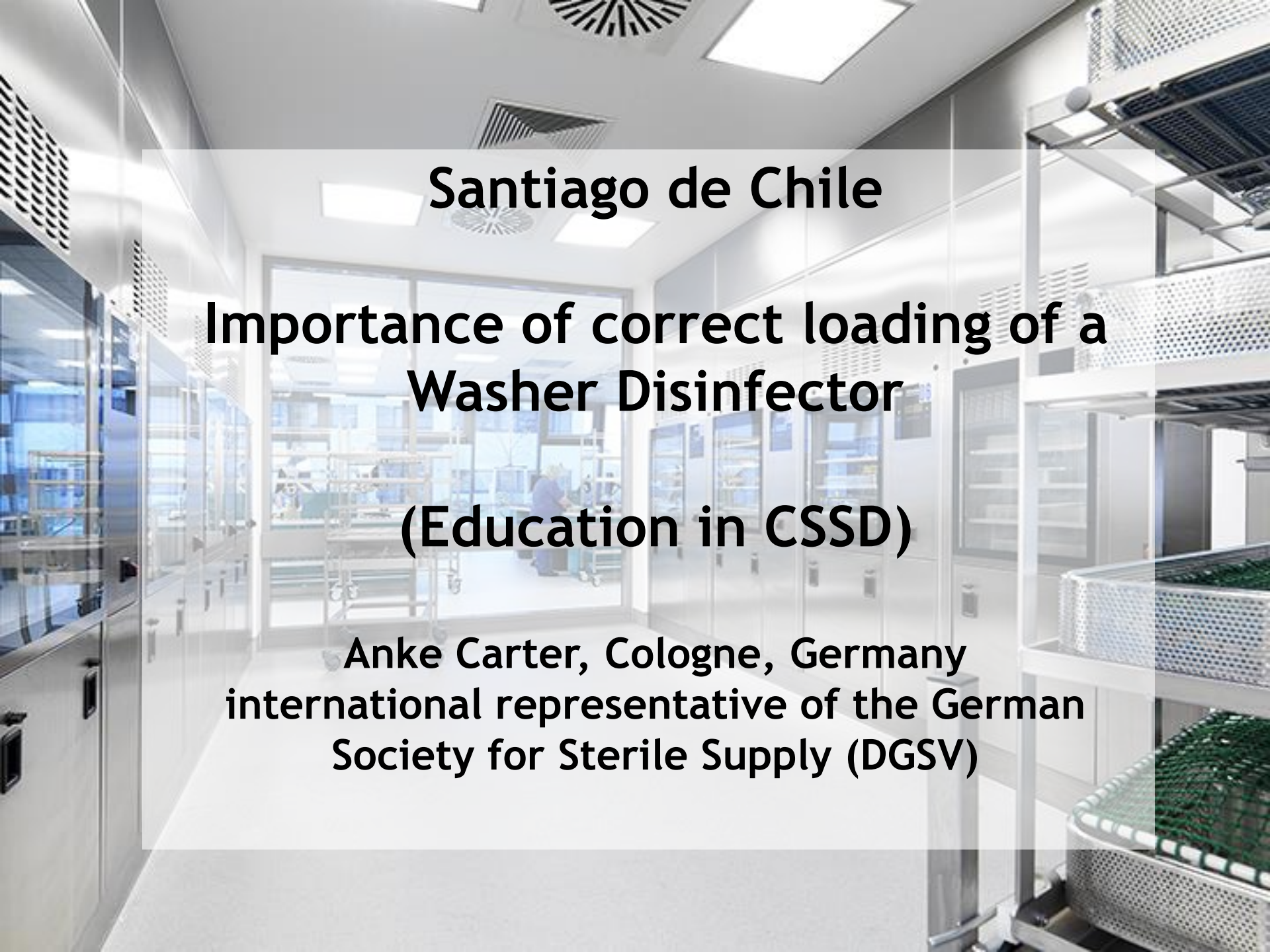


Santiago de Chile

Importance of correct loading of a Washer Disinfector

(Education in CSSD)

Anke Carter, Cologne, Germany
international representative of the German Society for Sterile Supply (DGSV)

Principles for reprocessing medical devices

Manufacturer‘s instructions - MD Classification

- Manufacturers instruction for reprocessing for sterilizable medical devices (ISO 17664)
- One of the most important measures for the proper execution of the reprocessing is the risk assessment and classification of the MP
- Internationally there are two main ways of classification
  - Classification acc. to Spaulding
  - Classification acc. to the RKI/BfArM Guideline
- The operator is responsible for the reprocessing of MD
- The training of the employees must be observed for the practical implementation

Principles for reprocessing medical devices

Manufacturer‘s instructions for reprocessing

According to ISO 17664 the manufacturer has to provide information about:

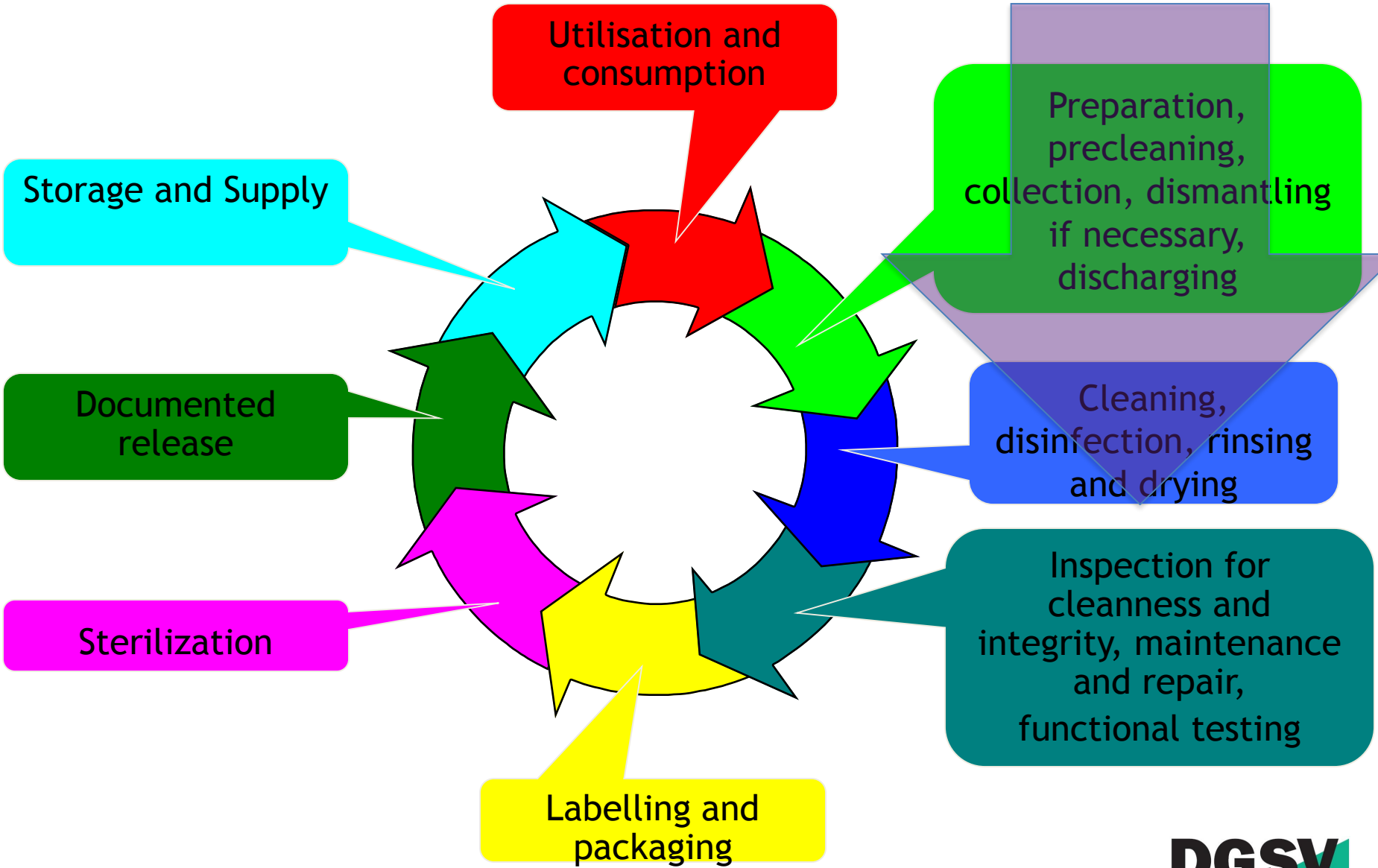
- preparation at the place of use
- preparation /Precleaning in CSSD
- Validated cleaning and disinfection procedures
- drying
- device checking, maintenance and testing
- packaging
- validated sterilization procedures
- storage

Principles for reprocessing medical devices

Before first reprocessing

- Before a MD is reprocessed the first time in a CSSD the following steps have to be carried out by a person responsible for reprocessing
- risk analyses, the risks are determined by:
  - Adverse effects from prior use,
  - prior processing, transport and storage
  - the nature of the following application
- Risk assessment
- Classification of the MD
- Set up of a SOP for reprocessing stating
  - how to reprocess the MD (with which procedure)
  - under which conditions (e.g., rooms, work equipment, personnel) MP are reprocessed

Medical device circle



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Preparation, precleaning, collection,

dismantling if necessary, discharging

- Procedures are worked together with CSSD staff for correct precleaning and preparing for discharge to CSSD
- consider requirements of both departments
- As far as possible dismantling / dismantling by the user
- Pre-sorting the medical devices by the user
- hollow body preparation by rinsing/flushing,
- Secure storage of medical devices for transport
- dry disposal is to be preferred
- start of reprocessing within 6 hours of use (red brochure from AKI)

