

Instructions for Use: Self-Looping labels IFU

Brand Name of Product	Self-Looping Labels
Generic Name of Product	Tray labels
Product Code Number(s)	403005, 403115, 403125, 403225, 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
Purpose of Product	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.
Range of Applications for Product	N/A
Key Specifications of Product	<ul style="list-style-type: none"> • Self-looping style for mounting on the handle of any closed container. • Compatible with steam, EO, and VHP sterilization. • Available in a variety of colors. • Reusable

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

Instructions for Using Product	
Description of Use(s)	The PET (polyethylene terephthalate) based label is suitable for sterilization and resistant to washing and disinfection; thus, it can go through repeated reprocessing cycle.
Preparation for Use	N/A
Diagrams (drawings, pictures)	N/A
Steps for Use of Product	<ol style="list-style-type: none"> 1. Loop the tray label through the handle of the container or tray. 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.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	<ul style="list-style-type: none"> • Labels are reusable. <ul style="list-style-type: none"> ◦ Discard label when showing signs of wear and tear (e.g., fading, scratches, tears, etc.). • Do not allow labels to be in physical contact with surgical instruments during sterilization cycles. • Do not block any vent holes in trays with labels, as this may interfere with sterilization. • Do not handle labels until they cool to room temperature after sterilization or thermal disinfection.
Disposal	Damaged labels should be disposed of in accordance with facility policy.

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	Manually wash labels with a neutral pH detergent and warm water.
Cleaning – Automated	<ul style="list-style-type: none"> • Compatible with washer-disinfectors
Disinfection	<ul style="list-style-type: none"> • Manually wipe labels with disinfectant wipes. • Thermal disinfection stage of an automated washer is sufficient for disinfection of the label.
Drying	N/A

Maintenance, Inspection, and Testing	Reusable labels should be inspected for damage prior to being reused.
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	<ul style="list-style-type: none"> • Compatible with steam, EO, and VHP sterilization. • Recommended cycle time for steam sterilization: <ul style="list-style-type: none"> ○ 132 °C (270 °F) for 4 minutes ○ 135 °C (275 °F) for 3 minutes.
Storage	N/A
Additional Information	<ul style="list-style-type: none"> • Make sure the label is hanging freely from the tray handle and not blocking holes in the tray. • As the result of repeated reprocessing cycles, the labels will begin to lose integrity. Replace when they become disfigured.

Related Healthmark Products	N/A
Other Product Support Documents	Labels Brochure, Labels Price List
Reference Documents	N/A
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com