

63619 OP-Towel, PRIMARY

Impermeable and absorbing drapes

Product details

Product group name: Non-adhesive OP-towels and OP-sheets
Size: 75 x 90cm
Descriptive feature: Absorbent
Sterile: Sterile
Brand: BARRIER®

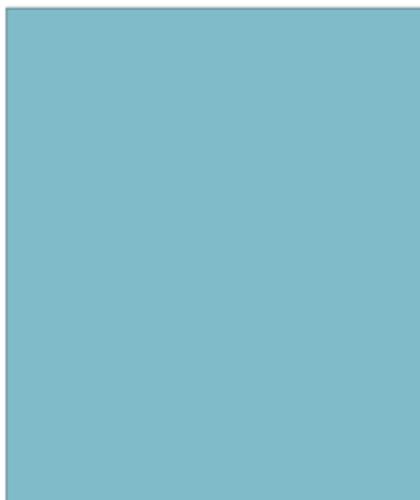
Product descriptions

Short description: Impermeable and absorbing drapes

Long description: BARRIER® non-adhesive Op-towels and OP-sheets are available in various sizes for general applications, contributing to a sterile working area.

- Impermeable material to prevent strikethrough.
- Absorbent top layer to contribute to a dry working area.
- Can be included in Mölnlycke® ProcedurePak® trays to support operating room efficiency.

Images

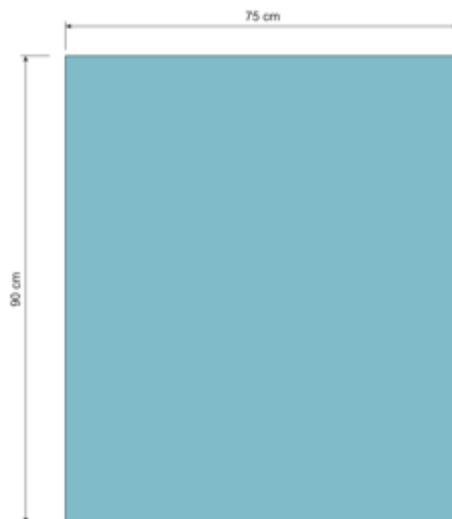


Find out more at www.molnlycke.com

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Delivered items

63619-00

Sales released in: Australia, Austria, Belgium, Chile, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hong Kong, Hungary, India, Ireland, Italy, Japan, Kuwait, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

Country of origin: China

Shelf life: 5 years

Sterilization method: EtO

Production Responsibility: 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

Packing information: First packaging layer is a peel-open sterile barrier, papaer/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

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
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Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7323190246144			373.333 cm ³	54.444 g / -
Consumer pack	1	6971004780257	6971004780257	290x150x0 mm		
Dispenser box	45	6971004780264	6971004780264	140x300x330 mm		
Transport box	90	6971004780271	6971004780271	300x320x350 mm	33.6 dm ³	4.9 / 4.38 kg
Pallet	1800	7323190246175		800x1200x1750 mm	1804.8 dm ³	98 kg / 178.4

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 content, FSC certified -C180555
TRP box	Corrugated board, 100% recycled content, FSC certified -C180555

Product Composition Drapes

Product Component	Composition
Drape material	Polypropylene nonwoven 28 g/m ²
Drape material	Polyethylene film 27 µm

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	-	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	8.4	14.4
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	2.04	2.04
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	>153	>153
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	184	184
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	177	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	85	85
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	92.9	-

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	1.1
Flammability	16 CFR 1610.4	N/A	s	Class I, > 3.5s

Technical

Dimension

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Dimension text	Dimension value
Outer dimension	75 cm x 90

Instructions

How product works:

The surgical patient drapes are intended to be used as protective patient coverings to create a sterile field for a surgical procedure.

Classifications

Regulation type(s)	MDR Class IS
Intended Purpose:	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)
Regulatory Released:	Austria, Belgium, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland

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

EN ISO 15223-1, EN ISO 13485, EN 13795-1, EN ISO 14971

Removable label

Yes

GMDN Code (Global Medical Device Nomenclature)

47783 Patient surgical drape, single-use

EMDN Code (European Medical Device Nomenclature)

T020199 SURGICAL DRAPES - OTHER

UNSPSC

42132103 Patient barrier drapes

Commodity Code

3005905000 Articles of Wadding, Gauze, Dressings, drapes singlepacked and Sets - textile

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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Basic UDIDI

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