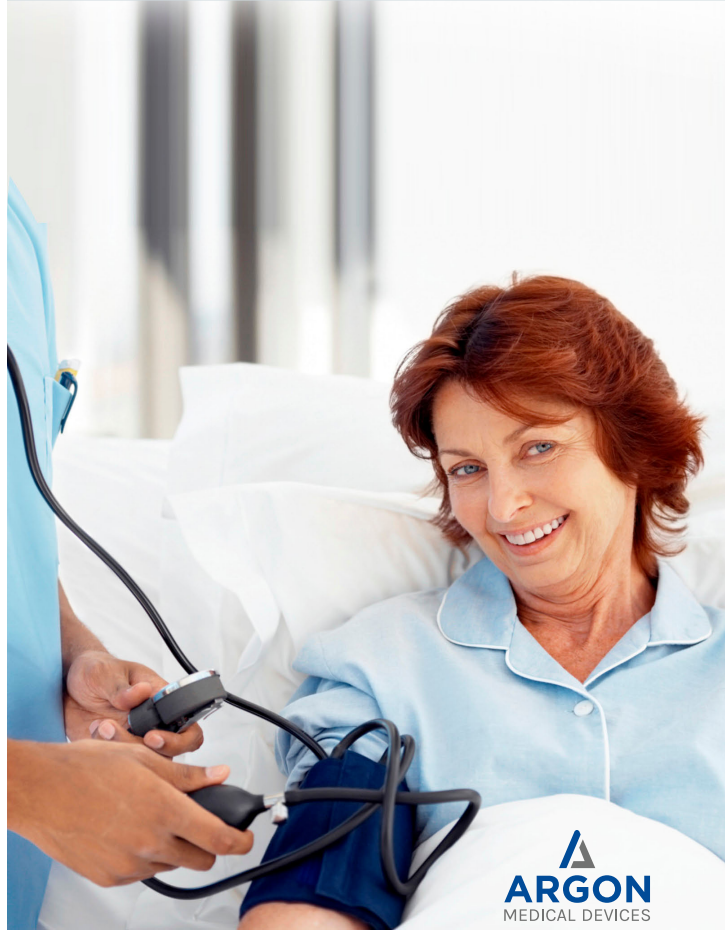


Option™ ELITE

Retrieval Vena Cava Filter

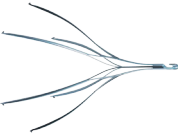
Patient Guide

A Safe Option for a Healthier You!



Option™ ELITE Retrieval Vena Cava Filter

Carry this card with you at all times.
The Option™ ELITE Vena Cava Filter is a Nitinol device placed in the inferior vena cava for the prevention of Pulmonary Embolism.



Fold Here



MR Conditional: The IMPLANT was determined to be MR Conditional according to ASTM F2503-05. A patient with this implant can be scanned safely immediately after placement under the following conditions:

1. Static magnetic field of 3 Tesla or less.
2. Spatial gradient magnetic field of 720 Gauss/cm or less.
3. Maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.

P/N: P-2017-0175-00 Rev B

ARGON MEDICAL DEVICES Patient Implant Card

This patient has an implanted Option™ ELITE Vena Cava Filter.

Show this card to any medical professional treating you and before any medical procedure.

Patient Name

Date of Implant

Implant Site

Lot #

Implanting Physician

Telephone

Implanting Hospital

City

State

Distributed By:

Argon Medical Devices, Inc.
1445 Flat Creek Road
Adriens, TX 75751
800-927-4669

Option™ ELITE Part #352506070E

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Patient name: _____

Physician name: _____

Physician phone #: _____

Date of filter placement: _____

Date filter to be removed: _____

Follow-up appointment: _____

Option™ ELITE
Retrievable Vena Cava Filter


ARGON
MEDICAL DEVICES

Glossary

Anticoagulant: a medication that inhibits the clotting of blood

Deep vein thrombosis (DVT): a condition marked by the formation of a thrombus within a deep vein (i.e. within the leg or pelvis) that may be asymptomatic or be accompanied by symptoms (such as swelling and pain) and is potentially life threatening if the thrombus dislodges, and migrates to the lungs, creating a pulmonary embolism

