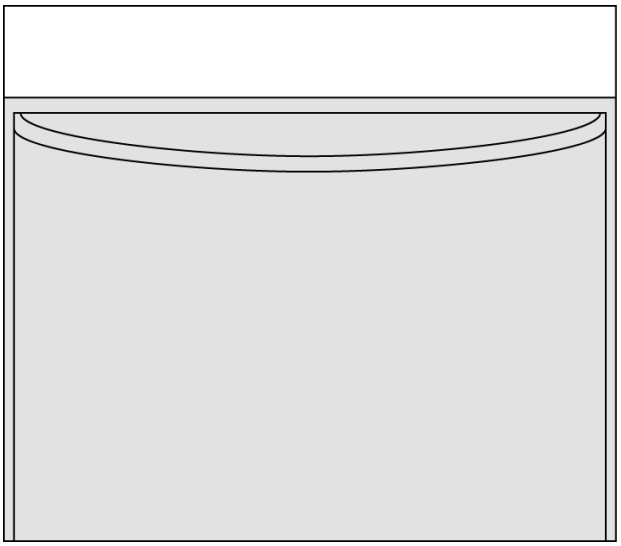
706035 Fluid Collection Pouch

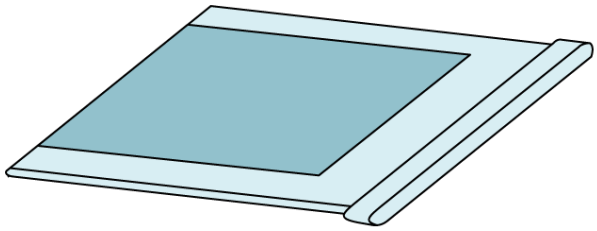


Size And Description	40x35cm, adh.
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	30
Transport Box Quantity	120
Pallet Quantity	5760
Standard	ISO 11607-1 ISO 10993 ISO 14001 ISO 14971-1 ISO 9001 ISO 13485
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Instruction Intended Use	The products shall manage or absorb fluids and/or handle instruments during surgical interventions.
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

610601 Mayo Stand Cover



Size And Description	79x145cm, abs. 65x85cm
Other information	Removable label
Sterile	Yes
Country Of Origin	Belgium
Sterility barrier quantity	1
Dispenser Box Quantity	25
Transport Box Quantity	75
Pallet Quantity	1500
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	Viscose nowoven 27 g/m2	
	PE-film 60 microns	PE-film 60 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 critica 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	1.9	NA (plastic film)
Linting	Log10 (lint count)	≤ 4	≤ 4	2.1	NA (plastic film)
Resistance to liquid penetration	cm H2O	≥ 100	≥ 10	> 140	> 140
Bursting strength - Dry	kPa	≥ 40	≥ 40	120	50
Bursting strength - Wet	kPa	≥ 40	Not required	80	50
Tensile strength - Dry	N	≥ 20	≥ 20	75	65
Tensile strength - Wet	N	≥ 20	Not required	75	70

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.

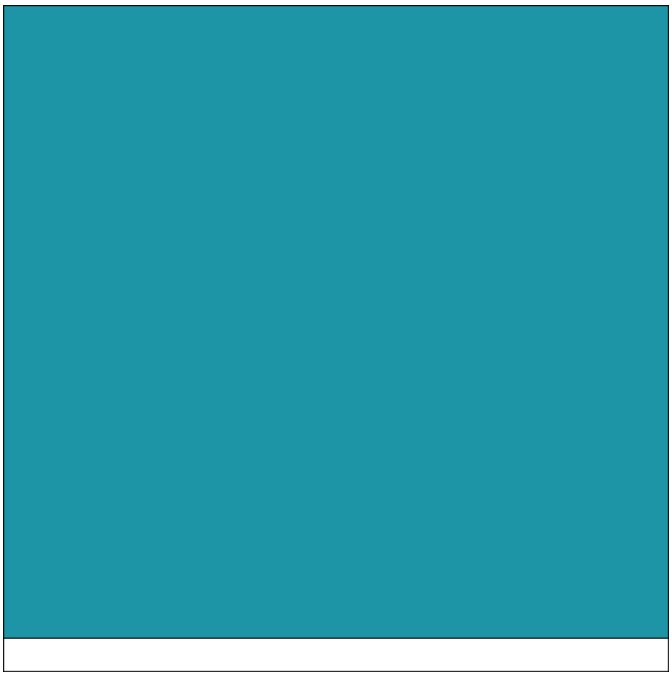
Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

