Thermal Sterilization of EO-compatible Medical Devices

Jonathan A. Wilder, Ph.D., Managing Director
Quality Processing Resource Group, LLC
Scope

• FDA has requested input on the subject of alternative technologies for sterilization of medical devices currently sterilized in ethylene oxide (EO) gas in an industrial setting
• This presentation explores the possibility of migrating those devices to steam or dry heat.
Basis of Presentation

• AAMI TIR17 addresses “Compatibility of materials subject to sterilization”

• The listing of materials shown as compatible with EO sterilization in Table 1 of that document is the basis of the listing and analysis presented here.

• The “rule-in/rule-out” process was based upon a compatibility in the AAMI document of “•••” or “••••”, with the latter preferred.
Background

• The decision to sterilize medical devices using EO is typically made for the following reasons:
  – Excellent product penetration
  – Reliability; established compatibility with the process and a long history of validated processing for the materials used
  – Cost; the size of industrial/contract sterilizer chambers enables economical sterilization
Materials Typically Sterilized In EO

- ABS
- PTFE
- PFA
- PCTFE
- PVF
- EFTE
- FEP
- Polyacetals
- Polyamides (nylons)
- Polycarbonates
- Polyesters
- Polyethylene
- Polyimides
- Polyketones
- Polypropylenes
- Polysulfones
- PVC
- Epoxies
- Silicone
- Butyl
- EPDM
- Nitrile
- Styrenic Block Copolymers
- Cellulosics
Subset of Materials Which are Less Compatible with Radiation than EO

- PTFE
- PFA
- FEP
- Polyacetals
- Polyamides (nylons)
- Polypropylenes
- Silicone
- Butyl
- Styrenic Block Copolymers
- Cellulosics
Subset of Materials Which are Less Compatible with Steam or Dry Heat Than With EO

- Polyacetals
- Polyamides (nylons) - depends upon specific grade
- Polypropylenes
- Silicone - depends upon specific grade
- Butyl - depends upon specific grade
- Styrenic Block Copolymers
- Cellulosics
### Potential Alternate Sterilization Methods for These Materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Method</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyacetals</td>
<td>Hydrogen Peroxide Vapor</td>
<td></td>
</tr>
<tr>
<td>Polyamides (nylons)</td>
<td>Hydrogen Peroxide Vapor</td>
<td>(depends on grade)</td>
</tr>
<tr>
<td>Polypropylenes</td>
<td>Hydrogen Peroxide Vapor</td>
<td></td>
</tr>
<tr>
<td>Silicones</td>
<td>None listed</td>
<td></td>
</tr>
<tr>
<td>Butyl rubber</td>
<td>Hydrogen Peroxide Vapor</td>
<td>(depends on grade)</td>
</tr>
<tr>
<td>Styrenic Block Copolymers</td>
<td>Hydrogen Peroxide Vapor</td>
<td></td>
</tr>
<tr>
<td>Cellulosics</td>
<td>None listed</td>
<td></td>
</tr>
</tbody>
</table>
Thermal Sterilization vs. EO

- Thermal sterilization uses fairly small chambers.
- Maintenance requirements of the equipment are similar to or less than those of EO sterilizers.
- Cycles are much faster (total cycle time).
- Thermal burns and pressure vessel considerations are the only hazards.

- EO uses large chambers and is well suited for bulk-quantity sterilization.
- Cycles are long; conditioning and aeration add to the cycle duration.
- EO is toxic.
Steam vs. Dry Heat

Steam Cycles are:
- Relatively fast (~1-2 hours total)
- Parametrically controllable
- Run at 121-135°C
- Penetrate loads well if prevacuum cycles are used

Dry Heat Cycles are:
- Slower (60-150 minute exposure plus heat up)
- Less able to be parametrically controlled
- Run at 150-170 °C
- Potentially slow penetration through the load
Alternatives

• Material Compatibility of Mixed Materials may be questionable
• Deep vacuum for VH2O2 processing may compromise design integrity
• Some materials cannot be sterilized in these alternative methods.
Results of this Review

• There are a large number of polymers that can be migrated to thermal sterilization methods

• The details of specific device construction may constrain this migration
  – Examples of potential interferences in migration can include:
    • Physical incompatibility arising from thermally-induced effects like differential expansion of overmolded parts
    • Effects of moisture on the product, not just the heat
    • Effects of high temperature on the finished product in dry heat sterilization

• Changing the production model will be costly
Conclusions

- Some materials currently sterilized in EO cannot be migrated to radiation sterilization
- Some materials currently sterilized in EO cannot be migrated to steam or dry heat sterilization
- The effects of high-temperature sterilization can make migration of otherwise-compatible devices impossible
- The logistics and equipment for thermal sterilization differ greatly from EO and would take a lot of capital and time to implement if devices can be migrated to these methods
Thank you!

• Please feel free to contact us with any questions

Jonathan Wilder, Ph.D.
Managing Director
Quality Processing Resource Group, LLC (QPRG)
jwilder@qprgllc.com
www.qprgllc.com
585-218-0385