



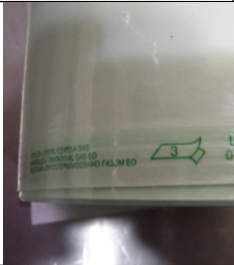







<b>Brand Name of Product</b>	STERIKING® LT-Blueline with Tyvek® Roll Packaging, manufactured by Wipak
<b>Generic Name of Product</b>	Pouches
<b>Product Code Number(s)</b>	LTR40 NI, LTR41 NI, LTR42 NI, LTR43A NI, LTR43 NI, LTR44 NI, LTR45 NI
<b>Purpose of Product</b>	The S STERIKING® LT-Blueline with Tyvek® Roll Packaging is intended for use as packing material for items that require low temperature sterilization.
<b>Range of Applications for Product</b>	N/A
<b>Key Specifications of Product</b>	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).

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions for Unprocessed Pouches/Rolls</b>	<ul style="list-style-type: none"> <li>When kept in the original packaging, no special storage conditions are required. When stored in the original, closed transportation packaging, items are protected from moisture, heat and direct sunlight or other sources of UV-light.</li> <li>Once the pouches and rolls are removed from the packaging, they are to be stored at a temperature of 18-24°C and humidity 30-70%.</li> <li>Pouches should be stored in closed cabinets or otherwise protected from a UV-light source. The process indicator is sensitive to UV-light and may change color over time, if not stored properly.</li> </ul>
<b>Packaging Contents</b>	
<b>Shelf Life of Unprocessed Pouches/Rolls</b>	<ul style="list-style-type: none"> <li>It is recommended that the pouches/rolls are used within 5 years of manufacture date. The recommended “best before” date and the manufacture date are stated on the carton label.</li> <li>Each pouch/roll has a lot number imprinted for traceability. This can be used to determine the manufacture date.</li> </ul>

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	The STERIKING® LT-Blueline with Tyvek® roll packaging is intended for use as sterile barrier packaging for items for low temperature sterilization.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>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.</li> <li>Cut the packaging to desired length.</li> <li>Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization.</li> <li>Place the proper type of indicator inside the pouch according to your facility’s guidelines.</li> <li>Ensure that pouch contents and the indicator are away from the seal area and will not get caught in the seal.</li> <li>Confirm that the temperature setting on the heat sealer is appropriately set. Recommended sealing temperature for final closing is 120-130°C (248-266°F) depending on pressure and time.</li> <li>Leave enough space beyond the seal for the opener to easily grasp (usually ½ - 2 inches).</li> </ol>
<b>Diagrams (drawings, pictures)</b>	N/A

	   
	   
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Hold the pouch taut in the sealer to prevent wrinkles or air bubbles from forming in the seal.</li> <li>2. If using a rolling type heat sealer, let the peel pouch move along the guide on its own.</li> <li>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 ½ inch to 2 inches to allow for aseptic presentation.</li> <li>4. When opening the pouch, verify you are opening the correct scallop cut opening end.</li> <li>5. Make sure the scallop cut recognizes the correct opening direction.</li> <li>6. Continue to roll down the seam, pulling film away from paper.</li> <li>7. Once the top seam is released, open the package using proper aseptic technique.</li> </ol>
<b>Interpretation of Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• The STERIKING® LT-Blueline with Tyvek® is meant for low temperature sterilization cycles only. Do not steam sterilize these pouches.</li> </ul>
<b>Disposal</b>	Please refer to the local/national regulations regarding waste disposal.

Reprocessing Instructions	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instruction</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	Materially compatible with VH2O2/O3/EO sterilization.
<b>Storage Conditions for Processed Pouches/Rolls</b>	<ul style="list-style-type: none"> <li>• The recommended storage conditions are 18-24°C and humidity 30-70%.</li> <li>• Do not exceed 40°C for sterile storage.</li> <li>• Packaging has been tested for 5 years after sterilization. Shelf life of processed pouches/rolls is event-related. 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.</li> </ul>
<b>Additional Information</b>	The products are for single-use only.

<b>Related Healthmark Products</b>	N/A
<b>Other Product Support Documents</b>	N/A
<b>Reference Documents</b>	Sterilization Packaging Brochure, Sterilization Packaging Price List
<b>Customer Service Contact</b>	US Distributor: Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> <a href="http://hmark.com">hmark.com</a>