

Gary Restani, CEO/President Spiracur Inc.

OWM: Please describe your education, training, and work experiences that have prepared you for your current position as CEO of Spiracur.

I studied at Sir George Williams University and Loyola University in Canada, and I also attended Dartmouth College's Tuck Executive Program, where I received a diploma in International Business. I have worked in the worldwide medical device industry for over 35 years. Specifically, I was the President of ConvaTec, a Bristol Myers-Squibb Company, where I developed a high performance management team that helped the company to become a leading wound and ostomy company with global revenue of over \$1 Billion. I also have over 11 years of experience in the orthopedic sector, where I held divisional president roles with both Smith & Nephew and Zimmer, leading Zimmer Europe/MEA through a significant turnaround and contributing to its growth. Most recently, I served as president and COO of Hansen Medical, a medical robotics company, and I directed the company from late stage development to early stage commercialization and first year revenues. I have dedicated many years to the healthcare and medical device world, particularly to wound care. Spiracur's SNaP® Wound Care System, coupled with its executive team, were the perfect fit for me.

OWM: What should our readers know about Spiracur?

First and foremost, I believe it is important that your readers understand Spiracur's steadfast commitment to the patient. Each and every one of our employees is dedicated to the development of innovative wound healing products that focus on patient care, as it is the principal goal of our company to make a positive difference in a patient's quality of life. Because of our size as a small startup business with a team of dedicated people, we are able to maintain a closeness with both the clinicians and their patients. As a result of these relationships and the knowledge we gain, we are able to react quickly and appropriately to their needs and requests.

Our first product is the SNaP Wound Care System (Smart Negative Pressure), which is the result of both patient and clinician feedback that current negative pressure wound therapies (NPWT) were too cumbersome. In August 2009, we received US Food & Drug Administration clearance for the SNaP System in a new therapy category the FDA defined as "non-powered" NPWT devices.



The System was also CE Marked in the European Union in December 2010. Our device is an ultraportable, discreet NPWT product indicated for patients who would benefit from wound management via the application of negative pressure for wound healing. The SNaP System is indicated for a full spectrum of wounds including chronic, acute, traumatic, subacute, and dehisced wounds, as well as ulcers (diabetic, venous, or pressure) and surgically closed incisions.

Today, we have seen first-hand that our SNaP System is significantly changing the approach of how wound healing is delivered to patients, and it is having a very positive effect not only on wound healing, but also on a patient's quality of life. The design of our device eliminates the need for any electricity or battery power, and it is completely silent and lightweight, weighing only 2.2 ounces. In addition, the device is discreet and can easily fit under a patient's clothing, which enables them to carry on with daily activities and no one has to know about it. In other words, a patient's wound care treatment is not exposed to the world.

This article was not subject to the Ostomy Wound Management peer-review process.

OWM: How were you first introduced to wound care and why do you enjoy working in this arena?

As the incoming president of ConvaTec in 1999, my first priority was to visit clinicians and patients to see the impact the current products had on patient care. This was an amazing learning experience for me and it set the stage for how I would lead wound care companies going forward. As I spent time “rounding” with clinicians, I realized what a significant challenge chronic wounds presented, not only for the patient, but also for the overall healthcare system. As a result, I pledged that I would do everything in my power to pursue innovative solutions in wound care that would directly benefit patients. While I was at ConvaTec, Aquacel and Aquacel AG were among the innovations developed. Now at Spiracur, the SNaP System has taken wound healing and the delivery of negative pressure to a whole new level.

OWM: What are some of the company’s biggest accomplishments thus far? What are some of your key products and/or functions that clearly distinguish your brand?

We have accomplished a lot in a short amount of time, but specifically I believe it is important to highlight Spiracur’s origin, as well as go a little deeper into our product design and describe why it is unique. Finally, I’d like to highlight key results from our randomized controlled clinical trial, as the findings may make a difference in wound healing choices for patients going forward.

Stanford Biodesign Innovation Program: The SNaP System is an out-of-the-box wound care solution that originated in the Stanford Biodesign Innovation Program. Kenton Fong, MD, Moshe Pinto, and Dean Hu all met while attending Stanford in a course designed to systematically teach students how to invent meaningful biomedical devices. For a class project, the team chose wound healing as a focus due to Dr. Fong’s experience as a surgeon. Together they addressed the problem of wound care and why so many patients for whom negative pressure wound therapy was indicated did not pursue treatment. They asked clinicians what the best wound care innovation was in the past 15 years and what they liked about it. Overwhelmingly, the answer was the application of negative pressure and the VAC. The team also asked what the drawbacks were. With this feedback, they set out to develop a product that replicated the positive aspects of the market-leading product and improved upon the drawbacks. From that feedback, the SNaP System was born. Spiracur was officially founded in 2007 with a license from Stanford University.

