DENALI®

Vena Cava Filter

Jugular/Subclavian Vein Approach
Instructions for Use

BARD | PERIPHERAL VASCULAR

ENGLISH

Instructions for Use

For use in the Vena Cava

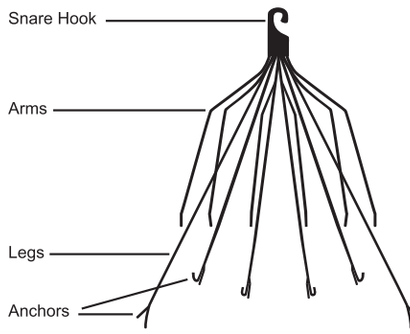
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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 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.

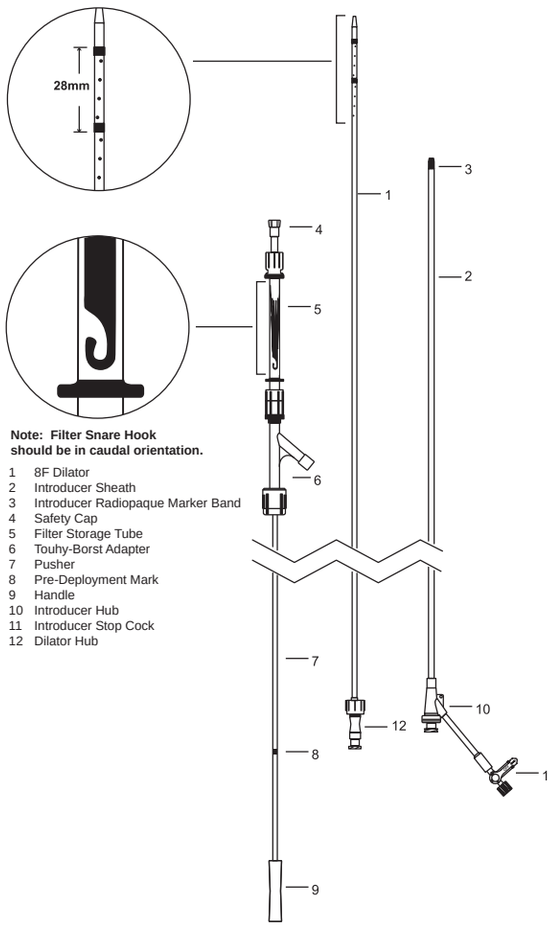
Figure 1: DENALI® Filter (Supplied Preloaded)



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 I.D. 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 not made with natural rubber latex**.**

Figure 2: DENALI® Vena Cava Filter Jugular/Subclavian System



Note: Filter Snare Hook should be in caudal orientation.

1 8F Dilator
2 Introducer Sheath
3 Introducer Radiopaque Marker Band
4 Safety Cap
5 Filter Storage Tube
6 Touhy-Borst Adapter
7 Pusher
8 Pre-Deployment Mark
9 Handle
10 Introducer Hub
11 Introducer Stop Cock
12 Dilator Hub

B. MRI Safety:

The DENALI® Vena Cava Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the DENALI® Vena Cava Filter is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 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

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

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

D. Contraindications for Use

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 hypersensitivity to nickel-titanium alloys.

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

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 suffer an allergic response to this implant, especially those with a history of metal allergies. Some patients may develop an allergy to nickel if this device is implanted. Certain allergic reactions can be serious. While devices that release nickel are not expected to result in symptoms such as difficulty in breathing or inflammation of the face or throat, if these types of allergic reactions occur, patients should be instructed to seek immediate medical attention. Some forms of nickel have also been associated with carcinogenicity (ability to cause cancer) in animal models. It is unknown whether nickel released from implants will increase a patient’s cancer risk.**
2. **Do not use the device or accessories after the expiration date.**
3. **Contents are supplied sterile. Do not use if the product sterilization barrier or its packaging is compromised.**
4. **This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for 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.**
5. **Do not deploy the filter prior to proper positioning in the IVC, as the DENALI® Vena Cava Filter cannot be safely reloaded into the storage tube. Do not deploy the filter unless IVC has been properly measured. Never re-deploy a removed filter.**
6. **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. Cleaning, reprocessing, and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.**
7. **Delivery of the DENALI® Filter through the introducer sheath is advance only. Retraction and twisting of the pusher during delivery could result in dislodgement of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer sheath.**
8. **The DENALI® Filter Jugular/Subclavian System is designed for Jugular/Subclavian approaches only. Never use the DENALI® Filter Jugular/Subclavian System for femoral approaches, as this will result in improper filter orientation within the IVC.**
9. **If the Vena Cava diameter is greater than 28mm do not deploy the DENALI® Filter.**
10. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.**
11. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.**
12. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**
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 retrieval 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. There have also been reports of caudal migration. Migration may be caused by placement of the filter in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
15. **After use, the DENALI® Vena Cava Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.**
16. **After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded, or filter may become entangled.**
17. **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 cava wall.**
18. **Remove the DENALI® Filter using an intravascular snare only. Refer to the “Optional Procedure for Filter Removal” section for details.**

Note: Reference “Potential Complications” section for further information regarding other known filter complications.

