Control your risks, control your outcomes

PICO⁶ sNPWT has been shown to help reduce the incidence of **surgical site complications**¹ **length of stay**¹ and overall **cost** of care³ following primary total joint arthroplasty (TJA)^{*}



SmithNephew

PICO^{\$} 7 Single Use Negative Pressure Wound Therapy System

Helping you get **CLOSER TO ZERO°** surgical site complications¹⁶

smith-nephew.com/pico

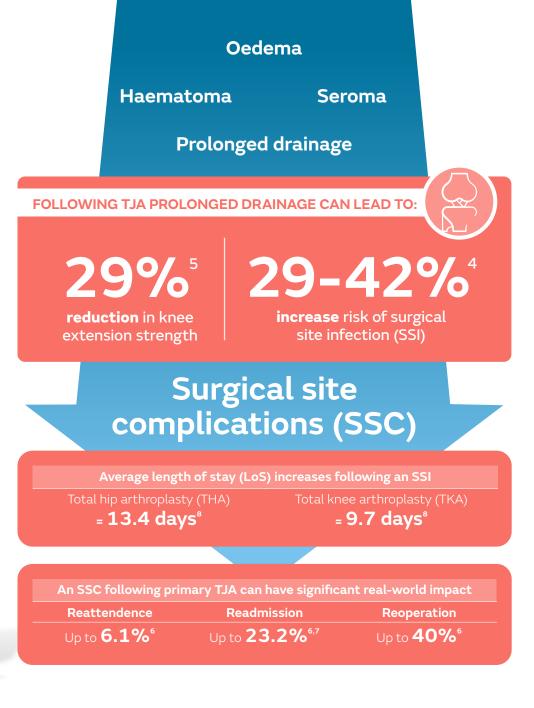
*compared with standard care

PICO° INCISIONAL ORTHOPAEDIC SURGERY

The real-world impact of oedema?

Physiologically, oedema compromises the diffusion of waste and nutrients between the capillaries and the cells, which puts the patient at risk of **delayed healing, infection, skin breakdown and cell damage**⁴⁶





CONTROL YOUR RISKS, CONTROL YOUR OUTCOMES | 2

Is your patient high risk?

Multi-morbid patients with common risk factors are more susceptible to developing SSCs⁸, which can have significant real-world impacts^{6,7}



BMI ≥ 40

Significantly more likely to suffer **prolonged drainage** following THA*⁴



BMI ≥ 35

4.5x times more likely to suffer an **SSC** following TKA or THA surgery^{†3}



ASA ≥ 3

 8x times more likely
 to suffer an SSC following TKA or THA surgery^{‡3}



Operative time

SSI risk increases by **11%** every 15 minutes during TKA^{§9}



Revision

Deep or organ space SSI can nearly quadruple with revision hip arthroplasty compared with primary procedures¹⁰



Emergency

Up to **16%** SSI rate following peri-prosthetic hip fracture^{11, 12}

*Compared with normal weight; p = 0.001. ¹Compared with BMI < 35. ⁴Compared with patients with ASA < 3. ⁹Where operative times had a significant independent effect on SSI rates (adjusted OR 1.007, 95% CI 1.004–1.011, P < .001;) which corresponded to an 11% (95% CI 6-17) increase in SSI risk with every 15-minute increase in operative time.





Is your patient high risk?



The risk of developing a post-operative SSC depends on the type of surgery and patient risk factors^{14,15}

The presence of just **1 major risk factor or 2** or more moderate risk factors, places patients at high risk of an SSC and means you should consider **PICO**^o sNPWT¹⁴



Category	Patient-related risk factor	Procedural-related risk factor		
	IBMI ≥ 40kg/m ² or ≤ 18kg/m ²	Extended surgery		
	Uncontrolled insulin dependent diabetes mellitus	Emergency surgery		
Major risk factor presence of 1 = high risk of surgical site complication	Renal dialysis	1 Hypothermia		
	ASA physical status >II	 Anaemia / blood transfusion 		
	Age < 1 year or > 75 years	High wound tension after closure		
Moderate risk factor	BMI 30-39.9kg/m ²	Dual antiplatelet treatment		
presence of 2 ≥ high risk of surgical site complication	Immunosuppression	Suboptimal timing or omission of prophylactic antibiotics		
	 Smoking (current) 	Tissue trauma / large area of dissection / large area of undermining		

