Top photo: Semiautomated conveyor curing of tube sets.
Bottom photo: Manual LED curing of adhesives for bonding connectors and tubing.

Streamlining adhesive decisions

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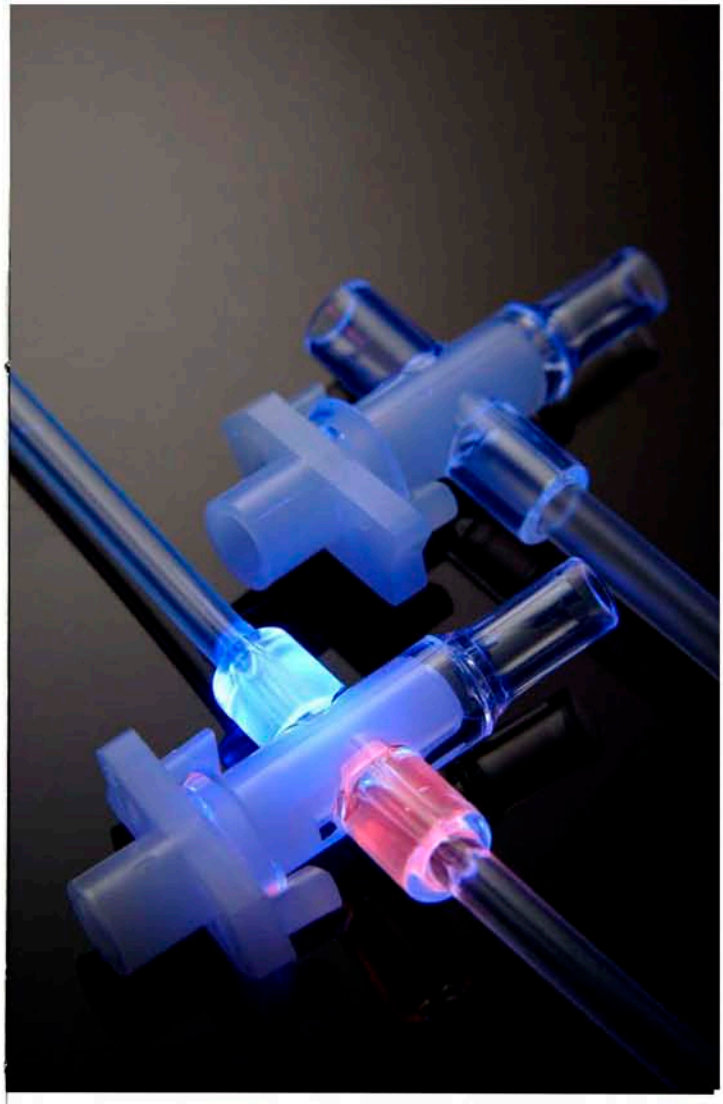
The selection of the right adhesive to meet the performance, biocompatibility, and environmental demands of medical-device applications can seem a daunting task. Yet, despite the hundreds of available options, the decision-making process can be streamlined with the right questions and, of course, answers. Here are the key criteria around which to base your adhesive decisions.

Chemistry

When bonding engineered plastics (such as polycarbonate, acrylic, urethane, ABS, nylon, or other resin systems) to other plastics, metal, or glass, there are several adhesive chemistry options. These range from light-curable acrylated urethanes, cyanoacrylates, 1- or 2-part epoxies, 2-part urethanes, and even a few hybrid combination adhesives such as thermally curable and light-curable adhesives or light-curable silicone hybrid systems. Bonding to silicones is often best accomplished with silicone adhesives, but under the right conditions bonding to silicone elastomers can be done with urethanes. This review will examine the bonding of plastics together to create a medical device. As a rule of thumb, transparent plastics are typically bonded using a light-curable acrylated urethane, a cyanoacrylate, a flexible urethane, or a rigid epoxy. Opaque plastics generally use cyanoacrylates, flexible urethanes, or rigid epoxies, to list a few of the available options.

