Case Studies of Medical Device Package Failures

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WESTPAK

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Agenda

Please note….

– Real test scenarios
– No medical device products are shown
– Everyday objects with similar physical characteristics are used to represent the actual products
– Client confidentiality is maintained!

• Case Study #1
• Case Study #2
Webinar Goals

• Learn from others
• Avoid these package failures
Packaging Info

• Chipboard carton
  – Straight Tuck End (STE)

• 2-pack shipper
Packaging Info (cont.)

• Shipper
  – 19” length x 13” width x 6” height
  – 10 lbs
Packaging Info (cont.)

- Shipper
  - End-loading Regular Slotted Container (RSC)
  - 200 psi singlewall corrugated fiberboard
  - Flutes parallel to the largest face
Test Inputs

- Conditioning per ASTM D4332
- Package Performance Testing per ASTM D4169
Conditioning

• Conditioning per ASTM D4332
  – Desert: +60°C and 15% RH for 24 hours
  – Frozen: -30°C and uncontrolled RH for 24 hours
  – Tropical: +40°C and 90% RH for 24 hours

Conditioning: 72 hours total
Package Performance

- ASTM D4169 Distribution Cycle (DC) 3
- Assurance Level (AL) I
  - Initial Manual Handling (Drop)
  - Vehicle Stacking (Compression)
  - Vehicle Vibration (Truck Spectrum)
  - Loose Load Vibration
  - Concentrated Impacts
  - Final Manual Handling (Drop)
### Initial Manual Handling (Drop)

<table>
<thead>
<tr>
<th>Shipping Weight, lb (kg)</th>
<th>Assurance Level I</th>
<th>Assurance Level II</th>
<th>Assurance Level III</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 20 (0 to 9.1)</td>
<td>24 (610)</td>
<td>15 (381)</td>
<td>9 (229)</td>
</tr>
<tr>
<td>20 to 40 (9.1 to 18.1)</td>
<td>21 (533)</td>
<td>13 (330)</td>
<td>8 (203)</td>
</tr>
<tr>
<td>40 to 60 (18.1 to 27.2)</td>
<td>18 (457)</td>
<td>12 (305)</td>
<td>7 (178)</td>
</tr>
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<td>60 to 80 (27.2 to 36.3)</td>
<td>15 (381)</td>
<td>10 (254)</td>
<td>6 (152)</td>
</tr>
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<td>80 to 100 (36.3 to 45.4)</td>
<td>12 (305)</td>
<td>9 (229)</td>
<td>5 (127)</td>
</tr>
<tr>
<td>100 to 200 (45.4 to 90.7)</td>
<td>10 (254)</td>
<td>7 (178)</td>
<td>4 (102)</td>
</tr>
</tbody>
</table>
• Initial Manual Handling (6 impacts/drops)
  – 1 Top
  – 2 Adjacent bottom edges
  – 2 Diagonally opposite bottom corners
  – 1 Bottom
• Vehicle Stacking (Compression)

\[
L = M_f \times J \frac{l \times w \times h}{K} \times \frac{H - h}{h} \times F
\]

where:
- \(L\) = computed load, lbf or N,
- \(M_f\) = shipping density factor, lb/ft\(^3\) or kg/m\(^3\),
- \(J\) = 1 lbf/lb or 9.8 N/kg,
- \(H\) = maximum height of stack in transit vehicle (if vehicle stack height is unknown, use 108 in. (2.7 m)), in. or m, see Note 3,
- \(h\) = height of shipping unit or individual container, in. or m,
- \(l\) = length of shipping unit or individual container, in. or m,
- \(w\) = width of shipping unit or individual container, in. or m,
- \(K\) = 1728 in.\(^3\)/ft\(^3\) or 1 m\(^3\)/m\(^3\), and
- \(F\) = a factor to account for the combined effect of the individual factors described above.

Note 3—The value for \(H\), when unknown, is reduced to 54 in. (1.4 m) from 108 in. (2.7 m) for packages under 30 lb (13.6 kg) and 2.0 ft\(^3\) (0.056 m\(^3\)) or less in size when applied to a vehicle stacking hazard element in LTL shipments.

