

LOCTITE[®]

HS Hardware Specialty Co., Inc.

Medical Product Selector Guide

Adhesives for Medical Device Assembly



Excellence is our Passion



All LOCTITE® brand Medical Device Adhesives are tested to the industry's most comprehensive ISO 10993 biocompatibility standards. In addition, Henkel employs strict manufacturing and quality controls to ensure continuity of compliance.

Tests include:

- Intracutaneous injection
- Systemic injection
- Muscle implantation
- Cytotoxicity (MEM elution)
- Hemocompatibility
- Physicochemical



FREQUENTLY ASKED QUESTIONS & ANSWERS:

What is ISO 10993?

ISO 10993 is an international standard created to facilitate international harmonization of test methods for biological evaluation of medical devices.

Why did Henkel move from a USP Class VI to ISO 10993 test program?

ISO 10993 standards offer compliance at a global level. Therefore, device manufacturers outside the U.S. have globally accepted standards, as opposed to the USP Program used in the U.S.

Is there a regulation requiring Henkel to revalidate its medical device adhesives to ISO 10993 on a regular basis?

There is no specific regulatory requirement regarding revalidation of our medical device adhesives. Henkel, as the industry leader, believes the revalidation is an important service to our customers in assuring continuity of compliance.

What controls does Henkel have in place after the product has been tested to ISO 10993?

While Henkel has no specific regulatory obligations under ISO 10993, we perform the following:

- Each batch of LOCTITE® medical device adhesive is validated by Henkel's Quality Control Department to include all raw material inputs, intermediates and raw material manufacturers, as well as compliance to the product formulation.
- Ensure that no changes will be made to composition materials, nor significant changes to our processes, without notifying customers who have a specification on file requesting such notification.



RESOURCES & CAPABILITIES

TRAINING SERVICES

Henkel offers training programs to device manufacturers around the globe. Additional support continues after the seminar as participants are linked to a network of information sources including adhesive design guides, research data and technical reports.

MEDICAL TECHNOLOGY ON-SITE SEMINAR PROCESS IMPROVEMENT TOURS/TRAINING

A training program customized to your needs. Select from a menu of medical device adhesive topics or request a customized seminar to meet your specific requirements. The course is presented on-site and includes instruction, hands-on demos, samples and technical guides.

CUSTOMER WORKSHOP

These unique, fully integrated programs are taught by Henkel engineering and technical representatives. Presenters review a range of issues specifically related to the medical device industry. Attendees benefit from hands-on demonstrations of adhesives and equipment.



ENGINEERING SERVICES

Our goal is to become your adhesive consultant. Whether you need a quick product recommendation or a full-blown turn-key process, Henkel Engineering Services can provide the right solution. Our skilled engineers have years of combined experience developing hundreds of solutions for medical device manufacturers. Consult with Henkel and gain access to:

- On-site engineering assistance and consultation
- Joint product development programs and custom formulations
- Contract lab services and testing, including environmental conditioning and accelerated aging studies
- Prototype testing and fixture preparation
- Analytical services to determine surface conditions and degree of cure



ADHESIVE PROPERTY COMPARISON



PERFORMANCE CONSIDERATIONS	ADHESIVE CATEGORY				
	CYANOACRYLATES	EPOXIES	LIGHT CURE ADHESIVES	SILICONES	URETHANES
BENEFITS	Wide range of bonding applications	Wide range of formulations	Rapid cure/adhesion to plastics	Excellent temperature resistance	Excellent toughness/flexibility
LIMITATIONS	Low solvent resistance	Mixing required	Light cure system required	Low cohesive strength	Sensitive to moisture
TEMPERATURE RESISTANCE					
TYPICAL FOR THE CATEGORY	-65°F to 180°F	-65°F to 300°F	-65°F to 300°F	-65°F to 350°F	-65°F to 250°F
HIGHEST RATED PRODUCT	250°F	300°F	300°F	350°F	250°F
ENVIRONMENTAL RESISTANCE					
POLAR SOLVENTS (e.g., H ₂ O, ETHYLENE GLYCOL, IPA, ACETONE)	Poor ¹	Very Good	Good	Good	Good
NON-POLAR SOLVENTS (e.g., MOTOR OIL, TOLUENE, GASOLINE, ATF)	Good	Excellent	Very Good	Poor to Fair	Good
ADHESION TO SUBSTRATES					
METALS	Very Good	Excellent	Good	Good	Good
PLASTICS²	Excellent	Fair	Excellent	Good	Very Good
GLASS	Poor	Excellent	Excellent	Good	Good
RUBBER	Very Good	Fair	Fair	Fair	Good
OVERLAPPING SHEAR STRENGTH	High	High	High	Low	Medium
PEEL STRENGTH	Low ³	Medium	Medium	Medium	Medium
TENSILE STRENGTH	High	High	High	Low	Medium
ELONGATION / FLEXIBILITY	Low	Low	Medium	Very High	High
HARDNESS	Rigid	Rigid	Semi-Rigid	Soft	Soft
PROCESS CONSIDERATIONS	ADHESIVE CATEGORY				
	CYANOACRYLATES	EPOXIES	LIGHT CURE ADHESIVES	SILICONES	URETHANES
NUMBER OF COMPONENTS	1	1 and 2	1	1	2
CURE TEMPERATURES	Room Temperature	Heat or Room Temperature	UV/Visible	UV/Visible	Room Temperature
FIXTURE TIME					
AVERAGE	60 seconds	5 hours	30 seconds	10 minutes	5 hours
FASTEST	5 seconds	15 to 20 minutes	5 seconds	60 seconds	5 hours
FULL CURE TIME	24 hours	1/2 to 24 hours	30 to 60 seconds	24 hours	24 hours
GAP FILL					
IDEAL (IN INCHES)	0.001 to 0.003	0.004 to 0.006	0.002 to 0.010	0.004 to 0.006	0.004 to 0.006
MAXIMUM (IN INCHES)	0.010	0.5	0.25	0.25	0.5
DISPENSING / MIXING EQUIPMENT REQUIRED	No	Yes (2 parts)	No	No	Yes
LIGHT CURE VERSIONS AVAILABLE?	Yes	No	Yes	Yes	No

