

63062 Perineal Cover

Complementary products to drapes

Product details

Product group name : Other supplementary products

Size : 20x42cm

Sterile : Sterile

Brand : BARRIER®

Product descriptions

Short description : Complementary products to drapes

Long description :

- The towels are intended to be used as sterile absorbent material during a surgical procedure. For absorption of liquids during surgical procedures.
- Baby blankets - single-use, absorbent, low-sensitising blanket for use with newborns.
- 3 ply Laminate rolls are intended to be used non-sterile as a fluid barrier. The material is impermeable to liquids and absorbent.

Images



Delivered items

63062-00

Country of origin: China

Shelf life: 5 years

Sterilization method: EtO

Packing information: First packaging layer is a peel-open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a corrugated board dispenser box. Third layer is a corrugated board transport box

Is suitable for Tray: No

Find out more at www.molnlycke.com

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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7313661267044			160 cm3	26.762 g / -
Consumer pack	1	6931747821648	6931747821648	150x290x0 mm		
Dispenser box	105	6931747821679	6931747821679	140x300x330 mm		
Transport box	210	6931747821686	6931747821686	300x320x350 mm	33.6 dm3	5.62 / 5.09 kg
Pallet	8400	7313661295641		800x1200x1880 mm	1804.8 dm3	249.8 kg / -

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
Primary Packaging	Top web: Paper, Base web:PE/PA Laminate
RET box	Corrugated board, 100% recycled pulp
TRP box	Corrugated board, 100% recycled pulp

Product Composition Drapes

Product Component	Composition
Drape material	Polyethylene film 50µm
Patch material	Polypropylene spunbond nonwoven 55g/m2
Adhesive material	Synthetic rubber based

Product Performance Surgical Drapes, EN 13795-1:2019 High Performance

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Characteristics	Test Method	Internal Test Method	Unit	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	Not required	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	6.0	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	0	0
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	1.4	1.5
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	324	190
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	195	192
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	196	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	98	32
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	104	-

Technical

Dimension

Dimension text	Dimension value
Width	20 cm
Length	42 cm

Instructions

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How product works :

The absorbent towels are intended to be used as sterile absorbent material during a surgical procedure. Baby blankets - single-use, absorbent, low-sensitising blanket for use with newborns.

The laminate roll is intended to be used non-sterile as fluid barrier.

Classifications

Regulation type(s)	MDD Class IS	MDD Class IS
Intended use MDD :	Used as a protective covering or a barrier to isolate a site of surgical incision or a surgical field from contamination found in operating theatre or catheterization laboratory, e.g. on instruments or tables.	Used as a protective covering or a barrier to isolate a site of surgical incision or a surgical field from contamination found in operating theatre or catheterization laboratory, e.g. on instruments or tables.
Notified body medical devices/PPE :	Notified Body (see CE certificate)	Notified Body (see CE certificate)

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

EN 13795, EN ISO 15223-1, EN ISO 13485, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 11607-1, EN ISO 11607-2

Removable label

Yes

GMDN Code (Global Medical Device Nomenclature)

47783 Patient surgical drape, single-use

UNSPSC

42132103 Patient barrier drapes

Commodity Code

3005100000 Wadding, Gauze, Dressings, drapes singlepacked - adhesive articles, Sets mainly consisting thereof

CE Responsibility / Legal Manufacturer

Xuchang Zhengde Environstar Medical Products Co., Ltd. Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang, Henan, China

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