

OVER SEALED

Over Sealed

A seal exhibiting roughness, bubbling, translucency, or distortion caused by excessive heat or dwell time, which weakens the transition zone and increases risk of failure during aging or transit.



© van der stahl scientific

How to Identify

An over-sealed pouch may exhibit a seal surface that appears excessively rough, distorted, bubbled, cloudy, or otherwise different from the normal validated seal appearance. Look for: excessive roughness, bubbling, cloudiness, unusual translucency or clearing of the porous web, distortion, curling, or a seal appearance that is noticeably different from the validated acceptable seal.

With porous-web materials such as Tyvek® sealed to clear film, excessive thermal exposure may cause the porous material within the seal area to become unusually translucent or transparent. Depending on the pouch construction, excessive heat may also contribute to curling, cupping, shrinkage, or distortion adjacent to the seal.

ASTM F1886/F1886M recognizes that visual seal characteristics can be associated with variations in process parameters, equipment, materials, and environmental conditions. A significant change from the established visual appearance of a validated seal can therefore provide an early indication that the heat-sealing process has shifted from its normal operating condition.

An over-sealed appearance may indicate excessive temperature, heat-contact dwell time, force/pressure, or a combination of these conditions. Excessive thermal exposure can also affect the transition between the sealed and unsealed material. Because visual appearance alone does not establish whether package integrity has been compromised, the observation should be evaluated against the manufacturer's validated process and established acceptance criteria. ASTM F1886/F1886M-25 specifically notes that a visual observation indicates that an issue could be present, and that additional testing may be required to determine whether an integrity breach exists.

POSSIBLE CAUSES AND CORRECTIVE ACTION

First compare the pouch with an acceptable reference seal produced within the validated process window. Verify that sealing temperature, heat-contact dwell, cool-down dwell, and applied force are operating at the established nominal settings. If the porous web is becoming excessively clear or translucent, investigate excessive thermal input rather than simply accepting the appearance as normal.

If the condition develops after validation or represents a change from previously acceptable production, verify the sealer's thermal and force calibration and inspect the sealing system for equipment-related changes. Examine the heating element, PTFE/Teflon® covers or tapes, sealing platen, temperature-control components, and other consumable parts for wear, damage, contamination, or deterioration. Worn components can change heat transfer and pressure distribution across the seal.

After corrective action, confirm that the seal has returned to its established visual condition and evaluate package performance using the manufacturer's validated methods. Depending on the nature of the observation and package configuration, complementary testing such as ASTM F88/F88M seal-strength testing or an appropriate package-integrity method may be used to determine whether the visual anomaly has affected package performance or integrity. ASTM lists these as distinct packaging test methods rather than treating visual inspection alone as proof of seal strength or leakage.

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.

van der stahl
SCIENTIFIC

Connecting medical device packaging to patient safety.

Call Customer Care: 800-550-3854