1. PRODUCT DESCRIPTION

Foam Cavity is a sterile, hydrophilic foam wound dressing with high absorption capacity. In the presence of exudate, Foam Cavity helps maintain a moist wound environment conducive to 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

- Deep cavity wounds
- Sinuses
- Wound tunnels
- Wounds with high exudates levels

2.2 INTENDED USER

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

3. INDICATIONS

Foam Cavity is particularly suited for:

- Deep cavity wounds
- Sinuses
- Wound tunnels
- Wounds with high exudates levels

4. CONTRAINDICATIONS/ SAFETY INFORMATION

Foam Cavity is contraindicated for:

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

In case of infection with inflammatory signs (temperature, oedema, redness, pain), contact proper medical authority. Resume use of Foam Cavity 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

Foam Cavity 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 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

a) Remove the sterile wound dressing from the pouch using local guidelines & best practices for handling sterile wound dressings
b) Insert Foam Cavity directly into the wound cavity. Do not pack the wound tightly.
c) Ensure that sufficient Foam Cavity is used to protrude out of the wound opening.
d) Cover with an appropriate secondary dressing, e.g. a fixation or compression bandage.
e) In case of venous leg ulcers, compression therapy may be used in conjunction with Foam Cavity treatment, when so directed by a physician.

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) Remove outer dressing.
b) Using sterile forceps gently remove the Foam Cavity from the wound.
c) Follow procedure 6.1 a) to 6.2 c) to apply a new dressing.

7 CLINICAL BENEFITS / SPECIAL NOTES

The wound may initially appear to increase in size in the early stages of Foam Cavity 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, Foam Cavity 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, Foam Cavity 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 Foam Cavity 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.

Foam Cavity 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 Foam Cavity.

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	
	

11. PRESENTATION

Foam Cavity is available in the following size:

- 2.5 x 40 cm

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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13. REVISION HISTORY

Revision	Date	Revision History	Originator
4		MDR Release	

14. APPROVAL

Review and Approval	
Name and Title	**Signature and Date**
Elaine Minagh Regulatory Affairs Manager	23/09/2020
Emmett McArdle R&D Manager	30/09/2020