



Fundamentals of Medical Device Assembly

Key concepts to help you take greater control over the performance of your medical device bonding process



Contents

Introduction	2
Common Materials Used in Medical Device Assemblies	3-4
Challenges in Medical Device Assembly	5-8
Adhesive Chemistries Commonly Used in Medical Device Assemblies	9-12
How to Ensure a Lasting Adhesive Bond	13-15
Testing For Medical Device Adhesives	16-19
Conclusion	20

Introduction

One of the most challenging aspects of manufacturing medical devices is permanently and safely attaching the parts together. Whether it's single use medical syringe production requiring bonding the stainless steel cannula to the plastic hub, or fastening a catheter balloon to a shaft, the bond is critical to the reliability of the device and ultimately the safety of the patient. In all medical applications, poor bonding could result in leakage of bodily fluids and medication or catastrophic device failure, situations that could be dangerous to the patient and medical professional.

To understand how the bonding process works and learn how you can use it to take greater control over the performance of your manufacturing process, let's take a look at some of the fundamentals of medical device assemblies.

In this e-book, we categorized the fundamentals into five primary categories. Each one is key to understanding certain insights that impact the performance of any medical device.





Common Materials Used in Medical Device Assemblies

For medical devices such as catheters, syringes, vials, test tubes, and injector pens, many manufacturers are turning to plastic substrates that are specifically formulated to resist harsh end-use conditions. They are valued in medical device manufacturing because of their strength, sterilization/chemical resistance, superior mechanical and dynamic properties, and their ability to sometimes replace glass. Plastics fall into two broad categories:

- thermoplastics, which can be softened and reformed after initial processing
- thermosets, which cannot be melted or reformed.

The plastic material itself determines the best adhesive for bonding. Certain plastics are considered easy to bond while others fall into the hard-to-bond category. Surface treatment can also be utilized to ensure the strongest bond possible.

Here are a few of the common difficult-to-bond materials:

NYLONS

Nylons are semi-crystalline polyamide materials that are very tough and offer good thermal, chemical, and pressure resistance. These polyamide materials deliver the flexibility, tensile strength, and compression resistance needed to meet the requirements of devices used for fluid management, surgical procedures, and diagnostics. Each different type of nylon provides individualized performance characteristics. For example, as the nylon's associated number increases, specific gravity, melting point, and moisture content decrease (Nylon 12 has a lower specific gravity than Nylon 6).

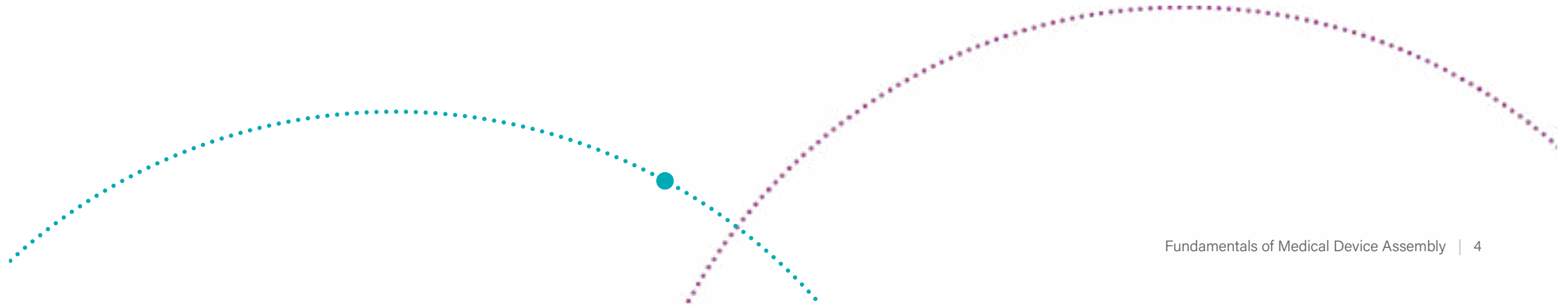
Extrusion tubing made of nylon is lightweight, corrosion and abrasion resistant, and will withstand repeated stress over long periods, making it a popular material for catheter shafts. Nylon is also well suited for use as a balloon material because of its ability to withstand high pressures in thin-walled sections. Nylon extrusion works well in balloon applications that require more compliance than polyethylene terephthalate (PET) balloons can provide.

