FUJIFILM

English

Endoscopic Ultrasonic Probe

OPERATION MANUAL

PB2020-M

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

202B1263042

Introduction

The medical endoscopic ultrasonic probe PB2020-M is intended for ultrasonographic observation and diagnosis of the trachea, bronchus, esophagus, stomach, duodenum, and large intestine via the instrument channel of a FUJIFILM endoscope in medical facilities under the management of a physician. Do not use this product for any other purpose.

This manual provides necessary information for using the endoscopic ultrasonic probe, such as the equipment overview, operation procedures and precautions to observe, as well as the cleaning, disinfection and storage methods.

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

⚠CAUTION

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

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

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

How to Read This Manual

Conventions Used in This Manual

This manual uses the following conventions for easier understanding.

■ General Conventions

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

Contents at a Glance

Contents

Chapter 1 Precautions

1.1 For Safe Operation

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

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

Be sure to prepare a spare of this product against unexpected accidents such as the failure of this product. Otherwise, you may not be able to continue the endoscopic procedure.
This product is intended for use by medical professionals who have received proper training in endoscopic procedures. This manual does not provide information about clinical procedures or any aspects of endoscopic techniques.

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

1.2 Classification

<Classification of Medical Electrical Equipment>

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

[Note] Use in combination with the SP-900 ultrasonic processor.

1.3 Safety

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

1.3.1 Infection

⚠WARNING

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

Meticulously clean all the surfaces of this product as per provided reprocessing instructions. Not doing so may pose an infection risk.

Wear personal protective equipment (such as goggles, facemask, chemical-resistant and waterproof gloves, antifouling protective clothing, cap and shoe covers) during an examination and treatment as well as during reprocessing to protect your eye and skin and to prevent infection. Not doing so may cause 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 this manual cannot eliminate the causal agents of Creutzfeldt-Jakob disease, the product could be a source of infection. For the treatment of Creutzfeldt-Jakob disease, refer to local guidelines.

Use a cleaned and disinfected (or sterilized) endoscopic ultrasonic probe. An inadequately cleaned and disinfected (or sterilized) probe may pose an infection risk.

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

⚠WARNING

Be sure to wear sterile gloves when inspecting this product. Not doing so may contaminate this product and pose an infection risk.

In clinical procedures in which this product that has been sterilized is used, exercise caution not to contaminate this product when placing it temporarily. Not doing so may pose an infection risk.

Slowly insert this product straight into the endoscope. Also, when withdrawing it, slowly pull straight out. If it is inserted or withdrawn quickly, body fluid may be splattered around due to breakage or accidental detachment of the instrument, leading to infection.

Slowly pull this product out of the end holder. If it is withdrawn quickly from the end holder, body fluid may be splattered around, posing an infection risk.

Be sure to clean and disinfect (or sterilize) this product as per instructions as per instructions in this manual after every case. If this product is not disinfected (or sterilized), it may pose an infection risk or cause an accident.

If the image often becomes dark during observation, air bubbles may be on the transducer inside the ultrasound head. However, do not remove air bubbles once this product is inserted. Body fluid adhered to this product may be splattered, posing an infection risk.

Do not withdraw this product sharply. In so doing, body fluids adhered to this product may be splattered, posing an infection risk.

This product is not compatible with cleaning and disinfection with an automated endoscope reprocessor. If an automated endoscope reprocessor is used, effective cleaning and disinfection cannot be achieved, and it may pose an infection risk.

Excessive foaming prevents detergent solution from sufficiently contacting the surfaces and channel walls of the endoscope, and may impair effective cleaning.

Do not reuse clean water and detergent solution that were used for cleaning. If reused, effective cleaning cannot be achieved, and it may pose an infection risk.

⚠WARNING

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

After immersing this product in disinfectant solution, remove air bubbles completely. If any air bubbles remain, effective disinfection cannot be achieved.

When immersing this product in disinfectant solution, immerse the entire unit. If not properly immersed, effective chemical disinfection cannot be achieved.

When this product is immersed in the chemical solution, remove air bubbles on the surface. Not doing so may pose an infection risk.

Proceed with gas sterilization after vaporizing water out of this product. If gas sterilization is performed while moisture remains in this product, sterilization of wet parts will be incomplete.

When performing ethylene oxide gas sterilization of this product, ensure that the surfaces are dry before attempting ethylene oxide gas sterilization. If any moisture remains in this product, sterilization of undried parts will be incomplete and it could be a source of infection.

When performing ethylene oxide gas sterilization of this product, detach the connector cap from the probe connector. If sterilization is performed while the connector cap is placed on the probe connector, sterilization will be incomplete and may pose an infection risk.

1.3.2 Preventing Electrical Shock

⚠WARNING

Connect the power plug to the protective earth receptacle. Not doing so may cause an electric shock.

This product is not intended to be used with an electrosurgical unit. If used with an electrosurgical unit, it may cause burn injury to the patient or end-user.

1.3.3 Direct Harm to Human Body

⚠WARNING

To avoid the potential for patient injury including perforation and bleeding, do not apply excessive force of this product against walls of the bronchus and digestive tract. Only advance this product under direct visualization.

When using this product for an endoscope with two instrumaent channels, do not use an electrosurgical unit at the same time. Doing so may cause thermal injury to a patient and/or end-user.

Do not hold or scratch this product with metallic forceps, needle, basket, etc. Doing so may damage the ultrasound head and result in damage to tissues inside the body cavities or leakage of the ultrasound transmission medium to the body cavities.

Do not insert this product into an endoscope when a clear endoscopic image is not obtained on the monitor or when an endoscopic image is frozen. Doing so may cause damage to tissues in the body cavities, bleeding, perforation or damage to the equipment.

When using this product under fluoroscopy, note that a contrast image of the region within approx. 5 mm from the distal end of the endoscopic ultrasonic probe is not obtained. If this product is inserted forcibly, it may cause bleeding or perforation.

Slowly insert this product into the endoscope. Inserting it quickly may cause damage to tissues in the body cavity, bleeding or perforation.

This product must be properly aerated after ethylene oxide gas sterilization to remove toxic components. Gas remaining in this product after ethylene oxide gas sterilization may harm human body.

⚠CAUTION

Clean and disinfect (or sterilize) this product in a clean environment. If dust adheres to this product after cleaning and disinfection (or sterilization), it may enter the patient's body.

After cleaning, rinse off any remaining detergent solution with water. If detergent solution remains, chemicals to be used in the subsequent steps may be diluted or adulterated.

After cleaning, rinse off any remaining detergent solution with clean water. If detergent solution remains, it may flow into the patient's body.

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

After immersing in chemical solution, rinse off the remaining disinfectant solution with sterile water. If disinfectant solution remains, it may flow into the patient’s body.

Proceed with aeration after gas sterilization. If this product is used without performing aeration, gas remaining in this product after gas sterilization may harm human body.

1.4 Electromagnetic Compatibility (EMC)

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

1.4.1 Electromagnetic Compatibility (EMC) Related Standard

This product has been tested and confirmed to comply with the limits for medical devices defined in EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful electromagnetic interference in a typical installation at medical facilities.
However, there is a possibility that this product may cause harmful electromagnetic interference to other devices in the vicinity, even if it is used according to the instructions. Also, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful electromagnetic interference to other devices, that can be determined by turning the equipment off and on, we recommend that you may try to correct the interference by one or more of the following measures:

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

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

⚠WARNING

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

CAUTION

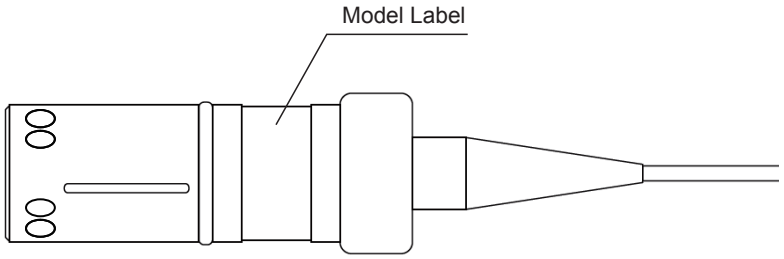
Noise may appear on the monitor of this product due to the effect of electromagnetic waves. In this case, turn off the device emitting the electromagnetic waves or move the device away from this product.

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

1.5 Location of Each Label

The position where the label is affixed on this product is shown below. The relevant safety signs are also described.

1.5.1 Location of Label



1.5.2 Symbols

Symbol	Description
SN	Serial number
	Date of manufacture
	Manufacturer
EC REP	Authorised representative in the European Community
 (Blue)	Refer to instructions for use
	Temperature limitation
	Keep dry
CE 0123	CE marking
IPX7	Degree of waterproof
	Type BF applied part
	WEEE marking [Note]
	Humidity limitation
	Atmospheric pressure limitation
1 pc.	Quantity
	Application site: Trachea and bronchus
	Application site: Upper and lower digestive tract
 20 MHz (Yellow)	Ultrasonic frequency: 20 MHz

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

1.6 Possible Combinations for Use

1.6.1 Peripheral Devices

⚠WARNING

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

1.7 Cautions/Warnings

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

⚠CAUTION

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

This product is a precision instrument. Unnatural force or impact on the insertion portion, ultrasound head or connector. If you encounter any resistance, insert it slowly. Do not insert this product into the endoscope or bend the endoscope without securing a clear endoscopic view on the monitor. Not doing so may cause damage to both this product and body cavities of the patient.

