

SNAP[®] Wound Care System **made easy**

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Introduction

The treatment of wounds with negative pressure wound therapy (NPWT) has revolutionised practice over the past decade. However, implementation of therapy can be a difficult process for both clinicians and patients — conventional NPWT devices often require a lengthy procurement process to obtain rental units, and complex dressing applications. This document discusses the use of the SNAP[®] Wound Care System (Spiracur Inc, Sunnyvale, USA), an ultraportable NPWT system for ambulatory and active patients. This system is easy to use, accessible, and may allow earlier discharge from hospital, helping to reduce costs and improve quality of life.

Authors: Piaggese A, Ivins N, Gibbons G, Fong K. Full author details can be found on page 6.

Using conventional NPWT systems

NPWT offers an important option for the advanced management of many wound types and has the potential to benefit a large number of patients^{1,2}. The role of NPWT therapy is well established; however, for patients who are ambulatory and active, conventional NPWT pumps can be bulky and intrusive to use, require electrical plug-ins or use battery power, and create noise that is often embarrassing in social situations and may interfere with sleep. Furthermore, these conventional systems are expensive and are not optimised for the typically smaller sized wounds seen in the ambulatory outpatient setting.

Why the SNAP System was developed?

The SNAP Wound Care System was developed at the Biodesign Innovation Program at Stanford University in Palo Alto, California, USA. The key insight that led to its development was that most of the chronic wounds that could benefit from NPWT, such as diabetic foot ulcers and venous leg ulcers, are relatively small in size^{3,4}. The SNAP System was therefore designed specifically for small-to-medium sized, slow-to-heal wounds.

The goal was to create a NPWT device that was easy to use by both clinicians and patients. Specifically, the device should be one that clinicians could take off the shelf like any other wound care dressing, was quick and easy to apply, and that patients could wear under their clothes and would not impinge on normal activities. The idea was to make it practical and cost-effective, allowing more patients to benefit from NPWT in the outpatient setting.

How does the SNAP System work?

The SNAP System (see Figure 1) is a disposable, ultraportable NPWT device that does not require an electrically- or battery-powered pump. The SNAP System is a mechanically-powered NPWT system comprising spring technology that reduces air density within an enclosure in a controlled manner. The specialised springs equilibrate even in the presence of exudate so that a constant controlled amount of negative pressure is delivered to the wound bed. Because there is no electrical pump, operation of the SNAP System is completely silent, and it is small enough to be worn on a patient's leg, arm, or belt and hidden under everyday clothing.

The SNAP Wound Care System consists of three basic elements:

- **The cartridge with activation/reset key**
- **Hydrocolloid dressing layer with integrated nozzle and tubing and choice of foam or antimicrobial gauze wound interface layer**
- **Strap with attachment clip.**

The cartridge is currently produced with three different pre-set pressure levels (-75mmHg, -100mmHg and -125mmHg). The cartridge portion of the device weighs 62.3g (2.2oz) and has a canister capacity of approximately 60mL of wound exudate. A visual indicator signals if the canister is full of exudate or if there is an air leak. The SNAP System also incorporates BioLock[®] technology that isolates or gels the wound exudate that collects in the cartridge. This helps to control potential contamination and odour.

A proprietary hydrocolloid dressing provides protection to the often friable periwound skin, improves dressing application handling properties, and provides a robust seal around the

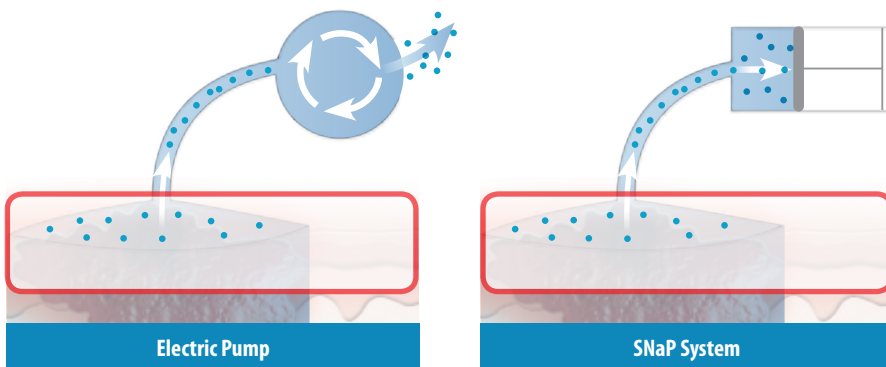
Figure 1 The SNAP Wound Care System (supplied courtesy of Spiracur Inc)



SNAP® Wound Care System **made easy**



Figure 2 Compared to conventional electrically-powered pumps, the SNaP System delivers the same negative pressure to the wound bed using a closed forced expansion of air instead of an open pump mechanism. As highlighted below, the wound bed experiences the same reduction in air molecule density with both modes of NPWT delivery (adapted from refs^{6,7}).