POLYETHER BLOCK AMIDE (PEBA)

Polyether block amide (PEBA) is also gaining in popularity as it delivers low-friction properties, kink and pressure resistance, softness, and flexibility in a chemical resistant, lightweight material. Manufacturers are starting to use it in place of common elastomers like polyurethanes, polyesters, and silicones due to the previously mentioned characteristics, as well as its lower density, and exceptional impact and fatigue resistance. PEBA is gaining in popularity for medical-grade tubing applications including catheters and connectors, as well as for medical films.

CYCLIC OLEFIN POLYMERS AND COPOLYMERS (COC & COP)

Cyclic olefin polymers and copolymers (COC & COP) are relatively new classes of amorphous polymers, whose purity, moisture resistance, clarity, and sterilization compatibility make them excellent alternatives to glass in a wide range of medical devices including prefilled syringes and serum vials. Resistant to organic polar solvents, these clear materials allow high light transmission with low haze and chromatic aberration. Absorbing one tenth the water of poly(methyl methacrylate) (PMMA), they deliver a longer shelf life for liquid contents than other plastic substrates and do not leach at detectable levels. These durable, shatter-resistant plastics will withstand gamma radiation, steam, and EtO sterilization.



Challenges in Medical Device Assembly

ASSEMBLY TECHNIQUE CHALLENGES

When it comes to assembling medical devices there's a need for consistent quality results, as lives may be at risk. From mechanical to chemical bonding, several assembly techniques are available for joining medical plastic parts. Each technique comes with its own set of challenges.



Medical Fasteners

Mechanical fasteners such as bolted assemblies and rivets require a hole – a point of weakness – to be made in the substrate. Because of this, fasteners are not suitable for small and delicate assemblies. They can only be used for larger, heavier-weight plastic assemblies that can handle the strain and high stress occurring at the insertion site.



Ultrasonic Welding

Ultrasonic welding, also known as fusion bonding, requires heating each plastic substrate, then holding the melted edges together by applying pressure until the two parts meld as the plastic cools. This process is functional, but gaps remain in the assembly due to bond gap variances. The image above demonstrates this disadvantage.



Solvent Welding

Solvent welding is similar to ultrasonic welding. It involves coating plastic parts with a solvent and pressing them together until the solvent evaporates and the parts are fused. This process comes with a high risk of stress cracking of the plastic substrate, which can be seen in the image above. In addition, solvent emissions can be very hazardous and require special handling and disposal procedures.



Adhesives

Adhesives can bond plastic parts together, while offering distinct advantages over other bonding processes. Although they require setting and curing time, adhesive bonding is more efficient and easier than the alternatives. There are several different adhesive chemistries which are appropriate for medical device assembly, each with their own pros and cons. We'll discuss this in more detail later in this book.

CHALLENGES WITH SUBSTRATES

Adhesives want to bond onto [reactive groups](#). Plastics featuring carbonyl groups, such as polycarbonate and polyetherimide, feature C double-O bonds. These plastics are considered easy to bond and are very popular due to the high electron density in the oxygen, which often crosslinks through the [double bond](#) site.

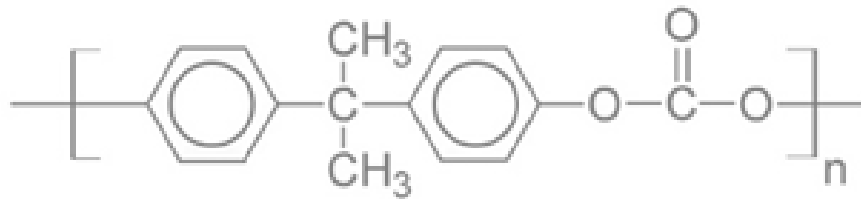


Figure 1. Chemical Structure of Polycarbonate (PC)

COC/COP are high-clarity copolymers that are difficult to bond because they are composed primarily of ethylene with random interspersed groups of norbornene. Polyethylene (PE) and polypropylene (PP) are also difficult as their chemical formulations provide no natural bonding sites. Soft, flexible silicone has the same bonding problems since it is very similar; i.e. it has no natural bonding sites. Hard-to-bond plastics usually require some type of pre-treatment to obtain good adhesion.

