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.**

Details on Affected Devices, to assist in identification of the product involved:	**Cordis OPTEASE® Retrievable Vena Cava Filter - Overview** Identification The following photo is provided to help you identify the Cordis OPTEASE® Retrievable Vena Cava Filter product.  Usage 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. **Cordis OPTEASE® Retrievable Vena Cava Filter – What's affected** • **This recall pertains to only the two catalog numbers listed above.** 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.) • **This recall pertains to all 217 unexpired distributed lots. (Refer to RECALL PRODUCT LOT LIST). The highest lot number is 15960131.**

	Cordis OPTEASE® Retrievable Vena Cava Filter – What's not affected This recall does NOT pertain to: • Any lot number higher than 15960131. • Any Cordis TRAPEASE® Vena Cava Filter product.

Actions requested on your part:	**Cordis OPTEASE® Retrievable Vena Cava Filter – What you need to do** 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.

Description of the problem:	**Cordis OPTEASE® Retrievable Vena Cava Filter – Further Details** How the product works 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. 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. See Figure 1 below:

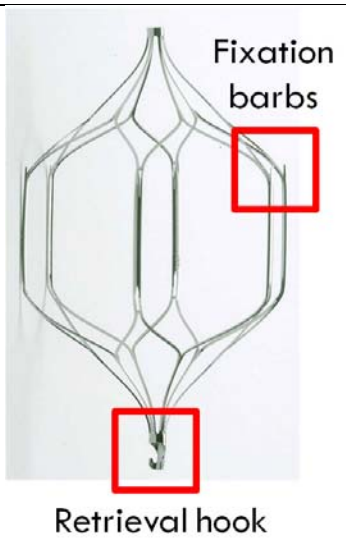


Figure 1 – Fixation Barbs & Retrieval Hook

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.

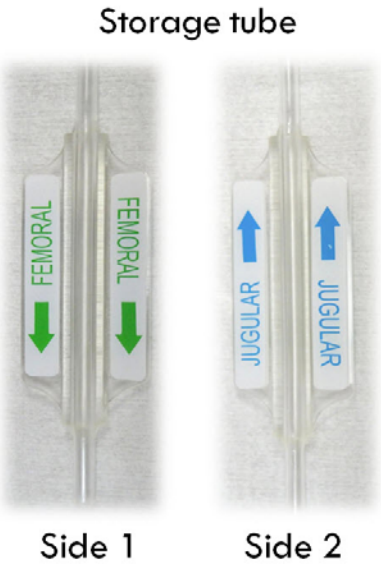


Figure 2- Correct storage tube printing

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

	approach. Why we are recalling this product? 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. There is no impact to the patient if the physician has successful 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. 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.

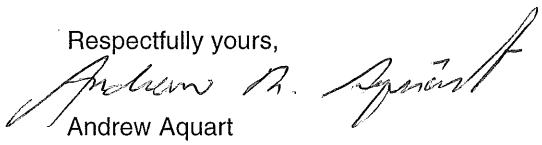
Why you are being contacted:	You are receiving this letter because our records indicate that you have received one or more of the affected lots of the listed catalog numbers.

Available Assistance:	**We can provide help or further clarification** We can provide help if you have any questions regarding this recall (removal) or product replacement issues. In addition to your local sales representative, you may contact the local Johnson & Johnson sales office to answer any questions you may have.

Additional Information:	**Prior Communication** 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". **Regulatory Notification** The applicable regulatory agencies are being notified that Cordis is voluntarily taking this action.

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

Cordis OPTEASE® Retrievable Vena Cava Filter
Product Recall Lot List
Catalog Numbers 466F210A and 466F210B

All 217 unexpired distributed lots as of date of this letter; Highest lot number 15960131.

466F210A; 164 lots.			
15274288	15454037	15612047	15781095
15279364	15457472	15614688	15788864
15282183	15462538	15618453	15793483
15286393	15466747	15619696	15793484
15289751	15469778	15619697	15798678
15294167	15482648	15628745	15802177
15299162	15484939	15631501	15806808
15306676	15487380	15637330	15806809
15311641	15494728	15642757	15813248
15315895	15500667	15644906	15815670
15322018	15501863	15647739	15822486
15324610	15504119	15652625	15825516
15329200	15507528	15653784	15828592
15333526	15510542	15658716	15828593
15338371	15513944	15659247	15834846
15339449	15514616	15666737	15838824
15349656	15517045	15670741	15841286
15354649	15518417	15678336	15847478
15355696	15527248	15678337	15852628
15360606	15527507	15681145	15855703
15364358	15536779	15689332	15863067
15367380	15546017	15693552	15868046
15374561	15546018	15696830	15872883
15378046	15550199	15704973	15878644
15389052	15555272	15704984	15880864
15393935	15556616	15707200	15884282
15395762	15558498	15711672	15889081
15402501	15565525	15721594	15894368
15405836	15568634	15736837	15899518
15409488	15576196	15736838	15899519
15417073	15578519	15741759	15913317
15421205	15584573	15741760	15918861
15427275	15584783	15747681	15922782
15431606	15589276	15751704	15926216
15435110	15591469	15755302	15932573
15437944	15593531	15760650	15939348
15440039	15597558	15764265	15943890
15445055	15599671	15764266	15948903
15445860	15599677	15771735	15948904
15448467	15605299	15772841	15954409
15450170	15607872	15777996	15960130

466F210B; 53 lots	
15300295	15653786
15309722	15659249
15319846	15686285
15354957	15696835
15364359	15702029
15369567	15704974
15402502	15709604
15405762	15709605
15409487	15752427
15430939	15771736
15440041	15782124
15454041	15788865
15457471	15789719
15471005	15793485
15491134	15798680
15494729	15813252
15506860	15815671
15513946	15828594
15529310	15841287
15544120	15857846
15563750	15894369
15572131	15913318
15591470	15939349
15612685	15943892
15623339	15954410
15637331	**15960131**
15644907	