

07 November 2022

Reference: FY23-EMEA-04

## URGENT: FIELD SAFETY NOTICE / FIELD SAFETY CORRECTIVE ACTION

Attention: Operating Room Manager

### Regarding: HF Resection Electrodes - incompatible HF Cable

Model Number	Model Description	Lot Number
WA22602S	HF-resection electrode "PlasmaLoop", medium, 12°/16°	1000090824
WA22603S	HF-resection electrode "PlasmaLoop", large, 12°/16°	1000092201
WA22621S	HF-resection electrode "PlasmaBand", medium, 12°/16°	1000080316
WA22657S	HF-resection electrode "PlasmaButton", 12°-30°	1000092202

Dear Customer,

OLYMPUS is implementing a Field Safety Corrective Action (FSCA) for the HF resection electrodes referenced above. Electrodes with HF cable are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current.

OLYMPUS has initiated this FSCA after receiving an increased number of complaints regarding an incompatible HF cable inside the sterile packaging of the referenced electrodes. The plug of such an incompatible HF cable cannot be connected to the electro-surgical generator. As a result, the surgical procedure may be delayed. If no compatible spare equipment is available, the procedure may need to be cancelled.

There has been no report of an adverse event or patient injury. However, in an effort to prevent a potential risk to patient health, OLYMPUS is undertaking this action to recall the model and lot numbers identified above.

The investigation has revealed that the incompatible HF cable was placed inside the sterile packaging of the electrodes during production.

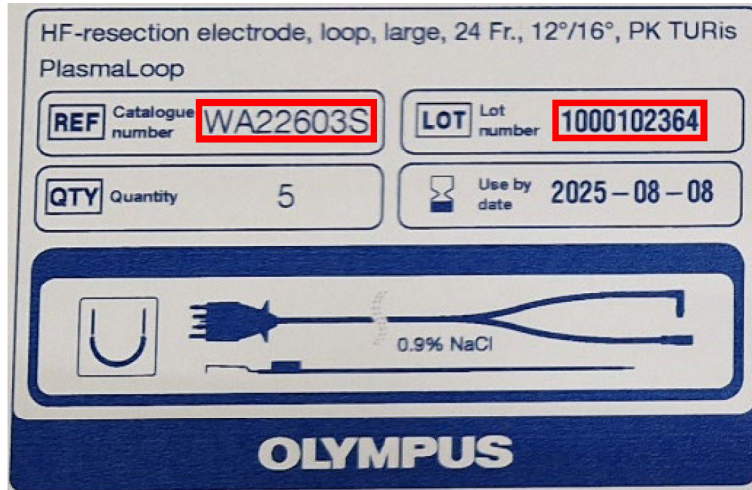
#### **Action steps to be taken by the end user:**

Our records indicate that your facility has purchased one or more of the electrode models with the lot numbers referenced above. **OLYMPUS requires you to take the following actions:**

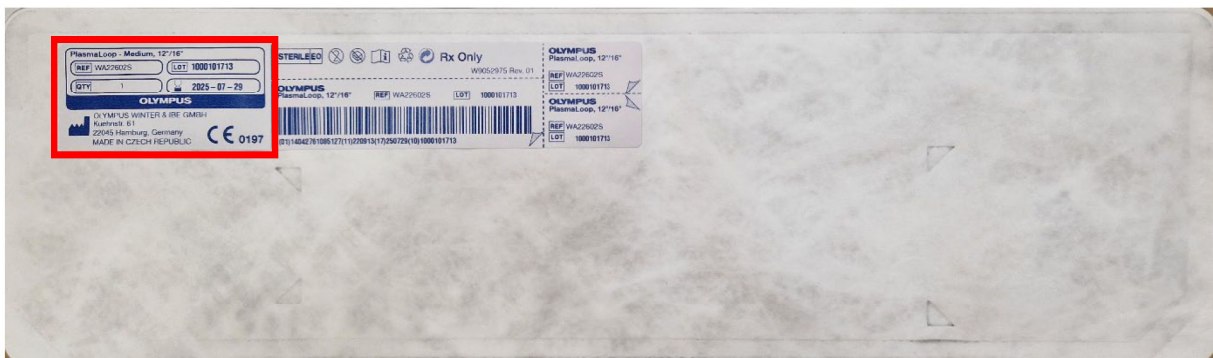
1. Inspect your inventory for the electrodes with the model and lot numbers specified above and check if an incompatible HF cable is included. The following pictures illustrate where the model and lot number can be found on the packaging labels and how to identify an incompatible HF cable:



