PENTAX MEDICAL

Instructions for Use

PENTAX GI Fiberscope

Model Name:

FD-34V2

FG-16V

FG-24V

FG-29V

FC-38FV

FC-38LV

FS-34V

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 fiberscope 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 fiberscope for any purpose other than its intended use.

In addition, review and fully understand the contents of this IFU. 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 fiberscope, accessories, and/or on their packaging are as follows:

Symbol	Description
	Caution
	Date of Manufacture
	Type BF applied part
	Do not re-use
	Follow the Instructions for Use
	Manufacturer
EC REP	Authorized representative in the European Community
CE 0123	The CE mark confirms the compliance to applicable European (EU) requirements.
SN	Serial number
	*If this bar code symbol is displayed on the product, see the following explanation. This is a UDI (Unique Device Identification) code required by Unique Device Identification System designed to adequately identify devices through distribution and use. The following information is coded in 2D bar code (GS1 Data Matrix). - (01) GS1 Commodity code (Global Trade Item Number) - (11) Production date - (21) Serial number

Prescription Statement

Federal (U.S.A) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

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Important information: Please read before use

Product summary

This fiberscope captures observation subjects under light transmitted from a dedicated light source and transmits it to the ocular section by optical fiber bundle. The image can be enlarged using the ocular lens to observe the intended area.
Endoscopic devices can also be inserted through the instrument channel inlet of the control body to perform treatments.
Angulation operation of the bending section can be done using the angulation control lever on the control body and suction adjustment can be done from the channel at the distal end of the fiberscope using the suction control valve.

Intended use

(Duodenoscope)

The Duodenoscope is intended to provide optical visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes, but is not restricted to, the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts.
This instrument is introduced per orally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

(Gastoroscopes)

These Gastroscopes are intended to provide optical visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes, but is not restricted to, the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and Small Bowel.
These instruments are introduced per orally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

(Colonoscopes and Sigmoidoscopes)

These Colonoscopes and Sigmoidoscopes are intended to provide optical visualization of, and therapeutic access to, the Lower Gastrointestinal Tract. The Lower Gastrointestinal Tract includes, but is not restricted to, the organs, tissues, and subsystems: Large Bowel.
These instruments are introduced per rectally when indications consistent with the requirement 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 fiberscope by the physicians (pediatric to adult patients).
Intended anatomical area	FD-34V2: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts FG-16V, FG-24V, FG-29V: Esophagus, Stomach, Duodenum and Small Bowel FC-38FV, FC-38LV, FS-34V: Large Bowel
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 fiberscope is not required.
Location of use	A medical facility (including the place where the high frequency generator is used)

Classification

Degree of protection against electric shock for the applied parts	TYPE BF applied part (when connected to a compatible PENTAX Medical light source)
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

■ Fiberscope specifications

For details, refer to “Specifications” (p. 96).

Compatible products

This section describes the equipment that can be used in combination with this fiberscope. For more details, refer to “System chart” (p. 97).
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.
- When this fiberscope 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.

Note

Some products are not available depending on the sales region. For details, contact your local PENTAX Medical service facility.

■ Light source

Light source models that can be connected with this fiberscope are shown below.
For instructions on light source operation, refer to the IFU of the respective light source.

Model Name	Brand Name
LH-150PC	PENTAX Medical
LX-750P	

■ Other ancillary equipment

They are intended to be used in a medical facility including the place where the high frequency generator is used. For instructions, refer to the respective manual provided with each equipment.

Category	Description	Model Name	Brand Name
High Frequency Generator	ICC Series	ICC 350	ERBE
		ICC 200	
	VIO Series	VIO 300D	
		VIO 200S	

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

■ Reprocessing before the initial use

The fiberscope 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 this IFU 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 fiberscope 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 fiberscope may result in its non-optimal function of and/or damage to the fiberscope 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 endoscopes and equipment. The endoscope and equipment used on these patients must be discarded so that they can NOT be used again on another patient.
The pathogenic agents that cause this disease, which are called “prions”, can NOT be destroyed or inactivated using the cleaning, disinfection, and sterilization methods presented in this IFU.
Please consult the guidelines that apply to your country or region for more detailed information regarding the handling of prion-contaminated endoscopes.

General warnings and cautions

Warning

- The medical facility should determine restrictions or non-use of the fiberscope 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 fiberscope for any purpose other than its intended use. Doing so may result in patient injury.
- Do NOT use this fiberscope with equipment other than those that have been specified for combined use. Fiberscope operation in the freeze or magnification mode may result in damage to the fiberscope and patient injury.
- Do NOT drop this fiberscope or apply a strong shock to it. Doing so may result in damage to the fiberscope. 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 control body such suction nipple, air/water port, venting connector, or feedback terminal according to the IFU. Incorrect connection or inappropriate use may result in unforeseen events.
- Always check the endoscopic image during fiberscope angulation and suctioning, use of endoscopic devices, and fiberscope insertion and withdrawal.
- Do NOT forcefully insert and withdraw the fiberscope. 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 fiberscope.
- After using operational/cleaning accessories (e.g., forceps, needles, snares, brushes etc.) with the endoscope, carefully check that all accessories are intact and that no parts have fallen off and become lodged within the endoscope's instrument/suction channel. Furthermore, ensure that any endoscopic devices (e.g., clips, stents, etc.) passed through the channel are accounted for after use. If the instrument/suction channel becomes blocked or clogged due to the accumulation of debris, an accessory that can NOT be removed, or other cause, do NOT attempt to correct the blockage or continue to use the endoscope. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired. The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or the introduction of debris and/or device components into a patient during a subsequent procedure, posing a risk of cross contamination.
- This product is intended to be used in the electromagnetic environment specified by "Electromagnetic disturbances". Using the product in an unintended environment may result in incorrect exposure control of the light emitted from distal end of the endoscope due to electromagnetic interference.

Caution

- Do NOT excessively twist, rotate, or bend any of the insertion portions, strain relief boots, or umbilical cable. Doing so may damage the fiberscope.
- Do NOT attach or remove the light guide connector of the fiberscope while the power of the light source is turned on. Doing so may damage the fiberscope.
- 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 fiberscope or shield the location of use.

Maintenance management

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

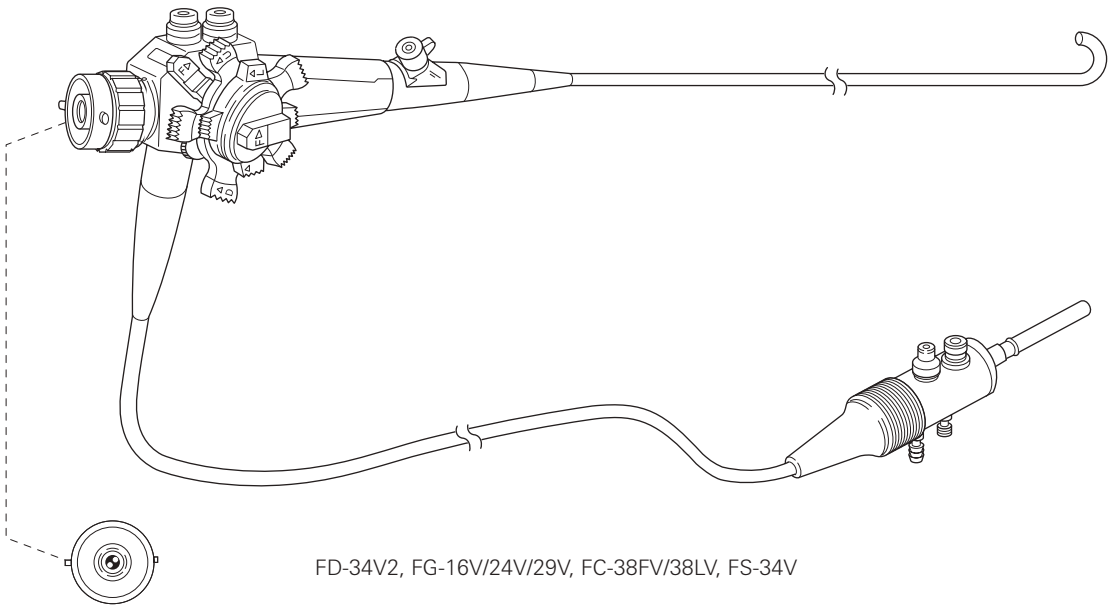
- Perform inspection before use, care after use, storage, and replacement of consumables according to this IFU.
- Have a specialist specified by PENTAX Medical perform repairs and at least annual periodic inspections.

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 fiberscope; immediately contact your local PENTAX Medical service facility (Optional depending on the model.).

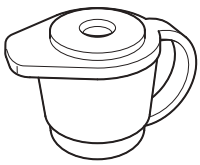
■ Fiberscope



FD-34V2, FG-16V/24V/29V, FC-38FV/38LV, FS-34V

Figure 1.1

■ Accessories



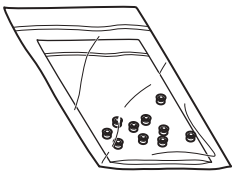
Inlet Seal (OF-B190)
(Installed)

Ventilation Cap (OF-C5)

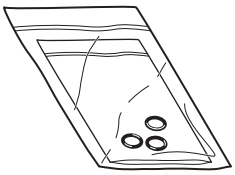
Silicone Oil (OF-Z11)

Figure 1.2

■ Accessories



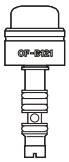
Check Valve Sets (OE-C15)



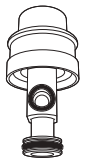
O Ring Set (OF-B127) *1

Cleaning Brush (CS-C5)

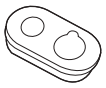
Cleaning Brush
(CS6021SN for all models)
(CS6015ST additionally for FG-16V/24V)



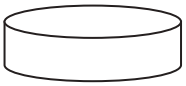
Air/Water Feeding Valve (OF-B121)
(Installed)



Suction Control Valve (OF-B120)
(Installed)



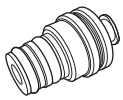
Air/Water/Suction Channel
Cleaning Adapter(OF-B115)



Eyepiece Cap (OF-D1)
(Installed)

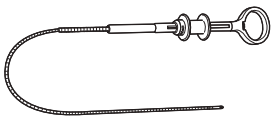
Eyeshield (OF-D3)

Bite Block (OF-Z5)
(Only for FD-34V2, FG-16V, FG-24V, and FG-29V)



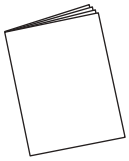
Cleaning Adapter
(OF-G17)

■ Endoscopic device *2

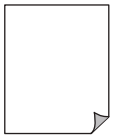


Biopsy Forceps with Window
(FD-34V2: KW2218CS)

■ Others



IFU (this document)



Standard Accessories List

Figure 1.2

*1: For Suction Control Valve (OF-B120)
*2: This is an optional device depending on the sales region.

2 Nomenclature and functions

2-1. Control body, insertion portion

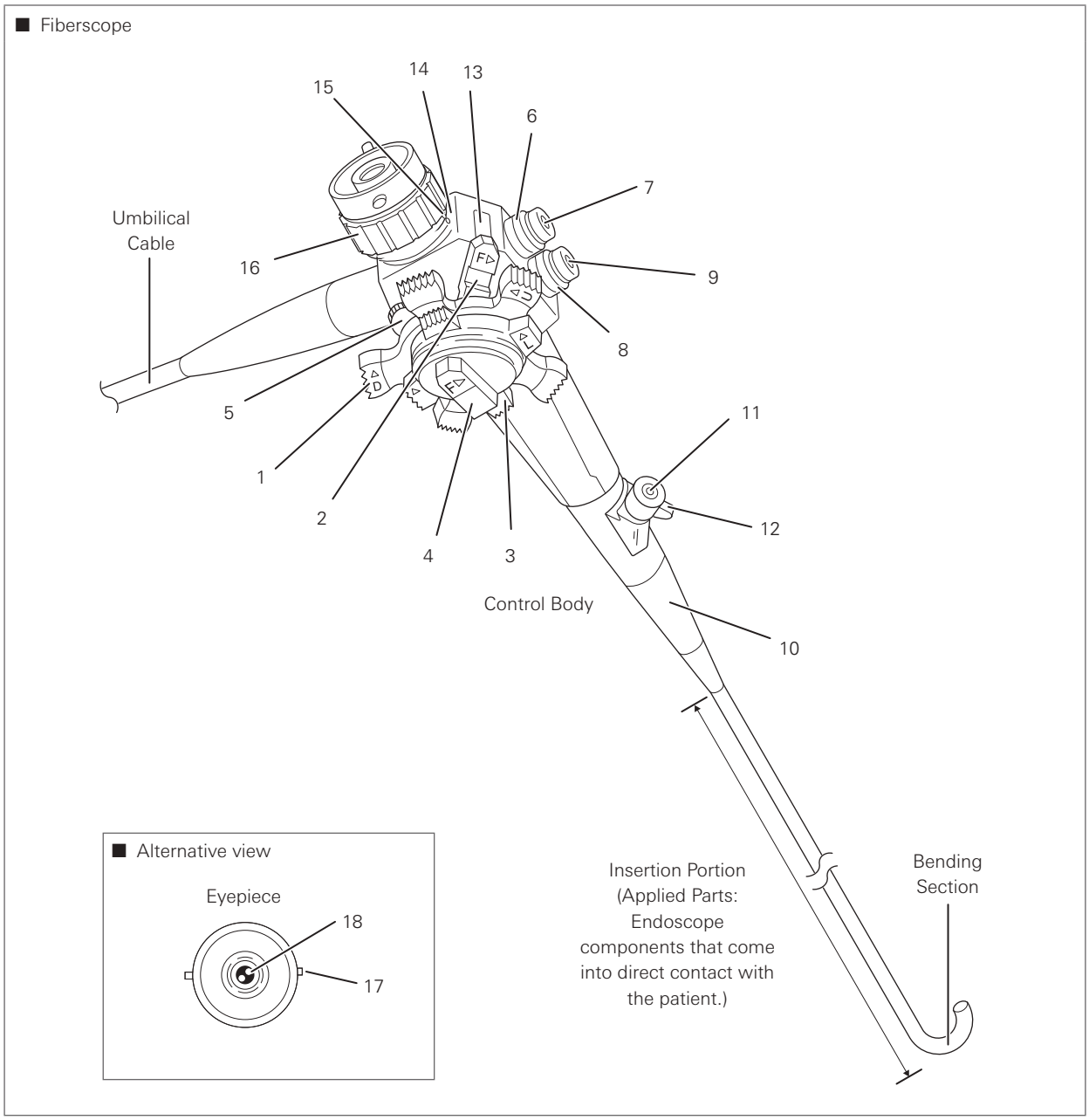


Figure 2.1

The functions related to the following parts are frequently used.

1. 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.
2. (Only for FD-34V2) 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.
3. 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.
4. 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.
5. Cannula Elevator Control Knob (Only for FD-34V2)
   To guide and direct cannula elevator or forceps.
6. Suction Cylinder
   Attach the suction control valve (OF-B120).
7. Suction Control Valve (OF-B120)
   Attach to the suction cylinder. Depress it to suction fluids or air through the instrument channel of the fiberscope.
8. Air/Water Feeding Cylinder
   Attach the air/water feeding valve (OF-B121).
9. Air/Water Feeding Valve (OF-B121)
   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 fiberscope. Depressing the valve feeds water from the water nozzle.
10. Strain Relief Boot
    The strain relief boot protects the connecting parts.
11. Instrument Channel Inlet
    The instrument channel inlet is an inlet for endoscopic devices. Attach the inlet seal (OF-B190).
12. Inlet Seal (OF-B190)
    The inlet seal is attached to the instrument channel inlet to avoid fluid/air leakage.
13. Model Name Label
    The model name label shows the model name.
14. Immersible Marking
    The blue line here indicates the scope is fully immersible.
15. Diopter positioning marks (white dots)
    Rotate the diopter adjusting ring to align the two positioning marks (white dots) when taking an image or when using the observer scope or a TV camera.
16. Diopter adjustment ring
    Rotate the ring to adjust the focus and enable visibility by the technician.
17. Bayonet pin
    This is used for positioning when attaching the imaging device.
18. Ocular lens
    Look into the lens to see the index in the field of view mask. The index indicates the upper side of the bend.

2-2. Connector

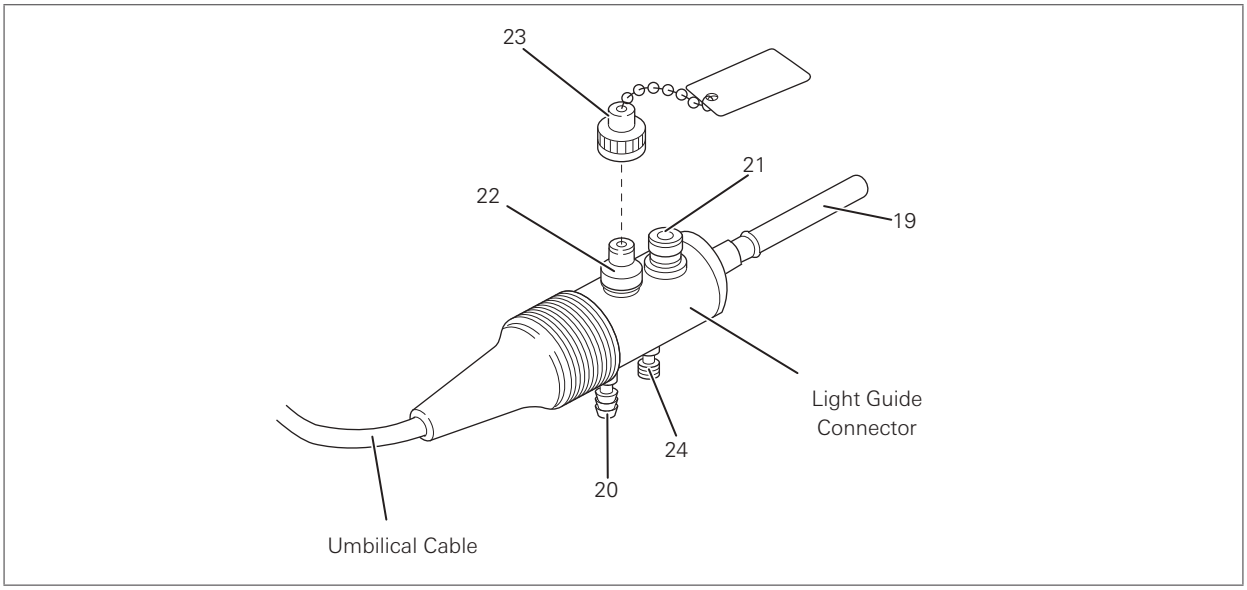


Figure 2.2

19. Light Guide
    The light guide transmits the light received from the light source to the distal end of the fiberscope.
20. Suction Nipple
    Connect the suction tube on the suction source to the suction nipple.
21. Air/Water Port
    Connect the air/water feeding hose on the water bottle assembly to the air/water port.
22. Venting Connector
    Attach the ventilation cap (OF-C5) or the endoscope connector of the leakage tester here.
23. Ventilation Cap (OF-C5)
    Be sure to attach this cap to prevent damage to the insertion portion when performing ETO gas sterilization. This cap must be removed before immersion.
24. Feedback Terminal
    When using an electrosurgical device, connect the High Frequency Generator 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 the product.)

3 Preparation and inspection

Before use, the fiberscope, accessories, light source, and other components must be prepared and carefully inspected according to the IFU. Any equipment used in combination with the fiberscope 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 fiberscope; send it for repair according to “6-3. Returning the fiberscope for repair” (p. 84).

Warning

Always perform pre-use inspection before each use. NEVER use a fiberscope with a suspected abnormality. Doing so may result in malfunction, fiberscope damage, and/or injury to the patient and/or user.

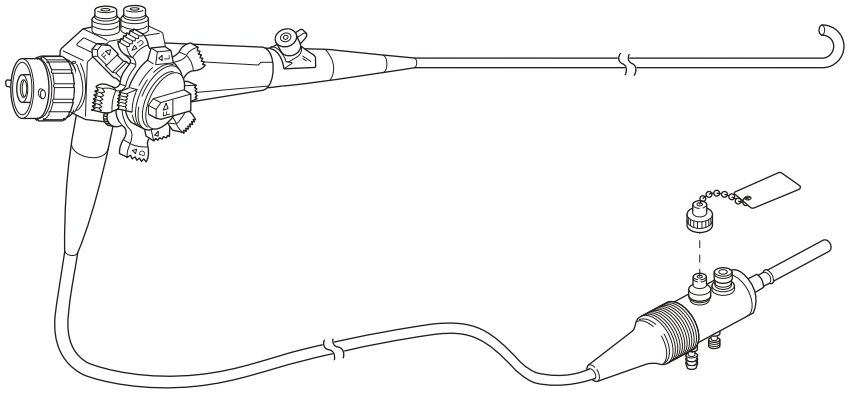
Caution

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

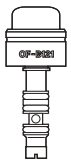
3-1. Preparation of the equipment

Prepare the fiberscope, 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 light source for its inspection.

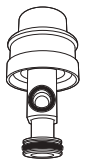
■ Fiberscope



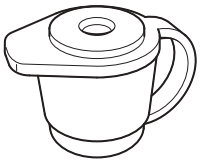
■ Accessories



Air/Water Feeding Valve (OF-B121)



Suction Control Valve (OF-B120)

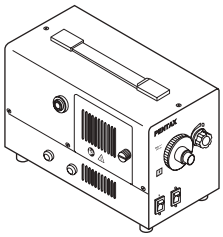


Inlet Seal (OF-B190)

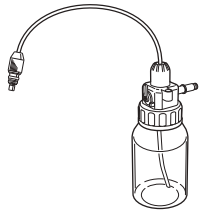
Silicone Oil (OF-Z11)

Figure 3.1

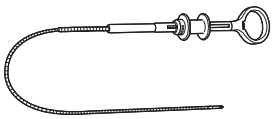
■ Ancillary Equipment



Light Source



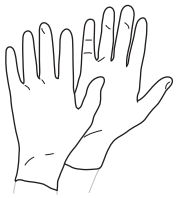
Water Bottle Assembly



Endoscopic Device

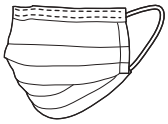
Suction Source

■ 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 fiberscope

Prepare a fiberscope that has been reprocessed according to the procedure specified in this IFU.