Additional tests

Absorption: 2,2ml/dm2
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

706900 Adhesive OP-Towel



Size And Description	100x100cm, 3-ply
Other information	Removable label
Sterile	Yes
Country Of Origin	Belgium
Sterility barrier quantity	1
Dispenser Box Quantity	43
Transport Box Quantity	86
Pallet Quantity	2064
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
	Paper tissue 20 g/m2	Paper tissue 20 g/m2

Product performance according to EN 13795

Characteristic	Unit	High Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critica 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	900	900
Bursting strength - Dry	kPa	≥ 40	≥ 40	102	78
Bursting strength - Wet	kPa	≥ 40	Not required	50	50
Tensile strength - Dry	N	≥ 20	≥ 20	32	31
Tensile strength - Wet	N	≥ 20	Not required	36	33

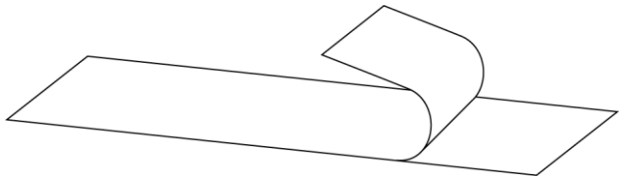
a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials 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.

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

381035 OP-Tape



Size And Description	9x49cm Impervious.
Sterile	Yes
Country Of Origin	Czech Republic
Sterility barrier quantity	1
Dispenser Box Quantity	100
Transport Box Quantity	400
Pallet Quantity	19200
Standard	EN 13795 High Performance EN 13795 ISO 10993 ISO 14001 ISO 14971-1 ISO 9001 ISO 13485
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Material composition

Areas Materials	Critical area	Less critical area
Drape material	Polyester nonwoven 40g/m2	Polyester nonwoven 40g/m2
	PE-film 27,5 microns	PE-film 27,5 microns
The tape is protected by a siliconised paper. The adhesive is a medical grade synthetic rubber based adhesive coated on the polyethylene film 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 critica 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	1.2	1.2
Linting	Log10 (lint count)	≤ 4.0	≤ 4.0	1.0	1.0
Resistance to liquid penetration	cm H2O	≥ 100	≥ 10	>100	>100
Bursting strength - Dry	kPa	≥ 40	≥ 40	-	-
Bursting strength - Wet	kPa	≥ 40	Not required	137	137
Tensile strength - Dry	N	≥ 20	≥ 20	MD 112, CD 26	MD 112, CD 26
Tensile strength - Wet	N	≥ 20	Not required	MD 110, CD 25	MD 110, CD 25

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.

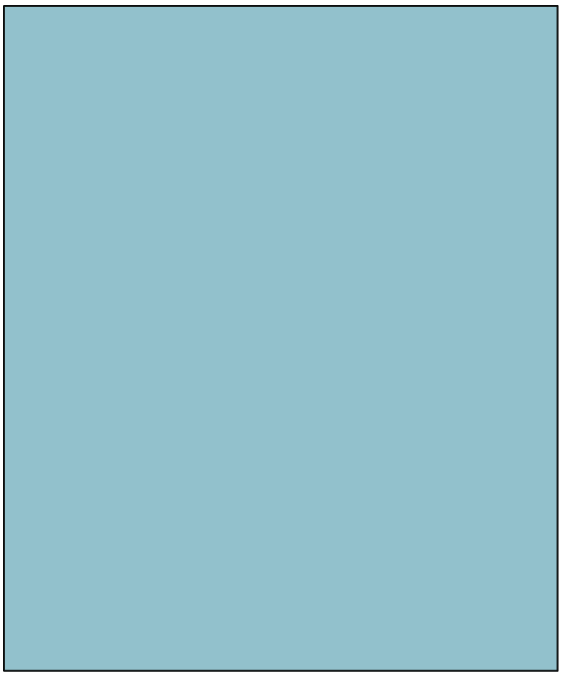
Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

Aditional Tests

Adhesion strength to human skin:
1,5N/25mm.

