SNAP™
THERAPY SYSTEM

SNAP™ Therapy System
MONOGRAPH

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Preface

The SNAP™ Therapy System is a mechanically powered, disposable negative pressure wound therapy (dNPWT) system that uses constant force springs, rather than electrical power, to generate negative pressure.

This monograph will:

- Introduce SNAP™ System
- Review clinical literature reporting use of SNAP™ System
- Describe the components and technology of the SNAP™ System
- Summarize scientific evidence describing SNAP™ System mechanisms of action
- Present case studies demonstrating SNAP™ System application and outcomes
- Review a SNAP™ System health economics study

Introduction

The aging US population and increasing prevalence of diabetes[1] have resulted in a growing number of patients with non-healing (chronic) wounds and ulcers[2,3] being treated in the outpatient care setting.[4] Venous leg ulcers[5] and diabetic foot ulcers[6] for example, are prone to recurrence – especially in older patients with age-impaired healing and multiple comorbidities (e.g., peripheral venous disease, diabetes, peripheral neuropathy).[7] These wounds are a burden to patients, challenging to physicians, and costly to the healthcare system.[3,8,9]

As research expands understanding of the wound healing process, increasingly sophisticated dressings and therapies have been developed to address barriers encountered during the sequential stages of healing.[10,11,12] Negative Pressure Wound Therapy (NPWT) is an adjunctive therapy that applies sub-atmospheric pressure through a foam or gauze dressing to create an environment that promotes wound healing by drawing wound edges together, removing exudate and infectious material, reducing edema.[13,14] Since the initial US clearance for commercialization of NPWT (V.A.C.® Therapy, KCI, an ACELITY Company, San Antonio, TX) in 1995, NPWT has been used effectively in a wide variety of acute and chronic wounds.[15]

While NPWT was initially available only for inpatient wound treatment, over time, a variety of portable NPWT systems have been developed for use across the continuum of care. The majority of these are electrically powered; however, recently a mechanically powered NPWT system, SNAP™ Therapy System, has been cleared for management of wounds that would benefit from the use of NPWT to promote healing through the removal of small amounts of exudate, infectious material, and tissue debris. The single-use SNAP™ System is lightweight (<3 ounces) **(Figure 1A)** to enhance patient mobility **(Figure 1B)**, quiet (no electrical components), and designed for low-exudating wounds (≤180cc/week) that are less than 13cm x 13cm in area.[16] This therapy is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts, and surgically closed incisions.

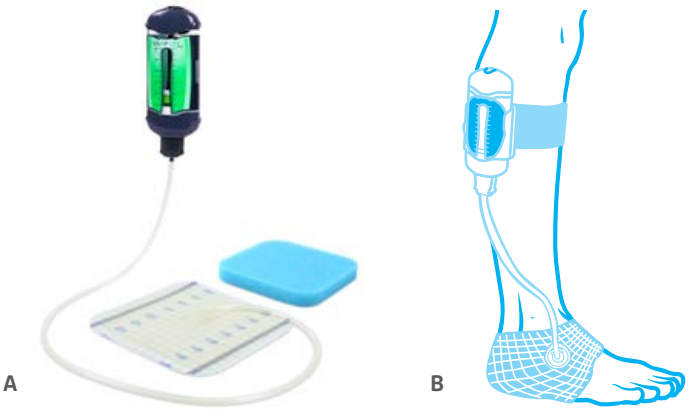


Figure 1. SNAP™ System: A) Lightweight cartridge, advanced hydrocolloid dressing and blue foam interface; B) Illustration of SNAP™ System applied to a lower extremity wound

Literature Review of NPWT

A number of SNAP™ System studies have reported clinical outcomes for over 150 patients with a variety of wounds, including venous leg ulcers and diabetic foot ulcers. These studies, which include 2 randomized controlled trials (RCTs) as well as a number of case series and case studies, are discussed below and summarized in Table 1.

