Instructions for Use

Vascular Solutions D-Stat® Flowable Hemostat

All instructions should be read before use.

This product contains thrombin and must not be injected intra-vascularly. The thrombin contained within this product is intended to be used with the Vascular Solutions D-Stat flowable hemostat.

DEVICE DESCRIPTION

Each Vascular Solutions D-Stat flowable hemostat (D-Stat) includes the following components:

- Thrombin vial (5,000 units)
- Collagen (200 mg), contained in 10 ml syringe with attached mixing luer
- Diluent vial (5 ml)
- Mixing accessories (10 ml syringe and needleless, non-coring vial access device)
- Applicator tips: (1 small bore tip, (1) 20-gauge 2.75" needle)

The thrombin is a protein substance produced through a conversion reaction in which prothrombin of bovine origin is activated by tissue thromboplastin of bovine-origin in the presence of calcium chloride. It is supplied as a sterile powder that has been freeze-dried in the final container. Also contained in the thrombin vial are mannitol and sodium chloride. Mannitol is included to make the dried product friable and more readily soluble. The material contains no preservatives and has been chromatographically purified. Thrombin requires no intermediate physiological agent for its reaction. It converts fibrinogen directly to fibrin.

The collagen is a soft, white, pliable, absorbent hemostatic agent derived from purified bovine deep flexor tendon. It is prepared in a loose fibrous form. Collagen attracts platelets that adhere to the fibrils and undergo the release phenomenon to trigger aggregation of platelets into thrombi in the interstices of the fibrous mass. The collagen provides a three-dimensional matrix for additional strengthening of the clot. The effect on platelet adhesion and aggregation is not inhibited by heparin in vitro.

The diluent is a sterile solution of calcium chloride and water, buffered with tromethamine (TRIS). Using the mixing accessories, both the thrombin and collagen are reconstituted with the diluent prior to use. The hemostat is delivered to the intended treatment site using the provided applicator tips. Hemostasis is achieved by the physiological coagulation-inducing properties of the D-Stat. The D-Stat is biocompatible, non-pyrogenic, and intended to be left *in situ*.

INDICATIONS

D-Stat is indicated 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.

D-Stat 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 anticoagulant therapy regimen (Heparin, LMWH, Coumadin, or Plavix), application of a compression bandage, and evacuation of the hematoma.

CONTRAINDICATIONS

D-Stat Flowable is contraindicated in persons with known sensitivity to bovine-derived materials.

WARNINGS

The effectiveness of D-Stat Flowable to reduce the frequency of prepectoral pocket hematomas in patients on coumadin therapy that have an INR > 2.0 has not been established.

Do not inject D-Stat into blood vessels. Extensive intravascular clotting and even death may result.

Do not use D-Stat in the closure of skin incisions because it may interfere with the healing of the skin edges due to mechanical interposition of collagen.

Do not use D-Stat if pulsatile arterial blood flow is observed at the femoral artery access site previously closed by suture/collagen-based hemostatic device. This may indicate incomplete closure of the arteriotomy and may result in inadvertent intra-arterial injection of the D-Stat. The acute onset of severely diminished or absent pulses in the limb treated with D-Stat may indicate that inadvertent intra-arterial injection has occurred. If this is suspected, immediately perform appropriate diagnostic and therapeutic procedures for thrombus dissolution/removal.

Do not use the D-Stat to treat residual oozing of a femoral artery access site tissue tract if a venous sheath was placed directly adjacent to the site. Inadvertent venous injection may occur.

D-Stat should not be used in the presence of an infection. It should be used with caution in contaminated areas of the body.

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 immunological basis of this condition. Patients with antibodies to bovine thrombin preparations should not be re-exposed to these products.

PRECAUTIONS

The D-Stat delivery procedure should be performed by physicians or physician-directed allied health care professionals with adequate instruction in the use of the device.

D-Stat is supplied sterile for single use only. Do not use the D-Stat if the packaging has been damaged. Do not re-sterilize.

D-Stat should be kept dry; it contains materials that are degraded by heat and moisture.

D-Stat is not intended to be used as a primary means for hemostasis for the femoral artery access site.

Adverse Events

D-Stat Flowable Hemostat was evaluated in a pivotal randomized, controlled clinical investigation involving 269 subjects. The results of the randomized investigation were used to support a Pre-Market Approval Supplement (PMAS) for this product.

