Najuta Thoracic Stent Graft System

Kawasumi Laboratories, Inc. announced the launch of its new Najuta thoracic stent graft system in Europe. The Najuta is indicated for thoracic endovascular aneurysm repair (TEVAR) of patients with thoracic aortic aneurysms. Each Najuta device is individually designed using three-dimensional (3D) CT for fitting into the aorta configuration.

Single or multiple fenestrations are created along the greater curvature to secure blood supply via the arch vessels. The device produced positive, long-term efficacy and safety results in the KSG-001 clinical trial study, a 5-year, a nonrandomized, multicenter study conducted in Japan.

“The Najuta is an attractive new TEVAR device option because its fenestration design and semi-customization allows physicians to consider this less invasive procedure for many patients, especially those with a short neck who might otherwise be ineligible for TEVAR,” said Prof. Franco Grego, MD, of the University Hospital of Padova in Padova, Italy.

Vanguard IEP Peripheral Balloon Angioplasty System With Integrated Embolic Protection

Contego Medical, LLC has initiated the ENTRAP study, which will evaluate the usage of the Vanguard IEP (integrated embolic protection) peripheral balloon angioplasty system. The study plans to enroll up to 130 subjects in centers throughout Belgium and Germany.

Vanguard IEP combines a peripheral angioplasty balloon and distal embolic filter on the same catheter and is designed for protection of lower limbs during angioplasty. The device features the first filter with in vivo adjustability to suit varying vessel sizes and maximize capture efficiency. The Vanguard IEP system received CE Mark in April.

Professor Thomas Zeller, Director of the Department of Angiology at Universitaets-Herzzentrum Freiburg in Bad Krozingen, Germany, commented, “The Vanguard IEP device will be of particular importance to patients at high risk for distal embolization, such as those with acute limb ischemia or chronic total occlusions, as well as those at higher risk should embolization occur, such as patients with critical limb ischemia and diabetes mellitus.” Prof. Zeller is the Principal Investigator of the ENTRAP study.