Surviving Transportation Testing

Oliver™

HEALTHCARE PACKAGING

ISO 11607 – Voluntary Standard

- **Part I**
  - Section 6.3 Packaging System Performance Testing
    - 6.3.1 Integrity of the sterile barrier system shall be demonstrated after sterilization and subsequent performance testing
    - 6.3.5 The packaging system shall provide adequate protection to the product through the hazards of handling, distribution and storage
- Worst Case – Product, Package, Process, and Sterilization
  - Climatic Conditioning
  - Shipping & Handling

MDR Revisions & Considerations

- Added clarity regarding the responsibility of maintaining sterility of the medical device throughout the lifecycle by the added wording "point of use"
- This may expand the need to design and assess a sterile barrier system that can survive storage and handling in a clinical setting **without the protection of shelf or shipping carton**

Climatic Conditioning

- Can packaging withstand extreme climates that may be encountered during the course of shipping?
  - Frozen
  - Tropical (Warm / humid)
  - Desert (High heat / dry)

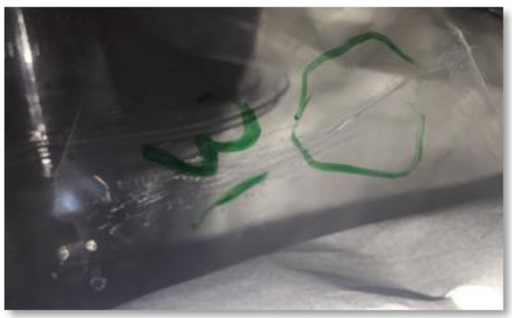
Transit Simulation

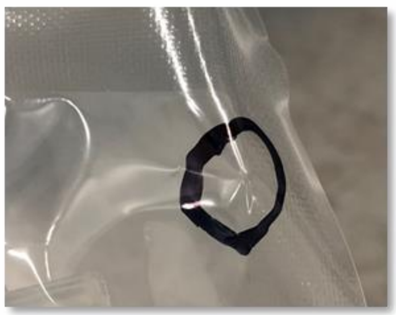
- Can packaging withstand dynamic forces of shipping & handling?
  - Drops
  - Stacking
  - Shock
  - Altitude
  - Vehicle vibration
  - Impacts

Transit Test Overview

Package Integrity Fail

- On average, 30% of projects tested result in a breach of the sterile barrier after transit simulation
  - Punctures, tears, cracks, open seals, pinholes
- How do I identify what caused the hole?
- How can I mitigate risk through improved packaging system design?

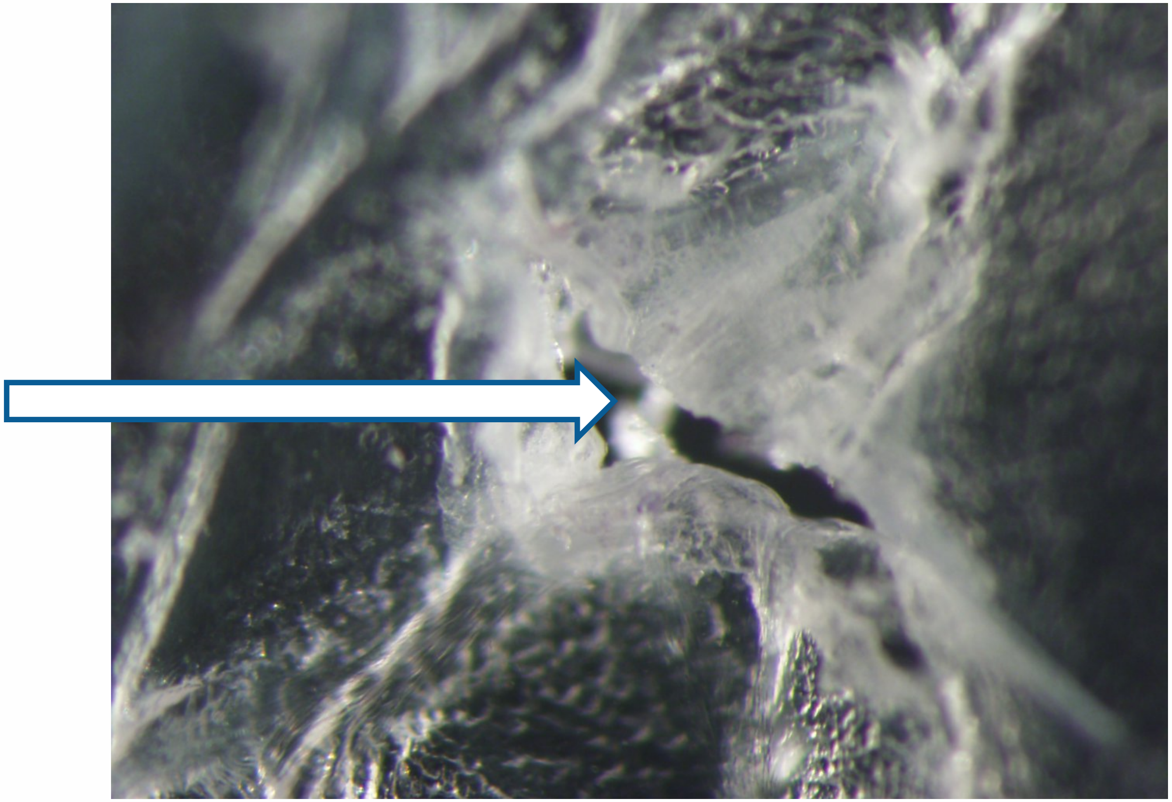




Analyze Defects to Understand Their Root Cause

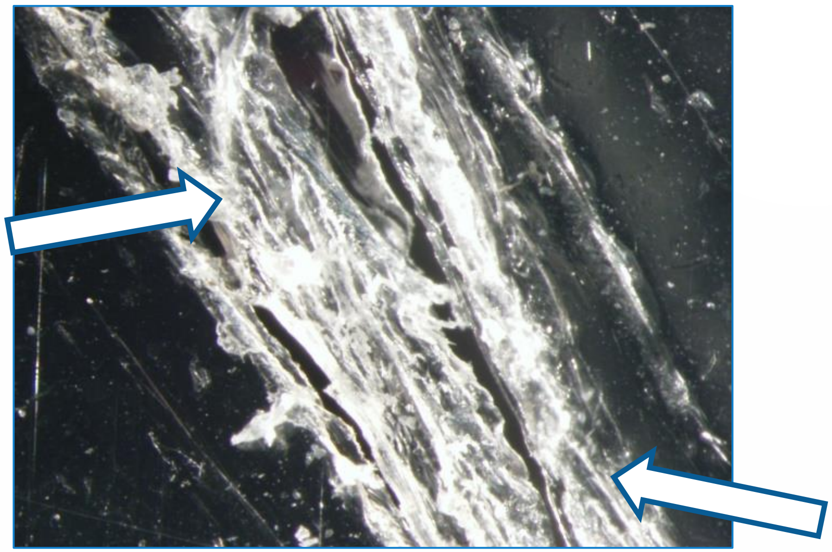
- “A PINHOLE IS NOT A PINHOLE IS NOT A PINHOLE!”

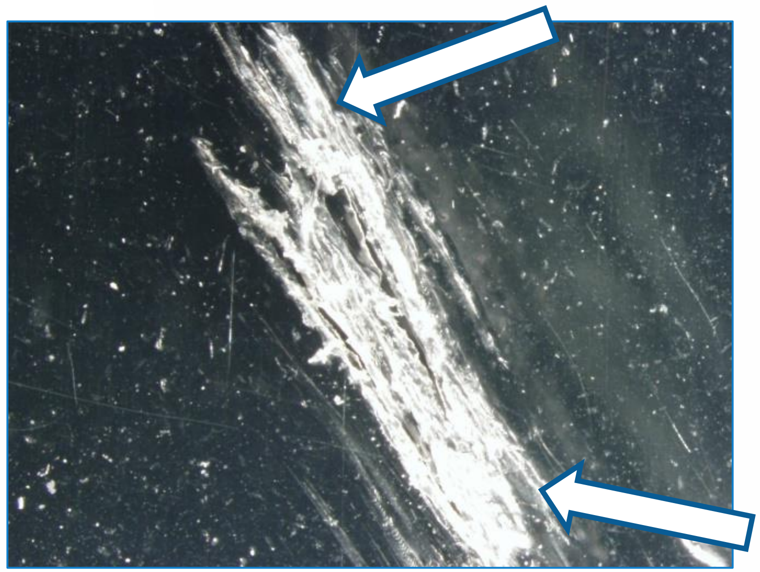
Sterile breach



Not All Defects are Created Equally

- Examine film in surrounding areas of pinhole
- Not all pinholes are created the same way
- Evidence supports something abrading the film from the inside out





