

TRAUMAGEL®

Category:

Best Medical Technology

Company Name:

Cresilon

Product/Solution Name:

TRAUMAGEL®

Compound/Tech Name:

TRAUMAGEL Hemostatic Gel

Trade Name:

TRAUMAGEL®

Corporate Name:

Cresilon, Inc.

Date of Approval:

2024-08-14

Indications:

TRAUMAGEL is a hemostatic gel indicated for temporary external use for controlling moderate to severe bleeding. It is indicated for use in injuries including: penetrating trauma such as gun shots and stab wounds; deep penetrating bleed sites; extremity injuries; non-compressible junctional injuries; injuries where a tourniquet cannot be applied; and bleeding that traditional methods may not address.

TRAUMAGEL, which utilizes Cresilon's proprietary hydrogel formulation, is the first gel in a syringe for traumatic hemorrhage, the only hydrogel that requires no preparation for use in traumatic bleeding, and the only flowable hemostatic cleared for temporary external use to control moderate to severe bleeding.

Cresilon's proprietary hydrogel is biocompatible, non-animal derived, contains no active

pharmaceutical ingredient, and made with an innovative blend of plant polymers that forms a durable mechanical barrier when applied to wounds and allows the body to create a natural clot. Cresilon's plant-based hemostatic gel is designed to rapidly stop bleeding and save lives.

Therapeutic Areas:

TRAUMAGEL is a revolutionary plant-based hemostatic gel that controls bleeding in seconds when applied to a wound at the point of care. It is supplied in a 30 mL sterile prefilled syringe, requires no preparation, is easy to apply and remove, stops bleeding rapidly, and provides immediate hemorrhage control.

TRAUMAGEL can be used by licensed medical professionals in various emergency and trauma care settings, including: prehospital care by EMS agencies and fire departments on-site at accidents or disaster scenes; hospital emergency departments for immediate intervention before surgical procedures; and military field hospitals for prehospital care in the field and in combat zones.

General Information File Document upload:

[Cresilon News Release FDA Clearance for TRAUMAGEL 81524.pdf](#)

[Cresilon K240713 TRAUMAGEL FDA Clearance Full Summary 8142024.pdf](#)

[Cresilon Media Coverage TRAUMAGEL FDA Clearance.pdf](#)

Background information and need for drug / device:

When a 38-year-old industrial worker walked into the University Medical Center Emergency Department in New Orleans, he was bleeding profusely from a devastating 12 x 18 cm wound that had completely severed his bicep muscle. The injury, caused by high-pressurized machinery, was too irregular and deep for traditional gauze packing. A tourniquet had been applied but it couldn't stop the bleeding. This patient was saved with one application of TRAUMAGEL.

Without TRAUMAGEL, this scenario plays out thousands of times across America, where severe blood loss kills more people aged 1 to 46 than any other preventable cause of trauma death. In combat zones, approximately 30-40% of the six million annual trauma patients worldwide die from hemorrhage, with half of these deaths occurring before they ever reach a hospital. Whether it's a gunshot wound in a firefight, a slip and fall on an icy driveway, or a catastrophic motor vehicle accident, seconds matter when it comes to controlling blood loss.

TRAUMAGEL is unlike any other hemostatic device currently being used. It is ready to use immediately, the first hemostatic gel in a syringe for traumatic hemorrhage, and the only hydrogel that requires no preparation for use in traumatic bleeding.

Additionally, TRAUMAGEL allows for easy access to hard-to-reach injuries and conforms to a wide range of wound geometries and bleed severities - making it a versatile front-line solution in emergency and trauma care settings for fast control of blood loss and immediate hemorrhage control.

Cresilon's proprietary hydrogel utilized in TRAUMAGEL is biocompatible and made with plant-based polymers that are algae-derived and specially purified and formulated to allow the hemostatic gel to form a mechanical barrier against bleeding on contact, while allowing the body to create a natural clot without causing chemical burn or tissue damage. And while several hemostatic devices and gauze bandages are currently available for the control of hemorrhage; many of these products may require time-consuming preparation, can be cumbersome and difficult to apply, and may not be as effective for severe hemorrhage.

