Fundamentals of Package Engineering & Design
Presenters

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Basic functions of medical package

- Product protection
  - Microbial barrier
  - Physical protection from damage and environment
- Allow for sterilization
- Maintain sterility and integrity until use
- Easy opening and aseptic presentation
- Identify the product, clearly state information and cautions
DuPont™ Tyvek® Properties

Feature
Outstanding microbial barrier

Benefit
Sterility maintenance
How Can Tyvek® Be Breathable and Provide a Sterile Barrier?
Louis Pasteur’s Experiment
Results of Experiment

- Would the broth Pasteur sterilized in 1863 still be sterile today?

- On display at Smithsonian... 130+ years and counting

- Adequate tortuous paths provide an effective sterile barrier

- Sterilized packages remain sterile until opened or damaged
DuPont™ Tyvek® Properties

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<th>Feature</th>
<th>Benefit</th>
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<td>Outstanding microbial barrier</td>
<td>Sterility maintenance</td>
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<td>Sterilization compatibility</td>
<td>Broad range of methods; processing flexibility</td>
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<td>Superior tear strength and puncture resistance</td>
<td>Reduction in packaging related complaints and recalls</td>
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<td>Clean peel</td>
<td>Low linting results in reduced risk of device contamination</td>
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Package Engineering & Design

- Materials can only perform as intended if used in combination with great design principles
- Even excellent materials can be sabotaged by poor design
Peel Pouches

Design tips

• Allow ample room between chevron tip and edge of pouch
  – Medical personnel come in all shapes and sizes, design enough room for everyone to get their hands between the chevron and the edge of the pouch
  – Remember, most medical personnel are “gloved” when opening packages
  – Thumb notches are okay, but proper design is better and costs less
Folding Pouches

- Not a good idea – leads to problems

- **Problem #1** – Tents
  - Form abrasion points with carton
  - Scuffing can cause holes in the package
Examples of Issues Caused by Folding

Tyvek®

Film
Microscopic Image of “Tent Abrasion”
Folding Pouches

Problem #2 – Sheet Separation

- False positives during integrity testing
  - Folding can cause sheet separation
  - Explanation of false positives caused by folding
  - ASTM F1929: Dye Penetration Integrity Test video
Tyvek®

High barrier against micro-organisms

Tough layered product through endless fibers
Observed Behavior

Complex Tyvek® morphology (bonded skin, unbonded core) dictates complex material model to capture package mechanics.
Objectives

A: Modest amount of bending

B: Severe amount of bending
Folding Pouches

**Problem #2 – Sheet Separation**

- False positives during integrity testing
- Folding can cause sheet separation
- False positives caused by folding
- ASTM F1929: Dye Penetration Integrity Test

Examples of internal Tyvek® separation due to hard crease or folding of the material
Wicking vs. Channel
Header Bags

Design tips

• Design the opening to be large enough to allow the product to be aseptically presented
  – Easy to fit in the bottom, not so easy to take out of the top

• Association of periOperative Registered Nurses (AORN)
  – Sets nursing standards and best practices
  – Consider the inner edge of the heat seal as the line separating sterile from non-sterile
Header Bag Example
Header Bag Opening Video
Rigid Thermoformed Trays with Tyvek® Lids

The “ultimate medical package”

- Product protection
- Aseptic presentation
- Organization of components
- Familiar to hospital personnel
Rigid Thermoformed Trays with Tyvek® Lids
Example of Delamination / Fiber Tear
Why Is Fiber Tear an Issue?
Rigid Thermoformed Tray with Tyvek® Lid

Design tips

- Eliminate fiber tear…yes!
  - The Problem…the lid is too close to the edge of the tray
    » Need a clean initiation point to not induce fiber tear
    » Potential sealant at interface of tray edge and lid
  - The Solution…
Three Things Cause Fiber Tear…
Avoid Them and Make Great Packages

1: Misplacement of the lid during sealing
Tray is **BLUE** / Lid is **WHITE**

- Unlikely Fiber Tear
- Possible Fiber Tear
- Severe Fiber Tear
Lid Experiment

- Proper lid placement with overhang
  - 32 out of 32 samples

- No overhang
  - 26 out of 32 samples
Solution: return flange

- Eliminates lid placement issues
- Solution is designed into the tray
Three Things Cause Fiber Tear…
Avoid Them and Make Great Packages

