Basics of sterilisation

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„STERILE“

- Specification for the term STERILE (defined in the European Pharmacopoeia and the European standard EN 556):
  - You can call a product STERILE, if the probability for the existence of microorganisms is less than 1: 1,000.000

sterile instruments

- Sterilisation is required for items, which are used in the bloodstream or in wound treatment or have contact with sterile tissues or organs

Disinfected instruments

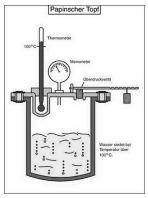
- You use disinfection to avoid the transmission of microorganisms from one patient to another (e.g. endoskopy)
- For reasons of safety and traceability and environmental reasons you should use an automatic thermic procedure

Water - Steam

- What is steam?
- Water in a gaseous state (more than 100°C)
- Can you see steam?
- No, only „steamclouds“, these are condensed waterdrops
- Where does water boil earlier? At the Copacabana or on the top of the K2?
- On the top of the K2 (boiling temperature depends on the atmospheric pressure)

Steam sterilisation

- Steam sterilisation is the safest sterilizing procedure and should be preferred to all others
- The effect is due to moist heat
- The proteins of the cell are destroyed
- The operation mode is comparable to a pressure cooker (in Austria we call it „Kelomat“)

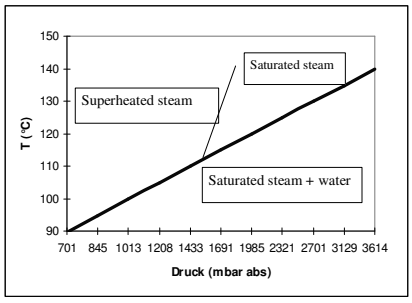


Steam sterilisation

- Water is heated up in a closed chamber till it boils and the chamber is filled with satured steam
- Under atmospheric pressure steam can not be hotter than 100 °C
- Pressure cooker: steam can‘t exhaust and reaches a higher temperature

Steam sterilisation

- Saturated steam has a high amount of energy
- Condensation heat destroys microrganisms
- Exactly the same amont of energy, which was needed to boil away the water, will be released at the condensation



Relation of temperature and pressure (curve of saturated steam)

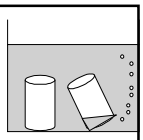
Quality of steam

- Superheated steam
  - **Casing temperature > chamber temperature**
  - **Reduction of pressure is to near to the chamber**
  - **Exothermic reactions**
    - **hygroscopic materials**
      - **papers, pulps, cotton**

Quality of steam

- Wet steam
  - **Condensate is carried along with the steam**
  - **Steam generator is to small**
  - **Casing pressure < chamber pressure**
  - **Incorrect leading of steam pipes**

Air and steam

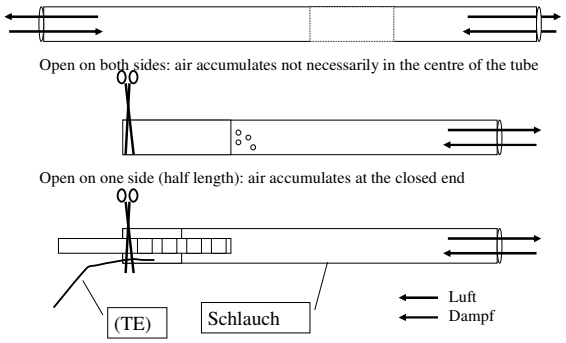


- They don‘t mix
- Where‘s air there can‘t be steam (vice versa)
- Air has to be removed
- fractionated vacuum process: the whole air is replaced by steam

Non condensable gases (NCG)

- Steam isa condensable gas
- Air is a non condensable gas
- If there is too much of the NCGs in the steam, they can accumulate in
  - Hohlkörpern hollow bodies
  - porous materials

Non-condensable gases (NCG)



Before sterilisation

- Only cleaned and disinfected MDs should be sterilized
- Residues of salt or proteins can be a protective cover for microorganisms and make ist difficult to kill them
- MDs should be disassembled, so the steam can lay itself down on all surfaces
- MDs must be dry bevor sterilising

