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Removing Retrievable Inferior Vena Cava Filters: Initial Communication

FDA issued an [updated safety communication \(/MedicalDevices/Safety/AlertsandNotices/ucm396377.htm\)](#) on May 6, 2014.

Date Issued: August 09, 2010

Audience: For implanting physicians and clinicians responsible for the ongoing care of patients with inferior vena cava (IVC) filters. Includes interventional radiologists, interventional cardiologists, vascular surgeons, emergency room physicians (trauma), bariatric surgeons, orthopedic surgeons, primary care physicians

Device:

IVC filters are small, cage-like devices that are inserted into the inferior vena cava (the main vessel returning blood from the lower half of the body to the heart) to capture blood clots and prevent them from reaching the lungs. IVC filters are frequently placed in patients at risk for pulmonary embolism (a blood clot in the lungs) when anticoagulant therapy cannot be used or is ineffective. Some patients may require long-term protection from PE, and implantation of permanent IVC filters is often performed in these cases. Others only require short-term protection, in which case retrievable IVC filters are typically used, as these devices have the option to be removed once the patient's risk of PE subsides.

Summary of Problem and Scope:

IVC filter usage has increased rapidly during the past thirty years. In 1979, 2,000 IVC filters were used, while in 2007, almost 167,000 filters were implanted, and the market for IVC filters is only expected to increase, with an estimated 259,000 IVC filters to be deployed in 2012 (Smouse and Johar, *Endovascular Today*, February 2010).

Since 2005, the FDA has received 921 device adverse event reports involving IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture. Some of these events led to adverse clinical outcomes in patients. These types of events may be related to a retrievable filter remaining in the body for long periods of time, beyond the time when the risk of PE has subsided.

The FDA is concerned that these retrievable IVC filters, intended for short-term placement, are not always removed once a patient's risk for PE subsides. Known long term risks associated with IVC filters include but are not limited to lower limb deep vein thrombosis (DVT), filter fracture, filter migration, filter embolization and IVC perforation.

Recommendations/Actions:

FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.

FDA encourages all physicians involved in the treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient. If a patient has a retrievable IVC filter that should be removed based on his or her individual risk/benefit profile, the primary care physician and/or those providing ongoing patient care should refer the patient for IVC filter removal when feasible and clinically indicated.

FDA Activities:

This initial communication is in keeping with FDA's commitment to inform the public about emerging device safety issues. The Agency will communicate its final conclusions when the analysis of available data is complete.

As part of developing our final position, FDA reviewed the literature and is conducting quantitative decision analysis modeling to evaluate the change in the risk/benefit profile after retrievable IVC filter implantation over time. More information about FDA's decision analysis model including risk/benefit implantation timeframe suggestions will be made available in an update to this communication as well as in a future publication in a peer-reviewed medical journal.

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@cdrh.fda.gov (<mailto:DSMICA@cdrh.fda.gov>) or 800-638-2041.

This document reflects FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

More in [Safety Communications](#)
[\(/MedicalDevices/Safety/AlertsandNotices/default.htm\)](/MedicalDevices/Safety/AlertsandNotices/default.htm)

[Information About Heparin \(/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm\)](/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

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