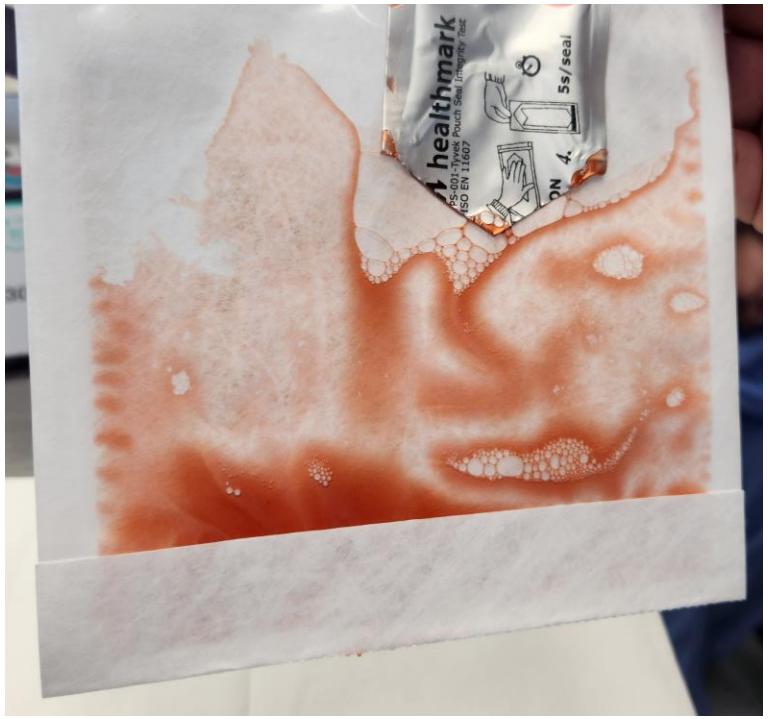
HONG KONG ASIAWORLD-EXPO 亞洲國際博覽館

3RD TO 6TH DECEMBER 2025

World Federation for Hospital Sterilisation Sciences

# Ensuring Sterile Safety: Pouch Seal Integrity in Healthcare Facilities

- A review of two studies

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# AIM – Study # 1

**When the Seal Breaks: Evaluating the Factors Behind Packaging Integrity Failures**

- To evaluate the effectiveness of current practices, equipment maintenance protocols & user techniques to provide insights into mitigating seal failures.
- Investigate & identify the underlying factors contributing to seal integrity issues observed in heat-seal and self-seal pouches within healthcare facilities.
- By highlighting critical deficiencies, the study aims to equip educators and healthcare leadership with the necessary knowledge & strategies to enhance sterile processing standards & safeguard patient safety.
- This study is a retrospective cross-section 12-month study that was conducted from January to December 2023, across 39 healthcare facilities.

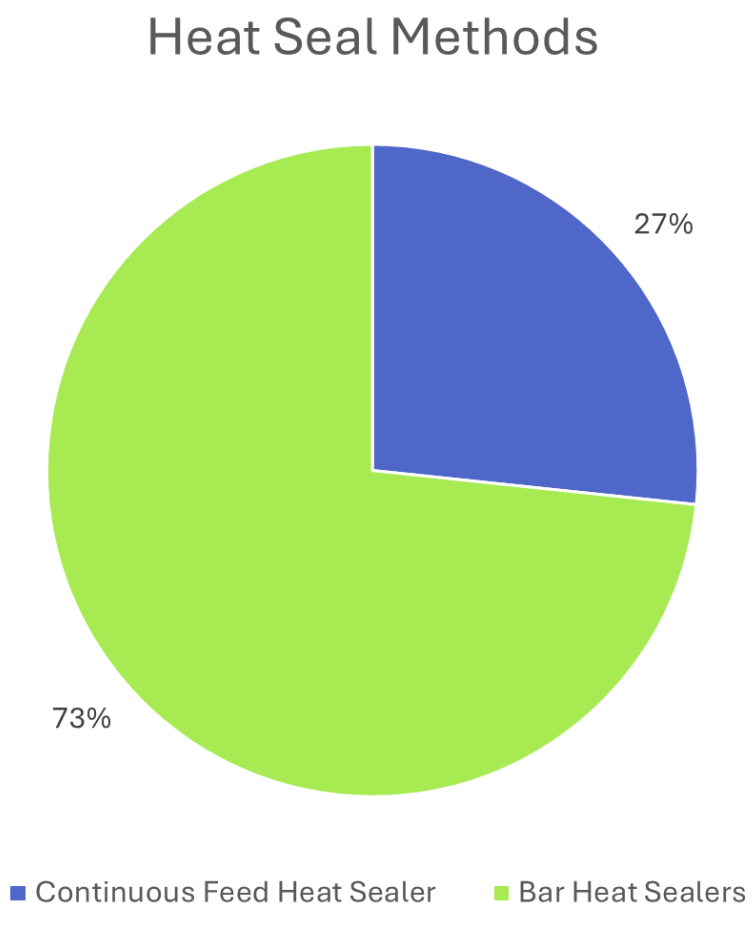
# Methods

- Conducted using multiple test methods:
  - For heat sealers, the Pouch Seal Integrity Test (PSIT) was employed alongside visual observation, both with magnification and the unaided eye.
  - The testing process involved roll stock pouch material designed for either steam or low-temperature sterilization.

