



D-Stat[®] Flowable
Hemostat
The Pocket Protector

Studied and proven to reduce the frequency of clinically relevant hematoma formation in the prepectoral pocket following pulse generator implantation in high-risk, anticoagulated patients

*The Flowable Hemostat
with the
Science of Thrombin[™]*



vascular
SOLUTIONS

D-Stat[®] Flowable

Hemostat

Reduces the incidence of hematoma formation

D-Stat Flowable is a flowable hemostat that utilizes clinically proven procoagulant components—collagen, thrombin and a buffered diluent. The thick, yet flowable procoagulant facilitates hemostasis by initiating the body's own clotting mechanisms.

Offers practical advantages

- Needle-free mixing requires no measuring
- Conveniently stored and applied at room temperature—no refrigeration required
- Pharmacy storage not required



Equipped with 2 applicator tips

D-Stat Flowable can be delivered through either the included flexible plastic tip or 20 Gauge needle. The two applicator tips provide multiple treatment options.



Information in pulse generator implantation

D-Stat Flowable was evaluated in a 269-patient, 10-center, prospective randomized U.S. clinical study comparing the incidence rates of clinically relevant hematomas and major adverse events when using standard of care (compression, electrocautery and/or untreated cotton pledgets) compared to standard of care plus D-Stat Flowable in an anticoagulated patient population undergoing placement of a pulse generator (pacemaker or ICD).

The Pocket Protector Study demonstrated a reduction in the incidence of clinically relevant hematomas with the use of D-Stat Flowable.

Incidence of Clinically Significant Hematoma Formation	D-Stat Flowable Group (n=136)	Control Group (n=133)	p-value*	95% Confidence Interval (CI)
All Generator Types	11.76%	22.56%	0.0231	1.37%, 20.03%
Pacemakers	8.11%	20.55%	0.0358	0.75%, 24.41%
ICDs	16.13%	25.00%	0.2659	-5.74%, 23.59%

* Calculated using Fisher's Exact Test

D-Stat Flowable was evaluated in high-risk, anticoagulated patients. High-risk patients are defined as those whose anticoagulation regimens 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.

Reduced by 48%

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.

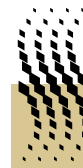
CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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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ML1693 Rev. E 10/09



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