	Title	Instructions for Use	
		Manuka Honey Tulle Dressing	
	Revision	02	
	Technical documentation Number	TF027	

1. PRODUCT DESCRIPTION

Manuka Honey Impregnated Tulle Dressing is a sterile, single-use, non-adherent wound dressing that helps preserve a moist wound environment, supporting the natural wound healing process. Manuka Honey Tulle is a 100% Manuka honey based tulle range. The dressings comes in two knitted tulle thicknesses, heavy and light, and is protected on either side by a polyethylene liner which has a low affinity to the honey. Dressings are presented in a poly film pouch for single use and are supplied sterile. Manuka Honey Tulle Dressing helps preserve a moist wound environment, conducive to the natural wound healing process.

2. INTENDED PURPOSE

Moist wound healing dressings which are intended to come into contact with injured skin and can only heal by secondary intent.

2.1 INTENDED POPULATION

Individuals of all ages who are at risk of developing

- Leg ulcers
- Pressure ulcers
- 1st and 2nd degree burns
- Diabetic foot ulcers
- Surgical wounds
- Trauma wounds
- Superficial wounds as minor abrasions, lacerations, cuts, scratches

2.2 INTENDED USER

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

3. INDICATIONS


Manuka Honey Impregnated Tulle Dressing is a single use dressing for moist wound management and is indicated for the treatment of:

- Leg ulcers
- Pressure ulcers
- 1st and 2nd degree burns
- Diabetic foot ulcers
- Surgical wounds
- Trauma wounds
- Superficial wounds as minor abrasions, lacerations, cuts, scratches

4. CONTRAINDICATIONS/SAFETY INFORMATION

Due to the osmotic action and/or low pH of the dressing, there may be temporary increased pain experienced. Discontinue use of dressing if pain persists and gently irrigate wound with sterile saline solution.

Do not use on individuals who have a known sensitivity to honey / bee venom as may cause an allergic reaction .

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5. WARNINGS



Do not use if pouch is damaged or opened



Do not re-use. Honey Impregnated Tulle is a single use dressing and re-use may lead to infection and cross contamination.



It is advisable to monitor elevated blood sugar levels in patients affected by diabetes.

6. INFORMATION FOR USE

6.1 Preparation

- a) Visually inspect pouch for damage prior to opening.
- b) Cleanse the wound with in accordance with normal procedures
- 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) Remove dressing from pouch and discard protective liners.
- c) Apply dressing to wound with either side facing towards the wound and cover with suitable secondary dressing.
- d) Depending on wound size, Honey Impregnated Tulle Dressing may be cut to size.
- e) For larger wounds, multiple dressings can be placed side by side.
- f) 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

7. CLINICAL BENEFIT


The Manuka Honey Tulle Dressing helps preserve a moist wound environment supporting the natural wound healing process. The acidity of honey increases the release of oxygen from the blood, thereby making the wound environment less favourable for the activity of destructive enzymes that block the wound healing process; secondly, the high sugar content of honey draws fluid out of the wound bed and allows replacement of fresh lymph fluids to take place.

8. STORAGE








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

9. DISPOSAL

The Manuka Honey Tulle 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

Honey Impregnated Tulle Dressing is available in the following sizes:

Article/ REF Number	Description	Size	Units/ Box
LM050510	Light Manuka Honey Tulle Dressing	5x5 cm	10
LM101010	Light Manuka Honey Tulle Dressing	10x10 cm	10
HM050510	Heavy Manuka Honey Tulle Dressing	5x5 cm	10
HM101010	Heavy Manuka Honey Tulle Dressing	10x10 cm	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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13. REVISION HISTORY

Revision	Change History	Date
02	MDR Release	30/09/2020

14. APPROVAL

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