



## PICO<sup>◇</sup> sNPWT for Venous Leg Ulcers

A solution that has been shown to reduce dressing change frequency, which may help healing to progress undisturbed, contributing to a faster time to healing<sup>1\*</sup>

For OUS audiences

\*in a study of VLUs and DFUs; compared to tNPWT, 12-week study

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# A worldwide concern

An open skin lesion resulting from chronic venous insufficiency and ambulatory venous hypertension, typically occurring on the medial lower leg between the ankle and the knee.<sup>2</sup>

- **About 1%** of the western population will **suffer from a VLU during their lifetime**<sup>2</sup>
- The overall prevalence of this condition is **1%**, **rising to 3%** in those over **65 years of age**.<sup>3</sup>
- More common in **women** than in men.<sup>2</sup>





# Negatively impacts patients' quality of life



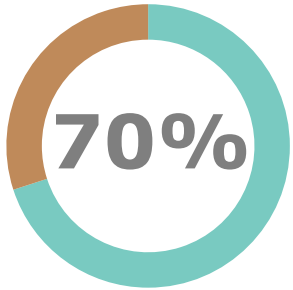
The issues associated with VLUs were described as **chronic pain and immobility, sleep disturbance, lack of energy, limitations in work and leisure activities, worries and frustrations, and a lack of self-esteem.**<sup>4</sup>



A systematic review found that patients felt that a leg ulcer limited their work capacity, and among non-working patients, **42% identified a leg ulcer as a key factor in their decision to stop working.**<sup>5</sup>



## How venous leg ulcers Affect patient wellbeing



Most chronic leg ulcers are VLUs.<sup>6</sup>

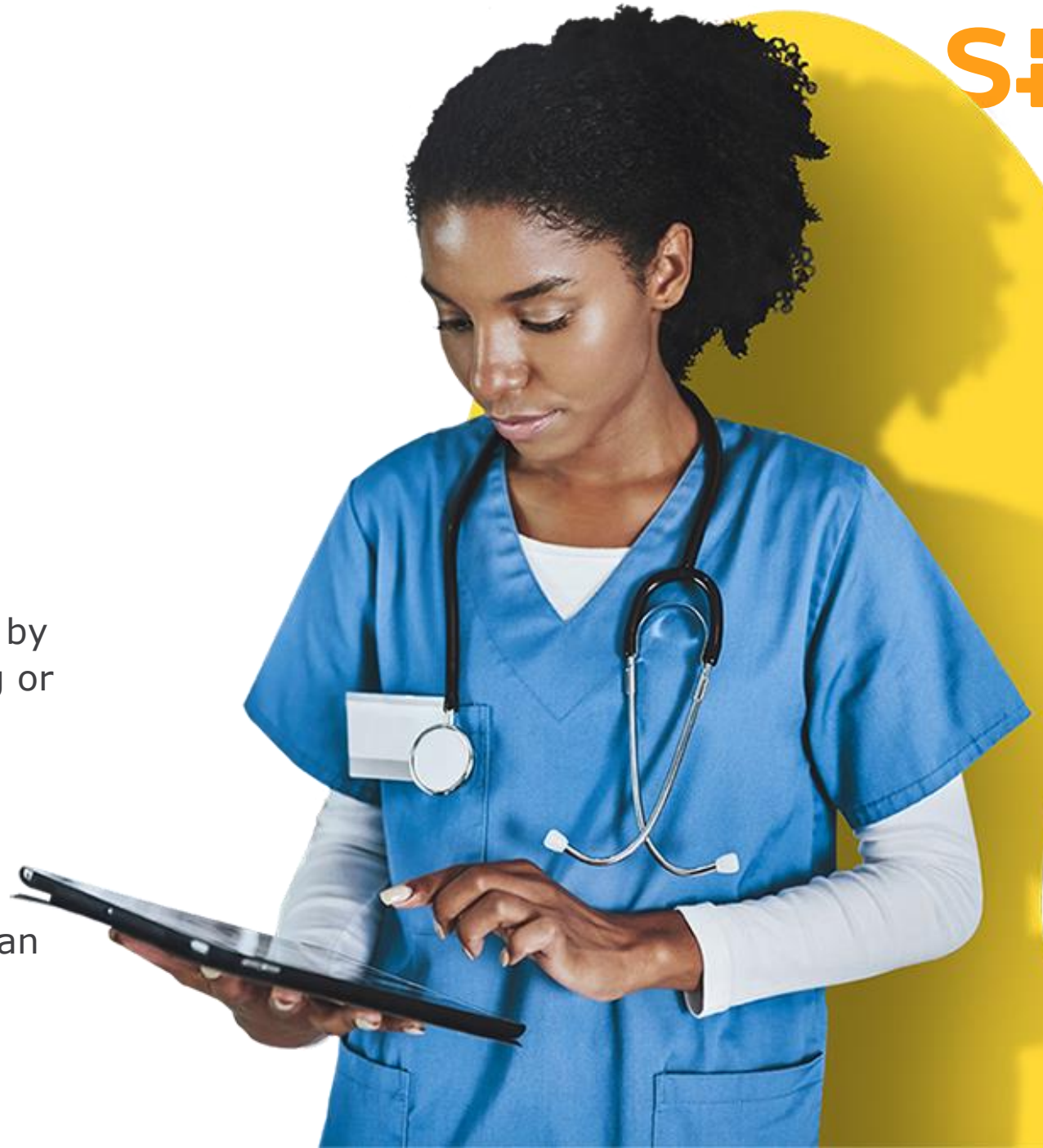


Time to heal a VLU takes approximately **6 months**.<sup>7</sup>

Some take longer – in a study by Drew P et al 2007, **42%** of leg or foot ulcers **had failed to heal within 6 months**.<sup>8</sup>



The ongoing management of pain, leaking exudate, odour can be challenging and may cause depression for patients.<sup>2</sup>



# Impact on the health system

Approximately 40% of VLUs have underlying deep venous disease; these VLUs are costly to manage, with conservative estimates of total annual economic burden of \$10.73 billion in seven countries, or \$5,527 per person per year.<sup>9</sup>

