AGENDA

• Types of Sensitive Materials
• Sterilization Modalities
• Important Considerations
• Cross-Linking
• Advancing Sterilization Processing of Biomedical Devices
• Influencing Success
• Five Questions to Always Ask
• Key “Take-Aways”
## WHO IS NUTEK?

### SERVICES
1. E-beam Sterilization
2. E-beam cross-linking
3. R&D consulting (no cost)
4. Sensitive Materials
5. Combination Devices
6. Microbiology Testing
7. High Volume
8. On-Demand Processing
9. EO R&D & Batch Sterilization

### HISTORY
1. 1990 – Founded, Palo Alto, CA
2. 1997 – Expansion, Hayward, CA
3. 1997 – Installed first DualBeam™
4. 2000 – Expansion x2 - DualBeam™
5. 2007 – Expansion x4 - DualBeam™
6. 2007 – Upgraded DualBeam™
7. 1998 – Proprietary Systems for to Sensitive/Combination:
8. 2013 – SmartDose™
9. 2015 – Brand new facility in Fremont
SENSITIVE MATERIALS

- Bioabsorbables
- Bioresorbables
- Hydrogels
- Implantables
- Drugs & Biologics
- Combination Devices
- Biomaterials
- Polymers & Advanced Polymers
- Teflon
- Allograft Tissue
STERILIZATION MODALITIES

4 common modalities:

1. E-Beam and/or X-ray
2. Gamma
3. EO (Ethylene Oxide)
4. NO₂ (Nitrogen Dioxide)
IMPORTANT CONSIDERATIONS

• Material Compatibility
• Packaging and Configuration
• Biocompatibility Testing
• Bioburden Testing
• Package Integrity/Shelf-life Testing
• Product Functionality Testing
• Toxicology Testing
## Examples of polymers used as biomaterials

<table>
<thead>
<tr>
<th>Application</th>
<th>Polymer</th>
</tr>
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<tbody>
<tr>
<td>Knee, hip, shoulder joints</td>
<td>Ultrahigh molecular weight polyethylene</td>
</tr>
<tr>
<td>Finger joints</td>
<td>Silicone</td>
</tr>
<tr>
<td>Sutures</td>
<td>Polylactic and polyglycolic acid, nylon</td>
</tr>
<tr>
<td>Tracheal tubes</td>
<td>Silicone, acrylic, nylon</td>
</tr>
<tr>
<td>Heart pacemaker</td>
<td>Acetal, polyethylene, polyurethane,</td>
</tr>
<tr>
<td>Blood vessels</td>
<td>Polyester, PVC, polytetrafluoroethylene,</td>
</tr>
<tr>
<td>Gastrointestinal segments</td>
<td>Nylon, PVC, silicones</td>
</tr>
<tr>
<td>Facial prostheses</td>
<td>Polydimethyl siloxane, polyurethane, PVC</td>
</tr>
<tr>
<td>Bone cement</td>
<td>Polymethyl methacrylate, PVC, polyvinyl chloride</td>
</tr>
</tbody>
</table>
Implant material requirements in orthopedic applications

Requirements of implants

Compatibility
- Tissue reactions
- Change in properties
  - Mechanical
  - Physical
  - Chemical
- Degradation leads to
  - Local deleterious changes
  - Harmful systemic effects

Mechanical properties
- Elasticity
- Yield stress
- Ductility
- Toughness
- Time dependent deformation
- Creep
- Ultimate strength
- Fatigue strength
- Hardness
- Wear resistance

Manufacturing
- Fabrication methods
- Consistency and conformity to all requirements
- Quality of raw materials
- Superior techniques to obtain excellent surface finish or texture
- Capability of material to get safe and efficient sterilization
- Cost of product

Courtesy of 'Hydrogels in Biology and Medicine: From Molecular Principles to Bionanotechnology'
By Nicholas A. Peppas, J. Zach Hilt,
Ali Khademhosseini, and Robert Langer -Advanced Materials  advmat.de
CROSS-LINKING

- Hydrogels/PEG devices/Biomaterials
- Special Applications
ADVANCING STERILIZATION PROCESSING OF BIOMEDICAL DEVICES

• Ever-increasing complexities and use of Biomaterials (including Thin Films, Hydrogels, Nanotechnology) for Cardiovascular, Ophthalmic, Orthopedic, Drug Delivery and Wound Healing applications

• Advanced Sterilization Methods - SmartDose™
INFLUENCING SUCCESS

First things first... what is “SUCCESS”???

- Sterilizing materials and combination products that could not be sterilized before
- Measurably decreasing the need for re-designs
- Measurably decreasing waste
- Measurably decreasing costs and increasing margins
- Measurably getting to market quicker
5 QUESTIONS TO ASK

1. Which sterilization modality?
2. At what stage is materials testing conducted?
3. What is my bioburden level?
4. How is dose mapping applied?
5. Are all approaches to packaging and configuration being explored? When?
3 KEY TAKE-AWAYS

1. New approaches allow for innovation, customization, and Sterilization... by Design

2. These new approaches can:
   - increase sterilization success
   - decrease product re-designs
   - decrease waste in production
   - save money and time
   - get products to market quicker

3. Ask the five key questions!
THANK YOU!

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