

+ Evidence in Focus

Preclinical evaluation

Sophie Berry,¹ Chris Casey.²

¹Smith & Nephew, Watford, UK; ²Smith & Nephew, Hull, UK

PICO[◇] 7

Single Use Negative Pressure Wound Therapy System

Consistent delivery of therapeutic negative pressure by PICO[◇] 7 Single Use Negative Pressure Wound Therapy System (sNPWT) in a wound model

Research goal

- To evaluate the performance of PICO 7 sNPWT in terms of achieving and maintaining negative pressure at -80mmHg according to the manufacturer's instructions for use and within therapeutic recommendations to provide quality assurance data in the absence of standardized industry testing. A wound model was used including a small air leak that could be representative of real-world treatment scenarios.

Clinical relevance

- Single use NPWT systems (ie, dressings and pumps) were developed to address size and portability issues associated with traditional NPWT systems; they are used in low to moderately exuding acute and chronic wounds and to help prevent complications in patients with closed surgical incisions.¹
- Ideally, single use NPWT systems should be small, easy to use for patients and healthcare professionals; they should also maintain negative pressure at manufacturer's nominal vacuum pressure and within the recommended therapeutic range (-40 to -150mmHg), as well as manage exudate, even where dressing application or patient activity may not have resulted in a completely airtight seal.²
- In addition, single use NPWT systems should be designed to deliver negative pressure across the entire dressing to ensure that treatment is delivered to a wider zone beyond the wound itself.

Results

- At low exudate flow rate, PICO 7 sNPWT delivered a mean negative pressure of -82mmHg, ranging from -80 to -82mmHg, over the 72-hour test period (Figure 1)³
- At moderate exudate flow rate, PICO 7 sNPWT delivered a mean negative pressure of -81mmHg, ranging from -79 to -83mmHg during the study (Figure 1)³
- At low and moderate exudate flow rates, PICO 7 sNPWT delivered negative pressure within the therapeutic range for 100% of the test period³
- In addition, no pooling under the dressing, leakage into the dressing border, or fluid in the dressing port tubing, extension tubing or PICO 7 sNPWT pump was observed during the test period at both flow rates³

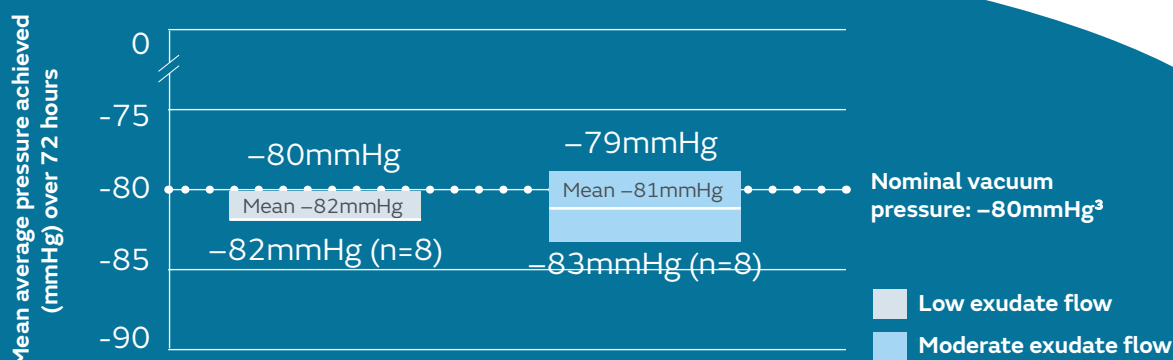


Figure 1. Mean negative pressure delivered under the dressing (mmHg) over 72 hours with PICO 7 sNPWT³

PICO[◇] 7 System overview

Conclusions and important considerations

In this wound model that incorporates a small air leak to replicate real-world clinical scenarios, PICO 7 sNPWT consistently achieved the manufacturer's specified nominal negative pressure value of -80mmHg over the 72-hour evaluation period under low and moderate exudate flow conditions. In addition, PICO 7 sNPWT maintained negative pressure at therapeutic levels at all times throughout the study period.

