PENTAX MEDICAL

Instructions for Use

PENTAX Video Upper G.I. Scope
PENTAX Video Colonoscope

Operation

EG-2990Zi
EC-3890LZi/FZi/MZi

Digitally signed by Ceaicovschi Tudor
Date: 2021.05.20 09:18:36 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

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

Symbol	Description
	Caution
	Date of Manufacture
	Type BF applied part
	Follow the Instructions for Use
	Manufacturer
EC REP	Authorized representative in the European Community
CE	This product complies with the applicable standards harmonised under the Directive 93/42/EEC and Directive 2011/65EU.

Contents

Important information: Please read before use

Product summary

This endoscope visualizes subjects under illumination transmitted from a dedicated video processor 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

■ EG-2990Zi:

This PENTAX Video Upper G.I. scope 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 or the nose, as decided by the physician, when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

■ EC-3890Zi series:

These PENTAX Video Colonoscopes are intended to provide optical visualization of (via a video monitor), and therapeutic access to, the lower gastrointestinal tract. This anatomy includes, but is not restricted to, the organs, tissues, and subsystems: large bowel to the cecum.
These endoscopes are introduced via the rectum 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	EG-2990Zi; Upper gastrointestinal tract (esophagus, stomach) duodenum EC-3890Zi series; Large intestine and terminal ileum
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.
Location of use	A medical facility

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 (with the soaking cap attached)
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	0 to 85 % RH
	Air pressure	700 to 1,060 hPa

■ Software version

For the software version for each model, refer to the back cover.

■ Endoscope specifications

For details, refer to "Endoscope specifications" (p. 80).

Compatible products

This section describes the equipment that can be used in combination with this endoscope. For more details, refer to "System chart" (p. 81).
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.

■ 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 respective video processor.

Model Name	Brand Name
EPK-i7000 series	PENTAX Medical
EPK-i5000 series	
EPK-i	

Reprocessing before the initial use, reprocessing, and storage after use

■ Reprocessing before the initial use

The endoscope identified in this IFU is a reusable semi-critical device. Since it is packaged non-sterile, it must be cleaned and high level disinfected, or cleaned and sterilized, or cleaned and disinfected and additionally can be sterilized (if applicable) according to the separate IFU (Reprocessing) of this product before initial use. 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

After use, the endoscope must be appropriately cleaned, high-level disinfected and/or sterilized, and stored. Insufficient and/or incomplete cleaning, high-level disinfection, and/or sterilization of this endoscope may result in its non-optimal function of and/or damage to the endoscope and may pose a risk of infection to the patient and/or users.

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 cannot be used again on another patient. The pathogenic agents that cause this disease, which are called “prions”, cannot 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, cleaning adapter, and soaking caps 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.
- Maintain adequate distances between the endoscope, its accessories, and devices, so that they do NOT hit against each other.

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 restrictions or non-use of the endoscope in patients suspected of having lowered immunity.
- 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 use this endoscope for any purpose other than its intended use. Doing so may result in patient injury.
- Do NOT use this endoscope with equipment other than those that have been specified for combined use. Endoscope operation in the freeze or magnification mode may result in damage to the endoscope and patient injury.
- Do NOT drop this endoscope or apply a strong shock to it. Doing so may result in damage to the endoscope. In particular, do NOT apply a strong shock to the lens surface at the distal end. Visual abnormalities may occur, which may result in unforeseen events.
- Ensure to attach/connect an appropriate device to the connectors of the PVE connector such suction nipple, air/water port, venting connector, or feedback terminal according to the IFU.
- 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/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 reverse observations inside a narrow lumen. Doing so may cause patient injury or make it impossible to withdraw the endoscope.

Warning

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 therapeutic 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 cannot 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.

Caution

- 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 PVE 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.

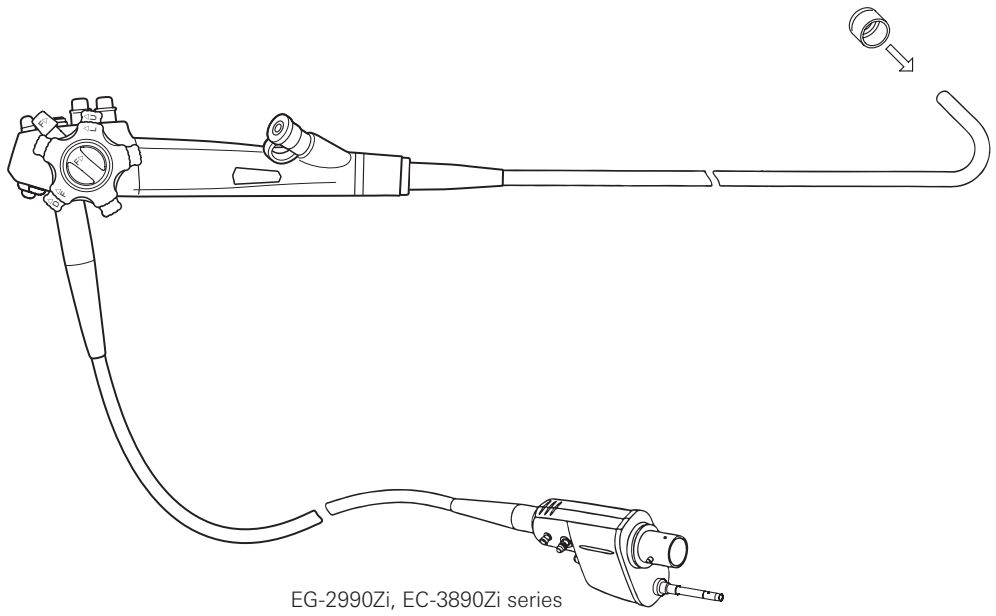
- Perform inspection before use, care after use, storage, and replacement of consumables according to this IFU.
- Have a specialist specified by PENTAX Medical perform repairs and at least annual periodic inspections.

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 in the IFU.
If there are any damaged or missing components, do not use the endoscope; immediately contact your local PENTAX Medical service facility. (Optional depending on the model.).

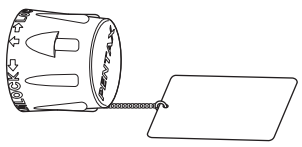
■ Endoscope



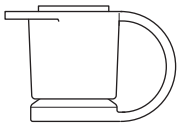
EG-2990Zi, EC-3890Zi series

Figure 1.1

■ Accessories

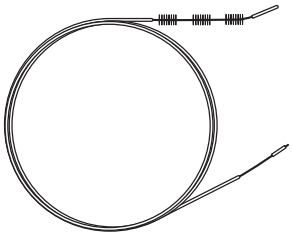


PVE Soaking Cap (OE-C9)

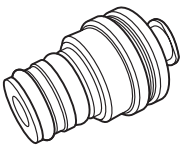


Inlet Seal (OF-B190)
(Installed)

Cleaning Brush (CS-C9S)



Cleaning Brush (CS6021T)

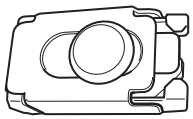


Cleaning Adapter
(OF-G17)

Silicone Oil Lubricant (OF-Z11)

Figure 1.2

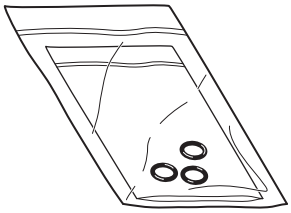
■ Accessories



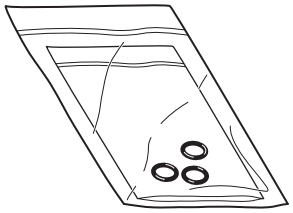
Cleaning Adapter
(OF-B153)

Irrigation Tube (OF-B113)

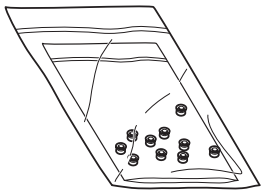
Ventilation Cap (OF-C5)



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

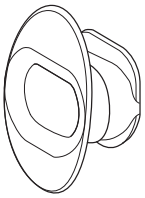


O Ring Set (OF-B127**)
** For Suction Control Valve (OF-B120)

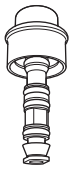


Check Valve Sets (OE-C15)

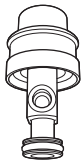
Distal Hood
(For EG-2990Zi, OE-A58)
(For EC-3890Zi series, OE-A59)



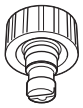
Bite Block (OF-Z5)
(For EG-2990Zi)



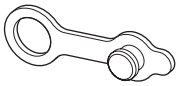
Air/Water Feeding Valve (OF-B188)
(Installed)



Suction Control Valve (OF-B120)
(Installed)



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



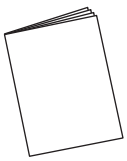
Water Jet Connector Cap (OF-B118)
(Installed)

■ Endoscopic device***
*** This is an optional device depending on the sales region.

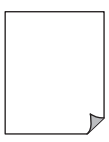
Biopsy Forceps
(EC-3890LZi/3890FZi: KW2422R), (EC-3890MZi: KW2418R), (EG-2990Zi: KW2415R)

■ Others

IFU (Operation; this document)



IFU (Reprocessing)



Standard Accessories List

Figure 1.2

2 Nomenclature and functions

2-1. Control body, insertion portion

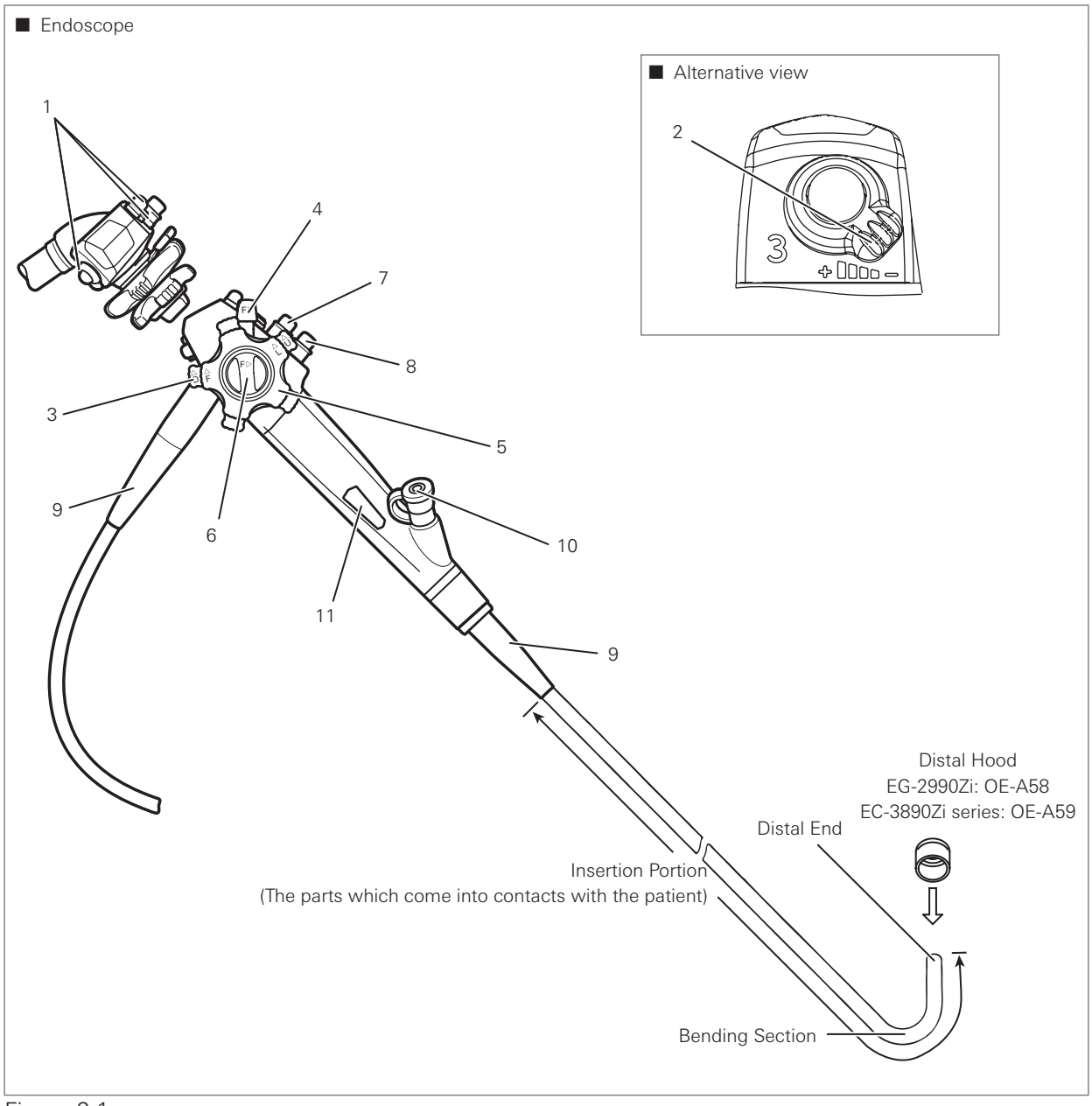


Figure 2.1

1. Remote Buttons 1-3
   Functions assigned to each button can be remotely controlled by pressing each of the remote buttons.
   Functions of the remote buttons 1-3 are assigned from the video processor.
   Refer to the IFU of the respective video processor for assignment of functions to each remote button.
2. Magnification control lever
   The optical zooming function is available through the magnification control lever operation.
3. 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.
4. 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.
5. 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.
6. 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.
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 Valve (OF-B188)
   Attach to the air/water feeding cylinder. Covering the hole on the top of the valve feeds air from the air nozzle at the distal end of the endoscope. Depressing the valve feeds water from the water nozzle.
9. Strain Relief Boot
   The strain relief boot protects the connecting parts.
10. Inlet Seal (OF-B190)
    The inlet seal is attached to the instrument channel inlet to avoid fluid/air leakage.
11. Model Name Label
    The model name label shows the model name, minimum instrument channel width, and other related information. (Figure 2.2)

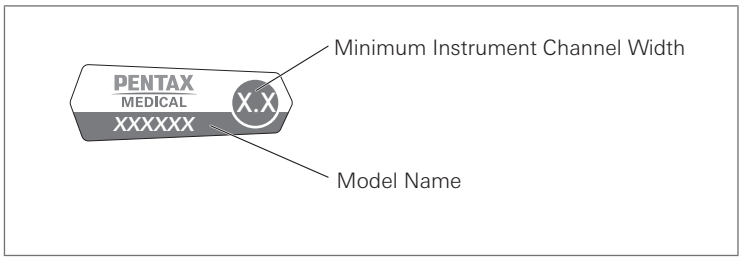


Figure 2.2

2-2. Connector

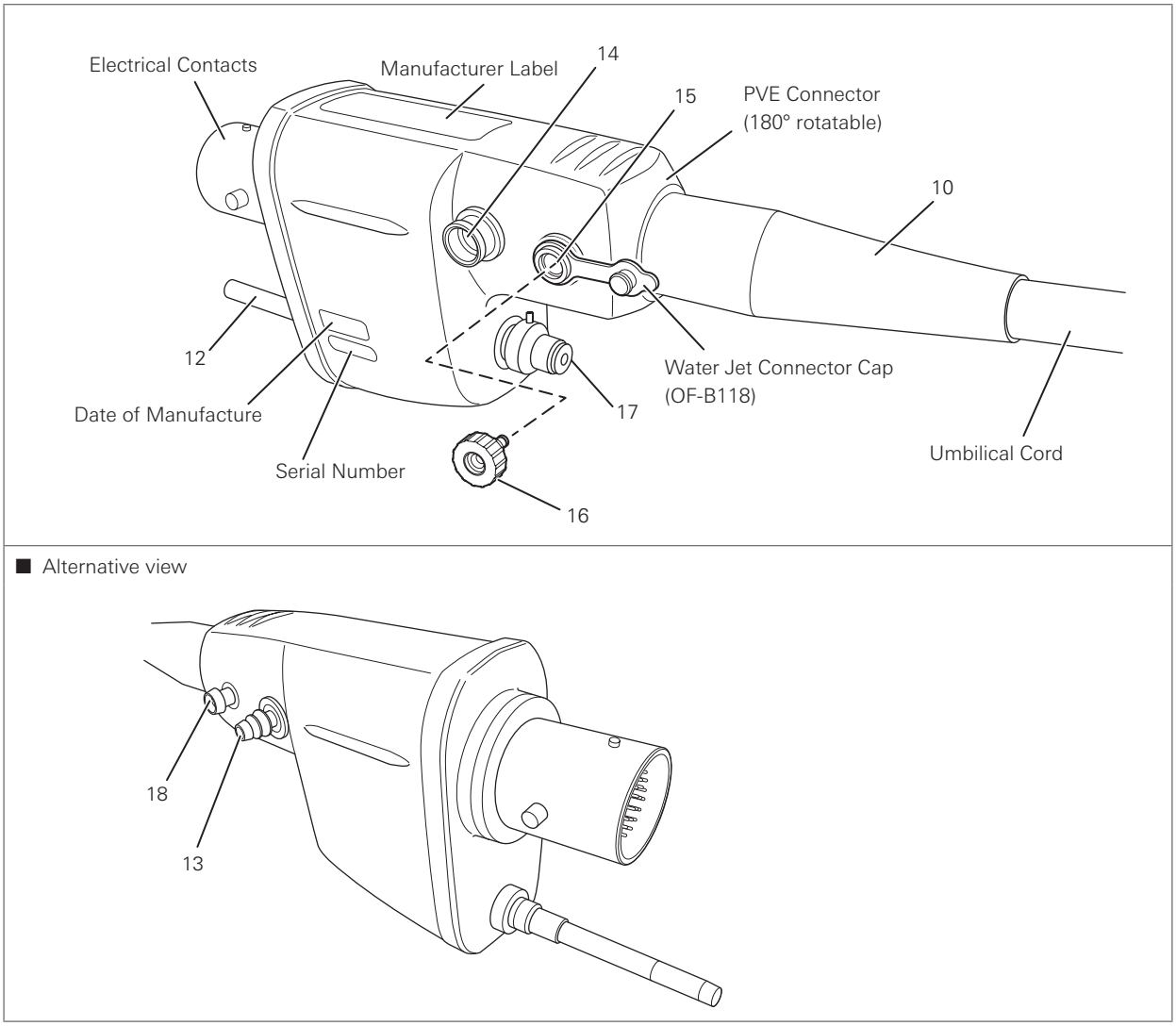


Figure 2.3

12. Light Guide Plug
    The light guide plug transmits the light received from the light source to the distal end of the endoscope..
13. Suction Nipple
    Connect the suction tube on the suction source to the suction nipple.
14. Air/Water Port
    Connect the air/water feeding hose on the water bottle assembly to the air/water port.
15. Water Jet Port
    Attach a water jet check valve adapter (OE-C12).
16. 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).
17. Venting Connector
    Attach the ventilation cap (OF-C5) or the endoscope connector of the leakage tester here.
18. Feedback Terminal
    When using an electrosurgical device, connect the electrosurgical unit's endoscope feedback cord (S-cord) or the condenser earth cable (OL-Z4/OL-Z3: check the package contents according to the separate standard accessories list provided with this product.).

