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wfk F-PCD - Monitoring system:

Process-Challenge-Device based on fibrin to check cleaning performance for evaluation of reprocessing surgical instruments (Recommended in ISO 15883-5)

To quantify the cleaning performance of automated washer-disinfector (WD)-reprocessing procedures for surgical instruments, it is important to find the right lead parameter - the chemical compound representing a substance or group of substances relevant for the occurring soiling of real-life instruments after use.

Essential preconditions for the right lead parameter (model soil):

- Must be present and relevant in clinically relevant soils
- Its cleaning is demanding or it cannot be removed more easily than other soiling components
- It must not be subject to degradation, so that false negative results are excluded
- Methods for the sensitive detection with high precision and accuracy must be available

With the wfk F-PCD Monitor we can offer you the latest state of the art Process-Challenge-Device (PCD) based on highly relevant fibrin soiling together with the evaluation service as a monitoring system.

The wfk F-PCD Monitoring system consists of:

1. *wfk F-PCD Monitor*
   (Steel discs carrying a defined quantity of fibrin soil) for:
   - Evaluation of the cleaning performance of your WD-reprocessing procedures for surgical instruments.
   - Comparative evaluation of instrument cleaners for the reprocessing of surgical instruments.

2. *wfk Evaluation Service for used wfk F-PCD Monitors* comprising of the quantitative determination of fibrin soiling residues using the OPA (*ortho*-phthaldialdehyde) evaluation Method

For more information see next page.

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wfk F-PCD - Monitoring system

Process-Challenge-Device based on fibrin soiling to check cleaning performance

Adequate reprocessing of reusable medical devices is a sophisticated job. The majority of instruments is heavily soiled with blood and tissue residues after each use. Automated reprocessing using washer-disinfectors (WD's) is golden standard enabling effective cleaning and disinfection. However, process performance of WD's has to be checked on a regular schedule i.e. by requalification tests according to the respective DIN EN ISO 15883-standard. Additionally, many central sterilisation service departments (CSSD) monitor the performance of their reprocessing procedures using process challenge devices (PCD's) for routine controls.
An assembly of suitable test methods and tools, i.e. PCD's and test soils, are given in DIN EN ISO 15883-5 which contains the notation of a new process challenge device soiled with fibrin.
Fibrin is formed upon coagulation of blood which usually occurs immediately during surgical procedure and proceeds during the instrument's way down to the CSSD. As constituent of blood, fibrin is the most challenging component to remove during cleaning as fibrin is a cross-linked high-molecular weight protein which is totally insoluble in water as well as in acidic, neutral or alkaline cleaners at usually applied temperatures.
Based on these most challenging properties fibrin was chosen to develop a new fibrin process challenge device (F-PCD). wfk F-PCD come as stainless steel (1.4301) discs in the size of 80 x 12 x 1 mm containing dried fibrin on an area of 6 cm^2, see picture below.
For testing, customers put these wfk F-PCD's in there WD's, send them back to the laboratory and get a few days later the resulting data. The new wfk F-PCD's are suitable to judge even the best cleaning processes and to give a quantitative result that allows comparison and evaluation of the respective cleaning process over time important for routine monitoring as well as for requalification.

Features of wfk F-PCD's:

- Worst-case soiling mimicking dried coagulated blood
- Quantitative results
- For high-alkaline, alkaline, neutral or acidic cleaning processes
- Suitable for evaluation of enzymatic cleaning processes or check of enzymatic cleaners
- For all cleaning temperatures: ambient to + 65 °C
- wfk F-PCD's can be stored up to one year
- High stability, high reproducibility, high reliability, high significance

wfk F-PCD's are a brand-new tool to assess performance of cleaning processes for medical devices.

wfk F-PCD's can be ordered at wfk America.

