

XSTAT[®] 12

1-PACK

Part Number: FIN-0001-04
Applicator contains approximately
38 minisponges

US PATENT 8,828,050 B2

FOR USE BY TRAINED
EMERGENCY RESPONDERS

Go to www.revmedx.com for training
video and product information.

ATTENTION: XSTAT 12 contains rapidly expanding cellulose sponges coated with chitosan and individually marked with an X-shaped radiopaque marker.

INDICATIONS FOR USE:

XSTAT 12 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 12 is a temporary device for use up to four (4) hours until surgical care is acquired. XSTAT 12 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, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT 12 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 12 has not been tested for use in extremity wounds that are amenable to tourniquet application.
- XSTAT 12 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 12 elicited a mild pyrogenic response in biocompatibility tests. Monitor patient for rise in temperature, chills, hypotension, and septic shock.
- Larger wounds may require more than one applicator. Having at least three (3) XSTAT 12 devices available at all points of care is recommended.
- Injuries with significant cavitation, such as those from a high-velocity gunshot wound, may require more than 3 applicators to appropriately pack the wound.

Label Part Number: RAW-0057-03
Label Issuance Date: 2016-09-06

NOT MADE WITH NATURAL RUBBER LATEX
STORE DEVICE IN ROOM TEMPERATURE

TRAINING WEBSITE: WWW.REVMEDX.COM