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Controversies on Fast Cycle Sterilization Protocols

Wim Renders

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WFHSS World Forum for Hospital Sterile Supply

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WFHSS Events

Annual WFHSS and ANES Conference 2011
12-15 October 2011
Estoril Congress Center, Estoril, Portugal
(Organized by WFHSS and ANES)

- Conference Poster
- Conference Website
- Conference Programme

WFHSS News

Tue, 09 August 2011
18:39 [GMT]

03 August 2011, 20:00 [GMT]
WFHSS Courses and Seminar Listings
Seminar Calendar Update:
Principles & Practices of Decontamination of Medical Devices: Endoscopy
Distance Learning via Virtual Learning Environment
Starting on 26 September 2011

03 August 2011, 19:30 [GMT]
WFHSS Courses and Seminar Listings
Seminar Calendar Update:
Principles & Practices of Decontamination of Medical Devices: Endoscopy
Distance Learning via Virtual Learning Environment

Overview

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- What is fast cycle sterilization?
- Controversies regarding:
  - Cleaning
  - Sterilizing
  - Wrapping
  - Storage and transportation
  - Personnel
- Why fast cycles?
  - Fallen instruments
  - Lack of time and shortage of instruments
- Conclusions

1. What is fast cycle sterilization?

- Or ‘Flash’ sterilization is: Open sterilization of non-wrapped, non-porous devices using a short program
- The sequence of the program (can be e.g.)
  - evacuate once
  - provide for steam penetration
  - heat to 134°C, 3 min sterilization time
  - possibly followed by a short drying period
- A cycle takes about 15 min

Perkins

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Principles and methods of sterilization in health sciences

- In the emergency sterilization of instruments, no compromise with safety can be tolerated
- The method selected must be adequate for the destruction of resistant spores
- These requirements can be met through the use of a high-speed pressure instrument sterilizer, adjusted for operation at 132° C and 27 to 28 pounds pressure.
- When an instrument is urgently needed, it is possible for a nurse to wash, degrease, sterilize the instrument, and return it to the operating table in 5 to 6 minutes with no compromise in safety.
- Steam should be maintained in the jacket of the high-speed pressure instrument sterilizer prior and during the entire surgical procedure

SOP of Perkins

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- Scrub the instrument with warm water containing detergent for about 15 seconds, followed by another 15 second wash in fat solvent
- Place the opened instrument in a tray with wire mesh or perforated bottom, insert tray in sterilizer, close and tighten door securely
- When chamber temperature reaches 270° F begin timing the sterilizing period for 3 minutes.
- At the end of the sterilizing period, when the chamber pressure has exhausted to zero gauge, turn operating valve wheel to OFF, open door, and remove instrument.


GEEN
AQUAPURIFICATA
WEL STERIEL
WATER
10 CR
12 CR
9 CR
STATIM

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Immediate-use steam sterilization

- ANSI/AAMI ST 79-2010:
  - “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” refers to “flash” sterilization
  - But in a joint announcement this name was changed because it did not accurately reflect current use and processes
- The new name is: ‘İmmediate-use steam sterilization’

Fast cycles

- Some manufacturers talk about ‘fast’ cycles:

- In small B sterilizers

- Or in big sterilizers while applying special techniques

- The time gained in both types is not of such an order that it is possible to consider them as a real breakthrough

Controversies

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- Cleaning
- Sterilization
- Wrapping
- Storage and transportation
- Personnel

Cleaning (1)

- Cleaning is the key element for a reliable sterilization
- A mechanical treatment in EN/ISO 15883 washer-disinfectors allows for standardized and thus reproducible treatment of the instruments.
- Thermal disinfection with an A_0 value of 3000 (5 min at 90° C) allows it to reduce the bioburden and makes it possible for the members of staff to safely handle the medical devices
- Around 60 min

Cleaning (2)

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- AAMI says that “The same critical reprocessing steps must be followed”
- If it concerns “flash” then this is because of the length of time, needed for cleaning, already a first and important contradiction
- The meeting of these criteria in the case of ‘immediate –use sterilization’ renders this way of sterilizing in principle superfluous
- The time gain only through a shortened sterilization cycle compared to normal treatment will be minimal