NOTE: Without proper preparation, cleaning in CSSD will not work all the time

Preparation, precleaning, collection, dismantling if necessary, discharging

Examples for discharging

- Instruments have to be sorted in CSSD
- Clamps are not open
- Silicon mat has to be removed
- Bipolar cable has to be detangled

Preparation, precleaning, collection, dismantling if necessary, discharging

Examples for discharging

- Instruments have to be sorted in CSSD
- Clamps are not open
- Silicon mat has to be removed
- Bipolar cables have to be detangled

Preparation, precleaning, collection, dismantling if necessary, discharging

Examples for discharging

- Instruments have to be sorted in CSSD
- Clamps are not open
- Spray shadows

Preparation, precleaning, collection, dismantling if necessary, discharging

Examples for discharging

- Instruments are sorted
- Clamps are open
- Bipolar cable is rolled up
- No spray shadows

Preparation, precleaning, collection, dismantling if necessary, discharging

Examples for discharging

- Instruments are sorted
- Clamps are open
- No spray shadows

Preparation, precleaning, collection, dismantling if necessary, discharging

Examples for discharging

- Instruments are sorted
- Clamps are open
- No spray shadows
- Cables rolled up

Cleaning, Rinsing, Disinfecting, Drying

- Personnel safety first, wear personnel protection clothing
- Follow SOP´s for cleaning and disinfecting various medical devices
- Precleaning using ultrasonic bath, brushes and other equipment as stated by the manufacturer of MD
- Daily check of washer disinfectors before use
- Automated cleaning and disinfection is to be preferred

Cleaning, Rinsing, Disinfecting, Drying

- Personnel safety first, wear personnel protection clothing

Cleaning, Rinsing, Disinfecting, Drying
manual precleaning, using various equipment

- Precleaning using ultrasonic bath, brushes and other equipment as stated by the manufacturer of MD
- Follow SOP´s for cleaning and disinfecting various medical devices

Cleaning, Rinsing, Disinfecting, Drying
Checklist for daily inspection of WD

Checklist 10: Daily Routine Checks of WD

Name of Central Sterile Supply Dept./CSSD																
WD No.:	Month:	**1.**	**2.**	**3.**	**4.**	**5.**	**6.**	**7.**	**8.**	**9.**	**10.**	**11.**	**12.**	**13.**	**14.**	**15.**	**16.**
Filters (tray filter) coarse/fine																	
Pump well																	
Rotary arms/cleaning nozzles																	
Loading trolleys																	
Connection																	
Connections/adapters/dummy plugs																	
Rollers																	
Loading trolley inspection																	
WD internal/external inspection																	
Door seals																	
Other daily checks specified in the Operating Manual																	
Demin. water quality (check conductivity)																	
Staff member's signature																	
		17.	**18.**	**19.**	**20.**	**21.**	**22.**	**23.**	**24.**	**25.**	**26.**	**27.**	**28.**	**29.**	**30.**	**31.**	
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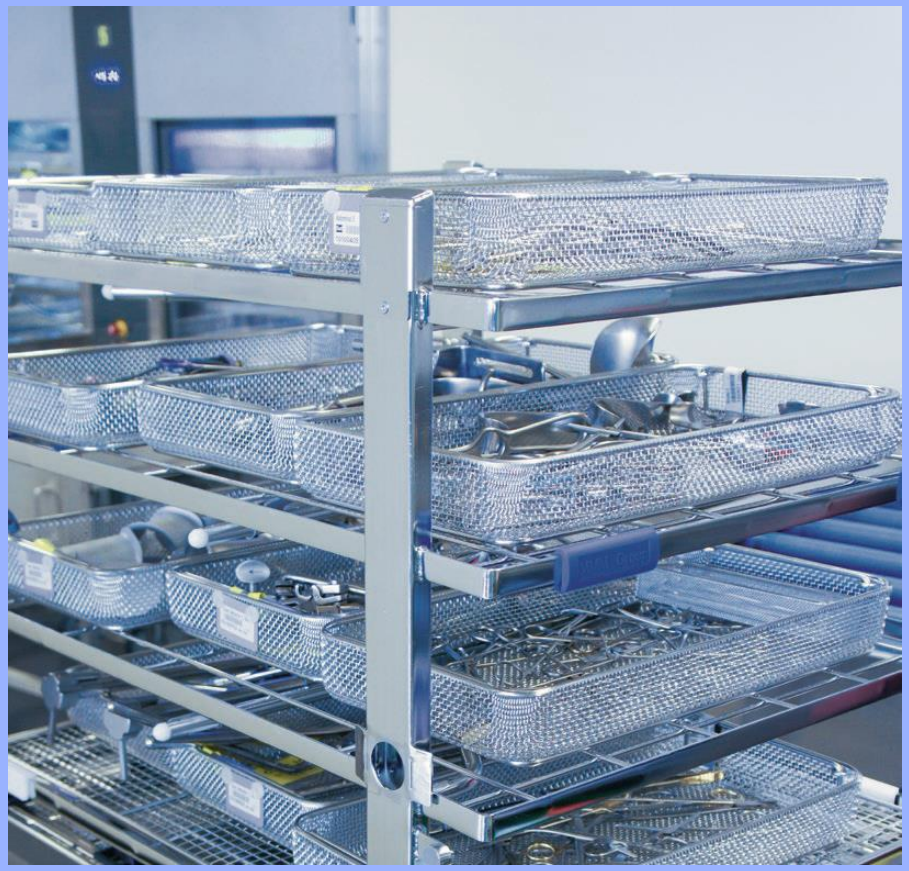
Other daily checks specified in the Operating Manual																	
Demin. water quality (check conductivity)																	
Staff member's signature																	

