XSTAT® P30

WOUND DRESSING

Quantity: 1 Applicator • Each Unit Contains: 3 MINISPONGE POUCHES

INDICATIONS FOR USE:

XSTAT P30 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 P30 is a hemostatic device for the control of severe, life-threatening bleeding from narrow entrance extremity wounds in the arms or legs in adults and adolescents.

XSTAT P30 is a temporary device for use up to six (6) hours until surgical care is acquired. It 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 or narrow entrance extremity wounds, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT P30 is **NOT** indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.

INSTRUCTIONS FOR USE:

1. **READ INDICATIONS FOR USE, WARNINGS AND CAUTIONS ON LABEL PRIOR TO USE.**
2. Open the package and remove applicator and plunger.
3. Insert applicator into wound track as close to bleeding source as possible.
4. Insert plunger into applicator. Push Plunger firmly to deploy XSTAT P30(s) into wound. Deploy within 30 seconds of insertion of applicator into the wound.
5. Do NOT attempt to forcefully eject the pouch(s) from the applicator. If resistance is met, pull back slightly on the applicator to create additional packing space, then continue to depress the plunger.
6. Use additional applicators as necessary to completely pack the wound.
7. Cover the wound with an occlusive or pressure dressing. If available, use an elastic bandage.
8. If bleeding persists, apply manual pressure until bleeding is controlled. Monitor patient for peripheral circulation.
9. Patients require professional care throughout the time of device deployment, including regular neurovascular checks.
10. Removal of the sponge pouch(s) from the site of injury should be performed by a surgeon capable of providing emergent surgical intervention in the event rebleeding should occur.

CONTRAINDICATIONS:

XSTAT P30 is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.

⚠ WARNINGS/CAUTIONS:

- Vascular compression greater than >6 hours is not recommended due to concerns related to limb ischemia, limb compartment syndrome with myoglobinuria, resulting in renal injury, reperfusion syndrome, need for fasciotomy, or limb amputation.
- Sterility not guaranteed if the package is damaged.
- XSTAT P30 use in conjunction with tourniquet application has not been assessed.
- **NOT MADE WITH NATURAL RUBBER LATEX**
- **STORE DEVICE AT ROOM TEMPERATURE**

VISIT: WWW.REVMEDX.COM FOR PRODUCT TRAINING VIDEO AND PRE-CLINICAL DATA FOR XSTAT P30 PRODUCT

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