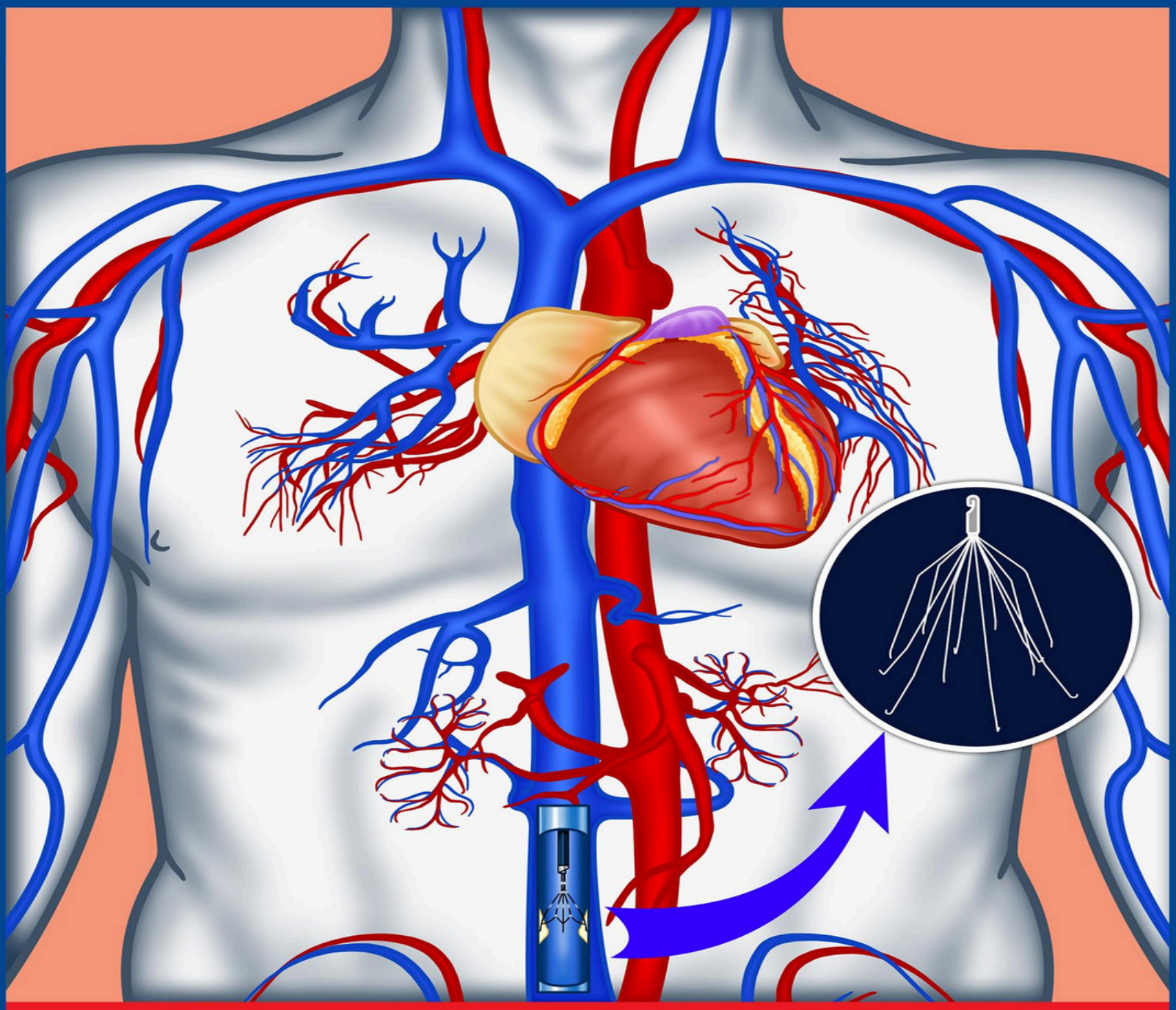
Blood Trap: The Dangers of IVC Filters



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First Edition

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Contents

Introduction

Technological advances in medicine are a testament to the ingenuity and progress that our world's scientists triumph for. From medicines to diagnostics and preventive therapies, advances in medicine are a long way from where they were, when many still believed our earth was flat and the center of the universe. With progress comes an expectation that available medical technologies are safe for consumer use; an expectation that the medicine will help, not cause harm. Unfortunately, that expectation has been compromised with the numerous injuries and deaths related to IVC Filters.

