



PRECISION COATING™

MICRALOX®
Micro-Crystalline Anodizing

Anodizing for Medical Applications: The Creation of MICRALOX and the Failings that Lead to It

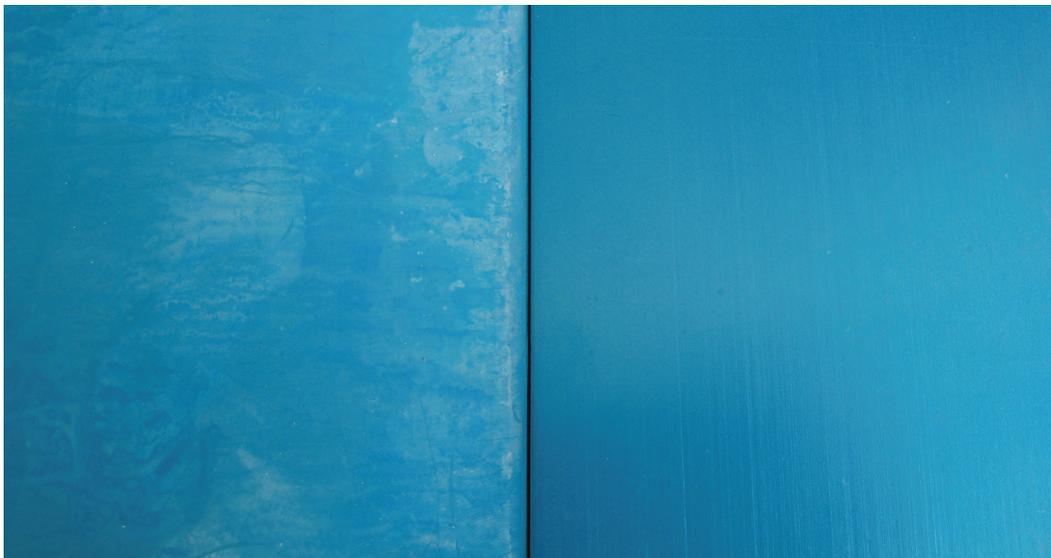
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Introduction

Demand for high performing aluminum anodized products in the medical industry has never been higher. Driven by poor performing anodic coatings, the medical industry has attempted to replace aluminum anodized products with several substitutes. A few that come to mind are nylon-coated trays and cases, painted and powder-coated aluminum handles and tools, while plastic, stainless steel, and titanium materials have also been investigated to replace aluminum equipment. The threat of substitutes to the anodizing world is real, and focus on this problem is of the utmost importance to ensure that anodized aluminum products have a place in the future of medical equipment. Luckily for the anodizing industry, the substitutes chosen to replace anodized aluminum, so far, have all had their share of problems as well.

Up to now there has been a certain amount of tolerance for these poorer performing anodized products, because it was accepted that this was just how anodize reacted to the conditions that the medical industry exposed them to. In particular, fading of color during sterilization, and more recently, the dissolution of the coating during cleaning with more aggressive cleaning agents. Thusly, there has been an increased call for improved anodize performance because aluminum—and specifically anodized aluminum—has many of the properties that are so desirable to the medical industry. Since the substitution choices have had other negative issues, the medical world has turned to the anodizing industry to improve their coating technology, consequently allowing for continued use of the product.

New technology, MICRALOX[®], has been born of this demand, which is increasing the chances that anodized aluminum will remain the top choice of manufacturers. This discussion explores this new technology, as well as the possible choices in the medical world for reusable medical equipment that undergoes sterilization, cleaning, and/or disinfecting.



A sample of anodized aluminum used in surgical trays that has been through a 12.5 pH cleaning and sterilization process 10 times.

A sample of aluminum coated with MICRALOX that has been through a 12.5 pH cleaning and sterilization process 10 times.

A Brief History

Anodizing on aluminum has been a widely accepted and significantly utilized metal finishing option for reusable, non-invasive medical products within the medical component manufacturing community for many years. The history of using anodizing as a medical finish dates back to when the first aluminum medical product was manufactured some 60-plus years ago. The benefits of this finish have been thoroughly examined, tested, and re-tested since that first aluminum product was introduced. Its durability, multiple and varied cosmetic choices due to its dye-ability, along with the low-cost advantage that aluminum anodizing carries, have long been the driving forces behind its world-wide acceptance as an aluminum finishing choice. The medical industry simply latched on to the anodizing bandwagon as it began to soar in popularity in the 1960s and 70s—and for good reason.

