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3M™ Snap™ Therapy System

Product monograph

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Preface

The 3M™ 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 Therapy System
- Review clinical literature reporting use of Snap Therapy System
- Describe the components and technology of the Snap Therapy System
- Summarize scientific evidence describing Snap Therapy System mechanisms of action
- Present case studies demonstrating Snap Therapy System application and outcomes
- Review a Snap Therapy 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 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 Therapy 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, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts, and surgically closed incisions.

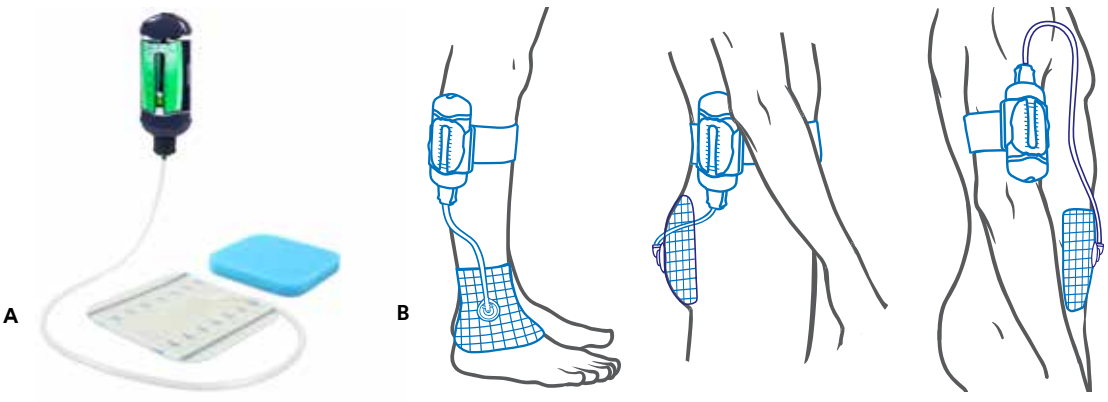

Figure 1. 3M™ Snap™ Therapy System: A) Lightweight cartidge, advanced hydrocolloid dressing and blue foam interface; B) Illustrations of 3M™ Snap™ Therapy System applied to a selection of wound types.

Literature review

A number of 3M™ Snap™ Therapy System studies have reported clinical outcomes for over 150 patients with a variety of wounds, including venous leg ulcers and diabetic foot ulcers. In addition, a cost and effectiveness study showed health economics for Snap Therapy System compared to advanced wound dressings and powered NPWT. These studies, which include 2 randomized controlled trials (RCTs), a health economics study as well as a number of case series and case studies, are discussed below and summarized in Table 1.

Clinical outcomes

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 Therapy 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 Therapy 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 Therapy System, 41 patients; V.A.C.® Therapy, 42 patients. On average, baseline wound size was significantly larger for V.A.C.® Therapy wounds (Snap Therapy System: 5.37 ± 6.14 vs V.A.C.® Therapy: 9.95 ± 11.38; $p<0.05$). In terms of wound size reduction, Snap Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy System to matched historical control patients treated at the same center with skin substitutes or skin grafts. Wound healing outcomes for the prospective Snap Therapy System patients were followed for up to 4 months. Of the 36 patients enrolled in the Snap Therapy 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 Therapy 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 Therapy 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 Therapy 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 3M™ Snap™ Therapy System group. When individual Snap Therapy 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 Therapy System patients.[23]

Fong et al[24] (2010) reported the first clinical use of Snap Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy System, while a second patient's wound closed in 5 weeks, following 4 weeks of Snap Therapy System and use of an offloading orthotic. For the remaining 2 patients, Snap Therapy 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 Therapy System initiation. The authors commented that Snap Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy 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 Therapy System, there was significant wound size reduction, and the wound achieved full closure. The patient preferred Snap Therapy 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 al[27] (2012), lightweight Snap Therapy 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 3M™ Snap™ Therapy 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 Therapy 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 Therapy System.[27]

Bohn[28] (2013) reported using 3M™ Snap™ Therapy System on a Haitian patient who had previously been treated for a pelvic fracture after the January 2010 earthquake. Initial treatment included colostomy and suprapubic urinary catheter placement to protect against infection while the injury healed. Five months later the colostomy was reversed, leaving a heavily colonized wound at the takedown site. Snap Therapy System was used for approximately 2 weeks until the wound was small enough for superficial bandaging. According to the author, having mechanically powered NPWT in this resource-poor setting was an advantage and allowed the patient to quickly return to normal activities. The wound fully healed at about 3 weeks post colostomy reversal.[28]

A case study by Awad and Butcher[29] (2013) presented use of Snap Therapy System to treat a dehisced surgical breast wound. The 38-year-old female patient had been treated for breast cancer with chemotherapy, breast cancer surgery, and postoperative radiotherapy. A seroma developed and was aspirated prior to radiotherapy; however, during radiotherapy the suture line broke down, resulting in full dehiscence of a deep peri-axillary cavity lined with necrotic tissue. Following debridement, the wound was initially treated with Manuka-honey-based dressings and oral antibiotics were prescribed to address heavy bacterial growth. After 2 weeks, the wound was 6cm long, ≥6cm deep, and lined with soft residual slough. NPWT was recommended. The patient chose Snap Therapy System so she could work and take care of her family without others being aware that she was undergoing treatment. Snap Therapy System was discontinued after 6 weeks, when the wound had decreased to <1.5cm in depth and was thereafter treated with dressings until closure was achieved.[29]

Isaac et al[30] (2014) provided the first reported use of Snap Therapy System to bolster a skin graft. An 83-year-old woman with Type 2 diabetes and peripheral neuropathy presented with a large painful wound on medial aspect of left ankle. After wound debridement and skin graft placement, Snap Therapy System at -75mmHg was placed as a bolster for 4 days. At 4 weeks, the graft was almost completely epithelialized and wound was closed by 12 weeks.[30]

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Economic

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 Therapy 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 Therapy System studies. The model also assumed equal efficacy between Snap Therapy System and powered NPWT based on clinical study results.[34]

Based on the model, Hutton and Sheehan reported that, compared to modern dressings, Snap Therapy 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 Therapy System; however, Medicare and private Payor costs were $2,300 and $2,800 less, respectively, for Snap Therapy System patients. The authors concluded that, in addition to cost savings, Snap Therapy System also allowed patients greater mobility.[34]

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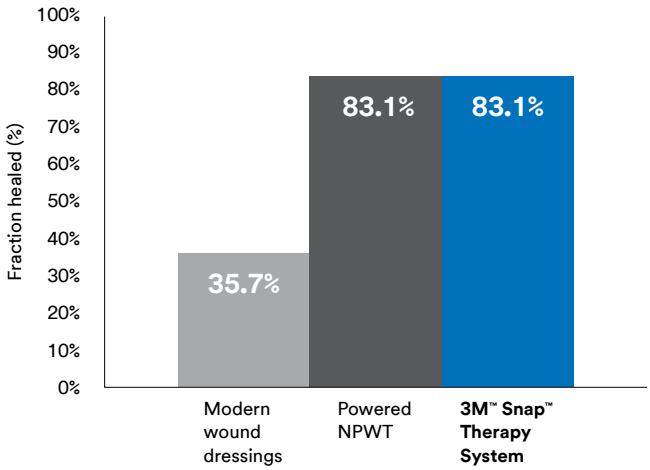
Assumption according base case results