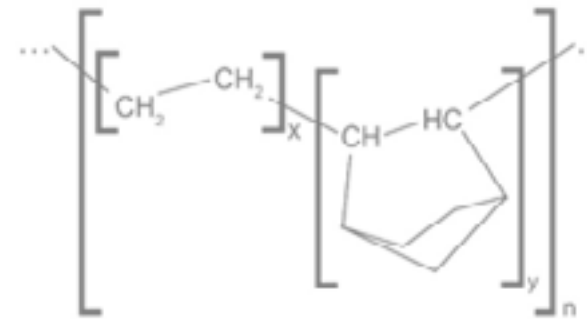


Figure 2. Chemical Structure of Cyclic Olefin Copolymer (COC)

PEBAs are a blend of nylon and other resins and are affected by the same bonding issues as nylons. The higher the [durometer](#) of a PEBA formulation, the greater the nylon content and the more difficult the material is to bond. When a PEBA formulation's R2 molecules form a long chain, the chain pushes the bond sites away from each other, increasing bonding difficulty.

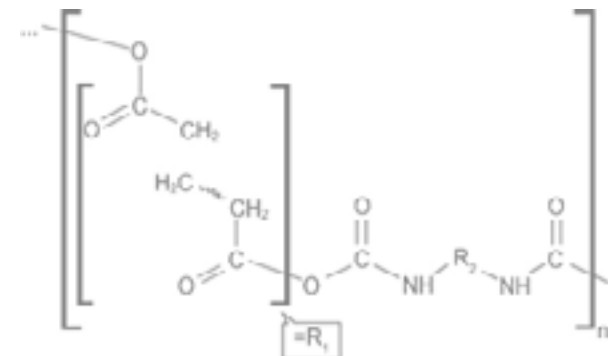


Figure 3. Chemical Structure of Polyester Block Amide (PEBA)

Nylon, COC/COP, and PEBA are all hard-to-bond thermoplastics. These plastics are classified as hard-to-bond materials because of their low surface energies and smooth and/or glossy surfaces. Nylon 6 has six non-reactive carbons between bonding sites. Nylon 12 has 12 non-reactive carbons between bonding sites. The greater the distance between bonding sites, the lower the level of adhesion to the thermoplastic; it becomes incrementally harder to bond Nylon 12 than it is to bond Nylon 6.

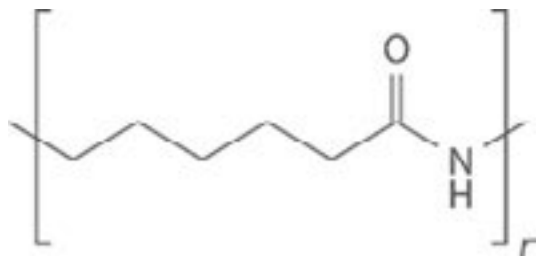


Figure 4. Chemical Structure of N6



Nylons are quickly becoming a favorite in catheter assemblies

Adhesive Chemistries Commonly Used in Medical Device Assembly

A number of adhesive technologies can be used in manufacturing medical assemblies to deliver high-strength bonding and sealing, gap filling, and easy in-line processing. Each adhesive application has a unique set of requirements, therefore some adhesive chemistries fit better than others. The correct adhesive for a specific assembly application will be determined based on variables such as the device design itself and the manufacturing process. Popular choices include light-curable adhesives, cyanoacrylates, and two-part epoxies.

LIGHT-CURABLE ADHESIVES

Light-curable adhesives are a popular choice among manufacturers because of the many advantages they have over other chemistries. A significant advantage is that they eliminate work in process by curing almost immediately when exposed to the right intensity and wavelength of light. They can also be formulated with fluorescing properties, allowing easy inspections of the bond-line to detect adhesive coverage and volume, or color-change technology, which allows manufacturers to visually confirm cure with no special equipment.

Another benefit of light-curable adhesives is that they are available with a wide variety of properties, making it easier to find an adhesive that is a perfect match for the application. Adhesive formulations are available from thin-wicking, newtonian grades to thixotropic gels. Part geometry, process design, assembly method, and speed should be considered together to determine appropriate adhesive viscosity for an application.

Light-curable adhesives range in cure times, from as little as 2 seconds, depending upon the color of the substrate, the design of the device, and any UV inhibitors present in the substrate. Once cured, these adhesives can achieve a rigid state or remain soft and flexible depending upon the formulation. They also offer very good thermal and chemical resistance, compatibility with sterilization, and reduced risk of blooming or stress cracking.



