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# XSTAT®

## SAVING LIVES ON THE BATTLEFIELD AND BEYOND

In the spring of 2015, a NATO Special Operations Operator is shot by a PKM machine gun during direct combat operations. The round enters the soldier's shoulder anteriorly, fracturing the clavicle before exiting just above the scapula. Faced with massive bleeding from the severed subclavian artery, the medic at the point of injury attempts to pack the wound with hemostatic gauze. The entry wound is too small to insert his fingers. The medic manages to pack gauze into the exit wound, but the dressing quickly becomes saturated and does little to stop the bleeding. Faced with a dying patient and few additional options, the medic grabs an XSTAT®30 hemostatic device from his pack, and inserts the XSTAT's applicator past the blood-soaked gauze into the exit wound. Next, he presses on the applicator and launches dozens of small, compressed sponges into the still-hemorrhaging wound. Within seconds, the sponges activate and rapidly expand to fill the cavity. With his free hand, the medic can feel firmness build as the sponges create pressure, and can see tissue bulging out slightly from the front of the wound. The medic finishes his assessment as the team packages the patient and waits for the helo to land. They hand him off to the medevac team, having arrested the bleeding and saved the soldier's life.

**W**hen it comes to junctional or truncal wounds on the battlefield, there has never been a truly effective means of controlling hemorrhage. No hemostatic agent or dressing has proven to be ideal for these types of trauma scenarios. Injury patterns during Operations Iraqi Freedom and Enduring Freedom highlighted this capability gap. During these conflicts, exsanguination from junctional (neck, axilla and groin) wounds was responsible for over 19% of the combat fatalities from potentially survivable wounds.<sup>1</sup>

Not surprisingly, after-action reports from medics returning from the battlefield in 2006-2008 clearly described the need for a better tool to control difficult bleeding. They requested a “fire and forget” solution that could apply a dressing to a wound and instantly achieve hemostasis, similar to Fix-a-Flat® for punctured tires.

Responding to this critical unmet need, the U.S. Army Special Operations Command contracted RevMedx, Inc. to design and develop a treatment for non-compressible junctional hemorrhagic injuries. The XSTAT® device represents the outcome of this effort. XSTAT encompasses all the characteristics of an ideal pre-hospital hemostatic agent: quickly and effectively controls bleeding within 2 minutes, sustains hemostasis for several hours, ready to use with little training or preparation in austere conditions, easy to remove, easy to manufacturer, low cost, shelf stable in extreme conditions and biocompatible.<sup>2</sup>

Following its launch in 2015, the first adopters of XSTAT were Special Operations medics. XSTAT was then added to the Tactical Combat Casualty Care (TCCC) guidelines by the CoTCCC, and was incorporated into the TCCC skill set curriculum for Combat Medics and Corpsman, as well as the JTS Clinical

1 BJ Eastridge et al., Death on the Battlefield (2001-2011): Implications for the Future of Combat Casualty Care, J Trauma Acute Care Surg. 2012;73 (6 Suppl 5):S431-S437.

2 Pusateri AE, McCarthy SJ, Gregory KW, et al. Effect of a chitosan-based hemostatic dressing on blood loss and survival in a model of severe venous hemorrhage and hepatic injury in swine. J Trauma. 2003;54(1):177-182.

Practice Guidelines (CPG ID:18). The device is currently standard issue in USSOCOM IFAKS, Aid Bags and CASEVAC Kits. Conventional active duty Army units have recently voted to include XSTAT in the Light Air Ambulance and Air Ambulance kits.

## XSTAT TECHNOLOGY

XSTAT stops life-threatening bleeding from non-compressible junctional and extremity wounds. It works by injecting small, rapidly-expanding sponges into a wound cavity using a syringe-like applicator. Once inside the cavity, the mini sponges absorb blood and expand up to 10 times their size, packing the wound and applying hemostatic pressure without the need to apply external manual pressure.

XSTAT is indicated for junctional bleeding, such as from shoulder and pelvic injuries, as well as any narrow, deep extremity wound where one cannot effectively pack gauze against the ruptured vessel. XSTAT30, with a 30-mm diameter, is designed to treat large-cavity wounds and exit wounds from high-velocity projectiles. XSTAT 12, with a 12-mm diameter, is designed to be inserted into narrow entrance wounds too small to pack with fingers, such as from low-velocity projectiles, stabbings, shrapnel or impalements.

