PENTAX
MEDICAL

Instructions for Use

PENTAX BRONCHO FIBERSCOPE

FB-8V
FB-10V
FB-15V
FB-18V
FB-19TV

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.19 11:29:06 EET
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Location: Moldova

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. Inappropriate use of the fiberscope 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
	Follow the Instructions for Use
	Manufacturer
EC REP	Authorized representative in the European Community
CE	This product complies with the applicable standards harmonised under the Directive 93/42/EEC and Directive 2011/65EU.

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.

CONTENTS

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

These fiberscopes are intended to provide optical visualization of, and therapeutic access to, the Airway and Bronchial Tree. This anatomy includes, but are not restricted to, the organs; tissues; and subsystems: Nasal passage, Trachea and Bronchial Tree. The fiberscope is introduced via the mouth or the nose, as decided by physician, when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

Application

Medical Purpose	Provide images for observation, diagnosis, visualization, and treatment.
Patient population	Patients who are considered suitable for the application of this endoscope by the physicians (pediatric to adult patients).
Intended anatomical area	Nasal passage, Trachea and Bronchial Tree.
User qualifications	Physicians (Experts who have been approved by the endoscopic medical safety administrator at each medical facility. If the eligibility requirements are defined by an official body, such as a government entity and/or an academic society, follow such requirements). Specific training to use this endoscope is not required.
Location of use	A medical facility

Classification

Degree of protection against electric shock for the applied parts	TYPE BF applied part (when connected to a compatible PENTAX Medical light source)
Degree of protection against water	IPX7 (with the soaking cap attached)
Mode of operation	Continuous operation
Use in an oxygen-rich environment	Suitable

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

Compatible products

This section describes the equipment that can be used in combination with this fiberscope. For more details, refer to “System chart” (p.15)
The combination of equipment that can be used with this fiberscope is 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.*

■ 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	

Reprocessing before the initial use and reprocessing

■ 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 endoscopes and equipment used on these patients must be discarded so that they cannot be used again on another patient.
The pathogenic agents that cause this disease, which are called "prions", cannot be destroyed or inactivated using the cleaning, sterilized and stored, high level 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.

NOTE

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

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 fiberscope 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. Doing so may result in damage to the fiberscope or 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 fiberscope such suction nipple, or venting connector 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 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 cannot 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 an 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.*
- *Transnasal insertion must be determined appropriately and cautiously according to the discretion of a medical professional.*
  - *No endoscope, including this one, can always be inserted transnasally into all patients. Ensure that transnasal insertion is possible for the patient by considering the shape and size of the patient's nasal cavity as well as his/her receptivity.*
  - *Do NOT forcefully insert the endoscope transnasally. Doing so may result in injury to the patient's nasal cavity.*
  - *Before transnasal insertion, apply the appropriate pretreatment such as enlarging the nasal cavity, etc. to the patient. Failure to do so may result in patient injury.*

⚠ CAUTION

- *Do NOT excessively twist, rotate, or bend any of the insertion portions, strain relief boots, or umbilical cord. 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.Nomenclature and functions

1-1. Fiberscope

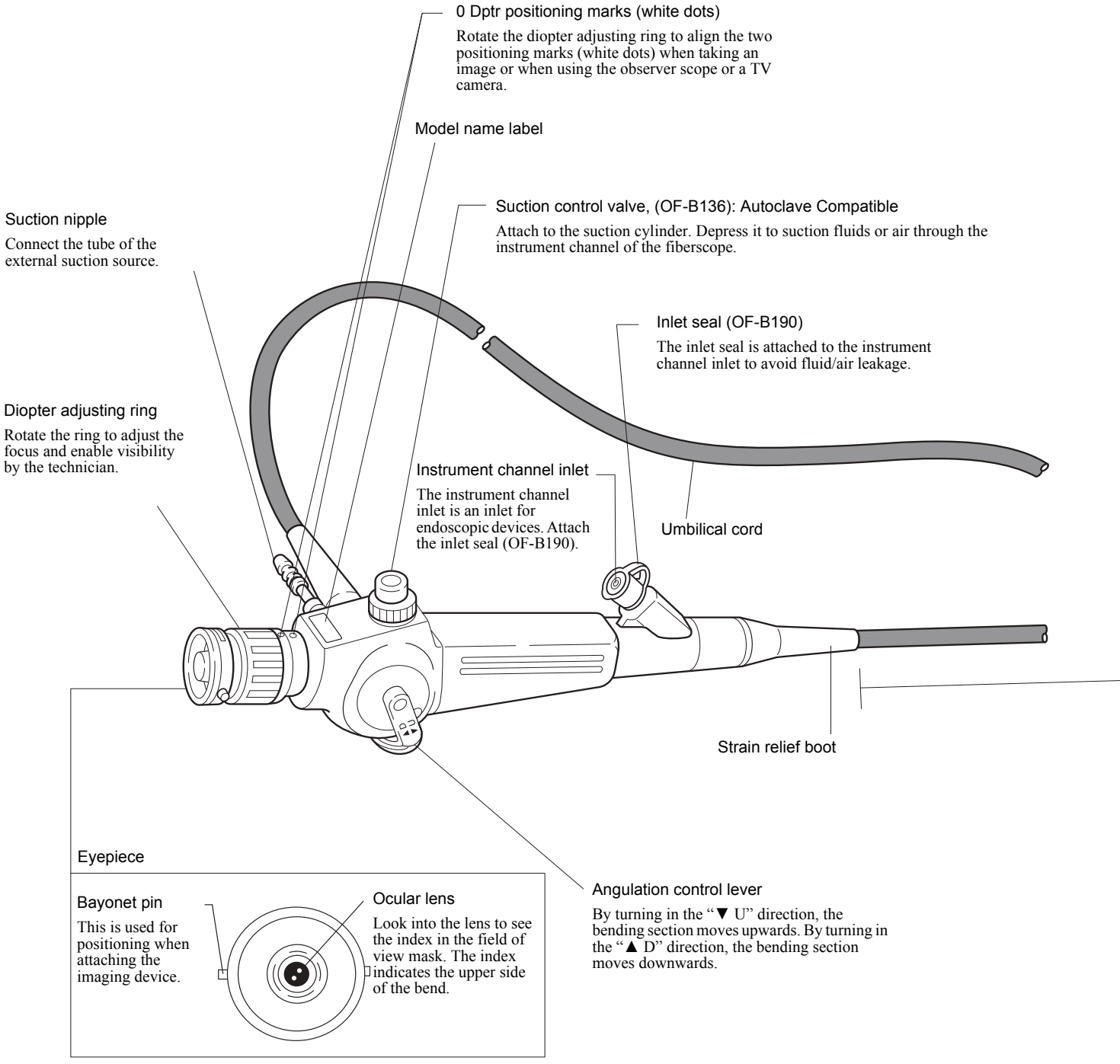


Figure 1.1

Ventilation cap red (OF-C5)

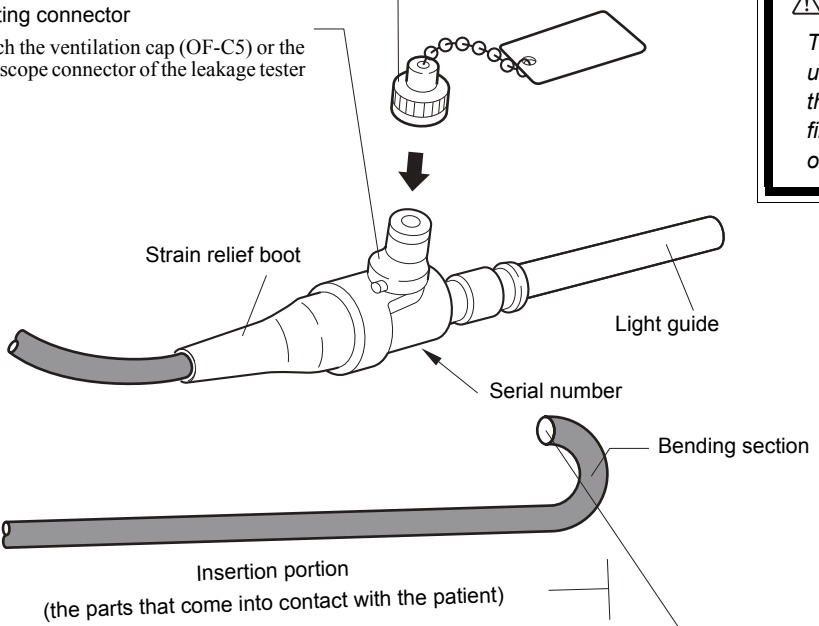
Be sure to attach this cap to prevent damage to the insertion portion when performing ETO gas sterilization. This cap must be removed before immersion.

NOTE

See important separate section, 4. Care after use, regarding the use of this cap.

Venting connector

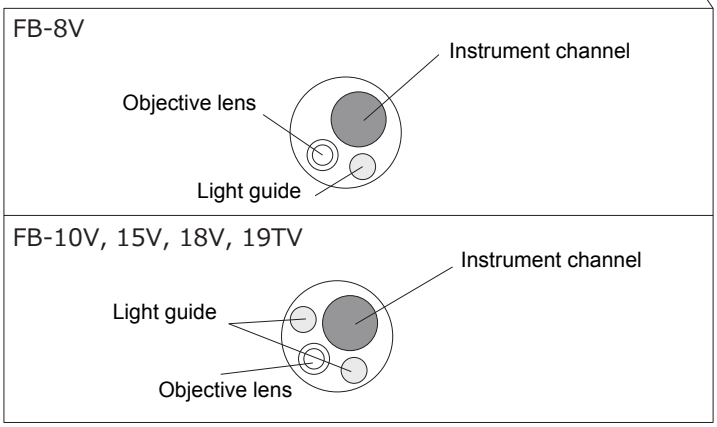
Attach the ventilation cap (OF-C5) or the endoscope connector of the leakage tester here.



⚠ WARNING

The metal light guide may be hot after use. To prevent burns, do NOT touch this section directly after use. Hold the fiberscope by the plastic section in front of the insertion area.

Distal end



⚠ CAUTION

The area inserted to the light source and the control body side of the insertion portion are reinforced with strain relief boots to protect the connecting parts. Do NOT excessively twist, rotate, or bend any of the insertion portions, strain relief boots, or umbilical cord. Doing so may damage the fiberscope.

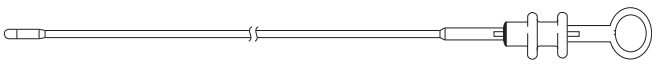
1-2. Package contents

NOTE

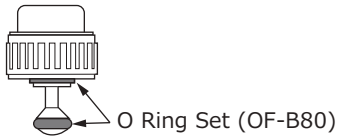
- *Some accessories are optional. Refer to the separate Standard Accessories List.*

Check the package contents according to the separate standard accessories list provided with this fiberscope. (The figure below includes all accessories for all endoscope models described in this 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.)