System resulted in a 50% improvement in time to healing. This was further supported by a multicentre randomised controlled trial (RCT) comparing the outcomes of the SNaP System and the V.A.C. Therapy System in 132 patients with lower extremity diabetic and venous ulcers. The two systems gave similar outcomes in terms of wound healing^{9,10}, while superior results were shown for the SNaP System in terms of quality of life.

When is the SNaP System indicated?

As the SNaP System delivers the same negative pressure as electrically-powered pumps, it was given clearance by the FDA in August 2009 and a CE Mark was obtained in December 2010. The SNaP System is indicated for the removal of small amounts of exudate from the following types of wounds:

- **Chronic (eg diabetic, venous or pressure ulcers)**
- **Traumatic/acute**
- **Subacute and dehisced**
- **Partial-thickness burns**
- **Surgically-closed incisions**
- **Flaps and grafts.**

Contraindications

As with most NPWT devices, the SNaP System should not be used over:

- **Actively infected wounds**
- **Inadequately drained wounds**
- **Necrotic tissue such as eschar or adherent slough**
- **Exposed blood vessels, anastomotic sites, organs, tendons or nerves**
- **Wounds containing malignancy**
- **Fistulae**
- **Untreated osteomyelitis**
- **Actively bleeding wounds.**

Application of the SNaP Wound Care System

The SNaP System is easy to apply, in general, taking less than 10 minutes per application. See Box 1.

wound for negative pressure delivery. The suction port and tubing (which can be cut to length) are fully integrated into the hydrocolloid dressing, simplifying the application process.

The hydrocolloid dressing is used over a wound filling material consisting of a specialised SNaP® BLUE foam dressing or antimicrobial gauze dressing (Kendall™ AMD gauze dressing, Covidien).

The BLUE foam dressings allows for similar mechanical transduction of stress and strain to the wound bed as other foam wound interfaces⁵. The bright blue colour of the foam dressing also allows for easy visualisation within the wound, helping to prevent retention of the foam at dressing changes. In general, the foam dressing is used when more robust granulation tissue formation is required or in deeper wounds. The antimicrobial gauze dressing is used in more superficial wounds or in wounds at higher risk of infection.

The BLUE foam dressing and antimicrobial gauze can be used in conjunction with commercially available wide mesh non-adherent base layers that prevent ingrowth or provide additional antimicrobial action. It is important that careful consideration is given

to the use of a base layer prior to application to ensure optimal delivery of negative pressure to the wound bed.

How does the level of negative pressure provided compare?

Both the electrically-powered and the disposable, mechanically-powered NPWT devices achieve the same air density reduction. This results in the delivery of identical negative pressure by both mechanisms at the level of the wound bed (see Figure 2).

To validate this, pre-clinical bench-top and animal studies were performed at Stanford University that demonstrated equivalent delivery of NPWT and equivalent wound healing between the SNaP Wound Care System and the V.A.C.® Therapy™ System (an electrically-powered NPWT device manufactured by KCI, San Antonio, Texas) and other electrically-powered pumps^{6,7}.

In addition, clinical trial data has shown equivalent outcomes to electrically-powered NPWT devices. In a case series of 63 patients with diabetic and venous ulcers, Lerman et al⁸ found that the SNaP

How frequently should the dressing be changed?

The patient or caregiver should visually inspect the SNaP System once every eight hours to ensure that the green indicator is still visible and the system is functioning properly. If the cartridge becomes full, this can be replaced with a new cartridge at home by the patient or caregiver.

It is recommended that the dressing be changed at least two times per week by the patient's healthcare provider. The frequency of dressing changes will depend on a number of factors (eg the level of exudate, bacterial load and rate of granulation tissue). Based on clinical experience, twice weekly dressing changes are sufficient for most small to medium-sized chronic ulcers. However, for healthy, young patients, three times weekly dressing changes may be needed as robust granulation tissue ingrowth can make dressing changes painful.

