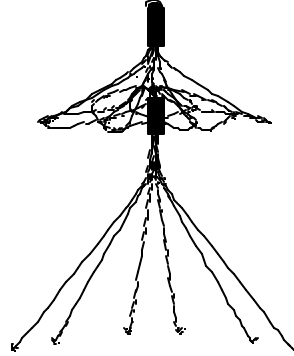
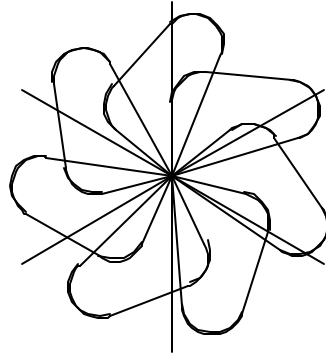


Simon Nitinol Filter™ SNF/SL™ Filter Sets



1-14	English	English
15-28	French	Français
29-42	German	Deutsch
43-56	Italian	Italiano
57-70	Spanish	Español
71-84	Dutch	Nederlands
85-98	Portuguese	Português
99-112	Greek	Ελληνικά
113-126	Danish	Dansk
127-140	Swedish	Svenska
141-154	Finnish	Suomi

**Simon Nitinol Filter™
SNF/SL™ Filter Sets
for use in the Vena Cava**

English

Instructions for Use



A. General Information



Simon Nitinol Filter™ SNF/SL™ Filter Set



Expiration Date.



Lot Number



Attention, See Instructions for Use.



Sterilized by Ethylene Oxide.

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



Nonpyrogenic.



Single Use.
Do Not Reuse.



Do not resterilize.



Sterile, non-pyrogenic unless package is damaged or opened.



MRI compatible: MRI-safe and neither interferes with nor is affected by the operations of an MRI device.



Warning: After use, the *SNF/SL* Filter Set may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.



Contents:

REF: 2120F	Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
	Kit B: One (1) <i>SNF/SL</i> Filter Femoral Delivery Set
REF: 2220J	Kit A: One (1) 7 Fr. Introducer Catheter 83cm Long with Dilator
	Kit B: One (1) <i>SNF/SL</i> Filter Jugular/ Subclavian Delivery Set
REF: 2320A	Kit A: One (1) 7 Fr. Introducer Catheter 103cm Long with Dilator
	Kit B: One (1) <i>SNF/SL</i> Filter Antecubital Delivery Set



Bard is a registered trademark of C. R. Bard, Inc. or an affiliate.
Simon Nitinol Filter and *SNF/SL* are trademarks of C. R. Bard, Inc. or an affiliate.
Glidewire is a registered trademark of Terumo Corporation.

B. Summary of Changes to this Device

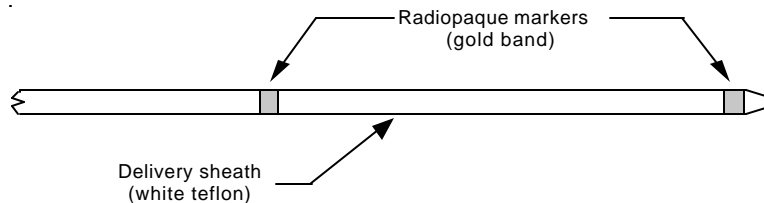
The SNF/SL™ Delivery System has been designed to provide the user several changes that will facilitate deployment and utility when placing the *Simon Nitinol Filter*.

Modifications include:

- Subclavian vein and antecubital access routes have been added as entry site approaches for filter placement.
- The radiopaque marker banding placement has changed from a gold deposition process to gold rings swaged to the introducer catheter.

C. Summary of Previous Modifications to this Device

- Cold saline solution has been eliminated as a requirement for filter delivery. Testing has been conducted to ensure that *room temperature saline* is acceptable.
- Radiopaque markers are placed on the delivery sheath catheter to assist visualization and in the predeployment positioning of the filter.



- A nitinol pusher wire has been developed to advance the filter through the introducer catheter, eliminating the ratcheting handle.

D. Device Description

The *Simon Nitinol Filter* is designed to prevent recurrent pulmonary embolism. It is primarily indicated for patients who cannot, for a variety of reasons, be treated with anticoagulants. The *Simon Nitinol Filter* allows for percutaneous placement through a standard 7 French I.D. angiographic introducer.

