
RX Accunet® Embolic Protection System
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.

1.0 DEVICE DESCRIPTION

The RX Accunet Embolic Protection System (EPS) is a filtration-type embolic protection device, with a nickel-titanium filter basket filtering distal to the interventional site. The RX Accunet EPS is comprised of a delivery system and two recovery catheters with different features to address varying patient anatomies and clinical challenges.

1.1 RX Accunet Delivery System

The RX Accunet EPS guide wire with filter basket is a single-use, steerable 0.014" (0.36 mm) guide wire system available in 190 cm and 300 cm lengths. The proximal end of the 190 cm device is coined to allow for attachment to a Doc® wire extension. Attached to the distal end is a filter basket made of a thin porous membrane supported by a metal basket (Figures 1 and 2). The filter membrane has a maximum pore size of 150 µm. Radiopaque markers are located on the guide wire, filter basket, and delivery sheath to aid in device positioning. The purpose of the filter basket is to capture and recover embolic material produced during interventional procedures in the carotid arteries.

Figure 1. Guide Wire with Filter Basket

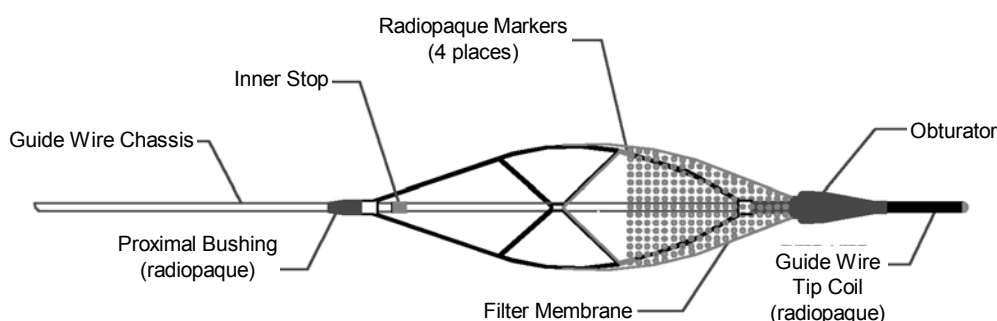
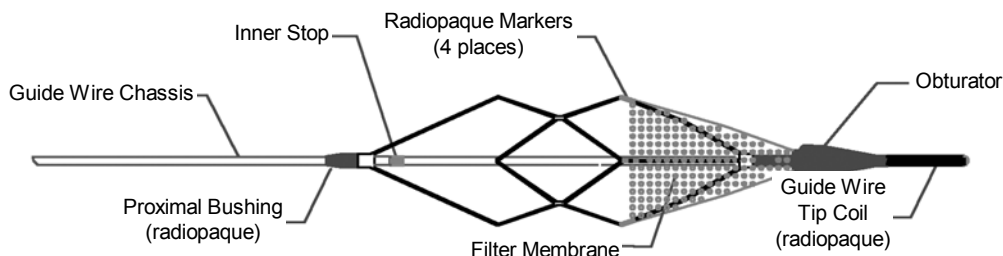


Figure 2. Guide Wire with Filter Basket (90° Rotated)



1.2 Filter Sizing Recommendation

Filter size selection is based on reference vessel diameter in the area where the filter basket will be expanded. Measurements of reference vessel diameters may be acquired through:

- Angiography
- Quantitative Angiography

Table 1. Filter Sizing Recommendation

Filter Size Fully Expanded	Reference Vessel Diameter Minimum to Maximum Range
4.5 mm	3.25 to 4.0 mm
5.5 mm	4.0 to 5.0 mm
6.5 mm	5.0 to 6.0 mm
7.5 mm	6.0 to 7.0 mm

1.3 RX Accunet Recovery Catheter – “Shapeable Tip Design”

The RX Accunet Recovery Catheter is a rapid exchange (RX) catheter used to remove the RX Accunet EPS guide wire with filter basket from the vasculature and guiding catheter / sheath while retaining any emboli or particulates collected in the filter basket during the procedure. The RX Accunet Recovery Catheter has a shapeable tip that is designed to provide torqueability or steerability to the tip of the device. The RX Accunet Recovery Catheter is available in four sizes and is compatible with the matching four sizes of RX Accunet filter baskets.

1.4 RX Accunet 2 Recovery Catheter – “Low-Profile, Flexible Design”

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 particulates collected in the filter basket during the procedure. The RX Accunet 2 Recovery Catheter has a lower profile and is more flexible than the RX Accunet Recovery Catheter. In addition, the RX Accunet 2 Recovery Catheter has an extended soft tip and was designed to deflect away from stent struts without the need to shape the distal tip. One size of RX Accunet 2 Recovery Catheter is used to capture all sizes of RX Accunet filter baskets.

2.0 INDICATIONS

The RX Accunet EPS is 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

The RX Accunet EPS is contraindicated for use in

- Patients in whom anticoagulant and / or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guiding catheter, sheath, embolic protection system, or stent system.
- Patients with known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.

4.0 WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

General

Refer to the instructions supplied with all interventional devices to be used in conjunction with the RX Accunet EPS for their intended uses, contraindications, and potential complications.

The safety and effectiveness of this device as an embolic protection system have not been established in vasculatures outside the carotid arteries.

The safety and efficacy of the RX Accunet EPS have not been demonstrated with carotid stent systems other than the over-the-wire or RX Acculink Carotid Stent System.

The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

Device Use

This 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.

Do not use the product after the "Use By" date specified on the package.

Maintain the patient's Activated Clotting Time (ACT) at > 250 seconds throughout RX Accunet EPS usage to prevent thrombus formation on the device.

During positioning, advance the RX Accunet EPS guide wire with filter basket and the delivery sheath as a unit. Advancing the guide wire independent of the delivery sheath may result in premature filter deployment.

Always advance or withdraw the RX Accunet EPS guide wire slowly using fluoroscopy to observe corresponding wire movement in general and tip movement in particular. Never push, auger, retract or torque a guide wire that meets resistance. If the wire tip becomes entrapped within a lesion or a device, such as a deployed stent, do NOT torque the guide wire. Determine the cause of resistance and take necessary remedial action. Torquing or retracting the guide wire against resistance may damage the wire, cause wire tip separation, or cause vessel trauma. Resistance may be felt and / or observed using fluoroscopy by noting any buckling of the guide wire tip.

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.

Overstretching of the artery may result in rupture and life-threatening bleeding.

When introducing the delivery system, confirm that the wire tip is free within the vessel lumen and is not directed against the vessel wall. Failure to do so may result in vessel trauma. Use the radiopaque marker on the interventional device to confirm position.

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.

The filter basket must be kept distal to the area to be covered by the stent and proximal to the petrous portion of the carotid artery to avoid excessive forces on the filter basket.

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.

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.

Maintain proper guiding catheter / sheath support in the common carotid artery throughout the procedure. If guiding catheter / sheath access cannot be maintained, the case should be discontinued. Failure to maintain proper support of the guiding catheter / sheath can lead to prolapse of the catheter into the aortic arch, resulting in any of the following:

- Movement of an open filter through an undilated lesion; or
- Filter-stent entanglement, filter basket detachment and / or proximal movement of the stent; or
- Filter guide wire breakage.

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

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

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 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 formation may increase.

Discard unused RX Accunet and RX Accunet 2 Recovery Catheters after completing procedure. Failure to discard unused recovery catheters can result in any or all of the following: the use of a device past its "Use By" date; or the use of an incorrectly sized RX Accunet Recovery Catheter, which can cause loss of particulates from the filter basket during recovery, filter-stent entanglement, filter basket detachment and / or proximal movement of stent.

5.0 PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do

not use damaged guide wires. Using a damaged guide wire may result in vessel damage and / or inaccurate torque response.

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

Confirm the compatibility of the RX Accunet EPS with the interventional devices before actual use.

To avoid air entrapment, do not leave the introducer tool in the valve while advancing the delivery system. Advance the delivery system slowly through the guiding catheter / sheath.

Ensure that the torque device is secured tightly to the guide wire to avoid difficulties with deployment. If the torque device is not tightened securely on the guide wire proper deployment may not occur.

For proper positioning of the filter basket, the vessel distal to the lesion should have an absence of excessive tortuosity and be of adequate length (approximately 4 cm distal to the lesion and proximal to the petrous portion of the vessel).

Reconfirm the filter basket position prior to deployment of the stent to ensure that there is adequate distance between the radiopaque proximal bushing marker on the guide wire with filter basket and the distal end of the desired stent position. Reposition the filter basket as necessary by gently advancing the guide wire. Under fluoroscopy, observe movement of the filter basket to the desired position.

Observe all guide wire movement in the vessels using fluoroscopic guidance.

Venous access should be available during carotid stenting in order to manage bradycardia and / or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

The delivery system is not designed for use with power injection. Use of power injection may adversely affect device performance.

Do NOT deliver the RX Accunet EPS guide wire with filter basket through any interventional devices other than the RX Accunet EPS delivery sheath.

Removal of the RX Accunet EPS guide wire with filter basket through any interventional devices other than the RX Accunet and RX Accunet 2 Recovery Catheters has not been tested.

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.

If the RX Accunet EPS is desired for intervention in additional vessels, use a new device.

6.0 ADVERSE EVENTS

6.1 Observed Adverse Events

The Acculink® Carotid Stent System and Accunet Embolic Protection System were evaluated for the treatment of high-risk surgical patients and non-surgical patients with lesions in the internal carotid

artery, in three separate clinical trials. A total of 581 registry patients were enrolled in the trials as follows:

- ARCHeR 1 evaluated the over-the-wire (OTW) Acculink Carotid Stent System only and included 158 registry patients. The primary objective of the study was to determine if the occurrence rate of the composite primary endpoint of stroke, death, and myocardial infarction (MI) at 30 days and ipsilateral stroke at one year for carotid stenting is not inferior to the occurrence rate for carotid endarterectomy (CEA) in the population under evaluation.
- ARCHeR 2 evaluated the OTW Acculink Carotid Stent System and OTW Accunet Embolic Protection System and included 278 registry patients. The primary objective of the study was the same as ARCHeR 1. A second primary endpoint for this study was Accunet EPS device success.
- ARCHeR 3 evaluated the rapid exchange (RX) Acculink Carotid Stent System and RX Accunet Embolic Protection System and included 145 registry patients. (The RX Accunet 2 Recovery Catheter was not evaluated in this study.) The primary objective of the study was to establish equivalence (non-inferiority) to the ARCHeR 2 results with respect to 30-day death, stroke and MI as a means of establishing equivalency between the OTW and RX devices.

