

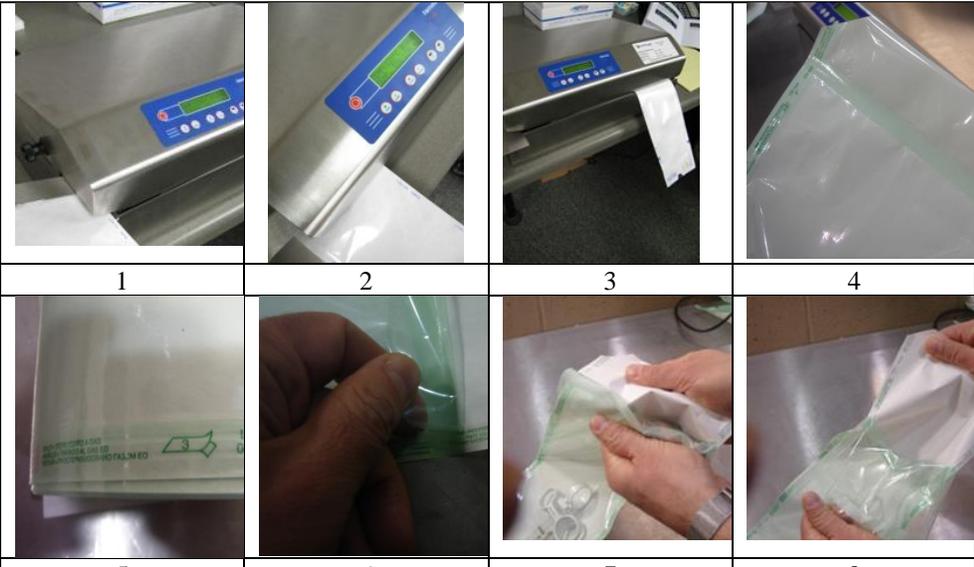


Instructions for Use: Steriking® Roll Packaging

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, R 39-655, R 40-655, R 41-655, R 42-655, R 43-655, R 44-655, R 45-655
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	N/A
Key Specifications of Product	The Steriking® Roll Packaging is used to create custom sized packaging.

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions for Unprocessed Rolls	<ul style="list-style-type: none"> ● When kept 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 ultraviolet UV light. ● Once the rolls are removed from the packaging, recommended long term storage conditions are: <ul style="list-style-type: none"> ○ Temperature: 18- to 24 °C (64.4- to 73.4 °F). ○ Humidity 30–60% rh. ● Store the rolls 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 Rolls	<p>It is recommended that the rolls are used with five (5) years of the manufacturer’s date.</p> <ul style="list-style-type: none"> ● The recommended “Best before” date and the manufacturing date are stated on the carton label. ● Each roll has a lot number imprinted for traceability. This can be used to determine the manufacturer 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	<ol style="list-style-type: none"> 1. Roll out packaging to appropriate length of the item to be packaged. Ensure there is enough room for the package to be sealed without damaging the contents. 2. Cut the packaging from the roll to the desired length. 3. Before sealing, remove as much air as possible from the pouch to help prevent rupturing in sterilization. 4. Place the proper class of indicator inside the pouch, according to your facility’s guidelines. 5. Ensure pouch contents and the indicator are away from the seal area and will not get caught in the seal. 6. Ensure the proper sealer conditions are used. <ol style="list-style-type: none"> a. Use a sealer designed for medical packaging. b. Each brand might have a slightly different melting point. c. Be sure to test your brand. 7. Confirm the temperature setting on the heat sealer is appropriate for Roll Stock Packaging. Green tinted 165- to 200 °C (329- to 392 °F). 8. Leave enough space beyond the seal for the opener to easily grasp; usually up to two (<2) inches. 9. 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)	<p>N/A</p>  <p>1 2 3 4</p> <p>5 6 7 8</p>
Steps for Use of Product	<ol style="list-style-type: none"> 1. Confirm the temperature setting on the heat sealer is appropriate for Roll Packaging. 2. Hold the pouch taut (stretched or pulled tight) in the sealer to prevent wrinkles or air bubbles from forming in the seal. (Note: 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 up to two (<2) inches to allow for aseptic presentation. 4. Find the thumb tabs and begin to peel down the seams. 5. Continue to roll down the seam, pulling film away from paper. 6. Once the top seam is released, open the package using proper aseptic technique.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • The Steriking® standard range of packaging is not suitable for sterilization by hot, dry air at temperatures over 140 °C. • 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. (Note: A manual test should be carried out to control the seal strength.)
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 Instructions	N/A
Packaging	N/A
Sterilization	<ul style="list-style-type: none"> • Compatible with steam and EO sterilization.

	<ul style="list-style-type: none"> ● <i>Pre-vacuum Sterilizer</i>: Wrapped trays (and instruments) should be exposed to: <ul style="list-style-type: none"> ○ 132 °C (270 °F) for four (4) minutes ○ 135 °C (275 °F) for three (3) minutes. ● Compatible with Gravity Steam Sterilization—30 minutes at 121 °C (250 °F). ● Be sure to arrange pouches in such a way that there is minimal to no contact between pouches. ● Chemical Indicators conform to ISO 11140-1:2005 Type 1: Process indicators. <ul style="list-style-type: none"> ○ 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 Conditions for Processed Rolls	<ul style="list-style-type: none"> ● The recommended long-term storage conditions: <ul style="list-style-type: none"> ○ Temperature: 18- to 24 °C (64.4- to 73.4 °F) ○ Humidity: 30–60% rh ○ 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 period of time for storage.
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 tested for double pouching. ● Sterilized roll pouches were tested to five (5) years of accelerated and real-time aging.

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-Steriking-Packaging.pdf
Reference Documents	Sterilization Packaging Brochure, Sterilization Packaging Price List
Customer Service Contact	U.S Distributor: Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com