Freedom Driver Designed to Power SynCardia’s Total Artificial Heart Uses Bayer MaterialScience LLC Materials

Bayer MaterialScience

Lux Aviation Engineering Corp. utilizes the Makroblend EL703 PC/PET blend to produce a battery pack designed to lighten patient’s load.

The Freedom driver designed to power the SynCardia temporary CardioWestTM Total Artificial Heart.

SynCardia Systems, Inc., manufacturer of the SynCardia temporary CardioWest Total Artificial Heart (the world's only FDA-, Health Canada-, and CE-approved Total Artificial Heart) needed to find the right material for a new portable driver, designed to power the Total Artificial Heart outside the hospital. Lux Aviation Engineering Corp. and Bayer MaterialScience LLC [1]got to the heart of the matter.

The result, a compact, lightweight lithium-polymer onboard battery pack designed and assembled by Lux Aviation using Bayer MaterialScience’s Makroblend EL703 polycarbonate/polyethylene terephthalate polyester (PC/PET) blend, is the driving force behind the small pneumatic driver intended to power the Total Artificial Heart.

The aptly named Freedom driver from SynCardia features twin battery packs with each measuring 7.0 in. x 2.7 in. x 1.5 in. and weighing slightly more than one pound each. The Freedom driver is designed to allow stable Total Artificial Heart patients to be discharged from the hospital to wait at home until a matching donor heart is found.

Originally used as a permanent replacement heart, the SynCardia Total Artificial Heart is currently approved as a bridge-to-heart transplant device for patients dying from irreversible biventricular failure. More than 800 patients, representing more than 180 patient years of life, have received the Total Artificial Heart. Until now, they've had to use a 450 lb. hospital driver, nicknamed "Big Blue," that forced even stable patients to stay in the hospital for months while waiting for a transplant.

"Never before has a driver been available in the United States that is intended to allow stable patients implanted with the Total Artificial Heart to be discharged," said Rodger Ford, president, SynCardia, based in Tucson, Ariz. "In developing the Freedom driver, we involved product management with people who know the complete ins and outs of what we are trying to accomplish," Ford said. "Working closely with Lux Aviation and Bayer MaterialScience, we developed a battery pack that weighs just slightly more than one pound."

The Freedom driver set next to the Big Blue hospital driver for size comparison.

The battery pack of the Freedom driver is a vital component for patient mobility. "The battery pack is unlike any other product on the market," said Curtis Brown, of Tucson, Ariz.-based Lux Aviation, which designs and assembles the battery pack for SynCardia. "The primary difference is the lithium polymer battery cells and custom battery management electronics integrated with the cells."

The user interface is designed to let patients quickly see how much capacity is remaining in the battery with a push of a button, Brown said. The battery pack includes two internal batteries. When one of the two batteries drops below 35 percent full charge, an alert sounds indicating it is time to switch and charge the batteries.

"The battery pack is designed to provide longer life and a more reliable charge, intended to provide stable patients with freedom and independence while they wait for a heart transplant," Ford said.

Bayer MaterialScience's Makroblend EL703 blend resin is used to mold the battery case. "This advanced engineering resin provides a combination of properties including impact resistance, ultraviolet stability, flame retardance, and chemical resistance needed for this application," said Kevin Dunay, market segment leader, Medical Polycarbonates NAFTA, Bayer MaterialScience LLC. "The reliability of this material is evident in its use for this critical application."

In developing the battery pack, Lux Aviation chose Bayer MaterialScience for its applications support, quick response to questions and comprehensive technical specifications required for the application. "The expertise of Bayer MaterialScience strengthened the product with great applications help to allow us to select a material that met all of our performance requirements," Brown added. Lux Aviation plans to use Bayer MaterialScience's color compounding capabilities in the future to create a colored material that will improve upon the current process of adding color at the press.

SynCardia has submitted an application to the U.S. Food and Drug Administration to conduct an Investigational Device Exemption clinical study of the Freedom discharge driver. The submission includes a request to conduct the clinical study at 30 U.S. sites. SynCardia has also submitted the Freedom driver design dossier for CE Mark approval in Europe.

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[1] http://www.bayermaterialscience.com