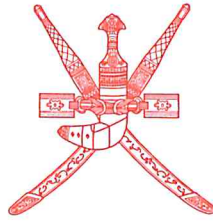


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَا اَمَانَا
وَزَارَةُ الصِّحَّةِ
الْمَدِيرِيَّةُ الْعَامَّةُ لِلصِّدْقِ
وَالرَّقَابَةِ الدَّوَلِيَّةِ
مَسْقَط

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. 1/2020 dated 1/1/2020 regarding OLYMPUS Recall of Duodenovideoscopes & Duodensfiberscopes (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

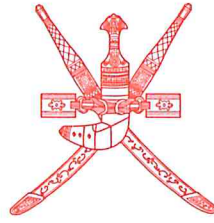
Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT

Circular No. 1 / 2020

5-05-1441 H

1 - 1-2020



سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
مسقط

Recall of Duodenoscopes & Duodensfiberscopes from OLYMPUS

Date: 25 th December 2019													
Source of Recall	OLYMPUS through Muscat pharmacy												
Product	Duodenoscopes & Duodensfiberscopes												
Manufacturer	OLYMPUS												
Local Agent	Muscat Pharmacy L.LC												
The affected products	<table border="1"><thead><tr><th>Model</th><th>Serial Numbers affected</th></tr></thead><tbody><tr><td>TJF-160R</td><td>ALL</td></tr><tr><td>TJF-140R, JF-140R, TJF-240, JF-240</td><td>ALL</td></tr><tr><td>JF-1T40</td><td>ALL</td></tr><tr><td>JF-TE3</td><td>ALL</td></tr><tr><td>TJF-260V & JF-260V</td><td>ALL</td></tr></tbody></table>	Model	Serial Numbers affected	TJF-160R	ALL	TJF-140R, JF-140R, TJF-240, JF-240	ALL	JF-1T40	ALL	JF-TE3	ALL	TJF-260V & JF-260V	ALL
Model	Serial Numbers affected												
TJF-160R	ALL												
TJF-140R, JF-140R, TJF-240, JF-240	ALL												
JF-1T40	ALL												
JF-TE3	ALL												
TJF-260V & JF-260V	ALL												
Reason for Recall	fraying elevator wires of the TJF-160VR Duodenovideoscope can occur												
Action	<ol style="list-style-type: none">1. Kindly check your stock, contact your local agent for remedial action2. Olympus is advising customers to inspect inventory for any TJ-160VR and any other mentioned model for elevator wire damage.3. If you find damage in the elevator wire contact your local agent to arrange repair.4. Download the updated Instructions For Use (IFU) which includes additional precautions regarding elevator wire damage and guidance on how to inspect this component <u>*IFU attached</u>												
Product image													
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om												

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

