Product families in steam sterilisation

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29+ product families [ISO TS 17665-3:2013]

How many steam sterilisation processes do ***you*** have on your steam steriliser?

- 134 °C standard
- 134 °C prion
- 134 °C extra drying
- …
- 121 °C standard
- …
- Steam penetration test
- Vacuum leakage test

- How do 29+ product families fit in 2 to 6 processes?
- Is it necessary to have 29 product families?

Sterilisation conditions have to be established at all locations to be sterile.

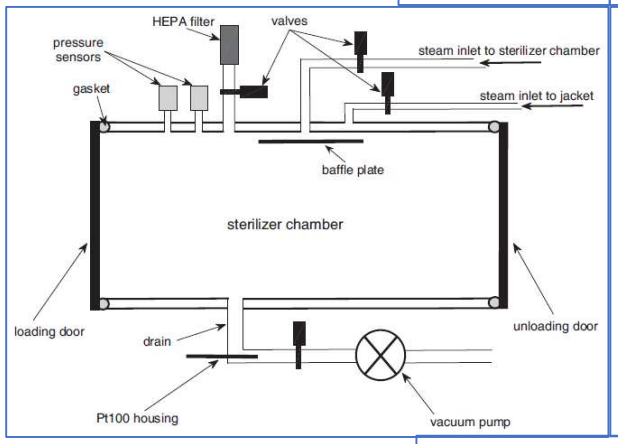
Sterilant have to be in contact with the organism to be killed

Surface steam sterilisation: moist and temperature (energy)

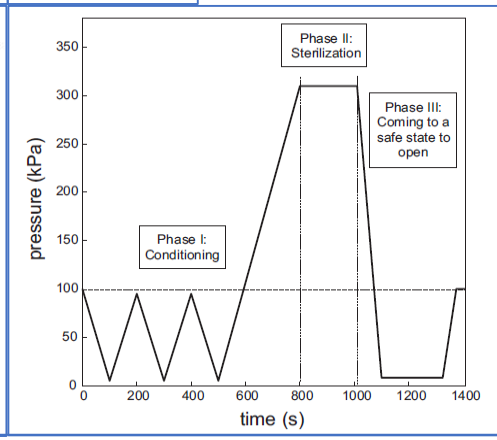
What phenomena play a role to create surface steam sterilization conditions

Success of steam sterilisation process

Steriliser



Process



Source: PhD Thesis: Surface steam sterilization: Steam penetration in narrow channels, 2013.

load

Loading pattern

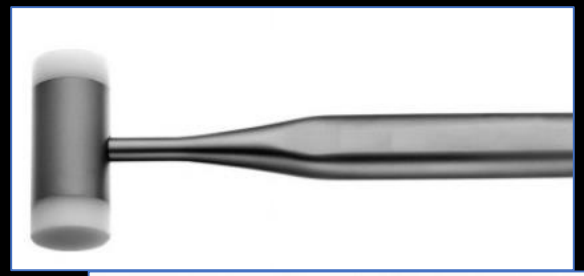
Microbiological Barrier

Dominating process phenomena (for steam sterilisation)

- Condensation
- Convection
- Diffusion

Use the phenomena
to classify the products to be sterilised



T_{steam} = 132 °C

Instrument

$T_{instrument}$ < 132 °C

Steriliser

Condensate

- Organisms in water (film)

Precht/Perkins:

- Precht JCH. Tempertur und Leben. Springer Verlag, Berlin, 1955
- Perkins JJ. Principles and Methods of Sterilization. Charles C Thomas, Springfield (IL), 1956.

2 minutes at 132 °C

Medical Research Council

- Working Party on Pressure Steam Sterilizers of the Medical Research Council. Sterilisation by steam under increased pressure. The Lancet, 273:425–435, 1959.