Because the RX Accunet EPS is used in an acute manner, periprocedural adverse events are most relevant to an evaluation of device safety. Table 2 presents the adverse events that were reported within the first 30 days following the procedure for registry patients enrolled within each trial. P values are given for the comparison of rates observed in the ARCHeR 2 and ARCHeR 3 trials. Because the ARCHeR 1 trial did not use embolic protection, it is not compared statistically to the other trials. Table 3 details the cause of any patient deaths.

Table 4 presents data for the ARCHeR 2 and ARCHeR 3 trials by occurrence in and out of hospital. For both ARCHeR 2 and 3, the median and mode of days-to-discharge were 1. The longest hospital stay post-stenting in each study was 30 and 13 days, respectively for ARCHeR 2 and 3. Roughly 7% of patients in the ARCHeR 2 and 3 studies remained in the hospital 7 days or more following the carotid stenting procedure, typically to be treated for other illnesses such as coronary artery disease.

Adverse events are categorized by body system and are defined as follows:

- Non-stroke neurological includes events such as visual / speech disturbances, confusion, seizure, weakness, and TIA.
- TLR is defined as any repeat invasive procedure, including angioplasty, stenting, endarterectomy, or thrombolysis, performed to open or increase the luminal diameter inside or within 10 mm of the previously treated lesion. To be considered clinically indicated, the patient must be symptomatic with $\geq 50\%$ stenosis or asymptomatic with $\geq 80\%$ stenosis.
- Access site complications include events such as bruising, hematoma, and bleeding.
- Vascular includes events such as peripheral arterial disease and deep vein thrombosis.
- Hemodynamic includes events such as hypo- and hypertension, syncope, and dizziness.
- Bleeding includes events such as non-access site bleeding, anemia up to 30 days, and GI bleed up to 30 days.
- Blood dyscrasia includes events such as anemia later than 30 days, and thrombocytopenia.
- Respiratory includes events such as pneumonia, embolism, chronic obstructive pulmonary disease (COPD), and respiratory failure.

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- Gastrointestinal (GI) includes events such as nausea, ulcer, bowel obstruction, and GI bleed later than 30 days.
 - Genitourinary includes events such as urinary tract infection, and prostatic hyperplasia.
 - Infection includes events such as laryngitis, sepsis, and endocarditis.
 - Metabolic includes events such as diabetes, electrolyte imbalance, and renal failure.
 - Musculoskeletal includes events such as pain, fractures, and joint replacements.

The numbers and types of adverse events observed were anticipated given the high co-morbid state of these patients.

Table 2. Serious Adverse Events Summary, ≤ 30 days

Event Categories ^{1,2}	ARCHeR 2 (N=278)		ARCHeR 3 (N=145)		P value ³	ARCHeR 1 (N=158)	
	n	%	n	%		n	%
All Death, Stroke, and MI ⁴	23	8.27	11	7.59	0.824	12	7.59
Death	6	2.16	2	1.38	0.625	4	2.53
Stroke-Related	2	0.72	0	0.00	0.406	1	0.63
Not Stroke-Related	4	1.44	2	1.38	0.965	3	1.90
Ipsilateral Stroke	14	5.04	7	4.83	0.933	6	3.80
Major	3	1.08	2	1.38	0.802	2	1.27
Minor ⁴	11	3.96	5	3.45	0.816	4	2.53
Non-ipsilateral Stroke	1	0.36	1	0.69	0.653	1	0.63
Non-stroke Neurological	6	2.16	1	0.69	0.341	3	1.90
Target Lesion Revascularization (TLR), Clinically Indicated	0	0.00	0	0.00	1.000	0	0.00
Cardiac	23	8.27	13	8.97	0.826	22	13.92
MI	8	2.88	2	1.38	0.406	4	2.53
Arrhythmia	3	1.08	3	2.07	0.433	4	2.53
Angina	3	1.08	3	2.07	0.433	1	0.63
Congestive Heart Failure (CHF)	5	1.80	4	2.76	0.542	4	2.53
Coronary Artery Disease (CAD)	0	0.00	1	0.69	0.087	3	1.90
Procedural Complication	27	9.71	8	5.52	0.194	11	6.96
Hypotension	15	5.40	2	1.38	0.092	6	3.80
Arrhythmia	11	3.96	0	0.00	0.048	5	3.16
Vasospasm	4	1.44	0	0.00	0.238	0	0.00
Dissection ⁵	2	0.72	3	2.07	0.223	0	0.00
In-stent Thrombosis	1	0.36	1	0.69	0.653	0	0.00
Emergent CEA ⁶	2	0.72	0	0.00	0.406	0	0.00
Emergent Intervention ⁷	1	0.36	1	0.69	0.653	0	0.00
Access Site Complication	13	4.68	4	2.76	0.405	9	5.70
Requiring Repair / Transfusion	8	2.88	2	1.38	0.406	6	3.80
Vascular	3	1.08	0	0.00	0.308	2	1.27
Hemodynamic	6	2.16	4	2.76	0.722	3	1.90
Bleeding	7	2.52	6	4.14	0.387	11	6.96
Requiring transfusion	5	1.80	5	3.45	0.310	9	5.70
GI bleeding	0	0.00	2	1.38	0.015	2	1.27
Blood Dyscrasia	5	1.80	2	1.38	0.776	0	0.00
Respiratory	5	1.80	0	0.00	0.186	2	1.27
Gastrointestinal	2	0.72	0	0.00	0.406	0	0.00
Genitourinary	1	0.36	1	0.69	0.653	1	0.63
Infection	4	1.44	0	0.00	0.238	1	0.63
Metabolic	5	1.80	0	0.00	0.186	1	0.63
Musculoskeletal	0	0.00	0	0.00	1.000	1	0.63
Miscellaneous ⁸	0	0.00	0	0.00	1.000	3	1.90

¹Patients may have had multiple events and therefore can be counted in more than one category / subcategory of event. Counts represent the number of patients who have experienced one or more events.

²Three of the reported adverse events were related to device failures / malfunctions. The three are described below in footnotes 5 – 7.

³Because of the multiple tests of significance performed, the individual test level for significance was set conservatively at $p < .01$ after a Bonferroni adjustment. Therefore, none of the AE rates were deemed significantly different statistically between ARCHeR 2 and ARCHeR 3.

⁴Two patients suffered strokes that were determined to be non-serious adverse events. Patient 249-3715 (ARCHeR 2) suffered blurred vision that was subsequently diagnosed by an ophthalmologist as "central retinal artery occlusion with multiple refractile emboli and macular edema." Patient 074-4804 had mild facial weakness that was subsequently diagnosed by MRI as an acute lacunar infarct. Both events resolved without treatment. The Clinical Events Adjudication Committee adjudicated both of these events as strokes. However, because the events did not meet the criteria for a serious adverse event (no intervention to prevent permanent impairment, no persistent or significant disability), they are not included in this table. The events are included as strokes in the composite endpoints.

⁵One dissection in the ARCHeR 2 study was attributed by the physician to the OTW AccUNET System. The physician was not able to cross the lesion with the device.

⁶One CEA in the ARCHeR 2 study resulted when the OTW AccUNET System became entangled with the deployed stent and could not be retrieved by the physician.

⁷The emergent intervention in the ARCHeR 3 study resulted when the RX AccUNET Filter Basket became entangled with the deployed stent and detached from the guide wire during the retrieval attempt. The physician opted to stent the basket in place in the artery. No additional adverse events related to this device malfunction were reported as of the last patient follow-up (9 months post-procedure).

⁸The 3 miscellaneous adverse events reported in the ARCHeR 1 study were bladder tumor, headache, and rash.

Table 3. Cause of Death, ≤ 30 days¹

Events	ARCHer 1 (N=158)		ARCHer 2 (N=278)		ARCHer 3 (N=145)	
	n	%	n	%	n	%
Stroke	1	0.63	2	0.72	0	0.00
Cardiac	3	1.90	4	1.44	1	0.69
Bleeding (GI)	0	0.00	0	0.00	1	0.69

¹None of the reported deaths were due to a device malfunction or failure.

²Of the deaths 0 – 30 days 5 were considered device or procedure related: 3 strokes, 2 cardiac events.

