

OLYMPUS

INSTRUCTIONS FOR USE

HF CABLE



A00010A	A0393
A00011A	A60000C
A00012A	A60001C
A0335.1	A60002C
A0355	A60003C
A0357	O0120.1
A0358	WA00013A
A0391	WA00014A
A0392	

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1 Using this document

This chapter provides a general information on how to use these instructions for use.



1.1 User instructions

Before use, thoroughly read these instructions for use and the instructions for use of all other products that will be used during the procedure.

If the required instructions for use are missing, immediately contact an Olympus representative.

Keep the instructions for use in a safe, accessible location.

1.2 Conventions throughout this document

Convention	Explanation
	This is the safety alert symbol. It is used to alert the user to potential physical injury hazards. Observe all safety messages that follow this symbol to avoid possible injury.
	This symbol indicates additional helpful information.
<ol style="list-style-type: none"> 1. 2. 3. 	A numeration indicates a sequence of actions.
<ul style="list-style-type: none"> ● 	Bullet points indicate individual actions.
<ul style="list-style-type: none"> – – – 	Dashes indicate the listing of data, options or objects.
<ol style="list-style-type: none"> 1) 2) 3) 	Numbers with right parenthesis name elements in illustrations.

1.3 Safety-related information in this document

For safe and efficient use of this product it is important to read the complete instructions for use. The safety related information of these instructions for use is not only described in this chapter. All information and instructions in this document are to ensure a safe and efficient use.

Safety information are described in 3 categories:

- General safety notes
- Specific safety notes
- Safety messages

1.3.1 General safety notes

General safety notes are located at the beginning of the instructions for use. They address safety issues that apply to the general use and handling of the product.

1.3.2 Specific safety notes

Specific safety notes are located at the beginning of a chapter or section. They address safety issues that are specific to the information and actions described in the chapter or section.

1.3.3 Safety messages

Safety messages focus on unexpected incidents that can occur during the intended use. They are placed in the context of such risks and actions. The safety messages are highlighted by a signal word.

WARNING

Indicates a potentially hazardous situation which, if not avoided, can result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, can result in minor or moderate injury.

NOTICE

Indicates a property damage message.

1.4 Trademarks

- STERRAD®
- NX™
- V-PRO®

are trademarks of their respective owner.

2 Safety information

This chapter provides general safety information for using the product. The safety information includes:

- Intended purpose
- Manufacturer information
- General safety notes

2.1 Intended purpose

2.1.1 Intended use and indications

A00010A, A00011A, A00012A, A0335.1, A0355, A0357, A0358, A0391, A0392, A0393, A60000C, A60001C, A60002C, A60003C, O0120.1, WA00013A, WA00014A

HF cables for electrosurgical use in laparoscopic, endoscopic, and open surgery in combination with compatible active accessories and compatible electrosurgical generators.

2.1.2 Contraindications

There are no known contraindications.

The intended use and contraindications of the equipment used in combination with the HF cable or adapter must be observed.

2.1.3 Patient target group

Not dedicated to any specific patient population.

2.1.4 Intended user

Medical use

Only for use by a qualified physician or medical personnel under the supervision of a physician.

Only for use in an adequate medical environment.

These instructions for use do not explain or discuss clinical procedures.

Reprocessing

Reprocessing of reusable products may only be performed by qualified hygiene personnel.

2.1.5 Clinical benefits

The device is used as part of a system. The clinical benefit of the device lies in its functionality as described by its intended purpose.

2.2 Contact

2.2.1 Manufacturer



Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Country-specific information

Refer to the contact information for customers included in the scope of delivery for country-specific information.

2.2.2 Incident reporting

European Union

If a serious incident occurs with the device, report it to the manufacturer and the relevant national authority.

Eurasian Economic Union

If an undesirable event occurs with the device, report it to the manufacturer or the authorized representative.

Other regions

If a serious incident occurs with the device, report it to the manufacturer and/or the relevant national authority according to national legislation.

2.3 General safety notes

The following safety information addresses points that apply to the general handling and use of the product. This information is to be supplemented by the information given in each chapter of this document.

Repair and product modifications

Unauthorized repairs and product modification can cause injury to the patient and the user. Repairs may only be performed by qualified servicing personnel that has been authorized by Olympus. Refer to the section “Repair” on page 51 for more details.

Spare equipment

Malfunctions of the product can delay the procedure. To avoid any delays, always have spare equipment available.



WARNING

Risk of injury to the patient and the user

An insufficient understanding of the dangers, warnings, cautions, and instructions can result in serious injury and damage to the product.

- Make sure to have the complete set of instructions for use.
- Before use, thoroughly read these instructions for use and the instructions for use of all other products that will be used during the procedure.
- In case of conflicting information, follow the dangers, warnings, cautions, and instructions in this document.

**WARNING****Risk of injury to the patient and the user**

The use of damaged equipment, equipment that does not function properly and equipment with illegible or missing markings can cause infection, toxic shock, electrical, mechanical and thermal injury and unintended nerve stimulation.

- Before each use, observe the instructions in the section “Inspection” on page 23.
- Do not use a damaged product or a product with improper functioning.
- Replace a damaged product or a product with improper functioning.

**WARNING****Risk of injury to the patient**

Improperly assembled equipment can cause infection, electrical, mechanical and thermal injury and unintended nerve stimulation.

- Observe the assembly instructions in these instructions for use and the instructions for use of all other products that will be used during the procedure.

**CAUTION****Risk of injury to the patient and the user**

Using incompatible equipment can lead to injury of the patient and the user as well as damage to the product.

- For information on compatible equipment, refer to the chapter “Compatible equipment” on page 54.

3 Product description

This chapter provides a general overview of the product and its functions. This includes the following information:

- Scope of delivery
- Product functions
- Operating elements
- Explanation of symbols
- Warranty information

The product is delivered in unsterile condition. Reprocess the product before first and each subsequent use.

3.1 Scope of delivery

Before use, check that all items listed below are available. Contact an Olympus representative or an authorized service center if any items are missing or damaged.

Contents

- 1 HF cable
- Instructions for use
- Contact information for customers

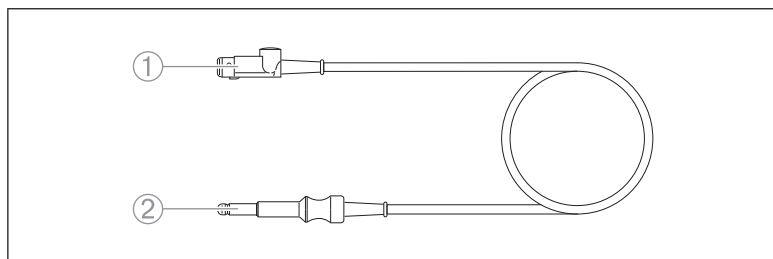
3.2 Product functions

The HF cable connects the electrosurgical generator to the instrument or HF-resection electrode for the application of HF current during laparoscopic, endoscopic procedures and open surgery.

3.3 Operating elements

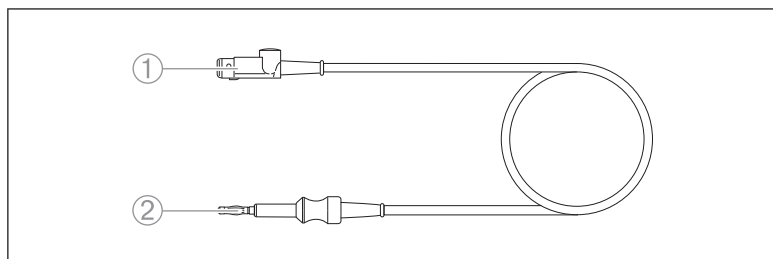
This section shows all operating elements of the product and gives a brief description of the purpose of these elements.

