

## Product Data Sheet

<b>1.0 Name of the product</b>	Leukomed® Control
<b>2.0 Product description</b>	
<b>2.1 Description</b>	Leukomed® Control is a sterile, bacteria, virus and waterproof, transparent film dressing for the treatment of surgical and other acute wounds. It consists of a semi-permeable polyurethane film with a skin-friendly adhesive border and an absorbent hydropolymer wound pad. The transparent dressing enables visual wound inspection without removing the dressing and thus promotes undisturbed wound healing.
<b>2.2 Intended purpose</b>	Leukomed® Control is indicated for dry and low exuding acute wounds such as surgical wounds, superficial and partial-thickness burns, skin donor sites, lacerations and abrasions.
<b>2.3 Instructions for use</b>	Yes
<b>2.4 Warnings and precautions for use</b>	<ul style="list-style-type: none"> <li>· Leukomed® Control is for single use only. Do not use if the pouch is already open or damaged as the sterility of the dressing is guaranteed only when the pouch is unopened and undamaged prior to use.</li> <li>· Leukomed® Control may be used on infected wounds only after consulting a healthcare professional.</li> <li>· Do not use on patients with a known sensitivity to glycerine or hydrogels. In case of intolerance, remove the dressing and gently cleanse the wound with water or sterile saline solution.</li> <li>· The hydropolymer pad may be moistened with sterile saline solution for easier removal, if required.</li> <li>· Should gel fragments remain in the wound bed after removing the dressing, these may be removed by irrigation with sterile saline solution or water.</li> <li>· During the body's normal healing process, non-viable tissue is removed from the wound, which could initially make the wound appear larger. If the wound continues to grow larger after the first few dressing changes, consult a healthcare professional.</li> <li>· Because Leukomed® Control creates an environment that favours the growth of new blood vessels, the delicate newly formed blood vessels may occasionally produce blood-stained wound fluid.</li> <li>· Monitor the wound carefully. Leukomed® Control can remain in situ for up to 14 days, depending on the wound condition.</li> <li>· The total duration of contact is 30 days if the treatment involves consecutive application of individual dressings and if the clinical conditions allow.</li> <li>· No data are available that support the use of topical medicinal preparations in conjunction with Leukomed® Control.</li> <li>· For external use only.</li> </ul>
<b>2.5 Contraindications</b>	Leukomed® Control is not indicated for surgical implantation, to control heavy bleeding, for third-degree burns or for the placement inside deep cavities or sinuses. Not suitable for use under a compression bandage or for radiation therapy.
<b>2.6 Transport Precautions</b>	Dry, clean, below 25°C/77°F and without exposure to direct sunlight

<b>2.7 Duration of application</b>	Leukomed® Control can remain in situ for up to 14 days, depending on the wound condition
------------------------------------	--

<b>2.8 Composition</b>	<p align="center"><u>5x7 cm; 7x10 cm; 8x15 cm:</u></p> <p align="center"><u>10x24 cm; 10x35 cm:</u></p> <table border="1"> <thead> <tr> <th>Designation (incl. no. in drawing)</th> <th>Description</th> <th>% of final product</th> </tr> </thead> <tbody> <tr> <td>Backing (1)</td> <td>Polyurethane film</td> <td>5</td> </tr> <tr> <td>Adhesive (2)</td> <td>Polyacrylate adhesive</td> <td>10</td> </tr> <tr> <td>Wound Pad (3)</td> <td>Viscose/Polypropylene non-woven</td> <td>82</td> </tr> <tr> <td>Release liner white (4)</td> <td>siliconized LDPE</td> <td>1,5</td> </tr> <tr> <td>Release liner clear (5)</td> <td>Option 1: siliconized PET Option 2: siliconized HDPE</td> <td>1,5</td> </tr> </tbody> </table>	Designation (incl. no. in drawing)	Description	% of final product	Backing (1)	Polyurethane film	5	Adhesive (2)	Polyacrylate adhesive	10	Wound Pad (3)	Viscose/Polypropylene non-woven	82	Release liner white (4)	siliconized LDPE	1,5	Release liner clear (5)	Option 1: siliconized PET Option 2: siliconized HDPE	1,5						
Designation (incl. no. in drawing)	Description	% of final product																							
Backing (1)	Polyurethane film	5																							
Adhesive (2)	Polyacrylate adhesive	10																							
Wound Pad (3)	Viscose/Polypropylene non-woven	82																							
Release liner white (4)	siliconized LDPE	1,5																							
Release liner clear (5)	Option 1: siliconized PET Option 2: siliconized HDPE	1,5																							
<b>2.9 Product range</b>	<table border="1"> <thead> <tr> <th>Size/ Color</th> <th>Per folding box</th> <th>Per shipper</th> <th>Product code</th> </tr> </thead> <tbody> <tr> <td>5 cm x 7 cm</td> <td>10</td> <td>28</td> <td>73230-00</td> </tr> <tr> <td>7 cm x 10 cm</td> <td>10</td> <td>20</td> <td>73230-01</td> </tr> <tr> <td>8 cm x 15 cm</td> <td>10</td> <td>20</td> <td>73230-02</td> </tr> <tr> <td>10 cm x 24 cm</td> <td>5</td> <td>20</td> <td>73230-03</td> </tr> <tr> <td>10 cm x 35 cm</td> <td>5</td> <td>10</td> <td>73230-05</td> </tr> </tbody> </table>	Size/ Color	Per folding box	Per shipper	Product code	5 cm x 7 cm	10	28	73230-00	7 cm x 10 cm	10	20	73230-01	8 cm x 15 cm	10	20	73230-02	10 cm x 24 cm	5	20	73230-03	10 cm x 35 cm	5	10	73230-05
Size/ Color	Per folding box	Per shipper	Product code																						
5 cm x 7 cm	10	28	73230-00																						
7 cm x 10 cm	10	20	73230-01																						
8 cm x 15 cm	10	20	73230-02																						
10 cm x 24 cm	5	20	73230-03																						
10 cm x 35 cm	5	10	73230-05																						
<b>2.10 Storage conditions</b>	Dry, clean, below 25°C/77°F and without exposure to direct sunlight																								
<b>2.11 Shelf life/ Storage time</b>	3 years																								

