Date: May 8, 2024

Bethpage Medical
3333 New Hyde Park Road, Suite 101
New Hyde Park, 11042 NY

URGENT: MEDICAL DEVICE REMOVAL
OES 4000 Hysteroscopes

Product Name	Model/Catalog Number	Serial Numbers	UDI-DI
OES 4000 Hysteroscope	A4674A	805904	04042761006361

Attention: Urology, Gynecology, Risk Manager

Dear Healthcare Professional /Provider:

Olympus is writing to inform you of a Medical Device Removal Action pertaining to one serial number of OES 4000 Hysteroscope model A4674A. This product is a 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 1 unit in the U.S. 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.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Examine your inventory and identify the above listed model and serial number.
3. Our Customer Solutions Department will arrange for the return of your device to Olympus, and we will replace this device at no charge.
4. If you no longer have this unit, please inform our Olympus team. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including foggy image, to the Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas