

FUJIFILM

Ultrasonic Endoscope

EB-530US

OPERATION MANUAL

(Preparation and Operation)

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



CE 0123

Important Safety Information

For the USA Market - CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

1. Intended Use

This product is a medical Ultrasonic Endoscope to be used under the control of doctors in medical facilities for the observation, diagnosis and medical treatment of tracheae and bronchi, as well as the inspection of tracheae, bronchi and adjacent organs, using ultrasonic imaging. Never use this product for any other purpose. This product is not intended for use on children and infants.

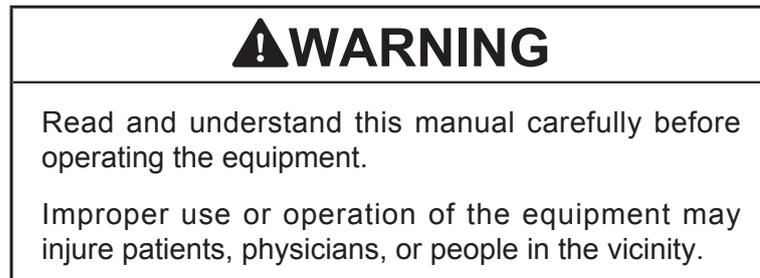
2. Safety

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

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

3. Warning

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



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

4. About Clinical Procedures

This manual assumes that the product will be used by medical specialists who have received proper training in ultrasonic endoscopic procedures. It does not provide information about clinical procedures. Regarding clinical procedures, use proper clinical judgment.

5. When Using this Product for the First Time

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

6. Treatment with Electrosurgical Instruments

This product cannot be used with an electrosurgical instrument for treatment.

7. About Latex Allergy

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

8. If Any Abnormality Occurs During Clinical Procedure

If any abnormality occurs with the equipment, refer to “Troubleshooting.” Especially, continued use of the equipment with abnormal images can cause burn and injury by heat generation from the distal of the Ultrasonic Endoscope.

9. Loss of Function

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

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

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

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

During an examination, if the ultrasonic image disappears, or a live image is not displayed after freeze mode has been cancelled, reset the ultrasonic processor.

During treatment, if the ultrasonic image disappears, or a live image is not displayed after freeze mode has been cancelled stop treatment immediately, remove the treatment tool from the ultrasonic endoscope, and then reset the ultrasonic processor.

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

[Note] Reset:

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

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Preface

This manual describes how to use EB-530US.

Conventions Used in This Manual

This manual uses the following conventions to make it easy to understand operations.

■ General Conventions

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

Chapter 1 Safety

This chapter summarizes the information necessary for safe use of Ultrasonic Endoscope.

Chapter 1 Safety

1. Precautions in Using Ultrasonic Endoscope

1) Applicable processor and light source

This product may be used in the following combinations:

- Processor VP-4450HD, light source XL-4450 and ultrasonic processor SU-8000
- Processor VP-4400, light source XL-4400 and ultrasonic processor SU-8000
- Processor VP-4400, light source XL-4400 and ultrasonic processor SU-7000
- Processor EPX-2500 and ultrasonic processor SU-8000
- Processor EPX-2500 and ultrasonic processor SU-7000

This product complies with the requirements of EN 60601-1:2006 when used in combination with VP-4450HD, XL-4450 and SU-8000 and those of EN 60601-1:1990+A1:1993+A2:1995 when connected to other equipment.

2) Preparation and inspection before use

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

Make sure to inspect the equipment before use according to the procedures provided in this manual, to avoid unexpected accidents, and take full advantage of the equipment's capabilities.

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

3) Combination of equipment

The 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 operation manual. Be sure to fully understand the contents of related operation manuals when using any peripherals.

4) Single use only



Balloon, suction button and forceps valve are intended for single use. To prevent infection, do not reuse them.

5) Expiration date for use



Do not use any balloon after its expiration date has passed.

6) Preparation for operation

Use a high-frequency surgical instrument and an Endoscope which can be used with a high-frequency surgical instrument to provide proper emergency treatment, in cases of bleeding.

7) Abnormality in use

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

8) Maintenance

The equipment will wear out and degrade after repeated use for a long period. Especially, the portions such as rubber and resin deteriorate also by chemicals to be used a change with the passage of time. Have it checked by specialists once every six months or once every 50 cases. Also have it checked if there is anything wrong with the equipment. Do not disassemble or modify the equipment.

9) Operation of Ultrasonic Endoscope

Ultrasonic Endoscope is a precision instrument. Unnatural force or impact on the insertion portion, flexible portion, or distal end may injure the inside of the patient as well as damage the instrument. If you feel any abnormal resistance, do not force the Ultrasonic Endoscope to insert and pull out. Please operate the Ultrasonic Endoscope slowly.

Do not perform the insertion, withdrawal, or bending without keeping a field of view.

A forward-oblique viewing direction is employed with this product and there is a difference between the inserting direction and viewing direction. Be sure to understand the characteristics of the equipment upon use.

10) Handling of Ultrasonic Endoscope

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.

Wear protective gear when handling an Ultrasonic Endoscope to prevent infection and static charges.

11) Handling of balloon

If the balloon is inflated while it is in patient's air passage, the air flow may become blocked. Before using the balloon, thoroughly check the balloon position in the air passage and the water flow rate to the balloon.

12) Temperature at distal end

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.

13) Electromagnetic interference

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

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

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

This equipment complies with the requirements of EN 60601-1-2:2001+A1:2006 when connected to VP-4400, XL-4400, EPX-2500 and SU-7000.

2. Cleaning and Disinfection/Sterilization

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

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

Wear protective gear during chemical cleaning and disinfection 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 manual (Cleaning, Disinfection and Storage) of this product cannot eliminate the causal agents of Creutzfeldt-Jakob disease, the product could be a source of infection. For the treatment of Creutzfeldt-Jakob disease, refer to the guidelines for it available.

3. Disposal

This product has heavy metal parts. When disposing of this product, comply with local laws and regulations in your area. Determine whether or not the product is to be treated as infective waste, depending on the usage state.

4. Indication symbol

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

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

5. “Warning” and “Caution” Messages Appearing in Individual Chapters

Chapter 5 Preparation for Use of Ultrasonic Endoscope

Do not use the abnormal equipment. The use of abnormal equipment will cause wrong diagnosis or injury.

5.4 Connecting Ultrasonic Endoscope

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

<Combination with the VP-4400 and XL-4400 or VP-4450HD and XL-4450>

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

<Combination with the EPX-2500 system>

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

5.5.3 Inspecting Suction, Water Feed and Forceps Channel

Firmly attach the forceps valve to the forceps inlet of the Ultrasonic Endoscope. There is a risk of infection.

5.5.5 Inspecting Objective Lens

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

5.7 Installation and Inspection of Balloon

Use a disinfected and sterilized balloon installation tool. There is a risk of infection.

Do not use a balloon on patients allergic to latex. It may cause an anaphylactic reaction.

5.8 Inspection of Puncture Needle

Do not use the puncture needle with an abnormally bent or deformed needle. There is a risk of bleeding or wrong puncturing.

Chapter 6 Method of Use

Do not use force during insertion or withdrawal of the Ultrasonic Endoscope. Slowly advance the instrument under direct visualization. Since this product is a precision instrument, excessive force or impact on the insertion portion, flexible portion, or distal end may cause patient injury as well as damage to the instrument. Do not advance or angulate the Ultrasonic Endoscope without obtaining a clear endoscopic view on the monitor.

6.2 Insertion and Observation

When a balloon is not used, fit the cap on the balloon water feed inlet. There is a risk of infection.

Do not sharply twist or bend during operation. It may cause damage inside body cavities.

Before attempting to clinically use this Ultrasonic Endoscope with an endotracheal tube, select an appropriate size tube whose inner diameter has sufficient clearance between the endotracheal tube and the Ultrasonic Endoscope to avoid restriction of oxygen flow which may impair patient breathing.

The endotracheal tube should pass easily over the Ultrasonic Endoscope's insertion tube - never force an endotracheal tube onto the Ultrasonic Endoscope and never apply excessive pressure or force when attempting to pass or withdraw the Ultrasonic Endoscope.

Do not insert the Ultrasonic Endoscope through the nose. There is a risk of bleeding.

Do not allow the distal end to touch the same part for 5 minutes or more. Energy of illumination may burn.

Do not look directly at the illuminated light guide. It may damage your eyes.

In order to inject solution by using a syringe, firmly and deeply insert the syringe straight into the forceps valve. Chemical solutions might splatter.

If the balloon or parts fall into a body cavity due to equipment failure or for other reasons, immediately stop the inspection and properly retrieve the parts in question. It may cause damage inside body cavities.

Whenever using the Ultrasonic Endoscope with other peripheral devices including endotracheal tubes, etc. strictly adhere to all manufacturers' instructions, cautions and warnings. Failure to follow the recommendations above can lead to Ultrasonic Endoscope damage and/or patient injury.

6.3 How to Use Balloon

Do not use a balloon on patients allergic to latex. It may cause an anaphylactic reaction.

Do not feed more than 1 mL of water into the balloon. There is a risk of suffocation.

Do not feed more than 1 mL of water into the balloon. There is a risk of aspiration.

6.4 Biopsy

Do not press forceps against the trachea or broncho wall with undue force. It may cause perforation or bleeding.

Do not insert the forceps if you cannot obtain an endoscopic image. Do not insert the forceps into the Ultrasonic Endoscope if you cannot see the forceps outlet on the endoscopic image. It may cause perforation or bleeding.

6.5 Puncture

Wear protective gear. There is a risk of infection.

Do not insert the puncture needle into the Ultrasonic Endoscope if you cannot see the forceps outlet on the endoscopic image. Do not perform puncture if you cannot see the puncture needle on the endoscopic image. Operate the puncture needle while checking the endoscopic and ultrasonic images. Do not insert the puncture needle into the forceps inlet while the bending portion of the Ultrasonic Endoscope is bent. Do not insert a bent puncture needle into the forceps inlet. Stop puncturing immediately if you cannot obtain an endoscopic or ultrasonic image. It may cause perforation or bleeding.

6.7.3 Removing Ultrasonic Endoscope from Processor

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

Chapter 7 Cleaning

7.1 Methods of Cleaning

Be sure to clean and disinfect or otherwise sterilize all the channels after every case, regardless of whether used or not. There is a risk of infection.

7.4 Manual Cleaning (cleaning in sink)

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

7.4.2 Remove Suction Button and Forceps Valve

Do not reuse an already used suction button and forceps valve. There is a risk of being a source of infection.

7.4.9 Cleaning Entire Ultrasonic Endoscope

Remove the balloon before cleaning, disinfecting or sterilizing the Ultrasonic Endoscope. There is a risk of infection.

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

7.5 Cleaning and Sterilizing Biopsy Forceps

Close the cap before putting the forceps in a sterile pack. Sterility might not be maintained if the sterile pack is ruptured.

Chapter 8 Chemical Disinfection

8.1 Methods of Chemical Disinfection

Be sure to clean and disinfect or otherwise sterilize all the channels after every case, regardless of whether used or not. Remove the balloon before cleaning, disinfecting or sterilizing the Ultrasonic Endoscope. There is a risk of infection.

8.4.1 Injecting Sterile Water

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

8.5 Cleaning and Disinfection Using Cleaning and Disinfection Devices

Use cleaning and disinfection devices appropriate for this Ultrasonic Endoscope. There is a risk of infection.

Chapter 9 Gas Sterilization

Clean, disinfect and sterilize all the channels after every case, regardless of whether used or not. Remove the balloon before cleaning, disinfecting or sterilizing the Ultrasonic Endoscope. Applying gas sterilization to wet parts presents incomplete sterilization. Proceed gas sterilization after vaporizing water out of Ultrasonic Endoscope. There is a risk of infection.

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

Chapter 10 Storage

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

Chapter 2 Composition of Set and System Configuration

This chapter describes the composition of Ultrasonic Endoscope set and system configuration.

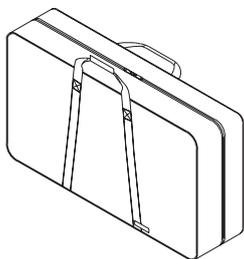
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Chapter 2 Composition of Set and System Configuration

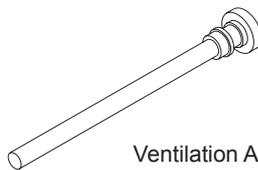
2.1 Composition of Set

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

[Note] Figures in parentheses indicate quantities.



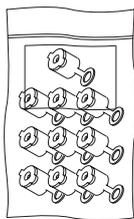
Carrying Case (1)



Ventilation Adapter
AD-7 (1)



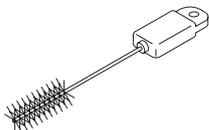
Cleaning Brush
WB3503FW (1)



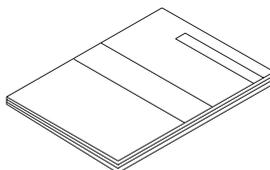
Forceps Valve
FOV-BU1 (10)



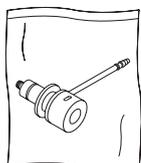
Cleaning Brush
WB3212FW2 (1)



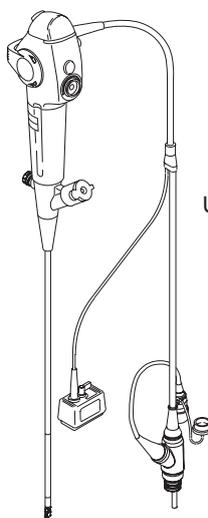
Cleaning Brush (for Valve)
WB11002FW2 (1)



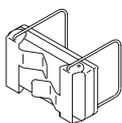
Operation Manual
Preparation and Operation (1)
Cleaning, Disinfection and Storage (1)



Suction Button
SB-500B/D (20)

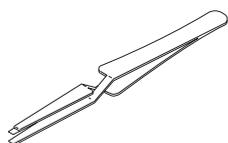


Ultrasonic Endoscope (1)

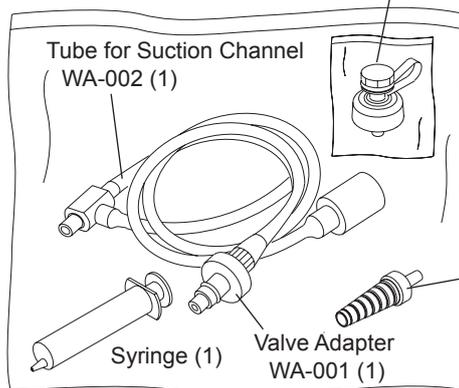


US Waterproof Cap
WA-7000 (1)

Forceps Inlet Cleaning Adapter (with a Cap)
WA-003 (1)



Balloon Installation Tool
BA-BU1 (1)



Tube for Suction Channel
WA-002 (1)

Syringe (1)

Valve Adapter
WA-001 (1)

Dry Adapter
WA-004 (1)

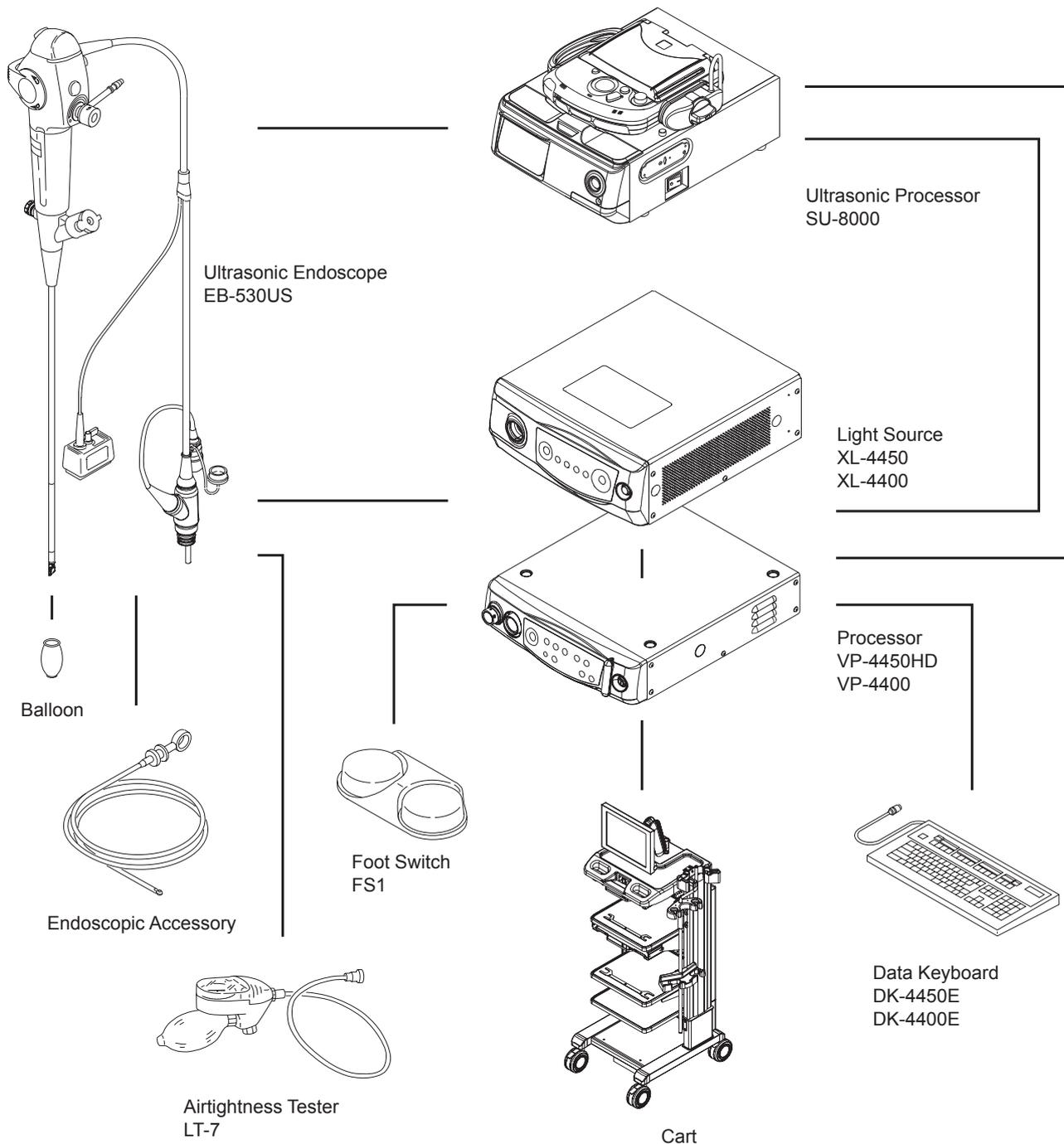
Cleaning Adapter
CA-500BU (1)

2.2 System Configuration

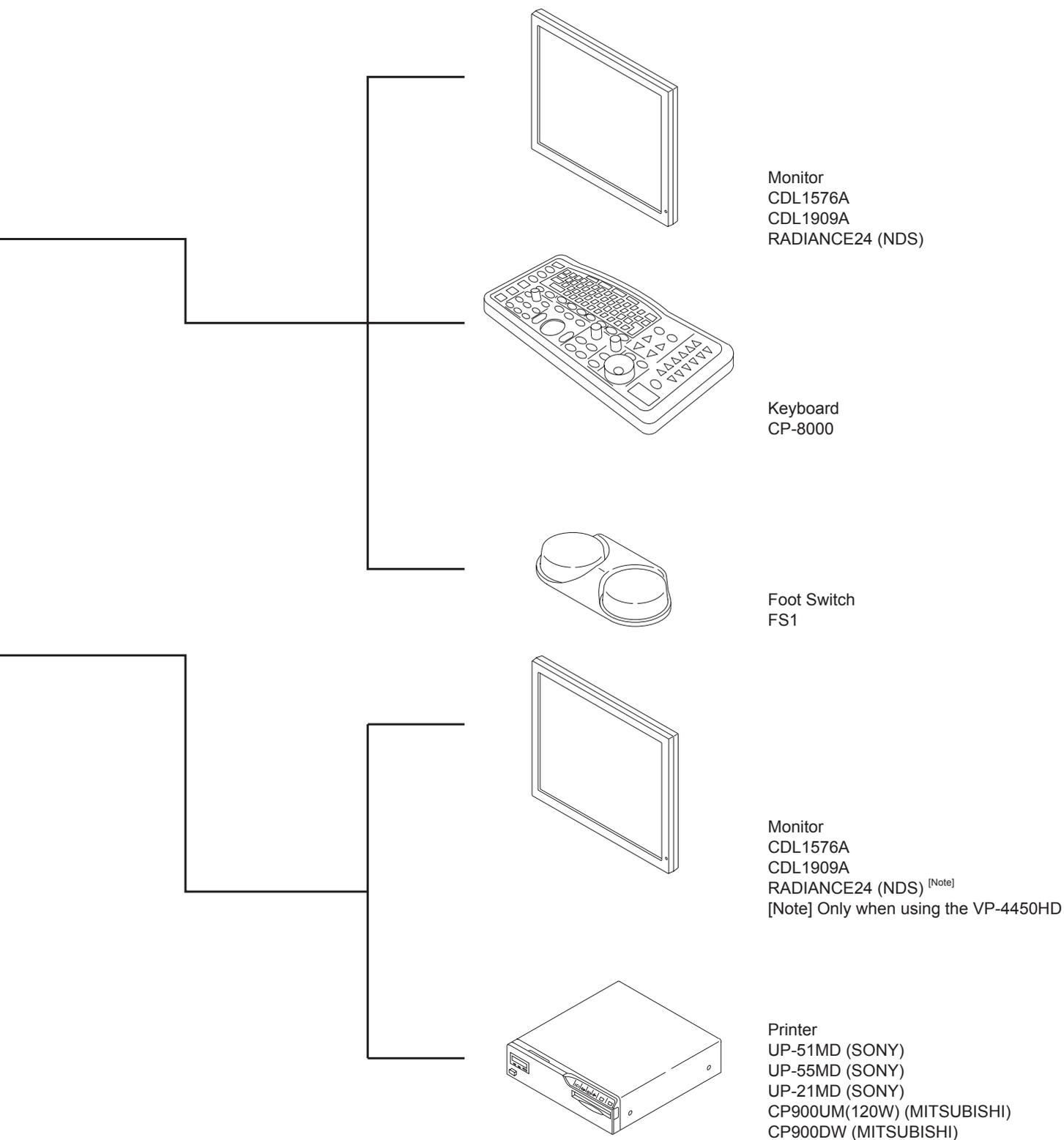
You may use the EB-530US with various peripherals attached to it. These peripherals are available separately. Extension makes the following possible.