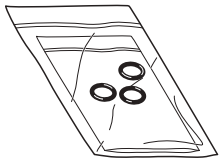
■ Accessories



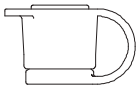
Biopsy Forceps with Windows
(FB-15V: KW1811S)
(FB-18V: KW1811S and KW2411S)
(FB-19TV: KW2411S)



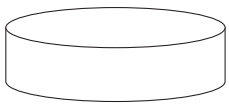
Suction Control Valve (OF-B136)
(Plastic, Autoclave Compatible)
(Installed)



O Ring Set (OF-B80)
* For Suction Control Valve (OF-B136)



Inlet Seal (OF-B190)
(Installed)



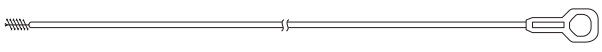
Eyepiece Cap
(OF-D1) (Installed)

Eyeshield (OF-D3)
(Only for FB-15V/18V/19TV)

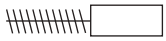
Bite Block (OF-Z5)

Silicone Oil
(OF-Z11)

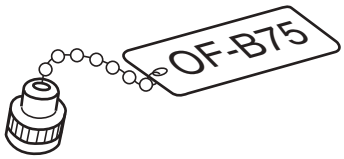
Ventilation Cap
(OF-C5)



Cleaning Brush
(FB-15V/18V/19TV: CS6015ST, CS6002SN)
(FB-8V/10V: CS3010S, CS6002SN)

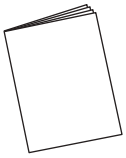


Cylinder Cleaning Brush
(CS-C3S)

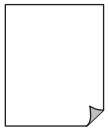


Suction Channel Cleaning & Disinfection Adapter
(OF-B75)

■ Other



Instructions for Use
(This IFU)



Standard Accessories List

Figure 1.2

1-3. Light Source

⚠ WARNING

- *Install, use, and store the light source where it will be protected from dust. If any dust is confirmed on the light source, wipe it off. Excessive amounts of dust accumulating inside the light source may cause it to malfunction, emit smoke, or catch fire or may cause other problems.*

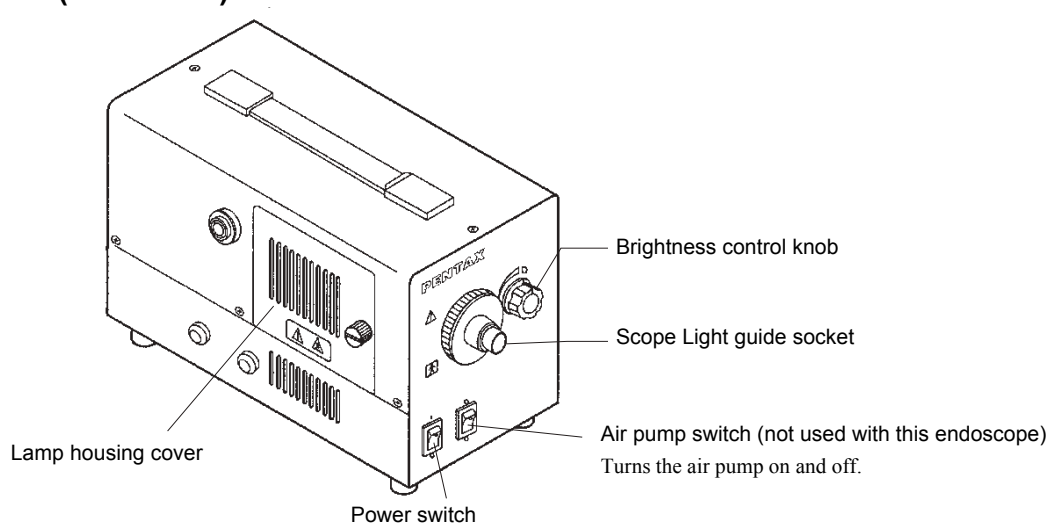
⚠ CAUTION

- *Thoroughly read the IFU provided with the light source before using them, and always perform a pre-use inspection.*
- *Do NOT use a water bottle assembly or air pump with the fiberscope. Turn off the pump switch.*

NOTE

- *Light source models that can be connected with this fiberscope are shown below. For details on the operation of each light source, refer to the IFU of the respective light source.*
- *The life of the lamp is 50 hours for the LH-150PC and 300 hours for the LX-750P, but frequent use may shorten the life.*

Halogen Light Source (LH-150PC)



Xenon Light Source (LX-750P)

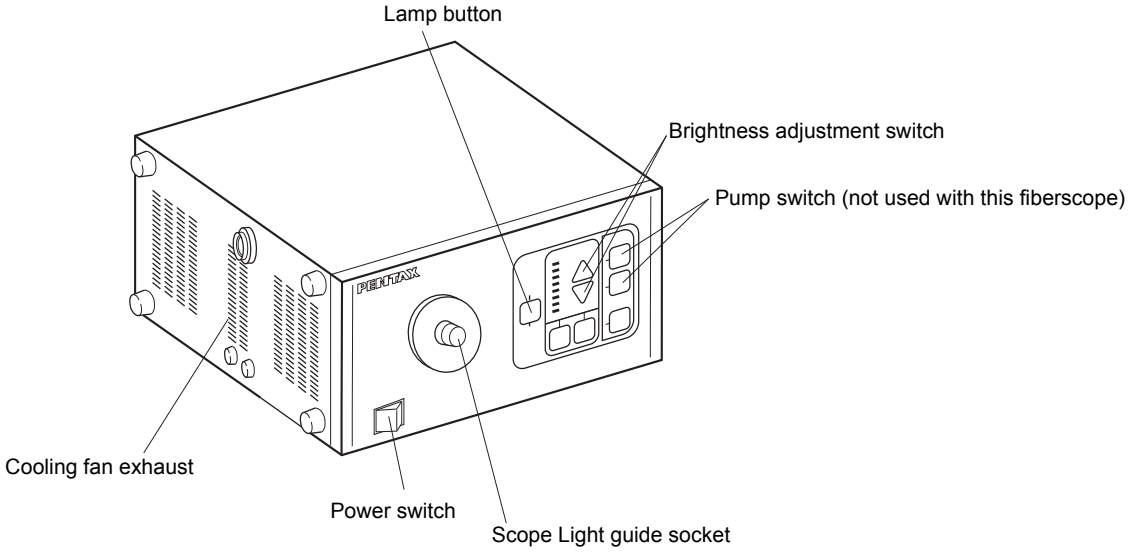


Figure 1.3

1-4. 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.7) and the "System chart". Failure to do so may result in lowered function and patient/user injury or damage to the equipment.*

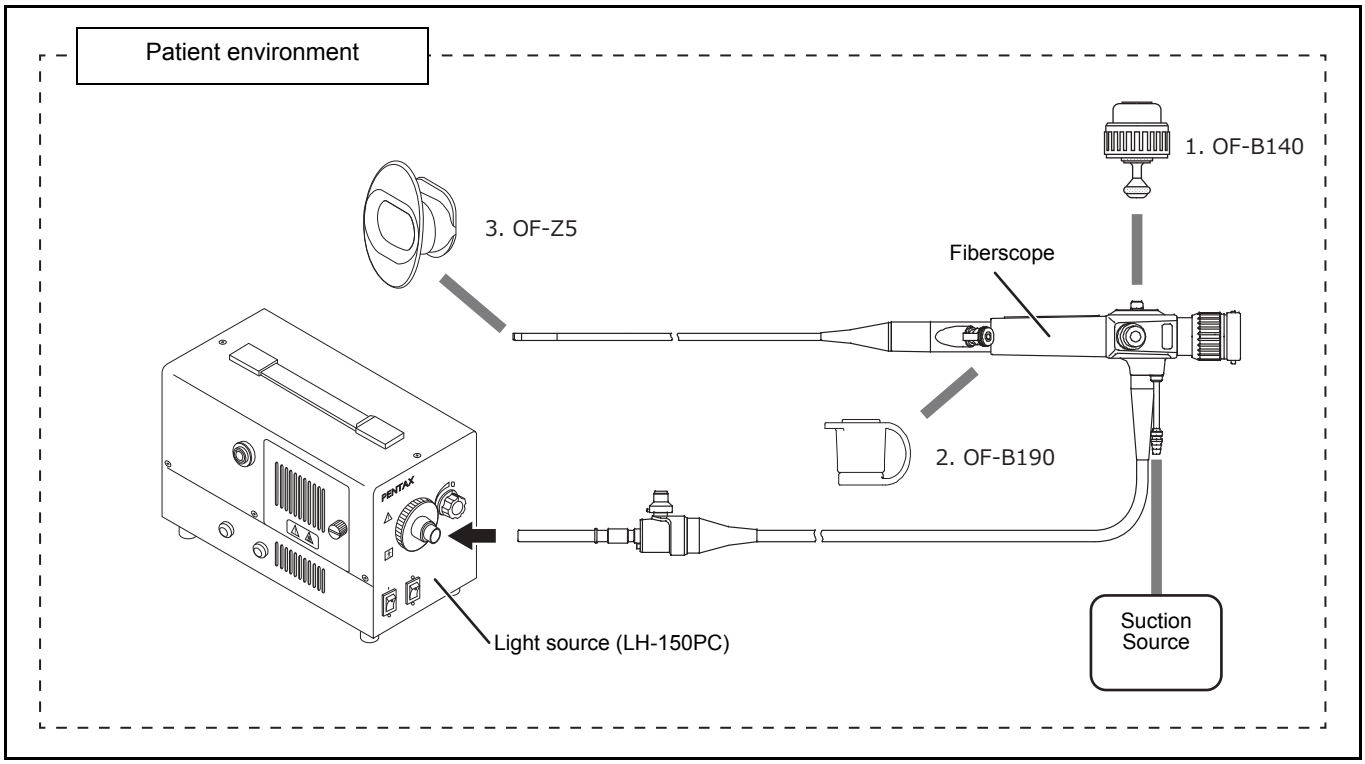


Figure 1.4

1. Suction Control Valve (OF-B136)
2. Inlet Seal (OF-B190)
3. Bite Block (OF-Z5)

2.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.

⚠ 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.

2-1. Inspection of the light source

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

⚠ WARNING

- *Do NOT use the light source where explosive or flammable gases are present or in an oxygen rich environment. Failure to observe this precaution may cause the light source to catch fire.*
- *Do NOT look directly at the light emitted from the distal end of the fiberscope or the light source. The intense light may cause eye injuries. Turn off the lamp when looking directly at the distal end of the fiberscope.*

NOTE

This fiberscope can be used with the PENTAX Medical LH-150PC or LX-750P light source. Be aware that other light sources cannot be connected without an adapter.

2-2. Inspection of the fiberscope

Prepare an 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 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, 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.*
- *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 and sterilization processes according to this IFU.*

⚠ CAUTION

The fibers used in this product may yellow due to repeated exposure to stroboscopic light emissions or X-ray emissions. This may cause the observation image to look excessively yellow.

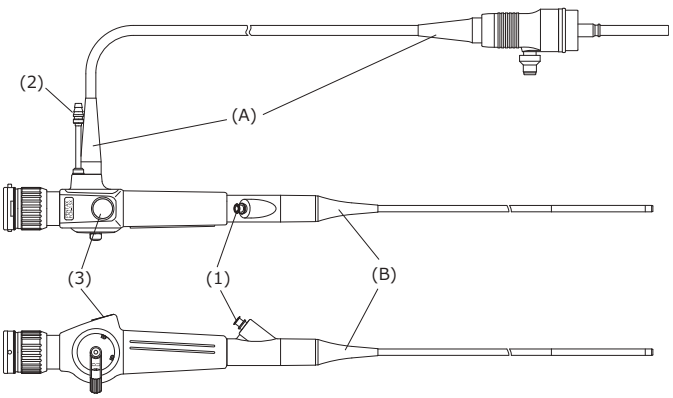
NOTE

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.

