DENALI
Vena Cava Filter

Femoral Vein Approach
Instructions for Use
Instructions for Use
For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. Device Description

The Denali® Vena Cava Filter is a venous interruption device designed to prevent pulmonary embolism. The Denali® Filter may be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach. The Denali® Filter is designed to act as a permanent filter. When clinically indicated, the Denali® Filter may be percutaneously removed after implementation according to the instructions provided under the "Optional Procedure for Filter Removal" section.

The Denali® Filter consists of twelve shape-memory laser-cut nickel-titanium appendages. These twelve appendages form two levels of filtration with the legs providing the lower level of filtration and the arms providing the upper level of filtration. The Denali® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28mm.

B. MRI Safety

The Denali® Vena Cava Filter was determined to be MR-conditional according to the terminology specified in 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 1.5-Tesla or 3-Tesla
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg in the normal operating mode
- Spatial gradient magnetic field of 720-Gauss/cm or less
- Static magnetic field of 3-Tesla or 1.5-Tesla
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg in 15-minutes of continuous MR scanning
- Magnetic resonance (MR) imaging in a 3-Tesla or 1.5-Tesla system using a transmit/receive body coil
- MR image quality may be degraded 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 10mm 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). It is recommended that patients with a vena cava filter register the MR conditions with the MedicAlert Foundation (www.medicalert.org).

C. Indications for Use

The Denali® Filter is indicated for use in the prevention of recurrent pulmonary embolism via placement in the inferior 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 when anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism when anticoagulant therapy has failed or is contraindicated

The Denali® Filter may be removed according to the instructions supplied under section labeled: “Optional Procedure for Filter Removal.”

Figure 1: Denali® Filter (Supplied Preloaded)

Figure 2: Denali® Vena Cava Filter Femoral System

Note: This product is not made with natural rubber latex.
DENALI® Vena Cava Filter should not be implanted in:

- Any condition where palliation is required
- Pregnant patients when fluorescein may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with risks for hypercoagulability, anticoagulation, and/or sepsis
- Patients with uncontrolled sepsis
- Patients with risk of septic embolism.

It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, and to flush and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminate period of time. The residue of biological material can promote the contamination of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues - are influenced by thermal and/or mechanical changes. Cleaning, reprocessing, and/or resterilization of the present medical device increases the risk of cross-patient contamination.

A small thrombus may be bypassed by the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the procedure or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the device.

The filter wires are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the removal of the filter and restoration of normal utilization of the IVC.

In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anticoagulation with warfarin, as bridging anticoagulation may increase embolic risk due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if necessary. Position the filter snare hook 1cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.

If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A thrombus may be aspirated prior to entry and/or removal.

If the Vena Cava diameter is greater than 28mm do not deploy the DENALI® Filter.

Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the vena cava. Using a saline flush without aspirating the introducer may prevent the filter from further advancement within the introducer sheath.

The safety and effectiveness of this device has not been established for morbidly obese patients. Abdominal narrowing.

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Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the vena cava. Using a saline flush without aspirating the introducer may prevent the filter from further advancement within the introducer sheath.
The study was conducted to assess the safety of the DENALI® Filter in morbidly obese patients. The risk/benefit ratio of any of these interventions should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

### Clinical Experience

A single-arm, prospective, multi-center clinical study was conducted to assess the safety of the DENALI® Filter as both a permanent and retrievable device. Clinical Success of Placement (CSP) was defined as freedom from placement failure or technical failure of placement. The pre-established performance goal was that the lower bound of the 95% confidence interval for the CSP was greater than 80%. Technical Success of Retrieval (TSR) was defined as retrieval of the filter such that the entire filter was retrieved intact. Clinical Success of Retrieval (CSR) was defined as successful technical retrieval of the filter without retrieval complications requiring intervention. Additionally, the secondary endpoints of retrieval success, new or worsening DVT, filter migration, filter fracture, penetration and tilt were assessed.

### Reasons Visit Not Completed

Events occurring after the retrieval of the filter were assessed.

### Potential Complications

- Venous ulceration
- Stroke
- Postphlebitic syndrome
- Pneumothorax
- Organ injury
- Thrombophlebitis
- Venous ulceration
- Blood loss
- Guidewire embolism
- Pain

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

### H. Clinical Experience

Of the 200 patients who underwent Filter placement, 120 had active thromboembolic disease (the presence of DVT or PE at the time of Filter placement). Of these 120 patients, 66 had a contraindication to anticoagulation, 9 had a complication related to the use of anticoagulant medication, 20 had a failure of anticoagulation, and 25 had a filter placed without contraindication, complication or failure related to anticoagulant medication.

