TRAUMAGEL®

HEMOSTATIC GEL

INSTRUCTIONS FOR USE

Each pouch has one, sterile, single-use syringe which contains 30 mL of hemostatic gel.

Federal Law restricts this device to sale by or on the order of a medical professional.

DESCRIPTION

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.

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 apply TRAUMAGEL on junctional wounds not amenable to pressure.
- Do not apply TRAUMAGEL unless the source of bleeding is easily visible. Do not blindly apply TRAUMAGEL.
- Do not use TRAUMAGEL on penetrating injuries of the chest or abdomen.
- 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.
- TRAUMAGEL's endotoxin levels may exceed those recommended per FDA guidance. Physicians should exercise caution in using TRAUMAGEL® on immunocompromised patients, patients receiving or likely to receive blood transfusions, or other high-risk patients for pyrogen response. Each lot of TRAUMAGEL® meets pyrogenicity requirements per ISO 10993-11:2017 and USP<151>.

PRECAUTIONS

- TRAUMAGEL® can only be used by a medical professional.
- Do not use if syringe is already opened and/or damaged, as a loss of sterility can present a risk of infection. Do not re-sterilize device.
- Do not use if packaging seal is torn and/or damaged.
- Due to the viscous nature of the material, air bubbles may be present in the syringe but will not affect safety and/or efficacy of the gel.
- TRAUMAGEL® must not be used beyond its expiration date.
- TRAUMAGEL® must be removed within 24 hours of application.
- TRAUMAGEL® cannot be sterilized before use or after its contents have been opened or exposed.
- The use of TRAUMAGEL® is not recommended in the presence of an active infection. If symptoms of infection are observed (i.e., redness, swelling, fever, drainage), please seek immediate medical attention.
- Do not ingest.

MECHANISM OF ACTION

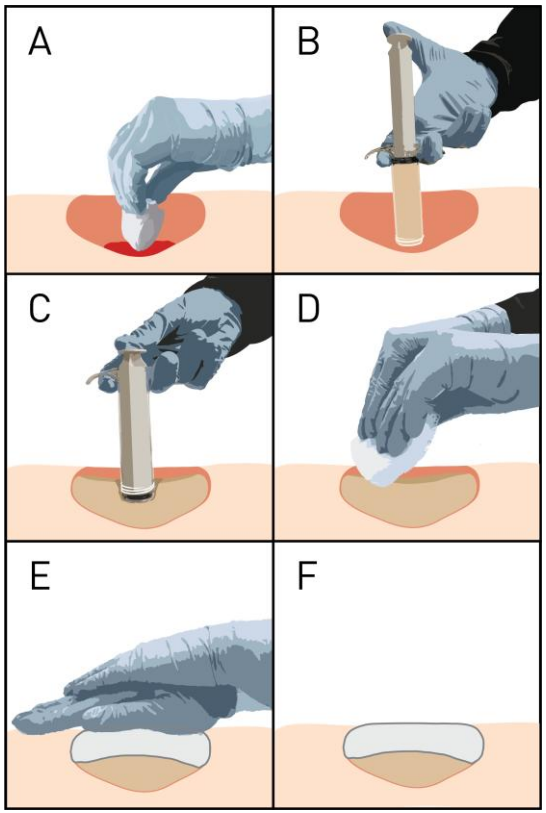
TRAUMAGEL® is comprised of a proprietary blend of polyanionic and polycationic polysaccharides. Sodium alginate is the primary polyanionic polymer, and poly(N-acetyl-D-glucosamine, D-glucosamine) is the primary polycationic polymer.

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

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.

CORRECT TRAUMAGEL® Application



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.

To remove TRAUMAGEL®:

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.

MANUFACTURER

TRAUMAGEL® is manufactured and packaged by Cresilon, Inc., a Brooklyn-based medical device company:

Cresilon®

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DEFINITIONS OF SYMBOLS

Symbol	Definition
	Use-by-date (YYYY-MM-DD)
	Consult Instructions For Use
	Caution (consult Instructions For Use)
	Manufacturer
	Batch code
	Sterilized using irradiation
	Do not reuse. Single-use only.
	Do not re-sterilize
	Temperature limit
	Federal Law restricts this device to sale by or on the order of a physician.
	Do not use if package is damaged
	Single sterile barrier with protective packaging
MD	Medical Device

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