



Description

QuikClot EMS 4x4 Dressing consists of a sterile, soft, white, 4 in x 4 in (10 cm x 10 cm), X-ray detectable hemostatic dressing. This product contains Kaolin.

Indications

QuikClot EMS 4x4 Dressing is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

Contraindications

The safety and effectiveness of the QuikClot EMS 4x4 Dressing for use in neurological, ophthalmic, spinal, GI, orthopedic (bone repair), all anastomoses (including vascular) and femoral artery puncture sites have not been established.

Warnings

- Product is not absorbable and must be removed from wound prior to wound closure.
- The QuikClot EMS 4x4 Dressing is not intended as a substitute for meticulous surgical technique, the use of sterile procedures, and the proper application of ligatures or other conventional procedures to control bleeding.
- The QuikClot EMS 4x4 Dressing must not remain in the wound for longer than 24 hours.
- Avoid contact with eyes.
- Reuse will cause risk of infection and loss of efficacy.
- Not indicated for use in internal surgical procedures

Precautions

- The QuikClot EMS 4x4 Dressing must be applied to the actual source of the bleeding. The dressing cannot influence hemostasis by being placed in the proximity of the bleed.
- If bleeding persists additional product should be applied to the wound.

Instructions for Use

1. Verify the expiration date on the package labels prior to using the product. Remove hemostatic dressing from packaging
2. Apply dressing directly to the source of the bleeding and use it to apply manual compression directly over the bleeding source. The dressing can be packed in the wound tract of penetrating injuries. More than one dressing may be required.
3. Continue to apply manual pressure for five minutes, or until bleeding is controlled.
4. The dressing may be left in place for up to 24 hours. Gently remove dressing. If the dressing is difficult to remove, hydrate with sterile saline. At the end of the procedure, thoroughly irrigate the wound to remove kaolin that may be released from the dressing.
5. Show product removal directions to medical personnel if patient is transported and the dressing remains in place.

Storage Conditions

Keep dry. Keep away from heat, including storage in direct sunlight or in direct contact with heat sources. Store at temperature of 77°F (25°C) or less.

Sterility and Expiration Product is sterilized by exposure to gamma radiation and is intended for single use only. Do not resterilize. Do not use if the sterile pouch is damaged or opened. Do not use the device after the expiration date listed on the package.

QuikClot