Polymer Coats Leads on Implantable Medical Device

Originating Technology/NASA Contribution

Langley Research Center's Soluble Imide (LaRC-SI) was discovered by accident. While researching resins and adhesives for advanced composites for high-speed aircraft, Robert Bryant, a Langley engineer, noticed that one of the polymers he was working with did not behave as predicted. After putting the compound through a two-stage controlled chemical reaction, expecting it to precipitate as a powder after the second stage, he was surprised to see that the compound remained soluble. This novel characteristic ended up making this polymer a very significant finding, eventually leading Bryant and his team to win several NASA technology awards, and an "R&D 100" award.

The unique feature of this compound is the way that it lends itself to easy processing. Most polyimides (members of a group of remarkably strong and incredibly heat- and chemical-resistant polymers) require complex curing cycles before they are usable. LaRC-SI remains soluble in its final form, so no further chemical processing is required to produce final materials, like thin films and varnishes. Since producing LaRC-SI does not require complex manufacturing techniques, it has been processed into useful forms for a variety of applications, including mechanical parts, magnetic components, ceramics, adhesives, composites, flexible circuits, multilayer printed circuits, and coatings on fiber optics, wires, and metals.

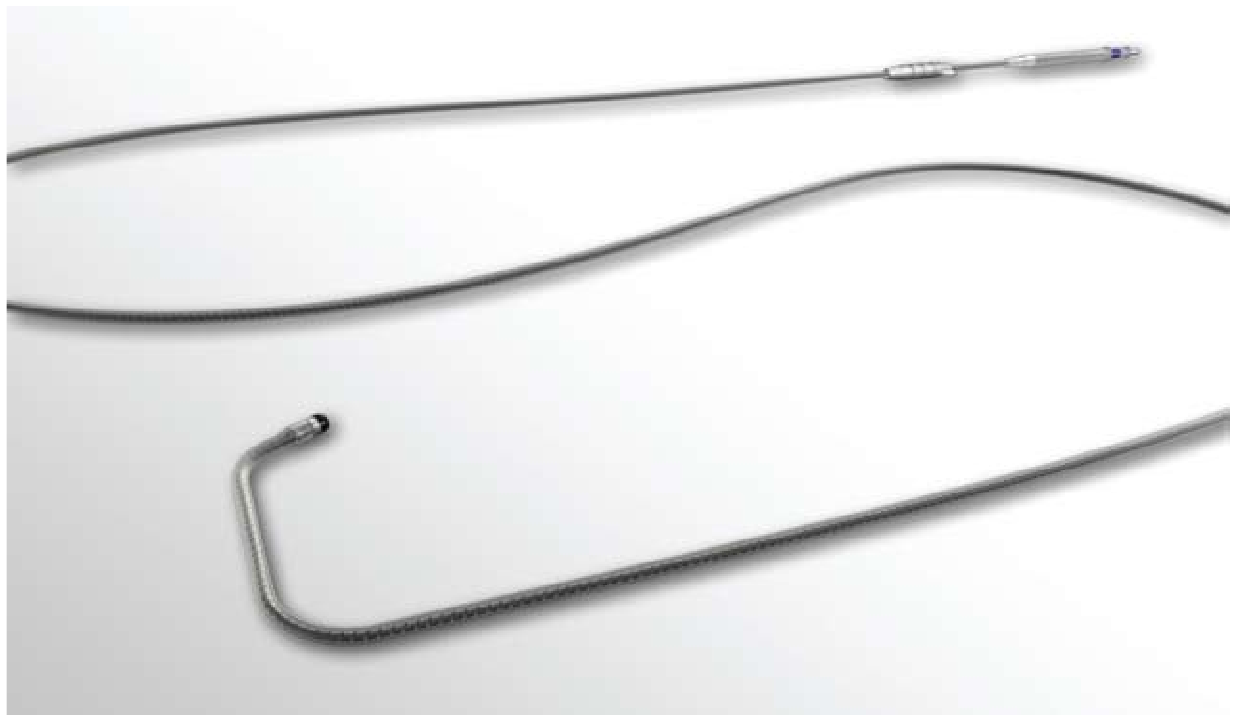
Bryant's team was, at the time, heavily involved with the aircraft polymer project and could not afford to further develop the polymer resin. Believing it was worth further exploration, though, he developed a plan for funding development and submitted it to Langley's chief scientist, who endorsed the experimentation. Bryant then left the high-speed civil transport project to develop LaRC-SI. The result is an extremely tough, lightweight thermoplastic that is not only solvent-resistant, but also has the ability to withstand temperature ranges from cryogenic levels to above 200 °C. The thermoplastic's unique characteristics lend it to many commercial applications; uses that Bryant believed would ultimately benefit industry and the Nation. "LaRC-SI," he explains, "is a product created in a government laboratory, funded with money from the tax-paying public. What we discovered helps further the economic competitiveness of the United States, and it was our goal to initiate the technology transfer process to ensure that our work benefited the widest range of people."

