Option™ ELITE

Retrievable Vena Cava Filter

Patient Guide

ARGON MEDICAL DEVICES

Introduction

For over 50 years, doctors have been placing small metal filters, called inferior vena cava filters, into the largest vein in their patients' to prevent pulmonary embolism. Last year, nearly 150,000 patients received one of these filters.

Given your current healthcare needs, your doctor has decided that implanting an 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, please be sure to talk with your doctor about any questions you have specific to your situation.

Definitions of italicized words can be found in the Glossary on page 10.

What is a pulmonary embolism?

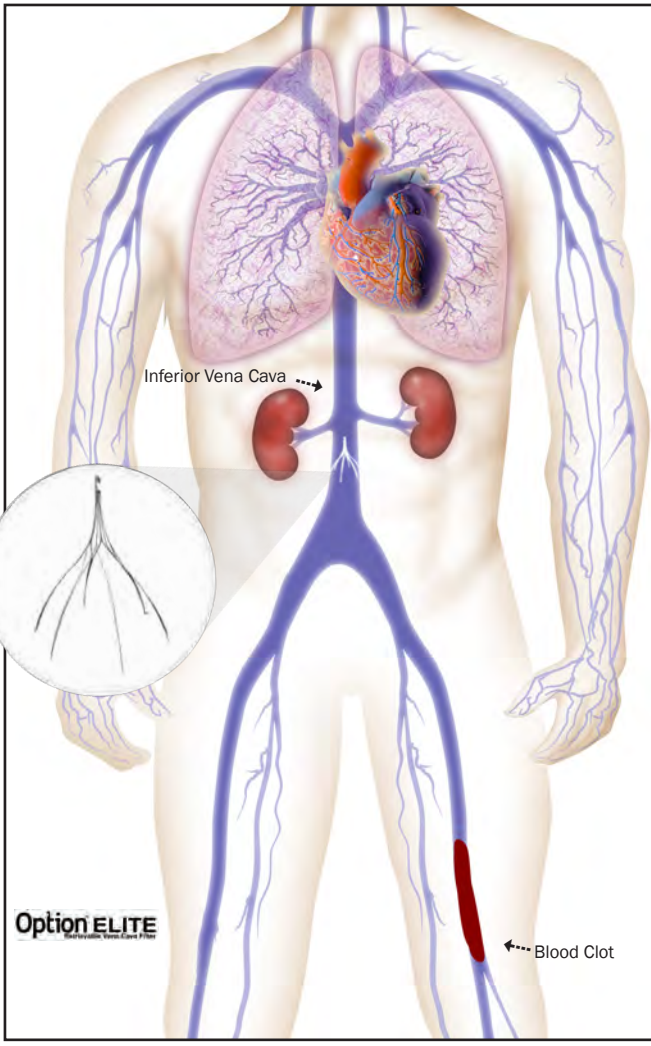
A *pulmonary embolism* is a blockage of one or more of the arteries that carry blood through the lungs. There are several possible causes for the blockage. The most common cause is a blood clot that started in a leg vein and has broken free. Many clear up without treatment, but others can cause serious illness or death.

How do I get a pulmonary embolism?

The greatest risk for having a pulmonary embolism is having a blood clot 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.

How can we treat or prevent a pulmonary embolism?

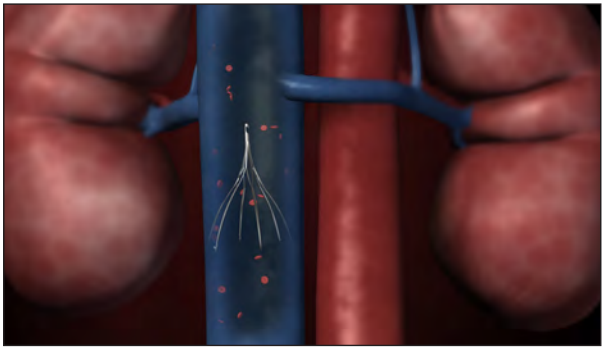
To prevent a pulmonary embolism, patients who have blood clots in their legs are often treated with *anticoagulants* (medications that stop blood from clotting). But these drugs do not work for all people and some people should not take them at all. Sometimes additional protection is needed for special,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



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.

What is the Option™ ELITE Filter?



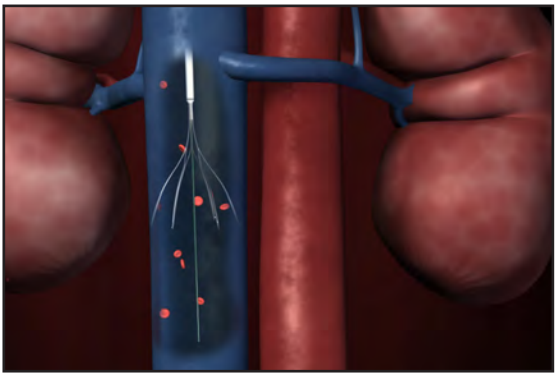
The Option™ ELITE Filter is made of high-tech nickel titanium alloy tubing (called Nitinol), which is a strong and flexible metal. A single piece of Nitinol tubing is laser-cut into a complex filter with six legs that rest gently against the inside of your inferior vena cava. This forms a cone-shaped 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.

