Direction for use **(DFU BCHT 01.2015 version A)**

This direction for use is applicable for the following Sterintech products:

103.203.0100 Batch Control Helix - 134°C- 3,5 / 121°C-15 min.
103.203.0250 Batch Control Helix - 134°C- 3,5 / 121°C-15 min.
103.203.0500 Batch Control Helix - 134°C- 3,5 / 121°C-15 min.

Batch Control Helix Test (BCHT)

Note: upon receipt of goods please check whether the package was undamaged and ensure you about the expiry date of the chemical indicators.

Introduction:

The BCHT and its indicator strips are used for the routine monitoring of all steam sterilization cycles in order to have a proof of proper functioning of the steam sterilizer.
During every sterilization cycle there is a risk that sterilization has not been accomplished due to various reasons. These can be a.o. presence of air in steam feed-in, Inert gases in generated steam or leakage of door seals but also low temperature or short holding times.
The print out parameters or chart of the recorded parameters by the steam sterilizers control is not sufficient to guarantee that sterilization conditions have been met in the complete chamber. Some of the above-mentioned disturbances cannot be detected by pressure and temperature sensors.

The BCHT is able to detect:

- Sterilization temperature too low
- Sterilization holding time too short
- Insufficient vacuum in depth and in number of vacuum pulses.
- Insufficient air removal
- Insufficient steam penetration
- Leakage of piping / valves / door seals
- Detection of presence of small volume inert gases (or air) in steam supply.
- Detection of excessive amounts of condensate

The indicator fields of the indicator strip are covered by a laquer and therefor no ink or any substance from the ink can migrate on your instrumentation. The indicator ink is not containing any dangerous of toxic components and can be discarded as normal waste.

How to use the BCHT

I. Take one of the indicator strips out of the plastic bag and close the bag in order that the indicators strips are protected against humidity. Bend the indicator strip in the middle in order that the indicator fields are pointing inwards.
II. Take the PCD and unscrew the cap.
III. Place the indicator strip into the cap in such a way that bended end is going into the cap as first.
IV. Close the PCD by screwing the cap incl. the indicator strip on the holder.
V. Place the PCD into the cotton bag and place it in an instrument tray near to the bottom of the steam sterilizer. Never place the PCD on the bottom of the sterilizer.
VI. Run the sterilization cycle
VII. After completion of the sterilization cycle and cooling off during a few minutes take the PCD and remove it from the cotton bag. Some condensate may drip out of the PCD.
VIII. Unscrew the cap and take the indicator strip form the cap (eventually use a plier)
IX. Judge the color change of the indicator. When all 4 indicator fields are equally pink the sterilization cycle has been successfully. You may use the color reference label for the end color judgement.
X. Dependent on the color change the staff may release the load.
XI. Remove the indicator strip double adhesive strip from the back and glue it into the daily documentation sheet.
XII. Add the sterilizer number, cycle number, date and release data on the sheet.
XIII. In case the Helix or its tube has been wetted by condensate, blow some compressed air through the Helix and let it dry in open condition.

Warnings

The indicator strips and Helix system are designed according to ISO 11140-1 and may not be used in combination with other indicator strips or other Helix systems as this may lead to malfunction and misinterpretations of the test results.

The plastic Helix device may not be dismantled or show any external damage before use. These defective, dismantled, damaged Helix devices should be replaced by a new Helix device in order to have right interpretations of test results.

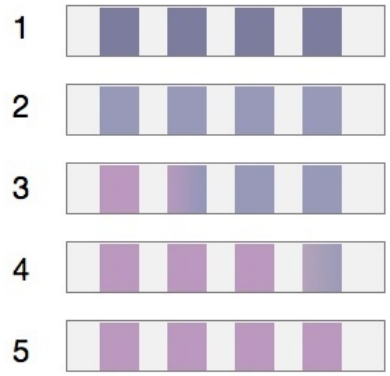
Storage conditions.

It is important to store the indicator strips in accordance with the storage conditions as displayed on the box label.

This Direction for use may be changed in the future. Check on our website regularly for updated Directions for use.

Reference of color change of BCH test

134°C - 3,5 min
121°C - 15 min



Explanation of the color reference

Position 1: Untreated indicator strip (original chemical indicator color)
Position 2: Low temperature / short holding time or absence of steam
Position 3: Typical for vacuum or leakage problem
Position 4: Typical for inert gas problem
Position 5: Complete successful color change

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