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**RX Accunet® 2 Recovery Catheter**  
*Information for Prescribers*

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

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**CAUTION:**

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS.**

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## 1.0 DEVICE DESCRIPTION

The RX Accunet 2 Recovery Catheter is a rapid exchange (RX) catheter used to remove the RX Accunet Embolic Protection System (EPS) guide wire with filter basket from the vasculature and guiding catheter / sheath while retaining any emboli or particulate collected in the filter basket during the procedure. The RX Accunet 2 Recovery Catheter has a soft tip useful for crossing tortuous carotid anatomies. One universal RX Accunet 2 Recovery Catheter can be used to recover all RX Accunet filter basket sizes, ranging from 4.5 mm to 7.5 mm in diameter.

## 2.0 INDICATIONS

The RX Accunet EPS and the RX Accunet 2 Recovery Catheter, are indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

## 3.0 CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE EVENTS

For contraindications, warnings, precautions and adverse events associated with the use of the RX Accunet 2 Recovery Catheter, please see Information for Prescribers for the RX Accunet Embolic Protection System.

## 4.0 CLINICAL STUDIES

The Acculink® for Revascularization of Carotids in High Risk Patients (ARCHeR) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. These trials were performed to demonstrate the safety and efficacy of the Acculink and RX Acculink Carotid Stent Systems and Accunet and RX Accunet Embolic Protection Systems when used to treat high-risk, surgical and non-surgical, symptomatic ( $\geq 50\%$  stenosis) and asymptomatic ( $\geq 80\%$  stenosis) subjects with disease in the internal carotid artery. For a description of the study and the results please see Information for Prescribers for the RX Accunet Embolic Protection System.

## 5.0 CLINICIAN USE INFORMATION

**WARNING: Do not use after the “Use By” date specified on the package.**

**WARNING: The device is intended for single-use only. Do not reuse. Do not resterilize as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.**

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## 5.1 Materials Required

- 6F guiding sheath or 8F guiding catheter compatible with the vascular anatomy. Minimum guiding catheter / sheath size inner diameter (I.D.) 0.085" / 2.2 mm.
- ≥ 0.096" (2.44 mm) Rotating Hemostatic Valve (RHV) (optional)
- RX Accunet Delivery System (optional)
- Balloon dilatation catheter (optional)
- 1,000 u / 500 cc heparinized normal saline (sterile)
- 10 – 20 cc luer-lock syringe

**CAUTION: Confirm the compatibility of the RX Accunet 2 Recovery Catheter with the interventional devices before actual use.**

**WARNING: Use with fixed (passive) hemostatic valves is not recommended.**

## 5.2 Inspection Prior To Use

Inspect the product prior to use. Do not use if the package is open or damaged.

## 5.3 Recovery Catheter Preparation

**CAUTION: Do not expose the recovery catheter to organic solvents (e.g. alcohol) as structural integrity and / or function of the device may be impaired.**

1. Remove the recovery catheter from the dispenser hoop.
2. Fill a 10 cc syringe with heparinized normal saline.
3. Flush the recovery catheter to remove air using one of two methods:
  - Align the tip of the syringe with the distal tip of the recovery catheter and flush to remove air;  
**or**
  - Use the flushing tool from the RX Accunet EPS delivery system: Attach a luer lock syringe to the distal end of the flushing tool, and insert the distal 3 cm of the recovery catheter into the proximal end of the flushing tool. Lightly close the RHV of the flushing tool, and flush gently to remove air from the recovery catheter. Do not close the RHV on the tip area of the recovery catheter.

Observe fluid exiting the exit notch.

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## 5.4 Monitoring the Filter Status

**WARNING: Maintain continuous flush while removing and reinserting devices on the guide wire. Perform all exchanges slowly to prevent air embolism or trauma to the artery.**

**WARNING: Avoid excessive movement of the RX Accunet EPS guide wire and filter basket during catheter device exchanges. Excessive movement of the deployed basket may cause vessel trauma or spasm.**

1. Keep the position of the guide wire with filter basket steady during the intervention.
2. Check the status of the expanded RX Accunet EPS filter basket at regular intervals during the interventional procedure.
3. Inject contrast through the guiding catheter / sheath and observe flow distal to the filter basket.

**WARNING: Allow for and maintain adequate distance between the radiopaque proximal bushing marker on the guide wire with filter basket and the stent delivery system or other compatible interventional devices to avoid potential entanglement.**

**WARNING: If excessive debris is collected in the filter basket such that distal perfusion of dye is significantly reduced or no dye is perfusing past the filter, the RX Accunet EPS Filter Basket may have reached its maximum capacity to contain emboli. Remove and replace the RX Accunet EPS. Otherwise, it may be difficult to completely recover all embolic debris and the potential for thrombus release may increase.**

## 5.5 Filter Basket Recovery

1. Remove all interventional devices from the RX Accunet guide wire.
2. Backload the prepared recovery catheter onto the proximal end of the wire and advance the system through the open RHV on the guiding catheter / sheath.

