



# Evidence in focus

## Compendium of evidence

June 2019

 **smith&nephew**  
**PICO<sup>®</sup>**

Single Use Negative Pressure  
Wound Therapy System

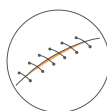
Supporting healthcare professionals

# Contents

## Abbreviations

**ASA:** American Society of Anaesthesiologists  
**ASEPSIS:** A quantitative scoring system used to identify and classify SSI  
**BMI:** Body mass index  
**CABG:** Coronary artery bypass graft  
**CI:** Confidence interval  
**DFU:** Diabetic foot ulcer  
**FEA:** Finite element analysis  
**ITT:** Intention-to-treat  
**LoS:** Length of hospital stay  
**MTG:** Medical technologies guidance  
**NICE:** National Institute for Health and Care Excellence  
**NNT:** Number needed to treat  
**NPWT:** Negative pressure wound therapy  
**POSAS:** Patient scale and observer scale  
**PP:** Per-protocol  
**QALY:** Quality adjusted life years  
**RCT:** Randomized controlled trial  
**RR:** Relative risk  
**RRR:** Relative risk reduction  
**sNPWT:** Single use negative pressure wound therapy  
**SSC:** Surgical site complication  
**SSI:** Surgical site infection  
**STSGs:** Split thickness skin grafts  
**TAA:** Total ankle arthroplasty  
**tNPWT:** Traditional negative pressure wound therapy  
**VAS:** Visual analogue scale  
**VLU:** Venous leg ulcer  
**WUWHS:** World Union of Wound Healing Societies

## Icons and wound descriptors



Closed incision



Evidence pyramid



Chronic/open wounds



Health economics

# Introduction

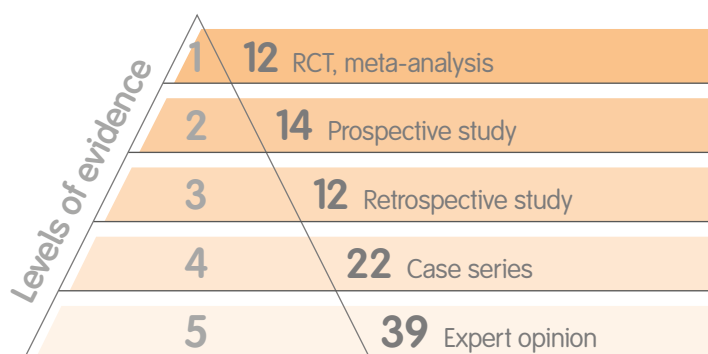
PICO sNPWT has a strong evidence base






**103\*** published papers of which 65 are clinical studies (including 4 NPWT meta-analysis which note PICO sNPWT)

Total published RCTs = **20†**

\*To 23rd January 2019.

†11 level 1 RCTs, 9 level 2 RCTs.



The evidence pyramid	Level of evidence <sup>1</sup>
	<b>RCT, meta-analysis</b> High-quality, <b>randomized controlled trial</b> with adequate power; or systematic review of these studies
	<b>Prospective study</b> <b>Lesser-quality randomized controlled trial; prospective cohort study;</b> or systematic review of these studies
	<b>Retrospective study</b> <b>Retrospective cohort study;</b> case-control study; or systematic review of these studies
	<b>Case series</b> Grouped case reports
	<b>Expert opinion</b> <b>Expert opinion</b> developed via consensus process; <b>case report</b> or clinical example; or evidence based on physiology, <b>bench research</b> , or “first principles”

# PICO sNPWT indication

PICO is indicated for patients who would benefit from a suction device [Negative Pressure Wound Therapy (NPWT)] as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Flaps and grafts
- Subacute and dehiscent wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Closed surgical incisions

PICO single use negative pressure systems are suitable for use both in a hospital and homecare setting.



# Consensus document/guidelines about prophylactic NPWT

## National Institute for Health and Care Excellence (NICE)

NICE Medical technologies guidance: *PICO negative pressure wound dressings for closed surgical incisions* (MTG43)

NICE aims to improve health and social care in England through evidence-based guidance. NICE guidance helps people make efficient, cost-effective and consistent decisions about adopting new medical technologies. NICE guidance is internationally recognized.

NICE recommends that PICO sNPWT should be considered as an option for closed surgical incisions in patients who are at high risk of SSIs.<sup>2</sup>

In a review of data from 31 clinical studies (15 randomized controlled trials and 16 non-randomized comparative observational studies), NICE concluded that PICO sNPWT is associated with fewer SSIs and seromas compared with standard wound dressings. Cost modelling suggests that compared with standard wound dressings, PICO sNPWT provides extra clinical benefits at a similar overall cost with standard wound dressings.<sup>2</sup>



The World Health Organization recommends the use of prophylactic NPWT “in adult patients on primarily closed surgical incisions in high-risk wounds, for the purpose of the prevention of SSI, while taking resources into account.”<sup>3</sup>



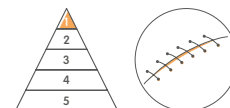
WUWHS proposes NPWT is used in patients with closed surgical incisions who have intrinsic risk factors for SSCs or who have had a surgical procedure associated with higher incidence and/or higher consequence of SSCs.<sup>4</sup>

The 2019 *WUWHS Consensus Document on Wound Exudate: effective assessment and management*, recognizes the benefits of sNPWT in the management of closed surgical incisions:<sup>5</sup>

- Provides a barrier to external contamination
- Removes excess wound exudate
- May aid healing by:
  - Reducing lateral tension across the closed incision
  - Improving lymphatic drainage
  - Reducing the risk of wound infection and separation (dehiscence)

### Meta-analysis of comparative trials evaluating a prophylactic single use negative pressure wound therapy system for the prevention of surgical site complications

Strugala V, Martin R. *Surgical Infections*. 2017;18:810–819



#### Study overview

- Meta-analysis of published data in which PICO sNPWT was compared to standard care for SSI, dehiscence or LoS
- Weighted analysis of 16 articles (comprising 17 studies); 10 RCTs and seven observational studies
- Total patients: 1,863 (2,202 incisions)

#### Key findings

- SSIs
  - Significantly reduced risk of SSIs by 58%, from 12.5% (140/1,117) to 5.2% (54/1,037) with PICO sNPWT (RR 0.43 [95% CI 0.32–0.57]  $p < 0.0001$ ) compared to standard care (16 studies, 1,839 patients; Figure 1)
  - Reduced risk of SSIs demonstrated by PICO sNPWT was significant across various surgical specialties including:
    - Orthopedic (RRR, 60%,  $p = 0.03$ )
    - Abdominal (RRR, 56%,  $p < 0.0001$ )
      - » Colorectal (RRR, 71%,  $p = 0.0004$ )
      - » Caesarean section (RRR, 49%,  $p = 0.007$ )

