

## Instructions for Use: Self-Looping labels IFU

<b>Brand Name of Product</b>	Self-Looping Labels
<b>Generic Name of Product</b>	Tray labels
<b>Product Code Number(s)</b>	403005, 403115, 403125, 403225, 403225 OR, 403225-QTO, 404225-351-GI, 403225 LNR, 403225 PK, 403225 RD, 403225 RD-BIO, 403225 SLOTTED, 403225 SLOTTED PINK, 403225 YL, 403225 BL, 403225 GN, SST-001
<b>Purpose of Product</b>	Self-Looping Labels facilitate specific markings/remarks for sterile containment trays. Designed to minimize misunderstandings about an instrument tray's contents and notify about the maintenance of an item.
<b>Range of Applications for Product</b>	N/A
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• Self-looping style for mounting on the handle of any closed container.</li> <li>• Compatible with steam, (ethylene oxide) EO, and (vaporized hydrogen peroxide (VHP) sterilization.</li> <li>• Available in a variety of colors.</li> <li>• Reusable.</li> </ul>

Shipping & Storage	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	N/A
<b>Packaging Contents</b>	Packaged; 500 per box.
<b>Shelf Life</b>	N/A

Instructions for Using Product	
<b>Description of Use(s)</b>	The polyethylene terephthalate (PET) based label is suitable for sterilization and resistant to washing and disinfection; thus, it can go through repeated reprocessing cycle.
<b>Preparation for Use</b>	N/A
<b>Diagrams (drawings, pictures)</b>	N/A
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Loop the tray label through the handle of the container or tray.</li> <li>2. When using a slotted label, push the count sheet through the tray label so that it hangs evenly. You can also affix an ID label to the front of the tag.</li> </ol>
<b>Interpretation of Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	N/A
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• Self-looping labels are reusable. <ul style="list-style-type: none"> <li>○ Inspect the Self-looping label prior to reuse.</li> <li>○ Discard label when showing signs of wear and tear (e.g., fading, scratches, tears, etc.).</li> </ul> </li> <li>• Do not allow labels to be in physical contact with surgical instruments during sterilization cycles.</li> <li>• Do not block any vent holes in trays with labels, as this may interfere with sterilization.</li> <li>• ⚠ (Caution: May be hot.) Do not handle labels until they cool to room temperature after sterilization or thermal disinfection.</li> </ul>
<b>Disposal</b>	Damaged labels should be disposed of in accordance with facility policy.

Reprocessing Instructions	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	Manually wash labels with a neutral pH detergent and warm water.
<b>Cleaning – Automated</b>	Compatible with washer-disinfectors.
<b>Disinfection</b>	<ul style="list-style-type: none"> <li>• Manually wipe labels with disinfectant wipes.</li> </ul>

	<ul style="list-style-type: none"> <li>Thermal disinfection stage of an automated washer is sufficient for disinfection of the label.</li> </ul>
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	Reusable labels should be inspected for damage prior to being reused.
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>Compatible with steam, EO, and VHP sterilization.</li> <li>Recommended cycle time for steam sterilization: <ul style="list-style-type: none"> <li>132 °C (270 °F) for 4 minutes</li> <li>135 °C (275 °F) for 3 minutes.</li> </ul> </li> </ul>
<b>Storage</b>	N/A
<b>Additional Information</b>	<ul style="list-style-type: none"> <li>Labels should hang freely from the tray handle and not block holes in the tray.</li> <li>Repeated reprocessing cycles will eventually cause the labels to lose integrity. Replace disfigured labels.</li> </ul>

<b>Related Healthmark Products</b>	N/A
<b>Other Product Support Documents</b>	Labels Brochure
<b>Reference Documents</b>	N/A
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com