¹ Cyanoacrylates have very good moisture resistance when applied to plastics.

² Uncured liquid adhesives may cause stress cracking of certain thermoplastics, e.g., polycarbonate, acrylic and polysulfone. Special products and process techniques are available. Consult the LOCTITE® Design Guide to Bonding Plastics (LT-2197) or contact 1-800-LOCTITE (562-8483) for more information.

³ Exception: Toughened cyanoacrylates have HIGH peel strength.



PRODUCTS

Our medical device adhesives cover a variety of chemistries, providing you with a wide range of choices and assembly solutions. Products are available in viscosities ranging from water-thin liquids to thixotropic gels and are compatible with common sterilization methods such as ethylene oxide, gamma radiation, electron beam, liquid sterilization, autoclave and peroxide plasma.

LIGHT CURING ADHESIVES

Upon exposure to the appropriate light source, these one-part adhesives cure completely in seconds to form thermoset or thermoplastic polymers (depending on the chemistry) with excellent adhesion to a wide variety of substrates. Cure times from 2 to 30 seconds are typical.

LIGHT CURING ACRYLICS

These products offer the most extensive variety of properties of all light cure chemistries. Upon exposure to suitable UV and/or visible light, acrylics produce tough, durable thermoset polymers. Cured properties range from hard and rigid to soft and flexible. Easily automated, fluorescent versions allow in-line detection of the adhesive.

The Indigo® family of products are designed to cure with high-wavelength visible light. These adhesives offer enhanced cure depth, cure through select colors, and are optimally cured with Indigo® visible light LED curing systems.

Light curing acrylics are used to assemble syringes, injectors, infusion sets, pressure transducers, drug delivery devices, IV sets, oxygenators, cardiotomy reservoirs, blood heat exchangers, hearing aids, anesthesia masks and blood filters.

LIGHT CURING CYANOACRYLATES

LOCTITE® FlashCure® light curing cyanoacrylates are well suited for applications where a secondary moisture cure is required, allowing the adhesive to cure completely in shadowed areas where light cannot reach. Exposure to low-intensity UV or visible light provides tack-free surfaces in less than 5 seconds. These adhesives eliminate the need for solvent-borne accelerators and minimize stress cracking and blooming (a whiteness around the bondline), due to their “instant” fixturing.

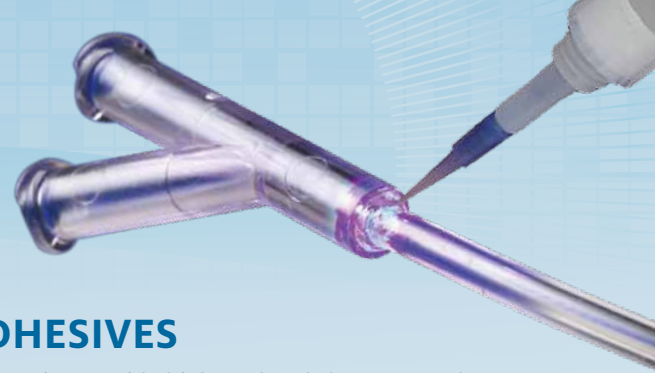
Light curing cyanoacrylates are ideal for the assembly of catheters, syringes, pressure transducers, orthopedic devices, infusion pumps, oxygen concentrators, blood gas analyzers and filters, as well as a number of other devices.

