BARD®
Snare Retrieval Kit

Instructions for Use

BARD | PERIPHERAL VASCULAR

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 Bard® Snare Retrieval Kit is intended to percutaneously remove all Bard® optional vena cava filters with a retrieval hook. The retrieval kit includes a single loop snare and two catheters for use with either a dual or single sheath retrieval technique, depending on the Bard® optional vena cava filter being retrieved:

Dual Sheath Technique

The Denali® Filter must be retrieved using the dual sheath technique.

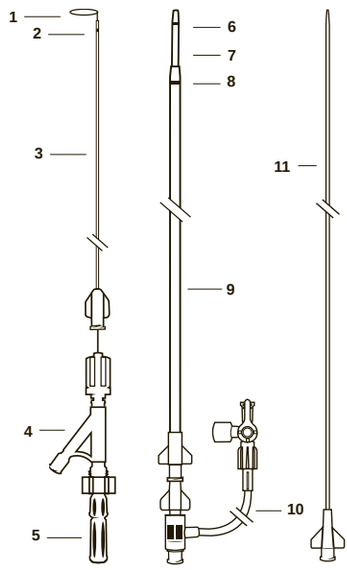
Single Sheath Technique

The Meridian®, Eclipse®, and G2®X Filters can be retrieved using the single sheath technique.

B. Device Description

The Bard® Snare Retrieval Kit consists of a nitinol snare with 6 French I.D. snare catheter assembly, 9 French I.D. retrieval sheath with dilator assembly, and 11 French I.D. access sheath (Figure 1). The nitinol snare has a 20 mm diameter (fully expanded) radiopaque loop and comes preloaded in the snare catheter. The snare catheter, retrieval sheath, and access sheath have radiopaque marker bands at the distal ends for enhanced fluoroscopic visualization. This product is not made with natural rubber latex.

Figure 1: Bard® Snare Retrieval Kit



1. Snare with 20 mm loop
2. Marker Band
3. 6F Snare Catheter
4. 6F Touhy-Borst Adapter
5. Torquer
6. Marker Band
7. 9F Retrieval Sheath
8. Marker Band
9. 11F Access Sheath
10. Hemostatic Valve
11. 8.6F Dilator

IMPORTANT: Read instructions carefully before using the Bard® Snare Retrieval Kit

C. Indications for Use

The Bard® Snare Retrieval Kit is intended for use to percutaneously remove all Bard optional vena cava filters with a retrieval hook.

D. Contraindications for Use

None known.

E. Warnings

1. **The Bard® Snare Retrieval Kit is intended for filter retrieval via jugular approach.**
2. **Do not use the device or accessories after the expiration date.**
3. **Contents are supplied sterile. Do not use if sterile barrier is damaged. If damage is found, contact your Bard representative.**
4. **Never advance the guidewire, snare assembly, or introducer sheath/dilator or deploy the snare without fluoroscopic guidance.**
5. **Do not use excessive force when manipulating the snare. Excessive force may damage the snare or other parts of the snare system.**
6. **Do not attempt to remove the filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall.**
7. **If resistance is experienced during the retrieval procedure, check the captured filter and retrieval sheath using fluoroscopy.**
8. **Never redeploy a removed filter.**
9. **After use, the Bard® Snare Retrieval Kit accessories, and insertion supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**
10. **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.**
11. **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.**
12. **Diethylhexylphthalate (DEHP) is a plasticizer used in some polyvinyl chloride medical devices. DEHP has been shown to produce a range of adverse effects in experimental animals, notably liver toxicity and testicular atrophy. Although the toxic and carcinogenic effects of DEHP have been well established in experimental animals, the ability of this compound to produce adverse effects in humans is controversial. Bard has not assessed any related adverse effects in relation to the exposure to DEHP when this device is used with neonates, infants, pregnant or breast feeding women. It is the responsibility of the physician to assess the risks associated with the use of a device containing DEHP.**

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

F. Precautions

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. Anatomical variances may complicate the removal procedure. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
3. Spinal deformations: It is important to exercise care when contemplating removing the filter from the inferior vena cava with the Bard® Snare Retrieval Kit 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.
4. Manipulation of product requires fluoroscopic control.
5. Care should be taken when using a snare to engage the retrieval hook of the filter, avoiding engagement of filter arms or legs.

6. Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent entrapment.
7. The retrieval of the Denali® Filter should only be performed using minimum 9F I.D./11F I.D. dual retrieval sheaths. Misuse of these devices or improper retrieval technique may result in intimal injury or caval narrowing.
8. Care should be taken when advancing the 9F retrieval sheath in the caudal direction to avoid completely covering the arms and legs of the filter.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications. Possible complications of Bard® Snare Retrieval Kit usage include, but are not limited to, the following:

- Pulmonary embolism
- Embolization
- Detachment of components
- Air embolism
- Damage to the artery or vein
- Vessel tear or disruption
- Hemorrhage
- Intimal tear
- Vessel injury
- Guidewire entrapment
- Infection
- Caval thrombosis/occlusion
- Insertion site thrombosis
- Extravasation of contrast material at time of venacavogram
- Hematoma or nerve injury at the puncture site
- Restriction of blood flow
- Stenosis at implant site
- Stroke
- Blood loss
- Pain

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.

