BUSTING 1.0 LB. MIN. SEAL STRENGTH

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INTRODUCTION

• Challenges in the early 90’s with 1.0 lb. minimum for pouches

• How do you validate to a 1.0 lb. minimum using 90° unsupported peel test method for uncoated pouches?

• The answers were that you can’t, unless you use the 180° supported test method.

• Over the last 25 years, people are still asking the same questions. What should my minimum value be, and how do I meet the 1.0 lb. seal strength “Standard”?

• 1.0 lb. minimum for all packages and applications doesn’t make sense.
OUTLINE

Value of seal strength
  Integrity requirement
  Seal strength vs. integrity

Seal strength references
  Literature
  Regulatory

Where does 1.0 lb. minimum come from?

A different approach for determining minimum strength
  Statistical value
Bottom line in Medical Device Packaging

- Maintenance of package integrity through sterilization and distribution to the point of use is the bottom line in Terminally Sterilized Medical Device Packaging.
- Package integrity simply means the materials and seals are without holes or channels.
Seal Strength vs. Integrity

Common seal integrity tests:

• ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

• ASTM F3039 Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration

• ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Common seal strength tests:

• ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials

• ASTM F1140 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
Seal Strength vs. Integrity

**ASTM F2097** - Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

**ISO 11607-1 Annex B** - Standardized test methods and procedures that may be used to demonstrate compliance with the requirements of this part of ISO 11607

- Seal strength and burst testing are not classified as integrity tests.
  - Integrity tests determine if a package has pathways that could allow for microbial penetration into the package.
  - Holes and channels are not typically detected during strength testing unless are grossly significant in size.
Importance of Seal Strength

1) Seal survival to the point of use
   • Withstand real world stresses of sterilization, distribution and product load on package seals

2) Process checks to ensure that sealing conditions are continually meeting expectations for above
Value of Seal Strength

Real world stresses of sterilization on package seals

Ethylene Oxide

Autoclave
Value of Seal Strength

Stresses from distribution effects on package seals
Value of Seal Strength

Stresses from distribution effects on package seals
Value of Seal Strength

Product load on package seals
Value of Seal Strength

Process checks for maintenance of strength
Value of Seal Strength

Force to open a package for the end user
Value of Seal Strength

Ease of opening for the user
Peel Strength in Medical Packaging Literature


"In actual practice, peel angles will vary considerably from test conditions and, in fact, will change continuously as a package is opened. Therefore, the measurement of peel values at a specified angle should only be used to establish standards and measure reproducibility of a material."

“A rule of thumb for comparing peelable packaging is that a 180° peel may have a value as much as twice that of a 90° peel for the same adhesive seal and materials."

Peel angle changes with opening
Seal Strength Values

Pouches

Lids/Trays

<table>
<thead>
<tr>
<th>Tail/seal</th>
<th>90°</th>
</tr>
</thead>
</table>

| Tail/seal | 180° |
Seal Strength Values

ASTM F88 demonstrates that peel strength values change with technique.
Seal Strength Values

Lower values / variability

Higher values / variability

Tail/seal

90°

Tail/seal

180°

Higher ~1.0

Lowest ~0.7

Supported 180°

(By Hand)

Technique C

Supported 90°

Technique B

Unsupported

Technique A

FIG. 1 Tail Holding Methods

Highest ~1.8-2.0
Peel Video 1
Peel Video 2
Peel Strength in Medical Packaging Literature

"The industry would like the seals to be strong enough to withstand the usual sterilization and handling rigors and yet weak enough to open easily without material failure."

"This normally means a seal strength of 0.75—2.64 lbf/in. (0.13—0.46 N/mm)."

