

Instructions for Use: Steam Sterilization Indicator Dot

Brand Name of Product	Steam Sterilization Indicator Dot
Generic Name of Product	Steam Indicator Dot
Product Code Number(s)	CI 150
Intended Use	The indicators are used to demonstrate that the unit or load has been exposed to a steam sterilization process.
Range of Applications for Product	To demonstrate that the load has been exposed to a steam sterilization process.
Key Specifications of Product	<ul style="list-style-type: none"> ● Lead free ● Type 1 Process Indicator ● Color change: light color (off-white/tan) to dark color (brown/black)

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	<ul style="list-style-type: none"> ● Best stored in a dry (<50% relative humidity) condition at room temperature 15-30°C (59-86°F). ● Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents. Store away from chemicals and sterilants (e.g., hydrogen peroxide).
Packaging Conditions	
Shelf Life	<ul style="list-style-type: none"> ● Shelf life is four years from the date of manufacture. ● Lot code and expiration date is printed on the package label.

Instructions for Using Product	
Description of Use(s)	To demonstrate that the load has been exposed to a steam sterilization process.
Preparation for Use	
Diagrams (drawings, pictures)	
Steps for Use of Product	<ol style="list-style-type: none"> 1. Place in/on item(s) undergoing steam sterilization. 2. Process the load. 3. After processing, check the indicator for the specified color change: <ol style="list-style-type: none"> a. After steam processing, the chemical indicator will show a visual color change from a light color (off-white/tan) to dark color (brown/black). b. If the indicator ink remains light, it indicates inadequate exposure conditions and the item(s) should be returned for reprocessing.
Interpretation of Test Results	<ul style="list-style-type: none"> ● After steam processing, the indicator ink should be dark (brown/black). If the indicator ink remains light, it indicates inadequate exposure conditions and the item(s) should be returned for reprocessing. ● After use, the indicator will not change visually when stored at recommended conditions. The indicator color change is permanent and irreversible.
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	<ul style="list-style-type: none"> ● Only for use in steam sterilization. ● Not for use to monitor dry heat, ethylene oxide, or other sterilization processes.
Disposal	Single use.

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	
Cleaning – Manual	
Cleaning – Automated	
Disinfection	
Drying	

Maintenance, Inspection, and Testing	
Reassembly Instructions	
Packaging	
Sterilization	Appropriate for use in the following FDA Cleared Steam Sterilization Cycles: Gravity cycle at 121°C for 30 minutes PreVac at 132°C for 4 minutes PreVac at 135°C for 3 minutes
Storage	<ul style="list-style-type: none"> • Best stored in a dry (<50% relative humidity) condition at room temperature 15-30°C (59-86°F). • Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents. Store away from chemicals and sterilants (e.g., hydrogen peroxide).
Additional Information	
Related Healthmark Products	
Other Product Support Documents	Sterilization Packaging Brochure, Sterilization Packaging Price List
Reference Documents	ISO: 11140-1:2014
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com



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