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Published Article

Competing to Relieve Back Pain

Two companies in NE Ohio developing artificial discs

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Two Northeast Ohio startup companies are moving toward human trials next year of flexible artificial spinal discs for back pain sufferers. Although their products are similar, the companies have very different business models for getting to market.

The Food and Drug Administration is expected to approve for sale later this year the first artificial disc, a ball-and-socket design made by another company.

Both AxioMed Spine Corp. of Beachwood and Theken Disc LLC of Akron, on the other hand, are working on what they say is a better design: a core of flexible polymer sandwiched between thin titanium plates. That combination, they say, allows more natural movement of the spine. If all goes well, their discs should hit the U.S. market around 2009 or 2010. Discs are the shock absorbers between the vertebrae, the bones of the spine. When discs rupture, they can press on spinal nerves and cause excruciating pain.

About 300,000 people in the United States have disc operations every year. About half are for problems in the lower back, or lumbar region, and half are in the neck area, or cervical region.

The best treatment available today involves removing the bad disc and fusing the vertebrae together with metal plates. But that puts added stress on the discs adjacent to the fused joint, sometimes leading to more back problems later.

And that is why the orthopedic world is eagerly awaiting the arrival of artificial discs and other "nonfusion" technologies.

"There is tremendous debate about how large this market will be," said John Englehardt, chief executive of Knowledge Enterprises Inc. of Chagrin Falls, and orthopedic industry research and consulting firm. The company's venture capital fund, Knowledge Ventures LLC, has a small investment in AxioMed. Next year, with just one product becoming available, the U.S. market for nonfusion spine implants will be about \$27 million, the consulting firm Frost & Sullivan predicted in a report this month. That figure could reach \$860 million a year by 2008, when doctors have perhaps 15 products to choose from, the report said. Other estimates are more generous – as much as \$5 billion a year.



Both Theken Disc LLC and AxioMed Spine Corp. are developing flexible spinal replacement discs made of polymers cores bonded to titanium and plastic. This is Theken's design, which also includes a microchip in the center. The chip stores data about the disc's performance and uploads it to a computer when a doctor scans a patient's spine.

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Theken Disc (pronounced "Taken") and AxioMed hope to grab a share of the spine implant market, which Frost & Sullivan says is the fastest-growing segment of the U.S. orthopedic business.

AxioMed's Freedom Lumbar Disc and Theken Disc's unnamed product are designed for the lower back. Both companies say their technologies can be adapted later for use in the neck. Theken's includes a tiny electronic chip that transmits data to doctors about how the disc is performing.



Theken Disc expects to sell 10,000 to 100,000 of its lumbar artificial discs a year, said Ric Navarro, vice president of business development and new technology. At roughly \$5,000 apiece, that's \$50 million to \$500 million a year in revenue.

"Those are big-company numbers," he said.

But Theken, with nine employees, and AxioMed, with six, are still small start-ups. Both need to raise large amounts of money for their upcoming human trials. And that is where the companies begin looking very different.

AxioMed, which Chuck Birchall and Jim Karas started in 2001, has raised about \$6.5 million so far, mainly in venture capital money. Five funds, including local investors Primus Venture Partners and Early Stage Partners, pumped more than \$3 million into the company last year and about the same amount this year.

In the process, however, Birchall and Kuras lost control of their company. Birchall, who was president, left the company last year. In March the board hired David Floyd, a 20-year veteran of the orthopedic device industry who grew up in Cuyahoga Falls. Kuras remains vice president of product development.

Theken Disc has raised about \$6 million since Randy Theken spun it off last year from Theken Surgical LLC of Akron, which makes the metal plates used in spinal fusion. Randy Theken also owns Theken Orthopaedic Inc. in Barberton which tests spinal implant devices.

Theken disc, however, opted to approach angel investors – individuals who have the means to invest in private early-stage companies – for most of its money. Some money also came from a state technology grant that Theken Surgical won for the disc project in partnership with Akron Plymex Laboratories, the University of Akron and the University of Toledo.

Randy Theken said he wanted no part of venture capital funds.

"I was adamant on that," he said, especially after watching what unfolded at AxioMed. The investors he recruited own about 40 percent of the company. They expect a return, he said, but also simply like helping someone else succeed. "They're not on my doorstep every day trying to run the company."

Floyd says AxioMed will approach a wider range of investors later this year to find \$12 million to \$15 million more. That will pay for human trials in Europe next year, the anticipated start of European sales in 2006 and preparations for U.S. human trials.

Theken Disc is considering a different route to the same size pot of gold. The company could sell exclusive distribution rights to a larger orthopedic device manufacturer, collecting the cash it needs without handing over control. Two manufacturers already seem interested," Randy Theken said.

It's no accident that two Northeast Ohio companies are working on flexible artificial discs. The former AcroMed Corp. of Cleveland was developing a flexible disc when DePuy Inc. brought it in 1998. AxioMed's founders, Birchall and Kuras, both worked for AcroMed, as did Navarro of Theken.

The region's expertise in polymers also has been a boon. The discs' polymer centers have to be flexible enough to allow normal movement, yet durable enough to withstand the loads of the spine.

Randy Theken said his company developed and tried about 35 polymers before finding one that outperformed off-the-shelf polymers already used in other medical devices. AxioMed went with a unique formulation derived from a family of polymers used in cardiovascular devices, Floyd said.

Both companies say their devices will be superior to the first generation of artificial discs that will be coming soon. But by the time the local discs hit the market, they will have to do more than compete against each other.

Englehardt of Knowledge Enterprises Inc. said he knows of at least three other projects looking at the feasibility of flexible artificial discs. Other nonfusion technologies, some simpler than disc replacement surgery, also are in the works.

Still, AxioMed and Theken Disc feel that their products will be a hit with doctors and patients.

"There's a paradigm shift going on in the industry right now. Surgeons are gradually warming up to the idea that we shouldn't be fusing the spine," Navarro said. "Companies that haven't had a disc development program in house know they're going to be left behind."

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