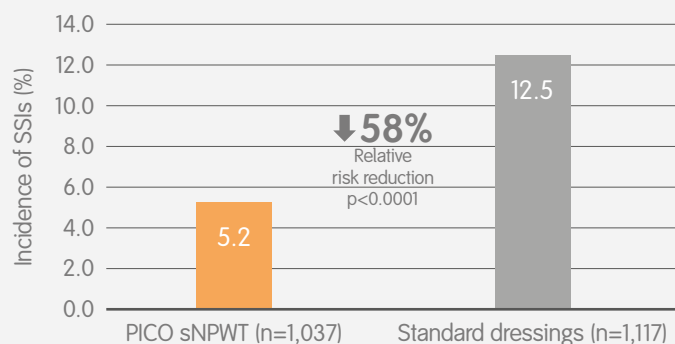


Figure 1. Incidence of SSIs

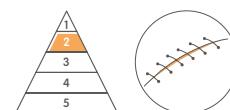
- Dehiscence
  - PICO sNPWT helped to significantly reduce the rate of dehiscence from 17.4% to 12.8% (relative risk 0.71,  $p = 0.01$ ) compared to standard care (6 studies, 1,068 patients)
- Length of stay
  - PICO sNPWT treated patients had significantly reduced hospital LoS compared to standard care (8 studies, 725 patients; -0.47 days,  $p < 0.0001$ )

**26.4%**  
relative risk reduction

**0.47**  
fewer days in hospital

### Preventive NPWT over closed incisions in general surgery: does age matter?

Pellino G, Sciaudone G, Candilio G, et al. *Int J Surg*. 2014;12(suppl 2):S64–8



#### Study overview

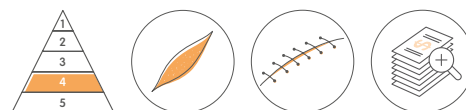
- Open-label, prospective controlled trial to assess the efficacy of PICO sNPWT in preventing SSCs compared with conventional dressings in patients undergoing primary wound closure for breast or colorectal diseases
  - Colorectal: PICO sNPWT, n=25; standard dressings, n=25
  - Breast: PICO sNPWT, n=25; standard dressings, n=25
- 40% (n=10) of each treatment group were aged >65 years

#### Key findings

- Rates of SSIs in patients aged >65 years were much lower with PICO sNPWT, compared with standard dressings regardless of surgery type ( $p = 0.003$ )
- SSCs were significantly lower in all patients receiving PICO sNPWT (breast,  $p = 0.04$ ; colorectal,  $p = 0.008$ )
- Rates of seroma were similar between both breast groups, while in colorectal patients these were higher in controls (8 vs 40%,  $p = 0.02$ )
- ASEPIS scores were lower with PICO sNPWT (breast,  $p = 0.03$ ; colorectal,  $p = 0.01$ )

### A retrospective, cost-minimization analysis of disposable and traditional negative pressure wound therapy Medicare paid claims

Delhougne G, Hogan C, Tarka K, Nair S. *Ostomy Wound Manage.* 2018;64:26–33



#### Study overview

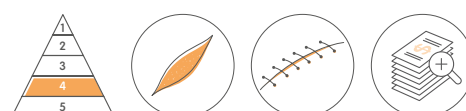
- Retrospective cost-minimization analysis assessed Medicare payments (2012–2014) associated with sNPWT and tNPWT to compare mean costs per patient episode of care for the two treatments
- Wound type included: surgical, generic open, skin ulcers, diabetic ulcers, circulatory disease wounds
  - sNPWT, n=3,522
  - tNPWT, n=2,938

#### Key findings

- Mean total direct cost per patient episode of care associated with sNPWT was three times less than for tNPWT (\$1,532±\$1,767 vs \$4,650±\$2,782; p=0.0001)
- Mean episode length was 15 days shorter with sNPWT than with tNPWT (28.3 vs 43.3 days)

### Application of the single use negative pressure wound therapy device (PICO) on a heterogeneous group of surgical and traumatic wounds

Payne C, Edwards D. *Eplasty.* 2014;14:152–166 



#### Study overview

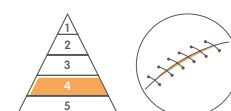
- Retrospective and prospective case evaluation designed to observe the efficacy of PICO sNPWT within a cost improvement programme
  - PICO sNPWT, n=21 (n=11 post-operative; n=10 post-traumatic)

#### Key findings

- PICO sNPWT was tolerated well in all patients, with no dressing failure or failure to comply
- Median time to healing was 16.25±9.5 days
- Estimated cost savings in patients with skin grafts compared to conventional therapy: 24 bed days (\$7,800; n=8)

### Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system

Hudson DA, Adams KG, Van Huyssteen A, Martin R, Huddleston EM. *Int Wound J.* 2013;12:195–201 



#### Study overview

- Prospective, open-label, non-comparative study to assess PICO sNPWT functionality and clinical performance on a variety of acute wounds including higher risk closed surgical incisions
  - PICO sNPWT, n=20 (surgical wounds, n=16; traumatic wounds, n=2 and meshed STSGs, n=2)

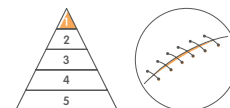
#### Key findings

- All wounds: 55% had closed by day 14 or earlier; further 40% of wounds progressing to closure
- Surgical wounds only: 69% closed by day 14; further 25% (n=4) progressing to closure
- No incidences of wound deterioration or dehiscence

Abdominal

Prophylactic negative pressure dressing use in closed laparotomy wounds following abdominal operations. A randomized controlled open-label trial: The P.I.C.O. Trial

O'Leary DP, Peirce C, Anglim B, et al. *Ann Surg.* 2017;265:1082–1086



### Study overview

- A randomized, controlled, open-label trial to investigate the effect of PICO sNPWT compared to standard dressing on postoperative SSI rates in closed laparotomy wounds at 30 days post-operatively
  - PICO sNPWT, n=24, worn for 4 days post-operatively
  - Standard dressing, n=25

### Key findings

- Significantly lower incidence of SSIs in the treatment group at 30 days compared to the control group (8.3 vs 32.0%; p=0.043, Figure 2)
- No difference in incidence of SSIs at day 4 postoperatively between groups
- Mean LoS for patients in the treatment group was significantly shorter by an average of 8.6 days (6.1 vs 14.7 days; p=0.019)

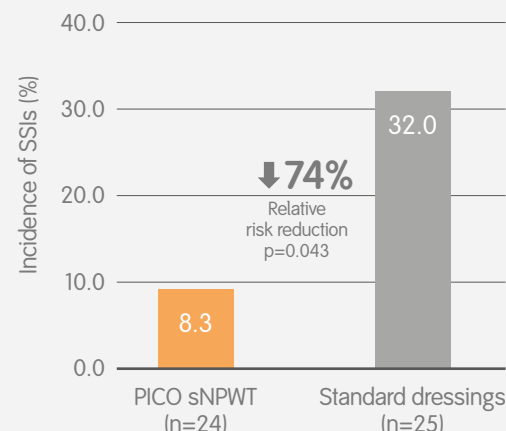


Figure 2. Incidence of SSIs in patients following open abdominal surgery

New advances in negative pressure wound therapy (NPWT) for surgical wounds of patients affected with Crohn's disease

Selvaggi F, Pellino G, Sciaudone G, et al. *Surg Technol Int.* 2014;24:83–9



### Study overview

- Prospective, open-label, controlled study to compare PICO sNPWT with conventional gauze dressings in patients undergoing elective surgery for structuring Crohn's disease
  - PICO sNPWT, n=25 patients
  - Conventional dressing, n=25 patients

