Date: XX.XX.XXXX

Olympus Reference: QIL FY25-EMEA-17-FY23-OSTA-17-Uropass

URGENT FIELD SAFETY NOTICE

RE: UroPass® Ureteral Access Sheath
Attention: Operating Room Manager, Urology Department, Risk Management Department

Material ID	Model Number	Material Description	LOT Numbers	UDI-DI
EG61024BX	61024BX	UroPass® Ureteral Access Sheath	All	00821925035317
EG61038BX	61038BX	UroPass® Ureteral Access Sheath	All	00821925035324
EG61046BX	61046BX	UroPass® Ureteral Access Sheath	All	00821925035331
EG61054BX	61054BX	UroPass® Ureteral Access Sheath	All	00821925035348
EG61124BX	61124BX	UroPass® Ureteral Access Sheath	All	00821925035355
EG61138BX	61138BX	UroPass® Ureteral Access Sheath	All	00821925035362
EG61146BX	61146BX	UroPass® Ureteral Access Sheath	All	00821925035379
EG61154BX	61154BX	UroPass® Ureteral Access Sheath	All	00821925035386
EG61224BX	61224BX	UroPass® Ureteral Access Sheath	All	00821925035393
EG61238BX	61238BX	UroPass® Ureteral Access Sheath	All	00821925035409
EG61246BX	61246BX	UroPass® Ureteral Access Sheath	All	00821925035416
EG61254BX	61254BX	UroPass® Ureteral Access Sheath	All	00821925035423
EG61324BX	61324BX	UroPass® Ureteral Access Sheath	All	00821925035430
EG61338BX	61338BX	UroPass® Ureteral Access Sheath	All	00821925035447
EG61346BX	61346BX	UroPass® Ureteral Access Sheath	All	00821925035454
EG61354BX	61354BX	UroPass® Ureteral Access Sheath	All	00821925035461

Dear Healthcare Professional:

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.

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 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 representative with regard to return and reimbursement procedure. 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 customers, and forward them this notification.
6. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX latest by XXX.

[If applicable:] [competent authority] is aware of the actions described in this letter.

Olympus requests that you report any complaints, including those related to UroPass tip breakages, to *[local facility complaint reporting contact]. [If applicable:]* Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method].*

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].

Sincerely,
Name
Olympus title

REPLY FORM: QIL FY25-EMEA-17-FY23-OSTA-17-Uropass

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert description of the product names and model numbers of the affected products

Catalog #	Serial / Lot #	Date Shipped	Qty Shipped to your facility	Qty remaining in Stock

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by date *XXX*.