MERIDIAN®
Vena Cava Filter

Jugular/Subclavian Vein Approach
Instructions for Use
Instructions for Use
For use in the Vena Cava

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

A. General Information
The Meridian® Jugular/Subclavian Filter is a venous interruption device designed to prevent pulmonary embolism. The unique design and material of the Meridian® Filter provide filtering efficiency and allow percutaneous placement through an angiographic introducer with minimum entry site difficulties. The placement procedure is packaged and designed to perform. This product is not manufactured with natural rubber latex. The Meridian® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The jugular/subclavian system allows for placement of the Meridian® Filter via a jugular or subclavian vein approach. The jugular/subclavian system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.030” side port wire and allows for an 800 psi maximum pressure contrast power injection. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The delivery device fits within the introducer sheath and consists of a side port for saline flushing and a delivery mechanism to deploy the Meridian® Filter. The delivery device contains a suture cap that mechanically separates the filter anchors from one another in a criss cross pattern to prevent leg entanglement. The Meridian® Filter is preloaded within the delivery device. Once the introducer sheath is within position, the delivery device is advanced through the introducer sheath until the introducer and delivery hubs snap together. The safety clip is then removed. The introducer hub is pulled back over the pusher wire handle to unsheath and release the Meridian® Filter allowing it to recover to its predetermined shape.

The Meridian® Filter is designed to act as a permanent filter. When clinically indicated, the Meridian® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Meridian® Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed (reference Optional Procedure for Filter Removal for specific removal instructions).

MRI Safety:

Non-clinical testing demonstrated that the Meridian® Filter is MR Conditional. A patient with this implant can be imaged safely immediately after placement under the following conditions:

-Static magnetic field of 3-Tesla or 1.5-Tesla
-Spatial gradient magnetic field of 720-Gauss/cm
–Maximum MR system reported whole-body averaged specific absorption rate (SAR) of 2-W/kg in the normal operating mode

In non-clinical testing, the Meridian® Filter produced a temperature rise of 2.2°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of continuous MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software GE 3.0-GS, General Electric Healthcare, Milwaukee, WI).

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 Meridian® Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

Artifact Information:
Image artifact of the Meridian® Filter was tested according to ASTM F2119-07 in a GE HDx 3-Tesla cylindrical bore scanner. The greatest artifact occurred at the hook and the ends of the arms and legs with the static field parallel to the length. The maximum extent of the artifact beyond the metal of the phantom was 5 mm for the spin echo sequence and 10 mm for the gradient echo sequence. Imaging parameters may need to be adjusted for artifact optimization.

It is recommended that patients with a venous cava filter register the MR conditions with the MedicAlert Foundation (www.medicalert.org).

B. Device Description
The Meridian® Filter System - Jugular/Subclavian consists of the filter and delivery system. The Meridian® Filter may be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The Meridian® Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The Meridian® Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005a.

The Meridian® Filter may be removed according to the instructions provided under the Optional Removal Procedure. The Meridian® Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed (reference Optional Procedure for Filter Removal for specific removal instructions).
1. This product is intended for use by physicians trained and experienced in diagnostic and interventional radiology.

2. The safety and effectiveness of this device has not been established for pediatric patients.

3. Remove the device remain permanently implanted.

4. The safety and effectiveness of this device has not been established for morbidly obese patients. Open abdominal procedures such as bariatric surgery may affect the integrity and stability of the filter.

5. Anatomical variances may complicate filter insertion and deployment. Careful attention to these general course of such anatomic deformations. This may make percutaneous removal of the intravascular snare only possible.

6. PVCS with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots or cavities, or due to thermal and/or mechanical changes.

7. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.

8. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

9. Do not resterilize. After resterilization, the sterility of the product is not guaranteed and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

10. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the intravascular snare only possible.

11. Do not attempt to reposition the filter. The filter orientation within the IVC.

12. If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency. If patent venous access into the IVC cannot be achieved, perform a diagnostic venogram to ascertain the site of blockage. If a thrombus is present, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer sheath.

13. After use, the IFU. Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

NOTE: It is possible that complications such as those described in the “Warnings,” “Precautions,” or “Potential Complications” sections of this Instructions for Use may result in improper Meridian Filter orientation within the IVC.