PICO 7 sNPWT features:

1. Single button operation for ultimate simplicity
2. Indicator for vacuum leak
3. Dressing full indicator
4. Low battery indicator
5. Operates on 2 x Alkaline AA batteries
6. Belt-clip
7. Soft port with integrated filter
8. Dressing with AIRLOCK[◇] Technology

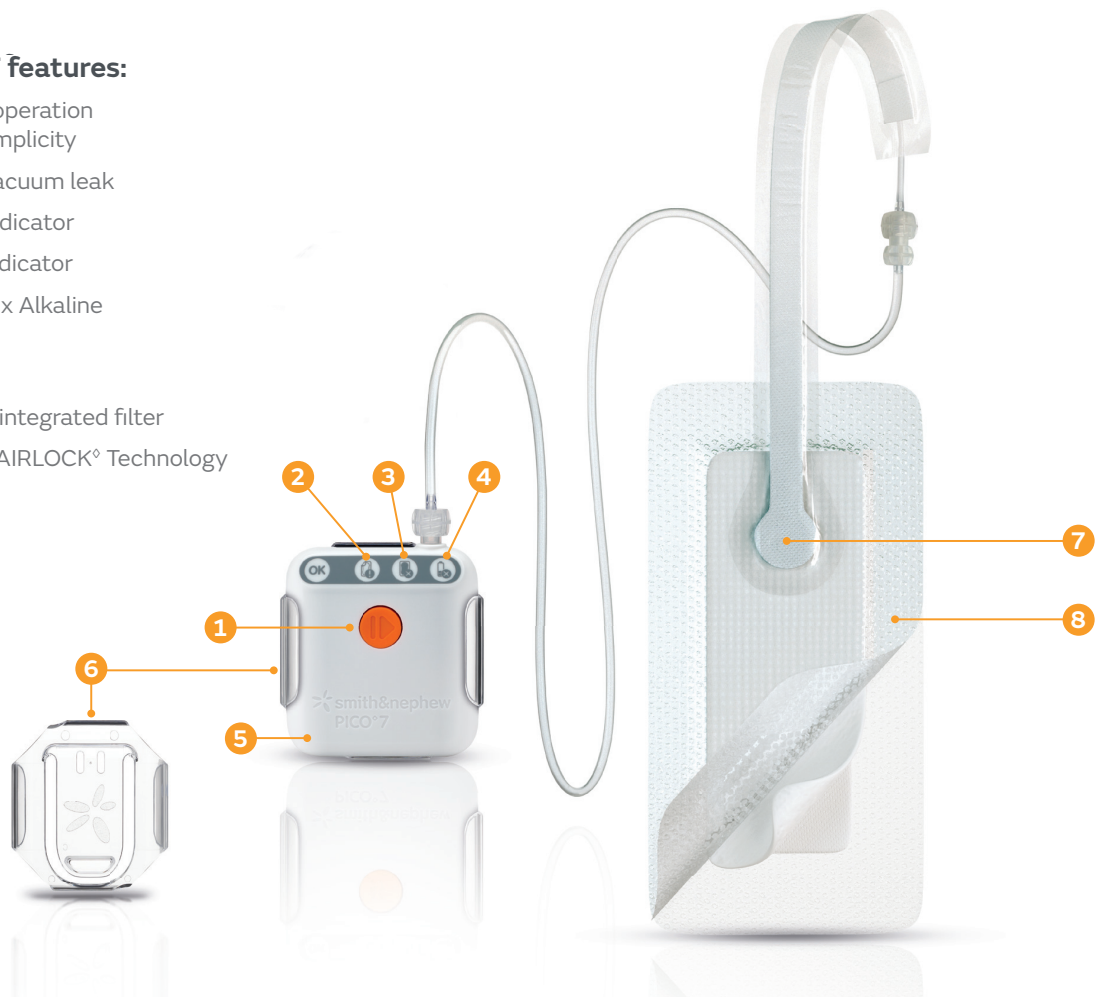


Figure 2. Features of the PICO 7 Single Use Negative Pressure Wound Therapy System

Important Safety Information

The PICO pumps contain a MAGNET. Keep the PICO pumps at least 4 inches (10 cm) away from other medical devices at all times. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. For full product and safety information, please see the Instructions for Use.

References: 1. Hudson DA, Adams KG, Van Huyssteen A, Martin R, Huddleston EM. Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system. *Int Wound J.* 2015;12:195-201. 2. Birke-Sorensen H, Malmsjo M, Rome P, et al. Evidence-based recommendations for negative pressure wound therapy: treatment variables (pressure levels, wound filler and contact layer)—steps towards an international consensus. *J Plast Reconstr Aesthet Surg.* 2011;64:S1-16. 3. Smith & Nephew. Negative pressure wound therapy (NPWT) delivery by the PICO 7 Single Use NPWT System in wound model testing. DS.18.542.R. November 2018.