OVERVIEW – REPROCESSING GUIDELINES

Sven Wurst
DGSV Certified Trainer

Rules And Standards

Laws & Government Regulations

- Germany: MPSV

Guidelines

- Official (RKI, Institut Pasteur, HTM)
- Associations (AAMI, DGSV, …)
- Red Brochure

Standards

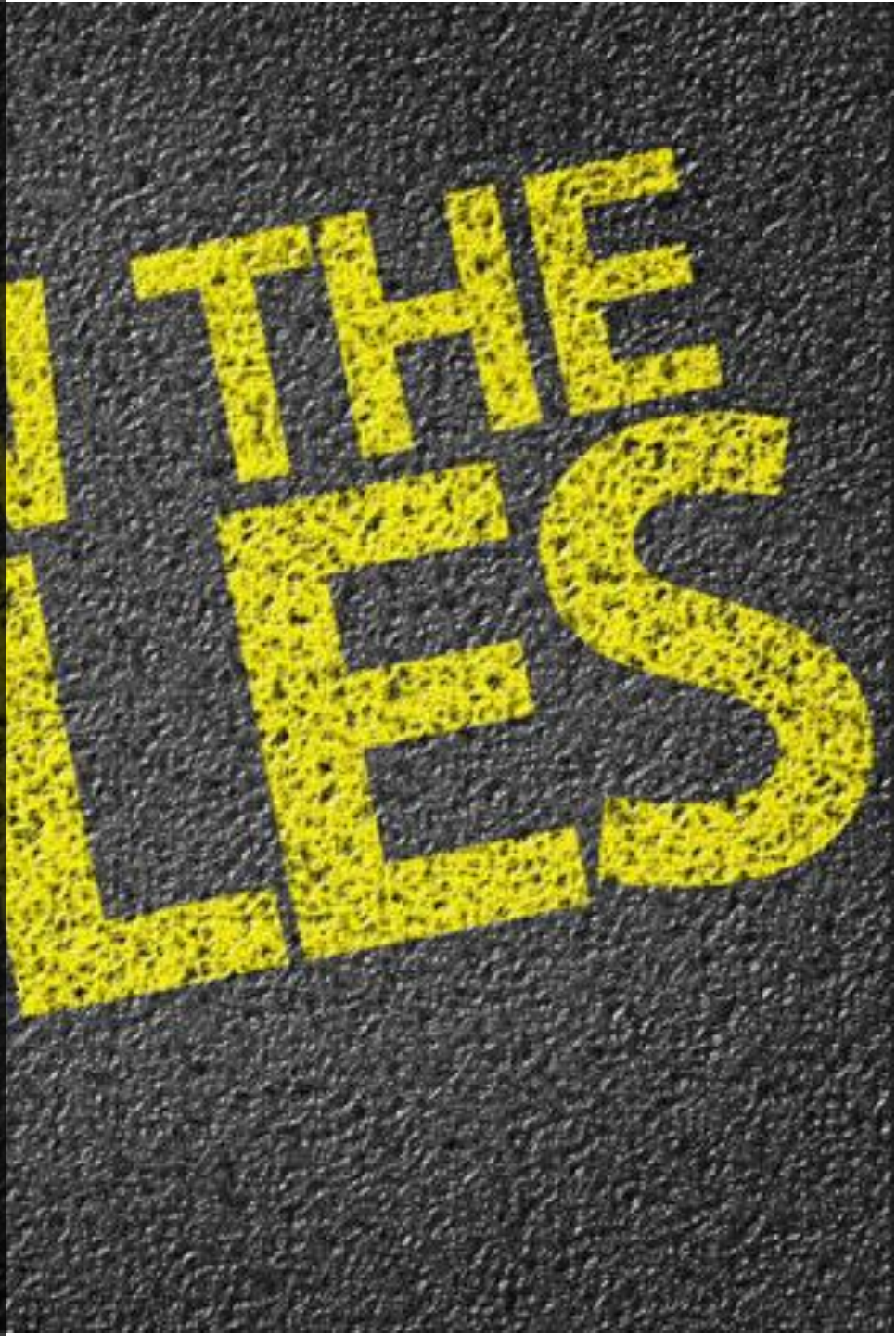
- ISO 13485 (QM for Medical Devices)
- ISO 15883 (Machine Cleaning)
- ISO 868, EN285 (Sterilization)
- ISO 11607 (Packaging)
- …

