



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**

**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**

**Director General of Engineering Affairs, MOH**

**Director General of Royal Hospital**

**Director General of Khoula Hospital**

**Director General of Medical Supplies (MOH)**

**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**

**Hospital Director (Al Nahda Hospital)**

**Hospital Director (Al Massara Hospital)**

**The Head of Medical Services in SQU Hospital**

**The Head of Medical Services in Royal Oman Police**

**The Head of Medical Services in Ministry of Defence**

**The Head of Medical Services in The Diwan**

**The Head of Medical Services in The Sultan's Special Force**

**The Head of Medical Services in Internal Security Services**

**The Head of Medical Services in Petroleum Development of Oman**

**The Head of Medical Services in LNG Oman**

**ALL PRIVATE PHARMACIES & DRUG STORES**

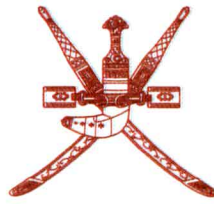
After Compliments,

Please find attached our Circular No 137 dated 26/6/2023 Regarding Olympus Field Safety Notice of HF-Resection Electrode.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 137 / 2023

نتقدم بـ  
Moving Forward  
with Confidence



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-06-2023

**Field Safety Notice of HF-Resection Electrode from Olympus.**

Source	Olympus through their local agent Muscat Pharmacy & Stores LLC.
Product	HF-Resection Electrode.
Description	Endoscopic electrosurgical electrode, bipolar, single-use.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Attached.
Reason	The loop wire at the distal end of the above HF resection electrode may 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.
Action	1. Ensure that all personnel are completely knowledgeable and thoroughly trained on the content of the attachment. In particular, observe the instructions of the additional Cautions. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General



**URGENT FIELD SAFETY NOTICE**

Attention: Urology and Gynecology Departments

**RE: 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, A2222C, 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, WA22305D, WA22305S, WA22306D, WA22331D, WA22332D, WA22351A, WA22351C, WA22355A, WA22355C, WA22503D, WA22507D, WA22521C, WA22523C, WA22537D, WA22538A, WA22538C, WA22539D, WA22540S, WA22541S, WA22542S, WA22544S, WA22557C, WA22558C, 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	HF-Resection Electrode



# OLYMPUS

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 gynecological 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 [ra@olympus-mea.com](mailto:ra@olympus-mea.com) latest by 23.06.2023.

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,

Andreh Alkhoury  
Regional Quality Assurance & Regulatory Affairs Team Lead Middle East & Africa  
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai  
Registration No. 93456 (Dubai Development Authority)  
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates



**REPLY FORM – FY24-EMEA-08-FY24-EMEA-01**

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

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 [ra@olympus-mea.com](mailto:ra@olympus-mea.com) latest by 23.06.2023.