## XSTAT KEY ADVANTAGES

**1** XSTAT’s unique applicator can access extremely narrow wounds, such as knife, shrapnel or bullet wounds, which may be impossible to pack with gauze or compress adequately.

A particularly challenging cause of non-compressible hemorrhage is shrapnel or bullet wounds to areas where the body armor lacks ballistic coverage, such as the junctional regions of the axilla and pelvis. Application of direct manual pressure to these wounds is generally ineffective due to skeletal obstruction, adverse vessel anatomy or depth. For these and other types of narrow wounds, XSTAT may be the only device capable of gaining access to the source of bleeding.

**2** XSTAT is extremely fast. An XSTAT applicator takes about 30 seconds to remove from the packaging and apply to a wound.



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“The patient survived all the injuries. I believe that the XSTAT was a key for success in this case, due to the fact that it would have been really hard to fill that cavity up with Combat Gauze or a similar product.”  
—After Action Report, Special Forces Medic

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"What I like about XSTAT is that it exerts the same pressure as an expert wound packer... XSTAT is an expert wound packer in a tube" —Dr. Mike Shertz, former Special Operations Medic

Once applied, the sponges expand and provide hemostatic pressure within seconds. Unlike hemostatic gauzes, XSTAT does not require external manual compression for effective hemostasis.

Rapid and effective hemorrhage control is key to increasing survival, and is the first priority in treating a casualty. Combat medics and civilian paramedics are taught to address the most critical situations first, as supported by the acronym MARCH (Massive hemorrhage, Airway, Respirations, Circulation, Head injury/Hypothermia). Speed is especially critical in situations where there are simultaneous casualties in a compressed time frame with inherent delays to definitive care. When multiple casualties are present, it is important to stabilize one patient as quickly as possible so that the medic can move on to the next. Under these circumstances, it is often not practical to apply manual compression for long periods of time.

**3** XSTAT's simple and intuitive design minimizes the need for extensive training and specialized wound-packing skills.

Ease of use is a significant differentiator. Some first responders may not see massive junctional hemorrhage very often, but when they do, they need to be able to respond quickly and effectively. Yet, wound-packing is a perishable skill and requires regular training to maintain proficiency.

When XSTAT is injected into a wound, it expands within the wound cavity, applying pressure in all directions. The mini sponges are able to migrate into channels and irregularities within the wound, applying sustained pressure directly at the source of bleeding. Therefore, XSTAT users do not

need to be expert wound-packers to achieve immediate, effective hemostasis.