1.7.1 Abnormalities During Use of This Product

⚠WARNING

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

1.7.2 Transportation and Storage

⚠WARNING

Do not store this product in a packaging box. Doing so may cause infection.

⚠CAUTION

Store this product under the storage conditions described in “Main Specification.” Use this product in the operating environment described in “Main Specification.”

CAUTION

Do not store this product in a place which does not meet the storage conditions. Doing so may cause equipment failure.

1.7.3 General Warnings

⚠WARNING

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

Never use this product for any purposes other than intended use. It may cause severe harm to patient and/or end-users.

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

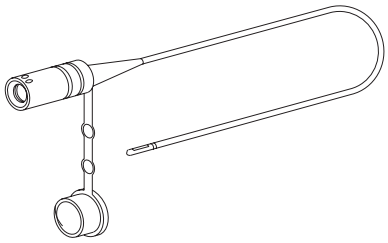
⚠CAUTION

In order to successfully sterilize this product by ethylene oxide gas sterilization, use the parameters described in "Table 7.2 Conditions of 20% ethylene oxide gas sterilization (chamber type)." Exceeding the recommended conditions may cause equipment damage.

Chapter 2 Product Overview

2.1 Components of This Product

This products consists of the following components.
Figures in parentheses indicate the number of articles.



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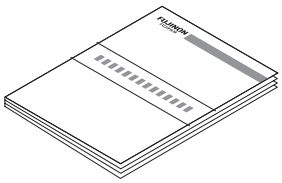
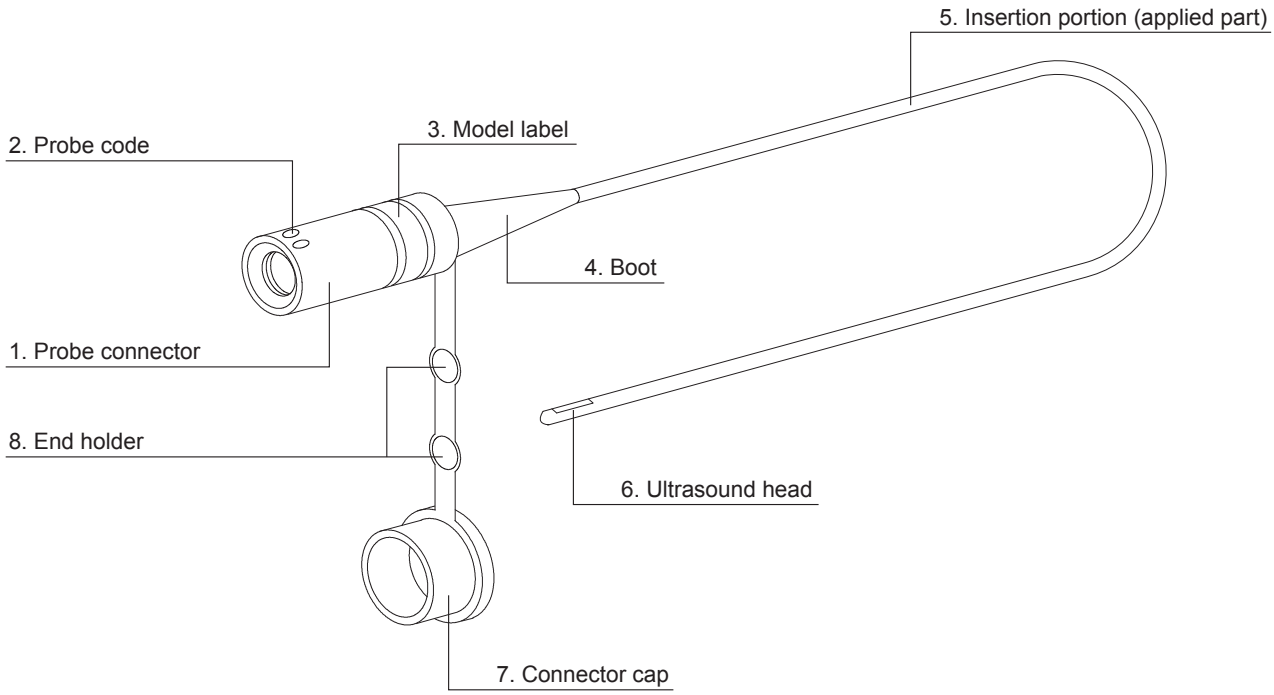


Operation Manual (1)

2.2 Names and Function of Parts

This section describes the names and functions of this product.



No.	Name	Function
1	Probe connector	Connects the scanner.
2	Probe code	Transmits the frequency of the endoscopic ultrasonic probe to the scanner.
3	Model label	Displays the model name.
4	Boot	Connects the probe connector and the insertion portion.
5	Insertion portion (applied part)	Inserted into the body cavity through the endoscope.
6	Ultrasound head	Contains a transducer which rotates while sending and receiving ultrasound waves.
7	Connector cap	Protects the electric contact in the connector from fluids during cleaning and disinfection.
8	End holder	Holds the ultrasound head when not in use by inserting it through this holder.

Chapter 3 Inspection Before Use

⚠WARNING

Be sure to wear sterile gloves when inspecting this product. Not doing so may contaminate this product and pose an infection risk.

In clinical procedures in which this product that has been sterilized is used, exercise caution not to contaminate this product when placing it temporarily. Not doing so may pose an infection risk.

⚠CAUTION

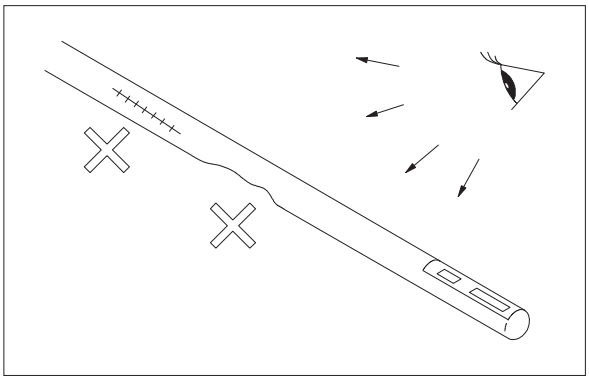
Do not use the equipment that shows any signs of abnormality or irregularity. Use of abnormal equipment may lead to misdiagnosis or increase risks to patient safety.

CAUTION

A liquid ultrasound transmission medium is sealed in this product. Depending on the storage conditions, air bubbles may appear inside the ultrasound head or an ultrasound transmission medium is not contained in the ultrasound head. Check this product for air bubbles inside the ultrasound head before use. If the ultrasound transmission medium is not in the ultrasound head or air bubbles are present in the ultrasound head, remove air bubbles. Clear ultrasound images cannot be obtained for air bubbles.

3.1 Inspecting Endoscopic Ultrasonic Probe

(1) Visually or manually check the external appearance of this product and the probe connector to make sure that they are free from abnormalities such as cracks, starches, and dents, as well as sharp edges and protrusions that may injure the patient.

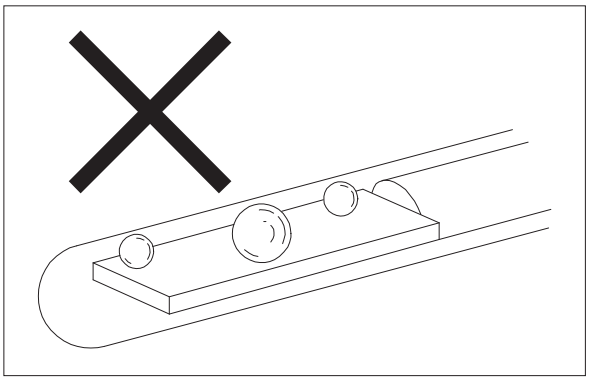


(2) Make sure that there are no air bubbles in the ultrasound head.

[Note]

Remove air bubbles if they are in the ultrasound head or if the liquid ultrasound transmission medium is not in the head.

➞ “3.2 Removing Air Bubbles”



3.2 Removing Air Bubbles

CAUTION

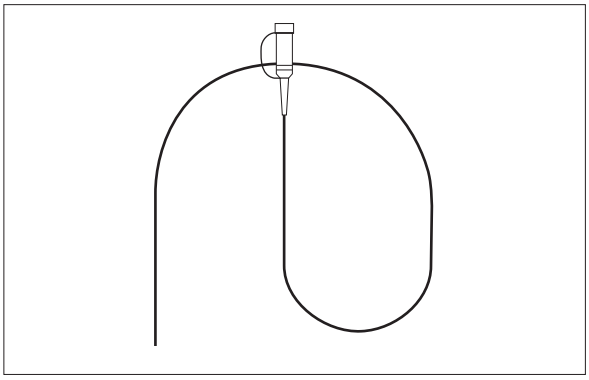
Detach the endoscopic ultrasonic probe from the probe drive unit before removing air bubbles. Removing air bubbles while both the devices are connected may damage them.

When shaking the endoscopic ultrasonic probe to remove air bubbles, exercise caution not to hit the ultrasound head or the probe connector. Not doing so may damage the endoscopic ultrasonic probe.

(1) Remove air bubbles according to the conditions of the liquid ultrasound transmission medium in the ultrasound head.

