

**PRODUCT**  
MONOGRAPH

# CELOX™ MONOGRAPH CONTENTS

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# FOREWORD

Severe traumatic injury is a major worldwide public health issue which causes significant social and economic consequences for societies.<sup>1</sup>

It contributes to one in every ten mortalities, and the annual global death rate is increasing year-on-year.<sup>2</sup>

The World Health Organization recognises road traffic accidents, suicides and homicides as the three leading causes of injury and violence-related deaths,<sup>3</sup> with uncontrolled post-traumatic bleeding being the leading cause of preventable death, both in civilian life<sup>4,5</sup> and on the battlefield.<sup>6</sup>

In response, a number of national and international initiatives have sought to prevent violence- and trauma-related injuries and to also improve the management of severe bleeds in trauma patients via innovative treatment approaches, educational measures and state-of-the-art clinical practice guidelines.<sup>7</sup>

**The aim is to improve outcomes by assisting in the timely identification of bleeding sources, followed by prompt measures to stop bleeding and restore haemodynamic stability.<sup>8</sup>**

“

**Celox™ Medical, together with our parent company Medtrade, is committed to finding the optimal method of controlling bleeding within the shortest time possible – we understand that, in an emergency trauma situation, every second counts.**

**We are proud to have launched Celox Rapid and to see the real difference that it has made to patients around the world.**

**We have shared just a few of these testimonies in this monograph, together with reporting on the available scientific data which supports the use of Celox Rapid and the rest of the Celox range. We hope you find it useful.**

”

# EXECUTIVE SUMMARY

Despite significant advancements in scientific understanding and technology, trauma remains a leading cause of human morbidity and mortality,<sup>9</sup> with haemorrhage as the main cause of preventable death in combat and civilian trauma situations.<sup>4,5,6</sup>

Overall, 25% of severely injured patients have an established trauma induced coagulopathy on arrival at the Emergency Department, a phenomenon associated with an increased rate of early and late mortality. These complications can be successfully prevented by the timely application of a haemostatic dressing<sup>10,11</sup> such as Celox Rapid.

Celox products contain a proprietary chitosan derivative in the form of microscopic flakes that is both biocompatible and biodegradable. It is highly compressed over a large surface area to rapidly promote clot formation, through absorption and dehydration. It does this independently of the body's

clotting mechanism and without exothermic reaction or damage to the surrounding tissues.<sup>12,13</sup> This is a key differentiator from some competitor products where, historically, according to data from both animal studies and case reports, thermal injury and burns were a result from exothermic reaction.<sup>14,15,16</sup> Celox is efficacious in those who receive anticoagulant medications i.e. heparin or warfarin, and in conditions of hypothermia.<sup>8</sup>

The efficacy of using chitosan-derived materials in haemostasis has been studied in depth, although results have been variable. Tissue response data reveals significant differences in efficacy between the different forms of chitosan and their sources e.g. crab, mushroom or shellfish. Degree of efficacy is dependent not only on the source, but importantly, on how it is activated into a haemostat. Celox is manufactured from the shells of a particular species of shrimp, harvested from a specific region in the North Atlantic to ensure both efficacy

and purity. Consequently, there have been no known or suspected allergic reactions resulting from the indicated use of Celox. Independent testing showed no allergic reaction on volunteers who had positive allergic response to fish or shrimp prick tests.<sup>17</sup> In addition, Celox is manufactured to rigorous standards, using the latest haemostatic technology to ensure a faster, effective emergency treatment in life-threatening situations.

Within the combat setting, the available time for controlling life-threatening haemorrhage is limited. In such conditions, the severity of the wound and the possibility of numerous associated wounds exacerbate the challenge of bleeding control.<sup>18</sup> In a meta-analysis, Celox Gauze has been shown to outperform the other haemostatic agents tested, and the only one to demonstrate a statistically significant improvement in survival, especially in the more severely injured.<sup>19</sup> Another challenge during combat

situations is the feasibility of maintaining compression on the wound for a sufficient length of time.<sup>20</sup> Celox Rapid, with its proven ability to quickly reduce blood loss and a reduced requirement for compression (minimum one minute, versus the conventional three minutes, or until bleeding stops),<sup>21</sup> makes it a valuable treatment option for first-responders.

Ease of removal of the agent at the time of further medical intervention is also important. Some marketed products, such as WoundStat,<sup>TM</sup> have been shown to be particularly difficult to remove, requiring several washouts, even after which small portions of the product still remained.<sup>3</sup> Celox is efficiently removed by irrigating the wound with water or saline, once clotting has occurred.

# INTRODUCTION TO OUR HERITAGE

Medtrade Products Ltd. is a world-leading product innovator, developer and the manufacturer of the Celox product range. Based in the UK since 1999, Medtrade is an independent company with a legacy of developing technologically advanced solutions in wound care, trauma wound care and surgical wound care.

Our Celox Medical team of highly skilled experts have a wealth of knowledge in materials science, regulatory, quality requirements and manufacturing processes, and use this to bring to

market ground-breaking innovations, that rapidly, safely and effectively treat life-threatening bleeding in pre-hospital emergency situations.

Our Celox range of products, first launched in 2006 with Celox Granules, have been used to save the lives of soldiers and civilians alike. Since then, we have launched three generations of Celox brands. The latest, Celox Rapid, is the first gauze with a compression time of one minute, or until bleeding stops<sup>21</sup> and is the UK Ministry of Defence's product of choice.<sup>22</sup>

Our Celox Academy now gives us the opportunity to share our knowledge and experience in recognising and treating external life-threatening haemorrhage, ensuring that first-responders receive accredited, certified training in line with the latest European Resuscitation Council (ERC) guidelines.

We are proud to work in partnership with civilian and military emergency response teams around the world to achieve successful clinical outcomes for millions of people each year.



Medtrade



CELOX™



# MODE OF ACTION

The Celox product range has undergone significant innovation since its first launching – as Celox Granules – in 2006. Celox granules are derived from chitosan, a natural polysaccharide with a good safety profile, and a proven ability to form an adherent gel clot.<sup>23</sup> However, while the biological and chemical properties of chitosan-derived materials in haemostasis have been extensively studied, tissue response studies have shown considerable variation in efficacy between the different forms of chitosan.<sup>24,25</sup>

The Celox granules contain a high-quality activated chitosan derivative that has been innovatively developed as a

haemostat and has proven to be fast-acting, safe and highly effective in controlling life-threatening bleeding. It comprises of a proprietary composition which contains chitosan in the form of micro granules, high surface area, granular flakes, designed for maximum effectiveness.

