CLINICAL PROCEDURE

TRAUMAGEL® HEMOSTATIC GEL		
DATE EFFECTIVE: XX/XX/202X	SUPERCEDES PROCEDURE DATED: NEW	PAGE: 1

TRAUMAGEL® HEMOSTATIC GEL INSTRUCTIONS FOR USE

TRAUMAGEL® is a single-use, hemostatic gel for temporary external use only.

TRAUMAGEL® is supplied as an individually pouched 30 mL hemostatic gel syringe, containing a sodium alginate and poly (N-acetyl-D-glucosamine, D-glucosamine) hydrogel and is enclosed in a protective pouch. Each syringe is terminally sterilized with gamma irradiation.

The hemostatic gel is viscous, opaque and tan in color. The polymer components, sodium alginate and poly (N-acetyl-D-glucosamine, D-glucosamine), are naturally derived and as a result syringe contents may appear darker over time.

All components of TRAUMAGEL® are non-animal derived.

INTENDED USE / INDICATIONS

TRAUMAGEL® is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding.

**Do Not utilize on wounds to Thoracic cavity (intrapleural) and/or Abdominal cavity (intraperitoneal) **

CONTRAINDICATIONS

• TRAUMAGEL® is for temporary external use only.

• TRAUMAGEL® is not intended for surgical use.

• TRAUMAGEL® is not intended to be used as a wound-closure device.

WARNINGS

• TRAUMAGEL® is single use only. Do not reuse. Reuse could result in risk of infection and/or loss of efficacy if less than 30 mL of gel is used.

• Do not use TRAUMAGEL® on individuals with known sensitivity to sodium alginate or poly (N-acetyl-D-glucosamine, D-glucosamine). If irritation occurs, flush site with saline or water until all product is removed. Ensure the wound site is visibly clear of all the residue. If irritation still occurs, seek immediate medical attention and follow the facility guidance if irritation is observed.

• Do not inject TRAUMAGEL® intravascularly due to risk of embolization.

MECHANISM OF ACTION

TRAUMAGEL® is comprised of a proprietary blend of polyanionic and polycationic polysaccharides. Sodium alginate is the primary polyanionic polymer, and poly (N-acetyl-D-glucosamine, D-glucosamine) is the primary polycationic polymer.

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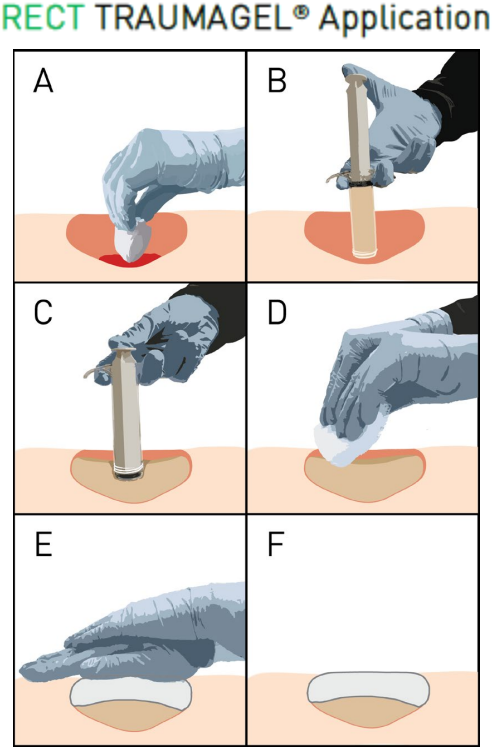
Sodium alginate forms a hydrogel in which poly (N-acetyl-D-glucosamine, D-glucosamine) particles are uniformly dispersed. When directly applied to a source of bleeding, the hemostatic gel rapidly adheres to the wound site. The hemostatic gel forms a mechanical barrier that stops the flow of bleeding and allows the body to create a natural clot.

DIRECTIONS FOR USE

**Do Not utilize on wounds to Thoracic cavity (intrapleural) and/or Abdominal cavity (intraperitoneal) **



1. Retrieve one TRAUMAGEL® syringe from pouch. TRAUMAGEL® does not require preparation.

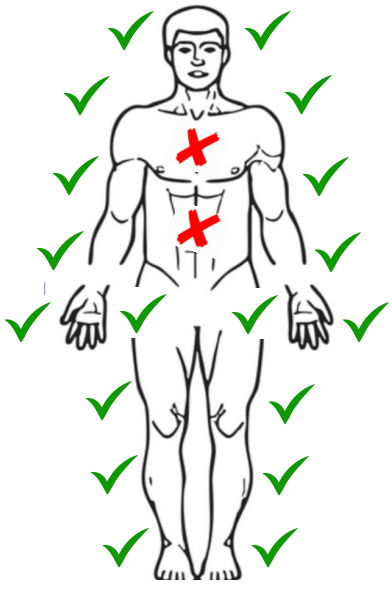
2. Identify the source of bleeding. Dry wound with gauze or suction. Clear as much blood as possible from the wound site prior to application. This will allow the hemostatic gel to come in direct contact with the source of bleeding when applied.

3. When ready to use, unscrew applicator cap, remove gauze and insert the applicator tip deep into the wound as close to the bleeding source as possible. Firmly and quickly expel all contents into the wound. Once all material has been deployed, withdraw the applicator as quickly as possible.

4. Pack gauze into the wound opening atop the applied TRAUMAGEL®, ensuring all gauze is inside the wound area and the wound is sufficiently packed. Apply moderate palm compression (hand over hand), covering as much surface area as possible. Continue compression for three minutes or until hemostasis is achieved. Avoid ejecting any of the underlying TRAUMAGEL®.

5. NOTE: If needed, additional gauze or a pressure dressing may be applied to maintain pressure. The time for formation of a stable clot may vary depending on several patient factors.

TraumaGel Demonstration Video



EMERGENCY MEDICAL SERVICES

In the event of misapplication:

Soak gauze with sterile saline and remove the entire gel.

6. Repeat Directions 2, 3, 4, & 5 with a new TRAUMAGEL® application until hemostasis is achieved.

****Removal is Not to be performed in the field – Emergency Department only procedure****

To remove TRAUMAGEL®: Informational purposes only

7. TRAUMAGEL® must be removed within 24 hours of application.

8. Remove the entire gel and repair the wound. Soak gauze with sterile saline and remove the entire gel. If there are still remnants of gel within the wound, use saline lavage to remove it.

9. If irritation occurs, flush site with saline or water until the wound site is visibly clear of all the residue. If irritation still occurs, seek immediate medical attention and follow the facility's guidance if irritation is observed.

STORAGE AND HANDLING

• TRAUMAGEL® should be stored dry and at an ambient temperature (20-25°C) upon receipt.

• TRAUMAGEL® is prepackaged sterile and is intended for single use only. It is recommended that TRAUMAGEL® be used as soon as the package is opened. Unused contents should be discarded.