Femoral Vein Approach

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 a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A 1-cm knuckle at the end of the wire is 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 distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsetheate and release the filter and allow it to recover to its predetermined shape. The centering system allows the G2 Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing. The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be puncture-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.)

MRA Safety

Non-clinical testing has demonstrated that the G2 Filter is MR Conditional. It can be scanned safely under the following conditions:

- Static Magnetic field of 1.5 Tesla or less;
- Spatial gradient field of 450 Gauss/cm or less;
- 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 System - Femoral consists of the filter and delivery system. The G2 Filter consists of 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 is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The G2 Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the G2 Filter, a storage tube with saline infusion port, and a pusher system. The G2 Filter is packaged pre-loaded within the delivery storage tube.

Figure A. G2 Filter System - Femoral

C. Indications for Use

The G2 Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via percutaneous 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

The G2 Filter should not be implanted in:

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

- 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 into the storage tube and is intended for single use only. Do not deploy the filter if the positioning in the IVC, as the G2 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 complex connections, points, and/or crevices between components - is 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 indeterminate period of time. The residue biofilm material or ducts 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. Delivery of the G2 Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and prevent the filter from further advancement within the introducer catheter.

6. The G2 Filter System - Femoral is designed for femoral approaches only. Never use the G2 Filter and Delivery System for superior approaches (jugular, subclavian or ante-cubital vein), as this will result in improper filter IVC fit.

7. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter tip 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 catheter.

8. Only use the Recovery Cone® Removal System to remove the G2 Filter. Never re-deploy a removed filter.

9. Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.

10. 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.

11. 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 causal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriately labeled dimensions in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

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 laws and regulations.

See 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 cava wall.

NOTE: It is possible that complications such as those described in the "Warnings." "Precautions," "Potential Complications," and "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 Becton Dickenson Recovery Cone® Removal System (packaged separately) to retrieve the G2 Filter. Use of other removal devices has resulted in recurrent embolus pulmonary.

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 the suprarenal placement position.

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

7. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate repositioning. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate repositioning.

8. If displacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the G2 Filter using a Recovery Cone® Removal System. Refer to the Optional Procedure for Filter Removal section 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 anatomical 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 considered for anti-thrombotic therapy as soon as it is deemed safe.

11. 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.

12. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "large" location between which the filter should be positioned prior to just prior to unsheathing and deployment.

13. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the venipuncture device.

14. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orient the filter legs does not become covered by clot. This will allow with filter deployment.

15. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

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.


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.


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 causal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate filter 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

- Cava 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 Till

- Hemorthorax

- Organ injury

- Phlebitis; cœle de 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

The following equipment is required for use:

- One G2® filter and Delivery System that contains:
  - One 48cm, 7 French i.d. introducer catheter and dilator set
  - One Storage tube with pre-loaded G2® Filter and pusher delivery system
  - 0.038” 3mm J-tipped Guidewire, 110cm 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.
  - If the physician chooses to percutaneously remove the G2® Filter, the Recovery Cone® Removal System is available from C.R. Bard, Inc.

1. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

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, drapes, gloves and anesthesia as described above.


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 venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a “target” location between which the filter should be positioned just prior to unheating and deployment.

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

Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram in both the AP and lateral view, (typically 30 mL of contrast medium at 15 mL/s). 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).

9. Advance the introducer catheter to the selected level under fluoroscopic guidance. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.

10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clogged over time.

This will interfere with filter deployment.

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

12. Advance the filter by moving the nitrol wire pusher forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator’s convenience, the nitrol pusher wire may be looped, without causing kinking to the nitrol material, to facilitate pusher wire handling and advancement.

Advancement of G2® Filter, Illustrated

13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Removal, Illustrated

15. Under fluoroscopic guidance, withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.

16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

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

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

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2® Filter using the Recovery Cone® 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
1. Select a suitable jugular venous access route on either the right or left side depending upon the stenosis at implant site post successful retrieval (n=1).

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt ing the caval wall. The filter was successfully retrieved and the pain resolved.

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 H depicting the time to retrieval.

**Figure H: Distribution of Filter Indwell Time in Retrieved Subjects**

Days from Implantation to Retrieval

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<thead>
<tr>
<th>Number of Subjects</th>
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<tbody>
<tr>
<td>0</td>
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<tr>
<td>30</td>
<td>60</td>
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<td>270</td>
<td>300</td>
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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 cava wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of 15 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 ing the caval wall. The filter was successfully retrieved and the pain resolved.

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 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. The introducer catheter may be 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. 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.
13. Advance the main body 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.
14. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
15. 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 retraction the introducer catheter.

**Capture of G2® Filter**

**G2® Filter Removal, Illustrated**

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

**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 techni ques may be used.

**Use of a Guidewire**

If it is difficult to align the cone with the G2® Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

With 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 storage tube. Each G2® 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 G2® Filter Delivery 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 should be stored in a cool (room temperature), 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 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 30 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:

- “Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism” [JVIR 2003; 14:S271-S275]

References:

G2® Filter System

Femoral

Femoral Introducer Catheter

Use By

Lot Number

Catalog Number

Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Non-pyrogenic

Single Use, Do Not Reuse

Do Not Resterilize.

Do Not Use If Package Is Damaged Or Opened.

MR Conditional

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System

Protect From Heat

Keep Dry

Recommended Guidewire

Manufacturer:

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

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