The mechanism of action for Celox granules is through the absorption of fluid in the blood, swelling and sticking together to create a robust mechanical gel-like clot that plugs the bleeding source and seals the wound.<sup>26</sup>

This mechanism works independently of

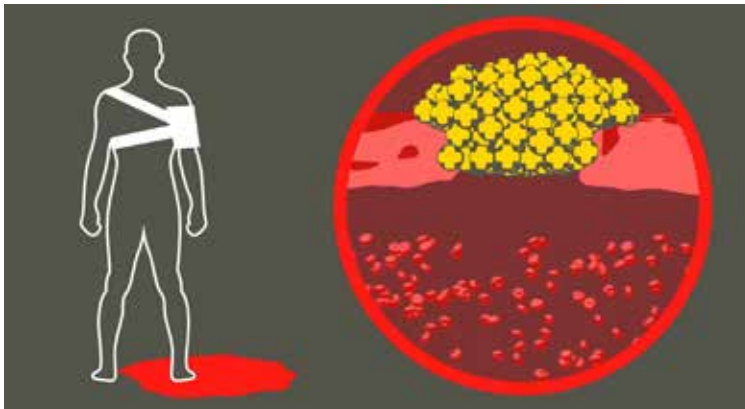
classical coagulation pathways (i.e., does not initiate a thrombogenic response<sup>25</sup>

Celox Gauze was developed to provide an improved method of delivering Celox granules to a wound. Applying the Celox Gauze dressing to a trauma wound allows the emergency responder to initiate compression to rapidly stop bleeding. Independent comparative tests in the form of a meta-analysis reported a statistically significant improvement in survival with Celox Gauze, compared to alternative agents (P<0.5).<sup>19</sup>

The most recent addition to the Celox product range is Celox Rapid, our fastest acting, high-density haemostatic gauze. Celox Rapid builds upon the proven effectiveness of Celox granules and

Celox Gauze, with latest Chito-R™ technology, which combines the high-grade chitosan derivative with a pharmaceutical-grade bioadhesive. This patented formulation lets sufficient penetration of blood and fluids through its layers to allow them to adhere to each other during life-threatening blood loss, bonding to the surrounding tissue and securing the gel plug in place, in order to maintain haemostasis.<sup>26</sup>

Consequently, Celox Rapid reduces blood loss in life-threatening injuries by speeding up packing time and reducing compression time to one minute or until bleeding stops.<sup>27,21,28</sup> This unique action does not rely on the body's intrinsic clotting capability and minimises the risk of re-bleeding when the patient is moved, or the dressing is removed.



*Granules absorb fluid, and gel forms a robust plug to rapidly stop the bleed.*

# SAFETY DATA

Celox Rapid and the rest of the Celox product range have been through extensive safety and biocompatibility testing, including ISO 10993 standards, the European Medical Device CE Mark class III (the highest classification of device) and the FDA device requirements.

Celox's proprietary chitosan derivative, is a specific high-quality grade selected for medical use from a shellfish source. Chitosan consists of glucosamine and N-Acetyl Glucosamine, which are naturally occurring sugars in the body.<sup>29</sup> This is in contrast to mineral-based haemostatic agents, where the particles are released at higher volumes.<sup>30,31</sup>

Celox has been tested for allergic reaction on humans with a known fish or shrimp hypersensitivity, and none of the subjects showed any skin reaction.<sup>17</sup>

Tests on Celox products have included examination of whether particles may enter the bloodstream, but this was found not to be the case. Rall *et al*<sup>32</sup> histologically examined tissue from the treated vessels in a swine model of lethal artery injury. Femoral artery injuries in ten swine were treated with Celox Gauze and these showed some granules on the outside of the treated vessel, as expected, but no particles inside the vessel walls. This is consistent with previous findings in other similar studies. Clay *et al*<sup>33</sup> used an

arterial catheter and showed diminished – but measurable – arterial pressure in the ipsilateral thigh, after treatment with Celox granules for extremity artery haemorrhage, indicating that circulation was not blocked. Kheirabadi<sup>34</sup> also showed continued distal blood flow with Celox, even after the treated vessel was occluded by the treatment.

## Regulatory information/ contraindications

Celox products have been approved by both the BSI (Class III CE Marked Medical Devices) and FDA (K110386) for use as a haemostat.

***Celox is not intended for internal (surgical) use. Celox should not be used in the eyes. It is not indicated for use in the mouth.***

## Biocompatibility

Celox and Celox Rapid have been reviewed in accordance with ISO10993 and FDA Blue Book memo G95-1.

The following results were obtained (data on file):

- Dermal Irritation - Passed
- Dermal Sensitisation - Passed
- Cytotoxicity - Passed
- Acute Systemic Toxicity - Passed

## Composition/ingredients

The glucosamine and N-Acetyl Glucosamine sugars in the chitosan are naturally occurring materials.

Celox Rapid uses the same chitosan material as Celox, which has been in use since 2006, with no medical adverse events reported. In addition, it uses Chito-R, a pharmaceutical grade (FDA National Formulary) bioadhesive, used in a range of medical devices and, as an excipient in pharmaceutical formulations, with a long history of safe use.

## Hazard information

**Specific hazards:** In common with other haemostasis agents, there is a risk the granules may irritate eyes and respiratory system.

As with other agents, there is a small possibility of the fabric shedding small amounts of granules and nuisance dust.

**No health hazard is anticipated during normal handling of the product.**

**Carcinogenic status:** Not considered carcinogenic.

## Skin contact (short- and long-term):

This product is intended for skin contact.

## Eye contact (short- and long-term):

Discomfort, irritation, blurred vision. Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Seek medical attention.

## Inhalation (short- and long-term):

May cause irritation of the mucous membranes. Move to fresh air. If symptoms persist, call a physician.

**Ingestion:** This product is not considered toxic but, as with any material, may be harmful if ingested in large quantities. May cause choking hazard. Do not breathe in dust. Consult a physician. The patient, if conscious, should drink plenty of water.

## Toxicological information

**Acute toxicity:** The product is considered non-toxic, when used in accordance with this information.

**Irritation:** The product has passed the following laboratory tests: irritation; sensitisation; cytotoxicity; acute systemic toxicity.

**Local effects:** Irritating to eyes. Inhalation may cause irritation of mucous membranes.

**Skin contact:** May cause slight skin irritation.

**Eye contact:** Eye irritation.

# SCIENTIFIC EVIDENCE

## CELOX RAPID

### Celox Rapid has a fast onset of action, good adherence and control of bleeding

**Title:** Mechanism of action of rapid-action gauze haemostat.

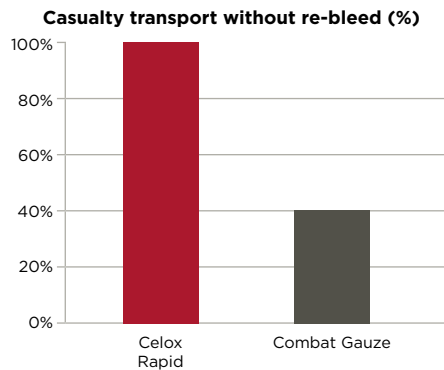
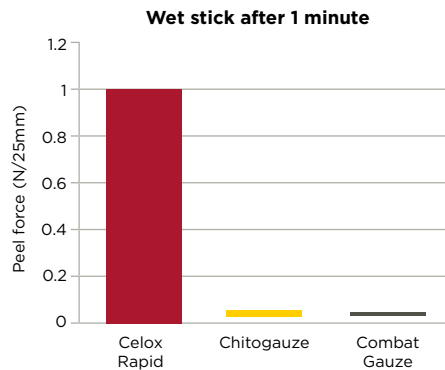
**Authors:** Hoggarth A, Hardy C, Eason G, Lyon A, Marsden C.

