

DEVICE TOO CLOSE TO SEAL AREA

Device Too Close to Seal

This usually happens when the pouch is too small for the device or when the operator uses an improper loading technique. It can place excess pressure on the seal, and there's a risk of the device pushing into the seal zone, which can damage the sealer.



How to Identify

A device positioned too close to the pouch seal occurs when the packaged medical device, tray, accessory, or other pouch contents are located within or immediately adjacent to the intended sealing area. During visual inspection, look for insufficient clearance between the device and the seal, localized pressure or distortion of the pouch material, narrowing of the effective seal width, wrinkles or folds extending into the seal, or evidence that the device has contacted the sealed area.

Particular attention should be given to rigid, heavy, or irregularly shaped devices that can place concentrated stress against the pouch seal. If the device presses against the seal during handling, distribution, or transportation, that mechanical stress may contribute to seal deformation, localized peeling, narrowing of the effective seal, or other damage to the sterile barrier system. ASTM F1886/F1886M visual inspection principles support evaluating observable package and seal characteristics that may indicate a potential integrity problem. Visual observations should be evaluated against the manufacturer's validated package configuration and established acceptance criteria. **ASTM F1886/F1886M-25**

POSSIBLE CAUSES AND CORRECTIVE ACTION

This condition is commonly associated with an undersized pouch, inadequate headspace, improper device positioning, movement of the device within the pouch, or incorrect operator loading technique. Verify that the pouch dimensions are appropriate for the medical device and provide sufficient clearance to allow the pouch to enter the sealing equipment flat and without interference from the product.

Determine whether the device can migrate toward the seal during handling or transportation. When appropriate, evaluate the use of a retention card, insert, thermoformed tray, or other validated method of controlling the device's position within the pouch. Package configuration should prevent the device from continually loading or stressing the seal during expected distribution conditions.

Special attention should also be given to the possibility of the device being captured between the sealing platens or jaws during the sealing cycle. Product trapped in the sealing area can prevent uniform contact between the pouch materials, resulting in an incomplete, narrow, distorted, or interrupted seal. A rigid device caught between the sealing surfaces may also damage the platen, sealing bands, PTFE/Teflon® covers, heating elements, or other machine components.

If product interference is observed, inspect both the pouch and sealing equipment before returning the process to production. Confirm proper pouch sizing and device placement, inspect the sealing surfaces for damage, and verify that the resulting package meets the validated visual and dimensional requirements.

Operator recognition statement: Look for adequate clearance between the medical device and the seal. The device should not contact, distort, narrow, or place pressure against the sealed area and should never be positioned where it can become captured between the sealing surfaces.

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

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