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INTERNATIONAL

endoNEWS

Best Practice: Processing of Endoscopes

Dear readers,

In this edition we would like to give you some special insights into the german market.

The KRINKO recommendation on surface hygiene has been updated after 18 years, primarily on account of the COVID-19 pandemic. What do the extensive changes to KRINKO mean? What areas are affected in endoscopy in particular? Dr Johannes Lenz, our Head of Microbiology/Hygiene, provides insight and a summary on p. 1–2.

The Dr. Weigert webinar "Revision of the KRINKO/BfArM Recommendation – What Does it Mean for Our Endoscope Processing?" was held on 9 November 2022. We have summarised the most interesting chat questions and answers for you on p. 3.

On p. 4, as part of our chemistry series "Basics of Our Raw Materials", we look at enzymes with a wide range of applications that are far from exhausted. As catalysts of chemical reactions, they perform specific tasks and are firmly established in the cleaning sector. Find out what a crucial role enzymes have been playing for millennia, and why they are still hugely valuable to the development of our products.

Enjoy the newsletter!
Best regards

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New KRINKO Recommendation on Surface Disinfection

What Does It Mean for Daily Endoscopy Practice?

A revised version of the recommendation "Hygiene Requirements for the Cleaning and Disinfection of Surfaces"[1] by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) was published in the German Federal Health Gazette in October 2022. This took the number of pages from 11 to 42. The recommendation is applied in the entire medical sector and is used by those responsible for hygiene as a guide for the selection and application of surface disinfectants.

Overview and Summary
by
Dr Johannes Lenz

The purpose of surface disinfection is always to stop surfaces from being a reservoir for pathogens, thus preventing nosocomial infections. In addition, it protects staff against possible infections and is therefore a key part of basic hygiene. Consequently, the recommendation is also hugely relevant to the endoscopy sector.

Help When Choosing the Optimum Surface Disinfectant

Measures intended to make application safer for users add extra complexity when deciding for or against a product. What efficacy is required? What exposure times are feasible for everyday use? How sensitive are the surfaces or materials to be disinfected? Can the product be easily stored to the required extent? Do certain occupational health and safety aspects need to be taken into account when using the product? None of these questions are answered by a symbol or a simple statement. That is why KRINKO endeavours to help users address numerous questions with its revised recommendation[1].

Clarification of Essential Authorisations

Disinfectants must be authorised for the required application. If the intended purpose is the disinfection of surfaces of medical devices[2] (MD), the product itself must also be an MD. This is apparent from the CE mark and the 4-digit number on the product label. If other surfaces are to be disinfected, the disinfectant must be a biocidal product and be subject to biocidal product legislation[3]. This is apparent either from the registration number (e.g. N-12345) of the German Federal Institute for Occupational Safety and Health (BAuA) or the authorisation number (e.g. DE-1234567-01-1234-01) as per the Biocidal Products Regulation (BPR), which can be found on the product label. Transitional arrangements mean that both authorisation forms are valid for biocidal products for the foreseeable future.

Clear Recommendation on Disinfection Performance

In addition, the required spectrum of efficacy must be identified. Specific effects for surface disinfection are recommended for the first time in the new KRINKO recommendation.

For instance, the effect against vegetative bacteria (bactericidal) and yeasts (yeasticidal) is described as a basic requirement. Depending on the pathogen, further

effects against specific pathogens such as Mycobacterium (M.) tuberculosis (tuberculocidal) may be advisable or even essential. Enveloped viruses such as influenza viruses, human immunodeficiency virus (HIV) or hepatitis C viruses frequently play a role in everyday clinical routines. Since the start of pandemic, there has also been a greater focus on an effect against coronaviruses. The viruses mentioned are enveloped viruses that are surrounded by a lipid membrane. This membrane is often a good point of attack for disinfectants and therefore results in an excellent effect against these viruses. To this end, disinfectants must have virucidal activity against enveloped viruses.