1) Check that the fiberscope is clean and properly sterilized before using on each patient.
Prepare the fiberscope that has been reprocessed according to the procedure specified in this IFU.

NOTE

Flexible endoscopes and other sophisticated medical endoscopes are constructed of special materials, unique parts and intricate components with strict dimensional tolerances. Specialized assembly techniques and application of specific sealants and/or adhesives are required to ensure the watertight integrity and maintain the functionality of these devices. It is therefore imperative that endoscopes be routinely checked to ensure that parts used in their construction are not loose, missing or compromised that could otherwise negatively affect the functionality of these devices. Compromised or loose components could result in device failure, endoscope damage (via fluid invasion) and/or in incomplete decontamination of used endoscopes. PENTAX recommends that prior to use endoscopes should be carefully inspected for their integrity and checked for any "looseness" in the mating or joining of components including the following parts/areas:



– Instrument channel inlet (1)
– Suction nipple (2)
– Cylinder (3)
– Strain relief boots (A), (B)

One method to check for looseness is to lightly grip the exposed part, and while grasping the component carefully attempt to move it in various directions. Use of a lint-free gauze while grasping metal parts is recommended as a protection for one's fingers. If any part/component remains loose (after attempting to tighten) and/or if there is any indication or suspicion of an abnormality or outward signs of damage, do NOT use the endoscope. Contact your local PENTAX Medical service facility.

Figure 2.1

⚠ CAUTION

- *Do NOT excessively twist, rotate, or bend any of the strain relief boots (See (1) and (2) in the figure to identify the strain relief boot). Doing so may result in fiberscope damage. Pay special attention to the careful handling of the strain relief boot (2) of the insertion portion of the endoscope, 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 insertion portion. Moreover, do NOT squeeze or forcefully bend the bending section. Doing so may damage the fiberscope.*

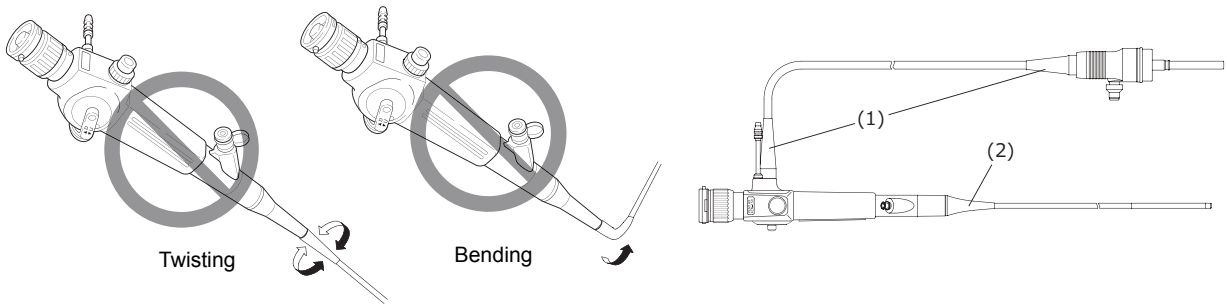


Figure 2.2

2) Inspection of the entire endoscope

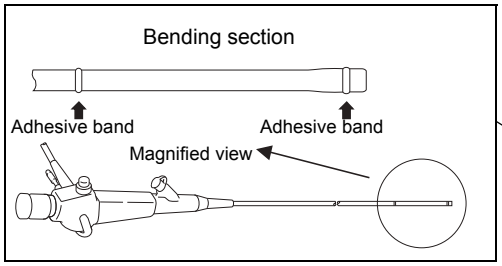


Figure 2.3

a) Check the entire surface of the fiberscope for any visible adhered material.
b) 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.
c) 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.

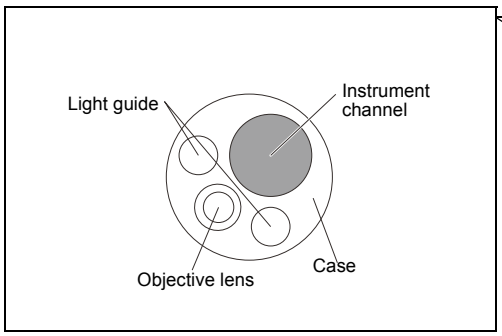


Figure 2.4

d) Check the case of the distal end of the fiberscope (especially around the periphery of the instrument channel) for any abnormalities such as deformation or chipping.
e) 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.
f) 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.
g) Gently clean the objective lens and light guides with clean gauze or a cotton-tip applicator moistened with 70%–90% medical grade ethyl or isopropyl alcohol. Check that there is no attachment of the adhesive on the gauze.

NOTE

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

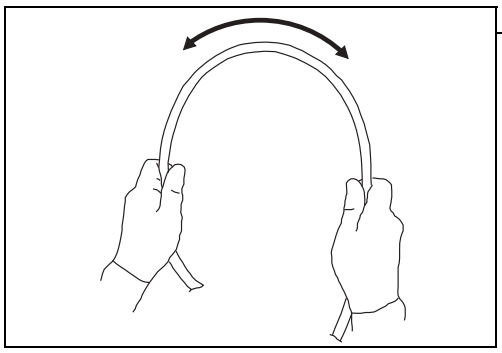


Figure 2.5

h) Form an arch with the insertion tube as shown in Figure 2.5 using both hands. By sliding the insertion tube in the direction of the arrow in the left Figure, check that the entire insertion portion can be bent smoothly and easily to form an arch.
i) Check that the fiberscope is cleaned, high level disinfected and/or sterilized before using it.
j) Check the entire surface of the umbilical cord for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, catching, protrusions, attachment of foreign materials, detachment of parts, etc.

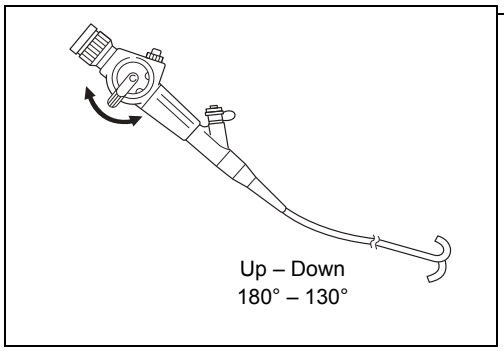


Figure 2.6

3) 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.

a) Slowly rotate the angulation control lever and check that the lever moves smoothly and that the bending section bends normally within the maximum angle range.

⚠ WARNING

- *To avoid damage, be especially careful NOT to hit the distal end of the fiberscobe. NEVER squeeze or severely bend the insertion portion.*
- *Do NOT use an 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.*

4) Inspection of the suction mechanism

a) Remove the suction control valve from the control body and check that there are no abnormalities in the exterior (cracking, wear, damage, etc.) on the exterior. If an abnormality is found, replace with a new, appropriately disinfected or sterilized part. Check that the O-ring has no abnormalities, is properly attached and a small amount of silicone oil (OF-Z11) has been applied.

⚠ WARNING

- *NEVER use a suction control valve that has any abnormality. Replace it 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-B80) for the suction control valve (OF-B136) for replacement.*
- *Before inspecting the suction function, attach the cap to the inlet seal. Failure to do so may cause lowered suction function.*

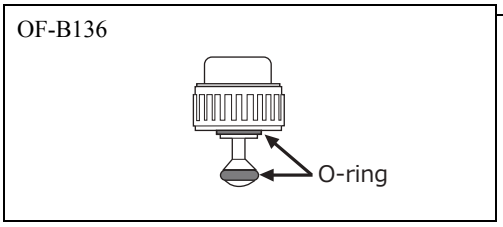


Figure 2.7

b) If the suction control valve does not move smoothly, remove the valve from the fiberscope. Apply a small amount of silicone oil (OF-Z11) onto the O-ring. Dry the suction control valve thoroughly, and then place a small droplet of oil on one's sterile gloved forefinger and gently swirl between thumb and forefinger. Next apply the silicone oil to the O-ring in-between thumb and finger and gently rotate the valve so that the oil is evenly applied to the outer edges of the O-ring. Remove/wipe off excess lubricant with a soft gauze. Do not use excessive silicone oil.

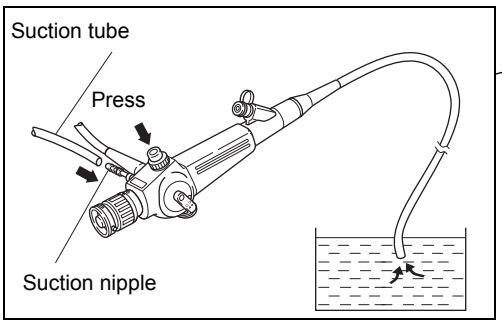


Figure 2.8

c) Connect suction tubing from an external suction source to the irrigation nipple located on the control body. Place the distal end of the fiberscope in a basin of sterile water and depress the suction control valve.
Water should be rapidly aspirated into the suction system collection container.

d) Release the suction control valve to determine if the valve freely returns to its OFF position and the aspiration of water ceases.

⚠ WARNING

- *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.*

⚠ WARNING

- *Full suction is NOT possible if the inlet seal is NOT correctly attached to the instrument channel inlet. NEVER use an inlet seal (OF-B190) that has any abnormality. Replace it with a new one that has been fully reprocessed. 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.*

NOTE

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.

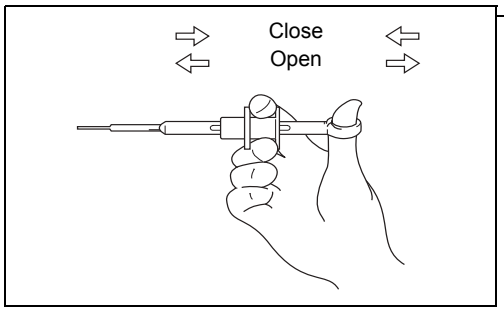


Figure 2.9

6) Inspection of the biopsy forceps and instrument channel.

⚠ WARNING

- *Electrosurgery cannot be performed with the FB-8V/10V.*
- *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.*

a) Check for twisting and damage in the shaft of the biopsy forceps.
b) Check for foreign materials remaining at the distal end of the forceps. Remove immediately if there is any foreign materials.
c) Check that the forceps cups open and close when the forceps are operated by hand. Also check that the operation is smooth.
d) Check that the forceps cups catch normally when they are closed. If using forceps with a needle, check that the needle is straight and is fully contained in the cups.

⚠ 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.

e) When inserting the forceps into the instrument channel inlet, gently insert them straight into the insertion portion of the fiberscope. If resistance appears to occur, do not insert the forceps any further. The instrument channel may be damaged. Contact your local PENTAX Medical facility and do not use the fiberscope.

⚠ WARNING

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

⚠ CAUTION

Take the following precautions, as damage to the instrument channel may compromise the safety and effectiveness of the fiberscope.

- *Before use, inspect the condition of the endoscopic device, whether they can be properly inserted into the fiberscope, and the waterproof performance of the fiberscope according to the IFU for the fiberscope and endoscopic device, to ensure that there will be no issues during use. NEVER use this fiberscope if there is a sign of damage or an abnormality.*
- *Slowly and gently insert and withdraw the forceps from the inlet seal. Applying strong force may cause fiberscope damage.*
- *Some resistance may occur at first when inserting a endoscopic device. Hold the area around 5cm from the end of the endoscopic device and push the tool in.*
- *Some endoscopic device may NOT be able to pass through the fiberscope if there is a tight bend in the distal end. Do NOT apply excessive force. Loosen the bend of the fiberscope and insert the endoscopic device again.*
- *When removing the endoscopic device, take care to remove it gently.*

⚠ CAUTION

Be sure to use PENTAX Medical devices that are confirmed to be compatible with PENTAX Medical fiberscopes, as the performance and safety of the fiberscope is affected by the endoscopic device passed through the instrument channel inlet of the fiberscope. If another company's treatment tools are used, they may damage the fiberscope or function defectively during use, damaging the patient's health. Please be aware that PENTAX Medical accepts no responsibility for any damage to the fiberscope or the health of the patient or user that results from the use of another company's endoscopic devices.

