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Best Practise: Reprocessing of Endoscopes

Dear readers,

the strategy of increased hygiene and reduced contacts determines our everyday life and this is how it will remain in the next few months. As hygiene experts you know exactly how important it is to consistently comply with hygiene regulations, and how crucial constant reminders are. It is also important to keep up to date and to exchange ideas with colleagues.

Since numerous congresses and training events had to be cancelled, we met virtually: on 9 September at the DEGEA online seminar "Safe Reprocessing of Flexible Endoscopes", an interactive live stream for endoscopy specialists, and on 14 October at our webinar "Preparation of flexible endoscopes: organization and contingency plan".

In case you did not have the chance to participate, we've summarized the most interesting facts from the online events in this issue of endoNEWS INTERNATIONAL. If you would like to know more details – you're welcome to read more on the web.

We hope you'll find this a stimulating read!

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DR. WEIGERT
Systematic Hygiene

Safe Reprocessing of Flexible Endoscopes

DEGEA Online Seminar - interactive live stream for endoscopy professionals with the Endoscopy Campus

As part of the Endoscopy Campus, Ms. Ulrike Beilenhoff, Dr. Johannes Lenz and Prof. Heike Martiny gave lectures on the topic of "Reprocessing of flexible endoscopes" on September 9, 2020. In addition to the disinfection and sterilization of flexible endoscopes, topics were also problems and solutions regarding reprocessing and about requirements for modern disinfectants. The DEGEA online seminar was supported by the company Chemische Fabrik Dr. Weigert.

Requirements for the cleaning and disinfection of endoscopes

Ulrike Beilenhoff, co-organizer and scientific secretary of ESGENA, looked at the problems that could be the cause of possible contamination of an endoscope and what solutions were available. In addition to damage to the endoscope, the reasons for contamination may be poor equipment for reprocessing or storage difficulties. The speaker also referred to the particular difficulties that loaner scopes can entail.

Disinfectants are classified as medical products and must therefore meet certain requirements. Dr. Johannes Lenz (Dr. Weigert) presented the various requirements for material compatibility, toxicology, environmental compatibility and stability. He reported that the disinfectants are tested for their effectiveness using the European standard testing methods. He also addressed various pathogens and the activity spectrum of various active substances.

Sterilisation of flexible endoscopes

The lecture by Prof. Dr. rer nat. Heike Martiny (Technical Hygiene, Berlin) dealt with the question of whether sterilization is also necessary for flexible endoscopes. The speaker explained what should be considered when sterilizing and disinfecting flexible endoscopes and also presented the requirements based on the recommendations by the Commission for Hospital Hygiene and Infection Prevention/ Federal Institute for Drugs and Medical Devices (German: Kommission für Krankenhaushygiene und Infektionsprävention/ Bundesinstitut für Arzneimittel und Medizinprodukte, KRINKO/BfArM). She also dealt with the question of what should be considered when the endoscope is in contact with the body's natural microbiome.

The detailed report of the DEGEA online seminar is published in: Zentralsterilisation. 2020; 5(28): 180-182.

You can find the German DEGEA online seminar (German language) online:

www.endoscopy-campus.com/veranstaltungen/degea-webinar-live-sichere-aufbereitung-flexibler-endoskope/

Fit for the Audit –
Preparation for the Inspection of your Endoscopy

Antje Hartwig is reprocessing specialist for medical devices in the company KARL STORZ SE & Co. KG. She is extensively experienced in reprocessing of medical devices and in management in this area.

When I read the word “audit”, terms such as certification, notified body or external auditor come to mind - and you know, that this text here will not suffice to cover these topics.

When I read “inspection”, then I think of our health officials or government authorities, that have received the assignment by our federal government to monitor, among other things, the scope of “reprocessing of medical devices” in Germany.

A list of health departments can be seen, for example, on the website of the German Society for Sterile Goods (Deutsche Gesellschaft fur Sterilgutversorgung, DGSV® e. V.). I cannot name each health department here, therefore the “Landesamt fur Gesundheit und Soziales Berlin”, lovingly called LAGeSo, will represent all health departments in this article.

The employees responsible for the area of “reprocessing of medical devices” at the LAGeSo know §26 of the Medical Device Regulation (German: MPG) and what requirements are to be fulfilled during monitoring.
Your endoscopy unit will either receive an unannounced visit, because there has been an extraordinary notification, or the inspection takes place routinely. In this case, the LAGeSo has notified you and you receive a date ahead of time.

At this appointment, your reprocessing of flexible endoscopes will be reviewed on the basis of the currently relevant requirements. Of foremost importance are in this case the regulations governing the installation, operation and use of medical devices (Medizinprodukte-Betreiberverordnung MPBetreibV). The MPBetreibV governs in §8 the “reprocessing of medical devices (MD)“ in four paragraphs. In these paragraphs, fundamental statements regarding the reprocessing of medical devices are made:

- Compliance with manufacturer‘s specifications
- Appropriate validated procedures
- Traceability and documentation
- Recommendation of the KRINKO at RKI and BfArM regarding hygiene requirements during reprocessing of medical products (also known as KRINKO 2012)
- Certification, quality management system
- Qualified staff

These aspects can be very helpful during preparation for the inspection and can also be used for establishing one’s own internal quality management (QM). You can download the MPBetreibV, KRINKO 2012 and the additional KRINKO 2002: “Hygiene requirements for the structural and functional design and technical equipment of endoscopy units”, at no extra costs, from the internet and thereby start preparing your inspection.