Note: It is possible that complications such as those described in the “Warnings”, “Precautions”, or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.

F. Precautions

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. The safety and effectiveness of this device has not been established for pregnancy, nor in suprarenal placement position.[1]
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 procedures such as bariatric surgery may affect the integrity and stability of the filter.
5. 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.
6. Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the filter.
7. Position the filter snare hook 1cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
8. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
9. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter.
10. Spinal deformations: It is important to exercise care when contemplating implantation or removal in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
11. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
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 venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
13. 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.
14. The introducer sheath has a radiopaque distal marker band to assist in visualization and predeployment filter positioning for proper filter placement.
15. Do not attempt to attach a syringe or power injection line to the proximal end of the introducer sheath hub.
16. Care should be taken to ensure the connection between the introducer sheath 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.
17. Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer sheath. Do not twist the pusher handle at anytime during this procedure.
18. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system.
19. If accidentally deployed, do not attempt to reinsert the filter into the filter storage tube as damage to the legs and hooks can occur.
20. For placement of the filter, the right jugular vein is preferable.
21. Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent entanglement.
22. The retrieval of the DENALI® Vena Cava Filter should only be performed using minimum 9F I.D./11F I.D. dual retrieval sheaths. Misuse of these devices or improper retrieval technique may result in intimal injury or caval narrowing.
23. Care should be taken when advancing the 9F retrieval sheath in the caudal direction to avoid completely covering the arms and legs.

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. FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed. 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 Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

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 caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- 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 utilizing endovascular and/or surgical techniques.
- Detachment of components
- Perforation or other acute or chronic damage of the IVC wall.
- 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.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow
- Occlusion of small vessels
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion.
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous ulceration
- Blood loss
- Guidewire entrapment
- Pain

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

H. Clinical Experience

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, insertion adverse events, and technical failure of placement. The pre-established performance goal was that the lower bound of the 95% confidence interval for the CSP 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 of the filter without retrieval complications requiring intervention. Additionally, the secondary endpoints of recurrent PE, new or worsening DVT, filter migration, filter fracture, penetration and tilt were assessed.

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 their filter successfully retrieved..

Of the 200 patients who underwent DENALI® Filter placement, 120 had active thromboembolic disease (the presence of DVT or PE at the time of filter placement). Of these 120 patients, 66 had a contraindication to anticoagulation, 9 had a complication related to the use of anticoagulant medication, 20 had a failure of anticoagulation, and 25 had a filter placed without contraindication, complication or failure related to anticoagulant medication. Eighty (80) patients without active thromboembolic disease (neither DVT nor PE at the time of filter 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=44, 22%), 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 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 conditions. Refer to the results sections for more details. Table 1 displays the completed patient follow-up at each time point.

Table 1: Patient Accountability

	Eligible for Visit (N)	Visit Complete (N, %)		Reason Visit Not Completed				Events Occurring Before Next Visit	
			Retrieved	Death	Lost to Follow-Up	Withdrawn	Missed Visit	Migration	Fracture
Baseline/ Implant	200	200	N/A	0	0	0	0	0	0
3 Months[1]	165	157 (95%)	30	11	1	0	6	0	0
6 Months[2]	130	112 (86%)	39	3	2	2	15	0	0
12 Months[3]	77	71 (92%)	38	3	2	2	4	0	0
18 Months[4]	54	53 (98%)	8	3	3	0	0	0	0
24 Months[5]	48	46 (96%)	6	1	2	0	0	0	0
Retrieval[6]	124	121	121	N/A	N/A	N/A	N/A	0	0
30 Days Post-Retrieval	121	119 (98%)	N/A	N/A	2	N/A	N/A	N/A	N/A

1 5 subjects had their filter retrieved in 3M window and are considered "visit complete"; 1 eligible subject died in 3M window; 1 eligible subject was LTF in 3M window.

2 13 subjects had their filter retrieved in 6M window and are considered "visit complete"; 1 eligible subject died in 6M window; 2 retrieved in 6M window missed the 6M visit; 2 eligible subjects were LTF in the 6M window; 2 eligible subjects were withdrawn in the 6M window.

3 4 subjects had their filter retrieved in 12M window and are considered "visit complete"; neither withdrawn subject was eligible for the 12M visit; 1 eligible subject died in 12M window; 1 eligible subject was LTF in 12M window.

