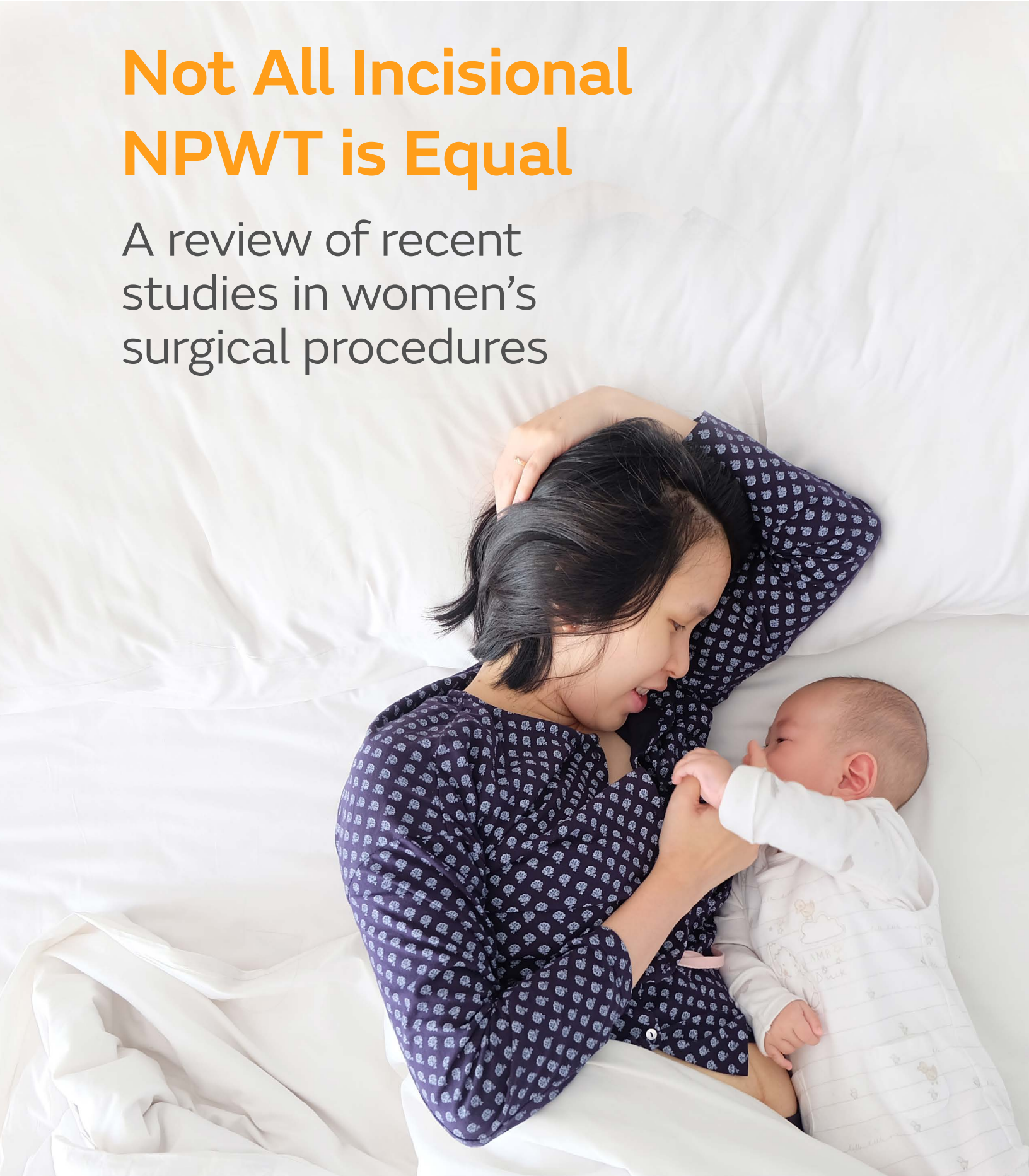
Smith+Nephew

Not All Incisional NPWT is Equal

A review of recent studies in women's surgical procedures



Incisional Negative Pressure Wound Therapy (NPWT)

Despite recent advances in many areas of healthcare, surgical site infections (SSIs) remain a considerable problem in the United States. It is estimated that approximately one in 20 surgical patients will develop an SSI,[1] affecting more than half a million patients per year.[2] Moreover, many of these infections are considered preventable, which implies an opportunity for intervention that reduces the risk of developing an SSI.