Tube Sets Traveling Through Light-Curing Conveyor System

7 Reasons Why Light-Curable Adhesives are Ideal for Medical Device Assembly

1 They easily bond irregularly shaped parts



2 Seals the bond line

3 Distributes stress evenly over large areas

4 Light-curable adhesives bond a wide variety of dissimilar substrates

ABS	PC	PEI	PETG
PMMA	PS	SS	PVC

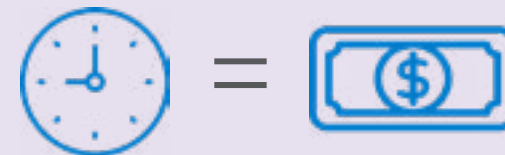
5 Adhesives are normally colorless and applied within the joint so bond lines are invisible and there are no aesthetic changes to the device



6 Users have unlimited time for parts adjustment before immediate cure is initiated



7 Cures on demand upon exposure to the appropriate wavelength of light. This speeds up the assembly process resulting in time and labor savings.



CYANOACRYLATES

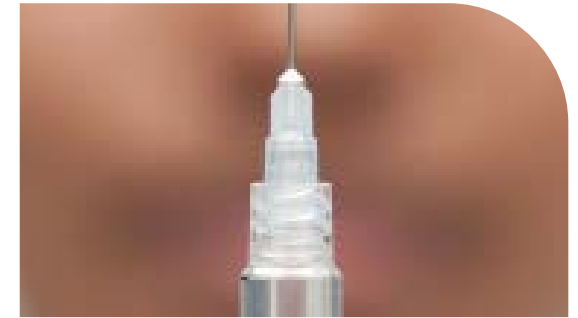
Commonly referred to as superglue, cyanoacrylates cure in the presence of moisture. They are attractive to manufacturers because of their high shear strength and quick fixture time. Unfortunately, they are subject to blooming and stress cracking, which can lead to bond failures. In addition, traditional cyanoacrylates are also very brittle with little impact resistance and are not always designed to bond dissimilar substrates.

How do Cyanoacrylates Compare to Light-Curable Adhesives?

	Cyanoacrylates	Light-Curable Adhesives
Cure Speeds	Fixture in 10-60 seconds	<input checked="" type="checkbox"/> Full cures in 1-30 seconds
Open Time (Time Before Cure Begins)	10-30 seconds	<input checked="" type="checkbox"/> No cure until exposed to high-intensity light
Moisture Resistance	Not designed for high-humidity or long term moisture exposure	<input checked="" type="checkbox"/> Some have excellent moisture resistance
Temperature Resistance	Not recommended for $\geq 225^{\circ}\text{F}$	<input checked="" type="checkbox"/> Can withstand greater temperature extremes or a broader range of temperatures
Opaque Substrate Bonding	<input checked="" type="checkbox"/> Not an issue	Opaque materials block UV and visible light
Impact Resistance	Brittle with little impact resistance	<input checked="" type="checkbox"/> Grades range from flexible to rigid
Equipment Needed	<input checked="" type="checkbox"/> No equipment required	Light-curing equipment required
Gap Cure	Requires intimate contact	<input checked="" type="checkbox"/> Can accommodate larger bond gaps
Blooming	Produce white haze around bond line after cure	<input checked="" type="checkbox"/> None
Stress Cracking	Tiny cracks in plastic can occur before cure	<input checked="" type="checkbox"/> Rarely an issue
Bondable Substrates	Does not bond dissimilar substrates	<input checked="" type="checkbox"/> Bonds dissimilar substrates

