PROCESSING OF MEDICAL PRODUCTS IN GERMANY

# HYGIENE AND SAFETY

The hygiene requirements for processing medical devices are defined in the joint recommendation of the Commission on Hospital Hygiene and Infection Protection (KRINKO, German CDC) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM, German FDA). The reference to this recommendation in the German Medical Devices Operator Ordinance (MPBetreibV) lends legal credibility.

In Germany, automated processes are favoured for processing of medical devices. In particular, cleaning and disinfection should always be carried out automatically for reasons of process safety. Manual pre-cleaning steps should be avoided if possible. This principle is only to be deviated from if the medical devices cannot be processed in the washer-disinfector (WD), for example due to material or design reasons. For thermolabile medical devices, chemo-thermal automated cleaning/disinfection is preferred, whereby the temperature of 65 °C is not exceeded. In Germany special load carriers for MIS instruments are used for processing medical devices with lumen. There are special load carriers which have nozzles for irrigation of hollow instruments.

For automated cleaning with subsequent thermal disinfection, the following parameters are customary in Germany:

| Process step | Water quality | Time | Temperature |
|---|---|---|---|
| Pre-cleaning | Tap water | 5 min | Cold (approx. 20 °C) |
| Cleaning | Deionized water | 10 min | 55 °C |
| Rinsing | Deionized water | 2 min | |
| Disinfection | Deionized water | 5 min | 90 °C |
| Drying | - | 15 min | 90 °C |

For steam sterilization the following parameters are common in Germany:

| Process step | Time | Temperature |
|---|---|---|
| Sterilization | 5 min | 134 °C |
| Sterilization (prion-program) | 18 min | 134 °C |

Besides neutral, alkaline, and enzymatic agents, mildly alkaline products are preferred for cleaning in Germany.

Spray disinfection is out of the question for reasons of occupational safety.

In Germany, medical devices have to be cleaned first and disinfected afterwards. This is to prevent a possible fixation of proteins through the disinfection process. As a further principle, only clean medical devices can be disinfected or sterilized effectively. After cleaning, disinfection is then carried out for reasons of personnel protection. Usually both processes take place in the WD.

The clean and disinfected medical devices are visually checked for cleanliness afterwards. Subsequently, maintenance or oiling of the medical devices is carried out if necessary. In the next step, the medical devices are packaged and finally sterilized.

For the German market, the disinfection performance is tested with the standard test germ E. faecium. Acceptance criterion for a successful disinfection is the reduction of germs by 5 log levels.

Thermal processes (thermal disinfection and steam sterilization) must be checked thermoelectrically, if measuring at the critical points of the medical device is possible.

The microbiological test shows that the disinfection and sterilization time and temperature on the medical device was sufficient to kill the test germs.