

**Änderungsnummer / Change Master: C2214**

**Objektverknüpfungen / Object Links:**

JBX 40002372 000 11 Cutimed Sorbact Dressing Pad

**Dokumentenstückliste / Document Structure:**

JBN ISO 13485:2016-03 000 Medical devices - Quality management sys  
JBN ISO 13485 PRACTICAL GUIDE 000 2016 -Medical devices -A practical guide  
JBN DIN EN ISO 13485:2016-08 000 Medical devices - Quality management sys  
JBN DIN EN ISO 13485 BER.2017 000 Medical devices - Quality management sys  
JBR JBR12186 000 IFU 72161/62/63-XX CMED SORB DP INT.  
JBR JBR12188 000 IFU 72161-02 CMED SORB DP DE IT FR

Status	Responsible	Date
IE in Erstellung	DEHANKG	09.01.2020
AF Freigabeanford.	DEHANKG	14.01.2020
FR freigegeben	DEHCHSU	14.01.2020

## Product Safety Data Sheet

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<b>1.0 Name of the product</b>	<b>Cutimed<sup>®</sup> Sorbact<sup>®</sup> Dressing pad</b>
<b>2.0 Product description</b>	
<b>2.1 Description</b>	<p>Cutimed<sup>®</sup> Sorbact<sup>®</sup> Dressing pad is a bacteria and fungi binding wound dressing. It consists of a green Sorbact<sup>®</sup> wound contact layer combined with an absorbent core and a white backing. Cutimed<sup>®</sup> Sorbact<sup>®</sup> Dressing pad absorbs and retains exudate, thereby reducing the risk of maceration and enabling a moist wound environment. The dressing can be used in compression therapy.</p>
<b>2.2 Characteristics</b>	<ul style="list-style-type: none"> <li>- Management of clean, colonized, contaminated or infected wounds</li> <li>- Suitable for moderately to highly exuding wounds</li> <li>- Suitable for prophylactic use to reduce the risk of infection / Can be used in infection prevention</li> <li>- Binds microorganisms, such as Staphylococcus aureus (including MRSA), Streptococcus species, Escherichia coli, Pseudomonas aeruginosa and Candida albicans, as shown in vitro. These microorganisms are removed from the wound each time the dressing is changed.</li> <li>- Binds common wound organisms (Data on file)</li> <li>- Supports the natural wound healing process by reducing wound bioburden</li> <li>- Binds bacteria from the wound, which facilitates the healing process</li> <li>- Binds bacteria from the wound, which prevents infections</li> <li>- Immediate binding of microorganisms</li> <li>- Irreversible binding of microorganisms</li> <li>- No antimicrobial agents released to the wound</li> <li>- Reduces bioburden in wounds</li> <li>- No mechanism for development of bacterial or fungal resistance to hydrophobic interaction/microorganism binding has been described</li> <li>- Absorbs and retains exudate</li> <li>- Maintains a moist wound environment</li> <li>- Can be used in compression therapy</li> <li>- Can be used for local wound management in conjunction with systemic antibiotic therapy</li> <li>- Does not adhere to moist wound bed</li> <li>- Easy to use</li> <li>- Comfortable for the patient</li> <li>- Easy to remove</li> <li>- Skin friendly</li> <li>- Helps reducing odor from wound area</li> </ul>


