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By Chris at 12:59 pm, Oct 24, 2019

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Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication

This safety communication updates FDA's 2010 Initial Communication. The update provides information on recently published research and postmarket studies for these devices. There are no new safety concerns related to this update.

Date Updated: May 6, 2014

Date of Initial Communication: August 9, 2010 (<https://web.archive.org/web/20170722215731/https://wayback.archive-it.org/7993/20161022180008/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm>)

Audience: Physicians who implant inferior vena cava (IVC) filters and clinicians responsible for the ongoing care of patients with these devices.

Medical Specialties: Interventional radiology, interventional cardiology, vascular surgery, trauma care, bariatric surgery, orthopedic surgery, primary care

Device:

IVC filters are small, cage-like devices that are inserted into the inferior vena cava to capture blood clots and prevent them from reaching the lungs. The inferior vena cava is the main vessel returning blood from the lower half of the body to the heart. 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. IVC filters are designed to be permanent implants although some of these devices may have the option to be removed.

Purpose: The Food and Drug Administration (FDA) is updating a previously issued Initial Communication to include information on recently published research and postmarket surveillance studies for these devices.

Summary of Problem and Scope:

The FDA has received reports of adverse events and product problems associated with IVC filters. Types of reports include device migration, filter fracture, embolization (movement of the entire filter or fracture fragments to the heart or lungs), perforation of the IVC, and difficulty removing the device. Some of these events led to adverse clinical outcomes. These types of events may be related to how long the filter has been implanted. Other known long-term risks associated with IVC filters include lower

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once the risk subsides.

Recommendations/Actions:

The 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 pulmonary embolism is no longer needed.

The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.

FDA Activities:

The FDA developed a quantitative decision analysis using publicly available data available in the medical literature to assess whether there is a time period during which the risk of having an IVC filter in place is expected to outweigh the benefits.

The decision analysis (Decision Analysis of Retrievable Inferior Vena Cava Filters in Patients without Pulmonary Embolism) was published in the **Journal of Vascular Surgery: Venous and Lymphatic Disorders** ([/web/20170722215731/https://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM396384.pdf](https://web.archive.org/web/20170722215731/https://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM396384.pdf)) in October 2013. The mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

Although the results of the decision analysis provide important insight for retrievable IVC filters, the FDA is requiring collection of additional clinical data for currently marketed IVC filters in the United States. The studies will address safety questions that remain unanswered for both permanent and retrievable filters. Manufacturers were given two options for obtaining the data. Some manufacturers are participating in the **PRESERVE** (<https://web.archive.org/web/20170722215731/http://evtoday.com/2012/10/preserve-trial-to-be-a-comprehensive-study-of-inferior-vena-cava-filters>) (PREdicting the Safety and Effectiveness of InferioR VEna Cava Filters) study, an independent national clinical study that will examine the use of IVC filters in the prevention of pulmonary embolism. Other manufacturers are conducting postmarket surveillance (**522 Studies** (<https://web.archive.org/web/20170722215731/http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm>)). The data gathered from the PRESERVE study and the 522 studies will help the FDA, manufacturers and health care professionals assess the use and safety profile of these devices, understand evolving patterns of clinical use of IVC filters and ultimately improve patients care.

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@cdrh.fda.gov** (<https://web.archive.org/web/20170722215731/mailto:DICE@cdrh.fda.gov>) or 800-638-2041.

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[Pulmonary Embolism \(PDF - 553KB\) \(/web/20170722215731/https://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM396384.pdf\)](/web/20170722215731/https://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM396384.pdf)

- **[Decision Analysis of Retrievable Inferior Vena Cava Filters in Patients Without Pulmonary Embolism \(Abstract\) \(https://web.archive.org/web/20170722215731/http://www.jvsvenous.org/article/S2213-333X\(13\)00051-6/abstract\)](https://web.archive.org/web/20170722215731/http://www.jvsvenous.org/article/S2213-333X(13)00051-6/abstract)**
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- **[PRESERVE Study to be Comprehensive Evaluation of Inferior Vena Cava Filter Use \(Endovascular Today\) \(https://web.archive.org/web/20170722215731/http://evtoday.com/2012/10/preserve-trial-to-be-a-comprehensive-study-of-inferior-vena-cava-filters\)](https://web.archive.org/web/20170722215731/http://evtoday.com/2012/10/preserve-trial-to-be-a-comprehensive-study-of-inferior-vena-cava-filters)**
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[2017 Safety Communications \(/web/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm\)](/web/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)

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