

INSTRUCTIONS



EVIS EXERA PLEURAVIDEOSCOPE OLYMPUS LTF TYPE 160

Refer to the endoscope's companion manual, the "OLYMPUS LTF TYPE 160 REPROCESSING MANUAL" for reprocessing information.



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Symbols

The meaning(s) of the symbol(s) shown on the package with the components, the back cover of this instruction manual and/or this instrument are as follows:

ī	Refer to instructions.
\triangle	Caution
(Do not reuse.
	Use by (expiration) date
LOT	Lot number
Ŕ	TYPE BF applied part
	Endoscope
STERILEEO	Sterilized using ethylene oxide
STERILE LOT	Sterilization lot number
***	Manufacturer
EC REP	Authorized representative in the European Community
SN	Serial number
業	Keep away from sunlight
Ť	Keep dry
andre	Do not resterilize
	Do not use if package is damaged

Important Information — Please Read Before Use

Intended use

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic diagnosis and treatment within the thoracic cavity. Do not use this instrument for any purpose other than its intended uses.

Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the equipment as instructed.

Note that the complete instruction manual set for this endoscope consists of this manual and the "OLYMPUS LTF TYPE 160 REPROCESSING MANUAL" which also accompanied the endoscope at shipment.

Keep this and all related instruction manuals in a safe, accessible location. If you have any questions or comments about any information in this manual, please contact Olympus.

User qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. For details on the clinical endoscopic procedures, the physician and operator are requested to form judgments from their viewpoints as specialists.

Instrument compatibility

Refer to the "System chart" in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014).

When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable.

Reprocessing before the first time use and reprocessing and storage after use

This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope's companion manual, the "OLYMPUS LTF TYPE 160 REPROCESSING MANUAL".

After using this instrument, reprocess and store it according to the instructions given in the endoscope's reprocessing manual. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Repair and modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and/or equipment damage can result. Only Olympus personnel is allowed to repair this instrument.

Signal words

The following signal words are used throughout this manual:

DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

Danger, warnings and cautions

Follow the danger, warnings and cautions given below when handling this instrument. This information is to be supplemented by the danger, warnings and cautions given in each chapter.

DANGER

The endoscope cannot be applied to the heart or any area near the heart. The cardiac function of the patient can be seriously affected (ventricular fibrillation, etc.).

WARNING

- After using this instrument, reprocess and store it according to the instructions given in the endoscope's companion reprocessing manual. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and infection.
- Never perform angulation control forcibly. Never forcefully pull, twist or rotate the angulated bending section. Patient injury can result.

- Never operate the bending section, perform suction, insert or withdraw the endoscope's insertion tube, use endo-therapy accessories without viewing the endoscopic image. Patient injury can result.
- Never use endo-therapy accessories while the image is frozen. Patient injury can result.
- Never operate the bending section, perform suction, insert or withdraw the endoscope's insertion tube, use endo-therapy accessories while the image is frozen. Patient injury can result.
- Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator and/or patient burn can result.
- Be sure to prepare another endoscope to avoid that the examination be interrupted due to equipment failure or malfunction.

CAUTION

- Do not pull the universal cord. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will not be visible.
- Do not coil the universal cord into a diameter of less than 12 cm. Equipment damage can result.
- Do not apply shock to the distal end of the insertion tube (MAJ-1222), particularly the objective lens surface at the distal end. Visual abnormalities may result.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.
- The endoscope's remote switches cannot be removed from the control section. Pressing or pulling them with excessive force can break the switches.
- Use the LTF-160 in combination with the flexible trocar 8 mm (MAJ-1058) only. Other trocars may damage the insertion tube and/or the bending section of the endoscope.
- Straighten the bending section of the endoscope before inserting or withdrawing the endoscope into/from the flexible trocar. Damage to the bending section may result.

 Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument, or shielding the location.



 Be sure that this instrument is not used adjacent to or stacked with other equipment (other than the components of this instrument or system) to avoid electromagnetic interference.

Precaution for disappeared or frozen endoscopic image

WARNING

- If the endoscopic image unexpectedly disappears or the frozen image cannot be restored during an examination, immediately stop using the instrument and withdraw the endoscope from the patient. Continued use of the endoscope in such condition may cause patient injury, bleeding and/or perforation.
- Follow the precautions given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
 - Connect the endoscope connector, videoscope cable and video system center completely. Otherwise, faulty contact can result.
 - Do not bend, hit or twist the insertion section, control section, universal cord and endoscope connector. The endoscope may be damaged and water leaks and/or breakage of internal parts like CCD cable can result.
 - Before immersing the endoscope, always attach the water-resistant cap. Otherwise, water will enter the endoscope and may cause short of the internal circuit. This may result in breakage of the switch and CCD.
 - If bubbles emerge from the endoscope continuously during leakage test, do not use the endoscope. Water may enter from the hole and short the internal circuit. This may result in breakage of the switch and CCD.

Examples of inappropriate handling

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are given below.