Table 4. Adverse Events, In and Out of Hospital (≤ 30 days)

Events ¹	In-Hospital					Out of Hospital				
	ARCHer 2 (N=278)		ARCHer 3 (N=145)		P value ²	ARCHer 2 (N=278)		ARCHer 3 (N=145)		P value ²
	n	%	n	%		n	%	n	%	
All Death, Stroke, and MI	14	5.04	5	3.45	0.510	9	3.25	7	4.83	0.451
Death	1	0.36	0	0.00	0.557	5	1.81	2	1.38	0.773
Stroke-Related	1	0.36	0	0.00	0.557	1	0.36	0	0.00	0.557
Not Stroke-Related	0	0.00	0	0.00	1.000	4	1.44	2	1.38	0.962
Ipsilateral Stroke	11	3.96	4	2.76	0.577	3	1.08	3	2.07	0.436
Major	2	0.72	1	0.69	0.975	1	0.36	1	0.69	0.654
Minor	9	3.24	3	2.07	0.547	2	0.72	2	1.38	0.526
Non-ipsilateral Stroke	0	0.00	0	0.00	1.000	1	0.36	1	0.69	0.654
Non-stroke Neurological	3	1.08	0	0.00	0.308	3	1.08	1	0.69	0.729
Target Lesion Revascularization (TLR), Clinically Indicated	0	0.00	0	0.00	1.000	0	0.00	0	0.00	1.000
Cardiac	9	3.24	5	3.45	0.917	14	5.05	8	5.52	0.853
MI	4	1.44	1	0.69	0.559	4	1.44	1	0.69	0.558
Arrhythmia	1	0.36	3	2.07	0.065	2	0.72	0	0.00	0.405
Angina	0	0.00	0	0.00	1.000	3	1.08	3	2.07	0.436
Congestive Heart Failure (CHF)	2	0.72	2	1.38	0.523	3	1.08	2	1.38	0.805
Coronary Artery Disease (CAD)	0	0.00	0	0.00	1.000	0	0.00	1	0.69	0.087
Procedural Complication	27	9.71	8	5.52	0.194	0	0.00	0	0.00	1.000
Hypotension	15	5.40	2	1.38	0.092	0	0.00	0	0.00	1.000
Arrhythmia	11	3.96	0	0.00	0.048	0	0.00	0	0.00	1.000
Vasospasm	4	1.44	0	0.00	0.238	0	0.00	0	0.00	1.000
Dissection ⁴	2	0.72	3	2.07	0.223	0	0.00	0	0.00	1.000
In-stent Thrombosis	1	0.36	1	0.69	0.653	0	0.00	0	0.00	1.000
Emergent CEA ⁵	2	0.72	0	0.00	0.406	0	0.00	0	0.00	1.000
Emergent Intervention ⁶	1	0.36	1	0.69	0.653	0	0.00	0	0.00	1.000
Access Site Complication	11	3.96	4	2.76	0.577	2	0.72	0	0.00	0.405
Requiring Repair / Transfusion	7	2.52	2	1.38	0.503	1	0.36	0	0.00	0.557
Vascular	0	0.00	0	0.00	1.000	3	1.08	0	0.00	0.307
Hemodynamic	5	1.80	4	2.76	0.542	2	0.72	0	0.00	0.405
Bleeding	2	0.72	4	2.76	0.083	5	1.81	4	2.76	0.546
Requiring transfusion	2	0.72	4	2.76	0.083	3	1.08	2	1.38	0.805
GI bleeding	0	0.00	0	0.00	1.000	0	0.00	2	1.38	0.015
Blood Dyscrasia	5	1.80	2	1.38	0.776	0	0.00	0	0.00	1.000
Respiratory	2	0.72	0	0.00	0.406	3	1.08	0	0.00	0.307
Gastrointestinal	0	0.00	0	0.00	1.000	2	0.72	0	0.00	0.405
Genitourinary	1	0.36	0	0.00	0.557	0	0.00	1	0.69	0.087
Infection	1	0.36	0	0.00	0.557	3	1.08	0	0.00	0.307
Metabolic	2	0.72	0	0.00	0.406	3	1.08	0	0.00	0.307
Musculoskeletal	0	0.00	0	0.00	1.000	0	0.00	0	0.00	1.000
Miscellaneous	0	0.00	0	0.00	1.000	0	0.00	0	0.00	1.000

¹Patients may have had multiple events and therefore can be counted in more than one category / subcategory of event. Counts represent the number of patients who have experienced one or more events.

²Because of the large number of tests of significance performed, the individual test level for significance was set conservatively at $p < .01$. Therefore, none of the AE rates were deemed significantly different statistically between ARCHer 2 and ARCHer 3.

³One of the in-hospital strokes in the ARCHer 2 trial occurred on day 5 following coronary artery bypass graft (CABG). The stroke was not considered to be related to either the ARCHer study or to the study device.

6.2 Potential Adverse Events

Based on the literature, and on clinical and commercial experience with the use of embolic protection systems with a carotid stent, the following alphabetical list includes possible adverse events associated with the use of this device:

- Allergic reactions to antiplatelet agents / contrast medium
- Aneurysm
- Angina / coronary ischemia
- Arrhythmia
- Arterial occlusion / thrombosis at puncture site or remote site
- Arteriovenous fistula
- Bacteremia or septicemia
- Bleeding from anticoagulant or antiplatelet medications
- Cerebral edema
- Cerebral hemorrhage
- Cerebral ischemia / transient ischemic attack (TIA)
- Congestive heart failure (CHF)
- Death
- Detachment and / or implantation of a component of the system
- Emboli, distal (air, tissue, or thrombotic emboli)
- Emergent or urgent endarterectomy surgery (CEA)
- Fever
- Filter thrombosis / occlusion
- Groin hematoma, with or without surgical repair
- Hemorrhage, with or without transfusion
- Hypotension / hypertension
- Infection and pain at insertion site
- Ischemia / infarction of tissue / organ
- Myocardial infarction (MI)
- Pain (head, neck)
- Pseudoaneurysm, femoral
- Renal failure / insufficiency
- Restenosis of stented / dilated vessel
- Seizure
- Severe unilateral headache
- Stent / filter entanglement / damage
- Stroke / cerebrovascular accident (CVA)
- Total occlusion of carotid artery
- Vessel dissection, perforation, or rupture
- Vessel spasm or recoil

Any adverse event occurring involving the RX Accunet EPS should be reported immediately to Abbott Vascular, Customer Service, at (800) 227-9902. If outside the USA, call (951) 914-4669.

7.0 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. A total of 581 registry patients were enrolled at 45 clinical sites in the United States and five sites outside of the United States.^a These trials are summarized in Table 5.

Table 5. An Overview of the ARCHeR Trials

	ARCHeR 1	ARCHeR 2	ARCHeR 3
Products Evaluated	Over-the-wire Acculink Carotid Stent System	Over-the-wire Acculink and Over-the-wire Accunet Systems	Rapid Exchange Acculink and Rapid Exchange Accunet Systems
Study Design	Non-randomized, multi-center, single-arm, prospective clinical trials		
Sample Size	158 (plus 51 lead-in patients)	278 (plus 25 lead-in patients)	145 patients
Number of Sites	25 Sites in the U.S.	37 Sites in the U.S. and 1 Site in South America	19 Sites in the U.S., 4 Sites in Europe, and 1 Site in South America
Primary Endpoint	30-day death, stroke, MI and ipsilateral stroke at 31-365 days	30-day death, stroke, and MI and ipsilateral stroke at 31-365 days; Accunet device success ²	30-day death, stroke, and MI
Secondary Endpoints- All Trials	-Device Success ^{1,2} -Clinical Success ³ -Target Lesion Revascularization -Access Site complications requiring treatment		
Specific Secondary Endpoints	-Six and 12 month ultrasound (annually thereafter)	-Six and 12 month ultrasound (annually thereafter) -Medical Resource Utilization	-Six and 12 month ultrasound -Ipsilateral stroke between 31 and 365 days ⁴
Study Hypothesis	Non-inferiority to historical control	Non-inferiority to historical control	Non-inferiority to ARCHeR 2 results at 30 days
Patient Follow-up	-Neurologic evaluation by an <u>independent neurologist</u> and patient assessment at 24 hours, 30 days, 6 months, 12 months (every 6 months thereafter for ARCHeR 1 and 2 only) -TIA / Stroke questionnaire and adverse event assessment at 30 days and 3, 6, 9 and 12 months. -ECG at 30 days -Ultrasound at 30 days, 6 and 12 months (annually thereafter for ARCHeR 1 and 2 only)		

¹ Attainment of final result, $<50\%$ residual stenosis covering an area no longer than the original lesion, using the Acculink System as described in the protocol.

² Device delivered, placed, and retrieved as described in the protocol.

³ Acculink device / procedure success without death, emergency endarterectomy, repeat PTA / thrombolysis of the target vessel, stroke, or MI within seven days of the procedure.

⁴ Data collection for the ARCHeR 3 study is not complete beyond 30-days. Secondary endpoints have not been evaluated.

The study hypothesis of the ARCHeR 1 and ARCHeR 2 trials was to show equivalence (non-inferiority) between carotid stenting and an historical control, based on the standard of care. The

^a The ARCHeR 1 and 2 trials each had a lead-in phase for initial clinical experience. An additional 76 patients were enrolled in this phase of the clinical study, 51 in ARCHeR 1 and 25 in ARCHeR 2. The natures and frequencies of endpoints and adverse events reported in lead-in patients were consistent with those reported in the pivotal trials, and thus are not reported here.

historical control was established based on a review of the current literature on carotid endarterectomy and medical therapy. From this review, the rate of 30-day death, stroke, MI, and ipsilateral stroke at 31 – 365 days was estimated at 15% for patients with medical co-morbidities, and estimated at 11% for patients with anatomy unfavorable for CEA. A weighted historical control (WHC) was calculated based on the proportion of each of these patient groups enrolled in the study.

$$WHC = pc * 15\% + pa * 11\%$$

Where: pc = the proportion of patients with medical co-morbidities, and
pa = the proportion of patients with unfavorable anatomy.

Using this equation, the WHC rate at one year was calculated for both ARCHeR 1 and ARCHeR 2 to be 14.5%. The ARCHeR 3 trial was designed to demonstrate equivalence (non-inferiority) of the safety and performance of the rapid exchange RX Acculink and RX Accunet Systems to results observed in the ARCHeR 2 trial for the OTW Acculink and Accunet Systems based on 30-day results.

As shown in Table 5, the protocol required regular patient follow-up by the treating physician and follow-up neurological assessments by an independent neurologist. Core laboratories provided independent assessments for angiographic, ultrasound, ECG, and pathologic evaluation of captured debris (Accunet only). Medical monitors reviewed all safety data to ensure appropriate reporting of adverse events. A Clinical Events Adjudication Committee adjudicated suspected primary endpoint events. A Data Safety Monitoring Board monitored adverse events to insure patient safety.

