

# FiberNet<sup>®</sup> Embolic Protection System

## INSTRUCTIONS FOR USE

**R** Only

**LUMEN**  
BIOMEDICAL

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### CONTENTS

The FiberNet<sup>®</sup> Embolic Protection System consists of one capture wire, one retrieval catheter, two 30ml syringes, one stopcock assembly, one actuator, one peel-away introducer, and one 40µm cell strainer.

### DEVICE DESCRIPTION

The FiberNet<sup>®</sup> Embolic Protection System is an intravascular filtration system that is placed distal to the lesion before interventional procedures. When deployed, the system captures and recovers emboli that may be produced during the procedure. The capture wire is used as a standard 0.014" steerable guidewire. Radiopaque markers at both ends of the filter and at the distal tips of the wire and retrieval catheter aid in placement and deployment visualization under fluoroscopic imaging. Post procedure emboli are aspirated, the filter retracted into the retrieval catheter, and the entire system removed.

### INDICATIONS FOR USE

The FiberNet<sup>®</sup> Embolic Protection System is indicated for use as a guidewire and emboli protection system to capture and remove embolic material (thrombus/debris) produced while performing percutaneous transluminal interventional procedures in carotid arteries in high surgical risk patients with reference vessel diameters of 3.5 to 7.0 mm.

### CONTRAINDICATIONS

The FiberNet<sup>®</sup> Embolic Protection System is contraindicated under these circumstances:

- Do not use in total chronic occlusions
- Do not use in vessels with excessive tortuosity
- Do not use in patients with bleeding disorders
- Do not use if massive peripheral vascular disease does not allow vascular access to the target lesion
- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated.

### WARNINGS

- **Only physicians trained in percutaneous, intravascular techniques and procedures should use this system.**
- The safety and effectiveness of this device as an embolic protection system have not been established in vasculatures other than carotid (coronary, cerebral, or peripheral).

- The safety and efficacy of the FiberNet Embolic Protection System have not been demonstrated with carotid stent systems other than the AccuLink, Precise, Protégé, NexStent, and Xact carotid stent systems.
- Refer to the instructions supplied with any interventional devices used in conjunction with the system for their intended uses, contraindications, warnings, precautions, and instructions for use.
- Do not undersize the filter with regard to the target vessel diameter to avoid inadequate vessel coverage and filter efficiency in capturing emboli. Exercise care when handling and loading devices over the proximal end of the capture wire to avoid kinking.
- Use an appropriately sized guiding catheter or sheath with a Tuohy-borst adapter when using this system.
- Do not use the retrieval catheter for delivery or infusion of diagnostic, embolic or therapeutic materials into blood vessels as it has not been designed for these uses.
- Minimize capture wire movement. The filter, once actuated, should be observed under fluoroscopy during catheter exchange to be sure the filter does not move. Excessive wire movement may lead to embolization of debris, and vessel and/or device damage.
- When retrieving the filter do not use excessive force to avoid damaging the filter integrity.
- Exercise caution and continue aspiration while withdrawing a partially retracted filter through a stent.

### PRECAUTIONS

- Store the system in a dark, dry place.
- Do not autoclave or expose system to organic solvents.
- Confirm compatibility of capture wire/catheter diameter and length with interventional devices prior to use.
- Use the system prior to "Use Before" date noted on the package.
- Carefully inspect the capture wire and catheter for bends, kinks or other damage before use. Do not use damaged or suspected damaged devices.
- Exercise care handling the capture wire and catheter before and during a procedure to reduce the possibility of damage.
- Confirm there is appropriate space distal to lesion to place device.
- Make certain the filter is thoroughly saturated with heparinized saline or an equivalent solution.
- Do not test (actuate) the filter prior to use.
- If using heparin, achieve an ACT near 300 seconds ( $\geq 200$  seconds if using GPIIb/IIIa Inhibitors).
- Carefully tighten the wire torquer to the wire. Overtightening may damage wire and increase friction in the system.
- Always advance or retract the system components carefully and slowly through the vasculature. Never advance or withdraw devices against resistance. Determine cause of resistance under fluoroscopic imaging and take any necessary action.
- If resistance is felt advancing the catheter through a stent, pull back on the catheter and torque the catheter  $\frac{1}{4}$  turn.
- If the filter cannot cross the lesion and dilation with an angioplasty balloon on a second wire is required, the filter should not be within the lesion during the dilation.
- The capture wire should be treated like any standard wire during exchanges.
- Keep the filter in the retracted position when advancing or repositioning.
- Do not torque the catheter more than 360° in one direction to avoid entangling catheter in the wire.
- If excessive debris is collected in the filter and blood flow becomes obstructed, use the retrieval catheter and remove debris or rapidly complete the procedure and then remove the filter.
- In the body, manipulate the catheter only under fluoroscopy. Do not attempt to move device without observing the resultant tip response.
- Do not flush the catheter while in the patient.
- To address lesions in subsequent vessels, use a new system for each vessel.

