

[XX] June 2023

Reference: FY24-EMEA-01

URGENT: FIELD SAFETY NOTICE

Attention: Urology and Gynaecology Department

Regarding: Information on additional Caution in Instructions for Use (IfU)

Model Number(s)	Model Description
A22201A, A22201B, A22201C, A22201D, A22202A, A22202B, A22202C, A22202D, A22203A, A22203C, A22205A, A22205B, A22205C, A22205D, A22206A, A22206B, A22206C, A22206D, A22207A, A22207C, A22211A, A22211C, A22221C, A22222C, A22223C, A22224C, A22231A, A22231B, A22231C, A22231D, A22250A, A22250C, A22251A, A22251C, A22253A, A22253C, A22255A, A22255C, A22257C, A22257D, A22258A, A22258C, A22259A, A22259C, A22266A, A22266C, A44728C, WA22037A, WA22037C, WA22038A, WA22038C, WA22039A, WA22039C, WA22301D, WA22301S, WA22302D, WA22302S, WA22305D, WA22305S, WA22306D, WA22306S, WA22331D, WA22332D, WA22332S, WA22351A, WA22351C, WA22351S, WA22355A, WA22355C, WA22355S, WA22503D, WA22503S, WA22507D, WA22507S, WA22521C, WA22521S, WA22523C, WA22523S, WA22537D, WA22537S, WA22538A, WA22538C, WA22538S, WA22539D, WA22539S, WA22540S, WA22541S, WA22542S, WA22543S, WA22544S, WA22557C, WA22557S, WA22558C, WA22558S, WA22559S, WA22566S, WA22602D, WA22602S, WA22603D, WA22603S, WA22605S, WA22606D, WA22606S, WA22607D, WA22607S, WA22621C, WA22621S, WA22623C, WA22623S, WA22632D, WA22632S, WA22637S, WA22638S, WA22639S, WA22640S, WA22641S, WA22642S, WA22643S, WA22644S, WA22651C, WA22651S, WA22655C, WA22655S, WA22657C, WA22657S, WA22666S, WA22702S, WA22703S, WA22705S, WA22706S, WA22707S, WA22721S, WA22723S, WA22732S, WA22737S, WA22738S, WA22739S, WA22740S, WA22741S, WA22742S, WA22743S, WA22744S, WA22751S, WA22755S, WA22760S, WA22766S, WA47505S, WA47506S, WA47507S, WA47540S, WA47551S, WA47555S, WA47560S, WA47566S, WA47705S, WA47706S, WA47707S, WA47721S, WA47723S, WA47732S, WA47737S, WA47738S, WA47739S, WA47740S, WA47741S, WA47742S, WA47743S, WA47744S, WA47751S, WA47755S, WA47760S, WA47766S	HF-Resection Electrode

Dear Customer,

OLYMPUS is implementing a Field Safety Corrective Action (FSCA) for the HF resection electrodes referenced above. The electrodes are intended for endoscopic treatment in urological and gynaecological applications, such as cutting, ablation, resection and coagulation with high-frequency (HF) current.

OLYMPUS has initiated this FSCA after receiving complaints where the loop wire at the distal end of the HF resection electrode broke after getting in contact with metal objects, such as other endoscopic equipment, implants or stents. As a result, fragments can fall inside the patient and must be retrieved.

The risk of such a breakage has been assessed as low. However, in an effort to further reduce a potential risk to patient health, OLYMPUS is undertaking this action to add an additional Caution to the Instructions for Use (IfU) of the HF resection electrodes. This Caution can be found on the Addenda to the IfU attached to this Field Safety Notice (FSN).

Please note that for some electrode models a second additional Caution has been added, which was already included in the IfU of the other models. The second Caution refers to the risk of sparkover when getting in contact with metal parts. This Caution can also be found on the Addenda to the IfU attached to this FSN.

Action steps to be taken by the end user:

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

1. Carefully read the content of this FSN.
2. Ensure that all personnel are completely knowledgeable and thoroughly trained on the content of this FSN. In particular, observe the instructions of the additional Cautions.
3. If you have further distributed this product, identify your customers and forward them this FSN. Please appropriately document your notification process and let us know the end-customer feedbacks accordingly.
4. Confirm that you have received and understood this FSN by filling out the enclosed Reply Form. E-mail the completed Reply Form until [XXXXXXXXXX] to [XXXXXXXXXXXX].

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,



REPLY FORM – FY24-EMEA-01

OLYMPUS URGENT FIELD SAFETY NOTICE HF-Resection Electrodes
Name & Address of the Hospital / Healthcare Facility
Department / Attention
Date

I herewith acknowledge the receipt of this Field Safety Notice.

Furthermore, I confirm that I have forwarded the content of this Field Safety Notice to all affected personnel, departments and customers on which this action has an impact. I understand the necessity to observe the instructions of the additional Cautions.

Name (Signature) _____

Name (Print) _____

Position / Title _____

Please e-mail the completed Reply Form until [XXXXXXXXXX] to [XXXXXXXXXXXX].