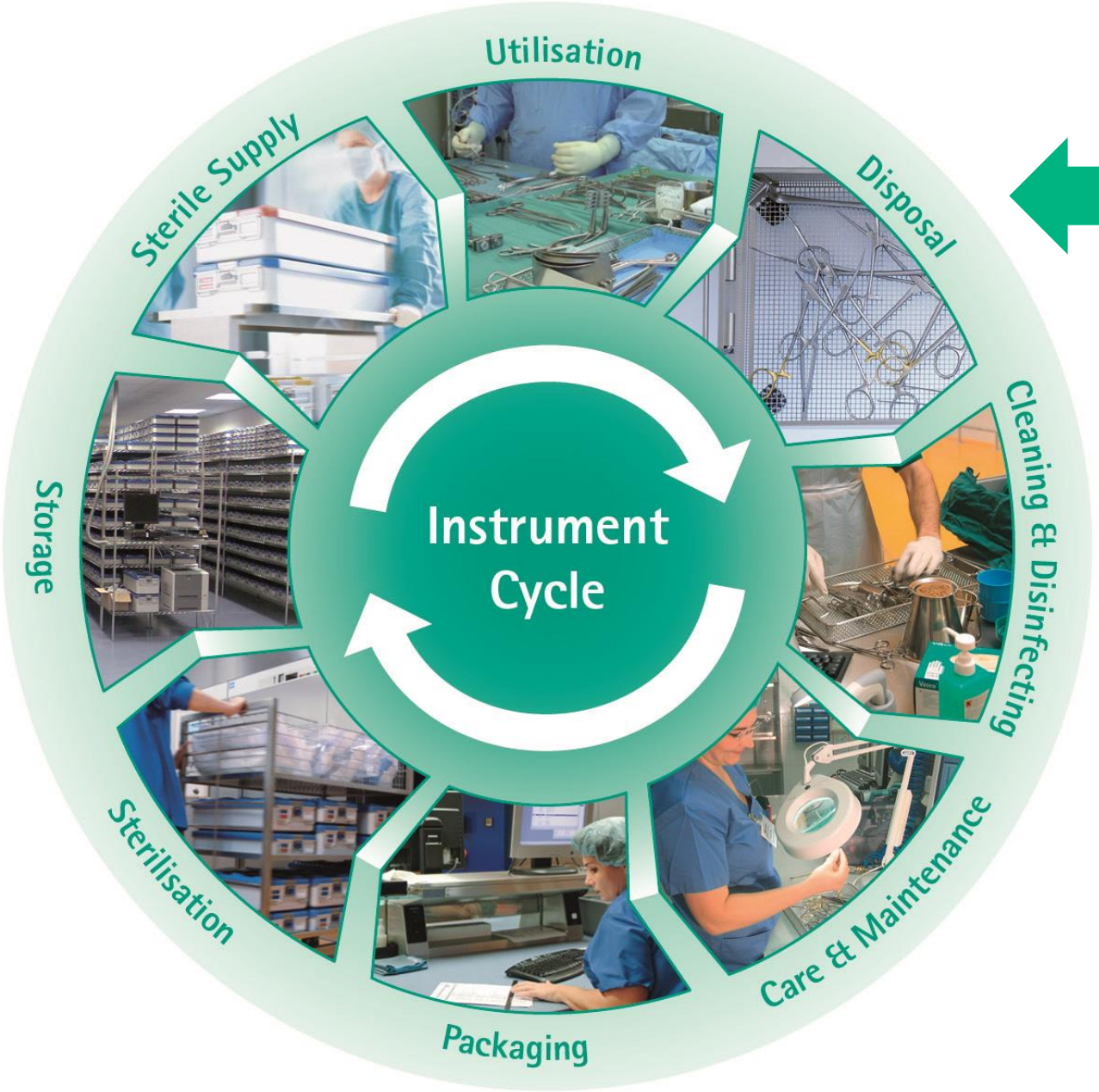
Manufacturer Instructions

Workers Protection

Audits

- Notified Bodies
- Government / Insurance




Utilisation
Disposal
Cleaning & Disinfecting
Care & Maintenance
Packaging
Sterilisation
Storage
Sterile Supply
Instrument Cycle

Post-Operative Disposal Procedures

Contaminated Instruments should be disinfected and cleaned as soon as possible (AAMI)

Avoid long delays overnight or over a weekend, blood residues can lead to corrosion (AAMI, AKI)

A reprocessing should take place within 6 hours (AKI)

Transport of contaminated goods has to be in closed containers (RKI)

Inside the O.R. no regulations

Clean & Dirty Elevator (AAMI)

Wet Disposal (AAMI)

All Surfaces and lumina must be covered completely by the solution

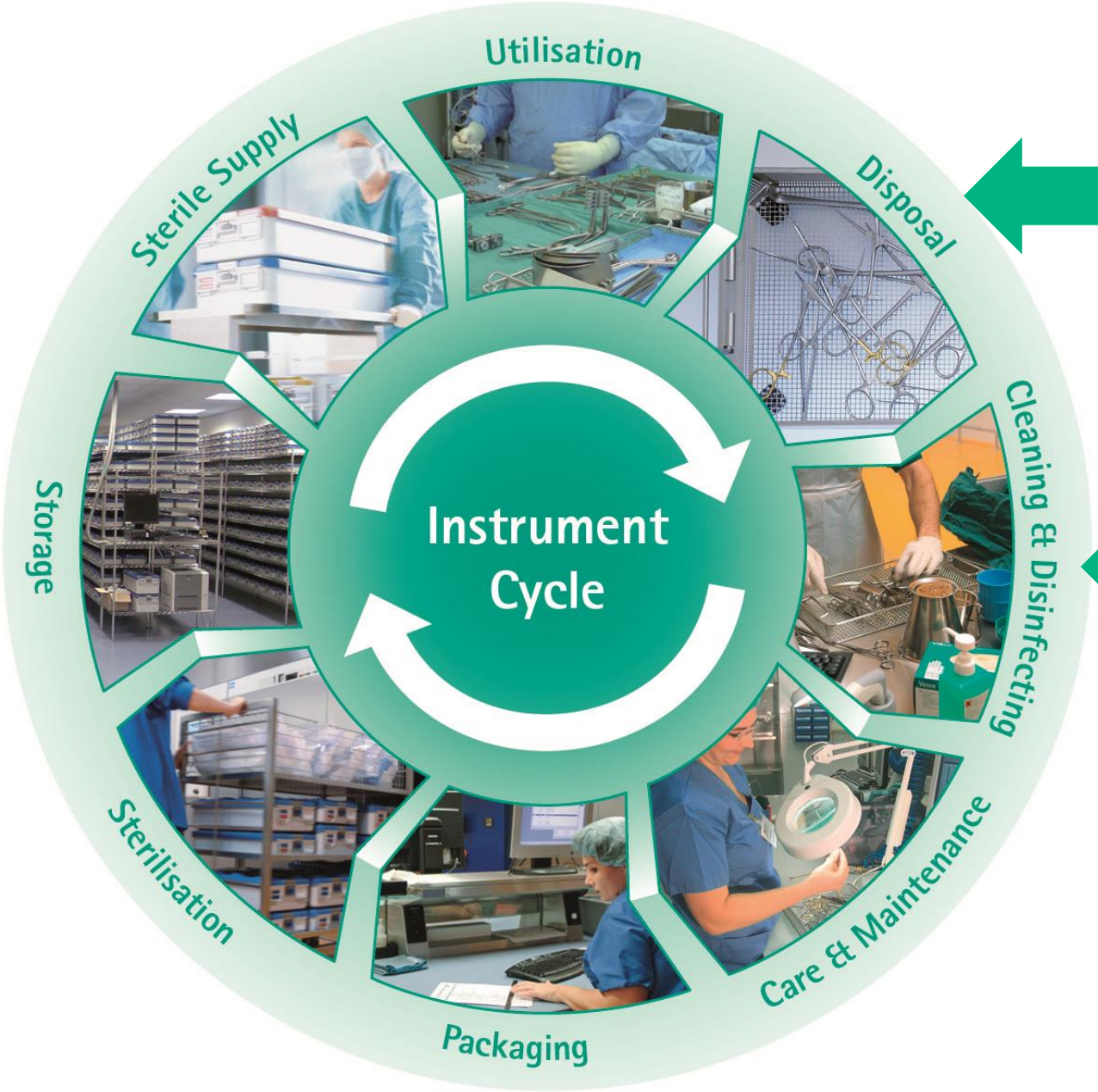
Rinse instruments thoroughly under cool running tab water prior to mechanical cleaning and disinfecting