**Publication:** Presented at ATACCC, FL, August 2011.

**Method:** Celox Rapid haemostatic gauze is designed to stick to wet tissue. Two tests were carried out to evaluate the effectiveness of the 'wet-stick.' First, strips of gauze haemostats were pressed on to pork belly and the force to remove was measured, using a tensiometer, after 1, 3 or 20 minutes. Secondly, swine femoral artery injury models were treated and

then the models were driven over rough ground for approximately five minutes to simulate a casualty movement, before being examined for evidence of re-bleeding.

**Results:** The force to remove Celox Rapid from pork belly was 1.02 N/25mm after one minute and consistent up to the end of test. Other products recorded forces <0.1 N/25mm, below the validated limit of the gauge. In the transport test, Celox Rapid had zero (0/5) bleeding after transport, whereas QuikClot Combat® Gauze showed evidence of re-bleeding in three of the five models.



#### Discussion:

- Celox Rapid adhered to wet tissue significantly more than other haemostatic gauzes.
- After haemostasis was achieved, Celox Rapid was able to maintain haemostasis in a model of casualty transport, without re-bleeding.

## CELOX RAPID

### Celox Rapid reduces blood loss and has a short application time

**Title:** Chitosan based haemostatic dressing is associated with decreased blood loss in a swine uncontrolled haemorrhage model.

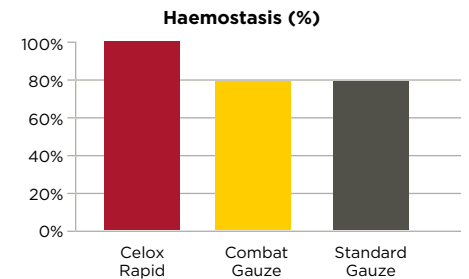
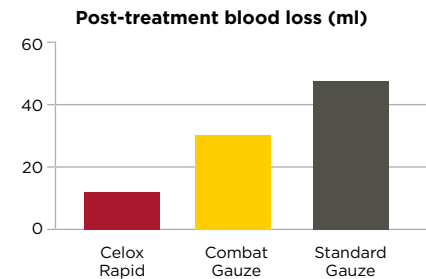
**Authors:** Kunio NR, Riha GM, Watson KM, Differding JA, Schreiber MA, Watters JM.

**Publication:** Am J Surg 2013 May; 205(5):505-510.

**Method:** The study consisted of a randomised, controlled, blinded trial of lethal femoral arteriotomy injury, utilising thirty-six swine. The injuries were treated with either Standard Gauze, Combat Gauze, or Celox Rapid Gauze. After packing, there was no further compression

applied. Animals were followed for 120 minutes after injury or until death.

**Results:** All animals survived to study end. Physiologic parameters were similar between groups throughout the study. Dressing success rates were: Celox Rapid: 12/12; Combat Gauze 10/12; Standard Gauze 10/12 (p=0.14). Post-treatment blood loss for Celox Rapid (12.8 ml) was significantly reduced compared to Standard Gauze (44.7 ml) or Combat Gauze (31.9 ml) (p=0.05). Packing time was also significantly shorter with Celox Rapid (37.1 seconds) compared to either Gauze (45.2) or Combat Gauze (43.5) (p=0.01).



#### Discussion:

- Celox Rapid had a shorter application time than Combat Gauze or Standard Gauze.
- Celox Rapid decreased secondary blood loss compared to Combat Gauze and Standard Gauze.
- Celox Rapid had a trend to higher haemostasis.
- The model had higher overall success rates than other models such as that used by Kheirabadi *et al.* This is probably due to the geometry of the wound.



## CELOX RAPID

### Celox Rapid achieves homeostasis, even without compression

**Title:** Testing a new gauze haemostat with reduced treatment time.

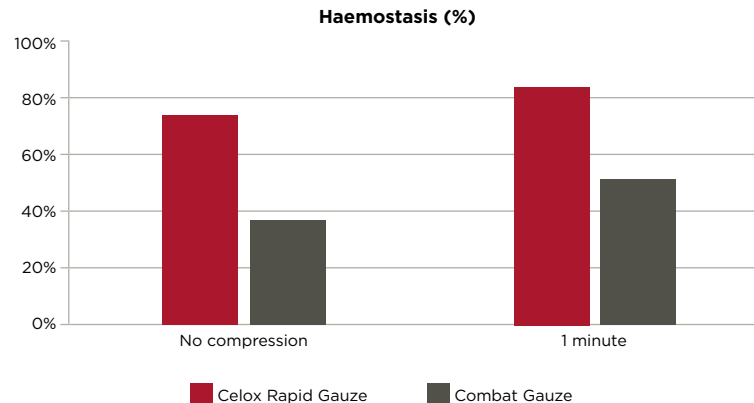
**Authors:** Hoggarth A, Hardy C, Millner R, Lyon A.

**Publication:** Presented at ATACCC, FL, August 2011.

**Method:** The test consisted of a lethal 6mm punch arteriotomy to the femoral artery of Yorkshire swine. Treatment was with Celox Rapid (n=12) or Combat Gauze (8). Haemostasis was assessed after no compression and (where needed)

after one-minute compression. Additional tests were carried out with Celox Rapid and three-minute compression to test equivalence to previous-generation products.

**Results:** Celox Rapid had 75% haemostasis with no compression, compared to 38% for Combat Gauze. After one-minute compression, the results were 83% and 50% respectively. Initial haemostasis was sustained to study end. Celox Rapid was removed intact, with no tissue damage.



#### Discussion:

- The study deliberately used short treatment time to test the effect of application in emergency or high-stress situations.
- Celox Rapid achieved haemostasis reliably with short compression time or zero compression time.

## CELOX RAPID

### Celox Rapid is quicker to pack a wound than Combat Gauze

**Title:** Reduced application time with a rapid packing gauze haemostat.

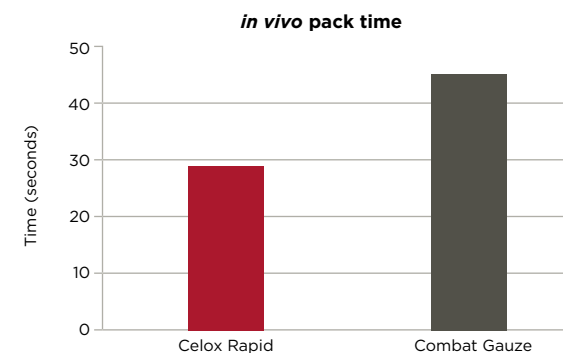
**Authors:** Hoggarth A, Hardy C, Eason G, Marsden C.