So much for the theory. What can this preparation look like in practice?

It is important not to lose sight of the overall process. It consists of several sub-processes. The reprocessing of flexible endoscopes is divided into sub-processes in the same way. Responsibilities for the overall process and the sub-processes have to be established in writing.

If at certain points in the process responsibilities are divided up, e. g. to the endoscopy, transport and the CSSD, then the individual areas of responsibility have to be defined in writing in interface descriptions that have to be signed by all those responsible.

One of the next questions of LAGeSo could be: Could you please show us your own internal QM-documents and records? Please pay attention during the preparation period that the individual documents and records contain up-to-date data and are not outdated. In any working areas/reprocessing rooms, also check the bulletins for order and cleanliness. Unlaminated, torn, yellowed papers or posters on the wall do not make a good impression on the LAGeSo.

We briefly look back at the four paragraphs of MPBetreibV §8. These documents should be on hand as well. All manufacturers’ instructions regarding the MDs that are part of your processes and in operation, have to be available and checked by you.

You have to commission and carry out validations of your processes on a regular basis. Make sure that the validation report is signed and checked. The LAGeSo will review selected validation reports. To provide proof that you employ only qualified personnel for reprocessing, set up a training plan. All colleagues entrusted with reprocessing will be listed by name with their respective qualification level in the training plan. Keep the certificates ready. For courses that are not yet completed, a date has to be set in the plan mentioning an acknowledged educational institution.

Now it is time to have a look at the reprocessing rooms. For that purpose, use KRINKO 2012, supplement 5 “Overview of requirements for reprocessing units for medical devices”, KRINKO 2002 as well as part 7 of the technical committee Hygiene Construction & Technology of the DGSV. Whatever kind of room you will decide on: Pay attention to a well thought out flow of materials from usage of the medical devices to the separate unclean areas and subsequently to the clean areas.

Ensure sufficient ventilation in the rooms and provide suitable work and storage areas. In the unclean area these are e. g. for performing the dry leak tests or for a

safe intermediate storage of the endoscopes that cannot be reprocessed right away. In the clean area these surfaces are e. g. for controlling the endoscopes, clearance and documentation.

For personnel hygiene it is sensible to have a separate sink. In the storage cabinets of the reprocessing rooms, only those materials and products should be stored that are related to reprocessing.

The equipment of the reprocessing rooms should be suitable for the tasks performed there. You can find a good example in the guideline for validation of the manual cleaning and manual chemical disinfection of medical devices, supplement 2 on page 17.

Suitable equipment includes, among other things, the washer disinfectors for flexible endoscopes (WD-E). These have to comply with standard 15883 part 4. The LAGeSo might ask at this point: What does your contingency plan look like in case the WD-E fails?

One approach for such a plan in case of failure could be: You train your employees on a regular basis in manual reprocessing of the flexible endoscopes according to KRINKO 2012 supplement 8, supplement 1 part A: „“Manual endoscope-reprocessing”. Alternatively, you provide a contractual arrangement with a business partner along with the related documentation.

The tasks during manual procedures and all other procedures in the course of reprocessing are described in standard operating instructions (SOP) and can be presented to the LAGeSo if prompted. In this SOP, you prove that there is regular training with date and signature of the employees. The SOP should be in tune with the manufacturer‘s specifications of the medical device.

By means of regular microbiological tests of the reprocessed endoscopes, you demonstrate that the validated procedures and also the contingency plan in case of failure are effective and remain valid.

Further appropriate devices could be e.g. storage cabinets with controlled environment conditions for reprocessed thermolabile endoscopes according to DIN EN ISO 16442.

If you store the reprocessed endoscopes in an endoscope storage cabinet according to KRINKO 2012 supplement 8 in a dry, hanging and dust-proof setting, you fulfil the minimum requirements.

Regarding the equipment pool, you set up a list containing all devices in operation, e. g. with name, type, manufacturer, build, last maintenance, last validation or rather re-qualification of the performance etc. Here you could as well deposit maintenance and service reports as a proof.

Another important point for reprocessing of flexible endoscopes are the appropriate resources. These include e. g. the qualities of compressed air and water, which have to be microbiologically checked in regular intervals. Special attention should be given to the water for the final rinse. Regarding the process chemicals, make sure all relevant documents of the chemical manufacturer are available.

For the practical implementation of preparing the inspection, we recommend to make a checklist. On request we can support you.

