

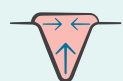
# Mechanism of action (MoA) may explain clinical outcomes with PICO<sup>®</sup> Single Use Negative Pressure Wound Therapy System (sNPWT)

European Wound Management Association (EWMA). 5–7 June 2019, Gothenburg, Sweden.

## Key results: PICO sNPWT data from EWMA 2019

PICO sNPWT (Figure 1) featured in several poster presentations at the EWMA 2019 meeting in Sweden, some of which contributed to the evidence base supporting an MoA distinct from that of traditional negative pressure wound therapy (tNPWT).<sup>1–3</sup> Other studies further demonstrated the benefits PICO sNPWT may provide in patients with surgically closed incisions compared with standard preventive care.<sup>4,5</sup>

### In chronic wounds versus tNPWT



- Significant reductions in wound area, depth and volume in patients ( $p < 0.05$ )<sup>1</sup>



- Less wound surface damage and bleeding in an animal wound model<sup>2</sup>



- Improved re-epithelialisation and quality of granulation tissue; periwound skin not compromised in an animal wound model<sup>2</sup>

### In closed surgical incisions versus conventional dressings



- Significant reductions in the odds of surgical site infections ( $p < 0.00001$ ), skin necrosis, seroma and dehiscence ( $p < 0.01$ )<sup>4</sup>



- Significantly reduced length of hospital stay ( $p = 0.0002$ )<sup>4</sup>



- Estimated cost savings for all evaluated surgery types and high-risk patients<sup>5</sup>

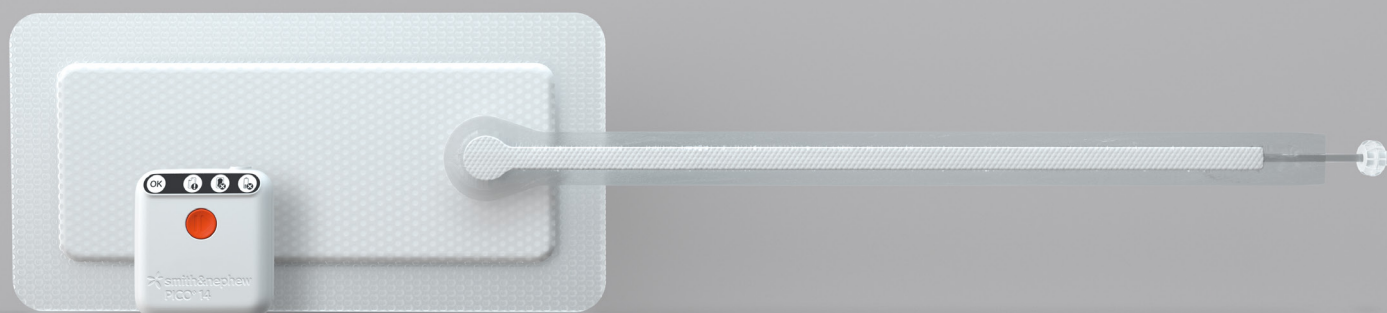


Figure 1. PICO 14 sNPWT, including the pump, tubing and dressing, which incorporates AIRLOCK<sup>®</sup> Technology

## PICO sNPWT versus tNPWT in chronic wounds

### Undisrupted healing with PICO sNPWT may improve outcomes

A recent randomised, controlled trial demonstrating better clinical outcomes in patients with chronic lower extremity ulcers treated with PICO sNPWT versus tNPWT,<sup>1,6</sup> raised the question of how PICO sNPWT works compared with tNPWT.

In this multicentre trial presented at EWMA, 161 patients with venous leg ulcers (VLUs) or diabetic foot ulcers (DFUs) received either PICO sNPWT or tNPWT for 12 weeks or until complete wound healing, whichever occurred first (Intention To Treat [ITT] population).<sup>1</sup>

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## Improved healing outcomes with PICO<sup>®</sup> sNPWT

PICO sNPWT was shown to be statistically superior to tNPWT in terms of progression towards healing (reductions in wound area, depth, and volume;  $p < 0.05$  for all; Figure 2), and was more readily accepted, more comfortable, and interfered less with patients' mobility and sleep at 12 weeks.<sup>1</sup>

The authors suggested that these clinical benefits for PICO sNPWT over tNPWT in the community setting require further investigation and may be explained by its MoA.<sup>1</sup>

