

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

*Myleiska M. Rosado Santana
Master of Engineering in Manufacturing Engineering
Advisor: Dr. Rafael Nieves, PharmD.
Polytechnic University of Puerto Rico
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Abstract — *This study addresses the removal of the second Alkaline Cleaning step in the dual-anodized process for titanium medical device components, which currently involves Color Anodize followed by Type II Anodize. Repetition of this cleaning step exposes silicone masking plugs to elevated temperatures, weakening their integrity and increasing the risk of cosmetic or functional defects. In addition, the redundant operation extends cycle time by 8–10 minutes per lot and reduces equipment availability. A structured validation methodology was applied, including risk and impact assessments, baseline scrap data review, confirmation runs, and operator readiness activities. Results demonstrated a significant and sustained reduction in scrap levels after eliminating the second cleaning step, with stability observed for multiple consecutive months. Process parameters remained within compliance, and throughput efficiency improved without compromising inspection rigor or product quality. The improvement aligns with lean manufacturing principles by eliminating non-value-added activities and strengthening process reliability.*

Keywords — *Alkaline Cleaning, Anodize Process, Lean Manufacturing, Scrap Reduction.*

INTRODUCTION

Dual-anodized products are widely used in the medical device industry to enhance surface properties, provide corrosion resistance, and support traceability through color differentiation. This process typically combines two electrochemical treatments: Color Anodize for appearance and identification, followed by Type II Anodize for improved durability and protection. While effective, the dual sequence introduces redundancy in surface preparation, specifically through the repetition of the Alkaline Cleaning step. In titanium anodizing,

surface preparation is critical—it directly impacts oxide uniformity, adhesion strength, and final color consistency. The process typically starts with an alkaline cleaning bath (often sodium hydroxide-based) heated to a specified temperature and time to remove machining oils, grease, and organic contaminants [1].

The second Alkaline Cleaning exposes silicone masking plugs to elevated temperatures ranging from 160 to 190 °F, which can compromise their integrity and increase the risk of cosmetic or functional defects [2]. In addition, the repeated operation extends processing time by 8–10 minutes per lot, limiting throughput and increasing equipment load without adding value to the product. These inefficiencies highlight the need for process simplification aligned with lean manufacturing principles.

This study investigates the removal of the second Alkaline Cleaning step within the dual-anodized flow. The objective is to demonstrate that eliminating this redundant activity reduces scrap, improves process stability, and increases throughput while maintaining product quality and regulatory compliance. The work integrates risk analysis, engineering confirmation runs, and operator readiness to validate the effectiveness of this improvement and ensure sustainable results across manufacturing operations.

PROBLEM STATEMENT

Dual-anodized products (Color Anodize followed by Type II Anodize) currently repeat Alkaline Cleaning in both treatments. During the second Alkaline Cleaning, process temperatures of 160–190 °F soften silicone masking plugs, increasing the likelihood of partial lift or detachment. This exposes previously treated areas to

chemical/electrochemical action, producing cosmetic nonconformities and, in some cases, functional risk.

In addition to quality exposure, the repeated cleaning introduces an avoidable 8–10 minutes of cycle time per dual-anodized lot, reducing throughput and creating WIP congestion. The improvement proposed is to remove the second Alkaline Cleaning step from the dual-anodized flow while preserving process outputs and compliance.

This process is described per the procedure.



Figure 1
Color Anodizing Process Flow

The Type II Anodize Process is described in the procedure.

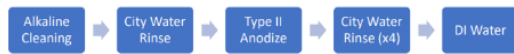


Figure 2
Type II Anodizing Process Flow

The dual anodized product flow per process.



Figure 3
Dual-Anodize Flow



Figure 4
Proposed Process Flow for the Dual-Anodized Parts

LITERATURE REVIEW

Surface treatment processes such as Color Anodize, Type II Anodize, and Nitric Acid Passivation are widely employed in the medical device industry to enhance surface performance, ensure corrosion resistance, and support product identification. All metal implants manufactured and

processed within the company undergo at least one of these treatments, depending on functional and design requirements.

Color Anodize is an electrochemical process that enhances the natural titanium oxide layer primarily for appearance and identification purposes. In daily operations, this treatment serves a dual role: it not only provides surface durability but also enables traceability, as part drawings specify distinct anodized colors for assembly and product differentiation. Literature emphasizes that adhesion and color uniformity depend on rigorous pre-treatment cleaning to remove organic and metallic contaminants before initiating the electrochemical process [3] [4].

