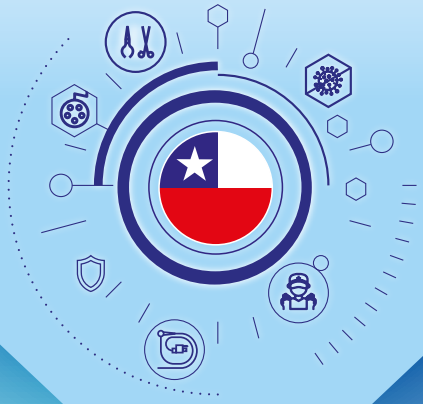
# 25th wfhss CONGRESS



## SCIENTIFIC PROGRAM

**20-23 NOV 2024**

**SANTIAGO-CHILE**

wfhss World Federation for Hospital Sterilisation Sciences

SPECH Sociedad de Profesionales en Esterilización de Chile

INDE Instituto Nacional de Esterilización y Reprocesamiento de Dispositivos Médicos

Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

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November 21, 2024
13:00 - 14:30, Cordillera room

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21 de Noviembre, 2024
13:00 - 14:30, Sala Cordillera

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# WEDNESDAY 20 NOVEMBER

| | |
|---|---|
| 16.00 - 18.00 | **OPENING OF THE REGISTRATION AND EXHIBITION /** APERTURA DE LA INSCRIPCIÓN Y DE LA EXHIBICIÓN |
| 18.00 - 19.00 | **OPENING CEREMONY /** CEREMONIA DE INAUGURACIÓN |
| 19.00 - 20.30 | **WELCOME RECEPTION IN THE GARDEN /** RECEPCIÓN DE BIENVENIDA EN EL JARDÍN |

# THURSDAY 21 NOVEMBER

| | |
|---|---|
| 07.45 - 08.30 | **OPENING OF THE REGISTRATION AND EXHIBITION /** APERTURA DE LA INSCRIPCIÓN Y DE LA EXHIBICIÓN |

**PLENARY ROOM - COSTANERA + VITACURA**

| | |
|---|---|
| 08.30 - 08.45 | **CONGRESS INTRODUCTION**<br>*David Bellamy* |
| 08.45 - 10.30 | **SESSION 1 - VALIDATION /** VALIDACION<br>*Moderators: Christine Delebeque & Sandra Riveros* |
| 08.45 - 09.30 | **CONFERENCE 1**<br>**Economic comparison of steam sterilization quality assurance policies in German and in Chilian hospitals /** Comparación económica de las políticas de garantía de calidad de la esterilización por vapor en hospitales alemanes y chilenos<br>*Markus Auly (Switzerland)* |
| 09.30 - 10.00 | **CONFERENCE 2**<br>**Importance of process validation according to ISO /** Importancia de la validación de procesos según ISO<br>*Matías Pilasi Pendás (Chile)* |
| 10.00 - 10.30 | **CONFERENCE 3**<br>**Process validation in real practice - A case study from a German hospital /** Validación de procesos en la práctica real: un estudio de caso de un hospital alemán<br>*Bianca Winkler (Germany)* |
| 10.30 - 11.30 | **COFFEE BREAK & VISIT EXHIBITION /** PAUSA DE CAFÉ Y VISITA ÁREA DE EXHIBICIÓN |

| CORDILLERA | | SALON PARQUE |
|---|---|---|
| 10.30 - 11.30 | **Holistic RUMED Solutions by MMM Group & RUMED Academy** | **Elevating Standards in Endoscope Reprocessing** |

**PLENARY ROOM - COSTANERA + VITACURA**

| | |
|---|---|
| 11.30 - 13.00 | **SESSION 2 - IMPROVEMENT OF THE PRACTICES: WHAT ARE THE OBSTACLES? /** MEJORA DE LAS PRÁCTICAS: CUÁLES SON LOS OBSTÁCULOS<br>*Moderators: Harry Oussoren & Cinthia Vera Fuentes* |
| 11.30 - 12.15 | **CONFERENCE 4**<br>**10 years of world experience, so what? /** 10 años de experiencia mundial, ¿y qué?<br>*Christine Delebeque (France)* |
| 12.15 - 13.00 | **CONFERENCE 5: ROUND TABLE 1**<br>**What is our strategy to move into the future? /** ¿Cual es nuestra estrategia para avanzar hacia el futuro?<br>**Interactive session with experts and audience /** Sesión interactiva con expertos y público<br>*Damien Berg (USA), Sandra Riveros (Chile), Christine Delebeque (France)* |

| 13.00 - 14.30 | **LUNCH - POSTERS AND EXHBITION /** ALMUERZO - VISITA PÓSTERS Y ÁREA DE EXHIBICIÓN |
|---|---|

| | CORDILLERA | SALON MANQUEHUE | SALON PARQUE |
|---|---|---|---|
| 13.00 - 14.30 | B\|BRAUN SHARING EXPERTISE<br>**How to empower your CSSD to improve and ensure the performance of the OR? Sharing the successful experience of benchmark CSSDs in Latin America** | matachana<br>**Balancing Innovation and Sustainability: New Trends in Reprocessing Complex MD for Healthcare Professionals** | STERIS<br>**Small Changes, Big Impact – Driving efficiency through innovation** |

**PLENARY ROOM - COSTANERA + VITACURA**

| 14.30 - 16.00 | **SESSION 3 - INNOVATION AND GREEN /** INNOVACION Y ECOLOGIA<br>*Moderators: Carolina Chiodini & Matías Pilasi Pendás* |
|---|---|
| 14.30 - 15.00 | **CONFERENCE 6**<br>**Increasing Sterile Service Department Reprocessing Capacity to Support Sustainability Outcomes /** Aumentar la capacidad de reprocesamiento del departamento de servicios estériles para apoyar los resultados de sostenibilidad<br>*Sulisti Holmes (United Kingdom)* |
| 15.00 - 15.30 | **CONFERENCE 7**<br>**AI for Developing countries CSSDs, threat or opportunity /** IA para Departamentos de suministro estéril en países en desarrollo , ¿amenaza u oportunidad?<br>*Hamid Zare Shah Mers (Iran)* |
| 15.30 - 16.00 | **CONFERENCE 8: ROUND TABLE 2**<br>**Green /** Ecologia<br>**Interactive session with experts and audience /** Sesión interactiva con expertos y público<br>*Harry Oussoren (The Netherlands), Patricia Jara Concha (Chile)* |

| 16.00 - 16.45 | **COFFEE BREAK & VISIT EXHIBITION /** PAUSA DE CAFÉ Y VISITA ÁREA DE EXHIBICIÓN |
|---|---|

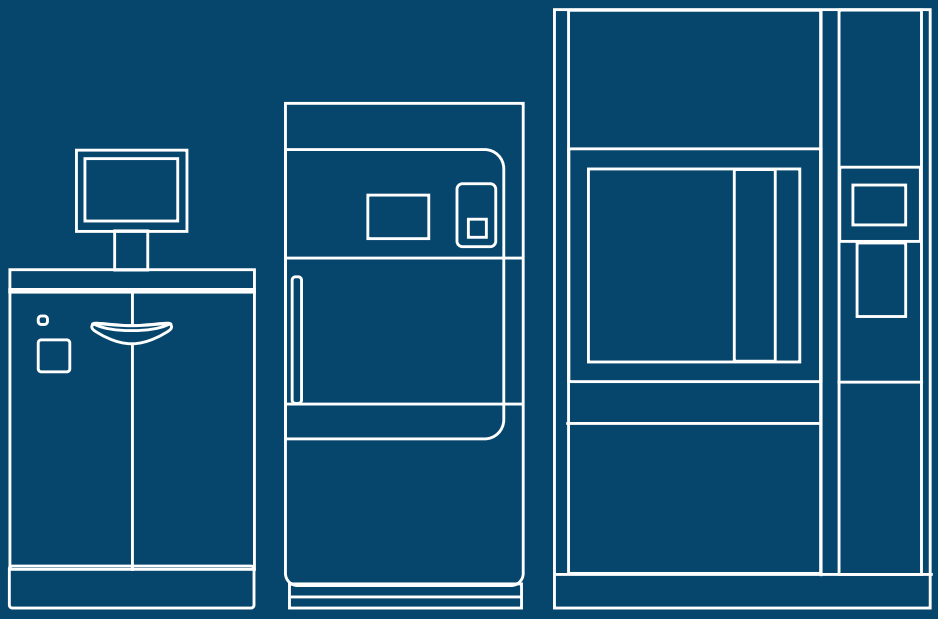
| | CORDILLERA | SALON MANQUEHUE | SALON PARQUE |
|---|---|---|---|
| 16.00 - 16.45 | SHINVA | solventum<br>**Advancing Sterilization Assurance: Exploring Next-Generation Solutions in Bowie-Dick Testing** | cisa<br>We care about life<br>**Quiz Time - Desafía tu Conocimiento** |

