Boston Scientific
Advancing science for life™

GREENFIELD™ Vena Cava

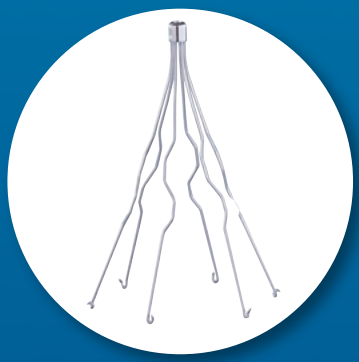
Trusted Performance, Timeless Design

Proven Stability

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

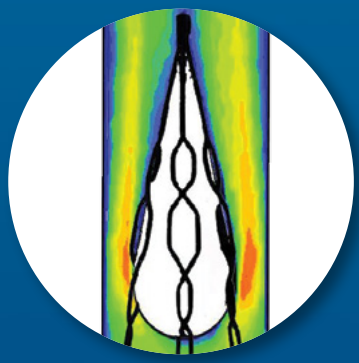
Established Filter Performance

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



Filter Design Promotes Clot Lysis

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



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

Greenfield™ Vena Cava Filters

Greenfield Stainless Steel Filter

Jugular Product Number[1]	50-400
Femoral Product Number[1]	50-501
Technical Information: MRI	MRI -Safe: No additional risk to the patients, but may affect the quality of the diagnostic information.
Delivery System (ID)	12 F
Indications	Caval diameter of 28 mm or less

Titanium Greenfield Filter and Entry Kit

Jugular Product Number[1]	50-300
Femoral Product Number[1]	50-301
Delivery System (ID)	12 F
Indications	Caval diameter of 28 mm or less
Titanium Entry Kit Product Number[2]	50-350 (recommended for each Titanium Greenfield Filter implant [sold separately])

[1]The C-code used for this product is C1880, Vena Cava Filter.
[2]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.

GREENFIELD VENA CAVA FILTER SS
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATION FOR USE:** The Greenfield Stainless Steel Vena Cava Filter with 12F (4.0 mm) Introducer System is indicated for the prevention of pulmonary embolism via placement in the vena cava in the following situations: 1. Venous thrombosis or pulmonary thromboembolism when anticoagulants are contraindicated or inadequate for management of venous thrombosis with significant risk of, or following, pulmonary thromboembolism. 2. Failure of anticoagulant therapy in thromboembolic diseases. 3. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. 4. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. **CONTRAINDICATIONS:** Patients in whom the diameter of the inferior vena cava exceeds 28 mm (for example, some patients with congestive heart failure) are contraindicated for Greenfield Stainless Steel Vena Cava Filter placement. Proper fixation of the Greenfield Stainless Steel Vena Cava Filter in the IVC may be compromised when caval diameter exceeds 28 mm. Presence of thrombus at the femoral puncture site, in the iliac vein, or in the inferior vena cava risks the dislodgement 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. Patients in whom pregnancy has been confirmed are contraindicated for Greenfield Stainless Steel Vena Cava Filter placement. **CAUTION:** The safety and effectiveness of the 12F (4.0 mm) Greenfield Stainless Steel Vena Cava Filter used in association with septic thromboembolism has not been conclusively demonstrated in the clinical setting. **WARNINGS:** Do not manipulate the FlexCarrier capsule prior to the procedure. Never advance the guidewire, sheath/dilator or introducer catheter without the use of fluoroscopic guidance. Always fully advance the included 0.035 in (0.89 mm) guidewire to a point beyond the desired implant site. The introducer catheter must be advanced over the guidewire and through the sheath. Do not activate the Filter release mechanism prior to proper positioning in the vena cava, as the Greenfield Stainless Steel Vena Cava Filter cannot be safely reloaded into the carrier capsule of the 12F (4.0 mm) introducer catheter. 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 12F (4.0 mm) jugular introducer catheter for femoral vein insertion or vice versa, as this will result in improper Greenfield Stainless Steel Vena Cava Filter orientation in the inferior vena cava. 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 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 patients, 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™ Stainless Steel 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 ADVERSE EVENTS:** Potential Adverse Events 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 (bruise) 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 dislodgement of clot during Filter placement • Air embolism during Filter insertion • Insertion site thrombosis • Death due to movement of clots to the heart or lungs

GREENFIELD VENA CAVA FILTER - TITANIUM
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATION FOR USE:** Current indications for Greenfield Titanium Vena Cava Filter placement are as follows: 1. When adequate anticoagulation fails to prevent recurrent embolism. 2. Patients with venous thrombosis or pulmonary embolism who have a contraindication to anticoagulation, or are difficult to manage on anticoagulation. 3. Patients with chronic, recurrent pulmonary embolism with associated pulmonary hypertension and corpulmonale. 4. Following an episode of massive pulmonary embolism. 5. Patients with deep vein thrombosis on anticoagulants who develop a complication forcing the discontinuation of anticoagulation. **CONTRAINDICATIONS:** Patients in whom the diameter of the inferior vena cava exceeds 28 mm (for example, some patients with congestive heart failure) are contraindicated for Greenfield Titanium Vena Cava Filter placement. Proper fixation of the Greenfield Titanium Vena Cava Filter in the IVC may be compromised when caval diameter exceeds 28 mm. Presence of thrombus at the femoral puncture site, in the iliac vein, or in the inferior vena cava risks the dislodgement 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 **WARNINGS:** Never advance the guidewire, sheath/dilator or introducer catheter without the use of fluoroscopic guidance. Always fully advance an 0.038 in (0.97 mm) guidewire to a point beyond the desired implant site The introducer catheter cannot be inserted through the sheath with the dilator or guidewire in place. The introducer catheter must be advance through the sheath. Do not activate the Greenfield Titanium Vena Cava Filter release mechanism prior to proper positioning in the vena cava, as the Greenfield Titanium Vena Cava Filter cannot be safely reloaded 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 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. **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 ADVERSE EVENTS:** Potential adverse events 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 (bruise) 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 dislodgement of clot during Filter placement • Air embolism during Filter insertion • Insertion site thrombosis • Death due to movement of clots to the heart or lungs

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