- Recording of video images
- Printer output

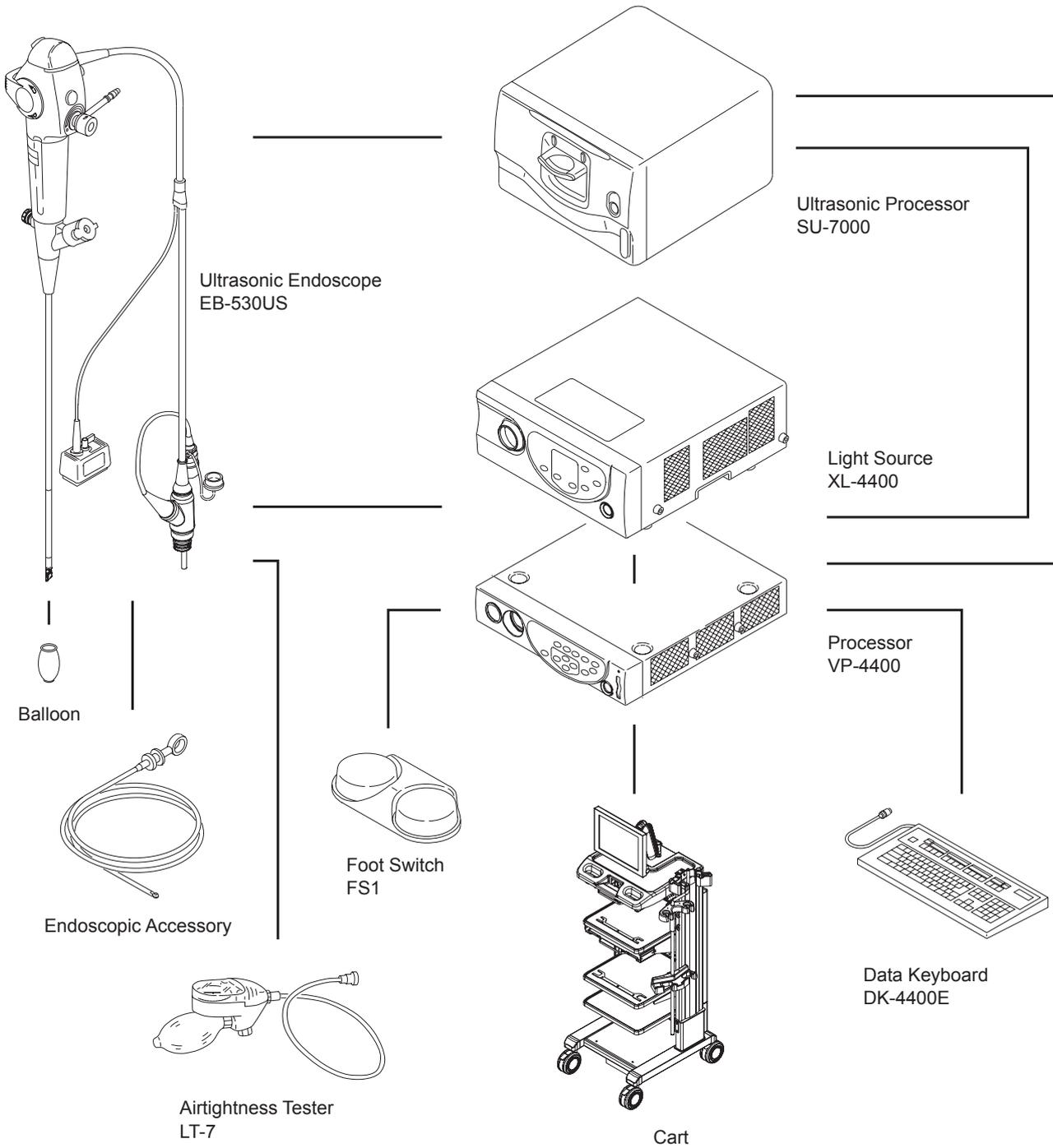
2.2.1 Combination with VP-4450HD or VP-4400 and SU-8000



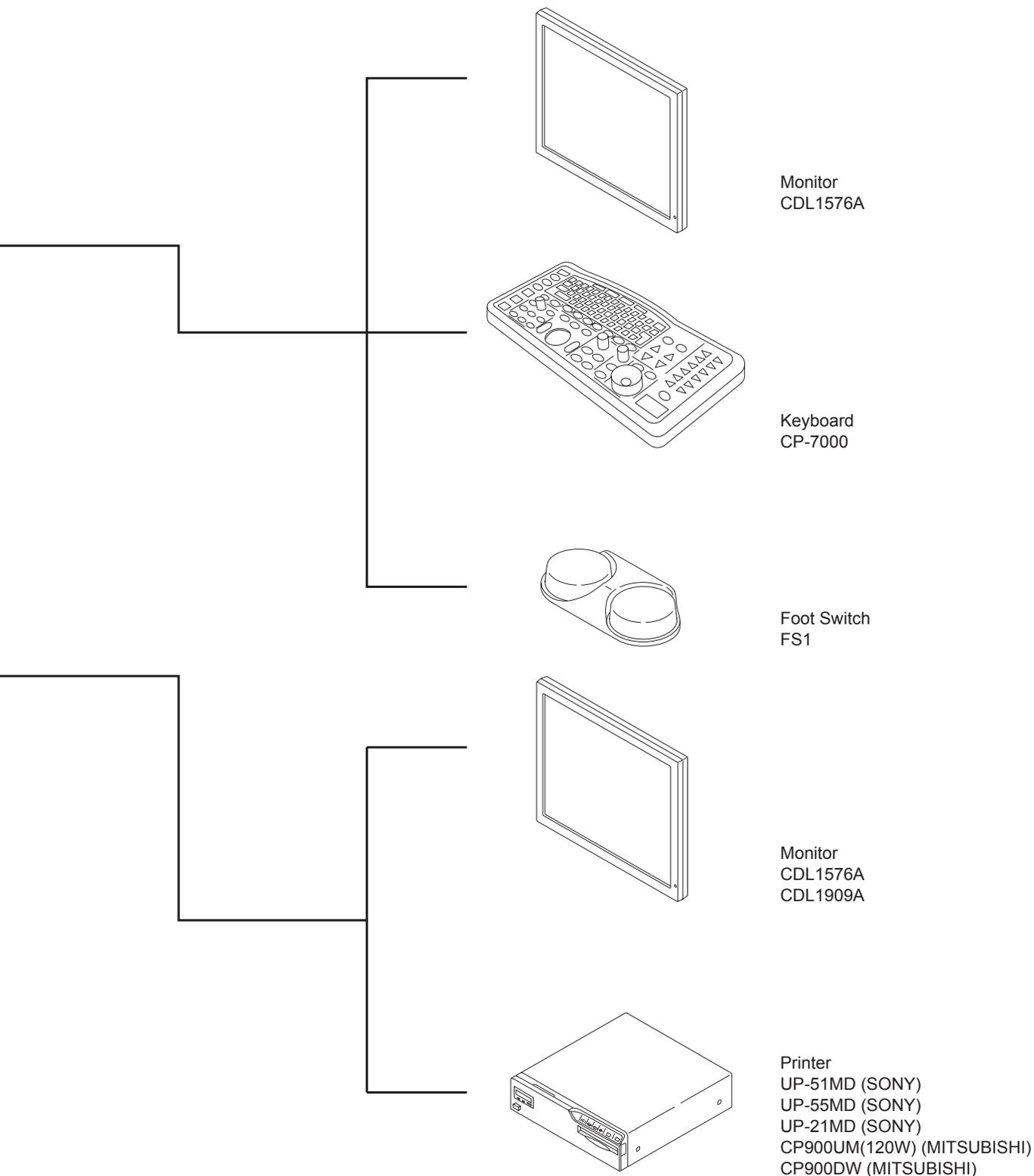
[Note] For details on the connections of peripherals other than those listed here, please contact your local dealer.



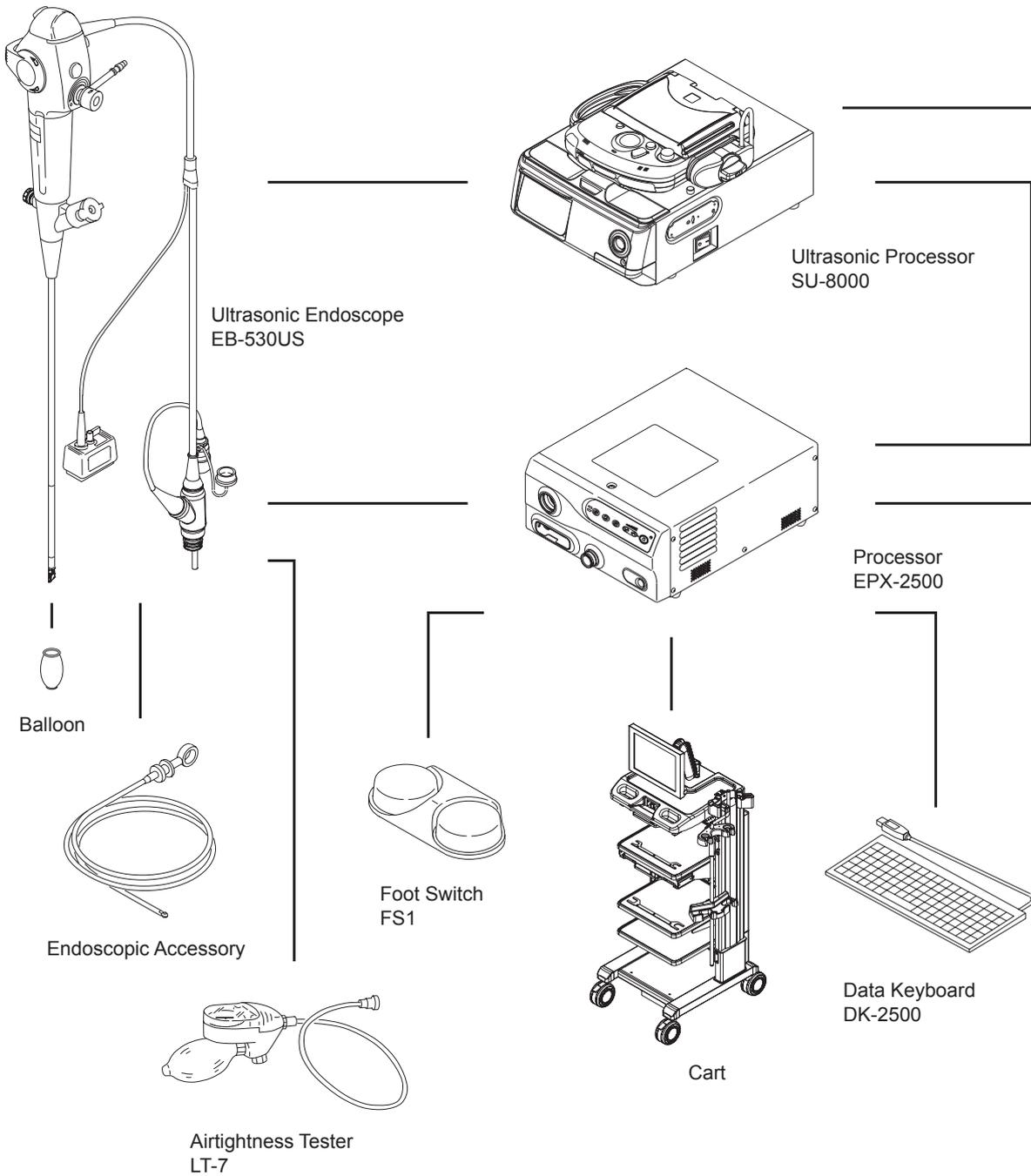
2.2.2 Combination with VP-4400 and SU-7000



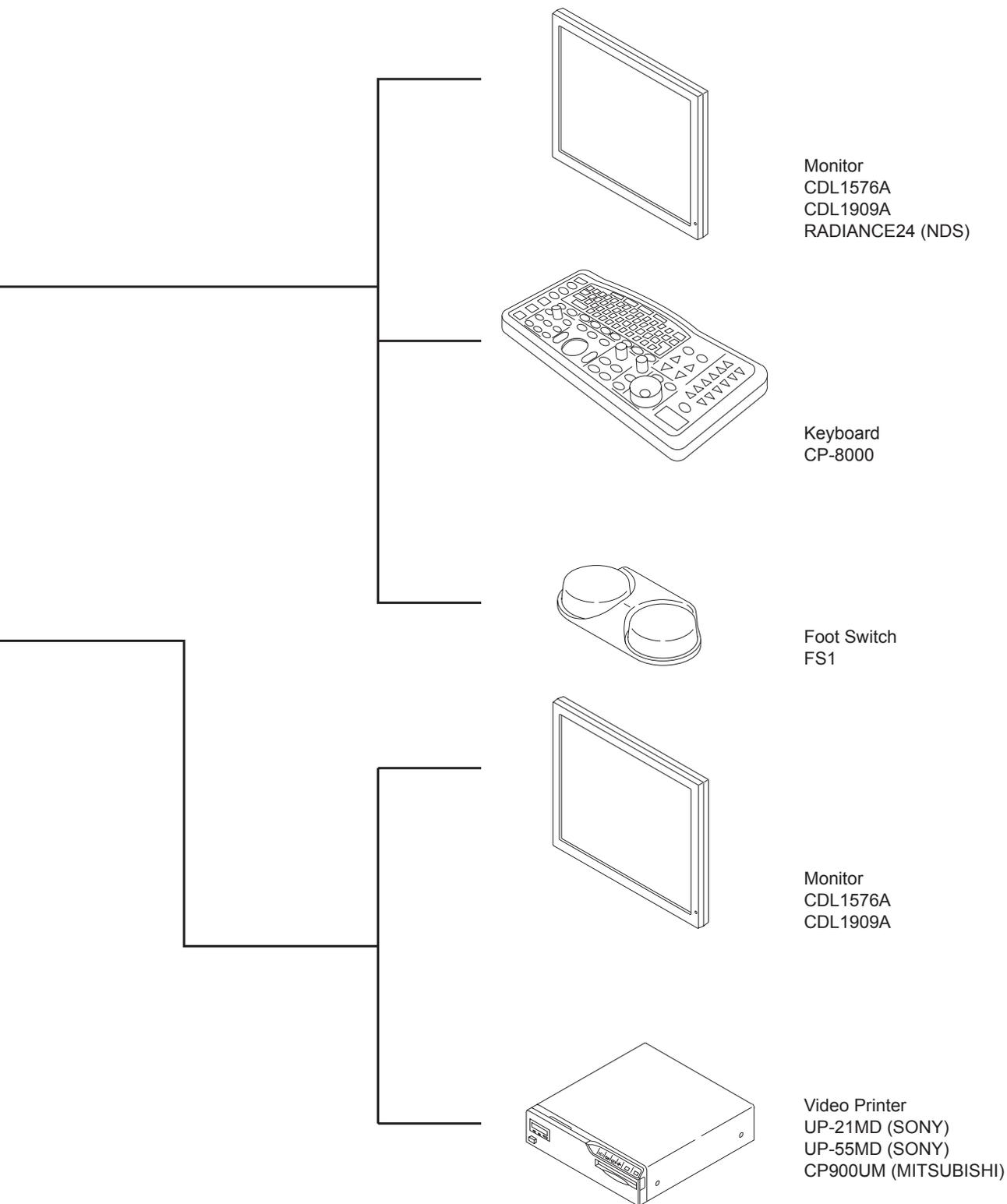
[Note] For details on the connections of peripherals other than those listed here, please contact your local dealer.



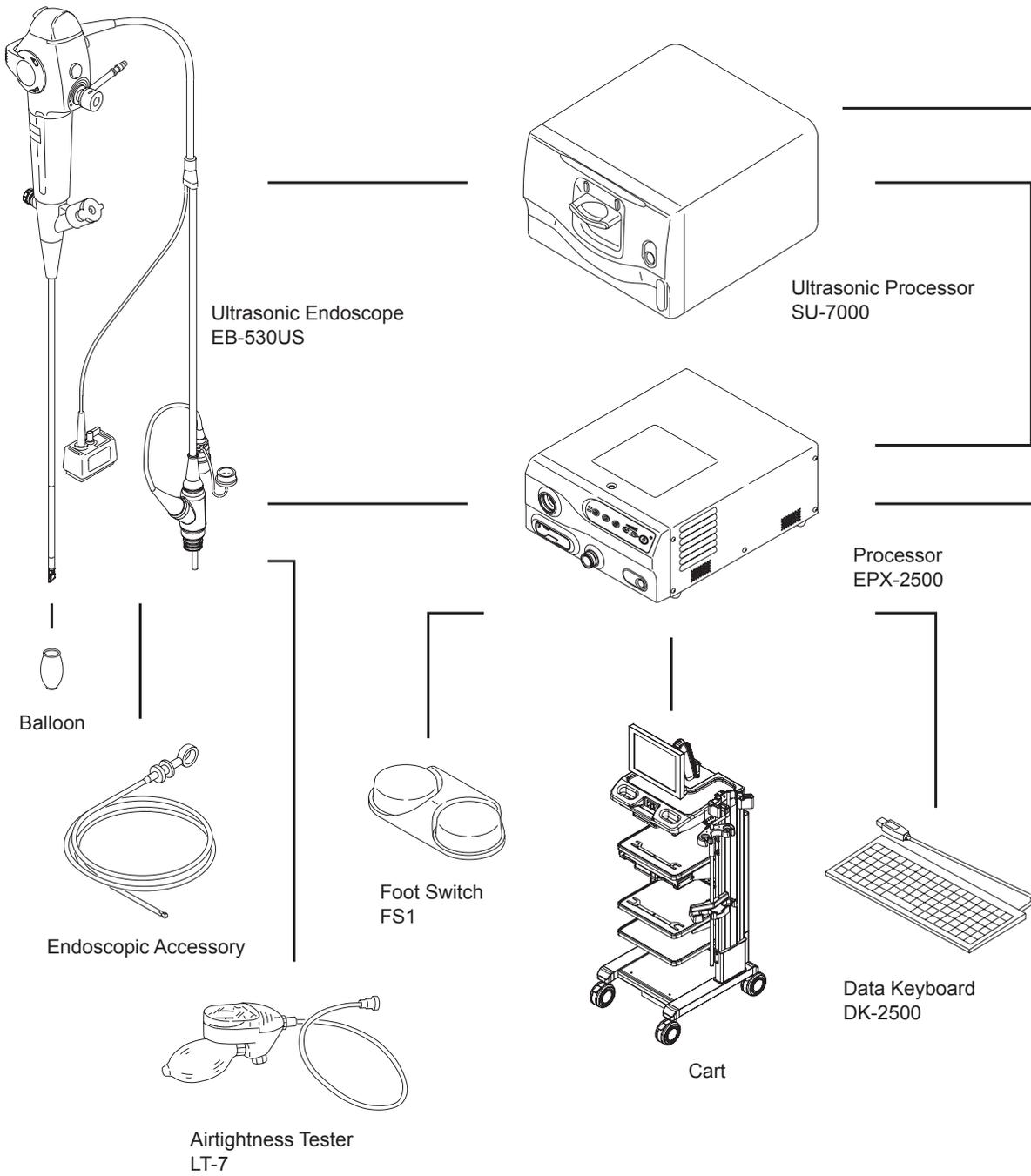
2.2.3 Combination with EPX-2500 system and SU-8000



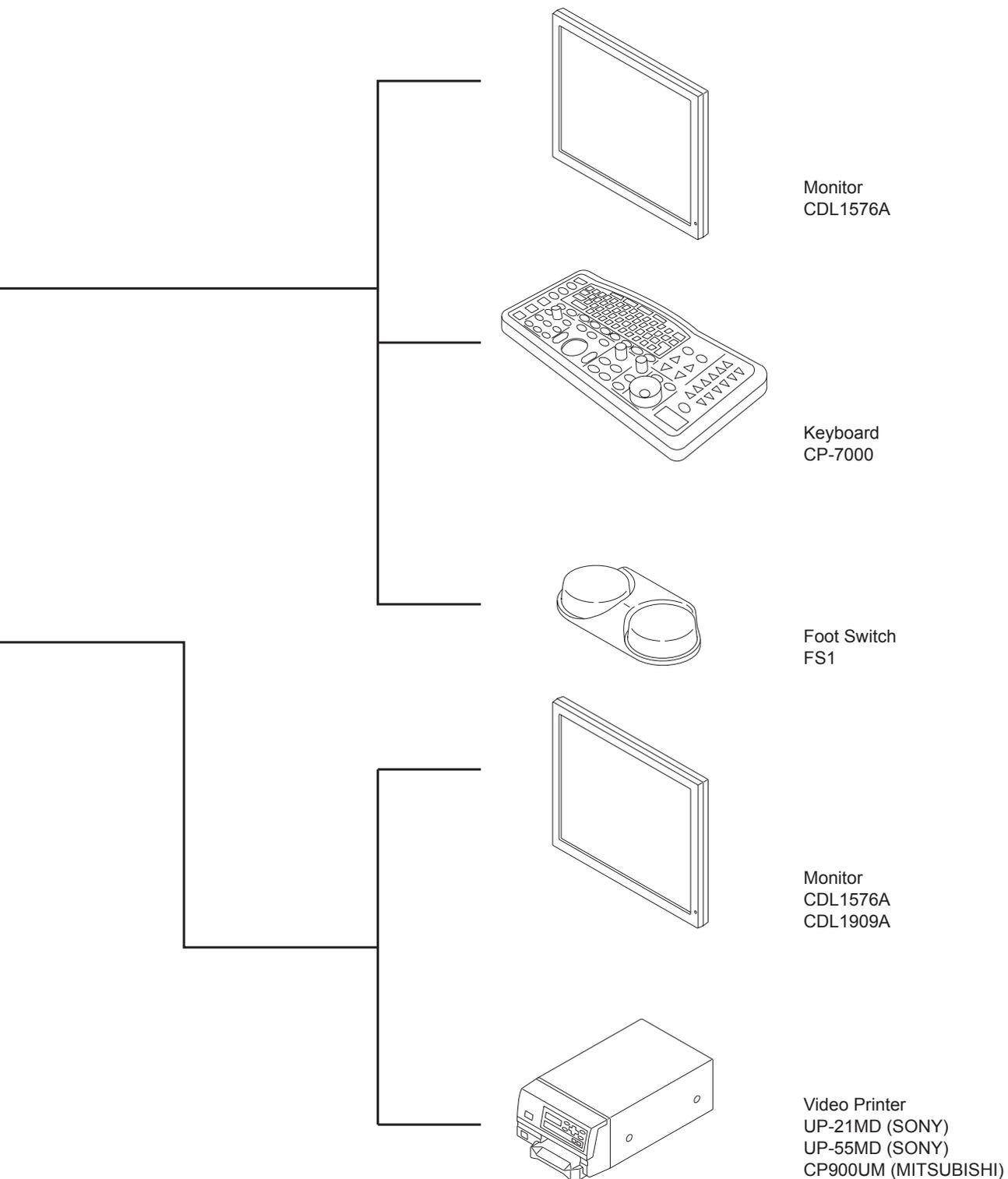
[Note] For details on the connections of peripherals other than those listed here, please contact your local dealer.



2.2.4 Combination with EPX-2500 system and SU-7000



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



Chapter 3 Names and Functions of Parts

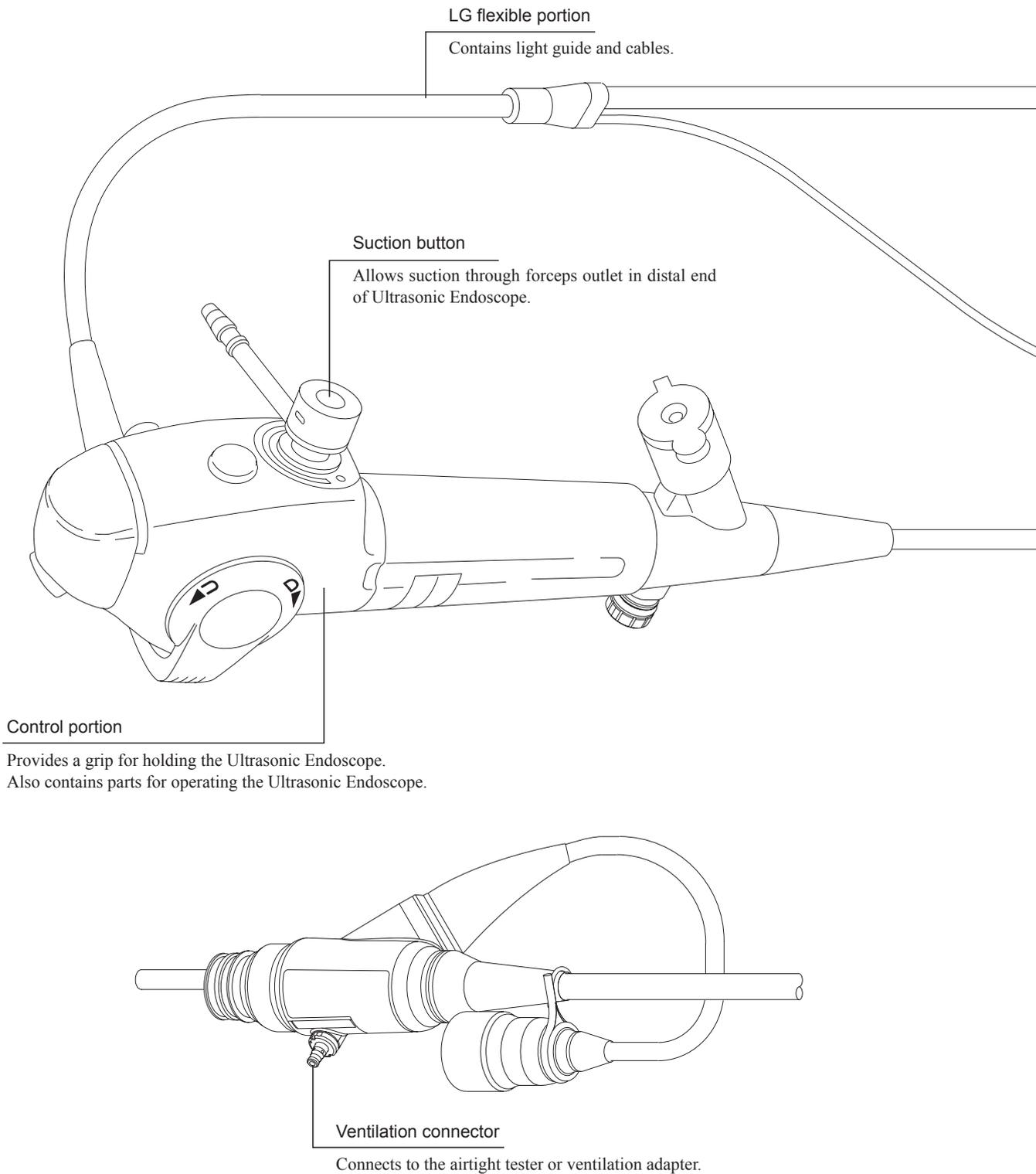
This chapter describes the names and functions of Ultrasonic Endoscope parts as well as the composition of the main body.

