

## **About This Manual**

P/N: 4710.00586A01

Release Date: May, 2016

Product Model: EC-500, EC-500T, EC-500L, EC-500L/T

Copyright © 2016 SonoScape Medical Corp. All Rights Reserved.

## **Statement**

SonoScape Medical Corp. (hereinafter called SonoScape) owns the intellectual property rights to this manual, and also maintains the contents of this manual as confidential information. This manual is a reference to operation, maintenance or cleaning for the product and does not convey any license under the patent rights of SonoScape, nor the rights of others.

This manual contains the information protected by copyrights or patents. Reproduction, amendment or translation of this manual in any manner whatsoever without the written permission of SonoScape is strictly forbidden.

All information contained in this manual is believed to be correct. SonoScape shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of this manual. SonoScape does not assume any liability arising out of any infringements of patents or other rights of third parties.

This manual provides operating instructions for a series products, and some options are not available on some model.

This manual is subject to change without prior notice and legal obligation.




## **Manufacturer's Responsibility**

SonoScape is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by SonoScape authorized personnel;
- the use or application of the product or the use of parts or accessories is approved by SonoScape.
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

## Signal Words

Signal words in this manual are defined as follows. Please understand their meanings clearly before reading this manual.

Signal Word	Meaning
 <b>WARNING</b>	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 <b>CAUTION</b>	Indicates a potentially hazardous situation which, if not avoided, may result in malfunction or damage of the system.
<b>NOTE</b>	Indicates precautions or recommendations that should be used in operating the system.
	Indicates a potentially biological hazardous situation which, if not avoided, may result in disease transmission.
<b>Boldfaced Word</b>	Indicates keys and controls located on the product.

## Contact Information

### Manufacturer: SonoScape Medical Corp.

Address: 4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building, Yuquan Road, Nanshan, Shenzhen, 518051, Guangdong, China

Zip Code: 518051

Tel: +86-755-26722890

Fax: +86-755-26722850

Website: <http://www.sonoscape.com>

E-mail: [sonoscape@sonoscape.net](mailto:sonoscape@sonoscape.net)

### EU Representative: SonoScape Europe S.r.l.

Address: Via Luigino Tandura, 74-00128 Rome, Italy

Tel: +39-06-5082160

Fax: +39-06-5084752

<http://www.sonoscapeurope.com>

# Contents

<b>Chapter 1 Safety</b> .....	<b>1</b>
1.1 Intended Use .....	2
1.2 Contraindications .....	2
1.3 Product Compatibility.....	2
1.4 Safety Precautions.....	2
1.4.1 General Warnings.....	2
1.4.2 Biohazard Considerations .....	4
1.5 Safety Symbols .....	4
<b>Chapter 2 Overview</b> .....	<b>5</b>
2.1 System Configuration .....	6
2.1.1 System Composition .....	6
2.1.2 Accessory List.....	6
2.2 Endoscope Overview .....	7
2.2.1 Connector Section .....	7
2.2.2 Control and Insertion Section .....	8
2.2.3 Distal End .....	9
<b>Chapter 3 Preparations</b> .....	<b>11</b>
3.1 Inspecting the Endoscope .....	12
3.1.1 Inspecting the Appearance and Flexibility.....	12
3.1.2 Inspecting the Angulation .....	12
3.2 Inspecting and Connecting the Accessories .....	14
3.2.1 Air/Water Valve.....	14
3.2.2 Suction Valve .....	15
3.2.3 Biopsy Valve .....	15
3.3 Connecting the Endoscopy System .....	16
3.3.1 Connecting the Endoscope Cable .....	17
3.3.2 Connecting the Light Source .....	18
3.3.3 Connecting the Image Processor.....	18
3.3.4 Connecting the Water Bottle.....	19
3.3.5 Connecting the Suction Pump.....	19
3.3.6 Connecting the Auxiliary Water-feeding Tube .....	20

3.4 Inspecting the Endoscopy System .....	21
3.4.1 Inspecting the Image .....	21
3.4.2 Inspecting the Air Feeding Function .....	21
3.4.3 Inspecting the Water Feeding Function .....	22
3.4.4 Inspecting the Suction Function .....	22
3.4.5 Inspecting the Instrument Channel .....	23
<b>Chapter 4 Operations .....</b>	<b>25</b>
4.1 General Operations .....	26
4.1.1 Inserting the Endoscope .....	26
4.1.2 Adjusting the Angle of Bending Section .....	27
4.1.3 Feeding Air/Water and Aspirating .....	27
4.1.4 Feeding Water Through the Auxiliary Water-feeding Port .....	28
4.2 Auxiliary Operations .....	28
4.2.1 Using the Biopsy Forceps .....	29
4.2.2 Using the Cytology Brush .....	29
4.2.3 Using the Syringe .....	29
4.3 Ending the Operation .....	30
<b>Chapter 5 Cleaning and Disinfection .....</b>	<b>31</b>
5.1 Detergent and Disinfectant .....	34
5.1.1 Detergent .....	35
5.1.2 Disinfectant .....	35
5.1.3 Flushing Fluid .....	36
5.2 Cleaning and Disinfection Tools .....	36
5.3 Accessory Inspection and Connection .....	36
5.3.1 Waterproof Cap .....	37
5.3.2 Channel Plug .....	38
5.3.3 Injection Tube .....	39
5.3.4 Cleaning Brush .....	40
5.3.5 Leakage Detector .....	41
5.4 Pre-cleaning .....	41
5.5 Leakage Test .....	42
5.6 Manual Cleaning .....	43
5.7 Rinsing .....	46
5.8 High-Level Disinfection .....	46

---

5.8.1 Automatic Disinfection .....	46
5.8.2 Manual Disinfection .....	47
5.9 Sterilization .....	50
5.10 Terminal Rinsing.....	51
5.11 Drying .....	52
<b>Chapter 6 Storage and Disposal .....</b>	<b>53</b>
6.1 Storage .....	54
6.1.1 Storing the Endoscope .....	54
6.1.2 Storing the Accessories.....	54
6.2 Transportation .....	55
6.2.1 Indoor Transportation .....	55
6.2.2 Outdoor Transportation.....	55
6.3 Disposal .....	55
6.4 Customer Service.....	55
<b>Chapter 7 Troubleshooting.....</b>	<b>57</b>
<b>Appendix A Specifications.....</b>	<b>61</b>
<b>Appendix B EMC Guidance and Manufacturer’s Declaration .....</b>	<b>63</b>
B. 1 Electromagnetic Emissions .....	63
B. 2 Electromagnetic Immunity.....	64
B. 3 Recommended Separation Distances between Portable and Mobile and RF Communications Equipment and the Equipment.....	66

*This page is intentionally left blank.*

# Chapter 1 Safety

This chapter describes important information for operating this endoscope. To ensure the safety of both operator and patient, please read the relevant details in this chapter carefully before using this endoscope.

The operator should be thoroughly familiar with the precautions provided in this manual. Otherwise, the manufacturer is not responsible for the effects on safety, reliability and performance of the endoscope.

## 1.1 Intended Use

The video colonoscope (hereinafter called endoscope) is intended for use in examination and diagnosis of the lower digestive tract (including the anus, rectum, colon and ileocecal valve).

## 1.2 Contraindications

Please do not use the endoscope in the following cases.

- Severe lower digestive obstruction and difficult exhaust or defecation.
- Organic mental disorders and non-cooperated patient.
- Severe disabled cardiopulmonary functions.
- Abdominal hernia or incision hernia.
- Suspicious colon perforation.
- Difficult insertion due to anus or rectal deformity or high-degree narrow.
- Severe spine deformity.

## 1.3 Product Compatibility

The endoscope is used with HD-500 image processor, HDL-330, HDL-330E or HDL-500E series light source, monitor, and recording device provided by the manufacturer.

## 1.4 Safety Precautions

Read and understand all precautions in this manual before attempting to use the endoscope. Keep this manual with the endoscope at all times. Periodically review the procedures for operation and safety precautions.

### 1.4.1 General Warnings



- **WARNING** Only the operator qualified and approved by hospital administrators or other official institutions can perform the endoscopy.
- Only the personnel authorized or trained by the manufacturer can maintain the endoscope. Any unauthorized personnel should not assemble or disassemble the endoscope.
- Do not operate this endoscope in an atmosphere containing flammable gases such as anesthetic gases, hydrogen, and ethanol, because there is a danger of explosion.
- Once hospital administrators or official institutions (such as the endoscopic academics) develop the application standard and operating procedures, the operator should perform the endoscopy in accordance with them.
- The physician should thoroughly evaluate the property, purpose, benefit and risks (including medical risks, unknown risks and the possibility) before performing the endoscopy. Perform the endoscopy only when benefit outweigh risks.



- The physician should make a detailed explanation to the patient about the benefit and risks of the examination and diagnosis, as well as the methods to be applied.
- Only perform the endoscopy with the patient's consent.
- Once start performing the endoscopy, the physician should evaluate potential benefit and risks all the time. Stop performing the endoscopy immediately and take measures when risks outweigh benefit.
- The physician should perform the endoscopy in accordance with the standards and principles developed by endoscopic academic institutions. Therefore, any endoscopic clinical technologies are not detailed in this manual.
- Do not use this endoscope around strong electric field, strong electromagnetic field and mobile wireless communication devices. Using the endoscope in improper environment may result in malfunction or damage.
- Only the peripherals (such as image processor, light source and etc.) provided or recommended by the manufacturer can be used. Using other devices may increase the RF radiation and degrade the system performance of resisting the electromagnetic interference.
- The endoscope is not strictly cleaned and disinfected in the factory. Therefore, the operator should strictly perform the cleaning and disinfection procedures described in this manual before use.
- To ensure the safety and functionality of the endoscope, a periodical maintenance should be performed as described in the manual.
- Disposable supplies can only be used for one time.
- The operator should prepare a spare endoscope in case of endoscope malfunction.
- Only the accessories provided or approved by the manufacturer can be used. Using other accessories may damage the endoscope and cannot achieve the expected performance described in this manual.
- The endoscope should be maintained and stored as described in the manual. Using an improperly maintained or stored endoscope may cause disease infection, product damage or performance degradation.
- When the endoscope is used with the electrosurgical accessories (such as high frequency electrotome), current leakage to the patient may be increased. Please use the accessories with the safety protection type of at least Type BF.
- Ensure that no flammable gas exists in patient body when using other accessories (such as high frequency surgical instruments). Otherwise, there is a danger of explosion.
- Do not use the peak voltage higher than the rated one when using the high frequency surgical instruments. The maximum peak voltages in the following modes are:
  - \* Electrosurgical knife mode: 800V
  - \* Mixed mode: 900V
  - \* Coagulation electrode mode: 500V










### 1.4.2 Biohazard Considerations



- Patients debris and chemicals for cleaning and disinfection are potentially dangerous. The operator should wear the medical protective clothing, goggle or gloves to minimize the risk of cross-contamination and disease infection. Take off the medical protective barriers before leaving the cleaning and disinfection room.
- The operator should take cautions to prevent the direct contact with the disinfectant or patient samples. If your skin is stained with them, thoroughly wash the area immediately with clean water. If the fluid comes into your eyes, immediately flush the eyes with water and seek the oculist for help.
- Dispose of the disinfectants, the strengthened cleaner and waste solution in accordance with the local laws or regulations. For details, please consult the manufacturer or the sales representative of the manufacturer.

## 1.5 Safety Symbols

The following table is provided for your identification of important symbols located in labels on the endoscope.

Symbol	Meaning
	Follow instructions for use
	Caution
	Date of manufacture
	Manufacturer
	Serial Number
<b>IPN<sub>1</sub>N<sub>2</sub></b>	Degree of IP protection
	Non-ionizing electromagnetic radiation.
	This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC.
	Type BF Applied Part
	Authorized representative in the European community

## **Chapter 2 Overview**

The endoscope is the hand-held, direct-viewing type.

To ensure the performance and availability of this endoscope, you should be thoroughly familiar with the operations of all components of the endoscope.

## 2.1 System Configuration

### 2.1.1 System Composition

The endoscope consists of the following parts.

- Distal end
- Insertion section
- Control section
- Connector section

### 2.1.2 Accessory List

The accessory list of the endoscope is as follows.

- Biopsy valve
- Injection tube
- Channel plug
- Distal end cap
- Waterproof cap
- Others: See the Packing List in the packaging box.

**NOTE:**

- The endoscope is not disinfected in the factory. Please preprocess the endoscope as described in this user manual before the initial use. For details, refer to Chapter 5 Cleaning and Disinfection.
- This user manual provides operating instructions for EC-500 series products, but some specifications of the products are not the same. For details, please refer to Appendix A Specifications.

## 2.2 Endoscope Overview

The endoscope consists of connector section, control section, insertion section and distal end.