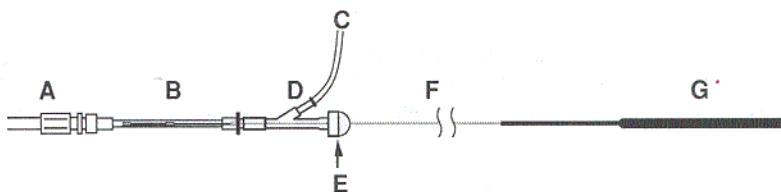
MRI Compatible: MRI-safe and neither interferes with nor is affected by the operations of an MRI device.

E. Indications for Use

The *Simon Nitinol Filter* is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy in thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Simon Nitinol Filter™



- A. INTRODUCER CATHETER
- B. FILTER STORAGE TUBE
- C. SALINE DRIP INFUSION SET
- D. SIDE PORT
- E. ADJUSTABLE TOUHY-BORST ADAPTER
- F. NITINOL PUSHER WIRE
- G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the *Simon Nitinol Filter*.

F. Contraindications for Use

CAUTION: If the corrected inferior vena cava (IVC) width exceeds 28mm the filter **must not be** inserted into the IVC. Furthermore, if a surgical procedure requiring general anesthesia is planned within two weeks, the filter **must not be** inserted if the vena cava exceeds 24mm in width.

The *Simon Nitinol Filter* should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus.
- Patients with vena cava diameters greater than 28mm.
- Patients with vena cava diameters greater than 24mm if those patients are scheduled for surgery requiring general anesthesia within two weeks.
- Patients with risk of septic embolism.

G. Potential Complications

- *Migration of the filter.* This may be caused by placement in oversized venae cavae greater than 28mm, or large migrating thrombus dislodging the filter from its deployed position.
- *Perforation of the vena cava wall by the legs of the filter.*
- *Recurrent pulmonary embolism.* This has been reported despite filter usage. It is not known if thrombus passed through the filter or via collateral means.
- *Caval occlusion.* The probability of this occurring should be weighed against the inherent risk/benefit ratio for a patient who is experiencing pulmonary embolism, or who is likely to do so without intervention.

H. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral, jugular, subclavian, or antecubital venous access route, on either the right or left side, depending upon the patient's size/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 appropriate femoral, jugular/subclavian, or antecubital filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an entry needle. For femoral insertion, insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer. If both femoral approaches are obstructed, the operator may switch to the jugular, subclavian, or antecubital approach using the *Simon Nitinol Filter Jugular/Subclavian System* or *Antecubital System*. Please refer to the *Delivery Tips* section (pg. 9–13) for specific procedure suggestions for these alternative techniques.

5. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

NOTE: The introducer catheter has radiopaque markers to assist in visualization and pre-deployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

6. Remove the guidewire and dilator, leaving the 7 French introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.

NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

7. Perform a standard inferior venacavogram (typically 30mL of contrast medium at 15mL/sec). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
8. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion the introducer catheter tip should be 1cm below the lowest renal vein. For jugular, subclavian, or antecubital insertion the introducer catheter tip should be 5cm below the lowest renal vein.

Insertion of the Filter

NOTE: Cold (40° to 50°F, 5° to 10°C) saline solution assists in making the nitinol material soft and malleable. The use of cold saline is optional, based on the operator's preference. However, room temperature saline is required to assist filter delivery and maintain catheter patency. Saline solution must be infused during the delivery of the *Simon Nitinol Filter* through the 7 French introducer catheter. Please follow the instructions described below.

9. Open Kit B Delivery System package. Remove storage tube end cap before using the SNF/SL delivery system.
10. Connect a 500mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. *If cold saline is being used, it is suggested to refrigerate it for at least one hour between 40° and 50°F (5° and 10°C) or pack it in ice chips for 30 minutes.* Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher wire from advancing freely.
11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.

Filter Delivery

12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A–D). *Do not pull back on the pusher wire, only advance forward with filter in place.* For the operator's convenience, the nitinol pusher wire may be looped or coiled, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement with the jugular, subclavian or antecubital approach.
13. Continue forward movement of the pusher wire until the filter advances to the radiopaque marker on the distal end of the introducer catheter.