While complete wound closure (100%) is the endpoint usually required by regulatory agencies to determine product efficacy, percentage of wound size reduction at certain time points can also provide important information as to whether a treatment is likely to heal a wound.[17,18] Studies have shown that diabetic foot ulcers achieving ≥50% wound size reduction in 4 weeks (30 days)[19] and ≥90% wound size reduction in 8 weeks[20] were more likely to achieve healing in 12 weeks. Some SNAP™ System studies report complete wound closure data, while others focus on percent wound size reduction at specific time points.

The initial noninferiority RCT by Armstrong et al[21] (2012) compared mechanically-powered SNAP™ System to electrically-powered V.A.C.® Therapy for 16 weeks in order to evaluate comparative efficacy between the groups for the primary endpoint of wound size reduction. A total of 132 patients with noninfected, nonischemic, nonplantar lower extremity diabetic and venous wounds were enrolled. Of these, 115/132 patients had follow-up data available for analysis, and 83/132 finished the study with either healing or 16 weeks of therapy: SNAP™ System, 41 patients; V.A.C.® Therapy, 42 patients. On average, baseline wound size was significantly larger for V.A.C. ® Therapy wounds (SNAP™ System: 5.37 ± 6.14 vs V.A.C.® Therapy: 9.95 ± 11.38; $p<0.05$). In terms of wound size reduction, SNAP™ System patients demonstrated noninferiority to V.A.C.® Therapy patients at 4, 8, 12 and 16 weeks ($p=0.0030$, 0.0130, 0.0051, and 0.0044, respectively). There were also no significant differences between the groups for complete wound closure at all time points and for device-related adverse events and complications (e.g., infection). Exit survey results showed that SNAP™ System patients reported less interruption of activities in daily living, less impact in overall activity, less interruption in sleep, less noise level, less impact on social situations, and wearability compared with V.A.C.® Therapy-treated patients. In this RCT, similar wound healing outcomes were demonstrated for SNAP™ System and V.A.C.® Therapy in the study population.[21]

In the second RCT (2015), Marston et al[22] compared 40 patients with venous leg ulcers who completed the study with either healing or 16 weeks of therapy and were treated with either SNAP™ System (n=19) or V.A.C.® Therapy (n=21). The primary endpoint was wound size reduction. Although patients were randomized, there were differences in the mean initial wound size (mean ± standard deviation) for SNAP™ System wounds (4.85 ± 4.49cm²) versus V.A.C.® Therapy wounds (11.60 ± 12.12cm²). There was no significant difference in the proportion of patients that completely healed over time (with [$p=0.4656$] or without [$p=0.3547$] adjustment for baseline wound size). In the SNAP™ System group, 52.6% (10/19) patients achieved the surrogate endpoint of 50% wound closure at 30 days, compared to 23.8% (5/21) V.A.C.® Therapy patients (odds ratio [OR] 3.56, 95% confidence interval [CI] of [0.923, 13.699]). Also, more SNAP™ System patients achieved complete closure at 90 days compared to V.A.C.® Therapy patients: 57.9% (11/19) patients vs 38.15% (8/21) patients, respectively (OR, 2.23, 95% CI [0.63, 7.93]).[22]

The prospective comparative study by Lerman et al[23] (2010) compared wound care center (WCC) patients whose lower extremity venous or diabetic wounds were treated prospectively with SNAP™ System to matched historical control patients treated at the same center with skin substitutes or skin grafts. Wound healing outcomes for the prospective SNAP™ System patients were followed for up to 4 months. Of the 36 patients enrolled in the SNAP™ System group, 21 completed the study. The center's wound treatment database was then searched to identify matches by wound size and type, and additional patient characteristics (e.g., age, presence of diabetes or peripheral vascular disease). Each SNAP™ System patient was matched with 2 control patients resulting in a total of 42 historical controls that were included in the study. In the SNAP™ System group, 21/21 (100%) patients showed improvement in wound size, while 18/21 (86%) had a statistically significant ($p<0.05$) healing trend. Because very few control patients achieved wound healing in 4 months, Kaplan-Meier survival analysis was used to compare the relative time to healing for the patients who healed in both groups. According to the Kaplan-Meier estimates, patients in the SNAP™ System group achieved healing in a significantly ($p<0.0001$) shorter average time (74.25 ± 20.1 days) compared to patients in the Matched Control group (148.73 ± 63.1 days). This represented a 50% absolute reduction in time to healing for patients in the SNAP™ System group. When individual SNAP™ System patients were compared to their 2 matched controls, the average difference in time to healing (54.27 ± 28.1 days) was also significantly ($p<0.0001$) shorter for the SNAP™ System patients. [23]