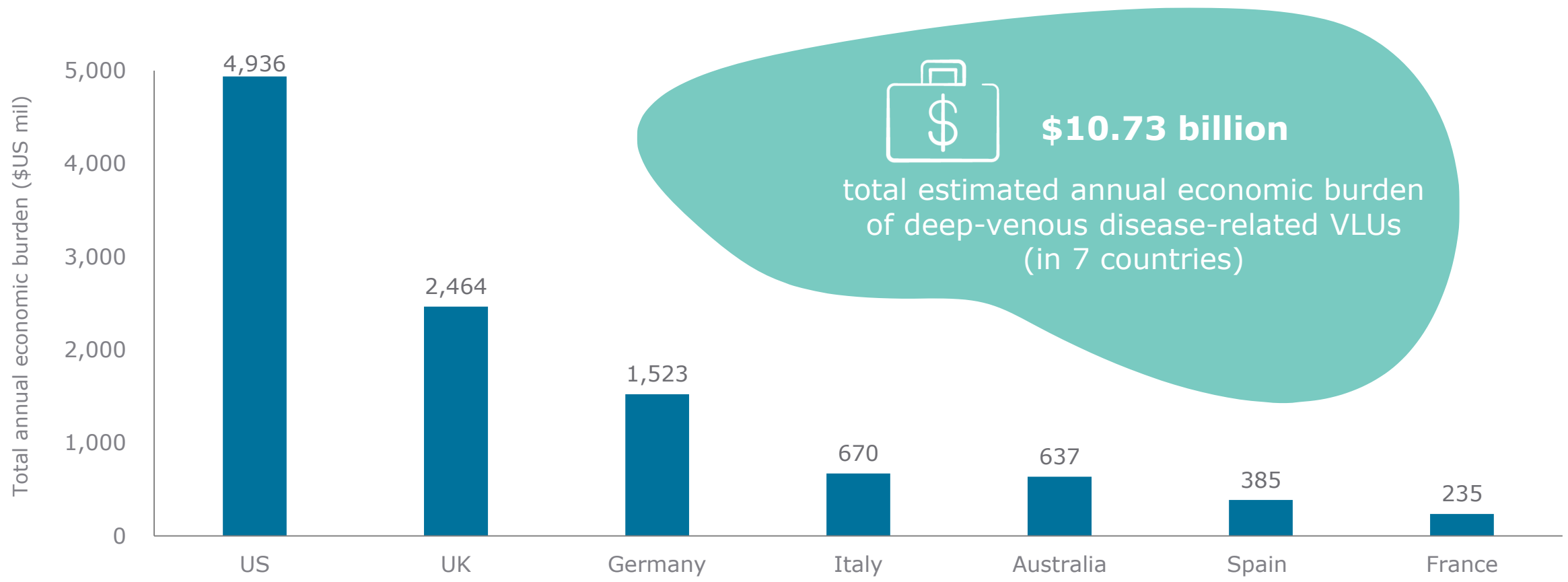


Figure. Total annual economic burden of deep-venous disease-related VLUs in seven countries<sup>9</sup>



# Management of venous leg ulcers (VLUs)



# Management of venous leg ulcers

Following are some of the treatment options for managing VLUs. It is suggested that the multimodal care pathway (which includes debridement, nutrition, vascular surgical intervention and compression therapy along with advanced wound management) would achieve the best clinical outcomes.<sup>10</sup>



**Compression therapy**

**Adjunct therapies**

(NPWT, electrical therapy, ultrasound)

**Leg elevation**

**Wound management**

**Medication**

**Nutrition**

**Surgical options**

**Patient education & follow-up**





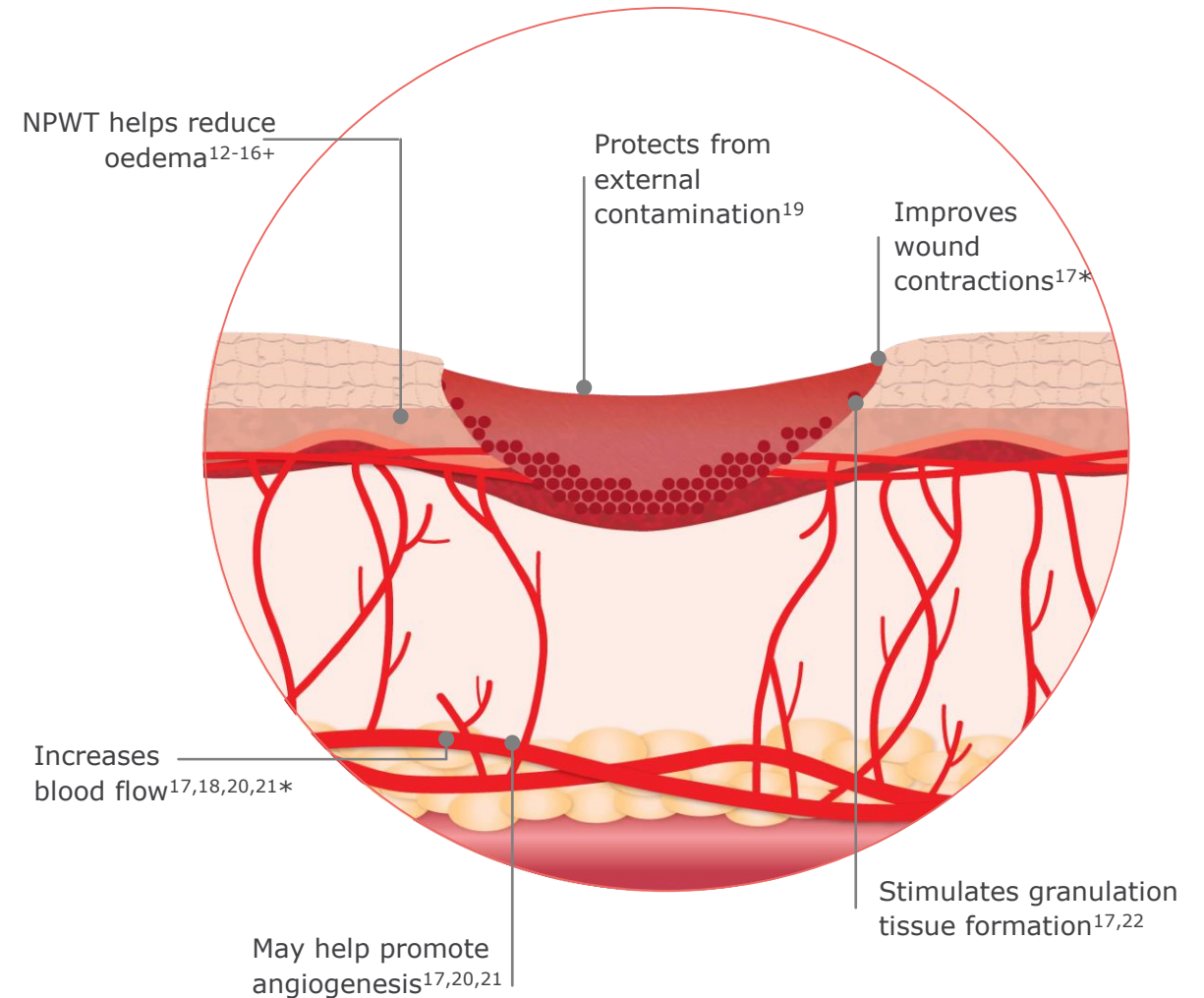
# Negative pressure wound therapy (NPWT)

