

- Endoscopic treatment
- Recording video images
- Printing still images

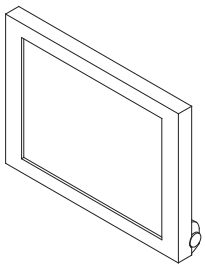


[Note] The devices described here may have already been discontinued. For details on the devices used in combination with this product, contact your local FUJIFILM dealer.

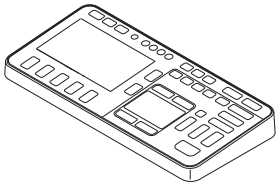


Electrosurgical Unit [Note 1]
ICC 200 (ERBE)

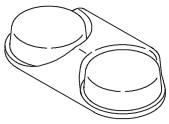
[Note 1] For details, refer to the manual of the electrosurgical instrument.



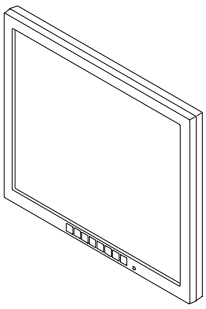
Monitor
CDL1909A
CDL1576A
RADIANCE24 (NDS)



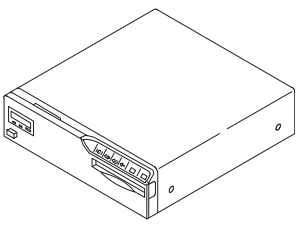
Keyboard
CP-1



Foot Switch
FS1



Monitor
CDL1909A
CDL1576A
RADIANCE24 (NDS)

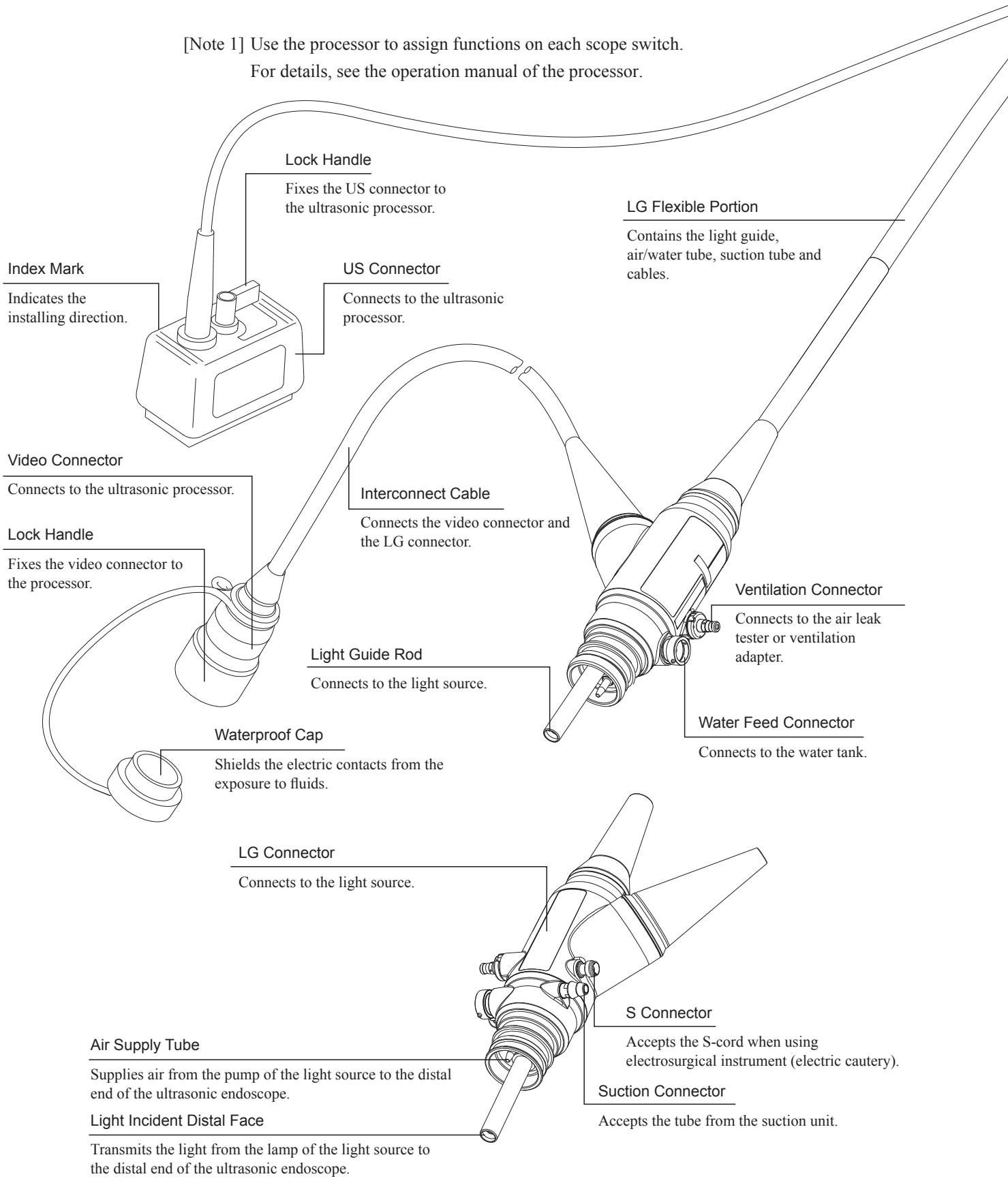


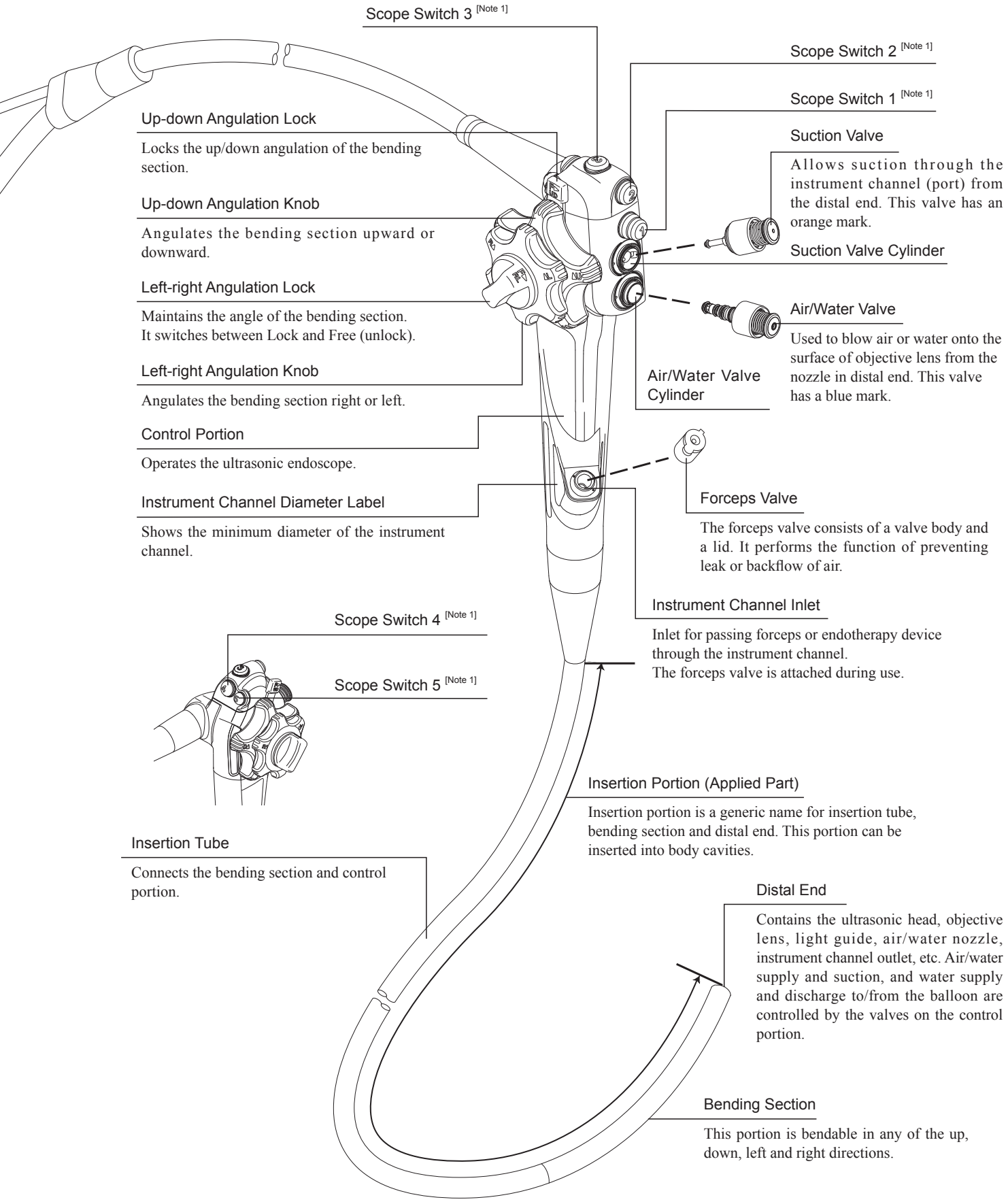
Printer
UP-55MD (SONY)
UP-21MDA (SONY)
CP900UM (120V)
(MITSUBISHI ELECTRIC)
CP900E (230V)
(MITSUBISHI ELECTRIC)

2.3 Nomenclature and Functions of Ultrasonic Endoscope

This product consists of the following parts.

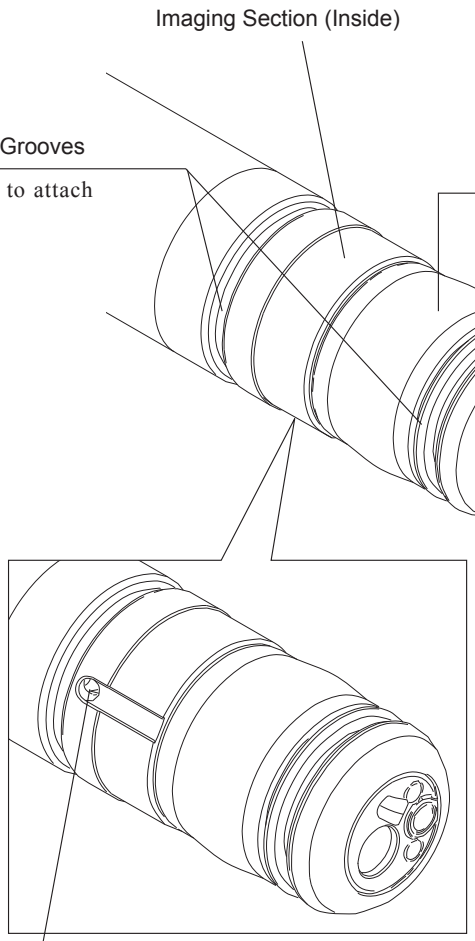
[Note 1] Use the processor to assign functions on each scope switch.
For details, see the operation manual of the processor.




Scope Switch 3 [Note 1]
Scope Switch 2 [Note 1]
Scope Switch 1 [Note 1]
Up-down Angulation Lock
Locks the up/down angulation of the bending section.
Suction Valve
Allows suction through the instrument channel (port) from the distal end. This valve has an orange mark.
Up-down Angulation Knob
Angulates the bending section upward or downward.
Suction Valve Cylinder
Left-right Angulation Lock
Maintains the angle of the bending section.
It switches between Lock and Free (unlock).
Air/Water Valve
Used to blow air or water onto the surface of objective lens from the nozzle in distal end. This valve has a blue mark.
Left-right Angulation Knob
Angulates the bending section right or left.
Air/Water Valve Cylinder
Control Portion
Operates the ultrasonic endoscope.
Instrument Channel Diameter Label
Shows the minimum diameter of the instrument channel.
Forceps Valve
The forceps valve consists of a valve body and a lid. It performs the function of preventing leak or backflow of air.
Instrument Channel Inlet
Inlet for passing forceps or endotherapy device through the instrument channel.
The forceps valve is attached during use.
Scope Switch 4 [Note 1]
Scope Switch 5 [Note 1]
Insertion Portion (Applied Part)
Insertion portion is a generic name for insertion tube, bending section and distal end. This portion can be inserted into body cavities.
Insertion Tube
Connects the bending section and control portion.
Distal End
Contains the ultrasonic head, objective lens, light guide, air/water nozzle, instrument channel outlet, etc. Air/water supply and suction, and water supply and discharge to/from the balloon are controlled by the valves on the control portion.
Bending Section
This portion is bendable in any of the up, down, left and right directions.

2.4 Nomenclature and Functions of Ultrasonic Endoscope Distal End

The distal end of the EG-580UR consists of the following parts.

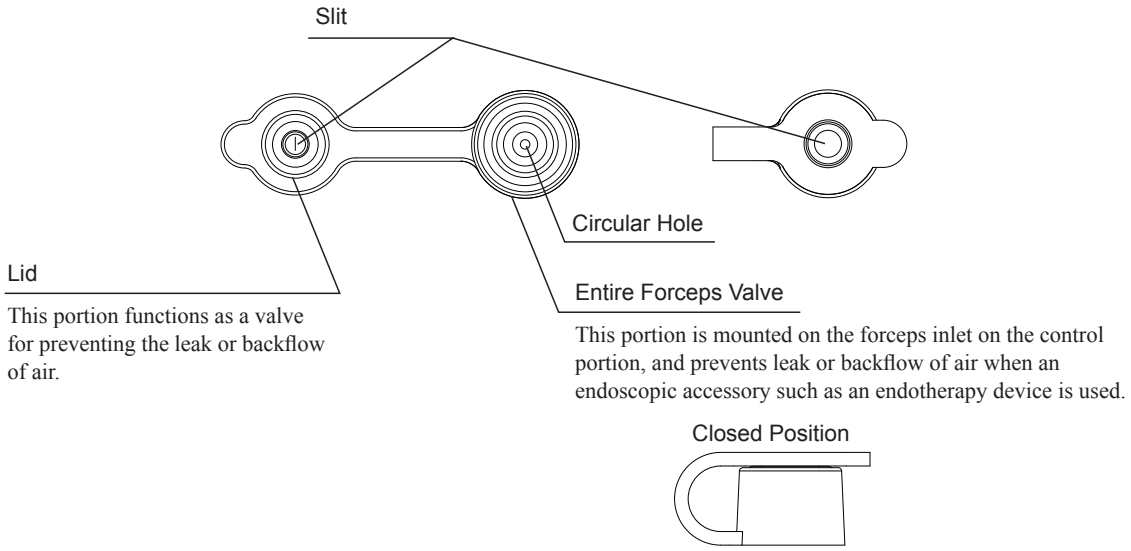


2.5 Nomenclature and Functions of Accessories

2.5.1 Forceps Valve

The forceps valve is provided without sterilization and must be cleaned and disinfected (or sterilized) prior to use following the instructions of the Reprocessing Manual.

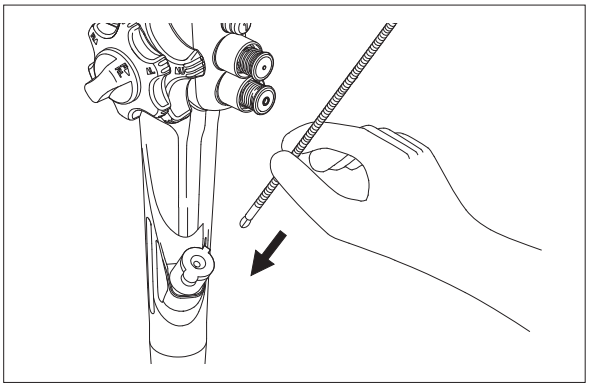
➡ Reprocessing Manual “7.1 Cleaning and Disinfecting (or Sterilizing) Forceps Valve”



<How to Use the Forceps Valve>

The forceps valve consists of a valve body and a lid. It performs the function of preventing leak or backflow of air. A lid should normally be kept closed.

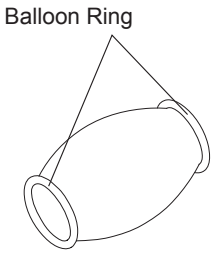
When attaching the syringe to supply water or fluid, remove this lid.



[Note]

When not using an endotherapy device or syringe through the instrument channel inlet, keep this lid closed.

