



STERIKING® See-through Pouches With 3 Indicators

The STERIKING® See-through Pouches with 3 indicators are intended 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 international product standards and norms: ISO 11607-1:2006, ISO 11607-2:2006, EN 868-5:2009.

The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive 93/42/EEC and its amendment 2007/47/EC. To show compliance with MDD the CE mark is printed on the label of the transport carton.

The products are registered by FDA under 510(k) Premarket Submission No. K953776.

Wipak Oy is certified to ISO 9001:2008; ISO 14001: 2004; OHSAS 18001: 2007, ISO 22000: 2005 and ISO 13485:2003.

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

Technical Data & Performance Characteristics

The STERIKING® See-Through packaging is constructed of medical grade paper (70g/m²) is heat sealed together with a multiply PET/PP-plastic laminate (12/40 microns). Recommended sealing temperature for final closing is 165-190°C (329-374°F) depending on pressure and time.

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 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

Flat pouches: Minimum strengths with tail supported
up to 100 mm wide 140 N/m (2.1 N/15 mm)
wider than 100 mm 165 N/m (2,5 N/15 mm)
Gusseted reels: 165 N/m (2,5 N/15 mm)

Thumb Cut

For easy filling and opening the pouches have a thumb cut at the filling and opening ends of the pouch.

Direction of Peel

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

Lot Coding

Each pouch 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 11140-1:2005 class 1: Process indicators
Steam indicator changes color from red to brown,
EO gas indicator from pink to gold/ochre and
FO gas indicator from pink to green

The paper is a high-weight medical grade with improved barrier and water repellent properties. The controlled pore size provides for effective air evacuation and steam penetration. 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 norm EN 868-3:2009 and it is free from dirt, toxic substances and odor.

Medical Grade Paper				
Property	Test Method	Unit	Typical	Tolerances
Grammage	ISO 536	g/m ²	70	67-73
Tensile strength, MD	ISO 1924-2	kN/m	7,3	>5,1
Tensile strength, CD	ISO 1924-2	kN/m	4,0	>2,6
Tear strength, MD	ISO 1974	mN	700	>550
Tear strength, CD	ISO 1974	mN	750	>550
Burst strength	ISO 2758	kPa	400	>270
Air permeability	ISO 5636-3	µm/Pa·s	13	5,3-14,2
Air resistance Gurley	ISO 5636-5	s	11	9-20

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). The materials have been permitted for use in contact with food and drugs by the German BGA and the American FDA.

Multi-X9 Film			
Property	Method	Unit	Nominal
Thickness		µm	52
Weight		g/m ²	53
Tear strength, MD	ISO 6383-2	mN	300
Tear strength, CD	ISO 6383-2	mN	300
Elongation at break, MD	ISO 527-3	%	70
Elongation at break, CD	ISO 527-3	%	70
Sterilization method	steam, gas		

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 Pouches is not suitable for sterilization by irradiation or by hot, dry air at the temperatures over 140 ° C. Some restrictions may also be valid when plasma sterilization processes are concerned.



Sales and Transport Packing

Pouches are bound with a plastic or paper strip into bundles: flat pouches à 100. These bundles are then packed into a polyethylene (LDPE) dust cover and into an unbleached corrugated cardboard case (partially recycled and further recyclable). The case is 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.

Labelling: Each case bears a label with the necessary information/instructions for the contents of the case in accordance with ISO 11607-1:2006 and EN 868-5:2009.

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 Oy.

Steriking® B-Pouches with Gusset

Code	Size (mm)	Sales Packing (pouches/case)
B35-3P	100 x 50 x 300	500
B30-3P	100 x 50 x 360	500
B31-3P	150 x 50 x 400	500
B32-3P	150 x 50 x 460	500
B36-3P	200 x 55 x 400	250
B33-3P	200 x 55 x 500	250
B37-3P	250 x 65 x 480	250
B34-3P	300 x 80 x 550	250
B38-3P	420 x 100 x 570	250

Steriking® 3P Flat Pouches

Code	Size (mm)	Pouches/Case
S 17-3P	50 x 200	3 600
S 1-3P	50 x 250	2 400
S 24-3P	75 x 150	2 400
S 2-3P	75 x 200	2 400
S 23-3P	75 x 230	1 800
S 4-3P	75 x 270	3 600
S 18-3P	75 x 300	4 200
S 22-3P	75 x 520	2 400
S 25-3P	100 x 150	2 400
S 3-3P	100 x 200	1 800
S 5-3P	100 x 270	3 000
S 8-3P	100 x 300	1 200
S 19-3P	100 x 350	1 200
S 9-3P	100 x 400	1 200
S 12-3P	100 x 570	1 800
S 27-3P	120 x 400	1 200
S 15-3P	150 x 200	1 200
S 6-3P	150 x 270	1 800
S 20-3P	150 x 300	1 800
S 26-3P	150 x 350	1 800
S 13-3P	150 x 400	1 200
S 28-3P	150 x 520	1 200
S 34-3P	160 x 600	1 200
S 33-3P	180 x 320	1 000
S 7-3P	205 x 270	600
S 7A-3P	205 x 340	1 000
S 10-3P	205 x 400	600
S10A-3P	205 x 440	600
S 35-3P	205 x 600	1 200
S 2070-3P	205 x 700	600
S 16-3P	250 x 380	1 200
S 11-3P	250 x 500	600
S 36-3P	250 x 600	500
S 37-3P	250 x 700	600
S 29-3P	270 x 350	600
S 30-3P	270 x 440	600
S 21-3P	300 x 500	600
S 14-3P	300 x 570	600
S 38-3P	320 x 500	600
S 31-3P	420 x 500	500
S 32-3P	420 x 600	500

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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