### Key findings

- Compared to standard dressing, PICO sNPWT:
  - Reduced SSIs by 83% (8 vs 48%; p=0.004)
  - LoS (7±2 vs 12±2 days; p=0.0001)
  - Reduced seroma by 82% (8 vs 44%; p=0.008)
  - Reduced early readmission rate by 100% (24 vs 0%; p=0.02)

Efficacy of negative pressure wound treatment in preventing surgical site infections after Whipple procedures

Gupta R, Darby GC, Imagawa DK. *Am Surg.* 2017;83:1166–1169



### Study overview

- Retrospective study evaluating the incidence of SSIs in patients following pancreaticoduodenectomy (Whipple procedure), performed by one surgeon at a single center in the USA
  - PICO sNPWT, n=25
  - Traditional dressing, n=36

### Key findings

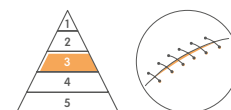
- PICO sNPWT resulted in a 71% reduction in SSIs compared with traditional dressings (12 vs 41%; p=0.01)
  - NNT: 3.4
- Pancreatic fistulas were less frequent with PICO sNPWT than with traditional dressings
  - All grades: RRR, 53% (8 vs 17%; p=0.33)
  - Grade B: RRR, 27% (8 vs 11%; p=0.69)
- PICO sNPWT reduced the incidence of deep SSIs by 6x compared to traditional dressings (4 vs 25%)



## Abdominal

### Prophylactic use of PICO negative pressure wound therapy to reduce surgical site infections following large bowel surgery

Caswell JF, Graham S, Whitehouse PA. Poster presented at Association of Surgeons of Great Britain and Ireland (ASGBI) conference; April 22–24, 2015; Manchester, UK



#### Study overview

- Open-label, prospective controlled trial to evaluate the impact of PICO sNPWT on SSI rates in high-risk patients following laparotomy. Data were compared to same period the previous year
  - Study period, n=102 (PICO sNPWT, n=27)
  - Control, n=119

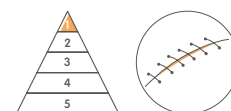
#### Key findings

- PICO sNPWT resulted in a 75% reduction in SSIs compared to the control (1.96 vs 7.69%; p=0.049)
- 27 patients in the study group were treated with PICO sNPWT, with 1 SSI (3.7%)
- Cost associated with 1 SSI ≈ 70 PICO sNPWT systems

## Breast and plastic surgery

### Incisional negative pressure wound therapy for prevention of wound healing complications following reduction mammoplasty

Galiano RD, Hudson D, Shin J, et al. *Plast Reconstr Surg Glob Open*. 2018;6:e1560 



#### Study overview

- A prospective, within-patient, randomized controlled, open-label, multicenter study assessing healing complications in patients having undergone elective bilateral reduction mammoplasty
- Patients were randomized within-patient to be treated with either PICO sNPWT or standard dressings for up to 14 days and followed up for up to 90 days post-operatively
  - PICO sNPWT, n=200
  - Standard dressing, n=200

#### Key findings

- PICO sNPWT significantly reduced wound healing complications within 21 days post-operatively compared to standard care (56.8% vs 61.8%; p=0.004, Figure 3)
- Incidence of wound dehiscence within 21 days of surgery was significantly reduced by application of PICO sNPWT compared to standard care (16.2% vs 26.4%; p<0.001, Figure 3)
- In an earlier presentation of this study, scar quality, measured by the VAS and POSAS scoring systems, was shown to be significantly better with PICO sNPWT compared to standard care, both at the 42 day and 90 day assessment (p<0.001)\*

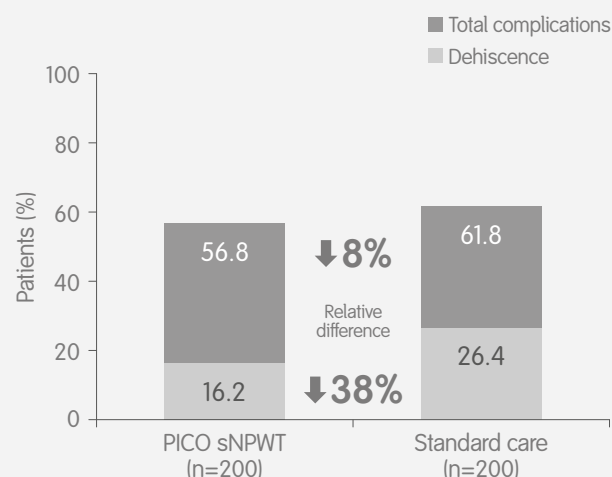


Figure 3. Frequency of wound complications and dehiscence within 21 days in patients treated with PICO sNPWT and standard care

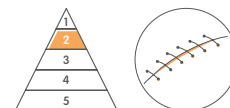
\*Galiano RD, Djohan R, Shin J, et al. The effects of a single use canister-free Negative Pressure Wound Therapy (NPWT) System on the prevention of postsurgical wound complications in patients undergoing bilateral breast reduction surgery. Poster presented at: British Association Of Aesthetic Plastic Surgeons; September 25–26, 2014; London, UK



## Breast and plastic surgery

### Randomized controlled study comparing disposable negative pressure wound therapy with standard care in bilateral breast reduction mammoplasty evaluating surgical site complications and scar quality

Tanaydin V, Beugels J, Andriessen A, Sawor JH, van der Hulst RRWJ. *Aesthetic Plast Surg.* 2018;42:927-935 



#### Study overview

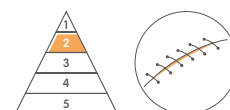
- A single-center, prospective, randomized, controlled study of patients undergoing bilateral breast reduction mammoplasty who received PICO sNPWT or standard care (fixation strips) on either the left or right breast
  - PICO sNPWT, n=32
  - Standard dressing, n=32

#### Key findings

- PICO sNPWT resulted in a significant 50% reduction in SSCs (incision not completely closed at 7 days, dehiscence or infection) compared to standard dressing (15.6% vs 31.3%;  $p < 0.004$ )
- POSAS and VAS scores at 42 and 90 days revealed a significantly better quality of scarring with PICO sNPWT compared to standard dressing

### PICO incision closure in oncoplastic breast surgery: a case series

Holt R, Murphy J. *Br J Hosp Med.* 2015;76:217-223



#### Study overview

- Prospective open-label case cohort study of consecutive patients undergoing oncoplastic mammoplasty or skin-sparing mastectomy and immediate reconstruction
  - PICO sNPWT, n=24 (therapeutic breast)
  - Standard dressing, n=24 (symmetrizing breast)

#### Key findings

- Overall wound breakdown rate was 75% lower with PICO sNPWT compared to standard dressing (4.2 vs 16.7%)
- Mean time to healing was 34% faster with PICO sNPWT compared to standard dressing (10.7 vs 16.1 days)

### Using portable, single use, canister-free, negative-pressure wound therapy for plastic surgery wounds

Edwards D, Bourke N, Murdoch J, Verma S. *Wounds UK.* 2018;14:56-62



#### Study overview

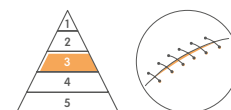
- Retrospective, single-center data review evaluating the pathway used to treat complex plastic surgery wounds using PICO in an outpatient setting
  - PICO sNPWT, n=213

