NICE advice

Prevena incision management system for closed surgical incisions

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Prevena. It is a single-use technology for the management of closed surgical incisions that may be at increased risk of infection.
- The **innovative aspects** are that Prevena has a multilayer, customisable design, LED display and vacuum-assisted closure connector intended to provide continuous negative pressure to any closed surgical incision.
- The intended **place in therapy** would be as an alternative to standard care for managing closed surgical incisions in people at risk of developing surgical site complications. Negative pressure wound therapy is not standard care in the NHS.
- The **main points from the evidence** summarised in this briefing are from 7 studies including 1 study done in the UK. They show that Prevena is more effective at reducing complications than standard care in people with closed surgical incisions.

- **Key uncertainties** around the evidence or technology are that it is unclear if Prevena is more effective than standard care for people with specific risk factors (such as diabetes or renal insufficiency) associated with surgical site complications. Further studies and analysis of subgroups would be helpful in determining this.
- The **cost** of Prevena is £299 or £351 per unit depending on size (exclusive of VAT). The **resource impact** may be less than standard care if surgical site complications are avoided. The resource impact compared to other negative pressure wound therapy devices was not considered in this briefing.

The technology

Prevena (Kinetic Concepts Inc. an Acelity Company) is a wound management system that is placed over a closed surgical incision. The device applies continuous negative pressure. This helps promote healing by holding the incision edges together, drawing fluid and exudate out of the wound, reducing oedema and stimulating perfusion. The device is single use and can stay in place for up to 7 days. Prevena is available in a range of sizes and can be customised to fit any incisions.

Prevena uses a stabilisation layer to make sure there is full and airtight adhesion to the skin. The part of the device touching the incision contains 0.019% ionic silver to minimise bacterial growth within the dressing.

Innovations

The company claims that Prevena is innovative because the device uses 2.5 cm of foam filler which, when 125 mmHg negative pressure is applied, gives uniform pressure across the wound. The company claims that this stops gaps in the dressing where excess fluid would otherwise collect. The foam filler also reduces lateral tension holding the edges of the wound together.

The Prevena 125 Therapy Unit provides the negative pressure. This unit has an innovative VisiCheck LED display that tells the patient or staff of the leak rate of the system so that any problems are identified at an early stage. The device can also be attached to other vacuum-assisted closure systems, allowing for more flexibility.

Current care pathway

The aim of closing an incision after surgery is to start the healing process. In some cases, there may be 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. 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 at risk if they have emergency procedures such as a caesarean section or elective procedures such as cardiac or colorectal surgery.

Post-surgical care of an incision site is aimed at promoting healing, avoiding complications and minimising scarring. According to NICE's guideline on preventing and treating surgical site infections, 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 a surgical site infection is suspected
- debridement (which may involve surgery) to remove the dead tissue if dead or infected tissues seem to be slowing down the healing process
- these are as well as other infection prevention measures at the pre- and intra-operative stages of a surgical procedure.

NICE has also published medical technologies guidance on PICO negative pressure wound dressings for closed surgical incisions.

Population, setting and intended user

Prevena would be used instead of conventional post-surgical wound dressings to manage closed surgical incision wounds. The company claim that Prevena can provide the most benefit to people who are at increased risk of surgical site infection. For example, people with obesity, diabetes, renal insufficiency, poor nutrition, traumatic injury, chronic obstructive pulmonary disorder and those having emergency surgery.

It would be applied by healthcare professionals. It could be used in an inpatient setting, to prevent surgical site complications peri-operatively, with treatment continuing in an outpatient department or community setting.

Costs

Technology costs

Prevena kits (including dressing, fluid collection canister and vacuum-assisted closure connector) are priced at £299 and £351 depending on size; this is more expensive than current standard of care. Prevena kits can also be bought without a vacuum-assisted closure unit so that they may be used with existing equipment.

Table 1 Cost of Prevena kits

Dressing	Size	Cost	Cost of dressing only (for use with existing pressure units)
Prevena Peel & Place System Kit	6 cm × 13 cm	£299	£179
Prevena Peel & Place System Kit	6 cm × 20 cm	£299	£179
Prevena Plus System Kit – customisable	6 cm × 90 cm	£351	£233

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

Dressing	Size	Cost
Opsite	10 cm × 12 cm	£0.55

Resource consequences

Over 30 NHS trusts and hospitals have ordered Prevena from the company.

The company claims that using Prevena is likely to lead to cost savings because of reduced incidence of surgical site infections and other complications. This in turn could lead to reduced readmissions, reoperations, length of stay and antibiotic use.

The company provides staff training through online resources and employs clinical advisers to provide advice and training in hospitals.

Regulatory information

Prevena is a CE-marked class IIa medical device.

The company recalled the device from sale in the US because there was a problem with the tubing connectors not fitting correctly in 2015. The device has since been redesigned. There were no other safety alerts identified.

