

888142 Craniotomy Set

Procedure-specific drape with integrated incise film

Product details

Product group name : Craniotomy drapes and sets

Sterile : Sterile

Brand : BARRIER®

Product descriptions

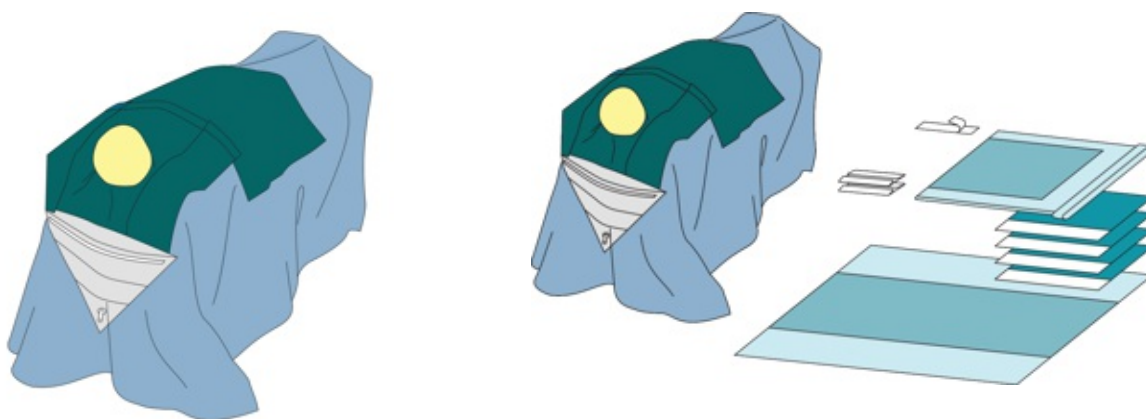
Short description : Procedure-specific drape with integrated incise film

Long description : BARRIER® drapes and sets for neurosurgery support patient safety with effective and efficient infection control.

The drapes are made of impermeable materials to help protect against liquid and bacteria strikethrough for the safety of the patient. Absorbent working area and fluid collection pouches help maintain a dry working area. The all-in-one design offers integrated relevant features and allow for easy and efficient draping by one person.

- Integrated clear and stretchable incise film for secure attachment.
- Integrated fluid collection pouch with outlets for effective fluid management and covered flex wire edges to stabilise the pouch when expanded.
- Extra foldings down the sides channels the fluid into the pouch, for effective fluid management.
- Integrated strong sieve for easy and safe collection of samples.
- Folded and packaged for easy, aseptic application by one person.
- Our drapes can be included in Mölnlycke® ProcedurePak® trays to support operating room efficiency.

Images



Products included in set

Find out more at www.molnlycke.com

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Product ID	Quantity	Product name	Size
996106	1	Mayo Stand Cover	79cm x 145cm
	2	Cellulose Towel	18cm x 25cm
911500	1	OP-Tape	9cm x 49cm
947064	4	Adhesive OP-Towel	50 x 50cm
965524	1	Craniotomy Drape	230cm x 300cm, Incise 30x20cm
90190	1	Table Cover	150cm x 190cm

Delivered items

888142-78

Country of origin: Thailand**Shelf life:** 5 years**Sterilization method:** Irradiation**Production Responsibility:** Mölnlycke Health Care (Thailand) Ltd, 160 Moo 17 Bangplee Industrial Estate, Bangna-Trad Road, Km 23 Tambol Bangsaothong, Amphur Bangsaothong, Samutprakarn 10570, Thailand**Packing information:** First packaging layer is a peel-open sterile barrier, plastic/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a plastic liner/bag. Third layer is a corrugated board dispenser box. Fourth layer is a corrugated board transport box.**Is suitable for Tray:** No

Packing level	Quantity	GTIN Code	UDI-DI	Width x Length x Height	Volume	Weight gross / net
Piece	1	7332551041670				1306 g / -
Consumer pack	1	07333350753818	07333350753818			
Dispenser box	5	07333350774431	07333350774431	291x356x421 mm		
Transport box	10	07333350494872	07333350494872	371x593x440 mm	96.801 dm3	13.06 / 10.48 kg
Pallet	160	7313661376357		800x1200x1904 mm	1827.84 dm3	233.96 kg / -