NOTE: With the filter positioned between the radiopaque markers of introducer catheter, the proximal end of the pusher wire handle should be positioned at the Touhy-Borst cap of the Y-adapter.

Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle with the right hand.

Figure E-1: shows filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

NOTE: Do not deliver the filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary filter by withdrawing the introducer catheter as described below.

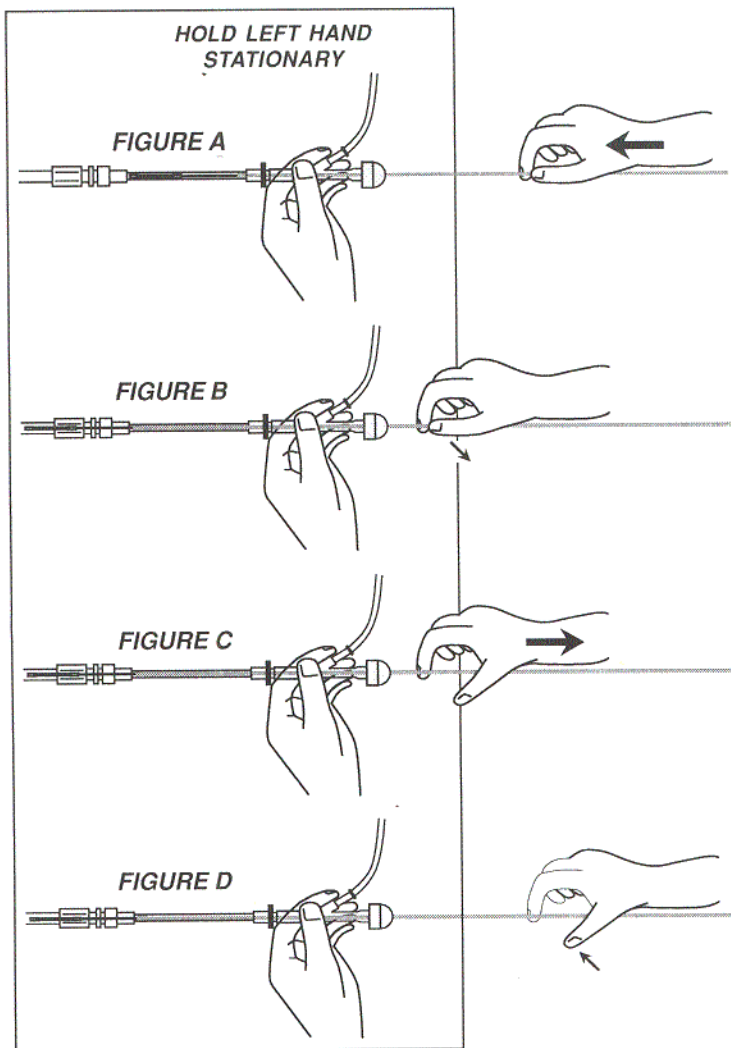
Now release the filter by unsheathing it in the IVC as follows:

Figure F: With the right hand held stationary, the left hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.

Figure F-1: shows unsheathing of filter in IVC.

Figure G: This shows the position of the hands at the completion of the unsheathing process, with the filter deployed in the IVC (**Figure G-1**).

Advancement of Filter, Illustrated



NOTE: The dome of the filter will normally descend 1–2cm during shape recovery so that its tip will be lower than its actual position in the introducer before unsheathing.

If the vena cava is too small to accommodate the fully centered filter dome, the dome may tilt toward the vena cava wall, or assume a spindle or cone configuration. These variations are functionally effective in undersized lumens.

15. If used during delivery, turn off cooled saline drip as soon as the filter has been delivered. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and delivery catheter assembly with the left hand and draw back on the pusher wire with the right hand.

