

Intended use

The EndoChallenge Process Challenge Device (PCD) is an auxiliary device for the routine monitoring of automated wash processes for the WASSENBURG® Endoscope Washer Disinfector (EWD). The EndoChallenge PCD should only be used with EndoChallenge PCD Cleaning Indicators (CI).

EndoChallenge PCD Cleaning Indicators (CI) are inserted into the EndoChallenge PCD which is attached to irrigation system of the WASSENBURG® Endoscope Washer Disinfector via the surrogate device. The purpose of the system is to simulate a contaminated flexible lumen device according to ISO 15883-5 and HTM 01/06.

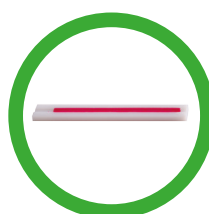
System Components



Surrogate
Device



Process Challenge
Device



Cleaning
Indicator



UV Light

Directions for Use

- 1 Open the PCD by twisting the top and bottom (figure 1).
- 2 Do not touch the red coloured test soil on the strip (figure 2). Insert the cleaning indicator into the designated slot within the chamber, making sure the soil is facing into the cavity (figure 3). Close the holder by attaching the two sections together.

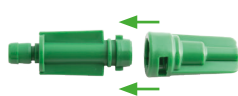


Figure 1



Figure 2



Figure 3

- 3 Attach the loaded PCD to the surrogate device. The PCD will connect to the end of the surrogate device via the CPC® connector (figure 4). When connecting the PCDs be careful to match the colour coding as the PCD is flow rate sensitive (figure 5).
- 4 Start the normal process cycle. After the wash and rinse stages but prior to the disinfectant stage; abort the cycle and remove the Surrogate Device from the EWD.



Figure 4



Figure 5

Disinfection and drying stages therefore should not be carried out when testing the cleaning efficacy as they will make a difference to the results.

- 5 Twist the cap on the PCD to open. Examine the CI for visual detection of colour. If the cleaning cycle was effective, all test soil should be completely removed with no pink/red visible against the white (figure 6).

This can be verified by placing the cleaning indicator under the UV light (figure 7). Presence of soil under the UV will fluoresce.



Figure 6

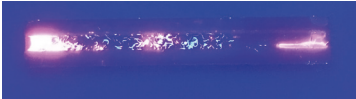


Figure 7

Assessment of the Indicator

Identification	Result	Required Action
Loaded EndoChallenge Cleaning Indicator		
	A reference indicator is identified by complete soiling of the channel.	
Successful Cleaning Process		
	No visible soil on the indicator, under naked eye or UV light.	No further action required.
Insufficient Cleaning		
	Soil visible on strip.	Check loading, dosage, contact time and critical process data.
Repeat test		
	Soil visible under UV light.	If failure repeated call the service provider.

Storage

CI Strips should be stored between 5 °C-30 °C out of direct sunlight. The product has a shelf life from date of manufacture of 12 months. The surrogate device and PCD must be stored dry in a clean environment.

