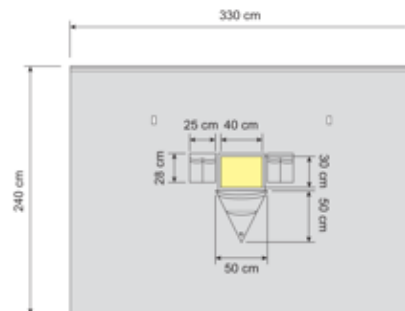
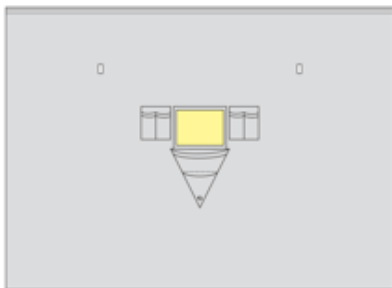


# 826020 Vertical Isolation Drape

## Product details

<b>Product group name :</b>	Vertical isolation drape
<b>Size :</b>	330cm x 240cm, Incise 40x30cm
<b>Descriptive feature :</b>	Incise film, Pouch
<b>Colour :</b>	Transparent
<b>Sterile :</b>	Sterile
<b>Brand :</b>	BARRIER®
<b>Equivalences :</b>	815301

## Images



## Delivered items

826020-78

**Country of origin:** Thailand

**Shelf life:** 5 years

**Sterilization method:** Irradiation

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

**Is suitable for Tray:** No

Find out more at [www.molnlycke.com](http://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	7332430080301				715.0 g / -
Consumer pack	1	07333350456764	07333350456764			
Dispenser box	8	07333350420246	07333350420246	246x366x569 mm		
Transport box	16	07333350369880	07333350369880	373x588x505 mm	110.8 dm3	11.4 / 8.4 kg
Pallet	192	7313661374902		800x1200x1659 mm	1592.6 dm3	162.3 kg / -

826020-14

**Country of origin:** Thailand**Shelf life:** 5 years**Sterilization method:** Irradiation**Production Responsibility:** Mölnlycke Health Care (Thailand) Ltd, 160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Road, Km 23 Tambol Bangsaothong, Amphur Bangsaothong, Samutprakarn 10570, Thailand**Packing information:** First packaging layer is a peel-open sterile barrier, plastic/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a plastic liner/bag. Third layer is a corrugated board dispenser 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	7332430080301			4840.1 cm3	653.5 g / -
Consumer pack	1	7323190030330	7323190030330			
Dispenser box	10	7323190028160	7323190028160	291x356x421 mm		
Transport box	20	7323190028153	7323190028153	371x593x440 mm	96.8 dm3	13.1 / 11.1 kg
Pallet	320	7323190028146		800x1200x1904 mm		

## Material

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<b>Animal tissues :</b>	No
<b>Human blood derivatives :</b>	No
<b>Natural rubber latex :</b>	No
<b>Medicinal substances :</b>	No
<b>Phthalates :</b>	No
<b>Polyvinyl chloride :</b>	No

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

Characteristics	Test Method	Internal Test Method	Unit	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	N/A	-	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	N/A	6	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm <sup>2</sup>	≤300	≤300	N/A	0	0
Particle release	EN ISO 9073-10	T-1006	Log <sub>10</sub> (lint count)	≤4.0	≤4.0	N/A	N/A, 1-ply PE-film	N/A, 1-ply PE-film
Resistance to liquid penetration	EN ISO 811	T-280	cm H <sub>2</sub> O	≥100	≥10	N/A	>150	>150
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A	72	72
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A	72	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	62	62	N/A
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	62	-	N/A

Technical

**Dimension**

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Dimension text	Dimension value
Outer dimension	330 cm x 240 cm
Incise	40 cm x 30 cm
Pouch	50 cm x 50 cm

### Disposal instructions

Used Mölnlycke products and sterile barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. Mölnlycke products do not contain any hazardous substances that can leach out if the products are land filled. Transport- and dispenser boxes are designed to fit existing recovery systems. The Mölnlycke packaging system complies with the EU Directive on packaging and packaging waste.

### Storage instructions

Mölnlycke Health Care recommends that Mölnlycke products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterile barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the sterile barrier is opened and the product is used.

### Classifications

Regulation type(s)	MDR Class IS	MDR Class IS	Locally Regulated	Locally Regulated
CE Certificate Number :	MDR 722028			
Intended Purpose :	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
MDR Classification Rule :	1			
Conformity Annexes :	IX			
Measuring Function :	No			
Notified body medical devices/PPE :	BSi 2797	BSi 2797	Local Authority CIS	Local Authority Mexico

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**Classifications**

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				
Intended Purpose :	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority Bosnia	Local Authority United Arab Emirates	Local Authority New Zealand	Saudi Authority

**Classifications**

Regulation type(s)	Locally Regulated	Locally Regulated	Locally Regulated	Locally Regulated
CE Certificate Number :				
Intended Purpose :	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority Hong Kong	Local Authority Hong Kong	Local Authority MEA	Local Authority Bosnia

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## Classifications

Regulation type(s)	Locally Regulated	AU Class IS	Class I	Class I
CE Certificate Number :		MDR 722028		
Intended Purpose :	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
Notified body medical devices/PPE :	Local Authority Thailand	TGA (Australia)	PMDA (Japan)	PMDA (Japan)

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

EN 1041, EN 556-1, EN 13795, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, ISO 15223-2, ISO 14001

### Removable label

Yes

### GMDN Code (Global Medical Device Nomenclature)

47783 Patient surgical drape, single-use

### UNSPSC

42131701 Surgical drapes

### Commodity Code

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

### CE Responsibility / Legal Manufacturer

Mölnlycke Health Care AB, Gamlestadsvägen 3c, Box 13080, SE-402 52 Goteborg Sweden

### Basic UDIDI

733243000000000322JZ

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