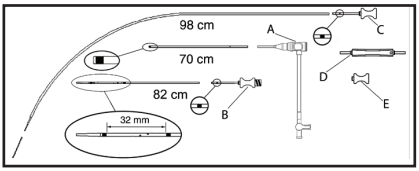
Option™ELITE Vena Cava Filter

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

Figure 1: Option™ELITE Filter System



Kit Contents

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

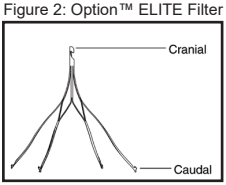
Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For single use only. Do not autoclave.

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

I. Device Description

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

Figure 2: Option™ ELITE Filter



The self-centering Option™ELITE Filter is laser cut from nickel – titanium alloy (Nitinol) tubing. The Option™ELITE 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) are located at the caudal portion of the filter. These anchors are intended for filter fixation to the vessel wall. The Option™ELITE 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™ELITE Filter is flexible and expands to the internal diameter of the IVC upon deployment. The Option™ELITE Filter imparts an outward radial force on the luminal surface of the vena cava to ensure proper positioning and stability. The Option™ELITE 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™ELITE 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

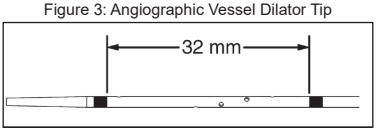


Figure 4: Pusher with Deployment Marker

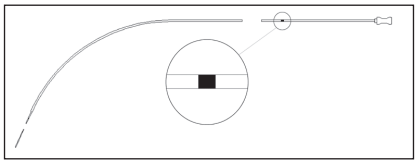


Figure 5A: Femoral Approach Cartridge Orientation

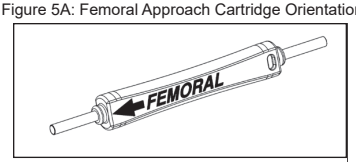
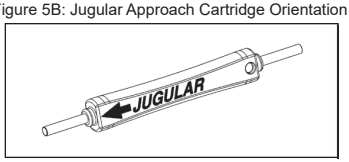


Figure 5B: Jugular Approach Cartridge Orientation



II. Indications For Use

The Option™ELITE 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™ELITE Filter may be removed according to the instructions supplied in the Section IX, 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™ELITE 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™ ELITE Filter introduction kit.
- Non-clinical testing has demonstrated that the Option™ELITE Filter is MR Conditional. A patient with the Option™ELITE 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™ELITE 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™ELITE 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™ELITE 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™ELITE Filter in the cartridge.
- The Option™ELITE 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 Option™ELITE Filter is advanced into the sheath, do not retract then re-advance the Pusher, which may cause premature deployment of the 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 IX labeled "Optional Procedure for Filter Retrieval".

V. Precautions

- Physicians should be properly trained prior to using the Option™ELITE 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.
- Do not continue to use any component damaged during the procedure.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding.
- The Option™ELITE 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.
- 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
- Reaction to contrast media/medication
- 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.

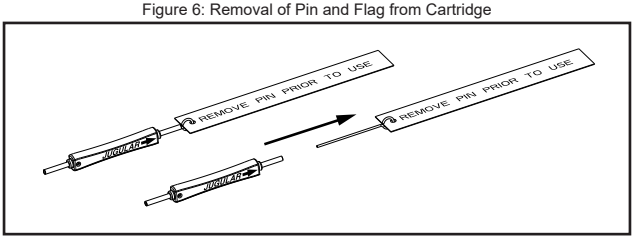
VII. Recommended Percutaneous Procedure for Filter Implantation

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).

1. 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.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Remove the components of the introduction kit from the package using sterile technique.
4. Remove the pin and flag from the cartridge prior to use (Figure 6).

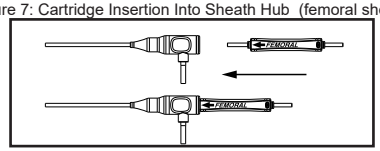
Figure 6: Removal of Pin and Flag from Cartridge



5. Wet the operator-selected guidewire (max .038”) with sterile heparanized saline or suitable isotonic solution.
   Note: Guidewire is not included in Option™ELITE Filter Introduction Set. Follow the guidewire manufacturer’s Instructions for Use. Use a guidewire with a minimum length of 200cm.
6. Flush the Catheter Sheath Introducer and Angiographic Vessel Dilator with heparanized saline or suitable isotonic solution.
7. Close the side-port after flushing by rotating the stopcock.
8. Insert the Angiographic Vessel Dilator through the Catheter Sheath Introducer, snapping it into place at the hub. Flush with heparanized saline or suitable isotonic solution.

