

Recommendations by the Quality Task Group (45) Decontamination of Narrow-Lumened Medical Devices

Cleaning and disinfection, as well as sterilisation if required, of narrow-lumened medical devices (MDs) are a problem, in particular if the diameter is < 0.8 mm. Moreover, the → **GEOMETRY AND MATERIAL** of the medical device (length, diameter) play a pivotal role. It is not possible to conduct thermoelectric measurements for verification of thermal disinfection in washer-disinfectors (WDs) or for steam sterilisation because the measurement probes cannot be inserted into the narrow lumens.

Narrow-lumened MDs are used primarily in ophthalmology, ENT and neurosurgery. They are mainly assigned to the Critical B and C groups.

The manufacturers of narrow-lumened MDs are required by DIN EN ISO 17664 to provide → **INFORMATION ON DECONTAMINATION**, specifying at least one process for cleaning, disinfection, and for sterilisation if applicable. And since this information has implications as far as a declaration of conformity with corresponding product liability is concerned, the manufacturers carry out extensive tests or have these conducted by qualified laboratories. Using model instruments or special → **PROCESS CHALLENGE DEVICES (PCDs)** in the laboratory, which pose at least the same or higher demands on reprocessing than the instrument itself, testing can be carried out with microbiological, radionuclide and cytotoxicity methods as well as with photoelectron spectroscopy (XPS) for quantitative determination of the cleaning and disinfectant action and for detection of any residues of contamination, chemical detergents or microorganisms. In addition, pH measuring instruments or pH loggers, placed within the WD, can be used to check that alkaline detergents have been properly rinsed off.

The → **EFFECTIVENESS OF STERILISATION PROCESSES** is ascertained, while bearing in mind ISO 14937, using process challenge devices (PCD) and the test organism *Geobacillus stearothermophilus* ATCC 7953.

Automated Cleaning and Disinfection

Validated decontamination can be carried out only in suitable WDs provided that the materials of which the MDs are made are amenable to decontamination with thermal disinfection. The process steps involved here are cleaning, rinsing off of process chemicals, thermal disinfection and drying. Only if validated processes are used can one assume that a successful outcome is continually assured for such processes.

The WD manufacturers have designed special inserts for → **FLUSHING OUT NARROW-LUMENED MDs**. Furthermore, special, small WDs have been constructed and validated for medical practitioners' offices, e.g. for ophthalmological MDs. A precondition to be met here is that the MD be connected via a Luer Lock and be amenable to cleaning at an adequately high pressure.

Roth published the findings from studies that revealed that the flow characteristics exert a significant influence. If → **ADEQUATE FLOW** is not assured, pre-cleaning must be conducted with a spray pistol (1). The test organism *Enterococcus faecium* ATCC 6057 is used for microbiological testing.

There are special inserts for WDs to decontaminate narrow-lumened ophthalmological MDs, e.g. Sauter cannulas. These are screwed on to Luer-Lock cleaning attachments. Following cleaning and thermal disinfection, the cannulas are removed for drying, and the residual liquid is dried out with filtered compressed air. Using pH paper, the pH of the expelled drops of water can be measured for alkaline detergent residues. A filter plate is used to ensure that the cannulas are not blocked by particles from the cleaning solution (2).

→ **THE GEOMETRY AND MATERIAL** play a role for the reprocessability of narrow-lumened medical devices besides the diameter.

→ **INFORMATION ON DECONTAMINATION** has to be provided by the manufacturer as required by DIN EN ISO 17664.

→ **USING PROCESS CHALLENGE DEVICES** the cleaning and disinfectant action can be quantitatively determined in the laboratory; residues can be detected.

→ **THE EFFECTIVENESS OF STERILISATION PROCESSES** is ascertained using PCDs and test organisms.

→ **FOR FLUSHING OUT NARROW-LUMENED MDs** special inserts for WDs have been designed.

→ **ADEQUATE FLOW** has to be assured.

Only to a certain extent can the laboratory results be extrapolated to other WDs or process chemicals. Besides, the outline conditions prevailing under everyday use conditions are very different, hence blockage can be caused by foam or by other particles which were not taken into account during laboratory tests.

The control methods that can be used in the laboratory are not available in a CSSD or doctor's surgery. → **CHECKING FOR CHEMICAL RESIDUES** constitutes a particular problem, especially if they cannot be monitored on the basis of the pH value or of electrical conductance, as is the case for example for residues of solvents, foam inhibitors or surfactants.

→ **CHECKING FOR CHEMICAL RESIDUES** constitutes a particular problem in practice.

Manual Cleaning and Disinfection in Everyday Practice

→ **STANDARD OPERATING PROCEDURES (SOPs)** must be available and observed for the steps on which manual decontamination is based. Nonetheless, these cannot be viewed as validated processes.

→ **SOPs** must be available and observed.

Flushing out of narrow-lumened MDs with a spray pistol will show that the device is not blocked. It is not possible to check cleanliness on the basis of visual inspection or using a chemical test.

If a device is immersed in a solution containing a combined detergent and disinfectant which does not give rise to protein fixation, it must be ensured that the internal surfaces are also exposed to the solution and that an adequate bactericidal, fungicidal and virucidal efficacy is achieved. An → **ADEQUATE DISINFECTANT ACTION** is impeded by biofilms, lipid films and air bubbles. If the solution is repeatedly used, protein effects will give rise to an uncontrollable decline in the disinfectant action.