Embolism: the sudden obstruction of a blood vessel by an embolus

Embolus: a plug, composed of material that became detached, for example from a thrombus, occluding a vessel; 'Emboli' means more than one embolus

Inferior vena cava: the largest vein in the human body, formed by the union of the two veins from the legs that returns blood to the right side of the heart from bodily parts below the diaphragm

Inferior vena cava filter: a device, that is inserted into the inferior vena cava to catch objects in the blood stream before they can reach the heart and lungs

Pulmonary embolism (PE): embolism of a pulmonary artery or one of its branches that is produced by foreign matter and most often a blood clot originating in a vein of the leg or pelvis and that is marked by labored breathing, chest pain, fainting, rapid heart rate, cyanosis, shock, and sometimes death

Thrombus: a blood clot

Notes: _____

For over 40 years, doctors have been placing small metal filters, called inferior vena cava filters, into the largest vein in their patients' abdomens to prevent pulmonary embolism. Last year, over 200,000 patients in the United States received one of these filters.

Your doctor has decided that the Option™ ELITE Filter is the best choice for you. This booklet answers some of the questions you may have about pulmonary embolism and how this filter works. After reading this booklet, talk with your doctor about any questions you have specific to your situation.

Definitions of italicized words can be found in the Glossary.

What is a pulmonary embolism?

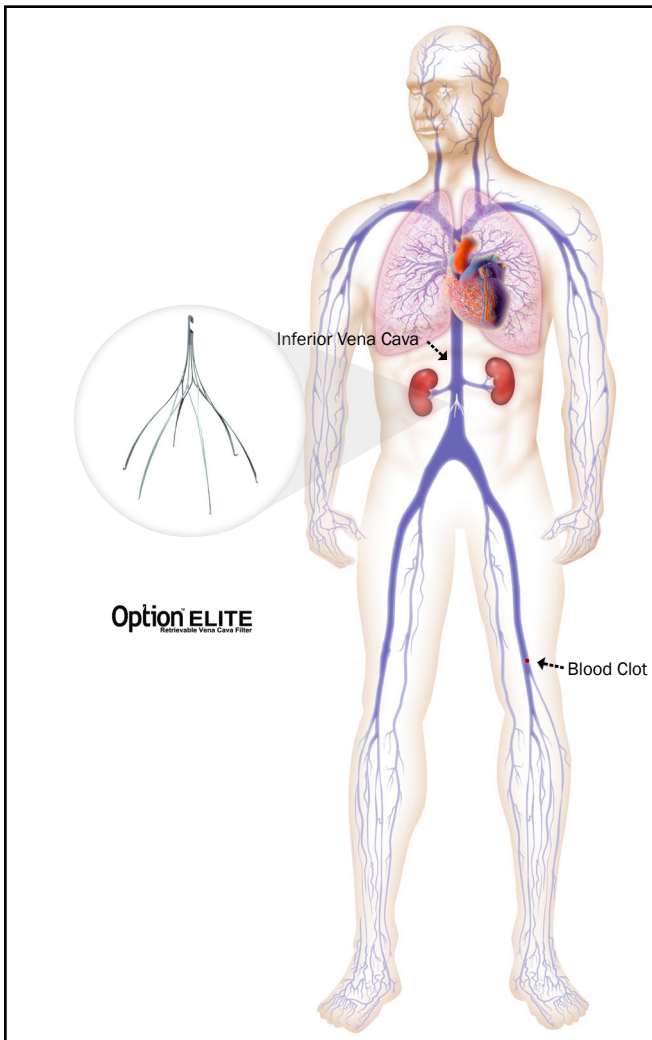
A *pulmonary embolism* is a blockage of one or more of the arteries that carry blood through the lungs. There are several possible causes for the blockage (called an *embolus*), including small balls of fat that get into the blood after injury or surgery. By far, the most common cause is a blood clot, or part of a clot, that started in a leg vein and has broken free. The clot has passed through the heart and is now lodged in the lungs. Usually, a number of these blockages happen at the same time. Many clear up without treatment, but those that don't can cause serious illness or death.