PSIT example of a failure on both ends

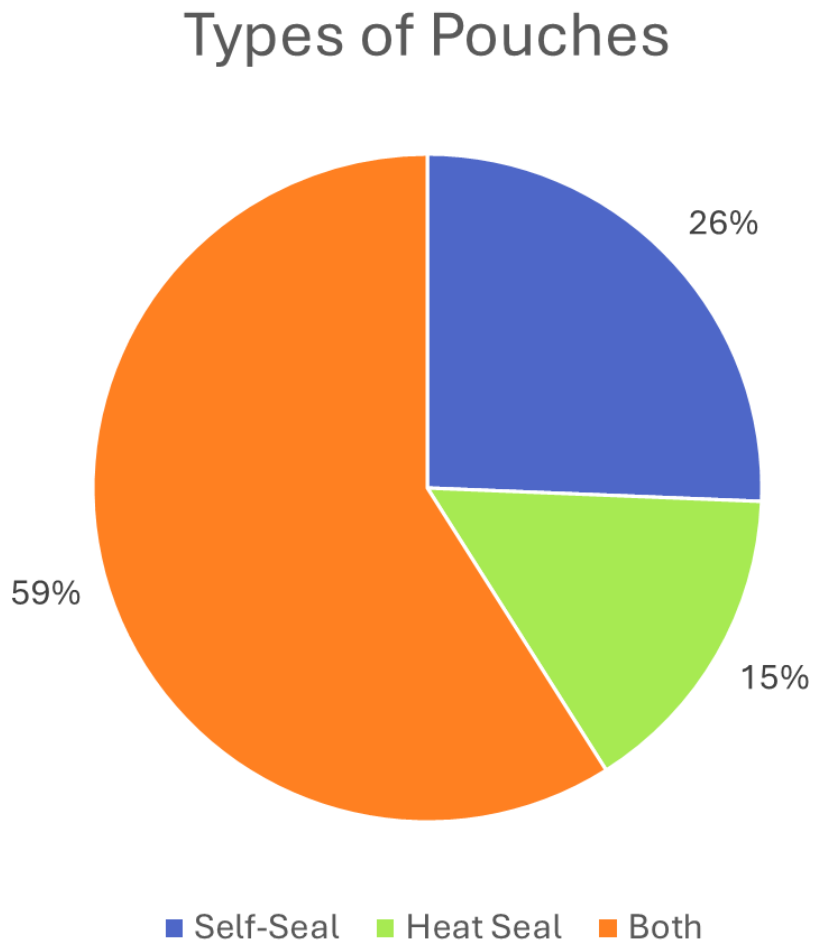
# Methods

- The facilities heat sealer was utilized to create a test pouch which included the PSIT inside.
- The ink in the PSIT was then activated to detect any potential seal integrity issues.
- This method was complemented by magnified visual inspection of the pouch seals as necessary.
- For facilities utilizing bar heat-sealers, additional inspection was performed on the Teflon rolls within the equipment.



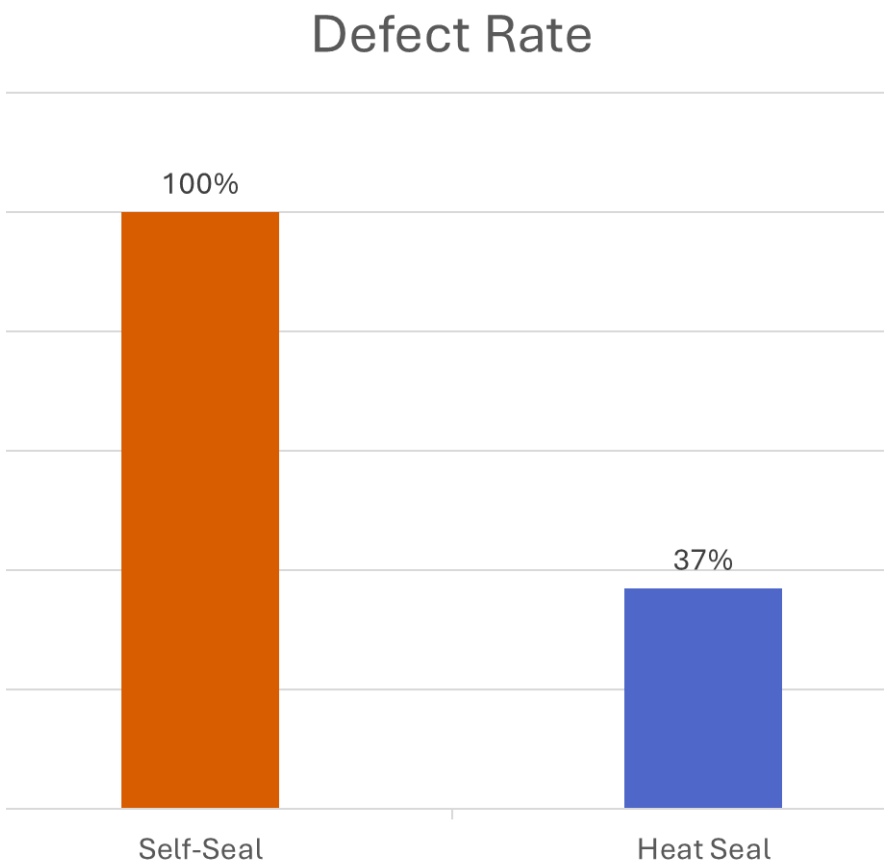
# Methods

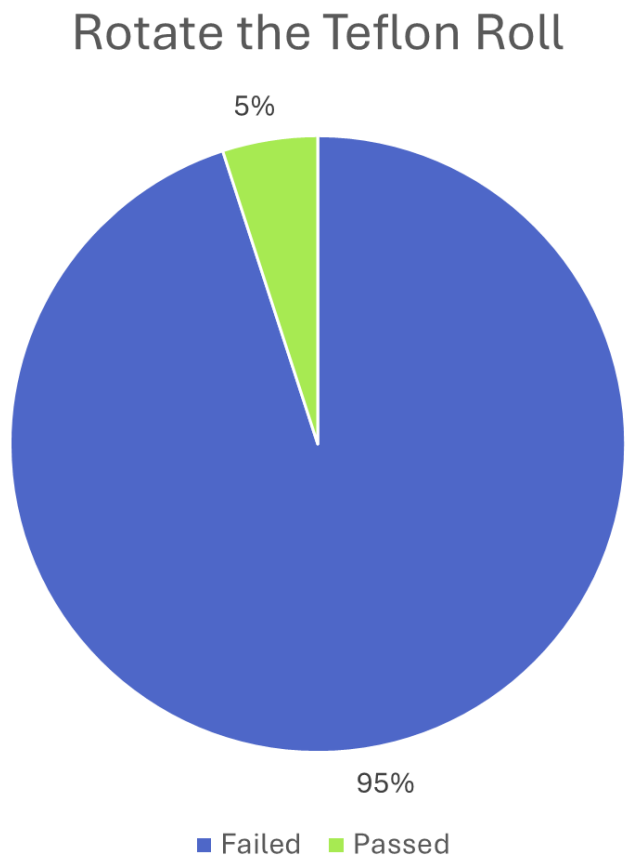
- Ready-to-use sterile pouches were also examined for integrity issues.
- At each facility, ten pouches (five self-seal and five heat-seal where applicable) were retrieved from sterile storage for evaluation.
- Furthermore, sterile storage practices were audited for any potential factors that could compromise pouch integrity.



