

PICO negative pressure wound therapy for closed surgical incision wounds

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the PICO single-use negative pressure wound therapy system. It is intended to promote healing in closed surgical wounds and to reduce surgical site complications such as surgical site infections.
- The **innovative aspects** are that PICO is portable and disposable with no separate canister (for exudate collection) and has a proprietary dressing layer, which is designed to consistently deliver negative pressure across the incision and zone of injury.
- The intended **place in therapy** would be as an alternative to standard care for preventing surgical site complications in patients at risk of developing surgical site complications, and for treating surgical site complications in patients who develop complications.
- The **main points from the evidence** summarised in this briefing are from 1 meta-analysis of 16 comparative studies (10 randomised controlled studies, and 6 observational studies) and 1 prospective randomised study, with a total of 1,895 people. Trials in 6 types of surgery are represented in the meta-analysis, which also includes 4 UK studies. Pooled estimates show lower rates of surgical site infections in patients treated with PICO.
- **Key uncertainties** around the evidence are that there was not a quality assessment of the included studies in the meta-analysis and that generalisability of results of studies done outside the UK to the NHS may be limited.

- The **cost** of PICO ranges from £126.88 to £145.68 (excluding VAT) per pack of 2 dressings and 1 pump, depending on dressing size. The **resource impact** would be significantly greater than standard care for closed surgical incisions with low-to-moderate exudate levels because of the difference in cost between PICO and conventional dressings. The additional costs might be offset and savings may be achieved if using PICO is associated with fewer surgical site complications and less healthcare resource use, particularly in patients at high risk of surgical site complications.

The technology

PICO (Smith & Nephew) is a canister-free, single-use negative pressure wound therapy (NPWT) system consisting of a single-use sterile pump and 2 multi-layered adhesive dressings.

The pump is operated by 2 AA batteries and delivers a continuous negative pressure of 80 mmHg to a sealed wound. Once activated, using a push button, the battery drives the pump for up to 7 days and light-emitting diodes (LEDs) provide alerts for low-battery status and pressure leaks.

Each dressing has 4 layers: a silicone adhesive wound contact layer, which is designed to minimise pain and damage during peel back and to reduce lateral tension; an airlock layer for even distribution of pressure; an absorbent layer to remove exudate and bacteria from the wound; and a top film layer, which acts as a physical barrier and allows moisture to evaporate. The dressing comes in 10 sizes (up to 25 cm × 25 cm). This includes a multisite dressing of up to 20 cm × 25 cm, which is used for awkward anatomical areas. PICO comes with 2 dressings, which between them can absorb up to 300 ml of exudate during 1 week of therapy. PICO can be used during MRI scans, if detached from the pump.

PICO is promoted for a range of wound types. This briefing focuses on surgical incisions with low-to-moderate levels of exudate in people at increased risk of surgical site infections (SSIs).

Innovations

PICO differs from conventional NPWT systems because it:

- has no separate canister (for exudate collection)
- is portable and disposable
- has a proprietary dressing layer that is designed to allow even distribution of negative pressure across the incision and zone of injury.

Current care pathway

The aim of closing an incision after surgery is to start the healing process; this is often successful. But in some cases the incision site may be associated with post-surgical complications such as infection, seroma, haematoma, dehiscence, delayed healing and abnormal scarring – especially in people at high risk of developing surgical site complications (SSCs). People could be considered to be at high risk because of intrinsic patient factors, such as uncontrolled insulin-dependent diabetes, renal dialysis, poor physical status (based on the American Society of Anaesthesiologists physical status classification) and a high BMI. A patient may also be considered to be at risk if they have emergency procedures such as caesarean section or elective procedures such as cardiac or colorectal surgery.

Post-surgical care of an incision site is targeted at promoting healing, avoiding complications and minimising scarring. According to the NICE guideline on [preventing and treating surgical site infections](#), which is currently being updated, patients should have post-surgical care that involves:

- applying wound dressings using aseptic techniques
- wound cleaning with sterile saline for up to 48 hours and cleaning with tap water afterwards
- antibiotics, if an SSI is suspected. If dead or infected tissues seem to be slowing down the healing process, debridement (which may involve surgery) can be used to remove the dead tissue.

This is in addition to preventive measures at the pre- and intra-operative stages of a surgical procedure.

