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## Seal Tensile Strength - Medistri

## **Seal Tensile Strength**

Making sure that the sterilization is done correctly is one of the main priorities in the medical device and packaging industry. All medical packaging, whether it is a single-use product or intended for resterilization and reuse, must be strong enough to be easily opened by healthcare providers while ensuring product sterility. To ensure that packaging achieves this delicate balance, many manufacturers follow test standards such as ASTM F88 to measure the tensile strength of adhesives used in medical device packaging.

Seal strength is a quantitative measure for use in process validation, capability, and control. Seal strength is not only relevant to opening force and package integrity, but to measuring the packaging processes' ability to produce consistent seals. Seal strength at some minimum level is a necessary package requirement, and at times it is also desirable to have an upper limit to the strength of the seal to facilitate opening.

In essence, seal tensile strength is a measure of the maximum load that a material can withstand without fracturing or being stretched, divided by the original cross-sectional area of the material. It's a key metric in many fields, including engineering and packaging.

Also, Seal Tensile Strenght is important for the following reasons:

- 1. Package Integrity: It ensures the integrity of a sealed package. This is particularly important in industries such as medical and food packaging, where maintaining sterility is critical.
- 2. Resistance to Leaks: Seal strength testing helps ensure that no weaknesses in the sealed areas of the package permit leaks to develop during sterilization, normal handling, transportation, and storage.
- 3. Validation and Conformance: It helps validate the package design as adequate for maintaining integrity, monitor process performance, and confirm shelf-life performance.
- 4. Control of the Peel: Seal strength also ensures control of the peel. This is important in packages that are designed to be peelable.
- 5. Material Bonding: Seal-strength testing evaluates the mechanical strength of the seal, ensuring proper material bonding.

ASTM F88 provides a way to quantify the mechanical strength of seals, specifically the maximum force required to separate a test strip of material containing a seal. This is particularly applicable to peelable medical package seals.

The test involves securing each tail of the sealed specimen in the opposing grips of a universal test bench. The tensile testing machine then measures the tensile load and separation between the grips during seal strength testing. The maximum tensile force required to separate the two ends of the seal is recorded.

Therefore, ASTM F88 is a crucial standard in determining seal tensile strength, ensuring the integrity of packaging seals.

ASTM F88 is a standard that has been developed and updated over time to ensure the quality and safety of seals in flexible barrier materials. The standard was last updated on August 3, 20231.

ASTM F88 was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

The standard provides a quantitative measure for use in process validation, process control, and capability. It measures the force required to separate a test strip of material containing the seal and also identifies the mode of specimen failure.

ASTM F88 covers the measurement of the strength of seals in flexible barrier materials. The test measures the force needed to separate a test strip of the material containing the seal. The mode of failure is also identified. The seal may be between flexible and ridged materials.

ASTM F88 plays a pivotal role in the medical device and packaging industry by providing a standardized method for measuring the tensile strength of seals. This ensures the integrity of the packaging and ultimately, the safety and effectiveness of the medical devices within.

- To learn more about Medistri's Seal Tensile Strength, visit on our website <a href="mailto:here">here</a> or directly contact our team at contact@medistri.swiss.
- The Medistri Team

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