



Firm sees sterilization as fertile business ground

J.K. Wall October 15, 2012

Indianapolis-based medical-device maker Catheter Research Inc. will receive a new kind of sterilization machine in December that it hopes will reduce costs and wait times for medical-device companies in the Midwest—including itself.

Catheter will set up a new-generation sterilization machine made by Maryland-based Noxilizer Inc. The company's lead investor is Indianapolis-based CHV Capital Inc., the venture capital arm of the Indiana University Health hospital system.

Sterilization is a required step, overseen by the U.S. Food and Drug Administration, in both the development and production of medical devices. In March, a [new sterilization facility](#) opened near Warsaw. But there are no contract sterilization facilities in the Indianapolis area.

Catheter Research, which makes catheter-based medical devices for itself and on contract for other companies, sends its products to sterilization facilities in either Illinois or Michigan. The total turnaround time is 10 days.

"It's a long way and it's expensive," said John Steen, CEO of Catheter Research, which employs about 130 people on West 82nd Street in the Park 100 industrial park.

But the Noxilizer machine will cut that down to one day—and shave off about 40 percent to 60 percent of typical costs.

The \$250,000 machine, which is about the dimensions of small family room in a house, uses nitrogen dioxide to sterilize medical devices. Inside the machine, the gas suffuses a medical device to kill off any bacteria and then gradually flows out of it in a process called out-gassing. One complete sterilization cycle runs about four hours.

But the most commonly used technology currently in use, known as ethylene oxide, takes days for out-gassing. It also costs the same amount of money to sterilize a pallet full of devices or just a few. So companies typically have to stockpile products before having enough to sterilize.

Neither the time nor the large batches are convenient for small companies trying to develop new products in small batches, which is a key reason having sterilization facilities has been a top item on the wish list of Indianapolis-based BioCrossroads, the life sciences development organization.

That's why Catheter Research thinks it can use the Noxilizer machine to develop a new line of business in contract sterilization work.

"As the life sciences continue to grow here," said Phil Sheingold, vice president of operations at Catheter Research, "what we will be able to offer is a low-cost alternative to sterilization so that they don't have their capital tied up in inventory."

Kyle Salyers, managing director of CHV Capital, said Noxilizer's technology is not as corrosive as ethylene oxide to medical devices made from polymers or that use optical technology in them. That difference, as well as the lower costs and quicker turnaround times, make it attractive to IU Health.

Noxilizer has yet to seek approval for its technology in hospitals, but it plans to do so by the end of 2013, said Larry Bruder, CEO of Noxilizer.

He also sees some market in the pharmaceutical industry, where injectible drugs are increasingly being packaged in pre-filled plastic syringes that need to be sterilized, typically with ethylene oxide.

In addition, he added, injectible drugs packaged in glass vials are usually topped with rubber stoppers. Ethylene oxide sometimes penetrates those stoppers, and then alter the drug inside the vial. But the nitrogen dioxide used by Noxilizer has no such effect.

Noxilizer's joint venture with Catheter Research is the first of several regional hubs Noxilizer plans to set up across the nation to perform contract sterilization services.

"Contract sterilization is an \$800 million business in the U.S. and Europe," Bruder said, noting that about 45 percent of those dollars go to ethylene oxide. Another 45 percent pays for gamma radiation for sterilization, and Bruder thinks Noxilizer could be a good alternative for some of that business, too.

"We feel like we're a really interesting alternative to ethylene oxide, and also some with gamma," he said. "So we feel there's an opportunity to grow a really significant business here."