SAFEGUARD MEDICAL

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URGENT: MEDICAL DEVICE RECALL

Battle Bandage® Compression Dressing

September 2, 2026

Dear Customer,

The purpose of this letter is to advise you that Safeguard Medical is voluntarily recalling specific lots of the Battle Bandage (Catalogue Number 32-700). The Battle Bandage is intended to provide a sterile pad combined with a transparent high compression wrap to control non-life-threatening hemorrhage at the point of injury. The Battle Bandage may have been purchased by you as either a single part or as a component of a kit – this recall is ONLY for the Battle Bandage, not for any kit containing the Battle Bandage.

This voluntary action is being taken out of an abundance of caution to ensure continued patient safety.

Recent internal testing identified a manufacturing process issue affecting the device's sterile pad, potentially causing the sterile pad to degrade over time. This degradation may cause unwanted foreign material to be introduced inside the wound. This degraded state has been observed in a limited number of units, but because it may complicate secondary wound care, we are initiating a field action for all potentially affected lots.

The affected product may have been purchased either as a single end item OR as a subcomponent of a kit. Please refer to the "affected parts" table as you may have more than one location where the affected product will be found.

Reason for the Voluntary Recall

The Battle Bandage has been found to have a manufacturing process issue where the degraded sterile pad may introduce unwanted foreign bodies into the wound that may complicate secondary wound management.

Risk to Health

A defect in the product may result in small gauze remnants adhering to or remaining on or in close proximity to the wound where the product was applied. The gauze remnants are visually apparent and readily detectable upon visual observation. The presence of gauze pieces could possibly lead to more complex wound healing, including by secondary intention (with resultant scar tissue formation) and may require further wound exploration and irrigation to fully remove retained pieces. Any retained product could result in an increased wound infection risk.

Actions to be taken by the Customer:

Direct Customers:

1. Upon receipt of this recall notice, customers and users must immediately quarantine and remove all Battle Bandages from all points of use, including emergency kits, ambulances, storage and training areas.
2. If the Battle Bandage was purchased as a component of a kit, physically open the kit, remove the Battle Bandage and place into quarantine.
3. Discontinue use of any devices from the recalled lots, even for training, and verify your inventory against the lot numbers listed in this recall notice to identify all affected products.

4. Please complete the attached Recall Acknowledgement and Receipt Form and return it to Safeguard US Operating LLC per the instructions on the form.

Product and Distribution Information
A complete list of the products received by your organization that are subject to this recall can be found in the Acknowledgement and Response Form attached to this letter.

Action by Safeguard US Operating LLC :
Safeguard US Operating LLC is committed to ensuring minimal disruption to your operations and readiness during this recall process. Upon receipt and processing of your completed Recall Acknowledgement and Receipt Form, we will promptly evaluate your replacement product requirements and expedite shipment of your requested replacement(s) to maintain your medical operational and readiness requirements.

OTHER INFORMATION:
Any questions directly associated with this recall should be directed to:

- Any questions directly associated with this recall should be directed to:
  Daniel Heffernan (recall coordinator) or
  Kimberly Reed, Director of Global Regulatory Affairs
  13359 Reese Blvd. East
  Huntersville, NC 28078
  Email: recalls@safeguardmedical.com Phone: 855-428-6074
  Website: safeguardmedical.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the appropriate Global Regulatory Agency (example: EU Authorized Representative or Competent Authority) or FDA's MedWatch Adverse Event Reporting program either online (www.FDA.GOV/MEDWATCH) , by regular mail or by fax.