Natvar & Gentex chose Eastman™ elastomer

to enhance Clearweld laser technology used to manufacture transparent Sure Bond medical tubing

Creating successful medical applications that deliver effective, safe, and accurate patient solutions often requires forging partnerships with the right mix of technological know-how. Natvar, a Tekni-Plex Company and a manufacturer of extruded products for the medical market, and Gentex Corporation, the leader in colorless laser welding technologies, recently partnered to develop the Sure Bond tubing solution. This new tubing with Gentex's patented Clearweld additive technology enables medical tubing to be laser welded to transparent medical components used in intravenous therapy, hemodialysis, cardiovascular, urinary drainage, catheterization, neonatal, and angioplasty applications.

The Clearweld additive eliminates the need for solvent or adhesive bonding, which often leaves behind residual bonding material. In addition, laser welded medical tubing helps eradicate the quality challenges that can occur when connecting a tube to a lure (connector), including leaking, occlusions, and crazing that might compromise a medical product's proper function. The ability to laser weld also creates a number of processing efficiencies, including a faster cycle time and reduced consumables. For example, with less bond surface area needed to weld, component manufacturers have the potential to reduce up to 50% in the amount of lure material needed in their applications.

Key to the success of the project was the role of Eastman Chemical Company, who applied their medical plastics expertise and assisted both companies in the selection of Ecdel™ elastomer as the outer layer of Natvar's 252 tri-layer tubing used for the delivery of unstable medications. The elastomer is the material critical in ensuring that the Sure Bond layer is clear, has optimal joint strength, and excellent product integrity.

"Gentex's Clearweld additive technology allows our medical tubing to be laser welded to other medical parts without compromising product performance," says Bob Donohue, Divisional Director of Technologies for Natvar. "Gentex's proprietary technology and Eastman's Ecdel™ [elastomer] medical plastics solution guarantees our customers are getting the best-performing medical tubing on the market."

Three is company

As part of its ongoing medical initiative, Eastman worked with Natvar and Gentex to conduct material testing and determine what product was most compatible with the Clearweld technology. The company's Ecdel™ elastomer was chosen because of its optimal laser welding characteristics — particularly its ability to remain crystal clear and to form a strong bond rapidly.

A PVC alternative, Ecdel™ elastomer (COPE) is orthophthalate-free and offers the clarity, toughness, flexibility, and chemical and heat resistance needed in crucial medical applications. Ecdel™ elastomer also withstands EtO and gamma sterilization techniques without the yellowing associated with PVC.

In this application, the Sure Bond tubing consists of a tri-layer coextruded tube of a polyethylene inner layer to prevent absorption, a proprietary middle layer for adhesion, and a layer of Ecdel™ elastomer for bonding. In the laser welding process, the Clearweld additive compounded into the layer of Ecdel™ creates an optically appealing, stable joint without unwanted gaseous inclusions.

"Other commonly used medical bonding techniques often create stress on an IV set or another medical device that delivers unstable medication, which after sterilization might create leaks or occlusions and negatively impact, for example, insulin delivery to a patient," says Donohue. "We haven't had any of these failures with the Ecdel™ [elastomer] — it's been great."

"Eastman's long-term relationship with Natvar proved pivotal to the Clearweld project," stated John Pullo, Vice President and General Manager, Performance Materials, Gentex Corporation. "Eastman's expert medical team educated and advised us on the best material choice that worked with our proprietary technology."

Color-flexible technology

The Clearweld additive technology is based on specially designed organic absorbers and enables a clear-to-clear weld that provides the necessary clarity and visibility medical personnel need when monitoring fluids being administered to patients via specialized tubing. Historically, the use of lasers for welding polymers in the medical market segment was limited due to the requirement of a transparent part being welded to an opaque, typically black or gray, substrate. Now the new technology offers color flexibility that is essential for creating custom solutions that meet application requirements.

The Sure Bond manufacturing process incorporates near infrared-absorbing colorless additives that are compounded into a thermoplastic before it is extruded into medical tubing. These light-absorbing additives focus laser energy at a wavelength of 808 to 1090 nm, converting it to heat. Localized heating at the interface of the lure and tube produce strong (60 to 70 pounds), hermetically sealed welds with minimal thermal and mechanical stress or presence of particulates.

"Our Clearweld technology enables two different materials to be joined into a single part that has excellent joint aesthetics," says Pullo. "Plus, Clearweld laser welding eliminates UV curing which may require up to 20 seconds of curing time."

The Clearweld technology produces a far superior bond than solvent or adhesive bonding, and creates assembly line efficiencies. Moreover, the technology is reproducible, making it ideal for medical applications that need optimum product integrity and consistent quality.

Market advantage

Clearweld technology has brought the tube-joining process of clear-to-clear parts to the next level. The Clearweld additive technology is non-invasive to the fluid path and can be used effectively within the high pressure injector tubing market. New Sure Bond tubing withstands pressures better and helps avoid catastrophic bond failure during intense surgical procedures. As a result, Sure Bond medical tubing is a more robust, effective product that can be used for a variety of patient-care products.

"Our goal was to create tubing products that provided our customers with a solution to their bonding issues, effectively meeting the needs of a wide range of medical markets," states Donohue. "We have an extensive list of customers who have entered the development and validation stage of this new Sure Bond technology."

About . . .

Gentex

Established in 1892, Gentex is a privately owned corporation with four operating units: Helmet Systems, Performance Materials, Respiratory Products, and Electro-acoustic Products. The company is a world leader in high performance products and systems for both the military and commercial markets with extensive research and development capabilities. For more information visit www.gentexcorp.com.

Natvar

For over 50 years, Natvar, a Tekni-Plex Company has been the leader in tubing extrusion technology for the medical and industrial markets. Teamwork starts with our associates gaining an understanding of what our customers value most, and we spend a lot of time developing that understanding. We believe that the team concept of manufacturing is essential for the long-term success of Natvar and our customers. Natvar's goal is to always exceed our customers' expectations in quality, service, engineering, and cost. Additionally, the Natvar team prides itself in its responsiveness and constantly works with customers to improve our ability to react to this ever changing medical market. For more information, please visit www.natvar.com.

Eastman in the medical market

For more than 65 years, Eastman™ plastics have been used in a wide range of medical devices and packaging applications that meet the performance demands and regulatory requirements of the medical industry. Our diverse product line of Eastman Tritan™, DuraStar™, and Eastar™ copolyesters, Ecdel™ elastomers, and Tenite™ cellulosics provides a broad range of properties that deliver application performance and flexibility in sterilization techniques. Eastman has enjoyed the trust of the industry's foremost innovators, and we continually collaborate with our partners throughout the industry to develop medical devices and packaging on the cutting edge of science. For more information, please visit www.eastman.com/medical.

Eastman Chemical Company

Eastman's chemicals, fibers, and plastics are used as key ingredients in products that people use every day. Approximately 10,000 Eastman employees around the world blend technical expertise and innovation to deliver practical solutions. The company is committed to finding sustainable business opportunties within the diverse markets it serves. A global company headquartered in Kingsport, Tennessee, USA, Eastman had 2009 sales of $5 billion.

For more information about Eastman and its products, visit www.eastman.com.

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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.

MBS-401A 2/11
Printed in U.S.A.