MERIDIAN®
Vena Cava Filter

Femoral Vein Approach
Instructions for Use

BARD | PERIPHERAL VASCULAR

ENGLISH

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® 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 8 French I.D. introducer sheath with minimum 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 via 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 I.D. 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 lowest renal vein. The introducer sheath and delivery device are then pulled back onto the pusher wire handle to unsheath 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:

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, 2005.
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
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 G3.0-052B, 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 end 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 vena cava filter register the MR conditions with the MedicAlert Foundation (www.medicalert.org).

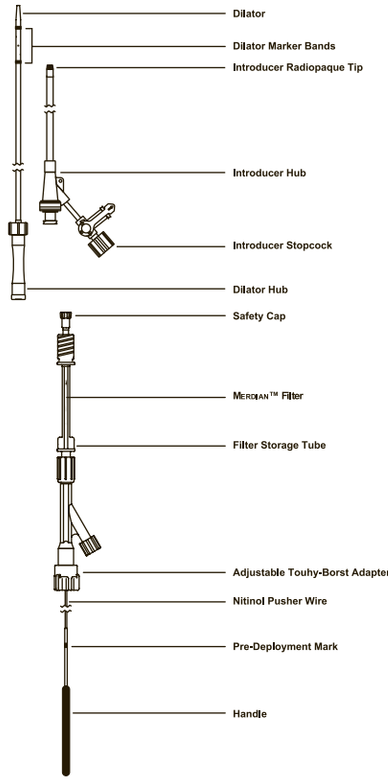
B. Device Description

The MERIDIAN® Filter 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 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 of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration.

The MERIDIAN® Filter System - Femoral is illustrated in Figure 1. The delivery system consists of a 8 French I.D. 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.

Figure 1: MERIDIAN® Filter System – Femoral



IMPORTANT: Read instructions carefully before using the MERIDIAN® Filter

C. Indications for Use

The MERIDIAN® Filter - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN® Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

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

The MERIDIAN® Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.

- Patients with risk of septic embolism.

E. Warnings

MERIDIAN® Filter Implantation

1. **The MERIDIAN® Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in 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 this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.**
3. **Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing, and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.**
4. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution #7.)**
5. **Delivery of the MERIDIAN® Filter through the introducer sheath is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer sheath.**
6. **The MERIDIAN® Filter - Femoral is designed for femoral approaches only. Never use the MERIDIAN® Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper MERIDIAN® Filter orientation within the IVC.**
7. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.**
8. **Never re-deploy a removed filter.**
9. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.**
10. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**
11. **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 requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
12. **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 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 and/or dislodgement due to large clot burdens.**
13. **The MERIDIAN® Filter consists of nickel-titanium alloy, which is generally considered safe. However, in-vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Persons with allergic reactions to nickel may suffer an allergic response to this implant, especially those with a history of metal allergies. Some patients may develop an allergy to nickel if this device is implanted. Certain allergic reactions can be serious. While devices that release nickel are not expected to result in symptoms such as difficulty in breathing or inflammation of the face or throat, if these types of allergic reactions occur, patients should be instructed to seek immediate medical attention. Some forms of nickel have also been associated with carcinogenicity (ability to cause cancer) in animal models. It is unknown whether nickel released from implants will increase a patient's cancer risk.**
14. **After use, the MERIDIAN® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

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

MERIDIAN® Filter Removal

1. **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 cava wall.**

NOTE: It is possible that complications such as those described in the "Warnings", "Precautions," or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

2. **Never re-deploy a removed filter.**
3. **Remove the MERIDIAN® Filter using an intravascular snare and 10 French I.D. retrieval sheath only. Refer to the Optional Procedure for Filter Removal section for details.**