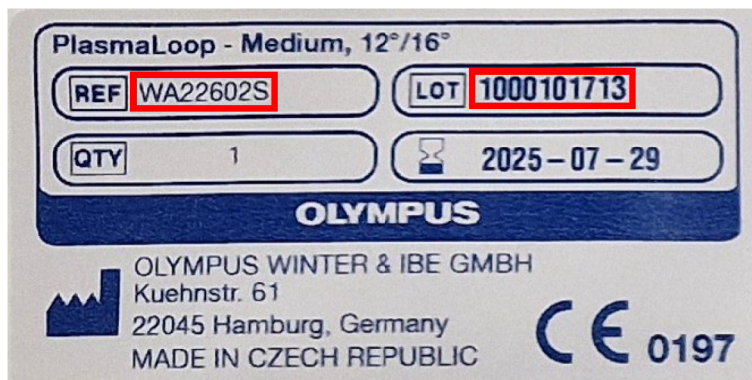
Picture 1: outer packaging of the HF resection electrodes



Picture 2: model (REF) and lot (LOT) number on the outer packaging label



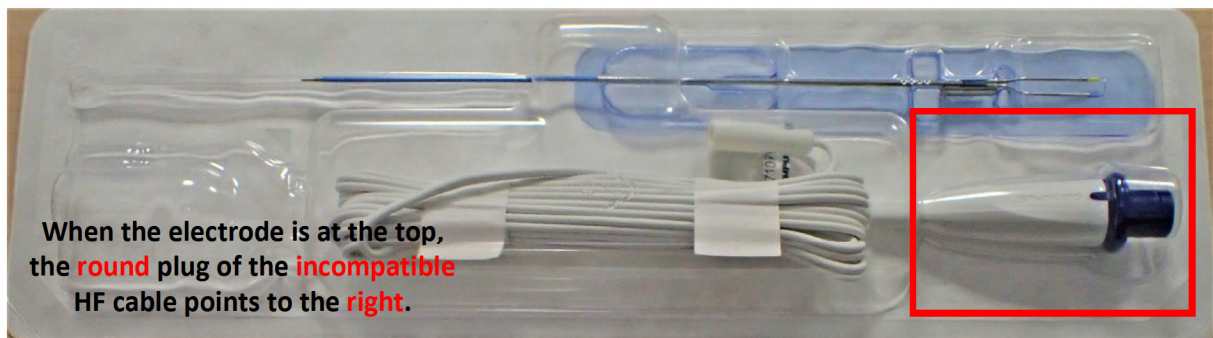
Picture 3: sterile packaging of the HF resection electrodes



Picture 4: model (REF) and lot (LOT) number on the sterile packaging label



Picture 5: compatible HF cable inside the sterile packaging



Picture 6: incompatible HF cable inside the sterile packaging

2. If electrodes with an incompatible HF cable were identified, contact your local OLYMPUS representative. You will be provided with instructions on how to return the electrodes and get a free replacement or credit note.
3. Please use the enclosed reply form to confirm that you have received this Field Safety Notice (FSN) and inspected your inventory. If electrodes with an incompatible HF cable were identified, please include the quantity you intend to return. E-mail the completed reply form until 22.11.2022 to [OSTE-Vigilance@olympus.com](mailto:OSTE-Vigilance@olympus.com).
4. If you have further distributed this product, identify your customers and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedbacks accordingly.

The local / national Competent Authority is aware of this action.

OLYMPUS regrets any inconvenience this action may have caused and appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact us.

Sincerely,

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I have received the Field Safety Notice (FSN) on the HF resection electrodes referenced above. I understand that I need to inspect my inventory and return electrodes with an incompatible HF cable to OLYMPUS.

Please contact your local OLYMPUS representative. You will be provided with instructions on how to return the electrodes with an incompatible HF cable and get a free replacement or credit note.

**Choose either A, B or C:**

- A)  I have checked my inventory and do NOT have any of the electrodes referenced above.
- B)  I have checked my inventory and do NOT have any electrodes with an incompatible HF cable.
- C)  I have checked my inventory and will return the following number of electrodes with an incompatible HF cable:

Model Number	Lot Number	Quantity

Facility / Hospital Name (please do not abbreviate):

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Address:

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Postal Code / City:

Country:

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Name:

Title:

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Date:

Signature:

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**Please send the completed and signed reply form until 22.11.2022**

**via e-mail to [OSTE-Vigilance@olympus.com](mailto:OSTE-Vigilance@olympus.com).**