Anodized aluminum created significant advancement in the areas of reusable medical instruments, components, and more recently, sterilization trays, as well as many other areas. Its use allowed and presented tremendous flexibility with product design due to the relative ease of machining and forming of aluminum. In addition, the light-weight nature of aluminum was, and continues to be, an important consideration given the alternatives. The fact that aluminum can be anodized for protection, wear resistance, and cosmetics, gave it the lead in the race for the best medical instrument material choice.

In the last several years, however, this is being re-examined. The medical case and tray industry, along with the medical device industry, has begun to place higher performance demands on reusable aluminum anodized products. This demand, it seems, is being primarily driven by the medical practitioners' need to clean, sterilize, and disinfect with more aggressive chemistries. The increased performance requirement of anodizing became necessary after it was discovered that cleaning in high-pH chemistry could be used in an effort to eliminate prion disease-causing proteins, and this method of cleaning has now found general acceptance in the European medical arena. As the chemical treatments that have proved effective in this cause became harsher and more aggressive, anodized aluminum finally began to show its weakness. Up to this point, anodized aluminum was enjoying an unmatched popularity as a material and finishing of choice.

Alternatives to Aluminum Anodizing for Reusable Medical Devices

As an amorphous coating, aluminum anodizing is at its most vulnerable state when exposed to very high- and very low-pH chemicals. While it will successfully withstand many less-aggressive chemistries, strong acids and bases are its “Achilles’ heel.” The chemical reaction that occurs when anodic coatings are exposed to these chemistries will, by nature, begin to dissolve the anodic coating until the aluminum is left exposed. However, the reaction usually will not stop there, as the aluminum itself will then be attacked and compromised.

The results of such a situation will be the removal of all, or a significant part, of the coating itself, as well as any markings and graphics that may be present. This situation renders the product useless if it is an instrument—and is not much better for cases and trays.

Obviously, when this type of cleaning protocol is to be employed, anodized aluminum becomes far less desirable than, let’s say, a stainless steel substitute that can withstand the vigorous cleaning and sterilization methods described above.

To combat the undesirable effects of this newly created problem, the call went out for better performing materials and/or finishes. While manufacturers loved the ease of manufacturing aluminum and the cosmetic attributes of anodizing, the newly arisen problem of degradation of the coating during cleaning created a concern large enough to be placed on high priority. Initially, many ideas were investigated and some were even launched with little test data; but all the while, aluminum and anodizing were still being widely used, though its combined performance was beginning to be criticized.

Medical Cases and Trays: Problems with Weight, Cosmetic Finishes, Markings

Let’s take a moment and look at the reaction from medical case and tray manufacturers. Up to this point, aluminum was being widely used and even increasingly so because of its light weight, decorative capability, ease of manufacturing, and cost.



Since instrument trays have a weight limit when filled with tools, changing to stainless steel was looked upon negatively for obvious reasons. And it wasn’t just for weight reasons. Stainless steel was more expensive to buy and more difficult to manufacture. Therefore, switching to stainless steel, due to the overall appeal and cost of the trays, would be prohibitive.

In addition, there was a lack of good cosmetic finishes that could be applied to the stainless steel; the cases were not attractive. Making it worse, there was no way to mark the trays with instructions, logos, and graphics that were easily visible—and more importantly—durable, while being practical and cost effective. Buyers were less enthusiastic about paying more for a product they believed still had too many negative attributes.

While stainless steel as a material certainly addressed the chemical resistance issue, other issues (as described above), were introduced, giving rise to new problems. The result is a product that still has many drawbacks from a functional and cosmetic viewpoint. Still, in many countries stainless cases are being used reluctantly.

The ability to mark or label a part in the medical world is very important. Not having easily read markings for instructional and safety reasons can become a legal issue. Markings that are not easily readable can cause great harm to patients and care-givers, alike. Therefore, markings that are not durable are problematic; as are markings that start off with poor contrast. It is also a concern if the marking is strong but the coating it sits on is not. In the end, the product's markings must be good through the life cycle of the product—and it's doubtful that manufacturers want the markings to determine a product's useful life.

