Form Ref. ST-62000 Rev.: A5
Date: 24 April 2014

STERIKING® See-through Self-sealable Pouches

The STERIKING® See-through Self-sealable pouches are intended for use as packing material for medical devices in sterilization by steam, ethylene oxide gas, or by formaldehyde in health care establishments. The common steam sterilization conditions are 3 minutes at 134º C or 15 minutes at 121º 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 and 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 the MDD the CE mark is printed on the label of the transport carton.

The products are registered by FDA under 510(k) Premarket Submission Nos.: K803293 and K953776.

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

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

Technical Data & Performance Characteristics

The STERIKING® See-Through packages are constructed of medical grade paper (70g/m^2) that is heat-sealed together with a multiply PET/PP-plastic laminate (12/40 microns). Pouches are intended for closing tightly with adhesive strip according to instructions printed.

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.	
Seal Strength	
Flat pouches:	Minimum strength tested 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)
Direction of Peel	
The correct direction of peel is marked on each individual pouch 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) e.g. 1201 = January 2012 etc. 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 blue to dark brown/black and EO gas indicator from pink to yellow/orange	

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 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
Sterilization method	Steam, gas			

The Wipak Multi-X film is transparent, non-toxic and heat sealable with medical grade paper. It can be sterilized at the extreme sterilization conditions of 140 º 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: 23ºC, 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 3 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 three 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 packages is not suitable for sterilization by irradiation or by hot, dry air at the temperatures over 140 ºC. 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 of 100 pieces. These bundles are first packed into a bleached cardboard dispenser, 2 bundles each. The dispensers are then packed into a polyethylene (LDPE) dust cover and then finally 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® SS- Pouches

Code	Size (mm)	Packing units (Pouches/Case
SS10	60 x 250	1 000
SS1	90 x 200	1 000
SS2	90 x 250	1 000
SS3	90 x 570	1 000
SS4	130 x 270	1 000
SS4A	130 x 380	1 000
SS5A	190 x 330	1 000
SS5	200 x 350	1 200
SS6	250 x 400	600
SS7	300 x 450	600