

WOUND CARE

Spiracur Inc.

A new model for negative pressure wound therapy

Negative pressure wound therapy changed the landscape of the advanced wound care industry. Until the introduction, in 1995, of V.A.C., a vacuum-assisted closure device from Kinetic Concepts Inc. (KCI), innovation in chronic wound care centered around ways to impart new properties to bandages. Negative pressure wound therapy (NPWT) however, was a novel device therapy, achieving benefits against a multi-factorial condition by delivering a therapy that operates by multiple mechanisms of action. Using suction, NPWT vacuums exude off of wounds, removes bacteria, draws the edges of the wound together, and stimulates the wound bed mechanically, and in doing so perhaps kicks off cellular signaling mechanisms and increases perfusion at the wound bed. Today, KCI holds more than 85% of an NPWT market that's worth \$2 billion, and the market is by no means saturated, as the recent bid of \$6.3 billion for KCI by a consortium of private equity investors suggests.

An already enormous market is certain to grow in lockstep with the increase of diabetes, a source of vascular disease leading to venous ulcers and diabetic foot ulcers, and the overall increase in the aging population. Perhaps a dozen companies have entered the NPWT field with similar electric pumps, because of the enormous market and the low barrier to entry. However, KCI has done a good job of creating customer relationships and a service infrastructure, and "me-too" manufacturers haven't gained much traction. Of the \$2 billion in sales of NPWT in 2010, \$1.4 billion went to KCI, and the balance was shared by a dozen or so other companies.

Now the SNaP Wound Care System, a new negative pressure wound therapy device from Spiracur Inc., has entered the picture and it is definitely not a me-too product. In fact, it's potentially very disruptive. SNaP, an acronym for "Smart Negative Pressure," delivers therapy that is equivalent to the gold standard negative pressure therapy devices on the market,

but it is nothing like them. Many of the existing NPWT products are toaster-sized machines, electrical devices that need to be plugged in or recharged and that are connected to patients via tubes. SNaP is a cell-phone sized, entirely mechanical device (no electrical components) that can be completely hidden under clothing. This is the kind of out-of-the-box solution that can arise when diverse clinicians and other inventors are allowed to brainstorm in an unfettered environment.

SNaP is a by-product of the attendance of Kenton Fong, a plastic surgeon, Moshe Pinto, a lawyer getting his MBA at Stanford University's Graduate School of Business, and Dean Hu, a bioengineering student at Stanford, at the Stanford Biodesign Innovation program. These colleagues met at a course designed to systematically teach students how to invent meaningful biomedical devices. For a class project, the team picked wound healing as a focus, because of Fong's experience as a surgeon, and began wrestling with the problem of why many patients for whom negative pressure wound therapy is indicated do not get the therapy.

As part of the research phase, the team queried numerous patients and clinicians in different wound care clinics to learn about the problems they faced, what worked for them and what didn't. They discovered that for one thing, the rental process by which conventional NPWT devices had to be procured was lengthy and complicated for the outpatient setting where many of the patients are treated. In addition, practitioners found the application of some of the pumps quite difficult, sometimes requiring 40 minutes to an hour to set up the patient. Finally, a lot of patients just didn't like the therapy. They didn't like the noise, so they turned the devices off at night, although they weren't supposed to. If they were ambulatory, they didn't like having to carry the large devices around in a satchel because of the inconvenience and the stigma. Homebound patients didn't like to be tethered to a machine.

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Business: Negative pressure wound therapy devices
Founded: October 2007
Founders: Kenton Fong, MD, CSO; Moshe Pinto, EVP; Dean Hu, Systems Manager
Employees: 50
Financing To Date: \$59.5 million
Investors: De Novo Ventures; Kleiner Perkins Caufield & Byers; Maverick Capital; New Leaf Venture Partners; Pinnacle Ventures
Board of Directors: Jeani Delagardelle (New Leaf); Chris Fashek (Systagenix Wound Management); Rich Ferrari (De Novo Ventures); Eric J. Kim (Maverick Capital); Dana Mead (Kleiner Perkins Caufield & Byers); Moshe Pinto; Gary Restani

The assignment: solve all those problems. In SNaP, the inventors think they have. Thus, in 2007 Spiracur was founded with a license from Stanford University. The company has raised \$59.5 million to date in three rounds of financing. First round backer De Novo Ventures provided \$4.2 million, then returned for a \$20.3 million Series B round (joined by Kleiner Perkins Caufield & Byers and New Leaf Venture Partners) and a \$35 million Series C round (which kept existing investors and added Maverick Capital and Pinnacle Ventures).