#### Key findings

- Use of PICO sNPWT within this pathway facilitated the management of complex wounds in an outpatient setting and facilitated early patient discharge, enabling 367 bed days to be released over 5 years
- A total of \$76,592 was saved in the plastic surgery department due to bed management efficiencies, after deducting device and nursing resource costs

### The use of PICO dressing in mastectomy patients: a retrospective analysis

Sim K, Mackowski A, Bevis H, Hamza S. Poster presented at: 47th World Congress of Surgery; August 13-17, 2017; Basel, Switzerland. Abstract PE144



#### Study overview

- A retrospective, single-center study comparing the use of PICO sNPWT with standard care dressings in patients post-mastectomy
  - PICO sNPWT, n=50, up to 7 days
  - Standard dressings, n=56

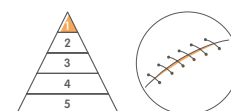
#### Key findings

- No significant differences in the incidence of SSIs, wound dehiscence or hematomas
- Number of patients with seroma and seromas requiring aspiration was significantly lower in the PICO sNPWT group than in the standard care group
  - Seroma reduced by 40% (37.9 vs 63.2%; p=0.0071)
  - Seromas requiring aspiration reduced by 55% (40.9 vs 90.1%; p<0.0001)

## Cardiothoracic and vascular surgery

### Preliminary outcome of treatment of postoperative primarily closed sternotomy wounds treated using negative pressure wound therapy

Witt-Majchrzak A, Żelazny P, Snarska J. *Polish J Surg.* 2014;86:456–465



#### Study overview

- Prospective, open-label RCT to evaluate wound healing in patients after an off-pump CABG procedure treated with PICO sNPWT
  - PICO sNPWT, n=40
  - Standard dressings, n=40

#### Key findings

- PICO sNPWT resulted in a 70% reduction in wound complications compared to standard dressings (7.5 vs 25.0%; p=0.034; Figure 4)
- Superficial SSI was reduced by 86% with PICO sNPWT compared to standard dressings (2.5 vs 17.5%; p=0.025; Figure 4)
- Significantly fewer SSIs in PICO sNPWT group required antibiotic treatment (p=0.043) and fewer patients underwent wound reopening on account of infection than with standard dressings (2.5 vs 7.5%; p=0.305)

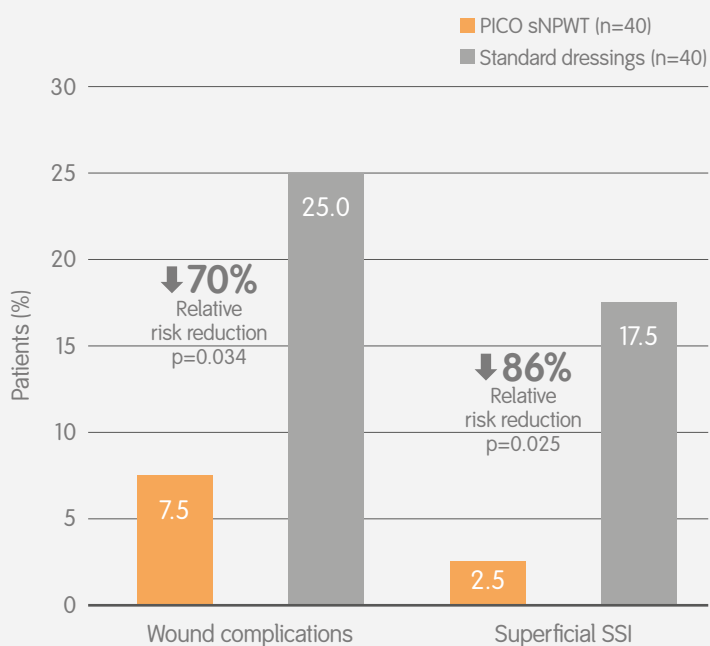
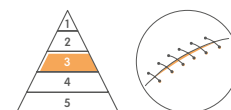


Figure 4. Wound complications and superficial SSIs following off-pump CABG in patients treated with PICO sNPWT or conventional dressings

### Routine use of PICO dressings may reduce overall groin wound complication rates following peripheral vascular surgery

Fleming CA, Kuteva M, O'Hanlon K, O'Brien G, McGreal G. *J Hosp Infect.* 2018;99:75–80



#### Study overview

- Single center, retrospective analysis of wound complications that occurred up to six weeks postoperatively in patients who underwent peripheral vascular surgery of the lower limb.
  - PICO sNPWT, n=73
  - Standard dressing, n=78

#### Key findings

- Significantly fewer wound complications occurred with PICO sNPWT than with standard dressings (8.2 vs 19.2%, p=0.042; Figure 5)
- Seroma incidence was substantially lower with PICO sNPWT than with standard dressings (1.4 vs 7.7%, p=0.069; Figure 5)
- Haematoma (2.7% vs 3.8%, p=0.531) and dehiscence rates (1.4% vs 1.3%, p=0.735) were similar between the two groups
- Mean hospital LoS for readmissions was shorter with PICO sNPWT (3 patients, 2.83 days) than with standard dressings (6 patients, 5.67 days, p=0.465)
- Mean time to resolution of wound complications was also reduced (53 vs 96 days, p=0.015)

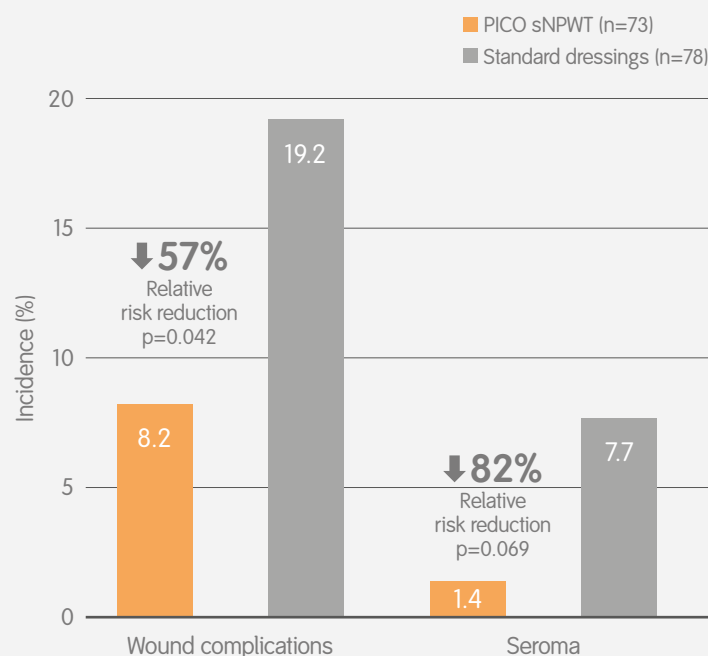
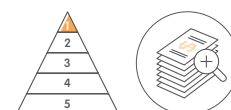


Figure 5. Incidences of all wound complications and seromas with PICO sNPWT and standard dressings

### Cost-effectiveness analysis of single use negative pressure wound therapy dressings (sNPWT) compared to standard of care in reducing surgical site complications (SSC) in patients undergoing coronary artery bypass grafting surgery

Nherera LM, Trueman P, Schmoeckel M, Fatoye FA. *J Cardiothorac Surg.* 2018;13:103-111



