

# FiberNet® Embolic Protection System

A new era of distal protection during carotid artery stenting?

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Stroke is the third leading cause of death in the United States, and approximately 30% of all ischemic strokes are secondary to carotid artery disease. Atherosclerotic occlusive disease of the extracranial internal carotid artery is responsible for the majority of ischemic strokes. Medical therapy has been shown to be effective in reducing the rate of neurologic complications; nevertheless, several large randomized trials have shown that carotid endarterectomy (CEA) is superior to medical therapy for the treatment of carotid artery disease in select groups of symptomatic and asymptomatic patients.<sup>1-4</sup> Therefore, CEA is considered the gold standard for treating carotid bifurcation disease. However, there are drawbacks and risks involved with the operation.

Percutaneous carotid angioplasty and stenting (CAS) has emerged as an alternative to CEA for high-risk patients, especially due to decreased 30-day morbidity and mortality rates and a reduction in procedural discomfort. One of the disadvantages of CAS is the risk of neurologic complications from distal embolism due to the carotid artery lesions containing friable, ulcerated, and thrombotic materials.<sup>4-6</sup> Cerebral protection techniques were invented to capture and remove debris generated from CAS and have been shown to reduce the incidence of neurologic complications.<sup>7-10</sup> Recent prospective, randomized, multicenter trials have shown that CAS with cerebral protection, along with specifically designed flexible carotid stents, coupled with the increasing skills of the interventionist, as well as an appropriate drug regimen (antiplatelets) in appropriately selected high-risk patients is at least equivalent to surgery.<sup>11,12</sup>

There are several classifications of cerebral protection strategies. Distal protection in the form of a balloon or filter, or proximal protection in the form of a flow interruption or reversal system, is designed to reduce the incidence of embolic events. However, all protection devices are not equivalent, and no one device can completely prevent all neurologic complications. With the various cerebral protection systems available, we will discuss a new concept of distal embolic protection using the FiberNet Embolic Protection System (EPS) (Lumen Biomedical, Plymouth, MN), distributed by Invatec, Inc. (Bethlehem, PA).

## DEVICE DESCRIPTION

FiberNet EPS is an intravascular, 0.014-inch, wire-based, three-dimensional filter system placed distal to the carotid artery lesion before stent placement. The

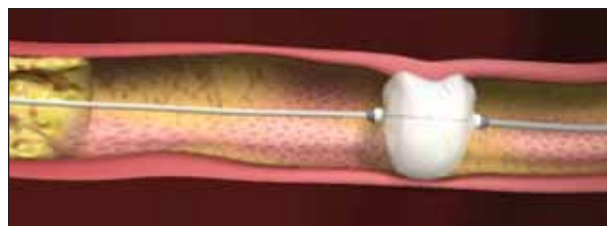


Figure 1. Conformability of the deployed filter to the vessel.

system consists of an expandable, polymeric, filter mounted onto a 190-cm wire, as well as an aspiration and retrieval catheter. A unique feature of the FiberNet EPS filter is the numerous strands of polymer fibers of equal length bundled together. Each fiber strand has deep channels along the longitudinal axis. These capillary channels with high surface area are capable of moving fluids, capturing particles, and conforming to vessels. The filter is of sufficient density to allow adequate blood flow, while simultaneously capturing particulate matter > 40  $\mu$ m within the fiber channels. When the filter is deployed, the proximal and distal ends of the filter cartridge are shortened, causing the filter strands to flare out radially and allow apposition to the vessel wall, even in eccentric vessels (Figure 1). By completely filling the vessel, this provides protection from emboli proximal to the deployed filter.

After the intervention, the rapid-exchange retrieval catheter is advanced over the 0.014-inch wire and positioned proximal to the expanded deployed filter. Two focal suction steps are required for the procedure. The first focal suction step allows for focal aspiration at the base of the filter to remove any loose material bound to the filter. The second focal suction is performed while the filter is being retrieved, allowing the filter and retrieval catheter to be removed from the patient as a single unit.

