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New bariatric device doesn't require surgery, can be removed

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COURTESY OF SENTINEL GROUP L.L.C.

Involved in the operation of the **Sentinel Group L.L.C.**, are, from left, Jerry Baker, Paul Kemmeter, Randy Baker, Jamie Foote and Fred Walburn. They are working to distribute the **Full Sense Bariatric Device**.

A Grand Rapids doctor has invented a new medical device that could become a lower-risk, lower-cost alternative to weight-loss surgery.

Dr. Randal Baker, a local bariatric surgeon, said he and his partners are negotiating with three well-known companies who are bidding to buy the rights to the device he invented, the patented **Full Sense Bariatric Device**.

The two-section implement, made of silicone and nitinol, sits at the end of the esophagus and just inside the stomach. It is inserted through the mouth by a flexible tube called an endoscope and kept in place by three sutures. Baker said the

pressure of the lightweight device is enough to convince the brain that the stomach is full.

The device induced significant weight loss in animal trials in dogs, Baker said. Last month, he and two other doctors inserted the device into three people in Mexico. He said they reported losing 18 percent of excess body weight in less than three weeks, without overwhelming hunger.

"We think it actually works better than present surgeries," said Baker.

Combined, Baker and his partners, Dr. James Foote and Dr. Paul Kemmeter, have performed more than 5,000 bariatric surgeries in the Grand Rapids area. Baker is medical director of the Spectrum Health bariatric program.

"The advantages of this are that, number one, it doesn't require surgery; number two, it's completely reversible, it can be taken out; number three, eventually, we believe, it will be adjustable," Baker said.

The bariatric market is expected to grow to \$6.4 billion worldwide by 2015, according to MedMarket Diligence, a medical business research firm. An estimated 205,000 people in the United States had bariatric surgery last year, which costs \$17,000 to \$25,000, according to the American Society for Metabolic & Bariatric Surgery.

Baker and his partners are entering a field that's drawing more attention as the limits of bariatric surgery become apparent. An article by ASMBS President Scott Shikora of Tufts University in the September edition of *Bariatric Times* noted that while the United States has millions of obese people, just 1 percent of them have had bariatric surgery. Most are put off by cost, complications and the drastic alteration of the digestive system. That leaves a huge, open market for approaches that are less complex and have fewer complications, Shikora wrote.

Among the contenders Shikora cites are the use of medical balloons in the stomach, gastric bands adjustable by radio waves, gastrointestinal sleeves inserted by endoscopy, and delivering electrical impulses to nerves in the digestive tract.

Baker, Foote and Kemmeter, who left MMPC earlier this year to form Grand Health Partners, created a company called Sentinel Group L.L.C. and brought in as president Fred Walburn, who left his job as a medical product development specialist for W.L. Gore & Associates, a firm best known for creating the high-performance Gore-Tex fabric. Much of the financing for the Full Sense project has come from Baker's father, Jerry Baker of First Companies.

Sentinel has taken the product through its first prototypes, the patenting process, working with local patent attorney Fred Burkhart, and two years of animal testing in Boston and Kalamazoo, Walburn said. With the first use in humans now underway at Hospital Galenia Cancun, he said the Sentinel partners would like to sell the device to a large company with the experience and money to get it through the Federal Drug Administration's approval process, including clinical trials in the United States.

It's likely to be several years before the Full Sense device will be available in the United States.

Baker said he was inspired by the experience of a local patient, who came to him for treatment of a tightening in her esophagus that forced her onto a liquid diet. He placed an esophageal stent so she could eat more.

"She came to my office and said, 'I want to thank you, Dr. Baker. I can now eat sloppy joes.' I glanced down at her chart and noticed she was losing weight, which didn't make sense. I said, 'I don't understand this, you're losing weight,' and she said, 'I'm not hungry at all.' That's what triggered this idea -- the eureka moment: What's going on here that's causing this lady to lose weight, and she has satiety all the time?"

Baker, Foote and Kemmeter worked with a Boston company to develop several generations of prototypes. The basic concept for the device was patented four years ago, Baker said.

In the animal trials, the animals lost as much as a quarter of their body weight in less than a month, and the experiments were stopped to prevent further weight loss. Yet during that time, the animals were playful and exhibited no signs of overwhelming hunger, Baker said.

The first use in humans was done in Mexico because the approval process is much speedier, Walburn said. But when word got out, at least 500 people lined up to participate, and just three were chosen, he said. Baker and Foote worked with U.S.-trained Dr. Jorge Trevino of Cancun to install the devices in November.

Baker said he expects that eventually the procedure will be done under sedation instead of general anesthetic. He said it takes just five minutes to install the device. And because it can be removed, it could be used for people who are overweight but not morbidly obese, and for adolescents, who generally are not considered candidates for the drastic measure of bariatric surgery.

Baker said he's proud that this device with the potential to produce "a paradigm shift" in treatment for obesity was homegrown in West Michigan. He said he envisions a training center here that would draw doctors from around the world and leverage the community's investment in local medical facilities.

Baker and his partners have started to make presentations at medical conferences, and he said interest is picking up from medical journals.

With gastric bypass surgery, Baker added, weight loss on average is about 70 percent of excess weight over 18 months. But after 20 years, the patients tend to gain weight until they're at just 49 percent, he said.

"We see initial weight loss that's significant, but then we see a gradual weight gain over time," Baker said. "What most patients will say is the biggest issue is they are hungry. The present scenario doesn't adequately deliver satiety.

"We've had three patients so far. They're losing weight, they're happy," Baker said.

"And they're not hungry," Walburn added.