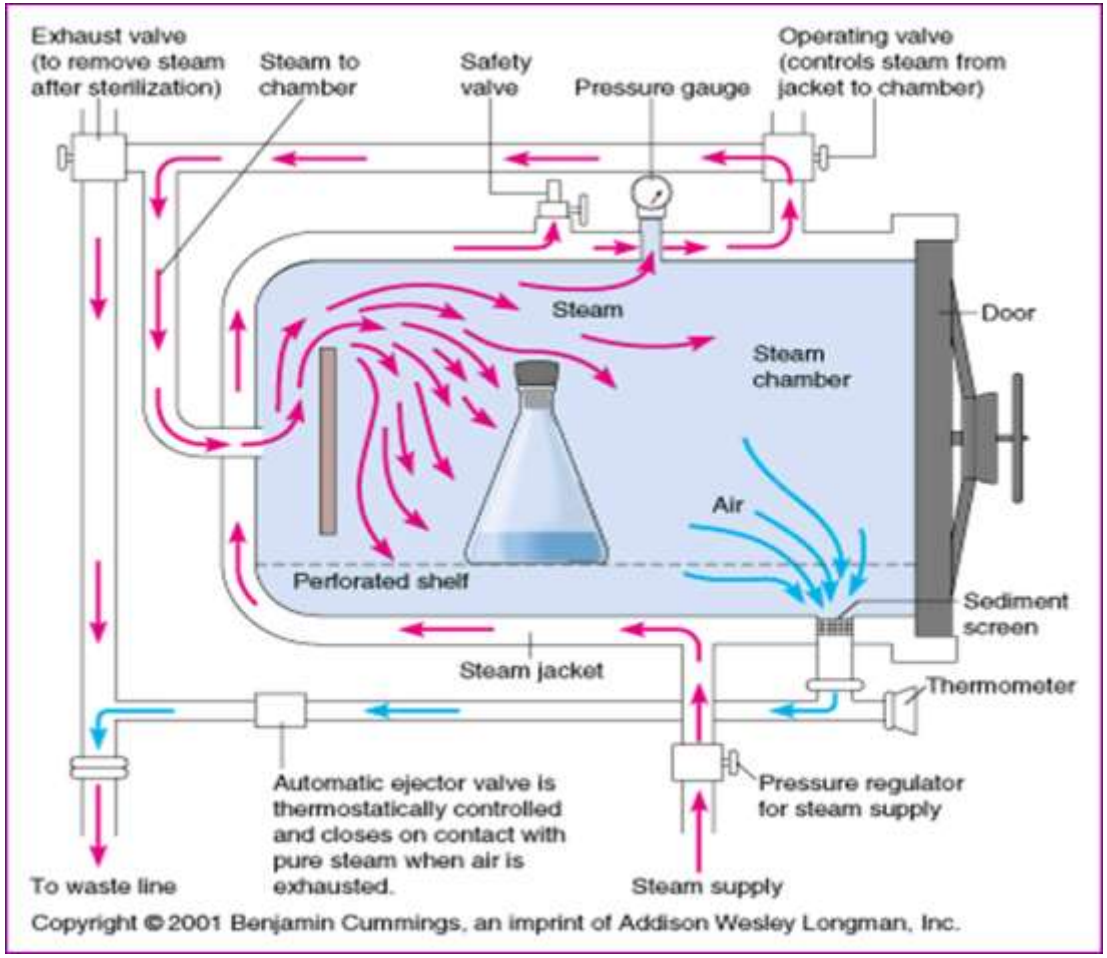
Sterilization

- Available cycles
  - Gravity displacement cycle
  - Prevacuum cycle
  - Single wrap cycle

Gravity displacement cycles

- Simplest type of steam sterilizer program
- Air removal is based on steam being lighter than air
- The steam will press the air towards the bottom of the autoclave chamber

Gravity displacement



Drawbacks

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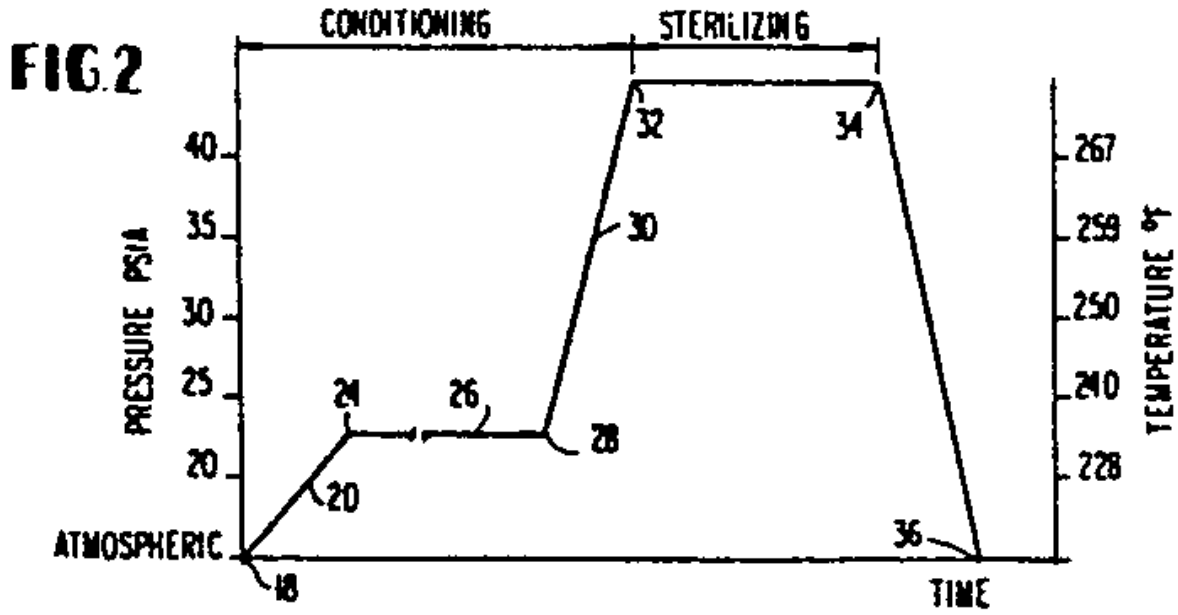
- Air can diffuse into the steam, remaining air-pockets will prevent the steam from getting into contact with the items to be sterilized
- High-velocity steam carries with it microscopically small water particles. This results in moist steam, which is not capable of releasing as much energy as saturated steam
- High-velocity steam can cause turbulence in the autoclave chamber, increasing the mixing of air with the steam

Gravity displacement



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Pre-vacuum cycle

Air is mechanically sucked out from the sterilizer during the conditioning phase (usually 4 steam injections) and steam is actively sucked out during the exhaust phase

