

## What are the Risks Associated with Implantable Filters?

As with all implantable devices there are some risks associated with vena cava filters. You should discuss the possible adverse effects of this procedure and the filter with your physician. Potential risks include the following:

- Any procedure where the skin is penetrated carries a risk of infection.
- The filter could accidentally be implanted in the wrong place, move from its initial implantation site, or poke or tear through the vessel wall.
- The events above may lead to pain, bleeding, injury to a nearby organ, or make it difficult or impossible to remove the filter (should your doctor wish to remove it).
- Blood clots could continue to reoccur and possibly obstruct the filter and vena cava, causing swelling in the legs.
- The entire filter or pieces of the filter may break loose and travel to the heart or lungs, causing injury or death. You may need to have additional surgery to retrieve the filter or pieces if they break loose.
- Even with a filter, it is possible to experience a recurrent pulmonary embolism due to clot material passing through the small openings in the filter.

## Can the Filter be Removed?

Yes. The filter can be removed when your physician determines that you no longer need it.

## Should the Filter be Removed?

FDA recommends that implanting physicians and doctors responsible for ongoing care, consider removing the filter as soon as protection from pulmonary embolism is no longer needed. Discuss your follow-up schedule with your physician.

## Removal Procedure

### How Will the Filter be Removed?

Your physician will remove the filter through either the right or left internal jugular vein (see anatomic illustration in the section “After The Procedure”). He/she will insert a small tube called a catheter. Through the catheter, a grasping device will be advanced to the filter. The filter will be grasped, then pulled into the catheter. Your physician will then remove the entire system. However, some filters may not be able to be removed. In this case, your physician may have to leave the filter in place as a permanent device. Should this occur, follow-up may be necessary to monitor the device.

### How Long Does the Retrieval Process Take?

Although it varies depending upon the individual patient and the specific circumstances, the retrieval of the filter generally takes less than an hour.

### Will I Experience Discomfort During and After the Procedure?

As with the implant procedure, local anesthesia, helped by a mild sedative given before the procedure, will normally result in little to no discomfort while the filter is being removed.

Afterwards, you may experience mild soreness in your neck for a few days. This is normal and will disappear. You will be left with a small scar on your neck at the puncture site.

### How Long Will it Take to Fully Recover From the Removal Procedure?

Recovery from the removal procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc. Typically, you will be discharged several (2-3) hours after the procedure.

### Does the Filter Have to be Removed?

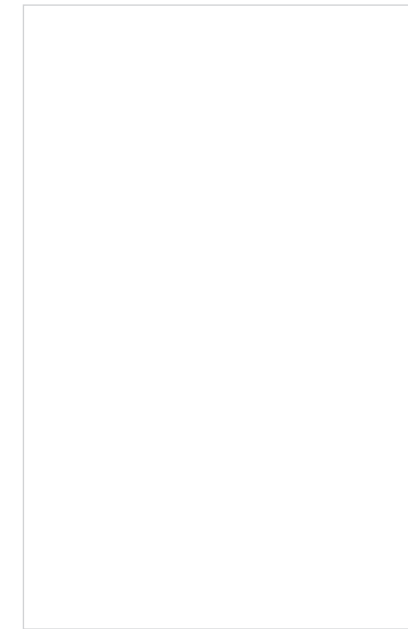
No. The MERIDIAN™ Vena Cava Filter is designed to be a permanent implant and does not have to be removed, repositioned or replaced. However, in the cases where the risk for pulmonary embolism is temporary, your physician may choose to remove the filter. You should discuss filter removal with your physician.

## Resuming Your Normal Lifestyle

### Should I Restrict my Activities After the Filter Implantation or Removal Procedure?

The implantation or removal of a vena cava filter is not necessarily a reason to restrict your normal activity level; however, each patient is unique and there may be other medical reasons for doing so. Be sure to discuss with your doctor what level of activity is most appropriate for you following the procedure.

Have your physician fill out the back of this Patient Implant Card for you. Keep the card with you at all times.