- Applying prolonged suction with the distal end in contact with the mucosal surface may cause bleeding or suction lesions.
- Inserting, withdrawing and using endo-therapy accessories without a clear endoscopic image may cause burns or perforation.
- Inserting or withdrawing the endoscope, applying suction or operating the bending section without a clear endoscopic image may cause patient injury.

Chapter 1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Olympus. This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope's companion manual, the "OLYMPUS LTF TYPE 160 REPROCESSING MANUAL".



Chapter 1 Checking the Package Contents

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature





2.2 Endoscope functions

1. Electrical connector

The electrical connector connects the endoscope to the EVIS video system center via the videoscope cable.

2. Endoscope connector

The endoscope connector connects the endoscope to the output socket of the light source and transmits light from the light source to the endoscope.

3. UP/DOWN angulation control lever

When the lever is moved in the "U" direction, the bending section moves UP; when the lever is moved in the "D" direction, the bending section moves DOWN.

4. Suction valve (MAJ-207)

The suction valve is depressed to activate suction. The valve is used to remove any remaining fluid and debris that obstruct the visual field.

WARNING

Use of the suction valve (MAJ-207) is not recommended for more than 6 procedures.

5. Single-use biopsy valve (MAJ-210) or biopsy valve (MD-495)

Accessories may be inserted through the slit in this valve. A syringe may be inserted for the introduction of fluids.

6. Instrument channel port

The instrument channel port functions as:

- channel for the insertion of endo-therapy accessories
- suction channel
- fluid feed channel (from a syringe via the biopsy valve)

7. Color code (Yellow)

The color code is used to quickly determine the compatibility of endo-therapy accessories. The endoscope can be used with endo-therapy accessories that have the same color code.

8. Remote switches 1 to 4

The functions of remote switches 1 to 4 can be selected on the EVIS video system center. When selecting the functions, refer to the instruction manual for the EVIS video system center.

9. Bending section

The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.

10. Identification mark for STERRAD[®] 200/NX[™] material compatibility This mark indicates that this endoscope has material compatibility with the STERRAD[®] 200/NX[™] Sterilization System. The endoscope without this mark is not applicable to STERRAD[®] 200/NX[™].

2.3 Specifications

Environment

Operating	Ambient temperature	10 – 40°C (50 – 104°F)
environment	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa
		(0.7 – 1.1 kgf/cm ²)
		(10.2 – 15.4 psia)
Standard storage	Ambient temperature	5 – 40°C (41 – 104°F)
environment (e.g.	Relative humidity	10 – 95%
within the hospital)	Atmospheric pressure	700 – 1060 hPa
		(0.7 – 1.1 kgf/cm ²)
		(10.2 – 15.4 psia)
Transportation	Ambient temperature	–47 to 70°C (–52.6 to 158°F)
environment	Relative humidity	10 – 95%
(conditions during transportation and	Atmospheric pressure	700 – 1060 hPa
short-term storage)		(0.7 – 1.1 kgf/cm ²)
		(10.2 – 15.4 psia)

Specifications

	Model	LTF-160
Optical	Field of view	120°
system	Direction of view	Forward viewing
	Depth of field	3 – 100 mm
Insertion tube	Distal end outer diameter	ø 7.0 mm
	Distal end enlarged	1. Objective lens
		2. Light guide lens
		3. Instrument channel outlet
		3. UP 2. 2. DOWN 1.
	Insertion tube outer diameter	ø 7.0 mm
	Working length	270 mm
Instrument	Channel inner diameter	ø 2.8 mm
channel	Minimum visible distance	3 mm from the distal end
	Direction from which endo-therapy accessories enter and exit the endoscopic image	e
Bending section	Angulation range	UP 160°, DOWN 130°
Total length		520 mm

O Endoscope functions

Medical Devices		This device complies with the
Directive	CE 0197	requirements of Directive 93/42/EEC
	N 0 197	concerning medical devices.
		Classification: Class II a
EMC	Applied standard;	This instrument complies with the
	IEC 60601-1-2: 2001	standards listed in the left column.
	IEC 60601-1-2: 2007	
	IEC 60601-1-2: 2014	CISPR 11 of emission:
	IEC 60601-2-18: 1996	
	IEC 60601-2-18: 2009	Group 1, Class B
		This instrument complies with the
		EMC standard for medical electrical
		equipment, edition 4 (IEC 60601-1-2 2014).
		When connecting to an instrument
		that complies with a previous edition
		of the EMC standard for medical
		electrical equipment edition, the EMC
		characteristics could be vulnerable.
Year of manufacture	2 <u>3</u> 12345	
	▲	The year of manufacture is given in
		the second digit of the serial number
Degree of protection		TYPE BF applied part
against electric		
shock		

Chapter 3 Preparation and Inspection

Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. If this instrument is found to be malfunctioning, do not use it and return it to Olympus for repair according to Section 5.3, "Returning the endoscope for repair".

If the irregularity is suspected after inspection, follow the instructions given in Chapter 5, "Troubleshooting".

WARNING

- Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.
- This instrument was not cleaned, disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope's companion manual, the "OLYMPUS LTF TYPE 160 REPROCESSING MANUAL".