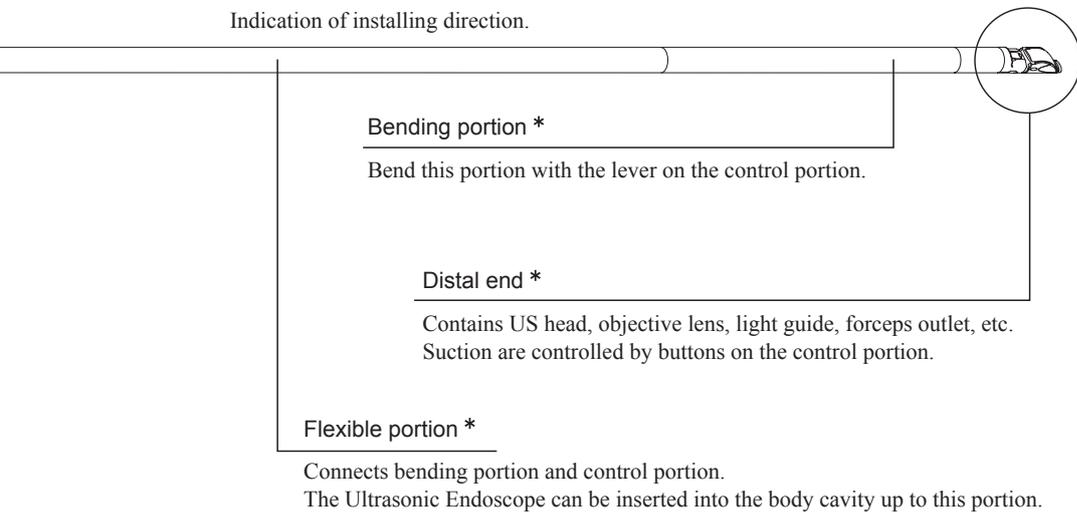
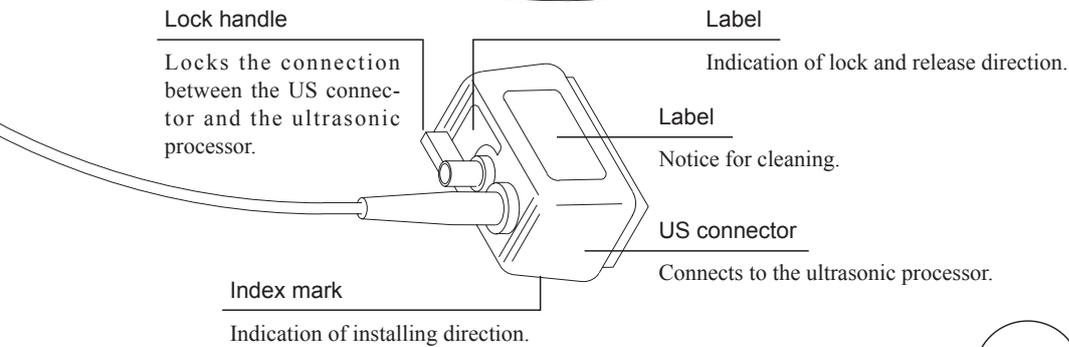
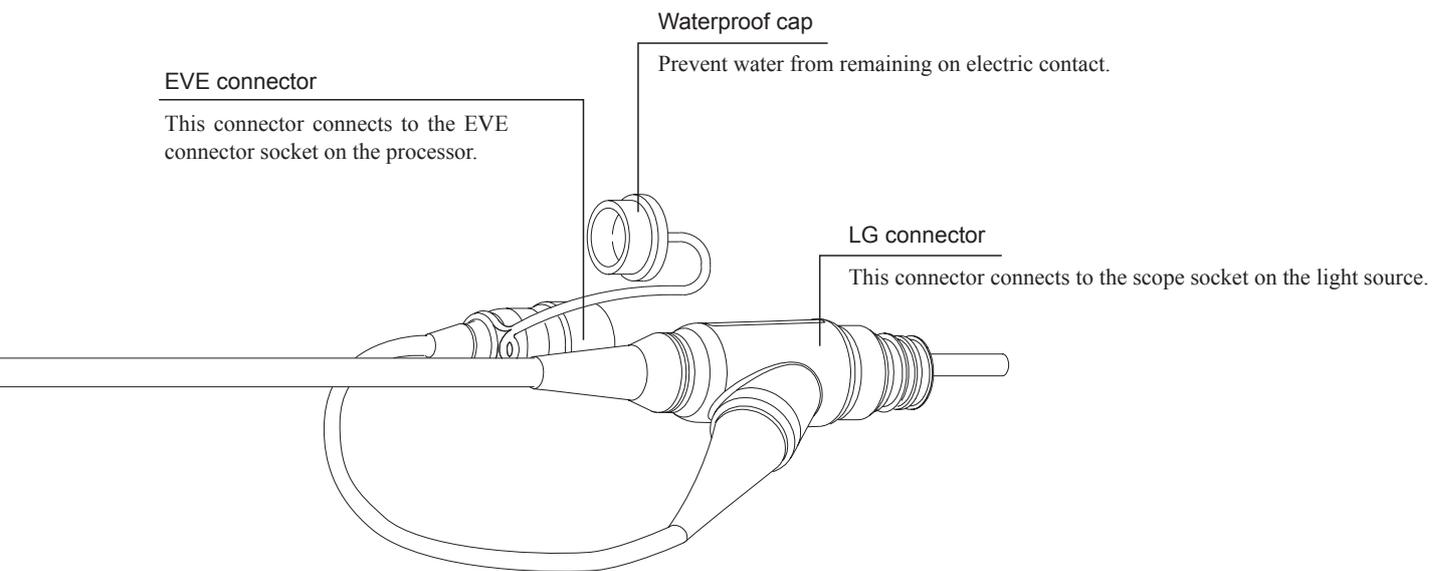
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Chapter 3 Names and Functions of Parts

3.1 Ultrasonic Endoscope

The EB-530US consists of the following parts.





*** Insertion portion (applied part)**

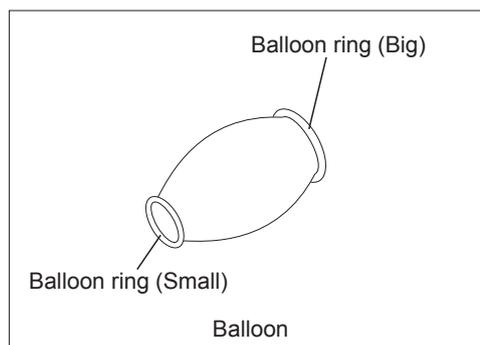
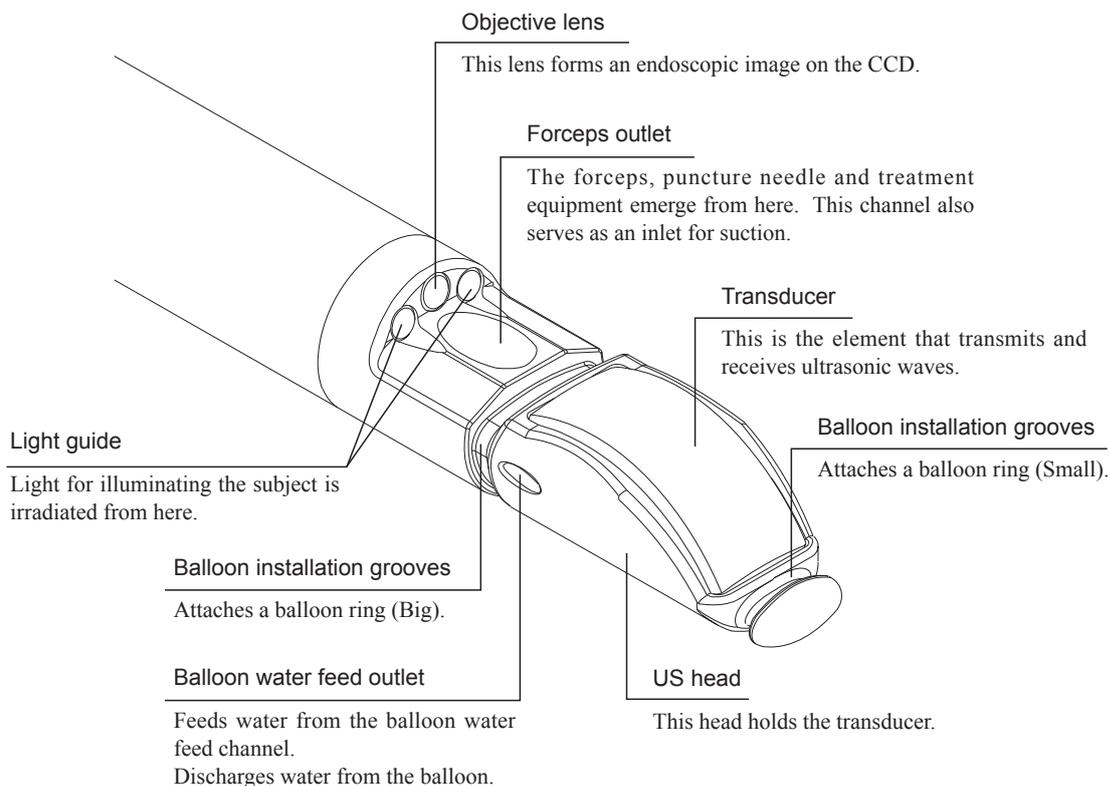
This portion is inserted into body cavities and contains the distal end, bending portion and flexible portion.

<Indication Marks>

Symbols	Location	Meanings
	LG connector US connector	Type BF applied part
	LG connector	Date of manufacture
	LG connector	Serial number
	LG connector	CE marking
	LG connector	WEEE marking
	US connector	Consult accompanying documents
IPX7	US connector	Degree of waterproof
	LG connector	Super CCD model
	LG connector	Phthalates marking

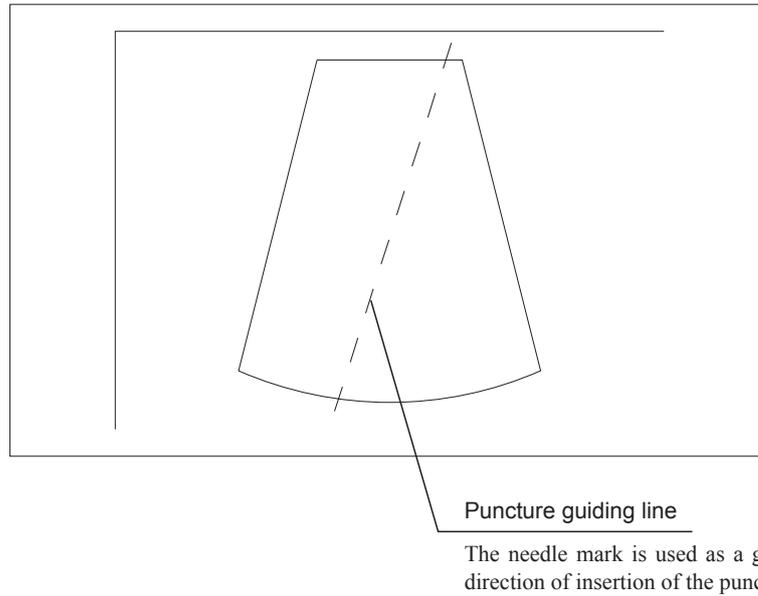
3.2 Distal End of Ultrasonic Endoscope

The distal end of EB-530US consists of the following parts.



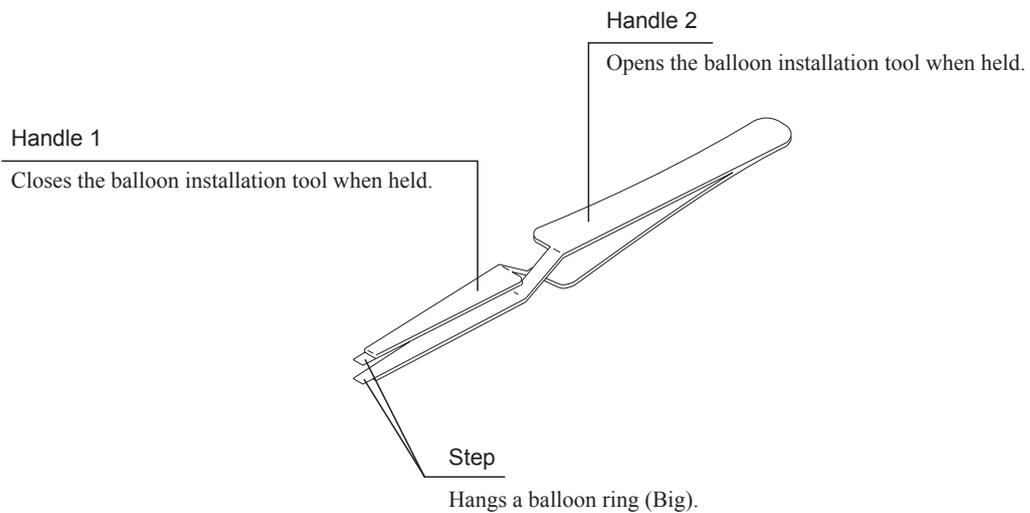
3.3 Ultrasonic Image

This section describes the functions specific to this Ultrasonic Endoscope.
The figure below shows a rough image of an ultrasonic image.



[Note] The puncture guiding line is only meant as a guide. Check the actual needle position on the ultrasonic image. For details, refer to the operation manual of the ultrasonic processor.

3.4 Balloon Installation Tool



Chapter 4 Control Portion

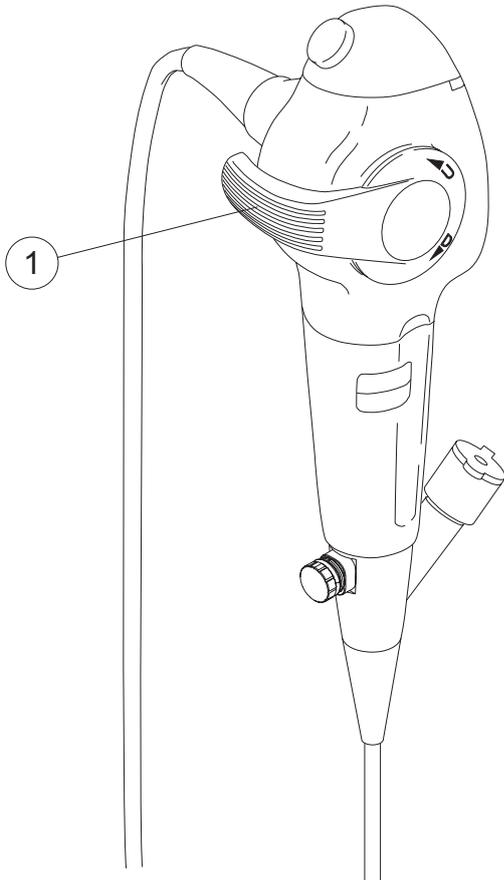
The control portion contains the angle lever for operating the bending mechanism and suction value, etc.

This chapter describes the operations and functions of these parts.

4.1	How to Operate Bending Mechanism	4-2
4.2	Suction Valve, Forceps Inlet and Water Feed Inlet.....	4-3
4.3	Remote Operating Switches	4-4
4.4	Forceps Valve.....	4-5
4.5	Suction Button.....	4-6

Chapter 4 Control Portion

4.1 How to Operate Bending Mechanism

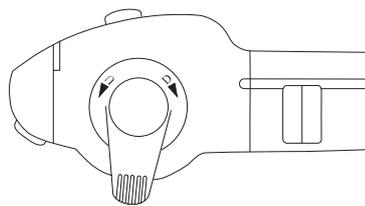
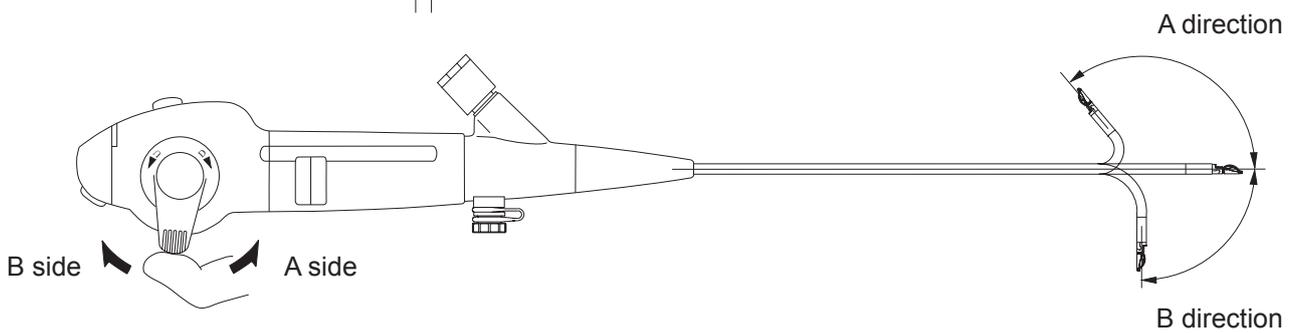


① Angle lever

To bend the bending portion upward and downward.

When the angle lever is slanted toward A side, the bending portion is bent upward (A direction).

When the angle lever is slanted toward B side, the bending portion is bent downward (B direction).



The lever position while the bending portion is in straight state.

4.2 Suction Valve, Forceps Inlet and Water Feed Inlet

② Suction Valve

Suction button is attached.

③ Forceps Inlet

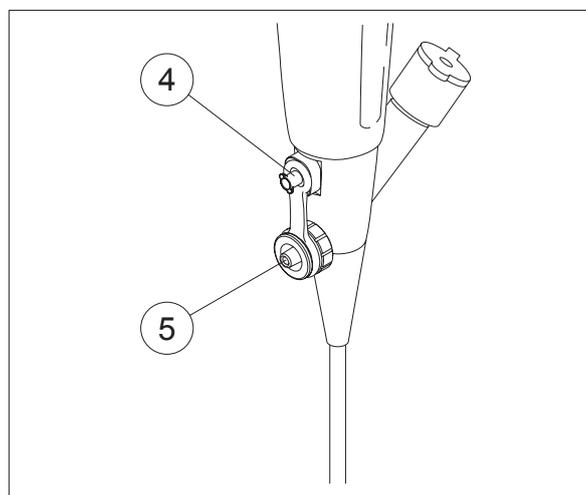
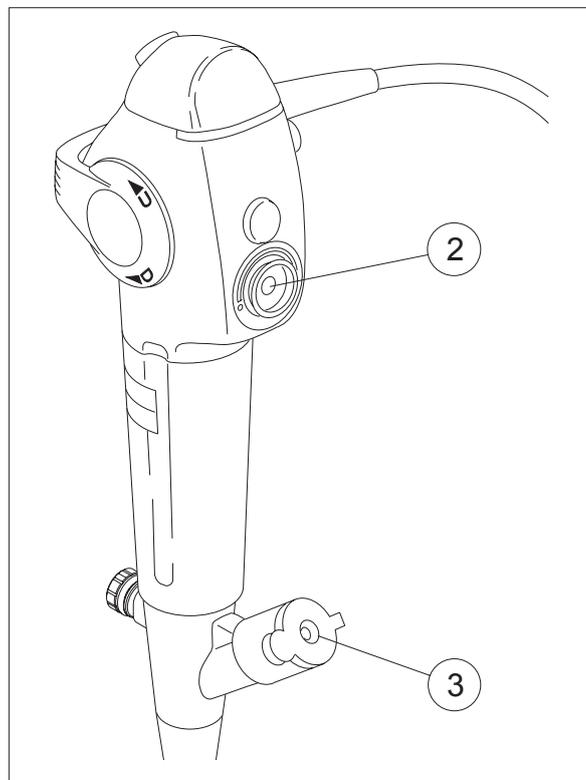
Opening for passing through endoscopic accessory.
Normally, the forceps valve is attached.

④ Balloon Water Feed Inlet

Feeds/discharges water to/from a balloon when the balloon is attached.

⑤ Balloon Water Feed Inlet Cap

Fit this on the balloon water feed channel to prevent foreign matter from entering and liquid from splashing out when no balloon is used.



4.3 Remote Operating Switches

⑥ Recording Switch

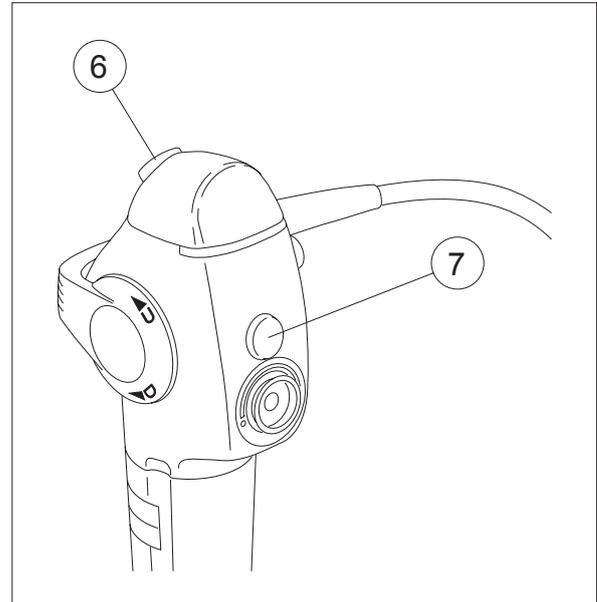
This is the remote switch for capturing image for a video printer.

This switch can be manipulated to capture images even while freezing an image with the freeze switch activated.

⑦ Freeze Switch

This is the remote switch for still image and the capture. The screen image is frozen while this button is being pushed. Image freezing is canceled a few seconds after it is released.

If the switch is pushed again while the image is still frozen, a trigger signal is output to the device connected to the hard copy terminal.



4.4 Forceps Valve

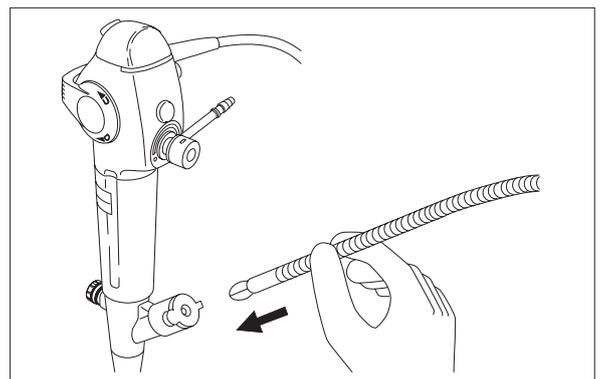
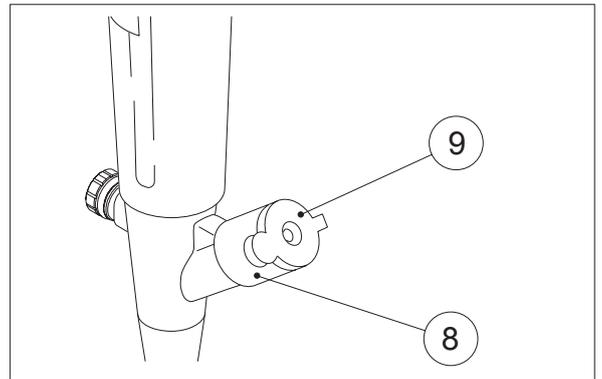
The forceps valve consists of a valve body and a lid. It performs the function of preventing the leak or flowback of air.

⑧ Valve Body

The valve body is a part that reduces the leakage or backflow of air when an accessory is used.

⑨ Lid

The lid functions as a valve for preventing the leak or backflow of air. It should be kept closed.



4.5 Suction Button

Suction button is attached in the suction valve.

Allows suction through forceps outlet in distal end of Ultrasonic Endoscope.

Suction button SB-500B/D has not been sterilized.

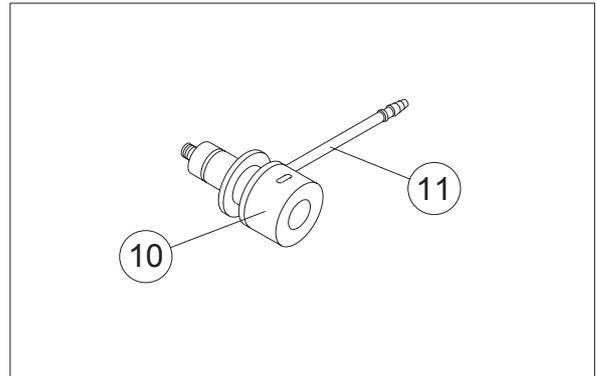
When using the suction button SB-500B/D, carry out cleaning and sterilization.

⑩ Suction Button

Suction is activated while this button is depressed.

⑪ Suction Connector Portion

Suction tube connected with the suction unit is connected to this portion.

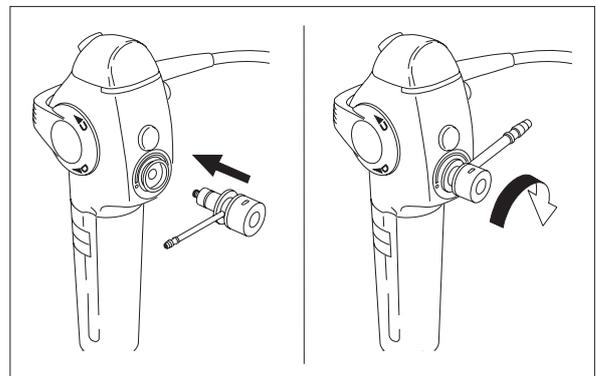


<Method of attaching suction button>

Set the direction of the suction connector portion at the “○” position of the index, and insert it into the Endoscope.

Rotate the suction connector portion in the direction of the arrow.

To remove the suction connector portion, return it to the index position, and pull out the entire equipment.



Chapter 5 Preparation for Use of Ultrasonic Endoscope

This chapter describes the system necessary for endoscopy.

5.1	Preparing Equipment.....	5-2
5.2	Preparing Suction Button	5-4
5.3	Preparing Forceps Valve	5-5
5.3.1	Method of Cleaning, Disinfecting and Sterilizing Forceps Valve	5-5
5.4	Connecting Ultrasonic Endoscope (Installation).....	5-7
5.5	Inspection of Ultrasonic Endoscope.....	5-11
5.5.1	Inspecting Insertion Portion	5-11
5.5.2	Inspecting Bending Mechanism.....	5-12
5.5.3	Inspecting Suction, Water Feed and Forceps Channel	5-13
5.5.4	Inspection of Distal End of Ultrasonic Endoscope, US Connector and Cable.....	5-15
5.5.5	Inspecting Objective Lens and Light Guide ...	5-16
5.5.6	Inspecting Ultrasonic Image	5-17
5.6	Removing Ultrasonic Endoscope	5-18
5.7	Attachment and Inspection of Balloon.....	5-21
5.8	Inspection of Puncture Needle	5-25
5.9	Inspection of Forceps	5-26

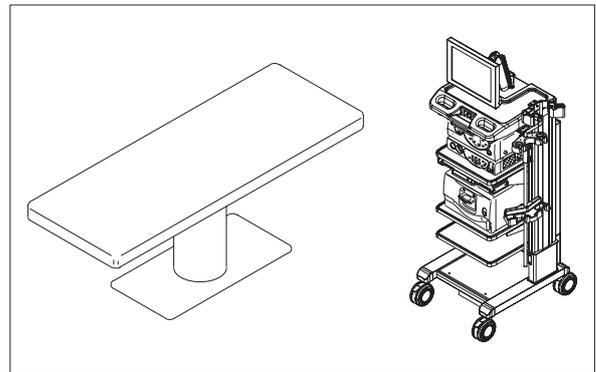
Chapter 5 Preparation for Use of Ultrasonic Endoscope

! CAUTION

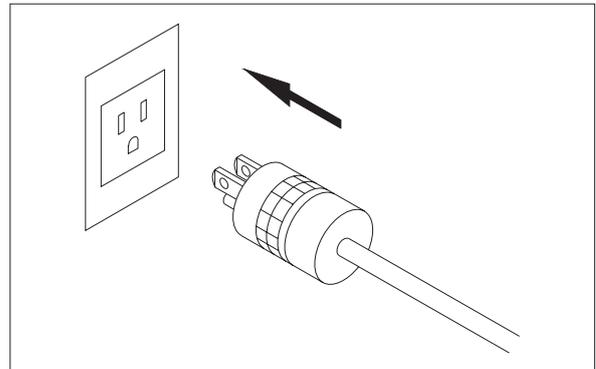
Do not use the abnormal equipment.
The use of abnormal equipment will cause wrong diagnosis or injury.

