

Topical Hemostat

D-Stat[®] Dry
Hemostatic Bandage

***Proven to reduce
time-to-hemostasis***

*Topical Hemostatic Bandage
with the
Science of Thrombin[™]*



vascular
SOLUTIONS

D-Stat[®] Dry

Hemostatic Bandage

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Clinical data to support a **true** hemostatic pad

Clinical results from a 376-patient, five-center, prospective randomized U.S. clinical study evaluating D-Stat Dry as an adjunct to hemostasis in diagnostic femoral catheterizations using 4F-6F introducer sheaths compared to standard manual compression (control).

50% reduction in median time to hemostasis

Time-To-Hemostasis (TTH) Results	Treatment Group	
	D-Stat Dry (n=187)	Control (n=189)
Median TTH (mins)	6.0	12.0
Mean TTH (mins)*	7.8	13.0
± Standard Deviation	3.0	6.4
Range (min/max)	6, 22	6, 31

*p-value of 0.001 calculated using Wilcoxon's Rank-Sum Test

Non-invasive application with a low rate of adverse events

Major Adverse Events	Treatment Group				p-value
	D-Stat Dry (n=187)		Control (n=189)		
	%	n	%	n	
Pseudoaneurysm	0.0	0	0.5	1	1.000*
Retroperitoneal bleed	0.5	1	0.0	0	0.497*
Other (rhythm disturbance)	0.0	0	0.5	1	1.000*
All adverse events	0.5	1	1	2	0.0001**

* Calculated using Fisher's Exact Test

**Calculated using Blackwelder's Test of Non-Inferiority

Minimum ambulation guidelines for the use of D-Stat Dry in diagnostic procedures*

Medication Status	Sheath Size	Ambulation Guidelines
Not anti-coagulated	4F-6F	1.5-2.5 hours bed rest post sheath removal
Anti-coagulated	4F-6F	2.0-3.0 hours bed rest post sheath removal

*Minimum guidelines to assist in determination of ambulation times for diagnostic endovascular patients; however, these guidelines should **not** supercede clinical judgment based on the medical condition of the individual patient.



D-Stat[®] Dry

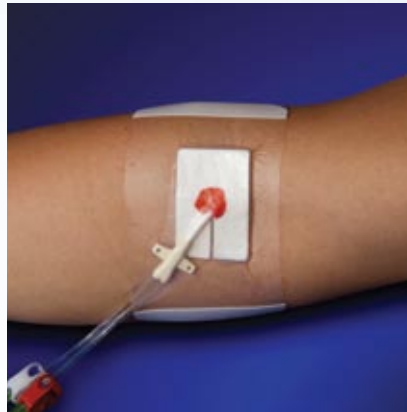
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The **solution** to active bleeding

Apply the D-Stat Dry pad directly to the source of topical bleeding.



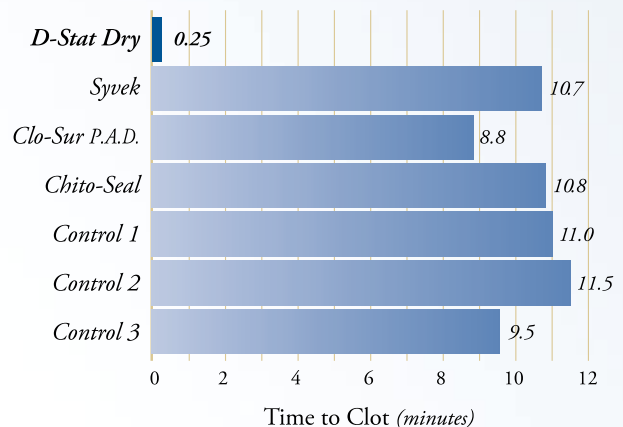
Once hemostasis is achieved, cover the D-Stat Dry pad with the custom adhesive bandage.



The science and clotting power of thrombin:

- Cleaves endogenous fibrinogen to fibrin
- Activates clotting factors V, VIII, XI and XIII
- Initiates platelet activation
- Stimulates platelet aggregation

Modified Lee-White Clotting Test*



*Each material was tested at a ratio of 50% of the test article in 10ml of blood in triplicates. Human blood was drawn into blood collection tubes containing 3.8% sodium citrate anticoagulant. The blood was re-calcified and immediately transferred into each test article tube. A stopwatch was started at drown of blood. Each tube was gently tilted every 30 seconds and the time taken for clot formation was measured in comparison with three controls (Control 1 = untreated blood, Control 2 = cellophane tape, Control 3 = gauze).

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Model	Description	Box Quantity
3000	D-Stat Dry Hemostatic Bandage	10*

* Devices packaged in quantities of 10 units per box.
Individual units are not sold separately.

The D-Stat Dry is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing 4-6 Fr. introducer sheaths.



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

The D-Stat Dry 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.

** 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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Chito-Seal is a trademark of Abbott Vascular.

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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.



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