

LOCTITE[®]

Medical Adhesive Technology



Henkel



Loctite® Adhesives for Medical Device Manufacturing

Henkel offers to the medical device industry a complete range of Loctite® adhesives including instant, light cure and structural adhesives along with flexible adhesives and sealants that are certified to comply with ISO 10993 or are USP Class VI approved. In addition to the adhesives listed Henkel offers specialty grades to satisfy your specific requirements.

Loctite® adhesives provide solutions that meet your high tech, quality and manufacturing process requirements. Whether your medical device assembly requires an adhesive that is biocompatible and sterilisable – or one that meets a host of other performance requirements – Henkel has the right Loctite® adhesive to satisfy your needs.

Benefits of Loctite® Medical Device Adhesives

- Improved productivity
- ISO 10993 certified or USP Class VI approved
- Safe and non-toxic
- Fast cure, room temperature, UV or heat cure
- Consistent bond strength after the sterilisation processes (ETO, gamma radiation or steam)
- Proprietary priming agents that improve the bond capabilities of instant adhesives to low surface energy plastics (e.g. polyethylene, polypropylene, Santoprene, EPDM, etc.)
- Suitable for manual or automated production

Certificates of Compliance to ISO 10993 or USP Class VI approvals (Acute Systemic, Muscle Implantation, and Intracutaneous, Cytotoxicity and Hemolysis) are available at www.loctite.com or through your local Henkel Representative.



The Loctite® Medical Device Adhesives Range

Type of adhesive	Cure Mechanism	Viscosity
Modified Light Curing	UV / Visible Light	100 – 10,000 mPa.s
Instant	Surface Moisture	1 mPa.s - gel
Specialty Flexible	UV / Moisture	50,000 mPa.s
Adhesion Promoters	N / A	0.5 mPa.s
Light Curing Instant	UV / Surface Moisture	20 – 900 mPa.s
Structural	Heat or Two Part	6,000 – 37,000 mPa.s

- Non-toxic
- Ability to bond dissimilar and difficult to bond substrates
- Structural bonds
- Convenient, fast assembly
- Excellent adhesion and gap filling capability
- Very good resistance to sterilisation processes

Application Areas

These Loctite® specialty adhesives and primers have been developed for the assembly of medical devices such as:

Needles	Syringes, lancets, hypodermics, injectors, introducer catheters and blood collection sets.
Tubesets	IV sets, blood and drug delivery sets and suction tubes.
Masks	Anaesthesia and face masks.
Polycarbonate Devices	Blood oxygenators, stopcocks, filters, blood pressure transducers, arteriograph manifolds, cardiomy reservoirs and heat exchangers.

These products are not recommended or endorsed for permanent or long term (> 3 days) implantable devices.

Instant Adhesives



The Loctite® one-component instant curing adhesives are available in viscosities ranging from water-thin liquids to thixotropic gels. Instant adhesives are formulated to polymerise rapidly in thin films between two surfaces to form rigid thermoplastics. They offer excellent adhesion to a wide variety of substrates and are ideal for joining plastics such as ABS, PVC, latex, polycarbonate, styrene, acrylic and thermoset plastics. These solvent-free products are easy to dispense in automated systems. By using Polyolefin Primer Loctite® 7701, even difficult to bond materials such as polypropylene, polyethylene and other low energy rubbers and plastics can be bonded to obtain maximum adhesion.

Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. gap	Properties	Suitable substrates
Bond balloon to multi-lumen tubes in angioplasty, thermo dilution, foley and high pressure catheters	4011 Surface insensitive	20 g 454 g	100	ETO Gamma radiation	0.1 mm	Colour: Clear Low viscosity	Rubber, urethane, foam, porous and other difficult to bond substrates
	4013	20 g 454 g	500	ETO Gamma radiation	0.2 mm	Colour: Clear Medium viscosity	Rubber, plastics, metals
	4014	20 g 454 g	3	ETO Gamma radiation	0.05 mm	Colour: Clear Low viscosity Wicking grade	Rubber, plastics, metals
	4031 Low odour low bloom	20 g 454 g	1,300	ETO Gamma radiation	0.25 mm	Colour: Clear High viscosity Low odour, low bloom	Rubber, plastics, metals Appearance sensitive applications
	4061	20 g 454 g	20	ETO Gamma radiation	0.1 mm	Colour: Clear Low viscosity	Rubber, plastics, metals
	4081 Low odour low bloom	20 g 454 g	5	ETO Gamma radiation	0.05 mm	Colour: Clear Low viscosity Wicking grade Low odour, low bloom	Rubber, plastics, metals Appearance sensitive applications
Bond needle to tubing in winged infusion sets and fistulas	4161	20 g 454 g	1,500	ETO Gamma radiation	0.25 mm	Colour: Clear High viscosity	Rubber, plastics, metals
	4541 Surface insensitive	10 g 200 g	Gel	ETO Gamma radiation	0.5 mm	Colour: Clear Non migrating gel	Rubber, urethane, foam, porous and other difficult to bond substrates
	4601 Low odour low bloom	20 g 454 g	50	ETO Gamma radiation	0.1 mm	Colour: Clear Low viscosity Low odour, low bloom	Rubber, plastics, metals Appearance sensitive applications
	4981	20 g 454 g	500	ETO Gamma radiation	0.2 mm	Colour: Clear Medium viscosity	Resists thermal cycling, Rubber, plastics, metals

Light Curing Instant Adhesives



Loctite® light curing instant adhesives combine the advantages of the cure on demand UV-technology with the features of instant adhesives. This benefit is especially useful 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 minimise stress cracking and blooming, due to their „instant“ light fixturing.

Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. gap	Properties	Suitable substrates
Join stainless steel cannulae to non transparent hubs and syringes, bond catheters, bond oxygen concentrators, bond blood gas analysers and filters	4304	20 g 454 g	20	ETO Gamma radiation	4 mm*	Colour: Light amber (4306 fluorescent)	Rubber, plastics, metals
	4305	20 g 454 g	900	ETO Gamma radiation	4 mm*	Colour: Light amber (4307 fluorescent)	Rubber, plastics, metals

* max. gap in shadow areas: 0.1 mm

Supporting Products for Instant Adhesives

Activators

Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. gap	Properties	Suitable substrates
Speed fixture time with instant adhesive	713	40 g	1	ETO Gamma radiation	N/A	Very fast fixture	Accelerates the fixturing time with all instant adhesives
	7451	40 g 360 g	3	ETO Gamma radiation	N/A	Fast fixture	Accelerates the fixturing time with all instant adhesives



Primers

Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. gap	Properties	Suitable substrates
Priming low energy rubber and plastics to obtain maximum adhesion with instant adhesive	7701	35 g 300 g	1.25	ETO Gamma radiation	N/A	Low viscosity liquid	Polyolefins e.g. polyethylene, polypropylene, Santoprene® and other difficult to bond substrates

Loctite® 7701 is best suited to Loctite® 4061 but can be used with any of the instant adhesives

Ultraviolet and Visible Light Curing Adhesives



These one-component, solvent-free Loctite® adhesives can be applied to a variety of different substrates. They are available in a wide viscosity range (100 to 10,000 mPa.s) and cure rapidly (on demand) to form a tough thermoset polymer. The products are specially designed for automated dispensing and curing in applications where high strength, clear bondlines and a 100% seal are required.

Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. gap	Properties	Suitable substrates
Cannulae/hubs	3011	1 l	100	ETO Gamma radiation	4 mm	Colour: Clear (3081 fluorescent)	Stainless steel, thermoset and thermoplastics
Glass assemblies and optical instruments	3051	1 l	1,100	ETO Gamma radiation	4 mm	Colour: Clear (3942 fluorescent)	Excellent for glass and optical applications
Bond subassemblies in blood pressure transducers, arteriograph manifolds, stopcocks, fittings, adapters and arterial filters	3201	25 ml 1 l	4,000	ETO Gamma radiation Steam	13+ mm	Colour: Clear (3933 fluorescent)	Polycarbonate, acrylic and other thermoplastics where a flexible joint is desired
	3211	25 ml 1 l	10,000	ETO Gamma radiation Steam	13+ mm	Colour: Clear (3936 fluorescent)	Polycarbonate, acrylic and other thermoplastics where a flexible joint is desired
Bond and seal anaesthesia, surgical and other masks. Bonding tubing to fittings in IV sets, gas inlet and arterial outlet connections on membrane oxygenators	3301	25 ml 1 l	150	ETO Gamma radiation Steam	13+ mm	Colour: Clear (3921 fluorescent)	Metals and plastics Best on rigid and flexible PVC, giving a flexible joint
	3311	25 ml 1 l	300	ETO Gamma radiation Steam	13+ mm	Colour: Clear (3922 fluorescent)	Metals and plastics Best on rigid and flexible PVC, giving a flexible joint
	3321	25 ml 1 l	5,000	ETO Gamma radiation Steam	13+ mm	Colour: Clear (3926 fluorescent)	Metals and plastics Best on rigid and flexible PVC, giving a flexible joint
	3341	25 ml 1 l	450	ETO Gamma radiation Steam	13+ mm	Colour: Clear fluorescent	Best on highly plasticised PVC, giving a flexible joint
Insulin glass syringes to metal needles	3345	250 ml 1 l	1,500	ETO Gamma radiation Steam	4 mm	Colour: Clear	Glass and metals