Eligibility Criteria Summary

The study population consisted of male and female patients, at least 18 years of age, with discrete lesions in the internal carotid artery. Patients had to be high-risk candidates for surgery or non-surgical candidates; both symptomatic ($\geq 50\%$ stenosis) and asymptomatic patients ($\geq 80\%$ stenosis) were eligible.

The inclusion criteria for ARCHeR 1, 2, and 3 were essentially identical. Key inclusion criteria included the following:

- Symptomatic patient: Transient ischemic attack (TIA), amaurosis fugax, or minor / non-disabling stroke (in the hemisphere supplied by the target vessel) within 180 days of enrollment; carotid stenosis had to be $\geq 50\%$ by angiography, using NASCET^b methodology to determine degree of stenosis.
- Asymptomatic patient: meets angiographic and clinical inclusion criteria; carotid stenosis had to be $\geq 80\%$ by angiography, using NASCET methodology to determine degree of stenosis.

^b Gasecki, A. P., M. Eliasziw, et al. (1995). "Long-Term Prognosis and Effect of Endarterectomy in Patients with Symptomatic Severe Carotid Stenosis and Contralateral Carotid Stenosis or Occlusion: Results from NASCET." J Neurosurg 83: 778-782.

- Patient had to meet **two** or more of the criteria listed in a-e **OR one** or more of the criteria listed in f-q to qualify as a high-risk or non-surgical candidate:
 - a) Knowledge of two or more proximal or major diseased coronary arteries with $\geq 70\%$ stenosis that have not, or cannot be revascularized;
 - b) Unstable angina defined as rest angina with electrocardiogram (ECG) changes;
 - c) MI within the previous 30 days and current need for carotid artery revascularization;
 - d) Concurrent requirement for aortocoronary bypass or cardiac valve surgery within 30 days;
 - e) Contralateral occlusion of the ICA.
 - f) Currently on a list for major organ transplantation (i.e. heart, lung, liver, kidney) or is being evaluated for such;
 - g) Ejection fraction $< 30\%$ or New York Heart Association (NYHA) Functional Class III or higher;
 - h) FEV1 $< 30\%$ (Predicted);
 - i) Dialysis-dependent renal failure;
 - j) Uncontrolled diabetes defined as fasting glucose > 400 mg/dl and ketones $> 2+$;
 - k) Restenosis after previous CEA
 - l) Patient is status / post radiation treatment to the neck;
 - m) Patient is status / post radical neck surgery;
 - n) Surgically inaccessible lesions (e.g. lesions above the level of C2 or below the clavicle, lesions obstructed by tumors in the neck);
 - o) Spinal immobility – inability to flex neck beyond neutral or kyphotic deformity;
 - p) Presence of tracheostomy stoma;
 - q) Contralateral laryngeal nerve paralysis.
- Patient had a discrete lesion located in the ICA (with or without involvement of the contiguous CCA).
- Target ICA vessel reference diameter had to be ≥ 4.0 mm and ≤ 9.0 mm by angiography.

Specific Inclusion Criteria for the OTW and RX Accunet EPS (ARChR 2 and 3 only)

- The vessel distal to the lesion had to have an absence of excessive tortuosity and an available straight or mildly angulated segment ≥ 4 cm, by angiography, in the distal ICA (prior to the petrous portion of the vessel) in which to place the embolic protection device.
- The diameter of the straight or mildly angulated segment, in the distal ICA prior to the petrous portion of the vessel, had to be ≥ 3.25 mm and ≤ 7.5 mm (ARChR 2) or ≥ 3.25 mm and ≤ 7.0 mm (ARChR 3) by angiography.

Description of Patients Evaluated

Baseline demographics and lesion characteristics for the three studies are presented in Table 6. All reported angiographic data on the treated lesions are based on measurements obtained by a centralized angiographic core laboratory.

Table 6. Baseline Patient Demographics

Demographics and Medical History	ARChEr 2 N=278	ARChEr 3 N=145	P value ¹	ARChEr 1 N=158
Age				
Mean ± SD	70.48± 9.38 (278)	71.13± 9.40 (145)	0.499	69.21± 9.65 (158)
Range (min, max)	(45.29, 92.67)	(38.94, 88.78)		(40.28, 90.14)
Age ≥ 80 year	15.5% (43/ 278)	17.9% (26/145)	0.579	13.3% (21 / 158)
Gender				
Male	68.3% (190/278)	68.3% (99/145)	1.000	63.9% (101 / 158)
Medical History				
Diabetes	39.9% (111/ 278)	34.5% (50/145)	0.293	37.3% (59 / 158)
Hypertension	84.2% (234/ 278)	83.3% (120/144)	0.889	83.5% (132/ 158)
Hypercholesterolemia	71.9% (200/ 278)	82.4% (117/142)	0.022	64.7% (101/ 156)
Current Smoker	17.7% (49/ 277)	17.7% (25/141)	1.000	23.7% (37 / 156)
Number of Symptomatic Patients (TIA, Stroke or Amaurosis Fugax Within 180 Days)	24.1% (67/ 278)	21.4% (31/ 145)	0.547	25.3% (40 / 158)
Baseline Lesion & Vessel Characteristics				
No Calcification	50.4% (139/ 276)	42.3% (60/ 142)	0.122	64.9% (98/ 151)
Unilateral Calcification	27.2% (75/ 276)	23.2% (33/ 142)	0.411	27.2% (41/ 151)
Bilateral Calcification	22.5% (62/ 276)	34.5% (49/ 142)	0.010	7.9% (12/ 151)
Lesion Length(mm)				
Mean ± SD (N)	14.55± 7.14 (276)	14.84± 7.82 (142)	0.707	16.17± 7.45 (157)
Range (min, max)	(0.00, 56.51)	(3.57, 43.81)		(4.72, 50.37)
Minimum Lumen Diameter (MLD, mm)				
Mean ± SD (N)	1.35± 0.56 (276)	1.21± 0.53 (142)	0.013	1.37± 0.64 (156)
Range (min, max)	(0.10, 3.57)	(0.00, 3.03)		(0.10, 3.15)
Percent Diameter Stenosis (%DS)				
Mean ± SD (N)	69.93±10.86 (276)	73.04±10.13 (142)	0.005	72.62±10.99 (156)
Range (min, max)	(31.03, 95.95)	(47.40, 100.0)		(42.96, 98.14)
High-Risk Inclusion Criteria	% (n/N)	% (n/N)		% (n/N)
Medical/Surgical Co-morbidities				
Two or More Diseased Coronary Arteries	27.7% (77/ 278)	25.5% (37/ 145)	0.647	28.5% (45/ 158)
Unstable Angina	7.9% (22/ 278)	6.9% (10/ 145)	0.847	7.6% (12/ 158)
MI Prior 30d & Need Carotid Artery Revasc.	3.6% (10/ 278)	2.1% (3/ 145)	0.556	4.4% (7/ 158)
Need CABG or Valve Surgery	14.0% (39/ 278)	15.2% (22/ 145)	0.772	19.0% (30/ 158)
Contralateral Occlusion of ICA	16.2% (45/ 278)	12.4% (18/ 145)	0.318	20.9% (33/ 158)
On List For Major Organ Transplant	0.0% (0/ 278)	0.7% (1/ 145)	0.343	0.0% (0/ 158)
Ejection fraction < 30% or NYHA ≥ III	38.8% (108/ 278)	27.6% (40/ 145)	0.024	29.7% (47/ 158)
FEV ₁ < 30% (Predicted)	3.2% (9/ 278)	4.8% (7/ 145)	0.429	5.1% (8/ 158)
Dialysis-dependent Renal Failure	2.2% (6/ 278)	2.1% (3/ 145)	1.000	5.1% (8/ 158)
Uncontrolled Diabetes	0.0% (0/ 278)	0.7% (1/ 145)	0.343	0.0% (0/ 158)
Restenosis after previous CEA	34.2% (95/ 278)	35.9% (52/ 145)	0.748	36.1% (57/ 158)
Unfavorable Anatomic Conditions				
Radiation Treatment to Neck	6.5% (18/ 278)	6.9% (10/ 145)	0.840	7.0% (11/ 158)
Radical Neck Surgery	2.2% (6/ 278)	4.8% (7/ 145)	0.146	3.2% (5/ 158)
Surgically Inaccessible Lesions	6.5% (18/ 278)	9.0% (13/ 145)	0.432	8.9% (14/ 158)
Spinal Immobility	2.9% (8/ 278)	6.2% (9/ 145)	0.119	0.0% (0/ 158)
Presence of Tracheostomy Stoma	1.4% (4/ 278)	2.1% (3/ 145)	0.695	1.9% (3/ 158)
Contralateral Laryngeal Nerve Paralysis	0.4% (1/ 278)	0.7% (1/ 145)	1.000	0.6% (1/ 158)

¹Statistical test of difference between ARChEr 2 and ARChEr 3, using Fisher's exact test for categorical values and t-Test for continuous variables.

Results:

The primary and secondary endpoints presented in Table 5 for the three studies were evaluated and categorized as either safety or efficacy endpoints.

Table 7 presents the periprocedural (30 day) safety endpoints related to short-term patient outcome. The 30-day primary endpoint rate (death, stroke, or MI within 30 days) was 7.59%, 8.63%, and 8.28% for ARCHeR 1, 2, and 3 respectively. Rates for each of the contributors to the composite rate are presented, as well as rates of other adverse events related to evaluation of procedure safety.

Table 8 presents efficacy endpoint and procedural success data. The one-year primary endpoint event rates (30-day primary endpoint + ipsilateral stroke between 31 and 365 days) were 8.28% and 10.22% for ARCHeR 1 and 2 respectively. These rates are estimated via Kaplan-Meier analysis presented in Figures 3 and 4. Device, procedural, and clinical success rates for all devices in all trials exceeded 91%.

