

May 20, 2019

Press release

Stryker receives FDA premarket approval for the Neuroform Atlas® Stent System to treat brain aneurysms

Kalamazoo, Michigan, USA – May 20, 2019 – Stryker announced today the Premarket Approval (PMA) of the Neuroform Atlas Stent System by the U.S. Food and Drug Administration (FDA). Neuroform Atlas is only the second aneurysm adjunctive stent to be granted PMA approval for the treatment of wide-neck, intracranial aneurysms in conjunction with embolic detachable coils. Neuroform Atlas Stent System was previously approved under a humanitarian device exemption restricting use to specific hospitals with institutional review board approval. PMA approval was granted based on robust clinical trial evidence proving the efficacy of the device.

“Neuroform Atlas represents a significant advancement in the treatment of wide-neck aneurysms which is now backed by the largest IDE stent-coil trial completed to date,” said Dr. Osama O. Zaidat, Director of the Neuroscience and Stroke Center at Mercy Hospital in Toledo, Ohio, and Co-Principal Investigator of the U.S. Neuroform Atlas investigational trial. “More impressive were the results with an 84.7% primary efficacy rate, a 4.4% primary safety rate and a 3.8% retreatment rate.”

“Enhanced stent conformability, a low-profile delivery system and high deployment accuracy even in distal anatomy puts Neuroform Atlas in a category of its own,” said Dr. Brian Jankowitz, Director of the NeuroEndovascular Fellowship program at the University of Pittsburgh Medical Center and Co-Principal Investigator of the study. “This product is changing my clinical practice by allowing more patients with difficult aneurysms an option at endovascular treatment while improving the quality and safety of treatment.”

Mark Paul, president of Stryker’s Neurovascular division, added, “Proving the safety and efficacy of our products through landmark clinical trials is a top priority and key differentiator for Stryker. Meaningful clinical data enables our market leading products to better serve patients suffering from debilitating cerebrovascular disease. PMA approval of Neuroform Atlas Stent System is a significant milestone in providing world class technology to our physicians.”

About Neuroform Atlas Stent System

Stryker's Neuroform Atlas Stent System is a self-expanding nitinol stent used in conjunction with metal coils to pack weakened blood vessel sacs called aneurysms within the brain. The stent is positioned across the aneurysm neck to hold metal coils and occlude the aneurysm. An estimated 6 million people in the United States have an unruptured brain aneurysm of which roughly 25,000 are treated each year¹.

The Neuroform Atlas Stent System is indicated for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked (neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm.

More information on the safety and efficacy of the Neuroform Atlas Stent System can be found in the Summary of Safety and Efficacy Data (SSED) available online at www.fda.gov.

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

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.

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