

## **Patient Information about FDA Blood Clot Device (IVC Filter) Advisory**

The Food and Drug Administration issued a medical alert on August 9, 2010 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.

Individuals with IVC filters who have concerns are encouraged to talk to their vascular surgeon 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 that are 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; 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.

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.

Reprinted with permission of the Society of Interventional Radiology(c) 2010, [www.SIRweb.org](http://www.SIRweb.org). All rights reserved.