## OBSERVED ADVERSE EVENTS

The FiberNet® Embolic Protection System was evaluated in the Embolic Protection in Carotid Artery Stenting (EPIC) Trial in patients at high risk for CEA., with 30 patients in the feasibility phase and 237 in the pivotal phase.

The FiberNet® Embolic Protection System is used in an acute manner and, therefore, peri-procedural adverse events are the most relevant evaluation of device safety. Table 1 presents the serious adverse events reported through the 30-day follow-up visit.

Event	EPIC Pivotal (n=237)	EPIC Feasibility (n=30)
Total Patients with a SAE	19% (51/267)	
Access site complication	0.8% (2)	0
Anemia	2.5% (6)	3% (1)
Arrhythmia	3.0% (7)	3% (1)
Bleeding	0.4% (1)	0
CHF, ACS, angina	1.7% (4)	3% (1)
CVA. stroke or TIA	3.0% (7)	13% (4)
Death	0.4% (1)	0
Embolization air, tissue, etc	0.4% (1)	0
Hyperperfusion syndrome	0.4% (1)	0
Hyper/hypotension, severe	8.4% (20)	0
Myocardial infarction	0.8% (2)	0
Neurological events, other	0.4% (1)	0
Pneumonia	0.4% (1)	3% (1)
Renal insufficiency/ failure	0.4% (1)	0
Seizure	0.4% (1)	0
Other	2.5% (6)	10% (3)

## POTENTIAL ADVERSE EFFECTS

Possible adverse effects with intervention and use of this device include, but are not limited to:

- Access site complication (e.g. AV fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection, surgical repair)
- Allergic, or other reactions, to procedure medications or device materials
- Aneurysm
- Angina / unstable angina
- Arrhythmias (e.g. ventricular fibrillation)
- Bleeding requiring transfusion
- Cerebral edema
- Congestive heart failure
- CVA/ stroke or transient ischemic attack
- Death
- Device malfunction, thrombosis, entanglement
- Embolization of air, tissue, thrombus, device
- Emergency surgical or percutaneous intervention, or retreatment
- Fever/infection
- Hyperperfusion syndrome
- Ischemic infarction of tissue or organ, e.g. MI
- Intracerebral bleeding (carotid only)
- Neurological events, e.g. amaurosis fugax
- No/slow reflow of treated vessel
- Pericardial tamponade
- Renal insufficiency/ renal failure
- Seizure
- Severe hypotension or hypertension
- Stent damage, migration, misplacement, thrombosis
- Vessel spasm, dissection, rupture, perforation, thrombosis, restenosis

## CLINICAL STUDIES

The EPIC Trial pivotal phase was a prospective, multi-center, single-arm trial. The objective of the study was to evaluate the safety and efficacy of the system used with commercially available carotid stents in the treatment of internal and/or common carotid artery stenoses in patients at high-risk for carotid endarterectomy. A total of 237 patients were enrolled at 26 clinical sites in the U.S. and Germany.

## ELIGIBILITY CRITERIA

Patients who presented for percutaneous treatment of an internal and/or common carotid artery were considered. Patients were required to be at least 18 years old and at high risk for CEA based on one or more criteria listed in Table 2. A target lesion stenosis  $\geq 70\%$  was required for asymptomatic patients,  $\geq 50\%$  for symptomatic patients (patients with a stroke or TIA  $\leq 6$  months prior to enrollment). Major baseline characteristics are summarized in Table 3.

