SpiderFX™

Embolic Protection Device

LOWER EXTREMITY, CAROTID & SVG INTERVENTIONS

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

- One dual-ended **SpiderFX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

INDICATIONS FOR USE

Lower Extremity (LE) Interventions

The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

Carotid Interventions

The SpiderFX Embolic Protection Device is indicated for use as a guidewire 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 3.0mm and 7.0mm.

Saphenous Vein Graft (SVG) Interventions

The SpiderFX Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders
- Do not use in the renal arteries

LOWER EXTREMITY INTERVENTIONS

INDICATIONS FOR USE

The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

NOTE: *Commercially available catheters may also be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary guidewire prior to use.*

WARNINGS

The SpiderFX Embolic Protection Device should be used only by physicians who are trained in the proper use of the device.

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device 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 the renal or iliac arteries.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Refer to **Table 5** Lower Extremity Sizing Guide for appropriate Filter sizing in lower extremities. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.
- Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered, see section titled, *"Recovery and Removal"*.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use the Capture Wire with mechanical rotational thrombectomy or with atherectomy devices that require use of a specific guidewire.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised, see section titled, *"Recovery and Removal"*.
- After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the SpiderFX (or comparable) Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- If using the SpiderFX Delivery Catheter for filter delivery, the Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the SpiderFX Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- If using the SpiderFX Catheter for filter delivery, DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Do not advance the Filter while the primary wire is still within the catheter lumen.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.

Summary of DEFINTIVE Ca++ Study

DEFINITIVE Ca++ was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk™/TurboHawk™ Peripheral Plaque Excision Systems and the SpiderFX Embolic Protection Device to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision.

The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk Device(s) and the SpiderFX Device for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

A total of 133 subjects were enrolled. Subject demographics are provided in Table 1.

Table 1: Subject Demographics and Baseline Clinical Characteristics for LE Interventions

Subject Characteristics	N=133
Age (yrs.)	
Mean ± SD (N)	69.7 ± 9.8 (133)
Range (min, max)	(41.0, 95.0)
Male	71.4% (95/133)
Diabetes	47.4% (63/133)
History of hypertension requiring medication	91.7% (122/133)
History of MI	30.8% (41/133)
Hyperlipidemia	88.0% (117/133)
History of CABG or PCI	52.6% (70/133)
History of major amputation	0.8% (1/133)
Family history of CAD	49.6% (66/133)
History of peripheral intervention	57.1% (76/133)
History of smoking	78.9% (105/133)
CVA/TIA	15.8% (21/133)
Renal insufficiency	24.8% (33/133)
Rutherford clinical category score	
2	31.6% (42/133)
3	52.6% (70/133)
4	15.8% (21/133)

MI- myocardial infarction, CABG- coronary artery bypass graft, PCI-percutaneous coronary intervention, CAD- coronary artery disease, CVA-cerebrovascular accident, TIA - transient ischemic attack

The primary safety endpoint of the DEFINITIVE Ca++ study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met. A summary of the MAEs is provided in Table 2.

Table 2: Summary of Major Adverse Events

Major Adverse Event	
Total	6.8% (9/133) [9]
Death	0.0% (0/133) [0]
Acute myocardial infarction	0.8% (1/133) [1]
Dissection, target vessel (grade C)	0.0% (0/133) [0]
Dissection, target vessel (grade D or greater)	0.8% (1/133) [1]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]
Pseudoaneurysm, target vessel	0.0% (0/133) [0]
Thrombosis, target vessel	0.8% (1/133) [1]
Distal embolism	2.3% (3/133) [3]
Amputation, above metatarsal line	0.0% (0/133) [0]
Clinically Driven TVR	0.0% (0/133) [0]

Presence of debris in the SilverHawk/TurboHawk Device and SpiderFX Filter by visual inspection at time of procedure was assessed. Debris (excised plaque) was present in the nosecone of the SilverHawk/TurboHawk Device in 97.0% (129/133) of cases. Debris was present in 88.4% (122/138) of deployed SpiderFX Filters upon recovery. Preservation of run-off distal to the SpiderFX Filter was determined by angiography of run-off vessels at the end of the procedure, as adjudicated by the angiographic core laboratory. Preservation of run-off was verified by the angiographic core laboratory in 98.3% (113/115) of subjects with available data. The proportion of asymptomatic subjects increased from 0% at baseline to 52.3% at the 30-day follow-up visit. Likewise, the proportion of subjects with severe claudication decreased from 52.6% at baseline to 6.2% at 30 days.

Adverse Events

A summary of device- and procedure-related adverse events is provided in Table 3. There were no Unanticipated Adverse Device Effects or deaths.

Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk Device - Related	TurboHawk Device - Related	SpiderFX Device - Related	% of subjects [# of events]
All Related Events	38.3% (51/133) [64]	1.5% (2/133) [2]	18.4% (14/76) [14]	19.3% (11/57) [11]	3.8% (5/133) [5]	39.8% (53/133) [66]
Access site adverse event	6.0% (8/133) [9]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	6.0% (8/133) [9]
AV fistula, target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Dissection, grade A or B; non-target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Dissection, grade A or B; target vessel	19.5% (26/133) [26]	0.0% (0/133)	13.2% (10/76) [10]	10.5% (6/57) [6]	0.0% (0/133)	19.5% (26/133) [26]
Dissection, grade D or greater; target vessel	1.5% (2/133) [2]	0.0% (0/133)	0.0% (0/76)	3.5% (2/57) [2]	0.0% (0/133)	1.5% (2/133) [2]
Distal embolism; plaque, thrombus (blood clot) or debris distal to the filter, clinically relevant	2.3% (3/133) [3]	0.0% (0/133)	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	2.3% (3/133) [3]
GI bleeding due to anticoagulation	0.0% (0/133)	0.8% (1/133) [1]	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Hypotension or hypertension	1.5% (2/133) [2]	0.8% (1/133) [1]	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	2.3% (3/133) [3]
Myocardial infarction, acute	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Pseudoaneurysm, non-target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Renal insufficiency	1.5% (2/133) [2]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	1.5% (2/133) [2]
Thrombosis (acute and subacute); target vessel	0.8% (1/133) [1]	0.0% (0/133)	1.3% (1/76) [1]	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Vasospasm	1.5% (2/133) [2]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	1.5% (2/133) [2]	1.5% (2/133) [2]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	0.0% (0/133)	2.3% (3/133) [3]
Other, respiratory	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Other	5.3% (7/133) [9]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	5.3% (7/133) [9]

The results of the DEFINITIVE Ca++ study demonstrate that the SilverHawk/TurboHawk Device(s) is safe and effective in the endovascular treatment of moderate to severely calcified lesions in the superficial femoral and/or popliteal arteries when used with the SpiderFX Embolic Protection Device. The data also showed that utilizing the SpiderFX Embolic Protection Device resulted in preservation of run-off in 98.3% of subjects, further supporting that the use of the SpiderFX Device is a safe and effective means of embolic protection in subjects undergoing endovascular treatment for peripheral arterial disease.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adjunct device entanglement
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amputation
- Aneurysm
- Arterial dissection
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hypotension or hypertension
- Infection
- Ischemia
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Repeat intervention to treatment site
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

TABLE 4: SpiderFX Embolic Protection Device Specifications*

SpiderFX Capture Wire			
Filter Diameter (mm)	5.0	6.0	7.0
Filter Length (mm)**	23	23	24
Capture Wire Length RX (cm)	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)			
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140
SpiderFX Catheter - Recovery End (blue)			
Diameter (F)	4.2	4.2	4.2
Functional Length (cm)	140	140	140
Total Catheter Length (cm)	180	180	180

*Nominal
**When delivered at maximum recommended vessel size.

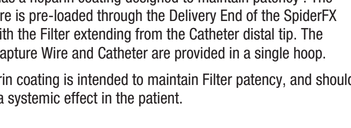
DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: *See Table 4 for Device product specifications.*

Capture Wire — The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

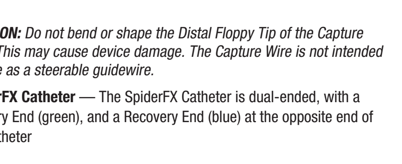
[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.



Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter — The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

INSTRUCTIONS FOR USE – SPIDERFX CATHETER

NOTE: *If using an alternate catheter for delivery/recovery of the SpiderFX Capture Wire see section titled, "Instructions for Use - Alternate Catheter of Choice".*

Preparing the SpiderFX Embolic Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Refer to **Table 5** Lower Extremity Sizing Guide for appropriate Filter sizing in lower extremities. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. (Table 5 Lower Extremity Sizing Guide).

TABLE 5: Lower Extremity Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (in)	Guide Catheter/ Sheath Min I.D.[2] (in)
3.0 - 4.0	5.0	0.014-0.018	0.066
3.5 - 5.0	6.0	0.014-0.018	0.066
4.5 - 6.0	7.0	0.014-0.018	0.066

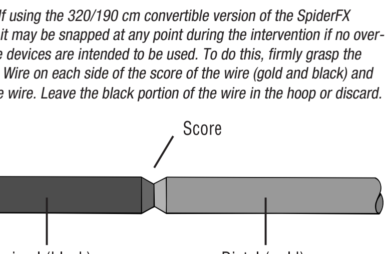
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*

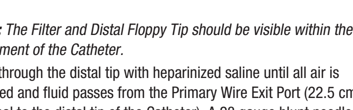


Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the proximal end of the Clear Segment of the Catheter.



Filter in Proper Position in Clear Segment

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

DELIVERY AND DEPLOYMENT

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the anticipated distal end of interventional device used to treat the lesion.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter placing the Primary Wire Exit Port at the apex of the curve*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm distal to the anticipated distal end of the interventional device used.

CAUTION: *Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

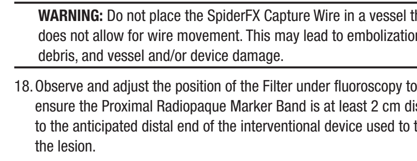
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

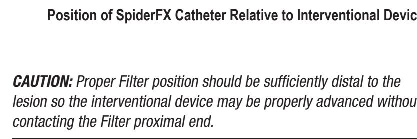
18. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of SpiderFX Catheter Relative to Interventional Device.

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent



19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered. See section titled, "*Recovery and Removal*".

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised. See section titled, "*Recovery and Removal*".

WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

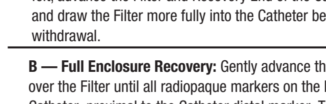
RECOVERY AND REMOVAL

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

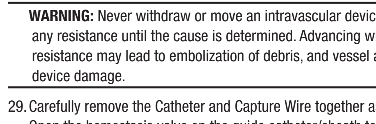
A — Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B — Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

INSTRUCTIONS FOR USE – ALTERNATE CATHETER OF CHOICE

NOTE: *Commercially available catheters can be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary wire prior to use.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Refer to **Table 6** Lower Extremity Filter Sizing Guide for appropriate Filter sizing in lower extremities. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.

TABLE 6: Lower Extremity Filter Sizing Guide

Target Vessel Size (mm)	Filter Size (mm)
3.0 - 4.0	5.0
3.5 - 5.0	6.0
4.5 - 6.0	7.0

NOTE: *Ensure that the length of the Catheter of Choice is such that it accommodates the Capture Wire length.*

4. Ensure the guide catheter/sheath size will accommodate the Catheter of Choice according to its instructions for use.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the SpiderFX Catheter near the Primary Wire Exit Port and gently pull to expose the SpiderFX Catheter. The remaining SpiderFX Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the SpiderFX Catheter.
8. Hold the SpiderFX Catheter near the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the SpiderFX Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the SpiderFX Catheter.

9. Continue holding the SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter and Distal Floppy Tip are fully contained within the distal tip of the SpiderFX Catheter.

WARNING: Failure to fully contain the Distal Floppy Tip within the distal end of the SpiderFX Catheter Delivery End during loading could result in kinking of the Distal Floppy Tip.

DELIVERY AND DEPLOYMENT

10. Access the vessel being treated using standard technique, and advance the primary guidewire and/or Catheter of Choice at least 5cm beyond the anticipated distal end of interventional device used to treat the lesion.
11. Hold the Catheter of Choice stationary and withdraw the primary guidewire.
12. Following removal of primary guidewire, flush the Catheter of Choice lumen with sterile heparinized saline.
13. Gently guide the tip of the SpiderFX Device Delivery End (green) into the proximal end of the Catheter of Choice or until the tip of the SpiderFX Catheter aligns with the lumen of the Catheter of Choice.

WARNING: Do not advance the SpiderFX Catheter against resistance. This may result in deformation of the embedded Radiopaque Marker Band contained within the SpiderFX Catheter tip.

14. Hold the SpiderFX Catheter and Catheter of Choice stationary, and gently advance the Capture Wire until the Filter enters the lumen of the Catheter of Choice.

NOTE: *The user should feel a reduction in force when the Filter has exited the SpiderFX Catheter and is fully contained within the Catheter of Choice.*

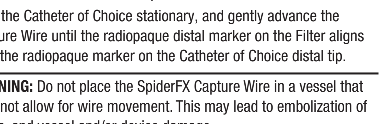
15. Continue to advance the Capture Wire through the SpiderFX Catheter and Catheter of Choice approximately 5 to 7 inches to ensure the Capture Wire's tapered section is fully supported within the Catheter of Choice.

CAUTION: *Failure to support the distal tapered section of the Capture Wire within the Catheter of Choice while advancing the Filter could result in kinking of the Capture Wire.*

16. Hold the Capture Wire stationary, and pull back on the SpiderFX Catheter to offload the SpiderFX Catheter from the Capture Wire. Keep the SpiderFX Catheter in the sterile field. **DO NOT DISCARD THE SPIDERFX CATHETER** in the event that the SpiderFX Catheter Recovery End (blue) may be needed for Filter recovery.
17. Place the SpiderFX Catheter in sterile heparinized saline or sterile field. Do not bend or kink the SpiderFX Catheter.
18. Hold the Catheter of Choice stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter of Choice distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

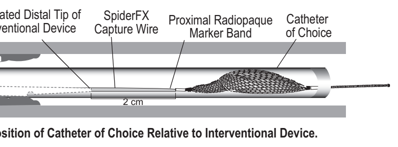
19. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of Catheter of Choice Relative to Interventional Device.

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent.



Position of Filter Relative to Interventional Device

20. Hold the Capture Wire stationary, and gently pull back on the Catheter of Choice to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter of Choice back over the Filter, adjust the position of the Catheter of Choice and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter of Choice.

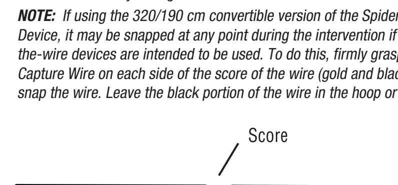
WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the Catheter of Choice or SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

21. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Catheter of Choice together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
22. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
23. Once the Filter is deployed in the desired location, carefully remove the Catheter of Choice from the patient. Keep the Catheter of Choice in the sterile field. DO NOT DISCARD THE CATHETER OF CHOICE. The Catheter of Choice may be used for Capture Wire recovery.
24. Place the Catheter of Choice in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter of Choice.

NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery.*

25. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



Capture Wire

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

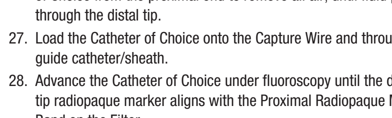
WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised. See section titled, "*Recovery and Removal*".

WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

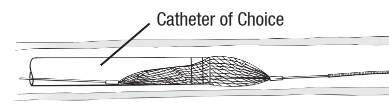
RECOVERY AND REMOVAL

26. After completion of the interventional procedure, flush the Catheter of Choice from the proximal end to remove all air, until fluid passes through the distal tip.
27. Load the Catheter of Choice onto the Capture Wire and through the guide catheter/sheath.
28. Advance the Catheter of Choice under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
29. Gently advance the Catheter of Choice over the Filter, until the proximal portion of the Filter is inside the Catheter of Choice, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the distal radiopaque marker of the Catheter of Choice.



