



STERIKING® See-Through Reels

The STERIKING® See-through Reels, made with or without gussets, 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 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 868-5:1999.

The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive MDD/93/42 which is incorporated in the Finnish Act 1505/94 and its statutes. To show compliance with MDD/93/42 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, K953776 and K973827.

Wipak Oy is certified to ISO 9001:2000; ISO 14001: 2004; OHSAS 18001: 1999; ISO 22000: 2005 and DS 3027: 2002.

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/m²) that is heat-sealed together with a multiply PET/PP-plastic laminate (12/40 microns). All raw materials are FDA approved. Recommended sealing temperature for final closing is 155-180°C (324-376°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

Flat reels:	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)
Gusseted reels:	165 N/m (2,5 N/15 mm)

Splices and Joints

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

Direction of Peel

The correct direction of peel is marked 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 11140-1:2005 class 1: Process indicators.
Steam indicator changes color from blue to dark brown/black and
EO gas indicator from pink to yellow

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 868-3:1999 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	7,2	>5,1
Tensile strength, CD	ISO 1924-2	kN/m	3,8	>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	11,4	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 °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-X 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.

The shelf life is event-related and not time -related. 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 reels 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

Each reel is wrapped in a polyethylene dust cover (LDPE) and then packed in an unbleached corrugated cardboard case (partially recycled and further recyclable). The case is hermetically closed with adhesive coated polypropylene tape. Cases are palletized to reusable wooden EUR 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 868-5:1999.

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 Medical.

Steriking® R-Flat Rolls

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

Steriking® R/100-Flat Rolls

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

Steriking® R/31-Flat Rolls

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

Steriking® RB-Rolls with Gusset

Code	Size (mm)	Sales Packing (Rolls/Case)
RB50	75x25:100	4
RB51	100x50:100	3
RB52	150x50:100	2
RB53	200x55:100	1
RB54	250x65:100	1
RB55	300x80:100	1
RB56	350x80:100	1
RB57	400x80:100	1

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.

