

Reference: 2026-003M

16 March 2026

URGENT - FIELD SAFETY NOTICE

To all users of **Olympus HF Cable, Bipolar**

Product Name	Model / Catalog Number	Lot Number
HF cable, bipolar	WA00014A	All

Re: Olympus to Remind Customers of HF Cable IFU Information.

Attention: Urology Department, Gynecology Department, Operating Room, Risk Management

Dear Healthcare Professional:

Olympus is issuing a Field Safety Notice for the HF (high-frequency) bipolar cable, model WA00014A. These cables are intended to connect the electrosurgical generator to the instrument or HF-resection electrode for the application of TUR resection in Urology and Gynecology.

Reason for Action:

Olympus received a complaint of a thermal event with the HF cable during a procedure, resulting in a minor burn injury to the user. During the investigation, it was identified that the device was being used beyond the service life defined in the product instructions for use (IFU), resulting in insulation wear, corrosion, and failure of the HF cable. In a review of complaint data over 4 years, a total of 109 complaints were identified as being potentially related to thermal events with no serious injuries, 17 of which were minor or superficial burns, or burn to PPE (personal protective equipment).

Action:

Olympus is reminding customers of the following information from the HF cable IFU, to reduce the likelihood of cable failure:

Section 4, Before Use:

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

The service life of this device begins from the date of initial use. If you are unable to determine this date, the date of manufacture can serve as a reference to determine the device age. The date of manufacture can be located as below.

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 lot number shown on the front face of the generator plug housing, as illustrated below.



Figure 1: Generator plug housing



Figure 2: HF cable

Lot number format: **YYMW-00000***

**sequential numbering for the last 5 digits*

- **YY** = year manufactured (e.g. 2025 = “25”)
- **M** = month manufactured (Jan to Sep = “1” to “9”, respectively. Oct, Nov, Dec = “X”, “Y”, “Z”, respectively)

e.g., 1: a manufacture month of August 2025 will have a lot number as follows: **258W-00000**

e.g., 2: a manufacture month of November 2024 will have a lot number as follows: **24YW-00000**

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 or negligible 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.

Therefore, Olympus require 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 instruction for use.
3. As stated in the instruction 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 and return the 'Response Form' to us.
5. If you have further distributed this product, identify them and forward this notification.

Olympus requests that you report any complaints device damage or failure and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.

Regulatory Affairs and Quality Assurance Department

Email : mes-ra.oml@olympus.com

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai

[Hideki Nagai \(Mar 16, 2026 16:09:07 GMT+8\)](#)

Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd

Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2026-003M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Remind Customers of HF Cable IFU Information.

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to this FSN letter.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date






2026-003M FSN Customer Letter

Final Audit Report

2026-03-16

Created:	2026-03-16 (Korean Standard Time)
By:	Rohaya Binti Asib (rohaya.asib@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAvshkkmodiOiEa9-bskUyilnEdj3XOM4R

"2026-003M FSN Customer Letter" History

-  Document created by Rohaya Binti Asib (rohaya.asib@olympus.com)
2026-03-16 - 4:31:17 PM GMT+9- IP address: 205.220.72.87
-  Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature
2026-03-16 - 4:33:38 PM GMT+9
-  Email viewed by Hideki Nagai (hideki.nagai@olympus.com)
2026-03-16 - 5:05:01 PM GMT+9- IP address: 104.47.56.126
-  Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)
Signature Date: 2026-03-16 - 5:09:07 PM GMT+9 - Time Source: server- IP address: 205.220.72.87
-  Agreement completed.
2026-03-16 - 5:09:07 PM GMT+9