A. General Information

The **EclipsE** Filter is a venous interruption device designed to prevent pulmonary embolism. The unique design and material of the **EclipsE** Filter provide filtering efficiency and allow percutaneous placement through a 7 French (F) introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform. The **EclipsE** Filter is an electropolished version of the G2® X Filter. This product is not manufactured with latex.

**EclipsE** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The femoral system allows for placement of the **EclipsE** Filter via a femoral vein approach. The femoral delivery system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.038" guidewire and allows for an 800 psi maximum pressure contrast power injection. The Micron, 7 French (F) introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The flexible nitinol pusher wire of the delivery device has a patel at the end of the wire designed to push on the filter apex and a grooved segment is designed to hold and prevent the filter from rotating. These components secure the filter to the pusher wire as it advances the filter, tip first, to the radiopaque distal end of the introducer sheath, positioned 1 cm below the inguinal rim. The introducer sheath and delivery device are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the **EclipsE** Filter to be deployed with the retrieval hook centered and minimizes the potential for legs crossing.

The **EclipsE** Filter is intended to be used as a permanent filter. When clinically indicated, the **EclipsE** Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The **EclipsE** Filter's anchors allow the filter to remain rigid and resist migration, but be elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions).

**MRA Safety:**

The **EclipsE** Filter was determined to be MR-conditional based on testing that was conducted on the G2® X Filter. The **EclipsE** Filter is an electropolished version of the G2® X Filter. The G2® X Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the G2® X Filter is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3.5W/kg for 15 minutes of scanning.

In non-clinical testing, the G2® X Filter produced a temperature rise of 0.8°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of MR scanning in a 3-Tesla magnetic system using a transmit/receive body coil (Eclips, Software G3.0-028B, General Electric Healthcare, Milwaukee, WI). MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2® X Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

B. Device Description

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

The **EclipsE** Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrievable hook at the apex of the filter. The 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 **EclipsE** Filter System - Femoral consists of the filter and delivery system. The delivery system consists of a 7 French (F) introducer sheath and dilator set and a delivery device. The **EclipsE** Filter System - Femoral is illustrated in Figure 1. The delivery system consists of a 7 French (F) introducer sheath and dilator, the **EclipsE** Filter, a storage tube with saline infusion port, and a pusher system. The **EclipsE** Filter System - Femoral is pre-loaded within the delivery storage tube. The filter produces a temperature rise of 0.8°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of scanning.

**MR Image Quality:**

**EclipsE** Filter produced a temperature rise of 0.8°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of MR scanning in a 3-Tesla magnetic system using a transmit/receive body coil (Eclips, Software G3.0-028B, General Electric Healthcare, Milwaukee, WI). MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2® X Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

**C. Indications for Use**

**EclipsE** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

**Indications for Use**

- Patients with risk of septic embolism.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

**E. Warnings**

**EclipsE** Filter Implantation

1. The **EclipsE** Filter is pre-loaded into the delivery storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the **EclipsE** Filter cannot be safely reloaded into the storage tube.

**Figure 1:** **EclipsE** Filter System - Femoral

**Figure 2:** **EclipsE** Filter System – Femoral
Possible complications include, but are not limited to, the following:

- With the possible complications. Complications may occur at any time during or after the procedure.

**G. Potential Complications**

1. **Anatomical variances may complicate the removal procedure.** Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

2. **Spinal deformations:** It is important to exercise care when contemplating removing the filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

3. **Do not attempt to reposition the filter.** The filter legs and arms cannot be repositioned. The filter should be removed by re-catheterization and deployment into clots and/or dislodgement due to large clot burdens.

4. **Anatomical variances may complicate filter insertion and deployment.** Careful attention to these Instructions for Use and the filter's Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

5. **Position the retrieval hook 1 cm below the lowest renal vein.** Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.

6. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.** Removal of the EclipsE Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable laws and regulations.

7. **Never re-deploy a removed filter.** Migration may be caused by placement in IVCs with diameters exceeding the appropriate placement position.

8. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter** through it as a clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer.

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

10. **If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal.** Do not attempt to reposition the filter. Retrieve the EclipsE Filter using an intravascular snare or the REcovERy™ System. Removal System, the cone must be fully retracted into the Y-adapter prior to repositioning the EclipsE Filter in the Y-adapter. The cone should be held in the Y-adapter until the cone is fully seated into the Y-adapter. The cone should be held in the Y-adapter until the cone is fully seated into the Y-adapter.