Negative pressure wound therapy (NPWT) became commercially available in 1995. Many publications arose throughout the 2000s related to the use of NPWT on closed surgical incisions. In the early 2010s, single-use NPWT (sNPWT) devices specifically designed for use on closed surgical incisions were introduced to the market. Today, there are multiple portable, sNPWT devices indicated for closed surgical incisions. Although suction is used across all NPWT devices, the method of delivery through the dressing at the interface of the skin or incision differs.

Traditional NPWT (tNPWT) has long been demonstrated as an effective treatment modality for many types of wounds, including surgical incisions. In a recent webinar, Dr. Kenneth Moquin of Henry Ford Health System and Dr. Runi Brownhill, Principal Scientist at Smith+Nephew, discussed how our understanding of the science behind NPWT continues to develop. In the webinar, they articulated that the efficacy of this treatment modality has shifted the question from “Why are you using NPWT?” to “Why are you not using NPWT?”

Incisional Management: Where We Are

It is vital to remember the annual prevalence of SSIs and how serious these wound complications can be. Of the half million instances of SSIs that occur in the United States each year, approximately 8,000 result in the death of the patient.[2] In fact, two out of five, or 40%, of hospital readmissions are related to SSIs.[3] SSIs represent the most common reasons for unplanned readmissions.[3] However, up to 60% of SSIs are considered preventable.[2]

In response, the World Health Organization (WHO) and the World Union of Wound Healing (WUWH) have provided guidelines and consensus documents that recommend the prophylactic use of NPWT on closed incisions for patients deemed at high risk for wound complications.[1] NICE Medical Technology Guidance from the National Institute for Health and Care Excellence (NICE) in the United Kingdom demonstrated that PICO™ sNPWT provides better outcomes than standard care for preventing surgical site complications in high-risk patients with closed surgical incisions, at a similar overall cost.[4]

The consensus documents all refer to risk factors that impact incision site healing. High-risk patients include those with comorbidities such as obesity, uncontrolled or poorly controlled diabetes, smoking, hypertension, renal disease, and other immunodeficiencies.[5]

Evaluation of the Variations in Data

Several recent studies in women's surgery have provided data related to the use of incisional NPWT with less than satisfactory outcomes. Knowing that the efficacy of NPWT for closed incisions has been studied and documented repeatedly over the last 20 years brings into question the cause of these reported findings.

SSIs in Obese Women After Cesarean Sections: This study[6] (n = 1,624) looked at the effect of prophylactic incisional NPWT using PREVENA™ vs standard dressings, such as gauze and tape or transparent, sticky dressings, in obese women after cesarean deliveries. This randomized controlled trial demonstrated that the risk of superficial or deep SSIs was not significantly different between groups (difference, 0.36%; 95% CI, -1.46% to 2.19%; *P* = .70). Additionally, adverse skin reactions were significantly more frequent in the NPWT group (7.0% vs 0.6%; difference, 6.95%; 95% CI, 1.86%-12.03%; *P* < .001). A second retrospective cohort study[7] (n = 4,391) analyzing this population found that incisional NPWT dressings (PREVENA™) were associated with an increased risk of SSIs (adjusted odds ratio [OR], 1.54; 95% CI, 1.01-2.34). The use of NPWT dressings also led to an increase in operative time, which was the primary predictor of infection.

Less than satisfactory outcomes in studies on the use of incisional NPWT may be the result of patient-related factors, device design, or both.

