

Mepilex Border dressings for preventing pressure ulcers

Medtech innovation briefing

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Summary

- The **technology** described in this briefing are Mepilex Border dressings, specifically the 2 variants designed to prevent pressure ulcers (Mepilex Border Heel and Mepilex Border Sacrum).
- The **innovative aspects** are that the dressing is designed to reduce pressure and friction caused by patient movements. It also uses the company's proprietary Safetac technology, which is intended to minimise pain when changing dressings or inspecting the skin.
- The **intended place in therapy** would be in addition to standard pressure ulcer prevention strategies for people at risk of developing pressure ulcers in acute care.
- The **main points from the evidence** summarised in this briefing are from 2 randomised controlled trials and 1 cohort study including a total of 956 adults in critical care and emergency room settings. The studies show that standard care plus Mepilex Border dressings is more effective than standard care alone in preventing pressure ulcers.
- **Key uncertainties** around the evidence or technology are the lack of evidence directly comparing Mepilex Border dressings and standard care in patients at high risk of developing pressure ulcers in the NHS, and a lack of evidence of effectiveness in children.
- The **cost** of Mepilex Border Heel is £6.61 per unit. The cost of Mepilex Border Sacrum is £3.13 to £7.26 per unit, depending on size (all figures exclusive of VAT). The **resource impact** would

be an increase in costs, but this might be offset if Mepilex Border dressings were to reduce the incidence or severity of pressure ulcers.

The technology

Mepilex Border dressings (Mölnlycke Health Care) are self-adherent, multilayer foam dressings which include proprietary soft silicone technology (called Safetac). They are available in various sizes; the company also provides variants which are specifically designed for use on the heel and sacrum, areas where there is a high risk of pressure ulcers forming.

Mepilex Border dressings can be used for a wide range of wound types in people of all ages, but this briefing focuses specifically on their use for preventing pressure ulcers and on the 2 variants designed for this indication (Mepilex Border Heel and Mepilex Border Sacrum).

The dressings are made up of 5 layers. The layer closest to the skin is designed to reduce friction between the skin and the dressing itself. The Safetac technology is designed to allow the dressing to be easily peeled back and reapplied, thereby enabling multiple inspections of the skin site without needing to fully replace the dressing. The other 4 layers are variously designed to cushion, prevent stretch or tear, absorb moisture and allow moisture to evaporate.

Innovations

Wound dressings are not routinely used to prevent pressure ulcers, but Mepilex Border dressings have a non-woven redistribution layer which is designed to reduce the effect of shear forces. Moreover, the Safetac technology is designed to reduce pain and allow for the dressing to be peeled back and reapplied with minimal discomfort or trauma to the area.

Current care pathway

The NICE guideline on [pressure ulcers](#) recommends that a documented risk assessment for pressure ulcers should be done in certain adults. It recommends using a validated scale to support clinical judgement, and that risk be reassessed if there is a change in the patient's clinical status.

The guideline recommends various strategies for preventing pressure ulcers, including regular patient repositioning, foam mattresses and pressure redistribution cushions.

NICE medical technology guidance on [Parafricta Bootees and Undergarments](#) considers that they show potential to reduce the development and progression of skin damage in people with, or at risk of, pressure ulcers, but it ultimately recommends further research on their use.

Several dressings are available for treating pressure ulcers, but they are not usually intended for or used for prevention. This is because most dressings are not widely considered to be able to influence the effects of compression (that affects blood supply to the area) or shear forces (that stretch and tear the skin) that cause pressure ulcers to develop. Research on the role of dressings in pressure ulcer prevention strategies has emerged as interest in other factors that contribute to pressure ulcer development, such as the microclimate around the site of pressure ulcers, has increased.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function as Mepilex Border dressings for the prevention of pressure ulcers:

- Askina DresSil Sacrum/Heel (Braun).

Population, setting and intended user

Mepilex Border dressings would be used in patients of all ages in acute care settings who are considered to be at risk of pressure ulcers. The dressings may also be used in the community in patients who are at risk of pressure ulcers through mobility issues. They would mainly be applied by nursing staff. No extra training is needed.

Costs

Table 1 Cost of Mepilex Border dressings

Description	Cost (per dressing)
Mepilex Border Heel	£6.61
Mepilex Border Sacrum 15×15 cm	£3.13
Mepilex Border Sacrum 18×18 cm	£4.45
Mepilex Border Sacrum 23×23 cm	£7.26
All dressings are sold in packs of 5. All prices exclude VAT. Note that several sizes of Mepilex Border are available at various costs; this table includes only the Heel and Sacrum variants (that is, areas at high risk of pressure ulcers).	

