DIRECTIONS FOR USE

Chemical Indicators Type 4, 5 and 6 according to EN ISO 11140-1 for steam sterilization processes

STEAM

Art.-No. *	Product Code	Product Description	EN ISO 11140-1	Stated Value	Dimension [mm]	Quantity [pc]
211-403	C-S-P-4-SV1	Indicators on cards, self-adhesive, without labelling option	Type 4	134 °C, 3 min 121 °C, 15 min	65 x 14	3.200
211-221	C-S-P-5-SV1		Type 5	135 °C, 3 min 128 °C, 8 min 121 °C, 16,5 min	14 x 65	100
211-224						400
211-226						3.200
211-230	C-S-P-5-78x48-SA-SV1	Indicators on roll, self-adhesive, with predefined data labels			78 x 48	1.000
211-241	C-S-P-6-SV1	Indicators on cards, self-adhesive, without labelling option	Type 6	134 °C, 3 min 121 °C, 15 min	23 x 66	2.000
211-242						500
211-243						250
211-238	C-S-P-6-SV2			134 °C, 18 min		2.000
211-240						250

(*) To the article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized version. It is only added on the outside label, the inside of the pack is identical to the article numbers in the above table.

Application

The GKE Steri-Record® integrating or emulating indicators allow reliable information about the quality of the sterilization process at the location where they are placed. Temperature and pressure versus time are easily monitored by the sterilizer. However, air or non condensable gases (NCG) in the sterilization chamber cannot easily be detected by those physical test methods. The presence of NCG negatively influences the result of the sterilization process. This may occur by insufficient air removal, leakages in the door seals or valves or in most cases NCG enter via the external sterilization gas supply into the sterilization chamber. Especially the combination of NCG, low temperature and dense packs may result in faulty sterilization processes.

If only cross contamination on surfaces of the instruments should be prevented, the instruments are sterilized unpackaged. In special combination autoclaves that clean, lubricate and sterilize dental instruments, the indicator is placed unpacked into the holder inside the chamber.

Packaging monitoring indicators should only be used if solid and porous goods are sterilized. They are not recommended if hollow devices are sterilized. In this case they may give false-positive information and Batch Monitoring Systems (BMS) based on an adequate hollow test Process Challenge Device (PCD) have to be used.

Handling Information

1. Select the correct indicator for the sterilization process (see table).
2. The label can be marked manually or with a printer.
3. Place the indicator in the middle of the package or container (most difficult location to sterilize). Alternatively place the indicator unpacked inside the chamber. In DAC UNIVERSAL combination autoclaves the indicator is fixed inside the indicator holder.
4. Run the sterilization program. At the end of the sterilization cycle or after opening of the package, remove the indicator and check the result:
   - If the indicator or all indicator bars have changed its colour to the final colour (see label for colour change) the sterilization was successful.
   - If the colour did not change to the final colour, the success of the sterilization process cannot be guaranteed. The content of the package should not be used in the operation theatre.
5. All indicators are adhesive and can be documented onto the patient documentation sheet to be able to check the result later on in case a nosocomialic infection occurs to exclude incomplete sterilization.

Storage and Disposal

1. For longer periods store all indicators in the original package.
2. Store indicators always between 5-30°C or 41-86°F and a humidity of 5 - 80% RH.
3. The vapour of chemicals especially hydrogen peroxide may change the indicator before or after sterilization. Therefore, do not store them together with other chemicals.
4. The indicators should not be used after expiry date. They may be disposed off with normal waste.

Safety Precautions

Monitoring indicators do not replace the basic validation according to national and/ or international standards. Follow the instructions of your local requirements.

For further technical details please visit our website at www.gke.eu, contact your local dealer or the GKE application laboratory. We will assist you with any technical questions.

760-016 ED V08 12/2022

GKE-GmbH | Auf der Lind 10 | 65529 Waldems | Germany | **tel** +49 6126 9432-0 | **fax** +49 6126 9432-10 | **web** www.gke.eu