5.1 Preparing Equipment

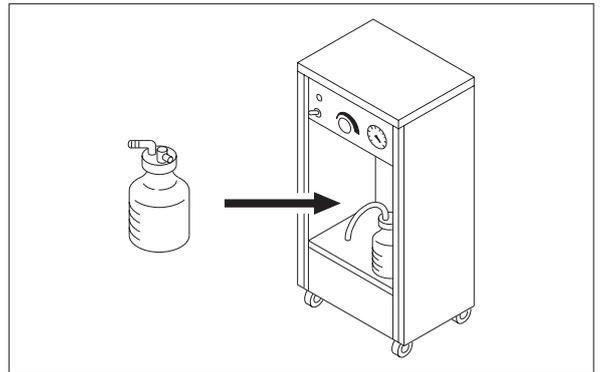
- (1) Move the cart with the processor to the place where the Ultrasonic Endoscope is to be used.



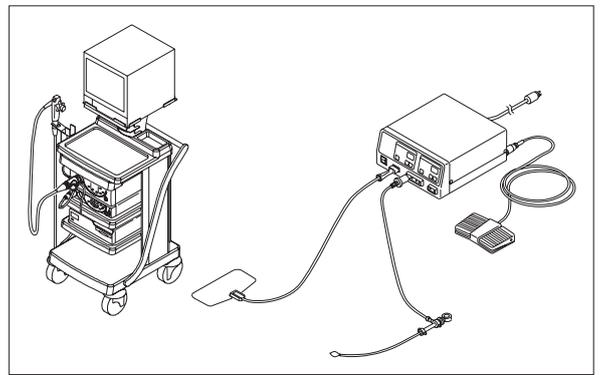
- (2) After turning the main switch on the cart to the OFF position, plug the power cord from the cart and the ultrasonic processor into a protective earth receptacle.



- (3) Mount the suction bottle on the suction unit.



- (4) Prepare an electrosurgical instrument and the applicable Endoscope for unexpected bleeding.



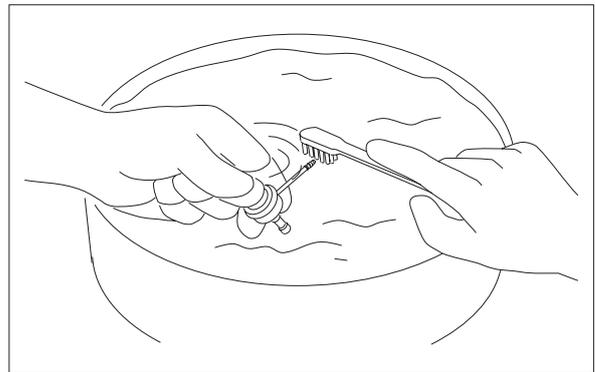
5.2 Preparing Suction Button

The suction button is a single-use product. Prepare a new suction button before use.
The suction button SB-500B/D has not been sterilized. Perform cleaning and sterilization before use according to the following procedure.

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

<Method of cleaning and sterilization>

- (1) Brush the entire button in the cleaning fluid while the button are actuated using a soft toothbrush.
- (2) Clean the button using the ultrasonic cleaning unit.
- (3) Pull the button out from the cleaning fluid and rinse with running water (clean water).
- (4) Wipe off the remaining water on the button with dry sterile gauze.
- (5) Seal the buttons in a sterile pack.
- (6) Carry out an autoclaving operation in accordance with the operation manual of the autoclaving unit.



Recommended steam sterilization (autoclaving) conditions

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

For France and Switzerland only:

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

Steam Sterilizer Class B according EN 13060

5.3 Preparing Forceps Valve

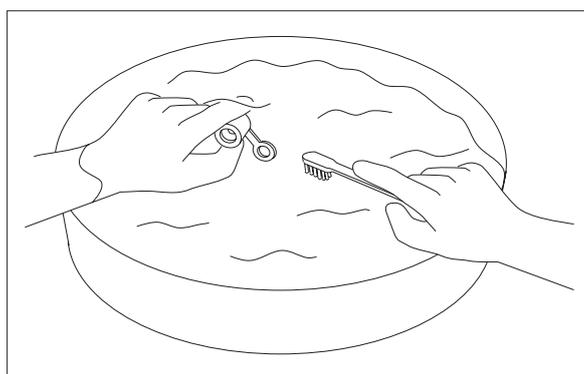
The forceps valve is a single-use product. Prepare a new forceps valve before use.

The forceps valve has not been sterilized. Perform cleaning and disinfection or sterilization before use according to the following procedure.

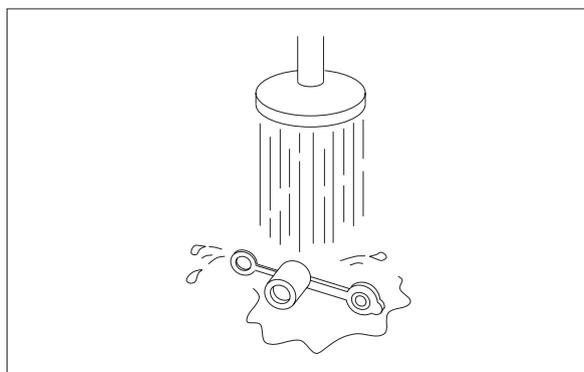
For operational methods of the ultrasonic cleaning unit/autoclaving unit, please follow the instructions described in each operation manual for the respective units.

5.3.1 Method of Cleaning, Disinfecting and Sterilizing Forceps Valve

- (1) Open the lid of the forceps valve.
- (2) Wipe the surface of the parts with gauze soaked in cleaning fluid.
- (3) Brush the entire forceps valve in the cleaning fluid using a soft toothbrush.



- (4) Clean the forceps valve using the ultrasonic cleaning unit.
- (5) Pull out the forceps valve from the cleaning fluid and rinse off with running water (clean water).
- (6) Wipe off the remaining water on the parts with dry sterile gauze.



<Autoclave sterilization>

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

Recommended steam sterilization (autoclaving) conditions

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

For France and Switzerland only:

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

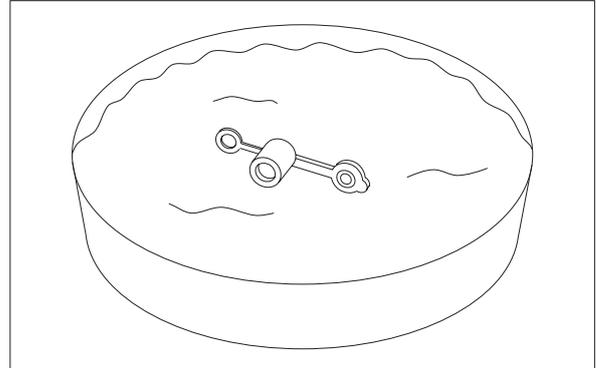
Steam Sterilizer Class B according EN 13060

<Chemical disinfection>

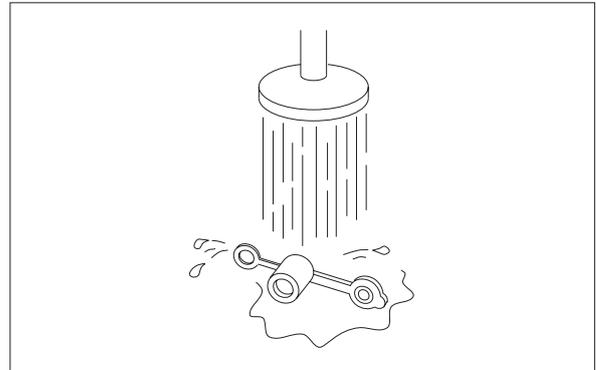
- (1) Immerse the forceps valve in disinfectant and disinfect.

[Note]

When performing disinfection using chemicals, follow the conditions indicated in Appendix “Chemicals and Conditions” attached to the cleaning, disinfection and storage section.



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



5.4 Connecting Ultrasonic Endoscope (Installation)

⚠ CAUTION

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

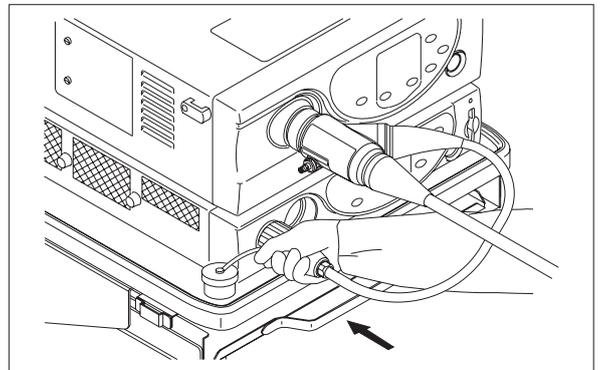
Touching the LG connector with hands immediately after use of the Endoscope may cause a burn injury.

<Combination with the VP-4400 and XL-4400 or VP-4450HD and XL-4450>

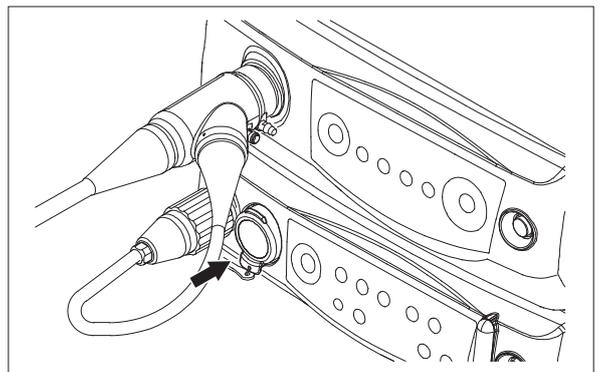
- (1) Insert the LG connector of the Ultrasonic Endoscope into the Endoscope socket on the light source.
- (2) Insert the video connector of the Ultrasonic Endoscope into the video connector socket on the processor.

[Note]

Put the waterproof cap on the edge of the tray.



- (3) Connect the dedicated connector cap to the connector socket not in use. (For VP-4450HD only)



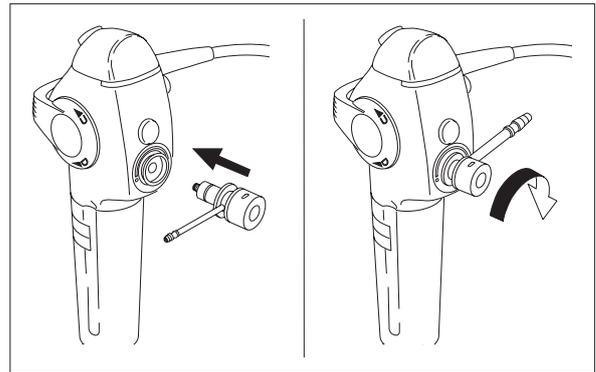
- (4) Attach the forceps valve and the suction button.

Use the level of disinfection or sterilization suitable to the application before using the forceps valve and suction button.

Set the direction of the suction connector at the “○” position of the index, and insert it into the Endoscope.

Rotate the suction connector in the direction of the arrow.

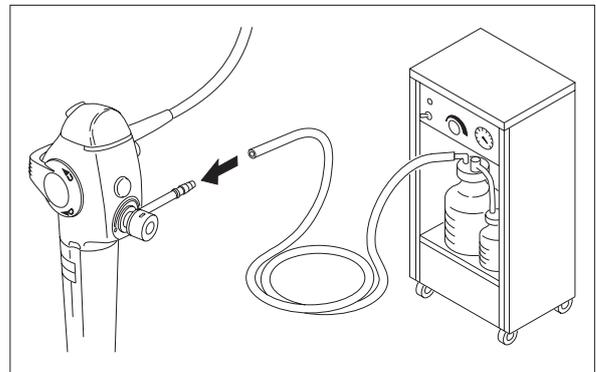
To remove the suction connector, return it to the index position, and pull out the entire equipment.



- (5) Connect the suction tube between the suction unit and suction connector portion of the Ultrasonic Endoscope.

[Note]

Firmly connect the suction connector portion with the suction tube to prevent any leaking.

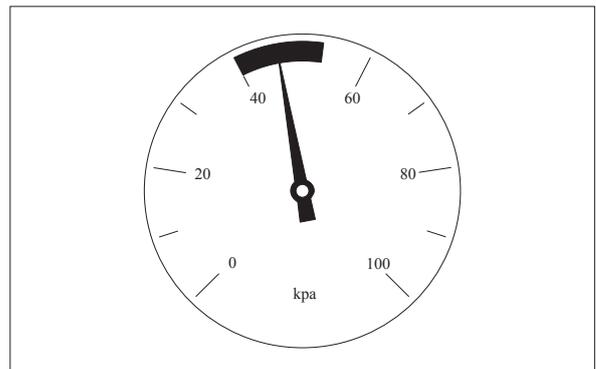


! CAUTION

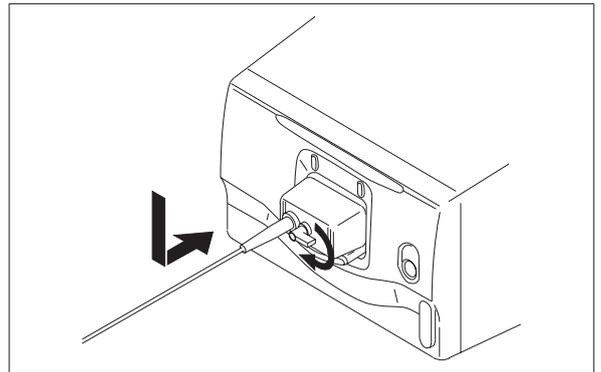
Set a suction pressure at 53kPa or less.

Ultrasonic Endoscope may adhere to mucous membrane, resulting in damage to the mucous membrane.

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

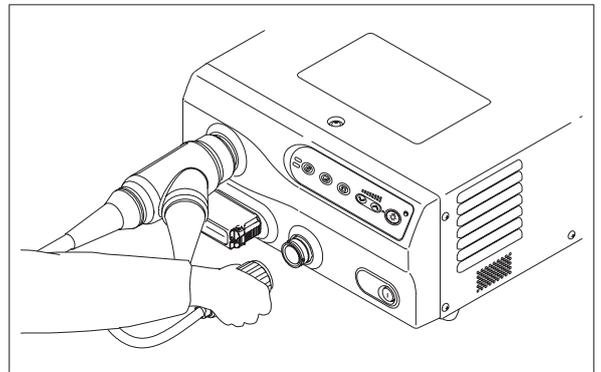


- (7) Connect the US connector to the Ultrasonic Endoscope connector of the ultrasonic processor.
- (8) Turn the lock handle of the US connector clockwise to lock the connector.



<Combination with the EPX-2500 system>

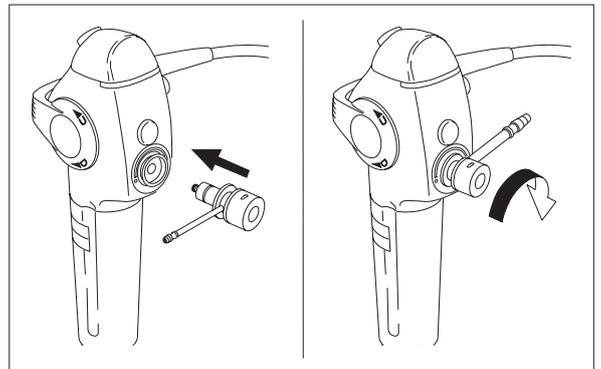
- (1) Insert the LG connector of the Ultrasonic Endoscope into the Endoscope socket on the processor.
- (2) Insert the EVE connector of the Ultrasonic Endoscope into the 500 system connector socket on the processor.



- (3) Attach the suction button.

Use the level of disinfection or sterilization suitable to the application before using the forceps valve and suction button.

Set the direction of the suction connector at the “○” position of the index, and insert the arm into the Endoscope.



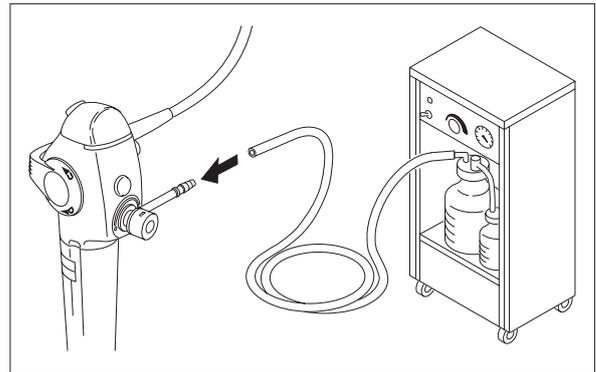
Rotate the suction connector in the direction of the arrow.

To remove the suction connector, return it to the index position, and pull out the entire equipment.

- (4) Connect the suction tube between the suction unit and suction connector portion of the Ultrasonic Endoscope.

[Note]

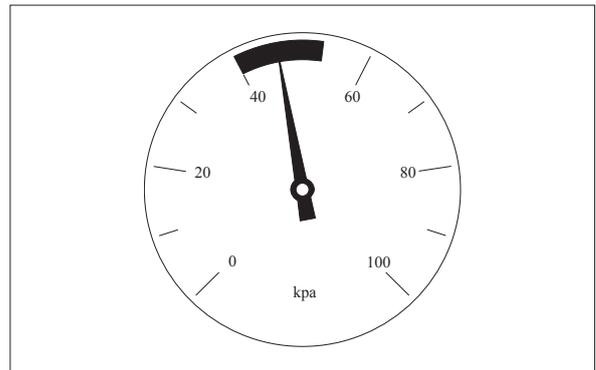
Firmly connect the suction connector portion with the suction tube to prevent any leaking.



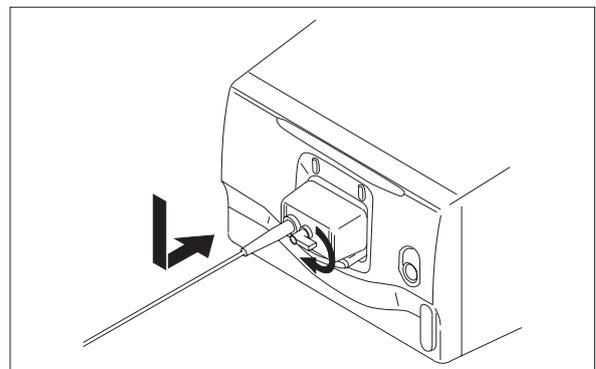
! CAUTION

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

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



- (6) Place the US connector on the top surface of the ultrasonic processor connector cover, and then press down the connector cover.
- (7) Insert the US connector straight into the connector outlet of the ultrasonic processor.
- (8) Turn the lock handle of the US connector clockwise until it stops (110°) to lock the connector.



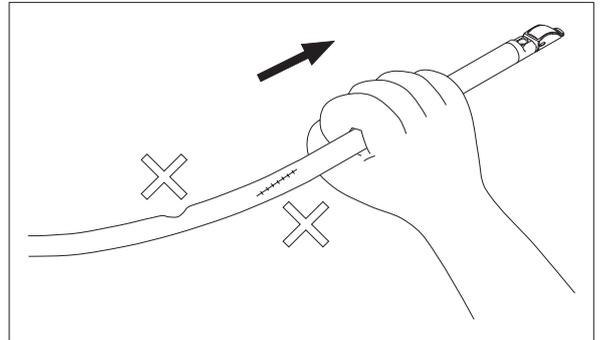
5.5 Inspection of Ultrasonic Endoscope

5.5.1 Inspecting Insertion Portion

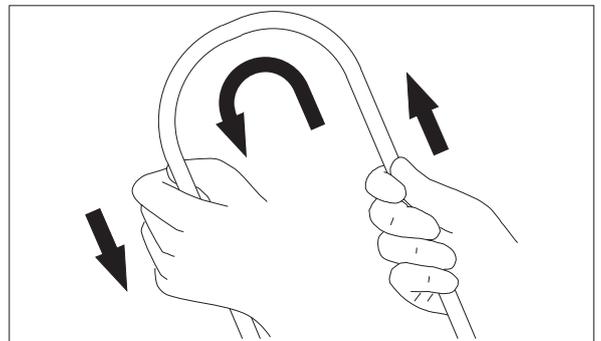
- (1) Visually check the insertion portion (distal end, bending portion and flexible portion) for abnormalities such as flaws or dents and for sharp edges on protrusions that may injure the patient.

[Note]

Do not use the Endoscope if there is deformation of bending section or slack of bending rubber.

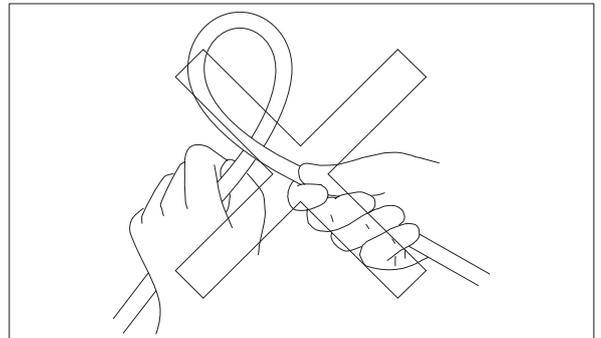


- (2) Hold the flexible portion with both hands and allow it to go over its full length in such a way that the apex of the semicircle with a diameter of about 200 mm gradually begins to slide. Check that the portion bends fully and there is no local difficulty in bending it.



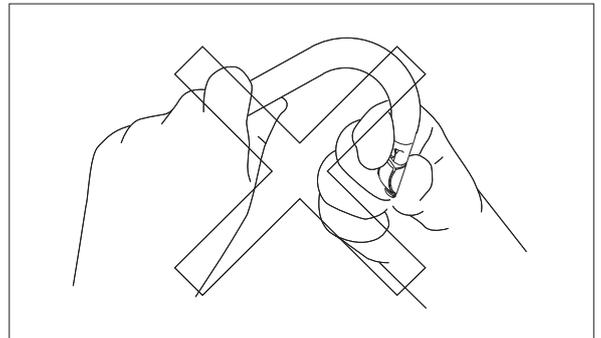
[Note]

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



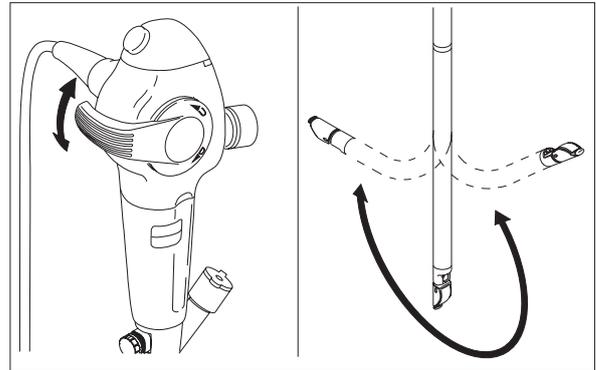
[Note]

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

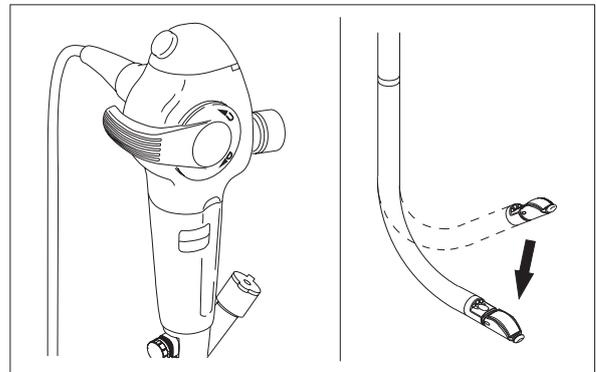


5.5.2 Inspecting Bending Mechanism

- (1) Turn the angle lever upward and downward until it stops.
Check that the bending portion moves smoothly.



- (2) Check that when the angle lever is released in bent state, the bending portion unbends a little.

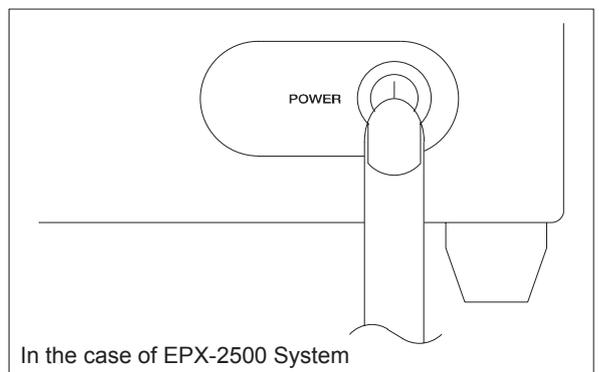
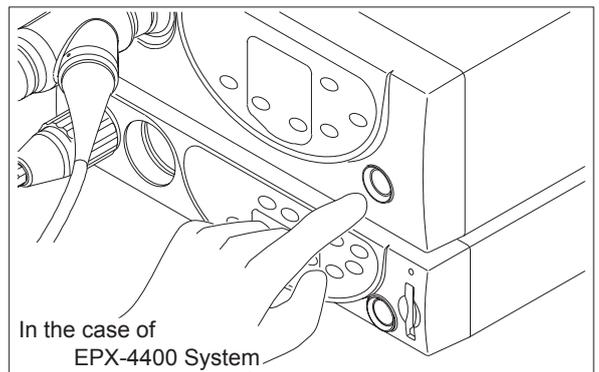


5.5.3 Inspecting Suction, Water Feed and Forceps Channel

! WARNING

Firmly attach the forceps valve to the forceps inlet of the Ultrasonic Endoscope.
There is a risk of infection.

- (1) Switch on the power to the suction unit, cart and processor and light source.
Keep the lamp off.
- (2) Have a glass of sterile water ready.



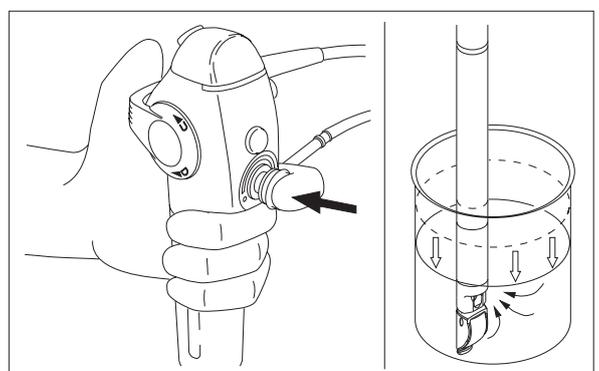
- (3) Put a forceps valve in forceps inlet.
Dip the distal end of the Ultrasonic Endoscope in water, and check that depressing the suction button sucks in water and that releasing it stops suction.