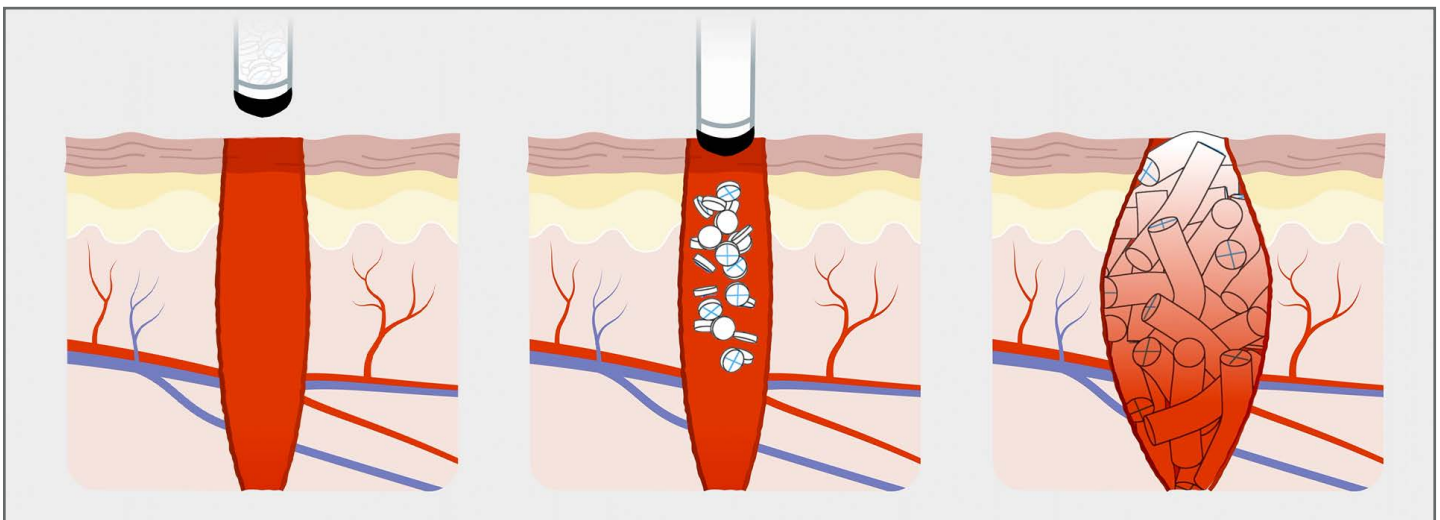
## WOUND PACKING WITH HEMOSTATIC GAUZE

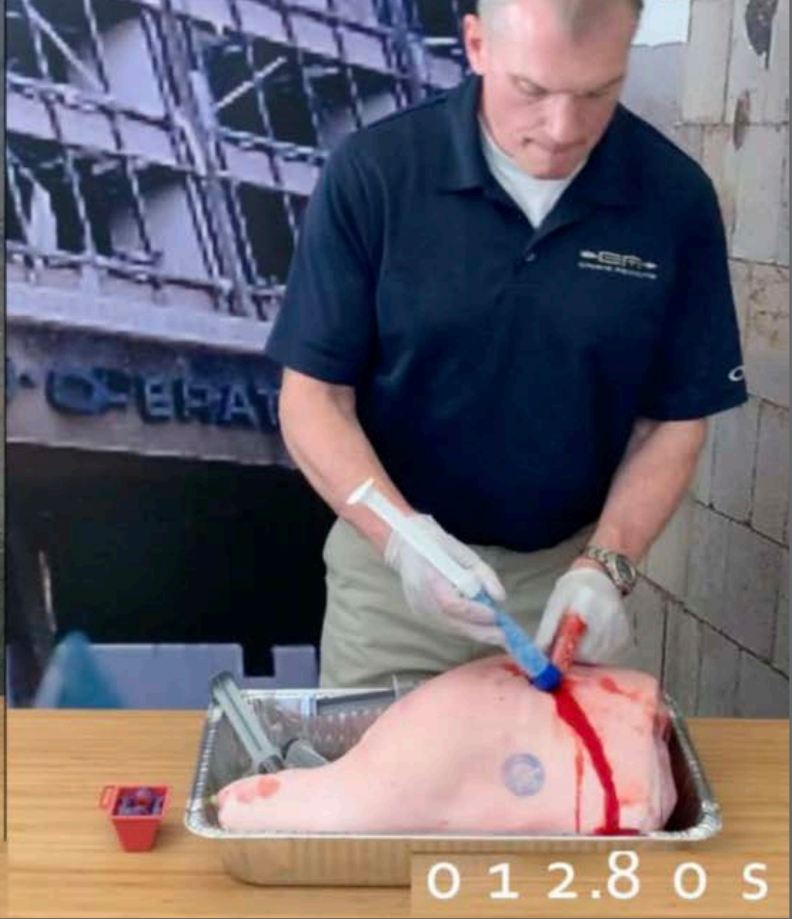
All hemostatic gauzes have fundamental physical properties that limit their effectiveness in treating penetrating junctional injuries: namely, their inability to be packed into narrow wound tracks, requirements for manual compression, and slow application times.

Most of today's hemostatic gauzes rely on either kaolin or chitosan, which work best when in direct contact with the bleeding vessel. However, packing gauze into a wound so that it stays tightly pressed against the source of bleeding requires a high degree of skill, experience and repeated training. When the wound is deep or narrow, it is often impossible to fit fingers inside the wound, much less find the ruptured vessel.

This may limit the effectiveness of gauze-based treatments for penetrating injuries where the source of bleeding is located on the side of the wound or in a hard-to-reach crevice. Wounds commonly sustained from bullets, knives or shrapnel, where the injured vessel does not sit neatly at the bottom of the wound cavity are difficult to manage with gauze-based dressings.

Standard gauzes and hemostatic agents do not create pressure by themselves. They rely instead on skilled packing and the application of several minutes of external manual compression to slow bleeding enough for the hemostatic agent to work. However, application of direct manual pressure to junctional wounds is generally





Dr. Mike Shertz demonstrates the difference in application time between gauze and XSTAT in a recent “Wound Packing Race”. Application time was measured at 12.8 seconds for XSTAT30 and 44 seconds for packing the same wound with gauze. Photo used with permission from Dr. Shertz / Crisis Medicine. [www.crisis-medicine.com/wound-packing-race-gauze-vs-xstat/](http://www.crisis-medicine.com/wound-packing-race-gauze-vs-xstat/)

ineffective due to skeletal obstruction, adverse vessel anatomy or depth. Additionally, it is often impractical to maintain minutes of consistent vascular compression in an austere tactical situation.

