Process and Design Control Improvements to Prevent Tray Seal Defects in Medical Device Packaging

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Master in Engineering Management
Graduate Project EXPO, May 2026

Abstract

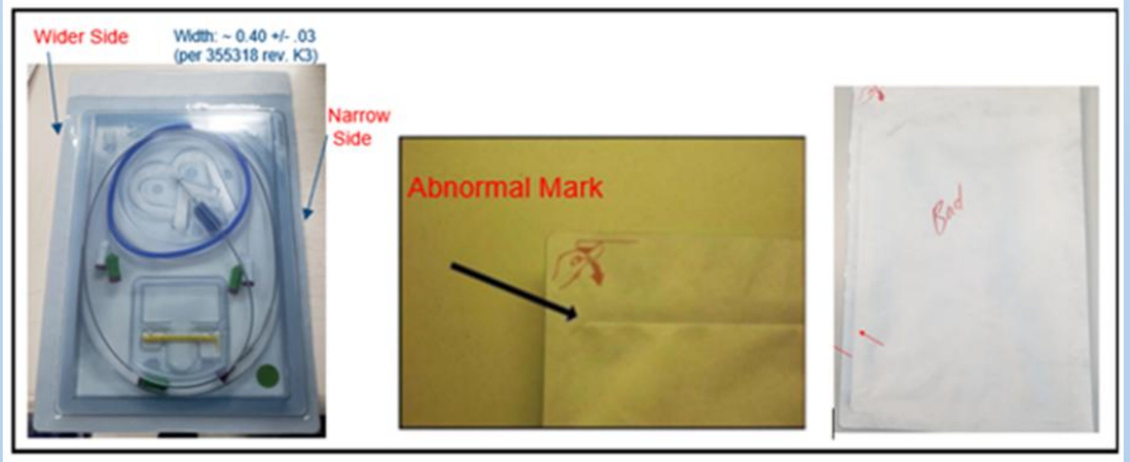
Tray seal variability in sterile medical device packaging can affect package consistency and reduce the effectiveness of inspection controls. This project evaluated abnormal seal width and Tyvek marking observed in thermoformed trays at a medical device manufacturing facility. A DMAIC-based approach was used, including record review, process mapping, dimensional assessment, and cause-and-effect analysis. The investigation identified three main contributors: supplier-generated flange variation during tray trimming, equipment setup associated with abnormal Tyvek marks, and unclear inspection criteria for seal width and mark interpretation. Supplier investigation found flange widths as low as 0.25 in., below the minimum acceptable width of 0.28 in. Corrective actions included revision of design and inspection requirements, supplier die-cutting improvements, and implementation of a Go/No-Go inspection. These actions strengthen packaging controls and support reliability.

Introduction

In a medical device manufacturing environment, finished devices are packaged using thermoformed trays and Tyvek lids to form a sterile barrier system. Because package integrity directly affects product sterility and regulatory compliance, packaging operations require strict control of component dimensions, sealing conditions, and inspection methods.

Problem

During routine production of a specific product family, abnormal sealing conditions were observed, including uneven seal width along the tray flange and visible marks on the Tyvek lid. The condition was not detected during earlier inspection stages, suggesting that trays with dimensional variation may enter the sealing process without being identified through existing controls.



Front view of Tray (actual unit)   Back View of Tray (actual unit)

Objective

Reduce tray seal variability and improve packaging process consistency by evaluating contributing factors and identifying opportunities to strengthen design, manufacturing, and inspection controls.

Methodology

A DMAIC-based approach was used to investigate tray seal variability and guide the project from problem definition through corrective action planning and sustainment.

D – Define
- Reviewed production and inspection records
- Assessed operator observations
- Developed process map of packaging workflow

M – Measure
- Collected tray flange width data
- Reviewed supplier documentation
- Assessed tooling and trimming conditions

A – Analyze
- Developed cause-and-effect diagram
- Completed Is/Is Not analysis
- Compared sample measurements to lower specification limit

I – Improve
- Identified corrective actions
- Evaluated feasibility and expected effectiveness
- Selected actions compatible with current operations

C – Control
- Defined updated inspection criteria
- Established process monitoring and documentation changes
- Planned sustainment of improved condition

In the **Define** phase, production records, inspection data, operator observations, and a process map were used to establish the scope of the issue and identify where it was detected in the packaging workflow. In the **Measure** phase, tray flange width data, supplier documentation, and tooling conditions were reviewed to characterize dimensional variation. In the **Analyze** phase, an Is/Is Not analysis, a review of sample flange-width measurements against the lower specification limit, and a cause-and-effect diagram were used to identify the main contributors to tray seal variability. This tool helped structure the investigation and narrow the most significant contributors to the observed defect. Root cause analysis identified three principal contributors: supplier flange variation, equipment setup, and inspection criteria.

