Low Temperature Sterilization

Hydrogen Peroxide

Formaldehyd

Low Temperature Solutions

Consumables

Ethyleneoxide

Service

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Robert Tornberger
Background

• Instruments used in MIS are often sensitive to high temperature and pressure. This leads to a growing demand of Low Temperature Sterilizers.

• Customer requests on a higher throughput and production capacity.

• New trend and demands of low temperature sterilization for semi critical instruments that might be categorized as critical, i.e. Duodenoscopes.
Background
Sterilization Methods

• Ethylene oxide

• Formaldehyde

• Hydrogen peroxide

• Hydrogen peroxide/Ozone
Standards

Standards – requirements, testing and acceptance criteria:

• EN 1422:2014 - Ethylene Oxide

• EN 14180:2014 – Formaldehyde

• draftEN XXXXX - Hydrogen peroxide TC 102 wg 6 (2019)
Standards

Standards for development, validation and routine control:

- EN-ISO 11135:2014 - Ethylene Oxide
- EN-ISO 25424:2009 – Formaldehyde
- ISO/NP 22441 - Hydrogen peroxide (ISO/TC 198)
Sterilization Methods – Ethylene oxide

Characteristics

• Very effective sterilant

• Applied in gas/steam

• Good penetration in longer lumens

• Cancer Hazard and Reproductive Hazard

• Explosive

• Wrapping/porous material absorbs the sterilant

• Degassing required outside the chamber
Sterilization Methods – Formaldehyde

Characteristics

• Very effective sterilant

• Applied in gas/steam

• Good penetration in longer lumens

• Dangerous breathing in…

• Dissolves in water

• Wrapping/porous material absorbs the sterilant

• Degassing in-chamber
Sterilization Methods – Hydrogen peroxide

Characteristics

- Very effective sterilant
- Applied as vapor
- Good penetration in lumens
- Reactive/Corrosive
- Dissolves in water
- Transforms into water and oxygen with plasma and catalytic converter
Sterilization Methods – Hydrogen peroxide & Ozone

Characteristics

• Very effective sterilant combination

• Applied as vapor that condensates (micro layer)

• Good penetration in longer lumens

• Reactive/Corrosive

• Dissolves in water

• Hydrogen peroxide decomposes to water and oxygen with Ozone

• Ozone decomposes to water and oxygen with the hydrogen peroxide
Instrument Flow and Production Solution
Low Temperature Sterilizers
Customer Requirements

- **High instrument compatibility:**
  - Material
  - Lumen length

- **Throughput:**
  - Cost effective
    - High/Medium/Low/Peaks
    - Type of instruments

- **Safety:**
  - User, patient & environment
    - Validated cycles

- **High Quality:**
  - Quality assurance
  - Notified bodies

Low temperature sterilization customer requirements
Low Temperature Sterilizers

Supplier Offer

- **Complete solution provider**
- **Wide product portfolio**
- **Complete consumable offering**

**High instrument compatibility:**
- Material
- Lumen length

**Throughput:**
- Cost effective
- High/Medium/Low/Peaks
- Type of instruments

**Safety:**
- User, patient & environment
- Validated cycles

**High Quality:**
- Quality assurance
- Notified bodies
Consumables - Low Temperature Sterilizers

- Sterilant
- Chemical Indicators
- Biologic Indicators
- Routine Monitoring Kits
- Packaging Materials

Total Consumable Offering
Hydrogen Peroxide & Plasma
Hydrogen Peroxide & Plasma
Low Temperature H2O2 Sterilizers
In-chamber Plasma vs. Out Side Plasma & No Plasma

In-Chamber Plasma

Antenna & RF Plasma
Catalytic Convertor

Vaporizer
Oil Filter
Vacuum Pump

Out Side Plasma & No Plasma

Vaporizer
Sterilization Chamber
Oil Filter
Vacuum Pump

Arc Plasma
**Vacuum Conditioning**
The Sterilization Process requires a deep vacuum to provide an optimal sterilization environment.

**Plasma Conditioning**
The Chamber is pre-conditioned with plasma in order to (i) remove moisture and (ii) enable homogenous heat distribution.

**1st Hydrogen Peroxide Injection**
The previously conditioned \( \text{H}_2\text{O}_2 \) Sterilant is injected into the sterilization chamber as a vapor.

**1st Diffusion (High)**
Dry air is inserted into the chamber to push the \( \text{H}_2\text{O}_2 \) further into any lumens.

**2nd Diffusion (low)**
Warmup of chamber to enable conditions for avg 55°C

**2nd Diffusion (high)**
760Torr = 1 Atm

**2nd Hydrogen Peroxide Injection**
Once again, conditioned \( \text{H}_2\text{O}_2 \) Sterilant is injected into the sterilization chamber as a vapor.

