PENTAX MEDICAL

Instructions for Use

PENTAX Medical Video Upper GI Scope EG29-i10c

Operation

EG29-i10c

Digitally signed by Ceaicovschi Tudor
Date: 2022.08.30 18:28:32 EEST
Reason: MoldSign Signature
Location: Moldova

For cleaning, high-level disinfection, and sterilization of the product after use, refer to the separate Instructions for Use (Reprocessing) with the model name of the endoscope.

Instructions for Use

This Instructions for Use (hereinafter referred to as "IFU") contains essential information, such as operating procedures and handling precautions, on using this endoscope safely and effectively. Before use, fully understand the contents of, and properly follow, this IFU and the instruction manuals of all equipment that are going to be used in combination. Do not use this endoscope for any purpose other than its intended use.

In addition, review and fully understand the contents of the separate IFU for reprocessing (hereinafter referred to as "IFU (Reprocessing)"). Inappropriate use of the product may result in damage to the equipment or injuries, including, but not limited to, burns, electric shock, perforation, infection, and bleeding.

This IFU does not describe specific endoscopic procedures. The specific procedures should be determined according to the discretion of a medical professional.

If you have any questions or concerns about any information in this IFU, contact your local PENTAX Medical service facility.

The content of the IFU may be changed without prior notice.

Keep this IFU and all related instruction manuals in a safe, accessible location.

Signal words and symbols

Signal words

The following signal words are used throughout this IFU.

 Warning	Indicates a situation that could result in death or serious injury if not avoided.
 Caution	Indicates a potentially hazardous situation that could result in minor or moderate injury or damage to equipment if not avoided.
 Note	Indicates supplementary or useful information regarding use.

Symbols
Symboles

The meaning(s) of the symbol(s) on the endoscope, accessories, and/or on their packaging are as follows:

Symbol	Description
	Caution Attention
	Year of Manufacture Année de fabrication
	Type BF applied part Partie appliquee du type BF
	Do not re-use Ne pas reutiliser
	Follow the Instructions for Use Suivre les instructions d'utilisation
	Serial Number Numero de serie
	Manufacturer Fabricant
	Authorized representative in the European Community Representant autorise dans l'Union europeenne
	This product complies with the applicable standards harmonised under the Directive 93/42/EEC and Directive 2011/65EU. Ce produit est conformé aux normes harmonisées au titre de la Directive 93/42/CEE et la Directive 2011/65EU

Contents

Important information: Please read before use

Product summary

This endoscope is inserted transorally. It visualizes subjects under illumination of the LED (light emitting diode) at the distal end of the endoscope with a solid-state image sensor located at the distal end of the endoscope and provides images for observation of the target anatomy through the images reproduced on the video monitor via the video processor.

It can be used with endoscopic devices which are introduced from the instrument channel inlet of the control body.

The endoscope also allows for angulation operation of the bending sections via operation of the angulation control knob; air/water feeding from the distal end of the endoscope via operation of the air/water feeding valve; and suction through the channel at the end of the endoscope via operation of the suction control valve.

Intended use

The PENTAX Medical Video Upper GI Scope EG29-i10c is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: esophagus, stomach, and duodenum.

This endoscope is introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

Application

Medical purposes	Provide images for observation, diagnosis, visualization, and treatment.
Patient population	Patients who are considered suitable for the application of this endoscope by the physicians (pediatric to adult patients).
Intended anatomical area	Upper gastrointestinal tract (esophagus, stomach) duodenum
User qualifications	Physicians (Experts who have been approved by the endoscopic medical safety administrator at each medical facility. If the eligibility requirements are defined by an official body, such as a government entity and/or an academic society, follow such requirements). Specific training to use this endoscope is not required of personnel who have been trained to use other endoscopes of this type.
Location of use	A medical facility (including the place where the high frequency generator is used)

Classification

Degree of protection against electric shock for the applied parts	TYPE BF applied part (when connected to a compatible PENTAX Medical video processor)
Degree of protection against water	IPX7
Mode of operation	Continuous operation

Specifications

■ Environment

Operating environment	Ambient temperature	10 to 40 °C
	Relative humidity	30 to 85 %RH
	Air pressure	700 to 1,060 hPa

Storage/transportation environment	Ambient temperature	-20 to 60 °C
	Relative humidity	10 to 85 %RH
	Air pressure	700 to 1,060 hPa

■ Software version

Refer to the back cover for the software version by model(s).

■ Endoscope specifications

For details, refer to “Endoscope specifications” (p. 89).

Compatible products

This section describes the equipment that can be used in combination with this endoscope. For more details, refer to "System chart" (p. 90).

For the equipment used in combination during cleaning/high-level disinfection/sterilization, refer to the separate IFU (Reprocessing) of this endoscope.

The combinations of equipment and accessories that can be used with this product are listed below. Prior to use, the product must be prepared and inspected according to its IFU.

Warning

PENTAX Medical does not warrant compatibility with unlisted products. If products are not listed, contact the manufacturer of the equipment or accessory to confirm the compatibility and instructions for use with PENTAX Medical products.

Note

- When this endoscope is used in combination with other equipment, depending on how it is connected, it may result in malfunction and/or unforeseen events to patients and/or medical professionals. Pre-use operation checks and risk management associated with such changes are recommended, particularly when the equipment used in combination is changed, added, or upgraded.
- Some products are not available depending on the sales region. For details, contact your local PENTAX Medical service facility.

■ Video processor

Video processor models that can be connected with these endoscopes are shown below. For instructions on video processor operation, refer to the IFU of the video processor.

Model Name	Brand Name
EPK-i5500c	PENTAX Medical

■ Endoscopic device

Category	Model Name	Brand Name
Biopsy Forceps	KW-D1816	PENTAX Medical
	KW-D2416T	
	KH-D2416T	
	KA-D2416T	
	KB-D2416T	
	KA1815S	
	KA2415S	
	KH2415S	
	KH2418CS	
	KS1022CS	
	KW1815S	
	KW1818CS	
	KW2215S	
	KW2218CS	
	KW2415R	
	KW2415S	
Retrieval Basket	GB-D1819L020	
	GB-D2415L030	
	GB-D2419L020	
	GB-D2423L035	
Injection Needle	NI-D1816-T2304	
	NI-D1816-T2305	
	NI-D1816-T2306	
	NI-D1816-T2308	
	NI-D2416-T2304	
	NI-D2416-T2306	
	NI-D2423-T2305	
	NI-D1816-T2504	
	NI-D1816-T2505	
	NI-D2416-T2504	
	NI-D2416-T2505	
	NI-D2416-T2506	
Electro-Surgical Snare	DO-D2416-15	
	DO-D2416-20	
	DO-D2416-25	
	DH-D2416-15	
	DH-D2423-20	
	DH-D2416-25	
	DO-D2618	
Electro-Surgical Knife	DN-D2718A	
	DC-D2618	
	DP-D2518	
	DP-D2622	
	DN-D2718B	
Electro-Surgical Hemostasis Forceps	H-S2518	
	HS-D2618	
	HDB2418W	
Spray Catheter	TJ-D2418PB	
	TJ1817WS	
	TJ2417WS	

■ Other ancillary equipment

For instructions, refer to the respective manual provided with each equipment.

Category	Description	Model Name	Brand Name
Irrigation Pump	EGA Series	EGA-500P	PENTAX Medical
CO_2 Insufflator		EGA-501P	
High Frequency Generator	VIO Series	VIO 300D	ERBE
		VIO 200S	

Reprocessing before initial use / Reprocessing / Storage after use

■ Reprocessing before the initial use

Warning

The endoscope identified in this IFU is a reusable semi-critical device.
Since it endoscope and accessories are packaged non-sterile, they must be cleaned and high level disinfected, or cleaned and sterilized according to the separate IFU (Reprocessing) of this product before initial use as well as after each procedure and after repair. Insufficient reprocessing may increase the risk of cross contamination.

Note

The wording "high-level disinfection" in this IFU defines the disinfection of the endoscope and the accessories with a completely virucidal disinfectant.

■ Reprocessing

Warning

When using an endoscope and its accessories on patients with Creutzfeldt-Jakob disease (CJD) or variant Creutzfeldt-Jakob disease (vCJD), use only dedicated instruments and equipment. The instruments and equipment used on these patients must be discarded so that they can NOT be used again on another patient. The pathogenic agents that cause this disease, which are called "prions", can NOT be destroyed or inactivated using the cleaning, disinfection, and sterilization methods presented in this IFU. Please consult the guidelines that apply to your country or region for more detailed information regarding the handling of prion-contaminated instruments.

■ Storage after use

Warning

Observe the following guidelines. Failure to do so may result in contamination of the endoscope with bacteria or pose a risk of infection to patients and/or users.

- Ensure that all removable accessories, such as air/water feeding valve, suction control valve, inlet seal, and cleaning adapter are removed from the endoscope when storing.
- Do NOT store the endoscope in areas of high humidity or high temperature.
- Do NOT store the endoscope, its components, and accessories in the carrying case.
- Ensure that the endoscope, its components, and accessories are completely moisture-free before storage.
- Before the next use, the endoscope, its components, and accessories that have been stored inappropriately or for a prolonged period of time must be subjected to appropriate cleaning, high-level disinfection, and/or sterilization processes according to the separate IFU (Reprocessing).

Caution

Observe the following precautions when storing the endoscopes, its accessories, or device. Failure to do so may result in damage to property.

- Endoscope insertion portion, umbilical cord, and endoscopic devices should be kept as straight as possible during storage.
- Keep away from chemicals, direct sunlight, or ultraviolet rays.
- Do NOT store the endoscope and its accessories in such a way that they might be damaged due to contact with other devices.

Note

It is recommended to store the endoscope hanging down straight in a well-ventilated room or cabinet dedicated for endoscope storage.

For storage after use, also refer to the separate IFU (Reprocessing) of this endoscope.

General warnings and cautions

Warning

- The medical facility should determine whether or not to conduct an endoscopic examination in patients determined to have lowered immunity.
- Do NOT use this endoscope with equipment other than those that have been specified for combined use. Doing so may result in damage to the endoscope and patient injury.
- Do NOT drop the endoscope onto a hard surface or subject it to severe impact. This applies particularly to the distal tip lens. Doing so may negatively impact image quality.
- Ensure to attach/connect an appropriate device to the connectors of the scope connector such suction nipple, air/water port, water jet port, or venting connector according to the IFU. Incorrect connection or inappropriate use may result in unforeseen events.
- Always check the endoscopic image during endoscope angulation, air/water feeding, and suctioning, use of endoscopic devices, and endoscope insertion and withdrawal. Ensure that these operations are performed in the normal (non-frozen, non-magnified) mode. Endoscope peration in the freeze or magnification mode may result in damage to the endoscope and/or patient injury.
- Do NOT forcefully insert and withdraw the endoscope. Doing so may result in patient injuries, including bleeding and perforation.
- Do NOT perform retroflexed observations inside a narrow lumen. Doing so may cause patient injury or make it impossible to withdraw the endoscope.
- After using operational/cleaning accessories (e.g., forceps, needles, snares, brushes, etc.) with the endoscope, carefully check that all accessories are intact and that no parts have fallen off and become lodged within the endoscope's instrument/suction channel. Furthermore, ensure that any endoscopic devices (e.g., clips, stents, etc.) passed through the channel are accounted for after use. If the instrument/suction channel becomes blocked or clogged due to the accumulation of debris, an accessory that can NOT be removed, or other cause, do NOT attempt to correct the blockage or continue to use the endoscope. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired. The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or the introduction of debris and/or device components into a patient during a subsequent procedure, posing a risk of cross contamination.
- This product is intended to be used in the electromagnetic environment specified by "Electromagnetic disturbances". Using the product in an unintended environment may result in incorrect exposure control of the light emitted from distal end of the endoscope due to electromagnetic interference.

Caution

- Users as well as the assisting personnel should always wear protective equipment (e.g., gloves, goggles, masks, medical gowns, etc.) to minimize the risk of cross contamination, as patient's body fluids may be dispersed from instrument components such as the instrument channel inlet and the suction control valve.
- Do NOT forcefully attach an accessory to the endoscope. Doing so may result in damage to the endoscope.
- Do NOT excessively twist, rotate, or bend any of the insertion portions, strain relief boots, or umbilical cord. Doing so may damage the endoscope.
- Do NOT hit the remote buttons with hard objects or pull or twist them. Doing so may cause internal damage to the endoscope that may lead to water leaks.
- Do NOT attach or remove the scope connector of the endoscope while the power of the video processor is turned on. Doing so may damage the endoscope.
- Electromagnetic interference may occur with equipment labeled with the following symbol or near mobile RF communication equipment such as mobile phones. If electromagnetic interference occurs, reorient or relocate the endoscope or shield the location of use.

Maintenance management

The service life of this endoscope is 6 years after date of shipment with the following conditions.

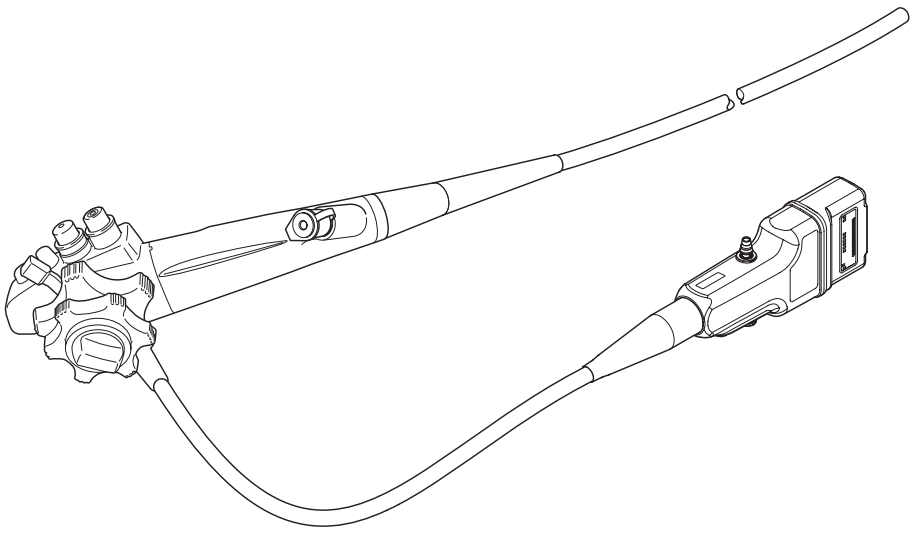
- Perform inspection before use, care after use, storage, and replacement of consumables according to this IFU.
- Have a specialist specified by PENTAX Medical perform repairs and at least annual periodic inspections.

1 Package contents

1-1. Package contents

Check the package contents according to the separate Standard Accessories List provided with this product. For detail picture of the contents/accessories, refer to Figure 1.1 and 1.2.
If there are any damaged or missing components, do not use the endoscope. Immediately contact your local PENTAX Medical service facility.

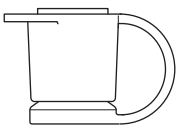
■ Endoscope



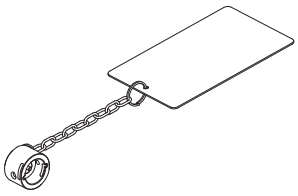
EG29-i10c

Figure 1.1

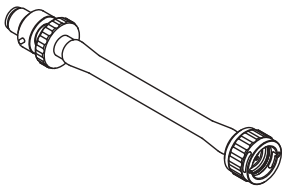
■ Accessories



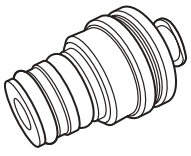
Inlet Seal (OF-B190)
(Installed)



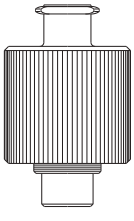
Ventilation Cap (OE-C28)



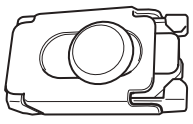
Venting Connector Adapter (OE-C29)



Cleaning Adapter (OF-G17)



Cleaning Adapter for Water Jet
Connector (OE-C20)



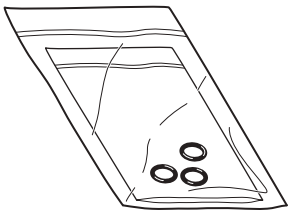
Cleaning Adapter
(OF-B153)

Figure 1.2

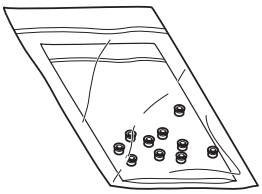
■ Accessories

Silicone Oil (OF-Z11)

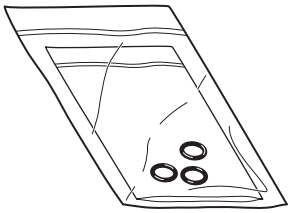
Irrigation Tube (OF-B113)



O Ring Set (OF-B192*)
* For Air/Water Feeding Valve (OF-B188)



Check Valve Sets (OE-C15)

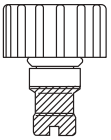


O Ring Set (OF-B127**)
** For Suction Control Valve (OF-B120)

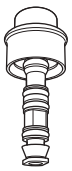
Cleaning Brush (CS-C13A)

Cleaning Brush (CS5522A)

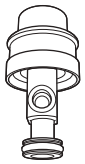
Bite Block (OF-Z5)



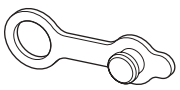
Water Jet Check Valve Adapter
(OE-C12) (Installed)



Air/Water Feeding Valve (OF-B188)
(Installed)



Suction Control Valve (OF-B120)
(Installed)

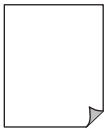


Water Jet Connector Cap (OF-B118)
(Installed)

■ Others

IFU (Operation; this document)

IFU (Reprocessing)



Standard Accessories List

Figure 1.2

2 Nomenclature and functions

2-1. Control body and insertion portion

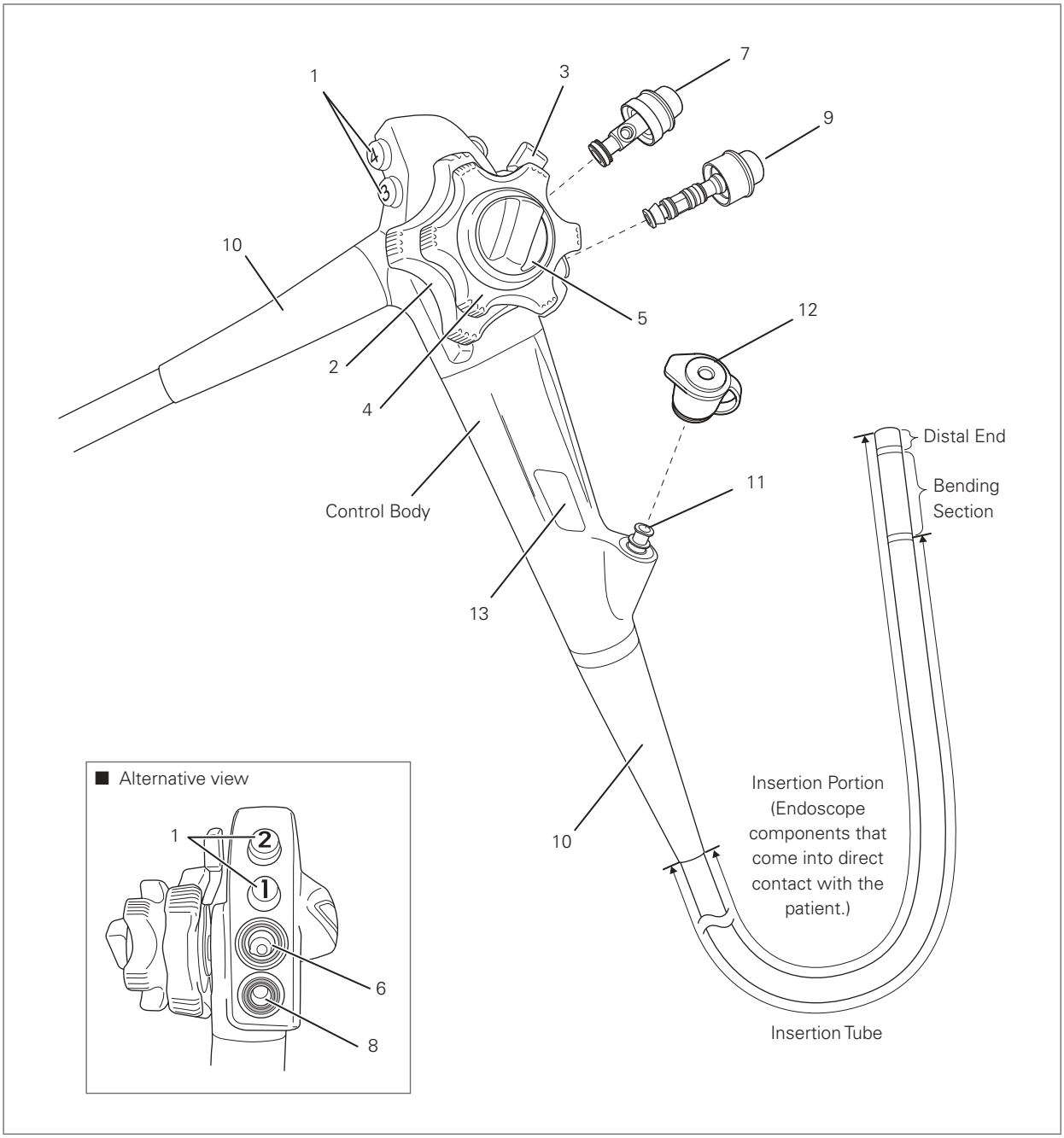


Figure 2.1

1. **Remote Buttons 1-4**
   Functions assigned to each button can be remotely controlled by pressing each of the remote buttons.
   Functions of the remote buttons 1-4 are assigned from the video processor.
   Refer to the IFU of the video processor for assignment of functions to each remote button.
2. **Up/Down Angulation Control Knob**
   By turning in the "▲U" direction, the bending section moves upwards.
   By turning in the "▲D" direction, the bending section moves downwards.
3. **Up/Down Angulation Lock Lever**
   By turning counterclockwise, upward/downward bending of the bending section is locked.
   By turning in the "F ►" direction, the bending lock is released.
4. **Right/Left Angulation Control Knob**
   By turning in the "▲R" direction, the bending section moves to the right.
   By turning in the "▲L" direction, the bending section moves to the left.
5. **Right/Left Angulation Lock Knob**
   By turning counterclockwise, right/left bending of the bending section is locked.
   By turning in the "F ►" direction, the bending lock is released.
6. **Suction Cylinder**
   Attach the suction control valve (OF-B120).
7. **Suction Control Valve (OF-B120)**
   Attach to the suction cylinder. Depress it to suction fluids or air through the instrument channel of the endoscope.
8. **Air/Water Feeding Cylinder**
   Attach the air/water feeding valve (OF-B188) or the optionally available gas/water feeding valve (OF-B194).
9. **Air/Water Feeding Valve (OF-B188)**
   Attach to the air/water feeding cylinder. Covering the hole on the valve button feeds air to the air/water nozzle at the distal end of the endoscope. Depressing the valve button feeds water to the air/water nozzle at the distal end of the endoscope.
10. **Strain Relief Boot**
    The strain relief boot protects the connecting parts.
11. **Instrument Channel Inlet**
    The instrument channel inlet is an inlet for endoscopic devices. Attach the inlet seal (OF-B190).
12. **Inlet Seal (OF-B190)**
    The inlet seal is attached to the instrument channel inlet to avoid fluid/air leakage.
13. **Model Name Label**
    The model name label shows the model name, minimum instrument channel width, and other related information.(Figure 2.2)