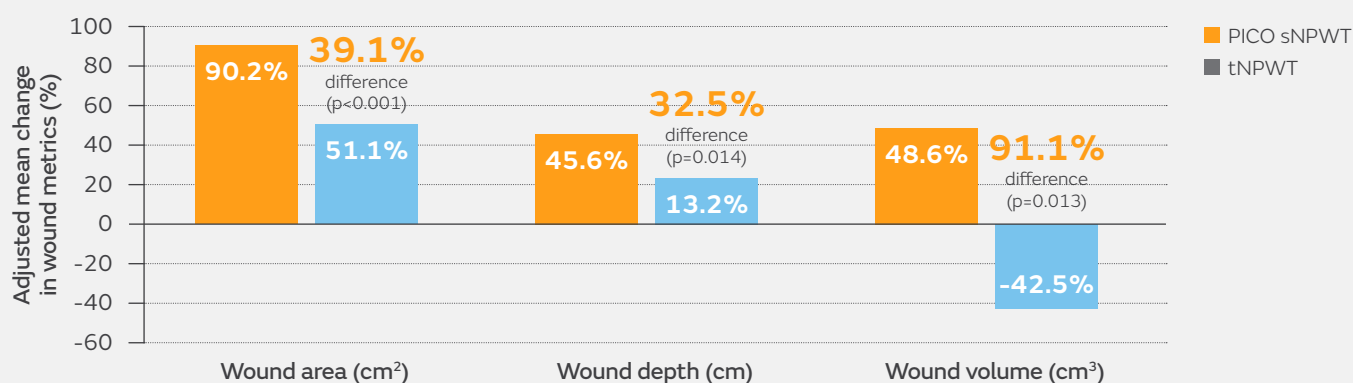


Figure 2. Mean changes in wound metrics with PICO sNPWT and tNPWT (adjusted for wound area, pooled site, wound type and wound duration at baseline) in the ITT population ( $n=161$ )<sup>1</sup>

## MoA and clinical outcomes — impact of foam filler and AIRLOCK<sup>®</sup> Technology

### PICO sNPWT – undisturbed healing, wide area of compression

A poster by Watkins H, et al. reviewed the mechanisms that could help to explain improved clinical outcomes with PICO sNPWT over tNPWT in chronic wounds and versus standard preventive care in patients with closed surgical incisions.<sup>3</sup>

The authors proposed that because PICO sNPWT facilitates NPWT delivery without the need for a wound filler, it may help wound healing to progress undisturbed until the dressing needs to be changed (up to 7 days).<sup>3</sup> Additionally, computed tomography (CT) images (ex vivo porcine tissue) demonstrated that tissue compression occurs over a wider area with PICO sNPWT than with tNPWT (Figure 3).<sup>3</sup>

The authors also suggested that the AIRLOCK Technology in the PICO sNPWT dressing may enable the physiological benefits of NPWT to be consistently delivered across a zone of tissue beyond the wound itself.<sup>3</sup>

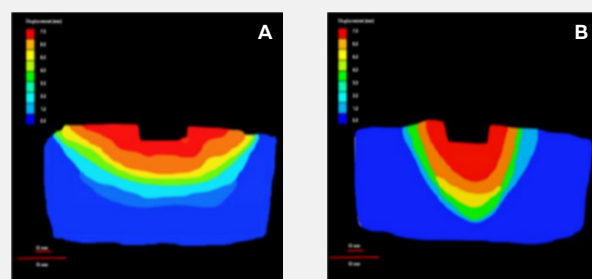


Figure 3. CT images showing differences in tissue compression (displacement) with (A) PICO sNPWT and (B) tNPWT at 24 hours<sup>3</sup>

### PICO sNPWT may deliver negative pressure beyond the wound

This hypothesis was supported by Brownhill R, et al. who presented results from a study of PICO sNPWT versus tNPWT in a porcine wound healing model.<sup>2</sup>

Compared with tNPWT, use of PICO sNPWT to treat experimentally created wounds resulted in:

