CLEANING
STERILIZATION

Reprocessing in medical and dental practises

GKE-Products for the practice

Cleaning and Disinfection

Cleaning process monitoring indicators for washer-disinfectors

Pre-cleaning

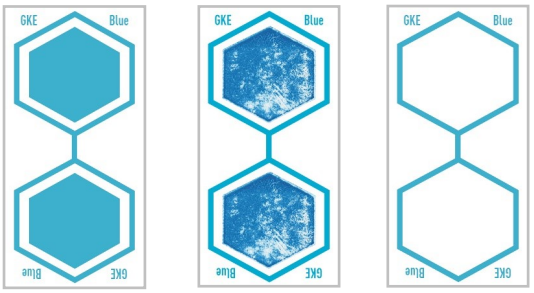
Used contaminated instruments require to be cleaned. For optimal cleaning the instruments are first rinsed off with cold water since 80% of all protein contamination are water-soluble and will be washed off. Pre-cleaning of highly contaminated instruments can be manually carried out with cold tap water with personal protective equipment (PPE), e.g. safety glasses, mask, safety gloves. If instruments with standard contamination can be directly put into a washer-disinfector (WD) and cleaned using a program that starts with pre-cleaning with cold water.

Cleaning

All components of a cleaning process have to be optimized to get a proper cleaning result. WD model, program selection, charging trolley, utilities, load configuration, water quality, detergent, detergent dosage, program runtime, temperature gradation etc. have to be optimized and adjusted to the instruments and its contamination.

Monitoring of the cleaning process

If a cleaning process has been designed and validated in an optimal way, it has to be assured that it works accordingly during daily routine and does not unnoticeable deviate from the date of validation. Instruments with higher requirements on the cleaning process (critical B-instruments) have basically be cleaned in a washer-disinfector. Cleaning process monitoring indicators can be used in each batch and checked after the cleaning process is completed. GKE offers cleaning process monitoring indicators that are designed with a new technology and simulate different wash-off characteristics. Thereby for each cleaning process an adequate indicator is available. The selection of the appropriate cleaning process monitoring indicator depends on the program used, temperature, time, detergent and other parameters that influence the cleaning process.



Original Indicator

Partly washed off

Completely Washed-off

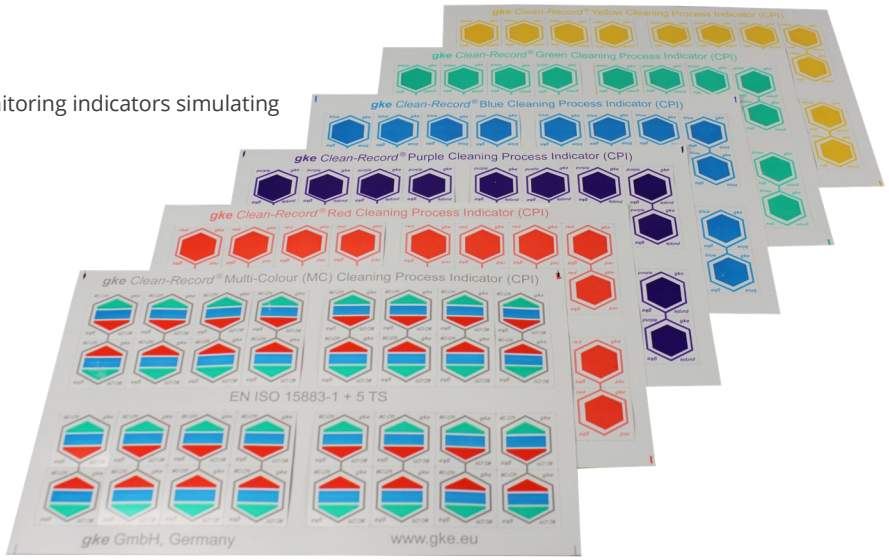
Holder

Hollow-Flow-PCD

Art.-No.	Product Code	Quantity
810-101	W-CPI-Y (CPI: yellow)	160
810-102		480
810-201	W-CPI-G (CPI: green)	160
810-202		480
810-301	W-CPI-B (CPI: blue)	160
810-302		480
810-351	W-CPI-P (CPI: purple)	160
810-352		480
810-401	W-CPI-R (CPI: red)	160
810-402		480
810-901	W-MC-CPI (CPI: green, blue, red)	160
810-902		480
800-102	W-PHO (Holder)	10
800-111	W-HF-PCD (Hollow-Flow-PCD)	1

