EO Flexible Chamber Technology (EO-FCT)
Characteristics, Applications & Potential for Reduced EO Emissions

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presented by:
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Presentation Overview:

1. Characteristics of Ethylene Oxide Flexible Chamber Technology (EO-FCT) sterilizers and key differences between flexible and rigid chambers.

2. Industrial applications of EO-FCT systems:
   Three case studies, including:
   a. Application type
   b. Scalability

3. How EO-FCT systems can help to reduce EO emissions to the environment.
Characteristics of Ethylene Oxide Flexible Chamber Technology (EO-FCT)
History of EO-FCT Systems

- EO-FCT sterilization method was developed in the 1960’s.
- Andersen systems have been used for healthcare and industrial sterilization since the early 1970’s (original systems recognized by FDA as Pre-amendment devices)
- Currently in use in over 50 countries around the world
- Considered a “Category B” sterilization method by FDA
- Specific guidance AAMI TIR 56
Characteristics of EO-FCT Systems

Cartridge sizes range from 5 grams to 18 grams of EO:

- AN1005: 5 g
- AN2011: 11 g
- AN2014: 14 g
- AN2018: 18 g
Characteristics of EO-FCT Systems

- Flexible Chamber (Sterilization Bag) – small, up to 60 liter
  - Originally gas permeable
  - Latest systems use EO impermeable bags
- Single Use Cartridge – under 18 grams EO per cycle
- Delicate Cycle - no deep vacuum or steam injection
- Applications and Scalability – add bags/capacity as needed. Never use more gas than is necessary
- Low emissions to environment
Traditional EO Chambers Versus EO-FCT Systems
Traditional EO Chambers Versus EO-FCT Systems
EO-FCT Process Description

Traditional EO sterilizers use fixed metal chambers that result in significant “dead space” even when fully loaded. These systems must use large amounts of EO to achieve a high gas concentration throughout the chamber. Andersen EO Flexible Chamber Technology (EOFCT) offers a much more efficient process.

Andersen sterilizers employ flexible bags as their sterilization chamber. The bag is filled with items to be processed along with a single use EO cartridge. The bag is sealed and loaded into the sterilization cabinet. At the start of the cycle a vacuum is drawn on the bag and excess air is removed. The bag, which is the sterilization chamber, collapses around the load, eliminating any dead space. When the EO cartridge is activated, a high gas concentration is achieved with a very small amount of gas (5 to 17.5 grams per cycle!).

When combined with an Andersen abator, this small amount of gas is effectively removed from the exhaust stream.
Applications, Scalability & Emissions of EO-FCT Systems
Applications, Scalability & Emissions of EO-FCT Systems

Three Case Studies:

1. In-house sterilization for specialty manufacturers and R&D
2. In-house sterilization for small & medium OEM device manufacturers
3. 3rd party commercial EO sterilization
Applications, Scalability & Emissions of EO-FCT Systems

1. Bring Sterilization In-House:

Specialty manufacturers and R&D

- High value, low volume devices
- Custom devices and implants (brachytherapy kits)
- Combination products (drug coated devices)
- R&D and device development/compatibility

Answer – EOGas 4
Tabletop EO-FCT system
Applications & Scalability of EO-FCT Systems

Bring Sterilization In-House – EOGas 4

### Emissions Data for Andersen Sterilization Systems:

**Andersen EOGas 4 Sterilization System**

The Andersen EOGas 4 sterilizer uses a 17.6 gram, 100% Ethylene oxide (EO) cartridge. The cycle time is 3.5 hours of sterilization and chamber purge (some loads may require additional aeration).

<table>
<thead>
<tr>
<th>Emissions based upon typical usage:</th>
<th>Daily (grams)</th>
<th>Weekly (grams)</th>
<th>Annual (grams)</th>
<th>Annual (lbs)</th>
<th>Annual Post 99% Abatement (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light use (two cycles per week):</td>
<td>17.6</td>
<td>35.2</td>
<td>1830.4</td>
<td>4.03</td>
<td>0.04</td>
</tr>
<tr>
<td>Medium use (five cycles per week):</td>
<td>17.6</td>
<td>88</td>
<td>4576</td>
<td>10.08</td>
<td>0.10</td>
</tr>
<tr>
<td>Heavy use (ten cycles a week):</td>
<td>35.2</td>
<td>176</td>
<td>9152</td>
<td>20.16</td>
<td>0.20</td>
</tr>
</tbody>
</table>
Applications of EO-FCT Systems

2. Bring Sterilization In-House:
   Small & Medium OEM Device Manufacturers
   - By daily sterilization, can achieve significant volumes
   - Reduce transportations and inventory costs
   - Scale capacity as production volume grows

Answer – EOChem 3 system
Applications & Scalability of EO-FCT Systems

2. Bring Sterilization In-House – EOGas 3 Case Study:
OEM device manufacturer purchased an EOGas 3 cabinet with a ten-bag capacity. By sterilizing devices only in final packaging (Tyvek®/plastic pouches), the customer estimates that they can sterilize the equivalent of approximately ½ of a finished pallet per day. Operating seven days a week, they can sterilize 2 ½ pallets per week, or ten pallets per month.

