Solutions That Cure™
Adhesives For Medical Device Assembly

Henkel
We provide cost-effective solutions that work for you.
Why take a chance on anyone else?
Whether your medical device assembly requires an adhesive that is biocompatible and sterilizable – or one that meets a host of other performance characteristics – Henkel has the right adhesive for your application.

Our adhesives have been specified by medical device manufacturers all over the world for over two decades. Our experience, products, and engineering services are second to none, with the world’s most diversified and comprehensive line of adhesives, dispensing equipment, and curing systems available anywhere. We offer over forty products for medical device assemblies requiring biocompatibility testing and hundreds of other products for applications not requiring such evaluation.

Adhesives can provide design advantages, improve overall product performance, speed assembly time, and increase production efficiency and quality. Loctite® adhesives combine all of these advantages, and more. When the total cost of a finished medical device is considered, adhesives are the most economical assembly choice. Loctite® adhesives offer many benefits, including:

- **Structural Bonds**
- **Ability to Bond Dissimilar and Difficult Substrates**
- **Increased Throughput**
- **Rapid Fixture and Overall Cure Times**
- **Excellent Gap Filling Capability**
- **Even Stress Distribution**
- **Comprehensive Biocompatibility Testing**
Our medical device adhesives cover a variety of chemistries, providing you with a wide range of choices and assembly solutions. We know one product won’t fit every design, and that’s why we continue to create and add new products, new chemistries, and even new technologies.

All of our 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 two to thirty seconds are typical.

**Light Curing Acrylics** – These products offer the most extensive variety of properties of all light cure chemistries. Upon exposure to suitable light, acrylics produce tough, durable thermoset polymers. Cured properties range from hard and rigid to soft and flexible. Newer products cure under either UV or visible light sources and respond to low, medium, or high intensity light. Easily automated, fluorescent versions allow in-line detection of the adhesive.

Light curing acrylics are used to assemble syringes, injectors, infusion sets, pressure transducers, drug delivery devices, IV sets, oxygenators, cardiomyom stable 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 five 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, filters, as well as a number of other devices.

**Light Curing Silicones** – When exposed to high intensity UV light, Loctite® Nuva-Sil® silicones cure into soft, flexible thermoplastic elastomers. Light curing silicones are excellent for sealing, gasketing and leakproofing, and are well suited for bonding silicone rubber.

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

These one-part adhesives cure 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® Prism® cyanoacrylates are high performance instant adhesives designed for the most challenging applications. The Prism® family 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 crosslinking thermostet 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 new 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, artherectomy devices, blood heat exchangers, syringes, and 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.
**TOXIC SOLVENTS ELIMINATED**

Loctite® 4011™ replaced solvent bonding in this PVC tube to copolymer fistula assembly. After bonding, the balloon is inflated fifty times to check bond durability.

**CATHETER SAFETY INCREASED**

A thermal dilution catheter manufacturer requested assistance for bonding a latex balloon to a rigid, multi-lumen PVC tube. The catheter is inserted into a major vein near the heart to take blood samples, administer fluids, and monitor blood pressure and body temperature. The transducer must endure temperatures ranging from freezing to 110°F, while the balloon must withstand pressures up to 110 lbs. After bonding, the balloon is inflated fifty times to check bond durability.

Loctite® 4014™ cyanoacrylate was selected on the balloon bond, for its low viscosity, thermal resistance and controlled setting time. This allowed time to assemble and place the balloon precisely. The customer reports that the adhesive works so well that “the balloon ruptures before the adhesive fails.”

**VETERINARY DEVICE SECURED**

Animal drugs for livestock management and the introduction of new vaccines and drug treatments have led to new delivery techniques in veterinary device technology. Since the FDA does not require the same standards for animal devices as those required for medical devices intended for humans, manufacturers may use non-medical products. Their responsibility is to assure that the animal medical device is safe, effective, and properly labeled.

