

Redpoint Engineering in the News

Biomedical Capability

In partnership with key manufacturing sources, Redpoint Engineering has the demonstrated capability for designing and delivering state-of-the-art biomedical products to our clients.

Biomedical products typically have physical requirements that differ in some respects from other products. Those requirements usually center around the need for materials that are compatible with the human body. Not only are such products regulated by FDA requirements, but they must also be able to withstand multiple sterilization cycles involving high temperatures or the use of solvents, or both.

Redpoint Engineering is experienced in the design of such products. We understand the properties of biomedical safe materials, and we understand the constraints on processing those materials to produce sound and economical parts. As an example, the parts we have been designing and molding at Ki Tat currently are using Lexan HP2NR and Lexan HPX4. Both of these are FDA approved biocompatibility tested (FDA USP Class VI/ISO10993) plastics.

Lexan HP2NR is clear Polycarbonate plastic. 121C autoclavable for a handful of cycles. We are utilizing it in a lens for a product used for skin care treatment. Ki Tat has been able to mold this material at almost defect free levels in the past 2 years.

Lexan HPX4 is a Siloxane copolymer. It performs better in autoclave at 121C (a few dozen cycles, again depends on in-mold stress, morpholine level in autoclave etc. It has a slight haze in its natural state. It is being colored with FDA approved dye to a gray Pantone 430C color when molded on an oral device used by sleep apnea patients. After molding at Ki Tat, the parts go through a thermal press process that creates 300+ features necessary for the retention of the epoxy applied by the user. Parts are thoroughly cleaned in isopropyl alcohol solution, heat dried then bagged and boxed for shipment.

Here is a picture of the product:



About the Author

Redpoint Engineering, www.red-pt.com, is a mechanical engineering design firm that designs and develops products for its clients. Serving as a mechanical engineering resource for clients virtually, Redpoint either augments or fills the role of a full service mechanical engineering department. In partnership with key manufacturing sources, Redpoint Engineering has the demonstrated capability for designing and delivering state-of-the-art biomedical products.

In addition to the products cited in the article above, [Redpoint Engineering](http://www.red-pt.com) has designed titanium parts used in spinal fusion surgery, and the plastic housings for several versions of disposable pregnancy testers.

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