**Publication:** Presented at ATACCC, FL, August 2011.

**Method:** Haemostatic gauze was packed into two different types of wound and the pack time measured. The first test was packing three different haemostatic gauzes (Celox Rapid, Chitogauze®, Combat Gauze) into a simulated wound cavity in pork belly, with trials of each

dressing by 10 users. The second test was carried out *in vivo* with Celox Rapid and Combat Gauze on a swine femoral artery sever model (n=5 for each product) by two experienced operators. The products were all capable of filling the same wound cavity size.

**Results:** Packing times in the laboratory were: Celox Rapid 12.8 seconds; Combat Gauze 28.3 seconds; ChitoGauze 30.6 seconds. Field packing times were longer: Celox Rapid 28.8 seconds, Combat Gauze 43.2 seconds.



#### Discussion:

- Celox Rapid was faster to pack than the other products in both tests.
- Celox Rapid is a shorter, denser bandage than the other products (1.5m as opposed to 3.7m).
- The difference in packing time is consistent with the difference in bandage length.

## CELOX GAUZE

### Statistically significant improved survival with Celox Gauze

**Title:** Catastrophic haemorrhage in military major trauma patients: a retrospective database analysis of haemostatic agents used on the battlefield

**Authors:** Winstanley M, Smith JE, Wright C

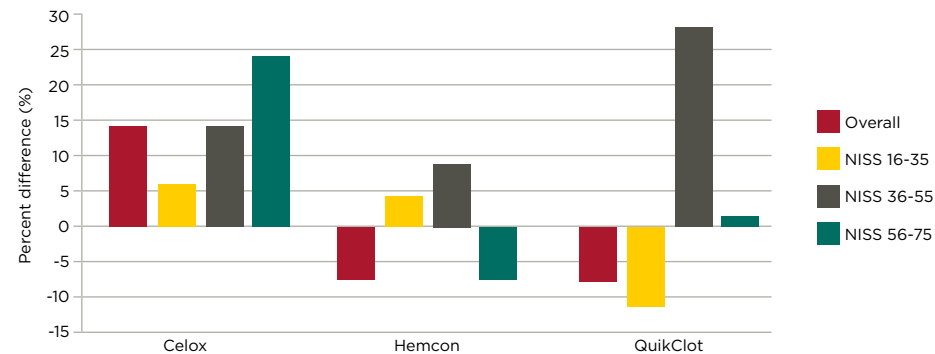
**Publication:** R Army Med Corps 2018;0:1-5.

**Method:** A retrospective database review was undertaken, using the UK Joint Theatre Trauma Registry from 2003 to 2014, during combat operations in Iraq and Afghanistan. Data included patient demographics, the use of haemostatic dressings, New Injury

Severity Score (NISS) and patient outcome.

**Results:** Of 3,792 cases, a haemostatic dressing was applied in 317 (either Celox, Hemcon or QuikClot). When comparing patients who had a haemostatic dressing applied versus no haemostatic agent, there was a 7% improvement in survival. Celox was the only individual haemostatic dressing that was associated with a statistically significant improvement in survival, which was most apparent in the more severely injured (NISS 36-75).

### Celox was the only dressing to demonstrate statistically significant increases in survival (p<0.05)



### Discussion:

We have shown an association between use of haemostatic agents and improved survival, mostly in those with more severe injuries, which is particularly evident in those administered Celox. This supports the continued use of haemostatic agents as part of initial haemorrhage control for patients injured in conflict, and suggests that civilian organisations that may need to deal with patients with similar injury patterns should consider their use and implementation.

## CELOX GAUZE

### Increased survival and reduced blood loss with Celox Gauze vs Combat Gauze and ChitoGauze®

**Title:** Comparison of novel haemostatic gauzes to QuikClot Combat Gauze in a standardised swine model of uncontrolled haemorrhage.

**Authors:** Rall JM, Cox JM, Conger AG, Cestero RF, Ross JD.

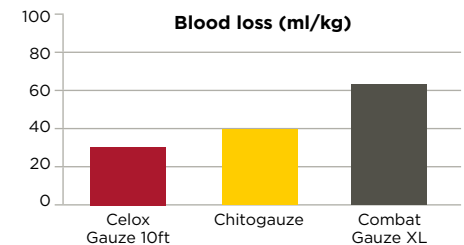
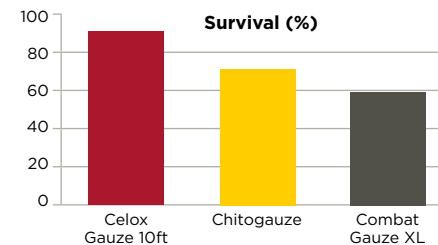
**Publications:** J Trauma Acute Care Surg 75(2) suppl 2 S150 -156 (2013).

**Method:** The study was carried out by the Office of Naval Research (ONR) at NAMRU-SA and was designed to update the US CoTCCC recommendations on haemostatic agents, leading to the CoTCCC decision to include Celox Gauze and ChitoGauze.

Four haemostatic gauzes (Celox Gauze 10 foot, Combat Gauze XL, ChitoGauze and Celox Trauma Gauze) were compared

to Combat Gauze in a swine model of groin arterial haemorrhage, with 10 models for each dressing type.

**Results:** Celox Gauze achieved 90% survival, while other dressings recorded 50-70%. Blood loss when using Celox Gauze was around half that lost when using Combat Gauze, and the difference was statistically significant after ten minutes' treatment. At study end, Celox Gauze had the lowest observed value for blood loss and highest percentage with haemostasis intact, although these figures were not statistically significant - the study was not powered to show significance. Particles of chitosan were found outside treated vessels, but no foreign material was found inside any vessels, and all products had similar scores for tissue compatibility.



### Discussion:

The authors suggest that the larger products (Celox Gauze 10 foot and Combat Gauze XL) had better results, possibly due to additional tamponade. However, Medtrade internal results on 1.5m and 3m dressings indicate that, for Celox Gauze, the dressing size does not affect the result.

# CASE STUDIES

## CELOX GAUZE

### Reduced blood loss and requirement for resuscitation fluids with Celox Gauze

**Title:** Advanced haemostatic dressings are not superior to gauze for care-under-fire scenarios.

**Authors:** Watters JM, Van PY, Hamilton GJ, Sambasivan C, Differding JA, Schreiber MA.

**Publications:** J Trauma. 2011 Jun;70(6):1413-9.

**Methods:** Celox Gauze was compared to QuikClot Combat Gauze in a model of a wound with no compression applied, the authors arguing that this represents a model of care-under-fire.