A00010A



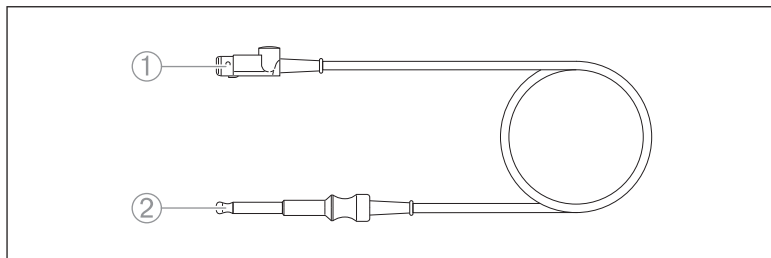
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A00011A



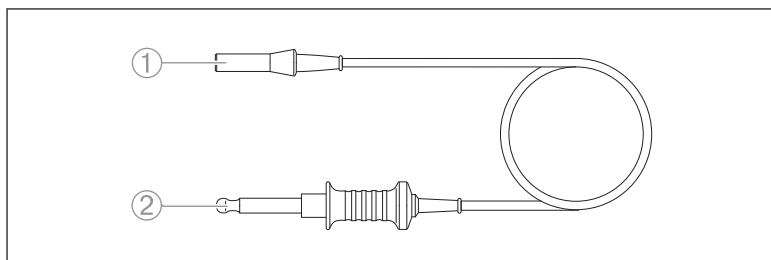
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A00012A



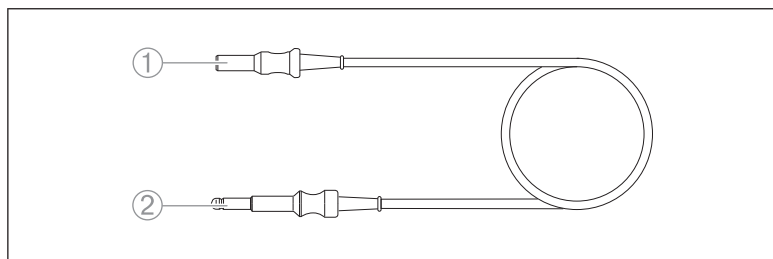
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0335.1



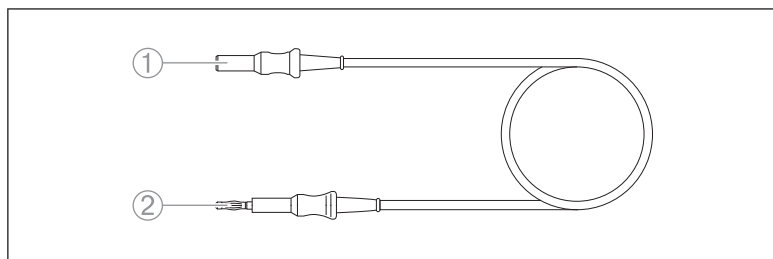
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0355



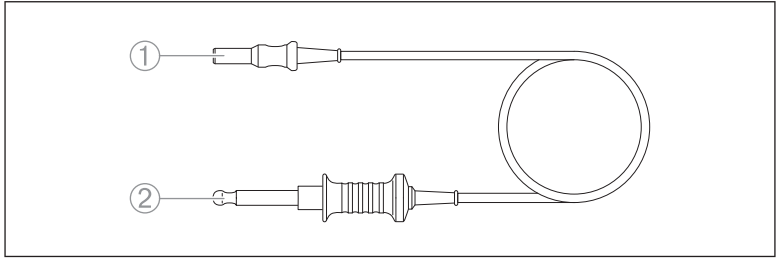
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0357



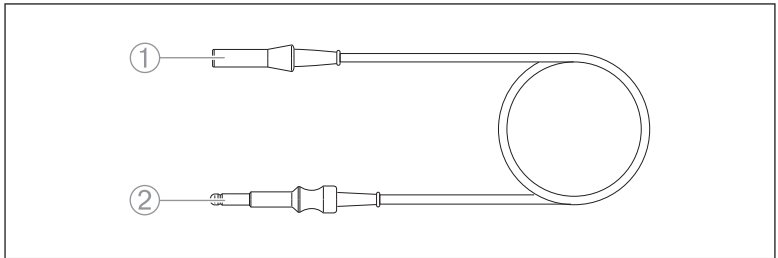
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0358



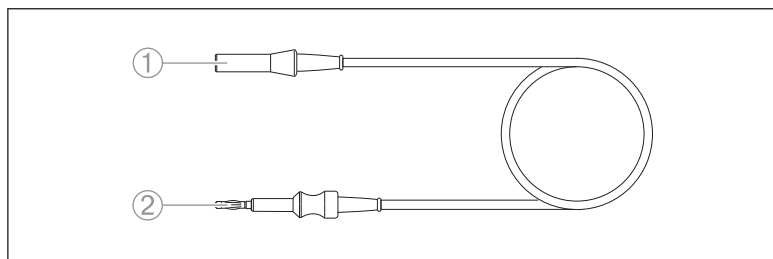
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0391



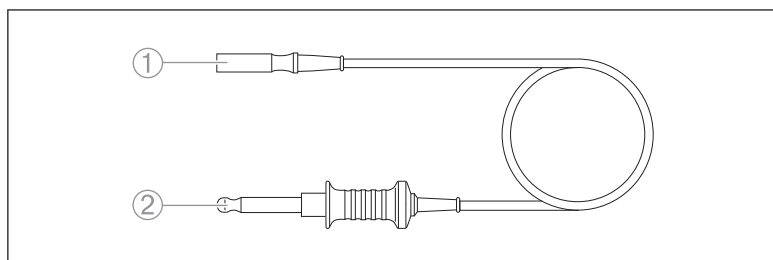
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0392



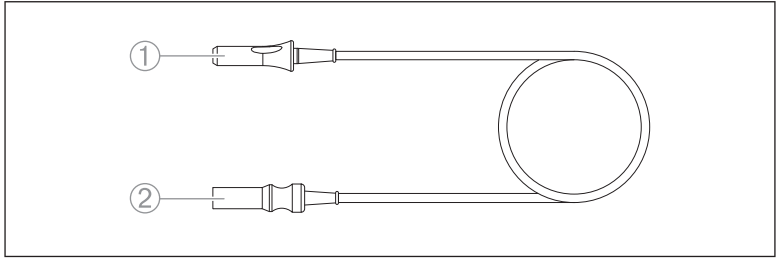
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A0393



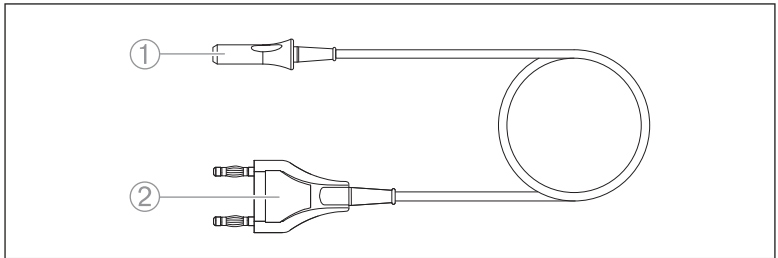
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A6000C



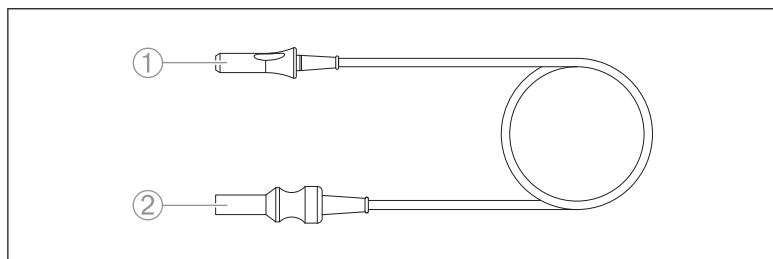
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A60001C



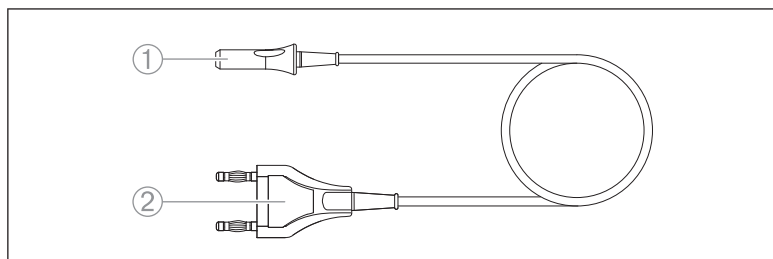
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A60002C



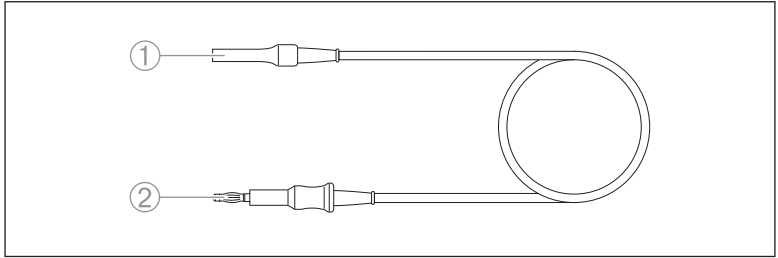
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

A60003C



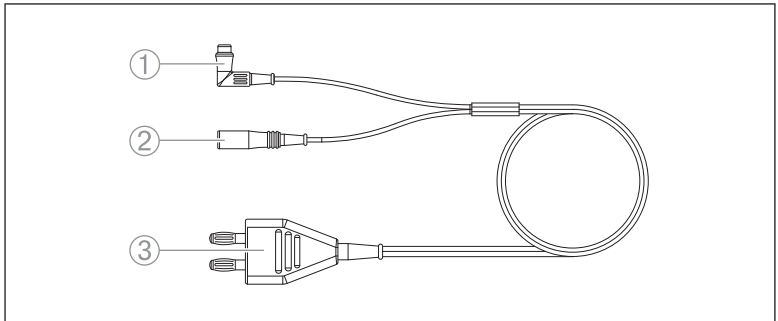
- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