Clinical Criteria	Anatomical Criteria
1. Age > 75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. CEA restenosis
3. CHF NYHA Class 3-4	3. Low infraclavicular lesion
4. LVEF < 35%	4. Tandem lesion $\geq 70\%$
5. MI within past 2-6 weeks	5. Hostile neck
6. CAD with $\geq 2$ vessel disease in major vessel	6. Cervical immobility
7. Severe pulmonary disease	7. High cervical lesion (above the angle of the jaw)
8. Dialysis dependent renal failure	
9. Requires CAB, cardiac valve, PV surgery, or abdominal aneurysm repair $\leq 60$ days	

Variable	
Age, mean $\pm$ sd	74 $\pm$ 8 (237)
Age $\geq 80$ years	21% (50/237)
Male	62% (148/237)
Symptomatic	20% (48/237)
Diabetes	40% (94/237)
Hyperlipidemia	93% (220/237)
Hypertension	93% (220/237)
Renal insufficiency	22% (51/237)
History of myocardial infarction	31% (74/237)
History of congestive heart failure	18% (42/237)
History of pulmonary Disease	25% (59/237)
Lesion length, mean $\pm$ sd	14 $\pm$ 7 (235)
Lesion stenosis, mean $\pm$ sd	72 $\pm$ 10 (235)

## CLINICAL RESULTS SUMMARY

The EPIC pivotal trial primary endpoint was a composite endpoint of all death, MI or stroke at 30 days post-procedure. Endpoint results are summarized in Table 4.

Primary Endpoint	
30-Day Death, Stroke, MI	3.0% (7/237)
Death	0.4% (1/237)
Stroke	2.1% (5/237)
Myocardial infarction (MI)	0.8% (2/237)
Secondary Endpoints	
Technical success rate	98% (231/237)
Device success rate	94% (223/237)
Non-stroke neurological event	1.7% (4/237)

Statistical analysis of the pivotal phase was designed to demonstrate that the primary endpoint event rate was less than a performance goal of 12.55%. Statistical analysis confirmed the FiberNet EPS rate was less than the performance goal.

No differences were noted among the stents used (AccuLink, Precise, Protégé, NexStent, Xact).

## ANTICOAGULANT/ANTIPLATELET INFORMATION

In the EPIC trial, acetylsalicylic acid (ASA) 81 mg was required one day before the procedure **AND** one of the following:

- Clopidogrel 75 mg daily for 3 days prior to procedure and the day of procedure **OR**
- Clopidogrel 450 mg one day before procedure and 75 mg the day of procedure **OR**
- Ticlopidine 1000 mg one day before procedure and 250 mg BID the day of procedure.

Patients remained on ASA 81 mg and clopidogrel 75 mg (or ticlopidin 250 mg BID) daily through 30 day follow-up visit.

## INSTRUCTIONS FOR USE

### SIZE SELECTION

Estimate vessel diameter where the device will be placed. The filter should be placed proximal to any side branch requiring protection.

### PREPARATION - Capture Wire

1. Open the shelf box and inspect the pouch for damage.

**CAUTION:** Do not use the device if the packaging is damaged or if sterility appears compromised.

2. Open the pouch using standard sterile handling procedure.
3. Place the protective coils and accessory kit into the sterile field on a flat surface.
4. Unclip the section of protective coil covering the filter. Remove and discard this section of coil.
5. Saturate the filter by dipping it into heparinized saline or an equivalent solution.
6. Remove the protective tube from the capture wire. Examine the filter and tip for any damage or defects.
7. If desired, attach a standard wire torquer onto the proximal end of the capture wire.
8. If desired, carefully shape the capture wire distal tip to facilitate navigation through the vessels.

### PREPARATION - Retrieval Catheter

1. Remove the retrieval catheter from the protective coil.
2. Fill the syringe with 10-20ml of saline or equivalent solution.
3. Attach extension tube with stopcock to the catheter and the syringe to the extension tube.
4. Open the stopcock and flush the entire catheter.
5. Close the stopcock.
6. Remove the syringe and set aside for future use.

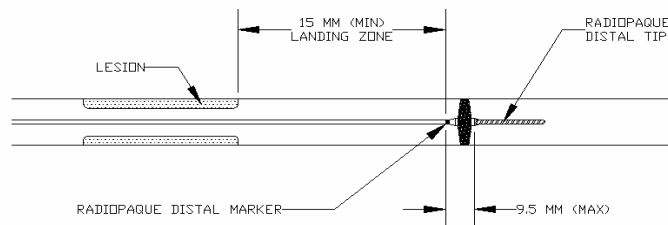
**CAUTION:** Do not attach the syringe until the catheter has been tracked in the vessel and positioned. Attaching the syringe prior to this will hamper navigation of the catheter.

### INSERTION AND PLACEMENT

**NOTE:** Always use a guiding catheter or sheath with an appropriate diameter and a Tuohy-borst adapter.

1. Sheath the filter by advancing the peel-away introducer over the filter.
2. Insert the capture wire/introducer assembly into the Tuohy-borst adapter of a guiding catheter or sheath.
3. Close the adapter around the peel-away introducer and allow back-bleeding.
4. Advance the capture wire through the introducer and into the guiding catheter/sheath until the black section is completely inside the guiding catheter/sheath.
5. Loosen the adapter and peel the pre-slit introducer off the wire to remove.