The instructions for use recommend that Mepilex Border dressings are changed as needed. In a study by [Kalowes et al. \(2016\)](#) evaluating the prophylactic use of Mepilex Border dressings in an intensive care unit, dressings were changed every 3 days.

Costs of standard care

No estimate for the overall cost of existing standard care for preventing pressure ulcers could be identified, but the cost of treating a pressure ulcer increases with severity ([Dealey et al. 2012](#)).

The NICE guideline on [pressure ulcers](#) estimated costs for repositioning based on the staff time involved, depending on grade. The costs of repositioning equipment were also included; high-specification foam mattresses were estimated to cost £120 to £200 for adults and £50 to £200 for children; constant low pressure and alternating pressure mattress replacements were estimated to cost around £3,500 to £3,600, or daily hire of around £13 to £14. Once purchased, the equipment can be used over a number of years, so the cost per patient would be low.

Resource consequences

Using Mepilex Border dressings would represent an additional cost to standard care. This could be offset if using the dressings reduced the severity or incidence of pressure ulcers.

The NICE guideline on [pressure ulcers](#) states that the daily costs of treating a pressure ulcer range from £43 to £374 in addition to the costs of standard care. Resources needed include nurse time, dressings, antibiotics, diagnostic tests and pressure redistributing devices.

[Santamaria et al. \(2015c\)](#) did a cost-benefit analysis of Mepilex dressings for preventing pressure ulcers from an Australian health service perspective, using the results from a randomised controlled trial which compared the Mepilex Border Sacrum and Mepilex Heel dressings plus standard care with standard care alone (the Border trial; Santamaria et al. 2015a). Based on dressing and staff costs, the estimated average marginal cost per patient for Mepilex dressings was A\$36.61 (£21.56; September 2017); this was offset by lower downstream costs for pressure ulcer treatment, meaning that the cost of using Mepilex dressings was lower than standard care alone (A\$70.82 [£41.71] compared with A\$144.56 [£85.14]).

Regulatory information

Mepilex Border dressings were CE marked as class IIb devices in 2001.

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 in the development of this briefing.

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

This briefing summarises 3 studies including a total of 956 adult patients. Table 2 summarises the included evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence includes 2 randomised controlled trials which were relatively well designed and conducted. However, the same lead author and most of the team from 1 of these, the Border trial, were involved in a cohort study that used data from this trial as the control. Furthermore, none of the evidence was from the UK and so it may not be generalisable to the NHS.

The evidence included adults only, but the technology can be used in children so further research evaluating the effectiveness of Mepilex Border dressings in children would be useful.

Table 2 Summary of selected studies

Santamaria et al. (2015a)

Study size, design and location	<p>Border trial: prospective, non-blinded, open-label randomised controlled trial, n=440 trauma and critically ill adult patients admitted to the ED and transferred to ICU. Results were reported on 313 patients (161 intervention and 152 control). Australia.</p> <p>Patients were followed up during their stay in ICU or until they had a pressure ulcer.</p>
Intervention and comparator(s)	<p>Intervention: Mepilex Border Sacrum and Mepilex Heel (precursor to Mepilex Border Heel), plus standard care.</p> <p>Comparator: standard care (including ongoing Braden risk assessment, regular repositioning and skin care).</p> <p>Dressings were changed every 3 days or earlier if soiled or dislodged.</p>
Key outcomes	<p>There were significantly fewer pressure ulcers in the Mepilex arm compared with the standard care arm (7 versus 20, p=0.002). The hazard ratio for developing a pressure ulcer was 0.198 (95% CI 0.065 to 0.555, p=0.002). The event rate for pressure ulcers was 3.1% in the Mepilex arm and 13.1% in the standard care arm.</p>
Strengths and limitations	<p>This was a well-designed trial, but is limited because it was non-blinded and involved only a single site.</p> <p>There is limited detail on what standard care involved and the study's relevance to the NHS is unclear (although further details appear in the cost-benefit analysis by the same authors). The intervention was Mepilex Heel, a precursor dressing to Mepilex Border Heel, so this may limit its relevance. Tubular bandages (Tubifast) produced by the company were used to keep the dressing in place.</p>
<u>Santamaria et al. (2015b)</u>	
Study size, design and location	<p>Prospective cohort study, n=150 adult patients admitted to the ED and transferred to ICU and 152 from the Border trial (historic cohort, heel only). Australia.</p>
Intervention and comparator(s)	<p>Intervention: Mepilex Border Heel plus standard care.</p> <p>Comparator: standard care.</p>

