CELOX RAPID X-RAY GAUZE - DESIGN FOR EXTREME AUSTERE MILITARY ENVIRONMENTS

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INTRODUCTION

When designing trauma medical devices for intended use, the testing must factor in **extreme austere military environments** such as combat zones, remote deployments, arctic/desert operations, maritime, airborne). The design requirements need to meet operational, environmental, and regulatory demands far beyond civilian hospital standards.

In military planning, **"extreme austere conditions"** usually refers to environments where troops operate with minimal infrastructure, limited resupply, and severe environmental stress. In terms of **temperature**, this typically includes both extreme cold and extreme heat that significantly affect human performance, equipment, and mission capability.
Hot temperatures are often encountered in desert or arid regions such as parts of the Middle East or the Sahara Desert. These may occur between **100°F to 130°F (38°C to 54°C)** air temperature.

Cold, freezing temperatures are common in Arctic or high-altitude regions like Alaska, Siberia, or mountainous terrain such as the Hindu Kush. These may occur between -20°F to -60°F (-29°C to -51°C). **CELOX™ Rapid X-Ray Gauze** was developed to ensure its hemostatic mode of action is not impacted by these extreme conditions to maximise efficacy when needed.

OBJECTIVE

The objective of this study was to assess CELOX Rapid Gauze X-Rays's mode of action and packaging after being subjected to freezing, ambient and hot environmental temperatures.

METHODS

The device was subjected to the following conditions for a minimum of one week, -57oC (-70.6oF), 25oC (77oF), 55oC (131oF). After acclimatising at these conditions the packaging and device were assessed for the following performance parameters (n=6).

Packaging:

1. Lot number and product expiration date readability
2. Physical assessment of packaging ensuring no tears or damage.
3. Packaging can be torn open with and with the user wearing gloves
4. All artwork can be visually read with no damage
5. The above were assessed to ensure that at the point of use the medic can access the device quickly and have all relevant information available if required related to user, intended patient population and warnings/contraindications.

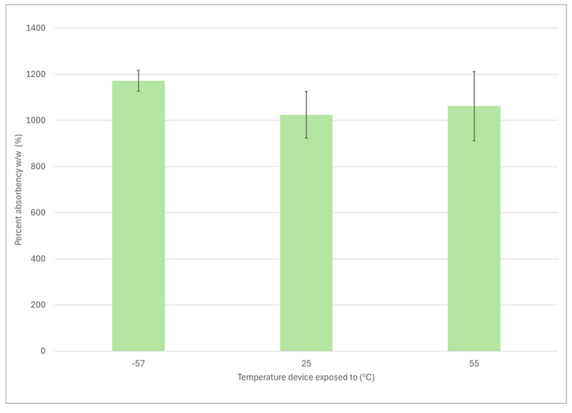
Device mode of action

CELOX Rapid X-Ray Gauze was assessed for:

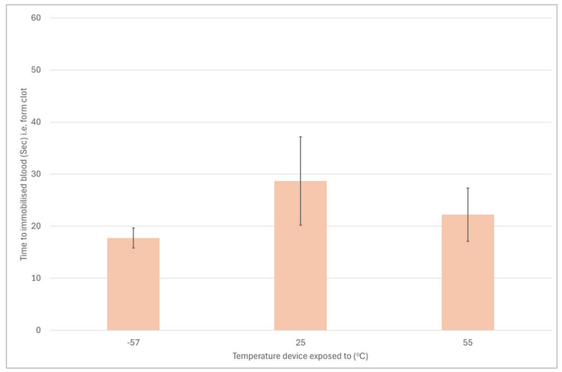
1. Gelling on contact with fluid. The device was subjected to fluid and visual assessment on the ability of the haemostatic granules on the Gauze to gel was determined.
2. Absorbency. The device was submerged in saline and the total absorbency potential determined.
3. Blood immobilisation. The granules coated in the device were subjected to heparinised rabbit blood to determine the speed in which the granules absorbed the blood and formed a gel plug.
4. Wet tensile strength. The device was submerged in saline to ensure all elements were fully saturated. The wet tensile strength i.e. the force to brake, was assessed using a tensiometer and load cell.
5. Cuttability and tear ability. The device was cut and torn to determine whether the changes in temperatures impacted this user requirement.

