TEAR TEAR

CELOX™ -A

Applicator with 6g Haemostatic Granules

Intended Purpose: To be used by trained emergency responders in the pre-hospital setting for temporary treatment of emergency life-threatening bleeding. Celox Applicator is indicated for narrow penetrating wounds.

Patient Target Group: Adults and children, excluding neonates and infants.

FOR TEMPORARY EXTERNAL USE

Do not use if package is damaged

Single sterile barrier system

Medical Device

Instructions for use on back

CE 2797

For wider surface wounds use Celox Haemostatic Granules in preference to Celox-A Applicator

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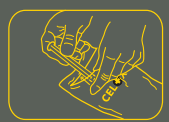
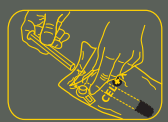
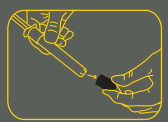
Instructions for use:



1 Wear gloves (if available). Tear open Celox-A packet, hold applicator in opened packet and remove plunger without touching the tip.



2 While still holding applicator in the pack, remove the end cap from the top of the applicator using the plastic tab. Insert plunger into applicator barrel containing the Celox granules.



3 Remove applicator fully from pouch using finger tabs (T-section). Grip and remove the blue plastic cap from end of applicator, just prior to use.

4 Insert applicator with attached plunger as far into wound as possible.

5 Slowly push plunger in while you withdraw the applicator from the wound. Based on wound size more than one applicator may be required.

6 Cover the wound with gauze to fill above skin level and apply firm pressure for five minutes.

7 If bleeding persists or restarts apply direct pressure for an additional 5 minutes. Additional applicators or Celox Haemostatic granules may be used for the wound, or other wounds requiring emergency haemostasis.

8 Wrap and tie bandage securely to maintain pressure on the wound.

9 Transfer patient to medical facilities as soon as possible.

10 Show empty pack to medical personnel at facility.

11 Dispose of used or partially used applicator or granules according to local standard protocols for biological waste.

ATTENTION MEDICAL FACILITY PERSONNEL:

This product is a highly absorptive and soluble haemostat.

1. Physically remove any unused granules and gel plug from the wound. Enlarge wound if necessary.
2. Thoroughly irrigate the wound and any surrounding tissues with sterile saline solution in order to remove any residuals.
3. Proceed with normal cleansing procedures.
4. Ensure all product is removed from the wound prior to initiation of wound treatment.
5. Dispose of removed gel plug and residuals according to local standard protocols for biological waste.

Duration of use: The device and residuals should be removed from the wound within 24 hours from application.

Warnings & Precautions: For external use only. Do not eat. If granules ingested, drink glass of water to avoid discomfort. Loss of sterility potentially poses a risk of infection. Do not re-sterilise. Avoid inhalation. Do not apply over eyes. If eye irritation occurs flush with water for 5 minutes. Keep away from children. Blue cap contains phthalates. Re-use could result in risk of cross infection and reduced performance. Do not refill. **Contains chitosan from shellfish - Allergy studies show no adverse reaction. Data on file at Medtrade Products Ltd.**

Contraindications: Do not use in abdominal wounds and wounds unamenable to pressure. Do not pack into body cavities. Device not intended for surgical use.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

The Summary of Safety and Clinical Performance (SSCP) for the device is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI. The Eudamed website is https://ec.europa.eu/tools/eudamed and the Basic UDI-DI is 506020663BP0993020037.

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