2-3. Connection of light source to the fiberscope

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

1) 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.
2) Connect the endoscope light guide plug to the light source.
3) Turn on the light source to check for proper functioning.

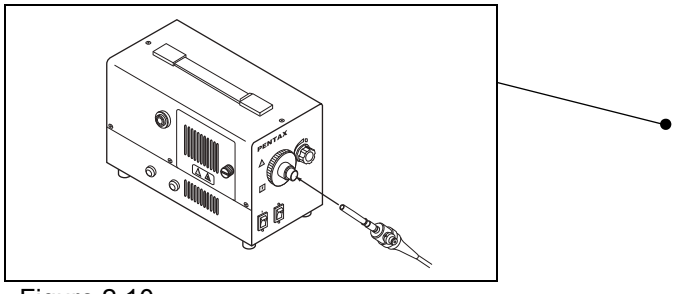


Figure 2.10

2-4. Preparation just before insertion of fiberscope

⚠ WARNING

- *Every fiberscope should be properly cleaned, and disinfected or sterilized before being used for the initial use. The fiberscope should have been properly cleaned, and disinfected or sterilized after any previous use and after being returned for any repairs/service.*
- *Current infection control guidelines require that endoscopes and their patient contact accessories that break the mucous barrier or enter a normally sterile tissue must be sterilized. Only the user can determine if an endoscope has undergone appropriate infection control procedures prior to each clinical use.*

NOTE

Contact the manufacturer and follow local regulations regarding safe use, appropriate handling and disposal of cleaning and disinfection solution including alcohol. Material Safety Data Sheets (Health and Safety Data Sheets or similar documents depending upon country) available from the cleaning and disinfection solution (including alcohol) manufacturer should provide guidance to end users about composition hazards, chemical and physical property, first aid, handling and storage, stability, precautions, disposal, etc. associated with cleaning and disinfection solution including alcohol.

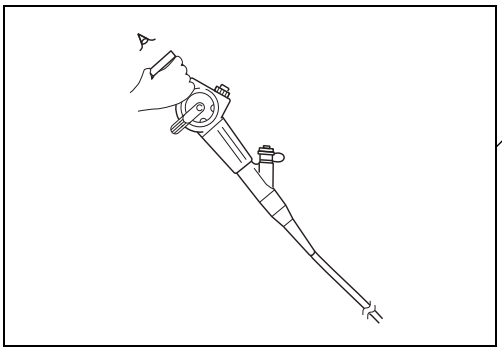


Figure 2.11

1) If the endoscope has just recently been reprocessed, has been prepared or stored properly and passed all pre-procedure inspections, the endoscope should be ready to use. If necessary, the fiberscope's insertion tube may be wiped down with a gauze dampened with 70-90% medical grade ethyl or isopropyl alcohol.
2) Check the optical image of the endoscope.
3) If necessary, gently clean the objective lens with a cotton-tip applicator moistened with 70-90% medical grade ethyl or isopropyl alcohol.
4) The individual user should adjust the diopter adjustment ring to make sure that a clear view can be obtained. No further adjustment should be necessary during a procedure.
5) (Fiberscopes to be introduced transorally)
   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.
6) Apply a medical grade water soluble lubricant to the insertion tube. Do not use petroleum based lubricants.

⚠ WARNING

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.

⚠ 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.

NOTE

The objective lens must be kept free of the lubricant and excess lens cleaner.

3.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 patient's body fluids may be dispersed from fiberscope components such as the instrument channel inlet and the irrigation 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.*
- *NEVER withdraw the fiberscope while the bending section is angulated. It may result in patient injury.*
- *Do NOT forcefully insert and withdraw the fiberscope. Doing so may result in patient injury.*
- *Transnasal insertion must be determined appropriately and cautiously according to the discretion of a medical professional.*
  - *No endoscope, including this one, can always be inserted transnasally into all patients. Ensure that transnasal insertion is possible for the patient by considering the shape and size of the patient's nasal cavity as well as his/her receptivity.*
  - *Do NOT forcefully insert the endoscope transnasally. Doing so may result in injury to the patient's nasal cavity.*
  - *Before transnasal insertion, apply the appropriate pretreatment such as enlarging the nasal cavity, etc. to the patient. Failure to do so may result in patient injury.*
- *Set the brightness to the minimum necessary. Maintain an appropriate distance between the distal end of the fibersope 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.*
- *Do NOT use a higher suction pressure than needed during suctioning. Also, do NOT suction the mucous membranes for long periods of time. Suctioning the mucous membranes at a high pressure or for a long period of time may cause damage to the patient's body.*

NOTE

Prior to a procedure, remove any debris or secretions from the observation area as much as possible to obtain a clear image.

3-1. Pretreatment

The patient should be prepared in your normal endoscopy regimen.

3-2. Insertion and observation

Insertion of the fiberscope

> ⚠ CAUTION
> *Do NOT forcefully bend the strain relief boot. Doing so may result in fiberscope damage.*

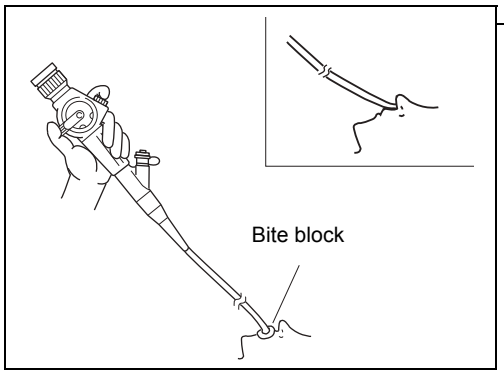


Figure 3.1

1) (When inserting transorally) Prior to the insertion, attach a bite block to the patient. Slowly insert the fiberscope, directly observing during insertion. 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.

> ⚠ CAUTION
> *Do NOT use excessive force when inserting the fiberscope into the body or withdrawing it. This may damage the mucosa or cause bleeding or perforation.*

2) Adjust the light source to set a suitable brightness for observation.

> ⚠ CAUTION
> *When using a light source with high-luminance xenon lamp, set the brightness as low as possible to prevent burns. Do NOT use the automatic brightness control mode, and also avoid close stationary viewing and unnecessary prolonged use.*

3) Slowly and carefully perform the angulation operation according to the location, directly observing during this process. If resistance is felt during the angulation operation, do not try to bend the fiberscope further.

> ⚠ WARNING
> - *Use X-rays as little as possible when inserting the fiberscope.*
> - *NEVER try to forcibly rotate the angulation control lever if a malfunction or abnormality is felt during the angulation operation. Immediately stop using the fiberscope and remove it slowly and carefully. Forcibly rotating the angulation control lever may damage the internal structure of the fiberscope and impede deangulation of the distal end.*

4) Perform suction if bronchial secretions or other debris in the lungs make observation difficult. Take care not to suction any hard matter during this procedure.

3-3. Biopsy

⚠ WARNING

- *Do NOT use the FB-8V/10V with electrosurgical devices.*
- *All reusable endoscopic devices must be cleaned and sterilized before initial use as well as before every subsequent use.*
- *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.*

⚠ CAUTION

Be sure to observe directly when inserting and withdrawing endoscopic device.

⚠ CAUTION

Take the following precautions, as damage to the instrument channel may compromise the safety and effectiveness of the fiberscope.

- *Before use, inspect the condition of the endoscopic device, whether they can be properly inserted into the fiberscope, and the waterproof performance of the fiberscope according to the IFU for the fiberscope and endoscopic device, to ensure that there will be no issues during use. NEVER use this fiberscope if there is a sign of damage or an abnormality.*
- *Slowly and gently insert and withdraw the forceps from the inlet seal. Applying strong force may cause fiberscope damage.*
- *Some resistance may occur at first when inserting an endoscopic device. Hold the area around 5cm from the end of the endoscopic device and push the tool in.*
- *Some endoscopic device may NOT be able to pass through the fiberscope if there is a tight bend in the distal end. Do NOT apply excessive force. Loosen the bend of the fiberscope and insert the endoscopic device again.*
- *When removing the endoscopic device, take care to remove it gently.*
- *Keep the fiberscope bending section as straight as possible when inserting the forceps.*

1) Insert the forceps in the instrument channel inlet. Before inserting, operate the forceps so that the cups at the end are completely closed.

⚠ CAUTION

Do NOT forcefully insert the endoscopic device when the instrument channel is clogged, as this may result in damage to the fiberscope.

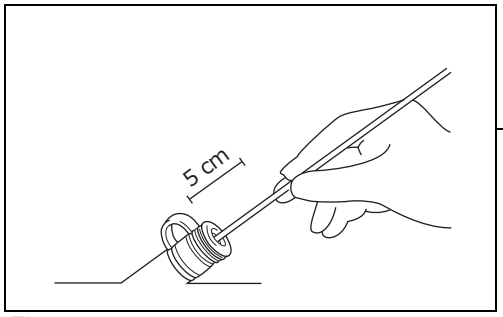


Figure 3.2

NOTE

When the cups are first passed through the inlet seal, temporary resistance will be encountered. Hold the shaft at approximately 5 cm from the cups and push the biopsy forceps through. If resistance is experienced during insertion and this makes insertion difficult, deangulate slightly and try inserting again.

2) When the distal tip of the forceps enters the field of view, carefully move the forceps closer to the examination area.
3) Open the cups and move the forceps toward the examination area. Carefully release grip, close the cups and extract tissue. Make sure that the forceps are always in the field of view when pushing them further in.
4) Slowly withdraw the forceps with the cups closed.

⚠ WARNING

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.

⚠ WARNING

If for any reason, the image is lost due to power shortage, lamp or light source failure, etc. the fiberscope distal end should be straightened to its neutral position, and the insertion tube should be carefully and slowly withdrawn from the patient.

⚠ 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 instrument/suction channel becomes blocked or clogged due to the accumulation of debris, an accessory that cannot be removed, or other cause, do NOT attempt to correct the blockage or continue to use the fiberscope.
In such a case, contact your local PENTAX Medical service facility to have the fiberscope repaired. The use of an 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.

3-4. Laser

⚠ WARNING

- *Laser equipment should be used only by experts who have thorough knowledge of the laser equipment and endoscopic laser treatment.*
- *Before using the laser equipment, thoroughly read the manual provided with it, and always perform pre-use inspection. Ensure that the laser equipment is ready for use by performing the safety checks specified in the manual.*
- *Use Nd:YAG laser (wavelength 1064 nm) or Diode laser (wavelength of 800–1000 nm) only.*
- *If using an add-on camera, the camera needs to support a YAG laser (wavelength 1064nm).*
- *This fiberscope cannot be used with other laser systems such as KTP, He-Cd or Excimer.*
- *Do NOT use the laser electrosurgical system in flammable surroundings, such as an oxygen-rich environment. If there is a possibility of a flammable gas being present within a body cavity, convert the gas to a non-flammable gas prior to laser electrosurgery. Using the electrosurgical system in flammable surroundings may result in combustion or an explosion.*

⚠ WARNING

- *Users as well as the assisting personnel should always wear goggles. Any laser electrosurgery operation without wearing goggles may result in damage to the eyes due to the reflected light of the laser.*
- *When wearing safety glasses, follow the Instructions for Use of the safety glasses.*
- *Do NOT look directly at the light of the laser through the ocular lens of the fiberscope.*
- *Users and the assisting personnel should wear rubber gloves, etc. to avoid burns while using the laser.*

1) Insert the laser probe by the same method as the insertion method for biopsy forceps described in 3-3.

