

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

LOCTITE®

Loctite Industrial

AUSTRIA
Loctite Europa Ges.m.b.H
Erdbergstraße 9
A-1030 Wien
Tel. + 43.1.718 7 80
Fax + 43.1.718 7 80 4194

BALTICS - ESTONIA
Henkel Balti OÜ
Business Unit Loctite
Riia 132, EE-51014
TARTU, Estonia
Tel. + 372-7.390171
Faks +372-7.380365

BENELUX
(Belgium, Netherlands,
Luxembourg)
Loctite Belgium N.V.
Prins Boudewijnlaan 5
B-2550 Kontich
Tel. + 32.3.4577833
Fax + 32.3.4577960

BULGARIA
Loctite Europa
Handelsges. m.b.H.
Representative Office Bulgaria
36, Dragan Tsankov Blvd.
bloek A, floor 9,
INTERPRED-World Trade Center
BG-1040 Sofia
Tel. + 02.9604945
Fax + 02.9604946

CROATIA
Henkel Croatia d.o.o.
Business Unit Loctite
Kucerina 5, HR-10000 ZAGREB
Tel. + 01.3651-375
Fax + 01.3651-377

CZECH REPUBLIC
Henkel CR spol. s.r.o.
skupina Loctite
U Pruhonu 10,
CZ-170 04 PRAHA 7
Tel. + 02.201.01401-2
Fax + 02.201.01400

DENMARK
Henkel Norden AB
Division Loctite
Hørsvinget 7
DKK-2630 Taastrup
Tel. + 45.43.301301
Fax + 45.43.301310

FINLAND
Henkel Norden Oy
Lyhtytie 3
FIN-00750 Helsinki
Tel. + 358.934.688444
Fax + 358.934.55611

FRANCE
Loctite France S.A.
10, Av. Eugène Gazeau
BP 40090
F-60304 Senlis Cedex
Tel. + 33.344216600
Fax + 33.344216625

GERMANY
Loctite Deutschland GmbH
Arabellastrasse 17
D-81925 München
Tel. + 49.89.92680
Fax + 49.89.9101978

GREECE
Henkel HELLAS SA
23, Kyprou str., GR-183 46
GR-Moschato Athens
Tel. + 03.10.4897232
Fax: + 03 10 4897107

HUNGARY
Henkel Magyarország Kft.
Business Unit Loctite
Dávid Ferenc u. 6
H-1113 BUDAPEST
Tel. + 36-1.372.5677
Fax + 36-1.372.5678

ITALY
Henkel Loctite Adesivi S.r.l.
Via Talete 56
I-20047 Brugherio (MI)
Tel. + 39.039.21251
Fax + 39.039.884672

NORWAY
Henkel Norden AB
Grensevein 88
NOR-0663 Oslo
Tel. +47.23.37.15.20
Fax +47.23.37.15.21

POLAND
Henkel Polska S.A.
Business Unit Loctite
ul. Domaniewska 41
PL-02-672 WARSZAWA
Tel. + 22.565.62.00
Faks + 22.565.62.22

ROMANIA
Henkel România S.R.L.
Business Unit Loctite
Str. Ionita Vornicu nr. 1-7
RO-71414 BUCURESTI 2
Tel. + 01.203.26.18
Fax + 01.203.26.01

SLOVAKIA
Henkel Slovensko s.r.o.
Business Unit Loctite
Záhradnícka 91
SK-821 08 BRATISLAVA
Tel. + 02.502.46.404
Fax + 02.502.46.405

SLOVENIA
Henkel Slovenija d.o.o. Maribor
Business Unit Loctite
Industrijska ul. 23
SI-2506 MARIBOR
Tel. + 02.2222.289
Fax + 02.2222.292

SPAIN
Loctite España, S.L.
Polígono Industrial Alparrache
Parcela 56
E-28600 Navalcarnero (Madrid)
Tel. + 34.91.8609000
Fax + 34.91.8112409

SWEDEN
Loctite Sweden AB
Box 8823
S-40271 Göteborg
Tel. + 46.31.75054 00
Fax + 46.31.75053 91

TURKEY
Türk Henkel Kimya Sanayi
ve Ticaret A.Ş
Business Unit Loctite
Kayışdağı cad. Karaman Çiftliği
Yolu Kar Plaza D Blok
TR-81120 İçerenköy-ISTANBUL,
Tel. + 0216.469.05.96
Fax + 0216.469.05.41

UNITED KINGDOM
Henkel Loctite Adhesives Ltd.
Watchmead
Welwyn Garden City
Hertfordshire AL7 1JB
Tel. + 44.1707.358800
Fax + 44.1707.358900

YUGOSLAVIA
Loctite Europa GmbH
Representative Office
Yugoslavia
29. novembra 81
YU-11000 BEOGRAD
Tel. + 011.322.59.85
Fax + 011.322.49.88

Medical Adhesive Technology



LOCTITE®

www.loctite.com

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A **Henkel** Company

Loctite® Adhesives for Medical Device Manufacturing

Henkel Loctite offers instant, structural and light cure adhesives along with flexible adhesives and sealants to the medical device industry. Whether your medical device assembly requires an adhesive that is biocompatible and sterilisable – or one that meets a host of other performance characteristics – Henkel Loctite has the right adhesive for your application.