<b>2.12 Sterilization</b>	Gamma radiation according to (DIN EN) ISO 11137-1, -2, -3																				
<b>2.13 Key quality parameters</b>	<table border="1"> <thead> <tr> <th data-bbox="528 371 850 421">Characteristic</th> <th data-bbox="850 371 1161 421">Method</th> <th data-bbox="1161 371 1487 421">Target</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 421 850 488">Adhesion to steel (final product)</td> <td data-bbox="850 421 1161 488">Essity internal</td> <td data-bbox="1161 421 1487 488">2.20 N/cm</td> </tr> <tr> <td data-bbox="528 488 850 521">MVTR</td> <td data-bbox="850 488 1161 521">DIN EN 13726-1</td> <td data-bbox="1161 488 1487 521">&gt; 800 g/m<sup>2</sup>*24h</td> </tr> <tr> <td data-bbox="528 521 850 555">Water activity</td> <td data-bbox="850 521 1161 555">supplier internal</td> <td data-bbox="1161 521 1487 555">45-70%</td> </tr> <tr> <td data-bbox="528 555 850 589">Saline uptake</td> <td data-bbox="850 555 1161 589">supplier internal</td> <td data-bbox="1161 555 1487 589">1000-2000%</td> </tr> <tr> <td data-bbox="528 589 850 636">Gel coat weight</td> <td data-bbox="850 589 1161 636">supplier internal</td> <td data-bbox="1161 589 1487 636">1.0-1.4 kg/m<sup>2</sup></td> </tr> </tbody> </table>			Characteristic	Method	Target	Adhesion to steel (final product)	Essity internal	2.20 N/cm	MVTR	DIN EN 13726-1	> 800 g/m <sup>2</sup> *24h	Water activity	supplier internal	45-70%	Saline uptake	supplier internal	1000-2000%	Gel coat weight	supplier internal	1.0-1.4 kg/m <sup>2</sup>
Characteristic	Method	Target																			
Adhesion to steel (final product)	Essity internal	2.20 N/cm																			
MVTR	DIN EN 13726-1	> 800 g/m <sup>2</sup> *24h																			
Water activity	supplier internal	45-70%																			
Saline uptake	supplier internal	1000-2000%																			
Gel coat weight	supplier internal	1.0-1.4 kg/m <sup>2</sup>																			

### 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](http://www.essity.com/gss)

Deviations are covered in 3.1 Components.

<b>3.1 Components</b>	Raw materials used in product formulation																																
	<table border="1"> <thead> <tr> <th data-bbox="528 1025 1007 1070">Substance</th> <th data-bbox="1007 1025 1487 1070">Included in formulation</th> </tr> </thead> <tbody> <tr><td>natural rubber Latex</td><td>No</td></tr> <tr><td>Lanolin and its derivatives</td><td>No</td></tr> <tr><td>Colophony</td><td>No</td></tr> <tr><td>Colophony derivatives</td><td>No</td></tr> <tr><td>Bisphenol A (BPA)</td><td>No</td></tr> <tr><td>Polyvinylchloride (PVC)</td><td>No</td></tr> <tr><td>Methylmethacrylate</td><td>No</td></tr> <tr><td>Butylacrylate</td><td>No</td></tr> <tr><td>Microplastics (&lt;5 mm)</td><td>No</td></tr> <tr><td>Nanoparticles</td><td>No</td></tr> <tr><td>Fragrance/parfum</td><td>No</td></tr> <tr><td>Antibiotics</td><td>No</td></tr> <tr><td>Triclosan</td><td>No</td></tr> <tr><td>Chlorhexidine</td><td>No</td></tr> <tr><td>Polyhexanide</td><td>No</td></tr> </tbody> </table>		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
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																																
	<table border="1"> <thead> <tr> <th data-bbox="528 2098 1007 2143">Substance</th> <th data-bbox="1007 2098 1487 2143">Included in formulation</th> </tr> </thead> <tbody> <tr><td>Polyvinylchloride (PVC)</td><td>No</td></tr> <tr><td>Natural rubber latex</td><td>No</td></tr> <tr><td>Recycled material</td><td>Partly used for shipper case</td></tr> </tbody> </table>		Substance	Included in formulation	Polyvinylchloride (PVC)	No	Natural rubber latex	No	Recycled material	Partly used for shipper case																							
Substance	Included in formulation																																
Polyvinylchloride (PVC)	No																																
Natural rubber latex	No																																
Recycled material	Partly used for 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 / 28.09.2015	All	Set up new document
02 / 10.04.2019	All	General revision according to current product family description
03 / 15.09.2021	All	General revision, update to new template
	Page 1 / Item 2.7	Duration of use is extended to 14 days