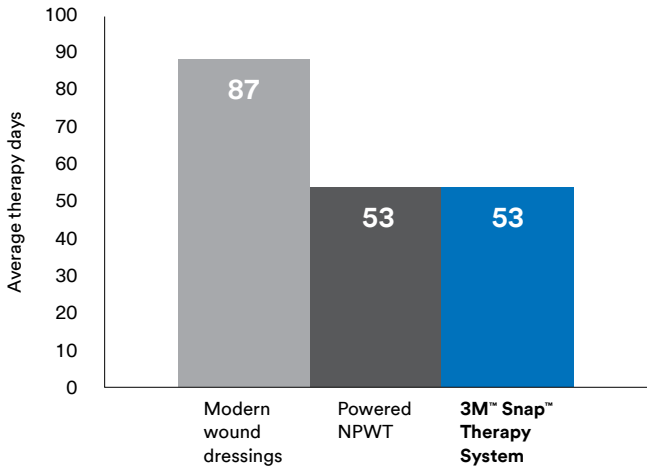
(Percentage of healing) Hutton DW, et al. 2011



All numbers are averages per patient treated. Effectiveness results are during 16 weeks of therapy.

Assumption according base case results

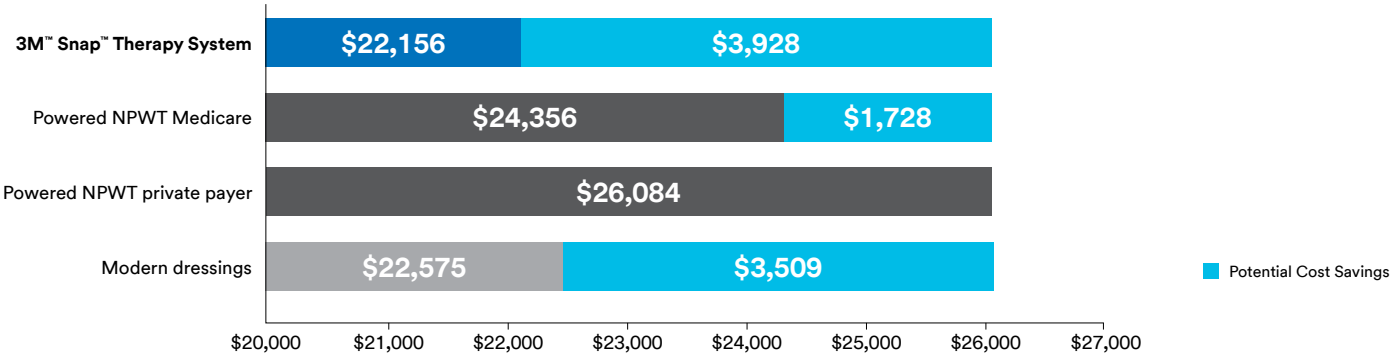
(Length of therapy) Hutton DW, et al. 2011



All numbers are averages per patient treated. Effectiveness results are during 16 weeks of therapy.

Economic value

Hutton DW, et al. 2011



An economic model with peer-reviewed data was used to simulate outcomes for treatment with different therapies. The model uses the best available data on each of the therapies and uses a modelling approach to predict the outcomes. All numbers are averages per patient treated. Numbers are given in USD ($).

Table 1: Key clinical evidence supporting use of 3M™ Snap™ Therapy System

Author	Study type	Patients	Results/conclusions
DG Armstrong et al[21] (Wound Repair and Regeneration; 2012)	• Randomized controlled trial (RCT) • 3M™ Snap™ Therapy System vs V.A.C.® Therapy	• 132 patients (pts) with noninfected, nonischemic, nonplantar lower extremity diabetic and venous wounds were enrolled. • 115/132 pts had follow-up data available for analysis • 83 pts finished the study with either healing or 16 weeks of therapy: – 3M™ Snap™ Therapy System: 41 pts – V.A.C.® Therapy: 42 pts	• Primary endpoint was wound size reduction. • Baseline wound size: 3M™ Snap™ Therapy System: 5.37 ± 6.14 vs V.A.C.® Therapy: 9.95 ± 11.38 ($p<0.05$) – V.A.C.® Therapy wounds were significantly larger than 3M™ Snap™ Therapy System wounds. • Study was powered to demonstrate comparative efficacy, noninferiority. • In terms of wound size reduction, 3M™ Snap™ Therapy System pts demonstrated noninferiority to V.A.C.® Therapy pts at 4, 8, 12 and 16 weeks ($p=0.0030$, 0.0130, 0.0051, and 0.0044, respectively). • There were no significant differences in complete wound closure at all time points. • Rates of device-related adverse events and complications (e.g., infection) were also similar between groups. • Study demonstrated similar wound healing outcomes between 3M™ Snap™ Therapy System and V.A.C.® Therapy in the study population.
WA Marston et al[22] (Advances in Wound Care, 2015)	• RCT Sub-analysis[21] • 3M™ Snap™ Therapy System vs V.A.C.® Therapy	• 40 pts with venous leg ulcers – 3M™ Snap™ Therapy System (n=19) – V.A.C.® Therapy (n=21)	• Primary endpoint: wound size reduction. • There were differences in the mean initial wound size: 3M™ Snap™ Therapy System, 4.85 ± 4.49cm² vs V.A.C.® Therapy, 11.60 ± 12.12cm² • There was no significant difference (without [$p=0.3547$] or with [$p=0.4656$] adjustment for baseline wound size) in the proportion of pts that completely healed over time. • 3M™ Snap™ Therapy System pts had significantly greater percent wound closure than V.A.C.® Therapy pts at 4, 8, 12, and 16 weeks ($p=0.0039$, 0.0086, 0.0002, and 0.0005, respectively). • 50% wound closure at 30 days: 3M™ Snap™ Therapy System: 52.6% (10/19) pts vs V.A.C.® Therapy: 23.8% (5/21) pts (odds ratio [OR] 3.56, 95% confidence interval [CI] of [0.923, 13.699]). • Complete wound closure at 90 days: 3M™ Snap™ Therapy System: 57.9% (11/19) pts vs V.A.C.® Therapy: 38.15% (8/21) pts (OR, 2.23, 95% CI [0.63, 7.93]).

Table 1: Key clinical evidence supporting use of 3M™ Snap™ Therapy System (cont.)

