EXPERT RECOMMENDATIONS FOR THE USE OF MECHANICALLY-POWERED Negative Pressure Wound Therapy

Donna Bond Becker, MSN, ACNP-BC
Lou D’Oro, MD
M. Dolores Farrer, DPM, MBA, CWS
Jeffrey Frenchman, DPM
Lawrence Harkless, DPM

Jake P. Heiney, MD, MS
Jodi Walters, DPM
Dot Weir, RN, CWON, CWS
Karin Zachow, MD, CWS

Supported by Spiracur Inc.

This supplement was not subject to WOUNDS® peer-review process.
Meeting Participants

M. Dolores Farrer, DPM, MBA, CWS, Dorn VA Medical Center, Columbia, South Carolina

Donna Bond Becker, MSN, ACNP-BC, Wound Care Specialist, Wound Healing Center Greenville, South Carolina VA OPC

Lou D’Oro, MD, VAMC Wilkes-Barre, Wilkes-Barre, Pennsylvania

Jeffrey Frenchman, DPM, Atlanta VAMC, Decatur, Georgia

Lawrence Harkless, DPM, Dean, Western University of Health Sciences, Pomona, California

Jake P. Heiney, MD, MS, President and CEO, Cutting Edge Orthopedics, LLC, University of Toledo Medical Center, St. Vincent Medical Center, Sylvania, Ohio

Jodi Walters, DPM, Diplomat, American Board of Podiatric Surgery, Southern Arizona VA Healthcare System (SAVAHCS), Tucson, Arizona

Dot Weir, RN, CWON, CWS, Osceola Regional Medical Center, Kissimmee, Florida

Karin Zachow, MD, CWS, Director, Multidisciplinary Wound Clinic, Bruce W Carter VA (Miami), Miami, Florida

Disclosures

Donna Bond Becker, MSN, ACNP-BC: Nothing to disclose

Lou D’Oro, MD, VAMC: Nothing to disclose

M. Dolores Farrer, DPM, MBA, CWS: Nothing to disclose

Jeffrey Frenchman, DPM: Nothing to disclose

Lawrence Harkless, DPM: Speaker's bureau—Organogenesis Inc.; advisory board—Anacor Pharmaceuticals, Inc.

Jake P. Heiney, MD, MS: Speaker and paid & unpaid consultant—Spiracur Inc.

Jodi Walters, DPM: Nothing to disclose

Dot Weir, RN, CWON, CWS: Speaker and consultant—Spiracur Inc.; speaker’s bureau—Healthpoint Biotherapeutics, Hollister, Organogenesis Inc., Mölnlycke Health Care

Karin Zachow, MD, CWS: Nothing to disclose

Acknowledgements

This article is financially supported by Spiracur Inc. The authors would like to thank Kristen Eckert, M. Phil, and Marissa Carter, PhD, MA for editorial and manuscript assistance. This supplement is provided as a courtesy to the readers of WOUNDS. This supplement was not subject to the peer-review process of WOUNDS.
# Table of Contents

Purpose of this Supplement ................................................................................................................................................. 4

1. Overview and Evolution of Negative Pressure Wound Therapy (NPWT) ......................................................... 5

2. Introduction to the SNaP Device for Mechanically Powered Negative Pressure Wound Therapy (MPNPWT) ........................................................................................................................................... 8

   2.1 How to Apply and Use the SNaP Device ........................................................................................................ 8

3. Effectiveness of MPNPWT: An Evidence-Based Review ......................................................................................... 10

4. Advantages of MPNPWT ............................................................................................................................................. 11

   4.1 MPNPWT and Quality of Life: A Major Improvement .............................................................................. 11

   4.2 Benefits of an Improved Safety Profile with MPNPWT ........................................................................... 11

   4.3 Cost-effectiveness of MPNPWT ............................................................................................................. 12

   4.4 Other Advantages of MPNPWT ............................................................................................................. 13

5. Contraindications and Disadvantages of MPNPWT ............................................................................................... 14

6. Patient Selection and Wounds Best Suited For MPNPWT .................................................................................... 15

   6.1 Case 1: Recurrent Venous Leg Ulcer ........................................................................................................ 15

   6.2 Case 2: Diabetic Foot Wound ................................................................................................................... 15

7. When to Initiate or Transition to MPNPWT? ......................................................................................................... 16

8. When to Stop MPNPWT? .......................................................................................................................................... 16

9. Using Combination Therapy and Other Advanced Modalities with MPNPWT ........................................... 17

10. Pressure Level Selection ......................................................................................................................................... 18

11. Summary of Key Consensus Statements ........................................................................................................... 18

---

©2013 HMP Communications, LLC (HMP). All rights reserved. Reproduction in whole or in part prohibited. Opinions expressed by authors, contributors, and advertisers are their own and not necessarily those of HMP Communications, the editorial staff, or any member of the editorial advisory board. HMP Communications is not responsible for accuracy of dosages given in articles printed herein. The appearance of advertisements in this supplement is not a warranty, endorsement, or approval of the products or services advertised or of their effectiveness, quality, or safety. HMP Communications disclaims responsibility for any injury to persons or property resulting from any ideas or products referred to in the articles or advertisements. Content may not be reproduced in any form without written permission. Reprints of articles are available. Rights, permission, reprint, and translation information is available at: www.hmpcommunications.com.

HMP Communications, LLC (HMP) is the authoritative source for comprehensive information and education servicing healthcare professionals. HMP’s products include peer-reviewed and non-peer-reviewed medical journals, national tradeshows and conferences, online programs, and customized clinical programs. HMP is a wholly owned subsidiary of HMP Communications Holdings LLC. Discover more about HMP’s products and services at www.hmpcommunications.com.
This supplement was developed to provide expert opinion and guidance on the appropriate use of mechanically powered negative pressure wound therapy (MPNPWT). In general, negative pressure wound therapy (NPWT) is an advanced therapy for wound management that applies subatmospheric pressure to wounds to remove exudates, infectious material, and tissue debris while mechanically stimulating the wound bed to promote healing. NPWT is one of the most studied advanced therapies in wound care with over 1,000 peer-reviewed articles from the past two decades that support the use of NPWT for a variety of wound types, including diabetic foot ulcers, venous leg ulcers, pressure ulcers, surgical wounds, and trauma wounds. NPWT has evolved in recent years through the advent of MPNPWT devices, which are designed to improve patient quality of life, ease of use, patient adherence, and costs associated with NPWT treatment. This new way of delivering NPWT is rapidly changing how clinicians are practicing wound care, and this supplement is intended to provide a reference for guiding clinicians on how to fully utilize this emerging technology as standards of care continue to evolve.