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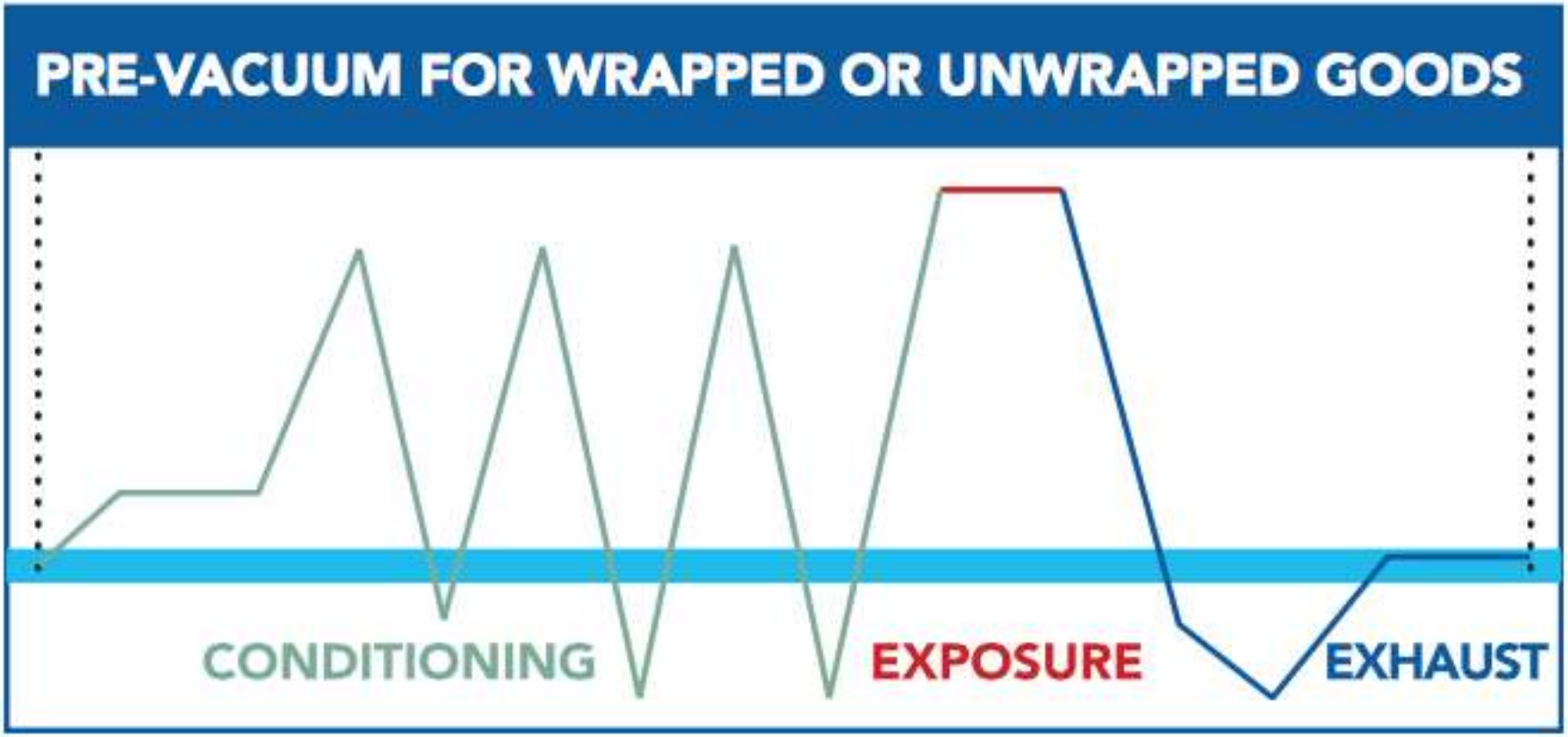
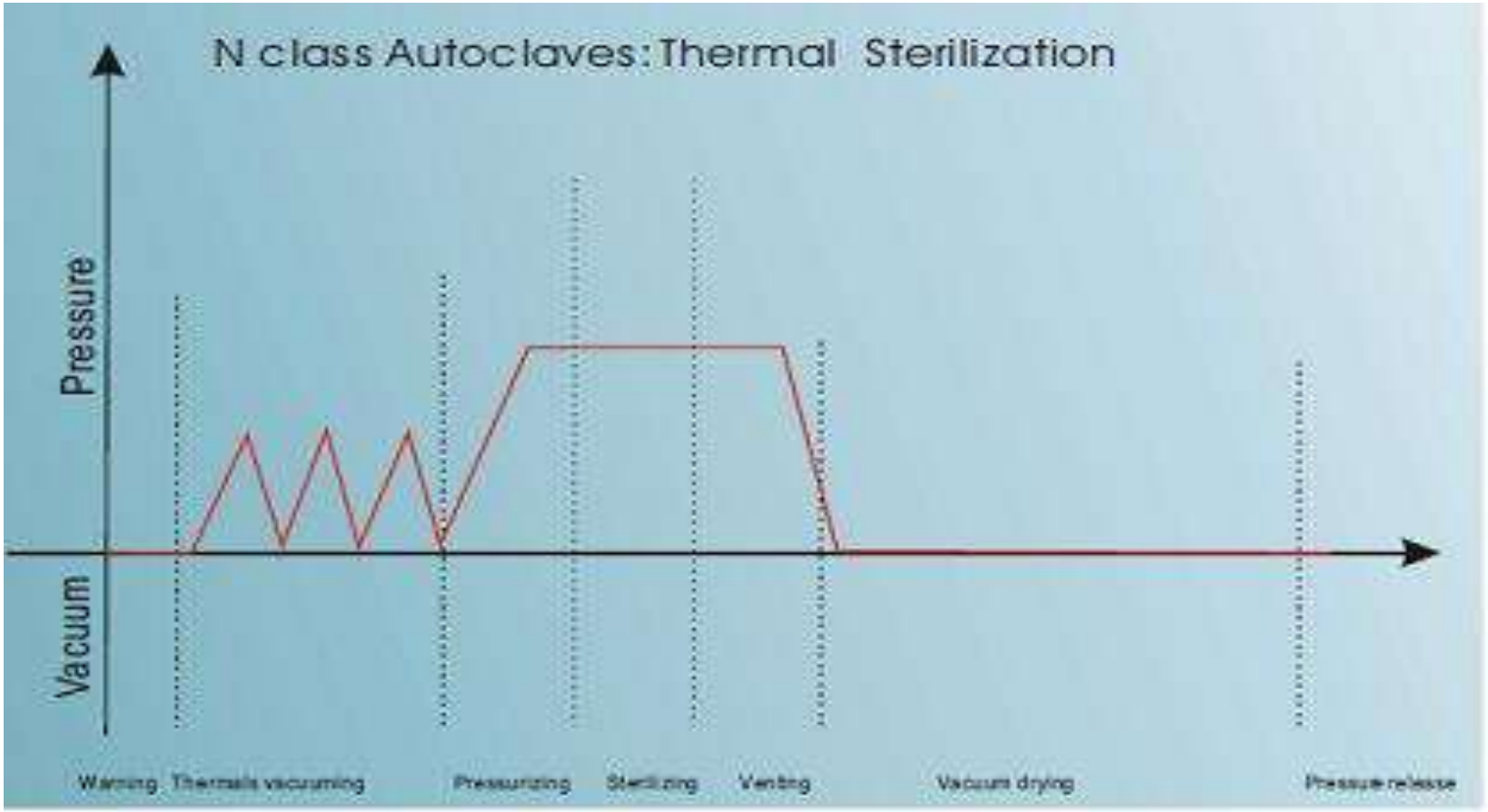


