The Option™ ELITE Filter is designed for the prevention of recurrent pulmonary embolism via percutaneous delivery in the inferior vena cava (IVC). The self-centering Option™ ELITE Filter is base cut from nickel–titanium alloy (Nitinol) tubing. The Option™ ELITE Filter (Figure 2) is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.

The introduction kit is comprised of a filter housed in a catheter, Catheter Sheath Introducer (CSI), Angiographic Vascular Sheath with an open lumen, Catheter Sheath Introducer (CSI), Angiographic Vascular Sheath with open lumen and a Pusher with deployment marker (Figure 4).

The Angiographic Vascular Sheath has side holes and 2 radio markers, separated by 20mm between the markers. The catheter also possesses the preferred orientation. The filter is guided through the IVC and positioned in the center of the vena cava using the Pusher with deployment marker. The filter is fully deployed at the cranial extremity. The retrieval hook is centrally located at the cranial extremity.

The constrained Option™ ELITE Filter is flexible and expands to the patent interior of IVC once deployed. 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.

A. Catheter Sheath Introducer

Kit Contents

- Catheter Sheath Introducer
- Angiographic Vessel Dilator
- Pusher with Deployment Marker
- Option™ ELITE Filter in Catheter
- Sheath

Not for Sale in the US

II. Indications For Use

The Option™ ELITE Filter is indicated for the prevention of recurrent pulmonary embolism (PE) via percutaneous delivery in the inferior vena cava (IVC). The Option™ ELITE Filter is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.

In non-clinical testing, the Option™ ELITE Filter produced a temperature rise of less than or equal to 1.5°C at a maximum whole body averaged specific absorption rate (SAR) of 1.0W/kg. The SAR of the Option™ ELITE Filter introduction kit.

The Option™ ELITE Filter meets the following spatial gradient magnetic field and SAR requirements of the U.S. Food and Drug Administration (FDA) and the European Commission: - Maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15min of scanning - Spatial gradient magnetic field of 720 Gauss/cm or less

No known contraindications for use of the Angiographic Vessel Dilator.

2. Patient is at risk for septic embolism.

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

- Acute PE and a contraindication to anticoagulation.
- Pulmonary hypertension.
- Bilateral PE.
- Severe aortic valve stenosis.
- Infection at site of intended entry.
- Known allergy to nickel alloys.
- Pregnant patient when radiation from fluoroscopic imaging may endanger the fetus.

5. Pregnant patient when radiation from fluoroscopic imaging may endanger the fetus.

6. Patients with acute PE and a contraindication to anticoagulation.

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, death or device failure. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, either of which may result in patient injury, death or device failure.

The Manufacturer or its Distributors will bear no responsibility for any direct, incidental or consequential damages or expenses resulting from use of the product. The Manufacturer or its Distributors will not be responsible for any direct, incidental or consequential damages or expenses resulting from use of the product. The Manufacturer or its Distributors will not be responsible for any direct, incidental or consequential damages or expenses resulting from use of the product. The Manufacturer or its Distributors will not be responsible for any direct, incidental or consequential damages or expenses resulting from use of the product.
The Option™ ELITE Filter has been tested and qualified with the accompanying or recommended devices. The use of any other filter retrieval system or device may increase the risk of complications and should be avoided. The Option™ ELITE Filter retrieval system and devices are intended to assist the operator in retrieving the filter from the target vessel, should it become necessary. The Option™ ELITE Filter should not be attempted if thrombosis is present in the filter and/or vessel. A vascular access site injury, including, bruising, AV fistula, or pseudoaneurysm should be ruled out using appropriate imaging technique. Do not withdraw the Option™ ELITE Filter retrieval system from the body until the retrieval is complete. Ensure that the guidewire, the retrieval catheter, or the similar device is retrieved before the filter is removed from the vessel. Do not attempt to remove the filter from the vessel by force. To prevent damage to the IVC, do not withdraw the filter until the IVC is confirmed to be patent. Do not use the filter for years beyond the filter expiration date or in any fashion other than that specified in the instructions for use.

Potential Complications

Procedures to place, retrieve, and re-introduce the Option™ ELITE Filter should not be attempted if thrombosis is present. Possible complications may include, but are not limited to the following:

- Vena cava or other vessel injury or damage, including, perforation, pseudoaneurysm, or thrombus formation.
- Injury or damage to organs adjacent to the vena cava, possibly requiring surgical repair or intervention.
- Vena cava or vessel rupture, including, hematoma, local or systemic infection.
- Vessel dissection or perforation, possibly requiring surgical intervention.
- Vena cava stenosis or occlusion, possibly requiring surgical intervention.
- Other vascular access site injury, including, bruising, AV fistula, pseudoaneurysm formation, or pseudoaneurysm rupture.
- Neurological complication, possibly requiring medical or surgical intervention (e.g., antibiotics or incision and drainage).
- Endovascular or other device-induced complications.
- 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 path of the spine.
- Femoral access site injury, including, hematoma, pseudoaneurysm formation or pseudoaneurysm rupture.
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