

DISPOSABLE HOT BIOPSY FORCEPS

FD-210U, FD-230U

EndoTherapy™

1 Symbols



Refer to instructions.



Single use only



Use by (expiration date)



Sterilized using irradiation



Sterilization lot number



Lot number



Manufacturer



Authorized representative in the European Community



Keep away from sunlight



Keep dry



Do not resterilize



Do not use if package is damaged



Not Made with Natural Rubber Latex



Temperature limitation

*For US Customers only*For a Symbols Glossary, visit us: <http://www.olympus-global.com/en/common/pdf/symbolsglossary.pdf>

2 Intended Use

This instrument has been designed to be used with Olympus endoscopes to collect tissue samples using high-frequency current under endoscopic observation. Do not use this instrument for any purpose other than its intended use.

3 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 that will be used during the procedure and use the instruments as instructed.

If you have any questions or comments about any information in this manual, contact Olympus.

4 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.

5 Signal Words

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.

6 Warnings

Follow the warnings described below when handling this instrument. This information is supplemented by the warnings and cautions described in each section.

WARNING

- When applied to a patient with a pacemaker implanted, the instrument or A-cord may cause malfunctioning or failure of the pacemaker, seriously affecting the patient. Before proceeding, always confirm that it is safe to do so with a cardiologist or the manufacturer of the pacemaker.
- When using the instrument or A-cord in the vicinity of the heart, be sure to use it with the minimum necessary output. Spark discharge during operation may affect the heart.
- When using an electrocardiograph or other physiological monitoring equipment simultaneously with the instrument or A-cord on a patient, any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrosurgical unit. Needle monitoring electrodes should not be used, as they may cause patient burns. Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.
- The electrosurgical unit should not be used adjacent to or stacked with other electrical equipment, except equipment that is intended for this purpose and tested by the manufacturer.
- Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable memory 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 equipment, or shielding the location.

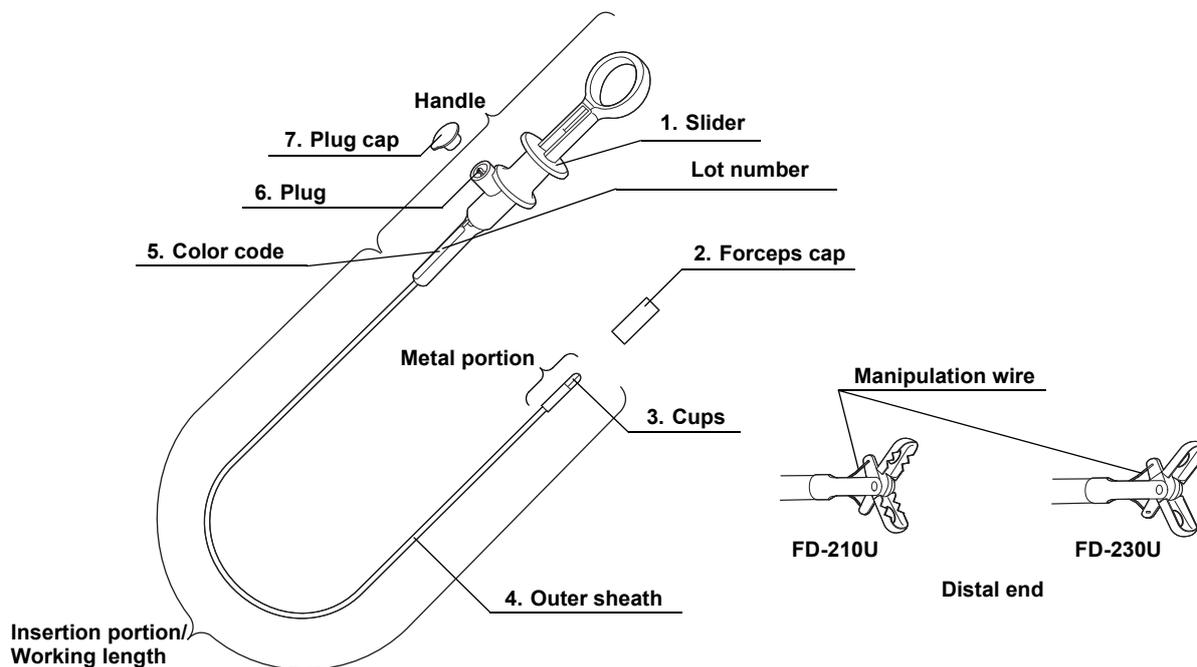


7 Nomenclature and Functions

This instrument must be used in combination with the A-cord.

