

Reduction of Material Variance for the Top Offender in Terumo

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Abstract — *Material variance associated with Suture Bondex Plus was identified as a significant cost opportunity in the final assembly process of the Angio-Seal® vascular closure device at Terumo Puerto Rico. This project applied the Six Sigma DMAIC methodology to investigate and reduce over-consumption while maintaining product quality and regulatory compliance. Financial variance reports and process-level review were used to establish baseline performance and confirm that scrap was not a primary contributor. Root cause analysis tools, including a Fishbone (Ishikawa) diagram and targeted “Why” questioning, determined that the absence of a standardized method to store and manage usable suture between shifts was the main contributor to material loss. A designated and standardized suture storage method was implemented, supported by updated work instructions and associate training. Weekly material variance decreased from \$2,830 in a high-variance week to \$1,809 during implementation and to \$1,467 in the following week. These results confirmed improved material control and reduced variance without compromising product quality or compliance.*

Key Terms — *Lean Manufacturing, Process Optimization, Root Cause Analysis, Standardized Work*

INTRODUCTION

The final assembly area of the Angio-Seal® vascular closure device at Terumo Puerto Rico operates in conjunction with a Subassembly area, where components are prepared prior to final assembly. The Bill of Materials (BOM) for the process includes Suture Bondex Plus, a high-cost suture used to secure critical elements of the device. During the previous fiscal year, USD \$75,000 in negative material variance was associated with this

suture. Material variance occurs when actual material consumption exceeds the standard quantity defined in the BOM, resulting in increased cost, reduced inventory accuracy, and potential impacts to financial reporting.

Addressing this issue requires both engineering and management solutions. Excess material consumption may be influenced by process variability, inconsistent cutting or handling practices, limited measurement discipline, and unclear material management procedures.

The objective of this project was to reduce material variance associated with Suture Bondex Plus while maintaining product quality and regulatory compliance. Standardized controls for suture retention and handling between shifts were implemented to address this objective. A structured Six Sigma DMAIC approach was applied to establish baseline performance, validate root causes, and develop effective control strategies.

LITERATURE REVIEW

The Six Sigma DMAIC framework combines Lean’s focus on waste reduction with Six Sigma’s emphasis on statistical analysis. DMAIC stands for Define, Measure, Analyze, Improve, and Control, and provides a structured roadmap to identify root causes of variation, implement improvements, and sustain performance over time. This integrated approach is widely used to support data-driven process improvement in complex operational environments [1].

Lean principles strengthen DMAIC by emphasizing standardized work and the elimination of non-value-added activities. Lean focuses on improving process flow and reducing waste sources that commonly drive inefficiencies, including excess motion, defects, and unnecessary steps. When applied effectively, Lean can improve

efficiency and reduce material costs and scrap, directly supporting the objective of lowering material usage variance in manufacturing environments [2].

Material variance is a key indicator of manufacturing performance because it reflects the difference between the actual amount of material used and the standard quantity expected to produce the actual output. In standard cost systems, the direct materials quantity variance specifically captures whether too much or too little material was consumed compared with the standard cost established in the BOM, helping identify inefficiencies tied to process variation, scrap, rework, or inconsistent methods. This concept supports the need to investigate and reduce abnormal consumption patterns in high-cost materials, such as Suture Bondex Plus, in the manufacturing process [3].

METHODOLOGY

This project applied the Six Sigma DMAIC methodology to investigate and reduce material variance associated with Suture Bondex Plus in the manufacturing process of the Angio-Seal® at Terumo Puerto Rico. The scope was limited to final assembly operations where the suture is issued, used, handled between shifts, and recorded in accordance with the Bill of Materials (BOM). The DMAIC framework was used to define the problem and project scope, measure current performance using historical and process-level data, analyze root causes of over-consumption, develop targeted improvements, and establish controls to sustain the achieved results.

Define Phase: Problem Identification

During the Define phase, the project scope, objectives, and problem statement were established to address material cost inefficiencies in the Angio-Seal® manufacturing process at Terumo Puerto Rico. A material variance of approximately \$75,000 associated with Suture Bondex Plus was identified, positioning suture as the primary

material cost offender. The project scope was limited to suture handling, usage, and return-to-warehouse activities. A high-level process understanding was developed using a SIPOC diagram to support structured analysis.

Measure Phase: Data Collection

During the Measure phase, historical material variance data related to Suture Bondex Plus were collected and reviewed for the final assembly process Terumo Puerto Rico. Financial variance reports were analyzed to quantify the magnitude of the problem and establish a baseline, confirming an approximate \$75,000 negative material variance. Additional process-level data were gathered to understand suture consumption behavior, including review of BOM standard usage versus actual usage, evaluation of returned material to the warehouse, and analysis of available scrap and usage records. This analysis confirmed that scrap represented approximately 16% of total suture consumption and was not a primary contributor to the observed material variance. This phase provided quantitative evidence that actual suture consumption frequently exceeds standard expectations, indicating gaps in process control and material management.