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.

If any abnormality is suspected during inspection, do not use the endoscope; send it for repair according to “5-2. Returning the endoscope for repair” (p. 75).

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.

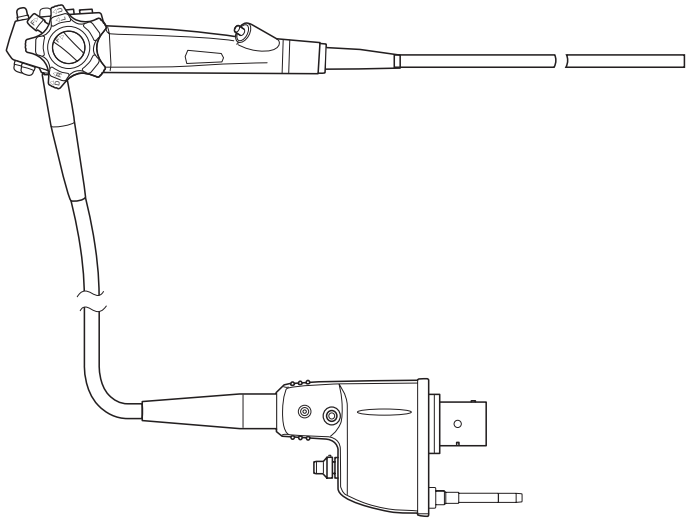
Caution

Ensure that another endoscope is also prepared to avoid interruption of the procedure due to endoscope failure or unforeseen events.

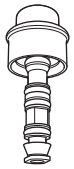
3-1. Preparation of the equipment

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.

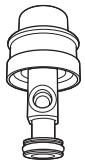
■ Endoscope



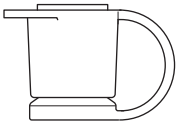
■ Accessories



Air/Water Feeding Valve (OF-B188)



Suction Control Valve (OF-B120)

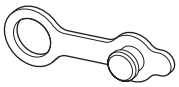


Inlet Seal (OF-B190)

Silicone Oil Lubricant (OF-Z11)

Water Jet Check Valve Adapter (OE-C12)

Irrigation Tube (OF-B113)

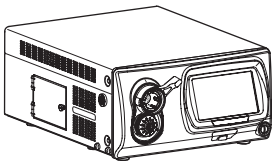


Water Jet Connector Cap
(OF-B118)

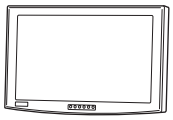
Bite Block (OF-Z5)
(For EG-2990Zi)

Distal Hood
(For EG-2990Zi, OE-A58)
(For EC-3890Zi series, OE-A59)

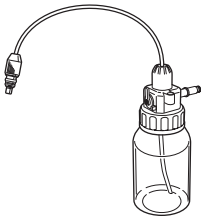
■ Ancillary Equipment



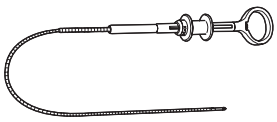
Video Processor



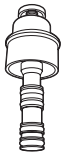
Monitor



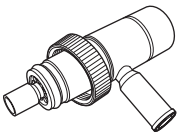
Water Bottle Assembly



Endoscopic Device

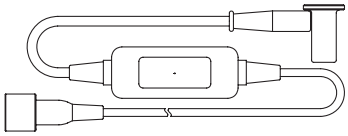


Gas/Water Feeding Valve (OF-B194*)
* Optional item



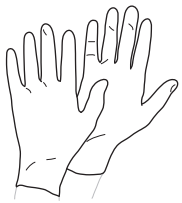
Gas Adapter (OF-G11*)
* Optional item

Suction Source



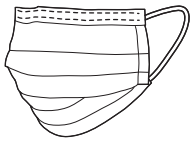
Condenser Earth Cable
(OL-Z4/OL-Z3)

■ Protective Equipment (example)



Gloves

Goggles



Mask

Medical Gown

■ Others

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.

Caution

- Do NOT excessively twist, bend, or rotate any of the strain relief boots on the instrument (See Figure 3.2 (1) and 3.2 (2) 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 (1)) 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.

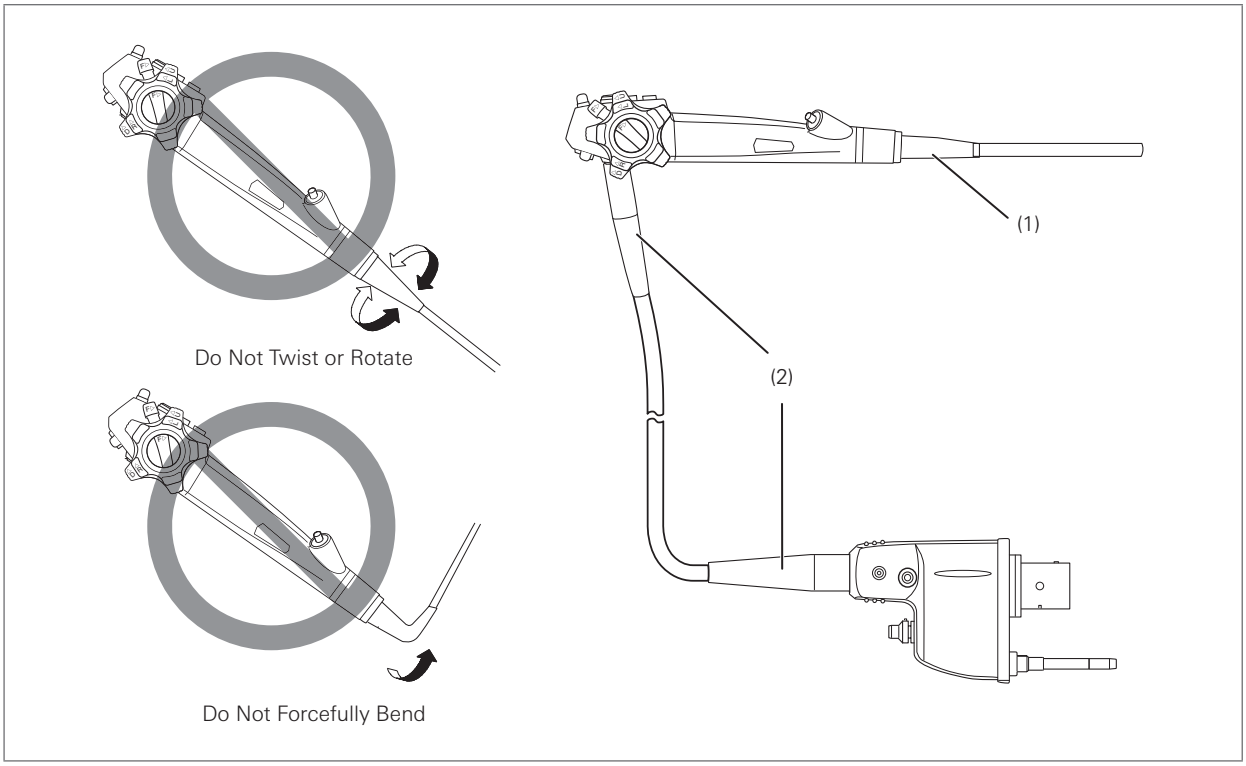


Figure 3.2

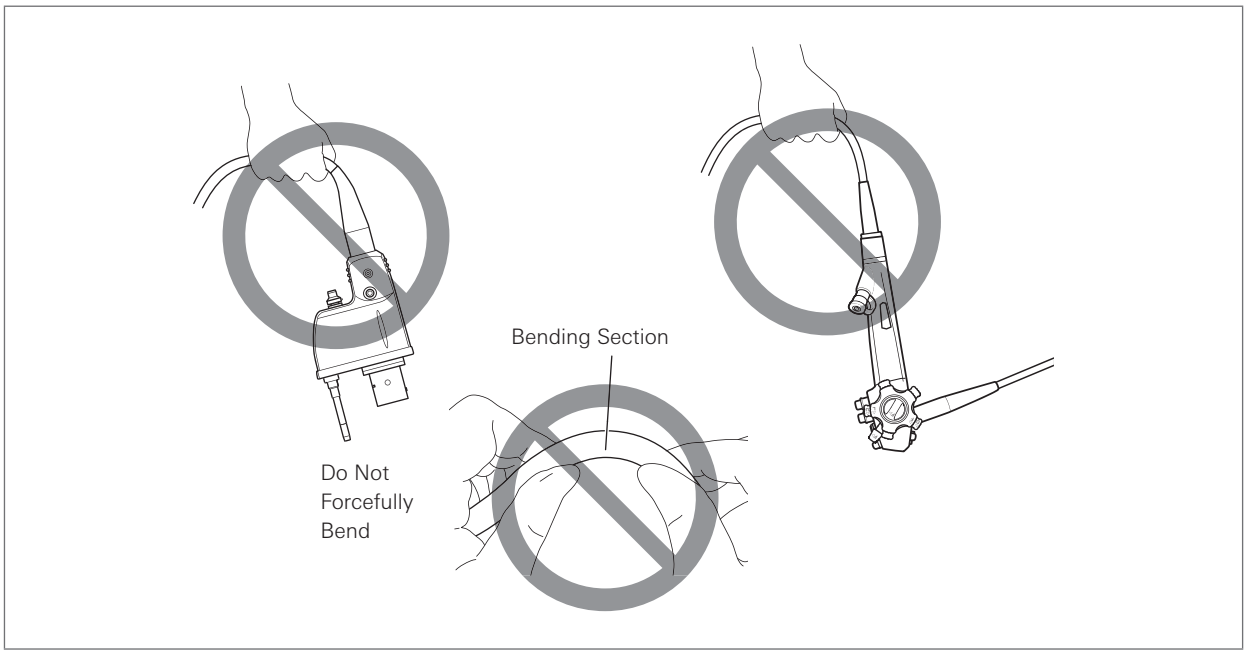


Figure 3.3

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. Observation may be hindered by fogging of lens and other effects because of the difference in the temperature of the endoscope and the room.

■ Carrying the endoscope by hand

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

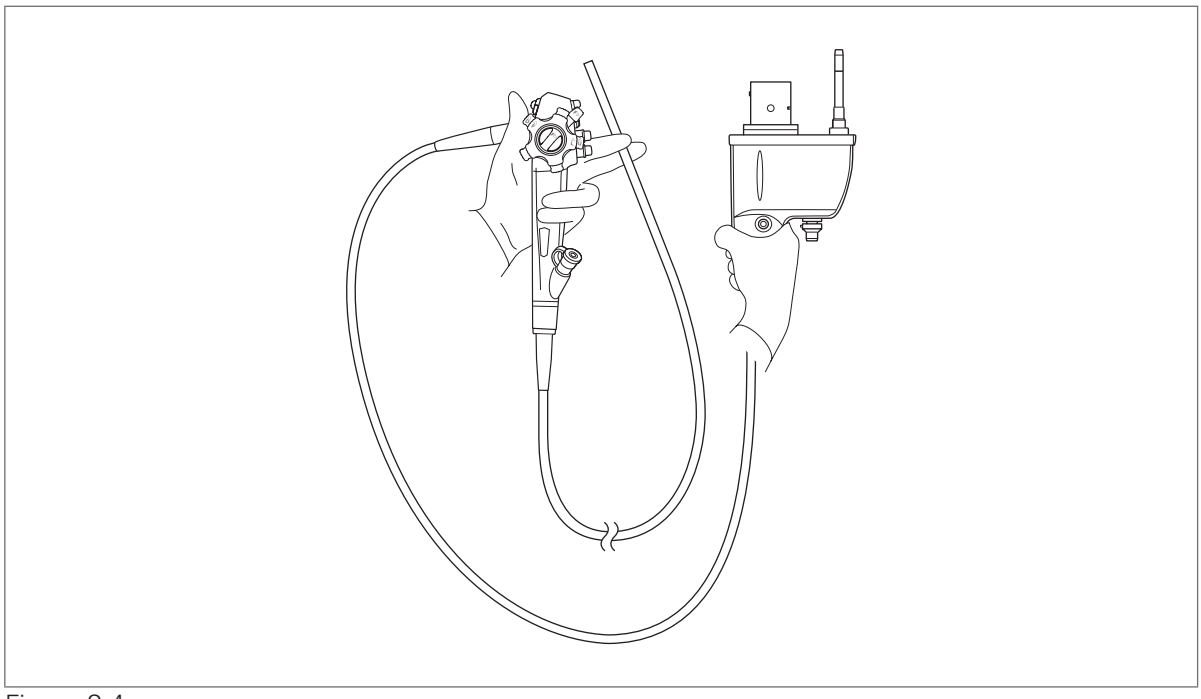


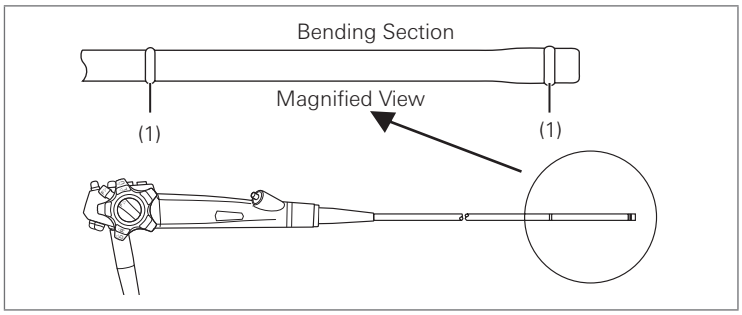
Figure 3.4

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.

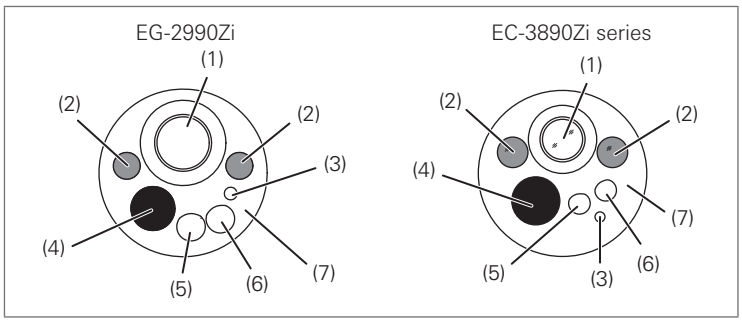
1. Check the entire surface of the endoscope for any visible adhered material.
2. Check the entire surface of the insertion portion for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, dents, catching, protrusions, attachment of foreign materials, detachment of parts, etc.
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 on 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 Guide
(3) Water Jet Nozzle
(4) Instrument Channel
(5) Air Nozzle
(6) Water Nozzle
(7) Case

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 it looks glossy.
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 on the gauze.

Note

Clear images cannot be obtained when there are any attachment of foreign material or residuals on the objective lens or light guides. When an endoscope with any attachment of foreign material or residuals on the objective lens or light guides is used, vapor may be generated from the water contents of the attachment of foreign material or residuals being heated by the light.

8. Check the air nozzle and water nozzle at the distal end of the endoscope for any abnormalities such as clogging, dents, deformations, chipping, etc.
9. Form an arch with the insertion tube as shown in Figure 3.7 using both hands. By sliding the insertion tube in the direction of the arrow in Figure 3.7, check that the entire insertion tube can be bent smoothly and easily to form an arch.