# Results

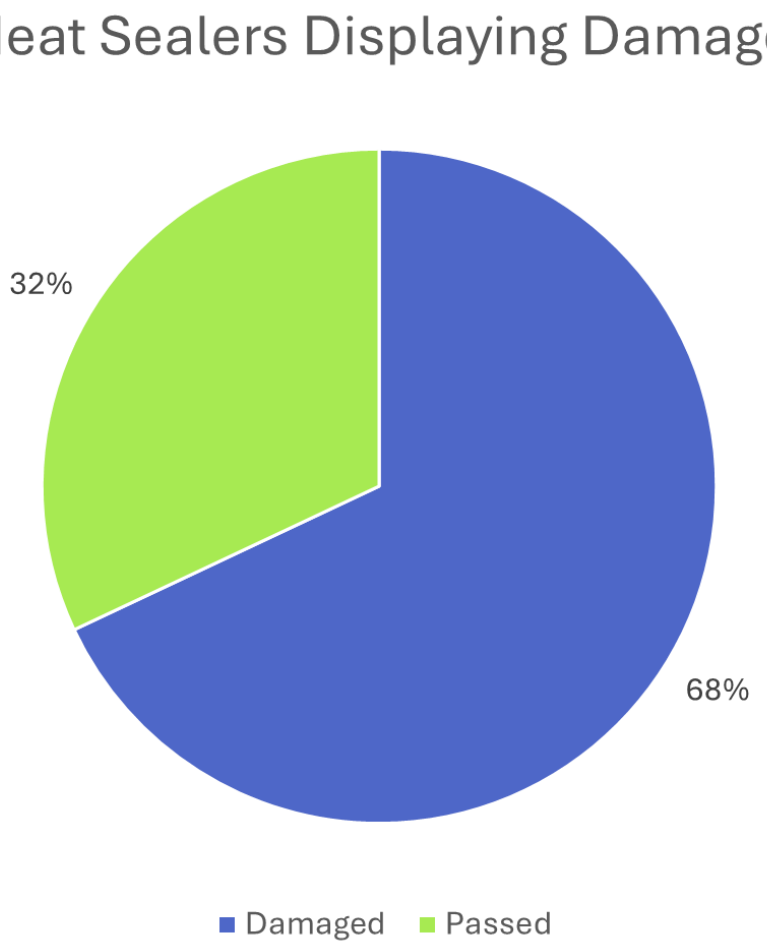
- Self-seal pouches exhibited a 100% defect rate, 37% for heat seal.
- 95% of facilities were unaware of, or failed to routinely rotate the Teflon roll, per the MIFU.

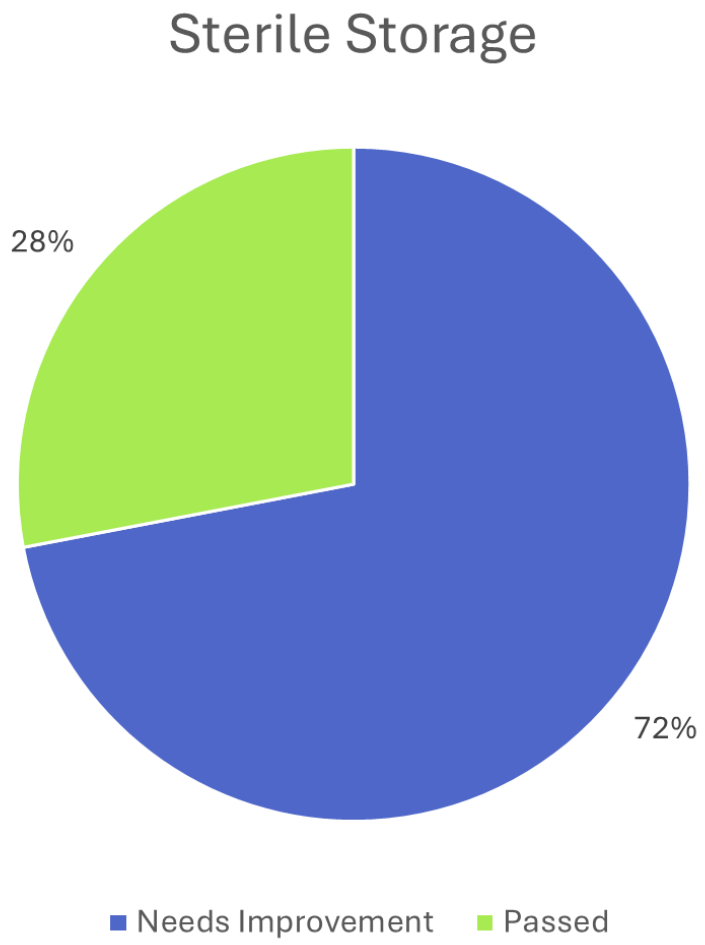


# Results

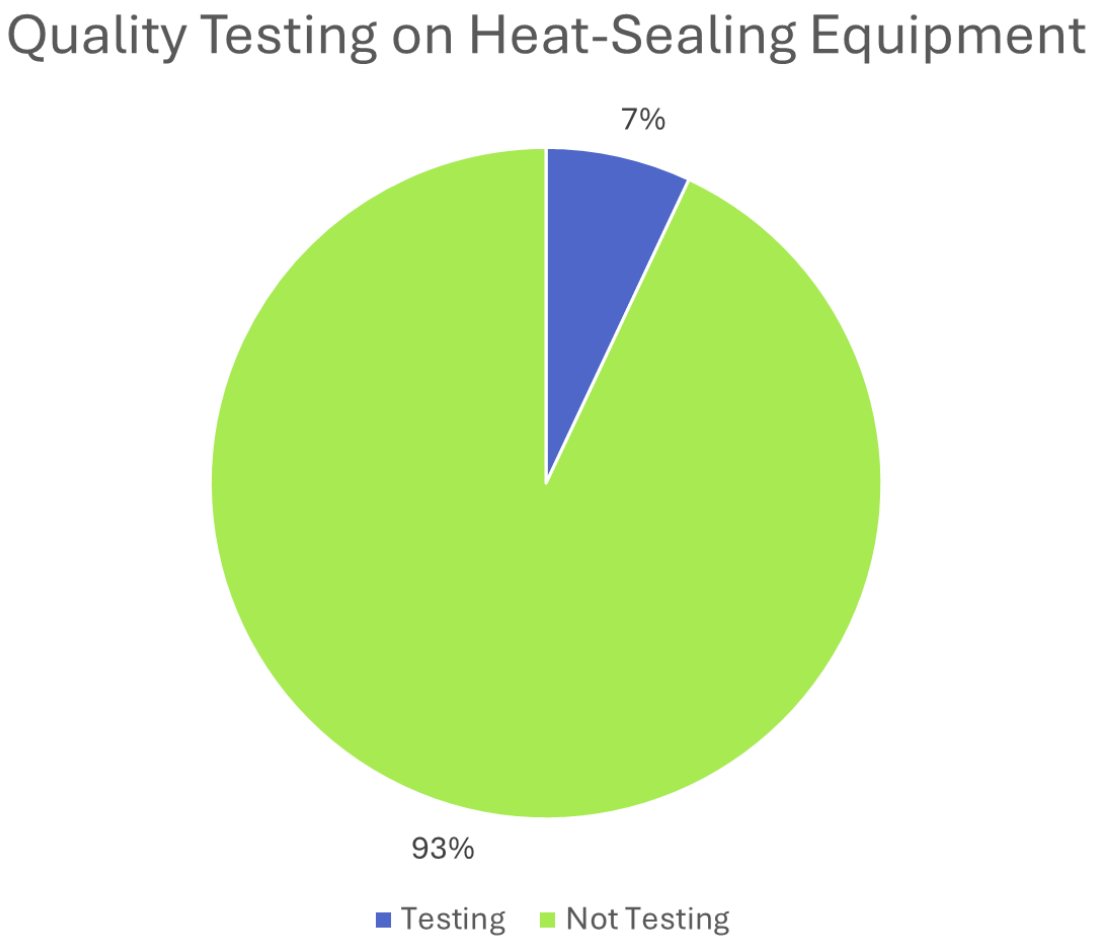
- 68% of heat-sealers displayed damage to the Teflon roll.
- 72% of facilities had opportunities for improvement in the storage practices for peel pouches.



