A. Device Description

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

The **Denali® Vena Cava Filter** consists of twelve wire-shape-memory laser-cut nitinol barium 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® Vena Cava Filter** is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28mm.

![Figure 1: Denali® Vena Cava Filter (Supplied Preloaded)](image1)

The **Denali® Vena Cava Filter System** consists of an introducer sheath and dilator, and a preloaded **Denali® Vena Cava Filter** in a storage tube with a pusher. The dilator accepts a 0.035” guidewire and allows for an 800 psi maximum pressure contrast power injection. Radiopaque marker bands on the end of the dilator aid in measuring the maximum indicated IVC diameter. They are spaced at a distance of 28mm (outer-to-outer). The 55cm, 8.4 French I.D. introducer sheath contains a radiopaque marker band and hemostasis valve with a side port. The pusher advances the filter through the introducer sheath to the predeployment marker band and is then used to fix the filter in place while the filter is sheathed. The **Denali® Vena Cava Filter Femoral System** is illustrated in Figure 2.

**Note:** This product is not made with natural rubber latex.

![Figure 2: Denali® Vena Cava Filter Femoral System](image2)

B. MRI Safety


Non-clinical testing demonstrated that the **Denali® Vena Cava Filter** is MR Conditional. A patient with this implant can be scanned safely 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 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).

C. Indications for Use

The **Denali® Vena Cava Filter** is indicated for use in the prevention of recurrent pulmonary embolism by placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy for thromboembolic disease
1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.

2. Do not use the device or accessories after the expiration date.

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

4. Anatomical variances may complicate filter insertion, deployment and removal. Careful attention to these
   potential complications can shorten insertion time and reduce the likelihood of difficulties.

5. Do not deploy the filter prior to proper positioning in the IVC, as the Denali® Vena Cava Filter cannot be
   safely released into the storage tube. Do not deploy the filter unless IVC has been properly measured.

6. Never re-deploy a removed filter.

7. Delivery of the Denali® Filter through the introducer sheath is advance only. Retraction and twisting of the
   pusher during delivery could result in dislodgement of the filter, crossing of filter legs or arms, and could
   impede or dislodge the filter.

8. The Denali® Filter Femoral System is designed for femoral approaches only. Never use the Denali®
   Femoral System for superior approaches (jugular, subclavian or antecubital vein), as this will result in
   dislodgement due to large clot burdens.

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

10. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it
    migration of the clot and/or filter may occur. Attempt filter delivery through an alternate small
    femoral approach and/or use the venipuncture site.

11. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic
    monitoring; it is possible that complications such as those described in the “Warnings”, “Precautions”, or “Potential
    Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the
    device malfunctioning if not detected early through visualization using fluoroscopy.

12. Never attempt to deliver the filter while the filter snare hook is embedded within the cava wall.

13. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
    • Patients with uncontrolled sepsis
    • Patients with an IVC diameter larger than 28mm.

14. Movement, migration or tilt are known complications of vena cava filters. Migration of filters to the
    heart or lungs may occur if the filter is not properly positioned in the IVC so that the filter is not stabilized
    by the IVC walls. If a large clot burden is present, re-implantation or removal may be necessary.

15. 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.

16. Patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of
    such anatomic narrowing.

17. Patients with uncontrolled sepsis

18. If accidentally deployed, do not attempt to reintert the filter into the filter storage tube as damage to the
    legs and hooks can occur.

19. If deployed, the filter, the right femoral vein is preferred.

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

21. The removal of the Denali® Vena Cava Filter System and accessories may be a potential biohazard. Handle and
    dispose of in accordance with accepted medical practices and applicable local, state and federal laws and
    regulations.
H. Clinical Experience

A single-center, multi-center clinical study was conducted to assess the safety of the Denali® Filter as both a permanent and retrievable device. Clinical Success Placement (CSP) was defined as freedom from subsequent PE, filter embolization, caval occlusion, filter or procedure related death, insertion adverse events, and technical failure of placement. The pre-established performance goal was that the lower bound of the 95% confidence interval for the CSP rate be greater than 95%. Technical success of placement (TSP) was defined as deployment into the IVC and/or deployment due to clot burden.

Filter failures are known complications of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the patient’s filter either by endovascular or surgical techniques.

• Detachment of components
• Perforation or other acute or chronic damage of the IVC wall
• Acute or recurrent DVT
• Venous thrombosis
• Extraction of contract material at time of vena caval occlusion
• Pulmonary embolism
• Hematoma or nerve injury at the puncture site or subsequent retrieval site
• Hemorrhage
• Ostomy
• Occlusion of small vessels
• Distal embolization
• Intimal tear
• Stentosis at implant site
• Failure of wire exchange/completion expansion
• Filter malposition
• Vessel injury
• Arteriovenous fistula
• Back or anterior pain
• Filter tilt
• Hernemothorax
• Organ injury
• Phlegmasia coerulea dolens
• Pneumothorax
• Postphlebitic syndrome
• Stroke
• Thrombophlebitis
• Venous ulceration
• Venous stasis
• Fat embolization
• Guidewire entrapment

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 various vena caval filters. The table below reports adverse events in the post-procedure period for the Denali® Filter as both a permanent and retrievable device. Clinical Success Placement (CSP) was defined as freedom from subsequent PE, filter embolization, caval occlusion, filter or procedure related death, insertion adverse events, and technical failure of placement.

