DuPont™ Tyvek® for Medical and Pharmaceutical Packaging
Presenters

Our Expert

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MDM Accounts & Latin America
Packaging News
DuPont Medical and Pharmaceutical Protection

Moderator

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Pharmaceutical & Medical
The Vision of DuPont
To be the world’s most dynamic science company, creating sustainable solutions essential to a better, safer, healthier life for people everywhere.
DuPont is a catalyst for innovation.

Our wealth of science, combined with market knowledge and technical expertise, provides the raw materials needed for exploration and innovation.

Pioneer Hi-Bred
Crop Protection
Nutrition & Health
Electronics & Communications
Performance Coatings
Performance Polymers
Packaging & Industrial Polymers
Protection Technologies
Building Innovations
Sustainable Solutions
Chemicals & Fluoroproducts
Titanium Technologies
Industrial Biosciences

DUPONT™ TYVEK® FOR MEDICAL AND PHARMACEUTICAL PACKAGING 4
Market-Driven Innovations

- Corian®
- Nomex®
- Kevlar®
- Teflon®
- Tyvek®
- Photovoltaics
- Oil and Gas
- Sorona®
- Pioneer Hi-Bred Corn
- Lightweighting Solutions
The Discovery of DuPont™ Tyvek®

Jim White – 1955

High Density Polyethylene (HDPE) Spun Fibers
History of DuPont™ Tyvek®

1955
Tyvek® Discovered

1959
Tyvek® Trial Uses

1967
Commercial Production

1972
Sterile Packaging
DuPont™ Tyvek® Manufacturing Locations

- Luxembourg City, Luxembourg
  - ISO 9001 Certified
- Richmond, VA USA
  - ISO 9002 Certified
DuPont™ Tyvek® Manufacturing Locations

Luxembourg City, Luxembourg
What is DuPont™ Tyvek® for Medical and Pharmaceutical Packaging?

- High-density polyethylene (HDPE)
- Flashspun and bonded using heat and pressure
- No binders/fillers, only virgin polymer
- No corona treatment
- No anti-stat treatment
- Continuous filaments formed into a sheet
- Fibers randomly distributed, non-directional
- Average diameter = 4 microns

High porosity for all sterilization gases

Tough, continuous fibers create a tortuous path for superior microbial barrier

Tough, continuous fibers for strength and puncture resistance
Unique Structure of DuPont™ Tyvek®

Top view (200x)  Cross-sectional view (200x)
How Is DuPont™ Tyvek® Made?

**Polymer**
- Raw Material
- Solutioning System
- Spinning Machine

**Processing Aid**
- Processing Aid Recovery

**SOLUTION & SPINNING:**
- Solutioning System
- Spinning Machine

**Bonding:**
- Soft Structure Finishing
- Hard Structure Finishing

**Finishing:**
- Slitting & Packaging
- Finished Product Inventory
Spinning to Bonding

Flashspun using a proprietary process

Then bonded

DUPONT™ TYVEK® FOR MEDICAL AND PHARMACEUTICAL PACKAGING
Bonding Process

For Hard-Structure DuPont™ Tyvek®

Unwind Bonding Surface Treatment (if applicable) Wind-Up

No anti-stat or corona treatment for Tyvek® medical and pharmaceutical packaging styles
Applications for DuPont™ Tyvek®

Soft Structure

Protective Apparel, Car Covers, Jackets and Bags

Hard Structure

HomeWrap®
Tag and Banners
Envelopes
Cocoon Wrapper and Wrapping System
DuPont™ Tyvek® medical and pharmaceutical packaging styles

A standard of excellence

- Tyvek® 1073B (2.20 oz/yd²)
- Tyvek® Asuron™ (1.99 oz/yd²)
- Tyvek® 1059B (1.90 oz/yd²)
- Tyvek® 2FS™ (1.76 oz/yd²)
Microbiological Barrier (ASTM F1608)

![Bar chart showing LRV values for different materials.]

