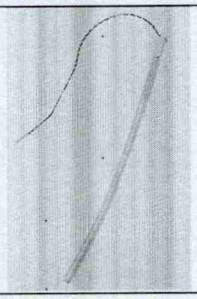
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 13 / 2022

21 -06-1443 H
24 -01-2022

Field Safety Notice of Philips Fetal Spiral Electrode from Philips Healthcare.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=16000
Product	Philips Fetal Spiral Electrode.
Description	Electrode, foetal scalp.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Product code: 989803137631
Reason	Additional warning messages to the "Warnings" section of the IFU.
Action	1. Philips is advising customers to review the below additional warnings included in the current edition of the IFU. 2. Reuse may cause degradation of physical or electrical properties. 3. Do not reuse on another patient due to risk of cross-infection. 4. Customers are to download and print the current edition of the IFU from www.Philips.com/IFU and search "fetal spiral electrode." 5. Contact the local agent for remedial action.
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 Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

A-S

Dr. Mohammed Hamdan Al Rubaie

Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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

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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. 13/2022 **dated** 24/1/2022 **Regarding NCMDR Field Safety Notice of Philips Fetal Spiral Electrode from (mfr: Philips Healthcare).**

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**

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Directorate General of Pharmaceutical Affairs & Drug Control

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Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الاجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

TGA Recall

Reference Number: mdprc 018 01 22 000 Back
Date submitted: 1/17/2022

Manufacturer:	Philips Healthcare
Device Type:	Philips Fetal Spiral Electrode
Description:	Electrode, foetal scalp
Medical Device Identifier:	Product code: 989803137631
Reason of Field Safety Corrective Action:	Additional warning messages to the "Warnings" section of the IFU.
Remedy Action:	Philips is advising customers to review the below additional warnings included in the current edition of the IFU. - Reuse may cause degradation of physical or electrical properties. - Do not reuse on another patient due to risk of cross-infection. Customers are to download and print the current edition of the IFU from www.Philips.com/IFU and search "fetal spiral electrode."
Athorized Representative/Importer/Distributor:	Philips Healthcare Saudi Arabia Ltd.
Report Source:	https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2021-RN-02432-1
Source Ref. Number:	RC-2021-RN-02432-1
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.
Attachments:	No Attachments

View History