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ZENTRAL STERILIZATION

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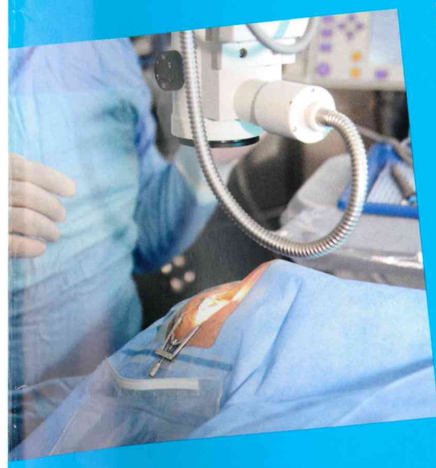

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DGSV

What's up in Geneva?

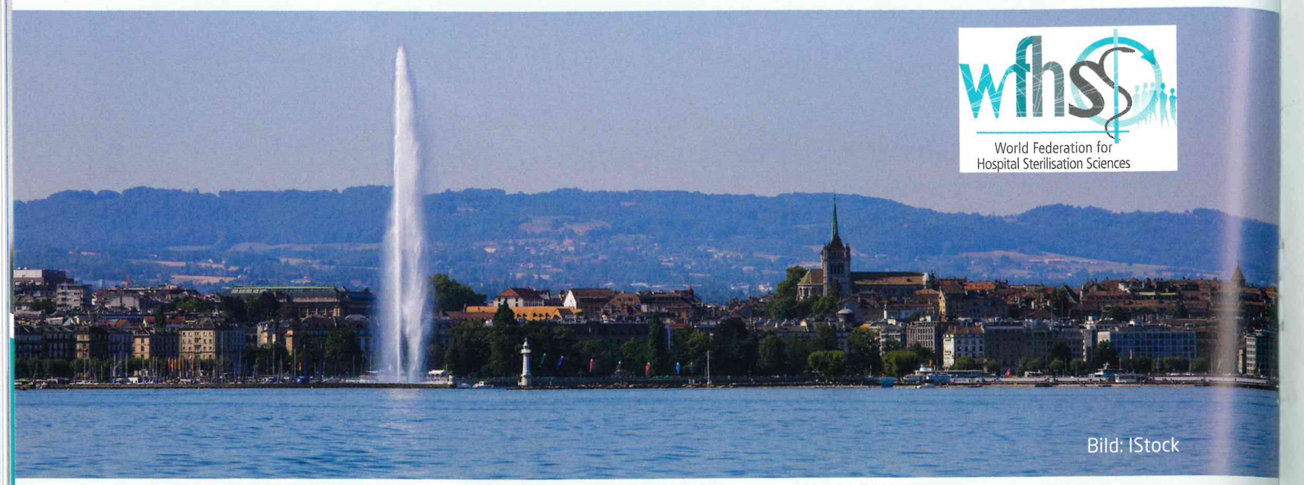
Christophe Lambert
Editor

The World Sterilization Congress which was held in Geneva from 17 to 20 November 2021 has just come to an end. Among the numerous topics discussed and innovations presented, I will report to you on those that drew my attention either because they testify to the dynamism of our field of activity, or because they are a precursor sign of an evolution of our practices. The first of these innovations relates to the pre-cleaning of surgical instruments based on pressurized sodium bicarbonate. Like the isolators used for preparation of anticancer chemotherapies in our hospital pharmacies, this entirely hermetically sealed, pre-cleaning cabin enables the operator, seated at a workstation, to remove the soils present on instruments after use (blood, mucus, bone, cement, etc.), thanks to the action of a jet of sodium bicarbonate microparticles. This semi-automated process which is carried out before the cleaning step in a washer-disinfector could be installed in the operating room or RUMED as an alternative or complement to the immersion pre-treatment, as used in France, as soon the soiled medical device is received in the RUMED or before soiled devices are transported in a humid environment, as is recommended in many other countries. Whatever the organizational setup planned, because of its easy application, user and environmental safety as well as its promising efficacy [1], this could be of interest to those who are on a constant lookout for improvements in the cleaning process.

Already demonstrated in The Hague in 2019 and introduced again at this 21st Congress, one of the most remarkable technological innovations concerns a robot for folding wrap and packaging sterilization baskets. Fully automated, this robot equipped with several arms makes a half-square fold around a surgical instrument basket (tray) without any human intervention, making the tray ready for the sterilization step. Apart from the originality and the technological feat, a robot of such a large scale seems to be able to fit only in a few RUMEDs in Europe or Asia or in settings where continuous productivity (24/7) is indispensable. I eagerly await its introduction!