If air bubbles are present	Perform steps (3) and (4) to remove air bubbles.
If the medium is not present	Perform steps (2) to (4) to move the medium and to remove air bubbles.

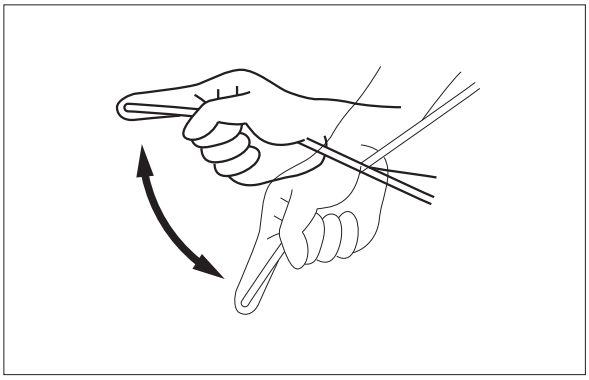
(2) Leave the ultrasound head downward. Wait for a while to confirm that the liquid ultrasound transmission medium is collected in the ultrasound head.



[Note]

If the liquid ultrasound transmission medium is not visible around the ultrasound head, contact your local FUJIFILM dealer.

(3) Hold the endoscopic ultrasonic probe approximately 5 cm away from its distal end, and then shake it vigorously with the distal end pointed downward until air bubbles disappear.



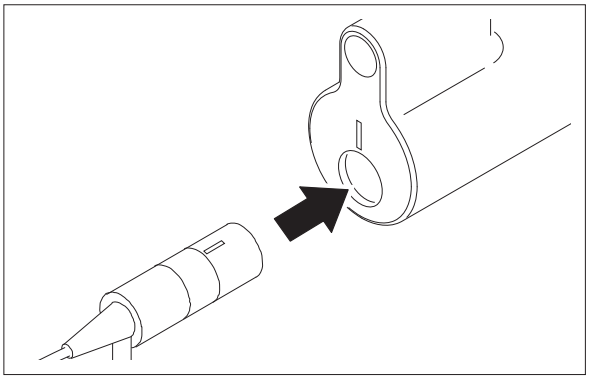
(4) Once air bubbles are removed, keep the endoscopic ultrasonic probe's distal end downward.

3.3 Inspecting for Combination

CAUTION

Do not detach the endoscopic ultrasonic probe from the prove drive unit while freeze mode is disabled (the transducer is rotating). Doing so may cause equipment failure of the endoscopic ultrasonic probe or the prove drive unit.

(1) Align the marks on the probe connector and the scanner, and insert the scanner until it clicks.



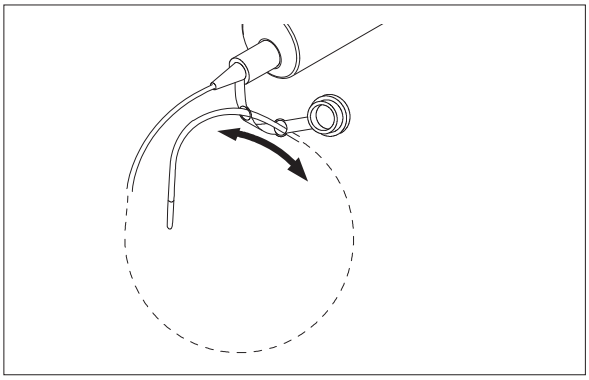
[Note]

To remove the probe connector, pull it straight out.

[Note]

Make sure that the probe connector is not wet. The wet probe connector may cause equipment failure.

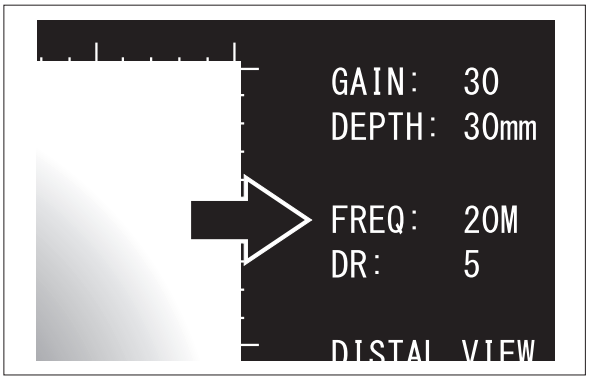
(2) Insert the insertion portion of this product through the end holder so as to keep the ultrasound head and insertion portion from touching the floor.



[Note]

In clinical procedures in which the endoscopic ultrasonic probe that has been sterilized is used, do not use the end holder and place it temporarily using a method that suits the clinical procedure.

(3) Make sure that the ultrasonic frequency of the connected endoscopic ultrasonic probe is displayed in the "FREQ" area on the right side of the monitor screen.



[Note]

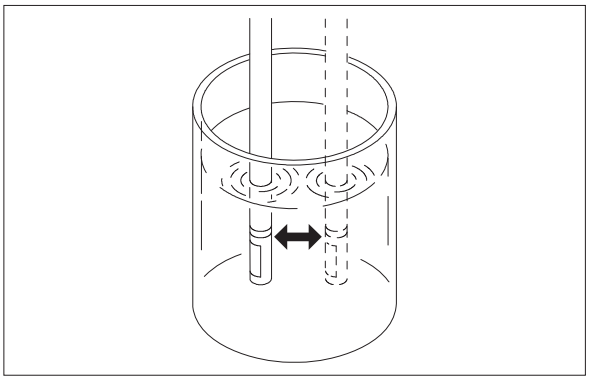
If the probe cord is dirty, the frequency may not be accurately displayed.

(4) Press the [FREEZE] key on the keyboard of the ultrasonic processor to disable freeze mode. Make sure that the transducer of the ultrasound head is rotating and that a multiple-echo image appears on the monitor.

[Note]

Make also sure that the insertion portion and other components function normally and do not produce abnormal sound.

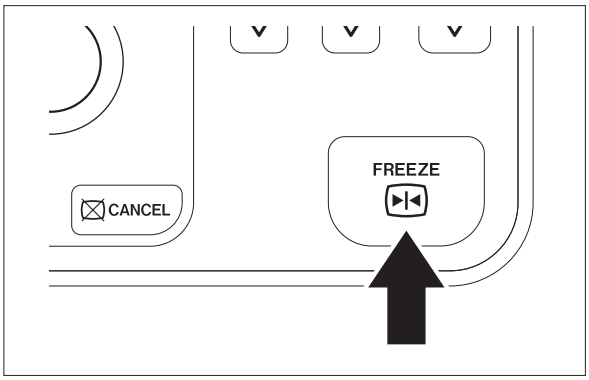
(5) Make sure that the image on the monitor shakes when shaking the endoscopic ultrasonic probe's distal end in sterile water.



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

[Note]

Make sure that the transducer of the ultrasound head stops rotating.



Chapter 4 Method of Use

This chapter outlines how to operate the equipment, according to the general procedures.
This manual does not provide information about clinical procedures. Users should exercise proper clinical judgment.

⚠WARNING

Slowly insert this product straight into the endoscope. Also, when withdrawing it, slowly pull straight out. If it is inserted or withdrawn quickly, body fluid may be splattered around due to breakage or accidental detachment of the instrument, leading to infection.

Slowly pull this product out of the end holder. If it is withdrawn quickly from the end holder, body fluid may be splattered around, posing an infection risk.

Be sure to clean and disinfect (or sterilize) this product as per instructions as per instructions in this manual after every case. If this product is not disinfected (or sterilized), it may pose an infection risk or cause an accident.

To avoid the potential for patient injury including perforation, do not apply excessive force of this product against walls of the bronchus and digestive tract. Only advance this product under direct visualization.

When using this product for an endoscope with two instrument channels, do not use an electrosurgical unit at the same time. Doing so may cause thermal injury to a patient and/or end-user.

Do not hold or scratch this product with metallic forceps, needle, basket, etc. Doing so may damage the ultrasound head and result in damage to tissues inside the body cavities or leakage of the ultrasound transmission medium to the body cavities.

Do not insert this product into an endoscope when a clear endoscopic image is not obtained on the monitor or when an endoscopic image is frozen. Doing so may cause damage to tissues in the body cavities, bleeding, perforation or damage to the equipment.

When using this product under fluoroscopy, note that a contrast image of the region within approx. 5 mm from the distal end of the endoscopic ultrasonic probe is not obtained. If this product is inserted forcibly, it may cause bleeding or perforation.

4.1 Inserting Endoscopic Ultrasonic Probe and Performing Ultrasound Examination

⚠WARNING

If the image often becomes dark during observation, air bubbles may be on the transducer inside the ultrasound head. However, do not remove air bubbles once this product is inserted. Body fluid adhered to this product may be splattered, posing an infection risk.

Slowly insert this product into the endoscope. Inserting it quickly may cause damage to tissues in the body cavity, bleeding or perforation.

CAUTION

Insert this product straight into the forceps valve of the endoscope. If this product is tilted, its insertion portion may be damaged.

If this product is inserted into the instrument channel, hold this product's insertion portion close to the forceps valve of an endoscope, and insert it slowly. Not doing so may damage the insertion portion of this product.

If this product is inserted into the forceps valve with a lid, open the lid before insertion. Not doing so may damage the insertion portion of this product.

If it is difficult to insert this product through the instrument channel, do not push in forcibly. Doing so may damage this product or an endoscope.

