SYNDAVER™ LABS
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Live Tissue Replacement

SynDaver™ Labs' portfolio of simulation products is designed to assist medical device engineers in the product development process. Our patented, award-winning models of human anatomy are unique in possessing a level of complexity that allows them to be substituted for benchtop models, cadavers, live animals, and even human patients in design and development tests. These products incorporate replaceable muscles, tendons, veins, arteries, and organs, all made from novel materials that mimic the structural, mechanical, and chemico-physical properties of living tissue. Trials in the medical device industry that require such complex models are generally known as **simulated use** tests, since they require a model that simulates the **actual use** (human) environment. The medical device industry often employs animals for this type of test because they have historically been the best model available for simulating human anatomy. However, cadavers and benchtop models are used as well.

Development Testing

The medical device industry uses our products in design verification and validation testing because they closely mimic the actual use environment. This resemblance is characterized by a similarity of structure, individual tissue component physical properties, and component-to-component interfacial properties. On the simplest level, individual **model components** are constructed so that they mimic the structure (length, width, diameter, thickness, cross-section, shape, etc) of a certain part (femoral artery, rectus femoris muscle, etc) of the target anatomy. In addition, the individual component **analog materials** are formulated to exhibit one or more physical properties (strength or modulus in tension, compression, or shear, coefficient of static or dynamic friction, elasticity, lubricity, surface energy, hydrophilicity, water content, electrical resistance, dielectric properties, light and heat absorption, adsorption, or transmission, porosity, etc) that are similar to the relevant target tissue. Finally, the model components are assembled in such a way that the interaction between adjacent components is similar to the interaction expected in the target tissue. This allows us to simulate interfacial properties such as adhesion and interlayer friction.

Novel Materials

The composition of the materials used to construct such complex models is unimportant as long as the relevant properties of the target structures are accurately modeled. However, typical engineering materials such as metals, ceramics, plastics, and elastomers are inadequate for these applications. In fact, where soft tissues are being modeled it will generally be advantageous to employ materials from our extensive library of **synthetic human tissue analogs**. These materials have been designed specifically to mimic individual tissues (muscle, tendon, intima, etc) so that the anatomical structures that use these materials will contain appropriate levels of water, fiber, and salts, and exhibit a combination of lubricity, abrasion resistance, modulus, and other physical properties characteristic of the target tissue. These materials are ideally suited to modeling vascular intima, ciliated epithelium, skeletal and cardiac muscle, and a wide variety of other soft tissues.

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Benefits

The synthetic human tissues and body parts produced by SynDaver™ Labs have a number of characteristics that make them useful for both medical device development testing and surgical simulation. **First**, since these products are designed to respond to physical stimulus in a fashion similar to the target (human or animal) anatomy, device performance in the model may be used to predict performance under actual use conditions. **Second**, in most cases the device-interfacing portion of the model may be removed for quasi-histological examination, allowing the effect of the device on the target anatomy to be quantifiably measured. This feature is particularly important because it allows the potential for injury to be predicted. **Third**, because the device interfacing portion of the model can be removed and replaced, a large number of tests can be performed under either identical or varying conditions as desired. This allows the generation of meaningful descriptive statistics on device performance and the execution of designed experiments, both of which are nearly impossible with live animals or cadavers. **Fourth**, the models may be fitted with integral pumps, heaters, and other accessories to more accurately simulate the physical aspects of actual use conditions. **Finally**, the models may be equipped with sensors that allow the measurement of pressure, flow, strain, or other characteristics in the target anatomy.

Summary

SynDaver™ Labs' portfolio of products facilitates the generation of animal study quality performance data at a risk level normally associated with a bench top study. By employing this technology early in the development process, reliable feedback on device performance may be collected before erroneous assumptions are allowed to adversely affect the device design. This capability reduces the probability of costly late stage design changes, shortens the development timeline, and reduces the overall cost of bringing a product to market. As an added bonus, these models may be used in a standard laboratory by a technician, so the need to contract with research facilities, retain costly medical professionals, and absorb the risks associated with biohazard exposure are all eliminated. These synthetic human tissues, organs, and body parts are by far the most sophisticated and complete hands-on anatomical simulation tools available in the world today.