



Option™ Vena Cava Filter

Instructions For Use
Catheter Sheath Introducer
5 Fr. ID (6.5 Fr. OD) / 70cm length

Kit Contents

- A. Catheter Sheath Introducer
- B. Angiographic Vessel Dilator
- C. Pusher with Deployment Marker
- D. Option™ Filter in Cartridge
- E. Sheath Cap

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For single use only. Do not autoclave.

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

I. Device Description

The Option™ Vena Cava Filter is designed for the prevention of recurrent pulmonary embolism via percutaneous delivery in the inferior vena cava (IVC).

The self-centering Option™ Filter is laser cut from nickel – titanium alloy (Nitinol) tubing. The Option™ Filter (Figure 2) consists of shape memory Nitinol struts emanating from a central location and is designed for optimal clot capture. Retention anchors (retention hooks), both large and small, are located at the proximal or caudal portion of the filter. These anchors are intended for filter fixation to the vessel wall. The Option™ Filter is intended to be used in caval diameters up to 30mm. A retrieval hook is centrally located at the cranial extremity.

The constrained Option™ Filter is flexible and expands to the internal diameter of the IVC upon deployment. The Option™ Filter imparts an outward radial force on the luminal surface of the vena cava to ensure proper positioning and stability. The Option™ Filter is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.

The introduction kit is comprised of a filter housed in a filter cartridge, Catheter Sheath Introducer (5F ID), Angiographic Vessel Dilator with an open end, (Figure 3) and a Pusher with deployment marker (Figure 4).

The Angiographic Vessel Dilator has side holes and 2 radiopaque markers, separated by 32mm (between the marker bands), that provide linear measurement of the inferior vena cava and assists in angiographic visualization when radiopaque contrast is delivered. The pusher advances the filter through the Catheter Sheath Introducer up to the deployment marker, and is then used to fix the filter in place during uncovering. The location of the distal end of the Catheter Sheath Introducer can be controlled by rotating the entire device to position the Catheter Sheath Introducer in the center of the vena cava.

The Filter Cartridge houses the Option™ Filter. The body of the Cartridge has text and colored arrows printed on it that identify assembly orientation, femoral is printed in green (Figure 5A) and jugular is printed in blue (Figure 5B). The arrow of the desired access site will point into the Catheter Sheath Introducer hub. The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

Figure 3: Angiographic Vessel Dilator Tip

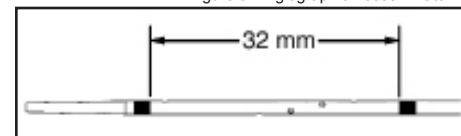


Figure 4: Pusher with Deployment Marker

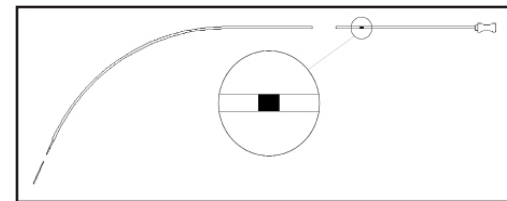


Figure 5A: Femoral Approach Cartridge Orientation

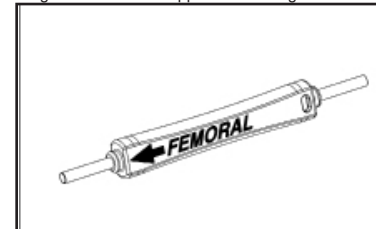


Figure 5B: Jugular Approach Cartridge Orientation

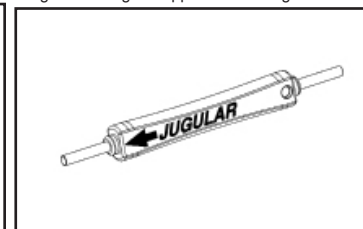


Figure 1: Option™ Filter System

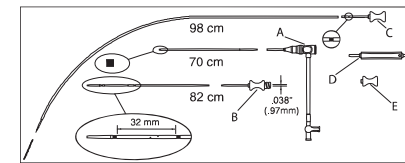
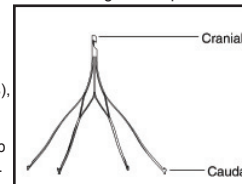


Figure 2: Option™ Filter



II. Indications For Use

The Option™ Filter is indicated for the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the inferior vena cava (IVC) in the following conditions:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy in 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 Option™ Filter may be removed according to the instructions supplied in the Section VIII, entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can only be performed by the jugular approach.

