

RECOVERY CONE® Removal System

for use with the

G2® X Filter, G2 EXPRESS™ Filter, G2® Filter and

RECOVERY® Filter

Foreign Body Retrievals



ENGLISH

Instructions for Use

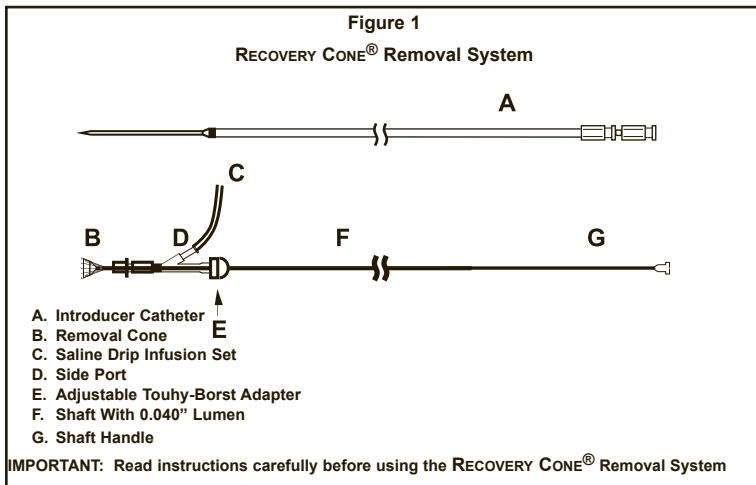
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The RECOVERY CONE® Removal System is intended to percutaneously remove the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter, RECOVERY® Filter or a foreign body as indicated. The cone is designed to advance through its 75 cm, 10 French I.D. introducer catheter using a flexible, Pebax shaft. A reinforced cone at the end of the shaft is designed to collapse over the tip of the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter, RECOVERY® Filter or a foreign body for percutaneous removal. This cone is reinforced by a wire basket. The introducer sheath has a radiopaque marker for enhanced visualization. The introducer sheath is used to collapse the removal cone over the G2® X Filter, G2 EXPRESS™, G2® or RECOVERY® Filter tip or a foreign body and pull the collapsed cone into the sheath to remove the Filter or foreign body.

B. Device Description

The RECOVERY CONE® Removal System consists of the Removal Cone and Introducer Catheter (Figure 1). The cone consists of a reinforced urethane cone, 15-mm in diameter. The cone is connected to a plastic (Pebax) shaft and handle. The shaft has a central lumen that accommodates a 0.035" guidewire. A Touhy-Borst Y-adapter is used to connect the cone to the Introducer Catheter and to a saline flush or drip. The Introducer Catheter consists of a 10 French I.D. introducer sheath and dilator. The introducer sheath has a radiopaque marker for enhanced fluoroscopic visualization.



C. Indications for Use

The RECOVERY CONE® Removal System is intended for use to percutaneously remove the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter and the RECOVERY® Filter from the vena cava, or facilitate the retrieval of foreign objects from the peripheral vascular system.

D. Contraindications for Use

None known.

E. Warnings

- Do not attempt to remove the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® Filter if significant amounts of thrombus are trapped within the Filter or if the Filter tip is embedded within the vena caval wall.
- Do not use excessive force when manipulating the cone. Excessive force may damage the catheter or other parts of the RECOVERY CONE® Removal System.
- When attempting to retrieve a G2® Filter or RECOVERY® Filter, only use the RECOVERY CONE® Removal System. Use of other devices has resulted in recurrent pulmonary embolism.
- Ensure adequate clearance in small vessels before deploying the RECOVERY CONE® Removal System.
- Withdrawal of large foreign bodies may require a cut-down at the peripheral site.
- If resistance is experienced during the retrieval procedure, check the captured Filter or foreign body and introducer sheath using fluoroscopy.
- Contents are supplied sterile. Do not use if sterile barrier is damaged. If

damage is found, contact your Bard representative.