11. **Never attempt to reposition the filter.** The filter legs and arms cannot be repositioned. The filter should be removed by re-catheterization and deployment into clots and/or dislodgement due to large clot burdens.

12. **The introducer sheath has a radiopaque distal tip to assist in visualization and predeployment filter positioning.** The radiopaque distal tip on the introducer sheath is advanced only. Retraction of the pusher wire during deployment into clots and/or dislodgement due to large clot burdens.

13. **Anatomical variances may complicate the removal procedure.** Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

14. **Spinal deformations:** It is important to exercise care when contemplating implanting 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.

15. **If large thrombus is demonstrated, remove the vein one side. A small thrombus may be bypassed by the guidewire and introducer.**

16. **The introducer sheath has a radiopaque distal tip to assist in visualization and predeployment filter positioning.** The radiopaque distal tip on the introducer sheath is advanced only. Retraction of the pusher wire during deployment into clots and/or dislodgement due to large clot burdens.

17. **Anatomical variances may complicate the removal procedure.** Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

18. **Spinal deformations:** It is important to exercise care when contemplating removing the EclipsE Filter in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter. When using the EclipsE Filter, the entire IVC must be visualized. The introducer sheath must be inserted into the Y-adapter before connecting the system to the introducer to ensure that the cone can be properly delivered through the catheter.
EclipsE
®
Filter.  If large...
1. Select a suitable jugular venous access route on either the right or left side depending upon the patient’s size.

Procedural Instructions

- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
- Sterile extension tube for saline drip or syringe for saline infusion
- Contrast medium
- Saline
- 18 gauge entry needle
- 0.035” 3 mm J-tipped Guidewire, 110 cm long or longer
- One 80-cm introducer sheath, 7F ID or greater, to be used as retrieval sheath
- One intravascular snare of user’s choice

Equipment Required

Following successful retrieval (n=1).

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), and filter was successfully retrieved and the pain resolved.

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 associated embedding of filter apex into caval wall.

Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter.

Follow-up Venacavogram

- A follow-up venacavogram may be performed after the successful retrieval into the iliac vein (typically 3045, of contrast medium at 15mL/s).

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

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the G2 Filter. 61 patients underwent a filter retrieval 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 was 49 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 associated embedding of filter apex into caval wall.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 6 depicting the time to retrieval.
2. Remove the retrieval sheath from its packaging using sterile technique.
3. Prior to use, flush the retrieval sheath with heparinized saline or suitable isotonic solution.
4. Prepare all other procedure components according to the manufacturer’s Instructions for Use.
5. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
6. Use the appropriate loop diameter size of the intravascular snare.
7. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein, or anatomy, operator’s preference, or location of venous thrombosis.
9. Remove the retrieval sheath from its packaging using sterile technique.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for visualization.
11. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location.
12. Insert and advance the intravascular snare assembly through the sheath until it protrudes out of the sheath such that the mark band of the snare catheter is cephalad to the filter retrieval hook.
13. Examine the filter to assure that the complete filter has been removed. Follow-up Venacavogram
14. A follow-up venogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
15. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Removal of EclipsE Filter using RicovErY conE Removal System

Equipment Required
• One RICOVERY conE Removal System that contains:
  -One 75 cm, 10 French I.D. introducer catheter and dilator set
  -One Y-adapter with RicovErY conE Removal System 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.

If the physician chooses to use the RicovErY conE Removal System to remove the EclipsE Filter, it is available from C.R. Bard, Inc.

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. Remove the retrieval sheath from its packaging using sterile technique.
3. Prior to use, flush the retrieval sheath with heparinized saline or suitable isotonic solution.
4. Prepare all other procedure components according to the manufacturers’ Instructions for Use.
5. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
6. Select the appropriate loop diameter size of the intravascular snare.
7. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.
8. Insert the guidewire and gently advance it to the location of the filter.
9. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3 cm cephalad to the filter retrieval hook.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s).
11. Insert and advance the intravascular snare assembly through the sheath until it protrudes out of the sheath such that the mark band of the snare catheter is cephalad to the filter retrieval hook.
12. The retrieval of the EclipsE Filter using an intravascular snare is illustrated in Figure 7 A-E.
13. Examine the filter to assure that the complete filter has been removed.

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

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

Figure 7 A: Slowly advance the loop forward over the filter apex.
Figure 7 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the filter loop no longer engages the retrieval hook.
Figure 7 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter.
Figure 7 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the intravascular snare system. Continue to advance the filter over the intravascular snare system until it is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the EclipsE Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the venas cava wall.

