Clinical Data to Support a True Hemostat

Results are from a 376-patient, five-center, prospective randomized U.S. clinical study evaluating D-Stat® Dry Topical Hemostat as an adjunct to hemostasis in diagnostic femoral catheterizations using 4–6 Fr. introducer sheaths compared to standard manual compression (control).[1,2]

50% Reduction in Median Time-to-Hemostasis*

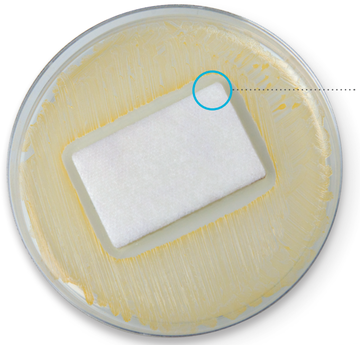
TIME-TO-HEMOSTASIS (TTH) RESULTS	D-STAT DRY (N=187)	CONTROL (N=189)
Median TTH (mins)	6.0	12.0
Mean TTH (mins)**	7.8	13.0
± Standard Deviation	3.0	6.4
Range (min/max)	6, 22	6, 31

*Applicable to diagnostic procedures only
**p-value of 0.001 calculated using Wilcoxon's Signed-Rank Test

Hold Times and Ambulation Guidelines*

MEDICATION STATUS	PUNCTURE SIZE	MINIMUM HOLD TIME RECOMMENDATIONS [3,4]	MINIMUM AMBULATION RECOMMENDATIONS*
Not anti coagulated	4–6 Fr.	6 minutes	1.5–2.5 hours bed rest post sheath removal
Anti coagulated[5]	4–6 Fr.	6 minutes	2.0–3.0 hours bed rest post sheath removal

*Applicable to diagnostic procedures only



D-Stat Dry Silver Topical Hemostat 99.99% Microbial Kill Rate[6,7]

Demonstrated for seven microorganisms commonly encountered in the clinical setting, including MRSA, MRSE, and VRE

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rüsch®, and Weck® – trusted brands united by a common sense of purpose.

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For more information, please visit teleflex.com.

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Teleflex®

D-Stat® Dry Topical Hemostat

Proven to Reduce Time-to-Hemostasis[1,2]

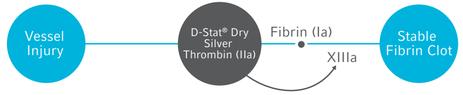
Teleflex®

The Power of Thrombin and the Antimicrobial Properties of Silver

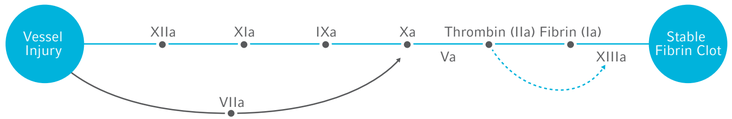
Thrombin is a powerful clotting agent and platelet aggregator for reducing time-to-hemostasis. Silver chloride (found in D-Stat® Dry Silver Topical Hemostat products only) is an active antimicrobial for preventing microorganisms from colonizing on the pad.[1]

Designed to Rapidly Form a Stable Clot

D-Stat Dry Topical Hemostat Clotting Pathway



Standard Clotting Pathway



A Convenient 2-Bandage Version of the D-Stat Dry

A powerful and simple "open and apply" solution

- Pad can be separated into two for application on two separate puncture sites
- Contains the power of thrombin to facilitate hemostasis
- Two custom adhesive bandages included

D-Stat 2 Dry Topical Hemostat

D-Stat Clamp Topical Hemostat Accessory

Utilizing the power of thrombin

- Reduce hand fatigue caused by the physical demand of manual compression
- The D-Stat Clamp works with a range of standard compression devices for ergonomic, mechanical compression with the power of thrombin

D-Stat Dry Topical Hemostat

Ordering Information

D-Stat Dry Silver Topical Hemostat

The D-Stat Dry Silver Topical Hemostat 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 Silver contains silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

D-Stat Dry Topical Hemostat

The D-Stat Dry Topical Hemostat 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.

MODEL	DESCRIPTION
3000	D-Stat Dry Silver Topical Hemostat
3005	D-Stat Dry Clear Silver Topical Hemostat
3001	D-Stat Dry Topical Hemostat
3006	D-Stat Dry Clear Topical Hemostat

Packaged in quantities of 10 units per box.

D-Stat 2 Dry Hemostatic Bandage

The D-Stat 2 Dry Hemostatic Bandage is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

MODEL	DESCRIPTION
3010	D-Stat 2 Dry Hemostatic Bandage

Packaged in quantities of 10 units per box. Individual units are not sold separately.

D-Stat Dry Clamp Topical Hemostat Accessory

The D-Stat Clamp Topical Hemostat Accessory is indicated for use with the D-Stat Handle, CompressAR® Universal System (Advanced Vascular Dynamics) and the Femoral Artery Vascular Clamp (Pressure Products) compression devices, or as a stand-alone device to assist in the control of bleeding following catheterization or cannulation procedures. Following achieving hemostasis the D-Stat Dry Bandage may be detached from the D-Stat Clamp Accessory and left in place for up to 24 hours, and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

MODEL	DESCRIPTION
3030	D-Stat Clamp Topical Hemostat Accessory

Packaged in quantities of 5 units per box. Individual units of D-Stat Dry Clamp Accessory are not sold separately.

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.

[1] Hallak OK, Cubeddu RJ, Griffith RA, et al. The use of D-STAT dry bandage for the control of vascular access site bleeding: a multicenter experience in 376 patients. *Cardiovasc Interven Radiol.* 2007;30(4):593-600.

[2] This data is applicable to the D-Stat Dry Silver as non-clinical bench and in vivo animal testing has demonstrated similar hemostatic performance profiles for the D-Stat Dry and D-Stat Dry Silver products. Bench and animal testing results may not be indicative of clinical performance.

[3] D-Stat Dry is intended to be used as an adjunct to manual compression, and times reflect minimum uninterrupted hold times and are not an indication of actual times to hemostasis. Firm, non-occlusive compression should be applied for the first 1/2 of time, followed by gradually decreasing force until completion.

[4] The hold times and ambulation suggested are minimum guidelines based on a 376-patient randomized U.S. clinical trial. These guidelines should not supersede clinical judgment based on the medical condition of the individual patient.

[5] Includes anti-clotting regime consisting of a single agent or combination of medications administered within 7 days of a diagnostic procedure. Medications include Heparin, LMWH, Coumadin, ASA and/or Plavix with an ACT≤ 270.

[6] Antimicrobial efficacy was demonstrated against all cultures at 24 hours, including antibiotic resistant cultures.

[7] Representative test samples from the D-Stat Silver product family (Dry, Wrap and Thrombix Silver) demonstrated an antimicrobial effect in these laboratory tests. Laboratory test results may not be indicative of clinical performance.