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

III. Contraindications

The Option™ Filter should not be implanted if any of the following conditions are present:

1. Patient has an inferior vena cava diameter larger than 30mm.
2. Patient is at risk for septic embolism.
3. Patient has confirmed bacteremia.
4. Patient has a known hypersensitivity to nickel or titanium alloys.
5. Pregnant patient when radiation from fluoroscopic imaging may endanger the fetus. Risks and benefits should be carefully assessed.

There are no known contraindications for use of the Angiographic Vessel Dilator.

IV. Warnings:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.

- For single product and patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Accordingly, the Manufacturer or its Distributors will not be responsible for any direct or consequential damages or expenses resulting from reuse, reprocessing or re-sterilization of any of the components in the Option™ Filter introduction kit.
- Non-clinical testing has demonstrated that the Option™ Filter is MR Conditional. A patient with the Option™ Filter can be safely scanned immediately after placement under the following conditions:
 - Static magnetic field of 3 Tesla or less
 - Spatial gradient magnetic field of 720 Gauss/cm or less
 - Maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15min of scanning
- In non-clinical testing, the Option™ Filter produced a temperature rise of less than or equal to 1.7°C at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla General Electric Healthcare MR scanner. The SAR calculated using calorimetry was 2.8 W/kg. 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 Option™ Filter. Therefore, it may be necessary to optimization of MR imaging parameters to compensate for the presence of this metallic implant.
- When injecting contrast medium through the Angiographic Vessel Dilator, do not exceed the maximum pressure rating of 800 psi.
- After filter implantation, any catheterization procedure requiring passage of a device through the filter may be impeded.
- The Option™ Filter is supplied loaded in a cartridge indicating the appropriate orientation for femoral and jugular approaches. Never reload a fully ejected filter into the Cartridge as this could affect its shape and function and could result in incorrect filter orientation for the selected access site. Never reload a (partially) ejected filter into the cartridge as this could affect its shape and function. Accordingly, the Manufacturer or its Distributors will not be responsible for any direct, incidental or consequential damages resulting from replacement of the Option™ Filter in the cartridge.
- The Option™ Filter should only be used by physicians who are trained in diagnostic and percutaneous interventional techniques, such as placement of vena cava filters. Accordingly, the Manufacturer or its Distributors will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel.
- Persons with allergic reactions to nickel-titanium alloys (Nitinol) may suffer an allergic response to this implant.
- Never advance the guidewire, introducer sheath/dilator or deploy the filter without fluoroscopic guidance.
- If large thrombus is observed at the initial delivery site, attempt filter delivery through an alternative site. A small thrombus may be bypassed with the guidewire and introducer.
- Never redeploy a malpositioned or retrieved filter.
- Once the Pusher deployment marker enters the metal tube of the Filter Cartridge, the filter must be fully deployed and it cannot be re-sheathed.

For Optional Filter Retrieval:

- Excessive force should not be used to retrieve the filter.
- Retrieval of the filter should not be attempted if thrombus is present in the filter, IVC or deep veins.
- Retrieval of the filter is possible only from the jugular approach. Before attempting retrieval of the filter from the jugular access site, verify that the filter retrieval hook is oriented in a cephalad direction – i.e. pointed toward the jugular access site. The retrieval hook at the cephalad end of the filter is the location for endovascular snare engagement.
- Retrieval of the filter should only be performed by physicians who are trained in percutaneous interventional techniques.
- Never redeploy a retrieved Filter.
- Please refer to Section VIII labeled "Recommended Percutaneous Procedure for Filter Retrieval".

