

About This Manual

P/N: 4710-01672A03

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Product Name: Video Duodenoscope

Product Model: ED-5GT

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- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- The product is used in accordance with the user manual.

Conventions

Understand the meanings of the following conventions clearly before reading this manual.

Item	Meaning
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	Indicates a potentially hazardous situation which, if not avoided, may result in malfunction or damage of the system.
NOTE	Indicates precautions or recommendations that should be used in operating the system.
Boldfaced Word	Indicates controls on the control panel, or on-screen objects such as menu items or keys.

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1 Safety

This chapter describes important information for operating this endoscope. To ensure the safety of both the operator and the patient, 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 duodenoscope (hereinafter called endoscope) is intended to provide endoscopic images for examination, diagnosis and treatment of the duodenum.

The endoscope should be used in the medical institution. The operator of the endoscope should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical endoscopy technology.



- The endoscope is intended for adults.
- Strictly follow the intended use to operate the endoscope. Otherwise, it may result in personal injury or damage to the endoscope.

1.2 Indications

The endoscope can be used for the following indications:

- Suspicious choledocholithiasis, tumour, inflammation, parasite or obstructive jaundice with unknown reasons.
- Recurrence of symptoms after performing cholecystectomy or bile duct surgery.
- Suspicious pancreatic neoplasm, chronic pancreatitis or relapsing pancreatitis paracmasis.
- Suspicious duodenal papilla or ampulla inflammation and tumour, biliary pancreatitis patients who need to cure the diseases.
- Suspicious choledochocyst and other congenital malformation, and pancreaticobiliary maljunction.
- Suspicious pancreas and biliary tract diseases patients due to agnogenic epigastric pain.
- Biliary-pancreatic diseases patients who need to collect the bile, pancreatic juice or perform Oddi sphincter pressure measurement.
- Biliary-pancreatic diseases patients who need to perform endoscopic therapy.
- Suspicious pancreatic duct rupture patients after pancreas trauma.
- Suspicious accidentally injured patients after bile duct surgery.
- Suspicious congenital lesion of pancreas.
- Cancer of biliary duct (common bile duct and gallbladder) and hilar cholangiocarcinoma.
- Cholelithiasis (common bile duct, gallbladder and intrahepatic bile duct).
- Property and degree of stenosis and dilation of the biliary system.
- Some liver diseases.

1.3 Contraindications

During clinical examination, diagnosis and treatment, the following contraindications should be specially paid attention to:

■ Relative Contraindications

- Upper gastrointestinal stenosis and obstruction patients, whose descending duodenum cannot be reached by the video duodenoscope.
- Cardiopulmonary insufficiency or other endoscopy contraindications.
- Non-calculus incarcerated acute pancreatitis or acute phase of chronic pancreatitis.
- Biliary stricture or obstruction patients without the qualification of performing biliary drainage.
- Patients allergic to Iodinated contrast medium should adopt nonionic contrast medium. Before surgery, the emergency preparations should be performed.

- Severe biliary infection patients, such as cholangitis, septicemia, duodenal papilla and bile duct injury, acute pancreatitis.

■ Absolute Contraindications

- Severe heart and lung diseases patients who cannot tolerate endoscopy, such as severe cardiac insufficiency, severe pulmonary insufficiency and severe arrhythmia patients.
- Patients who are in a shock or other critical conditions.
- Suspicious and diagnosed upper digestive tract perforation or perforation acute phase.
- Mental disorders and non-cooperated patients or patients with severe intellectual disabilities.
- Acute phase of stomach/esophageal chemical and corrosive injury.

1.4 Product Compatibility

The endoscope is used with the image processor (HD-650Exp, HD-650, HD-650Pro, HD-650Elite, HD-650S, HD-650Plus, HD-650Lite, HD-500, HD-550Exp, **HD-550**, HD-550Pro, HD-550S, HD-510, and HD-500Plus) and the light source (VLS-65, VLS-50T, VLS-50D, VLS-55Q, VLS-55T, VLS-51T, and VLS-51D) provided by the manufacturer.

1.5 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.

1.5.1 Electrical Safety



- If any qualifications for an operator are stipulated by the medical administration or other official institutions, the operator should meet the qualification requirements. Otherwise, only the medical staff approved by the hospital safety administrator or by the person who is in charge of the department can perform endoscopy.
- Only the personnel authorized or trained by the manufacturer can maintain the device. Any unauthorized personnel should not assemble or disassemble the device.
- If hospital administrators or official institutions (such as endoscopic academic institutions) have established an application standard for endoscopy and endoscopic treatment, follow the standard.
- Evaluate the property, purpose, benefits and risks (including medical risks, unknown risks and possibility) thoroughly before performing endoscopy. Perform endoscopy only when benefits outweigh risks.
- Make a detailed explanation to the patient about the benefits and risks of endoscopy and endoscopic diagnosis, as well as the methods to be applied.
- Only perform endoscopy with the patient's consent.
- Evaluate potential benefits and risks at all times during endoscopy and endoscopic diagnosis. Stop the endoscopy immediately and take appropriate measures when risks outweigh benefits.
- The operator should be capable of performing endoscopy and endoscopic diagnosis in accordance with the standards and principles developed by endoscopic academic institutions. Therefore, endoscopic clinical technologies are not detailed in this manual.
- Do not operate the device in an atmosphere containing flammable gases such as anesthetic gases, hydrogen, and ethanol, because there is a danger of explosion.
- The device is not strictly cleaned and disinfected in the factory. Therefore, the operator should strictly perform the cleaning and disinfection processes described in this manual before use.
- Prepare a spare endoscope to avoid an examination interruption caused by the device malfunction.
- The performance of the device and its accessories may be degraded over time. Perform periodic maintenance as described in this manual to ensure the safety of the device.
- Maintain and store the device as described in this manual after use. Improper maintenance and storage may cause cross infection, damage to the device or performance degradation.
- When the device is used with the electrosurgical accessories (such as high frequency electrotome), current leakage to the patient may be increased. Use the accessories with the safety protection type of at least Type BF.
- Ensure that no flammable gas exists in patient's body when using other accessories (such as high frequency surgical instruments). Otherwise, explosion may occur.
- When the device is used together with the endoscopically-used accessories which are the applied parts of

the high frequency surgical instruments, the isolation or insulation is provided by the endoscopically-used accessories.

- When the device is used with the high frequency surgical instruments, the recommended work mode and the maximum power of the high frequency surgical instruments are:
 - Cutting mode: 320W
 - Coagulation mode: 120W



All medical devices connected to the endoscope should comply with EN/IEC 60601-1. The entire system should meet the requirements of EN/IEC 60601-1.

1.5.2 Accessory Safety



- Only the accessories provided or approved by the manufacturer can be used. Using other accessories may cause damage to the device and the expected performance described in this manual cannot be achieved
- Do not reuse the single-use accessory.

1.5.3 Biohazard Considerations



- Patient debris and chemicals for cleaning and disinfection are potentially dangerous. The operator should wear the 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 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, cleaning solution and waste in accordance with local laws and regulations. For details, consult the relevant manufacturers or their local distributors.

1.6 Safety Symbols

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

Symbol	Meaning
	Refer to instruction manual/booklet
	Caution
	Manufacturer
	Serial Number
IPX7	Degree of protection against harmful liquid (Protection against short time immersion)
	This product is provided with a CE marking in accordance with the regulations stated in Regulation (EU) 2017/745.
	Type BF Applied Part
	Authorized representative in the European community
	Model number

Symbol	Meaning
	Country and date of manufacture; CHN is the country code of China.
	Medical device
	Unique device identifier
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Stacking limit by number
	Fragile, handle with care
	Keep dry
	This way up
	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

2 Overview

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 Packing

Make sure all the following items are in the packaging box of the device.

- Video duodenoscope
- Biopsy valve
- Injection tube
- Channel plug

Others: See the Packing List in the packaging box.

2.2 Component Introduction

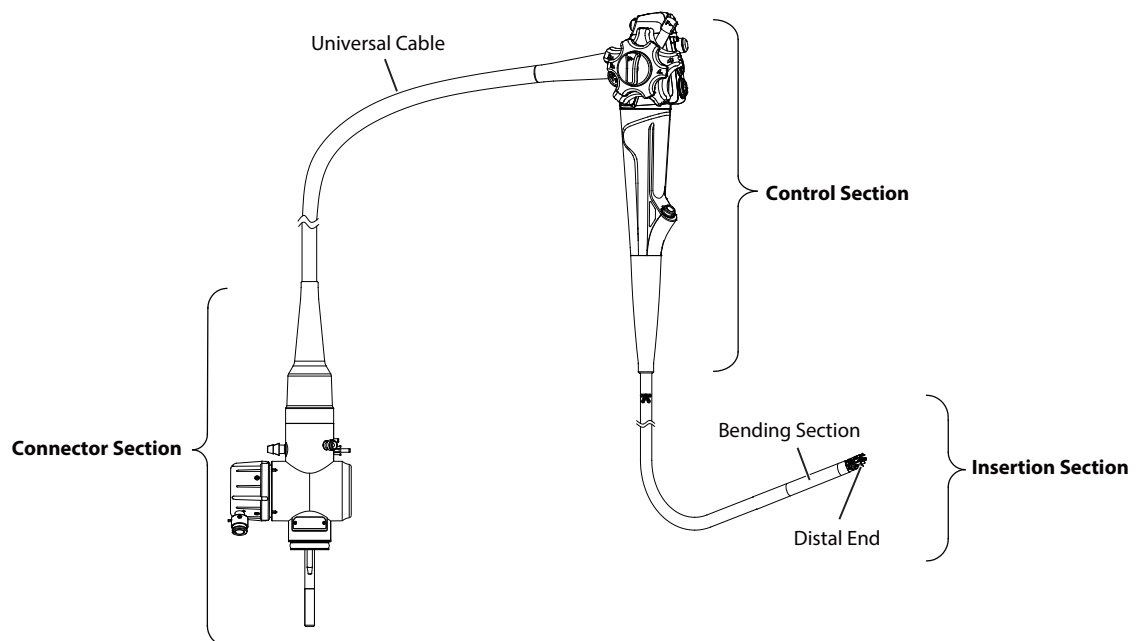


Figure 2-1 Endoscope

2.2.1 Connector Section

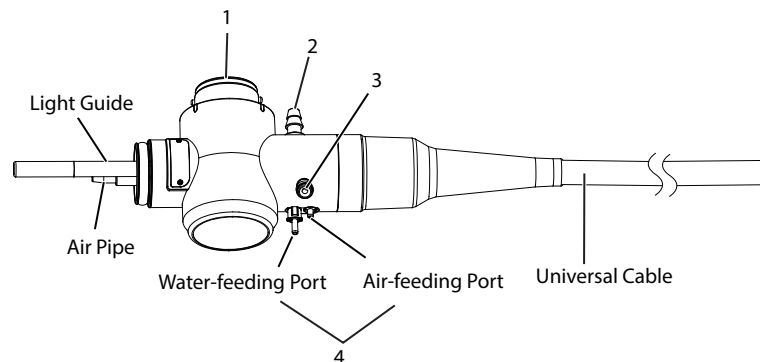


Figure 2-2 Connector Section

No.	Part Name	Description
1	Electrical Connector	Used for connecting the endoscope cable to acquire video signal of images.
2	Suction Port	Used for connecting to the suction pump through suction tube.
3	Electrosurgical Equivalent Terminal	Used for connecting the electrosurgical equipment.
4	Air/Water-feeding Port	Used for connecting the water container to feed water/air to the distal end.

2.2.2 Control and Insertion Sections

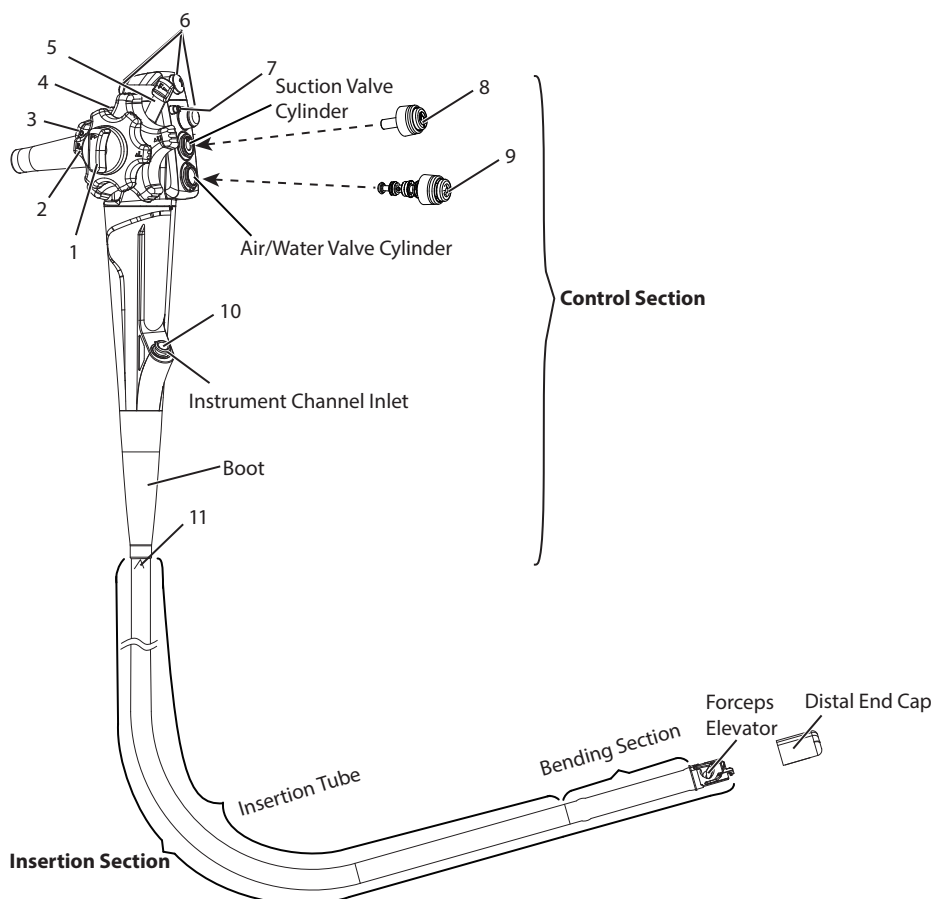


Figure 2-3 Control and Insertion Sections

No.	Part Name	Description
1	Left/Right Angulation Lock (F ►)	- Rotate it clockwise to free the bending section in the left or right direction. - Rotate it anticlockwise to lock the bending section at the current angle.
2	Left (▲ L)/Right (R ▲) Angulation Control Knob	- Rotate it clockwise to move the bending section right. - Rotate it anticlockwise to move the bending section left.
3	Up (▲ U)/Down (D ▲) Angulation Control Knob	- Rotate it anticlockwise to move up the bending section. - Rotate it clockwise to move down the bending section.

No.	Part Name	Description
4	Elevator Control Knob (U ▲)	- Rotate it anticlockwise to raise the forceps elevator. - Rotate it clockwise to lower the forceps elevator.
5	Up/Down Angulation Lock (F ►)	- Rotate it clockwise to free the bending section in the up or down direction. - Rotate it anticlockwise to lock the bending section at the current angle.
6	Remote Buttons (0-3)	Set the functions of the four buttons through the image processor connected with the endoscope.
7	Forceps Elevator Wire Channel Connector	Used to connect the cleaning tube for forceps elevator wire channel to clean and disinfect the forceps elevator channel.
8	Suction Valve	Press it to aspirate the liquid, debris or air from the patient's body.
9	Air/Water Valve	- Cover the hole on the valve with a finger to feed air. - Press it to feed water to clean the objective lens, and the air/water can remove the blood, debris or mucous membrane adhering to the objective lens.
10	Instrument Channel	This channel should be used with the biopsy valve and the functions are as follows. - Used to feed the liquid to the distal end of the endoscope. - Used for the endotherapy accessory. - Used as a part of suction channel.
11	Insertion Limit Mark	Indicate the maximum length of the insertion section that can be inserted into the body.

2.2.3 Distal End

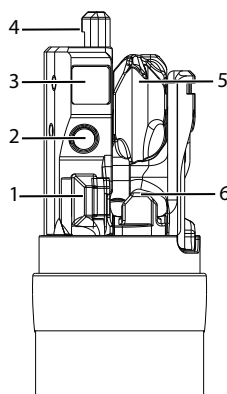


Figure 2-4 Distal End

No.	Part Name	Description
1	Air/Water Nozzle	Used as an outlet to feed air or water.
2	Objective Lens	Used for transmitting the optical signal of the target tissues to the image sensor.
3	Light Guide Lens	Light transmits through these lenses to assist endoscopic image observation.
4	Hook	Used for installing the distal end cap.

No.	Part Name	Description
5	Forceps Elevator	• Used for moving the endoscopy accessory through the elevator control knob. • Used for assisting to fix the guide wire when inserting or withdrawing the wire-guided endoscopy accessory.
6	Instrument Channel Outlet	Used as instrument outlet (such as biopsy forceps), liquid feeding outlet, or suction inlet.

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 any problem occurs, refer to Chapter 7 Troubleshooting for detailed solutions. If the problem persists, contact the local distributor of the manufacturer.



- The endoscope is not cleaned or disinfected in the factory. Therefore, the operator should clean and disinfect the endoscope as described in Chapter 5 Cleaning and Disinfection before use.
- For the safety of the patient and the operator, do not use the malfunctioning endoscope.
- The operator should inspect the device periodically to ensure the performance of the device.
- Disinfect, terminally rinse and dry the endoscope before the first use everyday.

3.1 Inspecting the Endoscope

Before inspection, clean and disinfect the endoscope as described in Chapter 5 Cleaning and Disinfection and remove the waterproof cap from the electrical connector.

3.1.1 Inspecting the Appearance and Flexibility

Perform the following inspections to inspect the appearance and flexibility of the endoscope.

