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

Génesis González Aponte
Master of Engineering in Manufacturing Engineering
Advisor: Rafael A. Nieves Castro, PharmD.
Polytechnic University of Puerto Rico
Graduate Project EXPO, February 2025

Abstract — *This research assessed the application of Lean manufacturing principles in the thermal bonding process of catheter production to reduce defects and improve operational efficiency. An analysis of the current state identified the root causes of the "Overflow" defect and established a foundation for process improvements. The implemented redesign allowed the transition from batch production to a single-piece flow system. Specifically for the thermal bonding process, applying Lean methodology allowed for the re-sequencing of process steps, which facilitated an optimal workload balance. Post-implementation results demonstrated a significant reduction in defect rates, from 1.91% to 0.24%, reflecting a statistical difference with a p-value of 1.59E-12. Additionally, scrap costs decreased substantially in the three months following Lean implementation, resulting in financial savings of $292K. However, despite time constraints, this study highlights the tangible benefits of process optimization through the Lean application methodologies by providing a clear example of its impact on improving operational efficiency.*

Keywords — *Lean Principles, Medical Device Manufacturing, Operational Excellence, Thermal Bond Process.*

INTRODUCTION

Within the healthcare industry, medical device manufacturing is a critical sector that is currently facing significant challenges in terms of efficiency, quality, and cost management. In an environment where the demand for innovative and high-quality medical devices is constantly increasing, industries in the sector must adapt to remain competitive while also complying with the strict regulations required by both customers and government agencies, such as the International Organization for Standardization (ISO), the Food and Drug Administration (FDA), and the Technischer Überwachungsverein (TÜV).

In a medical device organization in Puerto Rico, a significant challenge in catheter manufacturing has been the high defect rate associated with a thermal bonding process due to a condition known as "Overflow". Since the Fiscal Year 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 optimize processes and reduce defects. This research focuses on how the application of *Lean* principles in the new line design has improved the thermal bonding process, decreasing the occurrence of defects, minimizing scrap costs, and enhancing operational efficiency.

Research Description

This research investigates the improvement of the thermal bonding process in catheter manufacturing within the medical device industry through the application of *Lean* principles. Specifically, it addresses a quality issue related to the "Overflow" defect. The study focuses on reconfiguring (i.e., re-sequencing) the outer balloon sequence of events (SOE), a term used to describe the process by which the thermal bond process is executed, in order to balance workloads among operators and process steps, reduce process variability, and enable single-piece flow through the manufacturing line as part of the *Lean* transformation. Additionally, it examines the operational and financial improvements achieved by reducing rejects due to the "Overflow" condition, demonstrating the tangible benefits of implementing *Lean* strategies in a manufacturing environment.

Research Objectives

The primary objective of this research is to demonstrate how *Lean* principles can be applied to address specific quality challenges in medical device manufacturing, with a focus on reducing defects (i.e., "Overflow" condition) related to a thermal bonding process in catheter production. The specific objectives are as follows:

- ✓ To define, measure, and analyze the current state of the thermal bonding process, identifying key factors that contribute to the "Overflow" defect.
- ✓ To design and implement improvements in the thermal bond process based on *Lean* principles, with a focus on reducing defects.
- ✓ To evaluate the impact of these improvements on the defect rate and operational efficiency.

Research Contributions

This research offers valuable insights into the practical application of *Lean* principles in the medical device industry, specifically focusing on a critical issue within the thermal bonding process in catheter manufacturing. A key contribution of this study is its demonstration of how *Lean* strategies, such as process re-sequencing, implementation of a single-piece flow system, and inventory reduction, can effectively decrease defect rates and related financial losses. By presenting measurable outcomes, this study highlights the tangible benefits of process optimization through the application of *Lean* methodologies, providing a clear example of their impact on improving operational efficiency in the medical device industry.

