



# **PRECISION COATING™**

The Surface is Only the Beginning

Precision Coating supports the medical device industry as a reliable supply chain partner, providing years of coating and application expertise and world-class facilities that contribute to the manufacture of high-quality medical products. Working together with you, we help make the devices and instruments that improve health outcomes through the application of specialized coatings that advance and enhance functionality and performance.

## Informed Strategies to Solve Customer Needs

When your supplier understands your needs, they can provide the right solutions. And by adding value through specialization in your product area, and by leading with innovative technologies, they help you win in your market through superior performance and product differentiation.

Precision Coating (PCCI) works by a different model: we succeed only when you are successful. This understanding informs every aspect of how we run the business—how we hire, develop processes, and invest in new technologies.

Our consistent and reliable coating and finishing application services contribute to your success. We employ reliable, validated, and increasingly automated processes to ensure precise and repeatable results. By the time your product reaches market, you want assurance that it always performs exactly the way it was designed.

We work from a medical device mindset and collaborate with full and open communication among all stakeholders. Transparency is key to our partnership with you, and a backbone value instilled in our culture. It drives our behaviors—and behaviors combined with capabilities deliver results.

## Superior Outcomes for Your Medical Devices



Fluoropolymer and aluminum anodic coatings are mainstays across a range of medical devices and instruments. Bringing over 50 years of experience, Precision Coating works with you with these platforms, from product design through commercial production. Specifically, we help you:

- Translate your needs into specifications
- Produce evaluation and testing samples
- Collect and compile performance reports
- Develop the manufacturing process to achieve consistent results for your product
- Achieve your commercial production goals
- Manage your product demand requirements over its lifecycle

Our goal is to help ensure your product's success. If you need a tight-tolerance PTFE coating, or your aluminum device will be repeatedly cleaned and sterilized, we offer unparalleled resources and specialized capabilities to help you achieve your product goals.

With over 50 years of proprietary expertise, a deep R&D bench, and revolutionary advancements, PCCI offers the most comprehensive suite of coating, anodizing, and printing solutions—and continues to set the standard in the medical device industry.





## Dedicated to Patient Safety to Improve Lives

Your products are designed to improve patients' health and save lives. By enabling your products to work as you intend them to, we share in your mission. Our coatings are used on products across a wide range of medical procedures, including neurovascular, cardiology, urology, orthopedic, endoscopy, and many other surgical areas. Our breadth of experience and depth of expertise allows us to be a valued member of your team, helping to accelerate your product technology development from inception to commercialization. Envision beyond what you think is possible. Our insights help you identify opportunities to innovate and advance in your health care arenas.

## Experts in Fluoropolymer and Anodic Coatings, Handling, Cleaning, and Surface Preparation

Coated medical devices require a highly skilled coatings team with deep experience on how to handle, prepare, clean, and coat surfaces for specialty medical devices, such as guide wires, hypo tubes, core wires, coils, needles, mandrels, and instruments. Some of these products also need permanent printing and markings.

We have developed formulations, methods and application technologies, and deep know-how from years of working in the medical field; and we bring this together with extensively trained operators. This allows PCCI to meet your specifications and provide the coverage and uniformity, adhesion, processability, and other key attributes required by your products.

### Years of experience translate to a breadth of expertise:

- Capable of meeting the broadest range of customer needs across a wide range of devices and medical products
- Proven coating technology to achieve adhesion, lubricity and release, hardness, chemical resistance, and "cleanability"
- Operates validated processes for consistent and repeatable outcomes
- Best in class deposition control to consistently meet close tolerances
- Leverages an extensive catalogue of prior FDA submitted work based on the same formulations and processes
- Selection of coating chemistries/methods tailored various substrates
- Guidance on how to handle specific products and substrates, including nitinol wire, hypo-tubes, needles, etc.
- Expertise with simple to complex device geometries
- Able to meet branding and design requirements, including color and printing
- Expertise in surface preparation, with in-house processes for cleaning and material preparation
- Mechanical, chemical, and energy-based finishing to prepare substrate for coating applications

## Essential Medical Device Quality Standards—ISO Certification

We are committed to the highest quality customer and product service and hold certificates of registration for ISO 13485 for each of our operating locations. Our certified quality systems ensure PCCI's ongoing commitment to continuous improvement, customer satisfaction, and sustainability across each market segment served and device type.