Most syringes used for animal injections are made of solvent resistant polypropylene (PP). Because of the difficulty in joining PP, snap fittings are frequently used to connect tubes and barrels. However, the soft and pliable nature of PP often results in poor performance or joint failures. Because livestock is very expensive, if a syringe breaks during an injection it could mean the loss of an expensive drug, as well as internal injury to the animal, should the broken section be swallowed by a valuable racehorse, for example.

To permanently connect the components, Loctite® 406™, a low viscosity adhesive, was selected for its ability to bond difficult substrates. Loctite® 770™ polyolefin primer was applied to the PP, prior to applying the cyanoacrylate, to obtain maximum bond strength. The bonded parts met every drug resistance and strength test required by the manufacturer.

Note: For medical devices intended for humans, Loctite® 4061™ adhesive and 7701™ primer are recommended, as they comply with extensive biocompatibility testing.

**TOxic SOLVENTS ELIMINATED**

A manufacturer of a device used in dialysis machines to withdraw and return blood had a production line shut down. The problem: one vendor had supplied out-of-tolerance parts, and the solvent used for bonding could not fill the excessive gap. Their 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 .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.
**Bond Strength Increases 5X on Safety Syringes**

Loctite® 3051™ bonds K-Resin® to stainless steel cannulae in dental syringes, increasing product quality. Ready for injection (left), and K-Resin guard covering needle after injection (right).

**Solvents and Stress Cracking Eliminated**

This soft, flexible catheter uses a “peel away,” splitable needle introducer, a unique catheter insertion system for fragile veins. After insertion, the needle’s wing assembly is split apart and discarded, eliminating the need to repeatedly rustick the patient.

The manufacturer was dissatisfied with the process used to bond the stainless steel needle halves to lightly-tinted polycarbonate wings. A “solvent cocktail,” made by combining a plastic, such as PVC pellets, and adding solvent, to make a “glue,” was being used. Formulation inconsistency, stress cracking, and toxic solvent fumes were growing concerns.

The solution, Loctite® 3211™ was specified along with a Loctite® light cure chamber. The combination proved superior in every way – eliminating stress cracking while reducing rejects due to the solvent cocktail’s inconsistencies.

**Strong, Flexible Bonds Achieved**

This lower limb prosthetic device manufacturer builds prostheses made of carbon fiber, a material known for its superior strength, flexibility, and imperviousness to the elements as well as corrosion and stress. They wanted to provide amputees with proportional response, an active heel with natural ankle motion and a 95% energy return that actually powers the wearer through each step.

Loctite® Prism® 410™ is used to lock the stainless steel threaded fastener into position during the customized fitting of this prosthesis.

**Four-Second Cure Doubles Production**

A manufacturer wanted a better way to assemble anesthesia masks in order to double production. The substrates they were bonding were rigid cones to flexible, highly plasticized PVC face cushions. The masks were assembled with a cyanoacrylate that required 9 seconds to fixture and several hours to fully cure. Some brittleness and blooming during and after cure was experienced, with rework and rejections running high. A peel test demonstrating substrate failure was required, and no oxygen leakage could be exhibited from the mask after bonding.

Loctite® 3341™ proved to be the superior alternative, passing all tests and requiring only 4 seconds for complete cure under a Loctite® medium-intensity light cure conveyor. This enabled the customer to not only double production by adding another shift, it also presented a significant cost savings over their prior cyanoacrylate usage.
more consistent bonding choice. Loctite® 3211™ provides structural strength for collection reservoir manufacturer needed to provided the structural strength that the bondline the manufacturer wanted. It also eliminated with a new tongue and groove design and issues associated with solvent bonding were eliminated 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 their use of methylene chloride. Since the devices were made of glass-like plastics, their 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 bucket. Environmental concerns for use. It was necessary to reliably attach the swab to the inside of the tube and ensure the entire assembly be leak proof. It is also essential that the position of the cannula remains fixed. All Loctite® needle bonding adhesives are fluorescent to facilitate final inspection of the adhesive joint, ensuring that the adhesive is not only present but also that the adhesive has flowed into the bond joint correctly. The Loctite® Fluorescent Detector is used to perform a present or not present inspection. If more precision is desired, the fluorescence can be monitored using a vision system, albeit at much higher expense.

