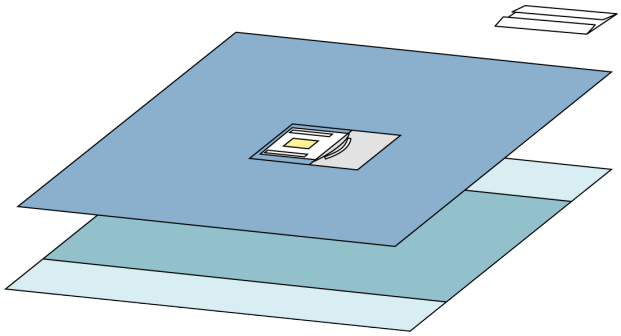
903167 OPHTHALMIC SET



Included Article Numbers	-	1	Cellulose Towel 18x25cm	Popierinis ranksluostis 10x25 cm
	900057	1	Ophthalmic Drape w/pouch 140x150cm, incise 8x10cm	Oftalmologinis apklotas su maišeliu (skysčiams) 140x150 cm, incizijos (plėvelės) dydis 8x10 cm
	90150	1	Table Cover 150x150cm, abs. 75x150cm	Stalelio apklotas 150x150cm, absorbuojantis plotas 75x150 cm
Other information	Removable Label			
Country Of Origin	Thailand			
Dispenser Box Quantity	16			
Transport Box Quantity	32			
Standard	EN 13795 High Performance EN 13795 ISO 10993 ISO 14001 ISO 9001 ISO 13485			
Label Of Standard	EN 1041 CEE 93/42 ISO 15223			
Instruction Intended Use	The product shall help to create an isolated sterile working area for surgical interventions, thus protecting patient from 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.

Material data

Included Article Numbers	-	1	Cellulose Towel	18x25cm

Included Article Numbers 900057 1 Ophthalmic Drape w/pouch 140x150cm, incise 8x10cm
Incizinė plėvelė

Material composition

Areas **Materials**	**Critical area** Polietileno plėvelė 50 mikrometrų storio	**Less critical area** Polietileno plėvelė 50 mikrometrų storio
Drape material	PE-film 50 microns	PE-film 50 microns
	Paper tissue 20 g/m2	Paper tissue 20 g/m2
The material is typically used as drape material where the top layer is the PE-film and the Tissue is on the comfort side.		

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	NA (plastic film)	NA (plastic film)
Linting	Log10 (lint count)	≤ 4.0	≤ 4.0	NA (plastic film)	NA (plastic film)
Resistance to liquid penetration	cm H2O	≥ 100	≥ 10	>140	>140
Bursting strength - Dry	kPa	≥ 40	≥ 40	175	75
Bursting strength - Wet	kPa	≥ 40	Not required	110	65
Tensile strength - Dry	N	≥ 20	≥ 20	35	35
Tensile strength - Wet	N	≥ 20	Not required	35	40

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.

Included Article Numbers 90150 1 Table Cover 150x150cm, abs. 75x150cm

Material composition

Areas Materials	**Critical area** Viskozė neaustinė	**Less critical area**
Drape material	Viscose nonwoven 23 g/m2	
	PE-film 55 microns	PE-film 55 microns
	Polietileno plėvelė 55 mikrometrų storio	Polietileno plėvelė 55 mikrometrų storio

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	NA	0
Resistance to microbial penetration - Wet	BI	6 b, c	Not required	6	NA
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	> 140	> 140
Bursting strength - Dry	kPa	≥ 40	≥ 40	125	75
Bursting strength - Wet	kPa	≥ 40	Not required	100	70
Tensile strength - Dry	N	≥ 20	≥ 20	55	50
Tensile strength - Wet	N	≥ 20	Not required	60	45

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 capacity, ml/100cm2; 2,1ml