The U.S. Army Institute of Surgical Research found that XSTAT is significantly faster than packing a wound with gauze: 67 sec vs 8 sec with a mean difference of 59 sec.<sup>3</sup>

In contrast to hemostatic gauzes, XSTAT is a fast, simple and effective way to deliver life-saving direct pressure to lethal wounds. It can be rapidly inserted into very deep, narrow wounds and does not require external manual compression to achieve hemostasis.

### JUNCTIONAL TOURNIQUETS

A junctional tourniquet is another device indicated for the control of life-threatening bleeding in the inguinal and axilla areas. If applied correctly, junctional tourniquets may be effective for the treatment of junctional bleeding. However, similar to wound-packing with gauze, junctional tourniquets

take significant training and judgment to apply. Correct placement may require a great deal of patient manipulation and is highly dependent on each patient’s unique anatomy.

A study conducted at the Naval Medical Center Portsmouth reported that the mean application time for a junctional tourniquet is 80 sec and that the device may lose effectiveness 43% of the time during patient transport.<sup>4</sup> By comparison, it takes about 20 seconds to un-package and apply a therapeutic dose of XSTAT, and there is no documented risk that an XSTAT will lose effectiveness during transport. A junctional tourniquet also has a significantly larger cube space (6" x 10" x 4") for a device that only treats one individual. A medic can carry 12 XSTAT applicators in the same cube space, allowing for the treatment of multiple junctional injuries in a fraction of the time.

3 Kragh JF Jr, Aden JK, Steinbaugh J, Bullard M, Dubick MA. Gauze vs XSTAT in wound packing for hemorrhage control. *Am J Emerg Med.* 2015;33(7):974-976.

4 Gasparly, M. et al. The Comparative Effectiveness of Three Junctional Tourniquet Devices in Human Volunteers. *Ann Emerg Med.* 2016;68(4): S104 - S105.

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“Multiple GSW. One bullet caused severe injury to the pelvis (shattering a portion of the pelvis) causing severe bleeding in the groin area. On scene paramedic attempted unsuccessfully to stop bleeding with gauze and direct pressure. One XSTAT 12 applicator was deployed and hemostasis achieved in approximately 20 seconds.”

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EMS PARAMEDIC CLINICAL USE REPORT  
(RevMedx)

## XSTAT BEYOND THE BATTLEFIELD

Since the first combat use of XSTAT in 2015, After Action Reports from soldiers returning from the battlefield have captured dozens of successful uses of XSTAT, and there have been no failures of XSTAT reported when used for life-threatening severe hemorrhage.

In the civilian arena, the medical response paradigm from fire/EMS and law enforcement has evolved over the last decades to meet the growing threats of active shooter and mass casualty events. Civilian first responders, like their military counterparts, are increasingly faced with the responsibility to provide timely stabilizing medical care in high-risk environments. Since every minute with uncontrolled bleeding increases risk of mortality, rapid stabilization of the wounded is vital.

Driving this evolution has been the Committee for Tactical Emergency Casualty Care (C-TECC), formed in 2010 to translate military trauma lessons learned from the battlefield into civilian medical response to high-risk situations. The TECC guidelines reflect the fact that patterns and mechanisms of injury may be similar in civilian incidents, and place emphasis on controlling massive hemorrhage as the first priority in saving trauma patients.<sup>5</sup>

Reflecting these dynamics, EMS and law enforcement personnel are increasingly being equipped with tourniquets and hemo-

static dressings to manage severe bleeding. However, these first responders need to stabilize massive hemorrhage as quickly as possible in order to address additional injuries and/or patients. XSTAT was designed to create pressure immediately and without external compression, allowing a first responder to treat multisystem trauma and stabilize multiple patients faster.

XSTAT is being adopted by trauma centers, EMS, fire and law enforcement agencies around the country. These early adopters tend to be former military medical personnel who understand the value of the technology, having seen it perform in the worst of situations. XSTAT is faster and more intuitive to use than traditional hemorrhage control

treatments and exerts the same pressure in the wound as an expert wound-packer. As XSTAT has the potential to profoundly impact how penetrating wounds are treated, it should be available to all potential hemorrhage-casualty responders, whether military or civilian.