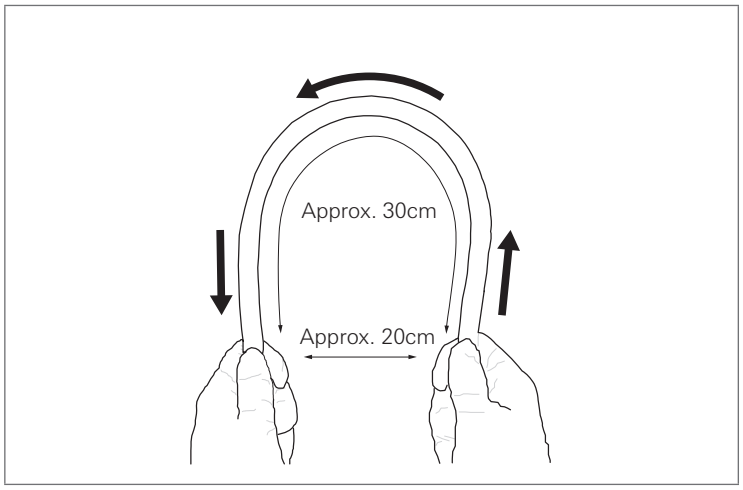
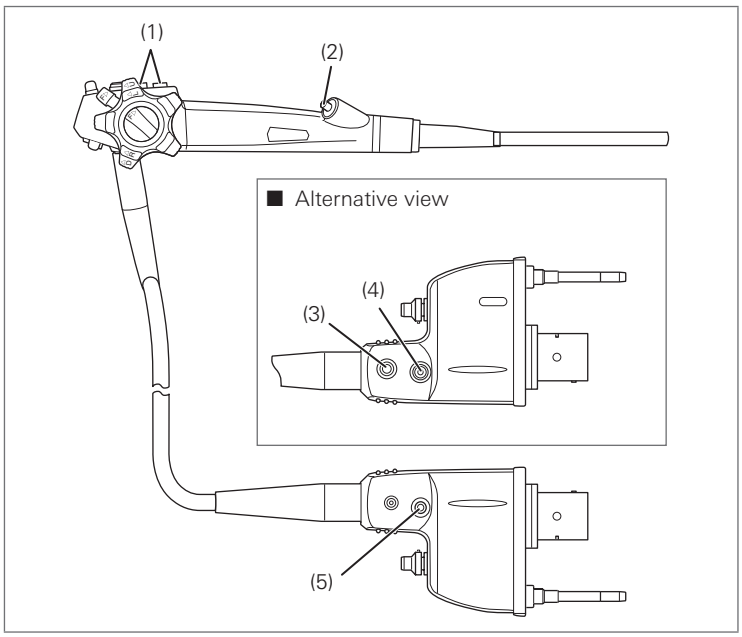


Figure 3.7

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, PVE 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. Take clean, lint-free gauze to 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

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 the endoscope with angulation abnormalities such as non-smooth operation, excessive play in the angulation control lever, or excessive angulation attenuation, as the inside of the endoscope may be damaged. Using the endoscope in this state may result in worsening of endoscope damage, malfunction during use, and 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.

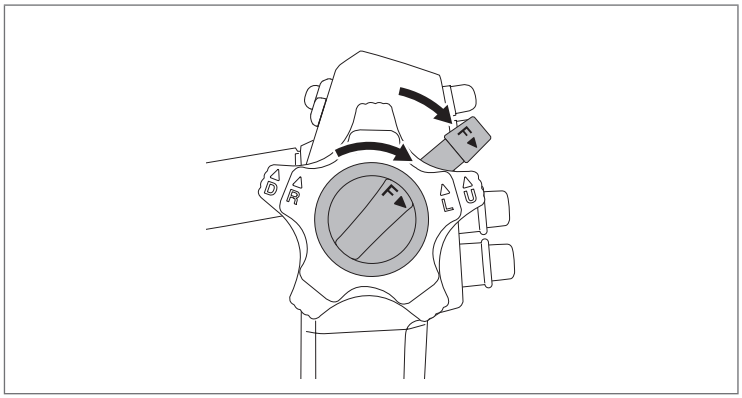


Figure 3.9

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.

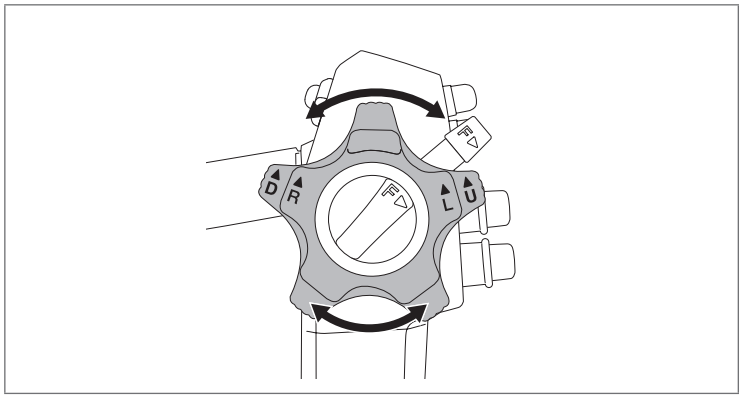


Figure 3.10

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.

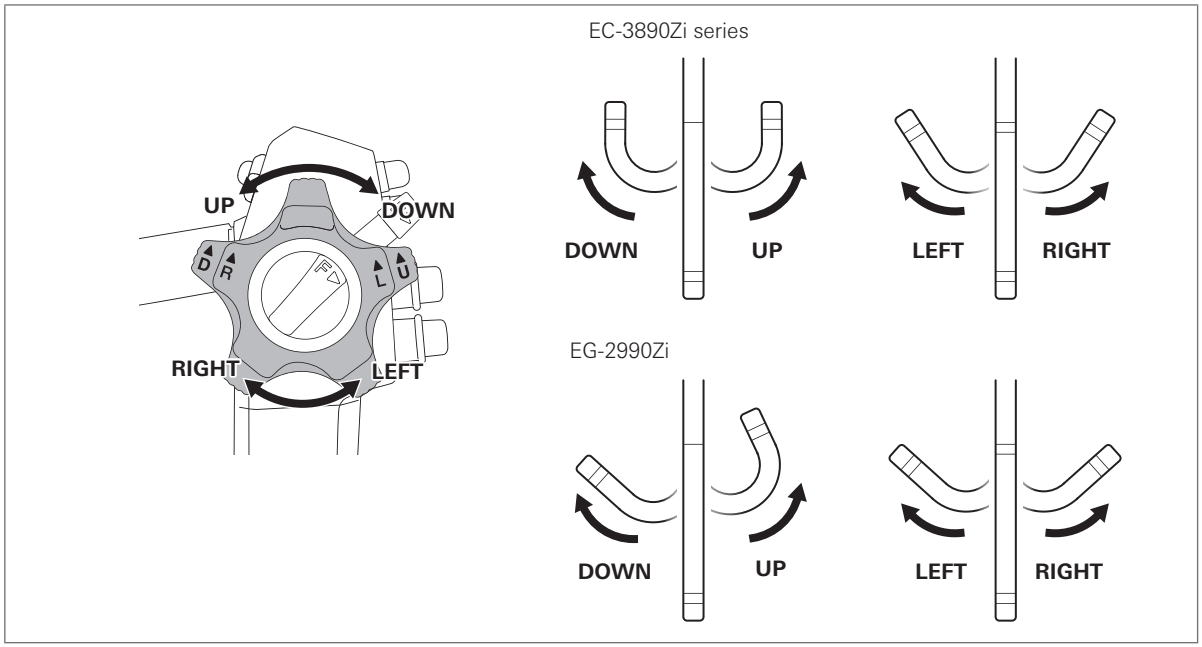


Figure 3.11

4. Turn the angulation control knobs back to the neutral position. Check that the bending section returns to an approximately straight condition.

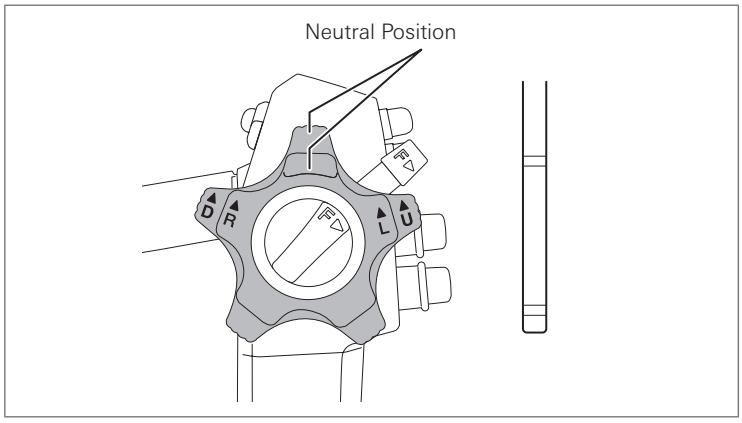


Figure 3.12

■ Inspection of the up/down bending lock mechanism

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

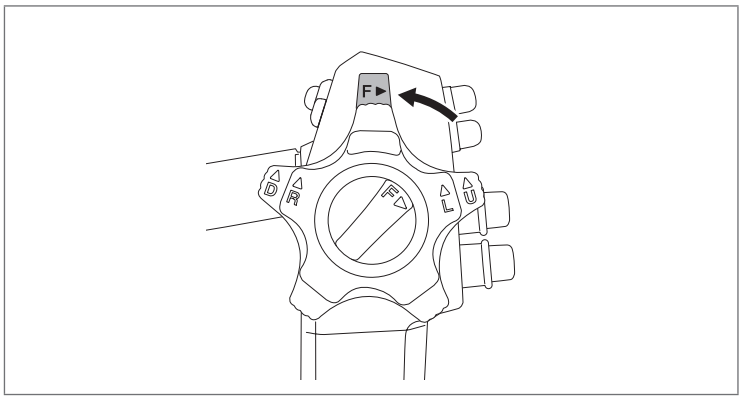


Figure 3.13

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

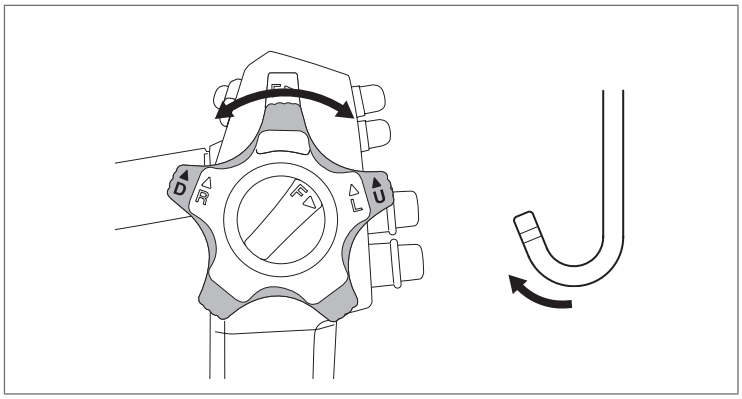


Figure 3.14

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 an approximately straight condition.

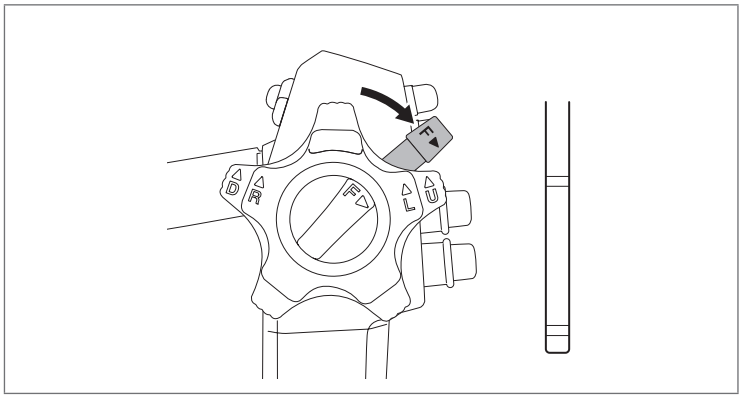


Figure 3.15

■ Inspection of the right/left bending lock mechanism

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

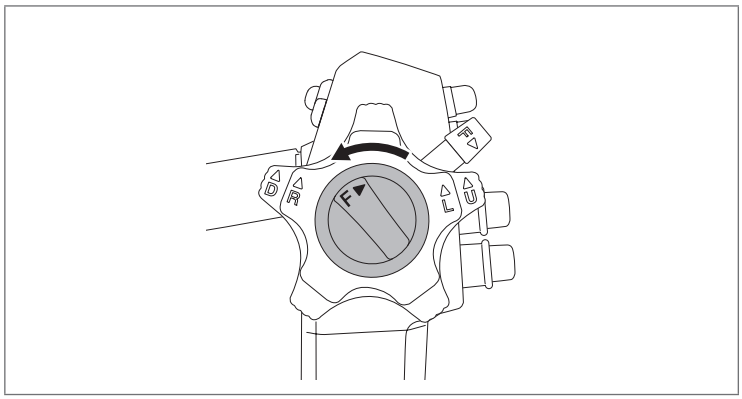


Figure 3.16

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

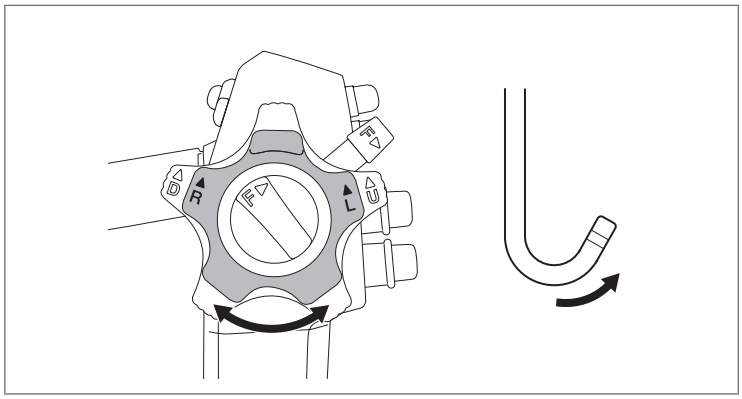


Figure 3.17

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 an approximately straight condition.

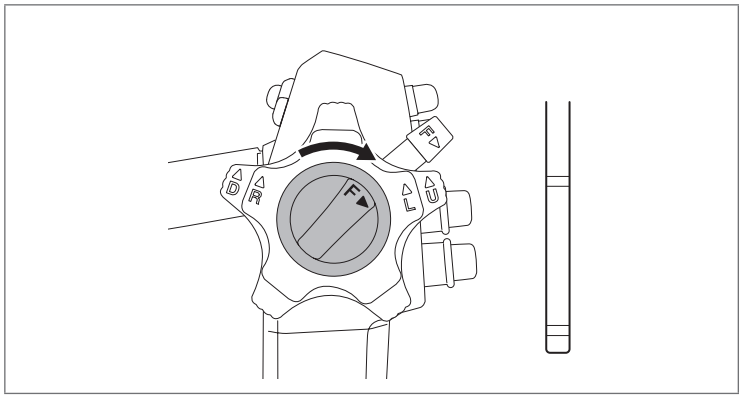


Figure 3.18

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) of 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.

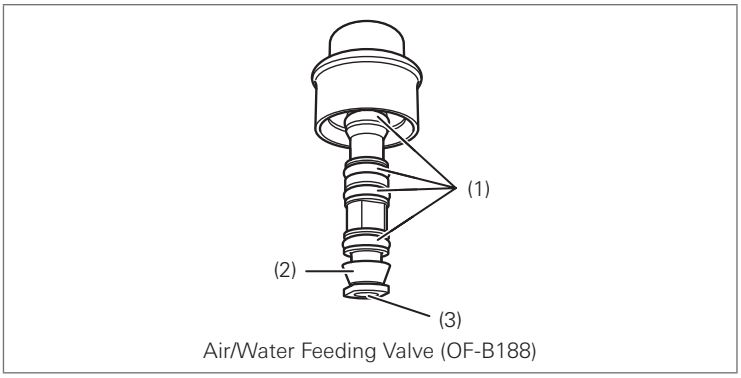
Inspection of the air/water feeding valve (OF-B188)

Warning

- If any abnormality is suspected with the check-valve, replace the air/water feeding valve with a new one. Continue use of the air/water feeding valve with abnormalities could cause unintended continuous air feeding and pose a risk of pain or perforation to the patient. It could also pose a risk of infection to the user as result of reflux or dispersal of patient's body fluids from the air/water feeding valve.
- The O-ring of the air/water feeding valve is a consumable. If any abnormality is suspected with the O-ring, stop use 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 or perforation to the patient. It could also pose a risk of infection to the user as result of reflux or dispersal of patient's body fluids from the air/water feeding valve.
- The replacement O-ring is 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.

Note

Use the O ring set (OF-B192) for air/water feeding valve (OF-B188) for replacement.
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.