Warning

- NEVER disassemble or modify the fiberscope. Doing so may impair its original functionality and possibly result in serious injury to the patient and/or user.
- NEVER use a fiberscope with any abnormality. Doing so may result in fiberscope 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 fiberscope 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 (A) and 3.2 (B) to identify the strain relief boots). Doing so may result in instrument damage. Pay special attention to the careful handling of the strain relief boot of the insertion portion (See Figure 3.2 (A)) of the fiberscope, because it has a small diameter and is more likely to suffer damage due to mishandling.
- When carrying the fiberscope, do NOT grasp or carry it only by its umbilical cable or insertion portion. Moreover, do NOT squeeze or forcefully bend the bending section. (Figure 3.3) Doing so may result in equipment damage.

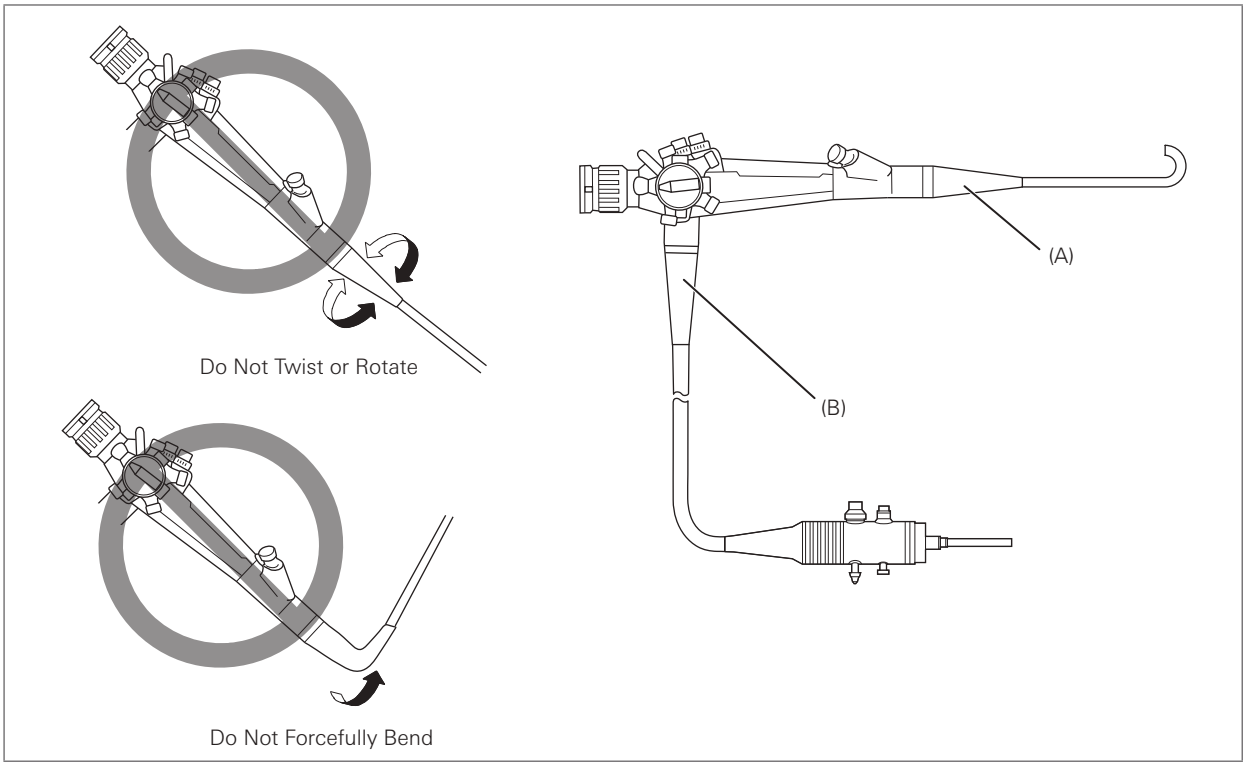


Figure 3.2

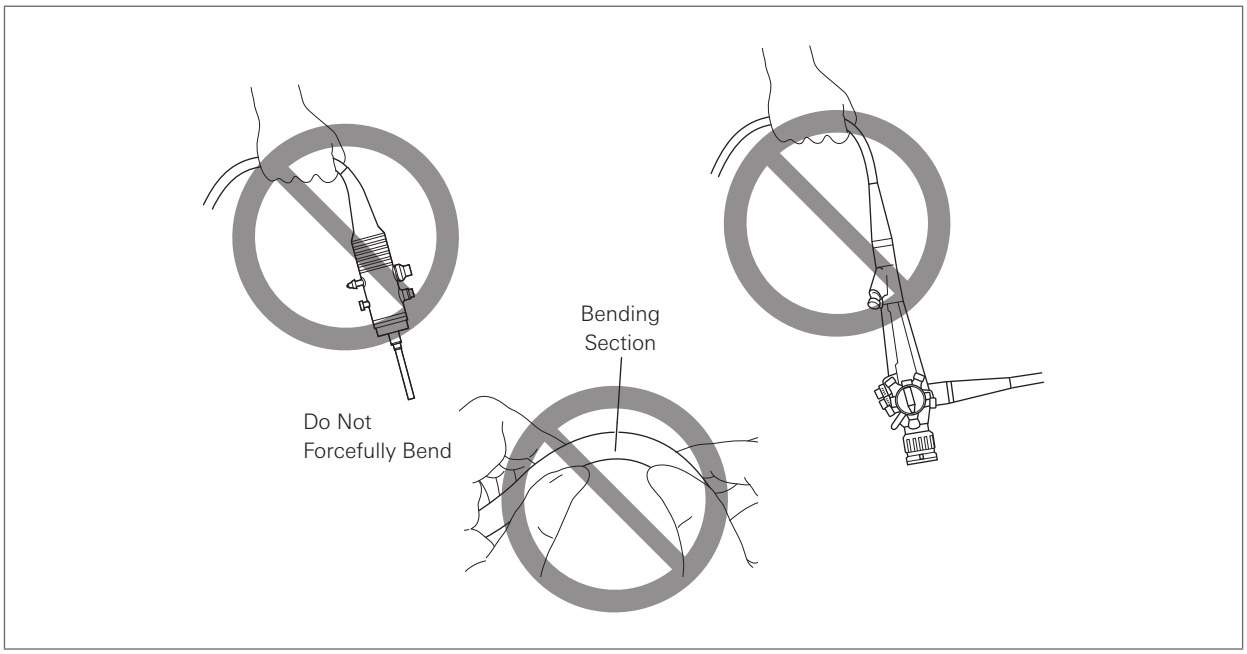


Figure 3.3

Note

In case the fiberscope 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 fiberscope and the room.

■ Carrying the fiberscope by hand

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

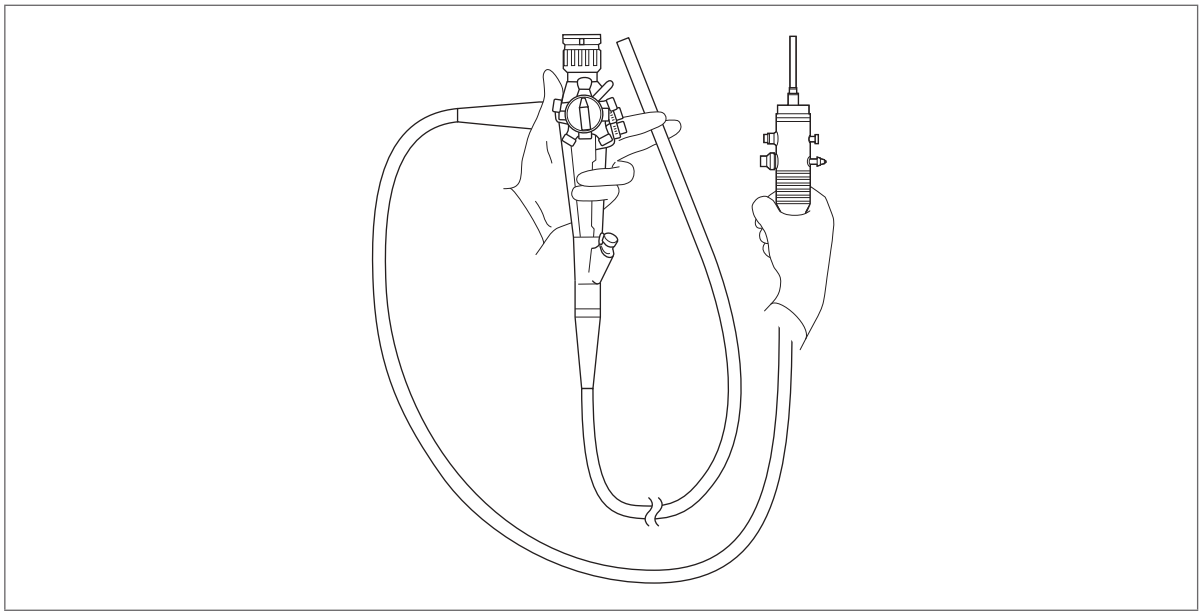


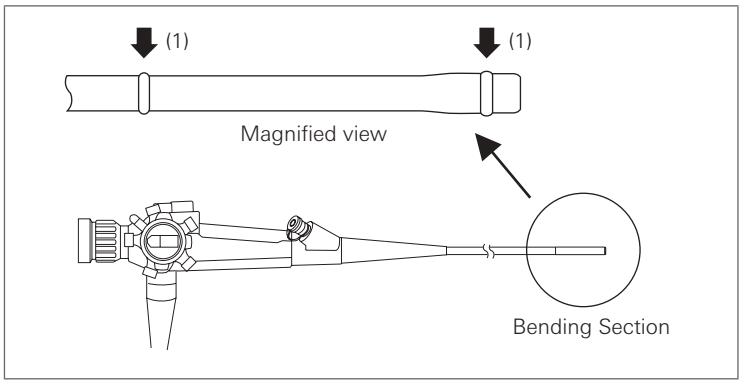
Figure 3.4

Inspection of the entire fiberscope

Warning

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

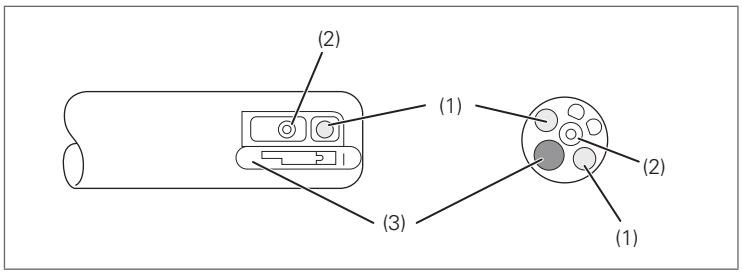
1. Check the entire surface of the fiberscope for any visible adhered material.
2. Check the entire surface of the insertion portion for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, dents, catching, protrusions, attachment of foreign materials, detachment of parts, etc.
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 distal end of the fiberscope (especially around the periphery of the instrument channel) for any abnormalities such as deformation or chipping.



(1) Light Guides
(2) Objective Lens
(3) Instrument Channel

Figure 3.6

5. Check the objective lens at the distal end of the fiberscope 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 fiberscope and it looks glossy.
7. Gently clean the objective lens and light guides with clean gauze or a cotton-tip applicator moistened with 70 to 90 % medical grade ethyl or isopropyl alcohol. Check that there is no attachment of the adhesive on the gauze.

Note

Clear images can not be obtained when there are any attachment of foreign material or residuals on the objective lens or light guides. When a fiberscope 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 fiberscope 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.

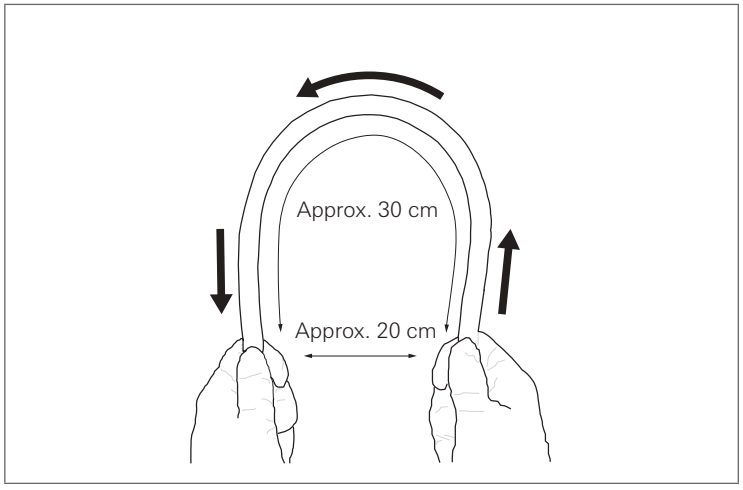
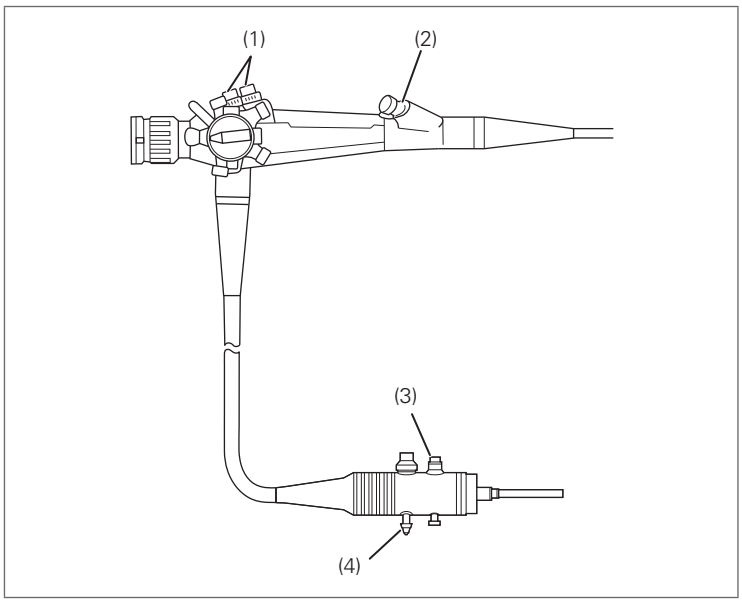


Figure 3.7

10. Check the entire surface of the umbilical cable 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) Air/Water Port
(4) 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 fiberscope with angulation abnormalities such as non-smooth operation, excessive play in the angulation control lever, or excessive angulation attenuation, as the inside of the fiberscope may be damaged. Using the fiberscope in this state may result in worsening of fiberscope 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.

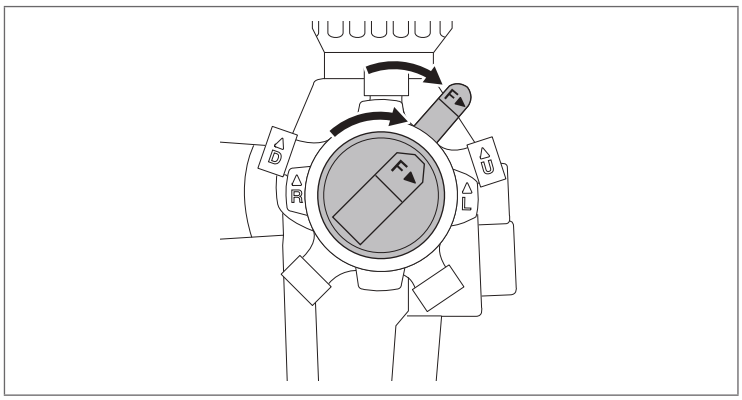


Figure 3.9

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.

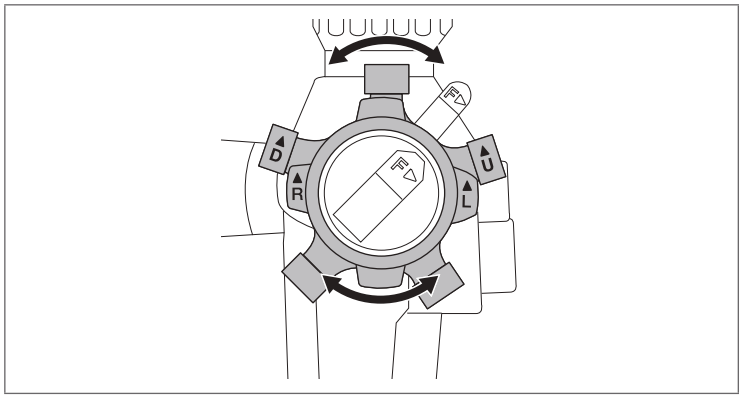


Figure 3.10

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. (The maximum angulation shown in the Figure is just an example.)

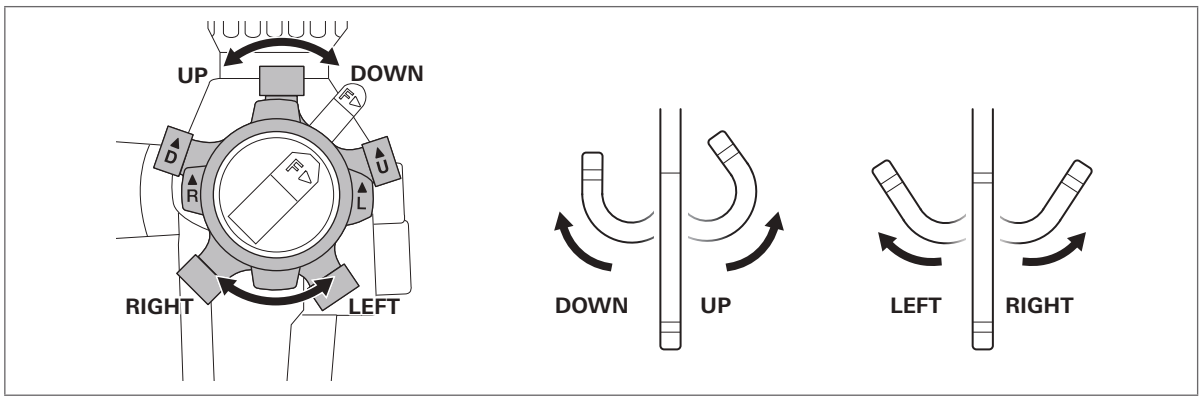


Figure 3.11

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

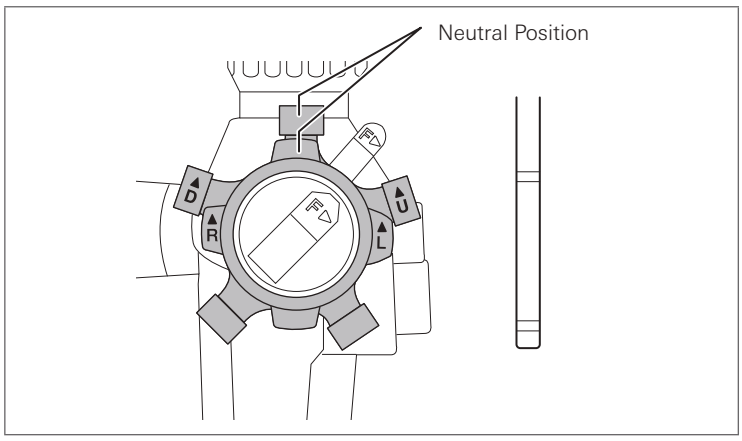


Figure 3.12

■ Inspection of the up/down bending lock mechanism

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

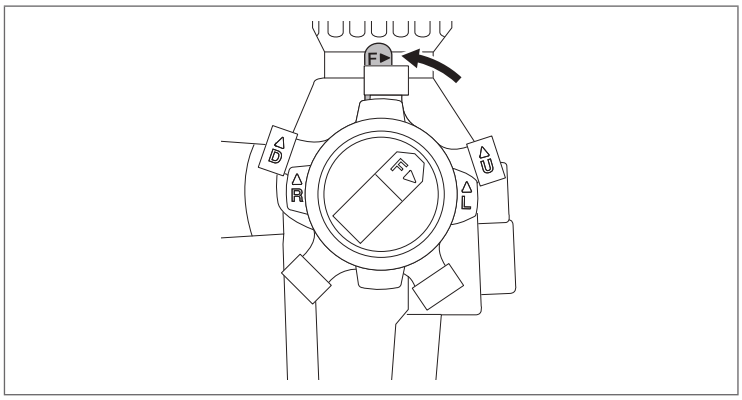


Figure 3.13

2. Turn the up/down angulation control knob slowly in the "▲U" or "▲D" direction until it stops. (The angulation shown in the Figure is just an example.)

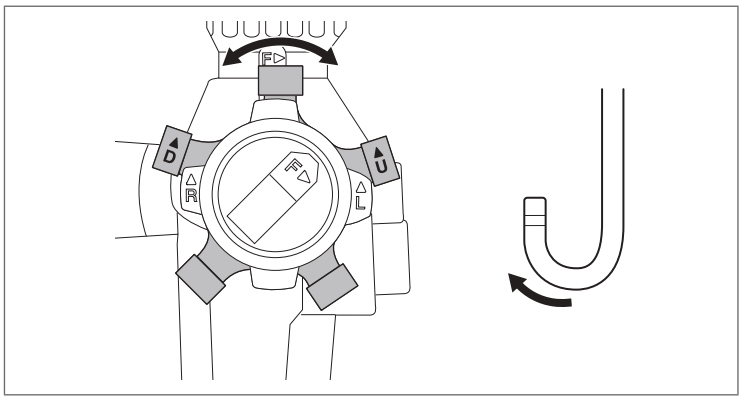


Figure 3.14

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

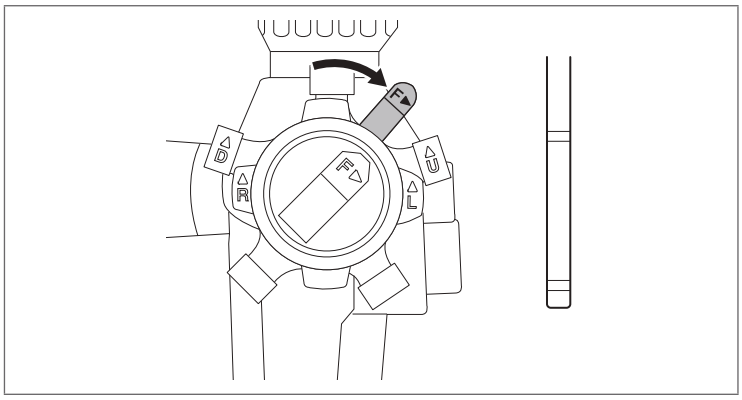


Figure 3.15

■ Inspection of the right/left bending lock mechanism

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

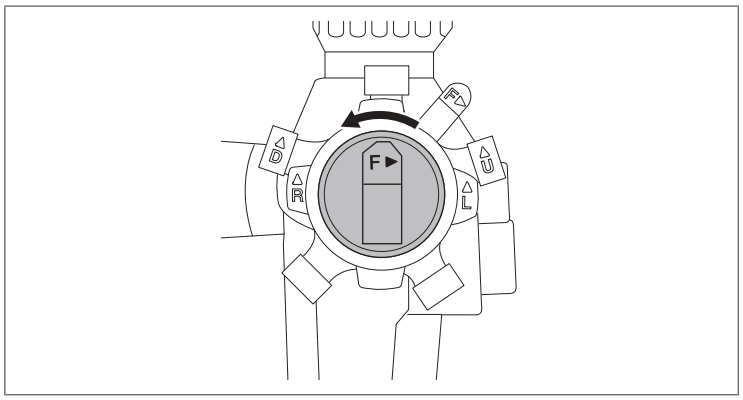


Figure 3.16

2. Turn the right/left angulation control knob slowly in the "▲R" or "▲L" direction until it stops. (The angulation shown in the Figure is just an example.)

