The Eclip® Filter is a variable interruption device designed to prevent pulmonary embolism. The unique design and material of the Eclip® Filter provide filtering efficiency and allow percutaneous placement through an angiographic introducer with minimum entry site difficulties. The placement procedure is quick and simple to perform. The Eclip® Filter is an electropolished version of the G2® X Filter. This product is not manufactured with latex.

The Eclip® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm. The jugular/subclavian system allows for placement of the Eclip® Filter via a jugular or subclavian vein approach. The jugular/subclavian system consists of a dilator and introducer set and a delivery device. The delivery device accepts a 0.038” guidewire and allows for an 800 psi maximum pressure contrast power injection. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the Eclip® Filter. The delivery device contains a saline cap that mechanically separates the filter anchors from one another in a unique pattern to prevent leg entanglement. The Eclip® Filter is deployed within the delivery device. Once the introducer sheath is within position, the delivery device is advanced through the introducer sheath until the introducer and delivery hubs snap together. The safety clip is then removed. The introducer hub is pulled back over the pusher wire handle to unsheath and release the Eclip® Filter allowing it to recover to its predetermined shape. The Eclip® Filter is designed to act as a permanent filter. When clinically indicated, the Eclip® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Eclip® Filter's anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed (reference Optional Procedure for Filter Removal for specific removal instructions).

MRI Safety: The Eclip® Filter was determined to be MR-conditional based on testing that was conducted on the G2® X Filter. The Eclip® 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 safely assessed immediately after placement under the following conditions:

- Static magnetic field of 3-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-W/kg for 15 minutes of scanning.
- Maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/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-W/kg for 15 minutes of scanning in a phantom containing a transmitting-receiving body coil (Excite, Software G3.0-05SB, General Electric Healthcare, Milwaukee, WI).

MRI 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

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

The Eclip® Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration to prevent leg entanglement. 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-W/kg for 15 minutes of scanning.

The G2® X Filter is illustrated in Figure 1. The Delivery System consists of a filter and delivery device. The G2® X Filter is an electropolished version of the G2® X Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

This product is not manufactured with latex.

The Eclip® Filter is an MR Conditional. A patient with this implant can be safely assessed immediately after placement under the following conditions:

- Maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

The G2® X Filter was determined to be MR-conditional based on testing that was conducted on the G2® X Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

The Eclip® Filter System - Jugular/Subclavian consists of the filter and delivery system. The Eclip® Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach. The Eclip® Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration to prevent leg entanglement. 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-W/kg for 15 minutes of scanning.

The G2® X Filter was determined to be MR-conditional based on testing that was conducted on the G2® X Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.
1. Do not attempt to remove the Eclip® Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall. NOTE: It is possible that complications such as those described in the “Warnings,” “Precautions,” or “Potential Complications” sections of this Instructions for Use may result in improper Eclip® Filter orientation within the IVC.

2. Position the retrieval hook 1 cm below the lowest renal vein. Venacavography must always clearly show the wall of the IVC, may be misleading.

3. When measuring caval dimensions, consider an angiographic catheter or Intravascular Y-adapter before connecting the system to the introducer catheter to ensure that the cone has been positioned for optimal placement, before deploying the filter.

4. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution #7).

5. If a large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the filter from this point may occur with a significant risk of embolization.

6. Position the retrieval hook 1 cm below the lowest renal vein. Venacavography must always clearly show the wall of the IVC, may be misleading.

7. When measuring caval dimensions, consider an angiographic catheter or Intravascular Y-adapter before connecting the system to the introducer catheter to ensure that the cone has been positioned for optimal placement, before deploying the filter.

8. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate filter retrieval. 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 thoracic spine in a caudally directed curve. Responsible medical practice and applicable local, state and federal laws and regulations.

10. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be referred to a cardiologist for evaluation.

11. If resistance is encountered during the insertion procedure, withdraw the guidewire and check the introducer, which may interfere with delivery device advancement.

12. Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal utilizing endovascular and/or surgical techniques.

13. After use, the Eclip® 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.

14. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution #7).

15. It is very important to maintain introducer patency with a saline flush to prevent occlusion of the guidewire and introducer catheter.

16. Aspirating the introducer sheath while leaving the guidewire in place may lead to the creation of a thrombus which may interfere with delivery device advancement.

17. To affect the recoverability of the device and result in the clinician’s decision to have the device removed permanently implanted.

18. Persons with allergic reactions to nickel may suffer an allergic response to this material.

19. Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper Eclip® Filter orientation within the IVC.

20. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate filter removal. Refer to the Optional Procedure for Filter Removal section for details.

21. Do not attempt to remove the Eclip® Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall. NOTE: It is possible that complications such as those described in the “Warnings,” “Precautions,” or “Potential Complications” sections of this Instructions for Use may result in improper Eclip® Filter orientation within the IVC.

22. Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal utilizing endovascular and/or surgical techniques.

23. Filter fractures are a known complication of vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

24. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution #7).

25. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the filter from this point may occur with a significant risk of embolization.

26. When using the Eclip® Filter Implantation System, the cone must be fully retracted into the introducer which may interfere with the introducer catheter to ensure that the cone can be properly delivered through the catheter.

27. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution #7).

28. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the filter from this point may occur with a significant risk of embolization.
Advancement.

To prevent occlusion of the introducer, which may interfere with delivery device implantation to ensure proper advancement.

NOTE: A 0.038” guidewire is used to guide the dilator/introducer assembly beyond the vein on the opposite side. A small thrombus may be bypassed by 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 guidewire and check vein patency fluoroscopically with a small injection of contrast medium.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium.

5. Insert a J-tipped guidewire and gently advance it into the inferior vena cava.

4. Nick the skin with a #11 blade and perform venipuncture with an 18G entry needle.

3. Select and open the carton and outer pouch. Open the introducer sheath and dilator inner pouch.

2. Prep, drape, and anesthetize the skin puncture site in standard fashion.

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 thrombus.

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 thrombus.

2. Prep, drape, and anesthetize the skin puncture site in standard fashion.

3. Select and open the carton and outer pouch. Open the introducer sheath and dilator inner pouch.

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 introduction 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 shipped 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 French introducer sheath together with its tapered dilator over the guidewire and into the inferior vena cava.

NOTE: A 0.038” guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

6. Remove the guidewire and 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, occlusion of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

All of the above complications may be 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

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

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

• 18G entry needle

• Saline

• Contrast medium

• Sterile venous access set: scalpel, #11 blade, local anesthesia, drapes, etc.

• 1.0 Ecologic® Filter Jugular/Subclavian System that contains:
  -One 55 cm, 10 French I.D. introducer and dilator set
  -One delivery device with pre-loaded Ecologic® Filter
  -0.038” 3 mm J-tipped Guidewire, 110 cm long or longer

• Phlebectomy set

• 20 French introducer sheath together with its tapered dilator over the guidewire and into the inferior vena cava.

FIG. 2. \( \text{ECOLOGIC} \) \( \text{®} \) Filter Jugular/Subclavian System that contains:

1.0 Ecologic \( \text{®} \) Filter Jugular/Subclavian System that contains:

- One 55 cm, 10 French I.D. introducer and dilator set
- One delivery device with pre-loaded Ecologic \( \text{®} \) Filter
- 0.038” 3 mm J-tipped Guidewire, 110 cm long or longer

- 18G entry needle

- Saline
NOTE: IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).

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 Eclips® 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 3). 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.

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 5). 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 Eclips® Filter.

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

12. Under fluoroscopic guidance, position the system for optimal placement. The distal end of the pusher pad provides a radiopaque indicator for positioning purposes (Reference Figure 6). NOTE: Do not remove the safety clip until step #13.

13. Remove the safety clip from the delivery device.

14. Insert and advance the delivery device through the introducer sheath until the introducer and delivery device hubs snap together (Reference Figure 5). PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the Eclips® Filter.

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

15. Under fluoroscopic guidance, separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.

16. Perform a venacavogram to confirm satisfactory deployment before terminating the procedure (typically 30mL of contrast medium at 15mL/s).

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:

Clinical Experience
A clinical study involving 100 patients was conducted to assess the safety of removal of the G2® Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement). The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis. The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 8 depicting the time to retrieval.

Figure 8: Distribution of Filter Indwell Time in Retrieved Subjects
If the 8F attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Coax® Removal System due to filter tilting leading to embedding of the filter apex into the venous wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be involved in a filter that was retrieved in spite of tilt and associated embedding of filter apex into the vena caval wall. The filter arms were found to be trapped within the filter retrieval hook.

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

NOTE: Under fluoroscopic guidance, ensure that the loop diameter of the snare catheter must be cephalad to the retrieval hook.

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 vena caval wall.

WARNING: Remove the Eclipse® Filter using an intravascular snare or the Recovery Coax® Removal System only.