2.5.2 Balloon

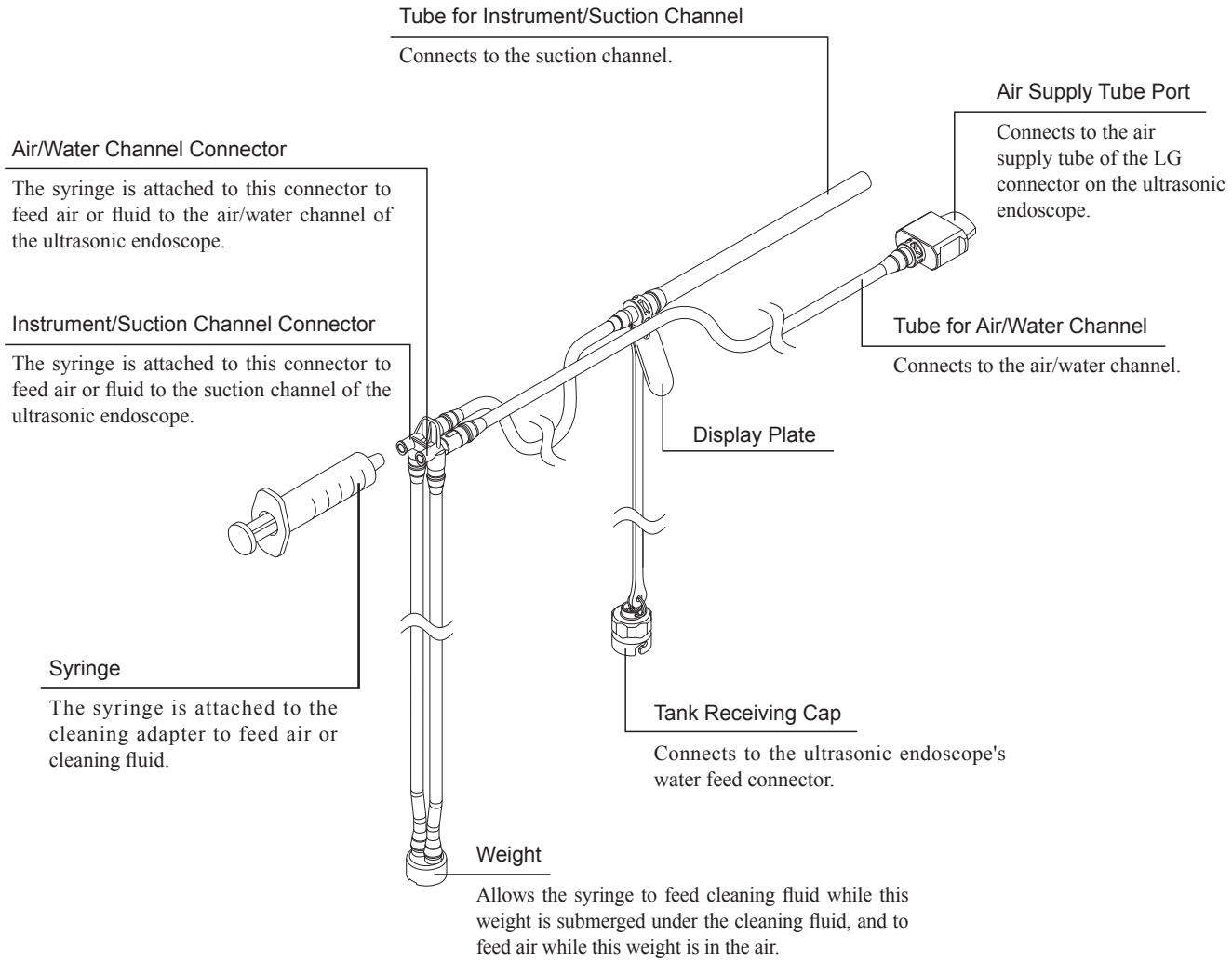


Balloon
B20UR

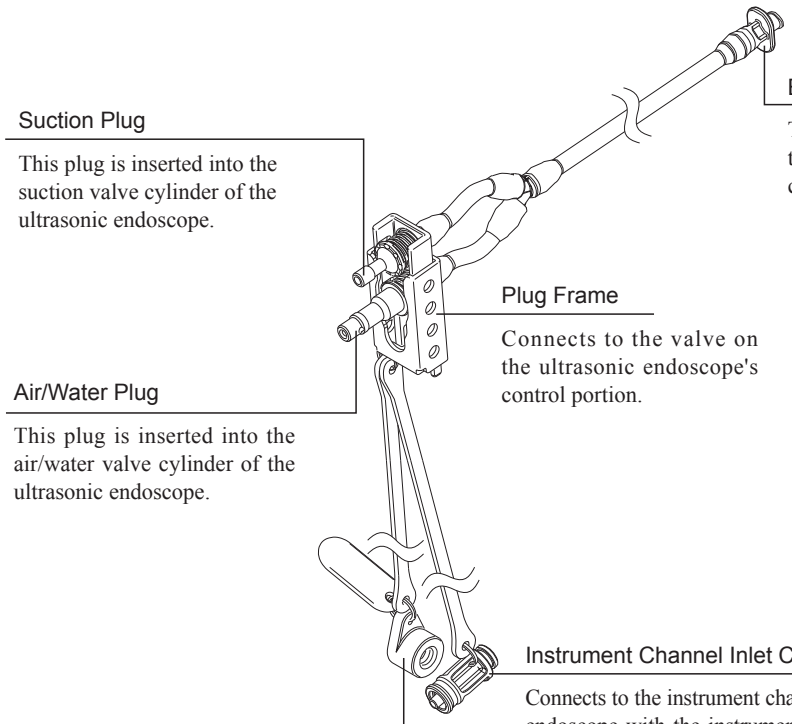
2.5.3 Cleaning Adapter

The cleaning adapter (CA-608) is comprised of the injection tube (WA-007) and channel plug (WA-008).

<Injection Tube (WA-007)>



<Channel Plug (WA-008)>



<How to Use Cleaning Adapter>

For details on how to use the cleaning adapter, see the Reprocessing Manual.

➞ Reprocessing Manual “2.3 Nomenclature and Functions of Cleaning Adapter”

2.6 Operating Bending Section

2.6.1 Operating the Bending Section

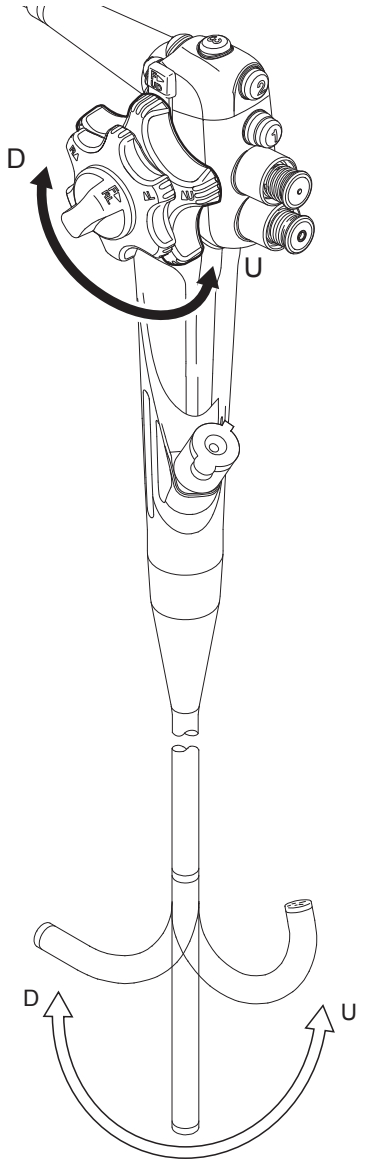
CAUTION

Do not forcibly twist or bend too sharply the insertion tube and the bending section by hand. It may cause a failure.

The bending section is operated by using up-down/left-right angulation knobs.

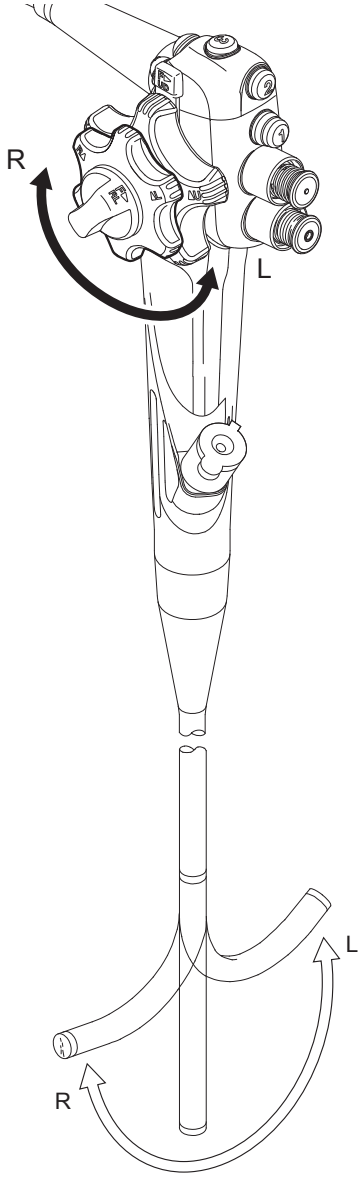
<Up-down Angulation Knob>

Turn the up-down angulation knob in the direction of U ► to angulate the bending section upward.
Turn it in the direction of D ► to angulate the bending section downward.



<Left-right Angulation Knob>

Turn the left-right angulation knob in the direction of L ► to angulate the bending section to the left.
Turn it in the direction of R ► to angulate the bending section to the right.



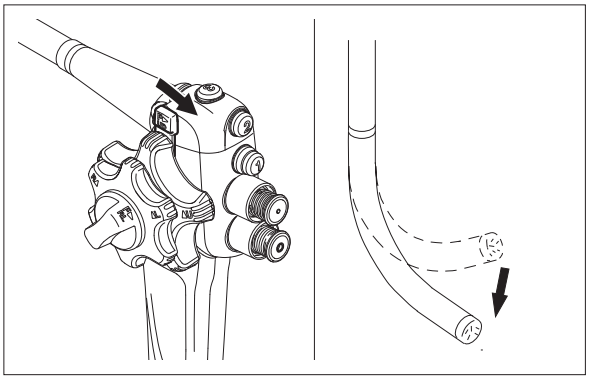
2.6.2 Angle Lock Function

This angle lock function is used to maintain a bent condition of the bending section.
With the up-down angulation lock operation, it switches between lock and free (unlock) of the up/down angulation.
With the left-right angulation lock operation, it switches between lock and free (unlock) of the left/right angulation.
The lever and knob can be operated either before or after operating the bending section.

[Note] When operating the bending section while the angle is locked, angulation knob rotation becomes heavy.

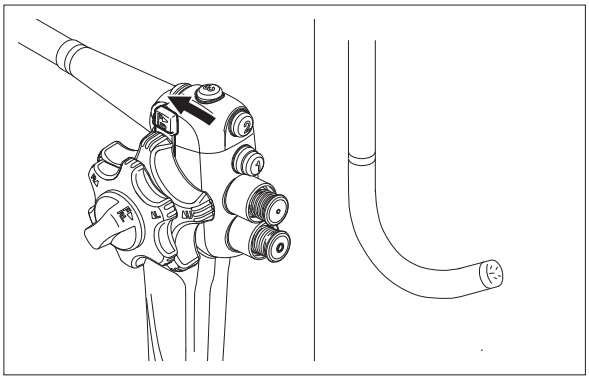
<Up-down Angulation Lock>

Move the lever in the direction of F ► to unlock the bending section.



[Note]
Free (unlock) : Allows external force to angulate the bending section freely.

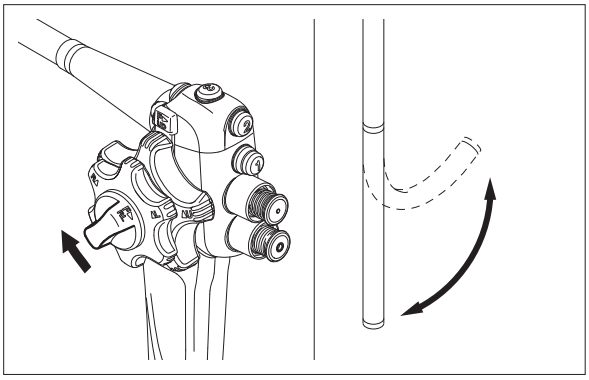
Move the lever in the direction opposite to F ► to lock the bending section.



[Note]
Lock : Maintains the angle of the bending section.

<Left-right Angulation Lock>

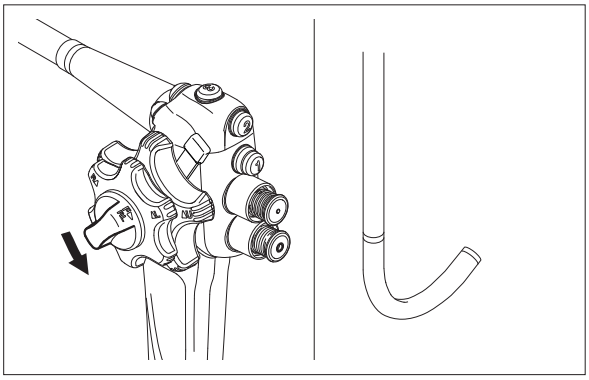
Rotate the knob in the direction of F ► to unlock the bending section.



[Note]

Free (unlock) : Allows external force to angulate the bending section freely.

Rotate the knob in the direction opposite to F ► to lock the bending section.



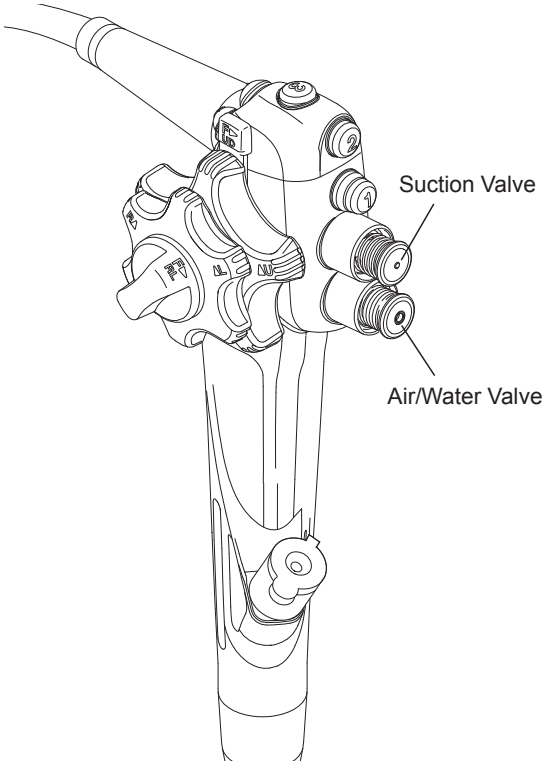
[Note]

Lock : Maintains the angle of the bending section.

2.7 Control Valves

<Suction Valve>

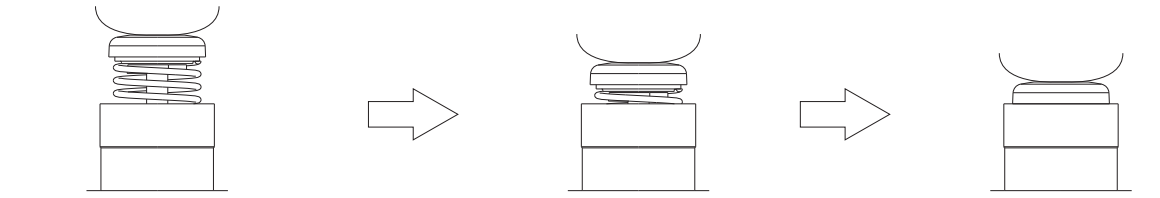
Used for suction from the instrument channel outlet at the distal end. Also used to discharge water from the balloon.
When the suction valve is pressed halfway, suction continues while the valve is pressed.
When the suction valve is fully pressed, water is discharged from the balloon.



<Air/Water Valve>

Used to supply air or water from the nozzle on the distal end onto the objective lens. Also used to feed water to the balloon.
To supply air, stop the hole in the center of this valve with a finger.
When the air/water valve is pressed halfway, the water is supplied.
When the air/water valve is fully pressed, water is supplied to the balloon.

Operation of the suction valve and air/water valve

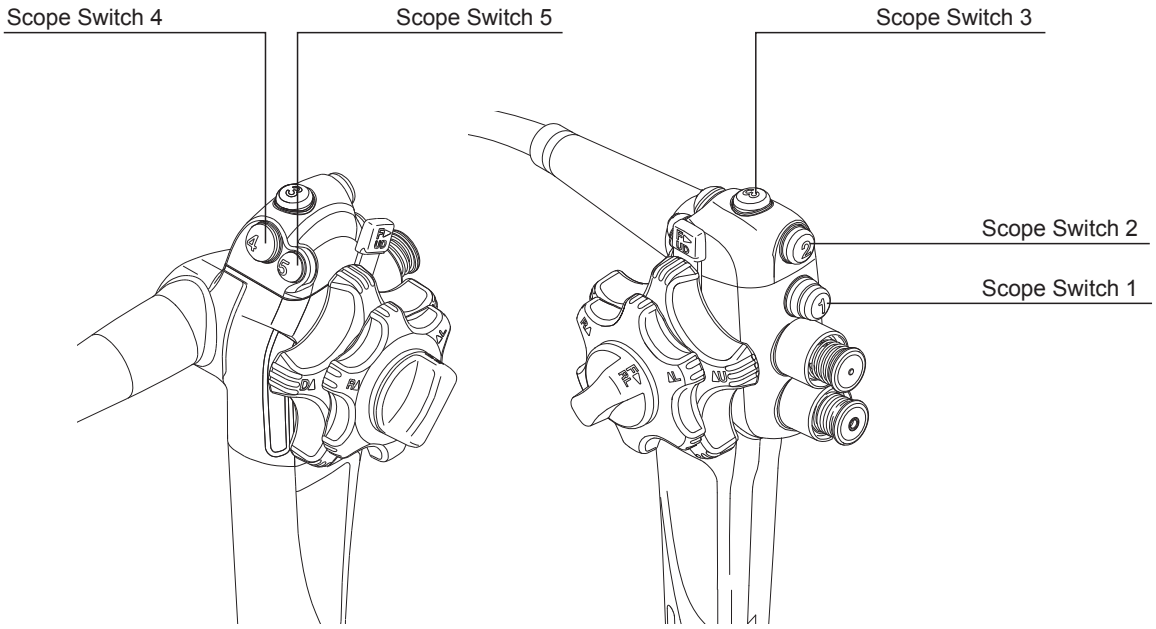


	Stopping the hole with a finger	Half press	Full press
Suction valve		Suctions water from the instrument channel outlet.	Suctions water from the balloon evacuation channel.
Air/water valve	Supplies air from the nozzle at the distal end.	Supplies water to the nozzle at the distal end.	Supplies water to the balloon water feed channel.

