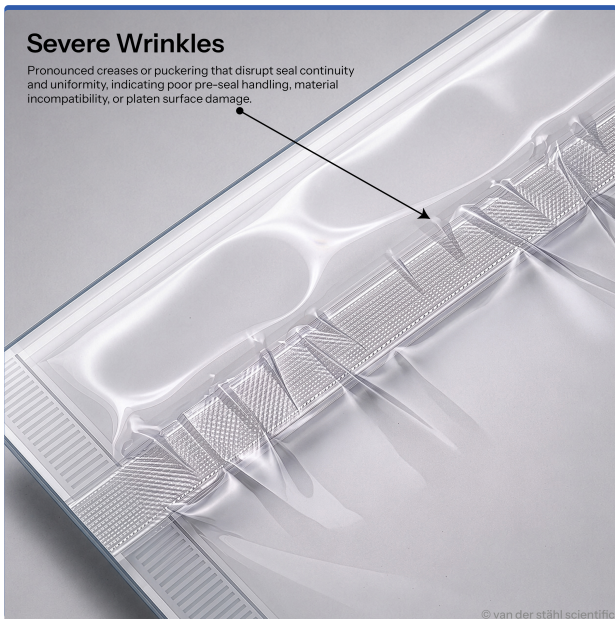


SEVERE WRINKLES

Severe Wrinkles

Pronounced creases or puckering that disrupt seal continuity and uniformity, indicating poor pre-seal handling, material incompatibility, or platen surface damage.



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How to Identify

Severe wrinkles are pronounced creases, puckers, or distortions that enter or disrupt the intended seal area. Unlike minor cosmetic surface irregularities, severe wrinkles may change the geometry of the seal, interfere with uniform contact between the packaging materials, or make portions of the seal difficult to visually evaluate.

During inspection, look for wrinkles that cross the seal, cause the seal boundaries to become irregular, produce visible gaps or channels, or significantly distort the normal validated seal appearance. ASTM F1886/F1886M recognizes that visual characteristics can provide evidence of potential integrity or production problems, but the observation itself does not necessarily establish that package integrity has been compromised.

POSSIBLE CAUSES AND CORRECTIVE ACTION

Severe wrinkles may result from inadequate pouch size, insufficient headspace, improper handling, material characteristics, device movement, poor feeding technique, platen irregularities, or worn sealing components. Verify that the pouch provides adequate space for the device without placing tension on the seal area and inspect unused pouches for pre-existing wrinkles.

Review pouch storage and handling practices and evaluate compatibility between the pouch material and sealing equipment. Inspect the platen for damage, distortion, contamination, or uneven contact and replace worn consumables when appropriate. Operator training and alignment aids may help maintain the pouch in a flat, controlled position during sealing. Any wrinkle that appears to create a continuous pathway through the seal should receive additional evaluation.

Visual Inspection Limitations and Disclaimer

1. Informational and Reference Purpose Only

This reference guide, including all associated visual failure mode examples, descriptions, and criteria is provided by Van der Stahl Scientific solely for general educational, observational, and reference purposes. It is compiled based on the visual inspection principles outlined in ASTM F1886 (Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection) combined with over 30 years of empirical laboratory experience at Van der Stahl Scientific. This reference is not exhaustive. It does not cover every potential visual failure mode, defect, or material anomaly that may occur during the manufacture, processing, or sealing of sterile barrier systems.

2. Inherent Limitations of Visual Inspection and Human Variables

While visual inspection is a valuable tool for monitoring machine functionality, process stability, and immediate packaging anomalies, it has significant inherent technical and human limitations. Visual evaluations are subject to human error, subjective interpretation, individual operator bias, fatigue, lighting variations, and optical limitations. To mitigate these operator-dependent variables, users are strongly advised to implement regular cross-checking across multiple trained operators and utilize standardized reference tools.

3. Material-Specific Visual Variability

Sterile barrier packaging substrates—including but not limited to Tyvek®, foil laminates, Mylar®, film, and paper—exhibit distinct visual characteristics and stress responses when sealed. Visual cues, clarity, seal transfer, and surface textures vary widely depending on material composition, thickness, and coatings. Operators and quality personnel must understand these material-specific visual traits prior to drawing quality conclusions.

4. Obligation for Multi-Method Quality Assurance (Destructive and Non-Destructive Testing)

Visual inspection must NEVER serve as the sole or final arbiter for determining seal integrity, package compliance, or pass/fail release into the sterile field. Satisfactory visual appearance does not guarantee microbial barrier properties, seal strength, or sterile integrity. A robust Quality Assurance (QA) and Quality Control (QC) program requires a comprehensive testing matrix that combines visual observations with validated destructive and non-destructive testing protocols, including but not limited to:

- ASTM F88 (Standard Test Method for Seal Strength of Flexible Barrier Materials)
- ASTM F1929 (Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration)
- Other applicable ISO 11607-1/2 physical and integrity testing protocols.

5. Limitation of Liability and Assumption of Risk

Van der Stahl Scientific makes no warranties, express or implied, including any implied warranties of merchantability, fitness for a particular purpose, or regulatory compliance regarding the use of this reference tool. The user assumes all risk and liability associated with the interpretation, application, or reliance upon visual inspections performed in their facility. In no event shall Van der Stahl Scientific be liable for any direct, indirect, incidental, consequential, special, or punitive damages—including product recalls, corrective and preventive actions (CAPA), regulatory non-compliance, or patient health risks—arising out of or related to the use of or reliance on visual inspection alone or on information contained in this reference.

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