If you or a loved one has been injured or otherwise negatively affected by an IVC filter, you are not alone. Reports of numerous deaths and injuries related to IVC filters have dominated headlines for the past several years. According to NBC News, at least 27 deaths and over 300 non-fatal instances have been reportedly linked to at least one type of IVC Filter.**1** Those are terrifying numbers when you consider that those statistics are several years old and hundreds of thousands of patients are implanted with multiple types of IVC filters manufactured by several well-known

companies. Anyone with an IVC filter or anyone considering having one implanted should have a thorough conversation with their doctor about the potential risks, so they can make a well-informed decision considering their next steps. Anyone injured by an IVC filter should speak to an experienced medical device attorney about their options. You have rights!

What Should You Do If You Have an IVC Filter or You Have Suffered Injuries from an Implanted IVC Filter?

- Talk to your doctor. If you think you may be having issues related to your IVC Filter, it is imperative that you seek immediate medical attention!
- Consider your options. Whether it is having your IVC Filter removed or finding out about additional treatment options, you should talk to your doctor and/or other medical professionals about what treatment plan is right for you.
- Keep Records, including but not limited to medical documents and insurance records related to your IVC filter. It is imperative to know what kind of filter you have. Additionally, consider keeping a diary of all the medical treatment(s) you have had related to issues with your IVC filter. Knowing as much as you can about your history with your IVC filter may be

helpful in determining what your options may be.

- Talk to an experienced medical device injury attorney about your options for obtaining compensation for your damages.

This informational guide on IVC filters is intended to help anyone that may have been injured by one of these devices. A brief history of the device and its reported problems is followed by the steps you can take to find out what help may be available to you or a loved one who is injured by an IVC filter. Our medical device attorneys hope this information will be useful in providing guidance to those that may not know what options they may have in regards to a potential IVC injury claim. Every case is different but hopefully the information in this guide will serve as a starting point for moving forward.

Section I: What You Need to Know About IVC Filters

Information on IVC filters ranges from complex medical studies from well recognized peer reviewed medical journals to eye catching articles in the news. We have gathered basic and easy to comprehend information about IVC filters:

What is an IVC Filter?

"IVC stands for Inferior vena cava which is a major blood vessel that returns blood from the lower body to the heart. An IVC filter is a small piece of metal, made of nitinol or stainless steel that can be placed into the IVC to prevent blood clots in the legs from traveling to the lungs2."

Why Would Someone Need an IVC Filter?

A simple explanation is that an IVC Filter may be implanted in a patient to prevent blood clots from traveling to the lungs or heart. Many IVC filter recipients are implanted with the device because they suffer from or are at risk of developing deep vein thrombosis (DVT). A DVT is a blood clot that generally forms inside the veins

in a patient's lower leg or thigh. DVT can cause swelling, pain and soreness in a patient's leg. In a severe case, a blood clot may become unattached from the initial position in the patient's legs and travel to the patient's lungs. When this occurs, there is a potential for a blockage in the lungs called a pulmonary embolism (PE). PE can result in trouble breathing or death.

In many patients, there is a need for the IVC filter because anticoagulant therapy (blood thinners) has failed or is contraindicated (unadvised). Additionally, an IVC filter may be prescribed when emergency intervention is required and other treatments have reduced anticipated benefits.

IVC filters are used to prevent patients from developing PE but ~~not~~ DVT. The inferior vena cava helps transfer blood throughout the body. The blood travels from the lower body to the heart and then from the heart to the lungs. This process is used to carry oxygen throughout the inside of your body and it is essential. An IVC filter is implanted in the inferior vena cava and designed to catch blood clots and prevent them from moving into the heart and lungs. Again, IVC filters do not prevent blood clots from developing, they work to prevent the blood clot from resulting in a PE.

How is an IVC Filter Implanted?

The short answer is that an IVC filter is typically implanted through a catheter in the femoral vein in the groin or internal jugular vein in the neck. A small incision will be made where the catheter is to be inserted. An interventional radiologist uses image guidance to help place the filter. This means that contrast material would be delivered into the patient's IVC via the catheter so the positioning of the IVC filter may be done with greater precision. The IVC filter is placed into the IVC through the catheter and once it is positioned in the preferred location, the catheter is removed. The procedure is typically an outpatient procedure that can take as little as an hour to perform. Patients will be lying down and IV sedation may be used. Depending on the level of sedation, the patient may or may not be awake during the procedure.

Is IVC Placement Permanent?

