IVC FILTERS A PUBLIC HEALTH CRISIS of EPIDEMIC PROPORTIONS

As estimated 2 million patients in the United States alone have been implanted with (Inferior Vena Cava Filters) IVC filters over the past several decades. Many of those implanted with IVC Filters are at risk of serious injury and death however, the vast majority of these individuals are unaware of the risk they currently face. Additionally, these individual's primary physicians may be unaware as well especially in situations where the IVC filter was implanted by a surgeon before the individual became their patient. This problem has been exacerbated by the changes in our healthcare system which have caused millions of Americans to switch their primary physician. The surgeons who initially implanted these filters have often discharged the IVC recipient from their care and many years have passed since the given patient has been under their care.

After a massive number of Adverse Event reports were filed with the FDA related to IVC filters and numerous studies demonstrated that many if not all IVC filters will eventually fail, the FDA finally took action.

In 2010 the FDA issued its first advisory regarding the safety of IVC " 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 indicate

In 2014 the FDA issued an even stronger advisory: " 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 2014 FDA Advisory also summarized the scope of the problem with IVC filters: "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."

The 2014 FDA advisory also summarized the problems with IVC filters as well as the scope of the problems: "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 limb deep vein thrombosis and IVC occlusion. For patients with retrievable filters, some complications may be avoided if the filter can be removed once the risk of pulmonary embolism has subsided. The FDA is concerned that retrievable IVC filters, when placed for a short-term risk of pulmonary embolism, are not always removed once the risk subsides."

Why Do IVC Filters Pose a Massive Public Health Risk

For the majority of the past few decades in which IVC Filters have been implanted, the majority of filters implanted were designed to be "permanent", after becoming aware of the problems with IVC filters manufacturers began designing IVC filters intended to be retrievable. In most cases the major difference in a "permanent" IVC filter and a retrievable IVC filter consists of the addition of a hook which will allow a surgeon to grasp with a wire or other retrieval device. These hooks are generally found on the top of the IVC filter and require the surgeon to approach the filter through the jugular vein to attempt removal.

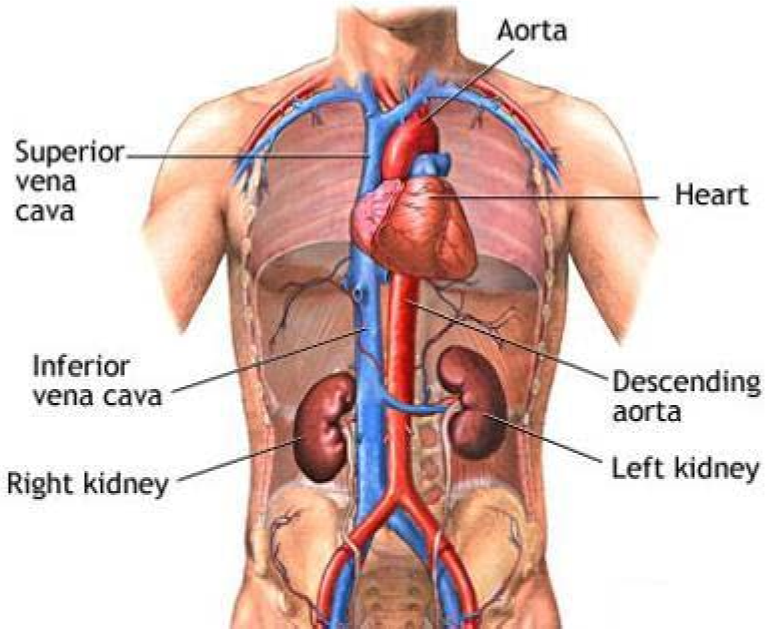
In 2010 and more strongly in 2014, the FDA advised surgeons to consider removing the device when the extreme risk of Pulmonary Embolism lessened, In most cases this would mean the IVC filter would be removed within weeks of implantation. The FDA advisory undoubtedly caused many surgeons who implant these devices to change their practices after the advisory was issued however, this change in practice does nothing for patients implanted with an IVC Filter implanted prior to the change.