Nylon Coatings, Titanium, and Plastics

To attack the challenge of cosmetics and markings on stainless steel, case manufacturers began to employ a nylon coating to their cases. This coating has the ability to contain color and can be marked with a fair (but not great) degree of visibility and acceptability and was considerably better than what was available on the raw stainless. Nylon seemed like a good solution to the problems that stainless steel presented, even though weight still played a role.

There were, however, two problems that would unfold with nylon coating. First, the trays with this nylon coating did not dry very well after sterilization. This characteristic proved to be a big problem, as it created cleanliness concerns. In addition, the coating itself began to delaminate after repeated usage. The latter issue created clogged nozzles in the washers and entrapment of unwanted chemistry in the splits and cracks. This coating created more issues than it solved for all involved.

Manufacturers also looked at titanium as an alternate light-weight material. Titanium can be machined and formed fairly well. It can also be anodized, but in limited colors, and does not hold its color well when handled repeatedly. There are no other finishing choices for titanium that would be an enabler. It faces the same problem as stainless steel does. The material is also very expensive and the marking options are generally limited to choices provided to stainless. Many of these are too easily removed during cleaning. Therefore, titanium has not been accepted as an alternative due to these problems.

Plastics, too, have been explored as an option, but they have varying issues that have also proven to be less than desirable in the case manufacturing arena, though they have had some very limited success in the instrument market. This, however, seems to be on a downward trend.

Thus far, there have been very few materials or coatings that have shown to be a better choice than anodized aluminum. As such, anodizing continues to be the top choice for manufacturers, but it doesn't mean they are happy about the performance shortcomings or have given up finding a better solution.

Cases, Instruments, and Devices Show Poor Performance Overall

However, to date, there are still many raw stainless steel cases being sold, despite the marking and cosmetic shortfalls, due to poor available choices regarding chemical attack. This is especially true in the European market.

As with case manufacturers, instrument and device manufacturers have faced similar problems. Instruments, in many instances, are being exposed to the same high-intensity cleaning protocols as are the cases and trays. Instruments have all the same problems as the cases, but with one major added complexity: machining. Machining adds a complexity, with material choice having a tangible influence on cost differentials. Moving to stainless as a material can add considerable labor and machining-time cost to the end product. Titanium is simply too expensive. Other materials have met with varied results and none have been accepted as the gold standard.

Some plastics have also been utilized, but many end-users complain of the appearance, perceived quality, and feel of the product, as well as other drawbacks. Marking these items has also proved to be an area of concern.

The underlying theme is that no material or finish to date has had a major impact on the positioning of anodized aluminum in the medical field; and there are still options being explored due to its shortcomings in chemical resistance.

Investigating the Problem

What can we do as members of the aluminum and anodizing industries to protect a market that clearly sees the benefits of the products we sell, but also sees the newly created gap between performance and need?

This was the question that was asked when it became evident that the trend in the market was shifting towards finding alternatives to aluminum anodizing on cases, trays, instruments, and reusable component medical parts. The reality was that the developing problem concerning anodized aluminum needed to be solved—and quickly. If the anodizing industry planned on relying on the medical industry to be a consistent revenue sector, then we needed to find a workable solution. We also believed that if we could solve these issues, then we could not only rely on this business as steady revenue, but make it a significant growth area.

However, as with most problems, there was a need to become intimate with the problem before it could be attacked and solved.

To understand the breadth and depth of the issue, a series of investigations and interviews needed to be performed. Information was gathered from anodize companies, machine shops, contract manufacturers, OEMs, and even hospital staff and doctors, to determine what the scope and depth of this problem really was. What did the “real monster” look like and how was the problem being perceived and framed? Was this an anodize industry issue? An OEM issue? To quote an unnamed source, “The real monster is in the lack of consistent [sterilization] procedures used throughout the country, and for that matter, the world.” The overarching response indicated that there were so many different procedures and methods for cleaning, sterilizing, disinfecting, etc., that it was hard to get a handle on the degree of the problem relating to underperforming anodized aluminum components.

The Two-Fold Truth about the Failing

What if anodizing was failing because it was being subjected to conditions it could never withstand? Was it a user training issue, or did it simply mean that manufacturers needed to find a better alternative so that incorrect treatment of their products would not negatively impact their life? The truth was both. The equipment was going to be sterilized by the methods that were available to each end-user. The finish and/or material just needed to be able to tolerate what was thrown at it.