Recovery of SpiderFX Capture Wire with Catheter of Choice.

WARNING: Exercise caution when withdrawing a full Filter through a deployed stent. If resistance is felt, advance the Filter and Catheter of Choice distally and draw the Filter more fully into the Catheter of Choice before re-attempting withdrawal as illustrated below.



30. Carefully remove the Catheter of Choice and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the Catheter of Choice to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

CAROTID INTERVENTIONS

INDICATIONS FOR USE

The SpiderFX Embolic Protection Device is indicated for use as a guidewire 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 3.0mm and 7.0mm.

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.

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device 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 (coronary or cerebral).
- The safety and efficacy of the SpideRX Embolic Protection Device 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 in accordance with standard medical practice.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Refer to **Table 14** Carotid Sizing Guide for appropriate Filter sizing in relation to the selected vessel diameter. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use thrombectomy, atherectomy, or laser devices with the Capture Wire.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised. See section titled, "*Recovery and Removal*".
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.

OBSERVED ADVERSE EVENTS – CLINICAL STUDY

The SpideRX™ Embolic Protection Device was evaluated for the treatment of internal and/or common carotid artery stenoses in high-risk patients via the Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Trial Clinical series. A total of 609 patients were enrolled in the trial as follows:

- CREATE Feasibility evaluated the ev3 over-the-wire (OTW) SPIDER™ Embolic Protection Device and PROTÉGÉ® Self-expanding Nitinol Stent and included 30 patients. The primary objective of the study was to evaluate the safety of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- CREATE Pivotal also evaluated the ev3 over-the-wire (OTW) SPIDER Embolic Protection Device and PROTÉGÉ Self-expanding Nitinol Stent and included 419 patients. The primary objective of the study was to evaluate the safety and efficacy of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- The SpideRX Arm of the CREATE Trial evaluated the ev3 rapid exchange SpideRX Embolic Protection Device and the commercially available ACCULINK™ Carotid Stent and included 160 patients. The primary objective of the study was to evaluate the safety and performance of the SpideRX Device in the treatment of common and/or internal carotid artery stenoses for patients at high-risk for carotid endarterectomy.

The SpideRX Embolic Protection Device is used in an acute manner and, therefore, peri-procedural adverse events are the most relevant evaluation of device safety. Table 7 presents the serious adverse events (defined as any event that may be either life-threatening or involve permanent long term injuries) that were reported through the 30-day follow-up visit in the SpideRX Arm and the CREATE Pivotal (SPIDER) Trial.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amaurosis Fugax
- Angina (unstable)
- Arterial dissection
- Cerebral hemorrhage
- Congestive heart failure
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention, resulting in TIA or stroke
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hyperperfusion syndrome
- Hypotension or hypertension
- Infection
- Intracerebral bleed
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Seizure
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

CLINICAL STUDIES

The Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. A total of 609 patients were enrolled at 35 clinical sites in the United States in three trials designed to demonstrate the safety and efficacy of the ev3 SPIDER over-the-wire and SpideRX Embolic Protection Devices as well as the PROTÉGÉ Self-Expanding Nitinol Stent when used to treat high-risk symptomatic and asymptomatic patients with internal and/or common carotid artery stenoses.

ELIGIBILITY CRITERIA

Male and female patients who presented for percutaneous treatment of an internal and/or common carotid artery intervention were considered for enrollment. To be included, the patients were required to be at least 18 years old and considered to be at high risk for carotid endarterectomy. The general and angiographic inclusion and exclusion criteria for the three trials were identical with the exception of vessel size in the SpideRX Arm of the CREATE Trial. Vessel size was changed in this trial to accommodate the limitations of the commercially available carotid stent.

Patients were considered symptomatic if their target stenosis was associated with ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral ischemic stroke within 6 months prior to enrollment. Patients who were characterized as symptomatic were also required to have a target lesion stenosis (as defined in the NASCET trial) ≥ 50%. Asymptomatic patients were required to have a target lesion stenosis ≥ 70%.

High risk criteria are included in Table 10.

TABLE 7: Serious Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Death	4/160 (2.5%)	8/417 (1.9%)	-0.6% (-3.3%, 2.2%)	0.7453
Ipsilateral Stroke				
Major	2/160 (1.3%)	14/417 (3.4%)	2.1% (-0.3%, 4.5%)	0.2569
Minor	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Non-Ipsilateral Stroke	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Total patients with complications	37/160 (23.1%)	130/417 (31.2%)	8.1% (0.2%, 16.0%)	0.0648
Access site complications:				
Hemorrhage	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Pseudoaneurysm	2/160 (1.3%)	6/417 (1.4%)	0.2% (-1.9%, 2.3%)	1.0000
Puncture site infection	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Amaurosis Fugax	1/160 (0.6%)	1/417 (0.2%)	-0.4% (-3.1%, 0.5%)	0.0478
Angina	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Arrhythmia	5/160 (3.1%)	12/417 (2.9%)	-0.3% (-3.4%, 2.9%)	1.0000
Artery perforation:				
Contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Non-contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Congestive Heart Failure	3/160 (1.9%)	0/417 (0.0%)	-1.90%	0.0021
Dissection	1/160 (0.6%)	5/417 (1.2%)	0.6% (-1.0%, 2.2%)	1.0000
Emergent surgery	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	1/160 (0.6%)	7/417 (1.7%)	0.8% (-0.9%, 2.5%)	0.6797
Hypotension	21/160 (13.1%)	73/417 (17.5%)	4.4% (-2.0%, 10.8%)	0.2568
Intracerebral bleed	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
MI	1/160 (0.6%)	4/417 (1.0%)	0.3% (-1.2%, 1.9%)	1.0000
Renal failure requiring dialysis	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Renal insufficiency	2/160 (1.3%)	5/417 (1.2%)	-0.1% (-2.1%, 2.0%)	1.0000
Seizure	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Stent / Vessel thrombosis	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Stent misplacement	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Stent or filter failure to deploy	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
TIA	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Other	9/160 (5.6%)	40/417 (9.6%)	4.0% (-0.6%, 8.5%)	0.1365

[1] Patients may have had multiple events. Counts represent the number of events reported.

Table 8 indicates the number of deaths that were considered to be related to a stroke or myocardial infarction.

TABLE 8: Cause of Death, 30 Days

Events	SpideRX (N=160)	SPIDER (N=417)
Stroke	2	5
Cardiac	2	3

TABLE 9: Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Total patients with complications	12/160 (7.5%)	30/417 (7.2%)	- 0.3% (-5.1%, 4.5%)	0.8598
Access site complication:				
Hematoma	5/160 (3.1%)	2/417 (0.5%)	-2.6% (-5.4%, 0.1%)	0.0198
Puncture site infection	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Allergic reaction to contrast dye	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Allergic reaction to procedure meds	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Arrhythmia	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Hypotension	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Renal insufficiency	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Restenosis	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stent or filter collapse or fracture	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Ipsilateral stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
TIA	1/160 (0.6%)	6/417 (1.4%)	0.8% (-0.9%, 2.5%)	0.6797
Vasospasm	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Other	1/160 (0.6%)	11/417 (2.6%)	2.0% (0.0%, 4.0%)	0.1942

[1] Patients may have had multiple events. Counts represent the number of events reported.

TABLE 10: High Surgical Risk Criteria

Clinical Criteria[1]	Anatomical Criteria[1]
1. Age >75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. High cervical lesion (above the angle of the jaw)
3. CHF class III-IV	3. Infraclavicular lesion
4. LVEF <35%	4. Tandem lesions >70%
5. MI <6 weeks	5. Hostile neck (cervical radiation treatment, tracheostomy/stoma, or radical neck dissection)
6. Coronary artery disease with >2 vessel disease in major vessel & history of angina	6. CEA restenosis
7. Severe pulmonary disease – home oxygen, resting pO2 <60 or FEV1 <50%	7. Cervical immobility due to fusion or arthritis
8. Permanent contralateral cranial nerve injury	8. Bilateral carotid stenoses, both requiring treatment*

[1] The subjects were required to meet at least ONE or more high-risk criterion in EITHER the clinical or anatomical section.
* Only the most severe lesion meeting the angiographic inclusion criteria could be treated in the SpideRX Arm of the CREATE Trial.