#### Study overview

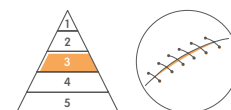
- An evaluation of the cost-effectiveness of PICO sNPWT compared with standard care in reducing the incidence of SSCs (superficial and deep infections or dehiscence) in patients undergoing CABG surgery from a German Insurance payer perspective

#### Key findings

- Estimated total mean treatment costs per patient were lower with PICO sNPWT than with standard care (\$20,572 vs \$19,986) with a cost-saving of \$586
- Use of PICO sNPWT was estimated to avoid more wound-related complications (0.989 vs 0.952) and provide more QALYs (0.8904 vs 0.8593) compared with standard care
- In high-risk patients (BMI ≥30 kg/m<sup>2</sup>, patients with diabetes and smokers), PICO sNPWT was estimated to result in greater savings versus standard care than in those with standard risk

### NPWT: Incision management in high risk cardiothoracic patients – reducing surgical site infection and length of stay

Rodden D, Taylor A. Poster presented at Wounds UK conference, November 9–11, 2015. Harrogate, UK



#### Study overview

- Single-center, prospective cohort study to assess the effectiveness of PICO sNPWT in reducing post-surgical complications and LoS in high-risk CABG patients compared to low-risk CABG patients managed with standard dressing
  - PICO sNPWT, n=42
  - Standard film dressing, n=345

#### Key findings

- SSI incidence with standard care was 3.5% compared to 0% with PICO sNPWT
- Healing problems (non-SSI) with standard care was 13.9% (48/345) versus 0% with PICO sNPWT
- Mean LoS with standard care was 11.1 days versus 5.2 days with PICO sNPWT

## Obstetrics and gynaecology

### Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women. A pragmatic randomized clinical trial

Hyldig N, Vinter CA, Kruse M, et al. *BJOG*. 2018;126(5):628-635



#### Study overview

- Open-label, pragmatic, multi-center, randomized trial to assess the effect of sNPWT on post-caesarean wound complications in obese women (pre-gestational BMI  $\geq 30\text{kg/m}^2$ )
  - PICO sNPWT, n=432
  - Standard dressing, n=444

#### Key findings

- Use of PICO sNPWT reduced the incidence of SSIs by 50% compared with standard dressings (4.6 vs 9.2%;  $p=0.007$ ; Figure 6)
  - NNT: 22
- Wound exudate was reduced by 31% with PICO sNPWT compared to standard dressings (22.4 vs 32.9%;  $p=0.001$ )
  - NNT: 10
- No differences between the groups in deep SSIs, dehiscence, or self-rated health status

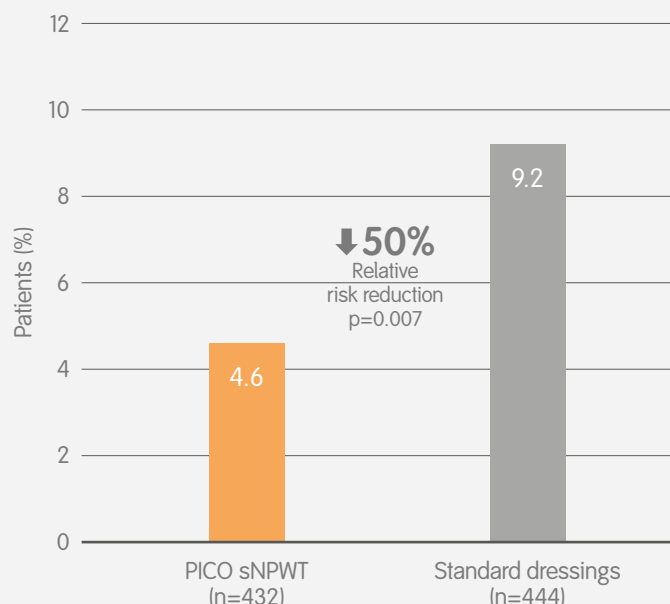
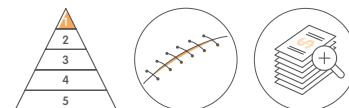


Figure 6. Incidences of SSIs with PICO sNPWT and standard dressing in obese pregnant women undergoing caesarean section

## Cost-effectiveness of incisional negative pressure wound therapy compared with standard care after caesarean section in obese women: a trial-based economic evaluation

Hyldig N, Joergensen JS, Wu C, et al. *BJOG*. 2019;126(5):619-627



### Study overview

- Cost-effectiveness evaluation of PICO sNPWT compared to standard dressings in preventing SSIs in obese women post-caesarean (pre-gestational BMI  $\geq 30 \text{ kg/m}^2$ )
  - PICO sNPWT, n=432
  - Standard dressing, n=444
- Analysis of data from patients treated in Hyldig *et al.* 2018 (see above)

### Key findings

- PICO sNPWT was dominant as it was more effective than standard care due to an absolute reduction in SSIs of 4.6%, though estimated total healthcare costs per patient were similar (\$5,794 vs \$5,841;  $p=0.81$ )
- Estimated costs per patient in women with pre-gestational BMI  $\geq 35 \text{ kg/m}^2$  were lower although not significant with PICO sNPWT than with standard dressings
  - Estimated cost saving with PICO sNPWT; €339

## Reducing C-section wound complications

Bullough L, Burns S, Timmons J, Truman P, Megginson S. *Clin Serv J*. 2015;Apr:2–6



### Study overview

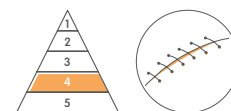
- Thirty-month audit study (UK) reporting 2-year experience with PICO sNPWT in high-risk patients (BMI  $> 35 \text{ kg/m}^2$ ) post-caesarean compared to low-risk patients (BMI  $< 35 \text{ kg/m}^2$ )
  - PICO sNPWT, n=239
  - OPSITE® Post-Op Visible, n=1,405

### Key findings

- Baseline SSI rate: 12.0%
- PICO sNPWT: 0.4% (n=1); patient had gestational diabetes mellitus
- OPSITE Post-Op Visible: 3.6% (n=51)
- No readmission for infection or wound dehiscence
- Use of PICO sNPWT in high-risk patients was cost-effective

## A survey of caesarean section surgical site infections with PICO sNPWT single use negative pressure wound therapy system in high-risk patients in England and Ireland

Searle R, Myers D. *J Hosp Infect*. 2017;97:122–124



### Study overview

- Audit study (4 sites in England and Ireland) of PICO sNPWT in patients post-caesarean with BMI  $> 35 \text{ kg/m}^2$
- PICO sNPWT was applied after surgery and left for 7 days in accordance with the instructions for use
  - PICO sNPWT, n=399

### Key findings

- Low incidences of SSIs and hospital readmission:
  - SSI incidence, 9.0%
  - Readmission incidence, 0.8%



## Additional studies

### A journey to zero: reduction of post-operative cesarean surgical site infections over a five-year period

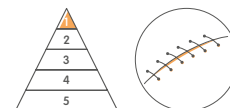
Hickson E, Harris J, Brett D. *Surg Infect*. 2015;16:174–177

### Cost of care using prophylactic negative pressure wound vacuum on closed laparotomy incisions

Lewis LS, Convery PA, Bolac CS, Valea FA, Lowery WJ, Havrilesky LJ. *Gynecol Oncol*. 2014;132:684–689

### Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: a randomized controlled trial

Karlakki SL, Hamad AK, Whittall C, Graham NM, Banerjee RD, Kuiper JH. *Bone Joint Res.* 2016;5:328–337



