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Stryker gets FDA premarket approval for the Neuroform Atlas® Stent System

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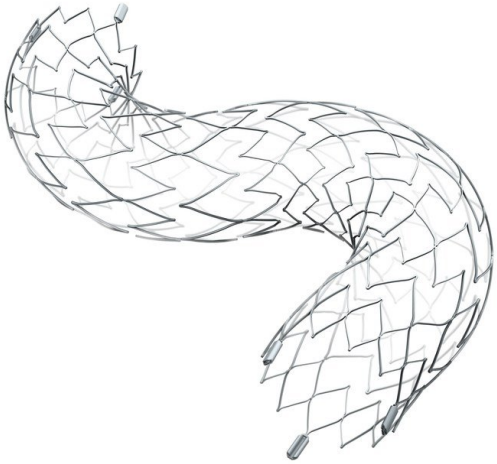
Neuroform Atlas is only the second aneurysm adjunctive stent to be granted PMA approval to treat brainaneurysms



Neuroform Atlas™ Stent Conformability
Image courtesy of Stryker

Stryker has announced 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."