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WHEN LIVES ARE AT STAKE, THE BATTERIES BETTER WORK

By Elizabeth Gardner
Small Times Correspondent

June 26, 2003 - When Alfred Mann, chairman and co-founder of Advanced Bionics Corp., began developing an injectable neuromuscular stimulator in the late 1990s, he searched to find a company that could make a tiny lithium-ion battery to power it. The battery needed to last 10 years, be rechargeable thousands of times over, be able to sit dormant for long periods without losing its oomph, be hermetically sealed for safety, and, oh yes, be no bigger than a grain of rice.

When he couldn't find any takers, he started another company, Quallion LLC, to take on the task. The resulting device, the Bion neurostimulator, started clinical trials in Europe for treating urinary incontinence, and is expected to start U.S. trials soon. Quallion worked with several collaborators, including Argonne National Laboratory in Illinois and the Organosilicon Research Center at the University of Wisconsin.

The cost of the battery alone is \$400, said Quallion President Werner Hafelfinger. A special pad attached to a belt or placed on a seat or bed recharges the battery through the patient's body. Potential uses include treating chronic pain, epilepsy and sleep apnea, and helping restore limb control for stroke victims.

"Quallion is unique in the area of developing batteries for implant applications," said Gerald Ceasar, a program officer at the Advanced Technology Program of the National Institute of Standards and Technology, which funded the battery's development to the tune of \$8.4 million. "Most implant devices use primary (nonrechargeable) batteries, so Quallion is blazing new ground."

Batteries for implantable medical devices have always posed challenges. The power has to be steady throughout the life of the battery and its life should match the life of the rest of the device. It can't be too bulky or heavy, and can't generate too much heat. Its casing has to resist the body's natural tendency to corrode

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Photo courtesy of Advanced Bionics
Clinical trials have started on the Bion neurostimulator, which contains a Quallion battery.



For perspective, Quallion's battery in contrast to a penny.

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foreign objects. And it has to work even if the body deposits a 2-millimeter-thick fibrous coating on it as a protective measure. Because of these challenges and the risk of being sued over a life-or health-threatening battery failure, large battery companies have been reluctant to get into this niche market.

Rechargeable batteries are even riskier, especially for life-saving devices, because they depend on the patient's ability to remember to recharge them, said Orhan Soykan, principal scientist at the Materials and Biosciences Center at Minneapolis-based Medtronic Inc., a leading manufacturer of medical devices. Medtronic typically develops its own batteries rather than relying on outside suppliers.

As small tech opens up the possibilities for ever-smaller implantables, they also need ever-smaller batteries. Potential solutions are coming not from big battery companies, but from research labs and startups like Quallion.

At least two companies – Cymbet Corp. of Elk River, Minn., and Excellatron of Smyrna, Ga. – are trying to commercialize research at Oak Ridge National Laboratory on rechargeable thin-film batteries. Excellatron is working on a \$1.4 million grant from the federal government's Advanced Technology Program to figure out how to produce the battery less expensively.

Cymbet is working with Medtronic to develop the same technology. In exchange for Medtronic's help in testing its batteries, the company receives a two-year exclusive deal.



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