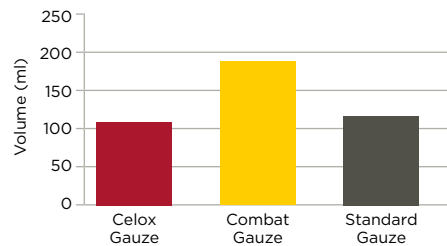
**Results:** Celox Gauze achieved haemostasis in 6/8 cases, compared

with Combat Gauze which achieved haemostasis in 4/8. Standard Gauze achieved higher haemostasis, which was explained by the high level of experience of the packer involved.

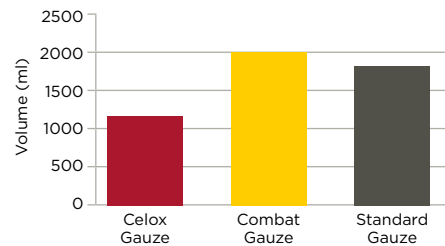
At 30 minutes, Celox Gauze recorded a significantly shorter time to clot, compared with Standard Gauze and Combat Gauze ( $p < 0.05$ ).

Post-treatment blood loss was lowest for Celox Gauze 110ml; Standard Gauze 120ml; Combat Gauze 194ml. Requirement for resuscitation fluid given was also lowest for Celox Gauze 1,170 ml; Combat Gauze 2,000; Standard Gauze 1,825.

Post-treatment blood loss is lowest with Celox Gauze



Resuscitation fluid requirement was lowest with Celox Gauze



### Discussion:

In the conference discussion when the study was presented, the author ascribed the performance of Standard Gauze in this model to the level of experience of the packer. Also, the wounds appear to be narrower than, for example the reports from the US Army ISR or Rall et al (see above). No inflammation, necrosis, or deposition of dressing particles in vessel walls were observed. No histologic or ultrastructural differences were found between the study dressings.

This section reports on several published and anecdotal case reports, to give an idea of the types of patients who have been treated with Celox and what outcomes have been achieved.

## PUBLISHED CASE STUDIES

### Publication 1: Field experience with a chitosan-based haemostatic dressing

**Title:** Authors: Tan ECTH, Bleeker CP.

**Publication:** MCI Forum 3.(4): 11-15, 2011.

**Details:** This case series records use of Celox Gauze in six cases of traumatic bleeding and one case of postsurgical bleeding, over a six-month period in 2010.

- Three cases are from a Dutch air ambulance service, and four are from a Role 2 Enhanced facility in Afghanistan treating Afghan casualties
- Patient ages ranged from 20 to 76
- Injury sites were lower limb/groin (4), pelvic girdle (1), side of neck (1), ears and nose (1)
- Injury cause was RTA (2), fall from height (1), IED blast fragment (1), gunshot wound (1), crush injury (1), sharp amputation (1)

**Outcome:** In 6 out of 7 cases, Celox was successfully used to stop bleeding.

- Treatment in one case, the fall from height with blood coming from the ear and nose, was not successful
- The authors consider this to be because the product could not be brought close to the source of the bleeding, which was probably deeper in the head

**Discussion:** In some cases, Celox was left in place for 12-24 hours before further treatment. All successful cases recorded no further leaks or re-bleed during the period observed, and no complications (up to maximum five days). The authors concluded that **Celox Gauze is a safe and effective tool for external bleeding.**

### Publication 2: A pre-hospital technique for controlling haemorrhage from traumatic perineal and high amputation injuries

**Authors:** Quayle JM, Thomas GOR.

**Publication:** Journal of the Royal Army Medical Corps 157(4): 419-420 (2011).

**Details:** This journal records successful use of Celox by the British military in treating the perineal and high amputation

blast injuries. It is a technique description showing how to pack extensive perineal injuries, stating:

***“This technique has been used to good effect on recent deployments in the MERT helicopter by the second author.”***

## ANECDOTAL CASE STUDIES

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### Haemorrhage control in the battlefield.

**The Royal Marines is a highly specialised infantry force, trained to deal with a wide range of global threats as part of the UK's rapid reaction force.**

**In recent years, the Royal Marines have played a leading role in the war in Afghanistan. Here, former Royal Marine Commando Robert Jacomb recounts 24 hours from his tour of Afghanistan, and how using haemostatic gauzes helped him to stabilise several injured comrades.**

J Company, 42 Commando, is one of the three Royal Marines commando units and comprises some of the world's finest combat fighters. In 2006, 42 Commando was first deployed as part of Operation Herrick, a NATO initiative to stabilise Afghanistan against the Taliban and bring security to the region.

During the operation, marines engaged in frequent firefights with Taliban forces and were responsible for the protection and monitoring of strategic areas. In addition to participating in direct combat, marines led patrols to uncover improvised explosive devices.

*"It was in 2011 that I was caught in the thick of two incidents in just under 24 hours. While scouring the area with a metal*

*detector, a nearby patrol was hit by a bomb, resulting in multiple casualties and the death of two men. I led my team to the affected area to help any survivors.*

*One of the leading causes of preventable battlefield death is blood loss from extremity wounds. Traditionally, the light-weight medical kits supplied to those on operation just contained pressure dressings which, depending on the severity of the wound, could be applied by the injured soldier or marine themselves.*

*Medical kits have since evolved and now feature a haemostatic gauze like Celox, which can treat life-threatening bleeding fast,<sup>32</sup> without the need for a tourniquet. Time is critical when treating injuries in the field and, on dangerous missions, teams need to be equipped with the most effective tools and technologies, like Celox Rapid.*

*The minimal application time required when applying Celox Rapid makes it possible to attend to multiple people in a short and tight time-span. I was able to stop the heavy bleeding of my injured comrades and attempt to stabilise the casualties long enough for a helicopter to arrive and evacuate them."*

### Emergency care in Afghanistan

**Since 2001, over 3,500 soldiers from the Western Coalition have been killed in Afghanistan, while on the US-led Operation Enduring Freedom (OEF). Many fatalities have resulted from hostile action. Here, Troy Robson, former Sergeant Major in the Royal Marines, recounts his experience while on tour and the benefits of carrying the latest haemostatic technology.**

*"Prior to deployment, it's mandatory for marines to take part in mission-specific training, where I was taught emergency first aid and how to manage heavy bleeds.*

*Given the nature of the job, you can expect that, at some point in the field, you find yourself having to bandage yourself up - or even help an injured fellow comrade. Never at any point during training did I realise how beneficial this knowledge would become.*

*While on tour, our team was caught in a shoot-out. I followed my officer to take cover from our attackers in a nearby alley, but when we reached the alley, we were faced with another complication.*

*As I looked to my officer for support, I could see that one sleeve of his uniform was ripped - which, at the time, I could only assume was caused by a bullet. I'd seen several injuries like this, and from my experience, I had learned that most do not bleed out immediately. It can take a few seconds before any blood emerges*

*and so everything you do during that time is crucial.*

*I knew that, any second, the wound would begin gushing, but the wound area was collecting fallen dust and grit from the ongoing combat. While fast action is important, I didn't want to add to the injury by causing an infection or further damage. With limited options, I had no choice but to rip my own sleeve and try cleaning around the wound, using the little amount of water I had available.*

*Once I could see the full extent of the wound, it was clear that a standard bandage would not be enough to control the blood that was now flowing freely from my officer's arm. In my medical kit, I had a variety of light tools and equipment to help control heavy bleeding, but I knew there was only one piece of kit that would help stop the bleeding and give me enough time to get the officer to safety, where he could be treated by a medic. I grabbed the Celox and began compacting the gauze into my officer's arm. Unlike some of the other products in my kit, the Celox Gauze was easy to apply and didn't require assistance in doing so; not that I had the option. Considering the conditions, and that I'd already cleaned the wound, packing the wound with a Celox gauze was the most appropriate solution, especially as I knew that it would stay in place during movement, with no re-bleeding. This is because I had learned*

that Celox Gauze works by sticking to wet tissue in the wound to form an adhesive gel that can seal the wound and stop the flow of blood.

