EASTMAN

Heat sealing film and sheet

of Eastman™ copolyesters for medical packaging

Eastman Chemical Company manufactures copolyesters that can be extruded into film or sheet and subsequently thermoformed or fabricated into various containers.

Most packages must be closed in some way, and the vast majority are closed by heat-sealing. Mechanical integrity of the seal is a primary consideration and requirements are based on the intended end use. For example, seals need to survive stresses incurred during distribution and handling. A peelable seal is desired for easy opening of packages so that the strength of the interface is less than that of the bulk package material and failure occurs at the seal interface. Seals in medical packages need to be hermetic — the seal must prevent the transmission of microorganisms into the package. The seal should not only be strong, but also should be designed to minimize film wrinkling or air entrapment.

Typical heated platen conditions for sealing Eastman™ copolyester packages to coated substrates (lidding, i.e. DuPont Tyvek, paper, etc.) will be discussed. This information can be useful in sealing thermoformed packages that meet the requirements discussed above.

Heated platen sealing

Thermoformed packages are placed into a frame that supports the package flange. Adhesive coated lidstock is placed over the package flange. A heated platen is lowered onto the lidding and pressure is applied for a specified time. The heat is transferred through the lidstock and activates the adhesive coating to form a seal at the flange.

Variables

Platen temperature — The temperature of the platen must be uniformly controlled. Note that the set point temperature is not the actual surface temperature of the platen nor the lidding material. Also note that the platen surface should be clean, not worn, and have an appropriate release coating.

Dwell or seal time — The time heat and pressure are applied to the substrates to be sealed to complete the bond.

Sealing pressure — Air pressure is typically applied to a cylinder or bladder that closes the platen.

Sealing conditions

Commercial lidstock with preapplied heatseal coatings is available that provides peelable seals with uniform adhesive transfer on thermoformed packaging made of Eastar™ and Eastman Tritan™ copolyesters. With the conditions listed below, seals are typically peelable (around 1 lb/in in 180 degree ultimate strength) but remain hermetic so that the sterile barrier can be maintained until opened for use.

- Platen temperature 127°–132°C (260°–270°F)
- Dwell time 1–2 seconds
- Sealing pressure 75–125 pounds per square inch of seal

Eastman™ medical copolyesters are versatile plastics for many packaging applications and can be effectively heat sealed.

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Material Safety Data Sheets providing safety precautions, that should be observed when handling and storing Eastman products, are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product in order to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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