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## Shock and ahh ...

By **THOMAS LEE**, Star Tribune

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Don Dumoulin is a self-described "classically trained" consumer marketer, having cut his teeth at giants like Procter & Gamble and GlaxoSmithKline.

But even someone as experienced as Dumoulin might need a moment or two to ponder the challenges presented by Empi, a 30-year-old medical company that still exists on the fringes of mainstream medicine.

"We are a funny market, a bit of pharma product, a bit of consumer product, bit of a medical device," said Dumoulin, who joined Empi as president a year ago.

The Shoreview-based company makes devices that uses low-level electricity to treat chronic pain. Empi's flagship product, Select TENS Pain Management System, is a staple at physical therapy clinics across the country. Yet the technology has struggled to gain acceptance among consumers and doctors, many of whom still doubt whether TENS actually works.

For doctors, there's another practical consideration: It's cheaper to write a prescription for Oxycontin than to procure the TENS device and train office staff to use it.

"Physicians don't make money giving people TENS," said Dr. Russell Portenoy, chairman of the pain management department at Beth Israel Medical Center in New York. "The challenge for a company like Empi is to not only convince doctors there is enough science to justify TENS but also that it's practically useful to doctors."

To that end, Dumoulin has launched a full-scale marketing blitz. The company is rebranding itself as Empi Recovery Sciences Inc. with a heavy emphasis on "sciences." Empi sales and marketing teams are courting doctors, armed with scientific literature that aims to validate TENS. And the public face of the new marketing campaign is former Miami Dolphins quarterback Dan Marino. The NFL Hall of Famer has used the device for years.

"This is 30-year-old technology that has been proven time and time and time again," Dumoulin said. "The therapy is quite powerful."

"The challenge is that it goes against current modern medicine, which says you have an ailment and the doctor gives you a pill," he said. "This therapy is a bit of a different therapy and what we've got to do is to get into the physicians' mind space and help them understand electronic therapy is good sound science. That's why we have the branding campaign."

## A huge market

It's easy to understand Empi's sense of urgency. Pain is the single most common reason patients seek medical care, accounting for half of all physician office visits in the United States, according to Medtech Insight, a market research firm.

An estimated 75 million Americans suffer from chronic or long-lasting pain. Last month, Sen. Orrin Hatch, R-Utah, and Sen. Christopher Dodd, D-Conn., introduced a bill to boost the quality of pain care by coordinating research, improving health care provider education and raising awareness of pain and pain management.

Devices accounted for only 6 percent of the \$20.4 billion Americans spent on pain management products in 2005 compared with 78 percent for prescription drugs, according to a report by Medtech Insight.

"Gosh, we could build a pretty good business [by grabbing] three, five, and maybe 10 share points," Dumoulin said.

Empi does not disclose revenue figures, but Dumoulin said sales were "hundreds of millions of dollars." He also said the company was growing at a double-digit rate.

The idea of using electricity to block the transmission of pain signals to the brain originated in 1965 but only now is gaining traction, experts say. Major firms such as Medtronic Inc. and Boston Scientific Corp. have developed implantable devices that stimulate the spinal cord.

"There is a lot of interest in electrical stimulation," said Ross Meisner, managing partner of Dymedex consulting in St. Paul. "The technology is evolving to the point where it is commercially viable."

Founded in 1977, Empi makes external devices that transmit electricity through wires attached to specific areas on a patient's skin. The company boosted its profile in 1992, when it spent \$3 million to acquire Medtronic's Nortech division, which also made TENS (transcutaneous electrical nerve stimulation) devices.

Over the years, Empi changed hands several times, including a stint as a public company, ownership by the Carlyle Group, an aborted attempt at a second IPO in 2004 followed quickly by a \$360 million sale to an orthopedics device maker in Texas. Today, the company is owned by the Blackstone Group, a major private equity firm in New York.

Empi's TENS technology has attracted controversy. In 1987, a University of Texas study that examined Empi's devices concluded that TENS was no more effective than a placebo in treating lower back pain and added no benefit to that of exercise alone. Citing that study, a 1995 story in Barron's noted that guidelines for Medicare patients released by the U.S. Department of Health and Human Services that year said that TENS devices weren't recommended to treat lower back pain.

## Doubts linger

The company strongly defended the technology at the time, but doubts about the treatment's effectiveness linger to this day. That's because doctors have yet to design a way to properly test pain management devices, including TENS, said Portenoy of Beth Israel.

"The evidence of efficacy is not great," Portenoy said. "It's difficult to determine if TENS works. ... The best thing we can say about TENS is that some people who are on TENS respond to the therapy and some do not."

Another major reason why doctors have not embraced TENS is simple economics: Doctors don't have much financial incentive to recommend TENS, Portenoy said. Although Medicare reimburses for the device, doctors can only bill the equivalent of an office visit. Considering the amount of work doctors and nurses must invest in TENS (instructing office staff and patients how to use the device, adjusting the therapy) and it's not hard to see why physicians would prefer writing a drug prescription, Portenoy said.

Empi is fully aware of this, which is why the company added 70 people, mostly reimbursement specialists, to its Shoreview headquarters this year. Through a series of acquisitions, the company is diversifying into areas such as rehabilitation and urinary incontinence.

Mitchell Yass, a physical therapist who owns PT2 Physical Therapy & Personal Training in Farmingdale, N.Y., says electric stimulation is most useful in reducing swelling and aiding rehabilitation. But when it comes to treating pain, Yass, author of "Overpower Pain: The Strength Training Program That Stops Pain Without Drugs Or Surgery," favors a cheaper alternative to the TENS device, which can cost as much as \$750 a year.

It's called ice, he said.

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