Product Catalog Number/Description

352506070E Option™ ELITE Retrievable Vena Cava Filter System

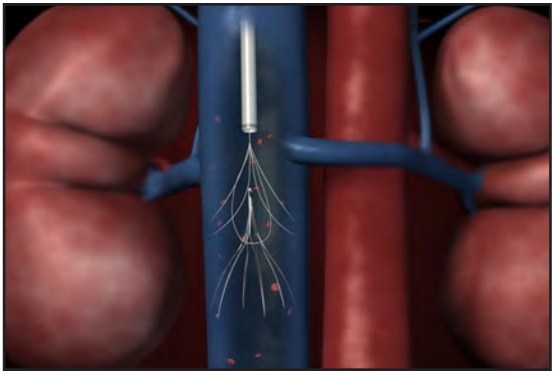
352506100E Option™ ELITE 100cm Retrievable Vena Cava Filter System

IVCF Insertion



Insertion of an IVCF occurs by having a specially trained doctor and medical team insert a small, flexible tube (called a catheter) through the veins in arm, neck, groin, or knee. 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.

IVCF Removal



Removal of the filter is done in a similar way. A catheter is inserted through a vein 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 of the filter folds back into its original, compact shape. The catheter with the Option™ ELITE Filter inside is then pulled out.

Living with the Option™ ELITE Filter

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. Examples of these procedures are cardiac catheterization, Magnetic Resonance Imaging (MRI) scanning, among others.

The implantation of the IVCF is an effort to decrease your risk of having a pulmonary embolism. It does not change what is causing the underlying condition. Be sure to consult your physician for instructions on ongoing management, lifestyle changes, and activity levels. It is also important to seek consultation if you experience any worsening symptoms.

Because you have an inferior vena cava filter, healthcare professionals may need to change the way they care for you during some medical procedures.

How long will I have the Option™ ELITE Filter?

The Option™ ELITE Filter may be permanent or it may be removed by your doctor.

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.

For Australian Customers

If you reside in Australia and experience a potential complication, not limited to the ones listed in this guide, please contact your doctor immediately. In addition, please report any event at www.tga.gov.au.

Information for Your Doctor

Contraindications for Implant:

The Option™ ELITE Filter should not be implanted if any of the following conditions are present:

1. Patient has an inferior vena cava diameter larger than 30mm.
2. Patient is at risk for septic embolism.
3. Patient has confirmed bacteremia.
4. Patient has a known hypersensitivity to nickel or titanium alloys.
5. Pregnant patient when radiation from fluoroscopic imaging may endanger the fetus. Risks and benefits should be carefully assessed. There are no known contraindications for use of the Angiographic Vessel Dilator.

Residual Risk:

Overall residual risks associated with the device are considered acceptable when weighed against the benefits of the patient.

Retrieval Considerations:

Excessive force should not be used to retrieve the filter.

- Retrieval of the filter should not be attempted if thrombus is present in the filter, IVC or deep veins.
- Retrieval of the filter is possible only from the jugular approach. Before attempting retrieval of the filter from the jugular access site, verify that the filter retrieval hook is oriented in a cephalad direction – i.e. pointed toward the jugular access site. The retrieval hook at the cephalad end of the filter is the location for endovascular snare engagement.
- Retrieval of the filter should only be performed by physicians who are trained in percutaneous interventional techniques.
- Never redeploy a retrieved Filter.

MRI Considerations:

- Non-clinical testing has demonstrated that the Option™ ELITE Filter is MR Conditional. A patient with the Option™ ELITE Filter can be safely scanned immediately after placement under specified conditions.
- MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Option™ ELITE Filter. Therefore, it may be necessary to optimization of MR imaging parameters to compensate for the presence of this metallic implant.
- Magnetic field interactions show the Option™ Vena Cava Filter will not present an additional risk or hazard to the patient with regard to translational attraction or migration.
- The highest temperature change measured for the Option™ Vena Cava Filter was 1.7 degrees C. This change in temperature is not considered to be physiologically consequential for a human subject.