**Vacuum Conditioning**
The Chamber evacuated to vacuum in preparation for the Plasma Abatement stage.

**Optional Aeration**
Sterilization cell is vented with purified dry air to provide further cleansing.

**Plasma Abatement**
The plasma at the end of the cycle, ensures that all \( \text{H}_2\text{O}_2 \) is decomposed (to water vapor and oxygen) and to contributes to the sterilization via the UV and free radicals generated.

**Vacuum Conditioning**
The Chamber evacuated to vacuum in preparation for the 2nd Injection Phase.

**Sterilization Completion**
The system will check all parameters before finalizing the sterilization cycle.

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**Process**

- Fast cycle = 59% \( \text{H}_2\text{O}_2 \) 2 injection
- Standard = 80-82% \( \text{H}_2\text{O}_2 \) 2 injections
- Advanced = 90-92% \( \text{H}_2\text{O}_2 \) 2 injections
# Low Temperature H₂O₂ Sterilizers

## Lumen Claims

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Description</th>
<th>Inside Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast Cycle 29 min</td>
<td>Fast sterilization for surface instruments e.g.</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>• General surface surgery instruments</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Rechargeable batteries</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ophthalmic Instruments W/O lumens</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Standard Cycle 42 min</strong> [Concentrated H₂O₂]</td>
<td>Sterilization of general surgical instruments with flexible and short rigid lumens e.g.</td>
<td>Flexi</td>
<td>Flexi</td>
</tr>
<tr>
<td></td>
<td>• General surface surgery instruments</td>
<td>1.0 mm</td>
<td>≤ 850 mm</td>
</tr>
<tr>
<td></td>
<td>• Single channel flexible scopes</td>
<td>2.0 mm</td>
<td>≤ 1200 mm</td>
</tr>
<tr>
<td></td>
<td>• Rigid lumens</td>
<td>Rigid</td>
<td>Rigid</td>
</tr>
<tr>
<td></td>
<td>• Maximum 6 lumens per load</td>
<td>1.0 mm</td>
<td>≤ 400 mm</td>
</tr>
<tr>
<td><strong>Advanced Cycle 53 min</strong> [Concentrated H₂O₂]</td>
<td>Sterilization of general rigid (not flexible) surgical instruments with long lumens e.g.</td>
<td>1.0 mm</td>
<td>≤ 500 mm</td>
</tr>
<tr>
<td></td>
<td>• General surface surgery metal instruments</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Instruments which have long rigid lumens</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Maximum 6 lumens per load</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Formaldehyde & Steam
Formaldehyde & Steam
Formaldehyde & Steam
Formaldehyde Process (55°-80°)
Low Temperature Steam Formaldehyde

**Low temp & high temp**

- 134°C Steam
- 121°C Steam
- 80°C Steam/FO
- 65°C
- 55°C

**Safety**

Typetested acc. to FO sterilizer norms
EN14180 Building and testing
EN25424 Development, validation and routine control

**Material compatibility**

Long lumen penetration & Non oxidizing
Low Temperature Steam Formaldehyde

Steam + Formaldehyde = Steam & formaldehyde
Low Temperature Sterilizers

Hydrogen Peroxide & Plasma

Hydrogen Peroxide & Ozone

Formaldehyde & Steam
Hydrogen Peroxide & Ozone
Hydrogen Peroxide and Ozone
Process
Low Temperature Sterilizers – TSO3

- First low temperature sterilizer with a “load sensing” Dynamic Sterilant Delivery System.
- First low temperature sterilizer with micro-condensation layer on device surfaces
- First “single cycle” low temperature sterilizer cleared to process a 34 kg load consisting of:
  - General instruments
  - Batteries, drills, cables, cameras
  - Single channel flexible endoscopes
  - Rigid and semi-rigid single and dual channeled devices including endoscopes.

*Note: long/multi-channel scopes are dedicated load, 1/cycle*
## Low Temperature Sterilizers – TSO3

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<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single Cycle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Cycle 1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>General surface surgery metal instruments, batteries, drills, cables, cameras, etc.</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Single channel flexible endoscopes</td>
<td>≥ 1.0 mm</td>
<td>≤ 850 mm</td>
</tr>
<tr>
<td></td>
<td>Single &amp; double channel flexible endoscope</td>
<td>≥ 1.0 mm</td>
<td>≤ 989 mm</td>
</tr>
<tr>
<td></td>
<td>Rigid channel devices including single channel and double rigid channel endoscopes</td>
<td>≥ 0.7 mm, ≥ 2.0 mm</td>
<td>≤ 500 mm, ≤ 575 mm</td>
</tr>
<tr>
<td></td>
<td>Multi-Channel flexible endoscope (Video colonoscope or gastroscope 4 channels total)*</td>
<td>≥ 1.2 mm, ≥ 1.45 mm</td>
<td>≤ 1955 mm, ≤ 3500 mm</td>
</tr>
</tbody>
</table>
Questions & Answers