

MicroVention Announces FDA Premarket Approval of a New Flow Diverter for the Treatment of Brain Aneurysms

Aliso Viejo, CA. – January 9, 2020 – MicroVention, Inc., a U.S. based subsidiary of Terumo and a global neurovascular company announced the FDA Premarket Approval (PMA) for the FRED® (Flow Re-Direction Endoluminal Device) device for the treatment of brain aneurysms.

The FRED® device is the first flow diverter in the U.S. to use a self-expanding braided nitinol mesh to help re-direct blood flow and promote aneurysm occlusion. The unique interwoven nitinol design of the FRED® device allows for smooth delivery to the target aneurysm, as well as reliable opening and vessel wall apposition, resulting in high treatment durability.

“The FRED® device represents a step forward in flow diversion technology with the inclusion of the lowest profile delivery platform in the U.S. This advancement will allow physicians to more easily access and treat wide-necked or fusiform aneurysms,” said Dr. Cameron McDougall, Director of Endovascular Neurosurgery and Professor of Neurosurgery at The Johns Hopkins Hospital, and primary investigator for the FRED® pivotal trial. “The pivotal study shows that a single FRED® device is safe and effective for use in a variety of aneurysm sizes and locations and expands treatment options for patients.”

The FRED® device has been CE marked since 2013, safely used in nearly 20,000 procedures, and published in numerous clinical studies around the world. The FRED® device pivotal study adds new evidence to the large existing body of global clinical data, further demonstrating the safety and effectiveness of the device.

“With our 3rd PMA approval by the Food and Drug Administration in 18 months, MicroVention is proud to introduce the FRED® flow diversion device to the United States. The FRED® device helps address a need for a clinically proven flow diverter with simplified delivery,” said Irina Kulinets, PhD, Sr. WW Vice President of Regulatory Affairs, Clinical Research & Quality at MicroVention. “MicroVention is dedicated to the development of novel technologies that improve patient outcomes and quality of life. We are excited to bring the FRED® device to patients in the U.S. who will benefit from treatment.”

For more information regarding the FRED® flow diversion device, please visit the [FRED® Device Product Page](#).

About the FRED® Device:

The Flow Re-Direction Endoluminal Device (FRED®) System is indicated for use in the internal carotid artery from the petrous segment to the terminus for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width \geq 4 mm or dome-to-neck ratio $<$ 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter \geq 2.0 mm and \leq 5.0 mm.

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

About Terumo

Terumo (TSE: 4543) is a global leader in medical technology and has been committed to "Contributing to Society through Healthcare" for nearly 100 years. Based in Tokyo and operating globally, Terumo employs more than 25,000 associates worldwide, to provide innovative medical solutions in more than 160 countries. The company's extensive business portfolio ranges from vascular intervention and cardio-surgical solutions, blood transfusion and cell therapy technology, to medical products essential for daily clinical practice. Terumo pursues quality in all we do – from product excellence to customer care – in order to give patients a better tomorrow.

www.terumo.com

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