In that the implanting surgeon generally discharges the patient from their care, leaving the patient to the care of their primary care physician, the public health crisis we now face can be summed up as follows:

- As many as 2 million Americans Have IVC Filters.
- Most if not all IVC Filters Will Eventually Fail
- Most IVC Filter Patients are no longer under the care of the implanting surgeon.
- Many IVC Filter Patients are no longer under the care of the same primary physician that would have **"followed up"** and aware of their implant.
- In that most implant patients were not told the filter would be removed, these individuals are not aware they are at risk.
- Although the FDA now recommends close **"Follow Up"** and quick removal of IVC Filters, in many if not most cases, the implanting IVC Surgeon is no longer in the picture and the patient's current primary care physicians are not "following up" unless the patient becomes symptomatic and present for care. Unfortunately, the first symptom in many cases may be death.
- Making the crisis even more is the fact that many of the IVC filter indwelling in patients, even those designed to be retrieved will have embedded and will require open cavity surgery to retrieve. In many cases the surgery necessary to retrieve a filter or filter part may also cause severe injury or death.

Conclusion: A massive number of Americans with indwelling IVC filters are seconds away from potential death. As this paper will explain, an IVC filter patient could be perfectly fine one moment and within less than a second, the IVC filter or part of the IVC could migrate, often to the heart, and the first symptom is often severe life altering injury or death.

The Function of the Inferior Vena Cava



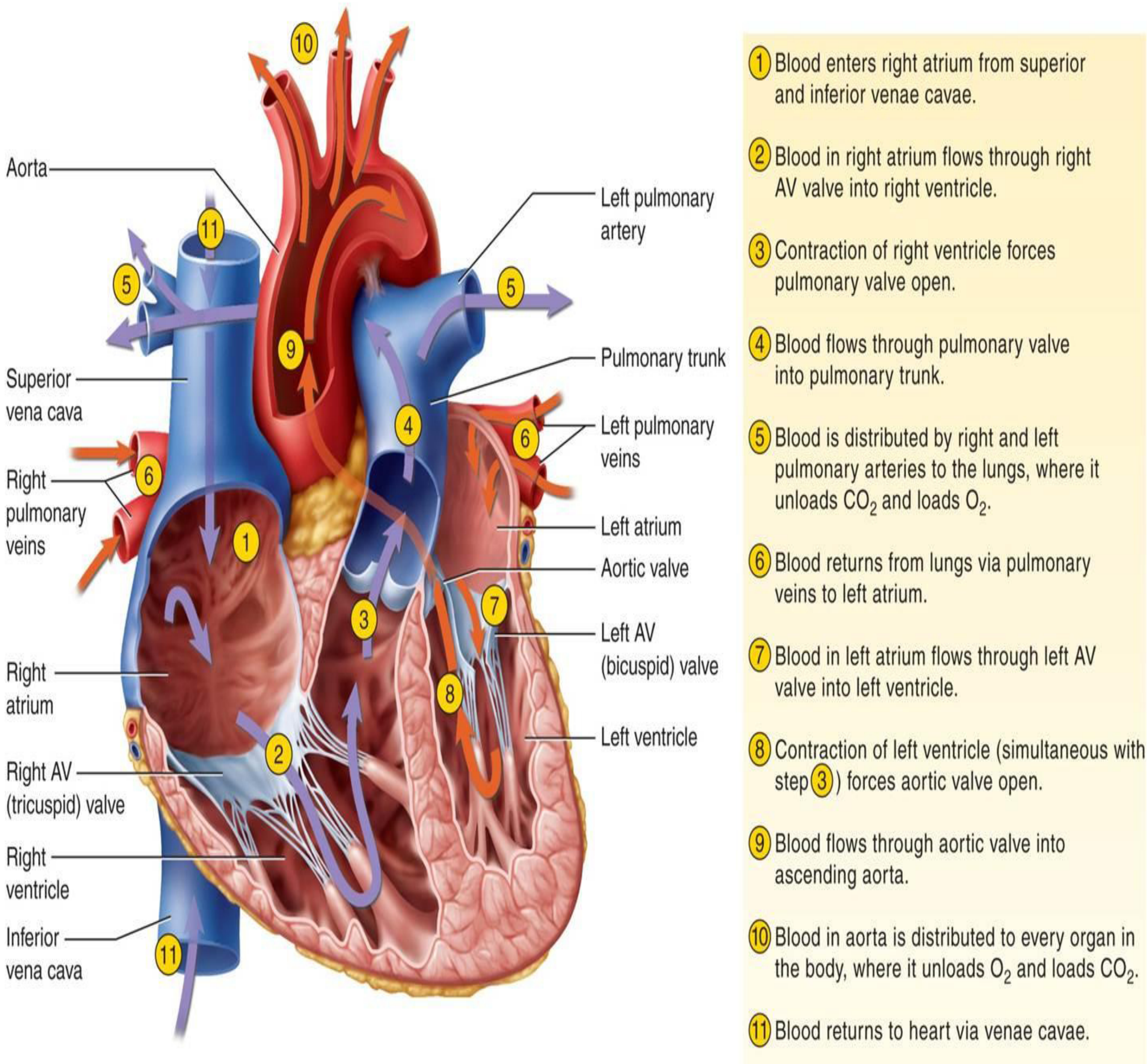
The inferior vena cava is the largest vein in the human body. It collects blood from veins serving the tissues inferior to the heart and returns this blood to the right atrium of the heart. Although the vena cava is very large in diameter, its walls are incredibly thin due to the low pressure exerted by venous blood.

