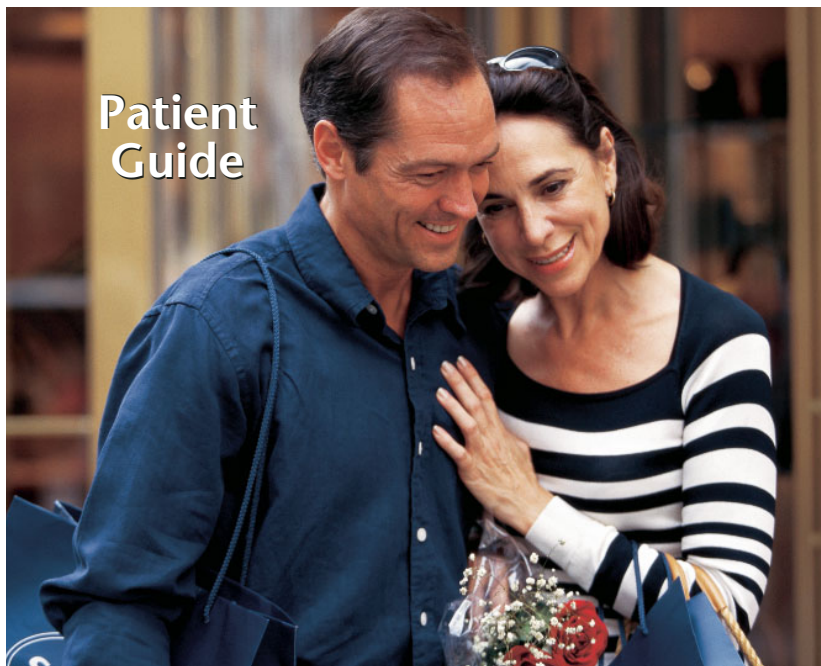


GÜNTHER
TULIP[™]
VENA CAVA FILTER

Patient
Guide



COOK[®]

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This information has been developed as a general guide for patients receiving the Günther Tulip™ Vena Cava Filter.

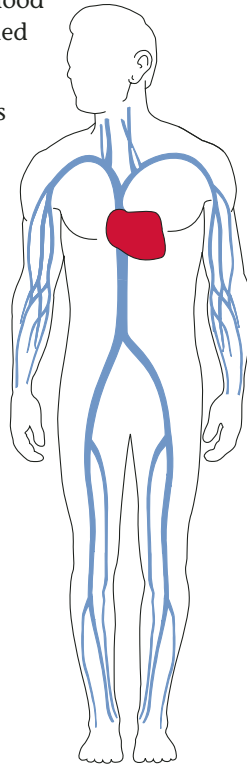
The booklet is only a guideline intended to help answer common questions. Each patient's case may vary according to the patient's condition and his/her physician's assessment and preference. If you have specific questions about your condition or treatment, please ask your physician.

Pulmonary Thrombo Embolism (PE)

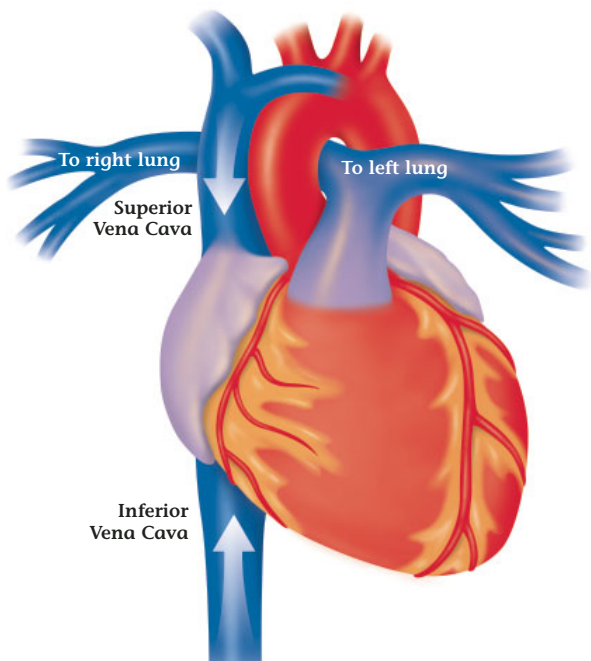
When blood clots form in the lower limbs, they can partly block the flow of blood from the legs. This condition is called deep vein thrombosis or DVT.