Baseline demographic characteristics are included in Table 11. They were evaluated to determine if subjects enrolled in the SpideRX Arm of the CREATE Trial and the CREATE Pivotal Trial are homogeneous. The differences reported, along with the associated p-values, correspond to the differences between the populations in the SpideRX Arm of the CREATE Trial and those enrolled in the CREATE Pivotal Trial. The only characteristics indicated to be significantly different were history of other treatment to the target artery (3.8% for RX, 0.7% for Pivotal).

TABLE 11: Subject Demographics and Baseline Clinical Characteristics for Carotid Interventions

Patient Characteristics	Pivotal (N = 419)	SpideRx (N = 160)	Difference	(p-value)
Age (yrs.) Mean SD (N) Range (min, max)	 73.6 9.1 (419) 49 (46, 94)	 73.5 9.0 (160) 57 (42, 100)	0.1	0.8812
Male	(255/419) 60.9%	(111/160) 69.4%	-8.5%	0.0670
Diabetes Mellitus	(131/419) 31.3%	(56/160) 35.0%	-3.7%	0.4268
Hypertension	(377/416) 90.0%	(146/160) 91.3%	-1.3%	0.7537
Hyperlipidemia	(367/419) 87.6%	(145/160) 90.6%	-3.0%	0.3834
Renal Insuffisiency	(80/419) 19.1%	(25/160) 15.6%	3.5%	0.3986
Smoking Never Current Former > 1 Year	 (96/419) 22.9% (69/419) 16.5% (254/416) 60.6%	 (34/160) 21.3% (36/160) 22.5% (90/160) 56.3%	 1.7% -6.0% 4.4%	0.2483
History of Arrhythmia	(84/419) 20.0%	(29/160) 18.1%	1.9%	0.6406
History of Myocardial Infarction	(126/419) 30.1%	(51/160) 31.9%	-1.8%	0.6873
History of previous PTCA/CABG	(219/419) 52.3%	(96/160) 60.0%	-7.7%	0.1126
History of CEA	(123/419) 29.4%	(38/160) 23.8%	5.6%	0.2132
History of Other Treatment to Target Artery	(3/419) 0.7%	(6/160) 3.8%	-3.0%	0.0160
History of TIA	(97/419) 23.2%	(24/160) 15.0%	8.2%	0.0305
History of Stroke	(85/419) 20.3%	(28/160) 17.5%	2.8%	0.4836
Current Carotid Bruit	(318/411) 77.4%	(119/157) 75.8%	1.6%	0.7384
Lesion Location Common Internal Both	 (25/444) 5.6% (334/444) 75.2% (85/444) 19.1%	 (10/160) 6.3% (132/160) 82.5% (18/160) 11.3%	 -0.6% -7.3% 7.9%	0.0667
Lesion Length (mm)	17.5	16.8	0.66	0.4207
Symptomatic	(73/419) 17.4%	(24/160) 15.0%	2.4%	0.5400
Pre-procedure% Stenosis (%)	82.2	82.6	-0.42	0.6076
Pre-reference Vessel Diameter (mm)	5.5	5.3	0.16	0.5753
High Risk Factors Anatomical Clinical Both	 (100/419) 23.9% (196/419) 46.8% (123/419) 29.4%	 (39/160) 24.4% (81/160) 50.6% (40/160) 25.0%	 -0.5% -0.4% 0.4%	0.4821

CLINICAL RESULTS SUMMARY

The primary endpoint of the SpideRX Arm of the CREATE Trial is a composite endpoint of MI, ipsilateral CVA, procedure-related contralateral CVA or death within 30 days of implantation, see Table 12. There are no significant differences between the SpideRX Arm and the CREATE Pivotal Trial with respect to the primary endpoint.

The relationship of patient or baseline lesion characteristics to outcomes through 30-days was considered in a multivariate analysis. This analysis did not result in any statistically significant predictor of outcomes (all p <0.05).

CLINICAL USE INFORMATION

Pre-procedure anticoagulant and antiplatelet requirements were specified in the clinical trial. A baseline dose of acetylsalicylic acid (ASA) of 325 mg was required the day prior and the day of the procedure. For patients on regular Coumadin® therapy, the dose could be reduced to 81 mg.

Several options were given with respect to the loading dose of antiplatelet medication:

- Clopidogrel 75 mg for three days prior to the procedure and the day of the procedure **or**
- Clopidogrel 450 mg the day before the procedure and 75 mg the day of the procedure **or**
- Ticlopidine 1000 mg the day before the procedure and two 250 mg doses the day of the procedure.

Patients were required to take 325 mg ASA **and** either 75 mg of clopidogrel each day or 250 mg of ticlopidine twice a day for three months following the procedure. For patients on regular Coumadin® therapy, the post-procedure ASA dose could be reduced to 81 mg.

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CAROTID INTERVENTIONS (continued)

TABLE 12: Primary and Secondary Endpoints

Efficacy Measures	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Primary Endpoint	9/160 (5.6%)	29/370 (7.8%)	N/A	N/A
30-Day MACCE	9/160 (5.6%)	26/414 (6.3%)	0.7% (-3.6%, 4.9%)	0.8480
Myocardial Infarction	1/160 (0.6%)	4/414 (1.0%)	0.3% (-1.2%, 1.9%)	0.6933
Ipsilateral CVA	7/160 (4.4%)	16/414 (3.9%)	-0.5% (-4.1%, 3.1%)	0.8133
Major	2/160 (1.3%)	14/414 (3.4%)	2.1% (-0.3%, 4.6%)	0.2570
Minor	4/160 (2.5%)	3/414 (0.7%)	-1.8% (-4.3%, 0.8%)	0.0988
Intracerebral Bleed	1/160 (0.6%)	0/414 (0.0%)	-0.60%	0.2800
Procedure-Related Contralateral CVA	0/160 (0.0%)	3/414 (0.7%)	0.70%	0.5638
Death	4/160 (2.6%)	8/414 (1.9%)	-0.6% (-3.4% , 2.2%)	0.7460
1 year Ipsilateral CVA	N/A	3/370 (0.8%)	N/A	N/A
Secondary Endpoints				
MANE	N/A	26/370 (7.0%)	N/A	N/A
TLR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
TVR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
Primary Patency at 1 year	N/A	286/304 (94.1%)	N/A	N/A
Technical Success	156/160 (97.5%)	408/419 (97.4%)	-0.13% (-3.01%, 2.76%)	0.9317
Acute Procedure Success (QCA)	147/148 (99.3%)	397/397 (100.0%)	0.68% (-0.65%, 2.01%)	0.3172
Acute Procedure Success (Site)	158/160 (98.8%)	437/444 (98.4%)	-0.3% (-2.4%, 1.8%)	1.0000

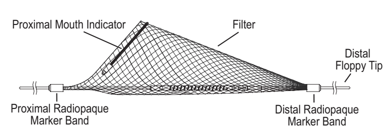
DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

***NOTE:** See **Table 13** for Device product specifications.*

Capture Wire– The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

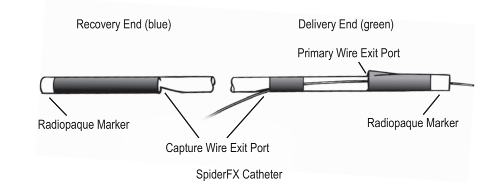
[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.



Capture Wire

***CAUTION:** Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter – The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter.



- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

TABLE 13: SpiderFX Embolic Protection Device Specifications*

SpiderFX Capture Wire					
Filter Diameter (mm)	3.0	4.0	5.0	6.0	7.0
Capture Wire Length RX (cm)	190	190	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)					
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140	140	140
SpiderFX Catheter - Recovery End (blue)					
Diameter (Fr)	4.2	4.2	4.2	4.2	4.2
Functional Length (cm)	140	140	140	140	140
Total Catheter Length (cm)	180	180	180	180	180

*Nominal

INSTRUCTIONS FOR USE

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the lesion site being treated. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the lesion, to allow for adequate Filter deployment.

WARNING: Refer to **Table 14** Carotid Sizing Guide for appropriate Filter sizing in relation to the selected vessel diameter. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. **(Table 14).**

TABLE 14: Carotid Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (inches)	Guide Catheter/ Sheath Min I.D.[2] (inches)
3.0	3.0	0.014-0.018	0.066
3.1-4.0	4.0	0.014-0.018	0.066
4.1-5.0	5.0	0.014-0.018	0.066
4.5-6.0	6.0	0.014-0.018	0.066
5.5-7.0	7.0	0.014-0.018	0.066

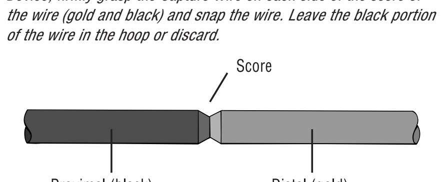
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

***CAUTION:** Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

***NOTE:** If using the 320/190 cm convertible version of the SpiderFX Device, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



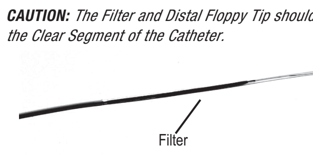
Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.

***CAUTION:** The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*



Filter in Proper Position in Clear Segment

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

***NOTE:** When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.*

***CAUTION:** Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

***CAUTION:** DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

***CAUTION:** Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

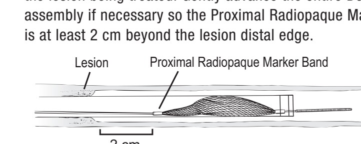
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

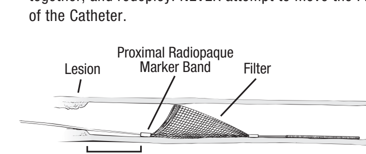
18. Observe the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the Proximal Radiopaque Marker Band is at least 2 cm beyond the lesion distal edge.



Position of SpiderFX Catheter

***CAUTION:** Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.



Position of Filter

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised. See section titled, *"Recovery and Removal"*.

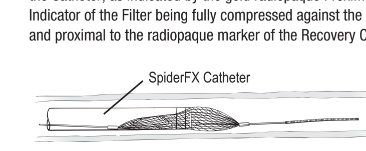
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

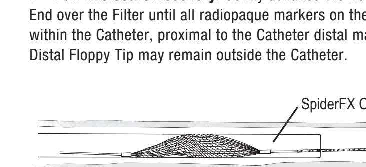
A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

STORAGE

- Do not store in direct sunlight
- Keep dry

SAPHENOUS VEIN GRAFT (SVG) INTERVENTIONS

INDICATIONS FOR USE

The SpiderFX Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

WARNINGS

The SpiderFX Embolic Protection Device should be used only by physicians who are experienced in coronary intravascular treatment and who are trained in the proper use of the device (see Physician Training section).

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Refer to **Table 21** SVG Sizing Guide for appropriate Filter sizing in relation to the selected vessel diameter. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See Recovery and Removal).
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Delivery End of Catheter prior to flushing.
- Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.
- Do not re-sterilize or reuse this device.
- The SpideRX Embolic Protection Device was a predecessor to the SpiderFX Embolic Protection Device. SpiderFX and SpideRX are similar in design and performance. The SpideRX Device has been tested for compatibility with drug eluting stents (DES) in vitro. The coating of the DES is not compromised when used in conjunction with this embolic protection system. However, care should still be taken not to disrupt the delicate drug coating if a coronary DES has been recently placed.

OBSERVED ADVERSE EVENTS – CLINICAL STUDY

The SpiderFX Embolic Protection Device has been demonstrated equivalent to the SpideRX Embolic Protection Device in bench and animal testing. The SpideRX Embolic Protection Device was evaluated in the Saphenous Vein Graft Protection In a Distal Embolic Protection Randomized (SPIDER) Trial for use as an embolic protection system to contain and remove embolic material (thrombus/debris) during percutaneous treatment of the saphenous vein bypass graft. A total of 963 patients were enrolled in the trial with 747 patients in the randomized portion. Three hundred eighty-three (383) patients were randomized to receive treatment with the SPIDER or SpideRX Embolic Protection Device and 364 patients were randomized to receive treatment with the control devices.

Adverse events associated with percutaneous intervention of a diseased saphenous bypass graft using the SPIDER or SpideRX Embolic Protection Device and the Control devices (GuardWire® Plus and FilterWire™ EX/EZ) occurred at the rates listed in Table 15.

TABLE 15: Serious Adverse Events Summary $\leq$ 30 Days

	SPIDER/SpideRX (N=383 Patients)		Controls (N=364 Patients)	
	No.	%	No.	%
MACE (Death, MI, Emergent CABG, TVR)				
In-Hospital	31	8.1 (31/383)	26	7.1 (26/364)
Overall	34	9.2 (34/368)	30	8.7 (30/345)
Death				
Overall	1	0.3 (1/368)	2	0.6 (2/344)
MI (Q Wave or Non-Q Wave)				
Overall	33	9.0 (33/368)	27	7.8 (27/345)
Non-Q Wave MI				
Overall	29	7.9 (29/368)	25	7.2 (25/345)
Emergent CABG				
In-Hospital	0	0.0 (0/368)	0	0.0 (0/344)
Target Vessel Revascularization				
Overall	4	1.1 (4/368)	4	1.2 (4/344)
Abrupt Closure*				
In-Hospital	13	3.3 (13/394)	2	0.5 (2/374)
Perforation*				
In-Hospital	3	0.8 (3/388)	1	0.3 (1/369)
Vascular Complications				
In-Hospital	13	3.4 (13/383)	6	1.6 (6/364)
Overall	14	3.8 (14/369)	9	2.6 (9/346)
Cerebrovascular Accident				
In-Hospital	2	0.5 (2/383)	2	0.5 (2/364)
Overall	2	0.5 (3/368)	5	1.4 (5/345)
Target Lesion Revascularization				
Overall	3	3/368	2	0.6 (2/344)

MACE is defined as: death, myocardial infarction (Q-wave or non Q-wave MI), target lesion revascularization, or emergent cardiac bypass surgery.

Myocardial Infarction (MI) is defined by the following criteria:

Q-wave MI: (QMI): Chest pain or other acute symptoms consistent with myocardial ischemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data, and new pathologic Q-waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data, the CEC may adjudicate Q-wave MI based on the clinical scenario and appropriate cardiac enzyme data.

Non Q-wave MI (NQWMI): Elevated CK-MB > 3 times the sites' upper laboratory normal in the absence of new pathological Q-waves. In the absence of CK-MB data, an elevated total CK to > 2 times the sites' upper laboratory normal without new pathological Q-waves.

Emergent CABG is defined as: coronary bypass surgery performed on an urgent or emergent basis for sever vessel dissection or closure, or treatment failure resulting in new ischemia.

Target Vessel Revascularization is defined as: any clinically driven repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel.

Abrupt Closure is defined as: the occurrence of new severely reduced flow (TIMI grade 0 or 1) within the target vessel that persisted and required rescue by a nonassigned treatment strategy (including emergency surgery), or resulted in myocardial infarction or death. Abrupt closure required proven association with a mechanical dissection of the treatment site or instrumented vessel, coronary thrombus, or severe spasm.

Perforations were classified as follows: Angiographic perforation: perforation detected by the clinical site or the core laboratory at any point during the procedure. Clinical perforation: perforation requiring additional treatment (including efforts to seal the perforation or pericardial drainage), or resulting in significant pericardial effusion, abrupt closure, myocardial infarction, or death. Pericardial hemorrhage/tamponade: perforation resulting in cardiac tamponade.

Vascular Complications are defined as: hematoma at the access site > 5 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion, vascular surgical repair or ultrasound compression required.

