G2®
Filter System
Timeless Performance®

G2® Filter System
Jugular/Subclavian 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 ***G2***® Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the ***G2***® Filter provide filtering efficiency and allow percutaneous placement through an angiographic introducer with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The ***G2***® 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 ***G2***® 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 0.038" guidewire 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 infusion and a delivery mechanism to deploy the ***G2***® Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to prevent leg entanglement. The ***G2***® 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 unsheathe and release the ***G2***® Filter allowing it to recover to its predetermined shape.

The ***G2***® Filter is designed to act as a permanent filter. When clinically indicated, the ***G2***® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The ***G2***® Filter's elastic hooks 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 has demonstrated that the ***G2***® Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the ***G2***® Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

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 ***G2***® Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

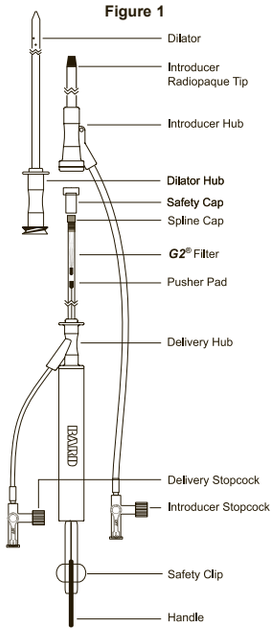
B. Device Description

The ***G2***® Filter- Jugular/Subclavian System consists of the filter and delivery system. The ***G2***® Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The ***G2***® Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve. 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 ***G2***® Filter System -Jugular/Subclavian is illustrated in Figure 1. The Delivery System consists of a 10 French I.D. introducer sheath and dilator, the ***G2***® Filter, and a delivery device. The ***G2***® Filter is packaged pre-loaded within the delivery device.

Figure 1



IMPORTANT: Read instructions carefully before using the ***G2***® Filter

C. Indications for Use

The ***G2***® Filter System- Jugular/Subclavian 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.
- ***G2***® 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 ***G2***® 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

G2® **Filter Implantation**

1. **The *G2*® Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2*® Filter cannot be safely reloaded.**
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 contract 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 # 6).**
5. **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.**
6. **Only use the *Recovery Cone*® Removal System to remove the *G2*® Filter. Never re-deploy a removed filter.**
7. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**

8. **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.**
9. **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.**
10. **Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2® Filter orientation within the IVC.**
11. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.**
12. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
13. **After use, the *G2*® Filter system 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.

***G2*® Filter Removal**

1. **Do not attempt to remove the *G2*® Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval 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. **Use only the Bard *Recovery Cone*® Removal System (packaged separately) to retrieve the *G2*® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.**
3. **Never re-deploy a removed filter.**

F. Precautions

***G2*® 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. 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.
5. Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the filter.
6. Position the filter tip 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.
7. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
8. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the ***G2***® Filter using the ***Recovery Cone***® Removal System Only. Refer to Optional Procedure for Filter Removal for details.
9. 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.
10. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to antithrombotic therapy as soon as it is deemed safe.
11. 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 use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
12. 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 ***G2***® filter.
13. Do not remove the safety clip until the introducer and the delivery device hubs are snapped together.
14. Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the ***G2***® filter.
15. 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.
16. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system.

***G2*® Filter Removal**

1. Anatomical variances may complicate insertion and deployment of the ***Recovery Cone***® Removal System. 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 ***G2***® Filter with the ***Recovery Cone***® Removal System 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 ***G2***® Filter using the ***Recovery Cone***® Removal System Only. Refer to the Optional Procedure for Filter Removal section for details.
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

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
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.
- 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 have been 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

- **One *G2*® Filter Jugular/Subclavian System that contains:**
  - **-One 55 cm, 10 French I.D. introducer and dilator set**
  - **-One delivery device with pre-loaded *G2*® Filter**
- 0.038" 3 mm J-tipped Guidewire, 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.

If the physician chooses to percutaneously remove the ***G2***® Filter, the ***Recovery Cone***® Removal System is available from C. R. Bard, Inc.

I. 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 jugular/subclavian delivery system package.
4. Nick 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.

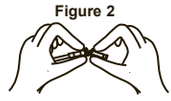
7. Perform a standard inferior venacavogram in both the AP and lateral view, (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

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 *G2*® 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 2). 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.

