gke Steri-Record® Indicators according to EN ISO 11140-1 Type 5 and 6

Appliation

All ***gke*** *Steri-Record*® monitoring indicators contain an integrating or emulating indicator that allows reliable information about the quality of the sterilization at the location where it was 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.

If the ***gke*** *Steri-Record*® integrating or emulating indicator is placed into the package/container, where the sterilization agent penetration is most difficult, the security is given that sterile conditions were reached when the indicator changed its colour according to the description on the indicator. If the colour is not changing according to the description on the indicator, this is an indication of presence of NCG in the pack resulting in too low concentration of the sterilant and/or an insufficient temperature-time window in the pack.

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.

Unfortunately, the result of the sterilization process can only be determined after opening the pack. Therefore, it is important to get the information on a successful sterilization process shortly after the process without opening the packs or containers. The batch monitoring PCD simulates the worst case penetration conditions in a pack. The integrating indicator placed inside the PCD can be taken out immediately after the sterilization process. The operator has the information about the efficiency of the sterilization process. Faulty batches are immediately detected and do not get into the operation room.

Product Description

The ***gke*** *Steri-Record*® indicator provides a reliable indication of the quality of the sterilization process, but only where it was placed.

After opening a sterile package and checking the correct colour change the self-adhesive indicator is removed from the package and glued into the OR protocol.

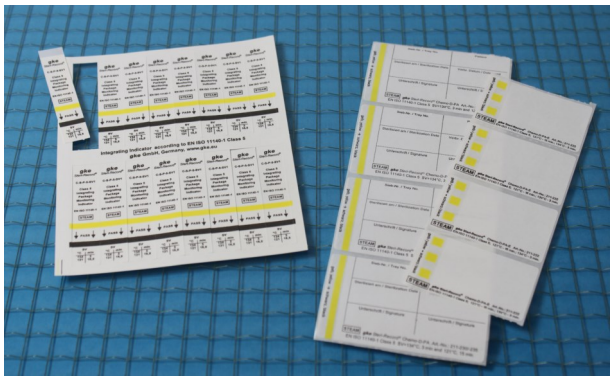

Fig. 1.: Type 5 Indicators according to EN ISO 11140-1 without labelling possibility (left), with labelling possibility (right)

Performance Characteristics

Package monitoring indicators respond to all critical parameters in a sterilization process. All indicators fulfil the requirements of type 5 or 6 indicators according to the European standard EN ISO 11140-1. Indicators only change its colour to the end point if the sterilization parameters have been achieved. In dry heat sterilization processes all indicators are tested at 140°C, 30 min and do not change its colour to the final end point.

Benefits

- Monitoring of all critical parameters of the sterilization process at the position the indicators are located.
- Environmentally friendly, no unnecessary waste.
- Patient-related documentation using self-adhesive properties.
- All ***gke*** chemical indicator strips are protected from bleeding by a polymer binder and surface coating and can be disposed off with normal garbage.
- Professional product design and manufacturing process provides cost-effective indicators.
- Easy interpretation of the results due to precise colour change.
- The indicator colour chemistry is a non-reversible chemical reaction. The indicators can be documented colour-proof for several years without changing back.

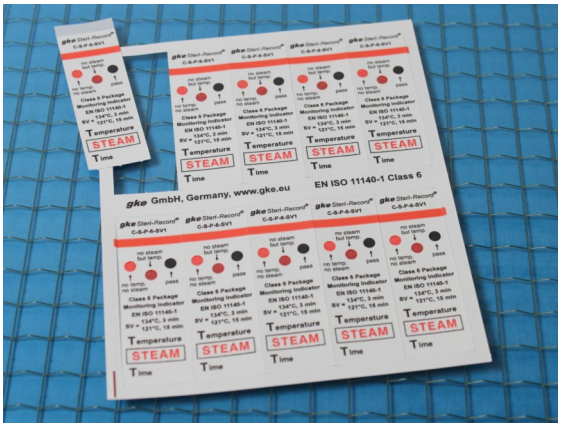

Fig. 2: Type 6 Indicators according to EN ISO 11140-1

Order Information

Art.-No.	Product Code	Quantity	Dimension [mm]	Description/Application	Sterilization process	Indicator type EN ISO 11140-1
211-224 211-225 211-226	C-S-P-5-SV1	400 800 3.200	14 x 65	Self-adhesive package monitoring indicators on cards, without labeling possibility	Steam	Type 5
211-230 211-235	C-S-P-5-78x48-SA-SV1	1.000 500	78 x 48	Self-adhesive data labels for subsequent patient-related documentation for printers applications or manual writing, on roll with 3“ core, endless		
211-220	C-S-P-5-58x35-SV1	1.000	58 x 35			
211-222		200				
211-241 211-242 211-243	C-S-P-6-SV1	2.000 500 250	23 x 66	Self-adhesive package monitoring indicators to monitor **T**emperature **S**team **T**ime		Type 6
211-238 211-239 211-240	C-S-P-6-SV2	2.000 500 250			Steam Prion program	

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“Promoting the Science of Sterilisation”