



Instructions for Use: Steriking® Heat Seal & Self-Seal Pouches for Long Medical Devices

Brand Name of Product	Heat Seal & Self-Seal Pouches for Long Medical Devices
Generic Name of Product	Pouches for Long Medical Devices
Product Code Number(s)	SDV10, SDV20, SSDV10, SSDV20
Intended Use	The STERIKING® see-through, self-sealable and heat seal pouches are intended for use as packing material for sterilization for items by steam.
Range of Applications for Product	N/A
Key Specifications of Product	The STERIKING® see-through packages are constructed of medical-grade paper (100 g/m ²) that is heat-sealed together with a multi-ply PET/PP-plastic laminate (1 ² / ₄₀ microns).

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	<ul style="list-style-type: none"> ● When kept in the original packaging (closed transportation packaging): <ul style="list-style-type: none"> ○ no special conditions are required. ○ items are protected from a) moisture, b) heat c) direct sunlight or other sources of UV light. ● Once the pouches and rolls are removed from the packaging, they are to be stored at: <ul style="list-style-type: none"> ○ Temperature: 18- to 24 °C (64.4- to 75.2 °F) ○ Humidity: 30–60 rh%.
Packaging Contents	N/A
Shelf Life Prior to Sterilization	<ul style="list-style-type: none"> ● Pouches should be used: <ul style="list-style-type: none"> ○ Self-seal: use within three (3) years of manufacture ○ Heat seal: use within five (5) years of manufacture ● The recommended “best before” date and manufacture date are labeled on the carton. ● Each pouch has a lot number imprinted for traceability and to determine the manufacture date.

Instructions for Using Product	
Description of Use(s)	The STERIKING® see-through, self-sealable pouches are intended for use as packing material for sterilization for items by steam.
Preparation for Use	<ol style="list-style-type: none"> 1. Before sealing, remove as much air as possible from the pouch to help prevent rupturing in sterilization. 2. Ensure pouch contents and the internal indicator are away from the seal area and will not get caught in the seal. 3. Seal the pouch securely. 4. Leave enough material beyond the seal for the opener to easily grasp (a minimum of 1 inch [2.54]).
Diagrams (drawings, pictures)	
Steps for Use of Product	<p>Heat Seal Pouches</p> <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 in the sealer to prevent wrinkles or air bubbles from forming in the seal. 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 the rolling side, verify the pouch is sealed and that material beyond the seal from the opening is a minimum of two (2) inches (5.08 cm). <p>Self-Seal Pouches</p> <ol style="list-style-type: none"> 1. Remove protective strip.

	<ol style="list-style-type: none"> 2. Fold flap. 3. Press down from the center with both thumbs and move outward. <ol style="list-style-type: none"> a. Apply even pressure along the entire length of the strip—including the entire length of the outer folded edge—while moving thumbs. b. Repeat at least three (3) times to ensure a proper seal. 4. Examine the seal to ensure there are no uneven spots or ridges. 5. Check each end of the seal. Ensure no channel exists and the seal is complete. 6. If there are uneven spots, ridges, or channels, apply pressure, again, (evenly) to smooth out those spots. 7. Peel pouches should be in the sterilizer on a rack and stood vertically on their edges to help ensure proper exposure to the sterilization process.
Interpretation of Test 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.: SDV10 and SDV20- K210810.510k SSDV10 and SSDV20- K221016.501k • 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	Be sure to check the seal is complete from end to end.
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	<ul style="list-style-type: none"> • Compatible with steam • <i>Prevacuum 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 at 121 °C (250 °F) for 30 minutes. • Arrange pouches so that there is minimal to no contact between pouches.
Storage for Sterilized Pouches	<ul style="list-style-type: none"> • Recommended storage conditions: <ul style="list-style-type: none"> ○ Temperature: 18- to 24 °C (64.4- to 75.2 °F) ○ Humidity 30–60 rh% ○ Do not exceed 40 °C for sterile storage area. • 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. • Heat seal pouches were tested to 5 years of storage from the date of sterilization • Sterilized self-seal pouches were tested to three (3) years of storage to the date of sterilization
Additional Information	<ul style="list-style-type: none"> • Single use only. • Maximum tested sterilization time: 30 minutes. • Maximum tested temperature: 135 °C. • Validation tested for 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-Steriking-Packaging.pdf
Reference Documents	Sterilization Packaging Brochure, Sterilization Packaging Price List

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