Product Differentiation: Our device is different from existing NPWT devices because it is mechanical (powered by a unique spring mechanism) versus electrical, and it is disposable. It uses volume expansion to create

negative pressure. The constant force spring mechanism is used to draw in fluid, and the system is engineered to continuously deliver controlled and dynamic negative pressure, even in the presence of wound exudate. The concept is simple and groundbreaking at the same time, and the system is considerably smaller and lighter (2.2 ounces) than what the market has to offer. The genius of our product is in its elegant simplicity. We have designed the system to do what the complex electrical machines do. There are no buttons to push or alarms to silence, making it a great product for caregivers and patients because it takes the burden away from the patient.

Randomized Controlled Trial (RCT) Results: One of the first endeavors Spiracur’s founders took on was the investment in strong data. They took their initial funds and used them to support a comparative randomized controlled trial, which is something that no other NPWT manufacturer has done to date. Their belief in this technology was so compelling; they took a financial risk and invested a significant portion of the start-up funds back into research. It paid off. The final results from the multi-center RCT support the efficacy and safety of our SNaP Wound Care System and non-inferiority compared to the electrically powered VAC system.

The trial evaluated the safety and efficacy for the treatment of chronic lower extremity wounds, as well as non-inferiority to the VAC system, and the final results will be published in the journal, Wound Repair and Regeneration. The results are very encouraging for negative pressure wound therapy, especially for patients who are well suited for treatment with the SNaP System because it has proven to be non-inferior to the VAC for complete healing, and it has shown to have less impact on patients’ quality of life during treatment. Quality of Life (QOL) surveys demonstrated no significant differences in reported pain, perceived effectiveness, and patient satisfaction between the devices. However, the SNaP System interfered less with overall activity, sleep, social, or workplace interaction than the VAC System.

We are thrilled with the results of the trial because they highlight the capabilities and the clinical effectiveness of our system, which underscores the fact there is a real need for the SNaP System in today’s wound care market. Needless to say, we are very excited about the opportunities for Spiracur and the broader adoption of our innovative NPWT device for the treatment of acute and chronic wounds.

OWM: Please describe the mission/vision of your company and how your personal vision fits with the company’s goals.

“Transforming wound care to heal patients and improve lives” is Spiracur’s mission, and it is our vision to break the mold of “me too” NPWT products by creating a new category of wound management. The SNaP

System combines the ease, simplicity, and cost savings of Advanced Wound Care with the proven efficacy of NPWT. Everyday I see how our employees live out both this mission and vision. In Research and Development, our employees take pride in making small changes to the product to better serve the patients and clinicians. For example, this year we launched a foam interface in response to clinician requests, as well as a microport on our dressing, which allows for improved flexibility and bending radius for wounds located in difficult areas. In our sales efforts, we have developed a partnership model where account executives and clinical specialists work together to best serve accounts and patients. It is not uncommon for our field team to show up at a patient's home to support a nurse with a wound dressing change. Our clinical trainers pay special attention to making sure that clinicians, patients, and caregivers are all trained on the ease-of-use of our system. This personal accountability and belief in Spiracur's mission is what convinced me to join this small, yet dedicated company, as I felt this is a place where people are successfully making a significant difference in wound care.

Throughout my career, I have been committed to three basic tenants. Quite simply, they are to: focus on the patient, maintain evidence-based medicine, and innovate to improve patient care. These directly align with the transformation of wound care to heal patients and improve lives. My personal commitment, coupled with Spiracur's mission, makes this company the ideal environment for me to contribute and help to meet short-term and long-term goals.

OWM: Please explain what must take place on a daily basis at Spiracur in order to accommodate patients, clinicians, and health-care facilities.

The bottom line is that we have the opportunity to develop and manufacture quality products that actually help people. As a result, we cannot settle for just "good enough" in any aspect – from design through commercialization. We are still a small company that has a long way to go before it can compete with the large advanced wound care corporations in terms of size. However, we think we are doing a decent job of competing on innovation. Our plan is to continue to listen and respond to clinician and patient input to place better, more fulfilling products into the marketplace. Because of our size, we can promise to be quick and nimble as we make and implement improvements. And, we are not locked into what the future should look like. Rather, our customers help us to determine that.

OWM: Looking ahead, what are some incentives or products the company is working on?

The ability to deliver negative pressure in a small and discreet format without the need for batteries or electricity provides us with a unique opportunity. As a result, we have several new innovations in our product pipeline that we are very excited about. We will be sure to keep you posted. ■