

Proof is in the devices, but name change helps

BY DYKE HENDRICKSON
SENIOR STAFF WRITER

The East Development Group, a medical device contractor, changed its name several years ago to Proven Process.

The idea behind the change was to provide a more descriptive explanation of the company to prospective customers.

The marketing move seems to have worked, for the East Walpole company has added both contracts and personnel in recent months.

"When we started, it was just three engineers and an idea," said James Sluetz, one of the co-founders. "In 2001 we changed the name to indicate to people that we are established, and we are successful.

"The medical device business is growing now, and in recent months more companies seem to be able to acquire financing to develop their ideas."

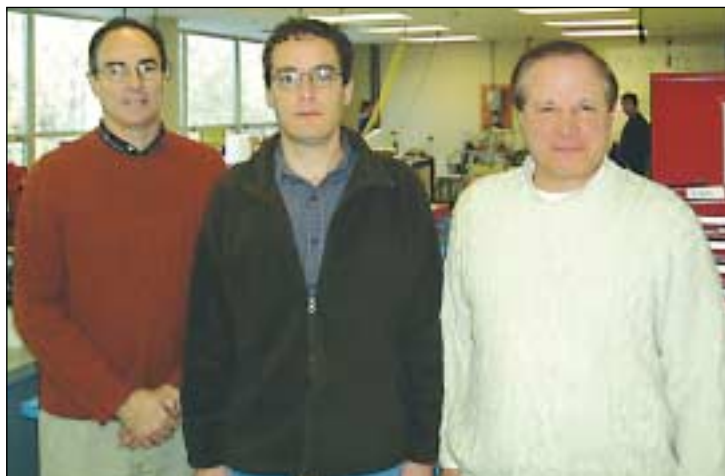
Many New England companies offer design and engineering services, but it appears that Proven Process is emerging as one of few firms that focuses completely on medical devices and delivery systems.

Founded a decade ago, the company employs about 50.

Its customers include high-profile corporations like C.R. Bard and Boston Scientific Corp. It also works with startups whose resources might be limited to a patent and a minimal amount of startup capital.

The company was founded by Kenneth Fine, Paul Burke and Sluetz, a trio of locally educated engineers.

Fine now is president, and holds an M.S. in electrical engineering from Northeastern University and a B.S. in biomedical



Proven Process executives, from left, James Sluetz, Paul Burke and Robert McCoy are pictured at the company's East Walpole research laboratory.

ical engineering from Boston University.

Sluetz holds a B.A. from DePauw University, a B.S.E. and M.S.E.E. from Purdue University and an MBA from Northeastern University, while Burke holds a degree in mechanical engineering from Northeastern.

All three have experience in Class II and Class III medical devices, they say.

Much of their work involves the implantation of medical devices. Their implantable programmable insulin pump, for instance, helps diabetics to self-regulate their meds without having to receive shots on a daily basis.

Company officials say one of their most successful devices in recent years is an implantable infusion pump for individuals who deal with chronic back pain.

The device releases pain-killing medication on a regular basis, which keeps the patient out of pain — and frequently, out of the hospital.

"One benefit (of implantation devices) is that medication delivered directly is much stronger than an oral medication," said

Bob McCoy, vice president of business development. "It's a big advantage to receive meds directly, which is what these pumps are capable of doing."

The company has also developed devices designed to improve cardiac performance.

As a joint venture, Proven Process and Apex Medical have completed animal tests for an implantable blood pressure device that will optimize operations of left ventricular assist devices.

Made of titanium, the device is being developed in part with funding by the U.S. Department of Commerce's National Institute of Standards and Technology.

Companies that have worked with Proven Process appear to be satisfied with the relationship.

Peter Hamilton, manager of operations at BioSphere Medical Inc., said, in a statement, "We are a small startup medical device company focused on embolotherapy. We didn't have a lot to budget on infrastructure for product testing. Their expertise in medical devices and their breadth of equipment were important."

The company has received positive response from larger clients as well.

Dave Conti, senior program manager for Boston Scientific Corp., said, in a statement, "We were impressed with their knowledge of electronics, experience with medical specifications, and ability to take on the entire scope of our project."

McCoy said that a key goal is to become an extension of the company with whom they are working.

"We know the process for medical device development," McCoy said, "and when we sit down with a customer we want them to feel that we are a part of their team."