POST MARKET CLINICAL FOLLOW UP USER SURVEY REPORT

Assessment of real world performance of CELOX™ Hemostat Device Family by trained emergency responders in 2022

CELOX™ Hemostat Devices achieved hemostasis after the first application in 99.3% of cases carried out by respondents including ER physicians, medics, nurses and other emergency personnel.

The study covered 292 cases involving single or multiple wounds ranging from cutting / piercing and blunt trauma to gunshots and RTAs – 85% of which were described as involving 'moderate to severe bleeding'.

There were no adverse events for any of the products including those used to treat patients on anticoagulation therapy.

KEY FINDINGS

99.3% success rate, 290/292 cases achieved hemostasis after the first application – even those involving the most severe bleeding cases

100% success rate in cases using CELOX Rapid, the most used product

100% success rate on safety: no adverse events reported when using any of the products

99% of respondents across the whole study rated the CELOX™ family of Hemostat Devices 'good' or 'excellent'

Objective

The study was designed to assess safety and performance of the CELOX™ range including CELOX™ Hemostatic Granules, CELOX™-A Applicator, CELOX™ Gauze, CELOX™ Z-Fold Gauze and CELOX™ Rapid Z-Fold Gauze.

Specifically, the criteria were:

- Performance of the device on first application in stopping the bleeding (achieving hemostasis) of primary bleeding wound sites
- Safety of the device – through the collection of adverse events over the life cycle of use from application to removal.

Methodology

Data was gathered from surveys completed by trained emergency responders who had used the devices to treat life-threatening primary bleeding in 292 cases.

Based in England, approximately 46% were physicians and 38% nurses, with 16% in other roles. A maximum of 10 survey submissions were permitted per trained emergency responder.

The majority of respondents (91%) had used three or more different classes of CELOX devices in the previous 12 months and 86% of respondents had used more than 50 CELOX devices in the previous 12 months.

Wound type and severity

Most wounds were single (64%) and caused by cutting and blunt trauma (43%), although there were also cases of multiple wounds and other causes of injury such as firearms / ammunition, explosions, road accidents and surgery.

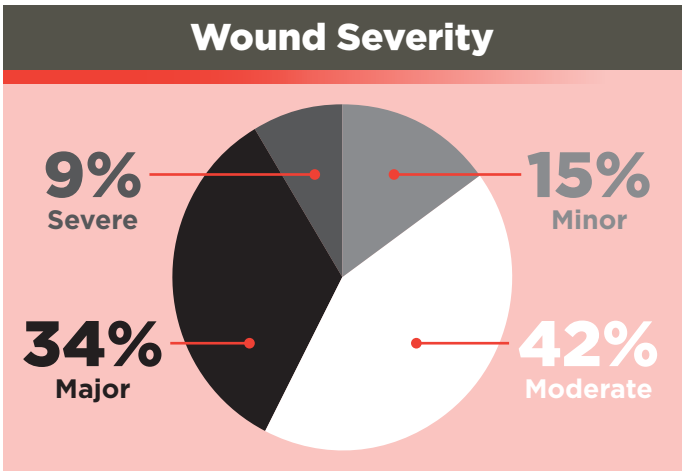
Injury mechanisms the Celox devices were used for:

INJURY MECHANISM	SINGLE WOUND	MULTIPLE WOUNDS	TOTAL (N)	TOTAL (%)
Cutting and piercing instruments and objects	98	27	125	43%
Blunt trauma	40	31	71	24%
Firearm / ammunition	28	5	33	11%
Explosive	2	20	22	8%
Road accident	2	12	14	5%
Surgery	5	2	7	2%
Not specified	20	0	20	7%

Wound depths and lengths were recorded: in terms of depth, 49% were below dermis level (31% to fascia level and 18% to muscle level) and most (73%) had a length of up to 10cms. The most registered primary wound location was the lower leg (25%).

PRIMARY WOUND LOCATIONS	N
Lower leg	119
Upper leg	107
Chest	10
Back	97
Head	64
Other	87
Total	**484**

Wound severity was calculated based on an NISS-score, with the majority (248 or 85%) of cases involving moderate to severe bleeding.



Performance

In 290/292 of the cases, hemostasis of primary (life-threatening) bleeding wound sites was achieved after the first application of one of the devices – even in cases of the most severe bleeding.

The most used product was CELOX Rapid - applied in 84 cases - followed by CELOX Gauze (76), CELOX Z-Fold (55) CELOX Granules (44) and CELOX-A (33).

Incorrect application

In the two cases where hemostasis was not achieved, the products were used incorrectly.

The first case involved a 5-10cm cutting / piercing injury to the patient's back, down to the fascia (as well as a second lesser injury to the chest). The responder used CELOX Granules which are designed primarily for large surface wounds over which the granules can be poured: using a CELOX Gauze to pack this wound with moderate bleeding would have been more suitable.

CELOX Gauze would also have been a better product in the second case – a gunshot dermis head wound with moderate bleeding. The responder used CELOX-A which is actually designed to allow for better control of granule application directly to the source of bleeding.

Safety

In terms of safety, there were no adverse events reported when using any of the products.

CELOX™ Rapid

Respondents recorded the performance of CELOX Rapid with a 100% success rate in the cases in which it was used.

It was the most frequently used product across the whole study which recorded that it exceeded expectations in terms of time to hemostasis.

CONCLUSION

Clinical performance of the CELOX range proves to be highly successful in addressing multiple wounds in the hands of multiple clinical personnel controlling moderate to severe bleeding.
99.3% of the survey participants said hemostasis was achieved after the first application – even in cases involving the most severe bleeding.
Every responder using CELOX Rapid said it was 100% successful, and 99% across the survey rated the CELOX family 'good' or 'excellent' with a 100% safety record; the survey conclusion is a clear endorsement of the effectiveness of CELOX in clinical practice – particularly the highly pressured and demanding environment of the Emergency Department.

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