Hot biopsy forceps (sterile, single use only)

The sterile instrument is sealed in a package.



1. Slider

Push the slider to open the cups. Pull to close.

2. Forceps cap

Prevents cups from becoming damaged during transportation.

3. Cups

Resect and collect tissue by applying high-frequency current.

4. Outer sheath

Isolates high-frequency current.

5. Color code

Indicates the minimum instrument channel diameter required for the endoscope to be compatible.

6. Plug

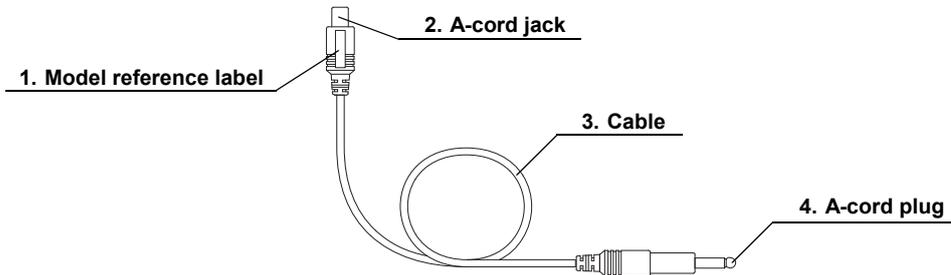
Connects to the A-cord jack.

7. Plug cap

Prevents the sterile package from becoming damaged during transportation.

A-cord (MAJ-860, MH-969, reusable, sold separately)

The A-cord is autoclavable.



1. Model reference label

Indicates the product number.

2. A-cord jack

Connects to the plug on the handle. A green reference label indicates that the A-cord is autoclavable.

3. Cable

Transmits high-frequency current to the instrument from the connected electrosurgical unit.

4. A-cord plug

Connects to the A-cord connector of the electrosurgical unit.

8 Specifications

WARNING

Use this instrument and A-cord only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient injury caused by increase in patient leakage current, operator injury, malfunction, and/or equipment damage may result.

CAUTION

Do not use this instrument and A-cord at an output higher than the rated high-frequency voltage in the following table. This could cause patient, operator, or assistant injury, such as thermal injury. It could also damage the endoscope, instrument, and/or A-cord.

NOTE

When using the UES-30 in combination with the A-cord (MH-969), the A adapter 2 (MAJ-619) is necessary.

8.1 Environment

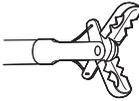
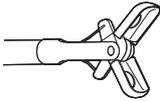
Operating environment

Ambient temperature: 10 – 40°C (50 – 104°F), Relative humidity: 30 – 85%
Atmospheric pressure: 700 – 1060 hPa (0.7 – 1.1 kgf/cm²) (10.2 – 15.4 psia)

Transportation and storage environment

Ambient temperature: -40 – +70°C (-40 – +158°F), Relative humidity: 10 – 95%
Atmospheric pressure: 700 – 1060 hPa (0.7 – 1.1 kgf/cm²) (10.2 – 15.4 psia)

8.2 Specifications

Model	FD-210U	FD-230U
Shape of the cups	Alligator jaw-step 	Oval type 
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Maximum insertion portion diameter (mm)	ø 2.45	
Working length (mm)	2300	
Fenestrated cups	Yes	
Compatible Olympus endoscopes (All of these parameters should be met.)	Length and model	Working length less than 2050 mm; GIF, SIF CF, PCF, OSF
	Channel inner diameter (mm) (Color code)	ø 2.8, ø 3.2 (Yellow); ø 3.7, ø 4.2, ø 6 (Orange)
	Other	UM series are not compatible Direction of view: 0° (Forward viewing type) only
Rated high-frequency voltage	CUT: 1600 Vp (3200 Vp-p) COAG: 2900 Vp (5800 Vp-p)	
Compatible Olympus electro-surgical unit	PSD-20, PSD-30, PSD-60, UES-20, UES-30*, ESG-100	
Compatible Olympus A-cord (sold separately)	MAJ-860 (UES-30 only), MH-969	
Total length of compatible Olympus A cord (m)	MH-969: 2, MAJ-860: 2	

*: This instrument may not be available in some areas.