THEORETICAL BACKGROUND

Cardiovascular diseases remain one of the leading causes of death worldwide. According to the American Heart Association Council on Epidemiology and Prevention Statistics Committee [1], nearly 46.7% of U.S. adults suffer from high blood pressure, with 38% unaware of their condition. These alarming statistics highlight the urgent need to increase production capacity in industries dedicated to the manufacturing of cardiovascular medical devices. As a result, improving operational efficiency while minimizing waste has become a top priority for manufacturers.

Lean manufacturing has emerged as a crucial approach, built on the two pillars of product quality at low cost and customer satisfaction [2]. Originating in the early 20th century, *Lean* principles were shaped by pioneers such as Taiichi Ohno, who introduced concepts like "Just-in-Time" to reduce waste, and Shigeo Shingo, who developed Poka-Yoke (i.e., error-proofing) techniques. This philosophy highlights several core principles, including defining customer value, mapping the value stream, establishing smooth process flows, implementing pull systems, and striving for perfection [3].

Case Study

Unlike traditional manufacturing, which prioritizes mass production, large inventories, and extended production cycles, *Lean* manufacturing emphasizes smaller production runs, inventory reduction, and the optimization of each step in the process [3]. *Lean* is recognized as a continuous improvement methodology that enhances process performance and operational excellence, aligning resources and processes for sustainable growth. For instance, Gomma [4] demonstrated the success and effectiveness of *Lean Six Sigma* in the automotive parts industry in Egypt. His study revealed that by applying an integrated *Lean Six Sigma* framework, defect-causing factors were identified, resulting in an increase in product quality rate from 26.7% to 80.0%, an improvement in rework quality from 80.0% to 100%, and a reduction in processing time from 1,847 to 915 seconds per unit.

Catheter Function

In a similar approach, this research leverages *Lean* principles to improve the thermal bonding process in catheter manufacturing, targeting process efficiency and defect reduction. To understand the importance of this process, it is essential first to consider the purpose of the catheter. A catheter is a medical device used in catheterization procedures, which involves using X-rays and a special dye to evaluate and treat blockages in the arteries supplying blood to the heart [5]. Specifically, during the procedure, a thin tube (i.e., catheter) is inserted into an artery in the wrist or groin to guide the dye and provide clear imaging of the blood vessels. This step is crucial as it allows for the identification of narrowing that may lead to angina or heart attacks, and, if needed, treatment such as angioplasty or stent placement can be performed immediately [6].

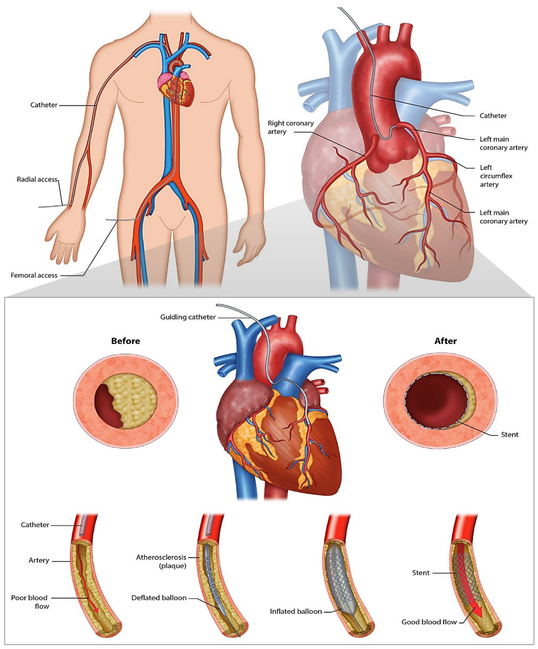

Figure 1
Representation of Catheter Function [6]

Thermal Bond Defect and *Lean*

Considering this, the thermal bonding process is a critical step in the manufacturing of catheters, as it ensures the secure attachment of the polyurethane (PU) balloon to the catheter tip. The success of this process depends on several factors, including material compatibility, temperature control, and precise alignment of the catheter in the machine used for both the pre-shrink process of the outer balloon distal neck end and the thermal bond process. When executed properly, thermal bonding results in a strong joint, ensuring the catheter's structural integrity. However, improper bonding can lead to defects, such as the "Overflow" condition, which appears on the catheter's distal end (i.e., catheter tip). This defect occurs when PU material flows into an unheated, unconstrained tip section, leading to an uneven bond.