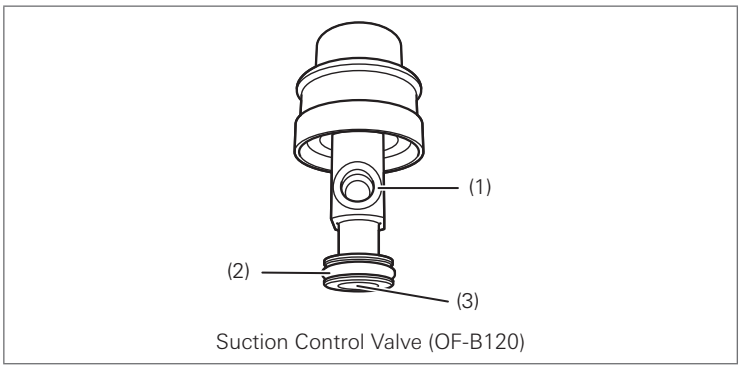
Inspection of the suction control valve (OF-B120)

Warning

- If any abnormalities are suspected in the rubber seal, replace the suction control valve with a new one. Using a suction control valve with any abnormality could result in continuous weak aspiration, which may hinder the procedure. It could also result in potential reflux or dispersal of patient's body fluids, posing a risk of infection.
- The O-ring of the suction control valve is a consumable. If any abnormality is suspected with the O-ring, stop use 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 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.
- The replacement O-ring is NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection, or sterilization of the suction control valve after O-ring replacement.

Note

Use the O ring set (OF-B127) for the suction control valve (OF-B120) for replacement.



Suction Control Valve (OF-B120)

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

Figure 3.20

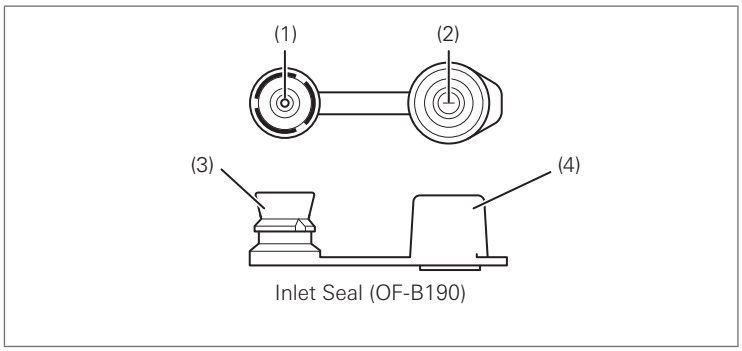
1. Check the suction control valve (OF-B120) for any abnormalities such as attachment of foreign materials, deformation, cracks, or hole blockage.
2. Check that the O-ring is properly attached and that there is no chipping, breaks, or peeling in the O-ring or sealing rubber part.

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.

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. Put the cap to the body of the inlet seal and check that the cap is correctly attached.

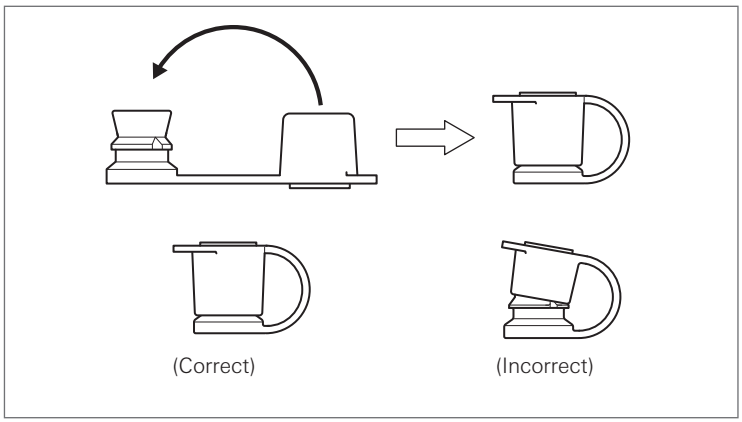


Figure 3.22

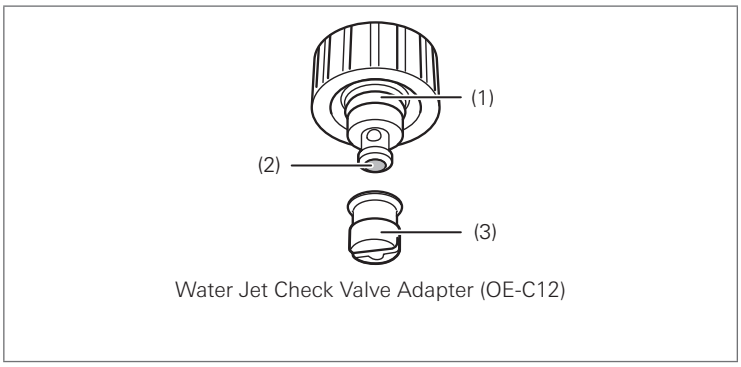
Inspection of the water jet check valve adapter (OE-C12)

Warning

- NEVER use a water jet check valve adapter (OE-C12) that has any abnormality. Replace it with a new one. Check valve adapters are consumables. Using a damaged check valve adapter may result in potential reflux or dispersal of patient's body fluids, posing a risk of infection.
- Replacement check valve sets (OE-C15) 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.

Note

Use the check valve set (OE-C15) for replacement.



Water Jet Check Valve Adapter (OE-C12)

(1) O-ring
(2) Hole
(3) Check Valve (OE-C14)

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.

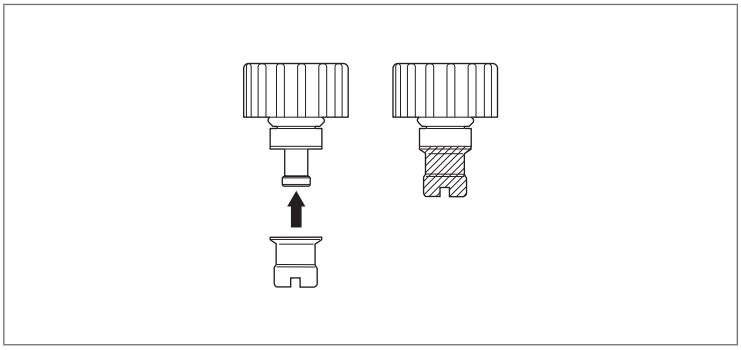


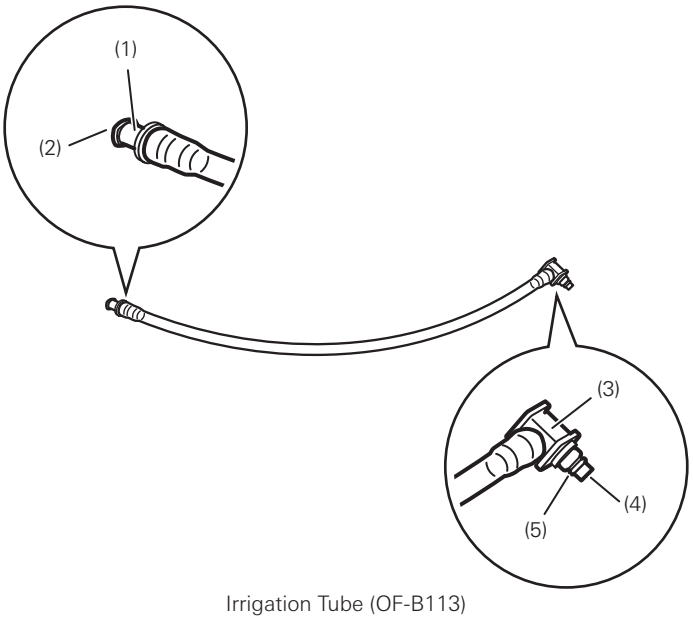
Figure 3.24

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 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 processing.



(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 the syringe filled with the sterile water to the luer connector of the irrigation tube (OF-B113) and flush sterile water.
3. Check that sterile water flows in a steady stream from the connector of the irrigation tube (OF-B113).

Inspection of the distal hood (OE-A58/OE-A59)

Warning

- The distal hoods (OE-A58 / OE-A59) are provided non-sterile and non-disinfected. Prior to the initial use, it must be subjected to appropriate cleaning and high-level disinfection, or sterilization according to the respective IFU for the distal hood (OE-A58 / OE-A59). Insufficient processing prior to use may increase the risk of cross contamination.
- NEVER use a distal hood that has any abnormality. Replace it with a new one. Using a distal hood with an abnormality may result in endoscope damage and patient injury.

Note

Distal hoods are consumables. Even while it is still within its service life, avoid reuse whenever possible, instead replace it with a new one on every use.

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

Distal Hood
(OE-A58 for EG-2990Zi, OE-A59 for EC-3890Zi series)

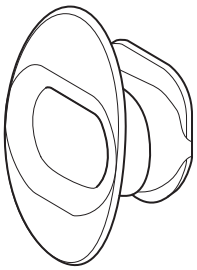
Figure 3.26

Inspection of the bite block (OF-Z5) (EG-2990Zi only)

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 3.27

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.
- All reusable endoscopic devices must be cleaned and sterilized before initial use as well as before every subsequent use.
- 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.

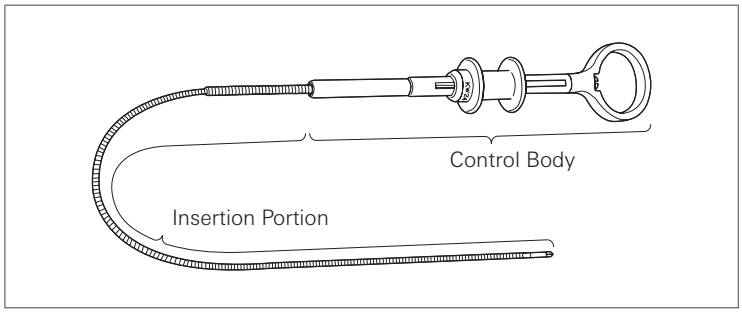


Figure 3.28

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

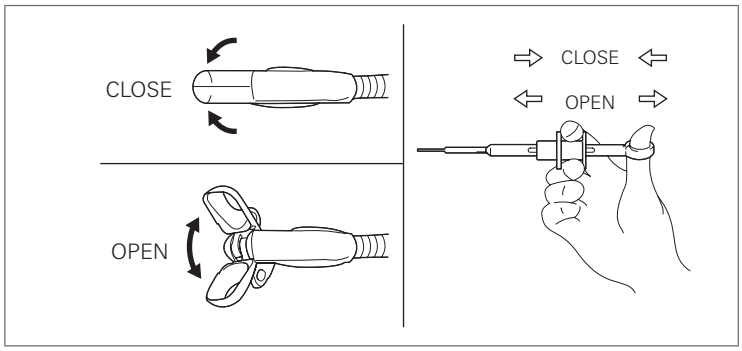


Figure 3.29

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.

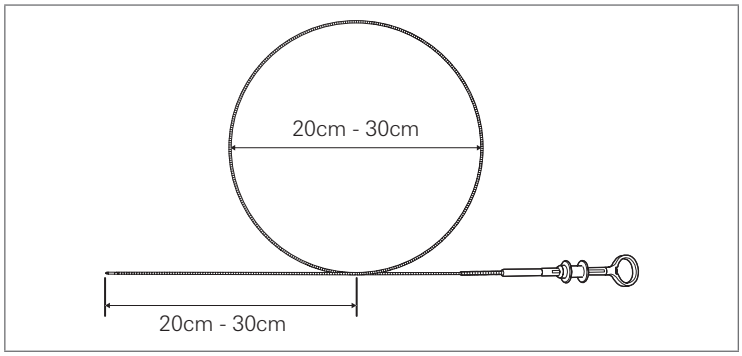


Figure 3.30

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

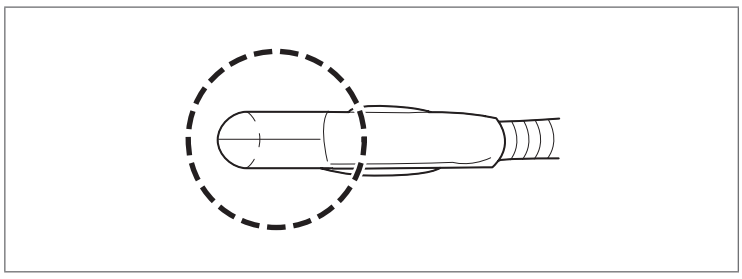


Figure 3.31

Attachment of accessories

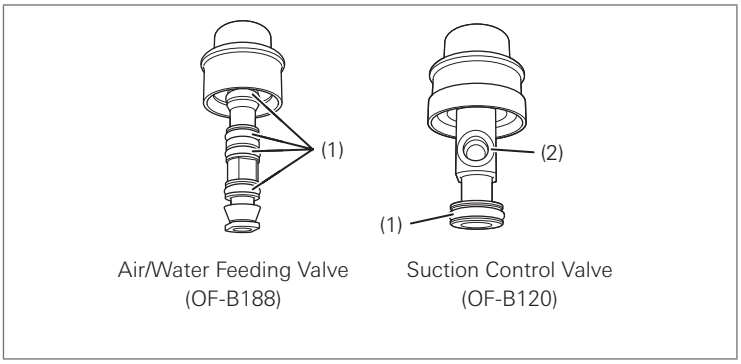
Warning

- 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.

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

Caution

- 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 to the cylinder of the endoscope. Pressing them at an angle may result in damage to the O-ring and check valve.



(1) O-ring
(2) Rubber Seal

Figure 3.32

1. Apply a small amount of silicone oil lubricant (OF-Z11) onto the O-rings of the air/water feeding valve (OF-B188) and suction control valve (OF-B120), and the rubber seal. 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.

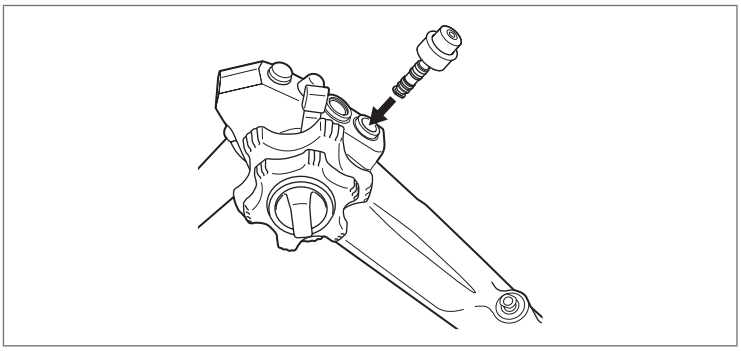


Figure 3.33

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.

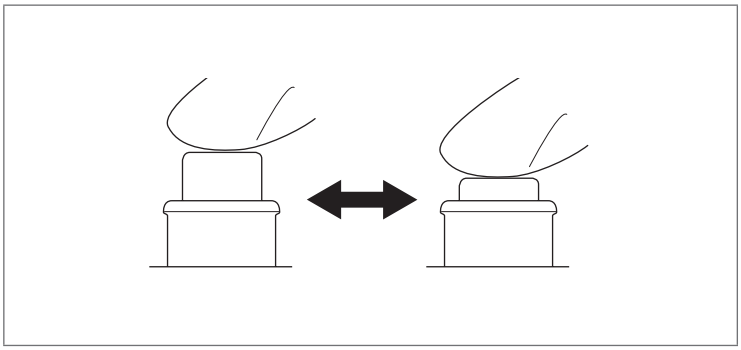
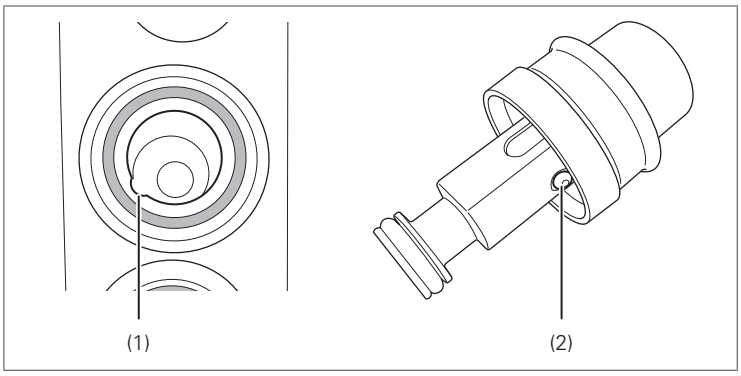


Figure 3.34

4. Align the metal tab on the shaft of the suction control valve (OE-B120) with the notch on the suction cylinder of the endoscope.



(1) Notch
(2) Metal Tab

Figure 3.35

5. Attach the suction control valve to the suction cylinder of the endoscope.

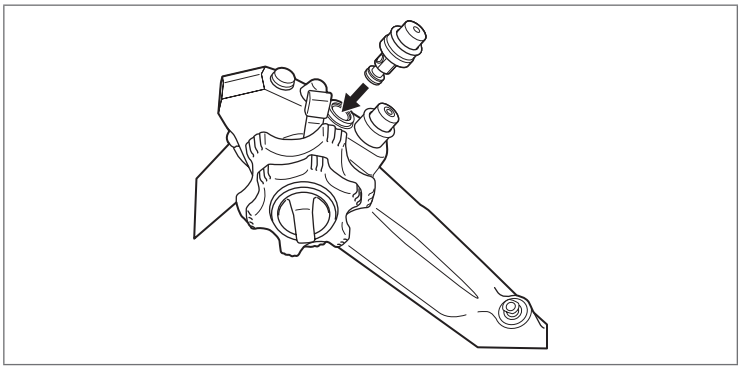


Figure 3.36

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.