Ten experienced wound care specialists reviewed the current evidence for the use of MPNPWT and discussed their clinical experience working with the SNaP® Wound Care System, an ultraportable, single-use MPNPWT device that has FDA (United States Food & Drug Administration) clearance for the treatment of chronic and acute wounds. The objectives of this meeting were to provide consensus on: (1) definitions of NPWT options, devices, and components; (2) the goals of MPNPWT therapy; (3) the benefits and drawbacks of MPNPWT over traditional NPWT; (4) a review of clinical evidence in making MPNPWT decisions; (5) when to initiate MPNPWT and the transition point from standard dressings or traditional NPWT to MPNPWT; (6) the patient/wound selection process for MPNPWT; and (7) recommendations regarding the optimal use of MPNPWT with other advanced modalities. The overall goal of these objectives is to provide MPNPWT guidelines based on the clinical literature on NPWT and clinical experience to educate clinicians on the use of MPNPWT in their clinical practices.

These guidelines are not intended to be an exhaustive review of wound care management. They were generated from a select number of key discussion items for the optimal application of MPNPWT, which were addressed by the meeting participants’ extensive clinical experience with the application of MPNPWT on wounds. The meeting participants from academic, Veteran Administration (VA), and private wound care clinical settings provided diverse perspectives that were generally experience-generated. M. Dolores Farrer, DPM, MBA, CWS at the Dorn VA Medical Center in Columbia, South Carolina, moderated the discussion. Following the meeting, draft guidelines based on the group discussion were written and finalized with the revisions and input of all meeting participants.
Overview and Evolution of Negative Pressure Wound Therapy (NPWT)

NPWT is an advanced wound therapy that applies subatmospheric pressure to the wound to stimulate healing and closure. NPWT promotes the healing process by maintaining an optimal moist wound environment, reducing peri-wound edema and bioburden, promoting granulation tissue formation through macro- and micro-deformation of tissues, and increasing wound perfusion. Although NPWT was initially developed for the treatment of acute wounds after surgery or trauma, there has been increasing emphasis on the treatment of chronic wounds with NPWT in recent years.

A chronic wound is one of the most challenging and frustrating conditions for clinicians to treat, with significant associated morbidity and mortality. Chronic wounds often require costly long-term treatments that greatly reduce the patient’s quality of life (QOL) and can be a significant burden to the patient’s family members and caregivers. Approximately 24% of refractory diabetic neuropathic ulcers treated with conventional therapy heal at 12 weeks, and only an estimated 31% heal at 20 weeks. After 5 years, the mortality rates of diabetic patients with neuropathic and ischemic ulcers are approximately 45% and 55%, respectively. Healing rates are not much better for venous leg ulcers (VLUs) with less than 40% healed at 12 weeks, and approximately 50% healed at 24 weeks. Importantly, if there is no significant wound healing progress observed in chronic wounds after 4 weeks, it is considered standard of care to re-assess treatment and consider the application of an advanced therapy, such as NPWT, to a wound as an adjunct to conventional moist wound dressings.

Multiple studies now demonstrate that NPWT is a safe, effective, and cost-effective therapy for treating chronic wounds, and there currently exist more randomized controlled trial (RCT) evidence for the effectiveness of NPWT for chronic wounds than for acute wounds. A recent meta-analysis was performed of 10 RCT utilizing NPWT to specifically evaluate the data supporting the use of NPWT on chronic wounds. The studies included compared NPWT to conventional moist wound therapy. Pooled data indicated that for the NPWT group, there was a significant decrease in wound size compared to the standard moist wound therapy group [relative change ratio, 0.77; 95% confidence interval (CI), 0.63 to 0.96]. There was also a significant decrease in the time to heal in the NPWT group versus the standard moist wound therapy group (ratio of median time to healing, 0.74; 95% CI, 0.70 to 0.78). The authors concluded that NPWT offers a significant benefit for the treatment of chronic wounds and is superior to conventional standard modern dressings.

Diabetic foot ulcers are a chronic wound type that has been studied extensively with NPWT treatment. An evidence-based consensus was developed in 2004 and updated in 2006 on the use of NPWT on DFUs and recommended the beneficial effects of NPWT on DFUs when used following debridement and reconstructive surgery for promoting adequate blood flow, providing infection control, and maintaining a wound environment that is beneficial to the healing process. More recently, a large RCT compared NPWT with alginate or hydrogel dressings in 342 patients with DFUs, noting faster healing rates and fewer amputations and a 60% reduction in reamputations in the NPWT group. The authors also observed no significant difference in infection, cellulitis, and osteomyelitis rates between groups at 6 months. They concluded that NPWT appears to be as safe as and more effective than moist wound therapy. A RCT conducted by Armstrong and Lavery, in which the effects of NPWT after partial diabetic foot amputation were studied, showed similar results and conclusions. A 75% reduction in reamputations in the NPWT group was observed with significant improvement in the proportion healed after just 3 weeks. Secondary analysis focused on the role of wound chronicity with NPWT, by evaluating the healing rates and outcomes of the acute wounds (<30 days after amputation) and chronic wounds (>30 days after amputation) that were treated with NPWT or conventional therapy. Healing rates were statistically significantly faster in the NPWT group in both acute (P=0.030) and chronic wounds (P=0.033); thus, wound chronicity should not be initially considered a factor of NPWT efficacy.

NPWT has also been studied and shown to be effective in the treatment of VLUs. Vuerstaek et al performed a RCT comparing NPWT to standard of care with hydrogel or alginate dressings in 60 patients with VLUs or combined venous/arterial leg ulcers. NPWT required significantly less time for wound bed preparation than moist wound therapy (7 days versus 17 days, 95% CI, P=0.005); NPWT healed wounds 35% faster than conventional therapy; and NPWT was more cost-effective with the average cost to heal a wound at $3,881 with NPWT versus $5,452 with moist wound dressings. The
authors recommended NPWT as the preferred treatment option for chronic VLUs in conjunction with compression therapy.

Although less studied, there is some evidence for the effectiveness of NPWT for the treatment of pressure ulcers (PUs). Ford et al\textsuperscript{14} performed a RCT that evaluated the use of NPWT compared to 3 topical wound products on PUs: Accuzyme, Panafil, and Iodosorb. During the 6-week treatment period, the mean reduction in ulcer volume in the NPWT and topical groups was 51.8% and 42.1%, respectively, trending towards significantly better improvement with NPWT. There were also decreased markers of inflammation and increased numbers of capillaries in the NPWT group, supporting the role of NPWT in optimizing the wound bed. Following biopsies, osteomyelitis was diagnosed in 15 cases, 3 of which (37.5%) improved with NPWT, while none improved with the other topical therapies, suggesting that NPWT may be used effectively with systemic antibiotic therapy for osteomyelitis. A recent meta-analysis performed by Schintler\textsuperscript{15} validated the beneficial effect of NPWT for infection control and management and supported its use on infected chronic wounds.

