

LOCTITE®

BEYOND THE BOND

GLOBAL SOLUTIONS FOR MEDICAL DEVICE ASSEMBLY

Adhesives, Equipment & Services



Henkel

Henkel Adhesive Technologies



INDUSTRY OVERVIEW

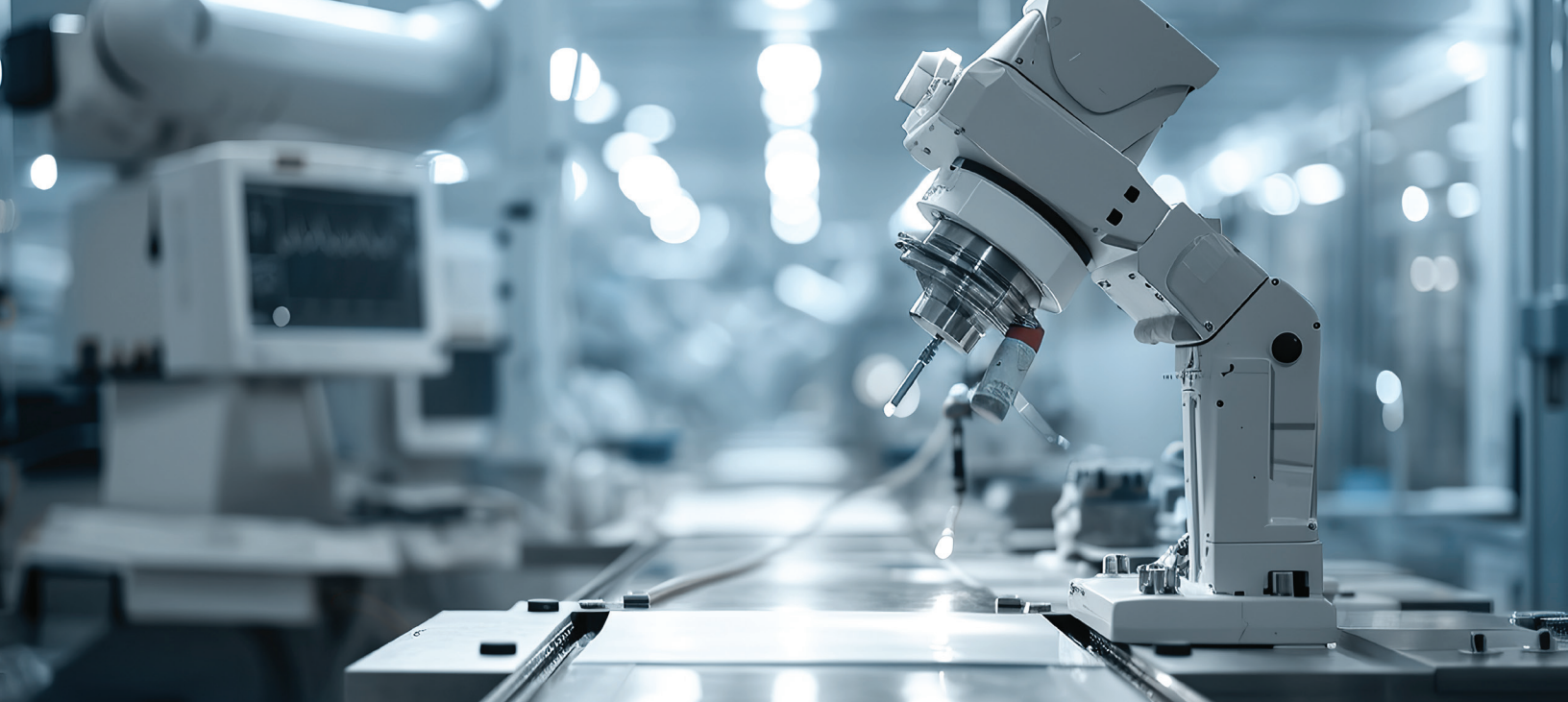
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INDUSTRY OVERVIEW

SOLUTIONS

LOCTITE® medical device assembly solutions have been specified by medical device designers and manufacturers for decades.

As device designs have advanced so have our innovative adhesive solutions to support the growing need for smaller, higher performing, smarter, and safer medical devices. Together, we can bring your medical devices to life.

