CELOX RAPID POST MARKET CLINICAL SURVEY REPORT

Assessment of real-world performance of CELOX™ Rapid by emergency physicians and trained emergency responders 2022

CELOX™ Rapid achieved hemostasis after the first application in 100% of cases carried out by respondents including ER physicians, medics, nurses, and other emergency personnel.

This sub-analysis from a larger CELOX™ 292 study covered 84 cases involving single or multiple wounds ranging from cutting/piercing and blunt trauma to gunshots and road traffic accidents – 90% of which were described as involving 'moderate to severe bleeding', 21% of which were on anticoagulation therapy.

There were no adverse events recorded.

KEY FINDINGS

100% success rate, 84/84 cases achieved hemostasis after the first application using CELOX™ Rapid – even those involving the most severe bleeding cases

No adverse events reported when using CELOX™ Rapid

All respondents across the sub-analysis rated CELOX™ Rapid 'good' or 'excellent'

Objective

The original Post-marketing Follow-up study was designed to assess safety and performance of the CELOX™ range of Hemostat Devices. Data was gathered from surveys completed by trained emergency responders who had used CELOX™ range to treat life-threatening primary bleeding in 292 cases. The most-used product was CELOX™ Rapid (84 cases). This sub-analysis specifically focused on an assessment of CELOX™ Rapid.

Specifically, the criteria were:

- Performance of CELOX™ Rapid 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 84 cases from 41 responders in 41 separate locations.

Based in England, approximately 44% were physicians and 42% nurses, with 14% in other roles. A maximum of 10 survey submissions were permitted per trained emergency responder.

All respondents had used two or more different classes of CELOX devices in the previous 12 months and 90% of respondents had used more than 50

CELOX devices in the previous 12 months.

Wound type and severity

Most wounds were single (54%) and caused by cutting and blunt trauma (35% and 35%, respectively), although there were also cases of multiple wounds and other causes of injury such as firearms or ammunition (4%), explosions (14%), road accidents (5%), and surgery (2%).

Injury mechanisms the Celox devices were used for:

INJURY MECHANISM	SINGLE WOUND	MULTIPLE WOUNDS	TOTAL (N)	TOTAL (%)
Cutting and piercing instruments and objects	21	8	29	35%
Blunt trauma	16	13	29	35%
Firearm / ammunition	0	3	3	4%
Explosive	1	11	12	14%
Road accident	0	4	4	5%
Surgery	2	0	2	2%
Not specified	5	0	5	6%

In two patient's multiple primary wound locations were identified, resulting in 87 primary wounds sites from in 84 subjects.

Wound depths and lengths were recorded. Most wounds (70%) had a length of 10 cm or less. In terms of depth, 53% of wounds were at the level of the dermis, and 47% were below dermis level (30% to fascia level and 17% to muscle level). Most primary wound locations were the upper leg (29%) followed by lower leg (26%).

PRIMARY WOUND LOCATIONS	N
Lower leg	23
Upper leg	25
Chest	0
Back	18
Head	10
Other	11
Total	**87**

Wound severity was calculated based on an NISS-score, with the majority (90%) of cases involving moderate to severe bleeding. In 21% of cases, anticoagulation therapy was used.

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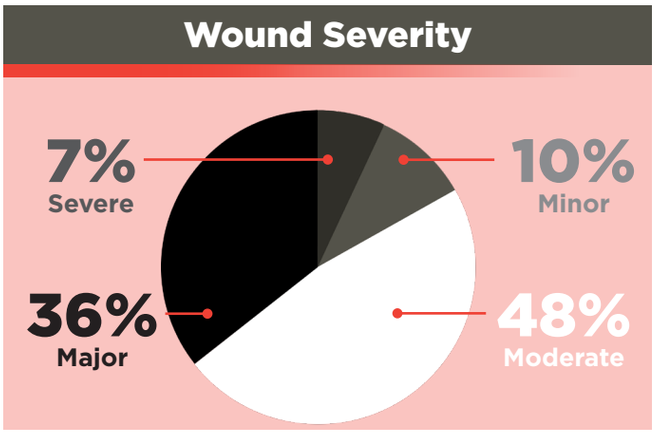

Performance

In 84/84 (100%) of the cases, hemostasis of primary (life-threatening) bleeding wound sites was achieved after the first application of one device – even in cases of the most severe bleeding.

User experience

User experience of CELOX™ Rapid was calculated by asking respondents to rate their experience with the device on a 5-point scale, ranging from 'very poor' to 'excellent'. All ratings given were either 'good' (24%) or 'excellent' (76%).

Safety

There were no (0%) adverse events reported when using CELOX™ Rapid.

CONCLUSION

Clinical performance of CELOX™ Rapid proves to be highly successful in addressing multiple wounds in the hands of a wide range of clinical personnel needed for controlling moderate to severe bleeding. 100% of survey participants of this sub-analysis said hemostasis was achieved after the first application – even in the cases involving the most severe bleeding.

Every responder using CELOX™ Rapid said it was 100% successful, and 100% rated CELOX™ Rapid 'good' or 'excellent', with a 100% safety record.

The conclusion drawn from the sub-analysis strongly supports the efficacy of CELOX™ Rapid in real world clinical settings, especially in the high pressure and challenging conditions of the Emergency Department.

CELOX™ Rapid is proven to control moderate to severe bleeding.

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CELOX™ RAPID