With the shift in emphasis of NPWT treatment of more chronic wounds versus acute wounds, NPWT devices themselves have also evolved with clinical practices. Twenty years ago, NPWT was mostly considered for large, acute wounds, such as abdominal wound dehiscence post-laparotomy, cancer excisions, or degloving injuries. The early electrically powered NPWT devices consisted of bulkier, heavier pumps that were only available as durable medical equipment (DME), which a clinician would rent in an inpatient or home care setting. These devices were not portable or easy to use for the patient or healthcare provider, but they were suited for the types of large wounds encountered in hospital settings where mobility and patient comfort were less important.
Chronic wounds, such as DFUs, are generally smaller in size, but very difficult to treat. Clinical evidence and consensus opinion suggest that DFUs should not be excluded from NPWT treatment based on their size or depth. A cohort study of 31,000 patients with DFUs found that the mean DFU size was 5.886 cm², and the median size was only 1.18 cm². The original larger NPWT devices were impractical for smaller sized ulcers, especially given that most of these patients are treated in the outpatient setting, not in the hospital. It was therefore necessary to develop NPWT technology more suitable for the outpatient and home care settings. Although more portable versions have been introduced in the past 10 years, these second generation devices were still difficult for some patients to carry comfortably; often interfered with activities of daily living (ADLs); were noisy, causing embarrassment and interfering with sleep; and prevented most patients from returning to work. The procurement and rental process involved for outpatient and home care treatment remained burdensome for healthcare providers and would often delay delivery of appropriate therapy. Placement of the specialized dressings required specific skill levels, necessitating the use of home nursing care and further increasing the costs associated with treatment. Although use of NPWT devices for treatment of the ambulatory patient increased in recent years, the difficulties of procurement, impact on QOL, resource utilization, and the associated costs often made treating chronic wounds with NPWT impractical. A more portable, user-friendly, and cost-effective NPWT device for outpatient care was still needed. Technology continued to evolve in response to the importance and need for change in care settings from acute to home to outpatient care.

Most recently, NPWT technology has transitioned to smaller canisters, made ultraportable and easy to carry, and disposable (thrown away after use instead of rented) devices. These devices have become even more cost-effective, allowing for decreased hospital stays and use on smaller wounds while still maintaining the safety and efficacy benefits of traditional, larger devices. There are now more options available for portable NPWT devices (Table 1) that have features for more practical application of NPWT to smaller chronic wounds. However, most of these electrically or battery powered devices are still not optimized for the specific requirements of the outpatient care setting and are not supported by randomized controlled trial data. For example, some portable electrically powered devices still must be obtained through a rental procurement process (DME) and are not readily available in the outpatient clinic setting. Other battery powered NPWT devices are disposable, but utilize non-optimal exudate collection methods, such as absorbent pads instead of an exudate collection chamber.

One of the most important features to note is how wound exudate is managed by the NPWT device. Exudate can be captured in canisters or absorbed into a pad. The absorbent foam pad serves as the collection device, which only allows treatment of relatively flat surfaces, as the pad is not customizable to many wound contours or more challenging anatomic locations (Table 2), which are often seen with chronic wounds. A canister device uses a foam or gauze interface, which can be cut to fit almost any wound shape, provides mechanical stimulation of the wound bed through macro and micro deformation, and unlike absorbent dressings, is supported by efficacy data from multiple RCTs.

The shortcoming of these electrically powered devices led to the development of mechanically powered NPWT. This newest form of NPWT delivery offers the proven benefits of canister-based, traditional, larger NPWT devices, in addition to the portability and cost savings of a disposable device. Mechanical power is generated by specialized springs within the device, which emit the same level of negative pressure as an electrically powered device with the added advantages of allowing for an ultraportable, smaller NPWT device that is much easier to use, improves patient QOL, and is more cost-effective than alternative NPWT treatment modalities. In summary, NPWT is shown as a safe and efficacious treatment modality for both acute and chronic wounds and has become a critical component of the clinician’s armamentarium for treating difficult wounds. With the development of the latest generation of NPWT devices, chronic wounds that are seen in the outpatient setting can now be treated more effectively with this therapy.
Introduction to the SNaP Device for Mechanically Powered Negative Pressure Wound Therapy (MPNPWT)

Currently the only mechanically powered NPWT device is the SNaP® Wound Care System (Spiracur Inc.). In 2009, the United States Food & Drug Administration (FDA) cleared this device as the first available MPNPWT device and established special controls for a new category of non-powered (ie, mechanically powered) NPWT devices. This was granted through a de novo process, which required the development of specific guidelines for this new type of NPWT device. Since then, the SNaP device has received CE mark for sale in Europe in 2010 and Shonin approval for sale in Japan in 2013.

The SNaP device weighs only 2.2 oz, makes no noise during operation, and can be completely hidden under clothing, but provides the same level of negative pressure therapy as existing larger format NPWT technologies. By creating the negative pressure using high energy springs and a piston rather than batteries and motors, this device has been able to reduce the size and weight of the entire negative pressure generating mechanism and exudate canister to the size of a cellular phone (Figure 1). The size, weight, and noise improvements of the SNaP device greatly enhance patient QOL during treatment (see section 4.4). In addition, the SNaP device was designed to be readily available off the shelf and fully disposable.

The device is comprised of 3 components: a cartridge, a dressing kit (containing a proprietary hydrocolloid cover and a foam or antimicrobial gauze interface), and a strap. The cartridge has 2 functions: it generates the negative pressure and provides the reservoir to store wound exudate. The canister contains a specially designed Biolock® isolayer that traps wound exudates and reduces odor issues. The hydrocolloid cover dressing is customizable to the wound size, flexible and absorbent, and protective to fragile periwound skin. Importantly, the custom hydrocolloid dressing forms a rapid and robust seal that makes dressing applications easier even in challenging anatomical locations. It also has the benefit of compatibility with any other hydrocolloid products such as rings, strips, pastes, or other hydrocolloid dressings and ostomy appliance barriers. For the most challenging anatomical locations, the sterile hydrocolloid SNaP SecuRing product is also available to allow for treatment between toes or over distal amputation sites. The blue foam interface can be cut to fit in the wound and improves visualization of the color and character of the exudate in the wound. Due to the apparent blue color, the risk of leaving small pieces of foam in the wound is also mitigated. Although most of the time the SNaP cartridge is used with traditional gauze or foam dressing kits, the SNaP foam bridging kit is also available for treatment of plantar wounds or wound that require offloading such as pressure sores.

In addition, the SNaP device has the same indications for use as electrically powered NPWT devices, which include the following type of wounds: chronic, acute, trauma, subacute/dehisced, ulcers (diabetic, venous, or pressure), surgically closed incisions, skin flaps/grafts, and partial thickness burns. Although available for use in all care settings, the SNaP system was designed specifically for the outpatient setting to treat acute and chronic wounds.