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 70 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, and increase production efficiency and quality. LOCTITE adhesives combine all of these advantages and more.

SUSTAINABILITY

At Henkel, we are committed to providing sustainable solutions to support our medical device partners and are constantly working on new innovations that drive impact for the environment and its safety.

Innovative Adhesives Formulated without Materials of Concern:

- New LOCTITE solutions that have reduced or removed known chemicals of concern and those that are coming under greater regulatory scrutiny including, but not limited to, CMRs, SVHCs, and skin irritants.

LOCTITE assembly automation equipment includes solutions that increase productivity, reduce waste and improve safety:

- LED-curing systems for the extensive line of LOCTITE light-cure acrylics offer lower energy, faster cures, less heat, longer life, and safer disposable parts.
- Dispensing equipment for a range of adhesive types and packages enable waste reduction, use of larger adhesive packs for reduced plastic waste, and improved safety for operators.

BIOCOMPATIBILITY

LOCTITE brand medical device adhesives are tested to the industry's most comprehensive ISO 10993 biocompatibility standards. In addition, LOCTITE employs strict manufacturing and quality controls to ensure continuity of compliance.

Tests include:

- Intracutaneous injection
- Systemic injection
- Muscle implantation
- Cytotoxicity (MEM elution)
- Hemolysis

LOCTITE medical device adhesives are not intended for implants nor invasive prostheses.

Due to unique requirements, please contact LOCTITE for the latest list of adhesives specifically designed for use in wearable medical devices.

STERILIZATION

Sterilization is defined as the validated process used to render a product free from viable microorganisms. Material compatibility, cost, and process flow concerns will affect the device manufacturer's choice of a sterilization method.

Also, the device type—disposable or reusable—will have bearing on the number of cycles as well as type of sterilization used. Both disposable and reusable devices will typically see initial sterilization at the OEM manufacturer via ETO, gamma or electron beam sterilization. Reusable devices may be sterilized multiple times at the point of use (e.g., hospital or clinic) and common methods include autoclaving, chemical immersion, and hydrogen peroxide gas plasma.

The majority of fully cured LOCTITE medical device adhesives maintain bond performance following exposure to typical sterilization methods and durations. It is always recommended that designers and users fully evaluate adhesives on actual parts and under actual end-use application to ensure that they meet or exceed requirements.



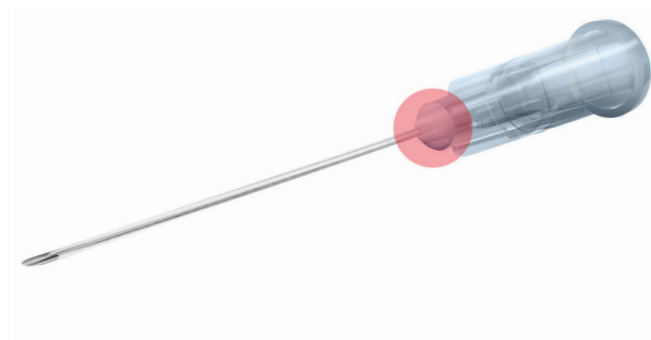
SOLUTIONS FOR DISPOSABLE MEDICAL DEVICES

Disposable or single-use devices are manufactured for the purpose of one-time use and can be constructed of a wide range and combination of materials. Biocompatibility, high-speed production, precision assembly, and sterilization resistance are key requirements that LOCTITE® medical device adhesives support.

