Steam penetration in steam sterilization processes

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Out line

- Steam sterilization conditions
- Loads
- Some physics
- Penetration of steam
- Standards

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Sterilization conditions

Perkins and the Medical Research Council

Perkins 1956[1]

Time [min]	Temp [°C]
2	132
8	125
12	121

[1] Principles and Methods of Sterilization, Perkins JJ, Springfield (IL), 1956
[2] Working Party on Pressure Steam Sterilizers of the Medical Research Council, Sterilisation by steam under increased pressure, 1959, 273, 425-435

Boiling and egg

Rational Medical Research Council[2]

- Perkins' experiments in water
- Steam sterilization with steam
- Quality of steam not perfect
- Safety margins necessary

Time [min]	Temp [°C]
2 + 1 = 3	132 + 2 = 134
8 + 2 = 10	125 + 2 = 127
12 + 3 = 15	121 + 0 = 121

[2] Working Party on Pressure Steam Sterilizers of the Medical Research Council, Sterilisation by steam under increased pressure, 1959, 273, 425-435

Steam sterilization conditions

- On all surfaces 100 % or saturated steam
- Predetermined temperature
  - E.g. 134 °C and 121 °C
- Predetermined time
  - E.g. 134 °C for 3 minutes and 121 °C for 15 minutes

7

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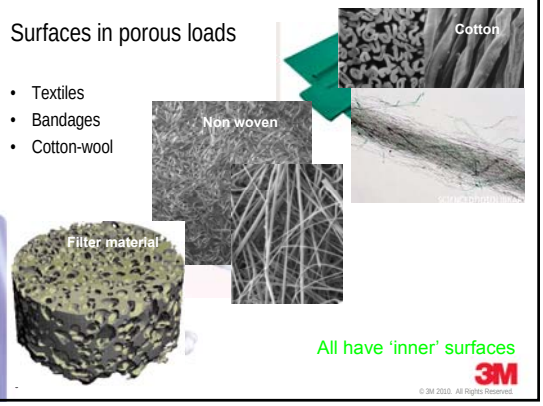
Loads

8

Surfaces in porous loads

- Textiles
- Bandages
- Cotton-wool

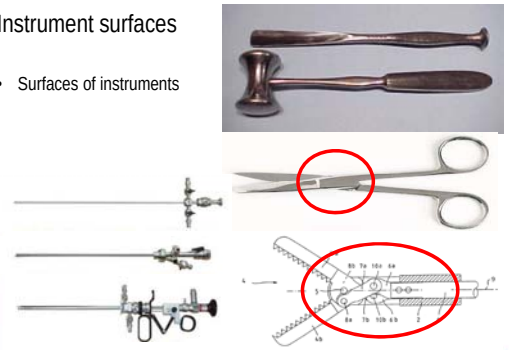


All have 'inner' surfaces

9

Instrument surfaces

- Surfaces of instruments



10

Change of loads in hospitals

- Porous loads are replaced by disposables or single use
  - E.g., cotton drapes replaced by non woven and crepe
- Instruments become more complex
  - E.g., More Minimal Invasive Surgery result in more lumened instruments

11

Capillary suction in porous loads

Decreasing capillary suction → Increasing capillary suction

12

Sterilization

13

Sterilization is a combination of

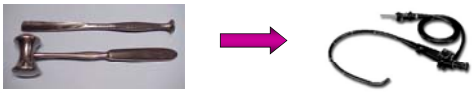
- Sterilizer
- Process
- Load
- Loading pattern
- Wrapping (Micro Biological Barrier)

Changes in one may have changes on the end result

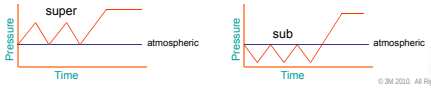
14

Example

Change:
Load from non hollow instruments to hollow instruments

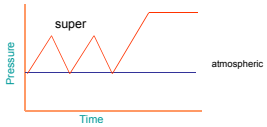


Action:
To establish steam sterilization conditions on all surfaces
Process from gravity to fractionated vacuum process