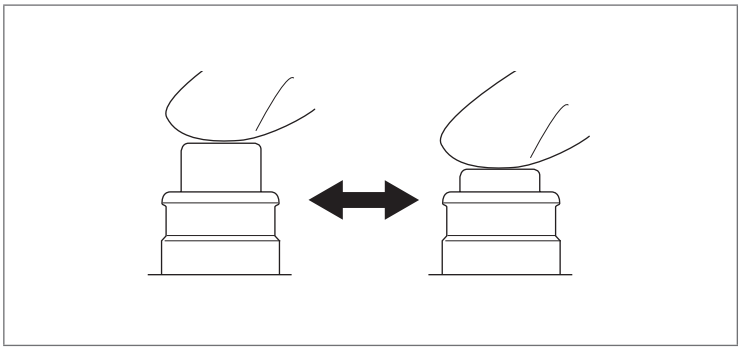


Figure 3.37

■ Attachment of the inlet seal (OF-B190)

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

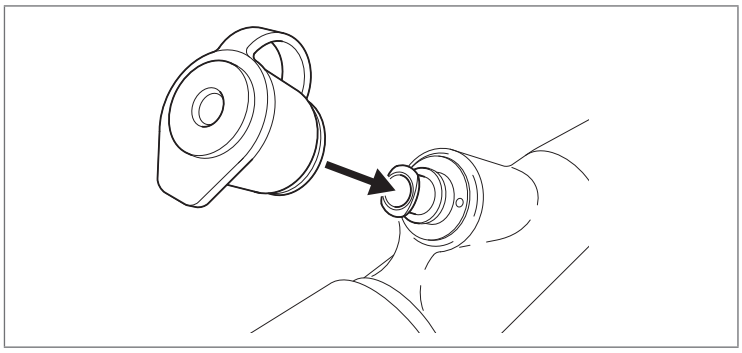


Figure 3.38

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

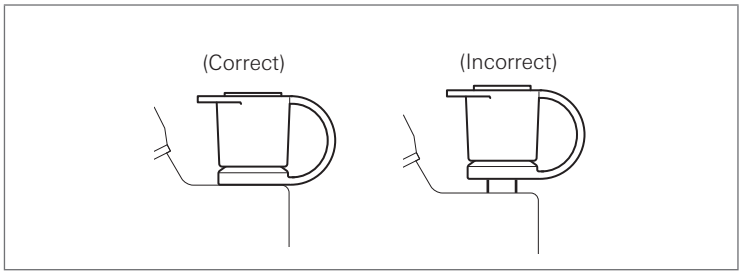


Figure 3.39

■ 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.

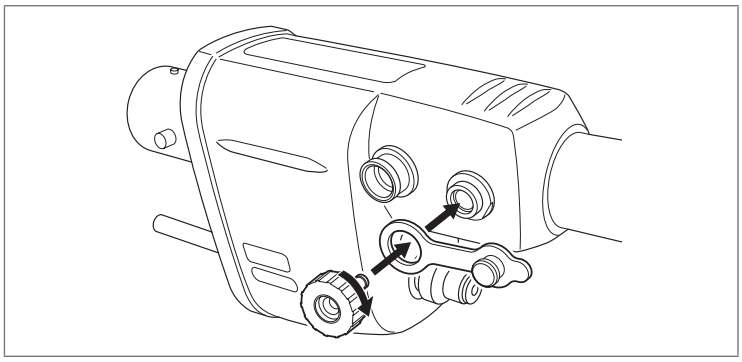


Figure 3.40

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.)

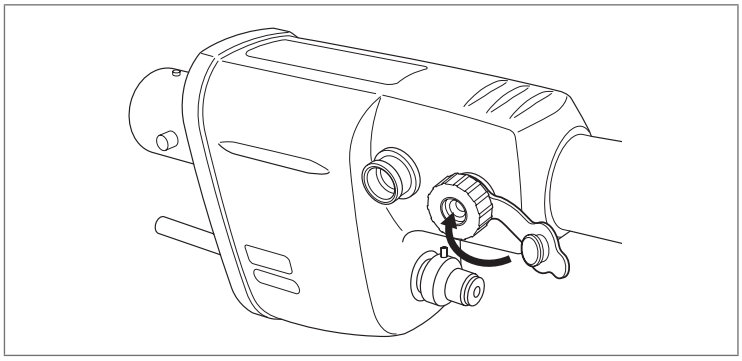


Figure 3.41

■ Attachment of the distal hood (OE-A58/OE-A59)

Warning

The distal hood (OE-A58/OE-A59) is provided non-sterile and non-disinfected. Prior to use, it must be subjected to appropriate cleaning, high-level disinfection, and/or sterilization processes according to the respective IFUs.

Caution

Lightly hold the distal end of the endoscope when attaching/removing the distal hood (OE-A58/OE-A59).
Do NOT apply excessive force to hold the distal end of the endoscope as it may deform the bending section and damage the endoscope.

Note

- The distal hood OE-A58 can be attached to EG-2990Zi, and the distal hood OE-A59 can be attached to EC-3890Zi series. By attaching the distal hood, the distance with the observed section is kept constant, making it easier for magnified observation.
- The distal hood may appear in the monitor in the non-magnified state.

1. Check the distal end of the endoscope for presence of lubricant or water.
2. Hold the distal end gently and push the distal hood into the flange portion inside.

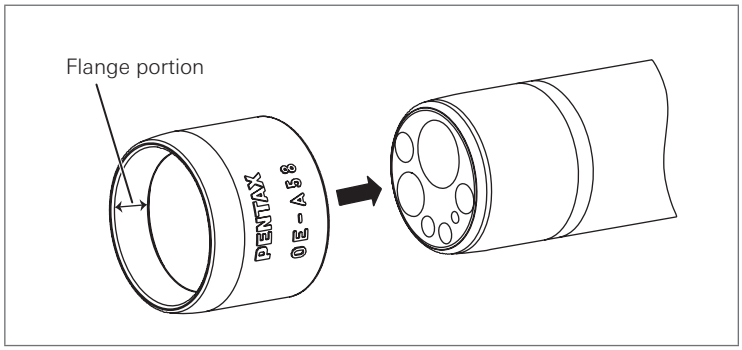


Figure 3.42

3. Ensure that there is no gap between the flange portion of the distal hood and the distal end of the endoscope.

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 manuals.

Video processor
Monitor
Water bottle assembly
Endoscopic device
Suction source, etc.

Inspection of the video processor

Only use compatible PENTAX Medical video processors.
For compatible video processors, refer to "Compatible products" (p. 7) or "System chart" (p. 81).

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

1. Ensure that all ancillary equipments are turned off.
2. Ensure that the endoscope locking lever is placed in the "OPEN" position. Securely insert the endoscope electrical contacts and light guide plug into the processor connector and receptacle.

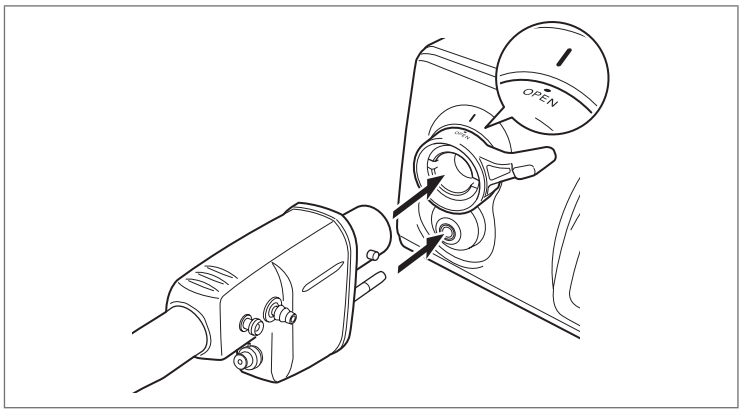


Figure 3.43

3. Turn the endoscope locking lever to the "LOCK" position.

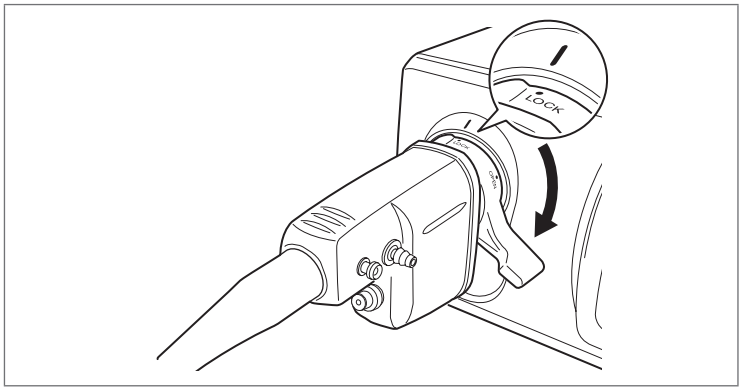


Figure 3.44

4. Lightly pull the PVE connector to ensure that it is connected securely.

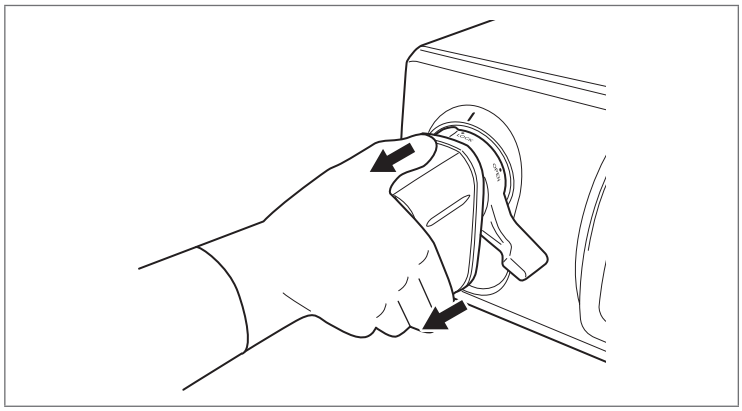


Figure 3.45

■ 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.
- 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.

Caution

Do NOT use defoaming agents in the water bottle assembly. Such agents cling to the inside channel of the endoscope. A blocked channel can lower the air/water feeding function and cause damage to the endoscope.

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.

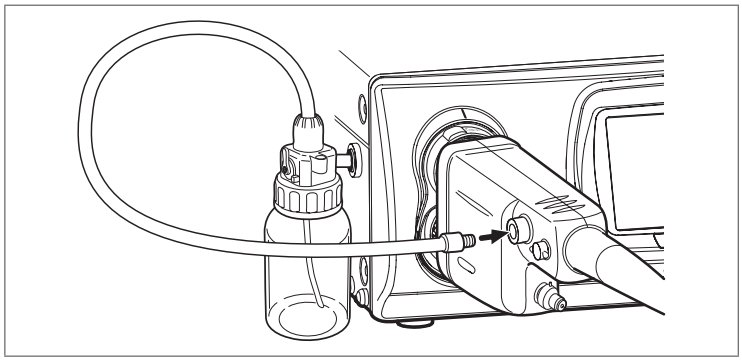


Figure 3.46

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.

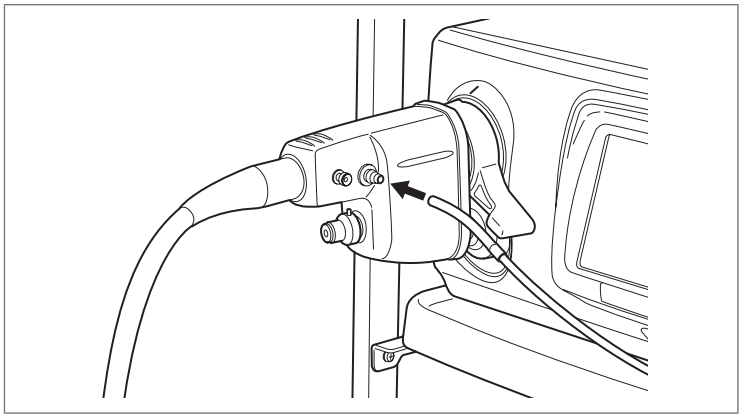


Figure 3.47

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.

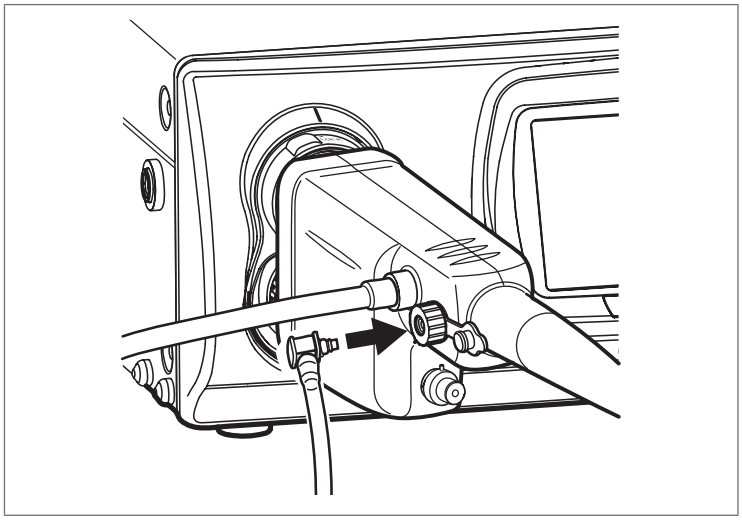


Figure 3.48

Caution

Have the irrigation tube (OF-B113) exactly parallel to the water jet check valve adapter (OE-C12) when attaching or removing it. Attaching or removing it diagonally may break the irrigation tube.

Note

Do not use the irrigation tube (OF-B113) if you have any difficulty in attaching or you could not feel a click feeling 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 or the video processor unit. The intense light may cause eye injuries. Turn off the lamp when looking directly at the distal end of the endoscope.
- Do NOT attach or remove the PVE connector while the video processor power is turned on. Doing so may damage the endoscope.

Note

- If the video processor connected has scope eject function, the PVE connector can be removed when the power of the video processor is turned on by using the scope eject function of the video processor. For details, refer to the IFU of the respective video processor.
- The video processor shown in the Figure is just an example. For details on the operation of each video processor, refer to the IFU of the respective video processor.

1. Turn on the video processor by pushing the Power Switch.

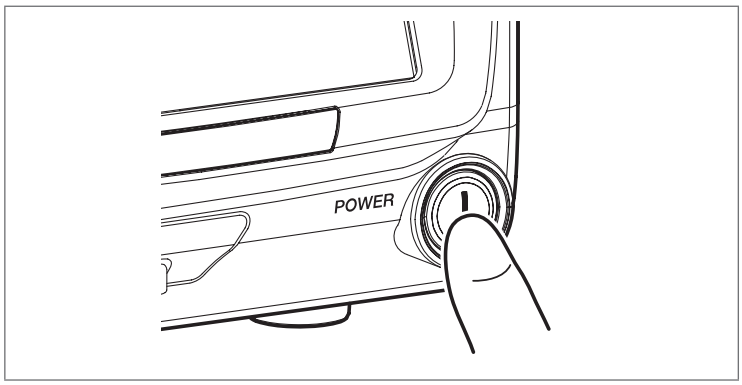


Figure 3.49

2. Turn on the lamp button of the video processor control panel.
3. Ensure that the lamp is lit and light is being emitted from the distal end of the connected endoscope. After pushing the lamp button, it takes several seconds for the lamp to light up.

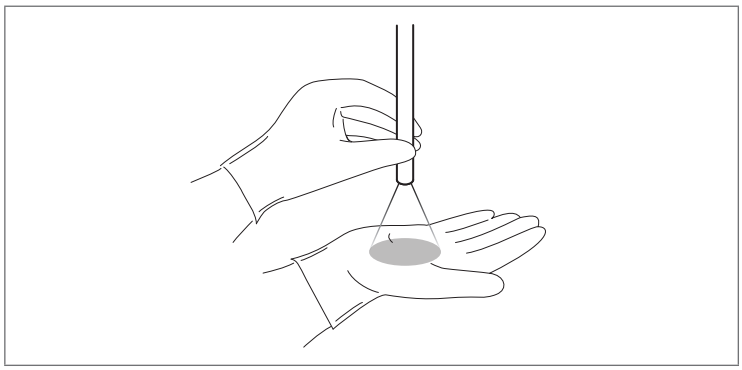


Figure 3.50

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

Note

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

5. On the control panel of the video processor, check that the exposure control is set to [AUTO].
6. While checking the image displayed on the monitor and following the IFU of the respective video processor, adjust the brightness level as appropriate.
7. Adjust the white balance by following the IFU of the respective video processor.
8. While observing the palm of your hand, check that the brightness adjustment is made normally by moving your palm closer to and away from the distal end of the endoscope.

