

Urgent Field Safety Notice (Removal)

Cordis OPTease® Retrievable Vena Cava Filter

Catalog Numbers	
466F210A	466F210B

All unexpired distributed lots as of date of this letter*; Highest lot number 15960131.

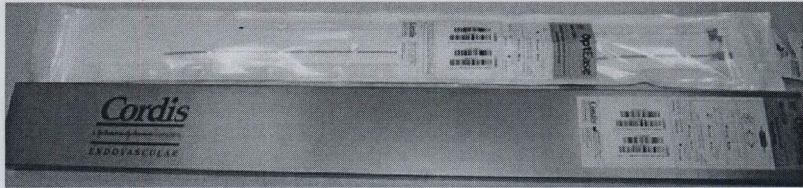
*See RECALL PRODUCT LOT LIST at end of letter

October 8, 2013

Dear Valued Customer,

The purpose of this communication is to inform you that **Cordis is recalling (removing) all unexpired distributed lots (lot number 15960131 and below) of Cordis OPTease® Retrievable Vena Cava Filter product.**

Recall Overview:	Cordis has identified a printing error on one unit of our OPTease® Retrievable Vena Cava Filter, in which the orientation arrow for the femoral approach was printed in the incorrect direction. The error resulted in the filter being implanted upside down, requiring an additional percutaneous procedure to retrieve the filter. All unexpired distributed lots of the Cordis OPTease® Retrievable Vena Cava Filter are being removed, since it cannot be absolutely determined that no other similar printing errors occurred.
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Details on Affected Devices, to assist in identification of the product involved:	<p><u>Cordis OPTease® Retrievable Vena Cava Filter - Overview</u></p> <p><u>Identification</u></p> <p>The following photo is provided to help you identify the Cordis OPTease® Retrievable Vena Cava Filter product.</p>  <p><u>Usage</u></p> <p>The OPTease® Retrievable Vena Cava Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the inferior vena cava as further described in the Instructions For Use.</p> <p><u>Cordis OPTease® Retrievable Vena Cava Filter – What’s affected</u></p> <ul style="list-style-type: none"> • This recall pertains to only the two catalog numbers listed above. <p>The catalog numbers comprise the CE-Mark multi-lingual version of the Cordis OPTease® Retrievable Vena Cava Filter product. (A separate related communication is being sent to customers in countries with the non CE-Mark English-language version of the product.)</p> <ul style="list-style-type: none"> • This recall pertains to all 217 unexpired distributed lots. (Refer to RECALL PRODUCT LOT LIST). The highest lot number is 15960131.
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	<p><u>Cordis OPTEASE® Retrievable Vena Cava Filter – What’s not affected</u></p> <p>This recall does NOT pertain to:</p> <ul style="list-style-type: none"> • Any lot number higher than 15960131. • Any Cordis TRAPEASE® Vena Cava Filter product.
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<p>Actions requested on your part:</p>	<p><u>Cordis OPTEASE® Retrievable Vena Cava Filter – What you need to do</u></p> <ol style="list-style-type: none"> 1) Read this Urgent Field Safety Notice letter. 2) Immediately identify and set aside all product listed below in a manner that ensures the affected product will not be used. 3) Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. 4) Return any affected product per the attached instruction, or contact your local sales representative to facilitate return of the affected product. Credit will be provided. 5) Share this letter with others in your facility that need to be made aware of this recall. 6) Contact any other facility to arrange the return of OPTEASE® if any product listed below has been forwarded to them. 7) Maintain awareness of this notice until all affected product has been returned to Cordis. 8) Keep a copy of this notice with the affected product.
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<p>Description of the problem:</p>	<p><u>Cordis OPTEASE® Retrievable Vena Cava Filter – Further Details</u></p> <p><u>How the product works</u></p> <p>The Cordis OPTEASE® Retrievable Vena Cava Filter is designed to be implanted in only one orientation, with the retrieval hook oriented in the caudal (towards the legs) position.</p> <p>The fixation barbs are designed to prevent the filter from migrating upwards towards the heart and allow retrieval of the filter via the femoral vein.</p> <p><u>See Figure 1 below:</u></p>
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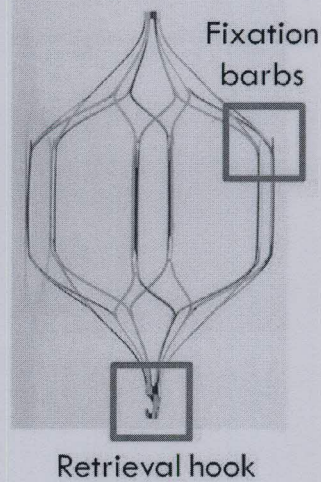