Disinfectant Lists as an Aid

Disinfectant lists can be consulted to find out which products have which effects. Although inclusion in lists is not an essential condition for the marketability of a disinfectant, it is a good way of comparing products. Effects of the products that are verified according to the authorisation-relevant EU standards are set out in the disinfectant list of the German Industrial Association for Surface Protection and Hygiene (IHO). Surface disinfectants with values relating to basic hygiene can be found in the disinfectant list of the German Association of Applied Hygiene (VAH). The disinfectant list of the Robert Koch Institute (RKI) is not suitable here, as it only contains products for use in the event of an outbreak as per Section 18 of the German Protection against Infection Act. All the cited lists can be viewed free of charge online.

Influence of Active Substances

The composition of a disinfectant is also important, especially with regard to disinfectant active substances, as they constitute the main portion of the product. The constituent materials of the surfaces to be disinfected must be checked carefully here. To find out whether specific materials cannot be treated with the favoured product, you can consult the product documentation (e.g. the product information on the manufacturer's homepage).

If you are unsure about material incompatibility, you must contact the disinfectant manufacturer, as this is the subject of extensive tests in the context of product development. It is also necessary to check which products are used in the wider environment. Visible reactions may arise here (e.g. if a disinfectant containing aldehyde is used in the instrument bath and drips onto a surface that has been disinfected with a surface disinfectant containing amine). In addition, the composition of the product also determines whether certain safety measures must be followed during storage or application. Relevant details can be found in the associated safety data sheet from the manufacturer.

Determining the Performance of Surface Disinfection

It is also necessary to decide the way in which surface disinfection should or, due to the conditions, must be carried out. The wiping method is recommended, mainly on account of the superior wetting of the surfaces and additional mechanical forces as well as advantages in terms of occupational health and safety. The spraying method is recommended only in places that are hard to access, as staff face a risk of exposure by inhalation.

Production of the application solution of disinfectants is also under discussion. This can be done either manually or through extraction via a (decentralised) dosing device. The benefits of using a dosing device are a high level of dosing accuracy and ease of use for staff.

Our Conclusion

It can be concluded that the new KRINKO recommendation is just as important to endoscopy as to other medical fields. When selecting the optimum disinfectant, a host of aspects must be borne in mind. One solution may be to select several products. The new KRINKO recommendation helps with preparation. We will be happy to help with the final decision!

Author: Dr Johannes Lenz
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at Dr. Weigert

Bibliography:
1 Hygiene Requirements for the Cleaning and Disinfection of Surfaces, German Federal Health Gazette 2022_65:1074–1115, Springer Verlag GmbH, Germany
2 Regulation (EU) 2017/745 of the European Parliament of the Council of 5 April 2017 on Medical Devices. Official Journal of the European Union 60 (L117):1–176
3 Regulation (EU) no. 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products. Official Journal of the European Union 55 (L167):1–123

Dr. Weigert Webinar – Useful Information from the Chat

Our webinar "Revision of the KRINKO/BfArM Recommendation – What Does it Mean for Our Endoscope Processing?" was held on 9 November 2022. The most interesting chat questions and answers can be found here.

1. Questions on KRINKO's working method*

How is possible to be involved in the revision of KRINKO guidelines?

The working group is appointed directly by KRINKO. Expert associations or individual experts are written to directly. First of all, there is a consultation procedure, after which the expert associations etc. receive the document for examination. There is an opportunity to make comments and notes in the document. This means that it is still possible to be actively involved in revising the guidelines. All comments that KRINKO receives are taken into account and dealt with.

Can employees in the industry be involved in revision?

The German Institute for Standardisation (DIN) was included in the revision of the KRINKO/BfArM recommendation in 2012. Other representatives or committees such as the Instrument Processing Working Group (AKI) can also be included. This gives employees in the industry the opportunity to submit their comments.

2. Questions to Ms Ulrike Beilenhoff, First Chair of the German Society of Endoscopy Nurses and Associates (DEGEA)

Is manual processing of flexible endoscopes still allowed?

In the KRINKO/BfArM recommendation, automated processing is recommended as the preferred type of processing, as it provides validatable results combined with maximum staff safety. Furthermore, the manual cleaning steps are important in order to remove coarse impurities from the flexible endoscope prior to processing in the endoscope washer-disinfector. In addition, manual processing continues to play a role as a contingency concept.

