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.

**ADVANCED DESIGN**

**TRULY REVOLUTIONARY**

**CLINICAL PERFORMANCE**

**DENALI® CLINICAL STUDY**

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**

<table>
<thead>
<tr>
<th>Patients Enrolled</th>
<th>200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients to 6 Month Visit</td>
<td>100</td>
</tr>
<tr>
<td>Patients to 12 Month Follow-Up</td>
<td>47</td>
</tr>
<tr>
<td>Patients to 18 Month Follow-Up</td>
<td>27</td>
</tr>
<tr>
<td>Patients to 24 Month Follow-Up</td>
<td>7</td>
</tr>
</tbody>
</table>

1 Stavropoulos, et al. JVIR 2014.
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

LONG-TERM PREVENTION OF PULMONARY EMBOLISM

The interim results of the Denali® Clinical Study demonstrate that the Denali® Filter can be safely implanted to provide immediate protection against pulmonary embolism (PE) for an extended indwell time and can be safely retrieved with low complication rates.

Interim Analysis

<table>
<thead>
<tr>
<th>Metric</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent PE Rate</td>
<td>3.0%</td>
</tr>
<tr>
<td>Caval Occlusion Rate</td>
<td>1.0%</td>
</tr>
<tr>
<td>Retrieval Success Rate</td>
<td>97%</td>
</tr>
</tbody>
</table>
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*

Interim Analysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Filter Fracture</td>
<td>0%</td>
</tr>
<tr>
<td>Cranial Migration</td>
<td>0%</td>
</tr>
<tr>
<td>Caudal Migration</td>
<td>0%</td>
</tr>
<tr>
<td>Filter Penetration at Placement</td>
<td>1.5%</td>
</tr>
<tr>
<td>Filter Penetration at Retrieval</td>
<td>1.8%</td>
</tr>
<tr>
<td>Filter Tilt at Placement</td>
<td>0%</td>
</tr>
<tr>
<td>Filter Tilt at Retrieval</td>
<td>0%</td>
</tr>
</tbody>
</table>

* Based on comparison to EVEREST Clinical Study results.
Atraumatic filter removal even after extended indwell times
Highly visible snare tip seamlessly welded to filter body
Smooth neck design encourages easy snare capture

LONG-TERM retrievability

CLINICAL PERFORMANCE
IMPLANTATION TO RETRIEVAL IN 108 SUCCESSFUL RETRIEVALS

Interim Analysis
Mean Indwell Time 165 days
Maximum Indwell Time 632 days
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 embolism when anticoagulation is contraindicated
• Failure of anticoagulant therapy for thromboembolic disease

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
• Patients with renal insufficiency

Warnings:

1) The Denali® Filter is made 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 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 the product sterilization barrier or its packaging is compromised.

4) This device has been designed for single use only. Reusing this medical device is the risk of cross-patient contamination as medical devices — particularly those with long and small lumina, ports, and/or crores between components — are difficult or impossible to clean once body fluids or tissues with potential genomic or microbial contamination have had contact with the medical device for an indeterminate period of time. The result of biological material can promote the contamination of the device with pathogens 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 retrieved in the storage tube. Do not deploy the filter unless IVC has been properly measured. Never re-deploy a removed filter. Do not reinsert. After retrieval, the integrity of the product is not guaranteed because of an indeterminate degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing, and/or reutilization 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 change.

6) 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, covering of filter legs on arms, and could prevent the filter from further advancement within the introducer sheath.

7) The Denali® Filter and/or Sublumen System is designed for use in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may be caused by placement of the filter in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration, movement 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 clot 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.

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9) Placement of the filter to the IVC 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.

BARD® Snare Retrieval Kit Ordering Information

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRK30</td>
<td>Dual Sheath Snare Retrieval Kit, 20 mm</td>
<td>1 ea</td>
</tr>
</tbody>
</table>

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