



Building better bonds

Eastman recently found that many medical device developers and original equipment manufacturers were seeking guidance on the best adhesives to use with Eastman Tritan™ copolyester. After finding that there was a lack of up-to-date research about adhesives and their use with Tritan, Eastman decided to conduct testing so the company could better advise its customers. Henkel Corporation and Eastman joined forces to test various resins and adhesives for use in medical devices.

The optimal collaboration

By collaborating with Henkel Corporation, whose LOCTITE® adhesive continues to be tested at the industry's most comprehensive ISO 10993 biocompatibility standards, Eastman looked to determine which resins and adhesives, when used together, could optimize a manufacturer's assembly process. Both companies hoped to demonstrate to their customers that using adhesives, as opposed to solvent bonding, would save them both time and money during production.

Testing took place in Henkel's ISO 17025 accredited laboratory following ASTM D3163. Through research, the companies discovered that the use of Tritan and LOCTITE together created superior results. From improved curing to increased flexibility, the advantages of using Tritan with LOCTITE adhesives were extensive, making for ideal optimization.

These results helped provide knowledge and key insights to Eastman's and Henkel's customers regarding the production process. By using Eastman and Henkel products in conjunction, producers can combat safety issues such as breaking and cracking, resulting in fewer defects and longer-lasting

products while lowering sunk costs. By helping manufacturers and developers understand the best adhesive option from the outset, Eastman can help clients eliminate the need for trials and testing, also reducing production costs.

Superior results mean saving money.

Through the collaboration with Henkel, Eastman sought to find the best adhesive solution for its customers. Henkel plans to continue testing Tritan with other products to help users choose the best-performing material when used in conjunction with the copolyester. By using products that perform better when made with Tritan, customers can increase a device's lifetime use and save time and money during assembly.

Through this proactive research approach, Eastman helped lower the hurdles for medical industry customers and provided guidance on best practices when using adhesives with Tritan. These actions helped customers speed up their manufacturing processes, improving their bottom line.



EASTMAN

The results of insight™

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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 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.

The suitability of an Eastman product in a given end-use environment is dependent on 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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