



# Dye Penetration

vs.

# Gross Leak Detection (Bubble)

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# Outline

- Porous Packaging
- Non-Porous Packaging
- Dye Penetration – ASTM F1929
  - Terminology
  - Procedure
- Gross Leak Detection – ASTM F2096
  - Procedure
- Gross Leak Detection & Dye Penetration
- Conclusions



# Porous Packaging

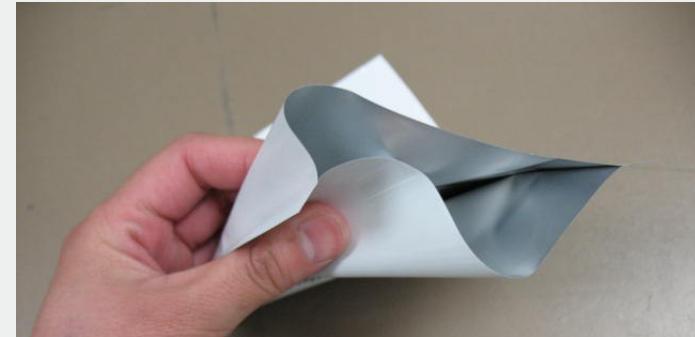
- Tyvek® - spunbonded polyolefin
- Paper





# Non-Porous Packaging

- Poly/poly
- Foil/foil





# Dye Penetration

- ASTM F1929-12
- Detecting Seal Leaks (Channel leaks) in Porous Packaging
- Focus on seals only
- Time duration = 5-20 seconds



# Dye Penetration-Terminology

- Dye penetrant
- Channel
- Wicking



# Dye Penetration-Terminology

- What is dye penetrant?

An aqueous solution of a dye and a surfactant designed to penetrate and indicate a defect location in the time prior to the onset of wicking which could mask its presence



# Dye Penetration-Terminology

- What does dye penetrant consist of?

Distilled water 99.45%

Wetting agent 0.5%

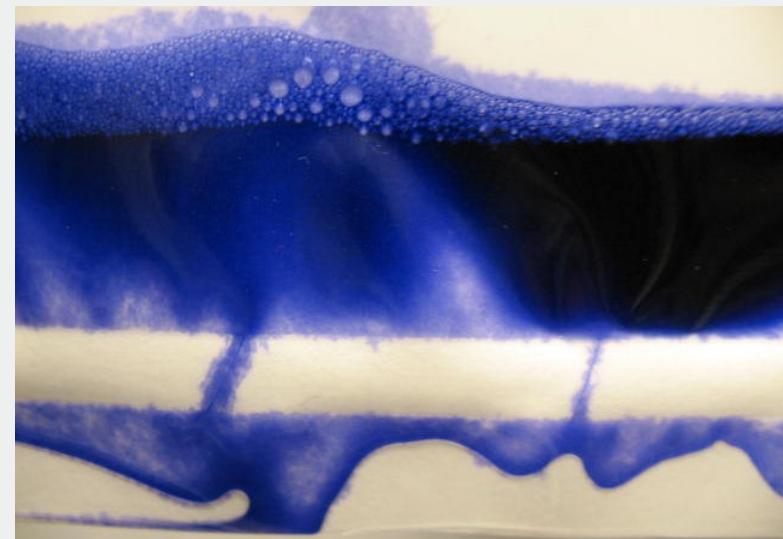
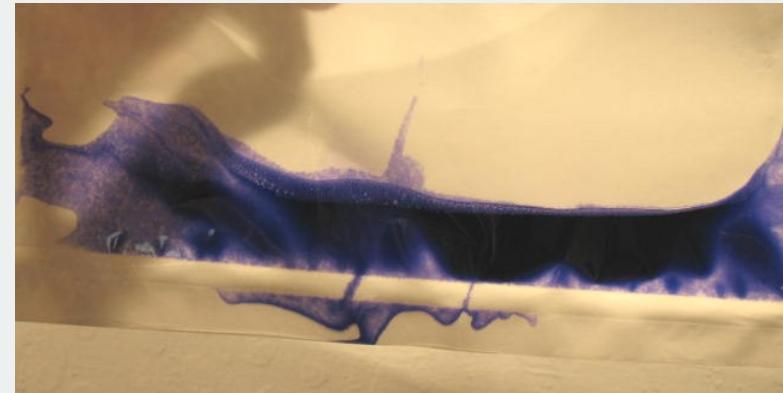
Indicator dye 0.05%



# Dye Penetration-Terminology

- What is a channel?