WARNING: Remove the EclipsE Filter using an intravascular snare or the RicovErY conE Removal System only.

16. A follow-up venogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
17. The retrieval of the EclipsE Filter using a RicovErY conE Removal System is illustrated in Figure 8 A-E.

Figure 8 A: After the cone has been opened superior to the filter, carefully advance the cone over the retrieval hook 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 retrieval hook.
Figure 8 B: Close the cone over the retrieval hook by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

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

Figure 8 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter.
Figure 8 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the intravascular snare system. Continue to advance the filter over the intravascular snare system until it is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the EclipsE Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the venas cava wall.

WARNING: Remove the EclipsE Filter using an intravascular snare or the RicovErY conE Removal System only.

16. Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the EclipsE Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the venas cava wall.

Figure 8 E: Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the EclipsE Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the venas cava wall.

Figure 7 A: Slowly advance the loop forward over the filter apex.
Figure 7 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the filter loop no longer engages the retrieval hook.
Figure 7 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter.
Figure 7 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the intravascular snare system. Continue to advance the filter over the intravascular snare system until it is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the EclipsE Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the venas cava wall.

WARNING: Remove the EclipsE Filter using an intravascular snare or the RicovErY conE Removal System only.

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

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

Removal of EclipsE Filter using RicovErY conE Removal System

Equipment Required
• One RICOVERY conE Removal System that contains:
  -One 75 cm, 10 French I.D. introducer catheter and dilator set
  -One Y-adapter with RicovErY conE Removal System 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.

If the physician chooses to use the RicovErY conE Removal System to remove the EclipsE Filter, it is available from C.R. Bard, Inc.
For additional vena cava filter clinical information please refer to the following societal guidelines:

• The EAST Practice Management Guidelines Work Group [J Trauma 2002; 53:142-614]

• Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism [JVR 2003; 14:5271-5275]

References:


Use of a Guide Wire

If it is difficult to align the cone with the Eclips® Filter retrieval hook, one may use a guide wire to facilitate advancement of cone over the hook.

Withdraw the introducer catheter and cone shaft away from the retrieval hook. Insert a 0.035” 260 cm guide wire through the central lumen (a stiff guide wire with J or angled tip is recommended). Advance the guide wire through the cone and through the filter near the retrieval hook. After it has been confirmed that the guide wire is in contact with or in close proximity to the retrieval hook, advance the cone over the guide wire to the retrieval hook. Advance the introducer catheter to slightly collapse the cone over the retrieval hook. Withdraw the guide wire into the introducer shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each Eclips® Filter is supplied preloaded in a storage tube. Each Eclips® 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 disconnected, do not attempt to re-assemble or reload it.

WARNING: After use, the Eclips® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Eclips® Filter should be stored in a cool (room temperature), dry, dark 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 purchase price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

WARNING: After use, the Eclips® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Eclips® Filter should be stored in a cool (room temperature), dry, dark 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 purchase price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

WARNING: After use, the Eclips® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Eclips® Filter should be stored in a cool (room temperature), dry, dark 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 purchase price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

WARNING: After use, the Eclips® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Eclips® Filter should be stored in a cool (room temperature), dry, dark 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 purchase price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

WARNING: After use, the Eclips® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Eclips® Filter should be stored in a cool (room temperature), dry, dark 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 purchase price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

WARNING: After use, the Eclips® Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Eclips® Filter should be stored in a cool (room temperature), dry, dark 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 purchase price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.
**Eclipse® Vena Cava Filter**

**Eclipse Filter Femoral Delivery Device**

**Eclipse Filter Introducer Sheath With Dilator**

**Femoral**

**Contents:**

1. Eclipse Filter - Femoral Delivery Device
1. 7 Fr. Introducer Sheath 48cm Long with Dilator

Use By

Lot Number

**REF** Catalogue Number

Attention, See Instructions for Use

Sterilized Using Ethylene Oxide

Bard, Eclipse and G2 and Recovery Cone 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, 6,258,026 and 6,156,055. Other U.S. and foreign Patents Pending.

Copyright © 2013 C. R. Bard, Inc. All rights reserved. Printed in U.S.A.

Non-Pyrogenic

Keep Dry

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use If Package Is Damaged

MR Conditional

Recommended Guidewire

Manufacturer

Does Not Contain Latex

**Non-Pyrogenic**