	<b>Title</b>	<b>Instructions for Use Adhesive Remover</b>	
	<b>Revision</b>	02	
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## 1.0 PRODUCT DESCRIPTION

Adhesive Remover is a uniquely formulated solution which ensures pain free removal of medical adhesive products. The skin conditioning component has been developed to leave the skin feeling smooth following application.

## 2.0 INTENDED PURPOSE

Short-term, non-invasive medical device that aids removal of adhesive devices and residues from intact skin.

### 2.1 INTENDED POPULATION

The product may be used on adults and children.

### 2.2 INTENDED USERS

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

## 3.0 INDICATIONS

For the safe and pain free removal of all medical adhesive devices and skin residues including:

1. Adhesive Tapes
2. Wound Dressings
3. Stoma Pouches

Adhesive Remover is particularly suited for removing difficult residues which build up on the skin over time.

## 4.0 CONTRAINDICATIONS

1. Adhesive Remover should not be used on skin where infection is present.
2. Do not use this product if there is a known allergic sensitivity to any of the ingredients.
3. Do not use on open wounds, damaged or broken skin.

## 5.0 WARNINGS


Adhesive Remover in liquid form is flammable; use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children. Do not use if pack is damaged or open. Avoid contact with eyes. For external use only. Do not swallow.

Do not re-use wipe. Re-use of single-use devices creates a potential risk of infection to the patient or user. It may also lead to degraded performance or a loss of functionality. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

## 6.0 DIRECTIONS FOR USE

When removing adhesive dressings:

1. Visually inspect the packaging for damage prior to use.
2. Lift up edge of plaster and apply Adhesive Remover under the dressing while lifting off.
3. Peel away the plaster slowly while continuing to apply more Adhesive Remover as the dressing begins to lift.
4. After wiping clean the surrounding skin area, a new adhesive dressing can be applied if required.

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For removing adhesive residue on the skin:

1. Apply Adhesive Remover to the affected area.
2. Allow the solution to rest on the adhesive for 5-10 seconds.
3. Gently wipe clean the skin area.
4. Re-apply for extremely difficult residues.

#### INGREDIENTS

Hexamethyldisiloxane, Octamethyltrisiloxane and Dimethicone

#### 7.0 CLINICAL BENEFITS

Dressings can be removed easily from the skin, while the moisturiser present ensures conditioning of the skin.







#### 8.0 STORAGE

Store away from direct sunlight at ambient temperature and humidity.

#### 9.0 DISPOSAL


The Adhesive Remover can be disposed of based on the hospital or healthcare professional advice.

#### 10.0 SYMBOLS ON LABELLING

WARNINGS	
	Flammable
	Caution
	Do not use if the pouch is damaged or opened.
	Do not swallow
	Avoid contact with eyes
STORAGE	
	

#### 11.0 PRESENTATION

The Adhesive Remover Spray product is supplied in 50ml bottles or 3ml/2ml wipes. The wipe is packaged in a packed in a paper foil laminate. The 50ml spray version is supplied in bottles with disperser /spray head.

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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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## 13.0 REVISION HISTORY

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

## 14.0 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