H. Equipment Required

The following equipment is required for use:

- Bard® Snare Retrieval Kit that contains:
  - One nitinol snare with 20 mm diameter radiopaque loop (fully expanded) and snare catheter assembly
  - One 63 cm, 9F I.D. retrieval sheath with dilator assembly
  - One 58 cm, 11F I.D. access sheath
- 0.035" straight guidewire, 110 cm long or longer
- 12 or 14 French dilator
- 18 gauge entry needle
- Heparinized saline
- Contrast medium
- Sterile syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

I. Pre-Determination of Implant

1. Determine filter type by taking a spot film.
2. If Bard optional filter is determined to be the Denali® Filter, continue to **Section J: Directions for Use: Dual Sheath Technique – Denali® Filter Retrieval.**
3. If Bard optional filter is determined to be Meridian®, Eclipse®, or G2®X Filter, continue to either **Section K: Directions for Use: Single Sheath Technique – Meridian®, Eclipse® and G2®X Filter Retrieval.**

J. Directions for Use: Dual Sheath Technique – Denali® Filter Retrieval

WARNING: Never advance the guidewire, snare assembly, or introducer sheath/dilator or deploy the snare without fluoroscopic guidance.

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. (The right jugular vein is recommended.)
2. Remove all components from packaging using sterile technique. Attach the Touhy-Borst adapter to the snare catheter and retract the snare loop until it is completely inside the catheter. Flush all components with heparinized saline or suitable isotonic solution prior to use.
3. Insert the kit dilator through the hemostatic valve and 9F retrieval sheath ensuring that the hubs connect properly.
4. Insert the dilator / retrieval sheath assembly into the 11F access sheath ensuring that the hubs connect properly.
5. Prepare all other procedural equipment required according to the manufacturers' Instructions for Use.
6. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.

PRECAUTION: Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent entrapment.

7. Perform a standard inferior venacavogram in AP and lateral views (typically 30 mL of contrast medium at 15 mL/s). Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.

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

8. Pre-dilate the accessed vessel with a 14F dilator.
9. Introduce the dilator / retrieval sheath / access sheath assembly over the wire such that the tip of the sheath is approximately 3 cm cephalad to the filter retrieval hook
10. Remove the dilator and guidewire together.
11. Insert and advance the snare assembly (with retracted snare loop inside the snare catheter) through the hemostatic valve and retrieval sheath until it protrudes out of the sheath such that the marker band of the snare catheter is cephalad to the filter retrieval hook.
12. Advance the snare until the 20 mm loop has fully expanded above the filter retrieval hook.
13. The retrieval of the Denali® Filter using the dual sheath retrieval technique is illustrated in Figure 2 A-F:

Figure 2 A-F: Dual Sheath Retrieval of the Denali® Filter using the Bard® Snare Retrieval Kit, Illustrated

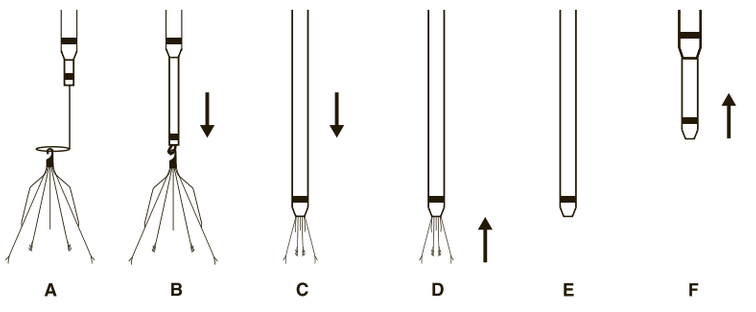


Figure 2 A: Slowly advance the snare loop forward over the filter retrieval hook.

Figure 2 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

NOTE: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the retrieval hook and that the retrieval hook, retrieval catheter and snare are aligned. Be careful to snare the apex of the retrieval hook, not the side. The marker band of the snare catheter must be cephalad to the filter retrieval hook.

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

Figure 2 C: Advance the retrieval sheath in the caudal direction until it covers half of the filter.

PRECAUTION: Care should be taken when advancing the 9F retrieval sheath in the caudal direction to avoid completely covering the arms and legs of the filter.

Figure 2 D: While keeping tension of the snare, hold the retrieval sheaths stationary and withdraw the filter into the sheath by retracting the snare.

Figure 2 E: Retract the snare until the filter and cranial anchors are completely contained inside the retrieval sheath.

Figure 2 F: Once the filter is fully collapsed inside the retrieval sheath, retract the filter, snare, and retrieval sheath as one unit out through the 11F access sheath.

