

## STERIKING® See-through Reels with 3 Indicators

The STERIKING® See-through Reels with 3 indicators are for use as packing material for medical devices in sterilization by steam, ethylene oxide gas or formaldehyde in health care establishments. The common steam sterilization conditions are 3 minutes at 134°C or 15 minutes at 121°C. The products are for single use only.

### Conformity to International Standards

The STERIKING® See-Through range of peel packages conform to the requirements set out in the Medical Devices Regulation (EU) 2017/745 (MDR) and international product standards and norms: ISO 11607-1, ISO 11607-2, EN 868-5.

Wipak Oy is certified to ISO 9001; ISO 14001; ISO 45001; FSSC 22000 and ISO 13485.

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

The Steriking® sterilization packaging materials, which are supplied by Wipak in non-sterile condition are class 1 accessories by the MDR Annex VIII, Chapter III, Rule 1.

### Technical Data & Performance Characteristics

The STERIKING® See-Through packages are constructed of medical grade paper (70g/m<sup>2</sup>) is heat sealed together with a multiply PET/PP-plastic laminate (12/40 microns). Recommended sealing temperature for final closing is 165-200°C (329-392°F) depending on pressure and time.

### Specific Product Features

#### Dimensions and Tolerances

Width: nominal +/- 2 mm  
Length: nominal +500, -0 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 necessary for autoclaving 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

The minimum value for seal strength shall be 1,5 N per 15 mm for steam sterilization and 1,2 N per 15 mm for other sterilization processes.

#### Splices and Joints

Reels 200m: max. 2 per reel  
Reels 100m: max. 1 per reel

#### Direction of Peel

The correct direction of peel is marked on each individual reel at specified intervals in order to ensure safe opening without breaks and/or fiber tear.

#### Lot Coding

Each reel bears a code number enabling traceability of the production history.  
The code is YYMM (year / month). Converting lane numbering offers added value for production traceability.

#### Chemical Indicators

conform to ISO 11140-1 type 1: Process indicators.  
Steam indicator change from red/pink to brown,  
EO gas from pink to gold/ochre and  
FO gas from pink/red to green

The paper is a high-weight medical grade with improved barrier and water repellent properties. The specially treated surface facilitates strong sealing against the film but allows fiber-free peeling off without breaks. The paper conforms to the requirements of the European EN 868-3:2017 and it is free from dirt, toxic substances and odor.

Property	Test Method	Unit	Nominal
Grammage	ISO 536	g/m <sup>2</sup>	70
Tensile strength, MD	ISO 1924-2	kN/m	7,3
Tensile strength, CD	ISO 1924-2	kN/m	4,0
Tear strength, MD	ISO 1974	mN	700
Tear strength, CD	ISO 1974	mN	750
Burst strength	ISO 2758	kPa	400
Air permeability	ISO 5636-3	µm/Pa·s	13
Air resistance Gurley	ISO 5636-5	s	11

The Wipak Multi-X9 film is transparent, non-toxic and heat sealable with medical grade paper. It can be sterilized at the extreme sterilization conditions of 140 ° C (284° F) for 10 minutes. In addition, it can be sterilized using low temperature sterilization methods (other than irradiation).

Multi-X9 Film			
Property	Method	Unit	Nominal
Thickness		µm	52
Weight		g/m <sup>2</sup>	53

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 5 years of manufacture. The recommended "Best before" date and the manufacturing date are stated on the carton label. However, depending on the requirements of the user, products older than five years may still be useable if the storage conditions have been according to the recommendations. No collapsing of performance of the product will take place after any time period. In the cases where the recommended expire date has been exceeded it is advisable to test the product prior to use.

### Restrictions in Use

The STERIKING® standard range of See-Through 3 indicator Reels is not suitable for sterilization by irradiation, by hydrogen peroxide, or by hot, dry air, or at the temperatures over 140 ° C.

### Sales and Transport Packing

Each reel is wrapped in a polyethylene dust cover (LDPE) and then packed in an corrugated cardboard case (partially recycled and further recyclable). The case is closed with 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.

Labeling: Each case bears a label with the necessary information/instructions for the contents of the case in accordance with ISO 11607-1, ISO 11607-2 and EN 868-5.

### 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 trademark of Wipak.

### Steriking® Flat Rolls

Code	Size (mm)	Sales Packing (Rolls/Case)
R39	50 : 200	5
R40	75 : 200	4
R41	100 : 200	3
R125	125 : 200	2
R42	150 : 200	2
R43	200 : 200	1
R44	250 : 200	1
R45	300 : 200	1
R46	350 : 200	1
R47	400 : 200	1

### Steriking® Rolls with Gusset

Code	Size (mm)	Sales Packing (Rolls/Case)
RB50	75 x 25: 100	4
RB51	100 x 50: 100	3
RB52	150 x 50: 100	2
RB53	200 x 55: 100	1
RB54	250 x 65: 100	1
RB55	300 x 80: 100	1
RB56	350 x 80: 100	1
RB57	400 x 80: 100	1

### Steriking® R/100-Flat Rolls

Code	Size (mm)	Sales Packing (Rolls/Case)
R39/100	50 : 100	8
R40/100	75 : 100	8
R41/100	100 : 100	4
R42/100	150 : 100	2
R43/100	200 : 100	2
R44/100	250 : 100	2
R45/100	300 : 100	1
R47/100	400 : 100	1
R49/100	500 : 100	1

### Steriking® R/31-Flat Rolls

Code	Size (mm)	Sales Packing (Rolls/Case)
R39/31	50 : 31	10
R40/31	75 : 31	10
R41/31	100 : 31	10
R42/31	150 : 31	16
R43/31	200 : 31	6
R44/31	250 : 31	6
R45/31	300 : 31	6

*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.*

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