### 2.2.1 Connector Section

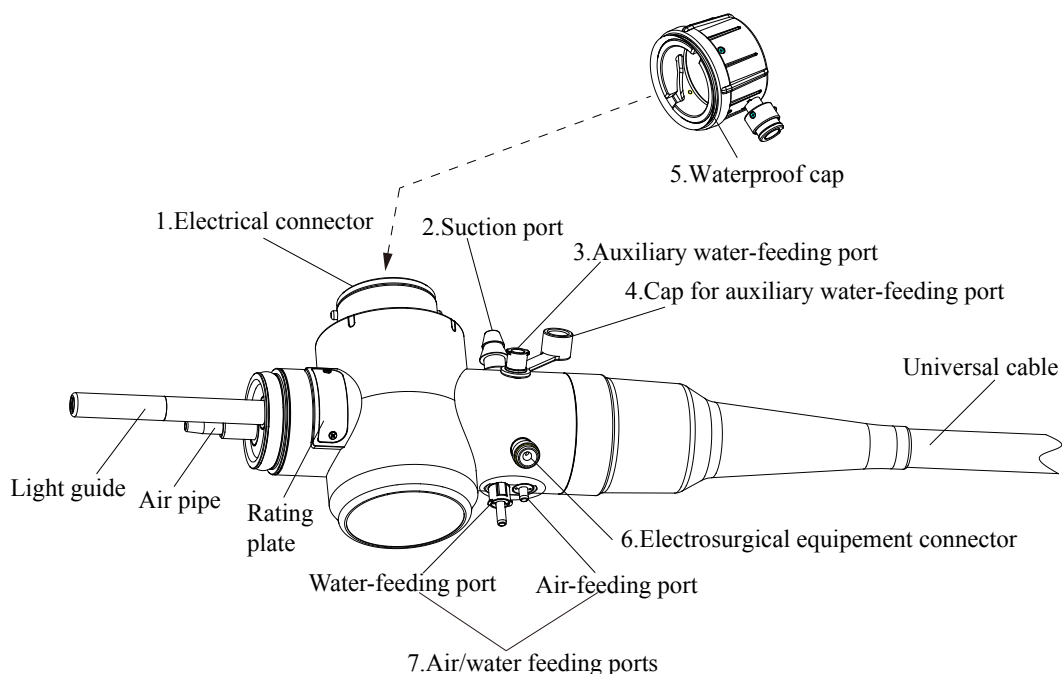


Figure 2-1 Connector Section

No.	Part Name	Descriptions
1	Electrical connector	Used for connecting the endoscope cable to acquire video signal of image.
2	Suction port	Used for connecting to the suction pump.
3	Auxiliary water-feeding port	Used for connecting to water pump or syringe to make water or solution jet from the distal end.
4	Cap for auxiliary water-feeding port	Used for protecting the auxiliary water-feeding port from being blocked by foreign objects. Cover the auxiliary water-feeding port with the cap when the port is not in use.
5	Waterproof cap	Install it to the electrical connector when immersing the endoscope for cleaning and disinfection.
6	Electrosurgical equipment connector	Used for connecting the electrosurgical equipment.
7	Air/water feeding ports	Used for connecting to the water bottle to feed water/air to the distal end.

### 2.2.2 Control and Insertion Section

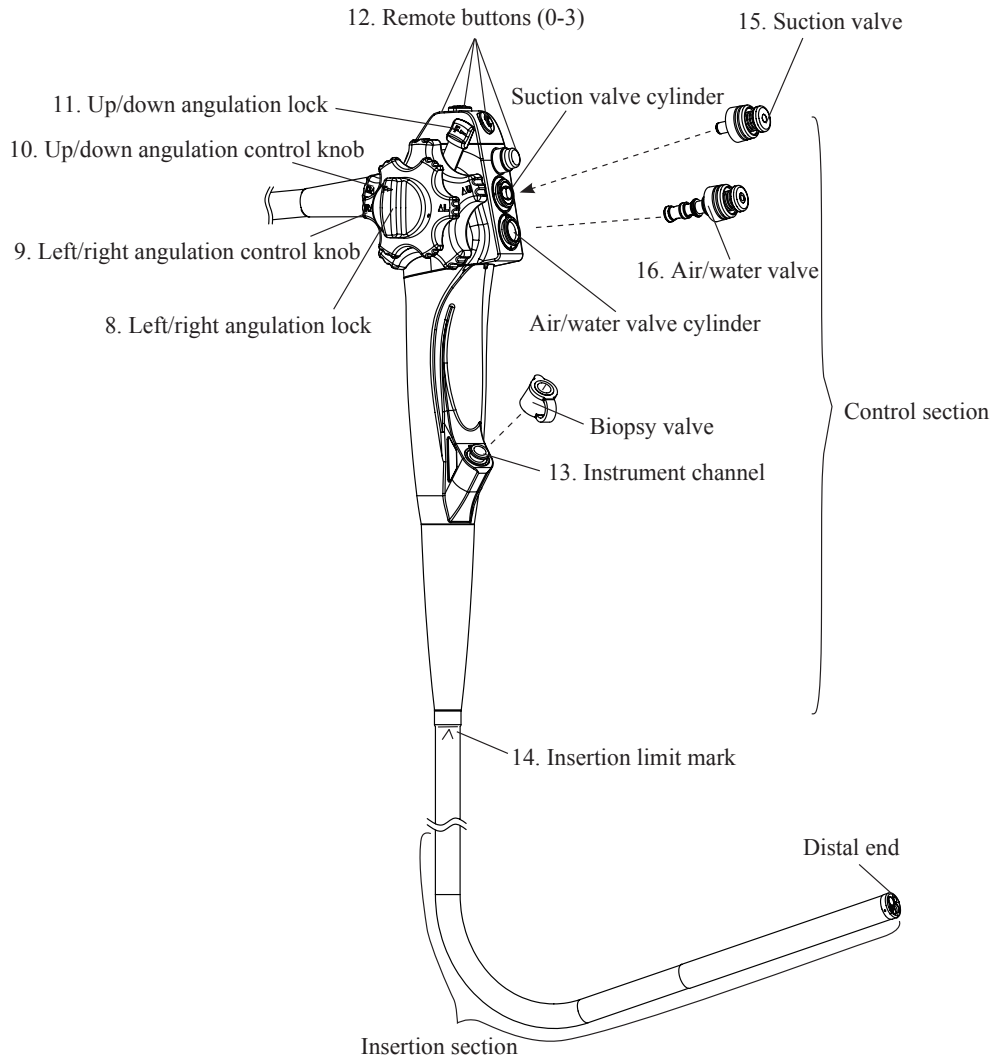


Figure 2-2 Control and Insertion Sections

No.	Part Name	Descriptions
8	Left/right angulation lock	<ul style="list-style-type: none"> <li>Rotating it to F ► direction (clockwise) frees angulation in the left/right direction.</li> <li>Rotating it in the opposite direction (anticlockwise) locks the bending section at any desired angle.</li> </ul>
9	Left/right angulation control knob	<ul style="list-style-type: none"> <li>Rotating it to R ▲ direction makes the bending section move right.</li> <li>Rotating it to L ▲ direction makes the bending section move left.</li> </ul>

No.	Part Name	Descriptions
10	Up/down angulation lock	<ul style="list-style-type: none"> <li>Rotating it to F ► direction (clockwise) frees angulation in the up/down direction.</li> <li>Rotating it in the opposite direction (anticlockwise) locks the bending section at any desired angle.</li> </ul>
11	Up/down angulation control knob	<ul style="list-style-type: none"> <li>Rotating it to U ▲ direction makes the bending section move up.</li> <li>Rotating it to D ▲ direction makes the bending section move down.</li> </ul>
12	Remote buttons (0-3)	The functions of these buttons can be set through the image processor used with the endoscope. For details, refer to the user manual of relevant image processor.
13	Instrument channel	<p>This channel should be used with the biopsy valve and the functions are as follows.</p> <ul style="list-style-type: none"> <li>Used to feed the liquid to the distal end of the endoscope.</li> <li>Used for the endo-therapy accessory.</li> <li>Used as a suction channel.</li> </ul>
14	Insertion limit mark	Indicates the maximum length of the insertion section that can be inserted into the body.
15	Suction valve	Press it to aspirate the liquid, debris or gas from the body.
16	Air/water valve	<ul style="list-style-type: none"> <li>Cover the hole on the valve with finger to feed air and press the valve to feed water.</li> <li>The air and water can remove the blood, debris or mucous membrane adhering to the objective lens.</li> </ul>

### 2.2.3 Distal End

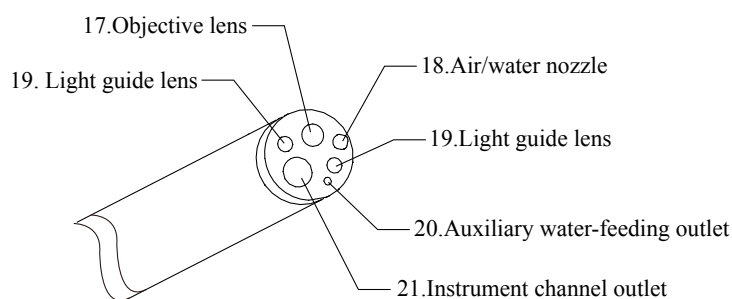


Figure 2-3 Distal End

No.	Part Name	Descriptions
17	Objective lens	Used to transmit the optical signal of the object to be observed inside human body to the CMOS sensor.
18	Air/water nozzle	The air or water will be fed to the distal end through this nozzle.
19	Light guide lens	Light is transmitted through these lenses for observing image.
20	Auxiliary water-feeding outlet	Water or solution spurts out from this outlet.
21	Instrument channel outlet	Used as instrument outlet (such as biopsy forceps), liquid feeding outlet, or suction inlet.



## **Chapter 3 Preparations**

Preparations are necessary before use, which include inspecting and connecting the endoscope and accessories.

Strictly follow the descriptions below to inspect the endoscope and accessories before each use and inspect the peripherals used with this endoscope by following their own user manuals. In case of a problem, solve the problem by referring to Chapter 7 Troubleshooting. If the problem persists, please contact the sales representative of the manufacturer.



- WARNING**
- The endoscope is not disinfected in the factory. Therefore, the operator should strictly follow the relevant descriptions in this manual to clean and disinfect the endoscope before the initial use.
  - For the safety of the patient and operator, do not use the damaged endoscope.
  - To ensure the functionality of the endoscope, the operator should inspect the endoscope once every three months.

### 3.1 Inspecting the Endoscope

The operator should clean and disinfect the endoscope and then take off the waterproof cap before inspection.

#### 3.1.1 Inspecting the Appearance and Flexibility

Perform the following inspections to inspect the appearance and flexibility.

- Ensure that there is no scratch, deformation or slack on the control section or the connectors.
- Ensure that there is no abnormal bend or twist on the insertion section.
- Touch the entire insertion section backwards and forwards gently to ensure that there is no dents, bulges, swelling, scratches, breakages, deformation, adhesion of foreign bodies, component missing or peeling.
- Hold the insertion section with two hands and bend it to a semicircle to ensure that the entire insertion section is flexible and can be smoothly bent.
- Ensure that there is no scratches or breakages on the objective lens and light guide lenses, and no spots or cracks on the surface of the distal end.
- Ensure that there is no dents, protrusion or bulge on the air/water nozzle and the instrument channel outlet located on the distal end.

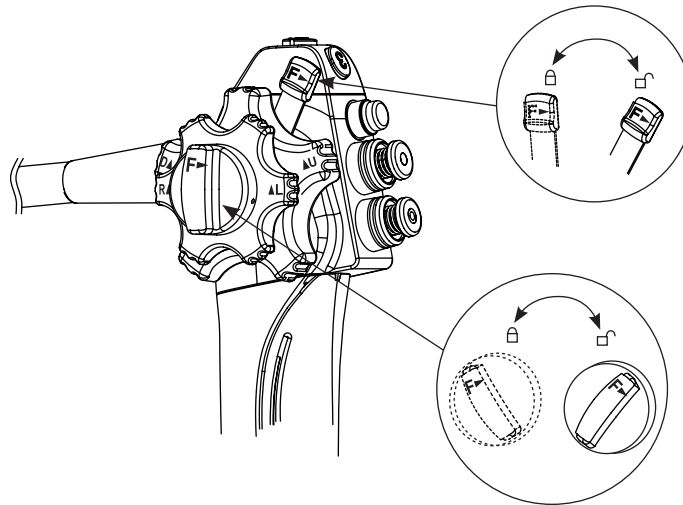
#### 3.1.2 Inspecting the Angulation



- WARNING** Do not use the endoscope if its bending section is hard to be angulated due to the loose steel wire or the damaged angulation control knob. Otherwise, it may result in patient injury.

Perform the following inspections only when the bending section is free.

- To inspect the flexibility
  1. Rotate the up/down and left/right angulation locks clockwise until they stop to ensure that the bending section is free.



2. Rotate the up/down and left/right angulation control knobs respectively until they stop to ensure that the bending section can be flexibly and properly bent, and slowly restore to almost its original position after the knobs are loosened.
- To inspect up/down angulation
1. Rotate the up/down angulation lock clockwise until it stops, and then rotate the up/down angulation control knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move up and down and reach its maximum angle.
  2. Rotate the up/down angulation lock anticlockwise until it stops to ensure that the bending section can be fixed at the desired angle.
  3. When the bending section is fixed, rotate the up/down angulation lock clockwise until it stops to ensure that the bending section can restore to its original position.
- To inspect left/right angulation
1. Rotate the left/right angulation lock clockwise until it stops, and then rotate the left/right angulation control knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move to the left and right and reach its maximum angle.
  2. Rotate the left/right angulation lock anticlockwise until it stops to ensure that the bending section can be fixed at the desired angle.
  3. When the bending section is fixed, rotate the left/right angulation lock clockwise until it stops to ensure that the bending section can restore to its original position.

## 3.2 Inspecting and Connecting the Accessories

The accessories include the ones for clinical examination, cleaning and disinfection. This section only introduces the clinical ones. For other accessories, please refer to 5.2 Cleaning and Disinfection Tools.

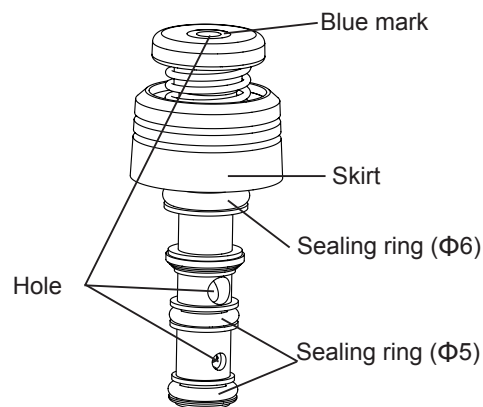
### 3.2.1 Air/Water Valve

The operator should clean and disinfect the air/water valve before inspection. For details, refer to Chapter 5 Cleaning and Disinfection.



**WARNING** Ensure that the hole on top of the air/water valve is not blocked. Otherwise, air is continuously fed into the patient body and it may result in patient injury.

#### ■ Inspection



- Ensure that holes are not blocked.
- Ensure that the valve is not deformed or damaged.
- Ensure that the sealing rings are not cracked, scratched or damaged.

#### **NOTE:**

If the air/water feeding function is abnormal, the operator should replace the sealing ring immediately.