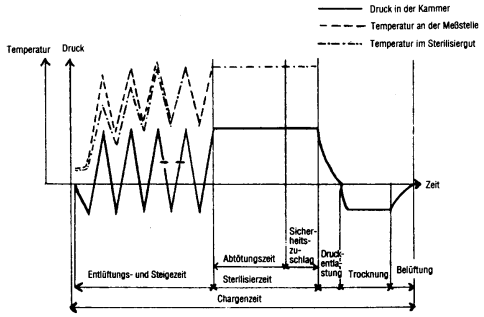
Loading

- Load in such a way the the steam isn‘t interfered and air can easily disappear
- Consider the directions of loading
- Put heavy goods down below (condensate)
- Use loading schema

steam sterilisation

- **exhausting phase**
  - fractionated vacuum
  - Compensation time / balancing period
- **sterilising phase**
  - Holding time (dwell period) + balancing period (+ security addition)
    - **121 °C / 15 Min (2,05 bar) + 5 min.**
    - **134 ° C / 3 Min (3,04 bar) + 2 min.**
- **drying phase**

Sterilizing procedure with fractionated vacuum

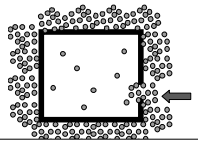


Servic, inspection and testing

- Per charge
  - control of parameters
  - Use of charge control systems
- daily
  - Bowie & Dick-Test
- weekly
  - Vacuum test
  - Cleaning of the chamber
- annually
  - Service according to the specifications given by the producer
  - (Re)validation by an expert

Vacuum test

- Vacuum test (leakage test): Is the chamber leak-proof and airtight?
- Neagtive pressure (~ 50-80 mbar)
  - Testing time 10 min
  - The rise of the pressure during the testing time must not be more than 13 mbar
- Weekly test



Bowie & Dick-Test

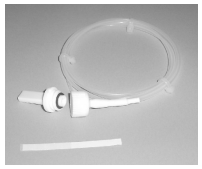
- Standard-Test package or a package for single-use only or a helix model
- Daily test before the production starts
- Analysis should be done immediately
- Documentation of the result (it is not necessary to store the indicator)

Treatment indicators

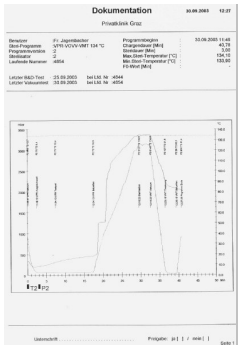
- Indicate with a colour change that something was in the sterilizer
- Are important to avoid mistakes (sterilized – non-sterilzed goods)
- **No** information, if the sterilisation process took place in the correct way

Control of charges

- Use certificated Charge controlsystems (e.g. Helix)
- Indicator + test specimen
- Air must be removed from the tube and steam must penetrate to the indicator



Parametric Release



- all tests (VT, BD-Test, controlsystem of the charges) are ok
- No dis is indicated
- Protocol of the charge is according to expectations
- Release by well-trained staff!

Validation of sterilisation processes

The validation of a sterilisation process is a verification that this process reproduceably generates sterile products when you use the special individual conditions on the location, the user´s MD and the kind of packing and loading.

Validation

- Installation Qualification/Operation Qualification:
- Are the operational preconditions, the organisational preconditions, the technical preconditions and documentation fulfilled?
- Performing Qualification:
- The PQ is the test with which you can demonstrate the efficacy of the sterilisation process using MD of the user (e.g. hospital), the user´s kind of packing and the kind of loading at the specific installation location of the sterilizer
- With the physical performance test you can proof that the necessary conditions are achieved at every point of the load.

Quality management

- Training of the staff (advanced training)
- SOPs for every step of the process
- Monitoring/controlsystem for the routines
- Release system
- Service plan
- validation
- documentation
  - In Austria: storing period 10 years

Sterilisation with dry heat

- **dry heat isn´t able to store that quantity of energy that water or steam does**
- Insufficient standardizable
  - In practice:
    - to open the sterilizer is possible at anytime
    - undefined compensation
- Do not accept for sterilisation of MD

Low temperature techniques

- **Gas sterilisation**
  - **Ethylenoxid (EO)**

    Mutagenous, cancerogenous, poisonous, explosive, desorption time, validation EN 550

  - **Formaldehyd (FO)**

    Poisonous, validation EN 15424

- **Plasma sterilisation (H_2O_2 hydrogenperoxide)**
- **(„cold sterilisation“)**