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 can 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 permanently removed after implantation 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.

Figure 1: Denali™ Filter (Supplied Preloaded)

The Denali™ Vena Cava Filter System consists of an introducer sheath and dilator, and a preloaded Denali™ 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 12 introducer sheath contains a radiopaque marker and hemostasis valve with a side port. The pusher advances the filter through the introducer sheath to the predeployment mark and is then used to fix the filter in place while the filter is unsheathed. The Denali™ Vena Cava Filter Jugular/Subclavian System is illustrated in Figure 2.

Note: This product is made with natural rubber latex.

Figure 2: Denali™ Vena Cava Filter Jugular/Subclavian System

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 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 5mm 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™ 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
NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend

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1. This product is intended for use by physicians trained and experienced in diagnostic and interventional radiology techniques. The DENALI® Vena Cava Filter should not be implanted in:

- Patients with an IVC diameter larger than 28mm.
- 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 nickel allergies.

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

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E. Warnings

1. The DENALI® Filter consists of nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device. Persons with allergic reactions to nickel may be at risk for an allergic reaction to nickel ions. Nickel allergy may occur in some patients without a history of allergies. Some patients may develop an allergy to nickel if this device is implanted. Certain allergic reactions can occur even in the absence of a history of nickel allergy. Nickel is released in vivo under conditions of continued delivery, such as difficulty in breathing or inflammation of the face or throat, if these types of allergic reactions occur, patients may require immediate medical attention. In some patients, nickel released in vivo may have been associated with cardiogenicity (ability to cause animal) in medical devices. It is unknown whether nickel released from implantation increases the patient's cancer risk.

2. Use the device or accessories as instructed after the expiration date.

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

4. This device has been designed for single use only. Reusing this medical device may result in the crossing of patient cultures, particularly where infectious agents are present, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues have contaminated these areas.

5. Do not deploy the filter prior to proper positioning in the IVC, as the DENALI® Vena Cava Filter cannot be safely steered into the storage tube. Do not deploy the filter unless IVC has been properly measured. Never re-deploy or remove a deployed filter.

6. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an undefined biologic or chemical process. Misuse of these devices or improper retrieval technique may result in intimal injury or caval injury. Utilizing endovascular and/or surgical techniques.

7. Denaliber insertion and removal may be impeded, or filter may become entangled.

8. The DENALI® Filter Jugal/Subclavian System is designed for Jugular/Subclavian approaches only. Do not use the DENALI® Filter Jugal/Subclavian System for femoral approaches, as this will result in improper filter orientation within the IVC.

9. If the IVC Cava size is diameter 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 as migration of the filter and/or cava will occur. Attempt filter delivery through an alternate site. A large thrombus may obstruct the guidewire and restrict flow of contrast medium and/or due to large clot burdens.

11. When injecting contrast medium during the dilator, do not exceed the maximum pressure rating of 60 lbs.

12. Never advance the guidewire or introduction sheath/dilator or deploy the filter without fluoroscopic visualization.

13. Filter fractures 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 fragment utilizing endovascular and/or surgical techniques.

14. Movement, migration, or tilt are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. Certain complications may be caused by placement of the filter in IVCs with diameters exceeding the appropriate labeled dimensions. Motion or migration is often observed immediately after deployment and/or due to large clot burdens.

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


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F. Precautions

1. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

2. Patients with known hypersensitivity to nickel-titanium alloys.

3. Patients with risk of septic embolism.

4. Patients with uncontrollable sepsis.

5. Do not deploy the filter prior to proper positioning in the IVC, as the DENALI® Vena Cava Filter cannot be safely steered into the storage tube. Do not deploy the filter unless IVC has been properly measured. Never re-deploy or remove a deployed filter.

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Due to the nature of the DENALI® Filter’s design and the procedures involved, the filter may not be removed by simple means.

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NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive “routine follow-up.”
time was 17.8 minutes and mean fluoroscopy time was 3.6 minutes. TSR for the filter successfully retrieved.

The mean age was 56.6±15.63 years (range 18 – 89 years). One hundred twenty-one (121) patients had PE, new or worsening DVT, filter migration, filter fracture, penetration and tilt were assessed. Deployment of the filter without retrieval complications requiring intervention. Additionally, the secondary endpoints of recurrent embolism without intervention.

