The V-Pro series of Hydrogen Peroxide Gas Sterilizers

Dr. Gerald McDonnell
Why Hydrogen Peroxide Gas?

• Broad spectrum antimicrobial efficacy
• Material compatibility
• Safety

But, depends on how it is used
  – Concentration
  – Liquid or gas
Hydrogen Peroxide Gas

Hydrogen Peroxide 3-60%

Heating

H₂O₂

H₂O + O₂

Low Concentrations (0.1-10 mg/L)
Odorless, colorless

Non-Toxic Residues
How gas processes can vary

- Pre-conditioning
- Gas concentration
- Liquid and/or Gas present
  - Condensed (saturated) or non-condensed gas
- Pressure levels
- Temperature ranges
- Exposure time
- Penetration capabilities
- Aeration process
  - e.g., use of plasma, as part of the process

Each Process is Unique
STERIS Gas Systems

1988

1998

2001

2004
Amsco® V-PRO™

2009

V-PRO™ 1

2010

V-PRO™ 1 PLUS

2011

V-PRO™ max
Chamber Pressure (Torr)

Time (min)

0 2 4 6 8 10 12 14 16 18 20 22 24 26 28

Moisture Check
Sterilize
Aerate

1/2 Cycle

Injection 1  Injection 2  Injection 3  Injection 4
1. **Lumen cycle**

- All devices, including endoscopes, with diffusion-restricted spaces
- Single, dual and triple channeled rigid and semi-rigid endoscopes
- Non-metal lumens with an inside diameter of \( \geq 6 \) mm and a length of \( \leq 310 \) mm
- 20 lumens, \( \sim 9 \)kg/load
- 55 mins

<table>
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<tr>
<th># Channels</th>
<th>ID &amp; Length</th>
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<tr>
<td>Single</td>
<td>( \geq 0.77 ) mm ID and ( \leq 500 ) mm</td>
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| Dual       | One lumen with \( \geq 0.77 \) mm ID and \( \leq 527 \) mm  
Second lumen with \( \geq 1.17 \) mm ID and \( \leq 500 \) mm |
| Triple     | Two lumens with \( \geq 1.2 \) mm ID and \( \leq 310 \) mm  
And third lumen with \( \geq 1.8 \) mm ID and \( \leq 300 \) mm or \( \geq 2.8 \) mm ID and \( \leq 317 \) mm |
2. Non-Lumen cycle

- Non-lumened rigid and semi-rigid medical devices (including endoscopes)
- ~9kg/load
- 28 mins
3. Flexible cycle

- All single or dual lumen surgical flexible endoscopes, including bronchoscopes
- Two flexible scopes or one scope with other non-lumened instruments
  - Inside diameter of ≥ 1 mm and a length of ≤ 1050 mm
- 35 mins
Validation (examples)

- ISO 9001 and ISO 13485
- ISO 14937: Sterilization of healthcare products-General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process
- And associated standards for safety (toxicity, electrical mechanics etc), compatibility and efficacy
Ongoing Validation
V-Pro Series

• Hydrogen peroxide gas sterilization
  – Conditioning, sterilization, aeration
  – Safe process
• Efficient and productive process
  – 3 cycles in one
  – Large and versatile load capacity
  – Reduces unnecessary cycle aborts (aids drying)
• Device compatibility
  – Lumened and non-lumened devices
  – Robotic devices
  – Continuing validation
    • Instructions for use

• Easy to use
  – Large screen
  – Simple interface
  – Manual on screen
• Integrated parametric monitoring
• Preventative maintenance
  – On screen reminders
  – Remote monitoring
• Can be integrated to tracking systems
• Lower costs