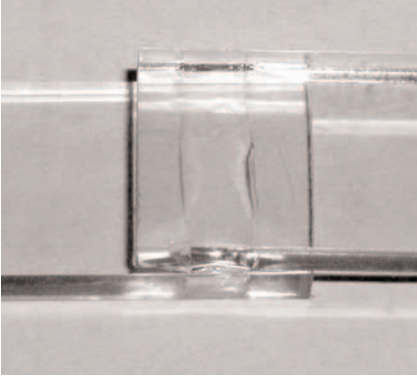


## The Material Difference™ In Medical Applications



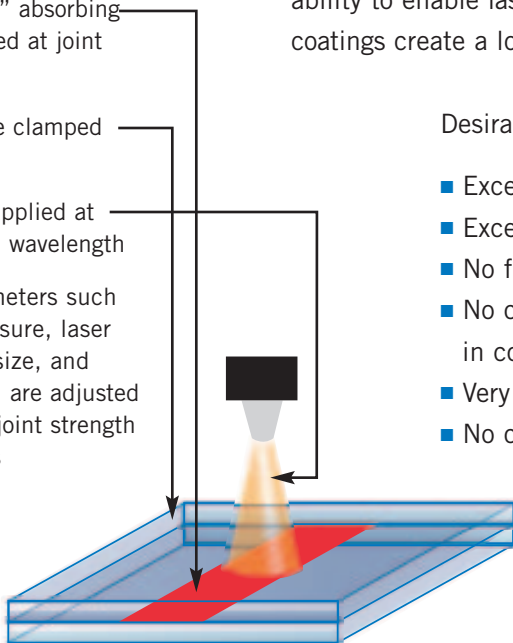
Injection molded plastic medical devices frequently require joining multiple components to form a functional assembly. Common assembly techniques include ultrasonic welding, hot plate welding, vibration welding, solvent bonding, and various types of adhesive bonding. A relatively new technique to the medical market segment is known as through-transmission laser welding.

## Laser Welding Eastman™ Medical Copolyester Materials

Through-transmission laser welding is accomplished using “near-infrared” laser energy at a wavelength of 810 to 1100 nm. Laser energy is passed through a “near-infrared” transmitting part and is absorbed at the surface of a second “near-infrared” absorbing part. This is enabled by the use of “near-infrared” additives. 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.

Historically, the use of lasers for welding polymers in the medical market segment has been limited due to the requirement for a transparent part being welded to an opaque, typically black or gray, substrate. Recent developments such as the Clearweld® welding process by Gentex Corporation have created a much greater scope of possible applications for laser welding by making it possible to laser weld two transparent parts. In this process, a “near-infrared” absorbing Clearweld® fluid is applied at the interface between two transparent parts. Alternatively, a Clearweld® additive is incorporated into the bottom substrate. When laser energy is applied, the Clearweld® material absorbs energy resulting in heat and a subsequent weld. Use of resins containing Clearweld® additives creates the ability to enable laser welding while matching a wide variety of colors. Clearweld® coatings create a localized weld that is essentially colorless.

- 1.) “Near-infrared” absorbing material applied at joint interface
- 2.) Mating surface clamped in position
- 3.) Laser energy applied at 810-1100 nm wavelength
- 4.) Process parameters such as clamp pressure, laser power, beam size, and welding speed are adjusted for maximum joint strength and aesthetics

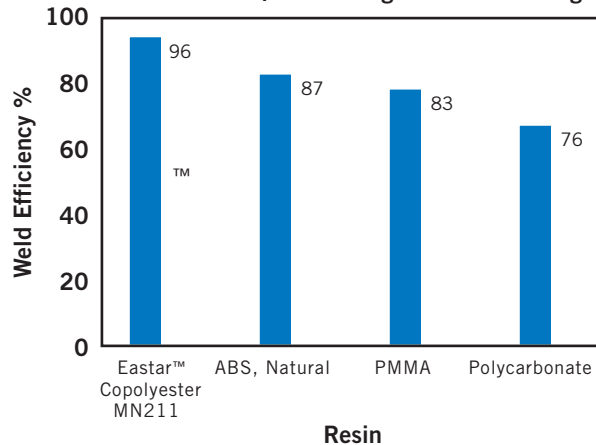


Desirable characteristics of the laser welding process:

- Excellent joint strength with Eastman™ copolyester resins
- Excellent welded joint aesthetics
- No flash or particulate created by the welding process
- No chemical attack or “crazing” of Eastman™ copolyesters in combination with the Clearweld® fluid
- Very short weld cycle time
- No cure time requirement

Weld efficiency is a measure of joint strength relative to the strength of the parent material. Butt joints of various resins were created using the Clearweld® Laser welding process and then pulled in a tensile tester until joint failure. Welded Eastar™ copolyester 6763 joints showed strength values very close to the parent material as shown in the chart below. Testing with other Eastman™ copolyester materials has shown similar results.

**Laser Welded Butt Joint Weld Efficiency of Various Resins (Weld Strength/Material Strength)**



Laser Wavelength—940 +/- 10 nm  
 Maximum Laser Power Output—300 W continuous  
 Laser Beam Size—2.0 mm x 2.0 mm  
 Maximum Laser Speed—10,000 mm/sec

Note: Welding conditions and sample geometry were not optimized in this experiment. Higher weld strength might be possible.

**Committed, Knowledgeable, and Enabling**

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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 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.*

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