# Single use negative pressure wound therapy (sNPWT) in the community management of chronic open wounds deeper than 2cm

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### Background

- Chronic wounds do not heal through the normal physiological manner in a predicted time period, and most commonly present as diabetic foot ulcers (DFUs), venous leg ulcers (VLUs), pressure ulcers (PUs), and dehisced surgical wounds.<sup>1</sup>
- The longer these wounds fail to achieve closure, the greater the risk of complications occurring (eg, infections, hemorrhage, and lower-extremity amputations).<sup>1</sup> Wounds that are >2cm in depth have significantly greater odds of failing to heal within ≥20 weeks following treatment.<sup>2,3</sup>
- A recent randomized phase-4 trial found that patients with chronic wounds treated with the PICO<sup>\$</sup> Single Use Negative Pressure Wound Therapy System (sNPWT) (Smith+Nephew, Hull, United Kingdom) had significantly greater reductions in wound area (p<.001), depth (p=.014), and volume (p=.013) than those receiving traditional negative-pressure wound therapy (NPWT) after 12 weeks of treatment.<sup>4</sup>

### Patient demographics

- Among 1,326 eligible patients tracked from admission to healing on a bundle including PICO sNPWT, 409 had wounds >2cm in depth (ranges: 2.0-4.2 for DFUs, 2.0-3.8 for VLUs, 2.4-4.0 for PUs, and 2.0-3.8 for surgical wounds). Demographics and wound characteristics for this cohort and the cohort not on an ICB are presented in Table 1.
- The cohort of wounds receiving PICO sNPWT was statistically older (p<.001) and had a higher (p<.001) co-morbidity score than the cohort of those not receiving PICO.

	Wounds >2cm deep treated with PICO sNPWT	Not on ICB
Number	409	2,242
Mean age (SD)	58.01 (14.71)	56.56 (16.43)
Age range	19-89	19-92
Sex (% male; % female)	39.85; 60.15	44.69; 55.31
Comorbidity index	2.51	2.40
Smokers (%)	2 (0.05)	58 (2.5)
Time wound present, weeks range	1-40	1-110

Table 1. Demographics and wound characteristics

### **PICO sNPWT**

The PICO sNPWT is a single-use system consisting of a small portable 'pocket-sized' pump, 2 lithium batteries, 2 dressings, and 10 fixation strips that deliver up to 7 days of NPWT.<sup>5</sup> Unlike a conventional NPWT system, which withdraws exudate to a canister, PICO sNPWT is a canisterless system. PICO system instead manages exudate within the dressing at the wound bed by absorbing and retaining it in the superabsorbent layer in combination with a high moisture vapour transmission rate uppermost film layer that removes fluid by evaporation (Figure 1).<sup>5-7</sup> Laboratory experiments have shown that 80% of fluid is managed by evaporation, with the residual 20% of fluid remaining in the dressing.<sup>6</sup>