The inferior vena cava forms at the superior end of the pelvic cavity when the common iliac veins unite to form a larger vein. From the pelvis, the inferior vena cava ascends through the posterior abdominal body wall just to the right of the vertebral column Along its way through the abdomen, blood from the internal organs joins the inferior vena cava through a series of large veins, including the gonadal, renal, suprarenal and inferior phrenic veins. The hepatic vein provides blood from the digestive organs of the abdomen after it has passed through the hepatic portal system in the liver. Blood from the tissues of the lower back, including the spinal cord and muscles of the back, enters the vena cava through the lumbar veins. Many smaller veins also provide blood to the vena cava from the tissues of the abdominal body wall. Upon reaching the heart, the inferior vena cava connects to the right atrium on its posterior side, inferior to the connection of the superior vena cava.

The inferior vena cava and its tributaries drain blood from the feet, legs, thighs, pelvis and abdomen and deliver this blood to the heart. Many one-way venous valves help to move blood through the veins of the lower extremities against the pull of gravity. Blood passing through the veins is under very little pressure and so must be pumped toward the heart by the contraction of skeletal muscles in the legs and by pressure in the abdomen caused by breathing. Venous valves help to trap blood between muscle contractions or breaths and prevent it from being pulled back down towards the feet by gravity.

Blood Flow To and Through the Heart

The following image depicts the blood flow to and through the heart. Understanding the initial placement of IVC filters and the blood flow pathway to the heart will assist the reader in understanding why, where and how IVC Filters migrate to other parts of the body without necessarily having penetrated the Inferior Vena Cava wall.



The heart consists of four chambers, two atria (upper chambers) and two ventricles (lower chambers). There is a valve through which blood passes before leaving each chamber of the heart. The valves prevent the backward flow of blood. These valves are actual flaps that are located on each end of the two ventricles (lower chambers of the heart). They act as one-way inlets of blood on one side of a ventricle and one-way outlets of blood on the other side of a ventricle. Each valve actually has three flaps, except the mitral valve, which has two flaps. The four heart valves include the following:

- tricuspid valve: located between the right atrium and the right ventricle
- pulmonary valve: located between the right ventricle and the pulmonary artery
- mitral valve: located between the left atrium and the left ventricle
- aortic valve: located between the left ventricle and the aorta

How do the heart valves function?

As the heart muscle contracts and relaxes, the valves open and shut, letting blood flow into the ventricles and atria at alternate times. The following is a step-by-step illustration of how the valves function normally in the left ventricle:

- After the left ventricle contracts, the aortic valve closes and the mitral valve opens, to allow blood to flow from the left atrium into the left ventricle.
- As the left atrium contracts, more blood flows into the left ventricle.
- When the left ventricle contracts again, the mitral valve closes and the aortic valve opens, so blood flows into the aorta.

How Quickly Can an IVC Filter Migrate to the Heart?

How long does it take for blood to make the round trip through the body? A typical human body contains 5.6 liters (6 quarts) of blood. “The heart pumps about 2,000 gallons (7,571 liters) of blood a day through its chambers.”

2,000 gallons per day works out to 83 gallons per hour, or nearly 6 quarts per minute. So it takes about one minute for blood to make the round trip to the heart. If you are running fast, your heart is pumping more blood so the time would be less.