Cleaning and Disinfection

Cleaning process monitoring indicators simulating different test soils



Cleaning Process Monitoring Indicators:
W-MC-CPI (green, blue, red), W-CPI-R (red), W-CPI-P (purple), W-CPI-B (blue), W-CPI-G (green), W-CPI-Y (yellow)

Testsheets for ulrasonic cleaning baths

GKE offers four different test sheets to check ultrasonic cleaning baths. The test sheet will be immerged in fluids vertically or horizontally to check the different intensity of the mechanical force inside the volume of the liquid.

It is recommended to use the test sheets at least once a day in every program used to ensure that no changes of the process parameter occur. It is also recommended to monitor each batch where loads are difficult to clean.

GKE offers different clip-holders of different heights to fix the test sheet inside the ultrasonic cleaning bath at different locations in the volume.

Anwendungsbeispiel:
Stativ-Halter mit Testbogen im Ultraschallbad

Art.-No.	Product Code	Quantity
810-111	W-U-CPI-Y (Ultrasonic test sheets: yellow)	40
810-112		120
810-211	W-U-CPI-G (Ultrasonic test sheets: green)	40
810-212		120
810-311	W-U-CPI-B (Ultrasonic test sheets: blue)	40
810-312		120
810-411	W-U-CPI-R (Ultrasonic test sheets: red)	40
810-412		120
800-115	W-U-HO-7 (Clip-Holder | 7 cm)	1
800-116	W-U-HO-20 (Clip-Holder | 20 cm)	1

STERILIZATION

Load-related batch monitoring systems (BMS)

In the past process challenge devices (PCD) were used to check the sterilizer specifications (type test according to EN 285 BD-Test or EN ISO 13060 "Hollow Load Test") to ensure that the sterilizer is working properly. However, the assurance that a sterilizer is working according to the sterilizer standard specification does not ensure that the load inside the sterilizer is sterilized successfully.

The GKE BMS (Batch Monitoring System) does not refer to what a sterilizer should be able to do, but to the requirements of the load, i.e. the instruments in their packages inside the sterilizer. Monitoring a steam sterilization process with the GKE-Dental-BMS (yellow) provides evidence that the steam penetration is sufficient to successfully sterilize all instruments suitable for steam sterilization in typical dental loads, including hand pieces , in their packages. The GKE Ophthal-BMS (white) monitors the steam penetration of typical ophthalmic loads including phaco handpieces.

Art.-No.	Product Code	Quantity
211-281	Start-up kit, PCD "Dental" and indicator strips	1+100
200-081	PCD "Dental" | yellow	1
211-291	Start-up kit, PCD "Ophthal" and indicator strips	1+100
200-091	PCD „Ophthal" | white	1
211-251	C-S-PM-SV1 Refill pack Indicator strips	100
211-252		250
211-255		500

Batch Monitoring for complex loads with hollow load test according to EN ISO 11140-6*

If more complex instruments are used that are not included in the dental load configuration of the Dental-BMS, it is recommended to use the GKE Steri-Record® process monitoring system. It is required that the instruments have been cleaned and disinfected in advance and the design of the instruments is validated so it can be sterilized in steam sterilization processes.

Art.-No.	Product Code	Quantity
211-264	Startpaket Prüfkörper | orange 100 Indikatorstreifen	1+100
200-026	Prüfkörper, oval | orange	1
211-251	C-S-PM-SV1 Nachfüllpack Indikatorstreifen	100
211-252		250
211-255		500

The GKE Steri-Record® Compact-PCD® consists of an external plastic casing with an internal stainless steel tube and capsule holding the indicator. All PCDs are re-usable and can be used for a considerable number of sterilization cycles. Only one indicator strips is required for each sterilization process.

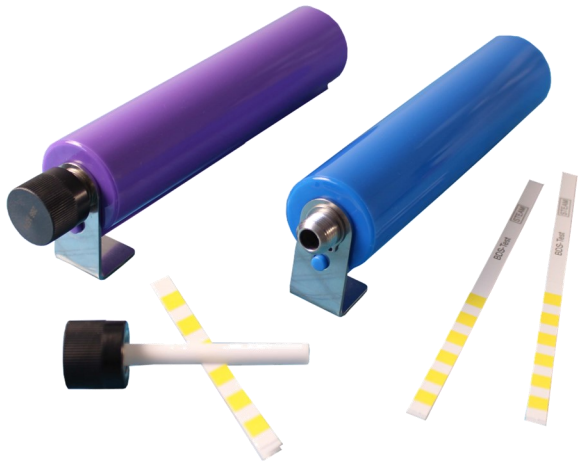
* All stated test characteristics were proved in an accredited test laboratory. Test reports are available on request.