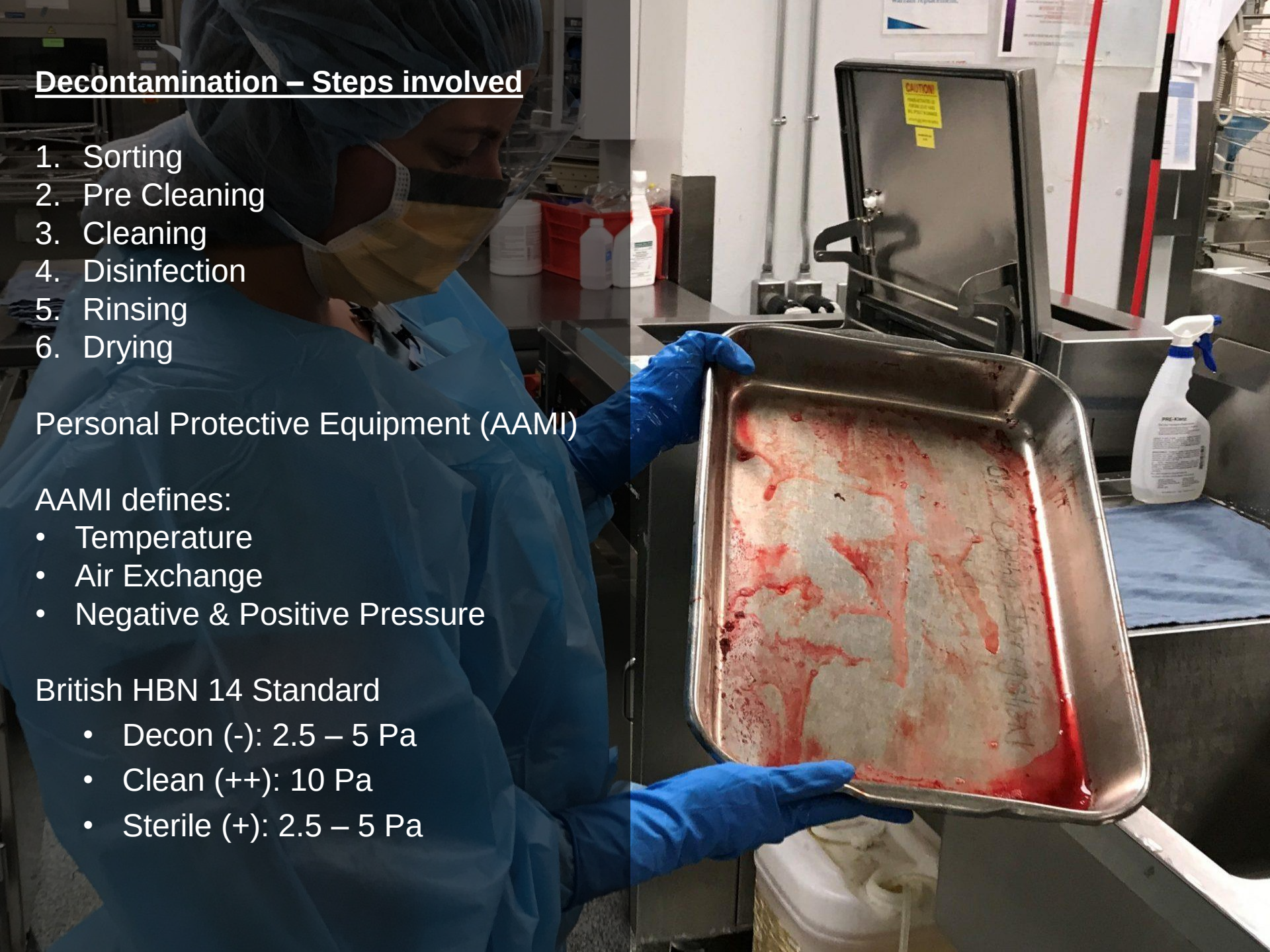
Residual disinfectant can cause a reduction of the efficiency of disinfectants and lead to foam formation

Moist Disposal with moist towel / foam spray

Advantage: Improved Cleaning

Disadvantage: Risk of corrosion


Instrument Cycle
Utilisation
Disposal
Cleaning & Disinfecting
Care & Maintenance
Packaging
Sterilisation
Storage
Sterile Supply



Decontamination – Steps involved

1. Sorting
2. Pre Cleaning
3. Cleaning
4. Disinfection
5. Rinsing
6. Drying

Personal Protective Equipment (AAMI)

AAMI defines:

- Temperature
- Air Exchange
- Negative & Positive Pressure

British HBN 14 Standard

- Decon (-): 2.5 – 5 Pa
- Clean (++): 10 Pa
- Sterile (+): 2.5 – 5 Pa

Decontamination – Procedures

- Manual cleaning and manual chemical disinfection
- Manual cleaning combined with ultrasonic treatment and manual chemical disinfection
- Mechanical cleaning and thermal disinfection (Washer & Disinfector)

NOTE:
Modern standard should be mechanical reprocessing

Manual Pre-Cleaning:
- AAMI / ASEAN: Increases Efficiency
- DGSV / EUROPE: Avoid as much as possible for staff protection

Guidelines – Red Brochure

- Use suiteable cleaning / disinfection solution
- Follow the IFU when dismantling detachable instruments
- Immerse instruments in a suitable solution – refer to the manufacturer's recommendations in regards of concentration, temperature, contact time and material compatibility)
- Completely dissolve all powdered chemicals
- All exposed surfaces and Lumina must be completely covered

Mechanical Reprocessing – W&D

Relevant Standard: ISO 15883

- 2 independent temperature sensors
- Sensor accuracy
- Dosage pumps and flow meters
- Disinfection
- Performance