Filter Release, Illustrated

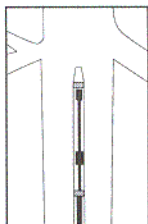


FIGURE E-1

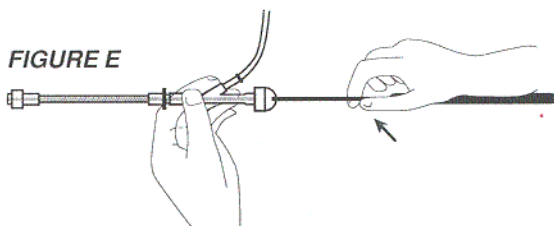


FIGURE E

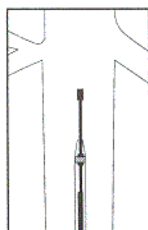


FIGURE F-1

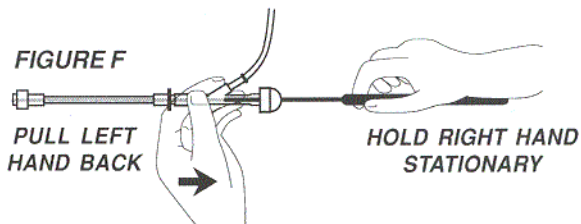


FIGURE F

PULL LEFT
HAND BACK

HOLD RIGHT HAND
STATIONARY

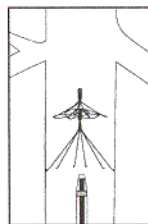
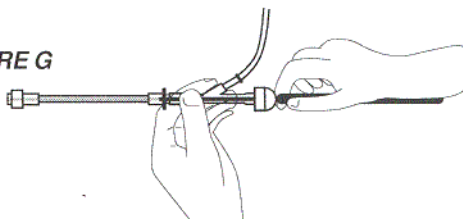


FIGURE G-1

FIGURE G



16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

1. After a femoral delivery, a follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/second). In the case of a jugular, subclavian, or antecubital procedure, the 7 French introducer catheter may be positioned 1cm above the filter for a retrograde injection of the contrast medium (typically 40mL at 20mL/second).
2. Remove the 7 French introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

I. Delivery Tips

General

Caudal shift of the dome

There is a natural shortening of the filter between its elongated form and its recovered shape. Normally this is 1–2cm in large venae cavae, but may be less or absent in smaller venae cavae.

Spindle shape

In very small venae cavae the *Simon Nitinol Filter* may form a spindle shape if there is not enough room for the dome to form. In some cases delayed recovery of the filter dome shape may be seen on follow-up films.

Replacement of pusher wire

If the pusher wire becomes separated from the Y-adapter, or must be replaced because of contamination, the following steps should be taken. Remove the storage tube and Y-adapter assembly from the catheter and replace the storage tube cap in the distal end of the storage tube. Loosen the Touhy-Borst fitting on the Y-adapter and remove the pusher wire. Push the replacement wire through the Y-adapter and tighten the fitting so that it is snug against the wire but not so tight that it impedes wire movement. Advance the wire until it contacts the filter inside the storage tube. For the femoral system, it is important that the pusher cup cover the feet of the 4 longest legs of the filter. Remove the storage tube cap and reattach the storage tube firmly to the catheter.

Femoral Delivery

The SNF/SL femoral set is designed to advance through the 48cm, 7 French introducer catheter using a flexible nitinol pusher wire. A cup at the end of the wire is designed to hold 4 of the 6 feet of the filter while it is being advanced to the distal end of the introducer catheter, positioned 1cm below the lowest renal vein. When the tip of the filter reaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back to unsheath and release the filter and allow it to recover its predetermined filter shape.