# Results

- 93% of facilities were not conducting required quality testing on heat-sealing equipment in accordance with ISO



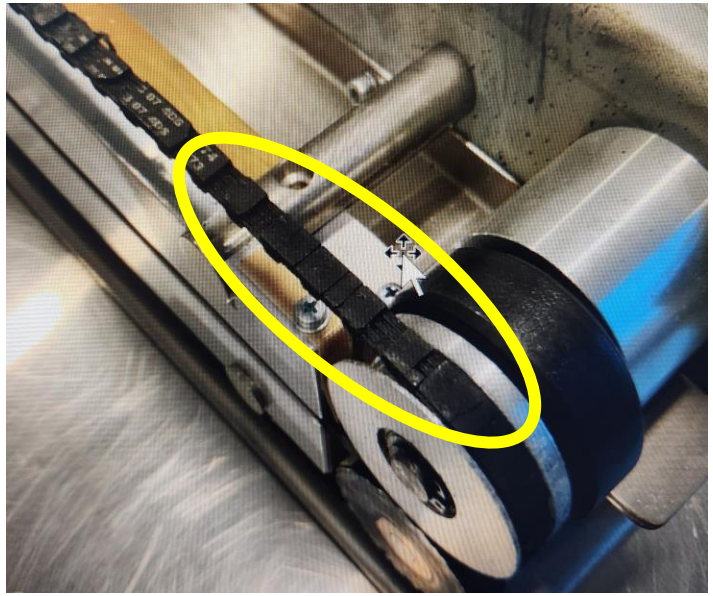
# Contributing Factors

- Ranged from:
  - Inadequate testing supplies
  - Equipment knowledge gaps
    - Regarding the importance of routine maintenance for heat-sealers
    - Correct self-seal pouch techniques