Fong et al[24] (2010) reported the first clinical use of SNAP™ System in a case series of 12 consecutive patients with chronic wounds treated at an academic outpatient dermatology clinic. The study evaluated the safety, feasibility and efficacy of SNAP™ System. The protocol required biweekly clinic visits to document complications and wound healing progress over a 4-week period. All 12 patients experienced at least partial wound healing after SNAP™ System treatment. The 6 patients that met all study requirements (including follow-up visits) had a statistically significant ($p<0.01$) mean wound area reduction of 97.2% at 4 weeks post SNAP™ System initiation. Five of these 6 patients achieved complete wound healing. Nine of the 11 patients who completed the exit survey stated that they would use SNAP™ System if they developed another chronic wound.[24]

Lerman et al[16] (2010) treated 4 diabetic patients in a WCC to evaluate the safety and efficacy of SNAP™ System as part of a treatment protocol for complex lower extremity wounds. Patients were followed for up to 4 months or wound closure. One patient's wound achieved complete closure after 4 weeks of SNAP™ System, while a second patient's wound closed in 5 weeks, following 4 weeks of SNAP™ System and use of an offloading orthotic. For the remaining 2 patients, SNAP™ System was used to prepare the wound bed by promoting granulation tissue formation followed by placement of APLIGRAF® (Organogenesis, Inc., Canton, MA) in the third patient and a skin graft in the fourth patient. Both of these wounds achieved complete wound closure at 8 weeks after SNAP™ System initiation. The authors commented that SNAP™ System's "off the shelf" availability, simple application process, and "ultraportability" were advantages in the outpatient care setting.[16]

In 2015, Bradbury et al[25] conducted an observational study of patients with chronic venous leg ulcers (n=15), mixed etiology leg ulcers (n=13), and neuropathic foot ulcers (n=9). While 38 patients were recruited, the Intention-to-Treat analysis was based on the 37 that received the 2 weeks of SNAP™ System required for evaluable patients, who were followed for up to 6 weeks. The primary endpoint was percentage change in wound size between weeks 1 and 8. Four (10.8%) patients discontinued treatment shortly after receiving 2 weeks of SNAP™ System; 33 (89.2%) completed the study. Mean percentage decrease in wound area for the study population as a whole was 42.64% with mean reductions of 64% for venous leg ulcers and 55% for neuropathic foot ulcers. In the 15 patients (41%) who experienced wound infections, SNAP™ System was temporarily suspended (maximum delay of 2 weeks) and restarted after resolution of the infection. The authors noted that infection is generally observed in patients with complex chronic wounds. Skin-related adverse events were also more likely to occur in the 2 leg ulcer groups.[25]

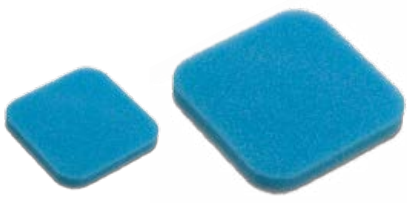
Awad and Butcher[26] (2012) reported the case of a middle-aged male with Type 2 diabetes who developed a new ulceration on the lateral border of his left foot. This was the site of 2 previous ulcerations treated with different battery-powered portable NPWT devices. The third ulceration was extensive and presented over his previous ray amputation. The wound had slough, high exudate levels, heavy bacterial colonization and exposed tendon. SNAP™ System (-125mmHg) was applied with a moistened antimicrobial gauze-interface layer beneath the hydrocolloid dressing and the cartridge was attached to the patient's leg to facilitate movement. After discharge from the hospital the patient returned to "light" work duties, although he had been advised to be non-weight-bearing. During and after discontinuation of SNAP™ System, there was significant wound size reduction, and the wound achieved full closure. The patient preferred SNAP™ System to the 2 prior NPWT devices, because it was lightweight, portable, and silent. As a result the patient's sleep was not disturbed, and his coworkers were not aware that he was undergoing treatment.[26]