#### ■ Installation

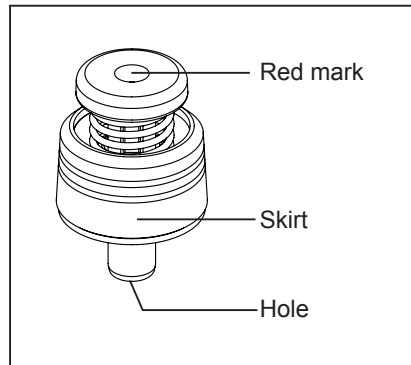
Install the air/water valve to the air/water valve cylinder of the endoscope properly.

#### **NOTE:**

- Do not apply lubricant on the air/water valve. Otherwise, the sealing ring may bulge to cause the valve malfunction.
- The air/water valve may be sticky for the initial use. After being pressed and released several times, it can be operated smoothly.
- Blue mark is used to distinguish this valve from the suction valve of the endoscope.

### 3.2.2 Suction Valve

#### ■ Inspection



Ensure that the valve is not cracked, deformed or damaged.

#### ■ Installation

1. Install the suction valve to the suction valve cylinder of the endoscope properly.
2. Ensure that there is no protrusion on the valve skirt, and the valve is firmly installed.

#### NOTE:

- Noise may be heard during use if the suction valve is dry. Therefore, it is recommended that the suction valve shaft be lubricated at regular intervals by using the lubricant provided by the manufacturer.
- The lubricant provided by the manufacturer can only be used to lubricate the suction valve shaft.
- Red mark is used to distinguish this valve from the air/water valve of the endoscope.

### 3.2.3 Biopsy Valve



**WARNING** The operator should ensure that the cap of the biopsy valve is intact before each use. If any abnormality is found, replace the biopsy valve immediately. Otherwise, the damaged biopsy valve may degrade the suction performance of the endoscope, which may result in the spray or leakage of patient debris or body liquid and disease infection.

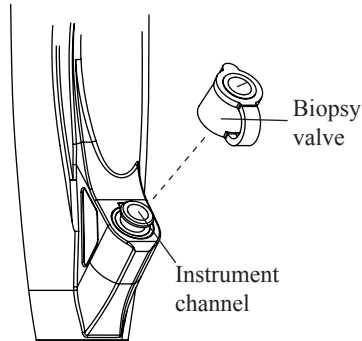
#### ■ To inspect the biopsy valve



- Ensure that the valve is not deformed or damaged.
- Ensure that the main body and the cap are connected firmly.

■ To install the biopsy valve

1. Cover the cap and ensure that the cap is firmly connected to the main body.



2. Install the biopsy valve to the instrument channel of the endoscope properly.

### 3.3 Connecting the Endoscopy System

**NOTE:**

Ensure that the peripherals are properly connected to the endoscope. For the detailed description about inspection and connection of the peripherals, please refer to relevant user manuals.

Connect the endoscopy system, as shown in Figure 3-1.

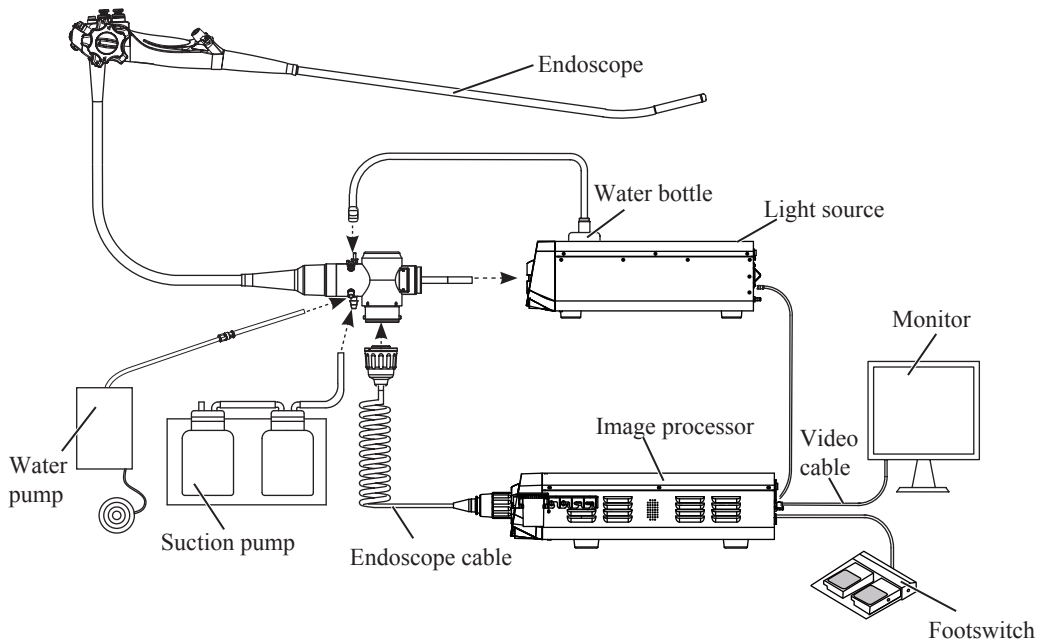


Figure 3-1 Connection of the Endoscopy System

### 3.3.1 Connecting the Endoscope Cable

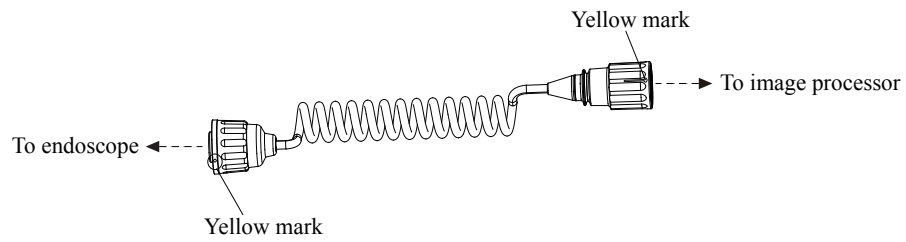


Figure 3-2 Endoscope Cable

Perform the following steps to connect the endoscope cable.

1. Align the two yellow marks on the endoscope cable connector and electrical connector of the endoscope, and connect the connector to the endoscope.

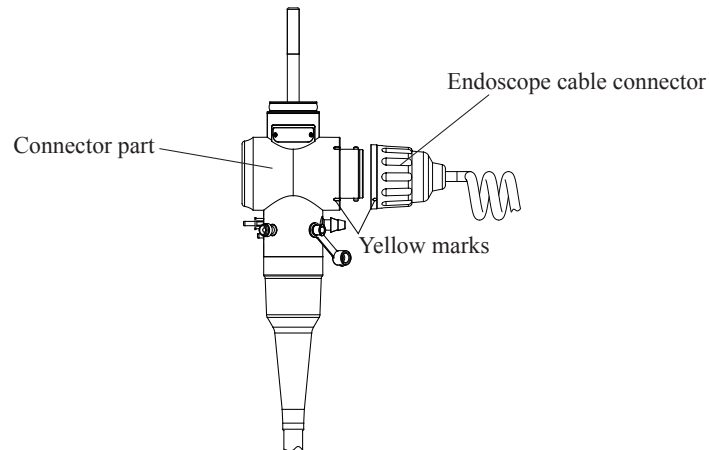


Figure 3-3 Endoscope Cable Connection 1

2. Rotate the connector clockwise and align the two yellow marks on the connector and on the electrical connector of the endoscope until you hear a click.

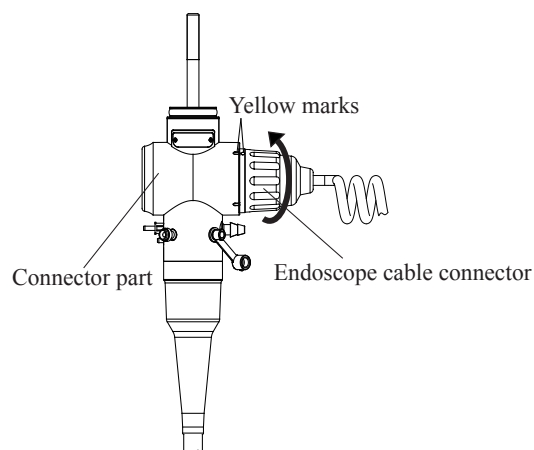
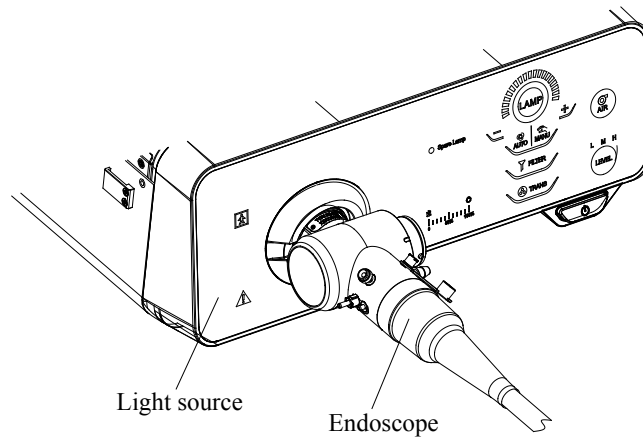


Figure 3-4 Endoscope Cable Connection 2

### 3.3.2 Connecting the Light Source

Insert the air pipe and light guide of the endoscope into the endoscope port of the light source firmly.



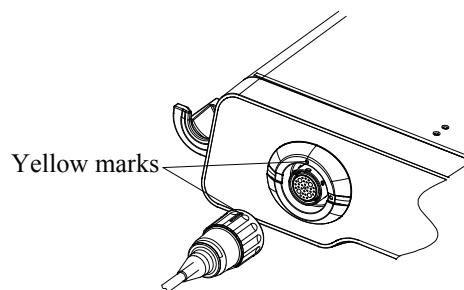
### 3.3.3 Connecting the Image Processor

**NOTE:**

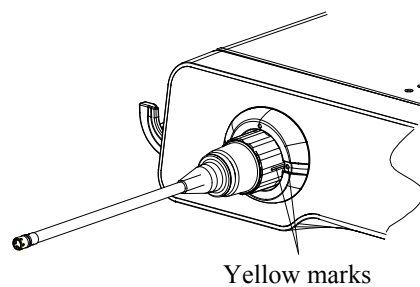
- Power off the image processor before connection. Otherwise, the image processor could be damaged or malfunctioned, and the data may be lost.
- Do not use the endoscope cable forcibly to avoid damage.
- Do not touch the pins inside the connector of the endoscope cable to avoid damage.

Perform the following steps to connect the endoscope to the image processor.

1. Align the yellow mark on the endoscope cable connector with the one on the connector socket of the image processor. Connect the connector to the socket firmly.



2. Rotate the connector clockwise until the mark on the connector is aligned with the other mark on the socket.





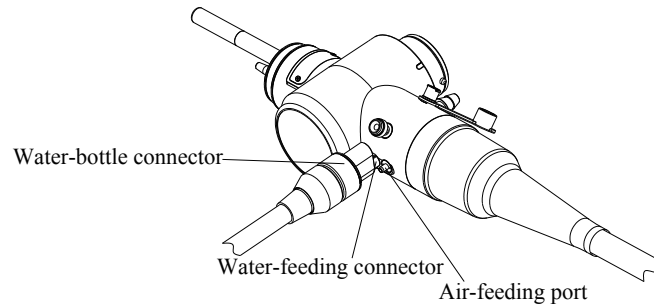
### 3.3.4 Connecting the Water Bottle



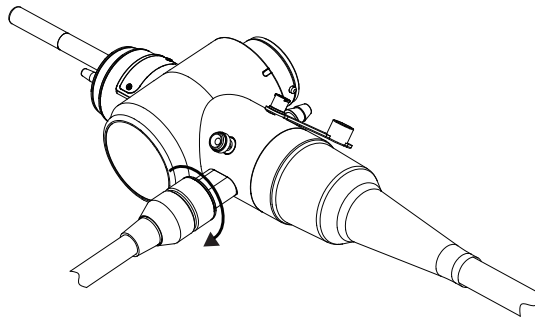
**CAUTION** The water bottle should be installed in the water bottle bracket at the right side of the light source.

Perform the following steps to connect the water bottle to the endoscope.

1. Connect the water-feeding connector of water bottle connector to the water-feeding port firmly.



2. Rotate the water bottle connector 90 degrees clockwise until the air-feeding connector is aligned with the air-feeding port. Connect them firmly.



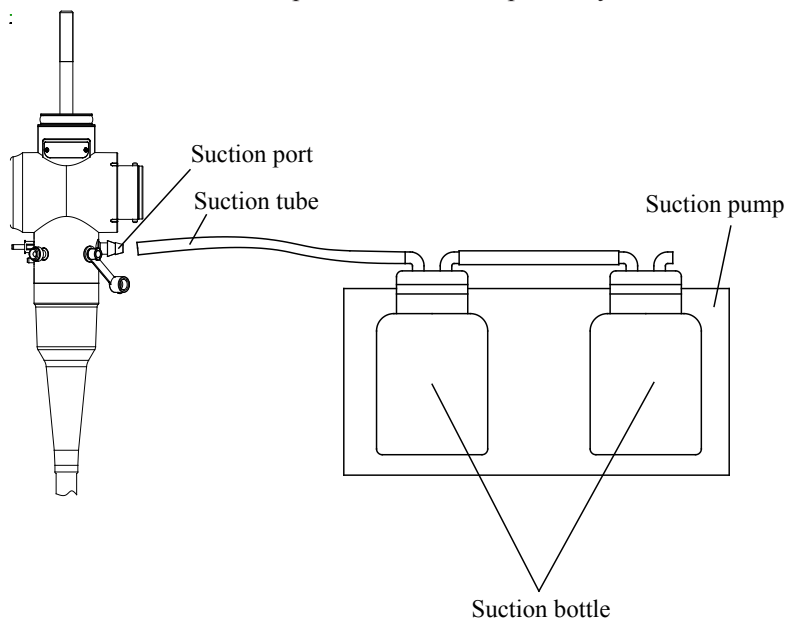
3. Ensure the water bottle connector is correctly connected and cannot be turned.