Getinge

Single wrap cycle

- Preset parameters by the sterilizer manufacturer
- Flash sterilization of all-metal, non-porous items only
- No sterilization of items with lumens or complex medical devices should be carried out because air removal and steam contact within them may not be achieved

Single wrap cycle



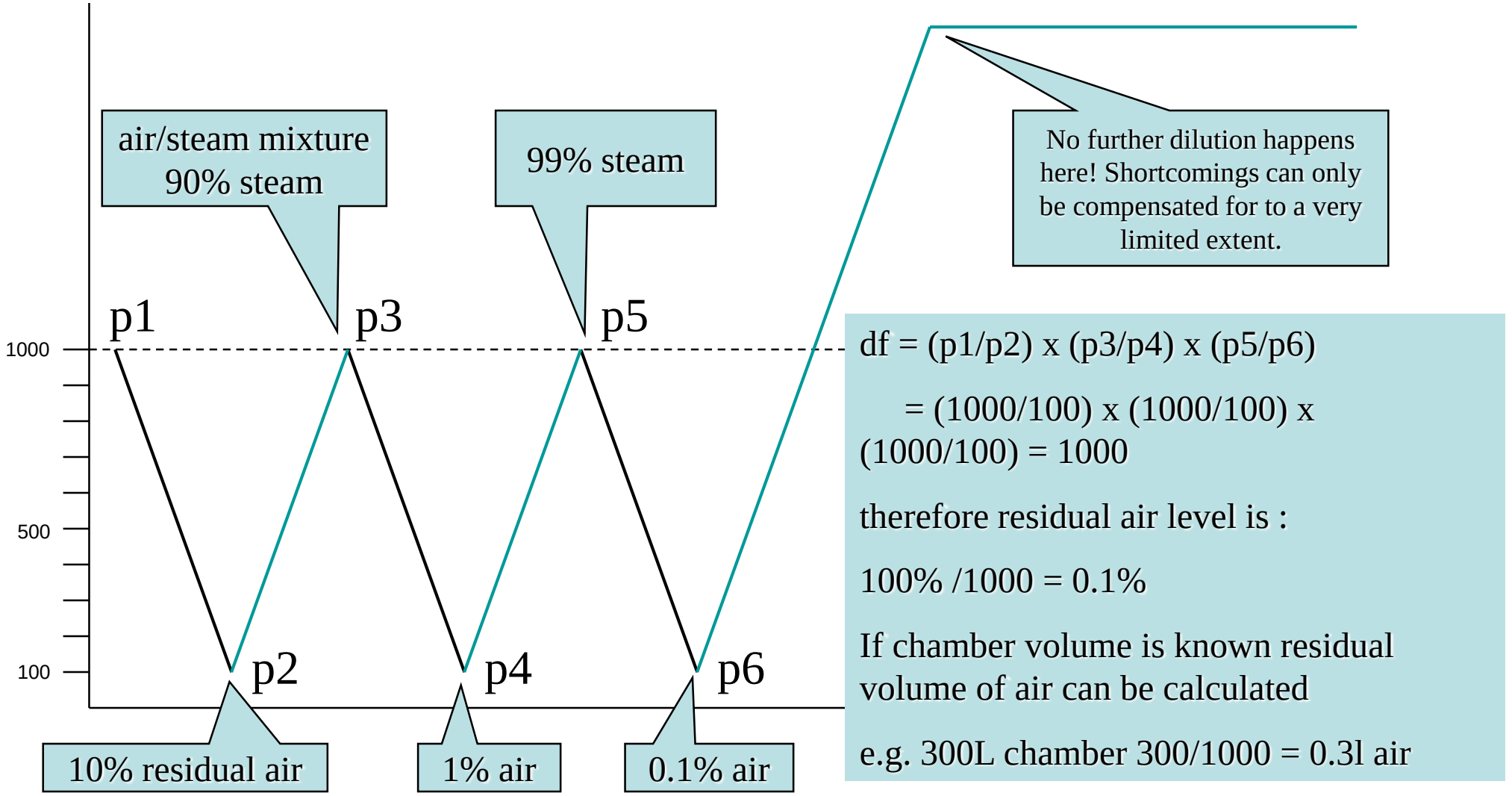
Air removal

- In all these types evacuation of air can be a problem because this depends on the depth and the number of vacuum pulses
- One long deep pre-vacuum had a worse result than a program with a fractioned pre-vacuum
- The helix study group of the Dutch Sterilization society – “ to achieve optimal air evacuation minimally 2 but preferably 3 subatmospheric pulses up to plus minus 5 kpa are necessary”

Dilution factor

		Ketel inhoud in liters			
Pulsen	**Druk in kPa**	**375**	**500**	**750**	
1e vacuum puls, van	100				
naar	5	18,75	25	37,5	liter restlucht
2e vacuum puls, van	95				
naar	5	0,99	1,32	1,97	liter restlucht
3e vacuum puls, van	95				
naar	5	0,05	0,07	0,10	liter restlucht
4e vacuum puls, van	95				
naar	5	0,00	0,00	0,01	liter restlucht
Verdunningsfactor		**137180**	**137180**	**137180**	

Dilution factor



df = (p1/p2) x (p3/p4) x (p5/p6)

= (1000/100) x (1000/100) x (1000/100) = 1000

therefore residual air level is :

