

Testing: Why It's Important for Your Instruments and What Types to Ensure Are Happening



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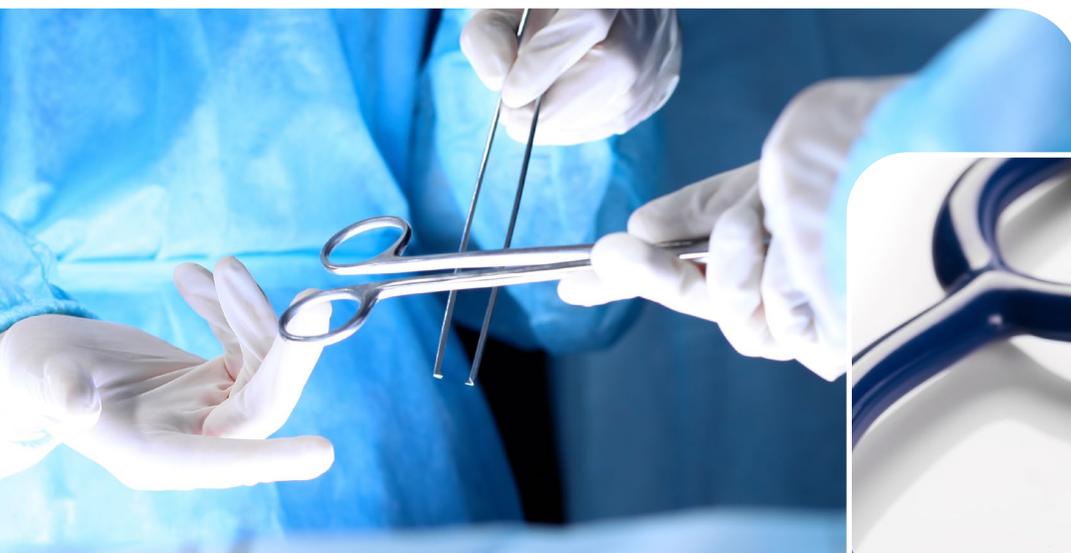




Ensuring Optimal Performance When It Matters Most

The proper performance of medical instruments is vital in all cases. But, in some scenarios, it's truly a matter of life and death. But how do you ensure your medical instruments are at their best? Applying advanced chromium coatings. This helps instruments function exactly as designed even through countless uses, cleanings, sterilization cycles, etc. These coatings also keep items looking like new even after many procedures.

Because coatings come into direct physical contact with patients, it is crucial that they—like the instruments themselves—meet exceptionally strict quality standards. Simply trusting that they will meet those standards based on past uses, is not enough. Careful and thorough testing is required to confirm that medical instrument coatings will adhere as expected and protect the items they are applied to under the most challenging of conditions.



Bath Composition and Wastewater Testing

The testing of advanced chromium coatings for medical instruments starts even before they are applied. In order for a coating to form a strong, durable bond with instrument surfaces, the "bath" into which the items are placed has to meet very precise criteria for several characteristics, including:

- Temperature
- pH level
- Electrical parameters
- Overall chemistry

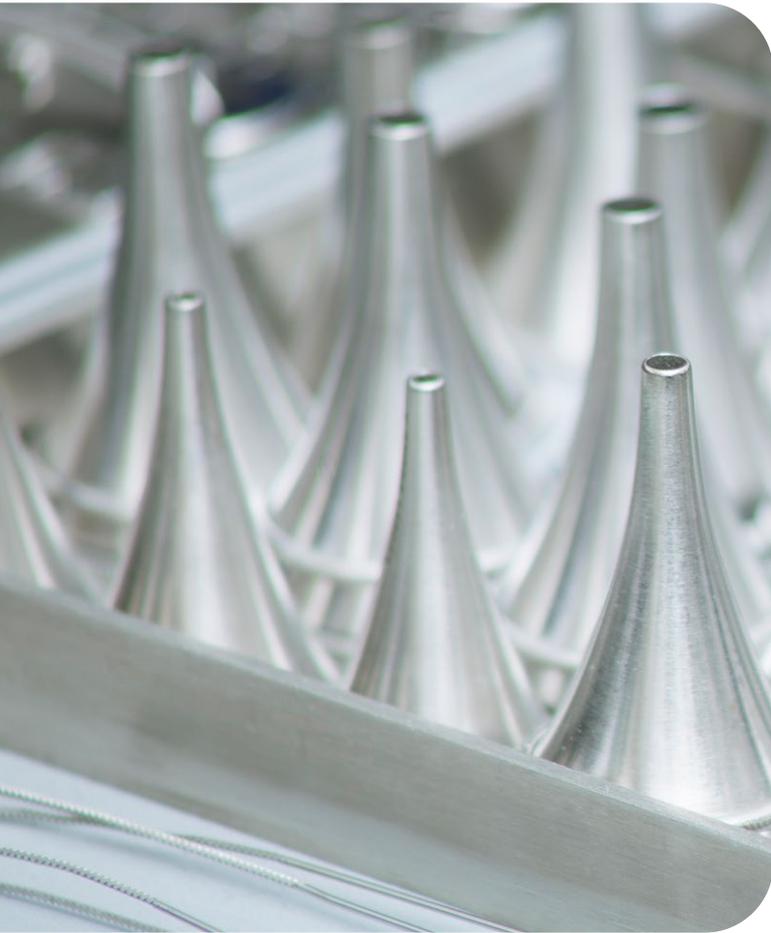
If these criteria are not met, adjustments must be made before the coating process begins.