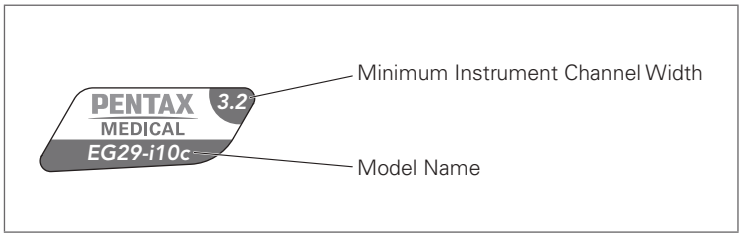


Figure 2.2

2-2. Scope connector

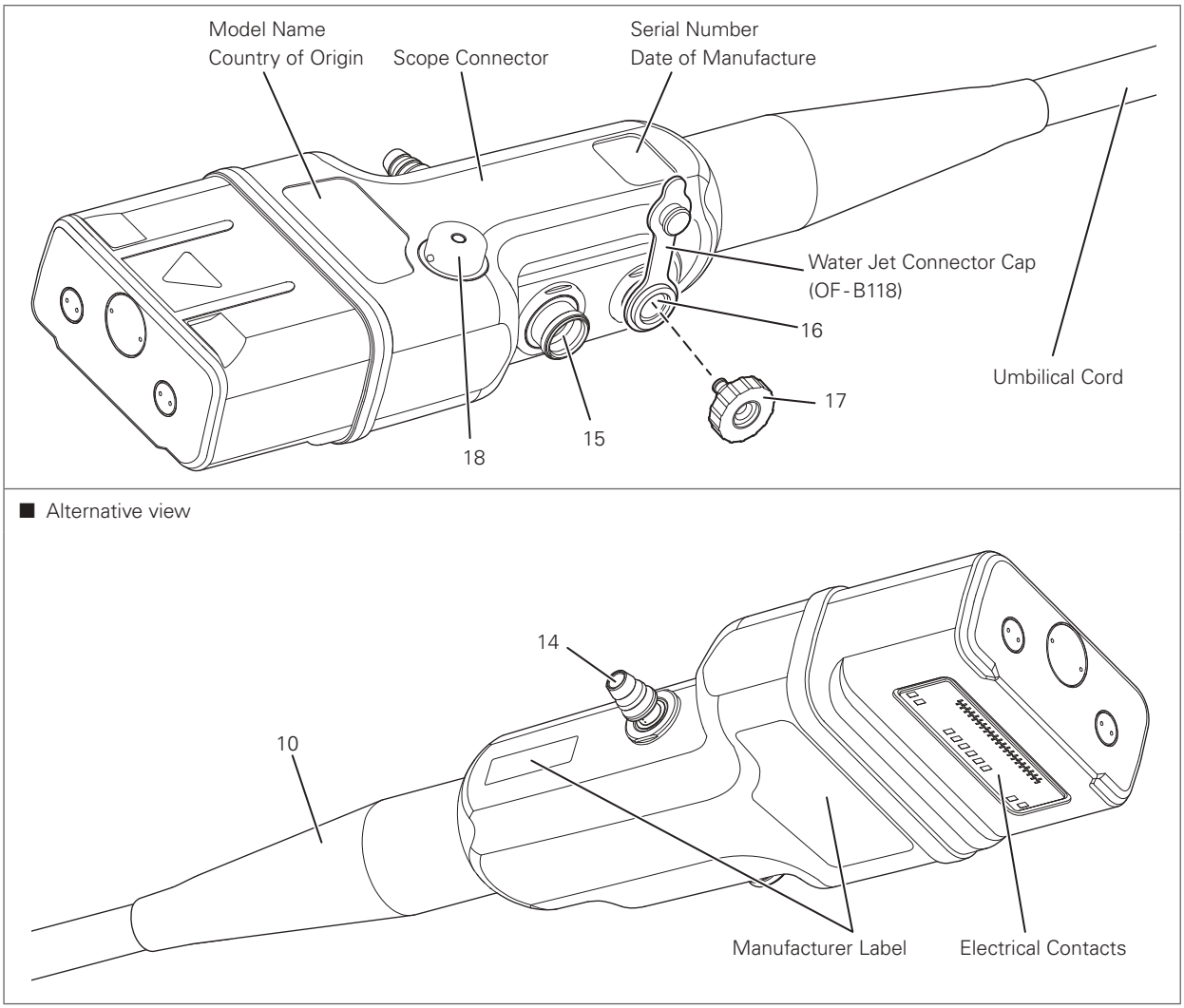


Figure 2.3

14. Suction Nipple

Connect the suction tube on the suction source to the suction nipple.

15. Air/Water Port

Connect the air/water feeding hose on the water bottle assembly to the air/water port.

16. Water Jet Port

Attach a water jet check valve adapter (OE-C12).

17. Water Jet Check Valve Adapter (OE-C12)

Use it by attaching to the water jet port.

Connect the irrigation tube (OF-B113) to send sterile water from a syringe or irrigation pump to the water jet nozzle at the distal end of the endoscope.

When an irrigation tube is not connected, close it with the water jet connector cap (OF-B118).

18. Venting Connector

Attach the ventilation cap (OE-C28) or leakage tester via the venting connector adapter (OE-C29) here.

3 Preparation and inspection

Before use, the endoscope, accessories, video processor, and other components must be prepared and carefully inspected according to the IFU. Any equipment used in combination with the endoscope must also be prepared and inspected according to the respective instruction manuals.
Always perform pre-use inspection before each use.

Refer to "5-1. Troubleshooting guide" (p. 76) for assistance in diagnosing an endoscope malfunction. If the problem persists after troubleshooting or there is an apparent failure, do not use the endoscope. Send it for repair according to "5-3. Returning the endoscope for repair" (p. 80).

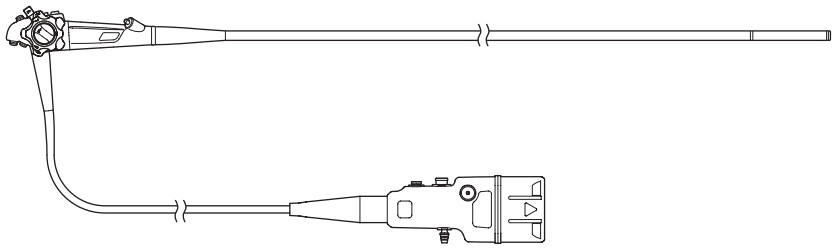
Warning

- Always perform pre-use inspection before each use. NEVER use an endoscope with a suspected abnormality. Doing so may result in malfunction, endoscope damage, and/or injury to the patient and/or user.
- Ensure that another endoscope is also prepared to avoid interruption of the procedure due to endoscope failure or unforeseen events.

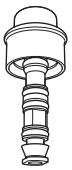
3-1. Preparation of the equipment

Prepare the endoscope, accessories, ancillary equipment, and protective equipment. Refer to the "Compatible products" to prepare the ancillary equipment as necessary and to the IFU provided with the video processor for its inspection.

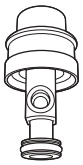
■ Endoscope



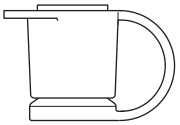
■ Accessories



Air/Water Feeding Valve (OF-B188)

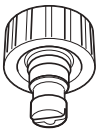


Suction Control Valve (OF-B120)



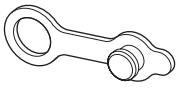
Inlet Seal (OF-B190 or OF-B215*)
* Optional item

Irrigation Tube (OF-B113)

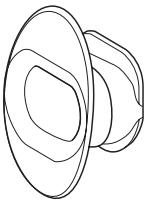


Water Jet Check Valve Adapter (OE-C12)

Silicone Oil (OF-Z11)

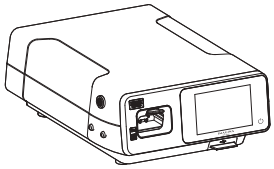


Water Jet Connector Cap (OF-B118)

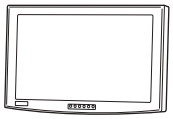


Bite Block (OF-Z5)

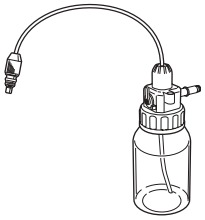
■ Ancillary Equipment



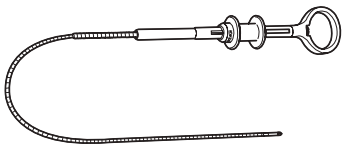
Video Processor



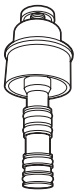
Monitor



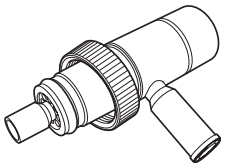
Water Bottle Assembly



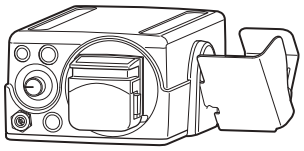
Endoscopic Device



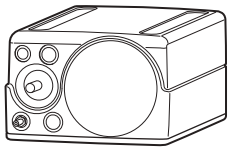
Gas/Water Feeding Valve (OF-B194*)
* Optional item



Gas Adapter (OF-G11*)
* Optional item



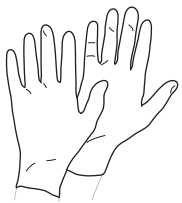
Irrigation Pump (EGA-500P)



CO_2 Insufflator (EGA-501P)

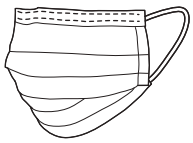
Suction Source

■ Protective Equipment (example)



Gloves

Goggles



Mask

Medical Gown

■ Other Equipment

Gauze, sterile water, container for sterile water, etc.

Figure 3.1

3-2. Inspection of the endoscope

Prepare an endoscope that has been reprocessed according to the procedure specified in the separate IFU(Reprocessing) of this endoscope.

Warning

- NEVER disassemble or modify the endoscope. Doing so may impair its original functionality and possibly result in serious injury to the patient and/or user.
- NEVER use an endoscope with any abnormality. Doing so may result in endoscope damage, detachment of parts into the patient's body cavity, malfunction during use, and/or injury to the patient and/or user.
- Use only sterile water for inspection. Failure to do so may result in contamination of the endoscope with waterborne bacteria and other microorganisms. Do NOT use water that has been left uncovered for a prolonged period of time.
- Do NOT excessively twist, bend, or rotate any of the strain relief boots on the instrument (See Figure 3.2 (A) and (B)) to identify the strain relief boots). Doing so may result in instrument damage. Pay special attention to the careful handling of the strain relief boot of the insertion portion (See Figure 3.2 (A)) of the endoscope, because it has a small diameter and is more likely to suffer damage due to mishandling.
- When carrying the endoscope, do NOT grasp or carry it only by its umbilical cord or insertion portion. Moreover, do NOT squeeze or forcefully bend the bending section. (Figure 3.3) Doing so may result in equipment damage.

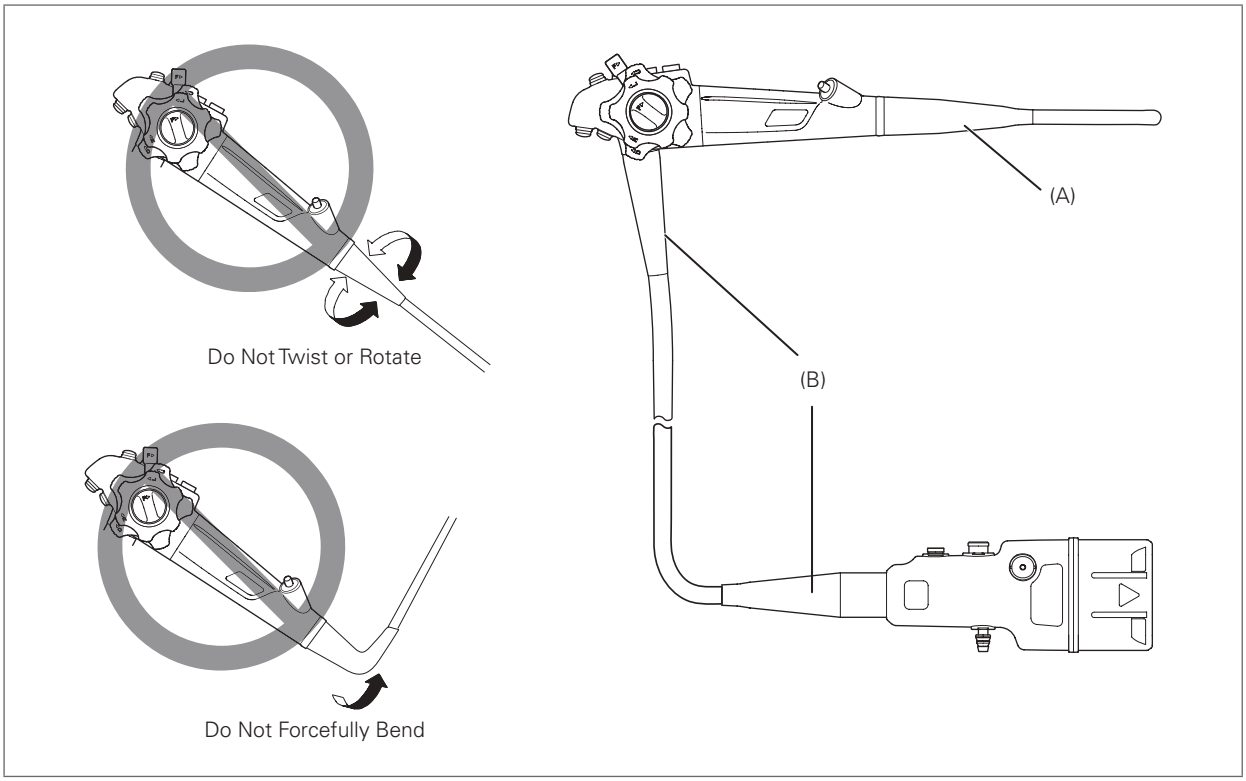


Figure 3.2

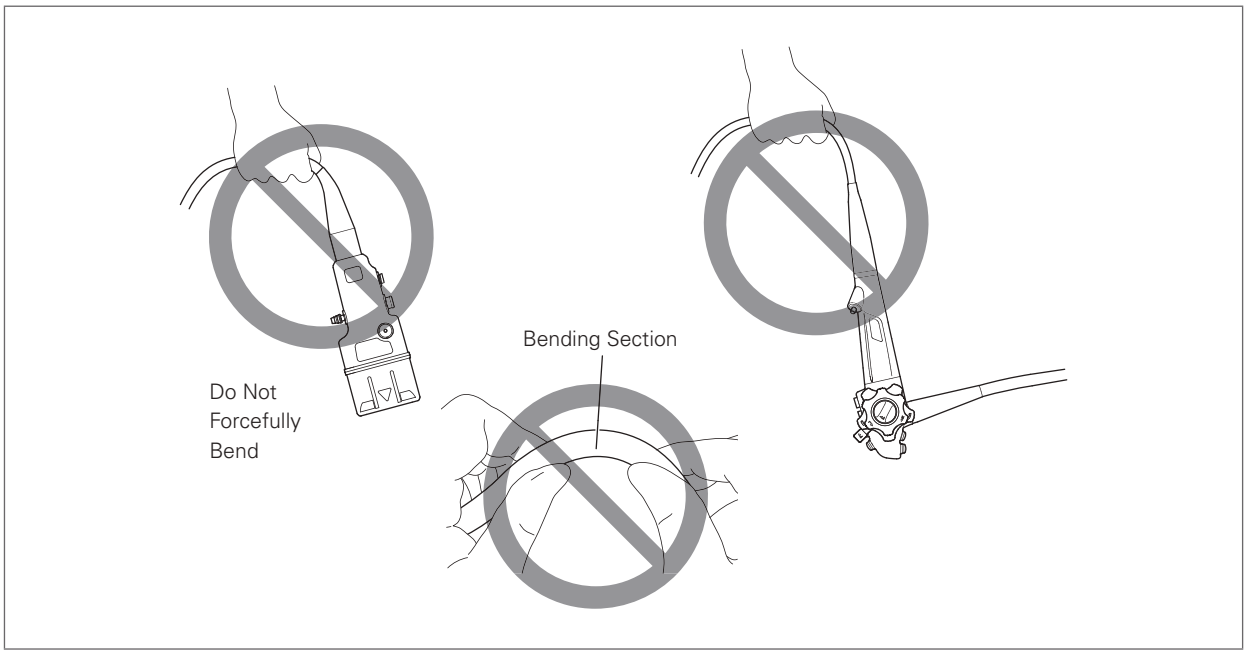


Figure 3.3

Note

In case the endoscope is hot/cold immediately after cleaning, high-level disinfection, and/or sterilization, wait until it returns to room temperature before using it. Lens fogging, which will result in blurry images, might result from abrupt changes in environmental temperature.

■ Carrying the endoscope by hand

When carrying the endoscope by hand, loosely loop the umbilical cord and insertion portion, hold the control body and the scope connector in gloved hand, and hold insertion portion (near the bending section) in the other gloved hand as shown in Figure 3.4.

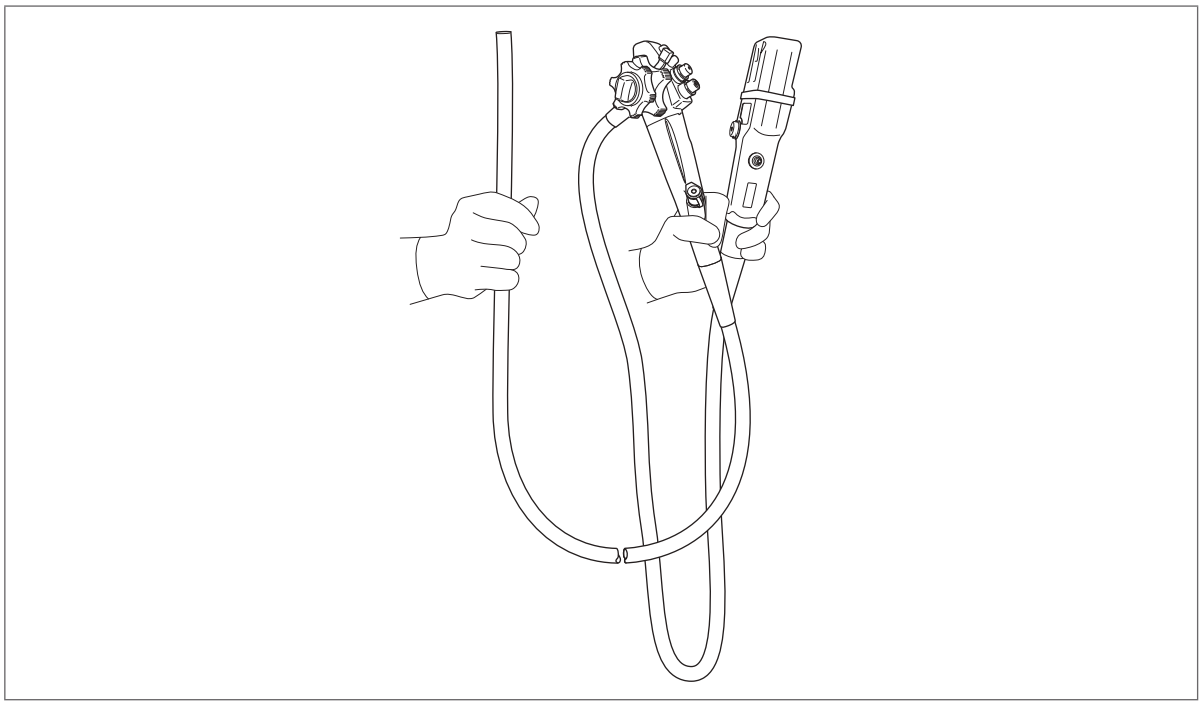


Figure 3.4

Inspection of the entire endoscope

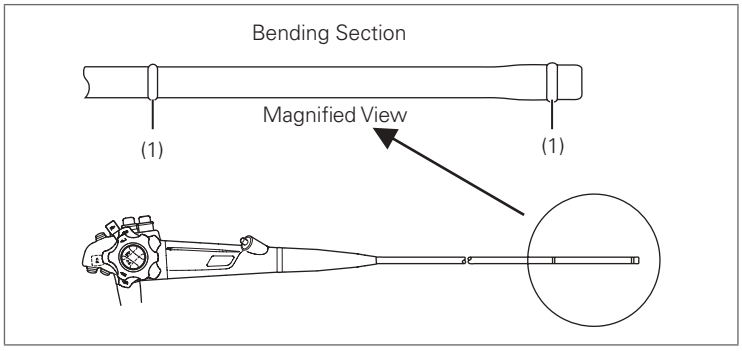
Warning

NEVER use the endoscope with any abnormality in function. Doing so may result in endoscope damage, detachment of parts into the patient's body cavity, endoscope malfunction during use, and/or injury to the patient and/or user.

Caution

Clear images can NOT be obtained if there is any foreign material attached to the objective lens or light guides. Water vapor from the foreign material may be released in response to heating by the light passing through these components, obscuring the image.