Type II Anodize is an electrochemical treatment designed to artificially thicken the oxide layer on titanium substrates. This controlled oxide growth increases corrosion resistance and provides a stable protective barrier. Studies report that the corrosion protection efficacy of Type II anodizing is strongly influenced by surface preparation, electrolyte parameters, and oxide thickness. Internal validations at the company have demonstrated that optimized Type II anodize significantly reduces defect rates when adequate cleaning and racking strategies are followed. In some operations, the by-product of the Type II process requires a glass bead blasting step to achieve the required gray surface finish [3] [4].

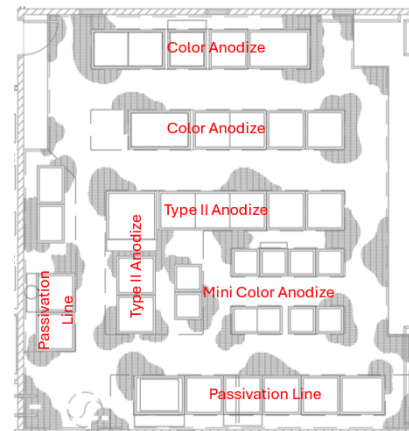


Figure 5
Anodizing Area

Nitric Acid Passivation is a chemical process that removes free iron and other surface

contaminants, promoting the formation of a stable passive oxide layer. This process improves resistance to environmental exposure by preventing further reactions with air or moisture. Literature confirms that passivation efficiency depends on the complete removal of iron residues and consistent post-treatment cleaning. For the anodized area, refer to Figure 5 [3] [4].

Across these treatments, masking practices are critical to protect designated surfaces from electrochemical exposure. Standard industry practice relies on non-conductive silicone plugs. However, repeated exposure to elevated temperatures and alkaline solutions can reduce plug stiffness, increasing the risk of leakage or failure. At process temperatures of 160–190 °F, silicone plugs may soften or even detach, allowing process solutions and current to reach previously treated areas. This condition compromises the protected finish and may result in cosmetic or functional defects. Research and internal audits highlight that unnecessary repetition of identical alkaline cleaning steps contributes to plug degradation and defect induction without providing additional benefit once parts have already been adequately cleaned and protected from contamination.

To process the units during these treatments, they are placed in manufacturing holding aids such as racks or baskets. In anodizing processes, titanium racks and baskets offer stable and reliable support, maintaining their structural integrity even under exposure to aggressive electrolytic solutions. This stability ensures the formation of high-quality anodized layers characterized by uniform thickness and consistent color distribution [5]. For dual-anodized parts, an additional masking step is required between the first and second treatment. This masking consists of inserting a silicone plug into the area that must remain with the initial surface treatment. Because silicone is resistive and non-conductive, it effectively prevents the masked surface from being affected during the second treatment, resulting in the required dual finish. For the dual-anodize area and flow in scope, refer to Figures 6 and 7.

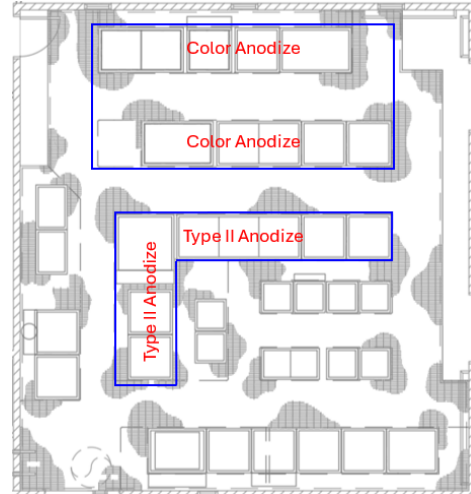


Figure 6
Dual-anodize Area

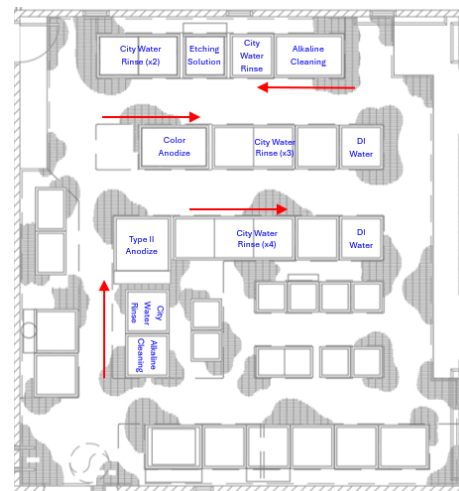


Figure 7
Dual-anodize Area and Process Flow

As observed in the process flows, both Color Anodize and Type II Anodize share very similar preparation and cleaning steps, including Alkaline Cleaning, city water rinses, and final deionized (DI) water rinses. For dual-anodized products, this means that these cleaning operations are repeated. Considering that the parts are already cleaned and masked after the first treatment, the additional Alkaline Cleaning step in the second sequence does not contribute to output quality or compliance.