Science behind the IVC filter is not new. In fact, the theory of preventing PE dates back into the 18th century3. The first filter that could be placed inside of a patient through the skin as opposed to an open surgery was

developed in 1967. That device was called the Mobin-Uddin Umbrella, also known as the first percutaneous IVC filter. The Mobin-Uddin filter was later replaced by the GreenfieldTM filter developed by Lazar GreenfieldTM which had a lower rate of filter related complications4.

IVC filters used today are most likely going to be marketed as being potentially removable if necessary but also suitable for permanent life time placement. They are referred to as optionally retrievable filters.

Patients with an IVC filter that is retrievable may have their IVC filter removed after the risk of a blood clot traveling to the lungs or heart has passed. A patient's doctor will be able to make the decision on whether it is safe to remove the filter. There is generally a limited amount of time to retrieve an IVC filter. The longer an IVC filter is placed inside of the IVC, the more difficult it may be to retrieve. Common reasons that a filter cannot be retrieved include the IVC getting stuck to the wall of the IVC, the filter becoming filled with large blood clots and the patient not being on the correct amount of blood thinning medication5. Note that a doctor may prescribe a blood thinner to IVC filter patients after the IVC filter has been implanted or to prepare for the IVC filter retrieval procedure. This is done to prevent clotting.

A 2014 FDA Safety Communication made the following recommendation:

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 status6.

What Are the Potential Risks of IVC Filter Implantation?

Potential complications from having an IVC filter implanted vary. There are reports that some IVC filters have fractured. There are also reports of IVC filters moving or "migrating" to positions in the IVC other than the site of initial placement. This can not only make the IVC filter less effective but it can also potentially cause injuries such as perforation of the IVC and an embolization, i.e. the whole blood clot filter or pieces of

it (fractures) from the IVC filter can travel to the heart and lungs, potentially causing death. Additionally, there is the risk that an implanted IVC filter may not be able to be retrieved. A temporary implantation may result in permanent placement inside of a patient's IVC.

IVC Regulation

"The first marketed IVC filter, the Mobin-Uddin umbrella filter, was introduced to the market in 1967 without the clearance currently required by the FDA, 9 years before the Medical Device Amendments were passed. Because the device was already on the market before the FDA began regulating medical devices, IVC filters were classified in 1976 as pre-amendments devices. Later, IVC filters were reclassified as Class II devices based on the FDA's current classification system7."

Medical devices are divided into three different groups. They are classified into Class I, II, and III. Regulatory control or FDA scrutiny increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.

Without writing a detailed description of all the statutory requirements and oversight required for IVC Filters to be lawfully marketed in the United States, it is important to note that the FDA works with over 6,500 medical device manufacturers. There are guidelines in place meant to protect people from dangerous drugs and medical devices. Unfortunately, they are not 100% effective in preventing serious injury and/or death. Regardless of the FDA's heavy work load and inefficiency of bureaucratic hoops manufacturers must jump through, there is a problem. If the current system did not need to be improved, we would not have the numerous reports of injuries and deaths related to the consumption and use of dangerous drugs and defective medical devices. Changes in the oversight of drugs and medical devices are necessary. Manufacturers of medical devices such as IVC filters must be made to design, manufacture and market medical devices that are safe for human consumption. When they fail, they should be held accountable.

Section II: Claims Against IVC Filter Manufacturers

Dangerous Devices?

It should be clear that there is no argument that all IVC Filters are defective or that all medical device manufacturers are negligent. There are thousands of safe products on the market and they are all examples of when oversight, testing, research and design are functioning properly. Unfortunately, there are examples of when there are failures and dangerous products do make it to market. The following are several examples of reported issues with certain types of IVC filters.

GreenfieldTM Vena Cava Filter

GreenfieldTM filters are manufactured by Boston Scientific, an international developer, maker and vendor of medical devices. Based on information from the manufacturer's website, the possible adverse events most commonly associated with GreenfieldTM Vena Cava filters include incorrect release or placement of the filter, filter migration, formation of clots that could create a complete blockage of the vein, bruising or bleeding of

the insertion site, infection, attachment failure, perforation of the inferior vena cava, pulmonary embolism, air embolism during device placement, insertion site thrombosis and death. There have been multiple lawsuits filed against the manufacturer of the GreenfieldTM Vena Cava Filter. Those claims argue that negligence on behalf of the manufacturer resulted in serious injury and death. Specifically, the cases argue that the manufacturer did not provide adequate warnings regarding the risks associated with these IVC filters. Those risks included product movement and migration and perforation of the IVC filter. One suit claims that despite knowledge of the defective nature of the filters as early as 2004, the manufacturer allegedly disregarded the risks related to the devices and continued to market the filters.