When negative pressure is applied to a wound, there is negative pressure in the dressing, as well as mechanical forces applied to the wound bed and peri-wound area.<sup>11</sup> The negative pressure system drains exudate from the wound and creates a mechanical force (macro-deformation) in the wound edges that result in an altered tissue perfusion, angiogenesis and the formation of granulation tissue (micro-deformation).<sup>11</sup>

In the case of VLUs, NPWT **stimulates the process of anastomosis creation (or granulation tissue formation)**<sup>1</sup> between bed and the graft vessels and **removes the exudate that may hamper the graft adherence.**<sup>1,10</sup>

+in partial thickness burns and in post-operative oedema around a surgically closed incision

\*versus standard dressings



# Compression therapy

Compression therapy helps reduce vessel diameter, transmural pressure, and thus improves the competence of one-way valves.<sup>23</sup>

Compression with a stiff, rigid material may provide stable support for the leg muscles, thereby increasing the effects of the muscle pump, which in turn results in improved venous return.<sup>23</sup>

It helps with pain and oedema reduction, thus improves the ability to function.<sup>23</sup>

In order to treat venous leg ulcers, it is recommended to use

high pressure compression  
**30–40 mmHg** at the ankle<sup>24</sup>



# The role of compression and NPWT in managing VLUs

**Compression therapy** is widely recognised as the most effective treatment strategy for managing VLUs.

However, complex VLUs that are hard to heal, despite optimal local wound management and compression therapy, may require use of advanced therapies such as NPWT.<sup>2</sup>

**Both traditional and single-use NPWT can be used as adjunct to compression therapy in patients with complex VLUs.**<sup>1,2</sup>





# PICO<sup>+</sup> 7

## Single Use Negative Pressure Wound Therapy System



### Features:

#### Device performance

- The PICO 7 Pump has a significantly higher maximum leak rate tolerance than the original PICO Pump<sup>+25</sup>

#### Ease-of-use

- The 'dressing full' indicator on the PICO System led to a low frequency of outpatient clinic visits and home visits, creating a potential saving in treatment costs<sup>26,27\*</sup>

#### Patient quality of life

- The PICO Pump is quiet (30db at 1m)<sup>28</sup>
- The belt clip is to enable portability worn by the patient during use

#### Increased flexibility

- Multipacks of five dressings available, allowing therapy to be tailored to patients' clinical needs

+p<0.001

\*As demonstrated in a 4-patient case study on complex DFU. Reduction per patient of 1-2 outpatient visits and 1-3 home visits per week; compared to pre-NPWT

# PICO<sup>◇</sup> 14 System

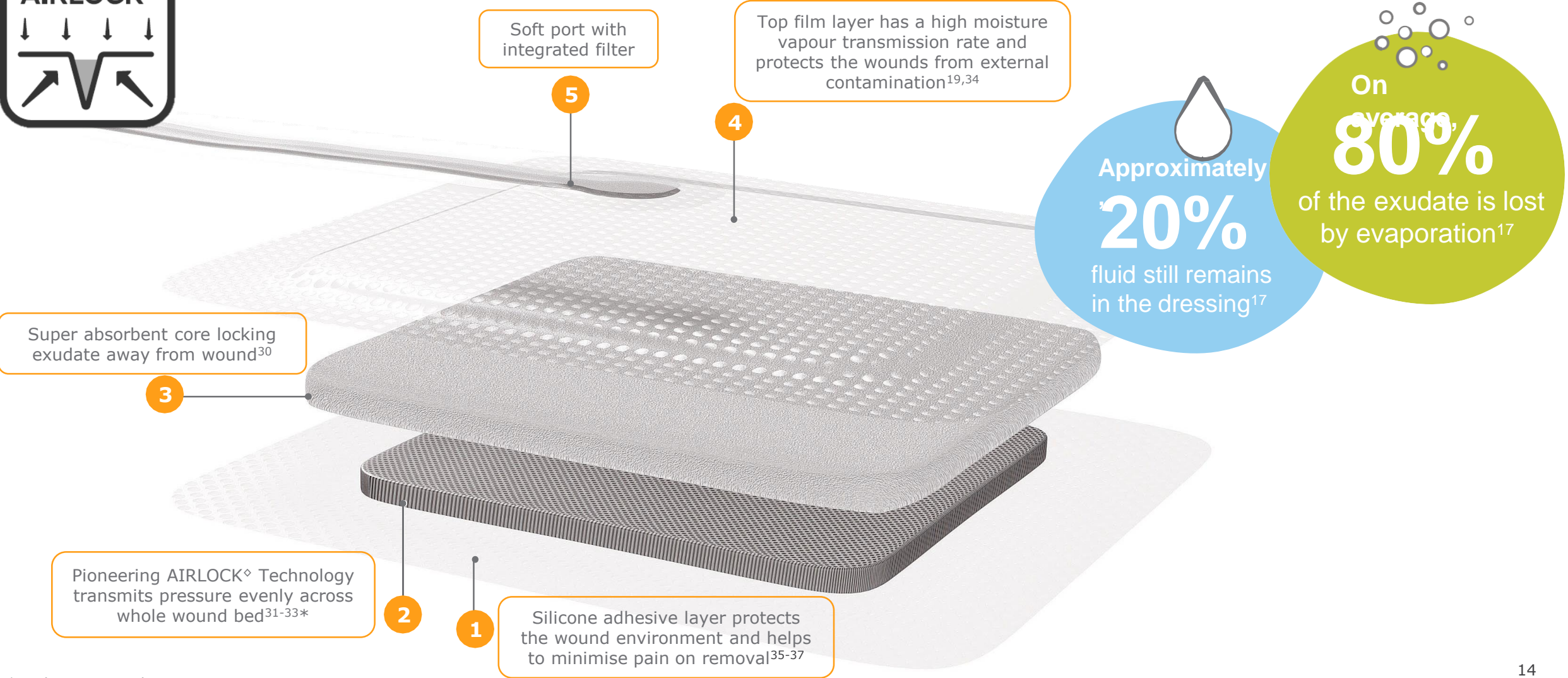
Designed to challenge  
**hard-to-heal wounds**



- Pump duration of up to **14 days**
- May be used in **deep wounds**.  
The PICO Dressing with Airlock<sup>◇</sup> Technology is capable of managing low to moderate levels of exudate in wounds of up to 4.5cm in depth, as demonstrated in vitro<sup>29</sup>

# PICO<sup>◇</sup> sNPWT dressing with AIRLOCK<sup>◇</sup> Technology

Wide delivery. Constant Pressure. Optimal outcomes.



