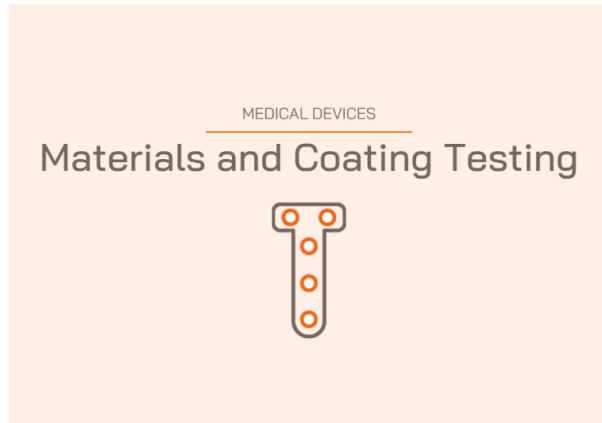


Medical Device Material and Coating Testing



What Is Medical Device Material and Coating Testing?

Medical device material and coating testing evaluates the suitability of the materials and coatings used with joint implants and other medical devices. Along with design testing, materials and coatings testing is crucial for **assessing the long-term success** after implantation of a joint implant.

At [Applus+ Laboratories](#), we carry out material and [coating testing](#) on **material samples** as well as on **finished implants** and **surgical instruments** ensure an increasingly reliable product for the patient. This is part of our comprehensive and dedicated service for [medical device testing](#).

What Medical Device Material and Coating Testing Services Do We Offer?

We offer testing services for materials used in joint implants, such as **metals, ceramics, organic materials prone to changes**, and coatings, ensuring they meet international standards for safe use in the human body.

By considering material properties, including surface variations in metallic systems like **topography** or **corrosion resistance**, and evaluating mechanical and chemical stresses, we ensure smooth qualification, validation, and **long-term reliability** of the medical device.

What Materials Testing Do We Offer?

For [materials testing](#), we test against the **standard ISO 13779-1** which tests ceramic hydroxyapatite. This standard requires testing **ceramic hydroxyapatite for its chemical composition** to ensure that it is suitable to be implanted into the human body as well as the physical properties to check for its density and porousness. The standard also includes testing ceramic hydroxyapatite for its **biocompatibility** as well as its **mechanical strength**.

We provide a **wide range of materials testing services**, including chemical identification through chromatography and spectrometry, mechanical and thermal characterisations to assess manufacturing impacts, and surface evaluations for roughness, wear resistance, friction, and corrosion.

We also offer microscopy, powder granulometry, and testing the quality and qualification of bonded assemblies, ensuring material behavior and performance meet industry requirements.

- **ASTM F2129**
This is a standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion susceptibility of small implant devices.
- **ISO 19403-2**
The surface energy of a surface or a coating and its polar and dispersive fractions are measured. This determines, for example, its wettability and the compatibility of the surface with a coating or adhesives.
- **ISO 13779-1 (Joint Implants)**
This standard requires testing ceramic hydroxyapatite for its chemical composition to ensure that it is suitable to be implanted into the human body, as well as its physical properties to check for its density and porousness. The standard also includes testing ceramic hydroxyapatite for its biocompatibility as well as its mechanical strength.
- **ISO 13320**
This standard evaluates the size of particles (powder or in a liquid) by a LASER granulometry measurement.

What Medical Coating Testing Do We Offer?

For coatings, we test against **four different standards** to assess the fatigue and life cycle of **different metallic and non-metallic coatings**. Here is an overview of the coatings testing that we offer:

- **ASTM F1160**
This standard tests the **fatigue resistance** of coatings made from **calcium phosphate or metallic composites** on medical implants. It evaluates how these coatings perform under cyclic loading conditions, **simulating the long-term wear** and tear they would experience during use.

