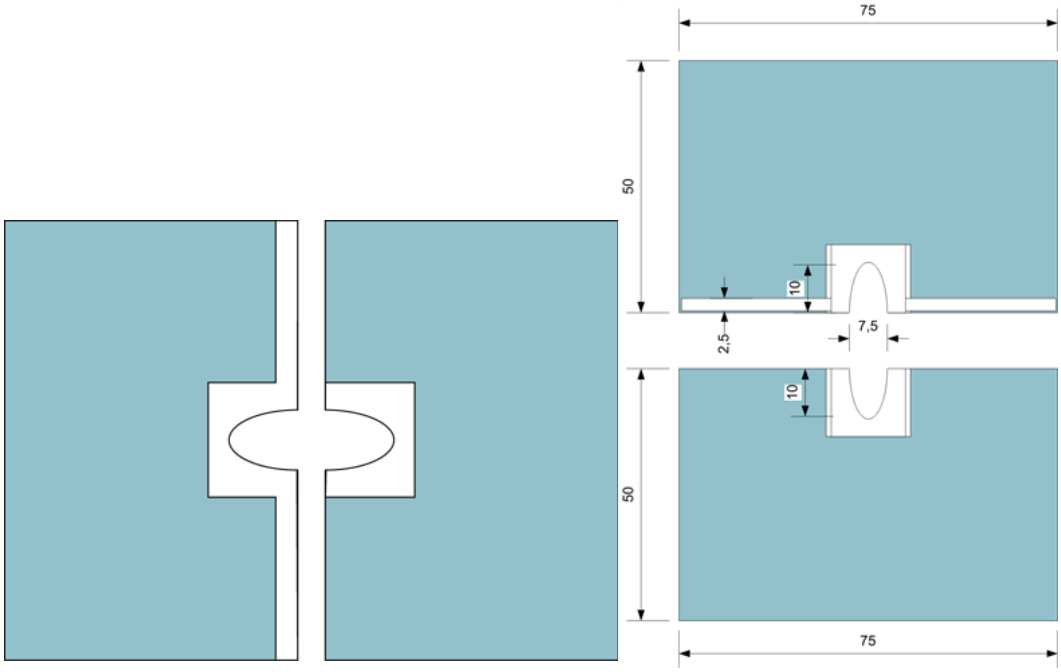
706620 Adhesive Aperture Drape



Size And Description	50x75cm ap. 2x 7,5x10 cm
Other information	Product sheet is available in MRM Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	40
Transport Box Quantity	240
Pallet Quantity	4320
Standard	EN 13795 High Performance EN 13795 ISO 10993 ISO 14001
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Material composition

Areas Materials	Critical area	Less critical area
Drape material	Nonwoven 23 g/m2	Nonwoven 23 g/m2
	PE-film 40 microns	PE-film 40 microns

Product Performance according to EN 13795

Characteristic	Unit	High Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration - Dry	Log10 (CFU)	Not required	≤ 2 a	0	0
Resistance to microbial penetration - Wet	BI	6 b, c	Not required	6	6
Cleanliness - Microbial	Log10 (CFU/dm2)	≤ 2	≤ 2	NA (sterile)	NA (sterile)
Cleanliness - Particulate matter	IPM	≤ 3.5	≤ 3.5	2.1	2.1
Linting	Log10 (lint count)	≤ 4.0	≤ 4.0	2.1	2.1
Resistance to liquid penetration	cm H2O	≥ 100	≥ 10	>100	>100
Bursting strength - Dry	kPa	≥ 40	≥ 40	78	78
Bursting strength - Wet	kPa	≥ 40	Not required	50	50
Tensile strength - Dry	N	≥ 20	≥ 20	31	31
Tensile strength - Wet	N	≥ 20	Not required	33	33

a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 BI are probably not different, materials varying by more than 0,98 BI probably are different (The 95% confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives).
c) BI = 6,0 for the purpose of this standard means no penetration. BI = 6,0 is the maximum achievable value.

Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

Aditional Tests
Absorption: 2,1ml/dm2
Lint
Laboratory report: 20081104-006

Instruction Intended Use	Surgical drapes, when sterilised, are intended to minimize the spread of microorganisms in order to reduce the risk for post operative wound infection.
Sterilization Method	Irradiation
MDD Classification	Class I Sterile

CEMark Certificate	01966
Instruction Storage	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.
Instruction Disposal Waste	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.
Shelf Life	5 years