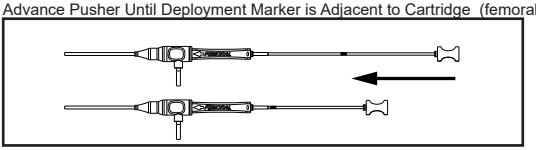
9. Puncture the access site using the Seldinger technique.
10. Holding the needle in place, insert the guidewire through the needle and into the vessel. Gently advance the guidewire to the desired location.
    Caution: Do not withdraw a PTFE-coated guidewire through a metal cannula as this may damage the guidewire coating.
11. Holding the guidewire in place, remove the needle over the guidewire
12. Advance the Catheter Sheath Introducer together with the dilator over the guidewire and into the IVC.
13. 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.
14. Remove the guidewire.
15. 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 Ethiodol* or Lipiodol contrast media, or other such contrast media that incorporate the components of these agents.
    Caution: Do not exceed 800 psi when injecting.
16. Reintroduce the guidewire.
17. Advance the Catheter Sheath Introducer tip to the desired location in the IVC.
18. 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.
19. Aspirate from the sideport extension to remove any potential air.
20. 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.
21. Place the appropriate end of the cartridge into the hub of the Catheter Sheath Introducer until a snap is achieved (Figure 7).

Figure 7: Cartridge Insertion Into Sheath Hub (femoral shown)



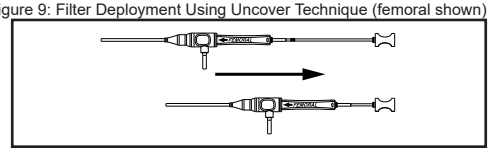
22. Insert the lead wire of the Pusher into the Cartridge.
    Note: No resistance should occcur while advancing the pusher wire through the cartridge.
    If resistance is felt, withdraw the pusher wire and and reinsert.
23. Slowly advance the filter using the pusher until the leading edge of the delivery marker on the pusher is positioned just proximal to the end of the filter cartridge.
    Note: Once the Option™ELITE Filter is advanced into the sheath, do not retract then re-advance the Pusher which may cause premature deployment of the filter.
    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 8).
    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 8: Advance Pusher Until Deployment Marker is Adjacent to Cartridge (femoral shown)



24. 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.
25. To deploy the Option™ELITE Filter, fix the Pusher in position, then pull the sheath back over the pusher to uncover the filter (Figure 9).
26. Ensure that the Option™ELITE Filter is fully released and deployed.
27. Carefully remove the Filter Cartridge along with the Pusher, ensuring that the pusher wire does not interfere with the deployed filter.

Figure 9: Filter Deployment Using Uncover Technique (femoral shown)



28. Place the Sheath Cap on the Catheter Sheath Introducer.
29. Perform a control cavagram prior to terminating the procedure. Verify proper filter positioning.

*Ethiodol is a trademark of Guerbet S.A.

30. Remove the Catheter Sheath Introducer by placing compression on the vessel above the puncture site, slowly withdrawing the Catheter Sheath Introducer.
31. 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.

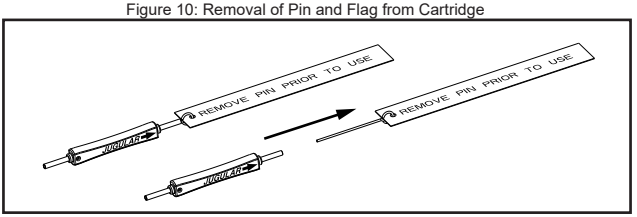
VIII. Alternate Over-the-wire Percutaneous Procedure for Filter Implantation

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).

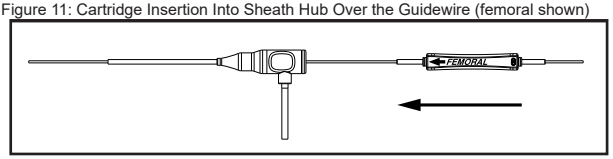
1. Select a suitable venous access site, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Remove the components of the introduction kit from the package using sterile technique.
4. Remove the pin and flag from the cartridge prior to use (Figure 10).

