

OPERATION MANUAL**PENTAX VIDEO DUODENO SCOPE****ED-3490TK**

This manual describes the recommended procedures for inspecting and preparing the equipment prior to its use. For cleaning, high-level disinfection, and sterilization, refer to the separate Instructions for Use (Reprocessing) with the model name of the instrument.

Intended Use / Indications for use (Duodenoscopes)

The Video Duodenoscopes are intended to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract. This anatomy includes, but is not restricted to, the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts.

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

Never use these endoscopes for any purpose other than that for which they have been designed.

The ED-3490TK can only be used with PENTAX Video Processors, Model EPK-i or EPK-1000.

Notes

Read this manual before operating, and save this book for future reference. Failure to read and thoroughly understand the information presented in this manual, as well as those developed for ancillary endoscopic equipment and accessories, may result in serious injury including infection by cross contamination to the patient and/or user. Furthermore, failure to follow the instructions in this manual or the companion Instructions for Use (Reprocessing) may result in damage to, and/or malfunction of, the equipment.

It is the responsibility of each medical facility to ensure that only well educated and appropriately trained personnel, who are competent and knowledgeable about the endoscopic equipment, antimicrobial agents/processes and hospital infection control protocol be involved in the use and the reprocessing of these medical devices. Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: perforation, infection, hemorrhage, burns and electric shock.

This manual describes the recommended procedures for inspecting and preparing the equipment prior to its use.

It does not describe how an actual procedure is to be performed, nor does it attempt to teach the beginner the proper technique or any medical aspects regarding the use of the equipment. For the cleaning and maintenance after its use, please refer to the separate "Instructions for Use (Reprocessing)".

The text contained in this manual is common for various types/models of PENTAX endoscopes and users must carefully follow only those sections and instructions pertaining to the specific instrument models appearing on the front cover.

If you have any questions regarding any of the information in this manual or concerns pertaining to the safety and/or use of this equipment, please contact your local PENTAX representative.

Sterility Statement

The instruments identified in this manual are reusable semi-critical medical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized BEFORE initial use. Prior to each subsequent procedure, they must be subjected to an appropriate cleaning and either high-level disinfection or sterilization process.

Refer to the companion PENTAX Instructions for Use (Reprocessing) describing in detail the recommended instructions on the care, cleaning, disinfection and sterilization of these endoscopes.

Conventions

Throughout this manual, the following conventions will be used to indicate a potentially hazardous situation which, if not avoided;



: could result in death or serious injury.



: may result in minor or moderate injury or property-damage.



: may result in property-damage. Also, advises owner/operator about important information on the use of this equipment.

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



Symbol for "MANUFACTURER"



Symbol for "DATE OF MANUFACTURE"



Symbol for "Authorised Representative in the European Union"



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SPECIFICATIONS	

1. NOMENCLATURE AND FUNCTION

1.1 VIDEO ENDOSCOPE

AIR/WATER FEEDING VALVE (OF-B188)

Covering of hole in the top of the valve delivers pressurized air. Covering of the hole and fully depressing the valve delivers pressurized water.

SUCTION CONTROL VALVE (OF-B120)

Depress to remove fluids or air through the instrument channel.

BUTTON 1

Push to freeze an image.

BUTTON 2

Push to activate the hardcopy system that was selected between "FILE" and "HARD COPY".

BUTTON 1

BUTTON 2

BUTTON 4

BUTTON 3

UP/DOWN DEFLECTION LOCK

When this lever is in the "F" position, turned clockwise, the bending section moves freely. When turned fully counterclockwise, the bending section becomes progressively more stabilized.

BUTTON 4

Push to select light measurement method, AVE/PEAK.

BUTTON 3

Push to activate the VCR for recording live procedures.

RUBBER STRAIN RELIEF

RUBBER INLET SEAL (OF-B190)

Allows passage of accessories while preventing escape of fluids and air.

INSTRUMENT CHANNEL INLET

For introduction of biopsy forceps and other accessories.

CONTROL BODY

MODEL DESIGNATION

RIGHT/LEFT DEFLECTION CONTROL KNOB

UP/DOWN DEFLECTION CONTROL KNOB

RIGHT/LEFT DEFLECTION LOCK

Functions similar to Up/Down lock

CANNULA/FORCEPS ELEVATOR CONTROL KNOB

To guide and direct cannula or forceps.

UMBILICAL CABLE

NOTE:

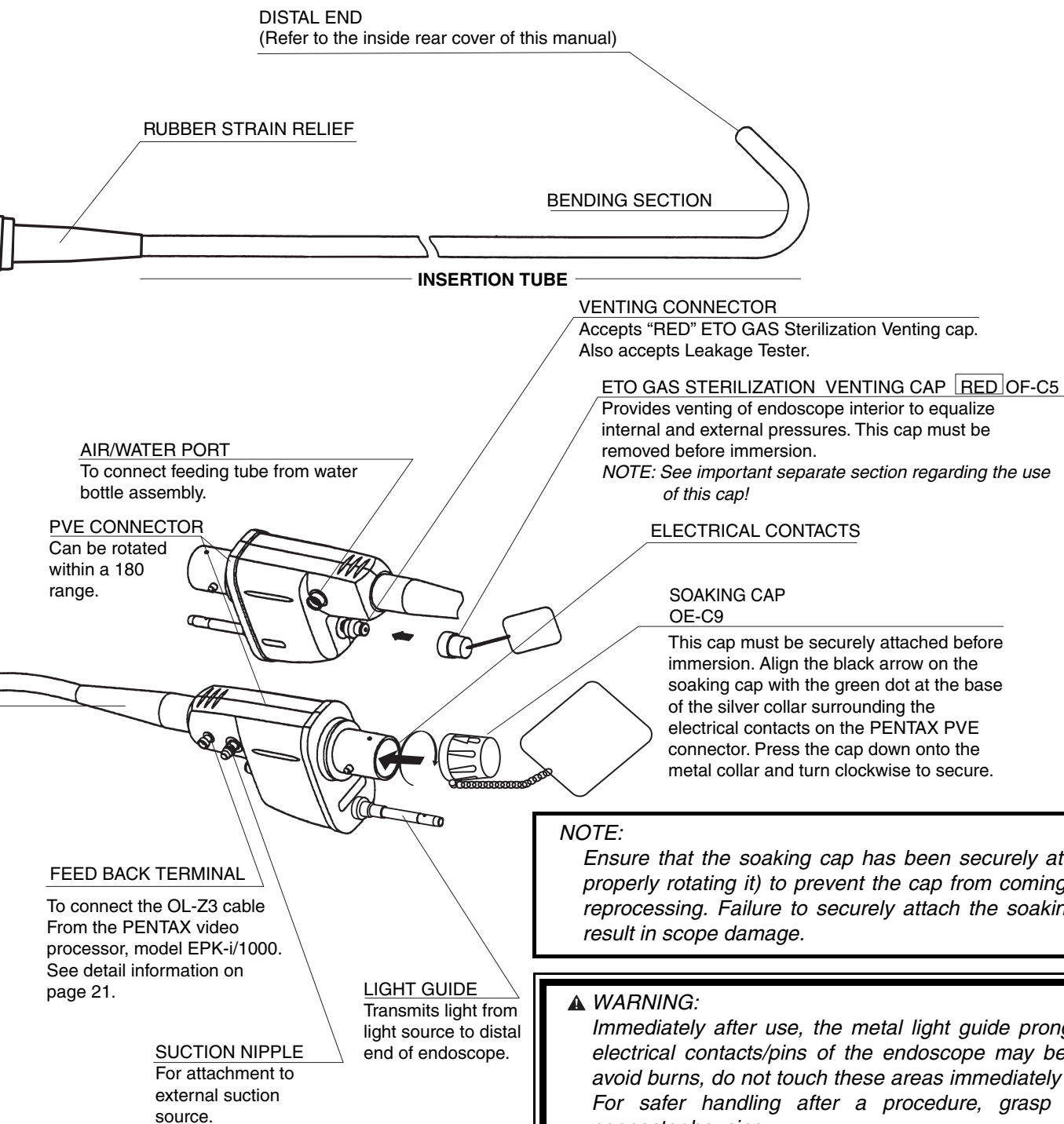
The function of each button can be changed. For more details, refer to the manual supplied with the EPK-i or the EPK-1000.