3 minutes at 134 °C

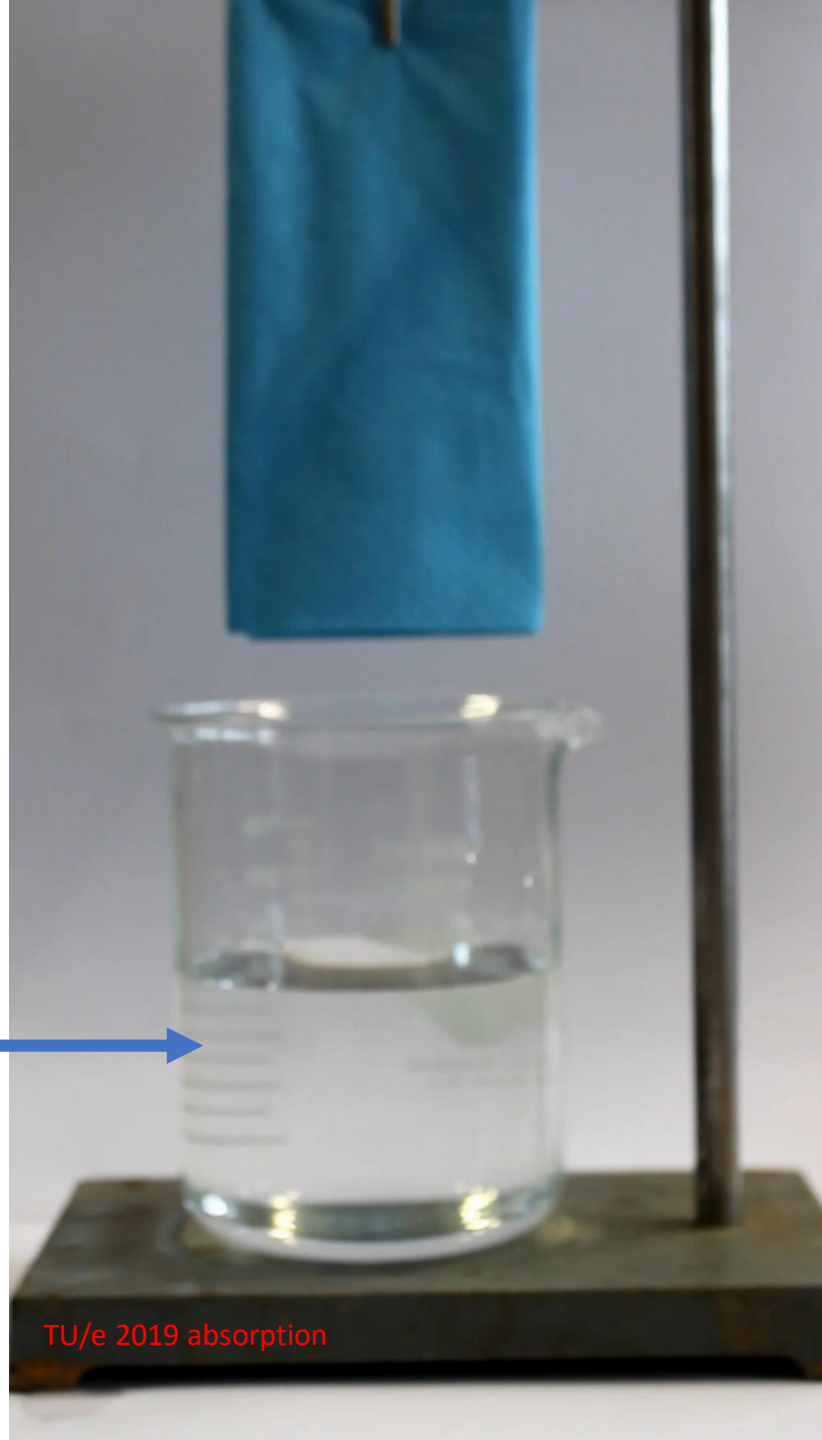
Product classification:	**I Non Hollow (Massive instruments)**
Driving phenomena:	Condensation
Additional parameter:	Time (physical properties)

