

## **Top Adhesives for Medical Device Applications**

Product guide for selecting the ideal medical adhesive for your requirements



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## How to select the right medical adhesive

Picking the right adhesive almost always entails a balancing act as engineers attempt to find products that meet conflicting end-use and manufacturability requirements. Medical device engineers, who also have to contend with a strict regulatory environment, often have the toughest time striking that balance.

Like engineers in less regulated industries, device engineers have to contend with difficult application requirements—such as high bond strength, thermal performance and chemical resistance. On top of these challenges, they have the added burden of picking materials that are biocompatible. Also, they often have to pick materials that can withstand aggressive sterilization methods. Not every adhesive can satisfy all of these requirements, and the ones that can may not be the easiest to work with on the manufacturing floor. Difficulties in selecting the proper compound often arise in choosing an adhesive that not only works together as a system but also minimizes performance and manufacturability trade-offs.

Finding the medical adhesive that can do it all may not be easy, but answering these questions is a good start:

- 1. Is the adhesive biocompatible?
- 2. How will the medical device be used and sterilized?

Master Bond has been manufacturing adhesives for medical devices for over 45 years. Learn about some of our materials and how they might solve your application challenges.

## **MEDICAL ADHESIVES AT A GLANCE** BIOCOMPATIBLE SYSTEMS

REUSABLE	DISPOSABLE	SELECTIVE USABILITY
EP42HT-2Med• GAEP42HT-2ND2Med Black• H	EPOXIES TEAM AUTOCLAVE • ETO AMMA • ELECTRON BEAM HYDROGEN PEROXIDE CHEMICAL IMMERSION	EP21LVMed EP30Med EP30DPBFMed EP41SMed
* Medical adhesives often combine biocompatibility with other desirable functional attributes. These two epoxy grades, for example, are also electrically conductive in addition to being USP Class VI and ISO 10993 certified.	CYANOACRYLA ETO • GAMMA ELECTRON BEAN	MB297Med-1 MB297Med-2
	LIGHT CURE ETO • GAMMA • ELECTRON BEAM • HYDROGEN PEROXIDE CHEMICAL IMMERSION	UV10Med UV15X-6Med-2 UV18Med LED403Med
	SILICONES ETO • GAMMA • ELEC BEAM • HYDROGEN PE CHEMICAL IMMERS	CTRON ROXIDE MasterSil 151Med
	ELASTOMER ETO • GAMMA ELECTRON BEAN	X21Med

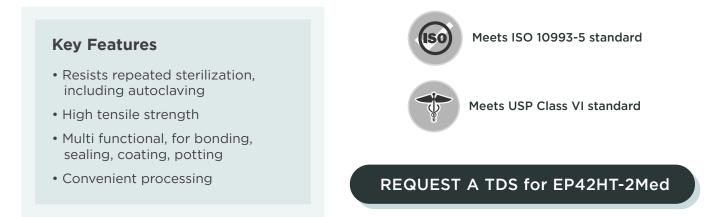
## FLAGSHIP EPOXY EP42HT-2Med

High temperature resistant two component epoxy



EP42HT-2Med meets the USP Class VI standard and is widely utilized for manufacturing and repairing endocscopes, catheters, surgical instruments, diagnostic equipment, and many other medical devices. It also meets the ISO 10993-5 standard for cytotoxicity and resists repeated sterilization, including steam autoclaving. In addition to bonding, sealing and coating, it can be used for encap-

sulation applications up to 3 inches deep. EP42HT-2Med is a higher Tg system with a service temperature range of -60°F to 450°F.





## **Case Study: Utilized in Prosthetics and Fully Implantable Medical Devices**

Master Bond medical adhesives have been cited in over hundreds of research articles published in peer-reviewed scientific journals, as well as U.S. and international patents. In this case study, EP42HT-2Med was designated for use in an implantable sensor device to be used for remote monitoring of metabolites, a tibial implant, and a transradial socket for an arm prosthetic.

