



# Instructions for Use-Indicator type 6

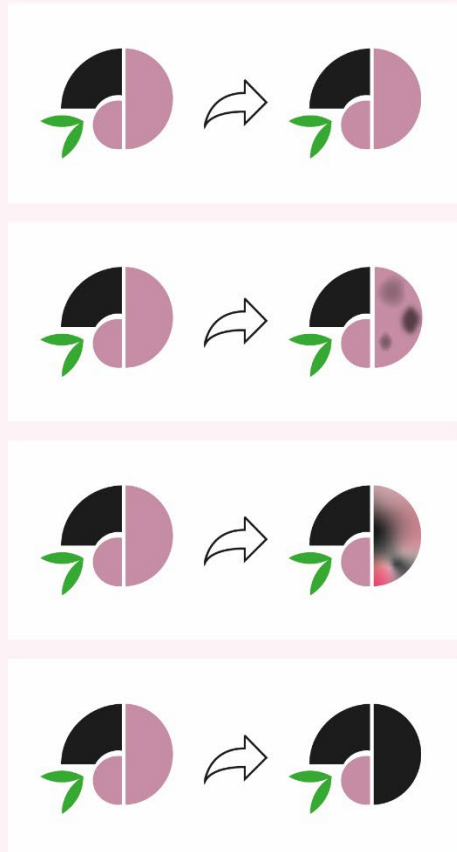
ST-MS-WI-02  
REV.05

**VALID**

**History of changes**

Revision No.	Date of issue	Reason for change	Summary of change	Provided by	Approved by
00	16/03/2019	NA	NA	<i>Saeed Nazari</i>	<i>Saeed Nazari</i>
01	30/4/2020	- Effective parameter - Change the storage temperature	- Adding an effective Parameter - Change the storage temperature	<i>Saeed Nazari</i>	<i>Saeed Nazari</i>
02	15/10/2021	Update	Review all items	<i>Saeed Nazari</i>	<i>Saeed Nazari</i>
03	06/08/2022	Avoid reasonably foreseeable misuse based on ISO 14971:2019	The application and method of using this product is according to the label and IFU.	<i>Saeed Nazari</i>	<i>Saeed Nazari</i>
04	05/03/2023	The design has changed	The new design was replaced	<i>Saeed Nazari</i>	<i>Saeed Nazari</i>
05	31/08/2023	Adding new symbols	Metal free and refrence/catalog number symbols	<i>Saeed Nazari</i>	<i>Saeed Nazari</i>



**Emulator Indicator- Type 6- Steam process**

## Unprocessed

**Failures**

One or more parameters of sterilization were not achieved. The materials cannot be considered sterile and must be processed again. These results are usually obtained when steam quality is poor or adequate vacuum has not been generated.

## Processed and correct

NOTE: Reference colors exhibited in printed prospects.

**Product description**

Indicator Emulators are designed for internal use in steam sterilization processes, for ensuring the achievement of all the critical variables (temperature, time, steam quality). The pink ink was developed to change to black when the process reaches the stated values (SV) of the critical process variables indicated in the emulator.

Use Emulator Indicators for monitoring Steam sterilization processes.

**Emulator Indicators**

For Steam sterilization processes Type 6 Indicator according to ISO 11140-1:2014

**How to Use**

- Place an Emulator Indicator within each package, bag or tray that will be sterilized by Steam.
- In rigid containers place an emulator indicator in every corner, or at least two diagonally or opposite corners, to ensure that the steam has reached the most inaccessible areas.
- Finished the process, analyze the results. The indicator must change to the reference color for considering that emulation conditions were reached.
- The application and method of using this product is according to the label and IFU.

NOTE: if any serious incident occurs in relation to the device, it should be reported to Sterifast and the competent authority of the State in which the user is established.

**Precautions**

- Do not expose Emulator Indicators to EO, Dry Heat, or any sterilization processes other than Steam.
- Do not use the sterilizer until the emulator's color change matches the emulation condition.

**Characteristics**

Emulator Indicators consist of a paper strip of 24 x 65 mm.

Indicators 100 % free of toxic heavy metals.

**Storage and shelf life**

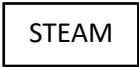






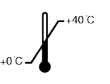






- Indicators should be stored in dry places, protect from light at temperatures between 0-40 °C, 10-70 % relative humidity. Do not wet. Do not store close to sterilizing agents.
- Indicators have an expiration date of 5 years from the date of manufacture when stored in the recommended conditions. Both expiration date and batch of the product are specified on the package label and on each unit of product. Do not use indicators after their expiration date.



### Disposal

Discard along with cardboard waste according to your country's healthcare regulations.

### Explanation of Symbols

Product designed for steam		Do not use if package is damaged	
Manufacture date		Keep dry	
Expiration date		for more information use IFU	
CE mark		Temperature range	
Lot number		Keep away from sunlight	
Manufacturer		Do not re-use	
This product is non-sterile		Metal free	
Reference / Catalog Number	