NOTE

Check that the distal end of the laser probe can be seen in the field of view before operating the laser.
The endoscopic image shown while using the laser is affected by various factors such as the intensity and output of the laser beam, the distance between the laser probe and the distal end of the fiberscope and the degree of tissue cauterization. Use the lowest laser beam output level that is ideal for clinical purposes.

2) Wear proper protective equipment as defined by each hospital's regulations concerning safety gear and other safety measures for the use of lasers.

⚠ WARNING

Check that the laser probe is protruding from the distal end of the fiberscope before irradiating the laser.

NOTE

- *The guide beam may appear white in endoscopic images. This is not an abnormality.*
- *If using a video module with this fiberscope, the guide beam may cause smearing in the image when the distal end of the fiberscope is close to the irradiated surface. If the smearing makes it too difficult to see the irradiated surface, lower the intensity of the laser beam.*
- *If the laser is used with a high output (higher than around 100W for a YAG laser or around 60W for a diode laser), a flare may occur around the image when the laser is irradiated with a distance of less than 10mm between the irradiated part and the distal end of the fiberscope.*

⚠ WARNING

- *If the laser is continuously irradiated at a high output (higher than around 100W for a YAG laser or around 60W for a diode laser) for longer than 5-6 seconds, this may seriously injure the patient and damage the distal end of the fiberscope. Set the output as low as possible.*
- *Set the laser output to the minimum level necessary.*
  --If the laser is continuously emitted at a high level, the endoscopic image may become white (whiteout). Do NOT perform laser cautery during whiteout, as it may result in patient injury.
  --Continuously emitting the laser at a high level may damage the endoscope.
- *Maintain an adequate distance between the distal end of the fiberscope and the patient's body cavity wall. Before activation of the laser, ensure that the distal tip of the laser probe emerges from the distal end of the fiberscope. Failure to do so may result in endoscope damage and patient injury.*

3-5. Electrosurgery (Only for FB-15V/18V/19TV)

⚠ WARNING

- *Electrosurgery cannot be performed with the FB-8V/10V.*
- *Thoroughly read the Instructions for Use of the high frequency generator before use. Be sure to perform the safety checks specified in the Instructions for Use and check that the high frequency generator and electrosurgical device are in a fit state for use. Using this product with some electrosurgical devices may increase the patient leakage current.*
- *High-frequency generators can be a floating system (BF or CF system) or a non-floating system (B system). Be sure to use a floating high-frequency generator to prevent burns to the patient and operator. Using a non-floating type may cause accidental burns to the patient or user.*
- *Users and the assisting personnel should wear rubber gloves, goggles, etc. to avoid burns while using the high frequency generator.*
- *Check that energy released from the high-frequency waves will not affect any nearby pacemakers.*
- *Check that there are no abnormalities such as cracks in the exterior of the fiberscope or protrusion of interior metal parts before performing electrosurgery.*
- *Use only insulated endoscopic devices to avoid burns.*
- *Do NOT use this product and the high frequency generator in flammable surroundings, such as an oxygen-rich environment.*

1) Prepare, inspect and connect the high frequency generator and electrosurgical device according to their manual.

2) Insert the endoscopic devices by the same method as the insertion method for biopsy forceps described in 3-3 of the IFU.

⚠ CAUTION

Before performing electrosurgery, perform a test with the high frequency generator, with the electrosurgical device protruding within the necessary range from the distal end of the fiberscope.

3) Check the following before performing electrosurgery.

⚠ WARNING

- *Make sure that the target area, the insulating medium at the distal end of the endoscopic devices and the active area of the endoscopic devices are always within the field of view of the fiberscope.*
- *Take care to ensure that the active area of the endoscopic devices does not touch the surrounding tissue either directly or via fluids.*
- *Users and the assisting personnel must not touch the patient.*
- *Set an acoustic frequency level and wave mode that are appropriate for the purpose. Set the powering time as short as possible.*

5) When treatment is completed, first turn off the power of the high frequency generator and then remove the active cord from the treatment tool.

3-6. Withdrawal and stopping of device

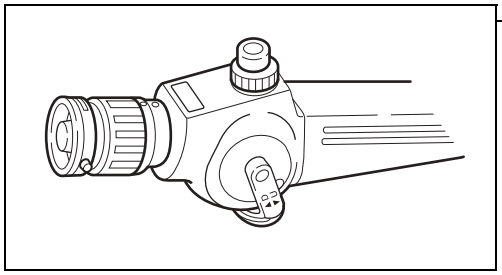


Figure 3.3

1) When withdrawing the fiberscope, deangulate it so that the bending section of the fiberscope is straight, and then slowly withdraw it. Be sure to directly observe while removing the fiberscope.
2) (When inserting transorally) Finally, remove the bite block.
3) Be sure to switch off and unplug the light source after each use.

> ⚠ WARNING
>
> *In the event of a power outage or if the picture darkens due to a lamp failure or malfunction of the light source, return the distal end of the fiberscope to its original straight condition, then slowly and carefully remove it from the patient.*

4. 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 and its removable components should be thoroughly and carefully cleaned. If the fiberscope or its components are left uncleaned for some time after use, dried blood, mucous or other debris may cause damage to the fiberscope/components or may interfere with the ability of the user to properly reprocess the fiberscope/components.

Note

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

(a) the ability of the AFR to provide a cleaned and high-level disinfected (or sterilized) endoscope and endoscope components (ex. valves),
(b) the identification of any special feature area (internal channel) or endoscope 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

Note

This IFU has been written having regard to ISO 17664 and national guidelines on reprocessing of medicalproducts (e.g. RKI, DGS/ DHOS).

⚠ CAUTION:(Automated Reprocessing)

Unless the AER/WD has validated channel monitoring capability for device-specific fiberscope models, prior to "automated reprocessing" check and check the patency of any lumens/channels to ensure that all internal channels are unblocked and/or unclogged prior to use of any AER/WD check the integrity of all channel tubes and recommended cleaning adapters once tubing sets are connected to the appropriate channels, check the tubing to check that there are no kinks or crimps that could restrict flow of solution throughout the fiberscope (if the unit allows) during reprocessing check and check that reprocessing solutions are exiting expected channel ports.
Failure to adhere to the above recommendations could result in inadequate cleaning, disinfection (or sterilization) of and/or improper removal of residues from all instrument channels/surfaces.

Note

The instructions for manual reprocessing of PENTAX fiberscope contained in this Instructions for Use are consistent with reprocessing guidelines, developed by medical professional organizations (eg., SGNA, ASGE, APIC, ESGE) and/or national consensus groups (including ASTM).

Note

Contact the manufacturer and follow local regulations regarding safe use, appropriate handling and disposal of cleaning and disinfection solution including alcohol. Material Safety Data Sheets (Health and Safety Data Sheets or similar documents depending upon country) available from the cleaning and disinfection solution (including alcohol) manufacturer should provide guidance to end users about composition, hazards, chemical and physical properties, first aid, handling and storage, stability, precautions, disposal, etc. associated with cleaning and disinfection solution including alcohol.

4-1. Care after Each Procedure

⚠ WARNING:(in the U.S.A. or other countries adhering to FDA regulations)

It is imperative that flexible fiberscopes and other semi-critical devices be reprocessed using at least high-level disinfection with a legally marketed sterilant/disinfectant. Only legally marketed fiberscope automated reprocessing devices/systems whose device specific claims have been validated by the AER/WD manufacturers and/or anti-microbial agents which have been tested and found to be compatible by PENTAX should be used with PENTAX Medical brand products.

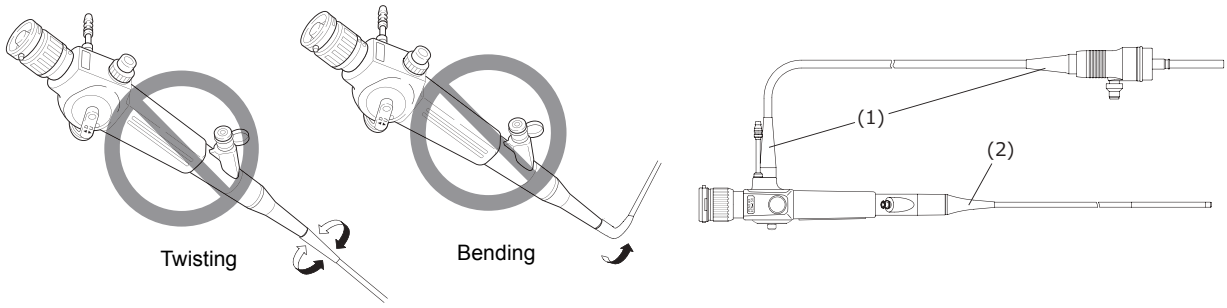
Fiberscopes are semi-critical devices that require at least high-level disinfection. Only use legally marketed solutions and/ or automatic fiberscope reprocessing machines or washing disinfection machines whose manufacturers have made validation testing with PENTAX Medical brand products (specific to PENTAX fiberscope model number). A listing of legally marketed solutions/ systems which have been determined to be compatible with PENTAX Medical brand products is available from your local PENTAX dealer/authorized service facility.

Be aware of the important note regarding infection control on the inside cover of this IFU.

Items required for reprocessing:
Syringes: various sizes can be used including 10/20cc, 50/60cc, etc.
Tray/Reprocessing basin (at least 40 cm by 40 cm/16 in × 16 in)
Soft sponge
Personal Protective Equipment (PPE) including gloves, face mask, etc.
Soft sterile gauze
Cleaning adapter (OF-B75)
Inlet seal (OF-B190)
Cleaning brush (CS6002SN, CS6015ST and CS3010S)
Cleaning brush (CS-C3S)
Detergent
Disinfectant
Alcohol
Source of compressed/forced air

⚠ CAUTION

Do NOT excessively twist, rotate, or bend any of the strain relief boots (See (A) and (B) in the figure to identify the strain relief boot). Doing so may result in fiberscope damage. Pay special attention to the careful handling of the strain relief boot (B) of the insertion portion of the endoscope, because it has a small diameter and is more likely to suffer damage due to mishandling.



⚠ WARNING

The importance of meticulous mechanical cleaning of the fiberscope and its removable components cannot be overemphasized. Prior to disinfection or sterilization all endoscopes/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 and face masks, etc. to minimize the risk of cross contamination.

4-1-1. Pre-Cleaning at the Examination Room

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 a detergent solution.

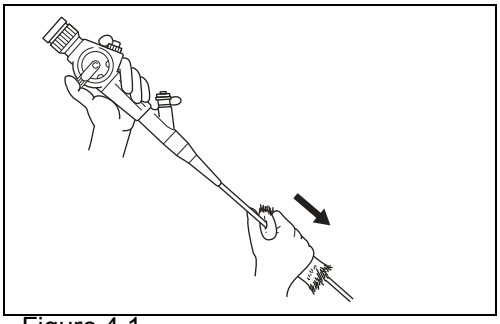


Figure 4.1

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.

