Directions for Use

Chemical Indicators to monitor Formaldehyde (LTSF) sterilization processes

FORM

Art.-No.*	Quantity [pc]	Product Code	Standard EN ISO 11140-1	Product Description
213-221	400	C-F-P	Type 4	Package Monitoring Indicators
213-202	250	C-F-PM	Type 2 in combination with a PCD	Refill pack indicator strips for formaldehyde sterilization processes

(*) 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

For monitoring solid instruments in low-temperature-steam-formaldehyde sterilization processes (LTSF) package monitoring indicators (1) can be used. If hollow instruments are sterilized, e.g. minimal invasive surgical (MIS) instruments, type 2 indicator systems (2) have to be used since only they can monitor sterility inside lumen instruments.

1. Package Monitoring Indicators, Type 4

Type 4 indicators are used to proof sterility inside of sterilization packs on the place of the indicator. They can only be used for solid instruments, for hollow instruments type 2 indicator systems have to be used.

2. Type 2 Indicator Systems

The Process and Batch Monitoring Systems (PMS/BMS) for formaldehyde sterilization processes ensures that the formaldehyde-vapor mix penetrates into the most difficult areas of the load. The indicator strips are used to monitor formaldehyde sterilization processes and are used with a process challenge device (PCD), e.g. Helix or Compact PCD. It must be ensured that the selected PCD simulates the most difficult penetration characteristics of the load. heaviest load to be sterilized. After the appropriate PCD is selected, it can be ordered separately and used with biological or chemical indicator strips.

By using the selected Type 2 indicator system, biological or chemical indicators are not necessary in each pack, assuming that the BMS represents the load. Using the BMS, the results of the process can be evaluated immediately after the process is finished without waiting, until the indicators inside the packages are checked after opening the packs in the operation theatre. The whole load can be released after checking the indicator inside the PCD. In order to securely identify all packages from one batch, each package should also be labeled with a documentation label with batch number, date of manufacture and expiry date. Thus, the operation theatre is informed about the release of the respective package and the traceability is ensured.

If no type 2 indicator systems are used, package monitoring indicators have to be placed in the worst-case position inside each package. The release can only take place after opening the package. The result of the release has to be documented with a label on each pack with the batch number, production and expiry date to inform the staff in the operation room about the sterilization.

Product Description

1. The package monitoring indicators / type 4 indicators are self-adhesive and available on sheets.
2. The indicator strip for the BMS contains four indicator bars and is placed inside a GKE PCD and put into the sterilizer chamber. Those indicator strips can only be used with GKE PCDs. The use of other PCDs leads to wrong results.

The chemical substances of both indicators are protected to bleed by a polymer binder coating and therefore, do not release toxic substances.

Performance Characteristics

1. The package monitoring indicators are type 4 indicators according to EN ISO 11140-1 and are tested as follows:

   Test conditions:

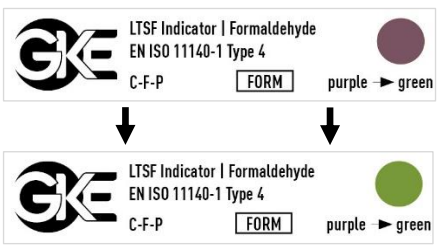
	FO-Concentration [mol· L-1]	Temperature [°C]	Time [min]
FAIL	0.0 (water)	80 ± 2.0	90 ± 1
FAIL	0.8	67	11.25
PASS	1.0	70	15

2. The GKE Process Monitoring System (PMS) 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). It is required that the PCD is adapted to the load in order to ensure the sterilization of the entire load. Since there are no specifications for type 2 indicators written in the standard, the same test conditions of the type 4 indicators are used, see table.

Handling Information

(1) for type 4 package monitoring indicators

1. If solid instruments are sterilized, place a type 4 package monitoring indicator in each sterilization pouch.
2. Run the sterilization process. After completion of the cycle or opening of the pack, pouch or container, remove the indicator and check the result:
   - If the indicator dot has turned into the final colour the sterilization process has been successful.



   - If the indicator dot remains purple or has not turned to the final colour completely this indicates inadequate penetration of the sterilant during the process. In this case do not release the goods.

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3. The indicator is self-adhesive and can be adhered in the patient documentation.

(2) for Indicator Strips
(Type 2, in combination with a PCD)

4. Open the cap and make sure the seal ring in the cap is in good condition.
5. Take out indicator strip from the card and fold it that the indicator bars are inside and place it in the white holder with the fold toward the screw cap.
6. Insert the white indicator holder into the PCD and tighten the cap.
7. Place the test device close in the worst-case position. Make sure the Helix-PCD is not bent. As a reference put another unpacked indicator into the chamber.
8. Run the sterilization program.
9. On completion of the cycle remove the test device carefully. After cooling down, remove the indicator strip and check the result:
   - If all four bars have turned into the final colour the sterilization process has been successful.

Example of colour change (Art.-No. 213-202)

   - If one or more bars remains the original colour or have not turned to the final colour completely this indicates inadequate penetration of the sterilant (formaldehyde) during the process. Compare indicator with reference indicator.
10. The person authorized will decide whether to release the batch or to re-sterilize the load.
11. 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.

If no Type 2 indicator system is used, package monitoring indicators have to be placed in the worst-case locations in each package.

Documentation Information

According to the specifications of the MDD and MDR the release must be documented in a way that compliance with all necessary release conditions can be proven. This requirement can be implemented by e.g. archiving the program data and the test results. The GKE indicators are self-adhesive and can be used for documentation.

A documentation sheet is available for download:
https://www.gke.eu/en/documentation-system-video.html
For each day and sterilizer one page is required.

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. The use of a Package Monitoring Indicators or BMS/PMS 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).
2. PCD and indicator strips are closely adjusted to achieve the required sensitivity. If the test device is used with other indicator strips, or GKE indicator strips are used with other test devices, GKE cannot guarantee proper results.
3. If the opening of the Compact-PCD® is not in the lowest position during sterilization condensate may come out of the PCD during removal from the sterilizer burning your skin.
4. Do not open the screws of the Compact-PCD®. An unscrewed PCD cannot be reassembled and must be replaced by a new one.

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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