4 1 eligible subject was LTF in 18M window.

5 2 subjects completed both the 24M visit and filter retrieval visit; 2 eligible subjects were LTF in the 24M window.

6 1 subject had an unsuccessful retrieval attempt but returned for a second attempt which was successful.

Results

CSP for the DENALI® 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 99.5%. Mean placement procedure time was 17.8 minutes and mean fluoroscopy time was 3.6 minutes. TSR for the DENALI® Filter was 97.6%. CSR for the DENALI® Filter was 99.2%.

Table 2: Primary Endpoints

Clinical Success of Placement (CSP)	95.0%
Technical Success of Placement (TSP)	99.5%
Technical Success of Retrieval (TSR)	97.6%
Clinical Success of Retrieval (CSR)	99.2%

There were no findings of filter fracture, cranial migration, caudal 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 case of 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 3.6 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 reported were 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

	0-6 Months[1]	0-24 Months[2]
Recurrent PE	5 / 188 (2.7%)	6 / 200 (3.0%)
Caval Occlusion	1 / 188 (0%)	1 / 200 (0.5%)
New DVT	14 / 188 (10.1%)	18 / 200 (9.0%)
Worsening DVT	6 / 188 (7.4%)	8 / 200 (4.0%)
Filter Fracture	0 / 186 (0%)	0 / 186 (0%)
Cranial Migration > 2cm	0 / 186 (0%)	0 / 186 (0%)
Caudal Migration > 2cm	0 / 186 (0%)	0 / 186 (0%)
Filter Penetration at Placement > 3mm	3 / 200 (1.5%)	3 / 200 (1.5%)
Filter Penetration at Retrieval > 3mm	2 / 82 (2.4%)	2 / 124 (1.6%)
Filter Tilt at Placement > 15°	0 / 200 (0%)	0 / 200 (0%)
Filter Tilt at Retrieval > 15°	0 / 82 (0%)	0 / 124 (0%)

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

DENALI® Filter Retrieval

DENALI® 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 removed due to thrombus in the filter in one case. Mean filter indwell time was 200.8 ± 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.

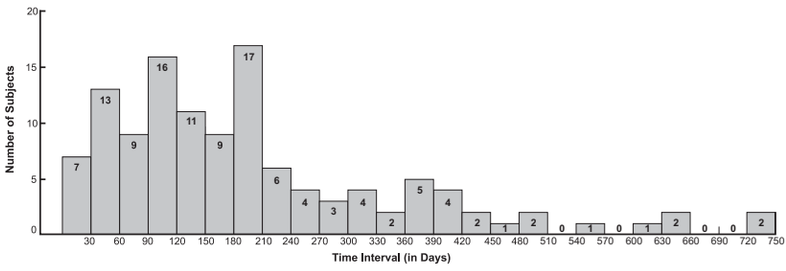
Venacavograms taken before and after the retrieval procedures of the IVC implant site revealed abnormalities that the CEC determined to be related to the device in four patients. One patient had minimal, self limited contrast extravasation post retrieval, one patient experienced intimal injury and caval narrowing of the IVC post retrieval, 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 due to the retrieval procedure.

One hundred nineteen (119) of the 121 patients who had their filter retrieved completed one month follow-up and 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.

Table 4: DENALI® Filter Retrieval Details

Number of Filter Retrieval Attempts	124
Number of Successful Retrievals	121
Retrieval Success Rate	97.6%
Mean Indwell Time	200.8 days
Maximum Indwell Time	736 days

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



I. Directions for Use - Implantation

1. Collect and prepare the following equipment for use.
   - One DENALI® Vena Cava Jugular/Subclavian System that contains:
     - One 55cm, 8.4 French I.D. introducer sheath and 8F 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.
2. Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient's size/anatomy, operator's preference, or location of venous thrombosis. Right jugular/subclavian veins are preferred.
3. Inspect 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 inner pouch and remove the introducer sheath and both dilators 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 congenital anomalies.

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 advancement.

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

11. Select the optimum location (For example 1cm below the lowest renal) for filter placement and measure the IVC diameter. 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).
12. Reintroduce the guidewire and advance the introducer sheath with dilator to the selected optimum location under flouroscopic guidance.

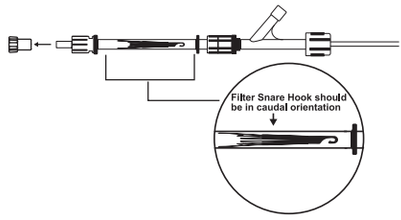
WARNING: If the vena cava diameter is greater than 28mm, do not deploy the DENALI® Filter.

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.