"Many health-care packages are opened under stress conditions requiring rapid access to the item packaged. Most items require sterile presentation. The opening mechanism must be such as to facilitate both of these functions. Easy opening is best attained with peelable seals (see Fig.5). What constitutes “easy” is ill-defined. The industry would like the seals to be strong enough to withstand the usual sterilization and handling rigors and yet weak enough to open easily without material failure. This normally means a seal strength of 0.75—2.64 lbf/in. (0.13—0.46 N/mm). Both the device and the packaging materials must be considered in selecting the seal-strength range. If the weight and shape of the device tend to exert more pressure on the seals, the minimum allowable seal strength must be adjusted upward (30). Conversely, for weaker packaging materials, one must lower the maximum allowable seal strength. To improve the peel, packages are often designed with chevron or corner starts to further promote quick opening."

Peel Strength in Medical Packaging Literature

Healthcare Packaging-Opening:

“Both the device and the packaging materials must be considered in selecting the seal-strength...”

“If the weight and shape of the device tend to exert more pressure on the seals, the minimum allowable seal strength must be adjusted...”

“Many health-care packages are opened under stress conditions requiring rapid access to the item packaged. Most items require sterile presentation. The opening mechanism must be such as to facilitate both of these functions. Easy opening is best attained with peelable seals (see Fig.5). What constitutes “easy” is ill-defined. The industry would like the seals to be strong enough to withstand the usual sterilization and handling rigors and yet weak enough to open easily without material failure. This normally means a seal strength of 0.75—2.64 lbf/in. (0.13—0.46 N/mm). Both the device and the packaging materials must be considered in selecting the seal-strength range. If the weight and shape of the device tend to exert more pressure on the seals, the minimum allowable seal strength must be adjusted upward (30). Conversely, for weaker packaging materials, one must lower the maximum allowable seal strength. To improve the peel, packages are often designed with chevron or corner starts to further promote quick opening.”

Effects of Product Weight on Seal Strength

< 1.0 lb.  > 1.0 lb.
Peel Strength in Medical Packaging Literature


“Typical peelability range of various substrates, with adhesive, shown in Table 6.”

<table>
<thead>
<tr>
<th>Substrate</th>
<th>Peel value (lb lin.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical kraft (nonreinforced)</td>
<td>0.5 — 1.2</td>
</tr>
<tr>
<td>Latex-reinforced kraft</td>
<td>1 — 2</td>
</tr>
<tr>
<td>Tyvek</td>
<td>2 — 3</td>
</tr>
<tr>
<td>Extensible films</td>
<td>1 — 2</td>
</tr>
<tr>
<td>Nonextensible films</td>
<td>2 — 3</td>
</tr>
<tr>
<td>Foil/paper laminations</td>
<td>1 — 3</td>
</tr>
<tr>
<td>Foil/film laminations</td>
<td>2 — 4</td>
</tr>
</tbody>
</table>

Medical Packaging Regulation


• 5.1.8 c) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.

• 5.1.9 b) If formed by sealing, the specified requirements for seal width and seal strength (tensile and/or burst) shall be met.
Medical Packaging Regulation

EN868-5:2009 Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

• 4.5.1 When tested in accordance with the method described in Annex D the strength of the seal joint shall be not less than required for the intended purpose, both before and after being subjected to the sterilization process.

• Minimum value for seal strength in (healthcare facility) shall be 1,5 N per 15 mm for steam sterilization processes and 1,2 N per 15 mm for other sterilization processes.

\[
1.5\text{N/ 15mm} = 0.57 \text{ lb/in. (Steam) } \\
1.2\text{N/ 15mm} = 0.46 \text{ lb/in. (all other sterilization)}
\]

• NOTE 2: For applications outside healthcare facilities requirements are given in EN ISO 11607.
**Medical Packaging Regulation**

**EN868-7:2009** Adhesive coated paper for the manufacture of sealable packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods: Clause 4.3.19

1.2N/ 15mm = 0.46 lb/in.

**EN868-10:2009** Adhesive coated nonwoven materials of polyolefines for use in the manufacture of sealable pouches, reels and lids - Requirements and test methods: Clause 4.3.10

>0.08kN/m =0.45 lb/in.