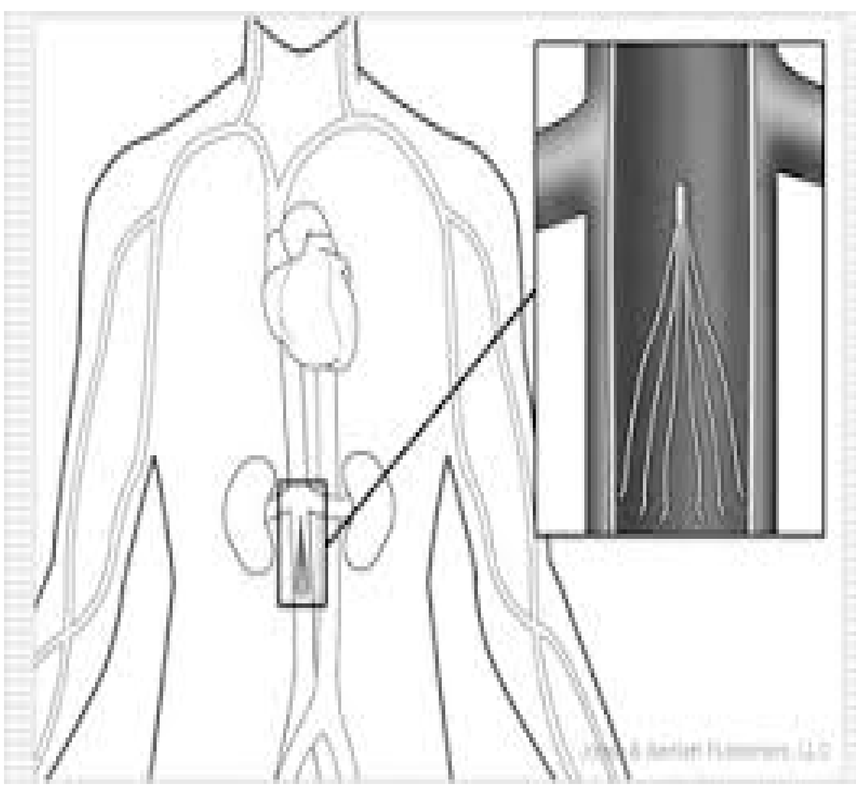
Clinically normal human blood pressure (120/80 mmHg): 2.32/1.55 Pounds Per Square Inch (psi). Therefore each time the heart beats the blood is alternately exerting a force of 2.32/1.55 psi on the filter structure.

The top number, which is also the higher of the two numbers, measures the pressure in the arteries when the heart beats (when the heart muscle contracts) and is called systolic.

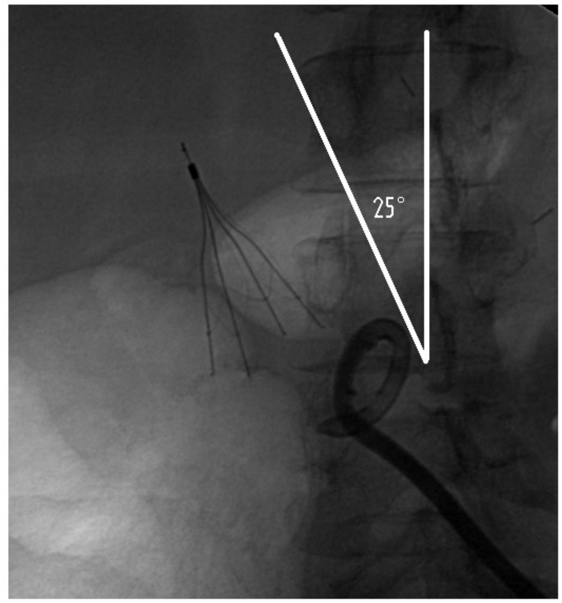
The bottom number, which is also the lower of the two numbers, measures the pressure in the arteries between heartbeats (when the heart muscle is resting between beats and refilling with blood) and is called diastolic.

The pumping action of the heart raises and lowers the pressure exerted on the IVC filter from 2.32 PSI to 1.55 PSI with blood pressure at 120/80.

In that the inferior vena cava empties directly into the right atrium and considering short distance between proper IVC filter placement and the right atrium, we can conclude that it would take approximately 1 to 2 seconds for a free floating IVC filter or IVC Filter part to migrate from its original placement to the right atrium of the heart.



This image depicts the normal placement of an IVC filter, slightly below the renal veins and only inches from the point at which the Inferior Vena Cava empties into the Right Atrium of the heart.