Finally, after 10 years of research, development and industrial perseverance, the RFID chip and its integration into the surgical instrument now seem to be mastered. This technological success is above all the result of a gamble, the cohabitation or marriage of a heat-resistant transponder (134 °C) and stainless steel constituting an omnipresent obstacle to the emission of waves (Faraday cage). But this accomplishment is above all the affirmation of reinforced health safety and assurance of the quality of the surgical basket/tray contents. While data matrix was until now the gold standard data storage medium on surgical instruments, its reading, sometimes slow and difficult, is now surpassed by the simplicity and speed of the RFID chip reader. So simple that it could be deployed at different stages of the process: from the time of exiting the operating room to confirm no instruments were lost or forgotten; from arrival in the RUMED to ensure the set is complete; or when assembling a tray to guarantee its accuracy. This individual monitoring of surgical instruments would be the ultimate guarantor of health safety, enabling one to know with precision and accuracy the conditions of use (patient coming into contact with CJD) and the reprocessing conditions for these instruments. With integration now perfectly successful, acceptable or even sophisticated aesthetics, the presence of the chip on surgical instruments is no longer an impediment for surgeons and goes unnoticed at times. With such advantages, the RFID chip could prove to be the obligatory UDI data storage medium which is expected from May 2027 on all surgical instruments. But for that, we urgently need studies under hospital conditions to evaluate, take ownership of and develop this identification system, which is now a key element in the traceability of reusable medical devices.

(1) Evaluation of a method for pretreatment of reusable medical devices based on pressurized sodium bicarbonate. Zentr Steril 2021; 29(5):284–287.



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21st World Sterilization Congress – on site and online

17 to 20 November 2021, Geneva, Switzerland

Gudrun Westermann, Stefan Dudzinski-Lange

The World Sterilization Congress, organized by the World Federation for Hospital Sterilisation Sciences (WFHSS) and the Swiss Society for Sterile Supply (SGSV), was held this year in Geneva. Despite the ongoing pandemic, several delegates attended the conference on site, while a further 200 tuned in remotely.

What's new? The first two sessions were devoted to this topic. **Richard Bancroft** from the United Kingdom spoke about harmonised standards in the era of MDR and Brexit. Standards have not only to be revised to maintain the state of the art, but also aligned with the new requirements of MDR and IVDR. ISO/TC 198, chaired by Bancroft, is responsible for 60 published standards, of which 18 are currently revised.

WFHSS president **Christine Denis** gave a talk on process challenge devices (PCDs), while focusing in particular on sterilization. PCDs were intended to help the user ensure that the process was executed in accordance with the specifications, such that a high-quality product could be delivered. PCDs could, for example, be fitted with indicators; in the hospital setting, in particular, chemical indicators were the most suitable. But the PCD concept was not a panacea – rather, a more precise definition would be beneficial. This would be addressed by a working group within the WFHSS in the near future.

Lionel Pineau dealt with high-level disinfection (HLD) using a liquid sterilant. The Spaulding classification assigns medical devices to the required reprocessing level for safe reuse in accordance with their intended purpose and application. Citing flexible gastrointestinal endoscopes by way of example, Pineau explained the approach undertaken. A much-discussed question was whether sterilization increased safety of endoscopes. What was crucial first of all was that cleaning had been carried out properly and that all surfaces had been accessible to disinfection.

What are the benefits of additional precleaning?

In the second session **Tiziano Balmelli** from Ticino reported on the use of a new precleaning method for medical devices (MDs) based on pressurized sodium bicarbonate (Safe Clean Box STK 103-113 from Bicarjet). In particular, the time needed to reprocess the MDs was investigated. In fact, reprocessing with STK 103-113 took twice as long and additional costs were incurred. However, the results were essentially better: the MDs were absolutely clean, and far fewer instruments had to be reprocessed a second time, sorted out and sent for repair or disposed of.

Medical devices from the printer

Mélanie Albert from Lyon reported on ways to produce MDs using 3D printing. There were different printing techniques on the market. The application fields included custom-made implants or prostheses but also preoperative anatomical models. Overall, this helped to reduce the operating time and the custom-made implants were a better fit. Production within the healthcare facility had the advantage of expediting availability and was also more cost effective. When produced in-house, appropriately trained staff members, including a quality officer, were needed. However, it was better to have external manufacturers produce more complex MDs. But that paid off if there was a high demand within a facility. The 3D-MDs had, of course, to be qualified, said Albert. In certain cases, the hospital, in its capacity of manufacturer, had to comply with the entire raft of regulatory demands.

