Instructions for Use
For use in the Vena Cava

CAUTION: Federal 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 percutaneously 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.

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 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

ENGLISH
1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.

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

3. The safety and effectiveness of this device has not been established for pediatric patients.

4. The safety and effectiveness of this device has not been established for morbidly obese patients. Abdominal anatomic variances may complicate filter insertion, deployment and removal. Careful attention to these variances may be needed. Certain reactions may occur. If resistance is encountered during a jugular/subclavian insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the thrombus with appropriate thrombolytic therapy as soon as it is deemed safe. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anticoagulation therapy as soon as it is deemed safe. Prognosis in patients with retained foreign material is influenced by thermal and/or mechanical changes.

5. Do not attempt to re-deploy a removed filter. The probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

6. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.

7. Delivery of the filter or if the filter snare hook is embedded within the cava wall. Migration of filters to the heart or lungs has been reported. There have also been reports of caval occlusion. Migration may be caused by pleuroperitoneal communications or by caval narrowing. This may require advanced interventional techniques to remove the filter. Anatomical variances may complicate filter insertion, deployment and removal. Careful attention to these instructions for use can shorten insertion time and reduce the likelihood of difficulties.

8. The safety and effectiveness of this device has not been established for pregnancy, nor in suprarenal positioning for proper filter placement.

9. Do not attempt to re-deploy a removed filter. The probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

10. The introduction sheath has a radiopaque distal marker band to assist in visualization and predeployment filter positioning for proper filter placement.

11. Do not attempt to attach a syringe or power injection line to the proximal end of the introducer sheath hub. Never use the Denali® Vena Cava Filter System for femoral approaches, as this will result in improper filter positioning within the IVC.

12. If resistance is encountered during a jugular/subclavian insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the thrombus with appropriate thrombolytic therapy as soon as it is deemed safe.

13. Do not attempt to re-deploy a removed filter. The probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

14. Movement, migration or tilt are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caval occlusion. Migration may be caused by pleuroperitoneal communications or by caval narrowing. This may require advanced interventional techniques to remove the filter.

15. Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent accidental deployment. If accidentally deployed, do not attempt to reinsert the filter into the filter storage tube as damage to the legs of the filter or if the filter snare hook is embedded within the cava wall. Migration of filters to the heart or lungs has been reported. There have also been reports of caval occlusion. Migration may be caused by pleuroperitoneal communications or by caval narrowing. This may require advanced interventional techniques to remove the filter.

16. After filter implantation, any catheterization procedure requiring passage of a device through the filter or if the filter snare hook is embedded within the cava wall.

17. In patients with uncontrolled sepsis or if the filter snare hook is embedded within the cava wall.

18. The Denali® Vena Cava Filter System is designed for Jugular/Subclavian approaches only.

19. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anticoagulation therapy as soon as it is deemed safe. In patients with retained foreign material is influenced by thermal and/or mechanical changes.

20. Do not attempt to re-deploy a removed filter. The probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

21. Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent accidental deployment. If accidentally deployed, do not attempt to reinsert the filter into the filter storage tube as damage to the legs of the filter or if the filter snare hook is embedded within the cava wall. Migration of filters to the heart or lungs has been reported. There have also been reports of caval occlusion. Migration may be caused by pleuroperitoneal communications or by caval narrowing.
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” subsequent to the placement of the device. The FDA recommends that implanting physicians and clinicians be responsible for the ongoing care of patients with retrievable IVC filters considering removing the filter as soon as protection from PE is no longer needed. The FDA encourages all physicians involved in the treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient. See Reporting Standards for Inferior Vena Cava Filter Placement and Patient Follow-up: Supplement for Temporary and Retrieval/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443. Interventions for Improved Retrieval/Optional Standard for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Cava Filter Consensus Conference: J. Vasc Inter Radiol 2003; 14:S437-S432; Guidelines for the Use of Temporary and/or retrievable Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J. Vasc Interv Radiol 2006; 17:491-499.

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, the following:

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. There have also been reports of caval migration of the filter from the common iliac veins to the aorta or the superior vena cava. Five (5) patients had asymptotic movement of the filter, no symptoms or complications were noted in these patients during treatment. Three (3) cases of penetration were noted at the implant and two (2) cases of penetration were noted at retrieval. Twelve (12) patients reported thirteen (13) cases of penetration; five (5) cases of asymptomatic penetration; none of which had clinical sequelae. Three (3) cases of penetration were noted at retrieval. There were two (2) cases of symptomatic PE; neither of which caused patient death. There were no reported cases of symptomatic PE due to caval obstruction.

- Death due to the filter.
- Severe pain or discomfort due to the filter.
- Acute or recurrent pulmonary embolism.
- Filter embolus.
- Infection.
- Distal embolization.
- Occlusion of small vessels.
- Renal or peripheral artery occlusion.
- Stroke.
- Venous ulceration.
- Pulmonary embolism.
- Arterial embolization.
- Postphlebitic syndrome.
- Thrombophlebitis.
- Hemothorax.
- Phlegmasia cerulea dolens.
- Occlusion of small vessels.
- Stenosis at implant site.
- Occlusion of small vessels.
- Hemorrhage.
- Air embolism.
- Occlusion of small vessels.
- Vessel injury.
- Malposition.
- Movement, migration or tilt of the filter.
- Filter fracture.
- Perforation or other acute or chronic damage to the IVC wall.
- Occlusion of small vessels.
- Venous ulceration.
- Postphlebitic syndrome.
- Stroke.
- Hemothorax.
- Phlegmasia cerulea dolens.
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- Occlusion of small vessels.
- Venous ulceration.
- Postphlebitic syndrome.
- Stroke.
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. Autoplace the introducer side port to remove any potential air.

