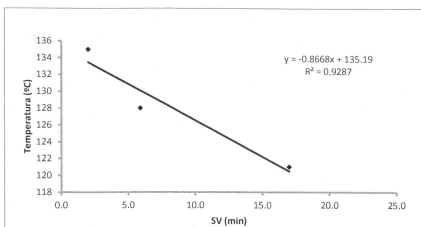


WTL198-0082 Chemical Integrator

LOT O41119

Stated Values (SV)

Temperature	SV (Time)	
121 °C	17.0	min.
128 °C	5.9	min.
135 °C	2.0	min.





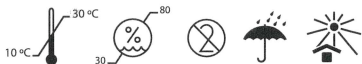
SV – stated value. Value of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.

According to ISO 11140-1:2014 standard


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Explanation of Symbols

 STEAM	Product designed for use in Steam sterilization processes		Manufacture date
 LOT	Batch number		Expiration date



Process Challenge Device

For a rapid and easy monitoring of Steam sterilization processes

Indications for Use

United States

WTL198-0146 provides a defined challenge resistance against the claimed cycles shown below and also demonstrated resistance equivalence to the AAMI/ANSI 16 towel pack. The device provides routine monitoring and sterilizer qualification testing steam sterilization processes. See Intended Use Table for reference.

Outside the United States

WTL198-0146 Steam Process Challenge Device has been designed for a rapid and easy monitoring of Steam sterilization processes at 132/135 °C ≥ 4 minutes.

Device Description

WTL198-0146 Process Challenge Device (PCD) Test Pack has been designed to simulate a load to be sterilized and to pose a challenge to the sterilization process. It is used to evaluate the effective performance of the process by detecting inadequate air removal and steam penetration. It also allows release of routine loads, especially implants. Furthermore, it allows to perform the routine monitoring and periodic validation of the sterilizers (after repair, installation, relocation).

WTL198-0146 consists of a disposable pre-assembled package as outlined in ANSI/AAMI ST79 which contains a WTL198-0072 Self-Contained Biological Indicator (SCBI), a WTL198-0149 Record Card and an WTL198-0082 moving front chemical integrator (Type 5 according to ISO 11140-1:2014 standard) that gives instant visible indication that sterilizing conditions have been reached.

Each pack consists of a stack of porous cards holding a self-contained biological indicator tube that contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores soaked on a carrier as well as growth indicator medium contained in a glass ampoule. Each SCBI has a process indicator (Type 1 according to ISO 11140-1:2014 standard) on label that changes from pink to brown when exposed to steam. The moving front chemical integrator shows ACCEPT result when sterilization conditions were reached while process indicator (Type 1 according to ISO 11140-1:2014 standard) on PCD box changes from light blue to grey when exposed to steam.

Precautions

WARNING: Do not use PCD for monitoring Ethylene Oxide, Dry Heat, Formaldehyde or any sterilization process other than Steam. Do not reuse biological indicators.

WARNING: Place one or more PCDs in sterilizing hard-to-reach areas to ensure all areas of the chamber are sterilized. Evaluate all load configurations to ensure all hard-to-reach areas have been identified, and place a PCD in each of those locations.

WARNING: Do not reuse the sterilizer until the biological indicator test result is negative.

Instructions for Use

- 1- Place the pack inside a normally loaded steam autoclave, in those areas which are considered most inaccessible for the sterilizing agent (e.g., the center of the load and areas near the door).
- 2- Run the sterilization cycle.

3- After the sterilization process has finished, open the sterilizer door, wait for 5 minutes and remove the test pack. **NOTE:** The color of the box may vary from the original after undergoing the sterilization cycle. This does not represent a problem regarding the operation or quality of the product.

4- Check that the process indicator printed on box has changed color from light blue to grey. Open the test pack, wait 5 minutes and remove the SCBI. Allow it to cool down to room temperature. **PRECAUTION:** Wear safety glasses and gloves when removing the biological indicator from the sterilized test pack. **WARNING:** Do not crush or handle the biological indicator excessively, since this might cause the glass ampoule to burst.

5- Check WTL198-0082 moving front chemical integrator for correct exposure. If the dark bar has reached the ACCEPT zone, this confirms that the inside of the pack has been exposed to correct sterilization conditions. For chemical integrator reference color, please refer to Result Reference Guide. Otherwise, check the sterilization process.

6- Check the chemical indicator printed on SCBI's label. A color change to brown confirms that the biological indicator has been exposed to Steam. **IMPORTANT:** This color change does not indicate that the process was sufficient to achieve sterility.

7- Identify the WTL198-0072 SCBI by writing the sterilizer number (in case of having more than one), load number, and processing date on the label. Fill out the required information on the Record Card.

8- Press the cap to seal the tube. Crush the glass ampoule contained in the SCBI with an individual ampoule crusher or with the ampoule crusher placed within the incubator's incubation area. Then shake the tube down vigorously, with movements similar to those performed to lower the temperature in a mercury thermometer, until the medium reaches the base of the tube and soaks the spore carrier entirely. **IMPORTANT:** Use a non-sterilized biological indicator as a positive control in order to ensure that correct incubation conditions were met; capability of culture medium to promote rapid growth; no alteration of spore's viability due to improper storage temperature, humidity or proximity to chemicals and also correct functioning of Auto-reader Incubator. Both, the positive control indicator and the processed indicator, should belong to the same batch.

9- Incubate the processed biological indicator and the indicator used as positive control in Auto-reader Incubators for 20 minutes at 60±2 °C to get the final fluorescence result. A 48-hour readout is optional to confirm the 20-minute result by visual color change after the 48-hour incubation means failure of sterilization process. If a negative fluorescence result is obtained (or culture medium remains the original color after 48-hour incubation), it means that sterilization process was successful.

10- Record the SCBI and integrator results and adhere the self-adhesive Record Card or, alternatively, only the area containing the integrator indicator. **WARNING:** Do not use the sterilizer until the biological indicator test results are negative.

11- Discard the pack and the indicators immediately.

Monitoring frequency

Follow facility Policies and Procedures, which should specify a biological indicator monitoring frequency compliant with professional association recommended practices and/or national guidelines and standards. As the best practice and to provide optimal patient safety, Tuttnauer recommends that every sterilization load be monitored with an appropriate biological indicator.

Storage

Store in a dark place, at temperatures between 10-30 °C, 30-80 % Relative Humidity. Do not freeze. Do not store near sterilizing agents or other chemical products.

Shelf Life

WTL198-0146 has an expiration date of 2 years from the date of manufacture, given by SCBI that carries, when stored at recommended conditions. Do not use after expiration date. Chemical Integrators and Process Indicators have an expiration date of 2 years when used in/on PCD.

End Point Stability Reaction: chemical indicator endpoint shall remain unchanged for a period 6 months when stored at previously indicated conditions.

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicators can be autoclaved in a gravity air displacement steam sterilizer at 121 °C for 30 minutes, 132 °C for 15 minutes or 134 °C for 10 minutes; or in a dynamic air removal steam sterilizer at 132 °C for 4 minutes or 135 °C for 3 minutes.

Intended Use Table

Autoclave/Steam Cycles		
Model	Gravity Displacement	
	WTL198-0146	132 °C
10 minutes 15 minutes 25 minutes		10 minutes
Dynamic Air Removal (Vacuum Assist)		
132 °C		135 °C
4 minutes		3 minutes
Fluorescence Read Time		pH Color Change
20 minutes		48 hours