- Single Patient Use Only. Do not reuse, reprocess or resterilize.
- 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 small lumina, joints, and/or crevices between components – are 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 indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.
- Do not resterilize. After reesterilization, 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 reesterilization 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.
- Do not use the device or accessories after the expiration date.

F. Precautions

- Anatomical variances may complicate insertion and deployment of the device. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemplating removing the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter, RECOVERY® Filter or a foreign body from the inferior vena cava with the RECOVERY CONE® Removal System in patients with significant kyphoscoliotic spinal deformations because the vessel may follow the general course of such anatomic deformations. This may require advanced techniques to remove the Filter or foreign body.
- After use, the RECOVERY CONE® Removal System and its accessories and insertions supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.
- The size and location of the foreign body may impact its ability to be successfully captured and retrieved.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications. Possible complications of RECOVERY CONE® Removal System usage include, but are not limited to, the following:

- Pulmonary Embolism
- Embolization
- Damage to the artery or vein
- Vessel tear or disruption
- Device entrapment
- Hematoma at the access site
- Infection
- Stroke

NOTE: Certain complications, including but not limited to filter tilt, filter fracture, and filter endothelialization may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

NOTE: It is possible that complications such as those described in the "Warnings, Precautions and Potential Complications" section of this IFU may affect the recoverability of the device or foreign body and result in the clinician's decision to have the device or foreign body remain permanently implanted.

H. Equipment Required

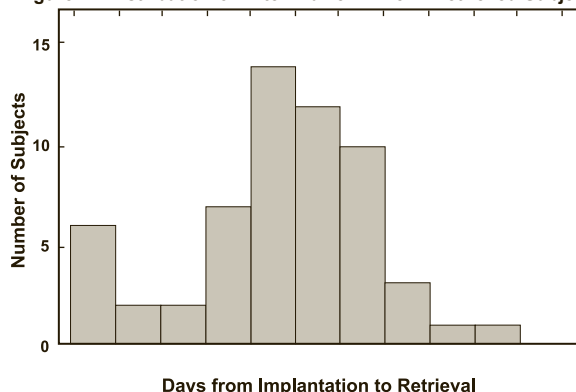
The following equipment is required for use:

- RECOVERY CONE® Removal System that contains:
 - One 75 cm, 10 French I.D. delivery sheath and dilator set
 - One Y-adapter with removal cone and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

I. Clinical Experience with the G2® Filter

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 (Figure 2) depicting the time to retrieval.

Figure 2: Distribution of Filter Indwell Time in Retrieved Subjects

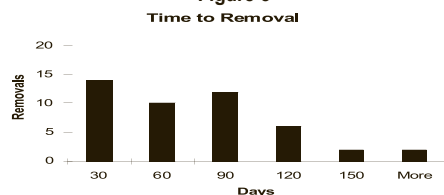


Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the removal cone due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was 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 penetrating the caval wall. The filter was successfully retrieved and the pain resolved. Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

J. Clinical Experience with the RECOVERY® Filter

The RECOVERY® Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment. Of the 58 Filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with Filters in place of causes unrelated to Filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days (see histogram in Figure 3).

Figure 3



Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein jugular (n=1). One was removed surgically during a cancer operation where the mass was impinging on the Filter. The two methods described in the Instructions for Use were used to retrieve the Filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the RECOVERY CONE® Removal System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other adverse event reported was a fractured Filter arm and hook. This Filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The Filter was retrieved, minus the hook.

Table 1

Clinical Experience Summary Table	
RECOVERY® Filters Implanted	58
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	8-89 years (52 years average)
Reason for Filter Placement	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	3
Prophylaxis	2
Time to removal	1-161 (60 days average)
Follow-up post-removal	1-901 (325 average)
Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1
Asymptomatic pulmonary embolism post-removal	1

K. Directions for Use – G2® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® Filter Removal

(See Section L. for Foreign Body Retrieval Directions for Use)

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.
3. Select and open the RECOVERY CONE® Removal System package. Open Kit A Introducer Catheter package.
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® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® 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, such that the tip of the sheath is approximately 3cm cephalad to the filter tip.

