

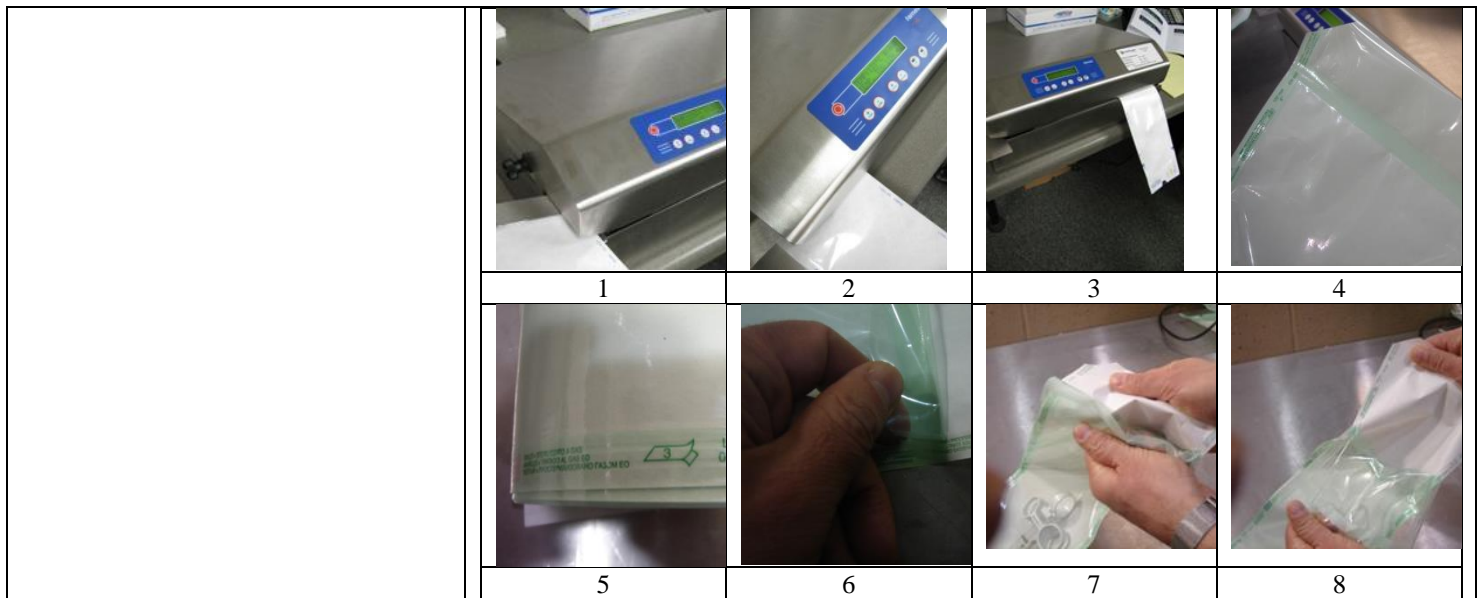


**Instructions for Use: Steriking® Tyvek® Roll Packaging**

<b>Brand Name of Product</b>	Steriking® 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, LTR44 NI, LTR45 NI
<b>Purpose of Product</b>	The STERIKING® Tyvek® Roll Packaging is intended for use as packing material for medical devices for low temperature sterilization.
<b>Range of Applications for Product</b>	
<b>Key specifications of product</b>	The STERIKING® Tyvek® Roll Packaging are constructed of Tyvek® that is heat-sealed together with multiple PET/PE-plastic laminate (12/50 microns).

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	
<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 40-60%.</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 Conditions</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 3 years of manufacture. The recommended “best before” date and the manufacturing 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® roll packaging is intended for use as packing material for medical devices for low temperature sterilization.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>1. Roll out packaging to 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>2. Cut the packaging as desired length.</li> <li>3. Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization.</li> <li>4. Place the proper class of indicator inside the pouch according to your specific facilities guidelines.</li> <li>5. Ensure that pouch contents and the indicator are away from the seal area, and will not get caught in the seal.</li> <li>6. Ensure that the proper sealer conditions are used.</li> <li>7. Use a sealer designed for medical packaging. Each brand might have a slightly different melting point.</li> <li>8. Be sure to test your brand.</li> <li>9. Confirm that the temperature setting on the heat sealer is appropriate for Tyvek® packaging. Recommended sealing temperature for final closing is 120-130°C (248-266°F) depending on pressure and time.</li> <li>10. Leave enough space beyond the seal for the opener to easily grasp (usually ½ - 2 inches).</li> <li>11. Rubber bands, non-approved tape, safety pins, paper clips, staples or other sharp objects should not be used to secure packages or to organize the contents.</li> </ol>
<b>Diagrams (drawings, pictures):</b>	



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| <b>Steps for Use of Product</b> | <ol style="list-style-type: none"> <li>1. Confirm that the temperature setting on the heat sealer is appropriate for Tyvek® packaging.</li> <li>2. Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal.</li> <li>3. If using a rolling type heat sealer, let the peel pouch move along the guide on its own. Sealing dotted line in the end indicates that the pouch shall be on top or above the printed line.</li> <li>4. 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” to 2 inches to allow for aseptic presentation.</li> <li>5. When opening the pouch, verify you are opening the correct scallop cut opening end.</li> <li>6. Make sure scallop cut recognizes the correct opening direction.</li> <li>7. Find the thumb tabs and begin to peel down the seams</li> <li>8. Continue to roll down the seam, pulling film away from paper.</li> <li>9. Once the top seam is released, open the package using proper aseptic technique.</li> </ol> |
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<b>Interpretation of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation</b>	<ul style="list-style-type: none"> <li>• The STERIKING® See-Through 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 under Class 1 as accessories in compliance with the European Medical Device Directive MDD 93/42/EEC and its amendment 2007/47/EC. To show compliance with MDD the CE mark is printed on the label of the transport carton.</li> <li>• The products are registered by FDA under 510(k) Premarket Submission Nos.: K973827. Wipak Oy is certified to ISO 9001; ISO 13485; OHSAS 18001 and ISO 22000.</li> <li>• STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.</li> </ul>
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• The STERIKING® Roll Packaging are meant for low temperature sterilization cycles only. Do not steam sterilize these pouches, as they will melt.</li> </ul>
<b>Disposal</b>	Please refer to the local/national regulations regarding waste disposal.

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	
<b>Cleaning – Automated:</b>	
<b>Disinfection:</b>	
<b>Drying:</b>	
<b>Maintenance, inspection, and testing:</b>	

<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	<ul style="list-style-type: none"> <li>• Compatible with vaporized hydrogen peroxide, gas plasma and EO sterilization.</li> </ul>
<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 40-60%.</li> <li>• Do not exceed 40°C for sterile storage area.</li> <li>• 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>	
<b>Other Product Support Documents</b>	
<b>Reference Documents</b>	Sterilization Packaging Brochure, Sterilization Packaging Price List
<b>Customer Service contact:</b>	US Distributor: Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com

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