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19.03.2015

Cyberbond in the Medical Device Industry – Bonding Solutions

Adhesives for Medical Device Industry

Medical device applications vary widely, but typically involve the bonding of plastics and metals. Though bond strength requirements are typically within reach for many adhesives from Cyberbond's standard line, medical devices present a variety of unique challenges beyond strength. In addition to bonding parts together successfully, medical device adhesives must also be compatible with direct or indirect contact with the body (depending on the application), and may be required to withstand sterilization through a variety of potential methods. Furthermore, certain substrates may necessitate the use of primers or other surface preparations in order to achieve satisfactory adhesion.

Medical Device Substrates to be Bonded

When selecting an adhesive solution, the most important factor to consider is the specific composition of the materials being bonded. Broadly speaking, surface energy is the primary determinant of a substrate's affinity for bonding—the higher the surface energy, the easier it is to bond the substrate. Recently—as a result of the growing concern over the health effects of phthalate-based plasticizers (e.g. DEHP), and the Bisphenol A monomer—PVC and polycarbonates have seen diminished use as substrates in medical device design. From an adhesive standpoint, the widespread replacement of these easy-to-bond, high surface energy plastics with low surface energy alternatives like Pebax® has made bonding medical devices much more challenging. It is therefore imperative to know exactly which substrates are being bonded, and to work with an adhesive supplier comfortable working with the difficult-to-bond substrates increasingly common in medical device design.
Below, some of the substrates most commonly used in medical devices are listed, along with their general characteristics and bonding affinities:

- **Metal**
  - Stainless steel:
    300-series grades are most common, used for needles, cannulae, wires and machined components. Like most metals, stainless steel has a very high surface energy and is therefore not difficult to bond, though its opacity renders use of UV-curable adhesives impossible, unless the second substrate is permeable to ultraviolet light.
  - NiTi (Nickel/Titanium alloy):
    NiTi (or Nitinol) is used as a wire. It has good shape memory, meaning that it may be molded as desired, then returned to its original shape when exposed to a specific high temperature. Its high surface energy makes it friendly to bond, although users of UV-curables will encounter the same opacity problems presented by all metals.
  - Molybdenum, Tungsten and Tantalum are also encountered, but infrequently. All are high surface energy and are readily bonded.

- **Plastic**
  - Polycarbonate (PC)
    Used in stopcocks, luers, hubs and molded components, such as housings for biopsy syringes. PC has a relatively high surface energy, making it relatively easy to bond.
  - ABS
    Used in tubing connectors and couplers; high surface energy.
  - Acrylic
    Used in hubs; high surface energy.
  - Polyisoprene
    Most often chlorinated and used for balloons on pressure catheters; very low surface energy and generally requires surface preparation.
  - LDPE & PE
    Used as tubing; low surface energy, generally requires surface preparation
  - SEBS
    Styrene-ethelyne-butadiene-styrene; used as tubing; rare
  - EVA & PVA
    Ethyl vinyl acetate and polyvinyl acetate; used as tubing
  - Polyurethane
    Used as tubing & in soft components such as breathing mask cushions
  - PP
    Used as tubing and in molded components
  - PET
    Used in catheter balloons
  - Silicone
    Used as tubing, in molded components, and for gastronomy tubes and ports
  - Pebax
    Brand name for polyether block amide based on TPE; used as tubing replacement for PVC
  - Grilamid
    Brand name for a transparent nylon; used in molded components
  - C-Flex
    Brand name thermoplastic elastomer; used as tubing

Medical Adhesive Requirements

- **Biocompatibility**
  Because of the extensive testing all medical instruments undergo before they are put into use, manufacturers find it advantageous to select adhesives they already know to be compatible for use with the human body. Several different standards exist to provide this assurance, most notably USP (United States Pharmacopia) Class VI and ISO 10993. Many Cyberbond cyanoacrylates and UV-curables are certified to both standards. We have recently emphasized ISO 10993, which is in more widespread use internationally.
  The 10993 standard encompasses a variety of different tests, each of which covers a different aspect of biocompatibility. Generally, manufacturers have one of the tests in mind when designing a medical device; Cyberbond has many adhesives that have passed the following:

  - **ISO 10993-5**: Test for In-Vitro Cytotoxicity
    An agar diffusion test checks to see if the tested cyanoacrylate or UV-curable will destroy a cell culture.
  - **ISO 10993-10**: Tests for Irritation and Sensitization
    Injections of the tested adhesive are administered intradermally to live test subjects to determine—through observation of vascular dilation—whether the adhesive will cause inflammation of the skin (erythema) or an accumulation of liquids (edema).
  - **ISO 10993-11**: Tests for Systemic Toxicity
    Injections of the tested adhesive are administered intravenously into the abdominal cavity. The test is passed only if no biological reaction is observed.

- **Tack-free bond**
  Adhesives used as coatings, or in other applications where they are not encapsulated within the device, are generally required to present a tack-free outer surface.

- **Sterilization processes**
  Even if an adhesive is certified as biocompatible, it must be capable of withstanding the sterilization required to render the rest of the device safe for use. Depending on a variety of factors, including device type and manufacturer preference, there are several different methods of sterilization to choose from.