LIGHT CURING SILICONES

LOCTITE® Nuva-Sil® silicones cure to soft, flexible, thermoset elastomers when exposed to high-intensity UV and/or visible light. These adhesives cure in seconds, thus reducing work-in-process, and offer high adhesion to silicone materials as well as plastics and metals. Select products offer a secondary moisture cure, ensuring cure in shadowed areas.

Light curing silicone applications include respiratory devices, tracheal and endotracheal tubes, foley catheters, colostomy devices and chest drainage tubes.





CYANOACRYLATE ADHESIVES

These one-part, highly flexible adhesives fixture in seconds at room temperature, forming slightly flexible to rigid thermoplastics. They are particularly suited for joining dissimilar substrates in almost any combination including polyolefins, thermoplastics, rubber and metals. LOCTITE® cyanoacrylates are high-performance, instant adhesives designed for the most challenging applications. The LOCTITE® family of cyanoacrylates includes flexible, toughened, low odor/low bloom, surface-insensitive and thermally resistant formulations.



Cyanoacrylates are widely used to bond components in the assembly of blood pressure transducers, endoscopes, IV sets, infusion pumps, catheters, orthopedic devices, hearing aids, cast boots and diagnostic imaging equipment.

CYANOACRYLATE ACCELERATORS AND PRIMERS

Accelerators speed the cure of cyanoacrylates and are used to reduce fixture and cure times, or to cure fillets on bondlines and/or exposed adhesive. They can be applied to a substrate prior to the application of cyanoacrylate adhesive, or they can be sprayed over a drop or fillet to initiate a rapid cure. Primers enable the cyanoacrylate to form strong bonds with polyolefins and other difficult plastics such as acetal resins. Depending on the plastic, bond strengths up to 20 times the unprimed bond strength may be achieved.

EPOXY ADHESIVES

LOCTITE® Hysol® epoxies provide high peel and shear strength on a wide variety of plastics and metals. When cured, these cross-linking thermoset plastics offer superior thermal and chemical resistance, as well as high cohesive strength and minimal shrinkage. Hysol® two-part systems are packaged in side-by-side cartridges, allowing them to be dispensed as easily as any one-part system.

Our single-component, heat cure formulas are excellent for bonding metals to a wide variety of plastics, providing superior pull strength when joining cannulae to hubs or syringes.

Epoxies are commonly used on endoscopes, catheters, arterectomy devices, blood heat exchangers and syringes, as well as dental, surgical and orthopedic instruments.

POLYURETHANE ADHESIVES

LOCTITE® Hysol® urethanes are ideal for bonding metals, plastics, glass and other substrates. Designed for potting and encapsulating applications, these two-part, room temperature curing products provide excellent peel and shear strength. They are ideal for opaque substrates that require high flexibility.

Urethanes are commonly used in potting applications on filters, kidney dialyzers, blood heat exchangers and catheters.





APPLICATION CASE HISTORIES

LED LIGHT SOURCE CONSISTENTLY CURES LIGHT CURE ADHESIVE

US Endoscopy is a manufacturer of accessories for rigid and flexible endoscopes – medical devices used for the exploration and/or biopsy of organs and tissue. One of its recent products is a biopsy inlet valve that would allow the operator to irrigate without performing an instrument exchange.

US Endoscopy had very specific requirements for the inlet valve production. The blue thermoplastic valve needed to be assembled using clear PVC tubing with an adequate pull strength. In order to meet the company’s production target, a 15- to 20-second cure time was required. Additionally, there was an optimal amount of adhesive that should be used for the joint. Too little adhesive and the bond strength or seal could be compromised. Too much adhesive would cause excess material to drip down the side of the valve, creating an aesthetic reject. Finally, US Endoscopy wanted the equipment and the adhesive to come from one supplier, thus ensuring a well-designed process and post sales support.

By using the LOCTITE® 7700 Hand-Held LED Light Source with LOCTITE® 3922™ Medical Device Light Cure Adhesive, US Endoscopy was able to consistently cure the assembly in 10 seconds, while nearly doubling the pull strength. This was possible because the spectral output of the LOCTITE® 7700 LED Light Source is very high-intensity visible light (as opposed to UV light) and the wavelength of the visible light exactly matches that absorbed by LOCTITE® visible light cure adhesives. Other benefits of this light source are that it is inexpensive, small in size, portable, and generates minimal heat and minimal ultraviolet energy, making it safer to work with than traditional UV light sources.



LOCTITE® 3922™ bonds thermoplastic inlet valve assembly.



LOCTITE® 3311™ offers adhesion to various swab substrates, resulting in a safer and more reliable device.

INNOVATIVE DEVICE PACKAGING SOLVES SAFETY HAZARD

For years, Medical Packaging Corporation produced a swab device in combination with a reagent-filled glass ampule used for various diagnostic tests. Following sample collection, the glass ampule was broken, releasing the test reagent for use in the analysis. Problems with the procedure included the possibility that glass shards could cut the technician, clog the dropper tube or get into the reagent. The development of an innovative package allowed for increased safety and a patented product, offering the manufacturer a competitive advantage in a very large market.