3.1 Preparation of the equipment

Prepare the equipment shown in Figure 3.1 (for compatibility, see the "System chart" in the Appendix) and personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves, before each use. Refer to the respective instruction manuals for each piece of equipment.



Figure 3.1

3.2 Inspection of the endoscope

Clean and sterilize the endoscope as described in its companion reprocessing manual. Then remove the water-resistant cap from the endoscope connector.

Inspection of the endoscope

- **1.** Inspect the control section and the endoscope connector for excessive scratching.
- 2. Inspect the insertion tube for bends, twists or other irregularities.
- **3.** Inspect the surface of the insertion tube for dents, bulges, swelling, peeling or other irregularities.
- **4.** Carefully run your fingertips over the entire length of the insertion tube. Inspect for any protruding objects or other irregularities (see Figure 3.2).





- **5.** Inspect the covering of the bending section for sagging, swelling, cuts, holes or other irregularities.
- **6**. Gently hold the midpoint of the bending section and a point 20 cm from the distal end. Push and pull gently to confirm that there is no play.
- 7. Inspect the objective lens at the distal end of the endoscope's insertion tube for scratching, cracks, stains, gaps around the lens or other irregularities.

Inspection of the bending mechanisms

Perform the following inspections while the bending section is straight.

- **1**. Turn the UP/DOWN angulation control lever slowly in each direction until it stops. Confirm that the bending section angulates smoothly and correctly and that maximum angulation can be achieved.
- Turn the UP/DOWN angulation control lever slowly to its neutral position. Confirm that the bending section returns smoothly to an approximately straight condition.

3.3 Preparation and inspection of accessories

Inspection of the suction valve (MAJ-207)

WARNING

Do not use the suction valve (MAJ-207) for more than six procedures.

Inspect the suction valve for damage (see Figure 3.3).

- 1. Confirm that the valve is not deformed or cracked.
- 2. Confirm that the button can be pushed without excessive resistance.



Figure 3.3

Inspection of the biopsy valve

WARNING

- The biopsy valve (MAJ-210) is disposable. Do not attempt to reuse or resterilize it.
 - Do not use the biopsy valve (MD-495) for more than six procedures.

CAUTION

The biopsy valve (MD-495) is subject to wear, and it should be inspected before each use. Replace the biopsy valve with a new one if irregularities and/or excessive wear are detected.

Single-use biopsy valve (MAJ-210) (For Europe except UK)

Confirm that the biopsy valve is free from cracks, tears or deformation (see Figure 3.4).



Figure 3.4

O Biopsy valve (MD-495) (For non-European countries)

- 1. Confirm that the biopsy valve is free from cracks, tears or deformation.
- 2. Attach the cap to the main body (see Figure 3.5).



Figure 3.5

3.4 Attaching accessories to the endoscope

Attaching the suction valve

WARNING

Firmly attach the suction valve to the instrument channel port. If the suction valve is attached to the endoscope improperly with gap between the base of the suction valve and the top of the suction cylinder, suction valve may detached from the endoscope and may cause patient debris to leak or spray from the gap.

CAUTION

The suction valve does not require lubrication. Lubricants can cause swelling of the valves' seals, which will impair the valve function.

- **1.** Place the suction valve into the suction cylinder, aligning the arm of the main body with the white mark on the endoscope (see Figure 3.6).
- **2.** Press down on the suction valve's top surface with your both thumbs until it "clicks" into place (see Figure 3.6).





3. Inspect and verify that the base of the valve is in contact with the suction cylinder properly. Improper attachment, where a gap still exists between the base of the suction valve and the top of the suction cylinder (see Figure 3.7).





NOTE

Sometimes the suction valve will click before it is fully seated in the suction cylinder. Press the suction valve down firmly to ensure that it is fully seated in the suction cylinder.

Attaching the biopsy valve

Attach the biopsy valve (MAJ-210, MD-495) to the instrument channel port of the endoscope (see Figure 3.8). Confirm that the valve fits properly.

NOTE

At lower temperatures, the biopsy valve may become stiff and difficult to attach. In this case, press it down more firmly.



Figure 3.8

3.5 Preparation, inspection and connection of ancillary equipment

Preparation and inspection of ancillary equipment

CAUTION

The LTF-160 is compatible with the EVIS video system centers CV-100/140/145/160 only.

Prepare and inspect the light source, video system center, video monitor, water container, suction pump and endo-therapy accessories according to described in their respective instruction manuals.

Connection of the endoscope and ancillary equipment

WARNING

If the endoscope connector, videoscope cable and video system center are not connected properly, the endoscopic image may have flicker or not be displayed. Continuous use of such endoscope may cause patient injury, bleeding or perforation.

CAUTION

- The LTF-160 is compatible with the videoscope cable 100 only.
- For more information on combining the endoscope with the video system center and the videoscope cable, refer to the "System chart" in the Appendix.
- **1.** Insert the endoscope connector completely into the output socket of the light source.
- 2. Turn the video system center OFF.



