

An Emerging Option for Your State-of-the-Art Medical Device Assembly Process

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Summary

LIGHT-CURE ADHESIVE TECHNOLOGIES ARE CRITICAL TO MANY OF TODAY'S STATE-OF-THE-ART MEDICAL DEVICE ASSEMBLY PROCESSES.

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LED technology holds the promise of reduced energy consumption, lower operating costs, minimal heat transfer and improved safety. As the industry continues to evolve toward single-use, disposable devices and pricing pressures from healthcare providers escalate, medical device manufacturers must embrace technologies that facilitate high-volume, low cost production—all without compromising the rigorous quality standards that define this market. Light-cure adhesives, with their cure-on-demand capacity, pave the way for more efficient manufacturing of a wide range of medical products, including syringe assemblies, balloon catheters, tubing connectors, endoscopes and ostomy devices.

Traditionally, light-curing of adhesives relies on high-intensity light sources such as high pressure mercury arc lamps and electrodeless fusion bulbs. The recent introduction of light emitting diode (LED) cure systems, however, offers an attractive alternative. LED technology holds the promise of reduced energy consumption, lower operating costs, minimal heat transfer and improved safety. With these potential benefits in mind, medical device design and process engineers may be considering LED-curing either to retrofit an existing process or to facilitate a next-generation assembly. Optimal specification of the most appropriate cure system, whether LED or conventional, requires consideration of a constellation of factors. Foremost, designers must be aware of the inherent differences in the performance characteristics of these curing systems and how these may impact processing as well as the quality and functionality of the end product.

Light Cure Fundamentals

ADHESIVES THAT SOLIDIFY WHEN EXPOSED TO A SPECIFIC WAVELENGTH AND INTENSITY OF LIGHT DELIVER IMPORTANT PROCESSING ADVANTAGES.



These adhesives provide almost unlimited open time for positioning parts during manufacturing and cure rapidly and completely, typically within seconds of exposure. The ease of automation afforded by this rapid cure relies on the presence of a photoinitiator compound in the adhesive formulation. Exposure to the proper intensity and wavelength triggers the photoinitiator to generate reactive species, which in turn convert the resin monomers into a fully-cured polymer network. UV curing is accomplished using light in the 200nm to 400nm range and newer visible cure systems are available that cure with light in the violet and blue portions of the spectrum from 400nm to 500nm.

Lower irradiance lamps cure more slowly and may adversely *influence adhesive* performance characteristics *such as depth of* cure, tack-free surface cure, and bond strength.

When specifying light cure equipment, manufacturers must match both the wavelength and intensity requirements of the photointiator present in the adhesive. Light intensity is typically specified in terms of irradiance, which describes the light energy that falls within a particular spatial dimension of the adhesive during exposure. This property, measured in Watts per cm², directly affects cure time and depth. The total light energy delivered to the adhesive depends on the irradiance delivered over time. Thus, lamp irradiance directly affects cure times. Higher irradiance lamps cure faster but may induce stress cracking; whereas, lower irradiance lamps cure more slowly and may adversely influence adhesive performance characteristics such as depth of cure, tack-free surface cure, and bond strength.

Benefits of LED Cure Systems

MASS MIGRATION TO LED LIGHT SOURCES, DRIVEN BY THE TECHNOLOGY'S OUTSTANDING ENERGY EFFICIENCY, IS CURRENTLY TAKING PLACE ACROSS INDUSTRIES.







stresses induced

bonding process.

during the

maintenance costs owing to LED's long-life and durability. LED systems also offer key processing benefits important to medical product manufacturers. LED curing These include consistent power output over time and near-zero heat transfer systems offer to substrates. the benefit of extremely low heat transfer, which may mitigate the

Key to LED's wide appeal, the technology's notable resistance to degradation equals more consistent processing over time and significant savings in lamp replacement costs. While in reality every light source degrades, conventional mercury arc lamps degrade much more rapidly than LEDs for several reasons. Conventional lamps require an ignition process with adequate time allotted for warm-up and spectral output stabilization. The greatest wear on the lamp occurs during this ignition process as the light is cycled on and off. As such, to maintain stable spectral output and conserve lamp life, these lamps effectively remain in "on" mode during the entire work shift while the exposure to the assembly shutters on and off. Essentially a semiconductor, the LED can be turned on and off instantaneously. Thus, "on" times for the LED lamps are significantly lower over the course of a shift. The relative consistency in output of LEDs results in superior process control and decreases the need for frequent calibration.

For medical device assembly processes LED-curing systems offer ongoing

costs savings in terms of decreased energy consumption as well as minimized

Another benefit of LED technology, particularly relevant for manufacturing of sensitive medical and electronic parts, is the fact that it virtually eliminates exposure to heat during the curing process. The temperature under some UV lamps can reach 150°F. When materials of markedly different coefficients of thermal expansion (CTE) are bonded at elevated temperatures, mechanical stresses may be induced when the assembly returns to ambient temperatures. The induced stress may result in an accelerated mean time to failure for the assembly design. LED curing systems offer the benefit of extremely low heat transfer, which may mitigate the stresses induced during the bonding process.

