OLYMPUS

URGENT: FIELD SAFETY NOTICE

HF Cable, Bipolar

Product Name	Model / Catalog Number	Lot Number	UDI-DI
HF cable, bipolar	WA00014A	All	04042761076449

Date: 12-MAR-2026

Attention: Surgical 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 about 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:

This product was previously discontinued in the U.S. market in 2019. If you still have this product on hand, 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.

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.

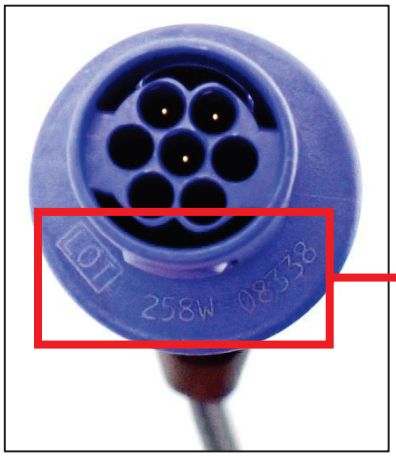

Figure 1: Generator plug housing

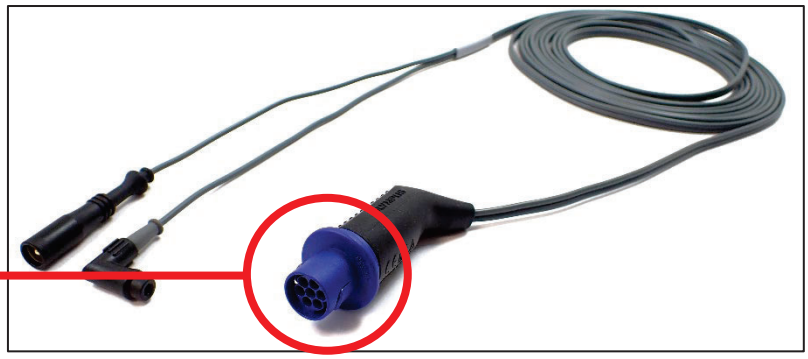

Figure 2: HF cable

Lot number format: **YYM**W-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: **258**W-00000

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

This product was previously discontinued in 2019 in the U.S. Our records indicate that your facility has received one or more 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 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. Even if you no longer have this product, Olympus requests that you acknowledge receipt of this letter through the Olympus web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0496"
    c. Complete the form as instructed.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests that you report any complaints of device damage or failure, to our Technical Assistance Center (TAC) at 1-800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (647) 999-3203 or by email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager
Field Corrective Action, Americas