Evidence of abrasion surrounding pinhole

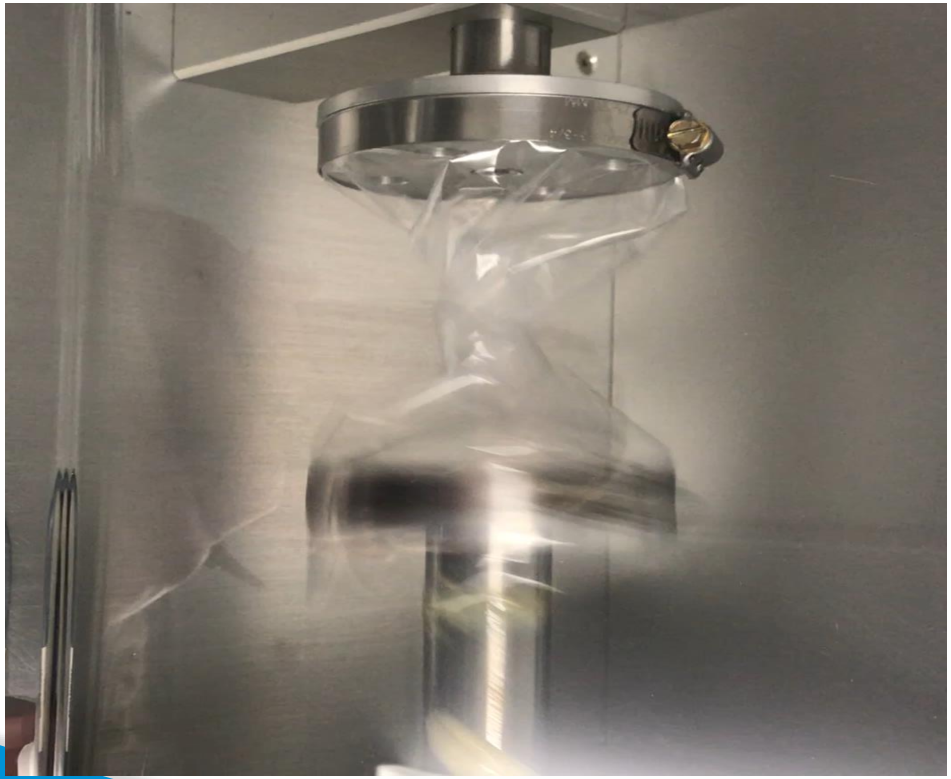
Not All Defects are Created Equally

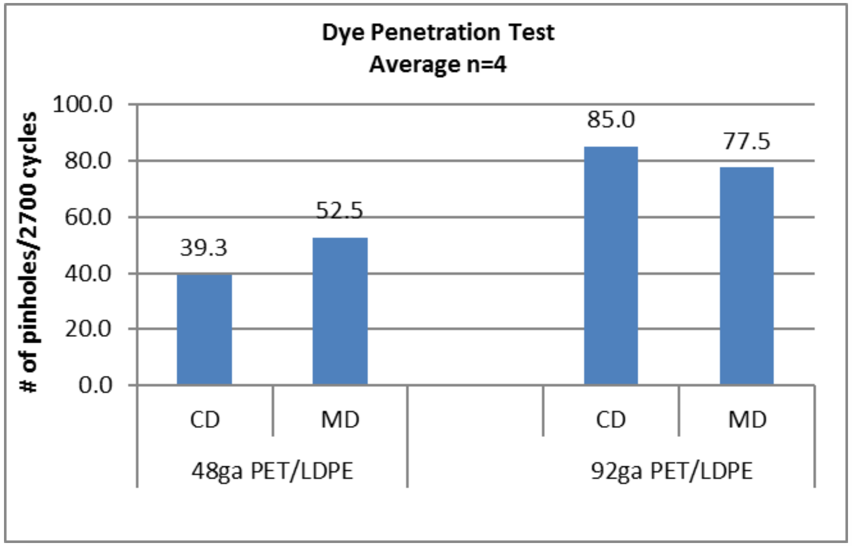
- Investigate the crime scene
- No evidence of abrading or flexing in areas surrounding the pinhole
- Evidence supports straight line puncture that is characteristic of an "exit wound"

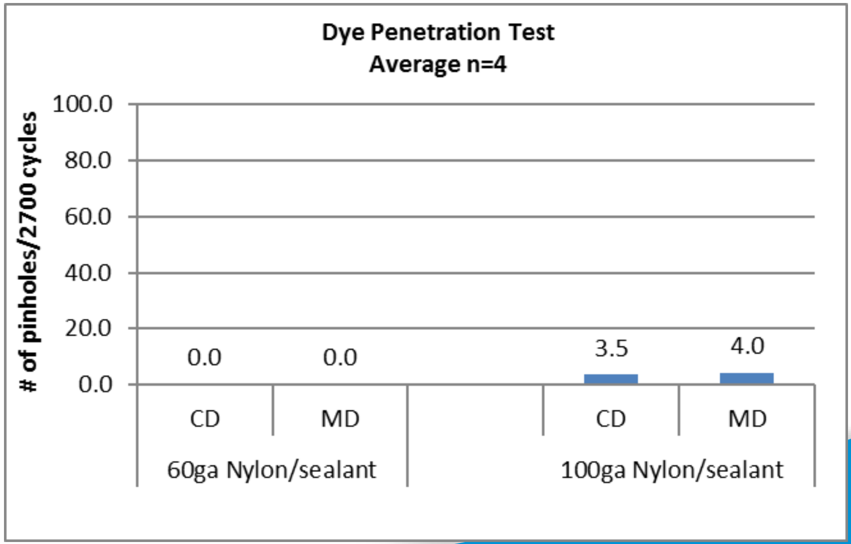
Understand Impact of Package System Design

Material Selection is Critical

- Thicker film doesn't necessarily mean better!

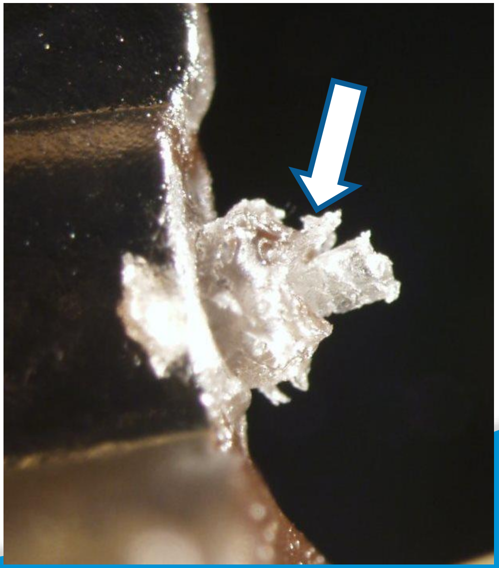






Takeaways

- Screening studies
  - Test to failure to understand potential failure modes…then design to mitigate
  - Have a contingency plan
    - Test multiple materials and designs in parallel
- Materials
  - Understand the properties of the materials you are using. Know their strengths and weaknesses
- Device / Pkg interaction
  - Review the medical device for sharp components and anomalies like mold flash
    - Cover with protective sheaths when possible
    - Work with molding folks to minimize excess flash



Workshop Will Take a Closer Look Using Four Real Life Case Studies

Workshop
Root Cause Failure Analysis

Transportation
Testing

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Case Study I

Pinholes in Header Bag

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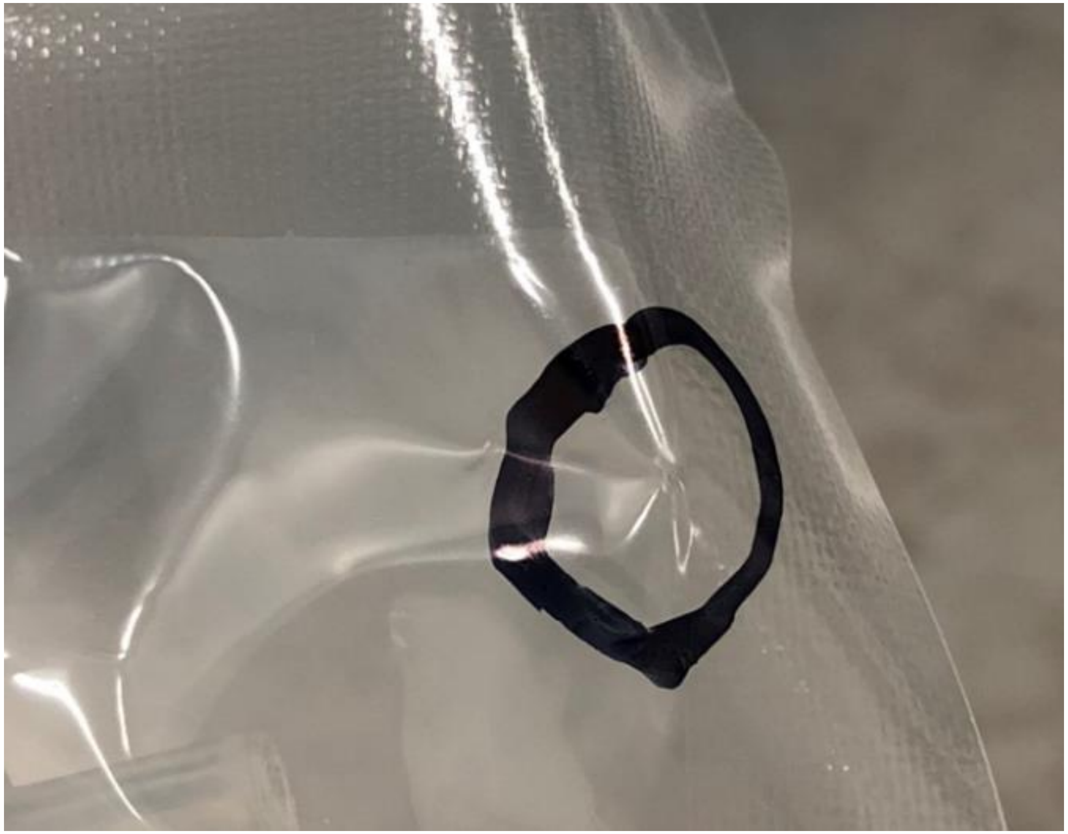
Case Study I – Pinhole in Header Bag