**PLENARY ROOM - COSTANERA + VITACURA**

| 16.45 - 18.15 | **SESSION 4 - FLEXIBLE ENDOSCOPY /** ENDOSCOPIA FLEXIBLE<br>*Moderators: Hervé Ney & Patricia Jara Concha* |
|---|---|
| 16.45 - 17.15 | **CONFERENCE 9**<br>**Establishing preconditions for effective duodenoscope reprocessing: an observational cohort study /** Establecimiento de condiciones previas para el reprocesamiento eficaz de duodenoscopios: un estudio observacional de cohortes<br>*Diana Bulkmans (The Netherlands)* |
| 17.15 - 17.45 | **CONFERENCE 10**<br>**Determination of residual endotoxins in endoscopic devices: implementation of a complementary monitoring tool for high-level disinfection (HLD) /** Determinación de endotoxinas residuales en dispositivos endoscópicos: aplicación de una herramienta de monitoreo complementaria para la desinfección de alto nivel (DAN)<br>*Troy Ejsmentewicz (Chile)* |
| 17.45 - 18.15 | **CONFERENCE 11**<br>**Flexible endoscopes: Importance of dry storage to prevent biofilm formation /** Endoscopios flexibles: Importancia del almacenamiento en seco para evitar la formación de biopelículas<br>*Michelle Alfa (Canada)* |

# VISIT US AT BOOTH #7

## See Innovation within Reach



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# FRIDAY 22 NOVEMBER

| | |
|---|---|
| **08.00 - 08.30** | **OPENING OF THE REGISTRATION AND EXHIBITION /** APERTURA DE LA INSCRIPCIÓN Y DE LA EXHIBICIÓN<br>**VISIT OF POSTERS AND EXHIBITION /** VISITA DE PÓSTERS Y EXPOSICIÓN |

**PLENARY ROOM - COSTANERA + VITACURA**

| | |
|---|---|
| **08:30- 10.30** | **SESSION 5 - CLEANING AND DISINFECTION /** LIMPIEZA Y DESINFECCION<br>*Moderators: Damien Berg & Silvia Araneda* |
| **08.30- 09.00** | **CONFERENCE 12**<br>**Good practice in reprocessing from the point of use /** Buenas prácticas en el reprocesamiento desde el punto de uso<br>*Patricia Guitérrez (Chile)* |
| **09.00 - 09.30** | **CONFERENCE 13**<br>**Identification and prevention of surface alterations on surgical Instruments caused by waterborne minerals /** Identificación y prevención de las alteraciones de la superficie de los instrumentos quirúrgicos causadas por minerales transportados por el agua<br>*Matthias Tschoerner (Germany)* |
| **09.30 - 10.00** | **CONFERENCE 14**<br>**Influence factors on instrument cleaning results - How to achieve a good result and what is good enough? /** Factores que influyen en los resultados de la limpieza de instrumentos - ¿Cómo conseguir un buen resultado y qué es suficientemente bueno?<br>*Gerhard Kirmse (Germany)* |
| **10.00 - 10.30** | **CONFERENCE 15**<br>**Basics of safe endoscopic reprocessing /** Fundamentos del reprocesamiento endoscópico seguro<br>*Eric Smith (USA)* |
| **10.30 - 11.30** | **COFFEE BREAK & VISIT EXHIBITION /** PAUSA DE CAFÉ Y VISITA ÁREA DE EXHIBICIÓN |

| | CORDILLERA | SALON MANQUEHUE |
|---|---|---|
| **10.30 - 11.30** | GETINGE PASSION FOR LIFE<br>**Understanding and addressing two complex technical challenges for CSSD managers** | Terragene<br>**Artificial Intelligence in CSSD: Maximizing its Potential for Daily Efficiency** |

**PLENARY ROOM - COSTANERA + VITACURA**

| | |
|---|---|
| **11.30 - 13.00** | **SESSION 6 - EDUCATION /** EDUCACION<br>*Moderators: David Bellamy & Patricia Guitérrez* |
| **11.30 - 12.00** | **CONFERENCE 16**<br>**A Well-structed Sterile Services Department Training System for Sustainable Development in a Volatile Environment /** Un sistema de formación en Centrales de reprocesamiento de dispositivos médicos bien estructurado para el desarrollo sostenible en un entorno volátil<br>*Teddy LEE Chun Kin (Hong Kong)* |
| **12.00 - 12.30** | **CONFERENCE 17**<br>**Educating CSSD: The self-regulating student Educar en /** CRDM: El alumno autorregulado<br>*Martijn Gerritsen-Ter Brugge (The Netherlands)* |
| **12.30 - 13.00** | **POSTER AWARDS SESSION /** SESIÓN DE ENTREGA DE PREMIOS POSTER<br>*Sérgio Jesus, Daniela Schneider & Toshihiko Okazaki* |
| **13.00 - 14.30** | **LUNCH - POSTERS AND EXHBITION /** ALMUERZO - VISITA PÓSTERS Y ÁREA DE EXHIBICIÓN |

| | | SALON MANQUEHUE | SALON PARQUE |
|---|---|---|---|
| 13.00 - 14.30 | | ASP Advanced Sterilization Products<br>**From Challenges to Solutions: Elevating the Standard of Care in Medical Device Reprocessing** | SteelcoBelimed Miele Group Member<br>**Best practices for safety and productivity in CSSDs and endoscopy departments** |

**PLENARY ROOM - COSTANERA + VITACURA**

**14.30 - 16.30** — **SESSION 7 - PACKAGING AND STERILIZATION /** EMPAQUE Y ESTERILIZACION
*Moderators: Tillo Miorini & Andrea Leisewitz Velasco*

**14.30 - 15.00** — **CONFERENCE 18**
**Sterilization Wrap - Check List for CSSD Manager /** Esterilización de empaques flexibles - Lista de comprobación para el gerente de la CRDM
*Menno Dufour (France)*

**15.00 - 15.30** — **CONFERENCE 19**
**Practical experience in implementing the validation of sterile barrier systems according to ISO 11607 at CSSD in Germany /** Experiencia práctica en la aplicación de la validación de sistemas de barrera estéril según la norma ISO 11607 en la CRDM de Alemania
*Rainer Stens (Germany)*

**15.30 - 16.00** — **CONFERENCE 20**
**Exploring differences between steam penetration in a B&D test pack and in a channelled instrument /** Explorando de las diferencias entre la penetración del vapor en un paquete de prueba B&D y en un instrumento canulado
*Francesco Tessarolo (Italy)*

**16.00 - 16.30** — **CONFERENCE 21**
**Influence of the load positioning during a steam sterilization cycle: An experimental and numerical study /** Influencia del posicionamiento de la carga durante un ciclo de esterilización por vapor: Un estudio experimental y numérico
*Simon Pletzer (Austria)*

**16.45 - 17.30** — **COFFEE BREAK & VISIT EXHIBITION /** PAUSA DE CAFÉ Y VISITA ÁREA DE EXHIBICIÓN

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Thursday
**21 November**
Time
**13:00-14:30**
Salón
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# SATURDAY 23 NOVEMBER

| | |
|---|---|
| **08.00 - 09.00** | **OPENING OF THE REGISTRATION AND EXHIBITION /** APERTURA DE LA INSCRIPCIÓN Y DE LA EXHIBICIÓN<br>**VISIT OF POSTERS AND EXHIBITION /** VISITA DE PÓSTERS Y EXPOSICIÓN |
| **PLENARY ROOM - COSTANERA + VITACURA** | |
| **09.00 -10.30** | **SESSION 8 - MISCELLANEOUS /** VARIOS<br>*Moderators: David Bellamy & Millaray Fonseca Chandia* |
| **09.00 - 09.30** | **CONFERENCE 22**<br>**Precision in Practice: Instrument Management as a Key to Cost Control and Safety Improvement /** Precisión en la práctica: La gestión de instrumentos como clave para el control de costos y la mejora de la seguridad<br>*Juana Baez Hernández (Spain)* |
| **09.30 - 10.00** | **CONFERENCE 23**<br>**Change management: a critical part of leadership success /** La gestión del cambio: una parte esencial del éxito del liderazgo<br>*Roel Beltran Castillo (Australia)* |
| **10.00 - 10.30** | **CONFERENCE 24**<br>**Optimizing CSSD Operations with QR Code Tracking /** Optimización de las operaciones de CRDM con el seguimiento de códigos QR<br>*Nathkritta Sookchum (Thailand)* |
| **10.30 - 11.00** | **COFFEE BREAK & VISIT EXHIBITION /** PAUSA DE CAFÉ Y VISITA ÁREA DE EXHIBICIÓN |
| **11.00 - 12.00** | **SESSION 9 - QUALITY AND RISK MANAGEMENT /** CALIDAD Y GESTIÓN DE RIESGOS<br>*Moderators: Harry Oussoren & Katherine López Tirado* |
| **11.00 - 11.30** | **CONFERENCE 25**<br>**Nonconformity and risk management on product /** No conformidad y gestión de riesgos en el producto<br>*Norma Hermann (Switzerland)* |
| **11.30 - 12.00** | **CONFERENCE 26**<br>**Transportation Environment of Contaminated Instruments before Reprocessing /** Ambiente del transporte de instrumentos contaminados antes de su reprocesamiento<br>*Karin Bundgaard (Denmark)* |
| **12.00 - 12.45** | **FLAG CEREMONY /** CEREMONIA DE LA BANDERA |
| | **END OF THE CONGRESS /** FIN DEL CONGRESO |

