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Society of Interventional Radiology Responds to FDA Blood Clot Device (IVC Filter) Advisory

On Aug. 9, the Food and Drug Administration issued a medical alert noting that certain devices used to keep blood clots from traveling to the lungs—retrievable inferior vena cava (IVC) filters—could move or break, perhaps causing life-threatening problems for patients. SIR members—interventional radiologists who specialize in minimally invasive targeted treatments, including diagnosing indications for placing and removing IVC filters—have noted an increase in calls from concerned individuals who have IVC filters.

As always, the Society of Interventional Radiology strongly urges close communications between doctor and patient. Those individuals with IVC filters are encouraged to talk to their interventional radiologists and their other physicians about any concerns or questions. Patients with filters should always discuss with their doctors whether and when filter removal is an option.

According to the U.S. Surgeon General, between 350,000 and 600,000 people each year in this country are affected by blood clots and between 100,000 and 180,000 people die of pulmonary embolism (a blood clot that travels to the lungs) each year. Most patients with blood clots are treated with blood-thinning drugs, which are usually effective in preventing pulmonary embolism. IVC filters—small devices that are inserted inside a large abdominal vein—are a treatment option for those individuals who can't take blood-thinning drugs or who develop clots despite medication and remain at risk for pulmonary embolism. Some types of IVC filters, called "retrievable IVC filters" can later be removed by a physician. According to the FDA, use of IVC filters has grown over the years, from 167,000 in 2007 with projections to 259,000 in 2012. The majority of filters placed are intended to be left in place forever and are not intended to be removed. It should also be noted that even the filters that have the option to be removed may be left in place permanently and the filters on the market have FDA approval for permanent placement.

The FDA has recognized that some retrievable IVC filters can fracture or migrate to other parts of the bloodstream. To reduce the risks to patients, the FDA has urged physicians who implant these filters to regularly consider the risk/benefit profile for each individual patient and to give strong consideration to removing these devices from patients who may no longer be at increased risk of pulmonary embolism.

In 2006, the SIR published the document "Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference" in the Journal of Vascular and Interventional Radiology to provide clinical direction for interventional radiologists who use IVC filters. SIR's recommendations cover the indications for placement of a retrievable filter, the management of patients, the conditions for removing the filter, the evaluation of patients before filter removal and patient management after filter removal.

It is worth noting that the SIR's recommendations closely parallel the current FDA recommendations. Specifically, the SIR recommends that patients with optional or retrievable IVC filters should be periodically re-assessed as to the appropriateness of leaving the filter in place, and that it is reasonable to consider both the individual patient's risk of suffering a fatal pulmonary embolism and the risk of late device complications in making this decision. In patients in whom resumption of blood-thinning drugs is judged likely to be safe and effective in preventing pulmonary embolism, it may be appropriate to remove the filter.

Interventional radiology is a recognized subspecialty requiring dedicated training that encompasses clinical patient evaluation and management, non-invasive venous imaging, catheter venography and hemodynamic assessment, and the delivery of targeted, image-guided minimally-invasive treatments to patients. Interventional radiologists are well trained to evaluate patients who may have an indication for a filter, to determine if and what type of filter is needed and to place the filter and remove the filter if indicated.

It should be noted that there have been no recalls on the filters. The FDA says that it will issue a final statement after completing an analysis on filter problems.

SIR will provide additional information for patients as it becomes available.