Medical Devices Directive	 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II b
RoHS Directive		This device complies with the requirements of Directive 2011/65/EU concerning electrical and electronic equipment.
Degree of protection against electric shock of applied part		The degree of protection against electric shock of this instrument depends upon the electro-surgical unit it is connected to. Refer to the unit and its instruction manual.
EMC	Applied standards; IEC 60601-1-2: 2001 IEC 60601-2-2: 2006 IEC 60601-1-2: 2007 IEC 60601-2-2: 2009 IEC 60601-1-2: 2014	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class B (standby mode) This instrument complies with the EMC standard for medical electrical equipment, edition 2 (IEC 60601-1-2: 2001), edition 3 (IEC 60601-1-2: 2007), and edition 4 (IEC 60601-1-2: 2014). However, when connecting to an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.

9 Storage

WARNING

- Do not store the instrument or A-cord in a sterile package that is damaged, wet, or improperly sealed. Otherwise, the sterility of the instrument or A-cord may be compromised, which could pose an infection control risk and/or cause tissue irritation.
- Do not store the sterile packages containing the instrument or A-cord in places where they will be damaged, wet, or improperly sealed. Otherwise, the sterility of the instrument or A-cord may be compromised, which could pose an infection control risk and/or cause tissue irritation.

Store the instrument and A-cord in sterile packages at room temperature in a clean and dry environment. Do not store them in direct sunlight.

10 Preparation, Inspection, and Operation

WARNING

- When applied to a patient with a pacemaker implanted, the instrument or A-cord may cause malfunctioning or failure of the pacemaker, seriously affecting the patient. Before proceeding, always confirm that it is safe to do so with a cardiologist or the manufacturer of the pacemaker.
- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Before use, prepare and inspect the instrument, and A-cord as instructed below. Inspect other equipment to be used with the instrument and A-cord as instructed in their respective instruction manuals. Should any irregularity be observed, do not use the instrument or A-cord; contact Olympus. Damage or irregularity may compromise patient or user safety, pose an infection control risk, cause tissue irritation, perforation, bleeding, mucous membrane damage, or thermal injury and may result in more severe equipment damage.
- When inspecting or using the instrument, and A-cord, always wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing, and water proof gloves having chemical resistance and insulation. Otherwise, blood, mucus, and other potentially infectious material stuck to the instrument or A-cord could pose an infection control risk and/or cause skin irritation.
- The A-cord was not sterilized before shipment. Before using the A-cord for the first time, reprocess it according to the instructions given in Chapter 12, "Reprocessing the A-cord". Do not use an A-cord that has not been cleaned and sterilized. This poses an infection control risk and can cause tissue irritation.

CAUTION

- Do not coil the insertion portion with a diameter of less than 15 cm. This could damage the insertion portion.
- Never use excessive force to open or close the cups. This could damage the instrument.

10.1 Preparation

Spare instrument and A-cord

Always have a spare instrument and A-cord available.

10.2 Inspection

Wear appropriate personal equipment used in accordance with their respective instruction manuals.

Inspection of the sterile package

WARNING

Do not attempt to sterilize the instrument. This could pose an infection control risk, cause tissue irritation, equipment damage, or malfunction.

Inspect the sterile package for tears, inadequate sealing, or water damage. If the sterile package shows any irregularity, the sterile condition of the instrument or A-cord may have been compromised. Do not use the instrument.

Appearance inspection

○ Inspecting the instrument

1. Remove the forceps cap and plug cap from the instrument and dispose of them.
2. While operating the slider to open and close the cups, confirm that the instrument has no disconnected or loose parts.
3. Make sure the cups close evenly and are properly aligned when the slider is pulled.
4. Gently run your fingertips over the entire length of the outer sheath to check for any crushed or broken areas, excessive bends, or other damages.
5. Confirm that the distal end of the instrument appears exactly as shown in the table in Section 8.2, "Specifications" and is not damaged.
6. Make sure that there are no cracks on the handle.

○ Inspecting the A-cord

Make sure that there are no scratches or cracks on the A-cord.

Making and inspecting the connections

CAUTION

- Do not connect any equipment or inspect any connections when the electrosurgical unit is ON. This could cause operator or assistant injury, such as thermal injury.
- Do not pull the cable to unplug the A-cord plug or the A-cord jack. This could damage the A-cord.

