XSTAT® P30
WOUND DRESSING

RevMedx, Inc.
25999 SW Canyon Creek Rd., Ste. C
Wilsonville, OR 97070
503.218.2172 www.revmedx.com
NSN: 6510-01-644-7335

XSTAT P30 PRE-CLINICAL DATA

NAME OF STUDY	**GLP EVALUATION OF XSTAT POUCH DRESSING IN A SWINE FEMORAL MODEL**
STUDY DESCRIPTION	GLP animal study to demonstrate the performance of the XSTAT Pouch Dressing compared to the XSTAT 30 Predicate dressing, using the United States Army Institute of Surgical Research ("USAISR") standard femoral animal injury.
NUMBER OF SUBJECTS	Ten (10) animals were treated with the XSTAT dressing (Test Article) and compared to Ten (10) animals were treated with the XSTAT 30 predicate device (via historical control)
INCLUSION / EXLUSION	Inclusion • Animal breed: Landrace/Yorkshire cross swine • Weight at procedure: 54.6-65.6 kg • Age at procedure: ~4 months (appropriate to weight) Exclusion criteria included inappropriate vessel anatomy, persistently low MAP (< 55 mmHg) prior to femoral artery injury, and significant blood loss (>300 mL) because of surgical complication or error before femoral artery injury.
STUDY PROCEDURE	• An incision was created (3 ± 05 cm long) through the skin and subcutaneous tissues in the groin area directly over the left femoral artery and an approximately 2-3 cm section of femoral artery was exposed. • The femoral artery was covered with a small piece of gauze and bathed with 2% lidocaine HCl solution for ~ 10 minutes to relax the vasospasm and dilate the artery to ≥ 5 mm outer diameter. • Non-traumatic vessel loops were placed proximally and distally on the femoral artery. • Using a 6.0 mm vascular punch, an arteriotomy was created. • The vessel loops were released, the injury start time was recorded and the vessel was allowed to bleed freely for 45 seconds before the Test (XSTAT), or Control Article (XSTAT 30) was applied. • The vessel loops were allowed to remain in the wound to facilitate hemorrhage control during test material removal. • XSTAT dressing was applied as per product instructions for use (IFU) starting immediately following the 45-second free bleed. • XSTAT was applied as quickly as possible and as many as necessary until the bleeding has stopped, or until the 5-minute limit, whichever was sooner. • A cloth bandage was wrapped around the limb and firmly secured over the packed wound. • Manual pressure was permitted if bleeding persisted following application of the dressing as per the IFU. POST-RANDOMIZATION CARE • Resuscitation began 5 minutes post-injury (i.e., free bleed start time) by infusing ~ 500mL of colloidal fluid at a target rate of 33 mL/min into the jugular vein. • Resuscitation was continued, if necessary, with pre-warmed lactated Ringer's solution (LRS) at a target rate of 100 mL/min to raise the MAP to at least 65 mmHg. If the MAP dropped to ~ 60 mmHg or less, LRS was infused into the jugular vein and discontinued when the MAP of at least 65 mmHg was reached. This was repeated up to a maximum of 10L of LRS over the observation period and/or 2L of colloidal fluids to maintain MAP. • Following the 6-hour observation period, the Test Article was removed from the wound site and the animal euthanized. • XSTAT Sponge Pouches were removed from the wound site and examined • The wound was observed for blood clots, adherence of dressing to wound tissue and re-bleeding. • The surgeon carefully removed the XSTAT Pouch(s) from the wound site. All attempts were made to not increase the wound size/cavity volume while removing the test material. During test material removal the status of hemostatic clots and the patency of the vessel (i.e., blood flow) were examined and evaluated by the surgeon. • After removal of all sponge pouches from the wound, a photograph of the removed test material sponge pouches was taken. • The mass of all the sponge pouches was measured and recorded.

RESULTS

ENDPOINTS	XSTAT 30 Pouch (Test Article)	XSTAT 30 (Historical Control)
1: Bleeding Time, mean: Duration of bleeding (visible blood shed from the wound site) occurring at any time immediately following test material application until was at exsanguination or end of the 6-hour observation period.	0.0 ± 0.0 min	1.8 ± 5.7 min
2: Post-Treatment Blood Loss, mean (stdev): Amount of blood shed from the wound cavity during the time period following the dressing application until study termination (which was at exsanguination or end of the 6-hour observation period).	0.0 ± 0.0 mL/kg	0.1 ± 0.2 mL/kg
3: Final Mean Arterial Pressure (MAP), mean (stdev): Final Mean Arterial Pressure recorded at study termination (which was at exsanguination or end of the 6-hour observation period).	64.3 ± 5.3 mmHg	66.0 ± 4.0 mmHg
4: Survival Time, mean (stdev): Time period immediately following the 45 second free bleed during which vital signs are; MAP >20mmHg and end tidal CO_2 >15 mmHg to study termination (exsanguination or end of the 6-hour observation period).	6.0 ± 0.0 hours	5.45 ± 0.0 hours
5: Percentage Survival: Percentage of animals surviving to the end of the study observation period (6 hours) for a given treatment, where survival was defined as the MAP >20 mmHg and end tidal CO_2 >15 mmHg.	100%	100%
The presence or absence of distal limb ischemia was not assessed in this study. There was no postmortem evidence of blood tracking beneath the skin.		