O0120.1

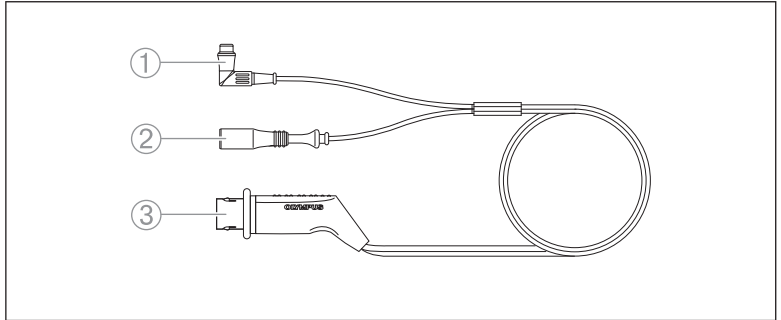


- 1) Plug (female)
For instrument
- 2) Plug (male)
For electrosurgical generator

WA00013A









- 1) Right angle plug
For working element
- 2) Straight plug
For working element
- 3) Plug (male)
For electrosurgical generator

WA00014A













- 1) Right angle plug
For working element
- 2) Straight plug
For working element
- 3) Plug (male)
For electrosurgical generator

3.4 Symbols

This section gives an explanation for each symbol used on the product and on the packaging of the product.

Symbol	Explanation
	Consult instructions for use
	Caution, consult accompanying documents
	Medical device
	Unique device identifier
	Batch code
	Quantity

Product description

Symbol	Explanation
	Catalog number
	CE marking indicating that the device is in conformity with the applicable requirements set out in applicable European Union harmonization legislation
	Manufacturer Date of manufacture
	Keep away from sunlight and from heat
	Temperature limit
	Humidity limit
	In accordance with European Directive on Waste Electrical and Electronic Equipment (WEEE), this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately
	General symbol for recovery/recyclable
	Green Dot-symbol for dual recycling system
	Transport conditions
	Storage conditions
	Duration of use in months

3.5 Warranty

Any warranty claims towards Olympus are forfeited if the user or unauthorized persons attempt repair or modification of the product. No warranty is provided for any damage due to misuse of the product.

4 Before use

This chapter describes all necessary steps to prepare the product for each use.

**WARNING****Risk of injury to the patient and the medical personnel**

Improper or incomplete reprocessing can cause infection of the patient and medical personnel as well as damage to the product.

- Reprocess the product before first and each subsequent use.
- For reprocessing the product, observe the instructions in this document
- Do not use a product that has not been reprocessed.
- Before each use, inspect the product as described in the section "Inspection" on page 23.

**WARNING****Risk of injury to the patient**

There is a risk of electric shock if the HF cable is connected to mains electricity.

- Do not connect the HF cable to a mains socket.

**CAUTION****Risk of injury to the patient and the user**

Using the HF cable after the restricted service life may cause electrical, mechanical and thermal injury. Signs of wear might not become visible.

- Do not use the HF cable after 12 months of use.
- Dispose of the HF cable after 12 months

4.1 Inspection

Before connecting the product to the ancillary equipment, a thorough inspection ensures that the product is fit for use. A damaged product can cause an electric shock, mechanical injury, infection and thermal injury.

Checking for mechanical defects

1. Check that the product has:
 - no dents, cracks, kinks, or deformations
 - no deep scratches
 - no corrosion
 - no missing or loose parts
 - no cuts and other defects on the insulation
2. Check all markings on the product for clear visibility.

Checking for performed reprocessing

1. Make sure that the product has been properly reprocessed.
2. Visually inspect the product thoroughly. The product must be visually clean.
3. Only use the product if it is visually clean. Reprocess the product again if necessary.

Replace if necessary

If the instrument is damaged or does not function properly, replace it. Contact an authorized service center for repair.

4.2 Attaching the neutral electrode

This section applies only to the following products:

A00010A, A00011A, A00012A, A0335.1, A0355, A0357, A0358, A0391, A0392, A0393, O0120.1

- Refer to the instructions for use of the electrosurgical generator and the neutral electrode.
- Attach the neutral electrode to the patient.
- Connect the neutral electrode to the electrosurgical generator.

4.3 Connecting the HF cable (not for WA00014A)

**CAUTION****Risk of injury to the patient and the user**

Accidentally disconnecting the HF cable can cause sparkover leading to electrical injury, thermal injury or unintended nerve stimulation.

- Check that the HF cable is securely connected to the instrument and the electrosurgical generator.

NOTICE**Risk of damage to the product**

Connecting the HF cable to the wrong socket of the electrosurgical generator can damage the HF cable and the electrosurgical generator.

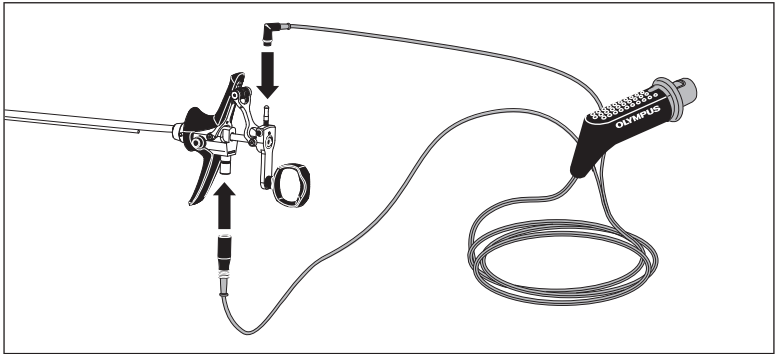
- Make sure to connect the HF cable to correct and intended socket on the electrosurgical generator.
1. Connect the HF cable to the compatible instrument.
 2. Connect the HF cable to the compatible electrosurgical generator.
Refer to the instructions for use of the electrosurgical generator and the instrument.

4.4 Connecting the HF cable (only for WA00014A)

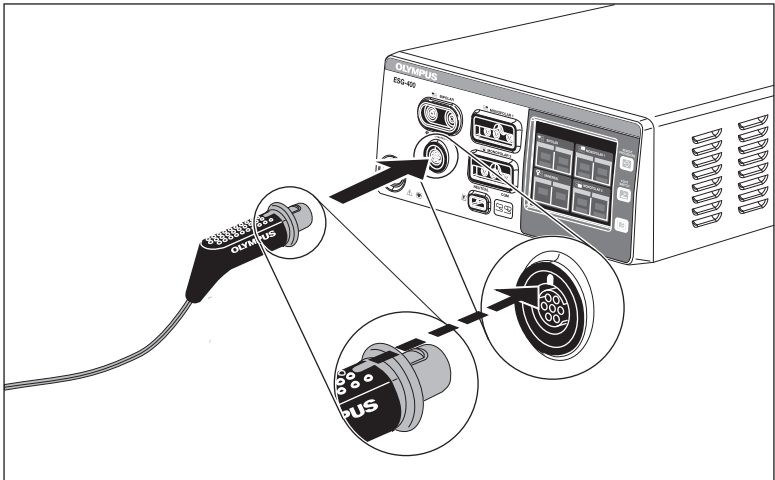
**CAUTION****Risk of injury to the patient and the user**

Accidentally disconnecting the HF cable can cause sparkover leading to electrical injury, thermal injury or unintended nerve stimulation.

- Check that the HF cable is securely connected to the instrument and the electrosurgical generator.



1. Connect the right angle plug of the HF cable to the respective HF connector of the working element.
2. Connect the straight connector of the HF cable to the respective HF connector of the working element.



3. Hold the plug so that the knobbed surface faces up and the angled part faces down.

4. Insert the plug into the socket "Universal" of the electrosurgical generator.
Make sure that the markings on the plug and the socket are aligned.

5 Use

This chapter describes the following:

- Safety information for use
- Information on how to use the product

5.1 Safety notes for use



CAUTION

Risk of injury to the patient

Contact between the HF cable and the patient can cause leakage current.

- Prevent contact between the HF cable and the patient when HF current is activated.



CAUTION

Risk of injury to the patient

The rated accessory voltage of the TURis/TCRis resectoscope and the bipolar hand instruments is limited. There is a risk of sparkover leading to electrical injury, thermal injury and unintended nerve stimulation.

- Use a maximum output voltage of 1000 V_p.
- For the maximum output voltage, refer to the instructions for use of the electro-surgical generator.



CAUTION

Risk of injury to the patient

The rated accessory voltage of the monopolar resectoscope and the monopolar hand instruments is limited. There is a risk of sparkover leading to electrical injury, thermal injury and unintended nerve stimulation.

- Use a maximum output voltage of 2000 V_p.
- For the maximum output voltage, refer to the instructions for use of the electro-surgical generator.

**CAUTION****Risk of injury to the patient and user**

There is a risk of sparkover leading to electrical injury, thermal injury and unintended nerve stimulation.