Prophylactic NPWT After Laparotomy for Gynecologic Surgery: This study (n = 505) was stopped for futility at interim analysis of 444 patients because it demonstrated increased complications, including blistering, rather than a decrease in complication rates in patients using PREVENA™ vs standard dressings. The rate of wound complications was 17.3% in the NPWT group vs 16.3% in the gauze group (absolute risk difference 1%; 90% CI, -4.5 to 6.5%; *P* = .77). Skin blistering occurred in 13% of patients in the NPWT group vs 1.2% in the gauze group (*P* < .001).[8]

Mastectomy and Flap Fixation: This study (n = 161) found that NPWT using Avelle™ increased postoperative wound complications (OR, 1.67; 95% CI, 0.77-3.63; *P* = 0.199) and did not lead to fewer patients requiring unplanned visits or fewer patients with a clinically significant seroma vs standard dressings.[9]

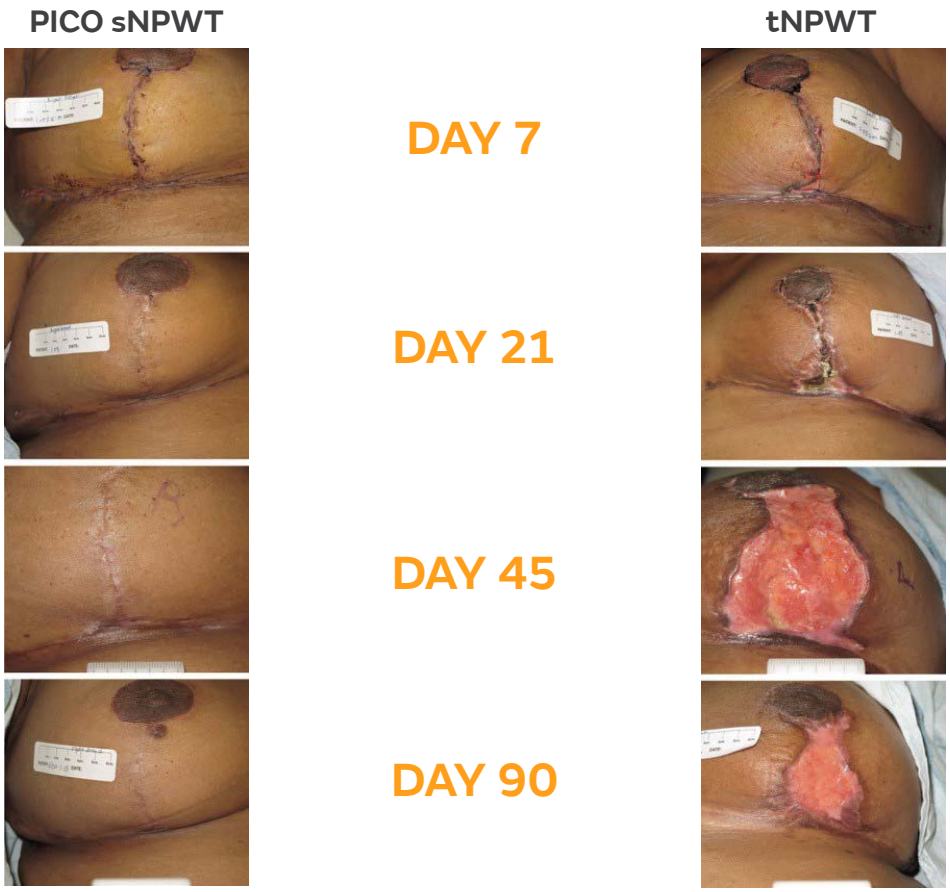
Dr. Moquin stated that these outcomes may be the result of patient-related factors, device design, or a combination of both.