- Ensure that there is no scratch, deformation or slack on the control section or the connectors.
- Ensure that there is no abnormal bending, twist or other abnormality on the boot or the insertion section near the boot.
- Ensure that there are no dents, bulges, swelling, scratches, breakages, deformation, adhesion of foreign objects, component missing or peeling on the outer surfaces of the entire insertion section (including the bending section) and the distal end.
- Hold the control section with one hand and run the other hand back and forth over the entire length of the insertion section. Ensure that no metallic wire or any object protrudes from the insertion section, and the insertion section is not abnormally stiff.

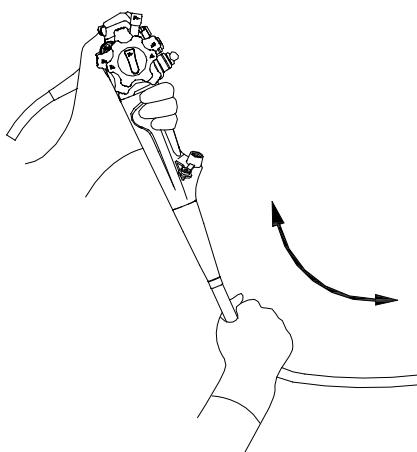


Figure 3-1 Inspecting the Insertion Section Surface

- Ensure that there is no scratch or breakage on the objective lens and light guide lenses on the distal end, and no spot or crack on the edges of the objective lens.
- Ensure that there is no dent, protrusion or bulge on the air/water nozzle and the instrument channel outlet on the distal end.
- 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.

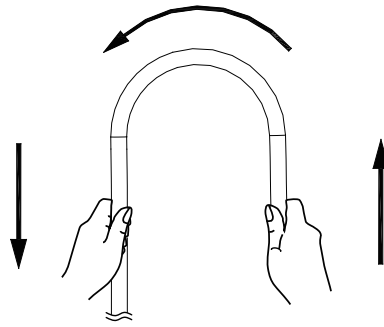


Figure 3-2 Inspecting the Flexibility of the Insertion Section

- Hold the position 20 cm from the distal end and the midpoint of the bending section respectively, and push and pull to ensure that junction between the bending section and the insertion section is not loose.

3.1.2 Inspecting the Angulation



WARNING Do not use the endoscope if any angulation control knob is too loose or tight. Otherwise, it may result in injury, bleeding or perforation to the patient during the examination.

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

■ To inspect the flexibility

Perform the following steps.

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

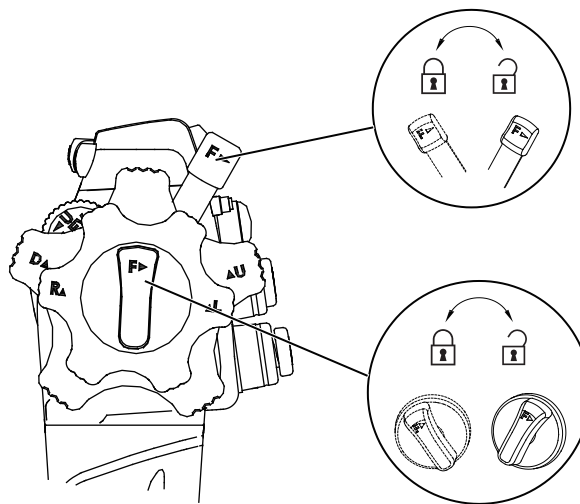


Figure 3-3 Rotating the Angulation Locks

2. Rotate the up/down and left/right angulation control knobs respectively. Ensure that the bending section can be smoothly and properly bent, and slowly return to a roughly straight condition after the knobs are released.
3. When the up/down and left/right angulation control knobs are rotated to their original positions, ensure that the bending section can return to a roughly straight condition.

■ To inspect up/down angulation

Perform the following steps.

1. Rotate the up/down angulation lock clockwise to unlock the up/down angulation control knob, and rotate the knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move up and down and reaches its maximum angle.
2. Rotate the up/down angulation lock anticlockwise until it stops to lock the up/down angulation control knob, and then release the knob. Ensure that the bending section can be fixed at the current angle.

- When the bending section is fixed, rotate the up/down angulation lock clockwise until it stops to free the up/down angulation control knob, and then release the knob. Ensure that the bending section can return to a roughly straight condition.

■ To inspect left/right angulation

Perform the following steps.

- Rotate the left/right angulation lock clockwise to unlock the left/right angulation control knob, and rotate the knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move to the left and right and reaches its maximum angle.
- Rotate the left/right angulation lock anticlockwise until it stops to lock the left/right angulation control knob, and then release the knob. Ensure that the bending section can be fixed at the current angle.
- When the bending section is fixed, rotate the left/right angulation lock clockwise until it stops to free the left/right angulation control knob, and then release the knob. Ensure that the bending section can return to a roughly straight condition.

3.1.3 Inspecting the Forceps Elevator

Perform the following steps.

- As shown in Figure 3-4, slowly rotate the elevator control knob clockwise and ensure that the forceps elevator wire stretching out from the distal end is not broken or bent.

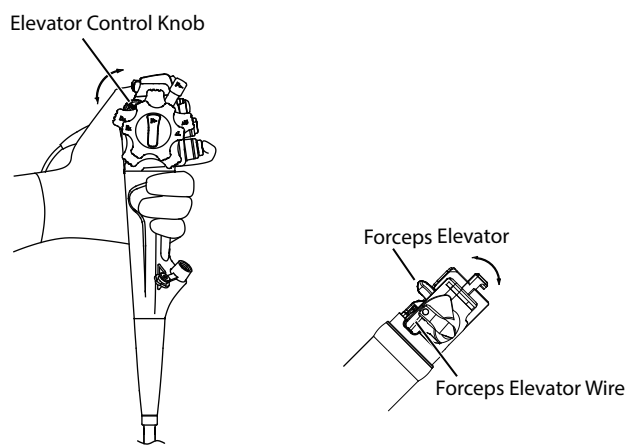


Figure 3-4 Inspecting the Forceps Elevator

- Slowly rotate the elevator control knob anticlockwise to ensure that the knob can be smoothly rotated and the forceps elevator can be raised.
- Slowly rotate the elevator control knob clockwise to ensure that the knob can be smoothly rotated and the forceps elevator can be lowered.

3.2 Inspecting and Installing the Accessories

The accessories include the ones for clinical examination and the ones for cleaning and disinfection. This section only introduces the clinical accessories. For information of other accessories, refer to Section 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's body and it may result in personal injury.

■ Inspection

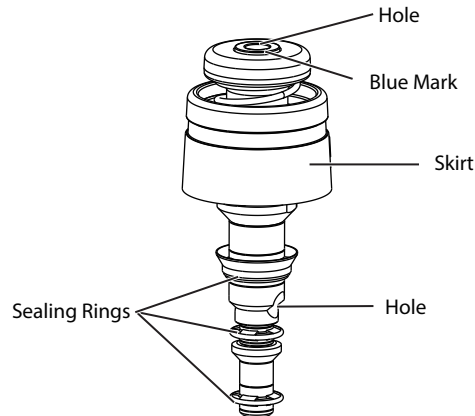


Figure 3-5 Air/water Valve

Perform the following inspections before using the air/water valve.

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

■ Installation

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

NOTE:

- *Do not apply lubricant on the air/water valve. Otherwise, the sealing rings may bulge, which may 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

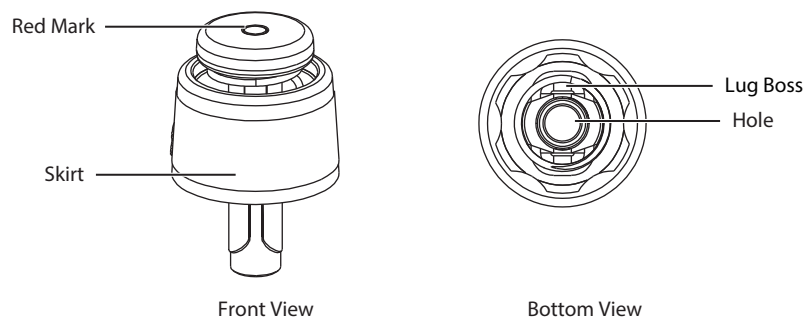


Figure 3-6 Suction Valve

Perform the following inspections before using the suction valve.

- Ensure that the hole on the suction valve is not blocked.
- Ensure that the suction valve is not deformed, cracked or damaged.

■ Installation

Align the lug boss on the suction valve skirt with the groove on the suction valve cylinder and press the suction valve to the end. Ensure that the suction valve cannot be rotated.

NOTE:

- *Noise may be heard during use if the suction valve is dry, which does not affect the valve function.*
- *Red mark is used to distinguish this valve from the air/water valve of the endoscope.*

3.2.3 Biopsy Valve



- 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.
- Using a damaged biopsy valve may degrade the suction performance of the endoscope, which may result in spray or leakage of patient's debris or body liquid, posing potentially infection risks to both the operator and the patient.

■ Inspection

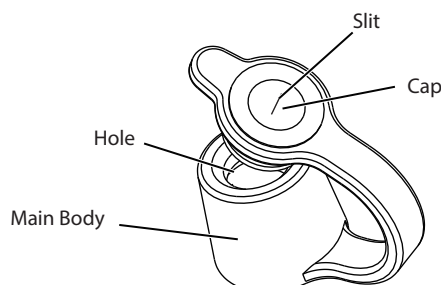


Figure 3-7 Biopsy Valve

Perform the following inspections before using the biopsy valve.

- Ensure that the hole and slit of the valve are not deformed, cracked or damaged.
- Cover the cap, and ensure that the main body and the cap are connected firmly.

■ Installation

Perform the following steps.

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

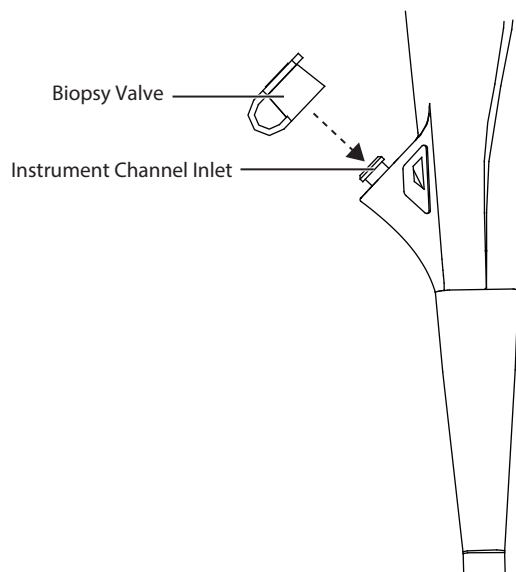


Figure 3-8 Installing the Biopsy Valve

2. Install the biopsy valve to the instrument channel inlet of the endoscope correctly.

3.2.4 Distal End Cap



- Ensure that the distal end cap is correctly installed. Otherwise, it may fall off during the examination and cause personal injury.
- Do not use the broken distal end cap. Otherwise, it may result in personal injury.



- Do not apply silicon oil, olive oil or lubricant on the distal end cap. Otherwise, it may be damaged.
- When installing the distal end cap, hold the bending section part closing to the distal end. Otherwise, the bending function of the other part of the bending section may be damaged, or the surface of the bending section may be deformed.

■ Inspection

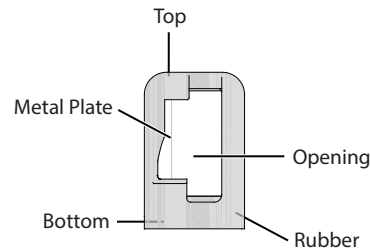


Figure 3-9 Distal End Cap

Perform the following inspections before using the distal end cap.

- Ensure that the metal plate in the distal end cap is not damaged.
- Ensure that the rubber does not drop off.
- Ensure that there is no crack, folding, discoloration, abrasion, hole or other abnormality on the distal end cap.

■ Installation

Perform the following steps.

1. Straighten the bending section, rotate the elevator control knob clockwise to lower the forceps elevator, and ensure that the forceps elevator is completely retracted into the distal end.

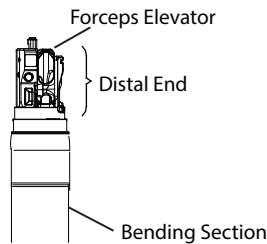


Figure 3-10 Adjusting the Forceps Elevator

2. Gently hold the bending section with one hand, hold the metal plate on both sides of the distal end cap opening with your thumb and middle fingers of the other hand, and put your index finger on the top of the distal end cap. Align the mark line on the distal end cap with the mark line on the distal end, and then advance the distal end cap to the distal end.

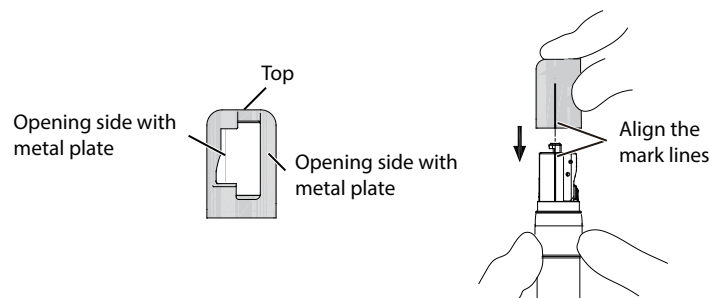


Figure 3-11 Aligning the Mark Lines

3. Install the distal end cap to the distal end and ensure that the bottom edge of the distal end cap does not roll up.

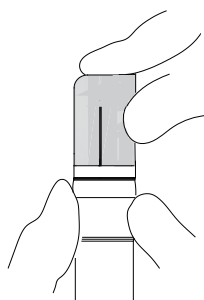


Figure 3-12 Installing the Distal End Cap

4. Press the top of the distal end with your index finger, and at the same time rotate the distal end cap clockwise until the light guide lens and the objective lens are completely out.

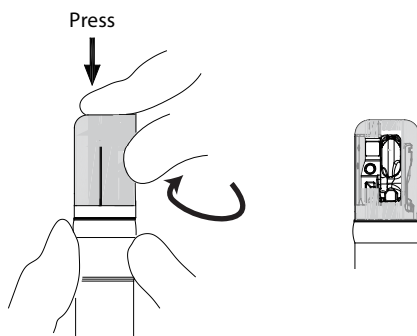


Figure 3-13 Rotating the Distal End Cap

After the installation, perform the following inspections.

- Ensure that there is no gap between the distal end and the distal end cap in areas indicated by arrows, as shown in Figure 3-14.

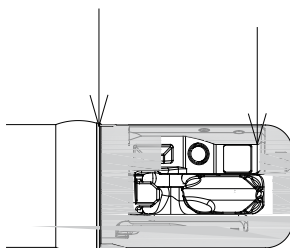


Figure 3-14 Confirming the Space

- Ensure that the position on the distal end cap and the surface of the light guide lens indicated by the arrow are parallel and that the light guide lens and the objective lens are completely out, as shown in Figure 3-15.

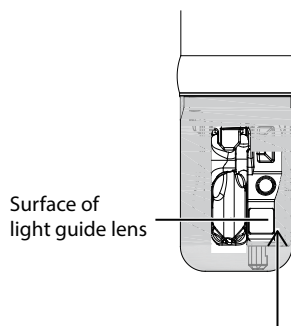


Figure 3-15 Confirming the Parallel

- Ensure that the bottom of the distal end cap does not stretch abnormally.

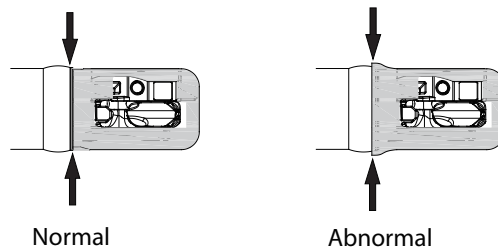


Figure 3-16 Confirming the Abnormal Stretching

- Stroke the distal end cap in the direction of the arrow gently and ensure that the edge of the distal end cap does not roll up. Otherwise, replace the distal end cap.

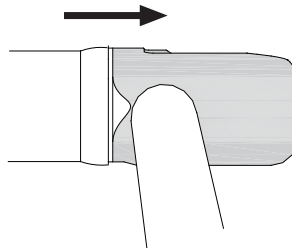


Figure 3-17 Confirming the Distal End Bottom

- Pull the distal end cap gently and rotate the distal end cap clockwise and anticlockwise respectively to ensure that the distal end cap does not drop off from the distal end.

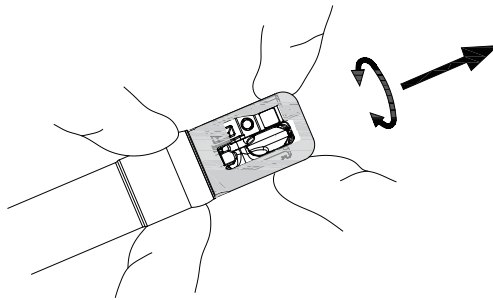


Figure 3-18 Confirming the Stability of the Installation

- Rotate the elevator control knob clockwise and anticlockwise until it stops several times, and ensure that the forceps elevator does not get stuck in the distal end cap.
- Ensure that the distal end cap cannot be observed in the image. Otherwise, install the distal end cap again.

3.3 Connecting the Endoscopy System

NOTE:

- Before connecting the endoscopy system, power off all the peripherals.
- Ensure that the peripherals are properly connected to the endoscope. For the detailed descriptions about inspection and connection of the peripherals, refer to relevant user manuals.

Connect the endoscopy system, as shown in Figure 3-19.