In the end, it became clear that anodized equipment was being subjected to a varying degree of treatments—performed with different cleaning agents, at different times, chemical strengths, temperatures, numbers of cycles, etc. Under some of these conditions, aluminum anodize began to fail. The major link in all of this was that when exposed to high pH at elevated temperatures, anodized aluminum failed rapidly. This failure was single-handedly igniting the drive to find alternative materials and/or finishes.

Micro Crystalline Aluminum Oxide

As explained earlier, any attempt to find an “anodizing” cure for this problem needed to begin with the fact that anodizing is an amorphous coating. It, like all amorphous structures, has weak bond strength and random molecular arrangements that are less ordered and less stable than crystalline structures. For example, typically, pharmaceutical companies place emphasis on creating amorphous drugs that can quickly dissolve into the body. Amorphous structures are more easily broken down or dissolved. In this case, the goal was to see if it was possible to create a partial crystallinity in the coating structure, thereby making the coating itself more stable.

The first challenges to answer concerning creating this type of structure change were: would it be possible, and if so, could we create crystallinity without making the coating completely crystalline? There were already fully-crystalline anodic coatings on the market, but they lost the characteristics that make aluminum anodizing so popular. Without the beneficial attributes of traditional aluminum oxide coatings, having chemical resistance alone wouldn't be a sufficient result and would not change the search for a substitute. Therefore, the challenge was to keep the beneficial characteristics of the amorphous anodic coating while forming some greater stability for chemical resistance. Hopefully, by creating partial crystallinity.

Initially the focus was simply on finding ways to try and enhance the stability of the coating by employing different, and even multiple, sealing methods. While we saw some better results, we couldn't claim victory over the major problem: very low and high pH.

Creating MICRALOX®

After two years of experimentation with many types of chemical reactions and testing the results, a process was developed that possessed a unique solution to the problem of chemical attack. The process maintained the amorphous structure and beneficial characteristics of type II and type III anodic coatings, but also was proven to have partial crystallinity throughout the coating. As was the hypothesis, this partial phase change showed that the coating was now able to resist chemical attack for far greater periods of time. When placed in a strong caustic solution, such as sodium hydroxide, which is used extensively in the anodizing industry to rapidly strip anodic coatings, the micro crystalline aluminum oxide (MICRALOX®) parts showed no sign of attack, even after the traditionally coated parts were completely stripped in the same bath.

In fact, MICRALOX was so unique that it was granted two U.S. patents, with multiple patents in other countries.

Sister Chemistries

Since the inception of the original MICRALOX, Precision Coating has introduced two sister chemistries to the MICRALOX family: MICRALOX® Ultra and MICRALOX® Lumina.

MICRALOX Ultra

When maximum performance for strong alkaline cleaning is critical to quality, MICRALOX Ultra provides 50X the chemical resistance compared to decorative type II anodizing. Aluminum parts coated with MICRALOX Ultra can withstand high-pH cleaning and sterilization protocols commonly used in European markets. MICRALOX Ultra coated parts can also withstand many other aggressive environments that would otherwise strip conventional anodic coatings and subject the parts to extensive corrosion.

As with all MICRALOX coatings, MICRALOX Ultra can receive embedded Sanford Print for crisp, permanent markings that do not delaminate, fade, or chip. This combination of best-in-class chemical- and corrosion-resistant coating and non-destructive markings provides the maximum protection for medical instruments for superior in-field performance.

For more information on MICRALOX Ultra performance, [download this coating datasheet](#).

MICRALOX Lumina

The clear, translucent oxide of MICRALOX Lumina provides a perfect balance of breakthrough chemical resistance and design flexibility for medical device applications. Whether left natural, or dyed one of nine vivid colors, MICRALOX Lumina coatings achieves 16X the resistance in a hot alkaline strip test compared to type II decorative anodizing. Unlike conventional anodizing and hard coat, the partially crystalline anodic coatings of MICRALOX Lumina hold up over a lifetime of regular cleaning and sterilization without fading, chalking, or corroding.

As with all MICRALOX coatings, MICRALOX Lumina can receive embedded Sanford Print for crisp, permanent markings that do not delaminate, fade, or chip. This combination of superior chemical- and corrosion-resistant coating and non-destructive markings provides assurance for a full lifetime of stringent cleaning and sterilization, as required of all medical devices.