* 775 grafts (396 versus 379) were treated for 747 subjects (383 versus 364) Only grafts assessed by the Angiographic Core Laboratory are included in this analysis.

POTENTIAL COMPLICATIONS

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Aneurysm
- Angina
- Arterial dissection
- Cardiac tamponade
- Coronary ischemia
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute, subacute, late)
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention, resulting in TIA or stroke
- Embolization or migration of the interventional device(s)
- Emergency surgery
- Failure to deliver stent to the intended site
- Hypotension/Hypertension
- Infection
- Intimal flap
- Ischemia
- Myocardial infarction
- Occlusion
- Renal failure requiring dialysis
- Restenosis of stented segment (greater than 50% obstruction)
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Thrombosis (acute, subacute and late)
- Vasospasm
- Vessel/filter occlusion
- Vessel perforation, rupture or spasm

CLINICAL STUDY

The clinical evaluation of the SpideRX Embolic Protection Device was performed through the SPIDER (Saphenous Vein Graft Protection In a Distal Embolic Protection Randomized) Trial. The SPIDER Trial was a prospective, randomized, multi-center trial in which a total of 963 patients were enrolled (747 in the randomized portion). During the trial, a rapid exchange design of the SPIDER Embolic Protection Device, the SpideRX Embolic Protection Device, was incorporated into the trial. The SPIDER Device and SpideRX Device both are percutaneously delivered distal embolic protection systems that can be delivered over any 0.014" or 0.018" guidewire. The SPIDER Device is an over-the-wire (OTW) system consisting of a Delivery Catheter, Stylet, Capture Wire, and Recovery Catheter. The SpideRX Device is a rapid exchange device with a dual-ended Delivery/Recovery Catheter combination. The SpideRX Device also incorporates a pre-loaded Capture Wire into the delivery system prior to packaging. The Capture Wires used in both devices are identical except for the color of the PTFE coating and snapped length. The SPIDER Capture Wire can be snapped to a usable length of 175 cm and the distal portion of the wire is green. The SpideRX Capture Wire can be snapped to a usable length of 190cm and the distal portion of the wire is gold.

The SPIDER Trial randomized 383 patients to the SPIDER/SpideRX Device Arm and 364 patients to the Control Arm (FilterWire EX™ Embolic Protection System, FilterWire EZ™ Embolic Protection System or GuardWire® Plus Temporary Occlusion and Aspiration System).

The primary objectives of this Trial were to compare the combined endpoint rates of death, myocardial infarction (Q-wave and non Q-wave MI), emergent CABG, or target vessel revascularization within 30 days of the index procedure.

ELIGIBILITY CRITERIA

Candidates for this study must have met all of the following criteria:

Inclusion Criteria

- The patient was $\geq$ 18 years of age.
- The patient had evidence of myocardial ischemia as evidenced by stable or unstable angina pectoris, reversible ECG changes consistent with ischemia, or a positive functional study.
- The patient's target lesion(s) was de novo or restenotic (non-in-stent restenotic lesions only).
- The target lesion(s) was within a coronary artery saphenous vein bypass graft and was $\geq$50% and <100% stenosed.
- The lesion(s) was located at least $\geq$ 5 mm distal to the proximal anastomotic site (for lesions located in the proximal segment of the graft) or $\geq$ 40 mm from the graft-native vessel anastomosis (for lesions located in the distal segment of the graft).
- The target vein graft was $\geq$ 3.0 mm and $\leq$ 6.0 mm in diameter by visual estimation.
- The vessel had TIMI flow $\geq$ 1.
- The patient and his/her physician agreed to an office visit at 30 days (+ 7 days) post-procedure.
- The patient or his/her legally authorized representative understood the nature of the procedure and provided written informed consent.
- The patient was male, or, if female, had either no childbearing potential or had a negative pregnancy test within 7 days prior to treatment.

Exclusion Criteria

Candidates were excluded from the trial if any of the following conditions applied:

- The patient had known hypersensitivity to cobalt, chromium, nickel, stainless steel or contrast agents that could not be controlled with prophylactic doses of antihistamines and/or steroids or any material in standard PCI devices.
- The patient was contraindicated for aspirin or both ticlopidine and clopidogrel
- Patient had a bleeding diathesis or coagulopathy or would refuse blood transfusion.
- Patient had a significant gastrointestinal bleed within the past 180 days.
- The patient experienced a myocardial infarction with documented total CK >2 times normal within the past 24 hours, and CK or CK-MB remained above normal limits at the time of treatment, or patient was symptomatic and suspected to be currently experiencing an acute myocardial infarction.
- The patient required treatment of any of the following:
  - native vessels;
  - more than two saphenous vein bypass grafts requiring treatment at the same time;
  - lesions in a target saphenous vein graft that did not meet the other lesion or graft specific inclusion/exclusion criteria;
  - Note: When more than two saphenous vein grafts or when a native vessel required treatment, staging was allowed 18 hours prior to the target vessel(s) PCI provided the CK (and CK-MB if available) were within normal limits or after the 30 day endpoint had been reached.
- The target lesion was in a saphenous vein graft that was less than six months post placement of the graft.
- The lesion required pre-treatment with directional or rotational atherectomy devices (i.e., DCA, Rotablator, etc.)
- The target lesion was in a native coronary artery or arterial conduit.
- The target lesion was in a jump graft beyond the first touchdown anastomosis (only lesions in the first segment, prior to the jump, could be treated).
- The guide catheter could not be adequately seated in the target vessel aortic anastomosis.
- The patient had documented left ventricular ejection fraction <25%.
- The patient had suffered a stroke or transient ischemic neurological attack (TIA) within the past 60 days.
- The patient demonstrated impaired renal function (creatinine >2.5 mg/dl at the time of treatment or patient on dialysis).
- The patient was currently participating in another investigational drug or device trial that had not completed the entire follow-up period, or had previously been enrolled in the SPIDER Randomized Trial.
- The patient had a co-morbidity, which reduces life expectancy to $\leq$12 months.
- Patient had a medical condition that precluded safe percutaneous intervention.

METHODS

Patients who met all inclusion criteria and did not meet any exclusion criteria were eligible for inclusion into the SPIDER Trial. Randomization was stratified by the intention to use adjunctive GP IIb/IIIa inhibitor ensuring an equivalent distribution of adjunctive drug use in both arms of the trial. Prior to randomization, the physician determined whether or not he/she intended to treat the patient with a GP IIb/IIIa inhibitor. After adjunctive drug use was determined, the drug was given and randomization occurred. Recommended medications included aspirin and clopidogrel within 24 hours of the procedure; heparin, intracoronary nitroglycerin and clopidogrel or ticlopidine during the procedure; and aspirin and clopidogrel or ticlopidine following the procedure (clopidogrel or ticlopidine for a minimum of 1 month post procedure). Angiography was performed during the procedure for documentation of standardized pre- and post- procedural morphologic criteria and the assessment of angiographic complications. At hospital discharge, clinical laboratory tests were repeated and patients were assessed for adverse events. Follow-up was scheduled for 30 days following the index procedure.

The equivalency of the SPIDER and SpideRX treatment groups was evaluated using a two-step approach outlined in the protocol. First, the groups were compared for differences on a number of baseline demographic and predictor covariates in a univariate analysis. Any covariates found to show clinically and statistically significant group differences would then be included in a multivariate logistic regression model along with the treatment group. In the second step, the model would attempt to predict the primary endpoint, 30-day MACE, as a function of these covariates. If the coefficient for treatment group was not significantly different from zero at the 0.05 level of significance, the groups would be considered comparable for 30-day MACE.

In the final analysis no covariate was found to have statistically significant differences between treatment and control at $\alpha = 0.05$. Thus no covariates were added to the final logistic regression model to assess treatment differences. The model, consisting only of an intercept and treatment group, showed a p-value of 0.747 for the difference between Spider and SpideRX, above the 0.05 level needed for significance. Thus the two groups are considered equivalent with respect to 30-day MACE.