#### Study overview

- Open-label, single-center, randomized, parallel-group, controlled study to assess effectiveness of PICO sNPWT in patients undergoing routine elective primary total hip and knee arthroplasty
  - PICO sNPWT, n=102
  - Standard dressing, n=107

#### Key findings

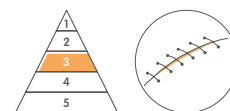
- Compared with standard care, PICO sNPWT:
  - Achieved nearly a 4-fold reduction (76%) in superficial SSCs (2.0 vs 8.4%; p=0.06; Figure 7)
  - Required fewer dressing changes (2.5 vs 4.2; p=0.002)
  - Significantly reduced peak post-surgical wound exudate (grade 4 exudate: 4 vs 16%; RRR, 75%; p=0.007)
  - Significantly reduced extreme LoS (p=0.003)
    - Reduced mean LoS by 0.9 days (p=0.07)



Figure 7. LoS with PICO sNPWT and standard care

### Prophylactic negative pressure wound therapy after lower extremity fracture surgery: a pilot study

Dingemans SA, Birnie MFN, Backes M, et al. *Int Orthop.* 2018;42:747–753



#### Study overview

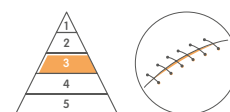
- Single-center, prospective case series pilot study assessing the feasibility of using PICO sNPWT to help reduce the incidence of SSIs in adult patients undergoing major foot and ankle surgery (incision length  $\geq 3$  cm)
  - PICO sNPWT, n=53 (total)
  - PICO sNPWT, n=47 (case-matched to historical cohort)

#### Key findings

- PICO sNPWT resulted in a 71% reduction in SSIs (total, superficial and deep) compared to controls (4.3 vs 14.9%; p=0.29)
- Patient satisfaction with PICO sNPWT was high

### Use of negative pressure wound therapy on closed surgical incision after total ankle arthroplasty

Matsumoto T, Parekh SG. *Foot Ankle Int.* 2015;36:787–794



#### Study overview

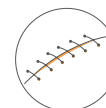
- Single-center, retrospective cohort study to investigate the role of PICO sNPWT in decreasing the rate of wound healing problems after TAA
  - PICO sNPWT, n=37
  - Standard care, n=37

#### Key findings

- PICO sNPWT resulted in an 88% reduction in SSCs compared to historic cohort (3 vs 24%; p=0.014)
- Differences in SSIs were not significant; PICO sNPWT, 3%; historic control cohort; 8% (p=0.615)

## Cost-effectiveness analysis of single use negative pressure wound therapy dressings (sNPWT) to reduce surgical site complications (SSC) in routine primary hip and knee replacements

Nherera LM, Trueman P, Karlakki SL. *Wound Repair Regen.* 2017;25:474–482 



### Study overview

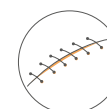
- Cost-effectiveness evaluation of PICO sNPWT in high risk patients undergoing elective primary hip and knee replacement
- Analysis of data from patients treated in Karlakki *et al.* 2016 (see above)
  - PICO sNPWT, n=102
  - Conventional dressings, n=107

### Key findings

- Karlakki *et al.* reported a reduction in dressing changes (p=0.002), SSC (p=0.06) and LoS (p=0.07) in favor of PICO sNPWT compared with standard care
- Estimated cost/patient was \$5,602 and \$6,713 for PICO sNPWT and standard care respectively, resulting in an estimated cost-saving of \$1,132 in favor of PICO sNPWT
- Greater cost savings were observed in subgroups of high risk patients with BMI  $\geq 35$  kg/m<sup>2</sup> and ASA  $\geq 3$  ie, \$7,955 and \$7,248 respectively

## Negative pressure wound therapy reduces incidence of post-operative wound infection and dehiscence after long-segment thoracolumbar spinal fusion: a single institutional experience

Adogwa O, Fatemi P, Perez E, et al. *Spine J.* 2014;14:2911–2917



### Study overview

- Retrospective study to assess the incidence of wound infection and dehiscence in patients undergoing long-segment thoracolumbar fusion with routine use of PICO sNPWT compared to a historic cohort
  - PICO sNPWT, n=46
  - Standard care, n=114

### Key findings

- PICO sNPWT resulted in a 29% reduction in SSIs compared to historic cohort (10.6 vs 14.9%; p=0.04)
- PICO sNPWT significantly reduced wound dehiscence by 48% compared to historic cohort (6.4 vs 12.3%; p=0.02)



## Additional studies

### End-users' assessment of prophylactic negative pressure wound therapy products

Gillespie BM, Finigan T, Kerr D, Lonie G, Chaboyer W. *Wound Pract Res.* 2013;21:74–81

### Negative pressure wound therapy for management of the surgical incision in orthopedic surgery. A review of evidence and mechanism for an emerging indication

Karlakki S, Brem M, Giannini S, Khanduja V, Stannard J, Martin R. *Bone Joint Res.* 2013;2:276–284

### Negative pressure wound therapy for seroma prevention and surgical incision treatment in spinal fracture care

Nordmeyer M, Pauser J, Biber R, et al. *Int Wound J.* 2016;13:1176–1179



PICO single use negative pressure wound therapy system demonstrated greater reduction in wound area compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities



Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H.

Poster presented at Wild on Wounds National Wound Conference. September 12–15, 2018; Las Vegas, USA

### Study overview

- Multicenter, controlled, randomized, 12-week, non-inferiority trial to compare PICO sNPWT with tNPWT in 161 patients with VLUs or DFUs (PP; n=115)

### Key findings

- Mean change in wound area after 12 weeks was non-inferior with PICO sNPWT versus tNPWT (PP; 88.7 vs 58.6%; Figure 8)
- After adjustment for pooled site, wound area, type and duration at baseline, least squares mean change in wound area after 12 weeks was 27% greater with PICO sNPWT than tNPWT
  - Results were similar for the ITT population (90.2 vs 51.0%; p<0.001)
- Use of PICO sNPWT also resulted in greater mean changes in wound depth and volume than tNPWT after 12 weeks in the PP population (Figure 8)
  - Results for the ITT population were mean reductions of 48.1% versus 12.7% for wound depth and a 60.8% decrease versus a 30.0% increase for wound volume, respectively