Figure 10: Removal of Pin and Flag from Cartridge



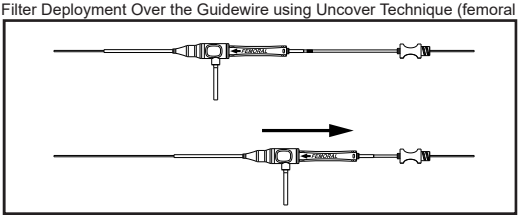
5. Wet the operator-selected guidewire (max .035") with sterile heparanized saline or suitable isotonic solution.
   Caution: Use a straight-tip guidewire
   Note: Guidewire is not included in Option™ELITE Filter Introduction Set. Follow the guidewire manufacturer's Instructions for Use. Use a guidewire with a minimum length of 200cm.
6. Flush the Catheter Sheath Introducer and Angiographic Vessel Dilator with heparanized saline or suitable isotonic solution.
7. Close the side-port after flushing by rotating the stopcock.
8. Insert the Angiographic Vessel Dilator through the Catheter Sheath Introducer, snapping it into place at the hub. Flush with heparanized saline or suitable isotonic solution.
9. Puncture the access site using the Seldinger technique.
10. 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.
11. Holding the guidewire in place, remove the needle over the guidewire
12. Advance the Catheter Sheath Introducer together with the dilator over the guidewire and into the IVC.
13. 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.
14. Remove the guidewire.
15. 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 Ethiodol* or Lipiodol contrast media, or other such contrast media that incorporate the components of these agents.
    Caution: Do not exceed 800 psi when injecting.
16. Reintroduce the guidewire.
17. Advance the Catheter Sheath Introducer tip to the desired location in the IVC.
18. Detach and withdraw the Angiographic Vessel Dilator from the Catheter Sheath Introducer by unsnapping the snap-fit at the hub leaving the guidewire in place.
    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.
19. Aspirate from the sideport extension to remove any potential air.
20. Determine which end of the cartridge (containing the filter) is to be placed over the guidewire 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, <u>femoral is green</u> and <u>jugular is blue</u>. The arrow of the desired access site will point into the Catheter Sheath Introducer hub.
21. Place the appropriate end of the cartridge over the guidewire and into the hub of the Catheter Sheath Introducer until a snap is achieved (Figure 11).

Figure 11: Cartridge Insertion Into Sheath Hub Over the Guidewire (femoral shown)



22. Insert the Vessel Dilator over the guidewire into the Cartridge.
23. Slowly advance the filter using the vessel dilator until the leading edge of the delivery marker on the vessel dilator is positioned just proximal to the end of the filter cartridge.
    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.
    Note: Check both A/P and Lateral views under angiographic visualization for optimal placement.
24. To deploy the Option™ELITE Filter, fix the Vessel Dilator in position, then pull the sheath back over the Vessel Dilator to uncover the filter (Figure 12).

Figure 12: Filter Deployment Over the Guidewire using Uncover Technique (femoral shown)



25. Ensure that the Option™ELITE Filter is fully released and deployed.
26. Carefully remove the guidewire and vessel dilator ensuring that the guidewire does not interfere with the deployed filter.
27. Carefully remove the Filter Cartridge.
28. Place the Sheath Cap on the Catheter Sheath Introducer.
29. Perform a control cavagram prior to terminating the procedure. Verify proper filter positioning.
30. Remove the Catheter Sheath Introducer by placing compression on the vessel above the puncture site, slowly withdrawing the Catheter Sheath Introducer.
31. 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.

IX. 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:

1. The physician believes that the risk of clinically significant pulmonary embolism is acceptably low and that the retrieval procedure can be performed safely.
2. 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:

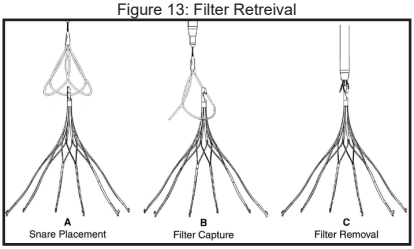
1. At the time of retrieval procedure, based on venography and the physician's visual estimate, more than one (1) cubic centimeter of thrombus/embolus is present within the filter or caudal vena cava.
2. Pregnant patients when radiation from fluoroscopic imaging may endanger the fetus. Risks and benefits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

Recommended Procedure for the Percutaneous Retrieval of the Option™ELITE Filter:
Warning: Excessive force should not be used to retrieve the filter. Retrieval of the Option™ ELITE Filter should not be attempted if thrombus is present in the filter and/or caudal to the filter.
Note: The devices for filter retrieval are not included with the Option™ELITE Filter Introduction Set. A minimum 8 Fr sheath is recommended for retrieval of the Option™ELITE filter.

