

NARROW SEAL

Narrow Seal

A seal whose width falls below the validated minimum specification, potentially caused by seal creep, contamination, or equipment operating outside nominal parameters.



© van der stahl scientific

How to Identify

A narrow seal is an area where the effective bonded seal width is visibly less than the minimum width established by the manufacturer's validated packaging specification. During visual inspection, compare the entire seal perimeter with an approved reference or established acceptance criteria, looking for localized reductions in seal width, uneven seal boundaries, or areas where the normal seal pattern becomes noticeably narrower.

Consistent with the visual-inspection principles of ASTM F1886/F1886M, particular attention should be given to changes in seal appearance that may indicate variations in the packaging process, materials, or sealing equipment. A narrow area should also be examined for associated abnormalities such as contamination, wrinkles, incomplete bonding, or a pathway that could extend through the effective seal. Visual identification of a narrow seal does not, by itself, establish an integrity breach. The condition should be evaluated against the validated minimum seal width and, when appropriate, investigated using additional package-performance or integrity testing.

POSSIBLE CAUSES AND CORRECTIVE ACTION

A narrow seal may result from pouch misalignment, inadequate pouch size, product interference, contamination, seal creep, platen distortion, worn sealing components, or equipment operating outside validated process parameters. Begin by confirming that the pouch size provides sufficient headspace for the medical device and that the device is properly controlled within the package. Inserts, retention cards, or thermoformed trays may be appropriate when needed to prevent the device from moving into or applying stress against the seal area.

Determine whether the medical device or another pouch component could have been caught between the sealing surfaces during the sealing cycle. If product interference is occurring, evaluate device placement and pouch size. Inspect the seal area for powders, dust, fibers, oils, chemical residues, or other contaminants that could prevent uniform contact and bonding between the packaging materials.

If narrow seals appear during production after the process has been validated, investigate the sealing equipment for changes in performance. Verify temperature and force calibration, inspect the sealing platen for distortion, wear, or loss of parallelism, and examine heating elements, PTFE/Teflon® covers or tapes, and other sealing-system consumables for deterioration or damage. A misshapen or improperly aligned platen may prevent full and uniform contact across the intended seal width.

Following maintenance or corrective action, verify that the equipment has returned to its validated operating condition and that the resulting seal meets the established minimum seal-width requirement. If the narrow area raises concern regarding package integrity, use the appropriate validated complementary test rather than relying solely on visual inspection.

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