  Disposable devices are typically sterilized in one of the following ways:
  - **ETO (Ethylene Oxide)**
    Parts are treated for several hours with a gas that penetrates packaging and kills micro-organisms. ETO is used for heat-sensitive parts that cannot withstand high-temperature sterilization methods. Very often, the ETO process is repeated twice; this is referred to as 2x ETO. Cyberbond products withstand this treatment.
  - **Gamma Radiation**
    Parts are treated with gamma rays, killing micro-organisms even through packaging. Cyberbond products withstand this treatment.

  Multi-use medical devices are typically sterilized in the following way:
  - **Autoclave Sterilization**
    Parts are put into an autoclave, which is a specialized type of pressure cooker. Inside, the heat, steam and pressure work together to sterilize the parts. Standard CAs and UVs do not withstand this procedure.

Medical Adhesive Applications

- **Biopsy and Infusion Needles**
  Biopsy and infusion needles are typically potting applications, where a metal needle is surrounded by adhesive in a recess in a plastic housing. Alternatively, as in the case of the bite-wing cannula pictured in green at left, adhesive is applied to a needle, which is inserted into a tight-fitting housing. In both applications, sealing is as important as strength–blood and fluids must not be allowed to penetrate the bond. Adhesive strength in these applications is usually evaluated by means of a simple tensile test.
  Dissimilar substrates are the primary challenge of needle bonding. Needles are almost always stainless steel, where the plastic housing could be any of a variety of substrates, including polycarbonate, nylon, ABS, or more exotic molded plastics. This creates a challenge from the standpoint of requiring an adhesive that has affinity for multiple substrates.
  Cyberbond is proud to offer several adhesive solutions with such affinity. Among our Cyberlite UV-curable acrylates, our U306 is 10993-5 tested and bonds well to both stainless and several different plastics. From our cyanoacrylate range, our 2008, 2028, and 2240-05 have all shown excellent results, and all are tested for biocompatibility.

- **Tube/Hub Bonding**
  Tube/hub applications are straightforward in that they require the terminus of a length of flexible tubing to be bonded within a rigid plastic hub.
  Though tube/hub bonding is not difficult to understand, it requires an adhesive to bond a variety of challenging substrates, and often times to accommodate an extremely tight fit between tube and hub. Traditionally, manufacturers have designed this tight fit to facilitate sealing and prevent foreign bodies from penetrating or leaking from the hub. In such cases, solvents were typically the adhesive of choice, as their low viscosity lubricated the fit between tube and hub.
  The benefit of Cyberbond products in tube/hub applications is that, unlike solvents, our adhesives do not attack plastic, allowing for a stronger bond. Additionally, our 2008 and 2028 cyanoacrylates, as well as our U301 and U304 UV-curables, provide excellent adhesion on the exotic extruded plastics increasingly used to replace PVC-based tubing.

- **Balloon Catheters**
  Balloon catheter applications involve small-diameter tubing that has been divided internally to allow it to deliver both air and treatment solutions simultaneously. This tubing is bonded to either end (the "cuff") of an inflatable balloon or "sleeve." As with needle bonding, sealing and strength are of equal importance, as air must not be allowed to exit the sleeve. In addition, balloon bonds are usually required to resist moisture at body temperatures. Materials in balloon catheter bonding tend to present the greatest challenge to adhesion, especially as manufacturers move away from phthalate-based tubing. PET balloons w/Pellethane tubing are typical. Combined with the need to resist water/moisture, balloon catheter applications can present difficulties that only an experienced and technically proficient adhesive manufacturer can overcome.
  Cyberbond has employed our U301 and U304 medical-grade UV-curables in balloon catheter applications, as both work effectively across an array of different substrates.

ISO 10993 Approvals

Cyberbond's experience in the medical device market means that we've had the opportunity to certify many formulas to various ISO 10993 standards for biocompatibility. These are listed below, along with the specific tests they have passed:

- **ISO 10993-5; Tests for Cytotoxicity**

Cyanoacrylate Adhesives

1006	2011	2245
1603	2028	2610/2611
1701	2028 F	2800/2000W
2003	2077	2999
2004	2150	5005
2006	2240	5240
2008	2241	5243
	2243	5248

UV-Curing Adhesive

U 301	U 304	U 306
U 303	U 305	

- **ISO 10993-10; Tests for Irritation and Sensitization**

2008	2028	2800
2011	2077	1603

- **ISO 10993-11; Tests for Systematic Toxicity**

2008	2028	2800
2011	2077	1603

Experience shows us that some products are particularly well-suited to certain applications—for example, 2008 is perfect for tight-tolerance needle bonding; 2028 or 2077 work better for wider gaps. Lower-viscosity UV-curables like U301 and U305 offer unique advantages for interference-fit tube bonding with their lubricity, allowing parts to be mated easily and cured on demand.

Custom Solutions
Our many ISO-approved adhesives illustrate our experience in the medical market, and the selection on the previous page covers a wide variety of different potential needs.
For more unique applications, our experience also gives us the ability to create custom formulas based on application-specific needs. Our list of custom formulas is necessarily confidential, but our size, responsiveness and expertise has allowed us to provide custom solutions to customers with a wide range of different requirements, from altering appearances to customizing viscosity.

In addition we also want to refer to our **LINOP Dosing and LED Curing Equipment**.