Henkel offers the most extensive line of needle bonding adhesives. These UV/visible acrylic and/or one-part epoxy products are specifically designed for the assembly of stainless steel cannulae to a variety of hub materials including polycarbonate, acrylic, ABS, and polypropylene. The wide range of adhesives includes viscosity, environmental, substrate and performance variations to ensure that there is a product to meet any needle bonding application requirement.

INNOVATIVE DEVICE PACKAGING SOLVES SAFETY HAZARD

For years, a swab device in combination with a reagent filled glass ampule has been used for various diagnostic tests. Following sample collection, the glass ampule was being 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 device. Rapid, semi-automated processing, and high adhesion to the various swab substrates resulted in a device that was safe, convenient, dependable, and inexpensive.

LIGHT CURE TECHNOLOGY IMPROVES APPEARANCE AND SPEEDS PRODUCTION

Hearing aid manufacturers have long relied on adhesives for the assembly of various hearing aid components including face plates and receiver components. Recent advances in light curing technology have allowed for increased throughput and reliability.

Loctite® Flashcure® cyanoacrylates are single component light curing adhesives. With exposure to low intensity light, the Flashcure® products cure in seconds offering strong facetype and componentry bonds. The need for solvent-based cyanoacrylate accelerators is eliminated and the potential for blooming (a whiteness around the bond line) is reduced. Loctite® Nova-S™ silicones are single component, light/moisture curing adhesives/sealants. The rapid cure with exposure to high intensity light makes the dual curing silicones the products of choice for the bonding of the receiver tube to the receiver, and the bonding of the receiver tube to the shell for hearing aid shell fabrication.

ON-PART DETECTION ENSURES QUALITY AND RELIABILITY

Adhesives are universally used for bonding cannulae to hubs in needle assemblies. It is critical that this joint is well bonded and sealed to prevent fluids such as blood or medicine from leaking. It is also essential that the position of the cannula remains fixed.

Henkel offers the most extensive line of needle bonding adhesives. These UV/visible acrylic and/or one-part epoxy products are specifically designed for the assembly of stainless steel cannulae to a variety of hub materials including polycarbonate, acrylic, ABS, and polypropylene. The wide range of adhesives includes viscosity, environmental, substrate and performance variations to ensure that there is a product to meet any needle bonding application requirement.
Henkel offers a complete line of dispensing, curing and process monitoring equipment designed specifically for use with our medical device adhesives. Our dispensing equipment options range from manual and semi-automatic 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.

We offer custom engineered systems for turnkey integration in high speed assembly processes. If your future production plans include significant growth, Henkel can even show you the advantages of installing a flexible system that can grow with your changing needs.

A variety of light curing systems, ranging from portable curing wands to modular flood chambers, and benchtop conveyors, are available. 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. Whether you are trying to determine the presence of adhesive via fluorescence detection, or 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 which 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 prior to making a capital investment.

For more information on our complete line of dispensing, curing and process monitoring equipment, visit us at equipment.loctite.com
Our goal is to become your adhesive consultant. Whether you need a quick product recommendation, or a full-blown turnkey 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:

- The best product and process solution for your specific application
- Products tested and in compliance with our ISO-10993 Biocompatibility Test Program – the most comprehensive in the industry
- Highly trained and skilled specialists with the know-how to consult, troubleshoot, and solve problems
- On-site product and application training and support
- State-of-the-art parts testing and evaluation facilities to simulate a wide range of environments

Whether we are reducing your assembly costs, providing design and application assistance, or increasing the reliability of your process, Henkel is dedicated to earning your trust. Count on Henkel to be your sole source for all of your medical device applications.