Depth of cure is dependent upon spectral output of lamp, radiation intensity, distance of parts from light source, transmittance of substrates and bonding gap and geometry.

Structural Adhesives



Loctite® high-performance structural adhesives provide high peel and shear strength on a wide variety of plastics, metals and glass. When cured, these thermoset plastics offer superior thermal and chemical resistance, as well as high cohesive strength and minimal shrinkage. Loctite® two-part epoxies are packaged in side-by-side cartridges, allowing them to be dispensed as easily as any one-part system. Heat cured one component products have the advantage of easy dispensing and fast cure.

One Component Heat Cured Structural Adhesive

Typical application	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. open gap	Properties	Suitable substrates
Cannula / Hub	9535	1 l	18,000	ETO Gamma radiation Steam	1 mm	Colour: White fluorescent Low temperature cure (> 80 °C)	Metals, ceramics, glass, rigid plastics

Two component Structural Adhesives

Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. open gap	Properties	Suitable substrates
Bond/seal endoscopes, bond/seal catheters, bond/seal arthroectomy devices, bond/seal blood heat exchangers, bond/seal syringes and dental instruments, surgical and orthopedic handheld tools, powered instruments	M-21HP	50 ml 200 ml	37,000 (mixed)	ETO Gamma radiation Steam	1 mm	Colour: Off-white tough	Metals, ceramics, glass, rigid plastics
	M-31CL	50 ml 200 ml	6,000 (mixed)	ETO Gamma radiation Steam	0.5 mm	Colour: Clear Low viscosity	Metals, ceramics, glass, rigid plastics
	M-121HP	50 ml 200 ml	11,000 (mixed)	ETO Gamma radiation Steam	1 mm	Colour: Amber Peel resistant	Metals, ceramics, glass, rigid plastics

Specialty Flexible Adhesive



Loctite® light and moisture curing specialty flexible adhesive is a non-corrosive product to form a thermoset elastomer resulting in excellent durability for medical device uses. Due to its UV cure mechanism, this product enables fast fixturing which results in enhanced productivity. It is thixotropic and stays flexible at low temperatures. In addition, the product withstands repeated steam sterilisations.



Typical applications	Product	Pack size	Viscosity (mPa.s.)	Sterilisation methods	Max. gap	Properties	Suitable substrates
Bond and seal extruded silicone parts in colostomy, ileostomy and urostomy bags and appliances. Bond and seal the cuff and tube assemblies in endotracheal, tracheostomy, gastrostomy devices, foley catheters and other fabricated silicone parts.	5248	300 ml	50,000	ETO Gamma radiation Steam	6 mm	Colour: Clear/Translucent Flowable	Extrudable and mouldable silicones, stainless steel, glass and aluminium

