





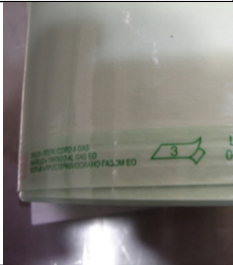





Instructions for Use: Steriking® LT-Blueline with Tyvek® Roll Packaging

Brand Name of Product	STERIKING® LT-Blueline with Tyvek® Roll Packaging, manufactured by Wipak
Generic Name of Product	Pouches
Product Code Number(s)	LTR40 NI, LTR41 NI, LTR42 NI, LTR43A NI, LTR44 NI, LTR45 NI
Purpose of Product	The Steriking® LT-Blueline with Tyvek® Roll Packaging is intended for use as packing material for items that require low-temperature sterilization.
Range of Applications for Product	N/A
Key Specifications of Product	The Steriking® LT-Blueline Roll Packaging is constructed with Tyvek® that is heat-sealed together with multi-layered PET/PE-plastic laminate (12/50 microns).

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions for Unprocessed Pouches/Rolls	<ul style="list-style-type: none"> When kept in the original packaging: <ul style="list-style-type: none"> No special storage conditions are required. Closed transportation packaging, items are protected from moisture, heat, and direct sunlight or other sources of UV light. Once the pouches and rolls are removed from the packaging, recommended long-term storage conditions are: <ul style="list-style-type: none"> Temperature of 18- to 24 °C (64.4- to 73.4 °F) Humidity 30–70% rh. Pouches should be stored in closed cabinets or otherwise protected from a UV light source.
Packaging Contents	N/A
Shelf Life of Unprocessed Pouches/Rolls	<ul style="list-style-type: none"> It is recommended that the products are put to their end use within five (5) years of manufacture. The recommended “Best before” date and the manufacturing date are stated on the carton label. Each pouch/roll has a lot number imprinted for traceability. This can be used to determine the manufacture date.

Instructions for Using Product	
Description of Use (s)	The Steriking® LT-Blueline with Tyvek® roll packaging is intended for use as sterile barrier packaging for items for low-temperature sterilization.
Preparation for Use	<ol style="list-style-type: none"> Roll out packaging to the appropriate length of the item to be packaged. Be sure there is extra room so that the package is not too tight with contents and there is enough room for sealing the package. Cut the packaging to desired length. Before sealing, remove as much air as possible from the pouch to help prevent rupturing in sterilization. Place the proper type of indicator inside the pouch, according to your facility’s guidelines. Ensure pouch contents and the indicator are away from the seal area and will not get caught in the seal. Confirm temperature setting on the heat sealer is appropriately set. Recommended sealing temperature for final closing is 120- to 130 °C (248- to 266 °F) depending on pressure and time. Leave enough space beyond the seal for the opener to easily grasp; usually up to two (< 2) inches.
Diagrams (drawings, pictures)	N/A

				
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Steps for Use of Product	<ol style="list-style-type: none"> 1. Hold the pouch taut (stretched or pulled tight) in the sealer to prevent wrinkles or air bubbles from forming in the seal. 2. If using a rolling-type heat sealer, let the peel pouch move along the guide on its own. 3. Once the pouch completes the slide down rolling side, verify the pouch is sealed and that material beyond the seal from the opening is up to two (< 2) inches to allow for aseptic presentation. 4. When opening the pouch, verify you are opening the correct scallop cut opening end. 5. Make sure the scallop cut recognizes the correct opening direction. 6. Continue to roll down the seam, pulling film away from paper. 7. Once the top seam is released, open the package using proper aseptic technique. 			
Interpretation of Results	N/A			
Contraindications of Test Results	N/A			
Documentation	<ul style="list-style-type: none"> • The Steriking® LT-Blueline with Tyvek® range of peel packages conform to the international product standards and norms: ISO 11607-1, ISO 11607-2, EN 868-5. • The products are registered by FDA under 510(k) Premarket Submission No.: K973827. Wipak Oy is certified to ISO 9001; ISO 13485; OHSAS 18001 and ISO 22000. 			
Special Warnings and Cautions	<ul style="list-style-type: none"> • The STERIKING® LT-Blueline with Tyvek® is meant for low-temperature sterilization cycles only. • Do not steam sterilize these pouches. 			
Disposal	Please refer to the local/national regulations regarding waste disposal.			

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instruction	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	Materially compatible with VH2O2/O3/EO sterilization.
Storage Conditions for Processed Pouches/Rolls	<ul style="list-style-type: none"> • The recommended storage conditions: <ul style="list-style-type: none"> ○ Temperature: 18- to 24 °C (64.4- to 73.4 °F) ○ Humidity 30–70% rh ○ Do not exceed 40 °C for sterile storage. • Sterilized heat seal pouches were tested to five (5) years of accelerated and real-time aging. Facilities should develop a policy identifying events that may compromise the sterility of packaged items. This could include a maximum period of time for storage.

Additional Information	<ul style="list-style-type: none">The products are for single use only.
Related Healthmark Products	N/A
Other Product Support Documents	N/A
Reference Documents	Sterilization Packaging Brochure, Sterilization Packaging Price List
Customer Service Contact	US Distributor: Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com