Stent For Wide-Necked Intracranial Aneurysms Approved In Japan

A new Vascular Reconstruction Device and Delivery System (VRD) is a self-expanding stent used to treat wide-necked intracranial aneurysms.

March 24, 2010

Codman & Shurtleff, Inc. (Codman), a global neuroscience and neurovascular company, announces that Johnson & Johnson K.K. Medical Company, headquartered in Tokyo, obtained approval of the CODMAN ENTERPRISE Vascular Reconstruction Device and Delivery System (VRD), a self-expanding stent used to treat wide-necked intracranial aneurysms, in Japan.

This is the first time an intracranial stent has been approved by Japan's Ministry of Health, Labour and Welfare (MHLW), and will be available in Japan when a reimbursement price is established by the Japanese government.

"This is an important approval for Japan in the evolution of advanced treatment for cerebral aneurysms," said Nobuyuki Sakai, MD, Director of Neurosurgery and the KCGH Stroke Center at Kobe City General Hospital in Japan. "Until now, there was no stent specifically designed for use inside the brain.

The CODMAN ENTERPRISE VRD is a very flexible stent pre-loaded onto a delivery system that enables precise navigation and ease of deployment in the cerebral vasculature. This new device will allow neurosurgeons to help more people who previously had limited treatment options."

A cerebral aneurysm is an abnormal bulge that fills with blood in the wall of a blood vessel in the brain. The larger the bulge, the greater the risk of the vessel rupturing and bleeding into the brain tissue, which can lead to stroke, a leading cause of death in Japan and around the world. According to the World Health Organization (WHO), each year about 15 million people worldwide suffer a stroke and as many as one-third die from it.1

To prevent rupture of an aneurysm, treatment options include clipping the vessel during open brain surgery to stop blood flow into the aneurysm or minimally invasive surgery using endovascular coils and stents. In the latter procedure, a catheter is inserted through a patient's leg and is maneuvered through the vascular system to the brain where tiny coils are placed directly inside the aneurysm to seal off the bulge and restore normal blood flow. An endovascular stent, a tube-like metal device, is sometimes used to hold coils in place. The entire procedure is performed using real-time image guidance.

The CODMAN ENTERPRISE VRD stent is made of nitinol, a combination of nickel and titanium, and is approved in Japan for use with wide-necked unruptured aneurysms, with a size of at least 7mm or greater from a parent vessel with a diameter of ≥2.5mm and ≤4mm. Wide-neck is defined as having a neck width ≥4mm or a dome-to-neck ratio <2. The stent is pre-loaded onto a delivery system composed of an introducer and delivery wire. The stent serves as a scaffold for the coils to help prevent herniation, and its unique closed cell design provides conformability and true vessel reconstruction at the neck of the aneurysm.

“The CODMAN ENTERPRISE VRD System fills an unmet clinical need in Japan and we will continue to bring more of this kind of innovation supported by world-class education and training to Japan and throughout the globe,” said P. Laxminarain, Worldwide President, Codman.

The CODMAN ENTERPRISE VRD System was approved in Europe in 2006 and in the U.S. in 2007.

HUMANITARIAN DEVICE (USA ONLY): The CODMAN ENTERPRISE™ Vascular Reconstruction Device and Delivery System is authorized by Federal Law for use with embolic coils for the treatment of wide-necked, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥2.5mm and ≤4mm. Wide-neck is defined as having a neck width ≥4mm or a dome-to-neck ratio <2. The effectiveness of this device for this use has not been demonstrated.

For more information, visit www.depuy.com [1].

1 http://www.who.int/cardiovascular_diseases/resources/atlas/en/ [2]

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