To investigate the long-term stroke prevention capabilities of the Acculink Carotid Stent, the primary endpoint Kaplan-Meier curves shown in Figures 3 and 4 were extended out with all available follow-up data for the ARCHeR 1 and ARCHeR 2 studies. Median time for follow-up of the ARCHeR 1 study is 726 days; the accompanying table presents the Kaplan-Meier analysis at 1, 6, 12, 24, and 30 months. Median time for follow-up in the ARCHeR 2 study is 378 days; the accompanying table presents the Kaplan-Meier analysis at 1, 3, 6, 12, and 24 months.

A meta-analysis of all ARCHeR registry patients was conducted to evaluate the clinical efficacy of carotid stenting in symptomatic (n=138) and asymptomatic (n=443) subsets. Because MI has not historically been included in the primary endpoint of the landmark symptomatic (NASCET^c) and asymptomatic (ACAS^d) trials, a composite of all death and stroke within 30 days plus ipsilateral stroke beyond 30 days is presented in Figures 5A and 5B as Kaplan-Meier freedom-from functions. The rate of this composite at 1 and 2.5 years is 12.6% and 14.5% in the symptomatic subset and 6.8% and 11.0% in the asymptomatic subset. Another relevant outcome is the composite of all death and major stroke within 30 days and major ipsilateral stroke beyond 30 days (Figures 5C and 5D). The rate of this composite at 1 and 2.5 years is 5.1% and 6.9% in the symptomatic subset and 2.6% and 4.3% in the asymptomatic subset.

The relationship of patient and lesion characteristics to periprocedural outcomes (specifically stroke within 30 days and the composite of stroke, death and MI within 30 days) was examined in a multi-variate analysis. The statistically significant predictors of the composite endpoint events of stroke, death or MI were: requirement for coronary artery bypass graft (CABG) or valve surgery, hypertension, and symptomatic carotid stenosis (all $p < 0.05$). The statistically significant predictors of stroke at 30 days were: symptomatic carotid stenosis, hypercholesterolemia, male gender, advanced age, and anatomic risk factors (all $p < 0.05$).

The primary objectives of the ARCHeR 1 and ARCHeR 2 trials were met. The upper confidence limits for primary endpoint rates fell below the 14.5% WHC for both studies, demonstrating that carotid stenting is non-inferior to carotid endarterectomy in the studied high-risk population.

^c Barnett, H.J., D.W. Taylor, M. Eliasziw, A.J. Fox, G.G. Ferguson, R.B. Haynes, R.N. Rankin, G.P. Clagett, V.C. Hachinski, D.L. Sackett, K.E. Thorpe, and H.E. Meldrum, Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. N Engl J Med, 1998. 339(20): p. 1415-25.

^d ACAS, Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. JAMA, 1995. 273(18): p. 1421-8.

The primary objective of the ARCHEr 3 study, that the 30-day primary endpoint for the ARCHEr 3 study was non-inferior to that of the ARCHEr 2 study, was met. The upper bound of the 95% confidence interval of the difference between ARCHEr 3 and ARCHEr 2 is 4.75%, which is less than the delta of 8% ($p=0.005$). Thus, results from ARCHEr 3 are determined to be non-inferior to those of ARCHEr 2, and the RX and OTW devices are determined to yield similar clinical results.

Table 7. ARCHEr Pivotal Trials - Safety Assessment Event Rates (≤ 30 days)

Event Categories ¹	ARCHEr 2 (N=278)		ARCHEr 3 (N=145)		P value ²	ARCHEr 1 (N=158)	
	n	%	n	%		n	%
30-Day Primary Endpoint (Death, Stroke, MI)	24	8.63	12	8.28	1.000	12	7.59
All Stroke, Death Endpoint	19	6.83	11	7.59	0.842	10	6.33
Death	6	2.16	2	1.38	0.625	4	2.53
Stroke-Related	2	0.72	0	0.00	0.406	1	0.63
Not Stroke-Related	4	1.44	2	1.38	0.965	3	1.90
Ipsilateral Stroke	14	5.04	7	4.83	0.933	6	3.80
Major	3	1.08	2	1.38	0.802	2	1.27
Minor ²	11	3.96	5	3.45	0.816	4	2.53
Non-ipsilateral Stroke	1	0.36	1	0.69	0.653	1	0.63
Non-stroke Neurological ³	6	2.16	1	0.69	0.341	3	1.90
MI	8	2.88	2	1.38	0.406	4	2.53
Procedural Complication	27	9.71	8	5.52	0.194	11	6.96
Hypotension	15	5.40	2	1.38	0.092	6	3.80
Arrhythmia	11	3.96	0	0.00	0.048	5	3.16
Vasospasm	4	1.44	0	0.00	0.238	0	0.00
Dissection	2	0.72	3	2.07	0.223	0	0.00
In-stent Thrombosis	1	0.36	1	0.69	0.653	0	0.00
Emergent CEA	2	0.72	0	0.00	0.406	0	0.00
Emergent Intervention	1	0.36	1	0.69	0.653	0	0.00
Access Site Complication ⁴	13	4.68	4	2.76	0.405	9	5.70
Requiring Repair / Transfusion	8	2.88	2	1.38	0.406	6	3.80
Bleeding ⁵	7	2.52	6	4.14	0.387	11	6.96
Requiring transfusion	5	1.80	5	3.45	0.310	9	5.70
GI bleeding	0	0.00	2	1.38	0.015	2	1.27
Adverse events related to device failure or malfunction ⁶	2	0.72	1	0.69	1.000	0	0.00

¹Patients may have had multiple events and therefore can be counted in more than one category / subcategory of event. Counts represent the number of patients who have experienced one or more events.

²Two patients suffered strokes that were determined to be non-serious adverse events. Patient 249-3715 (ARCHEr 2) suffered blurred vision that was subsequently diagnosed by an ophthalmologist as "central retinal artery occlusion with multiple refractile emboli and macular edema." Patient 074-4804 had mild facial weakness that was subsequently diagnosed by MRI as an acute lacunar infarct. Both events resolved without treatment. The Clinical Events Adjudication Committee adjudicated both of these events as strokes. However, because the events did not meet the criteria for a serious adverse event (no intervention to prevent permanent impairment, no persistent or significant disability), they are not included in the accounting of serious adverse events. The events are included as strokes in the composite endpoints.

³Includes events such as visual / speech disturbances, confusion, seizure, and TIA.

⁴Includes events such as bruising, hematoma, and bleeding.

⁵Includes events such as non-access site bleeding, anemia up to 30 days, and GI bleed up to 30 days.

⁶Three adverse events counted above were categorized as related to device failure / malfunction:

One dissection in the ARCHEr 2 study was attributed by the physician to the OTW Accunet System. The physician was not able to cross the lesion with the device.

One CEA in the ARCHEr 2 study resulted when the OTW Accunet System became entangled with the deployed stent and could not be retrieved by the physician.

One emergent intervention in the ARCHEr 3 study resulted when the RX Accunet Filter Basket became entangled with the deployed stent and detached from the guide wire during the retrieval attempt. The physician opted to stent the basket in place in the artery. No additional adverse events related to this device malfunction were reported as of the last patient follow-up (9 months post-procedure).

Table 8. ARChER Pivotal Trial Results – Efficacy Assessment Event Rates

Events	ARChER 2 n/N %	ARChER 3 n/N %	P value	ARChER 1 n/N %
One-Year Primary Endpoint (30-Day Primary Endpoint + Ipsilateral Stroke Between 31 and 365 Days) ¹ [95% Conf. Interval] ²	10.22% [–, 13.48%]	N/A	N A	8.28% [–, 12.25%]
AccUNET Device Success ³	264/277 95.3	139/145 95.9	1.000	N/A
Acculink Device/Procedural Success ⁴	268/271 98.9	141/142 99.3	1.000	153/156 98.1
Clinical Success ⁵	249/272 91.5	133/142 93.7	0.562	143/156 91.7
Post-procedure In-lesion Minimal Lumen Diameter Mean ± SD (N) Range (min, max)	3.64± 0.78 (272) (1.93, 6.89)	3.79± 0.75 (143) (1.93, 6.29)	0.064	3.95± 0.86 (156) (1.52, 6.67)
Post-procedure In-lesion Percent Diameter Stenosis Mean ± SD (N) Range (min, max)	18.66±11.88 (272) (0.00, 51.07)	15.85±12.47 (143) (-12.1, 55.66)	0.025	20.40±12.38 (156) (-12.1, 56.06)
Target Lesion Revascularization (Clinically Indicated) ^{1, 6}		N/A	N/A	
at 6 months	1 0.4%			1 0.7%
at 12 months	7 2.8%			3 2.2%
at 24 months	8 3.8%			4 3.0%
Ultrasound (Same or decreased stenosis from Baseline exam)		N/A	N/A	
at 6 months	143/196 73.0			84/102 82.4
at 12 months	124/173 71.7			78/97 80.4

¹ Estimated via Kaplan-Meier analysis.

² 95% 1-sided confidence interval by normal approximation, using Peto's formula for the Kaplan-Meier standard error.