2.8 Scope Switches

CAUTION

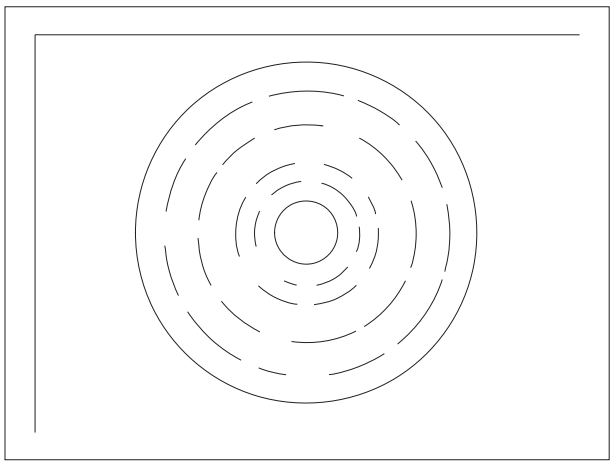
Use the processor to assign functions on each scope switch.
For details, see the operation manual of the processor.



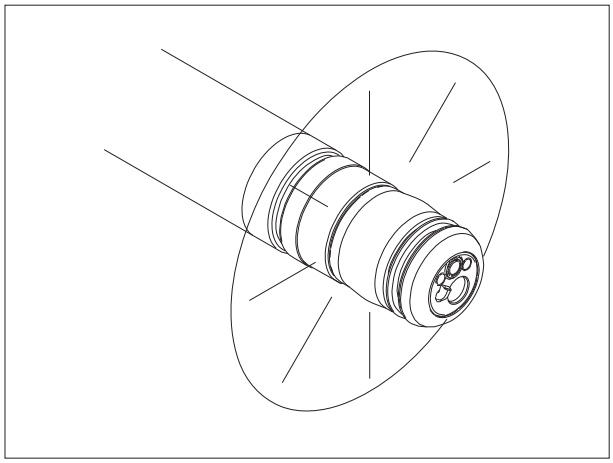
For details, see the operation manual of the processor.

2.9 Ultrasonic Image

This section describes the functions specific to this ultrasonic endoscope.
The following image is an overview image of the ultrasonic image.



[Note] The ultrasonic image is a radial image extending from the point approximately 10 mm ahead of the distal end of the ultrasonic endoscope. For details, refer to the operation manual of the ultrasonic processor.



Chapter 3 Preparation and Inspection Before Use

⚠CAUTION

Do not use the ultrasonic endoscope if the inspection result shows any abnormality. Doing so can negatively affect the functionality of the instrument or increase risks to patient safety.

3.1 Preparing Forceps Valve

⚠WARNING

Ensure that the forceps valve is properly attached to the instrument channel inlet. If this product is used without the forceps valve attached, body fluid may flow back and it could be a source of infection.

Attach a properly disinfected (or sterilized) forceps valve. If the forceps valve is not cleaned or disinfected (or sterilized) properly, it can create a risk of infection to patients and/or end-users.

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.

3.1.1 Cleaning and Disinfecting (or Sterilizing) the Forceps Valve

The forceps valve is provided without sterilization and must be cleaned and disinfected (or sterilized) prior to use following the instructions of the Reprocessing Manual.
The forceps valve is a single-use product. Do not reuse it to avoid infection.

[Note] For information on how to clean and disinfect (or sterilize) the forceps valve, refer to the Reprocessing Manual.

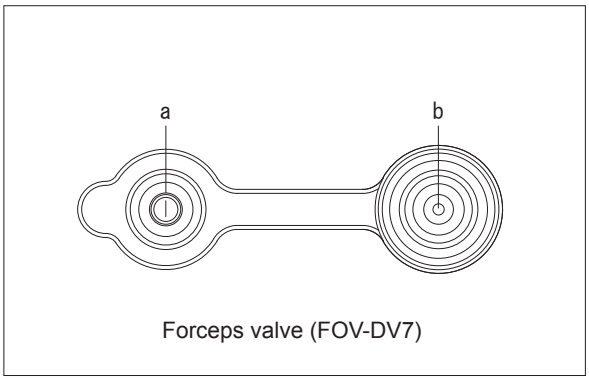
➞ Reprocessing Manual “7.1 Cleaning and Disinfection (or Sterilization) of Forceps Valve”

3.1.2 Inspecting the Forceps Valve

The forceps valve is intended for single use. If any abnormality is found, do not use the product, and use a new disinfected (or sterilized) forceps valve.

(1) Visually check that the slit in the cap (a) and hole in the main body (b) of the forceps valve are free from abnormalities such as tears, cracks, discoloration, etc.

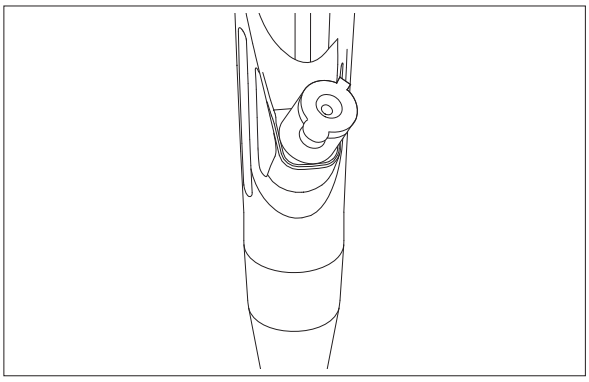
(2) Attach the lid to the main body of the forceps valve.



Forceps valve (FOV-DV7)

3.1.3 Attaching the Forceps Valve

(1) Attach the forceps valve to the instrument channel inlet of the ultrasonic endoscope.



3.2 Preparing Air/Water Valve and Suction Valve

⚠WARNING

Use a cleaned and disinfected (or sterilized) air/water valve and suction valve. An inadequately cleaned and disinfected (or sterilized) valve may pose an infection risk.

CAUTION

Do not apply silicone oil to the air/water valve or suction valve. Deterioration of the rubber seals may occur.

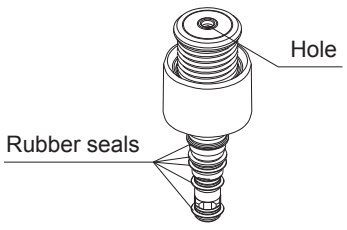
Prepare an appropriately cleaned and disinfected (or sterilized) air/water valve and suction valve.

3.2.1 Inspecting the Air/Water Valve and Suction Valve

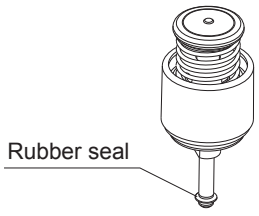
Visually check that the valves are free from abnormalities such as foreign substances adhering to the valves, tears, distortions, cracks, indentations, etc.

[Note]

The air/water valve and suction valve are consumable supplies. If any abnormality is found, use a new cleaned and disinfected (or sterilized) valve.



Air/water valve (AW-602)



Suction valve (SB-604)

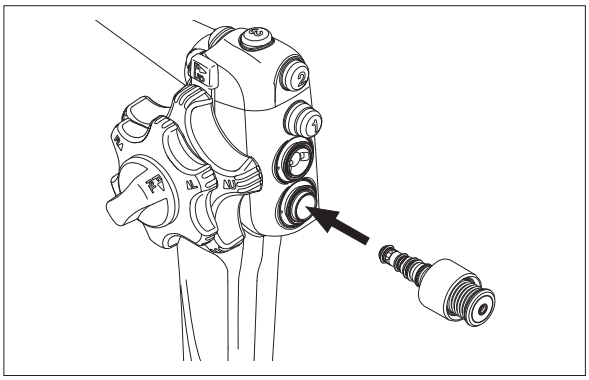
3.2.2 Attaching the Air/Water Valve and Suction Valve

Attach the air/water valve and suction valve to the control portion of the ultrasonic endoscope.

(1) Attach the air/water valve to the ultrasonic endoscope's air/water valve cylinder and push in the valve firmly.

[Note]

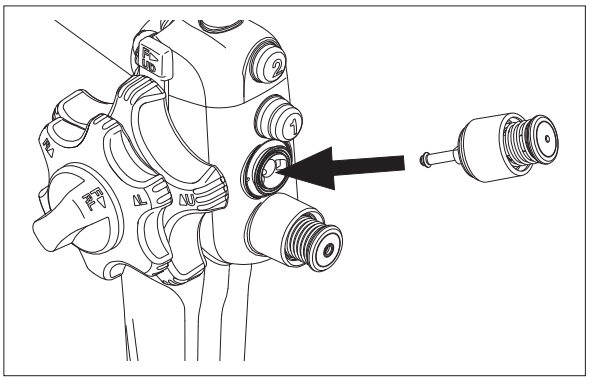
The air/water valve and the air/water valve cylinder have a blue mark.



(2) Attach the suction valve to the ultrasonic endoscope's suction valve cylinder and push in the valve firmly.

[Note]

The suction valve and the suction valve cylinder have an orange mark.



3.3 Preparing Peripheral Devices

For details on preparation and inspection of peripheral devices, refer to their manuals.

3.4 Preparing System

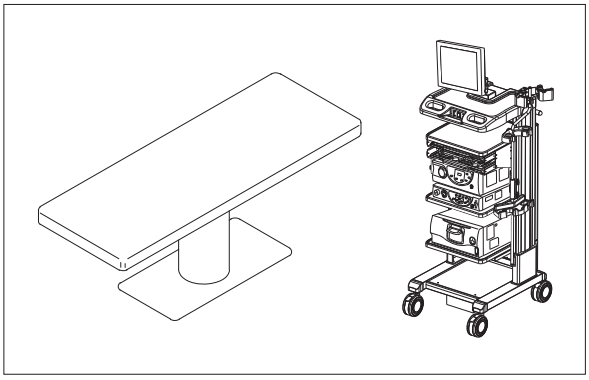
⚠WARNING

This product is not intended to stop bleeding with diathermic treatment equipment. Prepare an endoscope and diathermic treatment equipment that can be used with it, so as to take necessary actions in emergencies such as bleeding.

When supplying water, use sterile water. If sterile water is not used, it can create a risk of infection.

3.4.1 Preparing the System

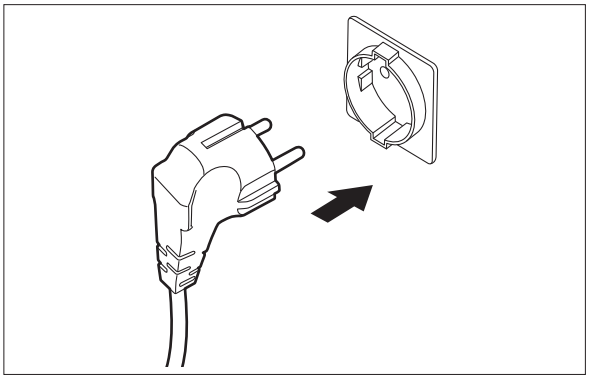
(1) Move the cart with the processor, light source, ultrasonic processor and peripherals to the place where ultrasonic endoscope is to be used.



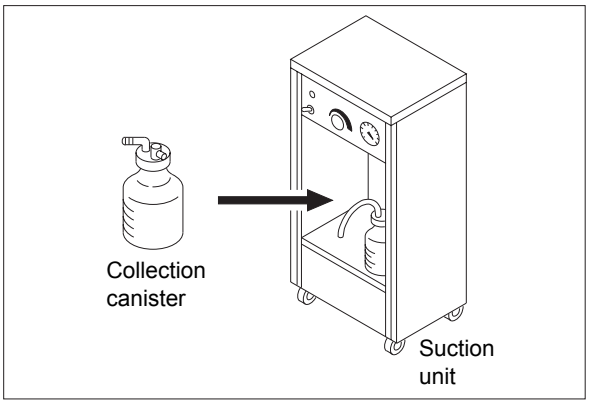
[Note]

Refer to the Installation Manual of the processor, light source and ultrasonic processor to install the peripherals onto the cart.

(2) After turning the main switch on the cart to OFF position, insert the AC plug of the cart into a hospital grade receptacle.



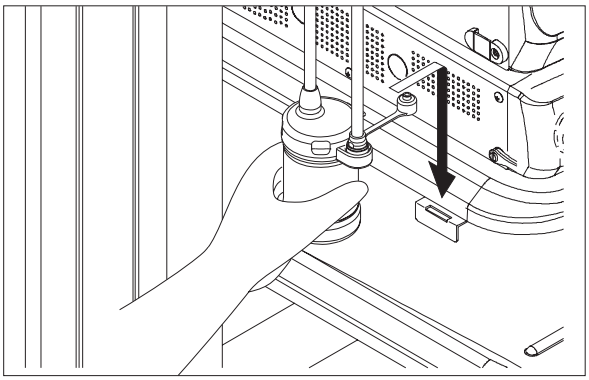
(3) Prepare the suction unit.



[Note]

For details on the suction unit, refer to the manual of the suction unit.

(4) Mount the water tank, 80% filled with sterile water, on the hook.



[Note]

The water in the water tank should be changed at least daily using sterile water.

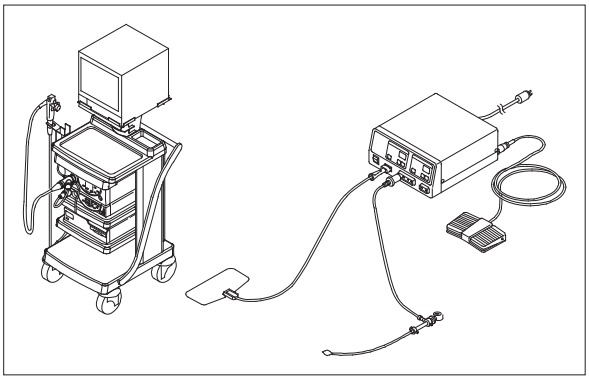
[Note]

When using the balloon, the sterile water in the water tank must be deaerated.

[Note]

Use a cleaned and disinfected (or sterilized) water tank.

(5) As a precaution in case of unexpected bleeding, prepare an endoscope and diathermic treatment equipment that can be used with it.



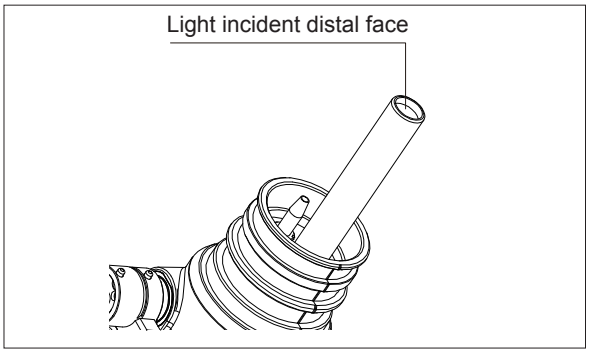
3.5 Connecting Ultrasonic Endoscope (Attachment)

⚠CAUTION

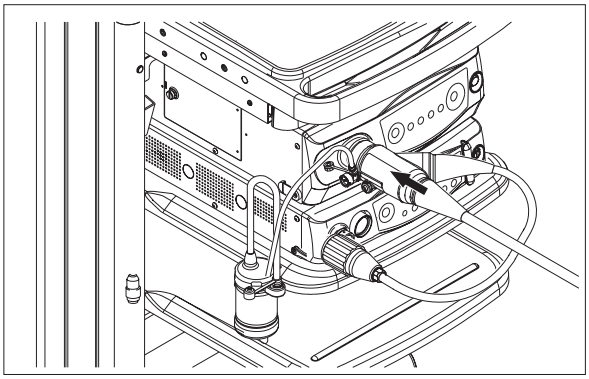
Set the suction pressure between 40 and 53 kPa. If the suction pressure is too high, the ultrasonic endoscope may adhere to mucous membrane, resulting in damage to the mucous membrane.

3.5.1 Connecting the Ultrasonic Endoscope (Processor, Light Source, Water Tank and Suction Unit)

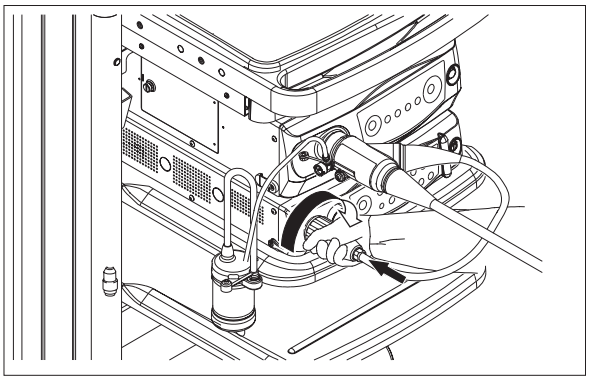
(1) Before attaching the LG connector to the light source, visually check that there is no dirt on the light incident distal face and no cracks on the glass of the light incident distal face.



(2) Insert the LG connector of the ultrasonic endoscope into the ultrasonic endoscope socket on the light source until it stops.



