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Product bulletin

Stryker receives US FDA Pre-market approval for the Surpass Streamline™ Flow Diverter to treat large and giant unruptured aneurysms

Kalamazoo, Michigan, USA – July 16, 2018 – Stryker Corporation announced today that the U.S. Food and Drug Administration has granted pre-market approval (PMA) for the Surpass Streamline Flow Diverter to treat unruptured large and giant wide neck intracranial aneurysms. The device is the second flow diverting stent to gain FDA approval in the U.S. It is also approved and available in many markets around the world.

“Surpass Streamline is the first flow diverter indicated for large and giant posterior communicating artery aneurysms. These unruptured aneurysms are more challenging due to their location and surrounding anatomy. Having Surpass approved for this and other locations is an important advantage for physicians and patients,” said Dr. Philip Meyers, Professor of Radiology and Neurological Surgery at New York Presbyterian/Columbia University Medical Center and Co-Principal Investigator for the SCENT Investigational Device Exemption (IDE) trial which provided clinical outcomes to support Surpass PMA approval. “The stent is designed to reliably open and provide consistent mesh density across the neck of the aneurysm to aid in aneurysm occlusion while maintaining perforator artery patency.”

Dr. Ricardo Hanel, Director of the Baptist Neurological Institute at the Baptist Health System in Jacksonville, Fla. and Co-Principal Investigator for the SCENT IDE trial added, “SCENT is one of the largest, prospective, multicenter clinical trials on flow diversion that is generalizable to real world outcomes. This was the first flow diverter IDE study to show single stent efficacy while successfully meeting the primary and secondary endpoints. The ability to resheath, reposition and recapture the device without losing distal wire position is a significant advantage for Surpass.”

“The PMA approval of Surpass Streamline Flow Diverter in the U.S. is an important milestone for the division. It expands our commercial footprint into the flow diversion market and reinforces our commitment to complete stroke care for patients suffering from cerebrovascular disease,” said Mark Paul, president of Stryker’s Neurovascular division.

About Surpass Streamline

Stryker’s Surpass Streamline Flow Diverter is a small cobalt chromium braided stent that is used to direct blood flow within an intracranial artery away from a weakened blood vessel sac or aneurysm. The diversion of blood flow occludes the aneurysm over time reducing the risk of future rupture. An estimated 6 million people in the United States have an unruptured brain aneurysm of which approximately 25,000 are treated with endovascular or surgical treatments each year¹.



About Stryker

Stryker is one of the world's leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes. More information is available at www.stryker.com.

1. Brain Aneurysm Foundation Statistics. www.bafound.org

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