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endoNEWS

Best practice: reprocessing of endoscopes

Dear reader

The global SARS-CoV-2-pandemic has presented us all with major challenges. Day by day, we learn more about the virus and COVID-19. You, being experts in hygiene, know of the importance of the best possible hygiene to prevent infections not only since Corona.

Have you wondered as well, whether endoscopic reprocessing requires additional steps due to SARS-CoV-2? Exactly this and many more questions we have asked Professor Dr. Heike Martiny. Prof. Martiny is one of the most well known hygienists in Germany. We are fortunate to have won her for an interview with endoNEWS.

In the third part of our practical series we provide suggestions about how to correctly conduct a leak test, for example to avoid water inleakage in the endoscope – which is a common reason for endoscope damage.

In addition, we would like to point you to Prof. Dr. Günter Kampf's statement about a novel testing procedure for sporicidal activity of disinfectants.

A thought-provoking read wishes

Guido Merk
guido.merk@drweigert.de
Tel. +49 40 / 789 60-261

DR. WEIGERT
Systematic Hygiene

"Only if we clean properly, can we disinfect correctly."

Expert Interview *with Professor Dr. rer. nat. Heike Martiny*

We are happy to have won one of the most well-known hygienists in Germany for an interview with endoNEWS: Professor Dr. rer. nat. Heike Martiny (in the following abbreviated with HM).

endoNEWS: Professor Martiny, do we have to take additional steps during endoscopic reprocessing because of COVID-19?

HM: No, we must conduct the reprocessing as correctly as before. Additional measures are not necessary. The Commission for Hospital Hygiene and Infection Prevention (German: Kommission für Krankenhaushygiene und Infektionsprävention, KRINKO) recommends virucidal products for disinfection. Against SARS-CoV-2, already a limited virucidal activity would suffice. The efficacy against SARS-CoV-2 is also included in the surface disinfectants recommended by the KRINKO.

endoNEWS: The guideline by the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) recommends freshly preparing the cleaning solution for each endoscope if a cleaning agent (without disinfecting efficacy) is used.

HM: These requirements are not new. This was demanded by the Gastroenterological Societies in the USA even in 2003 [1]. There, everyone used enzymatic detergents and it was stipulated: Enzymatic detergents must be replaced after cleaning each endoscope. This has not been adopted in Germany. Apparently, also a majority in the ESGENA can see the increase in safety with this change. However, there are no references or studies on this, not even within the ESGENA-guideline [2]. It is indispensable, though, to validate the process with the "contaminated" cleaning solution.

endoNEWS: Is it justified that the ESGENA-guidelines are tightened? The KRINKO actually permits with cleaners – equally to the disinfectant cleaners – fur-thermore a work-daily replacement unless contamination is visible. The ESGENA, in contrast, recommends replacement of cleaners after every endoscope.

HM: With cleaning solutions the ESGENA obviously is not doubtful of the cleaning efficacy, but instead of the safety of the personnel. However, I do not consider the protection of the staff guaranteed with disinfectant cleaners either. At least I do not know of any meaningful data regarding this topic.

The disinfectant efficacy is typically substantiated by expert opinion under "dirty conditions". However, "dirty conditions" are not comparable with a used gastro-, colo- or bronchoscope that has been placed in a formulation. In this case, the organic contamination is quite substantial, and I do not know of any data that show the efficacy of a cleaning disinfectant under these circumstances. On the contrary: The doctoral thesis of Patrick Haubrich shows, that disinfectants are not effective anymore, when they are confronted with larger organic contamination – larger than under "dirty conditions" [3]. He was also able to show that disinfectant solutions, that are listed with a potency of 5 log10, demonstrated in the experiments only an efficacy of 1 $\log_{10}$. I find this quite remarkable.

endoNEWS: With this in mind: Do you recommend to class cleaners and disinfectant cleaners similarly? In which interval should the user replace the solution?