These and other critical factors are evident when comparing TRAUMAGEL to legacy solutions such as traditional gauze and Kaolin or Zeolite impregnated gauze. For greater context on the critical need for TRAUMAGEL and its unique abilities compared to standard of care (SOC) impregnated gauzes, consider the following comparison:

Application Method

- TRAUMAGEL - Single syringe injection, no wound packing required
- SOC - Requires sheet-by-sheet wound packing technique

Time to Hemostasis in Severe Hemorrhage

- TRAUMAGEL - Less than 6 minutes
- SOC - Variable, often >10 minutes

Removal Process

- TRAUMAGEL - Easy saline irrigation removal, does not remove clot on removal
- SOC - Difficult removal, can cause rebleeding upon removal

Conformability

- TRAUMAGEL - Flows into irregular wounds
- SOC - Limited conformability

Pain/Discomfort

- TRAUMAGEL - Minimal (no wound packing)
- SOC - High (painful packing procedure)

Background File Document upload:

Cresilon Case Study A Case Study Demonstrating the Utility of TRAUMAGEL in Emergency Hemorrhagic Trauma Setting.pdf
Cresilon Case Study The Use of TRAUMAGEL for Hemorrhage

[**Control in a Facial Gunshot Wound.pdf**](#)

[**Cresilon RPT0077 Summary of TRAUMAGEL v Gauze in a Swine Jugular Vein Puncture Model.pdf**](#)

[**Cresilon TRAUMAGEL Package Insert Summary.pdf**](#)

[**Cresilon TRAUMAGEL Product Brochure.pdf**](#)

[**Cresilon TRAUMAGEL Thromboembolism Safety Pilot Study Summary Report.pdf**](#)

[**Cresilon TRAUMAGEL Thromboembolism Safety Pilot Study Summary Report.pdf**](#)

History of the development of the solution/product:

The development of Cresilon's proprietary hydrogel technology and the inception of TRAUMAGEL dates back to 2010, when the plant-based hemostatic gel was originally invented by CEO and co-founder Joe Landolina while he was a 17-year-old bioengineering student at New York University.

Cresilon validated its hemostatic technology through VETIGEL®, its first commercial product for veterinary use launched in 2021. Since then, VETIGEL has been successfully used in more than 60,000 surgical procedures across North America, Europe, and Asia - demonstrating the platform's safety and efficacy in stopping bleeding during traumatic wounds and complex surgical procedures including liver biopsies, tumor removals, and amputations.

In 2023, Cresilon received its first U.S. FDA 510(k) clearance for its proprietary hydrogel in managing bleeding from minor cuts, lacerations, and abrasions. The company's first FDA clearance for Cresilon Hemostatic Gel® (CHG) in human use served as a regulatory predicate for TRAUMAGEL's development and FDA 510(k).

Then, in August 2024, Cresilon received FDA clearance for TRAUMAGEL for temporary external use for controlling moderate to severe bleeding. Prior to its U.S. commercial launch in January 2025, Cresilon initiated a strategic rollout among regional EMS agencies, fire departments, academic medical centers, and Level I trauma centers at pilot sites in select markets, including Boston, Denver, and New Orleans.

Since the launch in January, TRAUMAGEL use has been documented in 55 clinical use cases and applied to a wide variety of moderate to severe bleeds, including gunshot wounds, equipment injuries, head lacerations, inguinal incision ruptures, and tourniquet conversions. Cresilon expects TRAUMAGEL will be used to save more than 30,000 lives this year.

Clinical feedback has also been overwhelmingly positive from use cases. Alison Barker, a Paramedic at East Baton Rouge EMS, said, "I absolutely loved using TRAUMAGEL over pressure dressings and tourniquets. I've had issues with tourniquets velcro sticking to

things and getting tangled on itself while trying to apply, it also is more time consuming than TRAUMAGEL."