### Table: Patient Accountability

<table>
<thead>
<tr>
<th>Event</th>
<th>Eligible</th>
<th>Retrieved</th>
<th>Reason</th>
<th>Not Retrieved</th>
<th>Events Occurring Below</th>
<th>Events Occurring After</th>
<th>Events Occurring Before</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline/ Implant</td>
<td>200</td>
<td>200</td>
<td>N/A</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3 Months</td>
<td>162</td>
<td>162 (100%)</td>
<td>N/A</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6 Months</td>
<td>130 (65%)</td>
<td>119 (98%)</td>
<td>39</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12 Months</td>
<td>121 (60%)</td>
<td>119 (98%)</td>
<td>34</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>18 Months</td>
<td>54</td>
<td>53 (98%)</td>
<td>8</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>24 Months</td>
<td>48 (45%)</td>
<td>48 (45%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Retrieved</td>
<td>124</td>
<td>124</td>
<td>N/A</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TSR (Post-Retrieval)</td>
<td>121 (98%)</td>
<td>N/A</td>
<td>2</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Results

CSF for the DENALI® Filter was 95.9% and the lower bound of the 95% confidence interval was 91.9%. It was concluded that the performance goal was met. TSP for the Denali Filter was 99.5%. Mean placement procedure time was 17.8 minutes and mean fluoroscopy time was 3.6 minutes. TSR for the Denali Filter was 97.6%, CSP for the Denali Filter was 99.2%.

### Table: Primary Endpoints

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CSP (%)</th>
<th>TSR (%)</th>
<th>TSP (%)</th>
<th>CSR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Months</td>
<td>100</td>
<td>98</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>6 Months</td>
<td>98</td>
<td>97</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>12 Months</td>
<td>98</td>
<td>97</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>18 Months</td>
<td>97</td>
<td>96</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>24 Months</td>
<td>96</td>
<td>95</td>
<td>99</td>
<td>99</td>
</tr>
</tbody>
</table>
The 0-24 month time frame includes all patients that reported an event regardless of length of follow-up. The 0-6 month time frame includes patients that completed the 6 month visit or had their filter retrieved within the 6 month window.

11. Select the optimum location for filter placement and measure the IVC diameter, (for example 1cm below the rating of 800 psi. occlusion of the introducer which may interfere with delivery device advancement.

10. Remove the guidewire and perform a standard inferior venacavogram in both the AP and lateral view,

9. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that

8. Remove the 18 gauge entry needle over the straight guidewire.

6. Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.

5. Open the inner pouch and remove the introducer sheath and both dilators using sterile technique.

4. Prep, drape and anesthetize the skin puncture site in standard fashion.

3. Inspect the packaging to ensure that it has not been opened or damaged.

2. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient’s size or anatomy, operator’s preference or location of venous thrombosis. Right femoral vein is preferred.

1. Collect and prepare the following equipment for use.

- One Denux® Vena Cava Femoral System that contains: one 55cm, 8.4 French I.D. introducer sheath and 8F dilator set - One storage tube with preloaded Denux® Filter and pusher delivery system - 0.035” straight Guidewire, 110cm long or longer - Syringe for saline infusion - All basic materials for venipuncture scalpel, #11 blade, local anesthetic, drapes, etc.

Select a suitable femoral venous access route, on either the right or left side, depending upon the patient’s site or anatomy, operator’s preference or location of venous thrombosis. Right femoral vein is preferred.

3. Inspect the packaging to ensure that it has not been opened or damaged.

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  - 0.035” straight Guidewire, 110cm long or longer
  - Syringe for saline infusion
  - All basic materials for venipuncture (scalpel, #11 blade, local anesthesia, drapes, etc.)

### Directions for Use - Implantation

1. Collect and prepare the following equipment for use.

| Number of Filter Retrieval Attempts | 104 |
| Number of Successful Retrievals | 61 |
| Retrieval Success Rate | 57.6% |
| Mean Indwnt Time | 200.5 days |
| Maximum Indwnt Time | 736 days |

WARNING: Contents are supplied sterile. Do not use if the product sterilization barrier or its packaging is compromised.

WARNING: If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

12. Reintroduce the guidewire and advance the introducer sheath with the selected optimum location under fluoroscopic guidance. For femoral insertion, the introducer sheath tip should be 1cm below the femoral artery. Note: The Introducer Radiopaque Marker Band Site a few mm away from the tip.

11. Select the optimum location for filter placement and measure the IVC diameter, (for example 1cm below the lowest renal vein) using a radiopaque marker band. Markers bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Figure 2).

10. Remove the guide wire and flush the introducer sheath with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer sheath.

9. Check the venipuncture sites fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer sheath.

8. Remove the 18 gauge entry needle over the straight guidewire.

7. Insert the 0.035” straight guidewire and gently advance it into the dilated vena cava or iliac vein.

6. Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.