15

Note

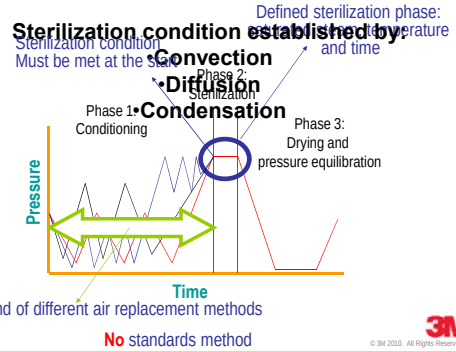


Because of capillary working of porous loads:
It is possible to sterilizer porous loads in super atmospheric processes

Disadvantages
- Less reproducible
- Longer process time

16

Steam Sterilization processes



All kind of different air replacement methods

No standards method

17

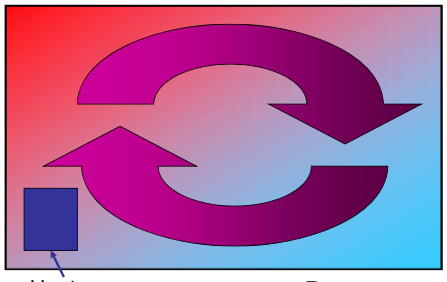
Convection

18

Convection

We control the flow

Ceiling



Heater

Room

19

Only convection

Sterilizer chamber

Process

Pressure

Time

Steam inlet

Pumping of gas mix

20

Only convection and tube in sterilizer chamber

Sterilizer chamber

Process

Pressure

Compressing and decompressing the gas

Convection can be imposed

Time

Steam inlet

Pumping of gas mix

Interface between air and steam
Act like a piston in a cylinder

21

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Diffusion

22

Diffusion

Diffussion needs time

Diffusion can**not** be imposed

Homogenous distubution of the gas

Bottle of Perfume

Room

23

Diffusion in lumen

Air

Steam

Air diffuses into the steam

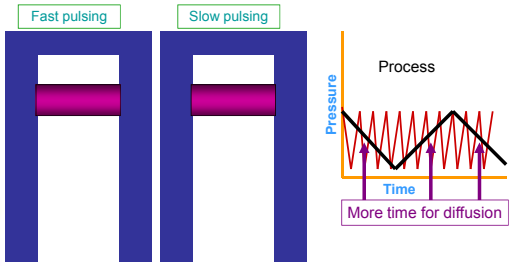
and

Steam diffuses into the air

Diffusion can**not** be imposed.
It is dictated by nature

24

Diffusion influences the air removal time



In steam sterilization processes diffusion is slower than convection

With fast pulsing NO time for diffusion

25

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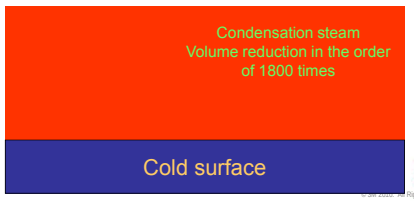
Condensation

26

Condensation

- Basic of condensation are understood
  - Basilcally:
    - Steam condenses on colder surfaces
    - Latent energy transferred to surface



27

Example steam needed to warm up stainless steel

- 1 kg stainless steel instruments
  - **Warm up for 24 to 134 °C (difference = 110 °C)**
  - **Heat capacity stainless steel ≈ 4.600 J / (kg ·°C)**
  - **Needs 1 kg x 4.600 J / (kg ·°C) x 110 °C = 50.600 J = 50.6 kJ**
- Steam at 134 °C
  - **Energy of steam ≈ 2700 kJ/kg**
- Steam needed to warm up instruments:
  - **(50.6 kJ) / (2700 kJ/kg) = 0.019 kg**
  - **0.019 kg steam equals about (0.019 kg) / (0.60 m3/kg) = 0,032 m3**
  - **0.032 m3 = 32 l steam**

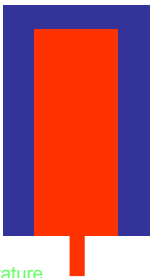
28

Back to lumen

Temperature lumen equals temperature steam

Temperature lumen lower temperature steam

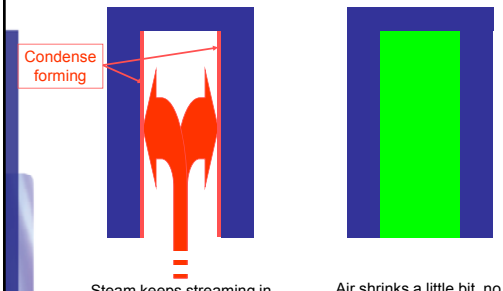
Steam condenses immediately on wall
Volume reduction of about 1700 times
More steam supplied to equalize pressure