1. Use appropriate techniques to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Wet the operator-selected guidewire with sterile heparanized saline or suitable isotonic solution via a syringe connected to the luer hub of the guidewire dispenser.
4. Flush the Retrieval Catheter (Table 1) and components with heparanized saline or suitable isotonic solution.
5. Insert Angiographic Vessel Dilator through the Retrieval Catheter, snapping it into place at the hub. Flush with heparanized saline or suitable isotonic solution.
6. Puncture the access site using the Seldinger technique.
7. 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.
8. Holding the guidewire in place, remove the needle over the guidewire.
9. 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.
10. Verify that the retrieval route is free of thrombus.
11. Prepare snare and snare catheter components according to the manufacturer's Instructions for use.
12. Remove the Guidewire and Dilator.
13. 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.
14. Push the snare shaft gently forward to open the snare loop cephalad of the filter retrieval hook.
15. Slowly advance the loop forward over the filter apex (Figure 13A).
16. Tighten the snare loop around the Option™ELITE 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 13B).
    Note: Verify that the snare has properly captured the Option™ ELITE Filter retrieval hook and the Retrieval Catheter and snare are aligned (Figure 11C).

17. 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 13C).

Figure 13: Filter Retreival



18. 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.
19. 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.
20. Continue to advance the Retrieval Catheter until increased resistance is felt.
21. Hold the Retrieval Catheter stationary and withdraw the filter into the Retrieval Catheter.
    Note: If for any reason the Option™ELITE 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.
22. Completely remove the filter by pulling the Snare Catheter until the filter exits the Retrieval Catheter.
23. Verify the status of the IVC before ending the procedure using an appropriate imaging technique.
24. Remove the Retrieval Catheter when clinically indicated by placing compression on the vessel above the puncture site and slowly withdrawing the system.
25. Discard the Option™ ELITE Filter, Retrieval Catheter, Snare Technologies, accessories, and packaging materials.
    Note: After use, the Option™ELITE 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.

X. Clinical Summary

No clinical data were collected to support clearance of the modified Option™ELITE device.
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.

XI. Disclaimer of Warranty and Limitation of Remedy

There is no express or implied warranty, including without limitation any implied warranty of merchantability or fitness for a particular purpose, on the Manufacturer or its Distributors product(s) described in this publication. Under no circumstances shall the Manufacturer or its Distributor be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind the Manufacturer or its Distributor to any representation or warranty except as specifically set forth herein.

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PRESERVE Study

I. Objectives and Design

PRESERVE (Predicting the Safety and Effectiveness of Inferior Vena Cava Filters) was a multi- center, prospective, open-label investigation of commercially available inferior vena cava (IVC) filters that were placed in subjects for the prevention of pulmonary embolism (PE). The study enrolled 1,429 subjects at 54 US sites. All treated subjects were scheduled for evaluation at procedure and at 3, 6 (phone), 12, 18 (phone), and 24 months post-procedure.

The primary objective of this investigational device exemption (IDE) study was to evaluate the safety and effectiveness of commercially available IVC filters (retrievable and permanent) in subjects with a clinical need for mechanical prophylaxis of PE with an IVC filter.

The following filters were evaluated in the PRESERVE Study:

1. ALN Vena Cava Filter (with and without hook; ALN Implants Chirurgicaux)
2. Option™ Elite Retrievable Vena Cava Filter (Argon Medical Devices Inc., designed and manufactured by Rex Medical)
3. VenaTech® LP and VenaTech® Convertible™ Vena Cava Filter (B Braun Interventional Systems, Inc.)
4. DENALI™ Vena Cava Filter (DL900F, DL900J; Bard Peripheral Vascular, Inc.)
5. Günther Tulip® Vena Cava Filter (Cook Medical)
6. Cordis OPTEASE™ Retrievable Vena Cava Filter and Cordis TRAPEASE™ Permanent Vena Cava Filter (Cordis Corporation)
7. Crux® Vena Cava Filter System (Volcano Corporation; discontinued after only 7 subjects were enrolled)

The Primary Safety Endpoint was a composite that included freedom from:

- clinically significant perforation after successful vena cava filter placement (protrusion of filter legs through the wall of the IVC causing hemorrhage or hematoma or touching, impressing, or perforating another organ [e.g., liver, bowel, aorta, psoas muscle, vertebral body, or lymph nodes] or that triggers the decision to remove the filter or requiring the other intervention; confirmed by imaging) within the first 12 months
- vena cava filter embolization (movement of the filter or its components to a distant anatomic site completely out of the target zone after successful vena cava filter placement; confirmed by imaging) within the first 12 months
- caval thrombotic occlusion (presence of an occluding thrombus in the IVC after filter insertion and documented by ultrasound, computed tomography, magnetic resonance imaging, venography, or autopsy; this may be symptomatic or asymptomatic after successful vena cava filter placement) within the first 12 months
- new deep vein thrombosis (DVT; lower extremity DVT that is confirmed present where it had not been present previously and that occurs after the placement of the vena cava filter) within the first 12 months
- filter-related serious adverse events (SAEs) within the peri-operative period (the peri-operative period was ≤ 30 days post-filter placement)

The hypothesis for primary safety was that at 12-months post-procedure, the rates of freedom from clinically significant perforation, freedom from filter embolization, freedom from caval thrombotic occlusion, freedom from new DVT and freedom from filter-related SAEs will be above the prespecified performance goal of 80%.

The Primary Effectiveness Endpoint was a composite of the following components assessed at 12 months in subjects with an IVC filter in-situ or at 1-month post-retrieval (whichever occurred first):

- Procedural and technical success (deployment of the initial vena cava filter such that the vena cava filter is judged suitable for mechanical protection against PE, and placement of second vena cava filter to address any anatomic variation without clinically significant perforation, vena cava filter embolization, or insertion problems)
- Freedom from clinically significant PE (new symptomatic PE confirmed by appropriate imaging)

The hypothesis for primary effectiveness was that at 12-months post-procedure in-situ or 1-month post-retrieval (whichever comes first) the rates of procedural/technical success and freedom from PE will be above the prespecified performance goal of 90%.

Both hypotheses were tested using the one-sided exact binomial test. For each hypothesis, success would be considered if the lower limit of the one-sided 95% exact binominal confidence interval was above the performance goal.

Various secondary endpoints, including several device safety measures, procedure related complications, and filter retrieval, were also evaluated.

All endpoint assessments were based on site reported events. A Clinical Events Committee was responsible for standardized adjudication of the following safety events: PE, caval thrombotic occlusion, DVT, clinically significant perforation, retroperitoneal hematoma, adjacent organ penetration, unanticipated adverse device effects. CEC adjudications were used if there was a discrepancy with the site reported data. Death, filter embolization, and peri-operative SAEs were not adjudicated by the CEC

II. Subject Accountability

In total, 1,421 of 1,429 enrolled subjects had IVC filters placed. Two (2) subjects died after enrollment, but before filter placement, and 6 subjects experienced treatment failures (i.e., failure to implant the IVC filter). Patient accountability is shown in Table 1. Results for the 1,421 patients that underwent IVC filter placement are summarized below.

Subjects with IVC filter retrieval: Forty-nine percent (49%) of 1,421 subjects underwent filter retrieval prior to 2-years of follow-up (690/1,421), and compliance with the 1-month post-retrieval visit was 86% (585/690). Fifty one percent (51%) of these filter retrievals took place prior to the 3-month follow-up visit (351/690), and 94% occurred prior to 12 months of follow-up (647/690).

Subject deaths: Almost 24% of subjects died prior to the 24-month follow-up or 1-month post-retrieval visit (337/1,421). Fifty two percent (52%) of these deaths occurred prior to the 3-month visit (174/337), and 85%, prior to 12 months of follow-up (286/337). Deaths were assessed for relatedness; 321 deaths were determined to not be device-related, 14 deaths were determined to be possibly device- related, 1 death was determined to be definitely device-related, and 1 death had missing relatedness information.

Consent withdrawal or lost-to-follow-up: Fifteen percent (15%) of subjects withdrew consent or were lost-to-follow-up (207/1,421), with 52% occurring within the first 3 months (108/207) and 85% (176/207) prior to 12 months follow-up. Over the course of the study, 110 subjects withdrew consent, and 99 were lost-to-follow-up.

12 Month Patient Accountability – CT Imaging:
Subjects receiving a filter at the index procedure were to complete a CT scan at 12 months if the filter was not retrieved. Approximately 22% (312/1,421) of subjects remained in the study with a filter in place at 12 months. Among these 312 subjects, 199

(63.8%) had a CT scan at 12 months. Among all subjects that received a filter, 14.0% (199 subjects) of subjects had a CT scan at 12 months.