Validation

- System: IQ, OQ, PQ
- Test Methods
- Test Soils

Germany: DGSV Guideline

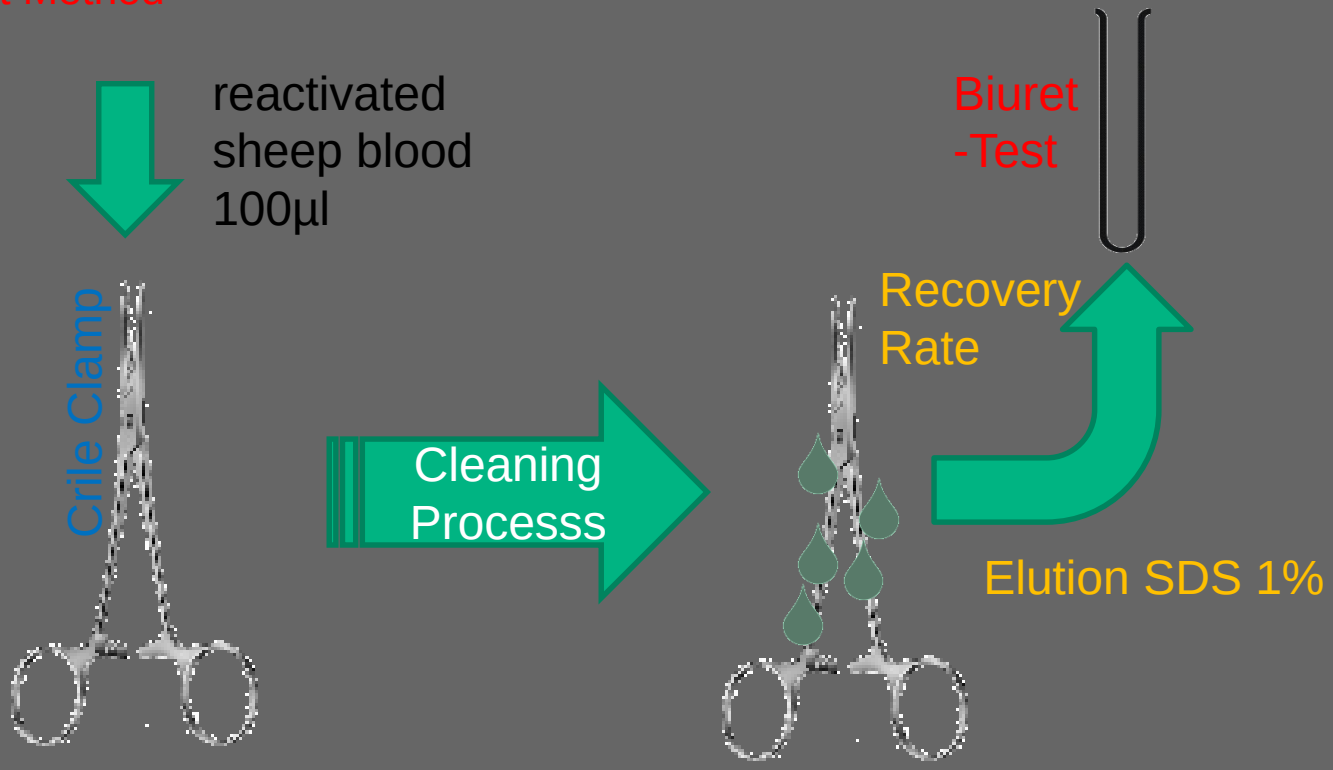
Performance Testing

Mechanical Reprocessing – W&D

Cleaning efficacy test

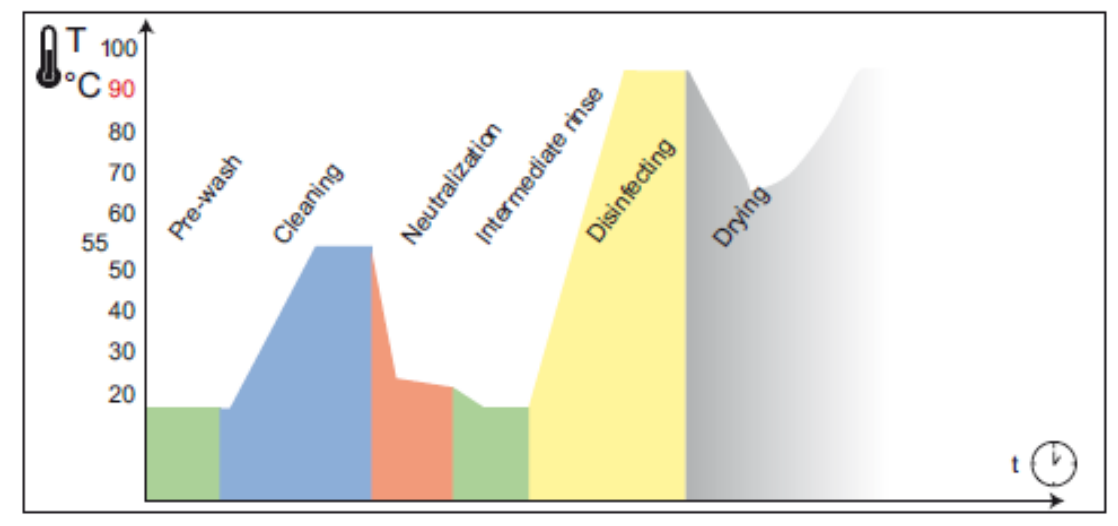
- Sytematics
  - Test Soil
  - Test Geometry
  - Recovery
  - Test Method

Example
German Validation
Guideline



Mechanical Reprocessing – W&D

Typical Instrument Program



- Pre-wash (not necessarily)
- Washing / Chemical Disinfection
- Neutralization ?
- Rinse
- Final Rinse
- Drying

- Safe
- less chemical reaction
- A^0-Value
  - Time/ Temperature

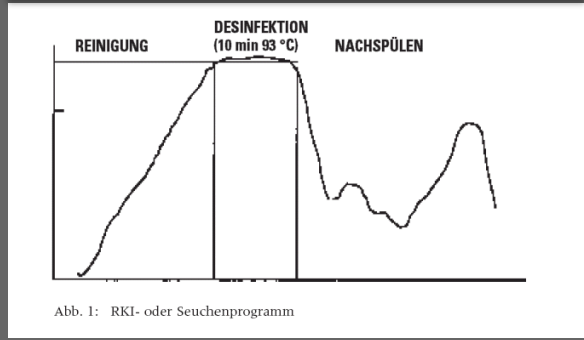
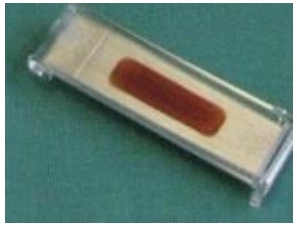