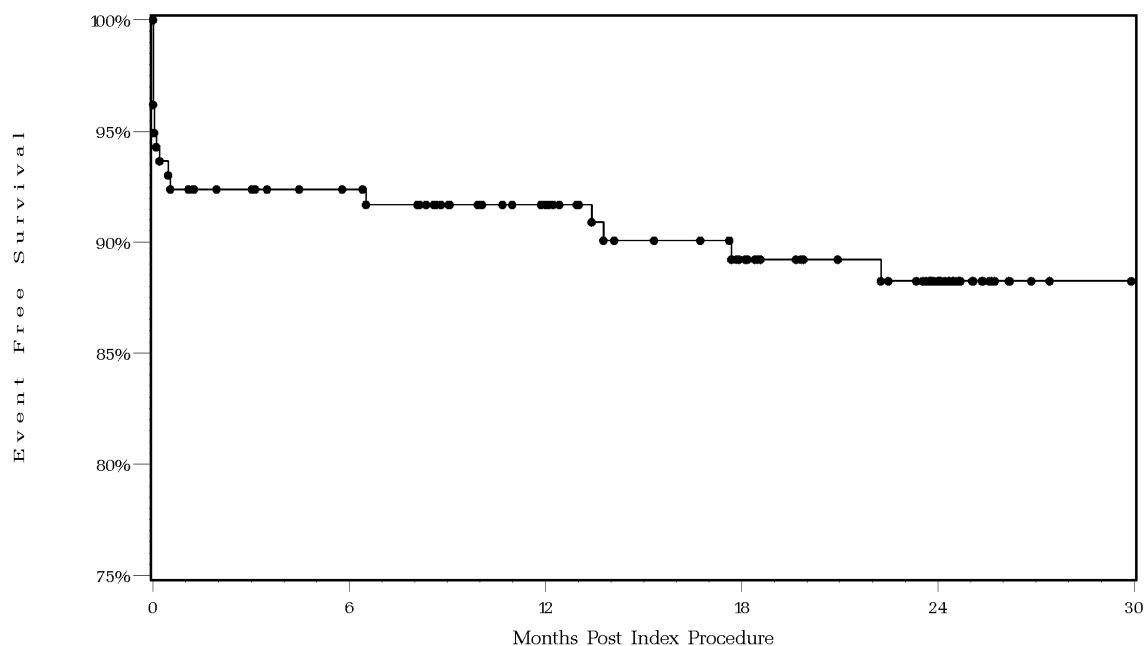
³ Device delivered, placed, and retrieved as described in protocol.

⁴ Stent successfully deployed and residual stenosis < 50% following stent placement, per core lab reading.

⁵ Acculink device / procedural success in the absence of death, emergency endarterectomy, repeat PTA / thrombolysis of the target vessel, stroke, or MI, within seven days of procedure.

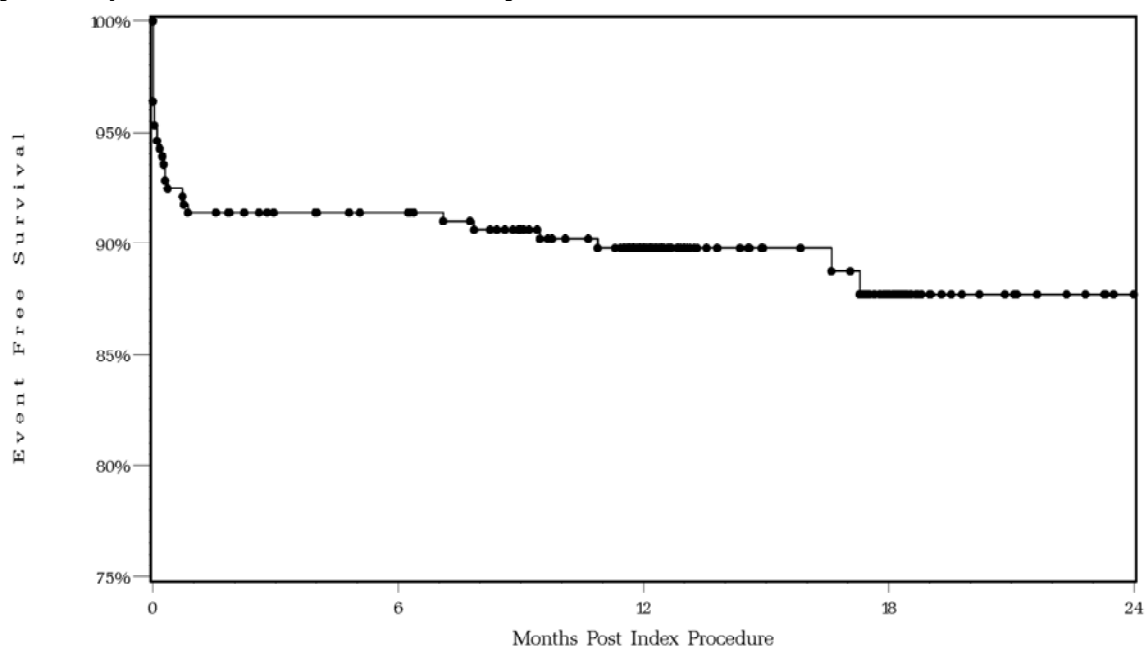
⁶ TLR is defined as any repeat invasive procedure, including angioplasty, stenting, endarterectomy or thrombolysis, performed to open or increase the luminal diameter inside or within 10mm of the previously treated lesion. To be considered clinically indicated, the patient must be symptomatic with ≥50% stenosis or asymptomatic with ≥80% stenosis.

Figure 3. ARChER 1 Study, Freedom from composite endpoint of Stroke, Death, and MI within 30 days and Ipsilateral Stroke between days 31 and 910



Months After Index Procedure	0	1	6	12	24	30
# At Risk	158	152	146	135	102	70
# Events	6	12	12	13	17	17
% Event Free	96.2%	92.4%	92.4%	91.7%	88.2%	88.2%

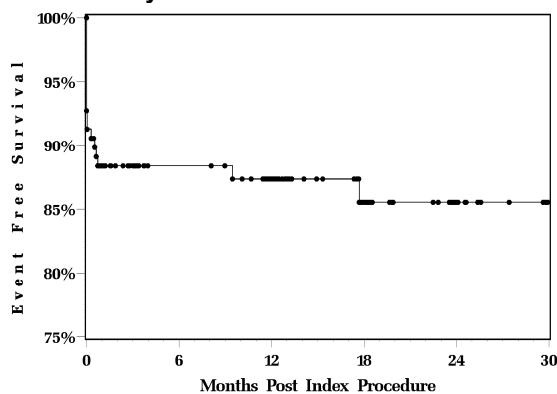
Figure 4. ARChR 2 Study, Freedom from composite endpoint of Stroke, Death, and MI within 30 days and Ipsilateral Stroke between days 31 and 730



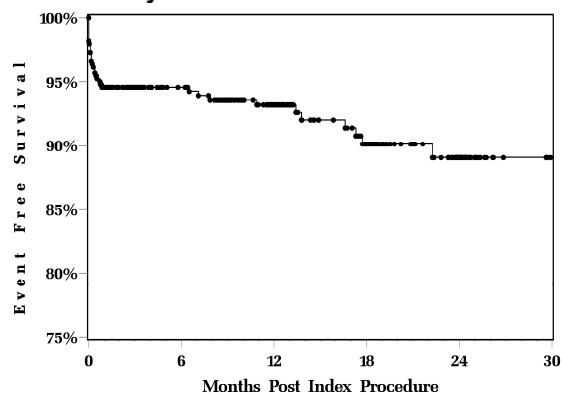
Months After Index Procedure	0	1	3	6	12	24
# At Risk	278	268	254	246	231	164
# Events	10	24	24	24	28	30
% Event Free	96.4%	91.4%	91.4%	91.4%	89.8%	87.7%

Figure 5. Symptomatic and asymptomatic registry patients in ARChR 1, 2 and 3

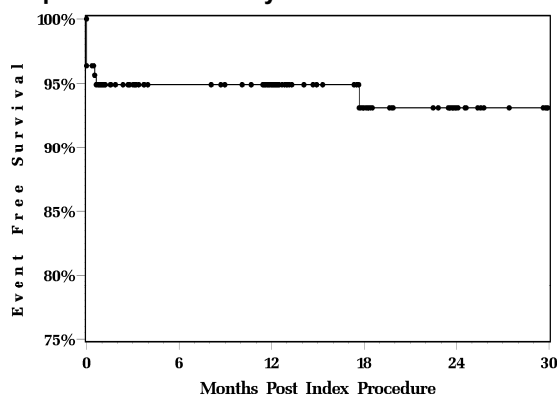
A. Symptomatic patients, freedom from composite of all Death or Stroke <30days, and Ipsilateral Stroke days 31-910



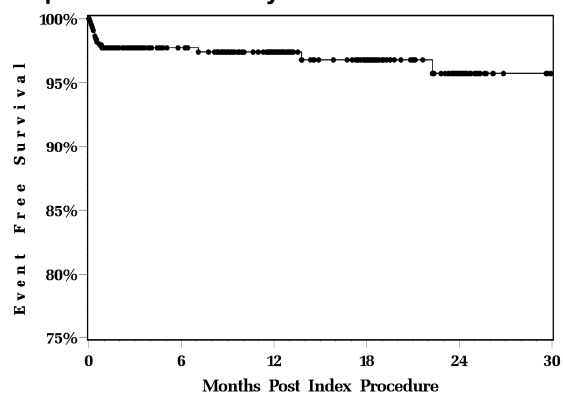
B. Asymptomatic patients, freedom from composite of all Death or Stroke <30days, and Ipsilateral Stroke days 31-910



C. Symptomatic patients, freedom from composite of all Death or Major Stroke <30days, and Major Ipsilateral Stroke days 31-910



D. Asymptomatic patients, freedom from composite of all Death or Major Stroke <30days, and Major Ipsilateral Stroke days 31-910



8.0 CLINICIAN USE INFORMATION

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

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.

8.1 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)
- Acculink (over-the-wire) or RX Acculink Carotid Stent System (optional)
- Balloon dilatation catheter (optional)
- 1,000 u / 500 cc heparinized normal saline (sterile)
- 10 – 20 cc luer-lock syringe
- Doc extension wire (optional)

Caution: Confirm the compatibility of the RX Accunet EPS with the interventional devices before actual use.

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

8.2 Periprocedural Care

During the clinical studies, when possible, aspirin 325 mg b.i.d and either clopidogrel 75 mg b.i.d. or ticlopidine 250 mg b.i.d. were started 48 hours prior to the procedure. After the procedure, either ticlopidine 250 mg b.i.d. or clopidogrel 75 mg daily for two to four weeks, and aspirin 325 mg daily for one month were prescribed, followed by aspirin 325 mg daily indefinitely, per physician discretion.

8.3 Filter Basket Size Determination

Filter size selection is based on reference vessel diameter in the area where the filter basket will be expanded. See Table 9 for filter basket diameters and recommended reference vessel diameters.