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

800530 OP-Towel



Size And Description	75x90cm, 2-ply
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	40
Transport Box Quantity	240
Pallet Quantity	4320
Standard	EN 13795 Standard 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	Paper tissue 27 g/m2	Paper tissue 27 g/m2
	PE-film 27,5 microns	PE-film 27,5 microns

Product Performance according to EN 13795

Characteristic	Unit	Standard Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critica product area
Resistance to microbial penetration - Dry	Log10 (CFU)	Not required	≤ 2 a	0	0
Resistance to microbial penetration - Wet	BI	≥ 2.8 b	Not required	6	6
Cleanliness - Microbial	Log10 (CFU/dm2)	≤ 2	≤ 2	NA (sterile)	NA (sterile)
Cleanliness - Particulate matter	IPM	≤ 3.5	≤ 3.5	0.3	0.3
Linting	Log10 (lint count)	≤ 4.0	≤ 4.0	3.4	3.4
Resistance to liquid penetration	cm H2O	≥ 30	≥ 10	100	100
Bursting strength - Dry	kPa	≥ 40	≥ 40	67	67
Bursting strength - Wet	kPa	≥ 40	Not required	48	48
Tensile strength - Dry	N	≥ 15	≥ 15	20	20
Tensile strength - Wet	N	≥ 15	Not required	28	28

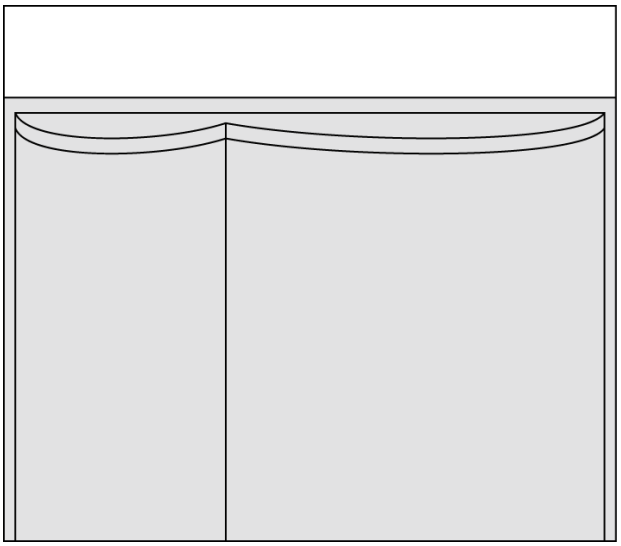
a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials 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).

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

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

707035 Suction and Diathermy Bag

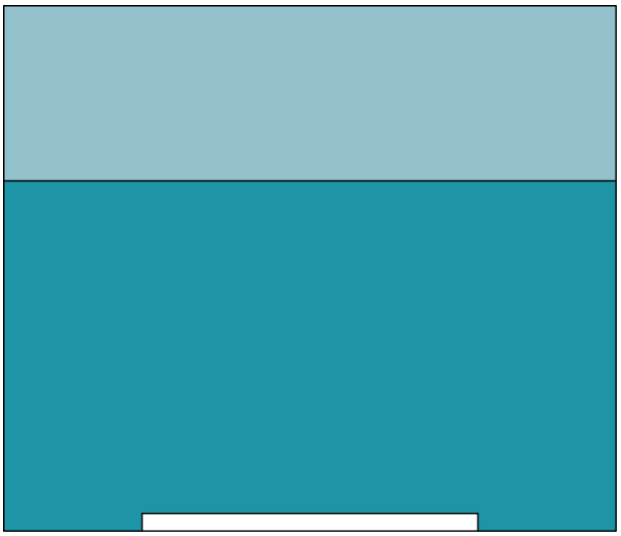


Size And Description	40x35cm, adh.
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	30
Transport Box Quantity	120
Pallet Quantity	5760
Standard	ISO 11607-1 ISO 10993 ISO 14001 ISO 14971-1 ISO 9001 ISO 13485
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Instruction Intended Use	The products shall manage or absorb fluids and/or handle instruments during surgical interventions.
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