SVG INTERVENTIONS (continued)

TABLE 16: Summary of Principle Results– Randomized Subjects

Primary Endpoints	Treatment (N=383 Subjects)	Control (N=364 Subjects)	All Subjects (N=747 Subjects)	Effect Size† [95% CI]	p--value
MACE to 30 Days	9.2% (34/368)	8.7% (30/345)	9.0% (64/713)	1.06 [0.67, 1.70]	0.896
Death	0.3% (1/368)	0.6% (2/344)	0.4% (3/712)	0.47 [0.04, 5.13]	0.612
Myocardial Infarction	9.0% (33/368)	7.8% (27/345)	8.4% (60/713)	1.15 [0.70, 1.86]	0.593
Q Wave MI	1.1% (4/368)	0.6% (2/344)	0.8% (6/712)	1.87 [0.34, 10.14]	0.687
Non-Q Wave MI	7.9% (29/368)	7.2% (25/345)	7.6% (54/713)	1.09 [0.65, 1.82]	0.779
Emergent CABG	0.0% (0/368)	0.0% (0/344)	0.0% (0/712)	-- [--, --]	--
Target Vessel Revascularization	1.1% (4/368)	1.2% (4/344)	1.1% (8/712)	0.93 [0.24, 3.71]	1.000
Target Lesion Revascularization	0.8% (3/368)	0.6% (2/344)	0.7% (5/712)	1.40 [0.24, 8.34]	--
TLR-Free at 30 Days	99.2%	99.5%	99.4%	-0.2% [-1.6%, 1.1]	--
TVR-Free at 30 Days	99.0%	98.9%	99.0%	0.1% [-1.6%, 1.8]	0.949
MACE-Free at 30 Days	91.1%	91.7%	91.4%	-0.6% [-5.4%, 4.2]	0.760
Device Success[1]	94.0% (360/383)	95.9% (349/364)	94.9% (709/747)	0.98 [0.95, 1.01]	--
Clinical Success[2]	86.7% (332/383)	89.0% (324/364)	87.8% (656/747)	0.97 [0.92, 1.03]	--
Procedure Success[3]	91.6% (350/382)	93.1% (337/362)	92.3% (687/744)	0.98 [0.94, 1.03]	--

† Effect size is the difference between the means for continuous parameters; relative risk for the dichotomous outcomes (measure of success; safety measures), and the difference between event-free rates for event-free analysis.

MACE: defined as a combined endpoint of death, MI (Q wave and non-Q wave MI), target vessel revascularization (TVR) or emergent CABG.

For incidence rates, sample size was defined as the number of subjects who died or had an event, or who did not have an event but had follow-up $\geq$ 23 days. For event-free rates, all randomized subjects were included and were censored at the last known date of follow-up.

[1] Device Success: a) The device was successfully delivered to the target location. b) The device operated as intended. c) The device was successfully retrieved intact. Note: Device success is determined on a per-subject basis.

[2] Clinical Success: defined as device success with no procedural events (no in-hospital major adverse cardiac events).

[3] Procedure Success: defined as the achievement of a final diameter stenosis of <50% (by QCA) using any percutaneous method, without the occurrence of cardiac death, MI, or repeat revascularization of the target vessel or emergent CABG during the hospital stay.

During the conduct of the SPIDER trial, there were 133 Treatment subjects and 126 Control subjects who had at least one missing CK-MB result with the remaining CK-MB results being <3x normal range; there were four Treatment subjects and five Control subjects with missing CK-MB at all three time points (6-8, 12-16, and 18-24 hours post procedure). To address this issue of missing CK-MB data, additional analysis on MACE was preformed. To estimate what the non Q wave MI rate would have been for these missing patients had their missing CK-MB(s) been measured, the following analysis was preformed. Data from the SPIDER trial with non-missing CK-MB at all three time points (6-8, 12-16, and 18-24 hours post procedure) were used to statistically estimate, for each of the SPIDER trial subjects with missing CK-MB, the probability that at least one missing CK-MB was abnormal ($\geq$ 3x normal range). The probabilities were then summed to obtain an estimate of the number of missing CK-MB subjects who would have had an abnormal CK-MB and hence non-Q wave MI. Therefore, based on an analysis of data within the SPIDER trial of all subjects with CK-MB values at all three time points, we estimate that 2 to 3 additional subjects in each group would have experienced non-Q wave MIs, and, hence, MACE. **Table 17** displays the results of revised MACE analyses where 3 additional MACE are added to each group with recalculation of the noninferiority hypothesis using the Farrington-Manning p value. In order to provide an even more conservative estimate of non-inferiority, the table also includes the calculation where 3 patients are added to the Treatment group and either 2 or 0 patients are added to the Control group.

As can be seen, there is no marked change in results from the primary analysis with any of these approaches in that non-inferiority according to the protocol criteria is met.

TABLE 17: Revised MACE Analysis Imputing 3 Additional Subjects

	SPIDER	Control	Delta	p*
30-day MACE[1]	37/368 (10.1%)	33/345 (9.6%)	5.5%	0.013
30-day MACE[2]	37/368 (10.1%)	32/345 (9.3%)	5.5%	0.018
30-day MACE[3]	37/368 (10.1%)	30/345 (8.7%)	5.5%	0.031

[1] 3 additional MACE imputed for Treatment group and 3 additional MACE imputed for Control.
[2] 3 additional MACE imputed for Treatment group and 2 additional MACE imputed for Control.
[3] 3 additional MACE imputed for Treatment group and 0 additional MACE imputed for Control.
* Farrington-Manning

TABLE 18: Myocardial Infarction and CK/CK-MB Elevations – Randomized Subjects

Myocardial Infarction to 30 Days	Treatment (N=383 Subjects)	Control (N=364 Subjects)	All Subjects (N=747 Subjects)	Relative Risks [95% CI]
Type 3 MI (Q Wave or CKMB >8x Normal)[1]	4.2% (16/383)	3.6% (13/364)	3.9% (29/747)	1.17 [0.57, 2.40]
Q Wave MI (Peri-Procedure)	1.0% (4/383)	0.5% (2/364)	0.8% (6/747)	1.90 [0.35, 10.31]
Non-Q Wave MI (CKMB >8x Normal)	3.1% (12/383)	3.0% (11/364)	3.1% (23/747)	1.04 [0.46, 2.32]
Type 2 Non-Q Wave MI (CKMB 3-8x Normal)[2]	4.2% (16/383)	3.3% (12/364)	3.7% (28/747)	1.27 [0.61, 2.64]
Type 2 Non-Q Wave MI (1<CKMB<3x Normal) with ECG Changes[2]	0.3% (1/383)	1.1% (4/364)	0.7% (5/747)	0.24 [0.03, 2.12]
Type 1 Non-Q Wave MI (1<CKMB<3x Normal) without ECG Changes[2]	12.0% (46/383)	10.4% (38/364)	11.2% (84/747)	1.15 [0.77, 1.72]
Type 3 or Type 2 MI[2]	8.6% (33/383)	8.0% (29/364)	8.3% (62/747)	1.08 [0.67, 1.74]
Any CKMB Elevation[2]	20.6% (79/383)	18.4% (67/364)	19.5% (146/747)	1.12 [0.84, 1.50]
Any Q Wave MI*	1.1% (4/368)	0.6% (2/344)	0.8% (6/712)	1.87 [0.34, 10.14]
Non-Q Wave MI (CK>2X) with elevated CK-MB in the absence of new pathological Q waves*	2.7% (10/368)	4.1% (14/345)	3.4% (24/713)	0.67 [0.30, 1.49]

[1] MI within 48 hours post-procedure with new Q waves or CKMB >8 times normal.
[2] Peri-procedure period (within 48 hours).
Type 3, Type 2, Type 1 MI and any CKMB elevation were all procedure related only; all subjects were included in the denominators for these categories.
* Subjects included in the denominator were those having at least 23 days of follow-up or having an event or death.