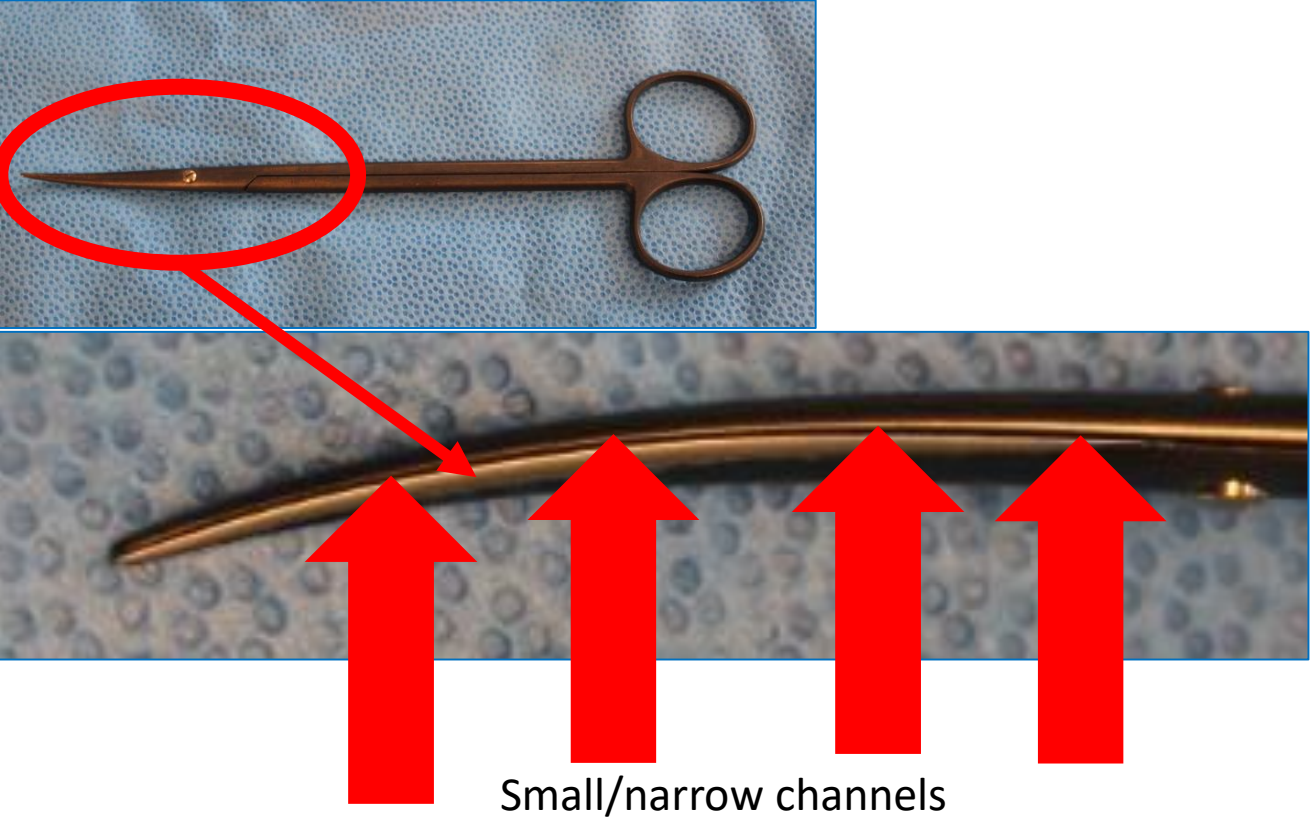
T_{steam} = 132 °C

Sterilizer

Condensate

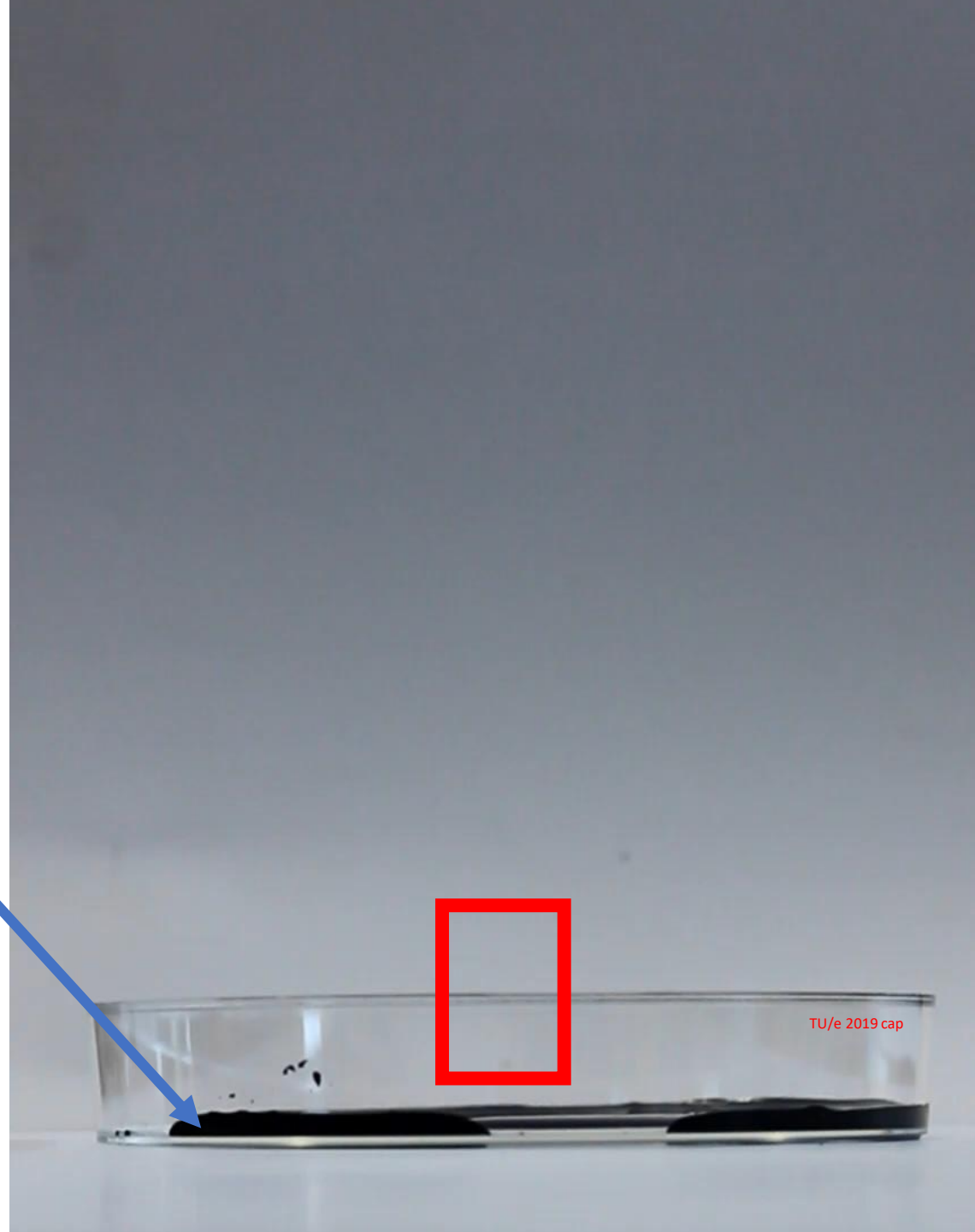
Product classification:	**II Textile or porous material**
Driving phenomena:	Condensation, absorption
Additional parameter:	Time





Small/narrow channels

Product classification:	**II Porous materials Including textiles**
Driving phenomena:	Condensation, absorption/capillary forces
Additional parameter:	Time



Diffusion and convection

Diffusion:
Difficult to influence

Diffusion: ‘wait’

