Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 120 **dated** 13/6/23 **Regarding NCMDR Recall of UroPass® Ureteral Access Sheath from (mfr: Gyrus ACMI).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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Circular No. 120 / 2023

24 -11-1444 H

13 -06-2023

Recall of UroPass® Ureteral Access Sheath from Gyrus ACMI.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19558
Product	UroPass® Ureteral Access Sheath.
Description	Dilator, catheter.
Manufacturer	Gyrus ACMI.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID: EG61338BX, EG61238BX, EG61024BX, EG61146BX, EG61346BX, EG61254BX, EG61324BX, EG61046BX, EG61054BX, EG61224BX, EG61138BX, EG61154BX, EG61038BX, EG61354BX, EG61124BX and EG61246BX Lot numbers: Products manufactured 01.01.2018 to 31.12.2019 Refer to the attachment for affected Material Names
Reason	Dilator tips may break in the package or in patients during surgical procedures.
Action	1. Customers should cease use of and quarantine any affected product. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

OLYMPUS

Date: 25.05.2023
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.

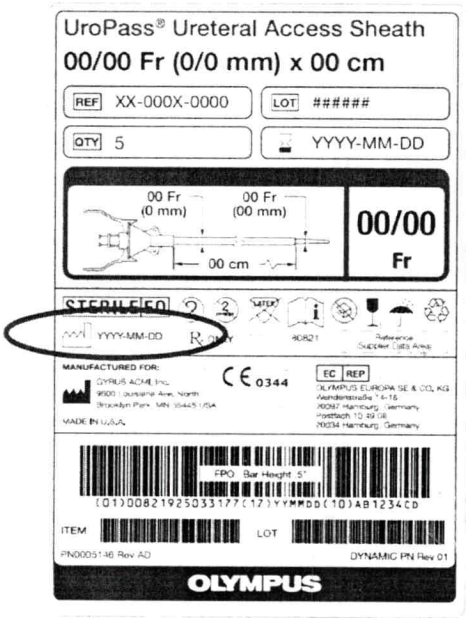
OLYMPUS

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 ra@olympusmea.com. 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 ra@olympusmea.com latest by 11.06.2023

OLYMPUS

Olympus requests that you report complaints to ra@olympusmea.com

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at ra@olympusmea.com for any additional information or support concerning this matter.

Sincerely,

Iman Ibrahim
Regional Head of Quality Assurance and Regulatory Affairs Middle East & Africa
Healthcare, Industrial and Life Science Divisions
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai
Registration No. 93456 (Dubai Development Authority)
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates

OLYMPUS

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 ra@olympusmea.com