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# MERIDIAN™

Vena Cava Filter

Patient Questions & Answers



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## Pulmonary Embolism and Vena Cava Filters

Your doctor has given you this booklet to help you learn more about pulmonary embolism – what causes it, how it can affect your body and, most important, how it can be treated. After reading the booklet, talk to your doctor about any questions you have. It's important to remember that each patient is different and that only your doctor can give you information about the details of your specific treatment.

### What is Pulmonary Embolism and What is the Cause of it?

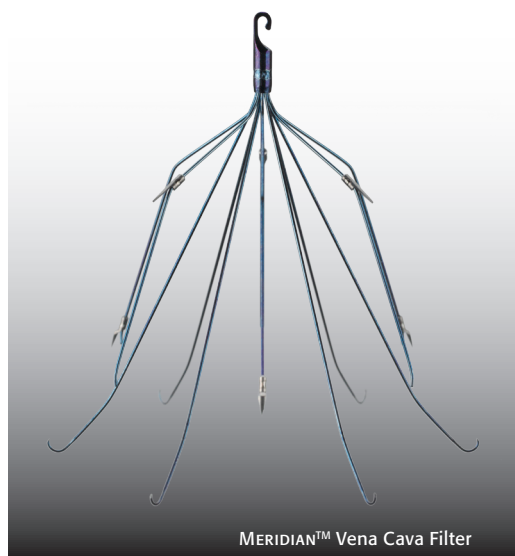
Pulmonary embolism is the condition that results when a blood clot forms, usually in the deep veins of the thighs, pelvis or lower leg, and becomes loosened, traveling upward in the bloodstream to lodge in the arteries that carry blood to the lungs. This can lead to decreased blood flow to the lungs and may cause lung damage or death.

### What Types of Treatment are Used for Pulmonary Embolism?

The most common treatment is a group of medications called anticoagulants or “blood thinners.” However, there are some patients who, for a variety of medical reasons, cannot take anticoagulants. For these individuals, a vena cava filter may offer an effective preventative option to prevent clot movement to the lungs.

### What is a Vena Cava Filter?

A vena cava filter is an expandable metal device specially designed to trap blood clots before they reach the lungs. The filter is placed in the inferior vena cava (IVC) – the large vein that carries blood from the lower extremities back to the heart and lungs – and remains in place to trap clots before they move further up towards the lungs.



### The Implant Procedure

The anatomical sites identified in Illustration 1 will provide general guidance on those areas that are important in an implant procedure.

#### How Will the Filter be Inserted?

Your physician will insert the filter through the femoral, jugular or subclavian vein (see anatomical Illustration 1).

To make the procedure as easy as possible, the

filter is delivered through a small plastic tube called a catheter. Once implanted, the filter expands to its predetermined shape and is held in place against the vena cava walls.

#### How Long Does the Procedure Usually Take?

Although it varies depending upon the individual patient and the specific circumstances, the implantation of the filter generally takes less than an hour.

#### Will I Experience Discomfort During and After the Procedure?

Local anesthesia, plus a mild sedative that might be taken before the procedure, will normally result in little to no discomfort while the filter is being implanted. Afterwards, you may experience mild soreness at the insertion site. This is normal and will disappear. You will be left with a small scar at the puncture site.

#### How Long Will it Take to Fully Recover?

Recovery from the procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc.

### After the Procedure

#### How Long Will the Filter Last and Can the Filter be Removed?

The MERIDIAN™ Vena Cava Filter is designed to be a permanent implant. However, the filter can be removed when your physician determines that you no longer need it.

#### Can the Filter Become Clogged?

In the great majority of cases, the answer is

“no.” Once a clot becomes entrapped in the filter, the normal flow of your blood through the vena cava and the filter will usually dissolve a trapped clot as the blood flows over it.

#### If I Should Need an MRI Exam, Will the Metal Interfere with the Test?

The MERIDIAN™ Vena Cava Filter is made from an alloy of nickel and titanium, which under certain circumstances has been considered safe. Present the patient implant card at the time of the MRI. It is recommended that patients with a vena cava filter register the MR conditions with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)). The MERIDIAN™ Filter can be safely scanned at 3-Tesla or 1.5-Tesla.

