

<i>gke</i> - Technical Information	730-126-EN		
Best practice to select the correct cleaning process monitoring indicator	Version 02		
	Erstellt	08.08.2014	JM
	Änderung	08.11.2017	UK
	Prüfung	10.11.2017	UK
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Cleaning processes can be monitored by using a cleaning process monitoring indicator (CPI) made by an artificial test soil. EN ISO 15883-1 requires that a routine monitoring procedure should be used.

Different cleaning indicators are available. ISO/TS 15883-5 lists 19 test soils, e.g. semolina pudding, egg yolk, water-soluble wallpaper paste, sheep blood, ink etc.. A uniform standard test soil is not possible because it must be adapted to the individual cleaning process with different cleaning requirements and different cleaning procedures.

It is always a question which CPI or standard test soil should be used for routine monitoring.

Different cleaning processes are necessary, since different instruments (orthopaedic, gynaecological, urologic, dental etc.) have to be cleaned with different procedures. Soils such as blood, bone meal, cement, mucus have different wash-off characteristics and require the use of different programs and detergents. Those programs differ e.g. in time and temperature gradient, different detergents with high and low pH value, enzymes, tensides, oxidants, silicates etc.

There is no definition of "clean". How good to clean an instrument depends on its later use and must be defined by the surgeon in charge, e.g. an implant must be even free of endotoxins.

Cleaning processes should be optimized to clean real instruments. This is why it is unrealistic to just use only one CPI.

An optimal indicator should have two characteristics:

1. It has to be washed off if the cleaning process has been validated correctly before.
2. It shall not be washed off in case of change of any critical parameter in the cleaning process, e.g. wrong detergent, false dosage or expired detergent, etc. making the process less efficient.

Tests have to be carried out to find a suitable CPI to fulfill both characteristics.

gke offers 6 different CPIs with different wash-off characteristics to select the right indicator for the process used.

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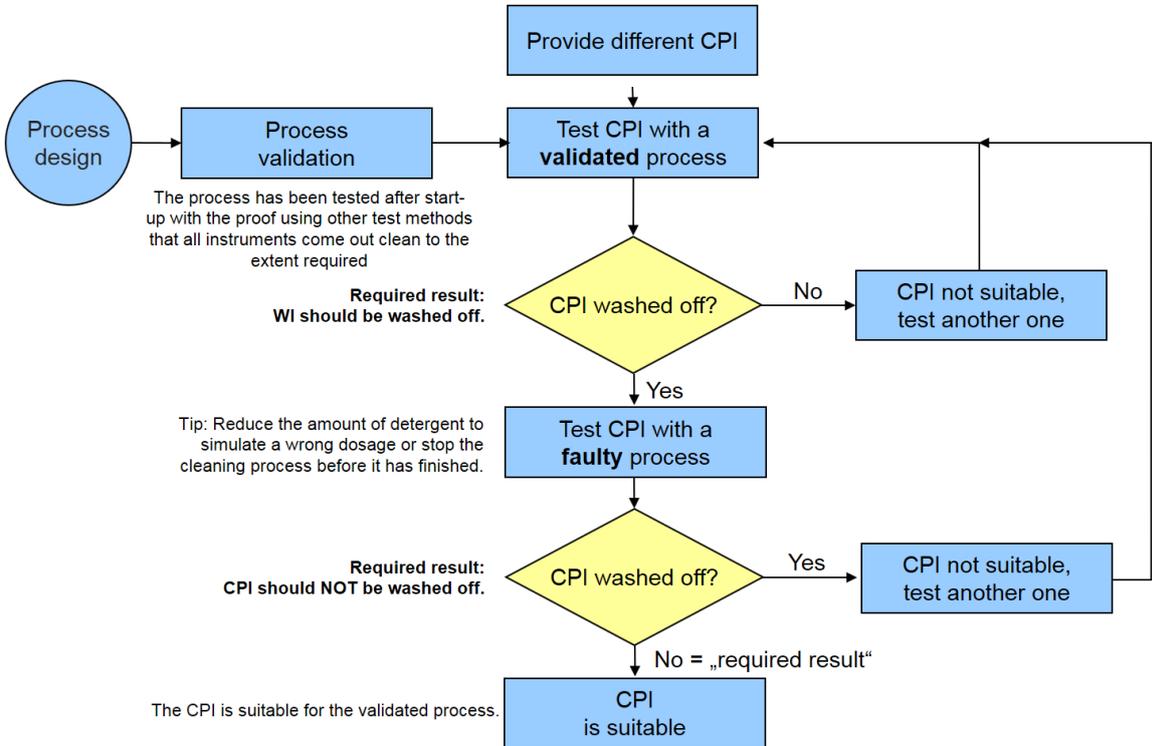
Practical approach:

All *gke* indicators are adhered to a plain stainless steel plate of a WD cart or fixed with a *gke* holder, so that one side of the indicator can be observed through a glass door, if installed. Also additional indicators of other manufacturers or test soils of the standard ISO/TS 15883-5 can be fixed visibly on a basket. Then a validated cleaning program is started and the progress of the indicator wash-off is observed through the window and documented. Some indicators are washed off already with cold water during the pre-cleaning procedure and others are only washed off partly, completely or not at all during main cleaning program. The results, after which time and in which program which indicator has been washed at which extent are documented. An indicator is suitable for routine monitoring which has just been washed off last.

The best practice to select a CPI can be shown at the following flow-chart:

How to select the correct cleaning process monitoring indicator (CPI)?

After validation this procedure is suitable for all goods incl. hollow devices and instruments with splits.



If the process has changed, the WI-selection has to be repeated.