ASP Advanced Sterilization Products

25th wfhss CONGRESS

# Symposium

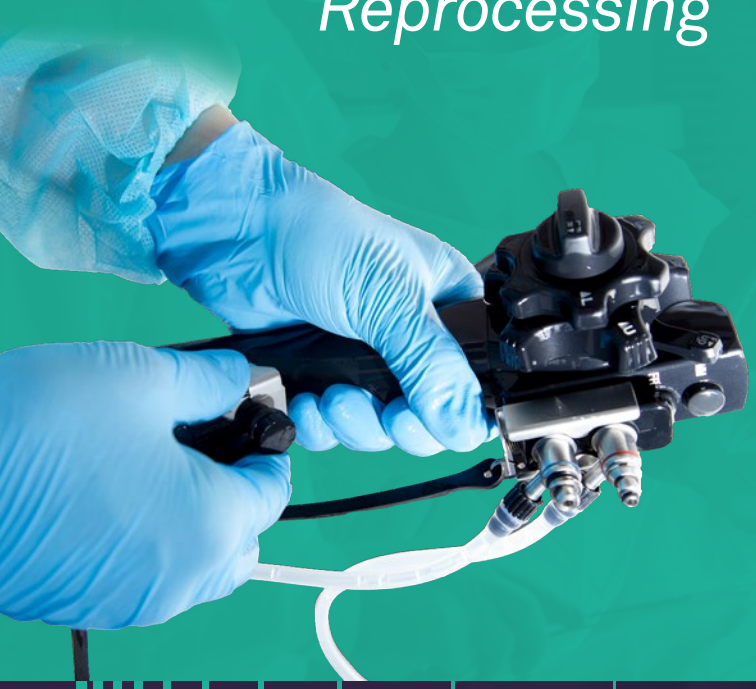
## From Challenges to Solutions:

*Elevating the Standard of Care in Medical Device Reprocessing*

**22nd November 2024**

From 1PM to 2:30PM

**Venue**
Salon Manquehue




**Speaker 1:**

**Anaclara Ferreira Veiga Tipple PhD**

Professor at Federal University of Goiás, Brazil

**Topic:** *Challenges in Cleaning Process*

**Speaker 2:**

**Ivan Salgo MD MS MBA**

ASP Chief Medical Officer ASP

**Topic:** *Margin of Safety*

**Speaker 3:**

**Philippe Destrez Msc MBA**

ASP Scientific Director

Topic: *ISO 22441*

**Speaker 4:**

**Christine Denis Phd**

President WFHSS

Topic: *Education and Guidelines*

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CONFERENCE 1
VALIDATION

# ECONOMIC COMPARISON OF STEAM STERILIZATIO QUALITY ASSURANCE POLICIES IN GERMAN AND IN CHILIAN HOSPITALS

**Markus Auly**
*Independent CSSD Consultant and Educator*
*Zug /*
*Switzerland*

## AIM

There is a big difference in the steam sterilization quality assurance systems between countries that are relying process validation and parametric release (mainly Europe) versus countries that are not used to validating processes but are mandating the use of certain steam sterilization indicators for quality control and batch release.
The goal of this study is to directly compare two exemplary countries of each of the respective approaches - Germany and the WFHSS host country Chile - by describing their legal requirements, their typical practices, associated workflows and the economic burden that these quality systems put on hospitals. By generating more transparence about both systems, we are hoping to support decision makers and policy shapers in taking technically and economically beneficial decisions in the future.

## METHODS

Survey-questionnaires and semi-structured interviews were used to collect information from 10 German and 13 Chilean hospitals about the steam sterilization quality systems they have in place. This was put in context with the guidelines in force that are defining the legally mandated minimum requirements in both countries.
From the above information the following scenarios were 3 groups per country:

1) Germany legally required minimum
2) Germany automated solution (integrated BDT and Batch control)
3) Germany over-compliant solution
4) Chile legally required minimum
5) Chile automated solution (integrated BDT and Batch control)
6) Chile over-compliant solution

Total yearly costs were calculated for all these based on prices received from surveys/interviews, from respective market leading indicator / equipment manufacturers and from public market information in Chile: https://www.mercadopublico.cl

## RESULTS

The average total cost (based on a 8 STU steam sterilizer with 2500 production batches per year) of 13 Chilean hospitals was found to be around 7'550 USD per sterilizer or 0.38 USD per STU sterilized. The total average cost of 10 German hospitals was found to be only around 3'200 USD or 0.16 USD per STU.
The total annual costs for the three scenarios were found to be roughly in these ranges:

| | | |
|---|---|---|
| 1) Germany legally required minimum | ~2300 | USD / year |
| 2) Germany automated solution | 3'000 – 3'500 | USD / year |
| 3) Germany over-compliant solutions | 3'200 – 4'000 | USD / year |
| 4) Chile legally required minimum | 2'300 – 2'800 | USD / year |
| 5) Chile automated solution | 5'500 – 6'300 | USD / year |
| 6) Chile over-compliant solutions | 5'400 – 16'000 | USD / year |

## CONCLUSIONS

The study shows a significant difference in the average total cost of quality assurance between the participating Chilean and German hospitals. These differences are most marked in the group of over-compliant hospitals in Chile which had costs that were by the factor 2-4 times higher than in over-complying German hospitals.
For all three comparable scenarios the policies based on process validation and parametric release had a lower yearly total cost per sterilizer than the indicator-based solution. With the current price structures the validation-based system in Germany has the higher cost efficiency than the indicator-based system in Chile.
The high variation of total costs in Chilean compared to a low variation in German hospitals suggests that the German validation-based system has a higher degree of clarity of what needs to be done to be "safe enough" while the Chilean framework leaves CSSD managers with some uncertainty of what is "safe enough". This appears to lead to a "more is better" attitude and generally higher spending where the budget situation allows for it.
These results suggest that besides safety and workflow considerations also the economy of a CSSDs is highly impacted by the regulations in place as well as by the decision of CSSD management to simply fulfill or widely overfulfill these regulations.

CONFERENCE 6
INNOVATION AND GREEN

# INCREASING STERILE SERVICE DEPARTMENT REPROCESSING CAPACITY TO SUPPORT SUSTAINABILITY OUTCOMES

**Sulisti Holmes**
*National Services Scotland*
***Edinburgh / United Kingdom***

## AIM

Research shows that the shift from single use to reusable medical devices can have positive financial and environmental impacts[1]. However, the reprocessing infrastructure and challenges have not been considered in most studies.

By using novel technologies, this proposed study focuses on exploring solutions to increase Sterile Service Department (SSD) reprocessing capacity, thereby overcoming barriers constraining the sustainability agenda.

## METHODS

A national working group was set up to explore the potential move from single use to reusable instruments reprocessed in SSD in the first instance. A national survey was issued to understand the current SSD landscape, infrastructure capacity, workforce and challenges. A medium-size SSD operating 24/7 with lack of spare capacity and limited space for extension was selected to be the pilot site. Information on cycle performance, machine utilisation/performance/operation were gathered using a smart monitoring tool, while workload schedule and resource allocation were transferred from the tracking system. All of this data was imported into a discrete event simulation tool (ProModel® Process Simulator) to analyse system flow/bottlenecks and predict 3 outcomes for:

1. As-is performance (test for accuracy using previous year data)
2. Resilience testing: volume increase without staff increase.
3. Volume increase for 20% with staff increase

## RESULTS

The survey results identified SSD challenges such as limited capacity and space, workforce, inconsistent training, aging facilities and equipment, breakdown of equipment, barrier to reprocessing due to design/materials. Capacity challenge was identified by 71% of respondees. Therefore, the priority focussed on exploring methods to increase SSD capacity in the existing facility.

The results from simulation exercise as follow:

1. An as-is model with output of 348,000 items per year was created with 95% accuracy;
2. A small output increase (6%) with output of 369,000 items per year was achievable with existing staffing;
3. The expected increase of 20% volume (417,000 items/year) was achievable but required a staffing increase of 15% to maintain current efficiency levels.