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## **Performance Properties of EP42HT-2Med**

Tensile strength, 75°F Hardness, 75°F Glass transition temperature (Tg) Service temperature range >12,000 psi

>75 Shore D

150-155°C

-60°F to +450°F [-51°C to +232°C]









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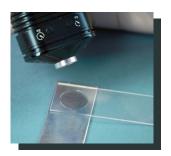
Double Barrel Cartridge

Gun Applicator

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Syringes

## **NEW FORMULATION UV17Med** *UV curable adhesive formulated for TPU bonding*



UV17Med is a one part, UV curable system specially formulated to provide excellent adhesion to many TPUs (thermoplastic polyurethanes). This compound provides very good toughness with a high elongation of 50-60%. It is capable of withstanding many chemicals including liquid sterilants, antimicrobial agents, ethylene oxide (EtO), e-beam, and gamma radiation. In addition to TPUs, it bonds well to metals, glass, ceramics and many plastics.

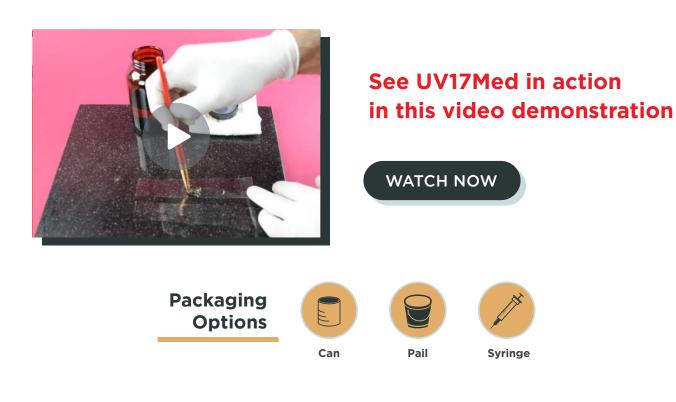
## **Key Features**

- Thin and highly flowable
- Low tensile modulus
- High elongation
- Resists rigorous thermal cycling



Meets ISO 10993-5 standard

## **REQUEST A TDS for UV17Med**



#### **TECH TIP What biocompatibility tests can be performed on an adhesive, to be considered for use in a medical device applications?**

It is important to not only be aware of the location of the adhesive, sealant, or encapsulant within the medical device but also the nature of the medical device in question. As a rule of thumb, in choosing such compounds, the adhesive must exhibit non-leaching characteristics. Biocompatibility is of utmost importance when there is skin or body contact involved, while in some non-contact type applications, this biocompatibility requirement may not be as stringent for the adhesive. In terms of biocompatibility testing for adhesives, there are two widely used standards, the USP class VI, which involves in vivo biocompatibility testing, and ISO 10993-5, which involves in vitro cytotoxicity testing. In applications, wherein the adhesive might come in contact with the skin, the ISO 10993-5 test is a good gauge to ensure compliance for the medical device in question.

In the ISO 10993-5 test, the biological reactivity of mammalian cell cultures is monitored through in vitro testing. This is often used as an important measure in gauging the cytotoxicity of a product.

To pass USP Class VI requirements for biocompatibility, 3 main tests need to be performed. These include the Systemic Injection, the intracutaneous injection, and finally implantation. After such testing, there are observations made for signs of toxicity and skin reactivity post treatment. Also, there are observations made macroscopically to ensure that there are no signs of infection. The

ISO 10993-5 test on the other hand involves non-cytotoxic deterministic procedures.

The USP Class VI test is conducted by producing an extract of the product in sodium chloride, alcohol, polyethylene glycol, and vegetable oil. These are also injected in specimens, so that the biological response to the extracts can be observed.



The Acute Systemic Toxicity (Systemic Injection) Test measures the toxicity and irritation when a sample of the compound is administered orally, applied to the skin, and inhaled.



The Intracutaneous Test measures toxicity and localized irritation (between the skin) when the sample is in contact with the tissue in question.



**The Implantation Test** measures toxicity, infection, and irritation of an intramuscular implantation of the compound into a test specimen over several days.

