Reduction of Material Variance for the Top Offender in Terumo

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Abstract

Material variance associated with Suture Bondex Plus represented a significant cost opportunity in the Angio-Seal® final assembly process at Terumo Puerto Rico. A Six Sigma DMAIC approach was applied to reduce over-consumption while maintaining product quality and regulatory compliance. Baseline performance was established using financial variance reports and process-level observations, confirming that scrap was not the primary contributor. Root cause analysis identified the absence of a standardized method to retain usable suture between shifts as the main driver of material loss. A designated suture storage method was implemented and supported through updated work instructions, associate training, and routine monitoring through Power BI dashboards. Weekly material variance was reduced by up to **48%** during the project timeframe, demonstrating measurable improvement in cost performance and material control.

Introduction

The final assembly process of the Angio-Seal® vascular closure device at Terumo Puerto Rico uses Suture Bondex Plus, a high-cost material that generated approximately USD $75,000 in negative material variance during the previous fiscal year. This variance indicated over-consumption beyond the Bill of Materials standard, affecting cost control and inventory accuracy.

The objective of this project was to reduce material variance associated with Suture Bondex Plus while maintaining product quality and regulatory compliance. The project applied the Six Sigma DMAIC methodology to identify the main drivers of over-consumption and to implement standardized controls for suture handling and retention between shifts.

Literature Review

The DMAIC framework integrates Lean principles with Six Sigma's statistical approach to provide a structured methodology for data-driven process improvement. By following the Define, Measure, Analyze, Improve, and Control phases, organizations can identify sources of variation, implement targeted improvements, and sustain performance over time [1]. Lean complements DMAIC by emphasizing waste reduction, standardized work, and improved process flow, which directly supports efficiency gains and cost reduction in manufacturing environments [2].

Material variance is a critical indicator of manufacturing performance, as it reflects deviations between actual material usage and standard quantities defined in the bill of materials. Direct material quantity variance helps identify inefficiencies related to process variation, scrap, rework, and inconsistent practices, underscoring the importance of controlling abnormal consumption in high-cost materials [3].

Methodology

This project applied the DMAIC methodology—Define, Measure, Analyze, Improve, and Control—to systematically reduce material variance associated with Suture Bondex Plus in the Angio-Seal® final assembly process at Terumo Puerto Rico. This structured approach enabled the team to quantify baseline performance, validate root causes of over-consumption, implement a targeted solution, and establish sustainable process controls to improve material management and cost performance.

Define Phase: Problem Identification- During the Define phase, a Project Charter was developed to define the problem, scope, objectives, stakeholders, and expected financial impact. The charter identified suture-related material variance as a major cost opportunity in the Angio-Seal® final assembly process at Terumo Puerto Rico. Project boundaries focused on suture preparation, handling between shifts, and return-to-warehouse activities, establishing clear direction for the DMAIC phases.

Measure Phase: Data During the Measure phase, Pareto analyses of material variance were developed to establish the baseline and prioritize the main contributors to suture-related variance, as shown in Figure 1. A Q-diagram was used to define key measurement questions for this phase and guide data collection. A current-state process flow for suture handling and return-to-warehouse activities was developed to visualize process steps and handoffs, as shown in Figure 2. In addition, the percentage of scrap was measured and analyzed to validate its contribution to material variance. The analysis confirmed that scrap accounted for approximately 16% of total suture usage and was not a primary contributor to the observed material variance.