○ Connecting the instrument to the A-cord and inspecting the connection

1. Insert the A-cord jack into the plug and confirm that it clicks into place (see Figure 1).

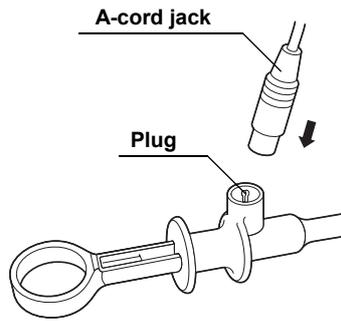


Figure 1

2. Remove the A-cord jack.

○ Connecting the A-cord to an electrosurgical unit and inspecting the connection

1. Insert the A-cord plug into the electrosurgical unit's A-cord plug connector and confirm that it clicks into place.
2. Remove the A-cord plug.

Inspection of operation

CAUTION

Do not move the slider rapidly. This could damage the instrument.

If the instrument does not operate smoothly and as intended, do not use the instrument; use a spare instead.

1. Holding the instrument as shown in Figure 2, form a loop in the insertion portion approximately 20 cm in diameter.

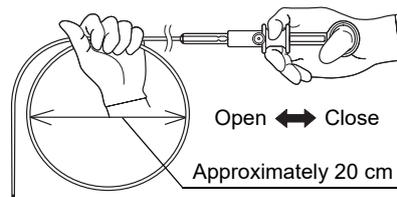


Figure 2

2. Operate the slider and confirm that the cups open and close smoothly.

Inspecting the system

No system inspection is necessary when using the UES-20, PSD-20, UES-30, PSD-30, PSD-60, or ESG-100. Prior to use connect the patient plate, S-cord, and P-cord or S-P cord as instructed in the electrosurgical unit's instruction manual.

NOTE

If there is any problem with the system when using the UES-20, PSD-20, UES-30, PSD-30, PSD-60, or ESG-100, a warning lamp lights up on the electrosurgical unit and output is shut down automatically.

10.3 Operation

WARNING

- Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view, do not use it. This could cause patient injury, such as perforation, bleeding, or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not angulate the bending section of the endoscope abruptly while the distal end of the insertion portion is extended from the distal end of the endoscope. This could cause patient injury, such as perforation, bleeding, or mucous membrane damage.
- Do not force the distal end of the insertion portion against body cavity tissue. This could cause patient injury, such as perforation, bleeding, or mucous membrane damage.
- If you use the instrument several times during one procedure, confirm that there is no irregularity with its operation and appearance, each time you use it. Do not use the instrument if you detect any irregularity. The breakage of the distal end such as the operation wire's detachment could cause mucous membrane damages.
- Do not use this instrument in combination with an endoscope which is not compatible with high-frequency current. Otherwise, this could cause patient injury, such as bleeding and/or thermal injury of tissue. It could also cause burns to the patient, operator, or assistant.

CAUTION

- When using the instrument with a two channel endoscope, never use other accessories at the same time. This could result in thermal injury to the patient, operator, or assistant.
- Do not use the instrument with an endoscope with a side viewing type or oblique viewing type forceps elevator. This could damage the instrument and/or cause burns to the patient, operator, or assistant. It could also damage the endoscope.

Attaching the patient plate

Attach the patient plate to the patient.

○ Inserting into the endoscope**WARNING**

- When inserting the instrument into the endoscope, hold the slider firmly. Otherwise, the cups may open and extend from the distal end of the endoscope abruptly. This could cause patient injury, such as perforation, bleeding, or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not force the instrument, if resistance to insertion is encountered. Reduce the angulation until the instrument passes smoothly. Forced insertion could cause patient injury, such as perforation, bleeding, or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not advance or extend the instrument abruptly. Doing so could cause patient injury, such as perforation, bleeding, or mucous membrane damage. It could also damage the endoscope and/or instrument.

CAUTION

- When inserting the instrument into the endoscope, hold it close to the biopsy valve and keep it as straight as possible relative to the biopsy valve. Otherwise, the insertion portion could be damaged.
- Insert the instrument slowly. Abrupt insertion could damage the endoscope and/or instrument.

1. Pull the slider to close the cups.
2. With the cups closed, carefully insert the instrument into the biopsy valve (see Figure 3).