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. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the Filter. If there is significant thrombus within the Filter, do not remove the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® Filter.

RECOVERY CONE® Removal System Insertion and Delivery

11. Remove the cone and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Loosen the Touhy-Borst and slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: 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 easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and Filter delivery system should be held in a straight line to minimize friction.
16. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
17. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the shaft and retracting the catheter.

Capture and Removal of the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter or the RECOVERY® Filter

18. The capture of the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® Filter is illustrated in - Figure 4 A-E:

Figure 4 A-E

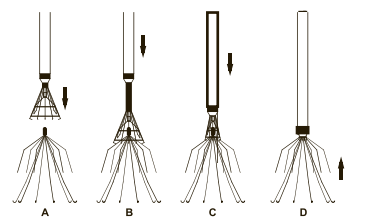


Figure A: After the cone has been opened superior to the Filter, advance the cone over the Filter by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the Filter tip.

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.

NOTE: It is recommended to fluoroscopically image the filter in AP and lateral views during retrieval.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed after 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® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® Filter, guidewire assisted techniques may be used.

Use of a Guidewire

If it is difficult to advance the RECOVERY CONE® over the G2® X Filter, G2 EXPRESS™ Filter, G2® Filter or RECOVERY® Filter tip, one may use a guidewire to facilitate advancement of the cone. Withdraw the introducer sheath and cone shaft away from the Filter tip. Insert a 0.035" 260cm guidewire through the central lumen (a stiff guidewire with J or angled tip 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 sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 18.

L. Directions for Use – Foreign Body Retrieval

1. Select a suitable entry site to access the foreign body.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the RECOVERY CONE® Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform puncture with an 18 gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the foreign body.
6. Remove the entry needle over the guidewire.
7. Pre-dilate the insertion site with a 12F dilator and then advance the introducer catheter together with its tapered dilator over the guidewire to the target area.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

8. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently with saline to maintain introducer catheter patency.
9. Remove the cone and pusher system from Kit B.
10. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
11. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: 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 easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

12. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
13. Attach the Y-adapter with the collapsed cone to the introducer catheter.
14. Advance the cone by moving the pusher shaft forward through the introducer catheter.
15. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter.
16. Open the cone by stabilizing the shaft and retracting the catheter.
17. After the cone has been opened adjacent to the foreign body, advance the cone over foreign body by holding the introducer catheter stationary and advancing the pusher shaft.
18. Close the cone over the foreign body by advancing the introducer catheter over the cone while holding the pusher shaft stationary.
19. Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
20. With the cone collapsed over the foreign body, remove the foreign body by stabilizing the introducer catheter and retracting the pusher shaft in one smooth, continuous motion.

M. How Supplied

Each RECOVERY CONE® Removal System is supplied preloaded. Each RECOVERY CONE® Removal System is sterile and non-pyrogenic unless package has been opened or damaged, and is ready to be used for single use only. The RECOVERY CONE® Removal System is pre-assembled. Do not attempt to re-sterilize this product. This product should be stored in a cool (room temperature), dry place.

N. 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.

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Some 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 country.

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet.

In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.



RECOVERY CONE® Removal System



Do Not Re-sterilize.



RECOVERY CONE® Removal System Introducer Catheter



Do Not Use If Package Is Damaged Or Opened.

REF

Catalog Number



Recommended Guidewire



Use By



Manufacturer

LOT

Lot Number



Contents: REF: FBRC Kit A: One (1) 10 Fr. Introducer Catheter 75cm Long with Dilator Kit B: One (1) Recovery Cone Removal System



Attention, See Instructions for Use



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STERILE EO

Sterilized By Using Ethylene Oxide




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NON PYROGENIC

Non-pyrogenic



Single Use. Do Not Reuse.

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