Benefits of LED Cure Systems

- LOW CAPITAL INVESTMENT
- LONG LAMP LIFE ELIMINATES BULB REPLACEMENT COSTS
- MINIMAL POWER DEGRADATION
- CONSISTENT, REPEATABLE PROCESSING OVER TIME
- INCREASED OPERATOR SAFETY ELIMINATES THE NEED FOR PROTECTIVE EQUIPMENT AND CLOTHING
- LOW ENERGY CONSUMPTION
- MINIMAL HEAT TRANSFER
- MULTIPLE, INDEPENDENTLY-CONTROLLED ASSEMBLY STATIONS FROM ONE SOURCE

Key Performance Differences: LED versus Conventional Curing

AS MEDICAL DEVICE MANUFACTURERS WEIGH THE POTENTIAL BENEFITS OF LED FOR THEIR ASSEMBLY PROCESSES, THEY MUST ALSO TAKE INTO ACCOUNT KEY DIFFERENCES IN THE PERFORMANCE CHARACTERISTICS OF THESE LAMP SYSTEMS VERSUS CONVENTIONAL MERCURY ARC SOURCES.

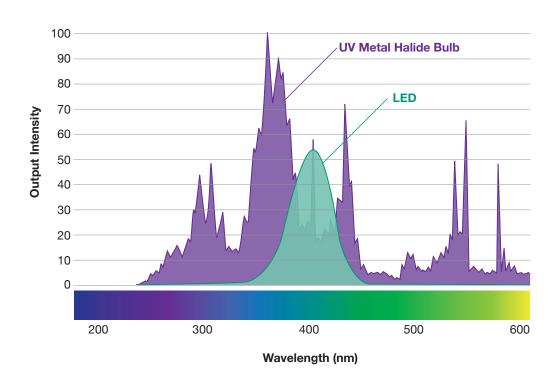


The most important intrinsic difference between semiconductor-based LED lamps and conventional electrical light sources arises from the distribution of their respective spectral outputs. LED sources produce an essentially monochromic light, emitting irradiance in a bell-shaped curve around a single wavelength. In contrast, conventional mercury lamps emit multiple energy spikes over a wide-range of wavelengths. (See figure, page 5) Present-day LED-curing systems are limited to discrete wavelengths between 365nm and

450nm, whereas mercury arc bulbs may emit multiple peaks over a range of several hundred nanometers. This difference has significant ramifications for adhesive selection and cure quality.

The number of adhesives compatible with LED systems is presently limited with the widest range of LED-compatible chemistries in the cyanoacrylate family. Efforts to expand the range of adhesives amenable to LED cure are currently underway. However, the legacy UV medical-grade light-cure adhesive systems respond most optimally to the spectral output from conventional curing lamps. The photointiators in these formulations are generally tuned to the wide spectral range and multiple wavelength emissions characteristic of these light sources. Indeed, the ideal surface cure for many of today's UV-cure adhesives occurs at a wavelength of 320nm, well outside the range of the current LED systems. While an "effectively" complete cure may be adequate for many applications, process and product designers must be aware of this limitation and its potential impact on biocompatibility. Output intensity can also differ considerably between LED and conventional curing sources. Because intensity directly affects cure time and quality, as well as adhesive bond strength process engineers must rigorously evaluate whether they can achieve the end product performance required when considering an alternative curing system.

SPECTRAL OUTPUT COMPARISON



A System Approach For the Future of LED

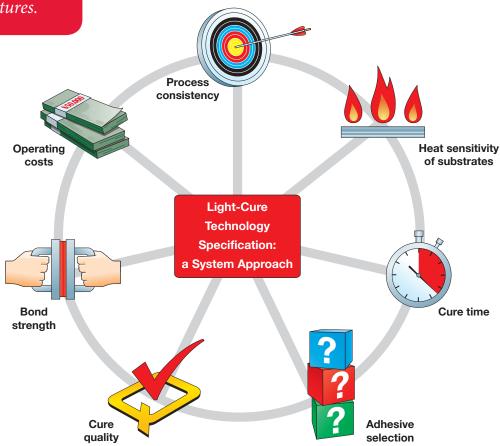
PRODUCT DESIGNERS SHOULD TAKE A SYSTEM-LEVEL APPROACH WHEN CONSIDERING LIGHT CURE ADHESIVES FOR THEIR APPLICATION.

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The advancement of LED curing technology depends on an ongoing collaboration between adhesives formulators and light-source manufactures.

The adhesive formulation and curing equipment need to be evaluated in tandem for the optimal combination to be selected. Comprehensive solution providers can be important partners in this selection process.

The advancement of LED curing technology depends on an ongoing collaboration between adhesives formulators and light-source manufactures. Formulators are currently developing new photointiators and adhesive chemistries to respond to the spectral characteristics inherent to LED light, while light manufacturers are exploring methods to achieve a more tailored spectral output. LED systems offering wider cure areas are expected to emerge in the coming years. The future of LED curing looks bright indeed.



Constellation of factors to consider when determining the optimal curing technology for your assembly process.

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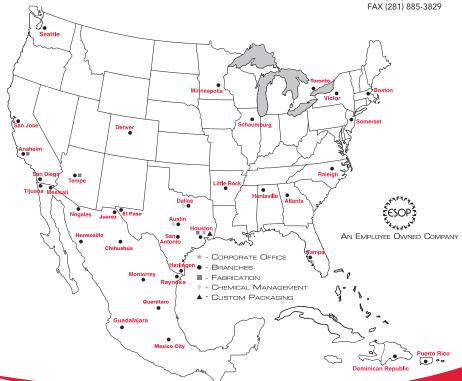
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