Table 1: Patient Accountability

<table>
<thead>
<tr>
<th>Event</th>
<th>Eligible for Visit</th>
<th>N</th>
<th>N, %</th>
<th>N, %</th>
<th>N, %</th>
<th>N, %</th>
<th>N, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>175</td>
<td>175</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-Hospitalized Events</td>
<td>175</td>
<td>175</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Migrated</td>
<td>6 Month</td>
<td>69 (39%)</td>
<td>69</td>
<td>32</td>
<td>32</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>12 Month</td>
<td>5 (10%)</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>CSP for the filter</td>
<td>6 Month</td>
<td>69</td>
<td>69</td>
<td>32</td>
<td>32</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>CSP for the patient</td>
<td>6 Month</td>
<td>69</td>
<td>69</td>
<td>32</td>
<td>32</td>
<td>32</td>
<td>32</td>
</tr>
</tbody>
</table>

CSP was adjudicated by the CEC, not device related.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to:

• Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported.[9, 10] There have also been reports of causal migration of the filter. Migration may be caused by placement in IVC with diameters exceeding the acceptable labeled diameters specified in the P.I. [10] Movement of the filter also may occur due to placement in a large IVC and/or through an inadequate sheath into IVC and/or due to clot burden.

• Filter failures 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 retrieval of the patient’s filter either by endovascular or surgical techniques.

• Detachment of components
• Perforation or other acute or chronic damage of the IVC wall
• Acute or recurrent DVT
• Venous thrombosis
• Extraction of contract material at time of vena caval occlusion
• Pulmonary embolism
• Hematoma or nerve injury at the puncture site or subsequent retrieval site
• Hemorrhage
• Ostomy
• Occlusion of small vessels
• Distal embolization
• Intimal tear
• Stentosis at implant site
• Failure of wire exchange/completion expansion
• Filter malposition
• Vessel injury
• Arteriovenous fistula
• Back or anterior pain
• Filter tilt
• Hernemothorax
• Organ injury
• Phlegmasia coerulea dolens
• Pneumothorax
• Postphlebitic syndrome
• Stroke
• Thrombophlebitis
• Venous ulceration
• Venous stasis
• Fat embolization
• Guidewire entrapment
10. Remove the guidewire and perform a standard inferior venacavogram in both the AP and lateral view, (typically 30mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and hubs connect properly. Advance the 8.4 French introducer sheath together with its tapered dilator over the 0.035” straight guidewire, 110cm long or longer.

11. Select the optimum location for filter placement and measure the IVC diameter, (for example 1cm below the lowest renal vein, or 1cm above the highest). IVC diameters should be measured below the renal veins. The IVC should be at least 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Figure 2).

12. Introduce the introducer sheath with its tip in the inferior vena cava. The Introducer Radiopaque Marker Band sits a few mm away from the tip.

13. Disconnect the dilator from the sheath and remove the dilator and guidewire, leaving the 8.4 French introducer bypassed by the guidewire and introducer sheath.

14. Aspirate from the introducer side port to remove any potential air.

15. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs connect properly. Advance the 8.4 French introducer sheath together with its tapered dilator over the 0.035” guidewire and into the distal vena cava or the iliac vein.

16. Remove the delivery system containing the filter orientation (Reference Figure 4).

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and into the introducer which may interfere with delivery device advancement.

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

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and introducer sheath with its tip in the inferior vena cava.

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 prevented clot from interfering with filter deployment.

WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.

PRECAUTION: If the vena cava diameter is greater than 28mm, do not deploy the filter. A small thrombus could be prevented clot from interfering with filter deployment.

WARNING: Any patient completing the one month post-retrieval visit.

Number of Filter Retrieval Attempts 86
Number of Successful Retrievals 86
Retrieval Success Rate 97.7%
Mean Indwell Time 138.2 days
Mean Indwell Time Maximum Indwell Time 454 days

Figure 3: Time from Implantation to Retrieval (N=86)

Table 2: Complication Rates

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number of Subjects</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent PE</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>New DVT</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Worsening DVT</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cerebral Embolism</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Filter Fracture</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cranial Migration</td>
<td>11</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Filter Tilt at Retrieval</td>
<td>31</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Filter Tilt at Placement</td>
<td>31</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Filter Penetration at Placement</td>
<td>31</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cranial Migration</td>
<td>11</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Filter Retrieval at Fluoroscopy</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Filter Retrieval at Contrast</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3: Denali® Filter Retrieval Details

Figure 4: Safety Cap Removal

Figure 5: Pusher Assembly Components

Figure 6: Denali Filter
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.

