

MONITORING STEAM PENETRATION IN CHANNELED INSTRUMENTS: AN EVIDENCE-BASED WORST-CASE FOR PRACTICAL SITUATIONS

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#### Steam sterilization for surgical

- Steam sterilization is recommended as the preferred sterilization method for medical instruments in hospitals.
- All accessible internal and external surfaces of the devices should be reached by steam
- Sterilization conditions should be achieved and maintained in all space within the sterilizer chamber



[https://www.who.int/infection-prevention/publications/decontamination/en/] [https://wfhss-guidelines.com/]





### Where to test steam sterilization





#### What is known: steam sterilization

Pressure, Temperature and Time are not enough to monitor steam sterilization process

Essential parameters for steam sterilization are:

- Temperature
- Time
- Humidity (steam fraction)



[Central Service 2014;4:250-253]





## What is known: surgical instrument

Surgical instruments can be divided into two main designs (product families):

- Bulky (or massive)
- Channelled (or lumened)

Channelled devices are more critical for steam penetration than massive instruments



Channelled instruments can contain channels:

- with both ends open
- with one end open and one closed

For the channelled instruments with both ends open, the most difficult location for steam penetration is the centre of the inner channel wall



[Journal of Physics D Applied Physics, 2013;46(6):065201]



Channelled instruments can contain channels:

- with both ends open
- with one open end and one closed

For the channeled instruments with one end open and one closed, the most difficult location for steam penetration is the inner channel wall at the closed end



[Journal of Physics D Applied Physics, 2013;46(6):065201]





In terms of steam penetration, a channel with both ends open can be represented as a channel of half the length with one end open and one end close.

1 m	50 c	:m

In the clinical practice the maximum length of steam sterilized channelled instruments is 1 m with both ends open.

Channelled instruments can be represented by a 50 cm long channel with one end open and one end closed.

[Journal of Physics D Applied Physics, 2013;46(6):065201]





#### What is known: thin and thick-walled channels

#### Thin-walled channels

 having a warming up time of the inner wall equal or less than the time required for steam penetration into the channel. The channel is warmed up mainly by steam condensation on the outer surface.

#### Thick-walled channels:

• are warmed up mainly by steam condensation on the inner channel wall, creating condensate inside the channel.



[Journal of Hospital Infection 2015;90:52-58]



## WORLD What is known: thin and thick-walled channels

Thick walled channels:

- Channel obstruction by water droplets can impair steam penetration into thick walled channels.
- The orientation during steam sterilization should guarantee an effective drainage of the condensate from the open end.

Instruments having thick walled channels need to drain condensate from the channel



<sup>[</sup>Journal of Hospital Infection 2015;90:52-58]



# What is known: channel diameter

Most of the channels present in medical devices for minimally invasive surgery have a diameter in the range from 1 to 5 mm.



Variations in the channel diameter in the range from 0.7 to 5 mm were shown not to significantly affect steam penetration at the start of the sterilization phase.

[Journal of Physics D Applied Physics, 2013;46(6):065201]

[Central Service 2015;6:429-433]





Simulations and experiments showed that having chambers in the channel favour steam penetration into the lumen.



Channels with a constant radius over the full length of the instrument are the most difficult to steam penetrate



[Central Service 2015;6:429-433]





No data are available on the worst case condition for steam penetration in channelled instruments in practical conditions, taking into consideration:

- Wrapping
- Load amount into the pack
- Position of the pack into the sterilizer chamber







The study was aimed at providing experimental proof that:

a 70 cm long tube is **the most difficult condition for steam penetration in a load representative for surgical instruments** (channelled and non channelled) **in practical situations**.





### MATERIALS AND METHODS





Allows to measure steam fraction (WVF) at the closed end of a channel in real time during the whole sterilization process.

- Do not affect steam penetration process
- Do not alter channel geometry





"During the exposure phase of a sterilization process, is the water wapour fraction measured by an IR sensor equipped with a 70 cm long tube lower than the steam fraction at the closed end of a 50 cm channelled device inside a pack?"

