**Instructions for Use: Steriking® Tyvek Heat Seal Pouches**

<table>
<thead>
<tr>
<th>Brand Name of Product</th>
<th>Steriking® Tyvek Heat Seal Pouches, Manufactured by Wipak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Name of Product</td>
<td>Pouches</td>
</tr>
<tr>
<td>Product Code Number(s)</td>
<td>LTS7520, LTS1025, LTS1530, LTS2038, LTS2538, LTS2550, B35, B30, B31, B36, B37, B34</td>
</tr>
<tr>
<td>Purpose of Product</td>
<td>The STERIKING® see-through heat-sealable Tyvek® pouches are intended for use as packing material for medical devices by vaporized hydrogen peroxide.</td>
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<tr>
<td>Range of Applications for Product</td>
<td></td>
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<tr>
<td>Key specifications of product</td>
<td>The STERIKING® see-through packages are constructed of Tyvek® that is heat-sealed together with a multiply PET/PE-plastic laminate (12/50 microns).</td>
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</tbody>
</table>

### Shipping & Storage

#### Storage Conditions

It is recommended that the STERIKING® products are kept in the original, closed transport carton and are stored in dry and clean conditions, protected from direct sunlight, UV light sources and excessive moisture.

#### Packaging Conditions

- **Shelf Life**: The shelf life is event-related and not time-related. It is recommended that the products are put to their end use within 5 years of manufacture. The recommended “best before” date and the manufacturing date are stated on the carton label.

### Instructions for Using Product

#### Description of Use(s)

The STERIKING® see-through heat-sealable Tyvek® pouches are intended for use as packing material for medical devices by vaporized hydrogen peroxide.

#### 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. Confirm that the temperature setting on the heat sealer is appropriate for Tyvek® pouches. Recommended sealing temperature for final closing is 120-130°C (248-266°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 ½ - 2 inches).
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):

![Diagram 1](image1.jpg)

![Diagram 2](image2.jpg)

![Diagram 3](image3.jpg)

#### Steps for Use of Product

1. Confirm that the temperature setting on the heat sealer is appropriate for Tyvek® pouches.
2. Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal.
3. If using a rolling type heat sealer, let the peel pouch move along the guide on its own.
4. 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.
### Interpretation of Results


- The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive MDD 93/42/EEC and its amendment 2007/47/EC. To show compliance with MDD the CE mark is printed on the label of the transport carton.
- 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 a 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
  - May be used in standard gas plasma cycles (validation data available online).
  - Be sure to arrange pouches in such a way that there is minimal to no contact between pouches. If touching, arrange so that Tyvek® side is facing the plastic side.

- Storage:
  - The sterilized products are sorted for storage or delivery to the wards.
  - 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.
  - It is recommended that the room climate has a humidity of 40% to 60% and a temperature of 15-25°C.

#### 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:

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