2.1 How to Apply and Use the SNaP Device

As mentioned above, a benefit of MPNPWT is its ease of application. Furthermore, the SNaP device requires less dressing changes than traditional NPWT devices—only 2 per week compared to 3 per week. In Table 3, the gauze system, foam system, and bridge dressing kit system application instructions are provided. For more
Table 3. Instructions for use for SNaP® Wound Care System

<table>
<thead>
<tr>
<th>Gauze System Application Instructions</th>
<th>Foam System Application Instructions</th>
<th>Bridge Dressing Kit System Application Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prepare the wound bed and periwound skin per institutional protocol and irrigate wound bed thoroughly with normal saline.</td>
<td>1. Follow steps 1-3 of the Gauze System Application Instructions.</td>
<td>1. Follow steps 1-3 of the Gauze System Application Instructions.</td>
</tr>
<tr>
<td>2. If necessary for the particular wound, apply a skin protectant to the surrounding skin.</td>
<td>2. Cut the foam interface to fit the size and shape of the wound. Do not cut foam directly over wound bed to avoid loose fragments from falling into wound. Brush off foam edges after cutting to remove any loose fragments.</td>
<td>2. Follow steps 2-3 of Foam System Application Instructions.</td>
</tr>
<tr>
<td>3. If necessary for the particular wound, cut a single layer of wide mesh non-adherent to size of wound and place on wound bed.</td>
<td>3. Place foam interface into wound cavity. Foam interface should fill the wound cavity and extend above the wound margins. Count and record the number of pieces used to ensure the same number of pieces are removed during dressing removal. If a piece of foam is used in a tunnel, ensure the foam is in contact with foam in the primary wound bed. Do not place foam into blind or unexplored tunnels.</td>
<td>3. Place the hydrocolloid of the SNaP® Bridge Dressing over the wound and seal. Ensure that the diamond mark on the bridge section is placed over the foam interface. Trim hydrocolloid if necessary. Ensure that a minimum of 1 cm of intact skin around the wound is adhered to the dressing to maintain a proper seal.</td>
</tr>
<tr>
<td>4. Loosely pack the wound with saline moistened gauze or gauze sponge. Do not tightly pack the wound. Moisten the gauze with normal saline. The gauze should be kept moist at all times.</td>
<td>4. Follow steps 5-11 of Gauze System Application Instructions.</td>
<td>4. Route the bridge section of the bridge dressing to a location away from the wound in order to mitigate contact pressure at the wound. Secure the bridge section to the patient.</td>
</tr>
<tr>
<td>5. Place a SNaP® Wound Care Dressing over the wound and seal. Ensure that the center opening of the port of the dressing is placed over the gauze. Ensure that a minimum of 1 cm of intact skin around the wound is adhered to the dressing to maintain a proper seal.</td>
<td></td>
<td>5. Follow Steps 6-11 of Gauze System Application Instructions.</td>
</tr>
<tr>
<td>6. Cut the dressing tubing to the desired length.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Fully insert the tube fitting into the tubing.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Connect the SNaP® Wound Care Cartridge to the tube fitting using both hands. Do NOT remove the cap at the end of the tube fitting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. To activate the cartridge, remove the activation/reset key from the cartridge by pressing the activation tabs on its side and pulling it out.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Secure the SNaP® Wound Care Cartridge to the patient’s extremity or belt using the SNaP® Wound Care Strap. When the strap is placed around an extremity, take care to ensure that the strap is not placed too tightly as this may cause discomfort or potentially decrease blood flow to the extremity. Distal perfusion may be assessed by noting skin color, altered sensation, or pulses.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Check negative pressure operation. The SNaP® Wound Care System is working properly if: green capacity indicator is both visible and stationary in the chamber window, dressing has a “sucked down” appearance, and dressing feels hard to the touch.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The panel reviewed studies that have shown that MPNPWT is effective, efficacious, and beneficial to wound healing.\textsuperscript{20,23-25} The first published clinical study\textsuperscript{23} of the SNaP device and MPNPWT was a case series at Stanford University of 12 patients with chronic wounds, 5 of which experienced wound closure within 4 weeks of MPNPWT. At 4 weeks, all subjects were healed or significantly healing ($P<0.01$), and there were no serious adverse events. Another comparison study\textsuperscript{24} matched 21 SNaP MPNPWT-treated patients with chronic lower extremity leg ulcers to 42 control patients with chronic leg ulcers treated with modern wound care protocols (Apligraf®, Regranex®, and/or skin grafting) at the same wound care center. Wound healing was evaluated up to 4 months. There was a 50% improvement in healing rates in the SNaP group. Healing outcomes were similar to results reported with electrically powered NPWT, suggesting that MPNPWT is as effective. The study also evaluated the rate of Apligraf application in each treatment group, based on the number of Apligraf dressings applied and the number of days in the study. Significantly fewer dressings were required in the SNaP group, which had an application rate (0.0099 grafts per day) of less than half of that of the control group (0.0087 grafts per days, $P=0.0355$). These results would suggest an additional cost savings, as fewer dressings were required in addition to better outcomes. These findings were supported by another small case series\textsuperscript{25} of patients with DFUs treated with MPNPWT and Apligraf that similarly found that after the SNaP was used to prepare the wound bed prior to application of Apligraf, improved effectiveness of Apligraf and improved healing outcomes were observed.

Armstrong et al\textsuperscript{20} recently performed the only head-to-head RCT that compared different NPWT devices, by evaluating healing outcomes and patient data with the SNaP system versus the NPWT industry leader device, the V.A.C.\textsuperscript{®} Therapy System (Kinetic Concepts, Inc). Prior to the publication of this study, there were no studies available that compared one NPWT device to the other.\textsuperscript{26} This study was carried out in 17 investigational sites across the United States with the participation of 132 subjects with lower extremity ulcers. The study was powered to evaluate non-inferiority and included planned interim analysis. Healing rates were measured every 4 weeks for 16 weeks. Not only were the healing rates and outcomes comparable and demonstrated non-inferiority at all time points tested between the 2 devices, but there was also no difference in the incidence of adverse events or complications. Interestingly, subanalysis of this data set revealed that for VLU patients treated in the study, healing outcomes were superior with the SNaP system compared to the V.A.C. at all timepoints tested ($P<0.05$) (Armstrong, unpublished data). Importantly, compression therapy was used in addition to NPWT in both treatment groups.