DEVICES & ADHESIVE APPLICATIONS

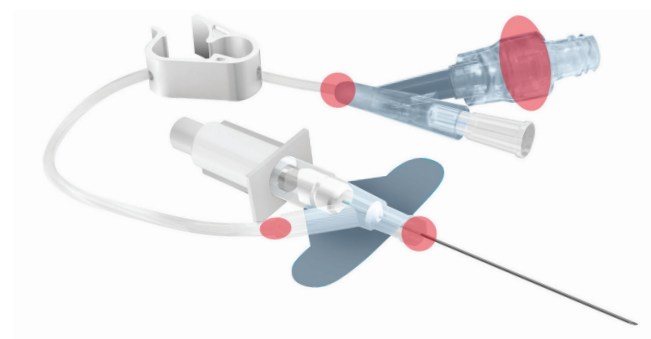
NEEDLES

Technology – Light-Cure Adhesives



CATHETERS

Technology – Light-Cure & Cyanoacrylate Adhesives



FLUID COLLECTION, STORAGE & MANAGEMENT

Technology – Light-Cure Adhesives



DEVICE CHALLENGES



Quick and effective quality checks in process



High-speed manufacturing



Small parts that require precision and accuracy



Biocompatibility



Durability for sterilization



Dissimilar materials, including hard-to-bond and flexible substrates

LOCTITE SOLUTIONS & BENEFITS

LIGHT-CURE ACRYLICS

- Fast, on-demand, light-cure
- Broad range of viscosities
- Gap fill
- Fluorescent



LIGHT-CURE CYANOACRYLATES

- Fastest, on-demand, light-cure
- Dual-cure: light and moisture
- Fluorescent



CYANOACRYLATES

- Adhesion to a broad range of substrates, including hard-to-bond
- Moisture-cure in shadowed areas



LIGHT-CURE SILICONES

- High-silicone substrate adhesion
- High flexibility
- High-temperature resistance



EPOXIES (1- & 2-PART FORMULAS)

- Superior environmental, chemical, and temperature resistance
- Large gap fill



CASE STUDY

QUALITY & RELIABILITY IMPROVED FOR FISTULA NEEDLE WITH LED LIGHT-CURING ADHESIVE & EQUIPMENT

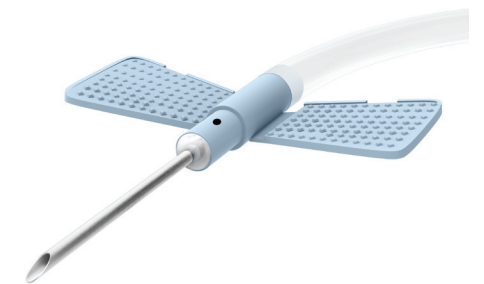
CHALLENGE:

A global medical device manufacturer of fistula needles was experiencing repeatability and reliability issues in their assembly process. In addition to current adhesive supply and support issues, the manufacturer was not achieving the pull strength requirements nor consistency in performance.

SOLUTIONS & BENEFITS:

LOCTITE AA 3922™, a rapid LED-curing medical device acrylic adhesive, was the solution and provided:

- Improved performance with higher bond strength
- Reduced rejection rate and improved precision with the use of LOCTITE dispensing and LED-curing equipment
- Improved quality control with adhesive fluorescence
- Consistent supply and technical support
- Enhanced end-use device safety with medical device grade adhesive



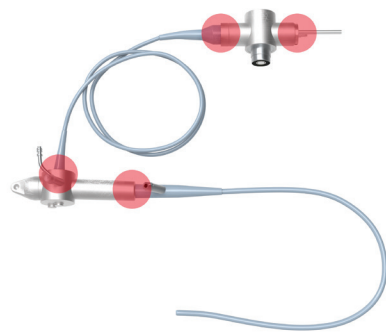
SOLUTIONS FOR NON-DISPOSABLE MEDICAL DEVICES

Non-disposable or reusable devices are frequently used more than one time in a healthcare environment. Biocompatibility, high durability, and repeated sterilization resistance are requirements that LOCTITE® medical device adhesives support.

DEVICES & ADHESIVE APPLICATIONS

ENDOSCOPES

Technology – Epoxies



SURGICAL TOOLS

Technology – Cyanoacrylates & Epoxies



KNEE BRACES

Technology – Cyanoacrylates



DEVICE CHALLENGES



Resistance to repeated cleaners and/or sterilization



Biocompatibility



Small parts that require precision and accuracy



High durability and strength due to rigorous and repeated use



Hermetic seals



Dissimilar materials, including hard-to-bond and flexible substrates

LOCTITE SOLUTIONS & BENEFITS

LIGHT-CURE ACRYLICS

- Fast, on-demand, light-cure
- Broad range of viscosities
- Gap fill
- Fluorescent



LIGHT-CURE CYANOACRYLATES

- Fastest, on-demand, light-cure
- Dual-cure: light and moisture
- Fluorescent



CYANOACRYLATES

- Adhesion to a broad range of substrates, including hard-to-bond
- Moisture-cure in shadowed areas



