Date: 20.10.2026

Olympus reference: FY26-018-F-1 HF Cable Thermal Event During Procedure

URGENT FIELD SAFETY NOTICE

RE: Olympus HF Cables (Reusable)

Attention: Surgical, Urology, and Gynecology Departments

Material ID / Model number	Material Description	Lot Numbers	UDI-DI
A00010A	HF-cable monopolar	All	04042761029377
A00011A	HF-cable monopolar	All	04042761029438
A00012A	HF-cable monopolar	All	04042761029445
A0335.1	HF-cable monopolar	All	04042761001465
A0355	HF-cable monopolar	All	04042761001533
A0357	HF-cable monopolar	All	04042761001540
A0358	HF-cable monopolar	All	04042761001557
A0391	HF-cable monopolar	All	04042761001632
A0392	HF-cable monopolar	All	04042761001649
A0393	HF-cable monopolar	All	04042761001656
A60000C	HF-cable HiQ+ bipolar	All	04042761045285
A60001C	HF-cable HiQ+ bipolar	All	04042761045292
A60002C	HF-cable HiQ+ bipolar	All	04042761045308
A60003C	HF-cable HiQ+ bipolar	All	04042761045315
00120.1	HF cable, monopolar	All	04042761000123
WA00013A	HF-cable	All	04042761030489
WA99510A	Cable, for neutral electrode	All	04042761085892
WA47784A	Versapoint Connector Cable grey plug, non-sterile, reusable	All	04042761086233
WA47785A	Versapoint II Connector Cable black plug, non-sterile, reusable	All	04042761086240

Dear Healthcare Professional,

Olympus is issuing a Field Safety Notice for reusable HF cables; affected models are listed above. These cables are intended to connect the electrosurgical generator to the instrument or HF-resection electrodes.

Reason for Action:

Olympus received a complaint involving a thermal event with HF cable WA00014A that caused a minor burn. The investigation found the cable had been used beyond its IFU-defined service life and was not inspected before use, resulting in insulation wear, corrosion, and failure. Following a March 2026 Field Safety Notice for WA00014A, Olympus identified 19 additional models that may experience the same failure; this notice addresses those models. Olympus identified 60 complaints potentially related to thermal events involving the 19 additional HF cable models over the past four years, with no serious injuries.

Action:

Olympus is reminding customers of the following information from the HF cable IFU included in **Attachment 1**, to reduce the likelihood of cable failure and observe the following cautions and instructions:

Model Numbers	**Instructions related to service life**
A00010A, A00011A, A00012A, A0335.1, A0355, A0357, A0358, A0391, A0392, A0393, A60000C, A60001C, A60002C, A60003C, 00120.1, WA00013A	Caution: Risk of injury to the patient or user - Using the HF cable after the restricted service life may cause electrical, mechanical and thermal injury. Signs of wear might not become visible. 1. Do not use the HF cable after 12 months of use 2. Dispose of the HF cable after 12 months
WA99510A	Caution: Risk of injury to the patient or user - Using the HF cable after the restricted service life may cause electrical, mechanical and thermal injury. Signs of wear might not become visible. 1. Do not use the cable after 6 months of use 2. Dispose of the cable after 6 months
WA47784A, WA47785A	Connector Cables are supplied non-sterile and reusable for a maximum of 20 uses.

Risk to Health:

Damage to the device cable can lead to loss of function, which may delay the start or completion of procedures. In addition, a compromised cable may expose users or patients to fire, heat, smoke, sparks, or electrical current, creating a risk of burns, smoke inhalation, or electric shock.

To date, injuries reported to Olympus have been minor and have not required professional medical treatment. Although the likelihood is extremely low, more serious harm could occur in rare circumstances.

Actions Required:

Our records indicate that your facility has received one or more of the affected units. Olympus requests you to take the following actions:

1. Carefully read the content of this notification.

2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification, and HF cable instruction for use. This is not a removal action. You may continue to use the device as per this letter and the Instructions for Use.
3. As stated in the Instructions for Use, do not use the device beyond the defined service life, and inspect all HF cables for mechanical defects prior to use. If any defects are identified, replace the cable, regardless of the first-use date or number of uses.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form (Attachment 3) that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX latest by XXX.
5. Forward this notice to other users who may have the affected products if you have further distributed it.