Dealing with the increasing workload

The talk by Ingrid Jullian Desayes from Chambéry, France, focused on the increasing workload in the Reprocessing Unit for Medical Devices (RUMED). Her lecture targeted solutions to improve workflows and process quality. A consultancy firm analysed the situation and applied lean management methods aimed at optimization of processes and workflows. In order to increase satisfaction and eliminate dysfunctions, a production manager was now appointed every day in the hospital to regularly monitor the RUMED and detect bottlenecks. The manager deployed circulating staff members to help out the staff on duty when there were peaks in demand. The speaker reported that the measures had increased staff satisfaction, which was due primarily to a reduction in the workload and the increased self-responsibility.

Management of loan equipment sets

Sigurd Vandendriessche, head of the RUMED of a private hospital group in Belgium, reported on a modern "Management of loan equipment sets" which was operated in collaboration with an MD manufacturer. The third-party provider delivered the sterilized sets just-in-time and collected them again after use. The logistics activities associated with the loan equipment sets took place at night, taking the pressure off the routine operations in the RUMED. Staff satisfaction had increased. According to the speaker, there was a cost saving of 33 per cent – mainly due to the reduced workload of the employees and less overtime.

To simplify and assure the complex process of the management of surgical equipment loans, **Laura Delassus** introduced a digital platform at the University Hospitals in Strasbourg. The project was aimed at exploring and evaluating the possibilities and advantages of a digital platform. The platform was developed on the basis of data from the loan equipment circuit. Comparison with the tracking software data produced the first results. The information flow between the various stakeholders as well as the entire loan equipment circuit optimized the process. The speaker advocated for the widespread adoption of the reservation and management platform.

Transport and storage - which conditions are best?

Gerhard Kirmse from Tuttlingen dealt in his talk with the best transport conditions between the OR and RUMED. All guidelines across the world called for cleaning at the point of use. Nonetheless, the used instruments were often transported in a contaminated condition. It was therefore important to identify the maximum acceptable holding time between use and the start of reprocessing.

In laboratory experiments stainless steel plates and PCDs were contaminated with different test soils. The test products were then stored under different conditions, then cleaned, inspected for corrosion and the cleaning results checked. After 6 hours' storage there were visible differences in the cleaning results, and after 16 and 24 hours holding time these differences were really significant. After 72 hours none of the storage methods yielded reliably good cleaning results.

Karin Bundgaard from Denmark also spoke about the storage conditions before reprocessing and their impact on instrument durability. To explore this irrigation syringes and forceps that had been contaminated with human blood harbouring *Enterococcus faecium* and then stored before reprocessing for 6, 12 and 24 hours at room temperature were inspected for protein residues. One half of the instruments were stored in a dry, and the other in a humid, environment. The results did not show any relationship between the storage environment and corrosion. It seemed that the cleanliness and durability were impacted by use and the number of reprocessing cycles rather than by the storage conditions before reprocessing.

Plasma sterilization studies: Plasma as unique sterilization agent

Plasma sterilization combines speed with safety and effectiveness. **Joao Henrique Campos de Souza** from Brazil demonstrated at the WFHSS congress a plasma source specially developed for sterilization studies at normal atmospheric pressure, and in which the plasma alone was responsible for the sterilization process. Petri dishes containing at least 10^7 CFU *Geobacillus stearothermophilus* spores (ATCC 12977) were subjected to different cycle times: 2, 5, 10, 15, 20 and 40 minutes. The number of viable cells was analysed with the pour plate method. Result: after 40-minute exposure all 10^7 CFU spores were eliminated on using plasma as the exclusive sterilization agent. Among the advantages of high-pressure plasma Campos de Souza mentioned, among others, the simplicity of the method, high stability of the discharge and low power consumption.

UV light-based reprocessing of flexible endoscopes without working channel in otorhinolaryngology

Stefan Alexander Rudhart from Marburg, Germany, spoke about "UV light-based reprocessing of flexible endoscopes (FE) without working channel in otorhinolaryngology". In the study the UV-C light technology Impelux™ (UV Smart, Delft, Netherlands), previously successfully employed for rigid endoscopes, was used. After reprocessing, no more bacterial contamination (0 CFU) was detected on any of the 50 standardized PCDs. Based on the results, the UV-C light technology effectively reduced bacterial contamination from FEs and might be useful in daily practice. Furthermore, the method offered substantial financial and practical advantages for standard FE disinfection methods.