HM: Definitely in the case of visible contaminations. And due to the high pathogen load, I recommend switching at least daily. But I know from teaching classes that in some areas, cleaners are actually replaced after every endoscope. We are in the process of developing a guideline for the validation of manual endoscope processing because nothing like this exists so far. The difficulty with this is that we do not have a testing specimen with which we can show the effectiveness of manual cleaning in endoscopy. If we take a test hose and brush it, we could check if it has been sufficiently brushed. But this has nothing to do with the actual conditions in the endoscope, because brushing there is much more difficult. If the endoscopes are pre-cleaned manually and are then reprocessing in the washer disinfector for endoscopes, we increase our safety by adding a second, automatic cleaning step. However, if we only reprocess manually, we can not prove that we are cleaning properly. And only if we have cleaned properly, can we properly disinfect.

endoNEWS: The other thing is the protection of personnel which ESGENA is presumably trying to ensure with these recommendations.

HM: A possibility for infection exists already with the first endoscope as well as after the fifth. The ESGENA has defined the guideline in this way, but does not justify it, and there is no mentioning of references. By the way, ESGENA states “should not be reused”, not “shall”.

With regard to disinfecting cleaners, there are various questions to be clarified in advance with regard to personnel protection: Which active ingredient is contained in the disinfecting cleaner? Can it work despite organic contamination and how large can this organic contamination be for it to still be effective? Is the contact time adhered to?

endoNEWS: Does this mean, whether a cleaner or a cleaning disinfectant is used, that personal protective equipment must always and foremost ensure the safety of the personnel?

HM: Correct. Because when you put the first endoscope in the solution, you introduce between 10^9 and 10^{10} bacteria per channel. Let’s say I have 10^9 on the first and second endoscope, respectively, that makes twice 10^9. With the third, I have 10^9 three times – that is not a large difference. The contamination does not get much greater because it was already high due to the first endoscope – which was highly contaminated. One always imagines that it will increase much more. Sure, there will be more, but when it comes to the power of ten, one or three billion are not relevant.

It is true that if the solution stands for longer periods and if it is warm in addition, another doubling is possible. Starting with twice 10^9 there will be possibly four times 10^9, if at all in the short time. So, that too can be ignored. By the way, this only applies to bacteria – viruses cannot multiply at all, they can only survive.

My message is this: Staff must always protect themselves. From the very beginning. And personnel protection is achieved first of all by wearing protective equipment. This has improved a lot in recent years, but you have to wear it. It is useless, if the mouth/nose protection is hanging under the nose, the visor is missing, or brushing is done above the water surface.

endoNEWS: Which trends do you see in endoscope reprocessing in general?

HM: In certain areas, the trend goes to disposable endoscopes. Especially on night shifts and during weekends, single-use bronchoscopes are increasingly used. Hospitals have calculated that it is cheaper to take a single-use/disposable endoscope than to let someone come in for endoscope reprocessing. A sensible trend.

A second trend goes towards single-use duodenoscopes. As far as I know, two companies here have already developed disposable products. The problem: Both companies say they cannot produce at a sufficiently low price to allow performing all ERCP with a single-use/disposable endoscope. A bit unsettling to me in this regard is the statement that it is necessary to choose who will be examined with a single-use endoscope and who will be examined with a reprocessed endoscope. That means, it is implied that one is not at risk with the disposable endoscope, but is at risk with the reprocessed/multi-use endoscope because it allegedly cannot be properly reprocessed. Just now, in the context of the Corona pandemic we have all learned that it is not so easy to decide which patient is at risk. And I fundamentally reject this decision as to who ”may“ get a disposable endoscope because reprocessing cannot be done safely. Also with reprocessing of duodenoscopes, staff must be sufficiently qualified to reprocess them properly. If this is not the case, this examination must not be carried out. These are moral and ethical issues. Otherwise, I have to ask myself whether I’ve been doing something wrong from the start. Or, even worse: Whoever can afford it, gets a disposable, and those who can‘t afford it get a reusable duodenoscope.

Another trend, at least in Germany, is the following: The authorities are more closely monitoring, and due to the tighter controls there is a trend to automated reprocessing. Small practices that cannot afford this will either give up or have the reprocessing done by service providers.

endoNEWS: Thank you very much for this discussion!

