NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

1 Technology

1.1 Description of the technology

Mepilex Border dressings (Mölnlycke Health Care) are self-adherent, multilayer foam dressings originally designed for use on a wide range of wound types. This evaluation focuses on the Mepilex Border Heel and Mepilex Border Sacrum dressings, which may be used in the prevention of pressure ulcers at the heel and sacrum.

Mepilex Border dressings are made up of five layers. The soft silicon layer closest to the skin includes a proprietary technology called Safetac, designed to reduce friction between the skin and the dressing itself and to allow easy peel back and reapplication of the dressing. The other 4 layers are variously designed to displace pressure forces, cushion, reduce shear and friction forces, absorb moisture and allow moisture to evaporate.

Mepilex Border Sacrum dressing is available in 3 sizes and Mepilex Border Heel is available in one size.

1.2 Regulatory status

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

1.3 Claimed benefits

The benefits to patients in acute care settings from the addition of the Mepilex Border dressings to standard care claimed by the company are:

- A reduction in the occurrence of pressure ulcers
- A reduction in the length of stay in hospital
- Reduced pain and discomfort

The benefits to the healthcare system from the addition of the Mepilex Border dressings to standard care in acute care settings claimed by the company are:

- Reduced costs associated with pressure ulcer treatment, nursing costs and hospitalization costs.
- Reduced risk of incurring financial penalties
- Reduced risk of legal action

1.4 Relevant diseases and conditions

Mepilex Border Heel and Sacrum dressings are intended for use in patients considered to be at risk of pressure ulcers. This assessment considers the use of these dressings in acute care settings.

Pressure ulcers are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on an area of the skin which is capable of impairing the skin's blood supply.

All patients in acute care settings are potentially at risk of developing a pressure ulcer. Older people aged 70 years and over are particularly vulnerable to pressure ulcers, because they are more likely to have mobility problems and ageing skin.

The NICE guideline on pressure ulcers: prevention and management notes that adults considered to be 'at high risk' of developing pressure ulcers will usually have multiple risk factors (such as significantly limited mobility, nutritional deficiency, inability to reposition themselves, and significant cognitive impairment) identified during risk assessment with or without a

validated scale. Also considered to be at high risk are patients who have a history of pressure ulcers or those who already have a pressure ulcer.

An NHS Safety Thermometer report states that from April 2014 to the end of March 2015, just under 25,000 patients developed a new pressure ulcer within the NHS in England. It is estimated that just under half a million people in the UK will develop at least one pressure ulcer in any given year. Measures to avoid the development of pressure ulcers are projected to reduce their incidence by approximately 50%.

1.5 Current management

The NICE guideline on pressure ulcers: prevention and management recommends that a documented risk assessment for pressure ulcers be done in adults admitted to secondary care or adults with defined risk factors receiving care in other settings. It recommends using a validated scale to support clinical decision-making, and proposes that risk be reassessed if there is a change in the patient's clinical circumstances.

Strategies recommended by the guideline for preventing pressure ulcers in adults assessed as being at risk, include a combination of regular repositioning and pressure redistribution using high specification foam mattresses or pressure redistributing cushions. The guideline also makes related recommendations specifically tailored at neonates, infants, children and young people at risk of developing a pressure ulcer. This includes skin assessment, repositioning, pressure redistribution, information and use of barrier creams. People considered to be at high risk receive similar individualised care including strategies to offload heel pressure where necessary.

NICE medical technology guidance on Parafricta Bootees and Undergarments states further research is needed before they can be recommended for routine adoption, although they show potential to reduce the development and progression of skin damage in people with, or at risk of, pressure ulcers.

There are numerous dressings available for the treatment of pressure ulcers, but they are not usually intended for or used in their prevention. This is because most dressings are not widely considered to be able to influence the effects of pressure or shear forces. The company claims that Mepilex Border dressings can impact both pressure and shear forces.

The adoption scoping report notes that, in some cases, clinicians use standard shape Mepilex dressings (Mepilex Border and Mepilex Border Lite) with Safetac, alongside standard care for the prevention and treatment of pressure ulcers at bony spines and heels in patients considered to be at high risk. Standard shaped Mepilex dressings are less costly and may require cutting to shape depending on the patient, they also tend to wrinkle at the borders, thereby posing a problem during reapplication after skin assessment. The adoption scoping report further notes that the shape and design of Mepilex Border Heel makes it less likely to wrinkle at the borders. It is however, uncertain if the available sizes of Mepilex Heel and Sacrum dressings will be suitable for all patients.