Taken together with benchtop testing data and existing NPWT RCT data, the panel consensus was that there was significant evidence, including Level I RCT data, supporting the efficacy of MPNPWT. The panel also discussed the superior efficacy data for VLUs found in the Armstrong RCT trial, and felt that this outcome was most likely due to increases in patient compliance (see section 4.1) with the SNaP system as compared to the V.A.C. system. However, additional studies would be required to fully support this conclusion.
Advantages of MPNPWT

4.1 MPNPWT and Quality of Life: A Major Improvement

The issue of patient adherence appears to be most related to QOL issues concerning NPWT. A literature review of 25 articles on the patient experience of NPWT recognized its treatment benefits, but also revealed the need for improvement on patient compliance and QOL. Traditional electrically powered devices must be carried on the upper torso, often making it difficult for patients to proceed with their daily activity. Wounds on the lower extremity require the lengthy tubing to extend to the device, increasing the risk for falls. Patients’ ADLs are restricted, not only because of the device’s weight, but also because the device needs to be plugged in or charged. Because most devices are large and visible, some patients are uncomfortable using the device in public. In addition, electrically powered devices can be noisy, causing embarrassment in social situations and disrupting sleep. These QOL issues surrounding NPWT were found to significantly raise patient anxiety in two different evaluations and most likely contributed to patient non-adherence. The loss of patient autonomy and immobility resulting from NPWT was also found in another study to worsen QOL and increase the workload of their nurses and caregivers. Immobility can lead to serious health issues, such as venous thromboembolism in addition to reduced QOL. Reduced QOL has been shown to negatively affect the wound healing process. The RCT conducted by Armstrong et al found that patient QOL was significantly better with the SNaP device versus the V.A.C. device on a number of measures. Patients answered a study exit survey on QOL with questions concerning the device’s wearability, noise levels, impact on activities of daily living (ADLs), and impact on sleep. Scores were better for the SNaP system, which was easier to wear in social situations, emitted no noise, did not interfere with ADLs, and did not disrupt sleep (Table 4). The consensus of the panel was that MPNPWT is a major improvement in response to long-standing patient non-adherence and QOL issues of traditional NPWT devices.

4.2 Benefits of an Improved Safety Profile with MPNPWT

Although no significant differences in adverse events were identified in the published literature between MPNPWT and traditional NPWT, there have been drawbacks to the use of traditional NPWT reported in the literature and reported to the FDA. Several safety issues that the panel members described through the MAUDE System or reported include bleeding and exsanguinations, fistula formation, dressing retention, worsening infections, toxic shock syndrome, tripping hazards, pressure spikes, pain, mortality, wound complications resulting from unanticipated power outages and interruption of therapy, and, most importantly, the lack of patient adherence. The panel reviewed their experience and literature and found that MPNPWT had an improved safety profile over conventional non-disposable electrically powered NPWT devices as demonstrated by the following safety points:

Table 4. Quality of life data from exit survey of randomized controlled trial comparing SNaP to KCI ActiV.A.C.

<table>
<thead>
<tr>
<th>Percentage of Patients Who…</th>
<th>SNaP</th>
<th>KCI ActiV.A.C.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Felt that their NPWT device was “never” or “rarely” noticed in social situations</td>
<td>81%</td>
<td>36%</td>
</tr>
<tr>
<td>Felt that the noise from their NPWT device “never” bothered them</td>
<td>94%</td>
<td>33%</td>
</tr>
<tr>
<td>Felt that the NPWT device did not interfere with their daily activities</td>
<td>85%</td>
<td>54%</td>
</tr>
<tr>
<td>Felt that the noise from the NPWT device did not bother them when trying to sleep</td>
<td>96%</td>
<td>64%</td>
</tr>
</tbody>
</table>

NPWT: Negative Pressure Wound Therapy
• As of May 23, 2013, there have been no adverse events recorded in the FDA Manufacturer and User Facility Device Experience database.
• Small 60 cc cartridge size mitigates known safety risks such as severe bleeding and exsanguination.
• Blue foam interface makes it visually easier than the black foam to evaluate for bleeding from the wound during treatment.
• No power cords and plugs to trip over, cut-to-length tubing to decrease the potential for tripping or falling.
• Integrated check valve and slit seals protect patients from exposure to exudate contained within the cartridge and dressing tubing.
• Does not allow the patient the ability to alter the pressure level or turn off device.
• No risk of electrocution when showering or bathing.
• Eliminates the chance of cross-contamination of “super-bugs” since the product is disposable and not reused between patients.

A final safety improvement that warrants its own discussion is that there is no risk of power failure, which can lead to poor healing outcomes and complications with MPNPWT. The advantage of mechanical power is that therapy can be maintained without interruption stemming from an exhausted battery or not having a power source (or power outages). A retrospective study by Collinge and Reddix found that 10% of patients with trauma wounds treated by electrically powered NPWT lost power in their device and experienced interruption of NPWT, which led to unhealthy appearing wounds, surgical debridement, and increased complications (p<0.05). Most wounds were considered to have an increased risk for infection as a result of the power failure. These power failure issues are completely eliminated with MPNPWT.

The consensus of the panel was that MPNPWT appears to have an overall improved safety profile compared to traditional NPWT. However, the panel recommended that additional direct comparison studies still need to be performed.

4.3 Cost-effectiveness of MPNPWT

Several studies demonstrated the cost-effectiveness of NPWT in general for the treatment of chronic wounds. For DFUs, these studies demonstrate that there is faster healing, less amputations, and less need for hospitalization when NPWT is utilized. In a RCT cost study that evaluated the use of NPWT on DFUs, a lower cost of care after at least 8 weeks of care was observed in the NPWT group compared the standard moist wound dressing group. The average direct cost per patient treated with NPWT was $27,280 versus $36,096 for patients treated with moist wound therapy. The average total cost to heal for the NPWT and moist wound therapy groups was $25,954 and $38,806, respectively. For the treatment of VLUs, one randomized controlled trial demonstrated NPWT was more cost-effective with the average cost to heal a wound at $3,881 with NPWT versus $5,452 with moist wound dressings. Based on the panel experience and review of the literature, they felt that there was good evidence for the cost-effectiveness of NPWT for the treatment of DFUs, but felt that the arguments for cost-effectiveness for VLUs needed additional support.

There is evidence that MPNPWT may be even more cost-effective than traditional NPWT. Hutton and Sheehan developed a mathematical model that compared the cost-effectiveness of MPNPWT with moist wound therapy and electrically powered NPWT for patients treated until they healed or up to 16 weeks. The SNaP device was shown to be the most cost-effective, as moist wound therapy required a longer treatment time and complication-related costs were increased with longer treatment time, while electrically powered NPWT still required home healthcare, more costly supplies and equipment, and more dressing changes. The SNaP device had a cost savings of $9,669 (42%) in comparison with moist wound therapy and a cost savings of $2,774 (17%) for private payers and $2,296 (15%) for Medicare patients in comparison with traditional NPWT. Importantly, this model did not consider costs associated with pain medication, rehabilitation, or long-term amputation-associated costs, and the authors concluded that they most likely underestimated the potential overall savings when MPNPWT is used.

The SNaP dressing is designed to be applied twice per week as compared to 3 times per week, further re-
ducing resource utilization and overall cost of treatment. Furthermore, in the RCT published by Armstrong,20 re-
source savings were demonstrated when the SNaP sys-
tem took an average 10 minutes to apply to the patient,
or almost half the time required for the V.A.C. (19 min-
utes). In addition, since the application is simpler and
the SNaP device is available off the shelf, there is no
need for a lengthy procurement process that may de-
lay treatment. Importantly, because the SNaP device is
available in the clinic setting and does not require home
nursing care to be administered (as is often required for
traditional NPWT devices outside the hospital setting),
the cost of having a home nurse is eliminated. Because
the device is readily available, patients can be sent home
from the hospital setting with the device earlier and
without unnecessary hospitalization days that might be
required for approval of traditional NPWT devices for
home use.

