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INTERNATIONAL

endoNEWS

Best Practice: Processing of Endoscopes

Dear readers,

Water is a basic requirement for life: drinking water supply, agriculture, industry – we come into contact with this valuable liquid everywhere. But not all water is the same: Even though our drinking water is quite pure, microbiologically safe water is required for endoscope processing. We explain exactly what is important here from page 1.

In endoscopy biofilms are a problem. We explain everything you need to know about their formation, the associated risks and, of course, their prevention and proper removal on page 3.

Our innovative, highly concentrated neodisher® MediClean advanced is now also suitable for endoscope processing. Extensive field testing with various customers confirmed the suitability of the product for both manual and automated endoscope processing. Find out more about the application and benefits on page 4.

Enjoy the newsletter!
Best regards

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DR. WEIGERT
Systematic Hygiene

www.drweigert.com

Not to be underestimated:

Provision of microbiologically safe water for endoscope processing

In Germany, water from the mains is so pure that it meets drinking water standards.

(Deutsches Ärzteblatt Vol. 105, Issues 31–32, August 4, 2008)

This statement may initially seem reassuring. However, there may be microorganisms in your tap water. And where microorganisms are present, biofilms are usually not far away. And worse still: wherever microorganisms are present, infection is also possible. Water quality therefore plays a decisive role, particularly in the processing of flexible endoscopes.

Use of water in the processing of flexible endoscopes

If you look at where water is used in the processing of flexible endoscopes, you quickly realise that it affects almost every single step. When preparing cleaning agents and disinfectants, when rinsing the ducts (intermediate rinsing), and during the final rinse. During final rinsing, the water used is the last medium to come into contact with the endoscopes or the channels. If the water is not microbiologically safe and contamination occurs, recontamination is possible. Even if performed correctly, the previous steps become invalid, thereby rendering the prior efforts wasted. This is why water quality is particularly important for the final rinse.

Requirements for endoscope processing

Appendix 8 of the KRINKO-BfArM recommendation (2024) “Hygiene requirements for the processing of thermolabile endoscopes” states that the water used for final rinsing “must be microbiologically safe”. This can be ensured “[...] by using suitable water filters that are regularly checked and maintained”.

Sterile filtration and membrane technology

Sterile filtration is defined as the reduction of at least 7 log levels of the test germ Brevundimonas diminuta per square centimetre of filter area (i.e. a germ reduction of 99.99999%). Brevundimonas diminuta is the reference organism for the test standard. It has a diameter of 0.3 µm and is considered the smallest waterborne micro-organism. Its size is crucial for the functionality of a sterile water filter. Sterile water filters usually have a hollow fibre or flat membrane with a pore size of 0.2 µm to provide reliable protection against water germs such as pseudomonads and legionella. The pore size of the membrane is therefore smaller than the size of Brevundimonas diminuta.

The hollow fibre membrane usually consists of many small tubes, each of which has many pores with a maximum pore size of 0.2 µm. The water flows into the tubes and out again through the pores. If the water contains microorganisms, the germ-laden water flows into the tubes. The microorganisms are too large and do not fit through the pores. They are retained, and sterile filtered water flows out of the filter outlet.

Bacterial retention test: ASTM F838-15a/ASTM F838-20

The functionality of the sterile filters is tested according to a technical standard, the ASTM F838-15a or ASTM F838-20. This test stand focuses on the bacterial retention testing of membrane filters for liquid filtration. This is a loading test (i.e. a bacterial suspension with a minimum concentration of 107 CFU/cm² is passed through the filter, collected in a sterile container and analysed microbiologically using membrane filtration). The reduction factor is then calculated. The test micro-organism is Brevundimonas diminuta.

Automated endoscope processing

The two relevant steps of the entire treatment cycle, in which water plays a major role (see Fig. 1), are:

1 Place the disinfected endoscope in a basin/tub with microbiologically safe/sterile water. Use fresh water for each device.

2 Thoroughly rinse the outer surfaces of the endoscope and all channels with microbiologically safe/sterile water.

The water filters should not be immersed in the rinsing water. Contamination by splashing water must also be avoided.