Items refer to all trays, supplementary and ward packs.

## CONCLUSIONS

The simulation process allows SSD to experiment with different operating scenarios in order forecast workloads and capacity, uncover and prevent bottlenecks in operations, and optimise capacity planning and scheduling (staff and machines), while streamlining production flows. In a facility with the perception of a lack spare physical capacity, it is possible to create a 20% increase in production, with a combination of a 15% staff increase, removal of process inefficiencies and resource re-allocation. Simulation data can inform the best areas of staff deployment and machines scheduling.

By adjusting to the current operating model, SSD could free up physical capacity to absorb additional workloads to support sustainability agenda.

## REFERENCES / ACKNOWLEDGEMENTS

[1]Keil, M. et.al.2023. The impact of switching from single-use to reusable healthcare products: a transparency checklist and systematic review of life-cycle assessments. Eur. J. Public Health. 33(1): 56–63. doi: 10.1093/eurpub/ckac174

CONFERENCE 7
INNOVATION AND GREEN

# AI FOR DEVELOPING COUNTRIES CSSDS, THREAT OR OPPORTUNITY

*Hamid Zare Shah Mers*
*Jam Sterilization Inst.*
*Tehran /*
*Iran, Islamic Republic of*

## AIM

In This presentation, I will try to analyze the dynamic relationship between artificial intelligence in central sterile service departments and the impact of it in healthcare quality in developing countries by researching potential benefits and challenges associated with AI. I will try to provide an insight that whether AI in CSSD may be a threat or can be opportunity for having an advanced sterilization practice. The aim is understanding of the implication and ethical concentration and potential solutions related to the insertion of AI in CSSD in the context of developing countris.

## METHODS

The method I use is the background check of AI in other industries and analyzing existing data that we can collect from other medical industries. I will try to define the expert's visions and the strategies can be engaged in quality assurance of sterilization handled by AI, and it will be affected on human resource.
Comparing existing models of enterprises that they are using AI in the departments which that in past were handling by human is also the part of method

## RESULTS

The potential benefits of AI in cost are undeniable. We can use this technology with Zero% mistake percentage instead of human, but there are too many challenges associated with AI adaptation. We will need to draw many recommendations and instructions to the hospitals to prevent any potential challenges that we didn't measure also AI must be tried in developed countries before other countris. Because of the fewer gaps between hardware's and the knowledge and existing professionals to prevent problems, and we should collect cases studies such as successes story and fail stories to improve guidelines for future.

## CONCLUSIONS

In conclusion, I believe that the integration of AI into Central Sterile Service Departments in developing countries should be done with caution and that success stories from developed countries should be used. The potential efficiency of artificial inteligence in quality control, data management and cost savings is a key factor for its quick implementation. Meanwhile, we need to have international cooperation, knowledge exchange and strategic partnerships with AI and medical industries to overcome the challenges with a global approach to the sterilization improvement movement. The future of CSSDs in developing countris depends on our ability to guide the ethical application of AI technology in classroom activities and ensure that we have a path to reap the benefits of all CSSDs.


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CONFERENCE 9
FLEXIBLE ENDOSCOPY

# ESTABLISHING PRECONDITIONS FOR EFFECTIVE DUODENOSCOPE REPROCESSING: AN OBSERVATIONAL COHORT STUDY

*Diana Bulkmans*
*Co-Author*
*Rotterdam / Netherlands*

## AIM

The use of contaminated duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) has caused numerous healthcare-associated infection outbreaks. Despite adherence to reprocessing protocols, duodenoscopes often remain contaminated. Moreover, there's a lack of evidence outlining the prerequisites for adequate duodenoscope cleaning, disinfection, drying and storage to prevent contamination. This study aims to identify risk factors involved in the reprocessing procedures of duodenoscopes that could affect the rates of contamination.

## METHODS

Cultures from duodenoscopes with a disposable cap design collected between February 2022 and December 2023 were included. Contamination was determined by the presence of microorganisms originating from the gut or oral cavity (MGO). Data on the use of duodenoscopes, reprocessing lead times and staff involved in the reprocessing were retrieved from electronic medical records. Risk factors were identified based on reprocessing guidelines and the literature. These included a delay of more than 30 minutes in initiating manual cleaning, manual cleaning duration of five minutes or less, drying time less than 90 minutes, experience level of reprocessing staff, and storage duration exceeding 7 days. A generalized linear mixed-effects model was employed to investigate the impact of these risk factors on duodenoscope contamination.

## RESULTS

A total of 307 duodenoscope cultures from eight different duodenoscopes were collected. Contamination with MGO was identified in 58 (18.9%) of the cultures. Throughout the study period, the duodenoscopes were reprocessed 1,296 times. Manual cleaning durations of five minutes or less were associated with higher odds of contamination (aOR = 1.61, 95% CI: 1.10-2.34, p = 0.01). Interestingly, the use of duodenoscopes was associated with reduced odds of contamination (aOR = 0.80, 95% CI: 0.64-0.995, p = 0.045). Factors such as a delay of 30 minutes in initiating manual cleaning, drying times less than 90 minutes, storage times exceeding 7 days, and the experience of reprocessing personnel did not show a clear association with contamination rates.

## CONCLUSIONS

This study highlights substantial knowledge gaps regarding the risk factors for duodenoscope contamination. Delays in reprocessing initiation and incomplete drying, traditionally considered as risk factors, were not associated with an increased risk of contamination in this study. However, a manual cleaning duration of five minutes or less was associated with an increased risk of contamination with MGO. Future research should explore whether more rigorous monitoring of reprocessing times could lead to a reduction in contamination rates.

CONFERENCE 10
FLEXIBLE ENDOSCOPY

# DETERMINATION OF RESIDUAL ENDOTOXINS IN ENDOSCOPIC DEVICES: IMPLEMENTATION OF A COMPLEMENTARY MONITORING TOOL FOR HIGH-LEVEL DISINFECTION (HLD)

***Troy Ejsmentewicz***
*Translational Medicine, Fundación Arturo López Pérez (falp)*
***Santiago / Chile***

## AIM

Gastrointestinal endoscopy is effective and safe for the detection, diagnosis and treatment of gastrointestinal diseases. Guidelines for reprocessing endoscopes should be continually reviewed to prevent infections. Most of these guidelines focus on eliminating live bacteria, without considering the residual membranes, nucleic acids, proteins and polysaccharides of dead microbes as a potential source of nonspecific inflammatory reactions or endotoxemia. The objective of this work was to develop a biological tool based on live human peripheral blood mononuclear cells (PBMCs) exposed to residual washing waters from routine reprocessing protocols and the measurement of interleukin 1-beta by real-time PCR to evaluate the compliance level and performance of the High Level Disinfection (HLD) protocol implemented in our institution.

## METHODS

Wash water was collected directly from each device using 40 ml of sterile saline, before and after applying the HLD protocol. PBMCs were obtained from healthy volunteers, cultured, and directly exposed to wash water for 1 h at 37 °C and 5% CO2. Total RNA was isolated and 100 ng was used for retrotranscription and real-time PCR to detect IL-1b mRNA levels. A pilot study to evaluate the optimal dose and correlation with the ATP bioluminescent assay used as routine testing considered 8 randomized devices collected after colonoscopy (4) and upper gastrointestinal endoscopy (4). Furthermore, to evaluate the sensitivity and linearity of our biological tool, we have proposed the analysis of 36 endoscopes that will be cleaned using a standardized (18) and non-standardized (18) HLD protocol. LPS and saline solution were used as positive and negative controls for each assay, respectively.

## RESULTS

The pilot study demonstrated that the bioluminescence assay performed before applying a HLD protocol reached a mean ATP value of 5029 RLU (min-max: 388-13280), and after the reprocessing protocol, the mean value decreased significantly to 28 RLU (min-max: 1-126) (p=0.0056, t-test). The presence of IL-1b mRNA was mainly correlated in water samples collected from devices used for colonoscopy. The biological assay was able to detect a two-fold increase in IL-1b compared to the negative control, and higher mRNA levels correlated with samples before the HDL protocol. All cases (8 of 8) after reprocessing were negative. We are currently still evaluating sensitivity and linearity using deliberately poorly cleaned endoscopes.

## CONCLUSIONS

We have developed a laboratory method based on cell and molecular biology to evaluate the presence or absence of remanent microbiological debris after applying a High-Level Disinfection protocol for reprocessing endoscopes used during routine clinical procedures in our center. Our method is able to detect the activation of early pro-inflammatory genes, such as IL-1b, allowing us to assess the risk of unexpected complications, such as local or systemic inflammation and the compliance level of the institutional standarized operational procedure.