100% /1000 = 0.1%

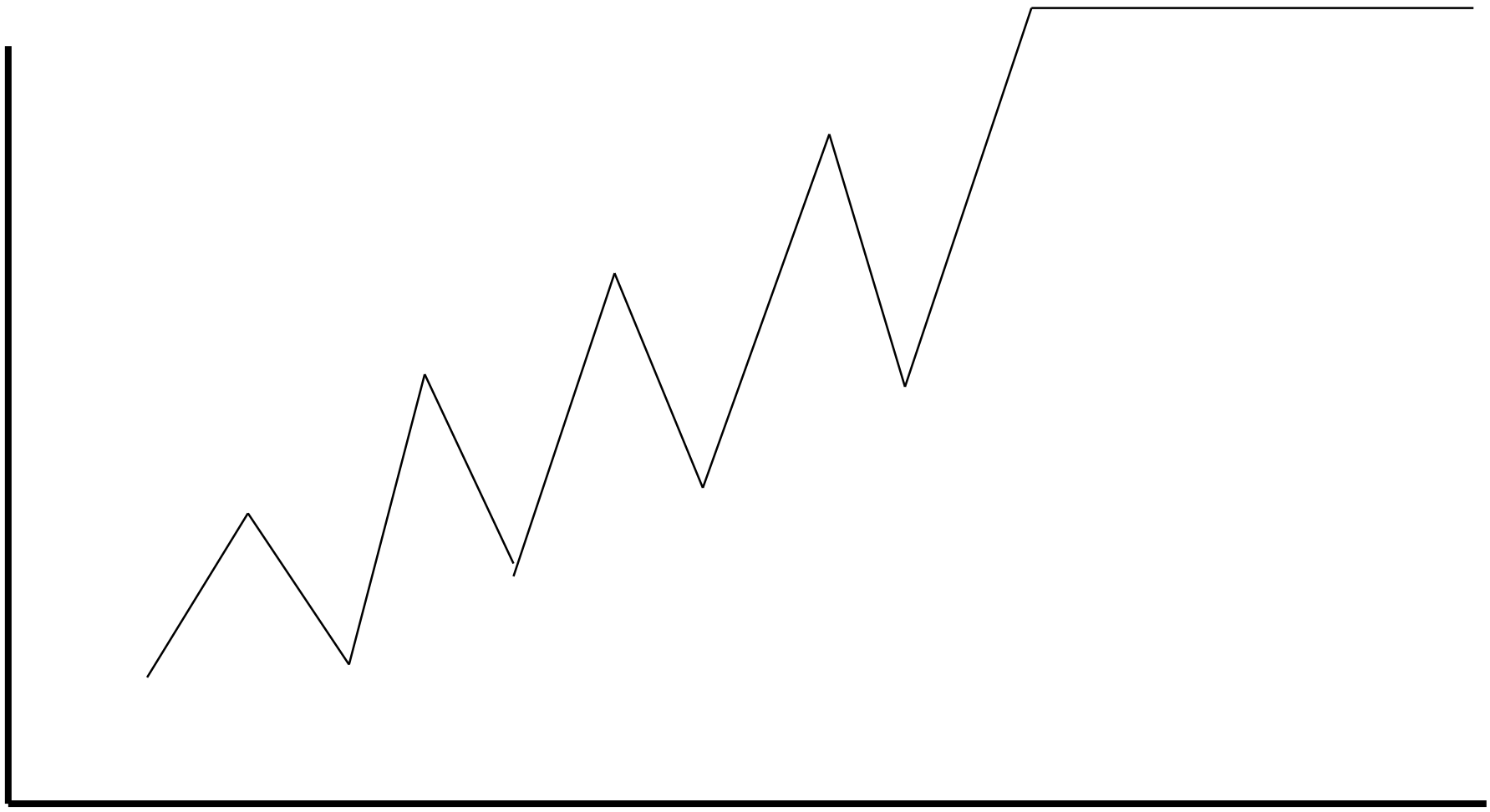
If chamber volume is known residual volume of air can be calculated

e.g. 300L chamber 300/1000 = 0.3l air

Non condensable gasses

- According to EN 285 the volume of non condensable gases can be maximally 3,5%
- or 3,5 mL gas per 100 mL condensate
- or 3,5 mL/169,4 L steam at 100˚ C
- or 3,5 mL/60,3 L steam at 134˚ C

Sawtooth profile



Dry heat sterilization

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- Dry heat sterilization is not very effective at temperatures below 160°C!

- at 160°C you need 2h for sterilization,
- at 121°C 6h,
- at 140°C 4h,
- at 180°C 30 min.

EN/ISO 13060 for small steam sterilizers

- B cycle for sterilizing all objects (solid instruments, porous objects and A and B hollow objects, both wrapped and not wrapped)
- N cycle for sterilizing only non wrapped solid instruments
- S cycle for sterilizing non wrapped solid instruments plus one other of the types indicated for cycle B (to be specified by the manufacturer)

Check also the microbiological quality of water used for steam production

The second contradiction

"Flash" – "immediate-use" sterilization makes use of programs in which air evacuation can be a problem

Wrapping

- Recontamination of the medical devices should be ruled out after processing until the time of use
- Wrapping is an essential part of the process
- Wrapped articles remain sterile if the packaging is intact

