

XSTAT[®]

**FOR USE BY
TRAINED EMERGENCY
RESPONDERS**

NSN 6510-01-632-9440

Part Number: FIN-0001-01

Quantity: 3 Applicators

Each Applicator contains approximately 92 pellets

US PATENT 8,828,050 B2

ATTENTION: XSTAT contains rapidly expanding cellulose sponges coated with chitosan and individually marked with an X-shaped radiopaque marker.

INDICATIONS FOR USE:

XSTAT is a hemostatic device for the control of bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents.

XSTAT is a temporary device for use up to four (4) hours until surgical care is acquired. XSTAT is intended for use in the battlefield.

XSTAT 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.

WARNINGS/CAUTIONS:

- XSTAT has not been tested for use in extremity wounds that are amenable to tourniquet application.
- XSTAT use in conjunction with tourniquet application has not been assessed for use in extremity wounds that are amenable to tourniquet application.
- Sterility not guaranteed if the package is damaged
- Contains material derived from shellfish.
- XSTAT elicited a mild pyrogenic response in biocompatibility tests. Monitor patient for rise in temperature, chills, hypotension, and septic shock.

REVMED X[™]

RevMedx, Inc.
25999 SW Canyon Creek Road Suite C
Wilsonville, OR 97070
PH: 503.218.2172 www.RevMedx.com
Label ID: RAW-0006-01
Label Issuance Date: 2015-05-22

STERILE R

ONE TIME USE

NOT MADE WITH NATURAL RUBBER LATEX
STORE DEVICE IN ROOM TEMPERATURE

RxOnly

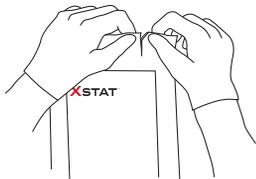


CASUALTY CARD & PACKAGE INSERT HERE



INSTRUCTIONS FOR USE:

1) Open the package and remove applicator.



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

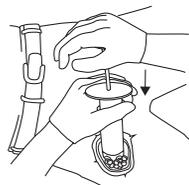


3) Place the tip of the applicator into the wound track as close to the bleeding source as possible.



4) Firmly depress black handle to deploy sponges into the wound. Material should flow freely into the wound. Deploy XSTAT within 30 seconds of insertion into wound.

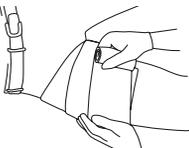
DO NOT attempt to forcefully eject the material from the applicator. If resistance is met, pull back slightly on the applicator body to create additional packing space, then continue to depress handle.



5) Use additional applicators as necessary to completely pack the wound with sponges.

DO NOT attempt to remove sponges from wound. Sponges must be removed intraoperatively by surgeon with the capability and equipment for achieving proximal and distal vascular control.

6) Cover the wound with an occlusive or pressure dressing. If available, use an elastic bandage.



7) If bleeding persists, apply manual pressure until bleeding is controlled.



8) Remove the included casualty card from the pouch located underneath this label. Assess patient for peripheral circulation and document presence of distal pulse on included casualty card. **WARNING:** Vascular compression greater than four hours is not recommended due to concerns related to limb ischemia.

9) Document clinical assessments, treatments rendered, and changes in the casualty's status on the included casualty card. Forward this information with the casualty to the next level of care.

WARNING: Triangular segments of the applicator tip may break away from applicator during treatment. If this occurs, do not attempt to retrieve it from the wound. Record number of separated applicator tips on casualty card.



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