This trial (The Pocket Protector) compared the incidence rates of clinically relevant hematoma formations and major adverse events in an anti-coagulated patient population undergoing new placement of a pulse generator (e.g., pacemaker or ICD) within the prepectoral pocket. The Control Group consisted of 133 study subjects treated with the standard of care (i.e., compression, electrocautery, and/or untreated cotton pledgets) to achieve hemostasis of the prepectoral pocket. The Investigation Group consisted of 136 study subjects treated with the same standard of care and placement of D-Stat within the prepectoral pocket as an adjunct to achieving hemostasis. Study participation concluded approximately 8-weeks beyond the study index procedure.

Twelve (12) deaths were reported (Control: 8, Investigation Group: 4). None of these deaths were determined to be device related.

Table 1 summarizes the adverse events reported within the randomized investigation eight (8) week follow-up period. Events are summarized by the percentage of randomized patients experiencing the event during the clinical investigation.

Table 1

Detailed Incidence Rates of Study Related Major Adverse Events (Excluding those related to Pre-existing Conditions)

Event Type	Investigation Group (n=136)		Control Group (n=133)		Combined Groups (n=269)	
	x	%	x	%	X	%
Pocket Related	**18**	**13.2**	**33**	**24.8**	**51**	**19.0**
Hematoma	15	11.0	27	20.3	42	15.6
Pocket Infection	1	0.7	5	3.8	6	2.2
Seroganguinous Drainage	-	-	1	0.8	1	0.4
Swelling Around Pocket	1	0.7	-	-	1	0.4
Wound Dehiscence	1	0.7	-	-	1	0.4
Lead Related Events	**4**	**2.9**	**1**	**0.8**	**5**	**3.7**
Lead Dislodgement	3	2.2	-	-	3	1.1
Lead Perforation of Cardiac Chamber	-	-	1	0.8	1	0.4
Diaphramatic pacing/lead dislodgement	1	0.7	-	-	1	0.4
Venous Access Related Events	**4**	**2.9**	**2**	**1.5**	**6**	**2.2**
Pneumothorax	4	2.9	2	1.5	6	2.2
Device (IPG) Function Related	-	-	-	-	-	-
"Other" Events*	**4**		**4**	**3.0**	**8**	**3.0**
Hypotension	-		1	0.8	1	0.4
Drop in hemoglobin	1	0.7			1	0.4
Irreversible Tachycardia			1	0.8	1	0.4
Cardiopulmonary Arrest			1	0.8	1	0.4
Pulmonary embolism			1	0.8	1	0.4
High Device Function Testing	1	0.7			1	0.4
Pneumonia	1	0.7			1	0.4
Abdominal Pain/Rectal Bleeding	1	0.7			1	0.4
Total	**29**	**21.3**	**37**	**27.8**	**67**	**24.9**

Table 2 summarizes the clinically relevant hematomas that were reported. The number of clinically relevant hematomas reported (16 investigational, 30 control) is a larger number than the hematomas reported in Table 1 above (15 investigational, 27 control) because not all clinically relevant hematomas progressed to the level of severity that was classified as a major adverse event

Table 2
Incidence Rates of Clinically Relevant Hematomas

Generator Type	Investigation Group			Control Group		
	%	x	n	%	x	n
All Generator Types	11.76	16	136	22.56	30	133
Pacemakers	8.11	6	74	20.55	15	73
ICDs	16.13	10	62	25.00	15	60

Caution
The following adverse events were reported in a clinical study using the DIAGNOSTIC DUETT sealing device. The DIAGNOSTIC DUETT sealing device uses a balloon catheter in addition to the procoagulant mixture containing thrombin, collagen and diluent found in the D-Stat Flowable Hemostat. The DIAGNOSTIC DUETT is indicated for sealing femoral arterial puncture sites in patients who have undergone diagnostic or interventional endovascular procedures using a 5 – 9 F introducer sheath. The procoagulant of DIAGNOSTIC DUETT seals the arteriotomy and tissue tract, while the D-Stat uses a similar procoagulant mixture for the adjunct treatment in sealing residual oozing of tissue tracts of femoral access sites that have been previously closed by suture/collagen based hemostatic devices.

