Date: XX.XX.XXXX
Olympus reference: QIL FY24-EMEA-05-FY23-OSTA-17

URGENT FIELD SAFETY NOTICE

Recall of UroPass® Ureteral Access Sheath

Attention: Urology Department, Risk Management

Material ID	Material Name	Lot Numbers
EG61024BX	UROPASS AS, 10/12 X 24, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61038BX	UROPASS AS, 10/12X38, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61046BX	UROPASS AS, 10/12 X 46, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61054BX	UROPASS AS, 10/12 X 54, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61138BX	UROPASS AS, 11/13X38, 5x	Products manufactured 01.01.2018 to 31.12.2019
EG61146BX	UROPASS AS, 11/13 X 46, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61154BX	UROPASS AS, 11/13 X 54, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61224BX	UROPASS URETER SHEATH 24CM 5x	Products manufactured 01.01.2018 to 31.12.2019
EG61238BX	UROPASS URETER SHEATH 38CM 5x	Products manufactured 01.01.2018 to 31.12.2019
EG61254BX	UROPASS URETER SHEATH 54CM 5x	Products manufactured 01.01.2018 to 31.12.2019
EG61324BX	UROPASS AS, 13/15 X 24, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61338BX	UROPASS AS, 13/15 X 38, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61354BX	UROPASS AS, 13/15 X 54, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61346BX	UROPASS AS, 13/15 X 46, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61124BX	UROPASS AS, 11/13 X 24, 5/BX	Products manufactured 01.01.2018 to 31.12.2019
EG61246BX	UROPASS AS, 12/14 X 46, 5/BX	Products manufactured 01.01.2018 to 31.12.2019

Dear Health Care Practitioner:

Gyrus ACMI Inc. (“Olympus”) is initiating a medical device recall for specific lot numbers of the UroPass Ureteral Access Sheaths (“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 this letter:

Olympus conducted an investigation after receiving complaints reporting broken dilator tips in the package and in patients during surgical procedures. The investigation showed that reported breakages were associated with devices aged more than three years. Devices manufactured after December 31st, 2019 are not impacted by this recall. Harms associated with this issue potentially include the following: foreign body in patients, prolonged surgery, delay to treatment/therapy, additional surgery, internal organ perforation and tissue injury.

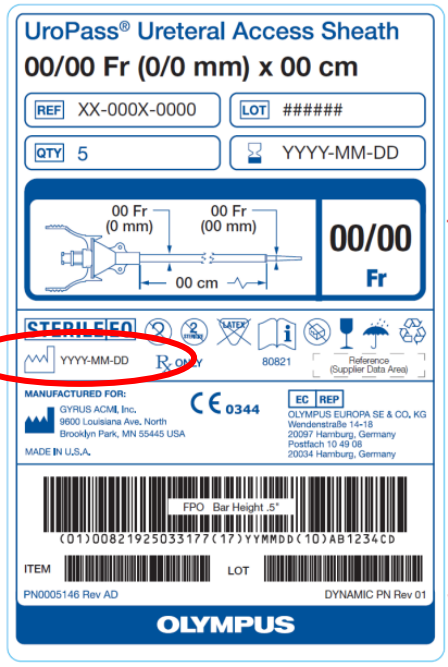
Consequently, Olympus is removing UroPass devices which have a shelf life greater than three years.

Action steps to be taken by the end user:

Our records indicate that you have purchased one or more of the affected products. Olympus requires you to take the following action:

1. Carefully read the content of this Field Safety Notice.

2. Immediately assess your inventory of UroPass products. You may have to identify affected product based on the Date of Manufacture located on the product label. **Cease use of and quarantine any product manufactured on or prior to December 31st, 2019.** The images below show the area where the Date of Manufacture can be found.



3. Contact your Olympus representative at [XXXXXXX]. Olympus will issue a Return Material Authorization to return any affected product at no charge to you. Olympus will issue a credit to your facility upon return of affected product.

4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

5. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative at [XXXXXXX] latest by [XX.XX.XXXX].

Olympus requests that you report complaints 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 regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at [phone] or at [email] for any additional information or support concerning this matter.

Sincerely,
Name
Title, Department/Region

REPLY FORM – QIL FY24-EMEA-05-FY23-OSTA-17

FIELD SAFETY NOTICE
Recall of Recall of UroPass® Ureteral Access Sheath

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[Inventory information (Material and Lot Number(s) of UroPass® Ureteral Access Sheath)]

Model	Lot Number	Quantity per piece

[Date]

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to **[XXXXXXX]**