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FDA Clears EnsiteVascular Femoral Compression Device

New Vascular Compression Device simulates manual compression, removes variability, and leaves nothing behind

OLATHE, KANSAS, Mar. 31, 2020 – [EnsiteVascular™](http://EnsiteVascular.com) announced that its SiteSeal™ Femoral Compression Device received market approval by the Food and Drug Administration (FDA) as a vascular closure device (VCD). SiteSeal™ is a next-generation VCD that simulates manual compression while significantly reducing patient and user variability and unnecessary complications.

The system is targeting fast-growing and unmet demand for large-bore closure systems in TAVR/EVAR procedures. Uniquely, the device can be used as standalone in these procedures to close arteriotomy sites whereas leading competitors require multiple applications and/or adjunctive manual compression. Taken together, SiteSeal™ is positioned for rapid market uptake due to safe and reliable closure at reduced costs. This approval follows the company's recent FDA approval for their small bore/peripheral closure system, SiteSeal SV.

"SiteSeal™ is unlike any VCD available on the market, and yet it's the one physicians have been asking for. The simple-to-use, atraumatic, single device can ambulate patients in approximately one hour after diagnostic procedures and approximately two hours after interventional procedures. Patients can lie more comfortably with their heads at a 30-degree angle, and allows free leg movement, This is remarkable and requires just a Z-stitch, yet solves a number of challenges such as: immediate re-access; risks of vessel wall injury; infection; embolization; patient size, anti-coagulation and calcification limits." said Tom Reidy, EnsiteVascular's president and CEO, "Moreover, SiteSeal™ closes the artery without leaving a foreign body behind or vascular alteration to the femoral artery."

SiteSeal™ represents a new approach to vascular closure as post-endovascular procedure hemostasis from manual compression takes up a third of a professional's time and other types of VCDs introduce significant variability. Dr. Rex Teeslink, a vascular and interventional radiologist and EnsiteVascular's co-inventor and medical director commented; "Since beginning my practice, I have been actively involved in cutting edge medical technology. Over the years, I've assisted in designing, developing and implementing many medical devices and interventional procedures. I look forward to

increasing awareness about our new technologies among endovascular physicians who are frustrated with inherent complications and limitations with existing VCD's."

About EnsiteVascular

EnsiteVascular is a clinical stage medical technology company that was founded to improve vascular closure outcomes for physicians and their increasing number of patients with peripheral arterial disease and structural heart diseases. The company's unique technologies replace the need for manual compression, as well as removing the variables and complication risks associated with other VCDs while leaving nothing behind to further assist the endovascular physicians' procedures and improve patient outcomes. Visit <http://www.ensitevascular.com> for more information.