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

The DiVinci® 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 DiVinci® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28mm.

Figure 1: DiVinci® Filter (Supplied Preloaded)

B. MRI Safety:


Non-clinical testing demonstrated that the DiVinci® 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 DiVinci® 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 DiVinci® 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 DiVinci® 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 MedAlert Foundation (www.medalert.org).

C. Indications for Use

The DiVinci® 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
The DENALI® Vena Cava Filter System and accessories may be a potential biohazard. Handle with care, follow standard practices in biohazard handling, and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.

In rare cases, if a patient is known to be allergic to nickel-titanium alloy, the DENALI® Vena Cava Filter should not be implanted.

### Contraindications for Use

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

- Patients with an IVC diameter larger than 28mm.
- Patients with known hypersensitivity to nickel-titanium alloys.
- Patients with risk of septic embolism.
- Patients with uncontrollable sepsis.
- Patients with history of exposure to nickel-titanium alloys.

The DENALI® Vena Cava Filter should not be re-deployed if significant amounts of thrombus are trapped within the filter or if the filter snare hook is embedded within the cava wall.

### Instructions for Use

The DENALI® Vena Cava Filter system and accessories may be a potential biohazard. Handle with care, follow standard practices in biohazard handling, and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.

**Note:** Standards and guidelines developed by the Society of Interventional Radiologists recommend

- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
- Patients with known hypersensitivity to nickel-titanium alloys.
- Patients with risk of septic embolism.
- Patients with uncontrollable sepsis.
- Patients with history of exposure to nickel-titanium alloys.

The DENALI® Vena Cava Filter cannot be safely loaded into the storage tube. Do not deploy the filter unless IVCs has been properly measured. Never re-deploy a filter without IVCS.

- If the Vena Cava diameter is greater than 23mm do not deploy the filter.
- The retrieval of the filter bones will not be used.
- To achieve proper placement, the introducer sheath has a radiopaque distal marker band to assist in visualization and predeployment filter guidance.
- Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, it is recommended that the filter be delivered in a 30° angle to the IVC. This can shorten insertion time and reduce the likelihood of difficulties.
- When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.
- Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications.
- Do not deliver the filter over the guidewire and introducer. If resistance is encountered during a jugular/subclavian insertion procedure, withdraw the guidewire and check for a catheter tip or guidewire interaction. Misuse of these devices or improper retrieval technique may result in intimal injury or caval thrombotic therapy as soon as it is deemed safe.
- 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 retrieval of the fragment or its fragments. In some cases, the filter fragments have not been retrieved and have caused by placement of the filter in IVC with diameters exceeding the appropriate labeled dimensions of the filter. Knowledgeable interventionalists may be required to remove these fragments.
- The DENALI® Vena Cava Filter System and accessories may be a potential biohazard. Handle with care, follow standard practices in biohazard handling, and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.

### Contraindications for Use

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

- Patients with an IVC diameter larger than 28mm.
- Patients with known hypersensitivity to nickel-titanium alloys.
- Patients with risk of septic embolism.
- Patients with uncontrollable sepsis.
- Patients with history of exposure to nickel-titanium alloys.

The DENALI® Vena Cava Filter cannot be safely loaded into the storage tube. Do not deploy the filter unless IVCS has been properly measured. Never re-deploy a filter without IVCS.

- If the Vena Cava diameter is greater than 23mm do not deploy the filter.
- The retrieval of the filter bones will not be used.
- To achieve proper placement, the introducer sheath has a radiopaque distal marker band to assist in visualization and predeployment filter guidance.
- Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, it is recommended that the filter be delivered in a 30° angle to the IVC. This can shorten insertion time and reduce the likelihood of difficulties.
- When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.
- Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications.
- Do not deliver the filter over the guidewire and introducer. If resistance is encountered during a jugular/subclavian insertion procedure, withdraw the guidewire and check for a catheter tip or guidewire interaction. Misuse of these devices or improper retrieval technique may result in intimal injury or caval thrombotic therapy as soon as it is deemed safe.
- 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 retrieval of the fragment or its fragments. In some cases, the filter fragments have not been retrieved and have caused by placement of the filter in IVC with diameters exceeding the appropriate labeled dimensions of the filter. Knowledgeable interventionalists may be required to remove these fragments.
- The DENALI® Vena Cava Filter System and accessories may be a potential biohazard. Handle with care, follow standard practices in biohazard handling, and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.

### Contraindications for Use

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

- Patients with an IVC diameter larger than 28mm.
- Patients with known hypersensitivity to nickel-titanium alloys.
- Patients with risk of septic embolism.
- Patients with uncontrollable sepsis.
- Patients with history of exposure to nickel-titanium alloys.