If resistance is encountered while advancing this product within the instrument channel, angulate the endoscope for smooth advancement of this product. Not doing so may damage this product or the endoscope.

When inserting this product into a duodenoscope, make sure that the forceps stand of the scope is lowered. Not doing so may damage this product.

When inserting this product into a duodenoscope, push out this product long enough from the distal end of an endoscope before moving up the forceps stand. If not enough, the ultrasound head may be crushed and damaged.

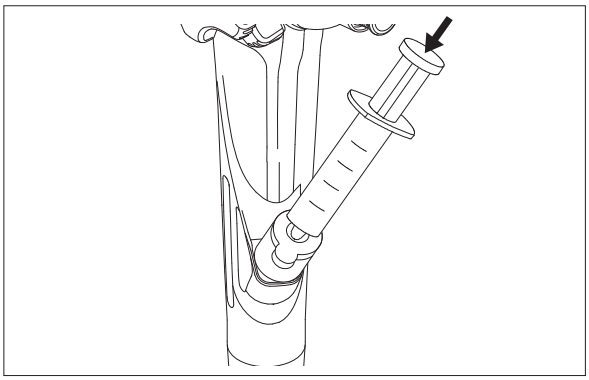
CAUTION

Do not push or pull this product or insert into the bending portion of an endoscope when this product is operating (freeze mode is disabled). If the endoscope is bent excessively or the forceps stand is moved up, slowly push or pull this product. Pushing or pulling the endoscope forcibly or suddenly may cause distortion of the image or damage to this product.

It is desirable that the endoscope is straight and the forceps stand is in neutral position before operating this product. Operating this product under unfavorable conditions may cause distortion of the image or damage to this product.

When performing an ultrasound examination with this product, it is necessary to have the ultrasound head directly contact the region of interest or have an ultrasound transmission medium such as sterile water between the ultrasound head and the region of interest.

(1) When necessary, inject an ultrasound transmission medium such as sterile water to the region of interest, for which an ultrasound examination is performed.

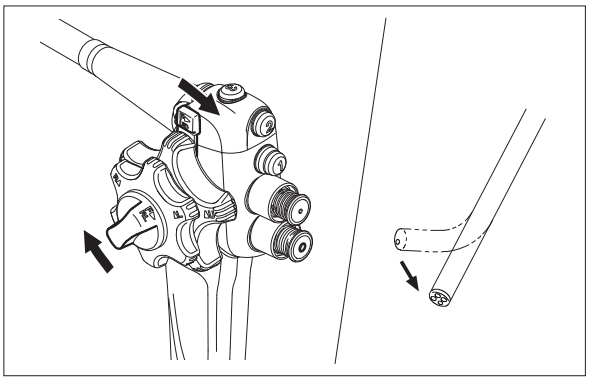


[Note]

Injecting an excessive amount of an ultrasound transmission medium such as sterile water may cause accidental swallowing or vomiting.

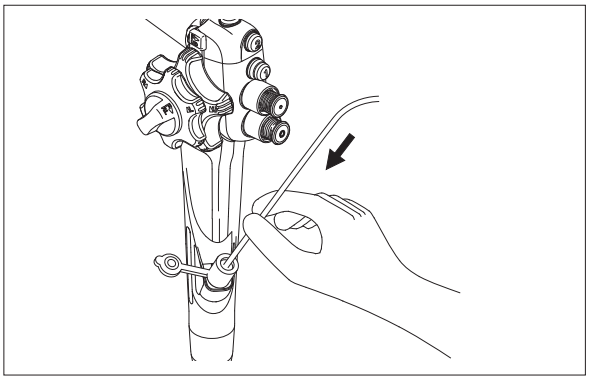
(2) Unlock the bending section by turning the up-down and left-right angulation locks.

(3) Operate the up/down and left/right angulation knobs to straighten the bending section to its neutral position.

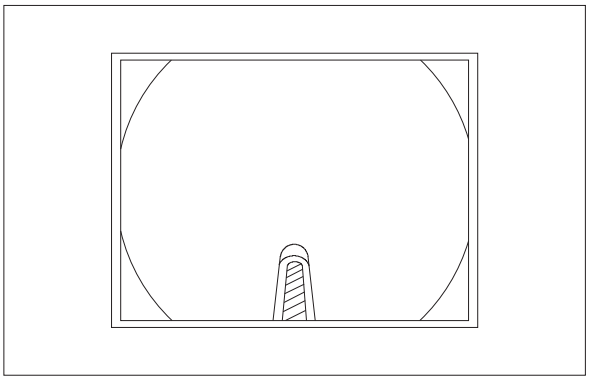


(4) Insert the endoscopic ultrasonic probe into the forceps inlet of an endoscope with the forceps valve on.

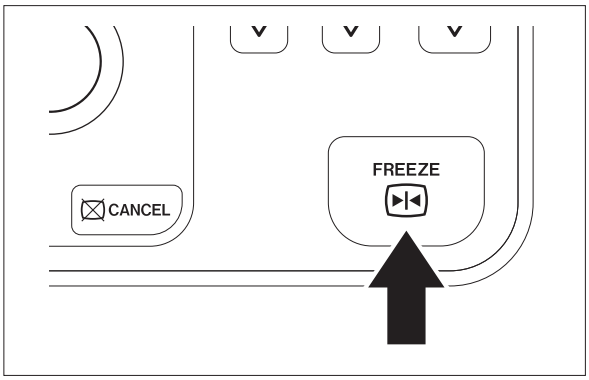
[Note]
Open the lid of the forceps valve before insertion.



(5) Insert the endoscopic ultrasonic probe up to a position where the ultrasound head is visible in the endoscopic image.

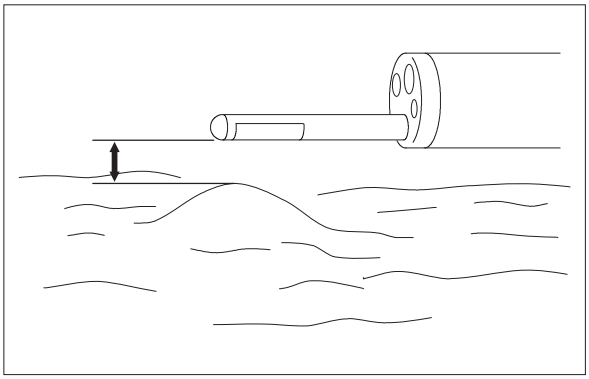


(6) Press the [FREEZE] key to enable freeze mode. "SCAN ON" is displayed at the lower right of the monitor, and the transducer starts rotating. The radial image will be displayed on the monitor.



(7) In radial scanning, ultrasound beam is radiated with the endoscopic ultrasonic probe as its center. In order to expose the target region perpendicular to ultrasound beam, angulate the endoscope so that the ultrasound head is parallel to the target region while monitoring the endoscopic image on the monitor.

A radial image is displayed on the monitor in real time.



4.2 Withdrawal of Endoscopic Ultrasonic Probe

⚠WARNING

Do not withdraw this product sharply. In so doing, body fluids adhered to this product may be splattered, posing an infection risk.

CAUTION

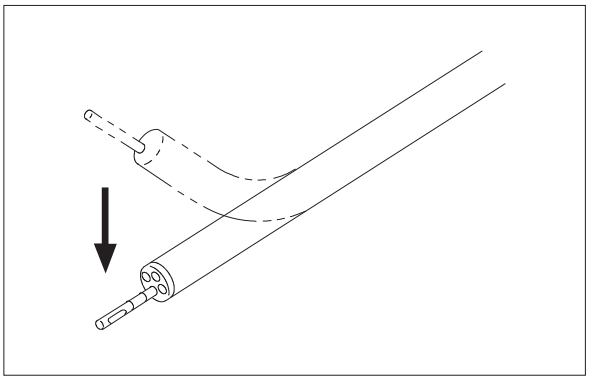
When withdrawing this product, be sure to press the [FREEZE] key on the ultrasonic processor to enable freeze mode. Withdrawing this product while it is in operation may cause damage to it.

When this product is used with an endoscope with a forceps stand mechanism, make sure that the forceps stand is in neutral position before withdrawing this product. Withdrawing this product with the forceps stand raised may cause damage to it.

If it is difficult to remove this product from an endoscope, slowly withdraw it while monitoring an endoscopic image in order not to damage body cavities.

(1) Unlock the bending section by turning the up-down and left-right angulation locks.

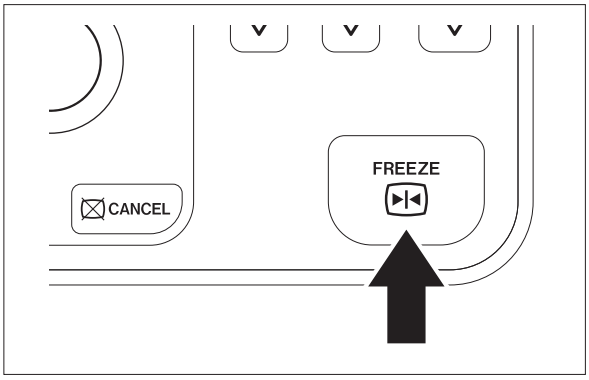
(2) Operate the up/down and left/right angulation knobs to straighten the bending section to its neutral position.