\*as demonstrated ex vivo

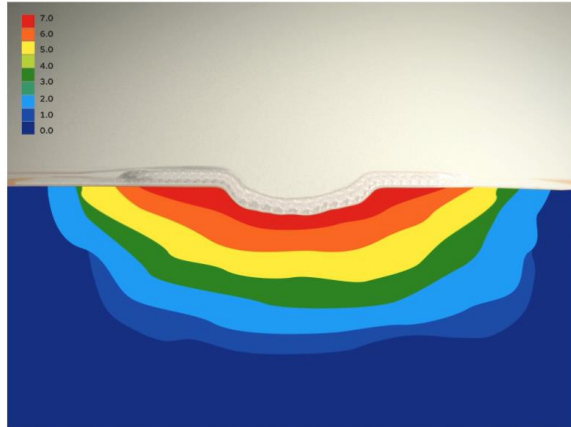


# The PICO System with proprietary AIRLOCK<sup>◇</sup> Technology

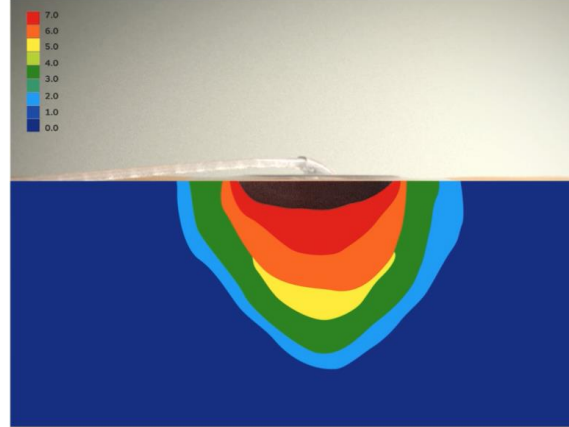


**Transmits negative pressure into the wound and peri-wound tissue across the dressing surface, providing benefits to the wound and surrounding area<sup>31-33\*+</sup>**

PICO<sup>◇</sup> sNPWT



tNPWT



**CT imaging of tissue compression**

- The PICO System provides compressive forces in the tissue, under and across the dressing area that could potentially manage excess oedema and interstitial fluid.<sup>31,33+</sup>
- **PICO<sup>◇</sup> sNPWT** showed less wound edge inflammation, yielding a pro-healing environment<sup>38,39#</sup>
- Fewer changes to skin health and barrier function than with tNPWT<sup>38±</sup>

Pain is a common side effect of foam-based NPWT.<sup>10</sup>



PICO<sup>◇</sup> Dressing can be **used without a filler**, thus creating a better quality<sup>38,40¶</sup> (less inflamed tissue, more collagen) granulation tissue for effective wound healing.<sup>1,38</sup>

In a study by Canonico S et al, the use of PICO<sup>◇</sup> sNPWT **was well tolerated by patients** and the **use of compression bandaging did not affect functionality** of the device (n=7).<sup>41</sup>

\*compared to tNPWT where negative pressure transmits into the foam filler area

+as demonstrated ex vivo.

#compared to tNPWT using a foam filler, as demonstrated in vivo

±as demonstrated in vivo at day 12

¶compared to tNPWT, as demonstrated in vivo at days 6 and 12; p<0.01

**Smith+Nephew**

**The clinical &  
financial outcomes**

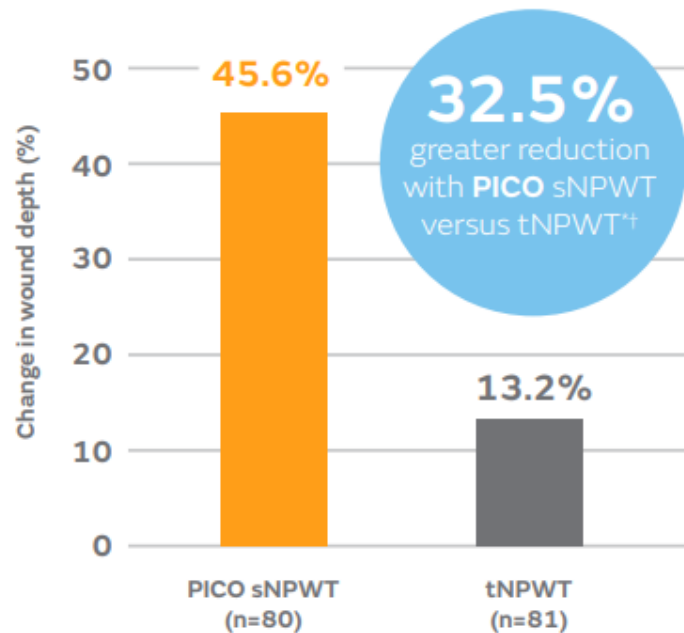


# PICO<sup>◇</sup> sNPWT has demonstrated **superior clinical outcomes** versus tNPWT in lower extremity wounds

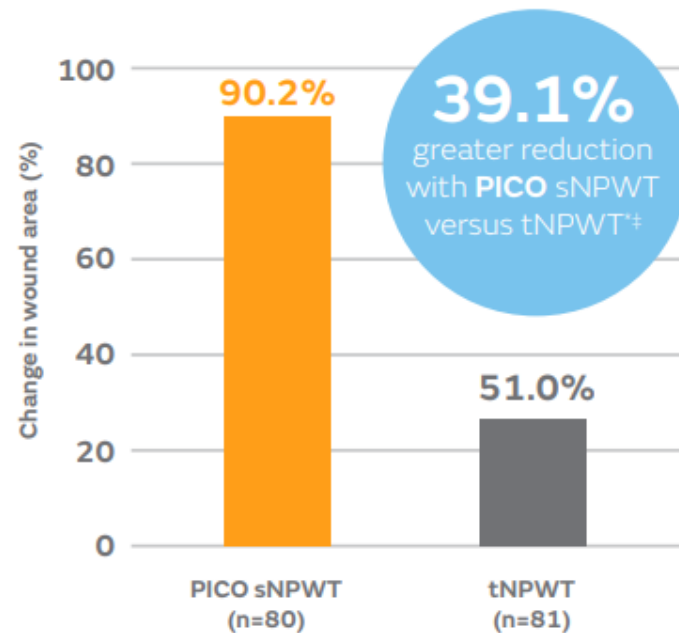


Over a 12-week treatment period for hard-to-heal venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs).<sup>1</sup>

