

steriCLIN®



Indicator strips

Stericlin® indicator strips for STEAM sterilisation processes

Chemical indicators for monitoring the sterilisation processes and to supplement the parametric process documentation

Stericlin® indicator strips

Applications and types

Indicators for the sterilisation process (according to ISO 11140)

In the STEAM sterilisation process, chemical indicators are used for monitoring and as a supplement to the parametric process documentation. Some of them work in accordance to specific "SV" – stated values, defined by the ISO 11140-1.

With sufficient exposure to the sterilisation agent (STEAM), the indicator changes its colour; none or incomplete colour change indicates a malfunction of the steriliser or unprocessed items.

- **PASS:** the sterilisation process was applied and successful with respect to specific SV's
- **FAIL:** the sterilisation process was NOT applied or was not successful with respect to specific SV's

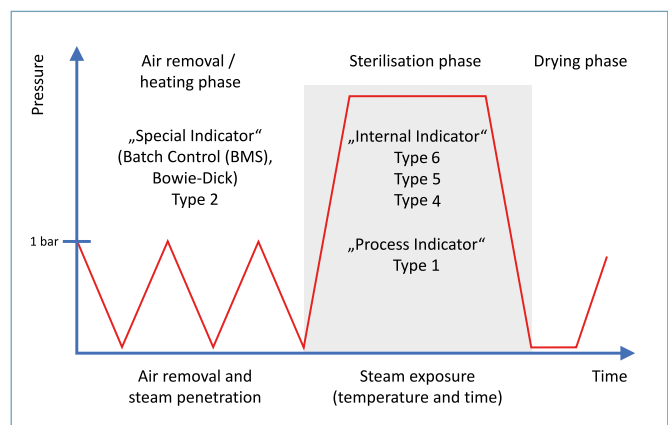


Which indicator type checks which phase of sterilisation?

The STEAM sterilisation process is separated in 3 phases:

- **Air removal phase:** the air inside of the steriliser is removed and steam penetration takes place
- **Sterilisation phase:** items are exposed to steam and pressure for a defined time
- **Drying phase:** the steam is removed from the steriliser to dry the items

For monitoring the sterilisation phase, Type 6, 5, 4 and 1 indicators are used.



Different types – and quality – of indicators

Indicators used in the sterilisation phase are either "Process Indicators" or "Internal indicators":

"Internal indicators" = Type 6, Type 5 and Type 4 indicator ("accuracy")

Indicators that are arranged inside of individual sterile barrier packaging units of the load, and are used to state the achievement of the critical process variables inside of the packaging. Internal indicators can be distinguished according to the process parameters they respond to, according to their accuracy and to specific SV's.

"Process indicator" = Type 1 indicator ("yes/no")

Shows the effect of a procedure to distinguish between non-processed and processed items.

Type 6 indicators respond to all the critical process variables *: "Emulating Indicator"

Type 5 indicators respond to all the critical process variables **: "Integrated Indicator"

Type 4 indicators respond to more than one critical process variables *: "Multiple Parameter Indicator"

Type 1 indicators just show whether the process was applied, they do NOT indicate a successful sterilisation.

*according to specific SV's **equivalent to biological indicators

Stericlin® indicator strips

Accuracy, handling and description

Accuracy of indicators (defined by ISO 11140-1)

“Internal indicators” = Type 6, Type 5 and Type 4 indicator

The accuracy of internal indicators in the STEAM process increases from Type 4 to Type 5 to Type 6:

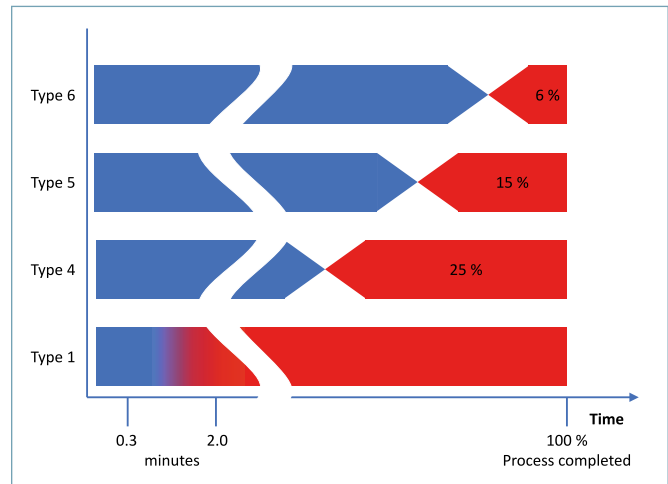
Type 6: With 6 % less exposure time at a temperature that is 1 °C lower, then the indicator must show a FAIL

Type 5: With 15% less exposure time at a temperature that is 1 °C lower, then the indicator must show a FAIL

Type 4: With 25% less exposure time at a temperature that is 2 °C lower, then the indicator must show a FAIL

“Process indicator” = Type 1 indicator

Type 1: With a treatment time of 0.3 minutes (+/- 5 sec) at 134°C (+3/- 0°C), the indicator must not show any colour change. With a treatment time of 2 minutes (+/- 5 sec) at 134°C (+3/-0°C), the indicator must show a distinct colour change.



