VHP Sterilization and Prion Inactivation

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VHP Sterilization and Prion Inactivation

Meeting the challenge of two trends that impact infection control:

1. How should we process increasingly complex instruments?
2. How should we deal with Prions and other new pathogens?

This has led STERIS research and development to a new VHP technology – Amsco V-Pro 1.
Trends in Medical Devices

- Inventory restrictions
  - Cost management
- Minimum Invasive Surgery (MIS)
- Increased complexity
- Integrated electronics
- Temperature-sensitive materials
- New technologies
  - Drug-device combinations
  - Nanotechnology
da Vinci Surgical System in a General Procedure Setting

EndoWrist® Instruments are designed with seven degrees of freedom and mimic the dexterity of the human hand and wrist.

- **Operating Room (OR) Monitor**
- **Patient-Side Cart**
- **Anesthesiologist**
- **Assistant**
- **Nurse**

**Surgical Setup**
- Surgeon uses open-surgery hand movements which are precisely replicated in the operative field by the EndoWrist® Instruments.
- **Surgical Console**
- InSight™ Vision provides true-to-life 3D images of the operative field.
Trends in Sterilization

- Sterilization standards
  - ISO 17665 series (moist heat)
  - ISO 14937 (all sterilization processes)
- Validation and record keeping requirements
- Increasing need for low temperature sterilization
- Faster turn-around time
- Reducing costs
- Environmental concerns
- New microbial concerns
  - Toxins, including endotoxins
  - Prions
  - Parvoviruses
<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>More Resistant</td>
<td></td>
</tr>
<tr>
<td>Prions</td>
<td>Scrapie, Creutzfeld-Jakob disease, Chronic wasting disease</td>
</tr>
<tr>
<td>Bacterial Spores</td>
<td>Bacillus, Geobacillus, Clostridium</td>
</tr>
<tr>
<td>Protozoal Oocysts</td>
<td>Cryptosporidium</td>
</tr>
<tr>
<td>Helminth Eggs</td>
<td>Ascaris, Enterobius</td>
</tr>
<tr>
<td>Mycobacteria</td>
<td>Mycobacterium tuberculosis, M. terrae, M. chelonae</td>
</tr>
<tr>
<td>Small, Non-Enveloped Viruses</td>
<td>Poliovirus, Paroviruses, Papilloma viruses</td>
</tr>
<tr>
<td>Protozoal Cysts</td>
<td>Giardia, Acanthamoeba</td>
</tr>
<tr>
<td>Fungal Spores</td>
<td>Aspergillus, Penicillium</td>
</tr>
<tr>
<td>Gram negative bacteria</td>
<td>Pseudomonas, Providencia, Escherichia</td>
</tr>
<tr>
<td>Vegetative Fungi and Algae</td>
<td>Aspergillus, Trichophyton, Candida, Chlamydomonas</td>
</tr>
<tr>
<td>Vegetative Helminths and Protozoa</td>
<td>Ascaris, Cryptosporidium, Giardia</td>
</tr>
<tr>
<td>Less Resistant</td>
<td></td>
</tr>
<tr>
<td>Large, non-enveloped viruses</td>
<td>Adenoviruses, Rotaviruses</td>
</tr>
<tr>
<td>Gram positive bacteria</td>
<td>Staphylococcus, Streptococcus, Enterococcus</td>
</tr>
<tr>
<td>Enveloped viruses</td>
<td>HIV, Hepatitis B virus, Herpes Simplex virus</td>
</tr>
</tbody>
</table>

Are we redefining what we expect sterility to be?
Prion introduction

- What do we think ‘Prions’ are?
  - Identified as the causative agents for a group of central nervous system diseases
    - TSEs
    - vCJD, CJD
  - *Still debated!*
    - Proteins
    - Appear to be devoid of nucleic acid
    - They are not “alive” so how can you kill them?
Prion Diseases

- Have been shown to be transmissible
  - *Transmissible* spongiform encephalopathies (TSEs)

- Animal examples
  - Mad cow disease (BSE = bovine spongiform encephalopathy)
  - Scrapie (sheep & goats)
  - Chronic wasting disease (CWD) of deer & elk

- Human examples
  - CJD (Creutzfeldt-Jakob disease)
  - vCJD (variant CJD)
New Clinical Concerns

- **Tissue infectivity**
  - Stage of disease
  - Spleen, tonsils, thymus and appendix
  - Muscle
  - Blood (and blood transfusion)
  - Skin

- **Diseases**
  - vCJD
    - Confirmation of BSE source (debate over scrapie)
    - Understanding of transmission
  - Chronic wasting disease
  - Protein deposition diseases
Prion Decontamination