STERILIZATION

Functionality test | Bowie-Dick-Test

The Bowie-Dick Test (type test, no sterility test) is used to check steam sterilizers for air removal and steam penetration after start-up. This test is carried out in an empty chamber and it is mandatory for large sterilizers according to EN 285. However, it is no substitution for routine monitoring. For small type B sterilizers according to EN 13060 a type test is also mandatory after start-up. If a Bowie-Dick-Test, a hollow load test according to EN ISO 11140-6 or any other test is used, depends on the type of sterilizer, process validation and specifications of the manufacturer.

GKE offers different BDS-Tests. The process challenge device (PCD), GKE Compact-PCD, colour blue, fulfils the requirements of EN ISO 11140-4 and also the hollow load test described in EN ISO 11140-6.*



Art.-No.	Product Code	Quantity
211-150	Start-up kit, PCD | blue and 100 indicator strips	1+100
211-120	Start-up kit, PCD | purple and 100 indicator strips	1 + 100
211-111	C-S-PM-SV1 Refill pack indicator strips for all GKE-BDS-Tests	100
211-112		250
211-115		500

Indicators according to EN ISO 11140-1 Type 6

For package monitoring

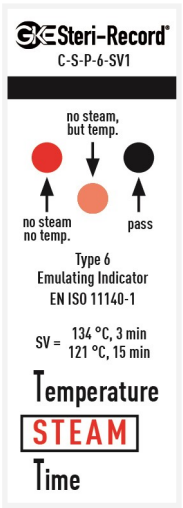
Type 5 and 6 indicators according to EN ISO 11140-1 (former class 5 and 6 until 03/2015) are used to monitor all relevant parameters of a steam sterilization process where they are placed. If indicators are used for routine monitoring they should be placed at the most difficult position to be sterilized, e.g. inside of packaged instruments. Physical data alone such as pressure, temperature etc. do not provide sufficient information to ensure sterility.

For use in special dental cominbation autoclaves

If only cross contamination on surfaces of the instruments should be prevented the instruments are sterilized without being packaged. In special combination autoclaves that clean, lubricate and sterilize dental instruments, the indicator is also placed unpacked into the indicator holder inside the chamber.

Art.-No.	Product Code	Quantity
211-243	C-S-P-6-SV1 Type 6 Indicators*	250
211-242		500
211-241		2.000
200-001	C-S-Clip (Indicator holder)	1

Use of a chemical indicator inside the clip of a combination autoclave, e.g. Sirona DAC UNIVERSAL



Indicator after successful colour change

Documentation

Manual documentation system

The GKE Steri-Record® documentation system is used for batch- and patient-related traceability after sterilization of medical devices.

The GKE labeling device is used to apply a label to each sterile package as well as to the documentation sheet, which contains information on the date of manufacture and expiry, responsible person and batch number. After opening the sterile package in the operating room/ OR, the labels can be removed from the the package and affixed to the patient's file for documentation purposes. In this way, with the information on the label for each package, all information can be traced back seamlessly from the patient to reprocessing and release. The labels for steam sterilization processes are available in four colors, optionally with or without indicator.

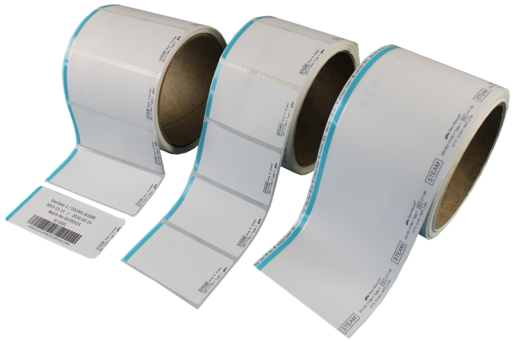
Art.-No.	Product Code	Quantity
240-820	Labelling device	1
Labels without indicator (750 pcs |roll)		
240-853	D-L-DA-R | red	4
240-861	D-L-DA-G | green	12
240-862	D-L-DA-B | blue	12
240-863	D-L-DA-R | red	12
240-864	D-L-DA-Y | yellow	12
Labels with indicator (750 pcs |roll)		
240-883	C-S-L-1-DA-R | red	4
240-871	C-S-L-1-DA-G | green	12
240-872	C-S-L-1-DA-B | blue	12
240-873	C-S-L-1-DA-R | red	12
240-874	C-S-L-1-DA-Y | yellow	12

