

16mm  
+/- 2.0mm

TEAR

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# CELOX™ GRANULES

## 15g Haemostatic Granules

**Intended Purpose:** To be used by trained emergency responders in the pre-hospital setting for temporary treatment of emergency life-threatening bleeding.

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

**FOR TEMPORARY EXTERNAL USE**



STERILE R



Do not use if package is damaged



Single sterile barrier system



Medical Device



Instructions for use on back



2797

### Instructions for use:

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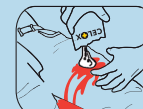
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**1** Wear gloves (if available). Tear open Celox packet.



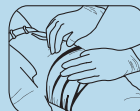
**2** Before application, identify and apply direct pressure on the main part of the bleeding then remove excess blood where practical.



**3** Immediately pour entire contents of pouch into the wound. Fill to above skin level.



**4** Apply FIRM pressure directly to the wound for 5 minutes using gauze. If bleeding persists or restarts apply direct pressure for an additional 5 minutes. Additional packs may be used if necessary for the wound, or other wounds requiring emergency haemostasis.



**5** Wrap and tie bandage securely to maintain pressure on the wound (according to manufacturer's instructions).

**6** Transfer patient to medical facilities as soon as possible.

**7** Show empty pack to medical personnel.

**8** Dispose of any unused portion according to local standard protocols for biological waste.

#### ATTENTION MEDICAL FACILITY PERSONNEL:

This product is a highly absorptive and soluble haemostat.

1. Physically remove the gel plug from the wound.
2. Remove loose surface granules prior to irrigation.
3. Fully flood entire wound area with sterile saline irrigation solution.
4. Proceed with normal irrigation and / or suction.
5. Ensure all product is removed from the wound prior to initiation of wound treatment.
6. 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 ingested, drink glass of water to avoid discomfort. Loss of sterility potentially poses a risk of infection. Do not resterilize. Avoid inhalation. Do not apply over eyes. If eye irritation occurs, flush with water for 5 minutes. Keep away from children. Re-use could result in risk of cross-infection and reduced performance. **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 S0620206638P0993020037.



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