Filter at Proper Angel

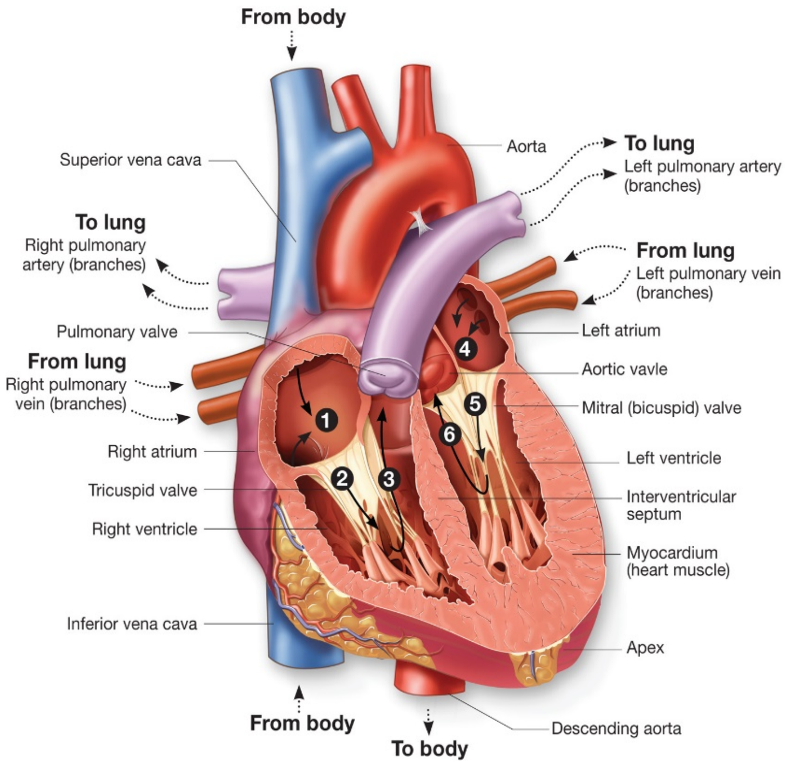
Filter Which has Tilted

<u>Effect of Blood Flow and Blood Pressure on IVC Filters</u>

This increase and decrease in pressure exerted on and IVC filter causes a similar effect that would be achieved by taking a coat hanger and bending it back and forth until metal fatigue occurred and the coat hanger broke. Anyone who has ever locked themselves out of a car should be familiar with this concept.

When filter "tilt" occurs, the struts distal to top of the filter tilt angle will penetrate deeper into the wall of the inferior vena cava (possibly penetrating the inferior vena cava completely) while the struts proximal to the filter tilt angel will become less or completely detached from the wall of the inferior vena cava. When tilt occurs, the natural increase and decrease of pressure exerted by normal blood flow will mimic the effect of bending a coat hanger back and forth. Ultimately struts or other components of the filter will break free and migrate.

Eventually as the filter is essentially torn apart by the pressure exerted by normal blood flow, the filter will become completely detached from the wall of the inferior vena cava resulting in a high probability of total filter migration. During this process struts and other components of the filter are likely to detach and become smaller free floating foreign bodies which can migrate and damage organs along the blood flow pathway.



As previously stated, the filter or any part of the filter is free floating in the Inferior Vena Cava, it will take less that one second for the filter to enter the right atrium of the heart. The Inferior Vena Cava empties directly into the right atrium. If the migrated filter makes it past the tricuspid valve, located between the right atrium and the right ventricle, the migrated filter or filter part will enter the right ventricle.

In the event the filter or filter part continues to migrate past the right ventricle, depending on the size filter or filer part migrating, the blood flow pathway will propel the filter into the right pulmonary valve. If the filter or filter part continues to migrate, it will enter the pulmonary artery and pass to the left lung.

As the IVC filter travels along the migration pathway described above, the possibility of the filter snaring to tissue is likely. If the filter snares in the right atrium, tricuspid valve, right atrium or the pulmonary artery, damage to these anatomical structures is likely. Additionally, once snared the same process that originally caused the filter to partially break apart, will likely occur again, resulting in an increased number of filter fragments free floating in the blood stream. The smaller filter fragments have an increased probability of making their way to the left lung. These smaller fragments can potentially pass through the lung, causing damage along the way and pass back into the blood stream with the oxygenated blood leaving the lung. Once a filter fragment has past the left lung, migration to other parts of the body becomes inevitable.

This is the first in a series of white papers intended to familiarize plaintiffs' attorneys with scope and intent of the problem with IVC filters. This first paper is intended to provide the reader with a general understanding of the function of the Inferior Vena Cava, why Fracture. Migration and other life threatening problems can occur so quickly and why all IVC filter recipients with an indwelling filter are at extreme risk.

In future papers we will cover other subjects such as:

1. Complications with IVC Filters
2. How to Identify a Specific Brand of IVC Filter on X-Ray even though many appear similar (Implant records may not be available and X-Ray identification of brand may be necessary)
3. What the makers of IVC Filters knew and when they knew it.
4. The current status of IVC filter litigations across all brands and manufacturers.
5. Why some filters pose greater risk than others.
6. What potential clients need to know and the steps they should consider taking to reduce the risk of death or injury from their IVC filter.
7. Why the implantation of a permanent filter even without injury, should be compensable.
8. The only IVC Filter Potential Client that does not have a claim.
9. The risks associated with (by defendant) associated with accepting IVC Filter cases on contingency. Should you or shouldn't you.