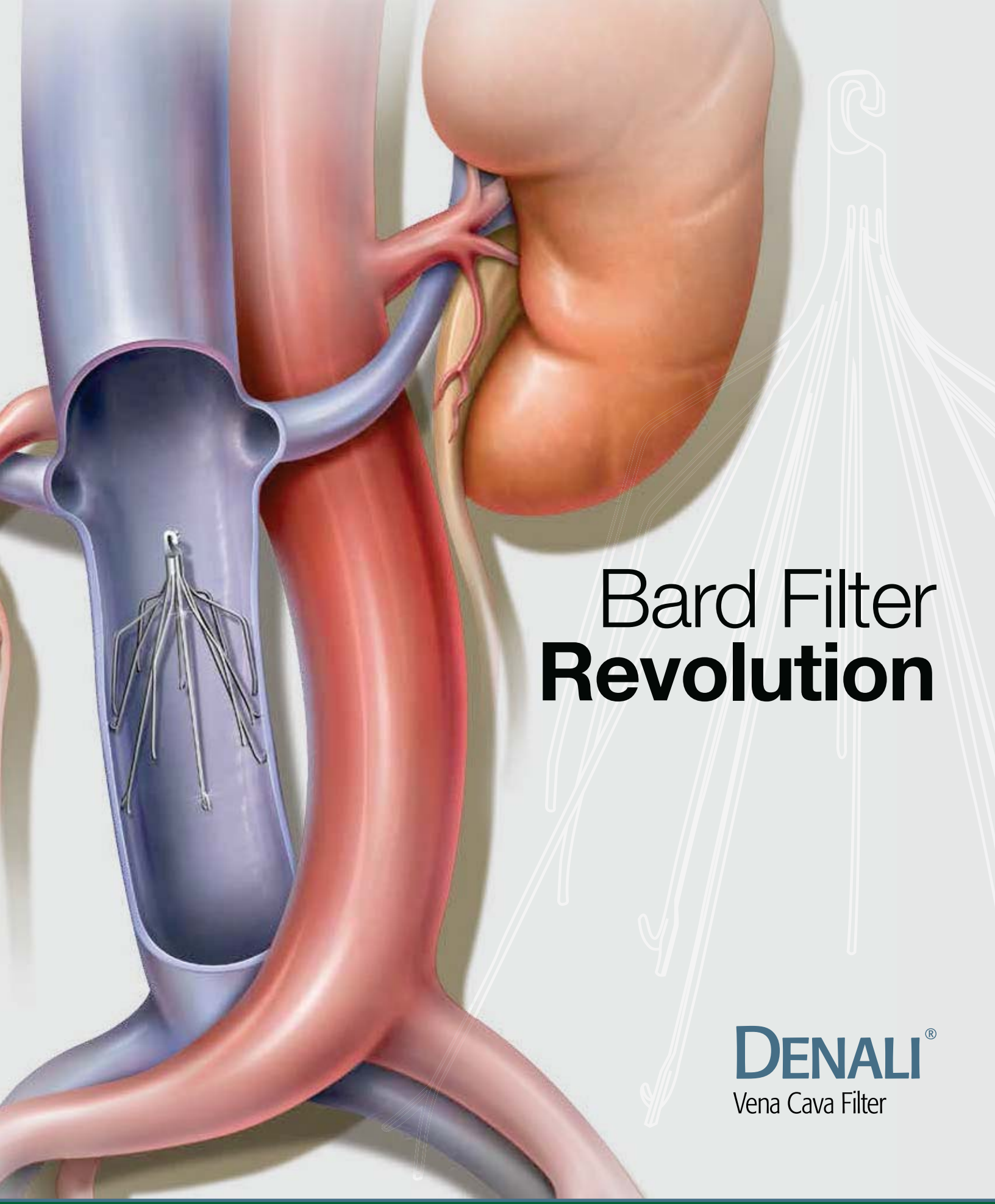


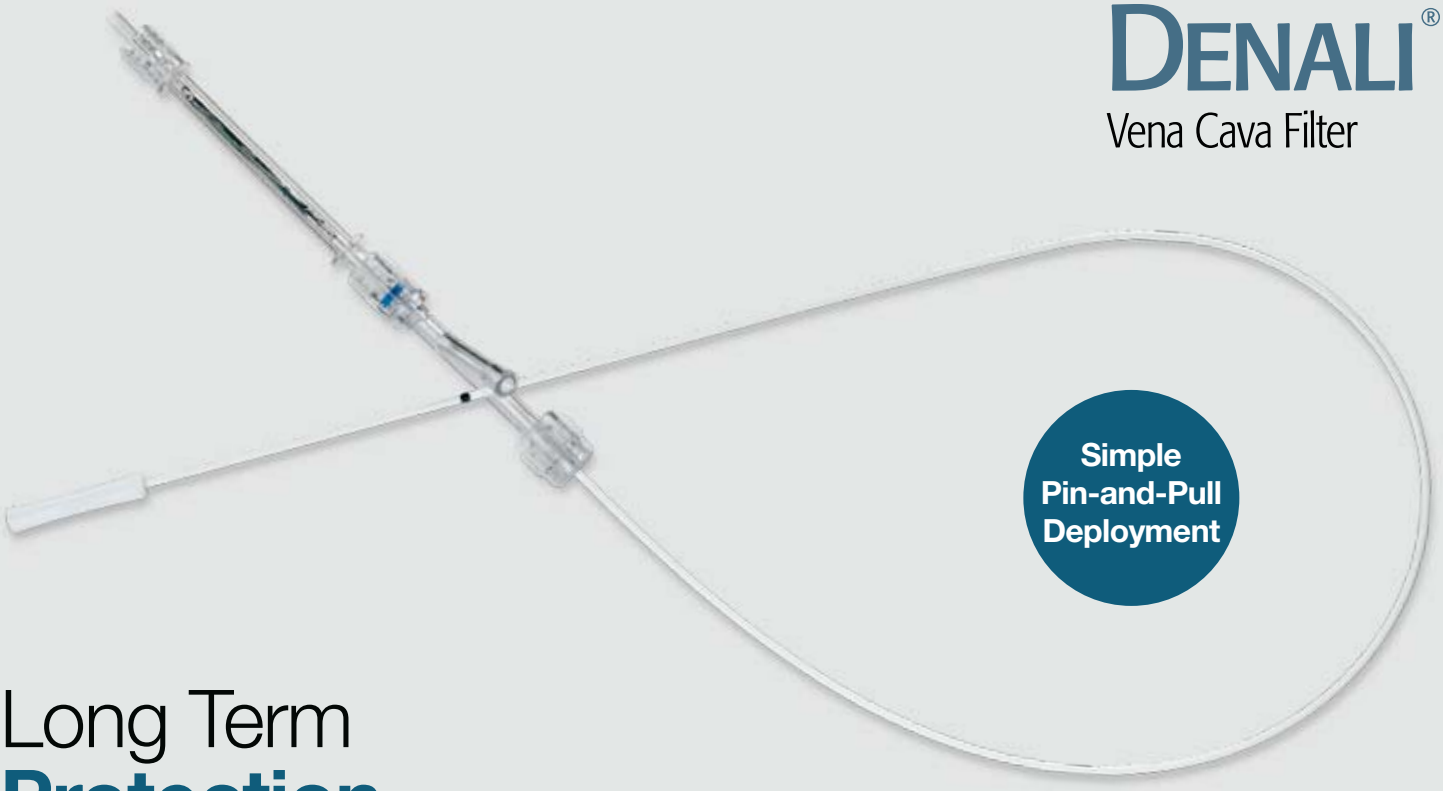
Bard Filter **Revolution**

DENALI®
Vena Cava Filter

Advancing Lives and the Delivery of Health Care™

BARD

DENALI®
Vena Cava 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

The final results of the DENALI® Clinical Study demonstrate that the DENALI® Filter exhibits high success rates for filter placement and retrieval while maintaining a low complication rate.

Final Analysis	
Recurrent PE Rate	3.0%
Caval Occlusion Rate	0.5%
Retrieval Success Rate	97.6%

Advanced Design
Truly Revolutionary

Bard Peripheral Vascular proudly continues its legacy as an innovator of optional IVC filter technology with the DENALI® Vena Cava Filter - a completely redesigned Bard Filter.

Clinical Performance
DENALI® Clinical Study[1]

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. All patients who did not have their filter retrieved were followed out to 2 years post-placement.

Final Analysis	
Patients Enrolled	200
Completed 6 Month Visit	98
Completed 12 Month Follow-Up	68
Completed 18 Month Follow-Up	53
Completed 24 Month Follow-Up	46

[1] Stavropoulos, et al. JVIR 2016

Stable and **Secure**

- Electropolished one-piece nitinol filter body
- Anchors help prevent cranial and caudal migration
- Unique penetration limiters help limit penetration

