A. General Information

The Meridian® Filter is a removable device intended to prevent pulmonary embolism. The unique design and material of the Meridian® Filter provide filtering efficiency and allow percutaneous placement through an 8 French (F) introducer sheath with minimal entry site difficulties. The placement procedure is quick and simple 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 Femoral system allows for placement of the Meridian® Filter through a femoral vein approach. The femoral delivery system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.038" guidewire and allows for an 800 psi maximum pressure contrast power injection. The 48cm, 8 French (F) introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The flexible nitinol pusher wire of the delivery device has a pad at the end of the wire designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the radiopaque distal end of the introducer sheath, positioned 1 cm below the iliac crest. The introducer sheath and delivery device are then pulled back onto the pusher wire handle to unlash and release the filter and allow it to recover to its predetermined shape. The centering system allows the Meridian® Filter to be deployed with the retrieval hook centered and minimizes the potential for legs crossing. 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 scanned 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 or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg in the normal operating mode
- Maximum SAR for the area of interest is in the exact same area or relatively close to the position of the Meridian® Filter
- 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 tors scan. The greatest artifact occurred at the hook end and the ends of the arms and the 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 vena cava filter register the MR conditions with the MedicAlert Foundation (www.medicalert.org).

B. Device Description

The Meridian® System - Femoral consists of the filter and delivery system. The Meridian® Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The Meridian® Filter consists of two shafts, a memory nitinol wire emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These 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® System – Femoral is illustrated in Figure 1. The delivery system consists of a 8 French (F) introducer sheath and dilator, the Meridian® Filter, a storage tube with saline infusion port, and a pusher system. The Meridian® Filter is packaged pre-loaded within the delivery storage tube.
The Meridian 
Filter is pre-loaded into the storage tube and is intended for single use only. Do not
reprocess or re-use the Filter in order to properly position the IVC, as the Meridian 
Filter cannot be safely reloaded into the storage tube.

This device has been designed for single use only. Reusing medical devices
may result in the risk of cross-contamination with different pathogens or disease
conditions, including but not limited to those associated with mycobacterium, strepto
coccus, tuberculosis, and other systemic infections.

Please refer to the Meridian 
Filter Instructions for Use for more information regarding these statements.

The Meridian 
Filter is intended for use in patients with risk of septic embolism.

• Patients with risk of septic embolism.

E. Warnings

1. Filters - Contraindications

a. The Meridian 
Filter is designed for use in clinical and interventional vascular procedures.

b. The system is intended to be used with the optional filter removal system.

2. Spinal deformations: It is important to exercise care when contemplating the implantation of vena cava filters 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 filter more difficult.

3. Patients with risk of septic embolism.

b. The Meridian 
Filter is pre-loaded into the storage tube and is intended for single use only. Do not
reprocess or re-use the Filter in order to properly position the IVC, as the Meridian 
Filter cannot be safely reloaded into the storage tube.

2. This device has been designed for single use only. Reusing medical devices
may result in the risk of cross-contamination with different pathogens or disease
conditions, including but not limited to those associated with mycobacterium, strepto
coccus, tuberculosis, and other systemic infections.

3. Patients with risk of septic embolism.

a. The Meridian 
Filter is designed for use in clinical and interventional vascular procedures.

b. The system is intended to be used with the optional filter removal system.

2. Spinal deformations: It is important to exercise care when contemplating the implantation of vena cava filters 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 filter more difficult.
I. Directions for Use

1. Select a suitable femoral 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. Prep, drape and anesthetize the skin puncture site in standard fashion.

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

4. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

5. 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 connect properly.

6. Advance the 8 French introducer sheath together with its tapered dilator over the guidewire and into the distal vena cava or iliac vein.

7. Remove the dilator, leaving the introducer sheath with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer sheath a constant saline drip infusion to maintain introducer sheath patency.

H. Equipment Required

The following equipment is required for use:

- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
- Contrast medium
- Saline
- 18 gauge entry needle
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- One storage tube with pre-loaded Meridian Filter and pusher delivery system
- One 48 cm, 8 French I.D. introducer sheath and dilator set
- One transfusion set

I. Potential Complications

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

- Blood Loss
- Venous Ulceration
- Thrombophlebitis
- Pneumothorax
- Phlegmasia cerulea dolens
- Organ injury
- Hemothorax
- Filter Tilt
- Back or abdominal pain
- Arteriovenous fistula
- Vessel injury
- Insertion site thrombosis
- Stenosis at implant site
- Occlusion of small vessels
- Hemorrhage
- Hematoma or nerve injury at the puncture site or subsequent retrieval site
- Air embolism
- Extravasation of contrast material at time of venacavogram
- Caval thrombosis/occlusion
- Deep vein thrombosis
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage.
- 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.

WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 900 psi.

If large thrombi are demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

7. 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 connect properly. Advance the 8 French introducer sheath together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

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.

8. Remove the dilator, leaving the introducer sheath with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer sheath a constant saline drip infusion to maintain introducer sheath patency.
11. Flush the delivery system with saline through the Y-adaptor.

12. Attach the free end of the filter storage tube directly to the introducer sheath already in the vein. The introducer sheath and filter delivery system should be held in a straight line to minimize friction.

13. Locate the Touhy-Borst and advance the filter by moving the red safety cap with one hand, pusher wire forward through the introducer sheath (Reference Figure 4 A-D). Do not pull back on the pusher wire, only advance the pusher wire forward.

14. The black indicator mark on the pusher wire provides a visual cue indicating that the filter is approaching the end of the sheath as the mark comes adjacent to the proximal end of the Touhy-Borst adaptor. Prior to deployment, the exact location of the filter within the sheath should be verified under fluoroscopy.

15. Deliver and release filter as described in Figure 5 A-C. Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer sheath as described above. Do not twist the pusher wire handle at anytime during this procedure.

16. Under fluoroscopic guidance, withdraw the pusher wire back into the storage tube by firmly holding the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

17. Resume the intermittent saline flush or constant drip infusion to maintain introducer sheath patency.

18. A follow-up venacavogram may be performed after withdrawing the introducer sheath into the iliac vein (typically 30mL of contrast medium at 15mL/s).

19. Remove the red safety cap (Reference Figure 3).

Precaution: Care should be taken to ensure the connection between the introducer sheath hub and the introducer radiopaque tip is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

Optional Procedure for Filter Removal: 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. Of the 42 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 retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement).

Clinical Experience: The time to retrieval of the G2 filter ranged from 5 to 300 days with a mean of 19.3-81.6 days from implantation to retrieval. Please see the histogram in Figure 6 depicting the time to retrieval of the G2 filter in the 61 patients.
The removal of the filter is contraindicated in the following situations:

1. An attempt at retrieval of the filter has been made within the last year.
2. The filter is not fully collapsed inside the retrieval sheath.
3. The retrieval sheath is not fully aligned with the filter retrieval hook.
4. The retrieval hook cannot be engaged with the snare.
5. The retrieval hook cannot be retracted into the retrieval sheath.

Follow-up Venacavogram

A follow-up venacavogram should be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).

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), dry, dark 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, if applicable, for the life of this product after first use.

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), dry, dark 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, if applicable, for the life of this product after first use.

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), dry, dark 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, if applicable, for the life of this product after first use.


