

Theken Focuses on the Future, Develops Revolutionary Spinal Implants

By Mark R. Raabe

Randy Theken has a story to tell. *Building a Better Implant* would be an appropriate title.

Theken is the founder of three orthopedic medical device companies, known as The Theken Family of Companies. Theken Orthopaedic™ conducts mechanical testing of orthopedic implants for major medical device companies in need of FDA approval. Theken Spine™ designs, develops, manufacturers and distributes spinal fusion implants to hospitals worldwide. Theken Disc™ designs and develops high-technology medical device products, such as a microelectronic artificial replacement spinal disc. A masters-degreed electrical and mechanical engineer, Randy Theken and his rapidly-growing family of privately-held companies are on track to be viable competitors in a multi-billion-dollar industry bolstered by the aging of the American population.



Randy Theken

“Disorders of the spine represent one of the largest public health problems in the United States, according to the North American Spine Society,” said Theken. “Last year, an estimated 300,000 Americans underwent disc surgery. As the baby boomer generation continues to age, that number will surely increase.”

Theken was born and raised in Northeast Ohio. He became interested in spinal implants while conducting research for his



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Richard Navarro, vice president of Research and Development for Theken Disc, displays the Theken eDISC™. Created from Theken-developed polymer, the disc includes embedded microelectronics.



thesis at the University of Akron. After finishing graduate school in 1993, he founded Theken Orthopaedic. Five years later, he founded Theken Spine. In mid-2003, Theken Disc was founded to specifically focus on R&D development of next generation artificial nonfusion disc technology.

“Prior to the formation of Theken Spine in 1998, Randy tested products for some of the largest orthopaedic companies in the world,” said Richard Navarro, vice president of Research and Development for Theken Disc. “As a courtesy, he often offered free advice on design improvements. Eventually, he realized he should design his own products.”

The Theken Family of Companies has other competitive advantages, as well. One is a team of expert engineers and machinists. Another is the use of in-house state-of-the-art technology to speed product development, many times cutting the cycle from months and even years to just days.

A COMPETITIVE EDGE

Three-dimensional (3D) CAD modeling systems, 3D reconstructive and finite element analysis (FEA) software, computer numerical control (CNC) machining centers and servo hydraulic mechanical testing machines — this is a sample of the technology used by The Theken Family of Companies to rapidly move products from conception to fruition. And it’s all in-house.

“Randy’s vision was to take advantage of the tools and technology available to gain that one competitive edge — speed,” said Navarro. “We have one of the most technologically advanced facilities in the world, so we’re able to respond to surgeon and market needs with record speed. Within hours we can conceive something, do the optimizing and FEA, make physical models and send them to surgeons. The entire product development cycle is accelerated. As a result, we’re able to

outperform companies that are 2- or 3- or even 10-times our size.”

Another competitive edge, according to Navarro, is the engineering.

“We have a very high-end engineering group,” said Dale Davison, vice president of Engineering for Theken Spine. “We don’t over-design just because we can. We take full advantage of our technology and testing capabilities to make products efficient for surgeons to use. Surgeons don’t like to put a lot of metal in their patients. Our implants are light without sacrificing strength, and that’s one reason why the doctors like them.”

Scot Dean Miller, DO, is one of those doctors. A member of the internationally-recognized Crystal Clinic Orthopaedic Group in Akron, OH, Dr. Miller is fellowship-trained in spinal surgery. He was the first to use Theken Spine’s Tether™ System in clinical trials, successfully repairing a patient’s degenerated cervical spinal discs.



Dr. Scot Miller

“Tether™ was designed to maximize fatigue strength while minimizing stiffness and profile,” said Dr. Miller. “And the system’s instrumentation is the most surgeon-friendly on the market, in my opinion. You can drill, tap and insert the screw through a single cannula while the large elliptical viewing windows enable preoperative plate placement and postoperative graft viewing. All of this reduces implantation time.”

Dr. Miller has also clinically trialed Theken Spine’s titanium-based C Pod™ Spinal VBR (vertebral body replacement) System and L Pod™ Lumbar VBR System. Both were computer modeled using FEA tools, which enabled the final design to closely match the characteristics of cortical bone. He explained that aggressive “teeth” allow for initial stability during implantation and long-term stability within the interbody space. A quick-connect insertion/removal tool and color-coded implant parts simplify the surgical procedures.

More recently, Dr. Miller participated in an evaluation study of Theken Spine’s Coral™ Spinal System, which received FDA approval in September. Coral™ is an implant system used to stabilize and fuse the lumbar region of the spine. Components of the system incorporate a number of features, one of which is the patent-pending pretimed set screw, which eliminates the tendency of cross-threading.

“I’ve used and evaluated all of Theken Spine’s products, and I’ve found them to be very physician-friendly in terms of ease of implantation,” said Dr. Miller.

“Our solutions are unique,” said Theken. “We’re always trying to improve the implant, so there are fewer parts that patients need to have in their bodies. And we’re always trying to improve the surgical instrumentation, so there are fewer steps for the surgeon.”