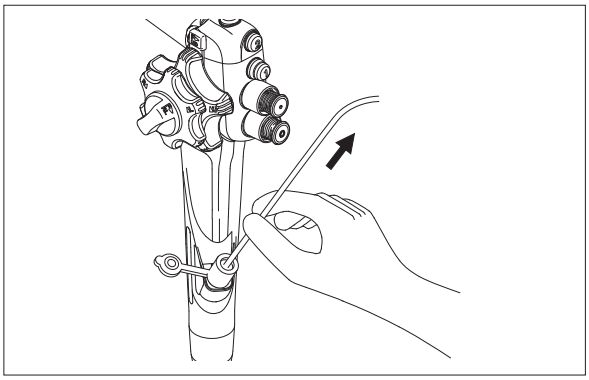
(3) Press the [FREEZE] key on the keyboard of the ultrasonic processor to enable freeze mode.

[Note]

Make sure that the transducer of the ultrasound head stops rotating.



(4) Withdraw the endoscopic ultrasonic probe from the endoscope.



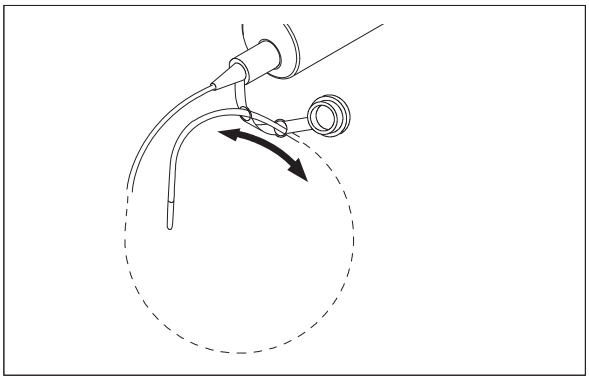
[Note]

Wipe the dirt on the endoscopic ultrasonic probe's insertion portion with a paper towel (or gauze).

[Note]

Insert the insertion portion of the endoscopic ultrasonic probe through the end holder so as to keep the ultrasound head and insertion portion from touching the floor.

When inserting the endoscopic ultrasonic probe into an endoscope again, pull out the insertion portion from the end holder.



[Note]

In clinical procedures in which sterilization is required and the endoscopic ultrasonic probe may be reused, place it temporarily using a method that suits the clinical procedure.

Chapter 5 Cleaning

This chapter explains how to clean this product.
Pre-cleaning is performed at the bedside immediately after an examination is completed.
Manual cleaning is performed in a sink, etc. after pre-cleaning.

⚠WARNING

This product is not compatible with cleaning and disinfection with an automated endoscope reprocessor. If an automated endoscope reprocessor is used, effective cleaning and disinfection cannot be achieved, and it may pose an infection risk.

⚠CAUTION

After cleaning, rinse off any remaining detergent solution with clean water. If detergent solution remains, it might flow into the patient's body.

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

5.1 Method of Cleaning

Use potable water or detergent solutions to clean this product. For detergent solutions, refer to “5.2 Detergent Solution”.

Table 5.1 Applicable methods of cleaning for the endoscopic ultrasonic probe

Chemical cleaning	Ultrasonic cleaning
Yes	No

5.2 Detergent Solution

⚠WARNING

Excessive foaming prevents detergent solution from sufficiently contacting the surfaces and channel walls of the endoscope, and may impair effective cleaning.

Do not reuse clean water and detergent solution that were used for cleaning. If reused, effective cleaning cannot be achieved, and it may pose an infection risk.

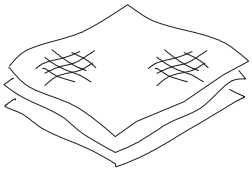
Use a medical grade, low-foaming enzymatic detergent. Follow the instructions provided by the detergent manufacturer regarding how to use and the expiration date. For the names of specific brands of detergent solution that have been tested for compatibility with this product, contact your local FUJIFILM dealer. Refer to the detergent solution manufacturer's instructions for preparation and use.

[Note] For the method of use and expiration date, refer to the instructions provided by the detergent solution manufacturer.

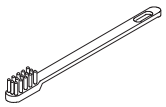
5.3 Necessary Equipment and Materials

Prepare the necessary equipments used in Chapter 5 “Cleaning” and Chapter 6 “Disinfection.”

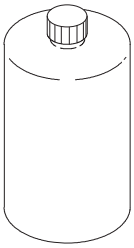
- Sterile gauze
- Toothbrush (soft type)
- Detergent solution/disinfectant solution
- Container for detergent solution/disinfectant solution
- Personal protective equipment
  - Rubber gloves
  - Goggle
  - Facemask
  - Protective clothing



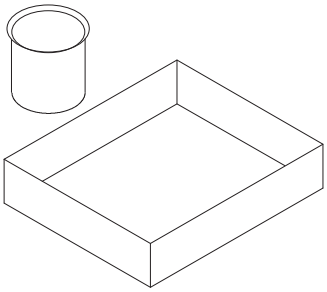
Clean lint-free gauze/
sterile gauze



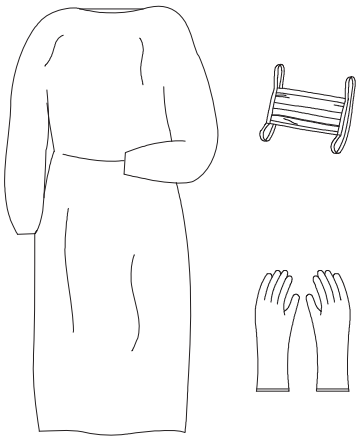
Toothbrush (soft type)



Detergent solution/
disinfectant solution



Container for detergent solution/
disinfectant solution



Personal protective equipment

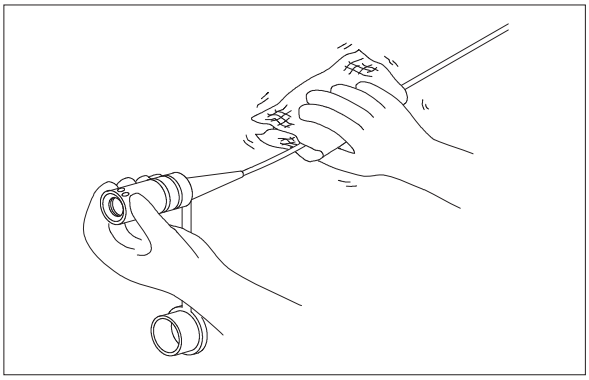
5.4 Pre-cleaning

Perform pre-cleaning at the bedside immediately after an examination is completed.

5.4.1 Wiping

(1) Wipe the dirt on the external surfaces of this product's insertion portion with gauze or a paper towel.

Gauze dampened with ethanol may also be used when required.

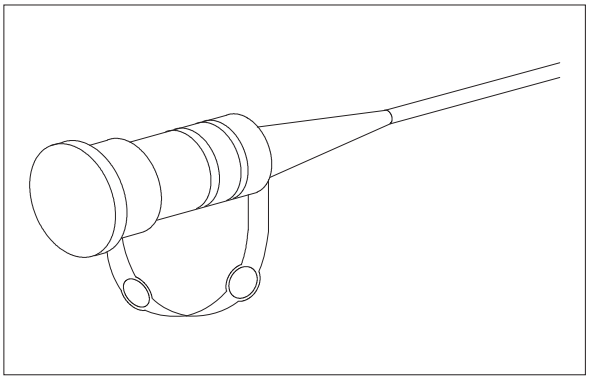


5.5 Manual Cleaning

Perform manual cleaning in a sink, etc. after pre-cleaning.
Manual cleaning must be performed immediately after pre-cleaning is completed.

5.5.1 Cleaning of Endoscopic Ultrasonic Probe

(1) Attach the connector cap to the probe connector.

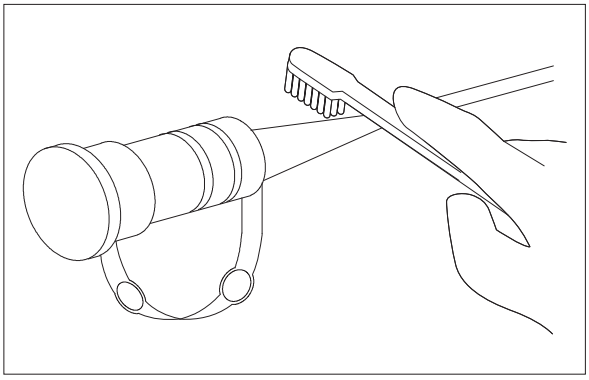


(2) Fill a clean basin with detergent solution at the temperature and concentration recommended by the detergent solution's manufacturer.

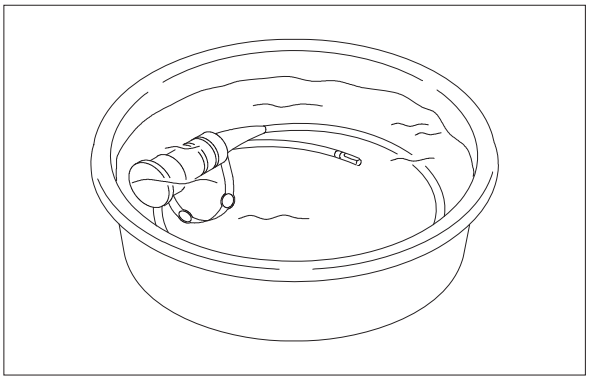
(3) Fully immerse the endoscopic ultrasonic probe in detergent solution.