Author	Study type	Patients	Results/conclusions
B Lerman et al[23] (Plastic and Reconstructive Surgery; 2010)	• Prospective comparative study • 3M™ Snap™ Therapy System vs patient-matched controls	• Prospective Study: 21 wound care center pts with refractory lower extremity ulcers treated with 3M™ Snap™ Therapy System over a period lasting up to 4 months. • Retrospective matched controls (2 unique matches per 3M™ Snap™ Therapy System patient): 42 pts treated over the preceding 4 years at the same clinic with modern wound care protocols including skin substitutes and skin grafting.	• Primary endpoint: Evaluate safety and efficacy of 3M™ Snap™ Therapy System for treatment of refractory lower extremity ulcers. • 3M™ Snap™ Therapy System group: – 100% (21/21) pts demonstrated reduced wound size – 86% (18/21) had a statistically significant healing trend ($p<0.05$) • Based on Kaplan-Meier estimates, mean time to healing for 3M™ Snap™ Therapy System group vs matched control group was 74.25 ± 20.1 vs 148.73 ± 63.1 days, respectively; $p<0.0001$. • This difference represented a 50% absolute reduction in time to healing for the 3M™ Snap™ Therapy System group. • The average difference in time to healing was also significantly ($p<0.0001$) shorter (54.27 ± 28.1 days), when individual 3M™ Snap™ Therapy System pts were compared to their 2 matched controls.
B Lerman et al[16] (Journal of Diabetes Science and Technology; 2010)	• Case Series • 3M™ Snap™ Therapy System	• 4 diabetic pts with refractory lower extremity wounds were treated with 3M™ Snap™ Therapy System in the outpatient WCC setting.	• 3M™ Snap™ Therapy System duration was 4 weeks in 3 pts and 6 weeks in 1 patient. • After use of 3M™ Snap™ Therapy System for wound bed preparation: – 2 wounds achieved complete wound closure – 1 wound was closed with a single application of a bi-layered skin substitute – 1 wound was closed with a skin graft
KD Fong et al[31] (Wounds; 2010)	• Case Series • 3M™ Snap™ Therapy System	• 12 consecutive adult pts with chronic wounds were followed biweekly for complications and wound healing over a 4-week period. • First clinical experience using 3M™ Snap™ Therapy System on pts.	• All 12 pts experienced at least partial wound healing after 3M™ Snap™ Therapy System treatment. • The 6 of 12 pts who met all study requirements had a statistically significant ($p<0.01$) mean wound area reduction of 97.2% at 4 weeks post 3M™ Snap™ Therapy System initiation. • Five of these 6 pts achieved complete wound healing.

Table 1: Key clinical evidence supporting use of 3M™ Snap™ Therapy System (cont.)

Author	Study type	Patients	Results/conclusions
S Bradbury et al[25] (Advances in Wound Care; 2015)	• Case Series • 3M™ Snap™ Therapy System	• Of 38 recruited pts, 37 received 2 weeks of 3M™ Snap™ Therapy System and were considered to be evaluable. • The Intention-to-treat analysis was based on data from the 37 evaluable pts who had 1 of 3 types of chronic ulcers: – Venous leg ulcers (n=15) – Mixed etiology leg ulcers (n=13) – Neuropathic foot ulcers (n=9) • Four patients discontinued the study shortly after 2 weeks of 3M™ Snap™ Therapy System. • The remaining 33 evaluable pts were followed for up to 6 weeks.	• Primary endpoint of percentage change in wound size was met with an overall: – Mean percentage decrease of 42.64% in wound area across the study population between weeks 1 and 8 – Mean reduction in wound size of 64% for venous leg ulcers and 55% for neuropathic foot ulcers • 15 (41%) pts developed wound infection. – Skin-related adverse events were more likely to occur in the leg ulcer groups
T Awad and M Butcher[26] (Wounds International; 2012)	• Case Series • 3M™ Snap™ Therapy System	• Middle-aged male with Type 2 diabetes and a history of 2 ulcerations presented with a new infected ulceration on his left foot over his previous ray amputation with exposed tendon.	• Antibiotic therapy was commenced. • 3M™ Snap™ Therapy System was applied with a moistened antimicrobial gauze-interface layer beneath the hydrocolloid dressing. • NPWT was initiated at -125mmHg; cartridge was attached to pt's leg to facilitate movement. • There was significant wound size reduction during and after discontinuation of 3M™ Snap™ Therapy System, wound achieved full closure. • Compared to the prior different 2 battery-powered NPWT devices, pt preferred 3M™ Snap™ Therapy System because it was light, portable, and easy to use.
K Neiderer et al[27] (Ostomy Wound Management; 2012)	• Case Series • 3M™ Snap™ Therapy System	• A 76-year-old male with a history of rheumatoid arthritis presented with a venous leg ulcer (1.8cm x 1.5cm) on his anterior left leg; the wound was re-diagnosed as pyoderma gangrenosum (PG) after failed treatment.	• Pt began treatment with APLIGRAF® (Organogenesis, Inc., Canton, MA) applied every 2 weeks for a total of 5 applications and 3M™ Snap™ Therapy System with twice weekly dressing changes. • Because of pt frailty, 3M™ Snap™ Therapy System was chosen because of its lightweight; initial negative pressure of -75mmHg was increased to -125mmHg after 4 weeks to better control exudate. • After 12 weeks, the wound decreased to 2.9cm x 2.5cm and fully epithelialized at 16 weeks after initiation of APLIGRAF® (Organogenesis, Inc., Canton, MA) and 3M™ Snap™ Therapy System.

Table 1: Key clinical evidence supporting use of 3M™ Snap™ Therapy System (cont.)

Author	Study type	Patients	Results/conclusions
G Bohn[28] (Journal of Wound, Ostomy and Continence Nursing; 2013)	• Case Series • 3M™ Snap™ Therapy System	• Haitian pt was treated for a pelvic fracture after the earthquake in January 2010. • Treatment included protective colostomy and suprapubic urinary catheter placement to protect against infection while injury healed.	• After 5 months, the colostomy was reversed resulting in a heavily colonized wound at the takedown site. • 3M™ Snap™ Therapy System was applied for approximately 2 weeks until the wound was small enough for superficial bandaging. • In this resource-poor setting, having mechanically powered NPWT was an advantage and allowed the patient to quickly return to normal activities. • The wound fully healed at about 3 weeks post colostomy reversal.
T Awad and M Butcher[29] (Journal of Wound Care; 2013)	• Case Series • 3M™ Snap™ Therapy System	• A 38-year-old woman was treated for breast cancer with chemotherapy, breast cancer surgery and postoperative radiotherapy. • Development of a seroma during radiotherapy eventually resulted in full suture line dehiscence, revealing a deep cavity lined with necrotic tissue. • Post 2 weeks of treatment with debridement, the peri-axillary wound was 6cm long, ≥6cm deep and lined with soft residual slough.	• When NPWT was recommended, the pt chose 3M™ Snap™ Therapy System because she could work and take care of her family without others being aware that she was undergoing treatment. • After 6 weeks of treatment, the wound was <1.5cm deep, and 3M™ Snap™ Therapy System was replaced with dressings until wound closure.
AL Isaac et al[30] (Plastic and Reconstructive Surgery – Global Open; 2014)	• Case Series • 3M™ Snap™ Therapy System	• An 83-year-old woman with Type 2 diabetes and peripheral neuropathy presented with a large painful wound on the medial aspect of the left ankle. • First reported use of 3M™ Snap™ Therapy System to bolster a skin graft.	• Following wound debridement and skin graft placement, 3M™ Snap™ Therapy System set at -75mmHg was placed as a bolster for 4 days. • At 4 weeks, the graft was almost completely epithelialized, and the wound was closed by 12 weeks.
Hutton DW, Sheehan P[34] (International Wound Journal; 2011)	• Health economics analysis • 3M™ Snap™ Therapy System versus V.A.C.® Therapy and standard of care modern wound dressings	• An economic model using peer reviewed data was used to simulate outcomes for three wound care therapies for diabetic lower extremity wounds were analyzed.	• The base case assumes that 3M™ Snap™ Therapy System has better effectiveness than modern dressings and equal effectiveness to powered negative pressure wound therapy. • 3M™ Snap™ Therapy System saves $9699 (42%) over modern dressings, $2774 (17%) over powered NPWT for a private payor and $2296 (15%) over powered NPWT for Medicare.