The above performance requirement were assessed to ensure that the device mode of action was not impacted by the different extreme temperatures.

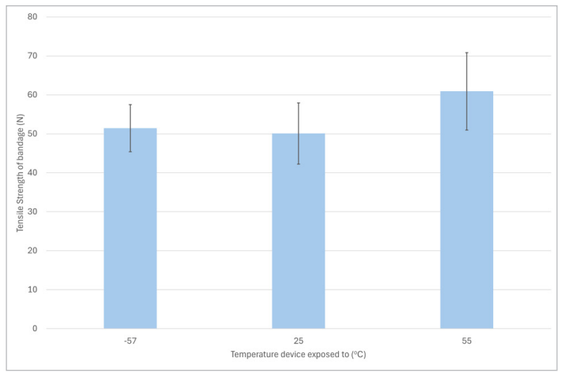
RESULTS



Graph 1 – Absorbency of device



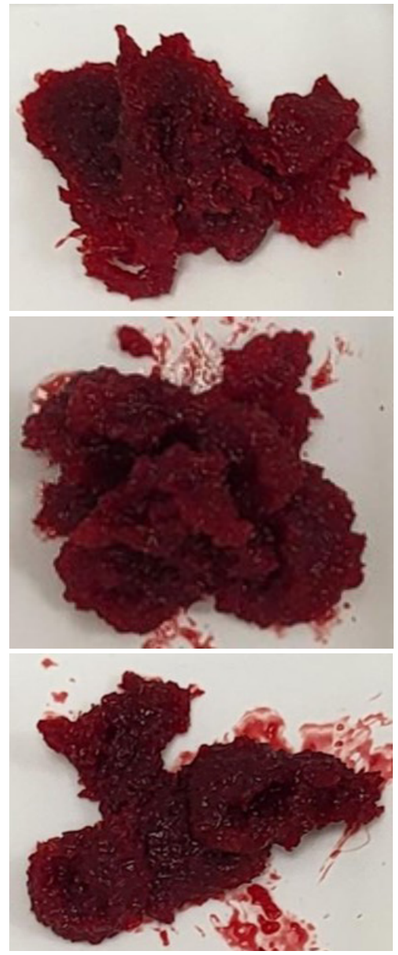
Graph 2 – Blood immobilisation of haemostatic granules



Graph 3 – Wet tensile strength

Performance parameter	Environmental condition		
	-57°C	25°C	55°C
Lot and Expiration readability	Pass	Pass	Pass
Physical assessment of packaging	Pass	Pass	Pass
Packaging can be torn open	Pass	Pass	Pass
Artwork visibility	Pass	Pass	Pass
Granules gel on contact with fluid	Pass	Pass	Pass
Gauze can be torn	Pass	Pass	Pass
Gauze can be cut	Pass	Pass	Pass

Table 1 – packaging and device visual and physical assessments



Photographs 1 – visual pictures of gelled granules after blood immobilisation testing (-57oC (-70.6oF), 25oC (77oF), 55oC (131oF) – left to right)

CONCLUSIONS

This study demonstrates that **CELOX™ Rapid X-Ray Gauze** maintains both its packaging functionality and its performance efficacy when subjected to extreme environments. These performance parameters are critical when used in austere environments and ensure that the medic or user can obtain haemostasis as quickly as possible in order to increase casualty survival.

References - 1. Lord S, Lee J. Critical Care in the Austere Environment. Crit Care Clin. 2024 Jul;40(3):451-462 . 2. Rund TJ. Casualty evacuation in arctic and extreme cold environments: A paradigm shift for traumatic hypothermia management in tactical combat casualty care. Int J Circumpolar Health. 2023 Dec;82(1).