### 3.3.5 Connecting the Suction Pump



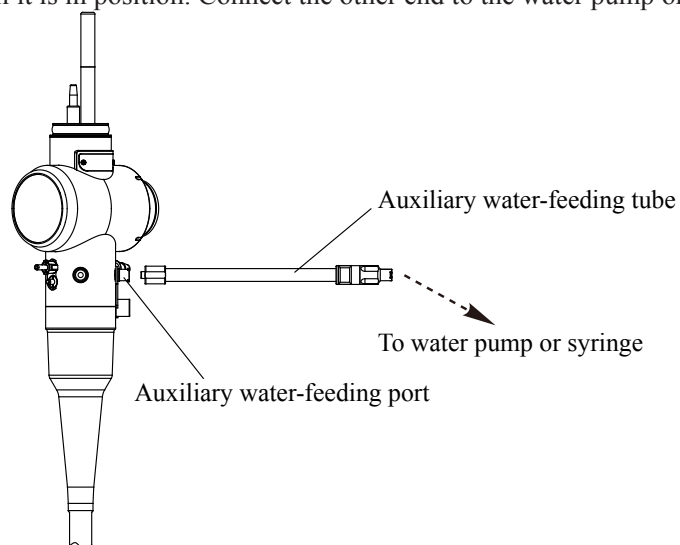
- WARNING**
- If the suction tube is not connected firmly, patient debris may leak from the tube during use and cause disease infection, suction degradation, and equipment damage.
  - If any malfunction occurs during the use, please turn off the suction pump immediately.

Connect the suction tube to the suction port of the endoscope firmly.



### 3.3.6 Connecting the Auxiliary Water-feeding Tube

Connect one end of the auxiliary water-feeding tube to the auxiliary water-feeding port and rotate the tube clockwise until it is in position. Connect the other end to the water pump or syringe.



## 3.4 Inspecting the Endoscopy System

### 3.4.1 Inspecting the Image



**WARNING** Do not look at the light emitted from the distal end straight. Otherwise, it may result in eye injury.

Perform the following steps to inspect the image.

1. Power on the light source, the image processor and the monitor.
2. Press **LAMP** on the light source and ensure that light is emitted from the distal end.
3. Place the distal end 10mm away from your palm and observe the image on the monitor while adjusting the brightness of the image by using relevant buttons on the image processor and the monitor.
4. Adjust the observation angle of the endoscope, and ensure that the image does not disappear suddenly and no exception occurs.

**NOTE:**

If the endoscopic image is unclear because the lens is dirty, use a soft lint-free cloth dampened with 70% ethyl alcohol to wipe the lens.

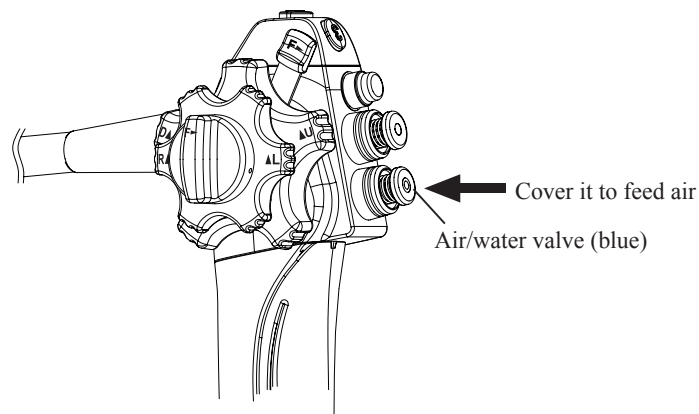
### 3.4.2 Inspecting the Air Feeding Function



**WARNING** Use sterile water to inspect the air feeding function to avoid disease infection.

Perform the following steps to inspect the air feeding function.

1. Press **AIR** on the light source to turn on the air pump.
2. Immerse the distal end of the endoscope in a container filled with the sterile water to a depth of 10cm. Do not operate the air/water valve and ensure that no bubble is emitted from the air/water nozzle.
3. Cover the hole on the air/water valve with finger to feed air. Ensure that continuous bubbles are emitted from the air/water nozzle.




4. Release the finger and ensure that no bubble is emitted from the air/water nozzle.

**NOTE:**

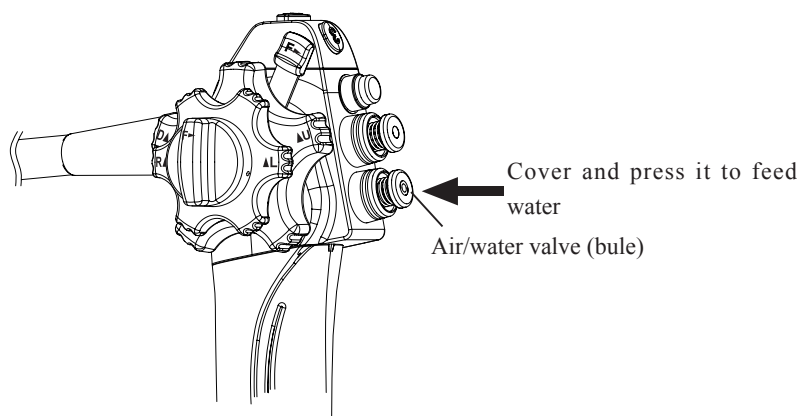
When the distal end of the endoscope is immersed in the water at a depth less than 10cm, a few bubbles will be emitted even if the air/water valve is not pressed. It is not malfunction.

### 3.4.3 Inspecting the Water Feeding Function

 **WARNING** Use sterile water to inspect the water feeding function to avoid disease infection.

Perform the following steps to inspect the water feeding function.

1. Cover the hole on the air/water valve with finger and press this valve to feed water. Observe the image on the monitor and ensure that water flows over the objective lens.




2. Release the finger and ensure that no water is sprayed and the air/water valve restores to its original position smoothly.
3. Cover the hole and press the air/water valve again to feed water. Release the valve and cover the hole to feed air. Ensure that the residual water can be cleared away from the objective lens and the image on the monitor is clear.

**NOTE:**

- If the air/water valve is pressed for the first time, it may take a few seconds before water is fed.
- If the air/water valve restores to the original position very slowly after water feeding, the operator should remove the air/water valve and moisten the sealing ring with sterile water.

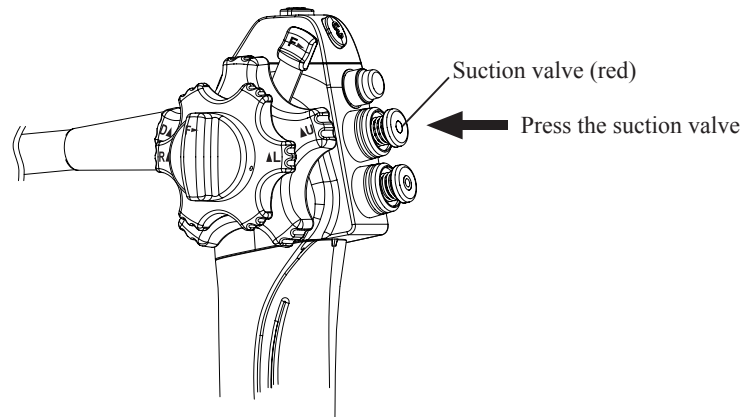
### 3.4.4 Inspecting the Suction Function

 **WARNING** • If the biopsy valve is leaky, patient debris and body liquid could leak out and cause disease infection.

- If the suction valve cannot be operated smoothly, it may result in suction malfunction and patient injury. Please re-install the suction valve or change a new one. If the problem still exists after the replacement, the endoscope may be malfunctioning. Please stop using the endoscope and contact the sales representative of the manufacturer.

Perform the following steps to inspect the suction function.

1. Adjust the suction pressure to the clinical standard.
2. Immerse the distal end in the sterile water and place the opening of instrument channel at the same height as the water level in the container filled with sterile water.
3. Press the suction valve and ensure that the water can be continuously extracted to the suction bottle.



4. Release the suction valve and ensure that the suction is stopped and the suction valve restores to the original position.
5. Press and hold the suction valve for a few seconds, and then release the valve. Repeat the operations for several times and ensure that no water leaks from the biopsy valve.
6. Take out the distal end from the container and press the suction valve to aspirate air for a few seconds to drain the water from the instrument channel and suction channel.

### 3.4.5 Inspecting the Instrument Channel



**WARNING** Keep your eyes away from the distal end when the biopsy forceps or other internal endo-therapy accessories are extracted from the distal end. Otherwise, it may result in eye injury.

Perform the following steps to inspect the instrument channel.

1. Insert the endo-therapy accessory into the opening of instrument channel. Ensure that the instrument can be successfully extracted from the distal end without foreign object.
2. Ensure that the instrument can be successfully withdrawn from the opening of instrument channel.

*This page is intentionally left blank.*

## **Chapter 4 Operations**

The operator of this endoscope must be a physician or the medical personnel who operates under the supervision of the physician and must have received sufficient training in clinical endoscope technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope.

**WARNING**

- Patients debris and chemicals for cleaning and disinfection are potentially dangerous. The operator should wear the medical protective clothing, goggle or gloves to minimize the risk of cross-contamination and disease infection.
- Disconnect the endoscope from the light source after use to avoid accident.
- The surface temperature of the distal end of the endoscope may exceed 41°C and reach 50°C due to intense illumination, which may cause mucosal burns. Always use the required level of illumination, time and distance to examine the patient.
- Do not insert or withdraw the endoscope in any of the following cases. Otherwise, it may result in patient injury.
  - When the biopsy forceps are extracted from the distal end.
  - When the bending section of the endoscope is fixed.
  - When it is hard to insert or withdraw the endoscope, or the patient feels pain.
- The patient should take off metallic accessories (watch, glasses, necklace and etc.) before the endoscopy when high frequency cauterization treatment is performed. Otherwise, it may result in skin burns around the accessories.
- Before using the endoscope, the operator should ensure that the endoscope can be operated properly. If any abnormality is found on the distal during the endoscopy, the operator should stop using the endoscope immediately and slowly withdraw it from the patient body to avoid patient injury.
- Do not operate the angulation control knob forcibly. Otherwise, the bending section could be inversely bent and it may result in patient injury.
- If the image is unclear or frozen, the operator should not operate the bending section of the endoscope, feed air or insert/withdraw the insertion section. Otherwise, it may result in patient injury.
- If the image or the function is abnormal, stop examining even if the abnormality disappears rapidly. Slowly withdraw the endoscope from the patient body while observing the image. Otherwise, the abnormality may occur again and it may result in patient injury.
- Before examining a patient with the endoscope, the doctor shall fully explain the risks of the examination to the patient and ask the patient to sign an informed consent form.

## 4.1 General Operations

### 4.1.1 Inserting the Endoscope

Perform the following steps to insert the endoscope.

1. Hold the control section of the endoscope with your left hand and operate the air/water valve, the suction valve and the remote buttons with the index finger, rotate the up/down and left/right angulation control knobs with the thumb. Operate the insertion section and the left/right and up/down angulation locks with your right hand.
2. If necessary, use the medical-grade water-soluble lubricant on the insertion section.
3. Turn on the lamp of the light source.



4. Observe the whole endoscope insertion process from the anus to colon on the monitor carefully. Do not insert the insertion tube beyond its limit mark.

#### 4.1.2 Adjusting the Angle of Bending Section



- WARNING**
- Do not rapidly change the angle of the bending section during use. Otherwise, it may result in patient injury.
  - Stop using the endoscope when the patient feels pain. Otherwise, it may result in patient injury.



- CAUTION**
- Do not adjust the angle of the bending section excessively. Otherwise, the steel wire may turn loose or be torn due to the excessive pulling and the bending section may be difficult to be adjusted.

Perform the following steps to adjust the angle of the bending section.

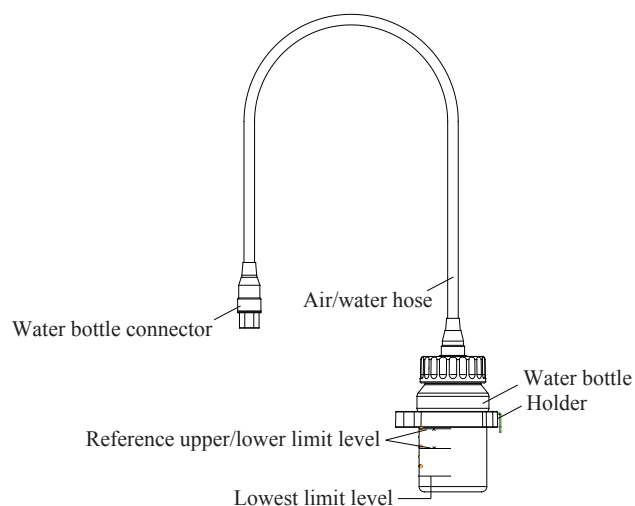
1. Rotate the up/down or left/right angulation control knobs to adjust the bending section to a desired observation angle.
2. Rotate the up/down or left/right angulation lock to fix the bending section.

#### 4.1.3 Feeding Air/Water and Aspirating



- WARNING**
- If the sterile water level in the water bottle is under the lowest limit level during use, add sterile water into the bottle. Do not exceed the reference upper limit level.

The water bottle is shown in the following figure.



- Cover the cap of the biopsy valve firmly before aspiration. Otherwise, the efficacy of the suction system is degraded and the patient debris and body fluid may be leaked, causing disease infection.
- During the process of aspiration, keep the suction pressure at the lowest level required to perform the endoscopy. Excessive suction pressure could cause mucous membrane injury.

- Avoid aspirating solid or sticky matters. Otherwise, it may block instrument channel or suction valve. If the suction valve is blocked, disconnect the suction tube and turn off the suction pump, then remove and clean the suction valve to clear the solid matters.

**NOTE:**

If the endoscope is used at a lower temperature, water vapor may condense on the surface of the objective lens, making the image cloudy. In this case, the operator should raise the temperature of sterile water in the water bottle to 40°C-50°C (104°F-122°F).

■ To feed water/air

1. Cover the hole on the air/water valve to feed air through the air/water nozzle.
2. Press the air/water valve to feed water onto the surface of objective lens.

■ To aspirate



- Empty the suction bottle before use. Otherwise, the overflow liquid may result in the suction pump malfunction.
- Discharge the waste in accordance with the local laws. For details, please consult the sales representative of the manufacturer.

Press the suction valve to aspirate excess liquid and debris in the patient body.

**NOTE:**

If air feeding and suction are performed synchronously, the liquid drops on the objective lens can be removed easily.

#### 4.1.4 Feeding Water Through the Auxiliary Water-feeding Port

Use a water pump or syringe to feed water to the endoscope through the auxiliary water-feeding port. The distal end of the endoscope spurts out water to flush the blood and debris attached to the mucosa.