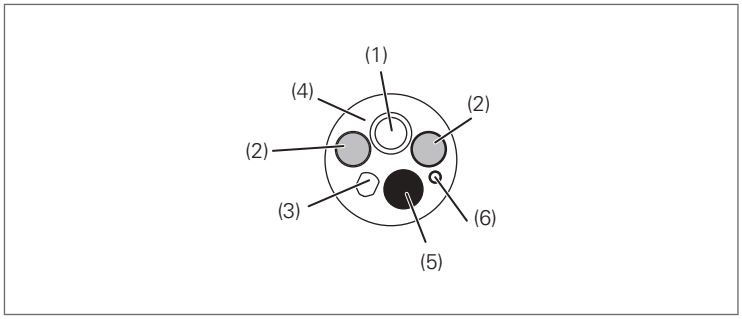
1. Check the entire surface of the endoscope for any visible adhered material.
2. Check the entire surface of the insertion portion for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, dents, catching, protrusions, attachment of foreign materials, detachment of parts, etc.
3. Check the surface of the adhesive bands on both ends of the bending section for abnormalities such as scratches, clouding, and peeling. With clean gauze, lightly wipe the surface of the adhesive bands to ensure that there is no catching and/or attachment of the adhesive to the gauze.



(1) Adhesive Bands

Figure 3.5

4. Check the case of the distal end of the endoscope (especially around the periphery of the instrument channel) for any abnormalities such as deformation or chipping.



(1) Objective Lens
(2) Light Guides
(3) Air/water Nozzle
(4) Case
(5) Instrument Channel
(6) Water Jet Nozzle

Figure 3.6

5. Check the objective lens at the distal end of the endoscope and the light guides for any abnormalities such as attachment of foreign material, scratches, or chipping, and ensure that there is no gap on the periphery of the lens.
6. Ensure that there are no scratches, clouding, or peeling on the surface of the adhesive glue around the objective lens at the distal end of the endoscope and that it has a glossy surface.

7. Gently clean the objective lens and light guides with clean gauze or a cotton-tip applicator moistened with 70% – 90% medical grade ethyl or isopropyl alcohol. Check that there is no attachment of the adhesive to the gauze.
8. Check the air/water nozzle at the distal end of the endoscope for any abnormalities such as clogging, dents, deformations, chipping, etc.
9. Using both hands, form an arch with the insertion tube as shown in Figure 3.7. Slide the insertion tube in the direction of the arrows in Figure 3.7, and check that the entire insertion tube can be bent smoothly and easily to form an arch.

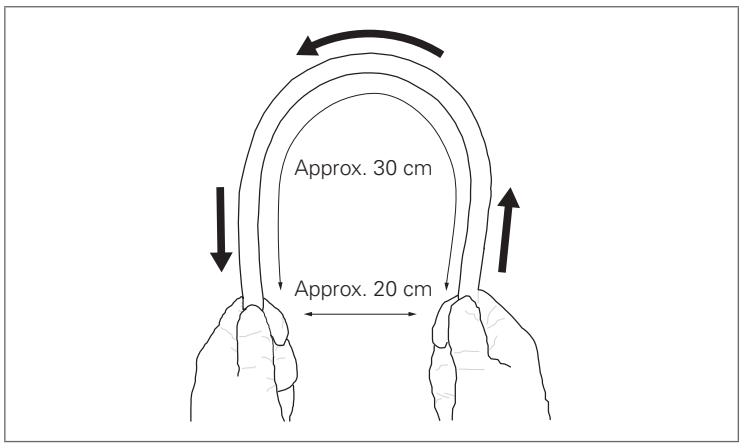
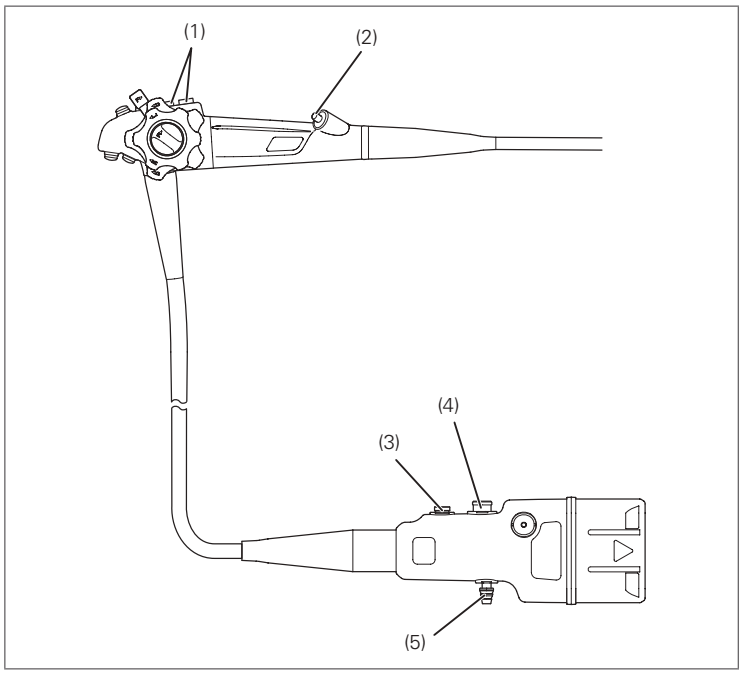


Figure 3.7

10. Check the entire surface of the umbilical cord for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, catching, protrusions, attachment of foreign materials, detachment of parts, etc.
11. Check the control body, scope connector, and electrical contacts for abnormalities such as scratches, deformities, loose parts, etc. Pay special attention when checking the parts shown in the Figure 3.8. Using a clean lint-free cloth, gently hold these parts and move them in various directions to ensure that there are no abnormalities such as looseness.



(1) Suction Cylinder & Air/Water Feeding Cylinder
(2) Instrument Channel Inlet
(3) Water Jet Port
(4) Air/Water Port
(5) Suction Nipple

Figure 3.8

12. Check the electrical contacts for any attachment of foreign materials such as residual chemical solution, water deposit, sebum, dust and gauze lint, etc.

Note

In case there are any attachment of foreign material or the endoscope has been left unused for a prolonged period of time, wipe the electrical contacts with gauze moistened with 70%–90% medical grade ethyl or isopropyl alcohol. After wiping, dry the electrical contacts sufficiently.

13. Ensure that the electrical contacts are sufficiently dry.

Inspection of the angulation mechanism

Ensure that there is nothing near the bending section that would hinder its operation, and inspect the angulation mechanism while the insertion portion is kept straight.

■ Inspection of bending function

Warning

Do NOT use an endoscope that can NOT be smoothly angulated, can NOT be fully angulated in any direction, or has excessive play in the angulation control lever. Use of an endoscope with any of these conditions may result in damage to the device, malfunction during use, and/or patient injury.

1. Turn the up/down angulation lock lever and right/left angulation lock knob in the "F ▶" direction until they stop to release the lock of the angulation control knobs.

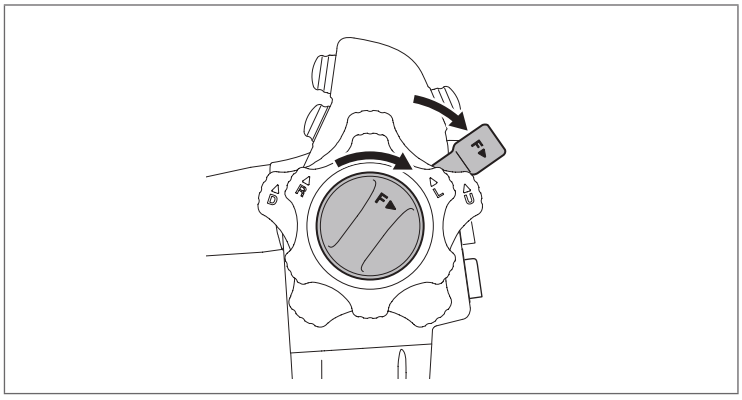


Figure 3.9

2. Turn the up/down and right/left angulation control knobs slowly in each direction until they stop, and return them to their original position. Check that the angulation control knobs operate smoothly with no roughness or catching.

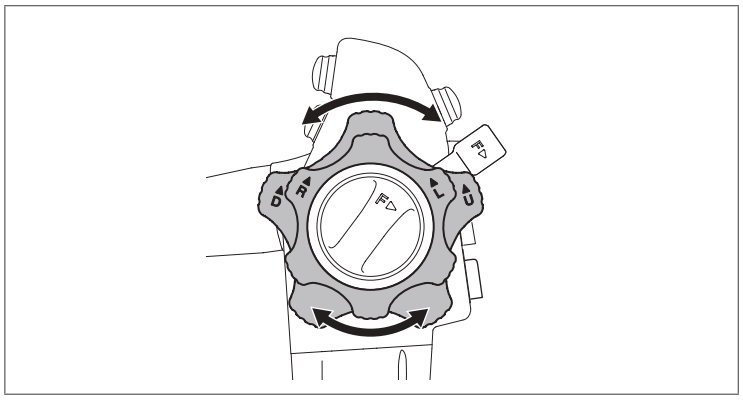


Figure 3.10

3. Check that the bending section angulates in the direction in which the angulation control knobs are turned and that the maximum angulation can be achieved.

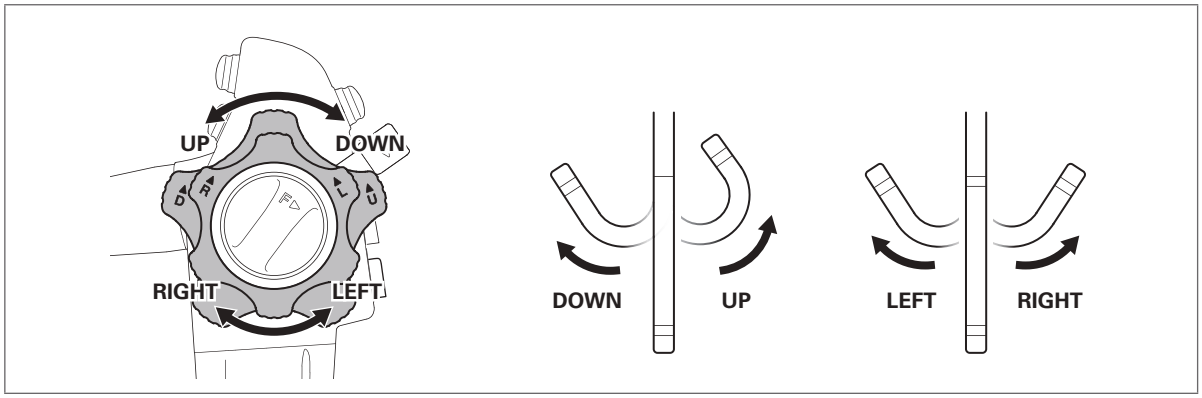


Figure 3.11

4. Turn the angulation control knobs back to the neutral position. Check that the bending section returns to a straight orientation.

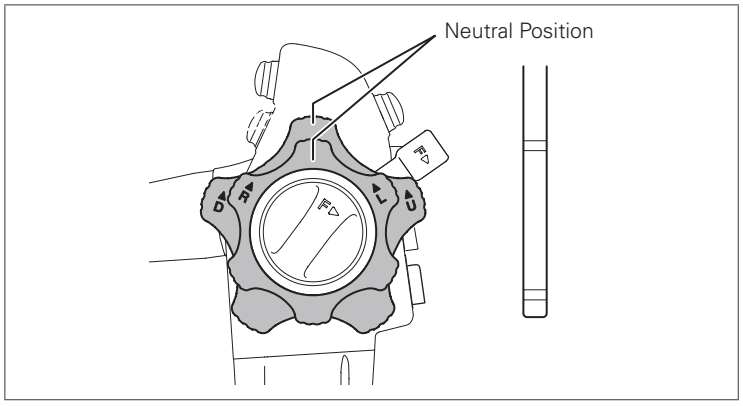


Figure 3.12

■ Inspection of the up/down bending lock mechanism

1. Turn the up/down angulation lock lever counterclockwise until it stops.

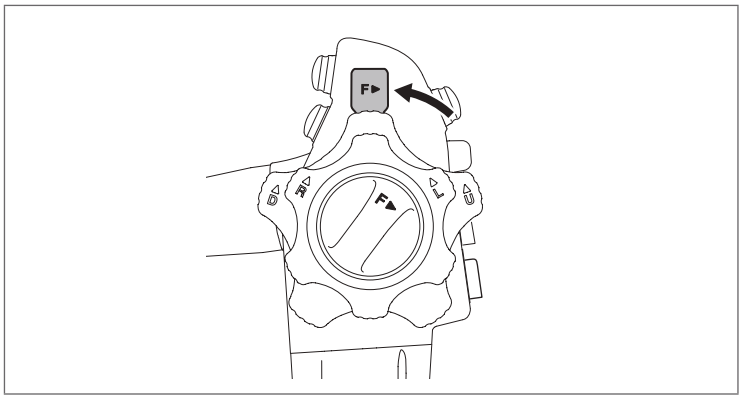


Figure 3.13

2. Turn the up/down angulation control knob slowly in the "▲U" or "▲D" direction until it stops.

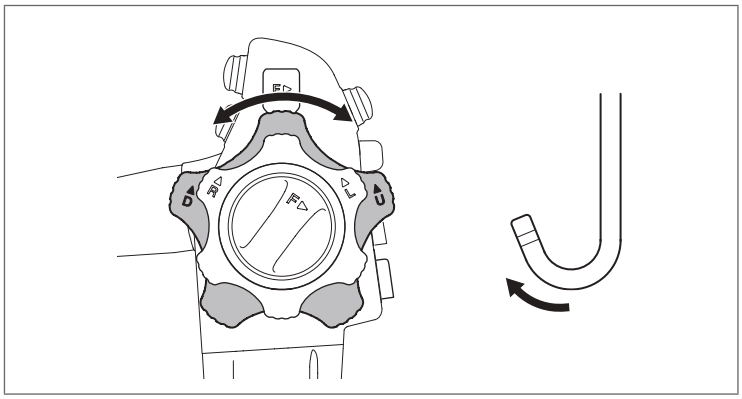


Figure 3.14

3. Check that the curved form of the bending section is fixed when releasing the angulation control knob.
4. Turn the up/down angulation lock lever in the "F ►" direction until it stops to release the lock. Check that the bending section returns to a straight orientation.

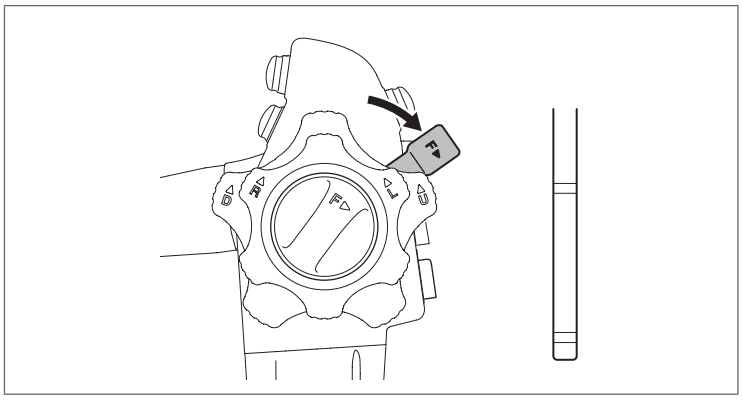


Figure 3.15

■ Inspection of the right/left bending lock mechanism

1. Turn the right/left angulation lock knob counterclockwise until it stops.

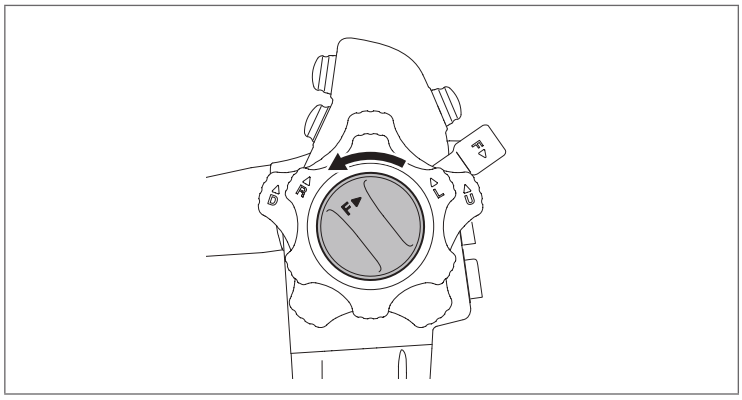


Figure 3.16

2. Turn the right/left angulation control knob slowly in the "▲R" or "▲L" direction until it stops.

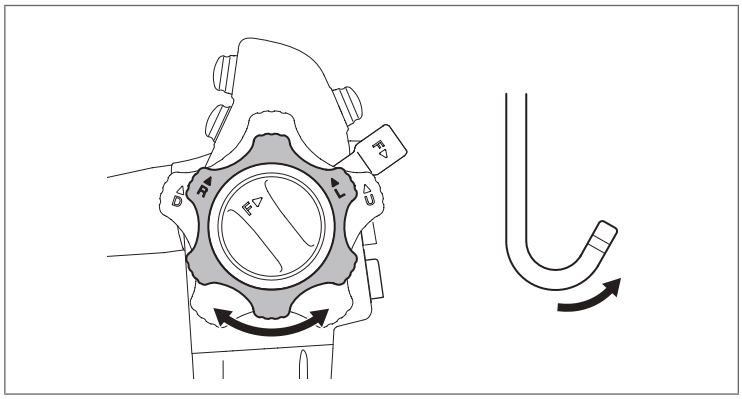


Figure 3.17

3. Check that the curved form of the bending section is fixed when releasing the angulation control knob.
4. Turn the right/left angulation lock knob in the "F ►" direction until it stops to release the lock. Check that the bending section returns to a straight orientation.

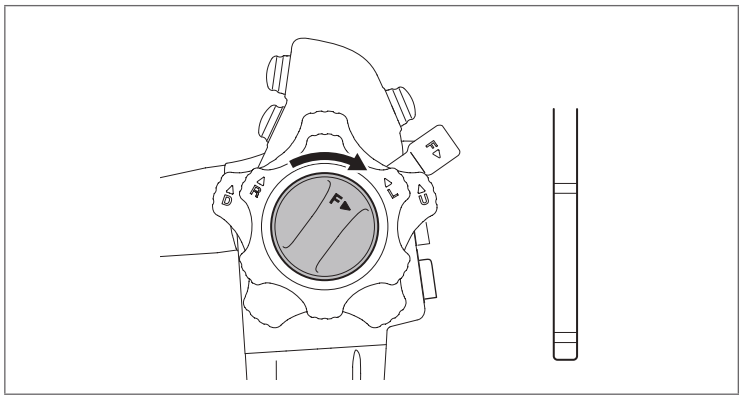


Figure 3.18

3-3. Inspection of accessories and attachment to the endoscope

When using reusable accessories, ensure that they have been cleaned, high-level disinfected, and/or sterilized according to the separate IFU (Reprocessing) for this endoscope.

Warning

NEVER disassemble or modify the accessories and endoscopic devices. Doing so may impair their original functionality and possibly result in serious injury to the patient and/or user.

Inspection of the air/water feeding valve (OF-B188)

Warning

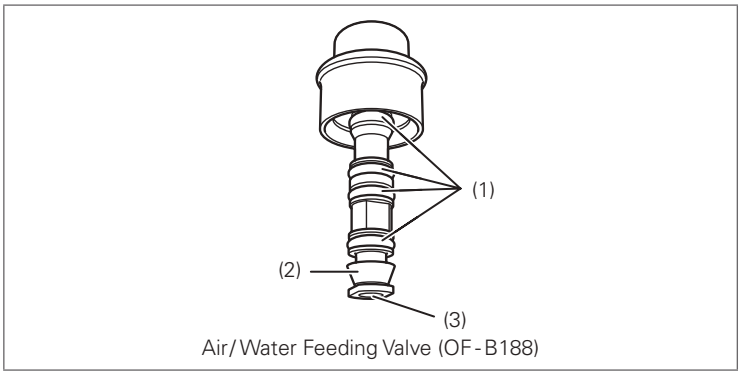
Replacement O-rings are NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection and/or sterilization of the air/water feeding valve after O-ring replacement.

Caution

- If any abnormality is detected with the check valve of air/water feeding valve (OF-B188) (Figure 3.19), replace the air/water feeding valve with a new one. Use of an air/water feeding valve with abnormalities can result in continuous air feeding into the patient, posing a risk of pain and/or perforation. Dispersal of patient material into the environment can also occur, posing a risk of infection to healthcare providers.
- The O-ring of the air/water feeding valve is a consumable. If any abnormality is detected with the O-ring, stop using it immediately and replace it with a new one. Use the compatible O-ring set for replacement. Using an O-ring with abnormalities or non-compatible O-ring could lower the function of air/water feeding, cause unintended continuous air feeding, and pose a risk of pain to the patient. Dispersal of patient material into the environment can also occur, posing a risk of infection to healthcare providers.

Note

- Use O ring set (OF-B192) to replace the O-ring of air/water feeding valve (OF-B188).
- For details on the O-ring replacement method, refer to the IFU provided with the O ring set (OF-B192).



Air/Water Feeding Valve (OF-B188)

(1) O-ring
(2) Check Valve
(3) Hole

Figure 3.19

1. Check the air/water feeding valve (OF-B188) for any abnormalities such as attachment of foreign materials, deformation, cracks, or hole blockage.
2. Check that the O-ring is properly attached and that there is no chipping, breaks, or peeling in the O-ring or check valve.

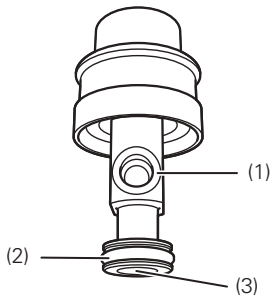
Inspection of the suction control valve (OF-B120)

Warning

- If any abnormality is detected with the rubber seal of suction control valve (OF-B120) (Figure 3.20), replace the suction control valve with a new one. Use of a suction control valve with any abnormality can result in continuously weak aspiration, which may hinder the procedure. Dispersal of patient material into the environment can also occur, posing a risk of infection to healthcare providers.
- The O-ring of the suction control valve is a consumable. If any abnormality is detected with the O-ring, stop use immediately and replace it with a new one. Use the compatible O-ring set (OF-B127) for O-ring replacement. Using an O-ring with abnormalities or non-compatible O-ring could result in unintended continuous suction and may hinder the examination. It could also pose a risk of infection to the user as a result of reflux or dispersal of patient's body fluids from the suction control valve.
- Replacement O-ring is NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection, and/or sterilization of the suction control valve after O-ring replacement.

Note

Use the O ring set (OF-B127) to replace the O-ring of the suction control valve (OF-B120).



