Recommendations by the Quality Task Group (95)

Optimization of Medical Device Positioning for Automated Cleaning and Disinfection

Part 2: Lumened medical devices

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Part 1 (Recommendation 92) described optimal positioning of non-lumened medical devices (MDs). This included an overview of the general prerequisites as well as photographs comparing suitable and unsuitable positioning methods.

➜ **POSITIONING** of lumened medical devices is challenging.

However, optimal ➜ **POSITIONING** of lumened medical devices (MDs) is essentially more challenging. These MDs belong to the semi-critical B as well as the critical B and C groups which cannot be inspected for cleanliness in their entirety.

Optimal lumen patency is an indispensable prerequisite for flawless cleaning and disinfection results. To that effect, suitable connectors or adapters must be available or procured.

➜ **THE FLOW RATE** through the lumens must be verified according to EN ISO 15883.

Standard EN ISO 15883 Part 2 calls for verification of the ➜ **FLOW RATE** through the lumens and powered devices (5.1.2 and 6.3.3). Accordingly, before loading the devices into the washer-disinfector (WD) the user should ensure that the unimpeded flow of water is assured through all channels of a medical device. All channels must be open and accessible; the MD manufacturer's instructions must be observed.

Before starting the process all the requisite connections must be fitted and these must be checked again at the end of the process to ensure that they are still securely in place.

Connectors on the loading trolley

➜ **CONNECTORS** are used to attach lumened medical devices to the irrigation system.

All lumened MDs must be attached via appropriate ➜ **CONNECTORS** to an irrigation system in a manner that ensures that all their inner surfaces, too, will be effectively cleaned and disinfected. The WD manufacturers offer a variety of loading racks to facilitate this, e.g. trolleys (carts) for minimally invasive surgical (MIS) instruments, anaesthesia equipment, ophthalmology instruments, injector trolleys as well as combi trolleys.

In addition to direct Luer lock connections, the loading racks are also frequently equipped with universally usable connectors. If irrigation sleeves are used one must ensure that the sealing rings are fitted tightly to the MDs but without covering them (spray shadowing).

Various firms supply additional irrigation strips with connectors that can be retrofitted to any type of mesh trays.

These connections can then be tailored to the individual needs by attaching various types of tubes. The length, lumen and materials of the tubes must lend themselves to the specific MDs and must not contain any toxic materials.

Only single-use (disposable) tubes should be employed for direct patient care (e.g. irrigation, insufflation, suction, etc.) since it is difficult to clean the inner surfaces of such tubes in the absence of brushing.

➜ **TUBES** should be fitted in the WD such that the cleaning/disinfection agents can access all inner and outer surfaces.

In general, the ➜ **TUBES** should be fitted in the WD such that the cleaning/disinfection agents can access all inner and outer surfaces.

Additional connections can result in reduced cleaning pressure and adversely affect the cleaning outcome. The responsibility for assuring flawless cleaning results rests with the operator of the respective premises who must provide for routine checks and validation to that effect.

Wherever possible, instruments must be dismantled in accordance with the manufacturer's instructions. Small components must be placed in closed trays designed for such small items. MIS instruments must be opened at their jaws and placed in special trays with holders to secure them and render them accessible to the spray jet (Fig. 1).
The irrigation sleeves are not designed to accommodate several lumened MDs since otherwise the irrigation opening at the bottom of the sleeve would be occupied by the first lumened instrument and this would mean that the other lumened instruments would not be irrigated.
The loading rack manufacturer must specify whether ,and which, connectors on the irrigation strip have to be closed when not occupied in order to assure adequate cleaning pressure (Fig. 2 and 3).
An optimal flow rate and cleaning pressure can be guaranteed only if the loading racks, tubular systems, fittings and sealing rings are also regularly checked by the operator and also serviced by the manufacturer. Defective components must be immediately replaced.
Some manufacturers supply mesh trays for securing the rolled-up tubes and cold-light cables on the loading rack. Cold-light cables will be damaged if wound too tightly. Since suction tubes and cables often become detached during the cleaning process they should be placed in a tray and secured or covered.
When using MIS loading racks with facilities for accommodating tubes, the tubes should be wound with the roller in a manner that avoids kinks (Fig. 4).
There are also special loading racks for anaesthesia accessories and tubes (AN trolley/cart). However, the latter are being increasing replaced with single-use items since such narrow tubes are difficult to clean. Here, too, one must ensure that fittings are still in place at the end of the process (Fig. 5).
If tubes are reprocessed one must ensure that the attachments provided are tailored to the size/diameter of the tubes to permit an adequate flow of water and cleaning solution through the tube.
Occasionally, automated irrigation of channels does not suffice and in such cases these items must be cleaned in advance by brushing or, if possible, using ultrasonic cleaning.