- The maximum output voltage of the electrosurgical generator must not exceed the lowest maximum rated voltage of any of the HF equipment used during the procedure.
- Check the maximum rated voltage of the HF cable and of the other HF equipment.

**CAUTION****Using physiological monitoring equipment**

Current can flow to the monitoring electrodes and can cause thermal injury where the monitoring electrodes are attached. Especially, the use of needle electrodes can result in burns to the patient.

- Place the physiological monitoring electrodes as far away as possible from the electrodes of the HF instrument.
- Do not use needle monitoring electrodes.
- Use physiological monitoring equipment with HF current limiting measures.

**CAUTION****Risk of injury to the patient**

For patients with implanted electronic devices, e.g. pacemakers or defibrillators, confirm its safety with a cardiologist or the manufacturer of the implanted electronic device before the procedure.

- Be aware that the connected HF instruments extend the BF or CF applied part of the electrosurgical generator.

**CAUTION****Risk of injury to the patient**

Unintended current flow can cause injury to the patient

- The patient must be insulated against all electrically conductive parts. Check that the patient does not come in contact with other metal parts (e.g., operating table) in any case.
- Ground the operating table.

- Place the patient on a dry, electrically insulating surface.
- Prevent any contact between different skin surfaces (arms, legs) of the patient. Place dry gauze between the body and arms and between the legs to prevent such contact.
- Prevent any skin contact between the patient and the user.



CAUTION

Risk of injury to the patient

Laying the HF cable in loops can lead to mechanical injury.

- To prevent tripping hazards, do not lay the HF cable in loops.
- Use only plastic clips, hook fasteners and loop fasteners to fix HF cables to surgical drapes.

NOTICE

Risk of damage to the product

Coiling the HF cable can damage the product.

- Do not coil the HF cable into a circle of less than 10 cm (4 inch) in diameter.

NOTICE

Electromagnetic interference

Using this cable with other medical devices can result in higher emission levels or reduced interference immunity.

- Only use compatible equipment and accessories.
- Observe the information regarding electromagnetic compatibility in the instructions for use of the compatible electro-surgical generator.

5.2 Using the product

Automatic presettings

When using the HF cable WA00014A, the electro-surgical generator automatically recognizes the HF-resection electrode and automatically applies appropriate presettings.

Instrument name: <Saline>

– Mode: <SalineCut> or <PlasmaCut>

- Power 200 W
- Effect 2
- Mode: <SalineCoag>
 - Power 120 W
 - Effect 2
- Check that the correct setting <Saline> appears on the display.
- If the correct setting is not displayed, disconnect the plug and try again.
- Do not pull on the cable to disconnect the plug. Always pull on the plug to avoid arcing.



The presettings may not produce optimum results for all tissue types and procedures. If necessary, adjust the settings to the procedure and the required tissue effect.

Duration of activation

Do not exceed the maximum time of activation. For the specific maximum activation time, refer to the instructions for use of the compatible instruments.

6 After use

This chapter describes all necessary steps to treat the product after each use.

This section provides the following:

- Disassembly instructions
- The necessary steps to prepare the product for reprocessing at the point of use

6.1 Disassembly

1. Switch off the electrosurgical generator.
2. Disconnect the HF cable.
Do not pull on the cable to disconnect the plug. Always pull on the plug to avoid arcing.

6.2 Preparation for reprocessing at the point of use

This section describes all necessary steps to prepare the product for reprocessing at the point of use. These steps need to be performed immediately after use.

Preparation at the point of use

1. Remove patient debris from the product immediately after use by wiping with a single-use, lint-free cloth.
Make sure that patient debris does not dry on the product.
2. Contain the product to avoid any environmental or personnel contamination.

Transport to the reprocessing area

- Transport the product directly to the reprocessing area.
Do not leave used products overnight before reprocessing.



The product can be transported to the reprocessing area in either dry or wet condition. If the product is transported in wet condition, make sure that the detergents or disinfectants do not cause protein fixation.

7 General information for reprocessing

This chapter gives a general overview of the reprocessing cycle and the compatible reprocessing methods for the product. The product is delivered in unsterile condition. Reprocess the product before first and each subsequent use.



WARNING

Risk of injury to the patient and the medical personnel

Improper or incomplete reprocessing can cause infection of the patient and medical personnel as well as damage to the product.

- Reprocess the product before first and each subsequent use.
- Reprocess the product according to the instructions in this chapter.
- Only use reprocessing methods which have been validated for the product.
- Only use detergents which have been validated for the product.
- Avoid any protein fixation prior to or during cleaning caused by the reprocessing process.



WARNING

Risk of injury to the user

Patient debris and reprocessing chemicals are hazardous. There is a risk of infection or skin irritation when they come into contact with exposed skin.

- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material in accordance with the applicable local guidelines.

7.1 Overview of the reprocessing cycle

This overview describes a complete reprocessing cycle. Users can select a validated reprocessing method for every phase of the reprocessing cycle.

Following the reprocessing process is important because improper and incomplete reprocessing can cause infections and can damage the product.

The following sections of these instructions for use include detailed information on every validated reprocessing method.

Preparation for reprocessing at the point of use

Refer to section "Preparation for reprocessing at the point of use" on page 32.



Select manual cleaning or automated cleaning method.



Manual cleaning

(Only for A0335.1, A0357, A0358, A0393, A60000C, A60001C, A60002C, A60003C, O0120.1, WA00013A, WA00014A).

Refer to section "Manual cleaning" on page 40.



Manual disinfection

(Only for A0335.1, A0357, A0358, A0393, A60000C, A60001C, A60002C, A60003C, O0120.1, WA00013A, WA00014A).

Refer to section "Manual disinfection" on page 42.

Automated cleaning and thermal disinfection

Refer to section "Automated cleaning and thermal disinfection" on page 43.



Inspection

Refer to section "Inspection" on page 46.



Steam sterilization

Refer to section "Steam sterilization" on page 48.



Storage for next use

Olympus recommends automated cleaning

Automated cleaning methods reduce infection risks for the reprocessing personnel. They also provide standardized and validated procedures.

Olympus recommends steam sterilization

Olympus recommends to use steam sterilization for the product.

7.2 Validated reprocessing methods

In accordance with ISO 17664, the following table provides an overview over the reprocessing methods that are validated for the microbiological efficacy of the product.

- ++ Method validated for microbiological efficacy and verified for material compatibility.
- Method incompatible
- * Only for “Preparation for automated cleaning”
- # Not tested

Phase	Method		Compatibility Only for A0335.1, A0357, A0358, A0393, A60000C, A60001C, A60002C, A60003C, O0120.1, WA00013A, WA00014A	Compatibility Only for A00010A, A00011A, A00012A, A0355, A0391, A0392			
Cleaning and disinfection	Preparation	Selection according to the reprocessing method					
	Cleaning	Manual	Ultrasonic	–	–		
			Alkaline detergent	#	#		
			Acidic detergent	#	#		
			Neutral detergent	++	#		
		Automated	Alkaline detergent	++	++		
			Acidic detergent	#	#		
			Neutral detergent	*	*		
	Rinsing			++	++		
	Disinfection	Manual			++	–	
Automated		Chemical	#	–			
		Thermal	++	++			
Sterilization	Steam	Autoclave (prevacuum)			++	++	
	Hydrogen peroxide plasma	Sterrad 100S				–	–
		Sterrad NX				–	–
		Sterrad 100NX				–	–
	Vaporized hydrogen peroxide	Steris V-PRO 1				–	–
		Steris V-PRO 1 Plus				–	–
		Steris V-PRO maX				–	–
		Steris V-PRO 60				–	–

Detailed instructions on the individual reprocessing methods are located in the following chapters of these instructions for use.

8 Cleaning and disinfection

This chapter describes all necessary steps for cleaning and disinfection of the product. This is a prerequisite for the subsequent sterilization steps.

8.1 Safety notes for cleaning and disinfection

Compatible detergents and disinfectants

Cleaning and disinfection avoid infections of patients and the medical personnel. Refer to the cleaning and the disinfection instructions for detergent and disinfectant information. Use compatible detergents and disinfectants to prevent damage to the product.

Personal protective equipment

Patient debris and reprocessing chemicals are hazardous. If these substances come into contact with exposed skin, they can cause infections or irritate the skin. Personal protective equipment can reduce these hazards.

To protect yourself against hazardous chemicals and infectious material, wear personal protective equipment like:

- Eye wear
- Face mask
- Moisture-resistant clothing
- Chemical-resistant gloves. Gloves must fit properly so that no skin is exposed.

Residues of detergents and disinfectants

Detergents and disinfectants can contain aggressive compounds. If residues of the compounds are left on the product after cleaning or disinfection, the residues can damage the product.

8.2 Manual cleaning

Cleaning removes patient debris from the product. For manual cleaning, start by selecting compatible cleaning brushes and detergents.



