

Änderungsnummer / Change Master: C1803

Objektverknüpfungen / Object Links:

JBX 40028479 000 01 Cutimed DebriClean

Dokumentenstückliste / Document Structure:

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
JBN ISO 13485:2016-03 000 Medical devices - Quality management sys
JBN DIN EN 556-1 000 Sterilisation von Medizinprodukten -Anfo
JBN DIN EN 556-1-BER-1 000 Sterilization of medical devices - Requi
JBN DIN EN ISO 11135-1 000 Sterilisation von Produkten für die Gesu

Status	Responsible	Date
IE in Erstellung	DEHANKG	16.04.2019
AF Freigabeanford.	DEHANKG	17.05.2019
FR freigegeben	DEHPASH	17.05.2019

Product Safety Data Sheet

Document will not be automatically updated

1.0 Name of the product	Cutimed[®] Debriclean
2.0 Product description	
2.1 Description	<p>The wound side of Cutimed[®] Debriclean consists of white mono-filament microfiber loops which effectively clean the wound and protect intact tissue. The blue, abrasive microfiber loops feature effective wound cleansing and remove even mild necrosis.</p> <p>The mono-filament microfiber loops:</p> <ul style="list-style-type: none"> - safely and effectively remove biofilm - bind and retain bacteria - absorb wound exudate, slough and dry skin flakes - are easy and safe to use with visible results after just a few minutes
2.2 Characteristics	<ul style="list-style-type: none"> - Binds bacteria in the Debriclean product - Binds debris between the loop fibers - No cross contamination within one wound, safely locks exudate, debris and bacteria in the loops - Product design leads to higher cleaning efficiency compared to gauze or Debrisoft - Easy to moisten and apply - Effectively removes bacteria and debris from the wound and therefore promotes development of healthy tissue (only a clean wound can heal) - Results can be seen after 2-5 minutes of cleaning, foam technology with additional unique fibers reduces time needed for cleaning - Absorbs exudate better than competitor debridement pads, due to additional foam technology - Removes hyperkeratosis and dead tissue of surrounding skin - Removes exudate, debris and bacteria in uneven wound condition - Lifts up superficial slough and debris, including biofilm, quickly and easily - Remove barriers to healing - Rough fiber technology for efficient use on leathery tissue - Product is compatible to commonly used wound cleansing solutions based on PHMB, sodium hypochlorite or hypochlorous acids, octenidine, 0.9% medical saline solution, water

2.2 Characteristics	<ul style="list-style-type: none"> - Easy and fast to use - Less contact to patient's exudate due to hydrophobic backing - Safe to use - better/easier handling of the product through hard blister packaging and loop on the back of the pad - Intuitive product and packaging design for safe usage independent of use environment - Can be used by any nurse without special trainings needed 												
2.3 Intended use	<p>Cutimed® Debriclean aids in the debridement of superficial wounds and surrounding skin in, for example:</p> <ul style="list-style-type: none"> - diabetic ulcers - venous and arterial ulcers - pressure sores - postoperative wounds and wounds healing by secondary intention - superficial burns - the absorption of exudate, slough and dry skin flakes 												
2.4 Instructions for use	Yes												
2.5 CE-class / GMDN - code	Class IIb / GMDN code: 58294												
2.6 Duration of application / Period of use	Not applicable												
2.7 Composition	<table border="0" style="width: 100%;"> <tr> <td style="width: 40%;">Debridement substrate:</td> <td>Nonwoven polyester / co-polyester</td> </tr> <tr> <td>Foam:</td> <td>Polyurethane foam</td> </tr> <tr> <td>Loop material:</td> <td>Polyamide / Elastane</td> </tr> <tr> <td>Backing</td> <td>PE spunbond Non Woven, Printed</td> </tr> <tr> <td>Adhesive tape</td> <td>Vancive double sided synthetic rubber adhesive transfer tape</td> </tr> <tr> <td>Hotmelt</td> <td>Low melt adhesive Polyurethane</td> </tr> </table>	Debridement substrate:	Nonwoven polyester / co-polyester	Foam:	Polyurethane foam	Loop material:	Polyamide / Elastane	Backing	PE spunbond Non Woven, Printed	Adhesive tape	Vancive double sided synthetic rubber adhesive transfer tape	Hotmelt	Low melt adhesive Polyurethane
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Hotmelt	Low melt adhesive Polyurethane												
2.8 Latex in product and packaging material	Product and packaging is not made with natural rubber latex												
2.9 Phthalate in product and	No content of phthalate in product. No content of phthalate in packaging												
2.10 Controls	Finished product: Appearance Absorption												

2.11 Product range				
Assortment	Size	Compresses per folding box	Per shipper	Product code
Cutimed® DeбриClean	9 cm x 13 cm	5 pieces	12	76170-00
2.12 Storage conditions		Dry, clean and without exposure to direct sunlight		
2.13 Shelf life/Storage time		3 years		
2.14 Sterilization		EO - sterile according to DIN EN 556-1, DIN EN 556-1 Ber. -1, ISO 11135		
3.0 Safety information				
3.1 Warnings and precautions for use		<ul style="list-style-type: none"> - Do not touch the pad on the wound side # use the strap on the back to hold the pad. - Do not cut Cutimed® DeбриClean. - Ensure that the shelf life has not expired and that the sterile packaging is not damaged or unintentionally opened. In such a case this pad shall not be used anymore. - Use the blue fibers on the wound side of the pad only for leathery slough and mild necrosis. Do not use on granulating tissue. - Be careful when applying pressure or rubbing fast and avoid causing the patient excessive pain. - Do not leave Cutimed® DeбриClean on the wound, it is only suitable for wound-cleansing. - Use a new pad with every wound # single use only, to prevent the spread of bacteria. 		
3.2 Flammable or		Combustible solid		
3.3 Health Hazards		None		
3.4 Contraindications		There are no known contraindications.		
3.5 Fire Hazard and Emergency Action		In case of fire any standard fire extinguisher may be used.		
3.6 Transport Precautions		Protect from moisture and store dry at temperatures below 25°C / 77°F		

	<p align="center">BSN documentation system JBM 40035009 000 01 PSDS Cutimed DeibriClean</p>	<p>Released: 17.05.19-... Seite 5 von 6</p>
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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	The user has to follow the instructions of the respective valid laws, standards and guidelines for disposal of garbage coming from the medicinal field.
4.0 General information	
4.1 Name, address and telephone number of legal manufacturer	BSN medical GmbH an Essity company Quickbornstrasse 24 20253 Hamburg GERMANY Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
4.2 Certificates for Quality	Certificate acc. EN ISO 13485 (notified body: Dekra) available

History

Version/Date	Page /Item	Description of Change
01 / 16.04.2019	Set up new document	