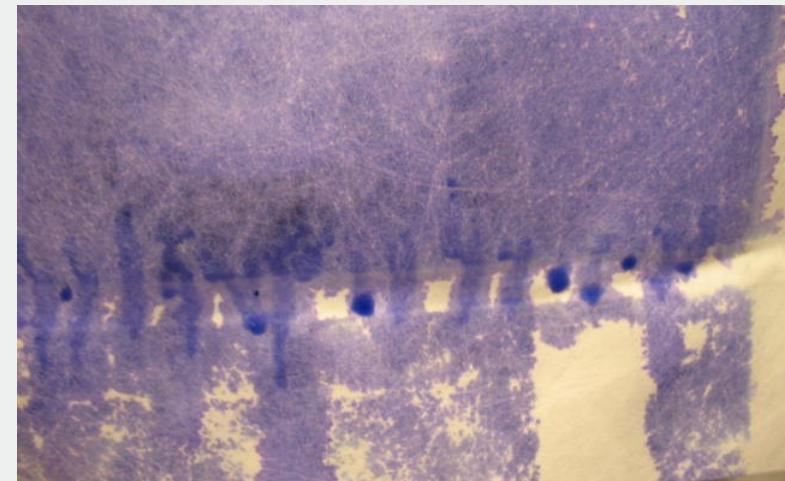
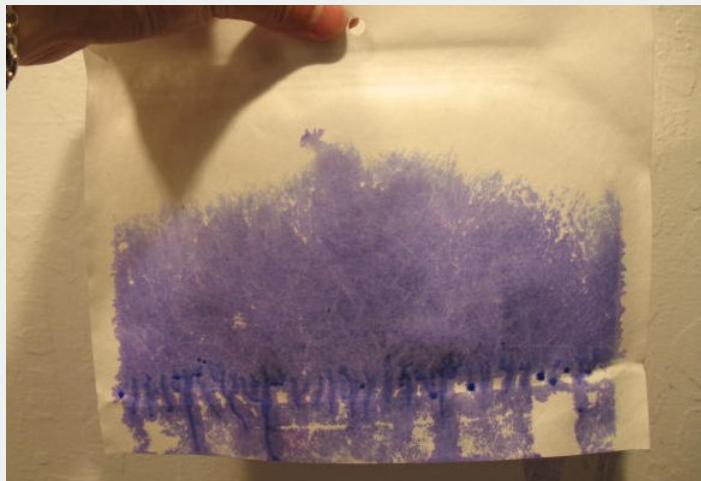
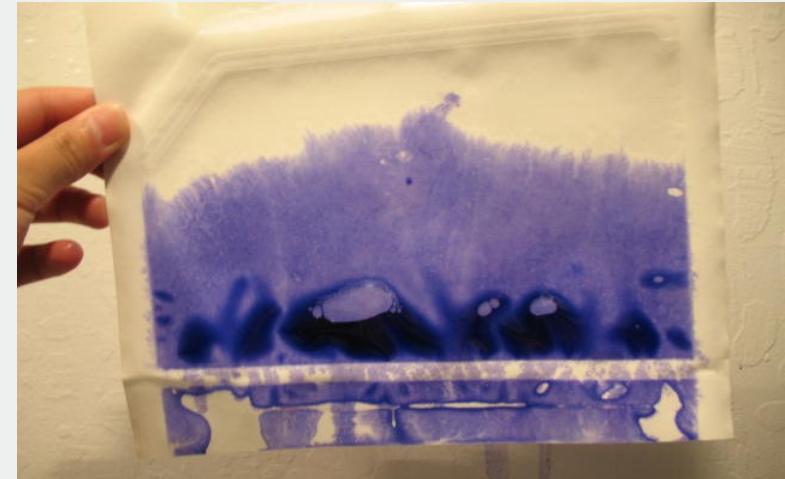
A small continuous open passage across the width of a package seal through which microorganisms could pass