F. Precautions

MERIDIAN® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. The safety and effectiveness of this device has not been established for pregnancy, nor in suprarenal placement position.[1]
3. 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.
4. The safety and effectiveness of this device has not been established for pediatric patients.
5. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
6. Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the filter.
7. Position the retrieval hook 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
8. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
9. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the MERIDIAN® Filter using an intravascular snare only. Refer to the Optional Procedure for Filter Removal section for details.
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 filter more difficult.
11 In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
12. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
13. The introducer sheath has a radiopaque distal tip to assist in visualization and predeployment filter positioning. The radiopaque distal tip on the introducer sheath, when used in conjunction with the radiopacity of the pusher wire spline, provides a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
14. Do not attempt to attach a syringe or power injection line to the proximal end of the introducer sheath hub.
15. Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.
16. It is very important to maintain introducer sheath patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
17. 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. Do not twist the pusher wire handle at anytime during this procedure.
18 Aspirating 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 minimum 10 French I.D. retrieval sheath only.
4. Caution should be employed when using a snare to engage the hook of the filter only, avoiding engagement of filter arms or legs.

NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device. FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed. FDA encourages all physicians involved in the treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient.

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

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 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 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 requiring 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 collateral vessels.
- Deep vein thrombosis
- Caval 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
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- 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

The following equipment is required for use:

• One MERIDIAN® Filter Femoral System that contains:

-One 48 cm, 8 French I.D. introducer sheath and dilator set

-One storage tube with pre-loaded MERIDIAN® Filter and pusher delivery system

• 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer

• 18 gauge 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

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. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

PRECAUTION: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, 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 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.

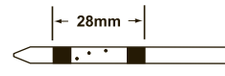
NOTE: A 0.038" guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

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.

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. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

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).

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. 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.

9. Advance the introducer sheath to the selected level under fluoroscopic guidance. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer sheath tip should be 1 cm below the lowest renal vein.
10. Open the delivery system inner pouch. Remove the delivery system containing the filter from the package and remove the red safety cap (Reference Figure 3).

Figure 3: Safety Cap Removal

11. Flush the delivery system with saline through the Y-adapter.

PRECAUTION: It is very important to maintain introducer sheath patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

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.

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

13. Loosen the Touhy-Borst and advance the filter by moving the nitinol 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.

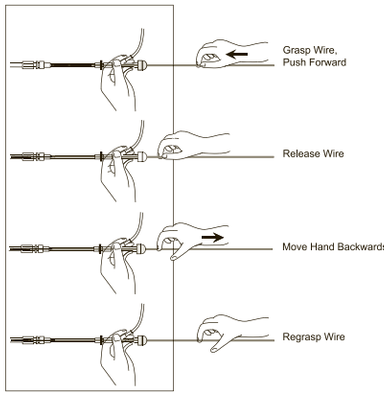
Figure 4 A-D: Advancement of Filter, Illustrated

FIGURE 4 A

FIGURE 4 B

FIGURE 4 C

FIGURE 4 D



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.

Filter Release/Deployment

15. Deliver and release filter as described in Figure 5 A-C:

Figure 5 A-C: Filter Release, Illustrated

FIGURE 5 A
FIGURE 5 A-1

FIGURE 5 B
FIGURE 5 B-1

FIGURE 5 C
FIGURE 5 C-1

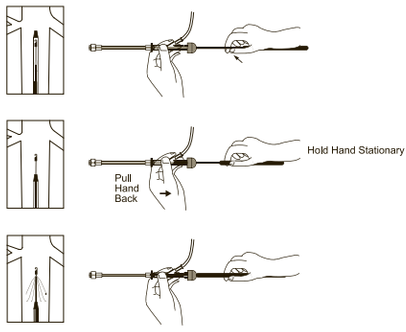


Figure 5 A: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.
Figure 5 A-1: Filter positioned at the distal end of the introducer sheath, with the filter retrieval hook, proximal to the introducer radiopaque tip.

PRECAUTION: 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 below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter retrieval hook 1 cm below the lowest renal vein.