In some cases the presence of superficial or deep infections may result in wounds opening or a wound separating along the incision. If a deep infection is ruled out, sometimes a NPWT may be used to manage the dehiscent surgical wound to promote healing by secondary intention.

Population, setting and intended user

PICO would be used in place of conventional post-surgical wound dressings to prevent and treat SSIs in closed surgical incision wounds with low exudate levels.

It would be applied by healthcare professionals (doctors or nurses). It could be used in an inpatient setting, to prevent SSC perioperatively, with treatment continuing in an outpatient department. Or it could be used in a community setting for treating postoperative SSC.

Costs

Technology costs

Table 1 Cost of PICO dressings

Standard PICO dressings	Cost* (£)
10 cm × 20 cm	127.06
10 cm × 30 cm	127.45
10 cm × 40 cm	145.68
15 cm × 15 cm	127.45
15 cm × 20 cm	127.45
15 cm × 30 cm	145.68
20 cm × 20 cm	145.68
25 cm × 25 cm	145.68
PICO multisite	
15 cm × 20 cm	126.88
20 cm × 25 cm	145.48
* All costs include 1 single-use pump and 2 dressings.	

Costs of standard care

No standard list of dressings for closed surgical incisions has been identified. The costs described below are for a selection of dressings in the NHS supply chain catalogue.

Table 2 Cost of conventional wound dressings

Dressing	Size	Cost
Tegaderm	10 cm × 10 cm	£1.29
Mepore	10 cm × 12 cm	£0.55
Opsite	10 cm × 12 cm	£0.55

Resource consequences

Using PICO for closed surgical incision wounds would cost more than conventional wound dressings because of the cost of the device. But if using PICO results in reduced healthcare resources – including fewer dressing changes, reduced length of hospital stay and fewer readmissions, this additional cost may be offset. According to [NICE support for commissioning for surgical site infection](#) (2013), the cost of an SSI could be as high as £20,000 for complex surgeries and £14,000 for general surgery.

Nherera et al. (2017) estimated the costs and benefits from an NHS perspective of single-use NPWT (sNPWT) compared with conventional post-surgical dressings, in reducing SSC in people having primary hip and knee replacements. The analysis used data from a non-blinded randomised controlled trial by Karlakki et al. (2016) comparing PICO to conventional dressings. Results from the economic model showed that patients who had sNPWT had a quality-adjusted life year (QALY) gain of 0.116 and 0.98 complications avoided compared with 0.115 QALY gained and 0.92 complications avoided for conventional dressings. The per-patient costs saving was estimated at £1,132 in favour of sNPWT. In the higher-risk subgroups, more cost savings were realised: in people with a BMI of 35 or above, this was £7,955, and in people with an American Society of Anaesthesiologists physical status classification of greater than 3, this was £7,248.

The Karlakki study also highlighted that, despite being supplied with 2 dressings, only 25% of patients needed the second dressing. According to the company, PICO is used for managing closed surgical incisions in 179 NHS organisations. The company provides training on how to apply the dressing for clinical and non-clinical staff at no additional cost.

Regulatory information

PICO single-use negative pressure wound therapy (NPWT) is CE marked as a class IIb medical device.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil

partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in line with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

One meta-analysis of 16 comparative studies (10 randomised controlled studies, and 6 observational studies) and 1 prospective randomised study are summarised in this briefing with a total of 1,895 people who had closed surgical incisions. The results of these studies suggest that negative pressure wound therapy (NPWT) has been associated with fewer surgical site complications (SSCs) compared with conventional wound dressings.

[Table 3](#) summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The studies included in table 3 highlight the use of PICO for managing closed surgical incisions following a variety of surgical procedures. Blinding was not feasible in the included studies because of the visual difference between PICO and conventional wound dressings.

Clinically relevant outcomes reported across the studies included rates of dehiscence and surgical site infections (SSIs).

The meta-analysis included 16 studies across 6 surgical procedures, 4 of the studies covering 4 surgical procedures (orthopaedic surgery, colorectal surgery, caesarean section and mastoplasty) were done in the UK. The pooled studies used the same intervention and comparator but the surgical procedures were different. Similar surgical procedures were pooled in a subgroup analysis. There was no assessment of the quality of the included studies by the authors. Results from trials done outside the UK may not be generalisable to the NHS.