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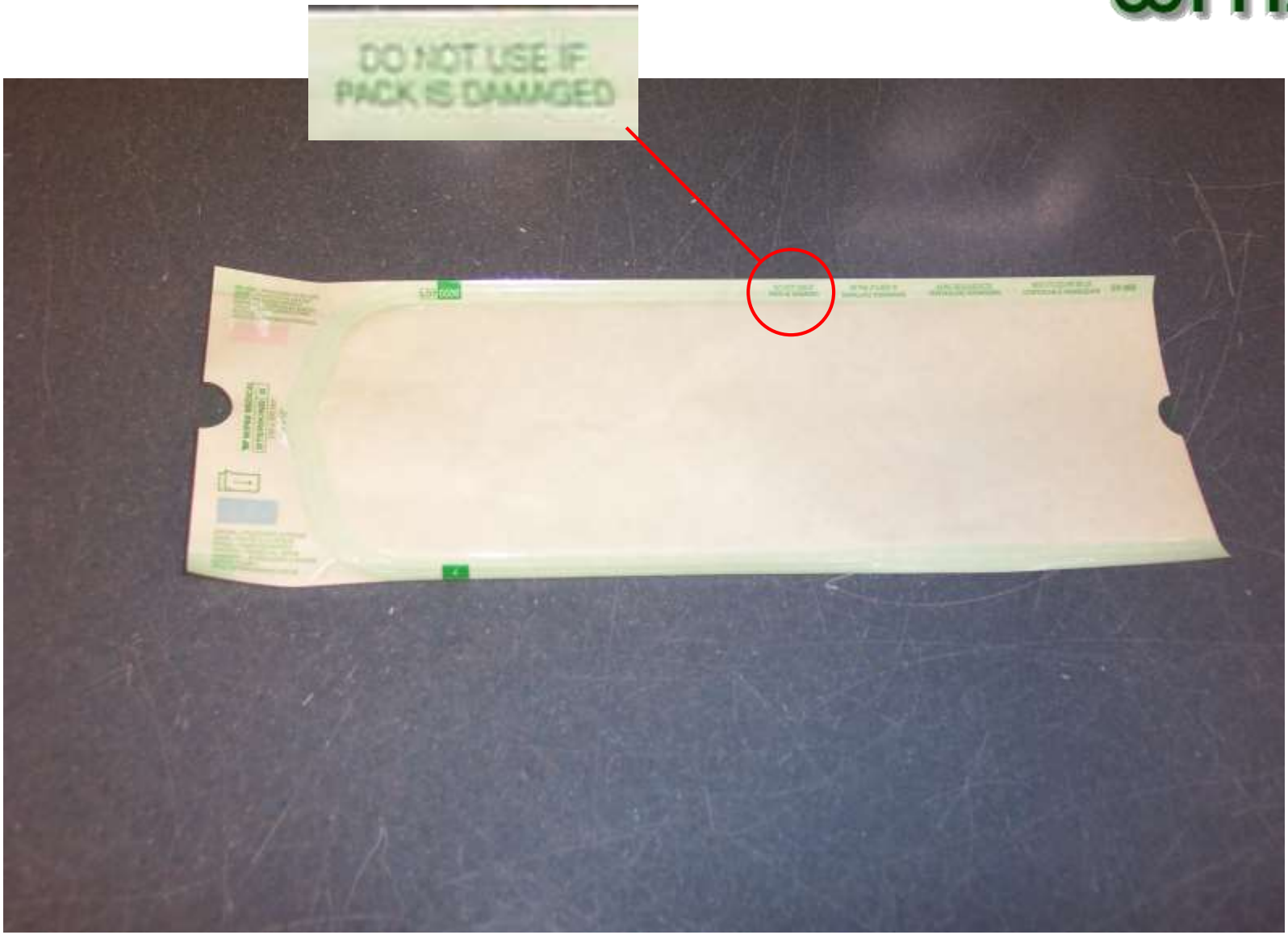

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The third contradiction

The wrapping keeps the device sterile until it is used. With “flash” sterilization no such guarantee can be given!

Storage and transport

- After sterilization the medical devices should cool down to room temperature in a conditioned environment
- A cooling down process which happens too quickly , e.g. by contact with a cold surface, furthermore can lead to condensation which increases the risk of recontamination

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Determination of the efficacy of sterile barrier systems against microbial challenges during transport and storage

Hartmut Dunkelberg and Ulrich Schmelz
Medical Institute of General Hygiene and Environmental Health,
University of Goettingen, Germany

J Bone Joint Surg Am. 2008 May;90(5):1022-5.

Time-dependent contamination of opened sterile operating-room trays.

Dalstrom DJ, Venkatarayappa I, Manternach AL, Palcic MS, Heyse BA, Prayson MJ.

Orthopaedic Surgery Residency Program, Miami Valley Hospital, 128 East Apple Street, Suite 2830, Dayton, OH 45409, USA. orthodjd@yahoo.com

Abstract

BACKGROUND: There are no clear guidelines for how long a sterile operating-room tray can be exposed to the open environment before the contamination risk becomes unacceptable. The purpose of this study was to determine the time until first contamination and the rate of time-dependent contamination of sterile trays that had been opened in a controlled operating-room environment. We also examined the effect of operating-room traffic on the contamination rate.

METHODS: Forty-five sterile trays were opened in a positive-air-flow operating room. The trays were randomly assigned to three groups. All trays were opened with use of sterile technique and were exposed for four hours. Culture specimens were obtained immediately after opening and every thirty minutes thereafter during the study period. Group 1 consisted of fifteen trays that were opened and left uncovered in a locked operating room (i.e., one with no traffic). Group 2 was identical to Group 1 with the addition of single-person traffic flowing in and out of the operating room from a nonsterile corridor every ten minutes. Group 3 included fifteen trays that were opened, immediately covered with a sterile surgical towel, and then left uncovered in a locked operating room (i.e., one with no traffic).

RESULTS: Three of the thirty uncovered trays (one left in the operating room with traffic and two left in the room with no traffic) were found to be contaminated immediately after opening. After those three trays were eliminated, the contamination rates recorded for the twenty-seven uncovered trays were 4% (one tray) at thirty minutes, 15% (four) at one hour, 22% (six) at two hours, 26% (seven) at three hours, and 30% (eight) at four hours. There was no difference in survival time ($p = 0.47$) or contamination rate ($p = 0.69$) between the uncovered trays in the room with traffic and those in the room without traffic. The covered trays were not contaminated during the testing period. The survival time for those trays was significantly longer ($p = 0.03$) and the contamination rate was significantly lower ($p = 0.02$) than those for the uncovered trays.

CONCLUSIONS: Culture positivity correlated directly with the duration of open exposure of the uncovered operating-room trays. Light traffic in the operating room appeared to have no impact on the contamination risk. Coverage of surgical trays with a sterile towel significantly reduced the contamination risk.