Handling and use of stericlin® indicators

Stericlin® indicator strips must be used in accordance with the sterilisation method and with the type specific stated values only. The indicator strips are ready to use and don't need an additional process challenge device (PCD).

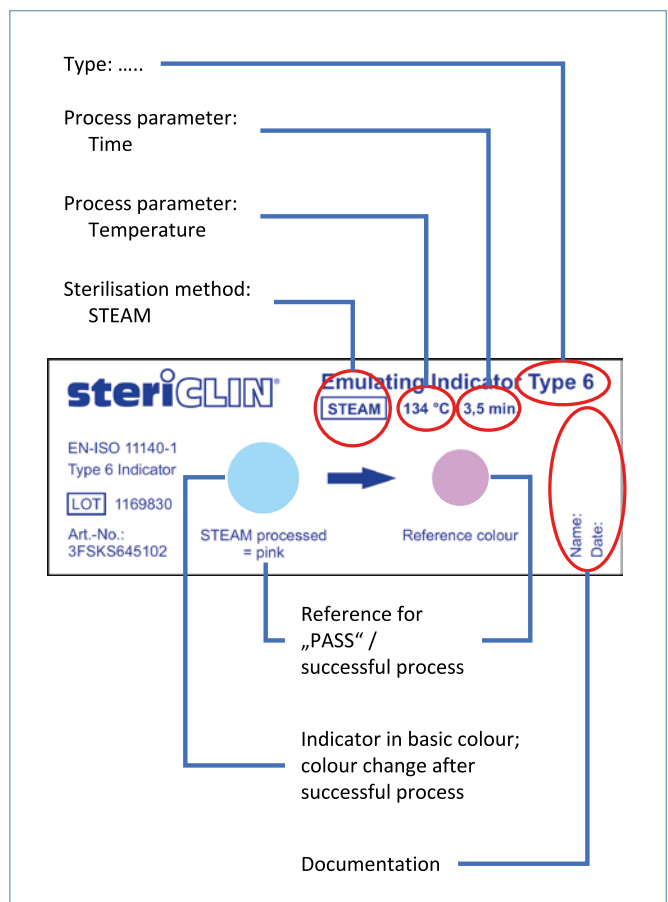
Handling instruction:

- Place at the desired locations in the loading area (inside of see-through packaging, wrapping materials, containers, etc.; inside and outside of the packaging, container, etc.)
- Run sterilisation process
- Remove indicator strip
- Check result

With sufficient steam exposure, the indicator changes its colour. Incomplete colour change indicates a malfunction of the steriliser or unprocessed items. After the colour change, the colour of the indicator will not change any more, giving you completely security of documentation. Stericlin® indicators contain no heavy metals or toxic substances.

Description of stericlin® indicators

Stericlin® indicator strips consist of a special paper board with the indicator ink directly printed on it. A stericlin® indicator strip includes the following information:



Product range of stericlin® indicators

stericlin® indicator strips for STEAM sterilisation

Product	Article No.	Process	Description / Time & Temperature	Size (mm)	Pack (pcs.)
Type 6 Indicator strips	3FSKS645102	STEAM	134 °C – 3.5 min.	80 × 30	500
Type 6 Indicator strips	3FSKS645104	STEAM	134 °C – 4 min.	80 × 30	500
Type 6 Indicator strips	3FSKS645106	STEAM	134 °C – 5.3 min.	80 × 30	500
Type 6 Indicator strips	3FSKS645108	STEAM	134 °C – 7 min.	80 × 30	500
Type 6 Indicator strips	3FSKS645112	STEAM	134 °C – 18 min.	80 × 30	500
Type 5 Indicator strips	3FSKS646102	STEAM	Equivalent to biological indicator (134 °C / 121 °C)	80 × 30	500
Type 4 Indicator strips	3FSKS647102	STEAM	134 °C – 3.5 min.	80 × 30	500
Type 4 Indicator strips	3FSKS647106	STEAM	134 °C – 5.3 min. / 121 °C – 15 min.	80 × 30	500
Type 1 Indicator strips	3FSKS650102	STEAM	self-adhesive, process indicator	150 × 30	250
Type 1 Indicator strips	3FSKS650104	STEAM	Process indicator	150 × 30	250

stericlin® indicator strips for FORM and EO sterilisation

Product	Article No.	Process	Description / Time & Temperature	Size (mm)	Pack (pcs.)
Type 1 Indicator strips	3FSKS650106	FORM	Process indicator	150 × 30	50
Type 1 Indicator strips	3FSKS650108	EO	Process indicator	150 × 30	250

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Vereinigte Papierwarenfabriken GmbH

Industriestrasse 6
D-91555 Feuchtwangen

Tel +49 (0) 9852 901-289
Fax +49 (0) 9852 901-77289

contact@stericlin.com
www.stericlin.com