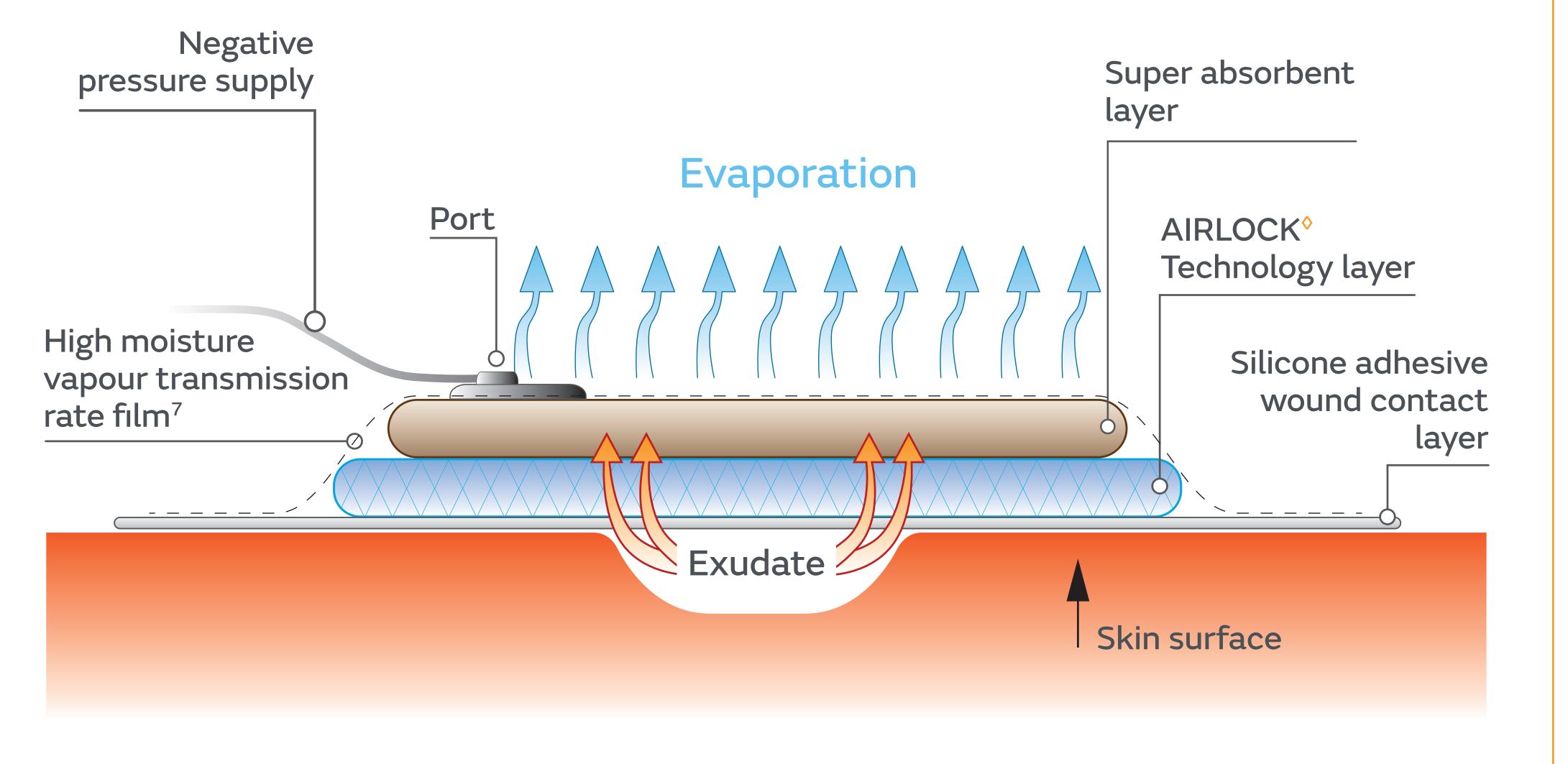


Figure 1. Operation of PICO sNPWT canisterless dressing to manage wound fluid

### Study design

- A retrospective analysis was conducted of data collected prospectively during the implementation of a change in practice for the treatment of chronic wounds in two large home and community care organizations serving Toronto, Canada.
- An integrated care bundle (ICB) including the use of PICO sNPWT in appropriate patients with chronic wounds was fully implemented beginning on March 31, 2016. IBCs provide standardized, evidencebased, best practice care requirements tailored to specific patient conditions.
- This analysis includes data obtained between ICB implementation until March 31, 2018. It compares outcomes of patients on the ICB with wounds >2cm in depth with a control population treated during the same time period but not on the ICB (either because they or their physicians refused), who therefore did not receive PICO sNPWT.

### Methods

#### Inclusion criteria

- All patients who received care for a chronic wound (DFU, PU, VLU, surgical ulcer [open incision]) in the home or community clinic

#### Exclusion criteria

Patients <18 years of age, taking</li> immunosuppressant drugs or receiving palliative care, or who had an active infection, positive HIV status, and/or scheduled chemotherapy. Patients with an established non-healable wound were also excluded