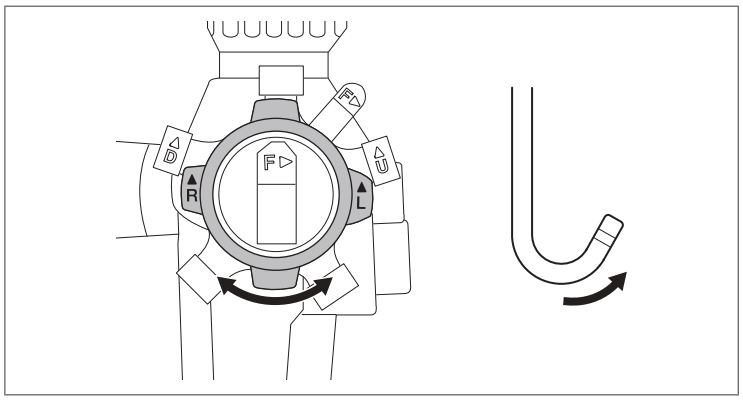


Figure 3.17

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

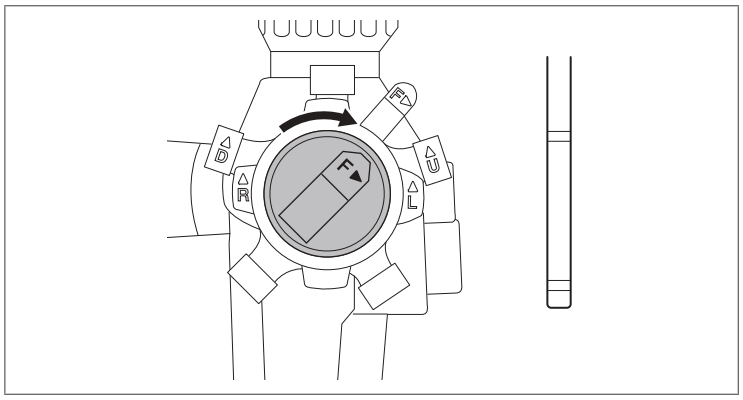


Figure 3.18

5. Inspection of Cannula Elevator (Only for FD-34V2)
   This is the control that will guide and direct either the cannula, biopsy forceps or other accessory during a procedure. To inspect, push cannula elevator control knob forward with thumb of the left hand. The cannula elevator in the distal end of fiberscope should elevate in proportion to the distance the control knob is moved. The motion of the elevator and the knob should be smooth and easy without any "play" involved.

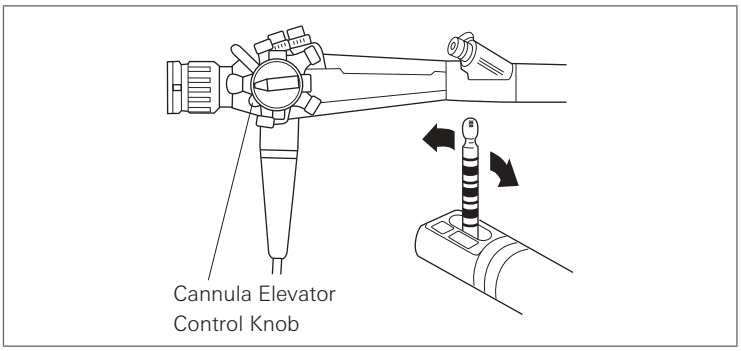


Figure 3.19

6. Inspection of Cannula (Only for FD-34V2)
   Make sure a cannula is clean and free from kinks, and the lumen is patent.

> **Warning**
> Cannulas and other accessories which enter the biliary tract should be sterilized.

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

When using reusable accessories, ensure that they have been cleaned, high level disinfected, and/or sterilized according to this IFU.

> **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-B121)

Warning

- If any abnormality is suspected with the check-valve, replace the air/water feeding valve with a new one. Continuous 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 (OF-B143) 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 set (OF-B143) 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-B143) for air/water feeding valve (OF-B121) for replacement.

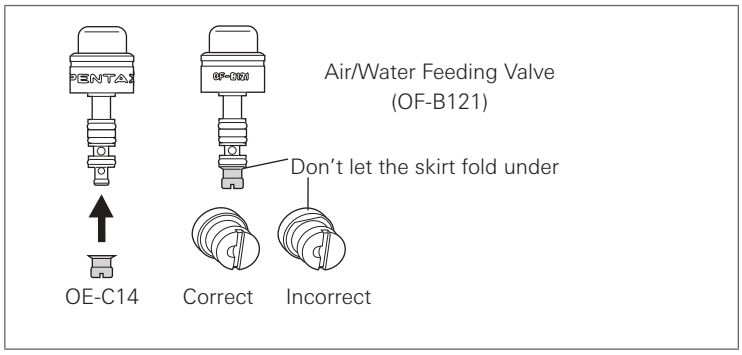


Figure 3.20

Note

The check-valve OE-C14 is a reusable component and it as well as the air/water feeding valve should be reprocessed after each use.

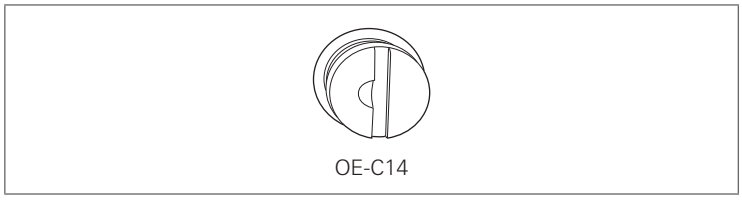


Figure 3.21

1. Check the air/water feeding valve (OF-B121) 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.

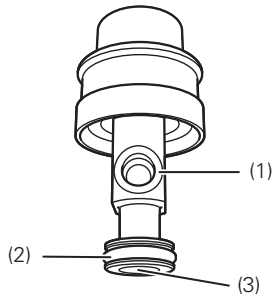
Inspection of the suction control valve (OF-B120)

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 3.22

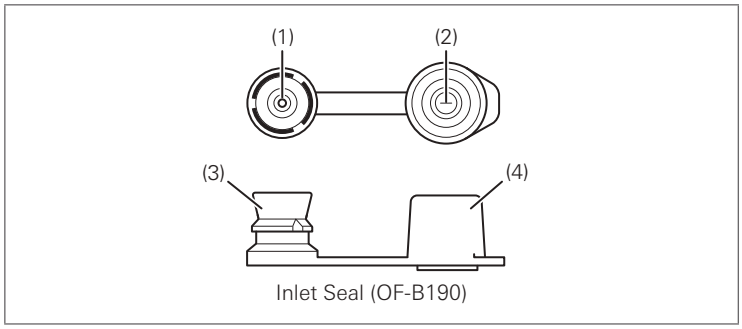
1. Check the suction control valve (OF-B120) for any abnormalities such as attachment of foreign materials, deformation, cracks, or hole blockage.
2. Check that the O-ring is properly attached and that there is no chipping, breaks, or peeling in the O-ring or sealing rubber part.

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 3.23

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

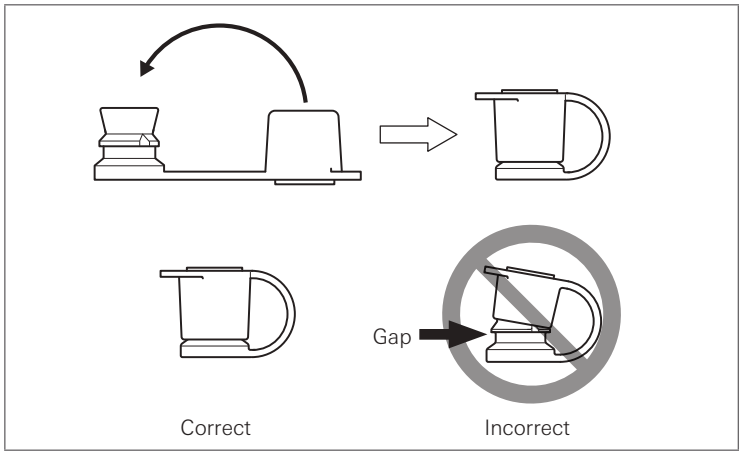


Figure 3.24

Inspection of the bite block (OF-Z5)
(Only for FD-34V2, FG-16V, FG-24V, and FG-29V)

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.

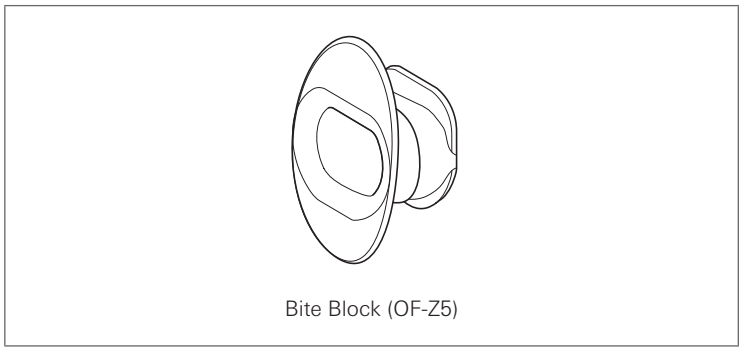


Figure 3.25

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, fiberscope 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 fiberscope 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.

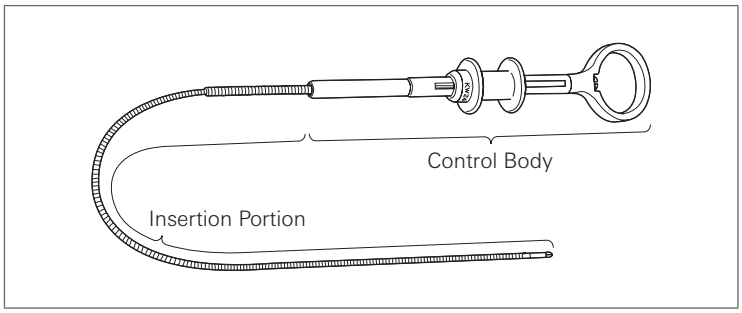


Figure 3.26

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

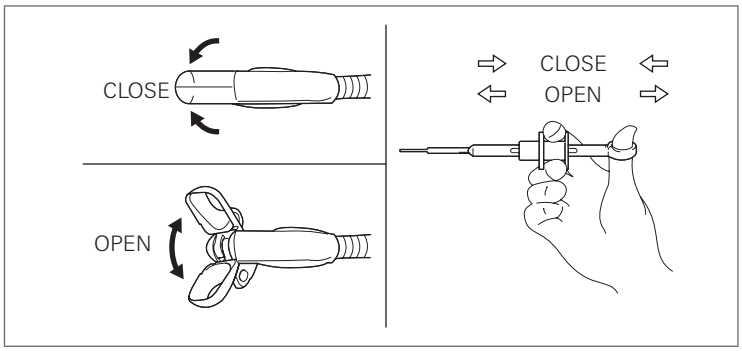


Figure 3.27

4. Form a loop with a diameter of 20 to 30 cm with the flexible shaft at approximately 20 to 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.

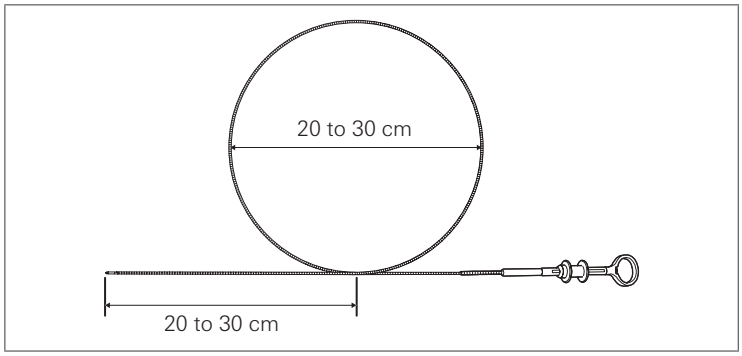


Figure 3.28

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

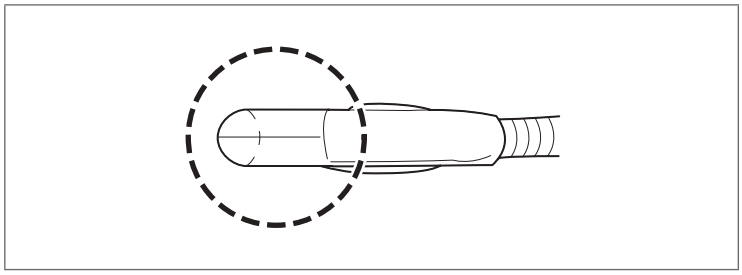


Figure 3.29

Attachment of accessories

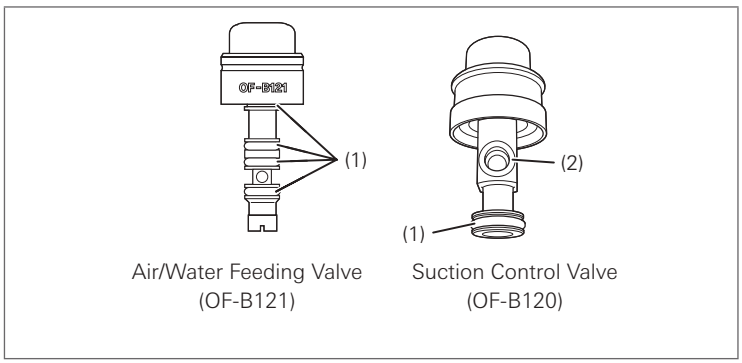
Warning

- Attach the accessories properly to the fiberscope. 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-B121) and suction control valve (OF-B120)

Caution

- Ensure to apply silicone oil (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 fiberscope and/or patient injury.
- Attach the air/water feeding valve (OF-B121) and suction control valve straight to the cylinder of the fiberscope. Pressing them at an angle may result in damage to the O-ring and check valve.



(1) O-ring
(2) Rubber Seal

Figure 3.30

1. Apply a small amount of silicone oil (OF-Z11) onto the O-rings of the air/water feeding valve (OF-B121) 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 fiberscope.

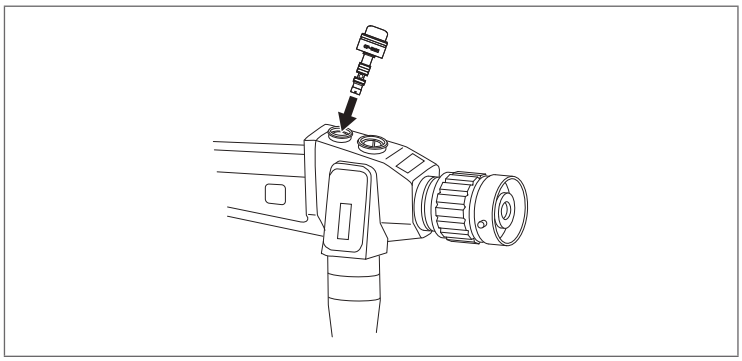


Figure 3.31

3. Ensure that the air/water feeding valve (OF-B121) is firmly attached. Press down the air/water feeding valve a few times to ensure that it moves smoothly.

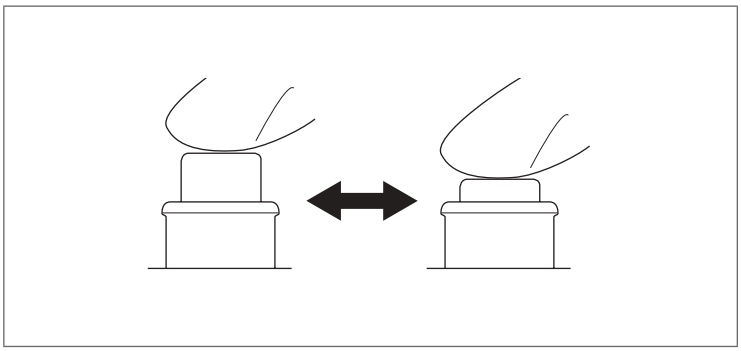
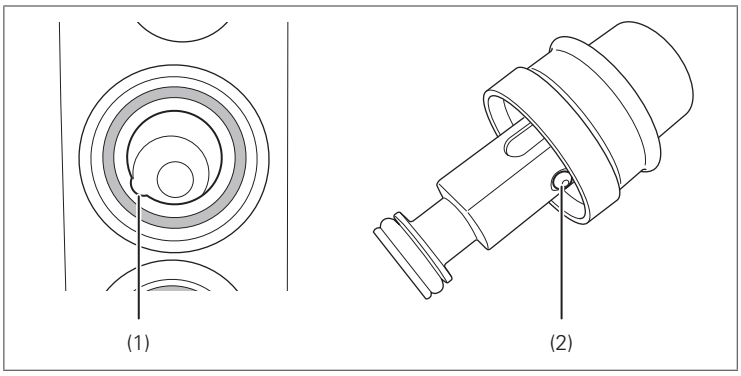


Figure 3.32

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



(1) Notch
(2) Metal Tab

Figure 3.33

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

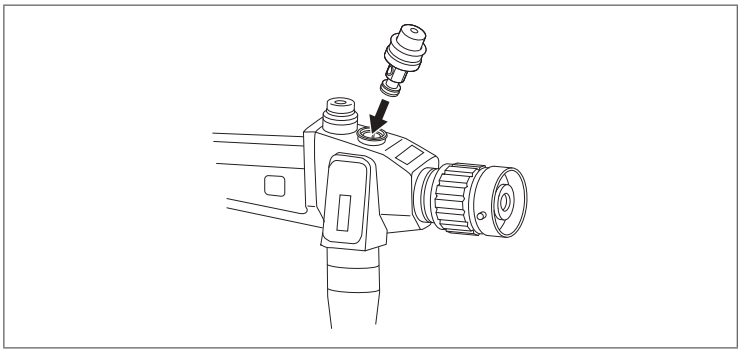


Figure 3.34

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.

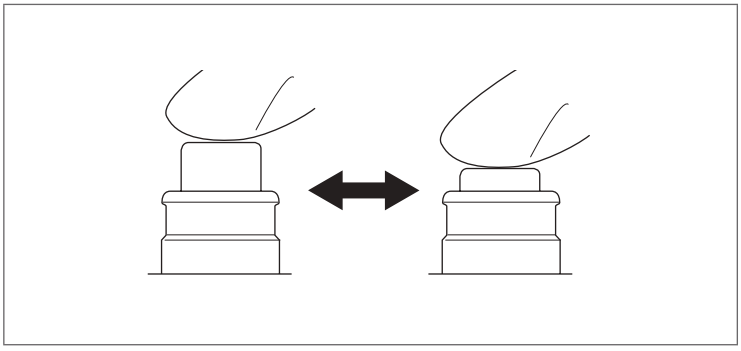


Figure 3.35

■ Attachment of the inlet seal (OF-B190)

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

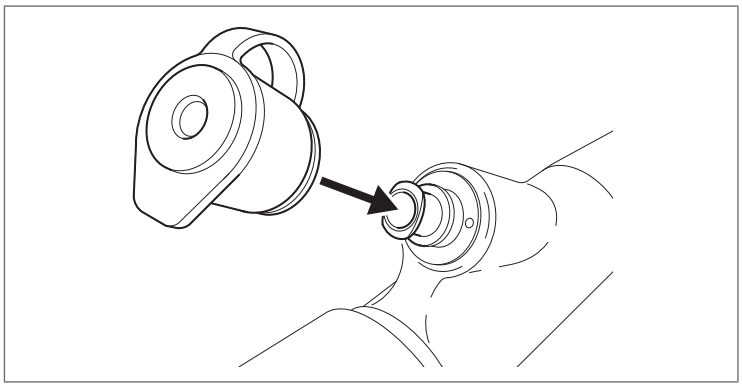


Figure 3.36

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

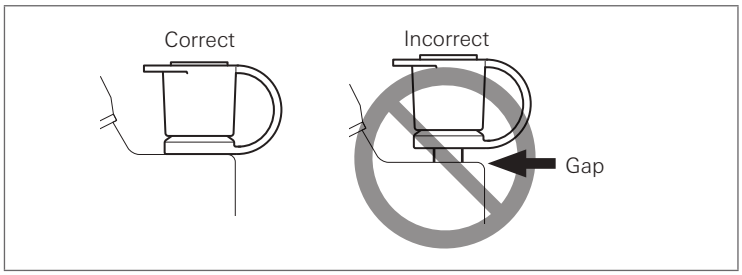


Figure 3.37

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

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

Light source
Endoscopic device
Suction source, etc.

Inspection of the light source

Only use compatible PENTAX Medical light sources.
For compatible light sources, refer to "Compatible products" (p. 8) or "System chart" (p. 97).

For details on the preparation and inspection of the light source, refer to the IFU of the respective light source.

Connection of the fiberscope and ancillary equipment

■ Connection to the light source

Warning

Use only sterile water in the water bottle assembly. Failure to do so may pose a risk of infection.

Refer to the IFU of the PENTAX light source involved for complete instructions.

1. Attach water bottle assembly, 2/3 filled with sterile water to the appropriate location on the light source.
2. Set the drain lever on the water bottle assembly to the A/W (air/water) position.
3. With the power switch in OFF position, plug light source into a properly grounded receptacle. PENTAX light sources have a hospital grade plug with a grounding conductor.
4. Connect the endoscope light guide plug to the light source.
5. Connect the air/water feeding tube from the water bottle assembly to the air/water connector.
6. Turn on the light source and the air pump to check for proper functioning.