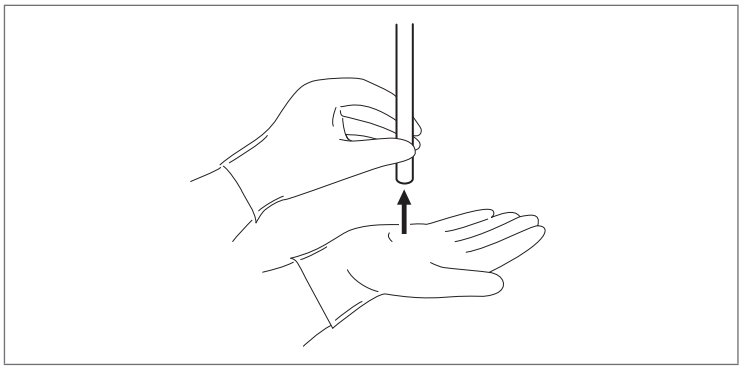


Figure 3.51

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.

9. Operate the angulation control knobs of the endoscope to move the bending section, and check if the image of the intended direction is displayed by corresponding to the angulation of the bending section. Also check for abnormalities such as appearance of noise in the endoscopic image or disappearance of the image.

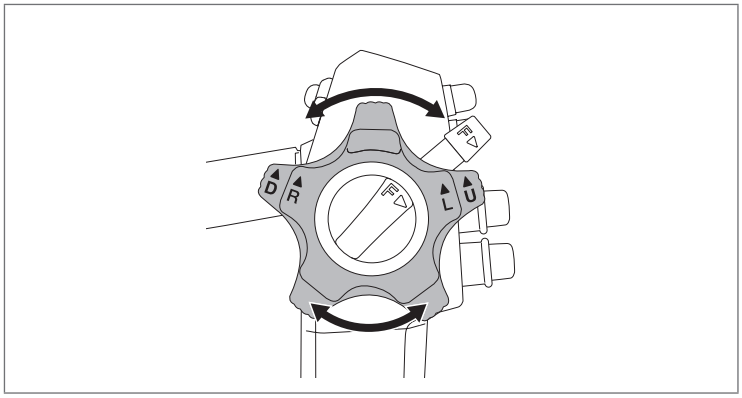


Figure 3.52

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.

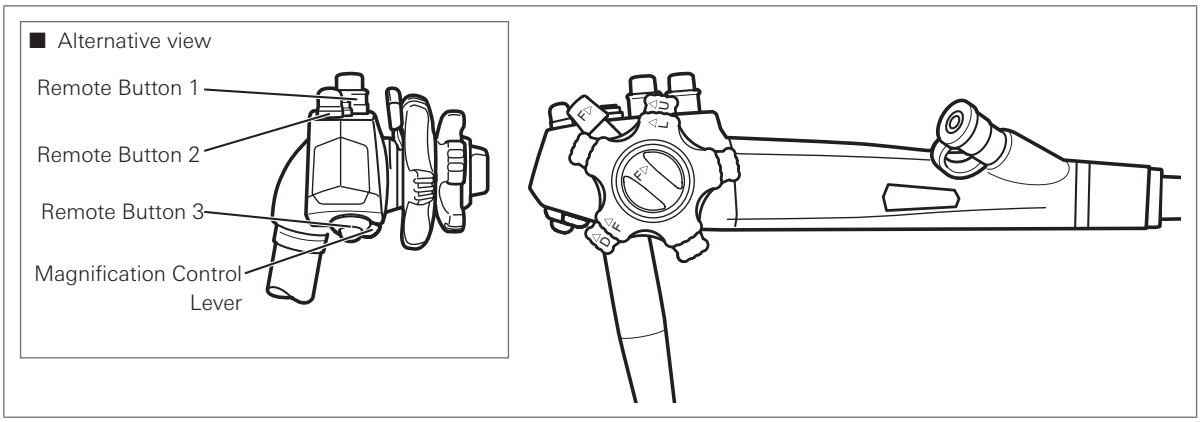
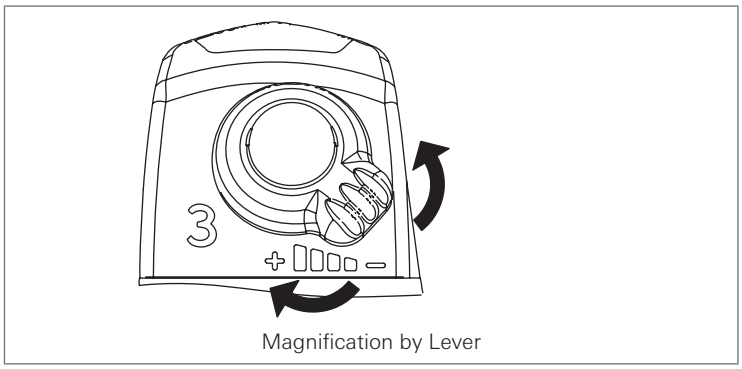


Figure 3.53

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

Inspection of the optical magnification function



Magnification by Lever

Figure 3.54

1. When the endoscope is connected to the processor, the lens position initialization starts automatically. When the initialization is finished, the standard (non magnified) image will appear on the monitor.
2. Check that turning the magnification control lever on the control body clockwise zooms the image, and turning it counter-clockwise returns the display to the standard image size.
3. Check that the magnification changes one by one with each operation of the magnification control lever, and that the image keeps the same state when the finger is removed from the lever.

Caution

When the monitor image stays zoomed after connecting with the video processor, remove the endoscope from the processor once, make sure that the bending section and insertion section are in the straight state, and then connect it again. The initialization may NOT have finished correctly. If the image remains zoomed, stop using this product and contact your local PENTAX Medical service facility.

Note

The optical magnification function and electrical magnification function can be used together in this product, however, the magnification control lever of the 90Zi series can be used only for the optical magnification function. The magnification control lever cannot be used for the electrical magnification function.

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.

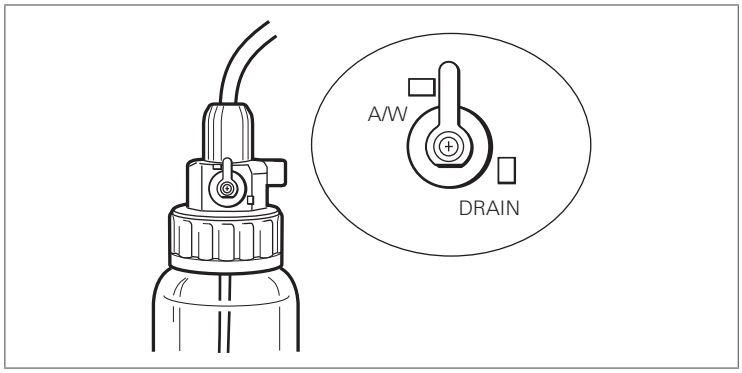


Figure 3.55

2. Press the pump button on the control panel of the video processor.
3. Set the pump level to “5” using the pump level setting button on the control panel of the video processor.
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 nozzle at the distal end of the endoscope. (The example shown in the figure is of the EC-3890Zi series)

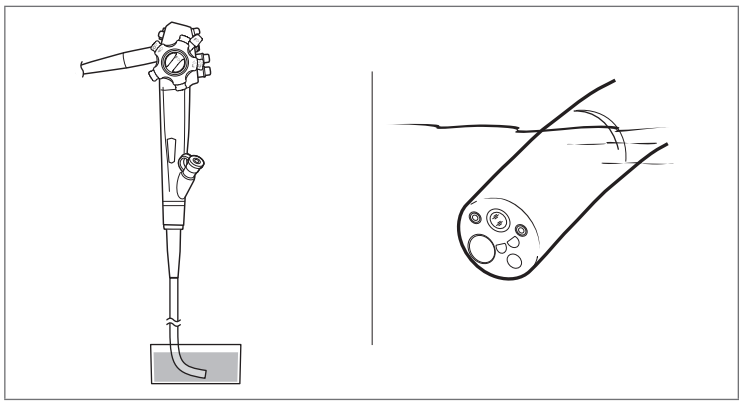


Figure 3.56

Warning

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 or perforation to the patient.

5. Block the hole in the top of the air/water feeding valve. Check whether air bubbles come out vigorously from the air/water nozzle of the distal end of the endoscope.

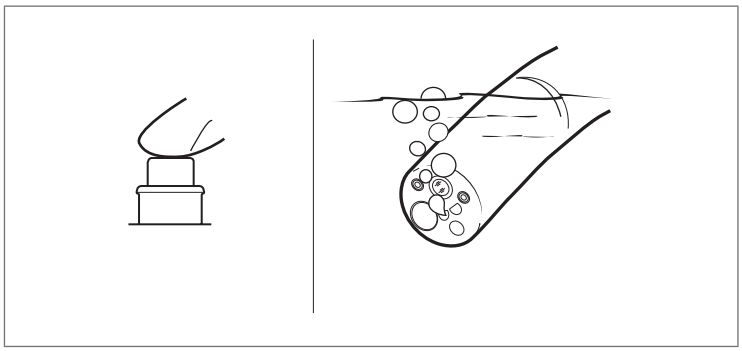


Figure 3.57

6. Check that the discharge of air bubbles stops when releasing the finger from the air/water feeding valve.

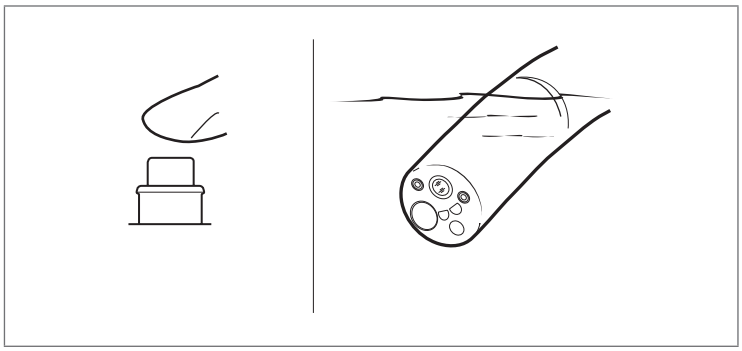


Figure 3.58

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.)

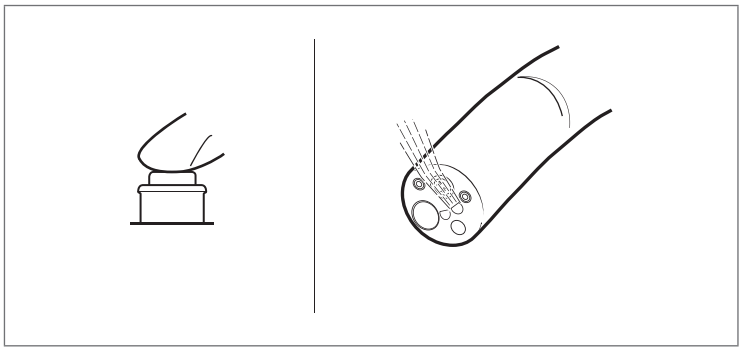


Figure 3.59

8. Remove the finger from the air/water feeding valve. Check that the air/water feeding valve returns to the original position smoothly and that the water stops at the same time as the finger is removed from the valve.

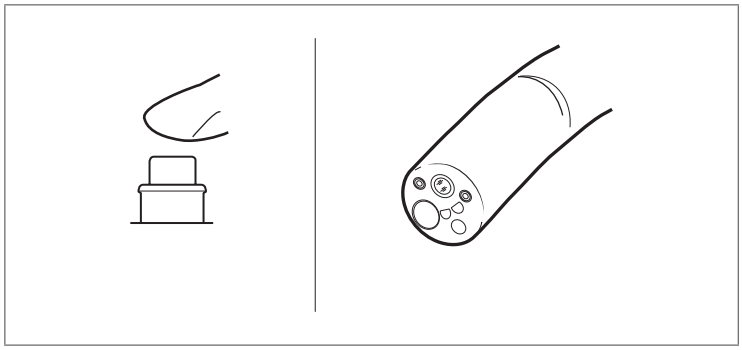


Figure 3.60

Caution

Do NOT attempt to clear the air or water nozzles with a needle or any other sharp object if nozzle blockage is suspected. It may result in lowered performance as well as damage to the endoscope.

Note

Do not attempt to correct the blockage or continue to use the endoscope, if air/water cannot be fed smoothly and blockage in the nozzle or channel of the endoscope is suspected. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired.

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, attach the syringe filled with sterile water, and insert it into the inlet seal (OF-B190).

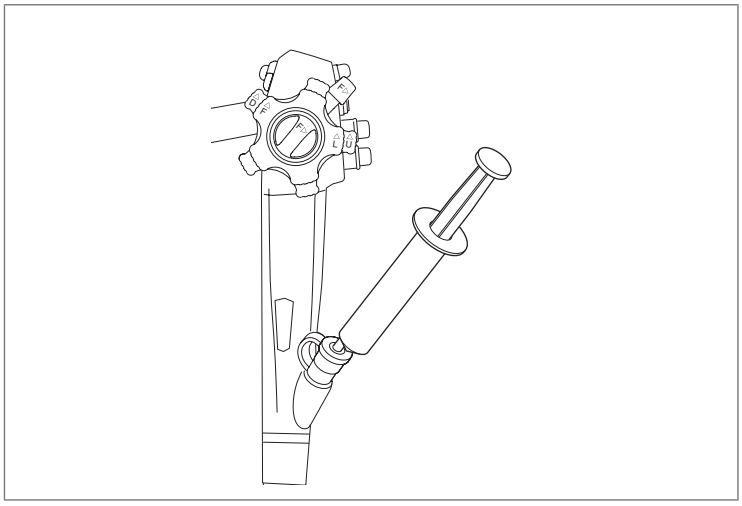


Figure 3.61

3. Check that sterile water comes out of the opening of the instrument channel when the syringe is pressed to flush the channel. Moreover, check that no foreign materials come out.
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, attach the cap to the inlet seal. Failure to do so may cause lowered suction function.

1. Turn on the suction source and adjust to an appropriate pressure 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. (The example shown in the figure is of the EC-3890Zi series)

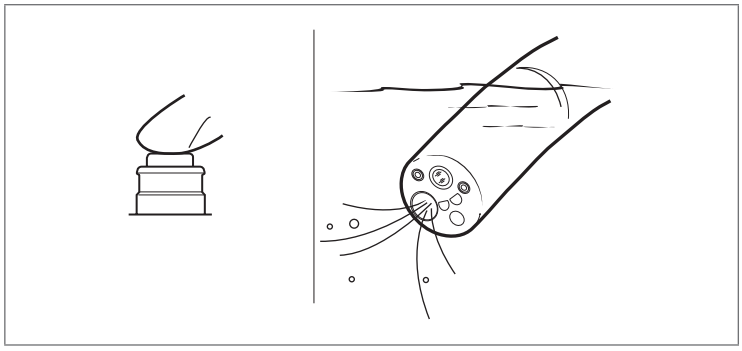


Figure 3.62

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

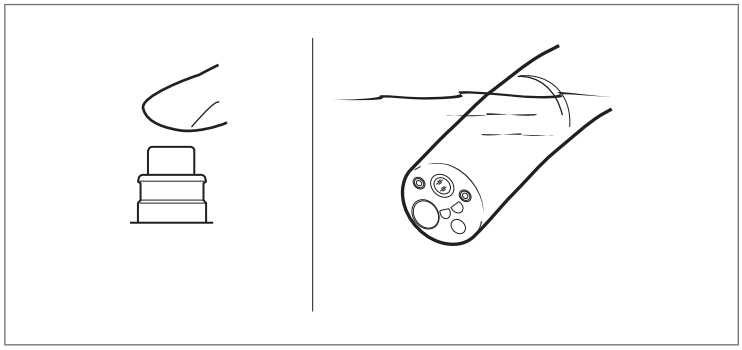


Figure 3.63

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. The inside of the channel may be damaged and it may result in 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. When the endoscope bending section is greatly angulated, it may NOT be possible to insert the forceps.

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

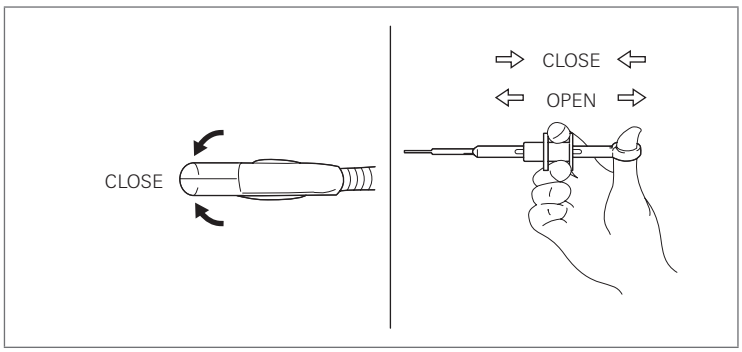


Figure 3.64

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. Hold the shaft at approximately 5cm from the cups and push the biopsy forceps through.

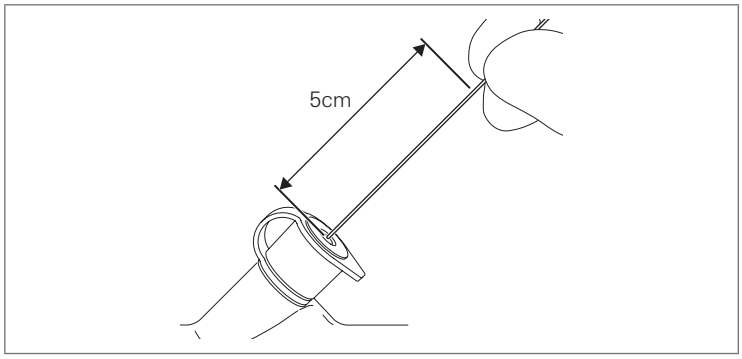


Figure 3.65

3. Slowly advance the biopsy forceps and check that its tip appears from the distal end of the endoscope. Moreover, check that no foreign materials come out.
4. Check that the biopsy forceps can be smoothly withdrawn from the inlet seal.

