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Robert McLafferty



SNaP

Wound Care System

A Unique NPWT Product, Seeking a Unique Code for Coverage

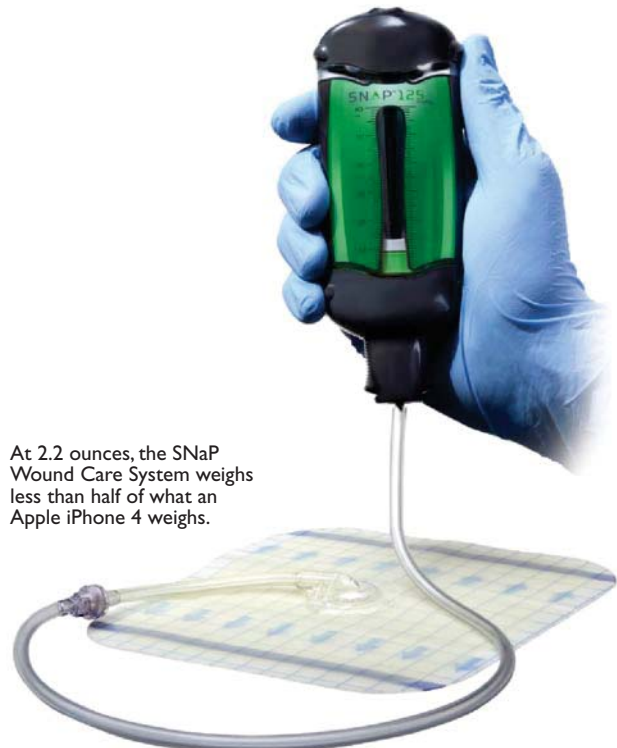
by **VEIN Staff**

Spiracur Inc. has a unique story. The company, located in Sunnyvale, CA, was founded out of the Biodesign Innovation Program at Stanford University (<http://innovation.stanford.edu>). What started as a class project in 2007, has developed into a leading-edge company selling its innovative FDA approved products across the US. The engine for fueling Spiracur's growth has always been the emphasis the company has placed on meeting the needs of patients.

Kenton D. Fong, MD, Founder and Chief Scientific Officer of Spiracur recalls, "As a plastic surgeon, I had seen a lot of chronic wounds that would stagnate and not heal for months or even years. I had also seen the amazing effects of negative pressure wound therapy (NPWT) on wound healing, with some wounds healing in half the time it would take with conventional dressings. NPWT literally sucks wounds closed through the application of topical reduced pressure onto wound beds. We observed that although there was good scientific and clinical evidence that chronic wounds benefit from this therapy, it seemed to us that many patients were not getting treated with NPWT."

To better understand why, team members talked to dozens of clinicians and chronic wound care patients to learn their concerns with current NPWT devices. It turned out that the bulky electrical pump and dressings of pre-existing NPWT devices were not being used because they were not optimized for treating the more typical smaller chronic wounds like diabetic foot ulcers, venous ulcers, and pressure sores seen in the outpatient clinic setting. Furthermore, patients didn't like wearing the devices because they interfered with their lifestyle and were often embarrassing when noticed in social situations. In addition, these devices were difficult to procure because they required monthly rentals that were also very expensive.

"With these considerations in mind, my teammates and I started with a blank sheet of paper and came up with the SNaP® Wound Care System." Fong says, "Although this new NPWT technology delivers the exact same negative pressure to wounds, it is different from any other system that is available. Unlike traditional NPWT devices that utilize electrically powered pumps, the SNaP System utilizes specialized mechanical springs to generate negative pressure at the wound bed. Because of its unique design, the SNaP device only weighs a couple of ounces (approximately 2.2 ounces) compared to several pounds for traditional electrical pumps, making it the first and only ultraportable NPWT device."



At 2.2 ounces, the SNaP Wound Care System weighs less than half of what an Apple iPhone 4 weighs.



