



STERIKING® Dust Cover Bag

The STERIKING® Cover Bags have been designed to be used in the health care establishments to provide extra protection to the sterilized health care items against contamination. It becomes necessary when extended sterility time is needed or the items become exposed to the conditions where the hygienic requirements are not fulfilled, for example during outdoors transportation. A dust cover bag will protect a product in its directly enclosing packaging from dust and environmental influences during transport or storage. A dust cover bag is used to extend the shelf life (in respect of the sterility) of packed sterile medical devices.

Conformity to International Standards

The STERIKING® Dust cover bags conform to the international product standards and norms: ISO 11607-1:2019 and ISO 11607-2:2019

Wipak Oy is certified to ISO 9001:2015; ISO 13485:2016; ISO 14001: 2015; OHSAS 18001:

2007 and FSSC 22000 version 3.1 – ISO 22002-1:2009.

The STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.

Technical Data & Performance Characteristics

The STERIKING® Dust cover bags are constructed of a multiply BoPET/PE plastic laminate (12/50 microns). Dust covers are a peel-open bag providing superior opening characteristics compared to the conventional tear-off bags. Bags are heat sealable with an impulse or rotosealer. Recommended sealing temperature for final closing is 130-160° C (272-335° F) depending on pressure and time. Let the items cool down after sterilization before packing them into a dust cover. STERIKING® Cover Bags are also suitable for sterilization by irradiation.

Specific Product Features

Dimensions and Tolerances

Width: nominal +/- 1 mm
Length: nominal +/-3 mm

Heat Seal Design

The seal is formed to facilitate easy opening. The width and the strength of the seal are specified in order to achieve the optimum strength and at the same time to facilitate easy opening of the pack. The seal is ribbed having 3 aligned sealed lines and the total width is minimum 6 mm.

Heat Seal Strength

Minimum: 1,5 N/15 mm (tail supported)

Direction of Peel

The correct direction of peel is marked on each individual bag in order to ensure easy opening

The materials have been permitted for use in the manufacture of food or drug packages by FDA (Food and Drug administration, the USA) as well as by BGA (National Health Authority, Germany).

| Transparent film BoPET/PE 1250 | | | |
|--------------------------------|------------------|------------------|---------|
| Property | Method | Unit | Nominal |
| Thickness | | µm | 62 |
| Weight | | g/m ² | 65 |
| Tear strength, MD | ISO 6383-2 | mN | 250 |
| Tear strength, CD | ISO 6383-2 | mN | 250 |
| Elongation at break, MD | ISO 527-3 | % | 60 |
| Elongation at break, CD | ISO 527-3 | % | 60 |
| Heat resistance | | °C | 90 |
| Sterilization method | Gas, irradiation | | |

MD= machine direction, CD= cross direction Test conditions: 23°C, 50 RH-%

Storage Recommendations & Shelf Life

It is recommended that the STERIKING® products are kept in the original, closed transport carton and are stored in dry and clean conditions protected from direct sunlight and excessive moisture.

It is recommended that the products are put to their end use within 10 years of manufacture. The recommended "Best before" date and the manufacturing date are stated on the carton label.

Restrictions in Use

The STERIKING® Dust Cover Bags are to be used after sterilization. The packages are not suitable for sterilization by steam, hot, dry air or by gas because the materials do not provide porosity enough to allow steam or gas to penetrate into the pouch. Anyhow, the STERIKING® Dust Cover Bags are suitable for sterilization by irradiation.

Sales and Transport Packing

Bags are bound with a plastic or paper strip into bundles of 100 pieces. These bundles are wrapped with plastic dust cover wrap of partially recycled and further recyclable, LDPE. Then they are packed into an unbleached corrugated cardboard case (partially recycled and further recyclable) and closed with adhesive coated polypropylene tape. Cases are palletized to reusable wooden EUR size pallet and covered by plastic pallet-tightening bands (PET). Partially recycled and further recyclable cardboard-sheet is placed on the bottom of the pallet.

Please refer to the local/national regulations regarding waste disposal.

This specification refers to the named product group and shall be valid until the next revision. Other product related documents may be available upon request.

The information contained here is to our knowledge accurate and reliable as of the date of the publication. Wipak extends no warranties and makes no representations as to the accuracy or completeness of the information contained herein, and assumes no responsibility regarding the consequences of its use or for any printing errors. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the products for the customer's particular purpose and suitability to the actual circumstances the product is exposed to. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products especially when recommendations for safe use and storage are given. Nothing herein shall constitute any warranty, nor is a protection from any law or patent to be inferred.

Labelling: Each case bears a label with the necessary information/instructions for the contents of the case in accordance with ISO 11607-1:2019.

In Case of Complaint

In event of any complaint, the lot number and identification code must be provided by the complainant. For evaluation of claimed product, a defective sample (or a digital photo) and description of the defect together with an unused specimen must be made available to Wipak.

STERIKING® is a registered trade mark of Wipak Oy

Steriking® CB –Dust Cover Bags

| Code | Size | Sales Packing (Bags/Case) |
|------|-----------|------------------------------|
| CB1 | 150 x 270 | 1 000 |
| CB2 | 205 x 300 | 1 000 |
| CB3 | 250 x 400 | 1 000 |
| CB4 | 300 x 500 | 500 |
| CB5 | 400 x 550 | 500 |
| CB6 | 420 x 700 | 500 |
| CB7 | 500 x 800 | 300 |