Suction Control Valve (OF-B120)

(1) Rubber Seal
(2) O-ring
(3) Hole

Figure 3.20

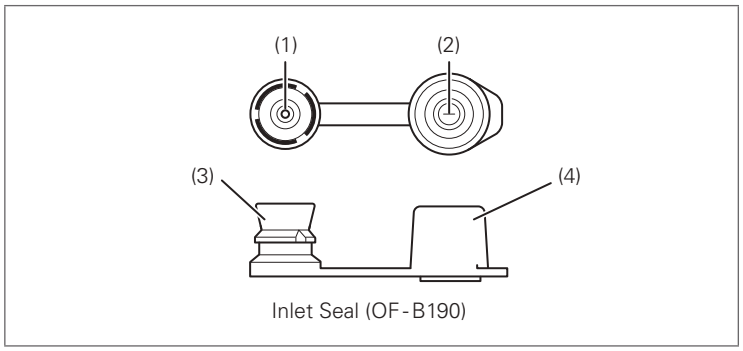
1. Check the suction control valve (OF-B120) for any abnormalities such as attachment of foreign materials, deformation, cracks, or hole blockage.
2. Check that the O-ring is properly attached and that there is no chipping, breaks, or peeling in the O-ring or the rubber seal (Figure 3.20).

Inspection of the inlet seal (OF-B190)

Warning

NEVER use an inlet seal (OF-B190) that has any abnormality. Replace it with a new one. Inlet seals are consumables. Using a damaged and/or worn inlet seal may result in lowered suction function and potential reflux or dispersal of patient's body fluids, posing a risk of infection to the user.

1. Check the slit in the cap of the inlet seal (OF-B190) and the hole of the body of the inlet seal for any abnormalities such as cracks, wear, chipping, and attachment or presence of foreign materials. Check that the light does not shine through the slit of the cap.



(1) Hole
(2) Slit
(3) Body
(4) Cap

Figure 3.21

2. Close the inlet seal as depicted in Figure 3.22.

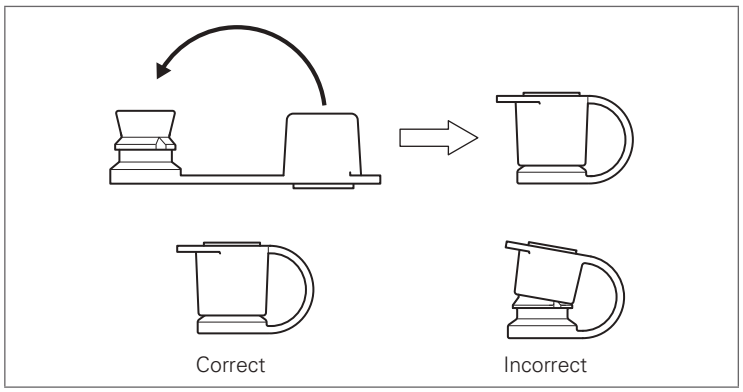


Figure 3.22

Note

PENTAX Medical PROfILE Single Use Endoscope Inlet Seal (OF-B215) can also be used. For details on the inspection method, refer to the IFU provided with the inlet seal (OF-B215).

Inspection of the water jet check valve adapter (OE-C12)

Warning

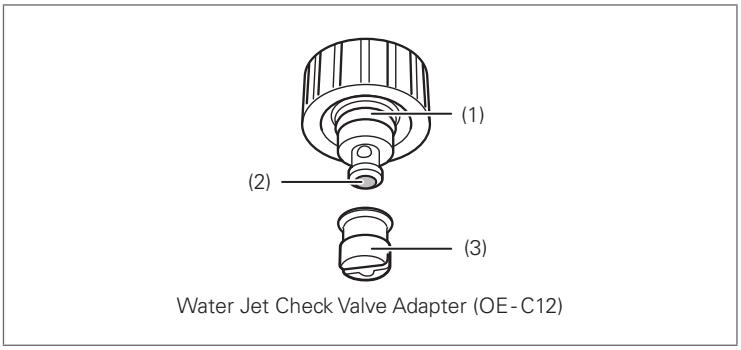
Replacement check valve sets (OE-C15, a packed set of multiple check valves) are NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection or sterilization of the water jet check valve adapter after check valve replacement.

Caution

NEVER use a check valve of the water jet check valve adapter (OE-C12) that has any abnormality. Replace it with a new one. Check valves are consumables. Using a damaged check valve may result in potential reflux or dispersal of patient's body fluids, posing a risk of infection.

Note

Use the check valve set (OE-C15, a packed set of multiple check valves) for replacement.



Water Jet Check Valve Adapter (OE-C12)

(1) O-ring
(2) Hole
(3) Check Valve

Figure 3.23

1. Check the water jet check valve adapter for any abnormalities such as attachment of foreign materials, deformation or cracks, or hole blockage.
2. Ensure that the check valve is attached correctly to the water jet check valve adapter without any gaps or pinching.

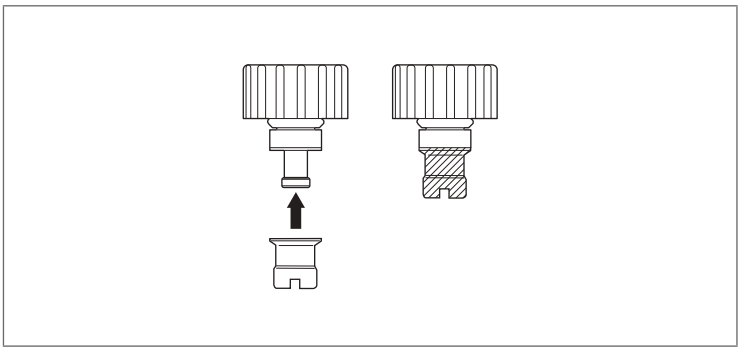


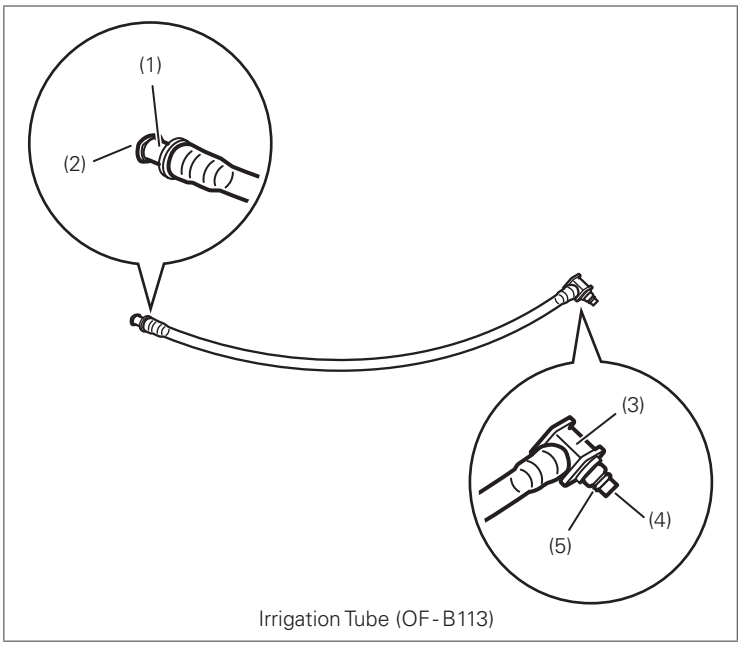
Figure 3.24

3. Check the O-ring and check valve for any abnormalities such as cracks, breaks, and peeling.

Inspection of the irrigation tube (OF-B113)

Warning

NEVER use the irrigation tube (OF-B113) when an abnormality is suspected in inspection. Replace it with a new one. Using the OF-B113 with abnormality in the process of cleaning, high level disinfection, or sterilization may cause leaking of detergent from the connection part and detachment of the OF-B113. The cleaning, high-level disinfection or sterilization may not be effective due to the insufficient reprocessing.



(1) Luer Connector
(2) Hole
(3) Connector
(4) Hole
(5) O-ring

Figure 3.25

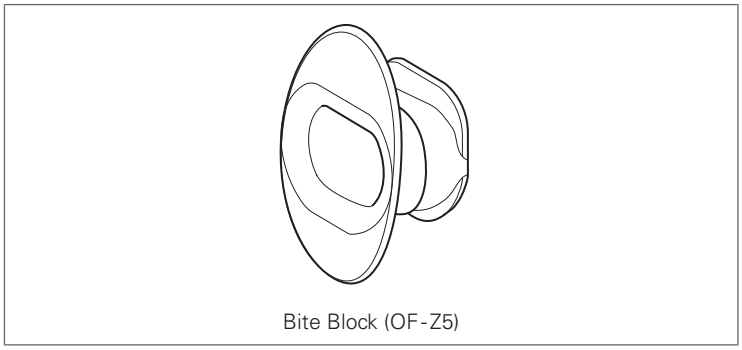
1. Check the entire surface of the irrigation tube (OF-B113) for abnormalities such as bending/breakage/looseness of the connector, cut/chip of the O-ring, buckling/deterioration/hardening of the tube, and/or broken luer.
2. Attach a syringe filled with the sterile water to the luer connector of the irrigation tube (OF-B113) and flush sterile water through the tube.
3. Check that sterile water flows in a steady stream from the connector of the irrigation tube (OF-B113).

Inspection of the bite block (OF-Z5)

Caution

NEVER use a bite block with any abnormality. Replace it with a new one.
Using a bite block with an abnormality may result in endoscope damage and injury to the oral cavity of patients.

Check the bite block for any abnormalities such as attachment of foreign materials, cracks, deformity, chipping, and discoloration.



Bite Block (OF-Z5)

Figure 3.26

Inspection of the endoscopic devices

For details on the inspection of each endoscopic device, refer to the instruction manual provided with the specific endoscopic device. For reusable endoscopic devices, prepare ones that have been cleaned and sterilized by following the instruction manual for the respective endoscopic device.

Warning

- NEVER use an endoscopic device with signs of damage and/or operational abnormality. Doing so may result in malfunction during use, endoscope damage, and/or patient injury.
- Use endoscopic devices specified by PENTAX Medical whose compatibility has been confirmed. Using endoscopic devices whose compatibility has not been confirmed may result in endoscope damage and/or patient injury caused by failure during use.

This section describes the use of a biopsy forceps.

1. Check the entire surface of the forceps for any visible adhered material.
2. Check the insertion portion and control body of the biopsy forceps for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, dents, catching, protrusions, attachment of foreign materials, falling of parts, etc.

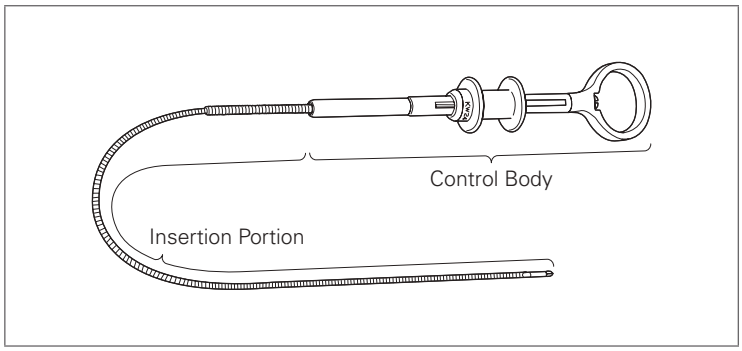


Figure 3.27

3. Check that the cups of the biopsy forceps open/close smoothly by operating its handle.

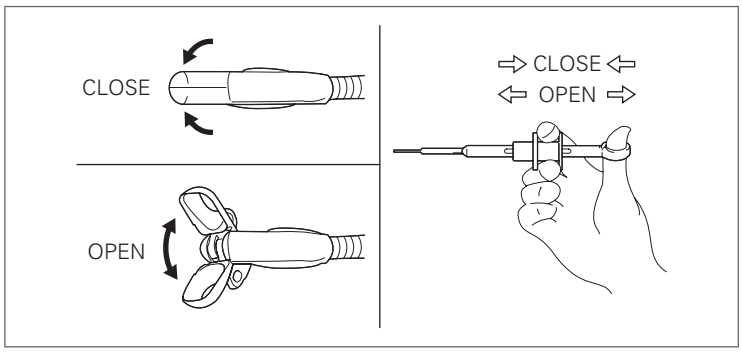


Figure 3.28

4. Form a loop with a diameter of 20-30 cm with the flexible shaft at approximately 20-30 cm from the tip of the insertion portion of the biopsy forceps. Check that the cups of the biopsy forceps open/close smoothly by operating its handle.

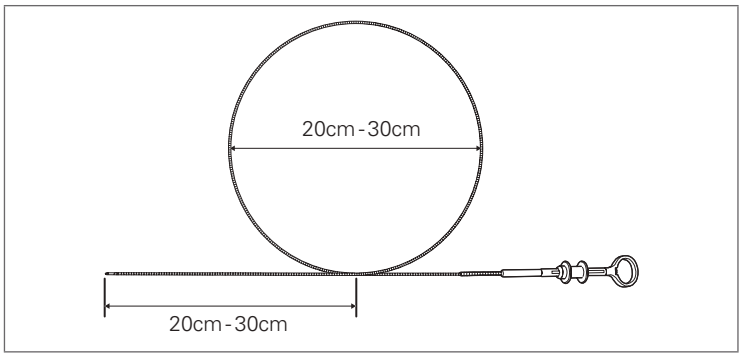


Figure 3.29

5. Check that the cups align with each other when closed.

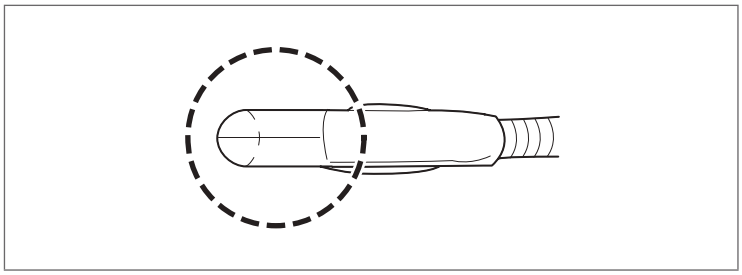


Figure 3.30

Attachment of accessories

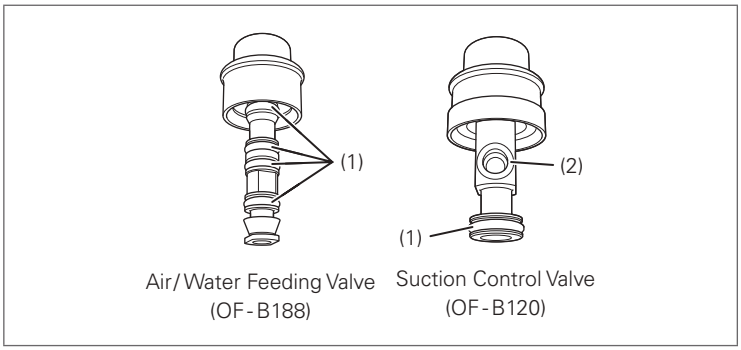
Warning

Attach the accessories properly to the endoscope. Failure to do so may result in lowered function and potential reflux or dispersal of patient's body fluids, posing a risk of infection to the user.

■ Attachment of the air/water feeding valve (OF-B188) and suction control valve (OF-B120)

Warning

- Ensure to apply silicone oil lubricant (OF-Z11) onto the O-ring of each valve and the rubber seal of the suction control valve (OF-B120). Using the valves without applying the oil or applying a silicone oil other than the specified one could deteriorate the functions and may result in damage to the endoscope and/or patient injury.
- Attach the air/water feeding valve (OF-B188) and suction control valve straight into their respective valve cylinders. Inserting them into their valve cylinders at an angle may damage valve O-rings and rubber seals.



(1) O-ring
(2) Rubber Seal

Figure 3.31

1. Apply a minimal amount of silicone oil lubricant (OF-Z11) to the O-rings of the air/water feeding valve (OF-B188) and the O-ring and rubber seal of the suction control valve (OF-B120). In order to apply the silicone lubricant, place a small droplet of oil onto a sterile gloved forefinger, gently swirl the oil between the thumb and the forefinger, and apply it onto the necessary parts. Wipe off the excess lubricant with soft gauze.
2. Attach the air/water feeding valve to the air/water feeding cylinder of the endoscope.

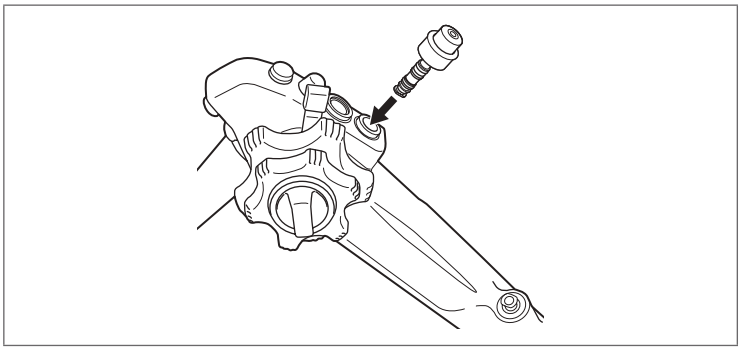


Figure 3.32

3. Ensure that the air/water feeding valve (OF-B188) is firmly attached. Press down the air/water feeding valve a few times to ensure that it moves smoothly.

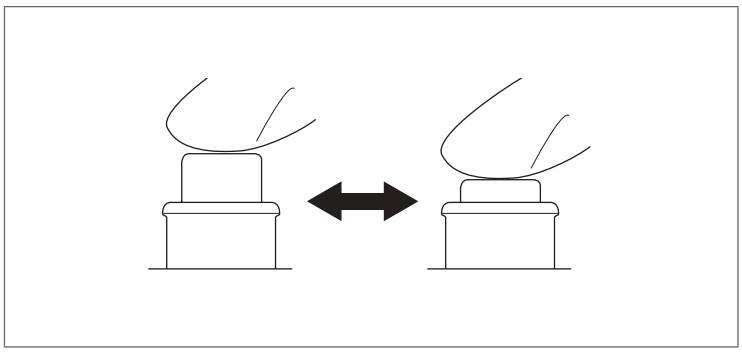
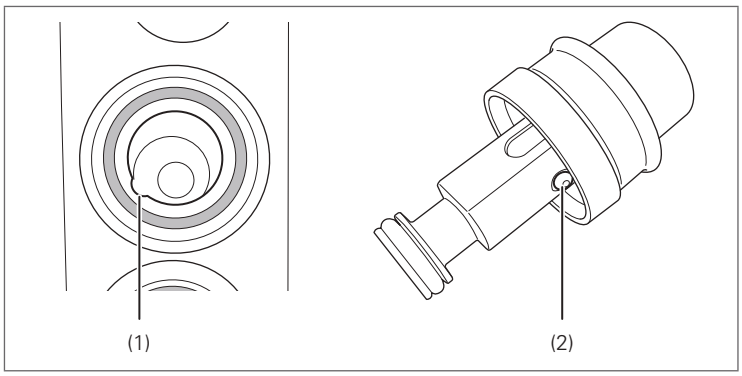


Figure 3.33

4. Align the metal tab on the shaft of the suction control valve with the notch on the suction cylinder of the endoscope.



(1) Notch
(2) Metal Tab

Figure 3.34

5. Attach the suction control valve (OF-B120) to the suction cylinder of the endoscope.

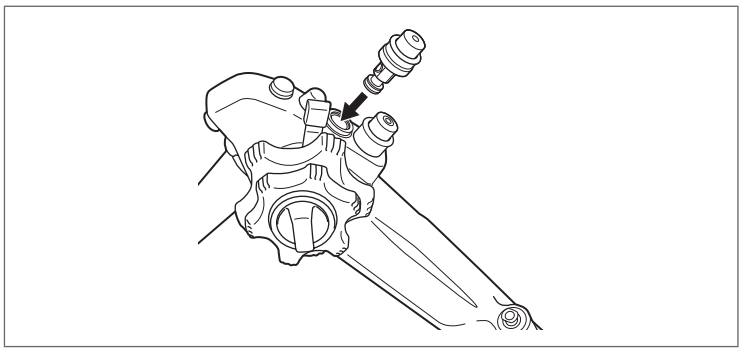


Figure 3.35

6. Check that the suction control valve is firmly attached. Press down the suction control valve a few times to ensure that it moves smoothly.

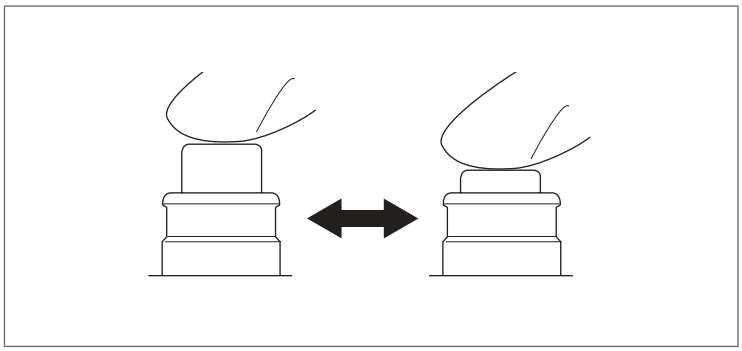


Figure 3.36

■ Attachment of the inlet seal (OF-B190 or OF-B215 (option))

1. Attach the inlet seal (OF-B190 or OF-B215 (option)) to the instrument channel inlet.

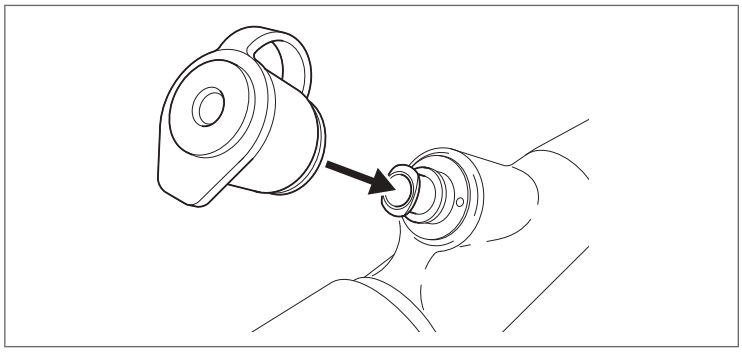


Figure 3.37

2. Ensure that the inlet seal is tightly attached to the instrument channel inlet without gaps.

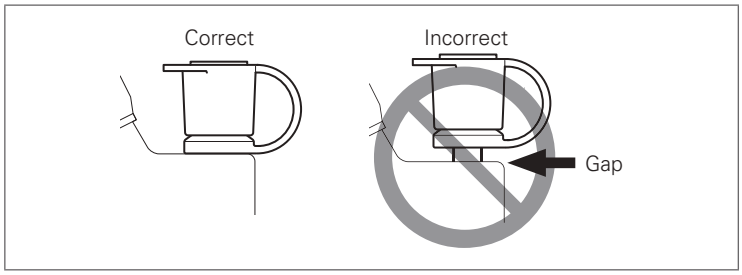


Figure 3.38

■ Attachment of the water jet check valve adapter (OE-C12) and water jet connector cap (OF-B118)

1. Attach the water jet connector cap (OF-B118) and water jet check valve adapter (OE-C12) to the water jet port of the endoscope.

