

Data Sheet

How effectively does your autoclave sterilize?

Testing Assurance with the Sterikon® plus color coded Bioindicator

Steam sterilization prevents contamination and is essential for cGMP & cGLP operations. But results aren't visible, so how can you confirm the effectiveness? Was the procedure adequate? Is the autoclave functioning optimally? Merck Millipore offers a simple and yet secure solution: the Sterikon® plus Bioindicator.

Fully compliant with USP standards, the Sterikon® plus Bioindicator consists of ampoules that contain everything required: nutrient broth, sugar, pH indicator and nonpathogenic bacterial spores. The ampoules display vibrant, color-coded results after autoclaving and incubation: red-violet indicates correct sterilization, whereas yellow-orange warns of inadequate procedures. Clear, reliable answers allow you to easily monitor your autoclaving process and, if necessary, quickly introduce corrective measures to avoid health risks.

Benefits

- **Easy to use:** Simply autoclave, incubate and read results
- **Vibrant colors:** Red-violet indicates adequate sterilization; yellow-orange indicates inadequate sterilization
- **Complete solution:** The ampoules contain everything you need for the test
- **Reliable results:** Fully compliant with USP guidelines
- **Safe handling:** Secure, high-quality ampoules with nonpathogenic bacterial spores



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 79531 (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 $121^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ (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.

Application

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



Procedure

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.

After sterilization, the ampules are removed and incubated up to 48 hours at $60 \pm 2^\circ\text{C}$. 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.

If sterilization is inadequate, the *Geobacillus stearothermophilus* spores survive. The contents of the ampules then usually turn yellow-orange 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 and may become turbid. If this does not occur, consider the test invalid.

Specifications

The specifications of Sterikon® plus Bioindicator are as follows:

$n = 5 \times 10^5 - 1 \times 10^7$ spores per unit

D121* = 1.5 – 2.0 minutes

F121 = 15 minutes

In accordance with the USP, the heat resistance and the number of spores are optimized so that after a sterilization time of 5 minutes ($121^\circ\text{C} \pm 0.5^\circ\text{C}$) all ampules contain living spores, whereas after 15 minutes of sterilization ($121^\circ\text{C} \pm 0.5^\circ\text{C}$) 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.

Stability

When stored at the prescribed temperature ($+ 2^\circ\text{C}$ to $+ 8^\circ\text{C}$) 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
1.10274.0001	15 ampules
1.10274.0002	100 ampules

Each with 2 ml of spore suspension



red-violet color indicates correct sterilization,
yellow-orange warns of inadequate procedures

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