14. Remove the filter from the retrieval sheath and examine the filter to ensure that the complete filter has been removed.

NOTE: Take care when handling the filter as the anchors are sharp.

15. A follow-up venacavogram should be performed prior to withdrawing the 11F access sheath (typically 30 mL of contrast medium at 15 mL/s).

Precaution: Do not use the 9F retrieval sheath for imaging or flushing once the filter has been removed.

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

K. Directions for Use: Single Sheath Technique – Meridian®, Eclipse® and G2®X Filter Retrieval

WARNING: Never advance the guidewire, snare assembly, or introducer sheath/dilator or deploy the snare without fluoroscopic guidance.

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. (The right jugular vein is recommended.)
2. Remove all components from packaging using sterile technique. Attach the Touhy-Borst adapter to the snare catheter and retract the snare loop until it is completely inside the catheter. Flush all components with heparinized saline or suitable isotonic solution prior to use.
3. Insert the kit dilator through the hemostatic valve and 9F retrieval sheath ensuring that the hubs connect properly.
4. Prepare all other procedural equipment required according to the manufacturers' Instructions for Use.
5. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.

PRECAUTION: Care should be taken when advancing a guidewire or imaging catheter through a filter to prevent entrapment.

6. Perform a standard inferior venacavogram in AP and lateral views (typically 30 mL of contrast medium at 15 mL/s). Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.

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

7. Pre-dilate the accessed vessel with a 12F dilator.
8. Introduce the dilator / retrieval sheath assembly over the wire such that the tip of the sheath is approximately 3 cm cephalad to the filter retrieval hook
9. Remove the dilator and guidewire together.
10. Insert and advance the snare assembly (with retracted snare loop inside the snare catheter) through the hemostatic valve and retrieval sheath until it protrudes out of the sheath such that the marker band of the snare catheter is cephalad to the filter retrieval hook.
11. Advance the snare until the 20 mm loop has fully expanded above the filter retrieval hook.
12. The retrieval of a Bard® Optional Filter using the single sheath retrieval technique is illustrated in Figure 3 A-E:

Figure 3 A-E: Single Sheath Retrieval of a Bard® Optional Filter using the Bard® Snare Retrieval Kit, Illustrated

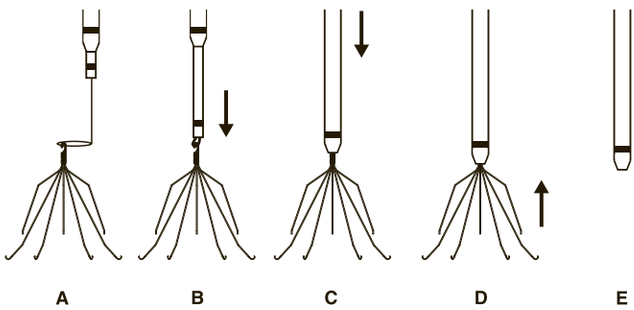


Figure 3 A: Slowly advance the snare loop forward over the filter retrieval hook.

Figure 3 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

NOTE: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the retrieval hook and that the retrieval hook, retrieval catheter and snare are aligned. Be careful to snare the apex of the retrieval hook, not the side. The marker band of the snare catheter must be cephalad to the filter retrieval hook.

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

Figure 3 C: Advance the 9F retrieval sheath in the caudal direction until the retrieval hook is contained within.

Figure 3 D: While maintaining tension on the snare and snare catheter hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the snare and snare catheter together.

Figure 3 E: Continue retracting the snare until the filter is completely contained inside the retrieval sheath. Once the filter is fully contained inside the retrieval sheath, fully retract the snare assembly with filter as one unit.

13. Examine the filter to assure that the complete filter has been removed.
14. A follow-up venacavogram should be performed prior to withdrawing the retrieval sheath (typically 30 mL of contrast medium at 15 mL/s).
15. Remove the retrieval sheath and apply routine compression over the puncture site in the usual way to achieve hemostasis.

L. How Supplied

Each Bard® Snare Retrieval Kit is sterile and non-pyrogenic unless package has been opened or damaged, and is ready to be used for single use only. Do not attempt to re-sterilize this product. This product should be stored in a cool (room temperature), dry place.

M. 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 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.

Nitinol Snare with Snare Catheter Assembly

Retrieval Sheath/Access Sheath Assembly

Dilator

Snare Loop

Contents
(1) 20 mm Nitinol Loop Snare with Snare Catheter Assembly
(1) 63 cm 9F I.D. Retrieval Sheath with Dilator Assembly
(1) 58 cm 11F I.D. Access Sheath

Catalogue Number

Use By

Lot Number

Attention, See Instructions for Use

Not Made with Natural Rubber Latex

Do Not Resterilize

Non-Pyrogenic

Sterilized Using Ethylene Oxide

Keep Dry

Single Use

Keep Away From Sunlight

Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised

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Distributed by

Manufacturer

Contains or Presence of Phthalates: Diethylhexl Phthalate

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