C.R. Bard Eclipse® Vena Cava Filter

A lawsuit filed in the U.S. District Court for the District of Arizona claims the manufacturer of the device sold defective devices with unreasonably dangerous risks and failed to warn of side effects. The suit also claims the manufacturer inadequately tested the device for safety. The product was approved by the FDA in January of 2010 but the FDA did not require clinical trials for the product

because it was so similar to another previously approved product. What is confusing about this is that the product that it was so similar to has previously been linked to safety concerns and withdrawals from the market by the manufacturer. That product was estimated to fracture in over 30% of patients within 6 years of it being implanted. If the allegations of negligence are true, it would stand to reason that a dangerous product was not prevented by reaching the market and while it was on the market the manufacturer knew of its potential hazards.

Cordis TrapEase® Permanent Vena Cava Filter

In November of 2011, the Journal of the American Medical Association Internal Medicine reported a study linking the device with a 50% risk of fracture. Studying people that had been implanted with the device for an average of 50 months, half of the study's participants had fractured devices. Additionally, the study suggests the risk increases over time. Some study participants had multiple fractures. If accurate and true why would anyone market this device for permanent use?

Cordis OptEase® Retrievable Vena Cava Filter

A 2005 study in the Journal of Trauma-Injury Infection & Critical Care reported that Cordis OptEase® IVC filter increased the risk of puncturing the vena cava wall after one month. Safe removal of the device after extended periods of time was prevented by strut perforation through the vena cava wall. Other issues with this device included a recall of 33,000 of the filters due to a labeling error that could cause the filter to be implanted backwards. If not implanted correctly the device would be able to easily migrate to the heart.

Cook IVC Filters

The Cook Gunther Tulip® IVC filter was approved by the FDA in 2003. It was followed by the Cook Celect® IVC filter, which was approved by the FDA in 2008. An April 2012 study published in Cardiovascular Interventional Radiology found that 100% of Cook Celect® and Gunther Tulip® IVC filters perforated patients' vena cavas within 71 days of being implanted. The researchers also determined that 40% of the devices were tilted and out of position. A year later, a JAMA Internal Medicine study stated that fewer than 10% of IVC filters were

successfully removed, and 8% of IVC filter recipients suffered a pulmonary embolism despite the devices' presence. Cases involving these IVC filters manufactured by Cook Medical are pending in a multidistrict litigation underway in U.S. District Court, Southern District of Indiana.

Section III: The Injured

IVC filters are associated with multiple known risks including serious injuries and/or even death. While physicians would never prescribe a treatment they knew would absolutely do more bad than good, thousands of people have been injured by these devices. These are just a few stories. Please note that these are not our clients.

IVC Filter Injury Victim 1

An Illinois woman underwent surgery in 2009 to insert a Bard G2 IVC Filter. Two years later she was admitted to the hospital for moderate chest pain and discomfort that had gradually worsened over several days. Her symptoms included nausea, vomiting, sweating, difficulty breathing, cough, weakness and dizziness. She was diagnosed with cardiac tamponade/pericarditis and

underwent a pericardiocentesis. Her discomfort continued and several days later she underwent a CT scan which showed metallic fragments in the right ventricle of the heart and in the right lung which were determined to be “spokes” that had broken off from the defective IVC filter. She later underwent open heart surgery for removal of the G2 IVC filter strut from the right ventricle of her heart. It was determined that the two remaining fractured struts in her lungs should not be touched, because removing them would be too dangerous. The IVC filter was removed through a separate surgery. Two fractured struts from the IVC filter are permanently lodged in her lungs. The fractured portions of the device migrated to vital organs, including her heart and lungs, causing injury and damage. She has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, disability, disfigurement and other losses, which are permanent in nature.

IVC Filter Injury Victim 2

In the fall of 2010, a Mississippi man underwent the placement of a Bard Eclipse IVC filter. The Eclipse Filter implanted in him subsequently “grossly tilted” to the point where it was “almost horizontal”; perforated the

inferior vena cava to the extent that “at least 5 of the prominence of the filter were seen outside of the IVC with 2 of the legs abutting the anterior and posterior wall of the abdominal aorta”; migrating such that the legs of the Eclipse filter now overlap the central end of his venous stent; and the filter, which was intended to be retrievable, can no longer be removed, which will ultimately result in the arms and/or legs of the Eclipse filter fracturing and embolizing (if this has not already occurred). He has suffered and will continue to suffer significant medical expenses, pain, suffering, emotional distress, loss of enjoyment of life, psychological trauma, anxiety, lost wages, loss of earning capacity, the need for medical monitoring of the Eclipse filter, and other damages as well.