Having ISO certifications in place drives us, across our organization, to adhere to qualified and validated processes for production, quality, and customer service. This means all product is handled with consistency to produce the same quality, exact depositions and tolerances, and performance over time, every time.



## Completing the Supply Chain in Costa Rica

Opening a new, state-of-the-art fluoropolymer coating facility for our customers in the middle of the medical device hub in Costa Rica was a natural progression of our dedication to complete the supply chain for you, our customers. It operates as an extension of our other facilities, offering exact like-for-like outcomes—in operations, products, and performance—so that we deliver the performance you and your customers rely on.

Applying the knowledge and technology that years of experience garnered, we created the next generation of processes and robotic automation when building the Costa Rica facility. The proximity with customers in Costa Rica allows us to respond more quickly to your needs, whether through enhanced communication, faster delivery, or the ability to work with you locally to develop solutions to your engineering requirements.



## Automation: Controlling Consistent Deposition for Tight Tolerances

Automation allows repeatability. Deep expertise in robotic coating application guides us to determine a set of operating conditions that yields a particular end result. We then set our automation to produce that output and an exact replication each and every time.

We use this repeatability to lock in a navigation “feel” required by the surgeon to deliver performance in a way no one else can. Surgeons are very sensitive to the feel of their guide wires. They depend on consistent design and function to ensure “stiction” when performing procedures requiring sensitive tactile feedback.

Any product changes can be disruptive to the expected navigation experience. Because patient welfare depends on it, we understand how vital it is that we deliver consistent production and product performance.

We have mastered the critical technology of deposition control over ovality, surface smoothness, consistency, completeness, and curing, and are capable of depositing coatings to the 5th decimal point. We achieve process repeatability through automation to keep tolerances exactly as they are specified. Our common end-users require very precise outcomes—and our proprietary processes to control deposition and tolerances ensure it.



## Research & Development

As you would expect and require, the medical device industry continues to push forward with innovations to improve patients' lives. We are single-mindedly committed to helping you achieve your goals to lead the industry and be the preferred choice of medical professionals. We work with you by supporting the newest discoveries, anticipating the next need, and providing innovative solutions to further your progress.

**Our dedication to ongoing progress spans the entire organization, and includes:**

- Research in our applications labs
- Relentless scrutiny by quality and process specialists for continuous improvement
- Development of novel solutions for high-value problems by expert chemists and process engineers
- Construction of a new facility to accommodate the latest automation advancements
- Patent grants on revolutionary innovations, such as MICRALOX®

Applying a combination of the above elements helps us answer customer needs. For example, when the medical device industry was facing an extensive problem with harsh cleaning and sterilization procedures compromising reusable anodized aluminum medical devices, PCCI stepped out ahead of the industry to create the solution to successfully counter these effects. MICRALOX® is the only anodic coating that solves this industry-wide issue, and now serves as the performance standard for major medical manufacturers worldwide.

## FDA Science Priorities and Repeatable “Cleanability”



Medical devices undergo harsh cleaning and sterilization processes. FDA science priorities focus on minimizing “patient harm from inadequately reprocessed devices and to enhance the safety, effectiveness, performance, and/or quality of these devices,” and call for the development of a comprehensive approach to address the effectiveness of reprocessing techniques. As the industry looked more carefully into re-usable product cleaning and sterilization, it became clear that existing anodic coating solutions did not achieve acceptable performance. Beyond meeting the performance challenge, PCCI also had to ensure that the solutions were clearly acceptable from a regulatory point of view.

### What this means:

In practice, medical device and instrument companies are now consistently and directly assessing how to reprocess their products between uses; and in doing so, the industry is becoming aware of the strong deficiencies of conventional anodic coating methods. Manifestations of poor coating performance often include color fading, smut and iridescence, corrosion, and pitting; while printing often delaminates, chips off, or fades, and laser marking can lead to corrosion.

