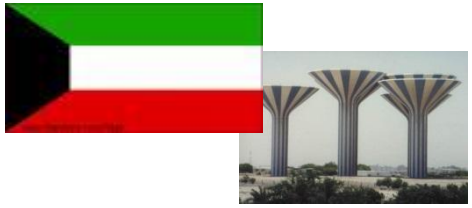

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# Current status of low temperature sterilization

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# Low temperature sterilization (LTS): a misleading term

| sterilization procedure | sterilizing agent |
|---|---|
| steam sterilization | steam |
| dry heat sterilization | dry heat |
| EtO sterilization | ethylenoxide |
| low temperature sterlization | **low temperature ??** |

# Low temperature sterilization (LTS): a misleading term

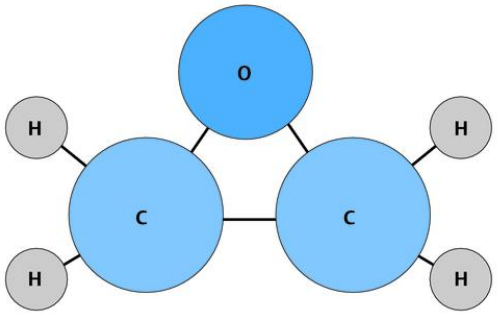
There is no standard which defines LTS:
In general, LTS includes procedures with a process temperature below the coagulation temperature of proteins.

- Ethylenoxide-gas sterilization (EtO)
- Low temperature steam-formaldehyde sterilization (LTSF)
- Hydrogenperoxide gas-plasma sterilization
- Hydrogenperoxide vapour sterilization
- (Radiation sterilization)

- [Ozone, peracetic acid, Cidex-OPA, chlorine dioxide …]

# Ethylenoxide sterilization properties of EtO (1)

Colorless gas, heavier than air, water soluble
Boiling point: 10.7°C



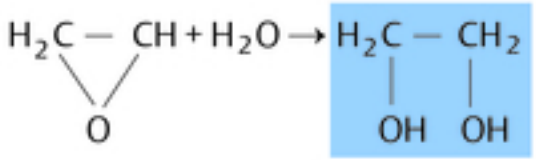

Sweet smell, threshold limit for smell 700 ppm

Limit of flamability in air: 3% EO
(6% EO in 94% $CO_2$ is not flamable)

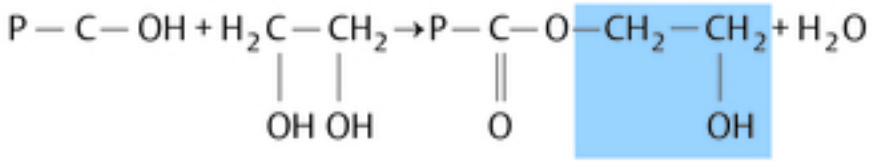
Toxicity: irritant, cancerogenic, mutagenic, teratogenic

Microbicidal activity through reactions with functional groups of proteins:
vegetative microorganisms, bacterial spores,
viruses (not prions)

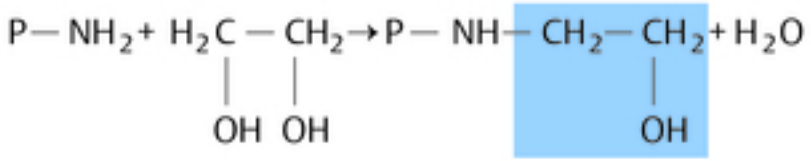
# Mode of action: alkylation of protein molecules



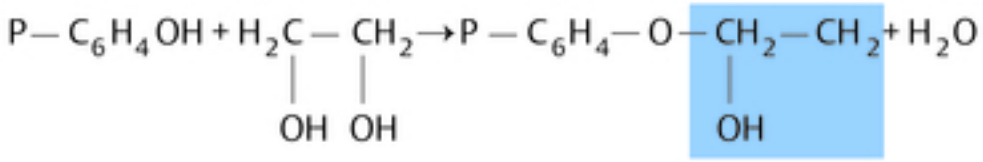
organische Säure



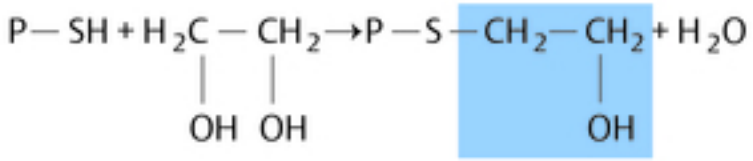
Aminogruppe



Phenol



Sulfhydrilgruppe



# Ethylenoxide sterilization properties of EtO (2)

Highly reactive, forms of toxic compounds with water (ethylene glycol) and chlorine radicals, eg. in PVC (ethylen chlorohydrin)

High penetration capacity (sterilization of inner surfaces of closed plastic vessels)

**Consequences:**

- aeration of sterilized items (sterilizer chamber or aeration chamber)

