Contact: Tom Reidy
1-816-260-8476 | Treidy@ensitevascular.com
Ensitevascular.com

FOR IMMEDIATE RELEASE

EnsiteVascular receives FDA market clearance for SiteSeal™ SV vascular closing device's second indication

The SiteSeal SV VCD is the only compression device currently with FDA market clearance for both radial and brachial arteries

OLATHE, KANSAS, April 20, 2021 — EnsiteVascular announces today it received its second U.S. Food and Drug Administration (FDA) market clearance for the company's SiteSeal SV (small vessel) VCD to achieve hemostasis of the brachial artery after a transbrachial endovascular procedure.

The FDA's market clearance occurred once the agency reviewed EnsiteVascular's Section 510(k) premarket notification of intent to market the SiteSeal SV device and determined it is substantially equivalent for the indication for use stated: brachial artery closure. Previously, EnsiteVascular received FDA market clearance for SiteSeal SV for radial artery closure.

SiteSeal SV is a new closure device designed for closure of small arterial vessels, specifically brachial, radial and pedal. It simulates external compression, but removes the associated variables, leaving nothing behind. SiteSeal SV applies invariant pressure to the vessel wall of the access site by utilizing an internal stainless steel spring, which functions as a shock absorber to dampen blood pressure fluctuation.

"The gold standard for closure of the brachial artery has always been manual compression. However, there is a significantly high rate of major complications associated with manual compression, up to 14%. These include pseudo aneurysms, thrombosis and excess bleeding, with over 60% requiring surgical repair," says Rex Teeslink, M.D., medical director, EnsiteVascular.

“Currently, there is no other device with FDA market clearance for closure of brachial artery access sites. With FDA’s clearance for SiteSeal SV to achieve hemostasis of the radial artery after a transradial procedure or the brachial artery after a transbrachial procedure, we are making progress toward a new and better standard of care for these endovascular procedures,” says Dr. Teeslink.

About Ensite Vascular

EnsiteVascular was founded to improve vascular closure outcomes for physicians and the increasing number of patients requiring endovascular procedures, both arterial and venous. In addition, SiteSeal SV leaves nothing behind within the vessel, vessel wall or surrounding soft tissues. Visit http://www.ensitevascular.com for more information.

###