Cleaning, Rinsing, Disinfecting, Drying
Mechanical Cleaning in a WD

- Automated cleaning and disinfection is to be preferred

Cleaning, Rinsing, Disinfecting, Drying different racks have to be used

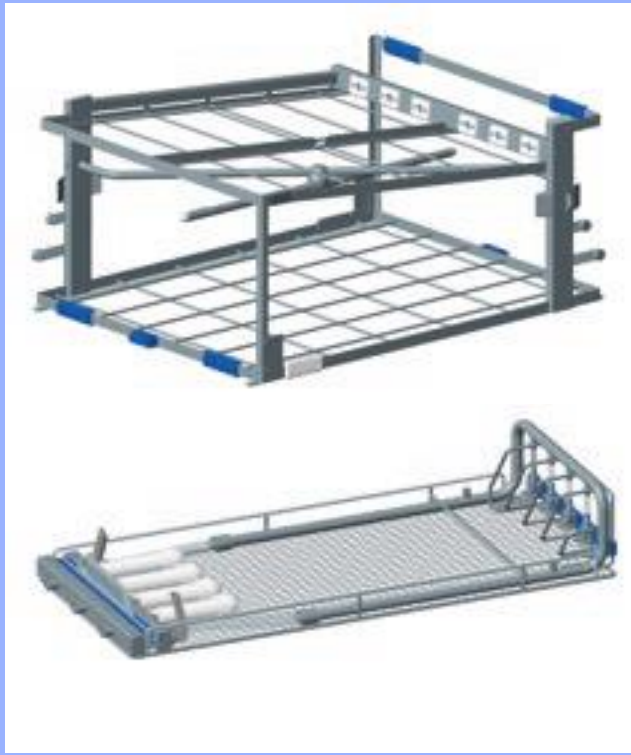
Rack 4-level
Application: Surgical instruments.
4 connections with blind plugs per intermediate level (M8x1).
Also available 3, 5, 6 levels



Cleaning, Rinsing, Disinfecting, Drying different racks have to be used

Rack MIS
Application: MIS instruments, ENT, normal surgical instruments.
4 connections with blind plugs (M8x1) per level for further hollow items (flush tubes).

Cleaning, Rinsing, Disinfecting, Drying different racks have to be used



Racks for robotic instruments (Da Vinci)

Cleaning, Rinsing, Disinfecting, Drying different racks have to be used

Racks for robotic instruments (Da Vinci)

Cleaning, Rinsing, Disinfecting, Drying different racks have to be used

Rack anaesthesia drum
Application: Anaesthesia material, breathing tubes, breathing masks, breathing pouches.

Plug-on rack AN material in the middle
Application: Plug-on rack for 25 AN material such as bushings.

Cleaning, Rinsing, Disinfecting, Drying different racks have to be used

Rack for 1 StU container with lid
Application: Sterile goods container with lid.

Typical load:
4 containers with lid, max. dimensions of container L=600 x W=300 x H=300 mm (without lid max. H=270 mm)

Cleaning, Rinsing, Disinfecting, Drying
different racks have to be used

Rack with various inserts for

- Bowls
- Instruments
- Kidney dishes
- Others (not on picture)

Note:
Manufacturers of WD have similar racks for their machines!

Cleaning, Rinsing, Disinfecting, Drying
correct loading of racks

- Staff has to be trained to load different racks, because mistakes made whilst loading a rack can result in dirty instruments

Plastic trays a not suitable for washing the instruments
Solution:
replace instruments in suitable mesh trays

Cleaning, Rinsing, Disinfecting, Drying
correct loading of racks

- Staff has to be trained to load different racks, because mistakes made whilst loading a rack can result in dirty instruments