Coral™ - Pedicle Screw System



LPOD™ - Lumbar VBR System



Tether™ - Anterior Cervical Plate System



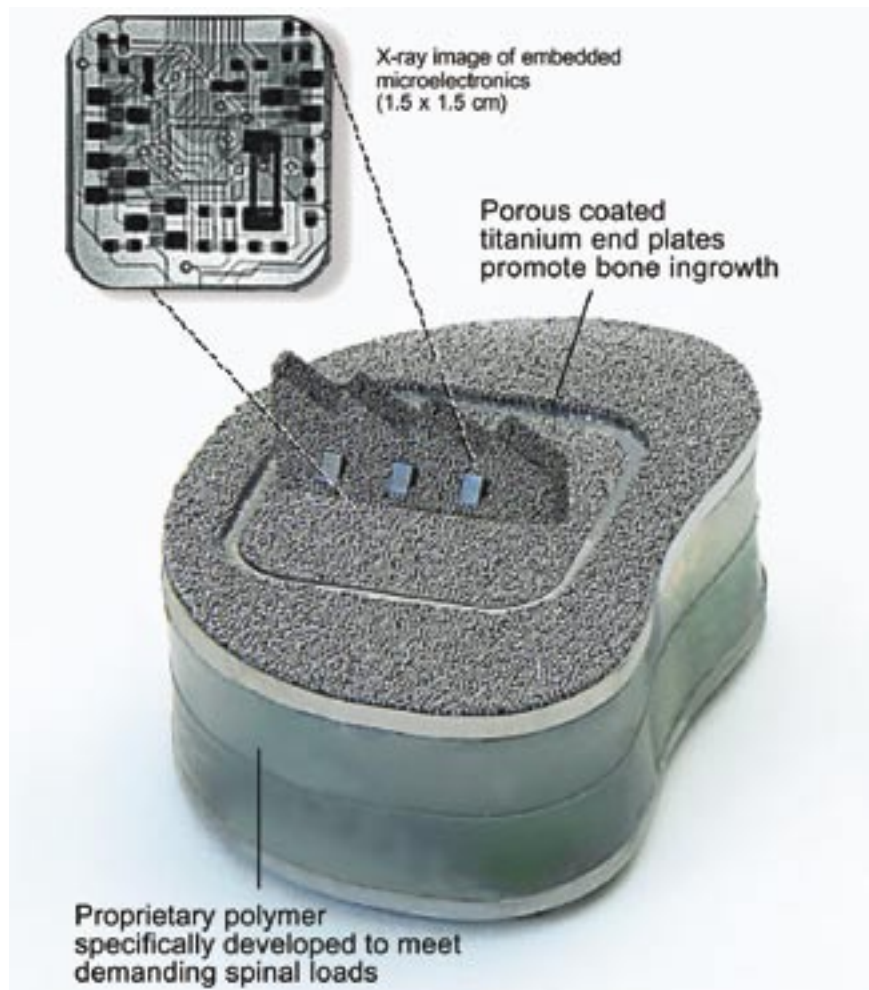
CPOD™ - Spinal VBR System



BodyForm™ - Thoraco-Lumbar System

FOCUSED ON THE FUTURE

2004 was also a year of rapid growth for the Theken companies, with six different products in research and development phases at Theken Spine and continued development on the artificial disc at Theken Disc. Three of the Theken Spine products (C Pod, L Pod and Coral) have already received FDA approval.



The Theken eDISC is described as a true “next generation” artificial disc, distinguished not only by its Theken-developed elastomer, but also by its pioneering use of embedded microelectronics to produce an information data stream for the surgeon.

A product in the pipeline for trauma patients is an expandable titanium corpectomy cage for the lumbar area of the spine. There are two cage sizes, each of which expands to fit tightly in the vertebral body area, to enable fusion using Theken’s BodyForm™ Thoraco Lumbar System. FDA approval for the expandable corpectomy cage is expected in 2005.

Perhaps the project generating the most excitement among distributors and surgeons, as well as interest by private inves-

tors who contributed \$5.5 million following Theken Spine’s State of Ohio Technology Action Fund grant, is the Theken artificial disc, eDISC. Its physiologic design is expected to create a new option for patients with degenerative disc disease — one which will offer pain relief without compromising spine stability and flexibility.

“Today’s artificial disc designs are replicating range of motion, but have no ability to exert force to restore a ‘neutral’ position of a motion segment. Thus, the task is left to the facets, ligaments, muscles and remaining annulus in the spine,” said Navarro, who helped design the Theken eDISC. “For the long-term health of the soft tissues and the facets, we believe the elasticity of the anterior column unit (ACU) should be restored to normal physiologic ranges. Our disc is being developed to restore not only the kinematics of the natural disc, but also its nonlinear elasticity.”

Unlike newer artificial spinal disc devices, which have been evolutionary in design, this polymer-based artificial disc is revolutionary. According to both Navarro and Theken, it’s a true “next generation” disc, distinguished not only by its Theken-developed elastomer, but also by its pioneering use of embedded microelectronics to produce an information data stream for the surgeon.

“During surgery, three sensors in the disc will tell the surgeon if the device is loading symmetrically. Post-operatively, the disc will have the ability to evaluate itself and monitor the patient’s compliance,” Theken explained. Animal trials have already begun. Human trials will begin in 2005.

“We are moving very, very quickly to become a total spine company,” said Theken. “There’s a lot of testing that needs to be done; I don’t want to oversimplify this. Still, word is spreading. We have a presence, and we hope the world will notice.”

Randy Theken has a story to tell. And it doesn’t end here.

For more information about The Theken Family of Companies, call 330-773-7677, or visit www.theken.com. ■