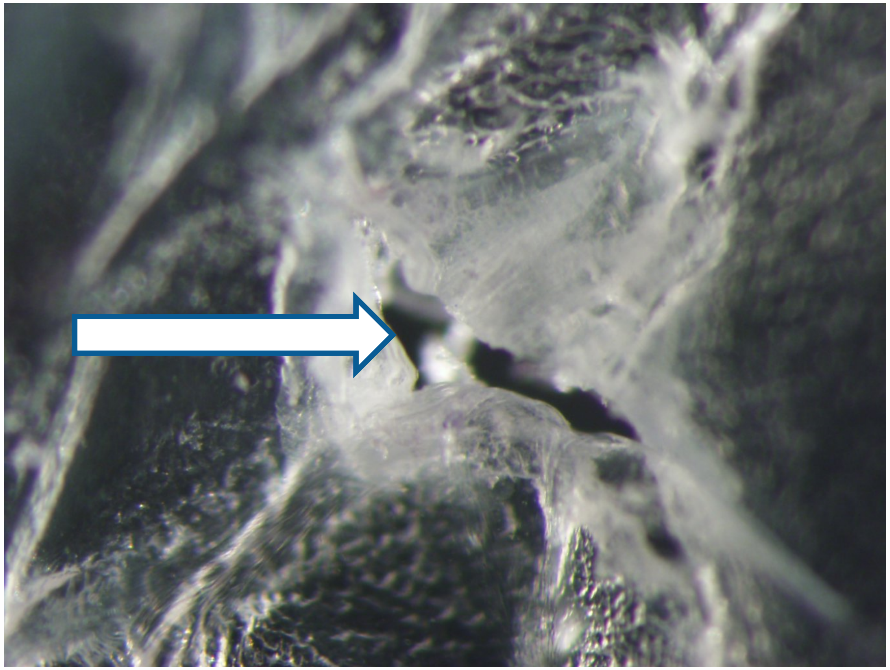


Pinhole in Film, Near Corner of Bag

Material Analysis

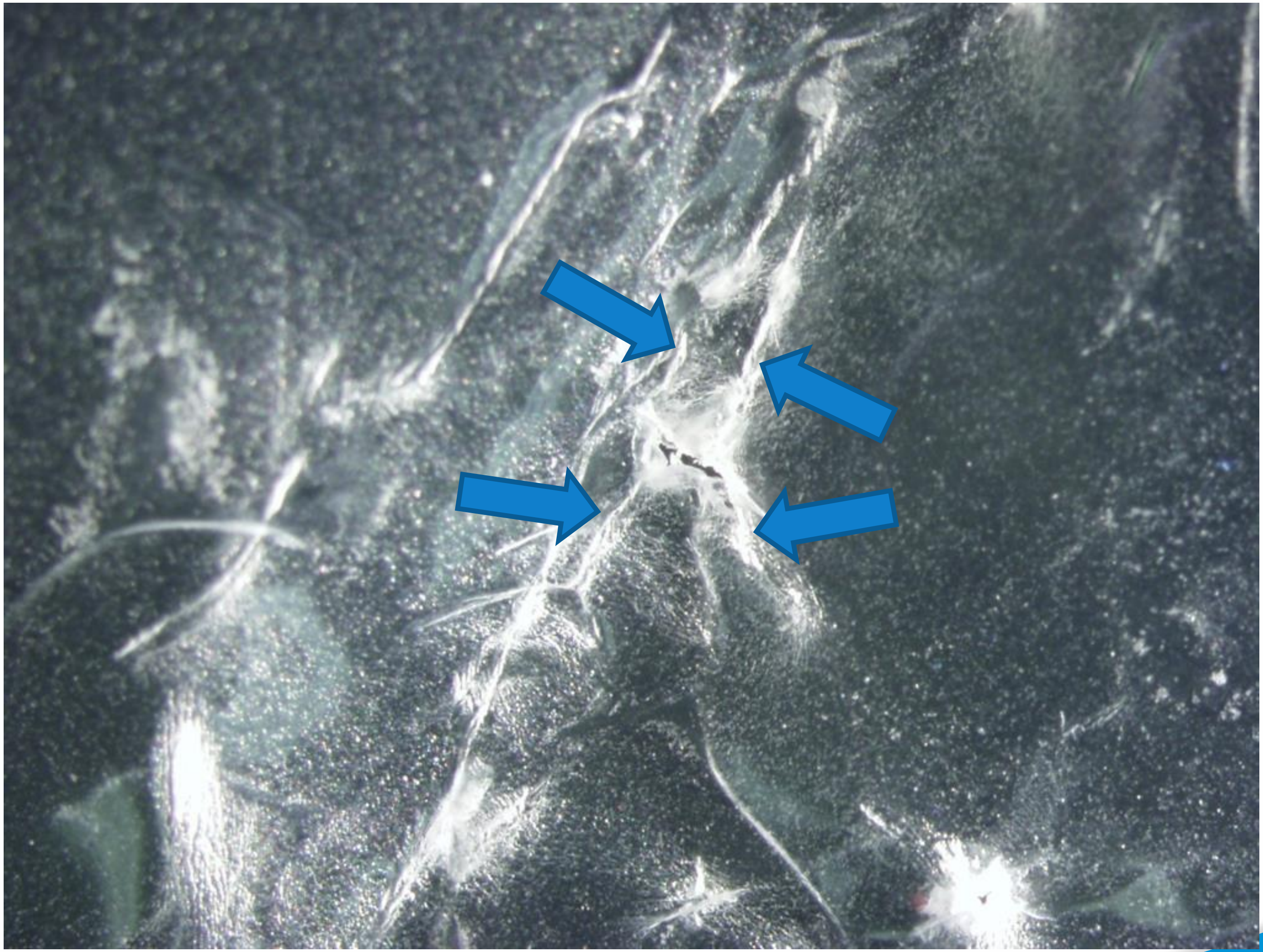
- "A PINHOLE IS NOT A PINHOLE IS NOT A PINHOLE!"
- Seek to understand the nature of the pinhole

