NICE National Institute for Health and Care Excellence

NICE guidance

# Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

Medical technologies guidance
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# Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# Contents

This guidance replaces MIB124.

# 1 Recommendations

1.1 Mepilex Border Heel and Sacrum dressings show promise for preventing pressure ulcers in people who are considered to be at risk in acute care settings. However, there is currently insufficient evidence to support the case for routine adoption in the NHS.

1.2 Research is recommended to address uncertainties about the claimed benefits of using Mepilex Border Heel and Sacrum dressings. This research should also explore issues such as:

- the incidence of heel and sacrum pressure ulcers in NHS acute care settings
- criteria for patient selection to reduce pressure ulcer incidence with Mepilex Border Heel and Sacrum dressings in addition to standard care.

NICE will consider reviewing this guidance when substantive new evidence becomes available.

**Why the committee made these recommendations**

Standard care to prevent pressure ulcers in acute care settings includes risk assessment, skin assessment, regular repositioning and the use of special devices.

Pressure ulcers are most common on the heel and sacrum. Mepilex Border Heel and Mepilex Border Sacrum dressings are designed to prevent pressure ulcers in these areas by reducing pressure, friction, shear and humidity.

There is limited evidence for the clinical effectiveness of Mepilex Border Heel dressings compared with standard care. Evidence from clinical trials suggests that Mepilex Border Sacrum dressings may reduce the incidence of pressure ulcers but it is unclear if the results are generalisable to patients in NHS acute care settings. On the basis of the published evidence and expert advice it is uncertain how patients might be selected for Mepilex Border dressings for the potential clinical benefits to be realised.

Cost modelling shows that Mepilex Border dressings may be cost saving when used with standard care, but the savings are difficult to estimate because of limitations in the evidence and uncertainty about the incidence of pressure ulcers in NHS acute care settings. The incidence rate is likely to fall over time as a result of improvements in preventative care but it will still vary across NHS trusts and it may be affected by proposed changes to the reporting arrangements.

Because of these uncertainties the case for routinely adopting Mepilex Border dressings is not supported, but further research to reduce the clinical and cost uncertainties would be helpful.

# 2 The technology

| Mepilex Border Heel and Mepilex Border Sacrum dressings (Mölnlycke Health Care) | |
|---|---|
| **Overview** | Mepilex Border dressings are self-adherent, 5-layer foam dressings that include a patented soft silicone technology (known as Safetac).<br>They are intended for use as part of a care bundle to prevent pressure ulcers in patients at risk of developing pressure ulcers. The current standard of care, and relevant comparators, are described in the NICE Pathway on pressure ulcers.<br>The company claims that the dressings reduce shear and friction and displace pressure.<br>Mepilex Border dressings are available in 3 variants: for use on the heel and sacrum (Mepilex Border Heel and Mepilex Border Sacrum), or as standard dressings (Mepilex Border) for use on any part of the body.<br>This guidance specifically considers the variants designed to prevent pressure ulcers of the heel and sacrum (Mepilex Border Heel and Mepilex Border Sacrum). |
| **Innovative aspects** | The proprietary Safetac technology allows the dressings to be easily removed and reapplied. The dressings also have a non-woven redistribution layer designed to lessen the effect of shear forces. |
| **Costs** | The costs stated in the company's submission are £6.47 to £7.21 for Mepilex Border Heel and £3.06 to £7.26 for Mepilex Border Sacrum, depending on size. |
| For more details, see the website for Mepilex Border Heel and Sacrum dressings. | |

# 3 Evidence

## Clinical evidence

### Relevant evidence comes from 13 studies, 4 of which are randomised controlled trials

3.1 Of the studies that met the inclusion criteria defined in the scope, 4 were randomised controlled trials (n=1,344) and 9 were non-randomised comparative observational studies (n=1,767). The 4 randomised controlled trials were based on the prevention of sacral pressure ulcers in adults, and none was done in the UK. For full details of the clinical evidence, see section 3 of the assessment report.

### Results of the randomised controlled trials are mixed

3.2 The 4 randomised controlled trials (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a and Walker et al. 2017) compared Mepilex Border Sacrum with standard care in adults at risk of developing pressure ulcers in intensive care units in Singapore, the US and Australia. The external assessment centre (EAC) considered these studies to have acceptable internal and external validity and to provide relevant evidence for the use of Mepilex Border Sacrum. Pooled treatment effect estimates from the fixed-effect meta-analysis of the 3 studies that reported pressure ulcer incidence rates as the number of patients with a pressure ulcer showed a non-significant relative risk (RR) in favour of Mepilex Border Sacrum (RR 0.51, 95% confidence interval [CI] 0.22 to 1.18; p=0.12). Based on the assumption of 1 pressure ulcer per patient in Santamaria (2015a), pooled treatment effect estimates from a fixed-effect meta-analysis of the 4 studies showed a significant relative risk in favour of Mepilex Border Sacrum (RR 0.42, 95% CI 0.20 to 0.86; p=0.02). However, a random-effects meta-analysis of the 4 studies showed a non- significant relative risk with Mepilex Border Sacrum (RR 0.45, 95% CI 0.20 to 1.04; p=0.06).