777400 Adhesive OP-Sheet



Size And Description	175x150cm, 3-ply
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	15
Transport Box Quantity	30
Pallet Quantity	720
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
	Paper tissue 20 g/m2	Paper tissue 20 g/m2

Product performance according to EN 13795

Characteristic	Unit	High Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critica 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	900	900
Bursting strength - Dry	kPa	≥ 40	≥ 40	102	78
Bursting strength - Wet	kPa	≥ 40	Not required	50	50
Tensile strength - Dry	N	≥ 20	≥ 20	32	31
Tensile strength - Wet	N	≥ 20	Not required	36	33

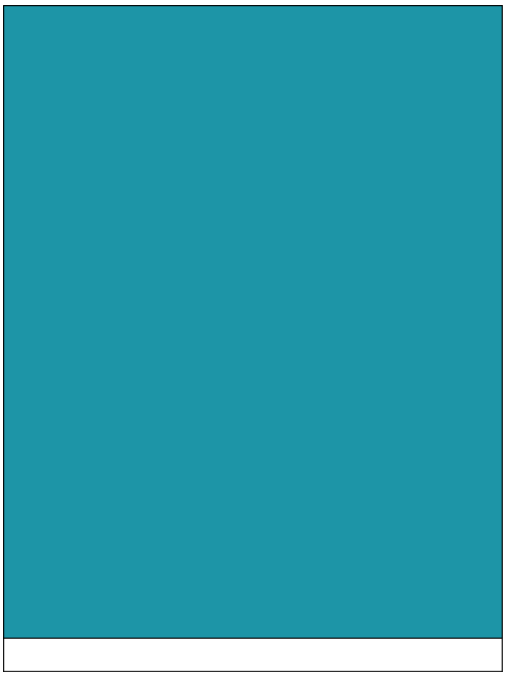
a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials 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.

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

706700 Adhesive OP-Towel



Size And Description	75x100cm, 3-ply
Sterile	Yes
Country Of Origin	Belgium
Sterility barrier quantity	1
Dispenser Box Quantity	22
Transport Box Quantity	132
Pallet Quantity	1980
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
	Paper tissue 20 g/m2	Paper tissue 20 g/m2

Product performance according to EN 13795

Characteristic	Unit	High Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critica 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	900	900
Bursting strength - Dry	kPa	≥ 40	≥ 40	102	78
Bursting strength - Wet	kPa	≥ 40	Not required	50	50
Tensile strength - Dry	N	≥ 20	≥ 20	32	31
Tensile strength - Wet	N	≥ 20	Not required	36	33

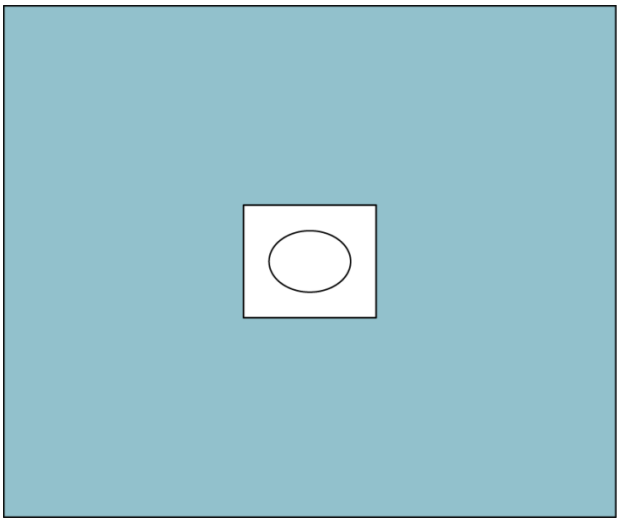
a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials 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.