The questions were asked by:
German Beck and Guido Merk

Professor Dr. rer. nat. Heike Martiny
Technical Hygiene, Berlin

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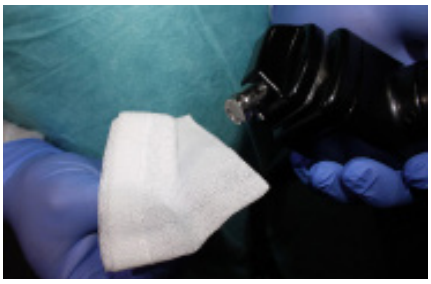
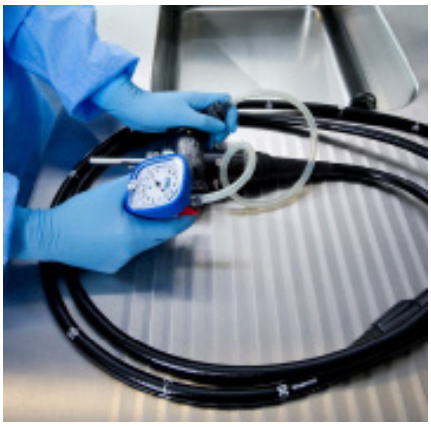
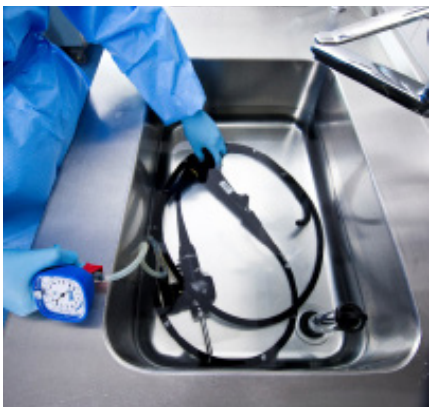
Protecting patients and personnel from infections and endoscopes from damage Part 3: Correct leak-test

Best practice

In the third part of our series we focus on the leak-test. A large part of endoscope damage is caused by water intrusion in the endoscope. Often the damage is serious, and the repair costs are high. A correct leak-test before reprocessing prevents water intrusion. Here you can see a few situations where water damage has occurred, along with recommendations on how they can be avoided. In addition, please always carefully read the information in the user manuals of the manufacturer of the endoscope and the washer disinfector.

Value-preserving handling of endoscopes – leak-test		
Problem	**Suspected cause and approach to a solution**	
The endoscope service detects water inside the endoscope, although the endoscope is tight and shows no perforation.	**In this case, water can only have entered the endoscope by the leak-test connector. The following reasons are possible:** • When connecting the endoscope to the manual leak testing device, there are small amounts of water on the side of the endoscope or pressure gauge, that are pressed into the endoscope. ➔ A possible remedy is to wipe, inside and outside, both sides with a lint-free gauze cloth. • When the endoscope is connected to the automatic leak-testing device, small amounts of water are pressed into the endoscope. ➔ A remedy is to wipe off both the endoscope and the side of the machine. • In some washer disinfectors, leak-test connectors are switched inside the machine, depending on the make of the endoscope. ➔ In this case, water entry into the system has to be prevented also at the connection between machine and leak-test connector.	 **Correct:** Wiping the leak-test connector with gauze Attention: The interior of the connector at the opposite side must be wiped with gauze as well.
The endoscope service detects water inside the endoscope. Endoscope service finds a perforation at inspection in the repair shop. However, this was not noticed during the leak-test. How can that happen?	**Omission of the manual leak-test:** Sometimes the manual leak-test is skipped because the washer disinfector automatically conducts a leak-test. This approach carries the risk that the brush-cleaning is conducted within the cleaning solution. In case of a perforation, leakiness will only be detected after manual pre-cleaning. Then it could be too late, and liquid has already entered the endoscope. • Principally, leakiness of the endoscope should be checked before the manual brush-cleaning in the reprocessing room. **Incomplete manual leak-test:** Sometimes the manual leak-test is only carried out in dry conditions. The user checks based on the pressure gauge and then removes the test. However, the leak-test with the pressure gauge is only a comparably rough measurement. Especially coloscopes have a large volume. Small leaks will not result in a quickly visible drop in pressure at the pressure gauge. • The leak-test must be conducted under water as well, while actuating the bending in all four directions. In case of leakage one can see small rising bubbles, even if the pressure gauge signals no pressure drop at the moment. • Some manufacturers of endoscopes recommend leaving the manual testing device on the endoscope also during manual brush-cleaning and to maintain pressure in the endoscope. **Incorrect removal of the leak-testing device:** Never should the manual leak-testing device be removed from the endoscope under water. The endoscope is in that case briefly opened and water can enter the endoscope. • The correct order must be observed: 1. Take the endoscope out of the water. 2. Drain the air pressure at the pressure gauge. 3. Remove the leak tester from the endoscope.	  **Correct:** Manual leak-test outside of the tub **and within the tub** under water