TABLE 19: Quantitative Coronary Angiography

Lesion Characteristics	Treatment (N=396 Grafts)	Control (N=379 Grafts)	Effect Size† [95% CI]	p--value
Baseline				
Reference Vessel Diameter (RVD, in mm) Mean±SD (N) Range (Min,Max)	3.26±0.67 (394) (1.75,5.62)	3.34±0.63 (374) (1.67,5.90)	-0.08 [-0.17, 0.01]	0.084
Minimal Lumen Diameter (MLD, in mm) Mean±SD (N) Range (Min,Max)	0.99±0.50 (394) (0.12,3.18)	1.04±0.48 (374) (0.17,2.63)	-0.06 [-0.12, 0.01]	0.122
Percent Diameter Stenosis (% DS) Mean±SD (N) Range (Min,Max)	70.02±12.46 (394) (38.01,95.04)	69.02±12.24 (374) (23.71,95.03)	1.00 [-0.75, 2.75]	0.261
Final (Post-Procedure) Within the Segment				
Reference Vessel Diameter (RVD, in mm) Mean±SD (N) Range (Min,Max)	3.29±0.66 (393) (1.78,5.64)	3.35±0.62 (371) (1.89,5.84)	-0.07 [-0.16, 0.02]	0.144
Minimal Lumen Diameter (MLD, in mm) Mean±SD (N) Range (Min,Max)	2.81±0.60 (393) (0.15,5.06)	2.85±0.59 (371) (0.00,4.91)	-0.04 [-0.13, 0.04]	0.330
Percent Diameter Stenosis (% DS) Mean±SD (N) Range (Min,Max)	14.20±8.67 (393) (0.74,95.25)	14.90±9.23 (371) (-15.45,100.00)	-0.69 [-1.96, 0.58]	0.287
Final (Post-Procedure) Within the Segment				
Minimal Lumen Diameter (MLD, in mm) Mean±SD (N) Range (Min,Max)	3.09±0.58 (391) (0.15,5.33)	3.11±0.58 (370) (0.00,4.97)	-0.01 [-0.10, 0.07]	0.760
Percent Diameter Stenosis (% DS) Mean±SD (N) Range (Min,Max)	4.89±10.86 (391) (-35.66,95.25)	6.70±12.36 (370) (-45.39,100.00)	-1.80 [-3.46, -0.15]	0.033

† Effect size is the difference between the means for continuous parameters; relative risk for the dichotomous outcomes (measure of success; safety measures), and the difference between event-free rates for event-free analysis.

775 grafts (396 vs. 379) were treated for 747 patients (383 vs. 364). Only grafts assessed by the Angiographic Core Laboratory are included into this analysis.

In segment is defined at the region between the proximal and distal normal reference segments that includes the stent and its 5 mm proximal and distal margins.

CONCLUSIONS

Thirty-day MACE rate was 9.2% for the Treatment Group and 8.7% for the Control Group. In the Treatment Group there was one death, 33 myocardial infarctions, four target vessel revascularizations and no emergent CABG procedures. In the Control Group there were two deaths, 27 myocardial infarctions, four target vessel revascularizations and no emergent CABG procedures. The non-inferiority hypothesis of Treatment when compared to Control required that the difference in the thirty-day MACE rate between the two groups be statistically significantly less than the delta of 5.5%. The observed difference between the Treatment and Control Groups was 0.5%, with a one-sided upper confidence limit of 4.1% which is less than the delta of 5.5%. Using the Farrington-Manning approach, the null hypothesis was rejected with the p-value = 0.012, and thus the Treatment Group was concluded to be non-inferior to the Control Group with the delta of 5.5%.

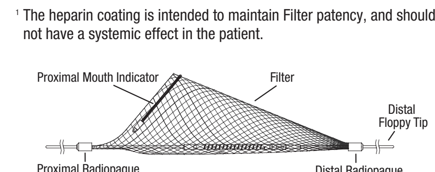
DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

***NOTE:** See **Table 20** for Device product specifications.*

Capture Wire– The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency1. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

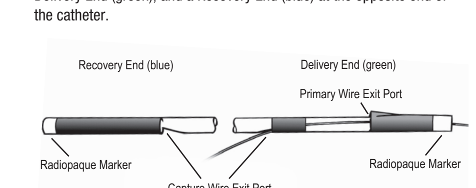
[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.



Capture Wire

***CAUTION:** Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter – The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter.



- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

TABLE 20: SpiderFX Embolic Protection Device Specifications*

SpiderFX Capture Wire					
Filter Diameter (mm)	3.0	4.0	5.0	6.0	7.0
Capture Wire Length RX (cm)	190	190	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)					
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140	140	140
SpiderFX Catheter - Recovery End (blue)					
Diameter (Fr)	4.2	4.2	4.2	4.2	4.2
Functional Length (cm)	140	140	140	140	140
Total Catheter Length (cm)	180	180	180	180	180

*Nominal

SVG INTERVENTIONS (continued)

INSTRUCTIONS FOR USE

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the lesion site being treated. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the lesion, to allow for adequate Filter deployment.

WARNING: Refer to **Table 21** SVG Sizing Guide for appropriate Filter sizing in relation to the selected vessel diameter. Undersizing or oversizing may result in inadequate vessel wall apposition or incomplete deployment of the Filter and could cause slow/no-flow, and/or embolization of debris.

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. **(Table 21).**

TABLE 21: SVG Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (inches)	Guide Catheter/ Sheath Min I.D.[2] (inches)
3.0	3.0	0.014-0.018	0.066
3.1-4.0	4.0	0.014-0.018	0.066
4.1-5.0	5.0	0.014-0.018	0.066
4.5-6.0	6.0	0.014-0.018	0.066
5.5-6.0	7.0	0.014-0.018	0.066

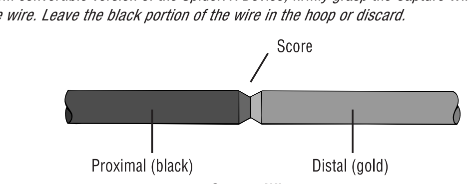
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

***CAUTION:** Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

***NOTE:** If using the 320/190 cm convertible version of the SpiderFX Device, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



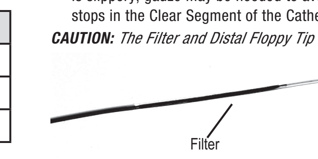
Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.

***CAUTION:** The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*



Filter in Proper Position in Clear Segment

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
13. Observe the Primary Wire Exit Port, indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

***NOTE:** When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.*

***CAUTION:** Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

***CAUTION:** DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

***CAUTION:** Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

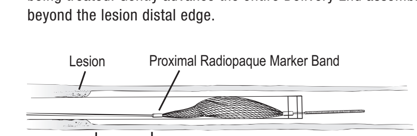
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the Distal Radiopaque Marker Band on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

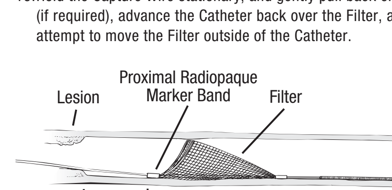
18. Observe the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the Proximal Radiopaque Marker Band is at least 2 cm beyond the lesion distal edge.



Position of SpiderFX Catheter

***CAUTION:** Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.



Position of Filter

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not deploy the Filter within a previously implanted stent.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER**. The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised See section titled, "Recovery and Removal".

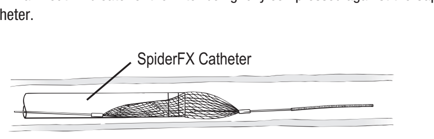
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Catheter with heparinized saline. Flush the distal tip of the Recovery End (blue) to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

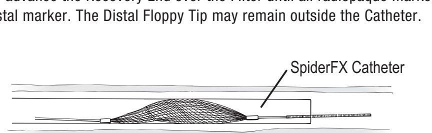
A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

***CAUTION:** Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

PHYSICIAN TRAINING

Only physicians thoroughly trained in percutaneous, intravascular techniques and procedures should use the SpiderFX Embolic Protection Device. Training on the proper use of the SpiderFX Embolic Protection Device is required. The training will include an in-service and will be based on physician experience. First-time users of the SpiderFX Device will be required to be proctored on the first 3 cases.