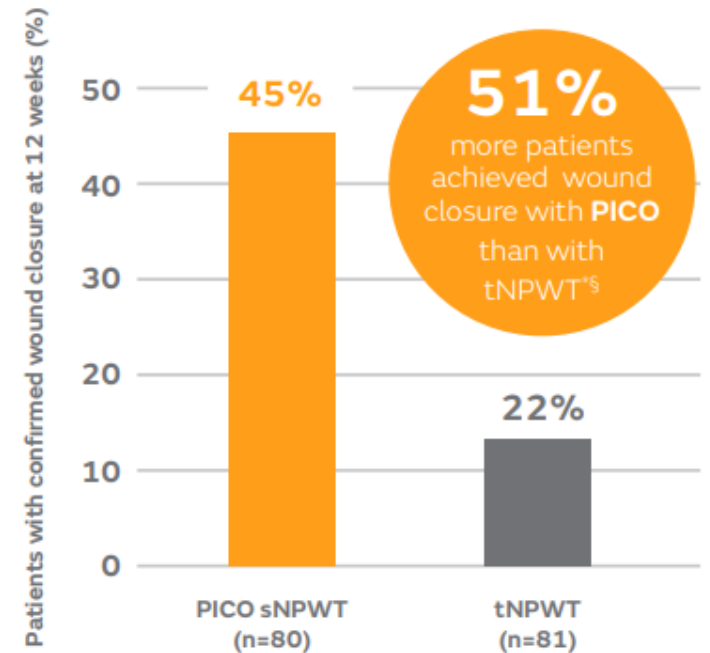
## Wound depth:



## Wound area:



## Wound closure:



\*n=161; Intention to treat analysis per protocol population; <sup>†</sup> p=0.001; <sup>‡</sup> p=0.014; <sup>§</sup> p=0.002.



# Successful intervention **releases resources**

PICO<sup>◇</sup> sNPWT is cost effective, providing resource savings vs. tNPWT for the treatment of VLU, as well as user satisfaction<sup>42</sup>



**US\$14,113**

expected **cost saving** per patient<sup>42\*</sup>



**3.94 weeks**

expected **reduction in open ulcer weeks** per patient<sup>42\*</sup>



**High**

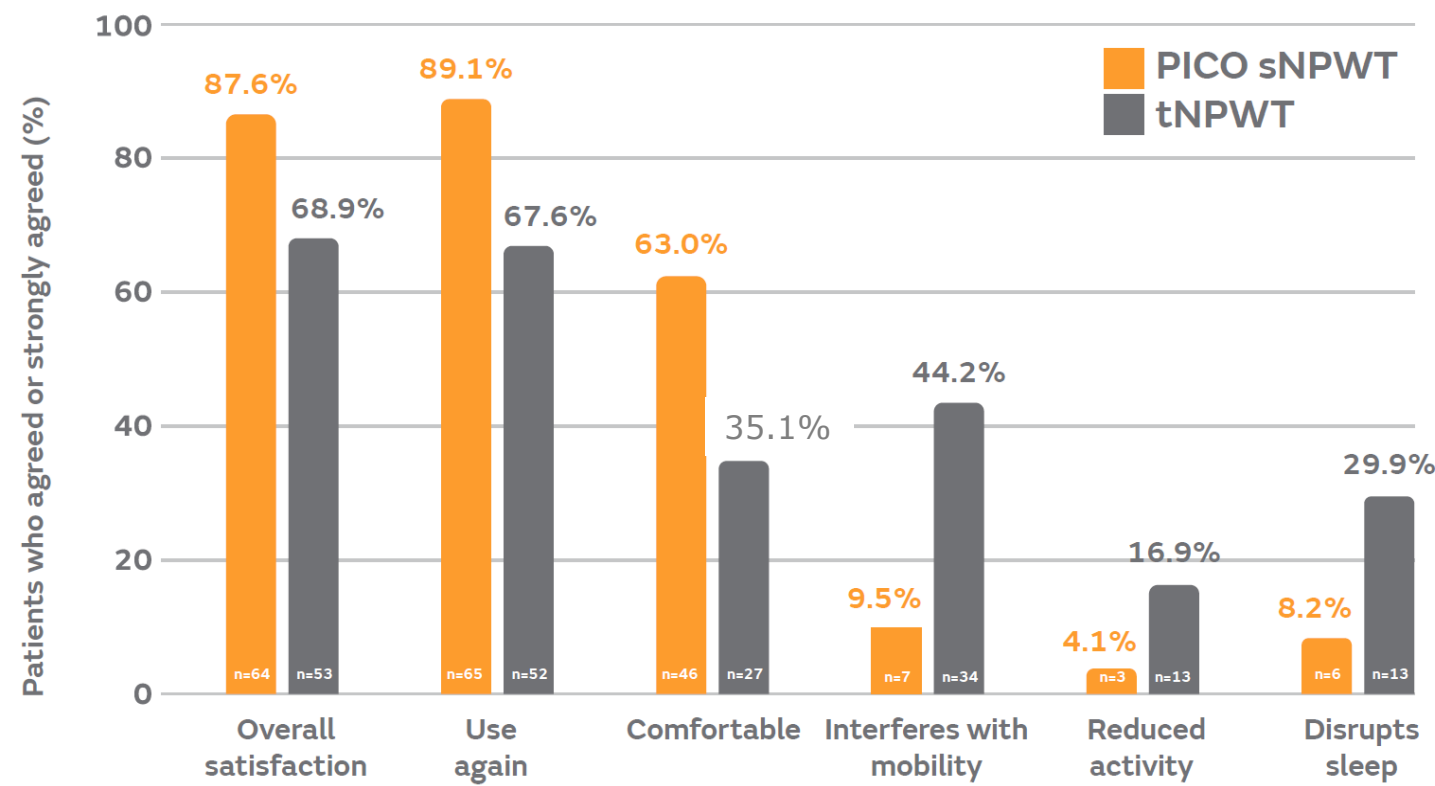
Satisfaction ratings from nurses<sup>43</sup>

\*when analysed over 26-week period

# Positive impacts



Positive impact of PICO<sup>◇</sup> sNPWT on **patients' everyday lives**<sup>1,44\*</sup>



**Less impact on:**

Mobility,<sup>‡</sup> activity levels<sup>§</sup> and on sleep,<sup>§</sup> compared with tNPWT<sup>1\*</sup>