Sterile breach



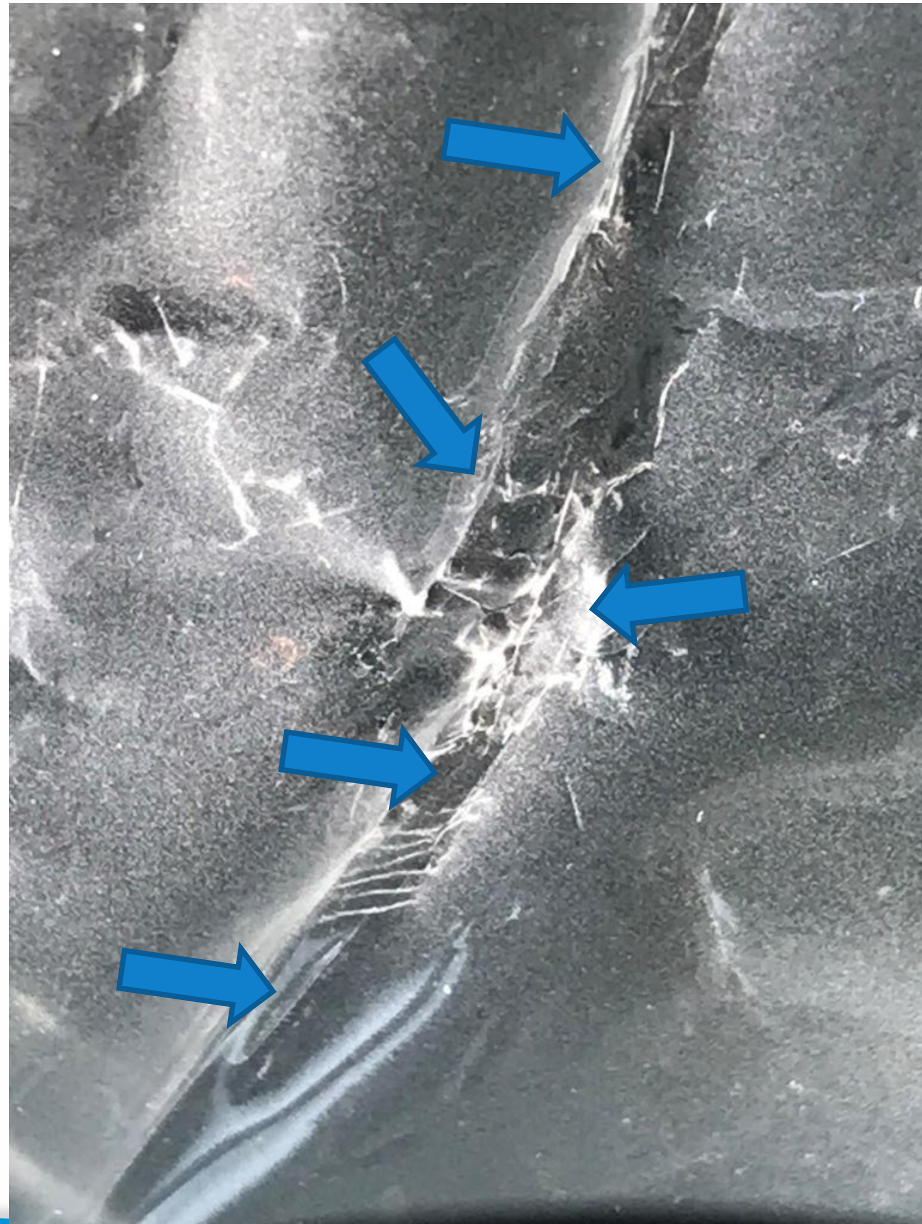
Material Analysis

Witness marks indicate severe flexing of film



Material Analysis

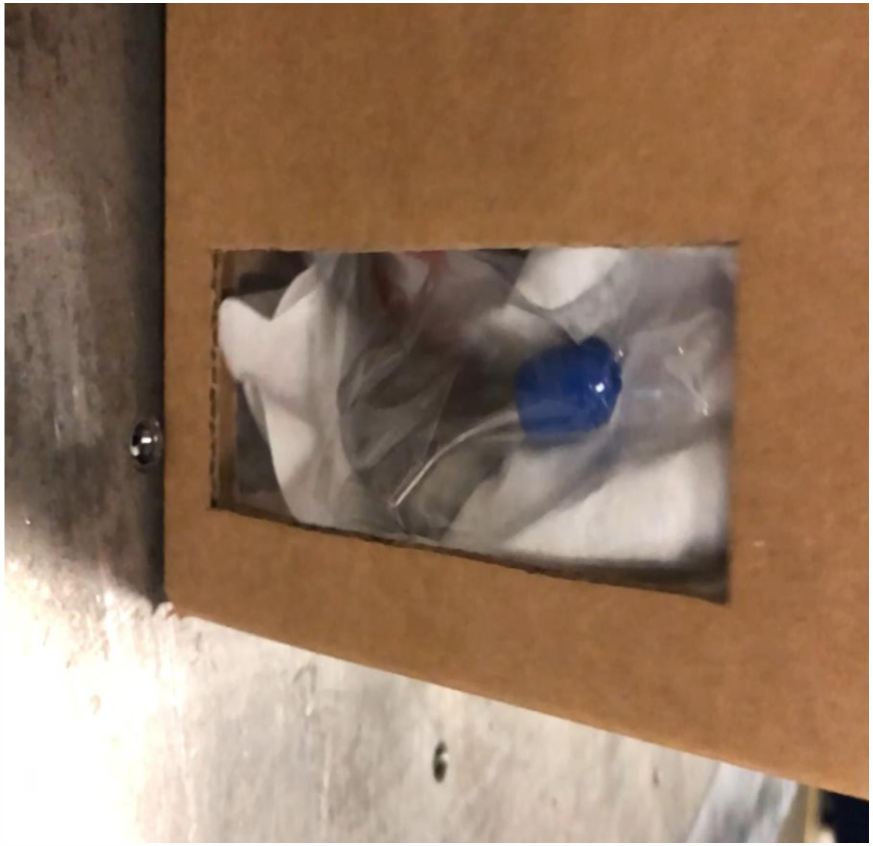
Expanded view and further evidence of flexing



Packaging System Analysis

- Large, bulky, heavy product
- Heavy box weight
- Opportunity for flexing / creasing of “bunched up” film in corners

A Look Inside the Shipper



Risk Mitigation Tactics

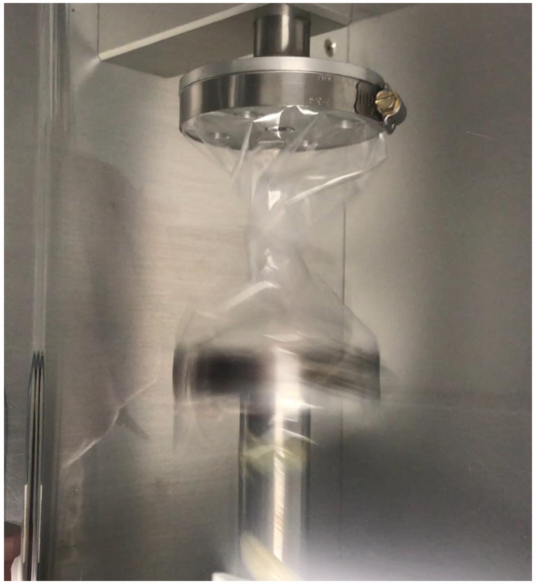
- ***Conclusion:*** Repeated flexing of film during vibration testing resulted in pinholes and breach of sterile barrier (flex crack failure)
- ***Mitigation:***
  - Material selection: used film with better flex crack resistance
  - Pouch design: reinforced problematic areas of pouch with double layer of material

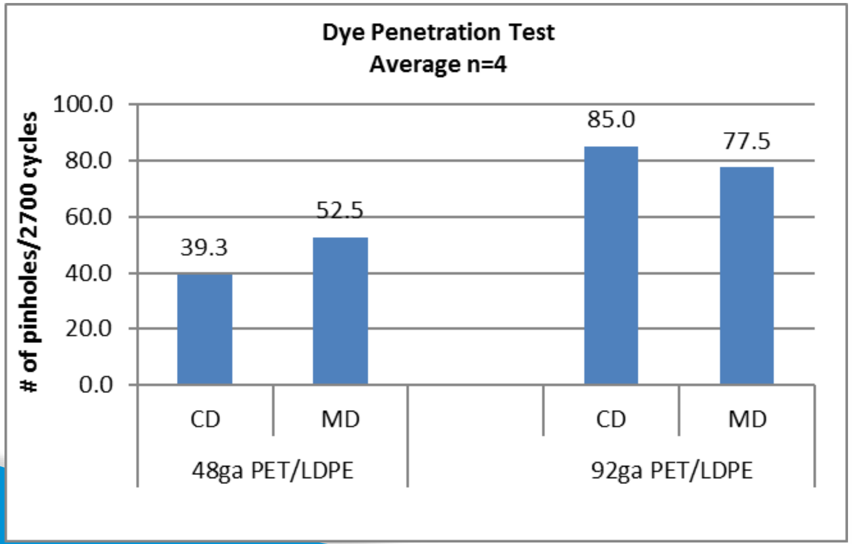
Before

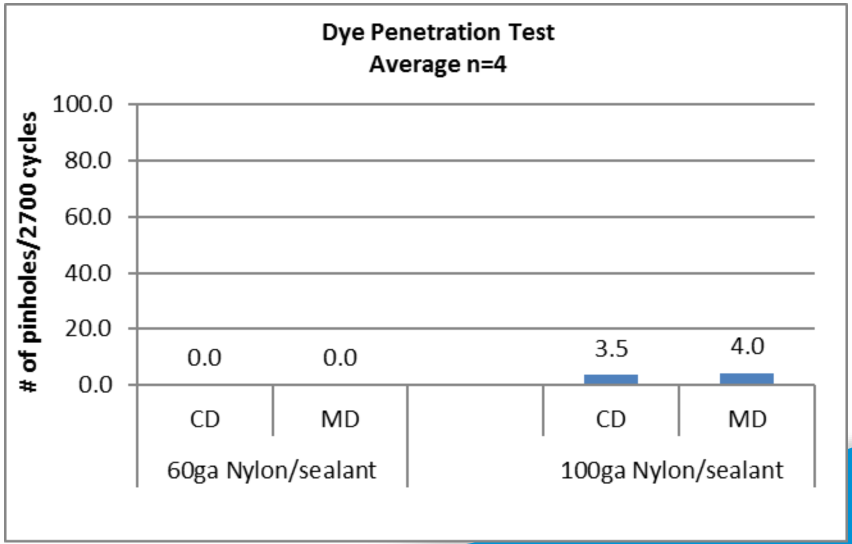
After

Risk Mitigation Tactics, cont'd

- Material selection can be critical
- ASTM F392-93 (Flex Durability of Flexible Barrier Materials) is a good method of ranking films
- Thicker film doesn't necessarily mean better flex crack resistance!



