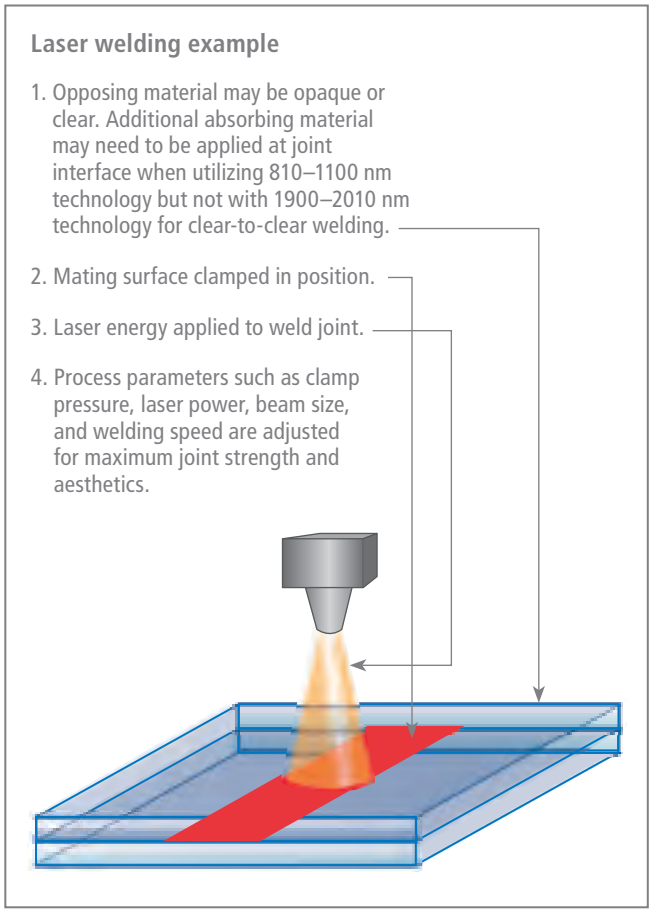
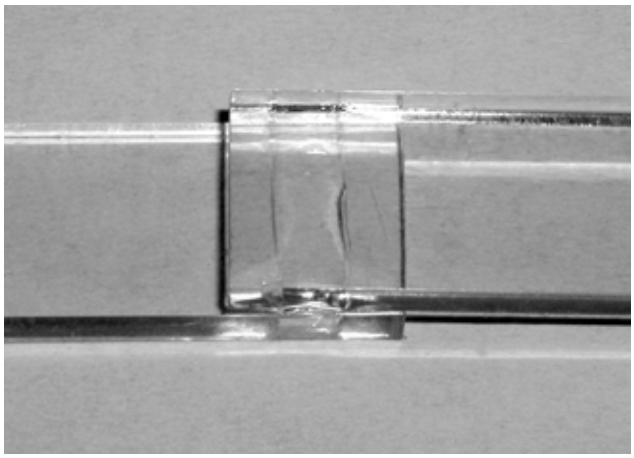
Laser welding Eastman medical copolyesters

Molded plastic medical devices frequently require joining multiple components to form a functional assembly. Common assembly techniques include ultrasonic welding, hot plate welding, vibration welding, solvent bonding, and various types of adhesive bonding. There are two laser welding techniques currently available for the medical market segment. Traditional laser welding operates at 810–1100 nm, and a more recent technology operates at 1900–2010 nm.



Laser energy is passed through a near-infrared transmitting part and is absorbed at the surface of a second near-infrared absorbing part. Energy sufficient to cause a temperature rise above the melting point of the polymer is supplied to the joint interface. Heat in combination with external clamping pressure causes the two surfaces to weld at the joint interface. Parameters such as laser power, laser beam width, and laser speed are used to optimize joint strength.



Laser welding can be accomplished with transparent to opaque or transparent to transparent. The part nearest the laser must be transparent/clear to allow proper transmittance of the laser to the weld joint for absorption.

Desirable characteristics of the laser welding process:

- Excellent joint strength with Eastman copolyester resins
- Excellent welded joint aesthetics with no surface damage
- No flash or particulate created by the welding process
- Very short weld cycle time, depending on part size
- No additional cure time required
- Clear-to-clear welds with no additives
- Automated process
- Simple joint designs
- Hermetic seals achievable
- Complex shapes possible
- Multiple welds possible
- Low residual stress

Weld efficiency is a measure of joint strength relative to the strength of the parent material. Weld strength data is currently being obtained, so feel free to reach out to Eastman for additional data, information, and assistance.

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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.

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 (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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