## 4.2 Auxiliary Operations



- When using the endo-therapy accessory, the distance between the distal end of the endoscope and the mucous membrane should be longer than the minimum visible distance to ensure that the accessory can be observed in the image. Otherwise, it may result in serious injury or endoscope damage.
- If it is difficult to insert or withdraw the endo-therapy accessory, you should straighten the bending section while observing the image. Inserting or withdrawing endo-therapy accessory forcibly may damage the instrument channel or the endo-therapy accessory.
- Do not forcibly or suddenly insert the endo-therapy accessory. Otherwise, the endo-therapy accessory extracted from the distal end may injure the patient.

- Do not inject excessive air or any non-flammable gas into the patient body during the endo-therapy operation. It may result in air block.
- Do not hang the endo-therapy accessory on the biopsy valve to avoid damage.

#### 4.2.1 Using the Biopsy Forceps



- WARNING**
- Do not open the claws of the biopsy forceps if they are not visible on the image. Otherwise, it may result in patient injury.
  - When inserting or withdrawing the biopsy forceps, ensure that the claws are closed. Slowly and straightly insert or withdraw the endo-therapy accessory into/from the instrument channel. Otherwise, the biopsy valve may be damaged and the biopsy tissues could fall off.
  - The biopsy forceps are disposable.

Perform the following steps to use the biopsy forceps.

1. Lock the up/down and left/right angulation control knobs and fix the bending section at the desired angle.
2. Ensure that the claws of the biopsy forceps are closed, and then slowly insert the biopsy forceps into the instrument channel.
3. Observe the image while slowly pushing the control handle of the biopsy forceps to ensure that the biopsy forceps move slowly in the instrument channel.
4. When the biopsy forceps are visible on the image, open the claws to nip the sample of tissue.
5. Slowly withdraw the biopsy forceps from the instrument channel. Ensure that the tissue is nipped securely during the withdrawal.

#### 4.2.2 Using the Cytology Brush

Perform the following steps to use the cytology brush.

1. Lock the up/down and left/right angulation control knobs and fix the bending section at the desired angle.
2. Slowly and gently insert the cytology brush into the instrument channel while observing the image.
3. When the cytology brush is visible on the image, collect the sample by brushing the dropped cell gently.
4. Slowly retract the cytology brush back to the instrument channel and withdraw it from the patient body with the endoscope.
5. Make the smear sample with the cytology brush and then retract the brush from the instrument channel so that the cell on the brush will not fall off.

#### 4.2.3 Using the Syringe

Perform the following steps to use the syringe.

1. Straightly insert the syringe into the instrument channel while observing the image.
2. When the syringe is visible on the image, inject the medicine or spray liquid on the patient tissue.
3. Slowly withdraw the syringe from the instrument channel.

### 4.3 Ending the Operation



**WARNING** If blood is found on the surface of the insertion section after the endoscope is withdrawn, the operator should take care to check the patient body.

Perform the following steps to withdraw the endoscope.

1. Ensure that the bending section of the endoscope is free.
2. Slowly withdraw the endoscope from the patient body while observing the image.

## Chapter 5 Cleaning and Disinfection

This chapter introduces the cleaning and disinfection methods recommended by the manufacturer for the endoscope and accessories.

Many medical science documents have recorded cross infection accidents caused by improper cleaning and disinfection. Therefore, the operator should follow the descriptions in this chapter to clean and disinfect the endoscope and its accessories in a scientific and standard manner. In addition, the operator should be familiar with the following items:

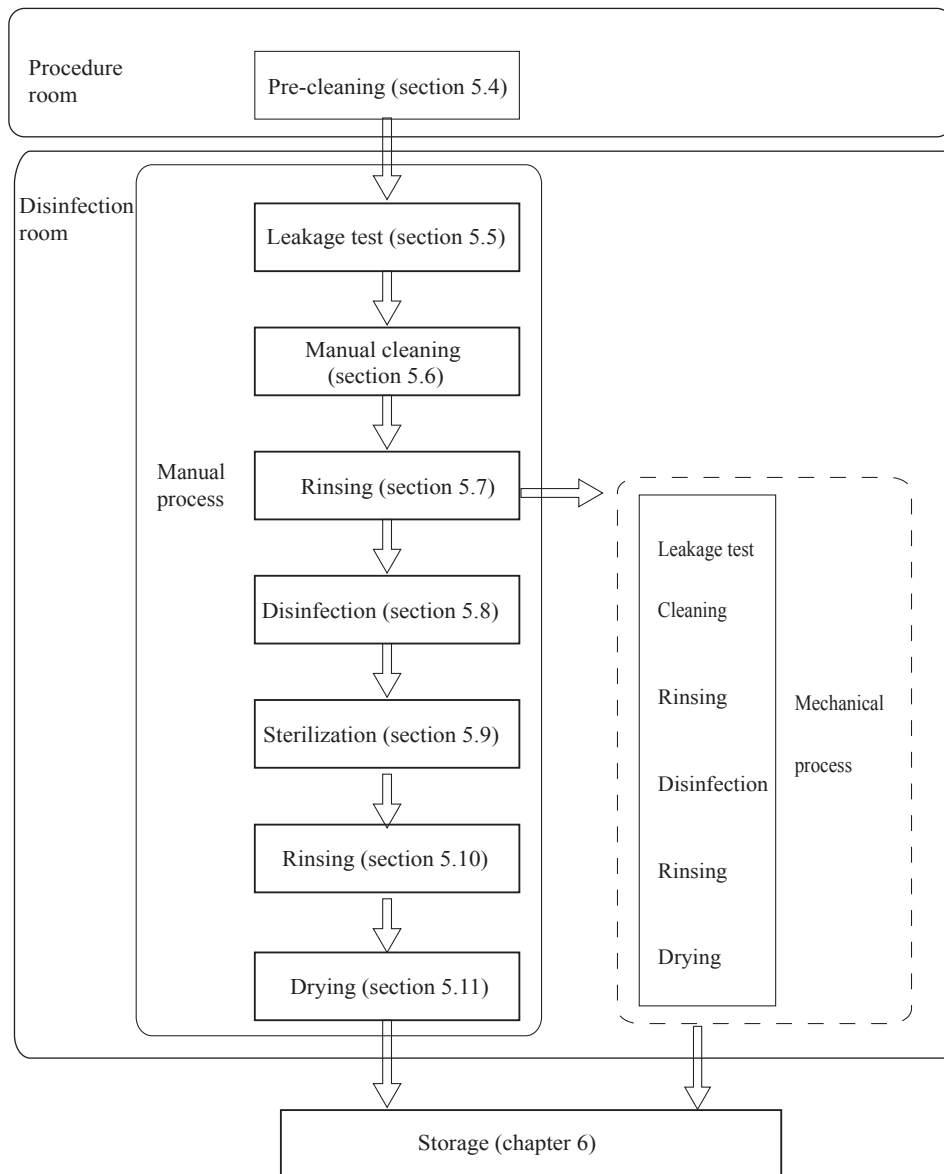
- Occupation health and the safety standards of your hospital
- Cleaning and disinfection standards
- Structures and usages of the endoscope and accessories
- Usage of relevant chemicals

For selecting the type and condition of cleaning and disinfecting the endoscope and accessories, you should refer to the requirements of the local hospital for professional judgment.

**WARNING**

- Patient debris and chemicals for cleaning and disinfection are potentially dangerous. The operator should wear medical protective clothing, goggles or gloves to minimize the risk of cross-contamination and disease infection. Take off the medical protective barriers before leaving the disinfection room.
- The disinfection room should be set separately and isolated from the procedure room. In addition, the disinfection room must have sufficient space and adequate ventilation.
- After being withdrawn from the patient body, the endoscope must be pre-cleaned at the bedside immediately.
- Before use each time, the outer surface, all channels (including the channel not used for diagnosis of the last patient), and accessories of the endoscope should be cleaned and disinfected completely.
- Perform a leakage test before each manual cleaning to prevent the leaky endoscope from being further damaged. When leakage is found, you should return the endoscope to the manufacturer for repair.
- Do not reuse disposable accessories.
- Multiple guidances recommend that the endoscope should be immersed in 2% glutaraldehyde for at least 20min to achieve high-level disinfection. After being used by a patient who is infected with mycobacterium tuberculosis or other mycobacterium, the endoscope should be immersed in 2% glutaraldehyde for at least 45min. The sensitivity of some pathogenic microorganisms to the disinfectant is very low. Therefore, sterilization should be performed as required and the endoscope should even be destroyed by melting or burning when necessary.
- After being contaminated by pathogenic bacteria that are hard to kill, such as prion virus, cryptosporidium, and mycobacterium tuberculosis, the endoscope and its accessories should be destroyed by melting or burning when necessary because they cannot be completely disinfected/sterilized.
- When finding that a patient is infected with unknown super bacteria after use of endoscope, please report the incident as requested by the local health department.
- You should dispose of endo-therapy accessories in accordance with the local laws or regulations.

Perform the following steps to clean and disinfect the endoscope.



## 5.1 Detergent and Disinfectant



- WARNING**
- Use effective and legally marketed detergent and disinfectant in accordance with the local regulations.
  - If you use the disinfectant recommended by the manufacturer, ensure that the disinfectant level and the endoscope soak period meet the recommended conditions in this chapter. Otherwise, the endoscope may be damaged or the expected disinfection effect cannot be achieved. If you have any special purpose or requirement, please ensure that the disinfectant level and the endoscope soak period are suitable for the clinical intended use.
  - Prepare, use, store and dispose the detergent and disinfectant according to the instructions provided by manufacturers.
  - Do not use expired detergent and disinfectant.
  - Do not perform steam sterilization (autoclaving) for the endoscope.
  - Do not dry any disinfectant on the endoscope in air.

### ■ Classification of the disinfection levels

The disinfection classification system first proposed by Dr. E. H. Spaulding classifies medical devices based on the risk of infection in use. This system is widely accepted and is used by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to help determine the degree of disinfection required for various medical devices.

Table 5-1 E. H. Spaulding Classification System

Classification	Definition	Level of Disinfection	Application
Critical	A device that enters normally sterile tissue or the vascular system	Sterilization	Biopsy forceps, snare, injection needle, cytology brush, incision knife, guide wire, dilating balloon, dilating bougie, radiography catheter, and foreign body forceps
Semi-critical	A device that comes in contact with intact mucous membrane and does not ordinarily penetrate sterile tissue	High	Endoscope
Noncritical	A device that does not ordinarily touch the patient or touch only intact skin	Medium or low	Stethoscope and blood pressure meter



**■ Disinfectant**

The following solutions are used during cleaning and disinfection.

- Detergent solution
- Disinfectant solution
- Flushing fluid

**5.1.1 Detergent**

Detergent can be used to dissolve and emulsify feculence and microbe, enhance the dirt-removing power, facilitate cleaning, and improve the cleaning quality. Detergent can be classified into the following types:

- Alkaline detergent: Its pH value is greater than or equal to 7.5. It functions well in dissolving various organics and it is slightly corrosive to metals.
- Neutral detergent: Its pH value ranges from 6.5 to 7.5, and it is not corrosive to metals.
- Acidic detergent: Its pH value is smaller than or equal to 6.5. It functions well in dissolving inorganic solid particles and it is slightly corrosive to metals.
- Detergent containing enzyme: The detergent that contains enzyme synergist contains one or multiple types of different enzyme. This type of detergent has strong dirt-removing power. It can be used to resolve various organic pollutants like protein. This type of detergent requires a certain contact time and temperature for its efficiency to reach the maximum. It must be used in proper conditions according to the product description of the manufacturer.

**NOTE:**

- Excessive detergent solution foaming could cause inadequate contact between the interior of the channels and the detergent solution. Consequently, the endoscope cannot be cleaned completely.
- Generally, common detergent solution does not contain antibiotic active substance and cannot restrain the growth of microbe. Therefore, common detergent solution cannot be used repeatedly. You should replace the common detergent solution after cleaning an endoscope.
- The detergent solution that contains antibiotic active substance can be used repeatedly within one day.

**5.1.2 Disinfectant**

The manufacturer recommends that phthalic dicarboxaldehyde solution with a level of 0.55% (0.5%-0.6%), alkaline glutaraldehyde solution with a level not smaller than 2%, peroxyacetic acid solution with a level of 0.2%-0.35%, or acidic electrolyzed oxidizing water solution with an active chlorine level of (60±10) mg/L be used for high-level disinfection of the endoscope. If using other disinfectants or disinfection tools, you should ensure that they comply with the standards of high-level disinfectant specified by the local health management department.

**NOTE:**

The glutaraldehyde solution may incur stimulus or anaphylactic reaction of the endoscope cleaning and disinfection personnel. Therefore, this solution should be used in an area with adequate ventilation and stored in a sealed container.

### 5.1.3 Flushing Fluid

After manual cleaning and disinfection, you should completely rinse the endoscope and its accessories with sterile water to remove the residual detergent and disinfectant. If no sterile water is available, you can also rinse the endoscope with water that has been processed, for example, filtered water or cold boiled water. However, the water used must at least reach the standard of drinking water.

If the endoscope and its accessories are not rinsed after manual disinfection, please use 75% alcohol or isopropyl to wipe the outer surface of the endoscope, rinse all channels, and leave the channels in natural environment for drying to avoid bacterial reproduction.

**NOTE:**

- You can use a filter membrane with a pore diameter not greater than 0.2 $\mu$ m to gain the recommended filtered water. The filter membrane should be replaced regularly. If a faucet with a filter mesh is used, the pipeline should be checked regularly, and the check record should be archived.
- Do not use running water as the flushing fluid.
- Do not use the flushing fluid repeatedly.

## 5.2 Cleaning and Disinfection Tools

Prepare the following items before cleaning and disinfection.