# Contributing Factors


Teflon inside a heat-sealer

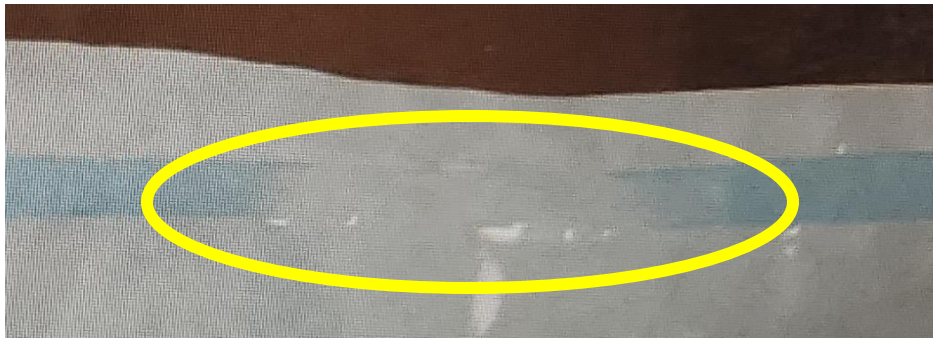
Teflon rotating knob missing

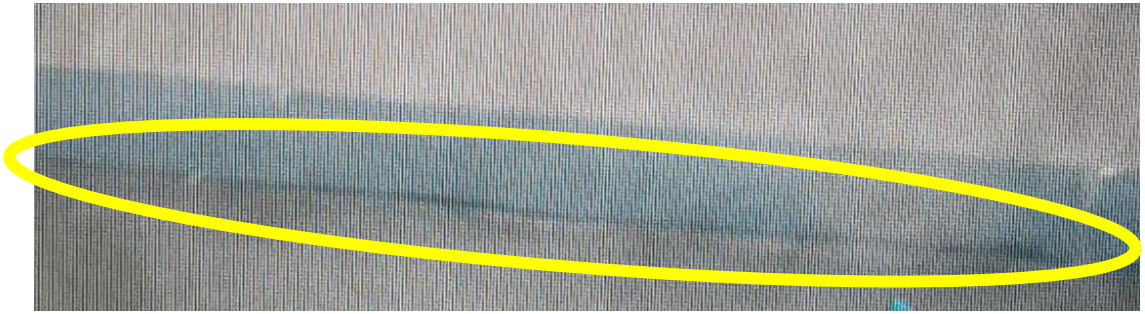


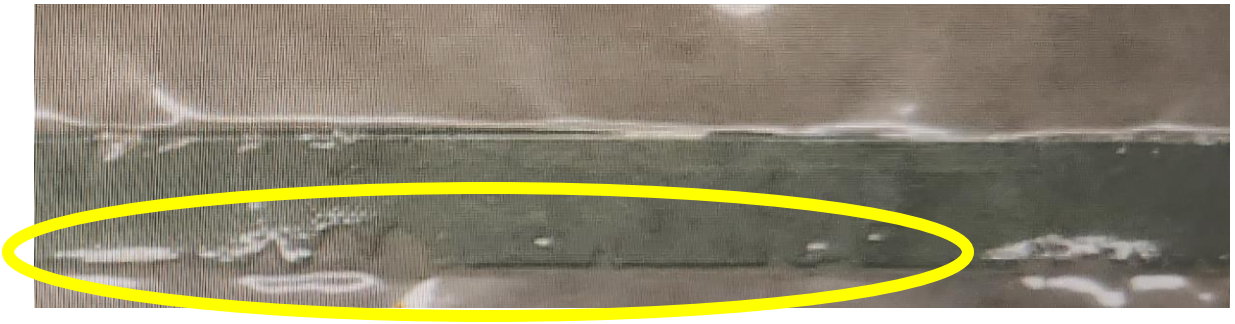
Belt damage and cracked rotating wheel

Variety of heat-sealer damage

# Contributing Factors

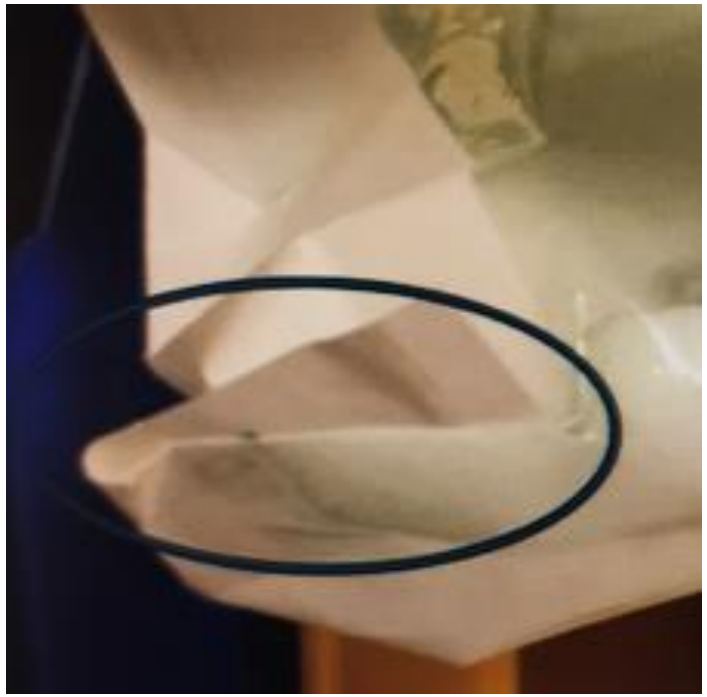




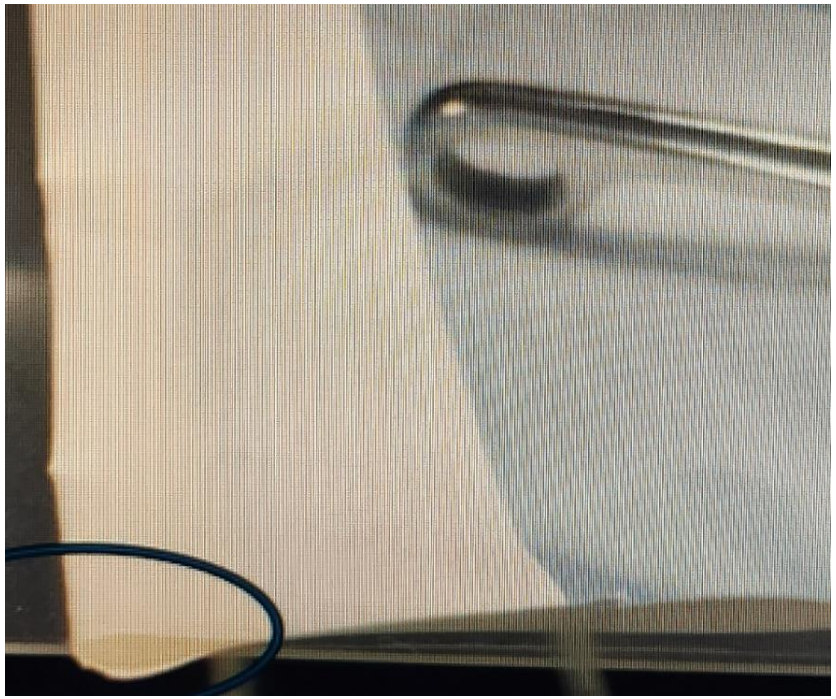


Variety seal integrity failures, due to heat-sealer issues.

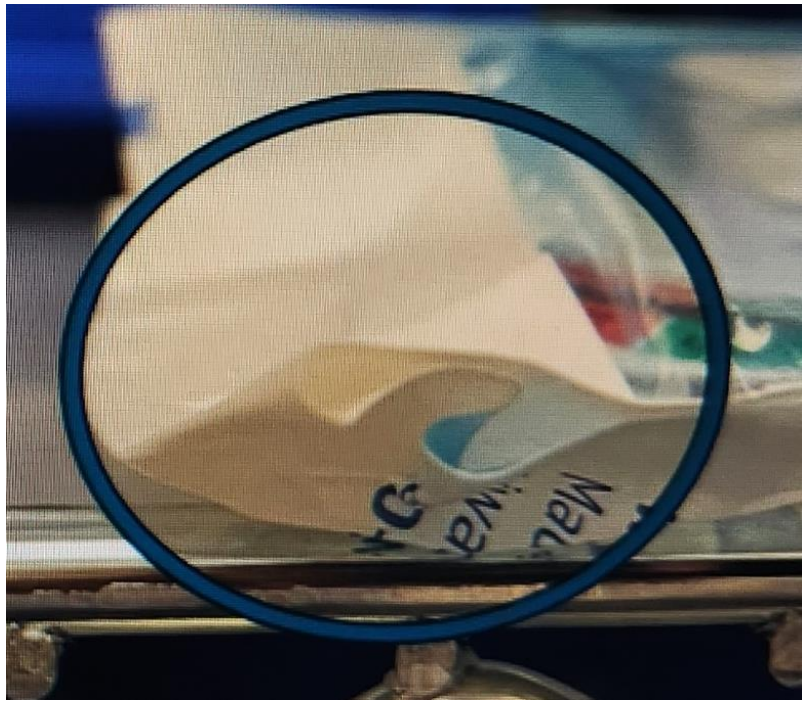
# Contributing Factors



Overlap



Gaps



Wrinkles

Variety seal integrity failures, due to poor technique with self-seal pouches

# Conclusion Study #1

**When the Seal Breaks: Evaluating the Factors Behind Packaging Integrity Failures**

- This preliminary study uncovered multiple factors contributing to compromised seal integrity in sterile processing pouches.
- These issues range from inadequate testing supplies and equipment to knowledge gaps among end-users regarding the importance of routine maintenance for heat-sealers and correct self-seal pouch techniques.
- Addressing these challenges should become an immediate priority for educators and healthcare leaders to enhance patient safety.
- Thank you to Malinda Elammari for the data collection.