Technology for 3M™ Snap™ Therapy System

In the mechanically powered Snap Therapy System, a set of specialized constant force springs creates the forced air expansion that maintains a predetermined negative pressure[32] even as the built-in canister fills with exudate. The cartridge uses a technology which turns the exudate into a gel to optimize containment. The use of mechanical (rather than electrical) power provides silent therapy that can facilitate discreet treatment in a work or social environment and cause less sleep disruption.

Similar to electrically-powered NPWT systems, mechanically-powered Snap Therapy System draws wound edges together and removes infectious material and exudate from the wound **(Figure 2)**.

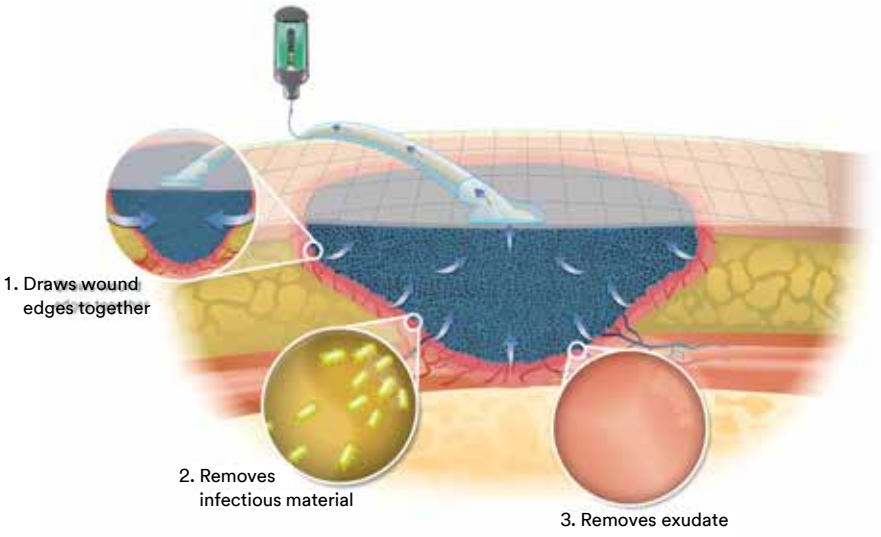


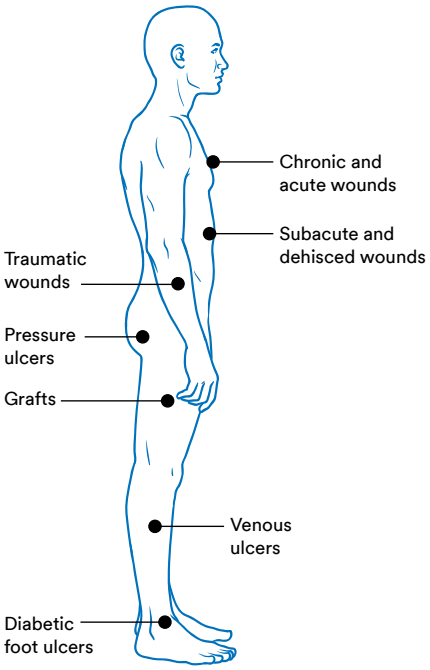
Figure 2. Snap Therapy System helps to promote wound healing by drawing wound edges together and removing small amounts of infectious material and exudate.

Indications for use

The Snap Therapy System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The Snap Therapy System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous, or pressure), surgically closed incisions, flaps and grafts.

Contraindications

- The 3M™ Snap™ Therapy System should not be applied over:
- Inadequately drained wounds
- Necrotic tissue, such as eschar or adherent slough
- Exposed blood vessels, anastomotic sites, organs, tendons or nerves
- Wounds containing malignancy
- Fistulas
- Untreated osteomyelitis
- Actively bleeding wounds



Warnings, precautions, and limitations

The 3M™ Snap™ Therapy Cartridge and fitting are not indicated for use in a hyperbaric oxygen therapy environment.

It is important to read and follow all instructions and safety information prior to use for any NPWT device.

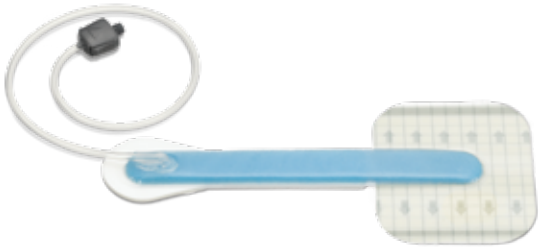
3M™ Snap™ Therapy System components

The Snap Therapy System cartridge, strap, interface layer and dressings are described in Table 2.

Table 2: 3M™ Snap™ Therapy System components

Name/description	Picture
3M™ 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. The exudate is turned into a gel to optimize containment.	
3M™ Snap™ Plus -125mmHg Therapy Cartridge A larger 3M™ Snap™ Therapy Cartridge is available that holds up to 150ml of exudate and delivers -125mmHg of negative pressure. The 150ml cartridge uses a technology which turns the exudate into a gel to optimize containment.	
3M™ 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").	
3M™ 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.	

Table 2: 3M™ Snap™ Therapy System components (cont.)

Name/description	Picture
3M™ Snap™ SecurRing™ Hydrocolloid Skin Barrier The Snap™ SecurRing™ Hydrocolloid Skin Barrier increases the adhesion of the 3M™ Snap™ Dressing on dry and uneven skin.	
3M™ Snap™ Advanced Dressing Kit Snap Advanced Dressing Kit includes the foam interface layer, hydrocolloid dressing (15cm x 15cm or 10cm x 10cm) with fully-integrated microport that allows a tight bending radius for wounds in difficult locations, and cut-to-length tubing with integrated one-way flow valve. The dressing can be customized and shaped to fit around challenging body contours to facilitate sealing.	
3M™ Snap™ Bridge Dressing Kit The Snap Bridge Dressing Kit includes the foam interface layer and a completely flat dressing (14cm x 11cm, or 14cm x 11cm with 3M™ Snap™ SecurRing™ Hydrocolloid Skin Barrier) to help minimize pressure damage and has a built-in bridge and port for one-step application. There is soft pad cushioning under the foam bridge to improve patient comfort.	

