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Standard Terminology Relating to Barrier Materials for Medical Packaging[1]

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1. Scope

1.1 This terminology contains related definitions and descriptions of terms used or likely to be used in medical packaging standards that involve barrier materials. The purpose of terminology is to promote clear understanding and interpretation of the standards in which they are used.

2. Referenced Document

2.1 *ASTM Standards:*

F 17 Terminology Relating to Flexible Barrier Materials[2]

3. Terminology Definitions

accelerated aging—a technique to simulate the effects of package aging by subjecting the product/package system to environmental stress; generally accomplished using temperature and humidity extremes, depending on application; other environmental elements, for example, ultraviolet light, may have to be considered.

adhesive transfer—a condition occurring when an adhesive-coated material is peeled away from an opposing material to which it has been sealed and shows visible evidence of the adhesive being left on the opposing material. This evidence is in the form of an adhesive layer that remains with the opposing material, the adhesive having separated either adhesively from the coated web or cohesively within the adhesive itself.

aseptic packaging— See Terminology F 17.

barrier—See Terminology F 17.

barrier materials—specialized porous or nonporous packaging materials that provide environmental protection to the package contents as well as protection to the environment from the package contents: (*1*) gas, vapor, humidity, liquid, microbial, or light resistant materials that control or eliminate the amount of those environmental constituents that pass into or out of a package; (*2*) a porous material preventing the passage of microorganisms that might contaminate the contents of the package.

biological evaluation test (biotest)—See Terminology F 17.

burst strength—a measure of the internal pressure necessary to rupture a package or seal.

channel—any unimpaired pathway across the entire width of the intended seal.

coextrusion—See Terminology F 17.

delamination—See Terminology F 17.

dispersion coating— See Terminology F 17.

extrusion coating— See Terminology F 17.

flexible—See Terminology F 17.

fusion seal—See Terminology F 17.

heat seal—the result of bonding surfaces by controlled application of heat, pressure, and dwell time.

hermetically sealed aseptic container—See Terminology F 17.

laminate—See Terminology F 17.

lamination—See Terminology F 17.

leak—any opening in a flexible package that is contrary to intention and either lets contents escape or permits substances to enter.

major package defect— See Terminology F 17.

microbial contamination— See Terminology F 17.

minor package defect— See Terminology F 17.

multilayered structure— See Terminology F 17.

package integrity—the physical capability of a given package to protect its contents with the desired level of protection over a defined period of service; for example, as a barrier to physical, microbiological, or chemical challenges.

peelable seal—the opening characteristic of forcibly separating two package substrates, which have been joined together by a sealing process, without tearing the substrates.

porous packaging material—a material used in medical packaging which is intended to provide an environmental and biological barrier, while allowing sufficient air flow to be used in gaseous sterilization methods (for example, EtO, steam, gas plasma).

retortable—See Terminology F 17.

seal—See Terminology F 17.

seal contamination— See Terminology F 17.

seal creep—the reduction in width of a seal due to a force being exerted on it, such as a bulky product, pouch distortion, or internal air pressure.

seal creep resistance—a measure of the ability of a sealed package or seal to remain intact when subjected to a constant force.

seal strength—a measure of the mechanical strength of the bond between sealed materials of a package.

seam—See Terminology F 17.

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[1] This terminology is under the jurisdiction of ASTM Committee F-2 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Packaging.

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[2] *Annual Book of ASTM Standards*, Vol 15.09.

solution coating—See Terminology F 17.
sterilant—See Terminology F 17.
sterile—See Terminology F 17.
thermal processing— See Terminology F 17.