Scope	ED-3490TK	
Processor	EPK-i	EPK-1000
*Button 1	Freeze	
*Button 2	Hard Copy	
*Button 3	VCR (NTSC)/Enhance (PAL)	
*Button 4	Enhance	Enhance (NTSC) AVE/PEAK (PAL)
Magnification Control Lever	—	

*Setting at factory

NOTE:

To avoid damaging the endoscope, do NOT twist, rotate or bend excessively any of the rubber strain reliefs.



NOTE:

Ensure that the soaking cap has been securely attached (by properly rotating it) to prevent the cap from coming off during reprocessing. Failure to securely attach the soaking cap can result in scope damage.

▲ WARNING:

Immediately after use, the metal light guide prong and the electrical contacts/pins of the endoscope may be HOT. To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the PVE connector housing.

1-2. ACCESSORIES

1) Cleaning Brush for Suction System (Instrument Channel, Suction Tube)



This brush is provided non-sterile for one time use. Never reuse this disposable brush on more than one instrument.

2) Cleaning brush for recessed areas, scope tip, valve/selector cylinders and channel ports (including A/W, Suction, Forward Water Jet, surrounding the elevator mechanism, etc.)



CAUTION:

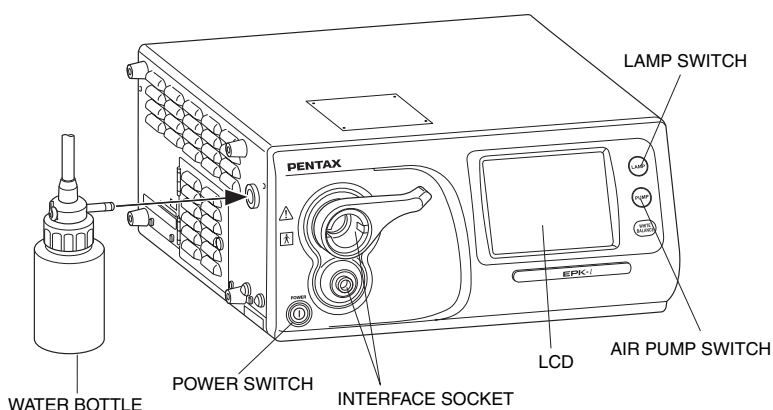
- Because of the effect that accessories used through the instrument channel of the endoscope can have on the performance of the endoscope itself, it is strongly recommended that PENTAX accessories be used with PENTAX endoscopes. If a unique or highly specialized accessory is available from another source, the accessory manufacturer should be consulted to confirm compatibility with PENTAX endoscopes before use.
- Maximum outer diameter of an endoscopic accessory instrument must be at least 0.2 mm less than the specified instrument channel diameter in PENTAX endoscopes. Working length of an endoscopic accessory instrument may be approximately 30 cm longer than the endoscope working length.

NOTE:

- Depending upon country and/or local PENTAX distributor, each PENTAX endoscopic accessory may be an optional accessory.
- For patient contact endoscopic accessories, follow the specific and detailed instructions on use, care and maintenance supplied with each product.
- To confirm the exact condition of any new accessory device, check the labeling/packaging accompanying the product. Each label/package should clearly identify the contents as either sterile or non-sterile.

1-3. VIDEO PROCESSOR

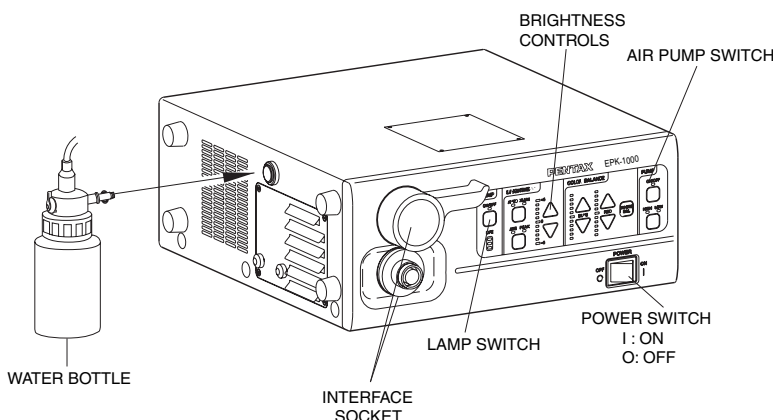
EPK-i



⚠ WARNING:

The lifetime of the lamp in EPK-i processor is 500 hours. Prior to use, check the lamp life meter on the rear panel to ensure the lamp life is less than 500 hours. After 500 hours of use, the image quality will deteriorate. Excessive use of the lamp beyond 500 hours could break the lamp inside the equipment resulting in damage to the equipment.

EPK-1000



⚠ WARNING:

The lifetime of the lamp in EPK-1000 processor is 400 hours. Prior to use, check the lamp life meter on the front panel to ensure the lamp life is less than 400 hours. After 400 hours of use, the image quality will deteriorate. Excessive use of the lamp beyond 400 hours could break the lamp inside the equipment resulting in damage to the equipment.

NOTE:

The lamp life could be affected by frequency of use. In which case, the lamp life might become shorter than its respective rated hours (EPK-i: 500 hours, EPK-1000: 400 hours)

CAUTION:

Please refer to the instruction supplied with the processor.

NOTE:

Use an air/water delivery system that is compatible with PENTAX endoscopes and video processors, and ensure that the cap assembly is securely fitted to the corresponding water bottle with matched model. Failure to properly secure the cap assembly to the water bottle may result in insufficient flows of air and water during the endoscopic procedure.

NOTE:

Software update may be required depending on the software version of the EPK-i processor. If the software is not updated, the image will not be displayed. If the images are not displayed correctly, please contact your local PENTAX service facility.

2. PREPARATION AND INSPECTION FOR USE

Prior to use, the endoscope, video processor and endoscopic accessory instruments must be carefully inspected for cleanliness and proper function to determine that they are appropriate for patient use:

NOTE:

PENTAX 90K series video endoscopes contained in this manual are only compatible with PENTAX video processor model EPK-i or EPK-1000.

CAUTION:

To avoid discontinuation of the endoscopic procedure, have an extra (spare) instrument available as a standby device. Should any unforeseen event or circumstance render the original instrument inoperable and/or unsafe for patient.

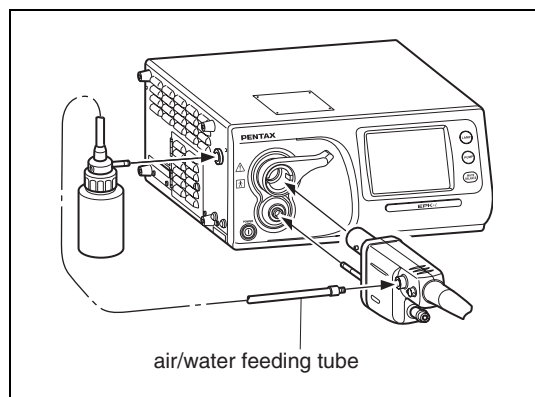
2-1. INSPECTION OF THE VIDEO PROCESSOR

Please refer to the Owner's Manual of the specific model of PENTAX video processor for complete instructions.