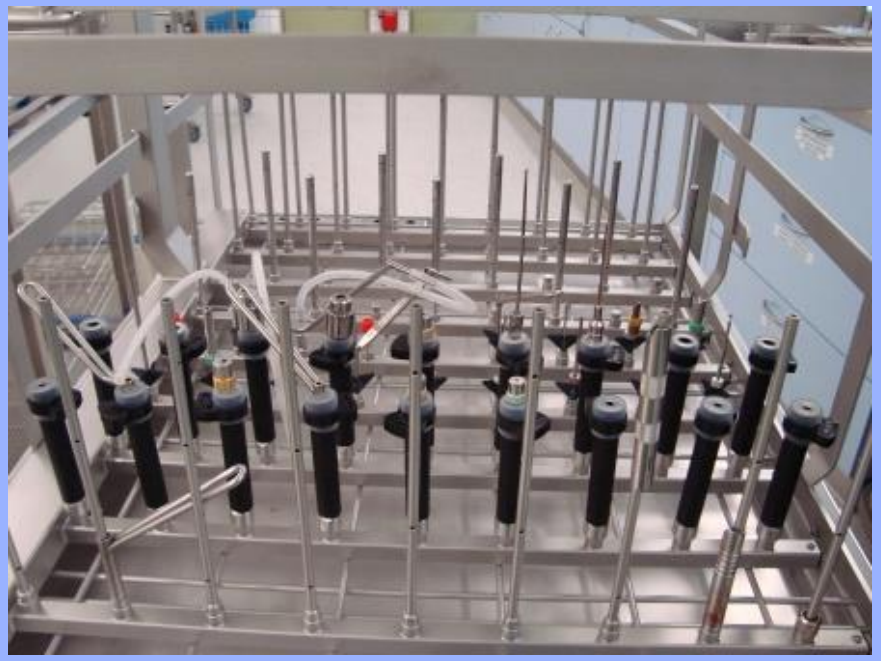
Load with spray shadows bear the risk of dirty instruments after the cycle

Solution:

use two trays

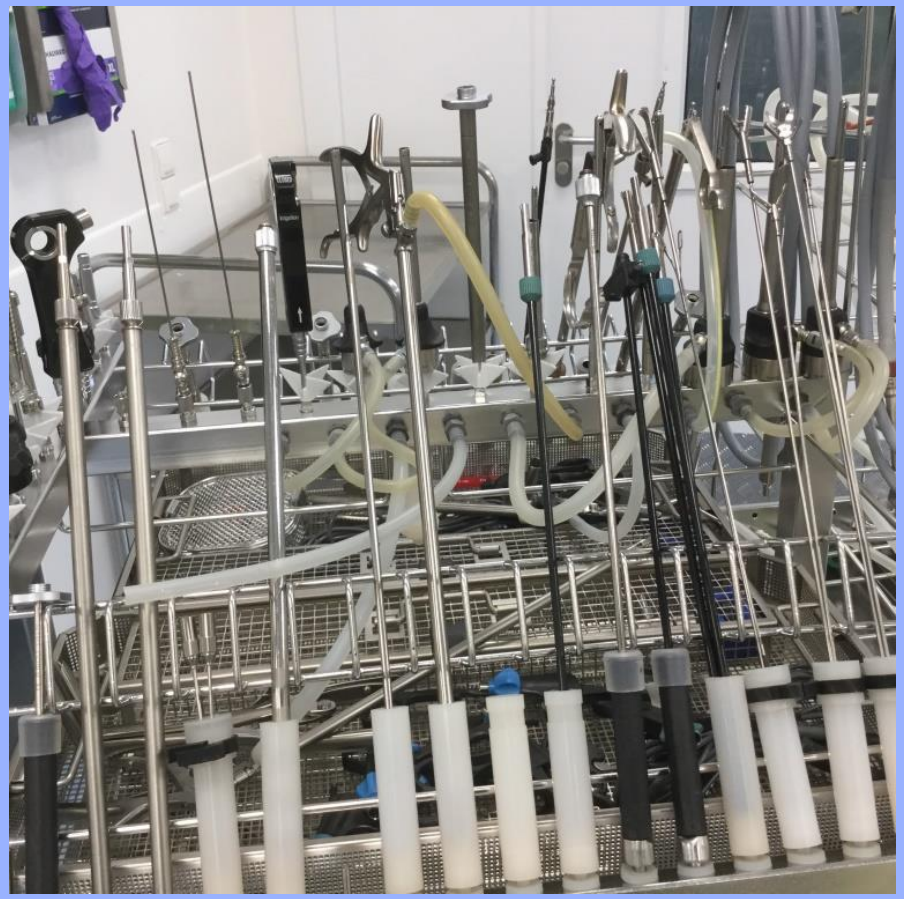
Cleaning, Rinsing, Disinfecting, Drying correct loading of racks

Loading MIS racks



Cleaning, Rinsing, Disinfecting, Drying
correct loading of racks

Loading MIS racks



Cleaning, Rinsing, Disinfecting, Drying correct loading of racks

Loading ophthalmic racks

Cleaning, Rinsing, Disinfecting, Drying
correct loading of racks

Everything ok with this load or are there mistakes?