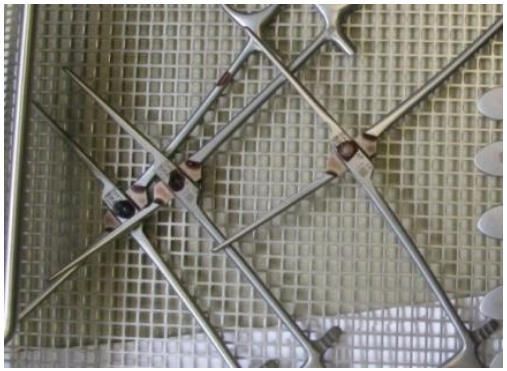
Abb. 1: RKI- oder Seuchenprogramm

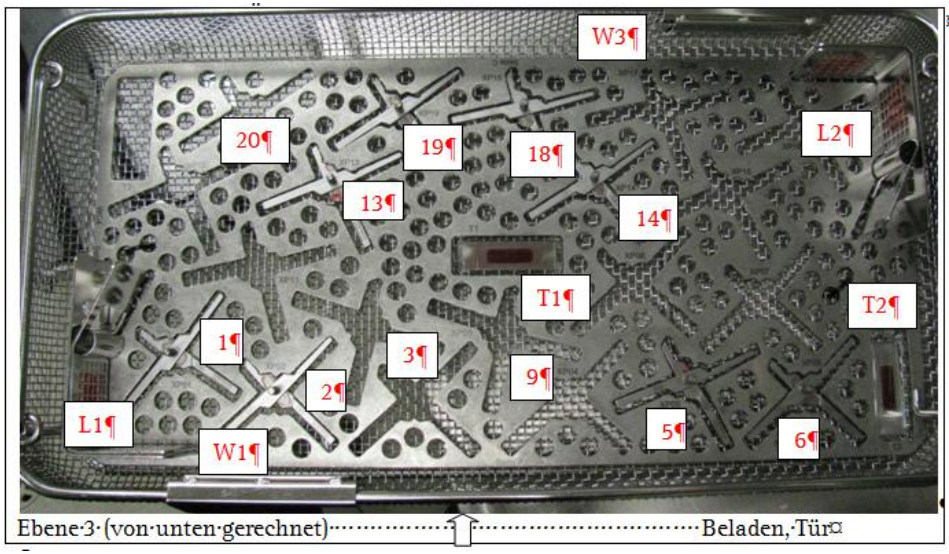
Combined Cleaning and Disinfection

Cleaning

- Alkaline, high temperature: Japan
- Prion-inactivating cleaner (alkaline): France
- Mild alkaline (pH ~10): Germany, Austria
- Neutral, enzymatic: USA, Asia







Water Quality – EN 285 and others

- EN 285: 15 µS; Si 1 mg/l; Cl 2 mg/l, Endotoxin not regulated
- British / Australian: 30 µS; Si 0.2 mg/l; Cl 10 mg/l, 0.25 EU Endotoxin
- AAMI TIR 34 2007: 10 µS, Cl 1 mg/l; Endotoxin not regulated

Contamination in the supply water to an assigned steam generator	
Substance/property	**Feed water**
Evaporation residue	≤ 10 mg/l
Silicates (SiO_2)	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metal residues, except for iron, cadmium, lead	≤ 0.1 mg/l
Chlorides (Cl-)	≤ 0.5 mg/l
Phosphates (P_2O_5)	≤ 0.5 mg/l
Conductivity (at 20 °C)*	≤ 5µS/cm
pH value (degree of acidity)	5 to 7.5
Appearance	colorless, clear, no deposits
Hardness (Σ of alkaline earth metal ions)	≤ 0.02 mmol/l

Dininfection

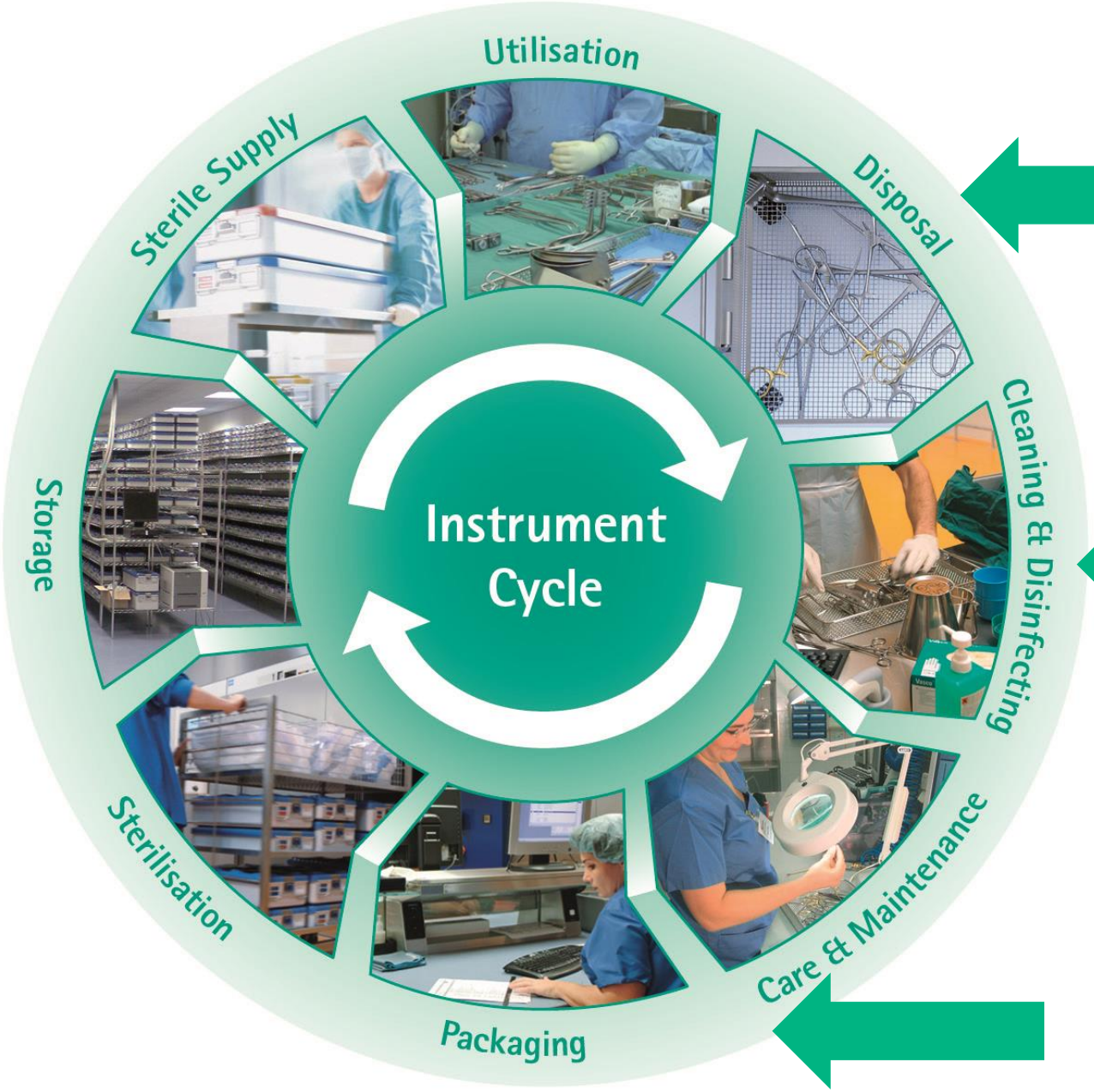
- European Philosophy: Workers protection in packaging area
  ⇒ A0 3000
- Demineralised water recommended to avoid staining and corrosion