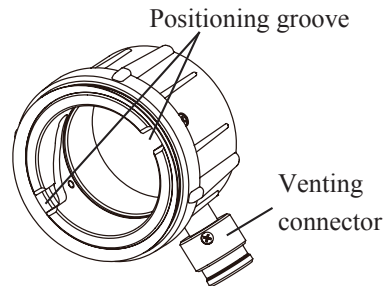
- Manual cleaning tank, rinse tank, disinfection tank, and terminal rinse tank
- Waterproof cap
- Channel plug
- Injection tube
- Cleaning brush
- Leakage detector
- Suction pump
- Timer
- Sterile lint-free cloth
- Clean lint-free cloth
- Sterile swab
- 50cm<sup>3</sup> (50ml) syringe

## 5.3 Accessory Inspection and Connection

For inspecting the accessories that are not mentioned below, please refer to the relevant user manuals.

### 5.3.1 Waterproof Cap

The waterproof cap is used to protect the electrical connector from water entering the endoscope during cleaning and disinfection. Before a leakage test, the venting connector needs to be connected to the waterproof cap, as shown in the following figure.

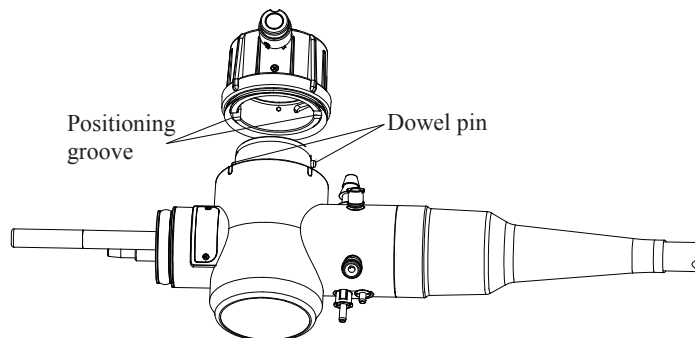


Before using the waterproof cap, perform the following inspections.

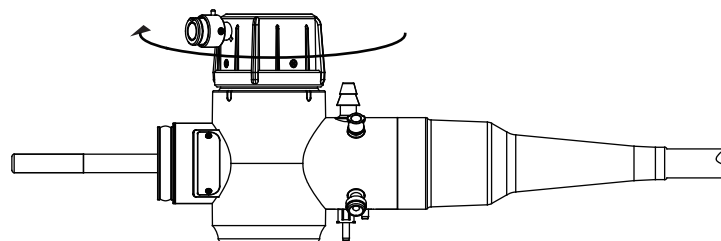
- Ensure that the inner wall of the waterproof cap is completely dry and there is no debris. If water drop or debris is found, please wipe with a dry lint-free cloth.
- Ensure that there is no scratch, crack or debris on the sealing components of the waterproof cap.
- Ensure that the venting connector is connected firmly.

Perform the following steps to attach the waterproof cap.

1. Align the dowel pin of the electrical connector with the positioning groove of the waterproof cap.



2. Press down and rotate the waterproof cap clockwise (about 90°) until you hear a click. Ensure that the waterproof cap is firmly attached onto the endoscope.

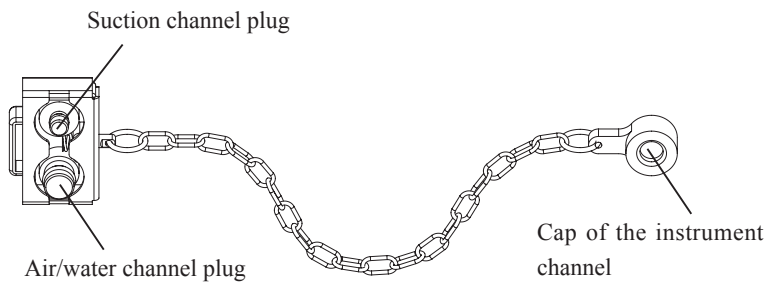


**NOTE:**

Ensure that no debris is attached onto the exterior of the electrical connector. Otherwise, the sealing ring in the waterproof cap may be scratched. In this case, liquid will enter into the endoscope and damage the endoscope.

### 5.3.2 Channel Plug

Channel plugs are used to plug the instrument channel port, air/water feeding ports, and suction channel during cleaning and disinfection of the endoscope. The following figure shows the channel plugs.



**NOTE:**

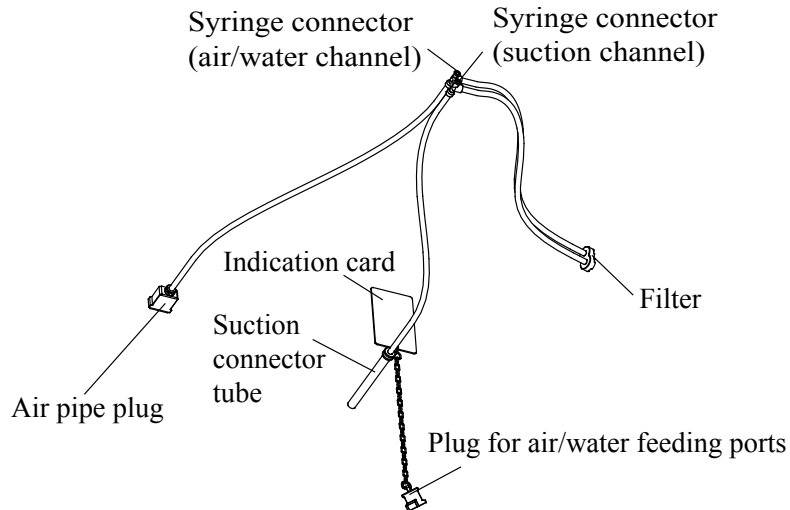
- Before using a channel plug, ensure that there is no crack, scratch, or debris on the plug.
- Ensure that the channel plug and the endoscope are firmly connected.

Perform the following steps to attach the channel plug.

1. Connect the suction channel plug and air/water channel plug to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
2. Connect the instrument channel plug to the instrument channel port of the endoscope, and ensure that they are firmly connected.

### 5.3.3 Injection Tube

The injection tube is used to inject detergent solution, disinfectant solution, sterile water or alcohol into the air/water and suction channels. It is also used to feed air into the channels to discharge residual liquid. The following figure shows an injection tube.

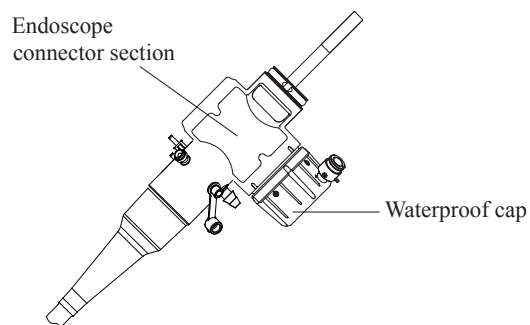


**NOTE:**

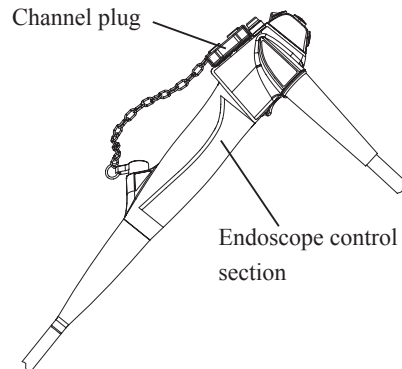
- Before using the injection tube, ensure that there is no crack, scratch, flaw, or debris on any component.
- Ensure that the filter mesh is intact.

Perform the following steps to connect the injection tube.

1. Connect the waterproof cap to the electrical connector of the endoscope.



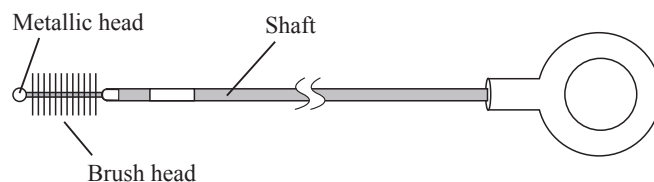
2. Use channel plugs to plug the suction valve cylinder, air/water valve cylinder, and instrument channel port respectively.



3. Connect the air pipe plug, suction connector tube, and plug for air/water feeding ports of the injection tube to the air pipe, suction connector, and air/water feeding ports of the endoscope connector section respectively.
4. Connect a 50cm<sup>3</sup> (50ml) syringe to the syringe connector (air/water channel). Immerse the filter mesh in the flushing fluid, pull out the plunger of the syringe, and ensure that flushing fluid is aspirated into the syringe. Then, push the plunger, and ensure that water flows from the air/water nozzle at the distal end and no water flows from the suction connector of the endoscope.
5. Connect a 50cm<sup>3</sup> (50ml) syringe to the syringe connector (suction channel). Immerse the filter mesh in the flushing fluid, pull out the plunger of the syringe, and ensure that flushing fluid is aspirated into the syringe. Then, push the plunger, and ensure that water flows from the instrument channel port at the distal end and no water flows from the air/water nozzle.

### 5.3.4 Cleaning Brush

The cleaning brush is used to brush the inner parts of all endoscope channels. The following figure shows a cleaning brush.



Perform the following inspections before using the cleaning brush.

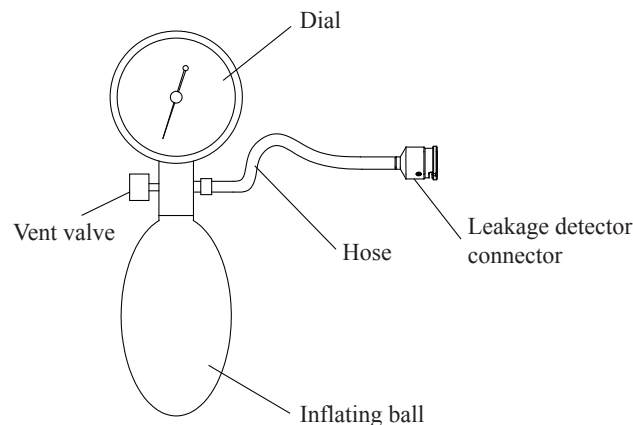
- Ensure that the brush head, metallic head, and bristle are firm.
- Ensure there is no bend, scratch, or damage on the brush shaft.
- Ensure that there is no debris on the brush shaft or bristle.

**NOTE:**

- Please select an appropriate cleaning brush to brush the accessories and channels of the endoscope.
- A disposable cleaning brush is recommended. If a reusable cleaning brush is selected, this brush should be disinfected every time after being used.

**5.3.5 Leakage Detector**

The leakage detector is used to perform leakage test before cleaning and disinfecting the endoscope. The following figure shows a leakage detector.

**NOTE:**

- Before using the leakage detector, ensure that there is no crack, scratch, flaw, or debris on any component of the leakage detector.
- Ensure that the hose of the leakage detector is firmly connected.

Perform the following steps to connect the leakage detector.

1. Align the dowel pin on the venting connector of the waterproof cap with the groove on the leakage detector connector.
2. Rotate the leakage detector connector clockwise until it is locked.

**5.4 Pre-cleaning**

- WARNING**
- Pre-cleaning should be performed before the endoscope is disconnected from the image processor and light source.
  - The endoscope should be pre-cleaned immediately after each procedure. Otherwise, the residual debris may solidify. Consequently, cleaning and disinfection of the endoscope will be difficult.
  - Do not touch the light guide lens of endoscope and the endoscope port of light source after disconnecting the endoscope from the light source after each use. The temperature of the two parts is extremely high. Touching them may result in skin burns.

Perform the following steps to pre-clean the endoscope.

1. After withdrawing the insertion section of the endoscope from the patient body, immerse the insertion section in the detergent solution.
2. Press the suction valve to aspirate detergent solution into the instrument channel for about 30s.
3. Take out the insertion section from the detergent solution and press the suction valve to aspirate air for 10s. Pre-cleaning of the instrument channel is completed.
4. Immerse the insertion section in the detergent again, press the air/water valve to feed water to the air/water channel for 10 to 15s (the water amount reaches 200 to 250 ml), and then release the air/water valve to feed air to the channel for 10 to 15s to pre-clean the air/water channel.

Steps 2-4 are performed to remove the blood, mucus, and debris attached to the endoscope channel, thereby ensuring that the channel is unblocked.

5. Use a lint-free cloth dampened with detergent solution to wipe the surface of the endoscope insertion section to remove all visible dirt.
6. After powering off the endoscope by pressing the power button on the image processor, remove the endoscope cable, suction hose, and water bottle hose from the endoscope.
7. After attaching the waterproof cap onto the endoscope, disconnect the endoscope from the light source, and then send the pre-cleaned endoscope to the disinfection room.
8. Take down the air/water valve, suction valve, and biopsy valve of the endoscope, and place these valves into a container filled with detergent solution.

**NOTE:**

- During aspiration, observe the liquid in the suction bottle carefully to avoid overflow, which might damage the suction pump.
- When wiping the endoscope, do not bend the insertion section excessively. Otherwise, the outer rubber of the insertion section may be damaged.
- Based on the distance, you can take out the pre-cleaned endoscope from the procedure room to the disinfection room directly or place the pre-cleaned endoscope in a sealed container and then take it to the disinfection room.

### 5.5 Leakage Test

A leakage test should be performed before cleaning of the endoscope.



- Before performing leakage test, attach the waterproof cap onto the electrical connector of the endoscope firmly. Otherwise, the endoscope may be damaged.
- When leakage is found on the endoscope, do not use the endoscope. Otherwise, the endoscope may be damaged and an electric shock may be caused. In case of leakage, please contact the sales representative of the manufacturer.

**NOTE:**

- The endoscope should be pre-cleaned before the leakage test.
- Ensure that the leakage detector and the waterproof cap are firmly connected to the endoscope. Otherwise, the leakage test is inaccurate because the pressure in the endoscope cannot increase.



- After the leakage detector is connected, the rubber wrapping the bending section will start swelling as the pressure in the endoscope increases, which is normal.
- During the test, do not place the leakage detector into the liquid.

After pre-cleaning the endoscope, perform the following steps to perform a leakage test.

1. Connect the leakage detector. For details, see section 5.3.5 Leakage Detector.
2. Rotate the vent valve of the leakage detector clockwise to fasten it, use an inflating ball to increase the pressure to 180mmHg (22kpa), and wait for 3 minutes. If the reading on the dial decreases continuously, the endoscope is leaky. In this case, contact the sales representative of the manufacturer.
3. Immerse the entire endoscope in clean water to perform accurate leakage test. Rotate the vent valve of the leakage detector clockwise to tighten it, use an inflating ball to increase the pressure to 180mmHg (22kpa), use the up/down and left/right angulation control knobs to adjust the angle of the bending section, and wait for 3 minutes. If bubbles are generated continuously in the water, the endoscope is leaky.
4. Take out the endoscope from the clean water.
5. Rotate the vent valve anticlockwise until the pointer on the dial goes back to the zero position again.
6. Disconnect the leakage detector and dry the endoscope completely.