#### Outcomes of interest

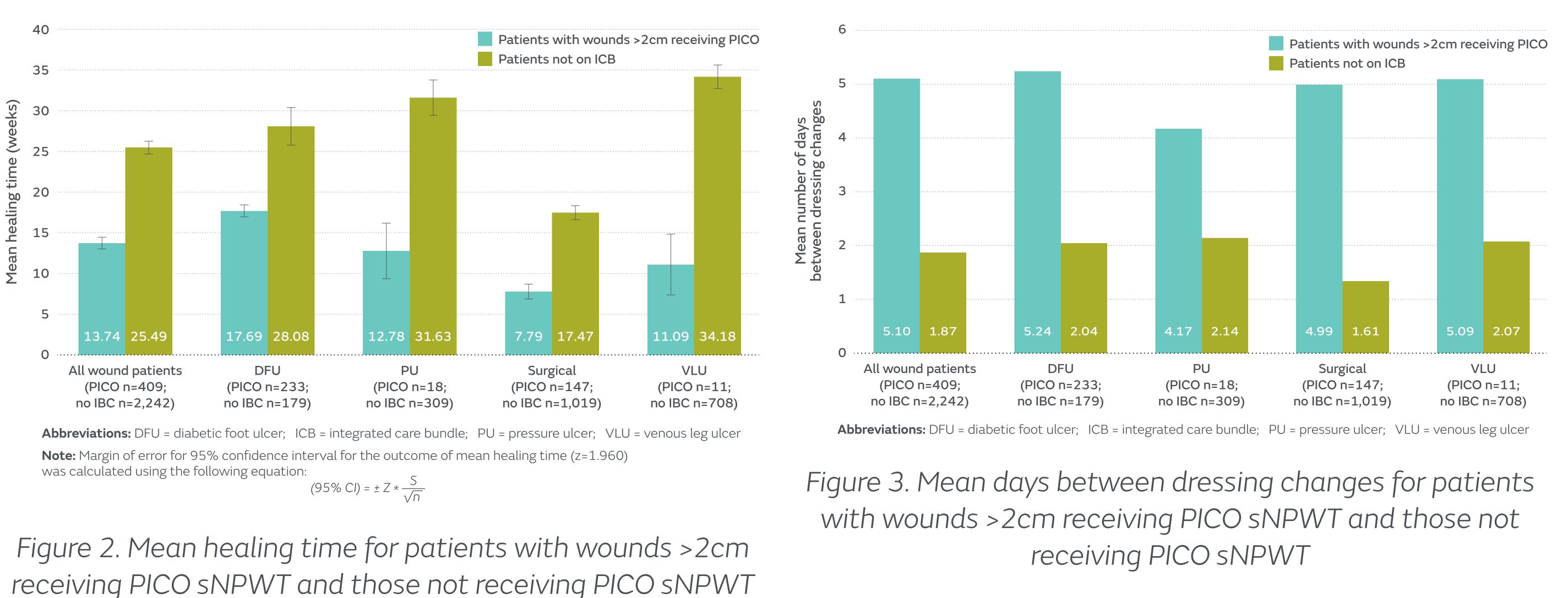
- Patient age, gender, and Charlson comorbidity index<sup>8</sup>
- Healing rates assessed using the Bates-Jensen Wound Assessment Tool<sup>9</sup>
- Wound depth assessed weekly by nurses using a soft-tipped probe and a per-centimeter measuring guide, with all wounds followed to the point of healing
- Time and date of each nursing visit/dressing change and the total number of visits per episode of healing for each patient
- Number of systematic wound infections, hospital admissions, and adverse effects potentially related to the use of the device

Approval was received from the local Institutional Review Board prior to conducting the study. Informed consent was not necessary, as this analysis did not include any data that could identify individual subjects.

#### Statistical analysis

– The margin of error was determined for the mean comorbidity index and mean healing time by wound type to a confidence interval of 95% for statistical testing. P values were used to compare demographic variables and z values to compare study outcomes, and considered statistically significant if they were ≤0.05

### Results



### Adverse events

- between the cohorts.

# Conclusions

- wounds >2cm deep
- predictive of less favorable outcomes<sup>10</sup>
- care organization

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 In comparison with the control cohort not receiving PICO sNPWT, wounds >2cm deep treated with PICO sNPWT had significantly shorter healing times (25.49 vs 13.74 weeks; Figure 2) and required less frequent dressing changes (1.87 vs 5.10 days; Figure 3).

#### There were no documented adverse events related to PICO sNPWT or its use.

• Of the 32 cases in which PICO sNPWT was withdrawn from treatment, the most frequent cause was due to increased "drainage" from the wound (10 cases). The clinician judged that an increase in wound exudate meant that the PICO sNPWT was no longer suitable to manage the wound, as it is only indicated for low-to-moderate exudate.

• There was no significant difference in the rate of systematic infection or hospital admissions

 The results of the evaluation demonstrated that implementing an ICB model including the use of PICO sNPWT can have a rapid, substantial, and predictable impact on wound care by reducing healing times and frequency of dressing changes in chronic open

 These results are particularly noteworthy, given that the PICO sNPWT group was statistically significantly older and had higher comorbidity scores, both of which are

In this study, there were no documented adverse events related to the use of PICO. These results support the use of PICO in the real-world setting of a high-volume community