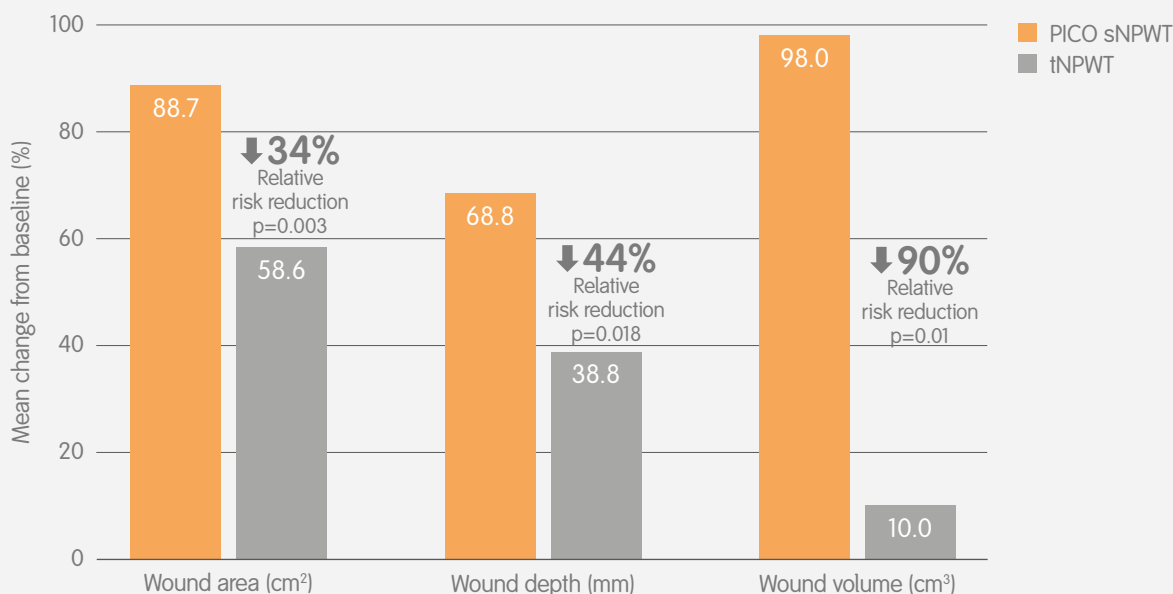


Figure 8. Mean changes from baseline (%) in wound area, depth and volume after 12 weeks (or until closure) with PICO sNPWT and tNPWT (PP population; n=115)

## Use of PICO to improve clinical and economic outcomes in hard-to-heal wounds

Dowsett C, Hampton J, Myers D, Styche T. *Wounds International*. 2017;8:52–59



### Study overview

- Clinical and economic evaluation of chronic wounds from multiple centers (10 sites across the UK, Denmark, Sweden and Canada) treated with PICO sNPWT to develop a decision-making pathway (Figure 9)
  - PICO sNPWT, n=52
- Data were compared to predicted standard of care (non-NPWT) to evaluate healing outcomes, financial costs and required nursing hours

\* Wounds with overt signs of clinical infection (e.g. increased pain, levels of exudate, cellulitis etc.) should be excluded from the evaluation. Colonised/critically colonised wounds are not excluded from the evaluation. Site standard protocol should be implemented to address bacterial burden.

\*\* Wounds that have healed by <10% but have shown significant improvement in granulation tissue quality/quantity may be considered for further PICO treatment based on clinician judgement.

#### Entry criteria

- Wound >6 weeks in duration — wound has reduced in area by <10% per week over previous 4 weeks
- Wound has not received NPWT within the last 6 weeks
- Wound is not clinically infected\*
- If VLU, ABPI confirmed as >0.8 and <1.3
- None of the PICO contraindications for negative pressure apply

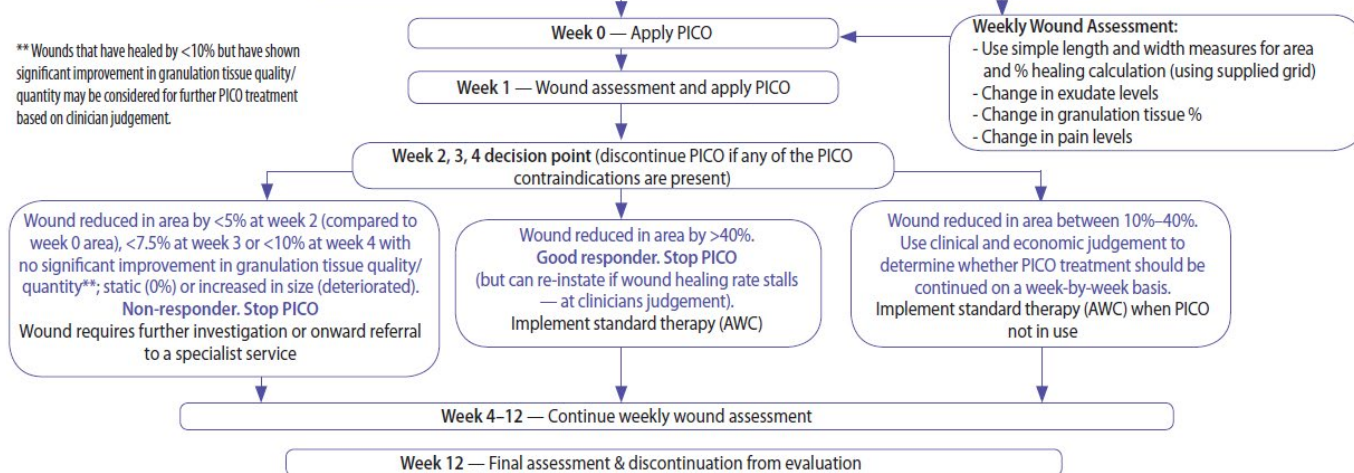


Figure 9. A PICO sNPWT decision-making pathway

### Key findings

- Application of the decision pathway using PICO sNPWT to stalled wounds improved healing trajectory compared to standard care (Figure 10)
  - 61.5% of wounds either healed (14/52) or were on a projected healing trajectory after 12 weeks (18/52)
- During PICO sNPWT treatment, wound areas reduced by a weekly average of 13.4% more than they did pre-PICO sNPWT ( $p=0.006$ )
- During the 12 weeks following PICO sNPWT application wound areas reduced by 9.6% per week more than pre-PICO sNPWT reductions ( $p=0.001$ )
- Implementing the pathway using PICO sNPWT reduced total costs by 33.1% for all 52 wounds over 26 weeks compared to predicted standard care (\$101,135 vs \$151,227)
- 92% of clinicians rated patient experience as 'good' or 'excellent'

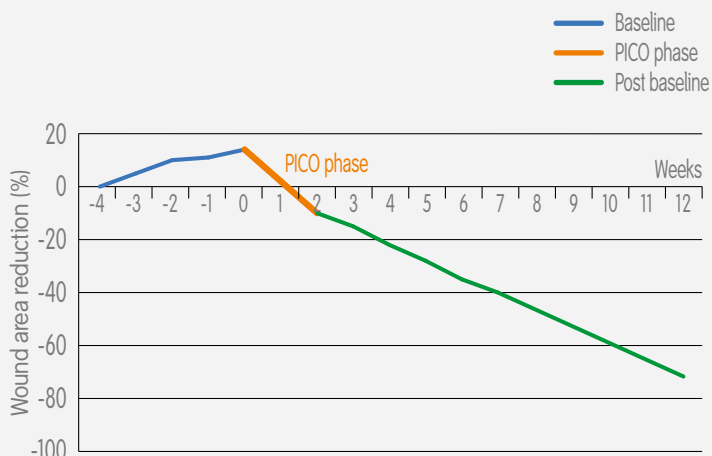


Figure 10. Weekly wound area reduction (%)

Chronic wounds

Providing cost-effective treatment of hard-to-heal wounds in the community through use of NPWT

Hampton J. *Br J Community Nurs.* 2015;20(Suppl6):S14–S20



Study overview

- Cohort case study involving patients with hard-to-heal leg ulcers and pressure ulcers
  - PICO sNPWT, n=9

