




Instructions for Use: Steriking® Heat Seal Pouches

Brand Name of Product	Steriking® Heat Seal Pouches, Manufactured by Wipak
Generic Name of Product	Pouches
Product Code Number(s)	24, 2, 4, 25, 3, 5, 8, 19, 12, 27, 15, 6, 26, 13, 28, 33, 7, 7A, 10, 16, 29, 30, 14, 21, 31, 32, B35, B30, B31, B36, B37, B34
Purpose of Product	The STERIKING® heat-sealable pouches are intended for use as packing material for sterilization of items by steam, or ethylene oxide gas.
Range of Applications for Product	N/A
Key Specifications of Product	The STERIKING® see-through packages are constructed of paper-laminate that is heat-sealed together with a multiply 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, no special 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. • 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%. • Pouches should be stored in closed cabinets 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.
	N/A
Shelf Life of Unprocessed Pouches/Rolls	<ul style="list-style-type: none"> • It is recommended that the pouches/rolls are used within 5 years of manufacture. • The recommended “best before” date and the manufacturing date are stated on the carton label. • Each pouch/roll has lot number imprinted for traceability. This can be used to determine the manufacturer date.

Instructions for Using Product	
Description of Use(s)	The STERIKING® see-through heat-sealable pouches are intended for use as packing material for medical devices by sterilization by steam, or ethylene oxide gas.
Preparation for Use	<ol style="list-style-type: none"> 1. Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization. 2. Place the proper class of indicator inside the pouch according to your facility’s guidelines. 3. Ensure that pouch contents and the indicator are away from the seal area and will not get caught in the seal. Confirm, that the temperature setting on the heat sealer is appropriate for paper-laminate pouches. 4. Recommended sealing temperature for final closing is 165°-200°C (329°-392°F) depending on pressure and time. 5. Seal the pouch securely. 6. Leave enough space beyond the seal for the opener to easily grasp (usually ½ - 2 inches). <ol style="list-style-type: none"> A. If new designed pouch, seal along or below the dotted line on the pouch. 7. 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.
Diagrams (drawings, pictures)	N/A

	
Steps for Use of Product	<ol style="list-style-type: none"> 1. Confirm that the temperature setting on the heat sealer is appropriate for paper pouches. 2. Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal. 3. If using a rolling type, heat sealer let the peel pouch move along the guide on its own. 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.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	<ul style="list-style-type: none"> • The STERIKING® See-Through range of peel packages conform to the international product standards and norms: ISO 11607-1, ISO 11607-2. • The products are registered by FDA under 510(k) Premarket Submission Nos.: K973827. Wipak Oy is certified to ISO 9001:2008; ISO 13485: 2004; OHSAS 18001: 2007 and ISO 22000: 2005. • STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.
Special Warnings and Cautions	<ul style="list-style-type: none"> • The STERIKING® standard range of see-through packages is not suitable for sterilization by irradiation or by hot, dry air at the temperatures over 140°C.
Disposal	Please refer to the local/national regulations regarding waste disposal.

Reprocessing Instructions	
Point of Use	N/A
Preparation for decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instruction	N/A
Packaging	N/A
Sterilization	<ul style="list-style-type: none"> • Compatible with steam and EO sterilization. • Pre-vacuum Sterilizer: Wrapped trays, and instruments, should be exposed to 132°C (270°F) for 4 minutes or 135°C (275°F) at 3 minutes. • Compatible with Gravity Steam Sterilization- 30 minutes at 121°C/250°F. • Be sure to arrange pouches in such a way that there is minimal to no contact between pouches. If touching, arrange so that paper side is facing paper side. • Chemical Indicators conform to ISO 11140-1 Type 1: Process indicators. Steam indicator changes color from blue to dark brown/black (New Design from pink to brown) and EO gas indicator from pink to yellow/orange on the outside of the pouch (New Design from purple-pink to beige-orange). Color can vary depending upon the concentration of EO gas and amount of humidity.
Storage for Sterilized Pouches/Rolls	<ul style="list-style-type: none"> • The recommended storage conditions are 18-24°C and humidity 30-60%. • Do not exceed 40°C for sterile storage area. • 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.
Additional Information	<ul style="list-style-type: none"> • The products are for single use only. • Maximum tested sterilization time – 30 minutes. Maximum tested temperature 135°C.

	<ul style="list-style-type: none"> Validation tested for double pouching.
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

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