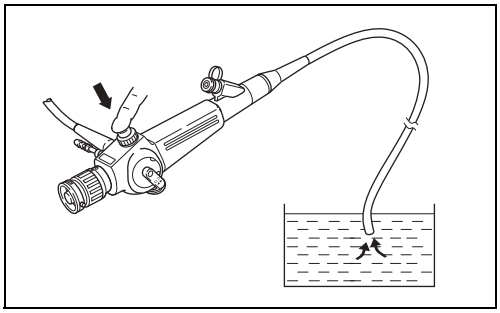


Figure 4.2

4-1-2. Cleaning at the Work Room

1) Before reprocessing and/or immersion in any fluids, PENTAX fiberscopes should be tested for the loss of integrity in their watertight construction by 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, electromechanical and "automated" versions, some of which are stand alone units and others which may be integrated into Automated Endoscope Reprocessors (AERs)/Washers-Disinfectors (WDs). 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 detergent per detergent manufacturer's instructions. The solutions must be detergent solutions or other cleaning agents specially formulated to clean flexible fiberscopes. Follow manufacturer's instructions. For specific brands of compatible solutions, please contact your local PENTAX Medical service facility.

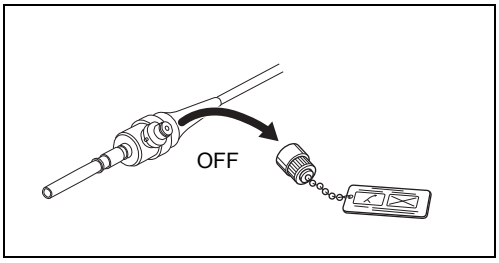


Figure 4.3

⚠ CAUTION

BEFORE IMMERSING:
The'Red' ventilation cap must be taken OFF.

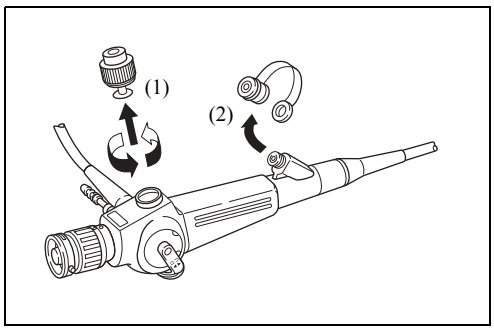
⚠ WARNING

Immediately after use, the metal light guide plug of the fiberscope may be HOT.
To avoid burns, do NOT touch these areas immediately after use. For safer hadling after a procedure, grasp the plastic light guide plug.

⚠ CAUTION

The use of a detergent solution 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 and the inlet seal, thoroughly (but gently) wash the entire surface of the fiberscope and its components. While fully immersed, manipulate valve mechanisms and inject detergent solution via syringe into/through removable fiberscope components. Also inject detergent solution through inlet seal, while immersed. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces & provide for better exposure of surfaces to detergent. Make sure that the recessed areas are brushed clean using the provided or similarly effective cleaning brushes. Allow all items to soak in a cleaning solution for a time period recommended by the manufacturer of the detergent solution.



(1) Suction Control Valve
(2) Inlet Seal

Figure 4.4

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.

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

⚠ 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 endoscopic 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 cannot 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 an 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.

⚠ CAUTION

1. *It is highly recommended that only PENTAX cleaning brushes specified in our Instructions for Use 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 provided brushes and cleaning adapters for cleaning PENTAX fiberscopes following PENTAX manual reprocessing instructions.*
3. *Over the years other manufacturers' cleaning brushes/devices have been found to damage PENTAX fiberscopes and/or create the need for servicing as some cleaning devices can become lodged ("stuck") inside various lumens of PENTAX fiberscopes. 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 IFU.*
4. *Cleaning brushes/devices, especially those with metal coiled flexible shafts should NOT be inserted into the distal exit/opening of channels. Doing so can damage the fiberscopes.*

a) 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 cylinder. Then gently withdraw the brush. Repeat until the brush is visibly clean.

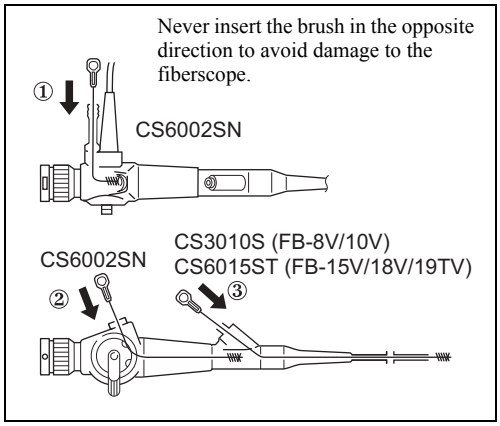


Figure 4.5

b) Next, insert the brush into the opening at the bottom of the suction cylinder on the control head and gently advance until resistance is felt (approximately 15 cm). Do not use excess force. Then gently withdraw the brush. Repeat until the brush is visibly clean.

Note

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

c) 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 several times ensuring that only a clean brush is introduced into the channel each time.

d) Using the specially designed suction cylinder cleaning brush (CS-C3S), scrub clean the surfaces inside the suction cylinder on the control head.

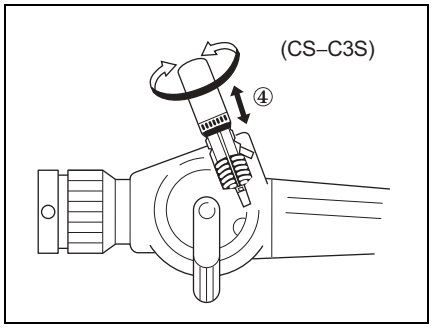


Figure 4.6

5) Install the cleaning adapter (OF-B75) as illustrated.

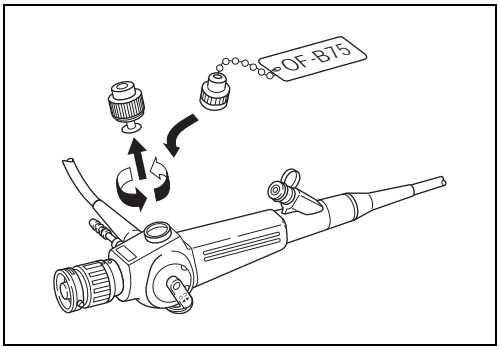


Figure 4.7

Note

Brushing of all internal channels is not a substitute for exposure to an appropriate cleaning solution. Manual cleaning by brush complements and augments the cleaning effectiveness of chemical cleaning (i.e. detergent solution).

Channel	Adapters/Components to be attached	Syringe	Detergent	Rinse water
Biopsy/Instrument	Cleaning adapter (OF-B75)	20mL	20mL or more	30mL or more
	Inlet Seal (OF-B190)			

6) The inlet seal should be in place. A 20mL syringe may be attached to the suction nipple. At least 20mL of fresh detergent solution should be injected into the entire suction/instrument channel until it exits the fiberscope distal end. Check and check that the flushed detergent solution flows out from the distal instrument channel opening. Once proper flow has been confirmed, the inlet seal and the syringe should be removed. Provided the detergent solution is allowed to remain in contact with the internal channel surfaces for the recommended exposure time, the detergent solution should dissolve and/or dislodge debris that may be within these internal areas. Provided the detergent solution is allowed to remain in contact with the internal channel surfaces for the recommended exposure time, the detergent solution should dissolve and/or dislodge debris that may be within these internal areas.
7) While fully immersed, manipulate the suction control valve and inject detergent solution via syringe into/through removable fiberscope components. Also inject detergent solution through inlet seal while immersed. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces and provide for better exposure of surfaces to detergent.

⚠ WARNING

The 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.

8) 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, external fiberscope surfaces and components be thoroughly rinsed with clean water to remove residual detergent solution.

9) Using clean water, immerse the entire fiberscope as well as all removed components and thoroughly rinse all items.
10) With the cleaning adapter, still attached to the fiberscope, flush all previously air purged channels with clean water more than 30mL. All internal channels must be thoroughly rinsed to remove residual detergent and debris. (The inlet seal should be in place.)
11) 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

70-90% medical grade ethyl or isopropyl alcohol followed by compressed air, not greater than 165kpa (1.69 kg/cm2, 24PSI), may be used to facilitate drying.

12) 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 and the ocular lens with a cotton tip applicator.

⚠ WARNING

Prior to disinfection or 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.

Note

All removable PENTAX fiberscope components and autoclavable accessories can be cleaned by ultrasonic cleaning methods in addition to mannual cleaning. Prior to steam sterilization, each component must first be manually cleaned and then subjected to ultrasonic cleaning.

4-1-3. Cleaning of Accessories and Fiberscope Components

Note

Not all manufacturers of automated endoscope reprocessors (AERs)/washers-disinfectors (WDs) make specific claims nor provide special instructions for reprocessing all of the removable endoscope 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 endoscope 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 endoscope components.

1) Reusable endoscopic accessory endoscopes (such as forceps) and removable fiberscope components (such as suction valve) should be cleaned immediately after each use since dried blood, mucous or other debris may cause damage to the fiberscope and render the mechanism inoperable, or may interfere with the ability of the user to reprocess the device.
2) Place the forceps and/or components in a basin with detergent solution being careful not to tightly coil or kink the flexible 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. Removable components such as suction valve 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. Similarly rinse component surfaces.
5) Ultrasonic cleaning of forceps and similar accessories is then recommended, provided the manufacturer's instructions and the parameters below are followed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent highlevel disinfection or sterilization.

Frequency Range	44 kHz ± 6%
Time	5 minutes

DO NOT use caustic or abrasive solutions in the ultrasonic cleaner.

Note

It is imperative that ultrasonic cleaning of the biopsy forceps be performed prior to steam sterilization. Heavily soiled 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 sterilization.

Note

All detergent must be removed from the inner mechanism of the forceps. 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 disinfection/sterilization process.

6) After cleaning and thorough rinsing, the forceps 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 forceps.

Note

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

4-1-4. Internal Schematics of A PENTAX broncho fiberscope

The following internal schematics have been provided as a service to help users better understand the intricate construction of PENTAX fiberscopes. Knowledge of the various internal channels and tubes within an fiberscope 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 fiberscopes and their cleaning/disinfecting components so that reprocessing of the fiberscopes before each patient use can be effectively and efficiently performed by either manual methods or automated processes.
Connectors on all PENTAX cleaning 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 the suction nipple at the control body, traveling up to the valve cylinder, passing through the channels in the insertion tube and finally exiting the channel opening 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:(in the U.S.A. or other countries adhering to FDA regulations)

It is imperative that semi-critical devices including most flexible endoscopes should be reprocessed using at least high-level disinfection with a legally marketed liquid sterilant cleared as a high-level disinfectant. Only legally marketed automated endoscope reprocessing devices/systems whose device specific claims have been validated by the AER manufacturers, and cleared anti-microbial agents that have been tested by PENTAX and found to be compatible with materials used in PENTAX endoscopes should be used to reprocess PENTAX products. Endoscopes are semi-critical devices that require at least high-level disinfection. Only use legally marketed solutions and/or automatic endoscope reprocessing machines or washing disinfection machines whose manufacturers have made validation testing with PENTAX products (specific to PENTAX endoscope model number). A listing of legally marketed solutions/systems which have been determined to be compatible with PENTAX brand products is available from your local PENTAX Medical service facility.