Barker, who used TRAUMAGEL on a patient with a through-and-through gunshot wound to the inner upper thigh, also noted the benefits of TRAUMAGEL over other means of bleeding control and pain management. She said, "This patient was given one dose of 60 mcg of fent for pain IV and no repeat dose was needed. ER also did not need to give further pain medications while EMS was in ER, which they tend to already have pain meds ready for the patient and given before EMS leaves the ER. This benefit reduces the amount of pain medication used/needed and risks/side effects (delays for orders, decrease in mental status, respiratory compromise, etc.)."

Additional benefits noted by Barker include cost and resources. "TRAUMAGEL eliminated the need for trauma activation and the patient was downgraded from critical to immediate then could be placed in regular ER room," said Barker. "Also, since the patient was not activated, trauma activation cost and resources were saved and available for possible incoming patient who may have not had TRAUMAGEL applied or for patients who could not be downgraded."

Development File Document upload:

[**Cresilon TRAUMAGEL Product Brochure.pdf**](#)

[**Cresilon TRAUMAGEL Provider Feedback Interim Summary Pre Hospital and Hospital.pdf**](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The ability to control severe bleeding in a matter of seconds can be the difference between life and death for a patient with traumatic bleeding. Not only is TRAUMAGEL a game-changing hemostatic device that can transform the standard of care, but also a life-saving tool that can get patients with traumatic wounds from point A to point B before they bleed to death.

TRAUMAGEL represents a significant innovation in an industry which has seen little to no innovation for decades. Prehospital whole blood transfusion is an increasing field, due to factors like rising trauma cases, advancements in trauma resuscitation, and a growing understanding of the benefits of whole blood in emergency situations. Additionally, the increasing frequency of mass casualty incidents and emerging national security threats have elevated hemorrhage control readiness as a critical strategic priority for emergency preparedness and homeland security initiatives.

In addition to TRAUMAGEL, Cresilon's proprietary hydrogel is being studied for broader applications by the U.S. Defense Department's Walter Reed Army Institute of Research

(WRAIR). In July 2024, Cresilon announced the successful completion of the first phase of a preclinical study conducted by WRAIR to evaluate the plant-based hemostatic gel's potential as a field and prehospital treatment following a penetrating traumatic brain injury (TBI).

Preliminary findings from the study demonstrated promising results in the ability of Cresilon's plant-based hemostatic gel to control bleeding when applied to a wound and provide neuroprotection following a penetrating TBI - which is the most severe form of traumatic head injury and can lead to death, permanent disability, neurodegenerative diseases, and long-term health issues. Based on results from the study, WRAIR will pursue further studies utilizing the company's proprietary hydrogel.

As Cresilon continues advancing in broader applications for its innovative hemostatic gel, TRAUMAGEL is now available for use across the U.S. by licensed medical professionals in prehospital, emergency, and trauma situations at the point of care. TRAUMAGEL's ability to rapidly stop bleeding and provide immediate hemorrhage control will improve the human condition by saving countless lives.

In the future and beyond the U.S., TRAUMAGEL could help address a global burden that has long impacted individuals, families, communities, and healthcare systems around the world. According to a report published in the journal Critical Care, \"Trauma is a worldwide problem, with severe and wide ranging consequences for individuals and society as a whole. Hemorrhage is a major contributor to the dilemma of traumatic injury and its care.\"

The report adds, \"Although it is often thought of as being composed of individual events, traumatic injury is a pandemic disease - one that affects every nation in the world without regard for economic development, racial or religious predominance, or political ideology. Trauma carries with it a great price that is paid at all levels of society - by individuals, families, communities, and nations. The burden of traumatic injury ranges from the significant financial costs of modern trauma care to the emotional distress of having a loved one, especially a young individual, become critically injured or die.\"

Innovation File Document upload:

[USAISR Research Priorities Hemorrhage and Edema Control CRT2.pdf](#)

[Cresilon TRAUMAGEL FAQs.pdf](#)

[Cresilon News Release Study Performed with Walter Reed Army Institute of Research.pdf](#)

Please provide appropriate references (PubMed, Abstract, Website):

TRAUMAGEL Website: <https://cresilon.com/traumagel/>

References File Document upload:

[Cresilon TRAUMAGEL FAQs.pdf](#)

[Cresilon TRAUMAGEL Instructions For Use.pdf](#)