

### Note: Small Wrinkle or Waves on seal:

Often low pressure on the sealing bar or platen may cause wrinkled or waves in a seal. Small wave like wrinkles on one or more parts of the seal, may be caused by several factors:

- inconsistent pressure parameters
- low or high temperature parameter
- inadequate sealing or cooling parameter
- failing consumable parts i.e., heating elements, teflon sheets or malfunctioning packaging equipment.
- material quality

Adjusting one of the three sealing parameters may improve the seals; sometimes a different combination of all parameters is required. Small wrinkles or waves should be identified differently than pleats and channels. A tight preventative maintenance program is essential to manage these seal anomalies. Examples: worn Teflon tape or sheets impart malformed attributes onto the seal.

If determining the sealing parameters are sound, consider potential material issue and contact the supplier with a sealed sample. When possible, seal the material on another sealer using similar settings.

After determining a possible seal failure using visual inspection we recommend other testing methodologies that may generate greater data. Dye penetration, burst and peel testing may help hone in on root causation. Operators performing visual inspection should be properly trained in order to better assure a successful visual inspection program.

### Specifications

Approximate magnification: 3X

Lumens and LED data:

Luminous intensity at the distance  
of 10cm=2.0/0.1X0.1=200lux

Luminous intensity at the distance of 5cm =

2.9/0.05X0.05=800lux 800x3LEDs = 2400lux

2400lux = 2400lm/m<sup>2</sup>

### VIU (Visual Inspection Unit)

The VIU system is designed to create an additional tool for quality teams to better evaluate the integrity of their sealed pouches. Although this machine has been designed in the spirit of the ASTM 1886, we do not claim to wholly synchronize with this or any other standard. Further, it's important to remember that, although visual inspection is a useful tool, it is never meant to be the final test methodology for seal strength or integrity.

Weak seals may not necessarily present their flaws visually, always use visual inspection in concert with other empirical test methodology such as the ASTM F-88 peel testing or whole pouch burst testing. Van der Stahl Scientific makes no claims of pass/fail seal integrity with the use of our visual inspection unit. It is vital that you understand the limited nature of visual inspection as it is a passive system with inherent shortcomings.

The VIU unit was designed to create a standard magnification and illumination process to better exaggerate flaws within the seal surface. Please refer to the illustrations on this sheet in order to better recognize failures within the seal. Its important to remember that visual seal inspection although a very valuable tool, is not designed to replace other non destructive or destructive test measures for your total quality plan. The visual inspection process is merely another layer of evaluation methodology that may help to understand seal integrity as a whole. The VIU device may be used with a variety of flexible films but the system is optimized to evaluate clear film to Tyvek®.

Our aim is to provide you with the most common seal issues, however this reference sheet does not include all possible failures. The failure causes are based on our collective experiences and again may not be the final word on causation. We always welcome feedback from other packaging engineers as this adds to our knowledge bank that serves the medical device packaging community.

## 800-550-3854

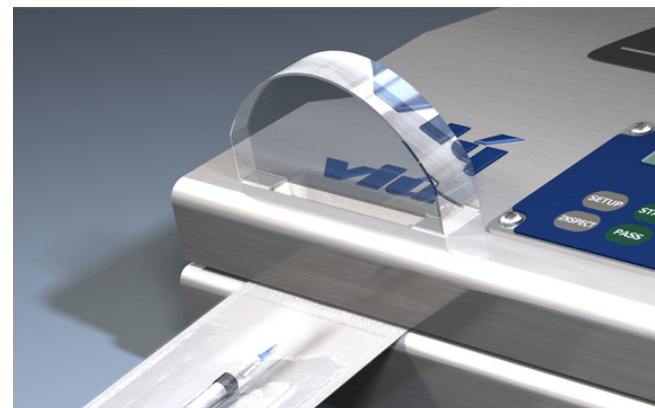
vanderstahl.com

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## Criteria Board for Heat Sealed Closure Systems on Pre-formed Sterile Barriers