A number of studies included in the meta-analysis were funded by the company. The meta-analysis and cost-effectiveness study noted in this briefing were authored by employees of the company.

Table 3 Summary of selected studies

<u>Strugala and Martin (2017)</u>	
Study size, design and location	A meta-analysis of 10 RCTs and 6 observational studies with a total of 1,863 patients (2,202 incisions) assessing the effect of PICO NPWT in preventing SSI in a variety of surgical procedures (orthopaedic, abdominal, colorectal, cardiovascular, mammoplasty or caesarean section).
Intervention and comparator(s)	NPWT dressing (PICO) for up to 14 days. Standard care (conventional dressings).
Key outcomes	<p>Across the 10 RCTs, pooled SSI rates were 4.8% in people who had PICO compared with 9.7% in controls (RR 0.49, 95% CI 0.34 to 0.69, $p < 0.0001$). In the 6 observational studies, the pooled SSI rate was 7.4% in the people who had PICO and 22.5% in controls (RR 0.32, 95% CI 0.18 to 0.55 $p < 0.0001$). A combined analysis of all studies showed a statistically significant reduction in SSI (RR 0.43 95% CI 0.32 to 0.57 $p < 0.0001$).</p> <p>There was a significant reduction in dehiscence from 17.4 to 12.8% with the use of PICO (RR 0.71, 95% CI 0.54 to 0.92 $p < 0.01$).</p> <p>There was significant mean reduction in hospital length of stay associated with PICO NPWT use (-0.47 days 95% CI -0.71 to -0.23, $p < 0.0001$).</p> <p>Subgroup analysis of surgical procedures with ≥ 3 studies showed the reduction in SSI risk was statistically significant for all types of surgery: orthopaedic (RR 0.48 [95% CI 0.25 to 0.94] $p = 0.03$), abdominal (RR 0.44 [95% CI 0.30 to 0.64] $p < 0.0001$), colorectal (RR 0.29 [95% CI 0.15 to 0.57] $p = 0.0004$) surgeries and caesarean section (RR 0.53 [95% CI 0.33 to 0.84] $p = 0.007$).</p>
Strengths and limitations	<p>4 UK studies were included in this evidence synthesis. This meta-analysis pooled a large number of patients and has overcome some level of heterogeneity, largely by focusing on studies with the same intervention and similar comparators. The random effects model used in this analysis further addresses within and between study differences.</p> <p>The authors of this study are employees of the company.</p>

<u>Tanaydin et al. (2018)</u>	
Study size, design and location	A within-patient prospective randomised study of 32 people who had bilateral breast mammoplasty with post-surgical incisions of similar length on each breast. Netherlands.
Intervention and comparator(s)	PICO NPWT (n=32 incision sites). Fixation strips (n=32 incision sites).
Key outcomes	Within 21 days after surgery, wound dehiscence occurred in 10 (31.3%) patients. 5 (15.6%) of these patients had bilateral wound dehiscence. The PICO-treated site healed faster in 2 of the patients with bilateral dehiscence. Unilateral dehiscence occurred in 5 patients at the site treated with fixation strips. There was a significantly lower number of wound complications (incision not completely closed at 7 days, dehiscence or infection) in the study group compared to the control group ($p<0.004$).
Strengths and limitations	Method of randomisation was noted. Patients served as their own control and the study was not clear on the specific characteristics of patients who had dehiscence and whether patient-specific factors might have had confounding effects on wound complications.
Abbreviations: CI, confidence interval; NPWT, negative pressure wound therapy; RCT, randomised controlled trial; RR, relative risk; SSC, surgical site complication; SSI, surgical site infection.	

Recent and ongoing studies

- Negative pressure wound therapy in groin dissection. NCT02408835. Devices: PICO negative pressure wound therapy. Study anticipated completion July 2019. Sponsor: South Eastern Health and Social Care Trust. Location: United Kingdom.
- WHIST – wound healing in surgery for trauma. PICO negative pressure wound therapy versus standard wound care. Study size: 1,540. Sponsor: NIHR health technology assessment programme.
- WHITE 7 – WHISH – wound healing in surgery for hip fractures. ISRCTN55305726. Device: PICO negative pressure wound therapy. Study completion December 2018. Sponsor: NIHR and Royal College of Surgeons of England.