5. Open the inner pouch and remove the introducer sheath and both dilators using sterile technique.

4. Prep, drape and anesthetize the skin puncture site in standard fashion.

3. Inspect the packaging to ensure that it has not been opened or damaged.

2. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient’s size or anatomy, operator’s preference or location of venous thrombosis. Right femoral vein is preferred.

1. Collect and prepare the following equipment for use.

### Table 4: Denali® Filter Retrieval Details

| Number of Filter Retrieval Attempts | 104 |
| Number of Successful Retrievals | 61 |
| Retrieval Success Rate | 57.6% |
| Mean Indwnt Time | 200.5 days |
| Maximum Indwnt Time | 736 days |

### Table 3: Complications Rates

<table>
<thead>
<tr>
<th>Time Frame</th>
<th>Events (total)</th>
<th>Number of Patients</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-24 Months</td>
<td>14</td>
<td>188</td>
<td>7.5%</td>
</tr>
<tr>
<td>0-6 Months</td>
<td>10</td>
<td>168</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

### Figure 3: Time from Implantation to Retrieval (N=121)

- **Number of Successful Retrievals**: 121
- **Number of Successful Retrievals with Return of Venous Access**: 114
- **Number of Successful Retrievals with Return of Venous Access but No Venous Access**: 6
- **Number of Unsuccessful Retrieval**: 5
- **Number of Unsuccessful Retrieval with Return of Venous Access**: 3
- **Number of Unsuccessful Retrieval with Return of Venous Access but No Venous Access**: 2
- **Number of Unsuccessful Retrieval with Return of Venous Access and No Venous Access**: 1
- **Number of Unsuccessful Retrieval with Return of Venous Access and No Venous Access but No Venous Access**: 0

<table>
<thead>
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<th>Events (total)</th>
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<th>Rate</th>
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### Note:

- One 55cm, 8.4 French I.D. introducer sheath and 8F dilator set
- One storage tube with preloaded Denux® Filter and pusher delivery system
- 0.035” straight Guidewire, 110cm long or longer
- Syringe for saline infusion
- All basic materials for venipuncture scalpel, #11 blade, local anesthetic, drapes, etc.

Select a suitable femoral venous access route, on either the right or left side, depending upon the patient’s size or anatomy, operator’s preference or location of venous thrombosis. Right femoral vein is preferred.

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Select a suitable femoral venous access route, on either the right or left side, depending upon the patient’s size or anatomy, operator’s preference or location of venous thrombosis. Right femoral vein is preferred.

The site medical examiner listed the primary cause of death as pulmonary embolism and the second-
14. Aspirate from the introducer side port to remove any potential air.

15. Flush the introducer sheath intermittently by hand to maintain introducer sheath patency. Maintaining patency helps prevent clot from adhering to the filter deployment system.

16. Remove the delivery system containing the filter from the package, remove the red safety cap and check for proper filter orientation (Reference Figure 4).

Note: Not all pusher assembly components are shown in Figures 4-9.

17. Flush the delivery system with saline through the Touhy-Borst adapter.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer which may interfere with delivery device advancement.

18. Attach the free end of the filter storage tube directly to the introducer sheath already in the vein. The introducer sheath and filter delivery system should be held in a straight line to minimize friction.

19. Remove the proximal end of the Touhy-Borst adapter and advance the filter through the introducer sheath by moving the pusher forward. Do not twist or retract the pusher at any time during the procedure.

PRECAUTION: Care should be taken to ensure the connection between the introducer hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

20. Advance until the black predeployment mark on the pusher is flush with the proximal end of the Touhy-Borst adapter. The introducer sheath and filter delivery system should be held in a straight line to minimize friction.

21. Prior to deployment, verify the location of the filter within the sheath using fluoroscopy and confirm that the filter snare hook is 1cm below the lowest renal or is in the intended location in the inferior vena cava.

22. Deliver and release filter as described in Step 22. A-B.

A. Firmly grasp the pusher handle. Keep this hand stationary throughout the entire filter release/deployment process. The filter should be positioned at the distal end of the introducer sheath.

B. Under fluoroscopic guidance, hold the pusher handle stationary, (it is recommended to stabilize the hand on a stationary object) and with the other hand draw the Touhy-Borst adapter, storage tube and introducer sheath assembly back all the way to the handle, unsheathing and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process.

Note: The assembly should be retracted in one smooth, continuous motion.

23. Under fluoroscopic guidance, carefully withdraw the distal tip of the pusher back into the storage tube by firmly holding the Touhy-Borst adapter, storage tube, and introducer sheath assembly and pulling back on the pusher. Then disconnect the storage tube from the introducer sheath.

24. Resume the intermittent saline flush to maintain introducer sheath patency.

25. A venacavogram may be performed to confirm satisfactory deployment before terminating the procedure (typically 30mL of contrast medium at 15mL/s).

PRECAUTION: Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent entanglement.

