Instructions for Use: Steriking® Roll Packaging

Brand Name of Product	Steriking® Roll Packaging, Manufactured by Wipak
Generic Name of Product	Pouches
Product Code Number(s)	R39, R40, R41, R42, R43, R44, R45, RB50, RB51, RB52, RB53, RB54, RB55, RB56, RB57
Purpose of Product	The STERIKING® Roll Packaging is intended for use as packing material for sterilization of items by steam, or ethylene oxide gas.
Range of Applications for Product	
Key Specifications of Product	The STERIKING® Roll Packaging is used to create custom sized packaging. The gusseted option is for over-sized contents. It is used to accommodate the appropriate size for bulky items. The extra folds in the laminate expand like an accordion.

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 store properly.
Packaging Conditions	
Shelf Life of Unprocessed Pouches/Rolls	• 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 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® Roll Packaging is intended for use as packing material for medical devices by sterilization by steam, or ethylene oxide gas.
Preparation for Use	1. Roll out packaging to appropriate length of the item to be packaged. Be sure there is extra room so that the package is not too tight with contents and there is enough room for sealing the package. 2. Cut the packaging from the roll to the desired length. 3. Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization. 4. Place the proper class of indicator inside the pouch according to your facility's guidelines. 5. Ensure that pouch contents and the indicator are away from the seal area and will not get caught in the seal. 6. Ensure that the proper sealer conditions are used. 7. Use a sealer designed for medical packaging. Each brand might have a slightly different melting point. 8. Be sure to test your brand. 9. Confirm that the temperature setting on the heat sealer is appropriate for Roll Stock Packaging. Green tinted 165°-200°C (329°-392°F). 10. Leave enough space beyond the seal for the opener to easily grasp (usually ½ - 2 inches). 11. 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)	

	 1  2  3  4  5  6  7  8
Steps for Use of Product	1. Confirm that the temperature setting on the heat sealer is appropriate for Roll Packaging. Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal. 2. If using a rolling type heat sealer, let the peel pouch move along the guide on its own. 3. 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. 4. When opening the pouch, verify you are opening the correct scallop cut opening end. 5. Make sure scallop cut recognizes the correct opening direction. 6. Find the thumb tabs and begin to peel down the seams 7. Continue to roll down the seam, pulling film away from paper. 8. Once the top seam is released, open the package using proper aseptic technique.
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.: 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	● 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. ● The seals need to be strong to withstand the most vigorous sterilization process and handling yet providing a clean peel. Closing too strongly should be avoided when sealing rolls as one of the seals needs to be opened fiber free. A manual test should be carried out for controlling the seal strength.
Disposal	Please refer to the local/national regulations regarding waste disposal.

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	
Cleaning – Manual	
Cleaning – Automated	
Disinfection	
Drying	
Maintenance, Inspection, and Testing	
Reassembly Instructions	
Packaging	
Sterilization	● Compatible with steam and EO sterilization.

	• Pre-vacuum Sterilizer: Wrapped trays, and instruments, should be exposed to 132ºC (270ºF) for 4 minutes or 135ºC (275ºF) 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 plastic side. • Chemical Indicators conform to ISO 11140-1:2005 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 Conditions for Processed Pouches/Rolls	• The 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

2019-09-17 msmith

Rev. B