Figure 2



9. Remove the delivery device from the package and remove the red safety cap (Reference Figure 3).

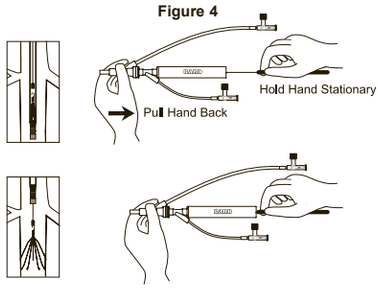
Figure 3

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 4).

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 *G2*® filter.

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

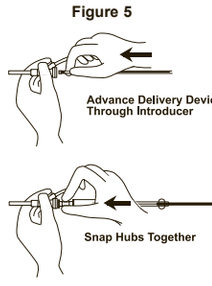
Figure 4



12. Under fluoroscopic guidance, position the system for optimal placement. The distal end of the pusher pad provides the radiopaque indicator for positioning purposes (Reference Figure 5).

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

Figure 5



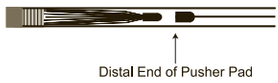
NOTE: A gap between the filter apex and pusher pad is normal.

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 ***G2®*** filter into position (Reference Figure 6).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the *G2®* filter.

Figure 6



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.
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:

CAUTION: Remove the *G2®* Filter using the *Recovery Cone®* Removal System only.

Removal of *G2®* Filter

Equipment Required

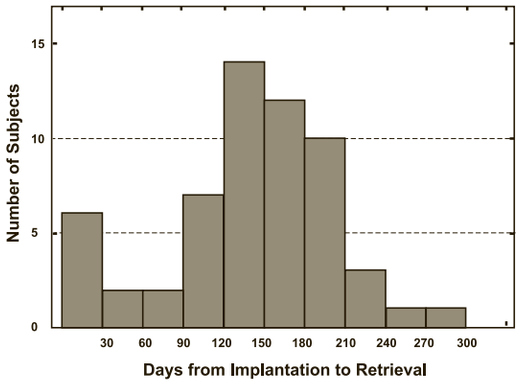
The following equipment is required for use:

- One ***Recovery Cone®*** Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with ***Recovery Cone®*** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- 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.

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 7** depicting the time to retrieval.

Figure 7: 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 with the ***Recovery Cone®*** Removal System 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).

Procedural Instructions

Insertion of the Introducer Catheter

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. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone®*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the ***G2®*** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the ***G2®*** Filter.

***Recovery Cone®* Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone®*** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Under fluoroscopic guidance, advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of *G2®* Filter

Filter Removal, Illustrated

NOTE: It is recommended to fluoroscopically obtain image(s) of the filter in AP and lateral views during the retrieval procedure.

17. The capture of the ***G2®*** Filter is illustrated in **Figures A-E**:

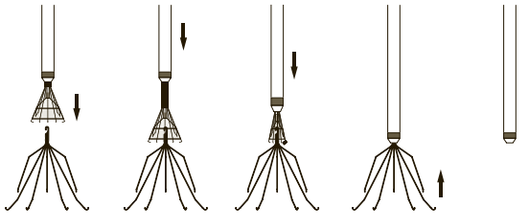


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

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

Follow-up Venacavogram

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

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***G2***® Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the ***G2***® Filter tip, a guidewire could be used to facilitate advancement of cone over the filter tip. Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip. After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the filter tip. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each ***G2***® Filter is supplied preloaded in a delivery device. Each ***G2***® Filter system is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

WARNING: After use, the *G2*® Filter system 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 ***G2***® Filter system 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.

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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.

G2® Filter

G2® Filter System Jugular/Subclavian Delivery Device

G2® Filter System Introducer Sheath With Dilator

Jugular/Subclavian

Use By

Lot Number

REF

Catalog Number

Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Non-pyrogenic

Keep Dry

Protect From Heat

Single Use, Do Not Reuse

Do Not Resterilize

Do Not Use If Package Is Damaged Or Opened.

MR Conditional

Contents:
G2® Filter Jugular/Subclavian Delivery Device
10 Fr. Introducer Sheath 55cm Long with Dilator

Recommended Guidewire

Manufacturer

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