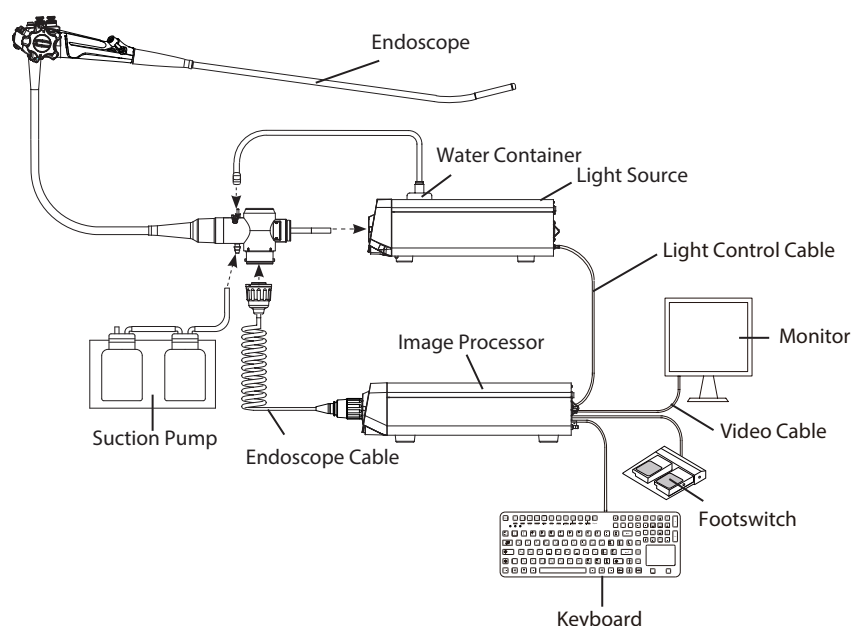


Figure 3-19 Connecting the Endoscopy System

3.3.1 Connecting the Light Source

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

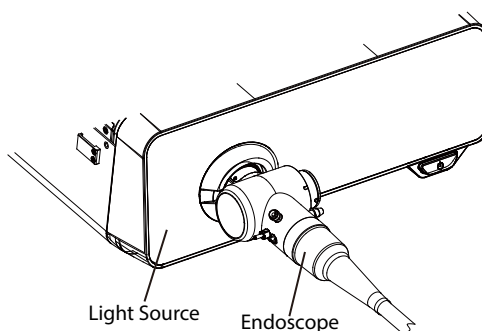


Figure 3-20 Connecting the Light Source

3.3.2 Connecting the Water Container



- The water container should be installed on the water container bracket at the right side of the light source. Do not place the water container casually. Otherwise, the water-feeding tube may leaking, causing device malfunction.
- When disconnecting the water container connector from the endoscope, ensure that no water splashes out from the water container connector. Otherwise, the splashed water may cause device malfunction.

Perform the following steps.

1. Connect the water-feeding connector of the water container connector to the water-feeding port on the connector section firmly.

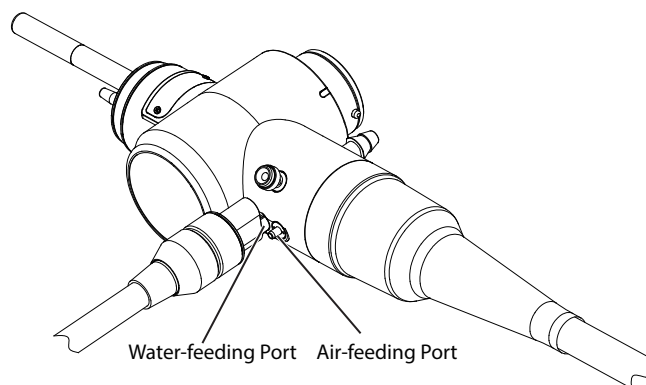


Figure 3-21 Aligning the Water-feeding Connector

2. Rotate the water container connector 90° clockwise until the air-feeding connector is aligned with the air-feeding port on the connector section. Connect the water container connector firmly.

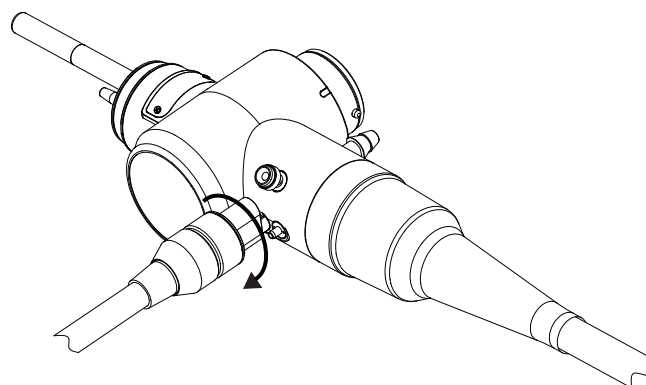


Figure 3-22 Rotating the Water Container Connector

3. Ensure that the water container connector is correctly and cannot be rotated.

3.3.3 Connecting the Endoscope Cable

The endoscope cable is shown in Figure 3-23.

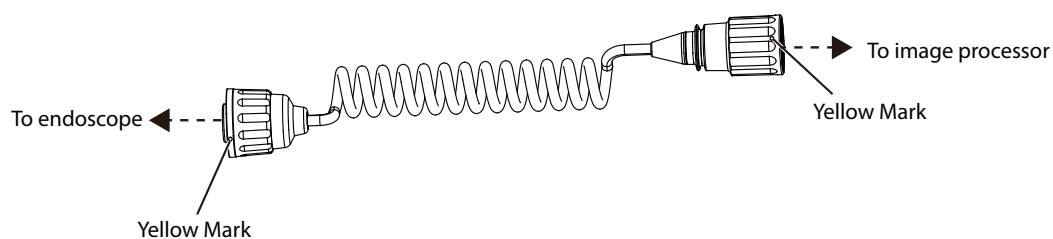


Figure 3-23 Endoscope Cable

Perform the following steps.

1. As shown in Figure 3-24, align the yellow mark on the endoscope cable connector with the yellow mark 1 on the electrical connector of the endoscope, and insert the endoscope cable connector into the electrical connector of the endoscope.

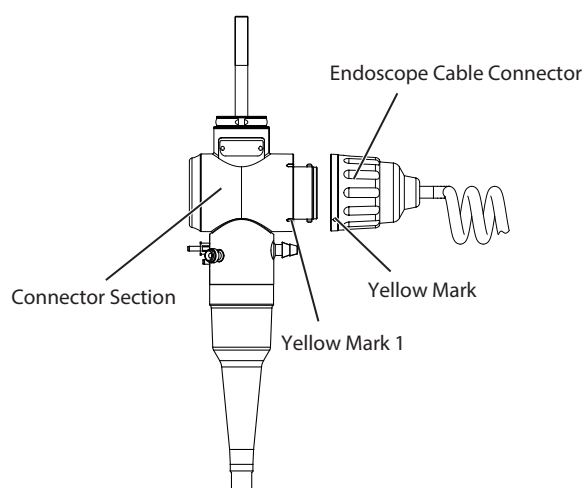


Figure 3-24 Endoscope Cable Connection 1

2. As shown in Figure 3-25, rotate the endoscope cable connector clockwise to align the yellow mark on the endoscope cable connector with the yellow mark 2 on the electrical connector of the endoscope until a click is heard.

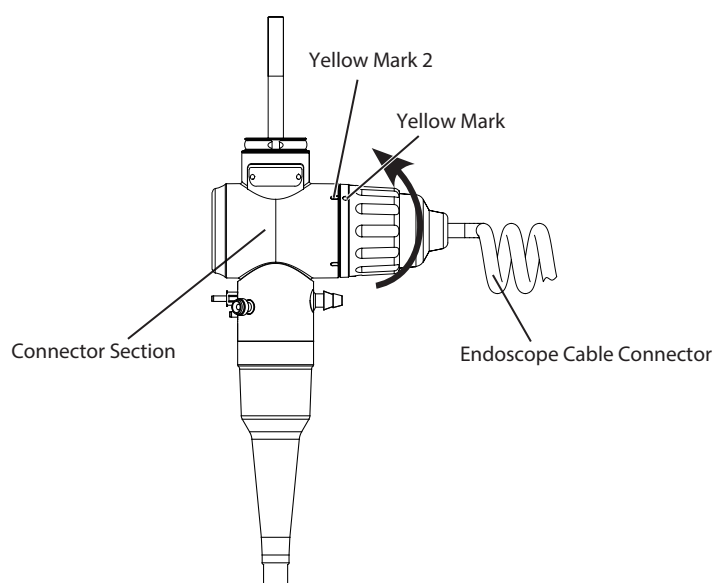


Figure 3-25 Endoscope Cable Connection 2

3.3.4 Connecting the Image Processor

NOTE:

- Do not use the endoscope cable forcibly. Otherwise, device malfunctions may occur.
- Do not touch the pins inside the connectors of the endoscope cable. Otherwise, the image processor may be damaged.

Perform the following steps.

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

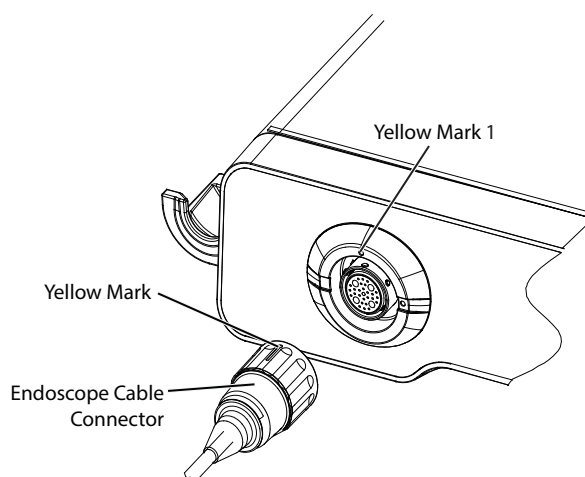


Figure 3-26 Connecting the Image Processor 1

2. Rotate the connector clockwise until the yellow mark on the connector is aligned with the yellow mark 2 on the connector port.

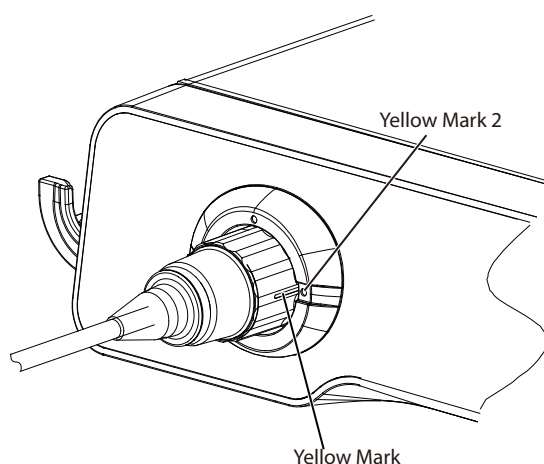


Figure 3-27 Connecting the Image Processor 2

3.3.5 Connecting the Suction Pump



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

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

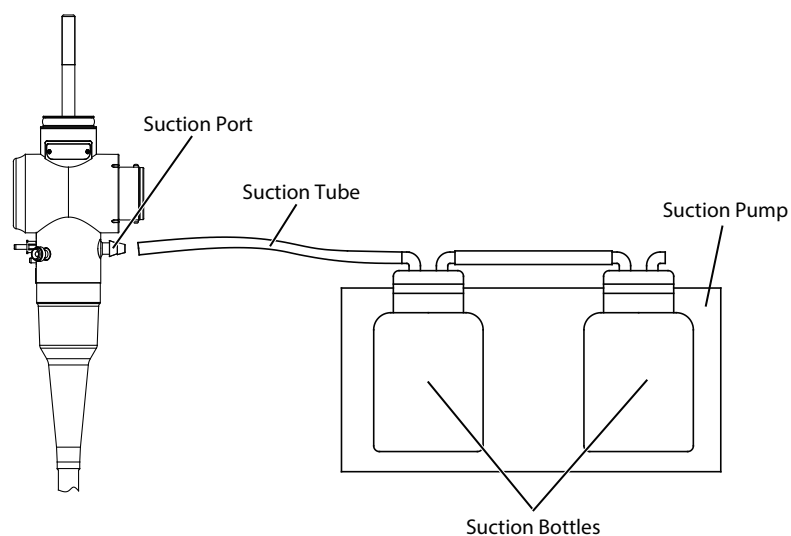


Figure 3-28 Connection the Suction Pump

3.4 Inspecting the Endoscopy System

3.4.1 Inspecting the Image

WARNING Do not look straight at the light emitting from the distal end. Otherwise, it may result in injury to eyes.

Perform the following steps.

1. Power on the light source, the image processor and the monitor.
2. Turn on the lamp of the light source and ensure that light emits from the distal end.
3. Observe the image on the monitor and ensure that there is no interference, blurring or other abnormality in the image.
4. Adjust the bending angle, and ensure that the real-time image is normally displayed and the image orientation is correct.
5. If the distal end cap can be seen on the image, install it again.

NOTE:

If the endoscopic image is unclear because the objective lens is dirty, use a soft lint-free cloth dampened with 75% ethyl alcohol to wipe the objective lens.

3.4.2 Inspecting the Remote Buttons

WARNING Even if the remote buttons are not intended to be used, it is also required to inspect their functions before performing an examination. Otherwise, the image may be frozen or other abnormality may occur, resulting in injury, bleeding or perforation to the patient.

Press each remote button and check if the preset function can be normally achieved.

3.4.3 Inspecting the Air-feeding Function

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

Perform the following steps.

1. Adjust the air-feeding level to **H** according to the light source user manual.
2. Immerse the distal end of the endoscope in a container filled with sterile water to a depth of 10 cm. Do not operate the air/water valve and ensure that no bubble generates from the air/water nozzle.

NOTE:

When the distal end is immersed to a depth of less than 10 cm, a few bubbles may appear even if the air/water valve is not operated. This is a normal phenomenon.

3. Cover the hole on the air/water valve with your finger to feed air. Ensure that bubbles generate from the air/water nozzle continuously.

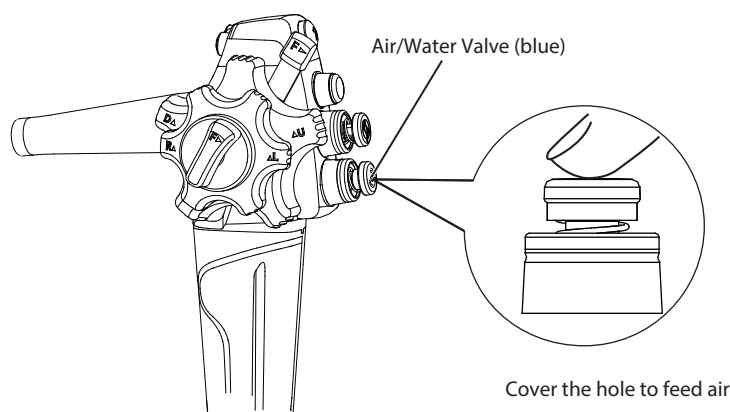


Figure 3-29 Inspecting the Air-feeding Function

4. Release your finger and ensure that no bubble generates from the air/water nozzle.

3.4.4 Inspecting the Water-feeding Function

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

Perform the following steps.

1. Cover the hole on the air/water valve with your finger, and press the valve to feed water. Observe the image on the monitor and ensure that water flows over the objective lens.
2. Release your finger and ensure that no water flows out and the air/water valve restores to its original position smoothly.
3. Cover the hole with your finger 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.*

3.4.5 Inspecting the Suction Function



WARNING

- If the biopsy valve is leaky, patient's debris and body liquid may leak out and cause disease infection.
- If the suction valve cannot be operated smoothly, it may result in suction malfunction and personal injury. Install the suction valve again or replace it with a new one. If the problem still exists after the replacement, the endoscope may be malfunctioning. Stop using the endoscope and contact the local distributor of the manufacturer.

Perform the following steps.

1. Place a bottle of sterile water and the endoscope on the workbench to inspect the suction function and adjust the suction pressure.
2. Immerse the distal end in the sterile water, and keep the instrument channel inlet and the sterile water surface at the same height.
3. Press the suction valve and ensure that water can be continuously aspirated into the suction bottle.
4. Release the suction valve and ensure that the suction stops, and the suction valve restores to the original position.
5. Press the suction valve to aspirate water for a few seconds, release the valve, and wait for several seconds. Repeat the operation 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.

3.4.6 Inspecting the Instrument Channel and Forceps Elevator



WARNING

Keep your eyes away from the distal end when the biopsy forceps or other endotherapy accessories stretch out from the distal end. Otherwise, it may result in injury to eyes.

Perform the following steps.

1. Lower the forceps elevator and insert the endotherapy accessory into the instrument channel through the slit on the biopsy valve. Ensure that the accessory can be smoothly extracted from instrument channel outlet on the distal end without any foreign object.
2. Stretch out the endotherapy accessory from the distal end for about 3 cm, rotate the elevator control knob anticlockwise to ensure that the forceps elevator can be raised smoothly.
3. Rotate the elevator control knob clockwise to ensure that it can be lowered smoothly.
4. Ensure that the endotherapy accessory can be smoothly withdrawn from the instrument channel inlet.

4 Operations

The operator of this endoscope should be a physician or the medical personnel who operates under the supervision of the physician and should 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.



