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CELOX™ GAUZE

Z-Fold Haemostatic Gauze

One Gauze Strip 1.5m x 7.6cm

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

MD

Medical Device

Instructions for use on back

CE 2797

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Instructions for use:

1. Tear open pack. Before application identify and apply direct pressure on the main part of the bleeding then remove excess blood where practical. Take out the Celox Z-Fold Gauze and take hold of one end with the other hand.
2. Tightly pack the unfolding Celox Z-Fold Gauze directly to the source of bleeding. Pack remaining wound with Celox Z-Fold Gauze or standard gauze above skin level. Excess Celox Z-Fold Gauze can be torn or cut if necessary.
3. Apply FIRM pressure directly to the wound for 3 minutes. If bleeding persists apply additional pressure for an additional 3 minutes.
4. Wrap and tie with a bandage so as to maintain pressure on the wound.
5. Dispose any remaining Celox Z-Fold Gauze according to local standard protocols for biological waste.
6. Transfer patient to medical facilities as soon as possible.
7. Show empty pack to medical personnel.

ATTENTION MEDICAL FACILITY PERSONNEL:

1. Physically remove Celox Z-Fold Gauze from the wound and any loose surface granules.
2. Fully flood entire wound area with sterile saline irrigation solution.
3. Proceed with normal irrigation and / or suction.
4. Ensure all product is removed from the wound prior to initiation of wound treatment.
5. Dispose of removed Celox Z-Fold Gauze 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 resterilise. 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 5060206638P0993020037.

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