→ **ADEQUATE DISINFECTANT ACTION** is impeded by biofilms, lipid films and air bubbles.

Rinsing constitutes a special problem because just what "thorough" rinsing means is generally subjectively evaluated.

Cleaning or combined cleaning and disinfection in an → **ULTRASOUND BASIN** is recommended for narrow-lumened, metallic MDs and for other filigree MDs, e.g. for biopsy forceps. The ultrasonically mediated cavitation generates a cleaning effect on hard surfaces. Ultrasonic cleaning must not be used for elastic MDs. Narrow-lumened MDs can be adapted and purged via tubes in a special ultrasound apparatus (3). Manufacturers have decreed that ultrasonic cleaning is not suitable for certain MDs because of the likelihood of damage to the MDs (4).

→ **AN ULTRASOUND BASIN** is recommended for cleaning of metal narrow-lumened MDs and other filigree, non-elastic MDs.

Sterilisation

If the MD must be assigned to the Critical B or C group in view of its intended use, it must be sterilised after cleaning and disinfection, preferably using steam sterilisation. If large steam sterilisers that have been subjected to type testing as per ISO 285 are used, the preconditions for safe sterilisation are in principle assured. However, when carrying out performance testing as per ISO 554 as part of on site validation, problems relating to → **STEAM PENETRATION** which are not detected by thermoelectric measurements can occur, depending on the loading configurations or on special design features. To overcome this lacuna, microbiological testing must be conducted with corresponding PCDs or receptacles.

→ **STEAM PENETRATION** can cause problems in narrow-lumened MDs which are not detected by thermoelectric measurements. Additional microbiological testing must therefore be conducted.

An extensive study has been carried out into these problems by MD manufacturers and the AKI (Instrument Preparation Working Group), among others. Using model instruments, it was possible to elucidate to what extent constructive elements hampered decontamination and how these could be countered. → **TEST MODELS** were designed to simulate the following design-mediated impediments to decontamination:

→ **TEST MODELS** simulating design-mediated impediments were developed to carry out studies to elucidate how these can be countered.

- Gap
- Metal/plastic and metal/metal sliding surface
- Seal
- Thread
- Hollow instrument
- Tube
- Insulation

As a model for hollow devices a lumened PCD, opened either at one or at both ends, measuring 500 mm in length and with a diameter 0.5 mm was used. The test organ-

ism used was *Geobacillus stearothermophilus* ATCC 7953. The results were satisfactory and instructive for the manufacturers of narrow-lumened MDs (5, 6).

However, the standard for validation of small sterilisers is still being drawn up. It is assumed that small sterilisers with a prevacuum as per EN 13 060 Class B produce satisfactory results. Here, too, microbiological tests for hollow devices and narrow-lumened MDs are discussed.

Alternatively, → **PLASMA STERILISATION** can be used. This process is validated according to the recommendations of ASP Johnson & Johnson as per ISO 14937 using special PCDs under half-cycle conditions. Depending on the materials of which the MDs are composed, the following limit values are specified, e.g. (7):

→ **PLASMA STERILISATION** can be used for narrow-lumened MDs within the validated efficacy limits.

	Lumen diameter	Length w/o booster	Length with booster
Stainless steel:	1 mm	125 mm	500 mm
	3 mm	400 mm	500 mm
PE and Teflon plastics:	1 mm	1000 mm	2000 mm
Flexible endoscopes:	1 mm	500 mm	2000 mm

In extensive studies Okpara-Hofmann et al. have demonstrated that depending on the MDs' geometry, sterility can be achieved for parameters going beyond those specified by the manufacturers (8).

Heat-sensitive narrow-lumened medical devices (Critical C Group) can also be sterilised with ethylene oxide or formaldehyde processes within the efficacy range ascertained for the process. In this respect, the requirements set out in the Hazardous Substances Regulation and in TRGS 513 must be observed additionally.

Summary

Decontamination of narrow-lumened MDs calls for an in-depth study of the processes to be used. Using → **RISK ANALYSIS AS PER EN ISO 13485**, it must be investigated whether there is a high or a low risk for occurrence of irritations or toxic reactions, caused by residues or endotoxins, or of other complications. If there is a high risk, it is recommended that the MD be classified as a single-use device.

→ **THE RISK ANALYSIS AS PER EN ISO 13485** has to be used to decide whether a narrow-lumened MD should be classified as a single-use device.

References

1. K. Roth, C. Schuler, J. Gauer: Maschinelle Aufbereitung chirurgischer Instrumente, ambulant operieren 2005 / 3
2. Documentation Fa. Miele
3. Documentation Fa. Medisafe
4. Aufbereitung von Instrumenten 8. Auflage, Arbeitskreis Instrumentenaufbereitung (AKI)
5. ZentrSteril (2001) 425–437.
6. ZentrSteril (2002) 100–104.
7. Documentation Fa. ASP Johnson & Johnson
8. J. Okpara-Hofmann, M. Knoll, M. Dürr, M. Borneff-Lipp: Comparison of low-temperature hydrogen peroxide gas plasma sterilization for endoscopes using various Sterrad models, Journal of Hospital Infection (2005) 280–285.