# Dye Penetration-Terminology

- What is wicking?  
Migration of a liquid into the body of a fibrous material





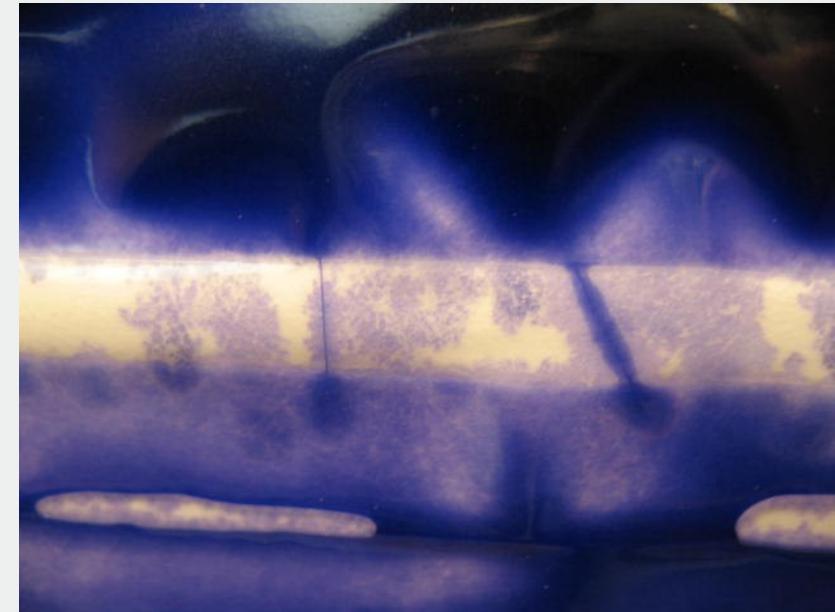
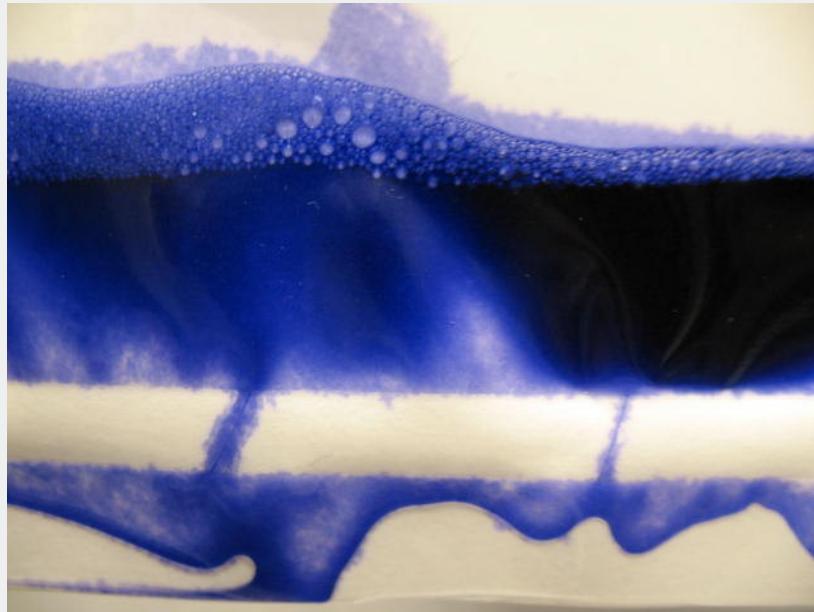
# Dye Penetration - Procedure

- Inject dye penetrant into package (0.25 inch)
- Time duration 5 to 20 seconds
- Rotate package to expose each seal edge to dye penetrant



