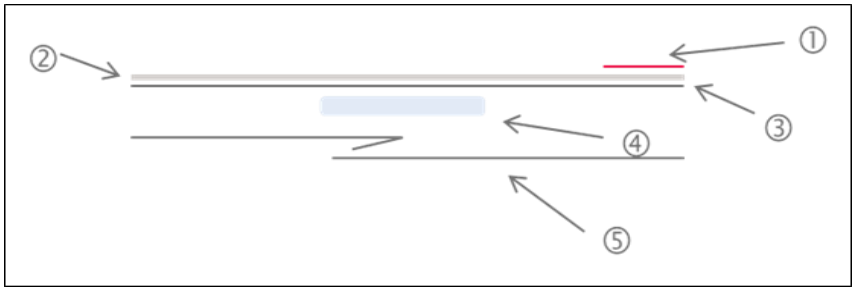
Product Data Sheet

1.0 Name of the product	Leukomed® T Plus
2.0 Product description	
2.1 Description	Leukomed® T plus dressings are an assortment of sterile wound dressings. 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 absorbent wound pad is placed centrally on the adhesive side.
2.2 Intended purpose	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. Intended users are health care professionals and patients. Use of the device is not restricted to specific populations.
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 labelling
2.4 Warnings and precautions for use	Do not use if pouch is damaged. Do not re-sterilize. Do not re-use.
2.5 Contraindications	There are no known contraindications for this device.
2.6 Transport Precautions	Keep dry. Keep away from sunlight.
2.7 Duration of application	The film dressing can stay in place for up to seven days depending on the status of the wound and on the skin condition.
2.8 Composition	

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

2.9 Product range

Size	Per folding box	Per shipper	Product code
5 x 7.2 cm	50	8	72382-00
8 x10 cm	50	6	72382-01
8 x15 cm	50	6	72382-02
10 x 25 cm	50	8	72382-03
10 x 30 cm	50	8	72382-04
10 x 35 cm	50	8	72382-05
5 x 7.2 cm	5	36	72382-06
8 x10 cm	5	36	72382-07
8 x15 cm	5	36	72382-08
10 x 25 cm	5	36	72382-09
10 x 30 cm	5	36	72382-10
10 x 35 cm	5	36	72382-11
10 x 20 cm	50	8	72382-14
10 x 20 cm	5	36	72382-15
5 x 7.2 cm	5	36	72382-16
5 x 7.2 cm	5	36	72382-19
8 x10 cm	5	36	72382-20
10 x 25 cm	5	36	72382-22
10 x 30 cm	5	36	72382-23
10 x 35 cm	5	36	72382-24
10 x 20 cm	5	36	72382-25
5 x 7.2 cm	5	36	79954-01
8 x10 cm	5	36	79954-02
5 x 7.2 cm	5	36	79954-03
8 x10 cm	5	36	79954-04
5 x 7.2 cm	5	36	79954-05
8 x10 cm	5	36	79954-06

2.10 Sizing Chart

See 2.9

2.11 Storage conditions

cool, dry place, avoid direct sunlight

2.12 Shelf life/ Storage time

5 years

2.13 Sterilization

Product is sterilized by Ethylene Oxide Sterilisation according to ISO 11135; DIN EN ISO 11135

2.14 Reimbursement Information

For country specific information please reach out to your local Essity contact.

2.15 Key quality parameters

Characteristic	Method	Target
Adhesion to steel (final product)	Essity internal	3.40 N/cm
MVTR	DIN EN 13726-2	> 800 g/m²*24h

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.

3.1 Components *[R&D & Packaging]*

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	no
Lanolin and its derivatives	no
Colophony	no
Colophony derivatives	no
Bisphenol A (BPA)	no
Polyvinylchloride (PVC)	no
Methylmethacrylate	no
Butylacrylate	no
Microplastics (<5 mm)	no
Nanoparticles	no
Fragrance/parfum	no
Antibiotics	no
Triclosan	no
Chlorhexidine	no
Polyhexanide	no

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Partly in shipper case

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 BSN medical GmbH cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change
01 / 14.12.2005	All	Set up new document
02 / 15.04.2009	All	General revision all pages. Product information and safety information included in one Product Safety Data Sheet. Latex information and duration of application included
03 / 15.11.2012	All	General revision all pages
04 / 15.11.2012	3 / All and 4 / 2.14	General revision Sterilization included Handling/Use/Protecting clothing deleted
05 / 13.06.2018	All	General revision - Update of description for content and of content
06 / 20.06.2018	All	Logo replaced with current BSN/Essity logo - Adaption to current template standard
07 / 29.10.2020	All	Complete rework
08 / 26.01.2020	1 / 2.3,2.8	Clarification of content
	2 / 2.16	Formerly 3.0 - was moved to chapter 2 to avoid jump when deleted
	3 / 3.0,3.1	Complete revision to reflect and reference Global Supplier Standard Annex A2
	3 / 3.2	Addition of 3.2
09 / 16. Feb. 2021	All	Error correction / Format lock removed
11. Jan. 2023	2.15	Added sentence "*For country specific information please reach out to your local Essity contact.*"

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