



Instructions for Use: Biological Indicator-Steam

Brand Name of Product	EZTest® Biological Indicator-Steam
Generic Name of Product	Biological Indicator- Steam
Product Code Number(s)	6005500537
Intended Use	A self-contained biological indicator for monitoring steam sterilization cycles.
Range of Applications for Product	N/A
Key Specifications of Product	<ul style="list-style-type: none"> • BI Growth Medium: purple to yellow with growth • Biological vial size: 1.79 inches

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	<ul style="list-style-type: none"> • Store at room temperature (15 - 30 °C) • Do not store near sterilants or other chemicals
Packaging Contents	Box of 100 biological indicators.
Shelf Life	Please refer to the expiration date printed on the product packaging.

Instructions for Using Product	
Description of Use(s)	N/A
Preparation for Use	N/A
Diagrams (drawings, pictures)	N/A
Steps for Use of Product	<p>Exposure</p> <ol style="list-style-type: none"> 1. Load the sterilizer as normal 2. Identify the indicators by labeling pertinent process information 3. Place an EZTest® biological indicator in the load to be sterilized in a horizontal position with representative materials to be sterilized and located in the most difficult to sterilize location of the load per the sterilizer manufacturer's IFU. 4. Select the appropriate cycle and expose the load to the sterilization cycle <ol style="list-style-type: none"> a. If a Flash cycle (i.e., IUSS) is selected the items should be unwrapped b. If the come-up time is less than one-minute, use of a three-minute exposure cycle may have to be extended to four minutes to ensure that biological indicator is inactivated 5. After the cycle is complete, remove the biological indicator from the sterilizer and allow cooling for at least 10 minutes 6. Retrieve the EZTest® biological indicators from the load 7. A chemical indicator on the label changes from blue to black when sterilization exposure has occurred. This distinguishes exposed from unexposed units. <i>(Note: A black color does not indicate acceptable sterilization).</i> <p>Incubation</p> <ol style="list-style-type: none"> 1. To activate the media, place the indicator using a “crushing” device in an upright position and gently squeeze the crusher tube to break the glass ampoule to allow the medium to mix with the spores 2. Place the activated indicator in an appropriate incubator adjusted at 55 - 60 °C in the incubator rack and incubate immediately <p>Use of Controls</p> <p>As a positive growth control, place an activated, un-sterilized EZTest® biological indicator, with the same lot number as those to be used in loads, in each incubator daily. Examine the positive indicator at regular intervals (i.e., 4, 8, 12 and 24 hours). The yellow color is evidence of bacterial growth. Record the results. Remove all positive</p>

	indicators as the yellow color is noticed and dispose of as mentioned below in the "Interpretation of Test Results" section. <i>(Note: If the positive control does not grow, do not use the units from this box.)</i>
Interpretation of Test Results	Biological Indicator: <ol style="list-style-type: none"> 1. Examine the biological indicator for signs of color change during incubation (i.e., 8, 12, 18 and 24 hours) <ol style="list-style-type: none"> a. Appearance of a yellow color indicates bacterial growth b. No color change indicates adequate sterilization 2. Act on a positive test (yellow color) as soon as the color change is noted. <ol style="list-style-type: none"> a. Notify appropriate hospital personnel (i.e., Infection Control) b. Always retest the sterilizer with an EZTest® biological indicators in another load. The incubation time is 24 hours (meets the US FDA, CDRJ, RIT protocol) 3. Record the results.
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	<ul style="list-style-type: none"> • After sterilization, the contents of the EZTest® biological indicator are hot and under pressure • Always allow for cooling at least 10 minutes. Failure to cool may cause the glass ampule to burst and may result in injury from hot liquid <i>(Note: Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be autoclaved then discarded.)</i>
Disposal	<ul style="list-style-type: none"> • Incinerate or autoclave any positive cultures at 121 °C (250 °F) for no less than 30 minutes • Dispose of in accordance with your institution's policy • Dispose of expired indicators by autoclaving at 121 °C (250 °F) for no less than 30 minutes

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	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	N/A
Storage	N/A
Additional Information	N/A
Related Healthmark Products	N/A
Other Product Support Documents	Sterilization Brochure, Sterilization 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