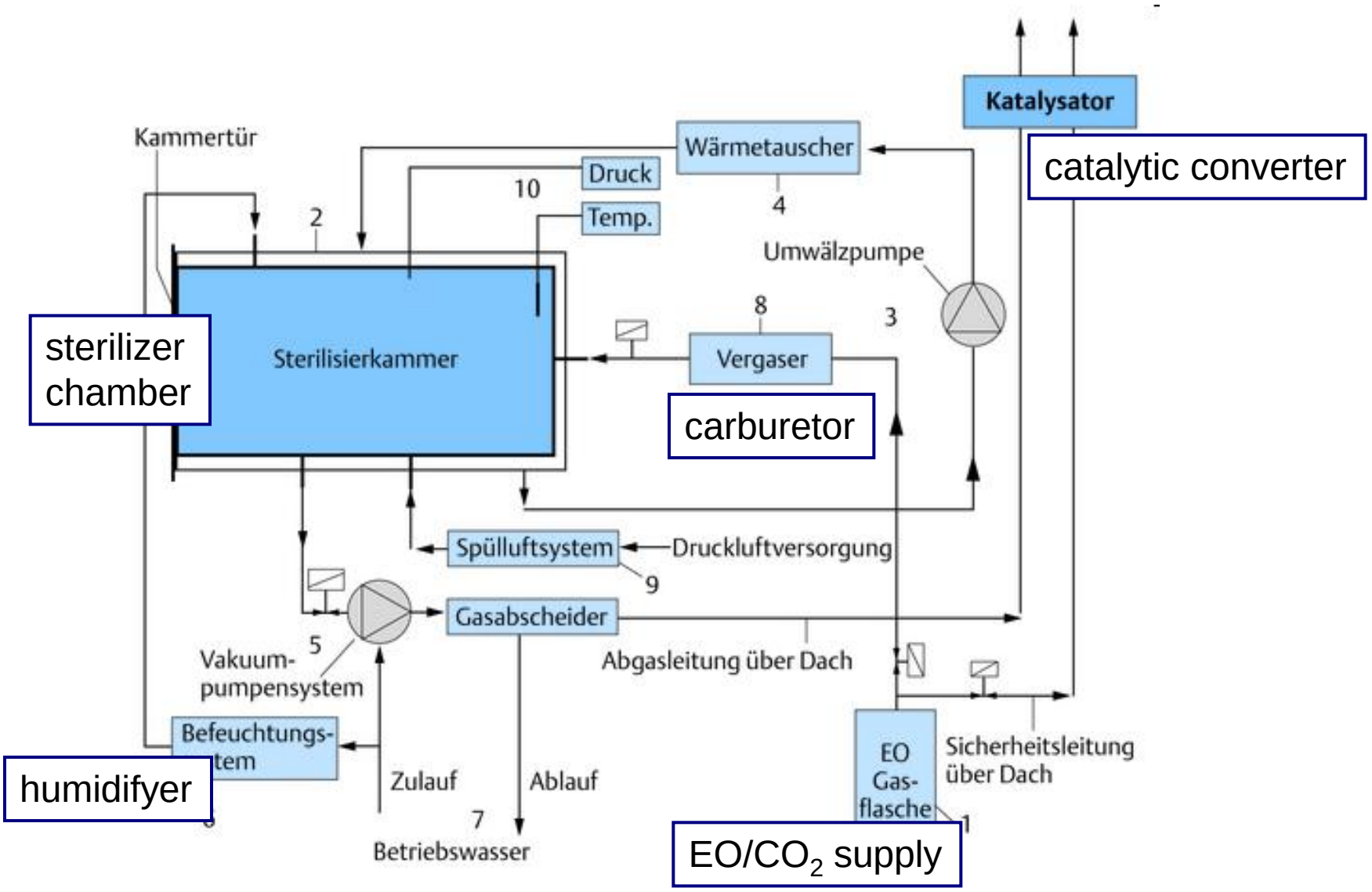
- removal of EO from the exhaust air of the sterilizer (catalytic converter)

# EtO sterilization using EtO/$CO_2$-combination

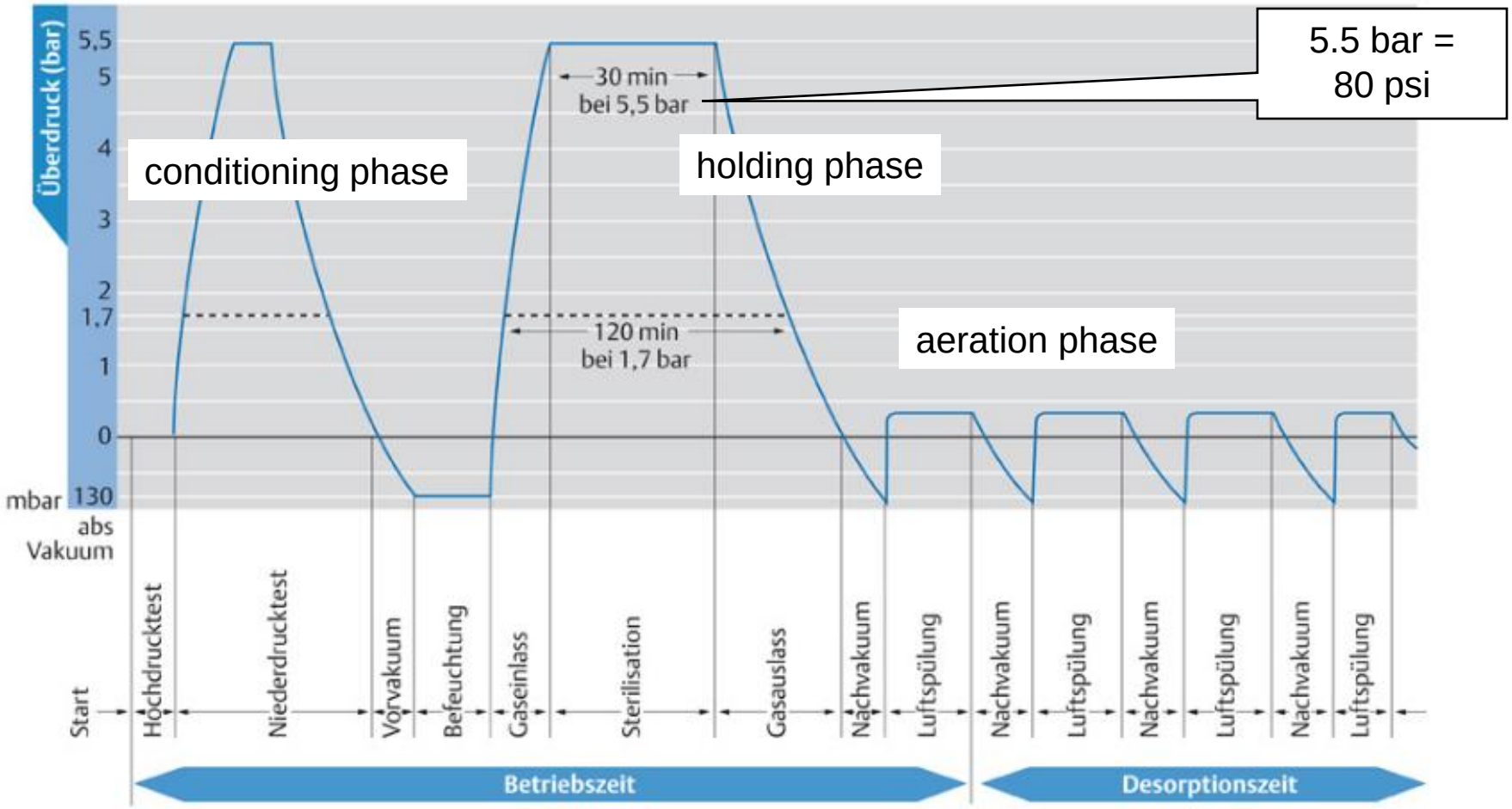
Essential parameters:

- concentration: 250 – 1200 mg EO/L
- process temperature: 28 – 55 °C
- relative humidity: - 90%
- positive pressure:  min. 120 – 150 kPa (1.2 - 1.5 bar /17.4 - 21.8 psi
- exposure time: 10 – 300 min

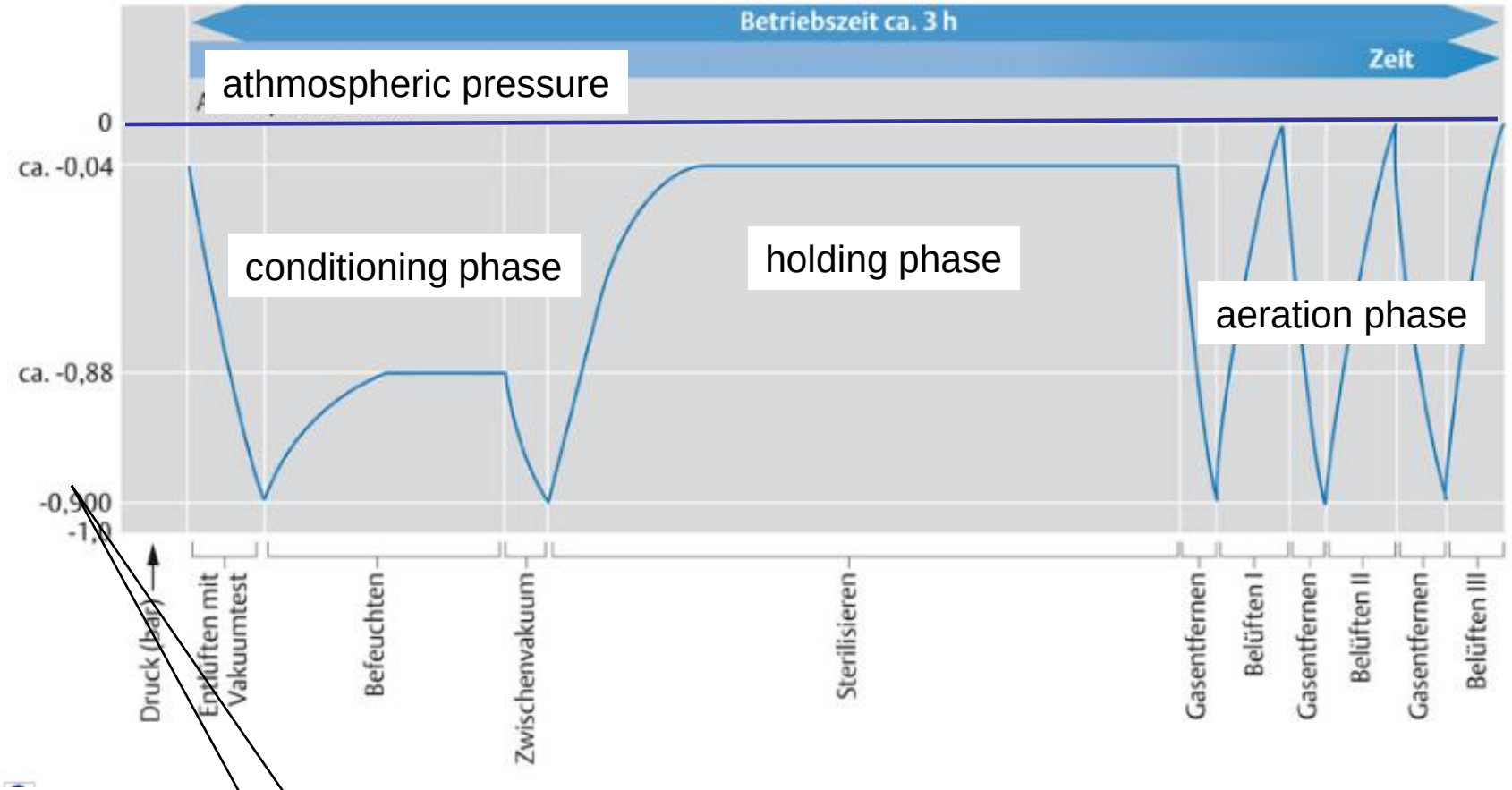
# EtO-Sterilizer for positive pressure cycle using 6% EtO + 94% $CO_2$



# Positive pressure cycle using 6% EtO + 94% $CO_2$



# EtO-Sterilizer: subathmospheric pressure cycle using 100% EtO



# Validation

- validation including performance qualification:
  ISO 11135 (includes measurement of EtO concentration during the cycle)

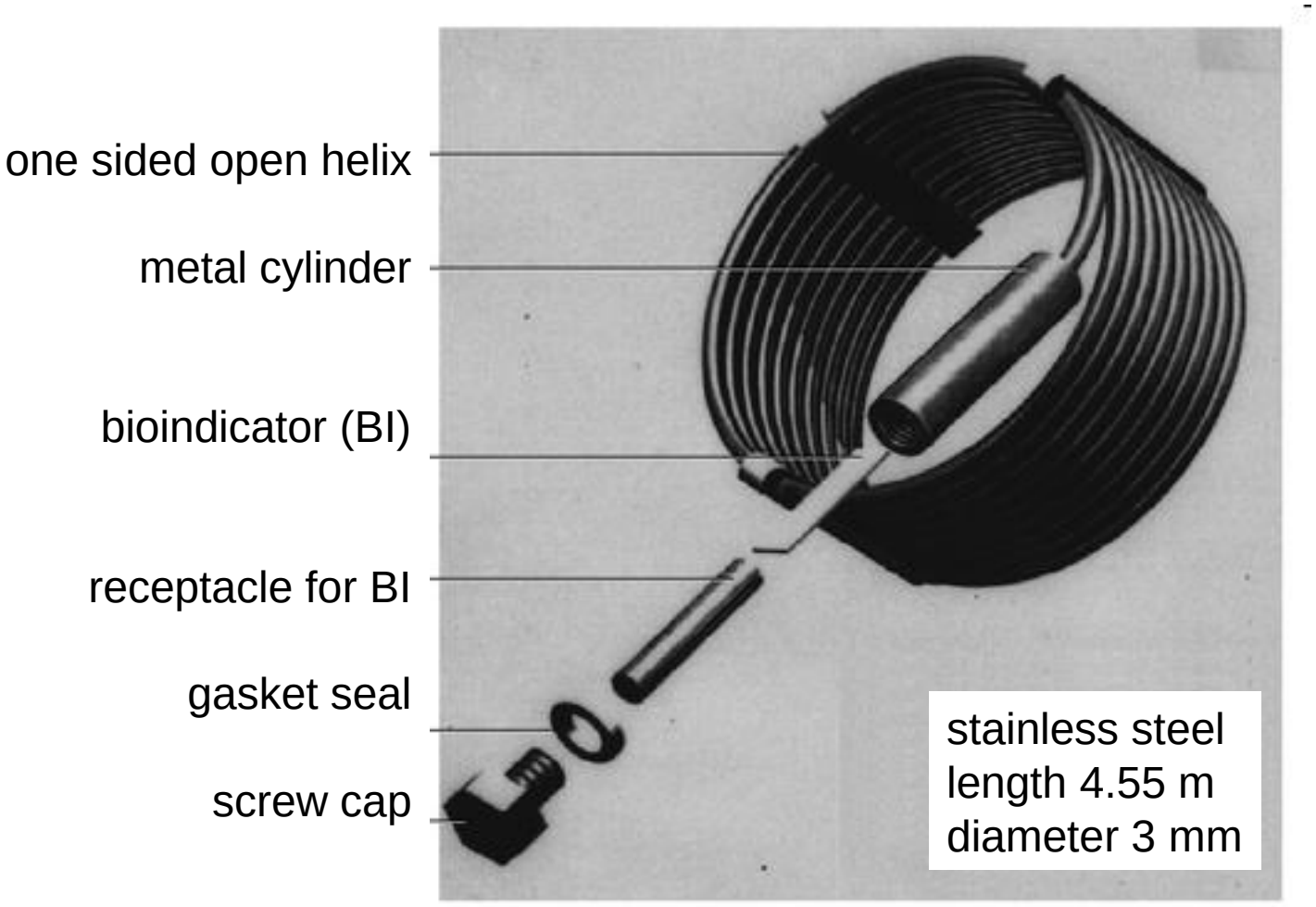
- bioindikators: *B. atrophaeus* spores, > 5 x $10^5$

