Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Measure Autoclave Sterilization Effectiveness

Testing Assurance with the Sterikon® plus color coded Bioindicator

Steam sterilization helps to prevent 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? The Sterikon® plus Bioindicator is a simple, yet secure solution.

Fully compliant with USP <1229>, 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 contamination 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

The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

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Principle

The Sterikon® plus Bioindicator consists of an ampoule that contains nutrient broth, sugar, a pH indicator and spores of *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 ± 0.5 °C (1 bar). At lower temperatures or lower exposure times, the spores can survive, at least partly. The ampoules 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 ampoules. No growth of *Geobacillus stearothermophilus* indicates adequate sterilization, whereas growth shows inadequate sterilization.

Application

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

Procedure

The ampoules 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 ampoules are removed and incubated up to 48 hours at 60 ± 2 °C. A non-sterilized ampoule should also be incubated to serve as a control.

Do not use the ampoules at temperatures exceeding 125 °C since overheating may result in color changes without spore growth. Consult the instructions before using the product.

Evaluation

If sterilization is adequate, the *Geobacillus stearothermophilus* spores are killed off. The contents of the ampoules remain transparent to slightly opalescent and red-violet in color. If sterilization is inadequate, the Geobacillus stearothermophilus spores survive. The contents of the ampoules 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 ampoule 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 x 10^5 – 1 x 10^7 spores per unit
D121* = 1.5 – 2.0 minutes
F121 = 15 minutes

The heat resistance and the number of spores are optimized so that after a sterilization time of 6 minutes (121 ± 0.5 °C) all ampoules contain living spores, whereas after 15 minutes of sterilization (121 ± 0.5 °C) all spores are dead. For the period in between, ampoules can be found either with or without living spores remaining.

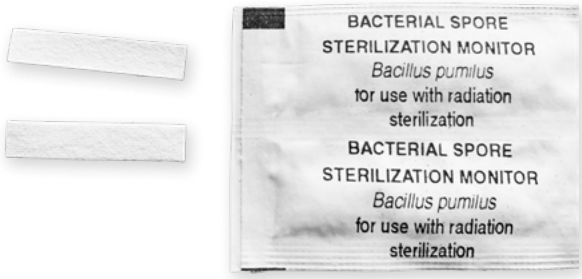
* D-value is determined at the time of manufacture using fraction negative analysis. The D-value is reproducible at the stated temperature and only under the exact conditions at which it was determined; the user may not necessarily obtain the same results.

Stability

When stored at the prescribed temperature (+2 °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.

Sterilization of solid objects

While self-contained liquid biological indicators like Sterikon® are appropriate to ensure adequate sterilization of liquid loads it is recommended to use spore strips for solid loads. Sterility Indicator (Steam Sterilization) spore strips contain about one million spores of *Geobacillus stearothermophilus* (ATCC® 7953™) impregnated on paper strips, individually placed into envelopes. After incubating a strip in Tryptic Soy Broth for 7 days at 55-60 °C a culture response indicates insufficient sterilization.



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

Ordering Information

Product	Catalogue No.	Pack Size
Sterikon® plus Bioindicator	**1.10274.0001**	15 ampoules*
Sterikon® plus Bioindicator	**1.10274.0002**	100 ampoules*
Sterility Indicator (Steam Sterilization)	**74041-25TESTS-F**	25 strips
Sterility Indicator (Radiation Sterilization)	**05290-25TESTS-F**	25 strips
Tryptic Soy B. acc. EP+USP (100 ml ready-to-use)	**1.46380.0010**	10 bottles
Tryptic Soy Broth (dehydrated)	**1.05459.0500**	500 g

* Each with 2 mL of spore suspension

Caution: For use as a manufacturing component. Industrial use only.

Not for use in a healthcare facility or to release clinical healthcare products.

To place an order or receive technical assistance

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Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

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