Process continues until wall is warmer or equal to steam temperature

29

Physical difference steam and Air (NCGs)

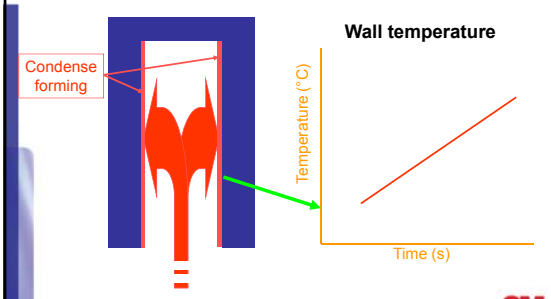


Steam keeps streaming in
Energy is transported in

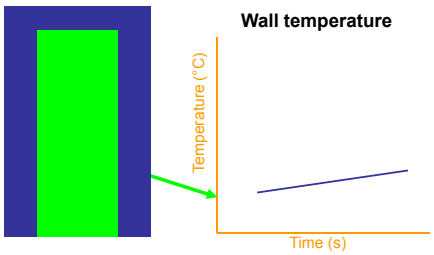
Air shrinks a little bit, no flow
Energy transport is slow

30

Wall temperature raise steam

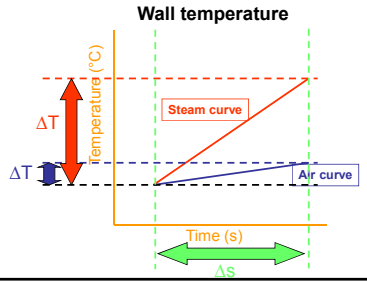


Temperature raise with air



Difference in wall temperature raise

Air warms up the surface slower than Steam



Conductivity and velocity

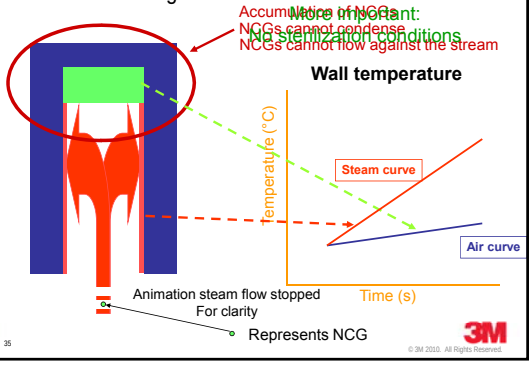
$$\frac{\text{Distance difference}}{\text{Time difference}} \text{ in } \frac{km}{hour}$$

$$\frac{\text{Temperature difference}}{\text{Time difference}} = \frac{\Delta T}{\Delta t} = \frac{dT}{dt} \text{ in } \frac{°C}{s}$$

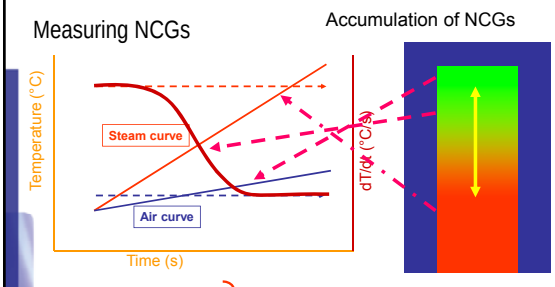
$$\text{Conductivity} = \frac{dT}{dt} \text{ X with some properties of the material}$$

