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 283 **dated** 25/12/23 **Regarding NCMDR Field Safety Notice of OPTEASE™ Retrievable Vena Cava Filter, OPTEASE™ Retrieval Catheter from (mfr: Cordis Corporation).**

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**

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

Sultanate of Oman
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Circular No. 283/ 2023

11 -06-1445 H

25 -12-2023

FSN of OPTEASE™ Retrievable Vena Cava Filter, OPTEASE™ Retrieval Catheter from Cordis Corporation.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19857
Product	OPTEASE™ Retrievable Vena Cava Filter, OPTEASE™ Retrieval Catheter.
Description	Retrievable Vena Cava Filter Set and Retrieval Catheter.
Manufacturer	Cordis Corporation.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Catalog Numbers: OPTEASE™ Retrievable Vena Cava Filter:466F210AF, 466F210AJ, 466F210BJ OPTEASE™ Retrieval Catheter: 466C210F.
Reason	Update the Warning statement in the Instructions for Use (IFU) for the above devices to inform end users of clarifications to the previously defined timeframe the OPTEASE™ Retrievable Vena Cava Filter device is implanted before retrieval.
Action	1. Please review the updated warning statement of IFU in the attachment with any of your staff involved in the use of this device. 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

PADC
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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Cordis

URGENT FIELD SAFETY NOTICE

Cordis OPTEASE™ Retrievable Vena Cava Filter and OPTEASE™ Retrieval Catheter

Catalog Numbers	Device Description
466F210AF	OPTEASE™ Retrievable Vena Cava Filter
466F210AJ	OPTEASE™ Retrievable Vena Cava Filter
466F210BJ	OPTEASE™ Retrievable Vena Cava Filter
466C210F	OPTEASE™ Retrieval Catheter
NOTE: This is highlighting labeling changes. Retain this letter with affected product.	
NOTE: This is a Field Safety Notice and does not involve removal of product.	

December 18th, 2023

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is issuing a field safety notice related to the labeling of: Cordis OPTEASE™ Retrievable Vena Cava Filter and OPTEASE™ Retrieval Catheter.

Overview:	This letter provides important information concerning the decision by Cordis to update the Warning statement in the Instructions for Use (IFU) for the Cordis **OPTEASE™ Retrievable Vena Cava Filter and OPTEASE™ Retrieval Catheter**: This Field Safety Notice (FSN) is being conducted solely to inform end users of clarifications to the previously defined timeframe the **OPTEASE™ Retrievable Vena Cava Filter** device is implanted before retrieval. Therefore, Cordis has **updated the Warning statement** in accordance with regulatory requirements as follows: "The OPTEASE™ Retrievable Filter has not been studied for long term implantation and must be retrieved within 12 days after placement." **Previous Warning statement**: "The OPTEASE™ Retrievable filter can be retrieved up to and including 12 days after placement. The OPTEASE™ Retrievable filter is considered a permanent implant if it is not retrieved within the specified time period." The statement **below was removed from the device description** for the **OPTEASE™ Retrieval Catheter** IFU in accordance with the updates made to the Warning statement in the IFU for the Cordis OPTEASE™ Retrievable Vena Cava Filter and OPTEASE™ Retrieval Catheter: "The OPTEASE Retrievable Filter can be retrieved within a specified period after implantation (refer to the OPTEASE Retrievable Filter Instructions for Use) or remain implanted as a permanent filter." **Please share this information with any of your staff involved in the use of this device.**

Details on Affected Device, to assist in identification of the product involved:	**Product Involved** This letter applies to all Cordis **OPTEASE™ Retrievable Vena Cava Filter and OPTEASE Retrieval Catheter** catalog numbers, listed above (all unexpired lots). **Intended Use:** "The OPTEASE™ Retrievable Vena Cava Filter is indicated for the prevention of Pulmonary Embolism (PE) via percutaneous placement in the IVC in patients considered at high risk of PE." "The OPTEASE Retrieval Catheter is indicated for the retrieval of the OPTEASE Retrievable Filter from the inferior vena cava."

Why you are being contacted:	You are receiving this letter because our records indicate that you have purchased one or more of the Cordis **OPTEASE™ Retrievable Vena Cava Filter and OPTEASE Retrieval Catheter** catalog numbers listed above.

Actions requested on your part:	1. Read this Urgent Field Safety Notice. 2. Sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. 3. Share this notification with anyone in your facility that needs to be informed. 4. Contact any other facilities that have been provided with units of the affected catalog codes (all unexpired lots). 5. Retain a copy of this notice with the product.

Why was this change initiated:	What is the issue? The rationale for this update was based on available data which indicated that while the data shows a follow-up duration ranging anywhere from 1 month to 2 years, however, the average time for retrieval of the OPTEASE™ Retrievable Vena Cava Filter was ~12 days. The previous Warning statement was unclear and hence was updated. The intent with this update was a clarification because there has not been any prospective clinical study to evaluate the long-term performance of the OPTEASE™ Retrievable Vena Cava Filter. Is there any concern with the product already used successfully in procedures? No, there has been no known patient safety risk identified through post market surveillance. Is there any concern where implantation is beyond 12 days? For implantation over 12 days there is no known risk to patient safety. For any current and ongoing follow ups, use your best medical judgement as a treating physician. The indications for the OPTEASE filter remain unchanged and there have been no known or new complications identified as a result of this IFU update. Please refer to the IFU for a complete list of potential harms associated with the use of this product.

Available Assistance:	If you have any questions regarding this field safety notice, please contact your local sales representative or local sales office, or Cordis at GMB-Cordis-Cashel-QRA@cordis.com

Additional Information:	Regulatory Notification The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.

We know that you place high trust in our products, and we appreciate your cooperation in this matter. Cordis is committed to maintaining your confidence in the safety and quality of the products that Cordis supplies.

Respectfully yours,

Miguel Ávila
Vice President, Global Quality, Regulatory, Medical and Clinical Affairs
Cordis