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. People who have had surgery may have existing comorbidities such as diabetes (which is more prevalent in some ethnic groups), obesity-

related renal insufficiency, and chronic obstructive pulmonary disorder and so may be protected under the disability (and race) element of the Equality Act 2010. For older people having surgery, age is a protected characteristic. People recovering from a caesarean section are protected by the Equality Act 2010 because pregnancy and maternity are protected characteristics.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance 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

There are more than 20 published studies on the Prevena device; this briefing summarises 7 studies that were considered to be the most relevant evidence to the NHS.

Six studies report outcomes for 596 people and 1 study for 119 incisions. One study was done in the UK and Ireland, 3 studies were done in Europe (Germany and Italy), 2 studies were done in the US and 1 in Canada.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The included studies are of good quality and compare Prevena with controls that are similar to NHS standard care for incision management, although only 1 study was done in the UK. The study designs comprise 2 randomised controlled trials, 2 prospective randomised studies, 1 prospective controlled study, 1 clinical feasibility study and 1 retrospective review. The studies included people recovering from a range of surgeries with incisions at different sites, such as groin incisions, femoral incisions, cardiac surgery, vascular surgery, breast cancer surgery, laparotomy and caesarean incisions. The studies included incisions that are considered difficult to heal such as bilateral groin incisions and caesarean incisions in people with obesity. The studies show that Prevena can lead to

significantly reduced incision site complications in comparison with standard care dressings.

Pleger et al. (2017)

Study size, design and location

Study of 100 people with groin incisions in a prospective randomised study in Germany.

Intervention and comparator

Prevena versus standard care (adhesive plaster). Prevena or standard care were applied postoperatively, Prevena was removed after 5 to 7 days. All wounds were evaluated 5 to 7 days and 30 days postoperatively using Szilagyi classification.

Key outcomes

Wound healing complications were statistically significantly lower in the Prevena group compared with standard care (p=0.0011).

There were 5 wound healing complications (4 grade 1 and 1 grade 2) recorded at 30 day follow-up.

Revisions surgeries were statistically significantly lower in the Prevena group (1) compared with standard care (10) (p=0.012).

Strengths and limitations

People included in the study all had at least 1 risk factor for wound complications (age over 50 years, diabetes mellitus, renal insufficiency, malnutrition, obesity or chronic obstructive pulmonary disease).

The company provided medical writing and editorial assistance to the authors (no financial or scientific involvement or support).

Kwon et al. (2017)

Study size, design and location

Study of 119 femoral incisions in a prospective randomised study in the US.

Intervention and comparator

Prevena versus standard care (gauze), control group split into high-risk and low-risk (for wound complications) subgroups.

Key outcomes

Major wound complications were statistically significantly lower in the Prevena group ($p<0.001$) compared with high-risk standard care; as was reoperation ($p<0.05$), and readmission ($p<0.04$).

There was no difference in length of stay between the 2 groups.

There was an average cost saving of $6,045 per patient in the Prevena group compared with standard care for high-risk patients.

Strengths and limitations

Complications rates, length of stay, reoperation and readmission rates were all lower in low-risk controls. The authors conclude Prevena should be used in people at high risk for groin wound complications such as those who have BMI over 30, pannus, reoperation, prosthetic graft, poor nutrition, immunosuppression, or poorly controlled diabetes.

The results of this study are presented as an abstract only. The authors state that there were no statistically significant differences in baseline population characteristics but no further information is provided.

Lee et al. (2016)

Study size, design and location

Clinical feasibility pilot study of 64 people recovering from open saphenous vein harvest in cardiac surgery in Canada.

Intervention and comparator

Prevena versus standard care (gauze).

Key outcomes

Use of Prevena was safe and well tolerated. Out of 33 Prevena systems, 3 were removed, 1 because of contact dermatitis and 2 because of a malfunctioning pressure alarm.

Length of post-operative stay was statistically significantly lower in the Prevena group compared with standard care (6 versus 10 days, p=0.008).

Strengths and limitations

The study reported no statistically significant differences in infections or complications between the 2 groups, however, it was not adequately powered to detect any difference and the authors state that the infection rate at the institution was very low (1.9%).

The study was funded by the company.

Engelhardt et al. (2018)

Study size, design and location

Randomised controlled trial of 132 people recovering from vascular surgery in Germany.

Intervention and comparator

Prevena versus standard care (absorbent dressing).

Prevena or standard care were applied postoperatively, Prevena was removed after 5 days. All wounds were evaluated at 5 days and 42 days postoperatively using Szilagyi classification.

Key outcomes

Infection rate was lower in the Prevena group compared with standard care but the difference was not statistically significant (14% versus 38%, p=0·055).

Strengths and limitations

The authors state that larger, multicentre studies are needed to show the efficacy of Prevena.

Ferrando et al. (2018)

Study size, design and location

Prospective controlled study 37 people recovering from breast cancer surgery in Italy.

Intervention and comparator

Prevena versus standard care (Steri-strip skin adhesive closure).

Prevena was removed after 7 days.

Key outcomes

People in the Prevena group had a statistically significantly higher number of risk factors for wound complications compared with those in the standard care group (p=0.04).

Complication rate was statistically significantly lower in the Prevena group compared with standard care (4% versus 45%, p=0.001).