Testing must also be performed on the effluent (outgoing) wastewater from the process to ensure that Environmental Protection Agency (EPA) standards are met. This includes verifying that the water does not exceed standards for components and characteristics such as:

- Chromium level
- pH level
- Oxidative-reductive potential (ORP)
- Acidity
- Total dissolved solids (TDS)

Coating medical devices in order to improve performance, enhance safety, and enable better patient outcomes can do more harm than good if the environment is damaged in the process. Fortunately, with proper testing, both patient safety and environmental safety can be achieved.



Coating Thickness Testing

The next step in the testing process is to closely examine instruments that have had the coating applied.

One of the most important of these tests is for plating (i.e., coating) thickness. Chromium coatings are customized to meet the requirements of a particular medical instrument and how it will be used. They can be applied in thicknesses ranging from 0.00004" to 0.001" per side (1.0-25.0 microns).

Tests are performed to ensure that the exact thickness called for in an instrument's design specifications has been met. This is essential to the item's functionality and the coating's ability to endure the stresses placed on it during procedures.

If [precision masking](#) is being used to ensure that the coating material is only applied to specific areas of an instrument, that is checked at this time, as well.

Additional Case-Specific Testing

Depending on how an instrument will be used or other factors, additional testing of instrument coatings may be performed. These assessments include:

Coating composition

A coating may be checked after it's applied to an instrument to confirm that it maintains the appropriate chemical makeup.

Salt spray

Corrosion is a significant problem with uncoated or poorly coated medical instruments—including those made of stainless steel—since stainless steel resists corrosion but is not 100% corrosion-proof. Salt spray testing determines if the coating will provide the degree of added protection required.

Adhesion

It's critical that the coating applied to an instrument stays adhered during its use in procedures, cleaning, and sterilization. If there is any question about a coating's durability on a particular instrument or for any intended use, special adhesion testing is performed.



Sterilization

Medical instruments must be capable of being fully sterilized after each use. Sterilization testing ensures that coated instruments can have all microorganisms removed effectively and the coating stays fully in-tact.

Contamination

As with adhesion testing, in the unlikely event that there is any reason to believe that a coating could potentially contain contaminants, tests can be performed to determine if that is the case.

Confirming That Testing Is Being Performed

As important as the performance of medical instruments is, it might be assumed that every coating provider is performing all of the necessary checks. Unfortunately, that is not necessarily the case. Many coating companies do few, if any, tests on their materials or items that have been coated. They simply trust that the coatings and the coated items are meeting the customer's specifications, with no sense of accountability or obligation to do testing.

Consequently, it is important that customers ask their coatings provider (or potential provider) about their testing procedures, and that those companies provide a detailed response. "Yes, we do extensive testing," does not answer the question. A provider that stands behind its work should not only be willing to explain their testing processes, they should be eager to do so. That includes providing stats on acceptance rates and other measures of the success of their coating operations.

At ME-92, our quality is anchored by rigorous testing and the highest level of industry certification:

- ME-92® Coatings conforms to AMS 2406, AMS 2460 (supersedes AMS QQ-C-320) and AMS 2438
- Process Validation completed in accordance with the Global Harmonization Task Force GHTF/SG3/N99-10:2004 and 21 CFR Part 820.
- ME-92® Coatings specified in and compliant to major medical Original Equipment Manufacturers (OEM) specifications
- Management system registered to ISO 9001:2015 requirements
- Certified Biocompatible to ISO 10993-1
- REACH and RoHS Compliant
- Hydrogen Embrittlement Tested per ASTM F519
- Salt Spray Tested (50 hour) per ASTM B117
- Adhesion Tested per ASTM B571 and BAC5709
- Hardness Tested per ASTM E384-17 and BAC5709
- Porosity Tested per AMS 2460
- Custom Testing per Customer Specifications



Coating companies that are unwilling to provide information on the tests they perform, or that will only do so grudgingly, should be viewed with concern.



Thorough Testing and More: What to Look for in an Instrument Coatings Company

Extensive industry experience, well-defined and tightly controlled coating methodologies, comprehensive testing, and a collaborative approach are important characteristics when looking for a medical device coatings partner. ME-92 Operations is a division of the [Armoloy Corporation](#) that focuses exclusively on chromium coatings for medical equipment. The company has been a leader in the industry for nearly 30 years and is a pioneer in the area of biocompatible chromium coatings.

ME-92® coating can be applied to medical instruments, tools, and devices as part of the manufacturing process or to items already in use. They can also be applied in the proof-of-concept phase.

ME-92 Operations is a recognized trailblazer in the industry as a result of ongoing R&D efforts and thought leadership. Its research not only continually improves existing coatings, it enables the company to adapt rapidly to the ever-changing requirements of medical technology designers, manufacturers, and end users.

Even as ME-92 is breaking new ground in advanced coatings, the company invests heavily in safeguarding the environment. That investment has produced eight consecutive years of perfect compliance with the wastewater discharge regulations of The Narragansett Bay Commission. ME-92 takes pride in that accomplishment, particularly since fewer than 5% of the commission's industrial accounts achieve even two consecutive years of perfect compliance.

Learn more about ME-92 Operations and the ME-92® coating by visiting me-92operations.com

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