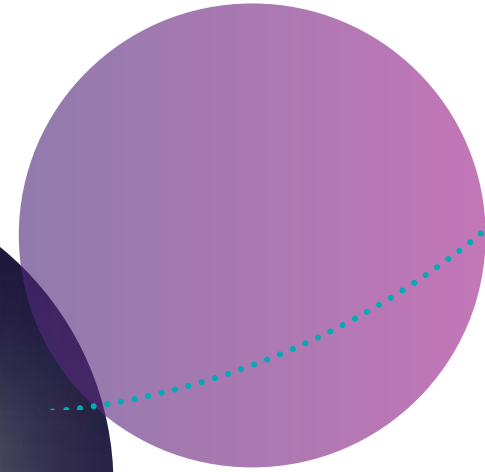
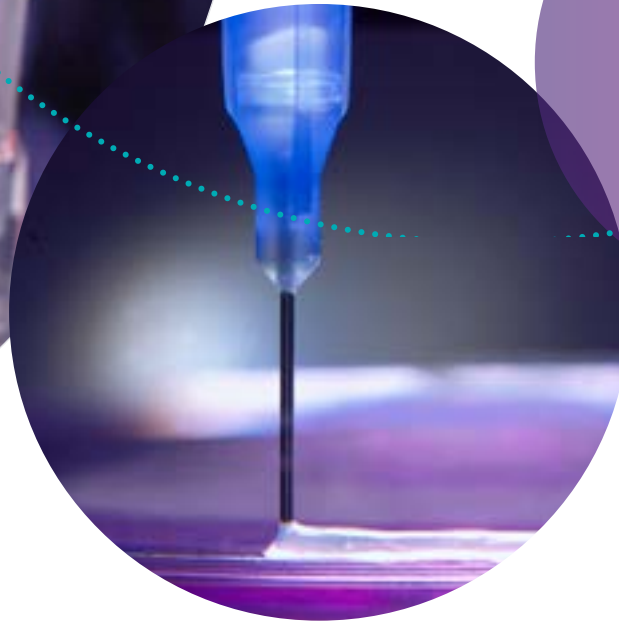
TWO PART-EPOXIES

Two-part epoxies are comprised of two components, a resin and a hardener, that must be mixed before dispense. They are attractive to manufacturers because of their low cost and extreme chemical resistance. Unfortunately, epoxies are very rigid with little impact resistance, limiting the applications where they can be used successfully.



How do Two-Part Epoxies Compare to Light-Curable Adhesives?

	Two-Part Epoxies	Light-Curable Adhesives
Cure Speeds	Cures in hours at room temperature or minutes using heat	<input checked="" type="checkbox"/> Full cures in 1-30 seconds
Price Per Pound	<input checked="" type="checkbox"/> Lower cost per pound	Higher cost per pound
Pot Life	Times are product specific and can range from minutes to days	<input checked="" type="checkbox"/> Unlimited
Purge Cycles	Required, resulting in hazardous waste	<input checked="" type="checkbox"/> Not required
Opaque Substrate Bonding	<input checked="" type="checkbox"/> Not an issue	Opaque substrates block UV light
Impact Resistance	Typically rigid with little impact resistance	<input checked="" type="checkbox"/> Grades range from flexible to rigid
Equipment Needed	Meter mix equipment required. Heat curing ovens optional for faster cure.	<input checked="" type="checkbox"/> Light-curing equipment required
Chemical Resistance	<input checked="" type="checkbox"/> Better for applications needing extreme chemical resistance	Some chemical-resistant grades



How to Ensure a Lasting Adhesive Bond

Medical design engineers can narrow their search for the most suitable adhesive by working closely with their adhesive partners to thoroughly test prototypes of devices on simulated production setups before actual production has launched. This testing can include dispense/dwell times, cure validation (wavelength selection and cure time), and pull evaluations. By conducting research and testing up-front during the design phase, device manufacturers can ensure the success of the assembly during high-volume manufacturing and over the life of the device. The following pages list a summary of factors to avoid or consider when designing medical device assembly processes.

Avoid these 4 Factors That Could Cause Bond Failure:

1

Harsh Sterilization Methods

Harsh device sterilization methods used to prepare medical devices for patient use can induce failure if not validated in process validation. These sterilization methods, or any high heat/humidity situation, can cause plasticizers like DEHP and BOP to migrate over time from high concentration areas to low concentration areas, typically at the substrate surface, eventually migrating into the adhesive. This migration causes the adhesive to change color and become gummy or tacky, and can lead to bond failure. Humidity can also cause the adhesive or plastics to swell and should be fully tested.

2

Photo-Oxidation

Some plastics degrade because of photo-oxidation on exposure to ultraviolet light. Processors may add pigments like carbon black and UV stabilizers like hydroxyl benzophenone to inhibit the rate of photo-oxidation, but at a cost to the device manufacturer. Similar to plasticizers, stabilizers will also migrate to the surface over time and degrade the adhesive bond, causing joint failure.

3

Mold Release Agents

Mold release agents act as a critical barrier between the mold surface and the plastic, facilitating separation of the cured part from the mold. These release agents can later contaminate the surface of cured parts, affecting adhesive bonding. Other contaminants like silicones, grease, oils (including hand oils), dust/ debris, etc. can also negatively affect the bond surface and may require additional cleaning and/ or surface preparation.

