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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٥٩/ ٢٥
رقم الصادر : ١٣/١١٧٥٦
بيروت، في: ٢ أيار ٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي

Implants, non active, vena cava filters, OPTEASE Vena Cava Filters

الجهاز المعني بالمتابعة:

- Implants, non active, vena cava filters, OPTEASE Vena Cava Filters
- Trade Mark: Cordis Corporation
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خطأ في طريقة استعمال الصنف المذكور أعلاه وهناك توصية صادرة عن الشركة المصنعة بهذا الخصوص، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
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Cordis®
a Johnson & Johnson company

URGENT Field Safety Notice Recommendations for Clinical Use – OPTEASE® Retrievable Vena Cava Filter

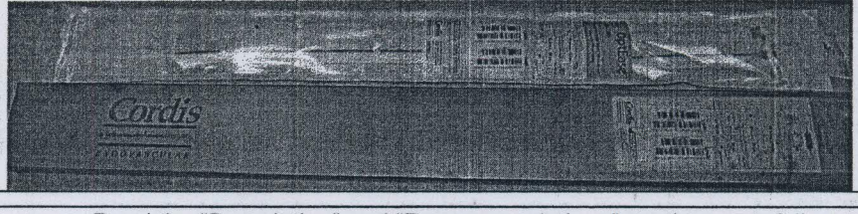
Catalog Numbers			
466F210A CE marked	**466F210B** CE marked	**466F220A** (Not CE marked)	**466F220B** (Not CE marked)

Note: This is additional labeling. Retain this letter with affected product.
Note: This is NOT a product removal.

