



XSTAT's Regulatory Journey

Andrew D. Barofsky
President & CEO

Hemostatic Medical Devices for Trauma Use
September 3-4, 2014

Acknowledgment

XStat project sponsored by the United States Special Operations Command and the US Army Medical Research and Materiel Command

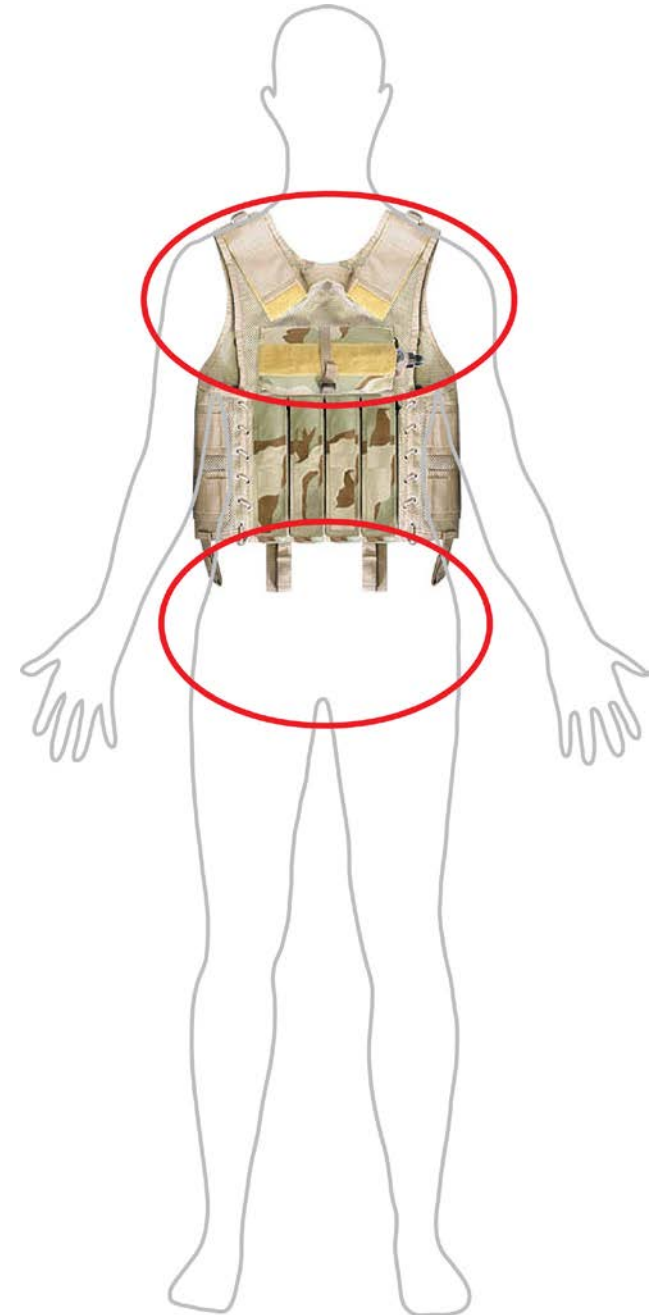
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Problem

Hemorrhage is the leading cause of death on the battlefield, and one of our most challenging forms of hemorrhage has been junctional hemorrhage, or hemorrhage from deep wounds on which it is impossible to put a tourniquet or apply manual compression externally...

Dr. Anthony Pusateri, Department of Defense Hemorrhage and Resuscitation Research and Development Program



XSTAT

First-in-kind non-absorbable, expandable, hemostatic sponge for temporary internal use

Each device comprises approximately 92 small chitosan-coated sponges individually marked with an x-shaped radiopaque marker.

Syringe-like applicator applies compressed mini-sponges into deep wounds



How it Works

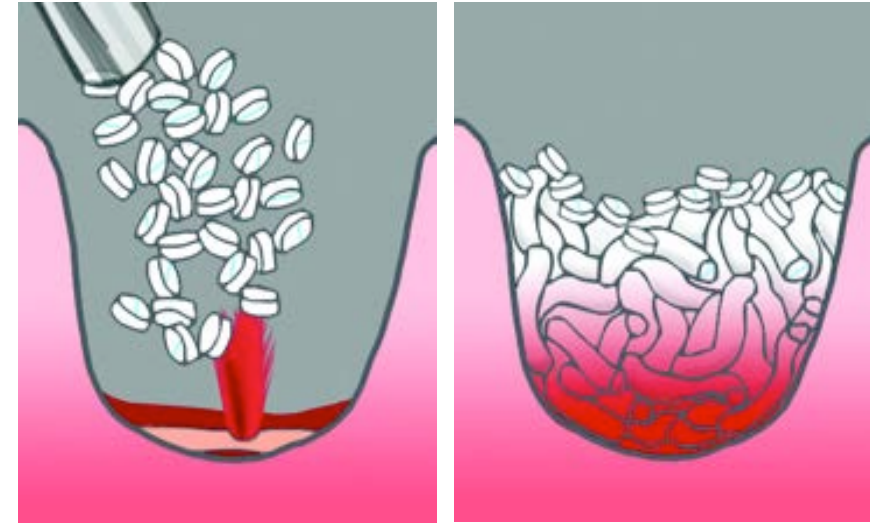
Applicator is removed from the package and the handle is pulled until it reaches a stop/click

Tip of applicator inserted into the wound track and handle depressed to deploy sponges into the wound

Sponges absorb blood and expands, thereby packing the wound

Sponges removed from wounds before surgical repair and closure of the wounds

Radiograph required prior to wound closure to confirm sponge removal



De Novo Classification

Approval Date: April 4, 2014

New Regulation Number: 21 CFR
878.4452

Classification: II

Product Code: PGZ

Submission Number: K130218



Indications for Use

XSTAT is a hemostatic dressing 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 dressing 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.

FDA Timeline

- April 9, 2009 – first successful animal use (swine transected femoral artery)
- April 27, 2010 – in-person meeting to brief the agency on the XStat dressing
- December 19, 2011 – filed pre-IDE submission for the XStat dressing
- January 25, 2013 – filed de novo petition for the XStat dressing
- April 4, 2014 – FDA approves de novo petition

Supporting Data

Bench Studies

Biocompatibility

Stability/Sterility

Mechanical Performance

Radiopacity

Animal

GLP Evaluation in a Swine Femoral Model (n=10)

Evaluation in a Swine Subclavian Model (n=8)

Human Factors

User Evaluation of XSTAT Device and Applicator Use (n=10)

Future 510(k)s

Expanded Indications
(e.g., civilian trauma)

Xstat 12