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

906693 Adhesive Aperture Drape



Size And Description	50x60cm, ap. 6x8cm
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	75
Transport Box Quantity	300
Pallet Quantity	4800
Standard	EN 13795 Standard 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	Viscose nowoven 23 g/m2	Viscose nowoven 23 g/m2
	PE-film 27,5 microns	PE-film 27,5 microns

Product Performance according to EN 13795

Characteristic	Unit	Standard Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critica product area
Resistance to microbial penetration - Dry	Log10 (CFU)	Not required	≤ 2 a	0	0
Resistance to microbial penetration - Wet	BI	≥ 2,8 b	Not required	6	6
Cleanliness - Microbial	Log10 (CFU/dm2)	≤ 2c	≤ 2c	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	≥ 30	≥ 10	> 800	> 800
Bursting strength - Dry	kPa	≥ 40	≥ 40	82	82
Bursting strength - Wet	kPa	≥ 40	Not required	67	67
Tensile strength - Dry	N	≥ 15	≥ 15	41	41
Tensile strength - Wet	N	≥ 15	Not required	23	23

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).

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

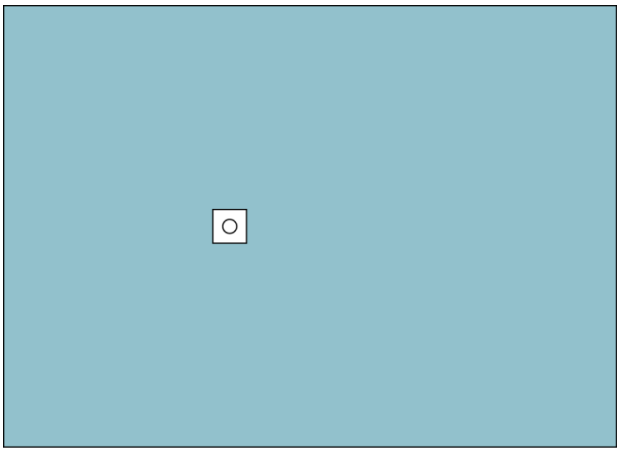
Aditional Tests

Absorption less critical area: 2,1ml/dm2

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

708870 Adhesive Aperture Drape



Size And Description	200x280cm, ap. 15cm, 100cm from top
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	15
Transport Box Quantity	30
Pallet Quantity	600
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 critica 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.

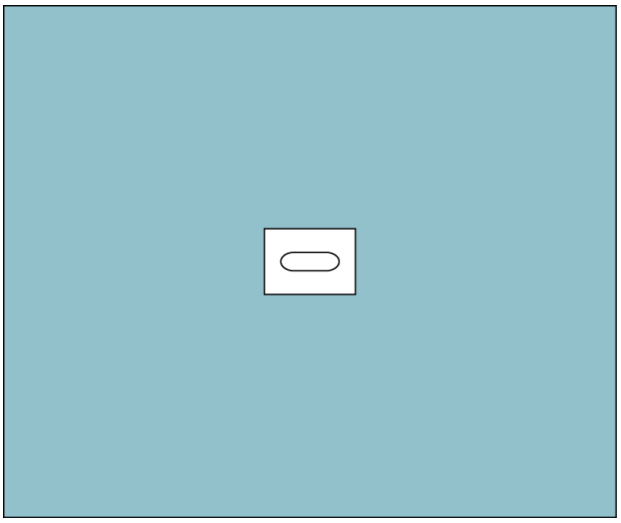
Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

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

708850 Adhesive Aperture Drape



Size And Description	150x180cm, ap. 5x15cm
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	20
Transport Box Quantity	40
Pallet Quantity	960
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 critica 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.

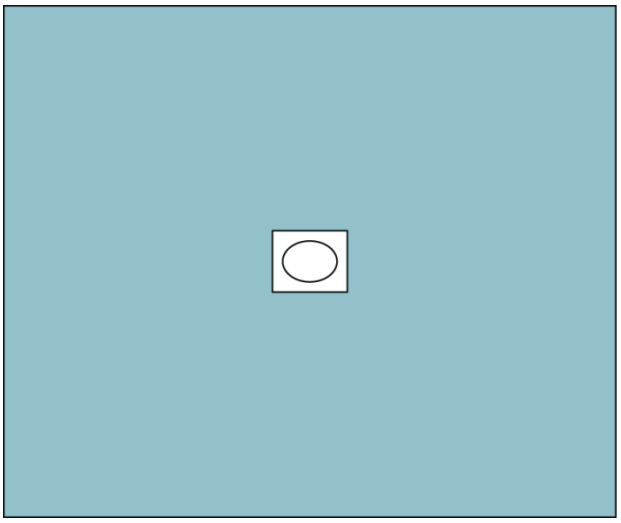
Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