- 1) Mount the water bottle assembly within reach of the air pump fitting on the video processor and the air/water port on the PVE connector of the endoscope.

▲ WARNING:

The addition of defoaming agents to the water supply is NOT recommended. Due to their nature, these silicone based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" could be created which could reduce the effectiveness of the disinfection/sterilization process. Additionally, repeated use of such defoamers could eventually lead to residual silicone build up resulting in equipment malfunction such as clogged air and/or water channels.



- 2) Plug the processor into a properly grounded receptacle with the power switch in the OFF position.
- 3) Make sure that the PENTAX PVE connector is aligned with the interface socket on the front panel of the processor.
- 4) Connect the endoscope to the interface socket on the processor as illustrated.
- 5) Rotate the lever of the interface socket clockwise after insertion.

CAUTION:

After connecting the endoscope to the EPK-i video processor, always make sure that the endoscope is firmly secured to the scope receptacle by turning the locking lever to the "lock" position.

- 6) Connect the air/water feeding tube from the water bottle assembly to the air/water port on the side of the PVE connector.
- 7) Turn the processor and air pump to the "ON" position and check for proper functioning.
- 8) Press the lamp switch of the processor to turn ON the lamp.
- 9) Prior to each procedure, check the endoscope image quality displayed on the monitor. Confirm that the image quality, color, automatic brightness (iris) functions are acceptable as per the instructions provided with the PENTAX video processor.

2-2. INSPECTION OF ENDOSCOPE

CAUTION:

If the endoscope is intended to be clinically used after testing of individual scope functions (suction, air/water delivery, water jet, etc.) without further reprocessing, the following precaution should be exercised. Use sterile water during individual scope function tests to avoid recontamination of the previously reprocessed instrument by waterborne microorganisms. Tap water, especially that which may be left idle and uncovered for a prolonged period of time, should not be used during any inspection/testing of the endoscope.

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

CAUTION:

Various types of endoscope leakage testers exist including manual, electro-mechanical and “automated” versions, some of which are stand alone units and others which may be integrated into Automated Endoscope Reprocessors (AERs)/Washer-Disinfectors (WDs). It must be recognized that PENTAX does not evaluate non-PENTAX leak tester systems to satisfy their specific products claims, for their effectiveness to accurately detect leaks and/or for their compatibility with PENTAX endoscopes. Insufficient 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 testermanufacturer 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 scope’s distal bending section.

1) Inspection of the Insertion Tube

- a) Check the entire surface of the insertion tube for abnormal conditions such as dents, crush marks, wrinkles, bumps, buckles, excessive bending, protrusions, bite marks, peeling of outer sheath, cuts/holes or other irregularities. Any crush or indentation of the flexible shaft of the endoscopes can cause damage to the internal mechanisms of the endoscopes.
- b) Similarly, check the condition of the umbilical cable for outward signs of damage such as buckling, crush marks, etc.

CAUTION:

To avoid further damage to the endoscope or the possibility of malfunction during a procedure, do not use any endoscope with any abnormalities or outward signs of damage.

- c) Make sure that the entire endoscope is clean and has been subjected to either a high-level disinfection or sterilization process before each patient use.

▲ WARNING:

All instruments must be reprocessed prior to first time use, after any repairs/service and before every patient use. When utilizing chemo-thermal processes for reprocessing PENTAX endoscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.

NOTE:

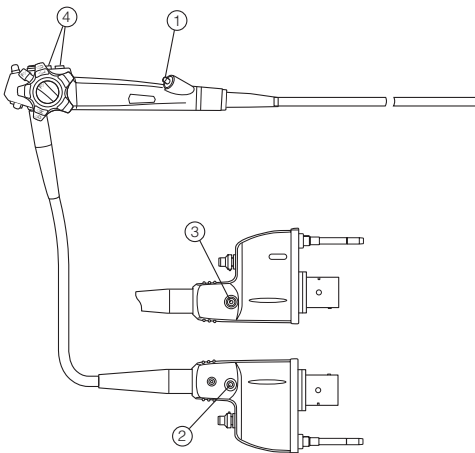
- The distal end of the endoscope as well as the electrical contacts/pins on the PVE connector must be protected against damage from impact. Never apply excess force such as twisting, or severe bending to the flexible portion of the endoscope.
- As indicated elsewhere in PENTAX product labeling, endoscopes particularly the quality of the endoscopic image should be checked prior to patient use.
- During pre-use inspection, ensure that the distal objective lens and the illumination (LCB) cover glass are clean and no residues are present on these distal surfaces. If not, crisp images can NOT be displayed. Wipe them with a gauze or the like moistened with a mild detergent solution (e.g. enzymatic detergent or cleaning solution specially formulated to clean endoscopes).
- Ideally all patients should be prepped well to maximize visualization of the intended areas of interest. Patient material and secretions should be removed from the area of observation to eliminate the potential to blur the endoscopic image and/or obscure the illumination system.
- Prior to a procedure, remove debris or secreta from observation area as much as possible.
- Continuing use of the light guide with sticky debris might cause steam because debris is deprived of moisture by heat. If steam is found on the light guide during a procedure, stop it immediately and withdraw the scope carefully from a patient.

NOTE:

Flexible endoscopes and other sophisticated medical instruments 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, scope damage (via fluid invasion) and/or in incomplete decontamination of used instruments.

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:

- the channel inlet assembly (biopsy inlet port) (①)
- the suction nipple/connector (②)
- the air/water inlet port (③)
- any valve cylinder (④)
- basically, any inlet or outlet port associated with an internal channel, an indirect patient contact portion of the endoscope
- rubber strain relief along insertion tube and umbilical cable (rotate clockwise only to tighten)

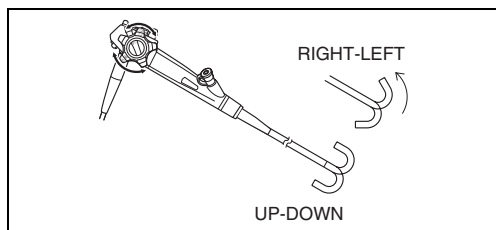
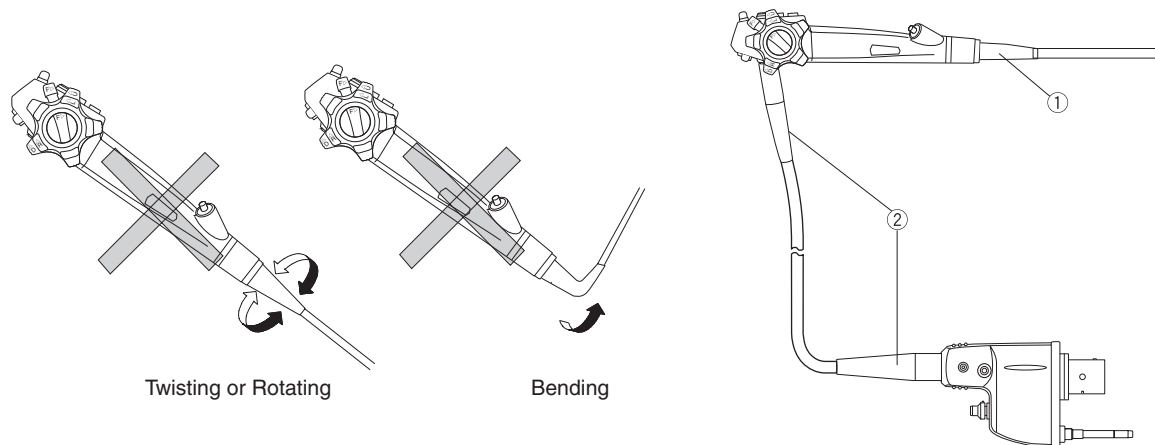


One method to check for looseness is to lightly grip the exposed part, and while grasping the component carefully attempt to move it in various directions. Use of a lintfree gauze while grasping metal parts is recommended as a protection for one's fingers.