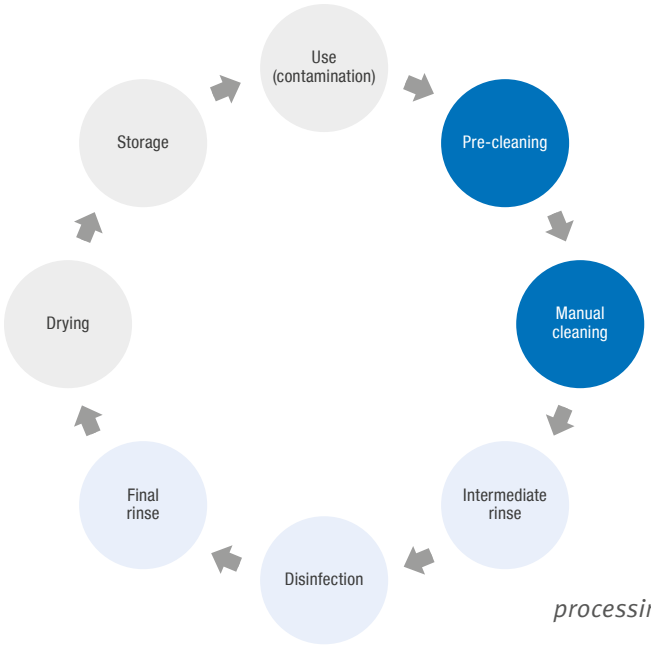


Fig. 1: Use of water in the processing of flexible endoscopes

In both cases, a terminal sterile water filter can be used. In the second step, the terminal sterile water filter is attached to a spray gun using an adapter. You should use a nozzle attachment that thoroughly rinses the endoscope channels and which can be processed.

What needs to be considered when using sterile water filters?

Terminal sterile water filters have a defined service life that must be followed. It is also important to disinfect the filter outlet every day to prevent retrograde contamination.

Automated endoscope processing

Annex 8 of the KRINKO-BfArM recommendation (2024) refers to the fact that "[...] during automated processing in the washer-disinfector [...] the water for final rinsing [...] is treated by heating, filtration, and UV lamps". The process or combination of processes used varies from manufacturer to manufacturer.

Author: Marcel Jung M. Sc.,
Product Manager, Endoscopy

Tab. 1: Check-list for manual (in some cases with automated support) and automated endoscope processing

Manual processing	Manual preparation partly with mechanical support	Automated processing in the washer-disinfector
Pre-cleaning (bedside cleaning)		
Leak test		
Manual cleaning		
Rinsing off the cleaning solution		
Disinfection	Connectivity with disinfectant pump	Equipping of the washer-disinfector
Final rinse		Removal the endoscope from the washer-disinfector
Drying and storage		Storage

Source: based on KRINKO/BfArM recommendation (2012)

Biofilms in endoscopy: occurrence and importance

Biofilms are microbial communities attached to surfaces. These consist of two main components: 1. Microorganisms (i.e. various bacteria, yeasts and moulds, and algae), which account for approx. 20% of the biofilm. 2. The remaining 80% are extra-cellular polymeric substances (EPS). These are all the (mainly organic) components available to the microorganisms in the environment to build up a biofilm.

What are the prerequisites for the formation of biofilms?

Biofilms always form at boundary layers. Microorganisms prefer to form these in transition areas of different aggregate states such as solid and liquid (e.g. water pipes) or solid and gaseous (e.g. endoscope channels). For the microorganisms to start forming a biofilm, they need optimal living conditions (i.e. sufficient nutrients, moisture, the right pH value, and the right temperature). The surface finish also plays an important role. If microorganisms cannot adhere to a surface, no biofilm can form. Rough and damaged surfaces therefore represent an increased risk of biofilm formation.

Why do microorganisms form biofilms?

Microorganisms in biofilms generally behave quite differently from their "free-living" counterparts, the planktonic cells. A certain "comfort zone" is created for the microorganisms in the biofilm matrix. They manage with a reduced metabolism; this can lead to an increased lifespan. They are also protected from external influences (e.g. predators, disinfectants) by the EPS and can react more quickly to stress situations thanks to internal biofilm communication. There is a community from which all the microorganisms involved benefit.

Why is a biofilm a problem?

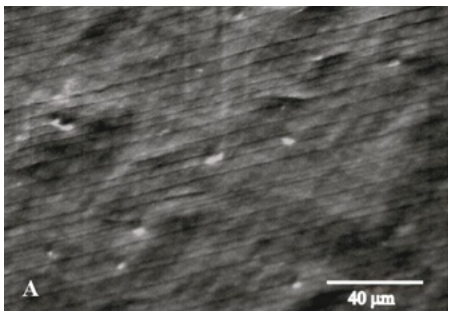
As long as the microorganisms remain in the biofilm, they do not pose an explicit danger. However, living cells are also repeatedly released from the biofilm into the environment. And if these are potential pathogens or contaminants, there is a risk to the patient, staff, and/or product. In addition, the biofilm is formed from the components of its environment, among other things. This can affect the condition of the materials it resides on (e.g. cause damage to endoscope channels).

What can be done against biofilms?