Table adapted from World Union of Wound Healing societies Consensus, 2016. The risk factors represented in this table are examples only and not an exhaustive list¹⁴ Defined as >T (hours) which is dependent on the type of surgical procedure, and is the 75th centile of duration of surgery for a particular procedure, e.g. coronary artery bypass graft has a T of 5 hours and caesarean section has a T of 1 hour



Control your risks, control your outcomes

0 0 0 0

PICO° sNPWT has shown to help reduce the incidence of **SSCs¹**, **LoS¹** and overall **cost** of care³ following primary TJA*

*compared with standard care



CONTROL YOUR RISKS, CONTROL YOUR OUTCOMES 5

Control your risks, control your outcomes

In an RCT of **209 patients** undergoing primary THA and TKA:

4-FOLD REDUCTION IN SSCs

76% relative reduction PICO° sNPWT reduced the incidence of SSCs by 76%^{*1}

CHANGE YOUR PRACTICE, NOT DRESSINGS

PICO[°] sNPWT significantly reduced both **wound exudate**^{*†1} and the number of **dressing changes by 40%**^{*‡1}

*compared with standard care; n = 107 (std care) v 102 (PICO system) +Grade 4 exudate: 4 vs 16%; p = 0.007 \pm 2.5 vs 4.2; p = 0.002





Evidence in Focus publication summary

CONTROL YOUR RISKS, CONTROL YOUR OUTCOMES 6

Control your risks, control your outcomes

In a prospective study of **296 patients** undergoing primary TKA:

The prophylactic use of **PICO**^o sNPWT significantly reduced the incidence of **SSCs** by

37%*45

THIS INCLUDES

Hyperaemia,[†] skin necrosis[‡] and wound dehiscence^{*§}

which resulted in a significant reduction in the incidence of **re-operation** by 76%^{II}

All compared with standard care; *28.5% v 45.7%, p = 0.001; †14.7% v 40.2%, p = 0.01; ‡2.1% v 8.5%, p = 0.04; §3.1% v 10.1%, p = 0.03 and v2% II 8.5%, p = 0.001.





High risk, low LoS

In an RCT of **209 patients** undergoing primary THA and TKA:

REDUCED LoS

PICO° sNPWT reduced mean LoS by an average of **0.9 days**^{*1}

Extremes of LoS were also reduced significantly with patients who received \mbox{PICO} sNPWT^{11}



Figure. Mean LoS (and range) with PICO sNPWT and standard dressings

*compared with standard care; n = 107 (std care) v 102 (PICO system) + p = 0.003



Prolonged operative time can increase the risk of SSI¹⁴



Revision hip arthroplasty can take, on average, 78 mins longer compared with primary procedures⁵¹

X2

SSI risk can **double** with revision hip arthroplasties compared with primary procedures¹⁰



The prophylactic use of incisional NPWT **significantly reduced LoS** by an average of **1.87 days*** following **revision hip and knee arthroplasties**²

*Compared with standard care; 6.71 days v 8.58 days; p = 0.019

REFERENCE

Seize the cost opportunity

Reductions in dressing changes, SSCs and LoS with **PICO**^o sNPWT demonstrated an estimated **£1,049 per patient** cost savings following primary **TJA**^{*3}



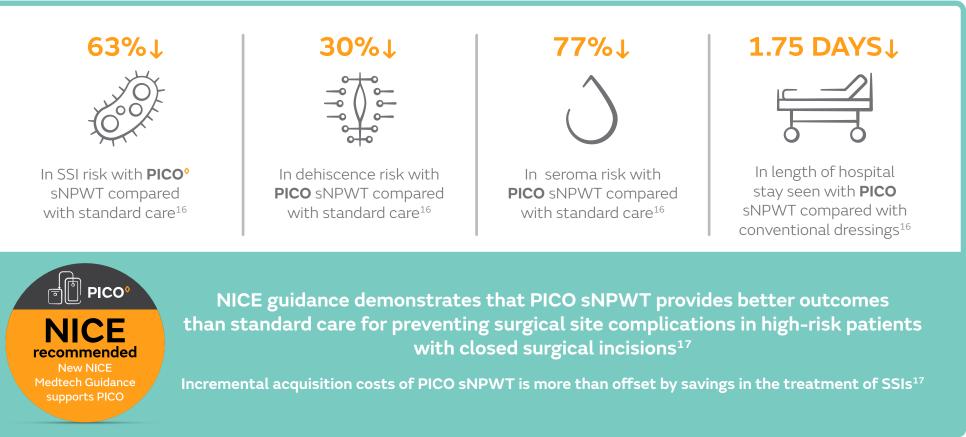
Abbreviations: sNPWT, single use negative pressure wound therapy; BMI, body mass index; ASA, American Society of Anesthesiologists.