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 service facility.

CAUTION:

To avoid damaging the endoscopes, do NOT twist, rotate or bend excessively any of the rubber strain relief (①,②) during inspection, clinical use, reprocessing or any handling activity. Be particularly cautious for the insertion tube strain relief (①). When wiping the insertion tube and the umbilical cable, use a slow back and forth motion to wipe them along the tube/cable. Never apply excessive force or torque on these strain reliefs or slim tubes/cables. During ANY handling of the instrument avoid excess force, twisting, rotation and/or bending of the actual insertion tubes and umbilical cables to prevent inadvertent damage (crush, compression, deformity, etc.) to these parts as well as to internal components contained within the endoscope.



2) Inspection of Deflection Controls and Locks

- Slowly manipulate the Up/Down and the Right/Left control knobs to see that they function smoothly. Be certain that a full and appropriate range of deflection is possible.
- Engage fully the deflection locks to be certain that the position of the deflected tip can be stabilized.

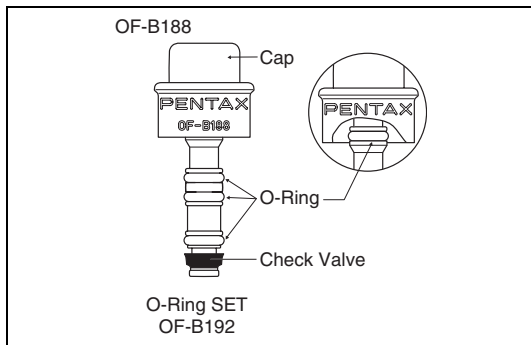
CAUTION:

ANY lack of smooth operation of the deflection controls may be an early indication of internal damage to and/or part(s) failure within the endoscope's angulation system. To avoid the possibility of further endoscope damage or the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly.

Prior to use ensure that the deflection controls can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the distal bending section bends freely and smoothly. NEVER APPLY EXCESSIVE FORCE TO THE DEFLECTION CONTROLS!

When an endoscope exhibits excessive "knob play" or if angulation is lost in any direction, do NOT use the instrument. Excessive "knob play" can be defined as rotating of the angulation control knob(s) in any one direction for more than 30 degrees without any corresponding distal tip deflection. The examples above are indications that service is required to avoid more serious problems with the angulation control system, including angle or pulley cable/wire breakage and/or the possibility of a "frozen" distal bending section.

A "frozen" bending section can make instrument extraction from a patient more difficult.



- 3) Prior to use, the air/water feeding valve (OF-B188) should be inspected. Remove the air/water valve from the control body and ensure that rubber O-rings (OF-B192) in good condition are properly attached.

CAUTION:

Since the rubber check-valve can NOT be replaced by the end user, replace the entire A/W valve with a new one if the check valve is damaged/ missing.




▲ WARNING:

Worn or damaged valves (O-rings in particular) should be replaced with new ones which have already been subjected to a high-level disinfection or sterilization procedure (O-ring set, model OF-B192, is optionally available). Failure to do so could create a risk of cross contamination to the end users due to the potential for reflux or spit-back of patient fluids out of the air/water valve. It could also create continuous air flow or excessive air insufflation and result in the potential patient injury such as pneumatic perforation.

- a) Install the valve into the A/W cylinder by gently pushing the valve into the cylinder. Never apply excessive force to push the valve into the A/W cylinder.
- b) Connect the scope to the video processor. Turn air pump "ON" to desired pressure setting. Place the scope distal tip into sterile water and confirm that no air bubbles exit the distal air nozzle.

▲ WARNING:

If air bubbles are observed during the test, the valve MUST BE REPLACED. Repeat the test procedure with a new valve (OF-B188).

Action			
Result	–	Air Feeding	Water Feeding

- c) To inspect air delivery, cover the hole at the top of the air/water valve and confirm that air flows freely from the air/water nozzle at the scope distal tip.
- d) By depressing the air/water feeding valve, the water delivery system is activated. Water should flow in a steady stream from the air/water nozzle at the distal tip of the endoscope. (This may take several seconds on the initial attempt.) **USE STERILE WATER ONLY.**
- e) Release the air/water valve to determine if the valve freely returns to its OFF (neutral) position and delivery of water (and air) ceases.

f) If air and/or water do not flow properly, NEVER attempt to clear the air or water nozzles with a needle or any other sharp object. Instead, the following steps should be followed.

- ① Disconnect the endoscope from the video processor.
- ② Remove the suction control valve and the air/water feeding valve.
- ③ Using a cotton tipped applicator and alcohol, clean the valve recess (receptacle) in the control body thoroughly to remove any debris. Do NOT attempt to insert the applicator into the small openings within the valve receptacle as the cotton or applicator could become lodged within these openings and cause channel blockage.
- ④ • Following the companion Instructions for Use (Reprocessing) for chemical cleaning of the air and water channel with detergent, flush detergent through both the air and water channels.
Rinse the air and water channel(s) with sterile water.
Then flush the air several times to force any residual solution out of the channel.
- Remove the adapters and install the air/water feeding valve.
(Alternate) By leaving the air/water valve in the cylinder instead of the OF-B153 adapter, one may direct pressured fluid (or air) independently to either channel to expel debris from and/or more forcefully flush solution into either the air or water channel. This should not be attempted on a completely clogged/blocked air or water channel/nozzle.

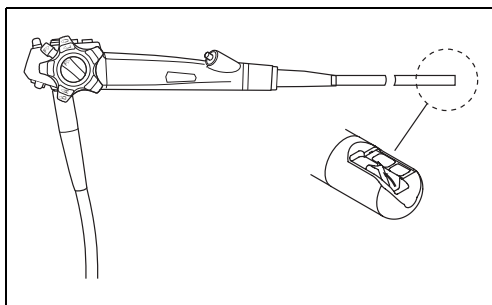
NOTE: If blockage of the line is encountered, avoid use of excessive pressure to prevent scope damage.

- ⑤ Test for normal delivery of air and water. It may be necessary to repeat the above procedure if normal air and water delivery is still not available.

NOTE: Do NOT apply excessive force in an attempt to unblock a clogged channel as the channel and/or brush could become damaged. Whenever channel damage is suspected, the endoscope should be leak tested.
If repeated attempts to flush the air/water system are unsuccessful, do not attempt to use the endoscope on a patient. Contact the PENTAX service facility.

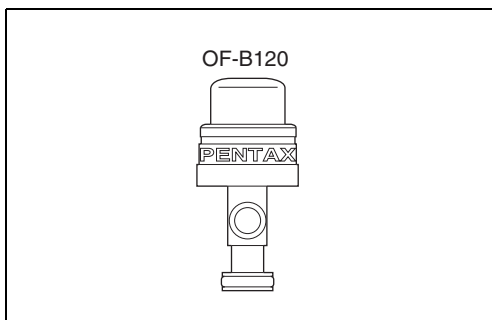
- g) If the air/water valve does not function properly, does not move smoothly or feels “sticky”, remove the valve and apply a very small amount of silicone oil lubricant onto all the O-rings. Do NOT use excess oil, avoid “blobs”, large drops and/or squirts of oil directly onto the metal valve stems - instead, simply place a small droplet of oil on one’s sterile gloved forefinger and gently swirl between thumb and forefinger. Next place the valve with O-ring in-between thumb and finger and gently rotate the valve so that the oil is evenly applied to the outer edges of each rubber O-ring. Make sure the oil is applied to all O-rings and wipe off all excess.
Do NOT apply excess oil. Doing so can allow for inadvertent migration of the oil inside channels or other areas not intended to be lubricated.