Lean manufacturing principles, which focus on eliminating waste, optimizing processes, and fostering continuous improvement, can significantly address various challenges. In the thermal bonding procedure, *Lean* strategies can help minimize defects by optimizing the sequence of process steps, enhancing flow efficiency, and reducing inventory, especially work-in-progress (WIP). The implementation of single-piece flow, a key *Lean* principle, allows for the identification of abnormalities in the thermal bond process, enabling immediate and effective action to minimize the occurrence of the "Overflow" defect.

Moreover, *Lean* emphasizes process standardization and reduction of variability, which directly supports precise control over critical factors during thermal bonding. By improving process flow, resequencing steps, reducing WIP, and standardizing critical parameters, this study aims to demonstrate how targeted *Lean* methodologies can substantially enhance thermal bonding process, ultimately reducing defects and lowering costs associated with scrap dollars.

Project Methodology

The methodology for this research was experimental, aiming to reduce the defect rate associated with the thermal bond process in catheter manufacturing by applying *Lean* principles. 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.

A. The first phase involved analyzing the current state of the defect using a Fishbone diagram. This initial analysis provided valuable insights into the root causes of "Overflow" defect and highlighted areas for improvement.

B. Following the identification of the root causes, targeted improvements were implemented, including a comprehensive process redesign, parameter standardization, and operator training. As part of the *Lean* transformation project, the outer balloon sequence of events (SOE) was updated to ensure that the distal thermal bonding step occurred before bonding the outer balloon's proximal end. This adjustment was strategically designed to balance the workload across operators and streamline process flow.

C. Finally, the impact of these improvements on the thermal bonding process was evaluated by monitoring the defects quantity reported in the area after *Lean* implementation. Additionally, the financial implications of the defects were assessed, translating the reduction in defects into tangible cost savings.

RESULTS AND DISCUSSION

All the information presented below was gathered from day-to-day results reported in the manufacturing area. To analyze the current state of the manufacturing line, specifically the defect behavior related to the thermal bonding process of the catheter, a Fishbone diagram was employed as a *Lean* manufacturing tool (refer to Figure 2). This initial analysis provided valuable insights into the root causes of "Overflow" defect arising from the thermal bonding and identified opportunities for improvement at the workstation where the process was performed.

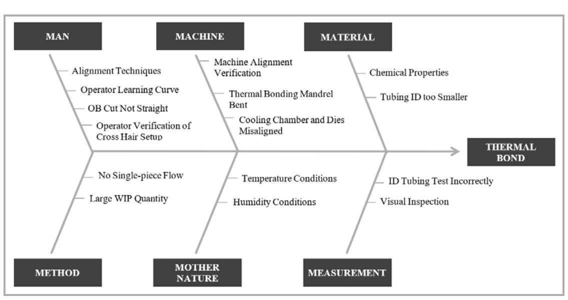

Figure 2
Fishbone Diagram of Thermal Bond Defect Condition

Improvements Implementations

Following the identification of the root causes, targeted improvements were implemented. Figure 3 illustrates a comparison between the traditional line design and the redesigned line after applying *Lean* methodologies. The figure illustrates that the redesigned line was restructured into three cells (Cell 1, Cell 2, and Cell 3) and incorporates the implementation of a streamlined work-path system. This new arrangement replaced the previous batch production flow, resulting in a reduction in training lead times, as the processes were divided into sub-stations. Consequently, the redesign enabled the development of a single-piece flow *Lean* operating system, which improved manufacturing flexibility, capacity, and productivity. Key drivers of this improvement included reducing production flow from four units at a time to one unit, decreasing non-cyclical work, and balancing work among operators and process steps. Specifically, for the thermal bonding process, the resulting benefits included a significant reduction in WIP, from 12 production units to just one, as well as a decrease in labor content per workstation, reducing the number of operators required to perform the pre-shrink and thermal bond process from two to one.