Table 9. Filter Sizing Recommendation

Filter Size Fully Expanded	Reference Vessel Diameter Minimum to Maximum Range
4.5 mm	3.25 to 4.0 mm
5.5 mm	4.0 to 5.0 mm
6.5 mm	5.0 to 6.0 mm
7.5 mm	6.0 to 7.0 mm

Warning: Overstretching of the artery may result in rupture and life-threatening bleeding.

8.4 Inspection Prior to Use

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

Caution: Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and / or inaccurate torque response.

8.5 Delivery System Preparation

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

1. Hold the dispenser hoop and flushing tool securely in one hand.
2. Loosen the RHV on the flushing tool.
3. Fill a 10 cc syringe with heparinized normal saline. Holding the flushing tool in an upright position (see Figure 6), attach the syringe as shown, and flush gently to remove air from the filter. Observe fluid exiting the RHV.
4. Confirm that no part of the light blue, distal section of the delivery sheath is within the RHV, then tighten the RHV onto the delivery sheath.
5. Release the flushing tool and delivery sheath from the dispenser hooks. Release the proximal end of the wire from its dispenser hook. Grasp the delivery sheath and the flushing tool securely together, and remove from the dispenser. Inspect the delivery system for kinks, or other damage.
6. Flush to remove air from the sheath. Observe fluid exiting the proximal end of the delivery sheath.
7. Place the torque device onto the proximal end of the RX Accunet EPS guide wire and tighten.
8. While observing through the flushing tool, pull the filter basket back into the delivery sheath (by pulling proximally on the torque device) until the distal tip of the delivery sheath aligns with the proximal end of the blue filter obturator (see Figures 7 and 8). DO NOT pull the torque device such that the proximal end of the blue filter obturator goes into the distal tip of the delivery

sheath. Doing so will cause a reduction in device flexibility and deliverability, and has the potential to damage (crumple) the delivery sheath and adversely affect filter basket delivery.

Note: Step 8 may be repeated a maximum of two additional times.

9. Loosen the RHV of the flushing tool, and slide the flushing tool off the distal end of the delivery system.
10. Loosen the torque device and position it so that the light blue, proximal end of the delivery sheath is within the central collet tube of the peel away adapter of the torque device. Tighten the torque device to the wire.

Figure 6.
Flush air from
filter with filter
expanded in
flushing tool

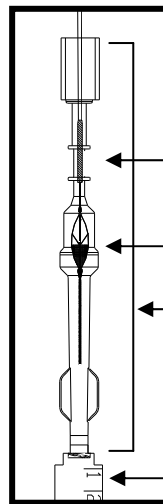
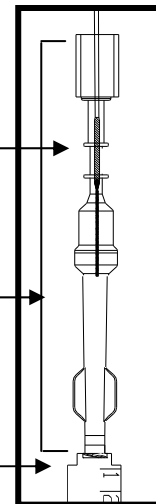


Figure 7.
Retract filter
into sheath



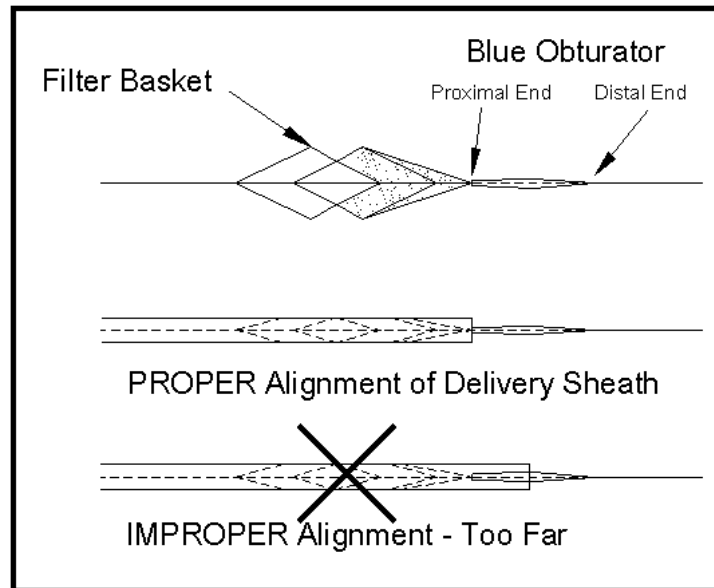
Delivery Sheath
Distal Tip

Filter Basket

Flushing Tool

Syringe

Figure 8.
Align distal tip of delivery sheath with proximal end of obturator (blue)



8.6 Recovery Catheter Preparation (for both the RX Accunet Recovery Catheter and the RX Accunet 2 Recovery Catheter)

1. Choose one of the two recovery catheters provided based on the relevant features of the device and how those features may best address the conditions of the case (e.g., CCA/ICA tortuosity, protruding stent struts, difficulty of aortic access). The RX Accunet Recovery Catheter – “Shapeable Tip Design” has a shapeable tip that is designed to provide torqueability or steerability at the tip of the device. The RX Accunet 2 Recovery Catheter – “Low-Profile, Flexible Design” is more flexible than the RX Accunet Recovery Catheter and has an extended soft tip and lower profile designed to deflect away from stent struts.
2. Remove the selected recovery catheter from the dispenser hoop.
3. Fill a 10 cc syringe with heparinized normal saline.
4. Flush the selected 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 clear tip area of the recovery catheter.

Observe fluid exiting the RX exit notch.

5. If using the RX Accunet Recovery Catheter - “Shapeable Tip Design”, the distal 3 cm of the catheter may be shaped as needed to allow for tip deflection.

General guidelines for shaping the RX Accunet Recovery Catheter - "Shapeable Tip Design":

- It is best to keep the shaping ribbon on the outside of the curve.
- Place the bend at the proximal part of the shaping ribbon. This section is the area where the orange catheter body transitions to the clear tip area.

8.7 Guiding Catheter / Sheath Support

Introduce the guiding catheter / sheath into vasculature and confirm that it is well positioned and firmly seated prior to introduction of the RX Accunet EPS. Always maintain view of the tip of the guiding catheter / sheath to minimize the likelihood of the catheter backing out or prolapsing into the aortic arch.

Warning: Maintain proper guiding catheter / sheath support in the common carotid artery throughout the procedure. If guiding catheter / sheath access cannot be maintained, the case should be discontinued. Failure to maintain proper support of the guiding catheter / sheath can lead to prolapse of the catheter into the aortic arch, resulting in any of the following:

- Movement of an open filter through an undilated lesion;
- Filter-stent entanglement, filter basket detachment and / or proximal movement of the stent; or
- Filter guide wire breakage

8.8 Lesion Preparation

Warning: Maintain the patient's ACT at > 250 seconds throughout RX Accunet EPS usage to prevent thrombus formation on the device.

Caution: Venous access should be available during carotid stenting in order to manage bradycardia and / or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

If desired, a 2 mm balloon may be used to predilate the lesion.

8.9 Delivery Procedure

Caution: Observe all guide wire movement in the vessels using fluoroscopic guidance.

Caution: The delivery system is not designed for use with power injection. Use of power injection may adversely affect device performance.

Caution: Do not deliver the RX Accunet EPS guide wire with filter basket through any interventional devices other than the RX Accunet EPS delivery system.

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

1. Use standard percutaneous techniques. Shape the tip of the RX Accunet EPS guide wire, if desired.
2. Carefully insert the guide wire tip of the delivery system into the funnel of the introducer tool and advance the unit completely into the RHV until the delivery sheath has entered the guiding catheter / sheath. Remove the introducer tool.

Caution: To avoid air entrapment, do not leave the introducer tool in the valve while advancing the delivery system. Advance the delivery system slowly through the guiding catheter / sheath.

Note: If using a long sheath with a hemostasis valve, the introducer tool should not be peeled off. Rather, it should be pulled back onto the sheath so that it can be reinserted later to facilitate deployment.

3. Under fluoroscopy, advance the tip of the delivery system into the selected vessel and across the lesion using the torque device to steer the guide wire. Do not torque the delivery sheath.

Warning: During positioning, advance the RX Accunet EPS guide wire with filter basket and the delivery sheath as a unit. Advancing the guide wire independently of the delivery sheath may result in premature filter deployment.

Warning: When introducing the delivery system, confirm that the wire tip is free within the vessel lumen and is not directed against the vessel wall. Failure to do so may result in vessel trauma. Use the radiopaque marker on the interventional device to confirm position.

Warning: Always advance or withdraw the RX Accunet EPS guide wire slowly using fluoroscopy to observe corresponding wire movement and tip movement in particular. Never push, auger, retract or torque a guide wire that meets resistance. If the wire tip becomes entrapped within a lesion or a device, such as a deployed stent, do NOT torque the guide wire. Determine the cause of resistance and take necessary remedial action. Torquing or retracting the guide wire against resistance may damage the wire, cause wire tip separation, or may cause vessel trauma. Resistance may be felt and / or observed using fluoroscopy by noting any buckling of the guide wire tip.

Note: A variety of techniques can be used to assist passage of the delivery system if it has difficulty advancing through the lesion. Some options to aid passage of the delivery system are:

- Have the patient rotate her / his neck from side-to-side. This motion may re-orient the carotid artery.
- If the RX Accunet EPS delivery system cannot cross the lesion, a 2 mm balloon may be used to predilate the lesion.
- If desired, insert a stiff 0.014" guide wire (buddy wire) to straighten the carotid vasculature to aid advancement of the delivery system. Leave the buddy wire in place while advancing the RX Accunet EPS delivery system. Remove the buddy wire prior to deployment of the RX Accunet EPS filter basket.

8.10 Filter Basket Positioning and Expansion

1. Position the delivery system in the artery such that the radiopaque markers are distal to the lesion to be treated.

Caution: For proper positioning of the filter basket, the vessel distal to the lesion should have an absence of excessive tortuosity and be of adequate length (approximately 4 cm distal to the lesion and proximal to the petrous portion of the vessel).