Science supporting 3M™ Snap™ Therapy System

Scientific studies have been conducted to evaluate the ability of Snap Therapy 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 Therapy 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 Therapy 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 Therapy System's ability to produce granulation tissue. Rats with surgically created 2.5cm x 3cm wounds were treated with either Snap Therapy System at -125mmHg or the Snap Dressing without negative pressure. Animals treated with Snap Therapy 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 Therapy System may have efficacy equal to that of vacuum assisted closure for some wounds."[32]

Case studies

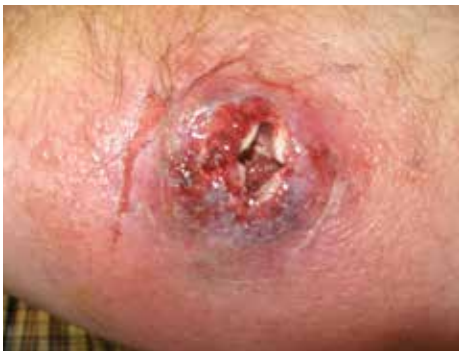
As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on the patient's circumstances and condition.

Case study 1: Venomous insect bite

Patient was a 58-year-old male who presented with an apparent insect bite on the left forearm. He initially noted a red pimple forming on the skin which rapidly enlarged over 2 weeks with increasing pain and swelling of the arm. He was immediately referred for hyperbaric oxygen therapy (HBOT) which was started the next day.

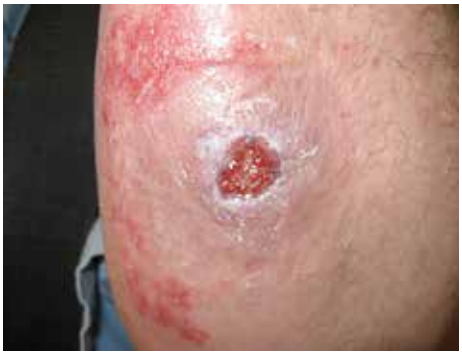
Irrigation and drainage was completed 48 hours after his initial presentation which revealed a large, crater-like defect extending to the muscle with minimal exudate or purulence (**Figure 3A**). After 2 days of wound packing with silver alginate and continued HBOT, the peri-wound inflammation had subsided and the wound bed color had improved. Continuous negative pressure therapy using the 3M™ Snap™ -125mmHg Therapy Cartridge with the 3M™ Snap™ Advanced Dressing Kit was initiated (**Figure 3B**), and after only two dressing applications the wound volume was completely reduced (**Figure 3C**). The patient was able to continue working while utilizing negative pressure and did not require disability. He went on to complete closure, only requiring 17 HBOT treatments and 6 weeks of care (**Figure 3D**).

Figure 3. Venomous insect bite

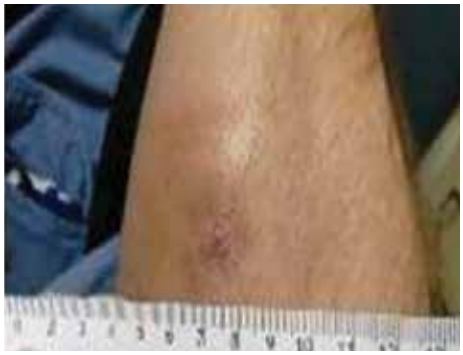


A. Wound appearance after irrigation and drainage; 48 hours after presentation.

B. Application of 3M™ Snap™ Therapy System, 2 days post irrigation and drainage.



C. Reduced wound volume after two dressing applications.



D. Wound closure after 6 weeks.

Patient data and photos courtesy of Christopher L. Barrett, DPM, CWS, FACCWS; Crozer Chester Medical Center, Chester, PA

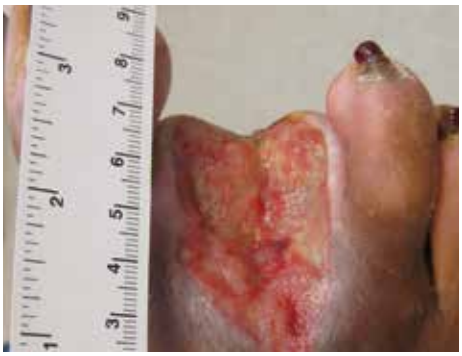
Case study 2: Diabetic amputation wound

A 62-year-old female was hospitalized for infected gangrenous toes resulting from her neuropathic diabetes and peripheral vascular disease. The patient was taken to the operating room and found to have osteomyelitis of the 2nd and 3rd ray and underwent partial amputations. The resulting wound was extensive, involving all the soft tissue overlying the metatarsophalangeal joints and extending to the mid shaft of the 2nd and 3rd metatarsals. When the patient presented to the wound care center, the wound bed had become necrotic with exposed bone and calcified vessels. She underwent debridement and dressing changes with Dakin's Solution® (quarter strength) (Century Pharmaceuticals, Inc., Indianapolis, IN). After approximately 1 month of traditional wound therapy, the infection appeared to have cleared, but there remained a large wound with exposed bone and minimal granulation tissue.

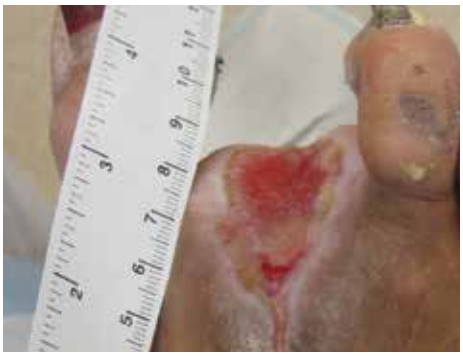
Prior to treatment with the 3M™ Snap™ Therapy System, the wound measured 65mm x 36mm with a depth of 6mm without undermining (**Figure 4A**). The patient had a complex medical history, most notable for insulin-dependent diabetes, peripheral vascular disease, hypertension, and hyperlipidemia.

The patient achieved full granulation of the wound bed and complete soft-tissue coverage of exposed bone as a result of 4 and 6 weeks of treatment with the Snap Therapy System with bi-weekly dressing changes (**Figures 4B and 4C**). The wound was then closed with an advanced cellular matrix. Wound closure was achieved at 10 weeks post-initiation of the Snap Therapy System (**Figure 4D**).