*compared with standard care

Ask for

High quality evidence for high risk patients

In a meta-analysis¹⁶ of **29 studies** in a variety of surgical indications; including **11 randomised** controlled trials (RCTs) with a total of **5,614 patients**, PICO^os NPWT was found to:





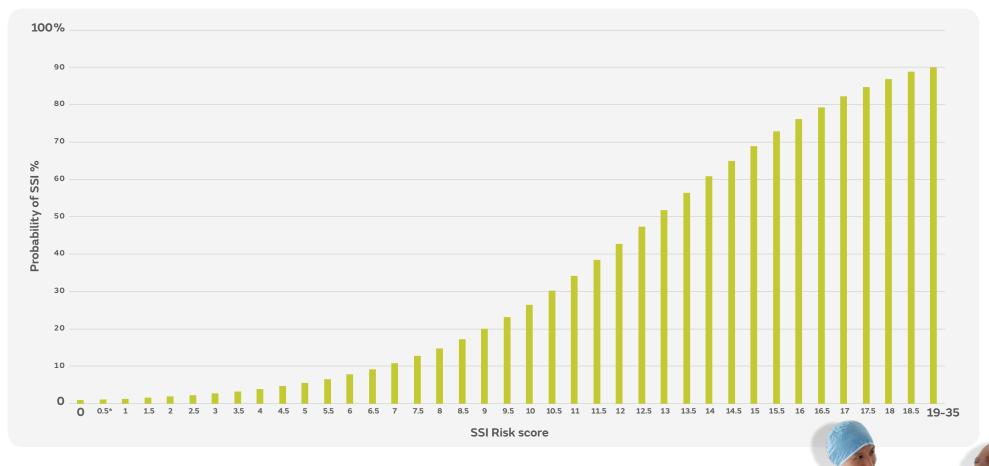


Is your patient high risk?

Certain patient factors correlate with SSI development following primary and revision arthroplasty¹³. Pre-operative identification can determine the probability of an SSI developing post-operatively¹³.

				ee Revisi		Revision knee	Presence		
Score						3	Score		
Diabetes				Long term in	sulin uso			thritis or inflar	nmatory arthropath
Presence		No		Presence	Yes		Presence	Yes	No
Score				Score			Score		
Tobacco use				Pelvis, thigh, leg traumatic fracture					
							Presence		
Score	1.5	0		Score	2	0	Score	2	0
_ower-extremit	v nathologic	fracture		Morbid obesi	tv (BMI > 4)	0)	Primary bone	cancer	
Presence	Yes	No		Presence	Yes	No	Presence	Yes	
Score				Score			Score		
Reaction to pros	thesis or imp	lant within 3		Staphylococo					SCODE.
Presence	Yes	No	years	Presence	Yes	No			-SCORE:
Score				Score					

SSI risk score and corresponding probability of SSI



Certain patient factors correlate with SSI development following primary and revision arthroplasty¹³. Pre-operative identification can determine the probability of an SSI developing post-operatively¹³.

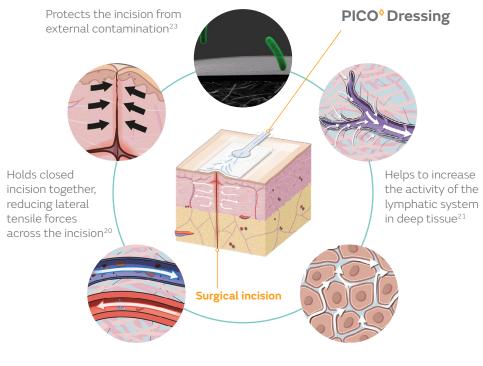
*Interpolated value. A score of 0.5 is not a possible result of any combination of positive risk factors