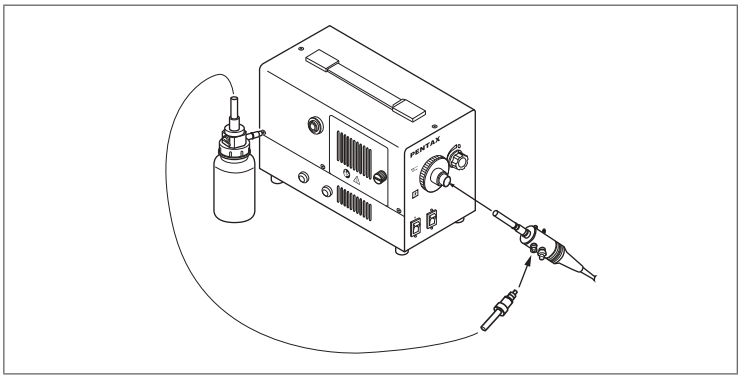


Figure 3.38

■ Connection of the suction tube

Warning

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 fiberscope. A blocked channel can lower the air/water feeding function and cause damage to the fiberscope.

Note

Turn off the air/water feeding pump of the light source beforehand.

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.

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

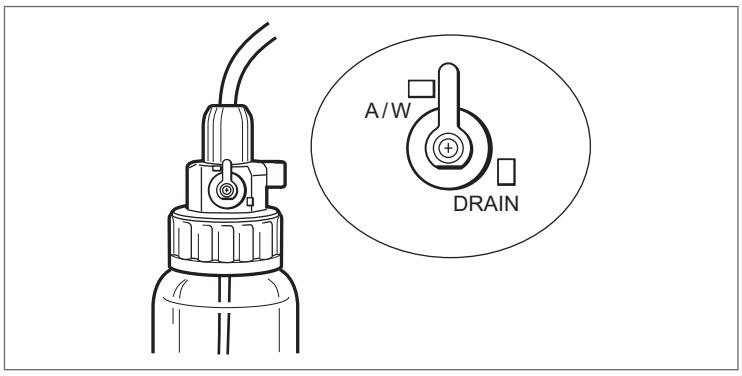


Figure 3.39

2. Press the air pump switch on the front of the light source to desired pressure setting.

3. Insert the distal end of the fiberscope into a clean container filled with sterile water, and check that air bubbles are not continuously discharged from the air nozzle at the distal end of the fiberscope. (The example shown in the figure is of the FG-24V/29V.)

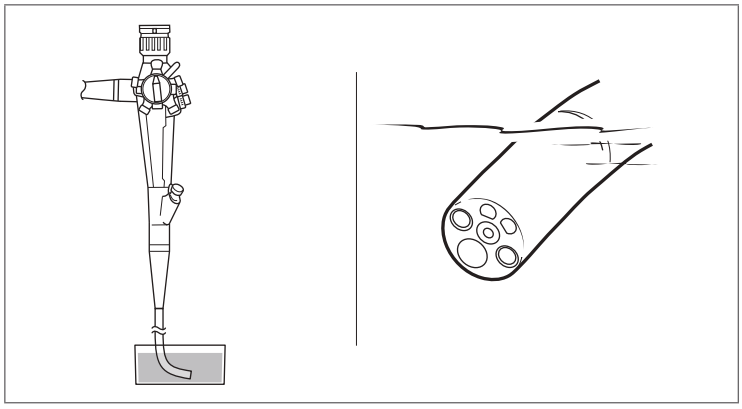


Figure 3.40

Warning

If air bubbles are continuously discharged from the air/water nozzle at the distal end of the fiberscope when the hole on the top of the air/water feeding valve is NOT closed, stop use immediately and replace the check-valve (OE-C14) 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.

4. 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 fiberscope.

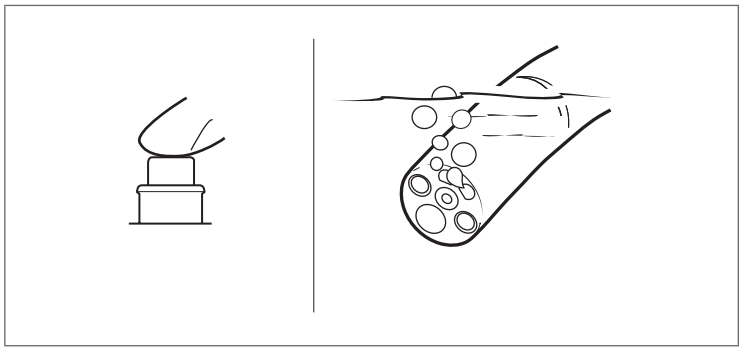


Figure 3.41

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

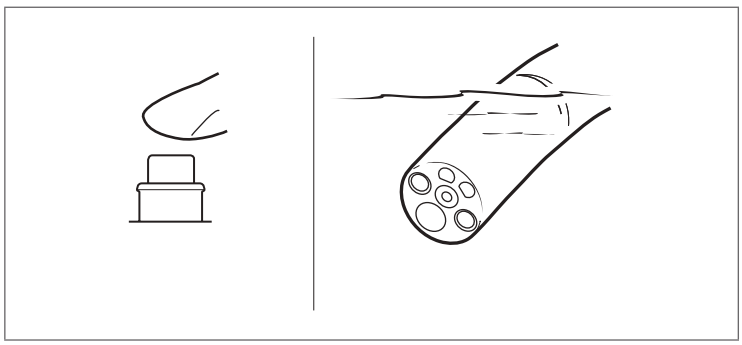


Figure 3.42

6. Pull the fiberscope 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.)

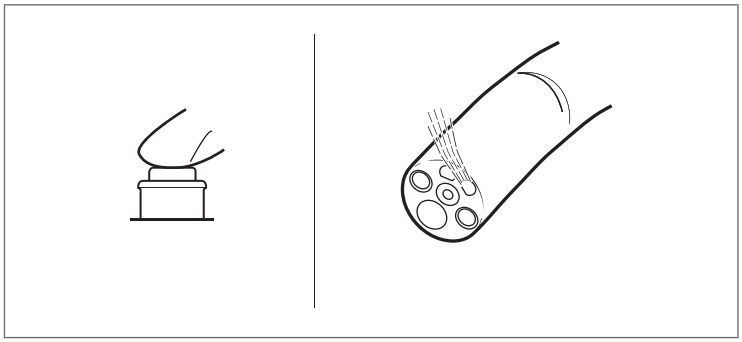


Figure 3.43

7. 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.

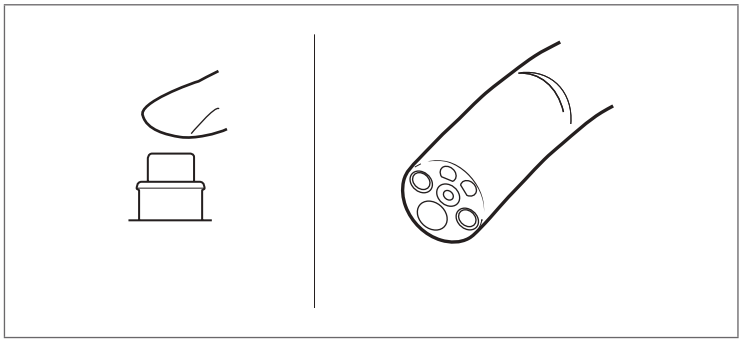


Figure 3.44

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 fiberscope.

Note

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

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 fiberscope into a container filled with sterile water and press the suction control valve (OF-B120). Check that water is being suctioned up.

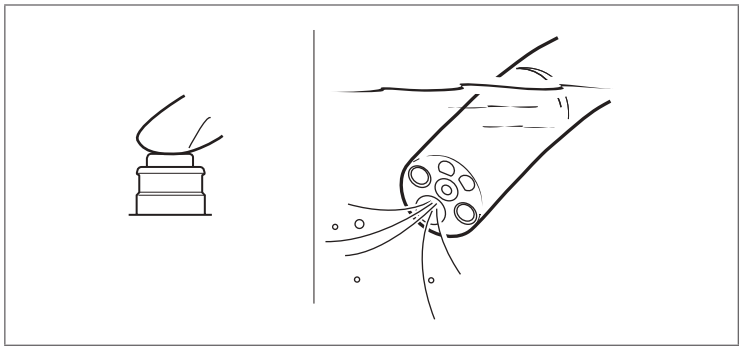


Figure 3.45

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

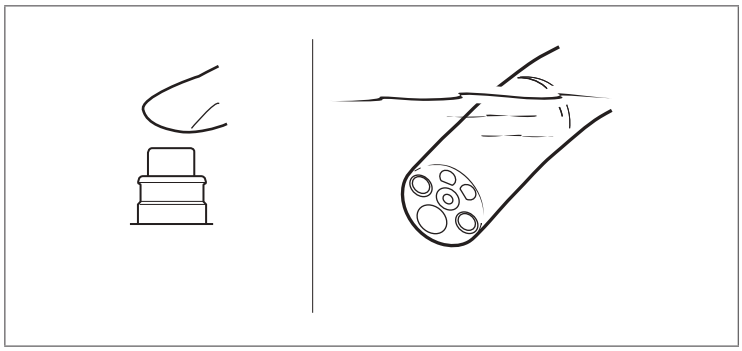


Figure 3.46

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 fiberscope 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 fiberscope 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 fiberscope damage.
- Keep the fiberscope bending section as straight as possible when inserting the forceps. When the fiberscope bending section is greatly angulated, it may NOT be possible to insert the forceps.

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

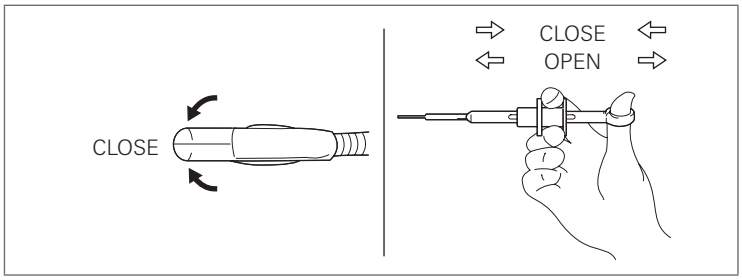


Figure 3.47

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.

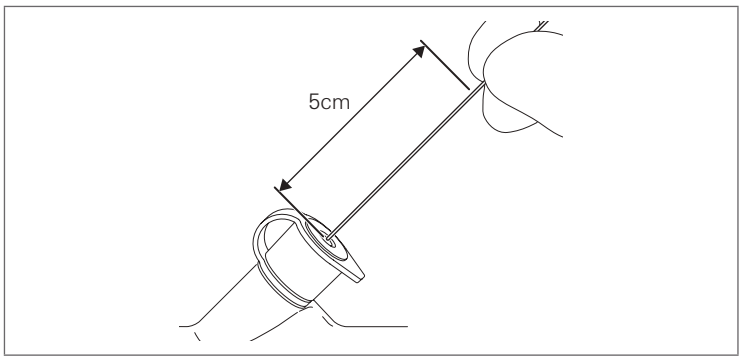


Figure 3.48

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

4 Directions for use

This fiberscope 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 fiberscope 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 fiberscope components such as the instrument channel inlet and the suction control valve.
- Immediately stop the endoscopic procedure and slowly and cautiously withdraw the fiberscope when any abnormality, such as roughness, is felt during angulation. NEVER forcefully turn the angulation control lever. Continuing to use the fiberscope with any abnormality may result in fiberscope damage and/or patient injuries, including bleeding and perforation.
- Do NOT withdraw the instrument while the bending section is angulated. Doing so may result in patient injury.
- Always check the endoscopic image during fiberscope angulation, air/water feeding, and suctioning, use of endoscopic devices, and fiberscope insertion and withdrawal. Ensure that these operations are performed in the normal (non-frozen, non-magnified) mode. Fiberscope operation in the freeze or magnification mode may result in damage to the fiberscope and patient injury.
- Do NOT forcefully insert and withdraw the fiberscope. Doing so may result in patient injury.
- When inserting the fiberscope into narrow lumina, Do NOT rotate the endoscopic image using the light source. Doing so may result in patient injury or make the withdrawal of the fiberscope impossible.
- Immediately stop the endoscopic procedure if the endoscopic image disappears unexpectedly because of blackout and/or damage to the lamp, light source, and/or fiberscope. Slowly withdraw the fiberscope following the instructions in "6-1. Withdrawal of a fiberscope with an abnormality" (p. 83). Continuing to use the fiberscope may result in patient injury.
- Set the brightness to the minimum necessary. Maintain an appropriate distance between the distal end of the fiberscope and the mucosa in order to avoid prolonged illumination of the mucosa. The temperature at the distal end of the fiberscope 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 fiberscope or direct it at the eyes of other individuals as the intense light may cause eye injuries.
- Do NOT use the fiberscope 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 fiberscope 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.

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.
- When using the distal hood, maintain a clear view by air/water feeding or suctioning. If it is difficult to maintain a clear view, stop using the distal hood as necessary.

4-1. Preparation immediately before insertion of the fiberscope

Perform appropriate patient preparation for endoscopy as necessary.

Caution

Do NOT spray or wipe the surface of the fiberscope 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 fiberscope damage.

1. Check the optical image of the fiberscope.
2. If necessary, gently clean the objective lens with a cotton-tip applicator moistened with 70 % alcohol. A lens cleaner (anti-fogging agent) may also be applied via gauze or other applicator.

3. The individual user should adjust the diopter adjustment ring to make sure that a clear view can be obtained. No further adjustment should be necesasry during a procedure.

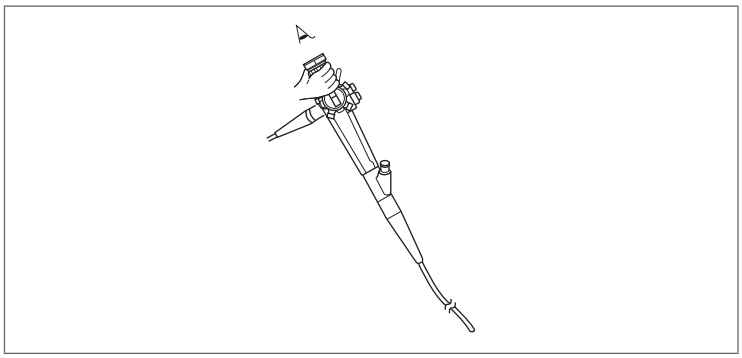


Figure 4.1

4. (Only for FD-34V2, FG-16V, FG-24V, and FG-29V)
   Prior to trans-oral insertion of the fiberscope, place a bite-block (mouthpiece) into the patient's mouth to protect the fiberscope from damage during the procedure. Failure to do so can result in scratches, tears and/or crushing of the insertion portion of the fiberscope.
5. Apply a medical grade water soluble lubricant to the insertion tube.
6. Do not use petroleum based lubricants.

Note

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

4-2. Insertion and observation

Insertion of the fiberscope

Caution

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

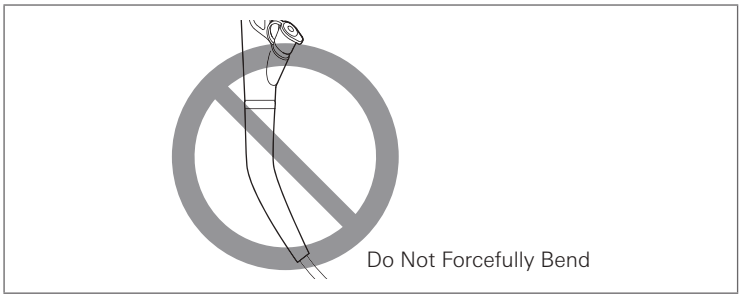


Figure 4.2

1. Slowly and cautiously insert the fiberscope.
2. (Only for FD-34V2, FG-16V, FG-24V, and FG-29V)
   When the distal end of the fiberscope is passed through the pharynx, the patient should be gently biting down on the bite block to maintain the bite block's position during the procedure.
3. Adjust the brightness as appropriate for observation with the light source.

Note

- Clear images can not be obtained if any foreign material is attached to the objective lens or the light guide. Continued use of the light guide with any foreign material attached to it might cause visible steam-like vaporization associated with water vaporization of the organic material heated by the light.
  If this vapor is observed, stop the procedure immediately and withdraw the fiberscope from the patient. Using clean gauze, clean off any foreign material that has attached and then resume endoscopy.
- The automatic brightness control mode of LX-750P should not be used with these scopes since there is no photosensor control circuitry within these instruments.
  The risk of thermal injury exists because in the absence of this electrical system, LX-750P, when in the automatic brightness mode, will transmit maximum illumination.

Angulation operation

Warning

Immediately stop the endoscopic procedure and slowly and cautiously withdraw the fiberscope when an abnormality, such as roughness, is felt during angulation. NEVER forcefully turn the angulation control knob as it may result in fiberscope damage and/or patient injuries, including bleeding and perforation.

1. Slowly and cautiously operate the angulation control knobs according to the position of the fiberscope.
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 fiberscope, 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. Press the air pump switch on the front of the light source.
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 fiberscope.
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 can NOT be removed, or other cause, do NOT attempt to correct the blockage or continue to use the fiberscope. In such a case, contact your local PENTAX Medical service facility to have the fiberscope repaired. The use of a fiberscope 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 fiberscope and the mucosa to ensure that the instrument channel opening of the distal end of the fiberscope 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.

4-3. Using an endoscopic device

Warning

- NEVER use a endoscopic device showing signs of damage and/or operational abnormality. Doing so may result in fiberscope 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 fiberscope 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 fiberscope 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 can NOT be withdrawn from the fiberscope. Do NOT attempt to forcefully withdraw the endoscopic device. Slowly and cautiously withdraw the fiberscope 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 fiberscope.
- Constantly check the endoscopic image while cautiously inserting and withdrawing the endoscopic device.
- Keep the fiberscope 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.

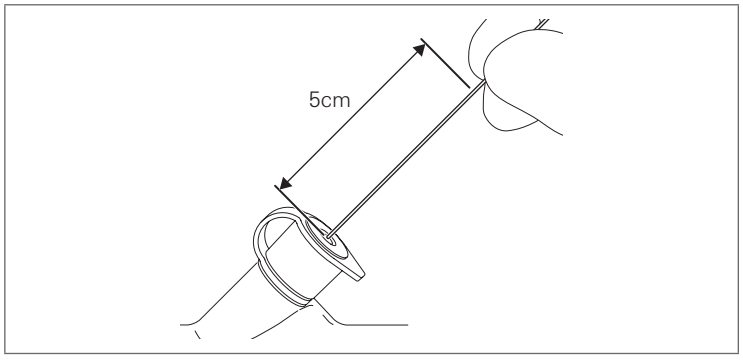


Figure 4.3

2. When a portion of the cups of the forceps becomes visible in the viewing field, carefully advance the forceps onto the target area.
3. Open the forceps cups and advance the forceps against the target area. Carefully squeeze the forceps handle to close the cups and obtain a specimen within the cups. Always maintain a view of the accessory during advancement.
4. Withdraw the forceps slowly with the cups closed.
5. Operate the endoscopic device according to the IFU provided with it.

Cholangiopancreatography (ERCP) only for FD-34V2

1. Insert the cannula into the biopsy channel through the inlet seal (OF-B190), there could be strong resistance from the inlet at first. Hold the cannula approximately 1cm from the distal tip and push it through the inlet. Use repeated short strokes to advance the cannula.

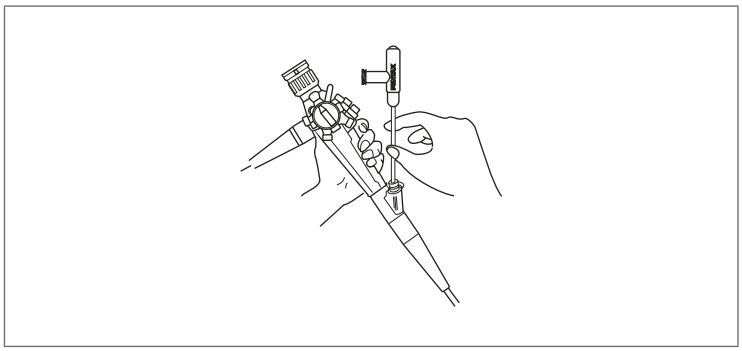


Figure 4.4

2. Attach a luer lock syringe filled with contrast material to the cannula. Inject, until air is eliminated from cannula. This will maintain the integrity of the lumen and contrast media while the cannula is in use. EX., if it becomes necessary to use more contrast media or flush with saline.
3. Insert the tip of the cannula into the Ampulla of Vater.
4. Inject contrast material slowly into the duct under visualization.
5. Remove cannula slowly.

Note

Should resistance in passing the cannula be encountered at the distal end of the fiberscope, gently pull back the cannula, reduce the angle of the cannula elevator, then re-advance the cannula.

Caution

If the cannula elevator is NOT angulated at all, the cannula may NOT be seen in the field of view since this is a side viewing instrument. It is recommended that the elevator be slightly angulated so that the cannula exits the distal end of fiberscope and advanced only under full view.

Warning

Accessories which ENTER STERILE TISSUE or THE VASCULAR SYSTEM must be sterile. Accessories intended for use in the biliary tract should be sterilized before patient use.

Biliary drainage (ERBD) only for FD-34V2

Note

Endoscopic Retrograde Biliary Drainage should be performed only by those physicians who are completely familiar with endoscopy and ERBD procedure.
The following is meant solely for the safe passage of catheters and biliary prosthesis through the flexible endoscope. It is not meant to be used as instructions for the procedure itself.

1. Pass the guidewire into the desired location and keep it in position for prosthetic implantation.
2. Thread prosthesis onto the guidewire, then using the pushing catheter, advance prosthesis through the scope and into position.
3. When the prosthetic has been placed in desired position, withdraw the guidewire and pushing catheter.

Note

There are several types of prosthetic devices available, be sure to review the instructions which come with the prosthesis.

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 can NOT be withdrawn from the fiberscope. 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 fiberscope 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.

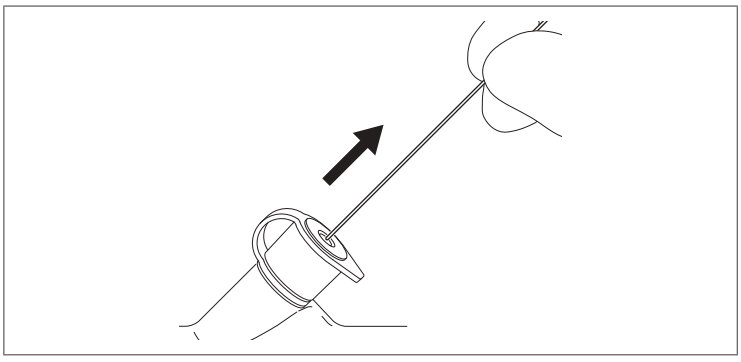


Figure 4.5

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 electrosurgery.