[If applicable:] [competent authority] is aware of the actions described in this letter.

Olympus requests that you report any complaints of device damage or failure, to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].

Sincerely,

Name
Olympus title

Attachment 1
Excerpt of Instructions for Use

Instructions for Models: A00010A, A00011A, A00012A, A0335.1, A0355, A0357, A0358, A0391, A0392, A0393, A60000C, A60001C, A60002C, A60003C, 00120.1, WA00013A

Section 2.3, General safety notes:

Spare equipment

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

Section 4, Before Use:

Caution: Risk of injury to the patient or user - Using the HF cable after the restricted service life may cause electrical, mechanical and thermal injury. Signs of wear might not become visible.

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

Section 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, 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.

Replace if necessary: If the instrument is damaged or does not function properly, replace it.

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.

Instructions for Model: WA99510A

Section 2.3, General safety notes:

Spare equipment

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

Section 4, Before Use:

Caution: Risk of injury to the patient or user - Using the HF cable after the restricted service life may cause electrical, mechanical and thermal injury. Signs of wear might not become visible.

3. Do not use the cable after 6 months of use
4. Dispose of the cable after 6 months

Section 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, 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.

Testing the instrument

- Test the product with a high-voltage tester or by functional testing to ensure integrity of the insulation.

Replace if necessary

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

4.2 General handling of the cable

Do not overrun the cable with carts or trolleys.
Do not pull, strongly bend or squeeze the cable.
Directly pull on the plug to disconnect the cable. Do not pull on the cable.

Models: WA47784A, WA47785A:

OLYMPUS VERSAPOINT II Electrosurgical System Connector Cables Versapoint Connector Cable, grey plug – REF #WA47784A
Versapoint Connector Cable, black plug – REF #WA47785A
Non-sterile, Reusable (20 Uses Only)

IMPORTANT: Follow the instructions in the User Manual so that the Generator displays the symbol: "INSERT ELECTRODE." If any of the Connector Cable connector pins are bent or the cable shows any signs of damage, cracking or distortion, the Connector Cable must be discarded and replaced.

IMPORTANT: Visually inspect the Connector Cable to ensure that it is clean and dry, and check for any evidence of damage before inserting the Electrode. Ensure that connections are correctly oriented before firmly home. Once connection is made, the Generator display will change to the default settings appropriate to the Electrode classification code.

After Surgery

Warning: Disconnect by pulling on the plug body. Do not pull the cable.
Pulling on the cable may cause damage to the device.

HOW SUPPLIED

Connector Cables are supplied non-sterile and reusable for a maximum of 20 uses.

Attachment 2
Locating HF Cable Manufacture Date

To follow the IFU, determine the service life of the device. To assist in determining the device's service life, the manufacturing month and year can be obtained from the UDI (Unique Device Identifier) number as detailed below. Table 1 details where the UDI can be located for each model, where available.

Models: A00010A, A00011A, A00012A, A0335.1, A0355, A0357, A0358, A0391, A0392, A0393, A60000C, A60001C, A60002C, A60003C, 00120.1, WA00013A, WA99510A

The direct part marking (DPM) of these models contains the Unique Device Identifier in Human Readable Interpretation (UDI-HRI) with **manufacturing date** and **LOT number** of the products. This helps supporting product traceability (incl. identifying age), batch identification and inventory control of the devices.

The UDI shows the product information in an international standardized format. Indicated for model A0393 in Figure 1.

(01)GTIN#(11)YYMMDD(10)LOT

- **(01)GTIN:** The Global Trade Item Number identifies the medical device product uniquely.
- **(11)Manufacturing.-Date:** The manufacturing date indicates when the device was produced.
- **(10)LOT:** The lot number identifies the production batch of the device.



Figure 1: Exemplary for model A0393 HF-cable monopolar the device identifier contains the following information on the instrument plug.

