

Sterikon® plus Bioindicator

For monitoring the effectiveness
of steam sterilization





Sterikon® plus Bioindicator

For Use During Steam Sterilization (121°C)

Application

The EMD Chemicals Sterikon® plus Bioindicator System is used to monitor the effectiveness of steam sterilization at 121°C for 15 minutes.

THIS PRODUCT IS NOT TO BE USED FOR MONITORING STERILIZATION OF MEDICAL DEVICES. THIS PRODUCT IS FOR LABORATORY USE ONLY.

Principle

The Sterikon® plus Bioindicator consists of an ampule that contains nutrient broth, sugar, a pH indicator and spores of an apathogenic organism, *Geobacillus stearothermophilus* ATCC 7953 (sporulation optimized).

The thermal resistance is such that the spores are totally killed after 15 minutes when heated in compressed steam at a temperature of 121°C $\pm$ 0.5°C (1 bar). At lower temperatures or lower exposure times, the spores can survive, at least partly.

The ampules are placed into the autoclave along with the batch to be sterilized. After autoclaving, the success of the sterilization process is checked by incubation of the ampules.

No growth of *Geobacillus stearothermophilus* indicates adequate sterilization, whereas growth shows inadequate sterilization.

Procedure

An appropriate number of ampules must be included in the batch to be sterilized. Autoclaves with a capacity of up to 250 liters should be checked with at least 2 ampules, while those with a greater capacity should have at least 6 ampules. In order to avoid contamination by accidental breakage, it is advised to place the ampules in a glass beaker.

The ampules are placed in the autoclave at sites where the most unfavorable conditions for sterilization are thought to exist, i.e. at the bottom and in the middle of the autoclave. When sterilizing liquids, it is normal for the autoclave chamber to achieve 121°C before the liquid does. Therefore, to monitor these cycles properly, the ampule can be either suspended in the center of the liquid (e.g., by hanging on twine from the top of the flask) or immersed in a parallel flask filled with liquid. The Sterikon® plus Bioindicator can also be used to monitor the functional efficiency, i.e. to test whether the prescribed temperature of 121°C is reached within the entire autoclave and whether the temperature remains constant over the entire prescribed period of 15 minutes.

After sterilization, the ampules are removed and incubated up to 48 hours at 60 $\pm$ 2°C. A non-sterilized ampule should also be incubated to serve as a control.

Do not use the ampules at temperatures exceeding 125°C since overheating may result in color changes without spore growth. Complete instructions for proper use are included with each order. Consult the instructions BEFORE using the product.





Evaluation

If sterilization is adequate, the *Geobacillus stearothermophilus* spores are killed off. The contents of the ampules remain transparent to slightly opalescent and red-violet in color (Fig. 1).

If sterilization is inadequate, the *Geobacillus stearothermophilus* spores survive. The contents of the ampules then usually turn yellow-orange (Fig. 2) within 24 hours due to the formation of acid as a result of sugar fermentation and may become turbid due to microbial growth. In cases in which the spores are partially damaged, the reaction may be delayed to 48 hours.

The contents of the control ampule also turn yellow-orange (Fig. 2) and may become turbid. If this does not occur, consider the test invalid.

Stability

When stored at the prescribed temperature (+ 2°C to + 8°C) in a refrigerator, the bioindicator is stable up to the expiration date printed on the pack. Sterikon® plus Bioindicator has a shelf life of 18 months from the date of manufacture.

Ordering Information

Catalog No.	Quantity
1.10274.0003	100 ampules
1.10274.0004	15 ampules

Each with 2 ml of spore suspension.

Specifications

The specifications of Sterikon® plus Bioindicator are as follows:

$$\begin{aligned} n &= 5 \times 10^5 - 1 \times 10^7 \text{ spores per unit} \\ D_{121}^* &= 1.5 - 2.0 \text{ minutes} \\ F_{121} &= 15 \text{ minutes} \end{aligned}$$

In accordance with the USP, the heat resistance and the number of spores are optimized so that after a sterilization time of 5 minutes (121°C ± 0.5°C) all ampules contain living spores, whereas after 15 minutes of sterilization (121°C ± 0.5°C) all spores are dead. For the period in between, ampules can be found with either living or dead spores.

* D-value is determined at the time of manufacture using fraction negative analysis. The D-value is reproducible at the stated temperature and only under the exact conditions at which it was determined; the user may not necessarily obtain the same results.

Figure 1



Figure 2



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