Reference: 2024-X002M

8 May 2024

URGENT: MEDICAL DEVICE REMOVAL
Product: OES 4000 Hysteroscopes
Model: A4674A
Serial Number: 805769

Attention: **Urology, Gynecology, Risk Manager**

Dear Healthcare Professional/Provider:

Olympus is writing to inform you of a Removal Action pertaining to the OES 4000 Hysteroscope model A4674A. This rigid endoscope intended for visualization of endoscopic diagnosis and therapeutic/surgical treatment in urology and gynecology.

Reason for Action:

Olympus has determined that 13 scopes did not undergo a leakage testing step required per the manufacturing process. This presents the potential of fluid ingress over time into the eyepiece of the device which may result in a foggy image in the proximal eyepiece of the device.

The missing leakage test affects 13 products in the market and Olympus has not received any complaints or adverse events related to the identified issue.

Risk to Health:

Fluid ingress after reprocessing may result in a foggy image in the proximal eyepiece of the device. This issue may be found either during the reprocessing phase (which includes cleaning, inspection, sterilization), during procedural set-up or intraoperatively when verifying the image quality with the video system. The potential patient harm(s) associated with this issue would be delays in initiating or completing procedures with these devices. Olympus has not received any reports of harm due to this identified issue.

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

Action steps to be taken by end user:

Our records indicate that your facility has purchased one of the affected products. **Olympus requests you to take the following actions:**

1. Carefully read the content of this notification.
2. Examine your inventory and identify the above listed device with serial number.
3. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understood this notification by filling out and returning the completed enclosed Response Form to us.
4. Olympus will contact you to arrange for the return of your device to Olympus, and we will replace this device at no charge.
5. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report complaints, including foggy image and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this matter. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact for enquiries
Regulatory Affairs and Quality Assurance 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,

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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

PRODUCT NAME: OES 4000 Hysteroscopes

Model: A4674A

Serial Number: 805769

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **8 May 2024** letter.

Yes ☐ No ☐

Any adverse incidents associated with recalled product?

Yes ☐ No ☐

If yes, please explain: _____

Check the applicable boxes below:

☐ I DO NOT have affected device remaining. All have been used or discarded.

☐ I DO have the affected device, which I will return to Olympus.

Name: _____

Designation: _____

....

Signature & Company Stamp Date

Please send the completed and signed Response Form to Regulatory Affairs Department to
[Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]

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