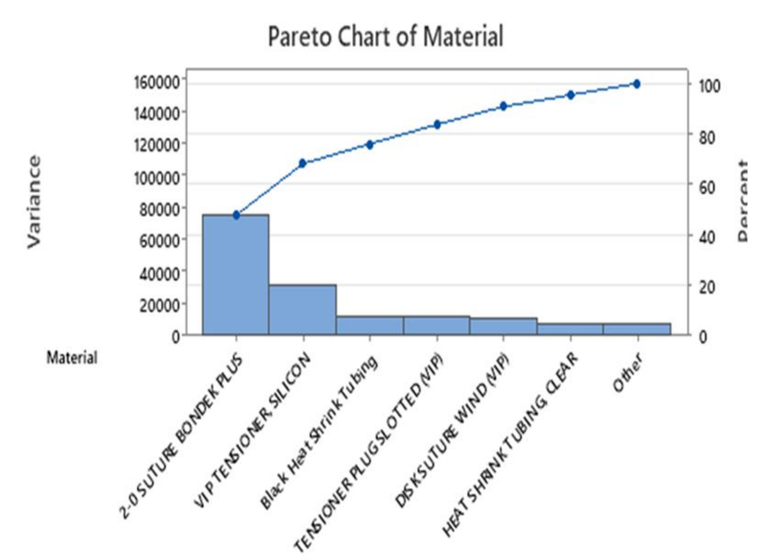

Figure 1
Baseline Pareto

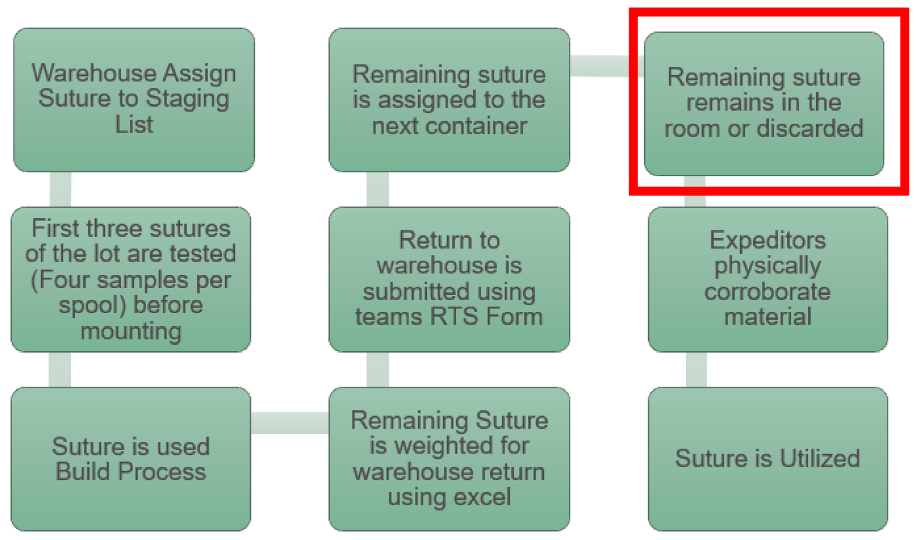

Figure 2
Process Flow

Analyze Phase: Root Cause Identification and Improvement Proposal- Using Fishbone (Ishikawa) analysis, 5 Whys, and a Kaizen event with cross-functional stakeholders, the primary contributor to material variance was identified as the lack of a standardized method to retain usable suture between shifts. A standardized suture storage method was proposed to prevent material loss during shift transitions.

Improve Phase: Solution Development and Execution- The improvement focused on implementing a designated and standardized suture storage area at the point of use to retain and protect usable suture between shifts. Work instructions were updated, installation qualification checklists were completed, and associates were trained on the new handling and storage method. Physical modifications to the suture preparation area were implemented and documented in the work order, as shown in Figure 3.

Control Phase: Standardization and Sustainability- The Control phase focused on sustaining the improvement through updated standard work, training, and routine monitoring. Material variance associated with suture was incorporated into Power BI dashboards for ongoing performance tracking by shift and line. Standard operating procedures and quality documentation were updated to reflect the new storage method, and routine reviews were established to ensure continued compliance and early detection of deviations.

Results

During the project timeframe, a measurable reduction in material variance associated with Suture Bondex Plus was observed following implementation of the designated suture storage method between shifts in the manufacturing process as. Weekly material variance decreased from $2,830 during a high-variance pre-implementation week to $1,809 during the implementation week, representing an approximate 36% reduction. In the following week, variance further decreased to $1,467, corresponding to an approximate 48% reduction relative to the high variance baseline, beginning to create a downtrend as illustrated in Figure 4.

