THERMARMOUR®

Hypothermia Evacuation Bag 2.0

UDI MD CE UK CA

Product Code	**0B605-56230---0VEM57**
Basic UDI-DI	**506088527THERMF8**
GTIN	**05061035930149**
Size	**56cm x 230cm**
Material	**THERMARMOUR Xtreme 8-layer laminated fabric**
Buy Online	**www.interweavetextiles.com/products/patient-warming/**

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HYPOTHERMIA EVACUATION BAG 2.0: Instructions for use

1. UNPACK

2. SECURE

3. EXAMINE

4. EVACUATE

- Lay the patient on the inner bag base, making sure the face access point is positioned around the face.
- Close the zips and adjust the straps to secure the casualty as required.
- Four access panels allow for easy casualty monitoring and treatment, while minimising heat loss.
- Any patient records/key information can be recorded and stored using the transparent triage pocket.
- To aid with casualty transportation, there are 8 carry handles as well as a harness for dragging.

Intended Purpose: THERMARMOUR is intended to help minimise loss of body heat and can be used continuously as appropriate to the user's needs and environment.

Indications For Use: Temperature management of trauma casualties, patients in the perioperative setting or those with/or at risk of hypothermia.

Patient Target Group: Those experiencing or vulnerable to hypothermia.

Users: Suitable for use by both laypersons and medical professionals.

Considerations: THERMARMOUR is designed as a passive warming aid and should not be used as the sole intervention or a substitute for professional medical treatment. In cases of moderate/severe hypothermia, extreme environmental exposure, or physical injury, additional warming measures and/or medical care should be sought as needed.

Clinical Benefits: When used in hypothermia-inducing environments, THERMARMOUR demonstrated a maximum temperature change of 0.66°C and reduced the incidence rate of hypothermia to 1.8%.

Performance Characteristics: Studies concluded that, in a medical setting, THERMARMOUR was comparable to Forced Air Warming across all measured outcomes, including maximum temperature change, post-anaesthesia care unit stay duration and the incidence of shivering, hypotension, arrhythmias and surgical site infections. In the clinical studies analysed, THERMARMOUR also demonstrated a favourable thermal discomfort rate, improved hypothermia outcomes and a shorter time to achieve target temperatures.

Storage, Handling and Disposal: Keep dry and store away from direct sunlight until needed. THERMARMOUR products are for single patient use, should be discarded once soiled and are not intended to be used on multiple patients. Please follow local guidelines to ensure all components are recycled or disposed of safely, as misuse may pose a suffocation risk.

Risks, Precautions and Contraindications: Following trial and testing, no known residual risks or side effects have been identified. However, incorrect reuse may increase the risk of skin irritation and abrasions. THERMARMOUR should not be used in conjunction with forced air warming. General Safety and Performance Requirements (GSPRs) Conformity Analysis available on request. Risk Analysis available on request.

If there is any damage identified upon receipt, please contact **sales@thermarmour.com** before use.

[1] Clinical Evaluation Report available on request.
[2] Risk Analysis available on request.

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If you have any safety concerns regarding the device, please inform THERMARMOUR and the MHRA.

2025-08-04 V6 LT/AB

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Interweave Textiles Ltd is a company registered in England & Wales: 05267141

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EC REP

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