Warning

- Do NOT use non-flammable gas cylinders whose pressure and flow settings can NOT be controlled. Set the gas pressure to 49 kPa or less, and the flow to 1 L/min or less. Using a gas cylinder whose settings can NOT be controlled or whose settings are uncertain may result in damage to the fiberscope 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 CO2 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 light source 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 light source, which may result in damage to the air/water feeding pump.

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 light source.
2. Remove the air/water connector of the water bottle assembly from the air/water port of the fiberscope, and connect the gas adapter instead.

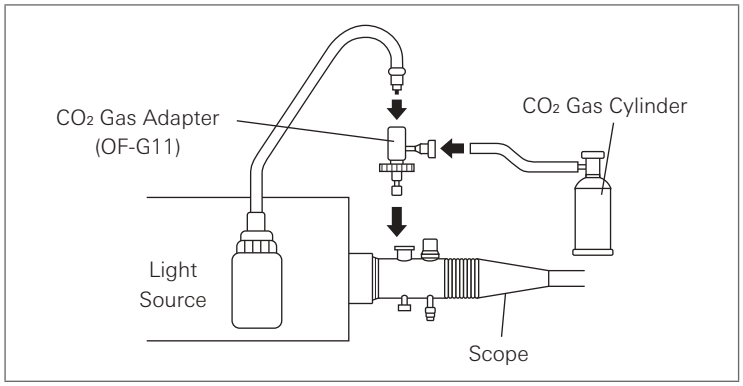


Figure 4.6

3. Connect the gas cylinder to the gas adapter (OF-G11).
4. Connect the air/water connector of the water bottle assembly to the gas adapter.
5. Ensure that all the devices are securely connected before opening the gas cylinder valve.

4-5. 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 fiberscope 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 generator may be of the floating (Type BF or Type CF) or non-floating (Type B) types. Only use floating-type high frequency generator to avoid patient and user burns.
- There are two types of floating-type high frequency generator: 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 light guide connector of the fiberscope.
  2) High frequency generator without an S-cord: Connect the condenser earth cable (OL-Z4/OL-Z3) between the endoscope feedback terminal and the light source 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 fiberscope before operating it. Failure to do so may result in fiberscope damage.
- During use, follow the precautions below, as failure to do so may result in fiberscope damage, burns, and/or mucosal injury.
  - Maintain an adequate distance between the distal end of the fiberscope 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 fiberscope 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”.

4-6. Withdrawal of the fiberscope

Warning

- When withdrawing the fiberscope, 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 fiberscope, do NOT remove the water bottle assembly from the light source while the water bottle assembly is connected to the fiberscope. Doing so may result in reflux of patient’s body fluids into the water bottle assembly.
- Do NOT withdraw the fiberscope 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. 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. While checking the endoscopic image, slowly and cautiously withdraw the fiberscope.
4. Turn the light source lamp off.

4-7. Care after use

Caution

Do NOT touch the light guide after use. It could result in burns.

■ Fiberscope:

Perform cleaning, high-level disinfection, and/or sterilization according to the procedure specified in this IFU.

■ Accessories:

Air/water feeding valve (OF-B121), suction control valve (OF-B120), inlet seal (OF-B190), 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, high level disinfected and/or sterilized according to the respective IFU provided with them.
Single use endoscopic devices:
Follow the national or local laws/guidelines to appropriately dispose of single use endoscopic devices.

■ Light source/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 fiberscope from the light source

Caution

Do NOT attach or remove the light guide connector while the light source power is powered on. Doing so may damage the fiberscope.

1. Immediately after use, perform pre-cleaning according to this IFU.
2. After completion of cleaning in the examination room, turn off power of the light source.
3. Hold the fiberscope light guide connector and remove the light guide from the light guide receptacle.

5 Care after use important instructions

Cleaning-Disinfection-Sterilization: PENTAX Fiberscopes

To maintain maximum performance and a long service life of the fiberscope, proper care after each procedure is extremely important. Immediately after the completion of a procedure, the fiberscope should be thoroughly and carefully cleaned. If the fiberscope is left uncleaned for some time after use, dried blood, mucous, contrast material or other debris may cause damage to the instrument or may interfere with the ability of the user to properly reprocess the fiberscope.

Note

This owner's manual contains detailed recommendations on the manual reprocessing of PENTAX fiberscopes using PENTAX supplied cleaning/disinfecting adapters. Automated endoscope reprocessors (AER) may provide a means of reprocessing flexible endoscopes, including PENTAX instruments. However, only those Automated Endoscope Reprocessors (AERs) should be used whose manufacturers provide device-specific instructions and have validation data that support each AER claim with respect to PENTAX model instruments.
AER manufacturers should be consulted for their specific claims including but not necessarily limited to

a) the ability of the AER to provide a cleaned and high level disinfected (or sterilized) endoscope and scope components (ex. valves),
b) the identification of any special feature area (internal channel) or scope component that can not be reprocessed and therefore requires manual reprocessing,
c) the microbial quality of the rinse water,
d) the inclusion of an "automated" alcohol rinse cycle,
e) the inclusion of a terminal drying cycle that removes the majority of water/fluid within fiberscope channels,
f) maintenance procedures for water filter replacement and/or decontamination of the filtration system to ensure the microbial claim of water, etc.
g) compliance with local regulations and/or guidelines

Warning

The importance of meticulous mechanical cleaning of the endoscope and its removable components can NOT be overemphasized.
Prior to disinfection or sterilization, all instruments and components must be scrupulously cleaned. Failure to do so could result in incomplete or ineffective disinfection and sterilization.
During the reprocessing process, always wear protective garments such as gloves, gowns, face masks, etc. to minimize the risk of cross contamination.

5-1. Care after each procedure

5-1-1. Pre-cleaning at the examination room

> Warning
>
> Immediately after use, the metal light guide prong of the fiberscope may be HOT.
> To avoid bums, do NOT touch this areas immediately after use.
> For safer handling after a procedure, grasp the plastic light guide plug.

1. Immediately after removing the fiberscope from the patient, gently wipe all debris from the insertion tube with a gauze or the like moistened with an enzymatic detergent solution.

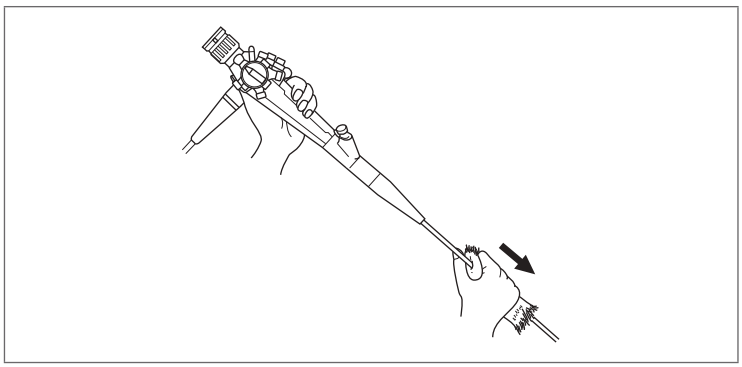


Figure 5.1

2. Place the distal end of the fiberscope into detergent solution and aspirate through the channel for 5~10 seconds. Alternate aspiration of solution and air serveral times to create agitation for better precleaning.

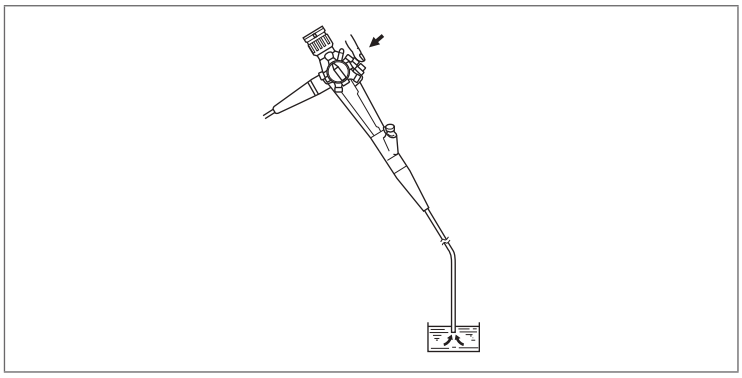


Figure 5.2

3. Set the lever on the water bottle to the drain position. With the air pump of the light source turned ON and set to the HIGHEST pressure setting, depress the air/water valve of the fiberscope fully until all water has been discharged from the fiberscope. Alternate covering of the hole in the valve and depressing the valve to forcefully expel mucous, debris, etc. which may have entered the air and water nozzles.
4. Place removable scope components in enzymatic detergent solution to pre-soak.

5-1-2. Cleaning at the work room

1. Before reprocessing and/or immersion in fluids, PENTAX fiberscopes should be tested for the possible loss of integrity in their watertight construction using PENTAX brand leakage testers. For specific details on PENTAX recommended leak detection procedures, please refer to the instructions provided with PENTAX leakage testers.

⚠ Caution

Various types of endoscope leakage testers exist including manual, electro-mechanical and "automated" versions, some of which are stand alone units and others which may be integrated into Automated Endoscope Reprocessor (AER)/Washer-Disinfector (WD). It must be recognized that PENTAX does NOT evaluate non-PENTAX leakage tester systems to satisfy their specific product claims for their effectiveness to accurately detect leaks and/or for their compatibility with PENTAX endoscopes. Insufficient pressures may reduce the likelihood for accurate leak detection, especially if the endoscope's distal bending section is NOT flexed during testing. Excessive pressures may adversely affect the endoscope, especially if pressurization occurs during automated reprocessing at elevated temperatures. PENTAX accepts no responsibility for use of non-PENTAX leakage testers. Users should check with the leakage tester manufacturer and confirm their specific product claims, including compatibility with PENTAX endoscopes at various temperatures and their ability to detect leaks with/without fluid immersion and with/without flexing of the endoscope's distal bending section.

2. Prepare a basin with warm water and a mild enzymatic detergent per detergent manufacturer's instructions.

⚠ Caution

The solutions must be enzymatic detergents or other cleaning agents specially formulated to clean flexible endoscopes. For specific brands of compatible solutions, please contact your local PENTAX service facility or sales representative.

⚠ Caution

BEFORE IMMERSING:
The ventilation cap must be taken OFF.

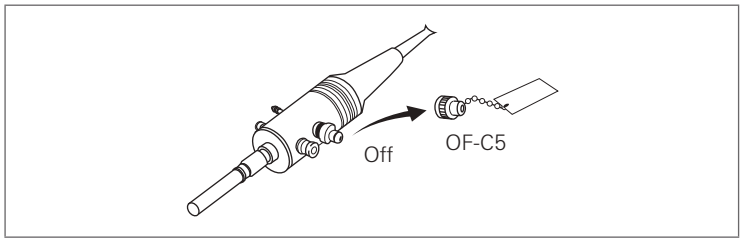


Figure 5.3

⚠ Warning

Immediately after use, the metal light guide prong and the electrical contacts/pins of the fiberscope may be HOT.
To avoid burns, do NOT touch these areas immediately after use. For safer handling after a procedure, grasp the plastic light guide plug.

Caution

The use of an enzymatic detergent immediately after each procedure to dissolve and remove organic contaminants and proteinaceous debris is essential to the care and maintenance of the fiberscope from the standpoints of infection control and functionality.

3. Immerse the fiberscope and its components in fresh detergent solution. After removing the suction control valve, air/water feeding valve, the rubber inlet seal, etc. thoroughly (but gently) wash the entire surface of the fiberscope and its components. Make sure that the recessed areas such as the fiberscope distal end, channel openings, valve cylinders, etc. are brushed clean using the provided or similarly effective cleaning brushes.

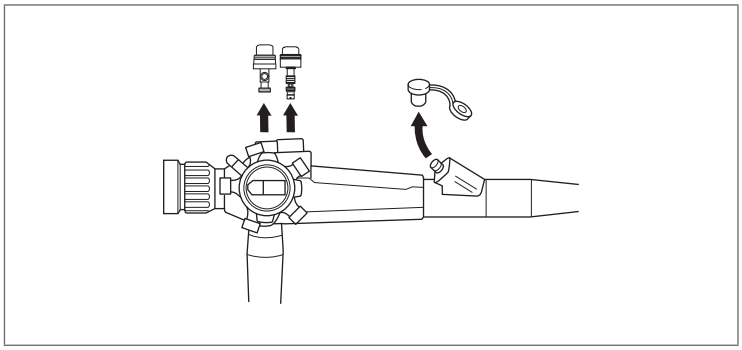


Figure 5.4

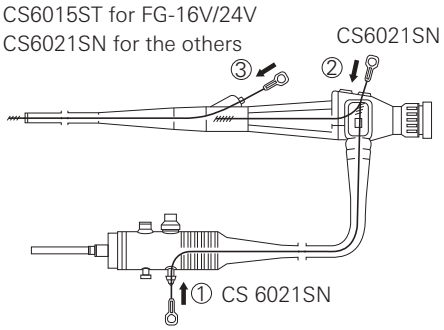
Caution

While fully immersed, manipulate valve mechanisms and inject detergent via syringe into/through removable scope components. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces & provide for better exposure of surfaces to detergent.

4. Allow all items to soak in an enzymatic solution for a time period recommended by the manufacturer of the enzymatic detergent.

Note

Do not squeeze or severely bend the insertion tube. Do not use any abrasive materials. Be careful to avoid damage to the distal lenses.



Never insert the brush in the opposite direction to avoid damage to the fiberscope.

Figure 5.5

5. Manual Cleaning by Brush

Warning

After using operational/cleaning accessories (e.g., forceps, needles, snares, brushes etc.) with the fiberscope, carefully check that all accessories are intact and that no parts have fallen off and become lodged within the fiberscope'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 channel becomes blocked or clogged due to the accumulation of debris, an accessory that can NOT be removed, or other cause, do NOT attempt to correct the blockage or continue to use the fiberscope. In such a case, contact your local PENTAX Medical service facility to have the fiberscope repaired.

The use of a fiberscope 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.

Note

(1) It is highly recommended that only PENTAX cleaning brushes specified in our manuals should be used to clean PENTAX fiberscopes.
(2) PENTAX cleaning brushes have been specially designed to clean various PENTAX internal channel systems and valves, ports or cylinders. Validation studies have been performed supporting the use of PENTAX supplied brushes and cleaning adapters for cleaning PENTAX scopes following PENTAX manual reprocessing instructions.
(3) Over the years other manufacturers' cleaning brushes/devices have been found to damage PENTAX scopes and/or create the need for servicing as some cleaning devices can become lodged ("stuck") inside various lumens of PENTAX scopes. The likelihood for fiberscope damage or servicing increases if a cleaning device does not have a protective tip (or contains any sharp-edged surface), if its flexible shaft uses a flimsy plastic material that is not firm enough to allow for easy accessory advancement and/or if the proper sequence and/or direction of channel cleaning is not followed as described in PENTAX manuals.
(4) The cleaning brushes should be always inserted as described in the reprocessing/maintenance manuals.
(5) While using the cleaning brushes, always make sure to use the cleaning brushes straight aligned with the insertion tube. Do not bend or angulate the cleaning brushes over the distal body while reprocessing as this could lead into distal body damage.
(6) Cleaning brushes/devices, especially those with metal colled flexible shafts should not be inserted into the distal exit/opening of channels. Doing so can damage the fiberscopes.

A variety of special brushes have been provided to mechanically brush clean the entire suction/instrument channels and tubes. Whenever possible, the entire fiberscope should be immersed in detergent solution during the remainder of the cleaning procedure.
Brush clean the entire instrument/suction channel system:

① Using the cleaning brush provided, insert the brush into the opening of the suction nipple and gently pass the brush until it appears in the suction control valve receptacle. This will clean the suction tube within the light guide/umbilical cable. Then gently withdraw the brush. Repeat at least 3 times until the blistles of the brush are visibly clean.
② Next, insert the brush into the opening at the bottom of the suction control valve receptacle (cylinder) on the control head and gently advance until resistance is felt (approximately 15cm).
DO NOT USE EXCESS FORCE.
Then gently withdraw the brush. Repeat at least 3 times until the blistles of the brush are visibly clean.

Note

Be sure to inspect the bottom of the suction control valve receptacle on the control head for any debris.

③ Insert the brush into the instrument channel inlet and gently advance the brush until it exits the distal end of the fiberscope. Clean debris off the brush and then gently withdraw the brush. Repeat at least 3 times until the blistles of the brush are visibly clean ensuring that only a clean brush is introduced into the channel each time.

④ Using the large bristle of the specially designed cleaning brush (CSC5S), scrub clean the surfaces inside the suction control valve receptacle on the control head.
Do not insert the brush excessively.

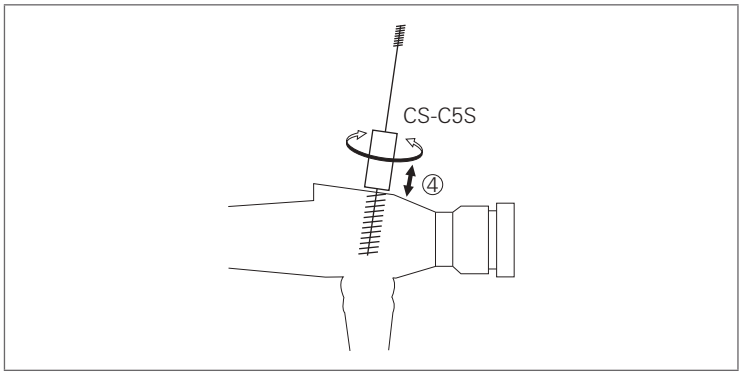


Figure 5.6

⑤ Scrub all internal and external surfaces of the suction valve (OFB120) using the smaller side of the cleaning brush (CS-C5S).

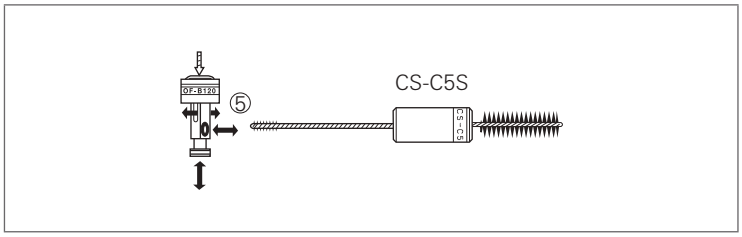


Figure 5.7

⑥ Remove the rubber check-valve (OE-C14) from the air/water feeding valve (OF-B121). Scrub all internal and external surfaces of the valve using the smaller side of the cleaning brush (CS-C5S).

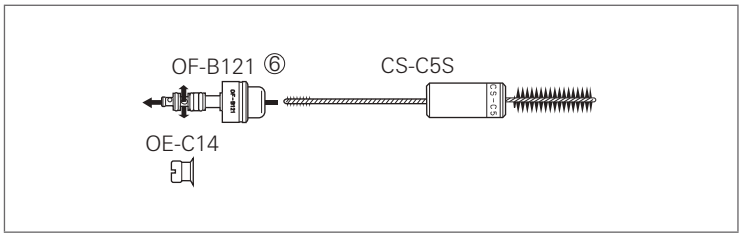


Figure 5.8

⑦ Using the larger end of the CS-C5S cleaning brush, scrub clean the surfaces inside the air/water cylinder.

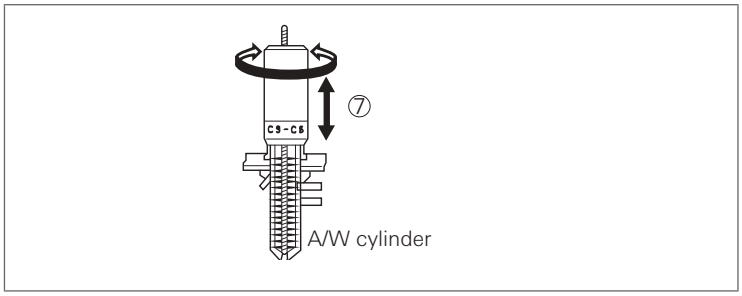


Figure 5.9

Note

Be sure to inspect the bottom of the suction control valve receptacle on the control head for any debris.

6. Chemical Cleaning by Detergent Solution
   The rubber A/W Instrument channel cleaning adapter (OF-B115) should be attached to the air/water and suction cylinders. This adapter caps (seals) off the air/water and suction cylinders to allow unidirectional flow of solution through these delivery/aspiration systems. Please note that the symbols on OF-B115 show a full circle (◯) and circle with notch (◔) which represent the shape of the respective cylinders for proper attachment. The notched symbol should align with the suction cylinder and the circle symbol, the air/water cylinder.

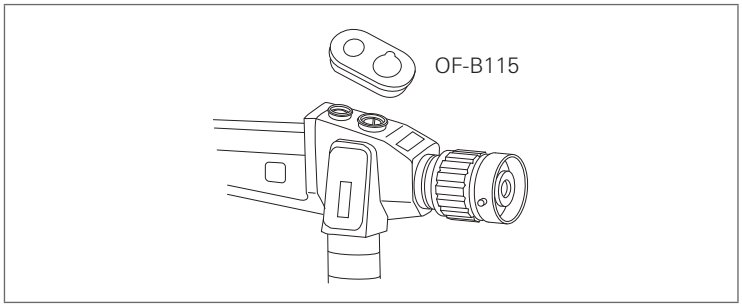


Figure 5.10

Note

It is imperative that the OF-B115 channel cleaning adapter be securely attached to their respective valve cylinders.
Failure to properly match and secure the cleaning adapter could result in ineffective and incomplete reprocessing.

a) For Air/Water Cleaning
   Air/water channel cleaning adapter, model OF-G17, has a standard ANSI luer lock connector to which a syringe or other device should be attached. Connect OF-G17 to the air/water port on the light guide plug. Fresh detergent should be flushed through this connector and will simultaneously flow through both the air and water channels and nozeles within the fiberscope.
   Please refer to the internal schematics.
   Provided the enzymatic detergent is allowed remain in contact with the internal channel surfaces for the recommended exposure time, the enzymatic solution should dissolve and clean any remaining debris within these channels.
b) For Biopsy/Suction Cleaning
   Install a rubber inlet seal to the instrument channel inlet prior to injecting detergent solution into the suction system.
   The suction nipple located on the light guide plug has a standard luer slip fitting to which a syringe (or other device) may be attached. Fresh detergent solution should be flushed through the entire instrument/suction system. The rubber inlet seal should be in place. (Please refer to the internal schematics.)

