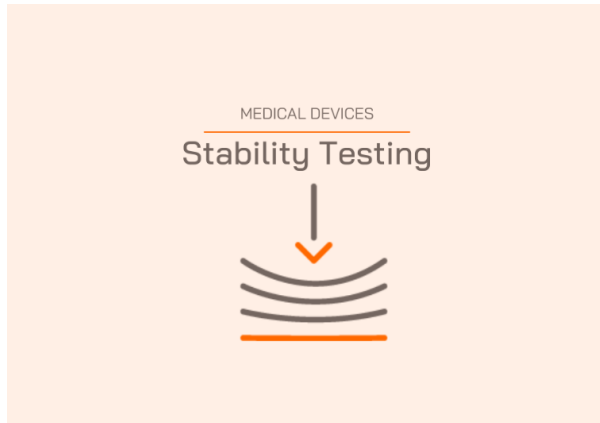


Medical Device Stability Testing



What Is Stability Testing?

Stability testing is part of our batch release testing services and an essential step in overall [medical device testing](#). Stability testing is crucial to validate the shelf life and to assess whether a medical device, such as a joint implant, is stable over time and does not present any crucial modification during storage or during use.

Applus+ Laboratories provides stability testing services to ensure that a medical device can maintain its performance and reliability in order to **comply with regulatory requirements**. Stability testing is the final stage of our batch release testing, where we also offer:

- [Biocompatibility testing](#)
- Cleaning validation
- [Packaging validation](#)
- Material and chemical characterisation

What Stability Testing Services Do We Offer?

We provide the **full range of stability testing for medical devices**. We perform both natural and accelerated ageing tests **against ASTM 1980** in order to assess longevity in differing storage situations, as well as offering customised testing for specific product needs. Here's a **full rundown** of the services we offer.

Natural and Accelerated Aging Tests Against ASTM F1980

Natural and accelerated ageing testing is essential for assessing how medical devices perform over time. These tests ensure that your **medical device will remain stable over time** as well as during storage. We test against the standard ASTM F1980.

- **Development and Validation of 'On Demand' Method**
We offer a **specialised 'on demand' service** creating tests tailored to the specific needs of a particular medical device. We offer this for **unique and novel designs using novel materials**, where standard test methods may not accurately predict its stability or the kinetics of its degradation and release profiles. This service aligns with **our desire to boost innovation** in the industry, providing the relevant, customised testing to cater to client needs.
- **Product Performance Stability During Lifetime**
We test the performance of medical devices and how stable they are over their lifetime. These are critical tests and include **accelerated life testing, real-time aging**, as well as **cyclic fatigue testing**. We test the device to see whether it can endure the **physiological strains, chemical conditions, and biological stresses** it will undergo during its lifespan.
- **Storage Stability**
Storage stability is a **vital part of stability testing** since it ensures how well a medical device **maintains its quality and safety** when it is stored. This requires assessing the **medical devices physical and chemical stability** reacting to **temperature, humidity and light exposure**. We also determine shelf life to ensure that the product will last under various conditions. This helps in completing the regulatory requirement of your medical devices

Examples of Stability Testing Tests We Perform

Here are some **examples of stability testing** we perform against different standards:

- **Analyses of Kinetics of Degradation**
We test **polyester-based implants** against **standard ISO 13781** to analyse the rate and mechanism by which they degrade during implantation. This assesses how the implant will behave **under physiological conditions**, including the **rate of absorption, mechanical integrity, and the release of byproducts**.
- **Stability Testing for Bone Cements**
We conduct stability testing on **bone cements** to ensure their **mechanical integrity, chemical stability, and chemical release profile** are maintained over time. These tests verify that the bone cement maintains its performance and that the **Gentamicin release profile** is in accordance with **customer expectations**. Then the customer or a toxicologist can assess its **adequacy to prevent post-surgical infections**. This ensures that the bone cement is safe, effective, and performs consistently **under real-world conditions**.
- **Degradation Product Identification**
We test against **ISO 10993-13** to ensure the safety of medical devices that are

made from **polymers** and are subject to degradation in the body. This involves **analysing the polymer materials** in medical devices and to assess chemical nature of the degradation as well as how much degrades over time. Understanding the **biological impact of degradation products** helps in mitigating any risks associated with the **use of degradable polymeric devices**.

What Are the Benefits of Stability Testing?

Stability testing is a **crucial component of our batch testing services** and offers numerous benefits, including ensuring patient safety and maintaining compliance with medical device standards. These advantages include the following:

- **Regulatory Compliance**
Stability testing ensures **adherence to the stringent standards required** for medical devices. This compliance boosts consumer trust by demonstrating that your product **remains effective and safe** over its intended shelf life.
- **Patient Safety**
By validating the stability of your product, we **minimise the risk of adverse effects** from materials interacting with bodily fluids or tissues over time. This significantly **reduces the potential for toxicity**, ensuring the product stays safe for patient use throughout its lifespan.
- **Performance and Reliability**
Stability testing confirms that your product **maintains its intended performance and reliability** under various stress scenarios throughout its shelf life. This ensures that the product functions as expected when used by patients.
- **Risk Mitigation**
Stability testing identifies **potential risks associated with product degradation** over time and provides guidance on necessary adjustments to mitigate these risks. This enhances **both patient safety and consumer confidence** in your product.
- **Market Access**
Complying with **stability standards for medical devices** enhances your market access on a global scale. Achieving the necessary certifications allows you to **operate in multiple countries**, expanding your market reach.

Why Choose Applus+ Laboratories for Stability Testing ?

Choosing Applus+ Laboratories for your stability testing means partnering with a **leader in medical device testing solutions**.

We provide **high-quality, ASTM and ISO-compliant stability testing services** that ensure the accuracy and reliability of your medical devices over time. Our **comprehensive range of testing capabilities**, coupled with our commitment to client service, makes us the ideal partner for your stability testing needs.



Applus+ Laboratories strives to be a **one-stop shop for medical device testing**, offering a full suite of services that can accelerate your time to market. We offer:

- Development testing and advice on stability enhancements
- Full lifecycle stability testing
- Product and process qualification with stability assessments
- Contract Manufacturing Organisation (CMO) services

With a **presence in multiple countries**, we can deliver our testing services to customers around the world, ensuring you have access to the best medical device testing no matter where you are.

Let [Applus+ Laboratories](#) be your **trusted partner for all your medical device testing needs**. We can support your projects with our high-quality services and expert guidance.