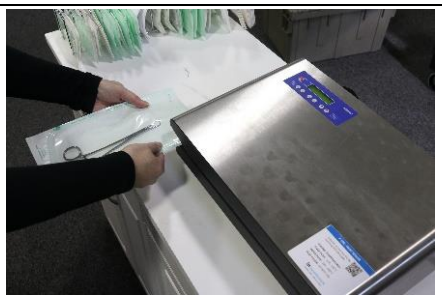
Instructions for Use: Steriking® Heat Seal Pouches

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 sterile barrier packaging 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/PP-plastic laminate (12/50 microns).

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions for Unprocessed Pouches	● When stored 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 and rolls are removed from the packaging, recommended long term storage conditions are: ○ Temperature: 18- to 24 °C (64.4- to 73.4 °F) ○ Humidity 30–60% rh.
Shelf Life of Unprocessed Pouches	● It is recommended that the products are put to their end use within five (5) 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. This can be used to determine the manufacture date.

Instructions for Using Product	
Description of Use(s)	The Steriking® see-through, heat-sealable pouches are intended for use as sterile barrier packaging for items for 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 during sterilization. 2. Place the proper type 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 the temperature setting on the heat sealer is appropriate for paper-laminate pouches. 4. Recommended sealing temperature for final closing is 165- to 200 °C (329- to 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 up to two (< 2) inches. (NOTE: If it is a newly designed pouch, seal along or below the dotted line.) 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)	

	  **Figure 1** **Figure 2**  **Figure 3**
Steps for Use of Product	1. Confirm the temperature setting on the heat sealer is appropriate for paper pouches. 2. Hold the pouch taut (stretched or pulled tight) in the sealer to prevent wrinkles or air bubbles from forming in the seal. (Fig. 1). 3. If using a rolling-type heat sealer, let the peel pouch move along the guide on its own. (Fig. 2). 4. Once the pouch completes the slide down the rolling side, verify the pouch is sealed and that material beyond the seal from the opening is up to two (<2) inches to allow aseptic presentation. (Fig. 3).
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.: K973827 and K210810 Wipak Oy is certified to ISO 9001; ISO 13485; OHSAS 18001 and ISO 22000. ● STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.
Special Warnings and Cautions	N/A
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	● Compatible with steam and EO sterilization. ● Pre-vacuum sterilizer for: ○ Four (4) minutes at 132 ℃ (270 ℉) ○ Three (3) minutes at 135 ℃ (275 ℉). ● Compatible with Gravity Steam Sterilization: 30 minutes at 121 ℃ (250 ℉). ● Be sure to arrange pouches in such a way that there is minimal to no contact between pouches.

Storage for Sterilized Pouches/Rolls	● Recommended long term storage conditions: ○ Temperature: 18- to 24 ℃ (64.4- to 73.4 ℉) ○ Humidity: 30–60% rh ○ Do not exceed 40 ℃ for storage. ● Facilities should develop a policy identifying events that may compromise the sterility of packaged items. This could include a maximum time period for storage. ● Sterilized heat seal pouches were tested for five (5) years of accelerated and real-time aging.
Additional Information	● The products are for single-use only. ● Maximum tested sterilization time: 30 minutes. ● Maximum tested temperature: 135 ℃. ● Validation testing 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