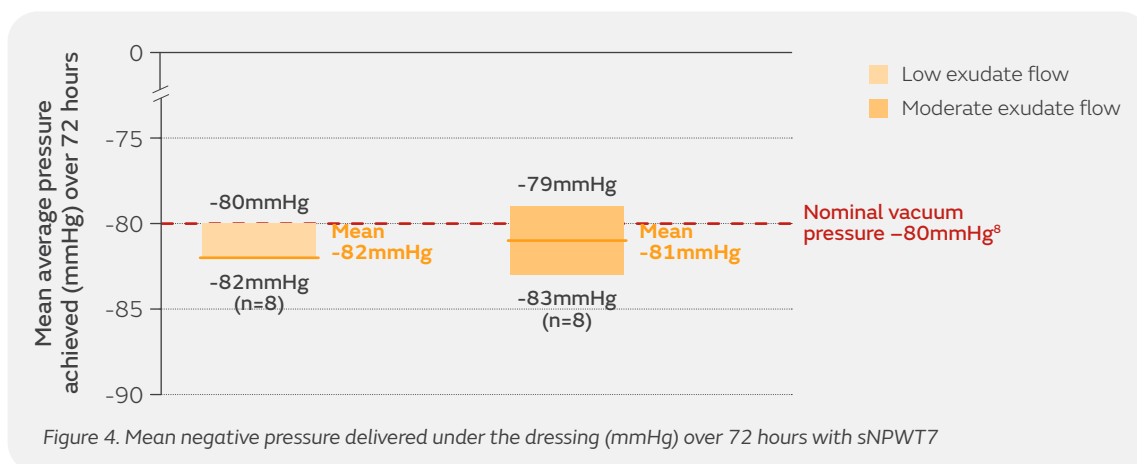
- Significantly greater re-epithelialisation ( $p < 0.001$  at days 6 and 12)
- Significant improvements in the quality of granulation tissue ( $p = 0.028$  at day 6,  $p = 0.025$  at day 12)
- Uncompromised skin in the area surrounding the wound (periwound area under the dressing)

Removal of foam filler from wounds in pigs treated with tNPWT resulted in wound surface damage with noticeable bleeding, unlike dressing removal with PICO sNPWT ( $p < 0.05$  at days 6 and 12).<sup>2</sup> Granulation tissue of some tNPWT-treated wounds contained trapped foam filler material, which was not observed with PICO sNPWT.<sup>2</sup>

## AIRLOCK<sup>®</sup> Technology facilitates delivery of negative pressure

Delivery of negative pressure, facilitated by the AIRLOCK layer, was evaluated by Casey C, *et al.* who used a wound model (low and moderate exudate flow) to demonstrate that PICO<sup>®</sup> sNPWT consistently delivers negative pressure under and across the entire dressing at approximately -80mmHg over a 72-hour test period (Figure 4).<sup>7</sup>

PICO sNPWT also delivered negative pressure at therapeutically relevant levels (-40 to -100mmHg)<sup>8</sup> for 100% of the 72-hour test period in this wound model that incorporated a small air leak to help reflect clinical practice.<sup>7</sup>



## Summary — PICO sNPWT in chronic wounds



These studies suggest that differences in clinical outcomes with PICO sNPWT may in part be because it delivers negative pressure in a different way to tNPWT. PICO sNPWT was shown to deliver negative pressure under and across the entire dressing, facilitated by its AIRLOCK Technology, potentially extending tissue compression to a zone of injury beyond the wound itself.<sup>2,3,7</sup>

## PICO sNPWT in closed surgical incisions

### PICO sNPWT helps to reduce the incidence of SSCs and length of stay

Differences in MoA may also be a contributing factor to the success of PICO sNPWT in helping to reduce surgical site complications (SSCs) in high-risk patients with closed surgical incisions.<sup>4</sup>

In May 2019, the National Institute for Health and Care Excellence (NICE) in the UK stated that PICO sNPWT should be considered as an option for closed surgical incisions in people who are at high risk of developing surgical site infections (SSIs).<sup>9</sup>

Dr. Kara Buzza presented the results of a systematic literature review and meta-analysis of prophylactic use of PICO sNPWT in patients with closed surgical incisions at EWMA 2019 that supported the recommendations from NICE.<sup>4</sup>

The meta-analysis, which included 11 randomised controlled trials and 18 observational studies, showed that PICO sNPWT significantly reduced the odds of patients developing SSIs by 63% compared with conventional dressings ( $p < 0.00001$ ; Figure 5).<sup>4</sup>

The odds of developing wound necrosis, seroma and dehiscence were also significantly reduced with prophylactic use of PICO sNPWT compared with conventional dressings (reductions of 89%, 77% and 30%, respectively;  $p < 0.01$  for all; Figure 5).<sup>4</sup> Length of hospital stay was also estimated to be 1.75 days shorter with use of PICO sNPWT compared with conventional dressings ( $p = 0.0002$ ),<sup>4</sup> which ultimately may result in cost savings.

