	Title	Instructions for Use Finsap Super-absorbent	
	Rev	B	
	Technical documentation Number	LFD-PKG-000320	

1.0 PRODUCT DESCRIPTION

FinSap Super-absorbent is a sterile, superabsorbent wound dressing for use on wounds with high to excessive amounts of exudate. The dressing consists of a superabsorbent core, a clear perforated polyethylene wound contact layer, and a hydrophobic backing which together combine to help minimize moisture leakage.

FinSap Super-absorbent absorbs exudate, this reduces the risk of maceration and damage to the periwound while helping maintain a moist wound environment. Fluids are absorbed and retained within the dressing. As a result of its high absorbency FinSap Super-absorbent helps increase dressing change intervals.

The perforated wound contact layer does not adhere to the wound and the non-woven backing layer forms a protective barrier preventing exudate leakage. The dressing is also effective under pressure.

2.0 INTENDED PURPOSE

Long term, non-invasive wound dressings intended principally for the management of high to excessive 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

The intended patient population would consist of those individuals with high to excessive exuding partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent.

2.2 INTENDED USER

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

3.0 INDICATIONS


Finsap Super-absorbent is indicated for chronic or secondary healing wounds with high to excessive exudate levels. Its indicated for the following:

venous leg ulcers, arterial leg ulcers, diabetic foot ulcers and pressure ulcers.

4.0 CONTRAINDICATIONS/SAFETY INFORMATION

The dressing should not be used on dry wounds, low exuding wounds, eyes, mucous membranes or in wound cavities (the dressing swells considerably after fluid absorption).

Do not use the dressing on patients with a known sensitivity to any of the dressing components.

	Title	Instructions for Use Finsap Super-absorbent	
	Rev	B	
	Technical documentation Number		LFD-PKG-000320

5.0 WARNINGS



- Do not use if pouch is opened or damaged.
- Do not cut the dressing. It must remain intact and uncut.
- FinSap Super-absorbent is packaged for single use. Do not re-use or re-sterilize. 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.

6.0 INFORMATION FOR USE

- a) Visually inspect the pouch for damage prior to opening.
- b) FinSap can be used as a primary or secondary dressing
- c) Remove the sterile wound dressing from the pouch using local guidelines & best practices for handling sterile wound dressings.
- d) Clean the wound in accordance with treatment protocol.
Select an appropriate dressing for the wound size, the dressing should overlap the wound by 2-3cm. Apply the perforated polyethylene side of the dressing down, facing towards the wound.
- e) Apply an appropriate dressing fixture should the wound and situation require such.
- f) Change the dressing as necessary, in accordance with facility protocols. At a minimum, dressing should be changed at least every 7 days. Change the dressing more frequently if the site has high levels of exudate or if the dressing integrity has become compromise.

7.0 CLINICAL BENEFIT

FinSap Super-absorbent absorbs exudate, which reduces the risk of maceration and damage to the periwound, while helping maintain a moist wound environment. Fluids are absorbed and retained within the dressing. As a result of its high absorbency, FinSap Super-absorbent helps increase dressing change intervals.


The perforated wound contact layer is effective at wicking fluid and the non-woven backing layer forms a protective barrier preventing exudate leakage. The dressing is also effective under pressure/compression.

8.0 STORAGE











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

9.0 DISPOSAL

To minimize the risk of potential infection hazards or environmental pollution, Finsap should be disposed of following disposal procedures according to applicable local laws, regulations and infection prevention standards.

	Title	Instructions for Use Finsap Super-absorbent	
	Rev	B	
	Technical documentation Number	LFD-PKG-000320	

10. SYMBOLS ON LABELLING

WARNINGS	
	Do not use if the pouch is damaged or opened.
	Medical Device
	Sterile Barrier System/ Sterile Packing
	Unique device identifier
	Distributor
	Country of Manufacture
STERILISATION	
	 
STORAGE	
	

11. PRESENTATION


Finsap Super-absorbent is available in the following sizes:

Cat. No.	Size	No. / Box
8101010	10 x 10cm	10
8102010	10 x 20cm	10
8202010	20 x 20cm	10

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.

	Title	Instructions for Use Finsap Super-absorbent	
	Rev	B	
	Technical documentation Number		LFD-PKG-000320



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



Date of Issue: May 2024

Made in Ireland

13. REVISION HISTORY

Revision	Change History	Date
A	Upload to Master Control	14 Dec 2021
B	Add date of issue Update disposal section Add UDI, country of origin and distributor symbols Remove approval box.	23 May 2024

RELEASE