Penumbra, Inc. Receives Shonin Approval for the Penumbra Coil 400™ in Japan To Treat Intracranial Aneurysms.

The Associated Press

ALAMEDA, Calif.--(BUSINESS WIRE)--Sep 5, 2012--Today, Penumbra, Inc. announced the Shonin approval by the Japanese Ministry of Health, Labor and Welfare of the Penumbra Coil 400 for treatment of intracranial aneurysms. Penumbra, together with its exclusive distribution partner, Medico’s Hirata, Inc., will immediately begin the launch of the device for sale to the Japanese endovascular community.

Endovascular coiling has been the gold standard for minimally invasive treatment of brain aneurysms for almost a decade. Conventional coils however have a very low volume per coil requiring many implants to achieve aneurysm occlusion. In addition, those multiple implants usually don’t achieve the high density of occlusion that is believed to be the most important determinant of long-term stability. The Penumbra Coil 400 solves these problems. Each coil is two to four times larger volume than a conventional coil. At the same time it’s capable of tighter packing, allowing greater occlusion density, which can improve long-term outcomes. The Penumbra Coil 400 enables endovascular surgeons to implant fewer coils, during shorter procedures, and achieve better results significantly improving minimally invasive brain aneurysm treatment.

“The Penumbra Coil 400 is the first major advance to significantly affect endovascular coiling technology since the original platinum detachable coil,” said Nobuyuki Sakai, MD, DMSc, Director, Neurosurgery and Stroke Center at Kobe City Medical Center General Hospital. “We are proud and excited to have this technology in Japan and very much look forward to its use treating our intracranial aneurysm patients,” said Dr. Sakai.

“I have been impressed with the ability of the Penumbra Coil 400 to durably occlude aneurysms quickly and efficiently in the wide range of aneurysms we treat. We are now seeing encouraging follow-ups and complete occlusion in aneurysms that would have been vulnerable,” said Dr. Aman Patel, Professor, Neurosurgery/Radiology, Mt. Sinai School of Medicine in New York, NY. “I am looking forward to introducing my colleagues in Japan to this remarkable new technology. It will be exciting to see an innovation like this take hold in a new market. Japanese neurosurgeons will now have an important alternative to treat brain aneurysms.” ABOUT Penumbra Penumbra, Inc. (www.penumbrainc.com) is an independent medical device company committed to delivering clinically beneficial products that help patients suffering from stroke and other vascular diseases. Penumbra’s global headquarters is located in Alameda, California with sales operations in North and South America, Europe, Australia and Asia.

ABOUT Medico’s Hirata With 90 years of history, Medico's Hirata was one of the first

companies in Japan to focus on catheter intervention and the development of minimally invasive devices for use in a wide range of fields, such as endovascular treatment. The company continues to grow with the evolution of new medical technologies, and using its substantial experience and performance will continue to be a leader in technology and relationships with medical professionals.

ABOUT The Penumbra Coil 400™ The Penumbra Coil 400 is a platinum embolic device placed into an aneurysm through the blood vessels leading to the brain, protecting the aneurysm from bleeding. The Penumbra Coil has two to four times more volume per unit length and is capable of denser occlusion than other embolic coils on the market leading to fewer implants, reduced procedure times, and durable long-term results.

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