LIGHT-CURE SILICONES

- High-silicone substrate adhesion
- High flexibility
- High-temperature resistance



EPOXIES (1- & 2-PART FORMULAS)

- Superior environmental, chemical, and temperature resistance
- Large gap fill



CASE STUDY

RELIABILITY & PRODUCTIVITY OF SURGICAL INSTRUMENTS IMPROVED WITH ULTRA-PERFORMANCE INSTANT ADHESIVE

CHALLENGE:

A global medical device manufacturer was experiencing challenges with their current epoxy process of attaching RFID (Radio Frequency Identification) tags to their surgical instruments. The process involved a messy mixing process, long fixture/cure times, the inability to apply with accuracy and efficiency, and poor bond performance following repeated autoclave exposure.

SOLUTIONS & BENEFITS:

LOCTITE 402™, an ultra-performance medical device instant adhesive, was the solution and provided:

- Enhanced reliability with higher temperature resistance for limited repeat autoclave exposure
- Increased productivity with rapid fixture speed and semi-automation equipment
- Minimized waste with one-part adhesive formula
- Enhanced end-use device safety with medical device grade adhesive



SOLUTIONS FOR MEDICAL PATIENT EQUIPMENT

Medical patient equipment is used to support critical human functions in healthcare and sometimes home settings. There are typically equipment elements as well as disposable components, with LOCTITE® medical device assembly solutions to support both.

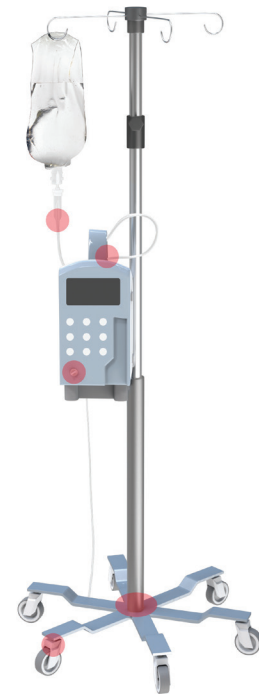
DEVICES & ADHESIVE APPLICATIONS

Epoxies and cyanoacrylate adhesives are the top choices for the equipment components of various medical patient equipment, while light-cure adhesives and silicones are typically used for the disposable components of these systems.

CPAP MACHINES









IV PUMPS



VENTILATORS



DEVICE CHALLENGES

-  Dissimilar materials, including hard-to-bond and flexible substrates
-  Resistance to surface cleaners
-  Quick and effective quality checks in process
-  High durability and structural strength for expected long-term use
-  Biocompatibility for disposable components
-  Small parts that require precision and accuracy

LOCTITE SOLUTIONS & BENEFITS

LIGHT-CURE ACRYLICS

- Fast, on-demand, light-cure
- Broad range of viscosities
- Gap fill
- Fluorescent



LIGHT-CURE CYANOACRYLATES

- Fastest, on-demand, light-cure
- Dual-cure: light and moisture
- Fluorescent



CYANOACRYLATES

- Adhesion to a broad range of substrates, including hard-to-bond
- Moisture-cure in shadowed areas



LIGHT-CURE SILICONES

- High-silicone substrate adhesion
- High flexibility
- High-temperature resistance



EPOXIES (1- & 2-PART FORMULAS)

- Superior environmental, chemical, and temperature resistance
- Large gap fill



CASE STUDY

DUAL-CURE MEDICAL DEVICE ADHESIVE SELECTED FOR NEW MEDICAL FLUID PUMP ASSEMBLY

CHALLENGE:

A global medical device manufacturer designing a new medical fluid pump required an assembly solution that would provide high bond strength and a hermetic seal for the disposable components, as well as strain relief on the pump itself.

SOLUTIONS & BENEFITS:

LOCTITE 4310™, a dual light- and moisture-curing medical device adhesive, was the solution and provided:

- Superior bond strength and sealing to the disposable and pump components
- Reliable and repeatable application process via LOCTITE dispensing and curing equipment
- Rapid LED light-curing to meet productivity requirements
- Enhanced end-use device safety with medical device grade adhesive



SOLUTIONS FOR DURABLE & IMAGING MEDICAL EQUIPMENT

Durable medical equipment is designed for the safe and comfortable support and transport of patients, while imaging (or diagnostic) medical equipment is used in healthcare facilities to detect potential health concerns. Long-term use and high durability are requirements that LOCTITE® assembly solutions support.

