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1. PRODUCT DESCRIPTION

The Heel dressing is a sterile, non-adhesive hydrocellular heel dressing which consists of the following:

- a polyurethane foam wound contact surface with high absorption capacity
- a vapour permeable, water and bacteria resistant polyurethane film outer layer.

Heel dressings maintain a moist wound environment to enhance the natural healing conditions.

2. INTENDED PURPOSE

Long term, non-invasive wound dressings intended principally for the management of moderately to heavily exuding, partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent.

2.1 INTENDED POPULATION

Individuals of all ages who are at risk of developing

- stage I – IV pressure ulcers
- surgical incisions
- first and second degree burns

2.2 INTENDED USER

Intended for use by a health professional, and may be used in a community or hospital setting.

3. INDICATIONS

Heel dressing may be used for the management of moderately to heavily exuding, partial to full thickness wounds on the heel, such as


- stage I – IV pressure ulcers
- surgical incisions
- first and second degree burns

Heel dressing may also be used as an aid for the prevention of skin breakdown on the heel.

4. CONTRAINDICATIONS/SAFETY INFORMATION

Heel dressing is contraindicated for

- ulcers resulting from infections, such as tuberculosis, syphilis, deep fungal infections
- bites or third degree burns
- dry wound conditions

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In case of infection with inflammatory signs (temperature, oedema, redness, pain), contact proper medical authority. Resume use of Heel dressing when normal healing conditions are present again.

5. WARNINGS



Do not use if pouch is damaged or opened.



Do not re-use. Re-use of single-use devices creates a potential risk to the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

6. INFORMATION FOR USE

Heel dressing is very simple to apply, requiring no special skills or equipment. The interval between dressing changes will depend entirely upon the state of the wound. On heavily exuding wounds, daily changes may be required at the beginning of treatment but this may be reduced to every 2 to 3 days for low exuding or epithelialising wounds.

6.1 Preparation

- a) Visually inspect the product pouch for damage prior to use.
- b) Cleanse the wound with sterile saline or Ringer solution and sterile swabs.
- c) Dry the skin surrounding the wound.

6.2 Dressing Application


Remove the sterile wound dressing from the pouch using local guidelines & best practices for handling sterile wound dressings. Apply Heel dressing to the wound. Heel dressing may be held in place using an appropriate secondary dressing, e.g. a fixation or compression bandage. Adhesive tape may also be used, but care must be taken not to injure fragile skin on its removal.

6.3 Dressing Changes

You should replace dressing if it becomes soiled, saturated or if exudate/drainage is observed or adhesion is compromised. Otherwise, replace dressing per established facility protocol.

Where leakage occurs the dressing should be changed immediately.

- a) Gently remove Heel as could be painful
- b) Follow procedure 5.1 to 5.2 to apply a new dressing.

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7. CLINICAL BENEFIT / SPECIAL NOTES

The wound may initially appear to increase in size in the early stages of Heel dressing treatment. This is normal and occurs as any wound debris is removed from the edges of the wound. This clears the way for healing.

In the management of moderately to heavily exuding wounds, Heel Dressing can only make the overlying environment more conducive to healing. There are cases where healing is impaired as a result of underlying conditions; in these instances, Heel dressing alone may make little or no progress, and suitable treatment of the underlying conditions will be necessary as well. Therefore, if after 4-6 weeks of Heel Dressing treatment, there has been no improvement then, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed with a healthcare professional.

Heel dressing should be left in place as long as possible in order to prevent trauma to the fragile newly formed tissue and to reduce cross contamination through frequent dressing changes.

Thick necroses should be removed before applying Heel dressing.








8. STORAGE


Store dressings at ambient temperature and humidity, away from direct sunlight.

9. DISPOSAL

The foam dressings can be disposed based on the hospital or healthcare professional advice.

10. SYMBOLS ON LABELLING

WARNINGS	
	Do not use if the pouch is damaged or opened.
	Medical Device
	Sterile Barrier System/ Sterile Packing
STERILISATION	
  	
STORAGE	
	

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11. PRESENTATION

Heel dressing is only available in one size. This size had been chosen to allow the majority of heel wounds to be managed appropriately.

12. COMPLAINTS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For complaints, questions or comments, contact Avery Dennison Medical Customer Support at phone +353 43 3349586.





Avery Dennison Medical Ltd.
IDA Business Park, Ballinalee Road
Longford, N39 DX73. Ireland
phone +353 43 3349586
fax +353 43 3349566

Made in Ireland

13. REVISION HISTORY

Revision	Change History	Date
04	MDR Update	02/10/2020

14. APPROVAL

Review and Approval	
<u>Name and Title</u>	<u>Signature and Date</u>
Elaine Minagh Regulatory Affairs Manager	 01/10/2020
Emmett McArdle R&D Manager	 02/10/2020