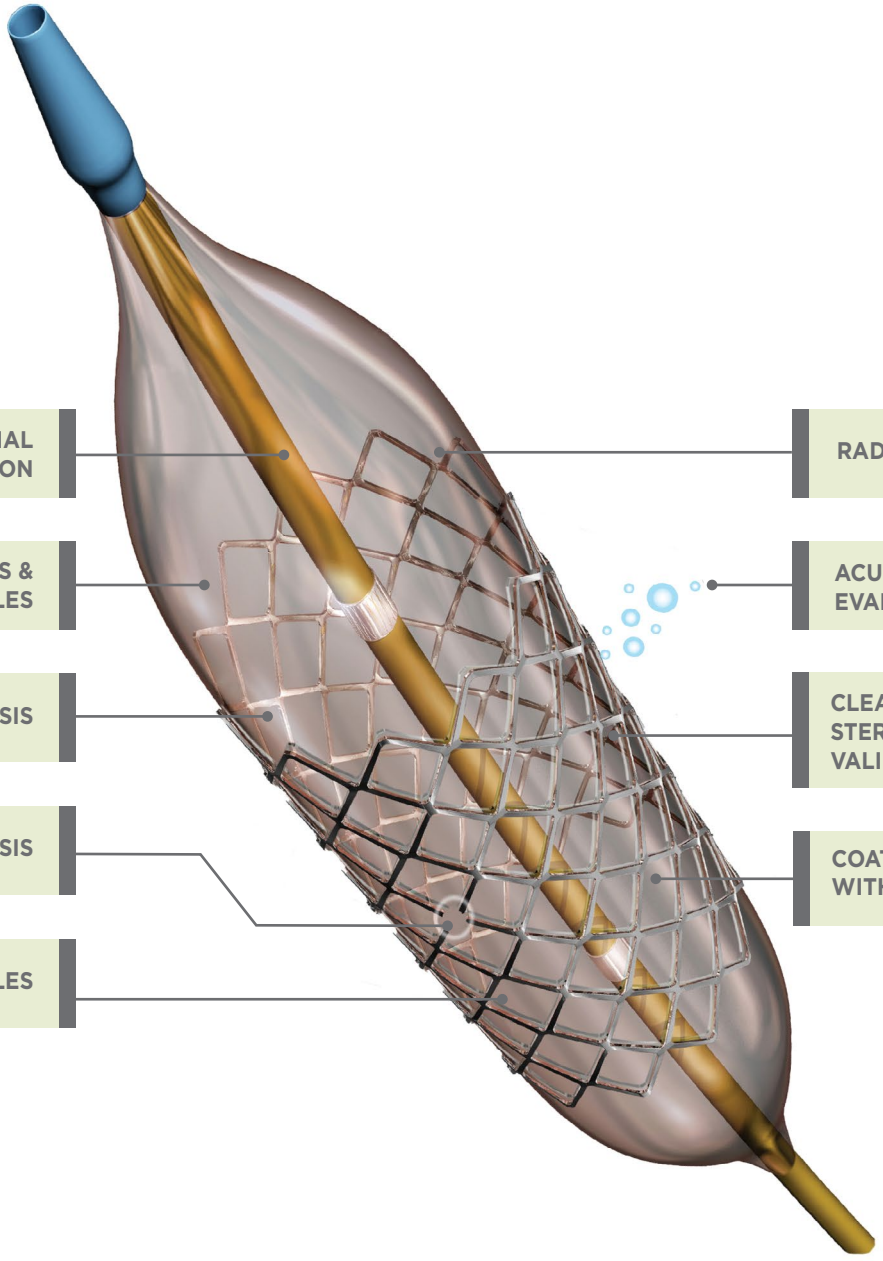
LUCIDEON

Materials Development and Commercialization

VASCULAR DEVICES SERVICES



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MATERIAL CHARACTERIZATION

In vascular applications it is important to understand your materials: their composition, key properties and how they behave. At Lucideon, we provide the answers with qualitative, quantitative and visual data to support a full understanding of your materials.

EXTRACTABLES & LEACHABLES

Extractables and leachables can pose a serious risk in vascular applications. When elements and compounds leach into your products, from packaging or manufacturing environments, they can render them unfit and even dangerous for use. We test not only for what does leach, but also for all potential extractables in your process and packaging; meaning you can test for and protect against them.

CORROSION ANALYSIS

Stability and safety is of utmost importance for implantable devices, especially where multiple materials are used. We offer expert materials selection and long and short-term performance testing, to ensure that your products function without fear of excessive corrosion leading to failure. If corrosion does appear, we can help you to understand why and make the necessary changes to your product design.

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.

DRUG RELEASE PROFILES

The next generation of vascular care materials will offer greater drug eluting and repair promoting properties. We have the technologies to control the release of key actives and make delivery more efficient.

RADIAL FATIGUE TESTING

To evaluate the long-term mechanical integrity of stents, stent grafts, and other endovascular devices, we perform radial pulsatile durability testing in customized mock silicone vessels to replicate in vivo conditions. Testing is carried out in accordance with recognized ISO, ASTM, and FDA guidelines to evaluate the fatigue performance and potential failure modes of your components prior to regulatory submission.

ACUTE PARTICULATE EVALUATION

ASTM and ISO regulations require acute phase particulate testing of medical devices destined for human vasculature in order to assess safety, risk, and efficacy during tracking, deployment, and withdrawal. We utilize a temperature-controlled positive-pressure flow loop with customizable deployment platform to simulate the vascular pathway your devices will travel for deployment. In-line particle sensors provide a time course of particle sizes and counts throughout the sample run. Collection of shed particles on the integrated filter membrane allow for subsequent SEM/EDX and/or FTIR analysis. This approach allows manufacturers to know the precise particle contribution of their devices and deployment accessories.

CLEANING & STERILIZATION VALIDATION

Whether it's single-use or reusable, your vascular 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.

COATING DURABILITY WITH PARTICLE ANALYSIS

To ensure stents or stent grafts do not pose an embolic risk over the lifetime of the implant, we perform simultaneous pulsatile durability and coating durability testing. In-line particle sensors provide a time-course of particle data throughout the test duration. Membrane filters are utilized to collect any particulates generated. Shed particles are sized, counted, and then captured for subsequent analysis via SEM/EDX and/or FTIR; providing an assessment of integrity and efficacy of coated implants.