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Designing better med devices on the N.H. seashore

With the exception of a few acclaimed inventors, engineers most often go unnoticed for their contributions to popular and profitable technologies. Many don't want to seek the limelight, though, preferring that the attention be on their wares rather than themselves.

Mechanical engineer **Karl Leinsing** fits the bill of an unsung inventor quite well, even if he has begun to gain some notoriety within his field of medical device development. For one, he operates his engineering company, **ATech Designs Inc.**, in an office and lab attached to his home in the cozy seaside town of Hampton, N.H., a fair distance from many of his industry peers along the Route 128 corridor near Boston.

Despite the unassuming front of his business, Leinsing has seen his work in the medical field featured on the cover of Life magazine, has played a role in the development of products that generate millions in revenue and has won

multiple awards for his engineering prowess.

"I've made a lot of companies a lot of money," Leinsing said. "Every project we've done is successful."

Lately his firm has served as the research and development arm of **Mardil Inc.**, a virtual medical devices company with a chief executive in North Carolina, a design engineer in North Dakota and outsourced manufacturing in Montana and California.

Leinsing heads development of Mardil's experimental device for patients with mitral valve regurgitation, a cardiac condition in which the valve between the left atrium and left ventricle allows blood to flow the wrong way, into the heart, rather than away from it. He said the device is expected to enter clinical trials in India in two months.

His previous inventions include a knitting machine for making a mesh material in a surgical device called NovaSure, marketed by **Cytec Corp.**, the Marlborough subsidiary of medical technology firm **Hologic Inc.** of Bedford. Another gem in his portfolio is a needle-free, intravenous valve system sold by industry giant **Cardinal**

Health Inc., based in Dublin, Ohio.

Leinsing, 42, said he applies the principles of German engineering to design, refine and optimize his medical inventions. In case you couldn't tell by his last name, Leinsing is of German descent and his father and grandfather were engineers. "It's almost like you're born with it," said Leinsing of the German engineering ethic. "It's hardheadedness and persistence — refine and make it perfect."

Leinsing crossed paths with a major celebrity of the engineering world, **Dean Kamen**, while growing up in southern New Hampshire. Kamen, known most recently for inventing the two-wheeled human transporter called the Segway, lived across the street from Leinsing's boyhood friend and they used to house-sit for Kamen, he said. Leinsing recalls the fully equipped machine shop in Kamen's house and how the inventor made a name for himself after designing the first wearable infusion pump in the 1970s. "At the time," Leinsing said, "I aspired to do the same things he did."

It appears as though Leinsing has realized at least some of those early aspirations.

ORAL INSULIN BACK IN WORCESTER

In the turbulent business of developing insulin taken orally rather than by injection, a Canadian biotech with R&D operations in Worcester hopes to pick up where such drug industry giants as **Pfizer Inc.** and **Eli Lilly & Co.** left off.

Generex Biotechnology Corp., a Toronto-based firm with a 12-person lab in Massachusetts, said last week it has launched a Phase 3 clinical trial of an oral insulin spray. Once seen as a Holy Grail of drug delivery, orally administered insulin has lost some luster because New York's Pfizer, Eli Lilly of Indianapolis, Denmark's **Novo Nordisk AS** have all pulled the plug on inhaled insulin programs in the past year.

No large U.S. drug companies have formed partnerships related to the oral insulin product with Generex — as Eli Lilly did with Cambridge biotech firm **Alkermes Inc.** — but Generex CEO **Anna Gluskin** indicated that her firm wouldn't jump into a partnership without a big payday. "They are the ones that failed," Gluskin said of Pfizer, Lilly and Novo. "So they really have to look at paying us a lot of money."

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