

906677

Adhesive OP-Towel

Product details

Size: 90cm x 75cm

Descriptive feature: 3-ply, Adhesive

Sterility: Sterile

Images



Delivered items

906677-20

Country of origin: Belgium

Shelf life: 5 years

Sterilization method: Beta

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 cardboard dispenser box. Third layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Consumer pack	1	7332430980311
Dispenser box	32	7323190180707

Packaging level	Pack count	GS1 code
Transport box	192	7323190180691
Pallet	2880	7323190180684

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 nonwoven 23 g/m ²	Viscose nonwoven 23 g/m ²
Drape material	Polyethylene film 40 µm	Polyethylene film 40 µm
Drape material	Polypropylene nonwoven 12 g/m ²	Polypropylene nonwoven 12 g/m ²
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/dm ²	1.17	1.17
Flammability	16 CFR 1610.4	N/A	s	Class I, > 3.5s	Class I, >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	2.3	2.3
Linting	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	2.5	2.5
Resistance to liquid penetration	EN 20811	T-280	cm H ₂ O	≥100	≥10	203	203
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	91	91
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	74	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	29	29
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	28	-

Technical

Dimension

Dimension text	Dimension value
Outer dimension	90 cm x 75 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
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.

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

No

GMDN Code (Global Medical Device Nomenclature)

47783