6. Steer the capture wire by applying torque to the wire. A standard wire torque device may be used.
7. Advance the capture wire until the filter is distal to the target lesion(s) and position as shown in Figure 1.



**FIGURE 1: Capture Wire Placement**

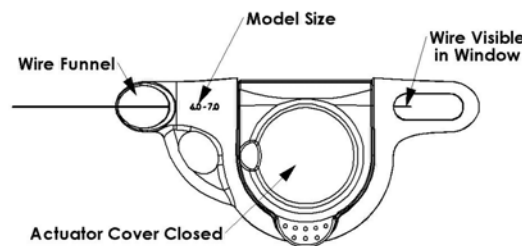
8. If the filter will not cross the lesion, balloon angioplasty with a small diameter balloon is acceptable prior to placement.

**CAUTION:** The filter should not be within the lesion during the dilation.

**CAUTION:** If the wire kinks before deployment remove device and replace with another system.

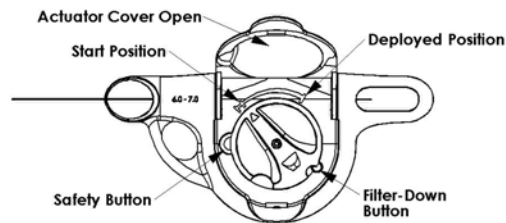
**CAUTION: Leave the Actuator cover closed until instructed to open.**

9. Attach the Actuator (Figure 2) to the capture wire's proximal end by sliding the wire end through the wire funnel until there is a hard stop and the wire is visible in the window.



**FIGURE 2. Actuator Tool, Cover Closed**

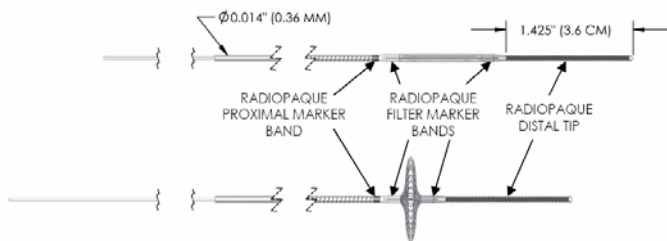
10. Fully open Actuator cover to lock wire in place. Figure 3 shows the Actuator with cover open.



**FIGURE 3: Actuator Tool, Cover Open**

11. Under fluoroscopy maintain the position of the capture wire and deploy the filter by holding the Actuator and turning the dial clockwise to the deployed position. Once fully deployed the Safety Button should snap into the up position.

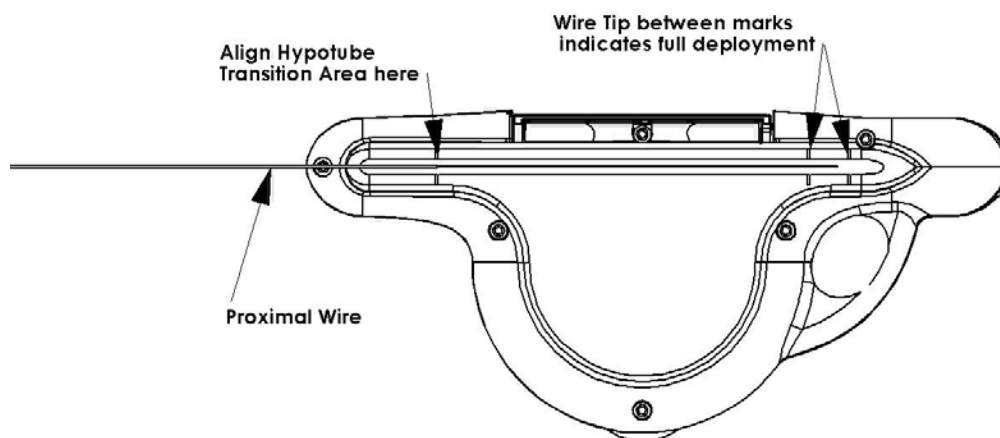
**NOTE:** The radiopaque capture wire tip will slide proximally toward the proximal marker band and the two inner markers will touch at the center of the filter upon deployment (Figure 4).