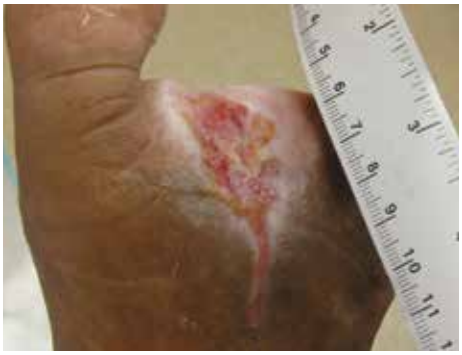
Figure 4. Diabetic amputation wound



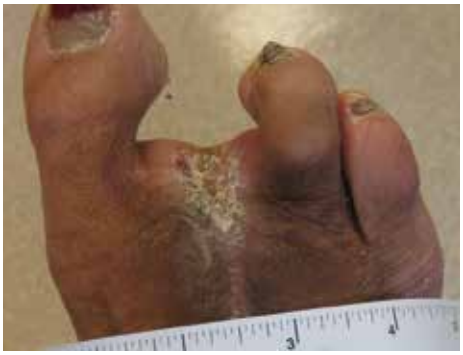
A. Wound at start of 3M™ Snap™ Therapy System.



B. Development of granulation tissue after 4 weeks of 3M™ Snap™ Therapy System.



C. Further granulation tissue development after 6 weeks of 3M™ Snap™ Therapy System.



D. Wound fully healed 11 weeks post presentation.

Photos courtesy of Armstrong DEG, Marston WA, Reyzelman AM, Kirsner RS

Case study 3: Trauma wound to the lower extremity

Patient:

An 83-year-old, healthy female presented to the clinic with a wound to the left lower extremity (LLE). The wound had its provenance from the patient falling from a ladder, and had resulted in subcutaneous hematoma, an extensive cavity and a necrotic flap of the anterior left leg (**Figure 5A**). The patient had been placed on cephalexin by the Emergency Department.

Diagnosis:

The patient had a traumatic wound to the LLE that measured 7 × 5 × 3cm3 with 10cm tunneling and extension to fascia/muscle. To address the traumatic wound, surgical debridement was performed to evacuate the residual hematoma and excise portions of the necrotic flap. The resultant defect was initially treated with a daily, wet-dry, antimicrobial packing using hypochlorous acid solution (Vashe® Urgo Medical North America, Fort Worth, TX) until the tunnel was resolved (3 weeks). Then the wound was managed via the application of a disposable negative pressure wound therapy modality to facilitate wound healing.

Course of treatment/Application of the 3M™ Snap™ Therapy System:

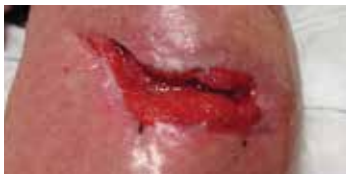
By Day 22, the wound dimensions measured 6 × 2.5 × 1.5cm3 (**Figure 5B**), and wound management transitioned to treatment using the Snap Therapy System. The Snap Therapy System foam interface dressing was applied over the wound, the 3M™ Snap™ Advanced Dressing was applied to establish a seal (**Figure 5C**). The 3M™ Snap™ Therapy Cartridge administered -125mmHg of subatmospheric pressure. The Snap Therapy System was applied twice weekly. After 3 days (Day 25) of Snap Therapy System use, the wound was evaluated and much of the undermining had resolved (**Figure 5D**). For the second Snap Therapy System application (Day 25), the wound received porcine small intestinal submucosa (SIS) matrix (Oasis® Wound Matrix; Smith & Nephew plc, London, UK) to facilitate native tissue growth (**Figure 5E**). The Snap Therapy System was reapplied to the wound as a bolster using a 3M™ Snap™ Bridge Dressing over the foam wound interface (**Figure 5F**). After 7 days (Day 32), the wound measured 4 × 2.2 × 0.3cm^3 and use of the Snap Therapy System was discontinued (**Figure 5G**).

Discharge and follow-up:

After only 10 total days, the wound bed was prepared for grafting. To promote wound closure, the patient received epidermal grafts harvested using the 3M™ Cellutome™ Epidermal Harvesting System. After 62 days of wound management that enlisted debridement, wet-dry antimicrobial packing, use of the Snap Therapy System, the application of SIS matrix, and epidermal grafting, the wound was completely healed (**Figure 5H**).

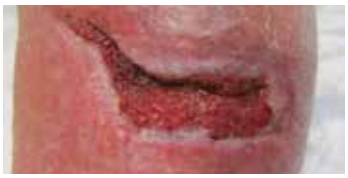
Figure 5. Trauma wound to the lower extremity

A. Traumatic wound to the LLE at initial presentation.



B. Traumatic wound (post debridement and wet-dry packing) at Day 22.

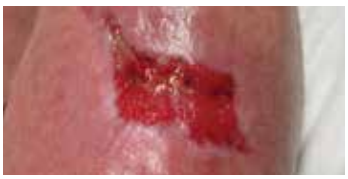
C. Traumatic wound (post debridement and wet-dry packing) at Day 22 with 3M™ Snap™ Therapy System applied over 3M™ Snap™ Therapy System foam wound interface.



D. Wound after 3 days use of the 3M™ Snap™ Therapy System.

E. Porcine small intestinal submucosa matrix grafting applied to wound bed.

F. 3M™ Snap™ Therapy System reapplied to wound using 3M™ Snap™ Bridge Dressing over the 3M™ Snap™ Therapy System foam interface as a bolster over the graft.



G. Wound after 10 days use of the 3M™ Snap™ Therapy System.

H. Healed traumatic wound 4-weeks post epidermal grafting at Day 62.

Patient data and photos courtesy of Animesh Bhatia, DPM, CWS, Columbus Podiatry and Surgery, Inc., Columbus, OH

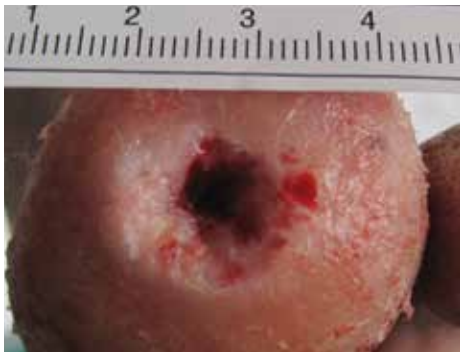
Case study 4: Diabetic hallux wound

The patient was a 52-year-old male with an ulcer on his left hallux present for 9 months. He reported the ulcer first appeared as a blister from a pair of tight fitting shoes. Previous medical history included diabetes mellitus. Previous treatments included daily silver sufadiazine dressing changes and weekly debridement. The wound extended to bone and required aggressive bedside debridement. Following debridement, the wound measured 9mm x 8mm with a depth of 20mm without undermining (**Figure 6A**).