Kenton D. Fong, MD

To give you an idea of the weight of the system, it weighs less than half of what an Apple iPhone 4 weighs (4.8 ounces). Most importantly, in a multicenter randomized-controlled trial, [Published in the March-April 2011 issue of Wound Repair and Regeneration] the SNaP device demonstrated similar healing to a traditional electrically powered pump device for refractory chronic wounds. To date, this 17-center study is the only head-to-head randomized controlled trial done comparing NPWT devices. This work also demonstrated that the SNaP Device was easier to use and had much less impact on the quality of life of patients, interfering less with overall activity level, sleep, and social interactions.

“The design of this device allows for the benefits of NPWT in a way that is more user-friendly than traditional-powered devices,” explains William Marston, MD, Chief of the Division of Vascular Surgery, University of North Carolina in Chapel Hill. “Many patients have some quality of life issues with the traditional therapy because you have to be hooked up to an appliance that is relatively bulky and it makes for less mobility. The noise, interference with sleep patterns, the need to be plugged into a power source – all those things limit a patient’s lifestyle while they are on the therapy. This unique device is designed to be highly portable, self-sufficient and is non-obtrusive so that the patient can attach it either to a belt or a leg holster without any issues with wearing regular clothing.” In fact, other people may not even know you’re wearing the device. For the population that needs to get back to work or perhaps want to return to activities they have not been able to do for weeks or even months, it became very apparent that the patients preferred this device to a powered device for the ease of use and return to activity that they are afforded.

What makes the SNaP System special is that it is a clinically proven NPWT system that provides better care for less cost than competitive technologies. Not only is the SNaP device dollar for dollar less expensive than electrically powered pump devices, one study from the University of Michigan School of Public Health demonstrated cost savings of around \$9,000 per patient if the SNaP System was used for diabetic foot ulcer treatment instead of traditional dressings. In addition, because the device is disposable, it is available off the shelf in the clinician’s office just like any other dressing supply, eliminating the need for expensive rental-based administrative support costs and hassle.

The SNaP technology does not require an electrical power source to work, and this makes the SNaP System a viable alternative for use in developing nations where electrical power is unreliable. Spiracur is committed to making a dif-

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Sustaining Medical Innovation

An Inside Point of View about a CMS Reimbursement Denial

“I was required to wear a cumbersome and noisy therapy device, making it difficult to even hear my patients to discuss their healthcare needs. For much of this time, I was forced to take disability leave, at a high cost to me and to the healthcare system. After all that intervention, the wound eventually healed, but twelve months later it re-opened.”

Mario Sanguily, MD Chief of surgery for Memorial Medical Center in Stuart, FL

Medical innovation, particularly within the private sector, is critical to reducing healthcare costs, yet there is more information circulating today about uncertainty surrounding the amount of regulations private companies face to get approval by the US Food & Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). Even when these new medical innovations prove medical benefit, added value, and safe and effective through clinical randomized controlled trials (RTC), or registry studies conducted according to the Agency for Healthcare Quality and Research (AHRQ), the agencies can be elusive and inconsistent with their decisions.

Take for example the results of the Centers for Medicare and Medicaid Services Reimbursement approval for 2011. Out of 87 applicants for Healthcare Common Procedure Coding Systems (HCPCS) submitted to the CMS, only two were approved. At the CMS HCPCS Public Meeting on May 24, 2011, there were 37 agenda items up for appeal. Of these 37 items, there were 14 covered products under an existing category according to the CMS, 29 that received no “new categories” and three that the CMS believes are covered in another budget. Of the 37 applications for medical devices, not one was granted a “new category.”

Mario Sanguily, MD, Chief of surgery for Memorial Medical Center in Stuart, FL, presented the following commentary at the CMS HCPCS Public Meeting, where he addresses his disagreement with the CMS’

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Mario Sanguily, MD

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preliminary decision and his support of Spiracur's request for new codes describing the innovative SNaP Wound Care System.