Henkel offers training programs that provide additional support to device manufacturers around the globe. Training continues after the seminar: you are linked to a network of informational sources including adhesive design guides, research data, and technical reports.

**Advanced Medical Device Adhesive Workshops:** These unique, fully integrated, four to seven hour programs are taught by Henkel engineering and technical representatives who have years of experience providing solutions to medical device manufacturers on design and assembly challenges. Presenters will review a range of issues specifically related to the medical device industry. Attendees will benefit from hands-on demonstrations of adhesives and equipment.

For dates and locations of upcoming Advanced Medical Device Adhesive Workshops, log onto our website at [www.loctite.com/medical](http://www.loctite.com/medical).

**On-Site Technology Seminars:** A training program customized to your needs. Select from a menu of seven of the most requested medical device adhesive topics or request a customized seminar to meet your specific requirements. The course will be presented on-site and will include instruction, hands-on demos, samples, and technical guides.

For more information on the On-Site Seminar program, contact Henkel at 1-800-LOCTITE.

We support our customers with a service program that is unmatched by others in the industry. It's what sets Henkel apart.
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Type</th>
<th>Color</th>
<th>M</th>
<th>RT</th>
<th>UV</th>
<th>V</th>
<th>P</th>
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<td>3982™</td>
<td>EPOXIES</td>
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<td>N</td>
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<td>N</td>
<td>M</td>
<td>400</td>
<td>65 to 125</td>
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<td>M</td>
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<td>80 (D)*</td>
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<td>N</td>
<td>M</td>
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<td>N</td>
<td>M</td>
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<td>M</td>
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<td>65 to 160</td>
<td>65 (Barcol)</td>
<td>200,000*</td>
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**Legend for Adhesive Properties**
- **M**: Moisture Resistance
- **RT**: Room Temperature
- **UV**: Ultraviolet
- **V**: Visible

**Legend for Adhesive Properties**
- **N**: Neutral
- **Y**: Yellow
- **G**: Green
- **X**: White

**Legend for Adhesive Properties**
- **TP**: Thermoplastic
- **PC**: Polycarbonate
- **ME**: Metallized
- **G**: Glass

**Legend for Adhesive Properties**
- **TP**: Thermoplastic
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- **G**: Glass
BIOCOMPATIBILITY TESTING & CERTIFICATES OF COMPLIANCE:
Loctite® Medical Device Adhesives meet ISO-10993 Biocompatibility standards. All ISO-10993 Certificates of Compliance are available on the Loctite® website and include the following tests:

- Intracutaneous Injection
- Cytotoxicity (MEM Elution)
- Systemic Injection
- Hemocompatibility
- Muscle Implantation
- Physicochemical

Although Henkel has no specific regulatory requirement regarding biocompatibility testing and revalidation of our medical device adhesives, as the industry leader we believe our triennial revalidation program is an important service to our customers in assureing continuity of compliance.

TECHNICAL AND MATERIAL SAFETY DATA SHEETS:
INSTANT access to comprehensive technical and material safety data sheets is available on the Loctite® website. Most are available in various languages. Technical data sheets are integrated with our material specifications and all products are tested on a batch to batch basis. Locate any Loctite® technical data sheet using a product or item number, and safety data sheets using an item number.

Visit us on the web at www.loctite.com/medical or call 1-800-LOCTITE (562-8483)

Visit us on the web at www.henkel.com/medical or call 1-800-323-5106

For your nearest Loctite® brand Adhesives and Sealants Specialist, to arrange an in-plant seminar or for technical product assistance, call: 1.800.323.5106

For your nearest authorized Loctite® brand distributor, to arrange an in-plant seminar, for technical product assistance or to place an order, call: 1.800.LOCTITE (1.800.562.8483)
To put Henkel to work for you, contact your Loctite® Adhesive and Sealants Specialist at 1-800-LOCTITE (562-8483).

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