October 04, 2024

URGENT: MEDICAL DEVICE CORRECTION

UroPass® Ureteral Access Sheath

Model Numbers: 61024BX, 61038BX, 61046BX, 61054BX, 61124BX, 61138BX, 61146BX, 61154BX, 61224BX, 61238BX, 61246BX, 61254BX, 61324BX, 61338BX, 61346BX, 61354BX
Lot Numbers: All lots
UDI-DI: 00821925035317, 00821925035324, 00821925035331, 00821925035348, 00821925035355, 00821925035362, 00821925035379, 00821925035386, 00821925035393, 00821925035409, 00821925035416, 00821925035423, 00821925035430, 00821925035447, 00821925035454, 00821925035461

Attention: Urology Department, Operating Room Director, Risk Management

Dear Healthcare 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. 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.

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. Inspect your inventory and determine if any of the devices listed above remain in inventory. Please check all areas of the facility/hospital. 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 Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. 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. Olympus requests that you acknowledge receipt of this letter. Access the Olympus recall portal to indicate that you have received this notification.
   a. Go to https://olympusamerica.com/recall
   b. Enter the recall number "0458"
   c. Complete the form as instructed.
6. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including those related to UroPass tip breakages, to the Olympus 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 email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow,
Field Corrective Actions Lead, Americas