Manual cleaning is not possible for the monopolar HF cables A00010A, A00011A, A00012A, A0355, A0391, A0392.

Only use automated cleaning and thermal disinfection for these products. Refer to the section “Automated cleaning and thermal disinfection” on page 43.

8.2.1 Compatible cleaning brushes

General requirements for all cleaning brushes

- Brushes must be intended for cleaning of medical devices.
- Brushes must not have metal bristles or any other types of bristles that can scratch and damage the product.

Surface brushes

Select a surface brush according to the following characteristics:

- Surface brushes are for outer surfaces only.
- Brushes must meet all general requirements for cleaning brushes as specified above.

8.2.2 Validated detergent

Olympus has validated manual cleaning of the product with the following detergent:

- Neodisher MediZym 0.5% manufactured by Chemische Fabrik Dr. Weigert GmbH und Co. KG
- 20 minutes immersion time at 45 °C (113 °F)

The instructions in this chapter are based on the validated detergent as specified above.

If other detergents are used, select immersion times, concentrations and temperatures of the solutions as instructed by the manufacturer of the detergent.

8.2.3 Manually cleaning the product

A complete manual cleaning cycle consists of 3 steps:

- Cleaning
- Rinsing
- Drying

Specific instructions for these steps are given on the following pages.

Cleaning

1. Create a detergent solution as instructed by the manufacturer of the detergent.
2. Completely immerse the HF cable in the detergent solution for 20 minutes.
Make sure that there are no air bubbles on the HF cable while immersed.
3. Thoroughly brush every gap at least 10 times with a surface brush.
4. Using a syringe, thoroughly rinse the HF cable and every gap at least 10 times with 10 ml of detergent solution.

Rinsing

1. Select a rinsing device (e.g. a cleaning pistol).
The rinsing device must be suitable for cleaning medical devices and deliver a minimum pressure of 1 bar (14.5 psi).
2. Connect the rinsing device to a supply of deionized water. Do not use tap water for rinsing because it can be chlorinated.
3. Thoroughly rinse the HF cable with deionized water for at least 30 seconds using the rinsing device.

Drying

1. Let the HF cable dry at room temperature.
To support drying, use a clean lint-free cloth or filtered compressed air.

2. Check that no residual rinse water remains on the HF cable.

8.3 Manual disinfection

Clean the product before disinfection to remove patient debris. Otherwise, disinfection will be insufficient. Refer to the section “Manual cleaning” on page 40 for detailed cleaning instructions.



Manual disinfection is not possible for the monopolar HF cables A00010A, A00011A, A00012A, A0355, A0391, A0392.

Only use automated cleaning and thermal disinfection for these products. Refer to the section “Automated cleaning and thermal disinfection” on page 43.

8.3.1 Validated disinfectant

Olympus has validated manual disinfection of the product with the following disinfectant:

- Cidex Activated Dialdehyde solution manufactured by Johnson & Johnson
- 45 minutes immersion time at 25 °C (77 °F)

The instructions in this chapter are based on the validated disinfectant as specified above.

If other disinfectants are used, select immersion times, concentrations and temperatures of the solutions as instructed by the manufacturer of the disinfectant.

8.3.2 Manually disinfecting the product

A complete manual disinfection cycle consists of 3 steps:

- Disinfection
- Rinsing
- Drying

Specific instructions for these steps are given on the following pages.

Disinfection

1. Create a disinfectant solution as instructed by the manufacturer of the disinfectant.
2. Completely immerse the HF cable in the disinfectant for 45 minutes.
Make sure that there are no air bubbles on the products while immersed.
3. Remove the HF cable from the disinfectant.

Rinsing

1. Completely immerse the HF cable in 8 liters of sterile deionized water for at least 1 minute.
2. Rinse all lumens with at least 100 ml of sterile deionized water.
3. Repeat steps 1 and 2 twice for a total of 3 rinses. Always use fresh portions of sterile deionized water for each rinse.

Drying

1. Dry the product using a clean lint-free cloth or filtered compressed air for at least 10 seconds until the HF cable is visually dry.
2. Check that no residual rinse water remains on the products.

8.4 Automated cleaning and thermal disinfection

Automated cleaning and thermal disinfection removes patient debris from the product. This is a prerequisite for the subsequent sterilization steps.

Use only washer-disinfectors with thermal disinfection programs in accordance with ISO 15883 for automated cleaning and thermal disinfection of the product.

For automated cleaning and thermal disinfection, place the product placed in compatible instrument baskets made from stainless steel wire mesh. The instrument baskets must be suitable for cleaning.

Do not use instrument trays made from plastic material for automated cleaning. They are designed for sterilization only.



WARNING

Risk of injury to the patient and the user

Manual precleaning is required for automated cleaning of the product. Without the manual precleaning, reprocessing will be insufficient and can cause infections.

- Reprocess the product according to the instructions in these instructions for use.

8.4.1 Validated detergents

Olympus has validated automated cleaning of the product with the following detergent and neutralizer:

Detergent for manual precleaning

- Neodisher MediZym manufactured by Chemische Fabrik Dr. Weigert GmbH und Co. KG
- 0.5% solution
- 5 minutes immersion time at 45 °C (113 °F)
- pH value: approx. 7.6

Detergent for automated cleaning

- Neodisher MediClean forte manufactured by Chemische Fabrik Dr. Weigert GmbH und Co. KG
 - 0.2% solution
 - pH value: approx. 10.4

Neutralizer

- Neodisher Z manufactured by Chemische Fabrik Dr. Weigert GmbH und Co. KG
 - 0.1% solution
 - pH value: approx. 2.6

8.4.2 Automatically cleaning and disinfecting the product

A complete automated cleaning and thermal disinfection cycle consists of 4 mandatory steps:

- Precleaning
- Preparing for automated cleaning
- Selecting programs for the washer-disinfector
- Removing the product from the washer-disinfector

Specific instructions for these steps are given on the following pages.

Precleaning:

1. Create a detergent solution as instructed by the manufacturer of the detergent.
2. Completely immerse the HF cable in the detergent solution for 5 minutes.
Make sure that there are no air bubbles on the HF cable while immersed.
3. Select a rinsing device (e.g. a cleaning pistol).
The rinsing device must be suitable for cleaning medical devices and deliver a minimum pressure of 1 bar (14.5 psi).
4. Connect the rinsing device to a supply of deionized water. Do not use tap water for rinsing because it can be chlorinated.
5. Thoroughly rinse the HF cable with deionized water for at least 30 seconds using the rinsing device.

Preparing

1. Select a compatible instrument basket to place the product.
2. Securely place the product in the instrument basket.
Make sure that instruments do not touch each other.
3. Place the loaded instrument basket in the washer-disinfector so that it can be properly cleaned and disinfected. Do not overload the washer-disinfector.
Refer to the instructions for use of the instrument basket and the washer-disinfector.

Selecting a program for the washer-disinfector

Select a program according with the following characteristics:

- The program must at least reach an A0 value of 3000.

- The temperature of the first water inflow must be below 25 °C (77 °F) to avoid protein fixation.
- The program does not include any sudden changes in temperature.
- The program must at least include the following steps:
 - Pre-cleaning
 - Cleaning
 - Neutralization
 - Final rinsing with deionized water

Olympus has validated automatic cleaning with the following program:

- Vario TD program
- Pre-cleaning for 4 min.
- Cleaning for 10 min. at 55 °C (131 °F)
- Neutralization for 6 min.
- Final rinsing for 3 min.

Removing from washer-disinfector

1. Remove the product from the washer-disinfector.
2. Let the product cool down at room temperature.
3. If the product is wet, dry the product.
To support drying, use a clean lint-free cloth or filtered compressed air.

8.5 Inspection

This section describes all necessary steps to make the product fit for use again:

Checking for mechanical defects

1. Check that the product has:
 - no dents, cracks, kinks, or deformations
 - no cuts and other defects on the outer sleeve of the cable
 - no scratches
 - no corrosion
 - no missing or loose parts
 - no cuts and other defects on the insulation

2. Check all markings on the product for clear visibility.

Checking for performed reprocessing

1. Make sure that the product has been properly reprocessed.
2. Visually inspect the product thoroughly. The product must be visually clean.
3. Only use the product if it is visually clean. Reprocess the product again if necessary.

Replace if necessary

If the instrument is damaged or does not function properly, replace it. Contact an authorized service center for repair.

9 Sterilization

This chapter describes all necessary steps for a complete sterilization of the product.

9.1 Safety notes for sterilization

Cleaning and disinfection before sterilization

Clean and disinfect the product before sterilization. Otherwise, sterilization will be insufficient.

Make sure that the sterilization process meets the requirements of the applicable international standards, such as ISO 17665 and ISO 14937.

Water residues from cleaning and disinfection

Water residues on the product from previous cleaning and disinfection steps can affect the sterilization process and lead to insufficient reprocessing.