The DIAGNOSTIC DUETT was evaluated in a prospective, multi-center non-randomized clinical investigation involving 302 patients in whom femoral artery access sites were sealed with the DIAGNOSTIC DUETT immediately following percutaneous diagnostic or interventional procedures (67% diagnostic, 33% interventional). DIAGNOSTIC DUETT performance was then compared to that of the historical control of Standard Compression (e.g., manual or mechanical methods) in the original, randomized, multi-center DUETT investigation.

No deaths were reported in the DIAGNOSTIC DUETT group during the investigation. One (1) non-device related death was reported in the Standard Compression group.

Table 3 summarizes the adverse events reported within the investigation's 30-day follow-up period. Events are summarized by percentage of patients experiencing the event during the clinical investigation.

Table 3

Incidence of All Complications:
Percentage/Number of Patients With an Event

Description of Event	Diagnostic Duett n = 302	Standard Compression N = 238[1]	Difference [95% C.I.][2]
Major Complications			
Vascular Repair			
Surgery for Vascular Complication	0.3% (1/302)	0.8% (2/237)	
PTA or Other Percutaneous Procedure	0.3% (1/302)	-	
Subtotal: Any Vascular Repair	0.7% (2/302)	0.8% (2/237)	
Bleeding Requiring Transfusion	-	1.3% (3/237)	
Infection Requiring Extended Hospitalization (with antibiotics)	0.3% (1/302)	-	
Total: Any Major Complication	1.0% (3/302)	1.7% (4/237)	-0.7% [-4.5%, 2.3%]
Vascular Complications			
Hematoma $\geq$ 6 cm	4.3% (13/302)	3.0% (7/237)	
Pseudoaneurysm	1.3% (4/302)	0.8% (2/237)	
AV Fistula	-	-	
Retroperitoneal Bleed	-	-	
Peripheral Arterial Occlusion or Peripheral Nerve Injury	0.7% (2/302)	0.4% (1/237)	
Total: Any Vascular Complications	5.6% (17/302)	3.8% (9/237)	1.8% [-2.9%, 6.7%]
Device Malfunctions	3.6% (11/302)	N/A	N/A

[1]The number of patients reported below is less than the total patients studied due to missing data for one patient
[2]C.I.: Confidence Interval for difference in rates; Difference = Diagnostic Duett – Standard Compression

Allergic reactions and inflammation have been reported following the use of collagen based hemostats.

Recognized risks associated with the use of absorbable hemostatic agents (including the use of marketed collagen hemostats) are described as follows:

- Hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth
- Foreign body reactions, encapsulation of fluid, and hematoma have been observed at the implant site
- Edema
- Adhesion formation
- Wound dehiscence

A recognized rare potential reaction associated with the use of bovine derived thrombin is the development of inhibitory antibodies, which interferes with hemostasis.

CLINICAL INVESTIGATIONS

"Pocket Protector"

D-Stat was evaluated in a prospective, randomized, multi-center investigation designed to assess the safety and effectiveness of the product in an anti-coagulated patient population undergoing placement of a pulse generator. The investigation was conducted at U.S. 10 centers and compared the incidence rates of clinically relevant hematomas and major adverse events between study treatment groups that received either the standard of care (compression, electrocautery and/or untreated cotton pledgets) or the standard of care plus D-Stat. A total of 269 subject were enrolled with 133 randomized to the Control Group and 136 randomized to the Investigation Group. Overall pulse generator distribution was 54.6% (147/269) pacemakers compared to 45.4% (122/269) ICDs (includes Bi-V ICDs and CRTs). The primary safety objective was designed for non-inferiority. The primary effectiveness objective was designed for superiority. Secondary objectives included evaluation of minor complication rates, length of procedure (incision of pocket to closure), duration of hospitalization (procedure end time to time approved for discharge), and patient satisfaction (modified Odom's Criteria).

Patients $\geq$ 18 years of age, undergoing a new placement of a pulse generator in the prepectoral pocket who's anti-coagulation therapy regime included administration of one or more of the following medications prior to the study procedure which was to be resumed within 24-hours post-procedure, were included in the trial: Heparin, LMWH, Coumadin, or Plavix. For patients receiving Coumadin therapy, an INR of $\leq$ 2.0 was required. Exclusion criteria included patients with bleeding disorders, recent administration (within 24 hours of procedure) of thrombolytic therapy, and active infections at the implant site.