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2. Loosen the torque device from the wire.
 3. Feed the light blue, proximal end of the delivery sheath into the adjacent port of the peel away adapter on the torque device (see Figure 9). Advance the torque device until it abuts against the darker blue part of the sheath where the slit in the sheath begins. Tighten down the torque device to the wire.

4. Remove all slack from the system.

Note: If using a long sheath with a hemostasis valve or if using the Abbott Vascular Copilot Bleedback Control Valve, advance and reposition the introducer tool within the valve to hold it in an open position. This will allow the delivery sheath to move freely within the valve.

5. Stabilize the torque device with one hand (preferably the left) and keep that hand resting over the delivery sheath, distal to the torque device. With the other hand (the right), grab the proximal, light blue end of the delivery sheath that has been fed through the peel away adapter.
6. Under fluoroscopy pull the end of the sheath approximately 3 cm in a horizontal direction away from the patient. The sheath will peel away as it is pulled through the adapter. Observe filter basket expansion.

Caution: Ensure that the torque device is secured tightly to the guide wire to avoid difficulties with deployment. If the torque device is not tightened securely on the guide wire, proper deployment may not occur.

Note: Avoid excessive movement of the filter basket during unsheathing by removing all slack between the patient, guiding catheter / sheath and delivery system.

Note: Slight advancement of the guide wire during the unsheathing of the filter basket may be required to avoid excess movement of the filter basket during unsheathing.

7. The filter basket should now be fully expanded within the vessel. While maintaining a stable guide wire position, continue to peel back and retract the delivery sheath from the wire using the peel away feature. When the light blue, distal section exits the guiding catheter, close the RHV. The light blue, distal section will not peel. Once it exits the RHV, remove the torque device and the remaining portion of the delivery sheath.

Note: If using a long sheath with a hemostasis valve, remove the introducer tool after the light blue, distal section of the delivery sheath exits the hemostasis valve.

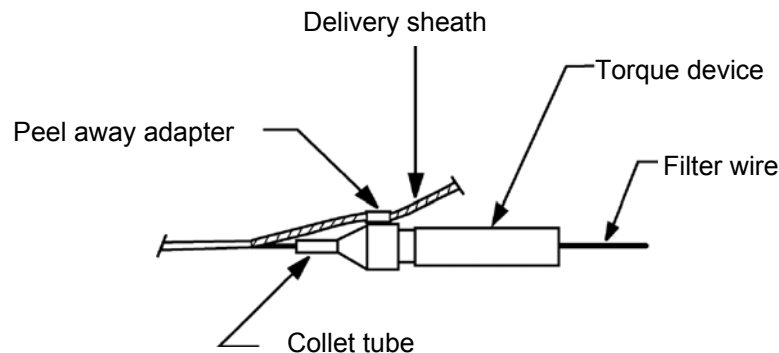
8. Confirm filter basket expansion by checking in two projections for visibility of the radiopaque markers on the frame of the basket and their apposition against the vessel wall. Under fluoroscopy, perform a contrast injection to determine that flow is adequate distal to the filter basket and that the filter basket is in the desired position.

Warning: The filter basket must be kept distal to the area to be covered by the stent and proximal to the petrous portion of the carotid artery to avoid excessive forces on the filter basket.

9. Compatible 0.014" guide wire-based interventional devices may now be backloaded onto the guide wire for treatment of the lesion.

Caution: Reconfirm the filter basket position prior to deployment of the stent to ensure that there is adequate distance between the radiopaque proximal bushing marker on the guide wire with filter basket and the distal end of the desired stent position to avoid stent deployment or entanglement on any part of the filter basket. If it is necessary to reposition the filter basket further distal to the desired stent position, gently advance the guide wire with filter basket. Under fluoroscopy, observe movement of the filter basket to the desired position.

Figure 9. Proximal End of Delivery Sheath Inserted in Peel away Adapter



8.11 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. During the case, keep the following three areas in the field of view at all times:
 - Filter basket and / or the proximal bushing marker
 - Lesion area
 - Radiopaque tip of the guiding catheter / sheath.

Maintaining a view of the tip of the guiding catheter / sheath will minimize the likelihood of the catheter backing out or prolapsing into the aortic arch.

Warning: Prolapse of the guiding catheter / sheath into the aortic arch can result in any of the following:

- Movement of an open filter through an undilated lesion;

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- **Filter-stent entanglement, filter basket detachment and / or proximal movement of the stent; or**
 - **Filter guide wire breakage**

4. 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 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.

8.12 Filter Basket Recovery (using the RX Accunet Recovery Catheter or the RX Accunet 2 Recovery Catheter)

1. Remove all interventional devices from the guide wire.
2. Backload the selected, 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.

Note: If using the RX Accunet Recovery Catheter -“Shapeable Tip Design”, the distal 3 cm of the recovery catheter tip may be shaped to allow for tip deflection to maneuver around stent struts or in bends. Tip deflection is accomplished by rotating the proximal luer of the recovery catheter up to 90 degrees in either direction.

3. Under fluoroscopy, carefully advance the selected 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 guiding sheath. The new position may either re-orient the entry of or give better support to the recovery catheter.
- If using the RX Accunet Recovery Catheter - “Shapeable Tip Design”, the tip shape of the recovery catheter can be shaped. If one shape does not pass through the stent, shape the catheter tip in another direction or modify the degree of angulation.
- 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.
4. If the above techniques are unsuccessful in advancing through the deployed stent, the alternate recovery catheter should be prepared and used, after withdrawal of the first recovery catheter; e.g., if the RX Accunet Recovery Catheter will not advance, carefully withdraw it and advance the RX Accunet 2 Recovery Catheter, or vice versa.
 5. Gently advance the selected recovery catheter over the filter basket until the radiopaque tip of the recovery catheter just covers the 4 (four) radiopaque wall apposition markers of the filter basket and causes the basket to collapse into the recovery catheter. The filter basket should not be completely contained within the catheter (see Figure 10).

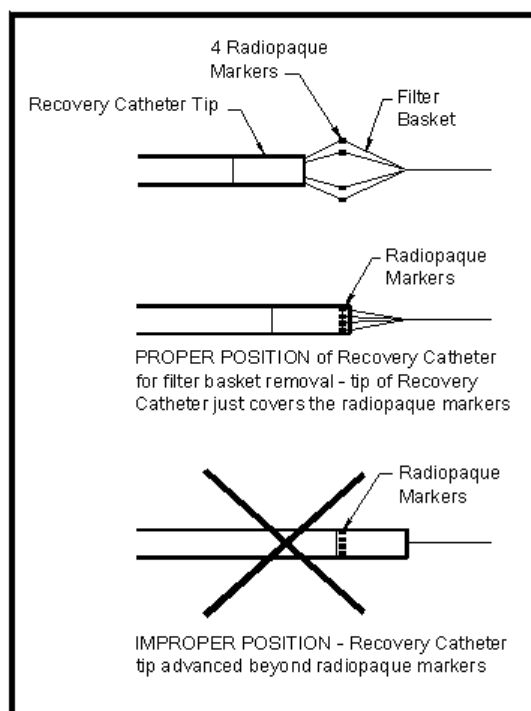
Warning: Always keep the open filter basket distal to the deployed stent. Do not attempt to pull an open filter basket through the stent. Do not attempt to capture the filter basket by pulling it into the recovery catheter if the recovery catheter tip is in the stent area. Pulling the filter basket into 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.

Note: If using the RX Accunet Recovery Catheter, there is a stop (you will feel resistance) when the tip of the recovery catheter is advanced far enough over the radiopaque wall apposition markers. However, the RX Accunet 2 Recovery Catheter does not have a stop within the tip of the device. This means that no resistance will be felt if the RX Accunet 2 Recovery Catheter is advanced too far over the RX Accunet Filter Basket. See Figure 10 for the proper positioning of both the RX Accunet and the RX Accunet 2 Recovery Catheters over the filter basket.

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.

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 or RX Accunet 2 Recovery Catheters.

Figure 10. Recovering the Filter Basket



6. 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, ensuring radiographically that the filter basket does not re-deploy.

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.

7. 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 an 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.

Warning: Discard unused RX Accunet and RX Accunet 2 Recovery Catheters after completing procedure. Failure to discard unused recovery catheters can result in any or all of the following: the use of a device past its "Use By" date; or the use of an incorrectly sized RX Accunet Recovery Catheter, which can cause loss of particulates from the filter basket during recovery, filter-stent entanglement, filter basket detachment and / or proximal movement of stent.

Caution: If the RX Accunet EPS is desired for intervention in additional vessels, use a new device.

9.0 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/.

10.0 HOW SUPPLIED

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

Contents: Three pouches containing:

RX Accunet Delivery System: One (1) 0.014" (0.36 mm) guide wire with filter basket, one (1) peel away delivery sheath, one (1) introducer tool, one (1) torque device with peel away adapter, one (1) flushing tool.

RX Accunet Recovery Catheter - "Shapeable Tip Design": One (1) recovery catheter, one (1) catheter clip.

RX Accunet 2 Recovery Catheter - "Low-Profile, Flexible Design": One (1) recovery catheter, one (1) catheter clip.

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

11.0 PATENTS AND TRADEMARKS

This product and / or its use are covered by one or more of the following United States Patents: 5,827,321; 6,106,548; 6,177,522; 6,245,090; 6,336,934; 6,402,771; 6,432,122; 6,475,236; 6,514,280; 6,540,722; 6,551,341; 6,565,591; 6,592,607; 6,645,224; 6,669,716; 6,695,813; 6,726,701; 6,752,819; 6,764,506; 6,887,256; 6,913,612; 6,918,921; 6,964,672; 7,014,647; 7,018,372; 7,037,320; 7,094,243; 7,144,408; 7,172,620. Additional patents pending.

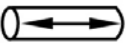
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Graphical Symbols for Medical Device Labeling

	
Manufacturer	Sterilized using irradiation
REF	
Catalogue number	Inner diameter
F	
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

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