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Cover Story

Cincinnati-made device could reshape the health care industry

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When he's not busy launching health care companies, Mike Hooven drives a race car in [Porsche Club of America](#) events. ¶ His car has a stock 3.4-liter engine, but everything else about the Porsche Cayman Interseries is modified for the track. The preparation he makes for race day is similar to what's underway now at his latest startup, medical device maker [Enable Injections](#), where Hooven is CEO.

"I've been on the track close to 1,000 times," Hooven said. At Evendale-based [Enable Injections](#), "we're still in the shop. What you want to do is put together a machine that you know is absolutely reliable – because you depend on it.

"You don't want to be thinking while you're on the track, 'Gee, what's that noise on the right rear that I just heard?'" said Hooven, who earned a bachelor's degree in physics and a master's in mechanical engineering. "You want to be concentrating on the competition."

While a couple of would-be competitors are working on something similar to the so-called bolus injector being developed by [Enable Injections](#), the local firm is off to a roaring start. Last year, Enable raised \$30 million in Series A funding – one of the largest investments in a Cincinnati company ever made by venture capitalists.

That should be enough for the firm to commercialize the disposable device, which will allow patients to self-inject prescription drugs with the touch of a button. Most people can't feel the needle going in. The bolus injector could be used to administer a large dose of a drug to combat anything from cancer to hemophilia.

A version of the Enable device that can inject 10 cubic centimeters of medicine is about 2.25 inches in diameter and less than a half-inch thick, so it's slightly larger than an Oreo cookie. But it could be the next big thing in health care.

About \$250 billion worth of biologic drugs are coming out due to advances in research, and the Enable injector has the potential to become the preferred way to administer them, Hooven said.



CORRIE SCHAFFELD | COURIER

Mike Hooven is the CEO and founder of Enable Injections Inc.



MIKE HOOVEN
CEO and founder of Enable Injections Inc.
Age: 62
Resides: Sharonville
Family: Wife, Sue Spies, vice president of administration for Enable; one son, Brian
Education: Bachelor's degree in physics, 1978, and a master's in mechanical engineering, 1981, University of Michigan
Career path: Launched Enable Injections in 2010; former CEO of AtriCure, which he founded in 2000; founded Enable Medical Corp. in 1994; led internal product development at Ethicon in Blue Ash, 1988-94; held engineering positions at Siemens-Pacesetter, 1986-88, and Cordis Corp., 1981-86



Worn on stomach

The injector would typically be worn on someone's abdomen, and it could be covered by clothing. That frees people to engage in other daily activities while being treated. After medicine is dispensed, the needle automatically retracts, the patient peels the device off, and he or she throws it away.

The medical device could reshape the health care industry, said Mark Collar, former president of Global Pharmaceuticals and Personal Health for Procter & Gamble Co.

Enable Injections is addressing a major unmet need for a convenient, body-worn device that can deliver higher quantities of injectable drugs, said Collar, who is a board member at the startup.

"This critical advantage has the potential to create a new standard of care for patients with conditions requiring these kinds of drugs," Collar said.

Pharmaceutical companies might take another look at some drugs in their portfolio that previously were presumed to be too difficult to deliver, Collar said.

Enable still needs approval from the U.S. Food and Drug Administration to market the device in the U.S., which could take years.

"We are very close," Hooven said. "We anticipate beginning clinical studies within the next year. And we anticipate a limited commercial release sometime the following year" - probably in Europe.

A lot of engineering and testing goes into both a medical device and a race car before either is rolled out. On the track, "it ultimately comes down to the skills of the driver," Hooven said. "The big difference with the Enable device is you don't have to be skilled to use it."

The bolus injector might eliminate the need for long intravenous treatments at a doctor's office.

"This is where it gets really exciting," Hooven said. "If you can change the delivery from in-clinic or in-hospital intravenous delivery to at-home deliver by the patient, look at the benefit you're getting."

CincyTech, a public-private partnership that invests in Southwest Ohio startups, played a key role in the Series A funding. John Rice, director of life sciences for CincyTech and a member of Enable's board, believes the medical device has the potential to generate billions in revenue.