There were no significant differences between the two randomized groups with respect to gender, age, risk factors, medications, body size, or standard lab values.

Primary safety (**Table 4**) was sufficiently demonstrated as there were no statistically significant differences ($p = 0.0008$, test for non-inferiority) demonstrated in the rate of major complications observed between study treatment groups (investigation: 21.3%, 29/136; Control 27.8%, 37/133).

Table 4

Analysis of Primary Safety Endpoint

Major Study Related Event Occurrence	Investigational (n=136)		Control (n=133)		p-value*
	n	%	n	%	
Pocket Related	18	13.2	33	24.8	0.0008
Lead Related	5	3.7	1	0.8	
Venous Access Related	4	2.9	2	1.5	
Device IPG Functions	2	1.5	-	-	
Other	1	0.7	3	1.5	
Total	29	21.3	37	27.8	

*p-values from Fisher's exact test

Primary effectiveness (**Table 5)** was sufficiently demonstrated as a statistically significant difference (p = 0.0231, 95% confidence interval: 1.37%, 20.03%) was observed between the study treatment groups. The control group demonstrated a clinically relevant hematoma rate of 22.56% (30/133) compared to 11.76% (16/136) in the investigation group, yielding a 48% reduction of clinically relevant hematoma formations in the D-Stat group.

Table 5

Analysis of Primary Effectiveness Endpoint

Generator Type	Investigation Group (n=136)			Control Group (n=133)			p-value*	95% Confidence Interval (CI)
	%	x	n	%	x	n		
All Generator Types	11.76	16	136	22.56	30	133	0.0231	1.37%, 20.03%
Pacemakers	8.11	6	74	20.55	15	73	0.0358	0.75%, 24.41%
ICDs	16.13	10	62	25.00	15	60	0.2659	-5.74%, 23.59%

*p-values from Fisher's exact test.

Diagnostic Duett

The DIAGNOSTIC DUETT, containing a procoagulant mixture that is similar to that found in D-Stat, was evaluated in a multi-center, non-randomized clinical investigation designed to prospectively examine DIAGNOSTIC DUETT safety and effectiveness in sealing femoral arterial puncture sites following diagnostic and interventional endovascular procedures The investigation, performed at 4 U.S. and 2 European sites, compared the performance of the DIAGNOSTIC DUETT (n = 302) with historical standard compression (n = 238) data collected in the original, multi-center, randomized DUETT investigation. Standard Compression was defined as arterial puncture site closure using either manual pressure or a mechanical clamp. The study was designed as an equivalency trial for the 30-day primary combined safety endpoint of freedom from major complications and as a superiority trial for the primary effectiveness endpoints of time to hemostasis (time from the end of the antecedent procedure to the time that hemostasis is first observed) and ambulation (time from the end of the antecedent procedure to when the patient stands at the bedside and walks 110

feet without re-bleeding). Major complications included: need for vascular repair (vascular surgery, PTA, or other percutaneous intervention), bleeding requiring transfusion, and infection requiring extended hospitalization and antibiotic administration. Secondary endpoints were procedure success rate and device success rate.

Patients undergoing an endovascular procedure (33% interventional; 67% diagnostic) performed via 5F-9F short length introducer sheath in the common femoral artery were eligible. A total of 34.7% of the interventional patients studied received GPIIb/IIIa receptor blockers. Exclusion criteria included patients who had significant peripheral vascular disease, bleeding disorders, hypertension (>180/110) refractory to medical therapy, or known allergies to bovine-derived products. Patients who were pregnant, experienced a hematoma > 6 cm prior to planned device deployment, or had an ACT of $\geq$ 400 seconds at the conclusion of the endovascular procedure were also excluded. Thirty-day clinical follow-up was obtained in 96% of DIAGNOSTIC DUETT patients and 96.6% of Standard Compression patients in accordance with the protocol.

In both the diagnostic and interventional groups, use of the DIAGNOSTIC DUETT resulted in statistically significant decreases in time to hemostasis ($p<0.001$). The median time to hemostasis in the DIAGNOSTIC DUTETT group was 9.0 minutes (7, 13) compared to 195.0 minutes (46,351) for the standard compression group. There were no significant differences in the overall major complication rate observed in the DIAGNOSTIC DUETT group as compared to the standard compression treatment group (1.0% vs. 1.7%, $p = 0.704$).

