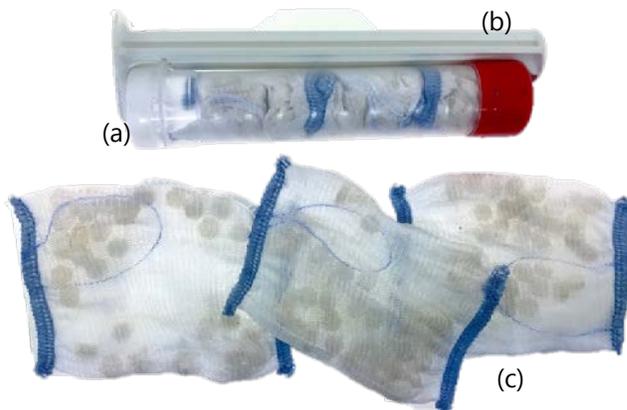


Executive Summary

XSTAT P30 stops life-threatening bleeding from non-compressible junctional and narrow entrance extremity wounds. It works by injecting small, rapidly-expanding sponges into a wound cavity using a syringe-like applicator. Once inside the cavity, the sponges absorb blood and expand up to 10 times their size, packing the wound and applying hemostatic pressure to stop bleeding within seconds.

The XSTAT P30 Pouch is a modified version of the original XSTAT 30 device. In the XSTAT P30 device, the minisponges are enclosed in three porous pouches to facilitate their removal from wounds.

- Each minisponge pouch is large enough to be easily seen and removed in a manner identical to other standard-of-care dressings used to treat or pack bleeding wounds.
- The encapsulation of the minisponges in a robust pouch minimizes the risk that a minisponges would be inadvertently left in a wound following treatment. This also eliminates the need for an X-ray detectable marker on each sponge. Each minisponge pouch is marked with an X-Ray detectable marker.
- XSTAT P30 has less packaging and a smaller cube space than original XSTAT.
- Results of a GLP Femoral Swine study demonstrate identical safety and effectiveness as original XSTAT.



XSTAT P30 applicator (a) and plunger (b). Each applicator contains three minisponge pouches (c).

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Key Attributes

- FDA-cleared - Indicated for life-threatening bleeding from non-compressible junctional wounds and narrow entrance extremity wounds.
- Fast Acting - XSTAT minisponge pouches expand and apply hemostatic pressure to a wound within seconds. In comparison, hemostatic gauzes require several minutes of manual compression, and based on published studies, often require additional time to reach hemostasis.
- Fast to Apply - XSTAT P30 take approximately 30 seconds to remove from packaging and apply to a wound.
- Easy to apply - XSTAT P30 is easy to use and requires minimal training, which increases the probability of effective use.
- No Manual Compression – Unlike hemostatic gauzes, XSTAT P30 does not require manual compression for effective hemostasis.
- Lightweight and Compact - XSTAT P30 was designed to optimize cube space and weight.

XSTAT Military Traction

- Recommended by CoTCCC for hemostatic devices and junctional wounds.
- Recommended by DHA for inclusion in Medic/Corpsmen Kits for all military departments (4/1/2018 DoD/DHA Memorandum, DoD Joint Trauma System Lifesaving Materials).
- Standard issue in USSOCOM IFAKs, CASEVAC sets and Medic/Corpsmen Kits.
- Included in Air Ambulance MES and under review for additional SKOs.