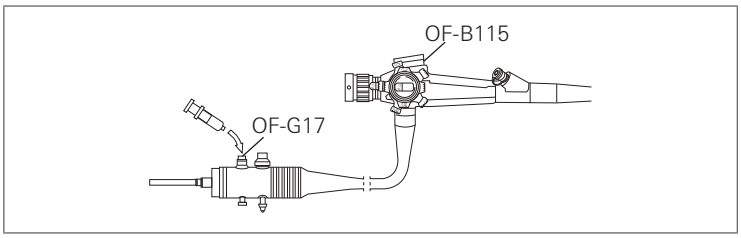


Figure 5.11

Note

If blockage of the line is encountered, avoid use of excessive pressure to prevent scope damage.

As an alternative, solution can be drawn into the instrument channel by attaching tubing from an aspirator to the suction nipple, as long as the aspirator is turned on, detergent solution can be suctioned through the fiberscope.

Warning

The enzymatic detergent solution should remain in contact with ALL internal channels and external fiberscope surfaces for the time period recommended by the manufacturer of the detergent.

7. Prior to rinsing, purge all internal channels with air (using a syringe) to expel residual detergent solution out from each channel.

Warning

It is important that ALL internal channels (air, water, instrument, etc.), external fiberscope surfaces and components be thoroughly rinsed with clean water to remove residual detergent solution.

8. Using clean water, immerse the entire fiberscope as well as all removed components and thoroughly rinse all items.
9. With all cleaning adapters, still attached to the fiberscope, flush all previously air purged channels with 200mL clean water. All internal channels must be thoroughly rinsed to remove residual detergent and debris.
10. Rinse water remaining within the channels should be purged using air to prevent dilution and/or adulteration of antimicrobial agents to be used in the subsequent disinfection or sterilization process.

Note

70 % alcohol followed by compressed air, not greater than 165kPa (1.69 kg/cm 2, 24PSI), may be used to facilitate drying.

11. Gently dry all external sufaces of the fiberscope with a soft gauze or the like. Do not put tension on the insertion tube on the fiberscope while drying since the outer cover of the bending section may be excessively stretched. Dry the objective lens with a cotton tip applicator.

Warning

Prior to disinfection of sterilization, it is imperative that any solutions previously used in the cleaning process be thoroughly rinsed and dried. Failure to do so, could result in ineffective or incomplete disinfection and sterilization.

Caution

Never subject the fiberscope to ultrasonic cleaning methods employing high-frequency ultrasound.

5-1-3. Cleaning of accessories

Caution

NOT all manufacturers of automated endoscope reprocessors (AERs)/washers-disinfectors (WDs) make specific claims nor provide special instructions for reprocessing all of the removable fiberscope components that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER/WD manufacturer's instructions NOT specifically address reprocessing of any particular fiberscope component (suction/irrigation valve, inlet seal, etc.) in the AER/WD, then those components must be reprocessed manually as described in PENTAX instructions/ labeling. Prior to use, check with each AER/WD manufacturer as to their specific claims with respect to reprocessing individual fiberscope components.

1. Reusable accessories such as forceps should be cleaned immediately after each use since dried blood, mucous, contrast material or other debris may cause damage to the instrument and render the mechanism inoperable, or may interfere with the ability of the user to reprocess the device.
2. Place the accessory in a basin with warm water and a mild enzymatic detergent being careful not to tightly coil or kink the flexible wire/shaft.
3. Clean the handle and flexible shaft by gently wiping with a soft gauze or the like. The biopsy cups and pivot pin area should be carefully and gently cleaned with a soft brush. Removal components such as air/water, suction valve, etc. should be manipulated and detergent injected directly into/onto components surfaces.
4. Rinse all residual detergent from the forceps by immersing the entire forceps under clean water and manipulating the handle and cup mechanism.
5. Ultrasonic cleaning of accessories is then recommended, provided the manufacturer's instructions and the parameters below are followed:

Frequency Range	44 kHz ± 6 %
Time	5 minutes

Do not use caustic or abrasive solutions in the ultrasonic cleaner.

Caution

Never place the fiberscope in a steam autoclave nor subject it to high-frequency ultrasonic cleaning methods.

Note

It is imperative that ultrasonic cleaning of the biopsy forceps be performed PRIOR to autoclaving. Heavily solied components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent high-level disinfection. Only those PENTAX accessories identified by their pink colored handle or labeled as being autoclavable may be subjected to steam autoclaving.

Note

All detergent must be removed from the inner mechanism of the forceps and individual scope components. Any detergent that remains after the water evaporates will cause increased friction that may render the mechanism inoperable. Residual detergent may also interfere in the subsequent sterilization process.

6. After cleaning and thorough rinsing, the accessory should be gently dried using a soft gauze or the like. Avoid tight coiling or kinking and do not put tension on the flexible shaft of the accessory.

Note

Other reusable accessories (channel cleaning adapters, cleaning brushes, bite block, etc.) and scope components (inlet seals, air/water and suction control valves, etc.) should be cleaned in a similar manner as above.
Ultrasonic cleaning methods are recommended for accessories and scope components whose entire surfaces are not easily accessible by manual cleaning.

Note

The following endoscopic accessory instruments and scope components may be subjected to ultrasonic cleaning methods:

- PENTAX biopsy forceps with pink handle
- PENTAX cleaning brushes
- PENTAX bite block OF-Z5
- PENTAX water bottle OS-H4
- PENTAX cannula TG1918S
- PENTAX suction valve OF-B120
- PENTAX A/W feeding valve OF-B121
- PENTAX A/W instrument channel cleaning adapter OF-B115
- PENTAX check-valve OE-C14

5-1-4. Internal channels of a PENTAX fiberscope

The following internal schematics have been provided as a service to help users better understand the intricate construction of PENTAX fiberscope.
Knowledge of the various internal channels and tubes within an instrument and their relation to each other allows one to care for and reprocess the fiberscope more easily and with greater confidence.
Much time and effort has been expended into designing fiberscope and their cleaning/disinfecting components so that reprocessing of the instruments before each patient use can be effectively and efficiently performed by either manual methods or automated processes.
Connectors on all PENTAX cleaning/disinfecting adapters and fiberscope inlet ports incorporate standard size luer-lock and/or luer-slip fittings to easily accommodate reprocessing devices or systems available from other manufacturers.
As can be seen from the internal schematics, the PENTAX cleaning system promotes efficient unidirectional flow of solution beginning from connections at the light guide plug, traveling up tubings in the umbilical cable to the valve cylinders in the control body, passing through the channels in the insertion tube and finally exiting nozzles or channel openings at the distal end of the fiberscope.
The elimination of multiple branching of channels, combined with a direct and straightforward pathway for solutions to travel maximizes flow efficiency and ensures contact of disinfectant/sterilant with all internally exposed channel surfaces.

Warning

It is imperative that flexible endoscopes and other semi-critical devices be reprocessed using at least high-level disinfection with a legally marketed sterilant/disinfectant. Only legally marketed endoscope automated reprocessing devices/systems whose device specific claims have been validated by the AER manufacturer and/or anti-microbial agents which have been tested and found to be compatible by PENTAX should be used with PENTAX products.
Generally speaking, “2 %” and “3.2 %” alkaline glutaraldehyde solutions which have been FDA cleared with High-Level Disinfection and/or Sterilization claims are recommended. It should be noted that the actual percentage of active ingredient (glutaraldehyde) in these solutions, as per their product label, may vary from the generic and traditional terms “2 % glutaraldehyde” and/or “3.2 % glutaraldehyde”.
For specific brands of compatible disinfectants/sterilants, please contact your local PENTAX service facility or sales representative. Please also refer to the inside front cover of this manual regarding infection control.

Internal channels of PENTAX gastroscope (except FG-16V), colonoscope and sigmoidoscope

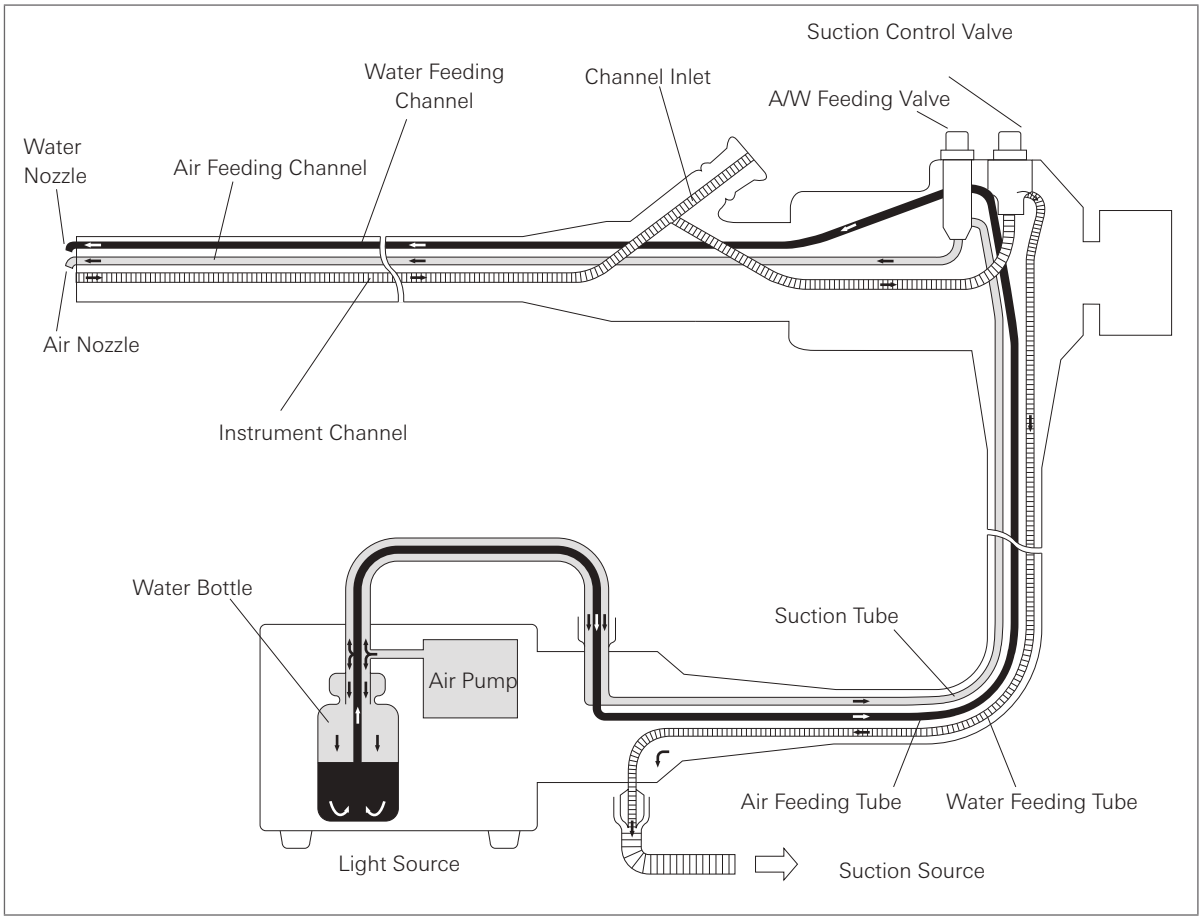


Figure 5.12

The illustration above shows the actual routes taken by air, water and suction through a PENTAX Gastroscope (except FG-16V),
Colonoscope and Sigmoidoscope. Please note that all delivery systems have separate independent channels, all of which must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

Internal channels of PENTAX gastroscope (except FG-16V), colonoscope and sigmoidoscope showing complete pentax cleaning/disinfecting system

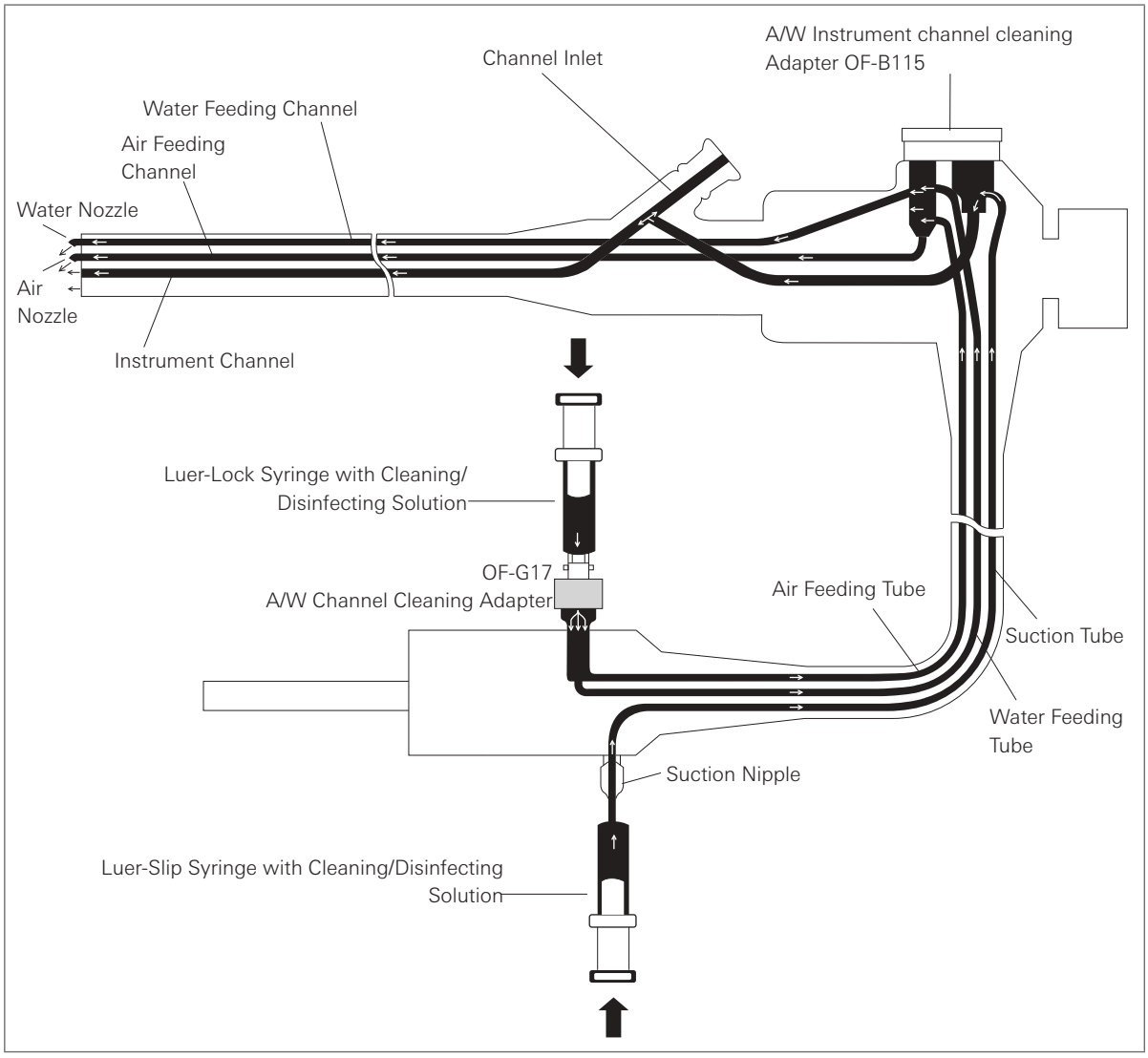


Figure 5.13

Caution

BEFORE IMMERSING, The ventilation cap must be taken off.

To reprocess a PENTAX Fiberscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

Note

Prior to exposure of all internal channels to an enzymatic detergent and high-level disinfectant (or sterilant) , PENTAX channels should be manually cleaned with cleaning brushes.

Internal channels of PENTAX gastroscope FG-16V

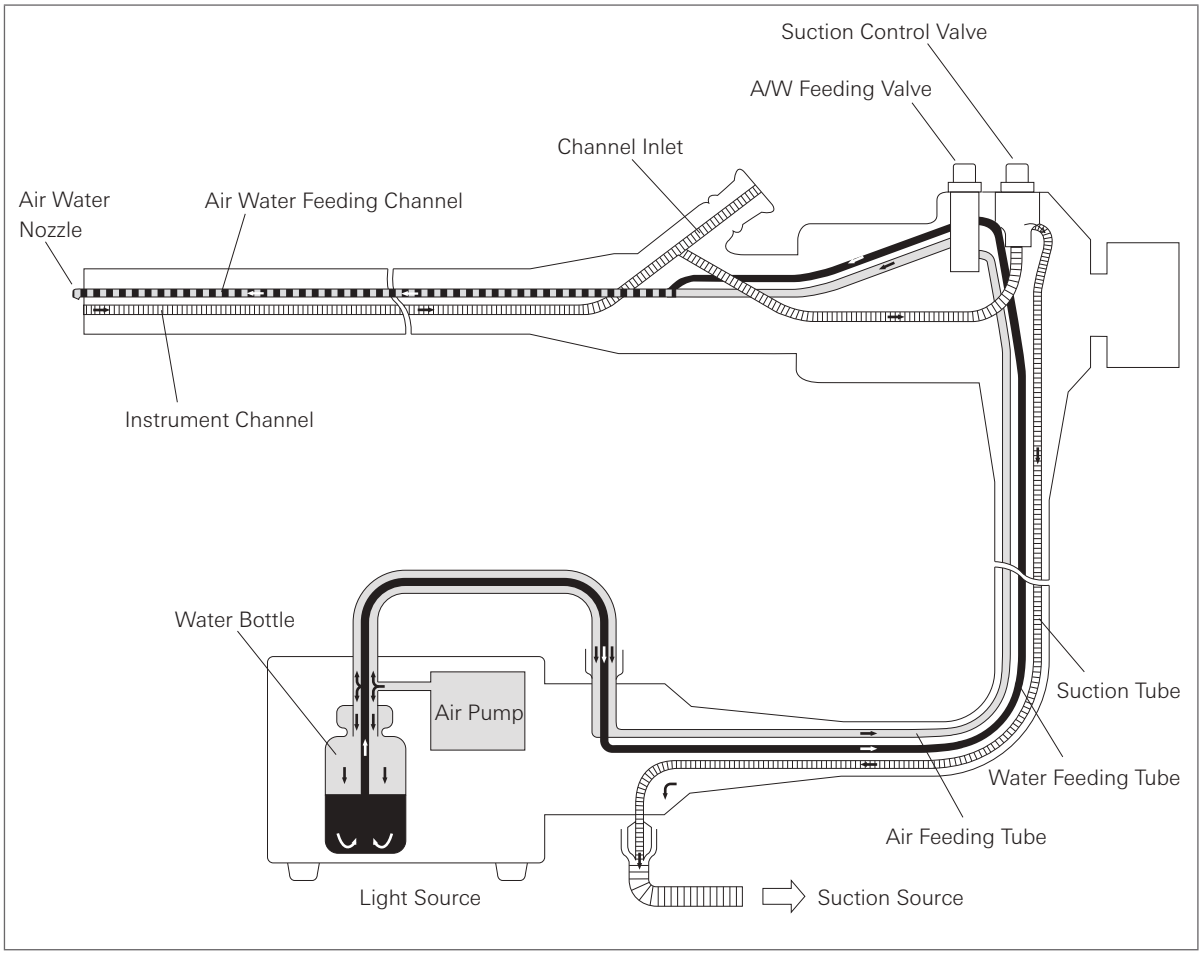


Figure 5.14

The illustration above shows the actual routes taken by air, water and suction through a PENTAX Gastroscope FG-16V, Please note that all delivery systems must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

Internal channels of PENTAX gastroscope FG-16V showing complete pentax cleaning/disinfecting system

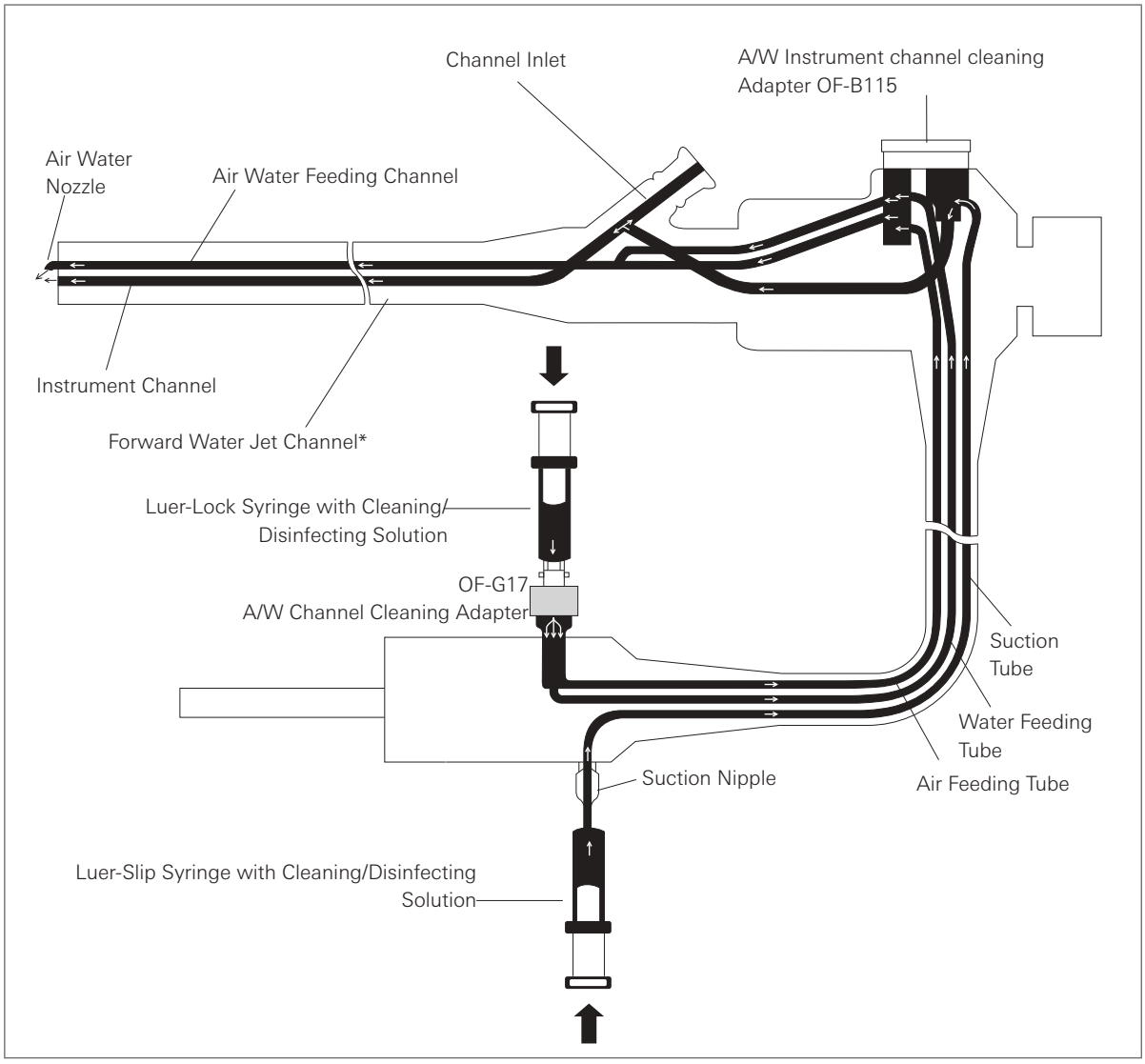


Figure 5.15

Caution

BEFORE IMMERSING, The ventilation cap must be taken off.