All of these are pass/fail tests, which means an adhesive either passes USP class VI standards, or doesn't. The USP Class VI is therefore considered one of the most stringent and useful specification for adhesives in medical device applications. It is a great guideline for medical equipment manufacturers, for qualification of the eventual device. It must also be noted that the extraction testing for adhesives can be performed at different temperatures and different time periods. The three most common temperatures and times are 50°C for 72 hours, 70°C for 24 hours, or 121°C for 1 hour.

## **EPOXY EP62-1Med** *Resists sterilization by autoclaving, radiation and chemicals*



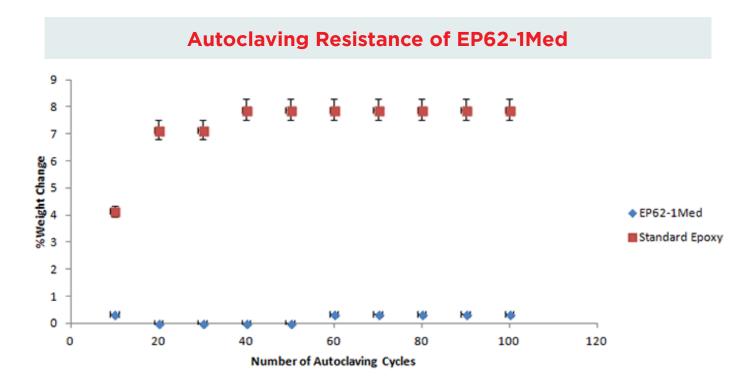
EP62-1Med is used for bonding, sealing, and coating in medical devices that are exposed to repeated sterilizations, including autoclaving, chemical sterilants and radiation. It also offers outstanding chemical resistance to acids, bases and many solvents. This two component epoxy system has an exceptionally long working life at ambient temperatures and cures rapidly at moderately elevated

temperatures. It also features excellent electrical insulation properties.

#### **Key Features**

- High temperature resistant
- Superior chemical resistance to acids, bases and many solvents
- Withstands 100 cycles of many sterilization methods
- Long working life at room temperatures





This graph displays the autoclave resistance of a casting of EP62-1Med, roughly 2 inches in diameter, and 0.125 inches thick. The casting was then subjected to multiple autoclaving cycles up to 100 cycles. Each autoclave cycle was around 20 minutes at 250°F (~121°C) and about 15 psi of steam pressure. The weight change was then measured periodically. Also included is a reference epoxy, which shows much more weight gain in comparison.



## **EPOXY SYSTEM EP3HTMed** *One part, heat curing epoxy*



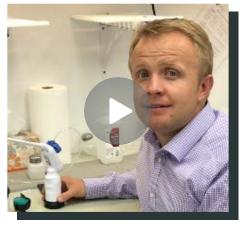
EP3HTMed is formulated to cure rapidly at elevated temperatures. It has excellent resistance to multiple cycles of radiation, EtO, autoclaving and chemical sterilants. Its service operating temperature range is -60°F to +400°F. Another benefit of this single component, no mix epoxy adhesive is its unlimited working life.

#### **Key Features**

- One component, no mix system
- Fast curing at 250-300°F
- Superb resistance to autoclaving, chemical sterilants, radiation and EtO
- Excellent adhesion to many substrates

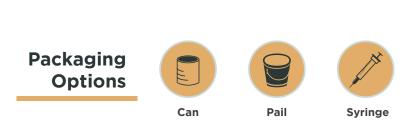


## **REQUEST A TDS for EP3HTMed**



## **Video Testimonial: Liger Medical**

Master Bond worked one-on-one with *Liger Medical* to meet their specific assembly and use requirements. After thoroughly reviewing their needs, the technical team recommended epoxy system EP3HTMed.



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## **EPOXY SYSTEM EP21LVMed** *Low viscosity, two component epoxy*



EP21LVMed medical grade epoxy resin system offers easy application, only contact pressure is required while curing. It provides good electrical insulation properties, making it ideal for potting and encapsulation. EP21LVMed produces high strength, durable bonds which hold up well to thermal cycling and resist many chemicals including water, acids, bases and most importantly, EtO, radiation and many cold sterilants.