Also participating in the funding round was Cincinnati Children's Hospital. Hooven launched Enable Injections in 2010 by licensing technology invented at the hospital.

Dr. Eric Wall, a surgeon at Children's, thought there should be a way to minimize or eliminate vaccination pain in infants, Hooven said. The hospital did more than 10 years of work, including clinical studies, and made intellectual property filings.

"One of the things Wall surmised is that if you use a small needle and you inject really slowly, you ought to be able to eliminate injection pain," Hooven said. "And so we started with that concept. For two years, we were focused on developing technology for painless vaccination."

But Enable discovered that pharmaceutical companies had no interest in buying such a device and the market would be tiny for a painless drug injector for infants.

"(Pharma companies) said, 'We're already selling vaccines. We're selling lots of vaccines. How is this going to benefit us?'" Hooven said. "They just didn't see the market opportunity."

"And so we pivoted the business. The original technology that Dr. Wall invented is not the technology that we have now."

In 2012, Hooven realized there was a market opportunity for body-worn injectors that could deliver a high volume of medication to adults with serious illnesses. It's too painful and time consuming for most patients to inject themselves with a large dose of medicine using a conventional needle and syringe, he said. While possible, it can take hours and require a motorized pump.

The Enable device could inject a drug in anywhere from a few minutes to an hour, depending on the medicine. A larger version of the device can inject 20 cc's of medicine, or about 4 teaspoons.

"It is unbelievably simple," Hooven said. "A patient will be able to take this vial (of medicine) out of her refrigerator, put it in the transfer, automatically fill the device, push the button – and that's it."

"And then you look at it from a health care cost standpoint," he said. "You're removing all cost from intravenous administration" at a health care facility.

Enable plans to sell its bolus injector to pharma companies for \$25 to \$50 apiece depending on production volumes.

"Some pharma companies are telling us this could be 10 million units a year," Hooven said. "But the nice thing is because these biologics are so expensive – your typical drug injection is \$500 to \$1,000 per injection – the pharma companies don't charge the patient for the device."

Enable Injections has had discussions about the device with virtually every major pharma company. About 30 preliminary agreements have been executed, along with four development agreements and one manufacturing and supply agreement. More deals are anticipated.

Enable could make up to 5 million bolus injectors a year locally, Hooven said. The company is partnering with Flextronics, a third-party manufacturer, to handle orders that could reach tens of millions of devices a year.

"What we're doing here is the initial prototypes, pilot production and clinical units," Hooven said. "If the volumes are low enough, just a few hundred thousand a year, we can do them out of here."

Now hiring

Hooven previously was CEO of AtriCure Inc., a Mason-based medical device maker he launched that specializes in treating atrial fibrillation. Its stock now trades on the Nasdaq exchange.

In 1994, Hooven founded Enable Medical Corp., which manufactured surgical devices he invented. He has been issued 62 patents and has another 41 pending. Enable Medical was acquired by AtriCure in 2005. Before that, Hooven headed up all internal product development at Ethicon Endo-Surgery in Blue Ash from 1988 to 1994.

Collar, the former P&G president who is on Enable's board, also is a director of AtriCure. He said Hooven brings a depth of know-how combined with tons of energy and contagious confidence.

"Mike is a brilliant engineer with a history of innovating in the medical device space," Collar said. "He has the vision, passion and courage to drive projects forward – in the process building a highly engaged and similarly passionate team. He is a winner. People want to be a part of it."

The bolus injector was a team design with about five key people responsible, Hooven said.

When it comes to lining up mechanics to work on a race car, "you make sure you've got the best people you can possibly get to make sure it's operating in a really predictable way," Hooven said. "It's the same thing with medical devices."

Enable's workforce, which totals about 70, might reach 100 by the end of 2017 – and 150 by the end of 2018. Everyone hired – from engineers to production workers – is given equity in the company in the form of restricted stock.

"It really helps because everyone is together in terms of achieving the company objectives, and they can see the value of their equity increase," Hooven said. "They can see the value of what they're doing contributes to building the value of the business."

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