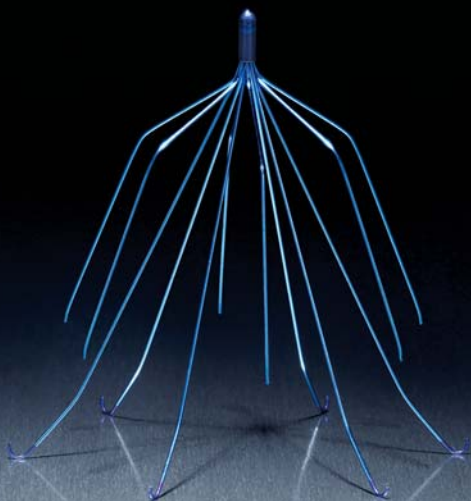


NOW INDICATED FOR RETRIEVAL

G2[®] FILTER SYSTEM



Vena Cava Filter

PATIENT QUESTIONS & ANSWERS

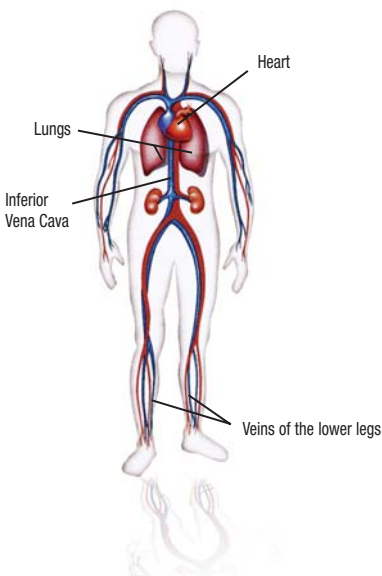


BARDD

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VASCULAR**

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 CAUSES IT?

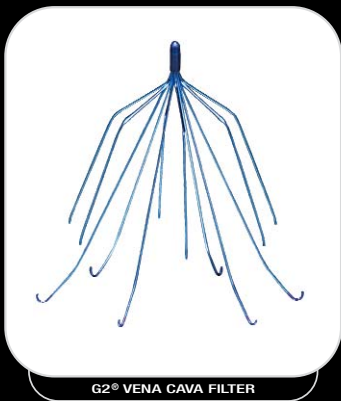
Pulmonary embolism is the condition that results when a blood clot forms, usually in the deep veins of the lower leg, and becomes loosened, traveling upward from the legs in the bloodstream. If left untreated, there is a possibility that the clot may move up into the arteries that carry blood to the lungs. If this occurs, the normal functioning of the lungs may be impaired.

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 treatment solution.

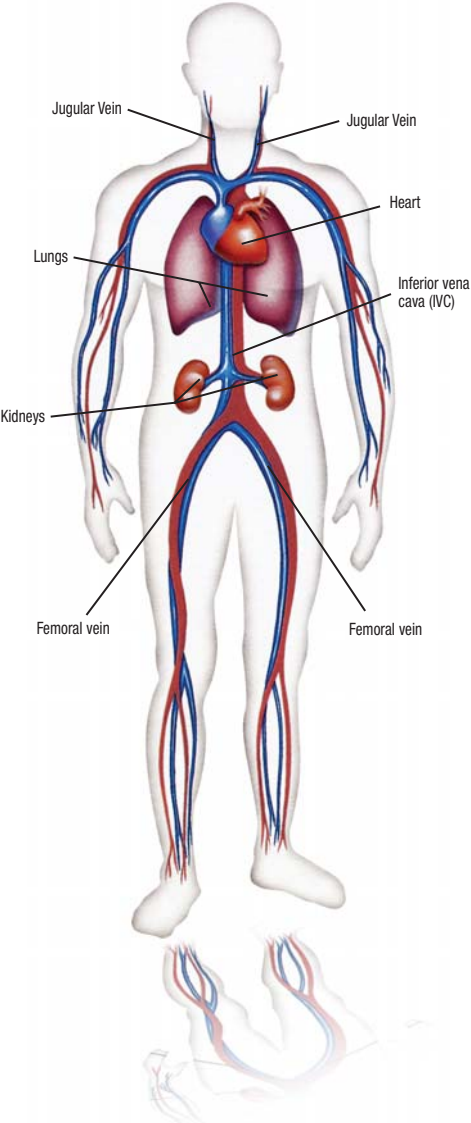
WHAT IS A VENA CAVA FILTER?

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 toward the lungs.



THE IMPLANT PROCEDURE

The anatomical sites identified below 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 either the right or left femoral vein in the upper thigh (see anatomical illustration on opposite page). To make the procedure as easy as possible, the filter is inserted inside a small plastic tube called a catheter. Once inserted, 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.

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?

The G2[®] Filter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced.

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 FILTER INTERFERE WITH THE TEST?

The G2[®] Filter is made from an alloy of nickel and titanium, and will not interfere with the test.

UNDER WHAT CIRCUMSTANCES SHOULD I CONTACT THE DOCTOR RIGHT AWAY?

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

- sudden onset of chest pain accompanied by shortness of breath
- swelling in both legs
- unexplained pain in the abdomen

CAN THE FILTER BE REMOVED?

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

WHEN CAN THE FILTER BE REMOVED? IS THERE A “CUTOFF DATE” BY WHICH THE FILTER MUST BE REMOVED?

The G2[®] Filter does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to 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 on page 4). 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, and then pulled into the catheter. Your physician will then remove the entire system together.

HOW LONG DOES THE RETRIEVAL PROCEDURE 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 G2[®] Filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced.

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.

PATIENT IMPLANT CARD

Patient Name _____

Date of Implant _____

Implant Site _____

Implanting Physician _____

Telephone No. _____

Implanting Hospital _____

City _____ State _____



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Bard Peripheral Vascular, Inc.

1625 W. 3rd Street

Tempe, AZ 85281

USA

www.bardpv.com

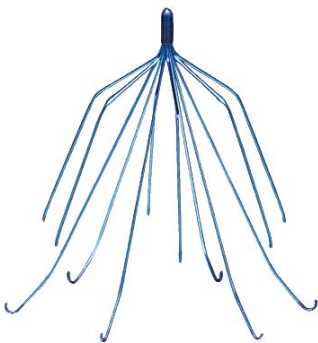
Tel: 1.480.894.9515

1.800.321.4254

Fax: 1.480.966.7062

1.800.440.5376

Have your physician fill out this Patient Implant Card for you. Then, tear off at perforation and keep the card with you at all times.



This patient has an implanted G2[®] Vena Cava Filter. This filter is implanted in the inferior vena cava to protect the patient from pulmonary embolism. This device is designed to be a permanent implant that can also be removed if the patient's condition warrants removal.

G2[®] Vena Cava Filter is non-ferrous and MRI-compatible.

The removal of G2[®] Filter must not be attempted using any device other than the approved removal device, Recovery Cone[®] Removal System.

The Recovery Cone[®] Removal System is available from Bard Peripheral Vascular, Inc. (Ref # FBRC).

Bard Peripheral Vascular, Inc.

1625 W. 3rd Street
Tempe, AZ 85281
USA

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1.800.321.4254

Fax: 1.480.966.7062

1.800.440.5376

www.bardpv.com



Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

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