24 Month Patient Accountability – CT Imaging:
Subjects receiving a filter at the index procedure were to complete a CT scan at 24 months if the filter was not retrieved. Just under 14% (193/1,421) of subjects remained in the study with a filter in place at 24 months. Among these 193 subjects, 104 (53.9%) had CT scans at 24 months. Among all subjects that received a filter, 7.3% (104 subjects) of subjects had a CT scan at 24 months. The final study visit was completed by 86% of the subjects (166/193) in the study at 24 months.

Table 1: Patient Accountability

Patient Censoring	Procedure (n[a]=1429)	3 Months (n=788)	6 Months (n=501)	12 Months (n=312)	18 Months (n=241)	24 Months (n=193)	1-Month Retrieval (n=684)	Total
Treatment Failure	6							6
Death	174	54	58	29	18	0	4	337
Filter Retrieval	351	200	96	31	12	0	0	690
Withdrew Consent/Lost to Follow Up	108	33	35	11	18	0	2	207
Total	**639**	**287**	**189**	**71**	**48**	**0**	**6**	**1240**

All counts in the table reflect subject disposition at the end of the respective visit window.
[a]At each time, n reflects the number of patients eligible for the follow-up.

III. Results

Baseline Demographics
The mean age of subjects was 62.7 years, 53% were male, and 78% were white. Seventy-one percent (71.7%) of subjects had current venous thromboembolism (VTE) and 34.3% of subjects had a history of VTE. **Table 2** shows patient baseline demographics.

Table 2: Baseline Demographics

Characteristic	N=1421
Age Yrs. [Mean (SD, Range)]	62.7 (14.7; 18.5 - 98.4)
Gender, Male (%,n)	759 (53,4%)
Race	
White	1,102 (77.6%)
Black	213 (15.0%)
Other	106 (7.5%)
Baseline Venous Thromboembolism Status	
Current VTE	1,019 (71.7%)
History of VTE	488 (34.3%)
Neither current nor a history of VTE	127 (8.9%)

[a]Other race includes: Asian (n=11), Native American or Alaskan Native (n=1), Native Hawaiian or Pacific Islander (n=1), other (n=70), more than one race (n=2), and unknown (n=21).

Indication for Filter Placement
In total, 1,421 of the 1,429 subjects had study filters placed. **Table 3** shows the indication for filter placement, the majority of which were for contraindication to anticoagulation (71.8%).

Table 3: Indication for Filter Placement

Indication	Total Number of Subjects (n=1421)
Contraindication to or complication of anticoagulation	72.2% (1,026)
Failure of anticoagulation	9.4% (133)
Prophylaxis in the absence of DVT or PE	8.9% (126)
Placed as part of thrombolysis procedure	6.3% (90)
Additional protection for patient receiving anticoagulation	3.2% (46)

IV. Primary Endpoint Results

Primary Safety Endpoint Results
Primary safety event rates were calculated for living subjects with the IVC filter in-situ at 12-months (i.e., IVC filter not removed, and patient had not died, withdrawn, or been lost to follow-up).

The prespecified performance goal for the primary safety endpoint was 80%. In total, 293 subjects were evaluable for the primary safety endpoint when evaluating living subjects who reached 12- months follow-up, excluding subjects who died, were withdrawn, were lost to follow-up or had their IVC filter removed prior to 12-months (whether or not they had a prior safety event). The primary safety endpoint rate was 89.4%, with a lower 95% confidence interval of 85.3%, meeting the performance goal (see **Table 4**).

Table 4: Primary Safety Endpoint Results*

Primary Safety Endpoint Event	***Rate****	***95% CI****
Freedom from Primary Safety Event Rate at 12-months	**89.4% (262/293)**	**(85.3%,-)**
Freedom from Clinically Significant Perforation	98.6% (289/293)	(96.5%, 99.6%)
Freedom from Filter Embolization	100.0% (293/293)	(98.8%, 100.0%)
Freedom from Caval Thrombotic Occlusion	98.6% (289/293)	(96.5%, 99.6%)
Freedom from New Deep Vein Thrombosis	91.5% (268/293)	(87.7%, 94.4%)
*Freedom from SAEs possibly, probably or definitely related to filter within Peri-Operative Period****	97.8% (1264/1292)	(96.9%, 98.6%)

*Excludes subjects who had died, withdrawn, or been lost to follow-up or had the IVC filter removed prior to 12-months (whether or not they had a prior safety event)
**The Exact binomial test model was used for analyses. The denominators are the number of subjects evaluable for the endpoint.
***SAEs possibly, probably or definitely related to the filter

Primary Effectiveness Endpoint Results
Primary effectiveness event rates were calculated for living subjects with the IVC filter in-situ at 12- months or 1-month post-retrieval, whichever occurred first (i.e., patient had not died, withdrawn, or been lost to follow-up prior to the 12-month visit or had their filter retrieved within 12 months and did not miss the 1-month post-retrieval visit).