Fig. 1: Positioning MIS instruments with jaws opened

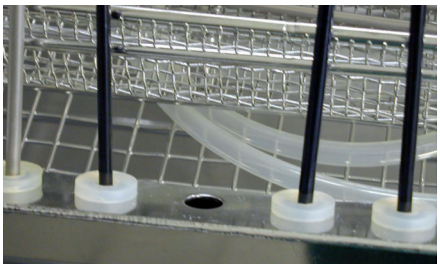

Fig. 2: Irrigation strip with missing plug

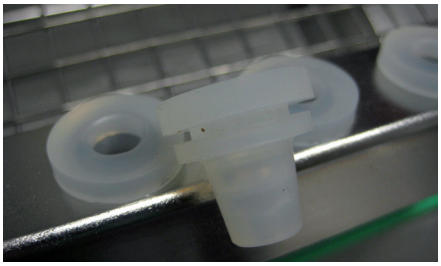

Fig. 3: Irrigation strip and plugs

Adapters and positioning aids

If the lumened MDs cannot be properly fitted to the connectors available in the WD adapters must be used to facilitate this. Some manufacturers supply matching positioning aids and adapters for the various types of WDs, e.g. for rigid endoscopes.
Positioning aids are offered by various manufacturers to secure the items to be reprocessed and prevent them from damaging each other. In general tubes are used to connect items to the spray system.

Fig. 4: Kinked tube connection

Instrument cleanliness, the problems caused by particles, and filters

In principle, the WD and endoscope washer-disinfector (EWD) must be clean and free from deposits. The connectors and adapters must be inspected daily. Defective or inappropriate adapters, missing rubber plugs or blocked pipes can be the cause of poor cleaning and disinfection results. Daily cleaning and functional testing must be carried out in accordance with a designated schedule and documented by the respective staff member.
Narrow lumened instruments, e.g. trocars and working shafts, can only be flushed out properly if the irrigation solution is free of coarse particles. Soils present in the irrigation solution as suspended particles can gain access to the lumens via the cleaning solution and block them. Hence, MDs with particularly narrow lumens (e.g. ophthalmological instruments), must be protected against foreign bodies in the cleaning water.
Various manufacturers offer a range of filters to protect against particle penetration. The ➜ **FILTERS** must be properly maintained and regularly cleaned as otherwise they will become blocked and impede the flow of media.
Since the filters reduce the cleaning pressure, the ability of the prevailing cleaning pressure to assure the requisite flow rate must be verified at the time of validation.

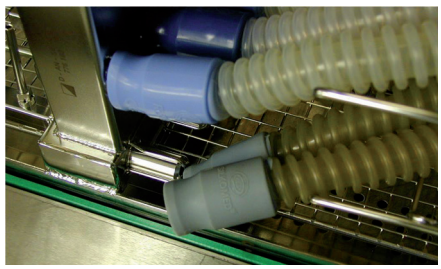

Fig. 5: Detached tubes

➜ **FILTERS** must be regularly cleaned. The requisite flow rate must be verified at the time of validation.

Checks and inspections

The Guideline for Validation of Washer-Disinfector Processes, compiled by the DGKH, DGSV and AKI [1], stipulates that mechanisms be in place to check media dosage, the water level, temperature, time and cleaning pressure ➜ **INDEPENDENTLY** of the WD logic controller. For those WDs that are unable to meet these requirements the Guideline [1] specifies that corresponding routine checks should be defined by the validation expert.

➜ **INDEPENDENT MECHANISMS** to check media dosage, the water level, temperature, time and cleaning pressure must be in place.

Within the framework of validation or performance requalification, in addition to Crile clamps, representative instruments, especially lumened MDs that are difficult to connect in the WD, should be used as process challenge devices (PCDs) to verify the cleaning efficacy by inspecting them for residual proteins.

The Guideline [1] stipulates that semi-quantitative tests for residual proteins be conducted to that effect.

There are also semi-quantitative and qualitative protein tests available for ➜ **ROUTINE VERIFICATION OF THE CLEANING RESULTS** by the user.

➜ **FOR ROUTINE VERIFICATION OF CLEANING RESULTS** by the user, semi-quantitative and qualitative protein tests are available.

The user can also use PCDs to check the flow rate, or pressure loggers to check the pressure, on a routine basis or as needed. ■

References

1 Guideline Compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for Validation and Routine Monitoring of Automated Cleaning and Thermal Disinfection Processes for Medical Devices Issue 2014