If a blood clot dislodges and travels through a person's body to his or her lungs, it causes a condition called pulmonary embolism or PE. A pulmonary embolism reduces or blocks your lung's ability to supply oxygen to your body.

A pulmonary embolism can cause shortness of breath with mild exertion, and can impair lung function. It may even cause heart failure or death. Each year, between 50,000 and 200,000 people in the U.S. die from pulmonary embolism.



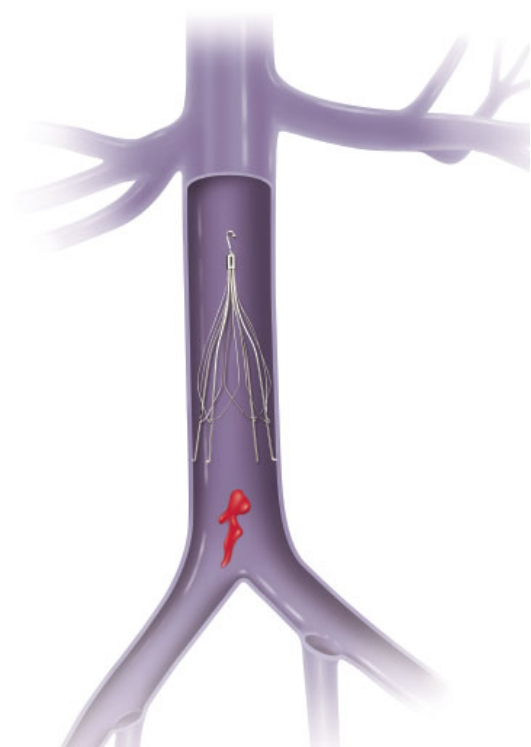
What Are the Venae Cavae?



The venae cavae are the two major veins that move blood from the upper and lower body to the heart.

The superior vena cava drains blood from the upper body into the heart. The inferior vena cava, the largest vein in the body, drains blood from the lower body into the heart.

Why Do I Need a Vena Cava Filter?



Your physician has chosen to give you a device called a *vena cava filter* to protect you from pulmonary embolism.

The vena cava filter is a Tulip-shaped wire device placed inside the vena cava to capture blood clots. Since most blood clots are formed in the legs, a filter placed in the inferior vena cava will capture clots before they migrate to your heart or lungs.

By trapping clots, the vena cava filter helps prevent pulmonary embolism and keeps the lungs functioning properly.

Indications for Use



Your physician has chosen to place a vena cava filter for one or more of the following reasons:

- You are not a candidate for anticoagulant therapy (the use of drugs that interfere with blood clotting).
- Anticoagulant therapy was not effective in treating your blood clot problem.
- Anticoagulation has produced problems in your medical care or condition.

If you have any further questions about why you are receiving a vena cava filter, please discuss them with your physician.