Cleaning, Rinsing, Disinfecting, Drying correct loading of racks

Everything ok with this load or are there mistakes?

Conclusion

- Education in CSSD is highly important
- Not only in Germany or Europe, but everywhere in the World
- Staff in CSSD have to be taught how to use the provided racks properly
- A WD can only produce clean instruments if the staff loading the load carriers is educated in the use of all equipment

At the start

Medical Device reprocessing has developed from a small appendage of an operating room into an independent, highly technical

- Central Sterile Supply Department(CSSD)/
- RUMED Reprocessing Unit for Medical Devices

From operating theatre to CSSD

A move away from…

- … an open area with wildly conflicting different activities, to a department that is strictly divided into different zones
- … mainly manual working towards automated instrument and device reprocessing
- … the use of chemical and biological indicators towards physical validation of reprocessing steps
- … a quality check at the end of the sterilization process towards permanent monitoring,

and also

a move away from untrained

to highly qualified personnel

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First attempts for education in Germany and Europe

- 1992 Foundation of European Society for Hospital Sterile Supply (ESH)
- The ESH was founded to create a first professional platform to exchange knowledge about the reprocessing of medical devices and how to use washer disinfectors and sterilizers properly. At that time it was obvious that education was needed for people working in CSSD.
- German ESH members set up the first 3 level education program to be used across Europe.
- Germany started using the program in 1994 together with Switzerland. Other countries did not follow at that time.
- 1998 Disassembling of ESH

Education programs developed by the German society for Sterile Supply (DGSV e.V.)

- Together with Switzerland the first courses were set up and carried out in 1995
- The certificate was from ESH
- 1996 Foundation of DGSV
- One of the main goals of DGSV was from the start to establish educational programs for CSSD in Germany
- Until 1998 there were only 2 places where the education took place in Germany
- 2017 there are 61 academies across Germany where people can get qualifications

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Chronology of development of courses

1997

- Level I
  80 hrs
- Level II
  80 hrs
- Level III
  160 hrs

2003

- Expertise for practices
  40 hrs
- successive courses for Podiatry , tattoo endoscopy

2010

- Level I
  120 hrs + 150 hrs practical work in CSSD
- Level III
  200 hrs + 16 hrs exams

2015

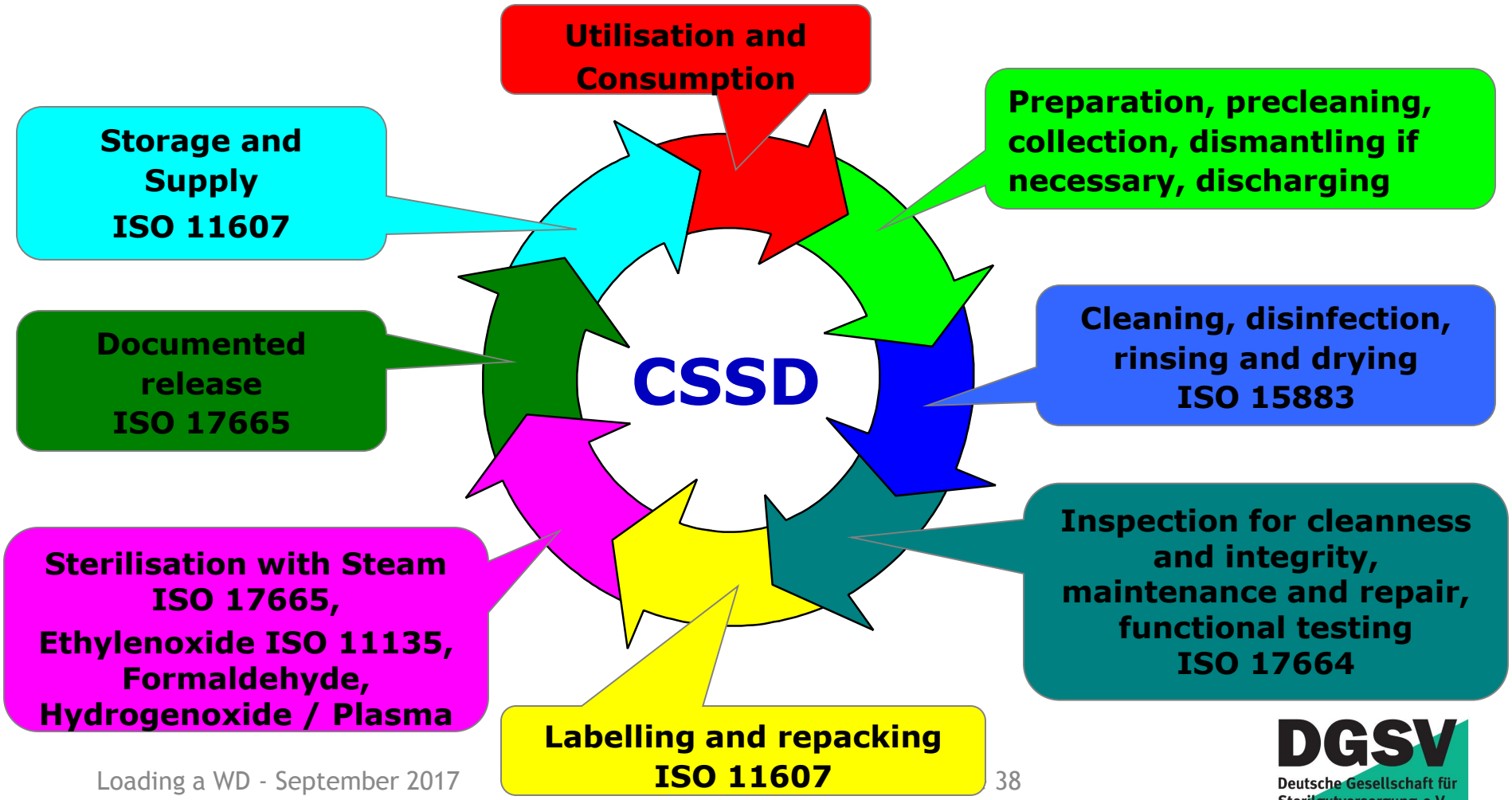
- Level II
  120 hrs + 3 Hospitations + Practical task
- Supplement Endoscopy
  24 hrs since 2012