  D-value > 2.5 min at 54°C/60% rh and 0.6 g EtO/L

  test carried out in a half cycle using a PCD

- acceptable residual EtO-concentrations: ISO 10993-7

# EtO-sterilization: process challenge device (PCD)



# Low temperature-steam formaldehyde sterilization (LTSF)

formaldehyde, $CH_2O$:

colorless, pungent smelling gas, threshold limit for smell 0.1– 1 ppm,

boiling point -19 °C, water soluble (methylenglycol as active agent?)

formalin: saturated solution of formaldehyde in water (35-39%)

Active against

- vegetative microorganisms by chain-forming reactions with functional groups of cellular proteins,
- viruses by alkylation of DNA and RNA,
- sporocidal effect requires LTSF conditions

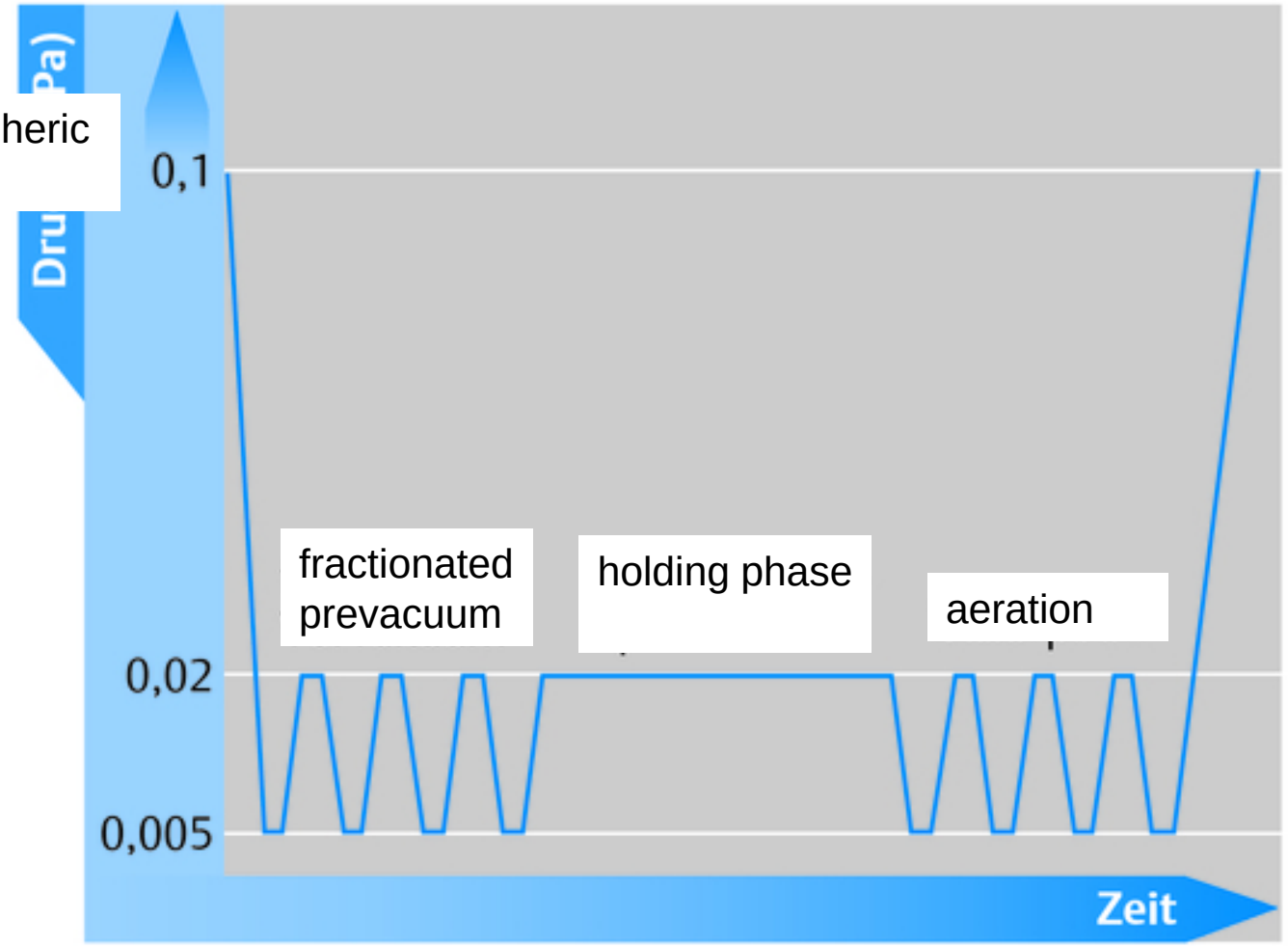
# LTSF sterilization: principles

Requirements for sterilization:
2-3% formaldehyde solution, 60°C, 100% rh, 20 kPa (2.9 psi),
exposure time 60 min

fractionated prevacuum (like for steam sterilization)
pressure regulation in the chamber between 5 und 20 kPa
(0.72 - 2.9 psi)
secures condensation and re-vaporisation of formaldehyde

low penetration ability!
short aeration period sufficient

# LTSF sterilization: process characteristics



# Validation

- validation including performance qualification (including concentration measurement and/or biological indicators: EN 14180, ISO 25424