The PICO™ sNPWT Difference

In contrast to the previously mentioned studies, Dr. Moquin presented an overview of clinical studies that support the efficacy of PICO therapy:

High-Risk Cesarean Section Study: In this multicenter randomized controlled trial (n = 876), the PICO System halved the SSI incidence compared with standard care (RR, 0.50; 95% CI, 0.30-0.84; *P* = .007). Wound exudate was decreased by 31% (RR, 0.69; 95% CI, 0.55-0.86; *P* = .001), and there was no difference in the incidence of deep SSIs and dehiscence.[10]

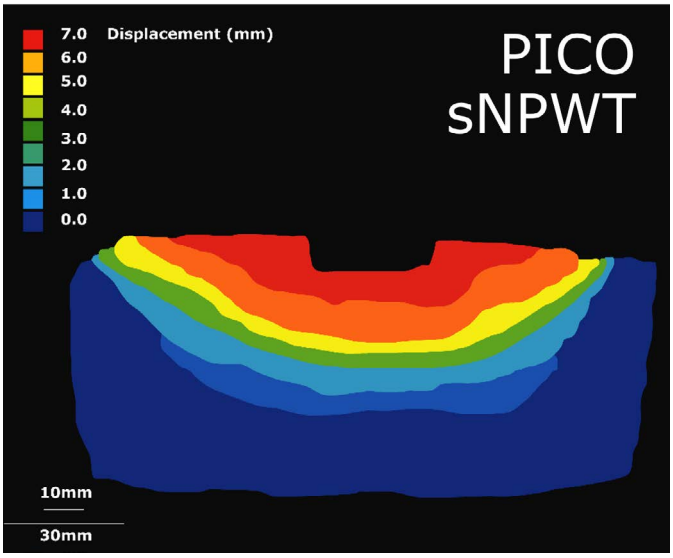
Prepectoral Breast Reconstruction: In these procedures (n = 307), the incidence of wound breakdown was lower with PICO sNPWT than with standard dressings (0.8% vs 5.5%; *P* = .01). Additionally, no implants were lost with PICO sNPWT, whereas seven implants were lost with standard dressings. In addition, the estimated cost savings with PICO sNPWT were $626 per patient.[11]

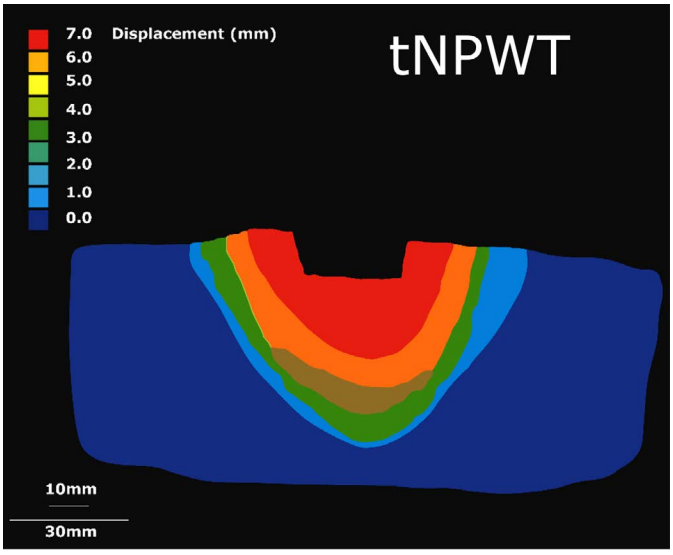


Reduction Mammoplasty: This prospective, within-patient, randomized, controlled, multicenter study (n = 200) observed fewer complications following PICO™ sNPWT treatment, and fewer incidences of dehiscence were observed by day 21 postoperatively ($P < .001$).[12]

Dr. Brownhill explained that PICO sNPWT has multiple mechanisms of action that differ from other NPWT systems, including tNPWT and sNPWT. These differences may help explain the differences in the outcomes of the clinical studies in women's surgery of the PICO System vs the other sNPWT devices used in these studies. The PICO Dressing with AIRLOCK™ Technology is designed to provide therapy that is delivered throughout the area of the PICO dressing pad. This system includes delivery of NPWT to the incision, as well as the surrounding area.[13,14] The PICO sNPWT system provides compressive forces in the tissue, under and across the dressing area, as demonstrated in ex vivo.[14,15]

