Process Improvement: Removal of the Second Alkaline Cleaning Step in Dual-Anodized Products

Author: Myleiska M. Rosado Santana
Advisor: Dr. Rafael Nieves, PharmD
Master of Engineering in Manufacturing Engineering
Graduate Project EXPO, October 2025

Abstract

This project focuses on eliminating the redundant second Alkaline Cleaning step used in dual-anodized titanium products (Color + Type II). The repetition exposed silicone masking plugs to high temperatures during the alkaline cleaning process, increasing the risk of cosmetic and functional defects while adding 8–10 minutes of non-value-added cycle time. Validation included risk assessment, data review, confirmation runs, and operator training. Results showed sustained scrap reduction and stable process performance without affecting compliance. The change improved throughput and equipment availability, aligning with lean manufacturing principles.

Introduction

Dual-anodized components are widely used in the medical device industry to enhance surface durability, corrosion resistance, and traceability through color differentiation. The process combines Color Anodize for identification with Type II Anodize for protection. However, both sequences include a full Alkaline Cleaning, creating redundancy that increases cycle time and exposes silicone masking plugs to excessive heat, which can weaken them and cause cosmetic or functional defects. This project seeks to validate whether removing the second cleaning step can simplify the process while maintaining quality and compliance.

Background

Anodizing enhances titanium surface properties by forming a controlled oxide layer. In the dual-anodized configuration, both Color and Type II treatments use nearly identical pre-cleaning operations, including Alkaline Cleaning, rinses, and deionized water steps. Literature indicates that once a titanium surface is adequately cleaned, repeating the same cleaning provides no additional benefit. Instead, excessive exposure to alkaline solutions (160–190 °F) softens silicone plugs, increasing the risk of residue or surface defects. Prior internal assessments showed that redundant cleaning cycles contributed to higher scrap and longer cycle times—key drivers for this process improvement project.

Problem

Dual-anodized products repeat the Alkaline Cleaning step, exposing masking plugs to high temperatures that can weaken or detach them, leading to Media or Type II Residue defects with cosmetic and functional risks. The redundant step also adds 8–10 minutes per lot, reducing throughput and creating bottlenecks. This project removes the second cleaning step to enhance efficiency, reduce scrap, and maintain product quality and compliance.

Methodology

A structured validation methodology was applied to ensure that the removal of the second Alkaline Cleaning step did not impact product quality, compliance, or masking performance.

1. Process Mapping and Flow Analysis: detailed mapping of Color Anodize and Type II Anodize flows was performed to identify duplicated steps, and specific attention was given to preparation and cleaning stages, where redundant Alkaline Cleaning operations were confirmed.
2. Risk and Impact Assessment was conducted, focusing on masking integrity, product cleanliness, and anodizing output.
3. Data Collection and Baseline Establishment: historical scrap data (Oct 2023 – Sep 2025) were analyzed for Media Residue and Type II Residue defects. These categories were directly linked to masking degradation events during the second cleaning.
4. Engineering Confirmation Runs: controlled validation lots were processed with the second Alkaline Cleaning removed. Units underwent 100% and 200% visual inspections to confirm the absence of residues, masking failures, or anodizing defects.
5. System and Documentation Control: a dedicated MES route was configured to apply the revised flow only to dual-anodized products, and manufacturing documentation was updated to reflect the change, maintaining inspection rigor and compliance requirements.
6. Operator Readiness and Training: training sessions and job aids were distributed to reinforce masking integrity, inspection points, and updated process flow. Focused On-the-Job Training (OJT) ensured a consistent understanding and execution among operators.

This methodology provided a robust validation framework combining risk analysis, process verification, and human performance alignment, ensuring the change was effective, compliant, and sustainable.

Results and Discussion

The validation confirmed that removing the second Alkaline Cleaning step produced measurable improvements in process performance, quality stability, and throughput efficiency.

1. Scrap Trend Analysis: Historical data for Media Residue and Type II Residue showed high variability before implementation, with peaks of 604 units (Apr 2024) and 1,254 units (Sep 2024) linked to masking degradation from repeated alkaline exposure.

Results and Discussion cont.

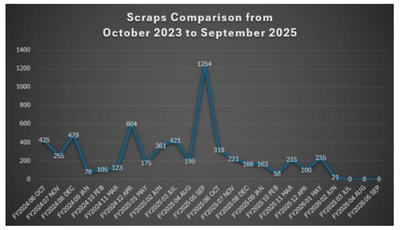

Figure 8 – Scrap Trend Comparison: Oct 2023–Sep 2025

2. Post-Implementation Results: After removal (Nov 2024–Sep 2025), scrap fell below 250 units/month, reaching zero from July to September 2025, confirming process stability.

Table 1 & 2 – Prior and Post-Change Scrap Data

FISCAL_MONTH	SCRAP_QTY
FY2024 06 OCT	425
FY2024 07 NOV	255
FY2024 08 DEC	479
FY2024 09 JAN	79
FY2024 10 FEB	105
FY2024 11 MAR	123
FY2024 12 APR	604
FY2025 01 MAY	175
FY2025 02 JUN	361
FY2025 03 JUL	421
FY2025 04 AUG	195
FY2025 05 SEP	1254
FY2025 06 OCT	319
Grand Total	**4795**

FISCAL_MONTH	SCRAP_QTY
FY2025 07 NOV	221
FY2025 08 DEC	166
FY2025 09 JAN	163
FY2025 10 FEB	58
FY2025 11 MAR	215
FY2025 12 APR	100
FY2026 01 MAY	235
FY2026 02 JUN	21
Grand Total	**1179**

3. Process Validation: Anodizing parameters (current, voltage, temperature and time) remained compliant. A single cleaning cycle achieved full cleanliness under 100% inspection.
4. Cycle Time and Throughput: Average cycle time decreased by 8–10 minutes per lot, increasing equipment availability and efficiency.
5. Masking and Quality Results: No masking failures or residues were observed. Color and Type II anodized surfaces met all visual and dimensional criteria.
6. Compliance and Training: Process documentation and MES routing were updated, and operators' OJT was revised.

Figure 5 – Dual-anodize Area and Process Flow

Overall, the change reduced scrap by >80%, improved process reliability, and sustained compliance, supporting lean manufacturing by eliminating non-value-added operations and enhancing flow.

Conclusion

The second Alkaline Cleaning step was proven unnecessary and non-value-adding to efficiency. Its removal reduced scrap, minimized masking failures, and improved throughput without affecting compliance or quality. The initiative aligns with lean manufacturing by removing non-value-added work, improving equipment utilization, and sustaining reliability across anodizing operations.

Future Work

- ✓ Continue monitoring defect trends to ensure long-term stability.
- ✓ Evaluate potential for similar optimization in single-anodize processes.
- ✓ Extend lean assessments to other surface-treatment operations.

Acknowledgements

Special thanks to the surface treatment team for their collaboration, approval, and training support during the implementation of the process changes; to the production operators for their commitment and teamwork; and to Dr. Rafael Nieves for his continuous guidance, expertise, and dedication to process improvement and quality excellence.

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