- biological indicators: *G. stearothermophilus* spores
  half cycle with PCD (1500 mm dead end tube, ∅ 2 mm), PCD for EtO sterilization also successfully sterilized *(Kanemitsu et al. 2005; 62: 928-932*

- acceptable residual concentration
  of FA: < 5 μg/cm$^2$

# Packaging materials for EtO and LTSF sterilisation

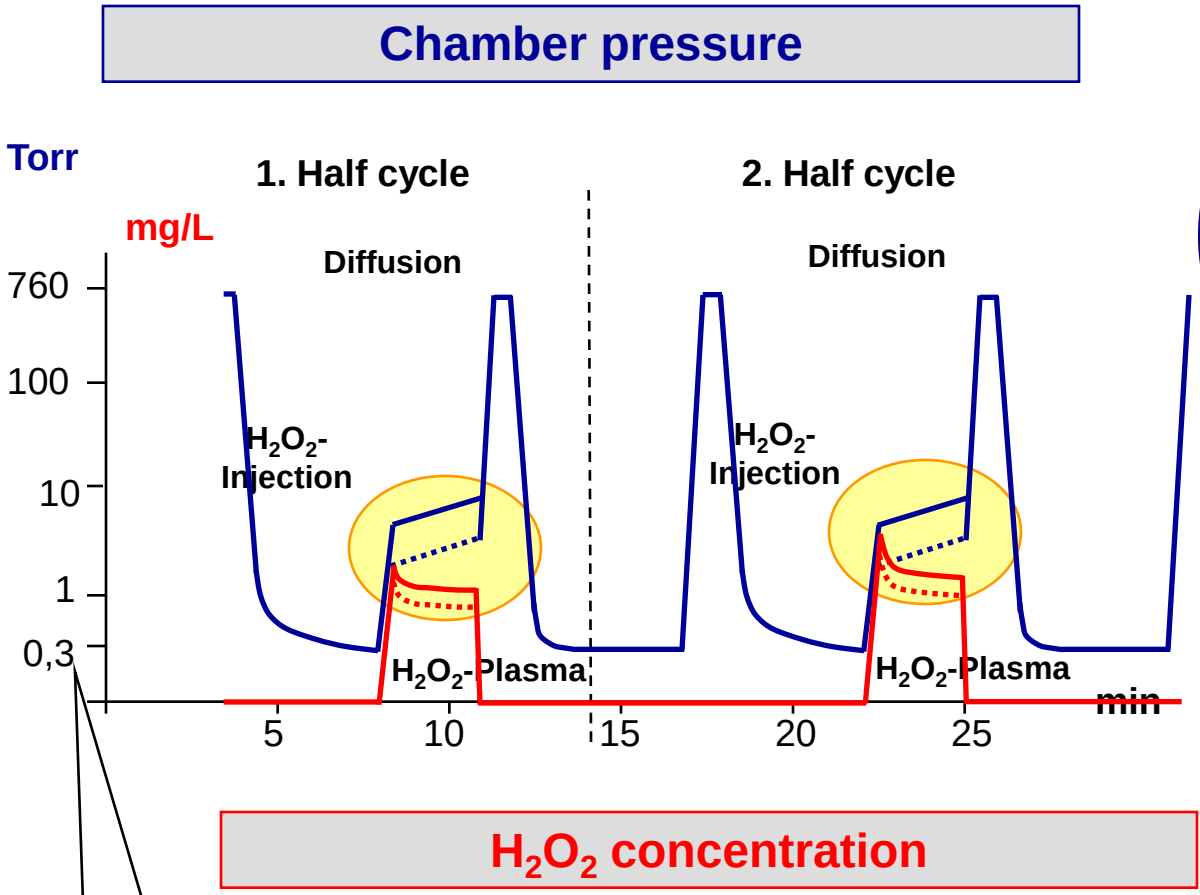
- pouches with transparent polyamide sheet and paper or Tyvek ® (high pressure welded polythylene fibres)

- not suitable:
  metal boxes, non-woven fabrics, polyethylene,cotton)