26. Remove the introducer sheath and apply routine compression over the puncture site to achieve hemostasis.

J. Optional Procedure for Filter Removal

Removal of DENALI® Filter Using an Intravascular Snare

Collect and Prepare the Following Equipment for Use:

- One intravascular snare
- Dual retrieval sheaths, 9F I.D. and 11F I.D.
- 0.035” Straight Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
- Imaging Catheter

WARNING: Remove the DENALI® Filter using an intravascular loop snare only.

WARNING: Do not attempt to remove the DENALI® Filter if significant amounts of thrombus are trapped within the filter or if the filter snare hook is embedded within the vein cava wall.

PRECAUTION: Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent entanglement.

PRECAUTION: The retrieval of the DENALI® Vena Cava Filter should only be performed using minimum 9F LD,11F LD. dual retrieval sheaths. Miseuse of these devices or improper retrieval technique may result in internal injury or caval narrowing.
Procedural Instructions
1. Select a suitable jugular venous access route on either the right or left side depending upon the patient’s size or anatomy, operator’s preference, or location of venous thrombosis. (The right jugular vein is preferred).
2. Prior to use, remove the retrieval sheaths from their packaging and flush them with heparinized saline or suitable isotonic solution.
3. Prepare all other procedure components according to the manufacturers’ Instructions for Use.
4. Perform a venacavagram in the AP and lateral views to determine the orientation and configuration of the filter, taking care not to disrupt the filter while crossing through. Also, use the appropriate technique to determine if the filter, the jugular retrieval route, and distal IVC are free of thrombus.
5. Select the appropriate loop diameter size of the intravascular snare.
6. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.
7. Assemble the components of both retrieval sheaths and ensure all components are flushed.
8. Carefully advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter if it is not positioned there already.
9. Introduce and advance the 11F retrieval sheath with dilator over the guidewire.
10. Remove the 11F dilator. Introduce and advance the 9F retrieval sheath with dilator over the guidewire such that the tip of the sheath is approximately 2cm cephalad to the filter snare hook.
11. Remove the guidewire and dilator.
12. Insert and advance the intravascular snare assembly through the 9F retrieval sheath until it protrudes out such that the marker band of the snare catheter is cephalad to the filter snare hook.
13. The retrieval of the DENALI® Filter using an intravascular snare is illustrated below.

**Figure 10:** Retrieval of DENALI® Filter using an Intravascular Snare

- **Figure 10A:** Slowly advance the loop forward over the filter snare hook.
- **Figure 10B:** Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare catheter until the loop encircles the filter snare hook.
- **Figure 10C:** Advance the retrieval system in the caudal direction until it covers half of the filter. PRECAUTION: Care should be taken when advancing the 9F retrieval sheath in the caudal direction to avoid completely covering the arms and legs.
- **Figure 10D:** While keeping tension of the hook, reposition and withdraw the filter into the sheath by retracting the intravascular snare.
- **Figure 10E:** Retract the snare until the filter and cranial anchors are completely contained inside the retrieval sheath.
- **Figure 10F:** Once the filter is fully collapsed inside the 9F retrieval sheath, retract the filter, the snare, and the retrieval sheath as one unit through the 11F retrieval sheath.
- **Figure 10G:** Remove the filter from the retrieval sheath and examine the filter to assure that the complete filter has been removed.
- **Figure 10H:** Note: Care when handling the filter as the anchors are sharp.

A follow-up venacavogram should be performed prior to withdrawing the 11F retrieval sheath (typically 30mL of contrast medium at 15mL/s).

PRECAUTION: Do not use the 9F retrieval sheath for imaging or flushing once the filter has been removed.

J. How Supplied
Each DENALI® Vena Cava Filter is supplied preloaded in a storage tube. Each DENALI® Vena Cava Filter is sterile and nonpyrogenic unless the package is damaged or opened. It is for single use only. The delivery system is pre-assembled.

K. Warranty
Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular’s sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of the product are not covered by this limited product warranty. TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT. Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country. An issue or revision date and a revision number for these instructions are included for the user’s information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

L. References:
2. Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country. An issue or revision date and a revision number for these instructions are included for the user’s information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

- **Practice Guidelines for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism** [JVIR 2003; 14:S271-S275].
- **American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease** [ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians’ evidence-based clinical practice guidelines].
- **Pulmonary Embolism** [ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians’ evidence-based clinical practice guidelines].
- **Pulmonary Embolism: The EAST Practice Management Guidelines Work Group** [J Trauma 2002; 53:142-64].
- **Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism** [JVIR 2003; 14:527-528].
Contents:
(1) Denali® Filter- Femoral Delivery Device
(1) 8.4F I.D. Introducer Sheath 55cm Long with 8F Dilator

Use By
Lot Number
Catalogue Number
Introducer Sheath

Attention, See Instructions for Use

Sterilized Using Ethylene Oxide

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