INDIVIDUALIZATION OF TREATMENT

Note that the safety and effectiveness of D-Stat components have not been established in the following patient populations:

- Women who are pregnant or lactating
- Patients under 18 years of age
- Patients with a known bleeding disorder, including thrombocytopenia (platelet count < 100,000), thrombasthenia, hemophilia, or von Willebrand's disease
- Patients with a rapidly expanding hematoma at the intended treatment site
- Patients with a baseline INR > 2.0 (e.g. Coumadin therapy)
- Patients who received thrombolytic therapy (e.g. streptokinase, urokinase, t-PA) in the preceding 24 hours

Further, in addition to the above populations, the safety and effectiveness of D-Stat has not been established in the following patient populations undergoing implantation of a pulse generator:

- Patients presenting for a pulse generator revision procedure
- Patients for which their anti-coagulation therapy regime does not include pre-procedure Heparin, LMWH, Plavix or Coumadin administration
- Patients with a previous exposure to injectable collagen implants
- Patients in whom absorbable hemostatic agents are contraindicated

CLINICAL PROCEDURES

The following instructions provide technical direction for use of the D-Stat. The techniques and procedures described here do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

Supplies

The D-Stat package contains the following:

- Thrombin vial (5,000 units)
- Collagen (200 mg), contained in 10 ml syringe with attached mixing luer
- Diluent vial (5 ml)
- Mixing accessories (10 ml syringe and needleless, non-coring vial access device)
- Applicator tips: (1 small bore tip, (1) 20-gauge 2.75" needle)

Other materials required for use of the D-Stat (but not provided) are:

- Sterile gauze pad
- Sterile saline solution
- Bandage

Procedure

Carefully inspect the D-Stat packaging (barrier bag and Tyvek® sealed inner tray) and components for damage prior to use. Using sterile technique, transfer the components into the sterile field.

The D-stat procedure consists of 2 steps:

1) D-Stat Preparation

2) D-Stat Application

D-STAT PREPARATION

NOTE: The D-Stat may be prepared up to 3 hours prior to application using standard sterile technique.

1) Remove the caps from the thrombin and diluent vials to expose the rubber stoppers.

2) Using the 10 ml mixing syringe and non-coring vial access device, withdraw all diluent from the diluent vial and transfer it into the thrombin vial.

3) Gently rotate the vial to reconstitute the thrombin. DO NOT SHAKE.

4) When the thrombin is completely dissolved, withdraw the reconstituted thrombin from the thrombin vial again using the mixing syringe and vial access device. Remove the vial access device from the mixing syringe.

5) Attach the collagen syringe with attached mixing luer to the mixing syringe.

6) VIGOROUSLY push the reconstituted thrombin into the collagen syringe. Wait briefly (10-15 seconds) to allow the collagen to become hydrated with the reconstituted thrombin. Next, push the hydrated collagen back into the mixing syringe. Continue exchanging the solution until all components are thoroughly mixed (approximately 20 exchanges).

D-STAT APPLICATION

Vascular Access Sites: Topical Application

1) Disconnect the mixing syringe containing the D-Stat and attach the desired applicator tip.

2) Remove the vascular access catheter if desired.

3) Wet gauze pad with sterile saline.

4) Manually approximate a gauze pad against the bleeding surface and apply the D-Stat between the gauze pad and the bleeding surface. The gauze pad will hold the D-Stat in place against the bleeding surface in the presence of active bleeding. Apply enough D-Stat to create a small "mound" of material at the site of placement. A sufficient amount of material will ensure that the D-Stat is delivered directly to the site of bleeding.

5) Apply direct pressure on the gauze pad so that it holds the D-Stat against the bleeding surface and causes it to conform to the site.

6) After approximately 2 – 5 minutes, gently lift the gauze pad and inspect the site. In cases of persistent bleeding, indicated by saturation and bleeding through the material, apply fresh D-Stat to the source of bleeding and resume light pressure for another 2 – 5 minutes. Inspect the site again. Repeat application as necessary.