Temp	Ao Wert	Ao Wert	Ao Wert	Ao Wert	Haltezeit (Sekunden)
°C	60	300	600	3000	
95	1,90	9,49	19,00	94,87	Sek
94	2,40	11,94	23,90	119,43	Sek
93	3,00	15,04	30,10	150,36	Sek
92	3,80	18,93	37,90	189,29	Sek
91	4,80	23,83	47,70	238,30	Sek
90	6,00	30,00	60,00	300,00	Sek
89	7,60	37,77	75,50	377,68	Sek

Additives
• AKI: nothing

Rinse Aids
• better drying (limited on metal, evtl cracks in pastic)
• compensation water quality

Instrumente milk
• oiling (AKI not sufficient)
=> targeted oiling


Instrument Cycle
Utilisation
Disposal
Cleaning & Disinfecting
Care & Maintenance
Packaging
Sterilisation
Storage
Sterile Supply

Standards in the Packaging

ISO 11607-1 Packaging Material, Requirements and test methods

Requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

Standards in the Packaging

EN 868 Sterilization of Medical Devices

Part 1: General Requirements and test methods for packaging materials and systems for medical devices which are sterilized.

Part 2: Requirements for test methods for sterilization wraps.

Part 3 – 5: Requirements for paper bags e.g. peel pouches.

Standards in the Packaging

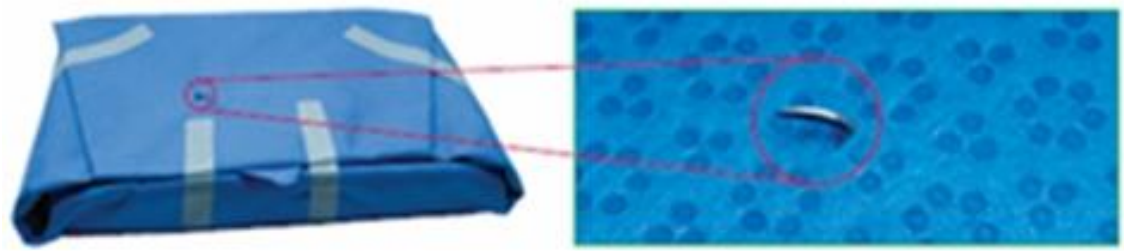
EN 868 Sterilization of Medical Devices

Part 6: Requirements and test methods for paper in low temperature sterilization processes

Part 7: Adhesive coated paper for low temperature sterilization processes.

Part 8: Re-usable sterilization containers for steam sterilization confirming to EN 285

