



Denali™ Vena Cava Filter

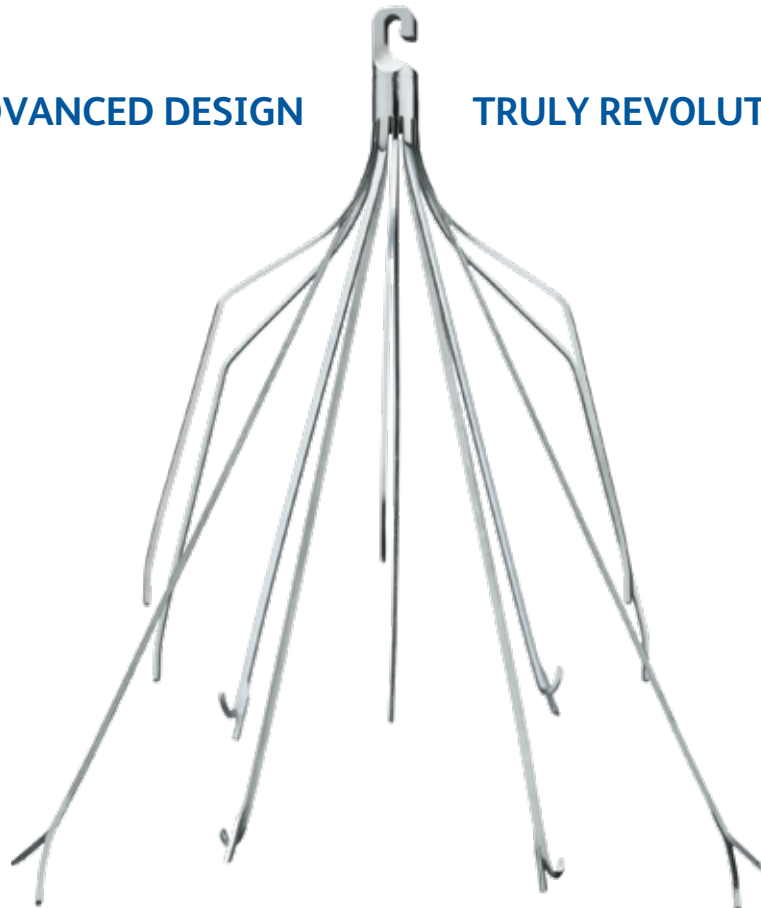
Bard Filter Revolution



Bard Peripheral Vascular proudly continues with the Denali™ Vena Cava Filter - a c

ADVANCED DESIGN

TRULY REVOLUTIONARY



Clinical Performance

Denali™ Clinical Study¹

The Denali™ Clinical Study is a single-arm, prospective, multi-center clinical study designed to assess the safety of the Denali™ Filter as both a permanent and retrievable device. Enrollment was completed in May 2013 and follow-up continues. All patients who do not have their filter retrieved will be followed to 2 years post-placement.