[Note]

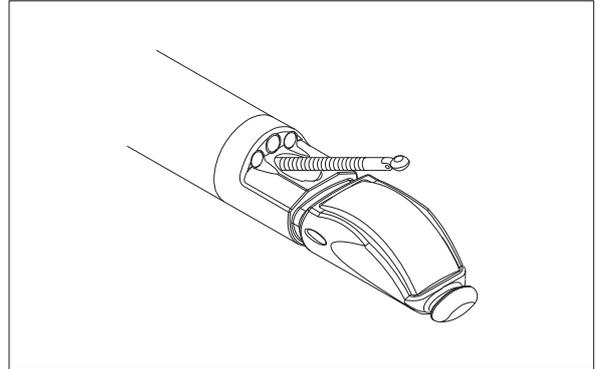
Check that the forceps valve is correctly connected to the forceps inlet.

[Note]

Do not use any expired forceps valve.



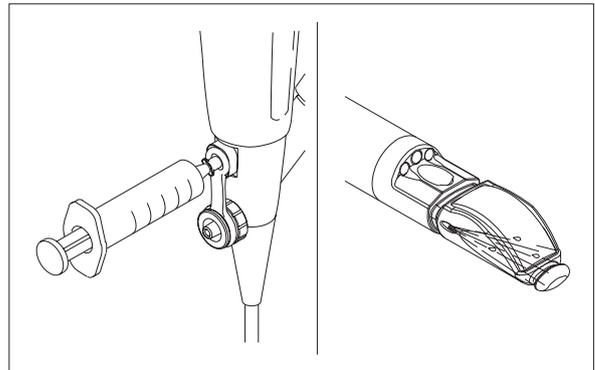
- (4) Insert the forceps from the forceps inlet and check that their tips come smoothly out of the forceps outlet in the distal end of Ultrasonic Endoscope.



- (5) Use the syringe to feed water from the balloon water feed inlet, and then check if water is discharged from the balloon water feed outlet at the distal end of Ultrasonic Endoscope.

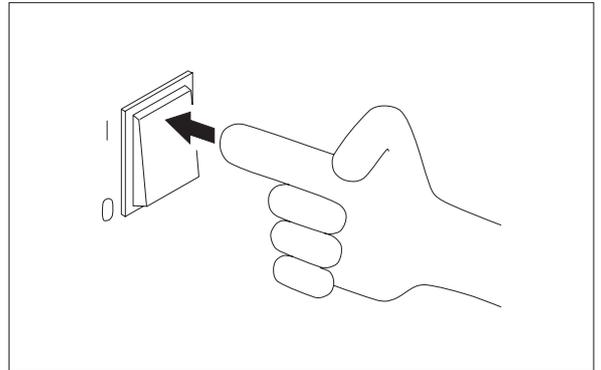
[Note]

The syringe can be attached to the balloon water feed channel via an extension tube.

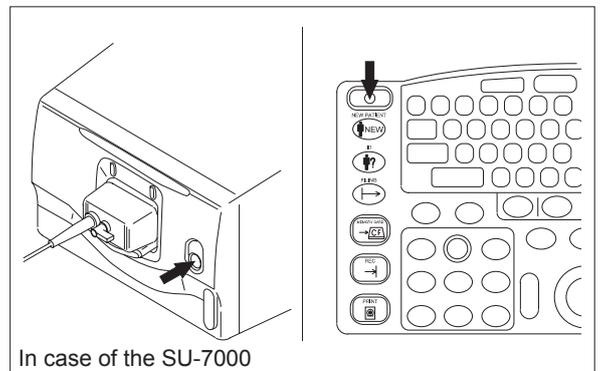


5.5.4 Inspection of Distal End of Ultrasonic Endoscope, US Connector and Cable

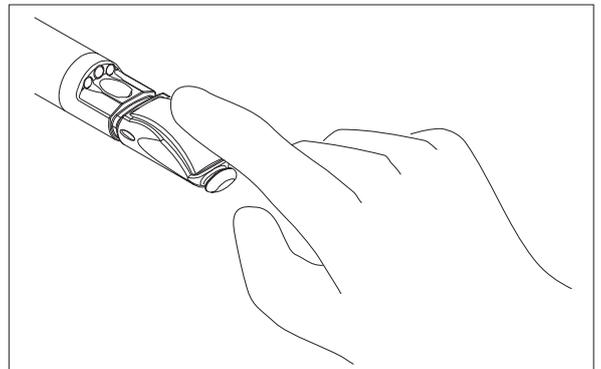
- (1) Turn the power on by pressing the standby switch on the ultrasonic processor or on the keyboard.



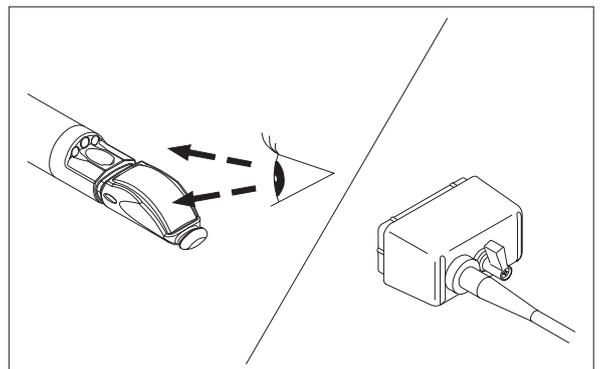
Turn the power on by pressing the STANDBY switch on the front side of the ultrasonic processor or STANDBY key on the left hand side of the keyboard.



- (2) Check to confirm by touching with a finger that the transducer of the distal end of Ultrasonic Endoscope is not hot.



- (3) Visually check the distal end of Ultrasonic Endoscope, the US connector and the cables for abnormalities such as cracks or dents etc.



5.5.5 Inspecting Objective Lens and Light Guide

! CAUTION

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

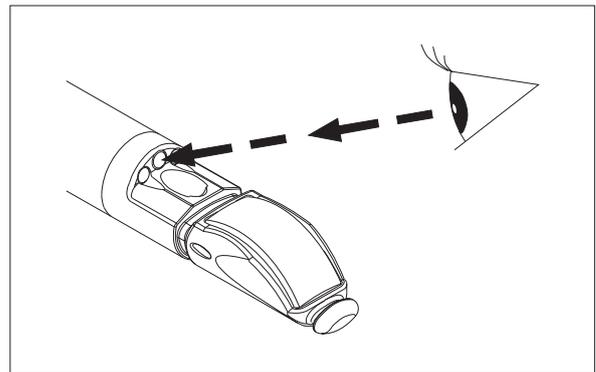
CAUTION

Do not apply lens cleaner to the transducer. Wipe off lens cleaner immediately if any adheres to the transducer.
The transducer may be degraded.

- (1) Turn OFF the lamp.

Look at the distal end of the Ultrasonic Endoscope at an angle and check that the objective lens is free of dirt or foreign matter.

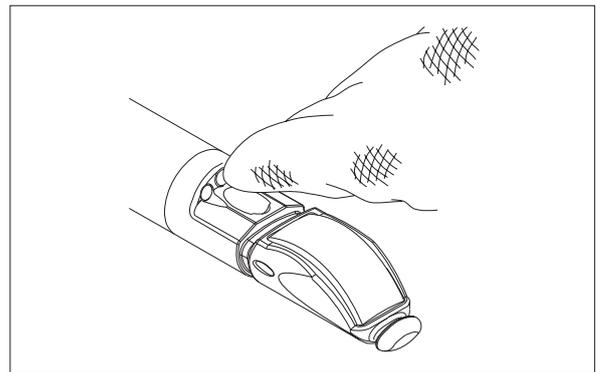
It checks that there are no scratches on the lens and its circumference of the lens.



- (2) If the lens is dirty, clean it.

[Note]

To clean the lens, wipe it with gauze (or something similarly soft) dampened with lens cleaner or ethanol.



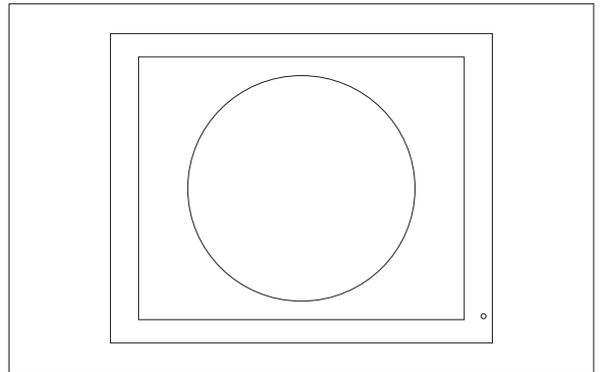
- (3) Switch on the lamp and observe the endoscopic image on the monitor. By observing your palm or something else, check whether the lamp lights normally and the luminous energy is sufficient. Check that the image is free of cloudiness or blurs.

[Note]

If wiping does not remove cloudiness from the objective lens, it is likely that the Ultrasonic Endoscope is not sufficiently airtight.

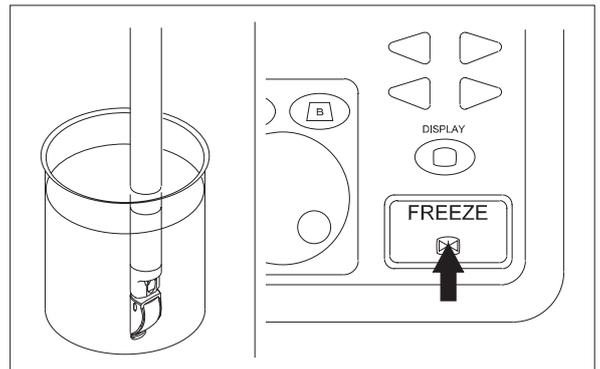
Run an airtightness test with an airtightness tester LT-7.

→ “7.4.1 Airtightness Test”

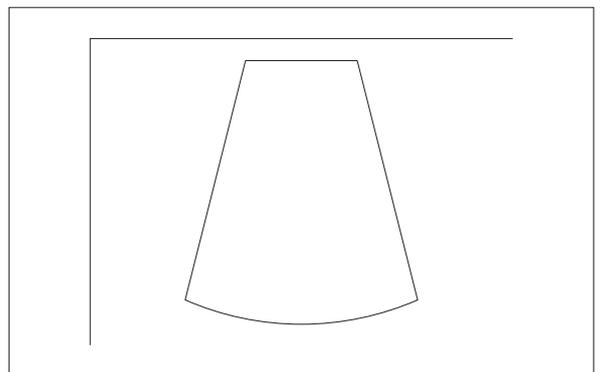


5.5.6 Inspecting Ultrasonic Image

- (1) Have a glass of water ready. Dip the distal end of the Ultrasonic Endoscope into the 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.



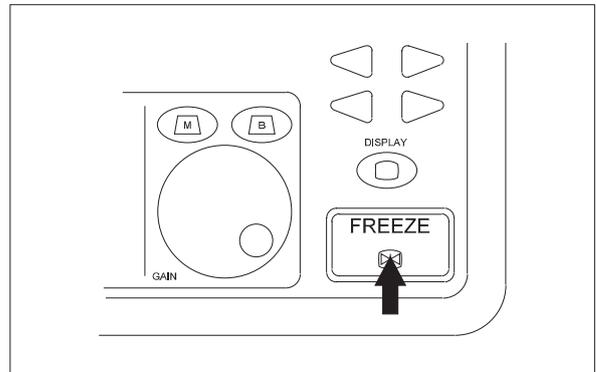
5.6 Removing Ultrasonic Endoscope

CAUTION

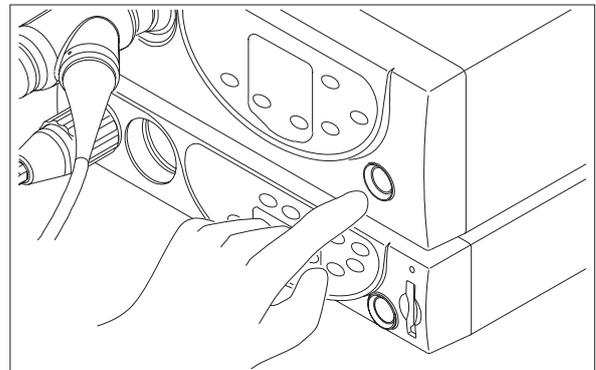
Freeze the ultrasonic image before removing the Ultrasonic Endoscope.
The Ultrasonic Endoscope may be damaged.

<Combination with the VP-4400 and XL-4400 or VP-4450HD and XL-4450>

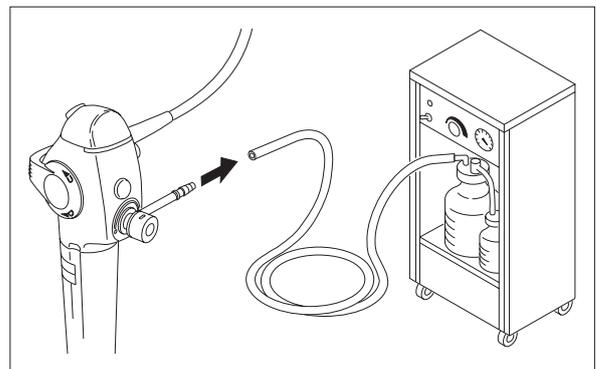
- (1) Press the **FREEZE** key on the keyboard of the ultrasonic processor to freeze the ultrasonic image.



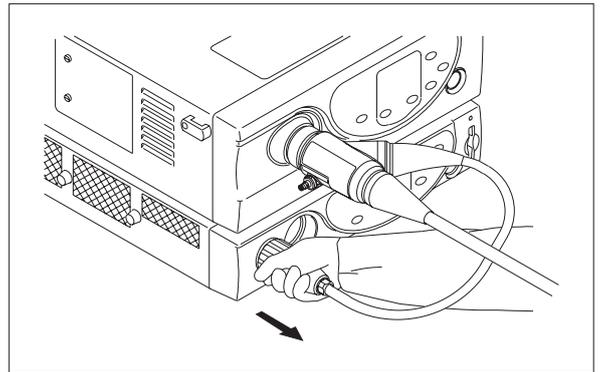
- (2) Turn OFF the power switch of the processor and the light source.



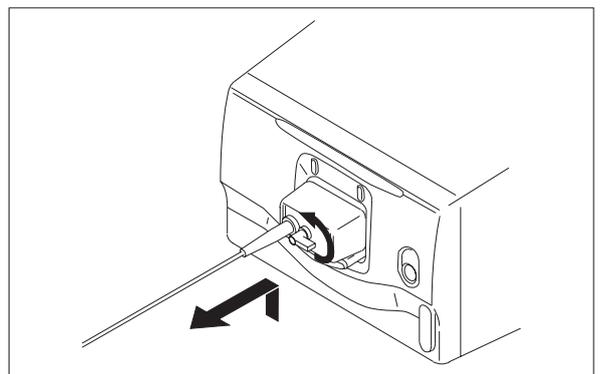
- (3) Remove the suction tube from the suction connector portion of the Ultrasonic Endoscope.



- (4) Remove the EVE connector from the processor.
- (5) Remove the LG connector from the light source.

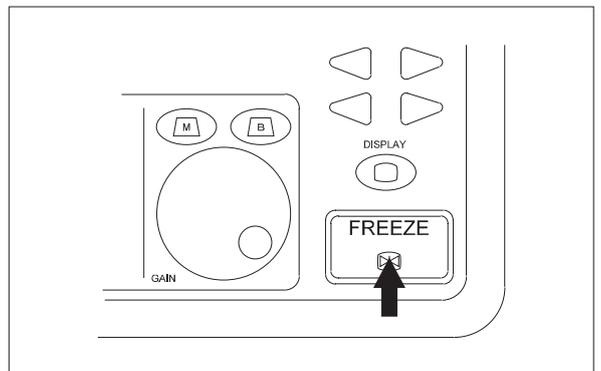


- (6) Turn off the power supply of the ultrasonic processor.
- (7) Loosen the lock handle and dismount the US connector from the ultrasonic processor.

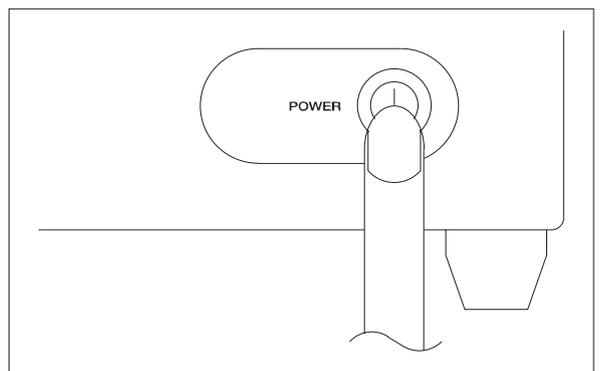


<Combination with the EPX-2500 system>

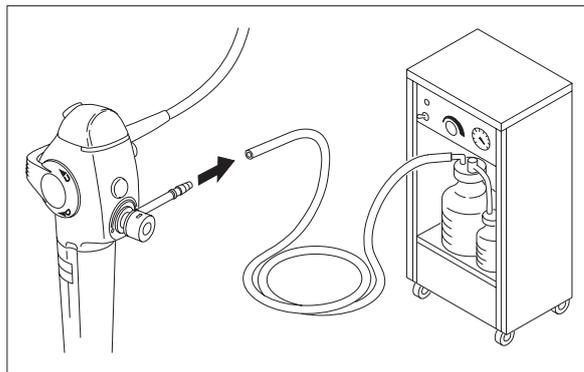
- (1) Press the **FREEZE** key on the keyboard of the ultrasonic processor to freeze the ultrasonic image.



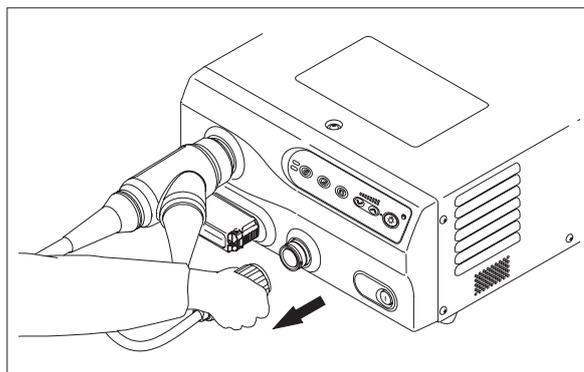
- (2) Turn OFF the power switch of the processor.



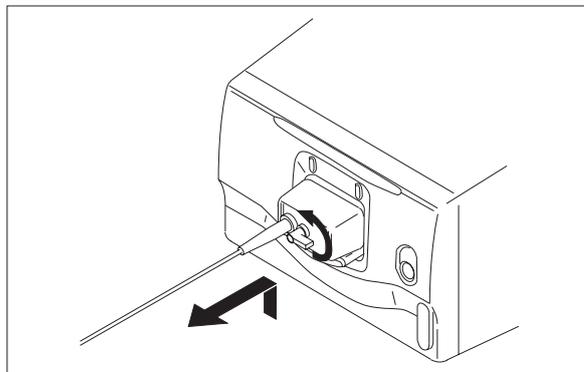
- (3) Remove the suction tube from the suction connector portion of the Ultrasonic Endoscope.



- (4) Remove the EVE connector from the processor.
(5) Remove the LG connector from the processor.



- (6) Turn off the power supply of the ultrasonic processor.
(7) Loosen the lock handle and dismount the US connector from the ultrasonic processor.



5.7 Attachment and Inspection of Balloon

⚠ WARNING

Use a disinfected and sterilized balloon installation tool.
There is a risk of infection.

Do not use a balloon on patients allergic to latex.
It may cause an anaphylactic reaction.

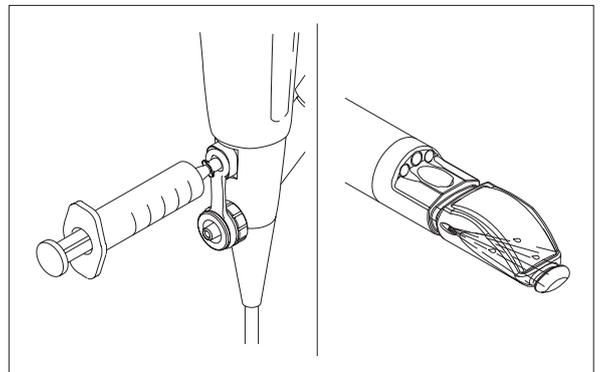
- (1) Feed sterile water from the balloon water feed inlet using a syringe and purge air from the balloon tubes.

[Note]

Feed water to the balloon manually by using a syringe.
Do not use any other instrument than syringe.

[Note]

The syringe can be attached to the balloon water feed channel via an extension tube.



[Note]

If the syringe is not connected firmly, air may enter the balloon.

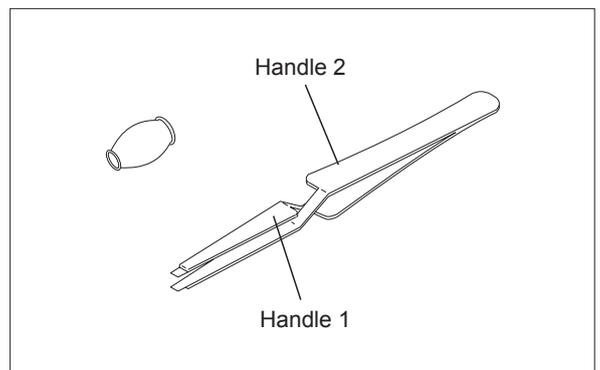
[Note]

When using a screw syringe, do not tighten the screw more than necessary.

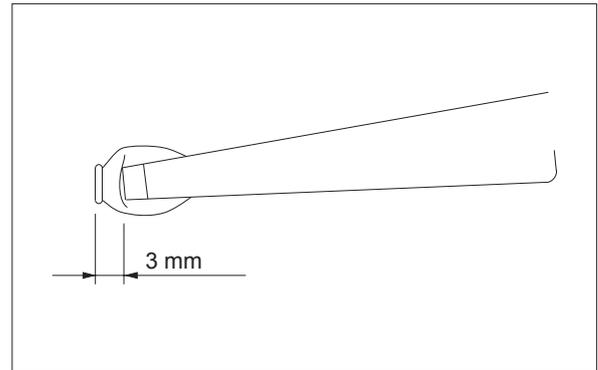
- (2) Prepare the balloon and balloon installation tool.

[Note]

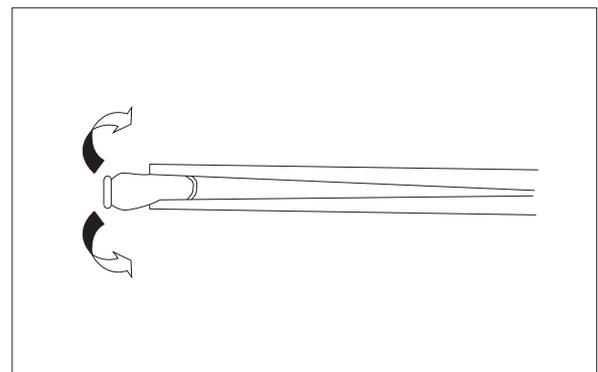
Do not use any balloon after its expiration date has passed.



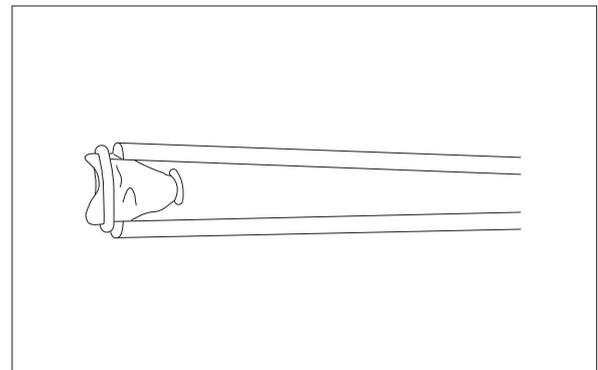
- (3) Hold handle 1 of the balloon installation tool and pinch the balloon at a position of 3 mm from the balloon ring (Big).



- (4) Turn over the balloon ring (Big) and hang it on the balloon installation tool.



- (5) Loosen your hand holding onto the balloon installation tool.



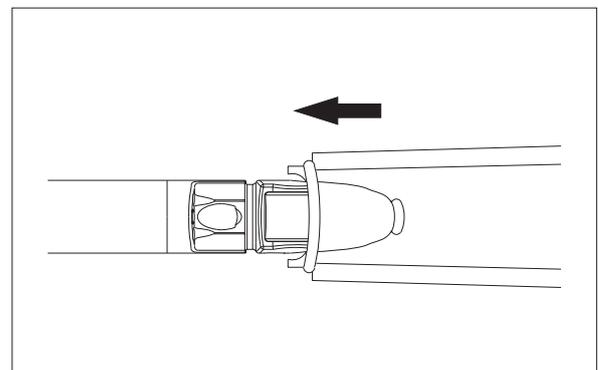
- (6) Hold handle 2 to widen the balloon ring and fit the balloon over the distal end of the Ultrasonic Endoscope.

[Note]

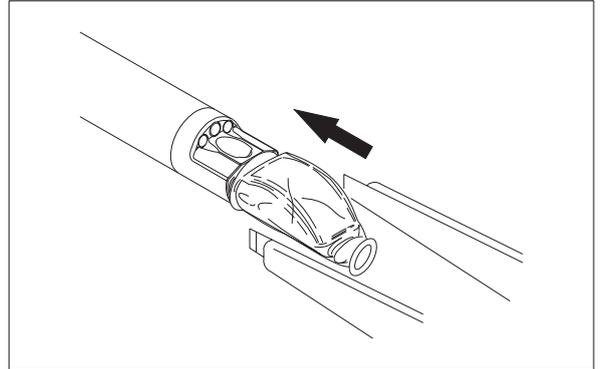
Saturating the balloon and the distal end of the Ultrasonic Endoscope with sterile water beforehand facilitates the attachment.

[Note]

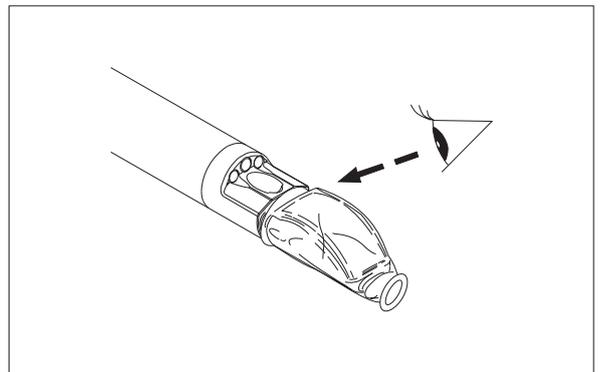
Use the balloon installation tool in the direction shown in the figure while attaching the balloon so that the installation tool does not pinch the transducer.