Clinical Experience

A single-arm, prospective, multi-center clinical study was conducted to assess the safety of the DENALI® Filter as a both a permanent and retrievable device. Clinical Success of Placement (CSP) was defined as freedom from subsequent PE, filter embolization, caval occlusion, filter or procedure related death, insertion adverse events, and failure of filter expansion/incomplete expansion. Stenosis at implant site.

Possible complications include, but are not limited to, the following:

• Thrombophlebitis
• Stroke
• Postphlebitic syndrome
• Pneumothorax
• Organ injury
• Perihepatic ocrela dorsens
• Pneumothorax
• Thromboplastic syndrome
• Stroke
• Hemorrhage
• Opioid culation
• Blood loss
• Guidewire entanglement
• 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 morbidity 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.

G. Potential Complications

Procedures requiring contraindications technical intervention 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, the following:

• Movement, migration or tilt of the filter
• Movement, migration or tilt of the filter
• Insertion site thrombosis
• Failure of filter expansion/incomplete expansion.

Table 1: Patient Accountability

<table>
<thead>
<tr>
<th>Eligible for Follow-Up</th>
<th>Vail Complete</th>
<th>Death</th>
<th>Lost to Follow-Up</th>
<th>Reason for Not Completing</th>
<th>Events Occurring Before Vail</th>
<th>Migration</th>
<th>Fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Months</td>
<td>163 (95.0%)</td>
<td>11</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6 Months</td>
<td>130 (92.7%)</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12 Months</td>
<td>77 (75.9%)</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>18 Months</td>
<td>53 (67.8%)</td>
<td>4</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>24 Months</td>
<td>46 (63.4%)</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Filter was 99.2%.

Filter was 95.0% and the lower bound of the 95% confidence interval was 91.2%. It was concluded that the performance goal was met. TSP for the DENALI® Filter was 99.2%. Mean placement procedure time was 17.8 minutes. 24 filters were removed by fluoroscopy prior to meeting the lower bound of the 95% confidence interval.

<table>
<thead>
<tr>
<th>Eligible for Follow-Up</th>
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<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>24 Months</td>
<td>46 (63.4%)</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Filter placement, 120 had active thromboembolic disease (the presence of DVT or PE at the time of filter placement). Of these 120 patients, 60 had a contradiction to anticoagulation. It had a contradiction related to the use of anticoagulation medication. Twenty had a failure of anticoagulation, and 25 had a filter placed without contraindication, complications or failure related to anticoagulated medication. Eighty (80) patients without active thromboembolic disease (neither DVT nor PE at the time of placement) were enrolled in the study. Reasons for filter placement were as follows: Surgery (n=87, 43.5%), Trauma (n=41, 20.5%), Hypercoagulopathy (n=6, 22%), Cancer (n=10, 5%), Stroke (n=3, 1.5%) and Other (n=10, 5%). Ninety eight (98) patients completed six month visit, sixty eight (68) patients completed a 12 month visit, fifty three (53) patients completed an 18-month visit, and forty six (46) patients completed a 24-month visit. Four patients were withdrawn from the study, twelve (12) were lost to follow up and twenty one (21) died from pre-existing or inter-current causes. Refer to the sections results for more details. Table 1 displays the completed patient follow up at each time point.

Results

CDH® Filter was 95.0% and the lower bound of the 95% confidence interval was 91.2%. It was concluded that the performance goal was met. TSP for the CDH® Filter was 99.2%. Mean placement procedure time was 17.8 minutes. 24 filters were removed by fluoroscopy prior to meeting the lower bound of the 95% confidence interval.
Table 2: Default Endpoints

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>0-6 Montha</th>
<th>0-24 Montha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrieved PE</td>
<td>0 / 124 (0%)</td>
<td>0 / 121 (0%)</td>
</tr>
<tr>
<td>Clinical Success of Retrieval</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Technical Success of Retrieval</td>
<td>97.6%</td>
<td>97.6%</td>
</tr>
<tr>
<td>Technical Success of Placement</td>
<td>99.5%</td>
<td>99.5%</td>
</tr>
<tr>
<td>Clinical Success of Placement</td>
<td>95.0%</td>
<td>95.0%</td>
</tr>
<tr>
<td>Maximum Indwell Time</td>
<td>736 days</td>
<td>736 days</td>
</tr>
<tr>
<td>Number of Successful Retrievals</td>
<td>121</td>
<td>121</td>
</tr>
</tbody>
</table>