How do I get a pulmonary embolism?

The greatest risk for having a pulmonary embolism is having a blood clot or *thrombus* in your leg veins. This condition is called *deep vein thrombosis*. Anyone can develop the blood clots that cause pulmonary embolism but some things increase the risk of getting them. Spending a long time without moving your legs increases your risk, like sitting still on long airplane or car trips. Prolonged bed rest increases your risk, and so does surgery and fractures of the hip or leg.

How can we treat or prevent a pulmonary embolism?

To prevent a pulmonary embolism, patients who have blood clots in their legs are often treated with moderate doses of *anticoagulants* (medications that stop blood from clotting). But these drugs do not work for all people and some people should not take them at all. Sometimes additional protection is needed for special, high-risk patients, such as those who are at risk from other types of blockages. Whenever possible, prevention is a better option. In many of these cases, an *inferior vena cava filter* is the best choice.



Does the Option™ ELITE Filter need to be checked by my doctor?

You need to be seen regularly by your doctor to check up on the condition that caused your blood clots in the first place. Your doctor may also send you for x-ray or ultrasound examinations to check up on the Option™ ELITE Filter. Problems are not common, but sometimes they do happen. Very rarely, some patients with inferior vena cava filters have had the vein wall punctured by the hooks on the legs of the filter. In other patients, the filter has moved from the position where it was placed. Sometimes, a pulmonary embolism happens even though the filter is in the right place. And other times, a large clot blocks the filter. These are just some examples. Ask your doctor if you have any questions about the safety of your filter.

If you experience new or increased swelling in your legs, or any new or unexpected pain in your chest or abdomen, you should contact your doctor immediately. These symptoms may suggest that you have one of these complications.

What is an inferior vena cava filter?

The *inferior vena cava* is the name of the large vein in the abdomen that returns blood from the lower parts of the body back to the heart. The heart then pumps the blood directly to the lungs where the blood vessels branch many times and become smaller and smaller. The location of the inferior vena cava makes it a good place to catch clots before they get to the heart and small vessels of the lungs. An inferior vena cava filter is a basket made of metal that fits into that vein. It works like a safety net to trap large clots that are carried along with the blood flow. Most of the trapped blood clots dissolve naturally over time.



Living with the Option™ ELITE Filter

Once the Option™ ELITE Filter is in place, you will probably not know it is there. In most patients, no changes in lifestyle or activities are needed because of it. However, you should discuss the appropriate level and types of activities with your doctor.

You also need to understand that the Option™ ELITE Filter only decreases your risk of having a pulmonary embolism. It does not change what is causing the blood clots in the first place. So, if you are at risk for blood clots and your doctor feels it is right for you, you may also be given anticoagulants along with the filter. Because of these drugs, you may need to make some changes in your lifestyle and diet. You should discuss this with your doctor.

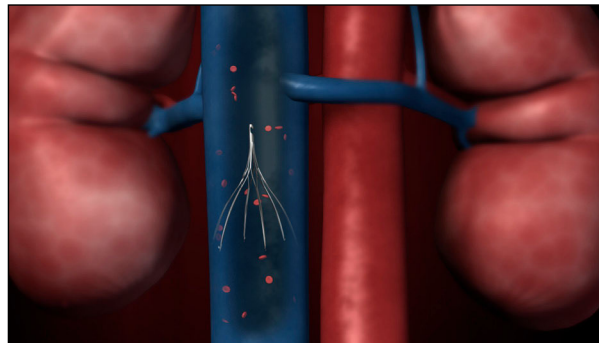
Once in place, the Option™ ELITE Filter should not cause you any discomfort. You should talk with your doctor immediately if you feel chest pain or are short of breath, if you have a cough that produces blood, or if you have rapid breathing or a rapid pulse. These may be symptoms of a pulmonary embolism caused by a clot that escaped the filter or may be due to another complication. If you have questions, ask your doctor.