**Better satisfaction**

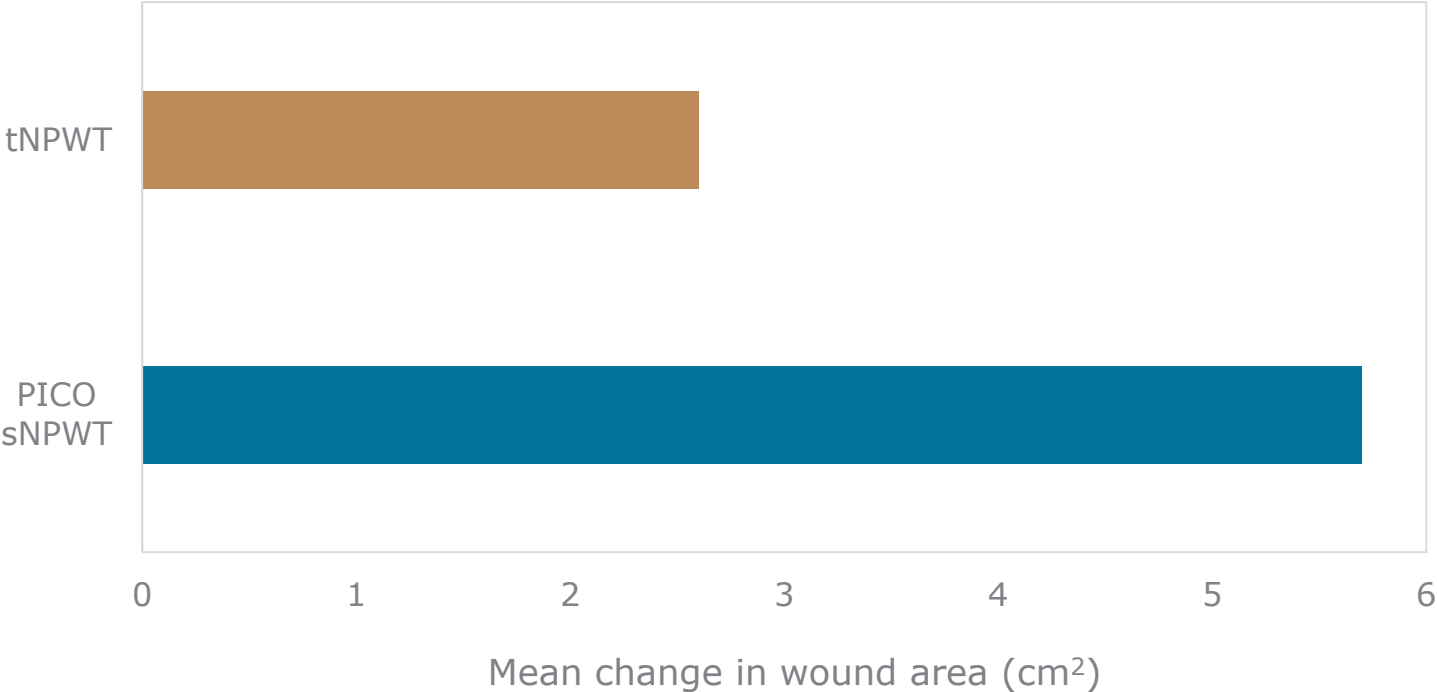
Greater satisfaction,<sup>||</sup> greater comfort and a greater willingness to use PICO<sup>◇</sup> sNPWT again,<sup>¶</sup> compared with tNPWT<sup>1\*</sup>


\*n=161, in a study of VLU and DFUs; ‡ (p<0.001); § (p=0.017); || (p=0.006); ¶ (p=0.003)

# Outcome of PICO<sup>◇</sup> sNPWT vs. tNPWT with compression therapy



Mean change in wound area from baseline (cm<sup>2</sup>) and least squares mean percentage difference in reduction in wound area over 12 weeks with PICO<sup>◇</sup> sNPWT and tNPWT with compression in patients with VLU<sup>s</sup><sup>1</sup>



**36.2%**

Significantly greater percentage reduction in wound area with PICO<sup>◇</sup> sNPWT with compression therapy

(\*n=101; ITT analysis. p=0.007; least squares mean values)

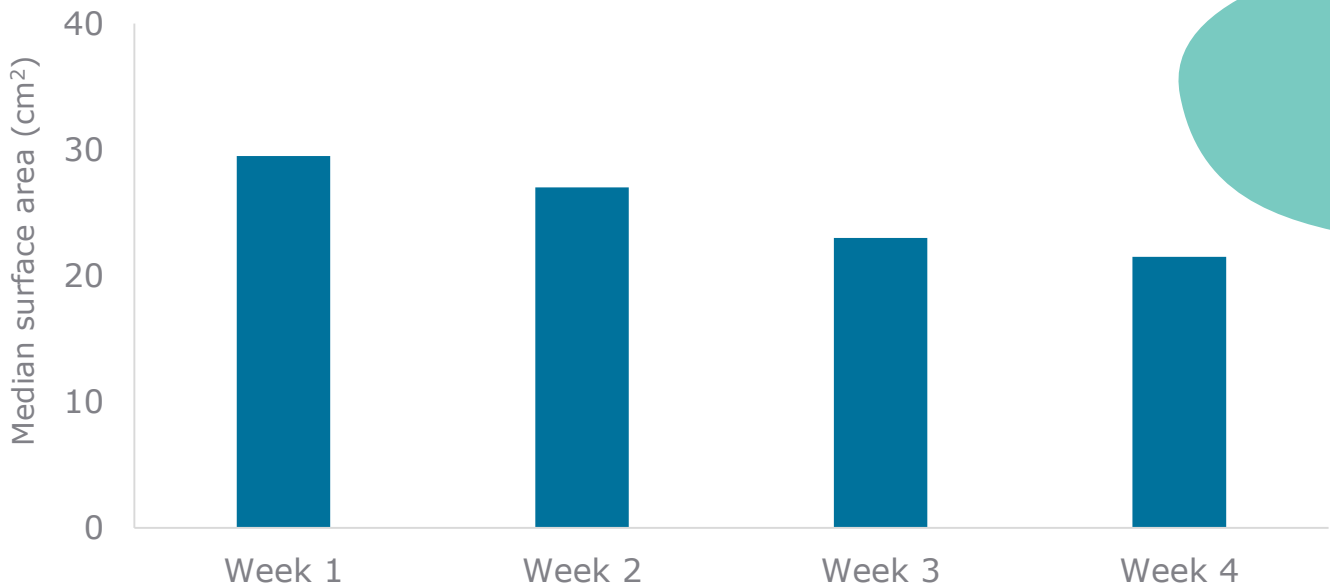


# Outcome of PICO<sup>◇</sup> sNPWT with compression therapy



The use of PICO<sup>◇</sup> sNPWT with compression therapy reduced mean surface area (as shown below) over a 4-week period.<sup>45</sup>

PICO<sup>◇</sup> sNPWT shown to manage exudate well, adequately **protected the peri-wound** skin and had **high patient satisfaction**.<sup>45</sup>



Change in mean VLU surface area from baseline (cm²) over 4-weeks (n=9) <sup>45</sup>

**32%**

relative reduction in mean  
VLU surface area

(mean baseline VLU surface  
area: 29.5cm²)

## Application & case studies



# Step-by-step application of PICO<sup>◇</sup> sNPWT under compression therapy

When applying compression therapy over PICO<sup>◇</sup> sNPWT, ensure tubing (Softport) is connecting to the PICO<sup>◇</sup> Pump



(Click on image below to **play** application video)



Ensure the **dressing runs over the top of the first layer and beneath the subsequent layers** as shown to avoid it being held against the skin



If using compression hosiery, run tubing outside of stockings. Do not store the pump within layers of compression.