V. Precautions

- Physicians should be properly trained prior to using the Option™ Vena Cava Filter.
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to "Use By" date.
- Do not autoclave or resterilize.
- The Option™ Filter has been tested and qualified with the accompanying or recommended accessories. The use of any other accessory could result in complications and/or an unsuccessful procedure.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding.

- Anatomical variances may complicate Filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the inferior vena cava may follow the general course of such anatomic deformations.

VI. 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 the implantation, indwelling period, or at the time of or following filter retrieval. Possible complications may include, but are not limited to, the following:

- Vena cava or other vessel injury or damage, including rupture or dissection, possibly requiring surgical repair or intervention
- Injury or damage to organs adjacent to vena cava, possibly requiring surgical repair or intervention
- Vena cava stenosis or occlusion
- Incorrect positioning or orientation of the filter
- Filter migration/movement
- Extravasation of contrast media
- Vasospasm or decreased/impaired blood flow
- Bleeding or hemorrhagic complications that require transfusion or medical intervention (e.g., IV fluids, medication)
- Thromboembolic events, including DVT, acute or recurrent pulmonary embolism or air embolism, possibly causing end organ infarction/damage/failure
- Infection, possibly requiring medical or surgical intervention (e.g. antibiotics or incision and drainage)
- Respiratory insufficiency or failure
- Cardiac arrhythmia
- Myocardial infarction or coronary ischemia
- Cerebrovascular accident or other neurologic event
- Renal insufficiency or failure
- Reaction to contrast media/ medication
- Hematoma, possibly requiring medical intervention or surgical revision
- Other vascular access site injury, including, bruising, AV fistula, or pseudoaneurysm
- Neurological deficit associated with vascular access, possibly requiring nerve intervention or neurology consultation
- Device breakage or failure or inability to retrieve implanted device as described in IFU, possibly requiring another intervention or treatment modality to complete procedure
- Death

These events may be serious in nature, and may require hospitalization or intervention to address the condition.

VII. Recommended Percutaneous Procedure for Filter Implantation

Pre-implant cavography is required:

- To confirm the patency and visualize the anatomy of the vena cava.
 - To mark the level of the renal veins.
 - To locate the highest level of any thrombus which may be present.
 - To determine the desired level for filter deployment and to mark the position with respect to the vertebral bodies.
 - To confirm that the diameter of the vena cava (AP projection) at the site where the filter is to be deployed is less than or equal to the maximum authorized diameter (refer to section I Device Description).
- Select a suitable venous access site, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
 - Prep, drape and anesthetize the skin puncture site in standard fashion.
 - Remove the components of the introduction kit from the package using sterile technique.
 - Wet the operator-selected guidewire (max .038") with sterile heparinized saline or suitable isotonic solution.
 - Flush the Catheter Sheath Introducer and Angiographic Vessel Dilator with heparinized saline or suitable isotonic solution.
 - Close the side-port after flushing by engaging the clamp.
 - Insert the Angiographic Vessel Dilator through the Catheter Sheath Introducer, snapping it into place at the hub. Flush with heparinized saline or suitable isotonic solution.
 - Puncture the access site using the Seldinger technique.
 - Holding the needle in place, insert the guidewire through the needle and into the vessel. Gently advance the guidewire to the desired location.

Caution: Do not withdraw a PTFE-coated guidewire through a metal cannula as this may damage the guidewire coating.
 - Holding the guidewire in place, remove the needle over the guidewire
 - Advance the Catheter Sheath Introducer together with the dilator over the guidewire and into the IVC.
 - Position the Catheter Sheath Introducers' radiopaque tip and the marker bands of the Angiographic Vessel Dilator in the inferior vena cava below the renal veins in preparation for an angiographic overview of the IVC.
 - Remove the guidewire.
 - Inject contrast media through the Angiographic Vessel Dilator to determine the diameter of the inferior vena cava at the intended implantation site below the lowest renal vein, using its marker bands as a reference. The distance between the two marker bands, inside edge to inside edge, is 32mm.

Caution: Do not use with Ethiodiol* or Lipiodol contrast media, or other such contrast media that incorporate the components of these agents.

