

Light Curing Cyanoacrylates Breakthrough Technology for Medical Device Assembly

Developed in 1999, light cure cyanoacrylate (UVCA) adhesives were created to provide all the advantages of cyanoacrylates and light cure adhesives without the limitations. Engineered to offer an immediate surface cure when exposed to low intensity light, this revolutionary technology cures in shadowed areas via a unique reaction with surface moisture.

Designed to provide tack-free fixture within seconds of low intensity ultraviolet light exposure, UVCAs are one-part and solvent-free. Uninhibited by oxygen, the adhesive forms a dry, glassy surface with even minimal light source exposure.

Tack-free cure is essential when an adhesive is used as a coating in device applications or when excess adhesive is inevitable. Even UVCA adhesives applied in shadowed areas cure quickly at room temperature due to a secondary moisture cure mechanism, and fillets of adhesive take only seconds to cure with exposure to low intensity light. Fast cure times prevent blooming and frosting without the need for accelerators.

UVCA adhesives deliver a range of high-speed assembly performance benefits. Fast and reliable, these adhesives process quickly and cure rapidly without heat or racking of parts. Based on cyanoacrylate chemistry, UVCAs offer high bond strength for a range of substrates to deliver enhanced performance with a guaranteed complete cure.

Processing: Dispensing and Curing UVCAs

There are two light cure cyanoacrylate variations currently available: low viscosity (20 cP) and high viscosity (900 cP) variations, which allow materials to be dispensed in various ways. For instance, manual dispense methods allow the adhesive to be applied directly from small packages to the device in moderate production quantities. Pressure-time and positive displacement dispense systems ensure consistent quality for semi- and fully-automated production applications.

Cyanoacrylate-based UVCAs are subject to the same challenges as their parent technology, and device manufacturers must therefore carefully consider dispenser type and method to avoid premature cure or accelerated aging. Using low intensity light sources to ensure a full cure, UVCAs produce a lower overall capital expenditure.

The improved cure through depth of UVCAs makes them ideal for applications such as filling large bond areas in fluid collection device housings, or potting of surgical monitoring device connectors and bodies. UVCAs prevent stress cracks while allowing an adhesive cure to depths of more than 0.25 inch in less than 15 seconds.

Typically dependent on the substrate, fixture time for the adhesive's secondary shadow cure can vary from seconds to several minutes. Shadowed areas require adequate surface moisture with relative humidity levels of 40 to 60 percent to achieve a full cure within approximately 24 hours.

Typical Performance Data

Often used for plastic disposable device assembly, light cure acrylics and cyanoacrylates provide unusually high bond strength to plastics.

<u>Plastic</u>	<u>Approximate Shear Strength (in PSI)</u>
ABS	5000
Polycarbonate	4000
PVC	4800
Polypropylene (untreated)	60
Polyethylene (untreated)	60

Specially developed primers can actually enhance bond strength of UVCAs on difficult-to-bond plastics like polyolefins and fluoropolymers, unlike most light curing acrylics, and are often used with medical device applications involving tubing, components and housing. Priming typically results in more than a 100% increase in shear strength of polyolefin substrates and fluoropolymers. UVCAs provide superior bond strength to elastomers, similarly to traditional cyanoacrylates.

Typical Resistance Properties

UVCAs form thermoplastic polymers with a typical maximum operating temperature of 180°F in their cured state. Heat aging polycarbonate specimens bonded with low viscosity UVCAs at 160°F for approximately 350 hours yielded in excess of 80% retention of initial shear strength, and approximately 100% with high viscosity cure. Both UVCA viscosities yield a minimum 100% retention of initial strength after as many as 500 hours of heat and humidity aging. For fluids such as isopropanol and water that are commonly used with medical devices, these adhesives offer good resistance while either maintaining or increasing in strength to ensure optimal long-term performance.

Post-sterilization bond strength retention is crucial to device manufacturers. As defined by *The Condensed Chemical Dictionary, 10th Edition*, sterilization refers to the complete destruction of all bacteria and/or infectious organisms in a product. While sterilization methods vary by manufacturer, gamma and ethylene oxide (EtO) are the most common large volume approaches.

- Gamma sterilization is dependent on a cobalt 60 radiation source for eradication of bacteria and infectious organisms. While this does involve significant capital expenditure, the process can easily be completed on fully packaged devices.
- Ethylene oxide involves use of poisonous gas to eliminate bacteria and infectious organisms. Because this process is performed at room temperature, EtO offers a viable option for thermally sensitive devices and is often administered once final packaging is complete.

Other common sterilization methods include autoclave, liquid sterilization and hydrogen peroxide. These approaches, however, are typically used with smaller batch processing at facilities such as hospitals or other health care operations.

- The autoclave method uses pressurized steam at temperatures of 120 – 132°C for a rigorous 5-15 minute cycle. The most widely used sterilization method, autoclave is also the most damaging to certain adhesive and substrates.
- Liquid sterilizers, which require extended submersion for up to 12 hours, are often not a viable solution for devices requiring rapid sterilization. However, this method is ideal for use with devices with high thermal limitations.
- One of the newer approaches to sterilization, hydrogen peroxide does not involve toxic chemicals or require heat or steam. Unfortunately the cost of a hydrogen peroxide sterilization system may not prove cost effective for many facilities.

Light curing cyanoacrylates are generally engineered to withstand exposure to all of the above sterilization methods aside from repeated exposure to autoclave. If autoclave sterilization is necessary, the adhesive, substrate and joint design should all be carefully considered.

Biocompatibility

Confirmed ISO-10993 compliant, UVCA's have been biocompatibility tested using Class VI screening evaluations for cytotoxicity and hemocompatibility.

UVCA Applications

Catheter Assembly

The traditional choice of catheter manufacturers due to rapid fixture and ease of use, standard cyanoacrylates can lead to excessive blooming within a sealed package if adhesive is squeezed from the bond joint. UVCA's allow for rapid assembly while eliminating this issue.

Infusion Device

There are two types of adhesives typically used for the assembly of an infusion device. A light curing adhesive acrylic will allow for rapid bonding but the device also requires a cyanoacrylate adhesive to ensure shadowed areas are sufficiently bonded.

Migration to a UVCA, however, will allow both assembly operations to be accomplished with a single adhesive. Low intensity light replaces the high intensity source required for a light curing acrylic, reducing overall handling and production time as well as the potential for stress and blooming.

Surgical Pressure Transducers

Adhesive used with PVC cable housing can migrate into shadowed areas to prevent a full cure, while traditional cyanoacrylate adhesives used in conjunction with an accelerator can result in whitening of the bond line. By replacing these options with UVCA technology, assembly is quickly and successfully accomplished using a single adhesive.

This article is based on an original publication by Loctite.