

# Medical Product Manufacturing News<sup>®</sup>

THE MAGAZINE FOR MEDICAL PRODUCT DESIGN AND DEVELOPMENT

## PATTERNING TECHNIQUE

Yields Nerve-on-a-Chip

PAGE 6

## CERAMICS

Proliferate in  
Medical Implants

PAGE 24

## NEW TESTERS

Provide Better,  
Nondestructive  
Results

PAGE 26



### Hydrophilic Coating

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

Page 8



### Polymer Optics

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

Page 14



### Synthetic Tissues

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

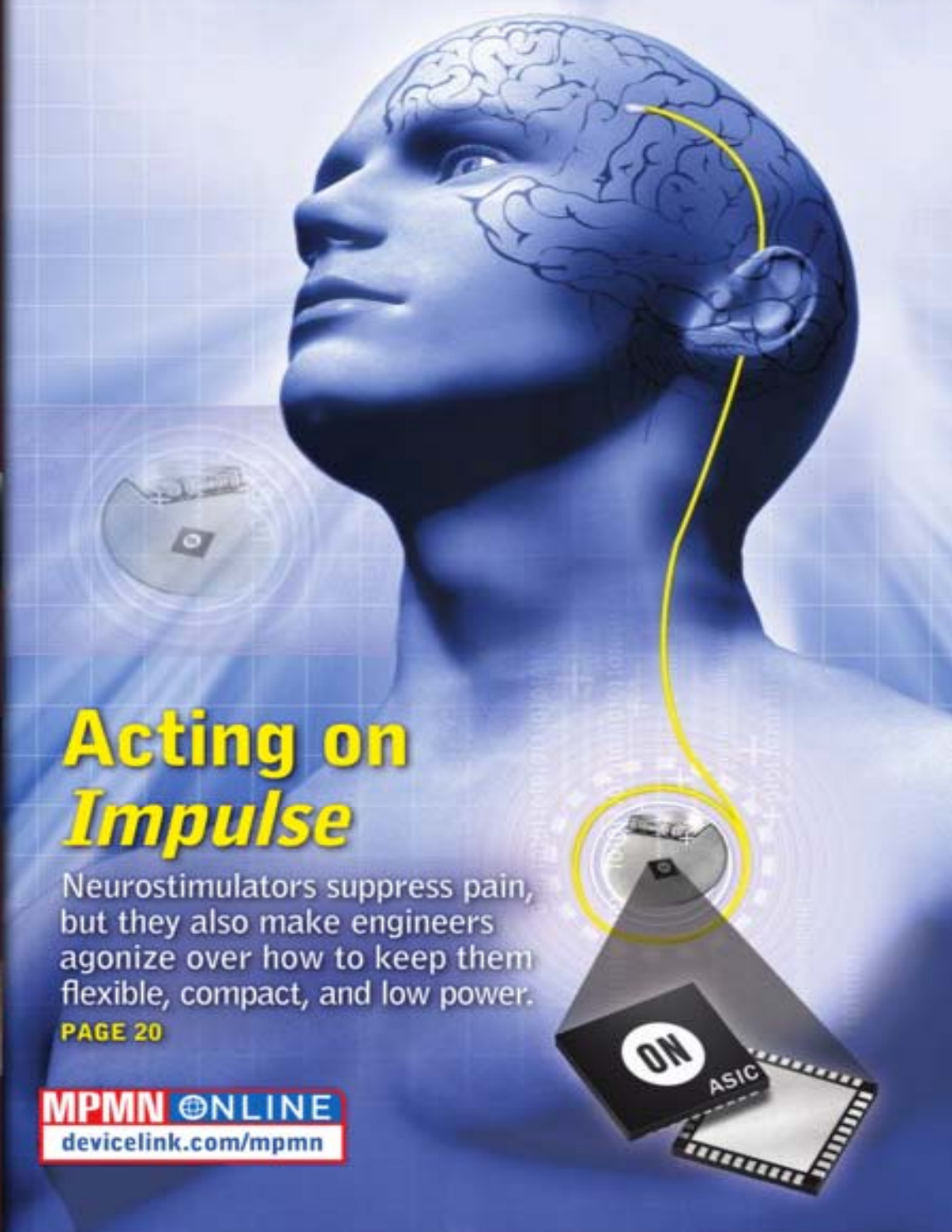
Page 36

## Acting on Impulse

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

PAGE 20

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

Based on tests performed on tissues while they are still living, SynDaver™ Labs' SynTissue™ brand synthetic human tissues mimic at least three different physical properties to model a particular target tissue. These 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 three different synthetic tissues that individually imitate arterial intima, media, and externa.

"When these materials are assembled into an 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 effects of prototype devices 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



*SynDaver™ Labs' synthetic human tissues and body parts offer the first real alternative to live animal and cadaver use.*

A live animal study or human clinical trial," according to Sakezles.

In addition to their use in medical device design verification and validation testing, 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 released its third-generation synthetic human arterial and venous models. At the same time, the company is working on shoulder, knee, thigh, arm, heart, and trachea models. Sakezles' comments, "We are building new body parts all the time."

- Bob Michaels

 **SynDaver™ Labs**  
TAMPA, FLORIDA

[www.syndaver.com](http://www.syndaver.com)