REFERENCE

CONTROL YOUR RISKS, CONTROL YOUR OUTCOMES | 13

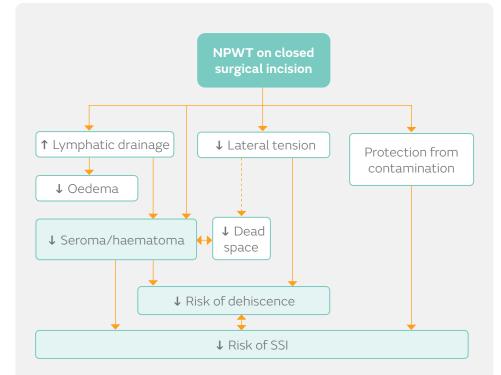
Negative pressure wound therapy (NPWT):

NPWT has multiple mechanisms of action that can help improve the speed, strength and quality of incisional wound healing which can minimise surgical site complications¹⁸⁻²³



Maintains an efficient blood supply to the wound (perfusion), which helps to support the immune response³¹⁻³³

Has been shown to increase the efficiency of functional lymph vessels helping to reduce oedema²⁸⁻³⁰



This pathway is adapted from the WUWHS guidelines document and it shows how NPWT can help reduce SSCs and lateral tension while increasing lymphatic drainage. This effect is likely to contribute to faster and stronger healing, and a reduced risk of infection and dehiscence¹⁴



One unique differentiator

AIRLOCK[°] Technology for consistent delivery of negative pressure, protecting the incision and treating the wider zone of injury. Only **PICO**[°] sNPWT dressings have **AIRLOCK** Technology

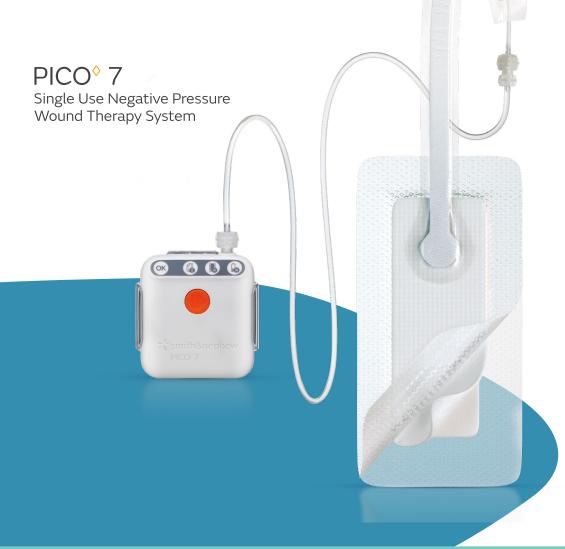


Ο

Up to

PICO^o 7 System

Completely portable and clinically effective in the treatment of surgical, chronic and acute wounds



Features:

Improved device performance*

 Enhanced management of air leaks helping to support healthcare professionals in delivering negative pressure and could potentially be used in problematic 'hard to seal' awkward areas²⁵

Improved ease-of-use

- New user interface with a 'dressing full' indicator, optimising dressing changes⁴¹
- Area to write start date of therapy, helping with healthcare protocols

Designed to improve patient quality of life

- Now even quieter pump than before²⁶
- New transparent belt clip for greater portability²⁷