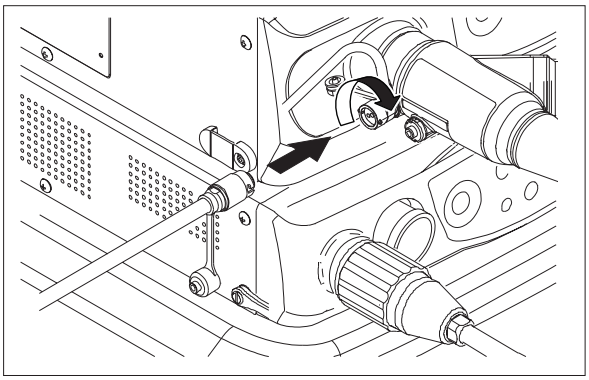
(3) Insert the video connector of the ultrasonic endoscope into the video connector socket on the processor.
Align the mark of the connector with the one of the connector socket, and attach the connector firmly by turning it clockwise while slightly pushing it.



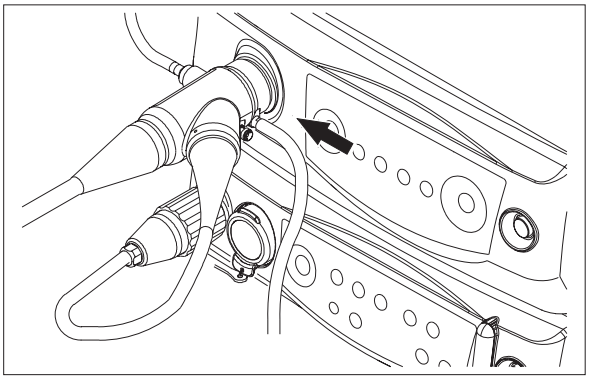
(4) Make sure that the forceps valve is attached to the instrument channel inlet of the ultrasonic endoscope.

(5) Insert the connector of the water tank to the water feed connector of the ultrasonic endoscope.

Align the groove on the connector and the pin of the water feed connector on the ultrasonic endoscope, and attach it firmly by turning the connector clockwise until it stops.



(6) Connect suction tube between the suction unit and suction connector of the ultrasonic endoscope.

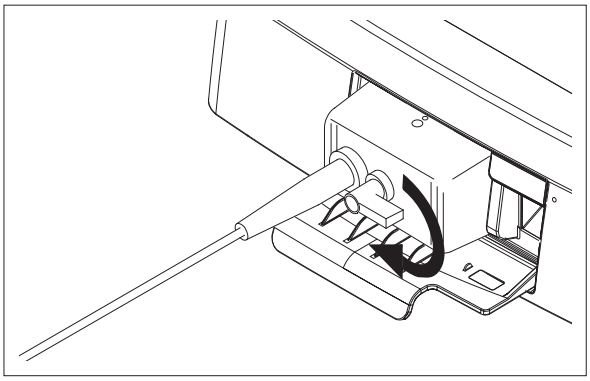


(7) Turn on the suction unit, and then set the suction pressure of suction source between 40 and 53 kPa.

(8) Check that the US connector and cable are free from scratches or dents.

(9) Align the index on the US connector with the mark on the ultrasonic processor, and insert the US connector straight to the ultrasonic endoscope connector of the ultrasonic processor.

(10) Turn the lock handle of the US connector clockwise to lock the connector.

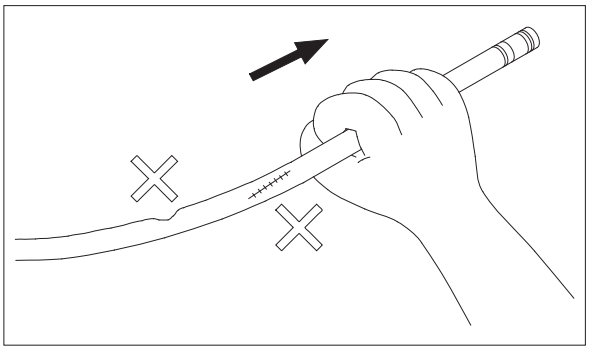


3.6 Inspecting Ultrasonic Endoscope

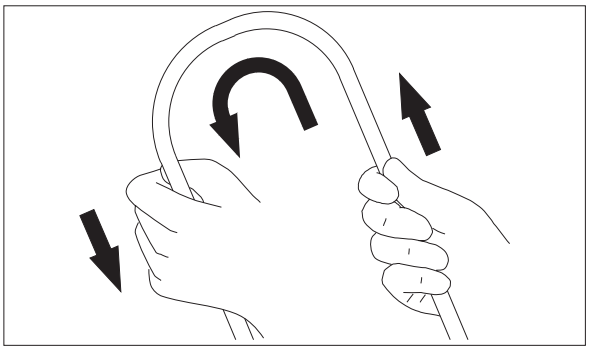
3.6.1 Inspecting the Insertion Portion

(1) Visually check the insertion portion (distal end, bending section and insertion tube) for abnormalities such as indentations, bumps, sharp edges or protrusions, etc. that could possibly harm a patient.

Confirm that the resin parts at each end of the bending section sheath are intact. If the adhesive surfaces are rough, pitted or flaking, return the instrument to your local FUJIFILM dealer.

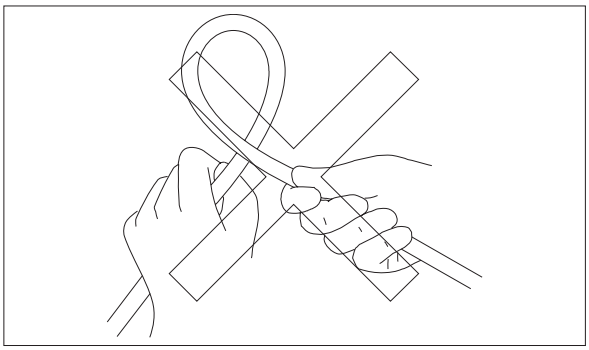


(2) Hold the insertion tube with both hands to make a semicircle with a diameter of approximately 200 mm, referring to the figure at right. Then, move the apex of semicircle sliding insertion tube for full length. Check that the tube bends fully and there is no local difficulty in bending it.



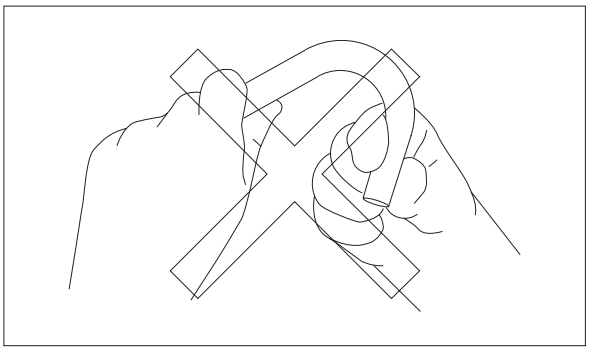
[Note]

Do not forcibly twist or bend too sharply the insertion tube by hands. It could damage the ultrasonic endoscope and/or negatively affect instrument functionality.



[Note]

Do not forcibly twist or bend too sharply the bending section by hands. It could damage the ultrasonic endoscope and/or negatively affect instrument functionality.



3.6.2 Inspecting the Bending Mechanism

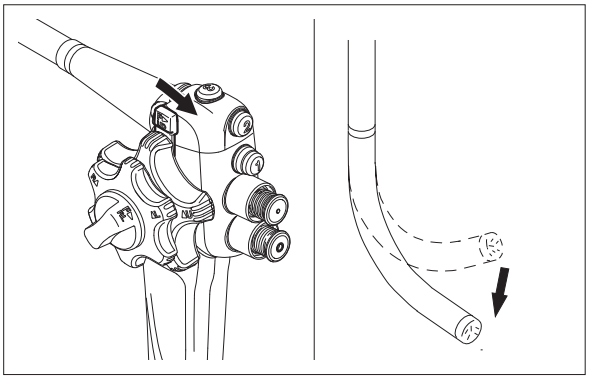
[Note] For information on how to operate the bending mechanism, refer to “2.6 Operating Bending Section” of this manual.

➞ “2.6 Operating Bending Section”

(1) Unlock both up-down and left-right angulation locks by turning them in the “Free” direction (F ►).

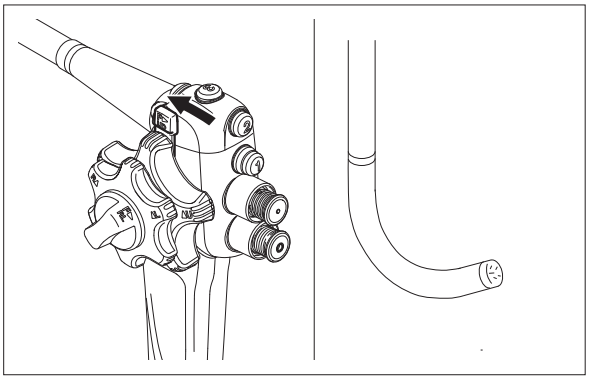
(2) Turn the up-down and left-right angulation knobs in the U, D, L and R directions until they stop.
Check that bending section turns smoothly.

When the angulation knob is released, the bending section should move toward its neutral position.



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

(4) Turn the angulation knobs in similar manner as in step (2), and check how the bending section angulates.
Check that the bending section maintains its angulated position after the angulation knobs are released.

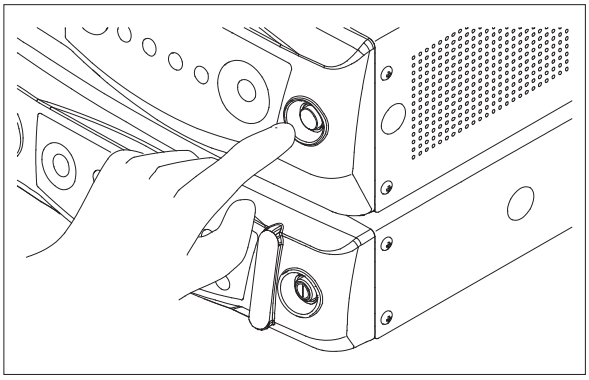


(5) Turn the up-down and left-right angulation locks in the direction of F ► to unlock them.

3.6.3 Inspecting the Air/Water and Instrument Channels

(1) Turn on the suction unit, cart, processor and light source. Keep the lamp off.

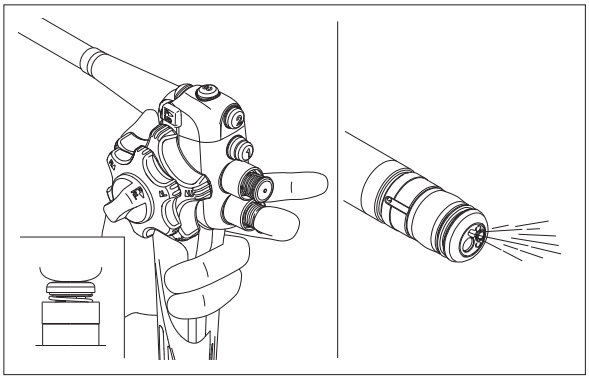
(2) Prepare a clean basin of sterile water.



(3) Place the distal end of the ultrasonic endoscope without touching the floor, etc., depress the air/water valve halfway, and check that sterile water comes out of the nozzle.

[Note]

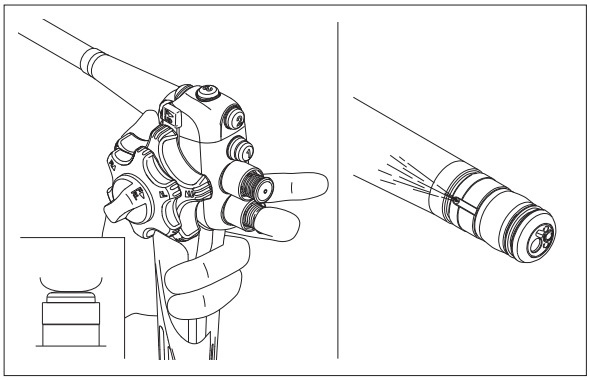
Mind the direction in which sterile water comes out since it may splash.



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

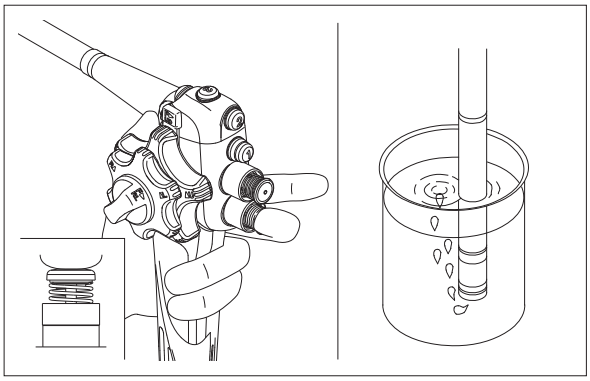
[Note]

Mind the direction in which sterile water comes out since it may splash.

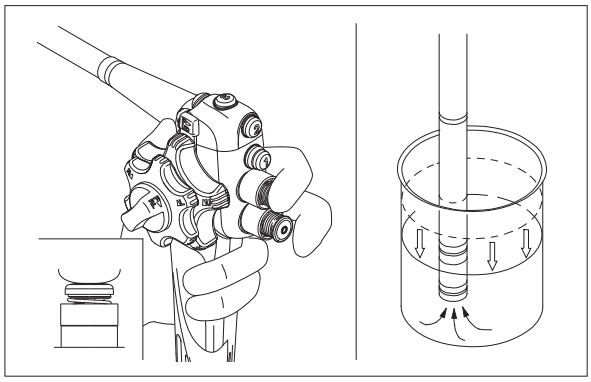


(5) Immerse the distal end of the ultrasonic endoscope in water, cover the hole at the center of the air/water valve with your finger, and then check that air comes out of the nozzle.

Release the finger from the hole and check that air does not come out of the nozzle.



(6) Attach the forceps valve to the instrument channel inlet. While immersing the distal end of the ultrasonic endoscope in water, check that the water is sucked in when the suction valve is pressed halfway and the suction stops when the finger is released from the valve.

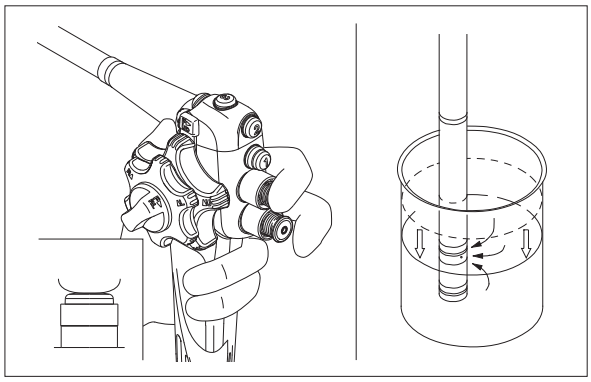


(7) Press the suction valve completely while immersing the distal end of the ultrasonic endoscope in water, and check that the water is sucked in from the balloon water port and suction stops when the finger is released from the valve.

[Note]

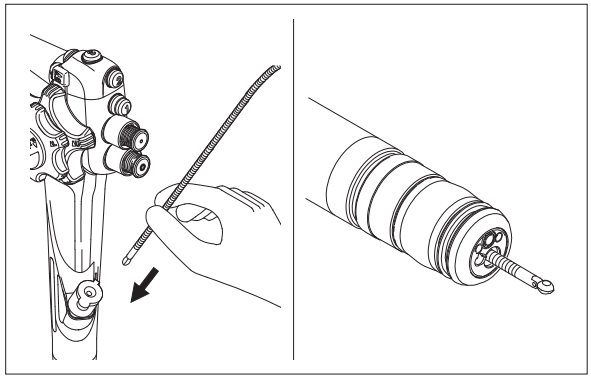
If little or no sterile water is aspirated, refer to “Chapter 5 Troubleshooting”.

➞ “Chapter 5 Troubleshooting”



3.6.4 Inspecting the Instrument Channel

Insert an endotherapy device from the instrument channel inlet and check that the tip of endotherapy device comes smoothly out of the instrument channel outlet in the distal end of the ultrasonic endoscope.



3.7 Inspecting Distal End of Ultrasonic Endoscope

⚠CAUTION

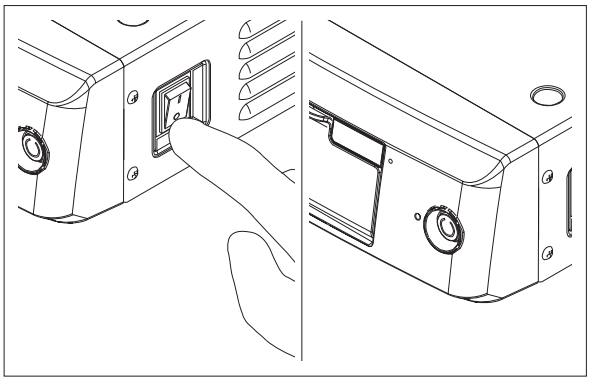
Turn off the lamp and stop the transmission of ultrasonic waves (freeze the ultrasonic processor) except during a procedure, inspection, etc., when necessary. If the lamp is left on, the distal end may become hot, causing burn injury to the operator, assistant or patient. Turn on the lamp and transmit ultrasonic waves immediately before starting a procedure.

Do not look directly into the light coming from the light guide at the distal end of the ultrasonic endoscope. Turn off the lamp before inspecting the objective lens. Viewing the light from the light guide directly may damage your eyes.

