

610601

Mayo Stand Cover

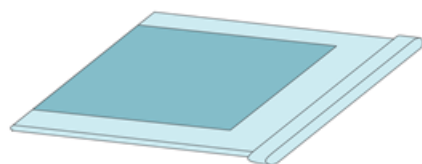
Product details

Size: 79cm x 145cm

Descriptive feature: Absorbent

Sterility: Sterile

Images



Delivered items

610601-07

Country of origin: Belgium

Shelf life: 5 years

Sterilization method: Beta

Packing information: First packaging layer is a plastic container/jar with a plastic pump. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Consumer pack	1	7332430977687
Dispenser box	25	7332430977670
Transport box	75	7332430977663

Packaging level	Pack count	GS1 code
Pallet	1500	7332430977656

Material

Animal tissues:

No

Human blood derivatives:

No

Medicinal substances:

No

Phthalates:

No

Polyvinyl chloride:

No

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 1, >3.5s	Class 1, >3.5s

Product Composition Drapes

Product Component	Critical Area	Less Critical Area	Edge Area
Patch material	N/A	Viscose nonwoven 27 g/m ²	N/A
Drape material	N/A	Polyethylene film 60 µm	Polyethylene film 60 µm

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	N/A - no critical area	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	N/A - no critical area	-
Cleanliness - Particulate Matter	EN ISO 9073-10	T-1006	IPM	≤3.5	≤3.5	N/A - no critical area	1,8
Linting	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	N/A - no critical area	2.5
Resistance to liquid penetration	EN 20811	T-280	cm H ₂ O	≥100	≥10	N/A - no critical area	≥ 150
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - no critical area	74
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - no critical area	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	N/A - no critical area	38
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	N/A - no critical area	-

Technical

Dimension

Dimension text	Dimension value
Outer dimension	79 cm x 145 cm
Absorbent	65 cm x 85 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
CE Certificate Number:	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