

EMERGENCY MEDICAL SERVICES AUTHORITY

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EMS Authority Approved Hemostatic Dressings May 2018

Background

The EMS Authority is responsible for approving hemostatic dressings for use in the prehospital setting for all levels of EMS personnel. The authority for this is found in the following sections of regulations:

- Section 100019(a)(4)(G) of the Public Safety Regulations, Ch. 1.5, Division 9, Title 22, California Code of Regulations.
- Section 100063(a)(8)(B) of the EMT Regulations, Chapter 2, Division 9, Title 22, California Code of Regulations.
- Section 100106(a) AEMT Regulations, Chapter 3, Division 9, Title 22, California Code of Regulations states AEMTs may perform skill identified in the scope of practice of EMT.
- Section 100146(a) of the Paramedic Regulations, Chapter 4, Division 9, Title 22, California Code of Regulations states that a paramedic may perform any activity identified in the scope of practice for an EMT.

EMS Authority Approved Hemostatic Dressings:

After an extensive review of the literature and advice from the Emergency Medical Services Medical Directors Association of California Scope of Practice Committee, the following hemostatic dressings are approved by the EMS Authority for use in the prehospital setting:

1. Quick Clot®, Z-Medica®
 - a. Quick Clot®, Combat Gauze® LE
 - b. Quick Clot®, EMS Rolled Gauze, 4x4 Dressing, TraumaPad®
2. Celox®
 - a. Celox® Gauze, Z-Fold Hemostatic Gauze
 - b. Celox® Rapid, Hemostatic Z-Fold Gauze
3. HemCon® Chito Flex Pro Dressing

Note:

- Hemostatic Celox Granules, or granules delivered in an applicator, are not authorized.

Who May Use Hemostatic Dressings?

Regulations authorize public safety personnel, emergency medical technicians (EMT), advanced EMTs, and paramedics in California to utilize hemostatic dressings.

Future Products

If other products become available on the market in the future, EMSA would review the product and available literature for potential inclusion to the approved list.

How Do I Get My Hemostatic Dressing Approved by the EMS Authority for use in California?

1. Submit a formal LETTER OF REQUEST FOR APPROVAL. The formal request must address the following topics:
 - Description of the Product or Device requested,
 - Description of the medical conditions and indications for which the Product or Device will be utilized,
 - Description of any contraindications for the Product or Device,
 - Description of the FDA approval used for this Product or Device,
2. The Request for Approval must include any supporting Relevant Data or Information regarding the “safety and efficacy” of the Product or Device, including:
 - Scientific Studies,
 - Medical Literature,
 - Recommendations for use by other groups or organizations,
 - Other supporting documentation demonstrating the safety and efficacy of the product.
 - Include at least 10 samples for EMS Authority review and evaluation.
3. The Request for Approval should have:
 - Description of the Manufacturer’s Recommendation regarding training and competency testing (if any), and,
 - Recommended Policies/Procedures to be instituted to implement the product or device.
4. Submit the completed request, samples, and supporting documentation to:
 - EMS Authority
 - 10901 Gold Center Drive, Suite 400
 - Rancho Cordova, CA 95670
 - Attention: EMS Personnel Standards
5. Please allow four to six weeks for staff to review the application.

Questions?

Please call (916) 322-4336 or email paramedic@emsa.ca.gov.