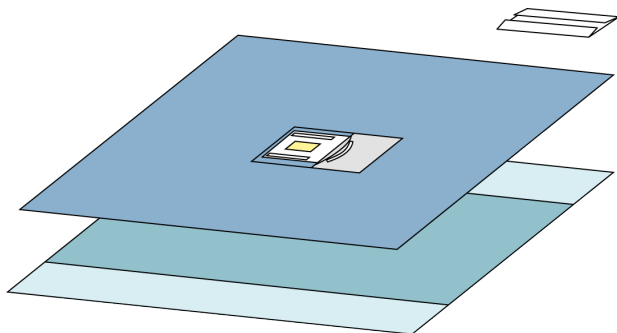


903167 OPHTHALMIC SET



| | | | | |
|-----------------------------------|---|---|--|--|
| 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

Inciziné plévelé

Material composition

| Areas | Critical area | Less critical area |
|--|--|--|
| Materials | Polietileno plévelé 50 mikrometru storio | Polietileno plévelé 50 mikrometru 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 10⁸ 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 | Less critical area |
|-----------------|--------------------------|--------------------|
| Drape material | Viskozė neaustinė | |
| | 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 10⁸ 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 capacity, ml/100cm²; 2,1ml