### REFERENCE CARD



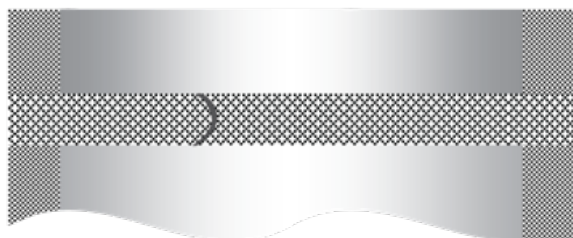
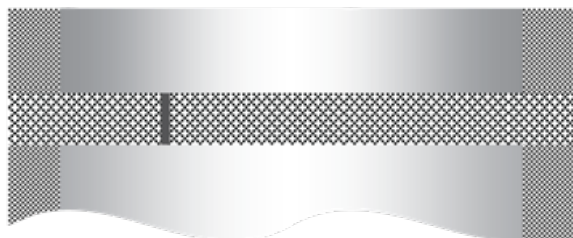
*VIU system on our PTT-100V pouch testing device*

Visual inspection should be an important part of your total quality plan. Visual cues are harbingers of possible seal failures. This reference card is designed to help your quality team with known anomalies and identify possible creep issues in your packaging process.

The **VIU System** helps eliminate inspection variations caused by changes in illumination intensity, reacting light angles, inspection distances, and inspector visual acuity. The VIU system also digitally records each inspection session for record archiving, traceability and process trend analysis. Many medical device companies are not inspecting regularly and have put their process at great risk. Often when device companies perform visual inspection they are not recording the finding, rendering little value to the visual inspection function. The VIU system encourages regulars visual inspection and allows for fast recoding of the process, including time, date, inspectors name lot number and seal failure based on this reference guide. For technical support or questions regarding this reference card please contact engineering at 800-550-3854

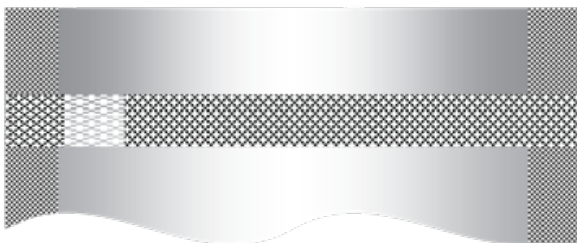
Created by medical device packaging engineer  
Jan Gates and Charlie A. Webb CPP, CMC

**1. CHANNEL:** A thin unsealed pathway across a seal width. The channel may appear within the seal in a variety of forms. The channel may allow leakage risking contamination.



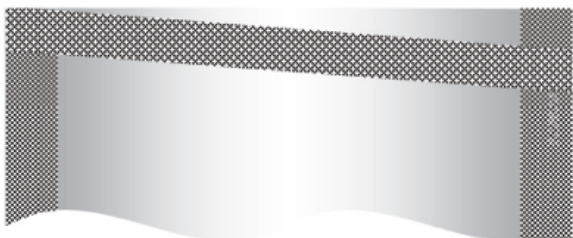
The channel may be caused by a wide variety of conditions. Including a damaged platen. Pouch can be moved to different areas to identify damaged area on platen.

**2. UNSEALED AREA:** a wide unsealed area or gap on a pouch.



The seal may not have been made properly or ruptured after sealing from environmental forces on the package.

**3. CLOSE TO EDGE:** Seal is closer to edge than specified on one end or the entire length.



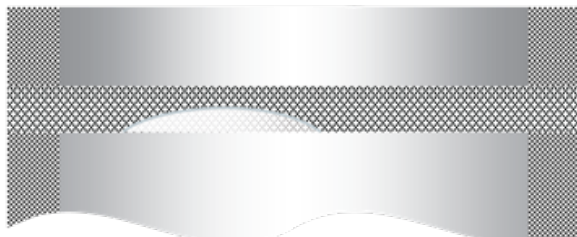
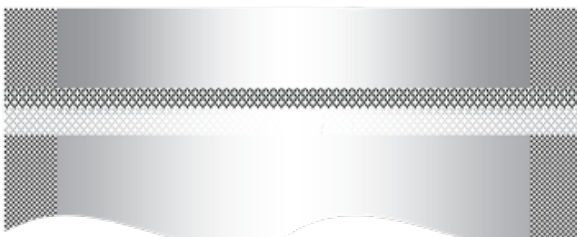
Pouch not positioned correctly while sealing, consider alignment guides for operators.

