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Advances in UV Curing for Medical Applications

Light-cure adhesive technology has been around for a long time. But recent advances in automated assembly and other areas make it a cost-effective method for bonding.

A set dose of UV light instantly hardens the adhesive, creating a very strong bond junction.

Light-cure adhesives offer a wealth of advantages, including very fast cure time and low energy use. The major benefit of ultraviolet (UV) curing is that it is a cure-on-demand process. The adhesive will not cure until the UV light hits it, and when that occurs, it takes only seconds to form a complete bond. The process is fast, solvent free, and economical.

UV curing has come a long way, particularly in the area of automated assembly, as a cost-effective method for bonding medical devices. Several years ago, UV-cured adhesives were thought to have limitations compared with other bonding methods, but recent developments in UV chemistry and cure-system hardware have greatly expanded the applications for UV curing.

Technology Overview: UV Curing Basics

Mercury arc lamps are commonly used for UV spot curing. A typical arc lamp consists of a burner, a reflector, and terminals.

To bond together two substrates, whether similar or dissimilar, the first step is to select the appropriate adhesive. The next step is to dispense a predetermined amount of that adhesive around the parts to ensure proper wetting. Once that process is complete, a light source that is set to deliver a preset dose of UV light is triggered. This process results in the instantaneous hardening of the material, creating a very strong bond junction.

Mercury arc lamps are commonly used for UV spot curing. A typical arc lamp consists of a burner (light generator), a reflector, and terminals. The burner is a hollow quartz tube sealed at both ends, filled with a starter gas and a trace amount of mercury. Metal electrodes pass through the ends of the sealed tube and form a small arc gap. The arc tube is held in an elliptical reflector, which has a highly reflective coating in a desired spectral range. During operation, a voltage spike is applied to the electrodes to break down the starter gas and vaporize the mercury. High-end systems now offer proprietary low-strike-voltage power supplies to increase lamp life. Once the gas has been broken down, a current passes through the gas at a lower voltage to generate the illumination power.

UV adhesive bonding is used in a wide range of medical applications for bonding, sealing, coating, and repair.

Lamp radiance is the total power emitted from the source divided by the area of the source. Irradiance, or intensity, is a measure of the power directed onto a target divided by the area of the target. Irradiance depends on the optical power output from the lamp, the design of the lamp reflector, and delivery optics. Radiance and irradiance are measured in power per unit area, typically expressed in milliwatts per square centimeter (mW/cm2).

Adhesives contain photoinitiators, which need a specific level of energy at a specific wavelength to create a curing reaction. Because each type of adhesive has individual curing needs, the wavelength and intensity of the light must be matched to the formula of the adhesive.

In the light spectrum, pure UV light is typically in the wavelength range from 200 to 400 nm. It falls below the visible portion of the light spectrum, which is the light beam’s intensity property. Radiometers are needed to measure the intensity of UV light. The intensity of light falling on a surface is measured in milliwatts per square centimeter.

Most medical adhesives have a UV component that usually absorbs at 365 nm. That wavelength offers enhanced surface cure to remove tackiness. The adhesive will also have a visible portion, which is 400 nm and above. Visible light, because it has a longer wavelength, actually travels farther into the part. Therefore, a combination of UV and visible light offers the best surface cure and cure depth, particularly when dealing with translucent plastic parts. It is important to recognize that most UV light can be attenuated or blocked by the part itself. To compensate for this attenuation, visible light must be present.

Applications of UV Curing

UV adhesive bonding is used in a wide range of medical applications for bonding, sealing, coating, and repair. Typical UV-bonded devices include:

• Catheters.
• IV delivery systems.
• Endoscopes.
• Atraumatic guidewire tips.
• Cannulae.
• Arterial locators.
• Tubing drainage sets.
• Endotracheal tubing.
• Angioplasty accessories.
• Blood oxygenators.
• Connectors.
• Hearing aids.
• Syringes.
• Medical filters.
• Silicone rubber components.
• Respiratory masks.
• Sensing devices.

In the light spectrum, pure UV light is typically in the wavelength range from 200 to 400 nm (click to enlarge).

Needle-hub bonding and catheter assembly offer a good overview of modern UV bonding. These applications are performed in semi- or fully automated assembly environments where the parts are delivered to the bonding process or indexed in a fixture. Needles are placed into their hubs and are cured using a multilegged light guide or special optical cylinder to ensure that the parts are evenly cured.

Because needles have a slanted point, accurate positioning of the part is key for automated curing. To hold the tube in place at the specific orientation needed, manufacturers originally built custom carriers, requiring additional expense and labor. Today, manufacturers can use a common fixture, and they can tack needles in place using adhesive and UV light for a quick spot cure. This process is not done to cure the material entirely, but rather to hold the parts in position temporarily as they move down the line.

