NCCAVS

Thin Film Users Group (TFUG)

BIOMEDICAL APPLICATIONS

Tuesday, August 19, 2014

"STERILIZATION FOR BIOMEDICAL DEVICES"

Presented By: Jeff Sauter

NUTEK CORPORATION

Sterilization By Design™

AGENDA

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- 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?

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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

1990 – Founded, Palo Alto, CA

1997 – Expansion, Hayward, CA

1997 – Installed first ***DualBeam™***

2000 – Expansion x2 - ***DualBeam™***

2007 – Expansion x4 - ***DualBeam™***

2007 – Upgraded ***DualBeam™***

1998 to Proprietary Systems for Sensitive/Combination:

2013 – ***SmartDose™***

2015 – Brand new facility in Fremont

SENSITIVE MATERIALS

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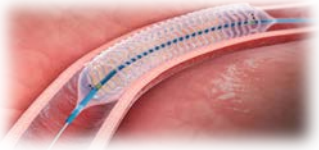
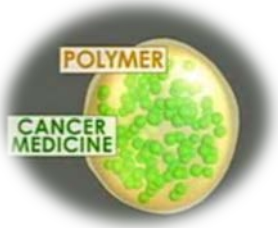
Bioabsorbables Bioresorbables



Drugs & Biologics

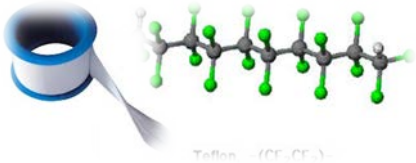
Polymers & Advanced Polymers



Hydrogels

Combination Devices

Teflon



Implantables

Biomaterials

Allograft Tissue

STERILIZATION MODALITIES

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4 common modalities:

1. E-Beam and/or X-ray
2. Gamma
3. EO (Ethylene Oxide)
4. NO_2 (Nitrogen Dioxide)

IMPORTANT CONSIDERATIONS

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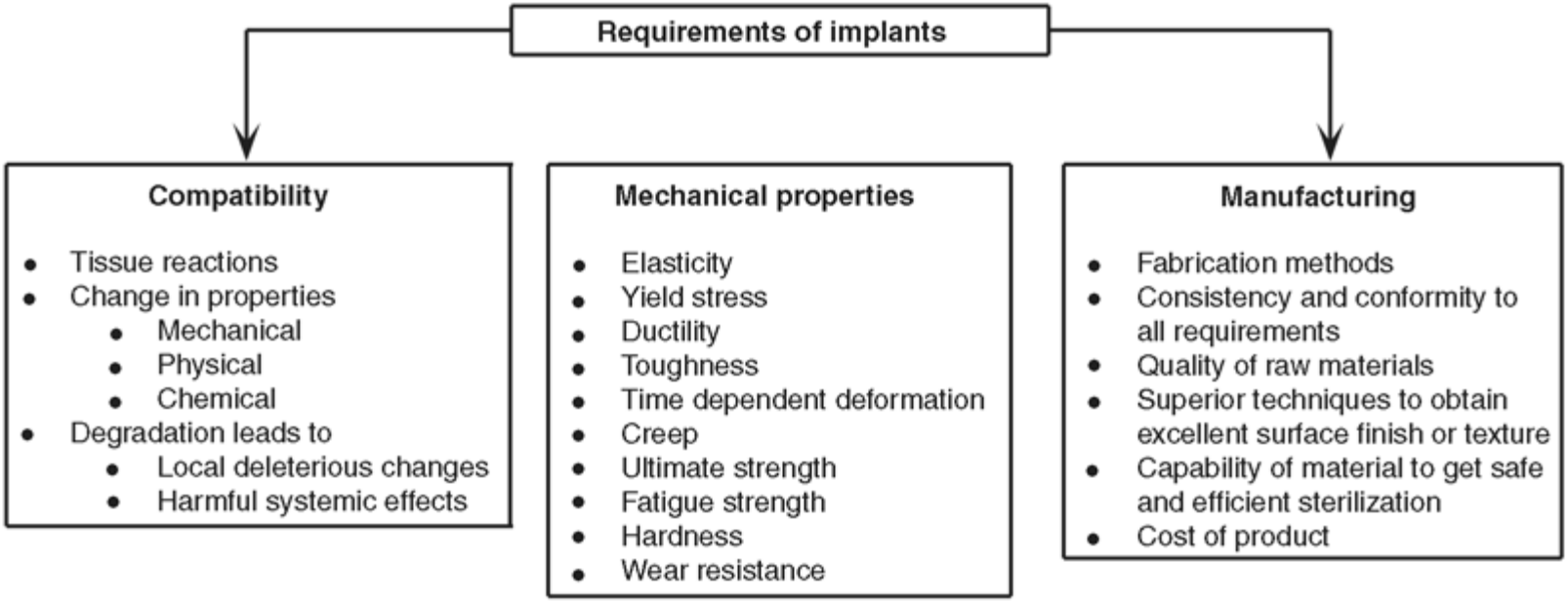
- Material Compatibility
- Packaging and Configuration
- Biocompatibility Testing
- Bioburden Testing
- Package Integrity/Shelf-life Testing
- Product Functionality Testing
- Toxicology Testing

Examples of polymers used as biomaterials

Application	Polymer
Knee, hip, shoulder joints	Ultrahigh molecular weight polyethylene
Finger joints	Silicone
Sutures	Polylactic and polyglycolic acid, nylon
Tracheal tubes	Silicone, acrylic, nylon
Heart pacemaker	Acetal, polyethylene, polyurethane,
Blood vessels	Polyester, PVC polytetrafluoroethylene,
Gastrointestinal segments	Nylon, PVC, silicones
Facial prostheses	Polydimethyl siloxane, polyurethane, PVC
Bone cement	Polymethyl methacrylate PVC, polyvinyl chloride

Implant material requirements in orthopedic applications



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

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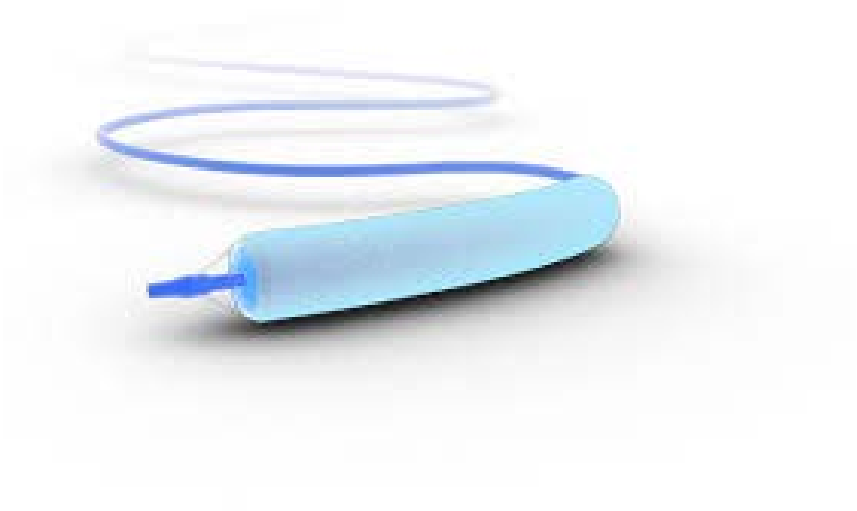
- Hydrogels/PEG devices/Biomaterials
- Special Applications



ADVANCING STERILIZATION PROCESSING OF BIOMEDICAL DEVICES

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- 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

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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

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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

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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!

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THANK YOU!

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