# Hydrogen peroxide plasma sterilization (Sterrad NX): process description

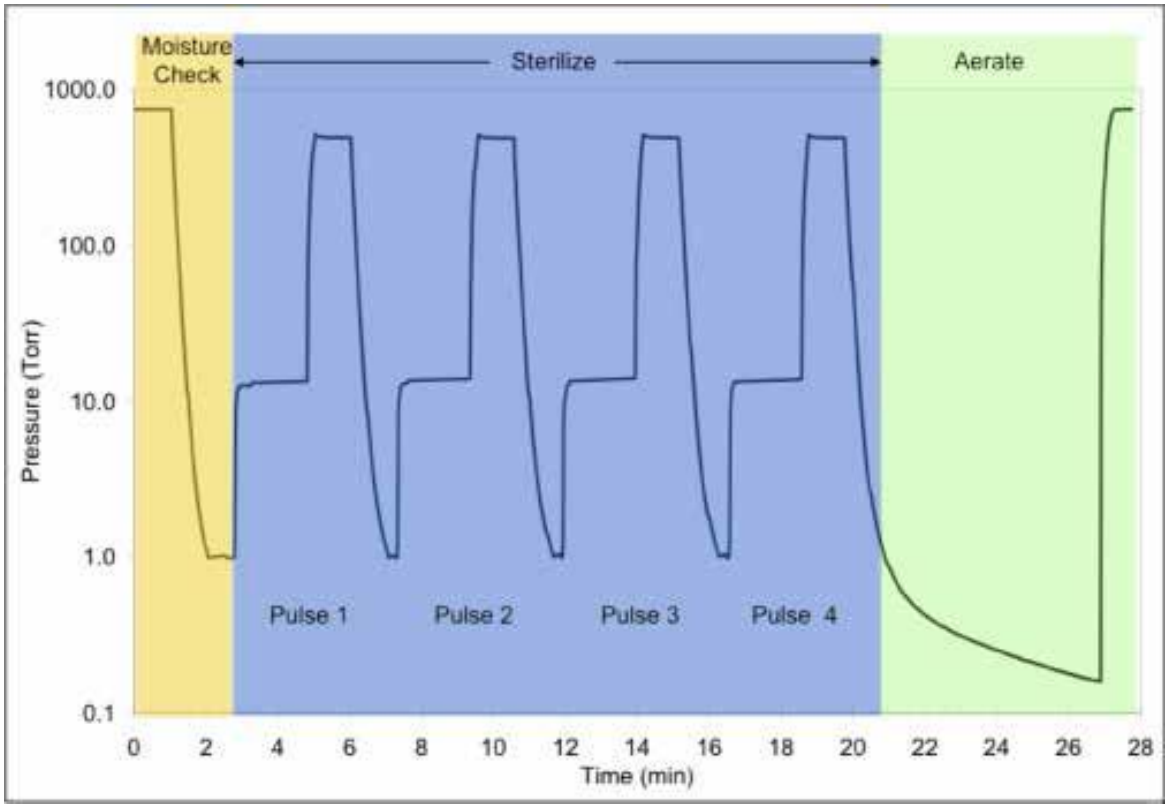
- Pressure reduction, injection and vaporisation of an aqueous solution of **hydrogen peroxide (59 %)**
- Diffusion of hydrogen peroxide vapour throughout the chamber and items to be sterilized, inactivation of microorganisms starts
- Reduction chamber pressure, application of **radio frequency (RF) energy** creates an electric field: **formation of low temperature plasma**.
- Formation of free radicals in the plasma by breaking apart the hydrogen peroxide vapor
- Activated components react with the organisms, then lose their high energy and re-combine to form oxygen, water vapor, and nontoxic by-products.
- This is the half cycle: cycle is completed by repeating the above sterilization steps.

# Hydrogen peroxide plasma sterilization (Sterrad 100S and Sterrad NX by Johnson and Johnson)




**Pressure** and **concentration** **are dependent on the load**

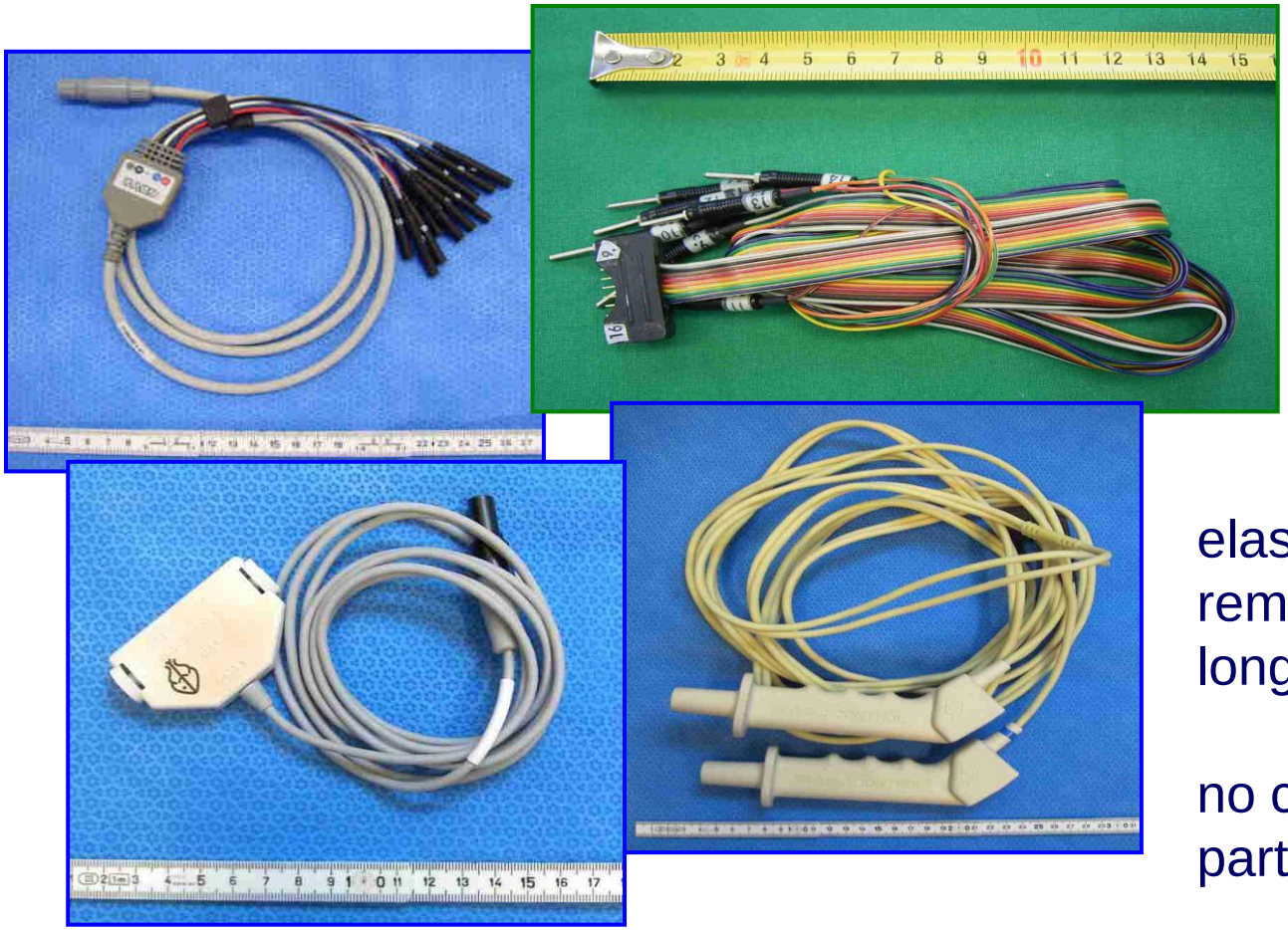
# Vaporized hydrogen peroxide sterilization (VHP system by Steris)




sterilant: 59% hydrogen peroxide
duration of cycle: 28 - 56 min (“lumen cycle”) at 30 - 40°C