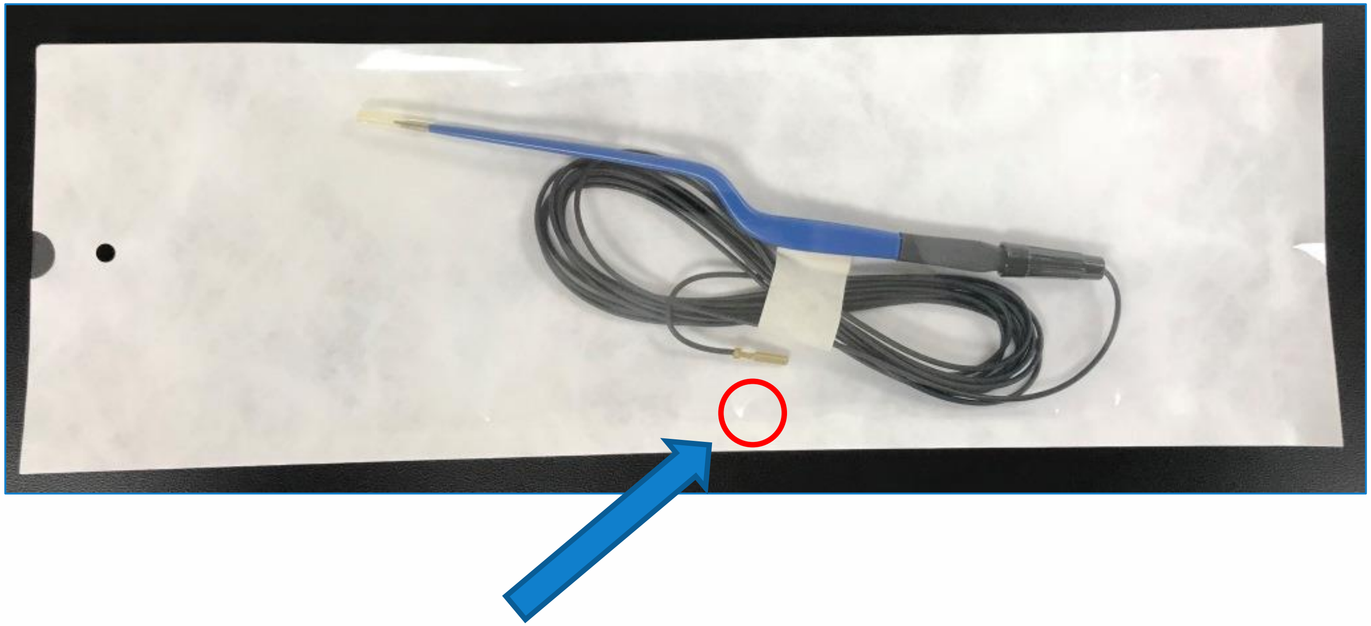




Case Study II

Pinholes in Pouch

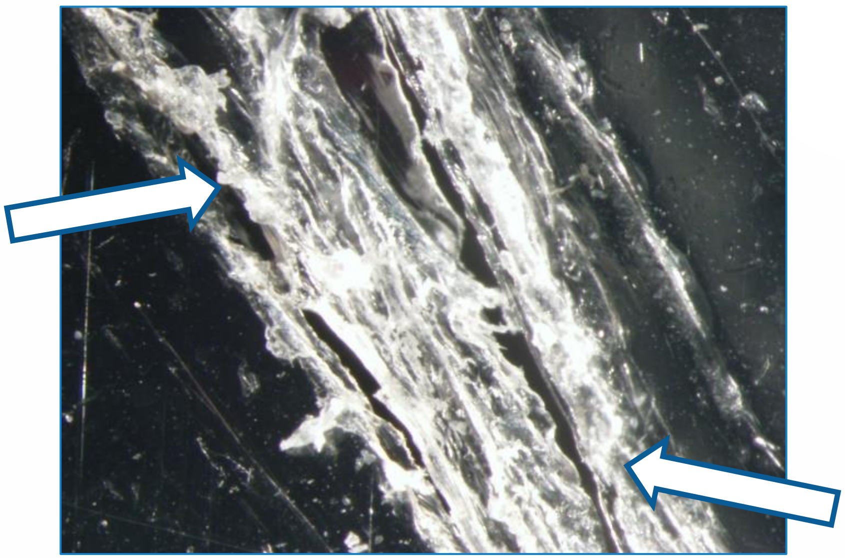
Background

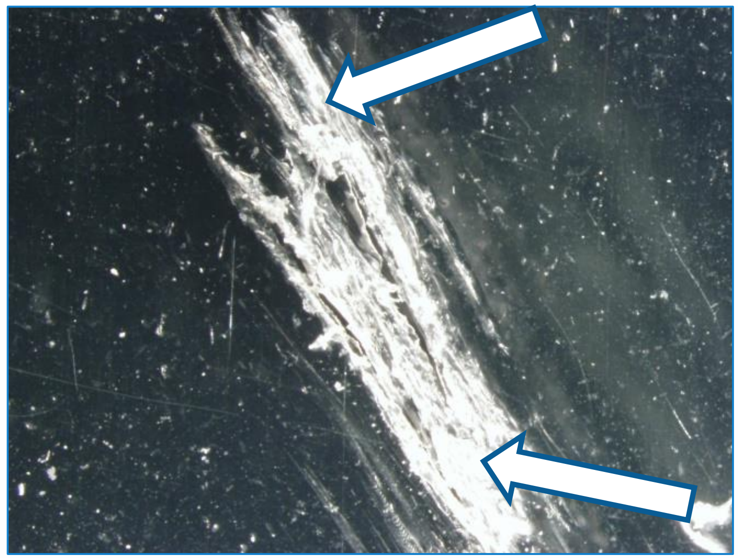


Pinhole Located in Film Material

Material Analysis

- Examine film in surrounding areas of pinhole
- Not all pinholes are created the same way
- Evidence supports something abrading the film from the inside out

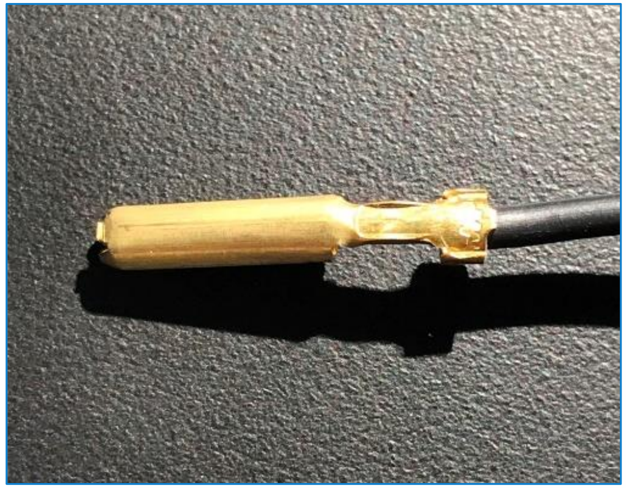


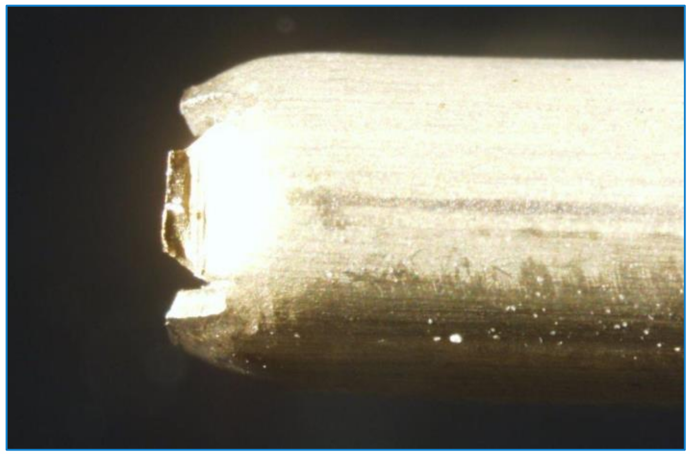


Evidence of abrasion surrounding pinhole

Packaging System Analysis

- Obvious culprit





Packaging System Analysis

Risk Mitigation Tactics

- ***Conclusion:*** Sharp device component was abrading through the pouch film during vibration testing
- ***Mitigation:*** Tip protector to cover sharp component
- Other considerations
  - Material selection
    - Generally, the thicker the film, the better the abrasion resistance. However, material type can influence results also
  - New ASTM standard to help rank materials:
    - ASTM F3300 Std Test Method for Abrasion Resistance of Flexible Pkging Films Using a Reciprocating Weighted Stylus

Case Study III

Pinhole in TFFS Package

Background

Pinhole Located Near Injection Molded Hub of Device, in Corner of TFFS Package

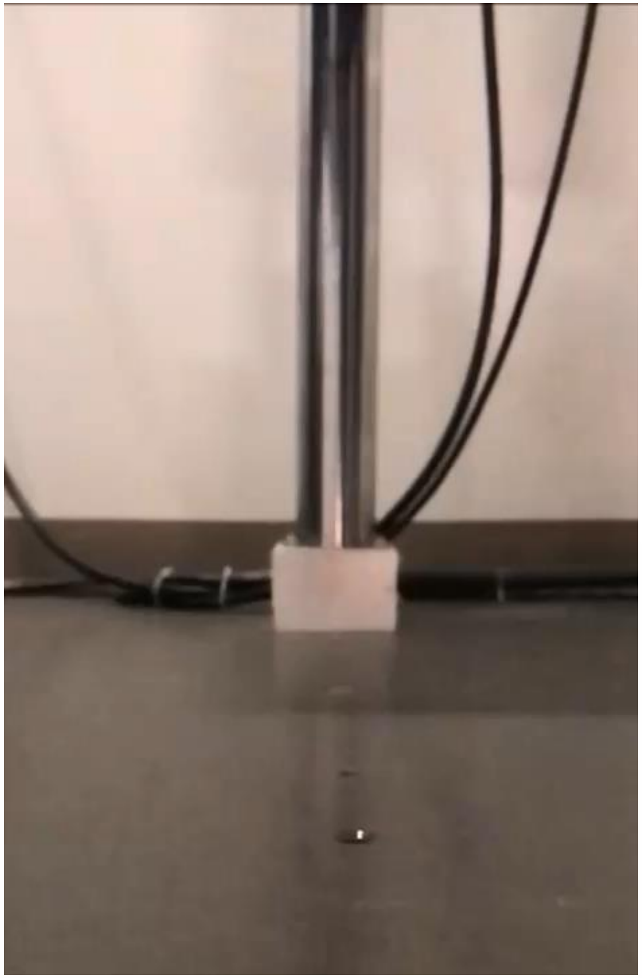
Material Analysis

- Investigate the crime scene
- No evidence of abrading or flexing in areas surrounding the pinhole
- Evidence supports straight line puncture that is characteristic of an “exit wound”

