1.0 PRODUCT DESCRIPTION

InterSil is a perforated, low adherence, non-irritating, silicone wound contact layer dressing consisting of a non-woven matrix, coated with a soft silicone layer on both sides.

InterSil forms a protective barrier for granulation tissue to grow undisturbed by frequent changes of the outer absorbent dressing being used. InterSil allows exudate to pass through it, preventing wound maceration without hindering the function of the absorbent dressing.

1.1 PERFORMANCE CHARACTERISTICS

The benefits and features of Intersil are:

- Perforated holes allows exudates to pass through to absorbent dressings
- Thin and soft allowing it to conform to the body and wounds
- Non irritating and latex free
- Minimizes trauma at dressing change and reduces the frequency of dressing changes needed
- Easy application and removal

2.0 INTENDED PURPOSE

Long term, non-invasive wound dressings intended principally for the management of 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, skin grafts, donor sites, post-operative wounds, skin tears, lacerations, stage I-IV pressure ulcers, venous and arterial ulcers and second degree burns which have breached the dermis on injured skin and can only heal by secondary intent.

2.2 INTENDED USER

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

3.0 INDICATIONS

Intersil is intended for use on a wide range of wounds including, skin grafts, donor sites, post-operative wounds, skin tears, lacerations, stage I-IV pressure ulcers, venous and arterial ulcers and second degree burns

4.0 CONTRAINDICATIONS/SAFETY INFORMATION

InterSil is contraindicated for

- If signs of infection develop or if the wound deteriorates unexpectedly, cease use of the product and consult a physician.
- Do not use InterSil on ulcers resulting from Infection or on third degree burns.
- Do not use if allergic to silicone.
- InterSil should not be changed for 5 days after skin graft fixation.

5.0 WARNINGS

Do not use if pack 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.

6.0 INFORMATION FOR USE

6.1 Skin Preparation

a) Visually inspect the dressing for damage prior to use.
b) Clean the wound bed thoroughly and dry the surrounding skin.

6.2 Dressing Application

a) Remove the dressing from its pouch. Intersil can be cut to size if needed, prior to removing outer liners.
b) Remove the first liner and place the dressing over the wound area.
c) Peel back the second liner whilst holding the dressing in place. This dressing can be placed with either side facing the wound.
d) Apply secondary absorbent dressing and/or fixation device if required.

6.3 Dressing Changes

Intersil may be left in place for several days, up to one week, depending on the condition of the wound and as long as the pores do not become blocked, preventing exudate from passing freely.
Remove secondary absorbent dressing as required leaving InterSil in place.
When Intersil is being removed, gently press down on the skin and carefully free the dressing edges one at a time to remove.

7.0 CLINICAL BENEFIT / SPECIAL CONDITIONS

Intersil dressings are accepted as a safe and effective treatment for a wide range of wounds. The low adherence and the thin construction of the Intersil dressing allows it to conform to the body and wounds provides an enhanced healing environment which results in minimal damage to the surrounding skin or peri-wound and decreased pain during dressing change.

8.0 STORAGE

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

9.0 SYMBOLS ON THE LABELING

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

10.0 PRESENTATION

Reference	Size	No. / Box
IS050710	5 x 7cm	10
IS081010	8 x10cm	10
IS101510	10x 15cm	10
IS203010	20 x30cm	10

11.0 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 1639

Made in Ireland

13.0 REVISION HISTORY

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

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