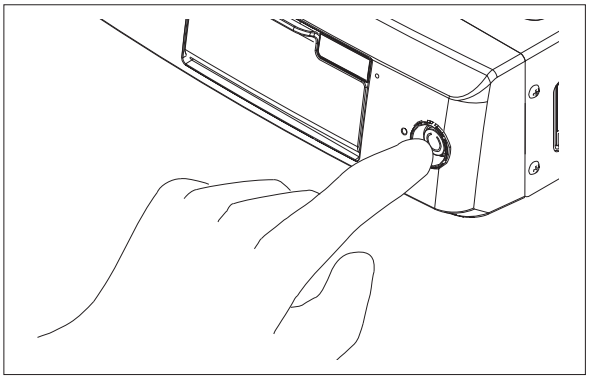
CAUTION

Do not apply a lens cleaner on the transducer. If the lens cleaner adheres to the transducer, wipe it off immediately. There is a risk of deteriorating the transducer.

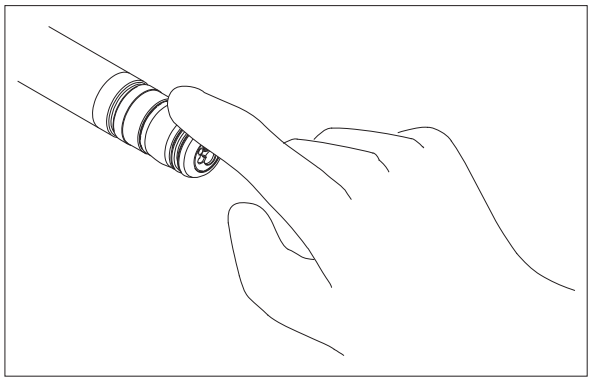
(1) Turn on the AC switch located on the side of the ultrasonic processor.



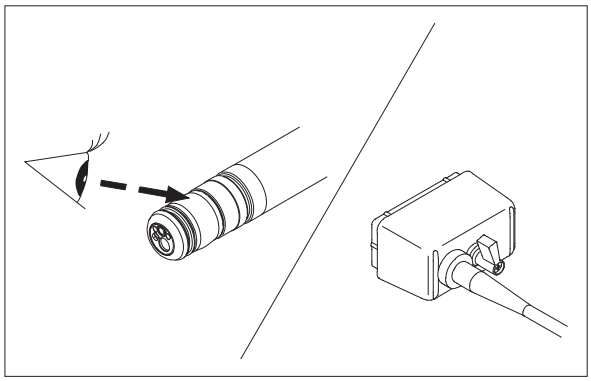
(2) Turn the power on by pressing the standby switch on the ultrasonic processor.



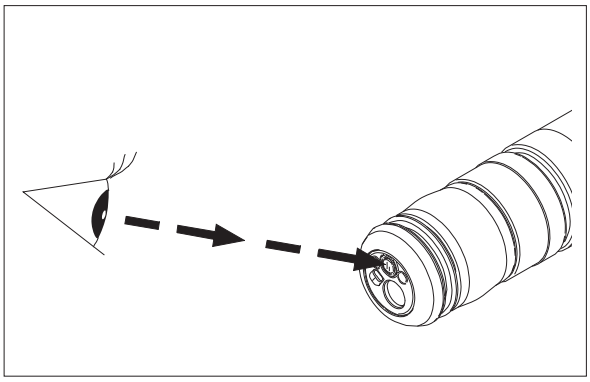
(3) Touch the transducer with a finger and check that it is not heated.



(4) Visually check the transducer, the US connector and the cables for abnormalities such as cracks or dents etc.



(5) Make sure that the lamp is turned off.



Be sure that the objective lens and light guides on the distal end of the ultrasonic endoscope are fixed correctly. Look the distal end from an angle to check no dirt or foreign substances adhering to the objective lens.

[Note]

Check that the objective lens and its surroundings are free from cracks.

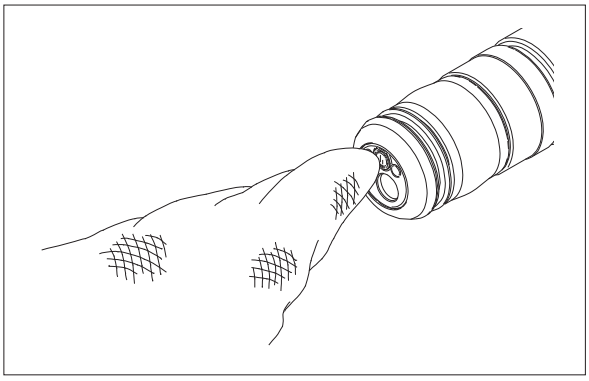
Also, check the following:

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

[Note]

If the distal adhesives are missing, peeling, deteriorated or if any lens is damaged or missing, contact your local FUJIFILM dealer.

(6) If the objective lens and the light guides are dirty or stained, thoroughly clean them.



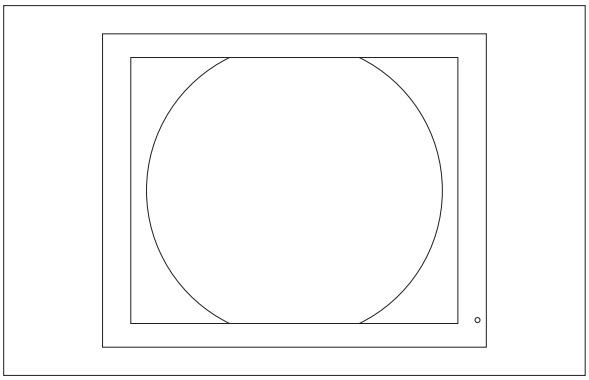
[Note]

To clean the objective lens and the light guides, wipe them with sterile gauze (or something similarly soft) dampened with lens cleaner (optional) or ethanol.

[Note]

Use lint-free sterile gauze to prevent fibers from entering the air/water nozzle.

(7) Press the Lamp button on the light source to turn on the lamp, and observe the endoscopic image on the monitor. Check that image is clear and nothing obstructs endoscopic view.

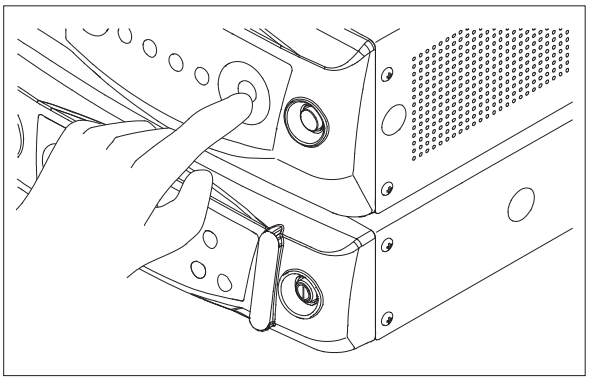


[Note]

If wiping does not remove cloudiness from objective lens, it is possible that ultrasonic endoscope is not sufficiently watertight. Perform air tightness test.

➞ Reprocessing Manual “4.6 Air Tightness Test”

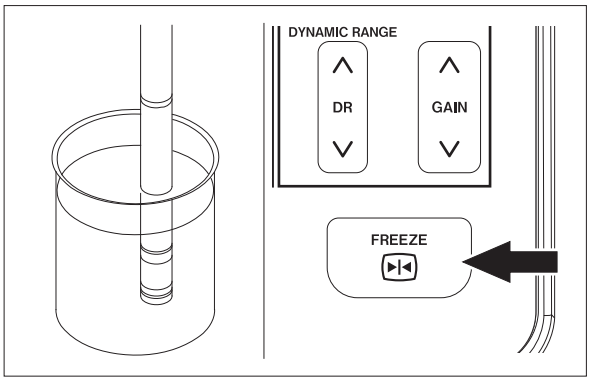
(8) When the inspection is over, press the Lamp button on the light source to turn off the lamp.



3.8 Inspecting Ultrasonic Image

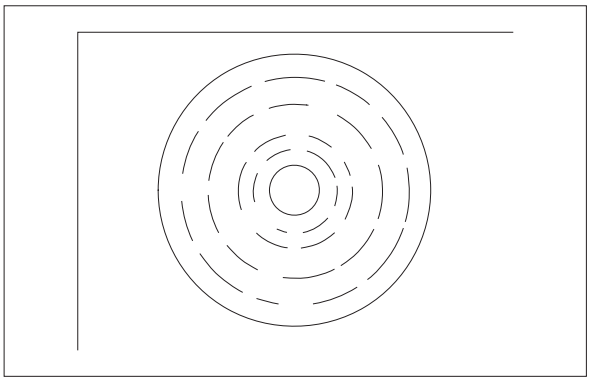
(1) Prepare a cup of water and immerse the distal end of the ultrasonic endoscope into water.

(2) Press the [FREEZE] key on the keyboard of the ultrasonic processor to cancel the freeze mode.



(3) Check that an ultrasonic image appears.

(4) Check that the ultrasonic image is displayed properly.



3.9 Attaching and Inspecting Balloon

⚠WARNING

Do not use this product with an endoscopic CO_2 regulator. If used, air bubbles may be generated in the sterile water inside the water tank and enter the balloon channel. This could prevent water discharge from the balloon and disable deflation of the balloon.

Use a disinfected (or sterilized) balloon attachment tool. There is a risk of infection.

Do not use a balloon on patients allergic to latex. There is a risk of an anaphylactic reaction.

CAUTION

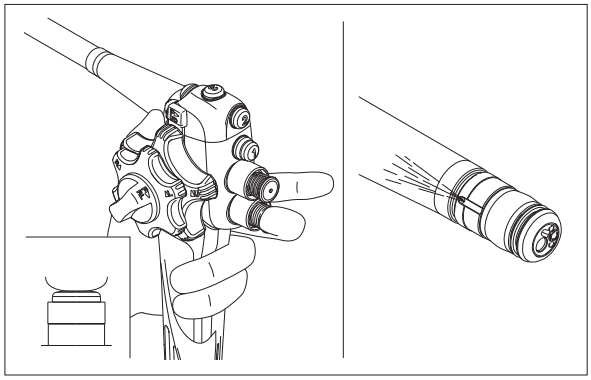
Do not feed more than 5 ml of water into the balloon. There is a risk of rupturing the balloon.

[Note] It takes approximately 3 seconds to feed in 5 ml of water. Check the amount of water to be fed before use.

[Note] If water cannot be discharged or little water is discharged from the balloon, refer to "Chapter 5 Troubleshooting".

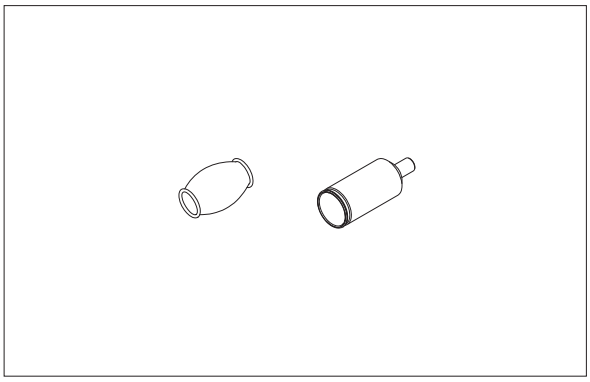
➞ "Chapter 5 Troubleshooting"

(1) Feed sterile water into the balloon water feed channel by fully pressing the air/water valve, and discharge air inside of the balloon water feed channel.

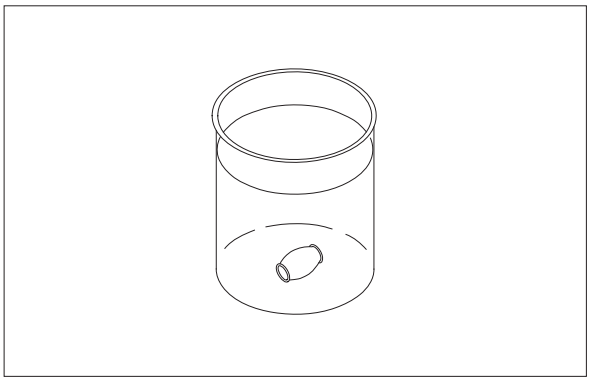


(2) Prepare a balloon and balloon attachment tool.

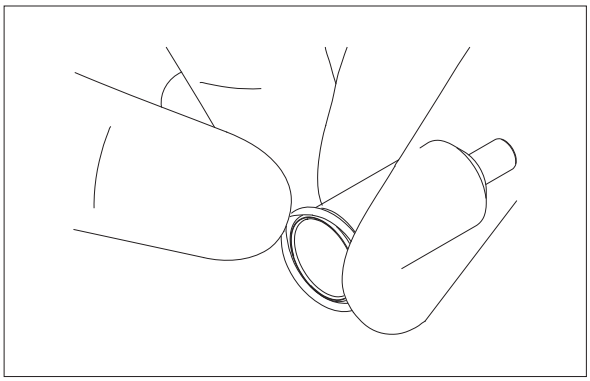
[Note]
Do not use the balloon if the expiration date has expired.



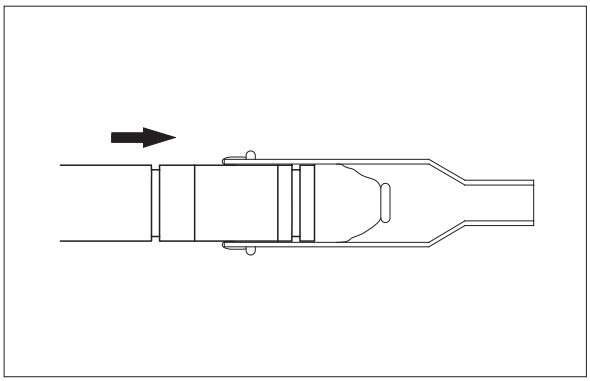
(3) Immerse the balloon into sterile water.



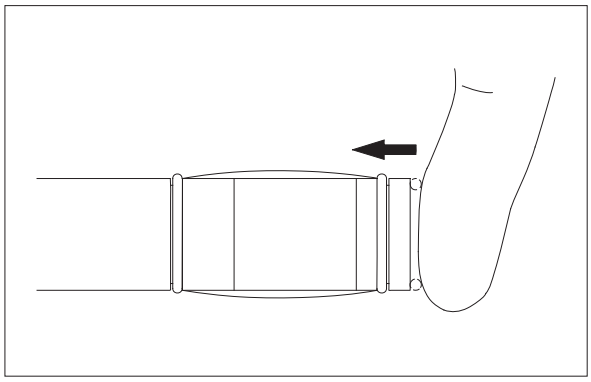
(4) Hold the balloon ring with your fingers and put it around the balloon attachment tool.



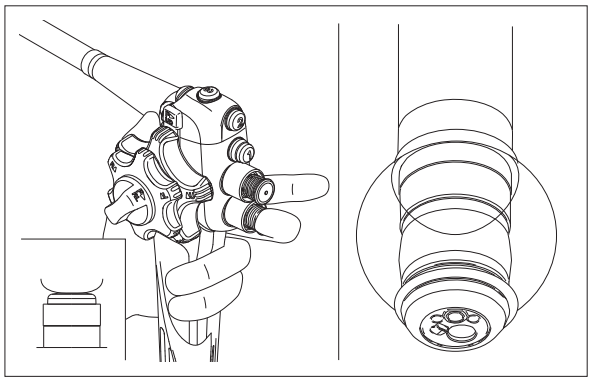
(5) Insert the distal end of the ultrasonic endoscope into the balloon attachment tool until the balloon ring fits firmly in the balloon attachment groove.



(6) Press the balloon ring on the other side with your thumb to fit it into the balloon attachment groove on the distal end side.



(7) Point the distal end of the ultrasonic endoscope downward. Press down the air/water valve fully to feed sterile water of 5 ml or less.



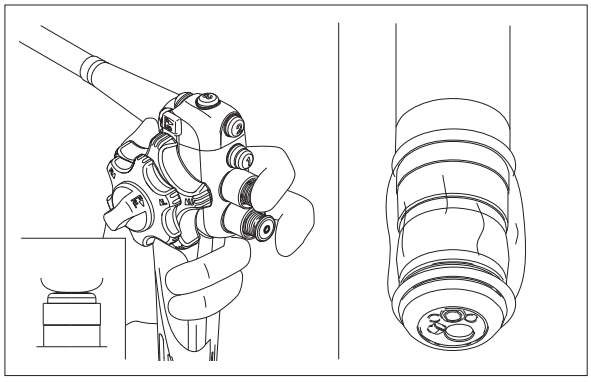
[Note]

It takes approximately 3 seconds to feed in 5 ml of water. Check the amount of water to be fed before use.

[Note]

Check that there is no water leak from the balloon.

(8) Press the suction valve fully to suck out all sterile water inside of the balloon.