<b>To 2.2 Characteristics</b>	<ul style="list-style-type: none"> <li>- Helps reducing pain</li> <li>- Safe for use in infants and children</li> <li>- Safe for use in pregnant and lactating women</li> <li>- May be left in place for up to 7 days if clinical condition allows</li> <li>- Suitable for prolonged duration of treatment</li> <li>- Biocompatible according to applicable parts of ISO 10993</li> <li>- Low allergy risk</li> <li>- Sterile</li> <li>- Latex free</li> <li>- May reduce the need for antibiotics</li> <li>- Sorbact<sup>®</sup> is significantly more effective in reducing the bacterial burden in critically colonized or locally infected chronic leg ulcers compared to Aquacel Ag</li> <li>- Packaging phthalate free or complies with applicable EC regulations</li> </ul>
<b>2.3 Intended use</b>	<p>Cutimed<sup>®</sup> Sorbact<sup>®</sup> Dressing pad is intended for use in management of clean, contaminated, colonized or infected wounds with moderate to high exudate levels, such as surgical wounds, traumatic wounds, pressure ulcers, diabetic ulcers and foot and leg ulcers.</p>
<b>2.4 Instructions for use</b>	<p>Yes, see leaflets JBR12186 (INT.) and JBR12188 (DE IT FR)</p>
<b>2.5 CE-class GMDN - code</b>	<p>Class II b Rule 4, sterile          GMDN Code: 58741</p>
<b>2.6 Composition</b>	<p>Cutimed<sup>®</sup> Sorbact<sup>®</sup> Dressing pad:</p> <p>Layer 1: Binding and removal of microorganisms          Coloured acetate gauze impregnated with the fatty acid ester derivative DACC (dialkyl carbamoyl chloride).</p> <p>Layer 2: Transport of wound exudate          Cotton gauze</p> <p>Layer 3: Binding and removal of microorganisms          Coloured acetate gauze impregnated with the fatty acid ester derivative DACC</p> <p>Layer 4: Absorbent core          Viscose 75 % and polyester 25 %</p> <p>Layer 5: Waterproof, helping prevent strike-through          Tissue paper impregnated with the fatty acid ester derivative DACC</p> <p>Layers 6 &amp; 7: Cover          Non woven fabric made of cellulose, rayon, polyester joined with vinyl acetate</p> <p>Hotmelt glue</p>

<b>2.7 Duration of application / Period of use</b>	The dressing change frequency depends on exudate levels and the overall condition of the wound and surrounding skin. Should the clinical condition allow, the dressing can be left in place for up to 7 days. The final decision on the therapy regimen needs to be taken by health care professionals.			
<b>2.8 Latex in product and packaging material</b>	Product composition: No latex content Packaging material: No latex content			
<b>2.9 Phthalate in product</b>	No content of phthalate in product No content of phthalate in packaging			
<b>2.10 Controls</b>	<b>Finished product:</b> Water repellence Appearance Colour fastness Packaging			
<b>2.11 Product range</b>				
<b>Assortment</b>		<b>Units per folding box</b>	<b>Per shipper</b>	<b>Product code</b>
Cutimed® Sorbact® Dressing Pad	7 cm x 9 cm	40 pieces	2	<b>72161-00</b>
	7 cm x 9 cm	5 pieces	16	<b>72161-01</b>
	7 cm x 9 cm	40 pieces	2	<b>72161-08<sup>*1</sup></b>
	7 cm x 9 cm	5 pieces	16	<b>72161-09<sup>*1</sup></b>
	10 cm x 10 cm	40 pieces	2	<b>72162-00</b>
	10 cm x 10 cm	5 pieces	16	<b>72162-01</b>
	10 cm x 10 cm	40 pieces	2	<b>72162-11<sup>*1</sup></b>
	10 cm x 10 cm	5 pieces	16	<b>72162-12<sup>*1</sup></b>
	10 cm x 20 cm	20 pieces	2	<b>72163-00</b>
	10 cm x 20 cm	20 pieces	2	<b>72163-06<sup>*1</sup></b>
<b>2.12 Storage conditions</b>	Well closed, dry, clean and without exposure to direct sunlight.			
<b>2.13 Shelf life/Storage time</b>	Expiry date is printed on the packaging Shelf life: 5 years			
<b>2.14 Sterilization</b>	This product is sterilized by Gamma radiation according ISO 11137-1, ISO 11137-2, ISO 11137-3			

