629900 EasyWarm Active Self-Warming Blanket

Active self-warming blanket

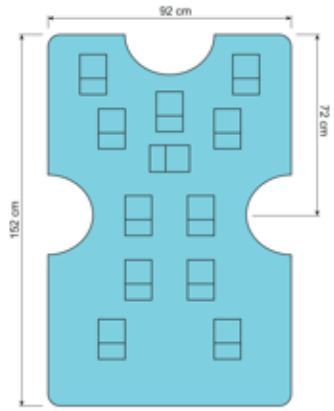
Product details

Product group name : EasyWarm
Size : One size
Descriptive feature : Single Use
Colour : Blue
Sterile : Non-sterile
Brand : BARRIER®

Product descriptions

Short description : Active self-warming blanket
Long description : EasyWarm is a non-sterile single-use blanket, intended to help prevent the patient from cooling during the perioperative period. The blankets are individually packed in vacuum bags. After removal of the blanket from the vacuum bag, the warming pads will start to generate heat when exposed to air.

Images



Delivered items

629900-00

Sales released in: Australia, Austria, Bahrain, Belgium, Bosnia and Herzegovina, Bulgaria, Chile, Colombia, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Japan, Jordan, Korea (the Republic of), Latvia, Libya, Lithuania, Luxembourg, Macedonia (the former Yugoslav Republic of), Malaysia, Malta, Martinique, Mauritius, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland
Country of origin: China

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Shelf life: 2 years
Sterilization method: Non-sterile
Production Responsibility: Copious International Inc., Wei 11 Road, Huada Street, New City, Heyuan, Guangdong, 517000, China
Packing information: First packaging layer is a tear open plastic bag. Second packaging layer is a plastic liner/bag. Third layer is a corrugated board transport box. Fourth layer is a corrugated board transport box.
Is suitable for Tray: No

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7332551998837			3432.429 cm3	785 g / -
Consumer pack	1	7332551999971	7332551999971			
Transport box	10	7332551998851	7332551998851	330x381x273 mm	34.324 dm3	7.85 / 6.78 kg
Pallet	360	7332551998844		800x1200x1788 mm		

Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Packaging Composition

Product Component	Composition
TRP box	100% corrugated cardboard. 100% recycled fiber content.
PE liner	100% Polyethylene PE liner and 100% polyethylene bubble plastic

Product Composition Patient Clothing, Active Self-Warming Blanket

Product Component	Composition
Main material	Polypropylene SMS (Spunbond Meltblown Spunbond) nonwoven 104 g/m²
Warming pads	Active coal, clay, salt, iron powder
Sewing thread	Polyester

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Product Performance Patient Clothing

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Ramp up time (after opening of the package)	N/A	T-1127	min	Approximately 30 minutes to reach 39 degrees Celsius	Mean value 31
Maintaining time (temperature at 39 degrees Celsius and above)	N/A	T-1127	h	≥10 hours	≥10
Product shall have acceptable burn time	16 CFR 1610 Class 1	N/A	s	Class I ≥3.5 s	≥3.5
The product shall have ignitability resistance	EN ISO 12952-1 EN, ISO 12952-3	N/A	Pass/fail	Cigarette and flame according to SS 876 00 01	Pass
The material is free of formaldehyde	BS EN ISO 14184-1:1999 UV-VIS	N/A	mg/kg	≤20	≤20
Particle release	EN ISO 9073-10	T-1006	Log_{10} (lint count)	≤ 4.0	Front and Reverse side: 2.8
Tensile strength - Dry, CD	EN 29073-3	T-229	N	> 30	59
Resistance to liquid penetration	EN ISO 811	T-280	cm H_2O	≥ 10	61
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100cm²	≤ 300	Mean value: 19
Bursting strength - Dry	EN ISO 13938-2	T-233	kPa	≥40	Blue nw: 133.5
Tear resistance - Dry, MD	EN ISO 9073-4	T-232	N	> 10	Blue nw: 21
Tear resistance - Dry, CD	EN ISO 9073-4	T-232	N	> 10	Blue nw: 21

Technical

Dimension

Dimension text	Dimension value
Length	152 cm
Width	92 cm

Instructions

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How product works :

BARRIER EasyWarm should be used by or under the supervision of a qualified health care professional.
BARRIER EasyWarm is intended for perioperative use in hospitals.
BARRIER EasyWarm should be used in ambient temperatures 18-24°C.
1. Remove from packaging by tearing at pre-cut tab.
2. Open and unfold the blanket completely.
3. Allow approx. 30 minutes for the blanket to warm.
4. Place the blanket on the patient with the warming pads facing up. Correct side indicated by “THIS SIDE UP” marking on the blanket.
The blanket should not be placed on patient’s face.
Do not tuck the blanket under patient’s arms, legs or body and do not place the blanket under the patient.
The anaesthetized patient’s hands, arms and limbs should not be placed on top of the blanket.
Fixation belts, tape, straps or supplemental bedding shall not be used on top of the blanket.
No extra weight or pressure should be added to the top of the blanket including supplemental bedding products, medical instruments and other weight bearing objects.
Monitor cutaneous response regularly, according to clinical judgment.
When accessing the patient, turn or slide the blanket and do not fold the blanket over itself.
The maximum time duration that the blanket can be used is 10 hours.

Precautions :

Do not use BARRIER EasyWarm on a patient with known hypersensitivity to the materials of the product.
• It is recommended to avoid direct skin contact in areas with bruising, swelling and frostbite.
• The warming pads are magnetic and not translucent. The blanket must be removed prior to images being taken by MRI or X-ray devices.
• Heat generated from the blanket may result in increased drug delivery from transdermal medication systems (patches).
• Do not reuse. If reused performance of the product may deteriorate, cross contamination may occur.

Warnings :

The blanket is not sterile. Take appropriate precautions, as necessary, to protect the sterile field

Classifications

Regulation type(s)	MDR Class IIb
CE Certificate Number :	UKCA 760665
Intended Purpose :	The active self-warming blanket is intended to help prevent the patient from cooling during the perioperative period.
MDR Classification Rule :	9
Conformity Annexes :	II
Measuring Function :	No
Notified body medical devices/PPE :	BSi 2797
Regulatory Released :	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Martinique, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland

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Applied standards : The standards presented below is a selection of the most essential standards that are adhered to.

EN 1041, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 15223-1, ISO 15223-2, EN ISO 10993-10, ISO 14001

Removable label

No

GMDN Code (Global Medical Device Nomenclature)

58416 Activated-medium surgical warming blanket

EMDN Code (European Medical Device Nomenclature)

T020103 SURGICAL THERMAL DRAPES

UNSPSC

42142106 Therapeutic heating or cooling blankets or drapes

Commodity Code

6307909200 BNS drapes mainly made of nonwovens

CE Responsibility / Legal Manufacturer

Molnlycke Health Care AB, Entreprenorsstraket 21, SE-431 53 Molndal Sweden

Basic UDIDI

733243000000000059K9

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