




Instructions for Use: Steriking® Self Seal Pouches

<b>Brand Name of Product</b>	Steriking® Self Seal Pouches, Manufactured by Wipak								
<b>Generic Name of Product</b>	Pouches								
<b>Product Code Number(s)</b>	SS10, SS1, SS-T1, SS2, SS-T2, SS3, SS-T3A, SS4, SS-T4, SS-T4A, SS5A, SS-T5A, SS6, SS-T6, SS7, SS-T7.								
<b>Purpose of Product</b>	The STERIKING® see-through, self-sealable pouches are intended for use as packing material for sterilization for items by steam, or ethylene oxide gas.								
<b>Range of Applications for Product</b>	N/A								
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• The STERIKING® see-through packages are constructed of medical-grade paper (70 g/m<sup>2</sup>) that is heat-sealed together with a multiply PET/PP-plastic laminate (1<sup>2</sup>/<sub>40</sub> microns).</li> <li>• Code numbers SS1-SS7 and SS10 only—strip is not an indicator</li> <li>• Pouches that have an indicator strip:             <ul style="list-style-type: none"> <li>○                 <table style="margin-left: 40px; border: none;"> <tr> <td style="padding: 0 20px;">SS-T1</td> <td style="padding: 0 20px;">SS-T2</td> <td style="padding: 0 20px;">SS-T3A</td> <td style="padding: 0 20px;">SS-T4</td> </tr> <tr> <td style="padding: 0 20px;">SS-T4A</td> <td style="padding: 0 20px;">SS-T5A</td> <td style="padding: 0 20px;">SS-T6</td> <td style="padding: 0 20px;">SS-T7</td> </tr> </table> </li> </ul> </li> </ul>	SS-T1	SS-T2	SS-T3A	SS-T4	SS-T4A	SS-T5A	SS-T6	SS-T7
SS-T1	SS-T2	SS-T3A	SS-T4						
SS-T4A	SS-T5A	SS-T6	SS-T7						

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions for Unprocessed Pouches</b>	<ul style="list-style-type: none"> <li>• When kept in the original packaging, no special conditions are required.</li> <li>• 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 - 60 rh%.</li> <li>• Pouches should be stored in closed cabinets 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>	N/A
<b>Shelf Life of Unprocessed Pouches</b>	<ul style="list-style-type: none"> <li>• It is recommended pouches are used within three years of the manufacturer’s date.</li> <li>• The recommended “best before” date and the manufacturing date are labeled on the carton.</li> <li>• Each pouch has a lot number imprinted for traceability and to determine the manufacturer date.</li> </ul>

<b>Instructions for Using Product</b>	
<b>Description of Use(s)</b>	The STERIKING® see-through, self-sealable pouches are intended for use as packing material for items by sterilization by steam or ethylene oxide gas.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>1. Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization.</li> <li>2. Place the proper class of chemical indicator inside the pouch according to your specific facilities guidelines.</li> <li>3. Ensure pouch contents and the internal indicator are away from the seal area and will not get caught in the seal.</li> <li>4. Seal the pouch securely.</li> <li>5. Leave enough material beyond the seal for the opener to easily grasp (usually 1 - 1 ¼ inches).</li> <li>6. 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>	

	
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Remove protective strip</li> <li>2. Place indicator inside pouch (Class 1 Indicator)</li> <li>3. Fold flap</li> <li>4. Press down from the center with both thumbs and move outward. <ol style="list-style-type: none"> <li>a. Apply even pressure along the entire length of the strip, including the entire length of the outer folded edge, while moving thumbs.</li> <li>b. Repeat at least three times to ensure a proper seal.</li> </ol> </li> <li>5. Examine the seal to make sure you do not see any uneven spots or ridges.</li> <li>6. Also, check each end of the seal to be sure no channel exists, and the seal is complete.</li> <li>7. If there are uneven spots, ridges or channels, apply pressure again (evenly) to smooth out those spots.</li> <li>8. Peel pouches should be located in the sterilizer on a rack so that the pouches stand vertically on their edges to help ensure proper exposure to the sterilization process.</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® 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.: K803293, K953776 and K973827. Wipak Oy is certified to ISO 9001:2000; ISO 14001: 2004; OHSAS 18001: 1999; ISO 22000: 2005 and DS 3027: 2002.</li> <li>• STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.</li> </ul>
<b>Special Warnings and Cautions</b>	The STERIKING® standard range of see-through packaging is not suitable for sterilization by irradiation or by hot, dry air at the temperatures over 140 °C.
<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 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>	Be sure to check the seal is complete from end-to-end.
<b>Reassembly Instruction</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 132 °C (270 °F) for 4 minutes or 135 °C (275 °F) for 3 minutes.</li> <li>• Compatible with Gravity Steam Sterilization at 121 °C (250 °F) for 30 minutes.</li> <li>• Arrange pouches so that there is minimal to no contact between pouches. If touching, arrange so that paper side is facing paper side.</li> <li>• Chemical Indicators conform to ISO 11140-1 Type 1: Process indicators. Steam indicator changes color from blue to dark brown/black (<b>New Design from pink to brown</b>) and EO gas indicator from pink to yellow/orange on the outside of the pouch (<b>New Design from purple-pink to beige-orange</b>). Color can vary depending upon the concentration of EO gas and amount of humidity.</li> </ul>
<b>Storage for Sterilized Pouches</b>	<ul style="list-style-type: none"> <li>• Recommended storage conditions are 18 – 24 °C and humidity 30-60 rh%.</li> <li>• Do not exceed 40 °C for sterile storage area.</li> </ul>

	<ul style="list-style-type: none"> <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>	<ul style="list-style-type: none"> <li>These products are for single-use only.</li> <li>Maximum tested sterilization time – 30 minutes. Maximum tested temperature 135 °C</li> <li>Validation tested for double pouching.</li> </ul>

<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> hmark.com