After applying the gauze, I was able to get the officer to base, where he was then transported to a hospital and given further treatment. While on operation, it's important to stay focused on the current mission, and so I did not receive an update on the officer's progress until

#### **Why haemorrhage control matters in motorsport**

**When you assemble a group of people with modified cars and ask them to drive at high speeds around a circuit of sharp turns and tight corners, accidents and injuries seem unavoidable. Despite this, motorsport accidents are infrequent, although they can be serious when they occur. Toni Murch, MCPara, HCPC registered paramedic and Business Development Manager at Celox Medical, recounts one incident where effective haemorrhage control was critical for survival.**

Motorsport is one of the most popular sports in the United Kingdom and, while racing venues uphold very high safety standards, employing trained emergency medical personnel for races, accidents may still happen. The critical factor is the speed and effectiveness of medical staff to respond when an accident occurs; something that can be a matter of life or death. For this reason, several medical

many weeks later. His arm didn't require amputation, and with physiotherapy, it was expected that he would make a full recovery. Following this incident, I used Celox Gauze for a number of other injuries, while on operation. Having the product in my kit gave me confidence in being able to handle any life-threatening injuries that could have arisen, whether in a team or by myself."

support teams at motorsport venues around the UK carry Celox products to provide fast, effective haemorrhage control, with Celox Rapid being the fastest-acting haemostatic gauze.

Meditech Global, the trackside emergency ambulance provider at the Rockingham Motor Speedway, recently reported a prime example of how its paramedics used Celox to save the life of a motorcycle racer.

*"During a race, a fault with a motorcycle's braking system developed. Unable to slow down, the racer turned through a high-speed corner and lost control of his bike. The momentum forced both the racer and his vehicle from the track, propelling them through the air until the rider thumped into the gravel, with his legs in the splits position. The speed and force were so intense that the rider continued through the air before crash landing on the Armco barrier.*

*While it was a relatively rare type of accident, it was extremely challenging to treat. The racer had suffered an open complicated fracture with a femoral laceration on the upper thigh and multiple fractures to his femur and pelvis. These fractures meant that the use of a tourniquet, which for many emergency responders is considered the first step when trying to control bleeding, was no longer an option. Failure to stem the flow of blood from the laceration would result in the racer bleeding out.*

*Time is of the essence with arterial bleeds, particularly as the time to treat after a motorsports accident is often not immediate. There was an unavoidable few minutes' delay between accident and emergency responders arriving at the scene due to the need to stop the race and clear the lanes.*

*With a two-minute haemorrhage already a reality, emergency treatment needed to be done quickly to stop the arterial bleed caused by the laceration. I immediately turned to Celox and it stopped the arterial bleeding within three minutes.*

*Given the severity of the wound, the air ambulance transferred the patient to Coventry emergency hospital. This was a 12-minute, high pressure, high vibration journey, with air-medics potentially ready for another haemorrhage situation on the flight. Celox kept the wound sealed without any re-bleeding en route from the raceway to the emergency hospital. The patient arrived safe and was taken straight into the operating theatre and was successfully treated."*



## CONCLUSION

As haemorrhage is still the primary cause of preventable death in many accident and wartime situations,<sup>4,5,6</sup> time is critical. Celox was used so successfully in these case studies because its innovative chitosan derived formulation creates a gel-like plug independently of the body's natural clotting mechanism. This seals over the point of bleeding and rapidly stops further blood loss.

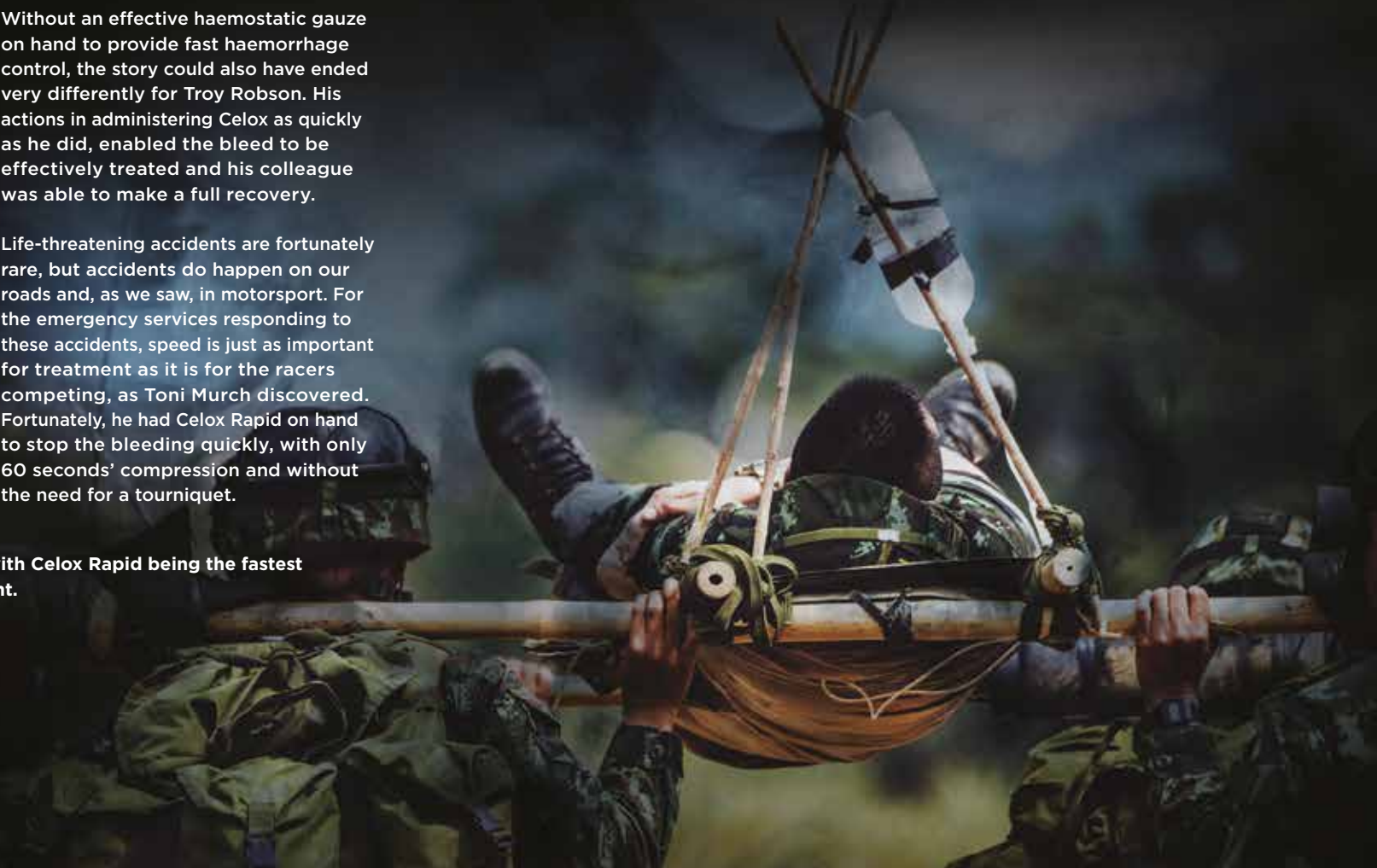
In combat situations, having Celox immediately at hand offers some reassurance to people such as former marine Robert Jacomb, that they can do their best to save their fellow comrades. Without an effective haemostatic gauze on hand to provide fast haemorrhage control, Jacomb's bravery may not have been enough to help save the lives that he actually did.