2 Statement of the decision problem

	Scope issued by NICE
Population	Patients at risk or at high risk of pressure ulcers in acute care settings.
Intervention	Mepilex Border Heel dressing or Mepilex Border Sacrum dressing or both dressings used as an adjunct to standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers.
Comparator(s)	Standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers. This may involve a combination of: • Risk assessment with a validated scale • Skin assessment • Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) • Pressure redistribution using devices such as high-specification foam mattress or pressure redistributing cushions. • Other dressings or skin applications to prevent pressure ulcers • Information • Barrier cream (specified situations)
Outcomes	The outcome measures to consider include: • Incidence of developing pressure ulcers • Incidence of skin breakdown at the heel and sacrum • Stage of pressure ulcer developed (stage I – IV, unstageable) • Level of patient satisfaction • Additional length of hospital stay as a result of pressure ulcers including ICU and conventional ward bed days. • Patient compliance with pressure ulcer prevention strategies • Level of pain and discomfort and impact on quality of life. • Complications avoided from pressure ulcer prevention e.g. Infection, abscess, septicaemia, bone infections, meningitis. • Ease of use of product • Device related adverse events

Cost analysis	Comparator(s): Standard of care (as listed in comparators) Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	None	
Special considerations, including those related to equality	The device is likely to be beneficial to diabetic patients who may be at an increased risk of foot ulcers, patients who have had spinal injuries and people with restricted mobility. These groups of patients may be considered disabled if their condition has a long term and substantial effect on their daily life. Disability is a protected characteristic covered by the Equality Act 2010.	
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE guidance

Published

- NICE clinical guideline 179 (2014) Pressure ulcers: prevention and management
- NICE guideline 19 (2015, updated 2016) Diabetic foot problems: prevention and management

Under development

None.

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations invited to participate in the evaluation

The following professional organisation and societies have been invited to register as stakeholders:

- Association of Surgeons in Primary Care
- British Association of Dermatologists
- British Dermatological Nursing Group (BDNG)
- British Geriatrics Society
- British Medical Ultrasound Society
- British Orthopaedic Association
- British Orthopaedic Foot and Ankle Society
- British Skin Foundation
- British Society for Dermatological Surgery
- Diabetes UK
- European Wound Management Association
- Intensive Care Society
- Pressure Ulcer Research Service User Network (PURSUN)
- Paediatric Intensive Care Society

- Primary Care Diabetes Society
- Primary Dermatology Society (PCDS)
- Royal College of Emergency Medicine
- Royal College of General Practitioners (RCGP)
- Royal College of Nursing (RCN)
- Royal College of Physicians (RCP)
- Scottish Intensive Care Society
- Society for Acute Medicine
- Society of Chiropodists & Podiatrists (Feet for Life)
- Society of Vascular Nurses
- Society of Vascular Technology for Great Britain and Ireland (SVT)
- Southern Alliance of Tissue Viability Nurses
- Surgical Dressing Manufacturers Association
- The Vascular Society
- Tissue Viability Society
- UK Oncology Nursing Society
- Welsh Wound Network
- Wound Care Alliance UK

4.2 Patient organisations

NICE's Public Involvement Programme have contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Action Cerebral Palsy
- Action for Elder abuse
- Age Related Diseases and Health Trust
- Age UK
- Bladder and Bowel UK
- Brain and Spinal Injury Charity (BASIC)
- Brain and Spine Foundation (UK)
- British Obesity Surgery Patients Association (BOSPA)
- Critical Care Patient Liaison Committee (CritPaL)

- Cure Parkinsons Trust, The
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Foot in Diabetes UK (FDUK)
- Hoop UK
- ICU Steps
- Independent Age
- Independent Diabetes Trust
- Juvenile Diabetes Research Foundation (JDRF)
- Leg Ulcer Charity
- Lindsay Leg Club Foundation
- Multiple Sclerosis Society (MS Society)
- Multiple Sclerosis Trust
- Multiple Sclerosis-UK
- National Obesity Forum (NOF)
- National Tremor Foundation (NTF)
- Parkinson’s UK
- Pressure Ulcers UK
- Spinal Injuries Association
- The Circulation Foundation
- The Relatives and Residents Association
- Trauma Care
- Vascular Society of Great Britain and Ireland
- Wound Care 4 Heroes