Figure 3.9

- **3.** Align the mark on the videoscope cable with mark 1 on the electrical connector and push it in until it stops (see Figure 3.9).
- 4. Turn the videoscope cable clockwise until it stops (see Figure 3.9).
- **5.** Confirm that the mark on the videoscope cable is aligned with mark 2 on the endoscope connector.
- **6**. Connect the suction tube from the suction pump to the suction connector on the suction valve.

Preparation and inspection of the flexible trocar

WARNING

- Confirm that the trocar end does not have a burr that could cause damage to the bending section cover of the endoscope.
- Do not use the flexible trocar after the expiration date given on the sterile package. An infection control risk and/or tissue irritation may result.
- Do not use the flexible trocar if the sterile package shows tears, inadequate sealing or water damage. An infection control risk and/or tissue irritation may result.
- The flexible trocar is a single-use item. Do not attempt to resterilize or reuse it. An infection control risk, tissue irritation and/or equipment damage may result.

CAUTION

Use the LTF-160 in combination with the flexible trocar 8 mm (MAJ-1058) only. Other trocars may damage the insertion tube and/or the bending section of the endoscope.

- 1. Inspect the sterile package for tears, inadequate sealing or water damage.
- 2. Inspect the flexible trocar for deformation or cracks.
- **3.** Confirm that the obturator passes smoothly through the trocar tube (see Figure 3.10).



Figure 3.10

3.6 Inspection of the endoscopic system

Inspection of the endoscopic image

- **1.** Before inspection, wipe the objective lens with clean, lint-free cloths moistened with saline solution or sterile water.
- 2. Turn on the video system center, light source, video monitor and inspect the endoscopic image as described in their respective instruction manuals.
- **3.** Adjust the brightness level as appropriate.
- **4.** While observing the palm of your hand, confirm that the examination light is output and that the endoscopic image is free from noise, blur, fog or other irregularities.
- **5**. Angulate the bending section and confirm that the endoscopic image is free from momentary disappearing or other irregularities.

Inspection of the remote switch

WARNING

All remote control switches should be confirmed to work normally even when they are not expected for use. Endoscopic image may freeze or other irregularities may occur during examination and may cause injury, bleeding and/or perforation.

Depress every remote control switches and confirm that the specified functions work normally.

Inspection of the suction function

WARNING

Set the aspiration pressure of the suction pump within the range of -34 kPa to 0 kPa. Excessive aspiration pressure may make it difficult to stop suction.

- Immerse the distal end of the insertion tube in sterile water and depress the suction valve. Confirm that water is continuously aspirated into the suction bottle on the suction pump.
- **2.** Release the suction valve. Confirm that suction stops and the valve returns to its original position.

3. Remove the distal end from the water. Depress the suction valve and aspirate air for a few seconds to remove any water from the instrument channel.

Inspection of the instrument channel

CAUTION

Keep your eyes away from the distal end when inserting endo-therapy accessories. Extending the endo-therapy accessory from the distal end could cause eye injury.

- 1. Insert the endo-therapy accessory through the biopsy valve.
- **2.** Confirm that the endo-therapy accessory extends smoothly from the distal end.

Inspection of the water feeding function

- **1.** Insert a syringe filled with sterile water into the biopsy valve and depress the plunger.
- 2. Confirm that water is emitted from the distal end.

NOTE

- For proper operation, the syringe must be inserted fully and held perpendicular to the biopsy valve. Angled or incomplete insertion may result in fluid leakage from the biopsy valve.
- Do not depress the suction valve during water feeding. If the suction valve is depressed during water feeding, water will be aspirated into the suction tube instead of being emitted from the endoscope's distal end.
- If fluid is not emitted from the endoscope's distal end, flush air through the channel.

Inspection of the insertion into the flexible trocar

WARNING

Confirm that the endoscope can be smoothly inserted into and withdrawn from any trocar that can be used for endoscopes and/or for accessories. Do not use a trocar that does not allow smooth insertion and withdrawal of the endoscope. Use of such a trocar may result in the bending section being damaged and detached.

CAUTION

- Straighten the bending section of the endoscope before inserting or withdrawing the endoscope into/from the flexible trocar. Damage to the bending section may result.
- Do not angulate the bending section of the endoscope while it is inside the flexible trocar. Damage to the bending section may result.

Insert the endoscope into the trocar tube after withdrawing the obturator from the trocar tube (see Figure 3.11).



Figure 3.11

Chapter 4 Operation

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument.

WARNING

- Anytime you suspect an abnormality in an endoscope function, stop the examination immediately and slowly remove the endoscope while viewing the endoscopic image. Using an endoscope that is not functioning properly may cause patient injury.
- If the endoscopic image on the video monitor should unexpectedly disappear or freeze during an examination, and cannot be restored, turn the EVIS video system center OFF and then ON again. If the image still does not appear, stop the examination immediately, turn the video system center OFF, and without touching the angulation control lever, carefully withdraw the endoscope from the patient.
- If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately; do not operate the angulation control lever unless absolutely necessary. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus. Forcibly withdrawing the endoscope may cause patient injury.
- Never insert or withdraw the endoscope's insertion tube while the endo-therapy accessory extends from the distal end of the endoscope. Patient injury can result.
- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During operation, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.

