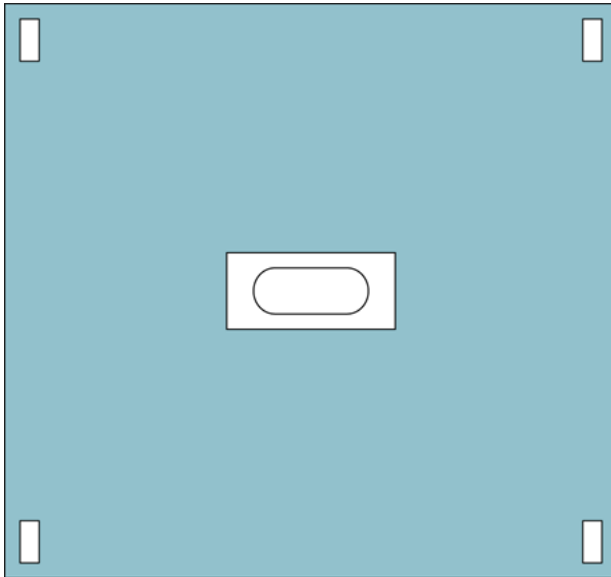


915447 Adhesive Aperture Drape



| | |
|-----------------------------------|---|
| Size And Description | 75x80cm, ap. 6x15cm |
| Other information | Removable label |
| Sterile | Yes |
| Country Of Origin | Thailand |
| Sterility barrier quantity | 1 |
| Dispenser Box Quantity | 36 |
| Transport Box Quantity | 216 |
| Pallet Quantity | 3240 |
| 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/m ² | Viscose nowoven 23 g/m ² |
| | 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 critical 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/dm ²) | ≤ 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 H ₂ O | ≥ 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 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).

Remark:

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

Additional 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