Reference: 2024-006M

9 October 2024

URGENT - FIELD SAFETY NOTICE

To user of **Olympus Uropass Ureteral Access Sheath**

Model Numbers: 61038BX, 61046BX, 61138BX, 61224BX, 61238BX, 61324BX, 61338BX,

Lot Numbers: All lots

Re: Olympus to Provide New Storage Instructions Regarding UV Exposure

Attention: **Operating Room Director, Urology Department & Risk Management**

Dear Health Care Provider:

Olympus is writing to inform you of a Field Safety Corrective Action pertaining to the UroPass Ureteral Access Sheath ("UroPass"). The Olympus UroPass Ureteral Access Sheath Set consists of a hydrophilic coated outer sheath and an inner tapered dilator intended to establish a conduit for the passage of endoscopes and retrieval devices into the ureter. The hydrophilic coating on the UroPass Ureteral Access Sheath eases passage and placement. Both the outer sheath and inner dilator are radio-opaque for ease of viewing radiographically. This product is intended for single use only.

Reason for Action:
Olympus conducted an investigation after receiving complaints reporting broken dilator tips in the package and in patients during surgical procedures. The investigation determined that exposing the UroPass product to Ultraviolet ("UV") Radiation can cause brittleness of the device dilator tip, which may lead to breakage. Since April 2023, Olympus has received 2 adverse event complaints reporting broken UroPass dilator tips for devices still within their shelf life.

To reduce the risk of UV exposure to your device(s), Olympus instructs users to implement the following actions:
Store individual UroPass Ureteral Access Sheath pouches away from ultraviolet (UV) light sources (including sunlight and artificial light). Exposure to UV light during storage periods may cause embrittlement of this device, increasing potential for breakage and patient injury.

Risk to Health:
Exposure to Ultraviolet light may cause embrittlement of this device potentially leading to breakage of the UroPass tip. Tip breakage may lead to a delay in initiating a procedure if the tip is broken in the package or discovered during use, or may result in a foreign body remaining in the patient resulting in potentially prolonged operative time or an additional procedure to locate and remove the broken piece. Additionally, tissue damage or perforation of the ureter could occur due to exposed sharp edges.

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

Actions Required:
Our records indicate that your facility has 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. Inspect your inventory and determine if any of these devices with the model name specified above remain in inventory. Please check all areas of the facility/hospital. Add a copy of this notification with your remaining inventory. You may continue to use the products in accordance with the instructions regarding UV exposure:

   Store individual UroPass Ureteral Access Sheath pouches away from ultraviolet (UV) light sources (including sunlight and artificial light). Exposure to UV light during storage periods may cause embrittlement of this device, increasing potential for breakage and patient injury.

3. Olympus is not requiring the return of your UroPass device(s) as a result of this action. However, if you want to return the UroPass device(s) in your inventory, please contact Olympus Sales Representative. Olympus will issue a credit to your facility upon return of your affected product.
4. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification, including the new information regarding UV exposure. Olympus is in the process of updating the Instructions for Use with this information.
5. If you have further distributed this product, identify your customer's, and forward them this notification.
6. Olympus request that you acknowledge receipt of this letter and return the 'Response Form' to us latest by 4 January 2025.

Olympus requests that you report any complaints, including those related to Uropass tip breakages and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

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,

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
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Response Form

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

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2024-006M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Provide New Storage Instructions Regarding UV Exposure

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

☐ I DO NOT have affected product remaining. Product has been condemned or discarded.

☐ I DO have the affected product, which I will adhere to the New Storage Instructions Regarding UV Exposure.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

....
Signature & Company Stamp Date

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

2024-006M FSN 1

Final Audit Report 2024-10-10

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