To reprocess a PENTAX Endoscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

Note

Prior to exposure of all internal channels to an enzymatic detergent and high-level disinfectant (or sterilant) , PENTAX channels should be manually cleaned with cleaning brushes.

Internal channels of a PENTAX duodenoscope

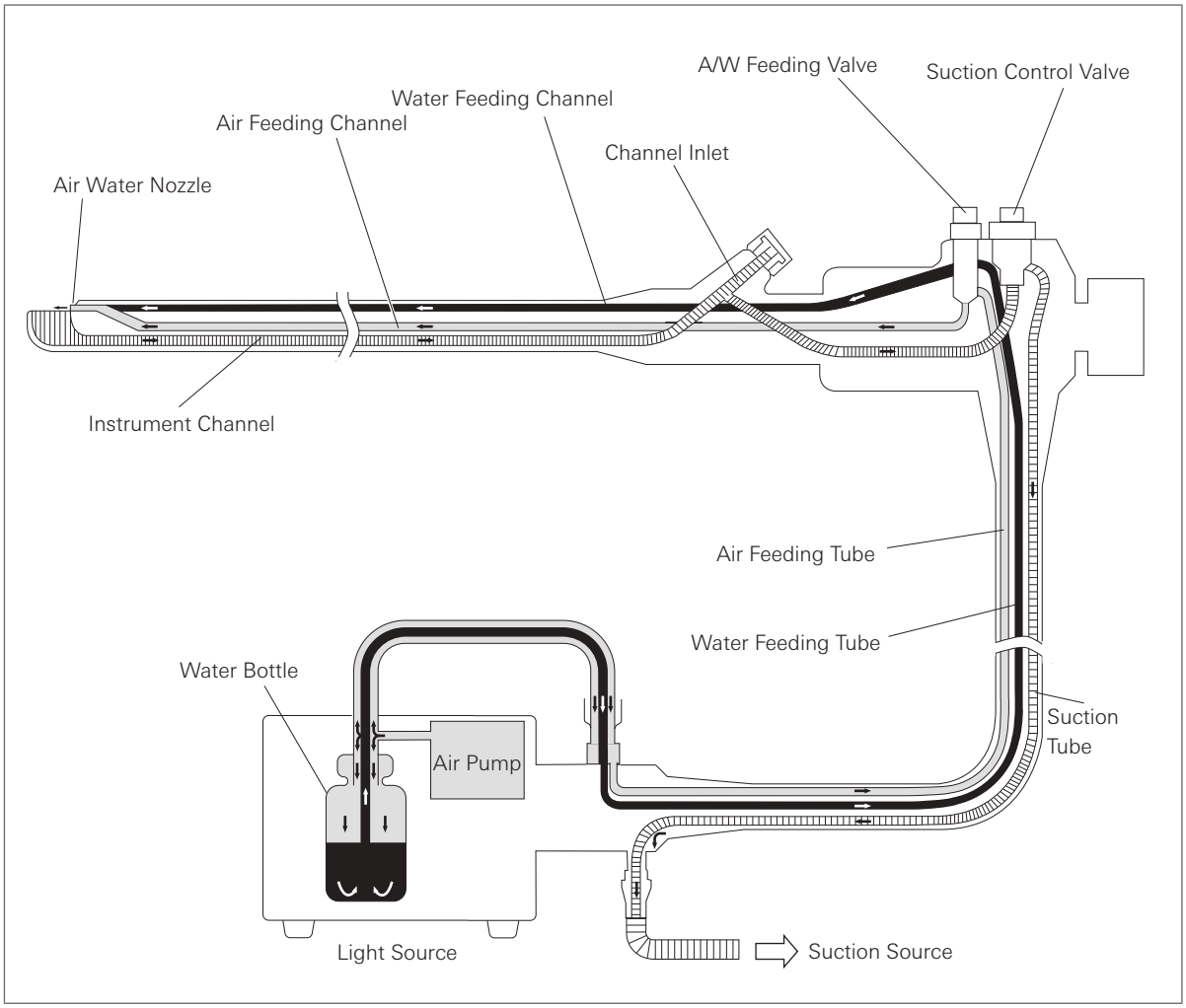


Figure 5.16

The illustration above shows the actual routes taken by air, water and suction through a PENTAX duodenoscope. Please note that all delivery systems have separate independent channels, all of which must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

Note

The new fully enclosed design of the elevator control wire within a PENTAX duodenoseope eliminates the risk of exposure to potentially contaminated patient material.
Therefore, the elevator control wire in PENTAX duodenoscope does not require special reprocessing.

Internal channels of a PENTAX duodenoscope showing complete pentax cleaning/disinfecting system

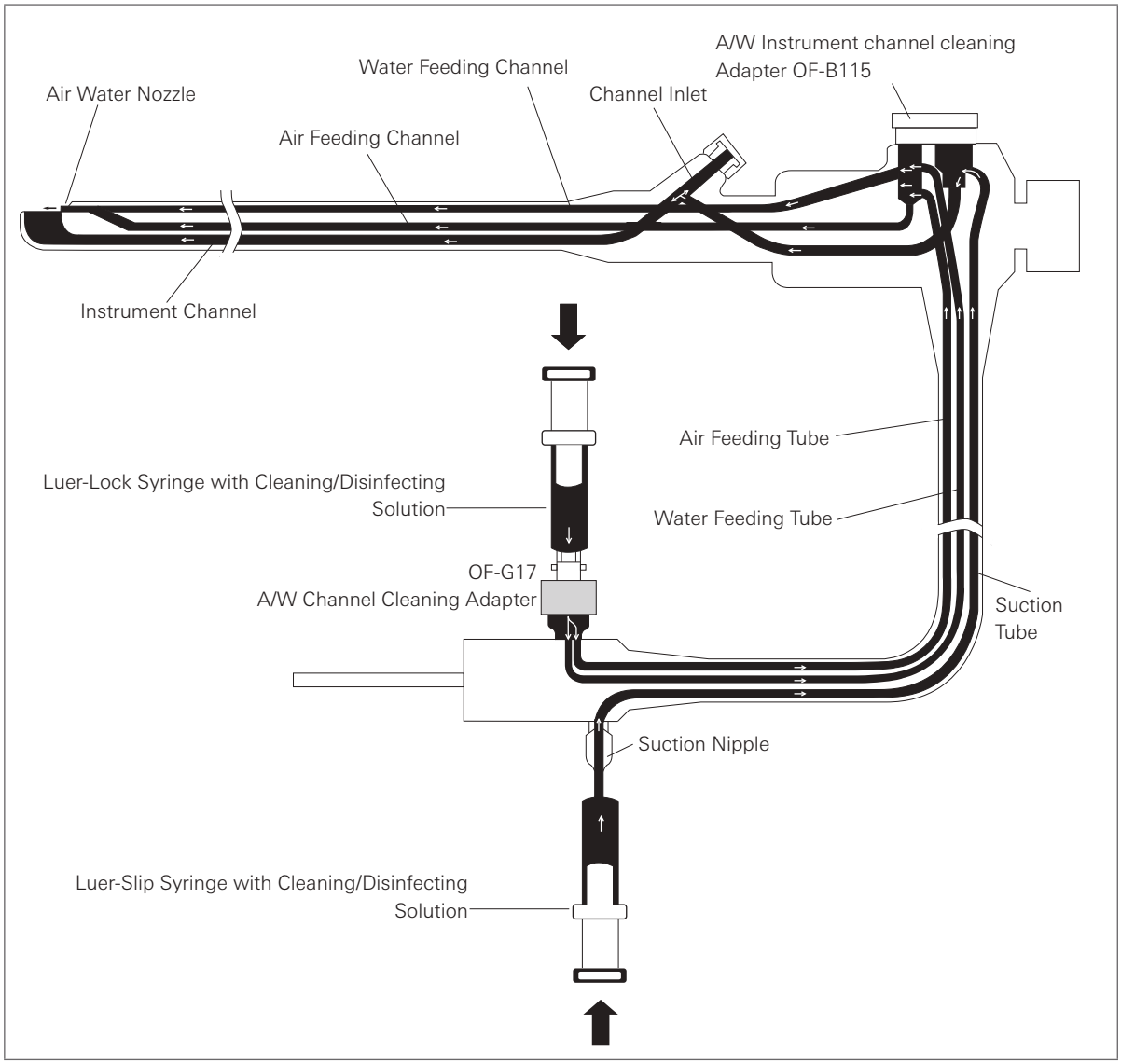


Figure 5.17

To reprocess a PENTAX duodenoscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

Note

Since the elevator control wire is fully enclosed and not exposed to patient material it does not require special reprocessing.

Note

Prior to exposure of all internal channels to an enzymatic detergent and high-level disinfectant (or sterilant), PENTAX channels should be manually cleaned with cleaning brushes.

5-1-5. High-Level Disinfection

Before any attempt is made to disinfect the fiberscope, the complete cleaning procedure described elsewhere in this manual must have been completed.
Prior to high-level disinfection, the end user should confirm the minimum effective concentration (MEC) of reused disinfectant, as per the manufacturer's instructions.

Warning

It is imperative that flexible endoscopes and other semi-critical devices be reprocessed using at least high-level disinfection with a legally marketed sterilant/disinfectant. Only legally marketed endoscope automated reprocessing devices/systems whose device specific claims have been validated by the AER manufacturer and/or anti-microbial agents which have been tested and found to be compatible by PENTAX should be used with PENTAX products.
Generally speaking, "2 %" and "3.2 %" alkaline glutaraldehyde solutions which have been FDA cleared with High-Level Disinfection and/or Sterilization claims are recommended. It should be noted that the actual percentage of active ingredient (glutaraldehyde) in these solutions, as per their product label, may vary from the generic and traditional terms "2 % glutaraldehyde" and/or "3.2 % glutaraldehyde"
For specific brands of compatible disinfectants/sterilants, please contact your local PENTAX service facility or sales representative. Please also refer to the inside front cover of this manual regarding infection control.

Caution

BEFORE IMMERSING:
The ventilation cap must be taken OFF.

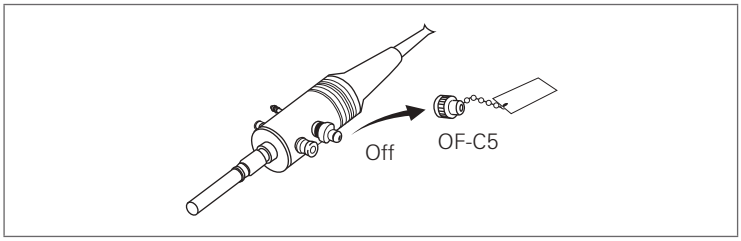


Figure 5.18

1. The air/water/instrument channel disinfecting adapters consisting of two separate components OF-B115 and OF-G17 should already be installed on the fiberscope from the previous cleaning procedure.
2. a) Model number OF-G17 incorporates a standard ANSI luer lock connector to which a syringe or other device should be attached. Fresh (or reused actively effective) disinfecting solution should be flushed through this connector and will simultaneously flow through both the air and water channels and nozzles of the fiberscope. (Please refer to the internal schematics.)

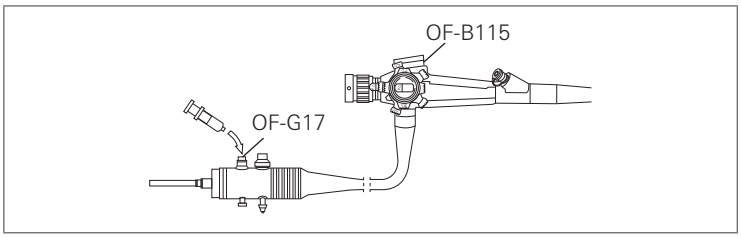


Figure 5.19

> **Warning**
>
> Avoid introduction of air during the flushing process, and confirm that no air bubbles exit from the channel openings at the fiberscope distal end. The presence of the air bubbles could prevent contact of the disinfectant with channel surfaces.

   b) After the entire fiberscope is completely immersed, and the air and water channels have been filled with disinfecting solution, Model Number OF-G17 should be removed.
   c) Adhere to proper exposure times for the disinfectant.
3. Confirm that a rubber inlet seal is attached to the channel inlet during the next step.
4. The suction nipple located on the light guide plug incorporates a standard luer slip fitting to which a syringe (or other device) can be attached. Fresh (or reused actively effective) disinfecting solution should be flushed through or drawn into the entire suction system.

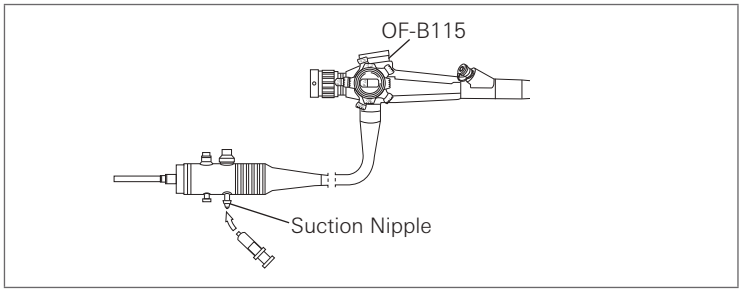


Figure 5.20

> **Warning**
>
> It is imperative that ALL internal surfaces of the channels are in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.

5. As long as the entire instrument is immersed in disinfecting solution, the cleaning adapter, the syringe used in previous steps and the rubber inlet seal should be removed while the instrument remains fully under the disinfecting solution. The removal of component parts and cleaning adapter from the fiberscope will eliminate the risk of mated surfaces not being exposed to the liquid chemical germicide.

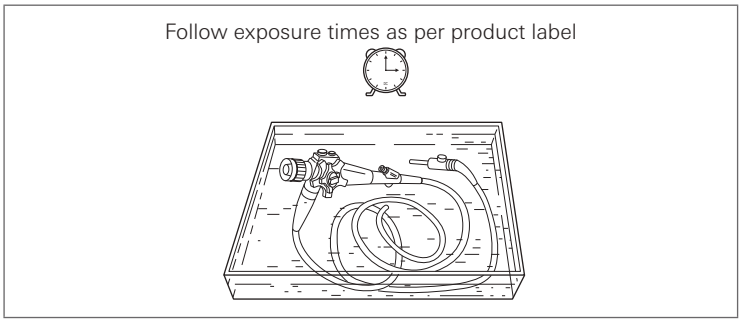


Figure 5.21

6. While fully immersed, manipulate valve mechanisms and inject disinfectant via syringe into/through removable scope components. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces and provide for better exposure of surfaces to germicide. Make sure disinfectant is injected into/through the rubber inlet seal. The fiberscope's component parts should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate to accomplish the desired clinical effect.
7. After the fiberscope and its component parts have been in contact with the disinfecting solution for an appropriate time, flush all channels with air to purge remaining disinfectant, then remove the fiberscope and its components from the solution. Thoroughly rinse the entire fiberscope and all its components with sterile water.
8. A syringe filled with sterile water (200mL or more) should be attached to adapter OF-G17 to flush disinfecting solution from the air and water channels of the fiberscope. Fill a syringe with air and flush through the air and water channels several times to force any residual water out of the tubing and nozzles. Dry thoroughly.
9. With the air/water/instrument channel cleaning adapter OF-B115 attached, rinse the entire suction system, including the instrument channel with sterilie water (200mL or more). Flush air through the instrument channel several times to remove residual water. Dry thoroughly.

Caution

Adequately rinse all internal channels and fiberscope surfaces with sterile water to remove residual disinfectant solution.
Insufficient rinsing may result in mucosal inflammation due to exposure to residual disinfectant solution.

Note

Ideally, all final rinses should be made with sterile water or bacteria-free water whose microbial quality has been confirmed via monitoring. After water rinsing, 70 % alcohol should be flushed through all channels, followed by compressed air, not greater than 165kPa (24 PSI) to facilitate drying. Channel cleaning adapters should be used for alcohol flushing/rinsing and forced air drying.
The outer surfaces of the fiberscopes can be dried by gently wiping with a sterile gauze or lint-free cloth saturated with alcohol.
Regardless of the liquid chemical germicide (sterilant or high-level disinfectant) and/or the quality of the rinse water used, a dry instrument accomplished by a final alcohol rinse followed by forced air is essential to prevent bacteria colonization and/or infections associated with waterborne microorganisms. Such infections are more likely to occur when wet/contaminated instruments are used on patients whose immune systems are compromised or suppressed or when these devices are used in anatomical areas considered sterile and/or susceptible to these organisms.

Following an alcohol rinse, the following steps may be performed to aid in the drying process.

10. Remove the air/water/instrument channel disinfecting adapters, part #OF-B115 and air/water/instrument channel adapter OF-G17, reinstall the previously reprocessed suction control valve, air/water feeding valve, and the rubber inlet seal.
11. Attach the fiberscope to an external suction source, and aspirate air through the channel of the fiberscope to remove any residual alcohol and to air dry channel surfaces.

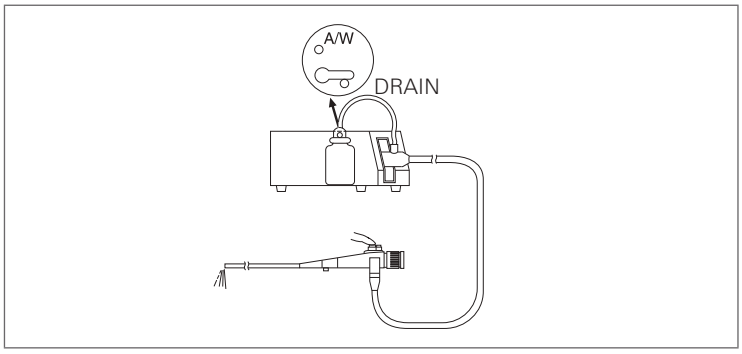


Figure 5.22

12. Attach the fiberscope to the light source with the air pump turned ON to its HIGHEST pressure setting and the drain lever of the water bottle set in the DRAIN position, depress the air/water valve of the fiberscope fully until all alcohol has been discharged from the fiberscope. Thoroughly drain all alcohol from the air channel as well by covering the hole in the air/water valve. Repeat until no moisture or alcohol is seen exiting the fiberscope or distal end.

Note

70 % alcohol should be flushed through all channels, followed by compressed air, not greater than 165kPa (1.69kg/cm2, 24 PSI), to facilitate drying.

13. Gently dry all external surfaces of the fiberscope with a soft gauze or the like. Do not put tension on the insertion tube while drying since the outer cover of the bending section may be excessively stretched.
    Dry the objective lens with a cotton-tip applicator.

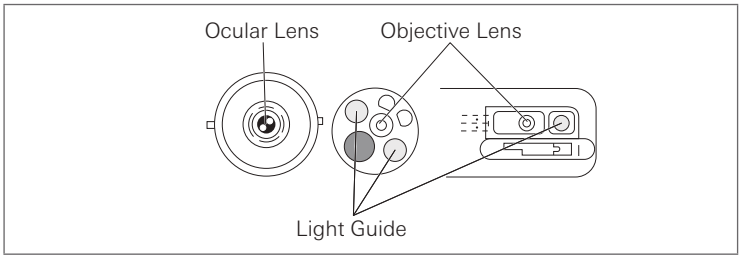


Figure 5.23

> **Warning**
>
> If the fiberscope is to be stored after reprocessing , detach removable valves, components, etc. All channels should be completely dry before storage.

5-1-6. Disinfection of accessories

> **Warning**
>
> Current infection control guidelines require that biopsy forceps and similar endoscopic accessory instruments which enter sterile tissue or the vascular system or break the mucosal barrier must be sterilized before each patient use. It is recommended that any endoscopic accessory instruments intended for use in the biliary tract be subjected to an appropriate sterilization process. For patient contact endoscopic accessories, follow the specific and detailed reprocessing instructions provided with each product.

Before any attempt is made to disinfect endoscopic accessory instruments and/or scope components such as bite block, air/water and suction control valve, brushes, etc. the complete cleaning procedure as described elsewhere in this manual, must have been completed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent high-level disinfection.

1. The entire accessory or component should be immersed in disinfecting solution.
2. Accessory and component surfaces should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate. To ensure better contact, manipulate components such as valves while injecting disinfectant into/ onto components surfaces.
3. After the accessories has been in contact with the disinfecting solution for the appropriate amount of time, remove it from the solution.
4. Rinse all residual disinfecting solution from the accessory/component by immersing it under sterile water.
5. After thoroughly rinsing, the accessories should be gently dried using a soft gauze or the like. Compressed air may also be used to facilitate drying.

Note

Ideally, all final rinses should be made with sterile water or bacteria-free water whose microbial quality has been confirmed via monitoring. After water rinsing, 70 % alcohol should be flushed through tubing of the endoscopic accessory instruments, followed by compressed air, not greater than 165kPa (24 PSI) to facilitate drying. The outer surfaces can be dried by gently wiping with a sterile gauze or lint-free cloth saturated with alcohol.
Regardless of the quality of the rinse water used, a dry instrument accomplished by a final alcohol rinse followed by forced air is essential to prevent bacteria colonization and/or infections associated with waterborne microorganisms. Such infections are more likely to occur when wet/contaminated instruments are used on patients whose immune systems are compromised or suppressed or when these devices are used in anatomical areas considered sterile and/or susceptible to these organisms.

5-1-7. Sterilization and aeration

Before any attempt is made to sterilize the fiberscope, the complete cleaning procedure as described elsewhere in this manual must have been completed.

Caution

NEVER place the fiberscope in a steam autoclave!! NEVER subject the fiberscope to ultrasonic cleaning methods employing high-frequency ultrasound!! Follow provided ETO gas sterilization Parameters.

Note

These following sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

A) Ethylene Oxide Gas Sterilization
Ethylene Oxide (ETO) Gas Sterilization can be performed on these fiberscope, provided the following special instructions, which may differ from other fiberscope, are followed to ensure the proper performance of the instrument. Adhere to the sterilization manufacturer's instructions and always use a biological indicator.

