DENALI®
Vena Cava Filter

MRI Safety

The DENALI® Vena Cava Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the DENALI® Vena Cava Filter is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or 1.5-Tesla
- Spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg in the normal operating mode

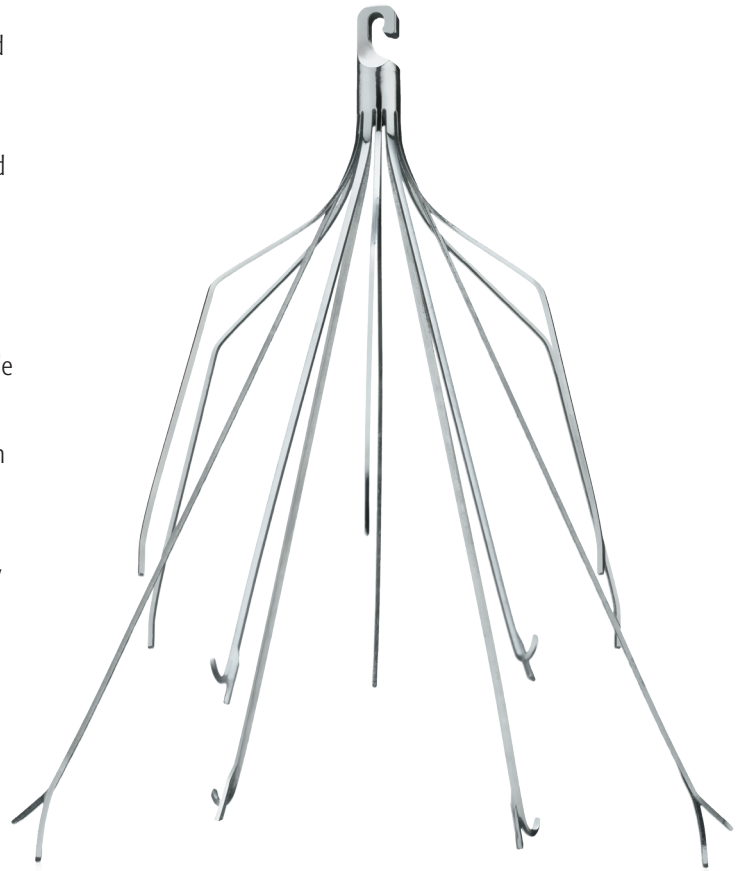
In non-clinical testing, the DENALI® Vena Cava Filter produced a temperature rise of 2.7°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of continuous MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the DENALI® Vena Cava Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

Artifact Information:

Image artifact of the DENALI® Filter was tested according to ASTM F2119-07 in a GE HDx 3-Tesla cylindrical bore scanner. The greatest artifact occurred at the snare hook and the ends of the arms and legs with the static field parallel to the length. The maximum extent of the artifact beyond the metal of the phantom was 5 mm for the spin echo sequence and 10 mm for the gradient echo sequence. Imaging parameters may need to be adjusted for artifact optimization.

It is recommended that patients with a vena cava filter register the MR conditions with the MedicAlert Foundation (www.medicalert.org).



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DENALI® Vena Cava Filter

Indications for Use

The DENALI® Filter is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- 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.

The DENALI® Filter may be removed according to the instructions supplied in the Instructions for Use under the section labeled: "Optional Procedure for Filter Removal".

Contraindications for Use

The DENALI® Vena Cava Filter should not be implanted in:

- Patients with an IVC diameter larger than 28 mm.
- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with risk of septic embolism.
- Patients with uncontrolled sepsis.
- Patients with known hypersensitivity to nickel-titanium alloys.

The DENALI® Vena Cava Filter should not be retrieved if significant thrombus is in or near the filter.

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

G70733 Rev 0

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