NOTE: Prior to clinical use, it is important that the entire air channel system be dry. Failure to thoroughly dry the air system could result in an unclear or blurry image caused by very fine droplets of moisture being swept over and/or onto the objective lens at the distal end of the scope.



4) Inspection of Elevator

- a) Make sure that the entire surfaces of the elevator (mechanism and surrounding area) are clean and have been properly reprocessed.
- b) This is the control that will guide and direct either the biopsy forceps or other accessory during a procedure. To inspect, push elevator control knob forward with thumb of the left hand. The elevator in the distal tip should elevate in proportion to the distance the control knob is moved. The motion of the elevator and the knob should be smooth and easy without any “play” involved.

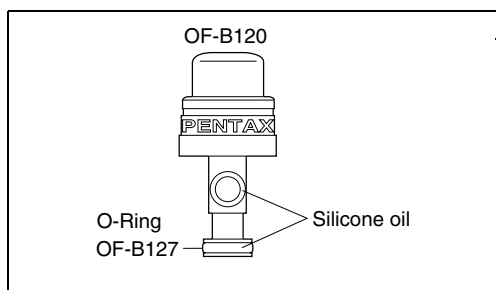
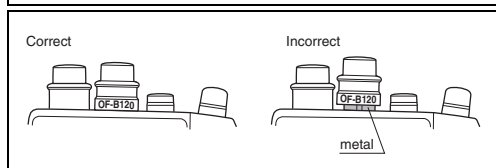
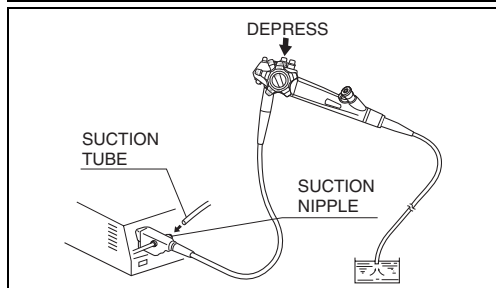
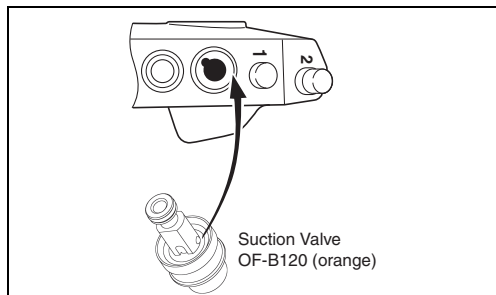


5) Inspection of Suction Mechanism

- a) Prior to use, the suction control valve (OF-B120) should be inspected. For easier identification, a orange colored indicator is placed on top of the OF-B120 valve mechanism. Remove the valve from the control body and make sure that rubber portions of the valve are not damaged or worn.

▲ WARNING:

A worn or damaged valve and/or O-ring should be replaced with a new one. The entire valve mechanism should be subjected to a high-level disinfection or sterilization procedure prior to use (O-ring set, model OF-B127, is optionally available). Failure to do so could result in continuous aspiration which in certain clinical situations can suction tissue into the distal channel opening at the scope tip and/or create a loss of insufflated air via the suction system. A compromised valve could also result in the potential for reflux or spit-back of patient fluids that may present infection risks.



- b) Position the valve OF-B120 so that the small metal tab near the base on the valve stem aligns with the notched suction valve cylinder, also color coded in orange. Install the valve into the suction cylinder by gently pushing the valve into the cylinder. Never apply excessive force to push the valve into the suction cylinder.

▲ WARNING:

Improperly installed valves may not function as originally intended. Such valves may not return to their neutral (released) positions and/or they may provide continuous suction. Continuous aspiration can cause loss of air/fluid, difficulty in maintaining proper insufflation and/or inadvertent suctioning of tissue into the distal instrument channel opening.

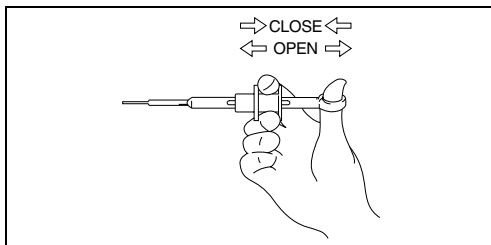
- c) Connect suction tubing from an external suction source to the suction nipple located on the PVE Connector at the end of the umbilical cable. Place the distal tip of the endoscope in a basin of sterile water and depress the suction control valve. Water should be rapidly aspirated into the suction 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.
- e) If the suction valve does not move smoothly or feels “sticky”, remove the valve from the suction cylinder on the control body of the endoscope. Apply a small amount of silicone oil lubricant, OF-Z11, onto rubber part and the rubber O-ring. Place a small droplet of oil on one’s sterile gloved forefinger and gently swirl between thumb and forefinger. Next place the valve with 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 rubber O-ring. Remove/wipe off excess lubricant with a soft gauze. Do not use excessive silicone oil.

CAUTION:

If the instrument is to be used immediately after the inspection, use only sterile water. To avoid recontamination of a previously reprocessed endoscope, avoid use of idle/uncovered tap water during any inspections.

NOTE:

A rubber inlet seal in good condition must be on the instrument channel inlet to prevent the loss of suction and a risk of cross contamination to the end user due to the potential for reflux (spit-back) of patient fluids. Worn seals will result in leakage and should be replaced. To ensure maximum performance of these sealing mechanisms, consider replacing the rubber inlet seal with a new fully reprocessed one for each procedure.



- 6) Inspection of Biopsy Forceps and Instrument Channel
 - a) Make sure there are no kinks in the flexible shaft of the biopsy forceps.
 - b) The jaws of the forceps must be free of any residual debris. Any debris must be cleaned from the forceps before they are used. **USE ONLY STERILE FORCEPS.**
 - c) The handle mechanism on the forceps should be operated to open and close the jaws. This mechanism should operate freely.

- d) Close and inspect the jaws of the forceps to make sure the cups are in proper alignment. If the forceps has a spike, the spike must be completely straight and fully within the cups.

▲ WARNING:

The use of any forceps or accessory that shows any sign of damage or difficulty of operation must be avoided. Any malfunction of a forceps or accessory during a patient procedure could result in serious injury to the patient. Also, the use of damaged forceps or accessories may result in serious and costly damage to the endoscope.

- e) Any accessory should be slowly inserted through the instrument channel inlet with the endoscope in a straight position. There should be no resistance encountered. If resistance is encountered, do not attempt to introduce the accessory further. The instrument channel may be damaged and the endoscope should not be used. Contact the PENTAX Service Department.

CAUTION:

Endoscopic accessory instruments (EAI) may be used with PENTAX flexible endoscopes. It should be understood that special care and caution must be exercised when using accessories, particularly non-PENTAX products through the instrument/suction channel of an endoscope. This is especially true when attempting to pass accessories through narrow channels when curved in a tight bending radius.

Please note that damage to the endoscope and/or accessory instrument is possible if excessive force is applied during insertion (or withdrawal) of the EAI. To prevent equipment damage or device failure, please adhere to the following precautions:

- Never apply too much pressure or excessive force during insertion through the instrument channel.
 - Never attempt to force endoscopic accessories, such as biopsy forceps through a fully angulated distal bending section.
 - Prior to using accessories from another source (non-PENTAX products), contact the manufacturers of the accessories to confirm if the device has been checked for compatibility.
- Failure to follow these recommendations can result in scope and/or accessory damage/failure, including but not limited to:*
- Channel puncture/leakage
 - Fluid invasion
 - Fiber breakage
 - Other internal component failure

Should resistance be encountered when inserting an accessory, STOP! If resistance is at the scope tip, slightly withdraw the accessory, reduce the angulation (within the distal bending section), then slowly and carefully advance the accessory under direct vision.

