What is the place for Hydrogen peroxide plasma sterilisation in hospital sterile supply?

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Background

- Growing interest in easy-to-operate sterilisers for complex medical devices (MD)
- Simplicity and reliability claimed for Sterrad™ hydrogen peroxide vapour (HPV) sterilisers
- Conflicting results from different investigator teams
- German/Austrian multicenter study warranted restrictions for HPV-steriliser use in clinical settings
Study protocol (1): authors

- Three STERRAD 100S sterilisers tested in parallel with the same protocol in Vienna/A (two centres ¹, ²) and Schwerin/Ge ³

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² GETREUER H, Dept. for Hospital affairs, Vienna County, Austria
³ WERNER H P, Hyg-Cen, Schwerin, and KRAMER A, Dept. Hygiene and Environmental Medicine, Ernst-Moritz-Arndt University, Greifswald, Germany
Study protocol (2): micro lab

- $10^7$/ml suspension of G. stearothermophilus dried onto carriers and exposed to HPV sterilisation cycle
- Spore recovery from carriers by vortexing in CSB and plating in serial dilutions on CSA
- Spore killing effect expressed as log reduction calculated from exposed and unexposed carriers
- Each variation tested in triplicate
Study protocol (3): variables

- Spore suspension media
- Carrier types
- Carrier wrapping
- Steriliser load size
- Steriliser cycle length
- Carrier position in steriliser chamber
Legends to figures  

**LOG-REDuctions** as calculated after HPV exposure in Sterrad

(LOG-RED = log $c_{fu_{\text{before}}}$ - log $c_{fu_{\text{after}}}$)

**SAL** $10^{-6}$

= sterility assurance level

**LABoratories/Investigators** (city):

- **koller** (Vienna)
- **werner/Kramer** (Schwerin/Greifswald)
- **getreuer** (Vienna)
Legends to figures (2)

**SPOR**e **SUSP**ensions:
G. stearothermophilus-spores (~$10^6$/carrier) in:
  - napec isotonic saline + peptone
  - adest dest. water
Legends to figures

**EXPOS**ition of spores: carriers/devices

- P*E*helix polyethylene-helix (*fine mesh metal*)
- Methelix metal-helix (*fine mesh metal*)
- Tyvekfol Tyvek-wrap (*fine mesh metal*)
Wraps for fine mesh metal spore-carriers

PEhelix

Tyvekfol

Methelix
Var‘s: **spore suspensions** and **carriers/expositions**

![Graph showing spore suspensions and carriers/expositions](image)

**SAL 10^{-6}**

**±Std. Dev.**

**±Std. Err.**

**Mean**

WFHSS May 07 Baden
General effect of position in dose/response curves on variances
Effect of **steriliser load size** (spore suspension **adest**)

![Graph showing the effect of steriliser load size on sterilisation success.](image-url)
Effect of **cycle length** (spore suspension adest)
Effect of **spore carrier position** in steriliser (spore susp adest)
Conclusions from study 2000

Sterrad™ 100S only acceptable with significant limitations:

- Absence of any organic or crystalline mini-residues on surfaces
- Absence of long fine bore channels esp. in metallic structures
- Steriliser load below critical limit
- Absence of cotton/cellulose and other organic components in MD and wrap

Control and documentation of critical process parameters urged!
2007 status

New generation of STERRAD 100-S, NX and 200 systems equipped with process control and documentation tools which allow validation.

In October 2006, a limited approval was issued by the Austrian ministry of health (AMH) for these STERRAD products. AMH Limitations for Sterrad™ use in human medicine comprise:

- Compliance with EN ISO 14937:2000 mandatory for use in medical settings (notably documentation and control of all relevant process parameters with suitable and calibrated instruments)
- Optimised and validated precleaning mandatory
Limitations (cont.)

- exclusion of any MD which can be autoclaved
- exclusion of (invasive) MD equipped with hardly accessible fine bores, joints, seams, grooves, lamellae or grills
- STERRAD not accepted as alternative to EO- or LTF-sterilisation unless suitability of and compatibility with MD in the given clinical setting proven and on site validation successfully performed
- Specialised instrument wraps (Tyvec) and sealing equipment as recommended by mfct. to be used in any case.
Recommendations

- New STERRAD 100-S, NX and 200 systems recommended for MD which require sterilisation and are not intended for invasive use and do not require special manipulations in the process steps preceding sterilisation = exclusively for highly specialised procedures and equipment!

- Specialised instrument wraps (Tyvec) and sealing equipment must be budgeted when comparing with other LT sterilising systems
Conclusions

- HPV can act sporocidal at moderate temperatures (40 - 60 °C) when high level cleanness and uninhibited access of HPV is guaranteed.
- New STERRAD 100-S, NX and 200 systems are equipped with process control and documentation tools which allow validated sterilising processes,
- approved by the Austrian ministry of health as niche products for sterilisation of highly selected MDs under strictly controlled conditions (EN ISO 14937:2000).
- Specialised instrument wraps (Tyvec) and sealing equipment are required.