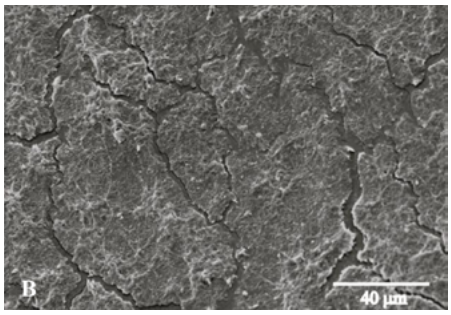
The best approach is to prevent biofilm formation from the outset. If the conditions are not optimal, microorganisms will not form a biofilm.

Undamaged surfaces, avoidance of moisture, and compliance with certain temperatures are basic requirements. It is therefore essential for endoscopes to be processed and stored appropriately (e.g. dry and at not too high a temperature). Damage must be avoided or repaired immediately.

If an existing biofilm is to be removed, the first step must always be thorough cleaning. This breaks up and removes the biofilm matrix. In addition, the microorganisms living in the biofilm are released and no longer protected against disinfectants. Subsequent disinfection can be successful only in this cleaned state.



SEM images of the surface of a A) sterile silicone tubing



B) of a 1 year old biofilm. Images taken at 1,000× magnification.

Conclusion

Biofilms can become a problem in many areas. The prerequisite for preventing biofilms in endoscopes is the proper handling of the instruments. Care, integrity, and thorough processing are the best prerequisites for preventing biofilm.

Author: Dr Johannes Lenz,
Head of Microbiology and Hygiene

neodisher® MediClean advanced – now also suitable for endoscope processing

In addition to the processing of medical instruments, the innovative high concentrated product is now recommended for endoscope processing. Extensive field testing with various customers has shown that the product is ideally suited for manual and automated endoscope processing. Customer feedback has been consistently positive.

Special properties:

- Highly concentrated with excellent cleaning performance and minimised dosages
- Sustainable because it conserves resources
- Excellent material compatibility and preservation – also suitable for flexible endoscopes

Fields of application:

For the automated cleaning of thermostable and thermolabile instruments, including MIS and micro instruments, flexible endoscopes, dental instruments, anaesthesia equipment, containers, and other medical technology equipment

For the manual cleaning of thermostable and thermolabile instruments in immersion or ultrasonic baths

Suitable for manual and automated cleaning of da Vinci EndoWrist instruments and other instruments used in robot-assisted surgery

Application and dosage

neodisher® MediClean advanced can be used in washer disinfectors as well as in immersion and ultrasonic baths. The dosage can be adjusted based on the application area, the level of instrument soiling, and the process requirements of the operator.

neodisher® MediClean advanced is the first highly concentrated product for the entire CSSD – from instrument to flexible endoscope processing.

neodisher® MediClean advanced:
www.drweigert.com/com/products-system-solutions/product/neodisher-mediclean-advanced

The benefits at a glance:

- A highly concentrated product for CSSD and endoscopy
- Excellent material compatibility
- Reduced canister changes
- Increased sustainability through resource conservation

Application and dosage

Automated cleaning of thermostable and thermolabile instruments	1–3 ml/l (0.1–0.3 %)*, 35–60° C, 5–15 min**
Automated cleaning of containers made of anodised aluminium	1–2 ml/l (0.1–0.2 %)*, 35–50° C, 3–5 min**
Automated cleaning of instruments used in robot-assisted surgery	2–3 ml/l (0.2–0.3 %)*, 40–60° C, 10–30 min***
Automated cleaning of flexible endoscopes	2–3 ml/l (0.2–0.3 %)*, 35–55° C, 5–10 min**
Manual cleaning of thermostable and thermolabile instruments in immersion and ultrasonic baths	1–10 ml/l (0.1–1 %)*, max. 40° C, 5–30 min**
Manual cleaning of instruments used in robot-assisted surgery in immersion and ultrasonic baths	5–10 ml/l (0.1–1 %)*, max. 40° C, 5–10 min**/***
Manual cleaning of flexible endoscopes and endoscopic accessories in immersion and ultrasonic baths	1–10 ml/l (0.1–1 %)*, max. 40° C, 5–10 min**

Interested?

Please contact your expert neodisher® advisor about endoscope processing. Or visit us at one of the upcoming congresses.

* the dosage depends on the level of contamination ** the contact times can vary depending on the water quality, the degree of soiling, and the cleaning mechanics *** the processing recommendations of the medical device manufacturer according to the requirements of DIN EN ISO 17664 and the procedure tests must be followed

Dates

November 2024–March 2024
(as of: 22 November 2024)

- **endo-update**
  Garmisch-Partenkirchen,
  28–30 November 2024
- **Dr. Weigert & DEGEA Webinar**
  Hamburg, 11 December 2024
- **Arab Health Congress 2025**
  Dubai, 27–30 January 2025
- **27th Int. Endoscopy Symposium**
  Düsseldorf, 6–8 February 2025
- **54. Kongress der DGE-BV**
  Würzburg, 19–21 March 2025

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