Models: WA47784A, WA47785A

These models contain the Unique Device Identifier in Human Readable Interpretation (UDI-HRI) with **LOT number** of the products **on a label tag near** the **generator plug**. This helps support product traceability, batch identification, and inventory control of the devices.
The UDI shows the product information in an international standardized format:

(01)GTIN#(10)LOT

- **(01)GTIN:** The Global Trade Item Number identifies the medical device product uniquely.
- **(10)LOT:** The lot number identifies the production batch of the device.

Overview of all models where UDI-HRI can be found and whether they are carrying Manufacturing date

The different models contain the UDI-HRI **on either generator or instrument plugs**, depending on the space for labeling. Table 1 provides guidance on which part of the product the manufacturing date and LOT can be found:

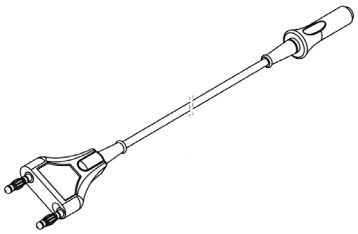
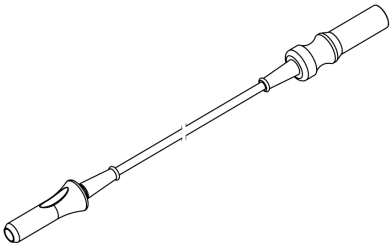
Model Number	Material Description	UDI-HRI located at	Carries Mfg. date	Service Life
A0358	HF-cable monopolar	**Instrument plug**	**Yes**	**12 Months**
A0335.1	HF-cable monopolar			
A0393	HF-cable monopolar			
A00010A	HF-cable monopolar	**Generator plug**		
A00011A	HF-cable monopolar			
A00012A	HF-cable monopolar			
A0355	HF-cable monopolar			
A0357	HF-cable monopolar			
A0391	HF-cable monopolar			
A0392	HF-cable monopolar			
A60000C	HF-cable HiQ+ bipolar			
A60001C	HF-cable HiQ+ bipolar			
A60002C	HF-cable HiQ+ bipolar			
A60003C	HF-cable HiQ+ bipolar			
00120.1	HF cable, monopolar			
WA00013A	HF-cable			
WA99510A	Cable, for neutral electrode	**Plug for neutral electrode**		**6 Months**
WA47784A	Versapoint Connector Cable grey plug, non-sterile, reusable	**Label tag on Generator plug, Currently not containing Mfg. Date**	**No**	**20 Uses**
WA47785A	Versapoint II Connector Cable black plug, non-sterile, reusable			

Table 1: Models, where UDI-HRI, Manufacturing date are located and their service life.

Exemplarily pictures of UDI-DPM for the different models are provided in Table 2.

HF cables and their plugs have different designs. The manufacturing date as part of UDI-HRI is indicated on either instrument plug, generator plug or clip to neutral electrode. On which part the UDI-HRI is printed on (per group) is indicated by bold text in the right columns.

Model Number	Name/Model and pictures of plugs with markings
Monopolar	
A00010A **A00011A** **A00012A** **A0355** **A0357** **A0391** **A0392** **00120.1**	**Exemplary picture of UDI-DPM on generator plug**  Model: A0357
A0393 **A0358** **A0335.1**	**Exemplary picture of UDI-DPM on instrument plug**  Model: A0393
WA99510A	 Model: WA99510A

Model Number	Name/Model and pictures of plugs with markings
Bipolar	
WA00013A **A60000C** **A60001C** **A60002C** **A60003C**	**Exemplary picture of UDI-DPM on generator plug**   Model: WA00013A A60001C, A60003C:  A60000C, A60002C: 

WA47785A **WA47784A**	**Exemplary picture of UDI-DPM on <u>label tag</u>** (without Manufacturing date)   Model: WA47785A

Table 2: Exemplary cable plugs carrying UDI-HRI containing GTIN (01), Manufacturing Date (11) and LOT (10).

Attachment 3

REPLY FORM – FY26-018-F-1 HF Cable Thermal Event During Procedure

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by date *XXX*.