- Patient 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 or even 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. Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.
- Do not insert or withdraw the endoscope in any of the following cases. Otherwise, it may result in personal injury.
 - When the endotherapy accessories 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.
 - When the image is magnified.
 - When the forceps elevator raises.
- The patient should take off metallic accessories (watch, glasses, necklace and so on) before the endoscopy when high frequency cauterization treatment is performed. Otherwise, it may result in skin burns around the accessories.
- Before inserting the endoscope into the patient's body, the operator should ensure that the endoscope can be operated correctly. If any abnormality is found on the distal end during the endoscopy, the operator should stop using the endoscope immediately and slowly withdraw it from the patient's body to avoid injury, bleeding or perforation.
- Do not operate the angulation control knobs forcibly. Otherwise, the bending section could be inversely bent and it may result in personal injury, bleeding or perforation.
- Before each use or after a change of viewing modes / settings, ensure that the view observed through the endoscope provides a real-time image (rather than a stored one) and has the correct image orientation.
- If the image is unclear or frozen, the operator should not operate the bending section of the endoscope, feed air or insert or withdraw the insertion section. Otherwise, it may result in personal injury, bleeding or perforation.
- If the image or the function is abnormal, stop examining even if the abnormality disappears rapidly. Withdraw the endoscope slowly from the patient body while observing the image. Otherwise, the abnormality may occur again and it may result in personal injury, bleeding or perforation.
- Before examining a patient with the endoscope, the physician shall fully explain the risks of the examination to the patient and ask the patient to sign an informed consent form.
- During the examination, if the distal end cap drops off or is about to drop off from the distal end, stop the exam and slowly withdraw the endoscope from the patient's body. Otherwise, it may result in patient injury.
- When switching between illumination modes, the image may be interfered. Therefore, do not operate the endoscope or perform a treatment while switching. Otherwise, it may result in personal injury.

4.1 Inserting the Endoscope



- To avoid the patient mistakenly biting the insertion section during the examination, provide mouthpieces for patients before inserting the endoscope.
- To prevent the patient's false teeth from dropping down, take them off before the exam.
- The mouthpiece is disposable. Do not reuse it.

Perform the following steps.

1. Hold the control section of the endoscope with your left hand, operate the air/water valve and suction valve with your left index finger, and operate the up/down angulation control knob, left/right angulation control knob, and elevator control knob with your left thumb. Operate the insertion section with your right hand.

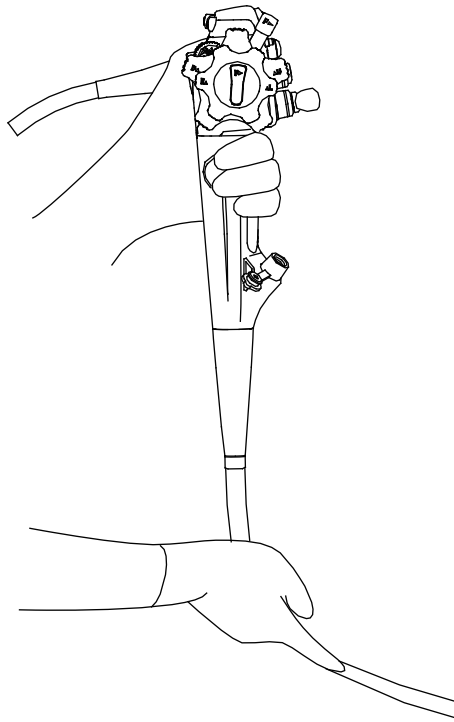


Figure 4-1 Holding the Endoscope

2. Rotate the elevator control knob clockwise to its maximum.
3. Place the mouthpiece between the teeth or the gingiva of the patient and insert the endoscope from the opening of the mouthpiece.
4. Observe the whole endoscope insertion process that is from the mouth to the throat through the monitor carefully. Do not insert the insertion section beyond its insertion limit mark.

4.1.1 Adjusting the Angle of Bending Section



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



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

Perform the following steps.

1. Rotate the up/down or left/right angulation control knob 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.

4.1.2 Feeding Air/Water and Aspiration

■ To feed air/water



If the sterile water level in the water container is under the lowest limit during use, add sterile water. Do not exceed the recommended upper limit.

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 container to 40°C - 50°C (104°F - 122°F).

The water container is shown in the following figure.

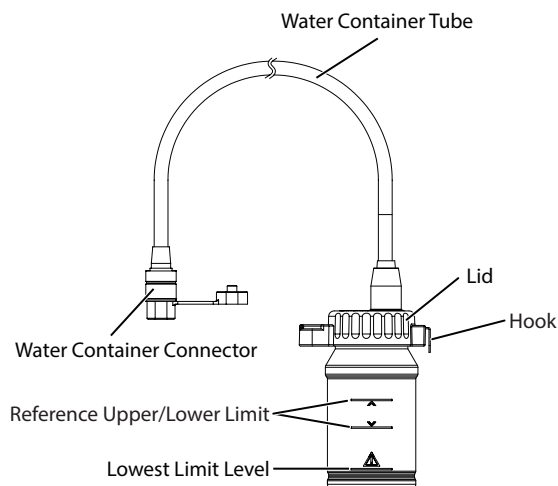


Figure 4-2 Water Container

Perform the following steps.

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 to the surface of objective lens.

■ Aspiration



- Attach the cap of the biopsy valve firmly before suction operation. Otherwise, it may degrade the performance of the suction system, which may result in leakage of patient's debris or body liquid, posing potentially infection risks.
- During aspiration, keep the suction pressure at the lowest level required to perform the endoscopy. Excessive suction pressure may result in aspiration of mucous membranes, causing injury to mucous membranes.
- Avoid aspirating solid or sticky matters. Otherwise, it may block instrument channel, suction channel or suction valve. If the suction valve is blocked, disconnect the suction tube, turn off the suction pump, remove the suction valve, and clean the foreign objects.



- Empty the suction bottle before use. Otherwise, the overflow liquid may result in the suction pump malfunction.
- Discharge the waste in accordance with local laws and regulations. For details, consult the local distributor.

Press the suction valve to aspirate excessive liquid and debris in the patient's body.

NOTE:

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

4.2 Observing the Image

Observe the endoscopic image on the monitor. For details, refer to the relevant user manuals of the light source and the image processor.

4.3 Using the Endotherapy Accessory



- When using the endotherapy 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.
- When inserting and withdrawing the endotherapy accessory, ensure that the tip of the endotherapy accessory is closed. Slowly insert or withdraw the accessory and get the accessory through the slit on the biopsy valve straightly. Otherwise, the biopsy valve may be damaged and tissue loss may be caused.
- If it is difficult to insert or withdraw the endotherapy accessory, you should straighten the bending section while observing the image. Inserting or withdrawing endotherapy accessory forcibly may damage the biopsy valve or the endotherapy accessory.
- If the tip of the endotherapy accessory is invisible in the viewing area, do not stretch the tip out or open the tip. Otherwise, it may cause patient injury, bleeding or accessory damage.
- Do not forcibly or suddenly insert the endotherapy accessory. Otherwise, the endotherapy 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 endotherapy operation. It may result in air embolism.
- Do not hang the endotherapy accessory on the biopsy valve to avoid damaging the valve.
- When using the endotherapy accessory, if the forceps elevator can not be lowered, stop the examination immediately and contact the local distributor.

4.3.1 Using the Non-wire Guided Endotherapy Accessory

Preform the following steps.

1. Select the endotherapy accessories that are compatible with the device.
2. Rotate the elevator control knob anticlockwise to raise the forceps elevator.
3. Lock the up/down, left/right angulation control knobs.
4. Ensure that the tip of the endotherapy accessory is closed or in the tube sheath. Slowly insert the endotherapy accessory straightly into the slit on the biopsy valve.
5. Hold the endotherapy accessory at a point 4 cm away from the instrument channel, slowly insert the accessory into the instrument channel while observing the endoscope image, until the accessory contacts with the forceps elevator.
6. Rotate the elevator control knob clockwise to lower the forceps elevator. Slowly insert the endotherapy accessory and rotate the forceps elevator anticlockwise to raise the forceps elevator. Ensure that the endotherapy accessory can be observed in the endoscopy image.
7. Rotate the elevator control knob to adjust the forceps elevator height.
8. Operate the endotherapy accessory. For details, refer to the relevant user manuals.
9. Close the tip of the endotherapy accessory or retract it into the sheath.
10. Slowly lower the forceps elevator and withdraw the endotherapy accessory.

4.3.2 Using the Wire-guided Endotherapy Accessory

When using the wire-guided endotherapy accessory and the guide wire, if the guide wire is fixed, only the wire guided endotherapy accessory can be replaced.



- Do not use the guide wire that the outer surface is damaged. Otherwise, electric leakage will occur, causing personal injury or device damage.
- When inserting or withdrawing the wire guided endotherapy accessory, ensure that the guide wire is locked. Otherwise, it may cause injury, bleeding or perforation to the patient.
- When locking the guide wire, do not move it and fast inset or withdraw the endotherapy accessory. Otherwise, the following situations may occur.
 - The guide wire drops off and cannot be locked.
 - The guide wire is inserted into the patient too deep, causing injury, bleeding or perforation to the patient.
 - The outer surface of the guide wire is damaged and its debris drops into the patient body.
 - The outer surface of the guide wire is damaged and electric leakage occurs, causing patient injury and device damage.
- When the guide wire tip stretching out from the endotherapy accessory is locked, observe the X-ray image and slowly insert or withdraw the wire guided endotherapy accessory. Otherwise, it may cause injury, bleeding or perforation to the patient.

■ To insert the guide wire

Perform the following steps.

1. Select the endotherapy accessories that are compatible with the device.
2. Rotate the elevator control knob anticlockwise to raise the forceps elevator.
3. Lock the up/down, left/right angulation control knobs.
4. Ensure that the tip of the endotherapy accessory is closed or in the tube sheath. Slowly insert the endotherapy accessory straightly into the slit on the biopsy valve.
5. Hold the endotherapy accessory at a point 4 cm away from the instrument channel inlet, slowly insert the accessory into the instrument channel while observing the endoscopy image, until the accessory contacts with the forceps elevator.
6. Rotate the elevator control knob clockwise to lower the forceps elevator. Slowly insert the endotherapy accessory and rotate the elevator control knob anticlockwise to raise the forceps elevator. Ensure that the endotherapy accessory can be observed on the endoscopy image.
7. Insert the guide wire from the endotherapy accessory end near your hand, observe the endoscopy image and X-ray image and insert the guide wire into the desired position.

■ To withdraw the wire-guided endotherapy accessory

Perform the following steps.

1. Lower the forceps elevator, observe the endoscopy image and X-ray image and withdraw the tip of the endotherapy accessory into the instrument channel.
2. Slowly rotate the elevator control knob anticlockwise to its end and fix the guide wire in the forceps elevator.
3. Observe the endoscopy image and X-ray image and slowly withdraw the endotherapy accessory.

■ To insert the wire-guided endotherapy accessory

Perform the following steps.

1. When the guide wire stretches out from the distal end, rotate the elevator control knob anticlockwise to raise the forceps elevator to fix the guide wire and keep it steady.
2. Observe the endoscopy image and X-ray image, slowly insert the wire guided endotherapy accessory from the guide wire end near your hand until the endotherapy accessory contacts with the forceps elevator.
3. Observe the endoscopy image and slowly rotate the elevator control knob clockwise to lower the forceps elevator.
4. Observe the endoscopy image and X-ray image and slowly insert the endotherapy accessory. Ensure that the guide wire is steady.

4.4 Ending the Examination



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

Perform the following steps.

1. Press the suction valve to aspirate the air, blood, mucus or other debris from the patient's body.
2. Ensure that the bending section of the endoscope is free.
3. Slowly withdraw the endoscope from the patient's body while observing the endoscopy image.

5 Cleaning and Disinfection

This chapter describes the methods for cleaning and disinfection of the series endoscopes mentioned in this manual and the basic information about how to safely and effectively clean and disinfect the series endoscopes.

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
- Individual 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 high-level disinfection, you can also refer to the cleaning and disinfection regulations 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, goggle 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 should have sufficient space and adequate ventilation.
- During the disinfection of endoscope, all channels of the endoscope should be cleaned and disinfected, including the channel not used during last examination. Otherwise, the next patient may be infected.
- Before manual cleaning of the endoscope each time, perform a leakage test. When leakage is found, stop using the endoscope and return it to the local distributor for repair to avoid further damage. When a leaky endoscope is used, the endoscopic image may disappear and the bending function or other functions may become abnormal.
- Do not reuse single-use accessories.
- When finding that a patient is infected with unknown super bacteria after use of endoscope, please report the incident in accordance with local laws or regulations.
- After being contaminated by pathogenic bacterium that is hard to kill, such as cryptosporidium or prion virus, the endoscope and the accessories can only be used on such patients, or you should immediately dispose of the endoscope and the accessories after use in an appropriate manner.
- Dispose of endotherapy accessories in accordance with local laws and regulations.
- Use the automated endoscope reprocessor (AER) that is legally listed for sale to disinfect the endoscope.
- Before using the automated endoscope reprocessor (AER), ensure that it can thoroughly clean and disinfect the endoscope, including all channels. Otherwise, the next patient or the operator may be infected. For the operation, specifications and connector information of the AER, please consult the AER manufacturer.
- The endoscope is not strictly cleaned and disinfected in the factory. Therefore, the operator should strictly perform the cleaning and disinfection processes described in this manual before use.
- After use each time, the endoscope should be cleaned, disinfected and stored as described in this user manual. Otherwise, it may result in disease infection of the patient or operator, damage to the endoscope or performance degradation.
- Before using the endoscope each time, you should clean and disinfect the endoscope according to the regulations of the local hospital based on the actual disinfection and storage conditions of the endoscope.
- Before cleaning and disinfection, ensure that the insertion section of the endoscope is in natural state (unlocked). Otherwise, the endoscope may be damaged during the cleaning or disinfection process.
- Store the ethyl alcohol in a sealed container. Otherwise, a fire may be incurred. Besides, the alcohol may become invalid due to volatilization.
- The quality of water used for cleaning and disinfection should accord with AAMI TIR34: 2014 standards.

5.1 Cleaning Solution, Disinfectant and Flush Fluid



- Use the cleaning solution and disinfectant that meet local laws and regulations.
- Use the cleaning solution and disinfectant recommended by the manufacturer, and ensure that their concentration 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 contact the manufacturer.
- Prepare, use, store and dispose of the cleaning solution and disinfectant according to the instructions provided by manufacturers.
- Do not use expired cleaning solution or disinfectant.
- The endoscope is not autoclavable or cannot be processed by low-temperature plasma.
- Do not dry any disinfectant on the endoscope in air.
- Do not immerse the endoscope in the anhydrous ethanol or wipe the endoscope with the anhydrous ethanol.

5.1.1 Cleaning Solution

Cleaning solution can be used to dissolve and emulsify feculence and microbe, enhance the power, facilitate cleaning, and improve the cleaning quality.

The following cleaning solutions are recommended to clean the endoscope.

Table 5-1 Recommended Cleaning Solution and Method

Cleaning Solution	Concentration	Temperature	Contact time	Using Method
Metrex EmPower	1:128	20 - 40°C	≥1 min	Pre-cleaning and manual cleaning before manual disinfection
Dr. Weigert neodisher endo® CLEAN	0.5%	20°C	1 min	Pre-cleaning and manual cleaning before automatic cleaning and disinfection
PROTEAZONE™ PLUS Detergent (Cantel Medical)	0.5%	40°C	3 min	Automatic cleaning

NOTE:

- Do not use the cleaning solution repeatedly.
- Excessive cleaning solution foaming could cause inadequate contact between the interiors of the channels and the cleaning solution. Consequently, the endoscope cannot be cleaned completely.

5.1.2 Disinfectant

The following disinfectants are recommended for disinfect the endoscope.

Table 5-2 Recommended Disinfectant and Method

Disinfectant	Concentration	Temperature	Contact time	Using Method
MetriCide 28 Long-life Activated Dialdehyde Solution	2.5%	25°C	90 min	Manual disinfection
Cidex OPA	0.55%	25°C	≥ 5 min	Manual disinfection
DISINEER® Peracetic acid (PAA)	0.2% - 0.30% (w/v)	25°C	≥ 5 min	Manual disinfection

Disinfectant	Concentration	Temperature	Contact time	Using Method
RAPICIDE™ PA Part A and RAPICIDE™ PA Part B (Cantel Medical)	2%	35°C	5 min	Automatic disinfection

NOTE:

- For the detailed usage and precautions of the disinfectant, refer to the instructions of the disinfectant manufacturer.
- The selected disinfectant should 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.
- 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.
- The glutaraldehyde solution is easy to condense on the surfaces of the endoscope and the cleaning and disinfection equipment.
- The OPA and PAA may irritate the skin, eyes and respiratory tract.
- The OPA is easy to stain the clothing, skin and device.

5.1.3 Flush Fluid

The sterile water is recommended as the flush liquid. After high-level disinfection, completely rinse the endoscope, accessories, cleaning and disinfection tools with sterile water to remove the residual of disinfectant. If no sterile water is available, filtered or tap water may be used only when the rinse is followed by 75% ethyl alcohol flushing and drying steps.

NOTE:

- Do not use running water as flush fluid.
- Do not use the flush 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
- Manual cleaning basin, rinse basin, disinfection basin, and terminal rinse basin
- Waterproof cap
- Channel plug
- Injection tube
- Cleaning tube for forceps elevator wire channel
- Distal end cleaner
- Cleaning brush
- Channel-opening cleaning brush
- Leakage detector
- Suction pump
- Timer
- Transport container for endoscope
- Transport container for accessories
- Sterile mat (single-use)
- Clean lint-free cloth (single-use)
- Sterile lint-free cloth (single-use)
- Sterile swab
- Syringe (50 mL and 5 mL)
- Air pressure gun
- Sterile container (500 mL)
- Drying container

5.3 Accessory Inspection and Connection

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

5.3.1 Waterproof Cap

Before cleaning or disinfection, the waterproof cap should be connected to the electrical connector of the endoscope to prevent water inflow. The waterproof cap is shown in Figure 5-1.

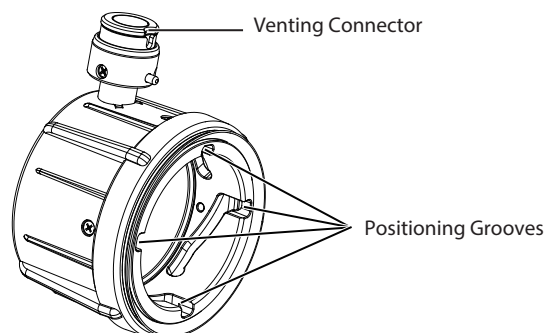


Figure 5-1 Waterproof Cap

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, wipe the inner wall with a dry and clean 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 pins of the electrical connector with the positioning grooves of the waterproof cap.