At dressing changes, care should be taken when removing the hydrocolloid dressing; this should be gently lifted to avoid stripping the surrounding skin.

What you might see at dressing changes

Hypergranulation tissue may be visible in the wound bed throughout the use of negative pressure, but this will resolve once therapy is stopped.

If the wound appears to have a green discolouration and the wound bed becomes friable, this may indicate increased bacterial burden under the dressing and can be resolved by applying an antimicrobial dressing.

Using the SNaP System at home

Before they leave the clinic, patients should be given clear instructions by the nurse on how to change the cartridge as well as any advice on troubleshooting (eg should the device lose pressure). They should then be given an instruction booklet and, if appropriate, a spare cartridge.

When should therapy be discontinued?

Treatment should be stopped when the treatment goals have been reached. For some wounds that will be when healthy granulation tissue is achieved. For other wounds, therapy may continue until an underlying structure is covered or the wound is almost healed. Often, wounds treated with NPWT will regress once the therapy is stopped. It is important therefore to continue therapy until the wound reaches a stage where it will go on to heal.

Box 1 How to apply the SNaP Wound Care System

1. Prepare the wound bed and periwound skin according to local protocols and irrigate the wound bed thoroughly. If appropriate, apply a skin protectant to the surrounding skin.
2. **If using foam as an interface layer**
Cut the foam dressing to fit the size and shape of the wound. Do not cut the foam directly over the wound and brush off foam edges after cutting to remove any loose fragments. If treating a wound with delicate structures underneath or the patient experiences significant pain at dressing changes, consider the use of a wide mesh, non-adherent base layer under the foam dressing. Place the foam dressing into the wound cavity. The foam should extend above the wound margins. Count and record the number of pieces used. Proceed to step 4.
3. **If using gauze as an interface layer**
Loosely pack the wound with saline moistened gauze. Do not pack tightly and keep the gauze moist at all times.
4. Place the hydrocolloid dressing provided over the wound, allowing sufficient overlap with intact skin to form a proper seal. Ensure that the centre of the opening of the port is placed over the foam/gauze interface layer. For some wound locations and smaller sized wounds, the hydrocolloid dressing may need to be trimmed to fit. Additional sealing strips can be used to reinforce the seal if required.
5. Cut the dressing tubing to the desired length and fully insert the tube fitting into the tubing.
6. Connect the SNaP cartridge to the tube fitting. Press the activation tabs on the side and pull out to activate the cartridge.
7. Secure the cartridge to the patient's belt or extremity using the strap. Take care to ensure that the strap is not too tight to avoid restricting the blood supply of the limb.
8. Check the device is working correctly. The 'green capacity indicator' should be both visible and stationary and the dressing should feel hard to the touch and have a 'sucked down' appearance.

The role of NPWT in diabetic foot disease

There has been a dramatic increase in the number of patients with diabetes and the management of the diabetic foot is a major management issue. The EURODIALE study examined 1,229 patients affected by diabetic foot disease who were followed for one year in 14 highly specialised centres in 10 different countries in Europe. The results show how this pathology is not only more severe than was once believed, but also that it is associated with significant comorbidity^{11,12}.

PRODUCTS FOR PRACTICE

The patient may be affected by neuropathic, ischaemic or neuro-ischaemic lesions, all of them often complicated by infection, which can be very aggressive. In such cases the clinical course of the ulcers is usually longer than in other pathologies, since in diabetes the tissue repair mechanisms are impaired. In addition, complications, such as re-infections, prolong the course even further, increasing the cost of management of these patients¹³. The application of NPWT has been demonstrated to be safe and effective in diabetic foot ulcers¹.

Armstrong et al demonstrated how NPWT was significantly more effective in healing post-surgical lesions after amputation of the forefoot than standard therapy in which the wound was left open to heal by secondary intention¹⁴. Blume et al¹⁵ confirmed the efficacy of this approach in a variety of ulcerative diabetic foot conditions, when used in

a multidisciplinary context¹⁵. These and other studies led to the recommendation for NPWT as the standard of care for diabetic foot ulcers in international guidelines for the management of diabetic foot disease¹⁶.

With the exception of critical limb ischaemia and active infection, almost all the conditions related to the acute ulcerated diabetic foot can be considered indications for NPWT. Once revascularised, infection treated and debridement has been performed, critical limb ischaemia wounds are also suitable for the application of NPWT.

