# 706300
# Adhesive OP-Towel

## Product details

**Size:** 75cm x 50cm
**Descriptive feature:** 3-ply, Adhesive
**Sterility:** Sterile

## Images

## Delivered items

### 706300-20

**Country of origin:** Belgium
**Shelf life:** 5 years
**Sterilization method:** Beta
**Packing information:** First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.

| Packaging level | Pack count | GS1 code |
|---|---|---|
| **Consumer pack** | 1 | 7323190198382 |
| **Dispenser box** | 50 | 7323190180554 |

| Packaging level | Pack count | GS1 code |
|---|---|---|
| **Transport box** | 300 | 7323190180547 |
| **Pallet** | 4500 | 7323190180530 |

## Material

### Animal tissues:

No

### Human blood derivatives:

No

### Medicinal substances:

No

### Phthalates:

No

### Polyvinyl chloride:

No

### Product Composition Drapes

| Product Component | Critical Area | Less Critical Area |
|---|---|---|
| Drape material | Viscose nonwoven 23 g/m² | Viscose nonwoven 23 g/m² |
| Drape material | Polyethylene film 40 µm | Polyethylene film 40 µm |
| Drape material | Polypropylene nonvowen 12 g/m² | Polypropylene nonvowen 12 g/m² |
| Adhesive material | Synthetic rubber based | N/A |

### Product Performance Drapes, Additional Tests

| Characteristics | Test Method | Internal Test Method | Unit | Product Performance Critical Product Area | Product Performance Less Critical Product Area |
|---|---|---|---|---|---|
| Absorption | ISO 9073-12 | T-1158 | g/dm² | 1.17 | 1.17 |
| Flammability | 16 CFR 1610.4 | N/A | s | Class I, > 3.5s | Class I, >3.5s |

## Product Performance Sterile Drapes, EN 13795 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 - Particulate Matter | EN ISO 9073-10 | T-1006 | IPM | ≤3.5 | ≤3.5 | 2.3 | 2.3 |
| Linting | EN ISO 9073-10 | T-1006 | $Log_{10}$ (lint count) | ≤4.0 | ≤4.0 | 2.5 | 2.5 |
| Resistance to liquid penetration | EN 20811 | T-280 | cm $H_2O$ | ≥100 | ≥10 | 203 | 203 |
| Bursting strength - Dry | EN ISO 13938-1 | T-233 or T-1179 | kPa | ≥40 | ≥40 | 91 | 91 |
| Bursting strength - Wet | EN ISO 13938-1 | T-233 or T-1179 | kPa | ≥40 | Not required | 74 | - |
| 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 | - |

# Technical

## Dimension

| Dimension text | Dimension value |
|---|---|
| Outer dimension | 75 cm x 50 cm |

## Disposal instructions

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.

## Storage instructions

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.

## Classification

| Regulation type | MDD Class IS |
|---|---|
| **MDD Classification Rule:** | 1 |
| **CE Certificate Number:** | CE 01966 |
| **Notified body medical devices/PPE:** | BSI (0086) |
| **Intended use MDD:** | Surgical drapes, when sterilised, are intended to minimize the spread of micro-organisms, in order to reduce the risk for post operative wound infection. |

## 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

No

## GMDN Code (Global Medical Device Nomenclature)

47783