Material

Animal tissues : No**Human blood derivatives :** No**Natural rubber latex :** NoFind out more at www.molnlycke.com

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Medicinal substances : No

Phthalates : No

Polyvinyl chloride : No

Technical

Instructions

How product works :

The surgical patient drapes are intended to be used as protective patient coverings to create a sterile field for a surgical procedure

Classifications

Regulation type(s)	MDR Class IS	MDR Class IS
CE Certificate Number :	MDR 722028	MDR 722028
Intended Purpose :	The surgical drape sets consists of both surgical drapes and supplementary products intended be used to create a sterile field for a surgical procedure.	The surgical drape sets consists of both surgical drapes and supplementary products intended be used to create a sterile field for a surgical procedure.
MDR Classification Rule :	5	1
Conformity Annexes :	IX	IX
Measuring Function :	No	No
Notified body medical devices/PPE :	BSi 2797	BSi 2797

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)

33961 General/plastic surgical procedure kit, non-medicated, single-use

EMDN Code (European Medical Device Nomenclature)

T0202 SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)

UNSPSC

42131701 Surgical drapes

Find out more at www.molnlycke.com

Commodity Code

3005905000 Articles of Wadding, Gauze, Dressings, drapes singlepacked and Sets - textile

CE Responsibility / Legal Manufacturer

Mölnlycke Health Care AB, Entreprenorsstraket 21, SE-431 53 Mölndal Sweden

Basic UDIDI

73324300000000182K9

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Material information for the ingoing products

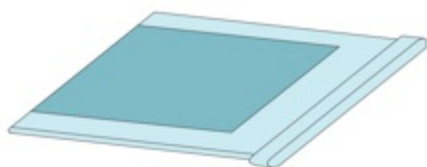
888142 Craniotomy Set, 996106 Mayo Stand Cover

Designed to protect the mayo stand and offer a sterile surface

Product details

Product group name : Mayo stand covers
Size : 79cm x 145cm
Descriptive feature : Absorbent
Brand : BARRIER®
Equivalences : 610601

Images



Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Packaging Composition

Product Component	Composition
TRP box	Corrugated board, 80% recycled content, FSC certified - C137267
PE liner	LDPE 35 microns

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Product Composition Drapes

Product Component	Composition
Patch material	Viscose nonwoven 27 g/m ²
Drape material	Polyethylene film 60 µm

Product Performance Surgical Drapes, EN 13795-1:2019 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 product area	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	N/A - no critical product area	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	N/A - no critical product area	<50
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	N/A - no critical product area	2.5
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	N/A - no critical product area	>150
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - no critical product area	74
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - no critical product area	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	N/A - no critical product area	38
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	N/A - no critical product area	-

Product Performance Drapes, Additional Tests

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Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	1,82
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s

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888142 Craniotomy Set, 911500 OP-Tape

Secure fixation of tubes and cables to surgical drapes

Product details

Product group name : OP-Tape & Tube holders
Size : 9cm x 49cm
Descriptive feature : Adhesive
Brand : BARRIER®
Equivalences : 381045, 381035

Images



Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Packaging Composition

Product Component	Composition
TRP box	Corrugated board, 95% recycled content

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Product Component	Composition
PE liner	PE bag 40 micron

Product Composition Drapes

Product Component	Composition
Drape material	Polyester nonwoven 40 g/m ²
Drape material	Polyethylene film 27.5 µm
Adhesive material	Synthetic rubber based

Product Performance Surgical Drapes, EN 13795-1:2019 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 - only critical product area
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	6.0	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	<50	N/A - only critical product area
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	1.6	N/A - only critical product area
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	>150	N/A - only critical product area
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	190	N/A - only critical product area
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	172	N/A - only critical product area
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	48	N/A - only critical product area

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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
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	47	N/A - only critical product area

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	N/A
Flammability	16 CFR 1610.4	N/A	s	Class 1, >3.5s

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888142 Craniotomy Set, 947064 Adhesive OP-Towel

Impermeable and absorbing drapes in smaller sizes for general application

Product details

Product group name : Adhesive OP-towels
Size : 50 x 50cm
Descriptive feature : 3-ply, Adhesive
Brand : BARRIER®
Equivalences : 706400

Images



Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Product Composition Drapes

Product Component	Composition
Drape material	Viscose nonwoven 23 g/m ²
Drape material	Polyethylene film 40 µm
Drape material	Polypropylene nonwoven 12 g/m ²
Adhesive material	Synthetic rubber based