The SNaP System in diabetic foot disease – the evidence

Although still limited, the experiences of using the SNaP System in diabetic foot disease are generally positive, with clinicians reporting a similar efficacy to

conventional devices, and suggesting better patient concordance, limited only by the fixed degree of negative pressure and reservoir capacity¹⁷.

This is supported by the recent findings from a multicentre, prospective RCT of 132 patients comparing the SNaP System with the V.A.C. Therapy System, in which Armstrong et al achieved similar wound healing times and rates with the SNaP System compared to the V.A.C. System. Moreover, the SNaP System was judged to be superior in terms of ease of use and acceptance by patients^{9,10}.

As the approach to diabetic foot ulcers becomes more surgically oriented, in order to be as conservative as possible, the indications for the application of the SNaP System are likely to increase over time, ranging from the management of post-surgical lesions to deep neuropathic ulceration to ischaemic lesions after revascularisation.

Use of the SNaP System in a neuropathic diabetic foot ulcer in a patient with a chronic Charcot's foot case study

A 68-year-old man presented at a diabetic foot disease referral clinic in Central Italy with type 2 diabetes and a history of Charcot's neuroarthropathy of the right foot. He had developed a mesoplatar neuropathic ulcer due to poorly-fitting shoes, which was complicated by infection with *Pseudomonas aeruginosa*. After initial debridement, one month of systemic antibiotic therapy and local application of an antiseptic dressing (Kerlix™, Covidien), the ulcer improved, with a progressive reduction in infection signs, and granulation tissue present on 100% of the wound bed.

Despite this initial improvement, and offloading with an Optima Diab® brace device (Molliter), the ulcer did not progress adequately toward complete healing, and neither a reduction in its area or depth was observed. An MRI scan excluded the presence of tarsal osteomyelitis and there were no signs of local ischaemia.

It was decided to apply the SNaP System because of the delay in ulcer healing (the ulcer had been present for two years). Figures 1-3 show the application of the SNaP device on this patient. The aim was to use the SNaP System to start the regenerative phase of wound healing through the stimulation of fibroblasts and endothelial cells and promotion of both angiogenesis and fibrogenesis. After the first application of the SNaP System the ulcer showed significant improvement, with a reduction in volume and granulating tissue actively proliferating on 100% of the base of the ulcer. It was decided to re-apply the SNaP® system for a further week. The ulcer went on to heal after two months.

Figure 1: Neuropathic foot ulcer in a patient with a chronic Charcot's foot



Figure 2: The ulcer is dressed with the Kerlix™ gauze and the SNaP System is applied



Figure 3: The ulcer is then protected with polyurethane foam and the patient, appropriately bandaged, can walk, offloaded with a Optima Diab® brace device



Use of the SNaP System in a venous leg ulcer case study

A 67-year-old lady agreed to take part in a clinical evaluation of the SNaP Wound Care System at the Wound Healing Research Unit at Cardiff University in the UK. The patient had a seven-year history of recurrent venous ulceration and the duration of the current ulcer on presentation was six months.

After five months of treatment with multilayer compression therapy and an antimicrobial dressing the wound had failed to progress. When the patient presented at the clinic her wound measured 10.1cm² with moderate to high exudate (Figure 1). The aim of the evaluation was to stimulate healing and reduce the wound size.

Following signed consent, Kendall™ AMD gauze (Covidien) was lightly packed in the wound and the SNaP System was applied using a -125mmHg cartridge (Figure 2). A multilayer compression bandage system was applied and the patient returned to the clinic three days later. At week 2, the wound exudate was changed in colour and the wound bed had become more friable. The clinician applied a silver dressing to the base of the wound and the patient continued with the gauze dressing, the SNaP® System and compression therapy. The wound continued to decrease in size, the amount of exudate recorded in the cartridge reduced, and by week 5 the patient was no longer experiencing any pain in the wound.

Twenty percent hypergranulation tissue was evident in the base of the wound when the patient completed the evaluation at the end of week 6. The wound measured 2.6cm² and the exudate level was low, measuring 6mL in the cartridge after four days. On completion of the evaluation (week 8), the patient continued with a non-adherent dressing and compression therapy and the wound healed within a month (Figure 3).