IVC Filter Injury Victim 3

A California woman underwent the placement of a Cook Celect® IVC Filter in 2008. The Cook Celect® IVC Filter subsequently failed, two limbs fractured and one arm of the filter fractured, embolized and lodged in the right side of her heart; the filter also migrated and perforated her inferior vena cava walls and protruded into her right kidney. She has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of

enjoyment of life, disability, scarring, disfigurement and other losses. She requires ongoing medical care.

IVC Filter Injury Victim 4

In November 2011, an Ohio man was implanted with a Gunther Tulip® Vena Cava filter manufactured by Cook Medical Inc. In 2012 he presented to a hospital with complaints of lower quadrant groin pain. A CT scan was taken and demonstrated that three of the four primary struts of the filter had perforated his IVC. One strut was projecting toward and eventually pierced through the duodenum, the first part of the small intestine immediately beyond the stomach. The other two are embedded within the anterior aspect of the right psoas muscle and the L3 vertebral body. Further removal procedures were not recommended. He required blood thinning medication for the rest of his life and he is at high risk for hemorrhage.

Every Case Is Different

The preceding brief accounts concisely described four life changing, debilitating and disabling injuries. They did not experience the exact same injuries, but they were all injured by IVC filters. These people probably have more

in common than just their IVC filter injuries. They probably work hard. They probably enjoy spending time with their family. They laugh, cry and feel pain just like everyone else. They also deserved better than they got. No one knows what will happen with them in the future. Hopefully they can be given the best potential outcomes through their future medical care and options that are available to them through the civil justice system.

Future Direction and Final Thoughts

IVC Filters are linked to numerous severe injuries. It isn't just one type or brand of IVC filter that is accused of causing injury and death, there are multiple manufacturers and products that are blamed. Some people may blame the FDA for fast tracking products to market with not enough testing and scrutiny. Others may blame the medical community for prescribing the product in the first place.

Whether or not manufacturers of these products will be held responsible, is a legal question that juries will have to answer for the many that will choose to protect their rights and present their facts in court. Victims willing to fight negligent product manufacturers not only protect

themselves but they make the world a safer place. Every time a large company is held responsible for their wrongs, the world takes notice. Whether it is exploding gas tanks, cigarettes or pharmaceuticals, a verdict against a negligent manufacturer most certainly results in safer products.

The information provided in this guide hopes to explain basic information about IVC filters and injuries related to IVC filters. This information is not a substitute for important questions that people should ask their doctors. Certainly, some IVC filters have provided benefits to some patients. Not every IVC filter is bad, but with the amount of people being injured by IVC filters of different makes and models, there is an obvious issue that needs to be addressed. Our hope is that patients will make informed decisions about whether or not IVC filters are right for them. We also wish for safer products through better oversight, testing, research and design.

Lastly, we want anyone injured by an IVC filter to investigate their options. Whether it is with our law firm or another, please make sure you speak to someone about your IVC filter injury case as soon as possible. Know your rights!

Have You Been Injured by an IVC filter?

If you or a loved one suffered harm after having an IVC filter implanted, you may have lots questions, such as:

- Who will pay for my medical bills?
- Am I entitled to compensation for lost wages?
- How will I pay for my future medical care?
- Who will pay for my loved one's funeral expenses?
- Can I be compensated for my loss of enjoyment of life?
- What damages does the law allow me to claim?

A qualified attorney that handles IVC filter injury claims can help you answer these questions.

You may be entitled to compensation that could reimburse you for economic damages and other claims such as loss of consortium and pain and suffering.

Your journey to a fair outcome begins with retaining the right lawyers – professionals who understand how to obtain fair compensation for clients; lawyers with systems and processes in place to keep you up to date about your case's status and clear about your options.

The medical device attorneys at Auger Law have experience fighting and obtaining successful results for clients that have been injured due to the negligence of others. Over the years, our firm has secured over $50 million for injury victims and their families.

At Auger Law, we offer a free initial consultation with one of our attorneys or professional staff members. A case evaluation allows us to review the specifics of your claim. We take our cases on a contingency-fee basis. We don't get paid unless there is a successful result in your case. Our Zero Fee GuaranteeTM is our trade mark promise to our clients that means we only get paid if we are able to successfully conclude your case with a positive result.

To get started with your free initial consultation today, contact us at (800) 559-5741. We are available to talk 24 hours a day, 7 days a week.

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