AVERY DENNISON	**Title**	**Instructions for Use Intersil**
	Revision	**D**
	Technical Documentation Number	**LFD-PKG-000302-D**

1. 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.

2. 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. This dressing is a meshed non-adherent wound contact layer allowing passage of exudate and providing fixation and protection of tissues.

2.1 INTENDED POPULATION

The intended patient population would consist of those individuals with skin tears, skin abrasions, sutured wounds including post-operative wounds, partial thickness burns, lacerations, partial and full thickness grafts, diabetic foot ulcers, venous and arterial leg ulcers.

2.2 INTENDED USER

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

3. INDICATIONS

Intersil is intended for use on skin tears, skin abrasions, sutured wounds including post-operative wounds, partial thickness burns, lacerations, partial and full thickness grafts, diabetic foot ulcers, venous and arterial leg ulcers.
Intersil can also be used as a protective layer on non-exuding wounds, blisters, fragile skin and exposed fragile tissues.

4. CONTRAINDICATIONS/SAFETY INFORMATION

- 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.
- Ensure dressing is capable of transmitting exudate.
- Peel dressing off carefully in event that dressing has adhered strongly to wound/ skin.
- If exudate has dried, soak dressing in saline to aid removal.
- Ensure that InterSil is secured in place when applied to concave surfaces. If application is difficult, consider a larger size dressing.

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5. 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. INFORMATION FOR USE

6.1 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) Follow local protocols on the handling of sterile product.
b) Remove the dressing from its pouch. InterSil can be cut to size if needed, prior to removing outer liners.
c) Remove the first liner and place the dressing over the wound area.
d) Peel back the second liner whilst holding the dressing in place. This dressing can be placed with either side facing the wound.
e) 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. InterSil should not be changed for 5 days after skin graft fixation.
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 below 26°C, away from direct sunlight.

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9.0 DISPOSAL

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

10.0 SYMBOLS ON THE LABELING

WARNINGS	
	Do not use if the pouch is damaged or opened.
	Medical Device
	Sterile Barrier System/Sterile Packing
STERILISATION	
	
STORAGE	
 26°C	

11.0 PRESENTATION

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

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12.0 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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Made in Ireland

InterSil e-IFU is accessible via the Avery Dennison Medical website at the following address:

https://medical.averydennison.com/en/home/product-selector/InterSil.html

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13.0 REVISION HISTORY

Revision	Change History	Date	Originator
03	MDR release	17 Sept 2020	E. Minagh
A	Updated to include disposal guidelines. Correction of NB number.	26 May 2021	D. Casey
B	Updated to include e-IFU access information.	05 Aug 2021	D. Casey
C	Update to intended purpose and indications. Remove word 'including' prior to indications in sections 3 and 2.1. Section 6.3 InterSil should not be changed for 5 days after skin graft fixation. Additional safety information added to section 4.	13 Oct 2021	P. Slattery D. Casey
D	Section 8.0 and Section 10.0 update to include maximum temperature limit to 26°C.	13 Apr 2022	I. Mats

14.0 APPROVAL

Review and Approval	
Name and Title	**Signature and Date**
Lisa Bartakovics Sr. Global Director RA & Quality	Approvals are captured via MasterControl
Emmett McArdle R&D Manager	Approvals are captured via MasterControl
Paul Saunders Sr. Global Marketing Manager	Approvals are captured via MasterControl
Elaine Minagh Regulatory Affairs Manager	Approvals are captured via MasterControl
Michelle Fitzpatrick Quality Engineer	Approvals are captured via MasterControl