In summary, although the panel felt that cost savings
was clearly demonstrated in the published literature for
NPWT treatment of DFUs, the panel felt that addition-
al cost data was required to generalize this cost saving
with treatment to other wound types. The panel also
felt that there were significant cost savings advantag-
es of the MPNPWT over traditional NPWT, mostly due
to decreased device costs, elimination of the need for
home nursing care, and reduced staff resources required
for applications.

4.4 Other Advantages
of MPNPWT

In addition to improvements in QOL and patient com-
pliance, the safety profile of the SNaP device, and cost-ef-
ficacy, the panel discussed other benefits and ad-
vantages of MPNPWT from their personal experience.

One of the most mentioned advantages of the SNaP
system was the customizable hydrocolloid dressing that
is designed to fit various wound types, especially those in
hard-to-treat areas, such as amputated toes, ray resections,
heels, and plantar surfaces (Figure 2). Combined with the
use of the bridge dressing, almost any wound on the lower
extremity from small plantar wounds to larger amputation
sites can be treated. Other advantages of the hydrocolloid
dressing mentioned were:

- Peri-wound protection of friable skin
- Easier and more durable sealing in hard-to-treat areas
  compared to polyurethane dressings
- No need to treat small secondary wounds with sepa-
  rate dressing

Several panel members felt that the SNaPs longer
dressing change intervals and customizable tubing in-
terface made treating VLUs with combined NPWT and
compression therapy more practical. They felt that MP-
NPWT helped to supplement the effects of compression
by removing edema in the wound bed and stimulating
healing. Figures 3A and 3B provide a before-and-after
snapshot of a VLU in a diabetic patient who underwent
MPNPWT with complete wound closure achieved.

Another benefit that was mentioned several times
during the meeting was that the SNaP system could be
used in the shower. Several panel members felt that this
was a distinct advantage over electrically powered sys-
tems that could not get wet and had a tremendous im-
pact on patient’s QOL.

In summary, the advantages of MPNPWT come back to
the improved QOL for the patient, safety of the SNaP prod-
uct, protection of the wound, ability to maintain ongoing
therapy without interruption and/or improved patient ad-
herence, and improved cost-effectiveness of MPNPWT.
Contraindications and Disadvantages of MPNPWT

MPNPWT is not without its limitations and the panel spent a significant amount of time discussing contraindications and disadvantages. Contraindications are the same as with most other NPWT devices and include:

- Actively infected wounds
- Inadequately drained wounds (undrained pus)
- Necrotic tissue, such as eschar or adherent slough
- Exposed blood vessels, anastomotic sites, organs, tendons, or nerves
- Malignant wounds
- Fistulas
- Untreated osteomyelitis
- Actively bleeding wounds

Concerning these contraindications, the panel did discuss using the SNaP system to successfully treat patients with exposed hardware and underlying structures, infected wounds, and wounds with osteomyelitis. Several of these cases were presented during the meeting. However, the panel as a whole was hesitant to make general recommendations concerning these uses.

The panel also noted additional precautions based on their clinical experience. With extensive tunneling, packing the sponge dressing into blind pockets was not recommended due to the risk of leaving pieces of the sponge inside the wound track. In addition, the panel mentioned the need for special precautions for patients with physical and/or mental impairment(s), such as having severe arthritis, blindness, or a demented patient, as these patients may have difficulty operating MPNPWT devices independently if they do not have an appropriate caregiver.

Several important disadvantages of MPNPWT were discussed in comparison to traditional NPWT devices. These included lack of an intermittent pressure mode, as well as the need to change the cartridge if a different pressure setting is desired after placement. Although larger capacity MPNPWT devices are currently under development, MPNPWT is currently indicated for low to moderate draining wounds and limited by the 60 mL cartridge capacity. When the cartridge is full, no pressure is delivered. It is important to note that MPNPWT is not meant to substitute for all NPWT, which remains a better option for larger, more heavily exuding wounds. Whereas the V.A.C. and some other electrically powered NPWT devices have Y-connectors to connect patients with multiple wounds to a single pump, for now, this is not an option for the SNaP device. Although like other systems, adjacent wounds can be bridged together.

Similar to other NPWT devices, the SNaP cartridge cannot be used in a hyperbaric oxygen therapy (HBOT) chamber, although, the FDA is presently considering evidence submitted on the use of the SNaP during HBOT treatment. In addition, the SNaP cartridge must be disconnected when undergoing an MRI, though the dressing portion can remain in place.

A final disadvantage discussed by the panel was the lack of an audible alarm feature to advise patients if there is a problem such as a leak. Instead, there is a red visual indicator that should be checked by the patient every 8 hours. Although the lack of an alarm and associated noise may be beneficial for some patients in terms of QOL, patients with visual impairment may not be able to see the red indicator and therefore would not know when negative pressure is no longer being applied to the wound. This might lead to the patient not seeking immediate medical help and could result in complications. An audible alarm clip that works with the SNaP device has been developed and is available in Japan, but currently is not available in the US or European markets.
A comprehensive patient and wound assessment must take into account the following factors specific to MPNPWT: location of the wound, size of the wound, level of exudates, tissue type, bacterial burden, the need for short-term wound bed preparation, and the needs of the patient (in terms of work, socialization, and/or fall risk). The panel felt that smaller (<18 x 18 cm), low to moderately exudating (<20 cc/day), chronic (>30 days), or otherwise hard-to-heal wounds are ideal candidates for MPNPWT.

The panel emphasized the close examination of the underlying etiology of the wound. Different types of wounds have different indications for NPWT in general. For example, the application of NPWT on PUs is recommended for stage III or IV chronic PUs. For DFUs, NPWT should be applied after revascularization if warranted and after infection and osteomyelitis have been treated. It was recommended to wait at least 24 hours after incision, drainage, and/or debridement for infection for DFUs before initiation of NPWT. For soft tissue trauma wounds, NPWT may be used after or in between debridements when primary closure is not an option. NPWT can also be used to prepare wound beds prior to surgical closure or grafting.

MPNPWT can be ideal for ambulatory patients or mobile patients who are not bed-bound. The benefits of MPNPWT for the working-age population was emphasized by the panel, especially when an estimated 2 million work days are lost every year to venous insufficiency. A series of MPNPWT case studies were presented during the meeting from one of the wound clinics that participated in the most recent MPNPWT RCT and 2 relevant examples of chronic wounds are highlighted.