There were no findings of filter fracture, cranial migration, caudal migration, filter tilt at placement, or filter tilt at retrieval. The six-month time point had five (5) cases of symptomatic PE. Through the 24-month time point there was one additional patient with symptomatic PE. One case of PE led to a patient death. The patient was considered active disease with DVT and PE noted at baseline and a contraindication to anticoagulation prior to surgery. The site medical examiner listed the primary cause of death as pulmonary embolism and the secondary cause of death as metastatic adenocarcinoma. The independent Clinical Events Committee (CEC) adjudicated that the death was possibly related to the device. Through the six-month time point there were five (5) cases of asymptomatic penetration; none of which had clinical sequelae. Three (3) cases of penetration were noted at implant and two (2) cases of penetration were noted at retrieval. Most instances of reported penetration were just over the threshold measurement of 3mm outside of the cava wall, with penetrations reported 0.3, 0.6, 0.7, 1.3 and 6.3 mm beyond the threshold. Penetration was determined by digital subtraction venography at placement and retrieval and was adjudicated by an independent core laboratory. Through the six-month time point there were 20 patients that reported new or worsening DVT. Through the 24-month time point there were 6 additional patients that reported new or worsening DVT. All new DVTs were reported in those patients that had active disease at the time of implantation. Six patients reported deep vein thrombosis, superficial vein thrombosis, iliocaval vein thrombosis, or iliofemoral thrombosis. All DVTs were considered hypercoagulable, suffered multi-trauma injuries, or those that had orthopedic procedures on their lower extremities. All site-reported adverse events were adjudicated by the CEC and imaging was analyzed by the Core Lab.

Table 3: Complication Rates

<table>
<thead>
<tr>
<th>Complication</th>
<th>0-6 Montha</th>
<th>0-24 Montha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Penetration at Retrieval &gt; 3mm</td>
<td>2 / 124 (1.6%)</td>
<td>2 / 121 (1.6%)</td>
</tr>
<tr>
<td>Caudal Migration &gt; 2 cm</td>
<td>0 / 124 (0%)</td>
<td>0 / 121 (0%)</td>
</tr>
<tr>
<td>Filter Migration &gt; 0.3 mm</td>
<td>0 / 124 (0%)</td>
<td>0 / 121 (0%)</td>
</tr>
<tr>
<td>Filter Tilt at Placement &gt; 15°</td>
<td>0 / 200 (0%)</td>
<td>0 / 200 (0%)</td>
</tr>
<tr>
<td>Filter Tilt at Retrieval &gt; 15°</td>
<td>0 / 82 (0%)</td>
<td>0 / 124 (0%)</td>
</tr>
</tbody>
</table>

Table 4: Denu® Filter Retrieval Details

<table>
<thead>
<tr>
<th>Endpoint</th>
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<th>0-24 Montha</th>
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DENALI® Vena Cava Jugular/Subclavian System that contains:
- One 18 gauge entry needle
- Saline
- Contrast medium
- Syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

I. Directions for Use - Implantation
1. Collect and prepare the appropriate equipment for use.
2. Identify the optimal location for the filter.
3. Under flouroscopic guidance, with the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
4. Select the 0.035” straight guidewire, and advance the introducer sheath with the guidewire and check vein patency fluoroscopically with a small injection of contrast medium.ilot thrombus is present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

PHASE 1: The 0-24 month time frame includes all patients that reported an event regardless of length of follow-up. Denu® Filter Retrieval was attempted in 124 patients and successful in 121 patients (97.6%). In the three (3) unsuccessful retrieval cases, the snare was unable to engage the filter retrieval hook due to anatomical curvature in two cases, and the filter was unable to be retrieved due to thrombus in the filter in one case. Mean filter retrieval time was 208.4 ± 156.9 days (median 160.0 days; range 5 – 736 days). The right internal jugular vein was used in all retrieval procedures. The mean retrieval procedure time was 23.1 minutes and the mean fluoroscopy time was 6.3 minutes.

