Lean Transformation in Medical Device Manufacturing: Improving the Thermal Bond Process to Reduce Defects

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Abstract

This research implemented *Lean* manufacturing principles in the thermal bonding process of catheter production to improve efficiency. By transitioning to a single-piece flow system and re-sequencing process steps, the "Overflow" defect rate was reduced from 1.91% to 0.24%. Additionally, scrap costs decreased, leading to savings of $292K. The results demonstrate the tangible benefits of *Lean* application in process optimization.

Introduction

In a medical device organization in Puerto Rico, a significant challenge in catheter manufacturing has been the high defect rate associated with a thermal bond process due to a condition known as "Overflow". Since FY 2024, this defect has resulted in a **defect rate trend of 1.82%**, leading to **financial losses of approximately $799K**. In this context, *Lean* manufacturing transformation of traditional lines offers a systematic approach to reduce defects.

Background

Traditional Line Process Overview:
Operates in batches of 4 units, resulting in 12 units of work-in-progress (WIP) between stations. This batch-based approach leads to high inventory levels, which can present challenges when anomalies are detected.

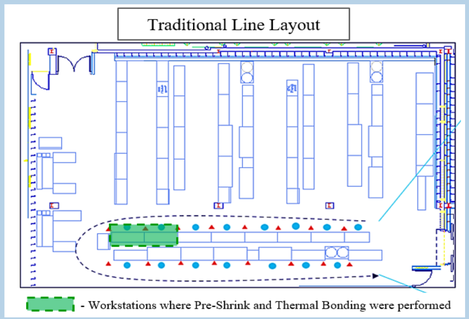

Figure 1. Representation of Traditional Line Layout

Thermal Bond Process and "Overflow" Defect:
The thermal bond process is a critical step in catheter manufacturing, ensuring the secure attachment of the polyurethane (PU) balloon to the Pebax tip of the catheter. The successful execution of this process depends on several factors including material compatibility, temperature, and precise alignment of the catheter within the machine during both the pre-shrink and thermal bond stages. The "Overflow" defect occurs when these factors are not synchronized. In the traditional line, one operator was responsible for the pre-shrink process, while another oversees thermal bond. By re-sequencing these steps to allow a single operator to manage both processes, the risk of "Overflow" defect can be significantly reduced.

Problem

In medical device manufacturing, particularly catheter production, the "Overflow" defect in the thermal bonding process presents significant challenges. Addressing this issue requires identifying key contributing factors and implementing effective solutions. This research applies *Lean* principles to reduce defects and improve efficiency in catheter production.

Research Objectives:

- Defining, measuring, and analyzing the **current state** of the thermal bond process, identifying key factors that contribute to "Overflow" defect.
- Designing and implementing *Lean*-based **improvements** to reduce defects.
- **Evaluating** the impact of these improvements on defect rate and operational efficiency.

Methodology

The methodology for this research was experimental. The following steps were executed to achieve the objective of this research, which is to demonstrate how *Lean* tools can optimize quality and operational efficiency.

Step 1 — Analyzing the current state of the defect using a Fishbone diagram and highlighted areas for improvement.

Step 2 — Improvements were implemented, as part of the *Lean* transformation project, the outer balloon sequence of events (SOE) was updated.

Step 3 — Impact of these improvements on the thermal bond process was evaluated by monitoring the defects reported in the area after *Lean* implementation.

Results and Discussion

Current State:
A Fishbone diagram identified key factors contributing to the "Overflow" defect in the thermal bond process.

Improvements:
The line was restructured into three cells with a single-piece flow system, reducing WIP from 12 units to 1.

Thermal bond steps were re-sequenced. This adjustment balanced the workload and reduced the number of required operators from 2 to 1.

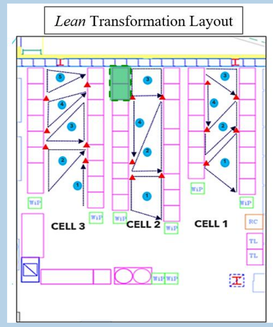

Figure 2. Representation of *Lean* Transformation Layout

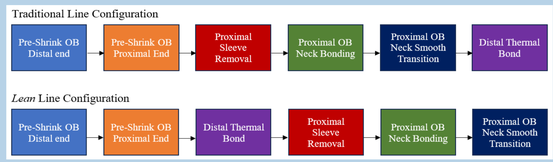

Figure 3. Outer Balloon SOE Comparison

Monitoring:
After *Lean* transformation (mid-August 2024), a decrease in "Overflow" defect rate was observed. Proportions Test confirmed a statistically significant defect reduction (**p-value = 1.59E-12**).

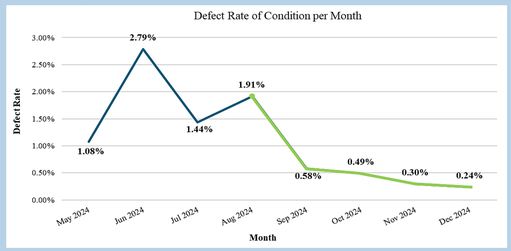

Figure 4. Monthly Defect Rate for "Overflow" Condition

Scrap costs were reduced from $589K in 2023 to $297K in 2024, with a **savings of $292K after *Lean* improvements**.

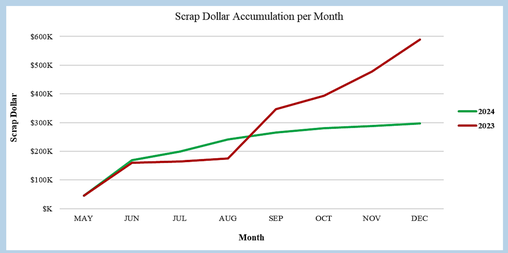

Figure 5. Comparison of Scrap Costs Accumulation in 2023 and 2024

Conclusions

- Implementing *Lean* methodologies in the thermal bond process **successfully reduced defects**.
- The "Overflow" **defect rate was reduced from 1.91% to 0.24%**.
- Transitioning to a **single-piece flow system** improved operational efficiency, resource utilization, and process anomaly detection.
- *Lean* improvements resulted in a **$292K cost savings** in scrap.
- The study highlights how ***Lean* tools** drive both immediate operational improvements and short-term financial benefits.

Future Work

Future studies will **extend the analysis timeframe** to comprehensively evaluate the l**ong-term effects** of *Lean* implementation across the entire production line, including its impact on overall efficiency, cost savings, and sustainability of improvements.

Acknowledgements

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