**Celox products stop bleeds and save lives, with Celox Rapid being the fastest haemostat – for when seconds really do count.**

Without an effective haemostatic gauze on hand to provide fast haemorrhage control, the story could also have ended very differently for Troy Robson. His actions in administering Celox as quickly as he did, enabled the bleed to be effectively treated and his colleague was able to make a full recovery.

Life-threatening accidents are fortunately rare, but accidents do happen on our roads and, as we saw, in motorsport. For the emergency services responding to these accidents, speed is just as important for treatment as it is for the racers competing, as Toni Murch discovered. Fortunately, he had Celox Rapid on hand to stop the bleeding quickly, with only 60 seconds' compression and without the need for a tourniquet.

## PRODUCT RANGE



With the primary cause of preventable death being haemorrhage,<sup>5,6</sup> it is essential that control of bleeding is rapid. In some circumstances, such as within the combat setting, the time available to control severe bleeding is limited. To enable effective life-saving treatment to be administered promptly, Celox Medical has developed a range of products, including Celox Rapid, which is the fastest-acting haemostat.

## CELOX™ RAPID

The only haemostatic gauze used by the UK Ministry of Defence, Celox Rapid is our fastest-acting haemostatic gauze that removes the delay by speeding up packing time<sup>27</sup> and reducing compression time to one minute, or until bleeding stops – typically saving over two minutes of treatment time, compared to other brands.

### Product benefits:

- Can work with one-minute compression or until bleeding stops<sup>21</sup>
- Faster packing time than another leading brand
- Rapid action reduces blood loss<sup>27</sup>
- Stops hypothermic bleeding<sup>37</sup> as found in severe traumatic injuries

### Ideal use:

- Life-critical bleeding injuries
- Critical situations where compression time is limited
- Emergency, pre-hospital care

**Indication:** Temporary external use by pre-hospital emergency responders, including military medics, civilian emergency services and other trained responders for the control of life-threatening haemorrhage.

**License classification:** Registered in many countries, including:

**Europe:** Medical Device Class III.

**North America:** 510k system clearance, Health Canada.

**Presentation:** 1.5m long x 7.6cm wide 'Z-fold' gauze.

**Thickness:** 0.68mm.

**Absorbency:** >500%.

**Administration:** Tightly pack to source of the bleeding, above skin level. Apply a firm compression for 1 minute or until bleeding stops.

**Details:** Celox Rapid contains Chito-R, a high-quality chitosan derivative, with the addition of a pharmaceutical-grade bio-adhesive. Chito-R is bonded to a high-density gauze which allows faster packing and greater adherence to surrounding tissue, compared to another popular brand.<sup>34</sup> Chito-R activated chitosan granules stick to wet tissue in the wound, improving the dressing's tamponade effect and controlling blood loss.<sup>21</sup> These faster and increased adherence performance advantages create a secure gel plug for maintained haemostasis.



## CELOX™ GAUZE

Recommended by the US Committee on Tactical Combat Casualty Care (CoTCC),<sup>36</sup> and the haemostat of choice by multiple NATO forces, Celox™ Gauze is designed to stop bleeding from arterial injuries, road traffic accidents and other life-threatening bleeding injuries.

### Product benefits:

- Highest observed survival in US DoD testing<sup>39</sup>
- Stops hypothermic bleeding<sup>37</sup>
- Stops severe traumatic bleeding
- Works independently of the body's clotting mechanism
- Not compromised by anti-coagulant medication i.e. warfarin, heparin<sup>27</sup>

**Ideal use:** Life-critical situations, including arterial injuries, gunshot wounds, road traffic accidents and other emergency bleeding injuries

**Indication:** Temporary external use by pre-hospital emergency responders, including military medics, civilian emergency services and other trained responders for the control of life-threatening haemorrhage.

**License classification:** Registered in many countries, including:

**Europe:** Medical Device Class III.

**North America:** 510k system clearance, Health Canada.

**Presentation:** 1.5m long x 7.6cm wide 'Z-fold' gauze and 3m x 7.6cm rolled gauze.

**Thickness:** 0.68mm.

**Absorbency:** >500%.

**Administration:** Tightly pack to source of the bleeding, above skin level. Apply a firm compression for three minutes, or until bleeding stops.

**Details:** Celox Gauze was developed to provide an improved method of delivering the proprietary granules and comprises macroscopic, high surface area, granular flakes, for maximum effectiveness.

Celox Gauze absorbs blood fluid, swells and forms a gel-like plug that covers the wound and stops the bleeding.

Independent comparative tests in the form of a meta-analysis reported a statistically significant improvement in survival with Celox Gauze, compared to alternative agents (p<0.5).<sup>19</sup>



## CELOX™ GRANULES

The original Celox product – proven to save lives and reliably stop arterial bleeding. Celox™ granules mould to the shape of the wound, even in complex shaped injuries.

### Product benefits:

- Significantly and quickly reduces blood loss<sup>38</sup>
- Treats irregularly shaped wounds and multiple injuries<sup>15</sup>
- Easy to use and remove, with residual chitosan-derived haemostat being naturally broken down<sup>8</sup>

### Ideal use:

- Arterial and venous bleeding
- Life-threatening bleeding
- Complex and deep wounds<sup>15</sup>

**Indication:** Temporary external use by pre-hospital emergency responders, including military medics, civilian emergency services and other trained responders for the control of life-threatening haemorrhage.