## Tips:

Following the first application of PICO<sup>◇</sup> Dressing under a compression system, check the dressing after 2-3 days to see if fluid handling is acceptable, or if a dressing change is required, and it is appropriate to continue with compression therapy.

# Case study | bilateral leg ulceration

By Lorraine Grothier, consultant nurse, tissue viability,  
Tissue Viability Centre, Provide CIC<sup>11</sup>



The patient had a history of leg ulceration. Healing was achieved but re-ulceration had always occurred. The ulcer had increased in size despite treatment with compression bandaging.

Despite treating with wound management products and compression bandaging, there was no significant healing for some time.

PICO<sup>◇</sup> sNPWT was used in conjunction with a PROFORE<sup>◇</sup> Multi-layer Compression Bandage System (4-layer bandaging system) for three weeks, with polyhexamethylene biguanide (PHMB) gauze to lightly pack the shallow cavity.

During the 21 days of treatment with PICO sNPWT, the wound made significant healing progress. The condition of the wound bed improved with islands of epithelial tissue emerging within the wound.

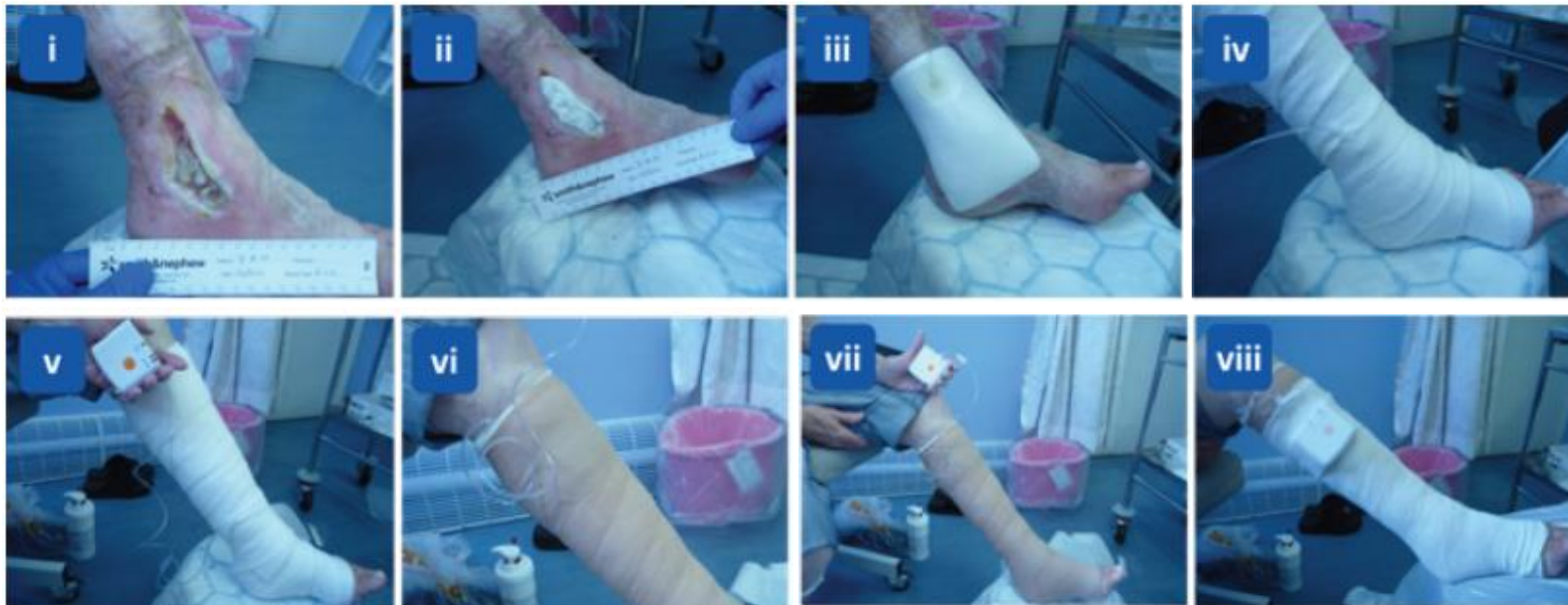


Figure 1i-1viii: The cavity in the wound was packed with saline soaked PHMB gauze (ii) and a PICO<sup>◇</sup> Dressing was applied over the wound (iii). The PICO<sup>◇</sup> Pump connector was passed through the Profore layer 1 to avoid indentation of the tubing on to the skin of the patient's leg (iv and v). The PROFORE Bandage layer 3 and layer 4 were applied (vi and vii). Tubular gauze was applied toe to knee and a double over to form a pocket to place the pump (viii).

**Note:** The PICO<sup>◇</sup> sNPWT Pump shown is no longer commercially available and has been superseded with PICO<sup>◇</sup> 7 sNPWT and PICO<sup>◇</sup> 14 sNPWT System.



# Case Study | Bilateral Leg Ulceration (Cont)

By Lorraine Grothier, consultant nurse, tissue viability,  
Tissue Viability Centre, Provide CIC<sup>11</sup>

Figure i before PICO<sup>®</sup> sNPWT was used and Figure ii after PICO<sup>®</sup> sNPWT was used. During this 21-day period of treatment the wound made significant progress toward healing



