Product Data Sheet

1.0 Name of the product	**Cutimed® Siltec®**
2.0 Product description	
2.1 Description	Cutimed® Siltec® dressings are an assortment of silicone coated foam dressings. Cutimed® Siltec® is a sterile, single use absorbent polyurethane foam dressing for atraumatic dressing changes that contains super-absorbent stripes which absorb and lock wound exudate. The wound contact surface is a perforated silicone layer that allows adherence to the periwound skin but not to the moist wound bed or to newly formed epithelial tissue. This minimizes trauma and pain during dressing changes. Theouter film is water-repellent, yet permeable to oxygen and vapour. The foam dressing and the super-absorbent stripes are designed to absorb and to lock away excess wound fluid inside the dressing, promoting a moist wound environment and minimizing the risk of maceration. Cutimed® Siltec® is highly conformable and provides protection of the wound site. Cutimed® Siltec® leaves no residues in the wound. The dressing reliably retains wound exudate, even under compression. If necessary, the dressing can be cut to size.
2.2 Intended purpose	Cutimed® Siltec® is intended for the treatment of exuding wounds with low to high exudate levels such as venous and arterial ulcers, pressure ulcers, diabetic foot ulcers, surgical incisions, skin grafts and donor sites, lacerations or abrasions. Cutimed® Siltec® may assist in the prevention of pressure ulcer as part of a comprehensive plan of continuous care, risk assessment and preventive care by a healthcare facility and healthcare professional. Please contact your health care professional if you are unsure whether the product is appropriate for you.
2.3 Instructions for use	Yes, see IFU
2.4 Warnings and precautions for use	Cutimed® Siltec® is packaged for single use. Do not re-use or re-sterilise as there is a risk of transmission of body fluids or contaminated tissue between patients. Do not use if the pouch is already open or damaged as the sterility of the device is guaranteed only when the pouch is unopened and undamaged prior to use. Discard open or unused material. Do not use with oxidizing solutions such as hypochlorite or hydrogen peroxide. Remove the dressing prior radiation therapy. For external use only. The wound should be inspected for signs of infection and treated according to clinical practice if required. In rare cases skin reactions (e.g. redness, itching) may occur. If the treated condition deteriorates, fails to improve or if a side effect is observed, consult a physician or an appropriate health care professional.
2.5 Contraindications	There are no known contraindications
2.6 Transport Precautions	Store dressing away from direct sunlight at ambient temperature and humidity.

2.7 Duration of application	Cutimed® Siltec® can remain in place for up to 7 days, depending on wound conditions and saturation of wound dressing. It is recommended to change the dressing every 24 hours initially, moving to less frequent changes as necessary.

2.8 Composition

Designation	Description	% of final product
Backing	Polyurethane film	3,8
Superabsorbent	Super-absorber hotmelt for moisture/exudate uptake	2,1
Absorbent core	Polyurethane foam	75,1
Adhesive	Silicone elastomer	13,1
Release liner	Polyethylene	5,9

2.9 Product range

Size	Per folding box	Per shipper	Product code
5 x 6 cm	10	10	73285-00
10 x 10 cm			73285-01
10 x 20 cm			73285-02
15 x 15 cm			73285-03
20 x 20 cm	5		73285-04
5 x 6 cm	12		73285-05
10 x 10 cm			73285-06
10 x 20 cm			73285-07
15 x 15 cm			73285-08
20 x 20 cm	6		73285-09

2.10 Sizing Chart	See 2.9
2.11 Storage conditions	Store dressing away from direct sunlight at ambient temperature and humidity. Keep out of the reach of children.
2.12 Shelf life/ Storage time	Expiry date is printed on the packaging. Shelf life: 3 years
2.13 Sterilization	EO Sterilisation DIN EN ISO 11135
2.14 Reimbursement Information	Product is reimbursable in most countries. For more information, please reach out your Essity contact or contact the market access department directly.

2.15 Key quality parameters

Characteristic	Method	Target
Free swell Absorption	DIN EN 13726-1	At least > 0,4 g/cm² Typically around 0,74 g/cm²
Total Fluid Handling Capacity	DIN EN 13726-1	At least > 12 g/(10cm²*24h) Typically around 20,1 g/(10cm²*24h)
MVTR inverted/Transport	DIN EN 13726-1	At least > 8000 g/(m²*24h) Typically around 11000 g/(m²*24h)

3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

3.1 Components

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	No
Lanolin and its derivatives	No
Colophony	No
Colophony derivatives	No
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Yes, except for the sterile peel pouch

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch *BSN medical GmbH* cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change
01 / 14.3.2023	All	Set up new document for MDR product family