A fourth anomaly

The risk of recontamination during cooling and by manipulation and transport of the “flash” sterilized instrument is substantially increased

Training of personnel

- Well trained personnel is the quality guarantee a sterilization department
- “Flash” and “immediate- use” sterilization are carried out by untrained members of staff
- The decentralized treatment of surgical instruments is in direct conflict with the principle of the centralization and standardization of the treatment of instruments

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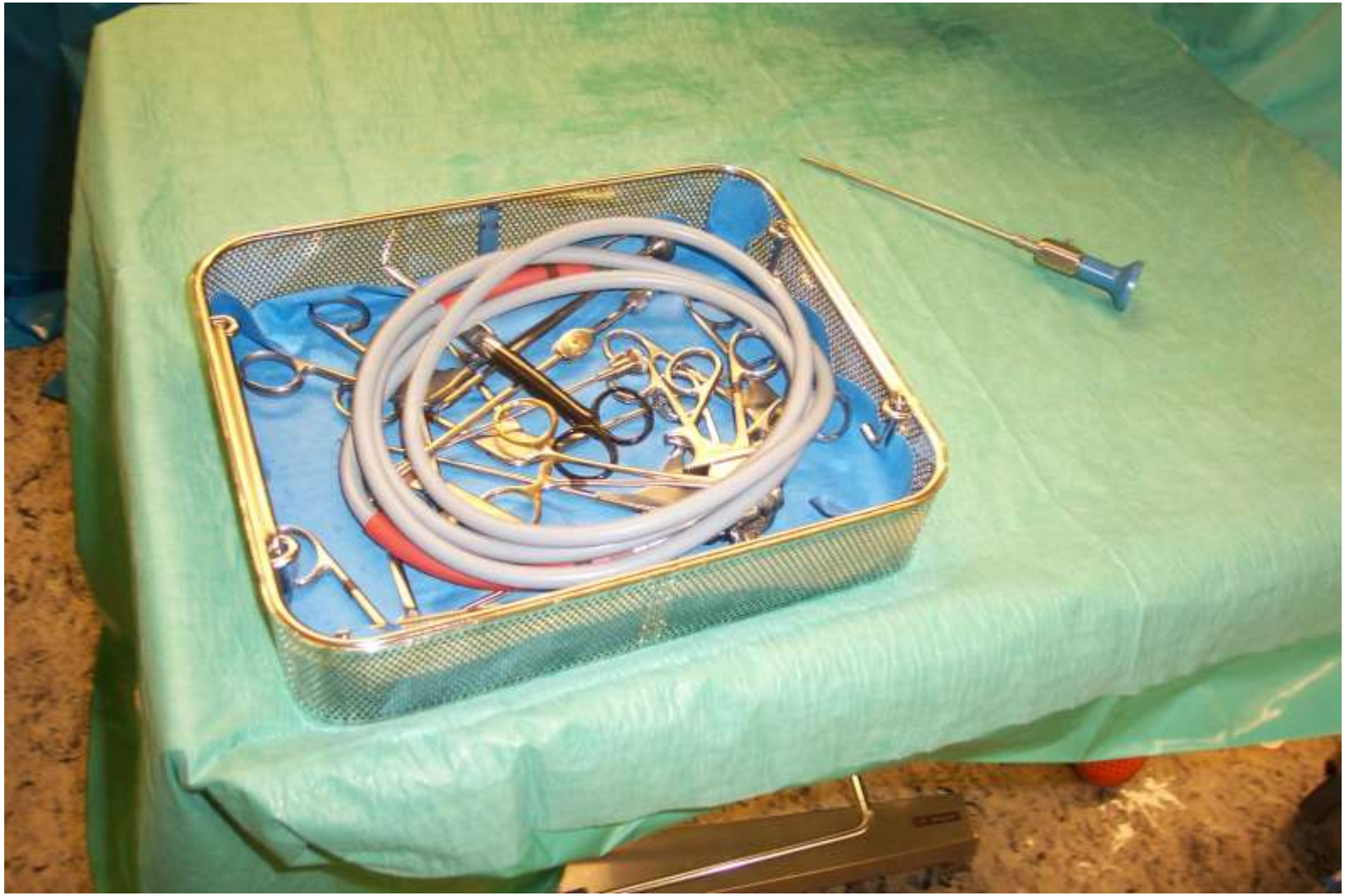

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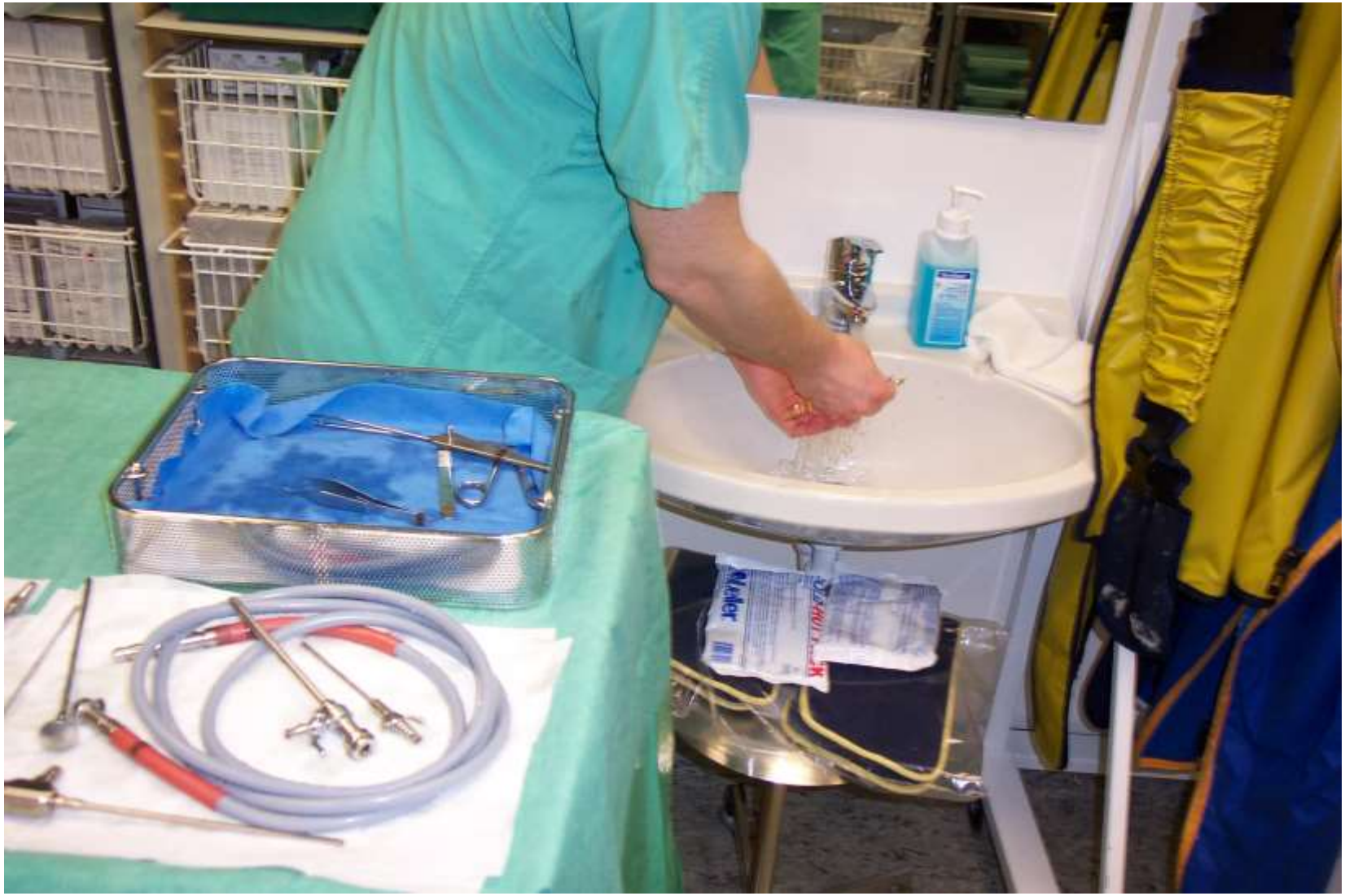