This action influences various biological systems in the surrounding regions, not just the wound site. In this manner, PICO™ sNPWT provides a barrier from the external environment, manages wound exudate, and promotes change in blood flow across the entire zone of injury to deliver outcomes.[16]





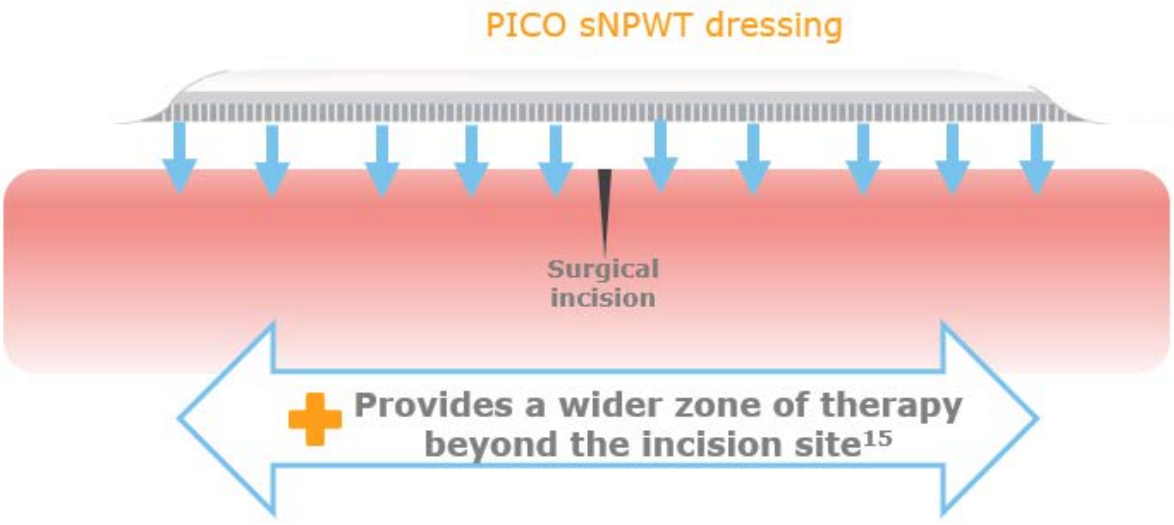
PICO sNPWT achieves these effects by using the AIRLOCK technology, which enables NPWT to be applied consistently across the entire dressing. The dressing includes a silicone adhesive layer, an AIRLOCK technology layer, an absorbent core to lock exudate away from the wound,[17] a top film layer to protect from external contamination,[18] and a soft port with an integrated filter.

To explain these processes, Dr. Brownhill presented PICO sNPWT mechanism of action studies spanning a range of data sets, including[16]:

- Blood flow measurements
- Porcine wound healing studies
- Ex vivo assessment tissue model
- In vitro wound model
- Human donor skin platform
- Modeling of forces on closed incisions

These data sets demonstrate that PICO™ sNPWT applies compressive forces in tissue that may result in multiple modes of action for closed surgical incisions that help deliver clinical outcomes, including:

- Providing a broader zone of therapy, targeting the zone of injury[15]
- Reducing lateral tension[19]



- Providing consistent delivery of negative pressure across the dressing surface[20]
- Reducing the risk of seroma and dehiscence and reducing the odds of developing SSIs[21]
- Protecting the periwound, creating a pro-healing environment.[15]
- Providing fewer changes than traditional NPWT.[22]

Conclusion: Choosing the Right NPWT Option for Your Patient

PICO sNPWT has multiple mechanisms of action that may help promote incisional wound healing. The mode of action studies for PICO sNPWT have shown that this wound care system helps achieve clinical benefits across many different types of closed surgical incisions.