Because you have an inferior vena cava filter, healthcare professionals may need to change the way they care for you during some medical procedures. Examples of these procedures are cardiac catheterization, Magnetic Resonance Imaging (MRI) scanning, among others. Attached to this booklet is a card with information for healthcare professionals about your Option™ ELITE Filter. You should carry this card with you and always show it to any healthcare professional before they care for you.

How long will I have the Option™ ELITE Filter?

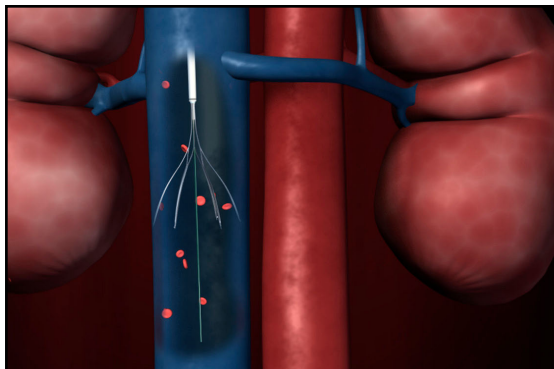
The Option™ ELITE Filter may be permanent or it may be removed by your doctor. Sometimes the doctor intends to remove the filter, but then the situation changes and it is better if the filter stays in place. Other times, the intent is to leave the filter in place, but the situation changes and it is better to remove it. With the Option™ ELITE Filter, your doctor has both options.

What is the Option™ ELITE Filter?



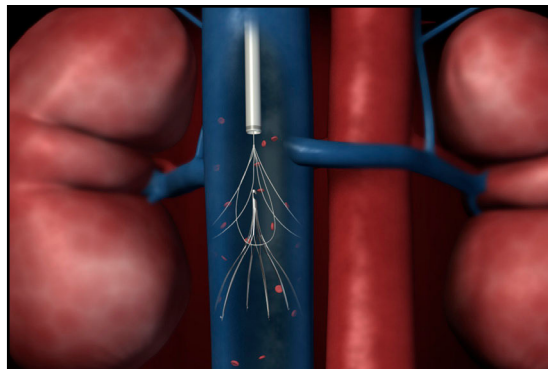
The Option™ ELITE Filter is made of high-tech nickel titanium alloy tubing (called Nitinol), which is an amazingly strong and flexible metal that remembers its shape. A single piece of Nitinol tubing is laser-cut into a complex filter with six legs that rest gently against the inside of your inferior vena cava. This forms a cone-shaped basket to catch clots in your bloodstream. At the end of each leg is a small anchor that is designed to keep the filter in place by grasping the vessel wall. There is another bigger hook at the top end of the filter where all the legs meet. This hook can be used to remove the filter if it is no longer needed.

How is the Option™ ELITE Filter placed?



Using x-ray equipment, a specially trained doctor and medical team insert a small, flexible tube (called a catheter) through the veins in your neck, groin or arm. The catheter is guided through your veins until it reaches the inferior vena cava. The doctor then threads the Option™ ELITE Filter, with its six legs folded tight together, through the inside of the catheter. The doctor checks that the filter has reached the proper place before pulling out the catheter. Once free of the catheter, the legs of the filter gently spread apart. The anchor on the end of each is designed to keep the filter in place by grasping the vein. Your doctor may choose to leave the Option™ ELITE Filter in place forever, or may choose to remove it depending on your situation.

How is the Option™ ELITE Filter removed?



Removal of the filter is done in a similar way. Using x-ray equipment, a catheter is inserted through the veins in your neck and guided to your inferior vena cava. Then, a device with a loop at the tip (called a snare) is guided through the inside of the catheter until it catches the hook at the top end of the Option™ ELITE Filter. As the catheter is slipped further over the end of the filter, the high-tech metal folds back into its original, compact shape. The catheter with the Option™ ELITE Filter inside is then pulled out.

Both of these procedures are usually quick, and are often done in less than an hour. Typically, you will be given a light sedative and a local anesthetic to make you more comfortable. Often, you can be discharged in 2 to 3 hours. You may have some tenderness at the site where the catheter was inserted. This will normally go away in a few days. A small scar may be visible after the site heals.