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 coinwith the 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment*. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The coinwithe 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.

  * 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 damage 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 (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.

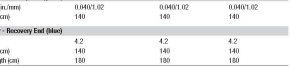
Saphenous Vein Graft (SVG) Interventions

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 and stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 5.0mm. 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:

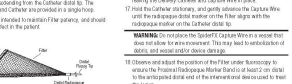
- Do not use with patients or where anticoagulant and antiplatelet therapy is contraindicated.
- Do not use in vessels with excessive tortuosity.
- Do not use in patients with uncorrected bleeding disorders
- Do not use in thrombi areas.



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 set inbended for use as a guidewire.*

SpiderFX Catheter — The SpiderFX Catheter's 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 extended from the distal tip.
- The catheter **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.

Listed 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, refer to the Section titled, "Instructions for Use – Alternate Catheter or Device".*

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 intraluminal interventions during 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 5 cm distal to the anticipated distal tip of the 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.
4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Capture Wire (refer to 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 ID (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

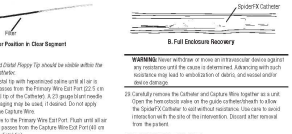
Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components from the packaging, and place in a sterile saline bowl.

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 Capture Wire. The remaining Capture Wire may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the SpiderFX Catheter.

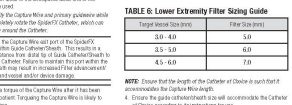
NOTE: *Should the 320/190 cm coinwithe version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave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



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 SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has been 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.



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 15 cm past the anticipated distal end of interventional device used to treat the lesion.
13. Observe the location and 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 as the interventional device may be properly advanced without contacting the Filter proximal end.*

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

Position of Filter Relative to Interventional Device

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

14. 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 as a single unit.

WARNING: Owed time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow-to-flow. If slow flow should occur, the Filter should be recovered. See section titled, "Recovery and Removal".

15. Confirm the Filter and the Proximal Radiopaque Marker Band are in opposition to the vessel lesion to be treated using side-view fluoro.
16. 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.
17. Place the SpiderFX Catheter in sterile hyperextend saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
18. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire Filter positioned distally.

WARNING: Owed time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow-to-flow. If slow 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: 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

19. After completion of the interventional procedures, mark the distal (20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End (blue) 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.

20. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
21. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.

Position of Catheter Relative to Interventional Device

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

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

Position of Filter Relative to Interventional Device

22. The Catheter will be felt to engage the Capture Wire. Continue advancing the Catheter until the radiopaque marker at the distal tip of the Delivery End (green) is at least 4-5 cm distal to the anticipated distal end of the interventional device used.

CAUTION: *Gently identify the Capture Wire and primary guidewire while advancing. Do not completely retire the SpiderFX Catheter, which can cause the wire 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 3X 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.

23. 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 pass. Use caution 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

LOWER EXTREMITY INTERVENTIONS (continued)

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
**Filters 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 coinwith the 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency*. 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.

* 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 set inbended for use as a guidewire.*

SpiderFX Catheter — The SpiderFX Catheter's 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 extended from the distal tip.
- The catheter **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.

Listed 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, refer to the Section titled, "Instructions for Use – Alternate Catheter or Device".*

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 intraluminal interventions during 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 5 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.
4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Capture Wire (refer to 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 ID (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

Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components from the packaging, and place in a sterile saline bowl.

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 SpiderFX Catheter.

NOTE: *Should the 320/190 cm coinwithe 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.*

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 SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has been 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.

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 15 cm past the anticipated distal end of interventional device used to treat the lesion.
13. Observe the location and 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 as the interventional device may be properly advanced without contacting the Filter proximal end.*

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

Position of Filter Relative to Interventional Device

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

14. 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.
15. Confirm the Filter and the Proximal Radiopaque Marker Band are in opposition to the vessel lesion to be treated using side-view fluoro.
16. 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.
17. Place the SpiderFX Catheter in sterile hyperextend saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
18. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire Filter positioned distally.

WARNING: Owed time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow-to-flow. If slow 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: 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

19. After completion of the interventional procedures, mark the distal (20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End (blue) 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.

20. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
21. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.

Position of Catheter of Choice Relative to Interventional Device

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

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

Position of Filter Relative to Interventional Device

22. The Catheter will be felt to engage the Capture Wire. Continue advancing the Catheter until the radiopaque marker at the distal tip of the Delivery End (green) is at least 4-5 cm distal to the anticipated distal end of the interventional device used.

CAUTION: *Gently identify the Capture Wire and primary guidewire while advancing. Do not completely retire the SpiderFX Catheter, which can cause the wire 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 3X 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.

23. 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 pass. Use caution 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

LOWER EXTREMITY INTERVENTIONS (continued)

TABLE 4: SpiderFX Embolic Protection Device Specifications*

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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
**Filters 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.*

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* 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 set inbended for use as a guidewire.*

SpiderFX Catheter — The SpiderFX Catheter's 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 extended from the distal tip.
- The catheter **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.

Listed 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, refer to the Section titled, "Instructions for Use – Alternate Catheter or Device".*

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 intraluminal interventions during 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 5 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.
4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Capture Wire (refer to Table 5: Lower Extremity Sizing Guide).

TABLE 5: Lower Extremity Sizing Guide[1]

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

[1] Nominal

Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components from the packaging, and place in a sterile saline bowl.

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 Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the SpiderFX Catheter.

NOTE: *Should the 320/190 cm coinwithe 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.*

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 SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has been 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.

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 15 cm past the anticipated distal end of interventional device used to treat the lesion.
13. Observe the location and 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 as the interventional device may be properly advanced without contacting the Filter proximal end.*

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

Position of Filter Relative to Interventional Device

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

14. 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.
15. Confirm the Filter and the Proximal Radiopaque Marker Band are in opposition to the vessel lesion to be treated using side-view fluoro.
16. 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.
17. Place the SpiderFX Catheter in sterile hyperextend saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
18. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire Filter positioned distally.

WARNING: Owed time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow-to-flow. If slow 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: 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

19. After completion of the interventional procedures, mark the distal (20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End (blue) 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.

20. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
21. Advance the Catheter under f