References

1. *World Union of Wound Healing Consensus Document: Closed Surgical Incision Management: Understanding the Role of NPWT.* Wounds International; 2016. **2.** Najjar PA, Smink DS. Prophylactic antibiotics and prevention of SSIs. *Surg Clin North Am.* 2015;95(2):269-283. **3.** Merkow RP, Ju MH, Chung JW, et al. Underlying reasons associated with hospital readmission following surgery in the United States. *JAMA.* 2015;313(5):483-495. **4.** NICE Medical technologies guidance: PICO™ sNPWT negative pressure wound therapy for closed surgical incision wounds (MGT43). Accessed June 11, 2020. https://www.nice.org.uk/guidance/mtg43 **5.** Guo S, DePietro LA. Factors affecting wound healing. *J Dent Res.* 2010;89(3):219-229. **6.** Tuuli MG, Liu J, Tita ATN, et al. Effect of prophylactic negative pressure wound therapy vs. standard wound dressing on surgical-site infection in obese women after cesarean delivery: a randomized clinical trial. *JAMA.* 2020;324(12):1180-1189. **7.** Buzhardt S, Chapple AG, LeMoine F, McCune K, Sutton EF. Surgical site infection risk in cesarean delivery patients with obesity after negative pressure wound therapy: a retrospective cohort study. *Surgery.* 2021;170(1):153-159. **8.** Leitao MM Jr, Zhou QC, Schiavone MB, et al. Prophylactic negative pressure wound therapy after laparotomy for gynecologic surgery: a randomized controlled trial. *Obstet Gynecol.* 2021;137(2):334-341. **9.** De Rooij L, van Kuijk SMJ, van Haaren ERM, et al. Negative pressure wound therapy does not decrease postoperative wound complications in patients undergoing mastectomy and flap fixation. *Sci Rep.* 2021;11(1):9620. **10.** Hyldig N, Vinter CA, Kruse M, et al. Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after cesarean section in obese women: a pragmatic randomized clinical trial. *BJOG.* 2019;126(5):628-635. **11.** Irwin GW, Boundouki G, Fakim B, et al. Negative pressure wound therapy reduces wound breakdown and implant loss in prepectoral breast reconstruction. *Plast Reconstr Surg Glob Open.* 2020;8:e2667. **12.** Galiano RD, Hudson D, Shin J, et al. Incisional negative pressure wound therapy for prevention of wound healing complications following reduction mammoplasty. *Plast Reconstr Surg Glob Open.* 2018;6(1):e1560. **13.** Casey C. Consistent delivery of therapeutic negative pressure levels by a single use negative pressure wound therapy system (sNPWT)* in a wound model. Paper presented at the European Wound Management Association conference, Gothenburg, Sweden, June 5-7, 2019. **14.** Smith+Nephew. *PICO Pressure Mapping Study.* Internal report DS/19/211/R - part B. 2021. **15.** Smith+Nephew. *PICO Biomechanical Study.* Internal report DS/19/211/R. 2019. **16.** Brownhill VR, et al. Pre-clinical assessment of single-use negative pressure wound therapy during in vivo porcine wound healing. *Adv Wound Care.* 202;?:1-29. **17.** Smith+Nephew. *PICO 7Y Non-NPWT Wound Model Summary.* Internal report DS.18.260.R. July 2018. **18.** Smith+Nephew. *Bacterial Barrier Testing of the PICO Dressing.* Internal report 2001002. 2020. **19.** Loveluck J, Copeland T, Hill J, Hunt A, Martin R. Biomechanical modeling of the forces applied to closed incisions during single-use negative pressure wound therapy. *Eplasty.* 2016;16:e20. **20.** 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(2):195-201. **21.** Saunders C, Nherera LM, Horner A, Trueman P. Single-use NPWT versus conventional dressings for closed surgical incisions: systematic literature review and meta-analysis. *BJS Open.* 2021;5(1):zraa003. **22.** Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H. A prospective, randomised, 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.

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