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IVC Filters

The use of inferior vena cava filters (IVC filters) has been linked to serious complications, including punctured veins and damaged organs, which can result in prolonged hospitalization and even death.

What Are IVC Filters?

IVC filters are small, metal cage-like devices designed to capture blood clots and prevent them from traveling to the heart and lungs where the clots can lodge in arteries and form life-threatening blockages. These filters are implanted in the inferior vena cava, a large vein that transports oxygen-poor blood back to the heart and lungs.

IVC filters are manufactured and marketed by several companies, including C.R. Bard (under brand names Recovery, G2, G2 Express, and Eclipse) and Cook Medical (under brand names Celect and Günther Tulip).

There are two types of IVC filters: permanent and retrievable. Permanent IVC filters are designed to stay implanted, while retrievable IVC filters are designed to allow their removal once the risk of clotting has subsided. Currently, the vast majority of the IVC filters being implanted into patients are of the retrievable kind.

Permanent IVC filters have been in use since the 1970s, but retrievable IVC filters are a much newer category. The FDA began clearing the use of retrievable IVC filters in and around 2003.

Since 2005, the FDA has been flooded with adverse device reports showing severe complications, including:

- blood vessel puncturing, followed by internal bleeding;
- organ damage such as heart punctures; and
- blockage of blood vessels, including deep vein thrombosis (DVT) and pulmonary embolisms (PE).

These are serious complications, often requiring hospitalization and sometimes leading to death.

The FDA and its counterparts in other countries have warned physicians and hospitals about the high risks associated with IVC filters. Due to the high number of reports of complications resulting from the use of these devices, both Health Canada and the Australian Therapeutic Goods Agency have recommended that hospitals identify all patients implanted with IVC filters and that they formulate a strategy to assess these patients for removal of IVC filters to reduce the known risks.

When Are IVC filters Used?

The FDA has cleared the use of IVC filters in very limited circumstances. All IVC filters on the market in the United States are only cleared for the prevention of recurrent PE when therapy with blood-thinning medication has either failed or is contraindicated.

A common off-label use (a use that falls outside the scope of FDA clearance) of IVC filters is for prevention of PE in patients without a history of PE. The prophylactic use of IVC filters is most common with trauma, cancer, and intensive care patients, as well as in bariatric surgery and neurosurgery. These are settings in which the risk of PE is very high, and other modes of treatment – such as blood-thinning drugs – are likely to be less effective or are contraindicated.

Complications and Long-Term Risks

IVC filters are known to be at risk of fracturing, shifting, migrating, or lodging in blood vessel walls. These events can lead to severe and potentially life-threatening health complications such as internal bleeding, blocked blood vessels, or organ damage. Moreover, according to the FDA, the long-term use of IVC filters is also known to increase the risk of DVT, and of the blockage of the inferior vena cava, the blood vessel in which the device is originally implanted.

Because the risks of complications increase the longer the IVC filter remains implanted, the FDA encourages clinicians to remove the filters as soon as the danger of PE has passed. But the reality is that the majority of retrievable IVC filters are never retrieved. Moreover, studies have shown that retrieval may not even be possible in some cases. Thus, these devices continue to pose a growing risk to the patients in whom they are implanted.

FDA Safety Warnings

Although the FDA has not banned the use of IVC filters, it has issued two Safety Communications about the severe risks associated with these devices.

- On August 9, 2010, the FDA issued an Initial Safety Communication about retrievable IVC filters, disclosing that it had received 921 device adverse reports since 2005. About a third of the reports involved device migration, while the remainder described components of the device detaching, perforation of the inferior vena cava, and filter fracture. The FDA stated that it was "concerned that these retrievable IVC filters, intended for short-term placement are not always removed once a patient's risk for PE subsides."
- On May 6, 2014, the FDA released an Updated Safety Communication, addressing the multiple reports of "adverse events and device problems associated with IVC filters." In view of these reports, the FDA now recommends that clinicians responsible for patients with IVC filters consider removing these filters "as soon as protection fro pulmonary embolism is no longer needed."

For more information, please visit the FDA's website: https://www.fda.gov/MedicalDevices/default.htm.

Lawsuits

Multiple lawsuits have been filed in the United States against the manufacturers of IVC filters, including C.R. Bard and Cook Medical. These lawsuits seek compensation for medical injuries associated with their respective IVC filters, claiming that the manufacturers were negligent in selling these dangerous devices.

How We Can Help

If you have suffered serious health problems after being implanted with an IVC filter, or if your doctor has advised you that you need special monitoring or care to make sure that an IVC filter does not cause any complications in the future, you may be entitled to reimbursement for medical expenses, lost wages, and other costs. Attorneys at Wilentz, Goldman & Spitzer P.A. may be able to help you recover compensation if you suffered serious harm from an IVC filter. As a nationally recognized personal injury law firm, Wilentz is committed to helping clients with their cases.

For a free consultation or more information about your legal options, please call the number below. Or, if you prefer to complete our free case evaluation form, our client relations representative will contact you shortly.

To speak with an attorney about your legal options, please call: 732-855-0375.