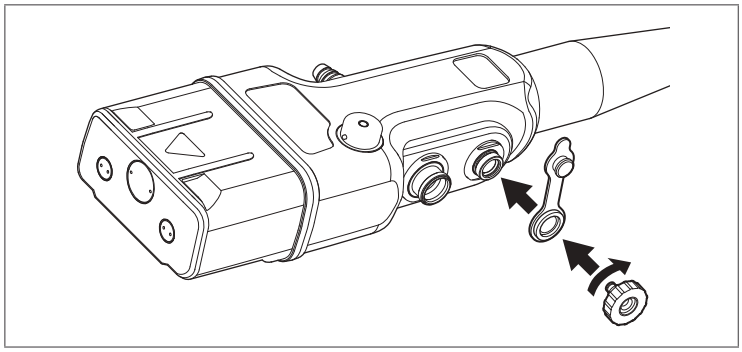


Figure 3.39

2. Ensure that the water jet check valve adapter is firmly attached to the water jet port without gaps. (Close the lid of the water jet connector cap.)

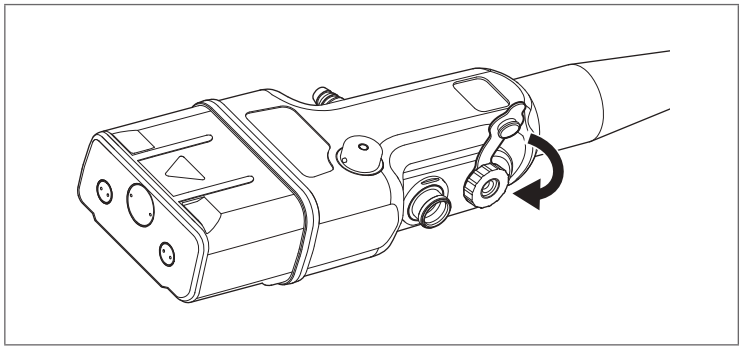


Figure 3.40

3-4. Inspection and connection of ancillary equipment to the endoscope

Inspect the ancillary equipment prepared in "3-1. Preparation of the equipment", such as the video processor, monitor, and suction source, according to their respective IFU.

Video processor
Monitor
Suction source
Endoscopic device
Water bottle assembly
Irrigation pump
CO_2 Insufflator, etc.

Inspection of the video processor

Only use compatible PENTAX Medical video processors.
For compatible video processors, refer to "Compatible products" (p. 8) or "System chart" (p. 90).

For details on the preparation and inspection of the video processor, refer to the IFU of the respective video processor.

Connection of the endoscope and ancillary equipment

■ Connection to the video processor

Warning

Ensure that the scope connector is securely attached to the video processor. Failure to do so may result in an abnormality such as disappearance of the image which may cause patient injury.

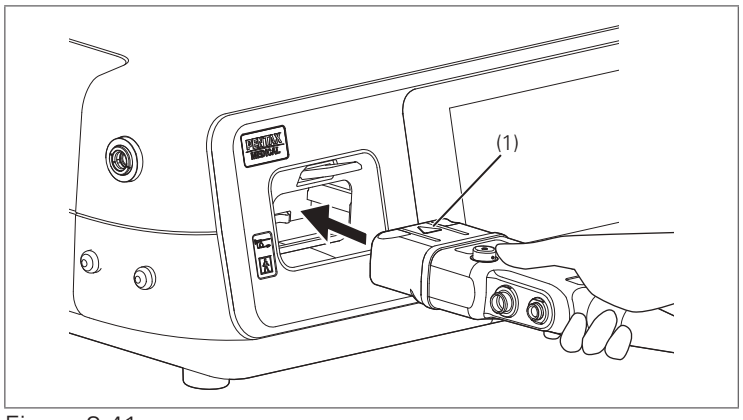
Caution

Ensure that the scope connector (including the electrical contacts) is sufficiently dry before connecting it to the video processor. In addition, check the electrical contacts for any attachment of foreign materials (such as residual chemical solution, water deposit, sebum, dust and gauze lint, etc.) before connecting. Failing to do so may result in the endoscope's malfunction or failure.

Note

When connecting the scope connector to the video processor, hold the video processor with one hand. It may become difficult to connect if the video processor moves.

1. Ensure that all ancillary equipments are turned off.
2. Hold the scope connector as shown in Figure 3.41, and turn the scope connector's Connector UP index ("▲") upward and push the scope connector into the video processor receptacle until it clicks.



(1) UP index

Figure 3.41

■ Connection of the water bottle assembly, suction tube, and irrigation tube (OF-B113)

Warning

- Use only sterile water in the water bottle assembly. Failure to do so may pose a risk of infection.
- Do NOT use defoaming agents in the water bottle assembly. These agents attach to the internal lumen of the air/water channel and may block the channel and/or damage the endoscope. They are also extremely difficult to remove during subsequent cleaning and can interfere with proper endoscope reprocessing.

Caution

Connect the suction tube of the suction source firmly to the suction nipple. Failure to do so may result in disconnection of the suction tube during use and pose a risk of cross contamination to the user as a result of reflux or dispersal of patient's body fluids.

Note

Turn off the air/water feeding pump of the video processor beforehand.

1. Attach the water bottle assembly correctly according to the IFU of the video processor.
2. Insert the air/water connector of the water bottle assembly into the air/water port of the endoscope until it clicks.

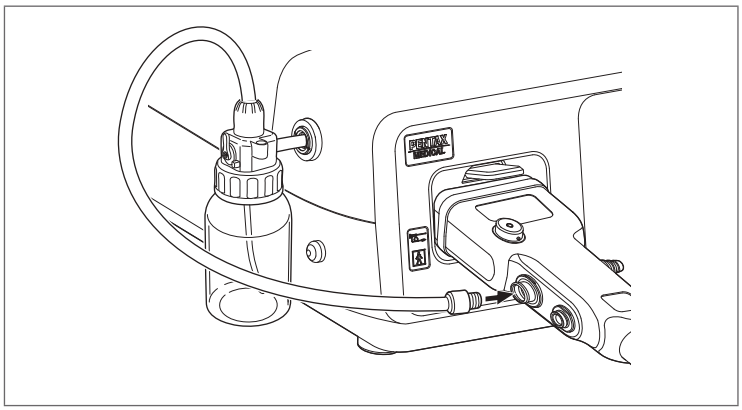


Figure 3.42

Note

Failure to connect the water bottle assembly correctly not only lowers the air/water feeding function, but may also cause insufficient cleaning of the objective lens.

3. Connect the suction tube of the suction source to the suction nipple of the endoscope.

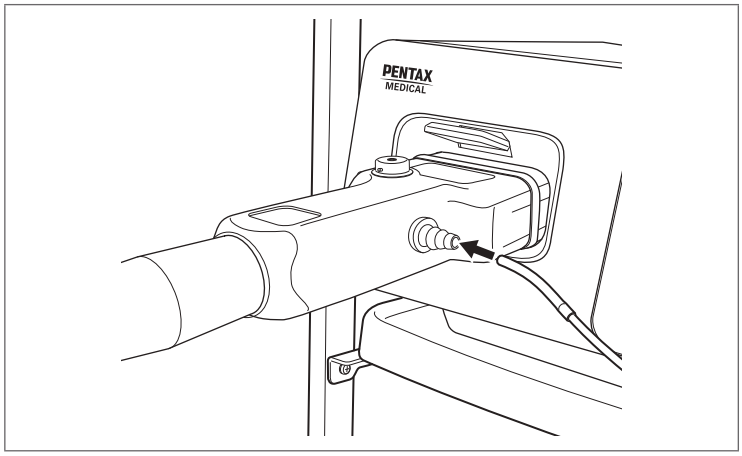


Figure 3.43

4. Remove the lid of the water jet connector cap (OF-B118) and push the irrigation tube (OF-B113) into the water jet check valve adapter (OE-C12) until it clicks.

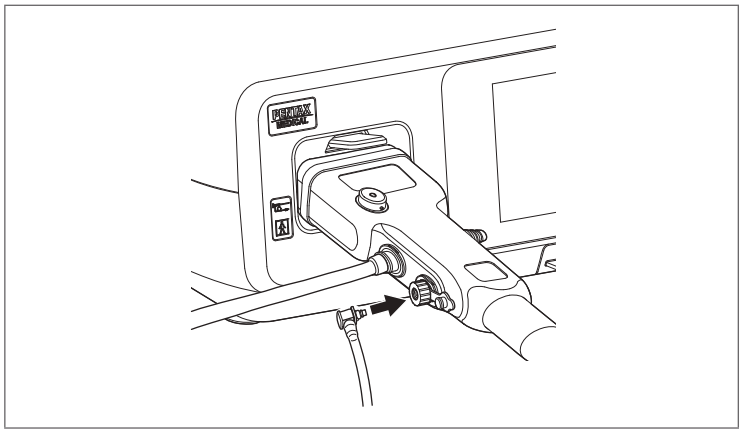


Figure 3.44

Caution

Do NOT orient the irrigation tube (OF-B113) at an angle when attaching it to or removing it from the water jet check valve adapter (OE-C12). Doing so may break the irrigation tube.

Note

Do not use the irrigation tube (OF-B113) if you have any difficulty in attaching it, or if you do not feel it clicking into place when attaching it to the endoscope. The use of damaged luer connector may result in water leakage from the connected part or tube disconnection.

3-5. Inspection of the endoscopic system

Inspection of the endoscopic image

Caution

Do NOT look directly at the light emitted from the distal end of the endoscope. The intense light may cause eye injuries. Turn off the lamp when looking directly at the distal end of the endoscope.

Note

The following instructions regarding the operation of a video processor are general in nature. For specific information regarding your video processor model, refer to the IFU provided with the video processor.

1. Turn on the main power switch on the video processor.
2. Press and hold the On/Standby switch on the lower right of the front panel on the video processor for 2 to 3 seconds.

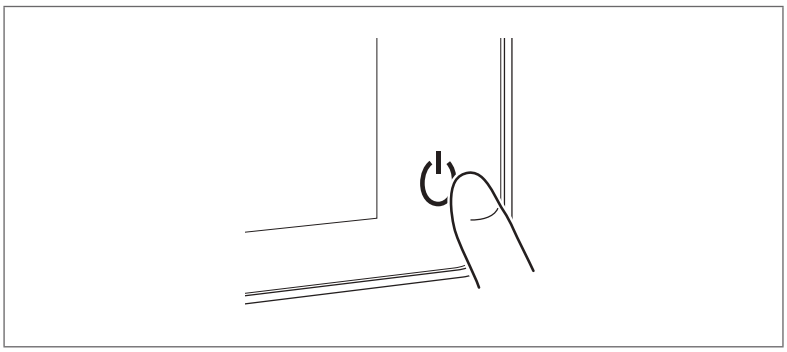


Figure 3.45

3. Tap a Lamp icon on the touch panel of the video processor.
4. Check that the distal end of the endoscope emits light.

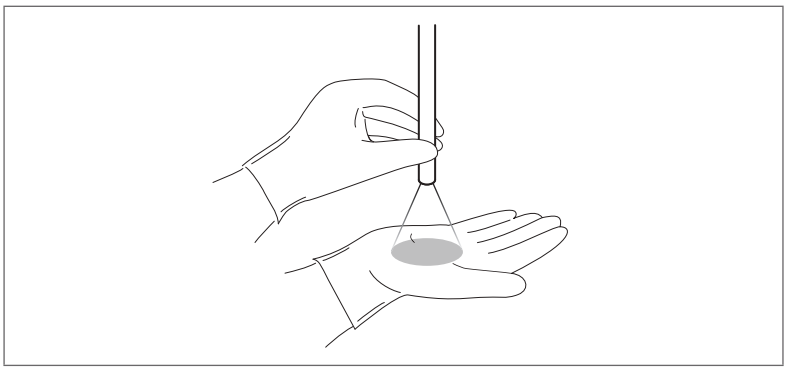


Figure 3.46

5. Check that the endoscopic image is clear and is displayed normally.

Note

If the image is not clear, gently clean the endoscope objective lens with clean gauze moistened with 70% – 90% medical grade ethyl or isopropyl alcohol.

6. On the touch panel of the video processor, check that the exposure control is set to [Average] or [Peak].
7. Place the distal end of the endoscope at a distance of approximately 1 cm from the palm of your hand and then move it approximately 5 cm away from your palm. Watch the image displayed on the monitor to ensure that the brightness at both distances is similar.

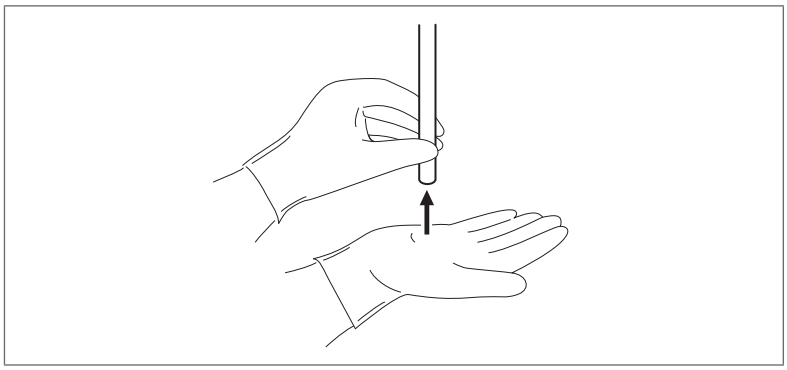


Figure 3.47

Caution

Do NOT directly touch the distal end of the endoscope (particularly the light guide) for a prolonged period of time when the light is being emitted. Doing so may result in burn injury.

8. While checking the image displayed on the monitor and following the IFU of the video processor, adjust the brightness level as appropriate.
9. Operate the angulation control knobs of the endoscope to move the bending section, and check that the image is traveling along with the direction of the angulated distal tip of the endoscope. Also check for abnormalities such as appearance of noise in the endoscopic image or disappearance of the image.

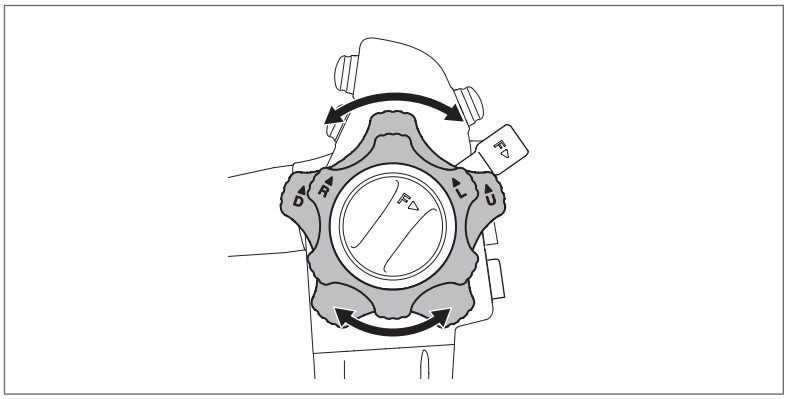


Figure 3.48

Inspection of the remote buttons

Warning

Always inspect the remote buttons even if they are NOT expected to be used. During a procedure, the endoscopic image may freeze or other abnormalities may occur, which may result in patient injury.

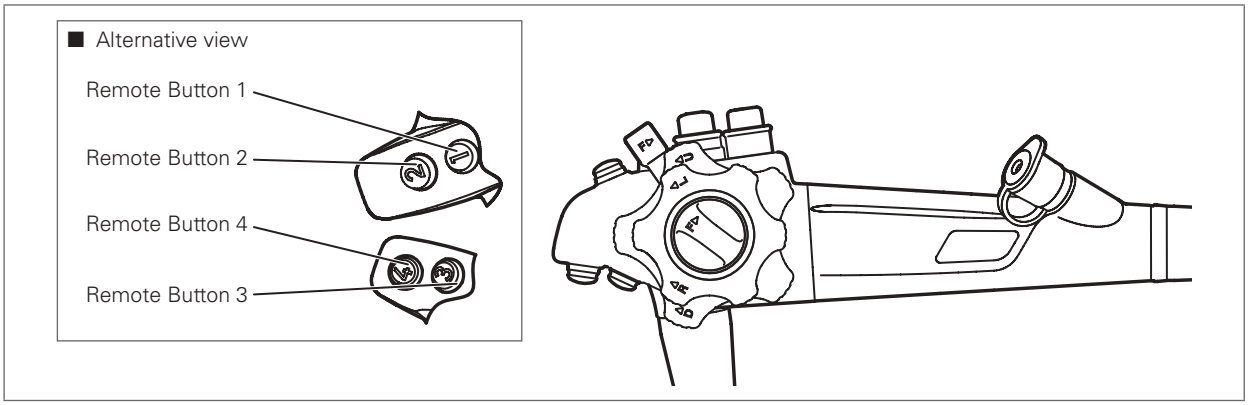


Figure 3.49

1. Press each remote button.
2. Check that the function assigned to each remote button is operating normally.

Inspection of the air/water feeding function

Warning

Use sterile water for inspection of the air/water feeding function. Failure to do so may pose a risk of infection.

Note

Refer to the separate IFU of water bottle assembly for details of the operating procedure.

1. Set the A/W-drain lever of the water bottle assembly at the "A/W" position.

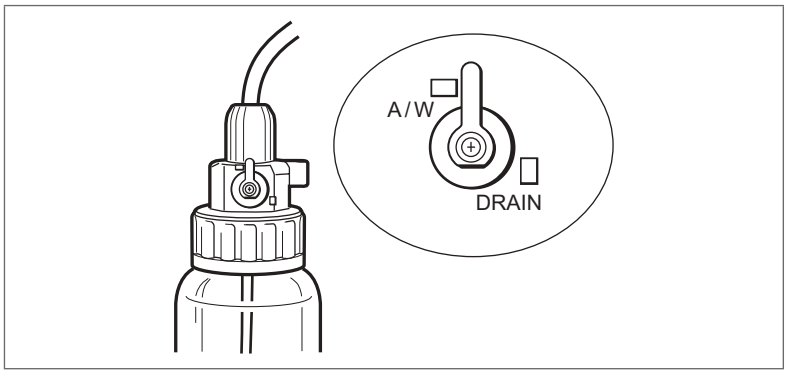


Figure 3.50

2. Tap the pump icon on the touch panel of the video processor.
3. Set the pump level to "5" by moving an adjustment slider on the pump level menu.
4. Insert the distal end of the endoscope into a container filled with sterile water, and check that air bubbles are not continuously discharged from the air/water nozzle at the distal end of the endoscope.

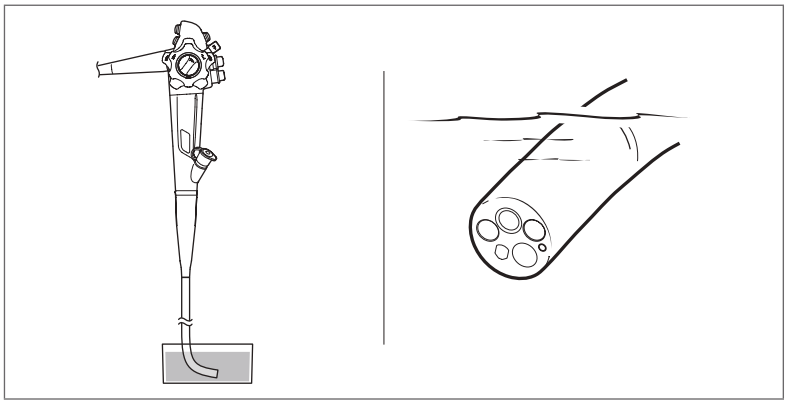


Figure 3.51

Caution

If air bubbles are continuously discharged from the air/water nozzle at the distal end of the endoscope when the hole on the top of the air/water feeding valve is NOT closed, stop use immediately and replace the air/water feeding valve with a new one. Continuous use of an air/water feeding valve with abnormalities could cause unintended continuous air feeding and pose a risk of pain to the patient.

5. Block the hole in the top of the air/water feeding valve. Confirm that a steady stream of air bubbles is being released from the air/water nozzle on the distal end of the endoscope.

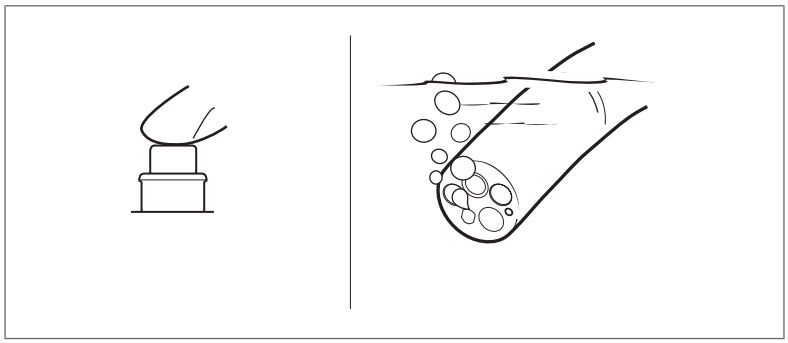


Figure 3.52

6. Check that the discharge of air bubbles stops when you remove your finger from the hole in the button of the air/water feeding valve.

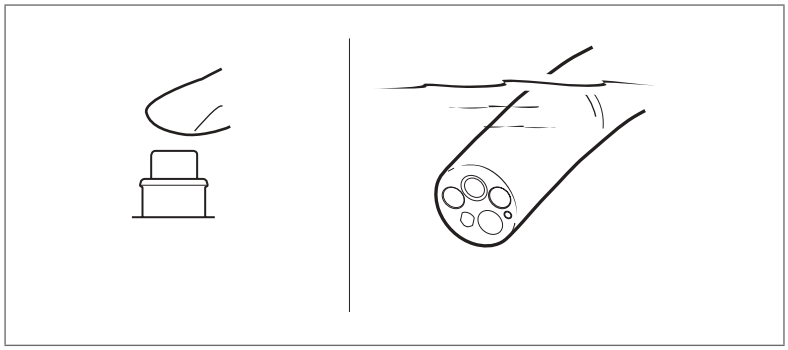


Figure 3.53

7. Pull the endoscope out of the container, and depress the air/water feeding valve. Check that a certain amount of water flows out from the air/water nozzle. (It takes a few seconds until water comes out the first time.)