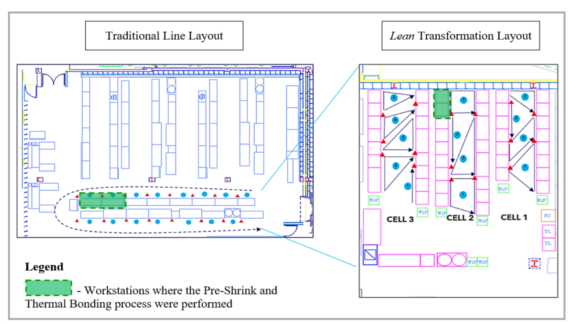

Figure 3
Representation of Traditional Line and *Lean* Transformation Layout with Pre-Shrink and Thermal Bonding Workstations Highlighted

*Green-highlighted sections indicate the locations where the pre-shrink and thermal bonding processes are performed in both the Traditional Line and *Lean* Transformation layouts. "Overflow" defect occurrence is influenced by these processes.

Additionally, as part of these *Lean*-aligned improvements, the steps required for the thermal bonding process were re-sequenced (refer to Figure

4). This update strategically positioned the distal thermal bonding step before bonding the outer balloon's proximal end, balancing the workload across operators and streamlining the process flow. By allowing a single-piece flow through the manufacturing line, a significant improvement in overall process efficiency was achieved.

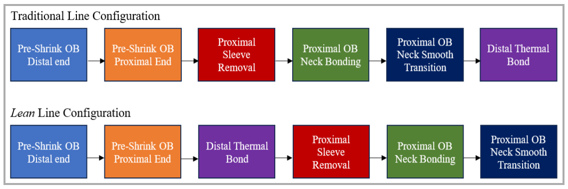

Figure 4
Outer Balloon SOE Comparison

Improvements Monitoring

On the other hand, the impact of these improvements on the thermal bonding process was evaluated by monitoring the number of defects reported after implementation. The *Lean* implementation occurred in mid-August 2024, with the associated benefits observed starting in September 2024. To measure the effects of the improvements, the monthly defect rate associated with defects under the thermal bonding (i.e., "Overflow" condition) was calculated using the following formula,

$$Defect\ Rate = \left(\frac{Defect\ Qty}{Total\ Production\ Qty}\right) \times 100 \quad (1)$$

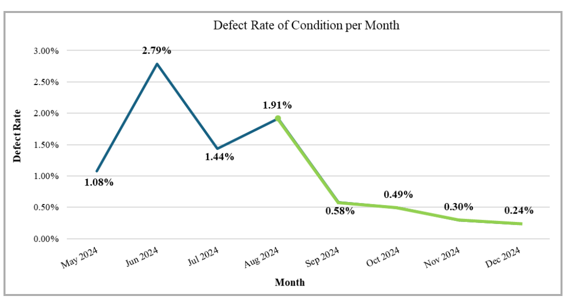

Figure 5
Monthly Defect Rate for "Overflow" Condition Caused by the Thermal Bond Process

*Green line zone marks the defect rate for the "Overflow" condition after implementing *Lean* design.

As shown in Figure 5, a significant improvement was observed in the monthly defect rate for the evaluated condition. A gradual decrease in defects trend over time demonstrated a positive impact of the improvement in the described process.

To validate the results shown in Figure 5, a Proportions Test was conducted using Minitab software to compare defect rates before and after the improvements. From this analysis, a p-value of 1.59E-12 ($p\text{-value} < 0.05$) was obtained using Fisher's exact method, indicating a statistically significant difference between the defect proportions in the months before and after implementing *Lean* principles in the thermal bonding process. Fisher's exact method was particularly suitable as it does not rely on approximations of the normal distribution and provides more accurate results. Consequently, the null hypothesis (H_0), which states that the proportions are equal, was rejected. This supports the conclusion that the improvements had a significant impact on reducing "Overflow" defect in catheter manufacturing.