## Evidence from most observational studies is low quality and less relevant

3.3 The EAC considered 3 of the 9 observational studies (Park 2014, Richard-Denis et al. 2017a and Santamaria et al. 2015b) to have acceptable levels of both internal and external validity. However, the observational studies overall had lower internal and external validity compared with the randomised controlled trials, because of unacceptable cohort recruitment, inconsistencies in describing procedures and measurements, and unclear presentation and precision of results. Because of this, the EAC concluded that the evidence from the 9 observational studies was less relevant to the decision problem.

## There is less evidence for Mepilex Border Heel

3.4 The EAC noted that the clinical effectiveness of Mepilex Border Heel is uncertain because of the limited comparative evidence. Only 2 observational studies assessing the heel dressing were identified (Haisley et al. 2015 and Santamaria et al. 2015b), and only the Santamaria study had acceptable levels of internal and external validity. This study (n=412) showed a significant difference in the proportion of patients who developed a pressure ulcer, in favour of Mepilex Border Heel (p=<0.001).

# Cost evidence

## The company's cost model shows that the use of Mepilex Border dressings is cost saving

3.5 The company's economic evidence was a cost model comparing standard care for preventing pressure ulcers with standard care and the use of Mepilex Border dressings. The time horizon was less than 1 year. The model was a single-level decision tree comprising health states for 2 possible outcomes, specifically whether or not a patient develops a pressure ulcer. The model assumed that:

- standard care and reductions in pressure ulcer incidence rates were generalisable from Santamaria et al. (2015a) to NHS practice
- resource use was generalisable from Santamaria et al. (2015a) to NHS practice
- the cost of pressure ulcer management in the UK is known and the estimates are reliable
- the costs of implementation and managing adverse events are negligible
- the treatment effect is comparable across different types of Mepilex Border dressing.

The EAC agreed that the structure of the model accurately depicts the patient pathway and any possible changes that may result from the use of Mepilex Border dressings, but it considered that some of the values of the parameters used to populate the model were inappropriate. The company's model showed that using Mepilex Border Heel and Sacrum dressings results in a cost saving of £177 per patient. For full details of the cost evidence, see section 4 of the assessment report.

## The EAC's changes to the cost model parameter values make Mepilex Border dressings less cost saving

3.6 The EAC identified limitations in some of the parameter values in the company's model and made changes to better reflect NHS costs, including:

- Applying baseline incidence rates of pressure ulcers from UK sources.
- Calculating the cost of pressure ulcer treatment by appropriately weighting treatment cost for different pressure ulcer stages using UK sources.
- Updating the number of dressing changes and the cost of nursing time.

Clinical-effectiveness estimates in the EAC's model were informed by the pooled treatment effect in the meta-analysis of the 3 randomised controlled trials. These changes to the model decreased the cost savings associated with Mepilex Border Heel and Sacrum dressings to £19 per patient. For full details of the changes, see section 4 of the assessment report.

# 4 Committee discussion

## Clinical effectiveness

### The effectiveness of Mepilex Border dressings is uncertain

4.1 Having considered the various meta-analyses done by the EAC, the committee preferred the meta-analysis of the 3 randomised controlled trials and concluded that any benefit provided by Mepilex Border Sacrum in preventing sacral pressure ulcers was of borderline statistical significance. The committee also noted that there was limited robust evidence on the clinical effectiveness of Mepilex Border Heel; indeed, only 1 observational study reported positive results for the Mepilex Border dressing. The committee concluded that Mepilex Border Sacrum is at best marginally effective, and that the effectiveness of Mepilex Border Heel remains uncertain.

### Pressure ulcer incidence rates in the NHS may be lower than those in the published evidence

4.2 The incidence of pressure ulcers with standard care is an important factor in determining the potential of Mepilex Border dressings. The clinical experts highlighted that there is variation in reported pressure ulcer incidence rates across the NHS; this is likely because of variation in how best practice to prevent pressure ulcers is implemented. However, they explained that preventing pressure ulcers is a priority for all NHS trusts and the incidence of pressure ulcers seems to be reducing through the widespread use of standard bundles of care. The EAC provided estimates of pressure ulcer prevalence from NHS safety thermometer data, but the committee concluded that there remains uncertainty because of the failure to capture grade 1 pressure ulcers and the voluntary nature of data submission. Proposed changes to reporting measures will also affect the future reported incidence rates and hopefully improve the consistency and completeness of the data. Based on the available data, the committee concluded that the proportion of

patients at risk of developing a new heel or sacral pressure ulcer in an acute care NHS setting is likely to be close to 3.8% (as estimated by the EAC), but that this is likely to decrease over time.