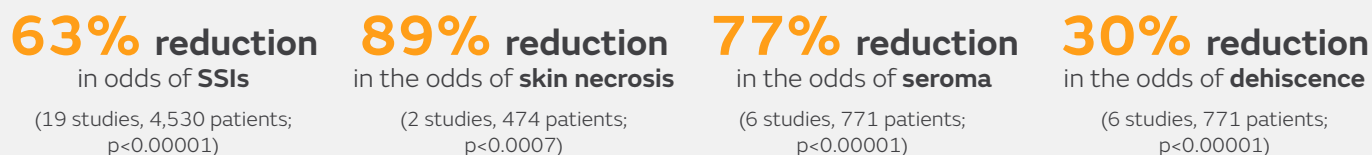


Figure 5. Odds reduction in SSIs and SSCs with PICO sNPWT versus conventional dressings in patients with closed surgical incisions<sup>4</sup>

## PICO<sup>®</sup> sNPWT helps to reduce costs

### Cost effectiveness of PICO sNPWT by surgery type and risk status

The value of cost effectiveness strategies that aim to reduce costs and improve patient quality of life is increasing in importance for all areas of healthcare,<sup>10</sup> including wound care. Two studies reported on the cost effectiveness of PICO sNPWT compared with conventional dressings.<sup>5,11</sup>

An economic analysis of PICO sNPWT compared with conventional dressings presented at EWMA 2019 estimated that PICO sNPWT was £120 cheaper and resulted in fewer SSCs.<sup>5</sup>

PICO sNPWT was the dominant treatment option for patients undergoing colorectal, cardiothoracic and vascular surgery, and was estimated to be cost effective for the other surgery types investigated (orthopaedic, caesarean section and breast surgeries), which are typically associated with short hospital stays.<sup>5</sup>

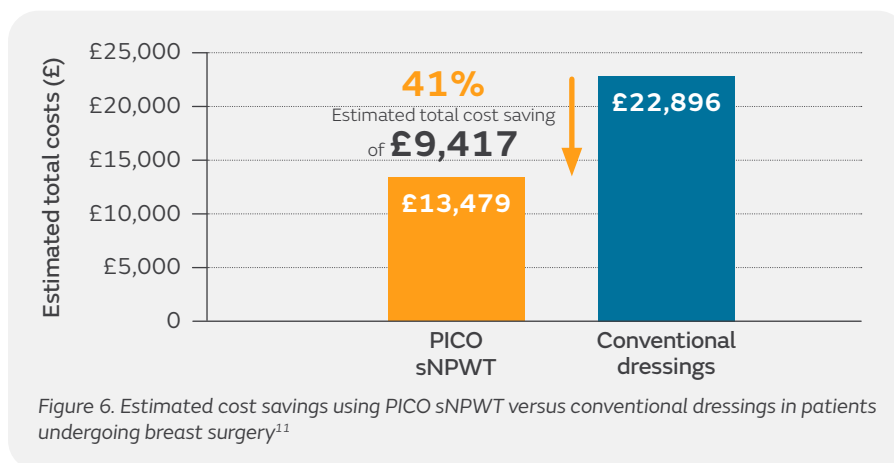
Further cost savings were estimated with prophylactic use of PICO sNPWT in high-risk patients compared with conventional dressings:<sup>5</sup>

- BMI  $\geq 35\text{kg/m}^2$
- American Association of Anaesthesiologists (ASA) score  $\geq 3$
- Diabetes

A multicentre evaluation of the impact of using PICO sNPWT prophylactically on surgical incisions following breast surgery conducted in the UK supported a reduction in SSCs with potential cost savings from using the device in real-world practice.<sup>11</sup>

In this audit of patients treated at three hospitals, the incidence of SSIs in 66 patients was 18.2% with conventional dressings before an initiative to introduce PICO sNPWT.<sup>11</sup> After implementation of PICO sNPWT for a further 66 patients at high risk of SSIs, the incidence was 4.5% – an overall relative reduction of 75%.<sup>11</sup>

The estimated total cost reduction with prophylactic use of PICO sNPWT compared with conventional dressings in this study was 41%, a saving of £9,417 (£22,896 vs £13,479; Figure 6).<sup>11</sup>



