

Medical Product Manufacturing News®

THE MAGAZINE FOR MEDICAL PRODUCT DESIGN AND DEVELOPMENT

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NEW TESTERS

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Hydrophilic Coating

A lubricious hydrophilic coating improves the maneuverability of metal guidewires in minimally invasive neurovascular procedures.

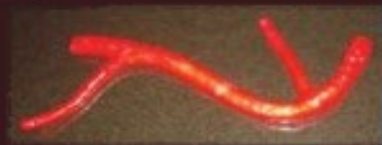
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Polymer Optics

A supplier specializes in the injection molding, diamond turning, and thin-film coating of custom-designed polymer optics.

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Synthetic Tissues

A service provider offers synthetic human tissues and body parts that mimic the structural, chemical, and mechanical properties of living tissues.

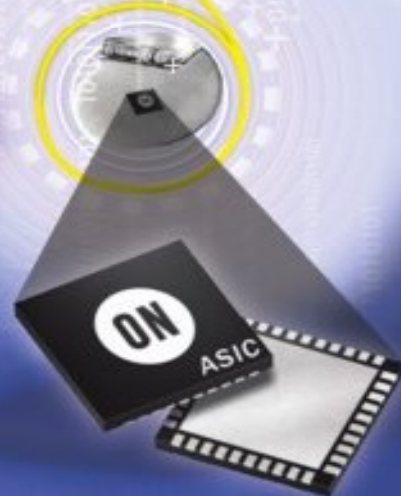
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Acting on Impulse

Neurostimulators suppress pain, but they also make engineers agonize over how to keep them flexible, compact, and low power.

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BREAKTHROUGHS

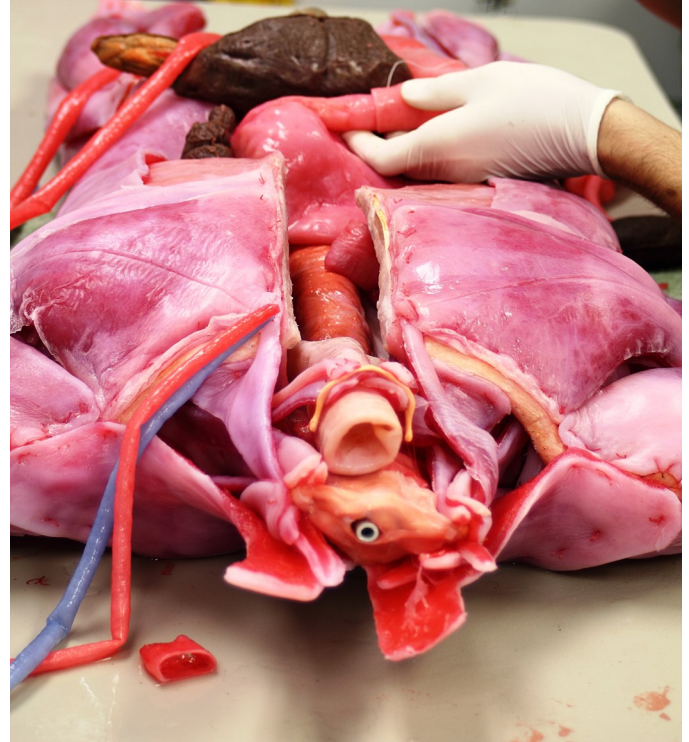
Synthetic Human Tissues Eliminate Need for Live Animal Use

Centuries of scientific strides and medical breakthroughs since the Renaissance would have been impossible without the experimental use of human cadavers and live animals. But modern society has become increasingly uncomfortable with such practices, especially animal research. Fortunately, **SynDaver™ Labs**, of Tampa, Florida, offers a feasible alternative—synthetic human tissues and body parts.

A great many companies offer what *they* consider synthetic tissues, but such products are almost invariably made from silicones, urethanes, or other plastics. In contrast, SynDaver™ Labs entire product portfolio is comprised of water, fibers, and salts. In addition, according to Dr. Christopher Sakezles, company President and Chief Technology Officer, the products are designed to mimic specific mechanical, chemical, and physical properties of actual living tissues. Featuring a product line that includes a complete human body with replaceable muscles, tendons, arteries, veins, and other organs, the company, in Sakezles' words, supplies a testing platform "that falls somewhere between live human subjects and bench top fixtures."

Based on tests performed on tissues while they are still living, SynDaver™ Labs' SynTissue™ brand synthetic human tissues are designed to mimic multiple physical properties of a particular target tissue. Such properties include strength and modulus in tension, compression, or shear, penetration and abrasion resistance, coefficient of friction, water and fiber content, density, and in some cases optical and dielectric properties. In addition, these models are structurally very sophisticated. For example, the company's synthetic human artery models are complex composite constructions fabricated from twelve different synthetic tissues that together model arterial intima, media, and adventitia.

"When these materials are assembled into a finished arterial construction, the resulting body part responds to stimulus—a medical device test for example—much like the real article," Sakezles says. This feature enables medical device engineers to evaluate the performance of prototypes in an environment that resembles end use and is both controllable and reproducible. "This capability is new and does not exist apart from our technology, even



with a live animal study or human clinical trial," according to Dr. Sakezles.

In addition to their use in design validation studies, surgical simulation, and clinical task training, SynDaver™ Labs' products have been employed by industry professionals to perform comparative benchmarking studies. Such tests allow developers to illustrate statistically significant performance differences between prototype variants or prototypes and previously released devices. As benchmarking tools, the company's SynDaver™ brand synthetic human body parts and SynTissue™ brand synthetic human tissues support substantial equivalence claims to FDA.

SynDaver™ Labs recently launched a completely synthetic adult human body and is ready to release the technology in both newborn and child sizes. The company is also working on platforms that incorporate living cells and respond to the environment autonomously.

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