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

**Jugular Product Number** 50-400

**Femoral Product Number** 50-501

**Technical Information:** MRI - Safe

**Delivery System (ID):** 12 F

**Indications:** Cephalic diameter of 28 mm or less

Titanium Greenfield Filter and Entry Kit

**Jugular Product Number** 50-300

**Femoral Product Number** 50-301

**Delivery System (ID):** 12 F

**Indications:** Cephalic diameter of 28 mm or less

**Titanium Entry Kit** 50-350 (recommended for each Titanium Greenfield Filter implant [sold separately])

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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.

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**GREENFIELD VENA CAVA FILTER:**

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician. 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 12 F (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 thromboembolism when anticoagulants are contraindicated for management of venous thrombosis with significant risk of, or following, pulmonary thromboembolism. 2. Failure of anticoagulant therapy in thromboembolic disease. 3. Emergency treatment following massive pulmonary embolism where anticoagulation therapy is not indicated. 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 function 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 Duplex Doppler evaluation. Patients in whom pregnancy has been confirmed are contraindicated for Greenfield Stainless Steel Vena Cava Filter use in association with suppel anticoagulation therapy which has not been conclusively demonstrated in the clinical setting. PRECAUTIONS: Do not manipulate the FlexCarrier capsule prior to this procedure. Never advance the guidewire, sheath/dilator, or introducer catheter without the use of fluoroscopic guidance. Always fully advance the included 0.35 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 if the 12 F (4.0 mm) introducer catheter is not in place. 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 12 F (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 puncture or 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 provide 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. POTENTIAL ADVERSE EVENTS: 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 would make insertion ill-advised will affect 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 organs 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.

**GREENFIELD VENA CAVA FILTER - TITANIUM:**

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. 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 Transvenous Vena Cava Filter placement are as follows: 1. When adequate anticoagulation fails to prevent recurrent embolism. 2. Patients with venous thromboembolism in whom anticoagulation is contraindicated or is difficult to manage on anticoagulation. 3. Patients with recurrent pulmonary embolism who have a contraindication to anticoagulation, or are difficult to manage on anticoagulation. 4. Patients with deep vein thrombosis in whom anticoagulation is contraindicated or difficult to manage on 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 function 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 Duplex Doppler evaluation. Patients in whom pregnancy has been confirmed are contraindicated for Greenfield Titanium Vena Cava Filter use in association with suppel anticoagulation therapy which has not been conclusively demonstrated in the clinical setting. PRECAUTIONS: Do not manipulate the FlexCarrier capsule prior to this 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 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 12 F (3.0 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 puncture or 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 provide 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. POTENTIAL ADVERSE EVENTS: 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 would make insertion ill-advised will affect 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 organs 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.

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