Figure 1 – Fixation Barbs & Retrieval Hook

If the filter is deployed with the retrieval hook in the cranial direction, the fixation barbs may not fixate the filter, and migration of the filter may occur

The Cordis OPTease® Retrievable Vena Cava Filter is supplied in a plastic storage tube, which is loaded as a system into a sheath introducer hemostasis valve. The product design allows for the deployment to be performed from either the femoral or jugular approach, by positioning the storage tube with the selected access site arrows pointing into the introducer. You will notice that the arrows on the Femoral storage tube are in the opposite direction to those that are on the Jugular storage tube.

See Figure 2 below.

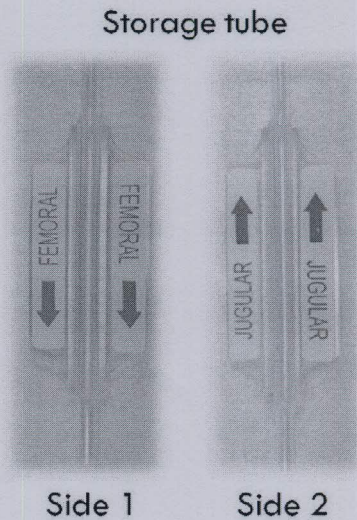


Figure 2- Correct storage tube printing

Information on the Complaint that led to the recall

Cordis recently received a complaint that the arrows printed on the storage tube pointed in the same direction for both the femoral and jugular orientation labels. The incorrect printing resulted in the filter being implanted upside down when the arrow orientation on the storage tube was followed for the femoral

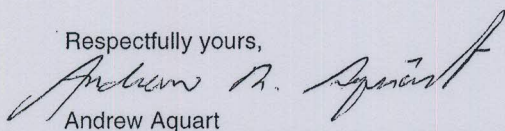
	<p>approach.</p> <p><u>Why we are recalling this product?</u></p> <p>Implant of the OPTEASE® Retrievable Vena Cava Filter with the hook oriented in the cranial direction can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures and ineffective pulmonary embolism prevention.</p> <p>There is no impact to the patient if the physician has successfully deployed and subsequently retrieved the filter. There is no impact to the patient if a filter has been deployed, and the hook confirmed to be in the femoral direction after deployment.</p> <p>Cordis has performed a root cause investigation and taken immediate corrective action. In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall the product.</p>
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Why you are being contacted:	You are receiving this letter because our records indicate that you have received one or more of the affected lots of the listed catalog numbers.
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Available Assistance:	<p><u>We can provide help or further clarification</u></p> <p>We can provide help if you have any questions regarding this recall (removal) or product replacement issues.</p> <p>In addition to your local sales representative, you may contact the local Johnson & Johnson sales office to answer any questions you may have.</p>
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Additional Information:	<p><u>Prior Communication</u></p> <p>This recall (product "Removal") is separate from the Field Safety Notice of April 3, 2013, which related to the same product, but did not involve "removal" of the product from customers. That Field Safety Notice (Event ID: Cordis20130403-OUS/C086) emphasizes the importance of correct orientation by the physician while deploying the filter. That Field Safety Notice will still apply for product shipped to customers after this product "Removal".</p> <p><u>Regulatory Notification</u></p> <p>The applicable regulatory agencies are being notified that Cordis is voluntarily taking this action.</p>
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We apologize for any inconvenience this communication may cause. We know that you place high value 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,

 Andrew Aquart
 Sr. Director, Quality Engineering, Quality Systems & Compliance
 Cordis Corporation