Cordis
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Urgent Field Safety Notice (Removal)

Cordis OPTEASE® Retrievable Vena Cava Filter

Catalog Numbers	
466F210A	466F210B

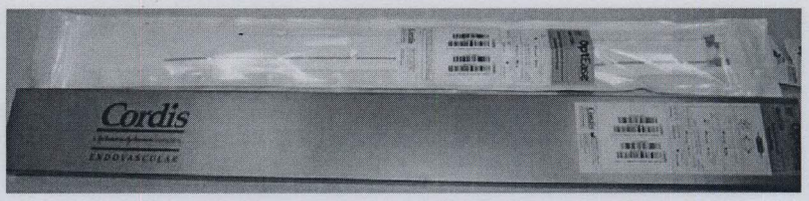
All unexpired distributed lots as of date of this letter*; Highest lot number 15960131.
*See RECALL PRODUCT LOT LIST at end of letter

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.**