The product must be completely dry before sterilization.

Steam sterilization in Olympus plastic instrument trays

Olympus plastic instrument trays are only compatible with steam sterilization. They cannot be used for any other sterilization method.

Sterilization wraps and pouches

Use only sterilization wrap and pouches that are certified for the selected sterilization method.

Consult local guidelines and hospital protocols.

9.2 Steam sterilization

This section describes all necessary steps for a complete steam sterilization of the product. A complete steam sterilization cycle consists of 3 steps:

- Preparing the product for steam sterilization
- Selecting compatible steam sterilization conditions

- Removing the product from the autoclave
- Specific instructions for these steps are given on the following pages.

9.2.1 Preparation for sterilization

1. Place the product in a compatible instrument tray.
For loading charts, refer to the instructions for use of the instrument tray.
2. Close the instrument tray.
3. Seal the instrument tray in sterilization wrap or pouches.
Consult local guidelines and hospital protocol.
4. Load the instrument tray into the autoclave.
Do not stack instrument trays. Do not load instrument trays on their side edges.

Validated sterilization accessories

Olympus has validated steam sterilization of the product with the following sterilization accessories:

- WIPAK sterilization pouches manufactured by Steriking
- H200 sterilization wrap manufactured by Halyard Health

9.2.2 Compatible steam sterilization conditions

Temperature and holding time

The products can be steam sterilized with fractionated prevacuum at:

- Temperature: 132 to 136 °C (269.6 to 276.8 °F)
- Holding time: 3 to 20 min.

Olympus has validated steam sterilization of the product with fractionated prevacuum at:

- Temperature: 132 °C (269.6 °F)
- Holding time: 3 min.

Drying time

For steam sterilization, Olympus recommends a drying time of at least 15 to 30 minutes.

- Choose a suitable drying time, depending on the autoclave.
- Refer to the instructions for use of the autoclave.

9.2.3 After sterilization

Removing from the autoclave

1. Remove the product from the autoclave.
2. Let the product cool down at room temperature.
Do not use additional cooling.
3. Check that the sterilization wraps or pouches are not damaged.
4. Resterilize the product if 1 of the following applies:
 - Sealing is open
 - Packaging is wet
 - Packaging is damaged

10 Repair, shipment and disposal

This chapter provides instructions on the following:

- How to contact Olympus for any repairs
- How to ship the product to Olympus for repair or warranty claims
- Disposal of the product

10.1 Repair

Authorized service centers

Repairs may only be performed by qualified servicing personnel that has been authorized by Olympus. Contact an Olympus representative or an authorized service center for repair and warranty information.

Otherwise, Olympus can not be held responsible for the safety, reliability, and performance of the product.

There is no repair service for this product.

Loss of warranty

Any guarantee or warranty claims are forfeited if the user or an unauthorized servicing agency attempts repair of a product.

10.2 Shipment



WARNING

Contaminated products can cause infection

Sending used and contaminated products to Olympus represents a risk of infection. Olympus is entitled to refuse soiled or contaminated products for reasons of safety.

- Reprocess the product before sending in.
If reprocessing will damage the product completely, clean the product as thoroughly as possible and mark it accordingly.

When sending products to an authorized service center for repair or warranty claims, use the original cardboard packaging for the transport of the product. If this is not possible, wrap each product individually in sufficient paper or sheets of foamed material and place them in a cardboard box. If applicable, use the respective transport protection (e.g. instrument tray) of the product.



Service centers do not accept warranty claims for damage caused by inadequate packaging.

10.3 Disposal

When disposing of the product or any of its components, follow all applicable national and local laws and guidelines. To prevent environmental contamination, reprocess the product before disposal.

11 Ordering information

Description	Catalog number
HF cable, monopolar	A00010A
HF cable, monopolar	A00011A
HF cable, monopolar	A00012A
HF cable, monopolar	A0335.1
HF cable, monopolar	A0355
HF cable, monopolar	A0357
HF cable, monopolar	A0358
HF cable, monopolar	A0391
HF cable, monopolar	A0392
HF cable, monopolar	A0393
HF cable, bipolar	A60000C
HF cable, bipolar	A60001C
HF cable, bipolar	A60002C
HF cable, bipolar	A60003C
HF cable, monopolar	O0120.1
HF cable	WA00013A
HF cable, bipolar	WA00014A

12 Compatible equipment

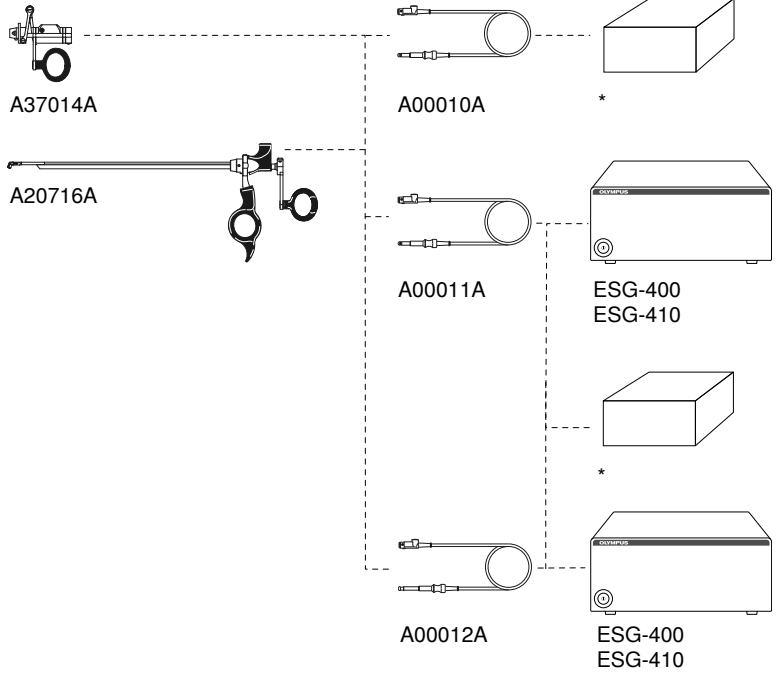
Olympus recommends the use of equipment as listed in this chapter. If combinations are used that are not listed in this chapter, the user takes the full responsibility.

Future equipment can also be compatible. For more information, contact an Olympus representative.

Some of the products listed in this chapter may not be available in all sales territories.

Before using non-Olympus electrosurgical generators, refer to the instructions for use of the electrosurgical generator and the instructions for use of the Olympus instrument.

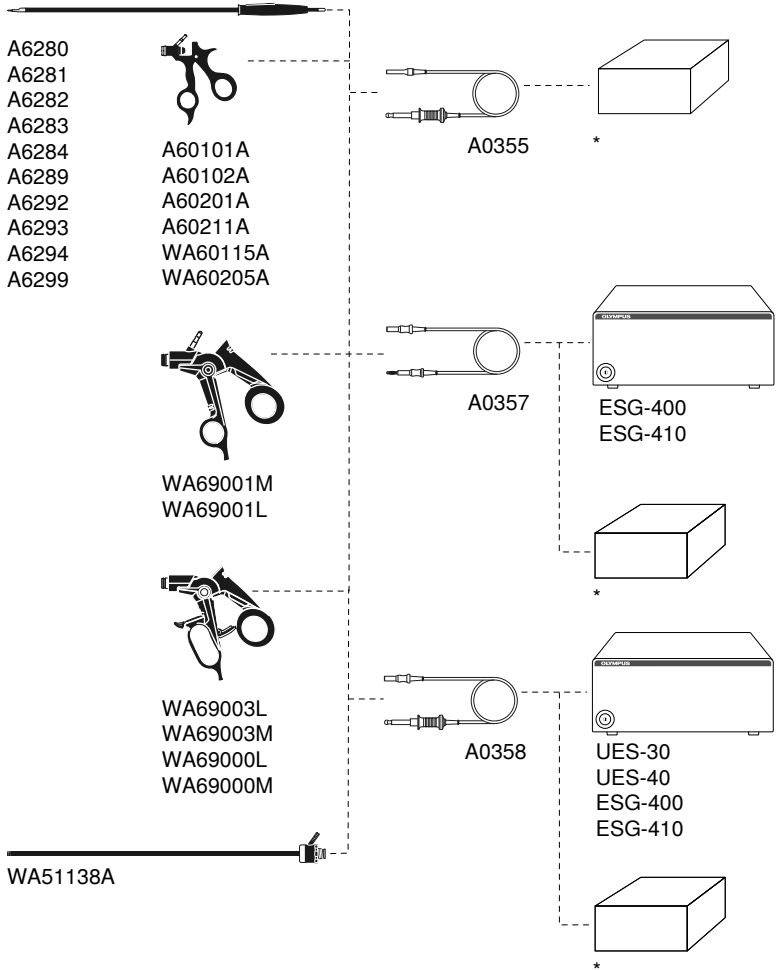
A00010A, A00011A, A00012A



* All electrocautery generators satisfying the interface requirements can be connected to the HF cable. For non-Olympus electrocautery generators, refer to the below interface requirements.