Figure 4: Safety Cap Removal



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.

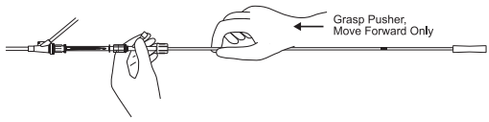
18. Attach the free end of the filter storage tube directly to the introducer sheath already in the vein. The introducer sheath and filter delivery system should be held in a straight line to minimize friction.

Figure 5: Attachment to Introducer Sheath

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.

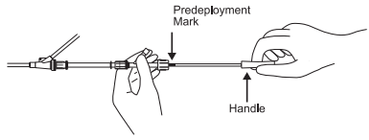
19. Loosen the proximal end of the Touhy-Borst adapter and advance the filter by moving the pusher forward through the introducer sheath. Do not twist or retract the pusher at anytime during the procedure.

Figure 6: Advancement of Filter



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

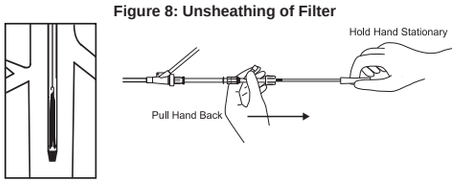
Figure 7: Advancement to Proximal End of Adapter



21. Prior to deployment, verify the location of the filter within the sheath using fluoroscopy and confirm that the filter 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 fluorscopic 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.

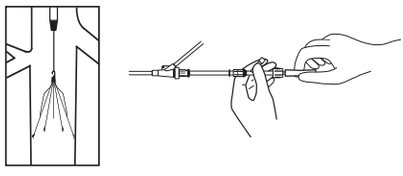
Note: The assembly should be retracted in one smooth, continuous motion.

Figure 8: Unsheathing of Filter



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.

Figure 9: Releasing of Filter



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 pusher. Then disconnect the storage tube from the introducer sheath.
24. Resume the intermittent saline flush to maintain introducer sheath patency.
25. A venacavogram may be performed to confirm satisfactory deployment before terminating the procedure (typically 30mL of contrast medium at 15mL/s).

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

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

J. Optional Procedure for Filter Removal

Removal of DENALI® Filter Using an Intravascular Snare

Collect and Prepare the Following Equipment for Use:

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

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

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

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

PRECAUTION: The retrieval of the DENALI® Filter should only be performed using minimum 9F I.D./11F I.D. dual retrieval sheaths. Misuse of these devices or improper retrieval technique may result in intimal injury or caval narrowing.

Procedural Instructions

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

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

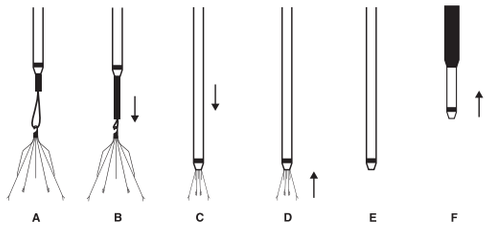


Figure 10A: Slowly advance the loop forward over the filter snare hook.

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

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

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

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

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

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

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

Figure 10F: Once the filter is fully collapsed inside the 9F retrieval sheath, retract the filter, the snare, and the retrieval sheath as one unit out 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 prior to withdrawing the 11F retrieval sheath (typically 30mL of contrast medium at 15mL/s).

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

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

J. How Supplied

Each DENALI® Vena Cava Filter is supplied preloaded in a storage tube. Each DENALI® Vena Cava Filter is sterile and nonpyrogenic unless the package is damaged or opened. It is for single use only. The delivery system is pre-assembled. If the filter is inadvertently deployed, do not attempt to re-sterilize or reload it. The DENALI® Vena Cava Filter should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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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:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Caplin, Nikolic, Kalva, et al.: J Vasc Interv Radiol 2011; 1499-1506.

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

- "Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684].
- "American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504].
- "Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614].
- "Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275].

DENALI® Vena Cava Filter

DENALI® Filter Jugular/ Subclavian Delivery Device

DENALI® Filter Introducer Sheath With Dilator

J/S

Jugular/Subclavian

KIT

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

INT

Contents:
(1) 8.4F I.D. Introducer Sheath 55cm Long with 8F Dilator

DD

Contents:
(1) DENALI® Filter- Jugular/ Subclavian Delivery Device to be used with DL900J

Use By

LOT

Lot Number

REF

Catalogue Number

Attention, See Instructions for Use

STERILE EO

Sterilized Using Ethylene Oxide

NON PYROGENIC **Non-Pyrogenic**

Keep Dry

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised

MR

MR Conditional

Recommended Guidewire

Manufacturer

Not Made With Natural Rubber Latex

WSL

Working Sheath Length

Introducer Sheath

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