[Note]
Perform all cleaning steps while the endoscopic ultrasonic probe is fully immersed in detergent solution.

(4) Brush the probe connector, the connector cap and the boot with the toothbrush for 20 seconds.

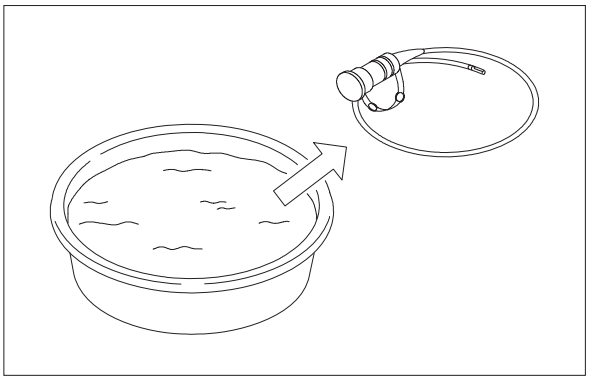


(5) Clean the external surface (insertion portion, boot, probe connector, end holder and connector cap) of the endoscopic ultrasonic probe with clean gauze in detergent solution.

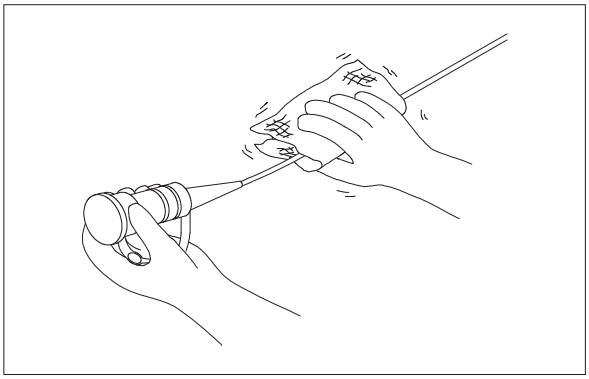


(6) Leave the endoscopic ultrasonic probe immersed in the detergent solution in accordance with temperature, concentration and time recommended by the detergent solution's manufacturer.

(7) Remove the endoscopic ultrasonic probe from detergent solution.



(8) Wipe any detergent solution remaining on the external surface of the endoscopic ultrasonic probe with clean lint-free gauze.



(9) If the endoscopic ultrasonic probe is still dirty, repeat steps (1) to (8).

5.5.2 Rinsing of Endoscopic Ultrasonic Probe

⚠WARNING

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

⚠CAUTION

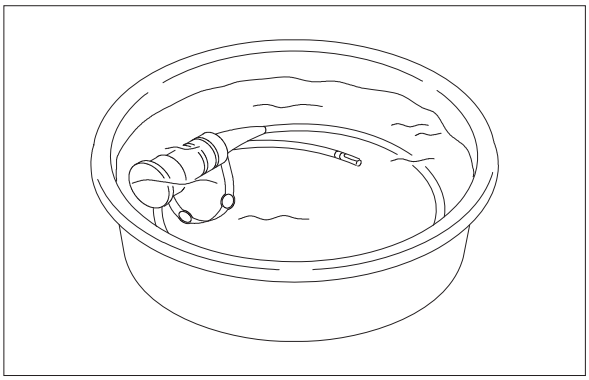
After cleaning, rinse off any remaining detergent solution with water. If detergent solution remains, chemicals to be used in the subsequent steps may be diluted or adulterated.

After cleaning, rinse off any remaining detergent solution with clean water. If detergent solution remains, it may flow into the patient's body.

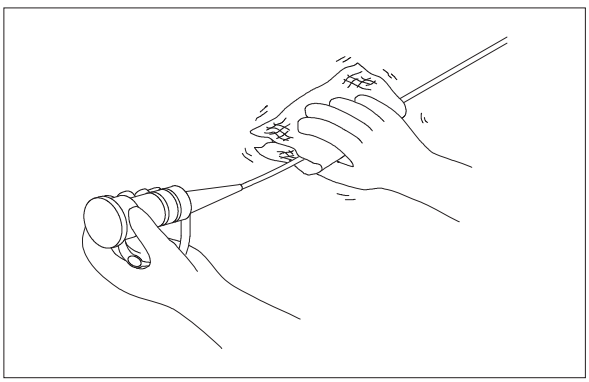
[Note] Perform all rinsing steps while the endoscopic ultrasonic probe is fully immersed in clean water.

(1) With fresh clean water, fill a basin of adequate size to completely immerse the endoscopic ultrasonic probe.

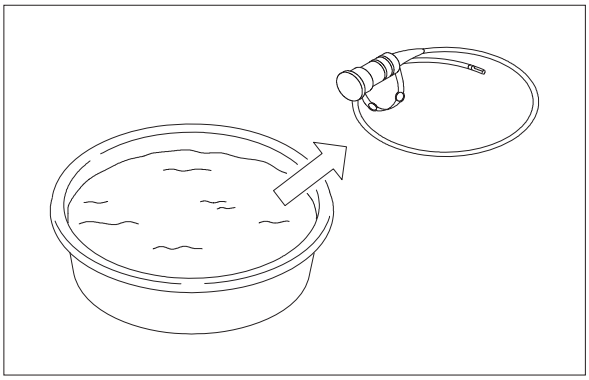
(2) Fully immerse the endoscopic ultrasonic probe in clean water, and then rinse it by gently shaking it.



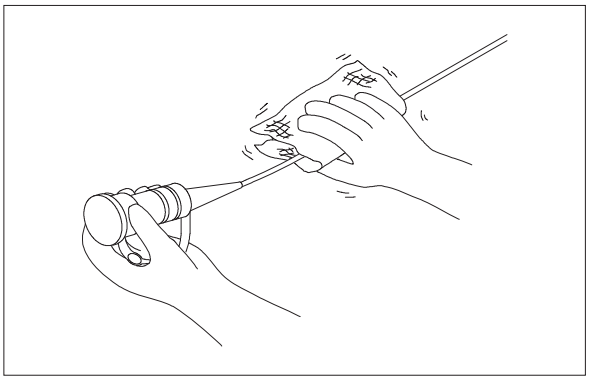
(3) Wipe the external surface (insertion portion, boot, probe connector, end holder and connector cap) of the endoscopic ultrasonic probe with clean lint-free gauze in clean water.



(4) Remove the endoscopic ultrasonic probe from clean water and transfer it to a clean basin.



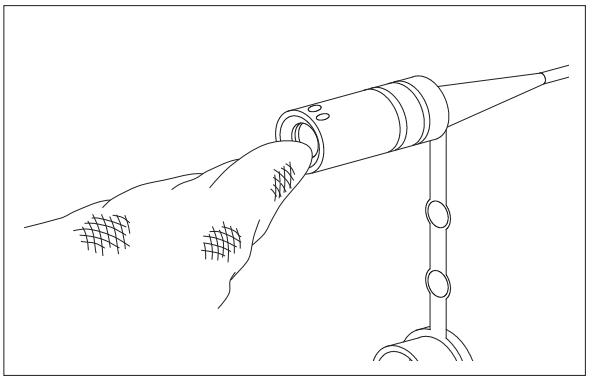
(5) Wipe any clean water remaining on the external surface of the endoscopic ultrasonic probe with clean lint-free gauze.



(6) Detach the connector cap from the probe connector.

(7) Wipe the end of the probe connector with clean lint-free gauze.

(8) Visually inspect the endoscopic ultrasonic probe for any visible soil.



Chapter 6 Chemical Disinfection

This chapter explains how to perform chemical disinfection.
Perform chemical disinfection after pre-cleaning and manual cleaning.

⚠WARNING

When immersing this product in disinfectant solution, immerse the entire unit. If not properly immersed, effective chemical disinfection cannot be achieved.

When this product is immersed in the chemical solution, remove air bubbles on the surface. Not doing so may pose an infection risk.

⚠CAUTION

After immersing in the chemical solution, wash off the remaining disinfectant solution with sterile water. Otherwise, disinfecting liquid might flow into a patient's body.

CAUTION

Do not use boiling or autoclaving for this product. Doing so may cause damage to the endoscopic ultrasonic probe.

6.1 Method of Chemical Disinfection

To enhance the effect of disinfection, perform pre-cleaning and manual cleaning carefully before disinfection according to Sections 5.4 and 5.5.
Use water (sterile water) to disinfect this product. For disinfectant solutions, refer to "6.2 Disinfectant Solution".

Table 6.1 Applicable methods of disinfection for the endoscopic ultrasonic probe

Chemical disinfection
Yes

6.2 Disinfectant Solution

CAUTION

Do not immerse the endoscopic ultrasonic probe in the ozone water. Doing so may damage the endoscopic ultrasonic probe.