Packaging System Analysis

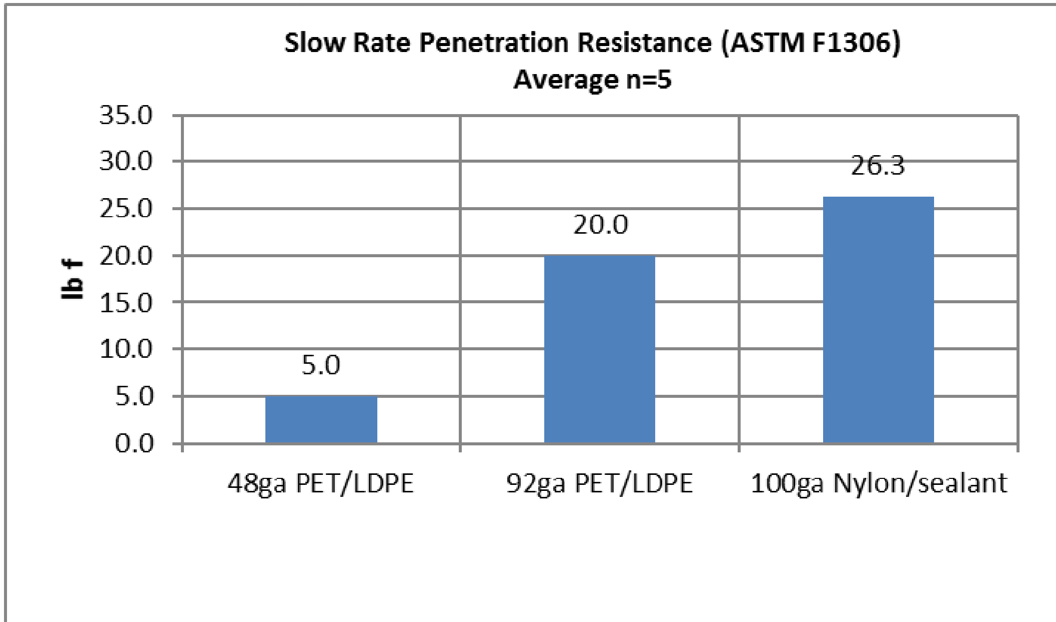
- Parts are loose in the box
- Weight & bulk unevenly distributed
- Excess headspace

Packaging System Analysis



Risk Mitigation Tactics

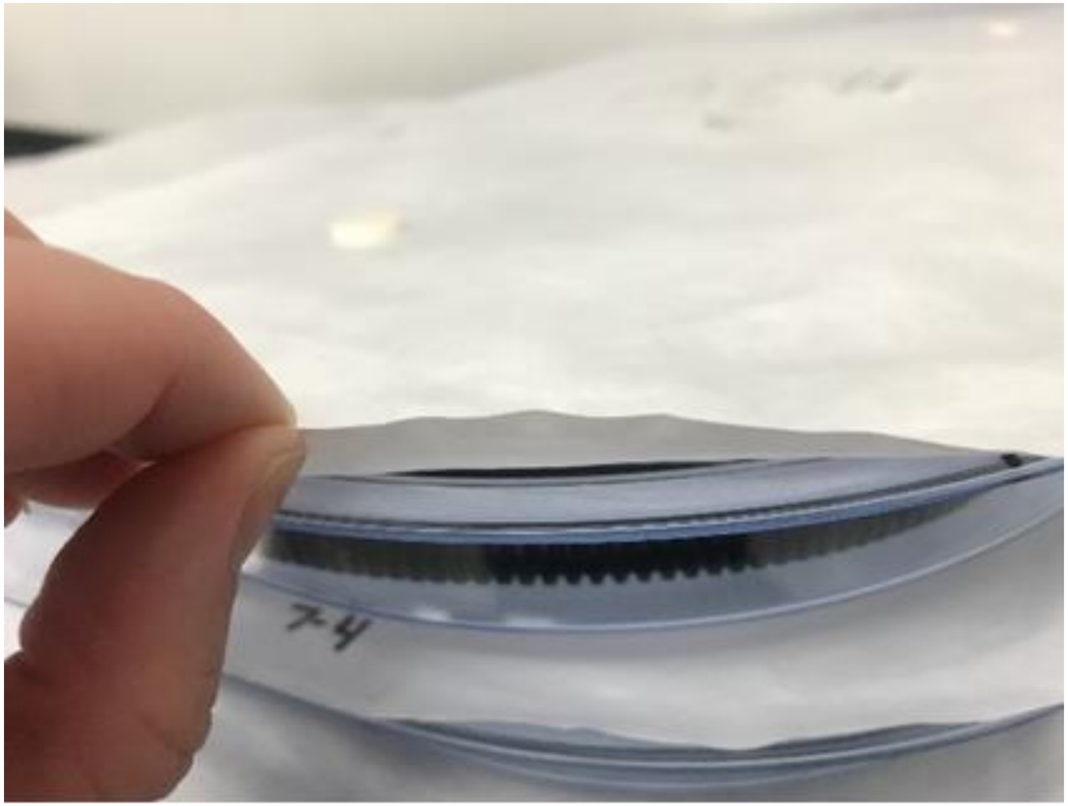
- ***Conclusion:*** Device punctured film during drop test
- ***Mitigation:*** Redesign shipping container to reduce movement of package during transit testing
- Other considerations
  - Protective sleeves
  - Material type and thickness will impact puncture resistance