Figure 5 B: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.
Figure 5 B-1: Unsheathing of filter in IVC.
Figure 5 C: The position of the hands at the completion of the unsheathing process.
Figure 5 C-1: The filter deployed in the IVC.

16. Under fluoroscopic guidance, withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer sheath assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer sheath patency.

Follow-up Venacavogram

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).

Note: If air is observed entering the system as a result of aspirating through the introducer side port, cover the introducer hub.

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

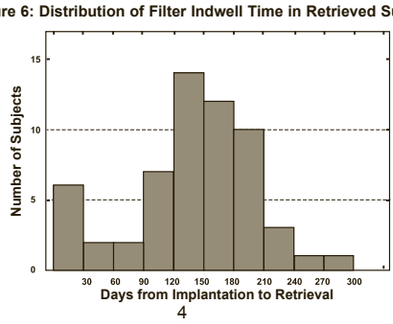
OPTIONAL PROCEDURE FOR FILTER REMOVAL:

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. 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.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6 . The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication 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 6 depicting the time to retrieval.

Figure 6: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability 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. 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.
Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Removal of MERIDIAN® Filter Using an Intravascular Snare

Equipment Required

- One intravascular snare of user's choice
- One 80-cm introducer sheath, 10F ID or greater, to be used as retrieval sheath
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge 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.

Procedural Instructions

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 manufacturers' 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 its manufacturer.
8. Insert the guidewire of choice into the retrieval sheath using the guidewire tip-straightener. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.
9. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3cm 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 of the sheath such that the marker band of the snare catheter is cephalad to the filter retrieval hook.
12. The retrieval of the MERIDIAN® Filter using an intravascular snare is illustrated in **Figure 7 A-E:**

Figure 7 A-E: Retrieval of MERIDIAN® Filter using an Intravascular Snare, Illustrated

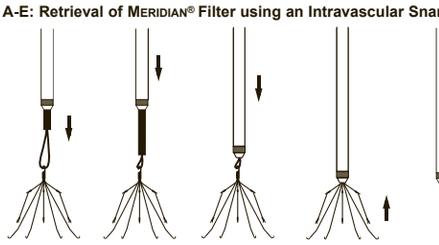


Figure 7 A: Slowly advance the loop forward over the filter apex.

Figure 7 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 retrieval hook and that the retrieval hook, retrieval catheter and snare are aligned. Caution should be employed when using a snare to engage 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.

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

Figure 7 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter.

Figure 7 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 7 E: 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.

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 cava wall.

WARNING: Remove the MERIDIAN® Filter using an intravascular snare and minimum 10 French I.D. retrieval sheath only.

13. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

14. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
15. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

J. How Supplied

Each MERIDIAN® Filter is supplied preloaded in a storage tube. Each MERIDIAN® Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

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.

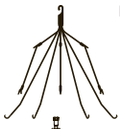
For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]**
- **"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]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter After Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.

4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.



MERIDIAN© Vena Cava Filter

MERIDIAN© Filter Femoral Delivery Device

MERIDIAN© Filter Introducer Sheath With Dilator

FEM

Femoral

KIT

Contents:
(1) MERIDIAN© Filter - Femoral Delivery Device
(1) 8 Fr. I.D. Introducer Sheath 48cm Long with Dilator

INT

Contents:
(1) 8 Fr. I.D. Introducer Sheath 48cm Long with Dilator

DD

Contents:
(1) MERIDIAN© Filter - Femoral Delivery Device

Use By

LOT

Lot Number

REF

Catalogue Number

Attention, See Instructions for Use

STERILE EO

Sterilized Using Ethylene Oxide

NON PYROGENIC

Non-Pyrogenic

Keep Dry

Keep Away From Sunlight

Single Use

Sterilize

Do Not Resterilize

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

MR

MR Conditional

R

Recommended Guidewire

LATEX

Does Not Contain Natural Rubber Latex

WSL

Working Sheath Length

Introducer Sheath

Manufacturer

® TM

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