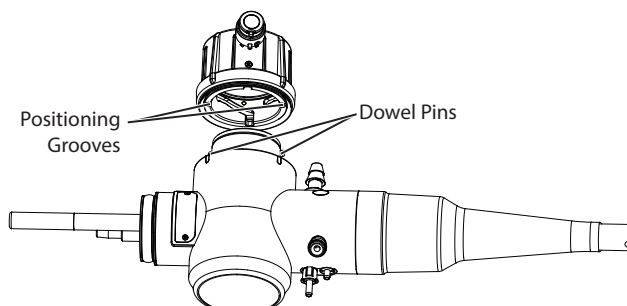


Figure 5-2 Attaching Waterproof Cap 1

2. Press down and rotate the waterproof cap clockwise till the end. Ensure that the waterproof cap is firmly attached onto the endoscope.

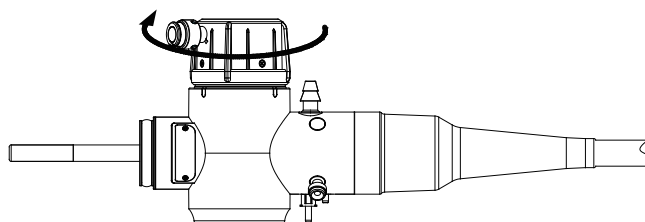


Figure 5-3 Attaching Waterproof Cap 2

NOTE:

Debris on the exterior of the electrical connector may scratch the sealing ring of the waterproof cap, and result in liquid leakage and damage to the endoscope.

5.3.2 Channel Plug

The channel plug is used to plug the instrument channel inlet, air/water valve cylinder and suction valve cylinder during cleaning and disinfection of the endoscope. The following figure shows the channel plug.

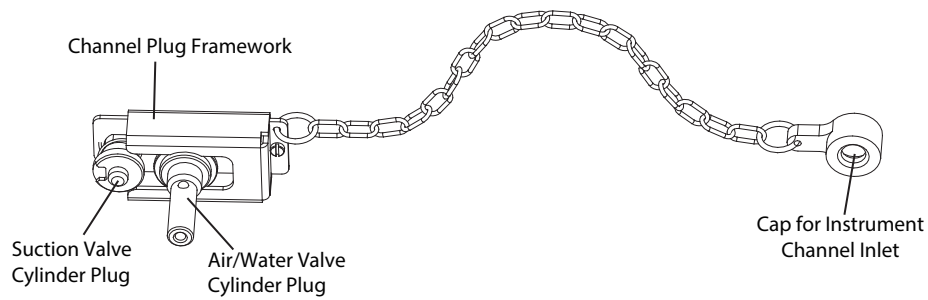


Figure 5-4 Channel Plug

NOTE:

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

Perform the following steps to connect the channel plug.

1. Hold the channel plug, and install the suction valve cylinder plug and air/water valve cylinder plug to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.

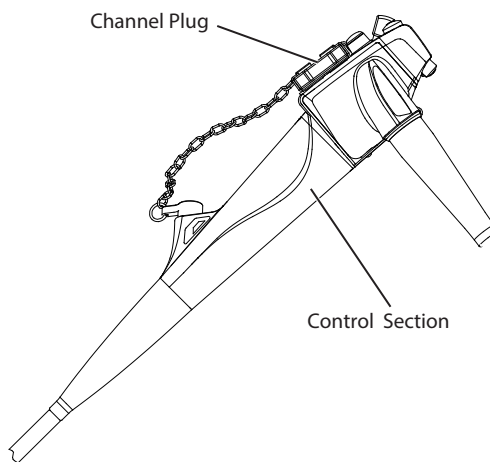


Figure 5-5 Installing the Channel Plug

2. Press and push ahead the channel framework until the installation is firm.
3. Press the cap for instrument channel inlet into the instrument channel inlet, and ensure that the connection is firm.

5.3.3 Injection Tube

The injection tube is used to inject cleaning solution, disinfectant, flush fluid and ethyl alcohol into the air/water channel and suction channel. It is also used to feed air into these channels to discharge residual fluid. The following figure shows the injection tube.

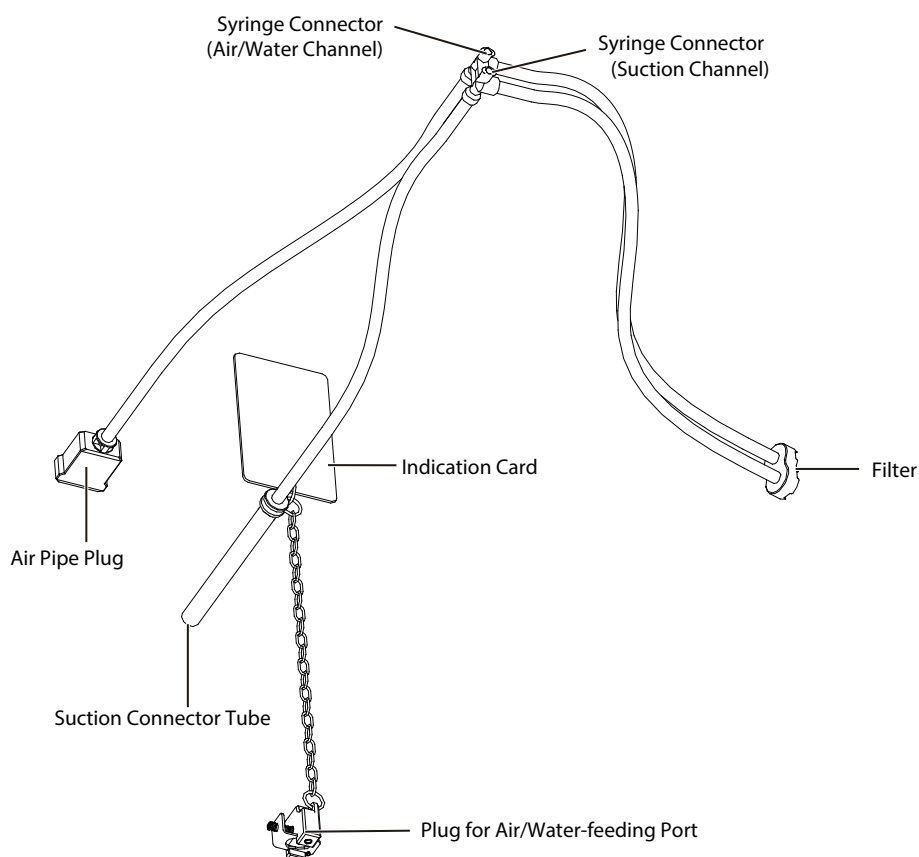


Figure 5-6 Injection Tube

NOTE:

- Before using the injection tube, ensure that there is no crack, scratch, flaws or debris on any component.
- Ensure that the filter mesh is intact.
- Connect a 50 mL syringe to the air/water channel connector. Immerse the filter in the flush fluid, pull out the syringe plunger of the syringe, and ensure that the flush fluid is aspirated into the syringe. Then, push the plunger, and ensure that flush fluid flows from the air pipe plug and no flush fluid flows from the filter.
- Connect a 50 mL syringe to the suction channel connector. Immerse the filter in the flush fluid, pull out the syringe plunger of the syringe, and ensure that the flush fluid is aspirated into the syringe. Then, push the plunger, and ensure that flush fluid flows from the suction connector tube and no flush fluid flows from the filter.

Perform the following steps to connect the injection tube.

1. Connect the waterproof cap and channel plug to the endoscope.
2. Connect the air pipe plug, suction connector tube and plug for air/water-feeding port of the injection tube to the air pipe, suction port and air/water-feeding port of the endoscope connector section respectively.

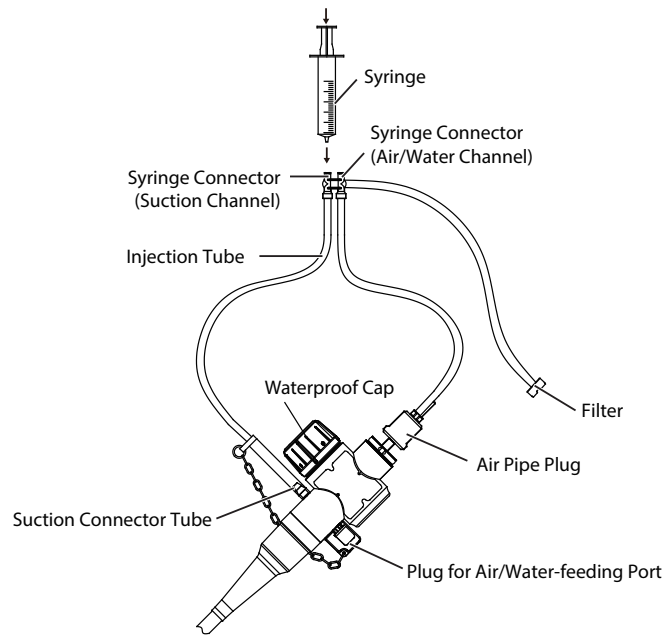


Figure 5-7 Installing the Injection Tube

5.3.4 Cleaning Tube for Forceps Elevator Wire Channel

The cleaning tube for forceps elevator wire channel is used to inject cleaning solution, disinfectant, flush fluid and ethyl alcohol into the forceps elevator wire channel during cleaning and disinfecting the endoscope. It is also used to feed air into the channel to discharge residual liquid.

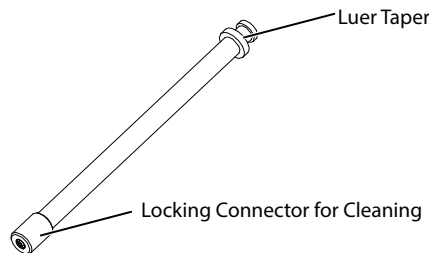


Figure 5-8 Cleaning Tube for Elevator Wire Channel

NOTE:

- Ensure that all parts have no damages, cracks, scratches and debris.
- Using a 5 mL syringe to inject flush fluid into the cleaning tube through the luer taper on the cleaning tube for forceps elevator wire channel. Ensure that the flush fluid can flow out from the locking connector for cleaning.

Install the cleaning tube for the forceps elevator wire channel.

Install the locking connector for cleaning to the forceps elevator wire channel connector on the control section and rotate it clockwise firmly.

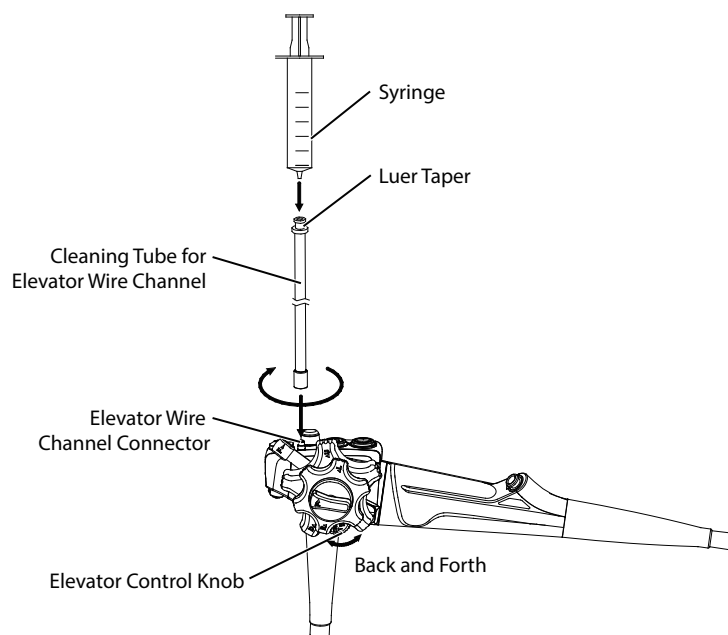


Figure 5-9 Installing the Cleaning Tube for Elevator Wire Channel

5.3.5 Distal End Cleaner

The distal end cleaner is used to inject cleaning solution, disinfectant, flush fluid and ethyl alcohol into the distal end during cleaning and disinfecting the endoscope. It is also used to feed air into the channel to discharge residual liquid. The distal end cleaner is shown in Figure 5-10.

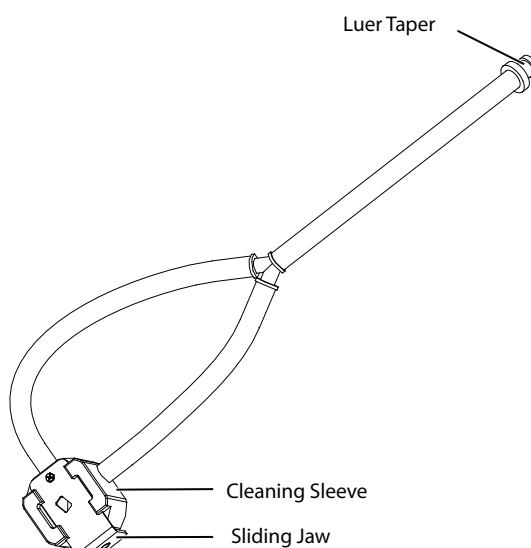


Figure 5-10 Distal End Cleaner

Before using the distal end cleaner, perform the following inspections.

- Ensure that all parts have no damages, cracks, scratches and debris.
- Ensure that the sliding jaw can be pressed smoothly.
- Using a 50 mL syringe to inject clean water into the cleaning tube through the luer taper on the distal end cleaner of the forceps elevator wire channel. Ensure that the clean water can flow out from the side of the cleaning sleeve on the cleaner.

Perform the following steps to install the distal end cleaner.

1. Press the sliding jaw on the distal end cleaner and put on the cleaning sleeve to the distal end.

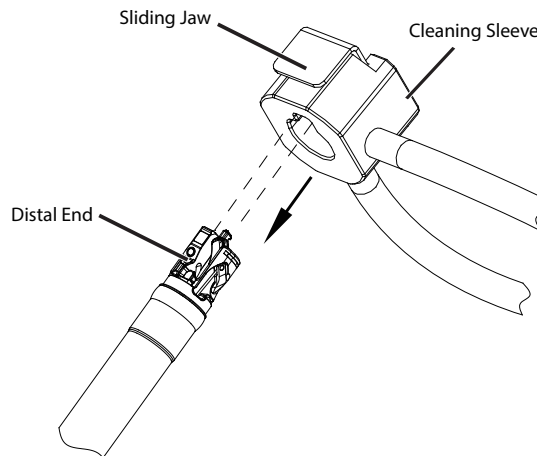


Figure 5-11 Aligning the Cleaning Sleeve with the Distal End

2. Put the distal end into the cleaning sleeve until the hook stretches out from the recess, release the sliding jaw and ensure that the hook and recess are locked firmly.

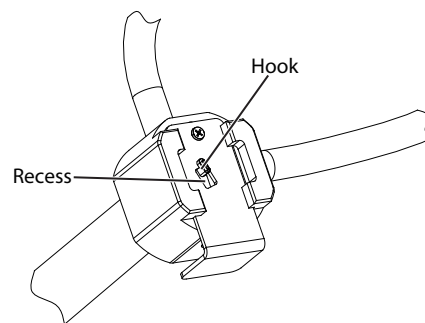


Figure 5-12 Fixing the Distal End Cleaner

5.3.6 Cleaning Brush

The cleaning brush is used to brush inner surfaces of the instrument channel and the suction channel. The following figure shows the cleaning brush.

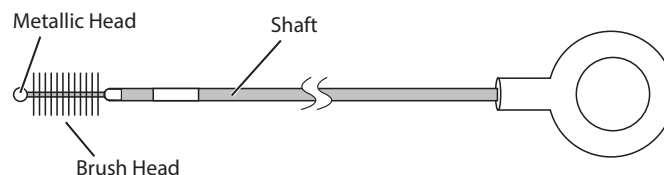


Figure 5-13 Cleaning Brush

Perform the following inspections before using the cleaning brush.

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

NOTE:

- *Select appropriate cleaning brushes to brush the channels and accessories.*
- *Clean and disinfect the reusable cleaning brush after each use.*

5.3.7 Channel-opening Cleaning Brush

The channel-opening cleaning brush is used to brush the air/water valve, suction valve, biopsy valve and, interiors and openings of the cylinder, suction valve cylinder and instrument channel inlet. . The following figure shows the channel-opening cleaning brush.

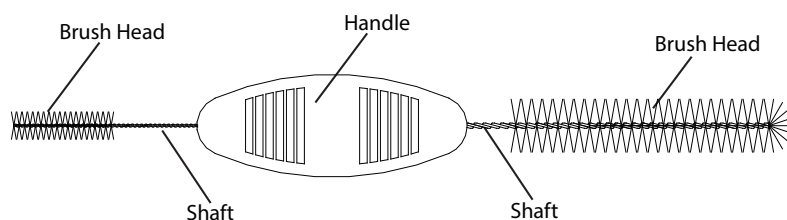


Figure 5-14 Channel- opening Cleaning Brush

Perform the following inspections before using the channel-opening cleaning brush.

- Ensure that the brush heads are firm.
- Ensure that there is no bending, scratch or other damage on the brush shafts.
- Ensure that there is no debris on the brush shafts, handle and bristle.