Deployment Suggestions

- Saline solution must be used during filter delivery to maintain catheter patency.
- The use of cold saline during delivery is optional. Room temperature saline may be used during deployment of the filter.
- When cold saline (40°–50°F, 5°–10°C) is used, it is best taken from the refrigerator or ice bath just prior to filter delivery. The nitinol material remains soft and malleable when chilled.
- If desired, the introducer catheter can be used for a pre- and post-procedure venacavogram (generally 30mL at 15mL/second).
- *Do not pull back on the pusher wire until filter deployment is completed.* Pulling back releases the feet of the filter from the pusher wire cup. Normally, readvancing the pusher wire cup will recapture the four feet within the cup but occasionally the feet may not easily slip back inside the cup. Also, further pulling back on the pusher wire while it is in the storage tube may cause the cup to get drawn back to, and possibly through, the Touhy-Borst adapter. If this occurs, it is advised to first replace the storage tube cap back into position, then readvance the wire through the Y-adapter and storage tube until the pusher cup covers the feet, making sure 4 of the 6 feet are in the cup. *Visually inspect the filter while still in storage tube to make certain the feet are in the cup.* Remove storage tube cap to reattach delivery system to catheter.
- Based on the operator's preference, the *Simon Nitinol Filter* may be deployed in a two-step method. The dome may be released first and form its intended petal design. The dome then may be repositioned cephalad to the desired location by advancing the entire introducer catheter forward before releasing the legs of the filter. This provides the operator a more accurate final positioning of the filter based on patient needs or personal preference.
- The feet are designed to disengage automatically from the cup as the filter forms. Occasionally, one foot or more may stick in the cup, particularly in tortuous vessels. If this occurs **do not** pull back on the pusher wire as this will likely cause the filter to be pulled back as well. Instead, do the following:
 1. Firmly hold the nitinol pusher wire in place.
 2. Advance the introducer catheter over the stuck feet until its tip reaches the point where the six legs come together. This stabilizes the filter.
 3. Now pull back slightly on the pusher wire to release the filter feet from the cup.
 4. Finally pull back the introducer catheter to release the filter legs into the vena cava.

Jugular Delivery

The *SNF/SL* Jugular/Subclavian set is designed to advance through the 83cm, 7 French introducer catheter using a flexible nitinol pusher wire. A flat-surfaced pad on the tip of the pusher wire advances the filter, feet first, to the distal end of the catheter, positioned 5cm below the lowest renal vein. When the feet of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back to unsheath and release the filter and allow it to recover its predetermined filter shape.

Entry Suggestions

- The *SNF/SL* delivery system may be used on the right or left jugular, either internal or external, vein.
- With the patient in the Trendelenberg position, locate the entry position for needle puncture.
- Use an 18-gauge needle for venipuncture.
- Advance a 3mm “J” guidewire, or appropriate substitute, and pass it into the vein and through the right atrium to the IVC.
- Perform the entry site skin nick with a #11 blade to facilitate dilator and introducer catheter passage.
- Pass dilator and introducer catheter to desired filter deployment position in IVC.

Deployment Suggestions

- Saline solution must be used during filter delivery to maintain catheter patency.
- The use of cold saline during delivery is optional. Room temperature saline may be used during deployment of the filter.
- When cold saline (40°–50°F, 5°–10°C) is used, it is best taken from the refrigerator or ice bath just prior to filter delivery. The nitinol material remains soft and malleable when chilled.
- If desired, the introducer catheter can be used for a pre- and post-procedure venacavogram (generally 40mL at 20mL/sec).
- Place distal end of introducer catheter 5cm below lowest renal vein.
- Advance legs of filter to distal tip of introducer catheter and position the filter between the radiopaque markers. Hold the pusher wire handle firmly and draw back the Y-adapter, storage tube and catheter assembly to unsheath filter, allowing the legs to engage the caval wall with the dome of filter being positioned directly below the renal vein.

Subclavian Delivery

The *SNF/SL* Jugular/Subclavian set is designed to advance through the 83cm, 7 French introducer catheter using a flexible nitinol pusher wire. A flat-surfaced pad on the tip of the pusher wire advances the filter, feet first, to the distal end of the catheter, positioned 5cm below the lowest renal vein. When the feet of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back to unsheath and release the filter and allow it to recover its predetermined filter shape.

Entry Suggestions

- The *SNF/SL* delivery system may be used on the right or left subclavian vein.
- With the patient in the Trendelenberg position, locate the entry position for needle puncture.
- Use an small-gauge needle attached to a syringe for initial venipuncture.
- Note: the subclavian vein is entered percutaneously at the point that identifies the junction of the outer and middle third of the clavicle.
- Attach introducer needle to syringe and insert into vessel alongside the small needle.
- Advance a 3mm “J” guidewire, or appropriate substitute, and pass it into the vein and through the right atrium to the IVC.
- Perform the entry site skin nick with a #11 blade to facilitate dilator and introducer catheter passage.
- Pass dilator and introducer catheter to desired filter deployment position in IVC.