April 3, 2013

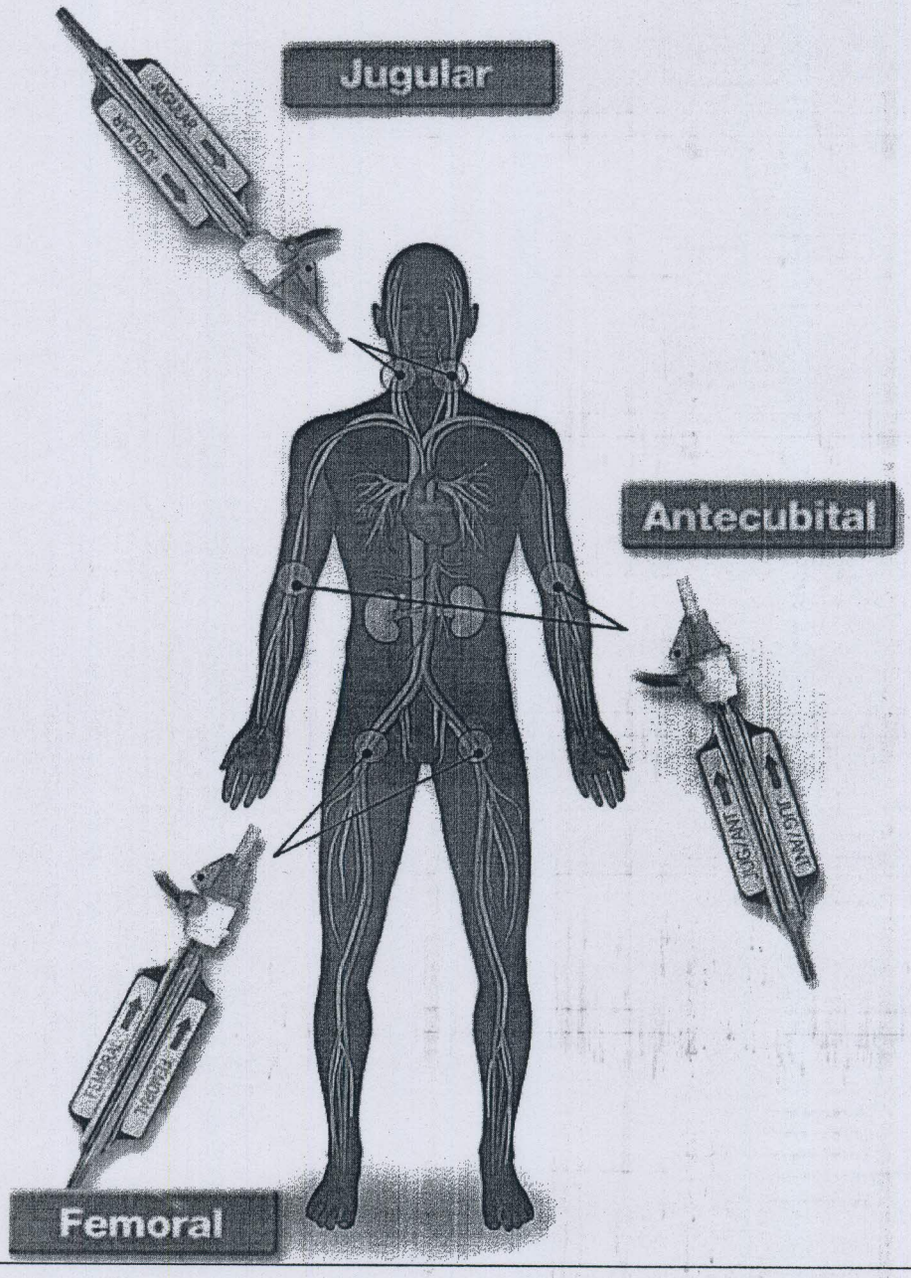
Dear Valued Customer,

Cordis Corporation ("Cordis") is providing clarification and additional information to the labeling of the OPTEASE® Retrievable Vena Cava Filter as the result of certain observations acquired through its routine post-market surveillance process of the device.

Overview:	This letter provides important information concerning the risks associated with the incorrect implantation of the OPTEASE® Retrievable Vena Cava Filter with the retrieval hook oriented towards the superior vena cava. As part of Cordis' commitment to patient safety, Cordis is highlighting the product's labeling and resources available to you in an attempt to reduce the risk of similar events in the future. This action is not related to a product defect. **Please distribute this information to the appropriate clinical personnel involved in the use of the OPTEASE® Retrievable Vena Cava Filter.** ***Please sign and return the Acknowledgement Form (See "Actions Requested" below).***
Details on Affected Devices:	This letter applies to OPTEASE® Retrievable Vena Cava Filter catalog numbers 466F210A, 466F210B, 466F220A, and 466F220B. Because the additional labeling does not relate to a product defect, the action is not lot specific, Therefore, this letter applies to all lots of the affected product until the labeling shipped with the product is updated.. Product Usage (to assist in identification of the product): The OPTEASE® Retrievable Vena Cava Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the vena cava as further described in the Instructions For Use. The OPTEASE® Retrievable Vena Cava Filter may be retrieved following recommendations and optional procedure for retrieval. Product carton and pouch pictorial (to assist in identification of the product) 
Actions requested on your part:	• Read the "Description" and "Recommendations" sections carefully. • Sign and return the enclosed Acknowledgement Form to your local sales representative. • Pass on this notice to anyone in your facility that needs to be informed. • Maintain awareness of this communication until the information has been incorporated into the Cordis OPTEASE® Retrievable Vena Cava Filter labeling.