# AIM – Study #2

**Beyond the Seal: Communication, Compliance, and Collaboration in Maintaining Peel Pouch Sterility**

- Communication from end users, such as the Operating Room (OR), back to the Central Sterile Supply Department (CSSD) regarding sterile packages with compromised sterility has been observed as a pattern.

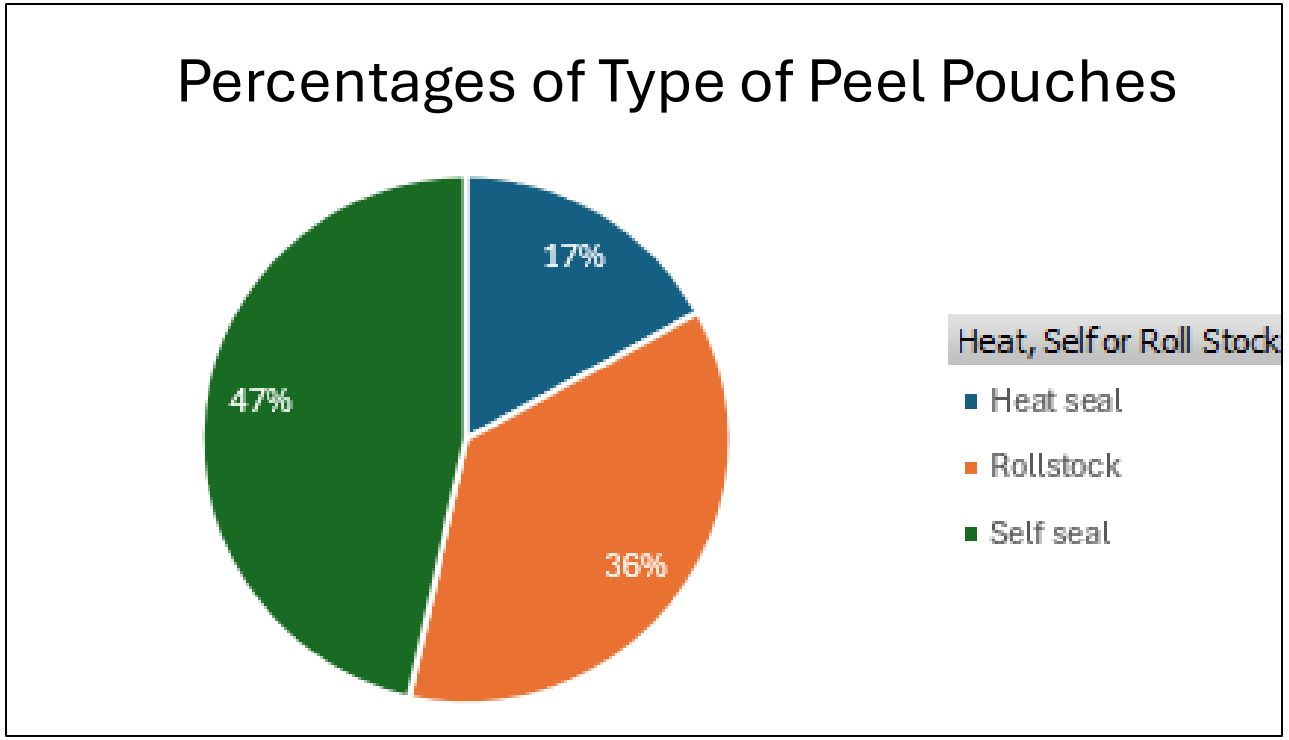
- It can be common to have calls or documented reports regarding compromised wrapped packages or those in rigid containers, but very seldom regarding a peel pouch.

- It has been observed that compromised pouches were found primarily by the CSSD during self-auditing procedures, rather than end-users.

- This study is a retrospective cross-section 1-month study that was conducted in August of 2024, across 2 healthcare facilities.