Expert Interview
with
Prof. Dr. Günter Kampf

New inspection method to test sporicidal activity of disinfectants

New inspection method to test sporicidal activity of disinfectants

Disinfectants for the automated reprocessing of flexible endoscopes are required to prove sporicidal activity according to DIN EN ISO 15883 part 4 (2019) [1]. There are various methods available for this, e.g. EN-methods. Manufacturers were until 2018 allowed to provide evidence for sporicidal activity of chemical disinfectants with EN 13704 [2]. This standard was only partially suitable, because it had not been developed for medicine, but instead for the food industry, industries, households and public institutions. The requirement for the efficacy amounted to a reduction of bacterial spores by at least 3 $\log_{10}$.

The new inspection method EN 17126 for the determination of the sporicidal activity in the area of human medicine

With the European Standard (EN) 17126 an inspection method has been available since 2018 to test sporicidal activity of disinfectants in the medical area. The scope of this method includes among others products for disinfection of instruments by immersion. This is a quantitative suspension trial, with which the fundamental activity of the disinfectant against bacterial spores can be determined. There are two possible approaches:

- sporicidal against C. difficile, demonstrated with spores of C. difficile ribotype 027
- sporicidal, demonstrated with spores of B. subtilis and B. cereus

In order to meet the requirement for a sporicidal effect, a disinfectant has to reduce the number of spores within at most 60 minutes by at least 4 $\log_{10}$ [3].

Spore-forming bacteria play a minor role in endoscopy

The infection with C . difficile (CDI) is one of the most common nosocomial infections in Germany – about 70 % are explained by a transmission in hospitals [4]. Other spore-forming bacteria do not play a relevant role here. The risk of transmission with spore-forming bacteria via flexible endoscopes is very small [5]. According to a review, there have been up to the year 2010 no reports of transmission of C. difficile via GI-endoscopes [6]. The probability for an endoscope-associated infection with other spore-forming bacteria is even smaller, case reports and studies could not be found.

The automated cleaning considerably contributes to the reduction of spores. With validated automatic processes it is possible to safely reprocess flexible endoscopes, even including bacterial spores [7]. Here, the high quality cleaning plays a decisive role as a procedural step for the best possible reduction of spores [5].

Expert opinion on the new EN 17126.

In my opinion, there is no need to prove sporicidal activity of disinfectants for automated reprocessing of flexible endoscopes with the test species B. subtilis and B. cereus, because C. difficile is by far the most important spore-forming bacterial species in the clinical and practice environment. This knowledge has been considered during the preparation of EN 17126 and has led to the two-tiered version that is now valid.

Author: Prof. Dr. Günter Kampf

Prof. Dr. Günter Kampf
Specialist for Hygiene und Environmental Medicine

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DATES

(As of June 16th 2020)
September – December 2020

- **DEGEA & Dr. Weigert Online Webinar**
  September 9th 2020
- **UEG Week Virtual**
  October 11 – 13, 2020
- **24. ESGENA-congress**
  October 10.–14. 2020, online
- **Postgraduate course**
  November 27.–28. 2020, Vienna
- **Endo Update**
  November 27.–28. 2020, Augsburg

Registration and further information regarding Dr. Weigert-events:
Anke Uhlmann
Marketing and Sales
info@drweigert.de
www.drweigert.de

Contact us at Dr. Weigert:

info@drweigert.de

You can find the information about your local contact (technical adivce / sales) on our website:

https://www.drweigert.com/com/contacts-distribution

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Chemische Fabrik Dr. Weigert
GmbH & Co. KG
Mühlenhagen 85, 20539 Hamburg
Tel.: +49 40 789 60-0
www.drweigert.com

Editors

Stefanie Küpper
stefanie.kuepper@drweigert.de

Guido Merk
guido.merk@drweigert.de

Daniela Schricker
daniela.schricker@drweigert.de

Jacqueline Treutner
jacqueline.treutner@drweigert.de

Production

MWI GmbH
50667 Köln