The Henkel Loctite expertise in speciality adhesives for the assembly of medical devices is now revealed by the introduction of the complete high technology range.

● Benefits provided by our new medical device adhesives range include:

- ▶ Improved productivity
- ▶ ISO 10993 USP or Class VI approvals. Safe and non-toxic
- ▶ Fast cure, room temperature or UV cure. No heat curing required
- ▶ 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 through Loctite's Quality Engineering Department.

● The Loctite® Medical Device Adhesives Family includes:

Type of Adhesive	Cure mechanism	Viscosity
Modified Light Curing	UV / Visible Light	100-10,000 mPa.s
Instant	Surface Moisture	1 mPa.s - gel
Speciality 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	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® speciality adhesives and primers have been developed for the assembly of the following types of medical devices:

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, cardiotomy reservoirs and heat exchangers.

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

Loctite® Medical Device Adhesives Range

Instant Adhesives

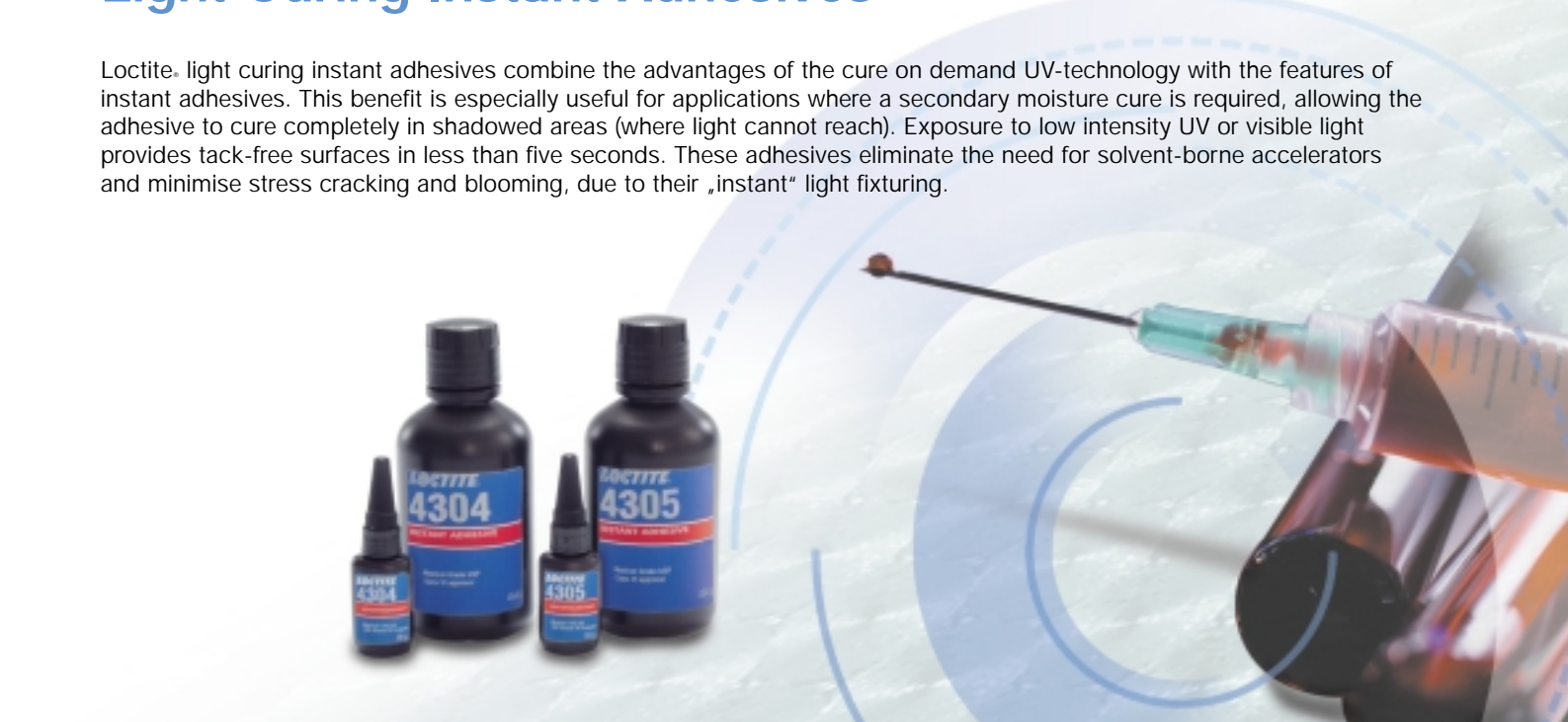
The Loctite® one-component instant curing adhesives are available in viscosities ranging from water-thin liquids to thixotropic gels. Instant adhesives are formulated to polymerise rapidly in thin films between two surfaces to form rigid thermoplastics. They offer excellent adhesion to a wide variety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