If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC. CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

Filter complications.

Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots or cavities, or due to thermal and/or mechanical changes.

Filter orientation within the IVC.

Filter cannot be safely reloaded.

Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Reference Potential Complications section for further information regarding other known filter complications.

Filter orientation within the IVC.

Filter complications.

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Filter orientation within the IVC.
deploy the Meridian® Filter.

16. It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

17. Aspiring the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system.

Meridian® Filter Removal

1. Anatomical variances may complicate the removal procedure. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

2. Spinal deformations: It is important to exercise care when contemplating removing the Meridian® Filter in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.

3. Remove the Meridian® Filter with an intravascular snare and maintain at least 10 French I.D. retrieval sheath only.

4. Caution should be employed when using a snare to engage the hook of the filter only.

G. 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 or after the procedure.

Possible complications include, but are not limited to, the following:

Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by failure of IVC filters with the filter appearing at the labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.

- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters without the retrieval of the fragment utilizing endovascular and/or surgical techniques.

- Detachment of components.

- Perforation or other acute or chronic damage of the IVC wall.

- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or inferior vena cava vessels.

- Deep vein thrombosis

- Cava thrombosis/occlusion

- Extravasation of contrast material at time of venacavogram

- Air embolism

- Hematoma or nerve injury at the puncture site or subsequent retrieval site

- Hemorrhage

- Restriction of blood flow

- Occlusion of small vessels

- Distal embolization

- Infection

- Intimal tear

- Stenosis at implant site

- Failure of filter expansion/ incomplete expansion

- Insertion site thrombosis

- Filter malposition

- Vessel injury

- Arteriovenous fistula

- Back or abdominal pain

- Filter Tilt

- Hemorrhax

- Organ injury

- Pneumogastria curdula doliens

- Pneumothorax

- Postphlebitic syndrome

- Stroke

- Thrombophlebitis

- Venous Ulceration

- Blood Loss

- Guidewire entrapment

- Pain

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

1. One Meridian® Filter Jugular/Subclavian System that contains:

- One 55 cm, 10 French I.D. introducer and dilator set
- One delivery device with pre-loaded Meridian® Filter
- 0.038” J-tipped Guidewires, 110 cm long or longer
- 18G entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

2. Directions for Use

1. Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient’s size/anatomy, operator’s preference, or location of venous thrombosis.

2. Prep, drape, and anesthetize the skin puncture site in standard fashion.

3. Select and open the cannon and outer pouch. Open the introducer sheath and dilator inner pouch.

4. Note the skin with a #11 blade and perform venipuncture with an 18G entry needle.

5. Insert a J-tipped guidewire and gently advance it into the inferior vena cava.
PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the 18G entry needle over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs snap together. Advance the 10 French introducer sheath together with its tapered dilator over the guidewire and into the inferior vena cava.

NOTE: A 0.038” guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

7. Remove the guidewire and perform a standard inferior venacavogram in both the AP and lateral view, (typically 30 mL of contrast medium at 15mL/s) through the dilator.

NOTE: IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).

WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.

WARNING: If the vena cava diameter is greater than 28mm, do not deploy the Meridian® Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

8. Separate the dilator and introducer hubs by bending and then pulling apart (Reference Figure 3). Remove the guidewire and dilator, leaving the 10 French introducer sheath with its tip in the inferior vena cava. Flush intermittently by hand or attach to the introducer stopcock a constant saline drip infusion to maintain introducer patency.

9. Open the delivery system inner pouch. Remove the delivery device from the package and remove the red safety cap (Reference Figure 4).

10. Flush the delivery device with saline through the delivery stopcock.

11. Insert and advance the delivery device through the introducer sheath until the introducer and delivery device hubs snap together (Reference Figure 5).

PRECAUTION: Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the Meridian® Filter.

NOTE: Do not remove the safety clip until step #13.

12. Under fluoroscopic guidance, position the system for optimal placement. The distal end of the pusher pad provides a radiopaque indicator for positioning purposes (Reference Figure 6).

NOTE: A gap between the filter apex and pusher pad is normal.