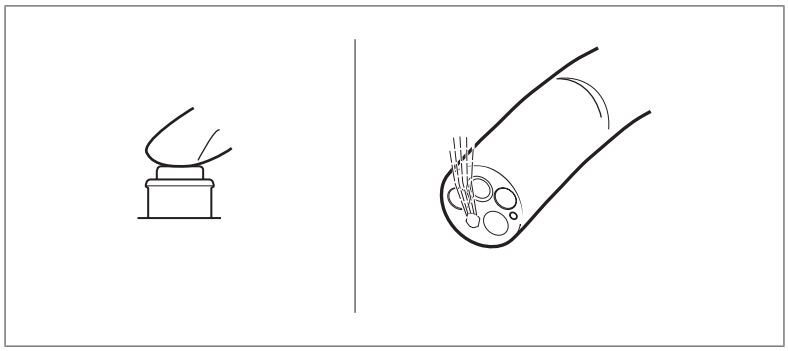


Figure 3.54

8. Remove your finger from the air/water feeding valve. Check that the air/water feeding valve returns smoothly to the original position and that the flow of water from the air/water nozzle stops when you remove your finger from the hole in the valve.

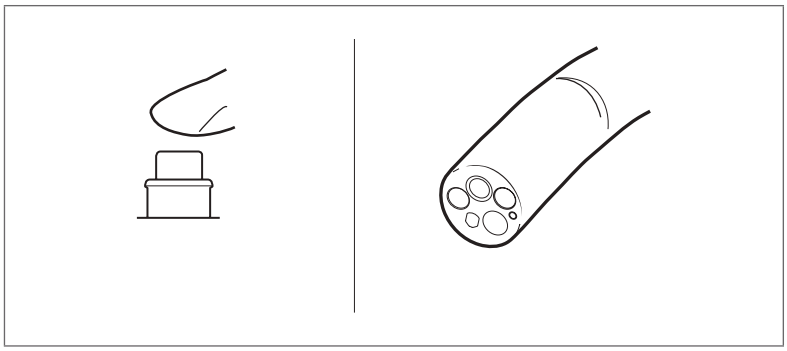


Figure 3.55

Caution

Do NOT attempt to clear the air or water nozzles with a needle or any other sharp object if nozzle blockage is suspected. This may result in suboptimal performance and/or damage to the endoscope.

Note

Perform the procedure described in "How to deal with the blockage in the air/water nozzle or channel" (p. 77) of the endoscope is suspected.

Inspection of the irrigation function

Warning

Use sterile water for inspection of the irrigation function. Failure to do so may pose a risk of infection.

1. Fill a syringe with sterile water.
2. Put the distal end of the endoscope to the clean container, and insert a syringe filled with sterile water into the inlet seal (OF-B190) as shown in Figure 3.56.

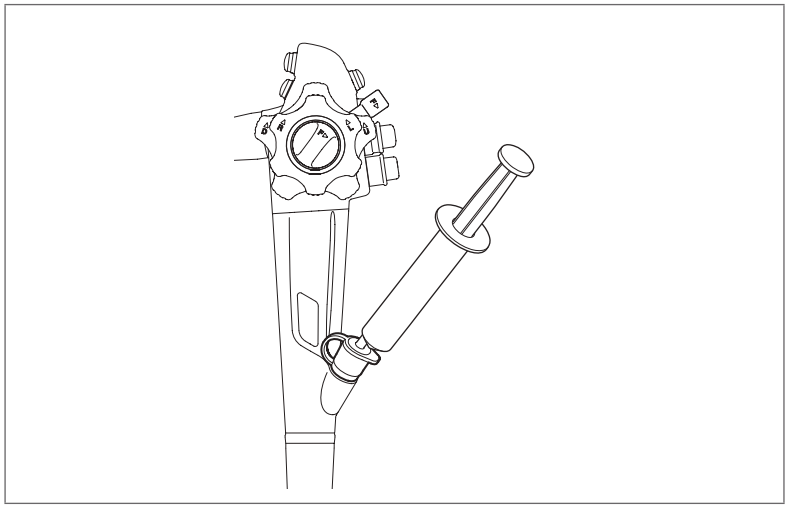


Figure 3.56

3. Infuse sterile water into the instrument channel and check to ensure that it flows from the instrument channel opening on the distal tip of the endoscope. Ensure that the effluent is free of foreign materials.
4. Remove the syringe from the inlet seal (OF-B190).
5. Fill the syringe with air and insert it into the inlet seal.
6. Flush the sterile water remaining inside the channel by pressing the syringe.
7. Remove the syringe from the inlet seal.

Inspection of the suction function

Warning

Use sterile water for inspection of the suction function. Failure to do so may pose a risk of infection.

Note

Before inspecting the suction function, close the cap of the inlet seal (OF-B190). Failure to do so may result in a decrease in suction strength.

1. Turn on the suction source and adjust it to a moderate suction setting.
2. Insert the distal end of the endoscope into a container filled with sterile water and press the suction control valve (OF-B120). Check that water is being suctioned up.

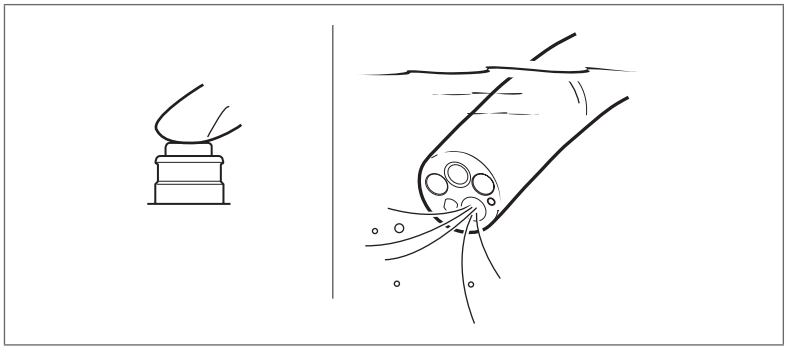


Figure 3.57

3. Check that when the suction control valve is released, it smoothly returns to the initial position and the suctioning stops.

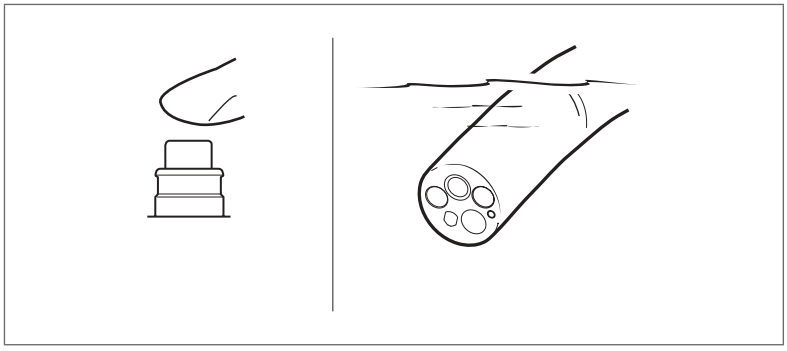


Figure 3.58

4. Repeat steps 2 and 3 several times to check that there is no water leakage from the suction control valve or the inlet seal.
5. Pull the distal end of the endoscope out of the container. Press the suction control valve, and suction air in order to remove the water remaining inside the instrument channel.

Inspection of the instrument channel

Use a biopsy forceps for inspection of the instrument channel.
Prepare a biopsy forceps which has been cleaned and sterilized according to the manual provided with that product and ensure to perform a pre-use inspection.

Warning

Do NOT use the endoscope if you feel a significant resistance when inserting a biopsy forceps. It may result in damage to the inside of the channel and unforeseen events to patients and/or medical professionals.

Caution

- Slowly and gently insert and withdraw the forceps from the inlet seal (OF-B190). Applying strong force may cause endoscope damage.
- Keep the endoscope bending section as straight as possible when inserting the forceps, as it may not be possible to pass the forceps through a highly angulated bending section.

1. Close the biopsy forceps cups by operating its handle.

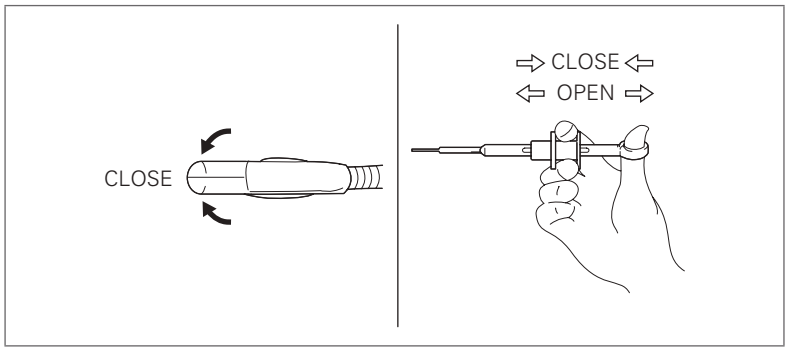


Figure 3.59

Note

Do not close the biopsy forceps cups tightly. Doing so may make its insertion into the instrument channel difficult.

2. Insert the biopsy forceps into the inlet seal (OF-B190). When the cups are first passed through the inlet seal, temporary resistance will be encountered.
3. Hold the shaft at approximately 5 cm from the inlet seal and slowly advance the biopsy forceps, and check that the tip exits the distal tip of the endoscope. In addition, check that no foreign materials were pushed out of the instrument channel by the biopsy forceps.

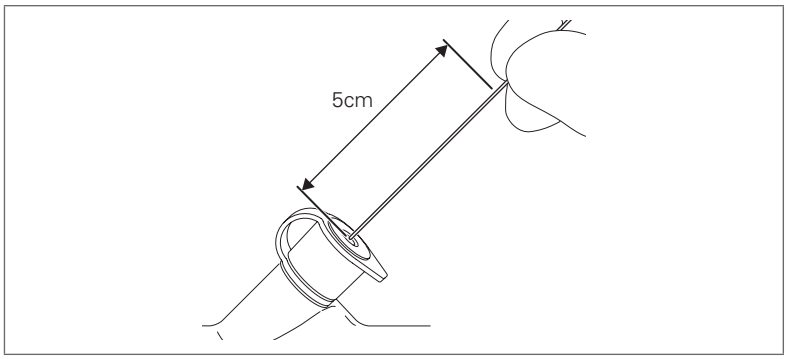


Figure 3.60

4. Check that the biopsy forceps can be smoothly withdrawn from the inlet seal.

Inspection of the water jet feeding function

Warning

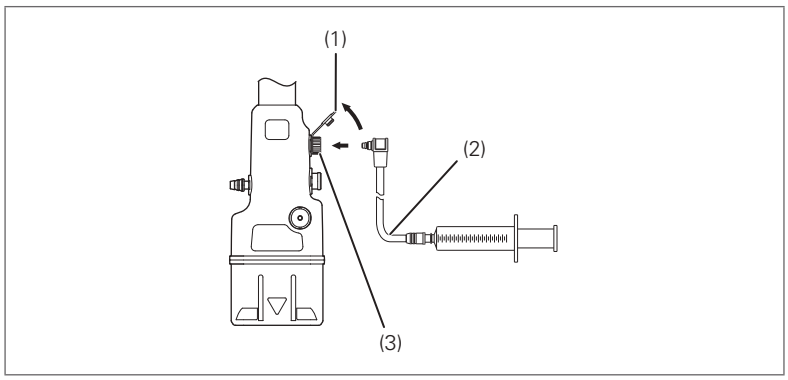
Use sterile water for inspection of the water jet feeding function. Failure to do so may pose a risk of infection.

1. To use the irrigation pump, prepare to feed sterile water by following the instructions for use for the irrigation pump.
2. Check the entire surface of the irrigation tube (OF-B113) for abnormalities such as bending/breakage/looseness of the connector, cut/chip of the O-ring, buckling/deterioration/hardening of the tube, and/or broken luer.
3. Open the water jet connector cap (OF-B118), connect the irrigation tube (OF-B113) to the water jet check valve adapter (OE-C12) until it clicks into position.

Note

Do not use the irrigation tube (OF-B113) if you have any difficulty in attaching it, or if you do not feel it clicking into place when attaching it to the endoscope. The use of damaged luer connector may result in water leakage from the connected part or tube disconnection.

4. Feed sterile water using the irrigation pump or syringe filled with sterile water attached to the luer connector of the irrigation tube (OF-B113).



(1) Water Jet Connector Cap (OF-B118)
(2) Irrigation Tube (OF-B113)
(3) Water Jet Check Valve Adapter (OE-C12)

Figure 3.61

Note

When the irrigation tube (OF-B113) is connected with locking type of luer connector, ensure that the luer connectors are properly locked. Do not use irrigation tube (OF-B113) if its luer connector is damaged and/or if it is not properly connected.

5. Check that a certain amount of water flows out forward from the water jet nozzle at the distal end of the endoscope. (It takes a few seconds until water comes out the first time.)

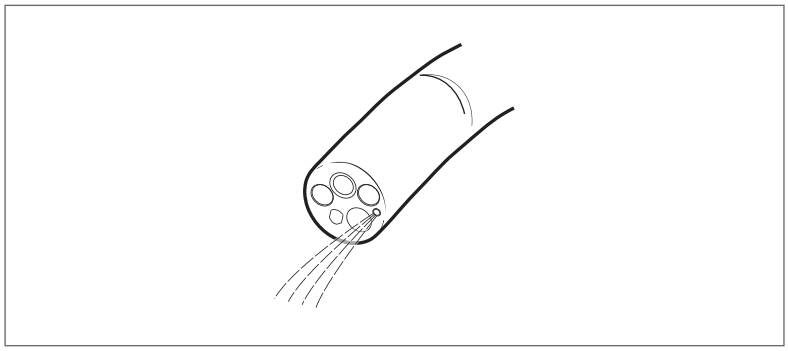


Figure 3.62

6. Check that there is no water leakage from the connection between the water jet port of the endoscope and the water jet check valve adapter (OE-C12), or from the connection between the water jet check valve adapter and the irrigation tube (OF-B113).

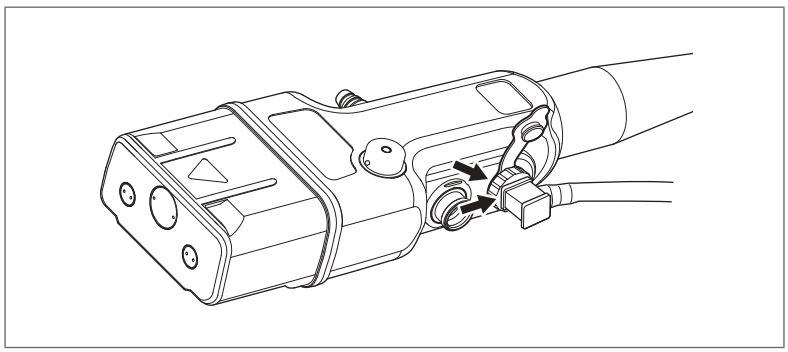


Figure 3.63

4 Directions for use

This endoscope should only be used by a physician authorized by the medical safety administrator at each medical facility to perform endoscopy.
The device should never be used by individuals who are not licensed medical professionals or used at facilities other than medical facilities.
This section describes essential information, such as operating procedures and handling precautions, on using this endoscope safely and effectively. This IFU does not describe specific endoscopic procedures. The specific procedures should be determined according to the discretion of a medical professional.

Warning

- Do NOT withdraw the endoscope while the bending section is locked. Doing so may result in patient injury.
- Always check the endoscopic image during endoscope angulation, air/water feeding, and suctioning, use of endoscopic devices, and endoscope insertion and withdrawal. Ensure that these operations are performed in the normal (non-frozen, non-magnified) mode. Endoscope operation in the freeze or magnification mode may result in damage to the endoscope and patient injury.
- Ensure that the released energy from the high-frequency does not affect the peripheral device such as pacemaker and to use the minimum necessary output level of high-frequency when using it near the heart. It may stimulate the heart.
- Do NOT forcefully insert and withdraw the endoscope. Doing so may result in patient injury.
- Do NOT perform retroflexed observations inside a narrow lumen. Doing so may cause patient injury or make it impossible to withdraw the endoscope.
- Immediately stop the endoscopic procedure if the endoscopic image disappears unexpectedly because of blackout and/or damage to the lamp, video processor, and/or endoscope. Slowly withdraw the endoscope following the instructions in “5-2. Withdrawal of an endoscope with an abnormality” (p. 79). Continuing to use the endoscope may result in patient injury.

Caution

- Users as well as the assisting personnel should always wear protective equipment (e.g., gloves, goggles, masks, medical gowns, etc.) to minimize the risk of infection, as the patient's body fluids may be dispersed into the environment from endoscope components such as the instrument channel inlet and the suction control valve.
- Do NOT look directly at the light emitted from the endoscope or direct it at the eyes of other individuals, as the intense light may cause eye injuries.
- Set the brightness to the minimum necessary. Maintain an appropriate distance between the distal end of the endoscope and the mucosa in order to avoid prolonged illumination of the mucosa. The temperature at the distal end of the endoscope may exceed 41°C and even reach 50°C due to the light emitted from it. This may result in mucosal injury to the patient.
- Do NOT use the endoscope when adherence of patient materials (e.g., blood, other body fluids) is suspected, as this will darken the image. This will also cause the temperature of the distal tip to increase, which might lead to mucosal injury to the patient.
- Use the minimum pressure necessary for suctioning. Do NOT suction from the mucosa for a prolonged period of time. Doing so may result in patient injury.
- Do NOT excessively pull the umbilical cord or give shocks such as objects or people hitting the scope connector. Doing so could cause temporary disappearance of endoscopic images. If any abnormality occurs in the images, connect the scope connector again to the video processor.

Note

- Prior to a procedure, remove as much debris as possible from the observation area in order to obtain a clear image.
- The objective lens may be cleaned during a procedure by performing air/water feeding and suctioning either alternately or simultaneously.

4-1. Preparation immediately before insertion of the endoscope

Perform appropriate patient preparation for endoscopy as necessary.

Warning

Do NOT spray or wipe the surface of the endoscope insertion portion with an anesthetic (particularly anesthetic sprays containing alcohol) or non-medical lubricants (such as petroleum jelly). Doing so could cause cracking or peeling of the external surface of the insertion portion and may result in endoscope damage.

1. Apply a medical grade lubricant to the insertion portion, as necessary.
2. Place a bite block (OF-Z5) into the patient's mouth.

Note

- Do not apply lubricants to the objective lens for getting clear observation images.
- When using lens cleaner, ensure to follow the instructions of that product.

4-2. Insertion and observation

Insertion of the endoscope

Warning

Do NOT severely and/or forcefully bend the strain relief boot as shown in Figure 4.1. Doing so may result in endoscope damage.

Caution

Clear images can NOT be obtained if any foreign material is attached to the objective lens or the light guide. Continued use of the light guide with any foreign material attached to it might cause visible steam-like vaporization associated with water vaporization of the organic material heated by the light. If this vapor is observed, stop the procedure immediately and withdraw the endoscope from the patient. Using clean gauze, clean off any foreign material that has attached and then resume endoscopy.

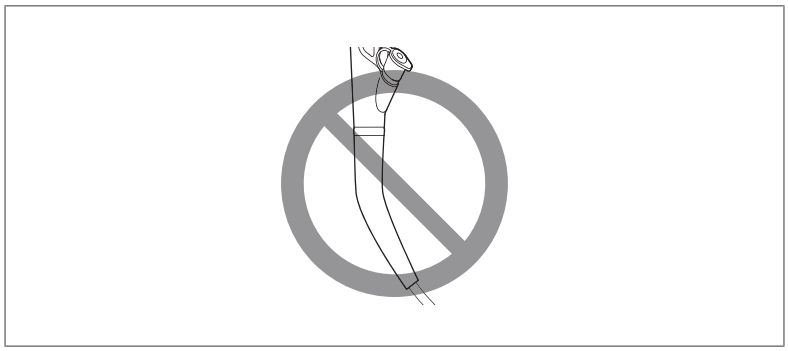


Figure 4.1

1. Slowly and cautiously insert the endoscope.
2. Adjust the brightness as appropriate for observation with the video processor.

Angulation operation

Warning

Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when an abnormality, such as an inability to smoothly angulate the endoscope, is experienced. NEVER forcefully turn the angulation control knob as it may result in endoscope damage and/or patient injuries, including bleeding and perforation.

1. Slowly and cautiously operate the angulation control knobs in order to adjust the position of the distal end of the endoscope.
2. Turn the up/down angulation lock lever and right/left angulation lock knob to hold the bending angle of the distal end of the endoscope, as necessary.

Air/Water feeding

Caution

Be careful NOT to feed too much air and to properly control air insufflation into the body cavity. Excessive air insufflation into the patient's body cavity may pose a risk of pain to the patient.

1. Set the appropriate pump level using the pump level menu on the touch panel of the video processor.
2. Cover the hole on top of the air/water feeding valve with your finger to feed air through the air/water nozzle at the distal end of the endoscope.
3. Depress the air/water feeding valve to feed water from the air/water nozzle onto the objective lens.

Suction

Warning

Do NOT aspirate solid materials as it may cause a clogging in the suction control valve and/or the suction channel.

Caution

- Securely attach the cap to the inlet seal. Failure to do so may result in weaker suction strength as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection to the user.
- Do NOT use a cleaning brush or biopsy forceps to remove a foreign object that has occluded the suction channel. This may result in damage to the channel.
- Observe these precautions when suctioning. Failure to do so may result in mucosal injury to the patient.
  - Do NOT apply excessively high suction pressure.
  - Maintain distance between the distal end of the endoscope and the mucosa to ensure that the instrument channel opening of the distal end of the endoscope does NOT suction the mucosa.
  - Immediately stop suctioning if the mucosa is suctioned. Do NOT suction mucosa for a prolonged period of time.
  - Stop use immediately when any abnormality in controlling suction is suspected.
- When attaching and detaching the suction tube to the suction nipple during inspection, hold the scope connector with one hand. In addition, do NOT forcefully attach or detach the suction tube. In case a load is applied to the connection between the video processor receptacle and the scope connector, failure such as temporary disappearance of endoscopic images may occur. If any abnormality occurs in the images, connect the scope connector again to the video processor.

Suction fluid from inside the body cavity through the instrument channel by pressing the suction control valve.

Water jet feeding

Warning

Use sterile water for water jet feeding. Failure to do so may pose a risk of infection.