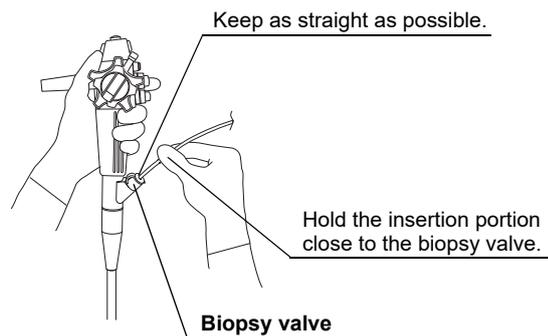


Figure 3

3. Advance the instrument until the distal end of the insertion portion appears within the endoscopic field of view.

Resection**WARNING**

- Aspirate fluids, such as mucus, that adhere to the distal end of the insertion portion and body cavity tissues. If output is activated with these fluids left attached, it could cause patient injury, such as perforation, bleeding, mucous membrane damage, or thermal injury (see Figure 4).

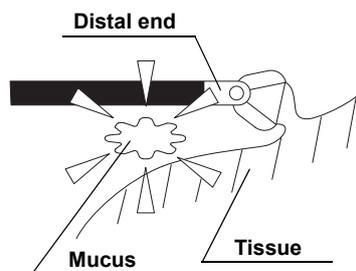


Figure 4

- Always operate the electrosurgical unit at the minimum output level and for the minimum time necessary to successfully complete the procedures. Excessive output levels or times may result in patient injury, such as perforation, bleeding, or mucous membrane damage.

WARNING

- Do not loop the A-cord or bundle it with cables from other medical equipment (electrocardiograph, endoscopic video system, electrosurgical unit, etc.). High-frequency signals and spark discharge noise during cauterization may cause malfunctions in the other medical equipment that could have an adverse effect on the patient. Another possibility is that output from the electrosurgical unit will be abnormal and patient injury, such as perforation, bleeding, or mucous membrane damage.
- Make sure electricity is supplied to the instrument when resecting tissue. Resecting without electricity could cause patient injury, such as bleeding or mucous membrane damage.
- When applying the current, do not use an excessive amount of conduction. Doing so could cause patient injury such as perforations and/or bleeding. When necessary, provide treatments to prevent perforations or bleeding from occurring after the procedure. Ensure that postoperative follow-ups are performed, and confirm that no abnormalities are found in the patient.

CAUTION

- Do not use this instrument and the A-cord at an output higher than the high-frequency voltage given in the table in Section 8.2, "Specifications" on page 4. This could cause patient, operator, or assistant injury, such as thermal injury. It could also damage the endoscope, instrument and/or the A-cord.
- Do not connect any equipment when the electrosurgical unit is ON. Doing so could cause operator or assistant injury, such as thermal injury.
- When flatus is present in the intestines, replace it with a non-flammable gas (CO₂, for example). Flatus may ignite or explode and cause thermal injury.
- To avoid burning healthy tissue, do not activate output if the metal portion at the distal end of the insertion portion is in contact with non-target tissue (see Figure 5).

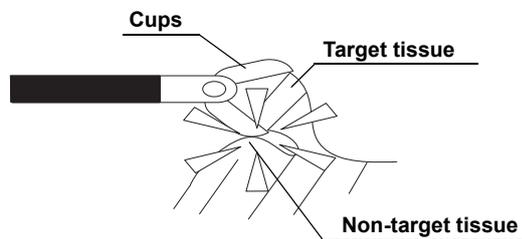


Figure 5

- Do not activate output when the distal end of the endoscope is too close to or in contact with body cavity tissue. This could cause patient injury, such as thermal injury and damage the endoscope.
- Do not activate output when the distal end of the endoscope is too close to or in contact with the metal portion at the distal end of the forceps insertion portion. This could cause patient injury, such as perforation, bleeding, or mucous membrane damage (see Figure 6).

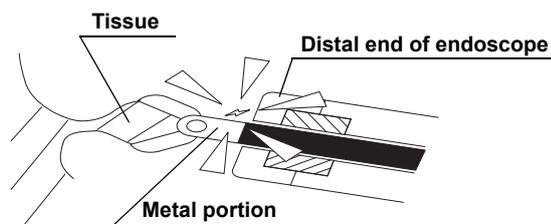


Figure 6

- Do not activate output if any of the patient's skin surfaces are touching each other (a bare arm and the side of the chest, for example). This could burn the patient.
- Do not activate output if the patient's clothes are wet. This could burn the patient.
- Do not activate output when the patient is in contact with metal parts of the operating table or other units. This could burn the patient, operator, or assistant.
- Do not touch the A-cord or allow it to touch anyone when output is activated. This could burn the patient, operator, or assistant.
- Do not pull the cable to unplug the A-cord plug or the A-cord jack. This could damage the A-cord.

