Änderungsnummer / Change Master: C1295

Objektverknüpfungen / Object Links:

JBX 40021042 000 01 Cutimed Siltec Sorbact (Re-Design)

Dokumentenstückliste / Document Structure:

JBN ISO 13485 000 Medical devices - Quality management sys

Status		Responsible	Date
IE	in Erstellung	SOEHLE	01.03.2018
AF	Freigabeanford.	SOEHLE	08.03.2018
FR	freigegeben	JUNGA	14.03.2018
FR	freigegeben	JUNGA	14.03.2018

Product Data Sheet

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1.0 Name of the product	**Cutimed® Siltec Sorbact®** **Cutimed® Siltec Sorbact® Sacrum**
2.0 Product description	
2.1 Description	Cutimed® Siltec Sorbact® is a sterile, bacteria-binding, absorbent polyurethane foam dressing for atraumatic dressing changes that contains super-absorbent stripes which absorb and lock wound exudate. The wound contact surface is bacteria-binding, constructed of Sorbact mesh using the Sorbact technology. The fixation border has a silicone coating. This minimises trauma and pain during dressing changes. The outer 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 minimising the risk of maceration. Cutimed® Siltec Sorbact is highly conformable and provides protection of the woundsite. Cutimed ® Siltec Sorbact leaves no residues in the wound. The dressing reliably retains wound exudate, even under compression.
2.2 Characteristics	- No antimicrobial agents released to the wound (user need: safe infection management with low risk of side effects) - Suitable for prophylactic use to reduce the risk of infection / can be used in infection prevention (user need: improved wound healing) - No mechanism for development of bacterial or fungal resistance to hydrophobic interaction / microorganism binding has been described (user need: safe infection management with low risk of side effects; improved wound healing) - Binds hydrophobic microorganisms, such as Staphylococcus aureus (including MRSA), Streptococcus species, Escherichia coli, Pseudomonas aeruginosa, and Candida albicans, as shown in vitro. These micoorganisms are removed from the wound each time the dressing is changed. (user need: safe infection management with low risk of side effects; improved wound healing) - Binds common wound organism - Reduces bioburden in wounds - Supports the natural wound healing process by reducing wound boburden - Binds bacteria from the wound, which prevents infections - Binds bacteria from the wound, which facilitates the healing process - Does not kill bacteria and therefor does not trigger endotoxin release - Does not adhere to a moist wound bed - Suitable for use on fungal Dermal infections (not for US market) - Suitable for use on children

	- Good flexibility and conformability (user need: wearing comfort) - Stable product construction/residue-free removal (user need: high wearing comfort, easy dressing changes) - Atraumatic removal from surrounding skin (user need: painless dressing changes) - Fixation border keeps dressing in place (user needs: easy to apply, skin friendly fixation) - Helps maintaining a moist wound environment (user need: improved wound healing) - Safe fluid handling for moderate to high exudating wounds (user need: quality of life, improved wound healing) - Visible level of dressing saturation (user need: less frequent dressing changes, easy monitoring) - Minimizes risk of maceration (user need: preventing skin damage) - Biocompatible according to apliccable parts of ISO 10993 (user need: safe infection management with low risk of side effects, minimised risk of Cytotoxicity) - Low allergy risk (user need: undisturbed wound healing) - Easy handling (user need: easy to apply) - Fluid retention under compression (user need: safe use together with compression therapy) - Bacteria-proof backing layer (user need: protects from outside contamination) - Reduces odour (user need: Odour reduction) - Readjustable (user need: easy to apply) - Shower proof (user need: convenience, less dressing changes)
2.3 Intended use	Cutimed Siltec Sorbact is indicated for the management of clean, colonized, contaminated or infected exuding wounds such as venous and arterial ulcers, pressure ulcers, diabetic gangrenes, surgical incisions, skin grafts and donor sites, lacerations or abrasions. Cutimed Siltec Sorbact is recommended for wounds with moderate to high exudate levels.
2.4 Instructions for use	Yes, see leaflet
2.5 CE-class **GMDN - code**	CE class IIb / rule 4 GMDN – code number: 44970
2.6 Duration of application / Period of use	Cutimed® Siltec Sorbact® should be changed as often as necessary, dictated by the wound condition. As with all absorbent dressings, monitoring is required to ensure the dressing does not dry out and adhere to the wound. The dressing should be changed when saturation of wound fluid becomes visible. In wounds that show signs of clinical infection, a more frequent wound inspection is advised. In these cases, an appropriate systemic treatment should also be considered.
2.7 Composition	<u>PU Film</u> High elastic and light blue polyurethane film : Basis weight: 26 – 35 g/m²:

	Wound Contact Surface Woven and coloured acetate fabric impregnated with a fatty acid ester derivate DACC (Dialkyl Carbamoyl Chloride) Absorbent adhesive: Transparent Hotmelt PU Foam Hydrophilic polyurethane foam, flexible and pliable. White colour Thickness: 3 ± 0,5 mm Silicone skin adhesive: Medical grade silicone skin adhesive coated on the PU film forming the border. Grammage: 420 - 460 g/m² Release Film: Transparent and embossed medical grade polyethylene film Basis weight: 84,5 ± 11 g/m²
2.8 Latex in product and packaging material	Product and packaging is not made with natural rubber latex.
2.9 Phthalate in product	No content of phthalate in product No content of phthalate in packaging
2.10 Controls	Organoleptic control Absorbency Minimum Sterility

2.11 Product range

Product	Size	Pieces per folding box	Ref.-no.
Cutimed® Siltec Sorbact®	7,5 cm x 7,5 cm	10 pouches	73251-00
Cutimed® Siltec Sorbact®	12,5 cm x 12,5 cm	10 pouches	73251-01
Cutimed® Siltec Sorbact®	15 cm x 15 cm	10 pouches	73251-02
Cutimed® Siltec Sorbact®	17,5 cm x 17,5 cm	5 pouches	73251-03
Cutimed® Siltec Sorbact®	22,5 cm x 22,5 cm	5 pouches	73251-04
Cutimed® Siltec Sorbact® Sacrum	17,5 cm x 17,5 cm	5 pouches	73251-05
Cutimed® Siltec Sorbact® Sacrum	23 cm x 23 cm	5 pouches	73251-06
Cutimed® Siltec Sorbact®	10 cm x 22,5 cm	10 pouches	73251-14
Cutimed® Siltec Sorbact®	10 cm x 10 cm	10 pouches	73251-16
Cutimed® Siltec Sorbact®	7 cm x 10 cm	10 pouches	73251-18

2.12 Storage conditions	Cutimed® Siltec Sorbact® should be stored in dry conditions.
2.13 Shelf life/Storage time	Expiry date is printed on the packaging Shelf life: 3 years
3.0 Safety information of Cutimed® Siltec Sorbact®	
3.1 Warnings and precautions for use	Cutimed® Siltec Sorbact® 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 pouch is opened or damaged. Do not use with oxidising solutions such as hypochlorite or hydrogen peroxide. (Germany: Cutilyth® Wundspüllösung kann vor der Anwendung von Cutimed® Siltec® Sorbact für die Wundspülung verwendet werden, dies beeinträchtigt die Produkteigenschaften nicht) Cutimed® Siltec Sorbact® is not intended to be cut. Avoid overlapping two or more Cutimed® Siltec Sorbact® dressings, always choose a dressing that is appropriate for the wound size. Do not use in combination with fatty products, such as ointments, creams and solutions, as they may decrease the binding of microorganisms. The green wound contact layer should always be applied in direct contact with the wound area to allow microorganisms to bind to the dressing. Remove the dressing prior radiation therapy. In wounds that show signs of clinical infection, a more frequent wound inspection is advised. In these cases, an appropriate systemic treatment should also be considered.
3.2 Flammable and Combustible Properties	Combustible solid
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product
3.4 Contraindications	Do not use Cutimed® Siltec Sorbact® on dry wounds. Do not use on patients with known sensitivity to the dressing components.
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used.
3.6 Transport Precautions	Not applicable
3.7 First Aid	a) Inhalation: Not applicable b) Contact with skin: Not applicable c) Contact with eyes: Not applicable d) Ingestion: Not applicable
3.8 Disposal	Controlled incineration/ landfill according to local environmental health guidelines.

4.0 General information	
4.1 Name, address and telephone number of legal manufacturer	BSN medical GmbH am Essity company Quickbornstrasse 24 20253 Hamburg GERMANY Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
4.2 Certificates for Quality Management	Certificates acc. EN ISO 13485 (notified body: Dekra) available

History

Version/Date	Page /Item	Description of Change
01/01.03.2018	All pages	Set up new document