

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 and evaluate residual soiling on medical instruments after reprocessing, it is important to find the right lead parameter - the chemical compound representing a substance or group of substances.

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

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

with the wfk F-PCD Monitor we can offer you the *game changing model soil* and *the evaluation service* as a monitoring system.

The wfk F-PCD Monitoring system consists of:

1. **wfk F-PCD Monitor**
(Steel tyles carrying a defined quantity of soil) for:
 - evaluating the effectivity of your reprocessing of used surgical instruments.
 - comparative evaluation of instrument cleaners for reprocessing of used surgical instruments.

Costs per wfk F-PCD Monitor USD 9.20

2. **wfk evaluation Service for used wfk F-PCD Monitors with the quantitative determination of residues OPA (ortho-phthaldialdehyde) evaluation Method**

Costs per wfk F-PCD evaluation USD 6.20

For more information see next page.

wfk F-PCD - Monitoring system

Process-Challenge-Device based on fibrin 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.

An assembly of suitable test methods and tools, i.e. process challenge devices 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 central sterilization service department. As constituent of blood, fibrin is the most challenging component to remove during cleaning as fibrin is a high-molecular weight protein which is totally insoluble in water or alkaline cleaners irrespective of the cleaning temperature.

Based on this most challenging character fibrin was chosen to develop a new fibrin process challenge device (F-PCD).

wfk F-PCD come as stainless steel (1.4301) plates in the size of 80 x 12 x 1 mm containing dried fibrin on an area of 6 cm².

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 process over time important 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

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.