Weighing in at just 2.2 ounces, SNaP is quite a departure from the bulky gold standard NPWT devices, yet it delivers the exact same therapy, and the company has validated this fact in a randomized clinical trial of more than 132 patients at 17 centers. Fong says, "Essentially, we have something that weighs half as much as an iPhone 4 delivering the exact same kind of negative pressure as the gold standard."

The device gained FDA clearance in 2009 for all of the usual broad applications of NPWT: acute, chronic, sub-acute and dehisced wounds; ulcers such as diabetic and pressure ulcers; grafts and flaps. Spiracur had to undergo the more rigorous de novo 510(k) process be-

cause SNaP is so different from existing NPWT devices, principally because it is mechanical, powered by springs, not electrical. Fong explains that it uses the principle of volume expansion to create negative pressure, a simplified example of which is a syringe that draws in fluid when it is pulled back. Here the system is engineered to continuously deliver controlled and dynamic negative pressure, even in the presence of wound exudate. It's a radical and simple concept, although President and CEO Gary Restani points out that these "springs" are made by the same supplier that made springs for NASA's Mars lander. Restani, the former president of ConvaTec Inc., says, "I have been in the industry for 35 years, and I have seen a lot of things. But the elegant simplicity of making this do what a complex electrical mechanism does is the genius of it." The device's simplicity is what makes it a good product for caregivers and patients, he says. "There are no buttons to push, no decisions for an 85-year-old grandmother to make. It delivers constant therapy and it takes the entire burden away from the patient."

SNaP is disposable, and a new device will be placed with each dressing change done by a health care provider. As usual, the patient's wound is assessed and cleaned, measured, and then an interface material is applied. An occlusive dressing with an integrated port is placed over the interface, the SNaP is hooked to it (in the manner of a cell phone in a holster)

and it's activated by removal of an activation key. Says Restani, "The application is very easy on a diabetic foot. You isolate the wound, clean it, and place the device on." Nurses are now using the product name as a verb, he says, "They say they're going to 'SNaP' the wound."

Restani believes the Spiracur device will be able to achieve substantial cost savings over standard NPWT devices, which are currently reimbursed at a rate of \$125 per day. He doesn't want to disclose specifics, and at any rate it would be difficult to compare apples-to-apples since the Spiracur business model, based on disposables, is completely different than the rental model of market incumbents. In addition to lower product costs, there are labor savings, and potential clinical benefits as well, if the form factor of SNaP increases patient adherence or even gets more patients into treatment. Says Fong, "With the current method, it is just not practical to treat a lot of wounds with negative pressure. With our device, it becomes practical to treat wounds that wouldn't otherwise get NPWT."

The device would appear to be well suited to emerging markets as well. Fong notes that as a surgeon, he did volunteer work in Haiti, donating some SNaPs to the cause. "It doesn't require power, and there wasn't any power, except in the surgical tent. We put the devices on patients, who could benefit from them even though they didn't have power back in their tent city." Outside the US, the com-

pany has started negotiations to supply products to regions where it has approval including Canada and Europe, where it has a CE mark. Spiracur will be expanding its sales force later this year.

The looming challenge for the company is reimbursement, as it is for all wound care companies. "With our randomized clinical trial data, we gained credibility. And in settings where we do have access to reimbursement, like the Veterans Administration [US Department of Veterans Affairs], the product is living up to its promise and is starting to generate a commercial value for us," says Restani. Spiracur has a particular challenge, however, because it is selling a disposable product into the outpatient market where reimbursement codes only exist for durable medical equipment. Obtaining broader CMS reimbursement is simply a matter of time and money, says Restani. "We believe we have the right solution, and we made the commitment to do the appropriate prospective, multicenter, randomized controlled clinical trial with a non-inferiority design compared with the gold standard NPWT. No other companies have done this."

For the future, the company sees itself as offering a platform, rather than a product. By the end of the year, Spiracur plans to come out with a second, related, but undisclosed product.

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— MARY STUART