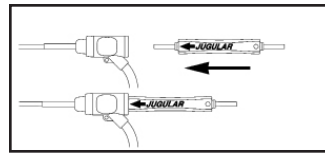
Caution: Do not exceed 800 psi when injecting.
 - Reintroduce the guidewire.
 - Advance the Catheter Sheath Introducer tip to the desired location in the IVC.
 - Detach and withdraw the Angiographic Vessel Dilator with the guidewire from the Catheter Sheath Introducer by unsnapping the snap-fit at the hub.

Caution: To avoid damage to the Catheter Sheath Introducer tip, do not withdraw the dilator until the Catheter Sheath Introducer tip is at the desired location in the IVC.
 - Aspirate from the sideport extension to remove any potential air.
 - Determine which end of the cartridge (containing the filter) is to be placed into the hub of the Catheter Sheath Introducer.

Note: The selected access site will determine the cartridge insertion orientation. The orientation is identified on the body of the cartridge, femoral is green and jugular is blue. The arrow of the desired access site will point into the Catheter Sheath Introducer hub.

- Place the appropriate end of the cartridge into the hub of the Catheter Sheath Introducer until a snap is achieved (Figure 6).

Figure 6: Cartridge Insertion Into Sheath Hub (jugular shown)

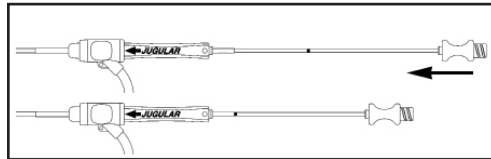


- Insert the lead wire of the Pusher into the Cartridge and slowly advance the filter using the pusher until the leading edge of the delivery marker on the pusher is positioned just proximal to the end of the filter cartridge.

Note: The delivery marker indicates that the filter is at the distal tip of the Catheter Sheath Introducer but still fully contained within the sheath (Figure 7).

Note: If filter advancement difficulties arise when using a tortuous vessel approach, stop filter advancement prior to the curve. Advance the sheath to negotiate the curve and then continue to advance the filter. Perform filter release (or deployment) under continuous fluoroscopy. Verify the intended filter location in the inferior vena cava is correct prior to releasing the filter from the Catheter Sheath Introducer.

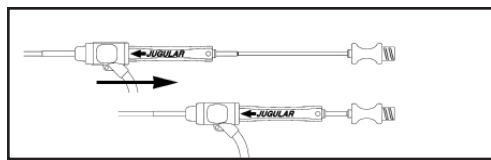
Figure 7: Assembly Showing Marker Band Advancement (jugular shown)



- In order to achieve optimal placement, center the distal end of the Catheter Sheath Introducer in the vena cava by rotating the entire delivery system, not the Pusher alone.

Note: Check both A/P and Lateral views under angiographic visualization for optimal placement.
- To deploy the Option™ Filter, fix the Pusher in position, then pull the sheath back over the pusher to uncover the filter (Figure 8).
- Ensure that the Option™ Filter is fully released and deployed.
- Carefully remove the Filter Cartridge along with the Pusher, ensuring that the pusher wire does not interfere with the deployed filter.

Figure 8: Filter Delivery Sheath Removal Showing Uncover Technique (jugular shown)



- Place the Sheath Cap on the Catheter Sheath Introducer.
- Perform a control cavogram prior to terminating the procedure. Verify proper filter positioning.
- Remove the Catheter Sheath Introducer by placing compression on the vessel above the puncture site, slowly withdrawing the Catheter Sheath Introducer.
- Discard the introduction kit and packaging materials.

Note: After use, the introduction kit and packaging materials may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

VIII. Optional Procedure for Filter Retrieval

If the filter is retrieved, it should be done within 175 days following implant. Additionally, the patient should meet all the following eligibility criteria for filter retrieval:

Filter Retrieval – Indications: Prior to filter retrieval, patients must meet ALL of the following criteria:

- The physician believes that the risk of clinically significant pulmonary embolism is acceptably low and that the retrieval procedure can be performed safely.
- Patient has a patent internal, external, or anterior jugular vein, in order to allow retrieval of the IVC filter device.