Deployment Suggestions

- Saline solution must be used during filter delivery to maintain catheter patency.
- The use of cold saline during delivery is optional. Room temperature saline may be used during deployment of the filter.
- When cold saline (40°–50°F, 5–10°C) is used, it is best taken from the refrigerator or ice bath just prior to filter delivery. The nitinol material remains soft and malleable when chilled.
- If desired, the introducer catheter can be used for a pre- and post-procedure venacavogram (generally 40mL at 20mL/sec).
- Place distal end of introducer catheter 5cm below lowest renal vein.
- Advance legs of filter to distal tip of introducer catheter and position the filter between the radiopaque markers. Hold the pusher wire handle firmly and draw back the Y-adapter, storage tube and catheter assembly to unsheath filter, allowing the legs to engage the caval wall with the dome of filter being positioned directly below the renal vein.

Antecubital Delivery

The *SNF/SL* antecubital set is designed to advance through the 103cm, 7 French introducer catheter using a flexible nitinol pusher wire. A flat-surfaced pad on the tip of the pusher wire advances the filter, feet first, to the distal end of the catheter, positioned 5cm below the lowest renal vein. When the feet of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers of the introducer catheter. The introducer catheter and delivery assembly are then pulled back to unsheath and release the filter and allow it to recover its predetermined filter shape.

Entry Suggestions

- The *SNF/SL* delivery system may be used on the right or left antecubital vein.
- With the patient lying as flat as possible, the right or left arm should be supinated and abducted 40 degrees.
- Place a tourniquet or blood pressure cuff (inflated to just above systolic pressure) as high on the arm as possible.
- Choose the entry vein according to the patient's size/ anatomy and/or condition and available access.
- If possible, use the medial branch of the large straight basilic vein along the ulnar aspect of the arm. This avoids the right angle of the cephalic vein intersecting the axillary vein.
- Initial use of 175cm angled guidewire such as the Terumo Glidewire® guidewire aids in negotiation through tortuous veins and may reduce risk of venous spasm.
- If the cephalic approach is required, introduce a heavy-duty exchange wire or right-angled tip catheter to facilitate entering the subclavian vein from the cephalic route.

Deployment Suggestions

- Saline solution must be used during filter delivery to maintain catheter patency.
- The use of cold saline during delivery is optional. Room temperature saline may be used during deployment of the filter.
- When cold saline (40°–50°F, 5°–10°C) is used, it is best taken from the refrigerator or ice bath just prior to filter delivery. The nitinol material remains soft and malleable when chilled.
- If desired, the introducer catheter can be used for a pre- and post-procedure venacavogram (generally 40mL at 20mL/sec).
- Predilatation of the antecubital entry site may be helpful.
- Place distal end of introducer catheter 5cm below lowest renal vein.
- Advance legs of filter to distal tip of introducer catheter and position the filter between the radiopaque markers. Hold the pusher wire handle firmly and draw back the Y-adapter, storage tube and catheter assembly to unsheath filter, allowing the legs to engage the caval wall with the dome of filter being positioned directly below the renal vein.

J. How Supplied

Each *Simon Nitinol Filter* is supplied preloaded in its storage tube. Each *Simon Nitinol Filter* is sterile and non-pyrogenic unless package is damaged or opened, and is ready to be used for a single use only. The storage tube and feeder system are preassembled. If the filter is inadvertently discharged, do not attempt to re-sterilize and/or reload it.

Warning: After use, the *Simon Nitinol Filter* accessories/insertion supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Filters should be stored in a cool (room temperature), dry place.

K. Warranty

Bard 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'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** BE LIABLE TO YOU FOR ANY 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.

Labeling Issue Date: 09/02

In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.

(Inside U.S.: 1-800-321-4254; Outside U.S.: 1-480-894-9515)

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

 Bard is a registered trademark of C. R. Bard, Inc. or an affiliate. Simon Nitinol Filter and SNF/SL are registered trademarks of C. R. Bard, Inc. or an affiliate. Glidewire is a registered trademark of Terumo Corporation.

© Copyright 2002, C. R. Bard, Inc.

BARD

C. R. Bard, Inc.

Tempe, AZ 85280

Inside U.S.: 1-800-321-4254

Outside U.S.: 1-480-894-9515

EEA Authorized Representative:

Bard Limited

Crawley, UK

RH11 9BP

PK5014851 Rev. 01 09/02

 0086