Analyze Phase: Root Cause Identification and Improvement Proposal

The Analyze phase was focused on identifying the technical and managerial root causes contributing to suture material overconsumption. Structured root cause analysis tools, including a Fishbone (Ishikawa) diagram and targeted “Why” questioning, were applied to evaluate potential contributors related to machine, method, material, manpower, measurement, and environment. The analysis determined that the primary driver of material variance is the lack of a standardized and designated method to store and manage usable suture between shifts, leading to material loss during shift transitions. Secondary contributors, such as variability in weight-based return-to-warehouse calculations and limited process-level measurement, were also identified.

Improve Phase: Solution Development and Execution

During the Improve phase, a targeted solution was developed to address the primary root cause identified during the analysis. The improvement consisted of implementing a designated and standardized suture storage area within the process to retain and reuse usable suture between shifts. This solution reduced material loss during shift transitions by providing a controlled storage location, as illustrated in Figure 1.

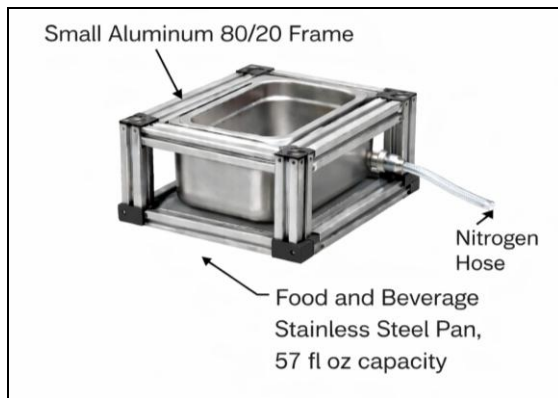


Figure 1
Controlled Storage Location

The implementation was successfully executed across all four production lines. To ensure proper execution, an installation qualification checklist was used, confirming that the utility parameters complied with the material specification without requiring full re-validation, since the improvement did not introduce changes to validated equipment or core manufacturing processes. Furthermore, the drawings were updated and approved within the system. A work order was generated and completed to document the physical modifications made to the Suture Prep machine, which is responsible for the suture cutting process. These actions standardized the new storage method while maintaining strict compliance with established specifications and validated processes.

Control Phase: Standardization and Sustainability

During the Control phase, standardization and monitoring mechanisms were established to sustain

the implemented improvement. Material variance related to Suture Bondex Plus was incorporated into existing Power BI dashboards to enable routine monitoring of usage trends and variance performance by production line and shift. Standard work instructions were updated to include the designated suture storage method between shifts, and associates were trained on the new material handling and storage process to ensure consistent application. Ongoing review of material variance reports supports early detection of deviations, ensuring that the achieved reduction in material variance is sustained over time without impacting product quality or regulatory compliance.

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. 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, as illustrated in Figure 2.

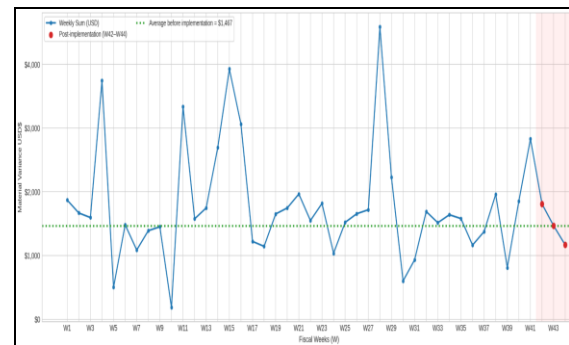


Figure 2
Weekly Material Variance (USD/week)

Financial Impact

Based on the stabilized post-implementation performance, the observed average weekly material

variance associated with Suture Bondex Plus was \$1,459. Applying the highest observed reduction rate of 48% as a sustained performance scenario, the estimated weekly material variance would decrease to approximately \$759. Under this scenario, the projected annualized material variance would be approximately \$39,468.

These results indicated a substantial long-term cost avoidance opportunity for the process if the implemented controls were sustained at the observed best-case performance level. The improvement required minimal implementation cost, resulting in a favorable return on investment and supporting the business case for continued standardization and monitoring of material handling practices. This estimate reflected a best-case projection and assumed sustained performance consistent with the lowest observed weekly variance during the project timeframe.

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

- [1] American Society for Quality (ASQ). (n.d.). *The Define Measure Analyze Improve Control (DMAIC) Process*. Retrieved from <https://asq.org/quality-resources/dmaic>
- [2] Crawford, M. "5 Lean Principles Every Engineer Should Know." *ASME Topics & Resources*. Retrieved from <https://www.asme.org/topics-resources/content/5-lean-principles-every-should-know>
- [3] OpenStax. *Principles of Accounting, Volume 2: Managerial Accounting*. Section 8.2 "Compute and Evaluate Materials Variances". Retrieved from <https://openstax.org/books/principles-managerial-accounting/pages/8-2-compute-and-evaluate-materials-variances>