Boston Scientific

Greenfield™ Vena Cava Filters

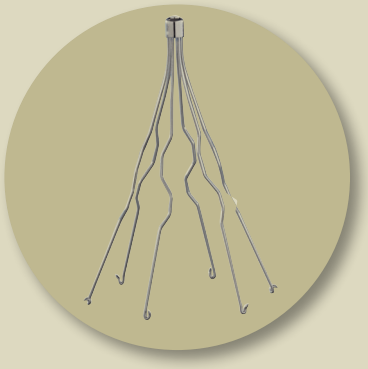
Trusted Performance, Timeless Design

Proven Stability

- 0.3% filter Fracture[1]
- 1% filter Migration > 2 cm[1]
- 1% filter Penetration[1]
- Recurved hooks are designed to provide protection against penetration[4,5]

Established Filter Performance

- 98.3% Clinical Patency[1]
- 2.6% Recurrent Pulmonary Embolism[1]
- Over 30 years of clinical experience



Filter Design Promotes Clot Lysis[2]

- Designed to maintain normal or high flow around captured clot[3] (*In illustration on right,* red denotes high-flow areas)
- Designed to limit stagnant flow that may lead to clot propagation[3]

When selecting a permanent Vena Cava Filter, choose the filter with over ***one million implants*** *in the past 30 years.*

CRV
Cardiology, Rhythm and Vascular

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Greenfield Stainless Steel Filter

Jugular Product Number	50-400
Femoral Product Number	50-501
Technical Information: MRI[6]	MRI Conditional: In vitro studies have demonstrated that magnetic force and torque at 0.35 T and 1.5 T cause no migration of Greenfield Stainless Steel Vena Cava Filters Greenfield Stainless Steel Vena Cava Filters generate moderate artifact when MR imaged
Delivery System (ID)	12 F
Indications	Caval diameter of 28 mm or less

Titanium Greenfield Filter and Entry Kit

Jugular Product Number	50-300
Femoral Product Number	50-301
Technical Information: MRI[7]	MRI Conditional: Lacks ferromagnetism (up to 4.7 T) and does not produce MR imaging artifact (at 0.35 T)
Delivery System (ID)	12 F
Indications	Caval diameter of 28 mm or less
Titanium Entry Kit	50-350 *recommended for each Titanium Greenfield Filter implant (sold separately)

The C-code used for this product is C1880, Vena Cava Filter.
The C-code used for this product (Titanium Greenfield Entry Kit) is C1769, Guide Wire.
C-codes are used for hospital outpatient device reporting for Medicare and some private payers.

Note: Boston Scientific is not responsible for the correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

REFERENCES

1. Greenfield LG, Proctor MC. The percutaneous Greenfield filter: outcomes and practice patterns. *J Vasc Surg.* 2000;32:888-893.
2. Couch GG, Kim H, Ojha M. In vitro assessment of the hemodynamic effects of a partial occlusion in a vena cava filter. *J Vasc Surg.* April 1997;25(4):663-672.
3. Proctor MC, Cho KJ, Greenfield LJ. In vito evaluation of vena caval filters: can function be linked to design characteristics? *Cardiovasc Intervent Radiol.* Nov.-Dec. 2000;23(6):460-465.
4. Greenfield LG, Cho KJ, Tauscher JR. Evolution of the hook design for fixation of the titanium Greenfield filter. *J Vasc Surg.* 1990;12:345-353.
5. Cho KJ, Greenfield LJ, Proctor MC, et al. Evaluation of a new percutaneous stainless steel Greenfield filter. *J Vasc Intervent Radiol.* 1997;8(2):181-187.
6. Boston Scientific Corporation Directions for Use 90418608
7. Boston Scientific Corporation Directions for Use 90418609

STAINLESS STEEL AND TITANIUM GREENFIELD VENA CAVA FILTER WITH 12 FRENCH INTRODUCER SYSTEM

Caution: Federal law restricts this device to sale by or on the order of a physician.

Indications: Venous thrombosis or pulmonary thromboembolism when anticoagulants are contraindicated or inadequate for management of venous thrombosis with significant risk of, or following, pulmonary thromboembolism. • Failure of anticoagulant therapy in thromboembolic diseases. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Contraindications: Patients in whom the diameter of the vena cava exceeds 28 mm. Presence of thrombus at the femoral puncture site, in the iliac vein, or in the inferior vena cava risks the dislodgment and embolism of thrombus during catheter manipulation. These conditions are absolute contraindications to implantation via femoral vein approach. Absence of thrombus at this level must be confirmed by venography or Doppler/duplex evaluation. • Percutaneous insertion in those patients with abnormal clotting times. • Patients in whom pregnancy has been confirmed are contraindicated for Stainless Steel Greenfield Vena Cava Filter placement.

Warnings: Do not manipulate the FlexCarrier capsule prior to procedure. Never advance the guide wire, sheath/dilator or introducer catheter without the use of fluoroscopic guidance. Always fully advance a .035-inch/0.89 mm guide wire to a point beyond the desired implant site. The introducer catheter cannot be inserted through the sheath with the dilator in place. The introducer catheter must be advanced over the guide wire and through the sheath. Do not activate the filter release mechanism prior to proper positioning in the vena cava, as the filter cannot be safely re-loaded into the carrier capsule. Do not attempt to modify the filter in any way prior to release. Always use the jugular sheath/dilator set with the jugular introducer catheter. Likewise, always use the femoral sheath/dilator set with the femoral introducer catheter. Never use the jugular introducer catheter for femoral vein insertion or vice-versa. Do not attempt to remove or reposition a filter when the hooks are engaged in vessel or heart walls. Do not attempt percutaneous removal and/or repositioning of a filter with hooks engaged in a vessel or tissue. A misplaced filter which nevertheless provides adequate protection against a pulmonary embolism should be left in place. If the filter is not positioned to give adequate protection against pulmonary embolism, a second filter should be placed. Operative removal has been recommended for a misplaced filter which may interfere with the function of the tricuspid valve and/or produce cardiac rhythm disturbance. MRI safe: No additional risk to the patient, but may affect the quality of the diagnostic information.

Precautions: A relative contraindication exists for this device for younger patients whose life expectancy is substantially greater than the clinical experience of the Greenfield Vena Cava Filter. Anatomical anomalies and other factors which can complicate insertion will alter the insertion technique. Careful attention to these instructions can shorten insertion time and reduce the likelihood of insertion difficulties.

Potential Complications: Potential complications associated with the use of vena cava filters include the following: Incorrect release or placement of the filter • Movement or migration of the filter • Formation of clots on the filter which could result in complete blockage of blood flow through the vena cava • Hematoma or bleeding at the insertion site • Infection • Failure of the filter to attach itself securely and potential migration of the filter to the heart or lungs • Perforation of the vena cava, adjacent blood vessels or organ by one or more hooks • Pulmonary embolism due to introducer catheter manipulation leading to dislodgment of clot during filter placement • Air embolism during filter insertion • Insertion site thrombosis • Death due to movement of clots to the heart or lungs.

Note: Please refer to the full Directions for Use manual prior to use of the device.

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To order product or for more information contact customer service at 1.888.272.1001.

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