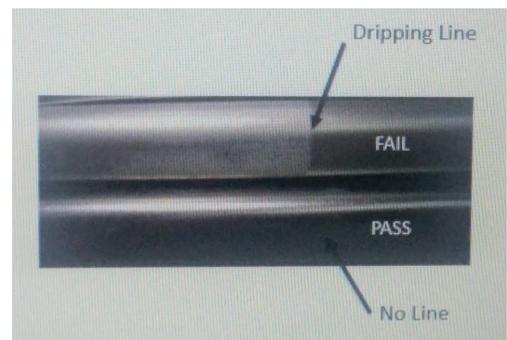
For more information on MICRALOX Lumina performance, [download this coating datasheet](#).

20 Times Longer Protection

It should be noted that due to the fact that there is only a partial phase change and that all the benefits of aluminum oxide remain, the new anodic coating is not impervious to chemical attack, but does have a far greater ability than traditional anodic coatings to fend off the attack. On average, the feedback is that the MICRALOX coating lasts five to 20 times longer than traditional anodic coatings when exposed to the same conditions. The result is that anodized aluminum for reusable medical products now have significantly higher performance capability and a longer life cycle, especially when subjected to the harsh treatments of the medical world.

Notably, there were two other important side benefits that came with this incredible innovation. The first was that the coating passed 15,000 hours of salt spray exposure without any pitting. This added benefit creates an alternative solution for marine applications as well, and could be a viable candidate to replace chromium-based seals. This could have an important environmental impact.

The second was the discovery that products anodized with this process now passed the Sterrad and Steris sterilization methods without any organic dye fading or discoloration. The ability to pass exposure to hydrogen peroxide, which is the dominant chemical in the Sterrad NX and Steris DO processes, has helped solve one of the biggest performance concerns for anodized aluminum in the North American medical market. Previously, with few exceptions, organic dyes would fade or discolor from repeated exposures and sterilization procedures. This, of course, would impact cosmetic appeal and could translate into perceived instrument performance issues. Eliminating this problem is a significant event.



Results of extreme alkaline resistance test (high pH 13.5), which confirms MICRALOX's virtually indescribable coating performance under extreme conditions.

What of the marking and graphics problem? Having the finish be more chemically stable certainly isn't helping the areas that are being laser or mechanically engraved through the finish. And it isn't making silk screening to the surface of the product stronger or more resistant to delamination. These types of marking have their place, but could now become the weak link in the chain of producing durable reusable medical products.

Understanding this problem, we can now employ a method of printing “into” the anodic coating before doing the phase change. The “embedded” printing is done by putting specialized dyes into the pores of the anodic coating. These dyes can be specifically placed by several methods and can create varying images. Logos, instructions, safety concerns, etc. can now all be encapsulated within the anodic coating. After sealing and phase change, the markings are permanent. Only complete destruction of the coating can destroy the markings. Given the new performance advancements available with micro crystalline aluminum oxide, the markings can be there through the life of the device, case, instrument, or tray. Problem solved.

Conclusions

Now that there is a much improved anodic coating on the market for use on reusable cases, trays, tools, and components, what is the reaction in the medical industry? Transformation. Engineers, buyers, and industry leaders are learning of the new anodic coating's capability and are realizing it can be an easy substitute for traditional anodic coatings—and they are taking note. More and more [tests have been performed](#) and acceptance is growing rapidly. Demand is increasing as more OEMs are specifying the finish on their prints.

Since MICRALOX is still classified as an aluminum anodizing, there are no major hurdles that have to be jumped to get approvals on its use. It is simply a better performing aluminum oxide coating!

The performance improvements brought on by the micro crystalline aluminum oxide coating will enable anodized aluminum to continue to grow in a market that was beginning to look away from it as a finish. Having retained the characteristics of type II and III anodize is helping this coating become the coating of choice in the medical device industry. Those characteristics such as dye-ability, hardness, thickness, and electrical insulation, along with cytotoxicity compatibility, etc. have made changing finishing specifications easy and quick. Adding embedded printing to these positive features makes the issues facing the medical industry far less intrusive. There is now a reasonable alternative.

The positive attributes of anodized aluminum, so dear to the medical industry, can continue to be utilized and developed. Aluminum products need not be subject to having their life limited by their unreadable markings or deteriorating finish.

Learn about further advances regarding MICRALOX[®], our revolutionary coating technology for medical device components. It produces a long lasting, virtually indestructible surface, which delivers dramatically superior chemical and corrosion resistances and eliminates color-fading due to super-heated steam. **Contact us** to find out how we can help you with your next medical device anodizing project.



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