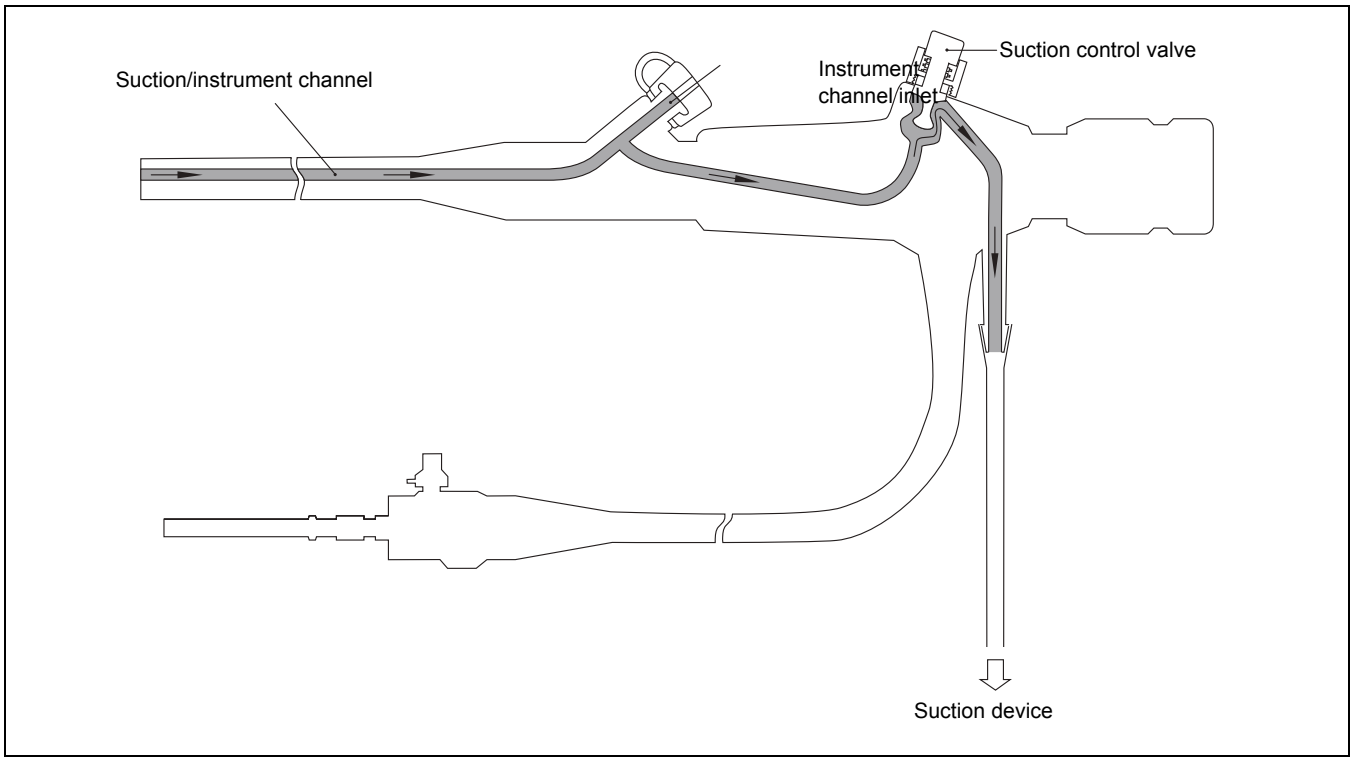


Figure 4.8

The illustration above shows the entire suction system in a PENTAX broncho fiberscope. Please note that all surface areas of the suction system must first be cleaned with a detergent solution and then exposed to a high-level disinfectant or sterilant.

Complete PENTAX Cleaning/Disinfecting System

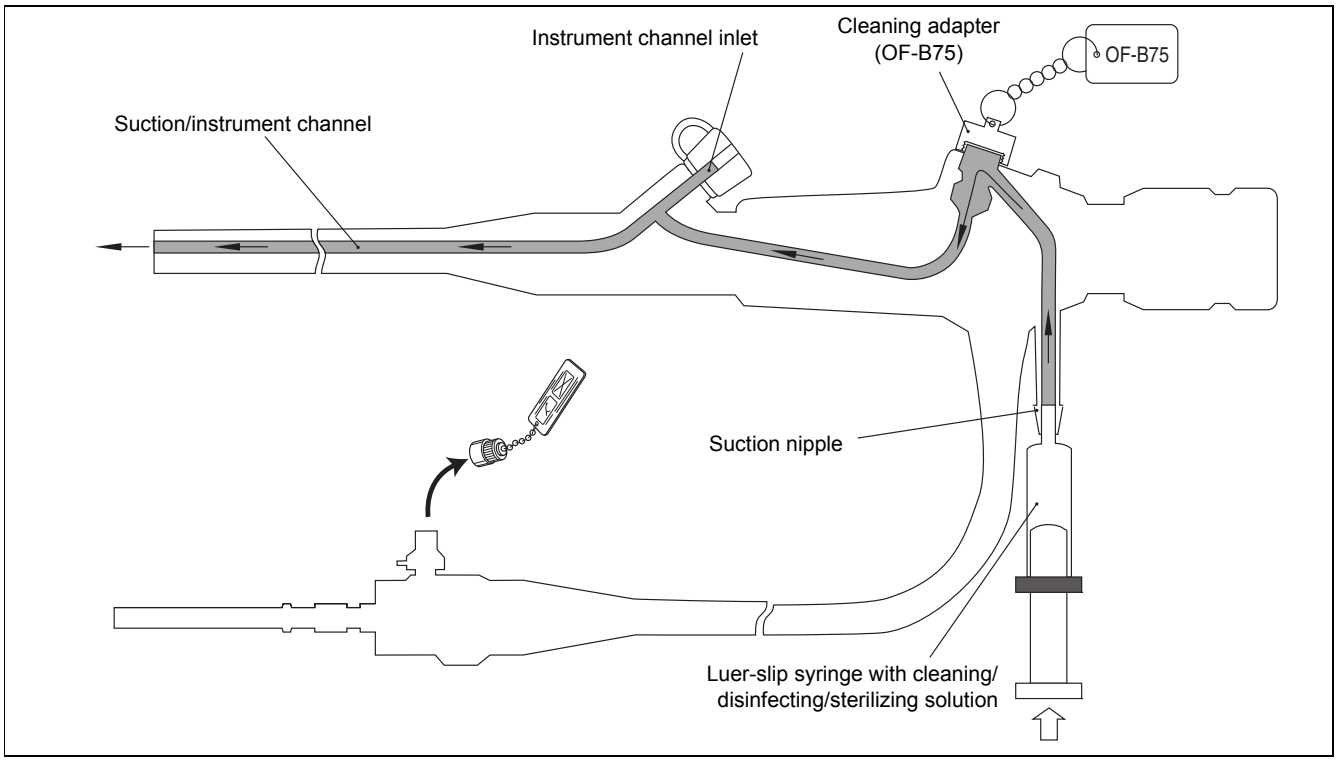


Figure 4.9

⚠ CAUTION

BEFORE IMMERSING:

The "Red" ventilation cap must be taken OFF.

To reprocess a PENTAX bronchoscope, first a detergent solution and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external fiberscope surfaces and fiberscope components (inlet seal, suction control 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 a detergent solution and high-level disinfectant (or sterilant), PENTAX channels should be manually cleaned with cleaning brushes.

4-1-5. High-Level Disinfection

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

⚠ WARNING:(in the U.S.A. or other countries adhering to FDA regulations)

It is imperative that semi-critical devices including most flexible endoscopes should be reprocessed using at least high-level disinfection with a legally marketed liquid sterilant cleared as a high-level disinfectant. Only legally marketed automated endoscope reprocessing devices/systems whose device specific claims have been validated by the AER manufacturers, and cleared anti-microbial agents that have been tested by PENTAX and found to be compatible with materials used in PENTAX endoscopes should be used to reprocess PENTAX products. Endoscopes are semi-critical devices that require at least high-level disinfection. Only use legally marketed solutions and/or automatic endoscope reprocessing machines or washing disinfection machines whose manufacturers have made validation testing with PENTAX products (specific to PENTAX endoscope model number). A listing of legally marketed solutions/systems which have been determined to be compatible with PENTAX brand products is available from your local PENTAX Medical service facility.

Before complete immersion in any disinfecting solution, the fiberscope should have been "Leakage Tested" as described elsewhere in this Instructions for Use.

Channel	Adapters/Components to be attached	Syringe	Disinfectant	Rinse water	Alcohol Flush
Biopsy/ Instrument	OF-B75	20mL	20mL or more	30mL or more	10mL or more
	Inlet Seal				

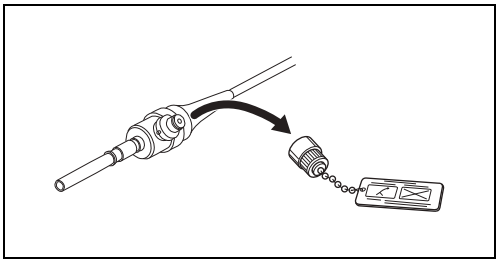


Figure 4.10

⚠ CAUTION

BEFORE IMMERSING:

The "Red" ventilation cap must be taken OFF.

1) The endoscope cleaning adapter (OF-B75) should already be installed as illustrated.

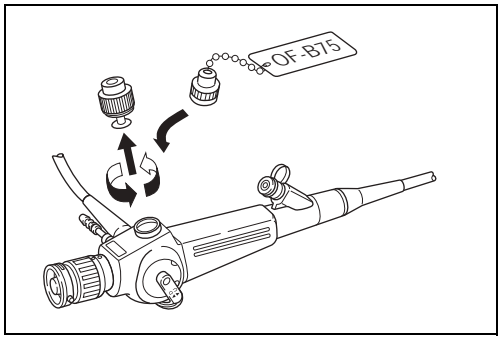


Figure 4.11

2) The inlet seal should be in place during the flushing process. A 20mL syringe may be attached to the suction nipple. At least 20mL of fresh (or reused actively effective) disinfecting solution should be injected into (or flushed through) the entire suction/instrument channel system. Please refer to the internal schematics on page 39.

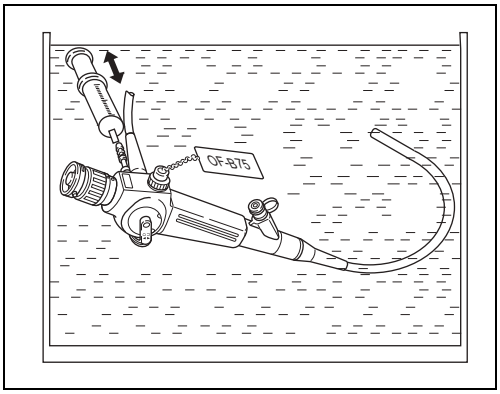


Figure 4.12

⚠ WARNING

Avoid introduction of air during this process and check that no air bubbles exit the fiberscope distal end during flushing (or exit the suction nipple, if aspiration is used.) The presence of air bubbles could prevent contact of the disinfectant with channel surfaces.

3) While the entire fiberscope and removed suction control valve are immersed and the suction/instrument channel system is filled with disinfectant, (OF-B75), the syringe and the inlet seal should be removed. The removal of component parts and cleaning adapters from the fiberscope will eliminate the risk of mated surfaces not being exposed to the disinfecting solution.