The DENALI® Vena Cava Filter cannot be safely loaded into the storage tube. Do not deploy the filter unless IVCS has been properly measured. Never re-deploy a filter without IVCS.

- If the Vena Cava diameter is greater than 23mm do not deploy the filter.
- The retrieval of the filter bones will not be used.
- To achieve proper placement, the introducer sheath has a radiopaque distal marker band to assist in visualization and predeployment filter guidance.
- Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, it is recommended that the filter be delivered in a 30° angle to the IVC. This can shorten insertion time and reduce the likelihood of difficulties.
- When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.
- Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications.
- Do not deliver the filter over the guidewire and introducer. If resistance is encountered during a jugular/subclavian insertion procedure, withdraw the guidewire and check for a catheter tip or guidewire interaction. Misuse of these devices or improper retrieval technique may result in intimal injury or caval thrombotic therapy as soon as it is deemed safe.
- 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 retrieval of the fragment or its fragments. In some cases, the filter fragments have not been retrieved and have caused by placement of the filter in IVC with diameters exceeding the appropriate labeled dimensions of the filter. Knowledgeable interventionalists may be required to remove these fragments.
- The DENALI® Vena Cava Filter System and accessories may be a potential biohazard. Handle with care, follow standard practices in biohazard handling, and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.

### Contraindications for Use

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

- Patients with an IVC diameter larger than 28mm.
- Patients with known hypersensitivity to nickel-titanium alloys.
- Patients with risk of septic embolism.
- Patients with uncontrollable sepsis.
- Patients with history of exposure to nickel-titanium alloys.

The DENALI® Vena Cava Filter cannot be safely loaded into the storage tube. Do not deploy the filter unless IVCS has been properly measured. Never re-deploy a filter without IVCS.

- If the Vena Cava diameter is greater than 23mm do not deploy the filter.
- The retrieval of the filter bones will not be used.
- To achieve proper placement, the introducer sheath has a radiopaque distal marker band to assist in visualization and predeployment filter guidance.
- Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, it is recommended that the filter be delivered in a 30° angle to the IVC. This can shorten insertion time and reduce the likelihood of difficulties.
- When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.
- Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications.
- Do not deliver the filter over the guidewire and introducer. If resistance is encountered during a jugular/subclavian insertion procedure, withdraw the guidewire and check for a catheter tip or guidewire interaction. Misuse of these devices or improper retrieval technique may result in intimal injury or caval thrombotic therapy as soon as it is deemed safe.
- 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 retrieval of the fragment or its fragments. In some cases, the filter fragments have not been retrieved and have caused by placement of the filter in IVC with diameters exceeding the appropriate labeled dimensions of the filter. Knowledgeable interventionalists may be required to remove these fragments.
time was 17.8 minutes and mean fluoroscopy time was 3.6 minutes. TSR for the Of the 200 patients who underwent
their filter successfully retrieved..

Two hundred (200) patients (126 males, 74 females) were enrolled at 21 investigational sites across the United
States. 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.

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.

G. Potential Complications

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

• Pain
• Guidewire entrapment
• Blood loss
• Thrombophlebitis
• Phlegmasia cerulea dolens
• Organ injury
• Hemothorax
• Blood loss
• Thrombophlebitis
• Arteriovenous fistula
• Vessel injury
• Insertion site thrombosis
• Failure of filter expansion/incomplete expansion.
• Stenosis at implant site.
• Infection
• Restriction of blood flow
• Hemorrhage
• Extravasation of contrast material at time of venacavogram.
• Caval thrombosis/occlusion
• Deep vein thrombosis
• Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi
passed through the filter, or originated from superior or collateral vessels.

• Venous thromboembolic event
• Fat embolization
• Infection
• Arterial loss
• Hemorrhage
• Organ injury
• Perforation or other acute or chronic damage of the IVC wall.

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 subsequent PE, filter embolization, caval occlusion, filter or procedure related death, intervention 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 was greater than 80%. Technical Success of Placement (TSP) was defined as deployment of the filter such that the physician judged the location to be suitable to provide sufficient mechanical protection against PE. 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
by the physician without retrieval complications requiring intervention. Additionally, the secondary endpoints of recurrent
PE, filter embolization, caval occlusion, filter migration, filter fracture, penetration and tilt were assessed.

Ten hundred (1000) patients (426 males, 574 females) were enrolled at 21 investigational sites across the United
States. The mean age was 60.6±15.83 years (range 18 – 89 years). One hundred twenty-two (122) patients had
their filter successfully retrieved.