# Application of $H_2O_2$ sterilization (1)

cables and connectors

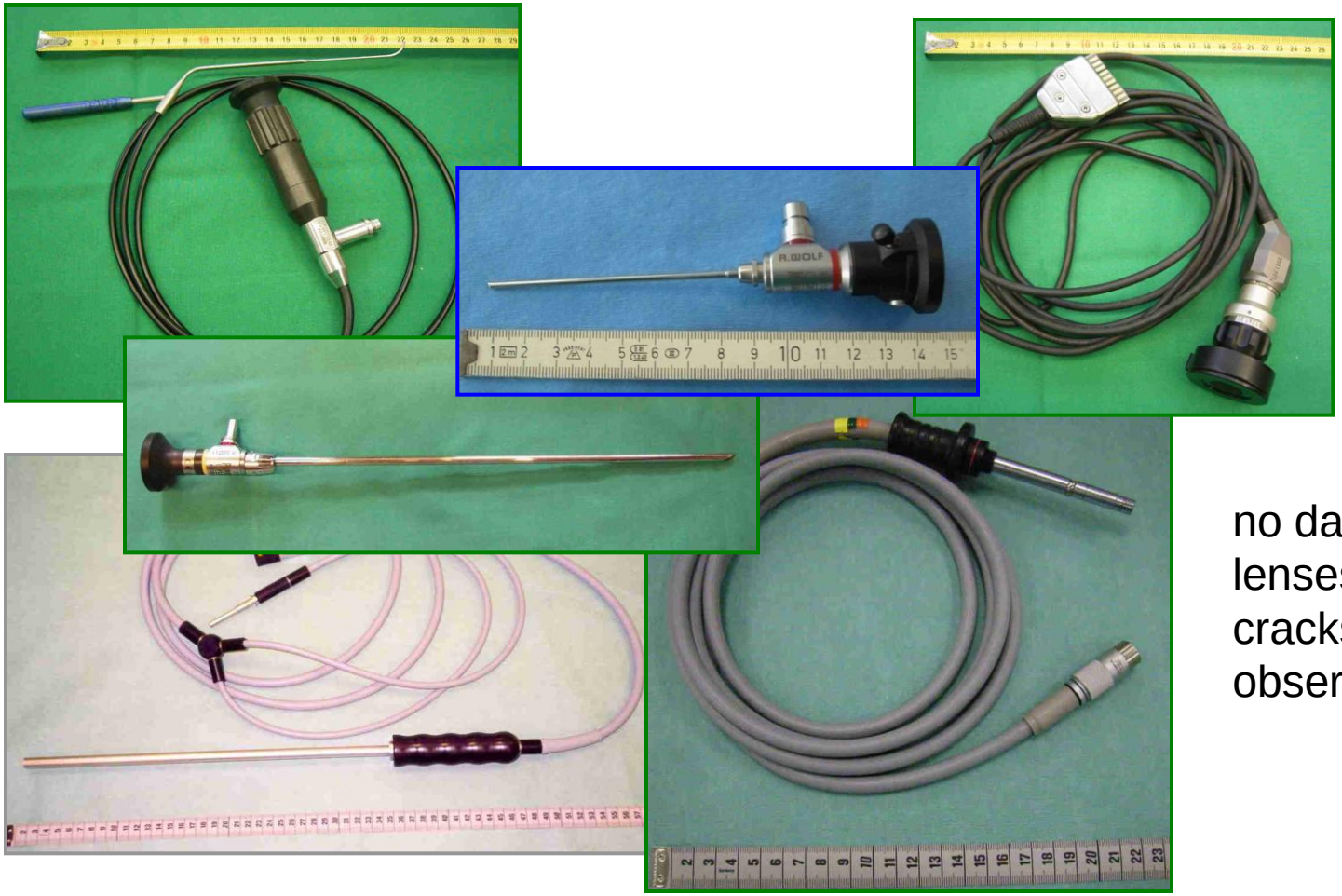


elastomeric insulation remains unaffected over a long period of time

no corrosion on metallic parts

# Application of $H_2O_2$ sterilization (2)

## optical and optoelectronoc devices




no damages of the lenses (cloudiness, cracks) were observed

# Application of H2O2 sterilization (3)

flexible endoscopes:
follow the manufacturers‘ recommendations regarding length-diameter-ratio!


