The G2 Filter System- Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the inferior vena cava in patients with indications limited to:

- 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.

The G2 Filter System- Jugular/Subclavian consists of the filter and delivery system. The G2 Filter contains twelve shape-memory nitinol wires emanating from a central nitinol sleeve. 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 G2 Filter System- Jugular/Subclavian is illustrated in Figure 1. The Delivery Device consists of a 10 French (ID) 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

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**Figure 1**
Filter fractures are a known complication of vena cava filters. There have been some reports of serious complications with vena cava filters requiring the removal of the fragment utilizing endovascular and/or surgical techniques.

Movement, migration, or tilt of the filter is a known complication 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 into the inferior vena cava (IVC). Migration may be caused by improper deployment, deployment into clotted vena caval systems 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 or hemostatic mediators of the dilator, do not exceed the maximum pressure rating of 80 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, federal and laws and regulations.

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

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 wall of the IVC.

2. The safety and effectiveness of this device has not been established for pregnancy, nor in supranormal placement.1

3. Never redeploy a removed filter.

4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to avoid misplacement, sub-optimal placement, or tilting of the filter, occurs, consider immediate removal. Do not attempt to reposition the filter. Refer to the Recovery®®® Removal System Only. Refer to Optional Procedure for Filter Removal section for details.

5. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-coagulation therapy on a long-term basis.

6. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm optimal position, prior to filter deployment.


8. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Refer to the Recovery®®® Removal System Only. Refer to Optional Procedure for Filter Removal for details.

9. 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.

10. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-coagulation therapy on a long-term basis.

11. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.

12. 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 wall of the IVC.

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, federal and laws and regulations.

14. 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 filters more difficult.

G3® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.

2. Vessel injury

3. Filter malposition

4. Insertion site thrombosis

5. Insertion site thrombosis

6. Failure of filter expansion/incomplete expansion

7. Hemorrhage

8. Distal embolization

9. Infection

10. Restriction of blood flow

11. Hemorrhage

12. Stenosis at implant site

13. Deep vein thrombosis

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

15. Acute or recurrent pulmonary embolism. This has been reported with use of filter. It is not known if thrombi passed through the filter, or originated from superior or collateral veins.

16. Deep vein thrombosis

17. Caval thrombosis/occlusion

18. Exlargation of contract material at time of venacavography.

19. Air embolism

20. Hemorrhage at the needle site, subcutaneous site, and injection site.

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 or hemostatic mediators of the dilator, do not exceed the maximum pressure rating of 80 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, federal and laws and regulations.

14. 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 filters more difficult.
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.

II. 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 device delivery 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.

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

10. Flash the device with saline through the delivery sheath until the delivery sheath is completely flushed (Reference Figure 4). 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 #11.

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 #12.
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.

15. Under fluoroscopic guidance, separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the device by stabilizing the pusher sheath and pulling back to expose 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 Y-adapter with Recovery® Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall.
- 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, it 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 46 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 caval stenosis at implant site post successful filter retrieval (n=1).

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 of filter apex into caval wall.

Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex into the Y-adapter. 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.

The mean time to retrieval was 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

- Filter Indwell Time in Retrieved Subjects
  - Number of Patients
  - Days from Implantation to Retrieval

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**Pre-Clinical Evaluation**

The G2® Filter Retrieval System due to filter tilt leading to embedding of the filter apex into the vena caval wall is illustrated in Figures A-E.

**Figure 6**

**Extral Oedem Peri-ure Pad**

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**Figure 6**

**Extral Oedem Peri-ure Pad**
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.

Follow-up Venacavogram

15. 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.

Guidelines - 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. Insert a 0.035” guidewire through the central lumen (J-shaped or angled tip; a hydrophilic-coated guidewire is recommended). Advancing the guidewire through the cone and then 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 introducer pusher shaft. Continue removing the Filter as described in step 17.

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 warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular’s sole discretion.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER IMPLIED WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD BE LIABLE FOR ANY DAMAGES, INCLUDING, BUT NOT LIMITED TO, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD BE LIABLE FOR ANY DAMAGES, INCLUDING, BUT NOT LIMITED TO, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

The warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion.

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 warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion.

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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 for additional product information is available.

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


References:


G2® Filter System Jugular/Subclavian Delivery Device

MR Conditional

G2® Filter System Introducer Sheath With Dilator

Contents: G2® Filter Jugular/Subclavian Delivery Device 16 Fr. Introducer Sheath 50cm Long with Dilator

Jugular/Subclavian

Recommended Guidewire

Use By

Manufacturer

LOT
Lot Number

REF
Catalog Number

Attention, See Instructions for Use

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