**4. OVER SEALED:** The seal surface may be rough, bubbly, cloudy, or appear burnt. The white Tyvek material appears transparent or translucent in the seal area.



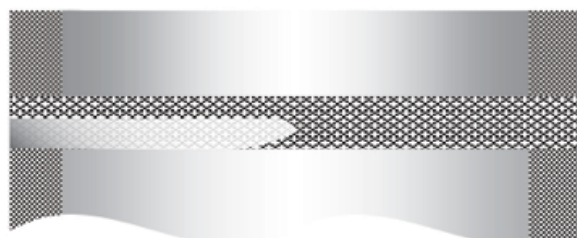
A combination of too much heat, dwell time, or pressure during sealing.

**5. NARROW SEAL:** The seal width is less than original minimum specification.



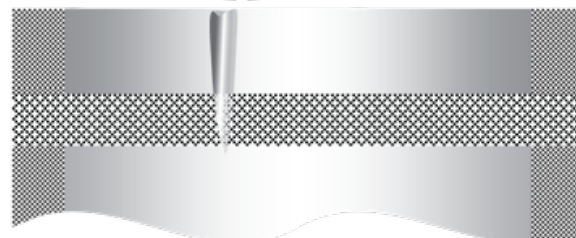
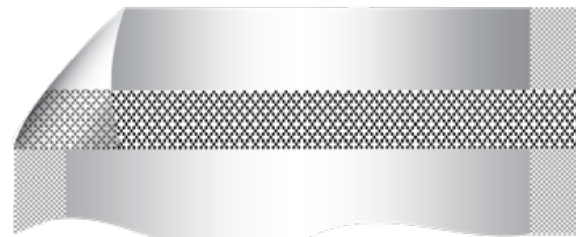
Seal creep or partial seal rupture on the seal surface due to environmental stresses, seal contamination, or sealer needs maintenance.

**6. UNDER SEALED:** A lifting of the material on part of the entire seal. Often appears as a lighter area on the seal surface



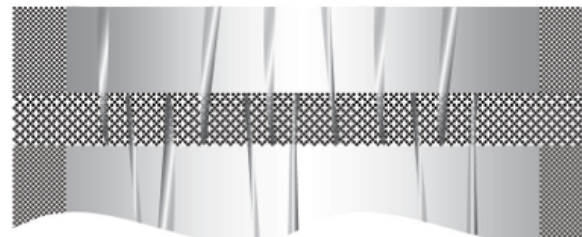
Possibly due to low platen pressure or low temperature during the sealing process or too short of a heat dwell.

**7.FOLD OVER AND PLEATS:** The material folds over before sealing and is in the seal area.



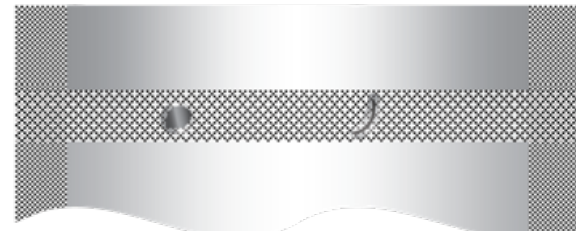
The folded area could result in a channel or poor seal strength. The material could fold at an edge or in the center of a sealed area.

**8. SEVERE WRINKLES:** Creases puckering or wrinkling along seal edges that may interfere with the seal. Small or minor wrinkles along the seal are not defects



Severe puckers or wrinkles are often associated with too small a packaging system for the contents or inconsistent/improper handling during sealing. See notes on reverse side.

**9. FOREIGN MATERIAL:** Product or foreign debris embedded in the seal area. Note: View seal directly down and to the side of the viewing plate for best results.



Seal contamination during shipping, storage, or packing of the product before sealing.