PHASE 2: Venacavagram taken before and after the retrieval procedures of the IVC implant site revealed abnormalities that the CEC determined to be related to the device in four patients. One patient had minimal extravasation post retrieval, one patient had minimal hematoma adjacent to the top of the filter prior to retrieval, and one patient had a failed retrieval attempt due to anatomical curvature limiting the filter retrieval hook. One patient had minimal thrombus adjacent to the top of the filter prior to retrieval, and one patient had a failed retrieval attempt due to anatomical curvature limiting the filter retrieval hook.

One of the 186 patients (119) of the 121 patients who had their filter retrieved completed one month follow-up and was adjudicated by an independent core laboratory. Through the six-month time point there were two (2) patients were lost to follow-up. No instances of recurrent PE or new or worsening DVT were reported for any patient completing the one month post-retrieval visit.

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

Figure 4: Time from Implantation to Retrieval (N=121)

Table 5: Primary Endpoints

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<td>121</td>
</tr>
</tbody>
</table>

In the 0-6 month time frame includes patients that completed the 6 month visit or had their filter retrieved within the 6 month window. In the 0-24 month time frame includes all patients that reported an event regardless of length of follow-up.

Denu® Filter Retrieval

The 0-24 month time frame includes all patients that reported an event regardless of length of follow-up.
13. Disconnect the dilator from the sheath, and remove the dilator, leaving the 8.4 French introducer sheath with its tip in the inferior vena cava.

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 interfering with filter deployment.

16. Remove the delivery system containing the device from the package and remove the red safety cap (Reference Figure 4).

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

17. Flush the delivery device 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. Loosen the proximal end of the Touhy-Borst adapter and advance the filter by moving the pusher forward through the introducer sheath. Do not twist or retract the pusher at anytime during the procedure.

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.

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-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 such as a table), 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

PRECAUTION: Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheath the stationary filter. Do not twist the pusher handle at anytime during this procedure.
WARNING: Remove the DENALI® Filter using an intravascular snare loop 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 vena cava wall.

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

PRECAUTION: The retrieval of the DENALI® Filter should only be performed using minimum 9F ID/11F ID, dual retrieval sheathes. Release of these devices or improper retrieval technique may result in inferior injury or caval narrowing.

<table>
<thead>
<tr>
<th>Procedure Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select a suitable jugular venous access route on either the right or left side depending on the patient’s size or anatomy, operator’s preference, or location of venous thrombosis. (The right jugular vein is preferred.)</td>
</tr>
<tr>
<td>2. Prior to use, remove the retrieval sheaths from their packaging and flush them with heparinized saline or suitable isotonic solution.</td>
</tr>
<tr>
<td>3. Prepare all other necessary components according to the manufacturer’s Instructions for Use.</td>
</tr>
<tr>
<td>4. Perform a venacavagram in the AP and lateral views to determine the orientation and configuration of the filter, taking care not to dilate the filter while crossing through it. Also, use the appropriate technique to determine that the filter, the jugular venous route, and distal IVC are free of thrombus.</td>
</tr>
<tr>
<td>5. Select the appropriate loop diameter size of the intravascular snare.</td>
</tr>
</tbody>
</table>

6. Assemble the intravascular snare according to the Instructions for Use provided by the 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 3cm 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 tip of the sheath is approximately 3 cm cephalad to the tip of the sheath.

13. The retrieval of the DENALI® Filter using an intravascular snare is illustrated below.

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

### 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 retrieve or reload it. The DENALI® Vena Cava Filter should be stored in a cool (not temperatures, dark, dry place.

#### 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 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. 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 back of the product. For additional vena cava filter clinical information please refer to the following societal guidelines:

DENALI® Vena Cava Filter

DENALI® Filter Jugular/Subclavian Delivery Device

DENALI® Filter Introducer Sheath With Dilator

Jugular/Subclavian

Contents:
(1) DENALI® Filter - Jugular/Subclavian Delivery Device
(1) 8.4F I.D. Introducer Sheath 55cm Long with 8F Dilator

MR Conditional

R. Recommended Guidewire

Manufacturer

Use By
Not Made With Natural Rubber Latex

Lot Number
Working Sheath Length

Catalogue Number
Introducer Sheath

Attention, See Instructions for Use

Sterilized Using Ethylene Oxide

Keep Dry

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