Description of the problem:	Through continuous post-market safety surveillance, Cordis has identified a series of recent events in which the OPTEASE® Retrievable Vena Cava Filter was implanted in the opposite orientation to that specified in the product Instructions For Use (IFU). A total of fifteen (15) events have been reported since 2006, including four events received in the last six (6) months. Based on Cordis' investigation, Cordis has learned the OPTEASE® Retrievable Vena Cava Filter was placed with the retrieval hook towards the superior vena cava, inadvertently in some cases, or by the implanting physician's decision in others. In at least four (4) cases, the filter migrated to the right heart; open heart surgery was needed in two cases. No deaths related to this issue have been reported.
Recommendations for Clinical Use:	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. Detailed diagrams and procedural steps for the implantation of the OPTEASE® Retrievable Vena Cava Filter are available in the IFU: "The self-centering **OPTEASE** Retrievable Filter is laser cut from nickel titanium alloy (Nitinol) tubing. The proximal and distal baskets of the OPTEASE Retrievable Filter, which consists of struts in a six diamond-shape configuration, are designed for optimal clot capture. The baskets are connected by six straight struts. A single row ***of fixation barbs is present at the cranial end of the struts.*** These barbs, intended for fixation to the vessel wall, are extensions of the parallel struts. ***A hook is centrally located at the caudal basket extremity*** and allows for filter retrieval using a snare." [1] "The constrained filter is supplied in a plastic storage tube, which is to be loaded as a system into the Sheath Introducer hemostasis valve. ***The storage tube is printed with colored arrows and text (femoral: green; jugular/ antecubital: blue) to indicate the correct orientation.*** The arrow of the desired access site will point into the sheath introducer hemostasis valve." [1] The filter must be deployed in the patient with the hook oriented in the caudal position. In this orientation, the fixation barbs are designed to prevent the filter from migrating towards the heart and it allows retrieval of the filter via the femoral vein. The IFU describes the process for correct orientation of the device: "According to the selected venous access site, determine which end of the storage tube (containing the filter) is to be placed into the Sheath Introducer hemostasis valve. This is indicated by the printed colored arrows and text ***(femoral: green; jugular/antecubital: blue)*** on the storage tube. ***The arrow of the desired access site will point into the Sheath Introducer hemostasis valve.***"[1] Per IFU, the OPTEASE® Retrievable Vena Cava Filter is only indicated for retrieval via the femoral vein: "Retrieval of the **OPTEASE** Retrievable Filter is possible only from femoral vein approach." Per IFU for the Cordis OPTEASE® Retrieval Catheter 466-C210F, the filter retrieval hook of the OPTEASE® Retrievable Vena Cava Filter needs to be in the caudal direction for retrieval.

[1] Emphasis added.

	"Before attempting retrieval of the **OPTEASE** Retrievable Filter from the femoral access site, verify that the filter retrieval hook is at the caudal end of the filter, i.e. caudal orientation in the IVC. The retrieval hook at the caudal end of the filter is the location for endovascular snare engagement." Cordis is in the process of supplementing the OPTEASE® Retrievable Vena Cava Filter labeling to further highlight the importance of the correct orientation of the filter and the potential consequences of failing to do so.
Recommendations for Clinical Use (Cont'd): Anatomical depiction of correct orientation	The below graphic depicts the correct orientation for each approach. 

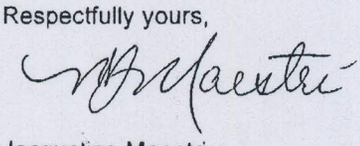
Cordis Training Assistance:	Cordis field representatives go through vigorous product training and are certified to deliver Product In-Service training sessions for physicians and hospital clinical staff when requested. The in-service includes hands-on step-by-step product preparation and filter delivery/retrieval via a Cordis designed demo box. Cordis is committed to patient safety and physician training and education. If you have questions about the orientation, fixation or retrieval of the OPTEASE® Retrievable Vena Cava Filter, please contact your local Cordis sales representative and we will arrange the requested training.

Why you are being contacted:	You are receiving this letter because our records indicate that you have received product of the listed catalog numbers that has not yet expired. Cordis OPTEASE® Retrievable Vena Cava Filter has a 3 year shelf life.

Available Assistance:	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:	The applicable regulatory agencies are being notified. Cordis is voluntarily taking this action and providing this information. 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 products that Cordis supplies.

Respectfully yours,



Jacqueline Maestri
WW Vice President, Quality and Regulatory Compliance
Cordis Corporation
Cardiovascular Care Franchise, Johnson & Johnson