Several factors can affect the ease/difficulty of accessory passage through the endoscope channel:

- Outside diameter of accessory compared to inside channel diameter
- Non-flexible (rigid) portions of an accessory
- The curve or bend (bending radius) within a channel through which the accessory will pass
- Damaged accessory

Due to the variables above, prior to each procedure, it is important to check the particular accessory intended to be used to satisfy the clinical procedure to be performed. Such pre-use inspections will allow for uninterrupted and more expeditious examinations.

To confirm the absence of severe channel damage affecting the watertight integrity of the endoscope, perform appropriate leak testing of the scope per PENTAX instructions.

⚠ WARNING:

All patient contact accessories must be thoroughly cleaned and subjected to an appropriate high-level disinfection or sterilization process before being used for the first time and subsequently after each clinical use.

CAUTION:

The instrument, A/W and the water jet channel systems are made of stainless steel, poly phenylene oxide and fluorine-contained polymers. When any fluids are used with this scope, please read carefully and follow all instructions in the manual supplied with the fluids for use and pay special attention to any reactions with the materials identified in the intended fluid path.

NOTE:

Accessories should always be inspected and checked with the particular endoscope prior to each procedure.

⚠ WARNING:

Do NOT clinically use the endoscope if any irregularity or abnormality is suspected. If there is any doubt as to the suitability of use for any endoscope component, replace it with a new fully reprocessed one. An instrument irregularity may cause scope damage and/or compromise patient or user safety.

2-3. PREPARATION JUST BEFORE INSERTION OF ENDOSCOPE

▲ WARNING:

Every endoscope should be properly disinfected or sterilized before being used for the first time. The endoscope should have been properly cleaned and disinfected or sterilized after any previous use and after being returned for any repairs/service.

Refer to the companion Instructions for Use (Reprocessing) describing in detail PENTAX reprocessing instructions.

▲ WARNING:

Current infection control guidelines require that endoscopes and their patient contact accessories either be sterilized or at the least be subjected to high-level disinfection. Accessories which ENTER STERILE TISSUE or THE VASCULAR SYSTEM must be sterilized before patient use. Only the user can determine if any instruments and accessories have undergone appropriate infection control procedures prior to each clinical use.

- 1) If the endoscope has just recently been reprocessed, has been prepared or stored properly and passed all pre-procedure inspections, the instrument should be ready to use. If necessary, the scope's insertion tube may be wiped down with a gauze dampened with 70-90% ethyl or isopropyl alcohol.

NOTE:

Contact the manufacturer and follow local regulations regarding safe use, appropriate handling and disposal of alcohol products. Material Safety Data Sheets (Health and Safety Data Sheets or similar documents depending upon country) available from the 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 alcohol solution.

- 2) Gently clean the objective lens with a cotton-tip applicator moistened with 70-90% ethyl or isopropyl alcohol. A lens cleaner (anti-fogging agent) may also be applied via gauze or other applicator.
- 3) Check the endoscopic image and confirm that it is of acceptable quality for clinical use. Refer also to the owner's manual supplied with the PENTAX video processor for inspection of the image quality.
- 4) Prior to trans-oral insertion of the endoscope, place a bite-block (mouthpiece) into the patient's mouth to protect the endoscope from damage during the procedure. Failure to do so can result in scratches, tears and/or crushing of the insertion portion of the endoscope.
- 5) Apply a medical grade water soluble lubricant to the insertion tube. Do not use petroleum based lubricants.

NOTE:

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

▲ WARNING:

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

3. DIRECTIONS FOR USE

▲ WARNING:

This instrument should only be used by physicians who have thoroughly studied all the characteristics of this instrument and who are familiar with the proper techniques of endoscopy. During the procedure, always wear protective garments such as gloves, gowns, face masks, etc. to minimize the risk of cross contamination.

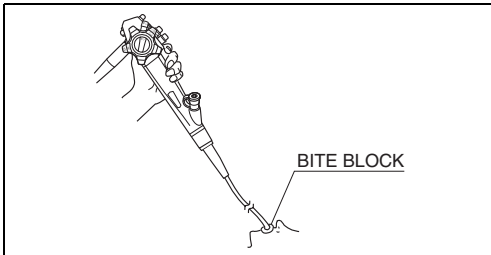
NOTE:

Do not use a water supply device that can exert 30kPa or greater of water pressure to the suction channel (suction valve) during endoscopic examination.

3-1. PRETREATMENT

- 1) The patient should be prepared in your normal endoscopy regimen.

3-2. INSERTION AND WITHDRAWAL



- 1) Slowly insert the scope under direct vision.
- 2) When the distal end of the scope is passed through the pharynx, the patient should be gently biting down on the bite block to maintain the bite block's position during the procedure.
- 3) Adjust the intensity of the video processor to obtain a brightness level suitable for observation.

▲ WARNING:

The light emission from the endoscope could cause thermal injury. To minimize the risk, use only the minimum amount of brightness and avoid close stationary viewing and unnecessary prolonged use.

- 4) The deflection controls should be used as needed to position the scope. Deflection of the tip should be performed under direct vision in a gentle and deliberate manner.

CAUTION:

ANY lack of smooth operation of the deflection controls may be an early indication of internal damage to and/or part(s) failure within the endoscope's angulation system. To avoid the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly.

Ensure that the deflection controls can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the distal bending section bends freely and smoothly.

NEVER APPLY EXCESSIVE FORCE TO THE DEFLECTION CONTROLS!

If during a procedure angulation is lost in any direction such as when "cables snap" (broken pulley wire, broken angle wire, etc.), do NOT continue to use the instrument and do NOT rotate the deflection controls. Should the angulation system fail for any reason, stop the procedure, release the lock lever and carefully withdraw the endoscope under direct visualization.

The examples above are indications that service is required to avoid more serious problems with the angulation control system, including the possibility of a "frozen" distal bending section.

A "frozen" bending section can make instrument extraction from a patient more difficult.

- 5) Insufflation should be controlled by the combined use of the air/water valve to increase the amount of insufflation and the suction control to decrease the level of insufflation.

CAUTION:

Be careful not to deliver too much air.

▲ WARNING:

*It must be recognized that variations in air flow (pressure and volume) for patient insufflation may exist from one manufacturer's equipment (light source, video processor and/or scope type) to another. It is, therefore, important to closely monitor the patient at all times and to **aspirate** excessive air to prevent overinsufflation and potential pneumatic perforation.*

- 6) Procedures involving poorly prepped patients should be avoided as excessive patient material can negatively affect certain scope channel functions as well as the ability to maintain a clear endoscopic view.
- 7) Mucous, fluids and/or other patient material should be aspirated via the instrument/suction channel and suction control valve to improve visualization. Maintain a clear view during aspiration, avoid prolonged suction time and use the minimum level of negative pressure required to perform the clinical procedure.