Case Study IV

Tray with Open Seals

Background

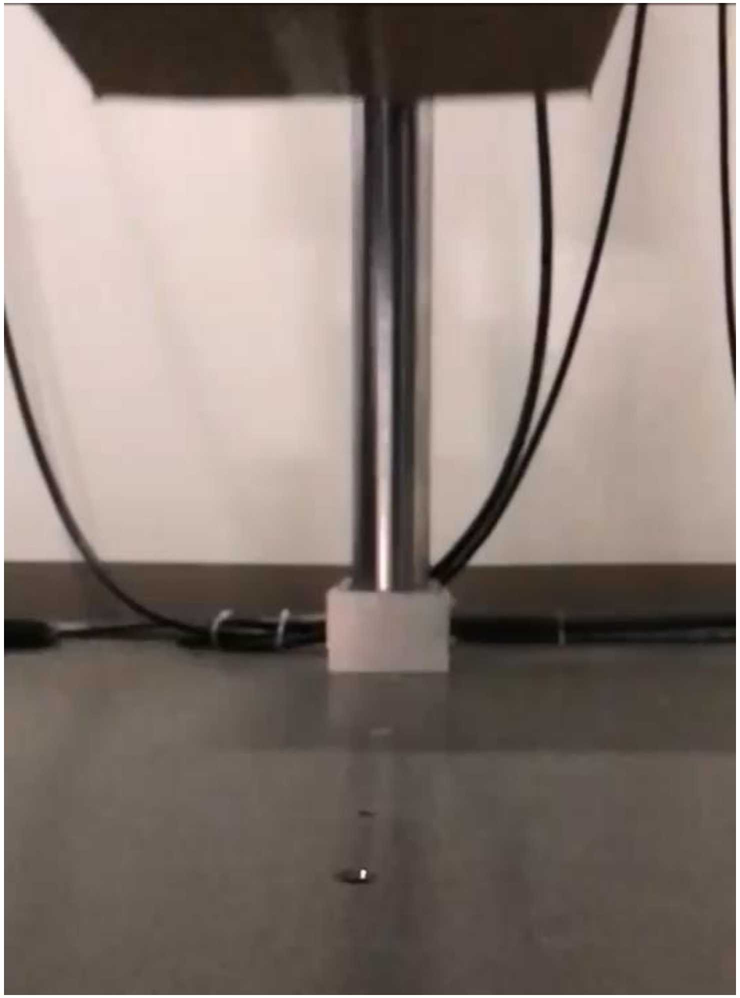


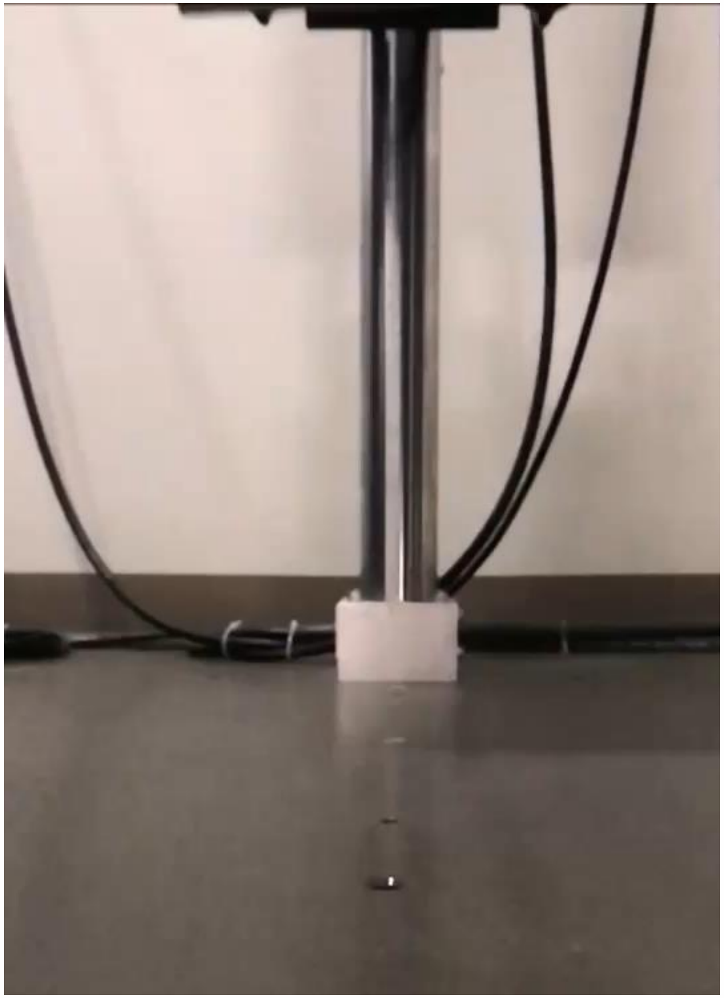
Seal is Popped Open in Corner of Tray

Package System Design Analysis

- Large Heavy Tray
- Placed inside carton, then into shipper

Drop Hazard Analysis





Risk Mitigation Tactics

- ***Conclusion:*** Heavy weight device combined with stress on tray flange/seal during drop test resulted in open seals
- ***Mitigation:***
  - Reduce headspace inside primary and shipping box.
  - Organize, contain and nest
  - Use corrugated inserts and shelf cartons if possible
  - Consider adhesive coatings as part of risk mitigation

Elevated Temperature (60°) Creep Resistance

Not all adhesive are the same!

Understand Risk Areas in Process

- All heat seal adhesives are <u>weaker at elevated temperature</u> vs room temperature

Example:

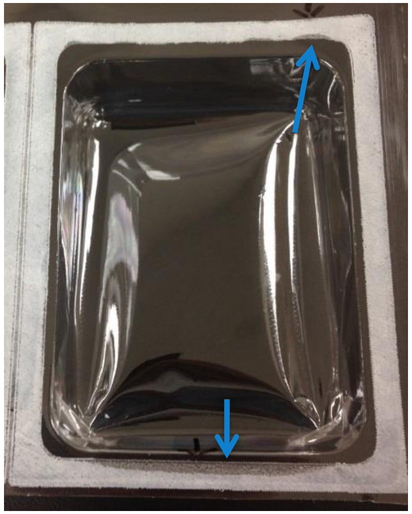
- Immediately after the seal is created ***<u>(hot tack)</u>***