4

Low Surface Energy

Substrates with a low surface energy like polyolefins (polypropylene, polyethylene) can prevent adhesives from wetting out properly, which is critical to achieving the strongest bond possible. Ideally, the surface energy of the substrate should be 7-10 dynes higher than that of the adhesive, with acrylate urethane adhesives normally falling in the 34-36 dyne/cm² range. Having a higher surface energy will allow for the adhesive to wet out on the surface, instead of "beading up" like water on a waxed vehicle. Some newer adhesive chemistries are designed to bond better to lower energy surfaces without treatment, but otherwise surface energy can be raised with various surface treatment techniques, including corona, plasma, or pre-exposure to UV light.

6

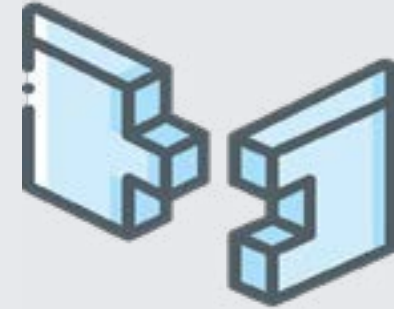
FACTORS TO CONSIDER WHEN DESIGNING YOUR MEDICAL DEVICE ASSEMBLY PROCESS



Validating the Appropriate Substrates



Adhesive Technologies



Joint Designs



**Process Parameters
(Including Dispense & Cure Equipment)**



Inspection Needs



**Sterilization Techniques are
All Critical to Avoiding Failures**

Testing for Medical Device Adhesives

Medical device assemblies require specific physical, chemical, electrical and thermal properties while being biocompatible. Biocompatibility is a general term used to describe the property of a material being compatible with living tissue or systems. Materials that are non-toxic, non-injurious, or not physiologically reactive to the body or bodily fluids are considered biocompatible.

Regulations for medical devices vary from region to region and have different regulatory agencies governing them. The path to market and registration requirements vary per agency. Device manufacturers bear responsibility to meet regulatory needs for each market. Regulatory agencies require manufacturers to meet biocompatibility standards designated for their device type, if applicable, in addition to functional and performance testing

In the US, medical devices are regulated by Food & Drug Administration (FDA) under the Center for Devices & Radiological Health (CDRH). The FDA requires manufacturers to prove a certain degree of biocompatibility prior to a product's introduction to the market. That degree can be confirmed through the following test.

ISO 10993 BIOCOMPATIBILITY TESTING

The ISO strategy categorizes medical devices by type of body contact (surface device, external communicating device, and implant device) and by contact duration (limited, prolonged, and permanent). For each resulting medical device category ISO provides a set of suggested evaluation tests. The ISO 10993 set entails a series of standards for evaluating the biocompatibility of medical devices and is a part of the international harmonization of the safe use evaluation of medical devices

The FDA uses ISO 10993-1 (Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in the Risk Management Process) to help establish the safety and suitability of devices being submitted for review.



Adhesive Being Tested for Strength



Prior to ISO 10993, the commonly used testing in the US was USP Class VI, which is the most stringent testing of the USP classification of plastics. ISO 10993 took precedence as an international standard (USP was US approved only).

Testing requirements per ISO 10993 are based on the type of device, amount of exposure, and the type of exposure. ISO certification on individual components (like adhesives and plastics) help to build the confidence of the manufacturer before submitting their final device for the necessary ISO 10993 tests.

In general, adhesives and sealants are not required to pass all ISO tests. However, it is expected that they pass the cytotoxicity test. As a fast, standardized, sensitive, and inexpensive test, the cytotoxicity test concludes if an adhesive has any adverse effect on mammalian cells. It involves culturing cells in vitro and systematically exposing them to the material in question to see if any reactions or signs of toxicity show up over a few days.

Tables 1 and 2 show the most common ISO tests and their implications.