▲ WARNING:

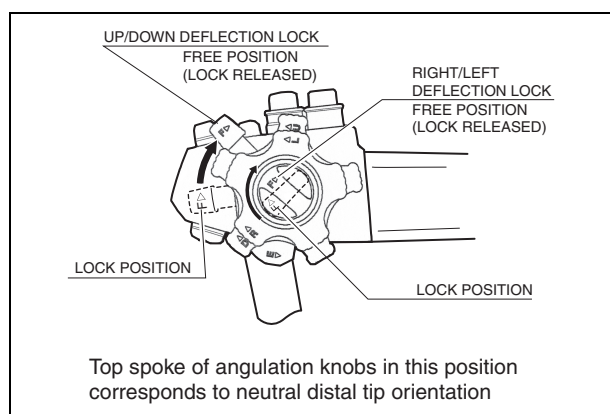
Do not apply excessively negative pressures (high suction settings) and/or prolonged contact of the distal instrument channel opening (scope tip) against mucosal surfaces to avoid "suction polyps", bleeding and/or other trauma to the patient. During aspiration keep as clear as possible an endoscopic view of patient anatomy and maintain some distance from scope tip to tissue to avoid suctioning of mucosa onto/into the distal channel opening.

- 8) The objective lens may be cleaned during the procedure by alternately using the air/water and suction control valves.

NOTE:

*Should debris on the objective lens be difficult to clean, one can **temporarily** use the HIGH air pressure setting on the processor and simultaneously press the air/water and suction control valves. Return air pressure setting to original selection before proceeding.*

- 9) Image capture, hard copy documentation, video recording, etc. may be carried out as necessary.
- 10) Before withdrawing the scope, trapped air should be suctioned to reduce patient discomfort.
- 11) When attempting to withdraw the scope, return the deflection locking levers to their free position. Always withdraw the scope under direct visualization.



▲ WARNING:

*If for any reason, the image is lost due to power shortage, lamp or processor failure, etc. the deflection locking levers should be released, the scope tip should be **straightened** to its neutral position, and the insertion tube should be carefully and slowly withdrawn from the patient.*

3-3. BIOPSY

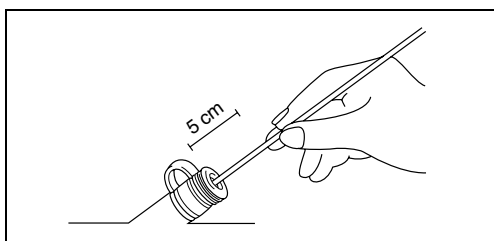
CAUTION:

For ALL types of endoscopic accessory instruments, always maintain a view of the accessory during advancement, use and withdrawal of the device.

▲ WARNING:

For safety reasons, always insert and advance the accessory in the standard, non-magnified mode. Magnified vision reduces the depth of the viewing field making it difficult to maintain a clear view of the accessory.

- 1) Raise the elevator mechanism.
- 2) Insert the forceps through the slit in the rubber inlet seal. Be certain to hold the forceps handle in such a way to ensure that the jaws of the forceps are in a fully closed position during insertion.
- 3) Once the accessory reaches the elevator, the mechanism should be lowered to allow accessory advancement of about 1 cm. The elevator may now be maneuvered as needed to bring the accessory into view and to aid in the application of the endoscopic accessory.



NOTE:

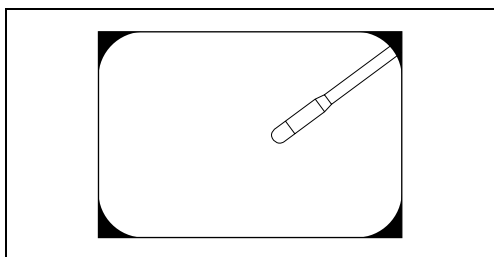
When the cups are first passed through the inlet seal, a temporary resistance will be encountered. Hold the shaft tightly at about 5 cm from the cups and push it through.

NOTE:

During insertion, if the forceps are found hard to advance further due to resistance, decrease the deflection of the bending section to a level suitable for smooth insertion and insert the forceps again.

CAUTION:

Never apply excessive pressure when introducing any accessory since the instrument channel may be damaged. Malfunction of the scope as well as costly repairs may result.



- 4) When a portion of the cups of the forceps becomes visible in the viewing field, carefully advance the forceps onto the target area.
- 5) Open the forceps cups and advance the forceps against the target area. Carefully squeeze the forceps handle to close the cups and obtain a specimen within the cups. Always maintain a view of accessory during advancement.
- 6) Withdraw the forceps slowly with the cups closed.

▲ WARNING:

After using operational/cleaning accessories (e.g., forceps, needles, snares, brushes etc.) with the endoscope, carefully check that all accessories are intact and that no parts have fallen off and become lodged within the endoscope's instrument/suction channel. Furthermore, ensure that any therapeutic devices (e.g., clips, stents, etc.) passed through the channel are accounted for after use.

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

The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or the introduction of debris and/or device components into a patient during a subsequent procedure, posing a risk of cross-contamination.

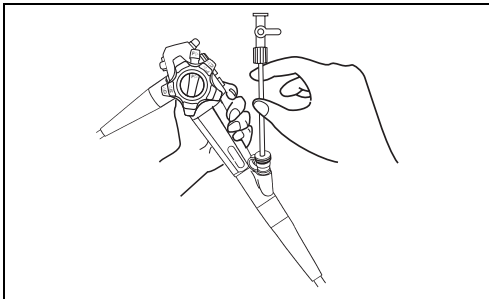
NOTE:

Because of the effect accessories used in the instrument channel of the endoscope can have on the performance of the endoscope itself, it is strongly recommended that only PENTAX accessories be used with PENTAX endoscopes. If a unique or highly specialized accessory is available from another source, the accessory manufacturer should be consulted to confirm compatibility with PENTAX endoscopes before use.

▲ WARNING:

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

3-4. CHOLANGIOPANCREATOGRAPHY (ERCP)



- 1) Insert the cannula into the biopsy/instrument channel through the rubber inlet seal, there could be strong resistance from the inlet at first. Hold the cannula approximately 5~10cm from the distal tip and push it through the inlet. Use repeated short strokes to advance the cannula.
- 2) Attach a luer lock syringe filled with contrast material to the cannula. Inject, until air is eliminated from cannula. This will maintain the integrity of the lumen and contrast media while the cannula is in use.
- 3) Insert the tip of the cannula into the Ampulla of Vater.
- 4) Inject contrast material slowly into the duct under visualization.
- 5) Remove cannula slowly.

NOTE:

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

CAUTION:

If the cannula elevator is not deflected at all, the cannula may not be seen in the field of view since this is a side viewing instrument. It is recommended that the elevator be slightly deflected so that the cannula exits the distal scope tip and advanced slowly only under full view.

▲ WARNING:

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

3-5. BILIARY DRAINAGE (ERBD)

NOTE:

Endoscopic Retrograde Biliary Drainage should be performed only by those physicians who are completely familiar with endoscopy and ERBD procedure.

The following is meant solely for the safe passage of catheters and biliary prosthesis through the flexible endoscope. It is not meant to be used as instructions for the procedure itself.

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

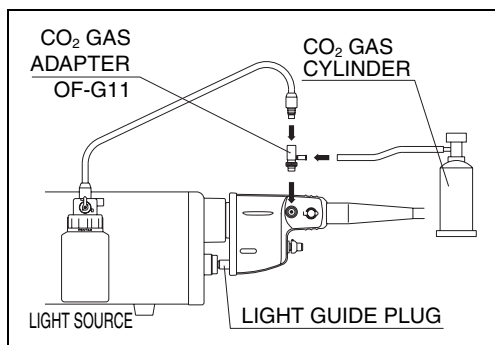
NOTE:

There are several types of prosthetic devices available, be sure to review the specific instructions supplied with each prosthesis.

3-6. ELECTRO-SURGERY

▲ WARNING:

Please refer to the operating manual provided with the electrosurgical unit. Electrosurgical systems may be of the floating type (BF type, CF-type) or non-floating (B type). To avoid patient and user burn, use only the floating type ESU (such as ERBOTOM ICC 200) /accessory systems. Do not use the non-floating (B type) electrosurgical systems. The electrosurgical generator and any electrosurgical accessory should be carefully and thoroughly inspected. Only the user can determine if the condition of the electro-surgical generator and the electro-surgical accessory are suitable.