The pre-defined performance goal for the primary effectiveness endpoint event rate was 90%. In total, 829 subjects were evaluable for the primary effectiveness endpoint. The primary effectiveness endpoint rate was 96.4%, with a lower 95% confidence interval of 94.9%, meeting the performance goal (see **Table 5**).

Table 5: Efectiveness Endpoint Rate

Endpoint Event	**Rate****	**95% CI****
Primary Effectiveness Event Rates at 12-months in-situ or 1-month post-retrieval	**96.4% (799/829)**	**(94.9%,-)**
Procedural and technical success at time of procedure	98% (1,393/1,421)	(97.2%, 98.7%)
Freedom from clinically significant PE	98.3% (815/829)	(97.2%, 99.1%)
*The Exact binomial test model was used for analyses. The denominators are the number of subjects evaluable for the endpoint.		

Additional Measures
The secondary measures reported include individual components of the primary effectiveness endpoint and primary safety endpoint, as well as other device-related measures. These individual outcome measures included freedom from clinically significant pulmonary embolism, freedom from caval thrombotic occlusion, freedom from new deep vein thrombosis, freedom from clinically significant perforation, freedom from adjacent organ perforation, freedom from filter perforation >5 mm outside the cava wall, freedom from filter fracture, freedom from filter embolization, freedom from filter migration >20 mm, and freedom from SAEs possibly, probably, or definitely related to the filter within the peri-operative period.

Notably, the primary safety endpoint analysis did not include all safety events that occurred since subjects who died, were withdrawn, were lost to follow-up, or had a filter removed prior to 12 months were not counted towards the primary safety endpoint rate. Therefore, Table 6 shows Kaplan-Meier estimates, as well as the number of patients at risk and the number of events, for the individual outcome measures at the protocol-defined follow-up time points; Kaplan-Meier analysis provides an estimate of cumulative survival (i.e., the probability that a patient is event-free over time). For freedom from clinically significant pulmonary embolism, Kaplan-Meier analysis indicated a 98.7% probability that a patient is free from experiencing clinically significant pulmonary embolism at 3 months (with 819 patients at risk or still in the study and not yet experienced clinically significant pulmonary embolism, and 16 events of clinically significant pulmonary embolism through 3 months) and a 96.2% probability that a patient is free from experiencing clinically significant pulmonary embolism at 24 months (with 192 patients at risk and 27 events of clinically significant pulmonary embolism through 24 months).

Finally, filter retrieval measures were reported. In total, 693 filters were retrieved; 690 of 706 retrieval attempts (assessed per subject) were successful. Some subjects underwent multiple retrieval attempts due to deferred or unsuccessful retrieval attempts, thus a subject may have one or multiple failed retrieval attempts. Failed retrieval attempts (39 attempts in 36 subjects) were attributed to an inability to engage the filter (n=13), an inability to detach the filter hook from the wall (n=8), thrombus detected in the filter or components (n=12), filter unable to be removed using planned approach (n=2), unsuitable position of filter (n=2), required imaging could not be obtained (n=1), or physician decision not to remove (n=1). Among the 693 IVC filter retrievals, there was one death resulting from an innominate vein injury.