Inspection of the water jet feeding function

Warning

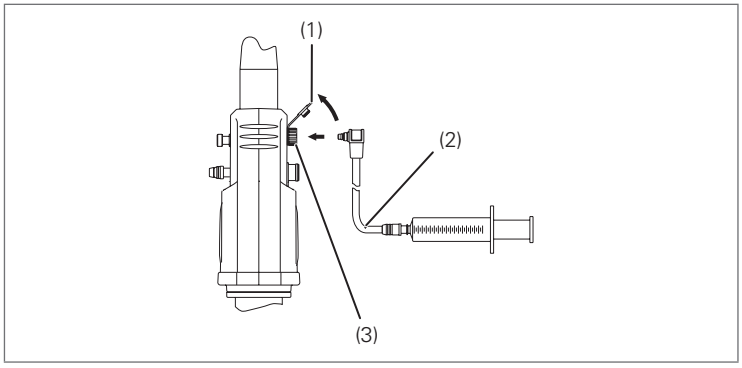
Use sterile water for inspection of the water jet feeding function. Failure to do so may pose a risk of infection.

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) and push tube for water pump irrigation or the irrigation tube (OF-B113) in until the water jet check valve adapter (OE-C12) clicks.

Note

Do not use the irrigation tube (OF-B113) if you have any difficulty in attaching or you could not feel a click feeling 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 3.66

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 the irrigation tube (OF-B113) if there is damage on the luer connector of the irrigation tube (OF-B113) and/or luer connection is not properly locked.

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.) (The example shown in the figure is of the EC-3890Zi series)

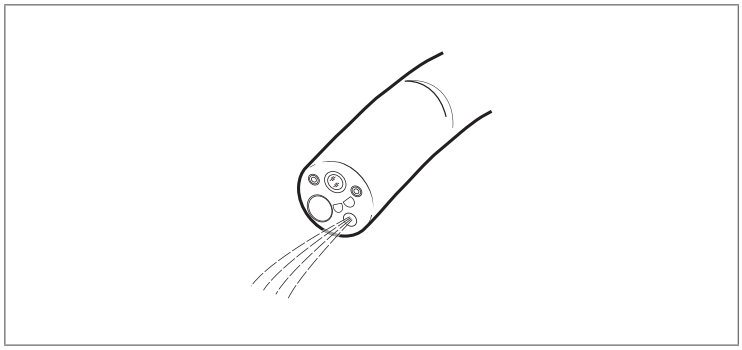


Figure 3.67

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).

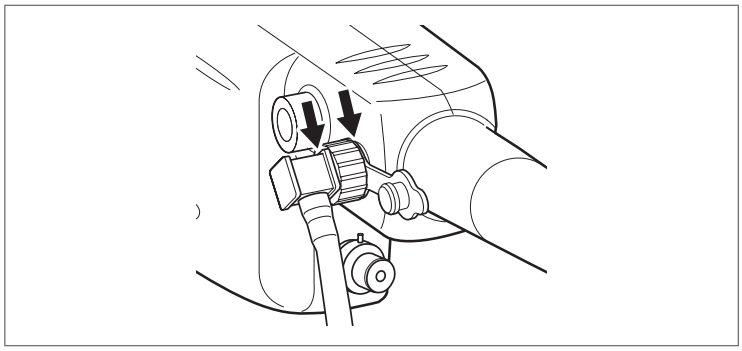


Figure 3.68

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 the 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

- 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 from endoscope components such as the instrument channel inlet and the suction control valve.
- Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when any abnormality, such as roughness, is felt during angulation. NEVER forcefully turn the angulation control lever. Continuing to use the endoscope with any abnormality may result in endoscope damage and/or patient injuries, including bleeding and perforation.
- NEVER withdraw the endoscope while the bending section is angulated. 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.
- Do NOT forcefully insert and withdraw the endoscope. Doing so may result in patient injury.
- When inserting the endoscope into narrow lumina, Do NOT rotate the endoscopic image using the video processor. Doing so may result in patient injury or make the withdrawal of the endoscope impossible.
- 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 "5-1. Withdrawal of an endoscope with an abnormality" (p. 74). Continuing to use the endoscope may result in patient injury.
- 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.

Caution

- 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.
- Do NOT use the endoscope with suspected adherence of patient's body fluid, blood, etc., on the light guide, as this causes the observation image to become dark. The temperature at the distal end of the endoscope may increase and result in mucosal injury to the patients.
- 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 use a water supply device that can exert 30kPa or greater of water pressure to the suction channel (suction valve) during endoscopic examination.

Note

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

4-1. Preparation immediately before insertion of the endoscope

Perform appropriate patient preparation for endoscopy as necessary.

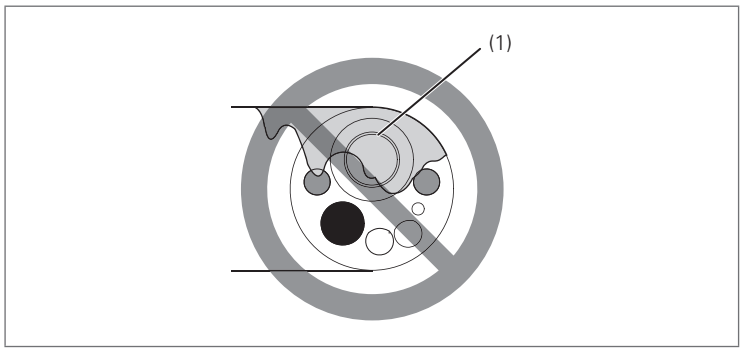
Caution

Do NOT spray or wipe the surface of the endoscope insertion portion with an anesthetic (particularly anesthetic spray containing alcohol) or non-medical lubricant (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 (only for EG-2990Zi).

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.



(1) Lubricant

Figure 4.1

4-2. Insertion and observation

Insertion of the endoscope

Caution

Do NOT forcefully bend the strain relief boot as shown (Figure 4.2). Doing so may result in endoscope damage.

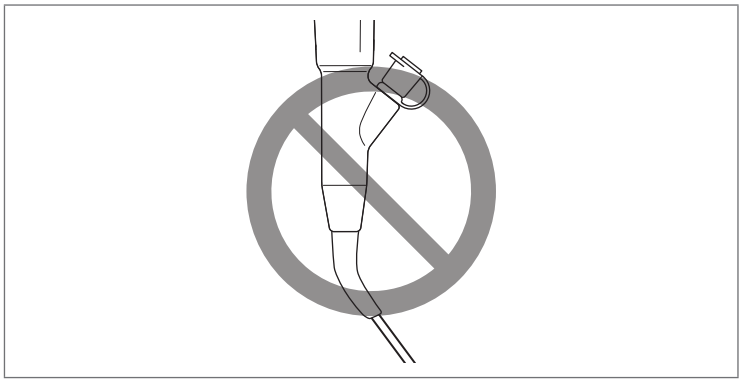


Figure 4.2

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

Note

Clear images cannot 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.

Angulation operation

Warning

Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when an abnormality, such as roughness, is felt during angulation. 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 according to the position 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

Warning

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, embolism, and perforation to the patient.

1. Set the appropriate pump level using the pump level setting button on the control panel of the video processor.
2. Cover the hole on top of the air/water feeding valve with a finger to feed air through the air/water nozzle at the distal end of the endoscope.
3. Press in 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.
- If the instrument/suction channel becomes blocked or clogged due to the accumulation of debris, an accessory that cannot 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, causing patient injury and/or posing a risk of cross contamination.
- 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, causing patient injury and/or posing a risk of cross-contamination.
- Securely attach the cap 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.

Caution

- 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 excessive 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 is suspected of the suction control.

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 for the irrigation pump 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 the irrigation tube (OF-B113) if there is damage of the luer connector of the irrigation tube (OF-B113) and/or luer connection is not properly locked.

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.

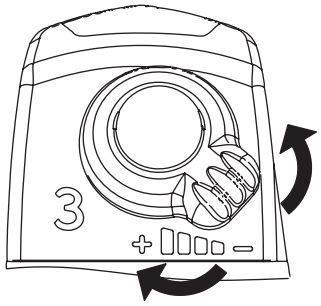
Optical Magnifying System

Warning

Ensure to insert the endoscope after turning the magnification control lever counterclockwise to return the standard size image. Under the magnified vision the field of view is limited, which worsens insertion operability and could result in a health hazard to the patient.

Note

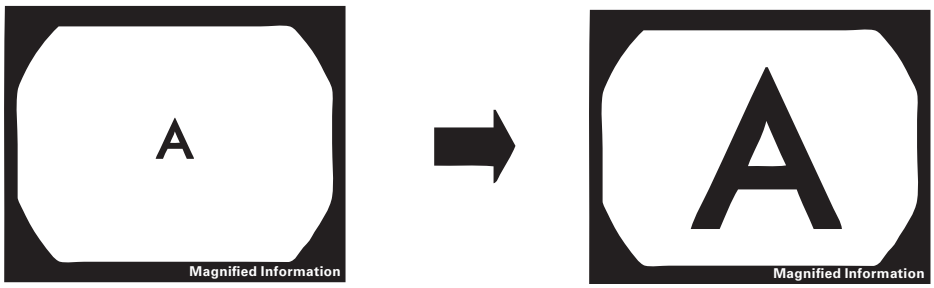
The optical magnification system gives change in the focal distance and the depth of field. Adjust the distance between the distal end of the endoscope and the observation area to obtain the optimum image. With the maximum magnification rate, the optimum image can be obtained with an observation distance of 2 to 3 mm from the observation area.



Magnification by Lever

Figure 4.3

1. Control the optical magnification system by the magnification control lever on the control body. Turning it clockwise magnifies the image, and turning it counterclockwise returns the image to the normal rate.
2. The operation speed of the magnification system can be adjusted in three stages: Low, Medium, and High. For how to change the operation speed, refer to the IFU of the respective video processor.
3. The figure below shows the monitor screen when the optical magnification system is in use. The information for the magnification is displayed in the lower right of the monitor screen. The "+" position in the magnification information shows the approximate magnification rate. On the normal rate of the image the mark "+" is positioned in the left end, and moves to the right with the magnified operation. With the maximum magnification rate, the mark "+" is displayed in the right end. When using EPK-i7000, the mark "▼" moves from left to right.



Normal

Optical Magnification

Figure 4.4

Note

The optical magnification system is also available using the foot switch. Each pressing of the foot switch can switch the magnification rate in four steps, from the normal rate (or the largest magnification rate) to the largest magnification rate (or the normal rate). For how to allocate the magnification system to the foot switch, refer to the IFU of the respective video processor.
The magnification system allocable to the foot switch can be allocated to the remote buttons 1 to 3 of the endoscope. For how to allocate the magnification system to the remote button of the endoscope, refer to the IFU of the respective video processor.

Electrical magnifying system

The electrical magnification system is available when this magnification system is allocated to the control panel, keyboard, or foot switch of the video processor, as well as to the remote buttons of the endoscope. For how to allocate the magnification system to the remote buttons of the endoscope, refer to the IFU of the respective video processor.

4-3. Using an endoscopic device

Warning

- NEVER use an endoscopic device showing 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 the endoscopic device may result in damage to the endoscopic device and patient injury.
- 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.
- 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.
- 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 from the instrument channel inlet while the instrument channel is clogged, the suction control valve may detach and result in potential reflux or dispersal of patient fluids, posing a risk of infection.
- Immediately stop the endoscopic procedure if the endoscopic device cannot 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 potential reflux or dispersal of patient's body fluids, posing a risk of infection.

Caution

- Do NOT forcefully insert the endoscopic device when the instrument channel is clogged, as this may result in damage to the endoscope.
- Constantly check the endoscopic image while cautiously inserting and withdrawing the endoscopic device.
- Keep the endoscope bending section as straight as possible when inserting and withdrawing the endoscopic device. Forcefully inserting and withdrawing the endoscopic device may result in damage to the instrument channel and endoscopic device and/or patient injury.

Note

The minimum instrument channel width is found on the model name 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 for the first time. Hold the shaft at approximately 5 cm away from its end, and press it in.

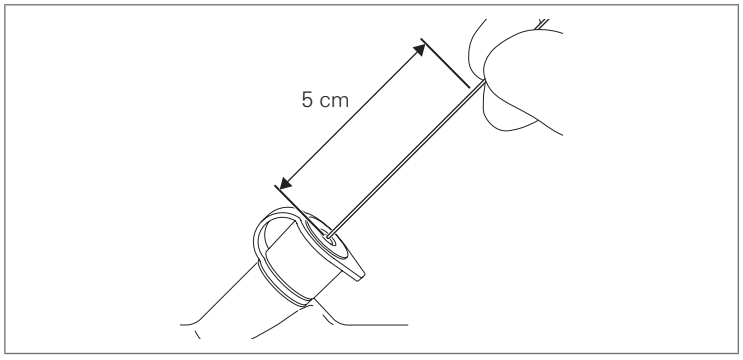


Figure 4.5

2. Slowly insert the endoscopic device, and check that the distal tip of the endoscopic device is within the field of view.

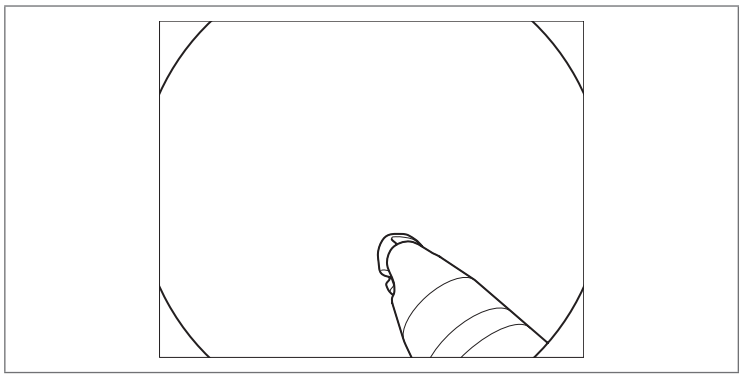


Figure 4.6

3. 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 lowered suction function 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. 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 against the inlet seal.
- Immediately stop the therapeutic procedure if significant resistance is encountered when withdrawing the endoscopic device or if the endoscopic device cannot 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 against the inlet seal.

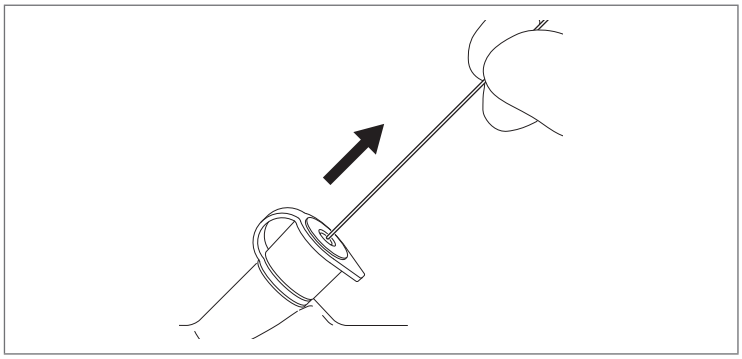


Figure 4.7

4-4. Using a non-flammable gas

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

Warning

- Do NOT use non-flammable gas cylinders whose pressure and flow settings cannot 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 cannot 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.
- 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 a pain, embolism, and perforation to the patient.

Caution

- Perform adequate ventilation when using a non-flammable gas in a small room prolong period of time. An elevated CO_2 concentration in the room may pose a risk of negative effects to the physical condition of the patient and/or user.
- Turn off the air/water feeding pump of the video processor before opening/closing the gas cylinder. If the gas cylinder is opened without turning it off, excessive load is applied to the air/water feeding pump of the video processer, which may result in damage to the air/water feeding pump.

Note

Use of the optionally available gas/water feeding valve (OF-B194) is recommended instead of the air/water feeding valve to prevent gas leakage into the room. 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.