Caution

Use minimum pressure for water feeding while observing the condition of the patient's mucosa. Water feeding with the excessive pressure may result in mucosal injury to the patient.

Use the irrigation pump by following its operation manual or by attaching a syringe to the luer connector of the irrigation tube (OF-B113) and delivering water into it.

Note

When the irrigation tube (OF-B113) is connected with locking type of luer connector, ensure that the luer connectors are properly locked. Do not use irrigation tube (OF-B113) if its luer connector is damaged and/or if it is not properly connected.

Remote control

Caution

Do NOT apply strong force to the remote button from its side or in an oblique direction, as the button may get stuck and become inoperable.

Operate the remote button for image capture, hardcopy, VCR recording, etc., as necessary.

Note

Leaving a finger on the remote button may result in unintentional pressing of the remote button, causing it to operate.

4-3. Using an endoscopic device

Warning

- NEVER use a endoscopic device that displays signs of damage and/or operational abnormality. Doing so may result in endoscope malfunction or damage and/or patient injury.
- All reusable endoscopic devices must be cleaned and sterilized before initial use, as well as before every subsequent use.
- Before using the endoscopic device, check its compatibility with the endoscope, and read and understand the respective IFU of the endoscopic device. Incorrect use of an endoscopic device may result in damage to the endoscopic device and patient injury.
- Constantly check the endoscopic image while cautiously inserting and withdrawing the endoscopic device.
- Ensure that the distal tip of the endoscopic device is adequately projecting from the distal end of the endoscope before operating it. Failure to do so may result in damage to the instrument channel and/or falling of the broken instrument channel particle(s) inside the patient's body cavity.
- After the endoscopic device is inserted into the inlet seal, NEVER let it hang down. Ensure that the endoscopic device is supported with a hand and no load is applied to the inlet seal. Failure to do so may result in lowered suction function as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection to the user.
- Use only compatible endoscopic devices specified by PENTAX Medical. Using non-compatible endoscopic devices NOT specified by PENTAX Medical may result in clogging and/or damage to the instrument channel and/or endoscopic device. If a liquid such as sterile water or physiological saline is injected with a syringe into the instrument channel inlet while the instrument channel is clogged, the suction control valve may detach, resulting in the potential dispersal of patient fluids into the environment, and posing a potential risk of infection to the user.
- Immediately stop the endoscopic procedure if the endoscopic device can NOT be withdrawn from the endoscope. Do NOT attempt to forcefully withdraw the endoscopic device. Slowly and cautiously withdraw the endoscope in which the endoscopic device is inserted. Failure to do so may result in damage to the endoscopic device and/or instrument channel, as well as the potential dispersal of patient fluids into the environment, posing a risk of infection to the user.

Caution

- When inserting or withdrawing the endoscopic device, ensure that its distal tip is closed or retracted within the sheath. Straighten the endoscopic device and slowly withdraw it. Failure to do so may result in inlet seal damage and/or falling of the broken inlet seal particle(s) into the patient's body cavity.
- Do NOT forcefully insert the endoscopic device when the instrument channel is clogged, as this may result in damage to the endoscope.
- Keep the endoscope bending section as straight as possible when inserting and withdrawing an endoscopic device. Forcefully inserting and withdrawing an endoscopic device may result in damage to the instrument channel and endoscopic device and/or patient injury.

Note

The minimum instrument channel width applicable to a particular endoscopic device may be found on the endoscopic device label.

Insertion and operation of the endoscopic device

1. Ensure that the distal tip of the endoscopic device is closed or retracted into the sheath. In case of biopsy forceps, operate the forceps to fully close the cups at the tip. There is a certain amount of resistance when inserting the endoscopic device for the first time. Insert it into the inlet seal (OF-B190).
2. Hold the shaft at approximately 5 cm away from the inlet seal, and advance the endoscopic device.

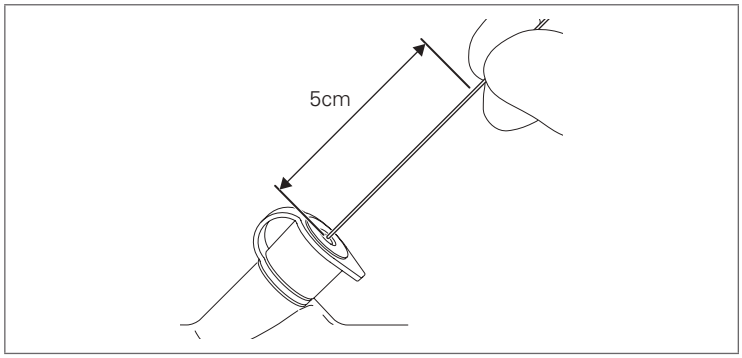


Figure 4.2

3. Check that the distal tip of the endoscopic device is within the field of view.

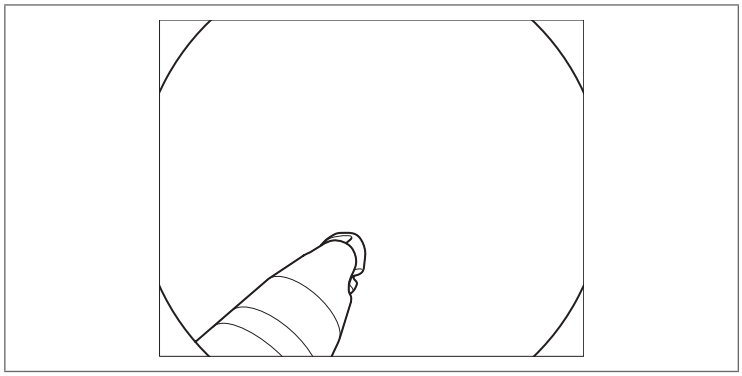


Figure 4.3

4. Operate the endoscopic device according to the IFU provided with it.

Withdrawal of the endoscopic device

Warning

- Do NOT forcefully withdraw the endoscopic device or in an oblique direction. Doing so may result in decreased suction strength caused by inlet seal damage, falling of the broken inlet seal particle(s) into the patient's body cavity, and potential reflux or dispersal of patient's body fluids, posing a risk of infection to the user. When withdrawing the endoscopic device, prevent the dispersal of patient's body fluids by covering the inlet seal with clean gauze, and withdraw the device slowly in a straight direction away from the inlet seal.
- Immediately stop the therapeutic procedure if significant resistance is encountered when withdrawing the endoscopic device or if the endoscopic device can NOT be withdrawn from the endoscope. Do NOT attempt to forcefully withdraw the endoscopic device. Failure to do so may result in equipment damage. Close or retract the distal tip of the endoscopic device and slowly withdraw the endoscope into which the endoscopic device is inserted.

1. Ensure that the distal tip of the endoscopic device is closed or retracted into the sheath.
2. Slowly withdraw the endoscopic device in a straight direction away from the inlet seal.

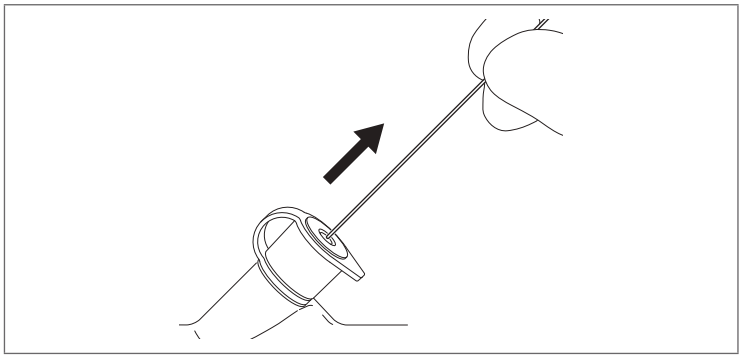


Figure 4.4

4-4. Using a nonflammable gas

If there is a possibility of an inflammable gas being present within a body cavity, convert the gas to a nonflammable gas using carbon dioxide prior to laser cautery or electrosurgery.

Warning

Do NOT use non-flammable gas cylinders whose pressure and flow settings can NOT be controlled. Set the gas pressure to 49 kPa or less, and the flow to 4 L/min or less. Using a gas cylinder whose settings can NOT be controlled or whose settings are uncertain may result in damage to the endoscope and excessive insufflation of gas into the patient's body cavity.

Caution

- Perform adequate ventilation when using a non-flammable gas in a small room for a prolong period of time. An elevated CO_2 concentration in the room may pose a health risk to the room's occupants.
- Turn off the air/water feeding pump of the video processor before opening/closing the gas cylinder. Failure to do so may damage the air/water feeding pump.
- Be careful NOT to deliver too much gas and to properly control gas delivery into the channel. Excessive insufflation of gas into the patient's body cavity may pose a risk of pain to the patient.

Note

Consider the use of the optionally available gas/water feeding valve (OF-B194) to prevent gas leakage when using gases other than air. Use the gas/water feeding valve according to the IFU provided with it.

1. Prepare a gas cylinder and the optionally available gas adapter (OF-G11). Ensure that the gas cylinder valve is closed. Turn off the air/water feeding pump of the video processor.
2. Remove the air/water connector of the water bottle assembly from the air/water port of the endoscope, and connect the gas adapter instead.

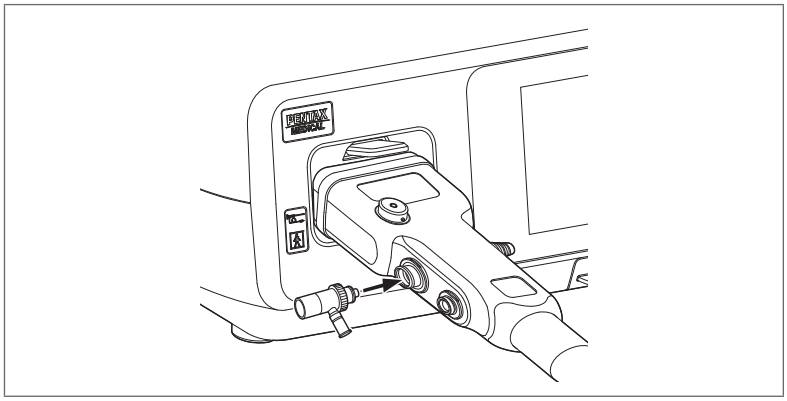


Figure 4.5

3. Connect the gas cylinder to the gas adapter (OF-G11).

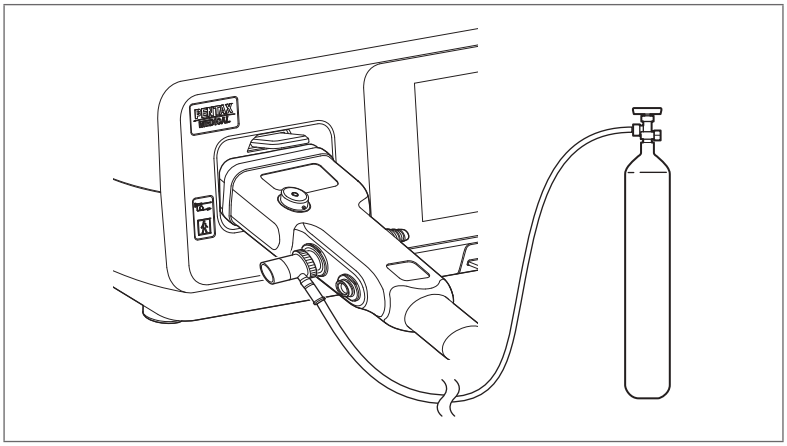


Figure 4.6

4. Connect the air/water connector of the water bottle assembly to the gas adapter.

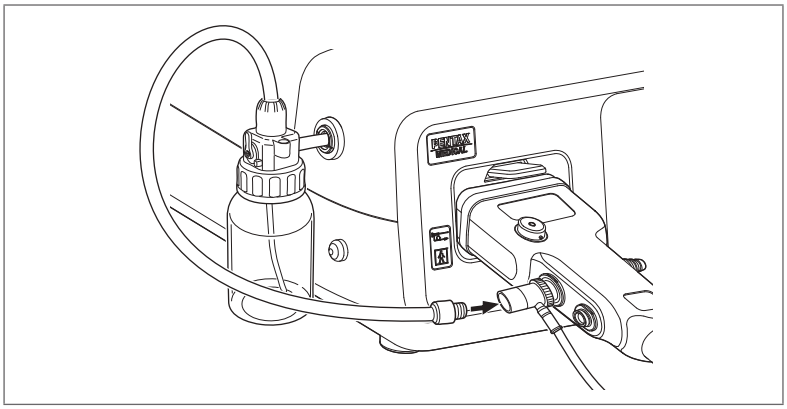


Figure 4.7

5. Ensure that all the devices are securely connected before opening the gas cylinder valve.

Note

In addition to the procedure described above, a CO_2 gas/water feeding equipment (EGA-501P) can also be used. Use the CO_2 gas/water feeding equipment in accordance with its IFU.

4-5. Laser cauterization

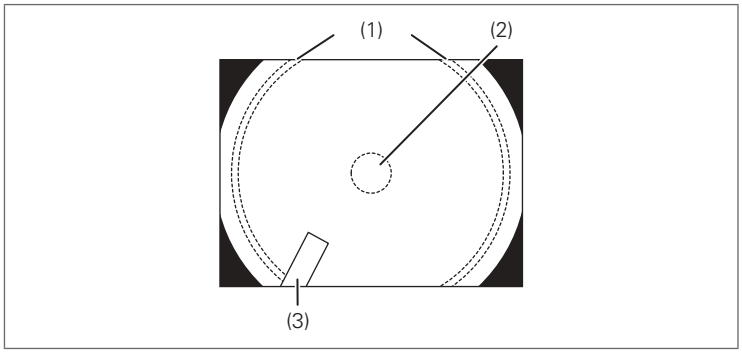
Warning

- Laser equipment should be used only by experts who have thorough knowledge of the laser equipment and endoscopic laser treatment.
- Before using laser equipment, thoroughly read the manual provided with it, and always perform pre-use inspection. Ensure that the laser equipment is ready for use by performing the safety checks specified in the manual.
- Use only Nd:YAG laser (wavelength 1064 nm) or a laser with a wavelength of 800–1000 nm.
- When using laser equipment, both users and the assisting personnel should wear goggles. Failure to do so may result in eye injuries.
- Do NOT use laser equipment in flammable surroundings, such as an oxygen-rich environment. If there is a possibility of a flammable gas being present within a body cavity, dilute the gas with a nonflammable gas prior to laser cauterization. Using the laser equipment in flammable surroundings may result in combustion or an explosion.
- Set the laser output to the minimum light level necessary.
  - If the laser is continuously emitted at a high level, the endoscopic image may become white (whiteout). Do NOT perform laser cautery during whiteout, as it may result in patient injury.
  - Continuously emitting the laser at a high level may damage the instrument.
- Maintain an adequate distance between the distal end of the endoscope and the patient's body cavity wall. Before activation of the laser, ensure that the distal tip of the laser probe emerges from the distal end of the endoscope. Failure to do so may result in instrument damage and patient injury.

1. Insert the laser probe into the inlet seal (OF-B190) as described in "4-3. Using an endoscopic device".
2. Operate the laser probe according to the manual provided with it.
3. When the procedure is complete, withdraw the laser probe from the inlet seal as described in "4-3. Using an endoscopic device".

Note

- It is normal for the guide beam to appear white in the video endoscopic image.
- When operating the laser at a high power and/or if the distal end of the endoscope is moved within 10 mm of the irradiated target, flares may appear at one or more corners of the image (Figure 4.9).



(1) Flare
(2) Irradiated target
(3) Probe

Figure 4.8

4-6. Electrosurgery

Warning

- Thoroughly read the manual provided with the high frequency generator and device before using them, and always perform a pre-use inspection. Ensure that the high frequency generator and device are ready for use by performing the safety checks specified in the manual. Use of the endoscope in combination with the electrosurgical device could result in increased leakage of current to the patient.
- Ensure that the released energy from the high-frequency does not affect the peripheral device such as pacemaker and to use the minimum necessary output level of high-frequency when using it near the heart. It may stimulate the heart.
- Use an endoscopic device having insulated insertion portion other than the distal tip (active portion). Failure to do so may result in burns from high-frequency current.
- Do NOT use the high frequency generator in flammable surroundings, such as an oxygen-rich environment. If there is a possibility of a flammable gas being present within a body cavity, dilute the gas with a nonflammable gas prior to electrosurgery. Using the high frequency generator in flammable surroundings may result in combustion or an explosion.
- Ensure that the active portion of the endoscopic device does NOT come into contact with the peripheral tissues, as it may result in patient injuries.
- Set the high-frequency output level and waveform mode appropriately according to usage. Minimize the duration of time during which high-frequency current is delivered, as prolonged exposure to electrosurgical energy can result in patient injury.
- Check the entire surface of the endoscope for any abnormalities such as cracks and exposure of internal metals before using an electrosurgical device. Failure to do so may result in burns.

Caution

- Users as well as the assisting personnel should always wear insulated gloves. Failure to do so may result in burns from high-frequency current.
- High frequency generator may be of the floating (Type BF or Type CF) or non-floating (Type B) types. Use only floating-type high frequency generator to avoid patient and user burns.
- During use, follow the precautions below, as failure to do so may result in endoscope damage, burns, and/or mucosal injury.
  - Maintain an adequate distance between the distal end of the endoscope and the insulated tip and active portion of the endoscopic device. Ensure that the distal tip of the endoscopic device is adequately projecting from the distal end of the endoscope before operating it.
  - Users and assisting personnel should NOT touch the patient during device use.
  - Turn on the high frequency generator just before the procedure and turn it off immediately after the procedure.

1. Insert the electrosurgical device into the inlet seal as described in "4-3. Using an endoscopic device".
2. Operate the electrosurgical device according to the IFU provided with it.
3. When the procedure is complete, withdraw the electrosurgical device from the inlet seal (OF-B190) as described in "4-3. Using an endoscopic device".

4-7. Withdrawal of the endoscope

Warning

- In order to prevent the possibility of patient material being drawn into the water bottle assembly, leave the water bottle connected to both the video processor and the endoscope before withdrawing the endoscope from the patient.
- Do NOT withdraw the endoscope while the bending section is locked. Doing so may result in patient injury.

Caution

When withdrawing the endoscope, prevent dispersal of patient's body fluids into the environment by holding clean gauze along the insertion portion. Failure to do so may pose a risk of infection to the user.

1. Operate the suction control valve to suction any fluid remaining inside the patient's body cavity.
2. If the electrical magnifying function was used, set it back to standard image size.
3. Unlock the angulation control knobs by turning the up/down and right/left angulation lock knobs in the "F ►" direction until they stop.
4. While checking the endoscopic image, slowly and cautiously withdraw the endoscope.
5. Remove the bite block from the patient's mouth.
6. Turn the lamp off.

4-8. Care after use

Caution

Do NOT touch the electrical contacts after use. This could result in a burn injury.

■ **Endoscope:**

Perform cleaning, high-level disinfection, and/or sterilization according to the procedure specified in the separate IFU (Reprocessing) of this endoscope.

■ **Accessories:**

Air/water feeding valve (OF-B188), suction control valve (OF-B120), inlet seal (OF-B190), bite block (OF-Z5), water jet check valve adapter (OE-C12), water jet connector cap (OF-B118), irrigation tube (OF-B113), and other optional equipment:

Perform cleaning, high-level disinfection, and/or sterilization according to the procedure specified in the respective IFU provided with them.

■ **Endoscopic devices:**

Reusable endoscopic devices:

All reusable devices must be cleaned and sterilized according to the respective IFU provided with them.

Single use endoscopic devices:

Follow the national or local laws/guidelines to appropriately dispose of single use endoscopic devices.

■ **Video Processors/irrigation pump:**

Follow the IFU provided with it for its care after use.

■ **Water bottle assembly:**

For cleaning and disinfection and/or sterilization of the water bottle assembly, refer to IFU provided with the water bottle assembly.

Disconnecting the endoscope from the video processor

Caution

Do NOT attach or remove the scope connector while the video processor power is powered on. Doing so may damage the endoscope.

1. Immediately after use, perform pre-cleaning according to the separate IFU (Reprocessing) of this endoscope.
2. After completion of pre-cleaning in the examination room, turn off On/Standby switch of the video processor.

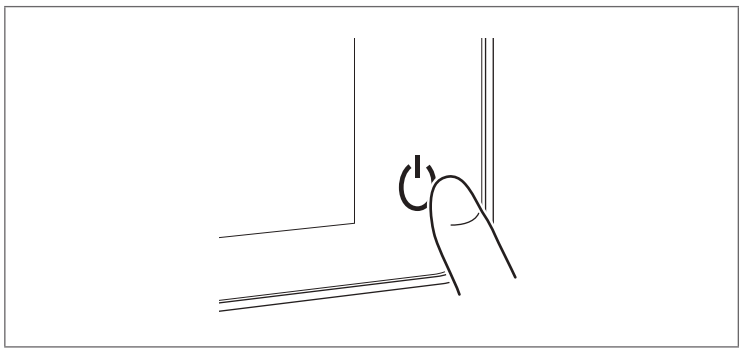


Figure 4.9

3. Hold the endoscope and press the endoscope eject lever.
   - The endoscope is unlocked.

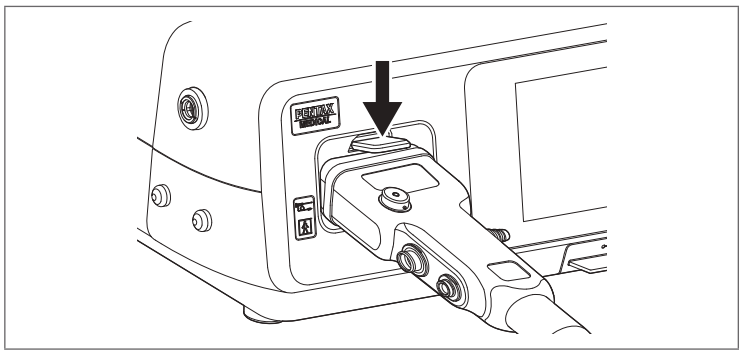


Figure 4.10

4. While depressing the endoscope eject lever, remove the scope connector from the processor.

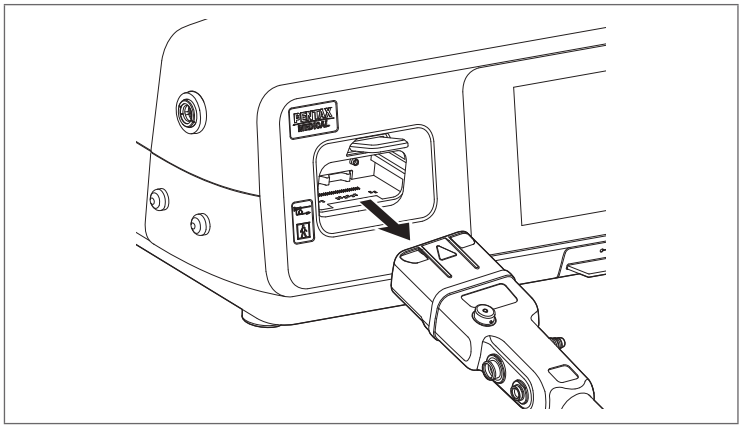


Figure 4.11

5 Troubleshooting

After inspecting the endoscope according to "3 Preparation and inspection", if any abnormality is suspected, follow the procedure described in "5-1. Troubleshooting guide". If an abnormality persists after troubleshooting, do not use the endoscope. Send it to PENTAX Medical for repair according to "5-3. Returning the endoscope for repair" (p. 80).