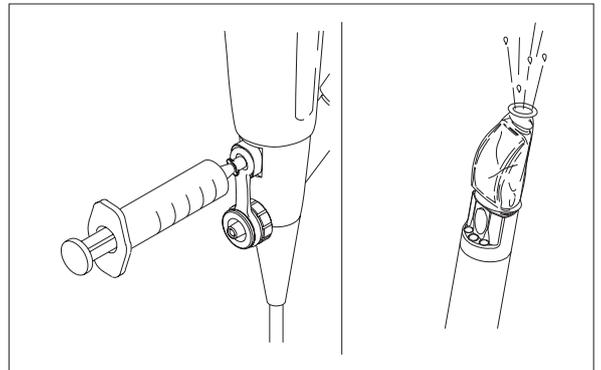
- (7) Remove the balloon ring (Big) slowly with your fingers and attach it into the balloon installation groove of the Ultrasonic Endoscope.



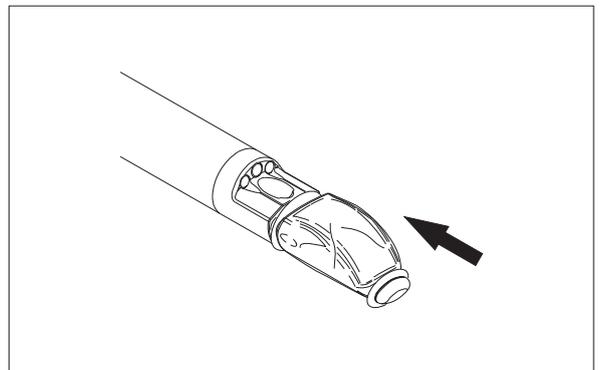
- (8) Check that the balloon ring (Big) is attached into the balloon installation groove.



- (9) Feed water to the balloon from the balloon water feed channel to discharge air from the balloon.
If air is not easily discharged from the balloon, press the balloon with your fingers while feeding water to discharge air completely.

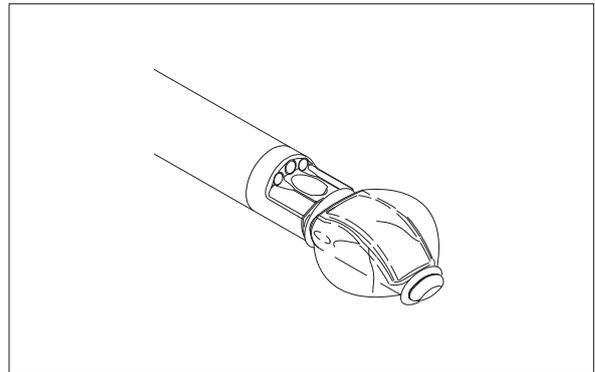


- (10) Attach the balloon ring (Small) into the balloon installation groove at the distal end of the Ultrasonic Endoscope by pushing back the ring with your fingers.

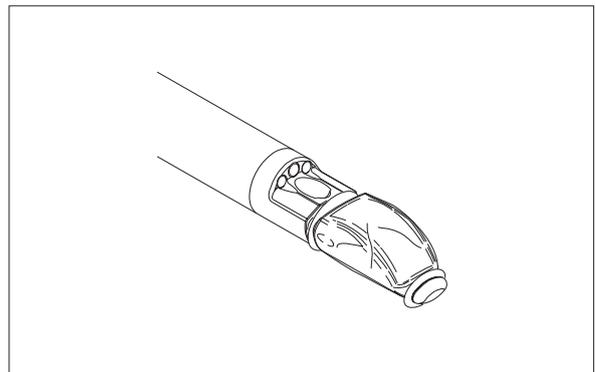


- (11) Feed 1 mL of sterile water into the balloon water feed channel, and check that the balloon is inflated.

Also, check that there is no leakage of sterile water, air entering into the balloon, or distortion of the balloon.



- (12) Suck out the sterile water and check that the balloon shrinks.



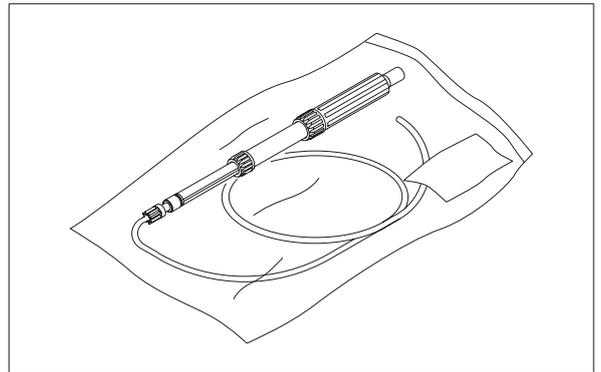
5.8 Inspection of Puncture Needle

⚠ WARNING

Do not use the puncture needle with an abnormally bent or deformed needle.

There is a risk of bleeding or wrong puncturing.

- (1) Check to confirm the expiry date of the puncture needle.
Do not use any expired puncture needle.
- (2) Inspect in accordance with the operation manual for the puncture needle.



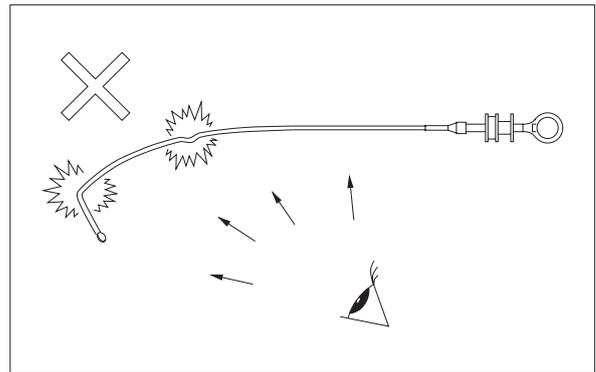
5.9 Inspection of Forceps

CAUTION

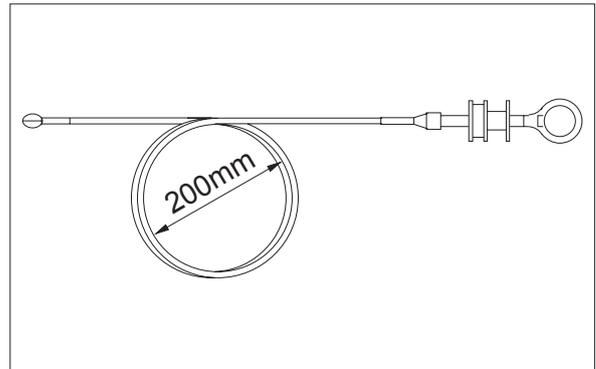
Do not bend forceps with a curvature radius of 10 mm or less.
Bending forceps with a small curvature may break it.

- (1) Inspect the operation of the forceps.

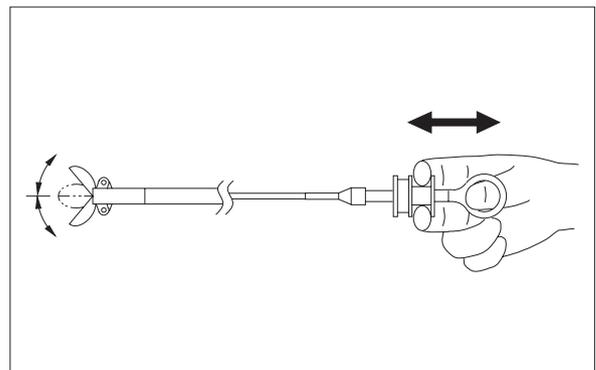
Visually check the forceps for breakage or significant bends, and for sharp edges on protrusions that may injure the patient.



- (2) Form the spring of the forceps into a ring approximately 200 mm in diameter.



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



Chapter 6 Method of Use

This chapter outlines how to operate the equipment, according to the general procedures. Regarding clinical procedures, use proper clinical judgment.

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6.1.2	Pretreatment of Patient.....	6-2
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Chapter 6 Method of Use

⚠ CAUTION

Do not use force during insertion or withdrawal of the Ultrasonic Endoscope.

Slowly advance the instrument under direct visualization.

Since this product is a precision instrument, excessive force or impact on the insertion portion, flexible portion, or distal end may cause patient injury as well as damage to the instrument.

Do not advance or angulate the Ultrasonic Endoscope without obtaining a clear endoscopic view on the monitor.

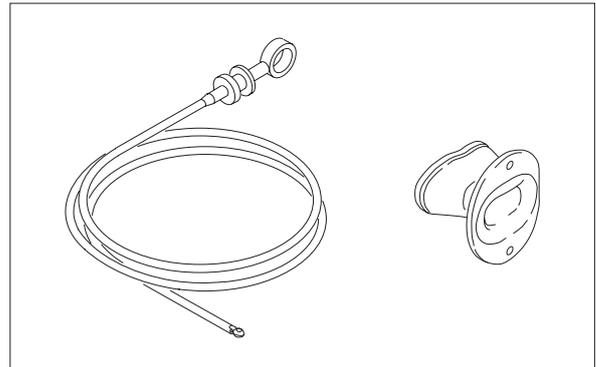
6.1 Preparation

6.1.1 Preparing Necessary Equipment

Prepare accessories and treatment equipment, etc. to be used.

[Note]

Prepare the appropriate accessories and treatment equipment (see the Appendix).



6.1.2 Pretreatment of Patient

Use pretreatment that suits the purpose of examination.

6.2 Insertion and Observation

 WARNING

When a balloon is not used, fit the cap on the balloon water feed inlet. There is a risk of infection.

Do not sharply twist or bend during operation. It may cause damage inside body cavities.

Before attempting to clinically use this Ultrasonic Endoscope with an endotracheal tube, select an appropriate size tube whose inner diameter has sufficient clearance between the endotracheal tube and the Ultrasonic Endoscope to avoid restriction of oxygen flow which may impair patient breathing.

The endotracheal tube should pass easily over the Ultrasonic Endoscope's insertion tube - never force an endotracheal tube onto the Ultrasonic Endoscope and never apply excessive pressure or force when attempting to pass or withdraw the Ultrasonic Endoscope.

 CAUTION

Do not insert the Ultrasonic Endoscope through the nose. There is a risk of bleeding.

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

Energy of illumination may burn.

Do not look directly at the illuminated light guide. It may damage your eyes.

In order to inject solution by using a syringe, firmly and deeply insert the syringe straight into the forceps valve.

Chemical solutions might splatter.

If the balloon or parts fall into a body cavity due to equipment failure or for other reasons, immediately stop the inspection and properly retrieve the parts in question.

It may cause damage inside body cavities.

Whenever using the Ultrasonic Endoscope with other peripheral devices including endotracheal tubes, etc. strictly adhere to all manufacturers' instructions, cautions and warnings.

Failure to follow the recommendations above can lead to Ultrasonic Endoscope damage and/or patient injury.

CAUTION

Do not directly apply Xylocaine spray to the insertion portion. Do not use olive oil as a lubricant for insertion.

It may cause deterioration of the outer surface.

When attempting to use the Ultrasonic Endoscope with an endotracheal tube, before applying lubricant ensure that the endotracheal tube slides smoothly over the Ultrasonic Endoscope without resistance.

Ensure that the Ultrasonic Endoscope's distal bending portion is straight - never angulate the Ultrasonic Endoscope while it is within the endotracheal tube.

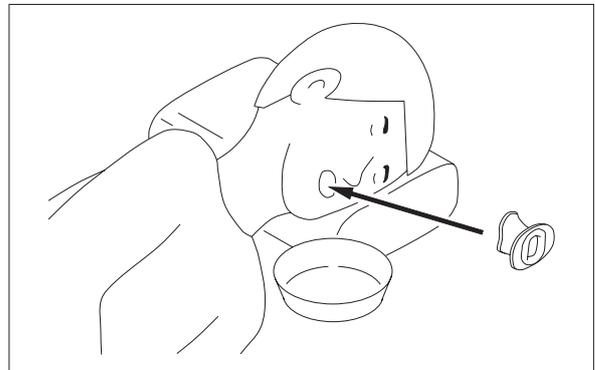
Do not use if either Ultrasonic Endoscope or endotracheal tube is damaged or compromised.

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

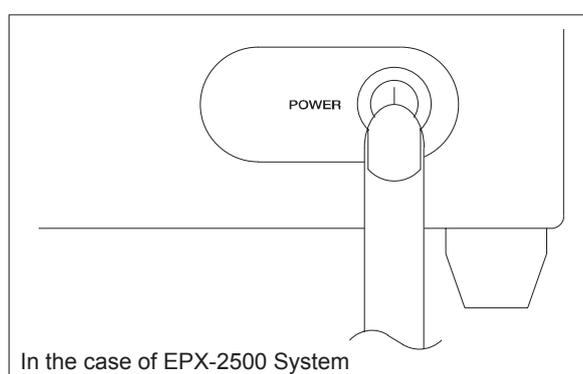
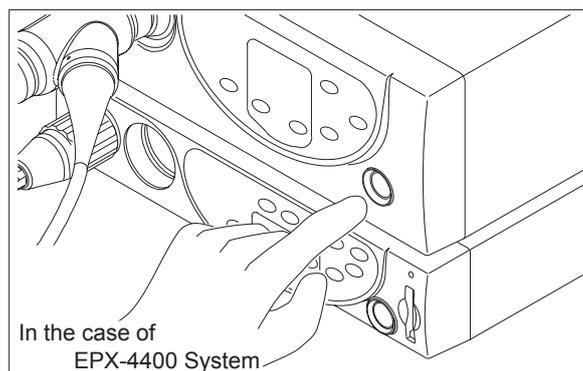
- (1) Have the patient hold the mouthpiece in his/her mouth.

[Note]

When you use the endotracheal tube insert the endotracheal tube to the patient in advance.



- (2) Turn on the power to the processor and light source, and light on the lamp by pressing lamp ON/OFF button.



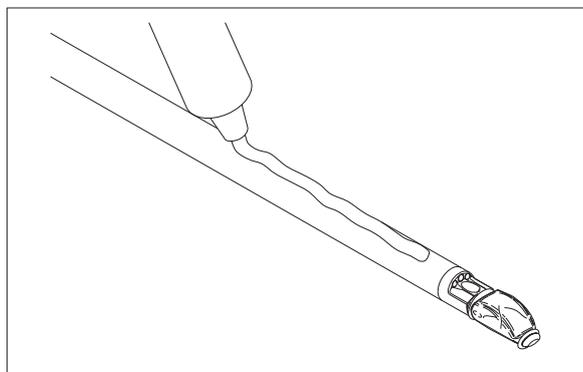
- (3) Apply clean lubricant (Xylocaine jelly or the like) to the insertion portion as required.

[Note]

Before using a balloon, always apply Xylocaine jelly to the balloon.

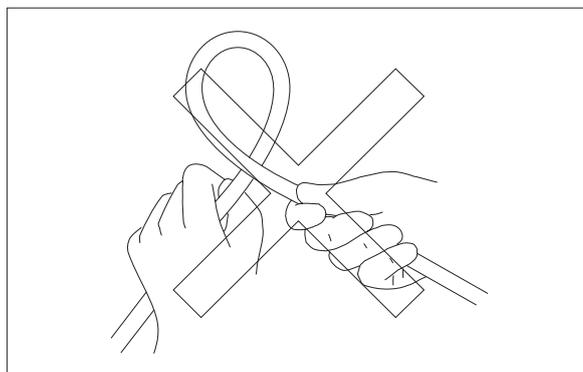
[Note]

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



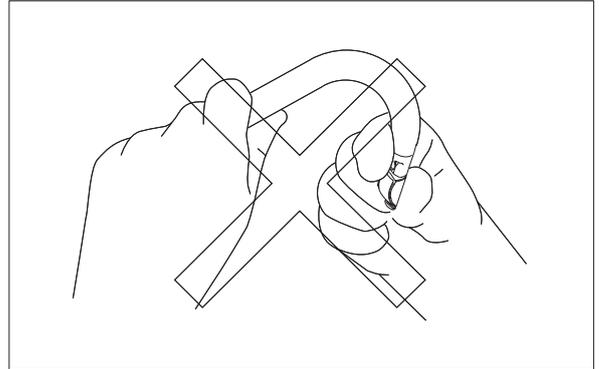
[Note]

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



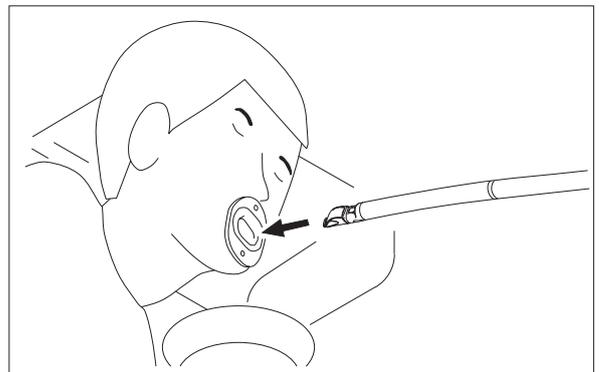
[Note]

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



- (4) Insert the distal end of the Ultrasonic Endoscope from the oral cavity to the pharynx, while observing the process.

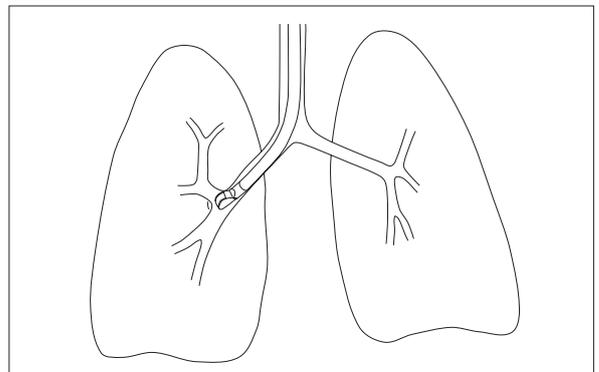
Adjust the brightness by operating the brightness control button on the light source unit.



- (5) Turn the angle lever to direct the distal end of the Ultrasonic Endoscope to the area to be observed.

[Note]

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



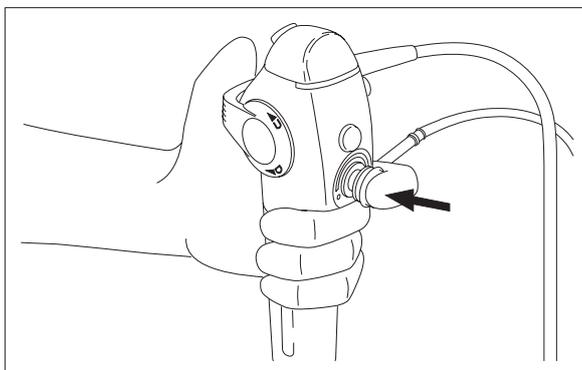
<To suck phlegm, mucus, blood, etc.>

Bring the distal end of the Ultrasonic Endoscope close to the objects to be sucked, and suck them by pressing the suction button.

[Note]

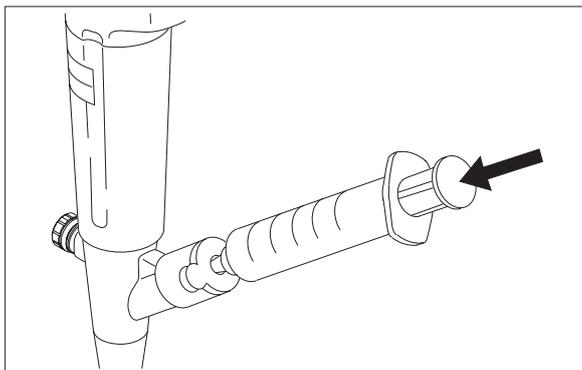
Do not suck in solid or viscous materials with the Ultrasonic Endoscope.

Such material may clog the suction pipe line or stick to the suction button preventing proper stopping of suction.



<To perform spray anesthesia>

Perform the spray anesthesia from forceps inlet to prevent coughing reaction.



6.3 How to Use Balloon

!WARNING

Do not use a balloon on patients allergic to latex.
It may cause an anaphylactic reaction.

Do not feed more than 1 mL of water into the balloon.
There is a risk of suffocation.

[Note] If the balloon is inflated while it is in patient's air passage, the air flow may become blocked.

Before using the balloon, thoroughly check the balloon position in the air passage and the water flow rate to the balloon.

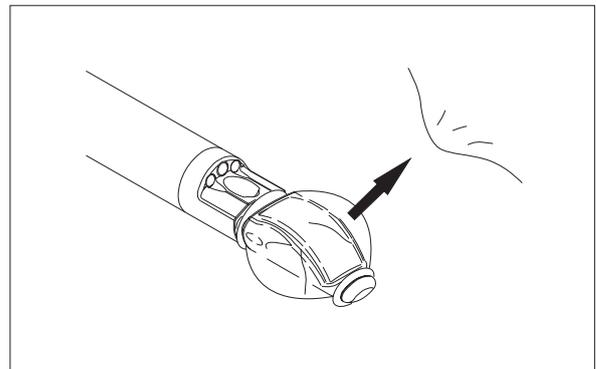
!CAUTION

Do not feed more than 1 mL of water into the balloon.
There is a risk of aspiration.

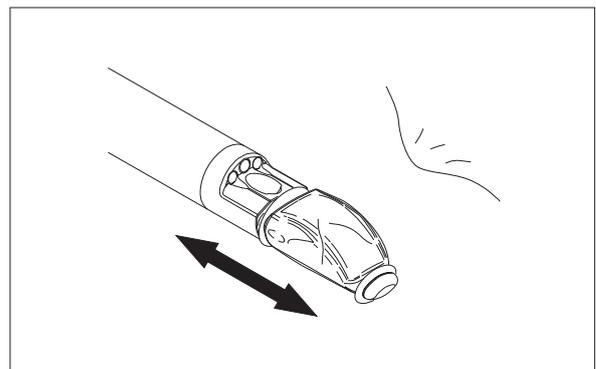
[Note] If more than 1 mL of water is fed into the balloon, water may leak from the balloon.

- (1) Operate the angle lever to bring the transducer close to the area to be observed with the Ultrasonic Endoscope.

To perform ultrasonic observation, feed sterile water to the balloon using the syringe until the balloon is inflated.



- (2) To move or pull out the Ultrasonic Endoscope, deflate the balloon beforehand.



6.4 Biopsy

⚠ WARNING

Do not press forceps against the trachea or broncho wall with undue force.

It may cause perforation or bleeding.

Do not insert the forceps if you cannot obtain a endoscopic image. Do not insert the forceps into the Ultrasonic Endoscope if you cannot see the forceps outlet on the endoscopic image.

It may cause perforation or bleeding.

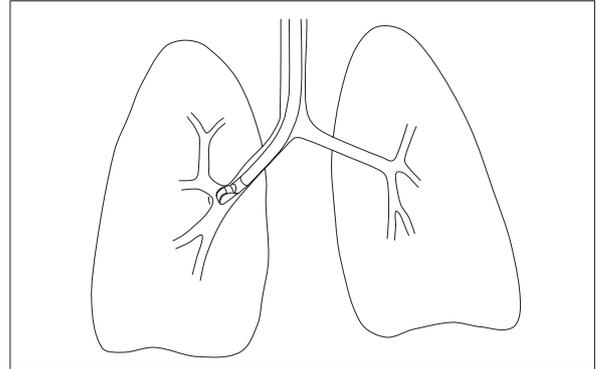
CAUTION

Do not push the forceps forcefully, when having in difficulty in insertion.

It may damage Ultrasonic Endoscope.

[Note] Sometimes the forceps become stuck in the bending portion and will not pass smoothly. In such case, unbend the bending portion a little and try to insert again.

- (1) Direct the distal end of the Ultrasonic Endoscope to the biopsy site.



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

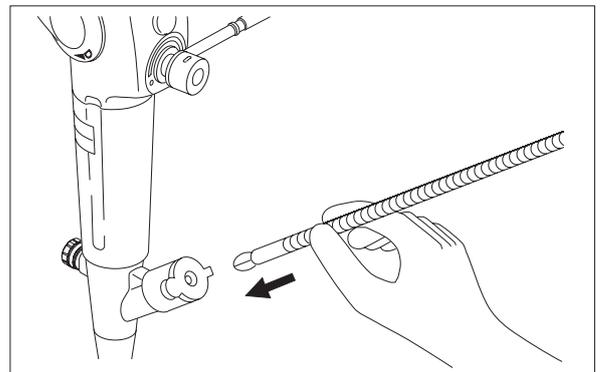
Insert the forceps from the forceps inlet by observing the image.

[Note]

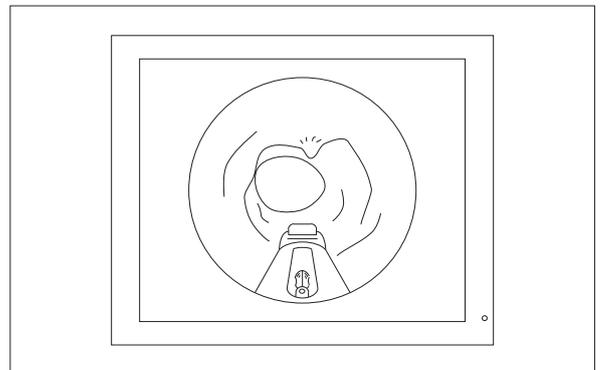
When inserting forceps, be sure to slowly insert it straight into the slit of the forceps valve.

[Note]

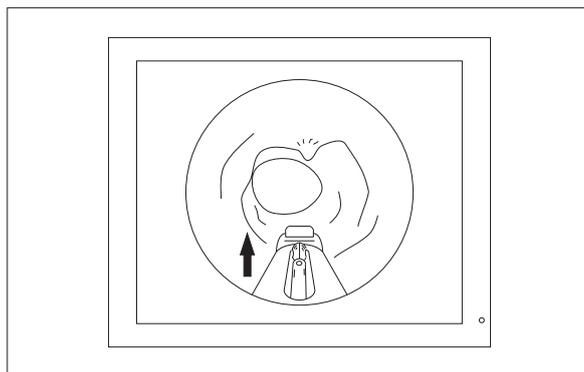
Keep the lid of the forceps valve closed.