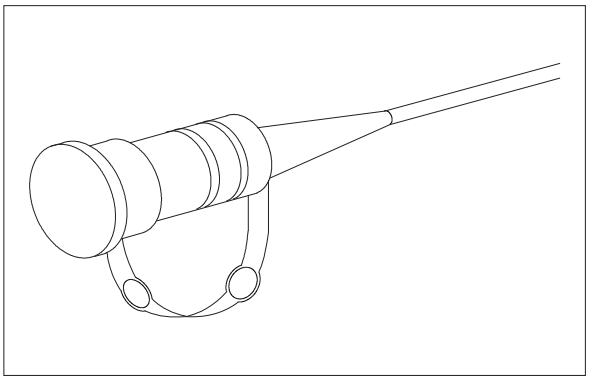
The material compatibility of the endoscopic ultrasonic probe with legally marketed 3.0 to 3.5% glutaraldehyde disinfectant solutions has been verified. Use glutaraldehyde disinfectant solutions in accordance with the manufacturer's instructions. For the names of specific brands of disinfectant solution, contact your local FUJIFILM dealer.

[Note] Refer to the disinfectant solution manufacturer's instructions regarding preparation, use, exposure conditions and expiration date.

[Note] Check the disinfectant solution's efficacy (Minimum Effective Concentration) before use according to the manufacturer's recommendation (such as using a test strip), referring to the disinfectant solution manufacturer's instructions.

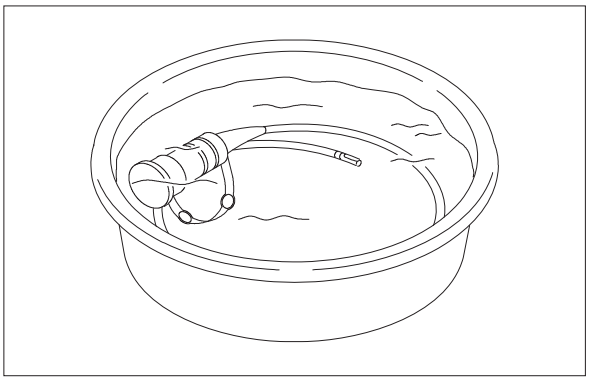
6.3 Chemical Disinfection of Endoscopic Ultrasonic Probe

(1) Attach the connector cap to the probe connector.



(2) Fill a clean basin with a lid with disinfectant solution at the temperature and concentration recommended by the disinfectant solution's manufacturer.

(3) Fully immerse the endoscopic ultrasonic probe in disinfectant solution.

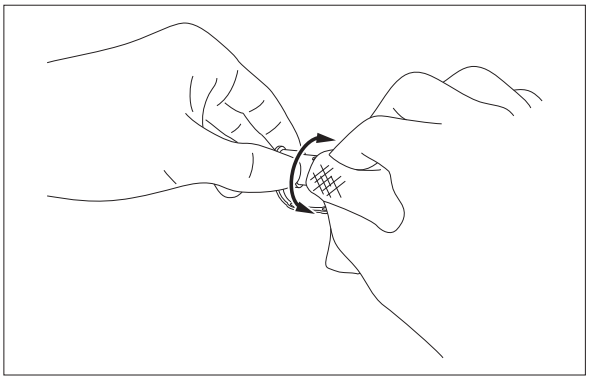


[Note]

Perform all disinfecting steps while the endoscopic ultrasonic probe is fully immersed in disinfectant solution.

(4) Wipe the external surface (insertion portion, boot, probe connector, end holder and connector cap) of the endoscopic ultrasonic probe with sterile gauze in disinfectant solution to remove air bubbles completely.

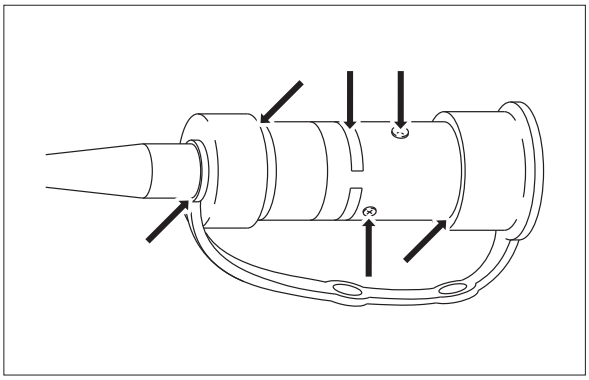
(5) Wipe the probe connector with sterile gauze saturated with disinfectant solution 3 times while rotating back and forth the probe connector.



[Note]

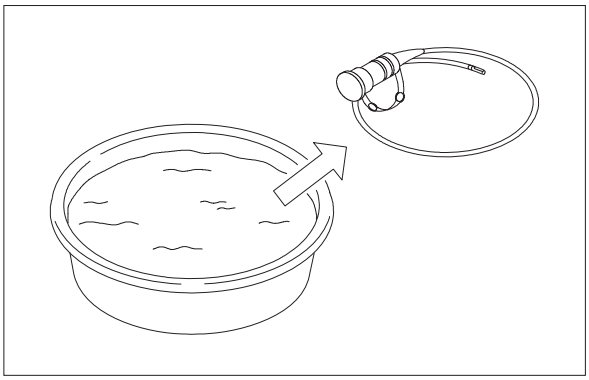
Ensure the connector cap is securely attached and is not loosened when wiping the probe connector.

(6) Using a syringe, flush 60 mL of disinfectant solution onto each gap and recess of the probe connector to remove air bubbles completely.

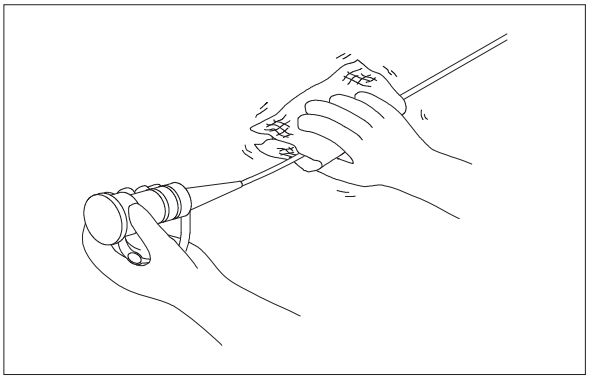


(7) Keep the endoscopic ultrasonic probe immersed in the disinfectant solution at the temperature, concentration and time recommended by the disinfectant solution's manufacturer. Cover the basin with a lid during disinfection.

(8) Remove the endoscopic ultrasonic probe from disinfectant solution.



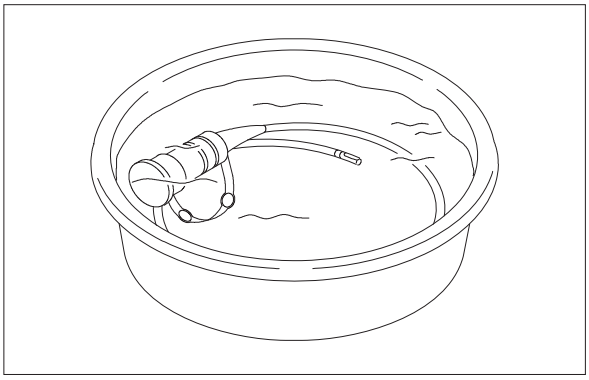
(9) Wipe any disinfectant solution remaining on the external surface of the endoscopic ultrasonic probe with sterile gauze.



6.4 Rinsing of Endoscopic Ultrasonic Probe After Disinfection

(1) Fill a sterile basin with sterile water.

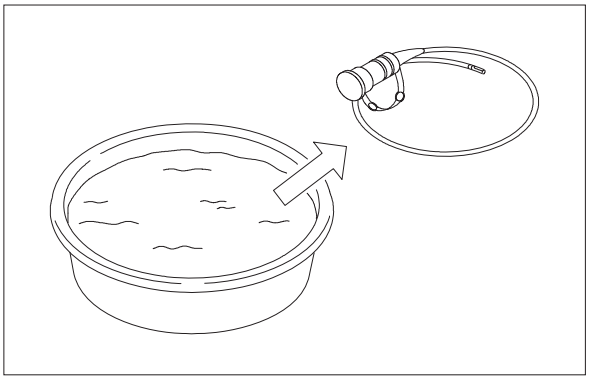
(2) Fully immerse the endoscopic ultrasonic probe in sterile water.



(3) Wipe the external surface (insertion portion, boot, probe connector, end holder and connector cap) of the endoscopic ultrasonic probe with sterile gauze in sterile water to remove air bubbles completely.

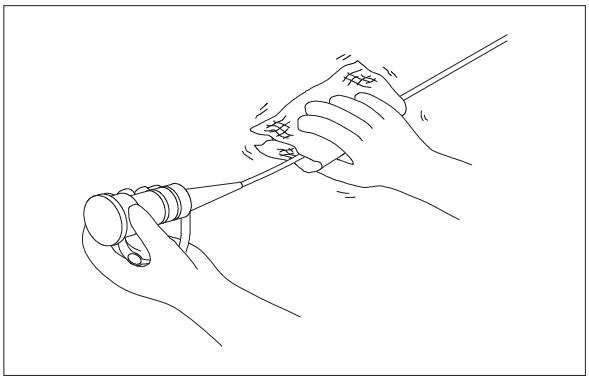
(4) Rinse the endoscopic ultrasonic probe by gently shaking it in sterile water for 30 seconds.

(5) Remove the endoscopic ultrasonic probe from sterile water and transfer it to a clean basin.