- If any of the following phenomena occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in section 5.2, "Withdrawal of the endoscope with an abnormality".
 - If any abnormality is suspected with the functionality of the endoscope.
 - If the endoscopic image on the video monitor disappears or freezes unexpectedly.
 - If the endoscopic image on the video monitor appears blur or fog unexpectedly.
 - If the angulation control mechanism is not functioning properly.

Continued use of the endoscope under these conditions could result in patient injury.

 If an abnormal endoscopic image/function occurs and returns to its normal condition by itself, the endoscope has malfunctioned. In this case, stop using the endoscope because the abnormality can occur again and may not return to its normal condition. Therefore, stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury can result.

4.1 Insertion of the flexible trocar

WARNING

- Never insert the flexible trocar into the thoracic cavity quickly and forcefully. Patient injury and/or equipment damage may result.
- The flexible trocar is a single-use item. Do not attempt to resterilize or reuse it. An infection control risk, tissue irritation and/or equipment damage may result.
- 1. Insert the obturator into the trocar tube.
- 2. Carefully insert the flexible trocar into the incised hole.
- **3.** After inserting the flexible trocar to the proper depth withdraw the obturator from the trocar tube while holding the trocar tube against the body,

4.2 Insertion of the endoscope

Holding and manipulating the endoscope

The control section of the endoscope is designed to be held in the left hand. The suction valve can be operated using the left index finger. The UP/DOWN angulation control lever can be operated using the left thumb (see Figure 4.1).



Figure 4.1

Insertion of the endoscope

DANGER

The endoscope cannot be applied to the heart or any area near the heart. The cardiac function of the patient can be seriously affected (ventricular fibrillation, etc.).

WARNING

Insert/withdraw the endoscope into/from the trocar slowly and deliberately after the bending section has been straightened by setting the angulation control lever back to the neutral position. View the endoscopic image during the complete process of insertion or withdrawal. The endoscope must be straightened until it is completely withdrawn from the trocar. Failure to do so may damage the bending section of the endoscope.

CAUTION

- Do not apply olive oil or products containing petroleum-based lubricants (e.g. vaseline). These products may cause stretching and deterioration of the bending section's covering.
 - Straighten the bending section of the endoscope before inserting and/or withdrawing the endoscope into/from the flexible trocar. Damage to the bending section may result.
 - Do not overly tilt an endoscope against the flexible trocar while the bending section of the endoscope is in the trocar. Damage to the bending section may result.
 - Avoid applying excessive force to the bending section of the endoscope while the scope is in the thoracic cavity. Damage to the bending section may result.

Slowly insert the endoscope into the trocar tube.
Angulation of the distal end

WARNING

Angulate the bending section of the endoscope carefully so as not to apply pressure to surrounding organs.

CAUTION

Do not angulate the bending section while it is inside the flexible trocar. Damage to the bending section may result.

Operate the angulation control lever as necessary to guide the distal end for insertion and observation.

Feeding and aspirating fluids

O Feeding fluids

CAUTION

Do not depress the suction valve while feeding fluids. Otherwise, the fluids will be aspirated into the suction pump.

Securely insert a syringe into the slit of the biopsy valve and depress the plunger.

O Aspirating fluids

WARNING

- Set the aspiration pressure of the suction pump within the range of –34 kPa to 0 kPa. Excessive aspiration pressure may make it difficult to stop suction. If the suction cannot be stopped, disconnect the suction tube from the suction connector on the suction valve and turn the suction pump OFF. While noting fluid dispersion, slowly detach the suction tube and remove all solid matter.
 - Avoid aspirating solid matter or thick fluids; channel or valve clogging can occur. If the suction valve clogs and suction cannot be turned OFF, disconnect the suction tube from the suction valve. Stop the procedure and withdraw the endoscope from the patient while viewing the endoscopic image.

CAUTION

During the procedure, make sure that the suction bottle does not fill completely or overflow. Aspirating fluids into a full bottle can damage the suction pump. Suction valve

Figure 4.2

Observation of the endoscopic image

WARNING

The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always use the minimum level of illumination, minimum time and suitable distance necessary for adequate viewing. Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.

Refer to the light source's instruction manual for information on how to adjust the brightness.

Depress the suction valve to aspirate excess fluid or other debris while observing the endoscopic image (see Figure 4.2).



4.3 Using endo-therapy accessories

For more information on combining the endoscope with particular endo-therapy accessories, refer to the "System chart" in the Appendix and the instruction manuals of the accessories.

WARNING

- In case of use of additional hand instruments take care not to damage the bending section of the endoscope.
 - If an endo-therapy accessory cannot be withdrawn from the endoscope, close the tip of the accessory or retract the tip of the accessory into its sheath and slowly withdraw the endoscope while observing the endoscopic image.

Insertion of endo-therapy accessories into the endoscope

CAUTION

Work carefully when using an open biopsy valve (MD-495); the biopsy valve may leak when uncapped.

- **1.** Refer to the "System chart" in the Appendix to determine instrument compatibility.
- 2. While holding the UP/DOWN angulation control lever stationary, slowly insert the endo-therapy accessory through the slit of the biopsy valve.