The new product was designated the SnapSwab™ and consisted of a Dacron® swab tip on a polystyrene shaft encased in a polyethylene tube. In use, a quick snap of the swab shaft releases the reagent and the swab is ready for use. It was necessary to reliably attach the swab to the inside of the tube and ensure the entire assembly be leakproof. LOCTITE® 3311™, a single-component light cure acrylic adhesive, was the adhesive of choice for the new swab device. Rapid, semi-automated processing, and high adhesion to the various swab substrates resulted in a device that was safe, convenient, dependable and inexpensive.

ENVIRONMENTAL CONCERNS ELIMINATED FOR COLLECTION RESERVOIR

A manufacturer of blood collection and processing systems used solvents such as methylene chloride for bonding various device components and subassemblies. OSHA and the EPA were encouraging industries to move away from using solvents, and this device manufacturer particularly wanted to eliminate its use of methylene chloride. Since the devices were made of glass-like plastics, the company's engineers required clear bonds with no stress cracking or crazing.

The collection reservoir, a disposable device used to clean and return blood to patients during various surgical procedures, consists of a clear polycarbonate lid assembly joined to a polycarbonate bucket.

Environmental concerns and issues associated with solvent bonding were eliminated with a new tongue and groove design and with LOCTITE® 3211™ – a safer, faster and more consistent bonding choice. LOCTITE® curing adhesive provided the aesthetic bondline the manufacturer wanted.

It also provided the structural strength that the collection reservoir manufacturer needed to maintain a competitive edge in the marketplace.



LOCTITE® 3211™ eliminates solvents and provides structural strength for collection reservoir.



LOCTITE® 4011™ replaced solvent bonding in this PVC tube to copolymer fistula assembly.

TOXIC SOLVENTS ELIMINATED

A manufacturer of a device used in dialysis machines to withdraw and return blood had a production line shutdown. The problem: One vendor had supplied out-of-tolerance parts, and the solvent used for bonding could not fill the excessive gap. The company's PVC tubing supplier also made a substitution, creating additional assembly problems.

The assembly process used solvent welding, a mixture of 90% methylene chloride and 10% cyclohexanone, to join a flexible PVC tube to a copolymer elastomer (TPE). The parts were joined by slip fit, with a gap of 0.002", using a dip and assemble technique. The assembled product had to meet a 20-25 psi burst test and a 15 lb. pull test.

LOCTITE® 4011™, a surface-insensitive cyanoacrylate, was specified. It filled the gap and had enough strength to pass the burst and pull tests with ease. Since the manufacturer already used LOCTITE® 4011™ in another area of the plant, making the switch was easy. Production goals were met, inventory was used, product quality was assured and a potentially troublesome toxic solvent was eliminated.



Dispensing, Curing and Process Monitoring EQUIPMENT

Henkel offers a complete line of dispensing, curing and process monitoring equipment designed specifically for use with our medical device adhesives.

A variety of light curing systems is available, ranging from portable curing wands to modular flood chambers and benchtop conveyors. All of our light cure equipment is engineered to match the spectral output of our range of light curing adhesives. As a manufacturer of both the adhesive and curing equipment, we understand the chemistry and the process needed to cure our products properly, so you can be assured of obtaining the maximum bond strength and cure speeds. Matching the adhesive to the correct curing system will optimize your assembly process and help you attain the fastest, most consistent cures. We offer a full line of accessories, including radiometers, replacement bulbs and UV safety glasses.

Henkel's state-of-the-art detection systems allow for real-time process monitoring of dispense cycles. If you are trying to determine the amount of adhesive dispensed from an individual dispense nozzle, Henkel has the system that will get the job done with high degrees of precision and reliability.



Henkel also provides engineering resources to assist customers in developing manufacturing and assembly processes that effectively integrate on-line dispensing and curing equipment. Rental and repair services are also offered, affording customers the opportunity to fully evaluate a process and equipment before making a capital investment.

JETTING DISPENSE SYSTEM

Our dispensing equipment options range from manual and semiautomatic to fully automatic systems, along with a complete line of accessories, such as needles, nozzles and syringes. Our dispensing technology enables customers to apply drops or beads of adhesives, making precise application of LOCTITE® products economical, fast and clean.

LED CURING

Henkel has introduced new LED light curing devices for a wide range of applications. These systems offer long LED life, minimal maintenance, high power, continuous duty cycle and portability.

ASSURE CURE™

**INTRODUCING...
LOCTITE® AssureCure®**

A revolutionary technology that combines adhesive, a detection system and software to provide inline, quantifiable confirmation of cure level for light cure acrylic adhesives.

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