



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 150 dated 18/7/23 Regarding Olympus Recall of PowerSpiral PSF-1 and associated accessories DPST-1 and PSCU.

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





Circular No. 150/2023

بنقدم بثقة
Moving Forward
with Confidence



30-12-1444 H

18 -07-2023

Recall of PowerSpiral PSF-1 and associated accessories DPST-1 and PSCU from Olympus.

Source	Olympus through their local agent Muscat Pharmacy & Stores LLC.
Product	PowerSpiral PSF-1 and associated accessories DPST-1 and PSCU.
Description	Enteroscope, flexible, video, Self-propelled endoscope spiral sleeve and Power Control Unit - Endoscope workstation.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID (Model Name, Model Description): 1- N5788540, N5788550 (PSF-1, INTESTINAL VIDEOSCOPE OLYMPUS PSF-1); 2- N5788700 (DPST-1, SINGLE USE POWERSPIRAL TUBE DPST-1); 3- N6003260 (PSCU, POWERSPIRAL CONTROL UNIT PSCU) All Serial numbers
Reason	Potential of a situation where the withdrawal of a PSF-1 by rotating the Tube DPST-1 from a patient become unsuccessful and have to be removed surgically. Inability to withdraw PSF-1/DPST-1 lead to catastrophic injury to the patient, contributing to the death of the patient.
Action	1. Cease usage of PowerSpiral products with immediate effect. You will be contacted by Olympus representative to arrange return and appropriate reimbursement. 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