DEVICES & ADHESIVE APPLICATIONS

DURABLE EQUIPMENT

Technology – Epoxies & Threadlockers

WHEELCHAIRS



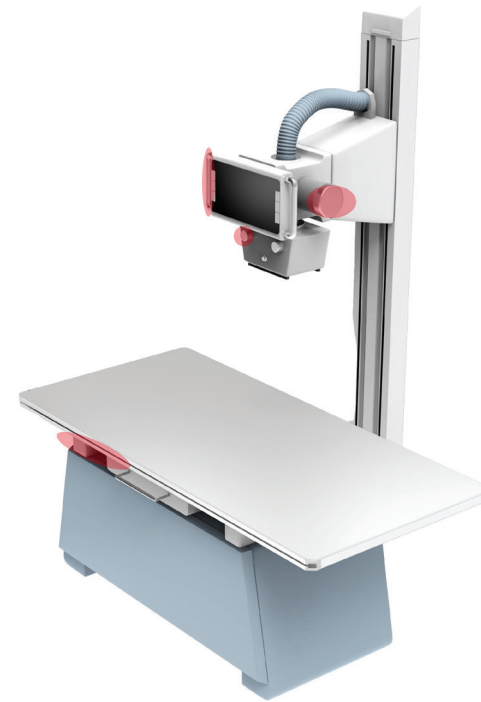
HOSPITAL BEDS



IMAGING EQUIPMENT

Technology – Epoxies & Polyurethanes

X-RAYS



DEVICE CHALLENGES



Dissimilar materials, including hard-to-bond and flexible substrates



High durability and structural strength for expected long-term use



Resistance to surface cleaners

LOCTITE SOLUTIONS & BENEFITS

EPOXIES (1- & 2-PART FORMULAS)

- Superior environmental, chemical, and temperature resistance
- High structural bond strengths and minimal shrinkage
- Large gap fill



POLYURETHANES (1- & 2-PART FORMULAS)

- Superior toughness and flexibility
- Large gap fill
- Adaptable for small and large surfaces



ANAEROBIC THREADLOCKERS & SEALANTS

- Low strength to permanent locking of metal threaded fasteners
- Hermetic seals



SILICONES (1- & 2-PART FORMULAS)

- High-silicone substrate adhesion
- High flexibility
- High-temperature resistance
- Light-curable options



CYANOACRYLATES

- Adhesion to a broad range of substrates, including hard-to-bond plastics
- Moisture-cure in shadowed areas



CASE STUDY

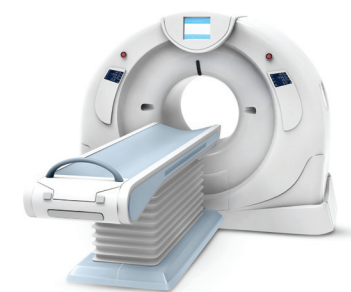
QUALITY & MANUFACTURING OF MEDICAL CT SCANNER IMPROVED WITH EPOXY ADHESIVE

CHALLENGE:

A global manufacturer of imaging equipment was having challenges in the assembly of their CT Scanner. The current two-part epoxy had slow process times and insufficient bond strength, which was causing misalignment between the scanning unit and patient table, resulting in significant rework prior to units being released to the market.

SOLUTIONS & BENEFITS:

- LOCTITE EA E-30HV™, a two-part clear, industrial epoxy was the solution:
- Eliminated misalignment issues with fast fixture speed and high strength
 - Reduced reworks, saving time and resources
 - Improved process time with enhanced fixture and speed of cure
 - Realized an overall cost savings of approximately 15%



ADHESIVE PROPERTY COMPARISON

LOCTITE® medical device adhesives cover a variety of chemistries, providing you with a wide range of choices and assembly solutions.

