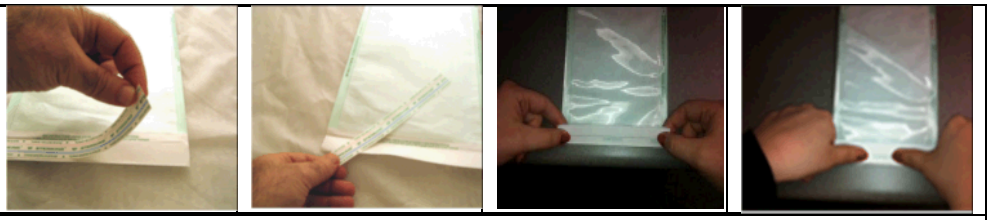
Instructions for Use: Steriking® Self Seal Pouches

Brand Name of Product	Steriking® Self Seal Pouches; manufactured by Wipak Oy™.
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	N/A
Key Specifications of Product	• The STERIKING® see-through packages are constructed of medical-grade paper 70 g/m^2 that is heat-sealed together with a multiply PET/PP-plastic laminate $^{12}/_{40}$ microns (0.30 microns). • Code numbers SS1-SS7 and SS10 only—strip is not an indicator. • Pouches having an indicator strip: SS-T1 SS-T2 SS-T3A SS-T4 SS-T4A SS-T5A SS-T6 SS-T7

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions for Unprocessed Pouches	• When kept in the original packaging: ○ No special conditions are required. ○ Closed transportation packaging, items are protected from moisture, heat and direct sunlight or other sources of UV light. • Once the pouches are removed from the packaging, recommended long-term storage conditions are: ○ Temperature of 18- to 24 °C (64.40- to 73.40 °F) ○ Humidity 30–60% rh. • 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.
Packaging Contents	N/A
Shelf Life of Unprocessed Pouches	• It is recommended that the products are put to their end use within three (3) years of manufacture. • The recommended "Best before" date and the manufacturing date are stated on the carton label. • Each pouch has a lot number imprinted for traceability and to determine the manufacturer date.

Instructions for Using Product	
Description of Use(s)	The Steriking® see-through, self-sealable pouches are intended for use as packing material for items 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 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 up to < 2 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. If desired, Place indicator inside pouch (Type1 Indicator).
	3. Fold flap.
	4. Press down from the center with both thumbs and move outward.
	  a. Apply even pressure along the entire length of the strip (including the entire length of the outer folded edge), while moving thumbs.
	  b. Repeat at least three times more to ensure a proper seal.
	5. Examine the seal to make sure you do not see any uneven spots or ridges.
	6. Check each end of the seal to be sure no channel exists, and the seal is complete.
	7. Apply pressure again (evenly) to smooth out uneven spots, ridges, or channels.
	8. Peel pouches should be located in the sterilizer on a rack and stood vertically on their edges to maximize exposure to the sterilization process.

Interpretation of Results	N/A
Contraindications of Test Results	N/A
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 packaging is not suitable for sterilization by irradiation or by hot, dry air at the temperatures over 140 °C (284 °F).
Disposal	Please refer to the local/national regulations regarding waste disposal.

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instruction	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	Be sure to check the seal is complete from end-to-end.
Reassembly Instruction	N/A
Packaging	N/A

Sterilization	● Compatible with steam and EO sterilization.
	● *Pre-vacuum Sterilizer*: Wrapped trays (and instruments) should be exposed to:
	  ○ 132 °C (270 °F) for 4 minutes
	  ○ 135 °C (275 °F) for 3 minutes.
	● Compatible with Gravity Steam Sterilization at 121 ºC (250 ºF) for 30 minutes.
	● Arrange pouches so that there is minimal to no contact between pouches.
	● Chemical Indicators conform to ISO 11140-1 Class 1: Process indicators.
	  ○ Steam indicator changes color from blue to dark brown/black (New Design from pink to brown)
	  ○ 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	● Recommended long-term storage conditions:
	  ○ Temperature: 18- to 24 °C (64.40- to 73.40 °F)
	  ○ Humidity 30–60% rh
	  ○ Do not exceed 40 °C for sterile storage area.

	• 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. • Sterilized self-seal pouches were tested to 3 years of accelerated and real time aging.
Additional Information	• These products are for single use only. • Maximum tested sterilization time: 30 minutes. • Maximum tested temperature: 135 °C. • Validation testing are performed for single and double pouching.

Related Healthmark Products	N/A
Other Product Support Documents	Marking and labeling Steriking® Packaging- https://www.hmark.com/wp-content/uploads/2022/03/Marking-and-labeling-Sterking-Packaging.pdf
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