

Knee Joint Implant Testing



What Is Knee Joint Implant Testing?

Knee joint implant testing is a vital process to ensure knee joint implants' viability and quality, testing these implants through many different testing methods. These tests are performed to confirm that the implants have the necessary resistance to be marketed and that they comply with international standards, without which they could not be approved for commercialisation.

<u>Applus+ Laboratories</u> revolutionises the world of <u>medical devices</u> by offering **a complete testing service**. We collaborate with our customers in the development of knee joint implants, optimising them for testing. Not only that, but we also provide rigorous full lifecycle simulation testing to ensure their excellence in the human body.

What Knee Joint Implant Testing Services Do We Offer?

At Applus+ Laboratories, knee joint implant testing involves three different processes: **static and fatigue testing**, **wear testing**, and <u>corrosion assessment</u>. Thanks to these methods, which are performed against **ISO and ASTM standards**, we can evaluate the overall **safety and durability** of the implant for patients.

Static and Fatigue Testing for Knee Joint Implants

Knee joint implants undergo testing to assess their durability under both **single, heavy loads** and **repetitive loads**, replicating the stresses experienced throughout their lifetime. We perform these tests in accordance with the following standards:



ASTM F1223

Static testing of the implant to evaluate the constraint characteristics of knee joint implants under **static loading conditions**.

• ASTM F1800

Fatigue testing of the **metal tibial tray** to simulate the mechanical stresses experienced simulating insufficient medial bone support.

ASTM F3140

It directs the use of loading profiles to mimic both dynamic and static conditions.

• ASTM F1814

This involves static, dynamic and corrosion testing to evaluate the mechanical properties and compatibility of **modular knee joint components**.

• ASTM F2777

This primarily involves fatigue testing of **knee bearing (tibial insert)** components under high flexion conditions.

• Patella F1672

A method for evaluating the stability and durability of patellar components used in addition to knee joint implants.

Wear Testing for Knee Joint Implants

We evaluate the durability of knee joint implants by subjecting them to wear testing that simulates the **pressures**, **stresses**, **and natural wear** experienced over their lifespan. This testing adheres to recognised standards for assessing implant performance.

• ISO 14243-1

We test the wear behaviour of total knee joint prostheses, including **ultra-high molecular weight polyethylene** and **other polymer components.**

• ISO 14243-2

Tests the wear of the **tibial component** of total knee-joint prostheses using several methods of measurement.

• ISO 14243-3

Where we test the wear of **polymer components in total knee joint prostheses**, specifically focusing on the wear under displacement control.

• ISO 14243-5

A standard that specifies testing parameters for durability testing of **patellofemoral joint components** in wear-testing machines.

Corrosion Testing for Knee Joint Implants

There is no corrosion **testing standard for knee joint implants** as of yet, but we do perform knee joint corrosion testing **based on the ASTM F1875 for hip joint implants** as well as several corresponding fatigue tests. ASTM involves seeing how an implant behaves against temperature, pH levels, and ions presence.



Our Testing Facilities and Equipment for Knee Implant Testing

We firmly believe that pushing the boundaries of knee joint implant testing is what makes our work at Applus+ Laboratories pivotal in setting new standards for implant durability and patient safety. That is why we use **state-of-the-art equipment** that accurately and dependably simulates **real world use** while complying with the necessary standards.

Our **multi-station simulator** is equipped with **5 controllable axes**, allowing for simultaneous testing of **up to 8 different implants**. This enables us to assess the implants' responses to different fitting types, fixation methods, designs, and bearing couples.

Our facilities allow for knee joint implants to be **loaded for up to ten million cycles** in the anatomically correct position under physiologic conditions in our laboratories, **accurately simulating a lifetime's use** in a few weeks.

What Are the Benefits of Knee Joint Implant Testing?

Knee joint implants must be both **durable and safe** for patients to derive benefit; that is why conducting essential tests is crucial to expedite your product's market entry.

Enhancing the Safety and Effectiveness of Knee Joint Implant Testing

Testing knee joint implants with innovative <u>materials</u> ensures their **safety and regulatory compliance**, rigorously assessing their efficiency to foster innovation and deliver **safer products to patients**.

Compliance with International Regulations for Knee Joint Implants

Adhering to international standards accelerates <u>market access</u> for knee joint implants, streamlining the path to global expansion and enhancing credibility in the international marketplace through recognised compliance.

Why choose for Applus+ Laboratories for Knee Implant Testing?

Selecting Applus+ Laboratories for your **knee joint implant** testing associates you with a **leading provider in medical device testing solutions**.



We offer high-quality testing services that are compliant with ASTM and ISO standards, ensuring both accuracy and reliability for your knee implant products. Our extensive testing capabilities, combined with a dedication to customer service, position us as your optimal partner for comprehensive knee implant testing requirements.

Applus+ Laboratories aims to serve as your **comprehensive resource for medical device testing**, providing a full suite of services designed to expedite your product's market entry. Our offerings include:

- Developmental testing and recommendations for enhancements
- Complete lifecycle testing
- Product and process certification including batch release testing
- Contract Manufacturing Organisation services

With **operations across multiple countries**, we deliver our testing services globally, guaranteeing that top-tier knee implant testing is available to you, regardless of your location.

Choose Applus+ Laboratories as your dependable ally for all your knee implant testing needs. We are here to assist your endeavours with our superior services and professional expertise.