

NiTi Challenges Surgical Staple Market

WOUND CLOSURE DEVICES

Surgical staples underpin surgeries in every operating room in the country, and are, well, staples of the businesses of **Johnson & Johnson's Ethicon Endo-Surgery Inc.** and **Covidien Ltd.** Together the two control 95% of what *Medtech Insight* estimates is a \$520 million US surgical staples market. Ethicon has managed to grab the lead, with an almost 56% market share, by introducing new products specifically for colorectal, bariatric, and thoracic procedures, but Covidien won't be left behind. In July it announced that it would acquire **Power Medical Interventions Inc.**, an innovative company developing computer-assisted endomechanical surgical instruments, endoscopic cutters and staplers, with, it just so happens, a focus on minimally invasive colorectal, bariatric, and thoracic surgeries. Covidien was acting on its announced intention of focusing on single-incision laparoscopic surgery as an interesting growth opportunity. It offered, in aggregate, \$64 million for Power Medical, which had 2008 sales of \$8 million. With Power Medical's *SurgASSIST* stapler, for minimally invasive surgery, Covidien defends its share of the wound closure business.

But another threat is entering from the wings. **NiTi Surgical Solutions Ltd.** has begun selling an alternative to staples, and it too is targeting the colorectal and bariatric markets, with a platform that it calls *BioDynamix Anastomosis Technology*, by which it describes compression devices that adjust to an organ's diameter to promote healing that's as natural as possible. Founded in Israel in 1996, NiTi is taking advantage of the features of the metal nitinol—shape memory, elasticity, and the ability to control the pressure—to advance devices for the reconnection, following resection, of the colon, small intestines, esophagus, the bowel, and other hollow structures in the body. Its initial market focus covers more

than 1,000,000 gastrointestinal tract resections each year worldwide.

NiTi is in the market already (in the US, several countries in Europe, Canada and Korea) and it recently gathered up some more resources to help it increase penetration. In August, NiTi raised \$18.5 million in a Series F financing round led by Forbion Capital Partners, which was joined by existing investors Evergreen Venture Partners, Israel Healthcare Ventures, MBVC, Alice Ventures and SCP Vitalife.

NiTi's first product is *ColonRing*, an alternative to staples for creating an anastomosis following colon resection, a treatment for colorectal cancer and diverticulitis. *ColonRing* is a two-part nitinol ring including an anvil ring, and a bottom ring, with nitinol leaf springs between the upper and lower halves of the ring that help the ring maintain compression against variable pressures. After surgical resection of the colon, the surgeon places the anvil ring in the proximal side of the colon (via trocar access). He next comes through the rectum and places the other half of the ring in the distal side of the resected vessel. He connects the anvil to the hand piece and clicks it in place. A series of small spikes holds the tissue in place while it is compressed together to begin what the company calls its "biodynamic" healing process. The surgeon then releases the cutting blades on the delivery device to clear the internal pathway. Finally, the delivery device is removed without disrupting the *ColonRing*.

In seven to 10 days, the tissue that's been crushed between the two ring halves becomes necrotic, causing the ring to release. The released *ColonRing* is expelled through the bowel, leaving nothing behind in the body. The tissue along the outer part of the ring then heals at approximately the same time.

For now, the *ColonRing* procedure takes approximately the same amount of time as

implanting staples, but *ColonRing* has other advantages over staples, says CEO Itay Itzhaky. Staples remain behind forever, potential sources of foreign body reaction, and are rigid objects that may contribute to the formation of strictures. Leaks may also occur along the staple lines, and cause infection. Finally, surgeons may have to have on hand five different sizes of staples to adjust to the varying sizes of the lumen and thickness of tissue in the colon. One *ColonRing* with a diameter of 27 mm fits all. *ColonRing* provides a rigid, solid union for the first seven to 10 days of healing; it makes no puncture holes in the bowel, and it results in smooth anastomotic healing, also preserving the natural lumen size, according to Itzhaky. Future products for the company's platform are lined up, rings of different sizes for the esophagus and bariatric surgery, and of an oval shape for the small intestine.

NiTi is conducting a Phase IV post-marketing study so it can better understand the advantages of natural healing. In the future, the company plans to also do a comparison study to quantify any areas of clinical superiority in terms of bleeding, leak rates, strictures, and how much time a patient spends in the hospital. The small company will have to get creative in order to face off with the likes of Ethicon and Covidien.

If NiTi isn't one day snapped up by the two market leaders, it might also get some help from those four or five companies that share the 5% of the surgical staple market not held by the giants. Or it could give another large company operating in the general surgery space without staples the chance to leap ahead to the latest innovation in colorectal, bariatric, or thoracic surgery. The company's prepared to go it alone, but as Covidien's recent purchase suggests, there's interest in the space.

[A#2009900190]

—MARY STUART