1. The fiberscope must first have been properly cleaned and thoroughly dried according to the instructions in this manual and each of the component parts such as air/water valve, suction valve, rubber inlet seal, should be removed.

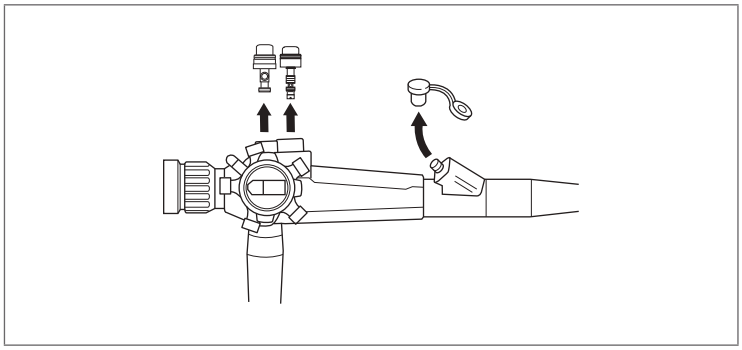


Figure 5.24

Warning

Failure to thoroughly dry all surface areas could result in incomplete or ineffective sterilization. Moisture could prevent contact of the ETO gas with the actual contaminated surfaces.

Note

Prior to placing these fiberscope in a Gas Sterilizer or Aeration Chamber, the ventilation cap MUST be “ON” securely.
This is opposite of the immersion instructions.

2. The following parameters for Ethylene Oxide Gas Sterilization are proposed.

	20:80 ETO/CO2	10:90 ETO/HCFC
Temperature:	55 °C (131 °F)	55 °C (131 °F)
Relative Humidity:	50 %	50 %
Vacuum:	71 kPa	71 kPa
Pressure (Start):	69 kPa	97 kPa
EO Concentration:	450 mg/L	600 mg/L
Pre-Conditioning:	1 Hour	1 Hour
Gas Exposure Time:	5 Hours	5 Hours
Aeration:	12 Hours at 55°C (131°F)	12 Hours at 55°C (131°F)

Caution

Adequately aerate the fiberscope to remove any remaining ethylene oxide. Insufficient aeration may adversely affect the human body.

3. Following ETO Gas Sterilization, aeration time of 72 hours at room temperature is required.
4. Aeration Chamber: To shorten the aeration time to 12 hours, an aeration chamber may be used, provided the temperature does not exceed 55°C (131°F).

Caution

Prior to placing these Fiberscopes in an aeration chamber the ventilation cap MUST be “ON” securely.

B) Other Methods of Sterilization

Other types of sterilization systems/processes are available for the reprocessing of medical devices. However, due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some of these marketed systems/processes/solutions could have detrimental effects on flexible endoscopes.

To avoid the potential for instrument damage, confirm the compatibility of such reprocessing systems/solutions with your local PENTAX representative or service facility prior to use with any PENTAX products.

Prior to using other methods, confirm specific claims of any sterilization methods/processes and ensure manufacturer of such processes has performed microbiological studies that support its claims of achieving sterilization of those specific flexible endoscopes.

5-1-8. Sterilization of accessories

Warning

Current infection control guidelines require that biopsy forceps and similar accessories which enter sterile tissue or vascular system or break the mucosal barrier must be sterilized before each patient use.

It is recommended that any accessory intended for use in the biliary tract be subjected to an appropriate sterilization process.

For patient contact endoscopic accessories, follow the specific and detailed reprocessing instructions provided with each product.

Caution

Use only the type of packaging material and package configuration as recommended by the manufacturer of the sterilizer. Use appropriate heat process indicators and/or biological monitors as recommended by the manufacturer of the sterilizer.

Note

The following sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

Before any attempt is made to sterilize the accessories, the complete cleaning procedure as described elsewhere in this manual must have been completed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent sterilization.

- ETO GAS sterilization
  1. ETO Gas Sterilization can be performed on these accessories and/or components, provided they have first been properly cleaned and thoroughly dried.
  2. Following ETO GAS Sterilization, aeration is required.

Note

For ethylene oxide sterilization of PENTAX accessories and fiberscope components, follow the same ETO parameters as for PENTAX fiberscope.

- Steam Sterilization (Autoclaving)

Note

The following accessories may be subjected to Steam Autoclaving:

- PENTAX biopsy forceps with pink handle
- PENTAX bite block OF-Z5
- PENTAX cleaning brushes
- PENTAX cleaning brushes for A/W suction valve cylinder
- PENTAX cannula TG1918S
- PENTAX A/W instrument channel cleaning adapter OF-B115
- PENTAX check-valve OE-C14
- PENTAX suction valve OF-B120
- PENTAX A/W feeding valve OF-B121

1. Prior to autoclaving, all autoclavable endoscopic accessory instruments and endoscopic couponents identified above should be thoroughly cleaned using manual and ultrasonic cleaning methods as described elsewhere in this manual.
2. Autoclaving can then be performed under the following conditions:

Sterilizer Type	Temperature	Exposure time
Pre-vacuum	132 to 135 °C (270 to 275 °F)	5 minutes

Also, the steam sterilization with the conditions below can be used.

Sterilizer Type	Temperature	Exposure time
Pre-vacuum	134 °C (273 °F)	18 minutes

Caution

Use only the type of packaging material and package configuration as recommended by the manufacturer of the sterilizer.
Use appropriate heat process indicators and/or biological monitors as recommended by the manufacturer of the sterilizer.

Caution

Never place the fiberscope in a steam autoclave nor subject it to ultrasonic cleaning methods!

6 Maintenance

6-1. Withdrawal of a fiberscope with an abnormality

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

1. When using the endoscopic device, close the distal tip or retract it within the sheath. Then, slowly withdraw the endoscopic device from the fiberscope.
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 fiberscope.

6-2. Storage after use

Warning

Observe the following guidelines. Failure to do so may result in contamination of the fiberscope 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 fiberscope when storing.
- Do NOT store the fiberscope in areas of high humidity or high temperature.
- Do NOT store the fiberscope, its components, and accessories in the carrying case.
- Ensure that the fiberscope, its components, and accessories are completely moisture-free before storage.
- Before the next use, the fiberscope, 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 this IFU.

Caution

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

- Fiberscope insertion portion, umbilical cable, 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 fiberscope, its accessories, and devices, so that they do NOT hit against each other.

Note

Store the reprocessed endoscope in a clean, dry, and well-ventilated place with the insertion portion and umbilical cable hanging vertically or it can be stored horizontally if it is completely dried. The method of storage should include adequate measures to reduce the possibility of recontamination.

1) Following reprocessing, the fiberscope may either be reused or placed in storage.

Note

When utilizing chemo-thermal processes for reprocessing PENTAX fiberscopes, the fiberscopes should be allowed to return to room temperature prior to use and/or further handling.

2) Prior to reuse, ensure that fiberscope has been properly inspected and fully prepared for the next clinical procedure.
3) Prior to storage, ensure that all internal channels, fiberscope components, fiberscope surfaces and accessories are thoroughly dry.
4) A cotton tipped applicator moistened with 70 to 90 % medical grade ethyl or isopropyl alcohol may be used to carefully remove any films or residues left upon the lens surfaces, such as the distal objective lens.
5) The fiberscope should be hung in a clean, dry, well-ventilated storage cabinet at room temperature. The insertion tube and light guide cable should be hung and kept as straight as possible during storage.

6-3. Returning the fiberscope for repair

When returning the fiberscope for repair, follow the instructions below. For more details, contact your local PENTAX Medical service facility. Always subject the fiberscope to cleaning and high-level disinfection before returning it for repair.

Warning

Only qualified personnel from PENTAX Medical are authorized to repair this fiberscope. 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 fiberscopes 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 fiberscope 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 fiberscope.
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.

6-4. Care and maintenance tips

Flexible endoscopes have been an invaluable tool in the medical community's armamentarium to successfully diagnose and treat a wide variety of illnesses in patients for several decades. Perhaps due to their longevity and progressive design changes over the years which have simplified their use, flexible endoscopes have been somewhat taken for granted and have erroneously not been considered highly technological medical devices.

In fact, current generation flexible endoscopes although easier to clinically use, are much more sophisticated than ever. Special reprocessing instructions must be followed to ensure the instruments are patient ready and patient safe. Special care and handling must be exercised and practiced to prevent instrument malfunction and prolong the reliability of the fiberscope.

The burden of responsibility to ensure safe and reliably functioning instruments is left in the hands of the healthcare professionals who actually care for and reprocess flexible endoscopes.

Naturally, equipment manufacturers share in this responsibility and tremendous efforts have been spent in designing instruments which could be reprocessed and maintained as easy as possible. However, due to the nature of their use and application, flexible endoscopes must be subjected to special cleaning procedures, followed by a disinfection or sterilization process after each and every patient use.

To highlight and simplify, what may appear to some as being complicated maintenance and reprocessing instructions, PENTAX strongly recommends the users review the following suggestions and advice on the care and maintenance of your PENTAX flexible endoscopes.

These tips, particularly those involving scope reprocessing should not be construed as "shortcuts" and are not intended as substitute directions for complete instructions found elsewhere in the owner's manual.

- Avoid soaking of the fiberscope with accessories (forceps, injection or aspiration needles, etc.) or any sharp edged objects which could inadvertently scratch or cut the distal bending section sheath. (Subsequent flexing back and forth of the rubber sheath could eventually stretch the scratched rubber until a pinhole and leak develops.)
- Exposure to a compatible enzymatic detergent is essential to thorough cleaning of all surfaces of the fiberscope. Rinsing and drying after cleaning is imperative to prevent dilution of the disinfectant/sterilant.
- Do not reuse disposable accessories intended for single patient or one time use.
- Do not expose the fiberscope or accessories to harsh chemical solutions. Strictly adhere to exposure times recommended by the manufacturers of compatible solutions.
- Avoid contact of any flexible portion of the fiberscope with any sharp edge objects (bed frames, table top corners, sink drains, accessories hanging in storage cabinets, etc.) at any time during the handling, reprocessing or storage of the fiberscope.
- Avoid stretching of the bending section rubber sheath at the distal portion of the fiberscope. During mechanical cleaning of the fiberscope with a dampened gauze, do not use excessive force. A gentle back and forth wiping motion should be sufficient to remove gross debris. Subsequent soaking in an enzymatic detergent will clean the remainder of debris.
- Not all manufacturers of automated endoscope reprocessors (AERs) make specific claims nor provide special instructions for reprocessing all of the removable fiberscope components that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER manufacturer's instructions not specifcally address reprocessing of any particular fiberscope component (air/water feeding valve, suction control valve, inlet seal, irrigation tube, check-valve, etc.) in the AER, then those components must be reprocessed manually as descrived in PENTAX instructions/labeling. Prior to use, check with each AER manufacturer as to their specific claims with respect to reprocessing individual fiberscope components.

- Disinfectants and sterilants are toxic substances by nature. All residual solution must be thoroughly rinsed and dried prior to each patient use.
- The key to preventing clogged air or water channels/nozzles is to immediately flush the channels with either air pressure or fluid/detergent right after removal from the patient. This should be followed by soaking with an enzymatic detergent.
- Avoid attempting to remove or unscrew scope components which should not be removed. Parts such as the distal portion of the light guide plug and any rubber strain reliefs on either the insertion tube or umbilical cable are essential to the watertight integrity of the instrument. Removal or loosening of these components and subsequent immersion could lead to fluid invasion into the fiberscope.
- Check for any sharp edges on all surfaces of an automated cleaning/reprocessing unit which may come in contact with a fiberscope. Some units may have sharp edged wire mesh filters and baskets or inlet/outlet ports which could damage your scope.
- Do not overtighten the cap to the water bottle assembly. The metal pipe at the top of the PENTAX water bottle assembly functions as an inlet port for air from the light source. This inlet pipe should not be used as a leverage tool to tighten the cap to the water container. Overtightening could cause the plastic cap to crack.
- Do not forget to confirm that a rubber check-valve has been properly attached to the air/water valve prior to use.
- Make sure that rubber air/water/instrument channel cleaning adapter is securely attached to the top of the air/water and suction valve cylinders.
- Do not introduce air bubbles into the scope's internal channels during flushing of cleaning and/or disinfecting/sterilizing solutions as these bubbles could interfere in the effectiveness of the disinfection/sterilization process.
- Do not store the fiberscope and accessories in the carrying case as this type of dark, humid and unventilated environment is conducive to bacteria colonization which increases the risk of cross-contamination.
- Prior to each use, check the condition of all accessories.
  Do not use any accessories with kinked or bent flexible shafts.
  Do not use forceps with misaligned cups and/or bent needles/spikes.
  Do not use aspiration or injection needles which are not retractable or whose sharp tips can not be protected.
  Do not use cleaning brushes without smooth or rounded distal tips.
  Do not use instruments with exceptionally long rigid sections or whose outer diameter restricts pasage through the instrument
  channel/channel inlet.
  Use of any of the above accessories could result in channel damage and costly repairs.
- Verification of the effective level of glutaraldehyde (via test strips or similar methods) is recommended to ensure potency of glutaraldehyde to achieve high-level disinfection.
- When utilizing chemo-thermal processes for reprocessing PENTAX fiberscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.

Warning

Instrument repairs should only be performed by an authorized PENTAX service facility. PENTAX assumes no liability for any patient/user injury, instrument damage or malfunction, or REPROCESSING FAILURE due to repairs made by unauthorized personnel.

Warning

Never drop this equipment or subject it to severe impact as it could compromise the functionality and/or safety of the unit.
Should this equipment to be mishandled or dropped, do NOT use it. Return it to an authorized PENTAX service facility for inspection or repair.

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 fiberscope(s).

Electromagnetic compatibility (EMC)

This product as the endoscope system, the endoscope with the video processor or the light source conforms to IEC60601-1-2: 2007: Medical electrical equipment, IEC standard.

Guidance and manufacturer's declaration-electromagnetic emissions

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

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

Guidance and manufacturer's declaration-electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Same as left	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Same as left	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 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the 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	Portable and mobile RF communications equipment should be used no closer to any part of this model including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/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.
- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
  a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
  b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

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

Note

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

Electromagnetic disturbances

(The following description applies to the products that start with serial number "N" or later.)
This product as the endoscope system, the endoscope with the video processor or the light source conforms to IEC60601-1-2: 2014: Medical electrical equipment, IEC standard.

Guidance and manufacturer's declaration-electromagnetic emissions

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

Table 1

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

Guidance and manufacturer's declaration-electromagnetic immunity

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

Table 2: Enclosure Port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table6
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3: Input AC Power Port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
Electrical fast transients/bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T; 0,5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 °
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0 °
Voltage interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycles

Note: If this product has the single rated voltage, U_T is the rated voltage.
If the rated voltage has the range, U_T is the lowest voltage and the highest voltage in the voltage range.

Table 4: PATIENT coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Table 5: Signal input/output parts PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transients/bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Immunity to proximity fields from wireless communications equipment

Table 6: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Modulation[a)]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 to 390	Pulse modulation[a)] 18 Hz	1.8	0.3	27
450	430 to 470	FM[b)] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	Pulse modulation[a)] 217 Hz	0.2	0.3	9
745					
780					
810	800 to 960	Pulse modulation[a)] 18 Hz	2	0.3	28
870					
930					
1720	1700 to 1990	Pulse modulation[a)] 217 Hz	2	0.3	28
1845					
1970					
2450	2400 to 2570	Pulse modulation[a)] 217 Hz	2	0.3	28
5240	5100 to 5800	Pulse modulation[a)] 217 Hz	0.2	0.3	9
5500					
5785					

a) The carrier shall be modulated using a 50 % duty cycle square wave signal.
b) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note

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

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

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

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

Warning

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

Note

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

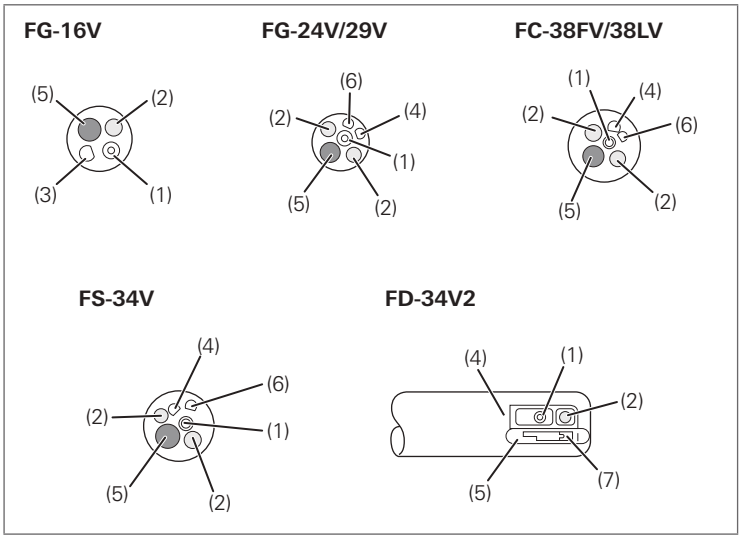
Specifications

Model Name		FG-16V	FG-24V	FG-29V	FC-38FV	FC-38LV	FS-34V	FD-34V2
Direction of view		Forward (0°)						Side-Viewing (retro 5°)
Field of view		125°	105°	100°	120°			80°
Depth of field		3 to 50 mm	3 to 100 mm					4 to 70 mm
Diopter		+3 to –8 Dptr						
Tip Deflection	Up/Down	180°/180°	210°/120°		180°/180°			120°/90°
	Right/Left	160°/160°	120°/120°		160°/160°			110°/90°
Rigid Distal Diameter		Ø5.2 mm	Ø7.8 mm	Ø9.8 mm	Ø13.4 mm		Ø11.5 mm	Ø13 mm
Insertion Tube Diameter *1		Ø5.3 mm	Ø7.9 mm	Ø9.8 mm	Ø12.8 mm		Ø11.5 mm	Ø11.3 mm
Diameter of Instrument Channel *2		Ø2.0 mm		Ø2.8 mm	Ø3.8 mm		Ø3.5 mm	Ø4.2 mm
Insertion Tube Working Length *1		925 mm	1,050 mm		1,500 mm	1,700 mm	700 mm	1,250 mm
Total Length		1,270 mm	1,395 mm		1,845 mm	2,045 mm	1,045 mm	1,595 mm

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



(1) Objective Lens
(2) Light Guide
(3) Air/Water Nozzle
(4) Air Nozzle
(5) Instrument Channel
(6) Water Nozzle
(7) Cannula Elevator

System chart

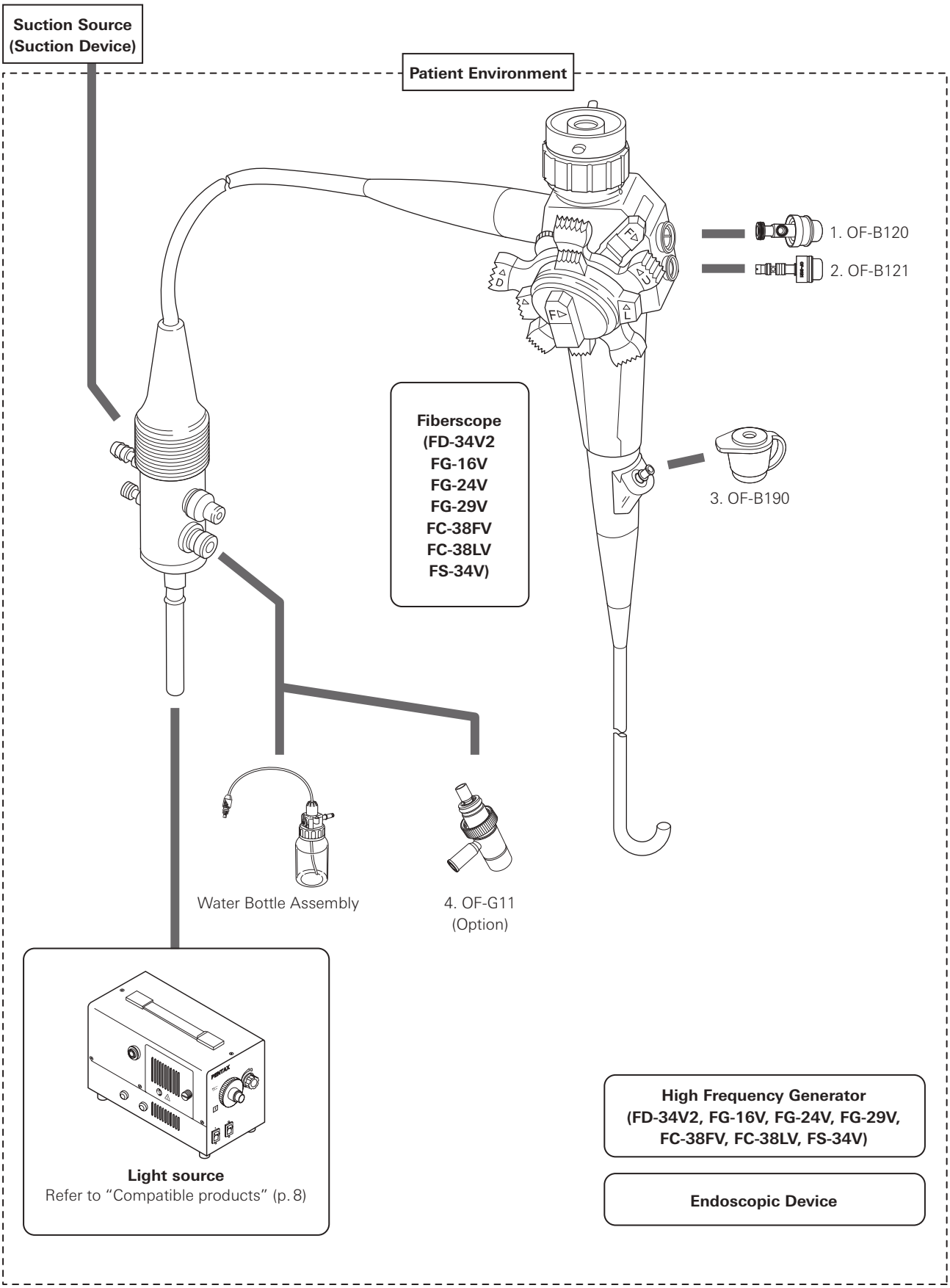
This section shows the system chart (configuration) for this fiberscope and the ancillary equipment.

Warning

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

Note

When this fiberscope 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-B121)
3. Inlet Seal (OF-B190)
4. Gas Adapter (OF-G11*) *Optional Equipment

Contacts

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