

Änderungsnummer / Change Master: C2258

Objektverknüpfungen / Object Links:

JBX 40041589 000 01 Leukomed T plus

Dokumentenstückliste / Document Structure:

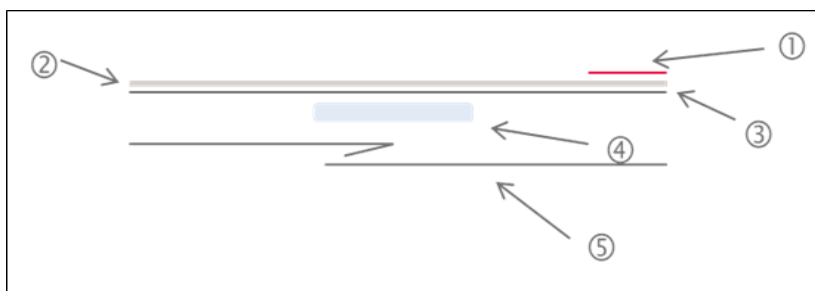
JBN DIN EN 13726-2 000 Prüfverfahren für primäre Verbandstoffe
JBN DIN EN ISO 15223-1 000 2017-04 Medical devices - Symbols to be
JBN ISO 11135 000 Sterilization of health-care products -
JBN DIN EN ISO 11135 000 Sterilisation von Produkten für die Gesu

Status		Responsible	Date
IE	in Erstellung	DEHNINA	23.11.2020
AF	Freigabeanford.	DEHNIRO	11.12.2020
FR	freigegeben	DEHVEDY	11.12.2020

Product Data Sheet

1.0 Name of the product	Leukomed® T plus
2.0 Product description	Transparent wound island dressing
2.1 Description	<p>Leukomed® T Plus dressings are an assortment of sterile wound dressings.</p> <p>Leukomed® T plus consists of a transparent PET/PU-laminate as backing material coated on the PU-side with a skin-friendly polyacrylate adhesive providing secure and reliable dressing retention. A white wound pad is placed centrally on the adhesive side.</p>
2.2 Intended purpose	<p>Leukomed® T plus is intended to cover minor to medium size wounds like wounds after surgery or minimal invasive surgery. The film dressing can stay in place for one day to several days depending on the status of the wound and on the skin condition.</p> <p>The device is sterile and for single use only.</p> <p>Intended users are health care professionals and patients. Use of the device is not restricted to specific populations.</p>
2.3 Instructions for use	No IFU is required for this kind of product due to the low risk to user. All necessary information for safe use is available on primary (pouch) and secondary packaging (folding box).
2.4 Warnings and precautions for use	<p>Warnings and Precautions related to the device are given in form of a symbols according to DIN EN ISO 15223 and are to read as follows:</p> <ul style="list-style-type: none"> - Do not re-use - Do not use if pouch is damaged - Keep away from sunlight - Keep dry.
2.5 Contraindications	none
2.6 Transport Precautions	not applicable
2.7 Duration of application / Period of use	The film dressing can stay in place for one day to several days depending on the status of the wound and on the skin condition.

2.9 Composition



Designation (incl. no. in drawing)	Description	% of final product
Application aid (1)	red Polypropylene tape	3
Backing (2)	Polyurethane film with Polyester release film	33
Adhesive (3)	Polyacrylate adhesive	10
Wound Pad (4)	Viscose/Polypropylene non-woven	25
Release liner (5)	siliconized paper	29

2.10 Product range

Product	Size	Per folding box	Per shipper	Product code
72382-00000-04	5x7.2 cm	50	8	72382-00
72382-00001-04	8x10 cm	50	6	72382-01
72382-00002-04	8x15 cm	50	6	72382-02
72382-00003-04	10x25 cm	50	8	72382-03
72382-00004-04	10x30 cm	50	8	72382-04
72382-00005-04	10x35 cm	50	8	72382-05
72382-00006-04	5x7.2 cm	5	36	72382-06
72382-00007-04	8x10cm	5	36	72382-07
72382-00008-04	8x15 cm	5	36	72382-08
72382-00009-04	10x25 cm	5	36	72382-09
72382-00010-04	10x30 cm	5	36	72382-10

72382-00011-04	10x35 cm	5	36	72382-11
72382-00014-04	10x20 cm	50	8	72382-14
72382-00015-04	10x20 cm	5	36	72382-15
72382-00016-04	5x7,2 cm	5	36	72382-16
72382-00019-04	5x7,2 cm	5	36	72382-19
72382-00020-04	8x10 cm	5	36	72382-20
72382-00022-04	10x25 cm	5	36	72382-22
72382-00023-04	10x30 cm	5	36	72382-23
72382-00024-04	10x35 cm	5	36	72382-24
72382-00025-04	10x20 cm	5	36	72382-25
79954-00001-03	5x7.2 cm	5	36	79954-01
79954-00002-03	8x10 cm	5	36	79954-02
79954-00003-02	5x7.2 cm	5	36	79954-03
79954-00004-02	8x10 cm	5	36	79954-04
79954-00005-02	5x7.2 cm	5	36	79954-05
79954-00006-02	8x10 cm	5	36	79954-06
2.12 Storage conditions	cool, dry place, avoid direct sunlight			
2.13 Shelf life/Storage time	5 years			
2.14 Sterilization	Product is sterilized by Ethylene Oxide Sterilisation according to ISO 11135; DIN EN ISO 11135			

3.1 key quality parameters	Characteristic	Method	Target
	Adhesion to steel (final product)	Essity internal	3.40 N/cm
	MVTR	DIN EN 13726-2	> 800 g/m ² *24h

List of substances that are not present in any of the products (as of November2020)

substance
antibiotics
Triclosan (CAS 3380-34-5)
Triclorban (CAS 101-20-2)
Silver and its compounds
Hexavalent chromium (Cr(VI)) and its compounds

substance	Yes / No	Remark
PVC in product	No	-
Softeners (Phthalates)	No	-
Latex	No	-
Lanolin and lanolin derivates	No	-
Colophony (CAS 8050-09-7, 8052-10-6, 73138-82-6, 73905-20-1) and derivates	No	-
chlorhexidine	No	-
PHMB (CAS-nr 27083-27-8, 32289-58-0, 28757-47-3, 28757-48-4) and its compounds	No	-
Lead and its compounds	No	-
Cadmium and its compounds	No	-
Mercury and its compounds	No	-
Arsenic and its compounds	No	-
Organotin compounds	No	-
Nanomaterials	No	-

Packaging / Labelling	Yes / No	remark
PVC in packaging	No	-
Cellulose in packaging, bleach / recycled	Yes	-
Producer responsibility for waste handling	No	-
Sterile products offered in 3-layer concept	No	-
Brown cardboard in distribution packaging	Yes	-
Ruler on the dispensing package	No	-
Recycled material	Yes	Brown distribution box is partly made from recycled fibers.

History

Version / Date	Page / Item	Description of Change
01 / 12.2020	All	New document