## Dye Penetration - Procedure

- 5 to 20 seconds
- > 20 seconds





# Gross Leak Detection

- ASTM F2096-11
- Detecting Gross Leaks in Medical Packaging
- Porous and nonporous packaging
- Whole packaging
- Time duration = varies



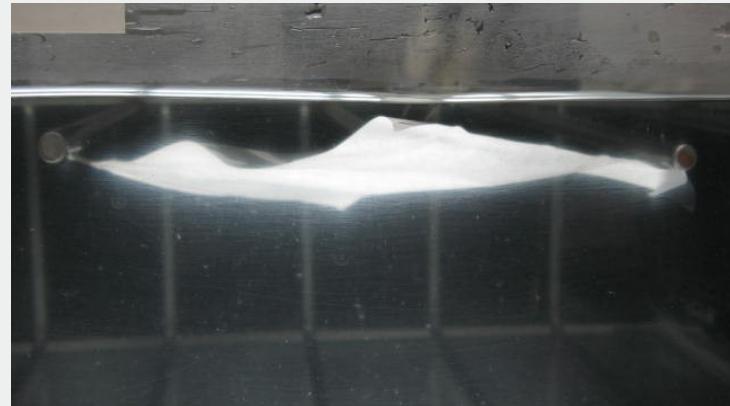
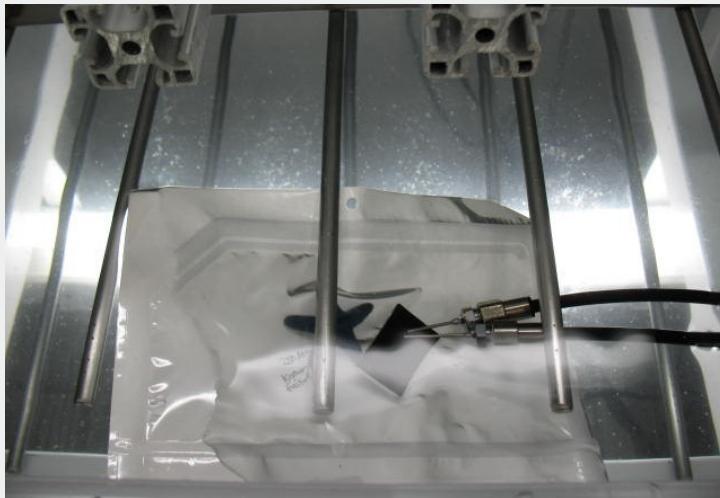
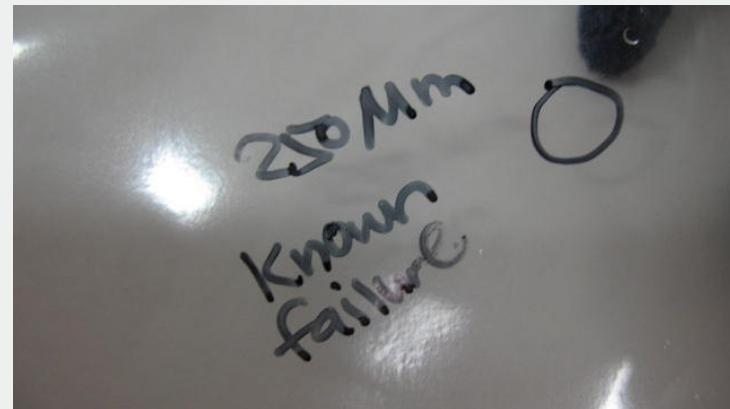
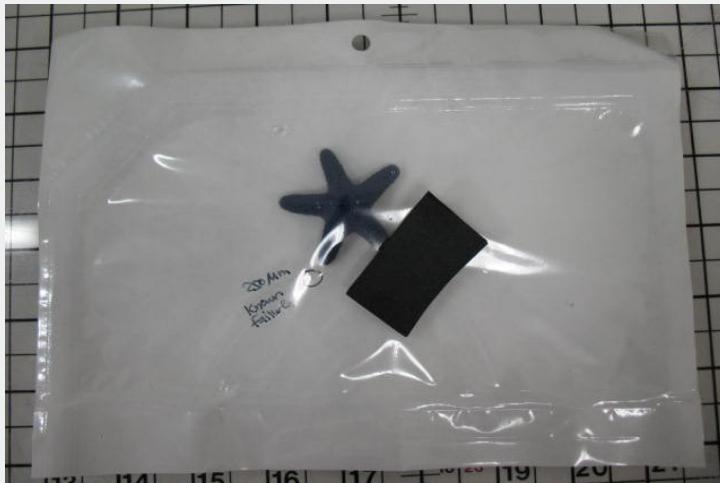
# Gross Leak Detection - Procedure