### 6.1 Case 1: Recurrent Venous Leg Ulcer

A 72-year-old male presented with a recurrent VLU. When he was 43-years-old, he had a major cerebral vascular accident, and since then, has had coronary artery disease and a coronary artery bypass graft. He walked with an unsteady gait with the help of a walker, and thus, had a very high fall risk. Of note is that he had been enrolled in the SNaP RCT in 2010 and had been randomized to the SNaP arm of the study. After 2 weeks of standard therapy, he continued with complaints of pain, the wound showed little improvement, and the patient asked for MPNPWT. After only 2 weeks of MPNPWT with the SNaP device, the wound was 40% smaller and the patient noted less pain. Ten days later, MPNPWT was discontinued due to further wound size reduction and the wound then closed without further use of advanced treatment modalities.

### 6.2 Case 2: Diabetic Foot Wound

A 59-year-old male was referred to the same wound care center with a diabetic foot wound resulting from an amputation that was secondary to his DFU and osteomyelitis (Figure 4A). He had type 2 diabetes and depression. He took insulin and Paroxetine and admitted to not adhering to a diet to control his diabetes. His HbA1c was 9.5. After 5.5 weeks of treatment, his wound completely closed (Figure 4B).
7. **When to Initiate or Transition to MPNPWT?**

Factors to consider when contemplating MPNPWT are based on when to initiate NPWT in general and the size and exudate level of the wound (for transition from NPWT to MPNPWT). Recent literature has emphasized the importance of earlier and more aggressive treatment of chronic wounds such as DFUs. For example, a recent publication by Yao et al. evaluated the outcomes of a series of DFU patients and found that earlier treatment with NPWT significantly reduced overall cost of treatment and greatly improved outcomes. However, wasting resources on wounds that will heal without advanced modalities like NPWT is inappropriate. There was consensus on the panel that wounds that had not improved significantly after 30 days of standard dressing treatment should be treated with an advanced modality such as NPWT. In addition, they felt that if the patient had other significant risk factors for slow healing and/or a history of slow healing wounds, then earlier use of advanced modalities may be appropriate. The panel also felt that acute wounds that could benefit from filling in with granulation tissue would also be indicated for earlier use of NPWT. However, because many insurance payers may not cover earlier use of NPWT, the panel suggested that earlier intervention with MPNPWT for chronic wounds should be evaluated on a case-by-case basis.

Many acute wounds may be initially too large and exudative for current MPNPWT devices. The panel felt that transitioning to MPNPWT device from electrically powered NPWT device was an appropriate practice due to the cost savings and QOL issues for the patients when a wound reached an appropriate size and exudate level, especially when the patient was treated outside of the hospital. It was noted that MPNPWT is not exclusively for outpatients; patients who are still being hospitalized can start MPNPWT once the size requirements are met. The panel's guidelines (in terms of size and exudate level) that indicate wounds as good candidates to transition from NPWT to MPNPWT are wounds less than 18 x 18 cm and produce less than 20 cc of exudate in a 24-hour period.

8. **When to Stop MPNPWT?**

Traditionally, the primary objective of electrically powered NPWT is the formation of new granulation tissue in the wound bed. For acute wounds, tertiary closure (delayed surgical closure) of these wounds after optimization with NPWT was a logical endpoint to therapy, and a healthy granulation bed was a logical endpoint. For example, guidelines recommended stopping NPWT on trauma wounds when delayed closure by surgery is possible to minimize costs and patient inconvenience. However, with the use of NPWT for treatment of chronic wounds, the endpoint of therapy has become less clear. Many chronic wound patients are not candidates for surgical closure methods, which have high failure rates in this population and significant morbidity. Thus, optimizing the wound for secondary intention closure or wound bed preparation for use of advanced biologic dressings becomes the primary objective for treatment.

The panel noted that when using advanced therapies, it is important to avoid overutilization, which can lead to unnecessary cost if healing progress is not observed. Economic stewardship is a very important consideration for the clinician when bringing a wound to closure. However, MPNPWT may be used longer than electrically powered NPWT on appropriate wounds because of the decreased costs associated with MPNPWT and the reduced burden on the patients during treatment. However, the panel concluded that discontinuing MPNPWT should be determined on an individual patient basis. The panel described cases where, once a wound was “jump started” with MPNPWT, the continued treatment with MPNPWT was not necessary. In addition, they described cases where wounds would regress and enlarge despite being relatively filled in and smaller in size once MPNPWT was discontinued.

The panel was able to agree that it is important to consider stopping therapy when the wound healing process is failing to progress. There should be a window of time given to observe the therapeutic effect prior to changing treatment. Evidence recommends that after 2-4 weeks of no progress with NPWT, the wound and patient should be reassessed for other barriers to healing and treatment plans reformulated. The panel consensus was that if a wound is failing to progress with MPNPWT and no change in wound size is observed, a complete secondary assessment is indicated.
S
everal panel members suggested using other advanced modalities with MPNPWT, noting that with multi-modal therapy, better results and outcomes are often observed on an anecdotal basis. However, the panel also noted that balancing the costs associated with multi-modal advanced therapies is critical and more data is needed to determine not only what are the most efficacious, but also most cost-effective combination therapies.

Evidence is strongest for the use of NPWT with skin grafts.\textsuperscript{1,7,39,43} NPWT helps conform the graft to the wound bed, prevents fluid build-up, prevents shearing and graft removal, and has been shown in RCTs to increase graft take significantly.\textsuperscript{7,43} The use of ultraportable NPWT devices was recommended as a standard adjunct therapy to skin graft application by Gabriel et al.\textsuperscript{17} A review of literature\textsuperscript{44} further concluded that portable and disposable NPWT (such as MPNPWT) may be a first line of application for pre/postoperative graft therapy. Additionally, because the use of NPWT for skin graft sites is generally only for less than a week, MPNPWT is an ideal choice to avoid more lengthy fixed rental costs associated with traditional NPWT devices when only a few days of therapy is required. Based on a review of the published literature, the panel supported the use of MPNPWT device with skin grafts as a recommended combination therapy.

Although not really advanced therapies, the panel recommended combination therapies of offloading for DFUs in conjunction with MPNPWT and the use of compression therapy for VLUs in conjunction with MPNPWT. Offloading and compression are the standard of care and first-line treatments for DFUs and VLUs, respectively, and the panel emphasized that treatment of these conditions with MPNPWT should be done with these combinations whenever possible. One specific offloading combination therapy that was extensively discussed by the panel is the use of MPNPWT with total contact casting (TCC) for DFUs. The combination of a SNaP bridge dressing placed under the TCC Easy Cast\textsuperscript{®} with a secondary pad was suggested by several panel members, as the SNaP dressing only needs to be changed twice weekly, and the secondary pad better cushions the wound. The SNaP tubing can run externally on the cast to avoid rubbing or pressure on the underlying skin. For compression dressing to be used effectively with MPNPWT, the panel recommended that when compression is applied, the nozzle on the dressing and tubing should be kept outside of the wrapping to prevent rubbing or pressure points on the underlying skin.