**WARNING: Do not rotate the recovery catheter more than 90 degrees in either direction since this can result in the guide wire wrapping around the catheter.**

**WARNING: Use with fixed (passive) hemostatic valves is not recommended.**

3. Under fluoroscopy, carefully advance the recovery catheter through the deployed stent.

**Note:** A variety of techniques can be used to assist passage of the recovery catheter if it has difficulty advancing through the deployed stent. These techniques are intended to adjust the bias of the guide wire. Some options to aid passage of the recovery catheter are:

- Have the patient rotate her / his neck from side-to-side. This motion may re-orient the carotid artery.
- Change the position of the guiding catheter or introducer sheath. The new position may either re-orient the entry of or give better support to the recovery catheter.
- If stent struts are impeding the advancement of the recovery catheter, post-dilate the stent.
- Insert a guide wire (“buddy wire”) to straighten the stented area.

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4. Gently advance the recovery catheter over the filter basket until the radiopaque tip of the recovery catheter covers the radiopaque markers of the filter basket and causes the basket to collapse. The filter basket will not be completely contained within the catheter.

**Note:** Clinical investigators have used other interventional devices, such as compatible guide or balloon catheters, to recover the filter basket in the instance when difficulty was encountered using the RX Accunet 2 Recovery Catheter.

**Note:** If necessary to facilitate recovery of the filter basket, a simultaneous push-pull maneuver may be used. This may be done when the tip of the recovery catheter is completely through the stent and at, or beyond, the radiopaque proximal bushing.

**WARNING: Always keep the open filter basket distal to the deployed stent. Do not attempt to pull an open filter basket through the stent. Do not attempt to capture the filter basket by pulling it into the recovery catheter if the recovery catheter tip is in the stent area. Pulling the filter basket into the stent area may lead to stent-filter basket entanglement and / or basket detachment. If filter basket entanglement or detachment occurs, surgical conversion or collapsing the basket with a second stent should be considered.**

5. Hold tension on the guide wire and grasp the recovery catheter. Retract the devices together as a single unit with no movement relative to the catheter and guide wire.

**CAUTION: Care must be used when removing the filter basket through a newly deployed stent to maintain filter basket integrity and to avoid disrupting the stent geometry.**

6. Remove the devices as a unit through the RHV. Ensure that the RHV is fully open when the filter basket is being removed to maintain filter basket integrity.

**Note:** If unable to retract the filter basket through the guiding catheter, stabilize the filter basket and recovery catheter at the guiding catheter tip by tightening down the RHV. Remove the guide wire with filter basket, recovery catheter and guiding catheter / sheath as a unit.

**Note:** If using a Abbott Vascular CoPilot® Bleedback Control Valve ensure that the CoPilot is held open while the filter basket is being removed to maintain filter basket integrity.

**CAUTION: If the RX Accunet 2 Recovery Catheter is desired for intervention in additional vessels, use a new device.**

## 6.0 PATIENT INFORMATION

A Patient Guide, which includes information on carotid artery disease and the carotid stent implant procedure using embolic protection, is available from Abbott Vascular upon request. Please contact Customer Service at 1-800-227-9902 to obtain copies.

The Instructions for Use booklet is available on the Abbott Vascular website at [www.abbottvascular.com/ifu/](http://www.abbottvascular.com/ifu/).

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## 7.0 HOW SUPPLIED

**Sterile:** This device is sterilized with electron beam radiation. Non- pyrogenic.

**Contents:** One pouch containing:

Recovery Catheter: One (1) recovery catheter, one (1) catheter clip.

**Storage:** Store in a dry, dark, cool place.

## 8.0 PATENTS

This product and / or its use are protected by one or more of the following United States patents. 6,336,934; 6,432,122; 6,569,184; 6,695,813.  
Additional U.S. patents pending.

### **Abbott Vascular**

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### CUSTOMER SERVICE

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






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## Graphical Symbols for Medical Device Labeling

 Manufacturer	 Sterilized Using Irradiation
<b>REF</b> Catalogue Number	 Inner Diameter
<b>F</b> French Size	 Outer Diameter
 Guiding Catheter	 Stent Length
 Consult Instructions For Use	 Date of Manufacture
 Contents (Numeral represents quantity of units inside.)	 Use By
 Do Not Reuse	 Batch Code