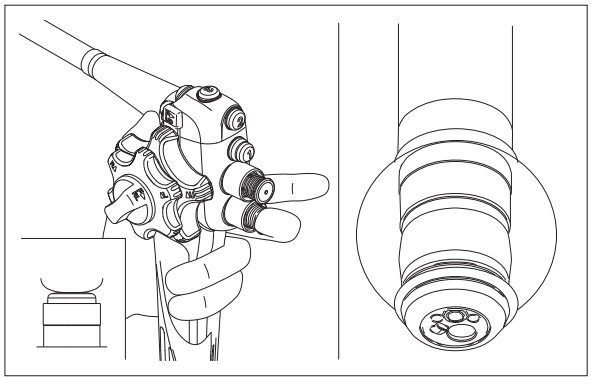


[Note]

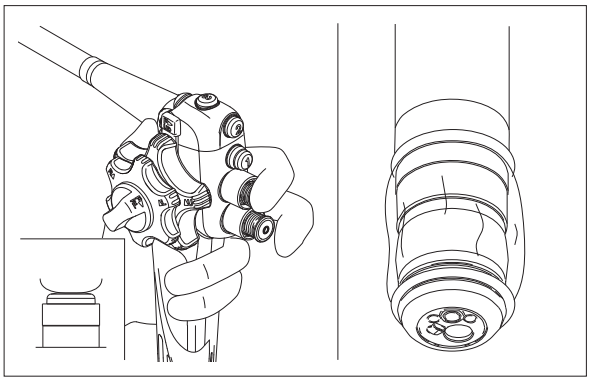
If water cannot be discharged or little water is discharged from the balloon, refer to “Chapter 5 Troubleshooting”.

➞ “Chapter 5 Troubleshooting”

(9) Feed water by pressing the air/water valve completely. The air inside the balloon will be discharged completely.



(10) Press the suction valve fully, and check that all of the sterile water is sucked out, and the balloon shrinks.



Chapter 4 Method of Use

⚠WARNING

Wear personal protective equipment during a procedure as well as during cleaning and disinfection (or sterilization) to protect your eye and skin and to prevent infection.

Use a cleaned and disinfected (or sterilized) endotherapy device. An inadequately cleaned and disinfected (or sterilized) endotherapy device may pose an infection risk.

Do not supply an excessive amount of air or gas during the procedure as doing so could cause an embolism. Do not overinsufflate during any clinical procedure to minimize the potential for pneumatic perforation.

[Note] Always observe the patient closely. If the patient has symptoms suggestive of an embolism or perforation, discontinue the endoscopic procedure immediately and give proper medical treatment.

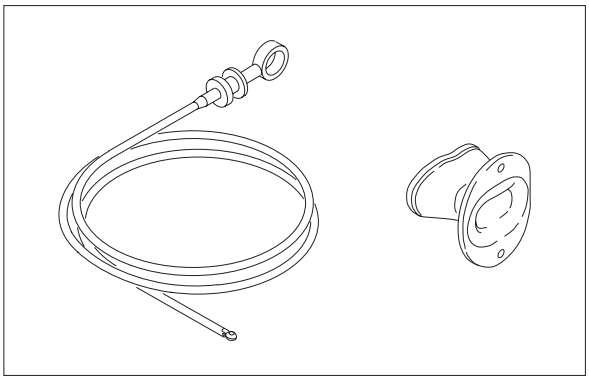
[Note] Electrosurgical procedures should be performed in accordance with operation manuals of electrosurgical instruments and electrosurgical generators.

[Note] For details on how to use endotherapy devices, refer to operation manuals of endotherapy devices.

4.1 Preparation

4.1.1 Preparing Necessary Equipment

Prepare the accessories and endotherapy devices, etc. to be used, and a spare forceps valve as well.



[Note]

Use a cleaned and disinfected (or sterilized) mouthpiece only.

4.1.2 Pretreatment of Patient

Prepare the patient in the normal endoscopy regimen.

4.2 Insertion and Observation

⚠WARNING

To avoid the potential for patient injury including perforation, do not apply excessive force of the ultrasonic endoscope or endotherapy device against mucosal surfaces. Only advance the endotherapy device while viewing the endoscopic image.

During ultrasonic procedures in which a balloon is not used, do not fully depress the suction valve and do not attempt to aspirate patient material into/through the balloon evacuation channel. Doing so can result in partial or complete clog of the narrow balloon evacuation channel, especially if the ultrasonic endoscope is not cleaned immediately after each procedure and if not reprocessed as per FUJIFILM recommendations. Once the balloon evacuation channel is clogged, it cannot be cleaned, disinfected or sterilized properly and can be a source of infection.

⚠CAUTION

Take extreme care when inserting the ultrasonic endoscope into the oral cavity. Otherwise, it may cause pain to the patient.

Do not forcibly advance or withdraw the ultrasonic endoscope into/from the patient. It may cause damage to the body lumen, bleeding or perforation.

Do not angulate the bending section forcibly or operate it quickly. It may cause damage to the body lumen, bleeding or perforation.

During an observation, do not perform close observation for an extended period of time. Use the ultrasonic endoscope with a minimum necessary amount of brightness and time while maintaining an appropriate distance. When the shutter speed is set to "HIGH", take care not to set the brightness level too high. Thermal energy created by illumination may cause burn injury.

For details on the settings, refer to the operation manual of the light source and processor in use. If the brightness level is high, the temperature at the distal end may exceed 41°C. Do not allow the distal end to remain in contact with the same site for an extended period of time. It may cause burn injury.

⚠CAUTION

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

CAUTION

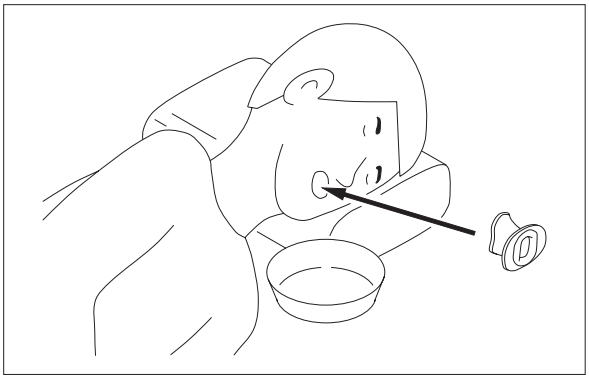
Do not directly apply Xylocaine spray to the insertion portion. It may cause deterioration of the outer surface. Do not use olive oil as a lubricant for insertion. It may cause swelling of the outer surface.

[Note] In cases with bleeding, use the light save function of the light source. Patient's blood adhering to light guide at the distal end of the ultrasonic endoscope may be coagulated by the energy of illumination. For details on how to use the light save function, refer to the operation manual of light source.

[Note] If any steam like smoke appears in the endoscopic image, or if the endoscopic image becomes dark, blood or other substances may adhere to the light guide at the distal end of the ultrasonic endoscope. Withdraw the ultrasonic endoscope from the patient immediately, remove foreign matter, make sure that the light guide has no abnormality, and then use the ultrasonic endoscope again. If foreign matter is not removed, the temperature at the distal end of the ultrasonic endoscope may rise, causing damage to the ultrasonic endoscope or burn injury to the patient or operator.

4.2.1 Preparing the Mouthpiece

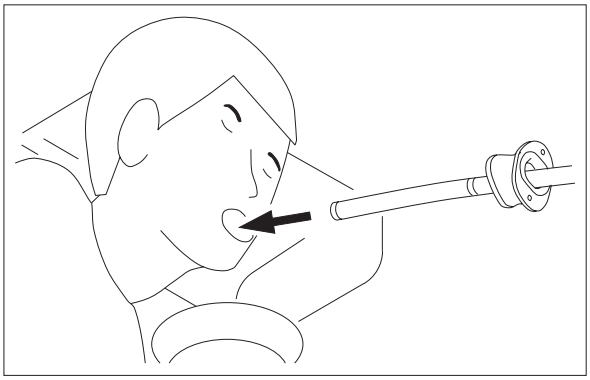
(1) Have the patient hold the mouthpiece in his/her mouth.



[Note]

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

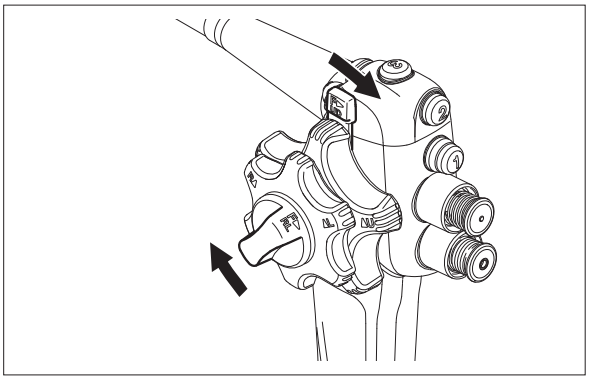
Have the patient hold it promptly after insertion.



4.2.2 Insertion

(1) Give instructions a patient to lie on examining table in a proper position according to endoscopy procedures.

(2) Unlock the bending section by turning the up-down and left-right angulation locks in the direction of F ► until they stop.



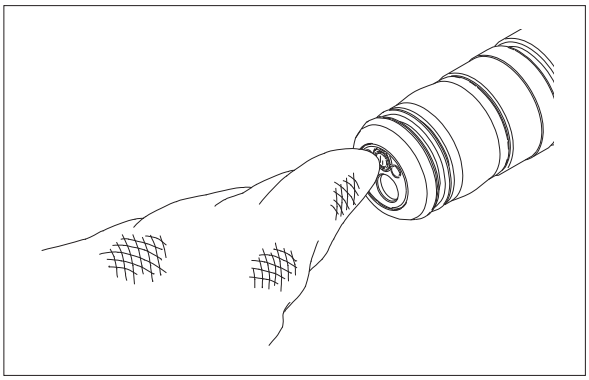
[Note]

We recommend the procedure above. However, another procedure is also available: you can insert ultrasonic endoscope by locking the bending section only in the left-right direction and unlocking it in the up-down direction.

(3) When necessary, apply lens cleaner to the objective lens and light guides.

[Note]

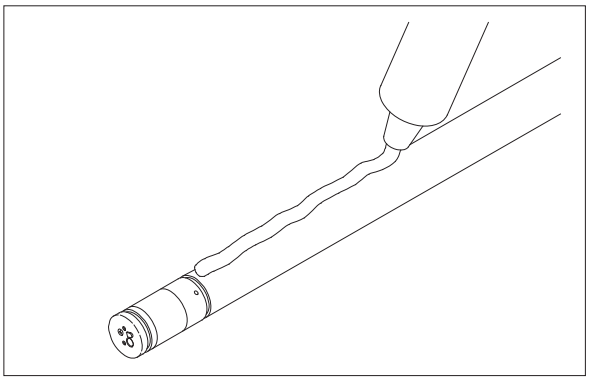
Use lint-free sterile gauze to prevent fibers from entering the air/water nozzle.



(4) Apply lubricant (Xylocaine jelly or the like) to the insertion portion.

[Note]

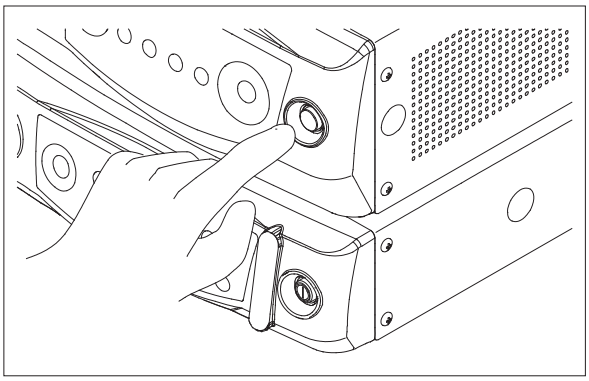
Do not apply Xylocaine spray, olive oil or the like directly to the insertion portion.



(5) Press the Lamp button on the light source to turn on the lamp.

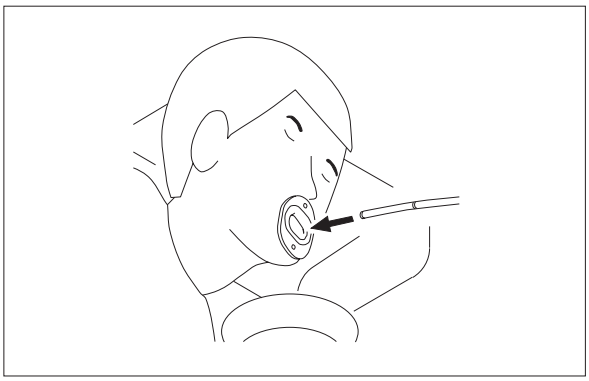
[Note]

If the light source is off, press the power button to turn it on.

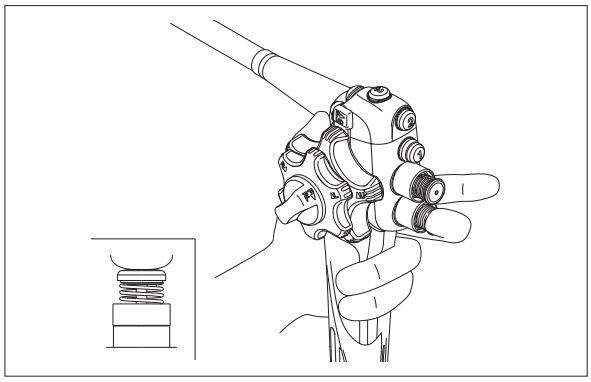


(6) Insert the distal end of the ultrasonic endoscope into the oral cavity and then move it down the pharynx while under constant observation.

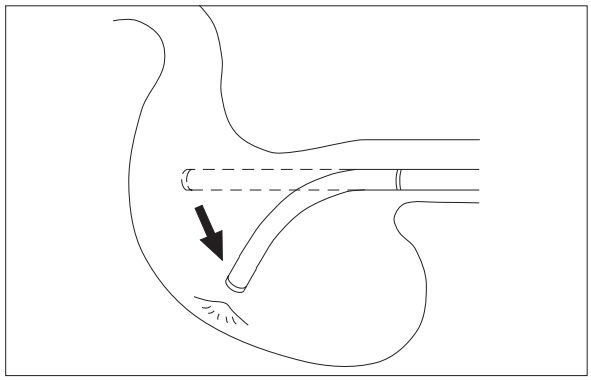
Adjust the brightness as needed by pressing the brightness adjustment button on the light source.



(7) Stop the center hole in the air/water valve with a finger to supply air to the digestive tract.
The mucous membrane of the digestive tract is displayed clearly.



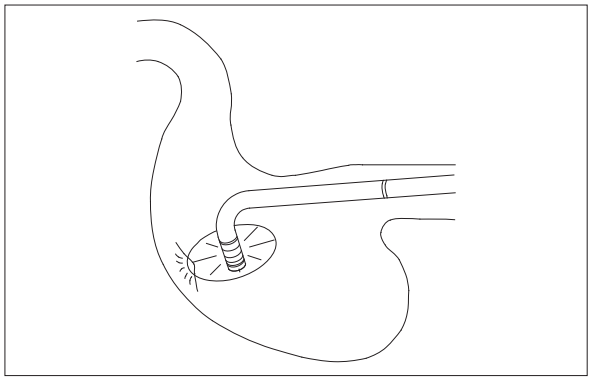
(8) Steer the distal end of the ultrasonic endoscope to the region of interest by turning the up-down and left-right angulation knobs.



[Note]
Never insert or withdraw the ultrasonic endoscope forcibly.

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

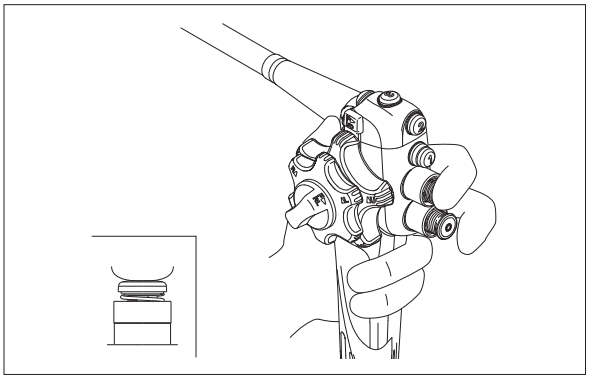
(9) Inject water through the instrument channel inlet to the area of interest and perform the ultrasonic observation.



[Note]
The ultrasonic image is a radial image extending from the point approximately 10 mm short of the distal end of the ultrasonic endoscope.

4.2.3 To Suck Mucus

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



[Note]

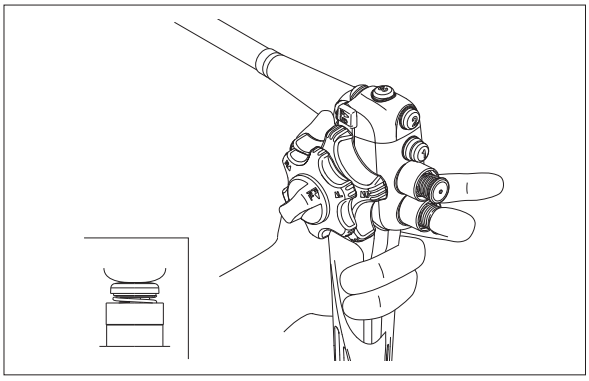
Do not suck in solid or viscous materials with the ultrasonic endoscope. Such material may clog the instrument channel or stick to the suction valve preventing proper stopping of suction.

[Note]

During ultrasonic procedures in which a balloon is not used, do not fully depress the suction valve and do not attempt to aspirate patient material into/through the balloon evacuation channel. Doing so can result in partial or complete clog of the narrow balloon evacuation channel, especially if the ultrasonic endoscope is not cleaned immediately after each procedure and if not reprocessed as per FUJIFILM recommendations.

4.2.4 If Mucus Adheres to the Distal Objective Lens or If the Image is Obscured

If mucus adheres to the distal objective lens or if the image is obscured, clean the surface of the lens by pressing the air/water valve halfway. When cleaning is complete, remove water from the surface of lens by activating air delivery and then suction.



[Note]

If any debris such as mucus is left adhered, or if air is supplied without supplying water, the debris may become hard to remove due to drying or fixation.

