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OPERATIONAL BULLETIN

Bulletin #	Title		Date Issued
#2026-08-25-01	Improperly Packaged Airway Devices and Supply Chain Integrity		August 25, 2026
Superseded	**Released By:**	**Source:**	**Pages**
N/A	Maine EMS	Rules	2
Approved By:	Wil O'Neal, Maine EMS Director		

Overview: Maine EMS recently discovered airway devices improperly delivered and stored in household vacuum-sealed bags, which compromise sterility, remove traceability, and risk damaging the equipment. Agencies are strongly urged to immediately inspect their inventory to ensure all devices remain in their original manufacturer packaging and are sourced exclusively from genuine, authorized medical distributors. Please quarantine and report any repackaged or suspicious equipment.

Issue

During a recent routine ambulance inspection, EMS inspectors identified supraglottic airway devices (specifically, Size 0 and Size 1 King Airways) stored outside of their original manufacturer packaging. As demonstrated in the image below, the devices were found sealed in household food preservation bags (FoodSaver® vacuum pouches) with hand-written labels. The agency stated that the devices may have been delivered to them in this condition by a supplier.

Risks of Repackaged Medical Devices

Maintaining the physical integrity and cleanliness of medical equipment is paramount for patient safety. Repackaged or improperly stored devices present several critical risks:

- **Compromised Sterility and Cleanliness:** Invasive airway devices must be maintained in their original, manufacturer-sealed packaging to prevent contamination. Household vacuum bags do not meet medical sanitation standards.
- **Loss of Traceability:** Original packaging contains vital information, including lot

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numbers, manufacturing dates, and expiration dates. Without this data, agencies cannot comply with FDA safety recalls or verify the safe shelf-life of the device.

- **Physical Damage:** The uncontrolled negative pressure of commercial vacuum sealers can distort, compress, or compromise the soft plastics, inflation lines, and cuffs of airway devices, potentially leading to catastrophic device failure during resuscitation.
- **Unauthorized Distribution:** Receiving equipment in non-standard packaging is a strong indicator of unauthorized distribution, gray-market sourcing, or potential counterfeit products.

Recommended Actions for EMS Agencies

To ensure regulatory compliance and operational readiness, all agencies should take the following steps immediately:

1. **Inventory Inspection:** Inspect all airway rolls, jump bags, and apparatus stock. Ensure all medical devices, especially invasive airways, are housed in their original, uncompromised manufacturer packaging. Any improperly packaged devices must be removed from service immediately.
2. **Supply Chain Verification:** Review all incoming deliveries from medical supply vendors. Devices should only be purchased from reputable, authorized medical distributors. If you receive equipment that appears tampered with, repackaged, or is lacking lot numbers, do not place it in service.
3. **Mandatory Reporting:** If your agency discovers devices packaged similarly to the one shown in the image below or otherwise improperly repackaged, quarantine the items immediately. Contact your Regional EMS Manager and consider filing a report with FDA MedWatch to prevent further distribution of potentially unsafe equipment.

Note

Combining items into Ziploc® or other similar sealed bags to customize setup by an agency is allowed, provided items remain in their original packaging, are not deformed or compromised, and the earliest expiration is clearly indicated. Please direct any questions to your Regional EMS Manager.