HF cable	Interface requirements for electrosurgical generators (non-Olympus)
A00010A	Pin diameter: 6 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A00011A	Pin diameter: 4 mm (spring basket)
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A00012A	Pin diameter: 8 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5

A0355, A0357, A0358

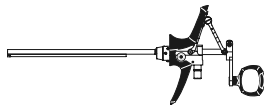


* All electro-surgical generators satisfying the interface requirements can be connected to the HF cable. For non-Olympus electro-surgical generators, refer to the below interface requirements.

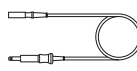
Compatible equipment

HF cable	Interface requirements for electrosurgical generators (non-Olympus)
A0355	Pin diameter: 6 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A0357	Pin diameter: 4 mm (spring basket)
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A0358	Pin diameter: 8 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5

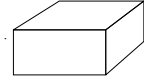
A0391, A0392, A0393



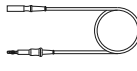
WA22066A
WA22067A



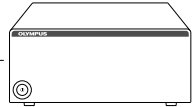
A0391



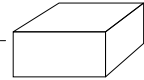
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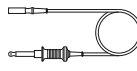
A0392



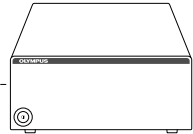
ESG-400
ESG-410



*



A0393

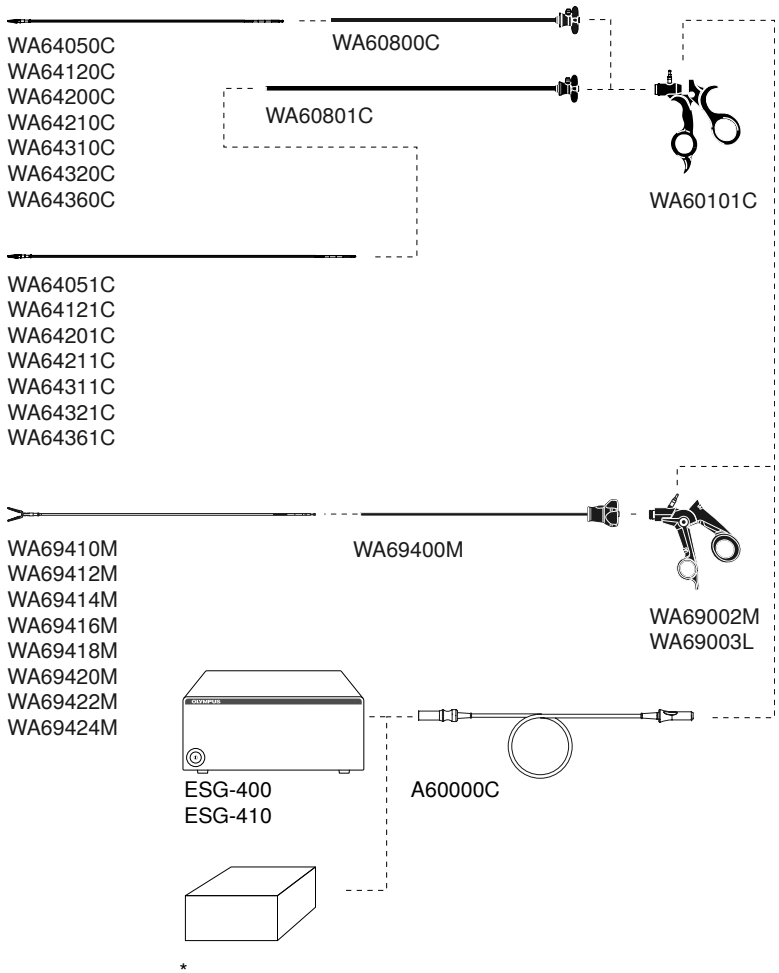


ESG-400
ESG-410

* All electrocautery generators satisfying the interface requirements can be connected to the HF cable. For non-Olympus electrocautery generators, refer to the below interface requirements.

HF cable	Interface requirements for electrosurgical generators (non-Olympus)
A0391	Pin diameter: 6 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A0392	Pin diameter: 4 mm (spring basket)
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A0393	Pin diameter: 8 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5

A6000C

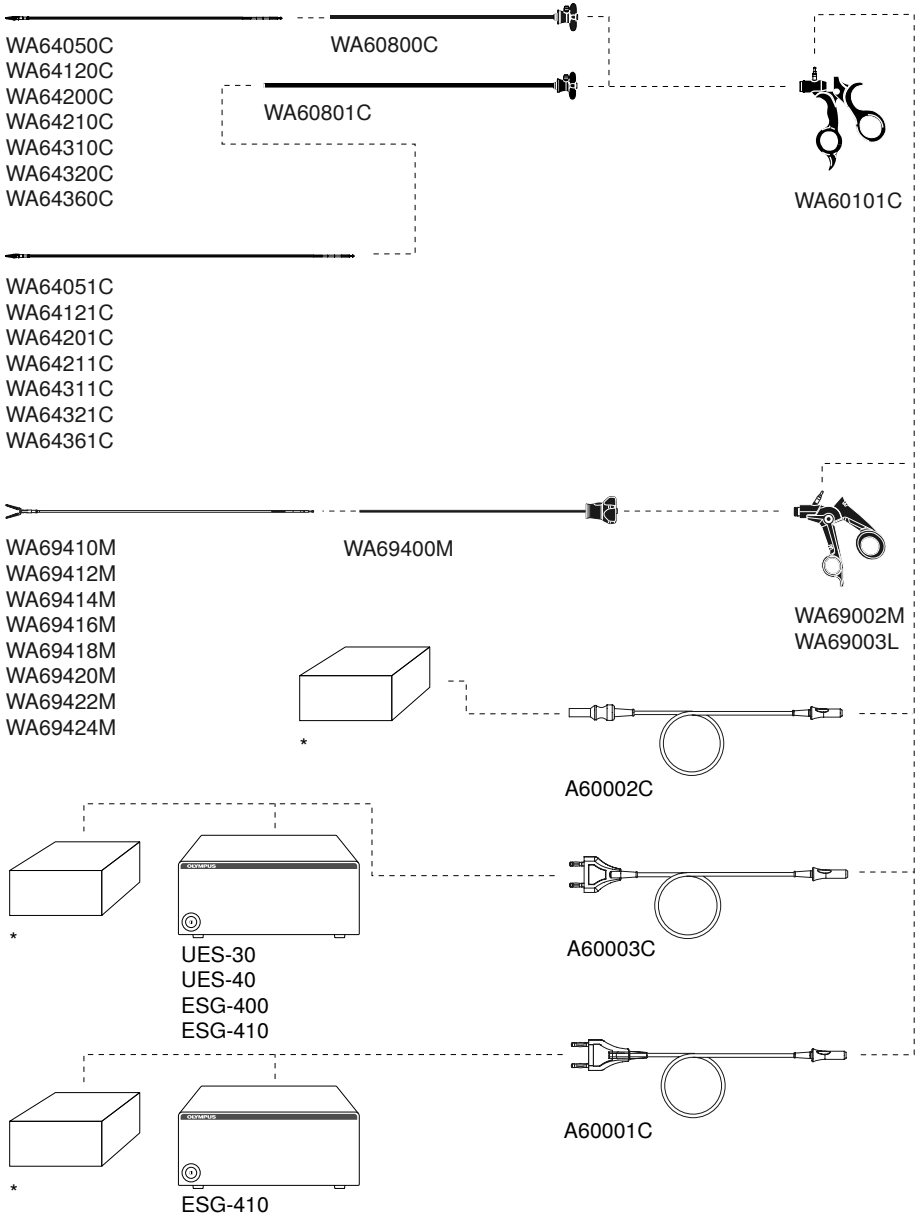


* All electrocautery generators satisfying the interface requirements can be connected to the HF cable. For non-Olympus electrocautery generators, refer to the below interface requirements.