## FUTURE OF XSTAT TECHNOLOGY

At RevMedx, our primary focus is educating and training first responder organizations on the important role XSTAT has in reducing preventable deaths caused by war and civilian violence. To that end, we have pilot programs established with EMS centers and police departments in cities throughout the



<sup>5</sup> <http://www.c-tecc.org/>

US, including Los Angeles, Chicago, Portland, Washington DC and New Orleans. We are also actively working with each branch of the military to expand XSTAT's availability and initial clinical successes.

RevMedx has several research initiatives underway to broaden XSTAT's indications for use and applicability to abdominal and other wounds. Additionally, a version of XSTAT adapted for the treatment of postpartum hemorrhage has recently been shown to be highly effective in a pilot human clinical trial.<sup>6</sup>

XSTAT was originally developed to address an urgent operational need to stop uncontrollable junctional hemorrhage within the armed forces. However, since its inception, its innovative minisponge technology has been used to save lives not only on the battlefield, but also in our nation's streets.

<sup>6</sup> Rodriguez MI, Bullard M, Jensen JT, Gregory K, Vwalika B, Barofsky A, Mart T, Edelman AB. Management of Postpartum Hemorrhage With a Mini-Sponge Tamponade Device. *Obstet Gynecol.* 2020. Epub ahead of print.

## FREQUENTLY ASKED QUESTIONS



XSTAT sponges applied in a torso wound. Each sponge is marked with a radiopaque marker.

### What skill level is required to use XSTAT?

XSTAT is a prescription device, to be used by physicians or trained medical professionals only.

XSTAT can readily be used by an EMT or medic following the basic package instructions. Just like all clinical skills, regular training is vital to ensuring positive patient outcomes. However, XSTAT is designed to be easier to use and more intuitive than wound packing with gauze. Since the sponges expand and create omnidirectional pressure within the wound cavity, regardless of the skill level of the responder who injected them, XSTAT reduces dependence on a high level of expertise to achieve hemostasis. To train on the use of XSTAT, first responders can use a wound-packing simulator or manikin, such as the XSTAT Multi-Task Training Manikin.

### How are XSTAT sponges removed?

Sponges are removed surgically once the patient reaches definitive care. Each individual sponge has a radiopaque marker so that they are visible on radiography.

### How many XSTATs are needed to treat a wound?

The majority of cases reported to RevMedx used a single XSTAT applicator, with a few cases using two devices. Similar to wound packing with hemostatic gauze, if an initial application of XSTAT dressing is insufficient to fill the wound or control the hemorrhage, the user may simply apply an additional applicator. The soft, pliable nature of the mini sponges makes them conformable to surrounding tissue surfaces and positioning within in the wound tract. These qualities enable the safe introduction of supplementary XSTAT dressing to treat another casualty.



XSTAT 30 Training applicator deployed into the RevMedx Multi-Task Training Manikin

## RELATED LITERATURE

Allison HA. Hemorrhage Control: Lessons Learned From the Battlefield Use of Hemostatic Agents That Can Be Applied in a Hospital Setting. *Crit Care Nurs Q.* 2019;42(2):165-172.

Buckley R, Conley S, Markham G, Stuart S, Yoder A, Zarow G. Efficacy of Two Novel Hemostatic Agents (XStat and Hydrogel) in a Coagulopathic Model of Severe Hemorrhage Combat Trauma. Research Group, Naval Medical Center Portsmouth, Virginia. 2014.

Bullard, M. et. al. Comparison of XSTAT with and without a hemostatic agent in swine hemorrhage models. Poster session presented at Military Health System Research Symposium; August 2016; Kissimmee, FL.

Butler FK. Leadership lessons learned in Tactical Combat Casualty Care. *J Trauma Acute Care Surg.* 2017;82(6S Suppl 1):S16-S25.

Cox JM, Rall JM. Evaluation of XSTAT® and QuickClot® Combat Gauze® in a Swine Model of Lethal Junctional Hemorrhage in Coagulopathic Swine. *J Spec Oper Med.* 2017;17(3):64-67.

Joint Trauma System / Committee on Tactical Combat Casualty Care. TCCC Recommended Devices & Adjuncts. Published May 6, 2019.

Kragh JF Jr, Steinbaugh J, Parsons DL, Mabry RL, Kheirabadi BS, Dubick MA. A manikin model for study of wound-packing interventions to control out-of-hospital hemorrhage. *Am J Emerg Med.* 2014;32(9):1130-1131.