Key findings

- Average weekly reduction in wound size was 21%; wound size achieved with PICO sNPWT on average 10 weeks earlier than predicted with standard wound dressings
- In wounds that responded, wound size reduction was 6 times faster than predicted with standard wound care dressings

Using single use negative pressure wound therapy for patients with complicated diabetic foot ulcers: an economic perspective

Sharpe A, Myers D, Searle R. *Wounds UK.* 2018;14:89–93



Study overview

- Case series of four patients using PICO 7 sNPWT to help manage complicated DFUs. Patients and their carers self-assessed the dressing status using the dressing-full indicator. Remote contact was used to determine the need for an outpatient clinic visit or district nurse visit
  - PICO sNPWT, n=4

Key findings

- All four DFUs improved (mean ulcer area reduction, 49%), exudate levels were managed effectively and the frequency of dressing changes was reduced
- Total combined weekly clinician time saving using PICO 7 sNPWT was 279 minutes (4hr 39min) for 4 patients
- Use of PICO sNPWT could release 13.5 clinician hours per patient on average over 12 weeks



## Additional studies

**Venous leg ulcer management: single use negative pressure wound therapy**

Dowsett C, Grothier L, Henderson V, et al. *Br J Community Nurs.* 2013;(Suppl.S6):S8–S10, S12–S15

**Single use negative pressure wound therapy for the treatment of chronic lower leg wounds**

Schwartz JA, Goss SG, Facchin F, Gendics C, Lantis JC. *J Wound Care.* 2015;24:S4–S9

**Use of a portable, single use negative pressure wound therapy device in home care patients with low to moderately exuding wounds: a case series**

Hurd T, Trueman P, Rossington A. *Ostomy Wound Manage.* 2014;60:30–36

**Evaluating the costs and benefits of innovations in chronic wound care products and practices**

Hurd T. *Ostomy Wound Manage.* 2013;Supplement:1–16

## Effects of cutaneous negative pressure application on perforator artery flow in healthy volunteers: a preliminary study

Innocenti M, Santini M, Dreassi E, et al. *J Reconstr Microsurg.* 2019;35:189–193



### Study overview

- A single-center study to evaluate of the effects of PICO sNPWT on blood flow in cutaneous perforator arteries in 10 volunteers (7 males, 3 females; mean age, 29.7 years; mean BMI, 22.8 kg/m<sup>2</sup>)
- PICO sNPWT was applied to skin overlying the muscle fascia emergence of one of the two preumbilical perforator vessels from the deep inferior epigastric artery (selected at random) for seven consecutive days; the other vessel was used as the control
- Flowmetries of both perforators were measured before and after the application of PICO sNPWT

### Key findings

- Mean flow velocity increased from 19.870 to 28.618 cm/sec (8.748 cm/sec) with use of PICO sNPWT and from 28.635 to 31.370 cm/sec (2.735 cm/sec) for controls (Figure 11)
- Use of PICO sNPWT significantly increased mean flow in perforator vessels by 8.765 cm/sec compared with controls ( $p < 0.0001$ )
- An increase in relative flowmetry of 2.74 cm/sec occurred in both perforator vessels after application of PICO sNPWT to just one perforator vessel ( $p < 0.0001$ )
- Estimates of interaction showed that mean flow value increased significantly by 6.0125 cm/sec after use of PICO sNPWT compared with controls ( $p < 0.0001$ )

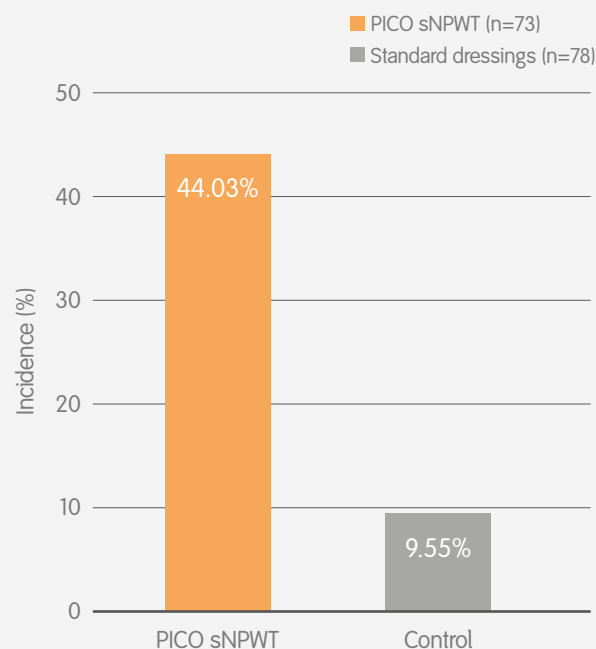


Figure 11. Percentage increase in mean flowmetry values for PICO sNPWT and controls at the end of the study

## Biological effects of a disposable, canisterless negative pressure wound therapy system

Malmsjö M, Huddleston E, Martin R. *Eplasty.* 2014;14:e15



### Study overview

- Preclinical assessment of the biological effect of PICO sNPWT compared with tNPWT in a porcine full thickness defect wound model and sutured incisional wound model. Fluid handling was assessed in an *in vitro* wound model

### Key findings

- PICO sNPWT delivers therapeutic levels of NPWT, with similar effects to tNPWT on:
  - Wound edge contraction
  - Microvascular blood flow
  - Pressure transmission
  - Effective exudate handling similar to tNPWT

## Biomechanical modeling of the forces applied to closed incisions during single use negative pressure wound therapy

Loveluck J, Copeland T, Hill J, Hunt A, Martin R. *Eplasty*. 2016;16:e20 



### Study overview

- Finite element analysis computer modelling and biomechanical testing with Syndaver SynTissue™ synthetic skin were used to explore the resulting biomechanical forces from the application of PICO sNPWT on a sutured incision

### Key findings

- FEA computer modelling:
  - Application of -80mmHg reduces the lateral tension on an individual suture from 1.31N to 0.4N and exerts a compressive closing force
- Biomechanical testing:
  - At a pressure of -80mmHg, 55% more force is required to disrupt an incision that had PICO sNPWT applied than an incision closed with sutures or staples with no NPWT applied

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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1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The level of evidence pyramid: indicating levels of evidence in Plastic and Reconstructive Surgery articles. *Plast Reconstr Surg*. 2011;128:311–4. 2. NICE Medical technologies guidance: PICO sNPWT negative pressure wound therapy for closed surgical incision wounds (MGT43). Available from: <https://www.nice.org.uk/guidance/mtg43>. Last accessed 9 May 2019. 3. WHO Global Guidelines for the Prevention of Surgical Site Infection. 2016. Available from: <https://www.who.int/gpsc/ssi-prevention-guidelines/en/>. Last accessed 18 Feb 2019. 4. World Union of Wound Healing Societies (WUWHS) Consensus Document. Closed surgical incision management: understanding the role of NPWT. *Wounds International*, 2016. Available from: [http://www.wuwhs2016.com/files/WUWHS\\_SI\\_consensus\\_Web.pdf](http://www.wuwhs2016.com/files/WUWHS_SI_consensus_Web.pdf). Last accessed 11 Mar 2019. 5. World Union of Wound Healing Societies (WUWHS) Consensus Document. Wound exudate: effective assessment and management *Wounds International*, 2019. Available from: <https://www.wuwhs.com/web/exudate.pdf>. Last accessed 11 Mar 2019.