CAUTION

- If significant resistance is encountered and insertion is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting endo-therapy accessories with excessive force may damage the endoscope and/or cause patient injury.
- Confirm that the tip of the endo-therapy accessory is closed or retracted into its sheath and slowly insert the endo-therapy accessory into the biopsy valve. Do not open the tip of the endo-therapy accessory or extend the tip of the endo-therapy accessory from its sheath while inserting the endo-therapy accessory into the instrument channel. The instrument channel and/or the endo-therapy accessory may become damaged.
- **3.** Hold the endo-therapy accessory approximately 4 cm from the biopsy valve and slowly advance it into the biopsy valve using slow, short strokes.

Operation of endo-therapy accessories

Operate the endo-therapy accessory according to the directions given in its instruction manual.

Withdrawal of endo-therapy accessories

Withdraw the endo-therapy accessory slowly while the tip of the endo-therapy accessory is closed and/or retracted into its sheath.

WARNING

Do not withdraw the endo-therapy accessory if the tip is open or extended from its sheath; patient injury and/or instrument damage may occur. If the endo-therapy accessory cannot be withdrawn from the endoscope, carefully withdraw both the endoscope and the endo-therapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

High frequency cauterization

WARNING

- Do not perform electrosurgery while supplying oxygen. This may result in combustion during cauterization.
- Always confirm that the electrode section of the electrosurgical accessory is an appropriate distance away from the distal end of the endoscope. Confirm that the flexible tube at the distal tip of the electrosurgical accessory can be completely observed on the endoscopic image (see Figure 4.3). If the electrode is used when too close to the distal end of the endoscope, the endoscope and/or ancillary equipment may be damaged. Using a damaged endoscope may cause patient injury.





 Always confirm that the tissue is an appropriate distance away from the distal end of the endoscope. If electrosurgery is performed when the distal end of the endoscope contact the tissue, patient injury may occur.

CAUTION

- Set the electrosurgical unit to the minimum necessary output level. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and cause operator and/or patient burns.
- Before electrosurgery, inspect the surface of the endoscope for any dents, bulges or other irregularities.
- When performing electrosurgery, do not use the electrosurgical unit's non-contacting coagulation mode such as SPRAY coagulation mode. The endoscope may be damaged.

Prepare, inspect and connect the electrosurgical unit and electrosurgical accessories as described in their instruction manuals.

NOTE

- The external surfaces of the LTF-160 endoscopes are insulated. This allows electrosurgery to be performed.
- Some Olympus endoscopes are equipped with a feedback circuit to lead leakage current from the endoscope to the electrosurgical unit. However, the LTF-160 is not equipped with a feedback circuit, because leakage current from the electrosurgical accessory to the endoscope is minimal as the insertion tube is short. Therefore, the S-cord is unnecessary.
- The application of high frequency current may interfere with the endoscopic image. This is normal and does not indicate a malfunction.

Laser cauterization

WARNING

- Do not perform laser cauterization while supplying oxygen. This may result in combustion during cauterization.
 - To avoid patient injury and/or damage to the endoscope, never emit laser radiation before confirming that an appropriate distance between the target and the endoscope's distal end is maintained and the tip of the laser probe is in the correct position in the endoscopic image.
 - Always wear protective eyewear when performing laser cauterization treatment. Otherwise, operator injury may occur.

CAUTION

- Before inserting or withdrawing the laser probe, move the UP/DOWN angulation control lever to its neutral position so that the bending section will be straight. If it is bent, there is a danger of damaging the instrument channel.
- Allow the tip of the laser probe to cool down before withdrawing it from the channel. If the laser probe is withdrawn while hot, channel damage may occur.
- Do not use a damaged laser probe. A laser probe with a damaged sheath or distal end may cause patient injury and/or equipment damage.

Prepare, inspect and connect the laser unit and laser probe as described in their instruction manuals.

4.4 Withdrawal of the endoscope

WARNING

Withdraw the endoscope from the trocar slowly and deliberately after the bending section has been straightened by setting the angulation control lever back to the neutral position. View the endoscopic image during the complete process of insertion or withdrawal. The endoscope must be straightened until it is completely withdrawn from the trocar. If a trocar with a valve is used, keep the valve open during insertion and withdrawal. Failure to do so may damage the bending section of the endoscope.

- 1. Keep the angulation lever in the neutral position.
- 2. Withdraw the endoscope from the trocar slowly and deliberately keeping the insertion tube straight.

4.5 Withdrawal of the flexible trocar

WARNING

- After use, dispose of the flexible trocar in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.
- The flexible trocar is a single-use item. Do not attempt to resterilize or reuse it. An infection control risk, tissue irritation and/or equipment damage may result.
- 1. Remove the trocar tube from the body slowly.
- 2. Dispose of the trocar tube in an appropriate manner.

4.6 Transportation of the endoscope

Transporting within the hospital

When carrying the endoscope by hand, hold the endoscope connector together with the control section in one hand.