#### Under What Circumstances Should I Contact the Doctor Right Away?

You should contact your physician right away if you experience the following:

- Sudden onset of chest pain accompanied by shortness of breath
- Swelling in the legs
- Unexplained pain in the abdomen or back
- Sudden numbness or weakness of the face, arm, or leg (especially on one side of the body)

- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden severe headache with no known cause
- Sudden trouble walking or dizziness
- Unexplained fever

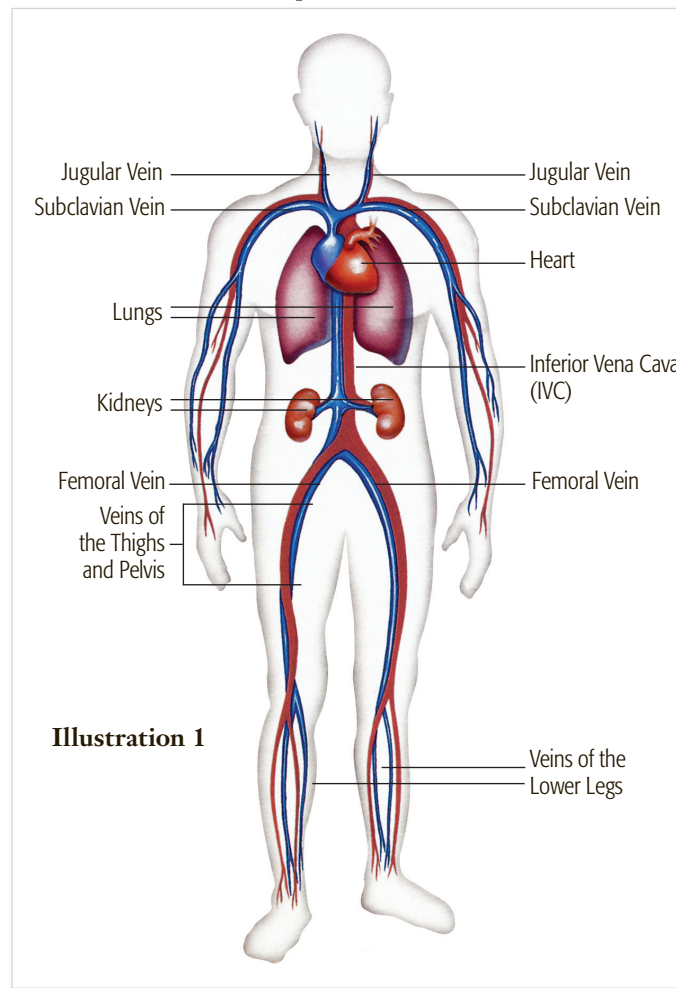


Illustration 1

## Front

This patient has a MERIDIAN™ Vena Cava Filter implanted for protection from Pulmonary Embolism.

**MERIDIAN™** Vena Cava Filter

The MERIDIAN™ Vena Cava Filter is retrievable and can be safely scanned immediately after placement under the following conditions.

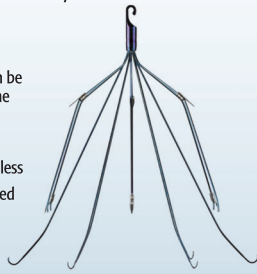
- Static magnetic field of 3-Tesla or 1.5-Tesla
- Spatial gradient magnetic field of 720 Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2 W/kg in the normal operating mode

Refer to product IFU for additional conditions.

MR Conditional

Retrieve with an endovascular snare and minimum 10F retrieval sheath.

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## Back

Patient Name \_\_\_\_\_

Implant Date \_\_\_\_\_

Implanting Physician \_\_\_\_\_

Implanting Physician Tel. No. \_\_\_\_\_

Hospital Name \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_

Place Product Label Here