Published guidance and internal validations converge on the importance of first-step cleaning effectiveness rather than redundant repetitions. No sources reviewed indicate a requirement to re-clean with the same alkaline method once the surface is

adequately prepared. Instead, lean manufacturing principles support the elimination of non-value-added steps to streamline flow, reduce processing time, and prevent defect introduction.

In the specific context of this project, the scope is to improve processing time for dual-anodized products, where parts undergo both Color Anodize and Type II Anodize sequences. The improvement aligns with lean principles by:

- Eliminating redundant cleaning activities.
- Preventing masking failures induced by unnecessary re-exposure.
- Reducing overall cycle time while maintaining inspection rigor (200% visual verification for dual-anodized components).

Thus, literature and internal knowledge jointly support a process simplification strategy that preserves product quality and compliance while directly improving efficiency.

METHODOLOGY

The validation of the process change was carried out through a structured engineering approach designed to confirm that the elimination of the second Alkaline Cleaning step would not negatively impact product quality or compliance. The methodology consisted of the following activities:

- 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.
- Risk and Impact Assessment was conducted, focusing on masking integrity, product cleanliness, and anodizing output.
- Historical data were reviewed to identify defects most frequently associated with dual-anodized products, specifically Media Residue and Type II Residue.
- Data Collection and Baseline Establishment: scrap data were extracted from the

manufacturing system, covering October 2023 to September 2025, and this baseline quantified rejection rates linked to masking-related failures prior to implementation of the change.

- Controlled Confirmation Runs: engineering lots were processed with the second Alkaline Cleaning step removed, and units underwent 100% and 200% visual inspections to confirm the absence of residues, masking failures, or anodizing defects.
- Parameter and Cleaning Validation: the capability of the Alkaline Cleaner to remove oil residues and foreign material was tested under standard operating conditions, and acceptance criteria were defined as zero visual residues under 100% inspection. Results confirmed that a single cleaning cycle was sufficient.
- System and Documentation Controls: 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.
- Operator Training and Readiness: Communication sessions were held with operators to explain the revised flow and its quality rationale. Quick-reference job aids were distributed, emphasizing correct masking practices and inspection points. Focused on-the-job training (OJT) was conducted to ensure consistent execution of the updated process.

This methodology provided a comprehensive validation framework that linked observed scrap data with engineering trials and compliance verification. By combining risk analysis, confirmation runs, and operator readiness activities, the study ensured that the removal of the second Alkaline Cleaning step was implemented in a controlled, documented, and effective manner.

RESULTS AND DISCUSSION

The objective of this section is to present the outcomes of the validation by comparing the scrap observed before the implementation of the process

change with the results obtained afterwards. The information analyzed was extracted from the manufacturing system, focusing on scrap associated with “Media Residue” and “Type II Residue.”

The validation was carried out based on the analysis of these recorded scrap events, as they represent one of the main sources of rejection in dual-anodized products. The purpose was to confirm whether the elimination of the second Alkaline Cleaning step had a positive impact on the reduction of these failures. In this way, the comparative results before and after the implementation allow for an objective evaluation of the effectiveness of the change and its contribution to process and product integrity.

To better explain the typical defects recorded in dual-anodized products, which affect the internal anodized surface when the masking cap deteriorates, the following were identified:

- Media Residue: occurs when silicone caps degrade under exposure to elevated temperatures during cleaning. As the cap softens or partially melts, it allows process solutions to penetrate and compromise the integrity of the anodizing.
- Type II Residue: occurs when residues from the Type II process remain inside the unit. This is caused by the expansion and retraction of the silicone cap under heat, which compromises masking integrity and allows process solution to enter. As a result, a powdery residue is formed that solidifies and damages the anodized surface.

Table 1 presents scrap data for Media Residue and Type II Residue for the period from October 2023 to October 2024, corresponding to the stage prior to the implementation of the removal of the second Alkaline Cleaning step in dual-anodized products.

Table 2 shows the results for the same defects after the change was implemented, in the period from November 2024 to September 2025. The comparison shows a significant reduction in scrap associated with these two failure modes. Figure 8

presents a comparison between October 2023 and September 2025 with the data prior to and after the implementation of the removal of the second cleaning.