Warning

Do NOT use an endoscope with any apparent abnormality. Continuing to use an endoscope with an abnormality may result in endoscope damage, malfunction, and/or injury to the patient and/or user.

5-1. Troubleshooting guide

■ Connecting the video processor

Description of abnormality	Possible cause	Solution
The scope connector removes from the video processor.	The scope connector is not all the way inserted and fixed.	Check the scope connector and the video processor for any inside attachment of foreign materials; then push the scope connector until it clicks and is fixed.
The scope connector cannot be fully inserted.	The scope connector is inserted in wrong direction (UP or DOWN).	Turn the scope connector's Connector UP index ("▲") upward and push the scope connector into the video processor.

■ Image

Description of abnormality	Possible cause	Solution
The image is not displayed.	The video processor, monitor, or other equipment is not turned on.	Turn on the power of the instrument and all other related devices.
	The scope connector is not connected securely to the video processor.	Push the scope connector into the video processor receptacle until it clicks; then ensure that the connector is securely attached until it stops.
	Foreign material has been attached to the electrical contacts.	Wipe the electrical contacts with gauze moistened with ethanol for disinfection; then dry it sufficiently before connecting to the video processor.
The image is too bright or too dark.	The brightness level setting of the video processor is not appropriate.	Set the video processor brightness to an appropriate level.
	The LED on the distal end of the endoscope is turned off.	Turn on the lamp icon of the video processor.
	Foreign material is attached to the light guide at the distal end of the endoscope.	Gently clean the light guide with clean gauze moistened with 70%–90% medical grade ethyl or isopropyl alcohol.
The image becomes foggy and/or unclear.	Foreign material is attached to the objective lens.	Gently clean the light guide with clean gauze moistened with 70%–90% medical grade ethyl or isopropyl alcohol.

■ Angulation

Description of abnormality	Possible cause	Solution
Angulation control knobs feel heavy to operate.	The bending section is fixed with the up/down angulation lock lever or right/left angulation lock knob.	Turn the up/down angulation lock lever or right/left angulation lock knob in the "F ►" direction.
The bending section does not return to straight condition even when the angulation control knobs are released.	The bending section is fixed with the up/down angulation lock lever or right/left angulation lock knob.	Turn the up/down angulation lock lever or right/left angulation lock knob in the "F ►" direction.

■ Air/Water Feeding

Description of abnormality	Possible cause	Solution
Air feeding is not possible.	The air/water feeding pump of the video processor is turned off.	Turn on the air/water feeding pump of the video processor.
	The water bottle assembly is not connected.	Connect the air/water connector of the water bottle assembly to the air/water port of the endoscope.
	Cap of the water bottle assembly is loose.	Tighten the cap of the water bottle assembly.
	Air/Water feeding valve is damaged.	Replace with a new air/water feeding valve.
Water feeding is not possible.	The air/water feeding pump of the video processor is turned off.	Turn on the air/water feeding pump of the video processor.
	The water bottle assembly is not connected.	Connect the air/water connector of the water bottle assembly to the air/water port of the endoscope.
	Cap of the water bottle assembly is loose.	Tighten the cap of the water bottle assembly.
	Switching lever of the water bottle assembly is set at the "DRAIN" position.	Set the switching lever of the water bottle assembly at the "A/W" position.
	There is no sterile water in the water bottle assembly.	Fill the water bottle with sterile water.
	Air/Water feeding valve is damaged.	Replace with a new air/water feeding valve.
Air feeding (air bubbles) cannot be stopped.	The check valve of the air/water feeding valve is damaged.	Replace with a new air/water feeding valve.
Sufficient amount of air/water cannot be fed.	Level setting of the air/water feeding pump of the video processor is low.	Set an appropriate pump level.
	Air/Water nozzle or endoscope conduit line is clogged.	Refer to the solution below (*) for when clogging seems to be the problem.
Air/Water feeding valve cannot be operated smoothly. Air/Water feeding valve cannot be restored once it is pressed in.	The check-valve of the air/water feeding valve is damaged.	Replace with a new air/water feeding valve.
	The air/water feeding valve O-ring is broken.	Replace the air/water feeding valve O-ring.
	The O-ring is not coated with silicone oil.	Remove the air/water feeding valve and coat the O-ring with silicone oil.
	Foreign material is stuck between the air/water feeding valve and air/water cylinder.	Remove the air/water feeding valve, and then clean out the foreign material.
Air/Water feeding valve cannot be attached.	Foreign material in the air/water cylinder.	Remove the foreign material from the air/water cylinder, and then attach the air/water feeding valve.
	Air/Water feeding valve is damaged.	Replace with a new air/water feeding valve.
	Incorrect air/water feeding valve is being used.	Use the correct air/water feeding valve.

*How to deal with the blockage in the air/water nozzle or channel

Perform the following procedure if air/water cannot be fed smoothly and blockage in the nozzle or channel of the endoscope is suspected.

1. Turn off the air/water pump of the video processor.
2. Turn off the video processor, remove any ancillary equipment attached to the endoscope, and disconnect the endoscope from the video processor.
3. Remove the air/water feeding valve (OF-B188) and suction control valve (OF-B120) from the endoscope.
4. Attach the cleaning adapter (OF-B153) and the cleaning adapter (OF-G17) to the endoscope in accordance with the IFU (Reprocessing) provided with this product.
5. Attach the syringe filled with water to the cleaning adapter (OF-G17), and inject water into the channel of the endoscope.
6. Repeat step 5 two or three times.
7. Fill the syringe with air, feed air into the channel of endoscope, and remove water remaining inside the channel.
8. Inspect the air/water feeding function again.

If the problem persists after performing the above procedure, send the endoscope for repair in accordance with "5-3. Returning the endoscope for repair" (p. 80). If the problem is resolved by the procedure, perform cleaning, high-level disinfection, and/or sterilization of the endoscope before using it again.

■ Suction

Description of abnormality	Possible cause	Solution
The suction function does not operate properly.	The inlet seal is not attached to the instrument port of the endoscope.	Attach the inlet seal.
	The cap of inlet seal is open.	Attach the cap section of the inlet seal to the main unit (body of the inlet seal).
	The suction source tube is disconnected from the endoscope.	Securely connect the suction source tube.
	The power of suction source is not turned on.	Turn the power of suction source on.
The suction volume is low.	The suction setting its too low.	Increase the suction setting.
	The inlet seal is damaged.	Replace it to a new inlet seal.
The suction control valve feels heavy to operate.	The seal rubber section of the suction control valve is damaged.	Replace the suction control valve with a new one.
	The suction control valve O-ring is broken.	Remove the suction control valve and replace the O-ring.
	Silicone oil has not been applied.	Remove the suction control valve and apply silicone oil.
	Foreign material is stuck between the suction control valve and suction cylinder.	Remove the suction control valve and clean out the foreign material.
The suction control valve cannot be properly inserted into the suction valve cylinder.	Foreign material is present in the suction cylinder.	Remove the foreign material(s) from the suction cylinder and reinsert the suction control valve into the suction cylinder.
	The suction control valve is damaged.	Replace the suction control valve with a new one.
	An attempt was made to attach a wrong suction control valve.	Use a compatible suction control valve.
The suction control valve gets stuck when depressed and does not return to the original position.	The pressure setting of the suction source is too high.	Set the pressure of the suction source at an appropriate level.
	The seal rubber section of the suction control valve is damaged.	Replace the suction control valve with a new one.
	The suction control valve O-ring is broken.	Replace the suction control valve O-ring.
	Silicone oil has not been applied.	Apply silicone oil to the suction control valve.
	Foreign material is stuck between the suction control valve and suction cylinder.	Remove the foreign material from the suction control valve and/or suction valve cylinder.
Fluid leaks out of the inlet seal.	The cap section of the inlet seal is not properly attached to the inlet.	Attach the cap section of the inlet seal properly to the inlet.
	The inlet seal is damaged.	Replace the inlet seal with a new one.

■ Water jet feeding

Description of abnormality	Possible cause	Solution
Water jet feeding function does not operate properly.	The irrigation pump is turned off. (when using the irrigation pump)	Turn on the power of the irrigation pump.
The water jet check valve adapter cannot be properly attached to the water jet port.	There is a foreign material in the water jet port.	Remove the foreign material(s) from the water jet port, and reattach the water jet check valve adapter.
	The water jet check valve adapter is damaged or broken.	Replace it with a new water jet check valve adapter.
Water leaks from the connection part.	The water jet check valve adapter is damaged or broken.	Replace it with a new water jet check valve adapter.
	There is a faulty connection between either the water jet port and water jet check valve adapter or the water jet check valve adapter and the irrigation tube.	Check the integrity of these connections.

■ Endoscopic device operation

Description of abnormality	Possible cause	Solution
An endoscopic device cannot be inserted.	The bending section of the endoscopic is angulated.	Straighten the bending section as much as possible and reinsert the endoscopic device.
	An incompatible endoscopic device is used.	Use an endoscopic device that is compatible with this endoscope.
	The handle (controlling portion) of the endoscopic device is held tightly.	Operate the endoscopic device with an appropriate force.
An endoscopic device cannot be withdrawn.	The bending section of the endoscope is angulated.	Straighten the bending section as much as possible and withdraw the endoscopic device.
	The handle (controlling portion) of the endoscopic device is held tightly.	Operate the endoscopic device with an appropriate force.

5-2. Withdrawal of an endoscope with an abnormality

Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when any abnormality occurs.

When the endoscopic image is displayed

1. When using an endoscopic device, close the distal tip or retract it within the sheath. Slowly withdraw the endoscopic device from the endoscope.
2. Operate the suction control valve to suction any fluid remaining inside the patient's body cavity.
3. If the electrical magnifying function used, set it back to standard image size.
4. Turn the up/down angulation lock lever and right/left angulation lock knob in the "F ►" direction until they stop to release the lock of the angulation control knobs.
5. While checking the endoscopic image, slowly and cautiously withdraw the endoscope.

When the endoscopic image is not displayed

1. When using an endoscopic device, close its distal end or retract it into its sheath. Slowly withdraw the endoscopic device from the endoscope.
2. Turn the up/down angulation lock lever and right/left angulation lock knob in the "F ►" direction until they stop to release the lock of the angulation control knobs.
3. Remove your hand from the up/down and right/left angulation control knobs.
4. Slowly and cautiously withdraw the endoscope.

5-3. Returning the endoscope for repair

When returning the endoscope for repair, follow the instructions below. For more details, contact your local PENTAX Medical service facility. Always clean and high level disinfect the endoscope before returning it for repair.

Warning

Only qualified personnel from PENTAX Medical are authorized to repair this endoscope. PENTAX Medical is NOT liable for any damage or injury that occurs as a result of repairs attempted by non-PENTAX Medical personnel. It must be recognized that PENTAX Medical does NOT evaluate non-PENTAX Medical parts, components, materials and/or servicing methods and therefore questions regarding material compatibility and/or functionality of PENTAX Medical endoscopes built with these unauthorized, untested and unapproved items, materials, repair/assembly methods must be referred to the third party service organization and/or device remanufacturer.

Caution

When transporting by air, ensure that the ventilation cap (OE-C28) is attached the endoscope in order to prevent it from being damaged during shipment.

1. Place this endoscope in the dedicated carrying case.
2. When transporting by air, ensure that the ventilation cap (OE-C28) is attached the endoscope in order to prevent it from being damaged during shipment.
3. Include any PENTAX Medical accessory that is suspected to be associated with the damage.
4. Contact your local PENTAX Medical service facility for shipping address and provide a description of failures that need repair, model name, serial number, and name/phone number/address of the appropriate contact person at the facility.

Disposal

Warning

Follow the national or local laws/guidelines to appropriately dispose of the consumables. Failure to do so may create a risk of cross contamination or infection.

Contact your local PENTAX Medical service facility when disposing of an endoscope.

Electromagnetic compatibility (EMC)

This product conforms to IEC60601-1-2: 2007: Medical electrical equipment, EMC standard.

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies Class A at power input 220 V, 230 V and 240 V with operating frequency 50 Hz or 60 Hz Otherwise, not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies at power input 50 Hz, 220 to 240 V Otherwise, not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It is recommended that this product be used apart from other devices operated with large current.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The recommended separation distance: $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The recommended separation distance: $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz
• P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. d is the recommended separation distance in metres (m).			

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Interference may occur in the vicinity of equipment marked with the following symbol:

- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
  a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
  b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this product

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

Rated maximum output power of transmitter (W)	Recommended distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic disturbances

This product conforms to IEC60601-1-2: 2014: Medical electrical equipment, IEC standard.

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies Class A at power input 220 V, 230 V and 240 V with operating frequency 50 Hz or 60 Hz Otherwise, not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies at power input 50 Hz, 220 to 240 V Otherwise, not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000 - 4 - 2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000 - 4 - 4	± 2 kV for power supply lines ± 1 kV for input / output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input / output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000 - 4 - 5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000 - 4 - 11	(>95 % dip in U_T) for 0.5 cycle Single phase: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 40 % U_T (0 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25 / 30 cycle (0.5 s) Single phase: 0° <0 % U_T (>95 % dip in U_T) for 250 / 300 cycle (5 s)	(>95 % dip in U_T) for 0.5 cycle Single phase: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 40 % U_T (0 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25 / 30 cycle (0.5 s) Single phase: 0° <0 % U_T (>95 % dip in U_T) for 250 / 300 cycle (5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field IEC 61000 - 4 - 8	30 A / m 50 Hz or 60 Hz	30 A / m 50 Hz or 60 Hz	It is recommended that this product be used apart from other devices operated with large current.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000 - 4 - 6	3 Vrms 150 kHz to 80 MHz 6 V in ISM bands 80 % AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 V in ISM bands 80 % AM at 1 kHz	
Radiated RF IEC 61000 - 4 - 3	3 V / m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V / m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	

Immunity to proximity fields from wireless communications equipment

Test frequency (MHz)	Band (MHz)	Modulation[a)]	Distance (m)	Immunity test level (V/m)
385	380 to 390	Pulse modulation[a)] 18 Hz	0.3	27
450	430 to 470	FM[b)] ± 5 kHz deviation 1 kHz sine	0.3	28
710	704 to 787	Pulse modulation[a)] 217 Hz	0.3	9
745				
780				
810	800 to 960	Pulse modulation[a)] 18 Hz	0.3	28
870				
930				
1720	1700 to 1990	Pulse modulation[a)] 217 Hz	0.3	28
1845				
1970				
2450	2400 to 2570	Pulse modulation[a)] 217 Hz	0.3	28
5240	5100 to 5800	Pulse modulation[a)] 217 Hz	0.3	9
5500				
5785				

a) The carrier shall be modulated using a 50 % duty cycle square wave signal.

b) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Interference may occur in the vicinity of equipment marked with the following symbol:

- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)]
  a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
  b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this product

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

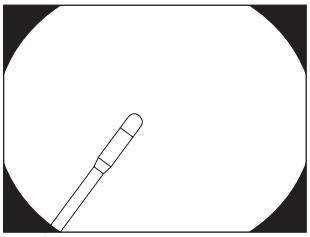
 Warning

Portable RF communications equipment should be used no closer than 30 cm to any part of this product or the peripheral equipment connected to this product, including cables specified by this IFU. Otherwise, degradation of the performance of this product could result.

 Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Endoscope specifications

Model Name		EG29-i10c
Direction of view		Forward (0°)
Field of view		140 °
Depth of field		3 to 100 mm
Tip angulation	Up–Down	210 ° to 120 °
	Right–Left	120 ° to 120 °
Rigid distal width		Ø 10.8 mm
Distal end width		Ø 10.8 mm
Insertion tube width		Ø 9.8 mm
Maximum insertion portion width *1		Ø 11 mm
Minimum instrument channel width *2		Ø 3.2 mm
Endoscopic device view on the endoscopic image		
Insertion Tube Working Length *1		1,050 mm
Total Length		1,366 mm
Laser cauterization		Available
Electrosurgery treatment		Available
Water jet feeding function		Available
Illumination		White LED (Color temperature: 5,000 K)

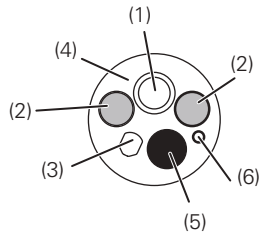
Specifications are subject to change without prior notice and without any obligation on the part of the manufacturer.

*1 There is no guarantee that equipment selected solely using the maximum insertion portion width and insertion portion working length will be compatible when used in combination.

*2 There is no guarantee that equipment selected solely using this minimum instrument channel width will be compatible when used in combination.

Distal End

EG29-i10c



(1) Objective Lens
(2) Light Guide
(3) Air/water Nozzle
(4) Case
(5) Instrument Channel
(6) Water Jet Nozzle

System chart

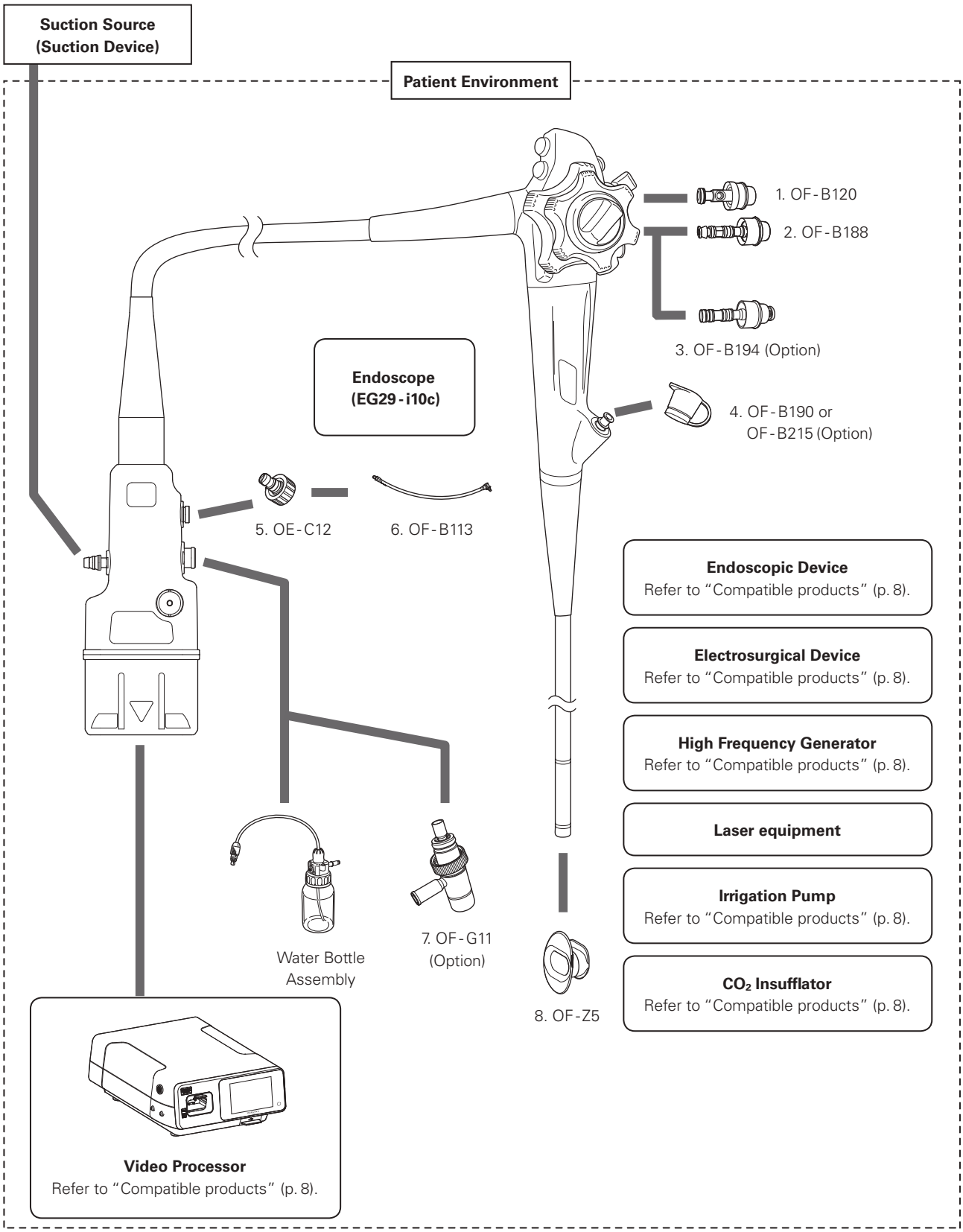
This section shows the system chart (configuration) for this endoscope and the ancillary equipment.

Warning

Use this product in combination only with compatible products shown in "Compatible products" (p. 8) and the "System chart". Failure to do so may result in lowered function and patient/user injury or damage to the equipment.

Note

When this endoscope is used in combination with other equipment, depending on how it is connected, it may result in malfunction and/or unforeseen events to patients and/or medical professionals. Pre-use operation check and risk management associated with changes are recommended, particularly when the equipment(s) used in combination is changed, added, or upgraded.



1. **Suction Control Valve (OF-B120)**
2. **Air/Water Feeding Valve (OF-B188)**
3. **Gas/Water Feeding Valve (OF-B194*) *Optional Item**
4. **Inlet Seal (OF-B190 or OF-B215*) *Optional Item**
5. **Water Jet Check Valve Adapter (OE-C12)**
6. **Irrigation Tube (OF-B113)**
7. **Gas Adapter (OF-G11*) *Optional Item**
8. **Bite Block (OF-Z5)**

Software Version

EG29-i10c	00D6C-1

Contacts

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