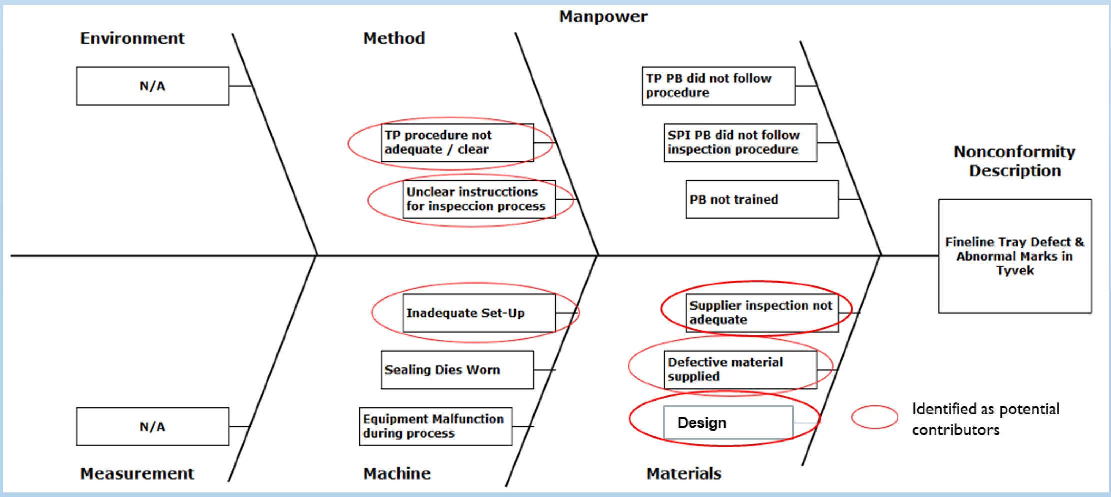


Figure 1
Cause-and-effect diagram

In the **Improve** and **Control** phases, corrective actions and sustainment methods were defined through evaluation of feasible improvements, updated inspection criteria, process monitoring, and documentation changes.

Results and Discussion

The investigation showed that the observed defect was not caused by a single factor, but by the interaction of material variation, equipment setup, and unclear inspection criteria. Review of training and device history records confirmed that product builders were trained and that no prior nonconformances related to uneven tray sides or abnormal Tyvek marks had been documented. Interviews and work instruction review indicated that the available visual aids and inspection criteria did not clearly define unacceptable abnormal marks or minimum seal width requirements, which increased the likelihood of inconsistent inspection decisions. Equipment assessment of the Belco blister sealer identified a misalignment between the sealing die and the hot plate recess area, contributing to abnormal Tyvek marks. At the material and design levels, the tray flange requirement was confirmed as 0.40 ± 0.03 in.; applying the 75% seal width requirement to the minimum flange width of 0.37 in. established a minimum acceptable seal width of 0.28 in. Supplier investigation found flange widths as low as 0.25 in., confirming that nonconforming trays could be produced and accepted. Overall, the most significant contributors were grouped into three principal areas: supplier-induced flange variation, inadequate equipment setup, and insufficient inspection criteria.

Table 1
Summary of Main Results

Main finding	Supporting evidence	Identified cause	Corrective action
Flange width below acceptable limit	Flange widths as low as 0.25 in.; minimum acceptable width = 0.28 in.	Supplier trimming issue and drawing designation as reference	Remove REF designation, update inspection requirements, improve supplier die-cutting process
Abnormal Tyvek marks during sealing	Belco blister sealer evaluation showed die misalignment with hot plate recess area	Inadequate equipment setup	Adjust equipment alignment and sealing parameters within validated range
Inconsistent inspection decisions	Interviews and work instruction review showed lack of clear criteria for abnormal marks and minimum seal width	Inadequate inspection criteria and unclear work instructions	Clarify work instructions and implement Go/No-Go inspection

Key Findings

- Product builders were trained; no prior related NCs documented
- Sealer die misalignment contributed to Tyvek marks
- Minimum acceptable seal width = **0.28 in.**
- Supplier flange widths observed as low as **0.25 in.**
- Main contributors: **material variation, equipment setup, inspection criteria**

Conclusions

Tray seal variability was driven by the combined effect of supplier flange variation, equipment setup, and unclear inspection criteria rather than a single isolated factor. The investigation showed that nonconforming trays could be produced and accepted when flange dimensions were not controlled and inspection requirements were not clearly defined. Corrective actions included revision of the design drawing and related inspection documents, strengthening of supplier die-cutting controls through equipment replacement and an internal locator, and implementation of a Go/No-Go inspection. These actions are expected to strengthen preventive and detection controls and support improved packaging consistency and sterile barrier reliability.

Literature Review

- ISO 11607 establishes requirements for sterile barrier systems and validation of packaging processes.
- ASTM F88, F1929, and F1886 provide methods for seal strength, leak detection, and visual inspection.
- Published studies show that sealing defects are often associated with process variation, unclear inspection criteria, and inadequate controls.

Acknowledgements

The author acknowledges the support of the project advisor, Graduate School faculty, and the manufacturing, quality, and supplier quality personnel who contributed to this work.

References

1. International Organization for Standardization, "ISO 11607-1:2019 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems," ISO, 2019.
2. International Organization for Standardization, "ISO 11607-2:2019 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes," ISO, 2019.
3. ASTM International, "ASTM F88/F88M-21: Standard test method for seal strength of flexible barrier materials," ASTM International, 2021.
4. ASTM International, "ASTM F1929-23: Standard test method for detecting seal leaks in porous medical packaging by dye penetration," ASTM International, 2023.