## 5.6 Manual Cleaning



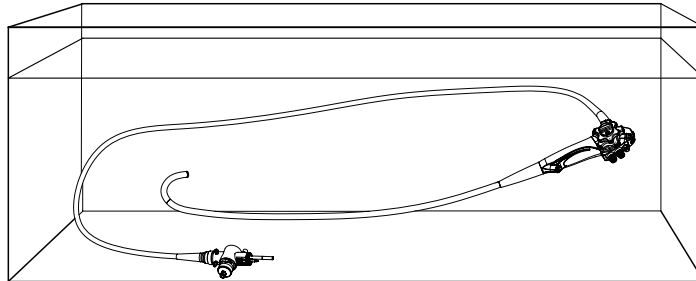
- WARNING**
- Insufficient cleaning and disinfection of the endoscope may result in a disease infection risk to the next patient who uses this endoscope.
  - To prevent detergent solution spatter, pull out the cleaning brush in the water.
  - The cleaning brush is consumable. The brush head will bend or knot and the brush bristle will even fall off due to repeated use. The operator should ensure that there is no damage or other abnormalities on the brush before and after each use.
  - If the bristle falls off in the channel, pull out it immediately, and insert a new cleaning brush or other endo-therapy accessory into the channel to ensure that no part is left inside the instrument channel or suction channel of the endoscope.

### NOTE:

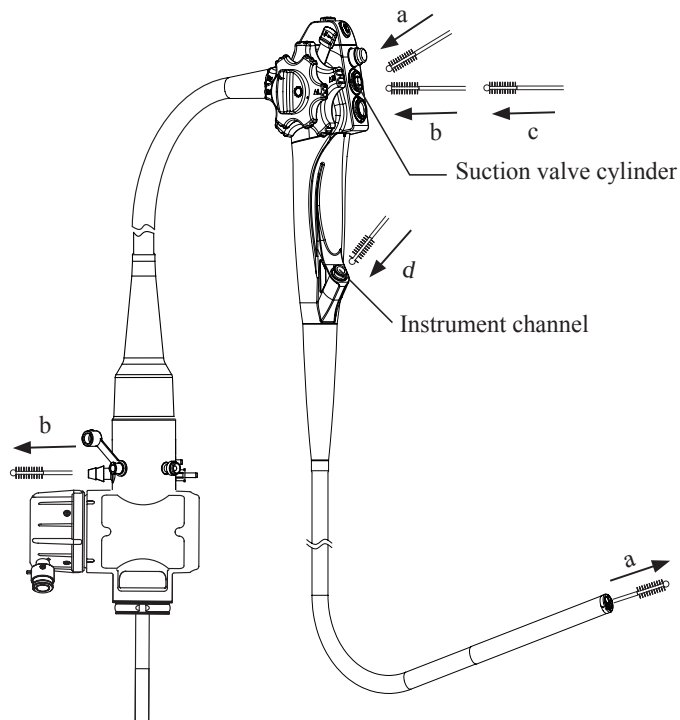
- The operator should gently pull out the cleaning brush from the instrument channel or suction channel to ensure that the shaft of the brush will not rub against the external opening of the suction valve. Otherwise, the brush may be damaged and the opening of the valve may be scratched, causing suction degradation or leakage.
- Do not attempt to insert the cleaning brush from the distal end of the insertion section or the suction connector. Otherwise, the cleaning brush could get stuck and cannot be pulled out.
- Do not immerse the endoscope together with its accessories to avoid damaging the endoscope.
- To avoid endoscope leakage, please clean the endoscope gently.
- Ensure that the accessories immersed in the detergent solution are not in contact with each other.

After the endoscope passes the leakage test, perform the following steps to clean the endoscope manually.

1. Attach the waterproof cap onto the endoscope and take down all valves.
2. Immerse the entire endoscope in the detergent solution.

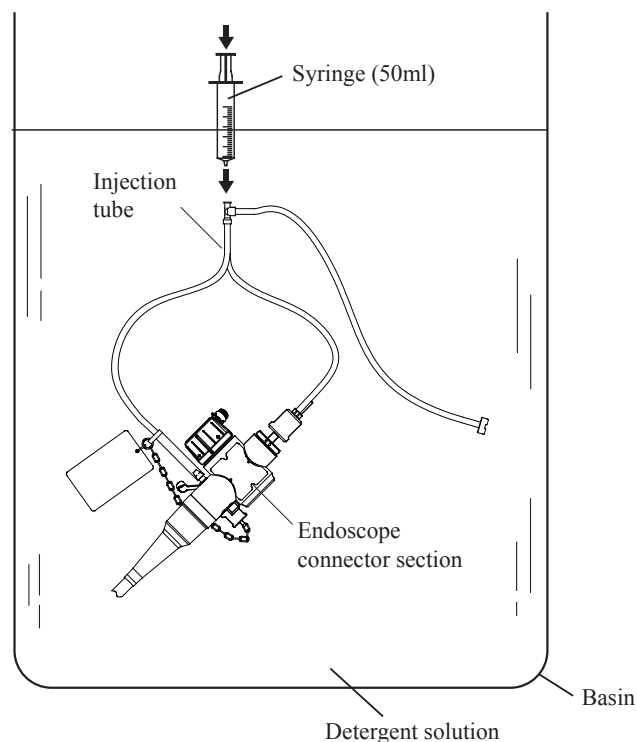


3. Brush channels according to the steps shown in the following figure.



- a. **To brush the suction channel from the control section to the distal end:** Straighten the bending section of the endoscope, insert the cleaning brush at a  $45^\circ$  angle into the suction valve cylinder, slowly advance the brush until the brush head emerges from the distal end, clean the bristles with your fingertips in the detergent solution, and then pull out the brush from the suction valve cylinder carefully.

- b. **To brush the suction channel from the control section to the connector section:** Insert the cleaning brush straightly into the suction valve cylinder, slowly advance the brush until the brush head emerges from the suction connector, clean the bristles with your fingertips in the detergent solution, and then pull out the brush from the suction valve cylinder carefully. Clean the bristles with your fingertips again. Repeat the above steps several times until no debris is left.
  - c. **To brush the suction valve:** Insert the cleaning brush into the suction valve until half of the brush is inserted, rotate the brush once, pull out the brush, and clean the bristles with your fingertips in the detergent solution. Repeat the above steps several times until no debris is left.
  - d. **To brush the instrument channel:** Insert the cleaning brush into the instrument channel, pull out the brush, and clean the bristles with your fingertips in the detergent solution. Repeat the above steps several times until no debris is left.
4. Connect the waterproof cap, injection tube, and channel plugs to the endoscope respectively. Ensure that the endoscope is completely immersed in the detergent solution.
  5. Inject 100ml disinfectant solution into the air/water and suction channels of the endoscope respectively through the syringe connector of the injection tube with a 50ml syringe.



6. Disconnect all channel plugs and the injection tube from the endoscope and immerse them in the detergent solution.
7. Use a lint-free cloth or cleaning brush to clean the outer surface and connectors of the endoscope.

## 5.7 Rinsing

After manual cleaning, perform the following steps to rinse the endoscope.

1. Connect the waterproof cap, channel plug, and injection tube to the endoscope, and then place them into the rinsing tank.
2. Inject 100ml sterile water into the air/water channel and suction channel of the endoscope respectively through the syringe connector of the injection tube with a 50ml syringe.
3. Flush the outer surface, buttons, and valves of the endoscope with flowing water.
4. Take out the endoscope and its accessories from the water.
5. Use a lint-free cloth to cover the distal end and control section of the endoscope.
6. Inject 100ml air into the air/water channel and suction channel of the endoscope respectively through the syringe connector of the injection tube with a 50ml syringe.
7. Take down the lint-free cloth. After being used, the lint-free cloth should be replaced in time.
8. Disconnect the channel plug and injection tube from the endoscope, and use a lint-free cloth to wipe up the outer surface, buttons, and valves of the endoscope.

## 5.8 High-Level Disinfection

### 5.8.1 Automatic Disinfection

After initial rinsing, connect the endoscope to the automatic disinfection machine for high-level disinfection.

Perform the following steps to connect the endoscope to the automatic disinfection machine.

1. Connect the suction and air/water connection pipes to corresponding connectors of the automatic disinfection machine.
2. Connect the other end of the air/water connection pipe to the air/water connector of the endoscope firmly.
3. Connect the other end of the suction connection pipe to the suction connector of the endoscope firmly, and ensure that they get stuck at the control section.
4. Start the automatic disinfection machine.

#### NOTE:

- For the detailed usage of the automatic disinfection machine, refer to the user manual of the automatic disinfection machine.
- The automatic disinfection machine can only be used for high-level disinfection. If the endoscope requires sterilization, please refer to 5.9 Sterilization.

## 5.8.2 Manual Disinfection

**WARNING**

- There is a cleared list of sterilants and high-level disinfectants for use in processing reusable medical and dental devices on FDA website. That list can be consulted to find agents that may be useful for disinfection of the endoscope and its accessories. Please refer to the following URL for FDA-Cleared Sterilants and High Level Disinfectants: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm>.
- For sufficient disinfection, ensure that the outer surface of the endoscope and all its accessories is in full contact with the disinfectant.
- Bubbles adhering to the channels may degrade the disinfection effect. The operator can forcibly inject disinfectant solution into the endoscope channels to ensure that no bubble exists. If any bubbles adhere to the outer surface of the endoscope and its accessories, you should use a clean lint-free cloth to wipe them off.
- The endoscope and its accessories should be completely immersed in the disinfectant solution for high-level disinfection.

After rinsing the endoscope for the first time, perform the following steps to disinfect the endoscope at high level.

1. Connect the channel plug and injection tube to the endoscope, and ensure that they are firmly connected.
2. Immerse the entire endoscope and all its accessories in the disinfectant solution.
3. Inject at least 100ml disinfectant solution into the air/water channel and suction channel of the endoscope respectively through the syringe connector of the injection tube with a 50ml syringe.

**NOTE:**

- Ensure that the syringe connector of the injection tube is completely immersed in the disinfectant solution.
  - Ensure that all channels of the endoscope are filled with disinfectant solution.
4. Take down the channel plug and injection tube and immerse them completely in the disinfectant solution.
  5. Immerse the endoscope and all its accessories by using the method recommended in Table 5-2 for high-level disinfection.

Table 5-2 Recommended high-level disinfection method

Disinfectant	High-Level Disinfection Parameter	Contact Period	Contact Type	Precautions
Phthalic dicarboxaldehyde (OPA)	Level: 0.55% (0.5%-0.6%)	≥ 5min	Immersion	<ol style="list-style-type: none"> <li>1. The cloth, skin, and instrument are prone to dyeing.</li> <li>2. Steam of this disinfectant may stimulate the respiratory tract and eyes.</li> </ol>
Glutaraldehyde (GA)	Level: ≥ 2% (alkaline)	≥ 10min	Immersion	<ol style="list-style-type: none"> <li>1. This disinfectant has sensitization and irritation on the skin, eye, and respiratory tract. In addition, it can cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma. It is suitable for use in the automatic disinfection machine.</li> <li>2. This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.</li> </ol>
Peroxyacetic acid (PAA)	Level: 0.2%-0.35% (W/V)	≥ 5min	Immersion	<ol style="list-style-type: none"> <li>1. This disinfectant has irritation on the skin, eye, and respiratory tract.</li> <li>2. This disinfectant has strong corrosion on metal.</li> </ol>
Acidic electrolyzed oxidizing water (AEOW)	Active chlorine level: (60±10) mg/L, pH value: 2.0-3.0, chlorination reduction potential: 1100mV, residual chloride ion level: < 1000mg/L	3-5min	Immersion	<ol style="list-style-type: none"> <li>1. When organic matters exist, the disinfection effect decreases sharply. The endoscope should be cleaned completely before the disinfection.</li> <li>2. This disinfectant has certain corrosion on the endoscope.</li> <li>3. Flowing immersion method should be adopted for disinfection.</li> <li>4. The endoscope should be rinsed with sterile or filtered water for 30s after disinfection.</li> </ol>

**NOTE:**

- For the preparation, usage, storage, and disposal of the detergent solution and disinfectant solution, refer to the instructions of the detergent and disinfectant manufacturers.
  - The disinfectant selected must have a hygienic license (within its validity period) or a test report, national health security assessment report, and disinfectant production license issued by an authoritative institution. The parameter values in the preceding table are for your reference. When they differ from those on the health permission approval document, the values on the approval document shall prevail. When the disinfectant usage differs from that on the health permission approval document, the usage on the approval document shall prevail.
  - Disinfectants listed in this manual are recommended because of their chemical compatibility with product materials, not their biological effectiveness. For the biological effectiveness of a disinfectant, refer to the guidelines and recommendations of the disinfectant manufacturer, Association for Practitioners in Infection Control, U.S. Food and Drug Administration, and U.S. Centers for Disease Control.
6. Before taking out the endoscope and its accessories from the disinfectant solution, connect the channel plug and injection tube to the endoscope.
  7. Take out the filter of the injection tube from the disinfectant solution.
  8. Inject air into the air/water channel and suction channel of the endoscope respectively for at least 30s through the two syringe connectors of the injection tube with a 50ml syringe to remove the disinfectant solution in the channels.
  9. Take out the endoscope and all its accessories from the disinfectant solution.
  10. Remove all accessories from the endoscope.

## 5.9 Sterilization

After the endoscope enters the sterile human tissue and organ and contacts damaged tissue, damaged mucous membrane, and blood (for example, in a surgery), it needs to be sterilized.

Perform the following steps to sterilize the endoscope.

1. Connect the channel plug and injection tube to the endoscope, and ensure that they are firmly connected.
2. Immerse the entire endoscope and all its accessories in the sterilant solution.
3. Inject at least 100ml sterilant solution into the air/water channel and suction channel of the endoscope respectively through the syringe connector of the injection tube with a 50ml syringe.