PERFORMANCE CONSIDERATIONS	ADHESIVE CATEGORY					
	LIGHT-CURE ACRYLICS	LIGHT-CURE SILICONES	LIGHT-CURE CYANOACRYLATES	CYANOACRYLATES	EPOXIES	URETHANES
BENEFITS	Rapid cure/adhesion to plastics	Excellent temperature resistance	Wide range of bonding applications	Wide range of bonding applications	Wide range of formulations	Excellent toughness/flexibility
LIMITATIONS	Light-cure system required	Low cohesive strength	Low elongation	Low elongation	Mixing required	Sensitive to moisture
TEMPERATURE RESISTANCE						
TYPICAL FOR THE CATEGORY	-54°C to 149°C	-54°C to 177°C	-54°C to 100°C	-54°C to 82°C	-54°C to 149°C	-54°C to 121°C
HIGHEST-RATED PRODUCT	149°C	177°C	100°C	135°C	149°C	121°C
ENVIRONMENTAL RESISTANCE						
POLAR SOLVENTS (E.G., H ₂ O, ETHYLENE GLYCOL, IPA, ACETONE)	Good	Good	Moderate	Poor ¹	Very Good	Good
NON-POLAR SOLVENTS (E.G. PENTANE, HEXANE, HEPTANE, MINERAL OIL)	Very Good	Poor to Fair	Good	Good	Excellent	Good
ADHESION TO SUBSTRATES						
METALS	Good	Good	Very Good	Very Good	Excellent	Good
PLASTICS²	Excellent	Good	Excellent	Excellent	Fair	Very Good
GLASS	Excellent	Good	Not Recommended	Not Recommended	Excellent	Good
RUBBER	Fair	Fair	Very Good	Very Good	Fair	Good
OVERLAPPING SHEAR STRENGTH	High	Low	High	High	High	Medium
PEEL STRENGTH	Medium	Medium	Low ³	Low ³	Medium	Medium
TENSILE STRENGTH	High	Low	High	High	High	Medium
ELONGATION / FLEXIBILITY	Medium	Very High	Low-Medium	Low-Medium	Low	High
HARDNESS	Semi-Rigid	Soft	Rigid	Rigid	Rigid	Soft
PROCESS CONSIDERATIONS	ADHESIVE CATEGORY					
	LIGHT-CURE ACRYLICS	LIGHT-CURE SILICONES	LIGHT-CURE CYANOACRYLATES	CYANOACRYLATES	EPOXIES	URETHANES
NUMBER OF COMPONENTS	1	1	1	1	1 and 2	2
CURE TEMPERATURES	UV/Visible	UV/Visible	UV/Visible/Room Temperature	Room Temperature	Heat or Room Temperature	Room Temperature
FIXTURE TIME						
AVERAGE	15 seconds	10 minutes	5 seconds	60 seconds	5 hours	5 hours
FASTEST	5 seconds	60 seconds	2 seconds	5 seconds	15 to 20 minutes	5 hours
FULL CURE TIME	2 to 30 seconds	24 hours	2 to 30 seconds	24 hours	12 to 24 hours	24 hours
GAP FILL						
IDEAL (IN INCHES)	0.002 to 0.010	0.004 to 0.006	0.001 to 0.010	0.001 to 0.003	0.004 to 0.006	0.004 to 0.006
MAXIMUM (IN INCHES)	0.25	0.25	0.17	0.010	0.5	0.5
DISPENSING / MIXING EQUIPMENT REQUIRED	No	No	No	No	Yes (2 parts)	Yes

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.

MEDICAL DEVICE ADHESIVES

Featured here are the latest global innovations of LOCTITE medical device adhesives. With more than 70 adhesives designed for medical device assembly, please contact us for additional options.