2016

Start of 3-year education course in November

For the first time in Germany

International Regulations Medical Device Circle



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Level I Syllabus content 1/2

Module 1 **Departmental organisation & basic quality procedures**

Objective of the training…

Module 2 **Legal requirements**

Survey of health authorities, MDD, laws and standards…

Module 3 **Health and Safety at work**

Safety measures, laws and standards, risk assessment…

Module 4 **Basic microbiology**

Classification of causal organisms, addition, transmission…

Module 5 **Infection control procedures**

Hospital infections, hospital and personnel hygiene…

Module 6 **Basics of Disinfection**

Composition of Disinfectants, microbiological effects…

Module 7 **Decontamination of Medical Devices**

Cleaning and disinfection of Medical Devices

Level I Syllabus content 2/2

Module 8 **Basics of fabrication of Instruments**

Materials and design, surface changes…

Module 9 **Packaging**

Types of packaging, storage, logistic of MD

Module 10 **Basics of Sterilization**

Methods, Steam, steam- water quality, documentation…

Module 11 **Quality Management and Validation**

Quality assurance in CSSD, validation of processes…

Module 12 **Cooperation with other Departments**

e. g. operating theatre, hygiene, purchasing dep., techniques

Module 13 **Reprocessing of Medical Devices**

Reproduction of optics, endoscopes, engines, anaesthesia devices, Risk management of Medical Devices

Module 14 **Examination**

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Examples of exam questions (Level I)

What is saturated steam?

1) A fixed relationship between pressure and temperature corresponding to the saturated steam curve
2) A fixed relationship between pressure and time corresponding to the saturated steam curve
3) A fixed relationship between time and temperature corresponding to the saturated steam curve
4) A fixed relationship between moisture and temperature corresponding to the saturated steam curve

☐ **A)** Only 1 is correct
☐ **B)** Only 2 is correct
☐ **C)** Only 3 is correct
☐ **D)** Only 4 is correct

Examples of exam questions (Level I)

What is saturated steam?

1) A fixed relationship between pressure and temperature corresponding to the saturated steam curve
2) A fixed relationship between pressure and time corresponding to the saturated steam curve
3) A fixed relationship between time and temperature corresponding to the saturated steam curve
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☒ **A)** Only 1 is correct
☐ **B)** Only 2 is correct
☐ **C)** Only 3 is correct
☐ **D)** Only 4 is correct

Examples of exam questions (Level I)

What possible error indicates the Bowie-Dick-Test?

1) Leaks in the sterilizer
2) Inadequate steam penetration
3) Inadequate air ventilation
4) Not condensable gases

☐ **A)** Only 3 is correct
☐ **B)** 2 and 3 are correct
☐ **C)** 1, 2, and 4 are correct

Examples of exam questions (Level I)

What possible error indicates the Bowie-Dick-Test?