### Our solution:

Prior to issuance of the latest FDA priorities, Precision Coating had developed solutions that encompass device design and validation methods for reprocessing, including cleaning and high-level disinfection. Our revolutionary coatings, MICRALOX® Ultra and Lumina, allow your products to withstand repeated cleaning and sterilization of medical devices. Further, the Sanford Print SP and DFF methods ensure permanent, non-destructive printing on the instruments. Your instruments will withstand cleaning and sterilizing over many more cycles, and will do so without loss of any printing on the part.



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.



MICRALOX® is a patented aluminum oxide coating with a micro-crystalline barrier that revolutionizes aluminum anodizing. MICRALOX® produces a long lasting, virtually indestructible anodic coating that replaces conventional anodic coatings for medical applications. Notably, it does so without introducing new chemistries or materials, is cyto-toxic safe, and meets or exceeds all of the other requirements for anodic coatings. Consequently, aluminum can be reintroduced into application areas where stainless steel, plastics, or other materials are in use. Medical devices anodized with MICRALOX® maintain superior corrosion resistance, avoid fading, and allow your products to last up to 50X longer in the field.

## MICRALOX® Ultra

Our most recent coatings additions with the MICRALOX® platform are Ultra and Lumina. MICRALOX® Ultra provides 50X the chemical resistance compared to decorative Type II anodizing and can withstand high-pH cleaning and sterilization protocols commonly used in European markets. As it withstands many other aggressive environments that would strip conventional anodic coatings, Ultra targets applications where maximum chemical/corrosion resistance is prioritized.

## Embedded Printing

Your medical device needs to be traceable and requires marking for identification. Company branding allows for product recognition, while enhancement with unique artwork can further product differentiation. Precision Coating has a range of proprietary and innovative in-house printing and laser-marking techniques to help you achieve your goals.



## Masking

Masking is a crucial step in ensuring that your parts and devices meet tolerances and are finished in accordance with specifications. Simple masking includes the use of plugs for blind and through holes, but masking complexity is endless, and a variety of tried and proven techniques are used.

Masked surfaces can be left uncoated or can receive a chemical conversion coating to prevent corrosion while maintaining electrical properties. Our experience in mastering all masking processes, as well as materials, helps you achieve a high, first-pass yield on your parts and meet your design and functionality requirements.

## MICRALOX® Lumina

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 achieve 16X the resistance in a hot alkaline strip test compared to Type II decorative anodizing. It targets applications that require a balance of design and functional properties.

Patented SANFORD PRINT SP addresses a deficiency of conventional screen and pad printing for certain applications where the ink is at risk of delamination and/or chipping where the same single-color image is required time and again. Unlike conventional printing where the ink dries on the surface of the anodic coating, the SANFORD PRINT SP methods are embedded into the coating, allowing them to be permanent and non-destructible. SANFORD PRINT DFF allows for direct-from-file printing into the coating on your device, and allows for unique images with little to no set up. Further, it can produce an almost infinite range of colors, be multi-colored, and allow for unique device identification.

Unlike laser engraving, Sanford Print BW is protected by the anodic coating and does not compromise the coating, which means it does not create pathways to the substrate that can start and propagate corrosion.





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Precision Coating Co., Inc. serves medical device manufacturing companies by providing coating, anodizing, and printing solutions for a broad range of medical devices, such as guidewires, core wires, hypo tubes, forming mandrels, and surgical tools and instruments. Precision Coating works with customers globally, providing a comprehensive set of skills and capabilities, that are employed from concept to commercialization, and offer distinct services from prototype and early-stage work through high-volume production. With facilities in Hudson, MA., Woonsocket, RI., and Altajuela, Costa Rica, Precision Coating provides a seamless supply chain experience, fulfilling the exacting demands of medical manufacturing across all major geographic hubs.

## Envision beyond what you think is possible.

We recognize that much responsibility for patient health outcomes rests on the performance of your products. As a dedicated supply chain partner, we commit to working with you to achieve your product specifications. Precision Coating has years of deep expertise with fluoropolymer and anodic coatings, surface preparation, and printing processes to serve your product needs. We have a proven record of precise deposition control, all with adherence to validated, high quality standards.

We'd be happy to begin a conversation with you for your medical device needs. Contact us now to get the conversation started.

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