

Zetuvit Plus Silicone

RespoSorb Silicone

General Product Description/Intended Purpose

Zetuvit Plus Silicone is a sterile dressing for the treatment of moderately to highly exuding, acute and chronic 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 is a single use sterile 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 healthcare professionals in clinical or homecare environments and can be combined with local antiseptics, primary and secondary dressings and under compression.

Indication

Zetuvit Plus Silicone is suitable for the treatment of wounds with moderate to high levels of exudate: acute wounds (traumatic wounds, burns, post-operative wounds) and chronic wounds (ulcers, pressure sores, tumor wounds, diabetic feet).

Application

- Clean the wound using a physiological solution or as instructed by a clinician.
- Select a suitable dressing size for the wound making sure that the dressing overlaps the margins of the wound by approx. 1 – 2 cm. Do not cut the dressing.
- Before applying the dressing, after rinsing the wound, make sure that the area around the wound is dry using swabs to ensure that the dressing adheres.
- Remove the protective sheets. Place the dressing with the adherent side onto the wound, so that the green side faces away from the wound.
- Secure the dressing using e.g. a Peha-haft bandage or any other suitable fixation, or, if need be, with compression bandages as instructed by a clinician.
- A 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 dressing.

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	413 810				
P10	Zetuvit Plus Silicone		413 820			
P10	Zetuvit Plus Silicone			413 830		
P10	Zetuvit Plus Silicone				413 840	
P10	Zetuvit Plus Silicone					413 850
P10	RespoSorb Silicone	685 040				
P10	RespoSorb Silicone		685 041			

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P10	RespoSorb Silicone	685 042
P10	RespoSorb Silicone	685 043
P10	RespoSorb Silicone	685 044
P3	Zetuvit Plus Silicone	413 860
P3	RespoSorb Silicone	685 045

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	413 114				
P10	Zetuvit Plus Silicone		413 115			
P10	Zetuvit Plus Silicone			413 116		
P10	Zetuvit Plus Silicone				413 117	
P10	Zetuvit Plus Silicone					413 118

Contraindications

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

Special precautions

- The wound dressing may not be cut to size.
- Before treating a wound with healing impairment, a clinician has to be consulted to establish a clinical diagnosis. Treatment with Zetuvit Plus Silicone 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!
- 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	171 ¹
	TM-404	g/100cm ²	100-220	185 ²
Absorption under load	TM-414	g/100cm ²	50-120	89 ²
Retention under load	TM-404	g/100cm ²	65-120	128 ²
MVTR	EN 13726-2 / TM-394	g/m ² 24h	> 900	2810 ¹

¹Internal data

²Data from external lab, SMTL, UK

Labelling

Lot-No. with 9+6 Digit Code

e.g.:



X	XXX	XX	XX	X	XX	X	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