Filter Retrieval – Contraindications: Candidates must not undergo filter retrieval if ANY of the following criteria are met:

- At the time of retrieval procedure, based on venography and the physician's visual estimate, more than one (1) cubic centimeter of thrombus/embolus is present within the filter or caudal vena cava.
- Pregnant patients when radiation from fluoroscopic imaging may endanger the fetus. Risks and benefits should be carefully assessed.

Retrieval is performed using the recommended accessories (refer to Table 1). These devices used for filter retrieval are not included in the Option™ Filter Introduction Set.

Table 1. Recommended Devices for the Retrieval of the Option™ Filter

Recommended Devices	Description	Cat. No.
Retrieval Insertion Sheath Catheter		
• Cook® Flexor® • Check-Flo® Performer®	• Accepts up to 8F devices, .038" wire compatible, 70cm length.	• KCFW-8.0-38-70-RB-RAABE
• Cook® Flexor® • Check-Flo® Performer®	• Accepts up to 10F devices, .038" wire compatible, 80cm length.	• KCFW-10.0-38-80-RB
• Arrow Super Arrow-Flex®	• Accepts up to 8F devices, .038" wire compatible, 80cm length.	• CL-07880
Endovascular Snare		
• ENSnare® Kit	• 18-30mm loop diameter, 7F delivery • 392007030 catheter, 100 cm catheter length.	
• EV3 Goose Neck® Snare Kit	• 25mm loop diameter, 6F delivery	• GN2500

Recommended Procedure for the Percutaneous Retrieval of the Option™ Filter:

Warning: Excessive force should not be used to retrieve the filter. Retrieval of the Option™ Filter should not be attempted if thrombus is present in the filter and/or caudal to the filter.

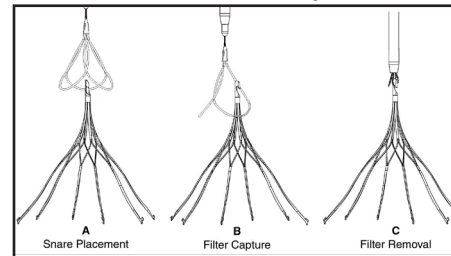
- Use appropriate techniques to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
- Prep, drape and anesthetize the skin puncture site in standard fashion.
- Wet the operator-selected guidewire with sterile heparinized saline or suitable isotonic solution via a syringe connected to the luer hub of the guidewire dispenser.
- Flush the Retrieval Catheter (Table 1) and components with heparinized saline or suitable isotonic solution.
- Insert Angiographic Vessel Dilator through the Retrieval Catheter, snapping it into place at the hub. Flush with heparinized saline or suitable isotonic solution.
- Puncture the access site using the Seldinger technique.
- Holding the needle in place, insert the guidewire through the needle and into the vessel. Gently advance the guidewire to the desired location (cephalad of the filter retrieval hook).

Caution: Do not withdraw a PTFE-coated guidewire through a metal cannula as this may damage the guidewire coating.
- Holding the guidewire in place, remove the needle over the guidewire.
- Advance the Retrieval Catheter together with the dilator over the guidewire and into the IVC. Advance the Retrieval Catheter such that the tip of the Retrieval Catheter is a short distance (approximately 3cm) cephalad of the filter retrieval hook.

Note: Verify that the retrieval route is free of thrombus.
- Prepare snare and snare catheter components according to the manufacturer's Instructions for use.
- Remove the Guidewire and Dilator.
- Insert and advance the endovascular snare assembly through the Retrieval Catheter until it protrudes out of the Retrieval Catheter such that the marker band of the snare catheter is cephalad of the filter retrieval hook.
- Push the snare shaft gently forward to open the snare loop cephalad of the filter retrieval hook.
- Slowly advance the loop forward over the filter apex (Figure 9A).
- Tighten the snare loop around the Option™ Filter by slowly retracting the snare and advancing the Snare Catheter simultaneously until the snare has locked into place by tightening into the hook recess. (Figure 9B).

Note: Verify that the snare has properly captured the Option™ Filter retrieval hook and the Retrieval Catheter and snare are aligned (Figure 9C).
- Pull the snare and advance the Snare Catheter until the tip of the Snare Catheter is in contact with the apex of the filter (Figure 9C).