Of the 200 patients who underwent Denali® Filter placement, 120 had had active thrombembolic disease (the presence of DVT or PE at the time of filter placement). Of these 120 patients, 60 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. Eighty (80) patients without active thrombembolic 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=26, 13.2%), Cancer (n=10, 5%), Stroke (n=3, 1.5%) and Other (n=15, 7.5%).

Ninety eight (98) patients completed a six month visit, sixty eight (68) patients completed a 12 month window. Thirty (33) patients completed an 18 month window, and sixty six (66) patients completed a 24 month visit. Five patients were withdrawn from the study, twelve (12) were lost to follow up and twenty one (21) died from pred
existent inter-current conditions. Refer to the results sections for more details. Table 1 displays the completed patient follow up at each time point.

Table 1: PatientAccountability
There were no findings of filter fracture, caval migration, caval migration, filter tilt at placement, or filter tilt at retrieval. Through the six month time point there were five (5) cases of symptomatic PE. Through the 24 month time point there were five (5) cases of symptomatic PE. 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 clot burden with an abnormal appearance of the IVC. No clinical sequelae were reported for any patient completing the one month post-retrieval visit.

Table 2: Clinical Success of Retrieval

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>Filter Retrieval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 Months</td>
<td>0-24 Months</td>
</tr>
<tr>
<td>Retrieval Success Rate</td>
<td>97.6%</td>
</tr>
<tr>
<td>Mean Interval Time</td>
<td>200.3 days</td>
</tr>
<tr>
<td>Maximum Interval Time</td>
<td>736 days</td>
</tr>
</tbody>
</table>

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

DENALI® Filter Retrieval

Denux® Filter Retrieval was attempted in 124 patients and successful in 121 patients (97.6%). In the three (3) unsuccessful retrieval attempts on one patient, the retrieval device was able 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 indwell time was 208.8 ± 167.9 days (median 160.0 days; range 5 – 736 days). The right internal jugular vein was used in 82% (162 / 200) of all patients. Venacavograms taken before and after the retrieval procedures of the IVC implant site revealed abnormalities in at least one patient completing the one month post-retrieval visit. There were no findings of filter fracture, cranial migration, caudal migration, filter tilt at placement, or filter tilt 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 3.6 mm beyond the threshold.

Penetration was determined by digital subtraction venography at placement and retrieval and was assessed 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 implant; were considered to be 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>Time Interval</th>
<th>Filter Penetration at Retrieval &gt; 3mm</th>
<th>Filter Penetration at Placement &gt; 3mm</th>
<th>Caudal Migration &gt; 2cm</th>
<th>Filter Fracture</th>
<th>Worsening DVT</th>
<th>New DVT</th>
<th>Caval Occlusion</th>
<th>Recurrent PE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 Months</td>
<td>2 / 82 (2.4%)</td>
<td>2 / 124 (1.6%)</td>
<td>0 / 186 (0%)</td>
<td>0 / 186 (0%)</td>
<td>6 / 188 (7.4%)</td>
<td>14 / 188 (10.1%)</td>
<td>1 / 188 (0%)</td>
<td>5 / 188 (2.7%)</td>
</tr>
<tr>
<td>0-24 Months</td>
<td>1 / 124 (0.8%)</td>
<td>3 / 200 (1.5%)</td>
<td>0 / 186 (0%)</td>
<td>0 / 186 (0%)</td>
<td>8 / 200 (4.0%)</td>
<td>18 / 200 (9.0%)</td>
<td>1 / 200 (0.5%)</td>
<td>6 / 200 (3.0%)</td>
</tr>
</tbody>
</table>

Filter Penetration at Retrieval > 3mm = 2 / 124 (1.6%) Patients who developed filter penetration at retrieval. Filter Penetration at Placement > 3mm = 3 / 200 (1.5%) Patients who developed filter penetration at placement. Caudal Migration > 2cm = 0 / 186 (0%) Patients who developed caudal migration > 2cm. Filter Fracture = 0 / 186 (0%) Patients who developed filter fracture. Worsening DVT = 6 / 188 (7.4%) Patients who developed new or worsening DVT after filter retrieval. New DVT = 14 / 188 (10.1%) Patients who developed new DVT after filter retrieval. Caval Occlusion = 1 / 188 (0%) Patients who developed caval occlusion after filter retrieval. Recurrent PE = 5 / 188 (2.7%) Patients who developed recurrent PE after filter retrieval.