### It is unclear if the evidence is generalisable to the NHS

4.3 All 4 randomised controlled trials were done outside the UK. The clinical experts explained that because of international guidelines on preventing pressure ulcers, overall standards of care are likely to be relatively consistent across different countries. Nonetheless, there may still be differences in terms of patient selection, length of hospital stay, staff ratios and the exact composition of care bundles. The committee noted the relatively high baseline incidence rate of pressure ulcers in the control arm of the trials compared with the EAC's estimate for the incidence in the NHS. It also noted that any benefits associated with Mepilex Border dressings observed in the trial were based on a small absolute number of pressure ulcer events. Moreover, the committee was aware that assessing and grading heel and sacral pressure ulcers is subjective, and the clinical experts confirmed that this often depends on individual staff experience. Healthcare professionals will often seek a second opinion to avoid the consequence of incorrect grading, and the availability of specialist tissue viability nurses across the NHS varies. The clinical experts confirmed that NHS acute care settings include a broad range of patients at risk of pressure ulcers, and that staff across different clinical areas will have different levels of expertise in preventing and recognising early evidence of pressure ulcers. Having considered these factors, the committee concluded that there were uncertainties about the generalisability of the evidence to NHS practice.

## NHS considerations

### Healthcare professionals should use the appropriate dressing for the specific location of the pressure ulcer

4.4 The clinical experts explained that little training is needed to be able to apply Mepilex Border dressings. Some clinical experts noted that because of the cost of the specific Mepilex Border Sacrum and Heel

variants, the less costly standard rectangular Mepilex Border dressings are sometimes used and instead cut to the appropriate shape. However, this may limit the effectiveness of the dressings and mean that they need to be changed more often. The committee noted that this improvised use is not included in the manufacturer's instructions for use. It concluded that healthcare professionals should use the appropriate dressing for the specific location of the pressure ulcer.

### Further research would help to inform patient selection

4.5 The clinical experts agreed that not all patients in acute care should have Mepilex Border dressings, but they described uncertainty in terms of best patient selection. They explained that it has not yet been determined how to identify patients for whom Mepilex Border dressings would be most suitable. The committee agreed that the evidence available does not allow for accurate patient selection and that further research would be helpful in this regard. The committee also noted that evidence was generated in other settings which are not covered by the scope of this evaluation.

## Cost modelling

### The EAC's updated model is more plausible than the company's model but uncertainties remain

4.6 The committee accepted the EAC's changes to the company's cost model (see section 3.6), and considered that the revised parameters better reflected costs and resource use in an NHS acute care setting. However, it noted that uncertainties remained with regard to important factors such as the incidence of pressure ulcers and how often dressings needed to be changed. The committee concluded that the cost consequences associated with Mepilex Border Heel and Sacrum were uncertain and that further research would help to inform more accurate cost modelling.

### Pressure ulcer incidence rates and frequency of dressing changes

### are uncertain and vary across settings

4.7 Cost savings in the updated model were mainly driven by the incidence of pressure ulcers in the standard care arm and the frequency of dressing changes. The committee recalled that pressure ulcer incidence rates may be lower in the NHS than those used in the model (see section 4.2). The committee also understood that according to the instructions for use, Mepilex Border Heel and Sacrum dressings should be changed every 3 days. However, the clinical experts explained that in certain patient groups, such as people with faecal or urinary incontinence, the dressings may need to be changed more often. The committee concluded that resource use data from clinical practice would help to inform more accurate cost modelling.

## Cost savings

### Mepilex Border Heel and Sacrum dressings may be cost saving compared with standard care

4.8 The EAC's updated cost model reported that compared with standard care, using Mepilex Border Heel and Sacrum may save around £19 per patient. However, the committee concluded that any proposed cost savings should be interpreted with caution because of the uncertainties in the cost modelling (see section 4.7).

## Further research

### Mepilex Border dressings show promise and further research would help to address the uncertainties

4.9 The committee concluded that Mepilex Border Heel and Sacrum dressings show promise, and that further research should be done to help resolve the uncertainties about clinical effectiveness and cost modelling. This research should also evaluate the incidence of pressure ulcers in patients at risk or high risk of pressure ulcers in an acute care setting, despite having standard care to prevent pressure ulcers. The

research should explore any benefits that Mepilex Border dressings may offer in addition to standard care for preventing heel and sacral pressure ulcers. Data from this research, combined with data from use of dressings in clinical practice, should allow conclusions to be drawn about which patients will benefit most, as well as practical considerations such as how often the dressings should be changed.

# 5 Committee members and NICE project team

## Committee members

This topic was considered by the medical technology advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

## NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

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# Accreditation