Label with indicator (full-scale)

Labels for IT-based printers

If a thermal transfer printer, for example, is used in conjunction with an IT-supported documentation system instead of labeling pliers, single- or double-self-adhesive indicator labels enable complete documentation of the sterilization process of a medical device in the autoclave.

The labels contain a chemical indicator in accordance with EN ISO 11140-1 Type 1, which is indicated by a which indicates that steam sterilization has taken place by means of a permanent color change from blue to brown. The single-self-adhesive labels are suitable for use on metal surfaces, e.g. on containers, and can be removed from a smooth surface after sterilization without leaving any residue. Double self-adhesive labels are used on soft packaging. Both label versions can be removed after the packaging has been opened and then glued into a paper file for documentation purposes.



Art.-No.	Product Code	Quantity
Labels, double self-adhesive		
211-342	C-S-L-1-60x40-SC-DA	800
211-349	C-S-L-1-80x40-SC-DA	800
Labels, single self-adhesive, removable		
211-142	C-S-L-1-60x40-SA-R	1.000
211-149	C-S-L-1-80x40-SA-R	1.000

SEALING

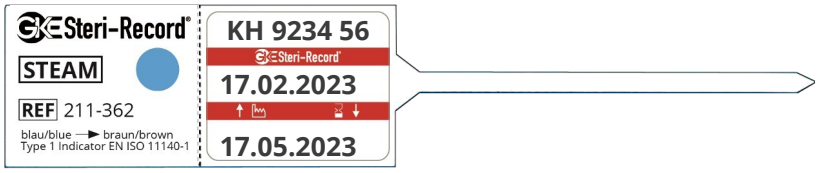
Container-Seal

Container seal are used for sealing sterilization containers or marking loading racks in steam sterilizers.

The seals are made of sturdy, self-adhesive cardboard with dimensions of 7 cm x 2.9 cm and a pin of 7.5 cm in length. The imprinted writing field offers the possibility to handwrite all relevant data such as date of manufacture and expiry date, content, batch number of the sterilization process as well as the responsible person. Alternatively, a label printed with the GKE labeling device (see „Manual documentation system“) can be affixed to the seal. The dimensions of the GKE labels and the seal fit each other.

The container seal secures a container against unauthorized opening and the indicator dot (process indicator type 1) provides logistical information as to whether the container has undergone the steam sterilization process.

Art.-No.	Product Code	Quantity
211-362	C-S-L-1-CS	1.008

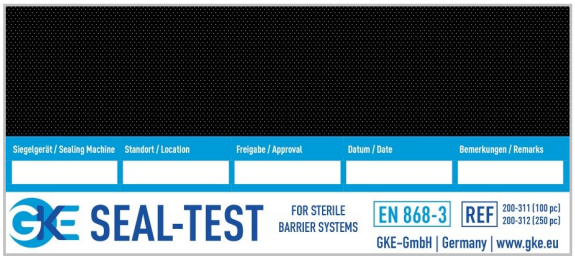


Container seal with label (not full-scale)

SEAL-TEST

The guideline for the validation of packaging processes according to EN ISO 11607 specifies that in everyday life the quality of the sealing of paper/film packaging is regularly checked with a test.

The GKE SEAL-TESTs for continuous sealers (indicator with 173 mm width) and bar sealers (indicator with 250 mm width) allow the testing of the seal seam quality for foil paper packaging.



Art.-No.	Product Code	Quantity
For continious sealers		
200-311	SEAL-TEST 173 x 76,2 mm	100
200-312		250

Art.-No.	Product Code	Quantity
For bar sealers		
200-331	BAR-SEAL-TEST 250 x 76,2 mm	100

710-011 EN V10

GKE-GmbH | Auf der Lind 10 | 65529 Waldems | Germany

tel +49 6126 94320 | **fax** +49 6126 943210
mail info@gke.eu | **web** www.gke.eu