

PRODUCT LAUNCH ANNOUNCEMENT



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Clinical Study Shows Use of D-Stat® Flowable Hemostat Reduced by 48% the Incidence of Clinically Relevant Hematomas in High-Risk, Anticoagulated Patients Undergoing Pulse Generator Implantation

MINNEAPOLIS, Minnesota — Vascular Solutions, Inc. recently announced the published results of a 269-patient, 10-center, prospective randomized U.S. clinical study regarding its thrombin-based D-Stat® Flowable hemostat.

The study demonstrated that when used as an adjunct to hemostasis in the pre-pectoral pocket during the implantation of pulse generators (i.e., ICDs or pacemakers), D-Stat Flowable reduced the incidence of clinically relevant hematoma formation in high-risk, anticoagulated patients by 48% compared to the standard of care (i.e., electrocautery, standard compression and/or non-treated cotton pledgets). High-risk patients were defined as those whose anticoagulation regimens would resume within 24 hours, including the administration of one or more of the following: Heparin, LMWH, Warfarin or Clopidogrel. For patients receiving Warfarin therapy, an INR of ≤ 2.0 was required for inclusion in the study.



The safety of the use of D-Stat Flowable in the pre-pectoral pocket also was successfully demonstrated, as the incidence rate of major complications experienced between the investigation group (D-Stat Flowable: 21.3%) and the control group (standard of care: 27.8%) was similar. The corresponding p-value for non-inferiority was 0.0008, below the a priori alpha level of 0.05, demonstrating non-inferiority of treatment to control for the safety endpoint. The primary effectiveness of D-Stat Flowable within the pre-pectoral pocket was determined by the incidence rate of clinically relevant hematomas.

A clinically significant hematoma was defined as alteration in the standard of care (e.g., application of a compression bandage, alteration of the patient's anti-clotting regime or evacuation of the hematoma).

Vascular Solutions, Inc. is a leading medical device company that delivers proprietary clinical solutions for diagnosing and treating vascular conditions. The company's rapidly growing product line consists of innovative devices across established and emerging areas of coronary and peripheral vascular medicine.

For more information, visit www.vascularsolutions.com.