Directions for Use

Process Challenge Device (PCD) Systems and Chemical Indicators to monitor Ethylene Oxide sterilization processes

EO

Art.-No.*	Quantity [pc]	Product Code	Standard	Product Description
Indicators				
212-201	250	C-E-PM	EN ISO 11140-1 Type 2 in combination with a PCD	Refill pack indicator strips for ethylene oxide sterilization processes
Process Challenge Devices (PCD)				
200-028	1	C-E-PM-HPCD	EN 1422:2009 (Line/Pickerill)	Stainless-steel Helix-PCD with 4,55 m stainless-steel tube (3 mm diameter) for chemical and biological indicators
200-210	10	PM-RCPCD-TS	Specification see product data sheet	Testset with 10 Compact-PCD®s to check the limitations of EO sterilization processes (PCD are available separately)

(*) All article numbers also contain a three-digit letter code that refers to the language version and possible special designs. These are included on the outer label of the packaging, but not in the table shown above.

Application

The indicator strips are used in combination with a GKE Steri-Record® process challenge device (PCD) to monitor ethylene oxide sterilization processes. The standard does not specify a test device as a type test for EO because, in contrast to steam sterilization processes, very different ethylene oxide sterilization processes are used, which are carried out at different temperatures, pressure curves, ethylene oxide concentrations and mixtures of inert gases, e.g. CO_2. Therefore, the indicator system should be validated with chemical indicators before use with biological indicators. This is the reason that type tests are no longer specified in the EN 1422 standard. Therefore, the PCD must be individually adapted to the sterilization process and to the load (EN ISO 11135 validation standard). The procedure is also described in this standard for monitoring and routine monitoring. GKE offers various test systems for this purpose:

1. Helix Hollow Load Test made of stainless-steel tubing
2. Compact-PCD® Testset with 10 PCDs, where the correct PCD is selected during validation and a PCD is used later for routine monitoring in each cycle.

If Type 2 indicator systems are not used, Type 5 indicators must be placed in the hardest to sterilize locations in each package. Release can only occur after the package has been opened.

Product Description

The type 2 indicators are available on sheets of polymer carrier material. Each indicator (indicator starting colour: yellow) turns to blue (final colour). The indicator is inserted into a GKE PCD, which is selected in advance as part of a validation process. The indicators are self-adhesive. The chemical indicators are protected to bleed by a polymer binder coating and therefore do not release toxic substances.

Performance Characteristics

The indicators as detector for an EO type 2 indicator system comply with EN ISO 11140-1. The GKE process monitoring system is a type 2 indicator system according to EN ISO 11140-1, consisting of a "specific test load" (Process Challenge Device = PCD) and "indicator" (BMS indicator strip).

Handling Information

1. Open the cap and make sure the seal ring in the cap is in good condition.
2. Take out an indicator strip from the sheet and fold it that the indicator bars are inside the folding and place it in the holder with the fold toward the screw cap of the PCD.
3. Insert the indicator holder into the PCD and tighten the cap.
4. Place the test device in the worst-case position outside of the load. The PCD does not require to be put into a pack, pouch or container.
5. Run the sterilization program.
6. On completion of the cycle remove the test device carefully. After cooling down, remove the indicator strip and check the result:

   The yellow indicator bar must turn blue with sufficient exposure to ethylene oxide.

Indicator starting colour	Indicator end colour
	

   - If all four bars have turned into the final colour blue the sterilization process has been successful.
   - If one or more indicator bars remain the initial colour or do not reach the final colour, this indicates inadequate penetration of the sterilant. The process cannot be released.
7. The person authorized will decide whether to release the batch or to re-sterilize the load.
8. The indicator is self-adhesive and can be adhered onto the GKE documentation sheet with date, sterilizer and batch number and the signature of the person authorized to do so.

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Maintenance Information

When properly used, PCDs can be used for several thousand cycles. However, it must be ensured that the seal ring in the screw cap is in good condition and it should be exchanged every 500 batches as a precaution. A seal ring is included in each refill pack.

Storage and Disposal

1. Always store indicators in the closed foil bag and in the outer packaging and away from the sterilizer or the sterilizing agent. Ideally keep in a separate room.
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 with normal waste.

Safety Precautions

1. During sterilization, ensure to monitor the relative humidity in addition, which should be above 30%. The ideal relative humidity during sterilization is between 60% and 70% RH.
2. The use of a process monitoring system does not replace the validation of the sterilization process after start-up, major repairs or changes of the load configuration (see EN ISO 17665-1).
3. PCD and indicator strips are closely adjusted to achieve the required sensitivity. If the gke test device is used with other indicator strips, or GKE indicator strips are used with other test devices, GKE cannot guarantee proper results
4. Routine monitoring with chemical indicators is no replacement for validation.
5. In case of using other sterilization programs or other load configuration, a new validation procedure with biological indicators is required.
6. In case of changing the supplier of the ethylene oxide cartridges, a re-validation of the complete sterilization process (especially when inert gas is added) is required.

For further technical details please contact your local dealer or GKE directly. We will assist you with any technical questions. Visit our website www.gke.eu for more information.

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