4.3 How to Use Balloon

⚠WARNING

Do not use this product with an endoscopic CO_2 regulator. If used, air bubbles may be generated in the sterile water inside the water tank and enter the balloon channel. This could prevent water discharge from the balloon and disable deflation of the balloon.

Do not use a balloon on patients allergic to latex. There is a risk of an anaphylactic reaction.

CAUTION

Do not feed more than 5 ml of water into the balloon. There is a risk of rupturing the balloon.

[Note] It takes approximately 3 seconds to feed in 5 ml of water. Check the amount of water to be fed before use.

[Note] Check the endoscopic and ultrasonic images while injecting/discharging water into/from the balloon.

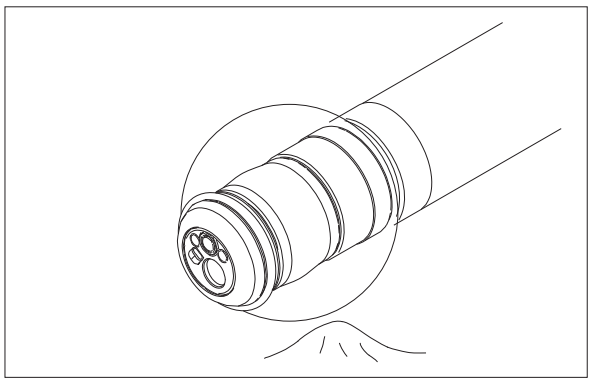
[Note] If water cannot be discharged or little water is discharged from the balloon, refer to "Chapter 5 Troubleshooting".

➞ "Chapter 5 Troubleshooting"

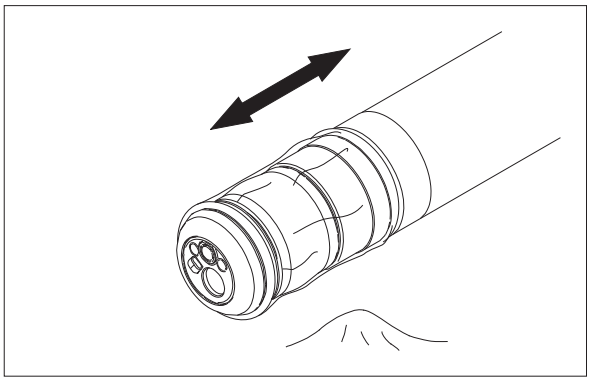
(1) Feed a small amount of sterile water to the affected area before using the balloon.

(2) Turn the up-down and left-right angulation knobs to bring the transducer closer to the area to perform the ultrasonic observation.

Feed the required amount of sterile water.



(3) To move or pull out the ultrasonic endoscope, deflate the balloon beforehand.



[Note]

If the balloon does not deflate while depressing the suction valve fully, remove clogs in the balloon channel using the cleaning brush (WB2221FW2).

➞ Reprocessing Manual
"4.9.4 Brushing the Balloon Channel"

4.4 Biopsy

⚠WARNING

Do not strongly press the forceps onto the digestive tract wall. There is a risk of perforation and bleeding.

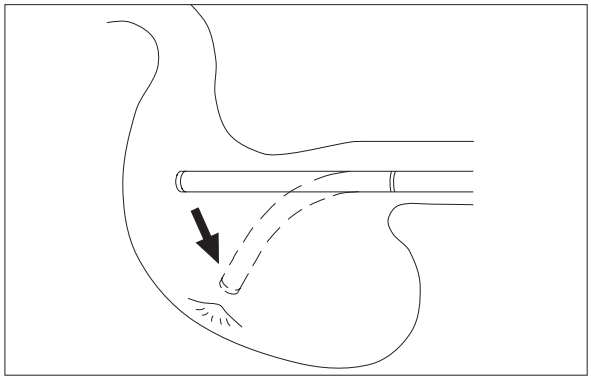
Do not insert the forceps if you cannot see the instrument channel outlet on the endoscopic image. There is a risk of perforation and bleeding.

CAUTION

Do not push the forceps in forcefully when encountering difficulty during insertion. There is a risk of damaging the ultrasonic endoscope.

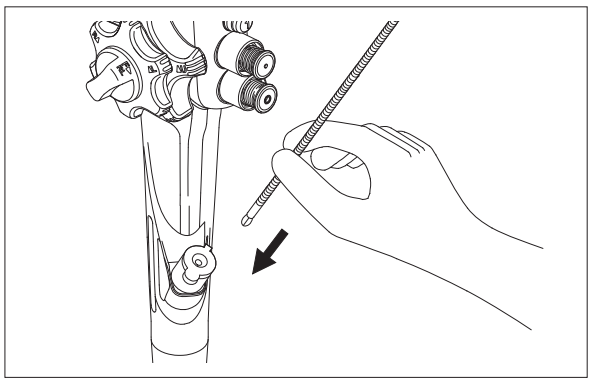
[Note] The forceps may not pass through the bending section smoothly. In such a case, slightly unbend the bending section and try to insert it again.

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

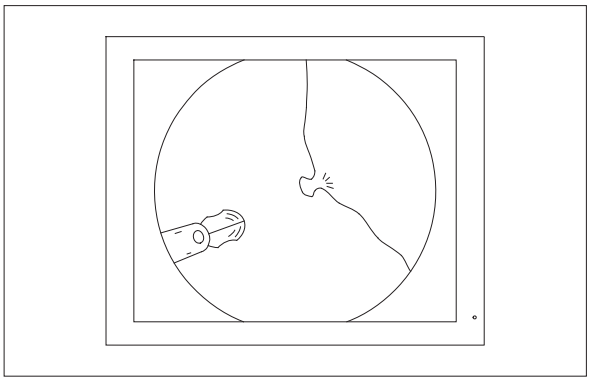


(2) Check the opening and closing of the forceps.

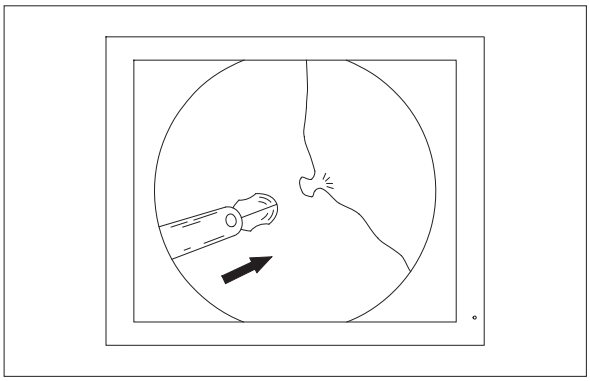
Insert the forceps from the instrument channel inlet by observing the image.



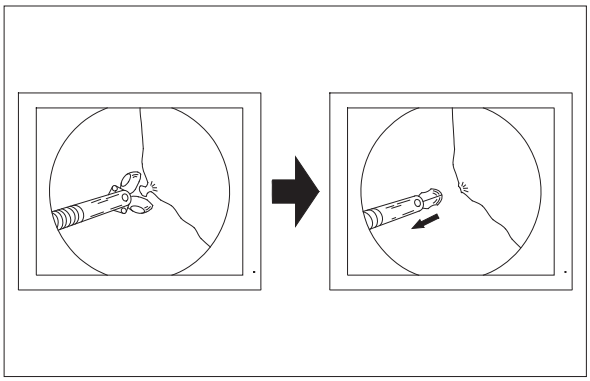
(3) Stop the insertion of the forceps when its tip appears on the field of view.



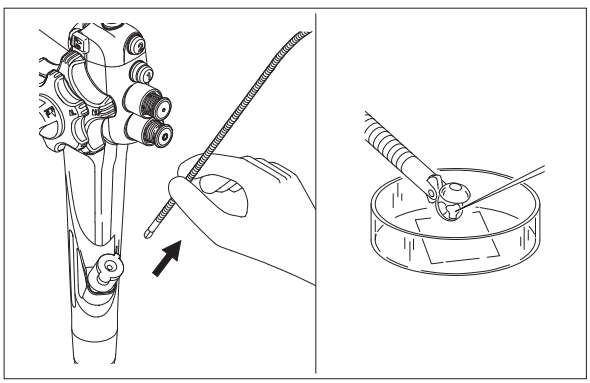
(4) Slowly move the forceps to the biopsy site.



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

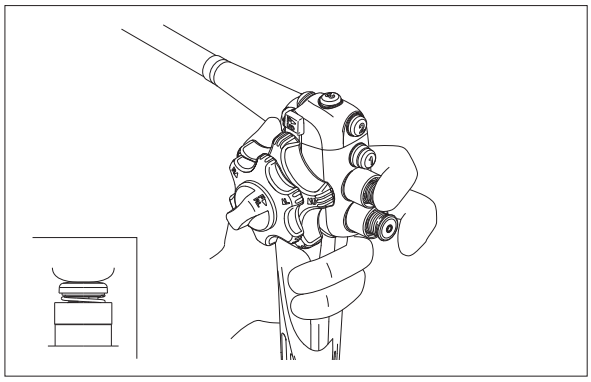


(6) Pull out the forceps slowly and take out the biopsy specimen.

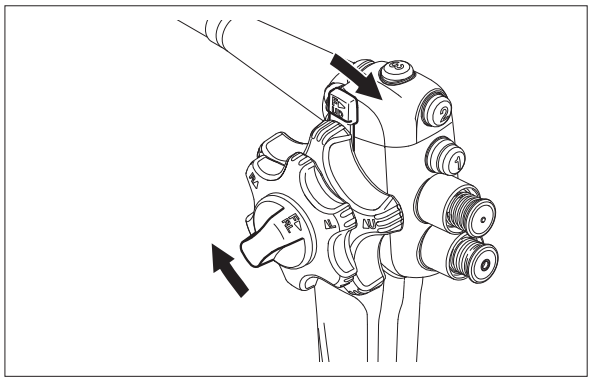


4.5 Endoscope Withdrawal

(1) When a procedure is over, discharge any excessive air from the body cavity.



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

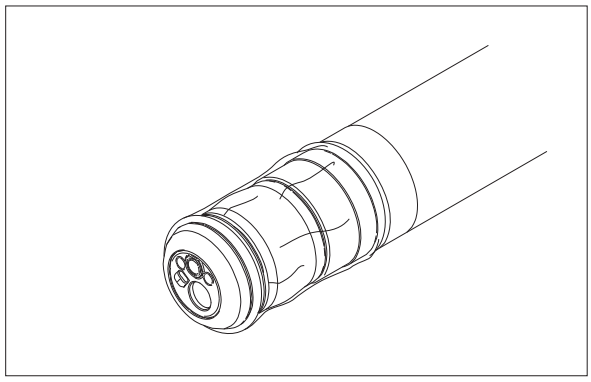


(3) If the balloon is attached, deflate it completely.

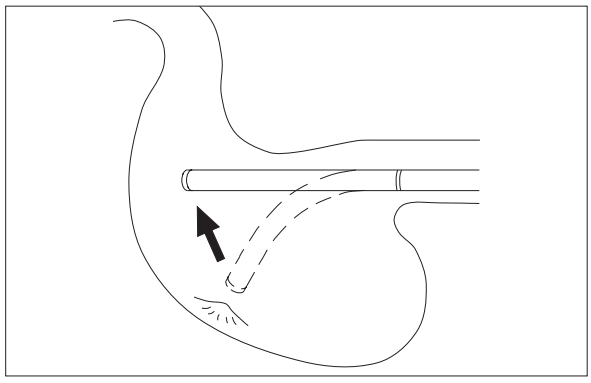
[Note]

If the balloon does not deflate while depressing the suction valve fully, remove clogs in the balloon channel using the cleaning brush (WB2221FW2).

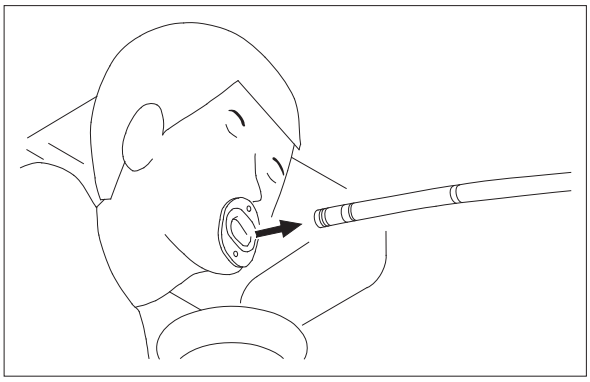
➞ Reprocessing Manual
"4.9.4 Brushing the Balloon Channel"



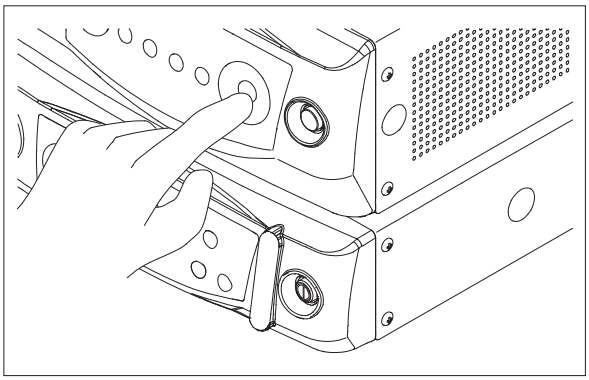
(4) Straighten the bending section by operating the angulation knobs.



(5) Slowly pull out the ultrasonic endoscope.



(6) Press the Lamp button on the light source to turn off the lamp.



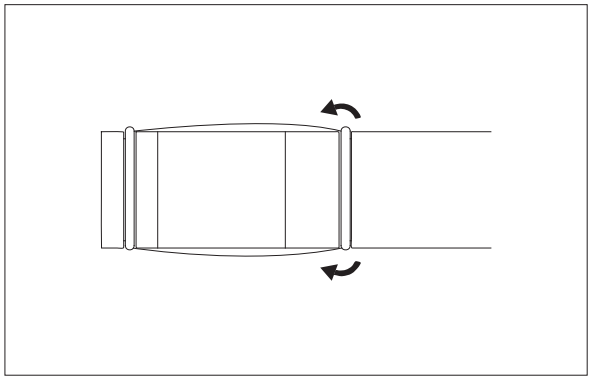
4.6 Removing Balloon

⚠WARNING

When removing the balloon, wear personal protective equipment and slowly remove the balloon. There is a risk of infection.

(1) Remove the balloon ring from the balloon attachment groove.

(2) Roll the balloon slowly toward the distal end of the ultrasonic endoscope to remove.



[Note]

Do not pinch the transducer with your fingers.

[Note]

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

Dispose of the removed balloon.

[Note]

Make sure to remove the balloon before cleaning the ultrasonic endoscope.

4.7 Pre-cleaning (Primary Cleaning)

Pre-cleaning (primary cleaning) means cleaning performed at bedside immediately after use of the ultrasonic endoscope. The ultrasonic endoscope is removed after pre-cleaning.

[Note] For details on pre-cleaning and removal of the ultrasonic endoscope, refer to the Reprocessing Manual.

➞ Reprocessing Manual “Chapter 3 Pre-cleaning”

Chapter 5 Troubleshooting

5.1 Troubleshooting

If this product should fail during use, follow these instructions to troubleshoot it.

Problem	Cause	Remedy
No images	1) The cart, monitor or processor is unplugged from the outlet.	1) Plug the cart, monitor or processor into the main outlet.
	2) The cart, monitor or processor is OFF.	2) Power ON the cart, monitor or processor.
Dark image [Note 1]	1) The imaging section is damaged.	1) Reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting, turn them off, straighten the bending section to unlock, release the angulation knobs, and then withdraw the ultrasonic endoscope slowly from the patient.
	2) The connection with ultrasonic endoscope is incomplete.	2) Reconnect the ultrasonic endoscope. ➞ "3.5 Connecting Ultrasonic Endoscope"
	3) The brightness level is set around "MIN."	3) Set the brightness level around 0. ➞ Operation manual of a light source
	4) The iris mode is set to "PEAK." [Note 1]	4) Set iris mode to "AVE." ➞ Operation manual of a light source
	5) There is dirt on the light incident end face of the LG connector.	5) Clean the light incident end face of the LG connector.
	6) There are blood clots adhering to the lens.	6) Stop the procedure. Withdraw the ultrasonic endoscope, and then clean the distal end.
	7) The light guide cable is broken.	7) Contact your local FUJIFILM dealer.

[Note] To reset the processor and the light source, turn them off, 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.

[Note] To reset the ultrasonic processor, turn it off, and wait for at least 5 seconds. Turn on the ultrasonic processor again.

[Note 1] When argon plasma coagulation (APC) is performed, some areas in the live image may become dark due to luminous beam of argon plasma.

Problem	Cause	Remedy
Halation	1) The imaging section is damaged.	1) Reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting, turn them off, straighten the bending section to unlock, release the angulation knobs, and then withdraw the ultrasonic endoscope slowly from the patient.
	2) The brightness level is set around "MAX."	2) Set the brightness level around 0.
	3) The iris mode is set to "AVE."	➞ Operation manual of a light source 3) Set iris mode to "PEAK." ➞ Operation manual of a light source
Loss of image during a procedure.	1) The imaging section is damaged.	1) Reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting, turn them off, straighten the bending section to unlock, release the angulation knobs, and then withdraw the ultrasonic endoscope slowly from the patient.
	2) The scope connection is incomplete.	2) Reconnect the ultrasonic endoscope. ➞ "3.5 Connecting Ultrasonic Endoscope"
	3) The system is malfunctioning possibly due to static charge. 4) The video signal cable has shorted out or broken.	3) 4) If the problem occurred during treatment, stop treatment and remove the endotherapy device from the ultrasonic endoscope. Then, reset [Note] the processor and the light source. If the problem occurred during an examination, reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting, turn them off, straighten the bending section to unlock, release the angulation knobs, withdraw the ultrasonic endoscope slowly from the patient.