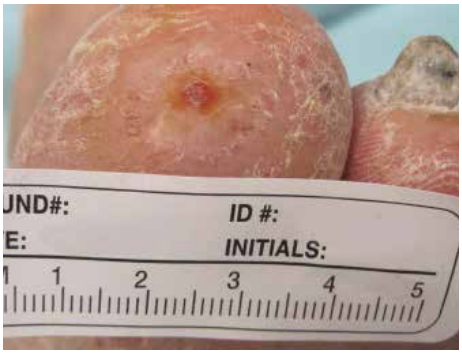
The patient was started on the 3M™ Snap™ Therapy System to help granulate the wound. At week 5, Snap Therapy System use was discontinued due to the small size of the wound, and a cellular tissue product was applied (**Figure 6B**). The patient was continued in a postoperative shoe and crest pad. One week after the cellular tissue product application, 8 weeks post presentation, the wound was completely epithelialized (**Figure 6C**). The patient was followed for an additional 2 months at increasing intervals and the wound remained healed.

Figure 6. Diabetic hallax wound

A. Wound at start of 3M™ Snap™ Therapy System use.



B. Wound after 5 weeks of 3M™ Snap™ Therapy System use.



C. Wound fully epithelialized 8 weeks post presentation.

Photos courtesy of Armstrong DEG, Marston WA, Reyzelman AM, Kirsner RS

Case Study 5: Pressure injury

Patient:

An 85-year-old female presented to the clinic with a calcaneal pressure injury. The patient's medical history included peripheral vascular disease, hypertension, hyperthyroidism, neuropathy, chronic kidney disease, cataracts, cardiomyopathy, and ischemic polymyalgia rheumatica.

Diagnosis:

The patient had a 30-day-old stage 3 pressure injury on the right heel (**Figure 7A**). Resolution of the pressure injury called for a multimodal approach including a disposable negative pressure wound therapy system to facilitate closure of the pressure injury.

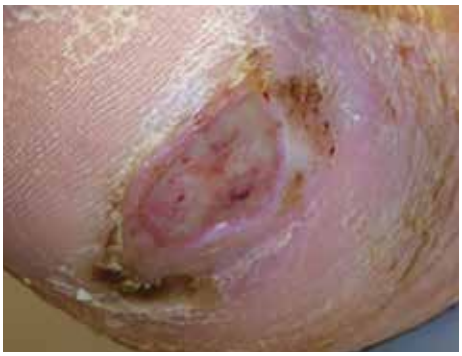
Course of treatment/Application of the 3M™ Snap™ Therapy System:

The calcaneal pressure injury would be a recipient site for an epidermal graft. To prepare the donor site for epidermal harvesting, the patient's thighs underwent depilation, and were washed with isopropyl alcohol. The vacuum head of the 3M™ Cellutome™ Epidermal Harvesting System was attached to the donor site to apply subatmospheric pressure (-400mmHg to -500mmHg) and warmth (37°C to 41°C) to generate epidermal microdomes for harvest. Following epidermal grafting, the Snap Therapy System was enlisted to bolster the graft. To protect the epidermal graft, a non-adherent silicone dressing (3M™ Adaptic™ Touch Non-Adhering Silicone Dressing) was applied. The Snap Therapy System, foam interface dressing was applied over the protected epidermal graft, and the 3M™ Snap™ Advanced Dressing was applied over the foam interface to establish a seal. The 3M™ Snap™ Therapy Cartridge administered -125mmHg of subatmospheric pressure.

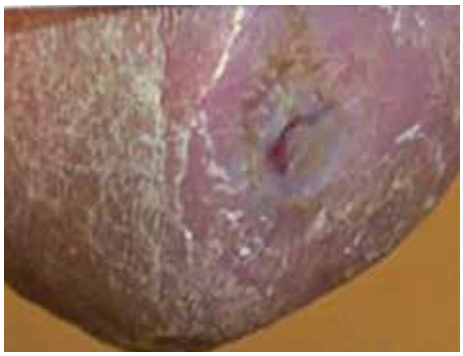
Discharge and follow-up:

The pressure wound was evaluated after the Snap Therapy System was discontinued. The pressure wound then underwent a round of sharp excisional debridement, and treatment transitioned to oxidized regenerated cellulose (ORC)/collagen/silver-ORC dressing (3M™ Promogran Prisma™ Matrix) and compression therapy with an Unna boot. The donor site healed without complications by 2 weeks post epidermal graft harvesting. The pressure wound was fully closed without complications at the 2-month follow-up visit (**Figure 7B**).

Figure 7. Pressure injury



A. Wound at presentation.



B. Wound fully closed at 2-month follow-up visit.

Patient data and photos courtesy of Animesh Bhatia, DPM, CWS, Columbus Podiatry and Surgery, Inc., Columbus, OH

Case Study 6: Venous ulcer

Patient:

An 80-year-old female presented to the clinic with a chronic venous stasis ulcer of the lower extremity, which resulted from blunt trauma with the corner of a table (**Figure 8A**). The patient's medical history included venous insufficiency and chronic lower extremity edema.

Diagnosis:

The patient had a chronic venous stasis ulcer, which necessitated excisional debridement of the necrotic tissue from the lower extremity, and a multimodal approach to facilitate wound healing.

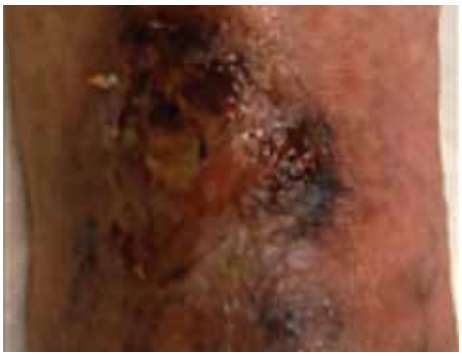
Course of treatment/Application of the 3M™ Snap™ Therapy System:

The venous stasis ulcer initially underwent sharp debridement and soaking with a stabilized hypochlorous acid solution, followed by coverage with an alginate and a foam dressing. A 2-layer compression kit was subsequently applied over the dressed wound. The wound was debrided weekly between dressing changes, and the patient was administered a prophylactic regimen of antibiotics. At post-treatment Day 17, the wound underwent further debridement, and the Snap Therapy System was initiated (**Figure 8B**). The Snap Therapy System dressings were changed twice per week. At post-treatment Day 73, the Snap Therapy System was discontinued; however, topical therapy with compression continued (**Figure 8C**).

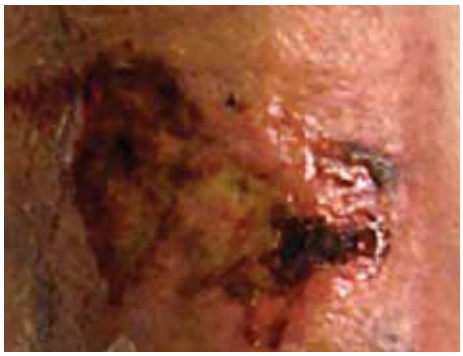
Discharge and follow-up:

At post-treatment Day 133, wound was near full reepithelialization after topical therapy and compression (**Figure 8D**). Placental allograft was used to facilitate wound closure. By post-treatment Day 196, the wound had completely reepithelialized (**Figure 8E**).