In the daily routine, automated processing of endoscopes in the endoscope washer-disinfector is preferred.

However, manual processing must remain an option, as it comes into play as a contingency concept if the endoscope washer-disinfector breaks down. Therefore, it is essential that Endoscopy departments also have the equipment for manual processing at hand and update corresponding operating procedures. The endoscopy and processing staff must continue to be trained in performing manual processing in order to keep their specialist knowledge up to date and follow current practice so that they can respond appropriately and instantly in the event of endoscope washer-disinfector problems.

If the flexible endoscopes are pre-cleaned manually at night and not processed in the endoscope washer-disinfector until the morning (approx. 5 hours later), is that a problem in terms of hygiene?

KRINKO recommends immediate processing of flexible endoscopes. Delays may lead to the drying of dirt, increased microbial growth and biofilm formation. Although cleaning solution is rinsed through the working channel of the endoscopes on the reprocessing tower straight after the endoscopy and channels are brushed particles of residual dirt and process chemicals as well as germs remain on the endoscope because the endoscope has not yet been disinfected. These substances may dry up. Therefore, after long periods without use, the endoscope should be placed in a cleaning solution again and totally filled. The manual cleaning steps must be repeated before the endoscope can be sent for final, automated processing. This can counter effects of delayed processing.

Manufacturers advise against leaving endoscopes in cleaning solutions for long periods because the process chemicals may cause material damage in the event of sustained contact. Consequently, storage in moist conditions is not an option.

3. Questions to Ms Adelheid K. Jones, coordinator of the Hygiene, Construction and Technology Expert Committee of the German Society for Sterile Supply (DGSV)

Who writes the job-specific procedures? What form must these procedures take?

The standard operating procedures are part of the facility's quality management system and are designed to ensure that activities run smoothly.

The employer can delegate the task of establishing and monitoring correct performance, e.g. to the head of a unit, Hygiene or QM (Quality Management). The format of the standard operating procedure is defined in-house in QM. The standard operating procedure must expressly name the responsible persons and the critical process steps. It describes the work steps and the equipment to be used in each case, with defined minimum requirements for performance. Appendix 1 of Annex 8 of the KRINKO/BfArM recommendation can be used as a guideline. Pre-cleaning in the examination room, the leak test, brush cleaning and rinsing must be documented in the event of automated cleaning and disinfecting. In the event of fully manual processing, which must also be validated, all individual steps must be documented.

What form does a reprocessing record take?

Documentation can preferably be performed electronically, or manually if required. In the event of automated processing, there is usually a batch log of automated cleaning and disinfecting. The pre-cleaning steps at the examination site, brush cleaning and rinsing of the channels can also be recorded electronically. All individual work steps must also be documented in the case of manual cleaning and chemical disinfecting. This means increased time for documentation, which can be carried out via a checklist with reference to the items in the standard operating procedure.

As the Head of Endoscopy, am I obliged to go through the KRINKO/BfArM recommendations with all employees? All employees have completed the advanced course in endoscopy.

The employees who have completed the advanced course in endoscopy learned the contents of the KRINKO/BfArM recommendation "Hygiene Requirements for the Sterile Processing of Medical Devices" as a basis for carrying out their work. Changes/revisions to the recommendations must be taken into account in the standard operating procedures. Training on the standard operating procedures must be carried out annually or in the event of changes.

Moderation:
Ulrike Beilenhoff from DEGEA, Guido Merk and Marcel Jung from Dr. Weigert

* Recommendations by the Commission for Hospital Hygiene and Infection Prevention

Chemistry Series: Basics of Our Raw Materials

Part 2: Enzymes

Enzymes are present everywhere in nature and were performing their tasks long before humans knew anything about them. Pancreas enzymes were used in detergents as long ago as 1914. At the end of the 19th century, enzymes in cells were first isolated as a cause of effects, and their catalytic properties were thus examined "in vitro", i.e. outside of the living organism.

What Are Enzymes?

Enzymes are catalysts that are involved in the occurrence of a chemical reaction without being consumed themselves. For instance, they reduce the reaction temperatures, thus enabling a reaction in the prevailing conditions. They are subsequently reusable and can catalyse this reaction again.