**Figure 5: Attachment to Introducer Sheath**

19. Loosen 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.

**Figure 6: Advancement of Filter**

20. Advance until the black predeployment mark on the pusher is flush with the proximal end of the Touhy-Borst adapter. The black predeployment mark on the pusher provides a visual cue indicating that the filter is near the end of the sheath.

**Figure 7: Advancement to Proximal End of Adapter**

21. Prior to deployment, verify the location of the filter within the sheath using fluoroscopy and confirm that the filter hook is ‘on’ (i.e. below the renal or is in the intended location in the inferior vena cava).

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

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, unsealing and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process.

C. Ensure that the filter is fully deployed.

**Figure 8: Unsealing of Filter**

23. Under fluoroscopic guidance, slowly 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.

**PRECAUTION:** Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unseal the stationary filter. Do not twist the pusher wire handle at anytime during this procedure.

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

**PRECAUTION:** 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 entrapped in the vena cava wall.

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

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

29. Optional Procedure for Filter Removal

**Removal of Denali® Filter Using an Intravascular Snare**

Collect and Prepare the Following Equipment for Use:

- One intracaval snare
- Dual retrieval sheaths, 12 F. and 11 F. I.D.
- 0.035” Straight Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Cortisol
- Syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
- Imaging Catheter

**WARNING:** Remove the Denali® Filter if using an intracavitary 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 entrapped in the vena 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 US-11F L.D. dual retrieval sheaths. Misuse of these devices or improper retrieval technique may result in intimal 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 isotonic saline.

3. Prepare all other procedure components according to the manufacturers’ Instructions for Use.

4. Assemble the components of both retrieval sheaths and ensure all components are flushed.

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. Introduce and advance the 11F retrieval sheath with dilator over the guidewire. Assemble 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 trapped by the filter or if the filter snare hook is embedded within the vena cava wall.

9. Introduce and advance the 9F retrieval sheath with dilator over the guidewire such that the tip of the sheath is approximately 3cm occluded to the filter snare hook.

10. Remove the guidewire and dilator.

11. Insert and advance the intracaval 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.

12. 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.

13. The retrieval of the Denali® Filter using an intracavitary snare is illustrated below.

<table>
<thead>
<tr>
<th>Collect and Prepare the Following Equipment for Use:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>One intracaval snare</td>
<td>Dual retrieval sheaths, 12 F. and 11 F. I.D.</td>
</tr>
<tr>
<td>0.035” Straight Guidewire, 110cm long or longer</td>
<td>18 gauge entry needle</td>
</tr>
<tr>
<td>Saline</td>
<td>Cortisol</td>
</tr>
<tr>
<td>Syringe for saline infusion</td>
<td>All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.</td>
</tr>
<tr>
<td>Imaging Catheter</td>
<td>Collect and Prepare the Following Equipment for Use:</td>
</tr>
</tbody>
</table>
Figure 10: Retrieval of Denali® 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 backwards until the loop engages the filter snare hook.

Note: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the filter snare hook and that the filter snare hook, retrieval sheath and snare are aligned. Be careful to snake the top of the hook, not the sides. The marker tip of the snare catheter must be cephalad to the filter snare hook.

Note: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter snare hook.

Figure 10C: Advance the retrieval sheath 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 snare, hold the retrieval sheath stationary 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.

14. Remove the filter from the retrieval sheath and examine the filter to assure that the complete filter has been removed.

Note: Take care when handling the filter as the anchors are sharp.

15. A follow-up venogram 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.

16. Remove the 11F retrieval sheath and apply routine compression over the puncture site in the usual way to achieve hemostasis.

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. If the filter is inadvertently deployed, do not attempt to re-sterilize or reload it. The Denali® Vena Cava Filter should be stored in a cool (room temperature), dark, dry place.

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 this product are not covered by this limited 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:


Denali® Vena Cava Filter

Denali® Filter Femoral Delivery Device

Denali® Filter Introducer Sheath With Dilator

Femoral

Contents:
(1) Denali® Filter - Femoral Delivery Device
(1) 8.4 F Introducer Sheath 55cm Long with Dilator

Use By
Lot Number
Catalogue Number

Attention, See Instructions for Use
Sterilized Using Ethylene Oxide
Non-Pyrogenic
Keep Dry
Keep Away From Sunlight
Single Use
Do Not Resterilize
Do Not Use if the Product Sterilization Barrier or Its Packaging is Compromised
MR Conditional
Recommended Guidewire
Manufacturer
Not Made With Natural Rubber Latex
Introducer Sheath
Working Sheath Length

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