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PROFESSIONAL MEDICAL PRODUCTS

TYPE 5 STEAM INTEGRATOR

User manual

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

ENGLISH

Product Description

The Type 5 integrating indicator has been developed for monitoring 121°C and 134°C steam sterilization processes and assures an adequate check whether steam sterilization conditions have been met at the place of usage. The Type 5 Integrating indicator was developed to reach end color when it is exposed to steam sterilization conditions as per SV. This condition is calibrated with the Kill time of a theoretical population of 10⁶ spores of *Geobacillus stearothermophilus* microorganisms.

Characteristics

This Integrator is composed of a special paper strip and a special indicating steam ink which is turning into end color under steam sterilization conditions. The Integrator was developed based upon the use of non-toxic, heavy metal free inks. The dimensions of the Integrator is 50 mm x 20 mm.

Use recommendations

This Integrator can be used inside pouches, trays and baskets wrapped in sterile barrier systems, as well as inside instrument containers to check on local steam sterilization conditions. This Integrator is recommended for the monitoring of steam sterilization cycles parameters between 121°C - 15 min and 134°C - 3,5 min.

Warning

Do not use this Integrator in any other sterilization cycle than Steam cycles with the SV as displayed above.

Instructions for use

Place the integrating indicator inside the pouch, pack, basket, tray or container together the materials which will be steam sterilized. Keep the Integrator away from the bottom of the object to prevent condensate to effect the results. In rigid systems, as containers, place the integrating indicator in each corner, or at least in two diagonally opposite corners to assure that the steam has reached the most critical points at those places. Place pouches sideways / vertically in order to avoid the collection of condensate which might influence the performance of the Integrator.

Results interpretation

If the indicator changes to the reference color printed on the product, it indicates that the process reached the condition and the sterilization process was successful. If one or more sterilization parameters were not accomplished the indicator is not reaching its full end color. The materials cannot be considered sterile and must be processed again, using a new Type 5 Integrator.

Storage

Maintain the indicators in a dry place, protected from light, preferable in the box, and at a temperature between 10 and 40°C, relative humidity between 20 and 80%. Do not expose the integrator to sterilizing agents or other chemical products of any kind.

Shelf life

The indicators have a shelf life of 5 years from manufacturing date, when stored in the recommended conditions. The manufacturing and expiry date as well as lot number are indicated on the packaging label. Do not use the indicators after the expiry date. After use, the indicator will maintain its color for a period of 5 years if stored under the given storage conditions.

Compliance to standard

The Integrating Indicator for Steam Sterilization Processes is manufactured according to EN ISO 11140-1:2014 Standard.

REF 35953



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Made in Turkey