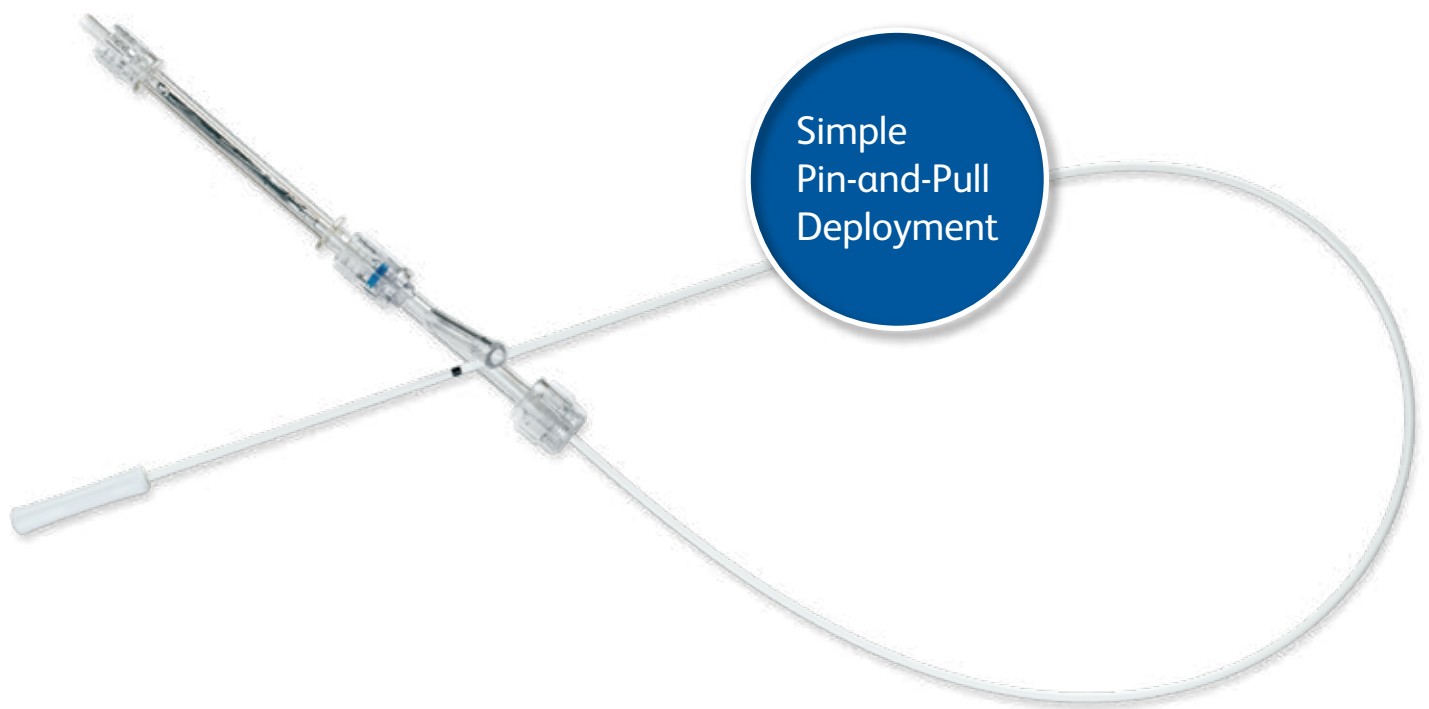
Interim Analysis

Patients Enrolled	200
Patients to 6 Month Visit	100
Patients to 12 Month Follow-Up	47
Patients to 18 Month Follow-Up	27
Patients to 24 Month Follow-Up	7

Continues its legacy as an innovator of optical completely redesigned Bard Filter.

Long-Term Protection

- Easy and accurate delivery system promotes self-centering
- Proven conical shape and dual level filtration
- Effectively traps clot without compromising caval patency



Clinical Performance

Long-Term Prevention of Pulmonary Embolism

Complication Rates		
Recurrent PE	2 / 175	1.1 %
Caval Occlusion	0 / 129	0 %
Filter Fracture	0 / 129	0 %
Cranial Migration	0 / 128	0 %
Caudal Migration	0 / 128	0 %
Filter Penetration at Placement	3 / 175	1.7 %
Filter Penetration at Retrieval	2 / 88	2.3 %
Filter Tilt at Placement	0 / 175	0 %
Filter Tilt at Retrieval	0 / 88	0 %

RESULTS

The results of the Denali™ clinical study constitute valid scientific evidence regarding the design and clinical performance of the Denali™ filter and delivery system.

The study outcomes demonstrate that the Denali™ filter can be safely implanted to provide immediate protection against PE for an extended indwell time and can be safely retrieved with low complication rates.

onal IVC filter technology

Stable and Secure

- Electropolished one-piece nitinol filter body
- Anchor prevents caudal migration of filter
- Unique penetration limiters help limit penetration



Cranial Anchor



Caudal Anchor

Clinical Performance

Improved Movement Resistance*

Interim Analysis

Filter Fracture	0 %
Cranial Migration	0 %
Caudal Migration	0 %
Filter Penetration at Placement	1.5 %
Filter Penetration at Retrieval	1.8 %
Filter Tilt at Placement	0 %
Filter Tilt at Retrieval	0 %

* Based on comparison to EVEREST Clinical Study results.

