CLINICALLY PROVEN FLOWABLE HEMOSTAT

Reduces the frequency of clinically relevant hematoma formation in pulse generator implants
D-STAT FLOWABLE
Comprised of collagen, thrombin and a buffered diluent, this thick, yet flowable procoagulant facilitates hemostasis by initiating the body’s own clotting mechanisms.

PRACTICAL ADVANTAGES
1. Fully sterile kit allows complete preparation within sterile field
2. Easy, needle-free mixing
3. No pharmacy storage required

MULTIPLE CLINICAL USES

PULSE GENERATOR IMPLANTS
Applied in the pre-pectoral pocket during pacemaker/ICD implantation to promote hemostasis and reduce the incidence of clinically significant hematoma formation.

POCKET PROTECTOR STUDY¹ SHOWS A 48% REDUCTION IN CLINICALLY SIGNIFICANT HEMATOMAS

<table>
<thead>
<tr>
<th>Generator Type</th>
<th>D-Stat Flowable (n=136)</th>
<th>Control (n=133)</th>
<th>Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined</td>
<td>11.76%</td>
<td>22.56%</td>
<td>48%*</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>8.11%</td>
<td>20.55%</td>
<td>61%*</td>
</tr>
<tr>
<td>ICD</td>
<td>16.13%</td>
<td>25.00%</td>
<td>35%</td>
</tr>
</tbody>
</table>

*Statistically significant reduction (p \leq 0.05) calculated using Fischer’s Exact Test.

The Pocket Protector Study was a prospective, randomized clinical study evaluating the incidence of clinically relevant hematoma formation after pulse generator implants using D-Stat Flowable plus standard of care vs. standard of care alone.²

POCKET PROTECTOR STUDY¹ SHOWS A 48% REDUCTION IN CLINICALLY SIGNIFICANT HEMATOMAS

VASCULAR ACCESS SITES
Applied topically to control bleeding from vascular access sites and percutaneous catheters and tubes.

TISSUE TRACT HEMOSTASIS POST VASCULAR CLOSURE DEVICE
Applied as an adjunct treatment to seal residual oozing of tissue tracts of femoral access sites that have been previously closed by suture/collagen-based hemostatic devices.

1. The pocket protector study evaluated 269 high-risk patients. High-risk patients are defined as those whose anticoagulation regimen will resume within 24 hours. This included the administration of one or more of the following medications: Heparin, LMWH, Coumadin, Plavix. For patients receiving Coumadin therapy, an INR of < 2.0 was required.
2. Standard of care is defined as compression, electrocautery and/or untreated cotton pledgets.

D-STAT FLOWABLE
Comprised of collagen, thrombin and a buffered diluent, this thick, yet flowable procoagulant facilitates hemostasis by initiating the body’s own clotting mechanisms.
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, anti-coagulated 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 anti-coagulation 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 anti-coagulant therapy regimen (Heparin, LMWH, Coumadin or Plavix), application of a compression bandage and evacuation of the hematoma.

WARNING: SEVERE BLEEDING AND THROMBOSIS COMPLICATIONS

- THROMBIN-JMI can cause fatal severe bleeding or thrombosis. Thrombosis may result from the development of antibodies against bovine thrombin. Bleeding may result from the development of antibodies against factor V. These may cross-react with human factor V and lead to its deficiency.
- Do not re-expose patients to THROMBIN-JMI if there are known or suspected antibodies to bovine thrombin and/or factor V.
- Monitor patients for abnormal coagulation laboratory values, bleeding, or thrombosis.