In the case study by Neiderer et al27 (2012), lightweight SNAP™ System was used because the 76-year-old male with rheumatoid arthritis was frail. The patient was originally diagnosed as having a venous leg ulcer (1.8cm x 1.5cm) on his anterior left leg. After 1 month of treatment with moistened gauze, the wound had increased to 4.5cm x 5.0cm. After the diagnosis was changed to pyoderma gangrenosum, the patient was treated with prednisone and topical application of tacrolimus and the wound continued to increase in size (7.2cm x 5.6cm). Treatment was changed to SNAP™ System at -75mmHg with twice weekly dressing changes and APLIGRAF® (Organogenesis, Inc., Canton, MA) applications every 2 weeks for a total of 5 treatments. After 4 weeks, SNAP™ System was increased to -125mmHg based on patient tolerance of the lower pressure and the need for increased exudate control. After 12 weeks, the wound decreased in size to 2.9cm x 2.5cm and was fully epithelialized by 16 weeks after initiation of APLIGRAF® (Organogenesis, Inc., Canton, MA) and SNAP™ System.[27]

SNAP™ Therapy System Components

The SNAP™ System cartridge, strap, interface layer and dressings are described in Table 2.

Table 2: SNAP™ System components

Name/Description	Picture
SNAP™ Therapy Cartridge Removal of the Activation/Reset Key from the SNAP™ Therapy Cartridge initiates delivery of negative pressure (-75mmHg, -100mmHg, or -125mmHg). These cartridges hold up to 60ml of exudate. BIOLOCK™ Technology turns the exudate into a gel to optimize containment.	
SNAP PLUS™ 125mmHg Therapy Cartridge A larger SNAP™ Therapy Cartridge is available that holds up to 150ml of exudate and delivers -125mmHg of negative pressure. The 150ml cartridge uses BIOLOCK™ Technology, which turns the exudate into a gel to optimize containment.	
SNAP™ Therapy Strap The SNAP™ Therapy Strap enables the 60ml cartridge to be worn conveniently under clothing. The strap comes in 3 sizes: Small (18"), Medium (21"), and Large (24").	
SNAP PLUS™ Therapy Strap The SNAP PLUS™ Therapy Strap enables the 150ml cartridge to be placed into a carrying case and attached to the patient. The strap comes in 3 sizes: Small (18"), Medium (21"), and Large (24").	
Interface Layers The blue foam interface layers come in small (8cm x 8cm), medium (13cm x 13cm), and large (18cm x 18cm, not shown) sizes and facilitate even levels of negative pressure in the wound bed.	

Science Supporting SNAP™ System

Scientific studies have been conducted to evaluate the ability of SNAP™ System to deliver NPWT. Because maintenance of a prescribed level of negative pressure is critical for NPWT, a scientific bench study compared the ability of both SNAP™ System and V.A.C.® Therapy to maintain target negative pressure (-125mmHg) with and without exudate inflow in a simulated wound model. Results indicated that with and without fluid in the model, SNAP™ System delivered negative pressure (at -125mmHg set point) similar to that delivered by V.A.C.® Therapy over a 24-hour period.[32]