Compatible equipment

HF cable	Interface requirements for electrosurgical generators (non-Olympus)
A60000C	Pin diameter: 4 mm (8 mm bushing)
	Maximum rated voltage: 1000 V _p
	Maximum crest factor: 2.0

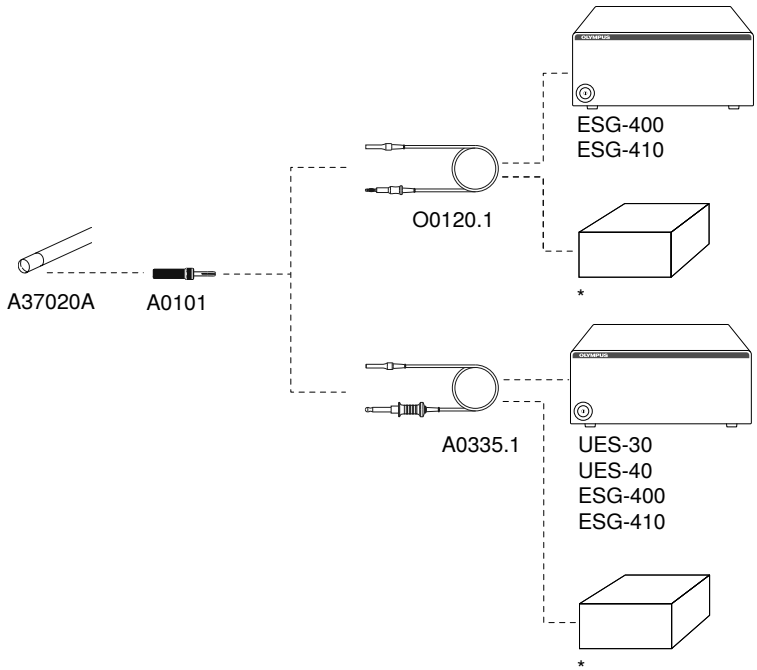
A60001C, A60002C, A60003C



* All electrosurgical generators satisfying the interface requirements can be connected to the HF cable. For non-Olympus electrosurgical generators, refer to the below interface requirements.

HF cable	Interface requirements for electrosurgical generators (non-Olympus)
A60001C	Pin diameter: 2 × 4 mm (spring basket)
	Pin spacing: 22 mm
	Maximum rated voltage: 1000 V _p
	Maximum crest factor: 2.0
A60002C	Pin diameter: 2 mm (5 mm bushing)
	Maximum rated voltage: 1000 V _p
	Maximum crest factor: 2.0
A60003C	Pin diameter: 2 × 4 mm (spring basket)
	Pin spacing: 28.6 mm
	Maximum rated voltage: 1000 V _p
	Maximum crest factor: 2.0

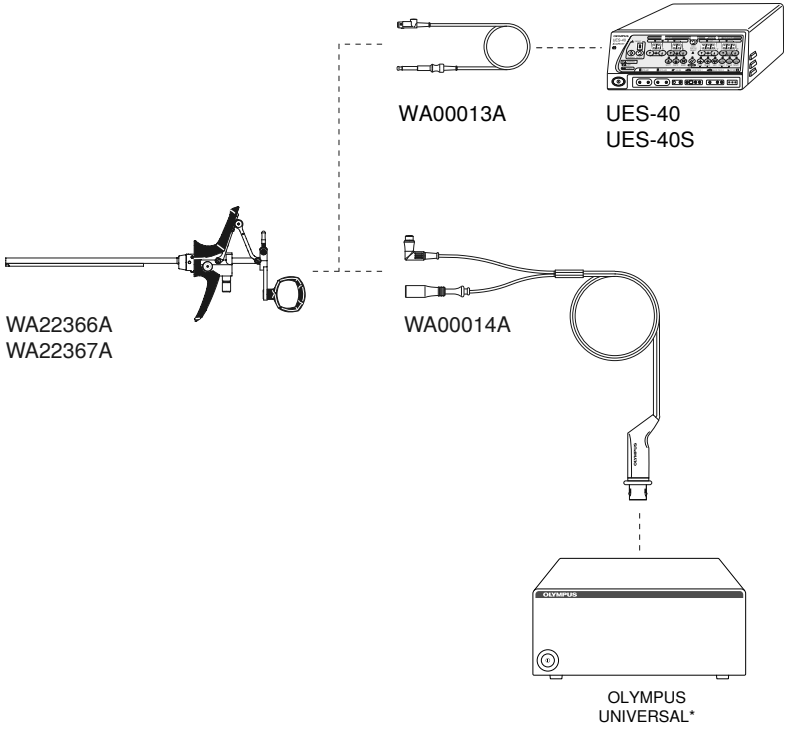
O0120.1, A0335.1



* All electro-surgical generators satisfying the interface requirements can be connected to the HF cable. For non-Olympus electro-surgical generators, refer to the below interface requirements.

HF cable	Interface requirements for electro-surgical generators (non-Olympus)
O0120.1	Pin diameter: 4 mm (spring basket)
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5
A0335.1	Pin diameter: 8 mm
	Maximum rated voltage: 2000 V _p
	Maximum crest factor: 6.5

WA00013A, WA00014A



*Olympus electrosurgical generators with a “Universal” socket

13 Technical data

This chapter provides all technical data of the product. The technical data includes information on:

- Dimensions
- Specifications
- Ambient conditions

13.1 Dimensions

Catalog number	Maximum total length	Maximum outer diameter
A00010A	4200 mm	3.2 mm
A00011A	4200 mm	3.2 mm
A00012A	4200 mm	3.2 mm
A0335.1	3600 mm	3.9 mm
A0355	3700 mm	4.0 mm
A0357	3600 mm	3.9 mm
A0358	3600 mm	3.9 mm
A0391	4200 mm	3.2 mm
A0392	4200 mm	3.2 mm
A0393	4100 mm	3.0 mm
O0120.1	3600 mm	3.9 mm
A60000C	3700 mm	4.0 mm
A60001C	3700 mm	4.0 mm
A60002C	3700 mm	4.0 mm
A60003C	3700 mm	4.0 mm
WA00013A	4200 mm	5.05 mm/2.55 mm
WA00014A	4000 mm	5.05 mm/2.55 mm

13.2 Specifications

Catalog number	Maximum rated voltage	Service life
A00010A	2000 V _p	12 months
A00011A		
A00012A		
A0335.1		
A0355		
A0357		
A0358		
A0391		
A0392		
A0393		
O0120.1		
A60000C	1000 V _p	
A60001C		
A60002C		
A60003C		
WA00013A		
WA00014A		

13.3 Ambient conditions

Operating conditions

Ambient temperature.....10 to 40 °C (50 to 104 °F)

Relative humidity30 to 85%

Storage conditions

Temperature.....10 to 40 °C (50 to 104 °F)

Relative humidity30 to 85%

Transport conditions

Temperature..... -40 to 70 °C (-40 to 158 °F)

Relative humidity10 to 95%

14 Glossary

Ancillary equipment

An equipment that supports and/or extends a device in its function.

Applied part

An applied part, according to standard IEC 60601-1, is a part of a medical electrical equipment that comes into physical contact with the patient, e.g. an HF instrument. Or, it is that part of a medical electrical equipment through which current can flow between the patient and the medical electrical equipment, e.g. the neutral electrode socket.

Autoclaving

Sterilization with saturated steam.

Crest factor

The crest factor is a waveform parameter of alternating current. It shows the ratio of peak values to the effective value. High crest factors indicate peaks. To give a reliable statement on the effect that the height of a crest factor has, it is necessary to distinguish if a cutting mode or a coagulation mode is used. For cutting modes it can be said, that the higher the crest factor is, the higher is the thermal effect on the tissue (incl. coagulation depth). For coagulation modes it can be said, that the higher the crest factor is, the stronger is the formation of sparks. This can be unwanted, as the risk of tissue carbonization rises with sparks. However, strong sparks can also be desired, e.g. for the SprayCoag mode, where very strong sparks are used for contact free, superficial coagulation.)

Deionized water

Water without anions and cations of salts. Also called demineralized water (DI water or DM water).

Detergent

A chemical mixture containing surfactants with cleansing properties in dilute solutions. Detergents remove residues on surfaces.

Electrosurgical generator

Medical device supplying high-frequency alternate current for electrosurgical applications.

HF surgery

Application of high-frequency (HF) alternate current for cutting, denaturation or vaporization of tissue.

Neutralizer

A chemical substance that is used for the rinsing phase of automated cleaning and disinfection to neutralize the microbicidal effect of detergent or disinfectant residues.

Qualified service personnel

Personnel certified or approved by Olympus to perform certain tasks.

Radio-frequency identification

Radio-frequency identification (RFID) uses electromagnetic fields to automatically identify and track electronically stored information in devices, e.g. for use as usage counters in electrodes or for card payments at cashier terminals.

Reprocessing

Reprocessing is the process that is carried out on a used medical device in order to allow its safe reuse including cleaning, disinfection and, if applicable, sterilization and related procedures. Reprocessing also includes the testing and restoring of the technical and functional safety of the used device.

Serious incident

Any incident that directly or indirectly led, might have led or might lead to any of the following: death, temporary or permanent impairment, serious public health threats.

Thermal disinfection

Describes a process of reducing the microorganism of a material to a minimum of 10^{-5} (five log steps) by using water with high temperature above 65°C for a certain amount of time.

UDI

Abbreviation for Unique Device Identifier. The Unique Device Identifier is a label on the medical device with human- and machine-readable information, which allows to uniquely identify the device through distribution and use.

Washer-disinfector

A machine used within the procedure of decontamination that is intended to clean and disinfect a device using a detergent for cleaning and chemicals for the disinfection phase.

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