Non-clinical testing has demonstrated that the Option™ ELITE Filter is MR Conditional. A patient with the patents: 7,704,266, 8,100,936, 8,162,972 and 8,715,313 Manufactured under one or more of the following U.S. Performer® is a Trademark of Medtronic, Inc.
Option is a Trademark of Argon Medical Descriptions or specifications in the manufacturer and distributor’s printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. 

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 caval filtration. The introduction kit is comprised of a filter housed in a filter cartridge, Catheter Sheath Introducer (CI), 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 32 mm (between the 2 radiopaque markers), that provide linear measurement of the inferior vena cava and assists in angiographic optimization of the catheter bore to the delivery system. The Pusher is used to deploy the filter after the Catheter Sheath Introducer has been withdrawn and the filter is in its position. The deployment marker (also referred to as the marker bands), that provide linear measurement of the inferior vena cava and assists in angiographic optimization of the catheter bore to the delivery system, are used to verify that the filter is placed centrally when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

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Option™ ELITE Vena Cava Filter

The Option™ ELITE Filter is a system consisting of shape memory Nitinol struts emanating from a central landing hook (Figure 1) that is designed to optimally capture the vena cava and prevent deployment of the filter. The retrieval hook is centrally located at the cranial extremity. The constrained Option™ ELITE Filter is intended to be used in caval diameters up to 30 mm. A filter migration resulting from reuse of the product.

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

Catheter Sheath Introducer

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the pulmonary vasculature and the IVC for the purpose of optimizing the delivery of the Option™ ELITE Filter introduction kit. The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the pulmonary vasculature and the IVC for the purpose of optimizing the delivery of the Option™ ELITE Filter introduction kit.

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. All medical device components are intended to be single use.

The Option™ ELITE Filter System

Embolization or fracture. The Option™ ELITE Filter is intended to be used in caval diameters up to 30 mm. The constrained Option™ ELITE Filter is intended to be used in caval diameters up to 30 mm. The 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 caval filtration. The introduction kit is comprised of a filter housed in a filter cartridge, Catheter Sheath Introducer (CI), Angiographic Vessel Dilator with an open end, (Figure 3) and a Pusher with deployment marker (Figure 4). 

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1. Insert the lead wire of the sheath into the Cartridge and advance the guidewire through the sheath. If resistance is felt, withdraw the sheath and reinsert.

2. Position the Cartridge in the hub of the introducer and advance the sheath through the Cartridge into the inferior vena cava (IVC) (Figure 6).

3. Close the side-port after flushing by rotating the stopcock.

4. Wet the operator-selected guidewire (max .035”) with sterile heparinized saline or suitable isotonic solution.

5. Flush the Catheter Sheath Introducer with heparinized saline or suitable isotonic solution.

6. Puncture the access site using the Seldinger technique.

7. Holding the needle in place, insert the guide wire through the needle and into the vessel. Gently advance the guide wire to the desired location.

Caution: Do not withdraw a PTFE-coated guidewire through a metal cannula as this may damage the guidewire.

8. Advance the guide wire into the IVC, being careful not to displace the filter into the inferior vena cava (IVC).

9. Using appropriate techniques, determine that the filter, the jugular retrieval route, and the inferior vena cava (IVC) distal IVC are free of thrombus.

10. Advise the patient that the post-procedural period may be extended due to the possible presence of the filter in the IVC.

11. Advance the Catheter Sheath Introducer together with the dilator over the guidewire and into the IVC. Advise the patient that the post-procedural period may be extended due to the possible presence of the filter in the IVC.

12. Position the Catheter Sheath Introducer in the hub of the introducer and advance the sheath into the inferior vena cava (Figure 7).

13. Insert the sheath over the guidewire into the vena cava.

14. Slowly advance the filter using the guidewire until the leading edge of the delivery mechanism is just over the specified limit of 20 mm. Ensure that the delivery mechanism is fully deployed and that the filter is seated. If resistance is felt, withdraw the sheath and reinsert. 

15. Determine that the sheath has not retracted into the vena cava (Figure 7).

16. To deploy the Option™ ELITE Filter, fix the filter to the sheath and advance the sheath into the inferior vena cava (Figure 8).

17. Ensure that the Option™ ELITE Filter is fully released and deployed.

18. Carefully remove the filter over the sheath along with the guidewire, ensuring that the sheath does not interfere with the retrieved filter.

19. Filter Deployment Using the Unroc Technique (familiarrend shown)

20. Insert the dilator into the catheter and advance the dilator over the guidewire into the vena cava. Advance the entire delivery system, then pull the sheath back over the catheter to uncover the filter (Figure 9).

21. Ensure that the filter is fully released and deployed.

22. To deploy the filter, remove the sheath over the guidewire. Ensure that the filter is fully released and deployed.

23. To deploy the Option™ ELITE Filter, fix the Positioner to the filter, then pull the sheath back over the catheter to uncover the filter (Figure 10).

24. Ensure that the Option™ ELITE Filter is fully released and deployed.

25. Carefully remove the guidewire and vena cava filter during the procedure. If the guidewire does not interfere with the filter, the filter can be retracted into the sheath and the sheath withdrawn from the IVC.

26. Close the sheath using the catheter and the catheter sheath introducer over the guidewire. Advance the sheath into the inferior vena cava (IVC) and aspirate the sheath for any blood, then withdraw the sheath from the IVC.

27. Place the sheath and catheter on the vessel. Advise the patient that the post-procedural period may be extended due to the possible presence of the filter in the IVC.

28. Perform a control cavagram prior to terminating the procedure. Verify proper filter positioning.

29. Re-orient the catheter sheath device to achieve optimal alignment with respect to the vena cava.

30. Discard the introduction kit and packaging materials.

*Note: The selected access site will determine the cartridge insertion orientation. The orientation is identified in Table 1. The manufacturer specifies the correct orientation for optimal deployment of the filter. The arrow of the sheath is used to identify the correct orientation (Figure 11).

Figure 11: Filter Retreival

Figure 7: Advance Pusher Until Deployment Mark is Adjacent to Cartridge (femoral shown)

O. Alternative Over-the-Wire Percutaneous Procedure for Filter Implantation

Pre-implant care is required:

1. To confirm the diameter of the inferior vena cava (IVC).

2. To determine the level of best fit for deployment with respect to the vertebral bodies.

3. To confirm that the diameter of the inferior vena cava (IVC) at the site where the filter is to be deployed is less than or equal to the maximum submatured diameter is the inferior vena cava.

4. To determine the desired level for filter deployment and to mark the position with respect to the vertebral bodies.

5. To select a suitable guidewire access site, either on the right or left side, depending upon the patient's size or anatomy, operator's preference or previous venous thrombosis.

6. To select a suitable guidewire access site, either on the right or left side, depending upon the patient's size or anatomy, operator's preference or previous venous thrombosis.

7. To use appropriate techniques to determine that the filter, the jugular retrieval route, and the inferior vena cava (IVC) distal IVC are free of thrombus.

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