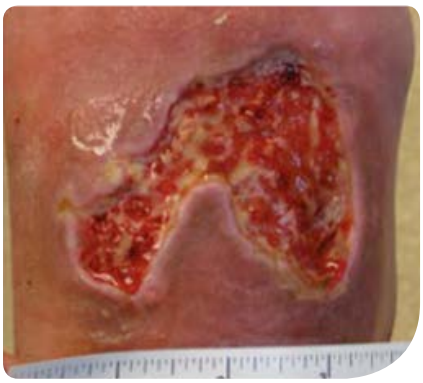
An animal study was used to evaluate SNAP™ System's ability to produce granulation tissue. Rats with surgically created 2.5cm x 3cm wounds were treated with either SNAP™ System at -125mmHg or the SNAP™ Dressing without negative pressure. Animals treated with SNAP™ System at -125mmHg had a significantly greater wound size reduction at 7 days compared to those treated with the SNAP™ Dressing and no negative pressure: 51%. vs. 12%, respectively, $p<0.05$.[32] This rodent study was modeled on a previous study in which animals treated with a V.A.C. ® Therapy Dressing and negative pressure at -125mmHg achieved a 40% decrease in wound size.[33] According to the authors, the similarity of results in these animal studies "suggests that the SNAP™ System may have efficacy equal to that of vacuum assisted closure for some wounds."[32]

Case Study 3: *Traumatic Wound*

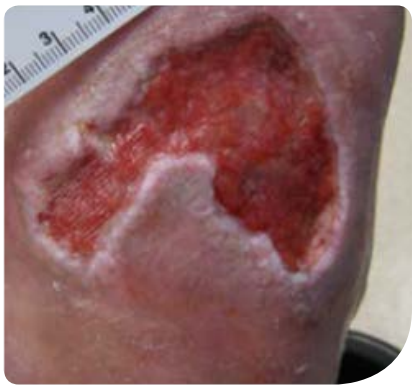
A 68-year-old male presented with a traumatic wound to the dorsal foot measuring 70mm x 54mm with a depth of 4mm **(Figure 5A)**. Patient medical history included diabetes mellitus, tobacco use, peripheral vascular disease, coronary artery disease, chronic obstructive pulmonary disease, hypertension, and hyperlipidemia.

The patient was treated with the SNAP™ System for 3 weeks until full granulation of the wound was achieved. Then, the therapy was used in conjunction with a cellular tissue product for an additional 5 weeks. Granulation tissue development was observed in the wound after 2 weeks of SNAP™ System use **(Figure 5B)**. Wound closure was achieved after 8 weeks of SNAP™ System and cellular tissue product use **(Figure 5C)**.

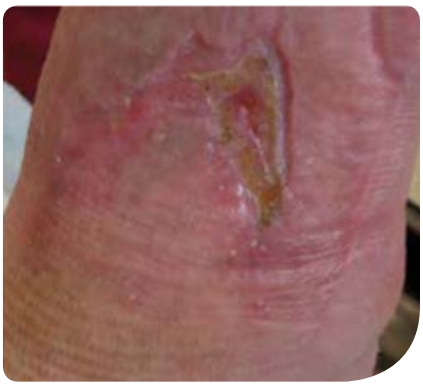
Figure 5. Traumatic Wound



A. Wound at start of SNAP™ System use



B. Granulation tissue development observed after 2 weeks of SNAP™ System use



C. Wound closure achieved after 8 weeks of SNAP™ System use

Health Economics

In 2011, Hutton and Sheehan[34] analyzed costs and effectiveness of 3 therapies for treatment of diabetic lower extremity wounds: modern wound dressings, powered NPWT, and non-powered SNAP™ System. An economic model using peer-reviewed data was used to simulate outcomes for the different treatments. The proportion of patients expected to heal over a period of 16 weeks was used to measure costs and effectiveness, because the 16-week time period was standard for NPWT trials. Healing progress was modeled as "exponential decay of individuals remaining in therapy each week."[34] The model incorporated healing and complication rates in the literature for diabetic foot wounds and recent SNAP™ System studies. The model also assumed equal efficacy between SNAP™ System and powered NPWT based on clinical study results.[34]

Based on the model, Hutton and Sheehan reported that, compared to modern dressings, SNAP™ System saved over $9,000 per wound treated by avoiding longer treatment times and costs for complications and healing more wounds than the modern dressings. Healing time was similar for NPWT and SNAP™ System; however, Medicare and private Payor costs were $2,300 and $2,800 less, respectively, for SNAP™ System patients. The authors concluded that, in addition to cost savings, SNAP™ System also allowed patients greater mobility.[34]

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NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies. Please consult a clinician and product instructions for use prior to application.

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