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

906542 Adhesive Aperture Drape



Size And Description	75x90cm, ap. 6x8cm
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	40
Transport Box Quantity	160
Pallet Quantity	2560
Standard	EN 13795 Standard 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	Viscose nowoven 23 g/m2	Viscose nowoven 23 g/m2
	PE-film 27,5 microns	PE-film 27,5 microns

Product Performance according to EN 13795

Characteristic	Unit	Standard Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critica product area
Resistance to microbial penetration - Dry	Log10 (CFU)	Not required	≤ 2 a	0	0
Resistance to microbial penetration - Wet	BI	≥ 2,8 b	Not required	6	6
Cleanliness - Microbial	Log10 (CFU/dm2)	≤ 2c	≤ 2c	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	≥ 30	≥ 10	> 800	> 800
Bursting strength - Dry	kPa	≥ 40	≥ 40	82	82
Bursting strength - Wet	kPa	≥ 40	Not required	67	67
Tensile strength - Dry	N	≥ 15	≥ 15	41	41
Tensile strength - Wet	N	≥ 15	Not required	23	23

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).

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

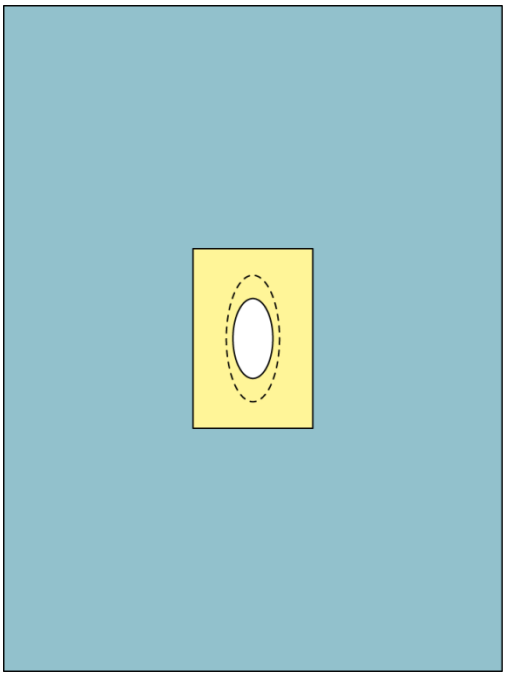
Aditional Tests

Absorption less critical area: 2,1ml/dm2

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

84551230 Adhesive Aperture Drape



Size And Description	75x100cm, ap. incise 6x12cm, wrapped
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	20
Transport Box Quantity	120
Pallet Quantity	2160
Standard	EN 13795 High Performance EN 13795 ISO 11607-1 ISO 10993 ISO 14001 ISO 14971-1 ISO 9001 ISO 13485
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 critica 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.

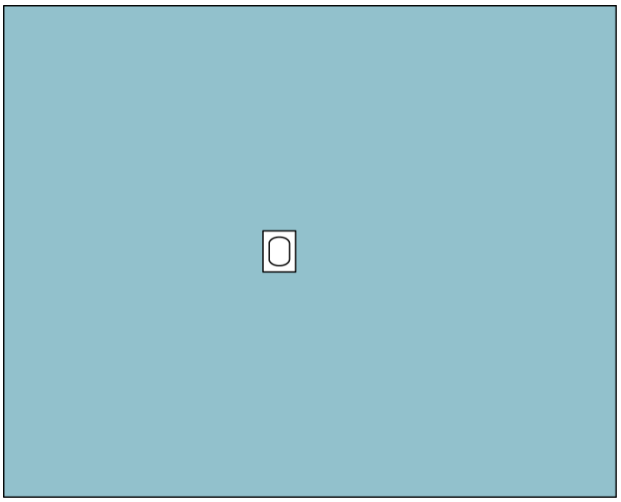
Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

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

935569 Adhesive Aperture Drape



Size And Description	120x150cm, ap. 5x7cm, 65cm from top
Other information	Removable label
Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	18
Transport Box Quantity	108
Pallet Quantity	1620
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 critica 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