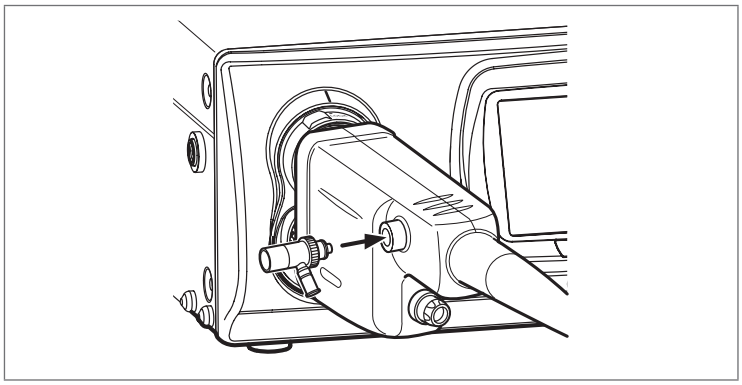


Figure 4.8

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

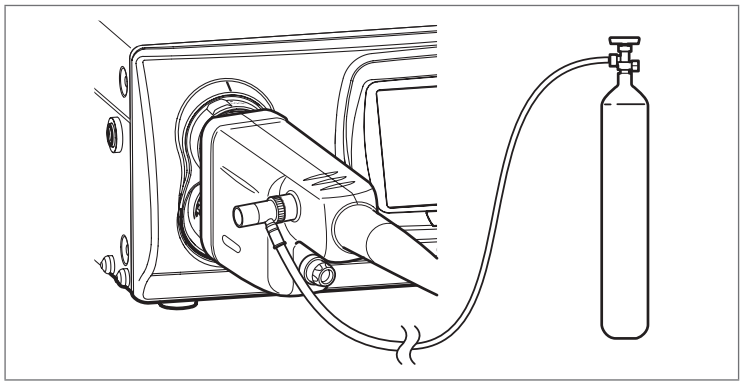


Figure 4.9

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

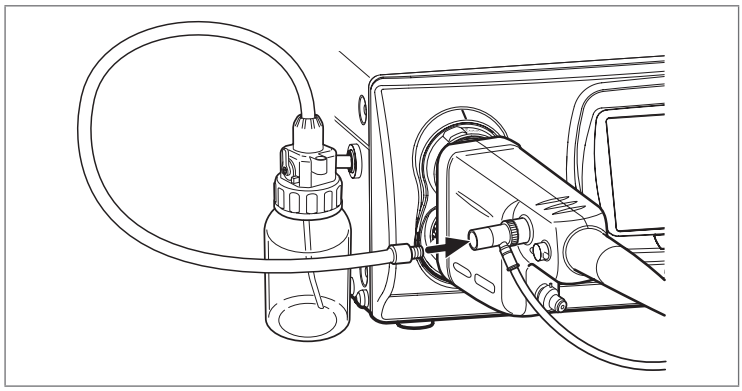


Figure 4.10

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

4-5. Laser cauterization

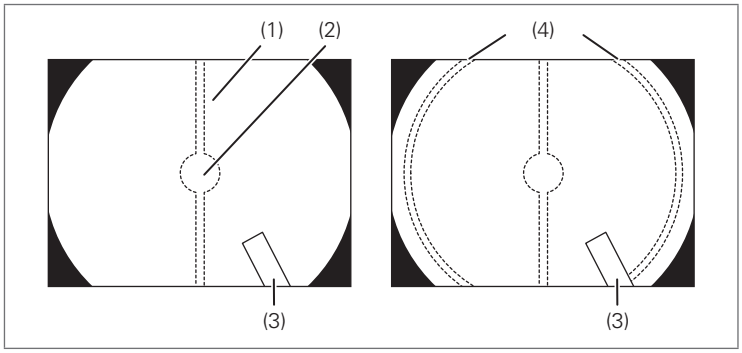
Warning

- Laser equipment should be used only by experts who have thorough knowledge of the laser equipment and endoscopic laser treatment.
- Before using the laser equipment, thoroughly read the manual supplied 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 Nd:YAG laser (wavelength 1064 nm) or a laser with a wavelength of 800–1000 nm only.
- 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 the 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, convert the gas to a non-flammable 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 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 via 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.
- If the distal end of the endoscope is within 20 mm of the irradiated target surface, the guide beam may create a smear in the image. If such a smear affects visibility of the target, decrease the intensity of the light.
- 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, a flare may appear at the corners of the image.



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

Figure 4.11

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 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.
- 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, convert the gas to a non-flammable 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 in 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 energization time, as it can result in patient injury.
- Before using an electrosurgical device, check the entire surface of the endoscope for any abnormalities such as cracks and exposure of internal metals. Failure to do so may result in burns from high-frequency current.

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 generators may be of the floating (Type BF or Type CF) or non-floating (Type B) types. Only use floating-type high frequency generators to avoid patient and user burns.
- There are two types of floating-type high frequency generators: those with an endoscope feedback cord (S-cord) and those without.
  1) High frequency generator with an S-cord: Connect the S-cord to the feedback terminal located on the PVE connector of the endoscope.
  2) High frequency generator without an S-cord: Connect the condenser earth cable (OL-Z4/OL-Z3) between the endoscope feedback terminal and the video processor potential equalization terminal.

  Follow the directions for each type described above, as failure to do so may result in burns from high-frequency current.
- Only use insulated devices. Failure to do so may result in burns from high-frequency current.
- Ensure that the distal tip of the electrosurgical device is adequately projecting from the distal end of the endoscope before operating it. Failure to do so may result in endoscope damage.
- 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 the 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 via the inlet seal as described in “4-3. Using an endoscopic device”.

4-7. Withdrawal of the endoscope

Warning

- When withdrawing the endoscope, prevent dispersal of patient’s body fluids by holding clean gauze along the insertion portion. Failure to do so may pose a risk of infection.
- Before withdrawing the endoscope, do NOT remove the water bottle assembly from the video processor while the water bottle assembly is connected to the endoscope. Doing so may result in reflux of patient’s body fluids into the water bottle assembly.
- Do NOT withdraw the endoscope while the bending section is angulated. Doing so may result in patient injury.

1. Operate the suction control valve to suction any fluid remaining inside the patient’s body cavity.
2. If the electrical magnifying function used, set it back to standard image size.
3. 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.
4. While checking the endoscopic image, slowly and cautiously withdraw the endoscope.
5. Remove the bite block from the patient’s mouth. (Only for EG-2990Zi)
6. Turn the video processor lamp off.

4-8. Care after use

Caution

Do NOT touch the light guide plug and electrical contacts after use. It could result in burns.

■ 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) (Only for EG-2990Zi), water jet check valve adapter (OE-C12), water jet connector cap (OF-B118), irrigation tube (OF-B113), distal hoods (OE-A58/OE-A59), 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 IFUs 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 PVE 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 cleaning in the examination room, turn off power of the video processor.

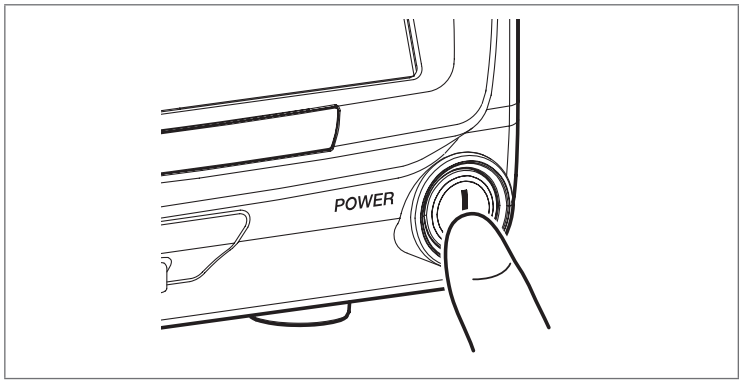


Figure 4.12

3. Turn the endoscope locking lever to the “OPEN” position; then, hold the endoscope PVE connector and remove the endoscope electrical contacts and light guide plug from the processor connector and receptacle.

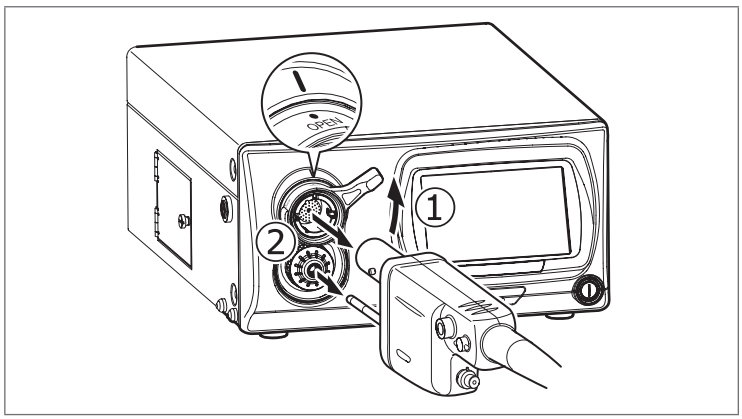


Figure 4.13

Note

- If the video processor connected has a scope eject function, the PVE connector can be removed when the power of the video processor is turned on by using the scope eject function of the video processor. For details, refer to the IFU of the respective video processor.

5 Troubleshooting

After inspecting the endoscope according to "Chapter 3 Preparation and inspection", if any abnormality is suspected, do not use the endoscope; send the endoscope for repair according to "5-2. Returning the endoscope for repair" (p. 75).

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. 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 the endoscopic device, close the distal tip or retract it within the sheath. Then, 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 the endoscopic device, close the distal tip or retract it within the sheath. Then, 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.

5-2. 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 subject the endoscope to cleaning and high-level disinfection 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.

1. Place this endoscope in the dedicated carrying case. Ensure that the PVE soaking cap is included for water leakage test.
2. When transporting by air, ensure that the ventilation cap is attached to prevent damage to the endoscope.
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 inform us the description of failures that need repair, model name, serial number, and name/phone number/address of the contact person.

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 the endoscope(s).

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	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	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 (50/60Hz) 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

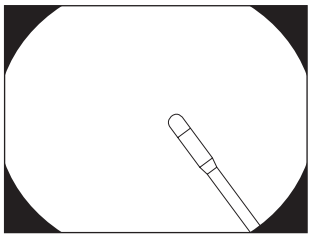
This product is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters)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

Endoscope specifications

Model Name		EG-2990Zi	EC-3890FZi	EC-3890MZi	EC-3890LZi
Direction of view		Forward (0°)			
Field of view		Normal observation (WIDE): 140°, Observation with the maximum zooming (TELE): 49°			
Depth of field		Normal (WIDE): 5-100mm	Normal (WIDE): 4-100mm		
Magnification method		Optical/electrical			
Tip angulation	Up–Down	210°-120°	180°-180°		
	Right–Left	120°-120°	160°-160°		
Rigid distal width		Ø10.6mm [Ø12.6mm]	Ø13.0mm [Ø15.0mm]		
Distal end width		Ø10.2mm [Ø12.0mm]	Ø12.0mm [Ø14.4mm]		
Insertion tube width		Ø9.8mm	Ø13.2mm		
Maximum insertion portion width *1		Ø11.6mm [Ø12.9mm]	Ø14.65mm [Ø15.3mm]		
Minimum instrument channel width *2		Ø2.8mm	Ø3.8mm		
Endoscopic device view on the endoscopic image					
Insertion Tube Working Length *1		1,050mm [1,053mm]	1,500mm [1,503mm]	1,300mm [1,303mm]	1,700 mm [1,703mm]
Total Length		1,376mm [1,379mm]	1,825mm [1,828mm]	1,625mm [1,628mm]	2,025 mm [2,028mm]
Laser cauterization		Available			
Electrosurgery treatment		Available			
Water jet feeding function		Available			

[ ]: Values when a distal hood is attached

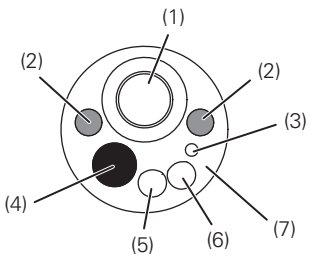
Specifications are subject to change without prior notice and without any obligation on the part of the manufacturer.

*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.

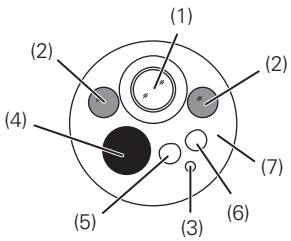
*2 There is no guarantee that equipment selected solely using this minimum instrument channel width will be compatible when used in combination.

Distal End

EG-2990Zi



EC-3890Zi series



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

System chart

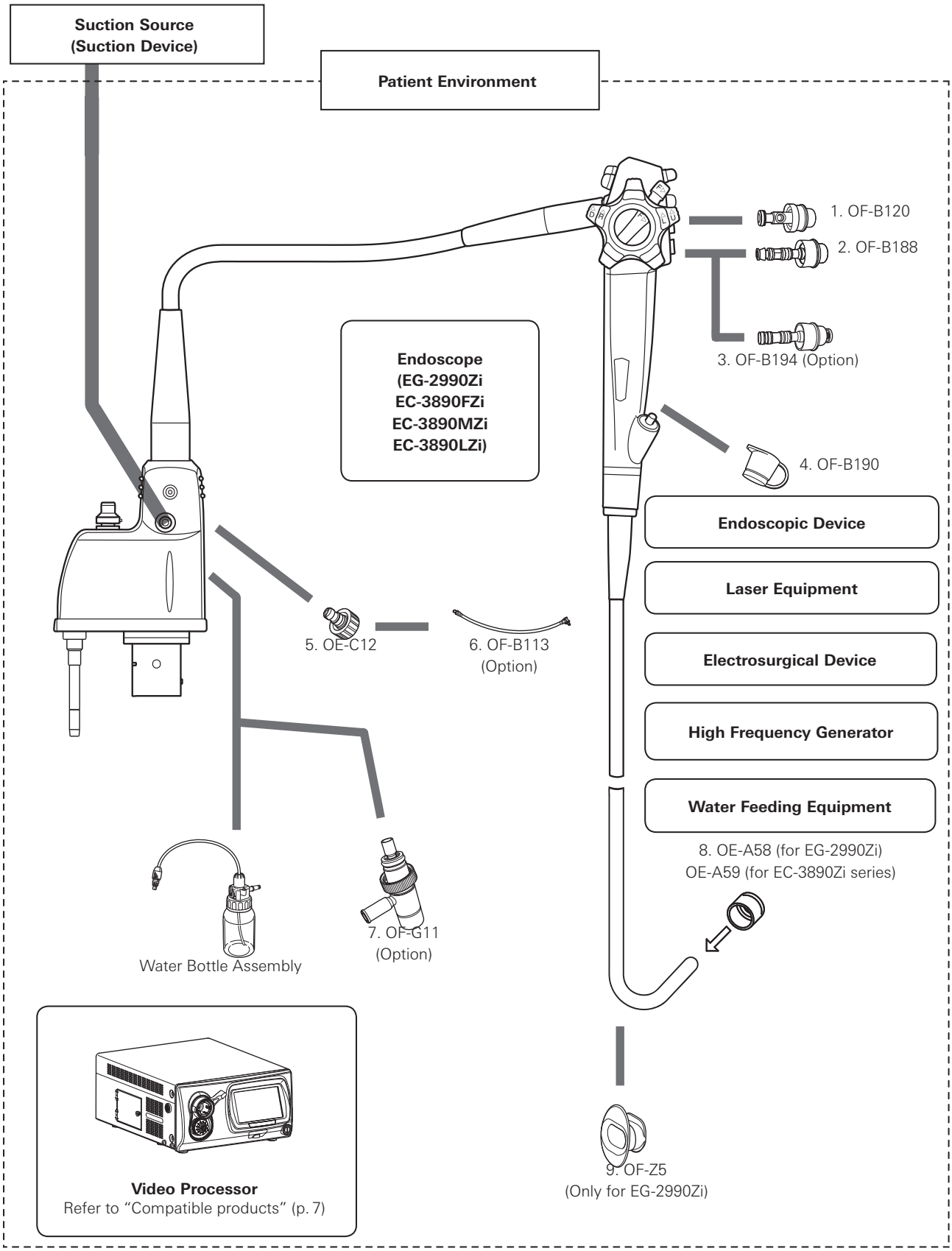
This section shows the system chart (configuration) for this endoscope and the ancillary equipment.

Warning

Use this product in combination only with compatible products shown in “Compatible products” (p. 7) 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 Equipment
4. Inlet Seal (OF-B190)
5. Water Jet Check Valve Adapter (OE-C12)
6. Irrigation Tube (OF-B113)
7. Gas Adapter (OF-G11*) *Optional Equipment
8. Distal Hood OE-A58 (for EG-2990Zi) OE-A59 (for EC-3890Zi series)
9. Bite Block (OF-Z5) (Only for EG-2990Zi)

Software Version

EG-2990Zi	00B3C-4
EC-3890Zi series	

Contacts

Manufacturer

HOYA Corporation
6-10-1 Nishi-shinjuku,
Shinjuku-ku, Tokyo
160-0023 Japan

Distributors

PENTAX Europe GmbH EC REP
Julius-Vosseler-Straße 104
22527 Hamburg, Germany
Tel: +49 40 561 92-0
Fax: +49 40 560 42 13

PENTAX Medical
A Division of PENTAX of America, Inc.
3 Paragon Drive
Montvale, NJ 07645-1782
USA
Tel: +1 201 571 2300
Toll Free: +1 800 431 5880
Fax: +1 201 391 4189

PENTAX Medical Shanghai Co., Ltd.
Room 701, 291 Fumin Road, Shanghai
200031 P. R. China
Tel: +86 21 6170 1555
Fax: +86 21 6170 1655

PENTAX Medical Singapore Pte. Ltd.
438A Alexandra Road, #08-06
Alexandra Technopark, 119967 Singapore
Tel: +65 6507 9266
Fax: +65 6271 1691
Customer Service Toll Free:
400 619 6570 (within China)
1800 2005 968 (within India)
1300 PENTAX (within Australia)

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