



GIMA

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

PROFESSIONAL MEDICAL PRODUCTS

INTEGRATORE MOVING FRONT TIPO 5 **TYPE 5 MOVING FRONT INTEGRATOR** **INTÉGRATEUR À VAPEUR À MOUVEMENT FRONTAL TYPE 5** **INTEGRADOR FRONTAL MÓVIL TIPO 5**

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

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

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

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 the accept window when a theoretical population of spores is eliminated, which indicates that the integration condition has been achieved. 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 absorbing paper strip and a special ink which is solid under room temperatures but melts under steam sterilization conditions. All is sealed in between a combination of aluminium and plastic film to seal all off from the environment. 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 is recommended for the monitoring of steam sterilization cycles parameters between 121°C - 20 min. and 134°C - 3,5 min. Depending on the temperature the absorbance and thus the 'moving' of the ink on the absorbing paper is taking more or less time.

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.

Results interpretation

If the ink reaches the blue accept area of the Indicator, it indicates that the process reached the condition and the sterilization process was successful.

The color of the ink is not changing during the sterilization process and is grey/blue of color.

Storage







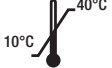
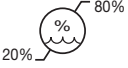


Maintain the indicators in a dry place, protected from light and at a temperature between 10 and 40°C, relative humidity between 20 and 80%.

Do not expose close 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. The Integrating Indicator for Steam Sterilization Processes is manufactured according to EN ISO 11140-1:2014 Standard.

| Symbols | | | | | |
|---|------------------------------|---|-------------------------|---|---|
|  | Consult instructions for use |  | Expiration date |  | Date of manufacture |
|  | Keep in a cool, dry place |  | Keep away from sunlight |  | Caution: read instructions (warnings) carefully |
|  | Store between 10 and 40°C |  | Moisture limitation | | |
|  | Product code |  | Lot number | | |

REF 35952

Importato e distribuito da / Imported and distributed by:
Importé et distribué par / Importado y distribuido por:
Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
Made in Turkey

