

Zetuvit Plus Silicone Border

RespoSorb Silicone Border

General Product Description/Intended Purpose

Zetuvit Plus Silicone Border is a sterile self-adhesive superabsorbent dressing with a silicone interface for the treatment of moderately to heavily exuding, chronic and acute wounds. The silicone layer in contact with the wound allows easy application and almost painless, atraumatic removal. The absorbent pad absorbs and retains the exudate.

Intended purpose

Zetuvit Plus Silicone Border is a single use sterile self-adhesive superabsorbent dressing with a silicone interface for long-term treatment of injured skin, acute and chronic wounds, with moderate to high levels of exudate. It is used on adults only, by health professionals in clinical or homecare environments and can be combined with local antiseptics and secondary dressings.

Indication

Zetuvit Plus Silicone Border is suitable for the treatment of wounds with moderate to high levels of exudate: acute wounds (burns, post-op, trauma wounds) and chronic wounds (venous ulcer, pressure ulcer, diabetic foot ulcer, tumors).

Application

- Clean the wound using a physiological solution or as instructed by a clinician.
- Choose a suitable dressing size for the wound, ensuring that the central pad exceeds the edges of the wound by approximately 1 to 2 cm. Do not cut the absorbent green pad. The transparent border can be cut in order to adapt the dressing e.g. to a concave form.
- Before applying the dressing, after rinsing the wound, make sure that the surrounding skin is dry by using swabs to ensure that the dressing adheres.
- Remove the two protective sheets. Place the adherent side of the dressing onto the wound, so that the green side faces away from the wound.
- Press down the adhesive edges firmly and avoid wrinkles in the border to ensure the dressing stays securely in place.
- No additional fixation is required, if indicated, compression bandages can be applied as instructed by a clinician.
- The dressing can remain on the wound for up to 5 days depending on the condition of the wound and the established clinical protocol.
- The dressing must be changed if clinically indicated or when exudate reaches the rim of the absorbent pad.

Reference Numbers

- **Products packed in paper/paper peelpouches** (The sealed seam of the peel pack contains natural rubber latex)

Packaging	10x10	12,5x12,5	17,5x17,5	15X25	20x25
P10 Zetuvit Plus Silicone Border	413 910				
P10 Zetuvit Plus Silicone Border		413 920			
P10 Zetuvit Plus Silicone Border			413 930		
P10 Zetuvit Plus Silicone Border				413 940	
P10 Zetuvit Plus Silicone Border					413 950

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P10	RespoSorb Silicone Border	685 140			
P10	RespoSorb Silicone Border		685 150		
P10	RespoSorb Silicone Border			685 160	
P10	RespoSorb Silicone Border				685 170
P10	RespoSorb Silicone Border				685 180
P3	Zetuvit Plus Silicone Border	413 960			
P3	RespoSorb Silicone Border	685 180			

Products packed in paper/film blisters (natural rubber latex is not intentionally added)

Packaging		10x10	12,5x12,5	17,5x17,5	15X25	20x25
P10	Zetuvit Plus Silicone Border	413 119				
P10	Zetuvit Plus Silicone Border		413 120			
P10	Zetuvit Plus Silicone Border			413 121		
P10	Zetuvit Plus Silicone Border				413 122	
P10	Zetuvit Plus Silicone Border					413 123

Contraindications

Do not use Zetuvit Plus Silicone Border in case of hypersensitivity to any of its components.

Special precautions

- Do not cut the absorbent green pad. The transparent border can be cut in order to adapt the dressing e.g. to a concave form.
- Before treating a wound with healing impairment, a clinician has to be consulted to establish a clinical diagnosis. Treatment with Zetuvit Plus Silicone Border cannot replace a causal treatment of the wound-healing impairment. If there are clinical signs of infection, the infection needs to be controlled with appropriate treatment before this dressing can be used.
- In all cases, follow the established clinical protocol.
- In the absence of available data supporting the use of this dressing on sensitive population groups such as infants, children, pregnant or nursing women, and in the absence of data to the contrary, on these population groups this dressing should be used with caution and following a clinician's recommendation.
- It is not recommended to stand on the dressing, e.g. in the case of wounds on the feet.
- For dressings which are packed in paper-paper peel packs: The sealed seam of the peel pack contains natural rubber latex, which may cause allergic reactions!

Do not use if package is damaged

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

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Product Disposal

In order to minimize the risk of potential infection hazards, or environmental pollution, disposable components of the medical device should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards. Dispose of the medical device with household waste.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Product				
Property	Test method	Unit	Requirements	Test results
Free absorption	EN 13726-1	g/100cm ²	100-220	147 ¹
	TM-404	g/100cm ²	100-220	168 ²
Absorption under load	TM-414	g/100cm ²	50-120	88 ²
Retention under load	TM-404	g/100cm ²	65-120	118 ²
MVTR	EN 13726-2 / TM-394	g/m ² 24h	> 900	1142 ²

¹ Internal data

² Data from external lab, SMTL, UK

Labelling

Lot-No. with 9+6 Digit Code

e.g.:



X	XXX	XX	XX	X	XX	X	X	XX
year	internal order number	charge of sterilization	plant	control digit	week	day	shift	machine

Manufacturing Date

e.g.:



2019	-	07	-	18
year		month		day

Use-by-Date

e.g.:






















2022	-	07	-	01
year		month		day

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Shelf Life: 3 years

	Medical Device
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Consult instructions for use
	The sealed seam of the peel pack contains natural rubber latex which may cause allergic reaction!
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Caution
	Sterilized using ethylene oxide
	Single sterile barrier system
	Unique Device Identifier
	Do not cut
	Store flat

Latest Date of Revision: 2020/09/01