G2 Filter System
Jugular/Subclavian Vein Approach
Information for Use
4. Only use the G2 Filter representation of 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.

5. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance. The guidewire accepts a 0.038" guidewire and allows for an 80 psi maximum pressure contrast power injection. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast via a syringe. 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 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 elastomeric deformation when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

6. Filter fracture is a known complication of vena cava filters. There have been reports of embolization and mortality. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

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.

The G2 Filter System – Jugular/Subclavian is also indicated for use in patients with temporary increased risk of pulmonary embolism requiring caval interruption. The G2 Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

• Pregnancy, 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.

• Patients with risk of pulmonary embolism requiring caval interruption.

The G2 Filter System – Jugular/Subclavian is also indicated for use in patients with temporary increased risk of pulmonary embolism requiring caval interruption. The G2 Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

The G2 Filter cannot be safely reloaded.

The G2 Filter System – Jugular/Subclavian Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

• Recurrent pulmonary embolism 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.

• Patients with current pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The G2 Filter – Jugular/Subclavian Delivery Kit is also indicated for use in patients with temporary increased risk of pulmonary embolism requiring caval interruption.

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The G2 Filter System – Jugular/Subclavian Delivery Kit is also indicated for use in patients with temporary increased risk of pulmonary embolism requiring caval interruption.

The G2 Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

E. Warnings

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.
2. Prep, drape, and anesthetize the skin puncture site in standard fashion.

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 tech-

2. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.

3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for

4. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if

5. If replacement or sub-optimal placement of the filter occurs, consider immediate removal. Retrieve the G2 Filter

6. If misplacement or sub-optimal placement of the filter occurs, consider immediate removal. Retrieve the G2 Filter

7. Movement or migration of the filter is a known complication of vena cava filters. This may be caused by place-

8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-

9. When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of

10. Ensure that the introducer and the delivery device hubs are snapped together and that the system has been

11. After use, the G2 Filter system and accessories may be a potential biohazard. Handle and dispose of

G. Potential Complications

Procedures requiring interventional interventional techniques should not be attempted by physicians unfamiliar with

References

- References to products and/or companies do not imply endorsement by the authors or the institution they represent.

- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

- Intermittent. Intimal tear.

- Hemorrhage.

- Sterile extension tube for saline drip or syringe for saline infusion

- All materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

- If the clinician chooses to percutaneously remove the G2 Filter, the Recovery Cone Removal System is available from

- Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the

- Prep, drapes, and anesthetize the skin puncture site in standard fashion.

1. Anatomical variances may complicate insertion and deployment of the Recovery Cone Removal System.

2. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age. 1

3. Never re-deploy a removed filter.

4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to

5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if

6. If misplacement or sub-optimal placement of the filter occurs, consider immediate removal. Retrieve the G2 Filter

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- If the clinician chooses to percutaneously remove the G2 Filter, the Recovery Cone Removal System is available from

- Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the

- Prep, drapes, 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 J-tipped guidewire 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 0.035” guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper placement.

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 (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombosis, 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.

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

12. Under fluoroscopic control, 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.

13. Separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.

14. Perform a venacavogram to confirm satisfactory deployment before terminating the procedure.

15. 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.

CAUTION: Remove the G2 Filter using the Recovery Cone® Removal System only.
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 59 had successful retrieval of their filter. Of the 42 that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew consent after filter retrieval and 30 were lost to follow-up or were not clinically indicated for 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 360 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 7 depicting the time to retrieval.

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.
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 retrieval.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the introducer catheter directly to 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.
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 catheter and set the catheter with saline—preferably heparinized saline.
13. Stabilize the cone and introducer catheter on the patient providing proper support so that the cone can be collapsed over the filter.

**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 and 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 in a straight line to minimize friction.
15. 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. Unthread the filters to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

**Capture of G2® Filter**

**Filter Removal, Illustrated**

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

Follow-up Venacavogram

A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s). This is recommended to document successful filter removal.

**Guidewire - Assisted Technique**

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

**Figure F:** 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-looped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and the filter near the filter tip. After it has been confirmed that the guidewire is in contact 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.

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.

**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.

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.

References:


G2 Filter System Jugular/Subclavian Delivery Device

MR Conditional

G2 Filter System Introducer Sheath With Dilator

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

Jugular/Subclavian

Recommended Guidewire

Use By

Manufacturer

Lot Number

REF Catalog Number

Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Bard, G2, Recovery Cone and Timeless Performance are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Variously Protected by one or more of the following U.S. Patent Numbers: 6,007,558, 61,156,055 and 6,258,026. Other U.S. and foreign Patents Pending.

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Non-pyrogenic

Keep Dry

Protect From Heat

Single Use.

Do Not Resterilize.