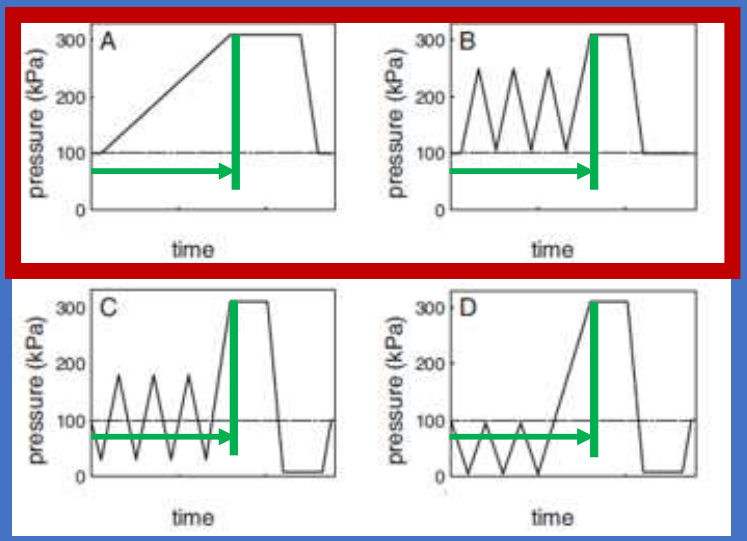
Convection:
Easy to influence

Convection: ‘switch on’

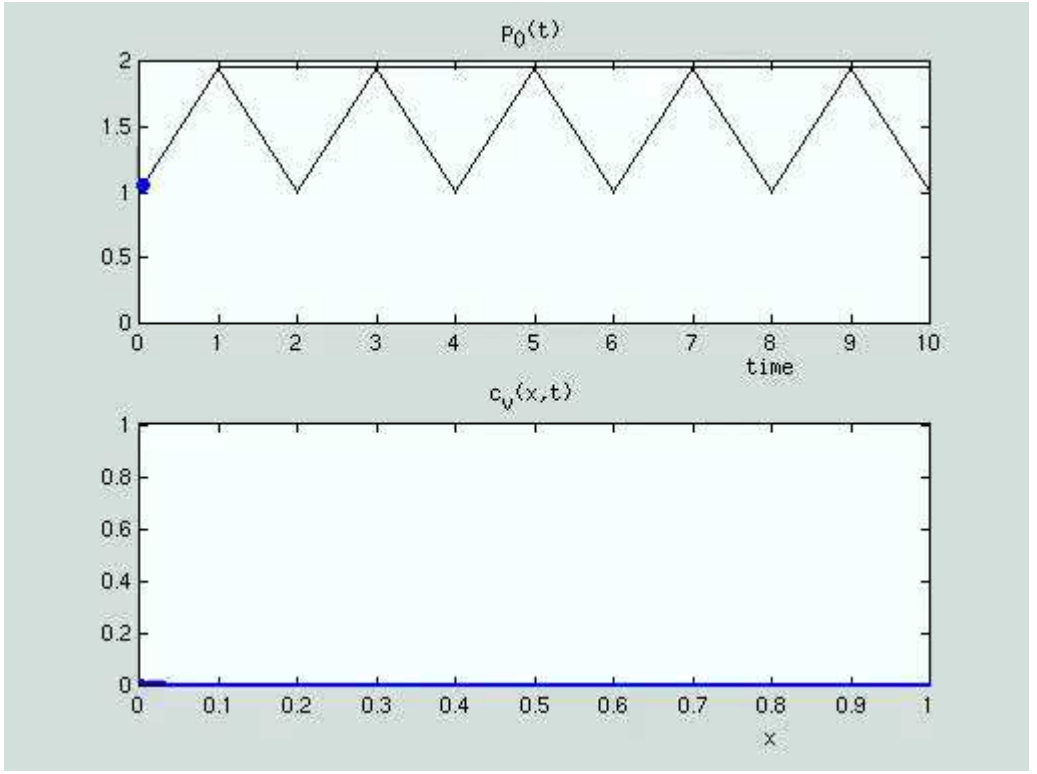
In steam sterilisation process
(Conditioning phase)