15. Flush the introducer shaft intermittently by hand to maintain introducer sheath patency. Maintaining patency could be bypassed by the guidewire and introducer sheath. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

16. Remove the delivery system containing the device from the package and remove the red safety cap.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the venous route.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw 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 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.

PRECAUTION: If the vena cava diameter is greater than 28mm, do not deploy the Filter. IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Figure 2).

Select the optimum location (For example 1cm below the lowest renal) for filter placement and measure the IVC distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Figure 2).

A small thrombus may be bypassed by the guidewire and introducer.

Filter Tilt at Placement

Filter Penetration at Retrieval

Caudal Migration

Cranial Migration

Filter Fracture

Worsening DVT

New DVT

Recurrent PE

Table 2: Complication Rates

<table>
<thead>
<tr>
<th>Number of Successful Retrievals</th>
<th>86</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Indwell Time</td>
<td>136.2 days</td>
</tr>
<tr>
<td>Maximum Indwell Time</td>
<td>454 days</td>
</tr>
<tr>
<td>Retrieval Success Rate</td>
<td>97.7%</td>
</tr>
</tbody>
</table>

Table 3: Denali® Filter Retrieval Details

<table>
<thead>
<tr>
<th>Filter Tilt at Placement</th>
<th>0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Penetration at Retrieval</td>
<td>0%</td>
</tr>
<tr>
<td>Cranial Migration</td>
<td>0%</td>
</tr>
<tr>
<td>Caudal Migration</td>
<td>0%</td>
</tr>
</tbody>
</table>

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

Figure 4: Safety Cap Removal

Figure 5: Snare Engagement

Figure 6: Filter Deployment

Figure 7: Snare Retrieval

Figure 8: Filter Occlusivity

Figure 9: Filter Position

Figure 10: Filter Fracture

Figure 11: Worsening DVT

Figure 12: New DVT

Figure 13: Recurrent PE

Figure 14: Vena Cava Jugular/Subclavian System that contains:

- One Denali®, Vena Cava Jugular/Subclavian System that contains:
  - One 15cm, 8.4 French I.D. introducer sheath and dilator set
  - One storage tube with preloaded Denali®, Filter and pusher
  - 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.
  - One set a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient's anatomy, operator's preference, or location of venous thrombosis. Right jugular/subclavian veins are preferred.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw 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.

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

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. Maintaining patency helps prevent clot from interfering with filter deployment.

12. 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 4-8.

Table 1: Directions for Use - Implantation

1. Collect and prepare the following equipment for use:

- One Denali®, Vena Cava Jugular/Subclavian System that contains:
  - One 15cm, 8.4 French I.D. introducer sheath and dilator set
  - One storage tube with preloaded Denali®, Filter and pusher
  - 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.
  - One suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient’s anatomy, operator’s preference, or location of venous thrombosis. Right jugular/subclavian veins are preferred.

2. Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient’s anatomy, operator’s preference, or location of venous thrombosis. Right jugular/subclavian veins are preferred.

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

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

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

5. Open the introducer sheath and dilator inner pouch using sterile technique.

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

7. Insert the 0.035” straight guidewire and gently advance it into the inferior vena cava.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw 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.

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

9. 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 inferior vena cava.

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 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.

11. Collect and prepare the following equipment for use:

- One Denali®, Vena Cava Jugular/Subclavian System that contains:
  - One 15cm, 8.4 French I.D. introducer sheath and dilator set
  - One storage tube with preloaded Denali®, Filter and pusher
  - 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.
  - One set a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient’s anatomy, operator’s preference, or location of venous thrombosis. Right jugular/subclavian veins are preferred.

12. Select the optimum location (For example 1cm below the lowest renal) for filter placement and measure the IVC distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Figure 2).

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. Autoplace the introducer side port to remove any potential air.

15. Flush the introducer shaft 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).
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.

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

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 any time during the procedure.

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.

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.

PRECAUTION: Do not deliver the filter using an intravascular snare or using an intravascular loop snare only.

21. Prior to deployment, verify the location of the filter within the sheath using fluoroscopy and confirm that the filter snare hook is 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 hub, unsheathing 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.

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 sheath. 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 contrast medium at 10mL/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” Guidewire, 10cm long or more
• 18 gauge entry needle
• The hub
• Contrast medium
• Syringe for saline infusion
• All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
• Imaging Catheter

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

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

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

1. Introduce and advance the intravascular snare through the 9F retrieval sheath until it protrudes out such that the matter band of the sheath knob is cephalad to the filter snare hook.

2. Remove the guidewire sheath and filter delivery system should be held in a straight line to minimize friction.

3. 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.

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

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 hub, unsheathing 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.

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 sheath. 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 contrast medium at 10mL/s).

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.

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” Guidewire, 10cm long or more
• 18 gauge entry needle
• The hub
• Contrast medium
• Syringe for saline infusion
• All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
• Imaging Catheter

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

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

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

1. Introduce and advance the intravascular snare through the 9F retrieval sheath until it protrudes out such that the matter band of the sheath knob is cephalad to the filter snare hook.

2. Remove the guidewire sheath and filter delivery system should be held in a straight line to minimize friction.

3. 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.

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

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 hub, unsheathing 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 10: Retrieval of Denali® Filter using an Intravascular Snare

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

Figure 10B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter snare hook.

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

PRECAUTION: Care should be taken when advancing the 9F retrieval sheath in the caudal direction to avoid completely covering the arms and legs.

Figure 10C: Advance the retrieval sheath in the caudal direction until it covers half of the filter.

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.

PRECAUTION: Care should be taken when advancing the 9F retrieval sheath in the caudal direction to avoid completely covering the arms and legs.

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 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 venacavogram should be performed to confirm complete retrieval of the filter.

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 relax 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:


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