Table 1
Media Residue and Type II Residue Scraps (October 2023 to October 2024)

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

Table 2
Media Residue and Type II Residue Scraps (November 2024 to September 2025)

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



Figure 8
Scraps Comparison October 2023 to September 2025

Figure 8 presents a month-to-month comparison of scrap levels from October 2023 through September 2025, covering the periods before and after the implementation of the process change to

remove the second Alkaline Cleaning step. The data show a clear downward trend in scrap once the change was introduced.

In the months prior to implementation, scrap levels fluctuated considerably, with peaks such as 604 units in April 2024 and a maximum of 1,254 units in September 2024, both primarily associated with Media Residue and Type II Residue defects. These fluctuations highlight the recurring impact of masking failures caused by repeated cleaning exposure.

Following the elimination of the second Alkaline Cleaning step, a significant and sustained reduction in scrap was observed. From October 2024 onwards, values consistently decreased, stabilizing below 250 units per month and in some months dropping to nearly negligible levels (e.g., 21 units in June 2025). Notably, for the months of July, August, and September 2025, no scrap has been reported to date, further confirming the effectiveness and stability of the process change.

This analysis confirms that the process modification not only reduced overall scrap volume but also improved process stability by eliminating one of the primary sources of variation. The results provide strong evidence that removing the redundant cleaning step effectively reduced masking-related failures, increased masking durability, and contributed to higher process reliability and throughput. This change has proven effective in addressing one of the company's top scrap offenders and supports process integrity while maintaining compliance with product acceptance criteria.

The validation also confirmed that process parameters for anodizing remained unaffected. All conditions stayed within compliance, and no deviations were detected. An Engineering Technical Report was developed to document the role of the Alkaline Cleaner, the situations in which it is applied, and the expected impact of reducing from two cleaning cycles to one. Tests evaluating its ability to remove oil residues and foreign material met acceptance criteria under 100% visual inspection. Similarly, during the second treatment sequence, no additional residues were observed,

confirming that a single Alkaline Cleaning cycle is sufficient to ensure adequate cleanliness and product quality.

Validation and confirmation runs further demonstrated that removing the second Alkaline Cleaning step maintained output quality while simultaneously improving flow efficiency. Observations at the production line level showed an average reduction of 8–10 minutes per dual-anodized lot, directly contributing to improved throughput. Masking integrity was preserved, with no plug-related defects observed, and visual acceptance for both Color and Type II anodized surfaces was maintained. Compliance requirements were not impacted, as cleaning qualifications for non-sterile products remain valid and no new worst-case conditions were introduced. In addition, process documentation and MES routing were updated to restrict the revised flow to dual-anodized products, while retaining the 200% inspection requirement. Operator readiness was also addressed through communication, quick-reference job aids, and focused on-the-job training emphasizing correct masking placement and inspection practices.

In summary, the results validate that eliminating the second Alkaline Cleaning step reduces scrap, shortens cycle time, and enhances overall throughput without compromising process integrity, compliance, or product quality. The change also aligns with lean manufacturing principles by removing non-value-added activities, mitigating historical masking-related failures, and strengthening process reliability. Operator readiness was ensured through communication sessions, quick-reference job aids emphasizing masking checks, and focused OJT on the revised flow, including correct masking placement and 200% inspection expectations.

CONCLUSION

The second Alkaline Cleaning step in dual-anodized products has been identified as redundant, as it does not provide measurable improvement once the initial validated cleaning step has been

completed. Instead, repeating the process increases the risk of masking failures, since silicone plugs may lose integrity after unnecessary exposure to chemicals and elevated temperatures. This additional cleaning also extends processing time, requires extra operator handling, and consumes equipment capacity without adding value to product quality.

Eliminating this redundant step ensures that quality and compliance remain intact, relying on the proven effectiveness of the first cleaning and the robust inspection controls already in place. The adjustment reduces 8–10 minutes per dual-anodized lot, improving throughput and making cleaning equipment more available for value-added operations. Beyond time savings, this change aligns with lean manufacturing principles by streamlining the process, eliminating non-value-added activities, and reducing the likelihood of induced defects.

Moreover, the improvement supports ongoing corporate initiatives focused on efficiency, cost reduction, and defect prevention, while maintaining rigorous verification standards such as 200% visual inspection for dual-anodized components. In conclusion, removing the second Alkaline Cleaning step strengthens process reliability, enhances flow, and sustains compliance with all internal validations and regulatory requirements.

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