13. Remove the safety clip from the delivery device.

14. Stabilize the handle and pull back on the introducer hub (blue) to retract both the introducer sheath and delivery device. Retract the introducer hub until the handle bottoms out against the proximal edge of the delivery catheter hub (white). This will release the Meridian® Filter into position (Reference Figure 7).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the Meridian® Filter.

15. Under fluoroscopic guidance, separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.

16. Perform a venacavogram to confirm satisfactory deployment before terminating the procedure (typically 30mL of contrast medium at 15mL/s).

17. Remove the introducer sheath and apply routine compression over the puncture site in the usual manner to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the G2® Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter.
Figure 8: Distribution of Filter Indwelling Time in Retrieved Subjects

Of the 61 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet the retrieval eligibility requirements. During the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 49 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, and DVT and/or PE with complications or failure of anticoagulation, and prophylaxis. The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 8 depicting the time to retrieval.

Figure 4: If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Figure 5: If the package is damaged or opened, and is ready for single use only. If the filter was successfully retrieved in spite of tilt and associated embedding of filter apex into caval wall.

Figure 6: There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Removal of Meridian® Filter Using an Intravascular Snare

Equipment Required

• One intravascular snare of user’s choice
• One 80-cm introducer sheath, 10 French I.D. or greater, to be used as retrieval sheath
• 0.035” 3 mm J-tipped Guidewire, 110 cm long or longer
• One 80-cm introducer sheath, 10 French I.D. or greater, to be used as retrieval sheath
• One intravascular snare of user’s choice

Procedure

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient’s size or anatomy, operator’s preference, or location of venous thrombosis.
2. Remove the retrieval sheath from its packaging using sterile technique.
3. Prior to use, flush the retrieval sheath with heparinized saline or suitable isotonic solution.
4. Prepare all other procedure components according to the manufacturer’s Instructions for Use.
5. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
6. Select the appropriate loop diameter size of the intravascular snare.
7. Assemble the intravascular snare according to the Instructions for Use provided by the manufacturer.
8. Insert the guidewire into the IVC under fluoroscopic guidance, and adjust the sheath to engage the filter apex due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.
9. Insert and advance the intravascular snare assembly through the sheath until it protrudes out through the sheath such that the marker band of the sheath catheter is cephalad to the filter retrieval hook.
10. Remove the guidewire.
11. Insert and advance the intravascular snare assembly through the sheath until it protrudes out through the sheath such that the marker band of the sheath catheter is cephalad to the filter retrieval hook.

WARNING: Do not attempt to remove the Meridian® Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena caval wall.

WARNING: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 9 A: Slowly advance the loop forward over the filter apex.

Figure 9 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

NOTE: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the hook of the filter only, avoiding engagement of filter arms or legs. The marker tip of the snare catheter must be cephalad to the filter retrieval hook.

Figure 9 C: Maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

NOTE: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular sheath.

Figure 9 D: Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

Figure 9 E: Illustrates the Meridian® Filter using an intravascular sheath and minimum 10 French I.D. retrieval sheath only.

Figure 9 F: Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

Figure 8: Distribution of Filter Indwelling Time in Retrieved Subjects

Figure 9 A-E: Retrieval of Meridian® Filter using an Intravascular Snare, Illustrated
WARNING: After use, the Meridian® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations. The Meridian® Filter should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular’s sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT. Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country. An issue or revision date and a revision number for these instructions are included for the user’s information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

• “American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians” [ Chest 1998 Feb; 113(2): 499-504]
• “Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism” [JVIR 2003; 14:S271-S275]

References:

Meridian® Vena Cava Filter

Meridian® Filter Jugular/Subclavian Delivery Device

Meridian® Filter Introducer Sheath With Dilator

Contents:
(1) Meridian® Filter - Jugular/Subclavian Delivery Device
(1) 10F I.D. Introducer Sheath 55cm Long With Dilator

Use By
Lot Number
Catalogue Number

Attention, See Instructions For Use

Sterilized Using Ethylene Oxide

Non-Pyrogenic

Recommended Guidewire

Manufacturer

Working Sheath Length

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised

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