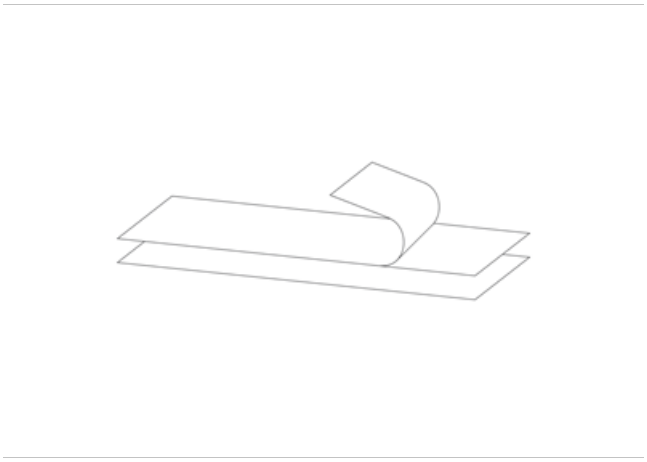
381045 OP-Tape

Product details

Size: 9cm x 49cm
Descriptive feature: 2 pcs, Adhesive
Sterility: Sterile

Images



Delivered items

381045-20

Country of origin: Czechia
Shelf life: 5 years
Sterilization method: Gamma
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.

Packaging level	Pack count	GS1 code
Consumer pack	2	7323190177424
Dispenser box	120	7323190168781
Transport box	480	7323190168774

Packaging level	Pack count	GS1 code
Pallet	23040	7323190168767

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	Polyester nonwoven 40 g/m²	N/A
Drape material	Polyethylene film 27.5 µm	N/A
Adhesive material	Synthetic rubber based	N/A

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	-	-

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 - 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	1.2	-
Linting	EN ISO 9073-10	T-1006	Log_{10} (lint count)	≤4.0	≤4.0	1.0	-
Resistance to liquid penetration	EN 20811	T-280	cm H_2O	≥100	≥10	>100	-
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	82	-
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	58	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	28	-
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	26	-

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	N/A	N/A

Characteristics	Test Method	Internal Test Method	Unit	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s	Class I, >3.5s

Technical

Dimension

Dimension text	Dimension value
Outer dimension	9 cm x 49 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)		

Regulation type	MDD Class IS	Locally Regulated	Unregulated
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)

58484