⚠ 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.

4) While fully immersed, manipulate the suction control valve and inject disinfectant via syringe into/through removable fiberscope components. Also inject disinfectant through inlet seal while immersed. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces and provide for better exposure of surfaces to germicide. The fiberscope's component parts, including all valves, should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.

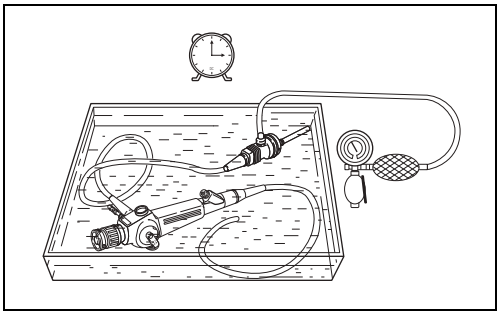


Figure 4.13

5) After the fiberscope and its component parts have been in contact with the disinfecting solution for an appropriate time, attach the OF-B75 and the inlet seal and flush the suction/endoscope system 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.
6) Reinstall the previously reprocessed suction control valve, and the inlet seal. Thoroughly rinse all outer surfaces of the fiberscope that were in contact with disinfecting solution.

7) Attach the fiberscope to an external suction source, and aspirate sterile water (30mL or more) through the channel of the fiberscope. Then, aspirate air through the channel to remove 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, 70-90% medical grade ethyl or isopropyl alcohol should be flushed through all channels, followed by compressed air, not greater than 165kPa (24 PSI) to facilitate drying. 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 and/or the quality of the rinse water used, a dry fiberscope 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 fiberscopes 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.

8) 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 ocular lens, the electrical contacts and the objective lens with a cotton-tip applicator.

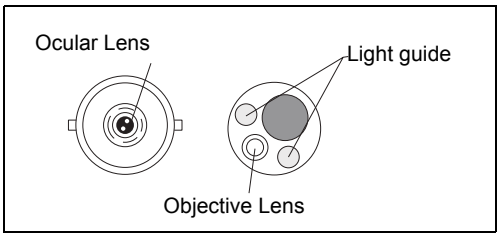


Figure 4.14

⚠ WARNING

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

4-1-6. Disinfection of Accessories and Fiberscope Components

Note

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.

⚠ WARNING

Current infection control guidelines require that biopsy forceps and similar endoscopic accessory endoscopes (EAIs) 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 endoscopes 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 EAIs and/or components such as bite block, suction control valve, brushes, etc. the complete cleaning procedure, as described elsewhere in this Instructions for Use, 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/components should be immersed in disinfecting solution.
2) Accessory/components 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 valve mechanism while injecting disinfectant into/onto surfaces.
3) After it 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/components by immersing it under sterile water.
5) After thoroughly rinsing, the accessories/components 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, 70-90% medical grade ethyl or isopropyl alcohol should be flushed through lumens of the endoscopic endoscopes, as well as any removable fiberscope components including valve mechanisms, followed by compressed air, not greater than 165kPa (24 psi) to facilitate drying. External fiberscope and component 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 fiberscope 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 fiberscopes 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.

4-1-7. Sterilization and Aeration

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

⚠ CAUTION

NEVER place the fiberscope in a steam autoclave!!
NEVER subject the fiberscope to ultrasonic cleaning methods!! Follow provided ETO gas sterilization parameters.

A) Ethylene Oxide Gas Sterilization

Ethylene Oxide (ETO) Gas Sterilization can be performed on these Fiberscopes, provided the following special instructions, which differ from other fiberscopes, are followed to ensure the proper performance of the fiberscope. 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 IFU and each of the component parts should be removed (suction control valve, inlet seals, etc.).

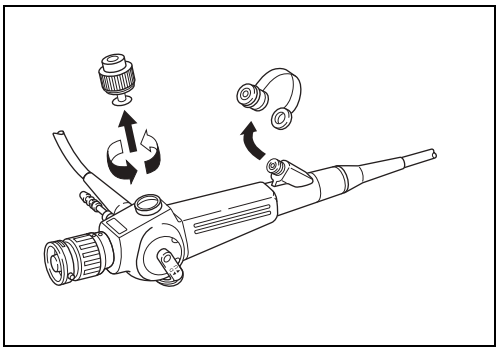


Figure 4.15

⚠ 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.

⚠ CAUTION

Prior to placing these Fiberscopes in a Gas Sterilizer or Aeration Chamber: The 'Red' ventilation cap MUST be "attached" securely. This is opposite of the immersion instructions.

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

Temperature:	55°C (131°F)
Relative Humidity:	50%RH
EO Concentration:	600-650 mg/L
Gas Exposure Time:	5 Hours
Aeration:	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.

B) Other Methods Of Sterilization

Other types of cleaning, disinfecting and/or 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 fiberscopes, some of these marketed systems/processes/ solutions could have detrimental effects on flexible fiberscopes.

To avoid the potential for fiberscope damage, check the compatibility of such reprocessing systems/solutions with your local PENTAX Medical service facility prior to use with any PENTAX Medical brand products.

Prior to using other methods, check the specific claim(s) of any sterilization process and ensure that manufacturer of such processes has performed microbilogical validation studies that supports their claim of achieving sterilization of those specific flexible fiberscopes.

4-1-8. Sterilization of Accessories and Fiberscope Components

⚠ WARNING

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

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

⚠ 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 endoscope 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 endoscope 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 endoscope components.

Before any attempt is made to sterilize the accessories, the complete cleaning procedure as described elsewhere in this IFU 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, provided they have first been properly cleaned and thoroughly dried.
2) Following ETO GAS Sterilization, aeration is required.

Note

For Ethylene Oxide (ETO) Gas sterilization of PENTAX accessories, follow the same parameters as for PENTAX fiberscopes.

- **Steam Sterilization (Sterilization)**

Note

The following accessories may be subjected to Steam Sterilization:
- *PENTAX forceps (with pink colored handle)*
- *PENTAX bite block (OF-Z5)*
- *PENTAX cleaning brush for instrument channel*
- *PENTAX cleaning brush for suction cylinder*
- *PENTAX suction control valve (OF-B136)*

1) Prior to steam sterilization, accessories such as biopsy forceps and bite blocks should be thoroughly cleaned using manual and ultrasonic cleaning methods as described elsewhere in this Instructions for Use.

2) Steam sterilization can then be performed under the following conditions:

Sterilizer Type: Prevacuum
Temperature: 132 ~ 135°C (270 ~ 275°F)
Time: 5 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.*

Note

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

⚠ CAUTION

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

5.Maintenance

5-1. 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 irrigation valve, inlet seal, and cleaning adapter 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 and sterilization processes according to this IFU.*

⚠ CAUTION

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

- *-- Fiberscope insertion portion, umbilical cord, and endoscopic devices should be kept as straight as possible during storage.*
- *-- Keep away from chemicals, direct sunlight, or ultraviolet rays.*
- *-- Maintain adequate distances between the fiberscope, its accessories, and devices, so that they do NOT hit against each other.*

NOTE

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

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

NOTE

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

2) Prior to reuse, ensure that endoscope has been properly inspected and fully prepared for the next clinical procedure.
3) Prior to storage, ensure that all internal channels, endoscope components, endoscope surfaces and accessories are thoroughly dry.
4) A cotton tipped applicator moistened with 70-90% 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 endoscope 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.

5-2. 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 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.

5-3. Disposal

⚠ WARNING

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

1) Contact your local PENTAX Medical service facility when disposing the fiberscope(s).

5-4. Care and maintenance advice

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 endoscopes are patient ready and patient safe. Special care and handling must be exercised and practiced to prevent endoscope malfunction and prolong the reliability of the endoscope.
The burden of responsibility to ensure safe and reliably functioning endoscopes 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 endoscopes 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 endoscope reprocessing should not be construed as "shortcuts" and are not intended as substitute directions for complete instructions found elsewhere in the instructions for use.

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* Avoid soaking of the endoscope 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 detergent solution is essential to thorough cleaning of all surfaces of the endoscope. 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 endoscope 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 endoscope 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 endoscope.
* Avoid stretching of the bending section rubber sheath at the distal portion of the endoscope. During mechanical cleaning of the endoscope 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 a detergent solution will clean the remainder of debris.
* Disinfectants and sterilants are toxic substances by nature. All residual solution must be thoroughly rinsed and dried prior to each patient use.
* Avoid attempting to remove or unscrew endoscope components which should not be removed. Parts such as the distal portion of the light guide plug and any strain relief boots on either the insertion tube or umbilical cord are essential to the watertight integrity of the endoscope. Removal or loosening of these components and subsequent immersion could lead to fluid invasion into the endoscope.
* Check for any sharp edges on all surfaces of an automated cleaning/reprocessing unit which may come in contact with an endoscope. Some units may have sharp edged wire mesh filters and baskets or inlet/outlet ports which could damage your endoscope.
* When utilizing chemo-thermal processes for reprocessing PENTAX endoscopes, the endoscopes should be allowed to return to room temperature prior to use and/or further handling.
* Do not introduce air bubbles into the endoscope'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 endoscope 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 jaws and/or bent needles/spikes.
  Do not use cleaning brushes without smooth or rounded distal tips.
  Do not use accessory endoscopes with exceptionally long distal rigid sections or whose outer diameter restricts passage 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.

Electromagnetic compatibility (EMC)

This product connecting to a PENTAX Medical light source conforms to IEC60601-1-2: 2007: Medical electrical equipment, EMC standard.

Guidance and manufacturer’s declaration – electromagnetic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic emissions

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this productshould assure that it is used in such an environment.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 ±8kV air	±6 kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fest transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for signal lines	±2 kV for power supply lines ±1 kV for signal lines	Mains power qualit y should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power qualit y 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	<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	Mains power qualit y should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	It is recommended that this product be used apart from other devices operated with large current.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The recommended separation distance: d = 1.2 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The recommended separation distance: d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz
• *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *d* is the recommended separation distance in metres (m).			

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

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

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

The EPK-i5000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EPK-i5000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EPK-i5000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	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.			

Notes:
- 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

Fiberscope Model		FB-8V	FB-10V	FB-15V	FB-18V	FB-19TV
Direction of View		Forward				
Field of View		100°	120°			
Depth of Field		2 ~ 50mm	3 ~ 50mm			
Diopter Adjustment Range		+3 ~ -8dptr				
Tip Angulation	Up	180°				
	Down	130°				
Rigid Distal Width		ø2.7mm	ø3.4mm	ø4.9mm	ø5.9mm	ø6.2mm
Insertion Tube Width		ø2.8mm	ø3.5mm	ø4.9mm	ø6.0mm	ø6.2mm
Maximum Insertion Portion Width *(1)		ø3.45mm	ø4.15mm	ø5.75mm	ø6.75mm	ø6.95mm
Minimum Instrument Channel Width *(2)		ø1.15mm	ø1.15mm	ø2.1mm	ø2.7mm	ø3.0mm
Insertion Tube Working Length *(1)		600mm				
Total Length		900mm				
Laser cauterization		Available				
Electrosurgery		-		Available		

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

*(1) There is no guarantee that a fiberscope selected solely using this maximum insertion portion width and insertion portion working length will be compatible in combination.

*(2) There is no guarantee that a fiberscope selected solely using this minimum instrument channel width will be compatible in combination.

Contacts

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