## REFERENCES / ACKNOWLEDGEMENTS

Funding: ANID-FONDECYT Grant N°1221415 and an internal grant from Fundación Arturo López Pérez FALP-LMT-2024

CONFERENCE 11
FLEXIBLE ENDOSCOPY

# IMPORTANCE OF DRY STORAGE TO PREVENT BIOFILM FORMATION

*Michelle Alfa*
*Canada*

## INTRODUCTION:

Flexible lumened endoscopes contaminated with multi-antibiotic resistant bacteria have transmitted these organisms to patients undergoing endoscopy. These exogenously transmitted organisms have resulted in long term colonization and/or infections in patients. Various clinical investigations have shown that repeated rounds of full reprocessing can lead to accumulated build-up biofilm formation within the channels of flexible endoscopes. The objective of this presentation is to identify why dry storage is crucial to prevent accumulated biofilm formation in flexible endoscope channels.

## METHODS

The "build-up biofilm" (BBF) and "cyclic build-up biofilm (CBB) models mimic endoscope reprocessing using repeated rounds of dual species biofilm formation by P. aeruginosa and E. faecalis. Each round of biofilm formation was followed by full reprocessing including high level disinfection (HLD). These models can be used to demonstrate how effective the cleaning protocol is, as well as determine if P. aeruginosa and E. faecalis survive over time.

## RESULTS

As early as 1991 there was clinical data from duodenoscopes showing recovery and rapid proliferation of bacteria to 6 Log10 levels over weekend storage that could be prevented by 10 min forced air drying. Recent data from the BBF endoscope channel model confirmed viable but non-culturable microorganisms could recover/proliferate to 6 Log10 /cm2 levels after room temperature storage and that these levels persisted for 6 months. Although 10 mins forced air drying is effective for larger diameter channels (i.e. no visible droplets) the optimal method and duration of channel drying for smaller diameter channels in flexible endoscopes is yet to be established. Recent worldwide clinical data confirms that survival of high concern microorganisms within endoscope channels after full reprocessing is still a frequent occurrence. These persistent microorganisms can then replicate and form BBF if moisture is left in the channels during storage. Although humidity indicator paper (e.g. blue cobalt chloride; turns from blue to pink when wetted) can detect gross fluid droplets, there are no current guidelines to detect low moisture levels in endoscope channels. As such it is difficult to determine what moisture level (if any) indicates adequate channel drying.

## CONCLUSIONS

It is clear there is a need for effective dry storage of flexible endoscopes to prevent accumulated buildup biofilm formation within channels. However, it is unclear how endoscopy clinics can confirm the adequacy of endoscope channel drying.


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CONFERENCE 13
CLEANING AND DISINFECTION

# IDENTIFICATION AND PREVENTION OF SURFACE ALTERATIONS ON SURGICAL INSTRUMENTS CAUSED BY WATERBORNE MINERALS

*Matthias Tschoerner*
*Chemische Fabrik*
*Dr. Weigert Gmbh & Co. Kg*
*Hamburg /*
*Germany*

## AIM

During the reprocessing of medical devices, in particular on surgical instruments, unwanted surface alterations and discolorations may occur. Some surface alterations and discolorations arise from waterborne minerals during the cleaning and disinfecting process when traces of these are able to dry on the surface.
Also known from steam sterilization, surface alterations and discolorations may occur when the water used for feeding the steam generator has a too high content of waterborne minerals.

## METHODS

To get a closer understanding of the nature of these alterations, instruments with characteristic discolorations from the clinical routine of different hospitals were used for further studies.
As methods of surface analysis the energy dispersive X-ray spectroscopy (EDX) and X-ray photoelectron spectroscopy for chemical analysis (ESCA) were used to investigate chemical nature of these discolorations. First, the overall elemental composition of the deposits were analyzed by energy dispersive X-ray spectroscopy. For further characterization of the deposits the X-ray photoelectron spectroscopy for chemical analysis was used which enables not only an elemental analysis but also an interpretation of the possible compounds. To get an idea on the thickness of some discolorations was subject to an iterative investigation of sputtering of the surface by means of ESCA measurements. These iterative investigations were ended when the surface of the instrument was reached and subsequently the composition of the plain instrument material were analyzed.
Further physical-mechanical investigations were made to find out if such surface alterations and discolorations are adherent to the surfaces or detach during mechanical stress. For this purpose, the surfaces were analyzed and documented by high resolution electron microscopy before and after stress to discolored surfaces.

## RESULTS

The results of the analysis of the different surface alterations found in the clinical day to day work directs them to their chemical and physical nature, their origin from specific water minerals, and their point of appearance in the processing cycle.
Depending on the chemical and physical nature and their adherence to the surface a crosslink to their hygienic importance is possible.

## CONCLUSIONS

The results lead to possible origins for the discolorations described. Such surface alterations are not tolerable, since, according to general accepted recommendations, no visible soiling, deposits or other residues have be recognized on the medical device after cleaning e.g. [1], furthermore, residues may have an adverse effect on the sterilization success.
The description of discolorations and surface alterations of surgical instruments and methods to identify their nature will help to find possible causes within the processing procedures and to define measures to avoid them.
Further measures will be presented which may be applied to eliminate identified discolorations from the instruments by corrective actions.
The importance of using appropriate water qualities is highlighted.

## REFERENCES / ACKNOWLEDGEMENTS

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CONFERENCE 14
CLEANING AND DISINFECTION

# INFLUENCE FACTORS ON INSTRUMENT CLEANING RESULTS – HOW TO ACHIEVE A GOOD RESULT AND WHAT IS GOOD ENOUGH?

*Gerhard Kirmse*
*Aesculap Ag*
*Tuttlingen / Germany*

## AIM

Meanwhile it is widely agreed that a good cleaning result is essential for a safe and efficient reprocessing but strategies and methods vary largely and many times we are lacking evidence. Therefore a systematic review of influence factors is performed in laboratory setting to delineate the most important factors and the most promising approach.

## METHODS

Design and evaluation of cleaning methods still show deficiencies. Therefore validation is the method of choice to ensure proper cleaning results but experience has been disappointing in several aspects. Most often, commercially available Crile clamps are used however, these are relatively easy to clean.
In addition the type of soil and its dry time shows a large influence and blood on its own is by far not the most difficult challenge. Therefore influence factors of soil and dry time were evaluated in a laboratory study. In parallel influence factors of machine cleaning results were evaluated in a multifactorial design study.
Three test methods for cleaning success are compared in terms of sensitivity, accuracy, handling and efficiency. Finally all these results are combined in a process and quality control strategy.

## RESULTS

The comparison of the test soils confirms that blood is relatively easy to clean and shows very little effect of extended dry time, while mixtures of blood with disinfectants and other body fluids represent a harder challenge, which increases over time.
On the basis of these results, a washer-disinfector test series is performed. PCDs contaminated with either blood or Browne test soil are cleaned in various positions of the washer-disinfector with different cleaners and processes. Process variables, such as pre rinse, temperature, dosage, holding time, pressure, and water quality are then tested. Pressure turns out to be the most influential factor. Other strong influence factors as position and loading depend on the users.
From the test methods used (BCA protein test with elution, TOC test with elution, fluorescence) BCA has been evaluated as most useful but it is cumbersome to test larger quantities of instruments or process challenge devices (PCDs).
The test method of PCDs was further developed by a camera system, which allows a quantitative, quick evaluation of a large number of PCDs with a good correlation to protein test, especially at low values.

## CONCLUSIONS

The methods and results allow a targeted optimization of cleaning processes.
First a cleaning process should be evaluated and optimized starting with the most promising factors based on PCDs. The optimized process is then challenged with manual factors and tested for stability, standard variation and safety margin. Results are afterwards confirmed by testing clinically used instruments (Validation).
During routine operation visual inspection of instruments is an important tool but not sufficient as joints, lumen and crevice cannot be fully evaluated. Therefore, simplified test should be used, however they have to be qualified.
By such an approach, cleaning results can be largely improved with reasonable resources, however methods, standards and limits need further discussion and development.

## REFERENCES / ACKNOWLEDGEMENTS

Dr. Gerhard Kirmse and Silke Haibt-Winandi are employees of Aesculap AG, Germany

CONFERENCE 15
CLEANING AND DISINFECTION

# BASICS OF SAFE ENDOSCOPIC REPROCESSING

*Eric Smith*
*Olympus America Inc.*
*Center Valley /*
*United States*

## AIM

To emphasize the critical role of each step in the endoscope reprocessing workflow in preventing infections and ensuring patient safety. This presentation focuses on the fundamentals of reprocessing, including pre-cleaning, leak testing, manual cleaning, high-level disinfection, drying, and storage.

## METHOD

A structured review of evidence-based practices and international guidelines was conducted, alongside a comparative analysis of manual versus automated reprocessing techniques.