- Create a hole (known failure/defect) less than or equal to 250 microns
- Insert air source
- Submerge under 1 inch of water
- Inflate to a pressure where the air bubbles are observed emanating from the defect

## **MINIMUM TEST PRESSURE**



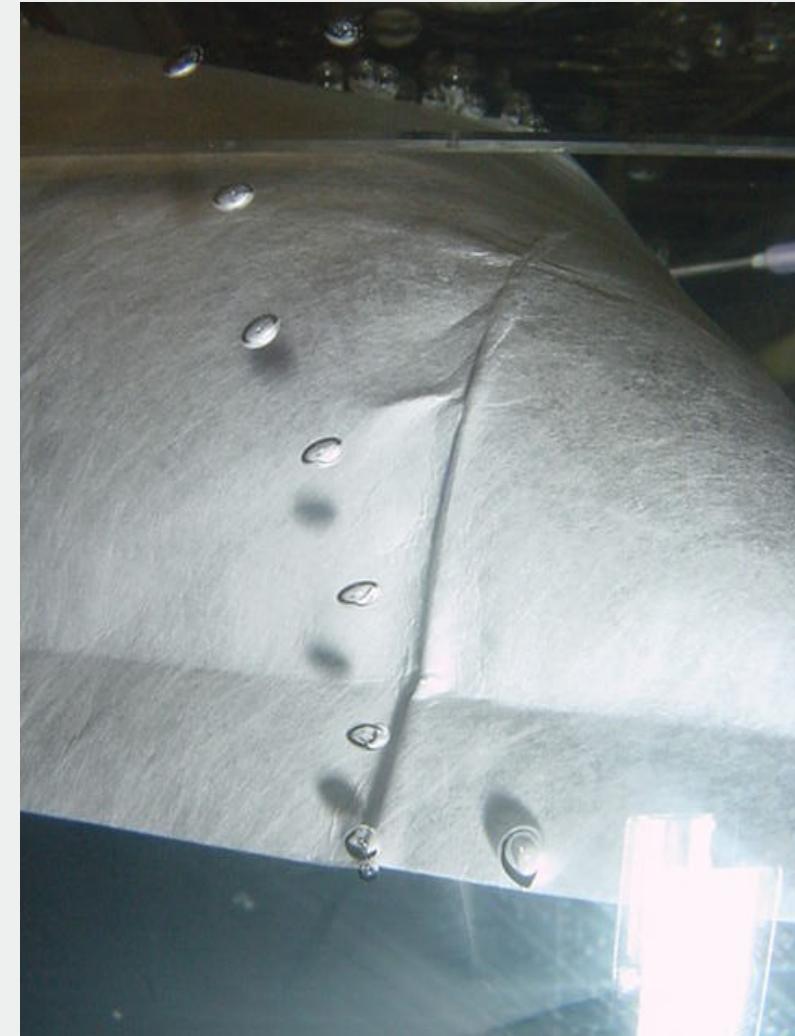
# Gross Leak Detection - Procedure





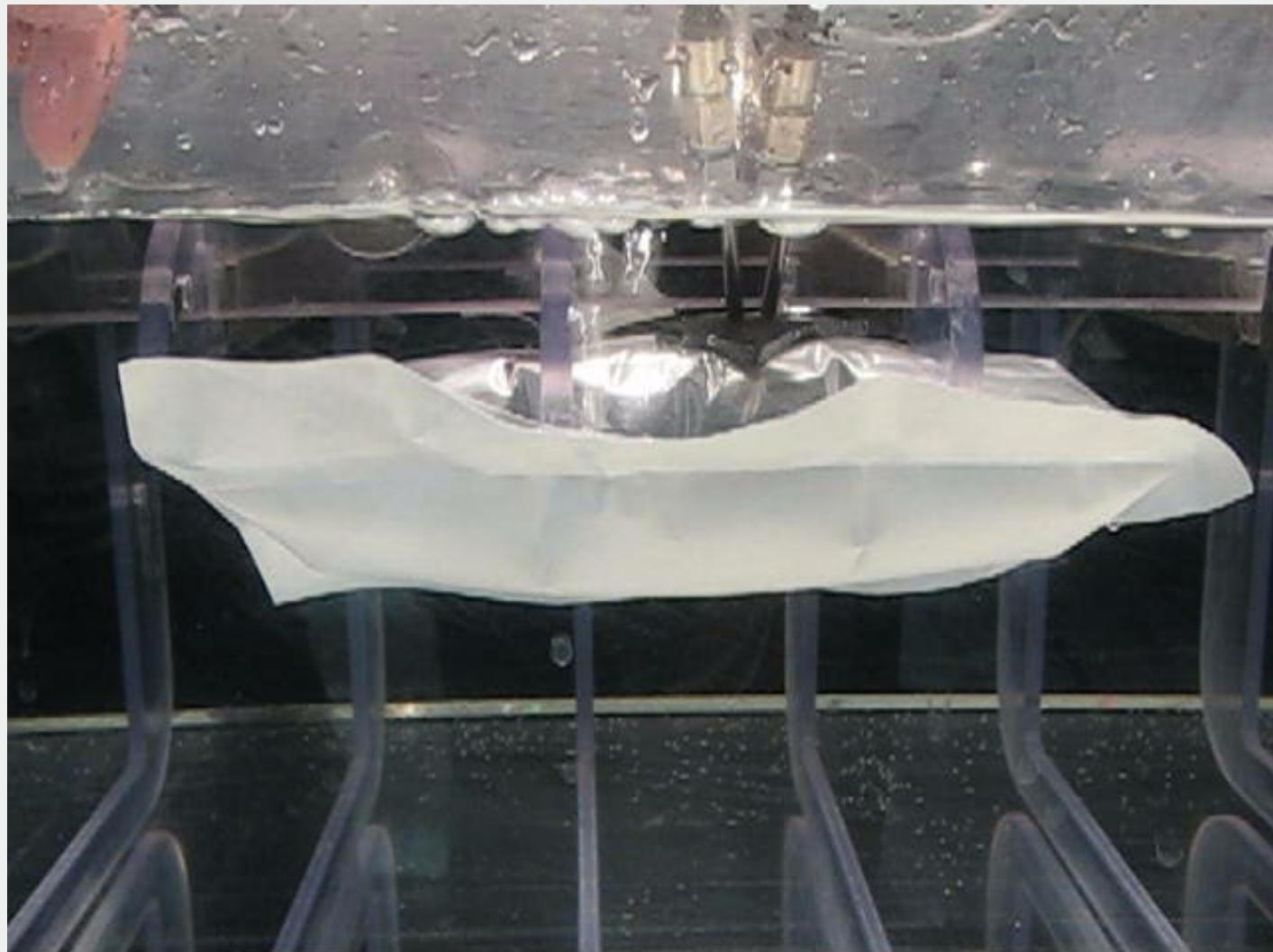
# Gross Leak Detection & Dye Penetration

- Tyvek® separation
- Abnormal breathing from seal
- Follow up with dye penetration test





# Gross Leak Detection & Dye Penetration





# Conclusions

## Dye Penetration

- Channel leaks
- Porous packaging
- Time duration  
5-20 seconds
- Focus only on seals

## Gross Leak Detection

- Leaks
- Porous and nonporous packaging
- Time duration varies
- Focus on the whole package (pouch or tray)