Reference: 2023-002M

9 June 2023

URGENT - FIELD SAFETY NOTICE

To all users of Olympus HF-Resection Electrode

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

Attention: **Urology and Gynecology Department**

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

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Dear Health Care Practitioner,

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

OLYMPUS 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. Olympus requests that you acknowledge receipt of this letter and return the 'Response Form' to us.

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.

Contact for enquiries
Regulatory Affairs 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
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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Response Form

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

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2023-002M

URGENT - FIELD SAFETY NOTICE

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

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: _____

Designation: _____

....
Signature & Company Stamp Date

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
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