Kragh JF Jr, Aden JK, Steinbaugh J, Bullard M, Dubick MA. Gauze vs XSTAT in wound packing for hemorrhage control. *Am J Emerg Med.* 2015;33(7):974-976.

Mueller GR, Pineda TJ, Xie HX, et al. A novel sponge-based wound stasis dressing to treat lethal noncompressible hemorrhage. *J Trauma Acute Care Surg.* 2012;73(2 Suppl 1):S134-S139.

Otrocka-Domagala I, Jastrzębski P, Adamiak Z, et al. Safety of the long-term application of QuikClot Combat Gauze, ChitoGauze PRO and Celox Gauze in a femoral artery injury model in swine - a preliminary study. *Pol J Vet Sci.* 2016;19(2):337-343.

Peng HT. Hemostatic agents for prehospital hemorrhage control: a narrative review. *Mil Med Res.* 2020;7:13.

RevMedx. Evaluation of XSTAT Dressing in a Swine Femoral Injury Model. Evaluation of XSTAT Dressing in a Swine Subclavian Model. XSTAT 30 Package Insert. RAW-0055-21.

RevMedx. Evaluation of XSTAT Dressing in a Swine Femoral Injury Model. Evaluation of XSTAT Dressing in a Swine Subclavian Model. XSTAT 30 Gen2 Package Insert. RAW-0101-01.

Rodriguez MI, Bullard M, Jensen JT, Gregory K, Vwalika B, Barofsky A, Mart T, Edelman AB. Management of Postpartum Hemorrhage With a Mini-Sponge Tamponade Device. *Obstet Gynecol.* 2020. Epub ahead of print.

Rodriguez, M.I., Jensen, J.T., Gregory, K. et al. A novel tamponade agent for management of post partum hemorrhage: adaptation of the Xstat mini-sponge applicator for obstetric use. *BMC Pregnancy Childbirth.* 2017;17(187).

Sims K, Montgomery HR, Dituro P, Kheirabadi BS, Butler FK. Management of External Hemorrhage in Tactical Combat Casualty Care: The Adjunctive Use of XStat™ Compressed Hemostatic Sponges: TCCC Guidelines Change 15-03. *J Spec Oper Med.* 2016;16(1):19-28.

Song BK, Sheppard FR, Macko A, Alvarez R. The effect of a third generation hemostatic dressing in a subclavian artery and vein transection porcine model. Naval Medical Research Unit San Antonio, NAMRU-SAREPORT#2014-22

Stuart S, Walchak A, Gamble C. A Novel Model for Studying the Application of the iClamp™ in Conjunction With Hemostatic Agents in Swine (*Sus scrofa*). *Ann Emerg Med.* 2016;68(S126).

Warriner Z, Lam L, Matsushima K, et al. Initial evaluation of the efficacy and safety of in-hospital expandable hemostatic minisponge use in penetrating trauma. *J Trauma Acute Care Surg.* 2019;86(3):424-430.

# PANAKEIA®

Panakeia is the proud military and federal government distributor for RevMedx™, the creators of XSTAT®. Since its first shipment of life-saving products to the US Military in November 2014, Panakeia and its partner, RevMedx, has been at the forefront of saving military lives due to blood loss with their line of hemorrhage control solutions. Panakeia is a certified Service-Disabled Veteran-Owned Small Business (SDVOSB) and nationally accredited by the Joint Commission for Home Care. We specialize in marketing, training and distributing advanced medical products to the military, pre-hospital care and EMS, law enforcement, fire/rescue, veterans administration, hospital critical care and home care. Panakeia's mission is to provide the medical community with unique solutions and innovative products that transform patient care and save lives. We bring medical innovations to life. More information regarding Panakeia can be found at [www.panakeiausa.com](http://www.panakeiausa.com) or email us at [info@panakeiausa.com](mailto:info@panakeiausa.com).

## REVMED<sup>™</sup>X

RevMedx is a privately-held medical device company dedicated to saving lives by creating groundbreaking hemorrhage control solutions. These devices, designed by and for combat medics and civilian first responders, are based on the simple precept that pressure stops bleeding. Revmedx has been recognized by the military and business communities for its innovation around the acute cessation of traumatic bleeding. Find additional information about our portfolio of self-expanding wound dressings, tourniquets and compression bandages at [www.revmedx.com](http://www.revmedx.com), email us at [info@revmedx.com](mailto:info@revmedx.com) or join us on social media.