	PRODUCT	CURE METHOD	VISCOSITY (cP)	FLUORESCENT	TEMP RANGE (°C)	KEY FEATURES
CYANOACRYLATES	402™	Moisture	150	No	-54 to 135	Low-viscosity, good heat aging and hot strength performance
	431™	Moisture	900	No	-54 to 82	Medium-viscosity, ideal for acidic substrates and in dry environments
	4011™	Moisture	100	No	-54 to 82	Low-viscosity, ideal for acidic substrates and in dry environments
	4061™	Moisture	20	No	-54 to 82	Wicking viscosity, ideal for acidic substrates and in dry environments
	4601™	Moisture	50	No	-54 to 71	Low-viscosity, minimizes need for ventilation, reduces frosted residue
	4902™	Moisture	200	No	-54 to 82	Very-high flexibility, low modulus
	SF 7701™	N/A	3	Yes	N/A	Adhesion promoter for cyanoacrylates, for use on low-energy plastics
LIGHT-CURES	4310™	UV, Visible, Moisture	175	Yes	-54 to 100	Low-viscosity, toughened, rapid tack-free surface and shadow curing
	4311™	UV, Visible, Moisture	1,050	Yes	-54 to 100	Medium-viscosity, toughened, rapid tack-free surface and shadow curing
	AA 3921™	UV, Visible	150	Yes	-54 to 149	Low-viscosity, highly fluorescent, superior sterilization resistance
	AA 3922™	UV, Visible	300	Yes	-54 to 149	Superior sterilization resistance, excellent adhesion to PC
	AA 3926™	UV, Visible	5,500	Yes	-54 to 149	High-viscosity, highly fluorescent, superior sterilization resistance
	AA 3951™	UV, Visible	200	Yes	-54 to 149	Low-viscosity, fast curing, highly flexible adhesive ideal for flexible bondlines
	AA 3953™	UV, Visible	550	Yes	-54 to 149	Fast-curing, highly flexible adhesive ideal for flexible bondlines
	AA 3961™	UV, Visible	80	Yes	-54 to 149	Ultra-low viscosity, fast LED-curing, ideal for rigid bonding applications
	AA 3963™	UV, Visible	350	Yes	-54 to 149	Low-viscosity, fast LED-curing, excellent humidity and accelerated aging resistance
	AA 3972™	UV, Visible	4,500	Yes	-54 to 149	High-viscosity, superior tack-free curing
	AA 3979™	UV, Visible	58,000	Yes	-54 to 149	Gel viscosity, fluoresces red, tack-free curing
	SI 5056™	UV, Visible	2,200	No	-54 to 149	Medium-viscosity, silicone adhesive, superior heat and humidity resistance
	EPOXIES	EA M-121HP	2-Part Mix	11,000 (mixed)	No	-54 to 149
EA M-31CL		2-Part Mix	6,000 (mixed)	No	-54 to 149	Epoxy offering excellent impact resistance, 30-minute worklife

EQUIPMENT SOLUTIONS

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



DISPENSING

LOCTITE equipment offers high-quality dispensing systems to the marketplace. Henkel's experience and partnerships between customers, application engineering, and equipment engineering means when you purchase LOCTITE equipment, you get the highest level of expertise, backed by technical service and support unmatched in the industry. The broad range of LOCTITE dispensing systems offers you solutions for an array of adhesive package sizes for various market applications.

AUTOMATED ROBOTIC DISPENSING

LOCTITE automated robotic dispensing systems are cost-effective solutions designed to simplify the dispensing of adhesives and sealants onto various surface configurations, ranging from simple to complex. Dispensing robots allow manufacturers to repeatedly and reliably dispense patterns of liquid materials on a programmed basis, resulting in improved process efficiencies, minimal material waste, and reduced manufacturing costs. Automated dispensing systems are offered in multiple configurations to meet all your process needs.



CURING

Henkel offers innovative LOCTITE LED light-curing systems that provide high-power, portability, continuous duty, and a long life. A wide range of systems are available—handheld point, spot wand, and flood systems—offering maximum flexibility for any application. These light sources are optimized for curing our extensive line of UV/Visible light-curing adhesive products, to provide optimal solutions for nearly every process need.

KEY BENEFITS OF LED-CURING SYSTEMS VERSUS TRADITIONAL BULB TECHNOLOGY



Long life – Up to 20,000 hours of operation (10x longer than typical UV bulbs) with minimal decay over time.



Environmental benefit (no mercury).



Instant on/off – No warm-up like traditional UV systems.



Low maintenance cost (no replacement bulbs).



Zero infrared emissions, reducing part heating (warping) to an absolute minimum.



Low energy consumption.



100% of LED light output is within the usable curing spectrum.



Low cost of ownership.

TRAINING & ENGINEERING SERVICES

SEMINARS & WORKSHOPS

LOCTITE® 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.

On-Site Technology Seminar

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.

Technology Workshop

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



CONSULTATION & TESTING

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

- On-site engineering assistance and consultation
- Process improvement tours
- 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
- Application and cure equipment/process control

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