



نقدم بثقة
Moving Forward
with Confidence



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 155 dated 4/11/2024 Regarding Field Safety Corrective Action of OmniWire Pressure Guide Wire Internal Wire from (mfr: Philips).

Copy to:

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



Circular No. 155 / 2024

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رؤية عمان
2040
OmanVision

02-051446 H
04-11-2024

Field Safety Corrective Action of OmniWire Pressure Guide Wire Internal Wire from Philips.

| | |
|-----------------------|--|
| Source | Philips through their local distributor Nexhold Medical Supply LLC. |
| Product | OmniWire Pressure Guide Wire Internal Wire. |
| Manufacturer | Philips. |
| Local agent | Nexhold Medical Supply LLC. |
| The affected products | All OmniWire Pressure Guide Wires manufactured since February 2022 (2022-02-01) are potentially impacted. |
| Reason | Internal wire component could become damaged due to the wire potentially not meeting an internal specification. |
| Action | <ol style="list-style-type: none">Continued use of the OmniWire Pressure Guide Wire should be according to the Instructions for Use (IFU).If any loss of signal were to occur during use, replace the wire with another OmniWire to complete the procedure. If you experience any signal issues when using the OmniWire, please notify your local distributor so that they can file a complaint and request for replacements. |
| 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: vigilance-md@moh.gov.om |

Dr. Mohammed Hamdan Al Rubaie
Director General