- Single-use negative pressure wound therapy system versus traditional negative pressure wound therapy system (sNPWT versus tNPWT). NCT02470806 Device: PICO Negative pressure wound therapy. Completed January 2018, Location: Canada, US.
- PICO negative pressure wound therapy in obese women undergoing elective caesarean delivery. NCT03414762. Device: PICO negative pressure wound therapy. Study start date: February 2018. Sponsor: Northwell Health.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Seven specialists who were familiar with and had used the technology contributed to this briefing. Three of the experts have been involved in research on the technology.

Level of innovation

All experts noted that the technology is innovative, with 2 experts describing it as an advancement to wound care for closed surgical incisions. Two experts felt that the technology is innovative in comparison to standard dressings. One expert noted that the concept of moisture absorption and vaporisation through the dressing is novel. Another expert noted that the innovation is the concept of applying an 'active' dressing to a primarily closed wound. One expert felt that although it is a novel concept, there is a lack of clear guidance on when it should be applied.

Potential patient impact

Two experts noted that using PICO negative pressure wound therapy (NPWT) for closed surgical incisions would result in reduced hospital stay. Two experts stated that the technology would improve scarring, particularly in patients having breast surgery. Two other experts felt that patients will benefit from a reduced postoperative dehiscence, reduced implant loss rates and fewer delays to adjuvant treatments. One expert stated that the technology would support the prediction of wound healing in patients susceptible to delayed wound healing; this expert noted that this would also make hospital discharge and bed management more predictable. Two experts noted that a benefit would be reduced rates of surgical site infection (SSI). One expert noted improved patient life quality because PICO allows for more patient mobility.

Potential system impact

One expert felt that using PICO would reduce mortality associated with delayed adjuvant treatments such as chemotherapy. Another expert noted that using PICO would result in early hospital discharge and prevent post-discharge complications. One expert considered that using PICO may be associated with fewer SSIs, shorter hospital stays, and reduced bed and community nursing care costs. One expert noted that if the technology is proven to reduce SSI rates, then it may result in cost savings. This expert also noted that an abdominal SSI wound incur an additional treatment cost of about £3,000 to £4,000.

General comments

One expert noted that in practice, PICO can only handle low levels of exudate and that the dressing floats with increased levels of exudate. This expert also suggested that PICO's lesser cost compared to similar technologies may be the reason for its widespread use. Another expert, who had used PICO in the community, noted that it can handle moderate exudate and less than 40% slough. One expert noted the importance of highlighting the other possible modes of action of NPWT, other than managing exudate, in closed surgical incisions. Another expert noted the importance of training on dressing application, because wrong application would result in wasted resources. One expert noted that there are ongoing clinical trials assessing the real-world use of the technology. One expert highlighted the need to implement care pathways that enable the technology to be used. One expert highlighted that PICO does not replace full topical negative pressure, but can be part of the healing process.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Thomas Pinkney, senior lecturer and consultant colorectal surgeon, Academic Department of Surgery, University of Birmingham. No conflict of interest.
- Mr John Murphy, consultant oncoplastic breast surgeon, Nightingale Breast Unit, Manchester University NHS Foundation Trust, Wythenshawe Hospital. Mr Murphy is the author of one of the studies included in the meta-analysis. This study was not funded by the company but has been presented at education events by the company.
- Mr Sudheer Karlakki, consultant orthopaedic surgeon, Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry. Mr Karlakki has been involved in research funded by the

company and is the author of one of the studies included in the meta-analysis. He has also provided speaker services for the company.

- Miss Pauline Whitehouse, consultant general and colorectal surgeon, Worthing Hospital, Western Sussex Hospitals NHS Foundation Trust. Miss Whitehouse has provided speaker services for the company.
- Ms Joanne Beresford, tissue viability nurse specialist, Leeds Community Healthcare NHS Trust. No conflict of interest.
- Dr Fania Pagnamenta, nurse consultant (tissue viability), Newcastle upon Tyne Hospitals NHS Foundation Trust. No conflict of interest.
- Ms Caryn Carr, lead tissue viability nurse specialist, Southern Health NHS Foundation Trust. No conflict of interest.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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