Figure 9: Filter Retrieval



- Tighten the torquer onto the snare such that the Snare Catheter hub is used to apply constant tension.

Note: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.
- Maintain tension on the snare and advance the Retrieval Catheter over the apex of the filter.

Note: The filter will begin to collapse as it is covered by the Retrieval Catheter.
- Continue to advance the Retrieval Catheter until increased resistance is felt.
- Hold the Retrieval Catheter stationary and withdraw the filter into the Retrieval Catheter.

Note: If for any reason the Option™ Filter is not retrieved and remains implanted as a permanent filter, remove the Retrieval Catheter when clinically indicated by placing compression on the vessel above the puncture site and slowly withdrawing the system and proceed to step 23.
- Completely remove the filter by pulling the Snare Catheter until the filter exits the Retrieval Catheter.
- Verify the status of the IVC before ending the procedure using an appropriate imaging technique.
- Remove the Retrieval Catheter when clinically indicated by placing compression on the vessel above the puncture site and slowly withdrawing the system.
- Discard the Option™ Filter, Retrieval Catheter, Snare Technologies, accessories, and packaging materials.

Note: After use, the Option™ Filter, Retrieval Catheter, Snare Technologies, accessories, and packaging materials may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

IX. Clinical Summary

A single arm, prospective, multicenter non-randomized study designed to collect data on the safety and efficacy of the Rex Medical Option™ Vena Cava Filter as both a permanent and retrievable device was conducted. One hundred (100) patients underwent filter placement. There were 52 male and 48 female patients enrolled. The mean age was 59.1 ± 16.7 years (range: 18-90). Fifty (50) patients received an Option™ filter as a prophylactic measure (50%), with thromboembolic disease present in 15% of patients. Fifty (50) patients received an Option™ filter due to the presence of active thromboembolic disease (50%) with a complication of anticoagulation, a contraindication to anticoagulation or a failure of anticoagulation. Thirty two (32) patients enrolled had a pre-existing condition of Cancer (32%). Thirty six (36) patients had their filter successfully retrieved. Forty seven (47) patients were considered Permanent filter patients as they completed a 6 month follow up assessment. Seventeen (17) patients died due to a pre-existing or intercurrent condition (e.g. Cancer). Based on independent Medical Monitor adjudication, no patient deaths were attributed to the filter device, or implant or retrieval procedures.

The implantation procedures were uneventful, with Placement Technical Success achieved in 100% of patients. During follow-up through 6 months, two patients (2.0%) exhibited an episode of mild filter migration (23 mm), just over the specified limit of 20 mm. Three patients (3.0%), all of whom had Cancer ± a hypercoagulable state at baseline, exhibited symptomatic

caval occlusion. Four patients exhibited episodes of pulmonary embolism, determined to be definite and filter related, for a rate of 4.0%. Observed rates of pulmonary embolism, symptomatic caval occlusion, and filter migration were consistent with published literature. There were no incidents of filter embolization or fracture.

Thirty nine (39) patients had retrieval attempts. Retrieval Technical Success was achieved in 36 of 39 patients (92.3%). Thirty nine (39) patients had retrieval attempts in forty two (42) procedures. Retrieval Technical Success was achieved in 36 of 42 procedures (85.7%). The rate of Retrieval Technical Success observed within this study occurs at the more favorable range of published literature. In three cases, the filter could not be retrieved, due to an inability to engage the filter, or disengage the filter from the caval wall. The mean implant period was 67.1 ± 50.4 days (range: 1.0 - 175.0 days). Following venous access, no adverse events were attributed to the retrieval procedure, demonstrating the safety of filter retrieval in patients who no longer require a vena cava filter.

In summary, the placement and retrieval of the Option™ filter can be performed safely with relatively high rates of technical and clinical success. For patients who are no longer at risk for thromboembolism, the Option™ filter can be implanted for several months and then safely retrieved. Data demonstrates the safety and effectiveness of the placement and retrieval of the Option™ filter system in a clinically relevant patient population.

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Option™ Vena Cava Filter



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Rev. C

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