Figure 3
Post Implementation Suture Prep Machine

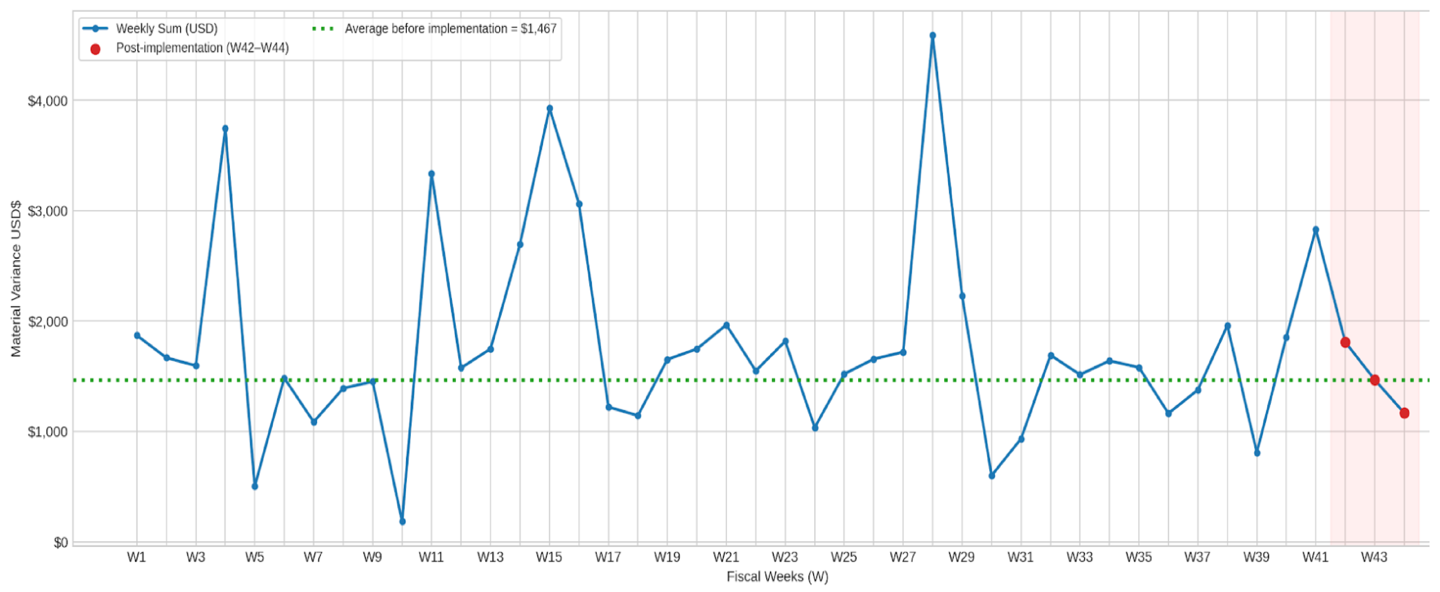

Figure 4
Weekly Material Variance(USD/Week)

Financial Impact

Based on post-implementation performance, the average weekly material variance was $1,459. Applying the highest observed reduction rate of 48% as a sustained scenario, the projected weekly variance would decrease to approximately $759, corresponding to an annualized variance of approximately $39,468. This represented a best-case projection assuming sustained performance and required minimal implementation cost, supporting a favorable return on investment and continued standardization and monitoring of material handling practices.

Conclusion

This project successfully applied the DMAIC methodology to reduce material variance associated with Suture Bondex Plus in the Angio-Seal® final assembly process at Terumo Puerto Rico. Root cause analysis confirmed that material loss during shift transitions was primarily driven by the absence of a standardized method to retain and reuse usable suture. A designated storage method was implemented and reinforced through updated work instructions, associate training, and routine monitoring through Power BI dashboards.

As a result, the project achieved a measurable improvement, reaching a **48%** reduction in weekly material variance during the project timeframe. Based on this best-case performance level, the projected annualized material variance was approximately **$39,468**. These outcomes demonstrated that standardized material handling controls can improve cost performance while maintaining product quality and regulatory compliance.

References

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