

UNSEALED AREA



How to Identify

An **unsealed area** is a localized portion of the intended pouch seal where the two packaging materials have not formed a complete, continuous bond. Visually, the affected area may appear lighter, clearer, or otherwise different from the surrounding properly sealed region. Look for an interruption in the normally uniform seal pattern, particularly a lighter or clear area where the expected bonded appearance is absent. If that unsealed area forms a continuous path from the inside edge of the seal to the outside edge, it should receive particular attention as a potential channel. It can sometimes be challenging to visually determine an unsealed pouch as the impression made by the platen can embossed a texture but not form the sealing bond.

POSSIBLE CAUSES AND CORRECTIVE ACTION

The ability to detect these conditions visually depends on factors including defect size, contrast between sealed and unsealed areas, packaging materials, lighting angle, magnification, and inspector training.

An unsealed area can be associated with variations in the sealing process, equipment, materials, or environmental conditions. Potential contributors may include insufficient sealing temperature, inadequate dwell time or sealing force, contamination within the seal area, misalignment of the sealing surfaces, wrinkles or folds, or interference from the packaged device. A visually apparent unsealed region should therefore be treated as an indication of a potential sealing or package-integrity problem and investigated according to the manufacturer's validated sealing and inspection procedures. ASTM F1886/F1886M-25 specifically cautions that a visual observation indicates that an issue could be present, and that additional testing may be necessary to determine whether the observation represents an actual integrity breach.

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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