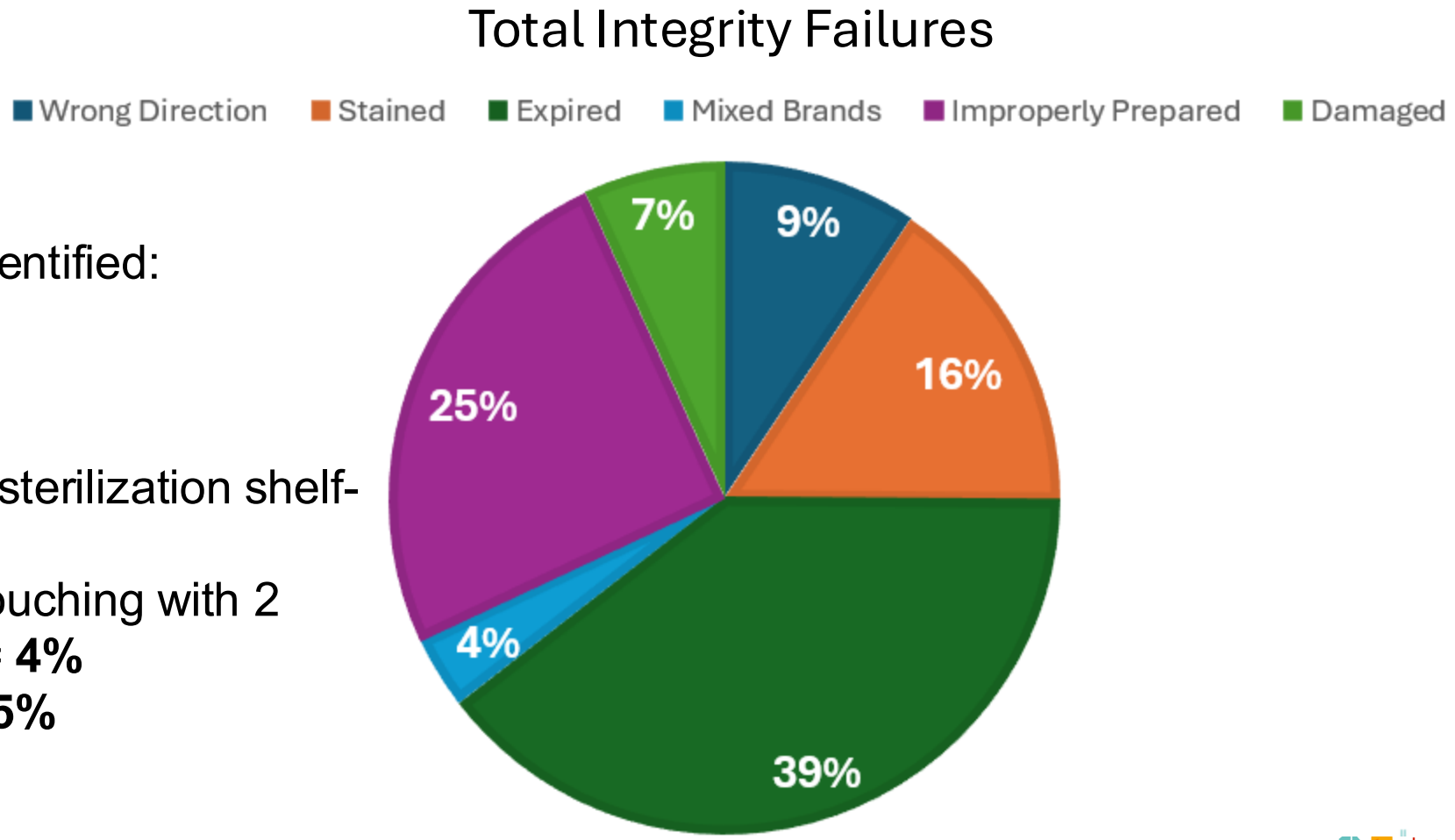
# Methods

- Utilized Microsoft Forms App for the team to enter data via cell phone or computer:
  - Pouch Manufacturer
  - Reason for failure: e.g., Outdated, damaged, improperly prepared
  - Date processed
  - Single or Double Pouched
  - Instrument/device type e.g., robotic
  - Sealing method e.g., roll stock, heat seal, or self-seal
  - Weight if recorded and type device in the pouch



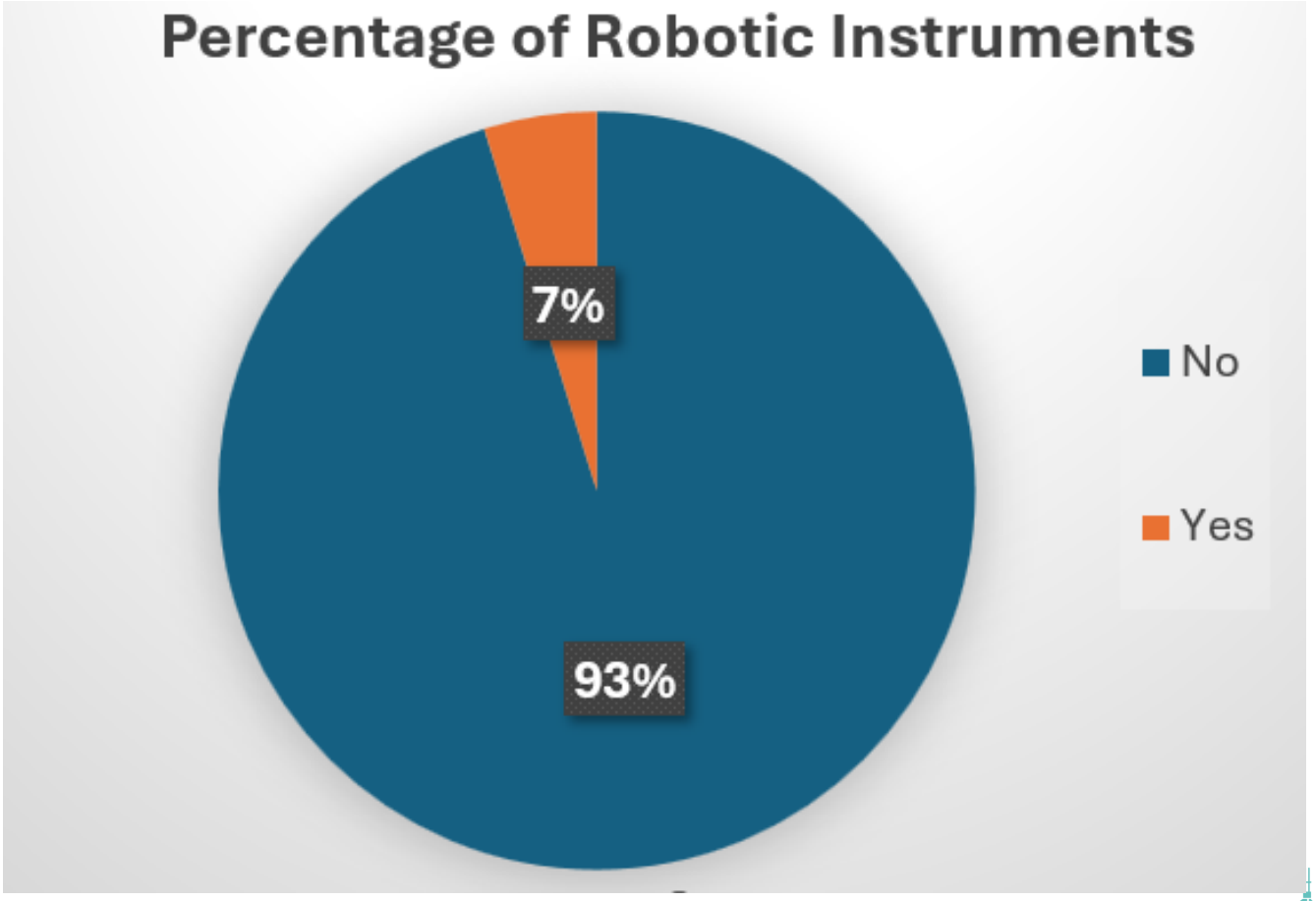
# Results

- 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%**



# Results

- Out of 1,778:
  - 7% of peel pouches were robotic instrumentation.
  - 93% were other types of instrumentation



# Results

## 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 |

# Results

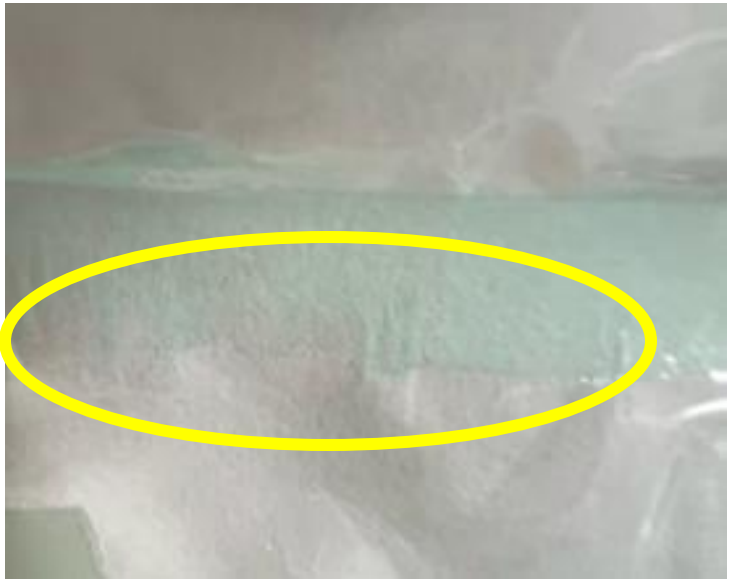
Financial Impact (USD) Robotics Instrumentation (Peel Pouching) Hospital #2