If output cannot be activated when the instrument is combined with the UES-20, PSD-20, UES-30, PSD-30, PSD-60, or ESG-100, inspect the electrosurgical unit as described in its instruction manual.

1. Insert the A-cord plug into the electrosurgical unit's A-cord plug connector until it clicks.
2. Plug the A-cord jack into the handle's plug until it clicks.
3. Insert the instrument until you can see the entire metal portion at the end of the insertion portion in the endoscopic field of view.
4. To grasp the target tissue, angulate the insertion portion of the endoscope or advance the instrument until it reaches the target site.

5. Push the slider to open the cups.
6. Press the open cups against the target tissue.
7. Pull the slider to grasp the tissue.
8. Switch the electrosurgical unit ON.
9. Press the foot switch to activate output and perform the resection.
10. Switch the electrosurgical unit OFF.
11. Remove the A-cord plug from the electrosurgical unit's A-cord plug connector.
12. Remove the A-cord jack from the handle.

○ **Withdrawing the instruments from the endoscope**

WARNING

- Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucus, or other patient debris and pose an infection control risk.
- Do not withdraw the hot biopsy forceps while the endoscope is angulated. The hot biopsy forceps' manipulation wire could become detached from the cup. A part of manipulation wire could be damaged and detached to fall of into the patient's body or the wire may stick out and damage the endoscope and/or cause bleeding or damage the mucous membrane.
- If the manipulation wire becomes detached from the cups, immediately stop using the instrument. With the wire detached, you may feel little or no resistance to moving the slider, and your impression of the manipulation of the instrument may differ significantly from what is actually taking place. If you notice any major changes in manipulation, check whether or not the wire has become detached from the cups.
- If the manipulation wire becomes detached while the biopsy forceps are inserted in the endoscope, first move the slider in the proximal direction in order that the cups may come as close to the distal end of the endoscope as possible. Then withdraw the biopsy forceps and the endoscope together from the patient's body with extreme care to avoid causing patient injury. At the same time, make sure that no part of the manipulation wire has fallen into the patient's body.

CAUTION

Do not withdraw the instrument from the endoscope while the cups are open. This could damage the endoscope and/or instrument.

Withdraw the instrument from the endoscope.

11 Disposal

WARNING

- After use, dispose of the instrument in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.
- The instrument is a single use, disposable item. Do not reuse or attempt to sterilize it. Reusing the instrument could pose an infection control risk, cause tissue irritation or malfunction.

After using the instrument, dispose of it in an appropriate manner.

12 Reprocessing the A-cord

WARNING

- The A-cord was not sterilized before shipment. Before using the A-cord for the first time, reprocess it according to the instructions given in this chapter. Do not use an A-cord that has not been cleaned and sterilized. Doing so could pose an infection control risk and/or cause tissue irritation.
- Failure to properly clean and sterilize the A-cord after each examination can compromise patient safety.
- If the A-cord is not cleaned meticulously, effective sterilization cannot be obtained. Clean the A-cord thoroughly before sterilization to remove microorganisms or organic material that can limit the effectiveness of the sterilization process.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, always wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective clothing before leaving the reprocessing area.
- The reprocessing procedures described in this manual should be completed the same day the A-cord has been used. If reprocessing is delayed, residual organic debris will solidify, and it may be difficult to effectively reprocess the A-cord.

Olympus EndoTherapy accessories are compatible with 2.0% – 3.2% glutaraldehyde solutions. However, routine biological monitoring is not feasible with glutaraldehyde and, therefore, it should not be used to sterilize reusable medical devices that are compatible with other methods of sterilization that can be biologically monitored, such as steam sterilization.

12.1 Required reprocessing equipment

To perform proper reprocessing, the equipment in the following table are required. For details on preparation and directions for use of the following equipment, refer to the respective instruction manuals or contact the equipment manufacturer.

Contact Olympus for the names of specific brands of detergent solutions.

1. Wear personal protective equipment as specified in the table on page 10.
2. Prepare the following equipment. The required amount of detergent solution and other equipment depends on the number of A-cords to be reprocessed.
3. Fill a basin with detergent solution at the temperature and concentration recommended by the detergent manufacturer. Also fill the ultrasonic cleaner with a detergent solution appropriate for ultrasonic cleaning.