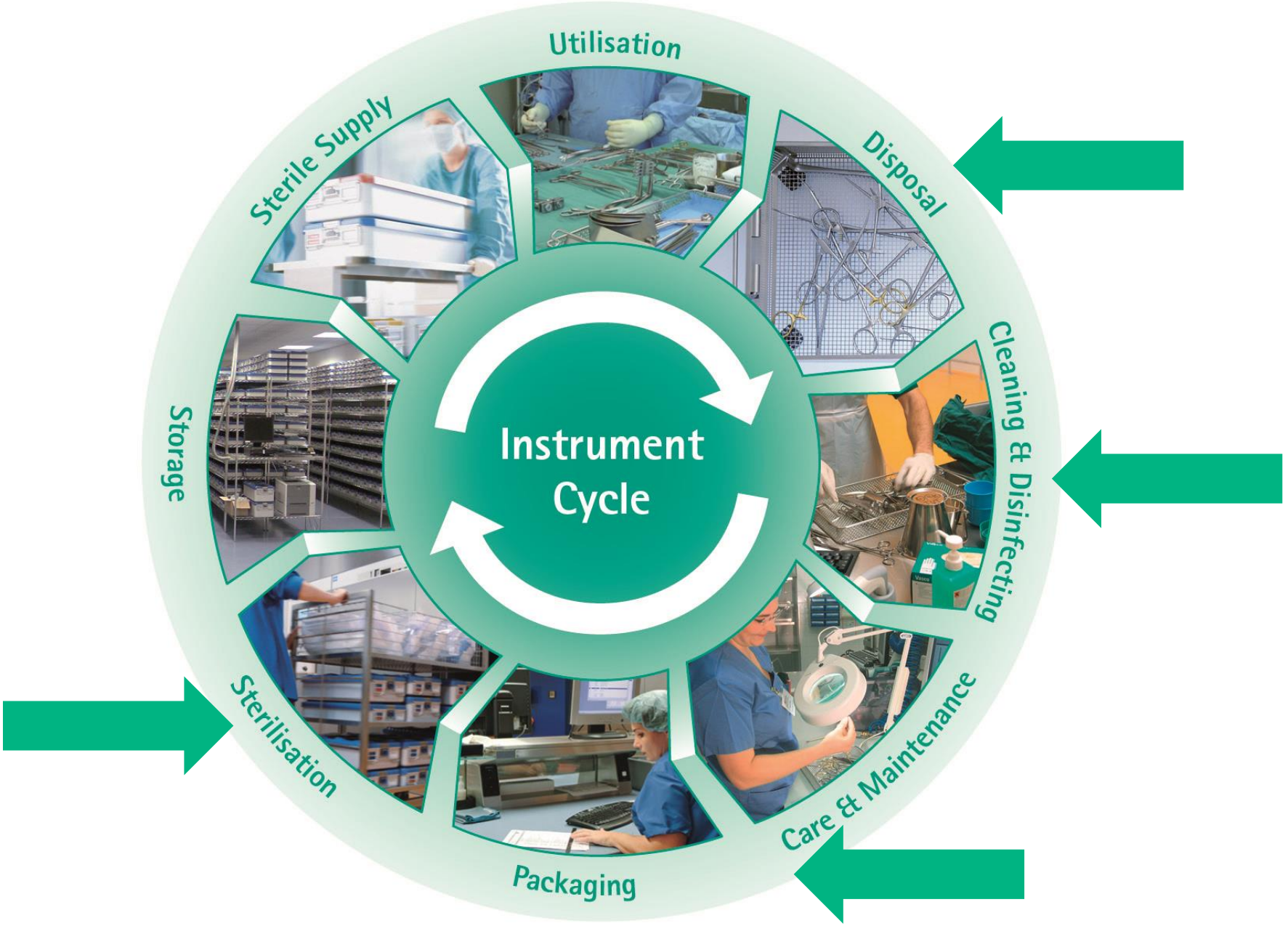
Part 9 (10): Uncoated / adhesives non woven materials of polyolefines.

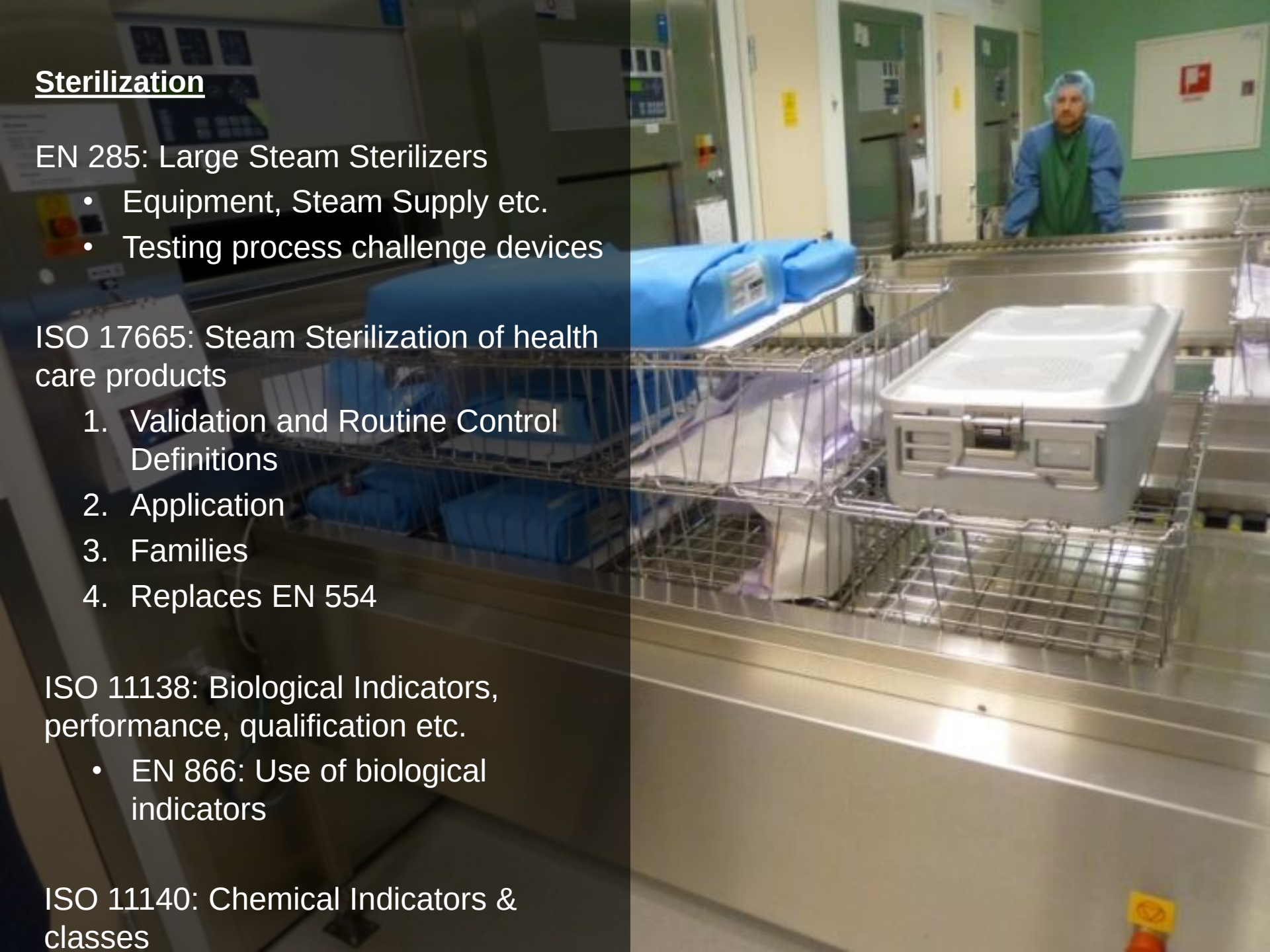


Soft Packs

Proper Folding
Germany: Validation is performed to avoid risks of damages during transportation and handling.

IFU of manufacturer: No pulling and no stacking – risk of perforations.