There is limited evidence available on the use of other advanced therapies with MPNPWT. The synergistic benefits of MPNPWT and Apligraf\textsuperscript{®} were previously discussed in section 4.\textsuperscript{24,25} These early data do indicate the use of MPNPWT with skin substitutes can improve outcomes and reduce costs compared to use of skin substitutes alone. However, more prospective randomized controlled data is needed. A published case report\textsuperscript{42} found that the use of the SNaP system with a bio-engineered cell-based product appeared to heal a long-term case of pyoderma gangrenosum, which after 9 months of standard care increased 4 times in size. Several of the panel members reported anecdotal successful use of MPNPWT with other bioengineered skin substitutes and cellular matrices. The panel felt that MPNPWT helped prepare the wound bed for these types of graft applications, and MPNPWT enhanced the effectiveness of these applications. However, the panel noted that these observations were not yet fully supported in the literature.

Advanced modalities that the panel mentioned were used successfully in combination with MPNPWT included:

- Topical collagenase (Santyl\textsuperscript{®})
- Collagen/oxidized regenerated cellulose dressing (Promogran\textsuperscript{®})
- Calcium alginate dressing (Restore\textsuperscript{®} or Kaltostat\textsuperscript{®})
- Cellular and/or tissue-based products (Derma-graft\textsuperscript{®}, EpiFix\textsuperscript{®}, Apligraf\textsuperscript{®})
- Extracellular matrices (OASIS\textsuperscript{®})
- Steri-Strips\textsuperscript{®}

The above modalities mentioned by the panel were experience-generated. The panel felt that the question of using these advanced modalities in combination with MPNPWT still needs evaluation and validation, as there is limited evidence to suggest that these other advanced therapies work better when applied with any kind of NPWT or work better than NPWT alone.

In summary, the panel concluded that MPNPWT is recommended for use in combination with skin grafts, offloading for DFUs (such as TCCs), and compression with VLUs. However, the panel felt that further evidence is needed for other potential combination therapies such as use of MPNPWT with cellular/tissue-based products, collagen dressings, or extracellular matrices.
10. **Pressure Level Selection**

MPNPT comes in 3 preset pressure delivery levels (75, 100, and 125 mmHg). Continuous 125 mmHg is the standard level of pressure applied in almost all published RCTs done on NPWT. However, studies of animal model wounds and human blood flow found that lower pressure levels resulted in a higher blood flow. The panel recommended starting most patients at 125 mmHg, as this pressure level was supported by the most clinical literature. They also recommended, where vascular compromise is an issue (such as in arterial wounds), a lower pressure of 75 mmHg to be applied to prevent exacerbation of tissue ischemia. In addition, the panel recommended lowered pressure levels if the patient experienced pain with higher pressure level treatment and potentially lower pressure of 75 or 100 mmHg over skin grafts depending upon clinical experience.

11. **Summary**

In summary, the panel discussion determined the following consensus statements to guide clinicians in the decision-making process for MPNPT:

- MPNPT is ideally suited for treating chronic wounds such as DFUs and VLUs in the outpatient care setting.
- If a wound fails to progress after 30 days of traditional treatment, MPNPT is indicated as long as the size and exudate criteria are met.
- MPNPT improves patient QOL and better supports patient adherence than traditional NPWT.
- MPNPT is cost-effective and timesaving over standard dressings and traditional NPWT.
- Major benefits of MPNPT include safety, customizability, and the ability to maintain ongoing therapy without interruption or disruption.
- MPNPT is an ideal option for ambulatory patients and working patients.
- In general, transition to MPNPT from standard electrically powered NPWT as soon as wound size and exudate requirements are met.
- The use of MPNPT over skin grafts, in conjunction with offloading, and with compression therapy is recommended, but evidence for combined use with other advance modalities requires more evidence.
- If a wound's healing process is failing to progress with MPNPT, a complete secondary assessment is recommended.
- MPNPT is a new category of NPWT.
- MPNPT cannot replace electrically powered NPWT as the sole NPWT treatment option; traditional NPWT will remain in use for larger more heavily exudative wounds.


4. Armstrong DG, Wrobel J, Robbins JM. Guest editorial: are diabe-


memento negative pressure wound therapy (V.A.C. Therapy) for the management of diabetic foot wounds. Ostomy Wound Manage. 2006;Suppl:1-32.

8. Robson MC, Cooper DM, Aslam R, et al. Guidelines for the treat-


11. Armstrong DG, Lavey LA; for the Diabetic Foot Study Consor-

12. Armstrong DG, Lavey LA, Boulton AJ. Negative pressure wound therapy via vacuum-assisted closure following partial foot am-

13. Vuerstaek JDD, Vainas T, Wuite J, Zeilemaker AM, da Costa SA, Oskam J. Does VAC increase the risk of venous thromboembo-

14. Edwards H, Courtneycry M, Finlayson K, Shuter P, Lindsay E. A ran-
domised controlled trial of a community nursing intervention: im-

15. Schintler MV. Negative pressure therapy: theory and practice. Diabe-


20. Leijnen M, Steenwolde F, van Doorn L, Zellemaker AM, da Costa SA, Oskam J. Does VAC increase the risk of venous thromboembo-

21. Edwards H, Courtneycry M, Finlayson K, Shuter P, Lindsay E. A ran-
domised controlled trial of a community nursing intervention: im-

22. Margolis DJ, Allen-Taylor L, Hoffstadt O, Berlin JA. Diabet-

23. Apelqvist J, Armstrong DG, Lavery LA, Boulton AJ. Resource utili-

24. Schintler MV. Negative pressure therapy: theory and practice. Diabe-

25. Margolis DJ, Allen-Taylor L, Hoffstadt O, Berlin JA. Diabet-


29. Leijnen M, Steenwolde F, van Doorn L, Zellemaker AM, da Costa SA, Oskam J. Does VAC increase the risk of venous thromboembo-

30. Edwards H, Courtneycry M, Finlayson K, Shuter P, Lindsay E. A ran-
domised controlled trial of a community nursing intervention: im-

31. Margolis DJ, Allen-Taylor L, Hoffstadt O, Berlin JA. Diabet-


33. Schintler MV. Negative pressure therapy: theory and practice. Diabe-

34. Margolis DJ, Allen-Taylor L, Hoffstadt O, Berlin JA. Diabet-


37. Schintler MV. Negative pressure therapy: theory and practice. Diabe-

38. Margolis DJ, Allen-Taylor L, Hoffstadt O, Berlin JA. Diabet-


41. Schintler MV. Negative pressure therapy: theory and practice. Diabe-
MANUFACTURER’S COMMENT:

The SNaP® Wound Care System is contraindicated for use on the following:

• 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
• Fistulas
• Untreated Osteomyelitis
• Actively bleeding wounds

The SNaP® Wound Care System is NOT indicated for use in Hyperbaric Oxygen Therapy (HBOT).

Clinicians should refer to the Instructions For Use (IFU) when using the SNaP® System for product information, including the full indications for use, warnings, cautions, and precautions.