Equipment needed

Protective equipment	Appropriate personal protective equipment may include: eye wear, face mask, moisture-resistant clothing, and chemical-resistant gloves.
Immersion basin for detergent solution	Use a basin with a depth and diameter large enough to allow complete immersion of the A-cord.
Detergent solution for immersion	Use a neutral pH, low-foaming, medical grade detergent solution.
Ultrasonic cleaner	Use a medical grade ultrasonic cleaner with a frequency range of 38 – 47 kHz.
Detergent solution for ultrasonic cleaning	Use a neutral pH, low-foaming, medical grade detergent solution with no abrasive.
Lint-free cloths	
Packages for steam sterilization	Use packages compatible with steam sterilization (autoclaving).
Sealing device for packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.
Autoclave	Use an autoclave that will operate at the conditions specified in Section 12.3, "Sterilization".

12.2 Cleaning

WARNING

When cleaning, avoid exposure to the reprocessing chemicals. They may pose an infection control risk and/or cause skin irritation.

Immersion

WARNING

Immerse the A-cord in detergent solution immediately after use. If the A-cord is not cleaned immediately, it may be difficult to effectively reprocess, and this could result in reduced performance.

1. Immerse the entire A-cord in the detergent solution for the time specified in manufacturer's instructions. If no time is specified, immerse for between 5 minutes and 3 hours.
2. Remove the A-cord from the detergent solution.

Ultrasonic cleaning

1. Immerse the entire A-cord in the detergent solution. Clean it ultrasonically for 30 minutes. For details on operation of the ultrasonic cleaner, refer to the instruction manual for the ultrasonic cleaner.
2. Remove the A-cord from the detergent solution.

Rinsing

CAUTION

- After ultrasonic cleaning, rinse the A-cord thoroughly to remove residual detergent. Residual detergent solution could cause tissue irritation in the next patient.
- Do not forcefully squeeze, wipe, or scrub the A-cord. This could cause damage to the A-cord or result in reduced performance.

1. Rinse the A-cord under clean running tap water.
2. Confirm that no debris is left on the surfaces of the A-cord.
3. Wipe the exterior of the A-cord with a clean, dry lint-free cloth, and allow it to air-dry.

12.3 Sterilization

Sealing the package

1. Before sterilization, the A-cord must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
2. Coil the A-cord and place it in the package, seal the package. For details on sealing, refer to the instruction manuals for the package, and the sealing device.

Steam sterilization (autoclaving)

WARNING

- Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.
 - Always leave space between the packages in the autoclave. If the packages are placed too close together, effective sterilization will not be possible.
 - Allow the packages to dry within the autoclave using the autoclave's drying cycle (if applicable) or by opening the door of the autoclave and allowing the packages to air-dry. Handling a wet package can compromise its sterility.
1. Place the sealed packages containing the A-cord in the autoclave and sterilize in accordance with the conditions listed in Table 1 on page 11. For details on operation of the autoclave, refer to the instruction manual for the autoclave or other manufacturer instructions.
 2. After steam sterilization, let the A-cord gradually cool down to room temperature. Sudden changes in temperature may damage the A-cord.

NOTE

Autoclavable products have a green reference label.

Process	Temperature	Exposure time
Prevacuum	132 – 134°C (270 – 274°F)	5 minutes

Table 1 Recommended steam sterilization (autoclaving) conditions

13 EMC information

○ Guidance and manufacturer's declaration — Electromagnetic emissions

This instrument is intended for use by medical personnel in hospitals and for use in the electromagnetic environment specified below. The customer or the user of this instrument 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 functions. 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	Not Apply	This instrument does not have AC power input.
Harmonic emissions IEC 61000-3-2	Same as above	Same as above
Voltage fluctuations/flicker emissions IEC 61000-3-3	Same as above	Same as above

WARNING

The use of accessories that are not approved by the manufacturer may result in an increase of electromagnetic emissions and the compliance with the stipulated limit values are not guaranteed anymore.

○ Guidance and manufacturer's declaration — Electromagnetic immunity (IEC 60601-1-2: 2014)

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

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.

Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: $\pm 2, \pm 4, \pm 8, \pm 15$ 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	Not apply	This instrument does not have AC power input.
Surge IEC 61000-4-5	Differential mode: $\pm 0.5, \pm 1$ kV Common mode: $\pm 0.5, \pm 1, \pm 2$ kV	Same as above	Same as above
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 <hr/> 70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/30 cycle (60 Hz) Phase angle causing voltage dips: 0° <hr/> 0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/300 cycle (60 Hz)	Same as above	Same as above
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.
Definition	U_T is the a.c. mains voltage prior to application of the test level.		

Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz - 80 MHz)	Same as left	Refer to the guidance in the left column.
	6V (ISM band of 150 kHz - 80 MHz) <hr/> ISM (industry, science, and medical care) band of 6.765 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	Same as left	Refer to the guidance in the left column.
Radiated RF IEC 61000-4-3	3 V/m (80 MHz - 2.7 GHz)	Same as left	Refer to the guidance in the left column.
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the next table.	Same as left	Refer to the guidance in the left column.

Test frequency [MHz]	Band* ¹ [MHz]	Modulation* ²	Maximum power [W]	Immunity test level [V/m]
385	380 - 390	Pulse modulation* ² 18 Hz	1.8	27
450	430 - 470	FM* ³ ±5 kHz deviation 1 kHz sine	2	28
710				
745	704 - 787	Pulse modulation* ² 217 Hz	0.2	9
780				
810				
870	800 - 960	Pulse modulation* ² 18 Hz	2	28
930				
1720				
1845	1700 - 1990	Pulse modulation* ² 217 Hz	2	28
1970				
2450	2400 - 2570	Pulse modulation* ² 217 Hz	2	28
5240				
5500	5100 - 5800	Pulse modulation* ² 217 Hz	0.2	9
5785				

*1 For some services, only the uplink frequencies are included.

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

*3 As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

○ Guidance and manufacturer's declaration — Electromagnetic immunity (IEC 60601-1-2: 2007, 2001)

This instrument is intended for use in the electromagnetic environment specified below. The customer or the user of this instrument should assure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of this instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601-1-2 (2007, 2001) test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	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	Not apply	This instrument does not have AC power input.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as above	Same as above
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 seconds	Same as above	Same as above
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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.
Definition	U_T is the a.c. mains voltage prior to application of the test level.		

Immunity test	IEC 60601-1-2 (2007, 2001) test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz - 80 MHz)	3 V (V_1)	Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m (80 MHz - 2.5 GHz)	3 V/m (E_1)	Recommended separation distance $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz - 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz - 2.5 GHz
Definition	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

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



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

○ Recommended separation distances between portable and mobile RF communications equipment and this instrument (IEC 60601-1-2: 2007, 2001)

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

Rated maximum output power of transmitter P(W)	Separation distance according to frequency of transmitter (m) (Calculated as $V_1=3$ and $E_1=3$)		
	150 kHz - 80 MHz $d = 1,2 \sqrt{P}$	80 MHz - 800 MHz $d = 1,2 \sqrt{P}$	800 MHz - 2.5 GHz $d = 2,3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
Others	For transmitters rated at a maximum output power not listed above, the recommended separation distance "d" in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where "p" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		

NOTE

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

Manufactured by



OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Fax: (042)646-2429 Telephone: (042)642-2111

OLYMPUS AMERICA INC.

3500 Corporate Parkway, P.O. Box 610, Center Valley, PA 18034-0610, U.S.A.
Fax: (484)896-7128 Telephone: (484)896-5000

OLYMPUS KOREA CO., LTD.

Olympus-Tower, 114-9 Samsong-Dong, Gangnam-Gu, Seoul 135-090 Korea
Fax: (02)6255-3494 Telephone: (02)6255-3210

OLYMPUS SINGAPORE PTE LTD

491B, River Valley Road #12-01/04, Valley Point Office Tower, Singapore 248373
Fax: 6834-2438 Telephone: 6834-0010

Distributed by



OLYMPUS EUROPA SE & CO. KG

(Premises/Goods delivery) Wendenstrasse 14-18, 20097 Hamburg, Germany
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany
Fax: (040)23773-4656 Telephone: (040)23773-0

OLYMPUS LATIN AMERICA, INC.

5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332

OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.

A&F, Ping An International Financial Center, No. 1-3, Xinyuan South Road,
Chaoyang District, Beijing, 100027 P.R.C.
Fax: (86)10-5976-1299 Telephone: (86)10-5819-9000

OLYMPUS AUSTRALIA PTY LTD

3 Acacia Place, Notting Hill, VIC 3168, Australia
Fax: (03)9543-1350 Telephone: (03)9265-5400

KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.

KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY

117071, Moscow, Malaya Kaluzhskaya 19, bld. 1, fl.2, Russia
Fax: (095)958-2277 Telephone: (095)958-2245