## RESULTS

The findings show that each stage, from pre-cleaning to storage, plays an essential role in successful endoscope reprocessing. Manual cleaning is crucial for removing bioburden, while thorough drying and proper storage are key in preventing recontamination. Automated disinfection provides consistency but requires adherence to manufacturer protocols.

## CONCLUSIONS

Effective endoscope reprocessing relies on adherence to fundamentals. Staff training, quality assurance, and routine equipment maintenance are essential for preventing infections and ensuring safe outcomes. Emphasizing these core practices helps healthcare teams uphold patient safety and meet regulatory standards.

## KEYWORDS

Endoscope reprocessing, infection prevention, high-level disinfection, manual cleaning, patient safety.

CONFERENCE 16
EDUCATION

# A WELL-STRUCTED STERILE SERVICES DEPARTMENT TRAINING SYSTEM FOR SUSTAINABLE DEVELOPMENT IN A VOLATILE ENVIRONMENT

***Chun Kin Lee***
*Hong Kong Hospital Authority*
***Hong Kong***

## AIM

Strategic staff training is one crucial element in SSD management and services development for the delivery of comprehensive sterile services.
In 2021-2023, the NTWCSSD's attrition rate of supporting and supervisor colleagues was 20% and 21%, respectively. In addition to the newcomers as replacements, maintaining a well-structured department training system is crucial for sustainable service development in such a volatile environment.
A Quality Index (QI) monitors and quantifies service quality. [QI = (number of product defect) / (workload in washing area)]

## METHODS

Training modules in NTWCSSD were distinctively designed based on job functions and staff experiences, ensuring an all-rounded step-by-step coverage of skills and knowledge.
All newly joined colleagues were required to participate in the Preceptorship Scheme, matching each with an experienced preceptor for nine weeks—a one-to-one mentoring process aimed at achieving effective trainer-trainee communications and prompt problem-solving. The Train-the-Trainer Program was launched to target all the qualified preceptors in the scheme to ensure training quality. Concepts of leadership, effective feedback, constructive feedback and praising were introduced to the preceptors for successful impartation of knowledge to their trainees.
On top of personalized preceptorship, a 6-week Tier 1 in-house training was scheduled quarterly to provide all newly joined colleagues with a macroscopic view of the department. Course content involved (i) Infection control and OSH issues, (ii) SSD workflow, (iii) Basic decontamination process and (iv) Storage management. Participants who successfully passed the final written assessment would be awarded a certificate upon course completion, acknowledging their qualifications as SSD staff. Existing colleagues with two years' experience would also take part in the course to refresh memories.
Sterile Supplies Supervisors or above were recruited into the weekly-based Tier 2 in-house training for professional enhancement in sterilization science. The course syllabus ranged from advanced theories on decontamination science to operation and quality management.
On the other hand, the current Supporting staff receive routine training each Friday. Sections involve disseminating good practices, sharing nearly missed cases, and reminding staff about workplace safety.
Besides, Four-week Autoclave Operator Trainings were also arranged voluntarily to enrich supporting staff's knowledge on (i) Sterilization theories, (ii) Sterilization area and sterile store workflow, (iii) Components of steam sterilizers, (iv) Re-validation, (v) Environmental control and (vi) OSH issues encountered by autoclave operators.

## RESULTS

The average QI (2021 – 2023) during this period is 0.26% (Range from 0.14% to 0.49%, Standard Deviation 0.09%). A departmental Key Performance Indicator, Quality Index (QI), has been adopted for monitoring service performance.

## CONCLUSIONS

Applying the QI and constantly refined training syllabus, NTWCSSD has become a sustainable training centre to equip all staff with the essential skills and concepts at work. All training courses arranged had achieved 100% full completion by their participants, benefiting both the department's production performance and staff's competencies.

CONFERENCE 17
EDUCATION

# EDUCATING CSSD: THE SELF REGULATING STUDENT

*Martijn Gerritsen-Ter Brugge*
*Educator*
*Lochem / Netherlands*

## AIM

As of last year we've made innovative steps making the CSSD course more flexible, accommodating the needs of the local Hospitals. By implementing new techniques we also made our students more ready for the modern age of CSSD.

## METHODS

We've created a modular, online, learning system fited for our students. We've worked out ten subjects over a two year course. These subject apply directly to the core activities the student shows in their workplace. Next to these subjects, we tied in the soft skills the students will require, as well as the mandatory courses required for a community college program (Language, Math, Citizenship).
Students who wish to complete one of the modules, can do so by completing some assignments fittng the development goals they assigned for themselves. As teachers we suggest multiple assignments (making video's, writing essays, presentations, games etc.), but students are also encouraged to come up with their own assignment. As long as the goals are met. This is in line with our vision, which follows the Self Termination Theory[1] of Deci & Ryan, and the works of Zimmerman[2].
At the core of these modules are competency based interviews. At these interviews the students have the chance to defend their product choices, show technical insights in their workplace and can elaborate on their development. They also get the chance to talk about their future goals.

## RESULTS

As of this schoolyear the participation of our students have become higher. They get to develop themselves. They are at the helm of their own future in the CSSD. In a workplace that is subjected to innovation we need a workforce that can keep up with the high demands of the OR. Students who graduate need to keep up their skills by themselves[3] and be able to do so.
We also have the chance to help our hospitals recruit more flexible. Instead of one start of the schoolyear, we have five.jump-off points. Our continuing contact with the teaching hospitals gives us the encouragement we are on the right path. We get the chance to visit once, twice a year (and they also can come to us) and this is where we get our feedback.

## CONCLUSIONS

We have classes were new students roll in, and old ones move out. This creates a class where the CSSD information is everflowing from student to student, within the walls of the college. We create everlasting content that is echoing through schoolyears. We make podcasts, and videos. Our classroom is adorned with posters from bacteria as well container labels from former alumni.
Lastly it's great to point out, the content we create is freely available on the internet. It's on an open source network. Of course it's in our native tongue, but we believe information should be given to all who want to use it!

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CONFERENCE 18
PACKAGING AND STERILIZATION

# STERILIZATION WRAP - CHECKLIST FOR CSSD MANAGER

*Menno Dufour*
*France*

When evaluating a new sterilization wrap for your CSSD, implementing a checklist is a smart way to stay organized and make direct comparisons, but what should be considered when developing a checklist?

Sterilization wrap is commonly used of two layers, sometimes bonded and sometimes unbonded, and must comply with ISO 11607-1:2019. The wrap allows for sterilization (compatibility with and penetration of a sterilant), aseptic presentation at point of use, prevention of microorganism from coming into contact with the sterile contents, and be strong enough to avoid damage during packaging, handling, transport, and storage.

The notion of a packaging system (PS), which is the combination of a sterile barrier system (SBS) and protective packaging (PP), was introduced in 2006 and published in ISO 11607-1. To help in differentiating between a SBS and PP, symbols[1] have been created and published in the 2019 version of ISO 11607-1. These symbols are a helpful way to navigate between various configurations manufacturers might offer. Additionally, according to EN 868-2, there are three types of single-use sterilization wrap materials: Spunbond-Meltblown-Spunbond (SMS) Nonwovens, Wetlaid Nonwovens, and Crepe. It is noted that reusable woven textile material is still within the standard but not recommended by WFHSS[2] as most do not provide a sufficient barrier to microorganisms.

This presentation will go into details of the above mentioned SBS wrap materials, including technologies, mechanical properties, microbial barrier, material safety, shelf-life limitations (before and after sterilization), sterilization compatibility, sustainability and wet packs. Regarding wet pack issues, a recent development in sterilization wrap has shown improvement with reducing the occurrence of this phenomenon (patent application pending - WO2023126647[3]).

Another item to reference when developing a checklist is the product Instructions for Use (IFUs), there you will find valuable information such as try weight limits, sterilization method compatibility, precautions and validated wrap folding methodologies which should follow ISO TS 16775:2021.

A future consideration for inclusion into a checklist is accessories such as baskets, corner protectors, or silicone pads. In regard to baskets, there are specific baskets for use with sterilization wrap (i.e.: flat base basket) and other types for rigid containers (i.e.: wire mesh baskets). If rigid containers are used, they should be checked for water tightness according to a water leak test (FD S98-053). In the event of issues, sterilization wrap could be used as the SBS to wrap the instrument basket and put into the rigid container which will act as a protective package[4].

There are many considerations to keep in mind when developing a checklist for the evaluation of sterilization wrap. These will be discussed, and suggestions made for possible inclusion.

