



FDA Approves Lumen Biomedical's FiberNet Embolic Protection System for Carotid Artery Stenting

PLYMOUTH, MN – November 19, 2008 – Lumen Biomedical, Inc. (Plymouth, MN) announced today that the U.S. Food and Drug Administration (FDA) has cleared its FiberNet[®] Embolic Protection System (EPS) for the treatment of patients receiving endovascular intervention for carotid artery disease. The approval follows the recent release of the EPIC Clinical Study data demonstrating the lowest stroke rates of any filter currently available on the US market.

“We are pleased to bring this proven technology to the US market,” said Matthew Ogle, Chief Executive Officer. “The effective design of the filter providing excellent patient outcomes set this system apart from other protection options currently available; further supporting carotid stenting as an alternative to surgery.”

The FiberNet EPS captures debris released during the stenting procedure and prevents it from traveling to the brain, where it has the potential to cause a stroke. The defining attribute of the FiberNet filter lies in the 3-dimensional design, comprised of a matrix of fibers, allowing for better capture efficiency (> 40 µm). The low-profile filter is mounted on a guide wire, needing no delivery system to cross the lesion. Remote actuation deploys the fiber-based filter – treating vessels ranging from 3.5 to 7.0 mm – filling the vessel and ensuring excellent wall apposition. After the particles have been captured, the FiberNet filter is retrieved into the retrieval catheter under aspiration, and removed from the patient.

“The optimal filtration and ease of use of the FiberNet filter have proven to be clinically significant advancements in the carotid arena,” said Subbarao Myla, M.D., U.S. Co-Principal Investigator of the EPIC trial. “The 2.1% 30-day stroke rate achieved in the EPIC trial further strengthens the parallel between technological advancements and the safety of carotid stenting.”

The FiberNet EP System was evaluated in the multi-center, EPIC trial during carotid artery stenting of 237 high surgical risk patients with a critical carotid artery stenosis. Overall, the combined major adverse event rate at 30 days for all death, stroke and myocardial infarction (MI)

was 3.0%. There were five strokes (4 ischemic and 1 hemorrhagic) for a 30-day stroke rate of 2.1%. There were no unanticipated adverse device effects.

Lumen Biomedical is driven towards the development and commercialization of unique interventional devices for use in multiple anatomical areas where embolic protection or thrombus removal may be required. These markets include peripheral vascular and coronary applications with potentials approaching 1.6 billion worldwide. To learn more about Lumen Biomedical, Inc. visit the web site at www.lumenbio.com.

Cautionary Statement Regarding Forward Looking Statements

These forward-looking statements are based upon beliefs and estimates using information available to us at present (Lumen Biomedical, Inc), and do not provide guarantees as to the future events or performance of our company or our products. Readers are cautioned not to place undue reliance on any of our forward-looking statements.

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