**FIGURE 4: Capture Wire**

12. Close Actuator cover to release wire. Remove the Actuator from the wire.
13. If desired, filter deployment can be further verified by placing the stainless steel hypotube transition area against the specified location on the Actuation Template on the back of the Actuator (Figure 5). The filter will be fully deployed if the proximal end of the wire is within the specified band on the Actuation Template.

**NOTE:** If unsure the FiberNet filter is deployed, retract the filter, remove device and replace with another system. To retract the filter slide the Actuator onto the proximal end of the wire until it comes to a hard stop. Open the Actuator cover. Turn the dial counter clockwise until the Filter-Down Button snaps into the up position.



**FIGURE 5: Optional Actuation Template (on the back side of Actuator)**

14. Inject contrast medium and verify the filter is in the proper position. Verify adequate flow through the filter.

**NOTE.** The filter can be retracted, repositioned, and re-deployed if necessary.

15. Use the capture wire as a standard guidewire to track compatible interventional devices to target treatment area.

**DURING THE PROCEDURE:**

1. Periodically inject contrast medium to visually verify that blood flow is not obstructed.

**CAUTION:** If blood flow is slowed or stopped during the procedure the filter may be aspirated to remove excess debris. However, at the discretion of the operator, the procedure may be completed as normal before final aspiration and filter retrieval.

2. Exercise caution when loading interventional devices onto the capture wire to avoid kinking.
3. Complete the procedure making sure the filter remains in the proper position distal to the lesion site.

**RETRIEVAL OF THE CAPTURE WIRE:**

1. Taking care not to kink the capture wire, insert the wire's proximal end into the loading tool distal end which extends out the distal end of the retrieval catheter.
2. Carefully advance the wire and loading tool out the side port of the catheter.
3. Remove the loading tool.
4. Open the Tuohy-borst adapter and insert the catheter.
5. Advance the catheter tip until the distal marker band on the catheter tip is aligned with the proximal filter marker.

6. Verify catheter tip placement using fluoroscopic imaging.

**NOTE:** If resistance is felt passing the catheter through the stent, pull back on the catheter and torque the catheter ¼ turn. Continue to advance the catheter to the proximal filter marker.

7. Attach the syringe to the extension tube assembly on catheter.
8. Retract and lock the syringe in fully extended position (30ml).
9. Open the stopcock to begin first aspiration cycle.

**CAUTION:** If filter will not fully retract into the catheter do not apply force. Remove partially retracted filter under aspiration.

**NOTE:** The catheter is designed to deliver effective aspiration vacuum for a minimum of 10-seconds. If blood is not filling the syringe within 5-seconds, check the catheter tip placement, unseat the catheter and re-position if necessary. If no blood is aspirated after re-positioning the catheter, close the stopcock and remove the catheter. Outside the patient, flush the catheter or use a new catheter. If aspiration stops before the syringe has filled close the stopcock and remove the catheter. Outside the patient, flush the catheter or use a new catheter.

**CAUTION:** Never flush the catheter while in the patient.

10. Attach the Actuator to the capture wire's proximal end by sliding the wire end through the wire funnel until there is a hard stop and the wire is visible in the window.
11. Fully open Actuator cover to lock wire in place.
12. Using fluoroscopic imaging, verify the distal marker band on the catheter is aligned with the proximal filter marker and prepare to retract the filter within the second aspiration cycle.
13. Open the stopcock to begin the second aspiration cycle.

14. Once aspirated fluid is visible in the syringe, under fluoroscopy retract the filter by pressing the Safety Button down and turning the dial counter-clockwise until the Filter-Down Button snaps into position.

**NOTE:** The radiopaque capture wire tip will slide distally away from the proximal marker band and the two inner markers will separate at the center of the filter upon retraction.

**CAUTION:** While retrieving the filter do not use excessive force to avoid damaging the filter integrity.

15. Under fluoroscopy, hold the catheter position with one hand and slowly pull the capture wire with the other hand completely into the catheter.

**NOTE:** Slight resistance will be felt while the filter is entering the catheter. The capture wire distal tip should be aligned or slightly proximal to the catheter marker band.

16. With the capture wire inside the catheter, slowly and carefully remove the entire system (as a unit) from the patient taking care that the filter does not exit the catheter.

**LIMITED WARRANTY**

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**Graphic Symbols for Medical Device Labeling**



One Use Only



Do Not Resterilize



Use Before Date



Refer to Instructions



Lot Number



Model Number



Keep dry



Keep away from sunlight



Sterilization method radiation



Do not use if package is damaged.



European Community Authorized Representative

**Latex Free** Product contains no latex