Filter Fracture and pusher

Filter Retrieval Details

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>Number of Filter Retrieval Attempts</th>
<th>Number of Successful Retrievals</th>
<th>%</th>
<th>Retrieval Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 Months</td>
<td>119</td>
<td>112</td>
<td>95.7%</td>
<td>95.0%</td>
</tr>
<tr>
<td>0-24 Months</td>
<td>163</td>
<td>154</td>
<td>94.2%</td>
<td>97.6%</td>
</tr>
</tbody>
</table>

Warnings and Cautions

This filter contains latex. Persons who are latex sensitive may experience an adverse reaction. This filter contains plasticizers and may release plasticizers into the bloodstream when placed in a vessel. The device may contain substances that are hazardous to the environment.

Precautions

Filter Retrieval:

1. There are no findings of filter fracture, caval migration, caval migration, filter tilt at placement, or filter tilt at retrieval. Through the six month time point there were five (5) cases of symptomatic PE. Through the 24 month time point there was one additional patient who had a symptomatic PE.

2. One patient was noted to have a symptomatic PE. The death was possibly related to the device. Through the six month time point there were five (5) cases of symptomatic PE. None of which had clinical sequelae.
WARNING: If the vena cava diameter is greater than 28mm, do not deploy the DENALI® Filter.

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.

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. Loose 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.

**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 can cause slippage of the threads and/or breakage of the hub. Care should be exercised. Activating the device should always be aligned with the introducer sheath.

20. Prior to deployment, verify the location of the filter within the sheath using fluoroscopy and confirm that the filter is near the end of the sheath.

21. 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.

**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.

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 fluoroscopy 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).

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: scalpels, #11 blades, local anesthetics, drapes, etc.
- Imaging Catheter

L. References:

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

A 15-20 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.

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

Figure 10B: While keeping tension of the snare, the retrieval sheath stationary and withdraw the filter into the sheath by retracting the intravascular sheath.

Figure 10D: Resume the snare until the filter and cranial anchors are completely contained inside the retrieval sheath.

Figure 10E: Once the filter is fully collapsed inside the 9F retrieval sheath, retrieve the filter, the snare, and the retrieval sheath as soon as the filter is removed.

Note: Take care when handling the filter as the snare have sharp tips.

PRECAUTION: The retrieval of the 9F retrieval sheath in the caudal direction to avoid damage to the filter.

PRECAUTION: Care should be taken when advancing the 9F retrieval sheath to avoid damage to the filter.

PRECAUTION: The retrieval of the 9F retrieval sheath should be performed prior to withdrawing the filter from the 11F retrieval sheath.

PRECAUTION: The retrieval of the 9F retrieval sheath from the filter should be performed prior to withdrawing the filter from the 11F retrieval sheath.

Note: Slowly advance the loop forward over the filter snare hook.

Figure 10A: Slowly advance the loop forward over the filter snare hook.

Figure 10C: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the filter snare hook and that the filter sheath, retrieval sheath and snare are aligned. Be careful to snare the tip of the hook; not the thread. The marker band of the retrieval sheath should be cephalad to the filter snare hook.

Figure 10D: While keeping tension of the snare, the retrieval sheath stationary and withdraw the filter into the sheath by retracting the intravascular sheath.

Figure 10E: Once the filter is fully collapsed inside the 9F retrieval sheath, retrieve the filter, the snare, and the retrieval sheath as soon as the filter is removed.

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

A 15-20 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.

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

PRECAUTION: The retrieval of the 9F retrieval sheath should be performed prior to withdrawing the filter from the 11F retrieval sheath.

PRECAUTION: Care should be taken when advancing the 9F retrieval sheath to avoid damage to the filter.

Note: Slowly advance the loop forward over the filter snare hook.

Figure 10A: Slowly advance the loop forward over the filter snare hook.

Figure 10C: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the filter snare hook and that the filter sheath, retrieval sheath and snare are aligned. Be careful to snare the tip of the hook; not the thread. The marker band of the retrieval sheath should be cephalad to the filter snare hook.

Figure 10D: While keeping tension of the snare, the retrieval sheath stationary and withdraw the filter into the sheath by retracting the intravascular sheath.

Figure 10E: Once the filter is fully collapsed inside the 9F retrieval sheath, retrieve the filter, the snare, and the retrieval sheath as soon as the filter is removed.

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

A 15-20 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.

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

J. How Supplied

Each Densil® Vena Cava Filter is supplied preloaded in a storage tube. Each Densil® 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 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 warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular’s sole discretion or refund of purchase price at the option of the first purchaser. Bard Peripheral Vascular shall not be liable for any incidental or consequential damages resulting from 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.

For additional vena cava filter clinical information please refer to the following societal guidelines:


For additional vena cava filter clinical information please refer to the following societal guidelines:


For additional vena cava filter clinical information please refer to the following societal guidelines:


For additional vena cava filter clinical information please refer to the following societal guidelines:


For additional vena cava filter clinical information please refer to the following societal guidelines:
