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Vivasure Medical Receives CE Mark for First and Only Fully Bioabsorbable Percutaneous Closure Device for Large-Bore Transcatheter Procedures

Sutureless Technology Designed to Facilitate Less-Invasive, Shorter Procedures

Galway, Ireland — January 8, 2016 — Vivasure Medical today announced Conformité Européenne (CE) Mark approval of the world's first fully bioabsorbable percutaneous vascular closure device for large-bore femoral arteriotomies. The Vivasure closure device is the first product from the company's patented PerQseal™ technology platform, and is the only approved bioabsorbable, sutureless and fully synthetic option to close large arteriotomies, which result from percutaneous transcatheter procedures.

An arteriotomy is a puncture hole in a vessel in the groin that provides access to arteries for catheter-based procedures. Large-bore arteriotomies, such as those made to facilitate transcatheter aortic valve replacement (TAVR) and endovascular abdominal aortic aneurysm repair (EVAR), have traditionally required a surgical cut-down and sutured repair via a 3- to 5-centimeter incision. The proprietary Vivasure closure device offers physicians an easy-to-use and fully percutaneous (through the skin) alternative to sutured repair.

"Percutaneous transfemoral access is a key enabler for TAVR procedures, which are rapidly becoming standard of care for patients with aortic valve disease," said Michael Laule, M.D., cardiologist at Charité University Hospital, Berlin. "The Vivasure closure device is an easy-to-use option that promises to significantly improve the patient experience and shorten overall procedure times by allowing physicians to utilize a fully percutaneous procedure to repair the access site."

"The bioabsorbable nature of the Vivasure closure device allows the surgeon to provide a complete repair at the surgery site, which helps avoid stenosis and maintains the integrity of the vessel," said Dr. Paul Teirstein, chief of cardiology and director of interventional cardiology for Scripps Clinic, director of the Scripps Prebys Cardiovascular Institute for Scripps Health, and chief medical officer of Vivasure Medical. "The demand for bioabsorbable solutions is growing as the transient nature of these products continues to demonstrate as good or better therapeutic results for patients."

"Patients with aortic valve stenosis, abdominal aortic aneurysms and other serious conditions are increasingly treated with minimally invasive procedures that offer improved clinical outcomes and faster recovery times over the open surgery alternative. The Vivasure closure device is intended to further facilitate the less invasive nature of these treatments," said Gerard Brett, co-founder and CEO of Vivasure Medical. "CE Mark is an important milestone for Vivasure as we continue development of our technology, which we plan to launch in Europe in the coming months."

The Vivasure closure device includes a delivery system and single-use patch-like device. The system has been evaluated in clinical studies, with patients treated in four EU countries, achieving 97 percent device technical success with no major device related complications. Long-term follow-up data has been collected to 12 months post-procedure.

To view an animation of the Vivasure closure device, please visit <http://www.vivasuremedical.com/>

The Vivasure closure device is not currently approved in the U.S.

About Vivasure Medical

Based in Galway, Ireland, Vivasure Medical has developed a patented bioabsorbable implant platform technology for applications in vessel closure. Its first product from this PerQseal™ platform features a bioabsorbable implant and percutaneous delivery system, designed to close large arteriotomies. For more information visit www.vivasuremedical.com.

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