Minimum top load: 687 lbf
• Vehicle Vibration

<table>
<thead>
<tr>
<th>Frequency</th>
<th>High Level</th>
<th>Medium Level</th>
<th>Low Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.00072</td>
<td>0.00072</td>
<td>0.0004</td>
</tr>
<tr>
<td>3</td>
<td>0.030</td>
<td>0.018</td>
<td>0.010</td>
</tr>
<tr>
<td>4</td>
<td>0.030</td>
<td>0.018</td>
<td>0.010</td>
</tr>
<tr>
<td>6</td>
<td>0.0012</td>
<td>0.00072</td>
<td>0.00040</td>
</tr>
<tr>
<td>12</td>
<td>0.0012</td>
<td>0.0036</td>
<td>0.0020</td>
</tr>
<tr>
<td>16</td>
<td>0.0060</td>
<td>0.0036</td>
<td>0.0020</td>
</tr>
<tr>
<td>25</td>
<td>0.0060</td>
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<td>0.0060</td>
<td>0.0036</td>
<td>0.0020</td>
</tr>
<tr>
<td>100</td>
<td>0.00060</td>
<td>0.00036</td>
<td>0.00020</td>
</tr>
<tr>
<td>200</td>
<td>0.000030</td>
<td>0.000018</td>
<td>0.000010</td>
</tr>
<tr>
<td>Overall G&lt;sub&gt;rms&lt;/sub&gt;</td>
<td>0.70</td>
<td>0.54</td>
<td>0.40</td>
</tr>
</tbody>
</table>

180 minutes total
60 minutes per axis

3 Levels
Low: 40 minutes
Medium: 15 minutes
High: 5 minutes
• Vehicle Vibration
• Loose Load Vibration
  – 60 minutes total
    • 30 minutes: base
    • 15 minutes: side
    • 15 minutes: end
• Concentrated Impacts
  – 6 faces
  – 32” vertical distance
  – Energy: 4.0 ft-lbf (5.4 joules)
• Final Manual Handling (6 impacts/drops)
  – 1 Vertical edge
  – 2 Adjacent side faces
  – 2 One top corner and one adjacent top edge
  – 1 Bottom (twice height: 48”)

<table>
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<th>Shipping Weight, lb (kg)</th>
<th>Drop Height, in. (mm)</th>
</tr>
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<tr>
<td></td>
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Failure Mode

- Compression failure
  - Not able to reach the calculated top load of 687 lbf
  - Maximum top load sustained was around 400 lbs
Recommendations

• Change flute direction
  – Parallel to perpendicular
Recommendations (cont.)

• Change box style
  – Regular Slotted Container (RSC) to Full Overlap
Recommendations (cont.)

- Change carton material
  - Chipboard to corrugated
Recommendations (cont.)

• Change carton style
  – Straight Tuck End (STE) to Roll-End-Locked-Front (RELF)
• Increase board strength of the shipper
  – 200 psi to 275 psi
Changes Made by Client

- Changed box style
- Changed flutes direction
- Changed carton material and style
- Increased board strength of the shipper
Results of Repeat Testing
QUESTIONS
Case Study #2
Product Info

• Round edges
• Height about 2.5”
• Square-like shape
• Sterilization
  – 2X Gamma Radiation
Primary Package Info

- **Pouch size**
  - 18” length x 12” width x 2.5” height
- **Pouch material**
  - Tyvek®/poly (44 GA PET/Uncoated Tyvek® 1073B)
Packaging Info

- Corrugated carton
  - Roll-end-locked-front (RELF)
- 2-pack
Packaging Info (cont.)

• Shipper
  – 19” length x 13” width x 6” height
  – 10 lbs
  – End-loading full-overlap container
  – 275 psi singlewall corrugated fiberboard
Sample Size

- 15 shippers
- 30 pouches
Test Info

• Test inputs
  – Conditioning per ASTM D4332
    • Desert: +60°C and 15% RH for 24 hours
    • Frozen: -30°C and uncontrolled RH for 24 hours
    • Tropical: +40°C and 90% RH for 24 hours
  – ASTM D4169 Distribution Cycle 3 Assurance Level I
  – Gross Leak Detection/Bubble
Failure Mode

• Gross leaks on the poly side of the pouch
• Compound fold because of the product height/depth
Recommendations

• Change pouch material for the poly side to include biaxial nylon layer (puncture resistance)
• Reduce pouch size
Changes Made by Client

• Had leaks on the poly side so eliminated poly material
• Tyvek® 1073B / Tyvek® 1073B
Results of Repeat Testing

• Leaks on the Tyvek® side (3 out of 30 pouches)
Recommendations

• Use thermoformed tray to hold the product in place
Final Test Results

• No gross leaks
• Thermoformed tray held the product in place to prevent movement and reduce abrasion
Change Summary

• Pouch: Case Study #2
  – Different pouch materials
  – Add a thermoform tray
  – Pay attention to interaction of pouch and product

• Shipper: Case Study #1
  – Flute direction to base orientation of testing
  – Different box style and material
Webinar Goals Met

• Learn from other customers
• Avoid these package failures
QUESTIONS
More Questions Later? Need a Quote?

Submit Questions or Request for Quote to: www.westpak.com/contactus.aspx

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