NOVEL INTRASACCULAR ANEURYSM TREATMENT DEVICE RECEIVES FDA PMA APPROVAL

The WEB® Aneurysm Embolization System is the first intrasaccular flow disruptor PMA approved for the embolization of wide neck bifurcation aneurysms

Aliso Viejo, CA. – January 7, 2019 – MicroVention, Inc., a U.S.-based subsidiary of Terumo and a global neurovascular company, announced today the FDA Premarket Approval (PMA) for the WEB Aneurysm Embolization System for the treatment of intracranial wide neck bifurcation aneurysms. The WEB System is the first and only PMA approved device in the new category of intrasaccular flow disruptors for aneurysm embolization. (The WEB System was developed by Sequent Medical, Inc. and Sequent was acquired by Terumo in 2016).

The WEB System is a unique, single-device treatment solution for wide neck bifurcation aneurysms, which may account for up to 35% of all aneurysms. When placed inside the aneurysm sac, the WEB device's proprietary microbraid technology bridges the aneurysm neck, disrupting blood flow, and creates a scaffold for long-lasting treatment.

"The WEB System provides a valuable alternative for the treatment of bifurcation aneurysms. In the WEB-IT pivotal trial, the WEB System demonstrated 84.6% adequate occlusion, and an extraordinary safety profile for a subset of aneurysms that are challenging to treat with standard embolization coils and assist devices," noted Adam Arthur, MD, Director of Cerebrovascular & Endovascular Neurosurgery at Semmes Murphey Neurologic & Spine Institute, Associate Professor of Neurosurgery at University of Tennessee, and a Principal Investigator of the WEB-IT Trial.

The pivotal WEB Intrasaccular Therapy Trial (WEB-IT) demonstrated that the WEB System is effective in attaining positive long-term clinical results in a safe, single-device procedure for wide neck bifurcation aneurysms. The WEB Aneurysm Embolization System has been CE marked since 2010 and has been safely used in more than 6,000 cases and multiple clinical studies throughout the world.

"We are proud to offer our latest innovation to the neuroendovascular market in the United States with the introduction of the WEB System, achieving the most rigorous standard of FDA approval through the PMA process," said Richard Cappetta, President and Chief Executive Officer of MicroVention. "At MicroVention, we work side-by-side with physicians to consistently deliver innovative technologies to advance patient care".

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"In the pivotal trial, patients benefited from the WEB System through a safe and effective treatment with excellent clinical outcomes, fast procedure times and limited radiation exposure. The WEB System is a first-to-market, innovative and highly studied intrasaccular solution that advances the treatment of wide neck bifurcation aneurysms," said David Fiorella, MD, PhD, Professor of Neurological Surgery and Radiology, Director of Neurointerventional Radiology, Stony Brook University Cerebrovascular and Stroke Center and a Principal Investigator of the WEB-IT Trial.

For more information regarding the WEB Aneurysm Embolization System, please visit www.microvention.com.

About Wide Neck Bifurcation Aneurysms

An intracranial aneurysm is a bulging, weak area in the wall of an artery that supplies blood to the brain. A weakness located at a junction between two diverging vessels is called a bifurcation aneurysm.

Important Information About the WEB Aneurysm Embolization System

This device is indicated for use at the middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) terminus, anterior communicating artery (AComm) complex, or basilar artery apex for the endovascular treatment of adult patients with saccular, wide neck, bifurcation intracranial aneurysms with dome diameter from 3 mm to 10 mm and either neck size 4 mm or greater or the dome-to-neck ratio is greater than 1 and less than 2.

About MicroVention, Inc.

Founded in 1997, MicroVention develops and markets medical devices that enable or significantly improve treatment of cerebrovascular diseases. In 2006, Terumo Corporation, a major worldwide medical device company headquartered in Tokyo, Japan, acquired MicroVention into their family of Companies. Terumo's acquisition of MicroVention allowed both Companies to leverage their unique, proprietary technologies toward an increased focus on treating cerebrovascular diseases.

Headquartered in California, MicroVention products are sold in more than 75 nations through a direct sales organization alongside strategic distribution partnerships.

www.microvention.com

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About Terumo Corporation

Founded in 1921, Tokyo-based Terumo Corporation is one of the world's leading medical device manufacturers with $5 billion in sales and operations in more than 160 nations. Terumo develops, manufactures and distributes world-class medical devices, including products for use in cardiothoracic surgery, interventional procedures and transfusion medicine. It also manufactures a broad array of syringe and hypodermic needle products for hospital and physician office use.

Terumo contributes to society by providing valued products and services to the health care market and by responding to the needs of health care providers and the people they serve. Terumo Corporation's shares are listed on the first section of the Tokyo Stock Exchange (No. 4543, Reuters symbol <4543.T>, or Bloomberg 4543: JP) and is a component of the Nikkei 225, Japan's leading stock index.

www.terumo.com

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