Adhesives used in catheter assembly and balloon-bonding applications are required to withstand severe temperature and pressure conditions. New UV cyanoacrylate formulations are well suited to catheter applications. The bonding of balloon catheters must have a 360° cure to maintain a uniform bond around the perimeter of the part. New curing systems provide a variety of custom-designed curing accessories that deliver 360° irradiation.

A handheld radiometer is similar in size to a personal digital
assistant and enables the user to set all systems remotely..

Syringe production is typically a very-large-scale automated process. Manufacturers may run 100–500 syringes per minute, requiring precise, highly repeatable doses of UV irradiation. Adhesives are automatically dispensed in the hub. The cannula is inserted into the hub, fixed in place, and presented in an array for curing. Systems use a multilegged light guide or multiple-light configuration to ensure that light is directed at all areas simultaneously for one-step curing. Curing is fast—parts need to be exposed to light only for a couple of seconds before moving down the line to the next stage.

Matching Materials to Applications

It is important to ensure that the right material is specified for each application. Just as substrate materials are selected for performance, the adhesive material must be designed into the process. UV-curable adhesives used for medical applications include:

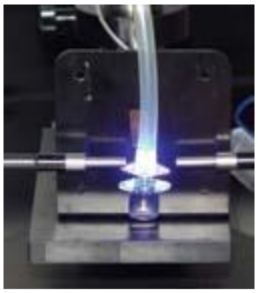
• Acrylics for needle assembly, anesthesia masks, and oxygenators.
• Cyanoacrylates for bonding catheter components.
• Polyurethanes for bonding tips onto various components and assembling components requiring considerable flexibility.
• Silicones for bonding and sealing silicone-based assemblies and device coating.
• Epoxies for needle assembly.

These adhesives are available in formulations with varying viscosities, cure times, temperature resistance, and strength properties. All UV-cured adhesives are characterized by low process temperatures and high polymerization rates (from several to approximately 60 seconds). It is imperative that the exact UV dose (time, temperature, irradiance) corresponds with the needs of the specific adhesive material.

Different types of light guides can be used for UV spot curing.

When matching a light source to any UV-curable adhesive, the key points are to determine the photoinitiator value in the adhesive and the transmission characteristics of the substrate. Cure depth depends on the wavelengths of light used, absorption properties of the adhesive material, and thickness of the adhesive bond. Again, the combination of UV and visible light provides an improved range of cure speeds and depths, and enables a wider range of applications.

Curing Equipment



Parts can be delivered, or indexed in a fixture, to the bonding process.

Two types of UV curing technologies—spot-curing and flood curing—are currently available. Spot-cure systems are designed to deliver high levels of focused energy onto small areas. The systems consist of a lamp that is typically focused onto a flexible light guide. The guide enables the user to deliver energy to cover areas up to approximately 3 in. in diameter on three-dimensional bond lines. Flood systems are designed to deliver light to a large area or focused band. These systems consist of a lamp and a parabolic or elliptical reflector that evenly distributes light over a larger area, typically in the range from 6 to 8 in. They are commonly installed above conveyors.

Spot curing is the most commonly used bonding technology for medical product applications. This irradiance may be delivered in an actual spot of light (3–8 mm diameter) or in a customized shape, which is delivered through attached optics.

In medical applications, it is important that the dose of irradiance delivered to the part be consistent to ensure repeatability. In a manufacturing process, each catheter, whether the first or the 200th, must be bonded identically with the exact dose of irradiance to ensure quality.

Cure rings enable a 360Þ cure and can be fixed (above) or hinged.

Undercuring or overcuring affects the integrity of the final product. Therefore, the criteria that need to be addressed when choosing a UV curing system are process control and repeatability. The system selected must be able to adjust lamp output. It is important to select a spot-cure system that incorporates closed-loop-feedback control, whether manual or automated, and an integrated radiometer or intensity monitor. These functions are critical for making necessary adjustments to compensate for lamp degradation.

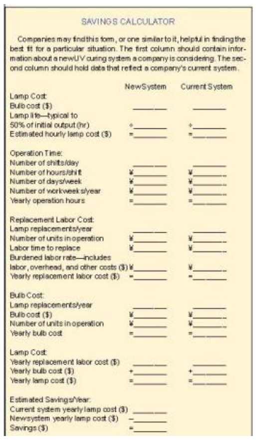
It is an inescapable fact that all mercury arc lamps degrade with use. The average life of a lamp is 2000 hours. Over an average 7.5-hour work shift, that corresponds to about a year’s use on one shift. Therefore, a good system must have the ability to adjust that light.