<sup>\*1</sup> German, French, Italian version

### 3.0 Safety information of Cutimed® Sorbact® Dressing pad

<b>3.1 Warnings and precautions for use</b>	<ul style="list-style-type: none"> <li>- If the treated condition deteriorates, fails to improve or a side effect is observed, consult a physician or an appropriate health care provider.</li> <li>- Do not use on patients with a known hypersensitivity to any of the dressing components.</li> <li>- The green wound contact layer should always be applied in direct contact with the wound area to allow microorganisms to bind to the dressing.</li> <li>- Should the dressing adhere to the wound, moisten or soak the dressing to assist removal and avoid disruption of the healing wound.</li> <li>- Do not use in combination with fatty products, such as ointments, creams and solutions as they may decrease the binding of microorganisms.</li> <li>- Cutimed® Sorbact® Dressing pad is for single use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination.</li> <li>- Do not re-sterilize.</li> <li>- Do not use if peel pouch is already open or damaged as the sterility of the dressing is guaranteed only when the package is unopened and undamaged prior to use.</li> <li>- Do not cut the dressing.</li> <li>- Prior to radiation therapy remove Cutimed® Sorbact® Dressing pad. A new dressing can be applied following treatment.</li> <li>- Cutimed® Sorbact® Dressing pad is Magnetic resonance imaging Safe.</li> </ul>								
<b>3.2 Flammable or combustible properties</b>	Combustible solid.								
<b>3.3 Health Hazards</b>	No health hazard is anticipated during normal handling of this product.								
<b>3.4 Contraindications</b>	There are no known contraindications to the use of Cutimed® Sorbact® Dressing pad. Attention is drawn to the warnings and precautions.								
<b>3.5 Fire Hazard and Emergency Action</b>	In case of fire any standard fire extinguisher may be used.								
<b>3.6 Transport Precautions</b>	Not applicable.								
<b>3.8 First Aid</b>	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">a) Inhalation:</td> <td>Not applicable</td> </tr> <tr> <td>b) Contact with skin:</td> <td>Not applicable</td> </tr> <tr> <td>c) Contact with eyes:</td> <td>Not applicable</td> </tr> <tr> <td>d) Ingestion:</td> <td>Not applicable</td> </tr> </table>	a) Inhalation:	Not applicable	b) Contact with skin:	Not applicable	c) Contact with eyes:	Not applicable	d) Ingestion:	Not applicable
a) Inhalation:	Not applicable								
b) Contact with skin:	Not applicable								
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	<b>BSN documentation system</b> JBM 40003203 000 11 <b>PSDS Cutimed Sorbact Dressing Pad</b>	<b>Released:</b> 14.01.20-... Seite 6 von 8
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<b>3.9 Disposal</b>	The user has to follow the instruction of the respective valid laws, standards and guidelines for disposal of garbage coming from the medicinal field.
<b>4.0 General information</b>	
<b>4.1 Name, address and telephone number of legal manufacturer</b>	BSN medical GmbH an Essity company Quickbornstraße 24 20253 Hamburg  GERMANY  Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
<b>4.2 Certificates for Quality Management</b>	Certificate according EN ISO 13485 (notified body: Dekra) available

### History

Version/Date	Page /Item	Description of Change
01/01.07.04	All pages	Set up new document
02/01.08.05	Item 7	See Change Control No.: 7_348
03/17.10.06	Item 15	Add of product range and claims Project – no. 3.25.001
04/14.02.07	Item 8	Layer 4: Absorbent material Viscose 75 % and polyester 25 %
04/27.08.07	Item 15	Add of NART 72163-01
05/01.05.08	General revision	Change of product name Update of the product claims (Item 3) Add disclaimer for Data Sheets Delete ref.-no. 72163-01
06/10.09.08	Page 4/ Item 8	Change in composition
07/21.01.09	General revision Change from PD to PSDS Page 4/ Item 2.7 Page 4/ Item 2.8	All pages including the safety data  Latex information added Duration of use added
08/12.07.12	Page 3 / item 2.0 Page 3 / item 2.2 Page 4 / item 2.3 Page 4 / item 2.5 Page 4 / item 2.9 Page 5 / item 2.10 Page 6 / item 3.1 Page 6 / item 3.4	Adjustment of description Adjustment of characteristics Adjustment of intended use New GMDN-code Phthalate added Adjustment of controls Precautions for use added Contraindications added
09/05.02.2016	Page 2 / item 2.2 Page 3 / item 2.5 Page 4 / item 2.14 Page 4 / item 3.7 Page 4 / item 3.8 Page 4 / item 3.10	Change of characteristics GMDN code changed Sterilization added Handling/ Use/ Protecting Clothing deleted new disposal text additional information deleted
09/10.06.2016	Page 2 / item 2.1 Page 2 / item 2.2 Page 3 / item 2.3	Change of description Adjustment of characteristics Adjustment of intended use

### History

Version/Date	Page /Item	Description of Change
10/ 27.07.2017	Page 2/ item 2.1 Page 2/ item 2.2  Page 5/ item 3.1 / 3.4  Page 6/ item 4.2	Update according valid PFD (JBX) Update according information of Scientific department Update according information of Scientific department Update according valid certification
11/08.01.2020	All pages/ items 2.1, 2.2, 2.3, 2.4, 2.11, 2.12, 2.14, 3.1, 3.4, 4.1, 4.2	C2214 – general revision and update acc. valid PFD and other changes