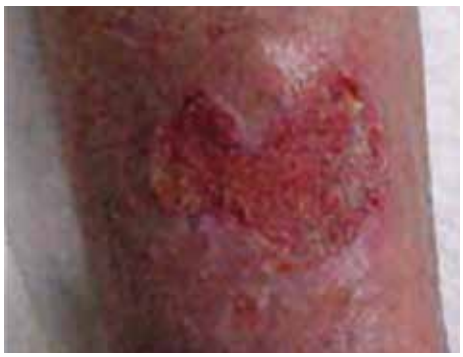
Figure 8. Venous ulcer



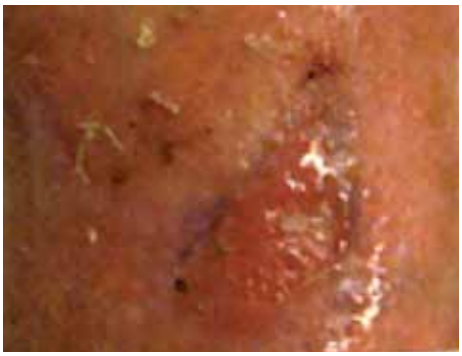
A. Chronic venous stasis ulcer at presentation.



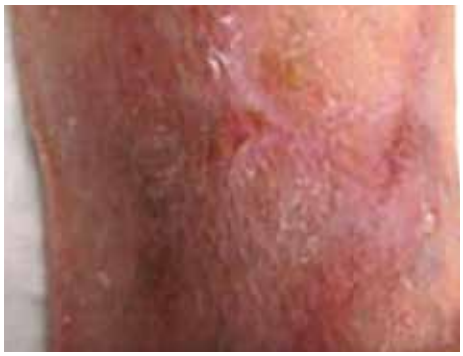
B. Wound at post-treatment Day 17 and prior to the initiation of the 3M™ Snap™ Therapy System.



C. Wound after discontinuance of the 3M™ Snap™ Therapy System at post-treatment Day 73.



D. Wound at post-treatment Day 133 after topical therapy with compression.



E. Wound closure on post-treatment Day 196.

Patient data and photos courtesy of William H. Tettelbach, MD, FACP, CWS, Wound Care & Hyperbaric Medicine Clinical Services, Intermountain Healthcare, Salt Lake City, UT

Case Study 7: Dehisced wound

Patient:

A 66-year old male underwent an open reduction internal fixation (ORIF) procedure of the left ankle.

Diagnosis:

Twenty-one days post ORIF, the patient presented with a dehisced ankle wound (**Figure 9A**).

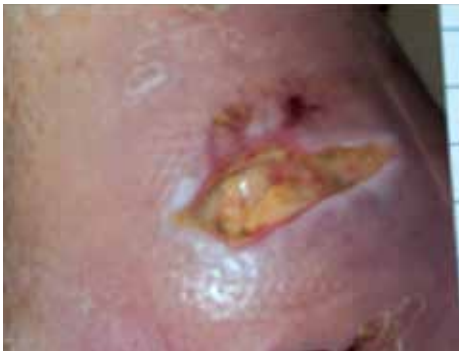
Course of treatment/Application of the 3M™ Snap™ Therapy System:

A peripherally inserted central catheter was placed, and a culture-specific antibiotic regimen (vancomycin) was administered for 14 days. The dehisced wound also received excisional debridement. The Snap Therapy System was applied over the wound. The foam interface dressing was applied within the wound, and the 3M™ Snap™ Advanced Dressing was applied over the foam interface to establish a seal. The 3M™ Snap™ Therapy Cartridge administered -125mmHg of subatmospheric pressure, and dressing changes occurred twice weekly. After 2 weeks of the Snap Therapy System, the wound was debrided to reduce slough (**Figure 9B**). After 4 weeks, the Snap Therapy System was discontinued. At week 5, wound management transitioned to the application of an oxidized regenerated cellulose (ORC)/collagen/silver-ORC dressing (3M™ Promogran Prisma™ Matrix) to the granulated wound bed to facilitate closure (**Figure 9C**).

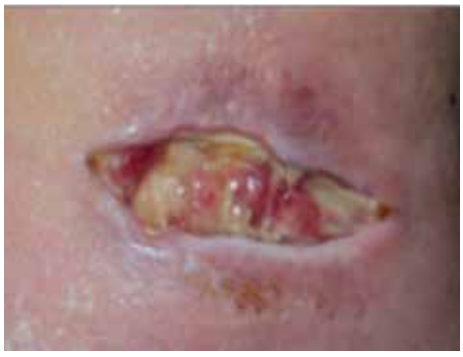
Discharge and follow-up:

At 7 weeks, the wound exhibited reepithelialization (**Figure 9D**). At the follow-up appointment, the wound demonstrated an uneventful resolution via secondary closure at 14 weeks (**Figure 9E**).

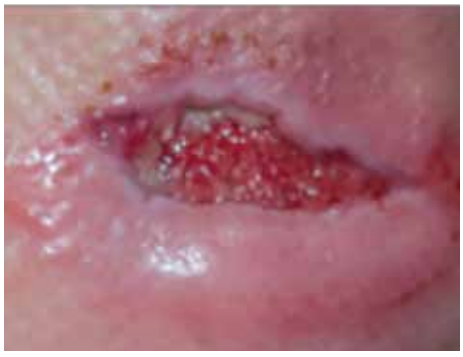
Figure 9. Venous ulcer



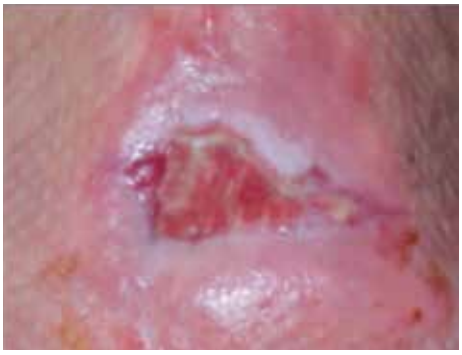
A. Dehisced ankle wound at presentation post ORIF.



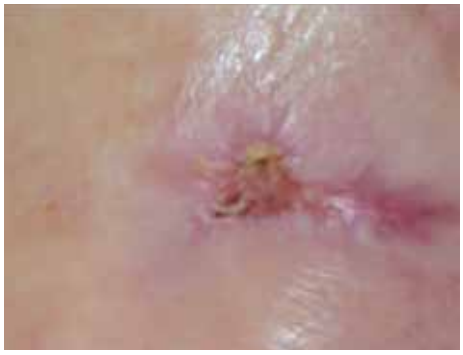
B. Slough was reduced after debridement and 2 weeks of the 3M™ Snap™ Therapy System.



C. The 3M™ Snap™ Therapy System was discontinued at 4 weeks: 3M™ Promogran Prisma™ Matrix at 5 weeks and wound remained granulated.



D. Epithelializing wound at 7 weeks.



E. Wound was healed at 14 weeks.

Patient data and photos courtesy of Marcus Speyrer, RN, CWS; and Kerry T. Thibodeaux, MD, FACS, The Wound Treatment Center, Opelousas, LA

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