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Product Performance Surgical Drapes, EN 13795-1:2019 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	-	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	6.0	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	<50	<50
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	2.5	2.5
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	203	203
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	85	85
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	72	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	29	29
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	28	-

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	1,10
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s

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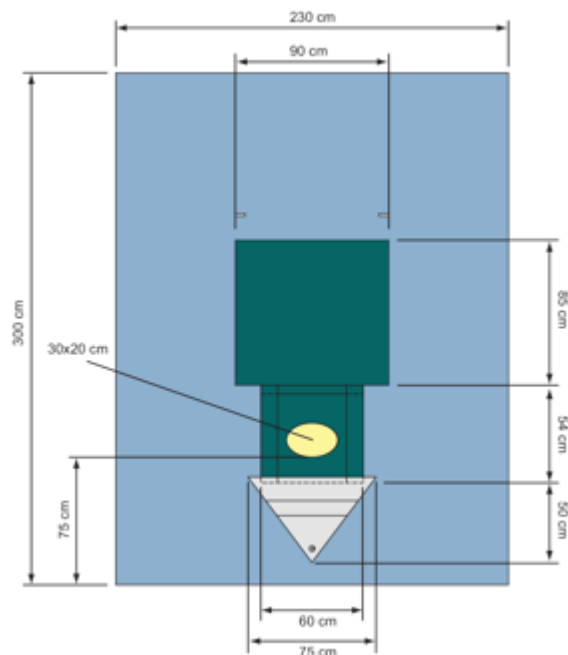
888142 Craniotomy Set, 965524 Craniotomy Drape

Procedure-specific drape with integrated incise film

Product details

Product group name : Craniotomy drapes and sets
Size : 230cm x 300cm, Incise 30x20cm
Descriptive feature : Pouch
Brand : BARRIER®
Equivalences : 888342

Images



Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Packaging Composition

Product Component	Composition
TRP box	Corrugated board, 90-95% recycled content, FSC certified - C137267

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Product Component	Composition
PE liner	Transparent Polyethylene film 40 µm

Product Composition Drapes

Product Component	Composition
Patch material	Viscose nonwoven 23 g/m ²
Patch material	Polyethylene film 40 µm
Drape material	Polyethylene film 50 µm
Drape material	Polypropylene nonwoven 12 g/m ²
Pouch material	Polyethylene film 100 µm, transparent
Adhesive material	Acrylate based

Product Performance Surgical Drapes, EN 13795-1:2019 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	-	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	6.0	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	<50	<50
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	1.7	0.7
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	>200	>200
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	174	98

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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
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	174	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	72	33
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	55	-

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	1,10
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s

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888142 Craniotomy Set, 90190 Table Cover

Impermeable and absorbing covers that conforms to the shape of the table

Product details

Product group name : Table covers
Size : 150cm x 190cm
Descriptive feature : Absorbent
Brand : BARRIER®
Equivalences : 80190

Images



Material

Animal tissues : No
Human blood derivatives : No
Natural rubber latex : No
Medicinal substances : No
Phthalates : No
Polyvinyl chloride : No

Packaging Composition

Product Component	Composition
TRP box	Corrugated board, 80% recycled content, FSC certified - C137267
PE liner	PE bag 40 micron

Product Composition Drapes

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Product Component	Composition
Drape material	Viscose nonwoven 23 g/m ²
Drape material	Polyethylene film 55 µm

Product Performance Surgical Drapes, EN 13795-1:2019 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 product area	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	N/A - no critical product area	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm ²	≤300	≤300	N/A - no critical product area	<50
Particle release	EN ISO 9073-10	T-1006	Log ₁₀ (lint count)	≤4.0	≤4.0	N/A - no critical product area	2.5
Resistance to liquid penetration	EN ISO 811	T-280	cm H ₂ O	≥100	≥10	N/A - no critical product area	>150
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	N/A - no critical product area	74
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	N/A - no critical product area	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	N/A - no critical product area	46
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	N/A - no critical product area	-

Product Performance Drapes, Additional Tests

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Characteristics	Test Method	Internal Test Method	Unit	Product Performance
Absorption	ISO 9073-12	T-1158	g/dm ²	1,10
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s

Find out more at www.molnlycke.com

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