Thermoforming tips

for Eastman Eastalite™ MP007F foamed copolyester

Follow these thermoforming recommendations to ensure optimum quality and performance of the package, especially for sterile applications:

- The temperature of the actual plastic sheet should be monitored and controlled. *NOTE:* The sheet temperature will not be the same as that of the oven temperature set point.
- Measure the maximum plastic sheet temperature (not surrounding metal) just prior to vacuum and/or pressure forming. Infrared thermometer, handheld pyrometer, and temperature-sensitive tapes can all be used for measurement.
- The sheet temperature should be as hot as possible without causing additional foaming, melting, sticking, or webbing. A good way to achieve the optimal forming temperature is to slowly increase forming temperatures until slight webbing occurs, then reduce temperatures until webbing disappears.
- **The recommended sheet temperature range is typically 230° to 285°F (110° to 140°C). This range can vary depending on the package/tool design.**
- If excess sag occurs, use cooler oven conditions toward the unwind and hotter conditions just before forming occurs.

Higher sheet temperature during thermoforming promotes lower internal stress in the final package and best dimensional stability on further processing, such as heat sealing and sterilization.

Should you have any further questions, visit the Eastman literature center at http://www.eastman.com/Literature_Center/S/SPMBS1604.pdf or contact your Eastman representative.

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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 to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

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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 (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

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