Viscosity

Viscosity is a measure of a fluid's resistance to flow. The lower the viscosity, the greater the ability or tendency of a fluid to flow or spread. As a frame of reference, water has a viscosity of 1 cP, and honey has a viscosity of around 10,000 cP. To select the best viscosity adhesive for the application, identify the flow properties that are required by your proposed assembly method. If you are potting or filling a groove molded into the plastic, then a

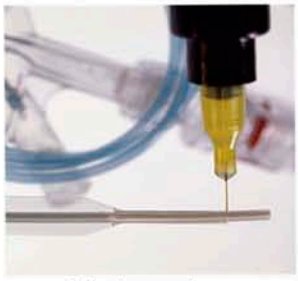


Quality enhancements such as red or blue fluorescing additives can help operators detect airbubbles and voids.

low- to medium-viscosity fluid would be ideal. If you are placing a bead or dot with a high profile, then a high-viscosity, thixotropic material would be ideal. Some materials are thixotropic, meaning that when placed under shear, the material will flow easily; but when the shear force is removed (dispensing stops) the material exhibits a higher viscosity. Ketchup is also around 10,000 cP, and behaves in a thixotropic, or shear thinning behavior, staying in place on top of the hot dog. Conversely, honey is considered a non-thixotropic, Newtonian fluid. No matter how much shear you apply during dispensing, it will flow at a consistent rate. Thixotropic Index (recovery) is a useful value to identify, with values of 2.0-3.5 being typical for very thick or gel-like materials, and materials that slump having values of 1.5-2.0.

Adhesion

Once a type of adhesive chemistry is selected, an individual product within that adhesive class will often be chosen based on its adhesion to the various substrates. The test criteria defined will depend upon the specific performance expectations of the adhesive, based on the design of the components. Lap-shear testing or peel-force testing is common, as well as pressurization to



Adhesives can be used to bond to engineered plastics like polycarbonate, acrylic, ABS, nylon, or various urethanes.

burst or leak testing. Accelerated aging of components will depend on expected storage conditions and useful life of the device. One should avoid attempting to "accelerate the accelerated aging test" by employing even more aggressive conditions. For example, by running the test at too high of a temperature, the performance of the adhesive can be negatively influenced by creating additional crosslinking within the adhesive, causing a reduction of elongation.

Ease of processing

If multiple choices still remain, evaluate the adhesive based on its ease of processing. 1-part adhesives only require a simple dispensing system versus a metered mix system for 2-part adhesives. Additionally, 1-part systems do not require dispense system purging or have issues with pot life. The ability to dispense and cure where and when needed make 1-part acrylated urethanes ideal for many medical devices, requiring only that light (UV or visible) reach some portion of the bond line. Careful consideration of the assembly method may help select the right adhesive, based on whether the components are being hand assembled, semi-automated, or fully automated. It is important to consider the different potential problems that might arise during a production run (e.g., line stoppage, shift change, distracted assembly employee) and how the adhesive assembly process may be affected. Can the system be stopped or shut off easily, or is there a shutdown process that needs to be followed? Can the process be adjusted or qualified to handle lot-to-lot variation in viscosity or cure time? These are all key questions to be considered.

Biocompatibility

Many adhesive companies classify their medical-related products as compliant to either ISO 10993 or USP Class VI, or some combination of both standards. These biocompatibility classifications are determined for fully cured adhesive samples under specific conditions. The medical device manufacturer still must run full testing on the completed device, since the cure method employed in assembly does play a part in passing the biocompatibility testing. Most materials are compatible with EtO (ethylene oxide) sterilization as well as gamma sterilization. Resistance to autoclave sterilization is limited to a few cycles for cyanoacrylates, urethanes, and even epoxies, and results can depend on the part configuration.

Quality enhancements

Since the quality of the medical device is of utmost importance, the ability to assure a high quality adhesive bond is critical. Some medical device adhesives are formulated to fluoresce under a black light. This enables quality technicians to determine that the adhesive covers the entire bond line, and also to detect any leads, air bubbles, or voids. Fluorescing adhesive formulations are available in both blue and red fluorescing color versions. Red is particularly useful in providing the proper contrast in situations where the surrounding plastics also fluoresce blue. An innovative, recent advancement that even further assures joint quality is the introduction of See-Cure technology. This technology offers a blue color in the uncured adhesive which changes to clear and colorless once the cure has been completed. A simple, post-cure visual inspection can thus determine completeness of adhesive cure.

Cost, not price

The true in-use cost of an adhesive considers all aspects of the process, including waste, downtime, start-up time, scheduled maintenance, tight quality specifications to minimize variability within the process, the number of workers required for a specific process, and scrap rate. Two adhesives may have slightly different dollar-per-gram prices, but may provide *vastly* different operating costs or in-use costs. For example, a light-curable acrylated urethane may be priced 50% higher on a dollar-per-gram basis. Yet, the same material could deliver a 300% cost savings in process efficiencies.