



## STEEL SPORE COUPONS For Monitoring Dry Heat Processes

True Indicating Code: SCA-05DH and SCA-06DH

### Product Description

Steel Spore Coupons for monitoring Dry Heat processes consist of:

- An inoculated steel carrier, 19.2 mm x 6.5 mm x 0.9 mm coupon with *Bacillus atrophaeus* Cell Line 9372
- Primary packaging in Tyvek® envelopes

### Indications for Use

The Steel Coupons are designed for use in high temperature dry heat applications where a paper carrier would not be appropriate or where a stainless-steel surrogate is needed. The Steel Coupons may be used for equipment or process validation and routine monitoring. The Steel Coupons are labeled for laboratory/industrial use only.

### Physical Properties

Process	Dry Heat
Coupon Dimensions	19.2 mm x 6.5 mm x 0.9 mm
Primary Packaging	28.5 mm x 63.5 mm
Packaging	100 / Pack

### Monitoring Frequency

For greatest control of sterilized goods it is recommended that a minimum of ten (10) Steel Coupons be included with every load.

### Instructions for Use

Remove the Steel Coupon from the primary packaging as Tyvek® is not recommended for use in temperatures greater than 118°C. Place a suitable heat-resistant tie, strap, or similar device through the hole located in the Steel Coupon. Hang the Steel Coupons (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized or within the oven or sterilization area.

Locate the test packages or Steel Coupons in areas most difficult to sterilize, as outlined in your specific sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.

After sterilization or exposure, aseptically remove the Steel Coupons or product from sterilizer.



Steel Coupons may be held at room temperature for up to 96 hours post-exposure prior to transfer without any impact to the performance. If the processed Steel Coupons are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated.

Aseptically transfer the Steel Coupons to 5-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, True Indicating Code GGM-100, may be utilized in place of the SCDB.





# Technical Data Sheet

Transfer one Steel Coupon which has not been exposed in a sterilization process as a Positive Control.

**Incubation:** At least one unused tube of culture medium from the same lot should be incubated with the test series as a Negative Control. Incubate the cultured Steel Coupons, the Positive Control and the Negative Control at 30°C to 40°C as outlined in the following table:

Sterilization Process	Media Type	Min. Incubation Time
Dry Heat	SCDB	7 Days
	GGM-100	48 Hours

**Monitoring:** Examine the Steel Coupons daily, whenever possible during incubation. Record observations.

### Interpretation:

Where SCDB (standard or unmodified) was utilized: Tubes which demonstrate turbidity with a cream/orange pellicle are considered positive for growth of *Bacillus atrophaeus*. Tubes which remain clear and without pellicle are considered negative for growth.

Where modified media, True Indicating Code GGM-100, was utilized: Tubes which transition in color from Green to Yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain Green in color and do not demonstrate turbidity are considered negative for growth.

For unexpected positives, it is recommended that a Gram Stain be performed. Gram positive rods are indicative for the indicator organism.

Positive Control: Tube(s) should demonstrate turbidity with a cream/orange pellicle. If the Positive Control does not result in growth, the exposure is considered invalid. Check the conditions during incubation and verify the capability of the medium to support growth.

Negative Control: Tube(s) of media should remain clear. If the Negative Control results in growth, there is a potential for false positives.

### Compliance

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

ISO 11138-4 Sterilization of health care products – Biological indicators – Part 4: Biological indicators for sterilization processes

USP <55> Biological Indicators – Resistance Performance Tests

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin for the outlined methodology.





# Technical Data Sheet

## Performance Characteristics

Population	SCA-05DH: $\geq 1.0 \times 10^5$ per Coupon SCA-06DH: $\geq 1.0 \times 10^6$ per Coupon
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Dry Heat Resistance	<i>D</i> value at $160^\circ\text{C} \pm 1^\circ\text{C}$ $\geq 2.0$ minutes  The Dry Heat <i>D</i> value range is based on the requirements outlined in the USP.  <i>z</i> value $\geq 20^\circ\text{C}$  Determined based on <i>D</i> values at three temperatures in the range of $150^\circ\text{C}$ to $180^\circ\text{C}$ . True Indicating typically uses <i>D</i> values determined at $150^\circ\text{C}$ , $160^\circ\text{C}$ and $180^\circ\text{C}$ for <i>z</i> value calculation.
Survival – Kill Times	Calculated based on the formulations outlined in the USP, ISO 11138-1.
Post Market Criteria	Population: 50% to 300% of certified population  <i>D</i> value: $\pm 20\%$ of the certified <i>D</i> value  Survival Time: All Steel Coupons result in growth at the certified survival time  Kill Time: All Steel Coupons result in no growth at the certified kill time

## Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	24 months from the date of manufacture		Protect from heat and radioactive sources
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Steel Coupons. Do not use damaged Spore Coupons. Do not use after the expiration date. The Steel Coupons contain live cultures and should be handled with care.		

## Disposal

Autoclave for not less than 30 minutes at  $121^\circ\text{C}$  or per other validated disposal cycle prior to discard.