As a result of this, only small quantities of enzymes need to be used, while still having a significant effect in terms of the desired reaction.

Of all the raw materials that are used for the formulation of detergents and cleaning agents, enzymes have by far the greatest specificity on account of their folding. They can perform only a very narrow range of tasks, but with a high level of precision. In contrast with other formulating raw materials, they cannot be used in multiple cases. Rather, on account of their substrate specificity, they are formulated only for the removal of precisely defined types of soiling, in line with the lock-and-key principle.

Lock-and-Key Principle

At the beginning of the 20th century, the effect of enzymes was explained by means of the "lock-and-key principle". Here, a enzyme is represented by a lock that can be opened only by a clearly defined key with a highly specific structure. Like a key, a specific substrate matches the structure of an enzyme, which specifically binds to the substrate. Different enzyme classes break down different products into their individual components, e.g. amylases break down starch and carbohydrates, proteases break down proteins, and lipases break down fats (see Figure 1).

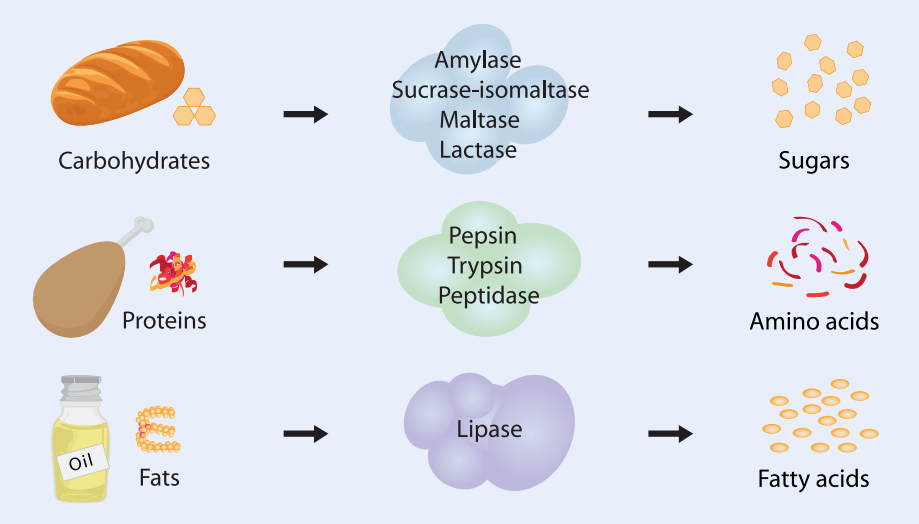

Figure 1: The various enzymes break down products into their individual components.

Dr. Weigert uses enzymes that are applied in automated and manual processing of medical devices and in automated dishwashing. The types of soiling encountered there are proteins, starch, fats and specific thickening agents. Since the mid-1970s, enzymes have been used at Dr. Weigert as formulation components in powder formulations for processing medical devices. This substance category has been used for liquid cleaning agents in the medical and kitchen hygiene sectors since 1990. The product **neodisher® BioClean**, whose patented formulation was a real innovation, embodies this. In instrument processing, the enzymatic and patented formulations of the products **neodisher® MediZym**, **neodisher® MediClean** and **neodisher® MediClean forte** are examples of innovative enzyme-based cleaning agents that have set standards.

Range of Applications of Enzymes Far from Exhausted

The range of new and enhanced enzymes is wide and subject to a constant cycle of innovation. Dr. Weigert is also involved in this development. New enzymes are constantly presented to us. We examine their performance spectrum and use them in new developments or enhancements if they are suitable.

Author: Dr Matthias Springer, Head of Research & Development

Do you want to find out even more about enzymes? If so, read the full article here (German only):

https://www.drweigert.com/de/aktuell/wissensdatenbank/enzyme-grundlagen-unserer-rohstoffe

Dates

April–June 2023
(As at: 1 April 2023)

- **ESGE Days 2023**
  20–22 April 2023, Dublin
- **Endoscopy – Live**
  28–29 April 2023, Berlin
- **Dr. Weigert webinar – endoscopy**
  (in German language)
  7 June 2023

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