Technical Data Sheet

INSTANT 20s INDICATORS
For Monitoring Steam Processes

True Indicating Codes: ISCS-06

Product Description

Instant 20s Indicator Kits for monitoring Steam processes consist of:

- A polypropylene vial and cap
- Tablet manufactured with proprietary materials extracted from *Geobacillus stearothermophilus* spores contained within the orange silicone base with foam insert
- One bottle of Indicator Solution, disposable tweezers and cups for viewing results

Physical Properties

Process	Steam at 121°C and 134°C
Dimensions	52 mm x 13.5 mm
Packaging	25 Indicators per box

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more Instant 20s Indicator be included with every load.

Indications for Use

The True Indicating Instant 20s Indicator, a multiple, interactive, bacterial enzyme indicator, is used for monitoring saturated steam sterilization processes operating at: 121°C, 30 minutes (Gravity) and 134°C, 3.5 minutes (Pre-Vacuum). The Instant 20s Indicators are ideal for monitoring non-liquid steam sterilization cycles within full, partial, or empty chambers. The Instant 20s Indicators can be exposed with mixed loads (porous and non-porous), porous only loads or non-porous only loads.

ISCS-06 may be used for monitoring steam sterilization efficacy.

Instructions for Use

The following instructions provide necessary information for an end user to understand how to use the Instant 20s Indicator. Always refer to the directions which are provided with the product and adhere to any and all warnings and cautions.

Exposure: The Instant 20s Indicator may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or the Instant 20s Indicator in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle. After sterilization exposure, remove Instant 20s Indicator and/or product from sterilizer.

Instant 20s Indicators may be held at room temperature for up to 72 hours post-exposure prior to activation without any impact to their performance of providing the efficacy of a sterilization cycle. If the processed Instant 20s Indicators are not activated within 72 hours of exposure, the Instant 20s Indicator should be discarded and the cycle should be repeated.

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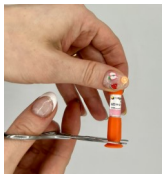
Result: Efficacy of the cycle can be determined in 20 seconds or less using the Biological Tablet and Indicator Solution which will determine the viability of enzymes derived from *Geobacillus stearothermophilus* post-sterilization.

Slowly remove the orange base from the vial to access the Biological Tablet. Scissors may be utilized to aid in accessing the Biological Tablet. If scissors are used, cut the bottom of the red base just above the widest portion as the Biological Tablet is on the foam insert inside of the red base.



Allow the Tablet to remain in the base or transfer to a plastic cup included in the kit, and add 1-3 drops of Indicator Solution onto the Tablet.

NOTE: No gloves are necessary as the Instant 20s Indicator and Indicator Solution have been evaluated and do not contain any irritants to the skin. Aseptic transfer is not required.

After 20 seconds, record the color of the Tablet and then discard immediately per the disposal instructions outlined on the Certificate of Analysis. Repeat process for one Instant 20s Indicator which has not been exposed as a Positive Control.

Tablet Interpretation: Processed Instant 20s Indicator: If the Tablet remains the initial off-white/yellow color for 20 seconds, the cycle was effective. This indicates a **Negative** result meaning all enzymes from *Geobacillus stearothermophilus* have been deactivated within the Instant 20s Indicator. If the Tablet turns a red color any time during or at 20 seconds, the cycle was not effective. This indicates a **Positive** result, meaning enzymes from *Geobacillus stearothermophilus* are still active within the Instant 20s Indicator. The cycle must be investigated and the load must be exposed again using an additional Instant 20s Indicator.

 Negative Result  Positive Result

Positive Control: The Biological Tablet should transition to red within 20 seconds. If the Biological Tablet does not transition to red, the test is considered invalid. Ensure the Instant 20s Indicator evaluated as the Positive Control had not been processed and that the Indicator Solution has not reached its expiration date. It is critical for the Tablet result to be visually determined within 20 seconds of adding the Indicator Solution to the Tablet. Do NOT view the color of the tablet after 20 seconds of adding the Indicator Solution. A secondary reaction may occur which is unrelated to the Biological Tablet enzyme's viability. If more than 20 seconds has passed and the result was not visually determined, the test is invalid. Discard the Tablet and conduct another Positive Control test again.

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

ISO 11138-3 Sterilization of healthcare products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes.

USP <55> Biological Indicators – Resistance Performance Tests

Disposal

Autoclave Instant 20s Indicator, steam at 121˚C for not less than 30 minutes, or incinerate (standard microbial waste; non-pathogenic species). Indicator Solution and Packaging: Discard as general waste.

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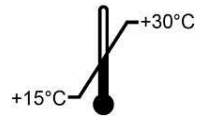
Performance Characteristics

Purity	Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the Instant 20s Indicator
Steam Resistance	*D* value at 121°C ± 0.5°C ≥1.5 minutes *D* value at 134°C ± 0.5°C ≥8 seconds The Steam *D* value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥10°C Determined based on three temperatures in the range of 110°C to 138°C.
Post-Market Criteria	*D* value: ± 20% of the certified *D* value Survival Time: All Indicators result in growth at the certified survival time Kill Time: All Indicators result in no growth at the certified kill time

Storage and Shelf Life

	15°C to 30°C		Protect from heat, radioactive sources and sterilizing agents
	20% to 80% Relative Humidity		Do not freeze
Shelf Life	The shelf life of the Instant 20s Indicator Kits is based on the shorter of two individual components (the Indicators and Indicator Solution), which have independent expiration periods. This is usually 20 months from the date of manufacture.		
	The Instant 20s Indicator could be hot from steam exposure and should be handled with care post-exposure. Exposure to temperatures above 138˚C could impact the integrity of the product. Store the Instant 20s Indicators and Indicator Solution at 15°C to 30°C. Failure to do so could damage the solution by exposing to elevated temperatures above 30˚C and cause false-negative results.		

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