5.3.8 Leakage Detector

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

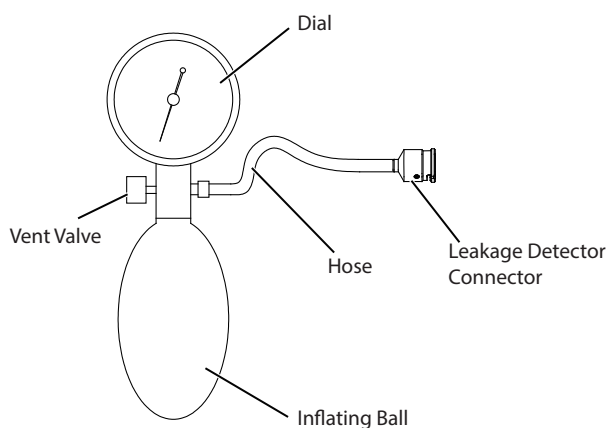


Figure 5-15 Leakage Detector

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 Cleaning and Disinfection Process

Clean and disinfect the endoscope in accordance with the following diagram.

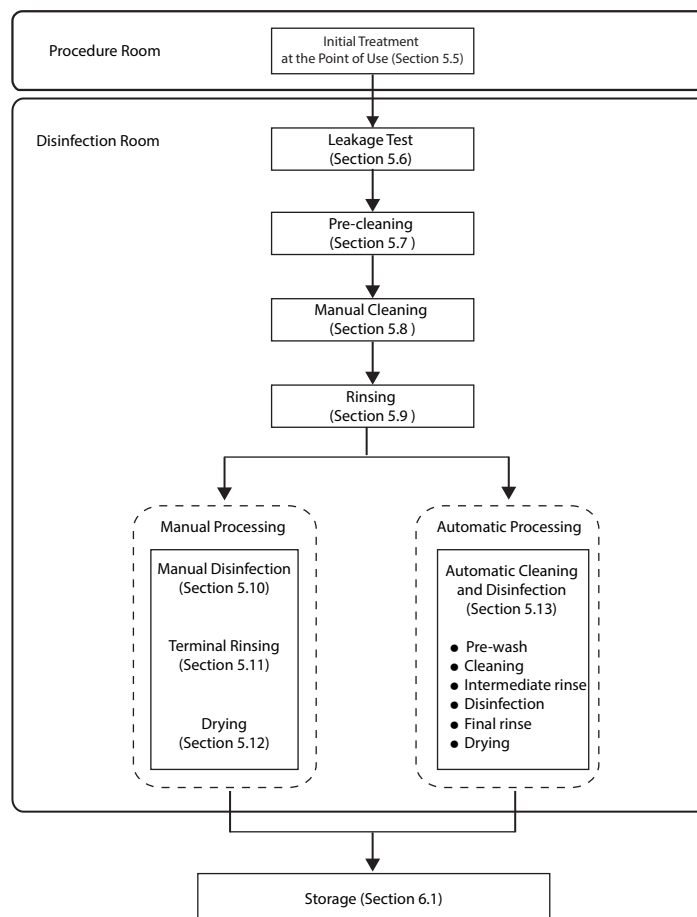


Figure 5-16 Cleaning and Disinfection Process

5.5 Initial Treatment at the Point of Use



- WARNING**
- After being withdrawn from the patient's body, the endoscope should be pre-cleaned at the bedside immediately.
 - 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.

5.5.1 Wiping the Insertion Section

NOTE:

When wiping the endoscope, do not bend the insertion section excessively. Otherwise, the outer rubber of the insertion section may be damaged.

Perform the following steps.

1. After the endoscope is withdrawn from the patient's body, use a clean lint-free cloth dampened with cleaning solution to wipe the surface of the endoscope insertion section to remove all visible soil.
2. Wipe the lens surfaces of the forceps elevator and objective lens gently.

5.5.2 Flushing the Suction Channel

NOTE:

During aspiration, observe the liquid in the suction bottle carefully to avoid overflow, which might damage the suction pump.

Perform the following steps.

1. Turn on the suction pump.
2. Install the biopsy valve properly.

3. Immerse the distal end of the endoscope in cleaning solution, and press the suction valve to aspirate solution into the instrument channel for 30s.
4. Take out the distal end from the cleaning solution, and press the suction valve to aspirate air for 10s.
5. Turn off the suction pump.

5.5.3 Flushing the Air/Water Channel

Perform the following steps.

1. Turn on the air pump of the light source, and adjust the air-feeding pressure to the maximum.
2. Press the air/water valve to feed water into the air/water channel for 30s.
3. Release the air/water valve and block the hole on the valve to feed air into the air/water channel for 10s.
4. Power off the light source.

5.5.4 Disconnecting the Reusable Parts



WARNING When the endoscope is removed from the light source, do not touch the light guide on the connector section and the endoscope connector on the light source. The temperature of the two parts are extremely high, which may cause skin burns.

NOTE:

The pre-cleaned endoscope can be directly transported to the disinfection room for short distance, but should be transported in a sealed container for long distance.

Perform the following steps.

1. Disconnect the endoscope from the image processor, and remove the endoscope cable, suction tube and water container connector from the endoscope.
2. Disconnect the endoscope from the light source.
3. Remove the air/water valve, suction valve and biopsy valve, and place these valves into the transport container for accessories filled with cleaning solution.
4. Connect the waterproof cap to the electrical connector, and transport the endoscope to the disinfection room with the transport container for endoscope.

5.6 Leakage Test

A leakage test should be performed before manual cleaning.



CAUTION When leakage is found on the endoscope, do not use the endoscope. Otherwise, the endoscope may be damaged and electric shock may occur. In case of leakage, contact the local distributor.

NOTE:

- Perform leakage test before cleaning the endoscope each time, and if the conditions do not permit, perform leakage test at least once a day.
- Before leakage test, connect the waterproof cap to the electrical connector of the endoscope tightly to prevent water inflow. Otherwise, the endoscope may be damaged.
- Connect the leakage detector to the waterproof cap tightly. Otherwise, the pressure in the endoscope cannot be increased.
- It is normal that the rubber surface of the bending section starts swelling as the pressure in the endoscope increases after connected to the leakage detector.
- During the test, do not place the leakage detector into the liquid.

Perform the following steps to perform a leakage test.

1. Connect the leakage detector. For details, refer to Section 5.3.8 Leakage Detector.
2. Rotate the vent valve of the leakage detector clockwise to fasten it, use the inflating ball to increase the pressure to 22 kPa, and wait for 3 minutes. If the reading on the dial decreases continuously, the endoscope is leaky. In this case, contact the local distributor.
3. Immerse the entire inflated endoscope in flush fluid and use a syringe to inject liquid into all channels to remove air. Rotate the up/down and left/right angulation control knobs to adjust the angle of the bending section, and wait for 3 minutes. Check if there are air bubbles generating at the insertion section, control section or connector section. If bubbles generate continuously, the endoscope is leaky. The leaky endoscope cannot be cleaned and disinfected. Contact the local distributor.
4. Take out the endoscope and leakage detector from the flush fluid.
5. Rotate the vent valve anticlockwise until the pointer on the dial goes back to the zero position again.
6. Disconnect the leakage detector.

5.7 Pre-cleaning



WARNING

- To ensure the effectiveness of disinfection, clean the endoscope and all accessories completely before disinfection to remove the microorganism or organism that may affect high-level disinfection.
- Ensure the instrument channel and the suction channel are sufficiently cleaned. Insufficient cleaning and disinfection of the endoscope may result in a disease infection risk to the next patient who uses this endoscope.
- To prevent cleaning solution from splattering, pull out the cleaning brush in the water.
- The brush may bend or knot and the brush bristle may 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 brush head falls off in the channel, remove it immediately, and insert a new cleaning brush or other endotherapy accessory into the channel to ensure that no part is left inside the instrument channel or suction channel.

NOTE:

- 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 suction valve cylinder. Otherwise, the brush may be damaged and the suction valve cylinder 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 may get stuck and cannot be pulled out.
- Do not immerse the endoscope together with its accessories. Otherwise, damage to the endoscope may occur.
- To avoid endoscope leakage, clean the endoscope gently.

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

1. Put the endoscope and all its accessories into the cleaning tank.
2. Prepare the cleaning solution in accordance with the temperature and concentration recommended in Table 5-1. Fill the tank with sufficient cleaning solution and immerse the entire endoscope in the cleaning solution.

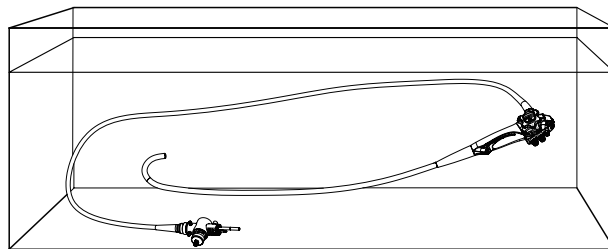


Figure 5-17 Immersing the Endoscope

3. Wipe the outer surface of the entire endoscope in the cleaning solution with a clean lint-free cloth, especially the opening of the air/water nozzle and the forceps elevator surface. Ensure that the outer surface of the endoscope is cleaned completely.
4. Brush channels and connectors in accordance with the steps shown in the following figure.

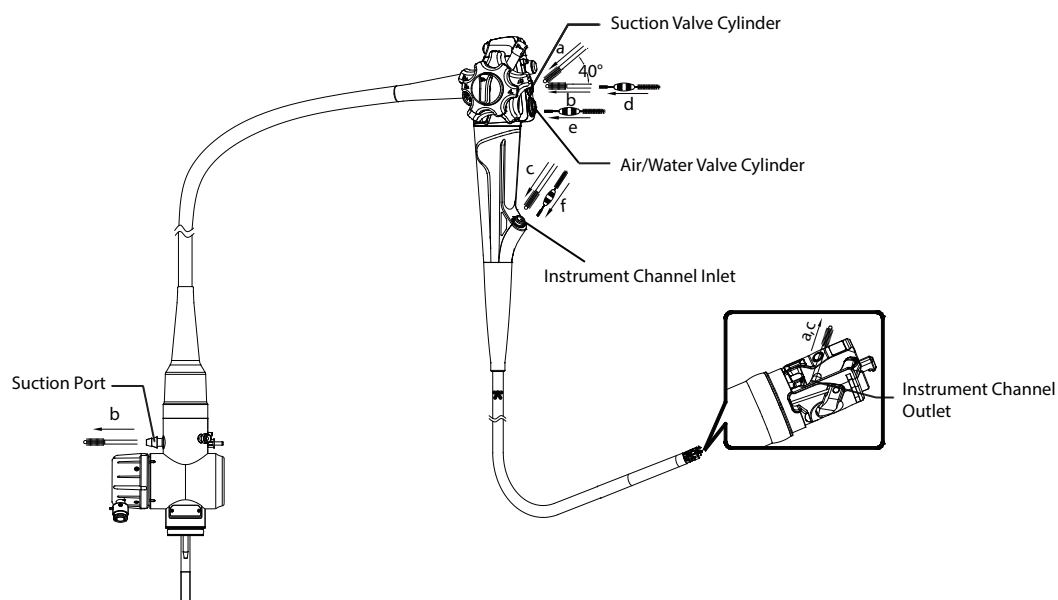


Figure 5-18 Brushing Channels and Connectors

- a. **To brush the suction channel from the control section to the distal end:** Straighten the bending section, insert the cleaning brush at a 40° angle into the suction valve cylinder, slowly advance the brush until the brush head emerges from the distal end, and clean the bristles with your fingertips in the cleaning solution. Pull out the brush from the suction valve cylinder carefully and clean the bristles with your fingertips in the cleaning solution again. Repeat the procedure at least 3 times to ensure that no debris is left.
 - b. **To brush the suction channel from the control section to the connector section:** Insert the cleaning brush vertically into the suction valve cylinder, slowly advance the brush until the brush head emerges from the suction connector, and clean the bristles with your fingertips in the cleaning solution. Pull out the brush from the suction valve cylinder carefully and clean the bristles with your fingertips again. Repeat the procedure at least 3 times to ensure that no debris is left.
 - c. **To brush the instrument channel from the instrument channel inlet to the distal end:** Straighten the bending section, insert the cleaning brush into the instrument channel inlet, slowly advance the brush until the brush head emerges from the distal end, clean the bristles with your fingertips in the cleaning solution and pull out the brush from the instrument channel inlet carefully. Clean the bristles with your fingertips in the cleaning solution again. Repeat this step at least 3 times to ensure that no debris is left.
 - d. **To brush the suction valve cylinder:** Insert the cleaning brush head into the suction valve cylinder until the brush handle contacts with the cylinder. Rotate the brush once and pull out the brush, and clean the bristles with your fingertips in the cleaning solution. Repeat the procedure at least 3 times to ensure that no debris is left.
 - e. **To brush the air/water valve cylinder:** Insert the cleaning brush head into the air/water valve cylinder until the brush handle contacts to the cylinder. Rotate the brush once, pull out the brush, and clean the bristles with your fingertips in the cleaning solution. Repeat the procedure at least 3 times to ensure that no debris is left.
 - f. **To brush the instrument channel inlet:** Insert the cleaning brush into the instrument channel inlet until the brush handle contacts with the inlet, rotate the brush once, pull out the brush, and clean the bristles with your fingertips in the cleaning solution. Repeat the procedure at least 3 times to ensure that no debris is left.
5. Remove the distal end cap, and brush the distal end cap and the distal end in accordance with the following steps.
 - a. Gently hold the bending section with one hand, hold the metal plate on both sides of the distal end cap opening with your thumb and middle fingers of the other hand, and put your index finger on the top of the distal end cap.
 - b. Press the top of the distal end with your index finger, and rotate the distal end cap anticlockwise at the same time until the light guide lens and the objective lens are completely covered by the left side of the rubber.

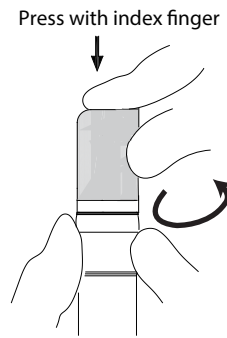


Figure 5-19 Rotating the Distal End Cap

- c. Gently hold the bending section and the distal end cap, and remove the distal end cap in the direction of the arrow.

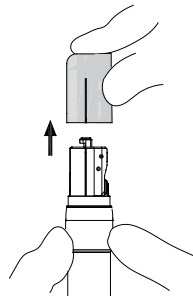


Figure 5-20 Removing the Distal End Cap

- d. Use the channel-opening cleaning brush to brush all parts of the distal end cap in accordance with Figure 5-21. Repeat the step at least 3 times to remove all debris.

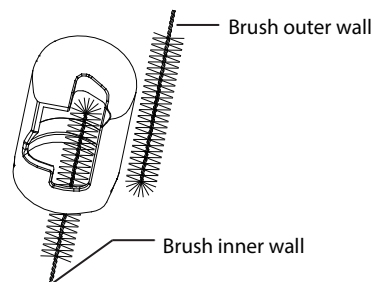


Figure 5-21 Brushing the Distal End Cap

- e. Rotate the elevator control knob clockwise to lower the forceps elevator and use the channel-opening cleaning brush to brush all parts of the distal end in accordance with Figure 5-22. Repeat the step at least 3 times to remove all debris.

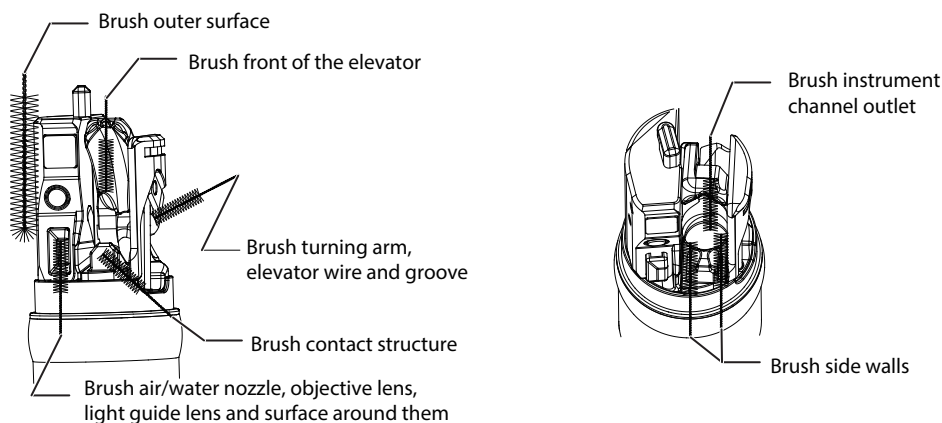


Figure 5-22 Brushing the Distal End 1

- f. Rotate the elevator control knob back and forth to rise or lower the forceps elevator and use the channel-opening cleaning brush to brush all parts of the distal end in accordance with Figure 5-23. Repeat the step at least 3 times to remove all debris.

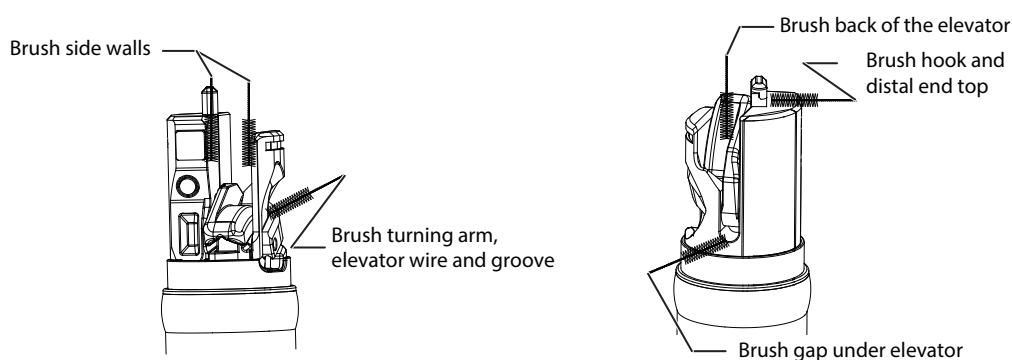


Figure 5-23 Brushing the Distal End 2

5.8 Manual Cleaning

Perform the following steps.