6.5 Rinsing of Endoscopic Ultrasonic Probe After Disinfection

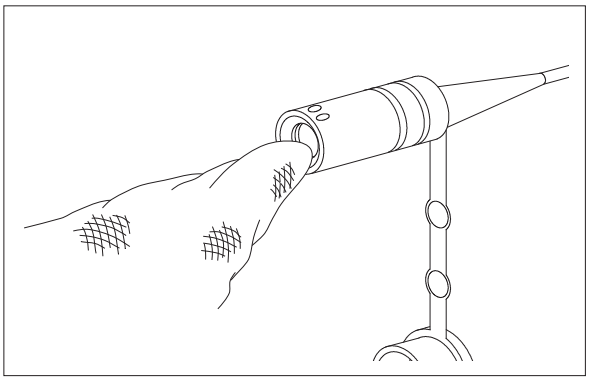
(1) Wipe any sterile water remaining on the external surface of the endoscopic ultrasonic probe with sterile gauze.



(2) Detach the connector cap from the probe connector.

(3) Wipe the end of the probe connector with sterile gauze.

(4) Ensure that the endoscopic ultrasonic probe is completely dry.



Chapter 7 Sterilization

This chapter explains how to sterilize this product.
Perform ethylene oxide gas sterilization for this product.

This product can withstand up to 30 times of ethylene oxide gas sterilization.
Ethylene oxide gas sterilization applies more load to this product than chemical cleaning and disinfection, and reduces the product life.

7.1 Methods of Sterilization

⚠WARNING

Proceed with gas sterilization after vaporizing water out of this product. If gas sterilization is performed while moisture remains in this product, sterilization of wet parts will be incomplete.

⚠CAUTION

Proceed with aeration after gas sterilization. If this product is used without performing aeration, gas remaining in this product after gas sterilization may harm human body.

CAUTION

Do not use boiling or autoclaving for this product. Otherwise, this product will be damaged by high temperature.

To enhance the effect of sterilization, perform cleaning before gas sterilization according to the procedures described in this manual.

Table 7.1 Applicable methods of sterilization for the endoscopic ultrasonic probe

Autoclaving	Ethylene oxide gas sterilization
No	Yes

7.2 Ethylene Oxide Gas Sterilization

⚠WARNING

When performing ethylene oxide gas sterilization of this product, ensure that the surfaces are dry before attempting ethylene oxide gas sterilization. If any moisture remains in this product, sterilization of undried parts will be incomplete and it could be a source of infection.

When performing ethylene oxide gas sterilization of this product, detach the connector cap from the probe connector. If sterilization is performed while the connector cap is placed on the probe connector, sterilization will be incomplete and may pose an infection risk.

This product must be properly aerated after ethylene oxide gas sterilization to remove toxic components. Gas remaining in this product after ethylene oxide gas sterilization may harm human body.

⚠CAUTION

In order to successfully sterilize this product by ethylene oxide gas sterilization, use the parameters described in “Table 7.2 Conditions of 20% ethylene oxide gas sterilization (chamber type).” Exceeding the recommended conditions may cause equipment damage.

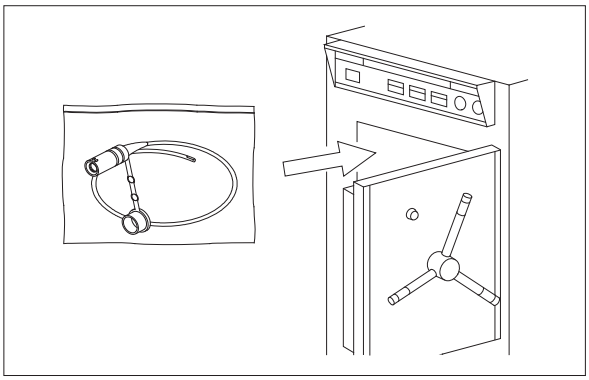
Table 7.2 Conditions of 20% ethylene oxide gas sterilization (chamber type)

Ethylene oxide gas sterilization				Aeration	
Temperature	Humidity	Pressure	Time	Temperature	Time
55ºC	Normal humidity	100 kPa or more (relative pressure)	4 hours	55ºC	12 hours

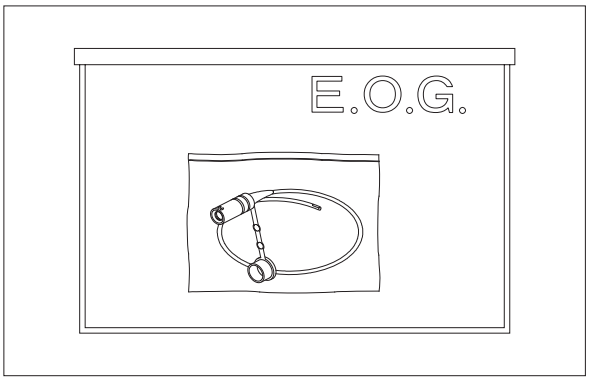
7.3 EOG (Ethylene Oxide Gas) Sterilization

(1) Ensure that this product is completely dry, and then detach the connector cap from the probe connector.

(2) Put this product in a sterile pack, and then seal the pack tightly. Place it in an EOG sterilizer.

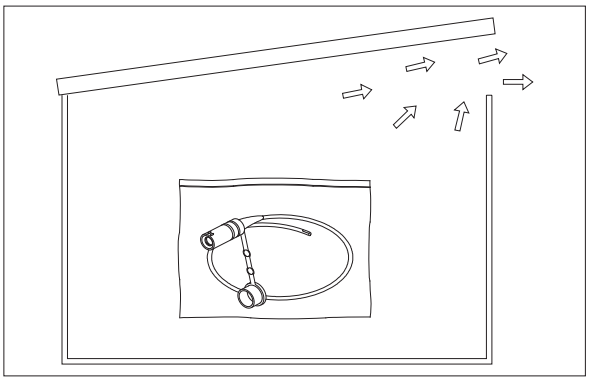


(3) Sterilize this product according to the operating procedure of the EOG sterilizer.



(4) Sterilize this product for a specified time, and aerate it according to operating procedure of the EOG sterilizer.

Temperature	Time
55ºC	12 hours



Chapter 8 Storage

⚠WARNING

Do not store this product in a packaging box. Doing so may cause infection.

CAUTION

Do not store this product in locations that do not satisfy storage conditions. Otherwise, a failure may result.

Store the endoscopic ultrasonic probe that has been disinfected in a location that meets the following conditions.

Storing conditions

Temperature	: -20 to +60°C
Humidity	: 10 to 85%RH (no dew condensation)
Pressure	: 70 to 106 kPa (within range of atmospheric pressure)

State of the endoscopic ultrasonic probe :
Hang this product with its distal end down.
Keep out of direct sunlight, UV light or X-ray.

[Note] Keep more than 250 mm diameter to store it round.

Main Specification

<Classification of Medical Electrical Equipment>

1. Type of protection against electric shock : Class I equipment (power supply: protective earth plug)
2. Degree of protection against electric shock : Type BF applied part
3. Degree of explosion protection : Use is prohibited in an oxygen-rich environment or in a flammable gas atmosphere.
4. Degree of protection against ingress of water : IPX7

[Note] Use in combination with the SP-900 ultrasonic processor.

<Applied Part>

Insertion portion

<Specifications>

Working length	2150 mm
Outside diameter of insertion portion	1.4 mm to 1.9 mm
Maximum diameter of insertion portion	2.0 mm
Axial resolution	2 mm or less
Lateral resolution	2 mm or less
Penetration depth	7 mm or more (assuming the attenuation coefficient of 0.3 dB cm^{-1} MHz^{-1})
Acoustic frequency	20 MHz ±15%
Spatial-peak temporal-average intensity	Izpta. α ≤ 720 mW cm^{-2} (α=0.3 dB cm^{-1} MHz^{-1})
Mechanical Index (MI)	Less than 1.0

<Peripheral Devices>

Compatible ultrasonic processor	SP-900
Compatible endoscope	Bronchoscope [Note] Upper gastrointestinal endoscope [Note] Large intestine endoscope [Note] Duodenoscope [Note]

[Note] The channel diameter of each endoscope must be 2.0 mm or more and the working length 1330 mm or less.

<Operating Environment>

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

<Storage Environment>

Temperature	-20 to +60°C
Humidity	10 to 85%RH (no dew condensation)
Pressure	70 to 106 kPa (within range of atmospheric pressure)

<Transport Environment>

Temperature	-20 to +60°C
Humidity	10 to 85%RH (no dew condensation)
Pressure	70 to 106 kPa (within range of atmospheric pressure)

<Medical Device Directive>

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

CE 0123

<Electromagnetic Compatibility (EMC) Information>

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

[Note] Use in combination with the SP-900 ultrasonic processor.

Electromagnetic emission compliance information and guidance

Emission standard	Compliance	Guidance
RF emissions EN 55011	Group I	This product uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electric equipment.
Radiated emissions EN 55011	Class B	This product is intended for use in medical facilities and commercial facilities. If this product is used in domestic establishments, electromagnetic interference may occur on any equipments. In this case, it is recommended to use this product according to “Chapter 1 Safety”.
Harmonic emissions EN 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Applicable	

Electromagnetic immunity compliance information and guidance

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

Electromagnetic immunity compliance information and guidance

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

Electromagnetic immunity compliance information and guidance

The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P (W)	Separation distance related to frequency of transmitter (m)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80 to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Disposal of Electric and Electronic Equipment

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

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

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

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

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

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

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Service Centers

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

<Europe>

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

<USA>

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

<Australia>

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

<Asia>

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

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

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

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

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