

SEAL CHANNEL

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A thin, unsealed pathway running across the seal zone, appearing as a straight or curved line, lighter or darker than the surrounding bonded area, representing a direct sterile-to-non-sterile leak path.



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How to Identify

A **seal channel** is a thin unsealed pathway across the width of the seal that may reach from the sterile to the non-sterile side of the pouch seal. The channel may appear within the seal in a variety of forms often presenting as a straight or curved thin line. Depending on the material the channel may present as a darker or a lighter colored line compared to the surrounding sealed area. The channel may indicate a direct leak pathway that may result in sterility loss and content contamination.

POSSIBLE CAUSES AND CORRECTIVE ACTION

A second level of evaluation could provide deeper insight to this visual anomaly. Consider performing a dye penetration test (ASTM 1929) to determine if the channel represents a gross leak fault. The channel may be caused by a wide variety of conditions, including a damaged platen, a bent heating element or worn consumable parts such as Teflon sheets or tape. This may also be a result of foreign material on the sealing platen. Perform a visual inspection of the sealing platen as well as run your finger across the entire sealing die to feel for surface anomalies. Move your pouch to different areas of the platen and seal a pouch as you move across the sealing area to help identify the damaged area.

Also determine if the medical device inside of the pouch (i.e., a needle or cannula) could have inadvertently been caught in the sealing jaws during packaging. We would also recommend that you revisit your DOE (design of experiment) to determine if you are at nominal settings for temperature, heat contact dwell, cool down dwell and force based on your pouch material. We would also recommend performing a high-level service and/or repair on the sealing machine by replacing all consumable parts connected to the sealing area. If it was determined that the pouch content entered the sealing zone, consider additional operator training or machine guards that will prevent your device from entering the sealing environment to prevent contact damage to the sealing platen.

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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