As their business grew, the customer kept adding cabinets. After ten years they are operating ten EOGas cabinets running 100 bags per day. Estimated volume is the equivalent of 25 pallets per week, or 100 pallets per month.

This is a good example of how daily in-house sterilization, as part of the production process, can achieve significant processing volumes.
# Applications & Scalability of EO-FCT Systems

## Bring Sterilization In-House – EOGas 3

## Emissions Data for Andersen Sterilization Systems:

### Andersen EOGas 3 Sterilization System

The Andersen EOGas 3 sterilizer uses a 10.5 gram, 100% Ethylene oxide (EO) cartridge. The cycle time is 16 hours of sterilization (some loads may require additional aeration).

<table>
<thead>
<tr>
<th>Emissions based upon typical usage:</th>
<th>Daily</th>
<th>Weekly</th>
<th>Annual (grams)</th>
<th>Annual (lbs)</th>
<th>Annual Post 99% Abatement (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light use (ten cycles per week):</td>
<td>21</td>
<td>105</td>
<td>5460</td>
<td>12.03</td>
<td>0.12</td>
</tr>
<tr>
<td>Medium use (thirty cycles per week):</td>
<td>63</td>
<td>126</td>
<td>6552</td>
<td>14.43</td>
<td>0.14</td>
</tr>
<tr>
<td>Heavy use (seventy cycles a week):</td>
<td>105</td>
<td>735</td>
<td>38220</td>
<td>84.19</td>
<td>0.84</td>
</tr>
</tbody>
</table>

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[Andersen Sterilizers logo]
Applications & Scalability of EO-FCT Systems

3. Third-Party Commercial EO-FCT Sterilization

Background:
The following calculations are based on the Andersen Scientific EO flexible chamber method and traditional pallet sterilization.

• A traditional pallet is defined as a single load that is approximately 48in x 40in x 80in. This equates to a volume of approx. 88.9 cubic feet or 153,600 cubic inches.

• Each Andersen Scientific flexible chamber is approx. 3,009 cubic inches.

• 153,600 in$^3$ (pallet) / 3,090 in$^3$ = ~50 EO-FCT sterilization bags.
Applications & Scalability of EO-FCT Systems

3. Third-Party Commercial Sterilization: Gas Usage

Traditional pallet sterilizer:
• A traditional pallet sterilizer uses between 6 and 8lbs. per pallet (AVG. 7lbs.)
• 7lbs. EO = 3,178g EO

Flexible Chamber:
• Pallet equivalent is 50 bags. Using a 17.6g EO cartridge, 50 bags = 880g EO
• Using a 10.5g EO cartridge, 50 bags = 525g EO

The EO-FCT commercial sterilization method uses 72-83% less gas than a traditional pallet sterilizer when sterilizing the same volume of product.
Applications & Scalability of EO-FCT Systems
Third-Party Commercial Sterilization

Emissions Data

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Chambers/pallet</th>
<th>Volume (in³)</th>
<th>EO used (lbs.)</th>
<th>EO emissions after 99% abatement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pallet chamber</td>
<td>1</td>
<td>153,600</td>
<td>6.0 – 8.0</td>
<td>0.06 - 0.08</td>
</tr>
<tr>
<td>EO-FCT method</td>
<td>50</td>
<td>153,459</td>
<td>1.16 -1.94</td>
<td>0.01 - 0.02</td>
</tr>
</tbody>
</table>

The EO-FCT sterilization method uses 72-83% less gas than a traditional pallet sterilizer when sterilizing the same volume of product, with a corresponding reduction of EO emissions to the environment.
Applications & Scalability of EO-FCT Systems
Third Party Commercial Sterilization

Throughput/Capacity:

<table>
<thead>
<tr>
<th>Weekly capacity</th>
<th>Chambers</th>
<th>Pallets</th>
<th>EO used (lbs.)</th>
<th>Weekly EO emissions after 99% abatement (lbs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using 2 cabinets</td>
<td>400</td>
<td>8</td>
<td>9.25 – 15.51</td>
<td>0.093 – 0.155</td>
</tr>
<tr>
<td>Using 4 cabinets</td>
<td>800</td>
<td>16</td>
<td>18.50 – 31.01</td>
<td>0.185 – 0.310</td>
</tr>
<tr>
<td>Using 6 cabinets</td>
<td>1200</td>
<td>24</td>
<td>27.75 – 46.52</td>
<td>0.278 – 0.465</td>
</tr>
</tbody>
</table>

Conclusion – While an industrial EO-FCT facility cannot match the volumes possible in a traditional pallet chamber facility, the flexible chamber process can achieve upwards of 24 pallets per week. Furthermore, the modest capital cost and very low emissions of these EO-FCT facilities may allow them to operate in locations that are not practical or possible for traditional EO sterilization chambers.
Summary – EO-FCT Sterilization

- An established method of device sterilization
- Very gentle cycle – ideal for certain device types
- Ideal for specialty devices, R&D and product development
- Attractive option for small and medium device manufacturers who can bring sterilization in-house
- EO-FCT sterilizers are the most gas-efficient system currently available, with corresponding ultra-low emissions.