Product / Substrate Selection Chart

Substrate 2	Substrate 1							
	Stainless steel	Glass	Rubber	PC (poly-carbonate)	PVC	Silicone	PE/PP and other difficult to bond plastics	Other thermoplastics and thermosets
Stainless steel	■ ■ ■ +	▲ +	▲ ■ ■ ■	▲ ■ ■ ■ +	▲ ■ ■ ■ +	◆ ●	▲* ●	▲ ■ ■ ■ +
Glass	▲ +	▲ +	▲	▲ +	▲ +	◆	▲*	▲ +
Rubber	▲ ■ ■ ■	▲	▲ ■ ■ ■	▲ ■ ■ ■	▲ ■ ■ ■	●	●	▲ ■ ■ ■
PC (polycarbonate)	▲ ■ ■ ■ +	▲ +	▲ ■ ■ ■	▲ ■ ■ ■ +	▲ ■ ■ ■ +	◆ ●	●	▲ ■ ■ ■ +
PVC	▲ ■ ■ ■ +	▲ +	▲ ■ ■ ■	▲ ■ ■ ■ +	▲ ■ ■ ■	◆ ●	●	▲ ■ ■ ■ +
Silicone	◆ ●	◆	●	◆ ●	◆ ●	◆ ●	●	◆ ●
PE/PP and other difficult to bond plastics	▲* ●	▲*	●	●	●	●	●	●
Other thermoplastics and thermosets	▲ ■ ■ ■ +	▲ +	▲ ■ ■ ■	▲ ■ ■ ■ +	▲ ■ ■ ■ +	◆ ●	●	▲ ■ ■ ■ +

*Corona or plasma pre-treatment of plastic required.

Note: For further information refer to appropriate Technical Data Sheet.

Adhesive Group

- = Instant Adhesives
- = Light Curing Instant Adhesives
- = Primer + Instant Adhesives
- ▲ = UV/Visible Light Curing Adhesives**
- + = Structural Adhesives
- ◆ = Specialty Flexible Adhesives

**One substrate has to be transparent or translucent.

Technical Support and Design Service

Henkel engineers can assist customers with the adhesive selection and the design of medical devices for optimum joint configuration, as well as engineering for accurate adhesive dispensing methods in manufacturing environments.

Please contact your local Henkel Representative for your special Loctite® solution.



Loctite® Dispensing Equipment

Henkel offers a comprehensive range of Loctite® equipment for manual, semi-automated and fully automated product dispensing. This range of equipment is especially designed to make application and use of Loctite® products fast, precise, clean and economical. The following is a selection from our manual and semi-automatic product dispensing equipment line. Please contact your local Henkel Representative for the complete range and your special Loctite® solution.



Loctite® 97006
Digital syringe dispenser system
This is a fully-integrated system that will dispense products from water-thin to paste-thick directly out of 10 g and 25 ml plastic-syringes.



Loctite® 98548
Benchtop Peristaltic Dispenser
This peristaltic pump is ideal for dispensing of liquid adhesives directly out of the bottle – offering air free dispensing with repeatable volume.



Loctite 97009
2 litre Integrated Semi-automatic Controller
With low level sensor (valve has to be selected and ordered separately)



Loctite® 98009
Light cure Dispensing valve
High resolution diaphragm valve for light curing adhesives

Loctite® 98013
Cyanoacrylate Dispensing valve
High resolution diaphragm valve for instant adhesives

Loctite® Light Curing Equipment

The lamp is the heart of the light curing system. Which lamp is right for the job is a matter of technical requirements and/or economic constraints. Loctite® light curing adhesives are cured by UVA light or UVA/visible light. Acceleration of surface (tack free) cure can be achieved with UVC light. All systems described are equipped with a UV intensity monitoring system. Please contact your local Henkel Representative for the complete range and your special Loctite® solution.



Loctite® 97057
High intensity spot curing system designed to emit UVA and visible light for extremely fast cure.

Loctite® 97034
High intensity spot curing system designed to emit UVC light for fast surface cure as well as UVA and visible light.



Loctite® 97055
UVALOC 1000
High intensity chamber cure system for manual loading. Designed to emit UVC, UVA and visible light.

Loctite® 97056
Tunnel version designed for integration into automated cure system.



Loctite® 97038
UVALOC 2500
High intensity chamber cure system for manual loading and large irradiation area, with adjustable dose of exposed UV-light. Designed to emit UVC, UVA and visible light.



Loctite® 98083E
Fluorescence Detector
Designed for monitoring the presence of fluorescent adhesives on assembled devices by PLC.

For more information about the adhesive application systems, dispensing equipment and ordering information, please contact your local specialist Henkel support group.

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The data contained herein are intended as reference only. Please contact your local Henkel Technical Support Group for assistance and recommendation on specifications for these products.