Small Packages, Significant Risks

A Failure-Focused Audit of Peel Pouch Integrity

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Introduction

Communication patterns revealed that end users—such as the Operating Room (OR)—rarely report compromised peel pouches back to the Sterile Processing Department (SPD).
While damaged wrapped trays or rigid containers are often reported / documented, issues with peel pouches tend to be identified internally by SPD staff during self-auditing procedures, rather than reported by clinical end users (OR/clinics). From July 2023-August 2024, zero reports of compromised pouches were reported to SPD at the study locations.
This retrospective, failure-focused, cross-sectional study was conducted over one month in August 2024 across two healthcare facilities. The findings highlight the need for stronger feedback loops between OR and CSSD, ensuring that all instances of compromised sterility—no matter the packaging type—are consistently reported and addressed.

Objective

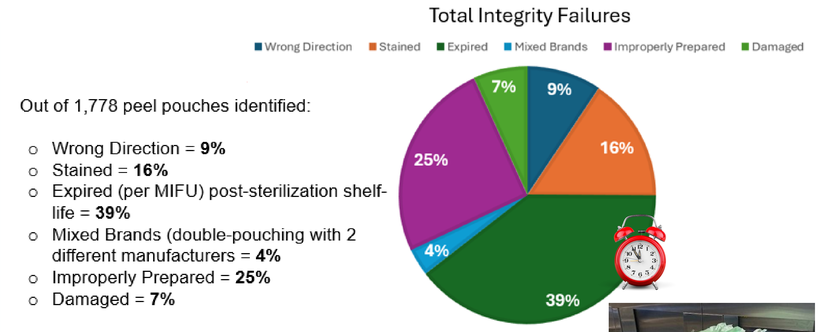
To characterize where, how, and by whom compromised peel pouches are identified and reported within healthcare facilities; to identify contributing factors and common types of pouch integrity failures; and estimate related financial impacts- particularly for robotic instrumentation.

Methodology

1. To streamline data collection and ensure consistency across sites, the team utilized the Microsoft Forms App, which allowed participants to record observations directly from a cell phone or computer. This digital collection method improved accuracy and real-time data entry across the two study sites.

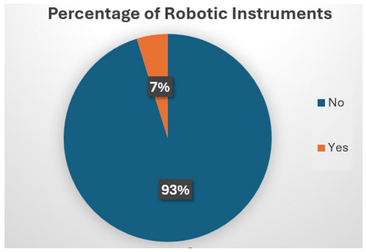
2. Each form captured detailed information for every compromised pouch, including:
Pouch manufacturer and type of seal (heat seal, roll stock, or self-seal).
Reason for failure, such as outdated packaging, damage, or improper preparation.
Processing details, including date, whether the pouch was single or double, and the type of instrument or device contained.
Weight of the package when recorded, as heavier contents can influence seal stress.

3. The data shown here indicates that among 1,778 pouches examined, 47% were self-seal, 36% roll stock, and 17% heat-seal, reflecting a broad representation of common packaging types used in healthcare facilities.



Out of 1,778 peel pouches identified:

- Wrong Direction = **9%**
- Stained = **16%**
- Expired (per MIFU) post-sterilization shelf-life = **39%**
- Mixed Brands (double-pouching with 2 different manufacturers = **4%**
- Improperly Prepared = **25%**
- Damaged = **7%**



Financial Impact (USD) Robotics Instrumentation (Peel Pouching) Hospital #1

Device	Number of Impacted Devices With (Integrity Failures)	Acquisition Cost (Average) Each	# of Allowed Sterilization Cycles Per IFU (Average)	Cost per Use (Average) Each	Financial Impact to Operational Budget (Integrity Failures)
Robotic Instrument Arms	59	$3,200.00	12	$266.67	$15,733.33
Robotic Cords	14	$284.00	25	$11.36	$159.04
Total Cost of Capital Expenditure					$15,892.37

Financial Impact (USD) Robotics Instrumentation (Peel Pouching) Hospital #2

Device	Number of impacted devices with (Integrity Failures)	Acquisition Cost (Average) Each	# of Recommended Sterilization Cycles Per IFU (Average)	Cost per use (Average) Each	Financial Impact to Operational Budget (Integrity Failures)
Robotic Instrument Arms	32	$3,200.00	12	$266.67	$8,533.44
Robotic Cords	7	$284.00	25	$11.36	$79.52
Total Cost of Capital Expenditure					$8,612.96

Results

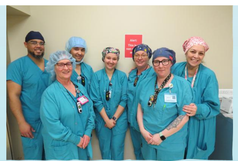
The results section presents the key findings of the study. It summarizes the data analysis and presents the results in a clear and concise manner. The results may be presented in various formats, such as tables, graphs, or charts, to enhance understanding. It is important to highlight the most significant findings and avoid unnecessary details.

Contributing Factors

The data revealed two primary contributing factors to pouch integrity failures:
Expired pouches – items exceeding their validated post-sterilization shelf life.
Improperly prepared or sterilized pouches – due to process or human error.
A significant theme identified was education gaps:
Many technicians had little to no training on proper pouching techniques or post-sterilization shelf-life requirements outlined in the MIFU.
In several cases, staff were unaware of changes in pouch manufacturers, which affected sealing performance.
Additionally, improper heat-sealer temperature settings were observed—too low to achieve compliant seals.
Finally, improper storage racks and holders contributed to seal damage, particularly with long robotic arms and laparoscopic instruments. Some racks were too tight, short, or improperly configured, causing flexing and stress on sealed edges.
These findings reinforce the need for comprehensive technician training, proper equipment calibration, and fit-for-purpose storage solutions to maintain packaging integrity and reduce waste.

Conclusion

The findings from this study emphasize the critical importance of communication, adherence to standards, and staff competency when managing peel pouches as sterile barrier systems.
Most instances of compromised sterility were detected internally by the CSSD rather than reported by end users. This highlights a communication gap and the need for greater collaboration between CSSD, the Operating Room (OR), and other clinical areas.
Although peel pouches are convenient and cost-effective, they are highly susceptible to human error. Maintaining integrity requires strict compliance with Manufacturer Instructions for Use (MIFU) and standards such as AAMI ST79 and AORN guidelines.
Ongoing staff training, documented competency verification, and proactive communication across departments are key to minimizing risk. Reinforcing correct pouch selection, sealing, handling, and inspection practices strengthens both patient safety and the overall reliability of sterile processing operations.



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