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

CUSTOMER ACKNOWLEDGEMENT FORM

Field Safety Notice

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

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Contact Person	
Department	
Hospital Name	
Postcode:	
Street	
City	
Contact Email	
Contact Phone	

Our records indicate that your facility received product subject to the above Field Safety Notice.

Part 1: Letter Acknowledgement (Customer)
We are aware of the notification of the above Field Safety Notice related to labelling of: **Cordis OPTEASE™ Retrievable Vena Cava Filter and OPTEASE™ Retrieval Catheter**. We will share this notification with anyone in our facility that needs to be informed and with any other facilities that have been provided with affected units.

_____ Name/Signature: (Customer)

_____ Position: (Customer)

_____ Contact Phone Number: (Customer)

_____ Date:

OR

Part 2: Letter Acknowledgement (Cordis Representative)
I confirm that the customer has been made aware of the notification of the above Field Safety Notice.

_____ _____
Name/Signature: Position:
(Cordis Representative)

_____ _____
Contact Phone Number: Date:
(Cordis Representative)

Please return this completed form by email to insert local email address.