Aspiration can also be performed within the stent, which could allow the particles against and through the carotid stent struts to be aspirated beforehand, decreasing the possibility of embolization during the retrieval process. The FiberNet products consist of three models to cover the target vessel with a size range of 3.5 to 7 mm, which is a wider range compared to other distal protection devices. In addition, the crossing profile of the FiberNet device ranges from 2.4 F in the smallest size to 2.9 F in the largest, allowing for atraumatic delivery and deployment. This low-crossing profile is smaller than comparable distal protection filters.

The FiberNet EPS is conformable to the vessel wall by providing 360° of atraumatic apposition and stability while allowing continual cerebral perfusion and minimizing vasospasm. This type of apposition to the vessel wall differs from other distal protection devices that may have a balloon-impeding cerebral blood flow or filter baskets that are designed to trap larger embolic particles without interruption of cerebral blood flow. These filters are essentially small baskets constructed from self-expanding nitinol. They come in various predetermined sizes to match the target vessel diameter. Because the FiberNet EPS filter shortens when deployed, this design allows for a smaller landing zone compared to other devices (Figure 2). This is advantageous because the short landing zone permits deployment and retrieval in tortuous anatomy, which might otherwise preclude placement of other devices requiring a more generous landing zone.

A prospective clinical study evaluating the safety and performance of FiberNet EPS was described by Henry et al.<sup>13</sup> Morphometric and histological analysis of the embolic debris captured were performed and evaluated. Debris captured with the FiberNet EPS was correlated with 10 other distal protection devices.<sup>13</sup> For the FiberNet EPS, the mean surface area of debris caught per patient was 101.2 mm<sup>2</sup> (range, 42–251 mm<sup>2</sup>) versus 13 mm<sup>2</sup> (range, 8–38 mm<sup>2</sup>) in other devices (Figure 3). The unique characteristic of the FiberNet EPS, with its suction steps prior to filter retrieval and its capillary fiber channels, may account for the difference in the amount of debris retrieved compared to other distal protection devices.

The EPIC trial (Evaluating the Use of the FiberNet Embolic Protection System in Carotid Artery Stenting), a prospective, multicenter, nonrandomized trial, evaluating the FiberNet EPS during CAS, was presented at the 2008 Transcatheter Cardiovascular Therapeutics (TCT) meeting.<sup>14</sup> Two-hundred thirty-seven high-risk patients with critical carotid artery stenosis were treated. The technical success rate was 97.5%, and visible debris was captured in 90.9% of cases. Overall, the combined major adverse event rate at 30 days for all death, stroke, and myocardial infarction was 3%. The 30-day stroke rate was 2.1% (four ischemic and one hemorrhagic), which was lower compared to other distal protection device studies.<sup>14</sup>

## CONCLUSION

The FiberNet EPS is a new distal protection device that has the capacity to capture small embolic debris while providing continual cerebral perfusion. The device allows for good deliverability with a low profile, flexibility, and a short landing zone. The 360° apposition of the vessel wall demonstrated a higher number of embolic particles and debris removed compared to other filters. The retrieval catheter delivers suction during the filter retrieval, removing the captured or contained embolic particles inside the stent or between the stent and filter.



Figure 2. Comparison with other distal protection devices.



Figure 3. Debris caught in the aspirate using FiberNet EPS.

Interestingly, in this author's institutional experience, inspection of aspirate samples after CAS performed with FiberNet protection has yielded a larger debris burden on average when compared with other neuroprotection devices. Moreover, we have yet to see any filter occlusion despite the small pore size.

Finally, based on the recent EPIC trial, the 30-day stroke rate was one of the lowest compared to other distal protection device studies, which makes the FiberNet EPS a promising distal protection alternative for CAS. ■

*The references for this article are available online at [www.evtoday.com](http://www.evtoday.com).*

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