



# D-Stat<sup>®</sup> Flowable Hemostat Pocket Protector

Consider the **potential savings** of using  
**D-Stat Flowable** to **reduce pocket hematoma formation**

## Cost Model<sup>1</sup> for Hematoma Treatment in High-Risk Patients<sup>2</sup>

| Projected Costs <sup>3</sup> for 100 Patients                  | D-Stat Flowable Used     | D-Stat Flowable Not Used |
|--|--------------------------|--------------------------|
| Projected Number of Clinically Relevant Hematomas <sup>4</sup> | 12                       | 23                       |
| Cost of D-Stat Flowable Treatment <sup>5</sup>                 | \$12,500                 | \$0                      |
| Hematoma Care and Treatment <sup>6</sup>                       | \$83,940                 | \$160,885                |
| Total Cost of Treatment <sup>7</sup>                           | \$96,440                 | \$160,885                |
| Average Patient Cost <sup>8</sup>                              | \$964                    | \$1,609                  |
| <b>Potential Cost Savings</b>                                  | <b>\$645 per patient</b> |                          |

*A recently published economic assessment found that hemorrhage/hematoma complications following implantation of an ICD increase patient length of stay by 3.1 days and add \$6,995 to the cost of care<sup>1</sup>. Applying the results of this study to 100 high-risk patients<sup>2</sup> shows that use of D-Stat Flowable can potentially save an average of \$645 per patient with regard to costs associated with post-implant hematoma care and treatment.*

<sup>1</sup> Cost model developed based on data presented in the economic assessment published by Reynolds et al., "The Frequency and Incremental Cost of Major Complications Among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators," JACC, Vol. 47, No. 12, 2006, 2493-2497.

<sup>2</sup> High-risk patients were defined in the Pocket Protector trial as those whose anticoagulation regimens would resume within 24 hours of implant.

<sup>3</sup> Costs discussed in this model selectively address the cost of treating a hematoma should it develop. Actual costs observed in individual institutions may vary.

<sup>4</sup> Presumed Hematoma incidence = 11.76% based on overall results observed in the Treatment Group of the Pocket Protector Trial and 22.56% based on overall results observed in the Control Group of the Pocket Protector Trial. Projected number of hematomas rounded to the next whole number. Clinically relevant hematomas were defined in this study as those that result in an alteration in the standard of care resultant of hematoma formation, including alteration (i.e., suspension or discontinuation) of the anticoagulant therapy regimen (Heparin, LMWH, Coumadin or Plavix), application of a compression bandage and evacuation of the hematoma.

<sup>5</sup> One unit of D-Stat Flowable is applied per patient at a cost of \$125 each.

<sup>6</sup> Cost of hematoma treatment = \$6,995 from Reynolds et al. and presumes that the cost of caring for a hematoma is equal across all types of pulse generators.

<sup>7</sup> Total cost equals cost of D-Stat Flowable plus the cost of hematoma care and treatment for the group.

<sup>8</sup> Average patient cost equals Total/100.

# D-Stat® Flowable Hemostat

| Model | Description              | Box Quantity |
|-------|--------------------------|--------------|
| 4000  | D-Stat Flowable Hemostat | 5*           |

\* Devices packaged in quantities of 5 units per box. Individual units are not sold separately.

*D-Stat Flowable is indicated for use under the direction of a health care professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes. D-Stat Flowable is indicated for use as an adjunct treatment in sealing residual oozing of tissue tracts of femoral access sites that have been previously closed by suture/collagen-based hemostatic devices. D-Stat Flowable is indicated for use in high-risk, anticoagulated patients undergoing implantation of a pulse generator (e.g., pacemaker or ICD) to reduce the frequency of clinically relevant hematoma formation in the prepectoral pocket. High-risk patients are defined as those whose anticoagulation regimens will resume within 24 hours of implant. Clinically relevant hematomas are defined as those that result in an alteration in the standard of care resultant of hematoma formation, including alteration (i.e., suspension or discontinuation) of the anticoagulant therapy regimen (Heparin, LMWH, Coumadin or Plavix), application of a compression bandage and evacuation of the hematoma.*



*D-Stat Flowable hemostat is part of Vascular Solutions' D-Stat line of hemostatic products, including D-Stat Dry hemostatic bandage, D-Stat Dry Wrap hemostatic bandage, D-Stat Rad-Band topical hemostat, D-Stat 2 Dry hemostatic bandage and D-Stat Clamp Accessory.\*\**

The use of topical bovine thrombin preparations has occasionally been associated with abnormalities in hemostasis ranging from asymptomatic alterations in laboratory determinations, such as prothrombin time (PT) and partial thromboplastin time (PTT), to severe bleeding or thrombosis which rarely have been fatal. These hemostatic effects appear to be related to the formation of antibodies against bovine thrombin and/or factor V which in some cases may cross react with human factor V, potentially resulting in factor V deficiency. Repeated clinical applications of topical bovine thrombin increase the likelihood that antibodies against thrombin and/or factor V may be formed. Consultation with an expert in coagulation disorders is recommended if a patient exhibits abnormal coagulation laboratory values, abnormal bleeding, or abnormal thrombosis following the use of topical thrombin. Any interventions should consider the immunologic basis of this condition. Patients with antibodies to bovine thrombin preparations should not be re-exposed to these products.

The D-Stat Flowable is contraindicated in persons with known sensitivity to bovine-derived materials. Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.  
CAUTION: The D-Stat Flowable procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of device.

\*\* These D-Stat products are available in the United States. Not all products are available in all countries. Please contact the Vascular Solutions distributor or direct sales office for product availability.

U.S. and International patents pending.  
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