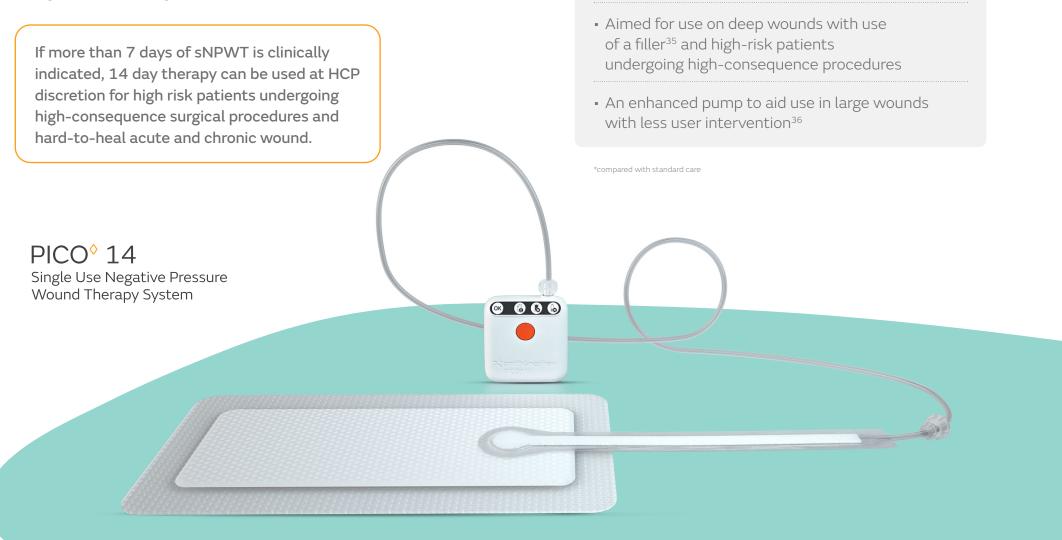
Increased flexibility

 New multipacks of five dressings now available, allowing therapy to be tailored to patients' clinical needs

*compared with standard care

PICO⁰ 14 system

Designed to challenge hard-to-heal wounds



Features:

• Pump duration of up to 14 days³⁴

Product ordering codes

The **PICO**° sNPWT portfolio is compatible with **ACTICOAT**° **FLEX** Antimicrobial Barrier Dressing, our silver-coated antimicrobial wound contact layer. ACTICOAT FLEX Dressing can be used for up to 3 days on closed surgical incisions at high risk of infection and open wounds with signs and symptoms of infection.⁴⁷⁻⁵⁰

		PICO 7 system		PICO 14 system	Multipack with	PICO 7Y device
		+ 1 dressing	+ 2 dressings	+ 2 dressings	5 dressings	+ 2 dressings
Dressing sizes		Code	Code	Code	Code	Code
	Multisite small 15cm x 20cm	66802010	66802000	66802040	66802020	_
	Multisite large 20cm x 25cm	66802011	66802001	66802041	66802021	66802031
	10cm x 20cm	66802012	66802002	66802042	66802022	-
	10cm x 30cm	66802013	66802003	66802043	66802023	-
	10cm x 40cm	66802014	66802004	66802044	66802024	_
	15cm x 15cm	66802015	66802005	66802045	66802025	—
	15cm x 20cm	66802016	66802006	66802046	66802026	_
	15cm x 30cm	66802017	66802007	66802047	66802027	-
	20cm x 20cm	66802018	66802008	66802048	66802028	_
	25cm x 25cm	66802019	66802009	66802049	66802029	-

Consumables		Code		
	Foam dressing filler	10cm x 12.5cm	66801021	For detailed production for use, contraindication
P	5 Antimicrobial Gauze Rolls + 1 SECURA [¢] NSBF Wipe	11.4cm x 3.7m	66802127	please consult the p for Use (IFU) prior to

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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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.