1) Leaks in the sterilizer
2) Inadequate steam penetration
3) Inadequate air ventilation
4) Non condensable gases

☐ **A)** Only 3 is correct
☐ **B)** 2 and 3 are correct
☒ **C)** 1, 2, and 4 are correct

Examples of exam questions (Level I)

Oral exam:

Participants have to be able to describe

- the multiple pre-vacuum process
- the correct sterilization procedure
- the documented release
- steps taken to prevent any incorrect sterilization procedure

“Validation in the practice of CSSD”

40 Hour Course to:

- acquire basic knowledge of process analysis
- ability to carry out routine checks
- gaining the ability to carry out or co-process validations
- ability to review, interpret and share validation reports

Admission requirements:

- Required: Technical Sterilisation Assistant level II, when Level III course is the objective to take part
- Advised: Technical Sterilisation Assistant level II, if the module is visited as a s stand alone course
- Written examination

“Validation in the practise of CSSD”

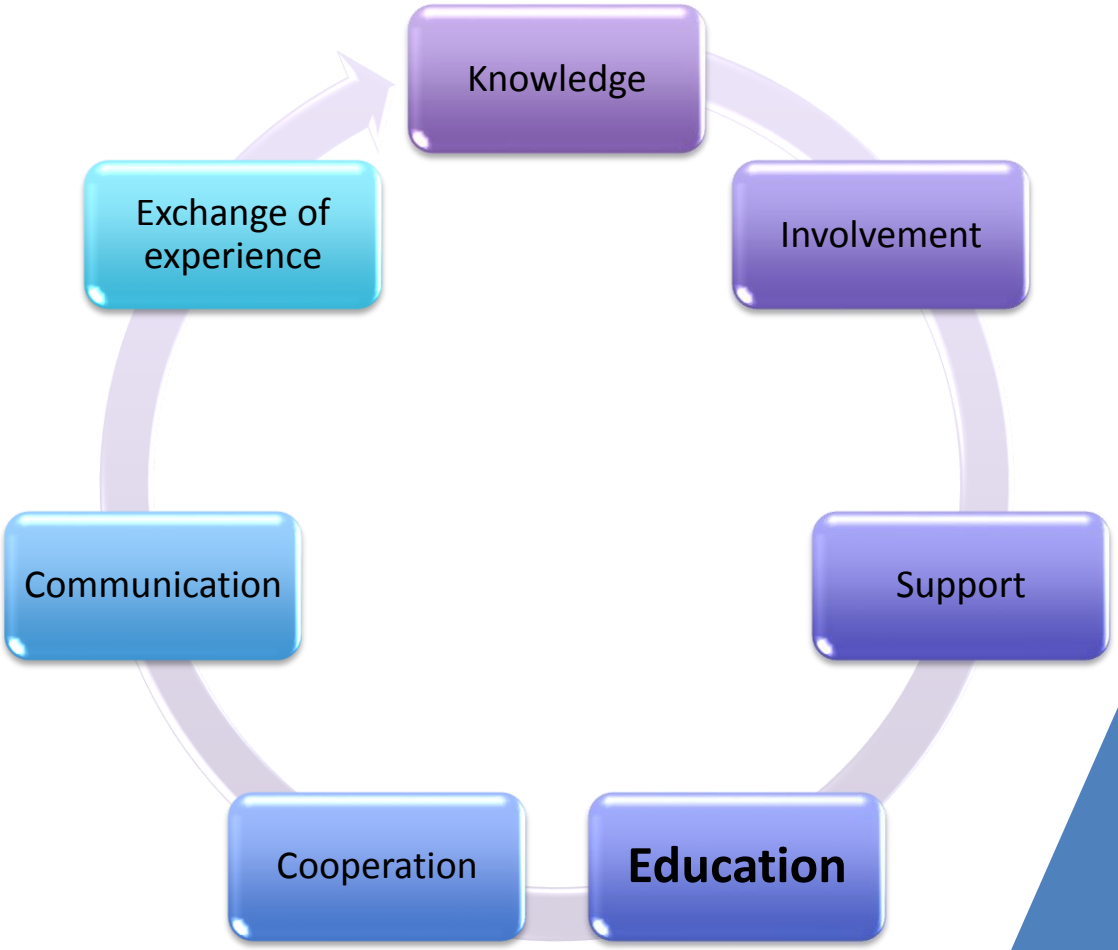
Syllabus content

- Day 1: What is Validation? Role of CSSD Manager during Validation of Procedures. International Standards, Risk Management, Validation of sealing process, parametric release
- Day 2: Equipment and resources needed for the correct operation of washer-disinfectors, sterilizers, sealing machines, chemicals used in WDs
- Day 3: Technical specifications of WDs and Steam Sterilizers, Processes used commonly, Verification of previous steps of reprocessing
- Day 4: Practical validation of cleaning process in a CSSD, reading and understanding the validation report
- Day 5: Practical validation of sterilization process in a CSSD, reading and understanding the validation report, examination

Summary

- Education has developed over the past years
- Different courses offer choices for participants and employers
- Looking at development in the past, education levels have definitely increased to fulfill the requirements
- In Germany we started a three year education in November 2016 and we hope that this will be the future for everyone working in CSSD
- Manager qualification will be extended as well, with an additional part for risk management according to ISO 14791. overall from 2019 Managers' education will take around one year and contain 720 hours theoretical lessons

The Future of reprocessing



For the wellbeeing

- of patients
- employees
- and everyone concerned

Thank you very much for your attention!
I am looking forward to the discussion!

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Deutsche Gesellschaft für Sterilgutversorgung e.V.

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