

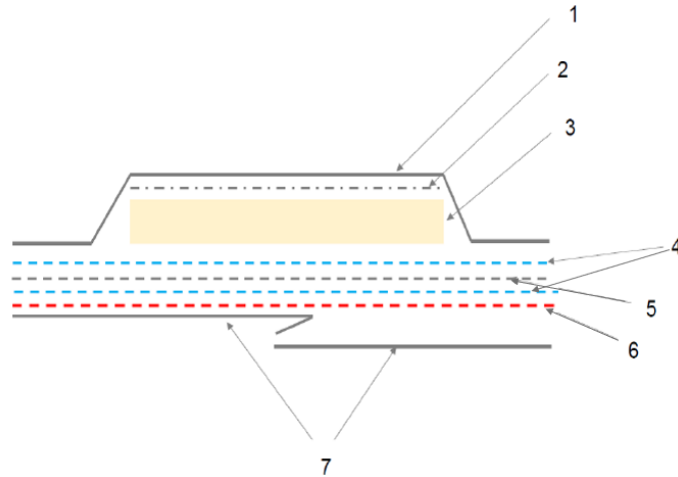
Product Data Sheet

1.0 Name of the product	Cutimed® Siltec® B/ Scarum
2.0 Product description	
2.1 Description	<p>Cutimed® Siltec® B/ Scarum dressings are an assortment of silicone coated foam dressings. Cutimed® Siltec® B/ Scarum is a sterile, single-use, absorbent polyurethane foam dressing for atraumatic dressing changes that contains superabsorbent stripes which absorb and lock wound exudate. The wound contact surface is a perforated silicone layer that allows adherence to the peri-wound skin but not to the moist wound bed or to newly formed epithelial tissue. This minimizes trauma and pain during dressing changes. The outer film is water-repellent, yet permeable to oxygen and vapor. The foam dressing and the superabsorbent 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® B/ Scarum is highly conformable and provides protection of the wound site. Cutimed® Siltec® B/ Scarum leaves no residues in the wound. The dressing reliably retains wound exudate, even under compression. If necessary, the dressing can be cut to size. Cutimed® Siltec® B/ Scarum has an additional silicone adhesive border, that allows secure and gentle fixation of the dressing.</p>
2.2 Intended purpose	<p>Cutimed® Siltec® B/ Scarum 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® B/ Scarum 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 healthcare professional if you are unsure whether the product is appropriate for you.</p>
2.3 Instructions for use	Yes, See IFU
2.4 Warnings and precautions for use	<p>Cutimed® Siltec® B/ Sacrum is packaged for single use. Do not re-use or re-sterilize 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. 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 healthcare professional.</p>
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 B/ Sacrum can remain in place for several days, dependent on wound conditions and exudates levels. It is recommended the dressing is changed every 24 hours initially moving to less frequent changes as necessary.

2.8 Composition



Designation		Description	% of final product
Backing (1)		Polyurethane film	6,3
Superabsorbent layer (2)		Super-absorber hotmelt for moisture/exudate uptake	0,8
Absorbent core (3)		Polyurethane foam	28,5
Silicone wound contact layer	Adhesive (4)	Polyacrylate	
	Film (5)	Polyurethane film	12,6
	Adhesive (6)	Silicone Adhesive	21
Release Liner (7)		Polyethylene Liner	17,8

2.9 Product range

Size	shape	Per folding box	Product code	
Cutimed® Siltec® B				
7.5 x 7.5cm/ 3 x 3in	square	10	73284-00	
12.5 x12.5cm/ 5 x 5in		10	73284-01	
15 x 15cm/ 6 x 6in		10	73284-02	
17.5 x 17.5cm/ 7 x 7in		5	73284-03	
22.5 x 22.5cm/ 9 x 9in		5	73284-04	
10 x 10cm/ 4 x 4in		10	73284-05	
10 x 22.5cm/ 4 x 9in		10	73284-06	
7.5 x 7.5cm/ 3 x 3in		12	73284-07	
12.5 x12.5cm/ 5 x 5in		12	73284-08	
15 x 15cm/ 6 x 6in		12	73284-09	
17.5 x 17.5cm/ 7 x 7in		6	73284-10	
22.5 x22.5cm/ 9 x 9in		6	73284-11	
10 x 10cm/ 4 x 4in		12	73284-12	
10 x 22.5cm/ 4 x 9in		12	73284-13	
7 x 10cm/ 2¾ x 4in		oval	10	73284-14
7 x 10cm/ 2¾ x 4in			12	73284-15
12.5 x12.5cm/ 5 x 5in	square	10	73284-16	
15 x 15cm/ 6 x 6in		10	73284-17	
10 x 10cm/ 4 x 4in		10	73284-18	
10 x 10cm/ 4 x 4in		3	73284-35	
10 x 22.5cm/ 4 x 9in		10	73284-19	
7 x 10cm/ 2¾ x 4in		10	73284-20	
13 x 16cm/ 5 x 6¼in	oval	5	73284-21	
13 x 16cm/ 5 x 6¼in		6	73284-22	
13 x 16cm/ 5 x 6¼in		3	73284-34	
Cutimed® Siltec® Sacrum				
17.5 x 17.5cm/ 7 x 7in	Sacrum	5	73287-00	
23 x 23cm/ 9 x 9in		5	73287-01	
17.5 x 17.5cm/ 7 x 7in		6	73287-02	
23 x 23cm/ 9 x 9in		6	73287-03	
17.5 x 17.5cm/ 7 x 7in		5	73287-04	
23 x 23cm/ 9 x 9in		5	73287-05	

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 – sterile EN 556–1, ISO 11135, EN ISO 11135															
2.14 Key quality parameters	<table border="1"> <thead> <tr> <th>Characteristic</th> <th>Method</th> <th>Target</th> </tr> </thead> <tbody> <tr> <td>Absorption by free swelling</td> <td>Essity internal</td> <td>> 0,3 g/cm²</td> </tr> <tr> <td>Adhesion to steel (final product)</td> <td>Essity internal</td> <td>0,15-0,6 N/cm</td> </tr> <tr> <td>Fluid Handling Capacity</td> <td>EN 13726-1</td> <td>> 10 g/10cm² 24 h</td> </tr> <tr> <td>MVTR inverted</td> <td>EN 13726-1</td> <td>> 8000 g/m² 24 h</td> </tr> </tbody> </table>	Characteristic	Method	Target	Absorption by free swelling	Essity internal	> 0,3 g/cm ²	Adhesion to steel (final product)	Essity internal	0,15-0,6 N/cm	Fluid Handling Capacity	EN 13726-1	> 10 g/10cm ² 24 h	MVTR inverted	EN 13726-1	> 8000 g/m ² 24 h
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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.

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	<p>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 <i>BSN medical GmbH</i> cannot provide proof of absence.</p>																															