The effect of fluid flow when cleaning hollow instruments

Laparoscopes have a complex geometry and were difficult to clean. However, in low-resource countries thorough cleaning as a prerequisite for effective sterilization is not always possible. That was borne out during a visit by **Daniel Robertson** from the Delft University of Technology in the Netherlands to four hospitals in India. To improve the cleaning process in low-resource settings, the goal was therefore to design an appliance that was effective and low cost – with the same standards as the washer-disinfectors (WDs) used in developed countries. A pilot study was initiated to investigate the relationship between the flow rate and the removed mass fraction when using different soaking times in order to gain insights into the effect of the fluid flow when cleaning hollow instruments. Maximum removal of the test soil was observed at 6 l/min. The soaking time, too, had a significant impact. The results would be used as a benchmark for subsequent studies to investigate other effects coming into play in

the cleaning process, such as the influence exerted by instrument geometry.

Air quality in the RUMED: How to deal with unexpected results

In Switzerland, the air quality in the RUMED is supposed to meet ISO Class 8 cleanroom requirements. **Marc Dangel** from Basle University Hospital reported in his talk that routine measurements had revealed unexpected results. For example, high bacterial counts with comparatively few air particles were measured in indoor environments, and at that in the new hospital building. As an emergency measure, the entire RUMED was disinfected with ultraviolet light (UV-C). The results showed that the bacterial thresholds stipulated by the Swiss Agency for Therapeutic Products (Swiss Medic) could be exceeded even when all other air quality requirements had been met.

Swiss guideline for transport of contaminated or sterile MDs

In Switzerland, the issues to be borne in mind around the transport of reusable contaminated and/or sterile medical devices reprocessed by an external provider or in-house RUMED are set out in a guideline. **Nicole Berset** from the Swiss Society for Sterile Supply (SGSV) gave an overview of that guideline, stating that it was a particular source of help to organizations to assure transport without the risk of contaminating the environment or the sterile MDs. The main risks during transport stemmed from mechanical stress, temperature fluctuations as well as humidity and dust. But natural events such as heavy snowfall were also included. Therefore, risk analysis had to be carried out before transport. Staff needed to be trained to enable the safe transport of reusable MDs.

Chemical indicators to estimate the sterilant dose?

Brian Kirk from the United Kingdom asked whether chemical indicators for sterilization with hydrogen peroxide could be used to determine the sterilant dose used for instrument sets. For VH_2O_2 processes the area under the exposure curve was defined as dose by the manufacturers. To clarify the question of whether CIs could be used as "dosimeters" for VH_2O_2, a number of CIs were exposed to VH_2O_2 gas to determine their performance. This generated a large pool of data expressed as colour coordinates as a function of exposure dose. Regression analysis was used to establish the relationship between colour change and exposure dose.

BD or PCD?

Florian Gallais from Rouen, France, asked how one could guarantee that saturated steam penetrated all medical devices. PCDs were often used in hospitals for routine checks. Gallais presented a study in which different commercially available PCDs were tested under worst-case conditions and their detection limits compared with paper-based and electronic BD tests. In his conclusion, Gallain said that the commercially available PCDs had good sensitivity and that a PCD packed in a container was more sensitive than a standard BD test.

Matías Pilasi from Chile reported on a study that investigated chemical indicators (CI) with nine different PCDs of variable length but with the same internal diameter size. He pointed out that chemical and biological indicators (BIs) were used in many countries to evaluate the sterilization process. Pursuant to ISO 11140-1, Class (Type) 5 CIs were designed to be equivalent or to exceed the performance of that of BIs. Despite this, certain recommendations did not allow BIs to be replaced with Class 5 CIs. The results of this study suggested that Class 5 CIs were more sensitive than BIs even in the presence of NCGs and could therefore be a safe and cost-effective alternative.

RFID tracking

Hervé Ney from Geneva reported on experiences with RFID marking of instruments. RUMED personnel were delighted with the impressive scanning speed. Trays could be assembled faster, in particular in the case of new staff members there was a time major difference versus the conventional method. However Ney acknowledged there were also reservations. What to do if the tags could no longer be read because of a malfunction? The system was also limited when dealing with small instruments. And finally there was still no interface to integrate the RFID into the existing tracking system. Ney explained the fundamental differences between the systems: It was possible to save more lifecycle data on RFID – that meant that RFID was also an investment in the future. Ney concluded by saying that for now he did not believe that RFID system had any clear advantage – the time may not yet be ripe.

Duodenoscopes: Contamination rates after reprocessing

Ross Segan, Olympus, USA, spoke about a multicentre trial on duodenoscope contamination rates after reprocessing. In the study sampling and culture preparation were done, after reprocessing the duodenoscopes, in accordance with the provisions of the FDA and CDC. High-concern (HC) microorganisms were defined. Approximately 10% of the models were contaminated with HC organisms. Most were due to inadequate reprocessing – mainly because of failure to comply with the reprocessing instructions. **Lionel Pineau** continued the presentation and cited the contamination rates reported for France. In 2021 still 16% of endoscopes were not safe. Hence, improvements were needed.

