

906544 Aperture Drape

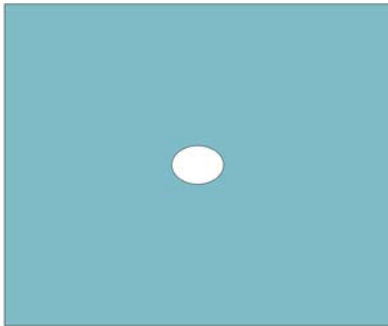
Product details

Size: 50cm x 60cm, Aperture 6 cm x 8 cm

Descriptive feature: Centered ellipse aperture

Sterility: Sterile

Images



Delivered items

906544-20

Country of origin: Thailand

Shelf life: 5 years

Sterilization method: Irradiation

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	1	7323190179725
Dispenser box	100	7323190178605
Transport box	400	7323190178599
Pallet	6400	7323190178582

Material

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 27.5 µm	Polyethylene film 27.5 µm

Product Performance Sterile Drapes, EN 13795 Standard Performance

Characteristic	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	≥2.8	Not required	6.0	-
Cleanliness - Particulate Matter	EN ISO 9073-10	T-1006	IPM	≤3.5	≤3.5	2.2	2.2
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	≥30	≥10	> 100	> 100
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	80	80
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	51	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥15	≥15	24	24
Tensile strength - Wet	EN 29073-3	T-229	N	≥15	Not required	24	-

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	0.75	0.75
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s	Class I, >3.5s

Technical

Dimension

Dimension text	Dimension value
Outer dimension	50 cm x 60 cm
Aperture	6 cm x 8 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

Yes

GMDN Code (Global Medical Device Nomenclature)

47783