Additionally, the financial implications of these defects were assessed, translating the reduction in scrap units into tangible cost savings. Figure 6 compares the accumulated scrap costs associated with the condition for the period from May to December in both the 2023 and 2024 periods.

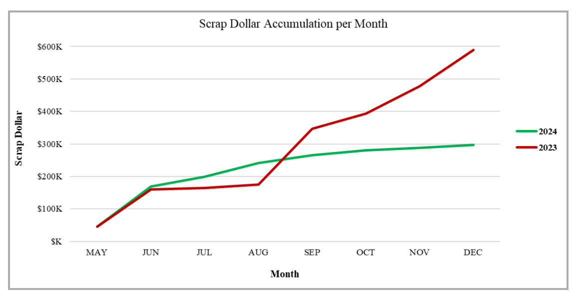

Figure 6
Comparison of Scrap Costs Accumulation in 2023 and 2024

It is important to note that the *Lean* implementation occurred in mid-August 2024, therefore the observed reduction in scrap costs during the latter months of 2024 reflected the gradual impact of the improvements. The total accumulated scrap costs from May 2023 to December 2023 amounted to approximately $589K, whereas for the same period in 2024, the accumulated scrap costs were $297K. When focusing on the months following the *Lean* implementation (i.e., SEP 2024 to DEC 2024), the savings become more evident, highlighting a marked decrease in scrap costs as the process improvements took effect. Overall, this represented a total positive cost saving of $292K, when comparing the two periods (i.e., 2023 and 2024). To assess whether there was a significant difference in scrap costs before and after the implementation of *Lean* tools in the thermal bonding process, an analysis of variance (ANOVA) was conducted (refer to Table 1).

Table 1
ANOVA of Scrap Costs Before and After Improvements

Source	Degree of Freedom	F-Value	P-Value
Improve	1	4.54	0.08
Error	6		
Total	7		

The analysis produced a p-value of 0.08 (p-value > 0.05), suggesting that there was no statistically significant difference in scrap costs between the two periods. The F-value of 4.54 suggested that the improvements in the thermal bonding process impacted scrap costs but because the p-value is greater than 0.05, this effect was not statistically significant. However, it is important to consider that these results may have been influenced by the limited timeframe analyzed. Due to time constraints, the study was based on data only up to December 2024. This restricted period affected the results, as it did not allow for an evaluation of the long-term effects of the implemented improvements.

CONCLUSIONS

Implementing *Lean* tools and methodologies successfully improved the thermal bond process in catheter manufacturing. Transitioning from batch production to a single-piece flow system streamlined the entire production structure, enabling more efficient operations, reduced training lead times, and improved resource utilization. This redesign also enhanced the ability to identify process anomalies, allowing for prompt corrective actions. As a result, after *Lean* implementation, the "Overflow" defect rate decreased from 1.91% to 0.24%. From a financial perspective, the impact of these improvements was evident. Scrap costs associated with the defect over the same period, in 2023 and 2024, revealed a positive cost savings of $292K.

This study contributes significantly to understanding how *Lean* methodologies can drive operational improvements in manufacturing processes. *Lean* transformation not only addressed the immediate challenges of the thermal bonding process but also established the foundation for sustainable improvements. Process optimization (i.e., steps re-sequencing) and the adoption of single-piece flow enhanced the productivity of the thermal bonding process, demonstrating the potential of *Lean* principles to generate both short-term and long-term financial benefits in the manufacturing sector.

While this study provides valuable insights, it was limited by time constraints and focused only on cost savings and defect reduction in the thermal bonding process. Also, the short period available for the analysis limited the observation of the long-term benefits of *Lean* implementation. Therefore, for future studies, it is recommended that the analysis be conducted over an extended period after *Lean* implementation to obtain a more complete understanding of its impact across the entire production line. Additionally, exploring the application of *Lean* tools in different manufacturing areas could further validate the generalizability of these findings and open new avenues for operational excellence.

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