Diffusion:
Waiting

Convection:
Pumping and steam injection



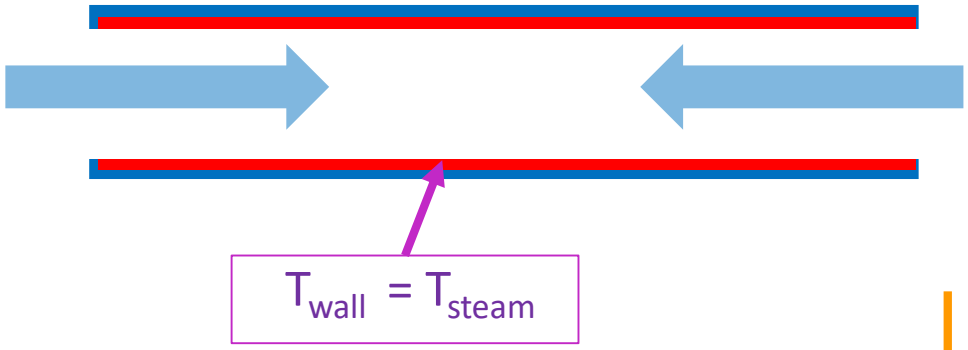
Steriliser


$P_0(t)$
2
1.5
1
0.5
0
0 1 2 3 4 5 6 7 8 9 10
time
$c_v(x,t)$
1
0.8
0.6
0.4
0.2
0
0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1
x

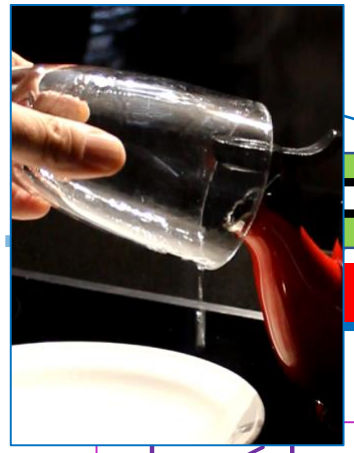
Thin/thick walled

[1] van Doornmalen JPCM and Kopinga K. Steam penetration in thin-walled channels and helix shaped process challenge devices. Central Service, 6:429-433, 2015.

Thin walled



$T_{wall} = T_{steam}$



[2] van Wezel RAC, van Doornmalen HWJM, de Geus J, Rutten S, and van Doornmalen JPCM. Second case study on the orientation of phaco hand pieces during steam sterilization. Journal of Hospital Infection, 94:193{208, 2016, DOI: http://dx.doi.org/10.1016/j.jhin.2016.06.017.

$T_{wall} < T_{steam}$

Conditions unknown

No sterilization condition

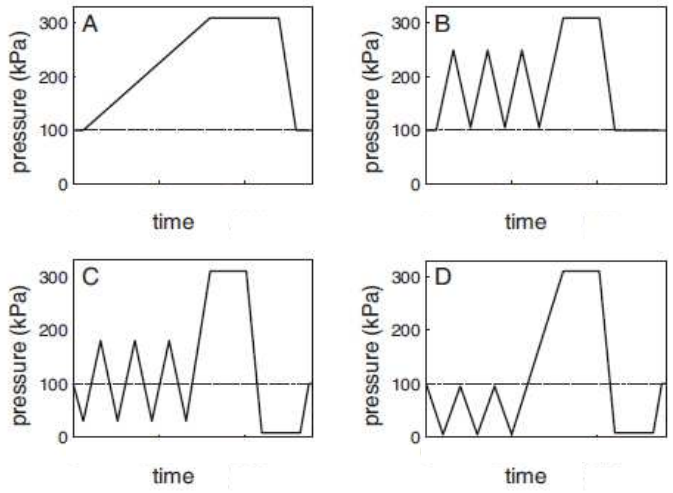
Product classification:	**III hollow**	**Product classification:**	**III hollow**
Subgroup:	**A thin walled**	**Subgroup:**	**B thick walled**
Driving phenomena:	Convection, Diffusion	Driving phenomena:	Condensation, Diffusion Condensation (issues)
Additional parameter:	None	Additional parameter:	Orientation

Thick or thin walled: depends on steriliser, process, load, loading pattern and microbiological barrier

To be acknowledged/determined in PQ [1,2]

Product family		Sub-group	Phenomena	Remarks	Example devices
I	Non hollow	-	Condensation		Surgical hammer
II	Porous	-	Condensation (boundary) Absorption/capillary working	Radi < approx. 1 mm	Textiles Filters Hinges
IIIA	Hollow	Thin walled	Convection Diffusion	Determined in PQ	Filling needle MIS instruments with channels
IIIB		Thick walled	Convection Diffusion Condensation (orientation)		Phaco hand pieces

Process indications



	Product family	Sub-group	Minimum Process Indication
I	None Hollow		A,B
II	Porous		A,B [1]
IIIA	Hollow	Thin walled	C,D [2,3]
IIIB		Thick walled	C,D, orientation [4,5]

[1] Muis B, de Bruijn ACP, Drongelen AW van, and Huys JFMM. Optimisation of the process for manually operated jacket steam sterilizers. RIVM report 318902011, 2001.