<table>
<thead>
<tr>
<th>Material</th>
<th>LRV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tyvek® 1073B (uncoated)</td>
<td>5.2</td>
</tr>
<tr>
<td>Tyvek® Asuron® (uncoated)</td>
<td>4.7</td>
</tr>
<tr>
<td>Tyvek® 1059B (uncoated)</td>
<td>4.7</td>
</tr>
<tr>
<td>Tyvek® 2FS® (uncoated)</td>
<td>3.2</td>
</tr>
<tr>
<td>Medical-grade papers</td>
<td>1.7-2.9</td>
</tr>
<tr>
<td>Synthetic fiber-reinforced paper</td>
<td>1.3</td>
</tr>
</tbody>
</table>
Superior Microbial Barrier Protection
Three Mechanisms of Filtration Theory

Interception

Inertial Impaction

Diffusion
Interception

- Occurs when the air stream that a particle is following is split by a filter fiber
- A particle is captured when the air stream it is following brings it sufficiently close to a filter fiber
- Interception is the primary capture mechanism for particles with diameters between 0.2 µm and 2.0 µm

Circle = fiber  Dashed line = air stream
**Inertial Impaction**

- A particle is captured by a fiber as it deviates from the air stream it is following.
- Most effective on particles with diameters >2 µm and higher internal velocities.
- Effectiveness is related to particle mass and speed of air stream.
Diffusion

- Interception by a fiber due to random particle motion (Brownian motion) and, for some materials, electrostatic attraction
- Most effective on particles <0.2 µm diameter and low flow rates
- Dependent on number of fibers encountered
Fiber Comparison

Small fibers = filtration

Large fibers = strength

All large fibers, no tiny fibrils

DuPont™ Tyvek®

Latex-saturated paper
Large Fiber Diameter

- Less flow distortion increases flow rate
- Reduces chance of capture by diffusion
- Straighter flow reduces chance of impaction
Small Fiber Diameter

- Increased flow path distortion decreases flow rate
- Increasing capture by diffusion
- Frequent changes in flow direction increase capture by impaction
Structure Comparison—DuPont™ Tyvek® and Medical-Grade Paper

**DuPont™ Tyvek®**
- Tough, continuous fibers (average diameter = 4 microns)
- Outstanding resistance to microbial penetration

**Medical-Grade Paper**
- Small number of short fibers
- Fewer layers/less tortuous path
Particle Penetration (ASTM F2638)
Spencer Puncture Properties (ASTM D3420, procedure B)
Elmendorf Tear (MD) Properties (ASTM D1424 & EN 21974)

MD = machine direction
Material Compatibility with Various Sterilization Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>DuPont™ Tyvek®</th>
<th>Coated, latex saturated medical-grade paper</th>
<th>Medical film</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene Oxide (EO)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Gamma Radiation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Electron-beam Radiation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Steam</td>
<td>Yes¹</td>
<td>Yes²</td>
<td>No</td>
</tr>
<tr>
<td>STERRAD¹</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

¹. Under controlled conditions (250°F to 260°F [121°C to 127°C]) at 30 psi for 30 minutes.
². May become brittle.
Unique Structure of DuPont™ Tyvek®

Top view (200x)  

Cross-sectional view (200x)
Storage

- Store under clean and dry conditions
- Take care to avoid dirt being attracted to DuPont™ Tyvek®
- At low temperatures, DuPont™ Tyvek® retains toughness and flexibility after exposure to -70°C
- At high temperatures, DuPont™ Tyvek® begins to shrink at 118°C and melts at 135°C
- DuPont™ Tyvek® can maintain sterility for at least five years, providing package integrity is not compromised (demonstrated by long-term shelf-life study conducted at the DuPont Haskell Laboratory for Toxicology)
DuPont™ Tyvek® Can Be Printed Using Standard Commercial Printing Equipment

- Flexography
- Offset Lithography
- Thermal Transfer
- Ink Jet
- Cool-Process Laser

For additional information about printing on Tyvek®, refer to the DuPont™ Tyvek® Users Manual at www.graphics.dupont.com
DuPont™ Tyvek® Delivers Trusted Protection

- Outstanding resistance to microbial penetration
- Significantly reduced risk of package failure during shipping and handling
- Low risk of device contamination when opened
- Compatibility with a broad range of sterilization methods
DuPont Medical and Pharmaceutical Protection—An Industry and Technology Leader

- Helping speed up your compliance process
- Providing packaging science support
- Conducting educational seminars
- Participating in industry standards organizations

**DuPont™ Tyvek® in 2012 and Beyond**

To meet growing global demand and to help ensure greater continuity and flexibility of future supply, DuPont will be transitioning Tyvek® 1073B and Tyvek® 1059B to manufacturing lines that use our latest flash-spinning technology.

Our goal is to make this transition process seamless for the healthcare industry.

If you have questions, visit MedicalPackaging.DuPont.com to schedule a meeting with one of our DuPont experts.
Q&A… Thank you!

Thank you for joining today’s presentation ‘DuPont™ Tyvek® for Medical and Pharmaceutical Packaging’.

Any questions, contact:
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