Table 6: Kaplan-Meier Estimates for Secondary Endpoints

	Kaplan-Meier Estimate (Number of patients at risk, Number of events)				
Endpoint	**3 months**	**6 months**	**12 months**	**18 months**	**24 months**
Freedom from clinically significant pulmonary embolism	98.7 (819, 16)	97.8 (502, 22)	96.9 (310, 25	96.6 (237, 26	96.2 (192, 27)
Freedom from clinically significant perforation	99.9 (830, 1)	99.7 (516, 2)	99.2 (319, 4)	97.7 (242, 8)	96.2 (196, 11)
Freedom from adjacent organ perforation	100 (830, 0)	99.8 (516, 1)	99.3 (319, 3)	98.6 (243, 5)	97.6 (198, 7)
Freedom from filter perforation>5mm outside apparent cava wall	99.7 (829, 3)	99.3 (516, 6)	98.4 (318, 9)	94.6 (239, 20)	93.7 (194, 22)
Freedom from filter embolization	99.7 (828, 3)	99.6 (517, 4)	99.6 (321, 4)	99.6 (246, 4)	99.6 (201, 4)
Freedom from caval thrombotic occlusion	99.0 (822, 11)	98.3 (510, 15)	98.3 (317, 15)	97.9 (242, 16)	97.1 (197, 18)
Freedom from new deep vein thrombosis	95.2 (789, 55)	93.3 (477, 67)	91.8 (294, 73)	89.2 (217, 80)	89.2 (179, 80)
Freedom from SAEs possibly, probably or definitely related to filter within peri-operative period	97.9 (815, 28)	97.9 (507, 28)	97.9 (315, 28)	97.9 (241, 28)	97.9 (196, 28)
Freedom from filter fracture	99.7 (828, 3)	99.5 (517, 4)	99.5 (321, 4)	99.5 (246, 4)	99.1 (201, 5)
Freedom from filter migration >20mm	99.8 (829, 3)	99.8 (516, 3)	99.8 (320, 3)	99.8 (245, 3)	99.8 (200, 3)

V. Study Conclusions and Strengths/Limitations

The PRESERVE Study provides safety and effectiveness data for up to two years of follow-up on 1,421 subjects treated with commercially available retrievable and permanent IVC filters in US subjects. This large, multicenter study was intended to address FDA questions related to observed safety events for IVC filters.

The primary safety endpoint rate was 89.4% (262/293), which met the prespecified performance goal of 80%. However, it is important to note that this rate excluded subjects who died, were withdrawn, were lost to follow-up or had the IVC filter removed prior to 12-months (whether or not they had a prior safety event). Thus, there was extensive censoring due to patient death, IVC filter retrieval, and subject lost-to-follow-up, which resulted in only 293 of 1,421 subjects (21%) evaluable at 12-months to assess the primary safety endpoint event rate. Given that only subjects who were still in the study at 12 months were included, subjects who experienced a primary safety endpoint event and then had a filter removed were not counted against the primary safety endpoint. For example, there were 4 instances of embolization of IVC filters or filter components, but this is not reflected in Table 4, which reports Freedom from Filter Embolization as 100% (293/293), since these filter embolizations occurred before IVC filter removal prior to 12-months. Kaplan Meier estimates for freedom from secondary measures for all subjects are shown in **Table 6.** Study endpoints were determined by site assessment, which could underestimate outcomes.

Another limitation of the study is that only 14.0% of the 1421 subjects that received a filter (or 63.8% of subjects still in the study at 12 months) had CT scans at 12 months and only 7.3% (or 53.9% of subjects still in the study at 24 months) had CT scans at 24 months.

The Primary Effectiveness Endpoint rate was 96.4% (799/829) and met the prespecified performance goal of 90%. Of note, the 12-month rate of freedom from new pulmonary embolism was 98.3% (815/829) and contributed to the primary effectiveness outcome.

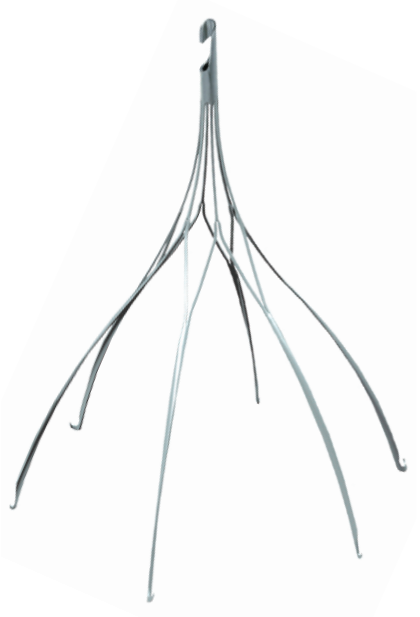
The results from the PRESERVE Study, especially when assessed for the full population and not just those in the study at 12 months, are consistent with previously reported rates for filter complications, including filter embolization, clinically significant perforation, new DVT, caval thrombotic occlusion, and SAEs.

XII. Symbol Definition

	Attention, See Instructions for Use
	Follow Instructions for Use
	Manufacturer
	Date of Manufacture
	Ethylene Oxide Sterilization
	Do Not Resterilize
	Singel Use Only
	Sterile, Unless Package is Damaged or Opened
	Fluid pathway components are NON-PYROGENIC
	Store Away From Sunlight
	Store in a Dry Place
	Date of Expiration
REF	Catalog Number
LOT	Lot Number
MR	MR Conditional
	Potential Biohazard

Option™ ELITE

Retrievable Vena Cava Filter



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