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

Follow-up Venacavogram

14. A follow-up venacavogram 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 the Recovery Coax® Removal System Equipment Required

The following equipment is required for use:

• One Recovery® Coax® Removal System catheter that contains:
  – One Y-adapter with Recovery Coax® Removal System and pusher delivery system
  – One 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer

• One 18-gauge entry needle

• Heparinized saline

If the physician chooses to use the Recovery Coax® 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. Insert the guidewire of choice into the retrieval sheath using the guidewire tip-straightener.

3. Prepare all other procedure components according to the manufacturers’ Instructions for Use.

4. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.

5. Select the appropriate loop diameter size of the intravascular snare.

6. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.

7. Insert the guidewire with its tapered dilator over the guidewire.

8. Pre-dilate the accessed vessel with a 12 French dilator.

9. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.

10. Remove the guidewire.

11. Insert and advance the intravascular snare assembly through the sheath until it protrudes out approximately 3cm cephalad to the filter retrieval hook.

12. The retrieval of the Eclipse® Filter using an intravascular snare is illustrated Figure 9 A-E.

Figure 9 A-E: Retrieval of Eclipse® Filter using an Intravascular Snare, Illustrated

12. Advance the guidewire into the IVC under fluoroscopic guidance such that it is cephalad to the filter.

13. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.

14. Remove the guidewire.

15. While keeping tension of the sheath, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 9 E: Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the sheath is fully collapsed inside the sheath, retract the complete system as a unit through the sheath.

16. Insert the Eclipse® Filter Retrieval System and pusher delivery system

17. While keeping tension of the sheath, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 9 F: Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is cephalad to the filter.

18. While keeping tension of the sheath, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 9 G: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

19. Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

20. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit through the sheath.

21. Remove the Eclipse® Filter from the retrieval sheath using an intravascular snare.


23. Open Kit B Introducer Catheter Pusher Delivery System package.

24. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.

25. Insert the guidewire and gently advance it to the location of the filter apex.

26. Remove the venipuncture needle over the guidewire.

27. Pre-dilate the accessed vessel with a 12 French dilator.

28. Advance the introducer catheter and dilator set together with its tapered dilator over the guidewire and into the vein, such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.
The introducer catheter has a radiopaque marker at the distal end of the catheter shaft. The introducer catheter should be stored in a cool environment, dark, dry, and horizontal to maintain introducer catheter patency.

Use of a Guidewire

Guidewire - Assisted Technique

Guidewire-assisted methods may be used. Due to anatomical variances with respect to the position of the vena cava, fluoroscopy or other imaging techniques may be used. The guidewire is usually placed into the vena cava using a procedure similar to that described under the guidewire-assisted retrieval method.

Follow-up Venacavogram

Follow-up venacavogram is recommended when radiopaque markers or other imaging methods are used to facilitate advancement of cone over the retrieval hook.

Figure 10 A-E: Retrieval of Eclipse® Filter using Recovery Cone® Removal System, Illustrated

In the event 36 months have elapsed between an issue or revision date and a revision number for these instructions are included for the user's reference. Check for thrombus within the filter to maintain introducer catheter patency. Flushing is recommended. It is recommended to fluoroscopically obtain image(s) of the filter in AP and lateral views during the retrieval procedure.

Flushing intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.

Perform a standard inferior vena cava (IVC) (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 Eclipse® Filter.

Recovery Cone® Removal System Insertion and Delivery

11. Insert a guidewire into the pusher shaft and retracting the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight line to minimize friction.

12. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.

13. Continue advancing the cone over the retrieval hook by holding the introducer catheter stationary and advancing the pusher shaft in one, smooth, continuous motion.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight line to minimize friction.

15. Insert a guidewire into the pusher shaft and retracting the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight line to minimize friction.

16. After it has been confirmed that the guidewire is in contact with or in close proximity to the retrieval hook, withdraw the guidewire into the pusher shaft. Continue removing the filter as described in step 17.

17. The retrieval of the Eclipse® Filter using a Recovery Cone® Removal System is illustrated in Figure 10 A-E.
References:
Eclipse Vena Cava Filter

Eclipse Filter Jugular/Subclavian Delivery Device

Eclipse Filter Introducer Sheath With Dilator

Jugular/Subclavian

Contents:
(1) Eclipse® Filter Jugular/Subclavian Delivery Device
(1) 10 Fr. Introducer Sheath 55cm Long With Dilator

Use By

Lot Number

REF Catalogue Number

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

Attention, See Instructions For Use

Sterilized Using Ethylene Oxide

Keep Dry

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use If Package Is Damaged

MR Conditional

Recommended Guidewire

Does Not Contain Latex

Non-Pyrogenic

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