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[4] Evaluation of the water test to assess the functionality of sterilization containers - Lambert, Christophe (Chambery, France), WFHSS Bonn 2017

CONFERENCE 19
PACKAGING AND STERILIZATION

# PRACTICAL EXPERIENCE IN IMPLEMENTING THE VALIDATION OF STERILE BARRIER SYSTEMS ACCORDING TO ISO 11607-2:2020 AT CSSD IN GERMANY

*Rainer Stens*
*Germany*

In this presentation, Rainer Stens, member of the executive board of the German Society for Sterile Product Supply (DGSV), is presenting how validation of packaging processes is implemented in Germany using the example of his own CSSD located in the city of Bonn.

While ISO 11607-2:2019 is demanding a thorough validation of the packaging process, it does not sufficiently describe how to do this in practice. In order to close this gap the DGSV created the "Guideline for the validation of packaging processes according to ISO 11607".

This guideline which was last updated in 2020 describes in detail how to perform the validation of all three commonly used packaging techniques - pouches, sheets & rigid containers – each one in its own chapter.

The 2020 version of this document was recently translated to English and to Spanish language and is available for free download on the website of the DGSV (link). Attending Rainer Stens' presentation will help English and Spanish speakers interested in this this recently translated document to understand its background and the way it has already been implemented by German CSSDs.

## DGSV GUIDELINES

https://www.dgsv-ev.de/fachinformationen/leitlinien/

CONFERENCE 20
PACKAGING AND STERILIZATION

# EXPLORING DIFFERENCES BETWEEN STEAM PENETRATION IN A B&D TEST PACK AND IN A CHANNELLED INSTRUMENT

*Francesco Tessarolo*
*Department Of Industrial Engineering, University Of Trento*
*Trento /*
*Italy*

## AIM

Explore whether significant differences exist between steam penetration in a B&D test pack and in a channelled instrument.

## METHODS

Experiments were performed in an 8-unit (614 L) steriliser equipped with a degassing system and fed with osmotic water. An infrared sensor[1] and a NCG sensor[2] were installed to monitor, respectively, the vapour fraction at the end of a 70 cm long tube and the amount of non-condensable gases (NCGs) in the steriliser chamber during the exposure phase.
A B&D test pack (stated values 134°-137°C, 3.5 min)[3], compliant with ISO 11140-4:2007, was positioned in the chamber in every cycle. A chemical indicator (CI) strip, obtained from a new B&D test pack (same brand and lot) was inserted up to the closed end of a stainless steel challenge tube (8 mm internal diameter, 50 cm long, and with 1 mm thick walls). The challenge tube represented a channelled instrument [1] and was positioned inside the chamber.
A range of sub-atmospheric, trans-atmospheric and supra-atmospheric processes were run introducing different amounts of NCGs in the steriliser chamber either by varying the pressure of the vacuum-points in the conditioning phase or injecting air (0-1500 mL) at the beginning of the come-up ramp, or changing the number of pulses in the preconditioning phase. All processes shared a 3.5 minutes-long exposure phase at 134.5°C.
Load amount included empty chamber (only B&D test pack and challenge tube) and full load ( 8 nets of 15 kg metallic unwrapped load each + B&D test pack and challenge tube).

## RESULTS

A total of 76 combinations of processes and loads were tested. All resulted in a pass of the B&D test pack, but only sub-atmospheric and trans-atmospheric processes with deep vacuum-points or a limited amount of injected air resulted in a colour change of the CI positioned in the 50 cm long challenge tube. Supra-atmospheric processes never produced a colour change of the CI in the challenge tube regardless of the number of pulses in the preconditioning phase (tested up to 40 pulses).
NCG sensor data documented that the more profound the vacuum-points in the preconditioning phase the lower the amount of NCGs in the exposure phase. Air injections in the come-up ramp also elevated the NCG amount in the exposure phase. Supra-atmospheric processes resulted in a low content of NCGs in the steriliser chamber only when several pulses were used.
The infrared sensor detected higher vapour fractions when deeper values of vacuum-points were achieved and no air was injected. Supra-atmospheric processes never resulted in high vapour fractions despite the low NCG amount in the chamber. Heavier loads favoured higher vapour fractions in channels.

## CONCLUSIONS

B&D test pack does not provide relevant information about steam penetration in channelled loads. Channels, even with relatively large diameter, and limited length, are challenging to be penetrated by steam and demand for low NCG amounts in the chamber and deep vacuum-points during sub-atmospheric or trans-atmospheric conditioning.

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CONFERENCE 21
PACKAGING AND STERILIZATION

# INFLUENCE OF THE LOAD POSITIONING DURING A STEAM STERILIZATION CYCLE: AN EXPERIMENTAL AND NUMERICAL STUDY

**Simon Pletzer**
*Graz University Of Technology, Institute Of Thermal Engineering*
***Graz / Austria***

## AIM

The objective of this study was to examine the impact of the spatial arrangement of medical instruments within table-top autoclaves. Previous studies[1,2] have already demonstrated that the orientation of hollow loads (horizontally or vertically) can exert a substantial influence on the sterility of medical devices.

## METHODS

Temperature measurements were conducted within multiple loads during a sterilization cycle. These loads were uniformly distributed on two separate trays in the entire chamber. Given the limitation of temperature measurements to singular points, a comprehensive three-dimensional computational fluid dynamics (CFD) model of the entire sterilizer (including the chamber, heater, and loads) was developed.

## RESULTS

The simulated data demonstrates excellent temporal and spatial alignment with the experimental results. Notably, the loads located at the front of the lower tray exhibited the fastest heating, whereas those positioned at the edge of the upper tray needed more time for heating. Consequently, it is advisable to prioritize placing heavier medical devices at the forefront of the lower tray to optimize heating efficiency and ensure sterilization.

## CONCLUSIONS

Utilizing CFD, recommendations regarding the placement of loads inside autoclaves can be established, underscoring the significant potential of computational models in both the advancement of current autoclave designs and the development of new ones. Furthermore, these models provide researchers, companies and users valuable insights into the complex physical processes occurring within steam sterilizers, offering high-resolution temporal and spatial details.

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25th wfhss CONGRESS

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# Artificial Intelligence in Sterilization Centers: Maximizing its potential for daily efficiency

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CONFERENCE 22
MISCELLANEOUS

# PRECISION IN PRACTICE: INSTRUMENT MANAGEMENT AS A KEY TO COST CONTROL AND SAFETY IMPROVEMENT

*Juana Baez Hernández*
*Ribera Salud Valencia / Spain*

## AIM

To achieve efficient management and control of the instruments through a coded and continuously updated inventory, detailing the cost of each instrument, associated repairs/replacements, and maintaining its usage history, enabling the assessment of its productivity, as well as real investment needs.
To improve healthcare quality by enhancing patient and professional safety through continuous computerized monitoring of the various phases of the process related to the processing and use of instruments, enabling immediate action upon detected incidents, and most importantly, actively contributing to their prevention.

## METHODS

To achieve these objectives, the University Hospitals of the Ribera Group use two integrated computer systems:
Trazins: Traceability Software. A system for managing surgical instruments and traceability where all surgical instruments are inventoried and coded using a unique datamatrix and alphanumeric code, along with associated costs. This tool records all processes applied to surgical instruments in the Central Sterilization Unit (washing/disinfection, assembly, and sterilization), including the results of quality controls for each process.
Cynara: Digital Clinical History. A digital clinical history computer system that records every episode of primary and hospital care associated with a medical record number, identifying the professionals responsible or involved in each process. This is where the instruments used in an intervention are registered (generating a unique code per intervention) by reading the barcode on the identification label of each instrument or instrument set. Automated reading prevents registration errors and improves efficiency.

## RESULTS

Effective tool for the control and management of surgical instruments: Trazins system allows real-time knowledge of the hospital's immobilized material value concerning instruments, essential for decision-making regarding future investments.
Increased safety and protection for the patient: Integration allows verification of all instruments used in a specific surgical process, along with the results of quality controls they underwent. It also facilitates the identification of all subsequent surgical processes in which they were used.
Enhance the professional's security: Having real-time access to the results of their management means gaining confidence and being prepared for immediate action in response to errors or problems.
Obtaining Multidirectional Traceability in an Instant: Integration between Trazins and Cynara enables the reconstruction of the usage history of a specific product with all associated variables instantly, thanks to the database created in the Ribera Group Hospitals

## CONCLUSIONS

Integration leads to improvements in:
Safety and Healthcare Quality: Ensured by a control system that guarantees safety at each stage and its traceability.
Cost/Expense Control and Management: Real-time knowledge of inventory levels, quantification, and productivity enables decisions based on objective and measurable needs.
Legal Framework: The unique identification of surgical instruments anticipates compliance with European regulations, which will require manufacturers to implement this type of identification for Class IIb products starting May 25, 2025, not ruling out the obligation to retain these records for healthcare institutions.

## REFERENCES / ACKNOWLEDGEMENTS

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2 / SEDE. (2023) Guía de Reprocesado de Dispositivos médicos y Quirúrgicos. Sociedad Española de Desinfección y Esterilización (SEDE).