Swiss Good Practice: Risk and quality management

On the last day of the congress, **Norma Hermann** from Bern spoke about the Swiss Good Reprocessing Practice (GRP). The third version, which took account of legislation at European level, was expected in December. Hermann pointed out that a separate Good Practice was in place for medical and dental practitioner offices, adapted to the conditions there. Quality management was an essential chapter of Good Practice, and risk management was also a mandatory requirement that might still be a bit abstract for many, Hermann said; but as past experience had proven, GPP was once again forcing the RUMEDs in the right direction.

Risk identification in MD reprocessing

When referring to safety in MD reprocessing, comparisons are often made with the aviation industry. **Mélissa Giroux** from Canada spoke about such an approach for risk identification. 90% of incidents resulting in adverse events in the RUMED were related to set composition or the packaging. A project had now been launched to increase compliance also with regard to the forms to be filled in and the reporting obligations. Packing work practices were observed. Ergonomic factors apparently played a role in error causation. Time was also important – more mistakes were made after 22.00 h. There were shortcomings when reporting incidents and accidents. An action plan was needed to prevent a repeat of adverse events, including e.g. various pre-emptive measures, staff training, updating working procedures and standard operating procedures as well as monitoring of the incidents and accidents associated with MD reprocessing.

Sterile Processing Technologists - the long road to a professional job description

Frédy Cavin described the rocky road to the job description for Sterile Processing Technologists in Switzerland. First, a lot of materials had to be compiled so that the competent authorities could really see that reprocessing was sufficiently complex to merit a professional job description of its own. Now there was finally a dual, competence-oriented training. Cavin explained that employers had to demand better trained personnel to effect change in matters relating to the job description. High demands were also made on the trainers. In 2021 the first group of 30 trainees completed their training. Incidentally, staff members who had worked for many years in the RUMED could also obtain the diploma provided that they had demonstrated the necessary competence and were in possession of Specialist Course 1 or 2 certificates and also had at least three years' experience.

Improvements to sterile processing at global level

Christina Fast from SPECT (Sterile Processing Education Charitable Trust) from Canada spoke about improvements to sterile processing in low-resource countries. Armed with impressive photos, she showed a long list of shortcomings – there was a lack of knowledge, equipment as well as of occupational safety and health. For example, inadequately cleaned instruments and careless handling of hazardous chemicals were commonplace.

But Fast also demonstrated what could be achieved within a relatively short of period of time, in particular through training. Fast stressed that for lasting improvements, competences and management had to be put in place on the ground. Furthermore, cooperation with the local authorities was important, even if that was often challenging.

WFHSS Vice President **Harry Oussoren** emphasized in his closing speech the importance of international friendships nurtured during these congresses. On this occasion, it was not possible to hand over the WFHSS flag directly to colleagues in Hong Kong, who are to organize the next congress – due to the pandemic they were unable to travel to Geneva.

To round off, SGSV chairman **Hervé Ney** announced the next Swiss Congress, which would be held from 22 to 23 June 2022 in Biel/Bienne, and naturally the next World Congress in Hong Kong – please make a note of the date: 23 to 26 November 2022!

You can find our detailed report at https://bit.ly/wfhss2021eng

Information for Authors

Zentralsterilisation – Central Service is a professional journal for all aspects of sterile supply. It contains original articles, reviews, recommendations, guidelines, reports from the field as well as short communications and letters.

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Articles should include a title page with the names, academic degrees and addresses of all authors, Summary, and Keywords. The text of scientific articles should be composed of Introduction, Material and Methods, Results, Discussion, Acknowledgments (if applicable) and References. Articles other than scientific papers may have a different outline, but should always contain a summary. All figures and tables must be mentioned in the text and be supplied with a short caption.

References must be listed in the numerical order of their appearance in the text (not alphabetically!). Use the following format for references:

- Reponen T, Wang Z, Willeke K, Grinshpun A: Survival of Mycobacteria on N95 Personal Respirators. Infect Control Hosp Epidemiol 1999; 20(4): 237-241.
- Eisen HN: Immunology: An introduction to molecular and cellular principles of the immune response. 5th ed. New York: Harper and Row, 1974: 406ff
- Weinstein L, Swartz MN: Pathogenic properties of invading microorganisms. In: Sodeman WA Jr, Sodeman WA, eds. Pathologic physiology: Mechanisms of disease. Philadelphia: WB Saunders, 1974: 457-472.

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