1. Connect the injection tube and channel plug to the endoscope firmly. Ensure that the endoscope is completely immersed in the cleaning solution, and the filter of the injection tube is immersed in the cleaning solution.
2. Use a 50 mL syringe to inject at least 200 mL (4 times) cleaning solution into the suction channel through the injection tube to fill the channel.
3. Use a 50 mL syringe to inject at least 200 mL (4 times) cleaning solution into the air/water channel through the injection tube to fill the channel.
4. Connect the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
5. Use a 5 mL syringe to inject at least 30 mL (6 times) cleaning solution through the luer taper on the cleaning tube to fill the forceps elevator wire channel.
6. Install the distal end cleaner to the distal end of the endoscope.
7. Use a 50 mL syringe to inject at least 200 mL (4 times) cleaning solution in the distal end cleaner through the luer taper. During the injection, rotate the elevator control knob back and forth several times to flush the distal end completely.

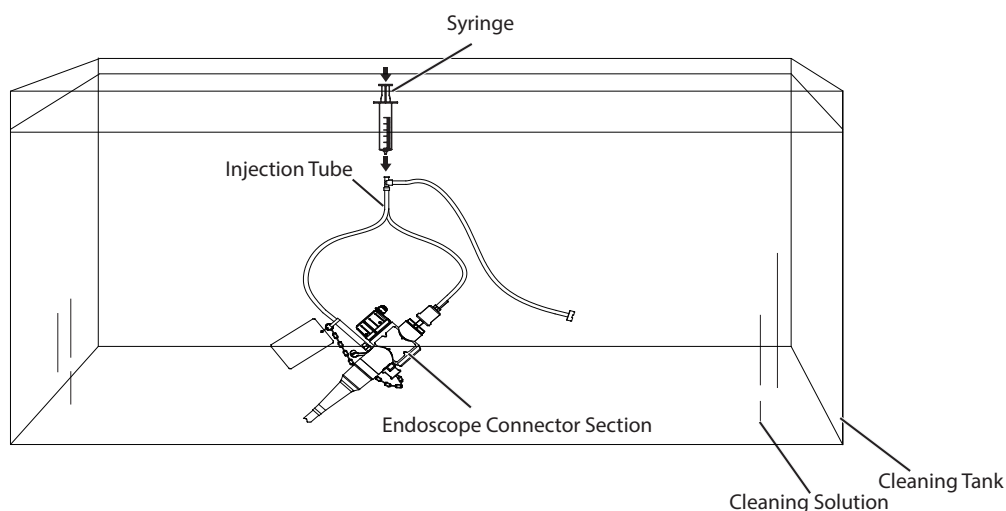


Figure 5-24 Flushing the Channel

8. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope, and immerse all accessories.
9. During the immersion, use a clean lint-free cloth or a channel-opening cleaning brush to clean the outer surface and connectors of the endoscope until no debris is left.
10. Cover the manual cleaning tank with a sealing cover to reduce cleaning solution volatilization.
11. Immerse the endoscope, and all cleaning and disinfection tools in accordance with the time, temperature and concentration recommended in Table 5-1.

5.9 Rinsing

Perform the following steps.

1. Put the endoscope and all its accessories into the rinse tank, and wipe the outer surface of the entire endoscope with a clean lint-free cloth.
2. Connect the channel plug and injection tube to the endoscope firmly. Ensure that the endoscope is completely immersed in the filtered water, and the filter of the injection tube is immersed in the filtered water.
3. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water into the suction channel through the injection tube to fill the channel.
4. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water into the air/water channel through the injection tube to fill the channel.
5. Connect the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
6. Use a 5 mL syringe to inject at least 30mL (6 times) filtered water to the forceps elevator wire channel through the luer taper on the cleaning tube to fill the channel.
7. Install the distal end cleaner to the distal end.
8. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to flush the distal end.
9. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
10. Flush the surfaces of the endoscope and all its accessories with running filtered water.
11. Take out the endoscope and all accessories from the filtered water.
12. Cover the distal end and control section with a clean lint-free cloth.
13. Connect the channel plug and injection tube to the endoscope firmly.
14. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube to remove water in the channel.
15. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel through the injection tube to remove water in the channel.
16. Connect the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
17. Use a 5 mL syringe to inject at least 40 mL (8 times) air to the forceps elevator wire channel through the luer taper on the cleaning tube to remove water in the channel .
18. Install the distal end cleaner to the distal end.
19. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to dry the distal end.
20. Remove the clean lint-free cloth from the distal end and control section.
21. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
22. Wipe the outer surface of the endoscope and all its accessories with a clean lint-free cloth.
23. Ensure that no debris is left on the endoscope or any of its accessories. Otherwise, repeat the procedures of Section 5.7 Pre-cleaning and Section 5.9 Rinsing.

5.10 Manual Disinfection



WARNING

- 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 inject disinfectant solution into the endoscope channels forcibly to ensure that no bubble exists. If any bubbles adhere to the outer surface of the endoscope and its accessories, use a lint-free cloth to wipe them off.
- The endoscope and its accessories should be completely immersed in the disinfectant solution for high-level disinfection.

Perform the following steps.

1. Put the endoscope and all its accessories into the disinfection tank.

2. Fill the tank with sufficient disinfectant and immerse the entire endoscope and all its accessories in the disinfectant.
3. Connect the channel plug and injection tube to the endoscope firmly. Ensure that the endoscope is completely immersed in the disinfectant, and the filter of the injection tube is immersed in the disinfectant.
4. Use a 50 mL syringe to inject at least 200 mL (4 times) disinfectant into the suction channel through the injection tube to fill the channel. Ensure that no bubble generates from the distal end.
5. Use a 50 mL syringe to inject at least 200 mL (4 times) disinfectant into the air/water channel through the injection tube to fill the channel. Ensure that no bubble generates from the distal end.
6. Connect the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
7. Use a 5 mL syringe to inject at least 30 mL (6 times) disinfectant into the forceps elevator wire channel through the luer taper on the cleaning tube to fill the channel. Ensure that no bubble generates from the distal end.
8. Install the distal end cleaner to the distal end.
9. Use a 50 mL syringe to inject at least 200 mL (4 times) disinfectant to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to flush the distal end. Ensure that no bubble generates from the distal end.

NOTE:

- *Ensure that the syringe connector of the injection tube is completely immersed in the disinfectant.*
- *Ensure that all channels of the endoscope are filled with disinfectant.*

10. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope, and immerse all its accessories in the disinfectant.
11. If bubbles adhere to the endoscope surface or the tools, wipe the bubbles with a clean lint-free cloth.
12. Cover the disinfection tank with a sealing cover to reduce disinfectant volatilization.
13. Immerse the endoscope and all its accessories in accordance with the time, temperature and concentration recommended in Table 5-2 for high-level disinfection.
14. Before taking out the endoscope and all its accessories from the disinfectant, connect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner to the endoscope.
15. Take out the filter of the injection tube from the disinfectant.
16. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel to remove disinfectant in the channel.
17. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel to remove disinfectant in the channel.
18. Take out the luer taper on the cleaning tube for forceps elevator wire channel from the disinfectant.
19. Use a 5 mL syringe to inject at least 40 mL (8 times) air into the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel to remove disinfectant in the channel.
20. Take out the luer taper on the distal end cleaner from the disinfectant.
21. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to remove disinfectant in the distal end.
22. Take out the endoscope and all its accessories from the disinfectant.
23. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.

5.11 Terminal Rinsing



After high-level disinfection, use filtered water and 75% ethyl alcohol or sterile water to completely rinse the outer surfaces and all channels of the endoscope to remove residual of high-level disinfectant.

■ To use sterile water for terminal rinsing

Perform the following steps.

1. Put the endoscope and all its accessories into the terminal rinse tank.
2. Fill the tank with sufficient sterile water and immerse the entire endoscope in the sterile water.
3. Thoroughly wipe the outer surface of the entire endoscope with a sterile lint-free cloth.
4. Connect the channel plug and injection tube to the endoscope, and immerse the entire endoscope into the sterile water. Ensure that the filter of the injection tube is completely immersed in the sterile water.

5. Use a 50 mL syringe to inject at least 200 mL (4 times) sterile water into the suction channel through the injection tube to fill the channel.
6. Use a 50 mL syringe to inject at least 200 mL (4 times) sterile water into the air/water channel through the injection tube to fill the channel.
7. Install the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
8. Use a 5 mL syringe to inject at least 30 mL (6 times) sterile water into the forceps elevator wire channel through the luer taper on the cleaning tube to fill the channel.
9. Connect the distal end cleaner to the distal end.
10. Use a 50 mL syringe to inject at least at least 200 mL (4 times) sterile water into the distal end through the luer taper on the distal end cleaner. During the immersion, rotate the elevator control knob back and forth several times to completely flush the distal end.
11. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and the distal end cleaner from the endoscope.
12. Flush the outer surface of the endoscope and all its accessories with sterile water.
13. Take out the endoscope and all its accessories from the sterile water.
14. Cover the distal end and control section with a sterile lint-free cloth.
15. Connect the channel plug and injection tube to the endoscope.
16. Use the air pressure gun to inject air at least 30s into the suction channel through the injection tube to remove water in the channel.
17. Use an air pressure gun to inject air at least 30s into the air/water channel through the injection tube to remove water in the channel.
18. Connect the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
19. Use the air pressure gun to inject air at least 30s to the forceps elevator wire channel through the luer taper in the cleaning tube for forceps elevator wire channel to remove water in the channel.
20. Install the distal end cleaner to the distal end of the endoscope.
21. Use the air pressure gun to inject air at least 10s to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to remove the water in the distal end.
22. Remove the sterile lint-free cloth from the distal end and control section.
23. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
24. Wipe the surface of the endoscope and all its accessories with a sterile lint-free cloth.

■ **To use filtered water and 75% ethyl alcohol for terminal rinsing**

Perform the following steps.

1. Put the endoscope and all its accessories into the terminal rinse tank.
2. Fill the tank with sufficient filtered water and immerse the entire endoscope in the filtered water.
3. Thoroughly wipe the outer surface of the entire endoscope with a sterile lint-free cloth.
4. Connect the channel plug and injection tube to the endoscope, and immerse the entire endoscope into the filtered water. Ensure that the filter of the injection tube is completely immersed in the filtered water.
5. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water to the suction channel through the injection tube to fill the channel.
6. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water to the air/water channel through the injection tube to fill the channel.
7. Connect the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
8. Use a 5 mL syringe to inject at least 30 mL (6 times) filtered water to the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel to fill the channel.
9. Connect the distal end cleaner to the distal end.
10. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to completely flush the distal end.
11. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
12. Flush the outer surface of the endoscope and all its accessories with filtered water.

13. Take out the endoscope and all its accessories from the filtered water.
14. Cover the distal end and control section with a sterile lint-free cloth.
15. Install the channel plug and injection tube to the endoscope.
16. Use the air pressure gun to inject air at least 30s to the suction channel through the injection tube to remove water in the channel.
17. Use the air pressure gun to inject air at least 30s to the air/water channel through the injection tube to remove water in the channel.
18. Install the cleaning tube for forceps elevator wire channel to the forceps elevator wire channel connector on the control section.
19. Use the air pressure gun to inject air at least 10s to the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel to remove water in the channel.
20. Connect the distal end cleaner to the distal end of the endoscope.
21. Use an air pressure gun to inject air at least 10s to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to completely flush the distal end.
22. Remove the sterile lint-free cloth from the distal end and control section.
23. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
24. Wipe the surface of the endoscope and all its accessories with a sterile lint-free cloth.
25. Place the endoscope and all its accessories on the drying table with sterile mat.
26. Inject 75% ethyl alcohol into the terminal rinsing tank.
27. Connect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner to the endoscope, and place the filter of the injection tube into the tank with ethyl alcohol.
28. Cover the distal end and control section with a sterile lint-free cloth.
29. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol to the suction channel through the injection tube.
30. Use a 50 mL syringe to inject at least 50 mL ((once) ethyl alcohol to the air/water channel through the injection tube.
31. Use a 5 mL syringe to inject at least 5 mL ((once) ethyl alcohol to the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel.
32. Use a 50 mL syringe to inject at least 50 mL ((once) ethyl alcohol to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times to completely flush the distal end.
33. Take out the filter from the ethyl alcohol.
34. Use the air pressure gun to inject air at least 30s to the suction channel through the injection tube.
35. Use the air pressure gun to inject air at least 30s to the air/water channel through the injection tube.
36. Use the air pressure gun to inject air at least 30s to the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel.
37. Use the air pressure gun to inject air at least 10s to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times.
38. Remove the sterile lint-free cloth from the distal end and control section.
39. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
40. Wipe the outer surface of the endoscope and all its accessories completely with a sterile lint-free cloth dampened with ethyl alcohol.
41. Wipe the air/water valve, suction valve, inner side of the instrument channel inlet and outlet, forceps elevator on the distal end and grooves with sterile swabs.

5.12 Drying



- 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.
- The sterile mat should be replaced every 4 hours.

Perform the following steps.

1. Place the endoscope and all its accessories on the drying table with sterile mat.

2. Connect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end to the endoscope and place the filter in the ethyl alcohol.
3. Cover the distal end and control section with a sterile lint-free cloth.
4. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol to the suction channel through the injection tube.
5. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol to the air/water channel through the injection tube.
6. Use a 5 mL syringe to inject at least 5 mL (once) ethyl alcohol to the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel.
7. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times.
8. Take out the filter from the ethyl alcohol.
9. Use an air pressure gun to inject air at least 30s to the suction channel through the injection tube.
10. Use an air pressure gun to inject air at least 30s to the air/water channel through the injection tube.
11. Use an air pressure gun to inject air at least 30s to the forceps elevator wire channel through the luer taper on the cleaning tube for forceps elevator wire channel.
12. Use an to inject air at least 10s to the distal end through the luer taper on the distal end cleaner. During the injection, rotate the elevator control knob back and forth several times.
13. Remove the sterile lint-free cloth from the distal end and control section.
14. Disconnect the channel plug, injection tube, cleaning tube for forceps elevator wire channel and distal end cleaner from the endoscope.
15. Thoroughly wipe the outer surface of the endoscope and all its accessories a sterile lint-free cloth dampened with ethyl alcohol.
16. Wipe the air/water valve, suction valve, inner side of the instrument channel inlet and outlet, forceps elevator on the distal end and grooves with sterile swabs .
17. Dry the endoscope, and all parts and tools.

5.13 Automatic Cleaning and Disinfection

Before automatic cleaning and disinfection, the endoscope should be initially treated at the point of use, pre-cleaned, manually cleaned and rinsed, and the leakage should be detected.

The AER can be used for cleaning and disinfecting the air/water valve, suction valve, biopsy valve and distal end cap. Before placing the accessories into the AER, these accessories should be pre-cleaned, manually cleaned and rinsed. For details, refer to Section 5.14.1 Pre-cleaning, Section 5.14.2 Manual Cleaning and Section 5.14.3 Rinsing.

For the cleaning and disinfection of other accessories, refer to Section 5.14 Reusable Parts and Cleaning and Disinfection Tools.

■ Recommended Automated Endoscope Reprocessor

The Endoscope WD BHT INNOVA® E3 CMS DC that meets EN ISO 15883-4 is recommended by the manufacturer in Table 5-3.

Table 5-3 Automated Endoscope Reprocessor

Equipment Name	Model	Manufacturer
Endoscope WD BHT INNOVA® E3 CMS DC	Innova E3-CMS DC-1000	BHT Disinfection Technology

■ Reprocessing Procedure

NOTE:

- Ensure that the AER is used in the room temperature.
- If the AER does not support the drying function, the endoscope and all accessories should be dried after automatic cleaning and disinfection. For details, refer to Section 5.12 Drying.

Perform the following steps to clean and disinfect the endoscope and accessories.

1. Prepare the cleaning solution and disinfectant for automatic cleaning and disinfection in accordance with the temperature and concentration recommended in Table 5-1 and Table 5-2 respectively.
2. Place the endoscope into the AER.

3. Connect the suction valve cylinder plug, air/water valve cylinder plug, and cap for instrument channel inlet to the suction valve cylinder, air/water valve cylinder, and instrument channel inlet of the endoscope respectively.
4. Connect the air pipe plug, suction connector tube, and plug for air/water-feeding port of the injection tube to the air pipe, suction port and air/water-feeding port of the endoscope connector section respectively.
5. Connect the locking connector for cleaning to the forceps elevator wire channel connector on the control section of the endoscope.
6. Connect the distal end cleaner to the distal end of the endoscope.
7. Connect the other ends of the injection tube, cleaning tube for forceps elevator wire channel, and the distal end cleaner to the AER.
8. Place the reusable parts in the AER.
9. Select the appropriate program, and set the processing parameters and check the values on the screen.
The recommended reprocessing parameters are as follows.

Table 5-4 Automated Reprocessing

Stage	Procedure	Temperature	Contact Time	Solution	Note
1	Pre-wash	20°C	1min	Cold water	/
2	Cleaning	40°C	3 min	Cleaning solution	Proteazone Plus in deionized water
3	Intermediate rinse	20°C	1 min	Deionized water	/
4	Intermediate rinse	20°C	1 min	Deionized water	/
4	Disinfection	35°C	5 min	Disinfectant	Rapicide A+B in deionized water
5	Final rinse	20°C	4 min	Deionized water	/
6	Final rinse	20°C	4 min	Deionized water	/
7	Drying	/	10 min	/	/

10. Start the automated cleaning and disinfection procedures.

11. Take out the endoscope and accessories after the reprocessing finishes.

5.14 Reusable Parts and Cleaning and Disinfection Tools



After each use, the reusable parts and cleaning and disinfection tools should be cleaned and disinfected. Otherwise, the patient or operator may be infected.

The following reusable parts and cleaning and disinfection tools should be cleaned and disinfected.

