II. Indications For Use

- Therapy are reduced
- Preference for percutaneous delivery in the inferior vena cava (IVC)
- 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 in the vena vas.
- The Option™ ELITE Filter is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.
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- 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 should only be performed by physicians who are trained in percutaneous retrieval techniques, such as placement of vena cava filters. According to the manufacturer or its Distributors will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel.
- The manufacturer/ Distributor will not be responsible for any direct, incidental or consequential damages resulting from use by untrained personnel.
- Monovector™ is a Trademark of Medtronic, Inc.Super Arrow-Flex® is a Trademark of Teleflex Medical.
- Arterial catheter retrieval from the jugular access site, verify that the filter retrieval hook is oriented in a cephalad direction and is firmly engaged in the jugular vein.
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21. Insert the lead end of the Pusher into the Cartridge.  Use a 1.25cm² (20G) or 1.40cm² (18G) needle stylet to advance the pusher wire through the cartridge.  If resistance is felt, withdraw the pusher wire and reinsert.

22. Slowly advance the Pusher wire through the cartridge until it is fully advanced into the hub of the Cartridge.  confirming that the pusher wire is seated properly to the exact position of the filter.

23. Insert the Pusher wire into the Catheter Sheath Introducer (Figure 6).  Verify proper filter positioning.

24. Ensure that the Option™ ELITE Filter is fully released and deployed.  Deploy the Option™ ELITE Filter using the tension control microsnare set until the filter is deployed (Figure 7).

25. 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.

26. Place the Sheath Cap over the Catheter Sheath Introducer.

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31. Insert the Vessel Dacron over the guide wire.  Use 1.25cm² (20G) or 1.40cm² (18G) needle stylet to advance the Vessel Dacron through the filter.  Confirm the position of the filter by pulling the Snare Catheter until the filter is retrieved, it should be done within 175 days following implant.  Additionally, the patient should meet all the following eligibility criteria for the retrieval of the filter device.

32. Prior to implantation, the patient should be aware that the filter device is not retrievable if anticoagulation therapy is continued after implantation.

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

Pre-insertion care is required.

21. Insert the lead end of the Pusher into the Cartridge.  Use a 1.25cm² (20G) or 1.40cm² (18G) needle stylet to advance the pusher wire through the cartridge.  If resistance is felt, withdraw the pusher wire and reinsert.

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