CONFERENCE 23
MISCELLANEOUS

# CHANGE MANAGEMENT: A CRITICAL PART OF LEADERSHIP SUCCESS

***Roel Beltran Castillo***
*Canberra Health Services*
***Canberra /***
***Australia***

## AIM

To share experience in change management Central sterilization Services. Positive outcomes and lessons learned in the implementation process of critical changes in the department. From major renovations, minor equipment changes to staffing restructuring, among others, CSS Leadership must find effective approach to successfully implement these changes.

## METHODS

One model of change management approach is the ADKAR which is an acronym that focuses on five outcomes that an individual or institution needs for a change to be successful. AAwareness of the need to change, Desire to support and participate in the change, Knowledge of how to change, Ability to implement the required skills and behaviour and Reinforcement to sustain the change.
Dr. John Kotter however, in observing one hundred companies identified eight steps that has been used in teaching change management.
Harrison et al. 2021, did a review of change management used in healthcare that included a 2012 research studies. The review also highlights the potential to integrate other models for change management with models commonly applied for improvement and implementation to support positive changes in healthcare.
Experiences in three major hospitals in a first world country will be shared, drawing lessons learned on the models of change within the CSSD.

## RESULTS

There is no perfect model in healthcare but the ability to flex and adapt to changes within the models will determine the level of success. Engagement with the team that are impacted most and recognizing champions of change in specific areas are critical to success. The complexity and nature of reprocessing requirements, constant fast paced advances in surgical interventions impacting medical device reprocessing outcomes, change management in CSSD has potetially evolved the infection control risks associated with our ability to address rapidly changing medical and surgical interventions.

## CONCLUSIONS

CSS team, determines the outcome and success of positive changes envisioned by its leaders. High level engagement within impacted teams, from conception to final implementation and maintaining these positive changes is an ongoing process. This is critical to our ability as reprocessing professionals to keep at pace with changes in standards and technological advances surgical interventions that impacts on our ability to provide safely reprocessed medical devices

## REFERENCES / ACKNOWLEDGEMENTS

Harrison, R., Fischer, S., Walpola, R.L., Chauhan, A., Babalola, T., Mears, S. and Le-Dao, H., 2021. Where do models for change management, improvement and implementation meet? A systematic review of the applications of change management models in healthcare. Journal of healthcare leadership, pp.85-108.

CONFERENCE 24
MISCELLANEOUS

# OPTIMIZING CSSD OPERATIONS WITH QR CODE TRACKING

*Nathkritta Sookchum*
*Cssd Vejthani Hospital*
*Bangkok / Thailand*

## AIM

This project aims to leverage the insights gained from QR code tracking to optimize equipment utilization, minimize waste generation, and promote a more sustainable and efficient CSSD operation.

## METHODS

To optimize CSSD operations, this project proposes a QR code tracking system. Each piece of equipment or surgical set will be tagged with a unique QR code. Staff will scan these codes at various stages of the sterilization and distribution process, recording critical information such as the item's status, who handled it, and the timestamp. This method streamlines equipment tracking, ensuring accurate and efficient management of equipment usage, sterilization cycles, and inventory levels. and quality control purposes, enhancing overall operational efficiency and safety within the CSSD.

## RESULTS

The findings of the project demonstrated significant improvements in several key areas. The use of QR code tracking led to a notable reduction in equipment search times, with an average decrease of 20%. This directly translated to increased staff productivity by allowing them to dedicate less time searching for equipment. Furthermore, 80% of staff members reported satisfaction with the new system, highlighting its user-friendliness, time-saving benefits, and improved equipment visibility.

## CONCLUSIONS

The implementation of QR code tracking in the CSSD department proved to be a successful strategy for optimizing operations. This resulted in a significant decrease in equipment search times, leading to increased staff efficiency. Additionally, the system fostered a more positive work environment through its user-friendly interface and improved equipment tracking capabilities. Overall, the research demonstrates the effectiveness of QR code technology in enhancing the efficiency and productivity within the CSSD department.

## REFERENCES / ACKNOWLEDGEMENTS

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CONFERENCE 25
QUALITY AND RISK MANAGEMENT

# NONCONFORMITY AND RISK MANAGEMENT ON PRODUCT

*Norma Hermann*
*Switzerland*

## AIM

The overall goal of the Medical Device Reprocessing Department (MDRD) is to provide a compliant medical device before each use to ensure patient safety. The person responsible for the MDRD must ensure that the MD reprocessing is done in compliance with laws and standards. Unfortunately, NCs (nonconformity defects – due to the products, processes or resources) can occur during reprocessing, which can have a direct or indirect impact on patient safety. Hence the obligation to define and implement a nonconformity management process while considering risk analysis. What are its characteristics according to the requirements SN EN ISO 9001, SN EN ISO 13485, SN EN ISO 14971, and Swiss best practices?

## METHODS

The results of various analyses were used to develop this work:
- Audit reports
- Customer satisfaction
- Customer complaints
- Management review

With these references and by considering the applicable norms and national guidelines, and primarily Swiss best practices, it was possible to conduct in-depth analyses of the main causes of non-conformities (NC).

## RESULTS

Identification of non-conformities (NC) that pose a high risk to patient health, as well as the main causes of these NCs and the necessary solutions.
- Evaluation NCs and manage the associated risks.
- Carrying out regular analyses to find the causes of NCs, eliminate them and ensure that they do not reoccur or do not occur at all.
- Taking necessary corrective and preventative measures.
- Reviewing the effectiveness of these implemented corrective and preventative measures.

## CONCLUSIONS

The MDMD must define and implement an NC management process to ensure the conformity of the MD. What characteristics must this have according to the requirements of SN ISO 9001, SN ISO 13485, SN ISO 14971 as well as the "good practice" with the goal to ensure patient safety.

CONFERENCE 26
QUALITY AND RISK MANAGEMENT

# REVOLUTIONIZING HOSPITAL STERILIZATION: HARNESSING AI, INDUSTRIAL INSIGHTS AND DIGITAL TRANSFORMATION

**Karin Bundgaard**
*Clinical Nursing Research Unit, Aalborg University Hospital & Department Of Clinical Medicine, Aalborg University*
***Aalborg / Denmark***

## AIM

To develop an evidence-based standardized method for transporting and storing surgical instruments between operating room and reprocessing site to ensure their optimal condition for future use.
International infection control guidelines recommend prompt reprocessing of sterilizable medical equipment immediately following surgical procedures[1,2]. Furthermore, that transportation and storage of surgical instruments between operating theater and reprocessing site should occur in a moist environment. These precautions should help reduce the risk of instrument degradation. Prolonged exposure to a dry environment is known to make instruments challenging to clean using standard reprocessing protocols and increases the risk of corrosion.
Traditionally, in Europe, the transportation environment for instruments has been kept dry to minimize the risk of corrosion. Conversely, in the UK and America, moist transportation environments are chosen to ensure efficient cleaning outcomes. However, limited research supports these recommendations and studies conducted in controlled laboratory conditions suggest the necessity to systematically reassess these recommendations under current clinical practice settings[3,4].

## METHODS

Data were collected at a large university hospital where two surgical departments' utilization of new basic instrument sets was monitored in a real-life setting. One department transported instruments under dry conditions, while the other under moist conditions. After approximately 10 and 100 reprocessing cycles, the instrument sets of the two departments were assessed and compared concerning cleaning efficacy (occurrence of protein residue) and preservation of instrument value (occurrence of corrosion). The BCA Protein Assay Kit was used for analyzing for protein residue and visual inspection and microscopy were used to test for corrosion.
The evaluation involved a comparative analysis between the two groups based on the following key parameters:
- The effectiveness of cleaning
- The occurrence and extent of corrosion and surface changes
- The severity of any observed surface alterations

Additionally, laboratory tests were conducted comparing the behavior of various test soils under dry and moist conditions for different time periods in order to compare laboratory and clinical results.

## RESULTS

Data collection will be concluded in May 2024 and findings will be presented at the WFHSS 2024 in Santiago, Chile.

## CONCLUSIONS

This study carries significant socio-economic implications by offering evidence-based insights into how to decrease the incidence of corrosion on reusable surgical instruments, and thereby prolong their lifespan. By reducing corrosion formation, hospitals can achieve substantial savings on the purchase of new instruments and allocate resources more effectively towards other critical healthcare needs.
Moreover, the study contributes valuable knowledge regarding the most effective way for transporting and storing instruments for ensuring their cleanliness. This understanding directly correlates with reducing the risk of potential cross-contamination between patients during surgical procedures. Ultimately, the implementation of optimal transpotation and storage environment enhances patient safety by minimizing the probability of post-operative infections, thereby safeguarding the well-being of individuals undergoing surgical interventions.

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