Several NASA centers, including Langley, have explored methods for using LaRC-SI in a number of applications from radiation shielding and as an adhesive to uses involving replacement of conventional rigid circuit boards. In the commercial realm, LaRC-SI can now be found in several commercial products, including the thin-layer composite unimorph ferroelectric driver and sensor (THUNDER) piezoelectric actuator, another "R&D 100" award winner (*Spinoff* 2005).

Partnership

Working with the Innovative Partnerships Program office at Langley, Medtronic Inc., of Minneapolis, Minnesota, licensed the material. This material has been evaluated for space applications, high-performance composites, and harsh environments; however, this partnership represents the first time that the material has been used in a medical device.

According to Bryant, "This partnership validates the belief we had that LaRC-SI needed to be introduced in (or by) the private sector: Lives can be saved and enhanced



Medtronic's cardiac resynchronization therapy devices use the NASA-developed polymer as insulation on thin metal lead wires.

because we were able to develop our laboratory findings and provide public access to the material."

Product Outcome

Medtronic is the world leader in medical technology providing lifelong solutions for people with chronic disease. It offers products, therapies, and services that enhance or extend the lives of millions of people. Each year, 6 million patients benefit from Medtronic's technology, used to treat conditions such as diabetes, heart disease, neurological disorders, and vascular illnesses.

The company is testing the material for use as insulation on thin metal wires connected to its implantable cardiac resynchronization therapy (CRT) devices for patients experiencing heart failure, which resynchronize the contractions of the heart's ventricles by sending tiny electrical impulses to the heart muscle, helping the heart pump blood throughout the body more efficiently.

"Our work with NASA Langley was very collaborative," said Lonny Stormo, Medtronic vice president of therapy delivery research and development. "Our scientists discussed Medtronic's material requirements and NASA shared what it knows about the compound's properties as we continued our testing and evaluations."

In March 2007, Medtronic conducted the first clinical implants in the United States and Canada of the Medtronic over-the-wire lead (Model 4196), a dual-electrode left ventricular (LV) lead for use in heart failure patients with cardiac resynchronization therapy devices.

"Through this partnership, Medtronic was able to deliver a product with enhanced material properties," said Stormo. "In turn this helps our patients, which is the core of Medtronic's mission."

Placing a lead in the LV is widely recognized by physicians as the most challenging aspect of implanting CRT devices. Anatomic challenges can make it difficult to access and work within the coronary sinus to place a lead in the desired vein of the LV. The lead is specially designed for optimal tracking over a guide wire, which is intended to allow physicians greater ability to deliver the left heart lead in difficult-to-access veins.

Once implanted in the LV, two electrodes located at the tip of the lead provide physicians with options to tailor delivery of stimulation for each patient. When approved by the U.S. Food and Drug Administration, the lead is expected to be the smallest LV lead in the U.S. market. ❖

LaRC-SI is an amorphous thermoplastic developed by Robert Bryant, a chemical engineer at Langley. LaRC-SI has excellent adhesive and dielectric properties and can be reformed at elevated temperature and pressures. It can be applied in the form of a spray, spin, dip coating, paint, or spread with a blade.