AVERY DENNISON	**Title**	**Instructions for Use Hydrogel**
	Revision	**E**
	Infocard Number	**LFD-PKG-000075**

1. PRODUCT DESCRIPTION

Hydrogel is a clear, viscous, sterile gel containing a modified starch polymer, glycerol, preservatives and water.

Hydrogel maintains a moist wound healing environment conducive to healing.

Depending on wound conditions, Hydrogel rehydrates dry necrotic tissue, to promote debridement in dry wounds, or absorbs wound slough and exudate where a small amount of exudate is present.

Hydrogel can be washed away by irrigating the wound with sterile saline; this produces little or no trauma to the wound, and so results in improved wound healing and pain-free Hydrogel changes.

2. INTENDED PURPOSE

The Hydrogel can be used for prolonged use, as a non-invasive wound dressings intended principally for the management of most types of ulcers, pressure sores and other low exuding sloughy or necrotic wounds.

2.1 INTENDED POPULATION

Individuals with the following wounds:

- Pressure ulcers
- Venous leg ulcers
- Diabetic foot ulcers
- First and second degree burns

2.2 INTENDED USER

Intended for use by health professionals and may be used in a hospital.

3. INDICATIONS

Hydrogel is indicated for the management of dry non-exuding wounds and also low exuding, partial thickness wounds, such as

- pressure ulcers
- venous leg ulcers
- diabetic foot ulcers
- first and second degree burns
- Incontinence Dermatitis

4. CONTRAINDICATIONS/SAFETY INFORMATION

Hydrogel is contraindicated for

- ulcers resulting from infections, such as tuberculosis, syphilis, deep fungal infections
- third degree burns
- heavily exuding wounds,
- patients with known sensitivity to the Hydrogel, or one of its components.
- babies under 12 weeks old.
- Do not use on areas where contact with the eyes is possible.

In case of infection with inflammatory signs (temperature, oedema, redness, pain), contact a doctor.

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5. WARNINGS

Do not use if packaging 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. Product is not suitable for re-sterilisation. For external use only and should not be used internally.

6. INFORMATION FOR USE

Hydrogel is applied by first removing the lid. This may be a 'snap-off' or a screw lid, exposing the applicator nozzle then squeezing the tube and applying Hydrogel directly to the wound area.
The interval between dressing changes will depend entirely upon the state of the wound. On exuding wounds, daily changes may be required at the beginning of treatment but this may be reduced to every 2 to 3 days for dry wounds after assessment by a suitably qualified healthcare professional.

6.1 Preparation

a) Visually inspect the tube for damage prior to opening.
b) Cleanse the wound with sterile saline or other suitable sterile cleaning solution with sterile swabs.
c) Dry the skin surrounding the wound.

6.2 Hydrogel Application

a) Remove a sterile Hydrogel tube from the unit box using local guidelines & best practices for handling sterile wound dressings. Inspect tube to ensure no damage or leaking Hydrogel.
b) Select the appropriate Hydrogel size that will completely cover the wound surface, 'snap-off'' the applicator nozzle cap or unscrew lid depending on product configuration.
c) Wipe tip of nozzle with proprietary alcohol wipe.
d) Keeping the nozzle clear of the wound surface, gently squeeze the tube, and apply Hydrogel to the whole wound, to a depth of at least 5mm.
e) Cover the wound with a suitable secondary dressing, compression therapy may be used in conjunction with Hydrogel treatment, when so directed by a physician.
f) Hydrogel tubes are indicated for single use. Discard the tube with any unused Hydrogel after first use.
g) To minimize the risk of potential infection hazards or environmental pollution, disposable components of Hydrogel should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

6.3 Dressing Change

Replace the secondary dressing if it becomes soiled, saturated or if exudate/drainage is observed. Otherwise, replace the dressing per established facility protocol.

a) Gently remove Hydrogel via irrigation using suitable sterile solution.
b) Follow procedure 6.2 to apply a new dressing.

7. CLINICAL BENEFIT

The wound may initially appear to increase in size in the early stages of treatment with Hydrogel wound dressing. 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 dry and low exuding wounds Hydrogel can only make the overlying environment more conducive to healing. Instances where Hydrogel treatment alone may make little or no progress, suitable treatment of the underlying conditions will be necessary as well. Therefore, if after 4-6 weeks of Hydrogel 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.

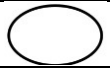
8. STORAGE

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

9. DISPOSAL

To minimize the risk of potential infection hazards or environmental pollution, disposable components of Hydrogel should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

10. SYMBOLS ON LABELLING

WARNINGS	
	Do not use if the product sterile barrier system or its packaging is compromised
	Medical Device
	Single Sterile Barrier System
STERILISATION	
	Method of sterilisation using irradiation
	Do not re-use
	Do not resterilise
STORAGE	

	Keep away from direct sunlight
	Keep dry

11. PRESENTATION

Hydrogel is available in the following packaging configurations:

Description	Sizes	Units/Box	Article Number
Hydrogel	8g	5	ML250P080S05
Hydrogel	8g	10	ML250P080S10
Hydrogel (snap-off lid)	15g	10	ML2502P0150S10
Hydrogel (screw lid)	15g	10	ML250P0150S10

12. COMPLAINTS

For a patient/user/third party in the European Union and in countries with a similar regulatory system (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority,

For complaints, questions or comments, contact Avery Dennison Medical Customer Support at phone +353 43 334 9586.

CE 2797 UKCA 0086

Avery Dennison Medical Ltd.
IDA Business Park, Ballinalee Road
Longford, N39 DX73. Ireland.

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 e-IFU is made available on the Avery Dennison Medical website at:
https://medical.averydennison.com/en/home/products/finished-goods/eIFUs.html

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13. REVISION HISTORY

Revision	Change History	Originator	Date
A	Initial Revision	D Casey	04/03/2021
B	Remove references to arterial ulcers in IFU and addition of date and PKG number to IFU body	D Casey	10/09/2021
C	Update document to refer to Hydrogel consistently throughout document. Replace 'moderately' and 'light exuding wounds' with 'low exuding' so document is consistent and accurate. Update section 6.3, section 4 and section 5 following feedback from Regulatory. Update date of issue and revision of document. Addition of e-IFU access information.	D Casey	04/02/2022
D	Section 11 updated table to include Description and Article numbers, Section 2.2 remove community and home setting from intended users	P Slattery	21 Apr 2022
E	Add UKCA symbol	P Slattery	22 Oct 2024