






Instructions for Use: Steriking® Heat Seal Pouches

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| 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 | Steriking® heat-sealable pouches are intended for use as sterile barrier packaging for sterilization of items by steam or ethylene oxide (EO) gas. |
| Range of Applications for Product | N/A |
| Key Specifications of Product | Steriking® see-through packages are constructed of paper-laminate that is heat-sealed together with a multiply PET/PP-plastic laminate 12/50 (0.24) microns. |

| Shipping & Storage | |
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| Shipping Conditions & Requirements | N/A |
| Storage Conditions for Unprocessed Pouches | <ul style="list-style-type: none"> • When stored in the original packaging: <ul style="list-style-type: none"> ○ No special conditions are required. ○ Closed transportation packaging items are protected from moisture, heat, and direct sunlight or other sources of UV light. • Recommended long-term climate-controlled storage conditions once pouches and rolls are removed from their original packaging: <ul style="list-style-type: none"> ○ Temperature: 18- to 24 °C (64.4- to 73.4 °F) ○ Humidity 30–60% rh. |
| Shelf Life of Unprocessed Pouches | <ul style="list-style-type: none"> • It is recommended that the products are put to their end use within five (5) years of manufacture. (NOTE: 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 | |
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| Description of Use(s) | Steriking® see-through, heat-sealable pouches are intended for use as sterile barrier packaging for items for sterilization by steam or EO gas. |
| Preparation for Use | <ol style="list-style-type: none"> 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 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) | |

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| |    <p style="text-align: center;">Figure 1 Figure 2</p> <p style="text-align: center;">Figure 3</p> |
| Steps for Use of Product | <ol style="list-style-type: none"> 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 | <ul style="list-style-type: none"> • The Striking® 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; and ISO 22000. • STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes. |
| Special Warnings and Cautions | <p>N/A</p> <ul style="list-style-type: none"> • Do not use rubber bands, non-approved tape, safety pins, paper clips, staples, or other sharp objects to secure packages or to organize the contents. • ⚠ Caution: Hot! Be careful not to get burned while using the heat sealer. |
| Disposal | Please refer to the local/state/national regulations regarding waste disposal. |

| Reprocessing Instructions | |
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| 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 | <ul style="list-style-type: none"> • Compatible with steam and EO sterilization. • Validated cycles for sterilization are as follows: <ul style="list-style-type: none"> ○ Pre-vacuum sterilizer for: <ul style="list-style-type: none"> a. 132 °C (270 °F) for 4 minutes. |

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| | <ul style="list-style-type: none"> b. 135 °C (275 °F) for 3 minutes. <ul style="list-style-type: none"> o Compatible with Gravity Steam Sterilization: 121 °C (250 °F) for 30 minutes. • Be sure to arrange pouches in such a way that there is minimal to no contact between pouches. |
| Storage for Sterilized Pouches/Rolls | <ul style="list-style-type: none"> • Recommended long-term climate-controlled storage conditions: <ul style="list-style-type: none"> o Temperature: 18- to 24 °C (64.4- to 73.4 °F) o Humidity: 30–60% rh o Do not exceed 40 °C 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 | <ul style="list-style-type: none"> • The products are for single use only. • Maximum tested sterilization time: 30 minutes. • Maximum tested temperature: 135 °C. • Validation testing was performed for single and double pouching. |

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| 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, A Getinge Company 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com |