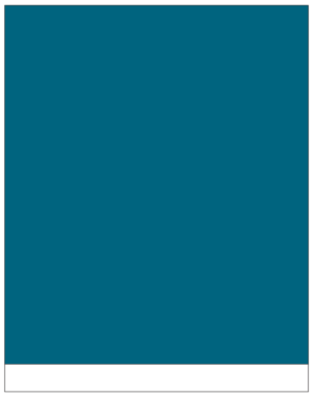
706100
Adhesive Absorbent Pad

Product details

Size: 55cm x 70cm
Descriptive feature: Adhesive, full length
Sterility: Sterile

Images



Delivered items

706100-09

Sales released in: Australia, Austria, Azerbaijan, Bahrain, Belgium, Czechia, Denmark, Finland, Germany, Hong Kong, Hungary, Iceland, Ireland, Italy, Luxembourg, Macedonia (the former Yugoslav Republic of), Moldova (the Republic of), Netherlands, New Zealand, Norway, Portugal, Russian Federation, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland
Country of origin: Belgium
Shelf life: 5 years
Sterilization method: Beta
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 corrugated board dispenser box. Third layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Consumer pack	1	7323190020065
Dispenser box	40	7323190019977

Packaging level	Pack count	GS1 code
Transport box	80	7323190019960
Pallet	1920	7323190019953

Material

Animal tissues:

No

Human blood derivatives:

No

Medicinal substances:

No

Phthalates:

No

Polyvinyl chloride:

No

Product Composition Drapes

Product Component	Critical Area	Less Critical Area
Drape material	Viscose/Polyester nonwoven 80 g/m²	Viscose/Polyester nonwoven 80 g/m²
Drape material	Polyethylene film 40 µm	Polyethylene film 40 µm
Adhesive material	Synthetic rubber based	N/A

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Absorption	ISO 9073-12	T-1158	g/dm²	3.66	3.66
Flammability	16 CFR 1610.4	N/A	s	Class 1, >3.5s	Class 1, >3.5s

Product Performance Sterile Drapes, EN 13795 High Performance

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 - Particulate Matter	EN ISO 9073-10	T-1006	IPM	≤3.5	≤3.5	1.5	1.5
Linting	EN ISO 9073-10	T-1006	Log_{10} (lint count)	≤4.0	≤4.0	1.8	1.8
Resistance to liquid penetration	EN 20811	T-280	cm H_2O	≥100	≥10	>100	>100
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	168	168
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	144	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	36	36
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	28	-

Technical

Dimension

Dimension text	Dimension value
Outer dimension	55 cm x 70 cm

Disposal instructions

Non-hazardous waste used BARRIER products and sterility 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. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.

Storage instructions

Mölnlycke Health Care recommends that BARRIER 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 sterility 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 package is opened and the product is used.

Classification

Regulation type	**MDD Class IS**	**Locally Regulated**	**Unregulated**
MDD Classification Rule:	1		
CE Certificate Number:	CE 01966		
Notified body medical devices/PPE:	BSI (0086)		
Intended use MDD:	Surgical drapes, when sterilised, are intended to minimize the spread of micro-organisms, in order to reduce the risk for post operative wound infection.		
Sales released in:	Austria, Belgium, Czechia, Denmark, Finland, Germany, Hungary, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Australia, Azerbaijan, Bahrain, Moldova (the Republic of), New Zealand, Russian Federation, United Arab Emirates	Hong Kong, Macedonia (the former Yugoslav Republic of)

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

MÖLNLYCKE
HEALTH CARE

Göteborg 2006-08-07

To Whom It may concern:

We hereby declare that,

Following Mölnlycke Health Care surgical drapes comply with the High Performance requirements of EN13795:

- Klinidrape® laminated Patient Drapes
- BARRIER® reinforced and laminated Patient Drapes
- Klinidrape® and BARRIER® Stockinettes and plastic/laminated Leggings
- Klinidrape® and BARRIER® Table Covers and Mayo Stand Covers

Following Mölnlycke Health Care surgical drapes comply with the Standard Performance requirements of EN13795:

- Klinidrape® Utility Drapes
- BARRIER® non-reinforced Patient Drapes (less critical area)
- Klinidrape® and BARRIER® nonwoven OP-tapes (less critical area)
- Klinidrape® and BARRIER® fluid repellent Leggings and Supplementary Products (less critical area)

Mölnlycke Health Care standard Klinidrape® and BARRIER® Surgical Gowns comply with the Standard Performance requirements of EN13795.

Mölnlycke Health Care reinforced Klinidrape® and BARRIER® Surgical Gowns comply with the High Performance requirements of EN13795

Mölnlycke Health Care Clean Air Suits comply with the performance requirements of EN13795

Anders Odmyr
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Drapes and Sets

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