



Instructions for Use: Steriking® Reinforced Roll Packaging

<b>Brand Name of Product</b>	Steriking® Reinforced Roll Packaging, Manufactured by Wipak
<b>Generic Name of Product</b>	Pouches
<b>Product Code Number(s)</b>	RR41, RR43, RR45, RR47, RR49
<b>Intended Use</b>	The Steriking® Reinforced Roll Packaging are intended for use as packaging material for sterilization of heavy items by steam and ethylene oxide gas (EO).
<b>Range of Applications for Product</b>	N/A
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• The Steriking® Reinforced Roll Packaging is used to create custom sized packaging.</li> <li>• Single use</li> <li>• Non-sterile</li> <li>• Latex free.</li> </ul>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	<ul style="list-style-type: none"> <li>• When kept in the original packaging:             <ul style="list-style-type: none"> <li>○ No special conditions are required.</li> <li>○ Closed transportation packaging items are protected from moisture, heat, and direct sunlight or other sources of ultraviolet (UV) light.</li> </ul> </li> <li>• Once the rolls are removed from the packaging, the recommended long-term storage conditions are:             <ul style="list-style-type: none"> <li>○ Temperature: 18- to 24 °C (64- to 75 °F).</li> <li>○ Humidity 30–60% rh.</li> <li>○ Store the rolls in closed cabinets protected from a UV light source. (Note: The process indicator is sensitive to UV light and may change color over time, if not stored properly.)</li> </ul> </li> <li>• Can withstand freezing temperatures during transportation.</li> </ul>
<b>Packaging Contents</b>	N/A
<b>Shelf Life</b>	<p>It is recommended to use the rolls within five (5) years of the manufacture date.</p> <ul style="list-style-type: none"> <li>• The recommended “best before” date and the manufacturing date are stated on the carton label.</li> <li>• Each 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® Reinforced Roll Packaging is intended for use as packaging material for medical devices by sterilization by steam and EO.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>1. Roll out packaging and cut to the appropriate length of the item to be packaged. (NOTE: Ensure there is enough room for the package to be sealed without damaging the contents).</li> <li>2. Cut the packaging from the roll to the desired length.</li> <li>3. Before sealing, remove as much air as possible from the pouch to help prevent rupturing in sterilization.</li> <li>4. Place the proper class of indicator inside the pouch, according to your facility’s guidelines. (Note: Ensure pouch contents and the indicator are away from the seal area and will not get caught in the seal.)</li> <li>5. Ensure proper sealer conditions:             <ol style="list-style-type: none"> <li>a. Use a sealer designed for medical packaging.                 <ol style="list-style-type: none"> <li>i. Each brand might have a slightly different melting point.</li> </ol> </li> <li>b. Be sure to test your brand. Confirm the temperature setting on the heat sealer is appropriate for Roll Stock Packaging. Green tinted 165- to 200 °C (329- to 392 °F).</li> <li>c. Leave enough space beyond the seal for the opener to easily grasp; usually up to two (≤ 2) inches.</li> </ol> </li> </ol>

	d. 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.
<b>Diagrams (drawings, pictures)</b>	N/A
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Confirm the correct temperature setting on the heat sealer for Reinforced Roll Packaging.</li> <li>2. Hold the pouch taut (stretched or pulled tight) in the sealer to prevent wrinkles or air bubbles from forming in the seal. (Note: 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: <ol style="list-style-type: none"> <li>a. The pouch is sealed.</li> <li>b. Material beyond the seal from the opening is up to two (<math>\leq 2</math>) inches to allow for aseptic presentation.</li> </ol> </li> <li>4. Find the thumb tabs and begin to peel down the seams.</li> <li>5. Continue to roll down the seam, pulling film away from paper.</li> <li>6. Once the top seam is released, open the package using proper aseptic technique.</li> </ol>
<b>Interpretation of Test Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	<ul style="list-style-type: none"> <li>• The Steriking<sup>®</sup> see-through range of peel packages conform to the international product standards and norms: ISO 11607-1, ISO 11607-2.</li> <li>• The products are registered by FDA under 510(k) Premarket Submission Nos.: K210810, Wipak Oy is certified to ISO 9001:2015; ISO 13485:2016; and ISO 22000:2018.</li> <li>• Steriking<sup>®</sup> 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<sup>®</sup> standard range of packaging is not suitable for sterilization by irradiation, hydrogen peroxide or by hot, dry air at temperatures over 140 °C (284 °F).</li> <li>• The seals need to be strong to withstand the most vigorous sterilization process and handling while providing a clean peel.</li> <li>• Closing too strongly should be avoided when sealing rolls, as one seal needs to be opened fiber free. (Note: A manual test should be performed to control the seal strength.)</li> </ul>
<b>Disposal</b>	Please refer to the local/national regulations regarding waste disposal.

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</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>	<ul style="list-style-type: none"> <li>• Compatible with steam and EO sterilization.</li> <li>• <i>Pre-vacuum Sterilizer</i>: Wrapped trays (and instruments) should be exposed to: <ul style="list-style-type: none"> <li>○ 132 °C (270 °F) for four (4) minutes</li> <li>○ 135 °C (275 °F) for three (3) minutes.</li> </ul> </li> <li>• Compatible with Gravity Steam Sterilization: 121 °C (250 °F) for 30 minutes.</li> <li>• Arrange pouches so that there is minimal to no contact with each other.</li> <li>• Chemical Indicators conform to ISO 11140-1:2014 Type 1: Process indicators. <ul style="list-style-type: none"> <li>○ Steam indicator changes color from pink to brown).</li> <li>○ EO gas indicator changes color from purple-pink to beige-orange.)</li> <li>○ Color can vary depending upon the concentration of EO gas and amount of humidity.</li> </ul> </li> </ul>
<b>Storage Conditions for Processed Rolls</b>	<ul style="list-style-type: none"> <li>• The recommended long-term storage conditions: <ul style="list-style-type: none"> <li>○ Temperature: 15- to 25 °C (59- to 77 °F)</li> <li>○ Humidity: 30–60% rh</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Do not exceed 40 °C (104 °F) for storage.</li> <li>● 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>	<ul style="list-style-type: none"> <li>● The products are for single use only.</li> <li>● Maximum tested sterilization time: 30 minutes.</li> <li>● Maximum tested temperature: 135 °C (275 °F).</li> <li>● Validation tested for double pouching.</li> <li>● Sterilized roll pouches were tested to five (5) years of accelerated and real-time aging.</li> </ul>
<b>Related Healthmark Products</b>	Steriking® Roll Packaging
<b>Other Product Support Documents</b>	<a href="#">Marking and labeling Steriking® Packaging</a>
<b>Reference Documents</b>	Sterilization Packaging Brochure, Sterilization Packaging Price List
<b>Customer Service Contact</b>	U.S. 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>