#### **Key Features**

- Outstanding thermal cycling resistance
- Cures at room temperature or elevated temperatures
- Excellent electrical insulation
- Convenient mixing: one to one mix ratio by weight



Meets USP Class VI standard

## **REQUEST A TDS for EP21LVMed**

## **Case Study: Sealant for a Wireless Optogenetic Microsystem**



Researchers at Michigan State and Georgia Tech used EP21LVMed in an implantable, wirelessly-powered/controlled LED array that can modulate the activity of mouse neurons by using light. A major concern of this approach was to ensure its biocompatibility after implantation. To ensure this, once all components of the device were assembled, the researchers applied a thick layer of biocompatible EP21LVMed, which was then wrapped in Parylene-C.

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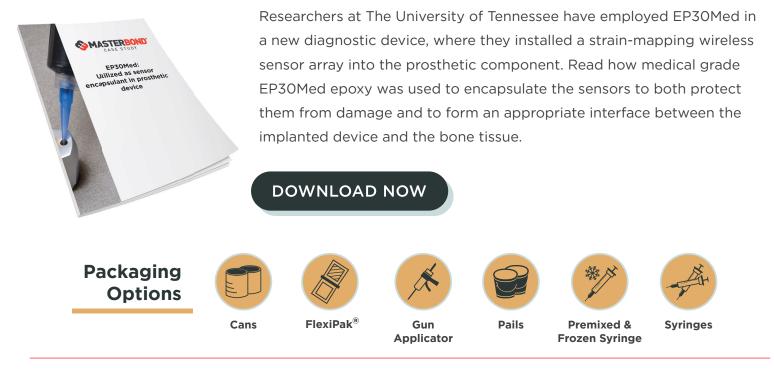
## **EPOXY SYSTEM EP30Med** Optically clear, two component epoxy



EP30Med is a two component, low viscosity epoxy resin system for high performance bonding, sealing, coating, and encapsulating. It is formulated to cure readily at room temperature or more quickly at elevated temperatures. It produces high strength, rigid bonds which are very resistant to chemicals including water, oils and many organic solvents, as well as cold sterilants, EtO and gamma radiation.



## Case Study: Utilized as Sensor Encapsulant in Prosthetic Device



## LED CURABLE ADHESIVE LED405Med Nanosilica filled compound



LED405Med is a one component, LED curing adhesive system for use in medical device assembly. "Since this system does not need a UV light for curing it is intrinsically more user friendly", says Rohit Ramnath, Senior Product Engineer. "It has a nanosilica filler resulting in both lower shrinkage upon cure, as well as greater dimensional stability. This product cures to a hardness of 65-75 Shore D, indicating that it is not too stiff, thereby offering good toughness."



- Fast cure by LED light without any oxygen inhibition
- Resists sterilization

**Key Features** 

- Can cure up to 1/8 inch thick
- Outstanding optical clarity



Meets ISO 10993-5 standard

#### **REQUEST A TDS for LED405Med**

#### **Performance Properties of LED405Med**

**Refractive index, 75°F** 1.50

Coefficient of thermal expansion, 75°F 35-40 in/in x  $10^{-6}$ /°C

Hardness, 75°F 65-75 Shore D

Service temperature range -60°F to +250°F [-51°C to +121°C]



# See LED405Med in action in this video demonstration

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Packaging Options



Can

S

Syringe

## **TWO COMPONENT EPOXY SYSTEM EP41S-5Med** *Resists sterilants, solvents and autoclaving*



EP41S-5Med is a two part epoxy system that can be used for bonding, sealing, and coating in medical devices. It features high temperature resistance and good strength properties. As an electrically insulative material, it can be utilized in medical electronic applications.

#### **Key Features**

- Highly resistant to solvents, including ethanol
- High glass transition temperature
- Resistance to hydrogen peroxide based sterilants
- Easy to use, available in a gun dispenser kits



#### Meets ISO 10993-5 standard

#### **REQUEST A TDS for EP41S-5Med**

## **Special Chemical Resistance Data of EP41S-5Med**

Castings of EP41S-5Med were prepared and subjected to 100 cycles of each sterilization method listed. An excellent performance is denoted by a weight change of 2% or less after repeated sterilizations. Below is a partial list of the chemicals or sterilization methods tested.