Note: The D-Stat is NOT indicated as a vascular sealing device. If using D-Stat in conjunction with arterial or venous catheter removal, hold manual compression for the timeframe specified by institutional protocol prior to the initial site inspection.

7) Once bleeding has ceased, the D-Stat and gauze pad may be removed. If the gauze pad adheres to the placement site, gently irrigate the pad with non-heparinized saline and carefully remove it. If desired, the D-Stat and gauze pad may be left in place and covered with an appropriate bandage.

8) Do not disrupt the clot by physical manipulation.

Femoral Artery Access Sites: Residual Tissue Tract Oozing

1) Disconnect the mixing syringe containing the D-Stat and attach the desired applicator tip.

2) Wet the gauze pad with sterile saline.

3) Manually approximate the gauze pad against the bleeding surface. From the applicator tip, dispense 1-2 ml of D-Stat under the gauze pad and approximately 1 cm into the tissue tract. If resistance is felt, do not force. If desired, aspirate prior to D-Stat delivery to ensure that the origin of bleeding is the tissue tract.

4) Apply light direct pressure with the gauze pad to support the site while the seal is forming.

5) After 2-5 minutes, gently lift the gauze pad and inspect the site. In cases of persistent bleeding, indicated by saturation and bleeding through the material, apply an additional 1-2 ml of D-Stat into the tissue tract and resume light pressure for another 2-5 minutes. Inspect the site again. The volume of D-Stat necessary for tissue tract hemostasis is dependent upon the depth of the tissue tract.

6) Once bleeding has ceased, remove the gauze pad. A sterile pressure dressing may be applied to the site per operator preference.

Prepectoral Pocket Site: Adjunct to hemostasis during implantation of pulse generator

1) Disconnect the mixing syringe containing the D-Stat and attach an applicator tip, as desired.

2) Following formation of the pocket and subsequent antibiotic flush per institution's protocol, lift the pocket skin flap and deliver a bolus of 5 ml of the D-Stat directly into the pocket.

3) Apply light manual compression directly over the pocket for 2 – 3 minutes as necessary.

4) Observe for bleeding within the pocket.

    - If hemostasis has been achieved, proceed to step 5.

    - If bleeding continues, prepare a second package of D-Stat and apply a subsequent bolus of no greater than 6 ml of D-Stat. Repeat light manual compression for an additional 2-3 minutes as necessary.

    - If bleeding persists, do not apply additional D-Stat. Rather, employ electrocautery, standard manual compression, or the institution's standard of care for persistent bleeding of the prepectoral pocket. Upon achieving hemostasis, proceed to step 5 of these application instructions.

5) Prior to pocket closure, assess pulse generator device function per manufacturer's instructions and place the pulse generator in the prepectoral pocket per institution's protocol. Apply slight manual compression for 2-3 minutes as necessary.

6) Close the pocket in accordance with institution's standard of care.

7) Following pocket closure, apply a maximum of 1 ml of D-Stat as needed to control oozing at the suture line.

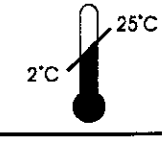
8) Apply an appropriate dressing to the treated site. Assess the site per institutional protocol.

PACKAGE LABEL REFERENCES

The *D-Stat* is for single use only.

The *D-Stat* should be kept dry.

The *D-Stat* should be stored at temperatures between 2° C and 25° C.



The *D-Stat* does NOT contain natural rubber latex.

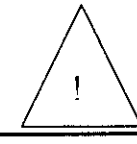
The *D-Stat* components have been sterilized in the following manner:

Component	Sterilization Method
Vial of thrombin, U.S.P. (5,000 units)	STERILE | A Aseptic filtration
10ml syringe, containing collagen (200mg), with attached mixing luer	STERILE | EO Ethylene oxide
Vial of diluent, 5 ml	STERILE High temperature
10 ml mixing syringe with non-coring vial access device	STERILE | EO Ethylene oxide
Applicator tips	STERILE | EO Ethylene oxide

D-Stat expiration date

YYYY-MM

Warning: "Attention, consult Instructions for Use (IFU)"



D-Stat lot number XXXXXX

43

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the Vascular Solutions D-Stat™ flowable hemostat is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the Vascular Solutions D-Stat™ flowable hemostat. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.