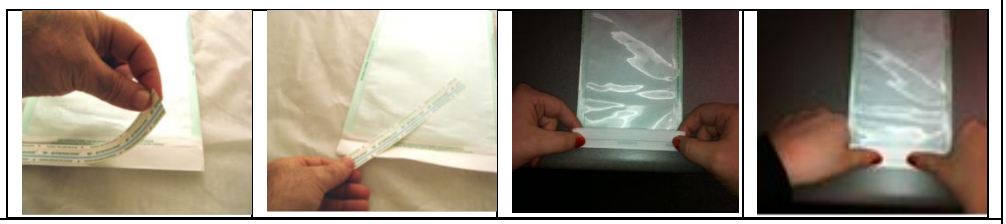
Instructions for Use: Steriking® Self Seal Pouches

Brand Name of Product	Steriking® Self Seal Pouches, Manufactured by Wipak
Generic Name of Product	Pouches
Product Code Number(s)	SS10, SS1, SS-T1, SS2, SS-T2, SS3, SS-T3A, SS4, SS-T4, SS-T4A, SS5A, SS-T5A, SS6, SS-T6, SS7, SS-T7.
Purpose of Product	The STERIKING® see-through self-sealable pouches are intended for use as packing material for sterilization for items by steam, or ethylene oxide gas.
Range of Applications for Product	
Key Specifications of Product	● The STERIKING® see-through packages are constructed of medical grade paper (70g/m^2) that is heat-sealed together with a multiply PET/PP-plastic laminate (12/40 microns). ● Code numbers SS1-SS7, SS10 only: The strip is not an indicator. ● Pouches that have an indicator strip: SS-T1, SS-T2, SS-T3A, SS-T4, SS-T4A, SS-T5A, SS-T6, SS-T7.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions for Unprocessed Pouches/Rolls:	● 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.
Packaging Contents	
Shelf Life of Unprocessed Pouches/Rolls	● 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.

Instructions for Using Product	
Description of Use (s)	The STERIKING® see-through self-sealable pouches are intended for use as packing material for medical devices by sterilization by steam, or ethylene oxide gas.
Preparation for Use	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 chemical indicator inside the pouch according to your specific facilities guidelines. 3. Ensure that pouch contents and the internal indicator are away from the seal area, and will not get caught in the seal. 4. Seal the pouch securely. 5. Leave enough material beyond the seal for the opener to easily grasp (usually 1- 1 ¼ inches). 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.
Diagrams (drawings, pictures)	
Steps for Use of Product	1. Remove protective strip 2. Place indicator inside pouch (Class 1 Indicator)

	3. Fold flap 4. Press down from the center with both thumbs and move outward. Apply even press while moving thumbs. Repeat at least twice to ensure a proper seal.
Interpretation of Results	
Contraindications of Test Results	
Documentation	● 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.: 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. ● STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.
Special Warnings and Cautions	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 ºC.
Disposal	Please refer to the local/national regulations regarding waste disposal.

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instruction	
Cleaning – Manual	
Cleaning – Automated	
Disinfection	
Drying	
Maintenance, Inspection, and Testing	
Reassembly Instruction	
Packaging	
Sterilization	● Compatible with steam and EO sterilization ● Pre-vacuum Sterilizer: Wrapped trays, and instruments, should be exposed to 132º C (270º F) for 4 minutes or 135º C (275º F) at 3 minutes. ● Compatible with Gravity Steam Sterilization- 30 minutes 121ºC/250ºF. ● 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	● Recommended storage conditions are 18-24℃ and humidity 30-60%. ● Do not exceed 40℃ 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	● The products are for single use only. ● Maximum tested sterilization time – 30 minutes. Maximum tested temperature 135ºC ● Validation tested for double-pouching.

Related Healthmark Products	
Other Product Support Documents	
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