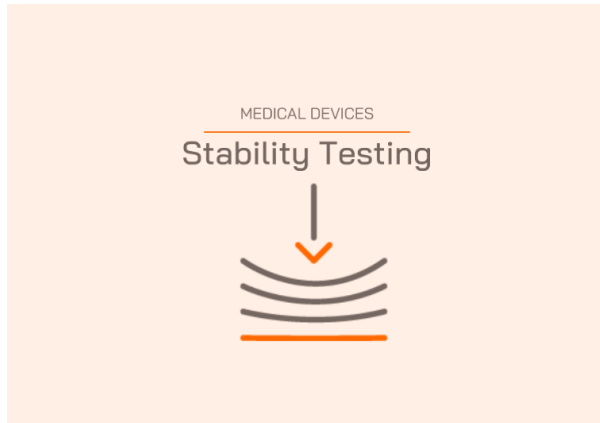


# Medical Device Stability Testing



## 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.