hysteroscope

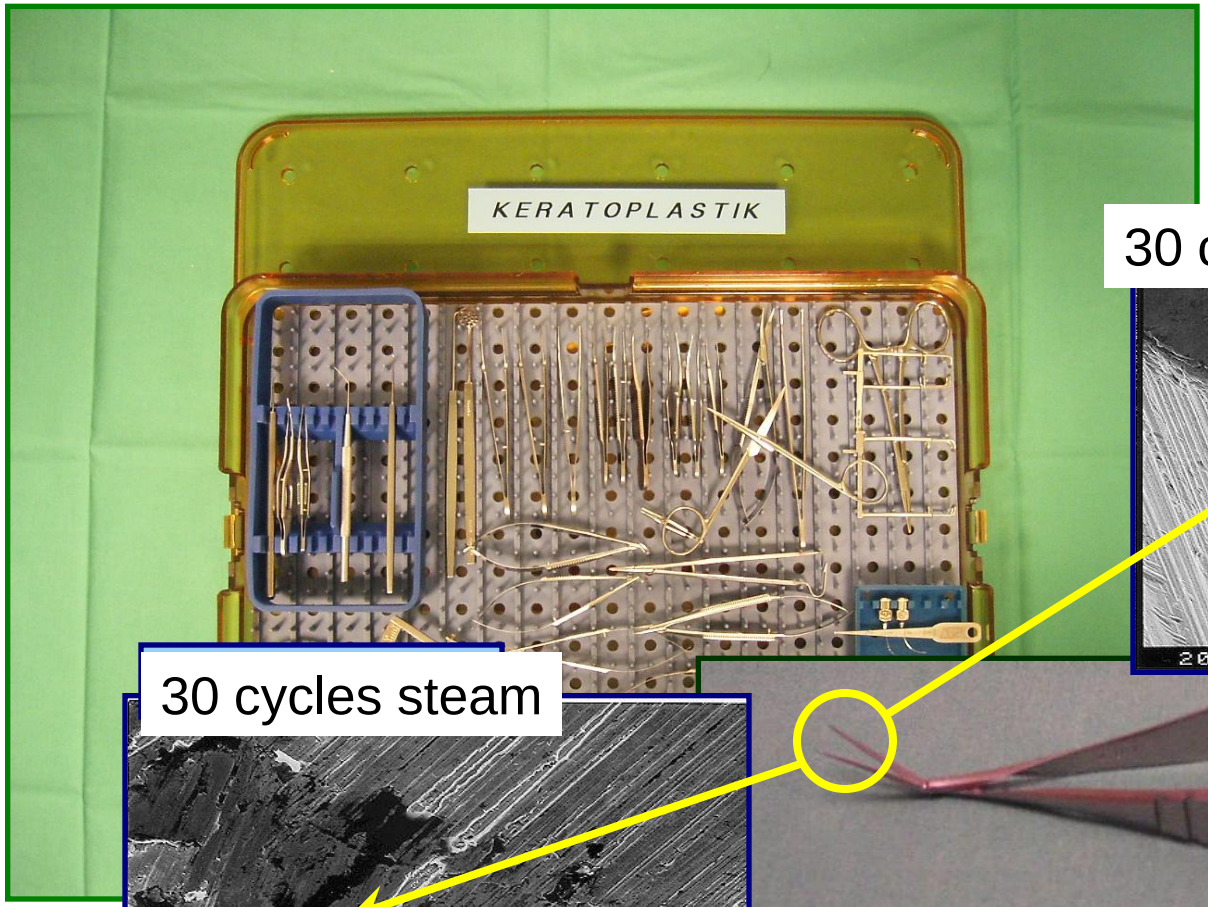

cystoscope


choledochoscope

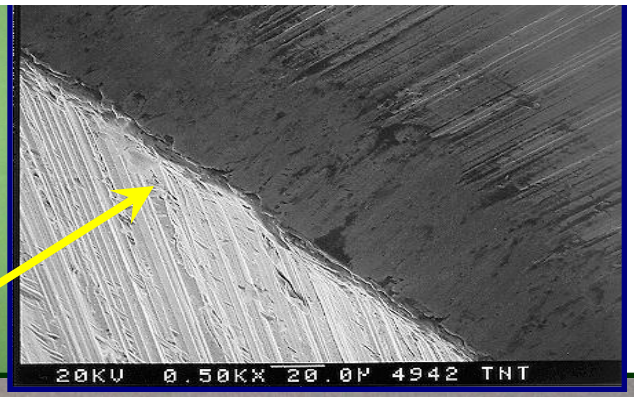
# Lumen-length-capacity of Sterrad sterilizers

| | lumen | length |
|---|---|---|
| Sterrad 100S | 1 mm | max. 500 mm (0.5 m) |
| | > 1mm | max. 2000 mm (2 m) |
| Sterrad NX | ≤ 0.7 mm | max. 500 mm |
| | 0.7 – 1 mm | max. 850 mm (0.85 m) |

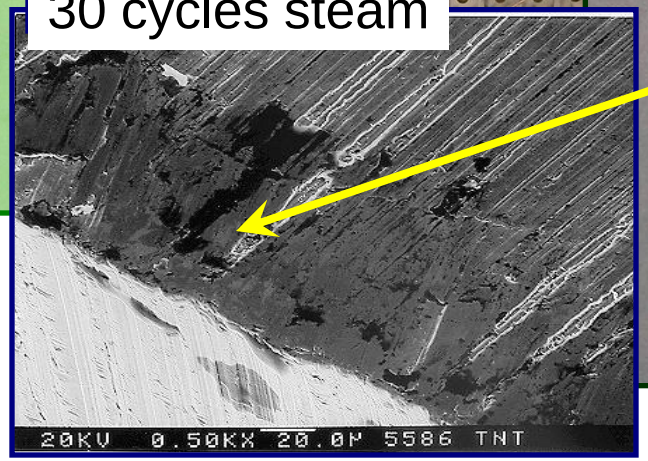
# Material compatibiliy

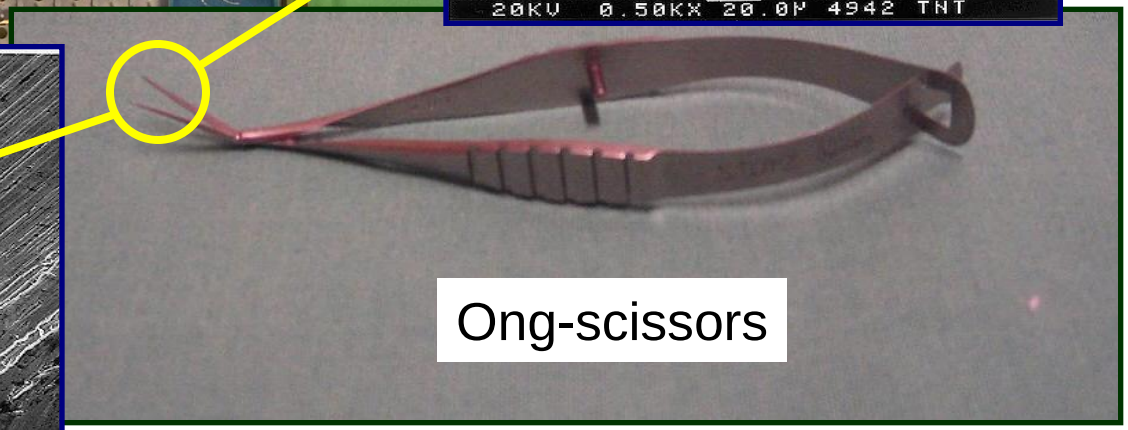



30 cycles hydrogen peroxide




30 cycles steam



Ong-scissors

# Conclusion (1): hydrogen peroxide sterilization

- effective procedure for heat-labile medical devices, and devices which are susceptible to corrosion
- no substitute for steam sterilization
- in combination with defined cleaning procedures very likely effective against prions
- low constructional efforts (electric power supply only), short cycles, adequate cost-benefit-ratio

# Conclusion (2): comparison of high and low temperature sterilization

| | steam | EtO/LTSF | $H_2O_2$ | peracetic a. Cidex-OPA |
|---|---|---|---|---|
| temperature °C | 121 - 134 | 40 -55/ 45 - 65 | 30 - 45 | 20 |
| cycle time min | 10 - 60 | 3 - 5 hrs | - 72 (flexible endoscopes) | 15 - 30 |
| sterilization | yes | yes | yes | high-level disinfection |
| environment | + | ± | + | ± |
| advantages | safe, effective, economical | effective, reliable, material compatibility | safe. effective, nontoxic, no aeration, mat. compatibility | quick, low effort |
| disadvantages | not for heat-sensitive items, corrosion possible | long cycles, costly, health concern (EtO) | expensive (packaging material) | costly, unpacked items only, validation questionable |

# Thank you!