- Air/water valve
- Suction valve
- Biopsy valve
- Distal end cap
- Cleaning brush
- Channel-opening cleaning brush

5.14.1 Pre-cleaning

NOTE:

- Ensure that the parts and tools immersed in the cleaning solution are not in contact with each other.
- Ensure that the sealing rings on the air/water valve are not scratched.
- Ensure that the grooves on the distal end cap are completely cleaned.
- Remove the cap from the main body of biopsy valve. Otherwise, the biopsy valve cannot be cleaned or disinfected completely.

Perform the following steps.

1. Put the parts and tools into the manual cleaning basin.

2. Fill the basin with sufficient cleaning solution and ensure that all the parts and tools can be immersed in the cleaning solution.
3. Wipe the outer surfaces of the parts and tools in the cleaning solution with a clean lint-free cloth.
4. Use the channel-opening cleaning brush to brush the openings of air/water valve and suction valve completely with remove all debris.
5. Use the channel-opening cleaning brush to brush the interiors and openings of biopsy valve to remove all the debris.

5.14.2 Manual Cleaning

1. Use a 50 mL syringe to flush the interiors and openings of all parts and tools completely to remove all bubbles.
2. During the immersion, press and release pistons of the air/water valve and suction valve at least 3 times to remove all bubbles.
3. Clean the bristles of the cleaning brush and channel-opening cleaning brush completely to remove all bubbles.
4. Cover the manual cleaning basin with a sealing cover to reduce cleaning solution volatilization.
5. Immerse the parts and tools in accordance with the time, temperature and concentration recommended in Table 5-1.
6. Take out all parts and tools from the basin, and ensure that no debris is left on the parts and tools.

5.14.3 Rinsing

Perform the following steps.

1. Put all cleaned parts and tools into the rinse basin.
2. Wipe the outer surfaces of parts and tools in the running filtered water with a clean lint-free cloth.
3. Use a 50 mL syringe to flush the interiors and openings of parts and tools to remove all bubbles.
4. During the immersion, press and release the pistons of air/water valve and suction valve at least 3 times to remove all air bubbles.
5. Clean the bristles of the cleaning brush and the channel-opening cleaning brush to remove all bubbles.
6. Take out all parts and tools and wipe the outer surfaces of parts and tools with a clean lint-free cloth.
7. Check if there is any residual debris left on the parts or tools. If any, repeat the operations of Section 5.14.2 Manual Cleaning and Section 5.14.3 Rinsing.

5.14.4 Manual Disinfection



- **WARNING** Ensure that all the bubbles adhering to the parts and tools are removed. Otherwise, it may degrade the disinfection effect.
- Disinfection process should be performed when all parts and tools are immersed in the disinfectant. For sufficient disinfection, ensure that all parts and tools are in full contact with the disinfectant.

Perform the following steps.

1. Put all parts and tools into the disinfection basin.
2. Fill the basin with sufficient disinfectant, and ensure that all parts and tools can be immersed in the disinfectant.
3. Wipe the outer surfaces of all parts and tools in the disinfectant with a clean lint-free cloth, and ensure that all air bubbles are removed.
4. Use a 50 mL syringe to flush the interiors, exterior grooves and openings of all parts and tools completely to remove all air bubbles.
5. During the immersion, press and release the pistons of air/water valve and suction valve at least 3 times to remove all air bubbles.
6. Clean the bristles of the cleaning brush and channel-opening cleaning brush completely to remove all air bubbles.
7. Cover the basin with a sealing cover to reduce disinfectant volatilization.
8. Immerse all parts and tools by using the method recommended in Table 5-2.
9. Take out all the parts and tools.

5.14.5 Terminal Rinsing



WARNING After high-level disinfection, use filtered water and 75% ethyl alcohol or sterile water to completely rinse all the reusable parts and cleaning and disinfection tools to remove the residue of high-level disinfectant.

■ To use sterile water for terminal rinsing

Perform the following steps.

1. Place all the cleaned parts and tools into the terminal rinse basin.
2. Fill the basin with sufficient sterile water and ensure that all parts and tools can be immersed in the sterile water.
3. Gently stir to completely clean the parts and the tools.
4. Wipe the outer surfaces of the parts and the tools in the sterile water with a sterile lint-free cloth.
5. Use a 50 mL syringe to rinse the interiors and openings of the parts and the tools to remove all bubbles.
6. During the immersion, press and release the pistons of the air/water valve and suction valve at least 3 times to remove all air bubbles.
7. Clean the bristles of the cleaning brush and channel-opening cleaning brush to remove all air bubbles.
8. Take out all parts and tools and wipe the outer surfaces of the parts and tools with a sterile lint-free cloth.

■ To use filtered water and 75% ethyl alcohol for terminal rinsing

Perform the following steps.

1. Put the parts and tools into the terminal rinse basin.
2. Fill the tank with sufficient filtered water and ensure that all parts and tools can be immersed in.
3. Use a sterile lint-free cloth to wipe the outer surfaces of the parts and the tools in the filtered water.
4. Use a 50 mL syringe to rinse the interiors and openings of the parts and tools to remove all bubbles.
5. During the immersion, press and release the pistons of the air/water valve and suction valve at least 3 times to remove all air bubbles.
6. Clean the bristles of the cleaning brush and channel-opening cleaning brush to remove all air bubbles.
7. Take out all parts and tools, and immerse them into the basin.
8. Fill the basin with sufficient 75% ethyl alcohol and ensure that all parts and tools can be immersed in the ethyl alcohol.
9. Immerse all parts and tools in the ethyl alcohol and gently stir them.
10. Use a 50 mL syringe to inject ethyl alcohol into the interiors and openings of the parts and tools to remove all bubbles.
11. During the immersion, press and release the pistons of the air/water valve and suction valve at least 3 times to remove all air bubbles.
12. Take out all parts and tool from the ethyl alcohol.
13. Place the endoscope and all its accessories on the drying table with sterile mat.
14. Use the air pressure gun to inject air the interior and openings of all parts and tools to dry them.

5.14.6 Drying

Perform the following steps.

1. Fill the basin with 75% ethyl alcohol.
2. Place all parts and tools in the ethyl alcohol and gently them.
3. Use a 50 mL syringe to inject ethyl alcohol to the interiors and openings of the parts and the tools to remove all air bubbles.
4. Clean the bristles of the cleaning brush and channel-opening cleaning brush to remove all air bubbles.
5. During the immersion, press and release the pistons of the air/water valve and suction valve at least 3 times to remove all bubbles.
6. Take out all parts and tools from the ethyl alcohol.
7. Place the endoscope and all its accessories on the drying table with sterile mat.
8. Wipe the outer surfaces of all parts and tools with a sterile lint-free cloth dampened with ethyl alcohol.
9. Use the air pressure gun to inject air the interior and openings of all parts and tools to dry them.

6 Storage and Disposal

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



WARNING

- Before storage, the endoscope should be cleaned and disinfected thoroughly.
- After being dried, the endoscope should be hung in the clean, dry, and well-ventilated endoscope cabinet.
- Do not store the endoscope in a carrying case.
- Do not store the endoscope and the accessories in a place with direct sunlight, high temperature, high humidity, X-rays, ultraviolet rays, chemicals, or ozone.
- If the endoscope has been stored for more than 24 hours, it should be reprocessed again.



CAUTION

- When storing or transporting the endoscope, twine the bending section and the universal cable into “S” or “O” shape, and ensure that the bending diameter is not less than 12 cm. Otherwise, the endoscope may be damaged.
- Do not forcibly bend, squeeze, or twist the bending section. Otherwise, the endoscope may be damaged.

6.1 Storage

6.1.1 Storing the Endoscope

NOTE:

Before storing the endoscope, ensure that the surfaces of the endoscope and the interiors of all channels are dry.

Perform the following steps.

1. Disconnect all accessories from the endoscope, including the air/water valve, suction valve, biopsy valve, distal end cap, and waterproof cap.
2. Ensure that the inner and outer surfaces of the entire endoscope are dry.
3. Rotate the up/down and left/right angulation locks to free the bending section of the endoscope.
4. Hang the endoscope in the endoscope cabinet and ensure that the insertion section is vertically hung and completely stretched.

6.1.2 Storing the Accessories

NOTE:

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

1. Store the accessories in the endoscope cabinet, and ensure that they are not in contact with each other.
2. Place the tools that can be repeatedly cleaned and disinfected into the container, and then store the container into the endoscope case.

6.2 Transportation



CAUTION

Transport the endoscope carefully to avoid collision or falling.

■ Indoor Transportation



CAUTION

Do not hold the distal end together with the metal parts or protrusions on the control section or connector section to avoid scratching the surface of the objective lens.

Perform the following steps.

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

■ 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.
- When storing the carriers with endoscopes, do not touch the forceps elevator or the forceps elevator wire that stretches out from the distal end. Otherwise, damages may be caused.

**CAUTION**

Do not over-compress the endoscope or place it in a narrow and small space. Use a carrying case provided by the manufacturer for outdoor transportation. Using other carrying cases may cause damage to the endoscope.

Perform the following steps.

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.
3. Place the endoscope into the carrying case provided by the manufacturer.
4. Lock the carrying case for transportation.

6.3 Disposal

The manufacture date of the device is on the nameplate. The expected service life of the device is five years with normal use, and its service life can be prolonged according to its using frequency and maintenance. Dispose of the discarded endoscope according to local laws or regulations, or contact the manufacturer for maintenance.

6.4 Customer Service

Only the service personnel of or authorized by the manufacturer can service the device. Any feedback or inquiries concerning our product or services should be directed to the manufacturer.

Contact address: 2F, 12th Building, Shenzhen Software Park Phase II, Keji Middle 2nd Road, Nanshan District, Shenzhen, 518057, Guangdong, China

Tel: +86-755-26722890

E-mail: service@sonoscape.net

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 local distributor of the manufacturer for replacement. During use, any serious incident that has occurred in relation to the device should be reported to the local distributor and the competent authority of the Member State.

NOTE:

If the maintenance personnel designated by the manufacturer confirm that circuit diagrams, component part lists, description, calibration instructions, or other relevant information is necessary for repairing the faulty parts, contact the local distributor of the manufacturer.

Item	Descriptions	Level	Cause	Solutions
Leakage	The leakage detector does not function or continuous bubbles appear.	B	The rubber wrapping the bending section of the endoscope is damaged.	Stop using the endoscope.
		B	The sealing ring is aging.	
		B	The channel is broken.	
Image	No image	C	The endoscope cable is not connected properly or the image processor is not powered on.	Check the connections. For details, refer to Chapter 3 Preparations, and power on the image processor.
		B/A	Others	Stop using the endoscope.
	The image is dim.	C	The light intensity of the light source is too low.	Adjust the intensity of the light source as described in the light source user manual.
	The image is blurry.	C	The objective lens is dirty.	Feed water to clean the objective lens.
		B	Water drops or color bar appears in the field of view.	Stop using the endoscope.
Feed air	The air is insufficient.	C	The lid of the water container is loose.	Fasten the lid of the water container.
		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.
	Air cannot be fed.	C	The air/water valve is damaged.	Replace the air/water valve.
		C	The air pump does not function	Enable the air pump on light source as described in the light source user manual.

Item	Descriptions	Level	Cause	Solutions
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 lid of the water container is loose.	Fasten the lid of the water container.
		B	Others	Stop using the endoscope.
	Water cannot be fed.	C	There is no water in the water container.	Pour the appropriate amount of sterile water into the water container.
		C	The air/water valve is damaged.	Replace the air/water valve.
		C	The air pump is powered off.	Turn on the air pump of light source as described in the light source user manual.
Suction	The endoscope cannot perform aspiration or the aspirated amount decreases.	C	The suction valve is blocked.	Remove the suction valve, and clean the inner valve with a 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, and clean the opening of the valve with the cotton swab dampened with alcohol solution.
	The instrument channel leaks.	B	The instrument channel is damaged by improper use of the accessories such as biopsy forceps.	Stop using the endoscope.
	Liquid or air is leaked from the biopsy valve.	C	The biopsy valve is aging or damaged.	Replace the biopsy valve.

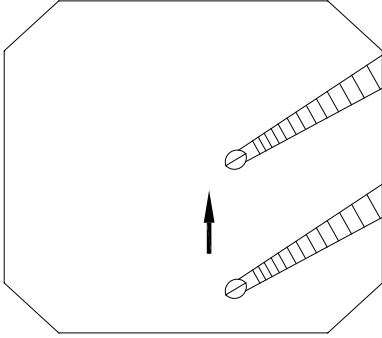
Item	Descriptions	Level	Cause	Solutions
Bending Section	It is hard to rotate the angulation control knob.	C	The angulation control knob is locked.	Unlock the angulation control knob.
		B	Others	Stop using the endoscope.
	The bending section is not sensitive.	B	The elasticity of steel wires inside the endoscope degrades after being used for a long period.	Stop using the endoscope.
	The bending section cannot reach the maximum angle.	B	The elasticity of steel wires inside the endoscope degrades after being used for a long period.	Stop using the endoscope.
	The bending section does not function.	A	The steel wires inside the endoscope are damaged.	Stop using the endoscope.
Accessories	The endoscope cable does not function.	B	The endoscope cable is damaged.	Stop using the endoscope.
	The forceps elevator angulation knob cannot move smoothly.	C	The forceps elevator wire or the forceps elevator wire channel is contaminated.	Clean and disinfect the forceps elevator wire channel.
	The air/water valve or the suction valve cannot be operated smoothly.	C	The air/water valve or the suction valve is contaminated.	Clean and disinfect the suction valve.
		B	The air/water valve or the suction valve is damaged.	Replace the air/water valve or the suction valve.
	The air/water valve or the suction valve cannot be installed.	C	The selected air/water valve or the suction valve is mismatched.	Use the correct air/water valve or the suction valve.
		C	The air/water valve or the suction valve is damaged.	Replace the air/water valve or the suction valve.
	The endotherapy accessory cannot get through the instrument channel smoothly.	C	The endotherapy accessory and the endoscope are incompatible.	Select compatible accessories.

Item	Descriptions	Level	Cause	Solutions
Accessories	The guide wire cannot be fixed.	C	The diameter of the guide wire is unfit.	Select qualified guide wire.
		C	The guide wire fixing recess has dirt.	Clean and disinfect the guide wire fixing recess.
		C	The contrast medium is in the guide wire channel.	Clean the guide wire channel and then withdraw or insert the guide wire.
		C	The guide wire is fixed at the wrong position.	Fix the hard part of the guide wire.
Distal end cap	The distal end cap cannot be installed.	C	The distal end cap installation is incorrect.	Refer to the user manual for the distal end cap installation.
Remote buttons	The function of the remote button is incorrect.	C	The wrong button is selected.	Operate the button correctly.
		C	The button function setting is incorrect.	Set the button function correctly.

NOTE:

- Level C means that you can solve the problem by yourself.
- Level B means that you should contact the local distributor for maintenance and repair.
- Level A means that you should return the endoscope to the local distributor.

Appendix A Specifications

Dimensions	Total length	1550 mm
	Working length	1250 mm
	Min. inner diameter of the instrument channel	$\geq \Phi 4.2$ mm
	Outer diameter of the insertion tube	$\Phi 11.3$ mm
	Outer diameter of the distal end	$\Phi 13.5$ mm
Optical System	Field of view	100°
	Direction of view	105°
	Depth of view	4 mm - 60 mm
	Biopsy entrance position	
Water/air feeding & suction system	Amount of fed water	≥ 40 mL/min
	Amount of fed air	≥ 800 mL/min
	Aspirated amount	≥ 400 mL/min
Bending section	Angle	Up 120°, down 90°, left 90°, right 110°
Operation Environment	Temperature	5°C ~ 40°C
	Relative humidity	30% ~ 80%
	Atmospheric pressure	700 hPa ~ 1060 hPa
Storage Environment	Temperature	-5°C ~ +40°C
	Relative humidity	30% ~ 80%
	Atmospheric pressure	700 hPa ~ 1060 hPa
Transportation Environment	Temperature	-20°C ~ +55°C
	Relative humidity	20% ~ 90%
	Atmospheric pressure	700 hPa ~ 1060 hPa

Safety type	Degree of protection against electric shock	Type BF applied part (Applied part: the video duodenoscope)
	Degree of protection against harmful liquid	IPX7

Appendix B EMC Guidance and Manufacturer's Declaration



- The device is suitable for use in professional healthcare facility environment. Do not use it in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
- Do not use this device around strong electric field, electromagnetic field (e.g. MRI scan room) and mobile wireless communication devices. Using the device in an improper environment may cause malfunction or damage.
- Only the peripherals (such as image processor, light source, etc.) provided or recommended by the manufacturer can be used. Using other devices may increase RF radiation and degrade the device performance of anti-electromagnetic interference.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

The essential performance of the device is as follows.

In expected use scenario, the device can continuously output normal real-time image signals without affecting the basic observation effect (such as unexpected image flip, black screen, blurred screen, and severe screen flickering).

B.1 Electromagnetic Emissions

Emissions Test	Compliance
Conducted and Radiated RF Emissions CISPR 11	Group 1 Class A
Harmonic Distortion IEC 61000-3-2	Not Applicable
Voltage Fluctuations and Flicker IEC 61000-3-3	Not Applicable

B.2 Electromagnetic Immunity

Immunity Test	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV Contact, ±2kV, ±4kV, ±8kV, ±15kV Air
Radiated RF EM fields IEC 61000-4-3	3V/m

Immunity Test	Compliance Level
Electrical Fast Transient and bursts IEC 61000-4-4	± 2 kV for power supply lines, ± 1 kV for SIP/SOP ports
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode
Conducted Disturbances IEC 61000-4-6	3V 6V at ISM bands
Voltage dips and interruptions IEC 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0% U_T for 1 cycle Single phase: at 0°
	70% U_T for 25 cycle Single phase: at 0°
	0% U_T for 250 cycle
Power frequency Magnetic field IEC 61000-4-8	30A/m