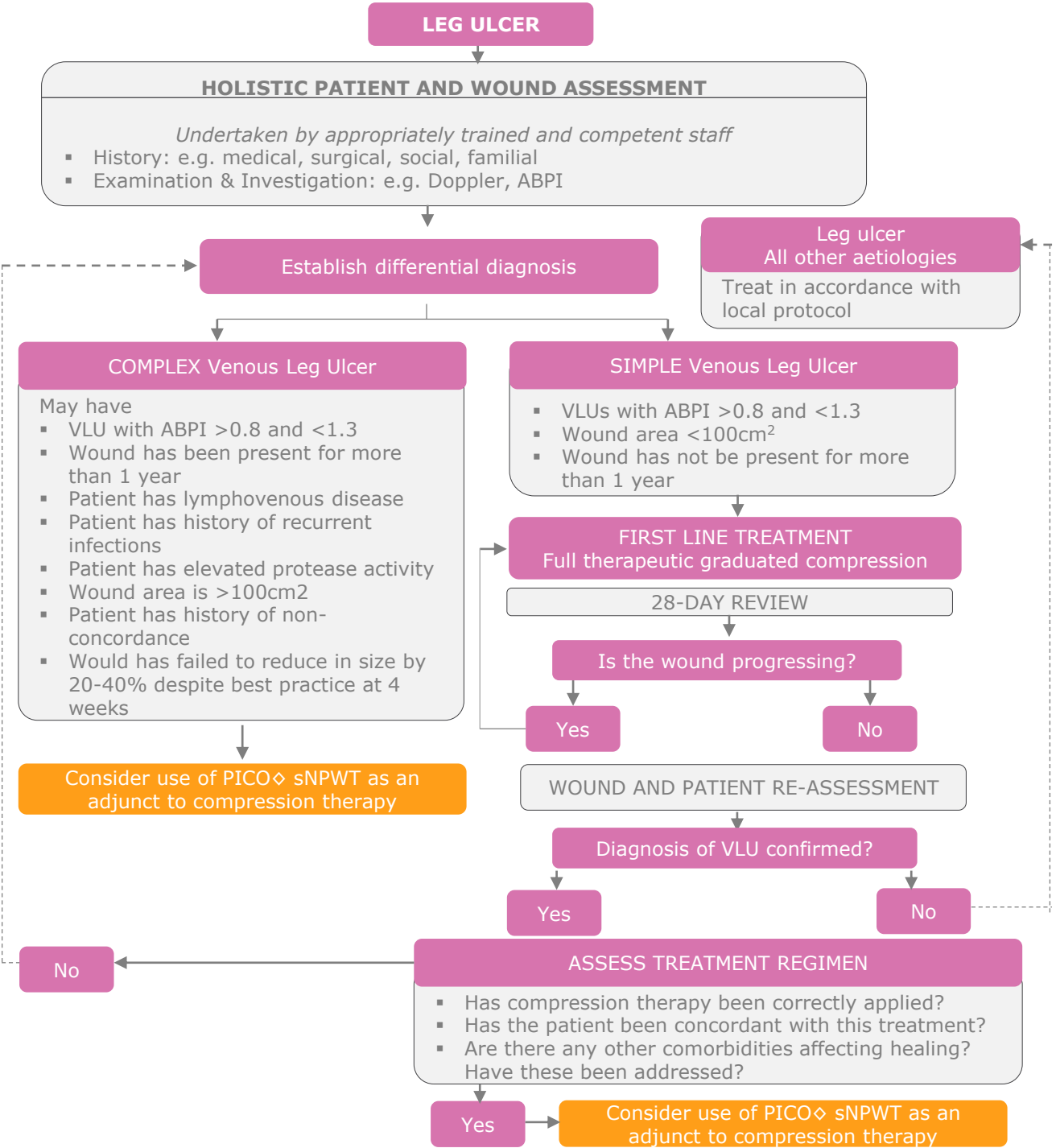
# Implementing a clinical pathway



# A decision-making process on the use of PICO<sup>◇</sup> System for venous leg ulcers<sup>46</sup>



This pathway is adapted from Dowsett C et al., 2013. It is designed to prevent overuse of the therapy and ensure that patients who may benefit most are able to access the treatment for an optimal period of time.<sup>46</sup>



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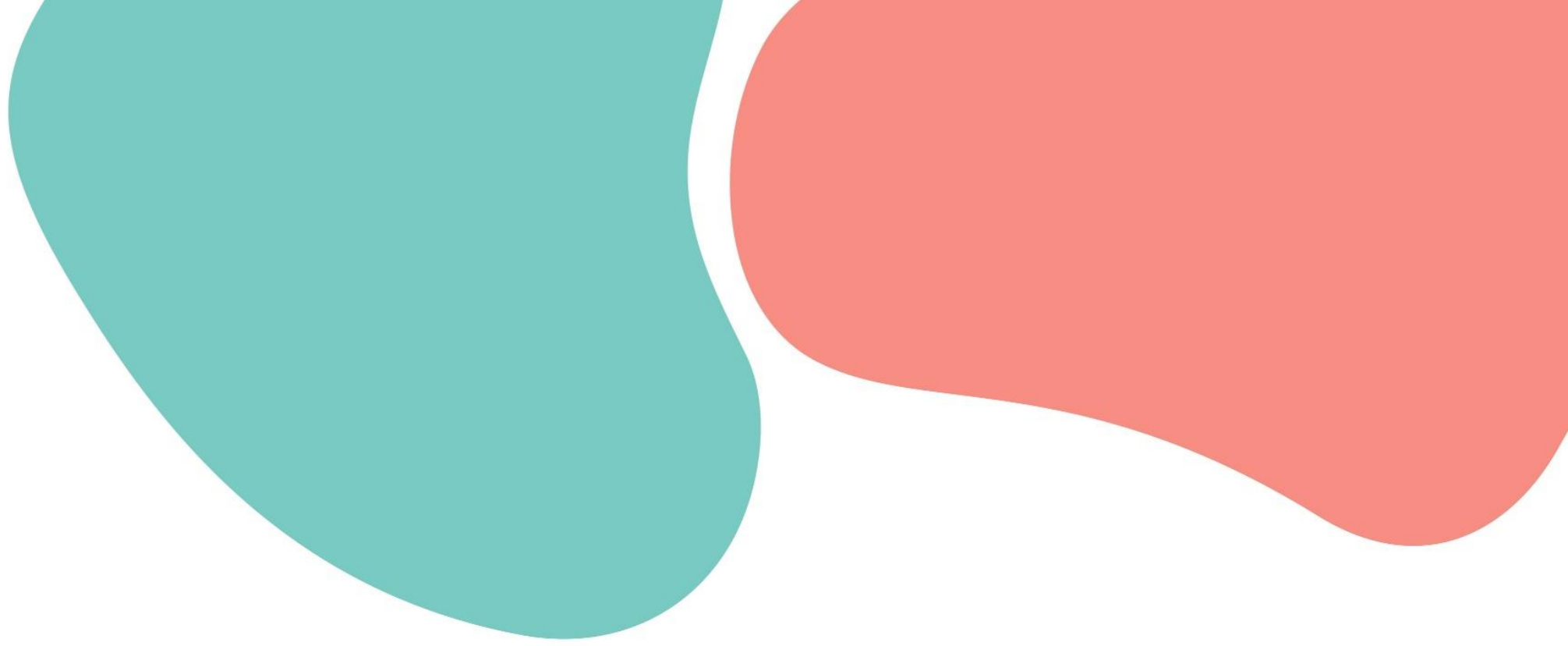
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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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