Key outcomes	<p>No patients had a pressure ulcer in the Mepilex arm compared with 9.2% in the standard care arm ($p < 0.001$). Common difficulties in applying and using the dressings were:</p> <ul style="list-style-type: none"> • that the adhesive tabs rolled up very easily and became difficult to unravel during skin inspection, making reapplication challenging, particularly when wearing gloves • that once the adhesive border began to roll because of patient movement, it soon became dislodged.
Strengths and limitations	<p>The study included patients from 2 separate studies which recruited at different time periods. However, the patient demographics were similar except for a longer ICU stay for patients in the Mepilex arm (which was not an advantage, because longer stays increase the risk of pressure ulcers).</p>
<u>Kalowes et al. (2016)</u>	
Study size, design and location	<p>Prospective, non-blinded, randomised controlled trial, n=366 patients in ICU. California, US.</p> <p>Patients were followed up for their stay in ICU.</p>
Intervention and comparator(s)	<p>Intervention: Mepilex Border Sacrum plus standard care.</p> <p>Comparator: standard care (SKIN bundle).</p>
Key outcomes	<p>There were more pressure ulcers in the standard care arm compared with the Mepilex arm (7 versus 1 respectively). Incidence rates per 1,000 patient days were 0.7% in the Mepilex arm and 5.9% in the standard care arm.</p>
Strengths and limitations	<p>The study was well conducted study with no statistically significant differences in patient characteristics. However, the results are limited to critically ill patients in 1 centre and the study was not blinded.</p>
<p>Abbreviations: CI, confidence interval; ED, emergency department; HR, hazard ratio; ICU, intensive care unit; SKIN, surfaces, keep the patients turning, incontinence management, nutrition.</p>	

Recent and ongoing studies

- [Effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention](#). ClinicalTrials.gov identifier: NCT02295735. Status: ongoing, currently recruiting.

Comparators: Mepilex Border Sacrum and Mepilex Border Heel. Estimated primary completion: December 2017. Location: Germany.

- [Pressure injury prevention in the ICU with multi-layer foam dressings](#). ClinicalTrials.gov identifier: NCT02962882. Status: ongoing, currently recruiting. Estimated primary completion date: December 2016. Location: US.

Specialist commentator comments

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

Two specialist commentators were familiar with or had used Mepilex Border before.

Level of innovation

One specialist commentator considered the dressings to be only a minor addition to current practice, whereas 2 considered that they were novel as a tool for preventing pressure ulcers. One of the specialist commentators who considered Mepilex Border to be novel noted that they use it in patients with sensory and motor deficits, where it is better received, and an improvement on current technologies. The other considered it innovative because it can be applied to high-risk patients as soon as they enter critical care to prevent damage such as shear, moisture or friction, and can be peeled back to inspect the skin underneath.

Potential patient impact

The specialist commentators considered that Mepilex Border dressings would have an incremental benefit in reducing pressure ulcers. One was unsure whether it would affect pressure and shear within deep tissue layers close to bony prominences. They felt that, other multilayer dressings could also be effective. The commentators identified several groups of people who would most benefit from the technology, including people who can't move, people with sensory and cognitive impairment, people who are critically ill, people who have had major surgery and people who are frequently moved. One commentator stated that there have been no pressure ulcers in their practice since the introduction of Mepilex Border dressings. They also felt that patient compliance is better with Mepilex Border than other dressings. Another specialist commentator stated that they had seen less shear and friction injuries resulting in less damage to skin since using the dressing to prevent pressure ulcers.

Potential system impact

All commentators identified reduction in pressure ulcers, shear, friction, moisture-related injuries and hospital length of stay as potential system benefits. Two specialist commentators considered that Mepilex Border dressings would save costs through reducing the incidence of pressure ulcers, and 1 thought it would add to system costs but not significantly.

Specialist commentators

The following clinicians contributed to this briefing:

- Professor Michael Clark, commercial director, Welsh Wound Innovation Centre. Professor Clark is a consultant to multiple wound care companies. Between 2011 and 2014, they co-chaired an advisory board for Mölnlycke Health Care on use of dressings in pressure ulcer prevention.
- Elaine Thorpe, Matron, University College London Hospitals. No relevant conflicts of interest.
- Carol Johnson, clinical matron for tissue viability, County Durham and Darlington NHS Foundation Trust. No relevant conflicts 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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