Figure 4.4

CAUTION

- Do not strike the distal end of the endoscope against other objects while carrying the endoscope. Damage to the distal end of the endoscope may result.
- Do not lift the endoscope while holding only the bending section of the endoscope. Damage to the bending section may result.

Transporting outside the hospital

Transport the endoscope in the carrying case.

WARNING

Always clean, disinfect or sterilize the endoscope removed from the carrying case again before use.

CAUTION

- The carrying case cannot be cleaned or disinfected. Clean and sterilize the endoscope before placing it in the carrying case. Sterilize the endoscope again before use.
- Do not attach the water-resistant cap when transporting the endoscope, to avoid damage to the endoscope caused by changes in air pressure.

Chapter 5 Troubleshooting

If the endoscope is visibly damaged, does not function as expected or is found to have irregularities during the inspection described in Chapter 3, "Preparation and Inspection", do not use the endoscope. Contact Olympus. Some problems that appear to be malfunctions may be correctable by referring to Section 5.1, "Troubleshooting guide". If the problem cannot be resolved by the described remedial action, stop using the endoscope and send it to Olympus for repair.

Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

WARNING

Never use the endoscope on a patient if an abnormality is suspected. Damage or irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.

5.1 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of consumables.

Troubles or failures due to other causes than below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair.

O Water feeding

Irregularity description	Possible cause	Solution	
Fluid is leaking from the biopsy valve.	The biopsy valve is not attached properly.	Attach it correctly as described in Section 3.4, page 21.	
	The syringe is not inserted securely.	Insert it securely.	
	The biopsy valve is damaged.	Replace it with a new biopsy valve.	
The biopsy valve cannot be attached.	The biopsy valve is damaged.	Replace it with a new biopsy valve.	

O Suction

Irregularity description	Possible cause	Solution	
Suction is absent or insufficient.	The biopsy valve is not attached properly.	Attach it correctly as described in Section 3.4, page 21.	
	The biopsy valve is damaged.	Replace it with a new biopsy valve.	
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.	
	The suction valve is damaged.	Replace it with a new suction valve, and do not use it more than six times.	
The suction valve is sticky.	The suction valve is damaged.	Replace it with a new suction valve, and do not use it more than six times.	
The suction valve does The aspiration pressure not return to its original is too high. position.		Lower the aspiration pressure.	
The suction valve cannot be attached.	An incorrect suction valve is used.	Use a correct suction valve.	
	The suction valve is damaged.	Replace it with a new suction valve.	

O Image quality or brightness

Irregularity description	Possible cause	Solution	
There is no video image.	Not all power switches are ON.	Turn all power switches ON.	
An image is not clear.	The objective lens is dirty.	Clean the objective lens with a cotton swab moistened with saline solution or sterile water.	
An image is excessively dark or bright.	The light source is not set properly.	Set the light source as described in its instruction manual.	
An image is too dark.	The endoscope is not properly connected to the light source.	Push the endoscope connector towards the light source unit it clicks into position.	

O Endo-therapy accessories

Irregularity description	Possible cause Solut	
The endo-therapy	An incompatible	Refer to the "System chart" in the
accessory does not	endo-therapy accessory	Appendix and select a compatible
pass through the	is being used.	endo-therapy accessory. Confirm
instrument channel		that the color code on the
smoothly.		endo-therapy accessory matches
		that on the endoscope.

O Other

Irregularity description	Possible cause	Solution
A remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set improperly.	Set the remote switch function correctly as described in the video system center's instruction manual.

5.2 Withdrawal of the endoscope with an abnormality

In case an abnormality occurs with the endoscope, take a proper measure according to either "When the endoscopic image appears on the monitor" or "When the endoscopic image does not appear on the monitor or the frozen image cannot be restored" below. After withdrawal, return the endoscope for repair according to Section 5.3, "Returning the endoscope for repair".

WARNING

If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus. Forcibly withdrawing the endoscope may cause patient injury.

When the endoscopic image appears on the monitor

- **1.** When equipment other than the video system center, light source, monitor and suction pump is in use, turn it OFF.
- 2. When using the endo-therapy accessory, withdraw the endo-therapy accessory slowly while the tip of the endo-therapy accessory is closed and/or retracted into its sheath.
- **3.** Aspirate accumulated air, blood, mucous or other debris by depressing the suction valve.
- 4. Carefully withdraw the endoscope while observing the endoscopic image.

When the endoscopic image does not appear on the monitor or the frozen image cannot be restored

- **1.** When equipment other than the video system center, light source and monitor is in use, turn it OFF.
- 2. Turn the video system center and light source OFF and then ON again. If the endoscopic image appears or the frozen image restored, follow the procedure of step 2. and below in "When the endoscopic image appears on the monitor" on this page.

When the endoscopic image still does not appear or the frozen image cannot be restored, perform the following steps.

3. Turn OFF the video system center, the light source and the monitor

- **4.** When using the endo-therapy accessory, withdraw the endo-therapy accessory slowly while the tip of the endo-therapy accessory is closed and/or retracted into its sheath.
- **5.** Turn the UP/DOWN angulation control lever to neutral position. Release the angulation control knobs and carefully withdraw the endoscope while observing the endoscopic image.