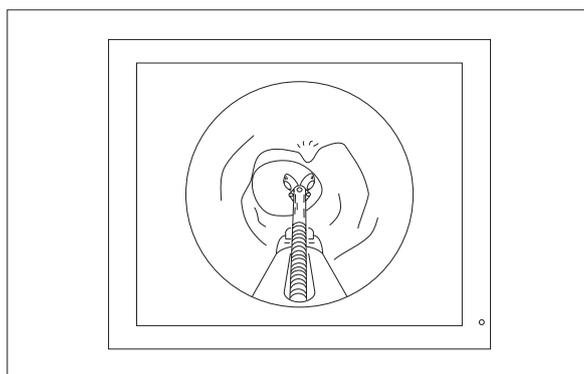
- (3) When the distal end of the forceps come into the field of view, stop insertion temporarily.



- (4) Bring the forceps closer to the biopsy site slowly.



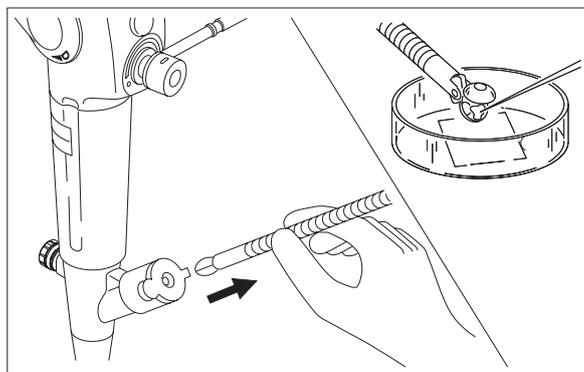
- (5) Take a biopsy specimen by manipulating the angle lever and letting the forceps in and out.



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

[Note]

When pulling out the forceps, be sure to slowly pull it straight out from the slit of the forceps valve.



6.5 Puncture

WARNING

Wear protective gear.
There is a risk of infection.

Do not insert the puncture needle into the Ultrasonic Endoscope if you cannot see the forceps outlet on the endoscopic image. Do not perform puncture if you cannot see the puncture needle on the endoscopic image. Operate the puncture needle while checking the endoscopic and ultrasonic images. Do not insert the puncture needle into the forceps inlet while the bending portion of the Ultrasonic Endoscope is bent. Do not insert a bent puncture needle into the forceps inlet. Stop puncturing immediately if you cannot obtain an endoscopic or ultrasonic image.

It may cause perforation or bleeding.

CAUTION

Pushing the puncture needle forcefully may damage the Ultrasonic Endoscope. Do not insert the needle with the sheath of the puncture needle not protruding from the forceps outlet at the distal end. Do not insert the puncture needle into the Ultrasonic Endoscope with the needle protruding from the sheath.

There is a risk of damaging the Ultrasonic Endoscope.

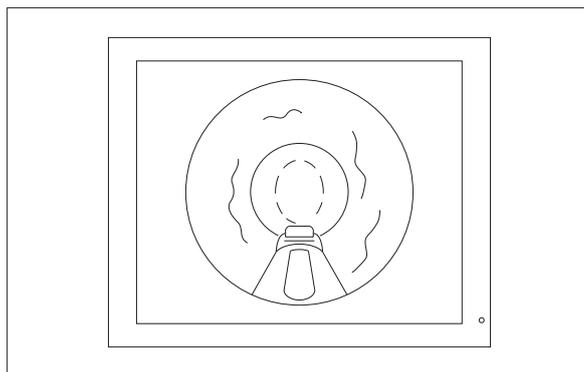
[Note] If the puncture needle is out of the ultrasonography area, it is not displayed on the ultrasonic image.

[Note] The puncture needle is bent when it is inserted into the Ultrasonic Endoscope.
The bent puncture needle may not be within the ultrasonography area.
Operate the puncture needle while taking into account the degree of bending.

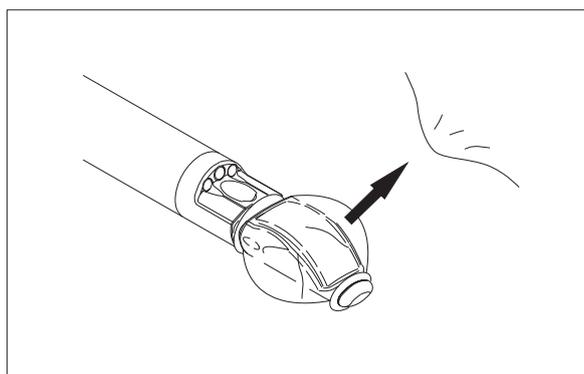
[Note] The puncture needle remains bent if it is inserted or pulled out while the bending portion of the Ultrasonic Endoscope is still bent. Straighten the bending portion of the Ultrasonic Endoscope when inserting or pulling out the puncture needle.

[Note] Use the puncture needle according to its operation manual.

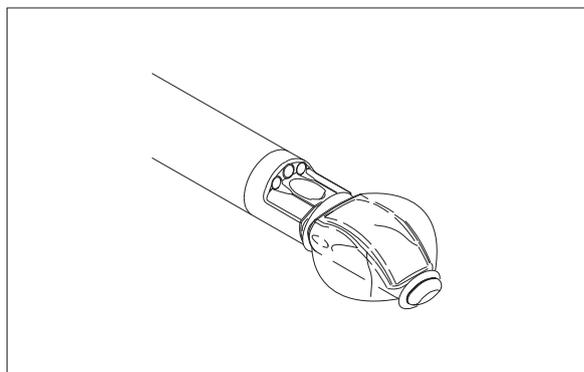
- (1) Check to confirm the site to be punctured using the Ultrasonic Endoscope.



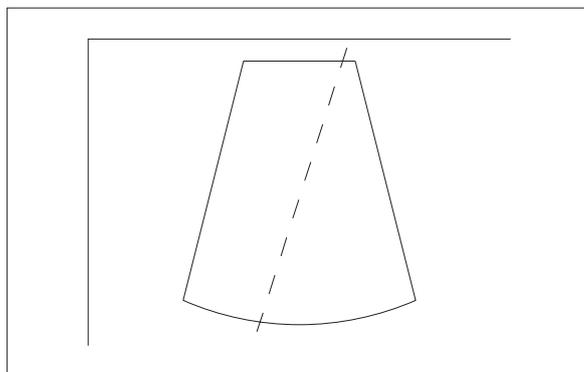
- (2) Contact the transducer at the distal end of Ultrasonic Endoscope near the puncturing point.



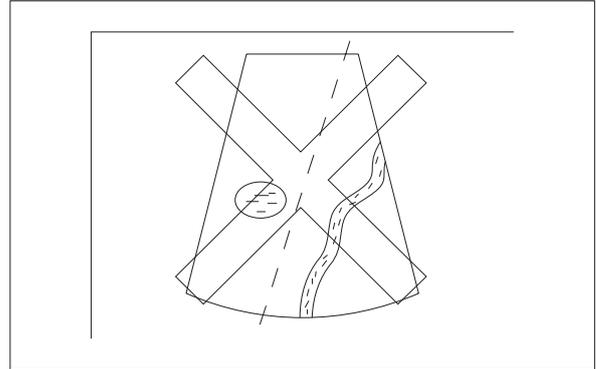
- (3) If a balloon is used, contract it until it is small but not touching the puncture needle, by observing the endoscope image.



- (4) Observe the target lesion with the ultrasonic image.

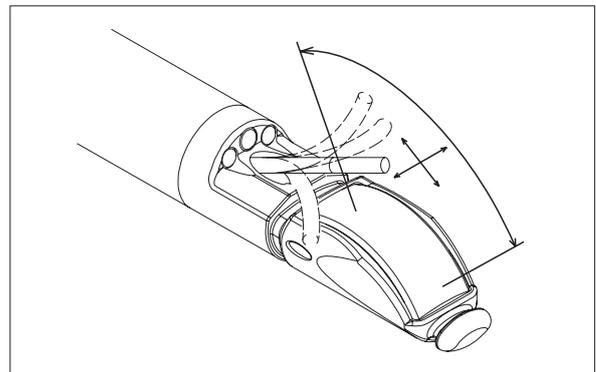


- (5) Determine the puncturing point by confirming that there are no nearby blood vessels on the ultrasonic image.

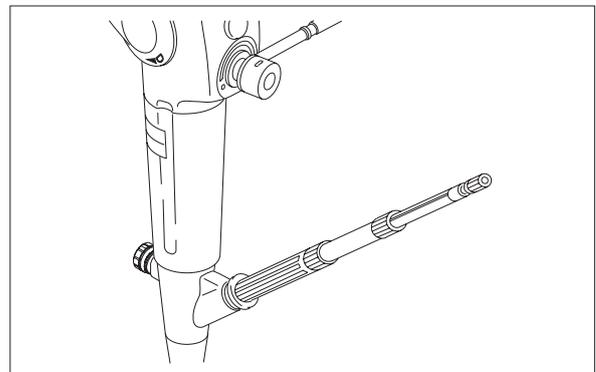


[Note]

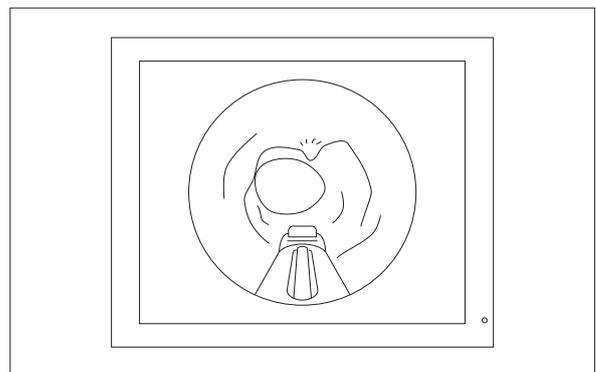
The puncture needle may be mistakenly inserted outside of the ultrasonography area or the puncture guiding line. For puncturing, confirm that there are no blood vessels nearby.



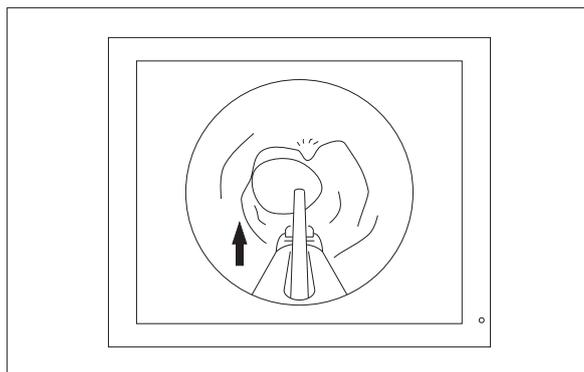
- (6) Unbend the bending portion until it is almost straight by operating the angle lever.
- (7) Insert the puncture needle into the Ultrasonic Endoscope. Attach the holding end of the puncture needle to the forceps inlet firmly.



- (8) When the distal end of the puncture needle come into the field of view, stop insertion temporarily.



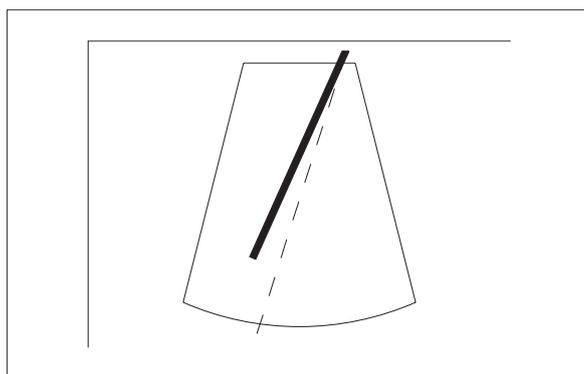
- (9) Bring the puncture needle close to the target part slowly.



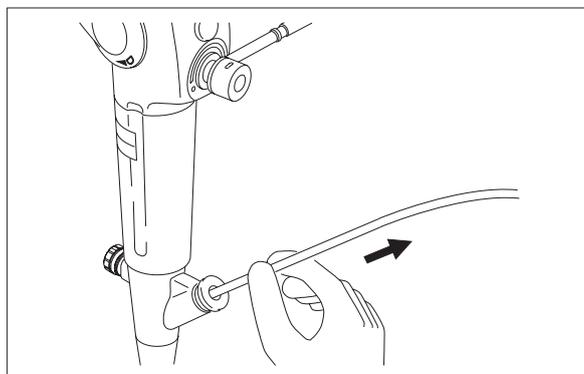
- (10) Carry out puncturing.

[Note]

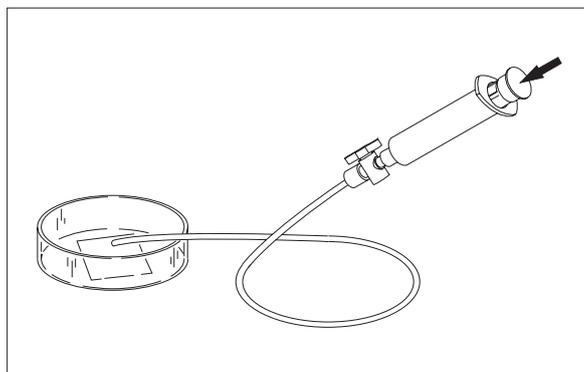
The puncture guiding line is only meant as a guide. Check the actual part to be punctured on the ultrasonic image.



- (11) After completing the puncture, store the needle in the sheath and pull out the puncture needle.

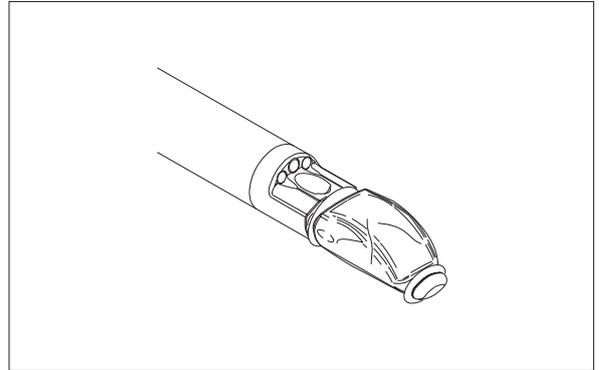


- (12) Eject the biopsy specimen using the syringe or wire.

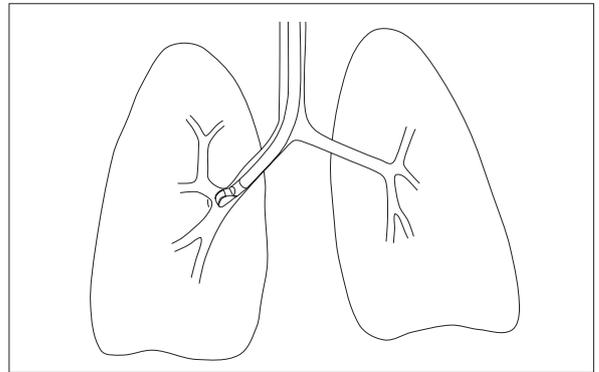


6.6 Pulling Out Ultrasonic Endoscope

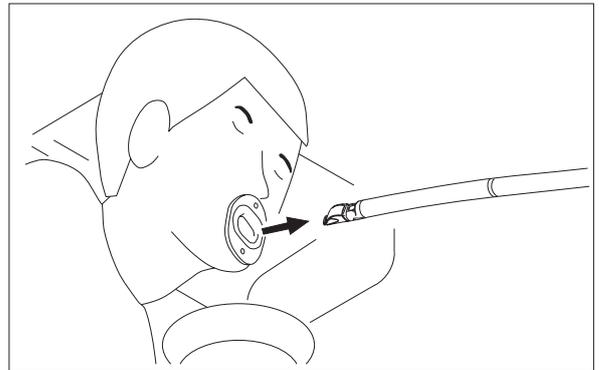
- (1) If a balloon is used, contract it fully.



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



- (3) Pull the Ultrasonic Endoscope out slowly.

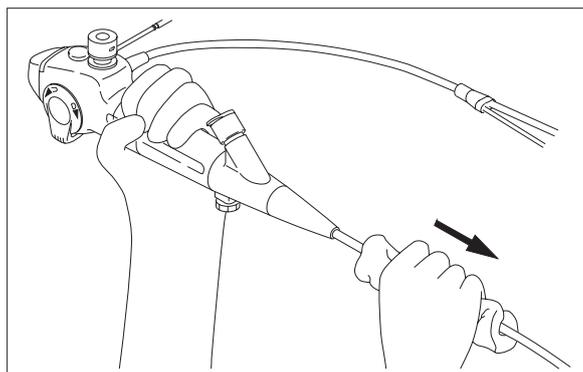


6.7 Pre-Cleaning (performed at bedside immediately after use of Ultrasonic Endoscope)

The pre-cleaning (the first cleaning) is performed at the bedside immediately after the use of the ultrasonic endoscope.

6.7.1 Wiping

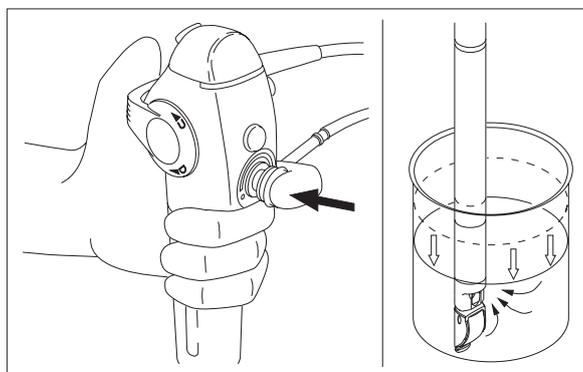
Wipe contamination off the outside of insertion portion of Ultrasonic Endoscope with gauze or paper towel.



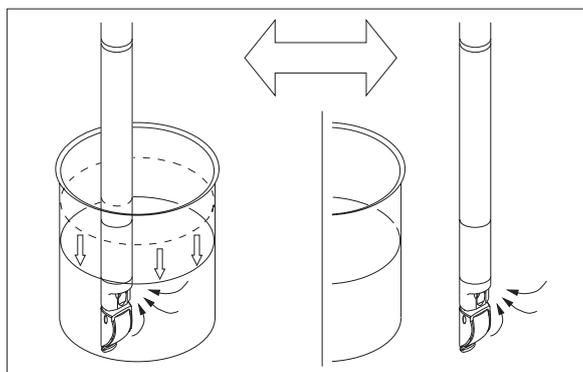
6.7.2 Cleaning Suction Channel

You are going to clean suction channel.

- (1) Put distal end of Ultrasonic Endoscope in cleaning fluid, and depress suction button to suck in cleaning fluid for 10 seconds.
- (2) Keeping suction button depressed, pull distal end of Ultrasonic Endoscope out of cleaning fluid and suck in air.



- (3) Repeat steps (1) and (2) above 2 or 3 times to suck in cleaning fluid and air alternately.
- (4) Finally, pull distal end of Ultrasonic Endoscope out of cleaning fluid and suck in air until cleaning fluid is completely drained from suction channel.



6.7.3 Removing Ultrasonic Endoscope from Processor

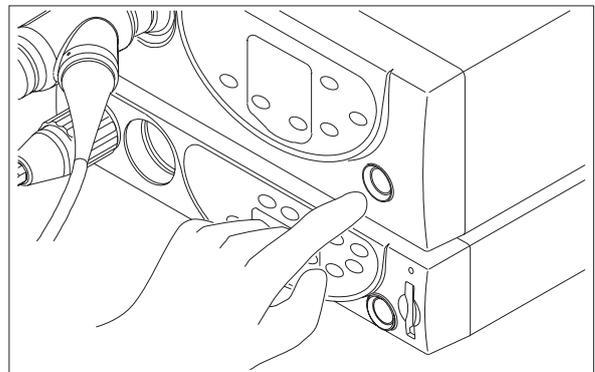
! CAUTION

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

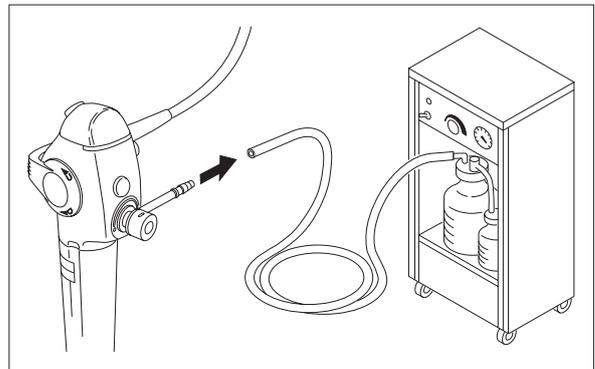
Touching the LG connector with hands immediately after use of the Endoscope may cause a burn injury.

<Combination with the VP-4400 and XL-4400 or VP-4450HD and XL-4450>

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

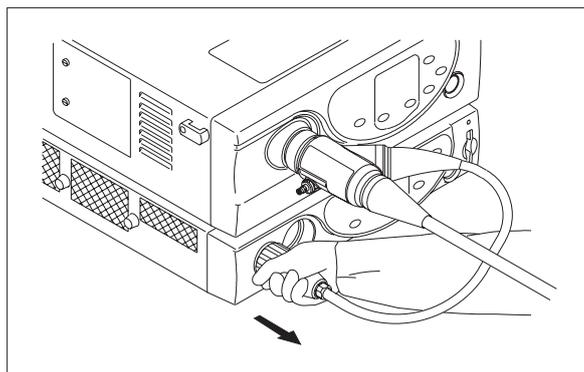


- (2) Remove the suction tube from the suction connector portion of the Ultrasonic Endoscope.



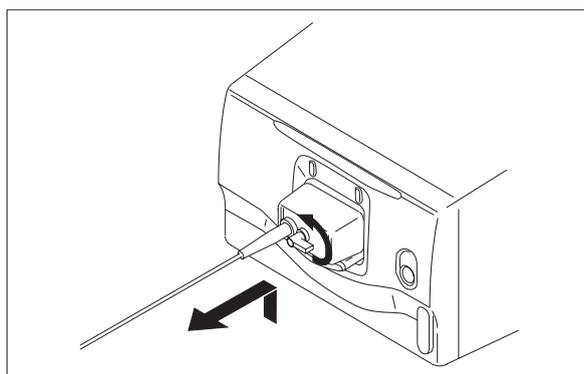
(3) Remove the EVE connector from the processor.

(4) Remove the LG connector from the light source.



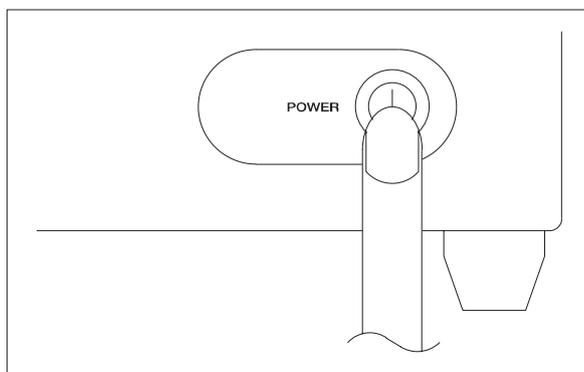
(5) Turn off the power supply of the diagnostic ultrasound system.

(6) Loosen the lock handle and dismount the US connector from the diagnostic ultrasound system.

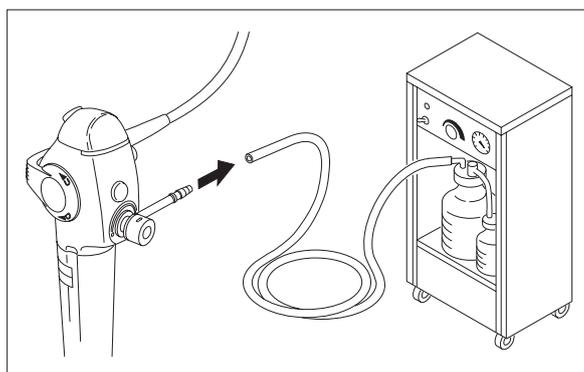


<Combination with the EPX-2500 system>

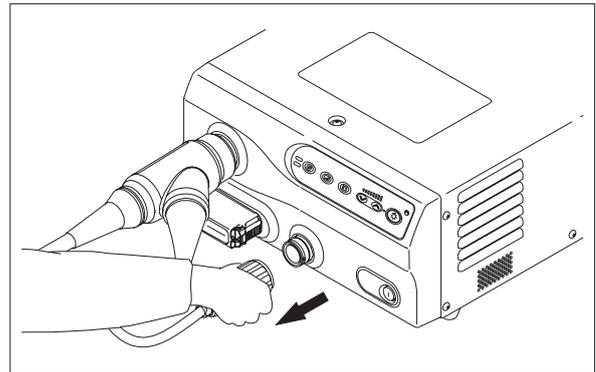
(1) Turn OFF the power switch of the processor.



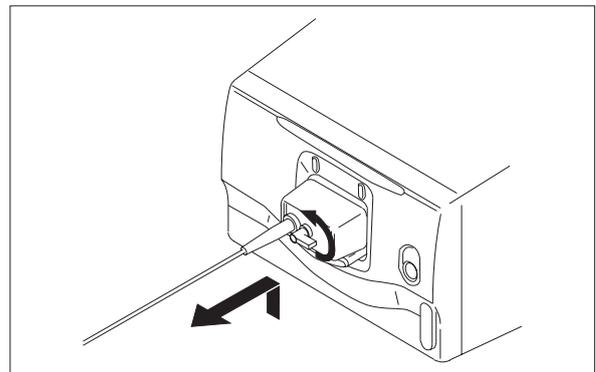
(2) Remove the suction tube from the suction connector portion of the Ultrasonic Endoscope.



- (3) Remove the EVE connector from the processor.
- (4) Remove the LG connector from the processor.



- (5) Turn off the power supply of the diagnostic ultrasound system.
- (6) Loosen the lock handle and dismount the US connector from the diagnostic ultrasound system.



6.7.4 Removing Balloon

- (1) Remove the balloon ring (Big) from the balloon installation 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.

