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 178 dated 24/8/23 Regarding NCMDR FSN of Laryngoscopes, flexible, Laryngoscopes, Bronchoscopes from (mfr: Olympus).

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







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



سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية

Circular No. 178/2023

08 -02-1445 H 24 -08-2023

Field Safety Notice of Laryngoscopes, flexible, Laryngoscopes, Bronchoscopes from Olympus

| C | NCMDR- National Center for Medical Devices Reporting- SFDA |
|--------------|--|
| Source | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19666 |
| Duaduat | Bronchofiberscope, Bronchovideoscope, Ultrasonic Bronchofibervideoscope, Tracheal |
| Product | Intubation Fiberscope, Tracheal Intubation Videoscope, and Airway Mobilescope. |
| Description | Laryngoscopes, flexible, Laryngoscopes, Bronchoscopes. |
| Manufacturer | Olympus. |
| Local agent | Muscat Pharmacy & Stores LLC. |
| The affected | Multiple model numbers (see the attachment). |
| products | All serial numbers. |
| Reason | Potential of injury that upon trying to use an Olympus pulmonary endoscope model with an endotracheal tube, the tip may become lodged (entrapped) inside the endotracheal tube connector, due to the scope (bending section) is too large for the endotracheal tube connector. |
| Action | Please refer to the attachment which is providing the additional information related to safe using an endotracheal tube. 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 Rubaje

Director General







Date: August 2, 2023

Olympus reference: QIL FY24-EMEA-12-FY24-OMSC-07

URGENT FIELD SAFETY NOTICE

Attention: Endosocopy Examination Room Manager, Operating Room Manager, Risk Management Department

RE: Bronchofiberscope, Bronchovideoscope, Ultrasonic Bronchofibervideoscope, Tracheal Intubation Fiberscope, Tracheal Intubation Videoscope, Airway Mobilescope

Serial numbers: all serial numbers

Dear Health Care Practitioner,

Olympus has become aware of a matter that requires your attention. This Field Safety Notice pertains to the below-referenced Olympus bronchoscopes/tracheal intubation scopes/airway mobilescopes models. Our records indicate that your facility has purchased one or more of these models.

BF Series Bronchoscopes

These bronchoscopes are intended for use in endoscopic diagnosis and treatment within the airways and the tracheobronchial tree.

| BF-1T150 | BF-260 | BF-MP160F | BF-P290 | BF-TE2 | DE HOLDE |
|-----------|----------|--|------------|-----------|------------|
| BF-1T180 | BF-3C160 | BF-MP190F | | | BF-UC180F |
| BF-1T260 | | | BF-P60 | BF-XP160F | BF-UC260FW |
| | BF-3C40 | BF-MP290F | BF-PE2 | BF-XP190 | BF-UC190F |
| BF-1T60 | BF-6C260 | BF-MP60 | BF-Q170 | BF-XP260F | BF-UC290F |
| BF-1TQ170 | BF-F260 | BF-P150 | BF-Q180 | BF-XP290 | B1-0C290F |
| BF-1TQ180 | BF-H190 | BF-P180 | BF-Q180-AC | BF-XP60 | T |
| BF-1TQ290 | BF-H290 | BF-P190 | BF-Q190 | | _ |
| BF-1TH190 | BF-N20 | ALLOND TO DEPOSIT AND THE PROPERTY OF THE PROP | | BF-XT160 | _ |
| | DI -1420 | BF-P260F | BF-Q290 | BF-XT190 | _ |

Note: Product availability is dependent upon country

LF Series tracheal intubation scopes

These tracheal intubation scopes are intended for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

| LF-TP | LF-DP | 15.65 | | |
|-------|-------|-------|------|------------------------------------|
| | LI-DF | LF-GP | LF-V | LF-P |
| | | | | LF-P ability is dependent upon cou |

MAF Series airway mobilescopes

These airway mobilescopes are intended for airway management, which includes diagnosis and observation to access airway anatomy, endotracheal/endobronchial intubation and management.

| MAF-TM | MAF-TM2 | NAAF CNA | 202.2 | |
|---|----------------|----------|---------|---------|
| 200000000000000000000000000000000000000 | IVIAI - I IVIZ | MAF-GM | MAF-GM2 | MAF-DM2 |