[Note] To reset the processor and the light source, turn them off, 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.

[Note] To reset the ultrasonic processor, turn it off, and wait for at least 5 seconds. Turn on the ultrasonic processor again.

Problem	Cause	Remedy
Live image is not displayed after image freezing is canceled during a procedure.	The system is malfunctioning possibly due to static charge.	If the problem occurred during treatment, stop treatment and remove the endotherapy device from the ultrasonic endoscope. Then, reset [Note] the processor and the light source. If the problem occurred during an examination, reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting, turn them off, straighten the bending section to unlock, release the angulation knobs, withdraw the ultrasonic endoscope slowly from the patient.
The endoscopic image is discolored during a procedure.	1) The imaging section is damaged. 2) The system is malfunctioning possibly due to static charge. 3) The video signal cable has shorted out or broken.	1) 2) 3) If the problem occurred during treatment, stop treatment and remove the endotherapy device from the ultrasonic endoscope. Then, reset [Note] the processor and the light source. If the problem occurred during an examination, reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting and it is impossible to continue the examination, turn them off, straighten the bending section to unlock, release the angulation knobs, withdraw the ultrasonic endoscope slowly from the patient.

[Note] To reset the processor and the light source, turn them off, 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.

[Note] To reset the ultrasonic processor, turn it off, and wait for at least 5 seconds. Turn on the ultrasonic processor again.

Problem	Cause	Remedy
Distorted image	1) The imaging section is damaged.	1) Reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting, turn them off, straighten the bending section to unlock, release the angulation knobs, and then withdraw the ultrasonic endoscope slowly from the patient.
	2) Noise generated by electrosurgical instruments.	2) Stop power supply to the diathermic treatment equipment to restore image output. The ultrasonic endoscope is working properly.
	3) The ultrasonic endoscope is not connected correctly to the processor.	3) Connect the ultrasonic endoscope properly to the processor.
	4) The video signal cable has shorted out or broken.	4) Reset [Note] the processor and the light source. If an appropriate image does not appear even after resetting and it is impossible to continue the procedure, turn them off, straighten the bending section to unlock, release the angulation knobs, and then withdraw the ultrasonic endoscope slowly from the patient.
No air and/or water delivery	1) Pump is switched off.	1) Switch on the pump.
	2) Abnormality in the air/water button.	2) Replace with a new air/water button.
	3) The air/water button is not pressed firmly while supplying sterile water.	3) Push in the air/water button firmly.
	4) Water tank cap is loose.	4) Close the cap firmly.
	5) Water tank is filled with too much sterile water.	5) Reduce the water level in the water tank to about 80% of its capacity.
	6) Water tank is empty.	6) Fill the water tank with sterile water.
	7) Water tank is not connected.	7) Connect the water tank.
	8) Clogged nozzle or channel.	8) Clean clogged channel per provided instructions.

[Note] To reset the processor and the light source, turn them off, 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.

[Note] To reset the ultrasonic processor, turn it off, and wait for at least 5 seconds. Turn on the ultrasonic processor again.

Problem	Cause	Remedy
Low air/water supply amount	1) Foreign matters have adhered to the air/water channels.	1) After pulling out the ultrasonic endoscope from a patient, clean the air/water channels according to the procedures specified in the Reprocessing Manual “Chapter 3 Pre-cleaning” and “Chapter 4 Manual Cleaning”. If air/water supply amount is still low, replace with a spare ultrasonic endoscope.
	2) The air/water channels are damaged.	2) Contact your local FUJIFILM dealer.
Air/water supply does not stop.	1) Foreign matters have adhered to the air/water valve.	1) After pulling out ultrasonic endoscope from a patient body, detach the air/water valve and clean it.
	2) The air/water valve is damaged.	2) Replace it with a new air/water valve.
	3) The air/water valve has been degraded.	3) Replace it with a new air/water valve.
No suction	1) Pump is switched off.	1) Switch on the pump.
	2) Pump is not connected.	2) Connect the pump.
	3) No forceps valve is attached.	3) Attach a forceps valve.
Low suction volume	1) The suction valve has been damaged.	1) Replace with a new suction valve.
	2) The forceps valve has been degraded.	2) Replace with a new forceps valve.
	3) The suction tube is not attached properly.	3) Reattach the suction tube.
	4) The forceps valve is not attached properly.	4) Reattach the forceps valve.
Suction valve cannot be removed.	The suction valve or the control portion of the ultrasonic endoscope has been damaged.	Contact your local FUJIFILM dealer.
The volume of water supplied to or discharged from the balloon is low. Water cannot be supplied to or discharged from the balloon.	1) The suction pump is turned “OFF”.	1) Turn power “ON” the suction pump.
	2) The suction tube is not attached properly.	2) Reattach the suction tube.
	3) The suction tube is not connected.	3) Connect the suction tube.
	4) The suction valve is damaged.	4) Replace with a new suction valve.
	5) The balloon evacuation channel is clogged.	5) Remove clogs in the balloon channel using the cleaning brush (WB2221FW2). ➞ Reprocessing Manual “4.9.4 Brushing the Balloon Channel”
Suction valve does not return to the original position.	1) Foreign matters or blood have adhered to the suction valve.	1) Disconnect the suction tube. After pulling out ultrasonic endoscope, detach the valve and clean or replace it.
	2) Suction valve is damaged.	2) Replace with a new suction valve.
Water cannot be fed from the balloon water port.	1) The suction pump is turned “OFF”.	1) Turn power “ON” the suction pump.
	2) The water tank cap is loose.	2) Close the cap firmly.
	3) The water tank is filled with too much water.	3) Reduce the water level in the water tank to about 80% of its capacity.
	4) The water tank is empty.	4) Fill the water tank with water.
	5) The water tank is not connected.	5) Connect the water tank.

Problem	Cause	Remedy
Endotherapy device cannot be inserted.	1) The endotherapy device (such as biopsy forceps) is left open. 2) The handle of the endotherapy device (such as biopsy forceps) is held firmly. 3) The endotherapy device (such as biopsy forceps) has difficulty being inserted due to bending. 4) Improper size is used.	1) Close the endotherapy device for insertion. 2) Loosen the grip to insert the endotherapy device. 3) Reduce the angle of the bending section slightly and then insert it. 4) Use an endotherapy device with an appropriate size.
Endotherapy device cannot be withdrawn.	1) The endotherapy device (such as biopsy forceps) is left open. 2) The handle of the endotherapy device (such as biopsy forceps) is held firmly. 3) The endotherapy device (such as biopsy forceps) has difficulty being inserted due to bending. 4) An abnormality occurs in the endotherapy device. 5) Improper size is used.	1) Close the endotherapy device and pull it out from the ultrasonic endoscope. 2) Loosen the grip and pull out the endotherapy device from the ultrasonic endoscope. 3) Reduce the angle of the bending section slightly and then pull out the endotherapy device from the ultrasonic endoscope. 4) Withdraw the tip of the endotherapy device to the instrument channel outlet of the ultrasonic endoscope, and then slowly pull out the ultrasonic endoscope and endotherapy device together. 5) Withdraw the tip of the endotherapy device to the instrument channel outlet of the ultrasonic endoscope, and then slowly pull out the ultrasonic endoscope and endotherapy device together. [Note] Use an endotherapy device with an appropriate size.
Endotherapy device (such as biopsy forceps) cannot be closed.	An abnormality occurs in the endotherapy device.	If it is difficult to close the endotherapy device, return the bending angle of the ultrasonic endoscope and pull it out upon closing it. If it cannot be closed for some reason, return the end of the endotherapy device to the instrument channel outlet of the ultrasonic endoscope, and then slowly pull out the ultrasonic endoscope and endotherapy device together.

Problem	Cause	Remedy
Bending section cannot return to neutral position.	1) The angle is locked. 2) The bending control mechanism is malfunctioning.	1) Operate the left-right and up-down angulation locks to unlock them. 2) Immediately stop using the ultrasonic endoscope. Do not forcibly withdraw the ultrasonic endoscope from the patient, or it may cause damage to tissues in the body cavity. Contact your local FUJIFILM dealer.
The bending section cannot bend by turning the angulation knob.	The angle wire is damaged.	Immediately stop using the ultrasonic endoscope. Do not forcibly withdraw the ultrasonic endoscope from the patient, or it may cause damage to tissues in the body cavity. Contact your local FUJIFILM dealer.
No ultrasonic image is displayed.	1) The power cord of the cart, the monitor or the observation device is not plugged in. 2) The power switch of the cart, the monitor or the observation device is OFF. 3) The transducer at the distal end is in the air (away from walls of the gastrointestinal tract). 4) The ultrasonic processor is malfunctioning.	1) Plug in the devices. 2) Turn the power switches ON. 3) Increase the amount of water fed to the balloon, or adjust the angle of the transducer by operating it so that it comes in close contact with the wall of gastrointestinal tract. 4) If an ultrasonic image disappears during a procedure, turn the ultrasonic processor off and turn it on again after 5 seconds or more. If the image is not recovered, turn the ultrasonic processor off and then pull out the ultrasonic endoscope slowly.
The ultrasonic image is dark.	1) The gain level is close to the minimum value. 2) The STC level is close to the minimum value.	1) Rotate the gain knob clockwise to adjust the brightness of the ultrasonic image. 2) Press the STC key to set the STC level closer to the center value.
The highlight portion in the ultrasonic image is too bright.	1) The gain level is close to the maximum value. 2) The STC level is close to the maximum value.	1) Rotate the gain knob counterclockwise to adjust the brightness of the ultrasonic image. 2) Press the STC key to set the STC level closer to the center value.
The image disappears during ultrasonic diagnosis.	The US connector is poorly connected.	Redo the scope connection. ➞ “3.5 Connecting Ultrasonic Endoscope”

Problem	Cause	Remedy
The ultrasonic image receives interference.	1) High-frequency interference.	1) Stop power supply to the diathermic treatment equipment to restore image output. The ultrasonic endoscope is working properly.
	2) The US connector is poorly connected.	2) Redo the scope connection. ➞ "3.5 Connecting Ultrasonic Endoscope"

Main Specification

<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.
4. Degree of waterproof : IEC 60529 IPX7 (with US waterproof cap attached)

[Note] Use in combination with the VP-4450HD processor, XL-4450 light source and SU-1 ultrasonic processor.

<Applied Part>

Insertion portion

<Data about Main Unit>

Endoscopic functions	Model		EG-580UR
	Viewing direction		0°
	Observation range		3 to 100 mm
	Field of view		140°
	Distal end diameter		11.4 mm
	Maximum diameter of insertion portion		12.7 mm
	Insertion tube diameter		11.5 mm
	Flex [Note 1]		6.0 N
	Bending capability	UP/DOWN	190°/90°
		LEFT/RIGHT	100°/100°
	Minimum diameter of instrument channel		2.8 mm [Note 2]
	Working length [Note 3]		1250 mm
	Overall length		1550 mm
	Insertion route		Peroral

[Note 1] Shows reaction force for the area of 200 mm from the distal end.

[Note 2] It does not mean that compatibility of machines selected based on only this instrument channel diameter is guaranteed.

[Note 3] Use an endotherapy device with a working length of 1800 mm or longer.

Ultrasonic functions	Model	EG-580UR
	Scanning mode	Color Doppler, Power Doppler, Pulse wave, B mode, M mode
	Scanning method	Electronic radial scanning method
	Scanning direction	Perpendicular to the insertion direction of the ultrasonic endoscope
	Scanning angle	360° (Combination with SU-1)
	Penetration depth	65 mm or more (assuming the attenuation coefficient of 0.3 dB cm^{-1} MHz^{-1} in B-mode 7.5 MHz)
	Axial resolution	1 mm or less
	Lateral resolution	2 mm or less
	Acoustic frequency	5.5MHz±20% (5 MHz in B-mode)
	Spatial-peak temporal-average intensity	Ispta. α≤ 720 mW cm^{-2} (assuming the attenuation coefficient of 0.3 dB cm^{-1} MHz^{-1})
	Mechanical Index (MI)	1.0 or less
	Frequency	5 MHz/7.5 MHz/10 MHz/12 MHz

<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)

<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)

<Transport 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 after beginning of use, if proper maintenance and inspection are performed. “Based on our company’s criteria”

[Note] Except consumable supplies

<Compatible Processor, etc.>

Ultrasonic processor	SU-1
Processor	VP-4450HD
Light Source	XL-4450

<Accessories>

Accessories listed below have a use-by date. If any deterioration or abnormality is found in accessories, they need to be replaced.
Accessories cannot be repaired or refurbished. Thus, if any abnormality is found, replace with a new one.

• Consumable Supplies (Supplied with the Ultrasonic Endoscope)

Name	Model
Air/water valve	AW-602
Suction valve	SB-604
Forceps valve	FOV-DV7
Cleaning brush	WB7024FW
	WB2221FW2
	WB11003FW
Cleaning adapter	CA-608
Air/water channel cleaning adapter	CA-609

• Essential Accessory (Optional Item)

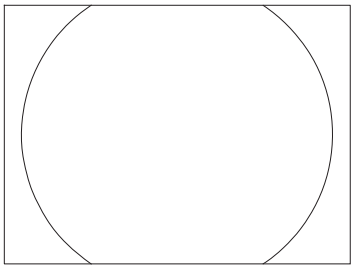
Name	Model
Balloon	B20UR
Air leak tester	LT-7F

• Compatible Endotherapy Devices

Name	Model
Biopsy forceps: Fenestrated	BF2418SF
Fenestrated with needle	BF2418FN
	BF3018FN
Slotted hole	BF2418LN
Alligator	BF2218A
Grasping forceps: Three prong	GF2318T
V-shape	GF2418V
Basket	GF2318B
High-frequency snare: Half-moon	DS2323M
Square	DS2323H
Coagulation: Round	DC1818R
Cleaning	DC2318S
Washing tube	WT1720ST

[Note] For combination with accessories other than those above, contact your local FUJIFILM dealer.

<Image Size>



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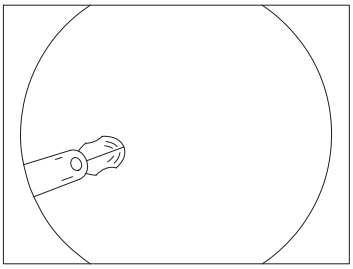

<Medical Device Directive>

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

CE 0123

<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 EN 55011	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 EN 55011	Class A	This product is intended for use in medical facilities and commercial facilities. If this product is used in domestic establishments, electromagnetic interference may occur on any equipments. In this case, it is recommended to use this product according to “Chapter 1 Safety”.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Applicable	

[Note] Use in combination with the VP-4450HD processor, XL-4450 light source and SU-1 ultrasonic processor.

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 ground	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 Radiated RF EN 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3V[V_1] 3V/m[E_1]	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 transmitter. Recommended separation distance $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 to 800MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.5GHz Where “P” is the maximum output power rating of transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m). This product complies with the requirements of EN 60601-1-2: 2007. However electromagnetic interference may occur on this product under electromagnetic environment that exceeds its noise level. Electromagnetic interference may occur in the vicinity of equipment marked with the following symbol. 

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 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

Service

<Service>

1) If this product does not work properly, check it first by reading this manual again and follow all instructions and troubleshooting tips.

2) If this product is still not working well, contact your local FUJIFILM dealer.

Contact your local Fujinon/Fujifilm dealer when this product is returned for repair.
Be sure to clean and disinfect (or sterilize) this product before returning for repair.
The product which is not cleaned and disinfected (or sterilized) may increase infection control risks to users, service personnel or other persons in contact with it.

3) Repairs during the warranty period

This product will be repaired free of charge within warranty guidelines.
The warranty period for the ultrasonic endoscope, excluding accessories, is one year after date of purchase.
Note that the warranty is void in the following cases:

a. Damage caused by fire or natural disaster such as storms or floods.
b. Problem caused by careless handling or misuse including use of non-compatible reprocessing systems or agents.
c. Problem caused by repair or modification by unauthorized personnel.

4) Repairs after the warranty period

This product will be repaired with charge at your request. When contacting your local FUJIFILM dealer, provide the following information.

Model name :
Serial number :
Description of failure : Provide as much details 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 resources. For more detailed information about recycling of this product, contact your local FUJIFILM 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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Service Centers

Contact our regional representative below or the distributor from which you purchased the product.

<Europe>

FUJIFILM Europe GmbH
http://www.fujifilm.eu/eu/
See our website to locate our representative in your country.

<USA>

Fujifilm Medical Systems U.S.A., Inc
http://www.fujifilmendoscopy.com/
(800) 385-4666

<Australia>

FUJIFILM Australia Pty Ltd.
http://www.fujifilm.com.au/
1800 060 209

<Asia>

FUJIFILM (Singapore) Pte. Ltd.
http://www.fujifilm.com.sg/
6380-5540

If you are not a resident of the regions above, contact the distributor from which you purchased the product.

FUJIFILM Corporation
26-30, Nishiazabu 2-chome, Minato-ku, Tokyo 106-8620, Japan

EC REP **FUJIFILM Europe GmbH**
Heesenstrasse 31, 40549 Duesseldorf, Germany

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