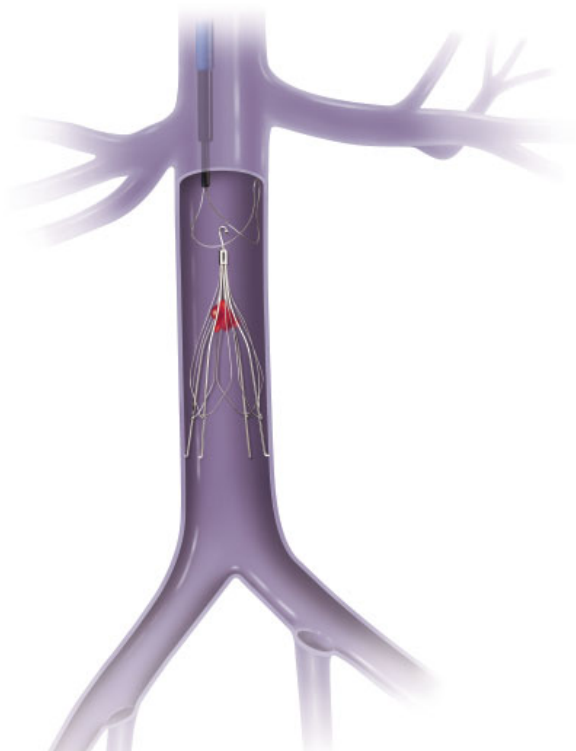
The Günther Tulip™ Vena Cava Filter

The Günther Tulip™ Vena Cava Filter was developed by William Cook Europe in cooperation with Dr. Rolf Günther. The filter was initially developed in 1992 for sale in Europe. Since that time, the Günther Tulip™ Vena Cava Filter has been placed in tens of thousands of patients worldwide. The Günther Tulip™ has been available in the United States since 2000.

The filter is implanted in the vena cava without surgery. A physician inserts the filter into the body through a small hole in the femoral vein (in the groin) or the jugular vein (in the neck). Using an imaging device called a fluoroscope, the physician tracks the filter's path through the body and moves it into precise position in the inferior vena cava. Then, the filter expands and secures itself to the wall of the vena cava.

The Günther Tulip™ Vena Cava Filter has been proven to effectively prevent pulmonary embolism.

Permanent or Temporary?



The Günther Tulip™ Vena Cava Filter is often used as a permanently implanted device. Patients are able to lead a normal, active lifestyle, and rarely have complications from having the filter implanted. The Günther Tulip™ Vena Cava Filter may also be removed if your risk of pulmonary embolism has diminished. However, there is a limited amount of time that the filter can be implanted if it is to be safely removed. Please consult with your physician to see if he or she plans to retrieve the filter or leave it in. Remember, the Günther Tulip™ Vena Cava Filter is safe and effective as either a permanent or temporary device.

Common Questions

Q: What are the possible adverse effects associated with vena cava filter placement?

A: Possible adverse effects include the following:

- The vena cava filter may move or migrate from its initial implantation site. (Extremely rare)
- The wall of the vena cava could be perforated (punctured) during the procedure. (Extremely rare)
- A hematoma (a swelling or mass of blood caused by a break in a blood vessel) may occur at the access puncture site. (Rare)
- The hooks of the filter can penetrate the vein wall of the inferior vena cava. This is common, and produces a problem only in extremely rare cases.
- Migrating blood clots can obstruct the inferior vena cava and filter, resulting in swelling of the lower extremities.

You should discuss the possible adverse effects of this procedure with your physician.

Q: What keeps the filter in position after placement?

A: Tiny hooks penetrate the inferior vena cava wall after placement.

Q: Should I be concerned about an allergic reaction to my vena cava filter?

A: There have been no known or reported cases of allergic reactions caused by the Günther Tulip™ Vena Cava Filter.

Q: Should I be concerned about having an MRI scan?

A: No. The Günther Tulip™ Vena Cava Filter is made of a special metallic alloy that is MRI compatible. You may have an MRI scan immediately after your filter has been implanted.

Notes

If you have any questions that are not covered in this booklet, we encourage you to talk to your physician. He or she should always be your primary source of information, and can discuss the details of this procedure and its impact on your health.

Use the space below to record your physician's name and phone number. You may also want to write down any questions, take notes, or keep a record of your discussions with your physician.

Patient name: _____

Date of filter placement: _____

Physician name: _____

Physician phone #: _____

Glossary of Terms

Caval Occlusion – A blockage of the vena cava caused by blood clots traveling from the lower limbs.

Embolism – A blockage in a blood vessel caused by a blood clot or foreign substance in the body.

Günther Tulip™ Vena Cava Filter – A cone-shaped filter that looks like a tulip, made from a special metallic alloy, which is implanted in the vena cava. The filter traps blood clots and helps prevent them from traveling to the lungs.

Hematoma – A mass of blood outside the blood vessel.

Inferior Vena Cava – The largest vein in the body, which drains blood from the lower body into the heart.

MRI (Magnetic Resonance Imaging) – An electromagnetic scanner that creates detailed images of the body for diagnosis.

Pulmonary Embolism (PE) – A condition in which blood clots have traveled through the lower limbs and have lodged in the lungs.

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