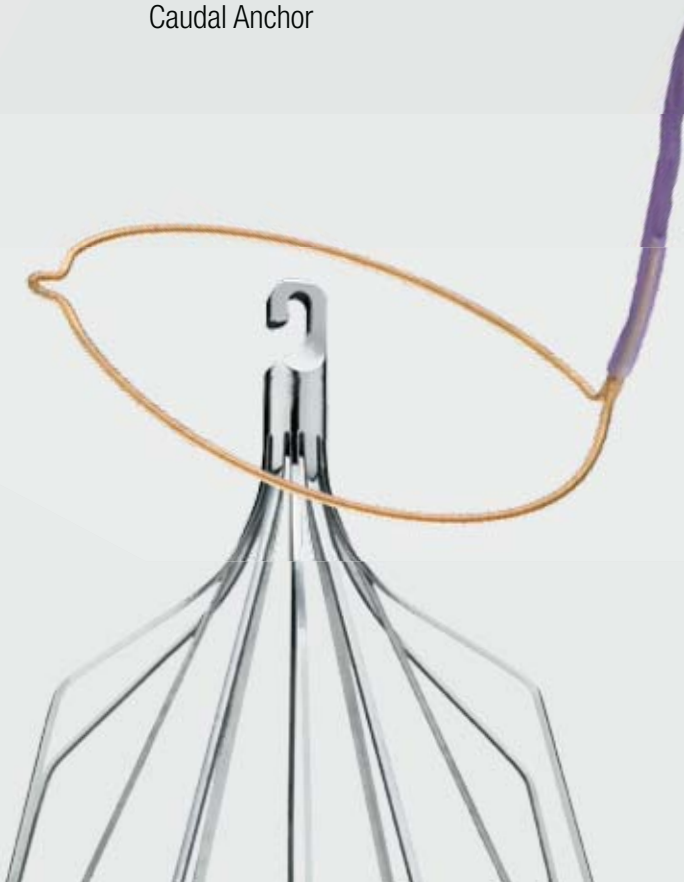
Cranial Anchor

Caudal Anchor

Clinical Performance
Improved Movement Resistance[2]

Final Analysis	
Filter Fracture	0%
Cranial Migration (>2 cm)	0%
Caudal Migration (>2 cm)	0%
Filter Penetration at Placement (>3 mm)	1.5%
Filter Penetration at Retrieval (>3 mm)	1.6%
Filter Tilt at Placement (>15°)	0%
Filter Tilt at Retrieval (>15°)	0%

[2] Based on comparison to EVEREST Clinical Study results.

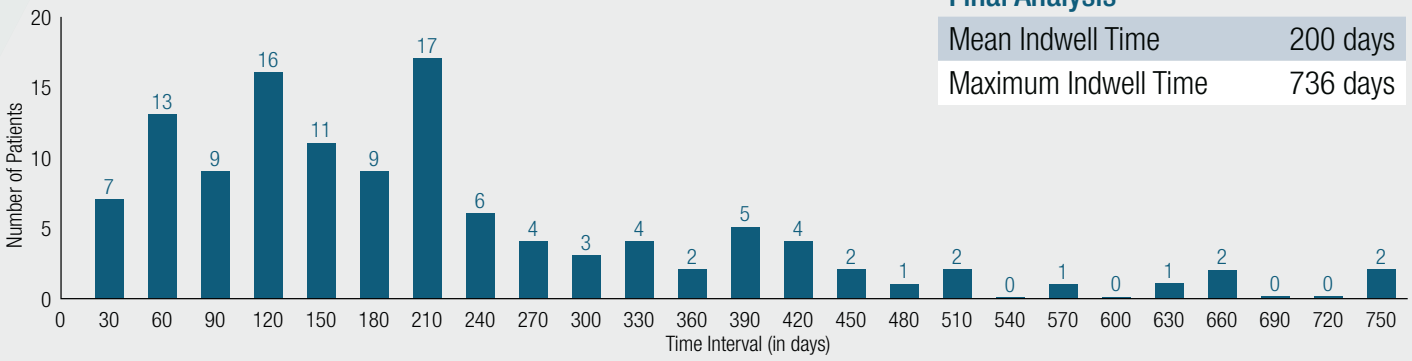


Long Term
Retrievability

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

97.6%
Retrieval Success Rate

Clinical Performance
Implantation to Retrieval in 121 Successful Retrievals



Final Analysis

Mean Indwell Time	200 days
Maximum Indwell Time	736 days

DENALI®
Vena Cava Filter

DENALI® Vena Cava Filter Ordering Information

Description	Product Code
DENALI® Vena Cava Filter, Femoral Delivery Kit	☐ DL900F
DENALI® Vena Cava Filter, Jugular Delivery Kit	☐ DL900J

BARD® Snare Filter Retrieval Kit Ordering Information

Description	Product Code
Dual Sheath Snare Retrieval Kit, 20 mm	☐ SRK30

REPRESENTATIVE'S NAME

CONTACT PHONE NUMBER

BARD REACH™ Program

The DENALI® Vena Cava Filter is now part of the BARD REACH™ Program, an industry-leading initiative designed to help physicians contact their Bard Optional Vena Cava Filter patients to bring them back to the practice. Learn more at www.bardreach.com

PHYSICIAN'S SIGNATURE

DENALI® Vena Cava Filter

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 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. · 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.

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 28 mm 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 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. · 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.

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

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