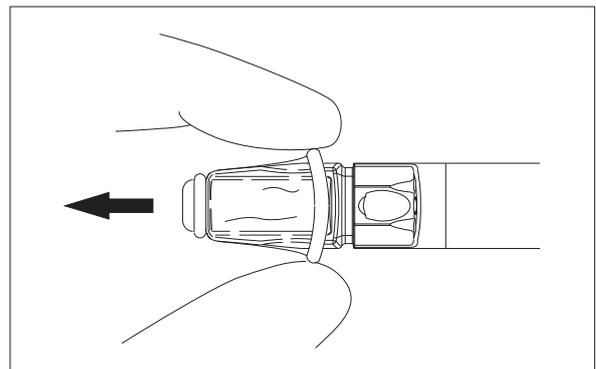
[Note]

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

Discard removed balloon.

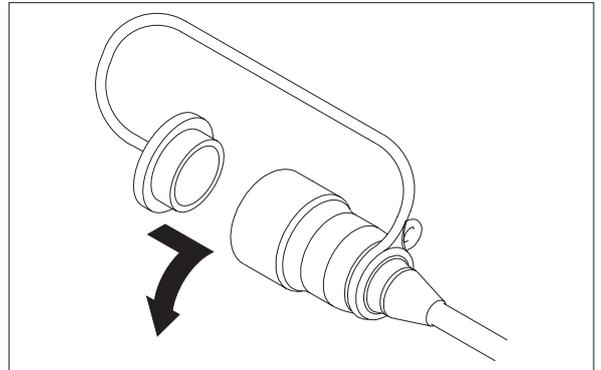
[Note]

Do not clean the Ultrasonic Endoscope with the balloon attached at the distal end.



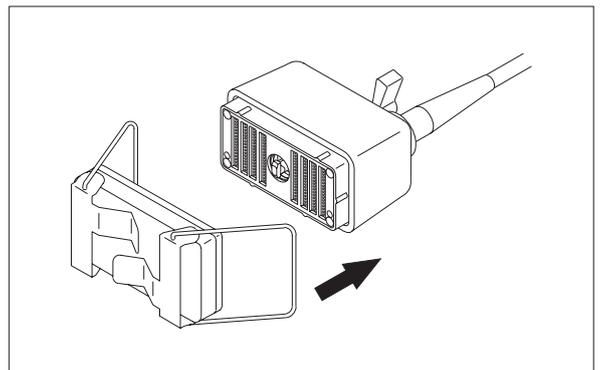
6.7.5 Waterproofing EVE Connector

If the EVE connector with water on the electrical contacts is used, it will cause a malfunction. Before cleaning, attach the waterproof cap to the EVE connector so that water do not reach the contacts.

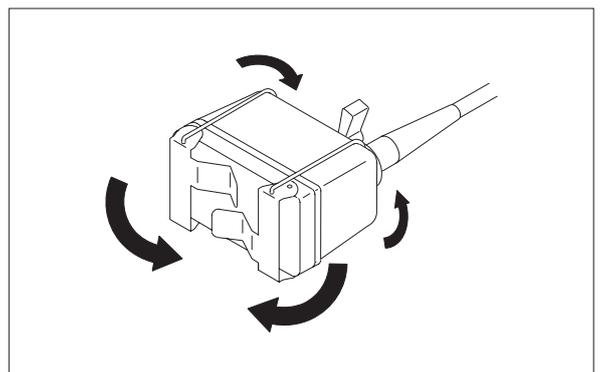


6.7.6 Waterproofing US Connector

- (1) Mount the US waterproof cap to the US connector.



- (2) Lock the US waterproof cap by laying the lever.



Appendix

Main Specification.....	Appendix-2
Troubleshooting (Combination with EPX-4400 system)	Appendix-8
Troubleshooting (Combination with EPX-2500 system)	Appendix-12
After-Sales Service.....	Appendix-16
Disposal of Electric and Electronic Equipment ...	Appendix-17
Index.....	Appendix-18
Service Centers.....	Appendix-19

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 water proof : IEC 60529 IPX7
(when the US waterproof cap is attached)

[Note] Use in combination with one of the following:

- Processor VP-4450HD, light source XL-4450 and ultrasonic processor SU-8000
- Processor VP-4400, light source XL-4400 and ultrasonic processor SU-8000
- Processor VP-4400, light source XL-4400 and ultrasonic processor SU-7000
- Processor EPX-2500 and ultrasonic processor SU-8000
- Processor EPX-2500 and ultrasonic processor SU-7000

<Applied Part>

Insertion portion

<Data about Main Unit>

Endoscopic functions	Viewing direction	10°	
	Observation range	3 to 100 mm	
	Field of view	120°	
	Distal end diameter	6.7 mm	
	Flexible portion diameter	6.3 mm	
	Bending capability	UP/DOWN	130° /90°
	Maximum diameter of insertion portion	7.3 mm	
	Minimum diameter of instrument channel	2.0 mm ^[Note]	
	Insertion route	Peroral	
	Working length	610 mm	
	Overall length	880 mm	
Ultrasonic functions	Scanning mode	Color Doppler, power Doppler, pulse wave, B mode and M mode	
	Scanning method	Convex	
	Scanning angle	60° (Combination with SU-7000) 65° (Combination with SU-8000)	
	Frequency	5 MHz/7.5 MHz/10 MHz/12 MHz	

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

<Operating Environment>

Temperature	+10 to +40°C
Relative humidity	30 to 85% ^[Note]
Atmospheric pressure	70 to 106 kPa

[Note] Except when there is condensation

<Storage Environment>

Temperature	+10 to +40°C
Relative humidity	30 to 85% ^[Note]
Atmospheric pressure	70 to 106 kPa

[Note] Except when there is condensation

<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 self-certification (data of our company)

<Applicable Processor and Light Source>

Ultrasonic processor	SU-8000 SU-7000
Processor	VP-4450HD ^[Note] VP-4400 Ver1.1993 Later EPX-2500
Light source	XL-4450 ^[Note] XL-4400

[Note] Only when used in combination with SU-8000

<Applicable Puncture Needles>

Use a suction puncture needle (single-use type) for bronchial Ultrasonic Endoscope whose applicable forceps inlet size is 2.0 mm in inner diameter and 700 mm or longer in working length.

<Accessory>

Name	Model
Biopsy forceps: Fenestrated	BF1812SF

<Consumable Supplies>

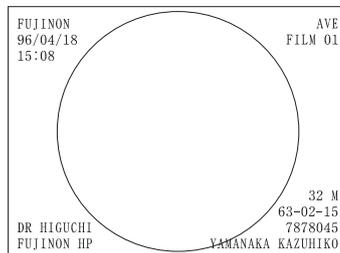
Name	Model
Cleaning brush	WB3212FW2 WB3503FW
Cleaning brush (for valve)	WB11002FW2
Forceps valve (single-use type)	FOV-BU1
Suction button (single-use type)	SB-500B/D SB-602

<Applicable Balloon>

Material	Latex
Entire length	12.3 mm ^[Note]
Inner diameter	5.9 mm ^[Note]
Balloon ring (small) inner diameter	1.1 mm ^[Note]
Balloon ring (big) inner diameter	2 mm ^[Note]
Maximum amount of water injection	1.0 mL
Usage	Single use
Sterilization	Sterilized

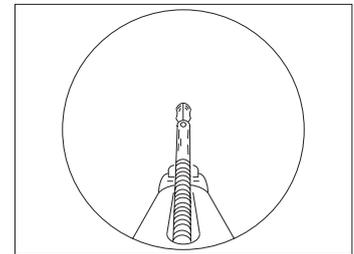
[Note] When no force is applied

<Image Size>



EB-530US

<Direction of Forceps>



EB-530US

<Medical Device Directive>

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



<Electromagnetic compatibility (EMC) information>

EB-530US is intended for use in the electromagnetic environments specified below.
The customer or the user of this product should assure that it is used in such an environment.

Electromagnetic emission compliance information and guidance

Emission standard	Compliance	Guidance
RF emissions CISPR 11	Group I	This product uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electric equipment.
Radiated emissions CISPR 11	Class A	This product is intended for use in medical facilities and commercial facilities. 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 the page 1-3 (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 one of the following:

- Processor VP-4450HD, light source XL-4450 and ultrasonic processor SU-8000
- Processor VP-4400, light source XL-4400 and ultrasonic processor SU-8000
- Processor VP-4400, light source XL-4400 and ultrasonic processor SU-7000
- Processor EPX-2500 and ultrasonic processor SU-8000
- Processor EPX-2500 and ultrasonic processor SU-7000

Electromagnetic immunity compliance information and guidance

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

Electromagnetic immunity compliance information and guidance

Immunity test	EN 60601-1-2 Test level	Compliance level	Guidance
<p>Conducted RF EN 61000-4-6</p> <p>Radiated RF EN 61000-4-3</p>	<p>3Vrms 150kHz to 80MHz</p> <p>3V/m 80MHz to 2.5GHz</p>	<p>3V[V₁]</p> <p>3V/m[E₁]</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \frac{3.5}{V_1} \sqrt{P}$ $d = \frac{3.5}{E_1} \sqrt{P} \quad 80 \text{ to } 800\text{MHz}$ $d = \frac{7}{E_1} \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <p>Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m).</p> <p>This product complies with the requirements of EN 60601-1-2: 2007.</p> <p>However electromagnetic interference may occur on this product under electromagnetic environment that exceeds its noise level.</p> <p>Electromagnetic interference may occur in the vicinity of equipment marked with the following symbol.</p> 

Electromagnetic immunity compliance information and guidance

<p>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.</p>			
Rated maximum output power of transmitter P (W)	Separation distance related to frequency of the transmitter (m)		
	150kHz to 80MHz d=1.2√P	80 to 800MHz d=1.2√P	800MHz to 2.5GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Troubleshooting (Combination with EPX-4400 system)

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

Problem	Cause	Remedy
No images come out	<ol style="list-style-type: none"> 1) The cart, monitor or processor is unplugged from the main outlet. 2) The cart, monitor or processor is off. 	<p>Plug the cart, monitor or processor into the main outlet.</p> <p>Power on the cart, monitor or processor.</p>
The image appears dark	<ol style="list-style-type: none"> 1) The connection with the scope and light source is incomplete. 2) The light intensity level is set around MIN. 3) The metering mode is set at PEAK. 4) Blood and/or mucous membranes adhere to the light guide. 	<p>Redo the scope connection.</p> <p>→ 5.4 “Connecting the Ultrasonic Endoscope”</p> <p>Set the light intensity level around 0.</p> <p>→ VP-4400, VP-4450HD</p> <p>5.6 “Adjusting the Brightness”</p> <p>Set the metering mode at AVE.</p> <p>→ VP-4400 5.7 “Switching the Iris Modes”</p> <p>→ VP-4450HD</p> <p>“5.12 Switching the Metering Mode”</p> <p>Remove the Ultrasonic Endoscope from the patient, and then wipe off any adhered blood and/or mucous membranes for reuse.</p>
The highlight portion of an image is too bright.	<ol style="list-style-type: none"> 1) The light intensity level is set around MAX. 2) The metering mode is set at AVE. 	<p>Set the light intensity level around 0.</p> <p>→ VP-4400, VP-4450HD</p> <p>5.6 “Adjusting the Brightness”</p> <p>Set the metering mode at PEAK.</p> <p>→ VP-4400 5.7 “Switching the Iris Modes”</p> <p>→ VP-4450HD</p> <p>“5.12 Switching the Metering Mode”</p>
An image disappears during examination.	<ol style="list-style-type: none"> 1) The connection with the scope, processor and light source is incomplete. 2) The system has malfunctioned due to such as static charges. 3) The video signal cable has burnt out or shorting. 	<p>Redo the scope connection.</p> <p>→ 5.4 “Connecting the Ultrasonic Endoscope”</p> <p>Reset ^[Note] the processor and the light source.</p> <p>If the image is still not displayed, turn the processor and the light source off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly. Submit the Ultrasonic Endoscope to expert repairs.</p>
A live image is not displayed after image freezing is cancelled during examination.	The system has malfunctioned due to such as static charges.	<p>Reset ^[Note] the processor and the light source.</p> <p>If the image is still not displayed, turn the processor and the light source off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly.</p>

[Note] Reset:

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

Problem	Cause	Remedy
An image is suddenly discolored during examination.	<ol style="list-style-type: none"> 1) The system has malfunctioned due to such as static charges. 2) The video signal cable has burnt out or shorting. 	<p>Reset ^[Note] the processor and the light source.</p> <p>If the image is not recovered and it is impossible to continue the examination, turn the processor and the light source off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly.</p>
Images appear garbled	<ol style="list-style-type: none"> 1) Not connected correctly 2) The video signal cable has burnt out or shorting. 	<p>Connect properly.</p> <p>Reset ^[Note] the processor and the light source.</p> <p>If the image is not recovered and it is impossible to continue the examination, turn the processor and the light source off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly.</p>
Suction is disabled	<ol style="list-style-type: none"> 1) The suction unit is switched off. 2) The suction unit is not connected. 3) No forceps valve is attached. 4) The suction button has been damaged. 	<p>Switch on the suction unit.</p> <p>Connect the suction unit.</p> <p>Attach a forceps valve.</p> <p>Replace with a new suction button.</p>
Low suction volume	<ol style="list-style-type: none"> 1) The suction button has been damaged. 2) The forceps valve has been degraded. 3) The suction tube is not attached properly. 4) The forceps valve is not attached properly. 	<p>Replace with a new suction button.</p> <p>Replace with a new forceps valve.</p> <p>Reattach the suction tube.</p> <p>Reattach the forceps valve.</p>
The suction button won't reset	<ol style="list-style-type: none"> 1) Foreign matter or blood adhering to the button is coagulated. 2) The suction button is damaged. 	<p>Disconnect the suction tube. After diagnosis, remove the button and clean or replace it.</p> <p>Replace with a new suction button.</p>
Treatment equipment cannot be inserted	<ol style="list-style-type: none"> 1) The treatment equipment is left open (such as biopsy forceps). 2) The handle of the treatment equipment is held firmly (such as biopsy forceps). 3) The treatment equipment has difficulty being inserted due to bending. 4) Nonapplicable treatment equipment is used. 	<p>Close the treatment equipment for insertion.</p> <p>Loosen the grip to insert the treatment equipment.</p> <p>Return the bending portion slightly and then insert it.</p> <p>Use applicable treatment equipment.</p>

[Note] Reset:

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

Problem	Cause	Remedy
Treatment equipment cannot be pulled out.	<ol style="list-style-type: none"> 1) The treatment equipment is left open (such as biopsy forceps). 2) The handle of the treatment equipment is held firmly (such as biopsy forceps). 3) The treatment equipment has difficulty being inserted due to bending. 4) An abnormality occurs in the treatment equipment. 5) Nonapplicable treatment equipment is used. 	<p>Close the treatment equipment and pull it out.</p> <p>Loosen the grip and pull out the treatment equipment.</p> <p>Return the bending portion slightly and then pull out the treatment equipment.</p> <p>Return the end of the treatment equipment to the forceps outlet of the Endoscope, and then slowly pull out the Endoscope and treatment equipment together.</p> <p>Return the end of the treatment equipment to the forceps outlet of the Endoscope, and then slowly pull out the Endoscope and treatment equipment together.</p> <p>[Note] Use applicable treatment equipment.</p>
Treatment equipment cannot be closed. (e.g. biopsy forceps)	An abnormality occurs in the treatment equipment.	If it is difficult to close the treatment equipment, 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 treatment equipment to the forceps outlet of the Ultrasonic Endoscope, and then slowly pull out the Ultrasonic Endoscope and treatment equipment together.
Treatment equipment cannot be retracted into the sheath. (e.g. puncture needle)	An abnormality occurs in the treatment equipment.	<p>Pull back the end of the treatment equipment until it no longer protrudes from the end of the forceps outlet. In this state, straighten the bending portion of the Ultrasonic Endoscope, and then draw in the needle again to pull out the treatment equipment.</p> <p>The Ultrasonic Endoscope might be causing an air leak. Immediately perform primary pre-cleaning and airtightness inspection to check for any abnormality.</p>
Images cannot be captured in the image recorder	<ol style="list-style-type: none"> 1) The image recorder is not connected. 2) Not connected correctly. 	<p>Connect the image recorder.</p> <p>Reconnect the image recorder to ensure correct connection.</p>
The bending portion won't reset	The bending control mechanism is malfunctioning.	Discontinue use immediately, and contact your dealer or the nearest service center without forcing the bending portion out of position. Forcing the bending portion out of position could result in body cavity damage.

Problem	Cause	Remedy
Sterile water cannot be fed from the balloon water outlet	Foreign matter has adhered to the balloon water feed channel or balloon water outlet.	Remove foreign matter.
No ultrasonic image is displayed.	<ol style="list-style-type: none"> 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 trachea and bronchi). 4) The ultrasonic processor is malfunctioning. 	<p>Plug in the devices.</p> <p>Turn the power switches ON.</p> <p>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 trachea and bronchi.</p> <p>If an ultrasonic image disappears during examination, 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 endoscope slowly.</p>
The ultrasonic image is dark	<ol style="list-style-type: none"> 1) The gain level is close to the minimum value. 2) The STC level is close to the minimum value. 	<p>Rotate the gain knob clockwise to adjust the brightness of the ultrasonic image.</p> <p>Press the STC key to set the STC level closer to the center value.</p>
The highlight portion in the ultrasonic image is too bright.	<ol style="list-style-type: none"> 1) The gain level is close to the maximum value. 2) The STC level is close to the maximum value. 	<p>Rotate the gain knob counterclockwise to adjust the brightness of the highlighted area.</p> <p>Press the STC key to set the STC level closer to the center value.</p>
The image disappears during ultrasonic diagnosis.	The ultrasonic connector is poorly connected.	<p>Redo the scope connection.</p> <p>→ 5.4 “Connecting the Ultrasonic Endoscope”</p>
The ultrasonic image receives interference.	The ultrasonic connector is poorly connected.	<p>Redo the scope connection.</p> <p>→ 5.4 “Connecting the Ultrasonic Endoscope”</p>

Troubleshooting (Combination with EPX-2500 system)

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

Problem	Cause	Remedy
No images come out	1) The cart, monitor or processor is unplugged from the main outlet. 2) The cart, monitor or processor is off.	Plug the cart, monitor or processor into the main outlet. Power on the cart, monitor or processor.
The image appears dark	1) The connection with the scope and processor is incomplete. 2) The level of brightness is close to the minimum (one LED on). 3) The metering mode is set at PEAK. 4) Blood and/or mucous membranes adhere to the light guide.	Redo the scope connection. → 5.4 “Connecting the Ultrasonic Endoscope” Set the brightness level to near the center of the indicator. → EPX-2500 5.6 “Adjusting the Brightness” Set the metering mode at AVE. → DK-2500 8.4 “Switch” Remove the Ultrasonic Endoscope from the patient, and then wipe off any adhered blood and/or mucous membranes for reuse.
The highlight portion of an image is too bright.	1) The metering mode is set at AVE. 2) The light intensity level is set around MAX.	Set the metering mode at PEAK. → DK-2500 8.4 “Switch” Set the brightness level to near the center of the indicator. → EPX-2500 5.6 “Adjusting the Brightness”
An image disappears during examination.	1) The connection with the scope and processor is incomplete. 2) The system has malfunctioned due to such as static charges. 3) The video signal cable has burnt out or shorting.	Redo the scope connection. → 5.4 “Connecting the Ultrasonic Endoscope” Reset ^[Note] the processor. If the image is still not displayed, turn the processor off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly. Submit the Ultrasonic Endoscope to expert repairs.
A live image is not displayed after image freezing is cancelled during examination.	The system has malfunctioned due to such as static charges.	Reset ^[Note] the processor. If the image is still not displayed, turn the processor off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly.

[Note] Reset:

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

Problem	Cause	Remedy
An image is suddenly discolored during examination.	<ol style="list-style-type: none"> 1) The system has malfunctioned due to such as static charges. 2) The video signal cable has burnt out or shorting. 	Reset ^[Note] the processor. If the image is not recovered and it is impossible to continue the examination, turn the processor off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly.
Images appear garbled	<ol style="list-style-type: none"> 1) Not connected correctly 2) The video signal cable has burnt out or shorting. 	Connect properly. Reset ^[Note] the processor. If the image is not recovered and it is impossible to continue the examination, turn the processor off, and then straighten the bending portion, and release the angle lever. Pull out the Ultrasonic Endoscope slowly.
Suction is disabled	<ol style="list-style-type: none"> 1) The suction unit is switched off. 2) The suction unit is not connected. 3) No forceps valve is attached. 4) The suction button has been damaged. 	Switch on the suction unit. Connect the suction unit. Attach a forceps valve. Replace with a new suction button.
Low suction volume	<ol style="list-style-type: none"> 1) The suction button has been damaged. 2) The forceps valve has been degraded. 3) The suction tube is not attached properly. 4) The forceps valve is not attached properly. 	Replace with a new suction button. Replace with a new forceps valve. Reattach the suction tube. Reattach the forceps valve.
The suction button won't reset	<ol style="list-style-type: none"> 1) Foreign matter or blood adhering to the button is coagulated. 2) The suction button is damaged. 	Disconnect the suction tube. After diagnosis, remove the button and clean or replace it. Replace with a new suction button.
Treatment equipment cannot be inserted	<ol style="list-style-type: none"> 1) The treatment equipment is left open (such as biopsy forceps). 2) The handle of the treatment equipment is held firmly (such as biopsy forceps). 3) The treatment equipment has difficulty being inserted due to bending. 4) Nonapplicable treatment equipment is used. 	Close the treatment equipment for insertion. Loosen the grip to insert the treatment equipment. Return the bending portion slightly and then insert it. Use applicable treatment equipment.

[Note] Reset:

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

Problem	Cause	Remedy
Treatment equipment cannot be pulled out.	<ol style="list-style-type: none"> 1) The treatment equipment is left open (such as biopsy forceps). 2) The handle of the treatment equipment is held firmly (such as biopsy forceps). 3) The treatment equipment has difficulty being inserted due to bending. 4) An abnormality occurs in the treatment equipment. 5) Nonapplicable treatment equipment is used. 	<p>Close the treatment equipment and pull it out.</p> <p>Loosen the grip and pull out the treatment equipment.</p> <p>Return the bending portion slightly and then pull out the treatment equipment.</p> <p>Return the end of the treatment equipment to the forceps outlet of the Endoscope, and then slowly pull out the Endoscope and treatment equipment together.</p> <p>Return the end of the treatment equipment to the forceps outlet of the Endoscope, and then slowly pull out the Endoscope and treatment equipment together.</p> <p>[Note] Use applicable treatment equipment.</p>
Treatment equipment cannot be closed. (e.g. biopsy forceps)	An abnormality occurs in the treatment equipment.	If it is difficult to close the treatment equipment, 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 treatment equipment to the forceps outlet of the Ultrasonic Endoscope, and then slowly pull out the Ultrasonic Endoscope and treatment equipment together.
Treatment equipment cannot be retracted into the sheath. (e.g. puncture needle)	An abnormality occurs in the treatment equipment.	<p>Pull back the end of the treatment equipment until it no longer protrudes from the end of the forceps outlet. In this state, straighten the bending portion of the Ultrasonic Endoscope, and then draw in the needle again to pull out the treatment equipment.</p> <p>The Ultrasonic Endoscope might be causing an air leak. Immediately perform primary pre-cleaning and airtightness inspection to check for any abnormality.</p>
Images cannot be captured in the image recorder	<ol style="list-style-type: none"> 1) The image recorder is not connected. 2) Not connected correctly. 	<p>Connect the image recorder.</p> <p>Reconnect the image recorder to ensure correct connection.</p>
The bending portion won't reset	The bending control mechanism is malfunctioning.	Discontinue use immediately, and contact your dealer or the nearest service center without forcing the bending portion out of position. Forcing the bending portion out of position could result in body cavity damage.

Problem	Cause	Remedy
Sterile water cannot be fed from the balloon water outlet	Foreign matter has adhered to the balloon water feed channel or balloon water outlet.	Remove foreign matter.
No ultrasonic image is displayed.	<ol style="list-style-type: none"> 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 trachea and bronchi). 4) The ultrasonic processor is malfunctioning. 	<p>Plug in the devices.</p> <p>Turn the power switches ON.</p> <p>Increase the amount of water fed to the balloon, or adjust the angle of the transducer by operating it so that it contacts closely with the trachea and bronchi.</p> <p>If an ultrasonic image disappears during examination, 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 endoscope slowly.</p>
The ultrasonic image is dark	<ol style="list-style-type: none"> 1) The gain level is close to the minimum value. 2) The STC level is close to the minimum value. 	<p>Rotate the gain knob clockwise to adjust the brightness of the ultrasonic image.</p> <p>Press the STC key to set the STC level closer to the center value.</p>
The highlight portion in the ultrasonic image is too bright.	<ol style="list-style-type: none"> 1) The gain level is close to the maximum value. 2) The STC level is close to the maximum value. 	<p>Rotate the gain knob counterclockwise to adjust the brightness of the highlighted area.</p> <p>Press the STC key to set the STC level closer to the center value.</p>
The image disappears during ultrasonic diagnosis.	The ultrasonic connector is poorly connected.	<p>Redo the scope connection.</p> <p>→ 5.4 “Connecting the Ultrasonic Endoscope”</p>
The ultrasonic image receives interference.	The ultrasonic connector is poorly connected.	<p>Redo the scope connection.</p> <p>→ 5.4 “Connecting the Ultrasonic Endoscope”</p>

After-Sales Service

- 1) If the equipment does not work properly, check it first reading this manual.
- 2) If the equipment is still not working well, ask for professional help.

Consult your local dealer.

- 3) Repairs during the warranty period

We will repair your equipment free of charge according to the provisions of the warranty.
The warranty period 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. Troubles caused by careless handling or misuse of the product on the part of the user.
- c. Troubles caused by repair or modification by an unauthorized person.

- 4) Repairs after the warranty period

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

Model name : EB-530US
Serial number :
Description of failure : as detailed as possible
Date of purchase :

Disposal of Electric and Electronic Equipment



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

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

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

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

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

In Countries outside the EU: If you wish to discard this product, please 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.



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