Denali™

Vena Cava Filter

Long-Term Retrievability

- Atraumatic filter removal even after extended indwell times
- Highly visible snare tip seamlessly welded to filter body
- Smooth neck design encourages easy snare capture



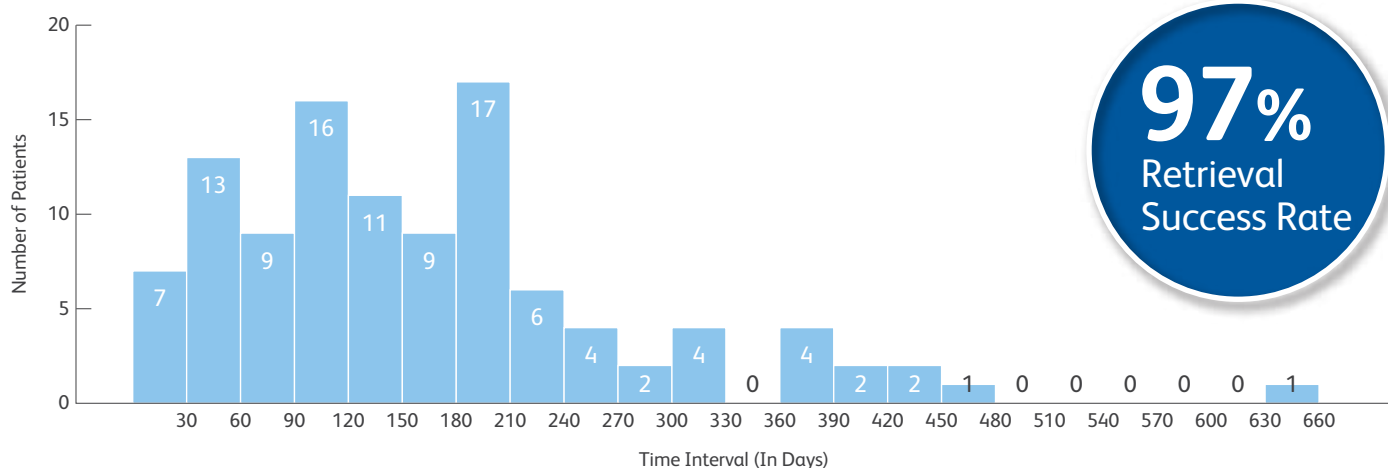
Clinical Performance

Implantation to Retrieval in 108 Successful Retrievals

Interim Analysis

Mean Indwell Time 165 days

Maximum Indwell Time 632 days



Indications for Use :

The Denali™ Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent 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 in the Instructions for Use under the section labeled: "Optional Procedure for Filter Removal".

Contraindications for Use :

The Denali™ Vena Cava Filter should not be implanted in: • Patients with an IVC diameter larger than 28 mm. • Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully. • Patients with risk of septic embolism.

Warnings:

1) Persons with allergic reactions to nickel may suffer an allergic response to this implant. **2)** 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. **3)** 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. **4)** 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. **5)** 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. **6)** The Denali™ Filter Femoral System is designed for femoral approaches only. Never use the Denali™ Filter Femoral System for superior approaches (Jugular, Subclavian or antecubital vein), as this will result in improper filter orientation within the IVC. **7)** If the Vena Cava diameter is greater than 28 mm do not deploy the Denali™ Filter. **8)** 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. **9)** When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi. **10)** Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance. **11)** 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. **12)** 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. **13)** 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. **14)** After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded, or filter may become entangled. **15)** 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 wall. **16)** 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 the Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

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. • Postphlebotic 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.

Please consult package insert for more detailed safety information and instructions for use.

Reference 1. Stavropoulos, et al. JVIR 2014.

Denali™ Vena Cava Filter Ordering Information

Product Code	Description	Quantity
DL950F	Denali™ Vena Cava Filter, Femoral Delivery Kit	1 ea
DL950J	Denali™ Vena Cava Filter, Jugular Delivery Kit	1 ea

Bard™ Snare Retrieval Kit Ordering Information

Product Code	Description	Quantity
SRK35	Dual Sheath Snare Retrieval Kit, 20 mm	1 ea

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