STERIKING® Reinforced Rolls

The STERIKING® Reinforced rolls 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 134ºC or 15 minutes at 121ºC. The products are for single use only.

Conformity to International Standards

The STERIKING® rolls conform requirements set out in the Medical Devices Regulation (EU) 2017/745 (MDR) and international product standards and norms: ISO 11607-1 and EN 868-5

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.

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

Technical Data & Performance Characteristics

The STERIKING® Reinforced Rolls are constructed of medical grade paper (100g/m^2) that is heat sealed together with a multiply BOPET/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 +/- 1 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 pouches:	Minimum strengths with tail supported
up to 100 mm wide	2.1 N/15 mm
wider than 100 mm	2,5 N/15 mm
Splices and Joints	
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 Indicator	
Conform to ISO 11140-1:2014 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 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 868-3:2017 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	100	95-105
Tensile strength, MD	ISO 1924-2	kN/m	12,7	>4,4
Tensile strength, CD	ISO 1924-2	kN/m	6,7	>2,2
Tear strength, MD	ISO 1974	mN	1000	>550
Tear strength, CD	ISO 1974	mN	1100	>550
Burst strength	ISO 2758	kPa	690	>230
Air permeability	ISO 5636-3	µm/Pa·s		3,9-5,7
Air resistance Gurley	ISO 5636-5	s	29	24-34

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 º C (284° F) for 10 minutes. In addition, it can be sterilized using low temperature sterilization methods (other than irradiation). Raw materials are in compliance with Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

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		

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 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® Reinforced Rolls are not suitable for sterilization by irradiation, by hydrogen peroxide, or by hot, dry air, or at the temperatures over 140 ° C.

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.

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 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 11607-1:2019, ISO11607-2:2019 and EN 868-5:2018

Steriking® Reinforced Rolls

Code	Size (mm: m)	Sales Packing (rolls/case)
RR41	100: 100	2
RR43	200: 100	1
RR45	300: 100	1
RR47	400: 100	1
RR49	500: 100	1