Strengths and limitations

People included in the Prevena group were expected to have poorer outcomes than those

in the standard care group. Despite this, there were fewer complications recorded in the Prevena group.

Patients were followed up 1 year after surgery; there were no differences in scar appearance suggesting total healing had happened.

Zaidi and El-Mastry (2016)

Study size, design and location

Retrospective review 181 people recovering from laparotomy in the UK and Ireland.

Intervention and comparator

Prevena versus retrospective review of standard care (adherent gauze).

Prevena was removed after 7 days.

Key outcomes

Complication rate was statistically significantly lower in the Prevena group compared with retrospective standard care (2.9% versus 20.5%, p=0.0009).

Strengths and limitations

Study design (retrospective review) introduces bias because Prevena group were treated under study conditions. The authors state that there were no statistically significant differences in baseline population characteristics between the 2 groups.

The company provided editorial assistance to the authors.

Gunatilake et al (2017)

Study size, design and location

Randomised controlled trial of 82 people with obesity recovering from caesarean section in the US.

Intervention and comparator

Prevena versus standard care (Steri-strips, sterile gauze and Tegaderm).

Prevena was removed after 5 to 7 days.

Key outcomes

Complication rate was lower in the Prevena group compared with standard care but the difference was not statistically significant (5.1% versus 16.3%, p=0.16).

Use of opioids (to treat incision pain) was statistically signicantly lower in the Prevena group compared with standard care (30% decrease, p=0.036).

Strengths and limitations

This study considered the use of Prevena in a single high-risk subgroup (obesity).

The study was funded by the company.

Recent and ongoing studies

- A phase III randomised controlled trial of negative pressure wound therapy in post-operative incision management. ClinicalTrials.gov identifier: NCT02682316. Status: recruiting. Primary comparator: usual standard dry gauze used for wound management. Expected enrolment: 686. Estimated study completion date: February 2024. Location: United States.
- Wound healing after dirty/contaminated emergency abdominal surgery: Prevena™ incision management system vs conventional management. ClinicalTrials.gov identifier: NCT02892435. Primary comparator: standard dressing. Expected enrolment: 120. Estimated study completion date: December 2017. Location: Italy.

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.

All 3 specialists were familiar with this technology and 2 specialists have used the technology before.

Level of innovation

All specialists agreed that Prevena was an innovative device but that its design was based on other topical negative pressure devices such as traditional vacuum-assisted closure therapy. All specialists noted that there are other negative pressure wound therapy devices available for use in the NHS, 2 specialists mentioned the PICO device. Two specialists stated that Prevena was better than PICO because it uses a higher negative pressure (75 mmHg compared with 125 mmHg) and has a thick foam dressing.

Potential patient impact

All specialists agreed that using Prevena could lead to reduced surgical site infection, incision wound reopening and length of stay. The specialists also noted that using Prevena may need a less frequent treatment pattern than standard care. For example, surgical incisions with standard care dressings would need changing and cleaning every day. People with diabetes, obesity and renal failure are at high risk of surgical site complications; as are people having complicated or repeated surgery or surgery that involves a bacteria colonised area of the body, such as the gut. People at high risk of surgical site complications are likely to benefit the most from Prevena.

Potential system impact

All specialists agreed that using Prevena would likely lead to cost savings because of reduced need for daily dressing changes and reduced surgical site complications. Two specialists advised that daily dressing changes are very costly to the NHS and 1 noted that major surgical site complications after laparotomy are likely to cost at least £10,000 per person. The specialists also noted potential reductions in the amount of time a patient needs to stay in hospital, follow-up procedures and antibiotic use that are likely to lead to cost savings. One specialist thought using Prevena could be cost saving, but felt that further evidence in specific subgroups would be needed to confirm this.

Two specialist stated that a small amount of training is needed to use Prevena. This training would apply to both surgeons and nurses because Prevena is applied by the surgeon and removed 7 days later by nursing staff.

General comments

One specialist stated that generally Prevena was easy to use but that occasionally there would be problems with achieving and maintaining the airtight seal over the wound. The specialist noted that in these cases, a colleague with more extensive training would be needed to help.

One specialist noted that since using Prevena, surgical site infection rates following laparotomy had halved. They noted that the sample size for these data were small (50 people) and that there was a need for better data collection on outcomes with Prevena. One specialist noted that the heterogeneous study populations included in the evidence for Prevena made it difficult to make general recommendations about the technology.

Specialist commentators

The following clinicians contributed to this briefing:

- Ben Griffiths, consultant colorectal surgeon, Newcastle upon Tyne Hospitals NHS Foundation Trust, ACPGBI, ASGBI, ESCP, BHS, FRCS. Occasionally acts as a consultant for the company but has not received any payments.
- Fania Pagnamenta, nurse consultant (tissue viability), Newcastle upon Tyne Hospitals NHS Foundation Trust, RCN.
- Professor Michael Clark, Welsh Wound Innovation Centre, EPUAP. Has received consultancy payments from wound care companies but not the manufacturer of Prevena.

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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