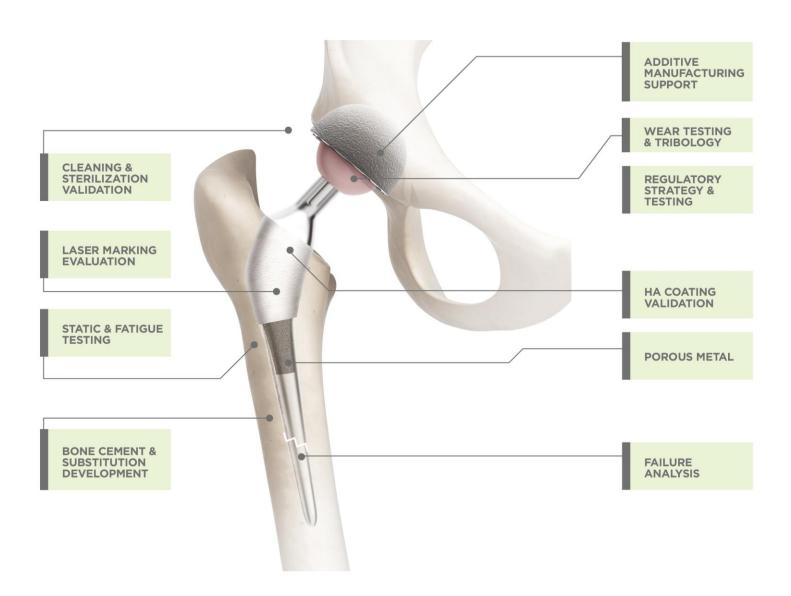


# ORTHOPEDIC SERVICES



# CLEANING & STERILIZATION VALIDATION

Whether it's single-use or reusable, your orthopedic device needs to be clean and sterile for use. Our cleaning and sterilization validation service ensures your processes and reagents are suitable to effectively clean your devices.

# ADDITIVE MANUFACTURING SUPPORT

Additive manufacturing (AM) offers a wide range of benefits and opportunities for the medical device sector, but is not without its challenges. At Lucideon we can help you navigate the obstacles of component testing and validation, failure analysis, materials development and process and cleanliness validation to help you develop an AM product that is fit for purpose.

### WEAR TESTING & TRIBOLOGY

Our wear testing facilities evaluate the wear, friction, and lubrication performance of your products. Wear testing is further supported by our world-leading surface evaluation, materials characterization, and debris, particulate and wear pattern analyses. We work to ISO methods and also develop customized protocols when your novel design doesn't quite fit the standard.

# REGULATORY STRATEGY & TESTING

If you need to prepare for regulatory submission it helps to have the people in the know on your side. We provide quality data and technical support with full documentation. In the heavily scrutinized area of medical device regulations it is reassuring to have experts, who have prior experience of performing the tests, on your side.

### STATIC & FATIGUE TESTING

To ensure your orthopedic devices are fit for purpose over the lifetime of the implant, Lucideon carries out an extensive range of physical and mechanical testing. We conform to a range of ASTM and ISO standards, but can also design and develop novel fixtures and frame modifications to accommodate complex designs.

## HA COATING VALIDATION

HA and other bioceramic coatings provide a porous and bioactive surface that allows better bone integration with your devices. Effective and robust coatings are important to provide optimal performance. Our experts can provide detailed analysis and method development to ensure your coating applications are consistent and adequate. We can measure the chemical, mechanical and microstructural properties of

the materials - validating both the process and the product for regulatory submissions.

### POROUS METAL VALIDATION

Porous metal coatings also allow for better bone integration. Lucideon has dedicated metallurgical engineers who specialize in the preparation, analysis and evaluation of metallic materials - from understanding the impact of a change in process to enabling you to visualize the structure you've formed.

# BONE CEMENT & SUBSTITUTION DEVELOPMENT

Bone cement and its alternatives play an important role in helping orthopedic implants integrate with the recipient's bones or helping bones heal themselves. We validate their properties, performance, safety and cleanliness, and even improve the functionality of bone cements and other adhesives through novel materials development or process optimization.

## **FAILURE ANALYSIS**

At Lucideon we perform extensive testing to predict and reduce failure risks in application. We also perform root cause identification of failures, should the failure have occurred in application, as well as recommending corrective actions.

## LASER MARKING EVALUATION

Laser marking is an important requirement for many implants, particularly with recent regulatory changes; however, research has shown that incorrect marking can lead to early fatigue failures. Our experts help you to optimize the laser marking process, limit the damage imparted to the underlying material, and identify the right site to apply your laser mark to ensure it will not have a negative effect on the performance and fatigue life of your products.