5.3 Returning the endoscope for repair

WARNING

Thoroughly clean and sterilize the endoscope before returning it for repair. Improperly reprocessed equipment presents an infection control risk to each person who handles the endoscope within the hospital or at Olympus.

CAUTION

Olympus is not liable for any injury or damage which occurs as a result of repairs attempted by non-Olympus personnel.

Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also include a repair purchase order.

When returning the endoscope for repair, follow the instructions given in "Transporting outside the hospital" on page 40.

Appendix

System chart

The recommended combinations of equipment and accessories that can be used with this instrument are listed below. Some items may not be available in some areas. New products released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

WARNING

If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

Appendix



Appendix



O Endo-therapy accessories

LTF-160	FB-55CR-1
Endoscope	
	BIOPSY FORCEPS Rat tooth with alligator jaws (Swinging type)

NOTE

For other ET accessories, please refer to the OLYMPUS ET catalogue.

EMC information

• Guidance and manufacturer's declaration — Electromagnetic emissions

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) 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.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11	_	
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

• Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

This instrument can be used with the high-frequency electrosurgical equipment that designated by Olympus.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 kV	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: $\pm 0.5, \pm 1 \text{ kV}$ Common mode: $\pm 0.5, \pm 1, \pm 2 \text{ kV}$ for signal input/ output lines: $\pm 2 \text{ kV}$	Differential mode: ± 0.5 , ± 1 kV Common mode: ± 0.5 , ± 1 , ± 2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$0\% U_T$ (100% dip in U_T) for 0.5 cycle/ 1 cycle - 70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage	< 5% U _T Same as left (> 95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycle 70% U _T (30% dip in U _T) for 25 cycle		Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrumer requires continued operation during pow mains interruptions, it is recommended th this instrument be powered from an uninterruptible power supply or a battery		
	dips: 0° 0% U _T (100% dip in U _T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)	< 5% U _T (> 95% dip in U _T) for 5 seconds	-			
	U_{T} is the a.c. mains voltage prior to application of the test level.					
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz, 60 Hz)	3 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current		
Conducted RF IEC 61000-4-6	3V (150 kHz – 80 MHz)	3V (V ₁) (150 kHz – 80 MHz)	Same as left	Recommended separation distance $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$		
	6V (ISM band of 150 kHz – 80 MHz)	-	Same as left	 L '1 J Where "P" is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and "d" is the recommended separation distance in meters [m]. 65 MHz – 6.795 MHz, 13.553 MHz – 13.567 		

MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz

Immunity test	IEC 60601-1-2 Immunity test (2014) test level		nunity test (2014) (2007, 2001) le		Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Radiated RF IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	3V/m (E ₁) (80 MHz – 2.5 GHz)	Same as left	Recommended separation distance $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$		
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the table of the next page.	_	Same as left	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 2.5 GHz Where "P" is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and "d" is the recommended separation distance in meters [m].		
	NOTE	 These Electric reflet Electric high 	se guidelines ma tromagnetic pro ction from struc tromagnetic inte -frequency elec pment marked v	MHz, the higher frequency range applies ay not apply in all situations. opagation is affected by absorption and stures, objects and people. erference may occur in the vicinity of trosurgical equipment and/or other with the following symbol:		
		elec	tromagnetic site	ixed RF transmitters as determined by an survey ^{a)} should be less than the each frequency range ^{b)} .		
		a)	stations for rad land mobile rad broadcast and theoretically w electromagnet transmitters, a considered. If location in whi applicable RF should be obse abnormal perfe	from fixed transmitters, such as base dio (cellular/cordless) telephones and dios, amateur radio, AM and FM radio TV broadcast cannot be predicted ith accuracy. To assess the ic environment due to fixed RF n electromagnetic site survey should be the measured field strength in the ch this model is used exceeds the compliance level above, this model erved to verify normal operation. If prmance is observed, additional / be necessary, such as re-orienting or model.		

b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Test frequency [MHz]	Band [MHz]	Modulation ^{*1}	Maximum power [W]	Immunity test level [V/m]	
385	380 – 390	Pulse modulation ^{*1} 18 Hz	1.8	27	
450	430 – 470	FM \pm 5 kHz deviation 1 kHz sine	2	28	
710		D 1 1 1		9	
745	704 – 787	Pulse modulation ^{*1}	0.2		
780		217 Hz			
810		Pulse modulation ^{*1} 18 Hz	2	28	
870	800 - 960				
930					
1720		Pulse modulation ^{*1}	2	28	
1845	1700 – 1990				
1970		217 Hz			
2450	2400 – 2570	Pulse modulation ^{*1} 217 Hz	2	28	
5240		D 1 1 1	0.2	9	
5500	5100 – 5800	Pulse modulation ^{*1} 217 Hz			
5785					

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

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the video system center, including cables specified by Olympus. Otherwise, degradation of the performance of this equipment could result.

O Guidance and manufacturer's declaration — Cables used for EMC compliance testing

Refer to the instruction manuals for each piece of equipment.

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