Failure Mode – Hot Tack

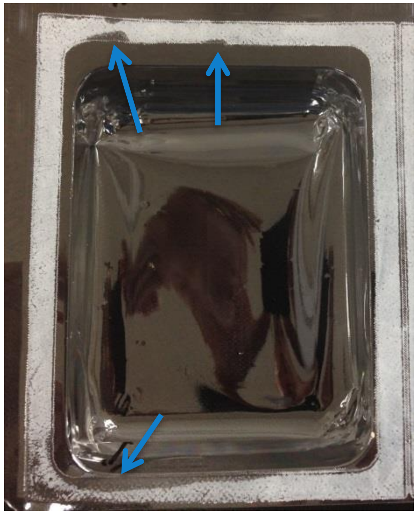
Sealed at
110° C

Sealed at
115° C

Sealed at
120° C

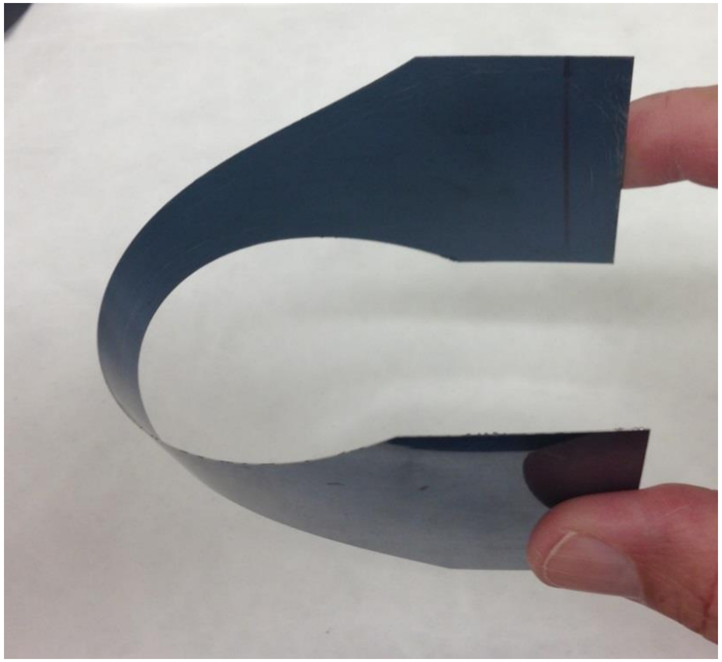


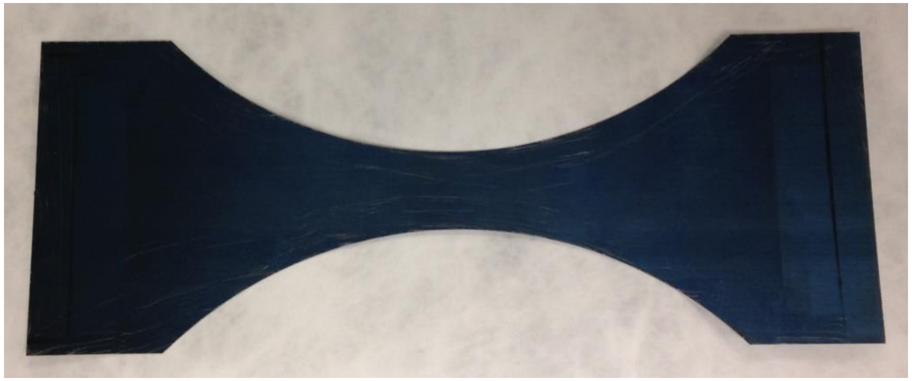
Sealed at
125° C



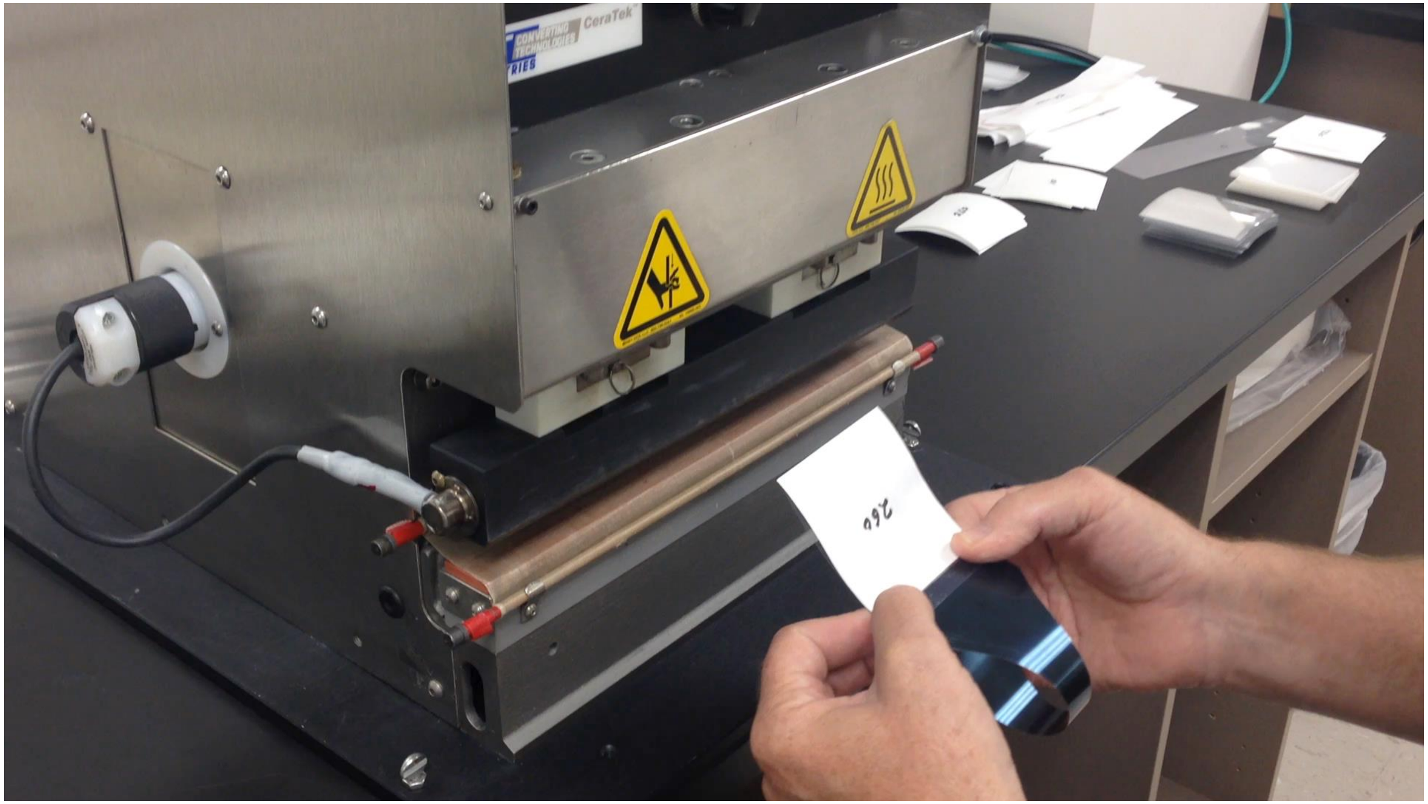
Failure Mode – Hot Tack

Bow Tie Test

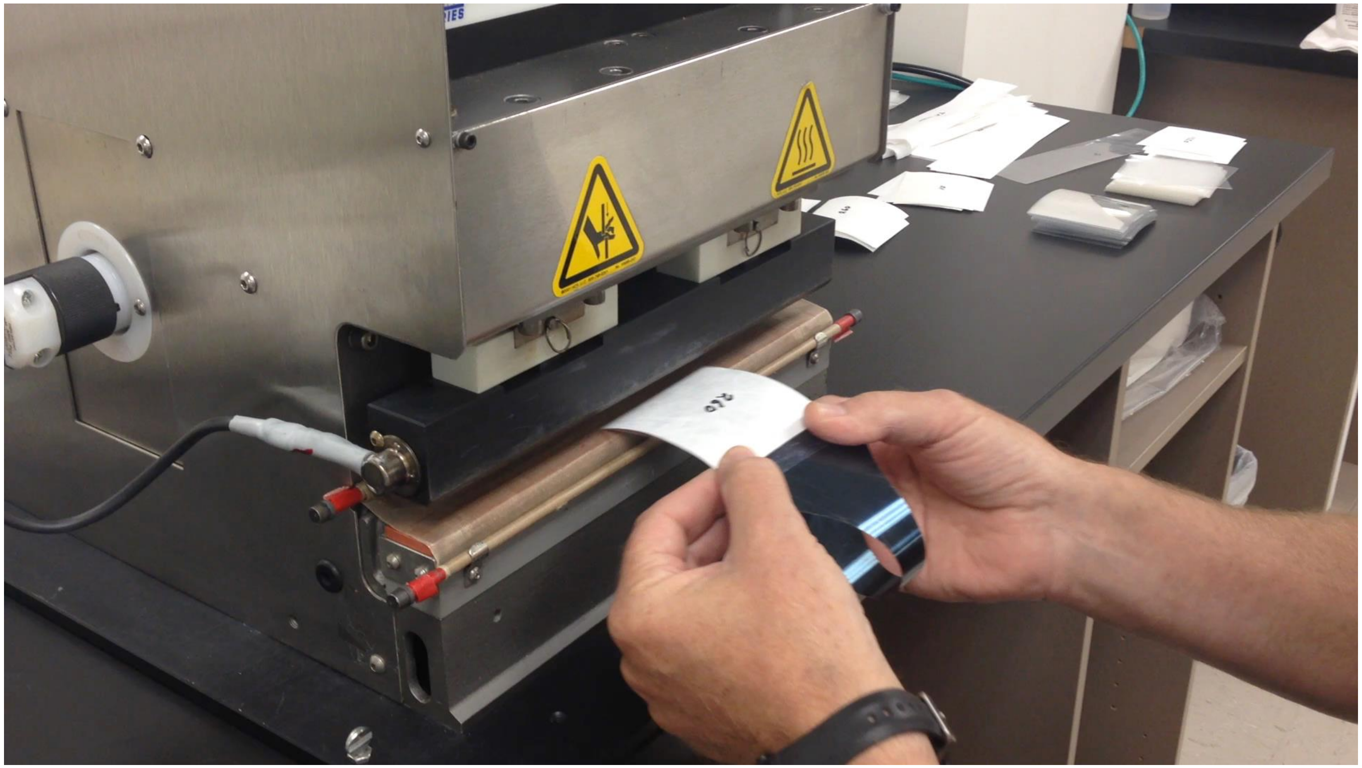




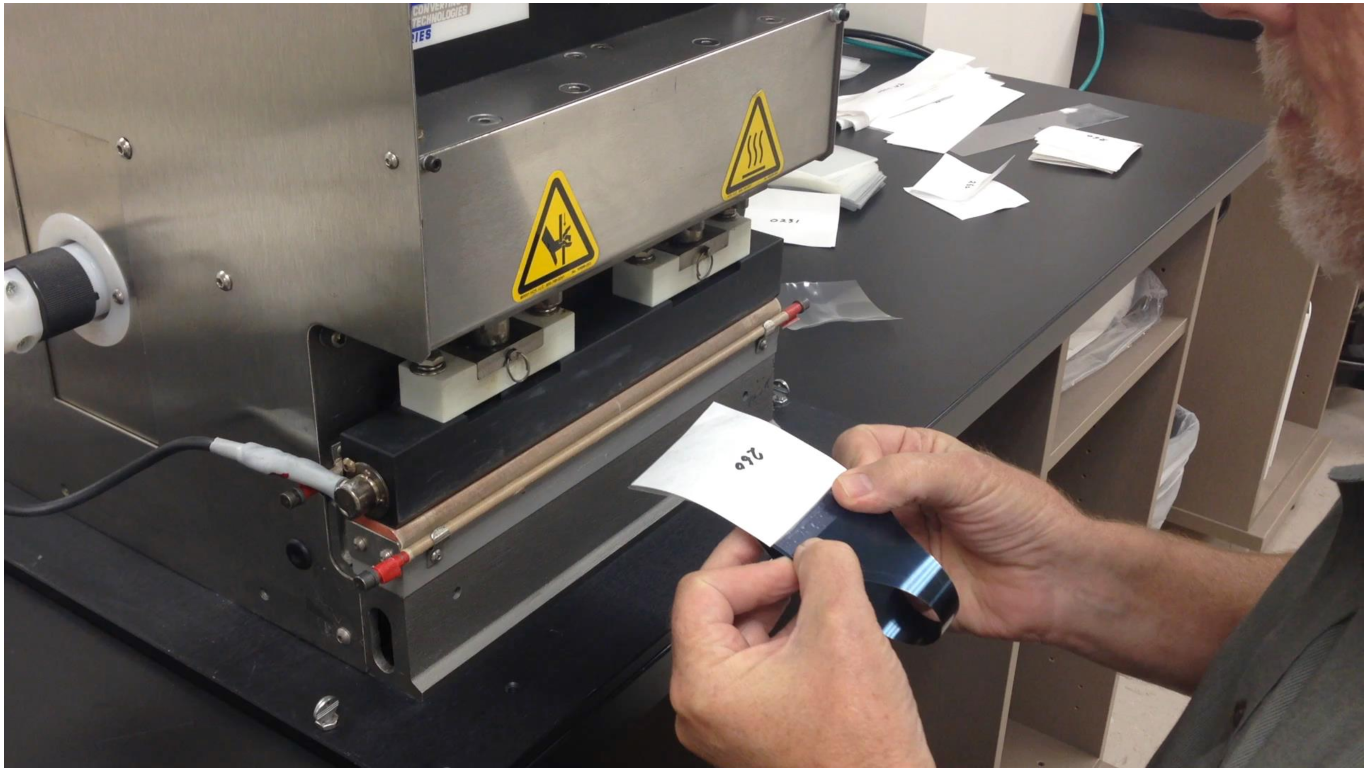
Failure Mode – Hot Tack



Failure Mode – Hot Tack



Failure Mode – Hot Tack



Design Best Practices

Do	Don't
Reduce Headspace • Within the sterile barrier • Within the box	• Bulk / Loose / Unorganized • Excessive Headspace
Reduce weight • Force = Mass * Acceleration • Use shelf cartons or corrugated inserts to redistribute forces	• Excessively heavy box • Heavy parts allowed to move freely around inside of shipper
Avoid Creasing / Folding • No double "compound" fold • Gentle curling of any excess material	• "Cram" into the box • Compound folding • Creasing
Protect from Sharp Edges • Tip protectors, Sheaths • Polyurethane Sleeves	• Direct Exposure of Sterile Barrier to Sharp Edges and Protrusions
Select Appropriate Materials • Puncture & Impact Strength • Abrasion Resistance • Flex Crack Resistance	• Make Incorrect Assumptions about Material Properties and Performance • Assume every pinhole can be solved with more puncture resistant material
Think About Packaging as a <u>System</u>	• Assume Package Integrity is a Material Issue • Focus only on the primary package when designing • Always default to using pre-existing primary and secondary package sizes

Takeaways

- Screening studies
  - Test to failure to understand potential failure modes…then design to mitigate
  - Have a contingency plan
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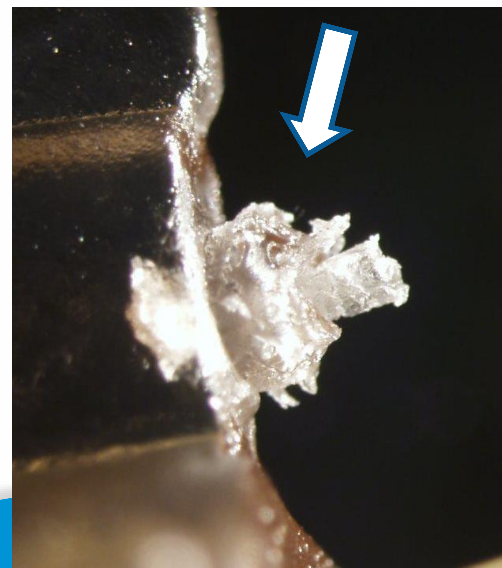


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