- **ASTM F1044**
This standard assesses the **shear strength** of calcium phosphate and metallic coatings, focusing on their **ability to adhere to the medical device's surface**. It specifically tests whether the coatings can resist forces that might cause them to slide across the substrate.
- **ASTM F1147**
This test measures the **tensile strength of coatings** to determine how well they adhere under tension. It ensures that the coatings remain **securely attached and intact** even when stretched.
- **ISO 13779-4**
This standard evaluates the **adhesive strength of hydroxyapatite coatings** on [metallic](#) implants. The test ensures that the **coatings maintain their position and structural integrity** under the normal stresses experienced within the body.
- **ISO 19403-2**
The surface energy of a surface or a coating and its **polar and dispersive fractions** are measured. This determines for example its wettability and the compatibility of the surface with a coating or adhesives.
- **ASTM G99**
This standard evaluates the wear resistance, wear rate and friction coefficient of coatings. This is also for materials testing.
- **ISO 21920**
This standard evaluates the **surface roughness**. This is also for materials testing.
- **ISO 2360**
This standard evaluates the **thickness of non-metallic coatings on metallic substrates**.
- **ISO 1518-4**
These standards evaluate the **scratch resistance** and **hardness of coatings**.
- **ISO 2409**
This standard evaluates the **adhesion of coatings** on a surface with a **cross-hatch test**.
- **ISO 4624**
This standard evaluates the adhesion of **coatings on a surface with a pull-off test**.
- **ASTMD4060**
This standard evaluates the **wear resistance of coatings**.
- **ISO 6272**
This standard evaluates the **impact resistance** of coatings.

We can also measure the coating thickness on all substrates with a **stylus profilometer** and characterise them by microscopy and Energy-dispersive X-ray spectroscopy.

Our Testing Facilities and Equipment for Medical Device Material and Coating Testing

To perform all the different testing methods mentioned above, we at Applus+ Laboratories offer a comprehensive testing service for medical device material and

coating testing where, thanks to our **advanced equipment and facilities**, we can test all the types of materials and coating in order to simulate constant **wear inside the body**.

What Are the Advantages of Medical Device Material and Coating Testing?

There are a **myriad of advantages** of getting materials and coatings testing performed on your medical devices. From improving the materials used to **improving market access**, here are the principal advantages:

Ensuring Patient Safety

Undergoing the relevant testing for materials and coatings ensures that patients will receive implants that have been **fully tested** and that they are safe to be placed in the human body. This massively **boosts patient confidence** that they are receiving an implant that has undergone stringent testing.

Boosting Innovation

Putting your medical device through its paces is a crucial step towards boosting innovation. As new and **more efficient materials** are being trialled for implants, having the relevant testing performed can **help resolve weak points** in the new materials and reveal whether they are good enough to be used. This means that more innovative materials can be **brought to the market quicker**.

Increasing Market Access

Complying with the international standards on materials and coatings can **vastly increase your [global market access](#)**. Being certified in complying with these standards can allow you to enter different marketplaces so you can sell your medical devices all over the world. In addition, undergoing testing can also **speed up your product to market**.

Why Choose Applus+ Laboratories for Medical Device Material and Coating Testing?

Opting for Applus+ Laboratories for your materials and coatings testing aligns you with a **leader in the field of medical device testing**.

We **provide ASTM and ISO-compliant services** to ensure that your **materials and coatings testing** meet the highest standards of assessment for fatigue and adhesion. With a broad spectrum of testing capabilities and a **focus on customer service**, we are perfectly suited to handle all your materials and coatings testing.



Applus+ Laboratories is committed to being your **one-stop shop for medical device testing**, offering a **complete catalogue of services** designed to reduce your product's time to market. Our services include:

- Development testing and suggestions for improvements
- Testing throughout the product life cycle
- Qualification of products and processes, along with batch release testing
- Contract Manufacturing Organisation (CMO) services

Present in various countries, we are equipped to **offer our testing services globally**, ensuring access to **top-notch materials and coatings testing** in multiple countries.

Choose Applus+ Laboratories as your dependable partner for materials and coatings testing. We are ready to support your endeavours with our **comprehensive services and expert advice**.