References: 1. Karlakki SL, Hamad AK, Whittall C, Graham NM, Banerjee RD, Kuiper JH. Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: a randomised controlled trial. Bone & joint research. 2016 Aug;5(8):328-37. 2. Mhaske AS, Budithi S, Karlakki S. Incisional Negative Pressure Wound Therapy Can Reduce Wound Complications And Hospital Stay In Revision Hip And Knee Arthroplasty. Paper presented at: EFORT; 2019; Lisbon. 3. Nherera LM, Trueman P, Karlakki SL. 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. Wound Repair and Regeneration. 2017 May;25(3):474-82. 4. Patel VP, Walsh M, Sehgal B, Preston C, DeWal H, Di Cesare PE. Factors associated with prolonged wound drainage after primary total hip and knee arthroplasty. JBJS. 2007 Jan 1;89(1):33-8. 5. Holm B, Kristensen MT, Bencke J, Husted H, Kehlet H, Bandholm T. Loss of knee-extension strength is related to knee swelling after total knee arthroplasty. Archives of physical medicine and rehabilitation. 2010 Nov 1;91(11):1770-6. 6. Tucker A, Walls A, Leckey B, Hill JC, Phair G, Bennett DB, O'Brien S, Beverland DE. Postdischarge unscheduled care burden after lower limb arthroplasty. The Journal of arthroplasty. 2018 Sep 1;33(9):2745-51. 7. Avram V, Petruccelli D, Winemaker M, de Beer J. Total joint arthroplasty readmission rates and reasons for 30-day hospital readmission. The Journal of arthroplasty. 2014 Mar 1;29(3):465-8. 8. Poultsides LA, Ma Y, Della Valle AG, Chiu YL, Sculco TP, Memtsoudis SG. In-hospital surgical site infections after primary hip and knee arthroplasty—incidence and risk factors. The Journal of arthroplasty. 2013 Mar 1;28(3):385-9. 9. Anis HK, Sodhi N, Klika AK, Mont MA, Barsoum WK, Higuera CA, Molloy RM. Is operative time a predictor for post-operative infection in primary total knee arthroplasty?. The Journal of arthroplasty. 2019 Jul 1;34(7):S331-6. 10. Leekha S, Sampathkumar P, Berry DJ, Thompson RL. Should national standards for reporting surgical site infections distinguish between primary and revision orthopedic surgeries?. Infection Control & Hospital Epidemiology. 2010 May;31(5):503-8. eek 11. Drew JM, Griffin WL, Odum SM, Van Doren B, Weston BT, Stryker LS. Survivorship after periprosthetic femur fracture: factors affecting outcome. The Journal of arthroplasty. 2016 Jun 1;31(6):1283-8. 12. Matharu GS, Pynsent PB, Dunlop DJ, Revell MP. Clinical outcome following surgical intervention for periprosthetic hip fractures at a tertiary referral centre. Hip International. 2012 Sep;22(5):494-9. 13. Everhart JS, Andridge RR, Scharschmidt TJ, Mayerson JL, Glassman AH, Lemeshow S. Development and validation of a preoperative surgical site infection risk score for primary or revision knee and hip arthroplasty. JBJS. 2016 Sep 21;98(18):1522-32. 14. Sugrue M, Ciprandi G, Djohan R, et al. World Union of Wound Healing Societies (WUWHS) Consensus Document. Closed surgical incision management: Understanding the role of NPWT. Wounds Int [Internet]. 2016. www.woundsinternational.com/wuwhs/view/consensus-documentclosed-surgical-incision-management-understanding-the-roleof-npwt. (Last accessed July 29, 2017) 15. The World Health Organisation (2016) Global Guidelines for the Prevention of Surgical Site Infection. [online] Available from: https://apps.who.int/iris/bitstream/handle/10665/250680/9789241549882-eng.pdf?sequence=8. Last Accessed June 2020 16. Saunders C, Buzza K, Nherera L. 2019. A single use negative pressure system reduces surgical site complications compared with conventional dressings in closed surgical incisions: a systematic literature review with meta-analysis. Poster presented at the European Wound Management Association annual meeting, June 5-7, 2019, Gothenburg, Sweden. 17. NICE (2019) PICO negative pressure wound dressings for closed surgical incisions [online] accessible from: https://www.nice.org.uk/guidance/mtg43. Last accessed June 2020 18. Canonico S, Campitiello F, Della Corte A. Therapeutic possibilities of portable NPWT. Acta Vulnologica 10 (2012): 57-64. 19. Hyldig N, Birke-Sorensen H, Kruse M, Vinter C, Joergensen JS, Sorensen JA, Mogensen O, Lamont RF, Bille C. Meta-analysis of negative-pressure wound therapy for closed surgical incisions. British Journal of Surgery. 2016 Apr;103(5):477-86. 20. 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. 21. Malmsjö M, Huddleston E, Martin R. Biological effects of a disposable, canisterless negative pressure wound therapy system. ePlasty. 2014;14. 22. Pellino G, Sciaudone G, Candilio G, Campitiello F, Selvaggi F, Canonico S. Effects of a new pocket device for negative pressure wound therapy on surgical wounds of patients affected with Crohn's disease: a pilot trial. Surgical innovation. 