Bleach	E-bea	am	Hydrog	gen peroxide	Steris	
Cidex	Ethyl	ene oxide	Periace	etic acid	Sterrad®	
Citric acid	Gamr	na	Steam		Sterrad NX®	
	Packaging Options			1 A		
		Cans	Double Barrel Cartridge	Gun Applicator	Pails	

## SILVER CONDUCTIVE EPOXY EP21TDCSMed Two part epoxy compound



EP21TDCSMed is a two component, silver filled, electrically conductive epoxy. It can be used for bonding, sealing and coating applications. This system has a paste consistency and a forgiving one to one mix ratio by weight. EP21TDCSMed is much less rigid than conventional silver epoxy and offers excellent low outgassing properties. It holds up very well to cleaning solutions and sterilants such as EtO and gamma radiation.

#### **Key Features**

- Cryogenically serviceable
- Electrically and thermally conductive
- Capable of resisting thermal cycling
- Good bond strength properties



Meets USP Class VI standard

#### **REQUEST A TDS for EP21TDCSMed**

## **Performance Properties of EP21TDCSMed**

Volume resistivity, 75°F	<0.001 ohm-cm
Thermal conductivity, 75°F	3.46-3.75 W/(m•K)
Hardness, 75°F	50-60 Shore D
Service temperature range	4K to +250°F [4K to +121°C]



Premixed & Frozen Syringe

## SILICONE SYSTEM MasterSil 153Med

Two part, addition cured silicone for bonding and sealing



MasterSil 153Med is a two part silicone with a paste consistency that features a convenient one to one mix ratio by weight, and does not require exposure to air and humidity for cross-linking. It delivers high temperature resistance up to 400°F and superior flexibility. Its flexibility allows it to withstand thermal cycling, vibration and shock.

## **Key Features**

- Self priming feature
- Low exotherm; very long pot life
- Superior electrical insulation
- Exceptionally high tensile lap shear strength



## **REQUEST A TDS for MasterSil 153Med**

## **Performance Properties of MasterSil 153Med**

Volume resistivity, 75°F	10 <sup>14</sup> ohm-cm
Elongation, 75°F	400-500%
Tensile lap shear strength, aluminum to aluminum, 75°F	550-750 psi
Service temperature range	-65°F to +400°F [-54°C to +204°C]



## **ETHYL CYANOACRYLATE SYSTEM MB297Med** *Fast curing compound for bonding applications*



MB297Med is a higher viscosity, 2,200-2,400 cps, one part cyanoacrylate. This kind of system, commonly referred to as an instant adhesive or super glue, cures very rapidly with the rate of cure dependent upon the humidity—the higher it is, the faster the cure. This high strength system requires no heating or mixing. It typically sets up within 20-50 seconds depending upon the humidity and the substrates.

#### **Key Features**

- One component, no mix system
- Rapid fixture time
- Contact pressure is usually sufficient for fixturing
- Excellent resistance to EtO and gamma sterilization



## REQUEST A TDS for MB297Med

## **Performance Properties of MB297Med**

Tensile strength, 75°F	6,000 psi
Coefficient of thermal expansion, 75°F	70-75 x 10 <sup>-6</sup> in/in/°C
Hardness, 75°F	70 Shore D
Service temperature range	-60°F to +250°F [-51°C to +121°C]



## Is the adhesive an afterthought?

One mistake engineers often make is treating the adhesive as an afterthought in the design process. Our technical service engineers have fielded countless calls in which the engineer has picked just the right material to meet their device's functional requirements—only to find out that they've severely constrained their bonding choices.

The point here isn't to avoid tough-to-bond materials altogether. Sometimes they really are the best choice for the job. Instead, the point is that there are many more bonding options available when materials and adhesives are evaluated as a system early in the design process.

## DISCUSS YOUR APPLICATION

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