Figure 1: On presentation

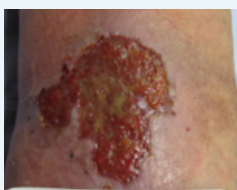


Figure 2: Application of the SNaP Wound Care System



Figure 3: On completion of the evaluation at eight weeks



The role of NPWT in venous leg ulcers

Venous leg ulcers are often hard-to-heal wounds that pose significant clinical challenges and can be painful and debilitating for patients. NPWT therapy has been shown to be effective in treating chronic venous ulcers and in a RCT by Vuerstaek et al¹⁸, the time to healing in 60 leg ulcer patients demonstrated a shorter healing time for NPWT when compared with standard therapy (29 vs 45 days).

The SNaP® Wound Care System has been used successfully in patients with venous ulceration requiring compression⁹ and can allow ambulatory patients to be treated at home, reducing the need for hospitalisation.

When applying the SNaP System under compression bandaging, care should be taken to ensure that the tubing remains outside of the bandage. If left under the bandaging, the tubing may cause pressure damage to the underlying tissue. Additional

padding can be placed beneath the device valve to prevent any indentation on the skin.

For many patients with venous eczema requiring topical steroid treatment, it is possible to apply the steroid ointment to the surrounding skin during application of the SNaP System. This can be applied and left to dry for 10 minutes; if there is any excess, the ointment can be removed before the hydrocolloid dressing is applied.

When applying compression bandaging, it is important to check that the SNaP System is working and the suction is being applied to the wound. The majority of patients with a venous leg ulcer prefer the cartridge to be placed below the knee, requiring the tubing to be cut to the appropriate length.

Using the SNaP System on mixed or arterial ulcers

When applying the SNaP System to patients with a mixed arterial venous ulcer or arterial ulcer the clinician should assess whether the patient is experiencing wound pain. If

so, it may be advisable to start with a lower pressure cartridge system and increase this if necessary. From clinical experience, patients with mixed or arterial disease are most comfortable using either a -75mmHg or -100mmHg cartridge. The dressing is applied in exactly the same way as that of a venous leg ulcer, although the use of compression will be at the discretion of the clinician.

The cost-effectiveness of using an ultraportable system

The consumption of resources for patients with chronic ulceration are considerable¹¹. This is largely related to the high cost of admission to hospital and inpatient stay for patients with the most complex problems, whose management requires interventional procedures, long-lasting intravenous antibiotic therapy and whose healing by secondary intention often takes several months.

In these circumstances, any contribution that can lead to a reduction in healing time, and eventually to a shortening of in-hospital stay,

Box 2 Advantages of the SNaP System

- Flexibility of use: patient's home, outpatient clinic or hospital setting
- Easy to use by non-specialist personnel (eg nursing home staff)
- Silent and discrete (can be worn under normal clothing)
- Improves concordance with therapy
- Off-the-shelf availability
- Ultraportable and fully disposable
- No need for batteries/need to plug in and recharge

is of great value, both in terms of quality of life for the patients and resource utilisation for the health system.

The efficacy of NPWT in many chronic ulcerative conditions has led to a reduction in length of hospital stay¹⁵. However, using conventional NPWT models meant that the high cost of the technology counterbalanced the reduction in the cost of admissions¹⁹. This has led to the need for a more portable device, making it possible to manage patients on an outpatient basis.

In a mathematical modelling study comparing the SNaP System with both standard care and with NPWT systems, Hutton and Sheehan demonstrated how the SNaP System doubled the number of patients healed compared to standard care, while saving more than US\$9,000 per patient treated. When compared to conventional NPWT, the SNaP System showed a similar performance profile, but saved US\$2,500 per patient. The authors concluded that the SNaP System was highly competitive in terms of resource consumption and could help to improve patient outcomes²⁰.

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Author details

Piaggese A¹, Ivins N², Gibbons G³, Fong K⁴

1. Director, Diabetic Foot Section, Department of Medicine, University Hospital of Pisa, Italy
2. Clinical Trials Manager, Wound Healing Institute for Translation, Innovation and Engagement (TIME), Cardiff University, UK
3. Professor of Surgery, Boston University School of Medicine, MA, USA
4. Chief Scientific Officer, Spiracur Inc, Sunnyvale, USA

Summary

The SNaP System represents an innovative option for the delivery of NPWT to a wide range of wound types. Its simplicity and flexibility are characteristics that make it suitable for the application in patients who are active, with the benefits of a reduction in costs and number of days in hospital, sparing resources and increasing patients' quality of life.

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