[2] van Doornmalen JPCM and Kopinga K. Steam penetration in thin-walled channels and helix shaped process challenge devices. Central Service, 6:429{433, 2015.

[3] van Doornmalen JPCM, Verschueren M, and Kopinga K. Penetration of water vapour into narrow channels during steam sterilization processes. Journal of Physics D: Applied Physics, 46:065201, 2013.

[4] van Wezel RAC, van Doornmalen HWJM, de Geus J, Rutten S, and van Doornmalen JPCM. Second case study on the orientation of phaco hand pieces during steam sterilization. Journal of Hospital Infection, 94:193{208, 2016, DOI: http://dx.doi.org/10.1016/j.jhin.2016.06.017.

[5] van Doornmalen JPCM, van Wezel RAC, and van Doornmalen HWJM. Case study on the orientation of phaco hand pieces during steam sterilization processes. Journal of Hospital Infection, 90:52{58, 2015.

Success of steam sterilisation depends on the combination of:

- Steriliser
- Process
- Load
- Loading pattern (orientation), and,
- Microbiological barrier (wrapping)

A classification of three product families (groups) is possible:

- I: None hollow (massive)
- II: Porous
- III A and B Hollow
  (thin and thick walled)

The most difficult/complex family group to steam sterilise is the

HOLLOW or group III

e.g., presentation Dr. Francesco Tessarolo
(tomorrow November 1, 12:30 to 14:00)

Practice Validation and monitoring

- Performance Qualification
  - Steriliser
  - Process
  - Load
  - Loading pattern (orientation), and,
  - Microbiological barrier (wrapping)
- Followed by ELSPT

[1] WFHSS Mexico 2019 Parametric Release of Loads in Surface Steam Sterilization November 2nd
[2] Routinemäβige Überwachung der Dampfdurch-Dringung bei Dampfsterilisationsprozen (English translation of title: Every Load Steam Penetration test in steam sterilization Processes) , December 2018.

When the combination has been 'PQ-ed' (worst case combination identified), the physical properties of a device have limited influence

(Density, weight, heat transfer, heat capacity, et cetera)

Most difficult process steam penetration

- Warm steriliser
- Lightest load

[1] van Doornmalen JPCM, van Wezel RAC, and Kopinga K. The relation between the load, duration and steam penetration capacity of a surface steam sterilization process; a case study. PDA Journal of Pharmaceutical Science and Technology, 2018, DOI:10.5731/pdajpst.2017.008490
[2] Lapanaitis N, Frizzell L, Downing A, and van Doornmalen JPCM. Case study: Correlation between the duration of a steam sterilisation process and the weight of the processed load. Central Service, 4(26):225-230, 2018..

It should be verified if a 'new 'device' can be sterilised in the 'standard' process.

If not consider what to change:

- The combination, or,
- the device.

For product family IIIB (thick walled instruments) the orientation is essential.

The lading pattern/method (orientation of device) may have to be changed

Disclaimers:
The microbiological barrier is not completely addressed in this presentation.

Information on this topic is available, but not (yet) published.

	Product family	Sub-group	Phenomena	Remarks	Example devices
I	Non hollow		Condensation		Surgical hammer
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IIIA	Hollow	Thin walled	Convection Diffusion	Determined in PQ	Filling needle MIS instruments with channels
IIIB		Thick walled	Convection Diffusion Condensation (orientation)		Phaco hand pieces

Thank you for your attention!

Special thanks to:

Claudia Siep and Dr.ir. Jan van Dijk