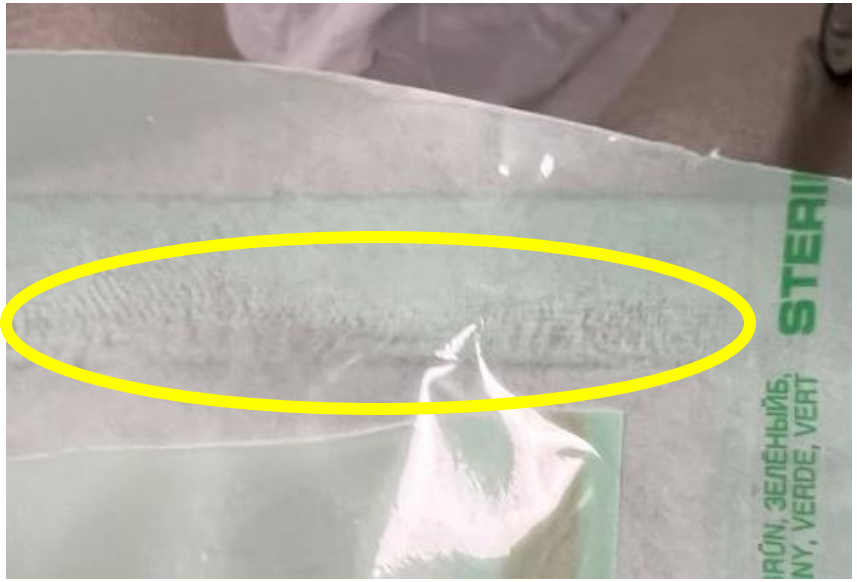
| Device | Number of impacted devices with (Integrity Failures) | Acquisition Cost (Average) Each | # of Recommended Sterilization Cycles Per IFU (Average) | Cost per use (Average) Each | Financial Impact to Operational Budget (Integrity Failures) |
|---|---|---|---|---|---|
| Robotic Instrument Arms | 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 |

# Contributing Factors

- **Data demonstrated two main contributing factors:**
  - Expired (post-sterilization shelf life)
  - Improperly prepared or sterilized
- **Education (Technique & MIFU)**
  - Technicians had lack or no knowledge of proper pouching techniques
  - Technicians had no knowledge of post-sterilization shelf-life guidance per the MIFU
  - Lack of education when peel pouch manufacturer was switched
- **Education (Heat Sealer)**
  - Temperature was too low to seal correctly per the MIFU
- **Sterilization pouch racks/holders**
  - Incorrect size to hold robotic arms and laparoscopic instrumentation e.g., rack was too tight, too short, improper holders

# Contributing Factors





Variety seal integrity failures

# Conclusion – Study #2

**Beyond the Seal: Communication, Compliance, and Collaboration in Maintaining Peel Pouch Sterility**

- Communication and adherence to standards are critical for maintaining pouch sterility.
- Peel pouches are convenient but prone to human error
  - Strict compliance with MIFU, AAMI ST79, and AORN is essential.
- Continuous training and competency assessment reduce sterility breaches.
- Collaboration among SPD/CSSD, OR, and satellite areas strengthens patient safety and process integrity.


- Special thanks to Rebecca Peplau for data collection


# References


**Study #1:**

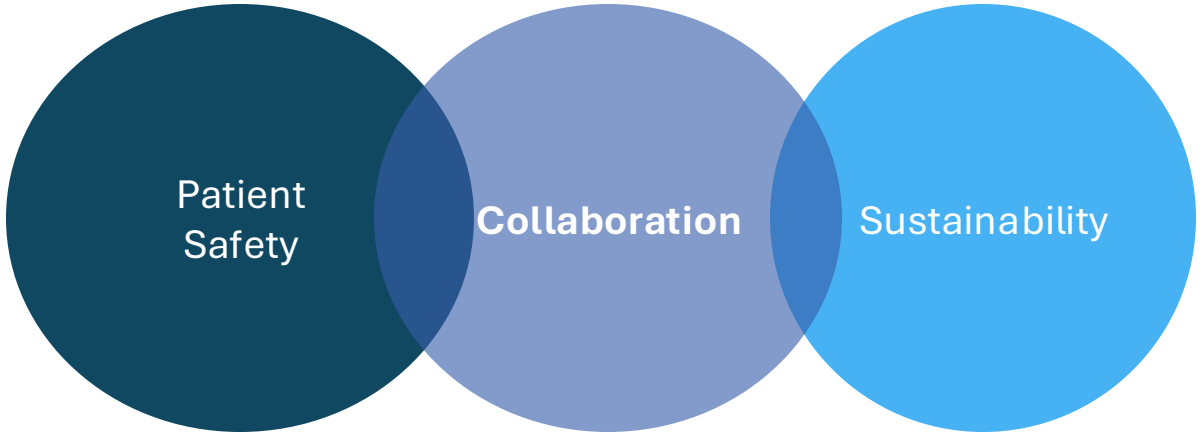
1. International Organization for Standardization. (2019). ISO 11607-1:2019 - Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems, and packaging systems. Geneva, Switzerland: International Organization for Standardization.
2. International Organization for Standardization. (2019). ISO 11607-2:2019 - Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing, and assembly processes. Geneva, Switzerland: International Organization for Standardization.
3. ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in health care facilities. (2017). https://doi.org/10.2345/9781570208027

**Study #2:**

1. ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in health care facilities. (2017). https://doi.org/10.2345/9781570208027
2. The Joint Commission 2022 Hospital Accreditation Standards – Standards, Elements of Performance Human Resources (HR) Standard HR.01.04.01, HR 01.05.03, HR.01.06.01, HR.01.07.01
3. Guideline for instrument cleaning. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN , Inc; 2025: 605-615.

# Hospital Survey: Managing Sterile Packaging Waste

Sterile Barrier Association



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# Thank you!

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