All state: “Report whether the tail was supported or unsupported”
Seal Strength Values Summary

Regulatory

- ISO 11607 – no minimum value specified
- EN 868–5 (1.5N/ 15mm) = **0.57 lb/in.** & (1.2N/ 15mm) = **0.46 lb/in.**
- EN868-7(1.2N/ 15mm) = **0.46 lb/in.**
- EN868-10 (0.08kN/m) = **0.45 lb/in.**

Literature

- PKG Ency. - (0.13 N/mm) **0.75lbf/in.**
- MED DEV PKG HDBK- **0.5lbs/in.** (paper substrate)

Experience

- Minimum values vary 0.3 , 0.5 , 0.6 ,0.7 – 1.0, 1.2 , 3.0 lbs. depending on materials and application.

**Most important: What does your package need to survive until point of use?**
“A rule of thumb is a homemade recipe for making a guess.”

“It is an easy-to-remember guide that falls somewhere between a mathematical formula and a shot in the dark.”

Rules of Thumb

Blasting a Tree Stump:
“You can blow most stumps out of the ground if you use one stick of dynamite for every 4 inches of stump diameter”

Technical Projects Rule of Two:
“Complex projects always take twice as long to finish as your most thorough and conservative estimate, even when you used this rule and doubled your first estimate.”

Stories Where 1.0 lb Originated

Stories:

• Guaranteed Minimum from Material suppliers
• Material suppliers – delamination strength of paper (average peel strength)
• TAPPI- (The Pulp and Paper Industry) committee easy open packaging
"The one-pound-per-inch peak "requirement" came mostly from material suppliers of unconverted and converted products."

"surgical-grade paper was king, seal-strength values were governed more by the internal bond strength of the paper”

"The one-pound-per-inch peak "requirement" came mostly from material suppliers of unconverted and converted products. This was the best value they could guarantee to medical device customers. Back in the 1960s, when surgical-grade paper was king, seal-strength values were governed more by the internal bond strength of the paper than by adhesive technologies. At that time, device manufacturers were equally concerned about clean peels, the opening of the package without generating loose fiber and encapsulating the device. The solution, though expensive at the time, was to provide a heat-activated coating on the paper.”

Stories Where 1.0 lb Originated

Material Suppliers:

- Delamination strength of paper
- Average peel strength of 1.0 lbs.
- Fiber tearing can start to occur at strengths greater than 1.0 lb.
Stories Where 1.0 lb Originated

TAPPI Committee:

• Communicated by two independent sources.
• 1.0 lb. was born out of a TAPPI committee looking at easy opening packaging.
• A seal strength of 1.0 lb. was easy opening and passed distribution challenges.
• Whether it was for rigid or flexible packaging or both, unknown.
• Contacted TAPPI, unable to verify story.
1.0 LB. ORIGIN STILL A MYSTERY
Statistical Approach to Establish Min. Seal Strength

- When qualifying packaging, a lot or batch of packages are produced at a seal condition.
- A statistically significant sample set is tested for seal strength.
- Since the sample size is statistically significant, the results are assumed to be representative of the lot.
Statistical Approach to Establish Min. Seal Strength

• For example: +/-3 sigma variation would then give a 99.73% representation of the lot.

• The -3sigma value would be representative of a minimum of the lot.

• Another statically significant sample set of the lot is sent through sterilization and distribution, then integrity tested.
Statistical Approach to Establish Min. Seal Strength

- If packages pass integrity then the -3sigma value of seal strength testing would be a statistical derived minimum value.
- Continued monitoring of the sealing process would then give a high level of confidence that seal integrity would be maintained.
Take Away

• 1.0 lb. seal strength minimum is not a standard
• Maybe guideline or rule of thumb as a starting point
• If choosing an arbitrary minimum seal strength requirement, like 1.0 lb., then understand the value and consequences
• Consider an alternate approach
• Finally, if you have any stories of the origin of 1.0 lb. contact me
Thank You

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