I am a Vascular Surgeon, with 20 years experience and I currently practice at Martin Memorial Medical Center in Stuart, Florida, where I have been Chief of Surgery and Private Practice for the past 20 years. As a busy vascular surgeon, I have treated wounds and their resulting complications throughout my entire career. I felt it was important for me to present my comments today not only because of my experience as a patient, but also because of my experience as a surgeon. It is not often that I become aware of products as a patient. Based on my personal observations, I believe it paramount that patients, including those covered by Medicare, have access to this wound care product.

Three years ago I ruptured my Achilles tendon. The treatment process consisted of Hyperbaric Oxygen treatment; three months using a leading electrically-powered negative pressure wound therapy device, and multiple skin grafts. During some of this time I was forbidden to go into the operating room. I wore a cumbersome and noisy therapy device, making it difficult to even hear my patients to discuss their healthcare needs. For much of this time, I was forced to take disability leave, at a high cost to me and to the healthcare system. After all that intervention, the wound eventually healed, but twelve months later it re-opened.

Fortuitously, I saw a sales representative in my hospital showing the SNaP System to a colleague. I was immediately intrigued by the efficacy data and quality of life factors. The SNaP Wound Care System was applied at a Wound Care Clinic in Miami. As soon as this small, silent, effective device was applied I was able to resume my practice and get back into the operating room. By increasing my mobility and allowing me to resume my medical practice, the SNaP System proved to be a non-invasive, yet effective treatment method. As a surgeon, there are huge benefits for my patients' quality of life to be as normal as possible throughout the healing process.

As a surgeon, the SNaP Wound Care System is a product I would want access to for my patient's care. Without CMS coding the majority of my patient population would not be able to afford this product out-of-pocket and would be subjected to less sophisticated methods of care. ▼

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ference in healing wounds worldwide, not just in developed Western countries. For example, the SNaP device has been used successfully in Haiti, and part of the licensing agreement with Stanford University requires making the SNaP System eventually available at cost to developing countries. "We see the commitment to worldwide wound healing and limb salvage as the strength of our current company and the company we want to become," stated Fong.

As one might expect, when the needs of patients and clinicians are being met by a product, sales grow rapidly. The SNaP Wound Care System has had great success in settings where the device is paid for by insurance. The major challenge that Spiracur faces is the need for broader recognition by government and private health insurance payers. Despite all the logical arguments as to why this therapy could be good for Medicare and its beneficiaries, CMS has been reluctant to even recognize this innovative, cost-saving technology with its own code, which is the first step in obtaining the ability to bill for the device. In recognition of the potential improvement in patient's lives, the American Podiatric Medical Association, representing around 15,000 podiatrists in the U.S., private insurance payers, and leading clinicians have even written letters urging CMS to provide coding for this new technology. Yet, despite this outcry and multiple meetings with CMS officials, as of now for the second year in a row, CMS has said that they would not recognize the technology. However, a number of payers have recognized the benefit of this revolutionary technology including several large private insurance companies and Veterans Administration Health Care Services. In January, the SNaP System was officially added to Marathon Medical's (Commerce City, CO) existing Federal Supply Schedule (FSS) contract, administered by the Department of Veterans Affairs (VA) on behalf of the US General Services Administration (GSA). And in June, Independence Blue Cross (Philadelphia, PA) added the SNaP System on, as well. "We believe that if we keep focusing on quality patient outcomes, eventually more insurance companies and the government will come around," notes Fong.

The future of wound care is bright. Better, more efficient ways of treating chronic wounds are becoming available. It will be important that the benefits of new therapies match the costs and that the patient's well being is the primary focus of policies by health care payers. The SNaP System has the potential to dramatically increase the healing rates of chronic wounds, improve limb salvage rates, and have a meaningful impact on patient's lives while saving healthcare costs. As access to our technology grows, we believe that with the help of dedicated and forward thinking clinicians, we will make a big impact on the lives of wound care patients everywhere. ▼