**License classification:** Registered in many countries, including:

**Europe:** Medical Device Class III.

**North America:** 510k system clearance, Health Canada.

**Presentation:** 15g sachets.

**Administration:** The Celox Granules mould to the shape of the wound to get firm pressure onto the source of the bleeding, even in complex shaped injuries. Just pour granules onto the bleeding site and fill the cavity. Apply a firm compression for five minutes, or until bleeding stops.

**Details:** In an independent trial by the US Navy, when compared to a competitor brand and Standard Gauze, Celox Granules was the only product to give 100% survival, and was also the only product to give robust clotting with no re-bleeding.<sup>39</sup>



## CELOX™ -A

Celox™-A is a unique applicator delivery system pre-packed with Celox granules and designed to get through a small entry wound, directly to the source of bleeding, in just a few seconds.

### Product benefits:

- Unique high-speed applicator
- Treats narrow wounds
- Bullet, blast fragments and stab injuries
- Gets to the source of the bleeding
- Stops hypothermic bleeding<sup>37</sup>

### Ideal use:

- Small entry wounds e.g. knife or bullet
- Penetrating wounds
- Shrapnel wounds from blasts

**Indication:** Temporary external use by pre-hospital emergency responders, including military medics, civilian emergency services and other trained responders for the control of life-threatening haemorrhage.

**License classification:** Registered in many countries, including:

**Europe:** Medical Device Class III.

**North America:** 510k system clearance, Health Canada.

**Presentation:** 6g granules in a pre-filled applicator.

**Administration:** Push the applicator into the wound and expel the Celox granules. Fill the cavity, cover and apply a firm compression for five minutes, or until bleeding stops.

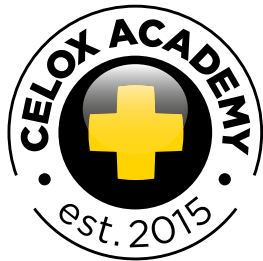
**Details:** Celox-A has excellent results in independent testing, demonstrating higher penetrating injury survival, compared with QuikClot® Gauze and Standard Gauze.<sup>40</sup>



# CELOX™ ACADEMY

In today's world, with continued global unrest, increased terrorism and violent acts, it is massively important that emergency responders, whether in the military or civilian services, are best equipped to recognise and manage catastrophic bleeding.

Celox Academy was established in 2015, to enable emergency responders to develop the skills, experience and confidence needed to save lives in highly stressful or hostile situations.



## Courses currently available:

### How to use: Celox haemostatic dressings

An online course available via the Celox Academy website. Registered learners can access this online resource and learn how to identify and treat an emergency haemorrhage situation, using Celox haemostatic dressings.

**Certificated, worth 1-hour CPD.**

### Haemorrhage Control Principles

A lecture-based course, delivered by approved course facilitators, in a classroom environment. Ideal as a refresher resource or for companies and organisations. Organised across various locations through Celox Academy's extended network of partners. Learners are taught to identify haemorrhage and treat it effectively through a variety of medical devices, including tourniquets, pressure dressing and haemostatic agents.

**Certificated, worth 2-hours CPD.**

### Manage catastrophic bleeding

An interactive course that combines theory and practice, to enable military and civilian emergency responders to recognise and manage catastrophic bleeding. The practical session includes prosthetic models with bleeding effects, so learners can demonstrate their skills in managing haemorrhage in almost real time.

**Certificated, worth 3-hours CPD.**

## About CPD

### (Continuous Professional Development):

**Celox Academy is a member of The CPD Certification Service. Established in 1996, The CPD Certification Service is the independent CPD accreditation centre, working across all sectors, disciplines and further learning applications.**



Their unique experience and history of working with training providers, professional bodies, academic institutions and corporate organisations enable us to provide emergency responders with an authoritative accreditation that supports the CPD policies of institutional and professional organisations on an increasingly global basis.

All Celox Academy courses are assessed and accredited against the universally accepted structured checklist which the CPD Service has developed over the past 20+ years and in line with international CPD protocols.

**For more information about our courses or to attend a course, please visit [www.Celoxmedical.com/CeloxAcademy](http://www.Celoxmedical.com/CeloxAcademy)**



# HOW WE CAN SUPPORT YOU

By now, you will have a good understanding of the clinical benefits that can be achieved from the Celox range of emergency haemostatic products – both from the published clinical data presented, and also from the testimonies that have been given in the case studies. These give first-hand accounts of the situations where Celox has been used and the successful outcomes for the patients who followed.

In addition to our Academy, Celox Medical also produces a range of materials to support healthcare professionals who care

for trauma patients in an emergency situation, including our illustrated step-by-step guides to using Celox products, as shown here. Please visit our website ([celoxmedical.com](http://celoxmedical.com)) to view our training videos and to download educational resources.

**At Celox Medical, we are here to help answer any remaining questions that you may have. Please get in touch with us on [celoxenquiries@medtrade.co.uk](mailto:celoxenquiries@medtrade.co.uk)**



# LOGISTICS

## Shelf-life

Each product pack is marked with an expiration date.

Product	Shelf -Life
Celox Granules	4 years from manufacture
Celox-A, Applicator	4 years from manufacture
Celox Gauze – 10ft roll and 5ft 'Z-fold'	5 years from manufacture
Celox Rapid – 5ft 'Z-fold'	5 years from manufacture

## Storage

Celox products should be stored in dry conditions at ambient temperature. No special storage conditions are required or indicated on the product labelling.

## Stability

Studies of Celox products stored at temperatures of 60°C and 40°C, and freeze-thaw studies, have all been completed, with no detrimental results to product or packaging reported.

## Caution

Discard any remaining product after use, as sterility will be compromised and re-use potentially poses a risk of infection.

## Ordering

Celox is sold through a network of distributors. To find out who represents Celox in your area, please contact [celoxenquiries@medtrade.co.uk](mailto:celoxenquiries@medtrade.co.uk) detailing what country you are in, and with details about your intended use.

## Individual product codes:

Other language packs are also available, please contact us for further information.

- **Celox Rapid 5' Z-Fold Gauze:**  
Product code: FG08839021
- **Celox Gauze:**  
Product code: FG08839031 (z-fold, 5ft)  
FG08834011 (rolled, 10ft)
- **Celox Granules:**  
Product code: FG08830181 (15g)
- **Celox-A Applicator with 6g Granules:**  
Product code:  
**EU:** FG08832021A;  
**USA:** FG08832071A

## Further information

To request a Material Safety Data Sheet (MSDS), or for any other information on the Celox product range, please contact:

**Nick Tsiakas, Marketing Manager.**

**Telephone:** +44 (0)1270 503 871

**www:** <https://celoxmedical.com>

**e-mail:** [nick.tsiakas@medtrade.co.uk](mailto:nick.tsiakas@medtrade.co.uk)

**Twitter:** <https://twitter.com/CeloxHaemostat>

**Facebook:** <https://www.facebook.com/pages/Celox/117577136964>



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