OBSERVATIONS FROM ANIMAL STUDY:

A gross necropsy was performed, and macroscopic evaluation of external organ surfaces did not reveal any tissue discoloration or abnormalities. Histological evaluation of the wound sites treated with either XSTAT Test Article or the XSTAT-30 Control Article in the swine femoral injury model observed at approximately 6-hours post-treatment showed no adverse effect of treatment and no qualitative or quantitative differences in tissue response or level of tissue necrosis between the Test and Control Articles.

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Human factor elements were also evaluated as part of the GLP Femoral study, with a ratings scale of "Poor", "Difficult", "Acceptable", "Good" or "Excellent", for the following factors:

- Ease of test material application
- Test material application time
- Ease of test material removal
- Test material removal time

1. Ease of Test Material Application: Ranked "Excellent" for 9/10 animals and "Acceptable" for 1/10 animals.
2. Test Material Application Time: Ranged from 1:04 minutes to 2:43 minutes.
3. Ease of Test Material Removal: Ranked "Excellent" for 9/10 animals and "Acceptable" for 1/10 animals.
4. Test Material Removal Time: Ranged from 0:20 seconds to 1:11 minutes.

When compared to the historical control, which had a test material removal time of 5 to 13 minutes, the XSTAT P30 shows a significant reduction in time for removal. There were no instances of retained minisponge pouches in the XSTAT P30 GLP Femoral Study.

XSTAT P30 TRAINING INFORMATION

XSTAT P30 is a hemostatic dressing for the control of severe, life-threatening bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents. XSTAT P30 is a hemostatic dressing for the control of severe, life-threatening bleeding from narrow entrance extremity wounds in the arms or legs in adults and adolescents.

XSTAT P30 is a temporary dressing for use up to six (6) hours until surgical care is acquired. XSTAT should only be used for patients at high risk for immediate life-threatening bleeding from, hemodynamically significant (Advanced Trauma Life Support class 3 or 4 hemorrhagic shock), non-compressible junctional wounds or narrow entrance extremity wounds, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT P30 is **NOT** indicated for use in: the thorax, the pleural cavity, the mediastinum, the abdomen, the retroperitoneal space, the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.

XSTAT P30 contains rapidly expanding cellulose sponges enclosed in a porous pouch, each containing a radiopaque marker.

XSTAT P30 works by applying the sponge pouches into a wound cavity using a lightweight applicator. In the wound, the XSTAT 30 sponge pouches expand and create a barrier to blood flow, present a large surface area for clotting, and provide gentle pressure.

The XSTAT P30 applicator is comprised of two primary parts:

- The main applicator which holds three (3) sponge pouches
- A plunger

XSTAT P30 is a hemostatic dressing for the control of bleeding from junctional wounds in the groin or axilla or narrow entrance extremity wounds in the arms or legs. In narrow, deep wounds, XSTAT works by expansion of cellulose sponges against the walls of the cavity to apply pressure inside the wound.

Prior to using XSTAT, fully examine the injured patient and assess for signs of bleeding. Arterial bleeding is caused by the laceration of an artery and is the most difficult type of blood loss to control. Arterial hemorrhage is characterized by spurting blood that is bright red in color. Even a small, deep, arterial puncture wound can produce significant blood loss.

If the wound is not amenable to tourniquet use and is located on the groin or axilla, it is a junctional wound. In the testing of the XSTAT dressing, hemorrhage from the groin was created in a swine using a 6.0mm vascular punch on the femoral artery. The injury bled for 45 seconds prior to device application. The XSTAT dressing would be appropriate for use under comparable conditions.

If the hemorrhage cannot be identified or the anatomical location is not a junctional or extremity wound, XSTAT is not the preferred dressing to achieve hemorrhage control and alternative treatments should be used such as other hemostatic dressings.

CONTRAINDICATIONS:

XSTAT P30 is NOT indicated for use in: the thorax, the pleural cavity, the mediastinum, the abdomen, the retroperitoneal space, the sacral space; tissues above the inguinal ligament, or tissues above the clavicle.

INSTRUCTIONS FOR USE:

- **READ INDICATIONS FOR USE, WARNINGS AND CAUTIONS ON LABEL PRIOR TO USE.**
- Open package and remove applicator and plunger.
- Insert applicator into wound track as close to bleeding source as possible.
- Insert plunger into applicator and push plunger firmly to deploy sponge pouches into wound. Deploy XSTAT within 30 seconds of insertion into wound.
- DO NOT attempt to forcefully eject the material from the applicator. If resistance is met pull back slightly on the applicator body to create additional packing space, then continue to depress handle.
- Use additional applicators as necessary to completely pack the wound with dressing.
- Cover the wound with an occlusive or pressure dressing. If available, use an elastic bandage.
- If bleeding persists, apply manual pressure until bleeding is controlled.
- Monitor patient for peripheral circulation.
- Patients require professional care throughout the time of device deployment, including regular neurovascular checks.
- Remove of the sponge pouch(s) from the site of injury should be performed by a surgeon capable of providing emergent surgical intervention in the event rebleeding should occur.

WARNINGS/CAUTIONS:

- Vascular compression greater than six hours is not recommended due to concerns related to limb ischemia, limb compartment syndrome with myoglobinuria, resulting in renal injury, reperfusion syndrome, need for fasciotomy, or limb amputation.
- Sterility not guaranteed if the package is damaged.
- XSTAT has not been tested for use in extremity wounds that are amenable to tourniquet application. XSTAT P30 use in conjunction with tourniquet application has not been assessed.