- Intrinsic resistance
  - Prions demonstrate resistance to routine methods of decontamination and sterilization
  - Prions are proteins, not microorganisms

- Cleaning is very important
- Some alkaline cleaners have been shown to inactivate prions
- Aldehydes fix proteins so are not likely to inactivate prions

Prions ?
- Bacterial Spores
- Mycobacteria
- Non-Enveloped Lipid Viruses
- Fungi
- Vegetative Bacteria
- Large Non-Enveloped Viruses
- Enveloped Lipid Viruses
Thermal Inactivation of Prions

<table>
<thead>
<tr>
<th>Method</th>
<th>Test Parameters</th>
<th>Mean Death (days)</th>
<th>‘Log’ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porous Load Autoclave</td>
<td>134°C, 18 minutes</td>
<td>197 ± 99</td>
<td>~5.5</td>
</tr>
<tr>
<td>Porous Load Autoclave</td>
<td>134°C, 18 minutes (immersed in water)</td>
<td>&gt;365</td>
<td>&gt;7</td>
</tr>
</tbody>
</table>

STEAM IS EFFECTIVE!
# Low Temperature Methods to inactivate Prions

<table>
<thead>
<tr>
<th>Method</th>
<th>Test Parameters</th>
<th>Mean Death (days)</th>
<th>‘Log’ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAA-based Formulation</td>
<td>~1500mg/L, 50°C, 12 mins</td>
<td>155 ± 75</td>
<td>~4.5</td>
</tr>
<tr>
<td>*VHP (vacuum)</td>
<td>4 pulses</td>
<td>&gt;540</td>
<td>&gt;7</td>
</tr>
<tr>
<td>Plasma/Hydrogen Peroxide gas (STERRAD 100S)</td>
<td>2 pulses</td>
<td>97 ± 4</td>
<td>~1</td>
</tr>
<tr>
<td>Plasma/Hydrogen Peroxide gas (STERRAD NX)</td>
<td>Advanced Cycle</td>
<td>&gt;540</td>
<td>&gt;7</td>
</tr>
</tbody>
</table>

*VHP: Vaporized Hydrogen Peroxide
Prion inactivation using a new gaseous hydrogen peroxide sterilisation process

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Received 19 January 2007; accepted 23 August 2007
Amsco V-PRO 1 Low Temperature Sterilization System

- New sterilization process
  - Plastics
  - Metals
  - Lumened instruments
- Hydrogen Peroxide Gas
- No plasma

VHP = Vaporized Hydrogen Peroxide
Amsco® V-PRO™ 1

Key Features

- Ease of installation
- Ease of use
- Productive
- Cost competitive
- Rapid cycle time (55 min)
- Antimicrobial efficacy
- Safety
- Compatibility
- Full range of consumables
- Compliant to ISO 14937 Standard
The Antimicrobial Used

Hydrogen Peroxide
\( (H_2O_2) \)

...but in gas phase
## Liquid vs. Gas Hydrogen Peroxide

<table>
<thead>
<tr>
<th>Test Organism (Spores)</th>
<th>D-value (mins)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liquid</td>
</tr>
<tr>
<td></td>
<td>370 mg/L</td>
</tr>
<tr>
<td></td>
<td>24-25°C</td>
</tr>
<tr>
<td><strong>G. stearothermophilus</strong></td>
<td>1.5</td>
</tr>
<tr>
<td><strong>B. subtilus</strong></td>
<td>2.0-7.3</td>
</tr>
<tr>
<td><strong>C. sporogenes</strong></td>
<td>0.8</td>
</tr>
</tbody>
</table>

Gaseous Hydrogen Peroxide is much more biocidally active and is less corrosive.

*Source: Block, 1991*
VHP Process

Heat Vaporization

50°C

Catalytic conversion

H₂O₂

H₂O

O₂

Non-Toxic Residues

Vaprox® HC

Hydrogen Peroxide 59%
The V-Pro 1 Process

V-PRO 1 Sterilization Cycle

Pressure (mm Hg)

Condition

Sterilize

Aerate

Time (min)

Pulse 1  Pulse 2  Pulse 3  Pulse 4
VHP Sterilization and Prion Inactivation

Conclusion:

- The new Amsco V-Pro 1 is a new weapon in your armoury as infection control professionals.
- A powerful low temperature sterilization process that has shown excellent human prion inactivation.
- Part of your overall strategy of combating the new challenges of new instrumentation and new microbial concerns both living and non-living.
"The madness started with the cow and spread to the others..."