Clinical Testing Summary:

A single arm, prospective, multicenter non-randomized study designed to collect data on the safety and efficacy of the Option™ Vena Cava Filter as both a permanent and retrievable device was conducted. One hundred (100) patients underwent filter placement. The implantation procedures were uneventful, with Placement Technical Success achieved in 100% of patients. During follow-up through 6 months, two patients (2.0%) exhibited an episode of mild filter migration (23 mm), just over the specified limit of 20 mm. Three patients (3.0%), all of whom had Cancer ± a hypercoagulable state at baseline, exhibited symptomatic caval occlusion. Four patients exhibited episodes of pulmonary embolism, determined to be definite and filter related, for a rate of 4.0%. Observed rates of pulmonary embolism, symptomatic caval occlusion, and filter migration were consistent with published literature. There were no incidents of filter embolization or fracture.

In summary, the placement and retrieval of the Option™ filter can be performed safely with relatively high rates of technical and clinical success. For patients who are no longer at risk for thromboembolism, the Option™ filter can be implanted for several months and then safely retrieved. Data demonstrates the safety and effectiveness of the placement and retrieval of the Option™ filter system in a clinically relevant patient population.

Potential Complications

Complications may occur at any time during the implantation, indwelling period, or at the time of or following filter retrieval. Possible complications may include, but are not limited to, the following:

- Vena cava or other vessel injury or damage, including rupture or dissection, possibly requiring surgical repair or intervention
- Injury or damage to organs adjacent to vena cava, possibly requiring surgical repair or intervention
- Vena cava stenosis or occlusion
- Incorrect positioning or orientation of the filter
- Filter migration/movement
- Extravasation of contrast media
- Vasospasm or decreased/impaired blood flow
- Bleeding or hemorrhagic complications that require transfusion or medical intervention (e.g., IV fluids, medication)
- Thromboembolic events, including Deep Vein Thrombosis (DVT), acute or recurrent pulmonary embolism or air embolism, possibly causing end organ infarction/damage/failure
- Infection, possibly requiring medical or surgical intervention (e.g. antibiotics or incision and drainage)
- Respiratory insufficiency or failure
- Cardiac arrhythmia
- Myocardial infarction or *coronary ischemia*
- Cerebrovascular accident or other neurologic event
- Renal insufficiency or failure
- Reaction to contrast media/ medication
- Hematoma, possibly requiring medical intervention or surgical revision
- Other vascular access site injury, including, bruising, AV fistula, or pseudoaneurysm
- Neurological deficit associated with vascular access, possibly requiring nerve intervention or neurology consultation
- Device breakage or failure or inability to retrieve implanted device as described in IFU, possibly requiring another intervention or treatment modality to complete procedure
- Death. These events may be serious in nature and may require hospitalization or intervention to address the condition.

Glossary

Anticoagulant: a medication that prevents blood clotting.

Coronary ischemia: a reduced blood flow in the coronary circulation through the coronary arteries.

Deep vein thrombosis (DVT): a condition marked by the formation of a formation of a blood clot 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 blood clot dislodges, and migrates to the lungs, creating a pulmonary embolism

Extravasation: the leakage of blood, lymph, or other fluid, such as a contrast media, from a blood vessel or tube into the tissue around it.

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 the lower body

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

Myocardial infarction: heart attack.

Occlusion: the blockage or closing of a blood vessel or hollow organ.

Pulmonary embolism (PE): often severe condition when a pulmonary artery becomes obstructed preventing normal flow of blood.

Stenosis: a narrowing of a lumen such as an inferior vena cava

Thromboembolic: the name for when a blood clot (thrombus) that forms in a blood vessel breaks loose, is carried by the bloodstream, and blocks another blood vessel.

System Composition:

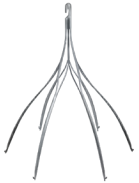
Material	Material's brand name
Isoplast 2510	Isoplast 2510
Pellathane	DOW Pellethane 2363-80AE
Polyether Block Amide (PEBA), PTFE, Irganox, Tinuvin	PEBAX 6333/5333, PTFE, Irganox 1010, Tinuvin 783
Silicone Rubber	Silicone Rubber VR 1024-50
HDPE / Polycarbonate	HDPE , MAT-107 / Polycarbonate, MAT-315
HDPE	HDPE LR 7320-01
HDPE	HDPE Chevron HiD 9018
Platinum-Iridium Alloy	90% Platinum 10% Iridium
Tantalum	Ta
Polyether Block Amide (PEBA), Irganox, Tinuvin	PEBAX 7033, Irganox 1010, Tinuvin 783
Isoplast 2510)	Isoplast 2510
PTFE coated Stainless steel	304V Stainless Steel Paragon Green PTFE
Nickel-Titanium Alloy	SE508
Acrylonitrile Butadiene Styrene (ABS)	GE PLASTICS MG47MD CYCLOAC ABS
Stainless Steel	304V
HDPE	HDPE Chevron HiD 9018

Option™ ELITE

Retrievable 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.



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 C

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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
Athens, TX 75751
800-927-4669

Option™ ELITE Part #352506070E