2014 Apr;21(2):204-12. 23. Data on file reference 1102010 – Bacterial Barrier Testing (wet-wet) of PICO Dressing with a 7 day test Duration against S. marcescens. 24. Smith & Nephew October 2017. Project Opal PICO 7 System Stability Testing, Initial Time Point. Internal report. DS/17/253/R. 25. Data on file, report DS.17/666/R2. Comparison of PICO 1.6 and 2.1 Device Air Leak Tolerance. January 2018. 26. Smith & Nephew January 2019. Acoustic Testing Report: Comparison of PICO v2 (PICO 7 and PICO 14) Devices to PICO v1.6 (PICO) devices. Internal report. RD/19/005. 27. Smith & Nephew December 2018. Summary of PICO v2 (PICO 7 and PICO 14) Human Factors Testing. Internal report. RD/18/136. 28. 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 Suppl:S1-16. 29. Scalise A, Calamita R, Tartaglione C, et al. Improving wound healing and preventing surgical site complications of closed surgical incisions: a possible role of Incisional Negative Pressure Wound Therapy. A systematic review of the literature. Int Wound J. 2016;13(6):1260-1281. 30. Shim HS, Choi JS, Kim SW. A Role for Postoperative Pressure Wound Therapy in Multitissue Hand Injuries. Biomed Res Int. 2018;2018. 31. Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): hematoma/seroma and involvement of the lymphatic system. Wound Repair Regen. 2011;19(5):588-596. 32. Ma Z, Shou K, Li Z, et al. Negative pressure wound therapy promotes vessel destabilization and maturation at various stages of wound healing and thus influences wound prognosis. Exp Ther Med. 2016;11(4):1307-1317. 33. Xia CY, Yu AX, Qi B, et al. Analysis of blood flow and local expression of angiogenesis associated growth factors in infected wounds treated with negative pressure wound therapy. Mol Med Rep. 2014;9(5):1749-1754. 34. Smith & Nephew 2018. PICO° 14 Service Life Testing: 14 Day Device Lifespan. Internal report. RD/18/132. 35. Smith & nephew 2018. The review of evidence supporting the use of PICO° in wounds ≥2cm in depth. Internal report. EO AWM. PCS230.001 v2 36. Smith & Nephew 2019. Research & Development Report. PICOº 14 and PICOº 7 Initial Pump Down and Maintenance Pump Down Time Outs RD/19/084. 37. 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. 38. Smith & Nephew 2018. Summary of rountine QA testing on MVP of PICO dressings. 2018. Internal report. DS/18/153/R. 39. Payne C, Edwards D. 2014. Application of the single use negative pressure wound therapy device (PICO) on a heterogeneous group of surgical and traumatic wounds. ePlasty, 14. 40. Rossington A. 2015. A prospective, open, non-comparative, multicentre study to evaluate the functionality and dressing performance of a new negative pressure enhanced dressing (NPED) in acute wounds. CT09/02, May. 41. Sharp E. Single use NPWT for the treatment of complex orthopaedic surgical and trauma wounds. Journal of Wound Care. 2013;22(10):S5-S9. 42. Stryja J, Staffa R, Říha D, Stryjová K, Nicielniková K. Cost-effectiveness of negative pressure wound therapy in outpatient setting. Prolekare. 2015. 43. Data on file 0810010 – The antimicrobial activity of ACTICOAT⁹ and ACTICOAT FLEX 3 while under negative pressure; Lumb, H; 2011. 44. Smith & Nephew 2019. Summary report of in vitro Wound Model and Negative Pressure Delivery (Nominal -80mmHg) testing for PICO v2 (PICO 7 and PICO 14) System. Internal report. RD/18/134 V2 45. Helito CP, Sobrado MF, Giglio PN, Bonadio MB, Pecora JR, Demange MK, Gobbi RG. The use of negative-pressure wound therapy after total knee arthroplasty is effective for reducing complications and the need for reintervention. 46. Villeco JP. Edema: a silent but important factor. Journal of Hand Therapy. 2012 Apr 1;25(2):153-62. 47. Smith & Nephew 2018. Wound Model Testing: Project Opal PICO 15x20cm dressings with ACTICOAT FLEX 7, Moderate Flow – 4 days. Internal report. DS/17/448/R V2. 48. Smith & Nephew January 2018. Wound model testing of PICO 7 Project Opal, low flow with ACTICOAT FLEX 7 wound contact layer - 7 days. Internal report. DS/17/627/R V2. 49. Sharpe A, Myers D, Searle R. 2018. Using single use negative pressure wound therapy for patients with complicated diabetic foot ulcers: an economic perspective. Wounds UK, 14(4). 50. Dowsett C, Hampton K, Myers D, Styche T. Use of PICO to improve clinical and economic outcomes in hard-to-heal wounds. Wounds International. 2017;8(2):52-58. 51. Bozic KJ, Katz P, Cisternas M, Ono L, Ries MD, Showstack J. Hospital resource utilization for primary and revision total hip arthroplasty. JBJS. 2005 Mar 1;87(3):570-6.