2. Edge of Tyvek® lid, jagged cut
Three Things Cause Fiber Tear…
Avoid Them and Make Great Packages

3: Over sealed tray
Flexible Form Fill Seal (FFS) – Typical Seal Configuration
Flexible FFS – Seal Skirt Design

Unsealed gap avoids the risk of delamination
Transparentization

- Occurs when Tyvek® fibers receive too much heat, flattening the fibers or even melting the fibers together, more like a film structure

- How to reduce/eliminate transparentization and spotty seals
  - Trays
    - Add DuPont™ Teflon® sheet to top of heat seal platen to allow for better heat distribution
    - Eliminate any “hot spots” on the tool, use pyrometer to confirm thermocouples are working properly
    - Check durometer/stiffness of rubber matting material
Too Much Heat for Tray, Not Enough Heat to Activate Heat Seal Coating
Transportation

Will your design survive?
Changes in Air Pressure

- Air pressure inside package vs. outside package
- Non-breathable materials can’t adjust to changes in air pressure
- Design your packaging to meet the challenges of the distribution environment
If Tyvek® pouches get wet, are they still sterile?
Are wet pouches still sterile?

It depends….

- Source
- Duration

Filamentous Fungi
Fire in the OR…is the product okay to use?
Fire in the OR...where there's fire, there's smoke

ISO 11607, 7.4.3.2

The manufacturer shall demonstrate that, under the rigors of distribution, storage, handling and aging, the integrity of the final package is maintained at least for the claimed shelf life of the medical device under storage conditions specified by the manufacturer, as long as the package is undamaged or unopened.
Package Engineering & Design

Basic Functions of Medical Package

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- Allow for sterilization
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- Identify the product, clearly state information and cautions
- Recyclability and sustainability
Recyclability and Sustainability

[Image of recycling symbol with HDPE and number 2]
Recyclability of Tyvek®

Tyvek®

- HDPE is the 2nd most recycled plastic
- High volume HDPE end uses
- Widely recognized by healthcare workers
- Plastic recycling programs
  - Thermoplastics commingled
  - Monomaterial (HDPE, PP, PET)
  - No paper or metal
- Compliance is the responsibility of the hospital
Healthcare Plastics Recycling Council

What is HPRC?

- Private, technical coalition of industry peers across healthcare, recycling and waste management industries seeking to improve recyclability of plastic products within healthcare.

Mission

- To inspire and enable the healthcare community to implement sustainable, cost-effective recycling solutions for plastic products and materials used in the delivery of healthcare.
HPRC is a private technical coalition of peers across the healthcare, recycling and waste management industries seeking to inspire and enable sustainable, cost-effective recycling solutions for plastic products and materials used in the delivery of healthcare.

HPRC PRESS RELEASE

HPRC exists in a collaborative effort to be a change agent for sustainable healthcare product and packaging lifecycle with the end goal of increasing the overall recycling of healthcare plastics.

HPRC is unique in its focus on identification of plastics recycling barriers and solution development.

07.08.11
Zeroing in on Plastics

04.15.11
Hospital Recycling Gets a Checkup

04.06.11
HPRC to Present Poster at CleanMed 2011
Helpful Reference Documents

- ANSI/AAMI/ISO 11607-1:2006
  “Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems”

  “Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes”

- AAMI TIR 22:2007

- Order a copy: www.aami.org
DuPont™ Tyvek® in 2012 and Beyond

DuPont will be transitioning Tyvek® 1073B and Tyvek® 1059B to manufacturing lines that use our latest flash-spinning technology to help ensure continuity and flexibility of supply to meet the growing demand for healthcare packaging around the globe.

The next DuPont webinar in this series will be focused on the Transition and next steps. Sign up now for this April 2012 event.

In the meantime, visit our website for information and frequent updates.

www.medicalpackaging.dupont.com
Helpful Reference Documents

www.medicalpackaging.dupont.com
Tyvek® …When What’s Inside Matters
Examples of Microbial Challenges

- Slime mold stack & spore cap
- E. coli
- Borrelia burgdorferi
- Streptococcus
- Fungal spores
- Amoebae
- Bacillus anthracis
- Pseudomonas
- Flu Virus
- Paramecium

*Photos from ASM.org

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Q&A… Thank you!

Thank you for joining today’s webcast on ‘Fundamentals of Package Engineering & Design’!

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