



	<b>Title</b>	<b>Instructions for use Hydrosorb Gel</b>	
	<b>Revision</b>	<b>F</b>	
	<b>Infocard number</b>	<b>LFD-PKG-000229</b>	

### 1. PRODUCT DESCRIPTION

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

Hydrosorb Gel maintains a moist wound healing environment conducive to healing.

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

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

### 2. INTENDED PURPOSE

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

#### 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 hospital.

### 3. INDICATIONS

Hydrosorb Gel 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

Hydrosorb Gel is contraindicated for:

- ulcers resulting from infections, such as tuberculosis, syphilis, deep fungal infections
- third degree burns
- heavily exuding wounds
- patients with a known sensitivity to Hydrosorb Gel, or one of its components
- babies under 12 weeks old
- on or in areas where contact with the eyes is possible

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



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## 5. WARNINGS



Do not use if the 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. The product is not suitable for re-sterilisation. For external use only and should not be used internally.

## 6. INFORMATION FOR USE

How to apply Hydrosorb Gel: remove the snap-off cap, exposing the applicator nozzle, then squeeze the tube and apply Hydrosorb Gel 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 another suitable sterile cleaning solution with sterile swabs.
- c) Dry the skin surrounding the wound.

### 6.2 Hydrosorb Gel application

- a) Remove a sterile Hydrosorb Gel tube from the unit box using local guidelines and best practices for handling sterile wound products. Inspect the tube to ensure there's no damage or leakage.
- b) Select the appropriate Hydrosorb Gel quantity that will completely cover the wound surface and snap off the applicator nozzle cap.
- c) Wipe the tip of the nozzle with a proprietary alcohol wipe.
- d) Keeping the nozzle clear of the wound surface, gently squeeze the tube and apply Hydrosorb Gel to the whole wound, to a depth of a least 5 mm.
- e) Cover the wound with a suitable secondary dressing, compression therapy may be used in conjunction with Hydrosorb Gel treatment, when so directed by a physician.
- f) Hydrosorb Gel tubes are indicated for single use only. Discard the tube with any unused Hydrosorb Gel after the first use.
- g) To minimise the risk of potential infection hazards or environmental pollution, disposable components of Hydrosorb Gel 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 according to established facility protocol.



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- a) Gently remove Hydrosorb Gel via irrigation using a 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 Hydrosorb Gel wound product. 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, Hydrosorb Gel makes the overlying environment more conducive to healing. However, in instances where Hydrosorb Gel treatment alone offers little or no progress, suitable treatment of the underlying conditions will also be necessary. Therefore, after 4-6 weeks of Hydrosorb Gel treatment, if there has been no improvement, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed with a healthcare professional.

### 8. STORAGE

Store Hydrosorb Gel away from direct sunlight at an ambient temperature and humidity.

### 9. DISPOSAL

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










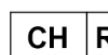


### 10. SYMBOLS ON LABELLING

<b>WARNINGS</b>	
	Consult instructions for use
	Warnings / Cautions
<b>STERILISATION</b>	
	Do not use if the product sterile barrier system or its packaging is compromised
	Single sterile barrier system
	Method of sterilisation using irradiation
	Do not re-use
	Do not re-sterilise
<b>STORAGE</b>	

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	Keep away from sunlight
	Keep dry
<b>GENERAL</b>	
	Medical device
	Catalogue number
	Manufacturer
	Date of manufacture
	Use By
	Batch Code ("Lot Number")
	Unique Device Identifier
	Swiss authorised representative (CH-REP)
	Distributor
	Importer

## 11. PRESENTATION

Hydrosorb Gel is available in the following packaging configurations:

Description	Quantity	Unit box quantity	Product Code
Hydrosorb Gel	8 grams	5 pieces	900831
Hydrosorb Gel	15 grams	10 pieces	900832

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## 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 authorised representative and to your national authority.

For complaints in Switzerland; A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and Swissmedic.

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



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**Made in Ireland**



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		Date
A	Initial Revision	Dearbhla Casey	04/03/2021
B	Remove references to arterial ulcers in IFU and addition of PKG number to IFU body	Dearbhla Casey	10/09/2021
C	Update document to refer to product name, Hydrosorb Gel instead of Hydrogel or gel as per customer request. Update disposal and contraindications to reflect original IFU document (LFD-PKG-000097). Update to keep wording throughout document standard i.e. 'low exuding wound' replacing 'moderately' and 'light exuding wounds'. Update date of issue and revision of document. Addition of e-IFU access information.	Blaithin McAdam	04/01/2022
D	Section 2.2 remove caregivers, community and home setting from intended users. Update section 4 to include 'heavily exuding wounds' and remove 'do not' before a number of the contraindications. Section 11 updated table to include product description and codes. Remove Fax number and replace with Tel number.	Blaithin McAdam	28/04/2022
E	Replace 'doctor' with 'physician' in section 4. Remove number 0 from end of product code in section 11. Addition of 'manufacturer', 'date of manufacture', 'UDI', 'LOT', 'use by', 'catalogue number' and 'consult instructions for use' symbols in section 10. Move 'Do not use if the product sterile barrier system or its packaging is compromised' and 'Single sterile barrier system' from warnings to sterilisation section in section 10. Addition of note in section 12 regarding complaints in Switzerland.	Blaithin McAdam	24/08/2022
F	Update wording from wound 'dressing' to wound 'product' or 'Hydrosorb Gel' throughout the IFU. Update wording from 'size' to 'quantity'. Date of issue updated. Remove 'components of Hydrosorb gel' in section 9 disposal. Addition of following symbols in section 10; Importer, Distributor and CH rep.	Blaithin McAdam	17/08/2023

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14. APPROVAL

<b>Review and approval</b>	
<u><b>Name and title</b></u>	<u><b>Signature and date</b></u>
Blaithin McAdam, R&D Engineer	Will be captured electronically via Mastercontrol
Emmett Mc Ardle, R&D Manager	Will be captured electronically via Mastercontrol
Elaine Minagh, RA Manager	Will be captured electronically via Mastercontrol
Paul Saunders, Marketing Manager	Will be captured electronically via Mastercontrol

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