**NOTE:**

- Ensure that the syringe connector of the injection tube is completely immersed in the sterilant solution.
  - Ensure that all channels of the endoscope are filled with sterilant solution.
4. Take down the channel plug and injection tube and immerse them completely in the sterilant solution.
  5. Immerse the endoscope and all its accessories by using the method recommended in Table 5-3 for sterilization.

Table 5-3 Recommended sterilization method

Sterilant	Sterilization Parameter	Contact Period	Contact Type	Precautions
Glutaraldehyde (GA)	Level: $\geq 2\%$ (alkaline)	$\geq 10\text{min}$	Immersion	<p>1. This disinfectant has sensitization and irritation on the skin, eye, and respiratory tract. In addition, it can cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma.</p> <p>2. This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.</p>



**NOTE:**

- For the preparation, usage, storage, and disposal of the sterilant solution, refer to the instructions of the sterilant manufacturer.
  - The sterilant selected must have a hygienic license (within its validity period) or a test report, national health security assessment report, and sterilant production license issued by an authoritative institution. The parameter value in the preceding table is for your reference. When it differs from that on the health permission approval document, the value on the approval document shall prevail. When the sterilant usage differs from that on the health permission approval document, the usage on the approval document shall prevail.
6. Before taking out the endoscope and its accessories from the sterilant solution, connect the channel plug and injection tube to the endoscope.
  7. Take out the filter of the injection tube from the sterilant solution.
  8. Inject air into the air/water channel and suction channel of the endoscope respectively for at least 30s through the two syringe connectors of the injection tube with a 50ml syringe to remove the sterilant solution in the channels.
  9. Take out the endoscope and all its accessories from the sterilant solution.
  10. Remove all accessories from the endoscope.

**NOTE:**

The endoscope should be sterilized according to the principles of sterile operation. After being sterilized, the endoscope should be rinsed with sterile water and stored in a sterile package for transportation.

## 5.10 Terminal Rinsing

**NOTE:**

After disinfecting the endoscope, the operator should use filtered water or sterile water to completely rinse the outer surface and all channels of the endoscope to remove residual disinfectant.

Perform the following steps to conduct terminal rinsing of the endoscope.

1. Connect the waterproof cap, channel plug, and injection tube to the endoscope, and then place them into the rinsing tank.
2. Inject sterile water into the air/water channel and suction channel of the endoscope respectively for two minutes through the syringe connector of the injection tube with a 50ml syringe. Ensure that no residual disinfectant is left in the endoscope channels.
3. Rinse the outer surface, buttons, and valves of the endoscope with filtered water or sterile water.
4. Take out the endoscope and all its accessories from the filter water or sterile water.
5. Remove the channel plug and injection tube from the endoscope, and use a lint-free cloth to wipe the outer surface, buttons, and valves.

## 5.11 Drying



- WARNING**
- After cleaning and disinfection, the operator should dry all channels of the endoscope completely to avoid breeding of bacteria that might cause disease infection of the next patient or operator.
  - Store alcohol or isopropyl in a sealed container. Otherwise, a fire may be incurred. Besides, the alcohol or isopropyl may become invalid due to volatilization.
  - The sterile lint-free cloth should be replaced every 4 hours.

Perform the following steps to dry the endoscope.

1. Connect the channel plug and injection tube to the endoscope, and place the filter of injection tube into 70% alcohol or isopropyl.
2. Inject 100ml 70% alcohol or isopropyl into the air/water and suction channels of the endoscope respectively through the syringe connectors of the injection tube with a syringe.
3. Place the endoscope and all its accessories on a sterile lint-free cloth which is placed on a medical drying table.
4. Inject 100ml air into the air/water and suction channels of the endoscope respectively through the syringe connector of the injection tube with a syringe to dry the channels completely. (The injection lasts for about 60s.)
5. Wipe the outer surface of the endoscope and all its accessories completely with a sterile lint-free cloth.
6. Install the disinfected valves, and check the air/water, suction, and instrument channels for next use.

Before storing the endoscope, use 70% alcohol or isopropyl to rinse all channels and dry them completely.

## **Chapter 6 Storage and Disposal**

Please store and dispose of the endoscope and its accessories as described in this chapter.



**WARNING**

- Before storage, the endoscope should be cleaned and disinfected completely.
- After being dried, the endoscope should be hung in the endoscope cabinet.
- Do not store the endoscope in a carrying case.
- The cabinet wall should be wiped with 0.05% chlorine solution twice a week. The cabinet must be handled soon if it is contaminated.
- If the endoscope has been stored for more than 24 hours, it should be cleaned and disinfected again.

## 6.1 Storage

### NOTE:

Before storing the endoscope, ensure that the surface of the endoscope and the interior of all channels are dry.

### 6.1.1 Storing the Endoscope

Perform the following steps to store the endoscope.

1. Rotate the up/down and left/right angulation locks to free the bending section of the endoscope completely.
2. Hang the endoscope in the endoscope cabinet and ensure that the insertion section is vertically hung and completely stretched.
3. Take down all accessories from the endoscope in the cabinet, including the air/water valve, suction valve, biopsy valve, and waterproof cap.
4. Wipe the objective lens and light guide lens carefully with a dry cotton swab, use a piece of gauze daubed with lens cleaner (silicon wax) to wipe the objective lens and light guide lens gently, and ensure that no water drop is left.

### 6.1.2 Storing the Accessories

### NOTE:

Before storing the accessories, ensure that the air/water valve, suction valve, biopsy valve, and waterproof cap that have been cleaned and disinfected are dry.

Store the accessories in the endoscope cabinet, and ensure that they are not in contact with each other. Lubricate the accessories as required.

## 6.2 Transportation

### 6.2.1 Indoor Transportation

Perform the following steps to transport the endoscope in the hospital.

1. Rotate the up/down and left/right angulation locks of the endoscope to free the bending section completely.
2. Hold the connector section and control section of the endoscope with one hand. Hold the insertion section of the endoscope with the other hand gently, and ensure that the distal end is upwards.

### 6.2.2 Outdoor Transportation



- WARNING**
- The endoscope should be cleaned and disinfected before being placed into the carrying case. Otherwise, the carrying case may be contaminated or cross contamination may be incurred.
  - The waterproof cap should be removed before transportation. Otherwise, the endoscope may be damaged by air pressure.

Perform the following steps to transport the endoscope outdoors.

1. Remove the waterproof cap from the endoscope.
2. Rotate the up/down and left/right angulation locks of the endoscope to free the bending section completely.
3. Place the endoscope into the carrying case provided by the manufacturer.
4. Lock the carrying case for transportation.

## 6.3 Disposal

The validity period of this product is five years. When the validity period expires, this product must be disposed of according to the local laws and regulations.

For the detailed disposal information, consult the manufacturer or the local distributor. The manufacturer is not responsible for any system content or accessories that have been discarded improperly.

## 6.4 Customer Service

Only the service personnel of or authorized by the manufacturer can service the endoscope and its accessories. Any feedbacks or inquiries concerning our product or service should be directed to the following address.

Address: 4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building, Yuquan Road, Nanshan, Shenzhen, 518051, Guangdong, China

Zip Code: 518051

Tel: +86-755-26722890

Fax: +86-755-26722850

E-mail: [service@sonoscape.net](mailto:service@sonoscape.net)

*This page is intentionally left blank.*

## **Chapter 7 Troubleshooting**

This endoscope should be repaired by the qualified technical personnel. If the problem still exists after resolving as described in this chapter, stop using the endoscope immediately and return it to the manufacturer for repair.

The manufacturer is not responsible for repairing the accessories of this endoscope. If an accessory is damaged, please contact the sales representative of the manufacturer for replacement.

Item	Descriptions	Level	Cause	Solutions
Leakage	Leakage detector does not function or appears the continuous bubbles.	B	The rubber wrapping the bending section of the endoscope is damaged.	Stop using the endoscope.
		B	The sealing ring is ageing.	
		B	The channel is broken.	
Image	No image	C	The endoscope cable is not connected firmly or the image processor is not powered on.	Check the connections. For details, refer to Chapter 3 Preparations.
		B/A	Others	Stop using the endoscope.
	Image is dimmer.	C	The brightness value of light source is too low.	Adjust the brightness of light source as described in the user manual.
	Image is blurred.	C	The objective lens is dirty.	Feed water to flush the mucus on the objective lens.
B		Water drops or color bar appears in the view field.	Stop using the endoscope.	
Feed air	The air is insufficient.	C	The water bottle cap is loosen.	Fasten the cap of water bottle.
		C	The air/water nozzle is blocked.	Immerse the distal end in the soapy water at the appropriate temperature and feed air to remove the objects from the air/water nozzle.
		B	Others	Stop using the endoscope.
	Cannot feed air.	C	The air/water valve is damaged.	Replace the air/water valve.



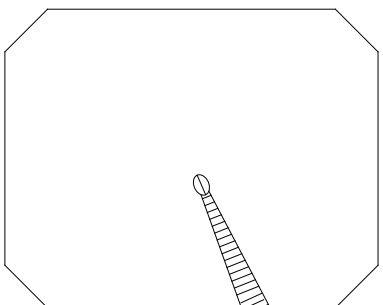
Item	Descriptions	Level	Cause	Solutions
Feed air	Cannot feed air.	C	The air pump does not function.	Enable the air pump on light source as described in the user manual.
Feed water	The water is insufficient.	C	The air/water nozzle is blocked.	Immerse the distal end in the soapy water at the appropriate temperature and feed air to remove the objects from the air/water nozzle.
		C	The water bottle cap is loose.	Fasten the cap of the water bottle.
	Cannot feed water.	C	There is no water in the bottle.	Pour the appropriate amount of sterile water into the bottle.
		C	The air/water valve is damaged.	Replace the air/water valve.
Suction	Cannot aspirate or the aspirated amount decreases.	C	The suction valve is blocked.	Remove the suction valve, and clean the inner valve with a cotton swab.
		C	The suction valve is damaged.	Replace the suction valve.
		C	The channel is blocked.	Brush the suction channel as described in the user manual.
		C	The biopsy valve is damaged.	Replace the biopsy valve.
	The suction valve is sticky.	C	The suction valve is dirty.	Remove and rinse the suction valve, clean the opening of the valve with the cotton swab dampened with alcohol solution.

Item	Descriptions	Level	Cause	Solutions
Suction	The instrument channel leaks.	B	The instrument channel is damaged by improperly using the accessories such as biopsy forceps.	Stop using the endoscope.
	Liquid or air is leaked from the biopsy valve.	C	The biopsy valve is ageing or damaged.	Replace the biopsy valve.
Bending Section	It is hard to rotate the angulation control knob.	C	The angulation control knob is locked.	Unlock the angulation control knob.
		B	Others	Stop using the endoscope.
	The bending section is not sensitive.	B	The elasticity of steel wires inside the endoscope degrades after using for a long period.	Stop using the endoscope.
	The bending section cannot reach the maximum angle.	B		
	The bending section does not function.	A		
Accessories	The endoscope cable does not function.	B	Endoscope cable is damaged.	Stop using the endoscope.
	Other problems	B	/	Change a new one.

**NOTE:**

- Level C means that you can solve the problem by yourself.
- Level B means that you should contact the authorized sales representative to withdraw the endoscope for servicing.
- Level A means that you can return the endoscope to the authorized sales representative.

## Appendix A Specifications

Technical Parameters		Product Model			
		EC-500	EC-500L	EC-500T	EC-500L/T
<b>Dimensions</b>	Insertion section length (mm)	1350	1350	1700	1700
	Total Length (mm)	1700		1950	
	Min. inner diameter of the instrument channel (mm)	Φ3.8	Φ4.2	Φ3.8	Φ4.2
	Max. outer diameter of the insertion section (mm)	Φ13	Φ13.5	Φ13	Φ13.5
	Outer diameter of the bending section	Φ12.5	Φ12.9	Φ12.5	Φ12.9
	Outer diameter of the distal end	Φ12	Φ12.9	Φ12	Φ12.9
	<b>Imaging System</b>	View field	140°		
View depth		3-100mm			
Resolution		≥ 12.50lp/mm (10mm)			
Biopsy entrance position					

Technical Parameters		Product Model			
		EC-500	EC-500L	EC-500T	EC-500L/T
Water/air feeding & Suction System	The amount of fed water	≥ 40mL/min			
	The amount of fed air	≥ 800mL/min			
	Aspirated amount	≥ 400mL/min			
Bending Section	Angle	Up 180°, Down 180° Left 160°, Right 160°			
Environment Requirements		Temperature	Relative Humidity	Atmosphere Pressure	
	Operation	5°C to 40°C	30% to 80%	700hPa to 1060hPa	
	Storage	-5°C to 40°C	30% to 80%	700hPa to 1060hPa	
	Transportation	-20°C to +55°C	20% to 90%	700hPa to 1060hPa	
Safety Types	Degree of protection against electric shock	Type BF applied part			
	Degree of protection against harmful liquid	IPX7			

# Appendix B EMC Guidance and Manufacturer's Declaration

## B.1 Electromagnetic Emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment and Guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	


## B. 2 Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment and Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	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 IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines; ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and Short interruptions IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0.5 period 40 % $U_T$ (60 % dip in $U_T$ ) for 5 periods 70 % $U_T$ (30 % dip in $U_T$ ) for 25 periods <5 % $U_T$ (>95 % dip in $U_T$ ) for 250 periods	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0.5 period 40 % $U_T$ (60 % dip in $U_T$ ) for 5 periods 70 % $U_T$ (30 % dip in $U_T$ ) for 25 periods <5 % $U_T$ (>95 % dip in $U_T$ ) for 250 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended for the equipment to be powered from an uninterrupted power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE:  $U_T$  is the AC mains voltage prior to application of the test level.

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment and Guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz-80 MHz	1 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80 MHz-2.5GHz	3 Vrms	<p>Recommended separation distance:</p> $d=3.5\sqrt{P}$ $d=1.2\sqrt{P} \quad 80\text{MHz}-800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 80 \text{ MHz}-2.5\text{GHz}$ <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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EQUIPMENT.</p>			
<p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

### B. 3 Recommended Separation Distances between Portable and Mobile and RF Communications Equipment and the Equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.