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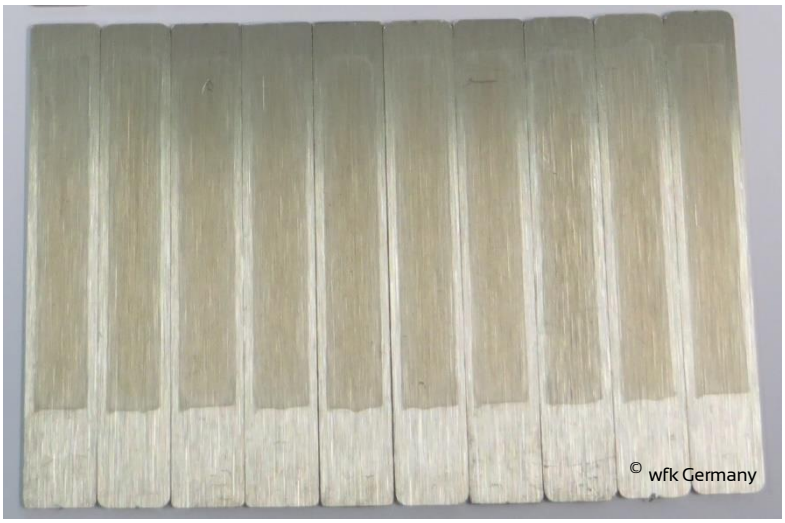
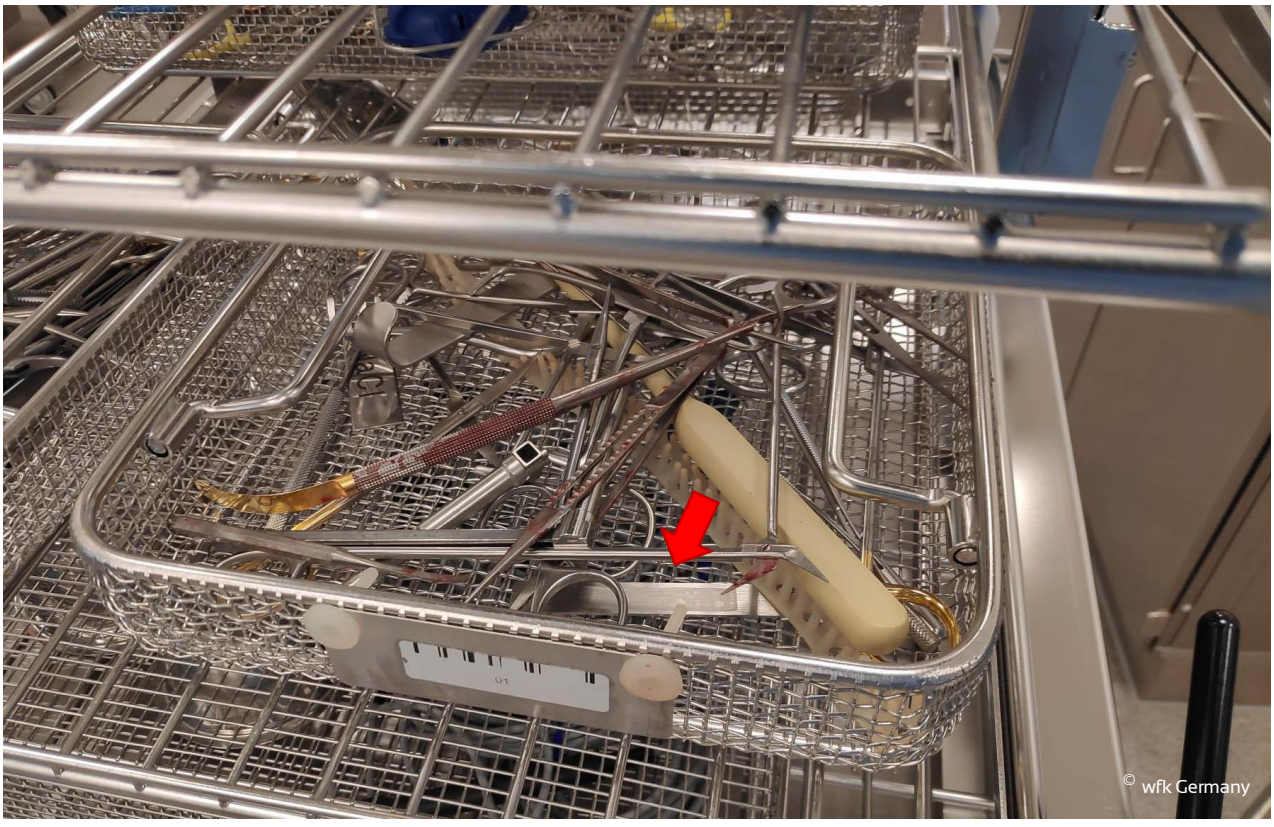


wfk F-PCD's ready for the assessment of the cleaning performance of WD's for surgical instruments: each PCD can be individually fixed at various positions of a tray and at different levels of a WD and cleaned together with real-life instruments, see picture below.



Application of a wfk F-PCD in a WD of a CSSD in a German maximum care hospital for routine control. The wfk F-PCD is put on the tray together with surgical instruments to be reprocessed. After reprocessing the wfk F-PCD is removed and assessed for the quantity of remaining fibrin. Due to the highly challenging properties of fibrin with regard to removal during cleaning processes wfk F-PCD give quantitative information about the performance of cleaning processes and what efficacy can be expected for reprocessed instruments.