

PowerPoint Slides for Change 15-03: XSTAT 30





Instructions for Change 15-03

• In TFC #1 of version 150603, replace slide #72 with slides #3 and #4 below to create new slides #72 and #73.

 Insert slides #5 through #18 below into TFC #1 after new slide #108 (Hemostatic Dressing Practical).



Tactical Field Care Guidelines

4. Bleeding

b. For compressible hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze as the CoTCCC hemostatic dressing of choice.

Alternative hemostatic adjuncts:

- Celox Gauze or
- ChitoGauze or
- XSTAT (Best for deep, narrow-tract junctional wounds)



Tactical Field Care Guidelines

4. Bleeding (continued)

Hemostatic dressings should be applied with at least 3 minutes of direct pressure (optional for XSTAT). Each dressing works differently, so if one fails to control bleeding, it may be removed and a fresh dressing of the same type or a different type applied.

If the bleeding site is amenable to use of a junctional tourniquet, immediately apply a CoTCCC-recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Apply hemostatic dressings with direct pressure if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.



XSTAT 30

- First-in-kind expanding wound dressing approved for internal use.
- Syringe-like applicator applies compressed mini-sponges into deep wounds.
- Mini-sponges rapidly expand on contact with blood compressing the wound to stop bleeding.



RevMedx, 25999 SW Canyon Creek Road, Suite C, Wilsonville, OR 97070 wwww.revmedx.com



XSTAT 30 Indications For Use

XSTAT 30 is a hemostatic device 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 30 Indications For Use

XSTAT 30 is a temporary device for use up to four hours until surgical care is acquired. It should only be used for patients at high risk for immediate life-threatening bleeding from hemodynamically significant, non-compressible junctional wounds when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT 30 is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space above the inguinal ligament; or tissues above the clavicle.



XSTAT 30's Technical Characteristics

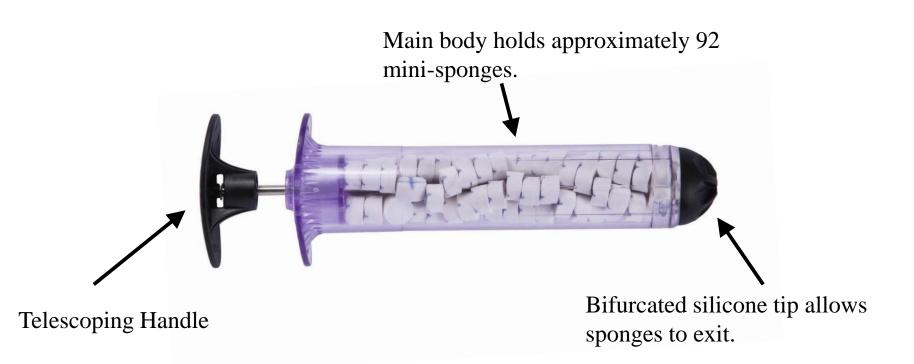
XSTAT 30 is composed of compressed mini-sponges coated with chitosan – a compound designed to stop bleeding.

Upon contact with blood, the mini-sponges absorb blood and, expand to 10 - 12 times their compressed volume within approximately 20 seconds.

A radiopaque marker is embedded into each of the mini-sponges to make them detectable by X-ray.



XSTAT 30 Applicator





XSTAT 30 Packaging

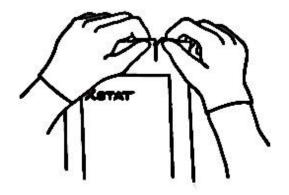
XSTAT 30 is available in single and triple packs. Having three applicators available at the point of injury is recommended by the manufacturer.





Open the package and remove the applicator.

Pull the handle out and away from the barrel until it stops and locks.

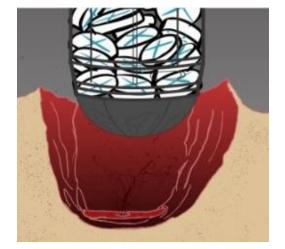


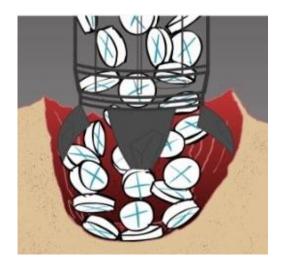




Place the tip of the applicator into the wound track as close to the bleeding source as possible.

Firmly depress the handle to deploy the mini-sponges. The sponges should flow freely into the wound.







- DO NOT attempt to forcefully eject the material from the applicator. If resistance is met, pull the applicator back slightly to create additional packing space, then continue to depress the handle.
- Use additional applicators as necessary to completely pack the wound with mini-sponges.
- Pack XSTAT into the wound to the same density you would gauze. The higher the sponge density in the wound cavity, the higher the pressure exerted on the damaged vessel.





- Cover the wound with a pressure dressing.
- If bleeding persists, apply manual pressure until the bleeding is controlled.
- Never attempt to remove the minisponges from the wound. They must be removed by a surgeon after achieving proximal and distal vascular control.









• XSTAT training video will be inserted here.



XSTAT Removal Instructions

- The manufacturer includes a casualty card inside the XSTAT package.
- Instructions to the surgeon for removing the sponges from the wound are included on the back of the card.
- Record the use of XSTAT on the DD 1380, and forward these instructions along with it to the Medical Treatment Facility.

XSTAT

ATTN TREATMENT FACILITY: A hemostatic dressing for non-compressible hemorrhage was used in the treatment of this casualty. Each device comprises approximately 92 small hemostatic sponges individually marked with an X-shaped radiopaque marker.

WABNING: Triangular segments of the applicator tip (FIG. 1) may break away during treatment and remain in the wound. These segments are visible under X-ray. If any separations occurred, the number of retained applicator tips may be noted on this casualty card.

RG. 1: TRIANGULAR SEGMENT OF APPLICATOR TO



PRODUCT REMOVAL INSTRUCTIONS:

WARNING: Sponges must be removed intraoperatively by surgeon with the capability and equipment for achieving proximal and distal vascular control.

- Survey the wound site and assess potential vascular bleeding sites and develop plan to achieve surgical control of injured vessel(s).
- Remove sponges from the wound site manually and/or with surgical forceps to the site(s) of bleeding.
- Thoroughly explore wound and remove all sponges and any triangular segments of the applicator tip.
- 4) Prior to wound closure, obtain plane x-ray, optimally in more than one projection. The presence of retained sponges may be easily missed on radiographic images. Thoroughly examine x-ray for radiopaque x-pattern of sponges and any triangular segments of the applicator tip that may be inadvertently retained in the wound cavity.
- 5) If sponges or applicator tip segments are identified via x-ray, carefully re-examine wound cavity and remove them. Perform and review second x-ray to confirm complete sponge and applicator tip segment removal.
- 6) The XSTAT elicited a mild pyrogenic response in biocompatibility tests. Monitor patient for rise in temperature, chills, hypotension, and septic shock.



Contains material derived from shellfish.

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Warnings/Cautions

- XSTAT contains material derived from shellfish.
 - A mild pyrogenic response has been elicited in biocompatibility tests.
 - -Monitor the casualty for fever, chills, hypotension, and shock.



Warnings/Cautions

- Segments of the applicator tip may break away during application and be left in the wound.
 - After injecting the mini-sponges, check the applicator tip for missing segments.
 - Do not attempt to retrieve missing segments from the wound.
 - Record the number of lost segments on the TCCC Casualty Card.