$$\text{in } \frac{W}{m\ °C}$$

Non Condensable gases in steam



Measuring NCGs

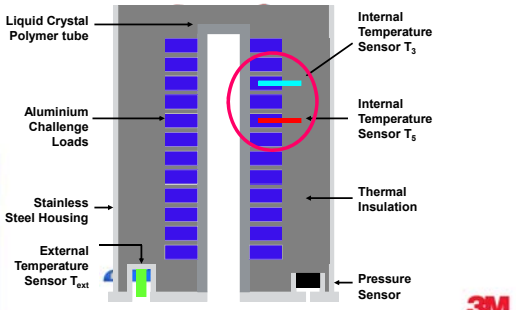


Accumulation of NCGs
Changes gas mix
Reduces dT/dt

Low dT/dt no steam present

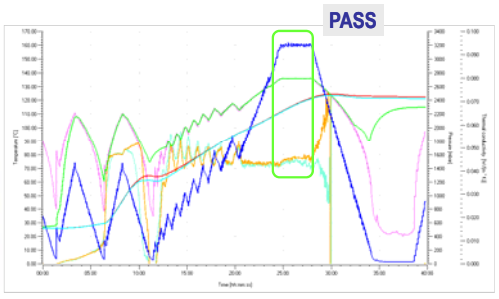
No sterilization conditions

Example: ETS



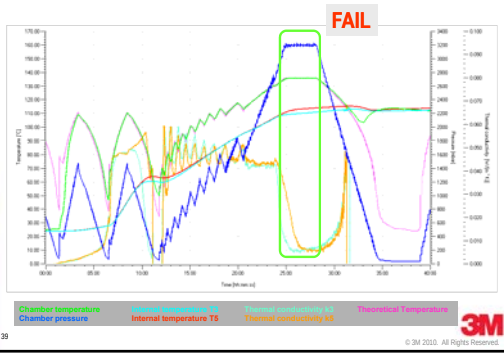
37

An example process



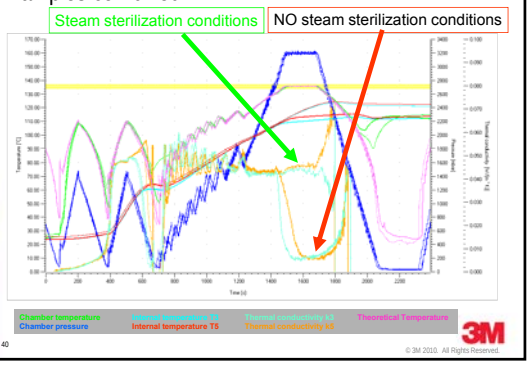
38

An example process



39

Examples combined



40

Causes for presents of NCGs resulting fails

- Insufficient air removal, e.g.,
  - Not deep enough vacuum
  - Not high enough steam injections
  - Too fast pulsing
- Leak in vessel, pipe work, valves or gaskets
- NCGs in steam

41

Consequently

- By measuring NCGs:

  Steam sterilization conditions can be checked

  State of the art technology

42

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Standards

Standards for steam sterilization and processes

1. **EN 285 Sterilization - Steam sterilizers - Large sterilizers (includes Amendment A2:2009)**
2. **EN 13060 Small steam sterilizers**
3. **ISO 17665 Sterilization of health care products - Moist heat**
   1. Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
   2. Part 2: Guidance on the application of ISO 17665-1
4. **ISO 14161:2009 Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results**
5. **ISO11138 Sterilization of health care products -Biological indicators**
   1. Part 1: General requirements
   2. Part 3: Biological indicators for moist heat sterilization processes
6. **ISO 15882:2008 Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results**
7. **ISO 11140 Sterilization of health care products - Chemical indicators**
   1. Part 1: General requirements
   2. Part 3: Class 2 indicators for steam penetration test sheets
   3. Part 4: Class 2 indicators for steam penetration test packs
8. **ISO 11607-1:2006 Packaging for terminally sterilized medical devices**
   1. Part 1: Requirements for materials, sterile barrier systems and packaging systems
   2. Part 2: Validation requirements for forming, sealing and assembly processes

Standard are

- Necessary to have
- Minimum requirements
- Not always state of the art
  - Developments continue
  - Developments may ahead
  - Knowledge may be ahead
- changing over time
  - New insights
  - New information
  - Innovation

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Summarized

Summary and conclusions

- Load to be sterilized have changed
- Standards are important and give minimum requirements
- Not all standards are evidence based (yet)
- Through research and studies more information become available
- With state of the art technology steam sterilization conditions can be confirmed and possibly optimized
- Over time standards will follow state of the art

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Thank you!

any questions?