- 1) The user has the option of using a non-explosive gas for insufflation. Non-explosive gas from a pressure-regulated and flow-rate controlled source can be connected to the provided or optionally available gas adapter, Model OF-G11, as described for Laser in section 3-6.
- 2) The electrosurgical accessories should be introduced through the endoscope in the same manner as described for biopsy forceps in section 3-3.

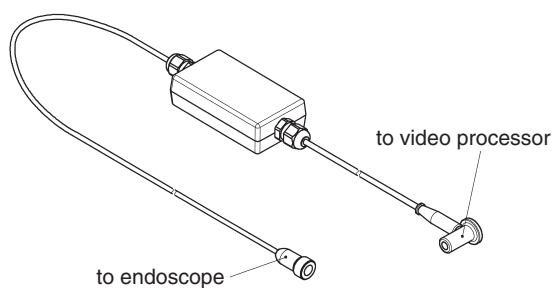
▲ WARNING:

To avoid patient and user burn, follow the instructions below before electrosurgical energy is delivered.

- 1) Use only the electrosurgical generator with the floating grounding type (BF or CF Type). Do not use the non-floating (B type) electrosurgical systems.
- 2) In Floating Ground Electro-Surgical Generator, there is a type with a scope feedback cord (S-cord) as well as the one without a scope feedback cord.
 - In case of Floating Ground Electro-Surgical Generator with a scope feedback cord: Connect the scope feedback cord between the scope's feedback terminal and the connecting socket of the patient ground of the electro-surgical generator.
 - In case of Floating Ground Electro-Surgical Generator without a scope feedback cord: Do not use optional functional ground cord. To do so may be dangerous if the metal portion of the scope tip comes in contact with patient tissue or mucous during procedures. In order to minimize the noise caused by the electro-surgical generator, use optionally available condenser earth cable OL-Z3. If the processor does not have an equipotential terminal, do not connect any functional ground cord.
- 3) Wear rubber gloves and face masks.
- 4) The position of the target area, the insulated distal portion of the electrosurgical accessory and the active portion of the electrosurgical accessory, should be visible.
- 5) The active portion of the electrosurgical accessory should not touch the metallic distal portion of the endoscope directly or via fluids.
- 6) The metallic portion of the endoscope should not touch the surrounding tissue directly or via fluids.
- 7) The active portion of the electrosurgical accessory should not touch the surrounding tissue directly or via fluids.
- 8) The head of any lesion such as polyp should not touch the surrounding tissue directly or via fluids.
- 9) Physicians and assisting personnel should avoid contact with the patient while high frequency energy is delivered.
- 10) Electro-surgical energy should be delivered for as short a time period as necessary to accomplish the desired clinical effect.
- 11) Select a high frequency output power setting suitable for the particular intended procedure in order to avoid thermal invasion of the tissue, or insufficient coagulation, resulting in excessive bleeding.
- 12) To avoid the risk of thermal injury, use only insulated accessories.
Never use non-insulated devices while performing endoscopic electrosurgical procedures.

NOTE:

It should be recognized that the use of electro-surgical accessory devices employing high frequency current may interfere with the normal endoscopic image and this interference is not indicative of a malfunction of the video endoscope system. PENTAX has developed an earth cable, model OL-Z3 intended to reduce potential RF interference and electronic noise that may appear in the endoscope image when using electro-surgical devices. Ensure that cable OL-Z3 is correctly connected between the endoscope and video processor as described in the instructions provided with the OL-Z3. If electronic noise appears in the endoscope image when using the OL-Z3, select a high frequency setting to minimum levels capable of achieving the desired clinical effect.



4. CARE AFTER USE

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

▲ WARNING:

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

Your local PENTAX distributor can provide a list of “compatible” reprocessing agents with PENTAX endoscopes based upon material compatibility and functionality studies performed by PENTAX, Japan. These tests of course apply only to genuine PENTAX parts, components and materials including proprietary adhesives, sealants, lubricants, etc. specifically selected for use in PENTAX endoscopes to satisfy their original design criteria. PENTAX manual reprocessing instructions supplied with each product have been validated for PENTAX endoscopes utilizing exclusive PENTAX parts/materials and assembled based upon proprietary PENTAX manufacturing technologies and/or servicing techniques.

It must be recognized that PENTAX does not evaluate non-PENTAX parts, components, materials and/or servicing methods and therefore questions regarding material compatibility and/or functionality of PENTAX instruments 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. It is unknown to PENTAX if serviced or remanufactured instruments (performed by unauthorized PENTAX entities) which still bear a PENTAX label are within PENTAX device specifications and/or if unauthorized activities have significantly changed the instrument's performance, intended use, safety and/or effectiveness.

These companies should confirm the ability for these serviced/remanufactured devices to be reprocessed safely and effectively with reprocessing agents/systems recognized as compatible by PENTAX for standard PENTAX products. These third party companies and/or remanufacturers should be consulted to confirm if they have performed reprocessing validation studies on instrument models which they have serviced (or remanufactured) that support the cleaning, high-level disinfection and/or sterilization of these endoscopes via the normal scope OEM reprocessing recommendations, standard AER device-specific instructions and/or their own unique reprocessing recommendations.

Ultimately, owners of these medical devices are responsible for selecting an appropriate service facility or vendor whose activities render an instrument to the same expectations and quality of a finished device supplied by the scope OEM.

▲ WARNING:

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

CAUTION:

The service life of this instrument 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.*
- *Send the endoscope to PENTAX Medical for inspection of the forceps elevator by PENTAX Medical once a year. Contact PENTAX Medical for any questions regarding annual Inspection.*

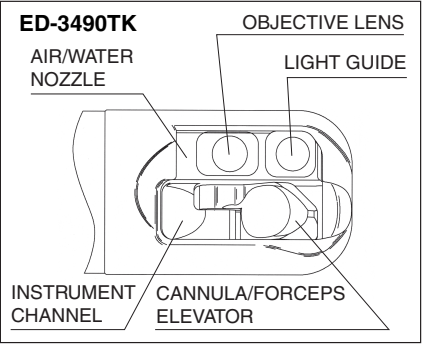
SPECIFICATIONS

		ED-3490TK
Direction of View		Side
Field of View		100°(retro 10°)
Depth of Field		4 ~ 60mm
Tip Deflection	Up-Down	120° -90°
	Right-Left	105° -90°
Rigid Distal Width		ø13.2mm
Distal End Width		ø13.2mm
Insertion Tube Width		ø11.6mm
Maximum Insertion Portion Width		ø13.4mm
*Minimum Instrument Channel Width		ø4.2mm
Insertion Tube Working Length		1250mm
Total Length		1573mm
Operating environment	Ambient temperature	10 ~ 40°C
	Relative humidity	30 ~ 85%
	Air pressure	700 ~ 1060 hPa
Storage environment	Ambient temperature	-20 ~ 60°C
	Relative humidity	0 ~ 85%
	Air pressure	700 ~ 1060 hPa
Degree of protection against electric shock		BF type

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

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

Distal End



NOTICE

These instruments are used with Class B Medical Equipment (specified EN55011) and are intended for hospital or health care districts.

Together, these endoscopes and the compatible processor comply with EN 60601-1-2 for EU, IEC 60601-1-2 for other countries.

When used in clinical or residential areas near radio and TV receiver units, these instruments may be subjected to radio interference.

To avoid and resolve adverse electromagnetic effects, do NOT operate these instruments near the RF energy equipment.

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

Our representative in your area:



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