Utilisation
Disposal
Cleaning & Disinfecting
Care & Maintenance
Packaging
Sterilisation
Storage
Sterile Supply
Instrument Cycle



Sterilization

EN 285: Large Steam Sterilizers

- Equipment, Steam Supply etc.
- Testing process challenge devices

ISO 17665: Steam Sterilization of health care products

1. Validation and Routine Control Definitions
2. Application
3. Families
4. Replaces EN 554

ISO 11138: Biological Indicators, performance, qualification etc.

- EN 866: Use of biological indicators

ISO 11140: Chemical Indicators & classes

Validation – EN 554, ISO 17665 and EN 285

IQ: Installation Qualification (Upon Set Up)

OQ: Operational Qualification (Sensors, sealing etc.): typically with maintenance

PQ: Performance Qualification

Test Loads

- Max. difference in chamber 2°C, one spot 1°C
- 134°-137°C saturated steam
- Typically 12 – 20 thermocouplers or loggers with repeated runs.

AAMI ST79: Validation by indicator use

- Half cycle with microbiological indicators

Steam Sterilization – Chemical Indicators

Classes by ISO 11140 and AAMI ST60

- Class 1: Process Indicators
- Class 2: Special Indicators (BD etc.)
- Class 3: Single variable
- Class 4: Multi variable
- Class 5 (Integrated): Temperature, Steam & time, reference to the biological indicator
- Class 6 (emulating): as class 5 but no reference to the biological indicator

Class 5 & 6 are commonly used inside packs.

Steam Sterilization – Steam Supply (EN 285)

Goal: Pure saturated steam, which does not leave residues

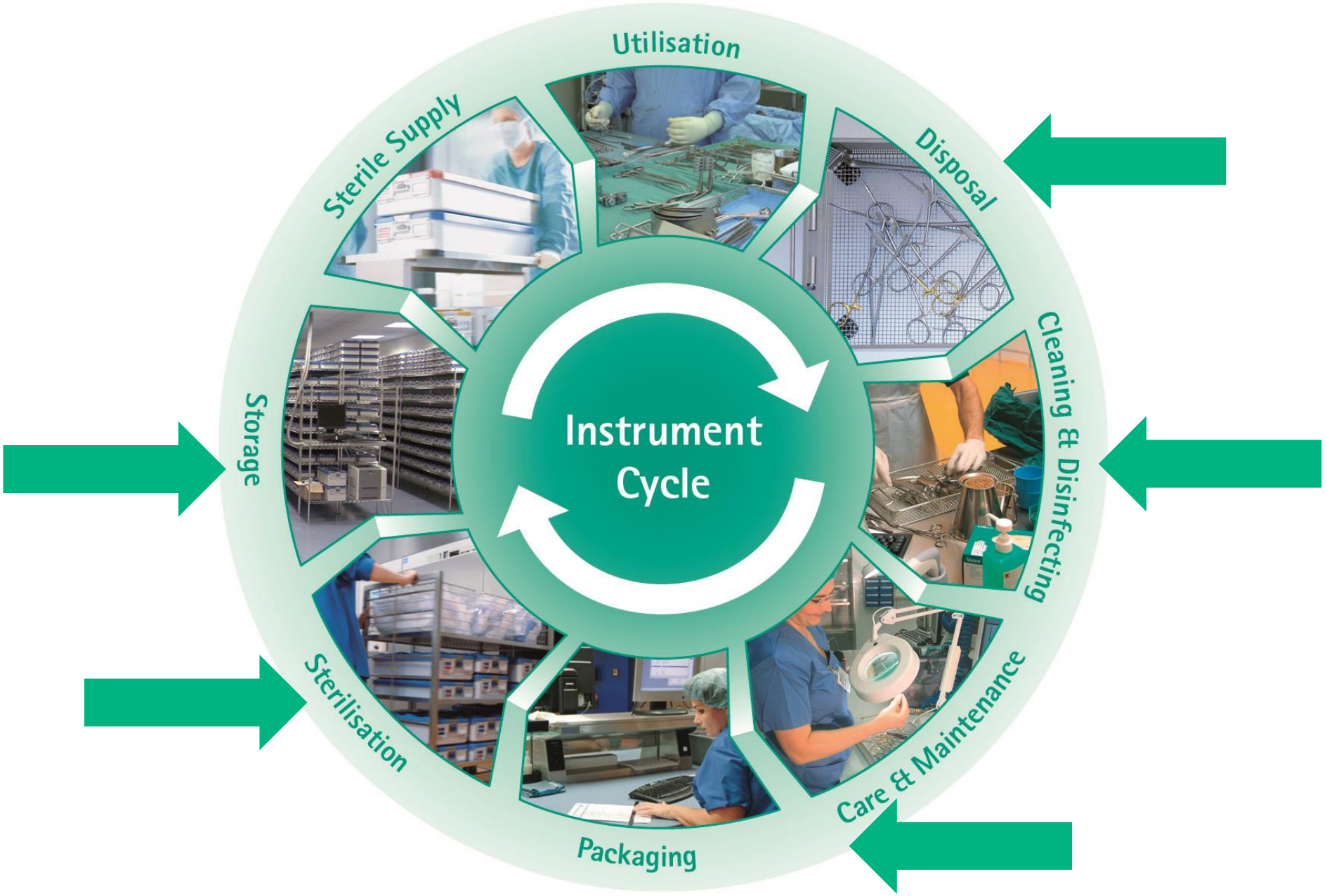
Clean steam supply through:

- Direct from the sterilizer
- Central steam supply
- Electrical or steam heated
- Steanless steel pipes
- Regular condensate removal

Saturated steam: Weight gain (wet load) of 0.2% of a container in the worst position of the chamber in a fully loaded chamber is acceptable!

Relevated guideline and norm:

EN 285 & AKI


Utilisation
Disposal
Cleaning & Disinfecting
Care & Maintenance
Packaging
Sterilisation
Storage
Sterile Supply
Instrument Cycle

Storage Conditions

In closed cupboards or drawers

Dust-free and dry rooms

Humidity and temperature controlled (AAMI)

Rooms free of vermin

Storage Time

Event related expiry dates (AAMI)

Testing (UK)

DIN 58953

- 4 weeks for paper
- 6 Months other packaging materials

THANK YOU

YOUR QUESTIONS…