Traditionally, UV spot-cure systems have controlled this adjustment via output voltage to the lamp. The limitation with decreasing lamp voltage is that it can only be reduced to a certain level, after which the lamp will not produce light. Lamps can only be adjusted to approximately 70% of their power supply. If 5 W/cm2 (a fairly common level) is required, a 20-W/cm2 lamp can only be adjusted down to possibly 13 or 14 W/cm2. This restricted adjustment range can limit the process window or consistency.

High-end UV spot-curing systems adjust the lamp output by mechanical means, using an iris for control. Incorporating an adjustable iris in front of the lamp does not affect the steady voltage flow to the lamp, and it offers a much wider adjustment range.

Many leading-edge UV curing systems also incorporate closed-loop-feedback control technology. The iris is automatically adjusted to open as the power of the lamp declines, providing repeatable output. If a new lamp has an output of 20 W/cm2 and the application requires 5 W/cm2, the system would initially be set to 25%. As the lamp degrades, the amount of light the iris lets out would increase to ensure that the critical 5 W/cm2 is constant. Once the iris has opened to 100% and the lamp can no longer produce 5 W/cm2, an alarm indicates that the lamp needs to be replaced.

This type of system uses a beam splitter in the optical path coupled to electronics that control an adjustable iris. The system detects when the lamp output begins to decline and opens the iris slightly to maintain the desired irradiance output.
Many different lamp configurations can affect the performance and output from a spot-curing system. Increasing a lamp’s electrical power rating does not translate into a proportional increase in deliverable light. To maximize collection and delivery of output from a lamp, a number of optical and engineering issues must be considered. Coupling the lamp output into the delivery system can maintain high system efficiency and optimize lamp life.



SAVINGS CALCULATOR

Companies may find this form, or one similar to it, helpful in finding the best fit for a particular situation. The first column should contain information about a new UV curing system a company is considering. The second column should hold data that reflect a company's current system.

	New System	Current System
Lamp Cost:		
Bulb cost ($)	______	______
Lamp life—typical to 50% of initial output (hr)	÷______	÷______
Estimated hourly lamp cost ($)	=______	=______
Operation Time:		
Number of shifts/day	______	______
Number of hours/shift	¥______	¥______
Number of days/week	¥______	¥______
Number of workweeks/year	¥______	¥______
Yearly operation hours	=______	=______
Replacement Labor Cost:		
Lamp replacements/year	______	______
Number of units in operation	¥______	¥______
Labor time to replace	¥______	¥______
Burdened labor rate—includes labor, overhead, and other costs ($)	¥______	¥______
Yearly replacement labor cost ($)	=______	=______
Bulb Cost:		
Lamp replacements/year	______	______
Bulb cost ($)	¥______	¥______
Number of units in operation	¥______	¥______
Yearly bulb cost	=______	=______
Lamp Cost:		
Yearly replacement labor cost ($)	______	______
Yearly bulb cost ($)	+______	+______
Yearly lamp cost ($)	=______	=______
Estimated Savings/Year:		
Current system yearly lamp cost ($)	______	
New system yearly lamp cost ($)	–______	
Savings ($)	=______	

Companies may find this form, or one similar to it, helpful in finding the best fit for a particular situation. The first column should contain information about a new UV curing system a company is considering. The second column should hold data that reflect a company's current system.

Modern high-end spot-curing systems offer an array of standard and custom light-delivery methods. The main type of light delivery used in conjunction with UV spot curing is a light guide. Since the light guide is responsible for collecting and transporting the light, many modern UV spot-curing equipment manufacturers have developed high levels of expertise in both liquid and quartz-fiber light guides. The attributes of each type of guide define the applications to which it is most suited. For example, a liquid light guide has higher collection efficiency than a quartz-fiber guide, and so it tends to be more economical for single-point curing. However, quartz-fiber light guides are also useful when numerous cure sites are to be exposed (up to 8 legs) or where uniformity is critical.

Light delivery is critical with circular devices or bond lines. If the cure hits unevenly, or from one side, it may skew the part, which can create a void. Today, a wide range of optical accessories is available to enhance the curing process. Optical accessories such as cure rings are available to provide a 360Þ cure via fibers that surround the part, making them ideal for syringes and catheter balloons. Using a cure ring or a fixture that will position as many as four light guides around the part ensures an even cure. But sometimes a 360Þ cure is not necessary. Some applications only need two light guides opposite one another to expose the entire circumference of a part. The savings calculator form on page 102 should enable a company to calculate its own numbers to help find the best fit for a particular situation.

