Instructions for Use: Steriking® Tyvek Self Seal Pouches

Brand Name of Product	Steriking® Tyvek Self Seal Pouches, Manufactured by Wipak
Generic Name of Product	Pouches
Product Code Number(s)	LTSS1 NI, LTSS2 NI, LTSS4 NI, LTSS4A NI, LTSS5A NI, LTSS6 NI, LTSS7 NI
Purpose of Product	The STERIKING® see-through self-sealable Tyvek® pouches are intended for use as packing material for medical devices for low temperature sterilization.
Range of Applications for Product	
Key specifications of product	The STERIKING® see-through packages are constructed of Tyvek® that is self-sealed together with a multiply PET/PE-plastic laminate (12/50 microns).

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions for Unprocessed Pouches/Rolls	• When kept in the original packaging, no special storage 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 40-60%. • Pouches should be stored in closed cabinets or 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 Conditions	
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. • 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® see-through self-sealable Tyvek® pouches are intended for use as packing material for medical devices for low temperature sterilization.
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 indicator inside the pouch according to your specific facilities guidelines. 3. Ensure that pouch contents and the indicator are away from the seal area, and will not get caught in the seal. 4. Seal the pouch securely. 5. Leave enough space 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. Fold flap 3. Press down from the center with both thumbs and move outward. Apply even pressure along the entire length of the strip while moving the thumbs. Repeat at least twice to ensure a proper seal.

	4. Examine the seal to make sure you do not see any uneven spots or ridges, if so apply pressure again evenly to smooth out those spots. 5. Peel Pouches should be loaded in the sterilizer on a rack so that the pouches stand vertically on their edges, to help ensure proper exposure to the sterilization process. 6. When loading pouches into the sterilizer be sure to arrange pouches where all tyvek are facing the same way
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, EN 868-5. ● The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive MDD/93/42 which is incorporated in the Finnish Act 1505/94 and its statutes. To show compliance with MDD/93/42 the CE mark is printed on the label of the transport carton. ● The products are registered by FDA under 510(k) Premarket Submission Nos.: K803293, K953776 and K973827. Wipak Oy is certified to ISO 9001; ISO 14001; OHSAS 18001; ISO 22000 and DS 3027. ● STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes.
Special Warnings and Cautions	● The STERIKING® Tyvek® pouches are meant for low temperature sterilization cycles only. Do not steam sterilize these pouches, as they will melt. ● Pouches should be stored in closed cabinets or otherwise protected from the UV-light source. The process indicator is sensitive to UV-light and may change color over time, if not stored properly.
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 vaporized hydrogen peroxide, gas plasma and EO sterilization
Storage for Processed Pouches/Rolls	● The recommended storage conditions are 18-24°C and humidity 40-60%. ● Do not exceed 40°C for sterile storage area. ● Shelf life of processed pouches/rolls is event-related. Facilities should develop a policy identifying event 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.

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 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

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