Pressure sensitive labeling of terminally sterilized medical device packaging:

“Testing label materials for adhesion and durability over time”

Presented by:

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Presentation Overview

- The Requirements
- The Issues
- Adhesion and Adhesives 101
- Printing on the Label Stock
- Printing Tests
- Adhesive Tests
- Industry Practices
- Questions on the ‘Nuts & Bolts’ of Label Systems
What the FDA requires......

Quality System Regulations, CFR 21, Part 820, Subpart K. “Label Integrity”.

“Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate, use”
Some unique issues with medical device package labeling:

• Government agencies are very interested in how your packages are labeled and tested
• Numerous substrates that need to be adhered to
• Demand printing of label sets requires that one adhesive work for all substrates.
• Harsh sterilization and transportation environments for terminally sterilized products
• Detailed qualification and validation records required by folks mentioned in bullet point #1
**Adhesives 101**

**Ad·he·sion (n):** is the molecular force of attraction between unlike materials. The strength of the attraction is determined by the surface energy of the material. The higher the surface energy the more attraction. The unit of measure is *dynes*.

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Fundamental adhesive properties

Pressure sensitive adhesives

Tack or ‘quick stick’ – the property that controls the instant formation of a bond when the adhesive and substrate are brought into contact.

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Fundamental adhesive properties

**Shear** – Pull directed across the adhesive, forcing the substrates to slide over each other.

Image Source: 3M Converter Markets Guide, pages 4-5, copyright 3M 2008
Fundamental adhesive properties

**Peel** – The force concentrated along a thin line at the edge of the bond, typically where one substrate is flexible.

Image Source: 3M Converter Markets Guide, pages 4-5, copyright 3M 2008
Fundamental adhesive properties

Peel, tack, and shear balance

PEEL

TACK

SHEAR
Printing on label stocks

• Flexographic water based ink is the standard for the majority of label printers. Additives can be mixed in for better film adhesion, increased temperature resistance, various catalyzers, or fade resistant pigments.

• Varnish, either water based or UV cured, can be added for protection and abrasion resistance.

• Thermal transfer ribbons are typically used to demand print manufacturing data at the device manufacturer. Wax or wax/resin for paper and typically pure resin for films.

• Standard laser toner is used for demand printing laser sheets.
Testing the printed package label

(Time to play with the sample packet!)

Ink, thermal transfer ribbon, and laser toner adhesion to label facestocks

ASTM F2252 – The Tape Test

• Cover the printed area to be tested
• Apply with a smooth even motion
• Hold label with one hand and peel at a 120-150 degree angle
• Peel with an even, moderate motion at 12-18” per second
• Inspect both tape and label for adhesive transfer
ASTM D5264 The Sutherland Rub Test

Used to determine the abrasion resistance of inks, coatings, and other printing.

- Dry rub
- Wet smear
- Wet rub
- Functional rub
Testing the adhesive bond

Tack or ‘quick stick’ is measured with a loop tack tester.

A loop of label stock one inch wide is applied to the substrate and then immediately removed.

Parameters are below

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Area:</td>
<td>1 inch Square</td>
</tr>
<tr>
<td>Delamination Speed:</td>
<td>12 inches/ min</td>
</tr>
<tr>
<td>Dwell Time:</td>
<td>“0” minutes</td>
</tr>
<tr>
<td>Temperature:</td>
<td>23 degrees C</td>
</tr>
<tr>
<td>Humidity:</td>
<td>50% RH</td>
</tr>
</tbody>
</table>
Shear test

Measures cohesion, or ability of the adhesive to resist movement under a force.

<table>
<thead>
<tr>
<th>Test Area:</th>
<th>0.5 inches X 1.0 inches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load:</td>
<td>1.0 Kg</td>
</tr>
<tr>
<td>Dwell Time:</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Temperature:</td>
<td>23 degrees C</td>
</tr>
<tr>
<td>Humidity:</td>
<td>50% RH</td>
</tr>
</tbody>
</table>
Peel testing

Measures the strength of the adhesive bond with applied pressure
Bond strength increasing over time

dwell time:          peel strength in lb / in:

10 min           0.71
30 min           0.81
1 h              0.94
3 h              0.97
24 h             1.42
Label testing in the industry

The Labeling Task Group of the IOPP Medical Device Technical Committee did a survey early last year. 24 companies ranging from startups to Fortune 500’s responded. Results are posted on the web site.

Results synopsis and feedback:

- 80% of respondents formally evaluate label stock for acceptable performance throughout the supply chain
- The same 80% have this process described in a formal test protocol.
- 60% perform a smudge or abrasion test on the printed text
- 60% test for specific performance or attributes based upon field experience or known risk areas
Survey results continued............

• Conditioning criteria – 86% use ASTM 4169 Distribution simulation, 28% use ISTA distribution simulation practices, 93% use ASTM F1980-Accelerated Aging, 7% use unspecified TAPPI criteria

• 28% control for humidity and perform a freeze/thaw cycle

• Evaluation of label samples - 47% pre sterilization, 73% post sterilization, 87% post distribution, and 13% after several pre defined conditioning events. 27% evaluate at more than one milestone.

• 67% determine sample size by statistical methods.

• 33% determine sample size by fixed sample size, eg n=30

• 90% have a simple visual inspection for legibility

• 13% require delamination or fracture/tearing of the face stock as part of the adhesive evaluation.
Conclusions and recommendations

FDA, EU, and ISO offer a general requirement for terminally sterilized device labeling but not many specifics

- Label testing seems to be a bit hit and miss, with no ‘official’ guidance or accepted standard

- Companies have developed their protocols based on a cafeteria type choice of test methods and procedures

- Most protocols are practical and based upon experience with the device manufacturers particular product
Thank you

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