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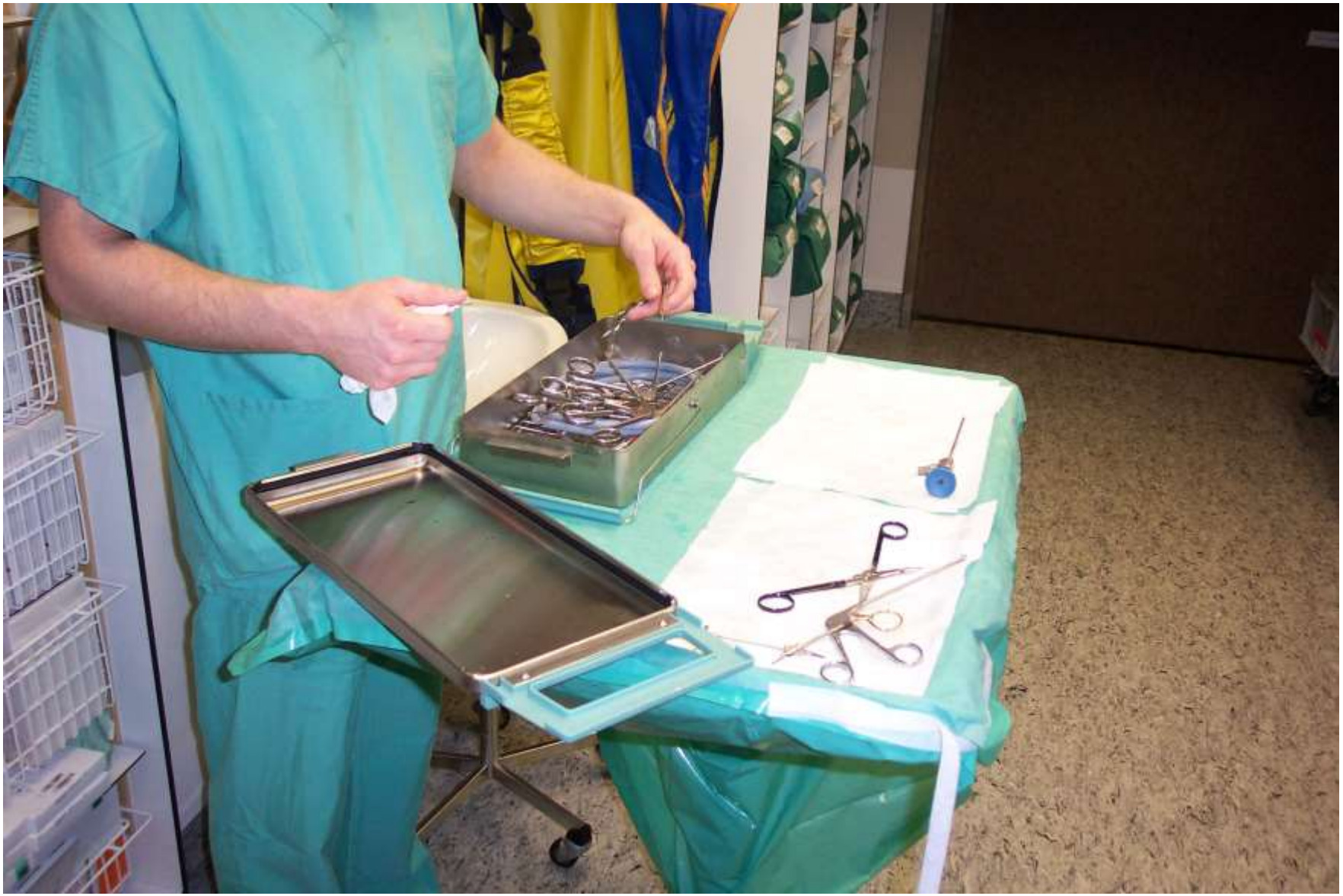

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The fifth anomaly

It is a requirement that the members of staff know what their duties are. But this cannot be expected of the personnel in the operating theatre

Why flash cycles?

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- The first argument: fallen instrument.
- What if the fallen instrument is not compatible with the available program?
- A shortage of instruments is the second argument. Solved by buying more instruments or by planning the interventions better

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Conclusion

- The following contradictions are insoluble:
  - between cleaning and rinsing in running water
  - between a regular pre-vacuum and a flash program
  - between wrapped and unwrapped sterilizing
  - between trained and untrained members of staff

Academic discussion

- A hospital does not need flash sterilization
- The organization of “flash” by stipulating the conditions it should meet, means institutionalizing a way of working which does not meet the present standards of care expected of a hospital and its sterilization department
- The responsibility of the CSSD is based on means, man and knowledge.
- injustice
- It is the duty of the CSSD to safeguard the right of every patient to be treated with a medical device of good quality

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THANK YOU!