## Summary — PICO sNPWT in closed surgical incisions



Prophylactic use of PICO sNPWT was shown to significantly reduce the incidence of SSIs, skin necrosis, seroma and dehiscence, compared with conventional dressings in a recent meta-analysis.<sup>4</sup> Hospital length of stay was also reduced,<sup>4</sup> which may result in cost savings. In other studies, PICO sNPWT was estimated to provide cost savings across several surgery types, as well as in high-risk patients, compared with conventional dressings.<sup>5,11</sup>

## Key evidence

- Data presented at EWMA 2019 support the efficacy of PICO<sup>®</sup> sNPWT to help improve progression towards healing for chronic wounds and help reduce the incidence of SSCs in patients with closed surgical incisions<sup>4,5</sup>
- Some presentations proposed reasons for these benefits based on differences in MoA<sup>2,3</sup>
- AIRLOCK<sup>®</sup> Technology helps to facilitate consistent delivery of negative pressure across the PICO sNPWT dressing to the wound itself and the periwound area in both chronic wounds and closed surgical incisions<sup>2,3</sup>
- PICO sNPWT can be used without a foam filler in patients with chronic wounds, which may help wound healing to progress undisturbed, as well as increasing re-epithelialisation and promoting an improved quality of granulation tissue compared with tNPWT<sup>2</sup>
- The unique means by which PICO sNPWT delivers negative pressure may help to explain the observed improvements in clinical outcomes, which may ultimately help to reduce the costs of wound care provision<sup>5,10</sup>

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**References:** **1.** Jaimes H, Kirsner R, Dove C, Reyzelman A. Randomized controlled trial on the efficacy and acceptance of a single-use negative pressure wound therapy versus traditional negative wound pressure wound therapy in the treatment of lower limb chronic ulcers (VLU and DFU). *Abstract EP072* (and poster). Presented at the EWMA annual meeting, June 5–7 2019, Gothenburg, Sweden. **2.** Brownhill R, Bell A, Hart J, Webster I, Huddleston E. Pre-clinical assessment of a no-canister, ultra-portable, single-use negative pressure wound therapy (sNPWT) system in a porcine model of wound healing: unlocking the mode of action. *Abstract PP043* (and poster). Presented at the EWMA annual meeting, June 5–7 2019, Gothenburg, Sweden. **3.** Watkins H, Huddleston E. Unlocking the mode of action: Why might a no-canister, ultraportable, single-use negative pressure wound therapy (sNPWT) device be clinically superior to traditional negative pressure wound therapy (tNPWT)? *Abstract PP044* (and poster). Presented at the EWMA annual meeting June 5–7 2019, Gothenburg, Sweden. **4.** Saunders C, Buzza K, Nherera L. A single-use negative pressure system reduces surgical site complications compared with conventional dressings in closed surgical incisions: a systematic literature review with meta-analysis. *Abstract EP065* (and poster). Presented at the EWMA annual meeting, June 5–7 2019, Gothenburg, Sweden. **5.** Nherera L, Verma S, Saunders C. An economic analysis of a single-use negative pressure wound therapy (sNPWT) device compared to conventional wound dressings in reducing post-surgical site complications following surgery. *Abstract PP036* (and poster). Presented at the EWMA annual meeting, June 5–7 2019, Gothenburg, Sweden. **6.** Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H. A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities. *Wound Repair Regen.* 2019;27(5):519–529. **7.** Casey C, Ambler G, Huddleston E. Consistent delivery of therapeutic negative pressure levels by a single-use negative pressure wound therapy (sNPWT) system in a wound model. *Abstract EP079* (and poster). Presented at the EWMA annual meeting, June 5–7 2019, Gothenburg, Sweden. **8.** Smith+Nephew. November 2018. Negative Pressure Wound Therapy (NPWT) delivery by the PICO 7 Single Use NPWT System in wound model testing. Data on file, report DS/18 /542/R. **9.** NICE National Institute for Health and Care Excellence. PICO negative pressure wound dressings for closed surgical incisions. Medical technologies guidance [MTG43]. May 2019. Available at: <https://www.nice.org.uk/guidance/MTG43>. Accessed June 10, 2019. **10.** Carter MJ. Cost-effectiveness research in wound care: definitions, approaches, and limitations. *Ostomy Wound Manage.* 2010;56(11):48–59. **11.** Tormey S, Mathers H, Sloan S, Styche T, Whittall C. Impact of single-use negative pressure wound therapy on surgical incisions following breast surgery: a multi-centre evaluation. *Abstract PP042* (and poster). Presented at the EWMA annual meeting, June 5–7 2019, Gothenburg, Sweden.