This question should be tested in practical conditions characterized by different combinations of:

- wrapping
- load amount in the pack
- different pack positions into the sterilizer chamber





## Experimental variables 1/3

## Wrapping

**ORLD** 

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- Crepe double wrapping
- SMS single wrap using double layer foils
- Pouch double
- Container large volume with paper filters











## Experimental variables 2/3

### Pack Load

GRESS

- No load but the open end of the channel
  - 0 Kg
- half load amount
  - 7.5 Kg of steel for SMS, crepe and containers;
  - 0.2 Kg of steel for pouches
- full load amount
  - 15 Kg of steel for SMS, crepe and containers;
  - 0.4 Kg of steel for pouches





### Experimental variables 3/3

#### Pack position into the sterilizer

• in the front upper level

ORLD

CONGRESS

- in the back upper level
- in the front lower level





World Federation for Hospital Steelkation Sciences

#### The steam sterilization process

WORLD





Eight units steam sterilizer equipped with built-in steam generator and water degassing system.

At the start of each experimental day, the sterilizer performed:

- a warming up cycle to warm up the sterilizer chamber
- an air leakage test
- a Bowie & Dick (B&D) test in accordance to ISO 17665-1 [ISO 17665-1:2006]





## RESULTS





A total of **180 experimental datasets** obtained from 60 sterilization processes covering the combination of:

- 4 wrappings
- 3 load amounts in pack
- 3 locations in the sterilizer chamber

5 replicates per each condition.





#### Qualitative overview of steam fraction CONGRESS results



#### VORLD Identification of the worst case for steam **ATION** ESS penetration

 $\Delta WVF = WVF_{50 \text{ cm}} - WVF_{70 \text{ cm}}$ 

 $\Delta$ WVF >0: the steam fraction in the 70 cm tube is lower than in the 50 cm packed channelled instrument

 $\Delta$ WVF< 0: the steam fraction in the 70 cm tube is higher than in the 50 cm packed channelled instrument

 $\triangle$ WVF >0 for any wrapping/load/position  $\rightarrow$  70 cm tube is the worst case







Steam penetration in channels is affected by wrapping, load in the pack and position in the sterilizer.







For soft packs (crepe, SMS), the higher the load into the pack, the lower the steam penetration







For soft packs (crepe, SMS), the higher the load into the pack, the lower the steam penetration







(containers), the higher the load into the pack, the higher the steam penetration

For rigid packing system







All tested wrapping/load combinations (but the 0/container) showed higher steam penetration in the 50 cm tube in the pack than in the 70 cm tube





Measuring water vapour fraction (or NCGs) in channels is key to properly sterilize channeled instruments in a sterilizer.

Experimental data showed:

- Steam penetration (in channels) is affected by packaging/wrapping systems.
- The amount of load inside the pack is a non negligible driver for steam penetration (in channels).







The worst case for steam penetration in channelled instruments can be represented by an unwrapped 70 cm long tube.

A steam fraction sensor equipped with this tube can be used as a **steam penetration test** in a steam sterilizer to allow **process monitoring** of **massive** and **channelled instruments loads**.







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Monitoring Steam Penetration in Channeled Instruments: An Evidence-Based Worst-Case for Practical Situations

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Steam sterilization of channeled medical devices requires ste channels. However, a quantitative characterization of this phenomenon in practice situations is lacking. This study evaluates the effect of load, loading pattern, and wrappin OPEN ACCESS tern on steam penetration into channels. We tested the hypo with one closed end could be representative of the worst case for steam penetration in wrapped channeled instruments in practical conditions. A validated sterilization process was run in a sterilizer equipped with infrared sensors for the measurement of wate vapor fraction (WVF). WVF values collected at the closed end of an unwrapped 70 cr reference tube were compared to those obtained at the closed end of wrapped 50 cm test tubes, representative for channeled devices in the clinical practice. The open ends of the test tubes were placed inside packs, testing the effects of different combinations of wrappings, load amounts, and pack positions. The worst case for steam penetration was experimentally defined as the condition showing the lowest WVF value during the exposure phase. WVF values at the closed end of 50 cm long tubes were affected by load amount, wrapping, and pack position. Steam penetration was higher for heavier loads in rigid containers, but lower for heavier loads in soft wrappings (pouch, non-woven fabric and crepe). In all the tested combinations of load/wrappings related to the clinical practic the 70 cm reference tube displayed lower WVF values than the wrapped 50 cm test tubes indicating worse steam penetration in the reference than test tubes. Our findings provide experimental evidence that a 70 cm is the worst case in all practical combinations of load and wrapping encountered in the field. The 70 cm tube is a representative for a wrappe 50 cm channel with one end closed and for a wrapped 100 cm channel with both ends open. A measuring system integrating the WVF sensor on a 70 cm tube may provide a physics-based, quantitative steam penetration test for real-time monitoring of the steam ation process of channeled instruments

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