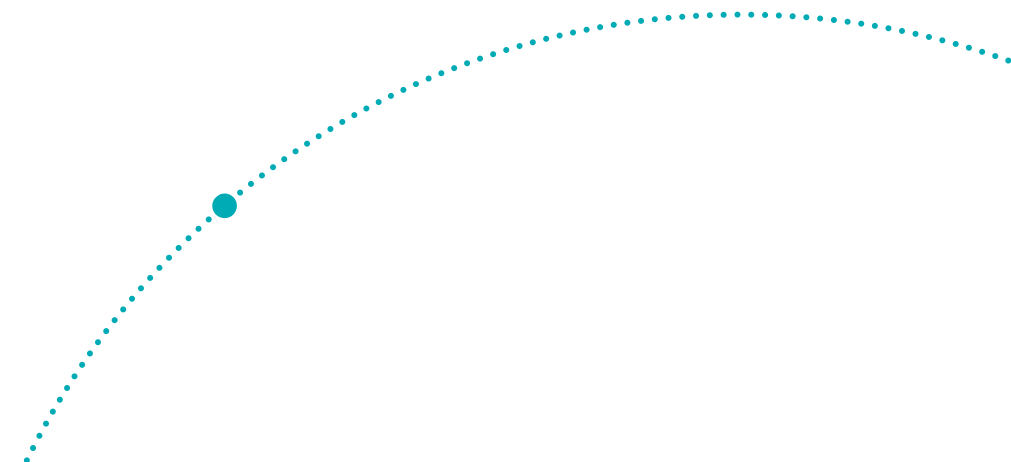


Table 1. ISO 10993-1 Biocompatibility Testing Selection Criteria

Medical Device Categorization By			Biological Effect								
Nature of Body Contact		Contact Duration A - Limited (≤24h) B - Prolonged (>24h to 30 d) C - Permanent (>30d)	Cytotoxicity	Sensitization	Irritation or Intra-cutaneous Reactivity	System Toxicity (acute)	Sub Chronic Toxicity (Subacute Toxicity)	Genotoxicity	Implantation	Haemocompatibility	
Category	Contact										
Surface Device	Skin	A	●	●	●						
		B	●	●	●						
		C	●	●	●						
	Mucosal Membrane	A	●	●	●						
		B	●	●	●						
		C	●	●	●		●	●			
	Breached or Compromised Surface	A	●	●	●						
		B	●	●	●						
		C	●	●	●		●	●			
External Communicating Device	Blood Path, Indirect	A	●	●	●	●				●	
		B	●	●	●	●				●	
		C	●	●	●	●	●	●	●		●
	Tissue/Bone/Dentin	A	●	●	●	●	●	●	●	●	
		B	●	●	●	●	●	●	●	●	
		C	●	●	●	●	●	●	●	●	
	Circulating Blood	A	●	●	●	●	●	●	●	●	●
		B	●	●	●	●	●	●	●	●	●
		C	●	●	●	●	●	●	●	●	●
Implant Device	Tissue/Bone	A	●	●	●	●	●	●	●		
		B	●	●	●	●	●	●	●		
		C	●	●	●	●	●	●	●	●	
	Blood	A	●	●	●	●	●	●	●	●	●
		B	●	●	●	●	●	●	●	●	●
		C	●	●	●	●	●	●	●	●	●

Table 2. Dymax ISO 10993 Testing

ISO 10993 Test	Type of Test	Test Conclusion
10993-4 Interactions with Blood (Hemolysis)	ASTM Hemolytic Properties of Materials	Non-Hemolytic
	ISO Interactions with Blood	
10993-5 In Vitro Cytotoxicity	ISO Agarose Overlay Method	No Cell Lysis or Toxicity (Non-Cytotoxic)
10993-6 Local Effects After Implantation	ISO Muscle Implantation	Non-Irritating (Macroscopically or Microscopically)
10093-10 Intracutaneous Irritation Sensitization*	ISO Intracutaneous Study ISO Maximization Sensitization	Non-Irritating (no erythema or edema) Non-Sensitizing
10993-11 Systemic Toxicity	ISO Acute Systemic Toxicity	No Mortality or Systemic Toxicity

*Sensitization testing is performed on select products only and not as part of the standard ISO 10993 matrix.

Conclusion

Some of the challenges of achieving reliable bonds in medical device assemblies are outlined in this e-book. To ensure proper assembly of finished components, it is important for manufacturers to understand the reasons for utilizing light-curing technology in their process. Using light-curable materials can help optimize assembly speeds to enable faster processing, greater output, and lower overall processing costs.

Manufacturers should always ensure the selected materials are compatible with all the component substrates and chemistries used to assemble their medical disposable devices. For this reason, it is advisable to work with a supplier who can provide a complete custom solution for the manufacturing process. With a global team of technical experts, Dymax understands the demands of the medical device market and is readily available to assist you with adhesive selection, dispensing options, curing recommendations, biocompatibility testing, component design, and process validation.



Want to Learn More?

Visit the dymax.com resource center for more information on light-curable maskants.

A wide variety of educational materials are available, including:

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