AVERY DENNISON	Title	**Instructions for Use** **Finsap Super-absorbent**
	Rev	**05**
	Technical documentation Number	**TF024**

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.

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 wide range of wounds including, venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers and similar types of wounds.

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, e.g. venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers and similar types of wounds.

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.

The perforated polyethylene wound contact layer side of the dressing lies against the wound. Before applying the product, make sure that the wound has sufficient amount of exudate. In case of doubt, we recommend combination with a silicone wound contact layer.

5.0 WARNINGS

Do not use if pouch is opened or damaged.

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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

The FinSap Super-absorbent dressings should be disposed of based on the hospital or healthcare professional advice.

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10. SYMBOLS ON LABELLING

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

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CE 2797

Made in Ireland

LFD-PKG-000320 Rev A

13. REVISION HISTORY

Revision	Change History	Date
04	MDR release	
05	Updated to include a guideline around a maximum wear time. Removal of the 20 x 30cm size	27 April 2021

14. APPROVAL

Review and Approval	
Name and Title	**Signature and Date**
Elaine Minagh Regulatory Affairs Manager	27/04/2021
Emmett McArdle R&D Manager	27/04/2021