The Latest in Process Control

One of the most recent developments in curing is the ability to use a National Institute of Standards and Technology (NIST)–traceable handheld radiometer that can program and calibrate multiple curing systems. It uses a radiometer outside of the light box that enables the user to set all systems remotely through an IR link—similar to a personal digital assistant. Once irradiance has been set, a user can walk down the production line and set all systems to that same benchmark. The radiometer takes approximately 5–10 seconds to set and self-calibrate each system.

Even with individual-calibration radiometers that are NIST traceable, there can be a variance between systems of typically ±10%. Many UV spot-cure systems notify the user when the system is due for calibration, eliminating guesswork from the process. These types of intelligent systems offer the highest level of process control and repeatability. From a production standpoint, having an external radiometer also eliminates the need to send back the entire UV spot-curing system for calibration, saving time and reducing cost. Any variance in the calibrated set point will result in an automatic warning that enables action to be taken before any process variations can occur. Once the system is calibrated, feedback control is automatic.

Manufacturers can tack needles in place using adhesive and UV light for a quick spot cure (click to enlarge).

Another recent control technique that saves time and helps maintain repeatability is embedding sensors and electronic controls within lamps to optimize performance and monitor lamp hours. Doing so ensures that each system maintains a constant lamp temperature, thereby promoting long lamp life and constant output. Some manufacturers offer lamp warranties of 2000+ hours that can reduce the risk of higher lamp costs. These warranties are easiest to administer if the lamp automatically tracks its hours through electronic monitoring devices.

Closed-loop-feedback technology also aids in overall process control. When dissimilar substrates are heated, parts absorb heat differently and expand at different rates. There is the potential to build stress into the bond; therefore, it is important to deliver the proper amount of energy while ensuring that all other variables are kept in check.

Systems that include embedded software enable the user to set different cure profiles via a PC. This control allows the user to program specific times, dwell (duration of exposure), and irradiance levels. The ability to create multistep curing profiles for controlling the curing process can minimize shrinkage and facilitate alignment between components during the cure.
The combination of computer programming and lamp control enables quick parameter changes. Parts can be easily processed at one setting in the morning and, if needed, all parameters can be quickly and seamlessly changed to process parts with different curing requirements in the afternoon.

Linking Curing to the Total SPC Chain

Optimum curing must be based on monitoring all critical information during cure. This process includes repetitive analysis of key performance criteria measured via functional performance tests on the bond. Commonly, these criteria include specifications for pull strength testing, leak testing, pressure testing, or hardness testing of the material.

To optimize the cure, the dose of energy should be adjusted and each part tested to build a knowledge database. This way, a user can easily access data for specific applications. The comparison of actual characteristics to predicted values derived from computer simulations of cure cycles allows the control of processes by determining the rate and direction of change of variables in relation to other process variables.

Many commercial curing systems now incorporate intelligence through the use of embedded microcontrollers. Using electromagnetic interference shielding and proprietary lamp ballast board design, this is possible even with the high levels of radio-frequency noise generated by arc lamps. With onboard intelligence, systems can regulate output, control feedback, perform process monitoring and recording, and include integral safety features. Custom software developed for each system ensures optimal system performance and ease of use.

The key, of course, is that a statistical process control (SPC) program must be easy to operate or it won't be used. Modern systems have been streamlined to cut to the basics and remove data clutter. High-end systems have RS-232 ports and direct PC control, as well as 2–15-pin I/Os. From an automation standpoint, the user can pull all the alarms and information right from the systems. This ensures good SPC data for comparison, tracking, and analysis. Users can give each unit an ID address, and personnel on or off the production floor can monitor all the UV systems from one computer. Data from specific processes can be saved to individual menus for process control analysis and can allow operators to generate product history travelers.

Conclusion

Several product attributes influence a manufacturer's choice of the most suitable UV light source. These attributes include system efficiency, spectral output and available control mechanisms, and the physical response of the adhesive being cured. The goal is to deliver light effectively in a system with a fairly low operating cost. Therefore, it is important to compare systems and look for versatile equipment with good control mechanisms.

Taking an informed approach when selecting equipment will help to optimize the process performance, repeatability, and reliability, and minimize cost per completed assembly. Traceability and repeatability are the critical elements in medical device manufacturing, where rigorous certification and stringent quality controls must be met.

There are adhesive formulations to bond any two substrates together, whether polycarbonate to stainless, polycarbonate to polycarbonate, or, more recently, silicone to silicone. Thousands of different chemistries are available. The first thing to do is talk to the adhesive company to get the right chemistry for the application, since these engineered materials must be designed into the process from the start. Next, users should speak with a UV equipment manufacturer to specify the proper system for ideal process development. This ensures a smooth transition from development to prototype, through full scale-up. The final step is to discuss all curing needs with a range of knowledgeable equipment technicians.