Instructions for Use
### 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 venous caval 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 venous caval filter being retrieved.

#### 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.

#### C. Indications for Use

The **Bard**® Snare Retrieval Kit is intended for use to percutaneously remove all Bard optional venous caval 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. Never try 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.

6. Do not attempt to remove the filter if 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 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.

11. Do not resterilize. After resterilization, the sterility of the device 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.

### IMPORTANT:

Read instructions carefully before using the **Bard**® Snare Retrieval Kit.

#### Dual Sheath Technique

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

#### Single Sheath Technique

The **Meridian**, **Equus**, and **G2** Filters can be retrieved using the single sheath technique.

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**Figure 1: **Bard® Snare Retrieval Kit

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<td>Marker Band</td>
<td>6F Snare Catheter</td>
<td>6F Touhy-Borst Adapter</td>
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<td>9F Retrieval Sheath</td>
<td>8F Marked Sheath</td>
<td>11F Access Sheath</td>
<td>Hemostatic Valve</td>
<td>11.6F Dilator</td>
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**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.** Torque

**6.** Marker Band

**7.** 9F Retrieval Sheath

**8.** 8F Marked Sheath

**9.** 11F Access Sheath

**10.** Hemostatic Valve

**11.** 11.6F Dilator

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### Potential Complications

It is possible that complications such as those described in the “Warnings”, “Precautions”, or “PotentialComplications” 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 other parts of the snare system.
6. Care should be taken when advancing a guide wire or imaging catheter through a filter to prevent entrapment.

7. The retrieval of the **Bard** 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 entrapment 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**
- **Guide wire entrapment**
- **Infection**
- **Caval thrombosis/thrombus**
- **Insertion site thrombosis**
- **Extravasation of contrast material at time of venacavogram**
- **Hematoma or nerve injury at the puncture site**
- **Restriction of blood flow**
- **Silence at implant site**
- **Stroke**
- **Pain**

NOTE: Certain complications, including but not limited to filter lift, 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 or suitable isotonic solution prior to use.

- **Kimray**, **Ecce**, or **G2X** Filter, continue to either Section K: Directions for Use: Single Sheath Technique – **Kimray**, **Ecce**, or **G2X** Filter Retrieval.

- 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
- Plastic 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 **Bard** Filter, continue to Section J: Directions for Use: Dual Sheath Technique – **Bard** Filter Retrieval.

3. If Bard optional filter is determined to be the **Marlantes**, **Ecce**, or **G2X** Filter, continue to either Section K: Directions for Use: Single Sheath Technique – **Marlantes**, **Ecce**, or **G2X** Filter Retrieval.

J. Directions for Use: Dual Sheath Technique – **Bard** Filter Retrieval

**WARNING:** Never advance the guidewire, snare assembly, or introducer sheath/dilator to 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 catheter is cephalad to the filter retrieval hook.

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. Place the catheter in the IVC and fluoroscopy to ensure that the sheath is fully deployed. (The right jugular vein is recommended.)

7. Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare loop until it is completely inside the catheter. Flush all components with heparinized saline or suitable isotonic solution prior to use.

8. Insert the dilator through the hemostatic valve and 9F retrieval sheath ensuring that the hubs connect properly.

9. Insert the dilator retrieval sheath assembly into the 11F access sheath ensuring that the hubs connect properly.

10. Prepare all other procedural equipment required according to the manufacturers' Instructions for Use.

11. 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 guide wire or imaging catheter through a filter to prevent entrapment.

**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.

**IMPORTANT:** Filtration of the retrievable filter prior to retrieval is critical.

**WARNING:** 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.

12. 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 capitated to the filter retrieval hook.

13. Advance the snare until the 20 mm loop has fully expanded above the filter retrieval hook.

14. Slowly advance the snare loop forward over the filter retrieval hook.

**NOTE:** Filtration of the retrievable filter prior to retrieval is critical.

**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.

**IMPORTANT:** Filtration of the retrievable filter prior to retrieval is critical.

**IMPORTANT:** Filtration of the retrievable filter prior to retrieval is critical.
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 thrombus. (The right jugular vein is recommended.)
2. Place all procedural equipment required according to the manufacturers’ Instructions for Use.
3. Insert the kit dilator through the hemostatic valve and 9F retrieval sheath ensuring that the hubs connect properly.
4. Advance and retract the dilator 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.
5. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.
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.
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 9F retrieval sheath.
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:** 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, 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 stationery 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, 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). Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.

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

**K. Directions for Use: Single Sheath Technique –**

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 thrombus. (The right jugular vein is recommended.)
2. Remove all complete procedural packaging using sterile technique. Attach the ‘‘T’’-shaped 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 tip 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:
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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