You can find the webinar “Fit for the Audit - How Do I Prepare My Endoscopy for an Inspection” online (in German):

Author: Antje Hartwig

www.drweigert.com/de/aktuelles/webinar-aufbereitung-flexibler-endoskope-organisation-und-notfallkonzept-nun-als-video-on-demand-verfuegbar-288

Are there endoscopes for giraffes?
... And if so,
how long are they?

Has this question occurred to you?

If you visited us at our booth at the Düsseldorf Endoscopy Symposium or if you have received issue 1 of endo NEWS 2020 by mail, you may have received our “animal” postcard.

We have followed up on the question and would like to answer it in this issue.

No, there are no endoscopes especially for giraffes.

If a gastroscopy has to be performed on a giraffe, zoos approach for example a clinic for large animals. There, endoscopes with a length of 3 metres are available.

We thank Hanover zoo for answering this question.

Author: Jacqueline Treutner

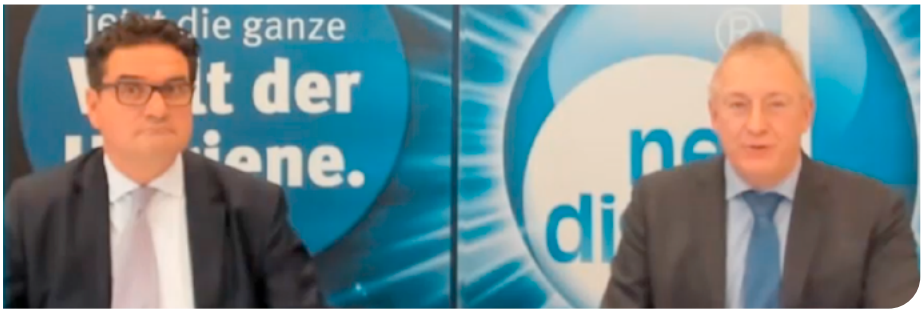
Reprocessing of Flexible Endoscopes: Organisation and Contingency Plan

Dr. Weigert
Webinar

On 14.10.2020, Dr. Weigert organised the webinar "Reprocessing of flexible endoscopes: organisation and contingency plan".

WD-E-failure - What to do?

Daniela Schricker (Dr. Weigert) lectured on the topic "WD-E-failure – What to do?" 53 % of the participants indicated that they compensated for a failure of an WD-E by using another WD-E in their department. 12 % can use a WD-E of a different department and 35 % are capable to disinfect manually. If an external WD-E is available, the guideline "Transport for supply and disposal of reprocessable medical devices" should be followed. If no WD-E is available, manual disinfection comes into play.



German Beck (Head of Marketing) and Guido Merk (Key Account Endoscopy) moderated the Dr. Weigert webinar.

For the selection of process chemicals, Daniela Schricker pointed out the importance of ensuring that the products are compatible with each other. Furthermore, there are new test procedures available in the area of disinfectants regarding virucidal (EN17111) and sporicidal (EN17126) activity, according to which manufacturers have to test their process chemicals. The KRINKO/BfArM calls for a proven bactericidal, mycobactericidal, virucidal and fungicidal activity. Glutaraldehyde and peracetic acid are suitable as active ingredients. Concentration, application time and temperature, however, must be considered. Some products with peracetic acid can be used for disinfecting precleaning and at a higher concentration for final disinfection - an advantage for emergency situations.

Ms Schricker elaborated on the most important sources of errors: Instruments not completely immersed, channels filled with bubbles, process solutions too cold, entry of proteins from the cleaning step, reduction of the disinfectant efficacy by carrying over cleaning solution, or a too extensive use of the final disinfection solution, which can result in a dilution of the solution by fluid introduced if endoscopes have not sufficiently drained. This can lead to degradation of the active substance.

The rule for Dr. Weigert's products is: Products containing aldehyde must be replaced at least each workday or in the event of visible contamination. Because peracetic acid underlies a natural decay, local circumstances such as temperature and the natural degradation under conditions of use have to be considered. The activity of the solution can be tested with a control strip.

Forms of organisation in endoscopy exemplified by the RoMed-Clinic Rosenheim

Marion Kristen (deputy head of endoscopy) and Andreas Ofner (head of endoscopy) presented specific solutions at the RoMed-clinic that comprise four endoscopy rooms, one ERCP-room, which is used by both endoscopy and radiology, and a recovery room with nine observation beds (six for inpatients, three for outpatients). Endoscope reprocessing has been in the hands of CSSD for 2.5 years, but continues to take place in the endoscopy department, because otherwise many more endoscopes would be needed. CSSD-employees need to be given more time to fully understand the functioning of the flexible endoscopes, as they do not work with them. However, the employees in this area have a deeper understanding of reprocessing itself. Altogether, the RoMed-clinic is happy with the sharing of work between CSSD and endoscopy. For the entire endoscopy, the teams of the examination rooms do the detailed planning and respond to deviations. Thereby the employees can take on a high degree of responsibility and the teams can react swiftly and flexible.

The report on Antje Hartwig's lecture "Fit for the audit – how do I prepare my endoscopy for an inspection" can be found on page 2 of this issue.

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1 Zentralsterilization Vol. 26, Suppl 2018

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