Typical Applications	Product	Pack Size	Viscosity (m.Pa.s.)	Sterilisation Methods	Max. Gap	Adhesive 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
	4061	20 g 454 g	20	ETO Gamma Radiation	0.1 mm	Colour: Clear Low Viscosity	Rubber, urethane, foam, porous and other difficult to bond substrates
Bond needle to tubing in winged infusion sets and fistulas.	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
	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
	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 (m.Pa.S.)	Sterilisation Methods	Cure Depth	Adhesive 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	28.3 g 454 g	20	ETO Gamma Radiation	4 mm*	colour light amber	Rubber, Plastics, Metals
	4305	28.3 g 454 g	900	ETO Gamma Radiation	4 mm*	colour light amber	Rubber, Plastics, Metals

* max. gap in shadow areas: 0.1 mm

Surface Preparation

Activators

Typical Applications	Product	Pack Size	Viscosity (m.Pa.S.)	Sterilisation Methods	Max. Gap	Adhesive Properties	Suitable Substrates
Speed fixture time with Instant Adhesive	713	40 g	1	N/A	N/A	Very fast fixture, Low Viscosity, Liquid	Accelerates the fixturing time with all Instant Adhesives.
	7451	40 g 360 g	3	N/A	N/A	Fast fixture, Low Viscosity, Liquid	Accelerates the fixturing time with all Instant Adhesives.

Primers

Typical Applications	Product	Pack Size	Viscosity (m.Pa.S.)	Sterilisation Methods	Max. Gap	Adhesive Properties	Suitable Substrates
Priming low energy rubber and plastics to obtain maximum adhesion with Instant Adhesive.	7701	35 g 300 g	1.25	N/A	N/A	Low Viscosity Liquid	Polyolefins e.g. Polyethylene, Polypropylene, Santoprene and other difficult to bond substrates.

7701 is best suited to 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 (m.Pa.s.)	Sterilisation Methods	Cure Depth	Adhesive Properties	Suitable Substrates
Cannulae/hubs	3001	1ltr	100	ETO Gamma Radiation	3 mm	Colour: Clear, Low Viscosity, Fluorescent	Stainless steel, thermoset and thermoplastics.
Cannulae/hubs	3011	1ltr	100	ETO Gamma Radiation	4 mm	Colour: Clear Low Viscosity	Plasma etching or corona discharge increases bond strength of polypropylene.
Glass assemblies and optical instruments	3051	1 ltr	1,100	ETO Gamma Radiation	4 mm	Colour: Clear Medium Viscosity	Excellent for glass and optical applications.
Bond subassemblies in blood pressure transducers, arterio-graph manifolds, stopcocks, fittings, adapters and arterial filters	3201	25 ml 1 ltr	4,000	ETO Gamma Radiation Steam	13+ mm	Colour: Clear High Viscosity	Polycarbonate, acrylic and other thermoplastics where a flexible joint is desired.
	3211	25 ml 1 ltr	10,000	ETO Gamma Radiation Steam	13+ mm	Colour: Clear High Viscosity	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 ltr	150	ETO Gamma Radiation Steam	13+ mm	Colour: Clear Low Viscosity	Best on rigid and flexible PVC, giving a flexible joint.
	3311	25 ml 1 ltr	300	ETO Gamma Radiation Steam	13+ mm	Colour: Clear Low Viscosity	Best on rigid and flexible PVC, giving a flexible joint.
	3321	25 ml 1 ltr	5,000	ETO Gamma Radiation Steam	13+ mm	Colour: Clear High Viscosity	Best on rigid and flexible PVC, giving a flexible joint.
	3341	25 ml 1 ltr	450	ETO Gamma Radiation Steam	13+ mm	Colour: Clear Medium Viscosity Fluorescent	Best on highly plastisied PVC, giving a flexible joint.
Insulin glass syringes to metal needles	3345	250 ml 1 ltr	1,500	ETO Gamma Radiation Steam	4 mm	Colour: Clear Medium Viscosity	Bond glass to metal.

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

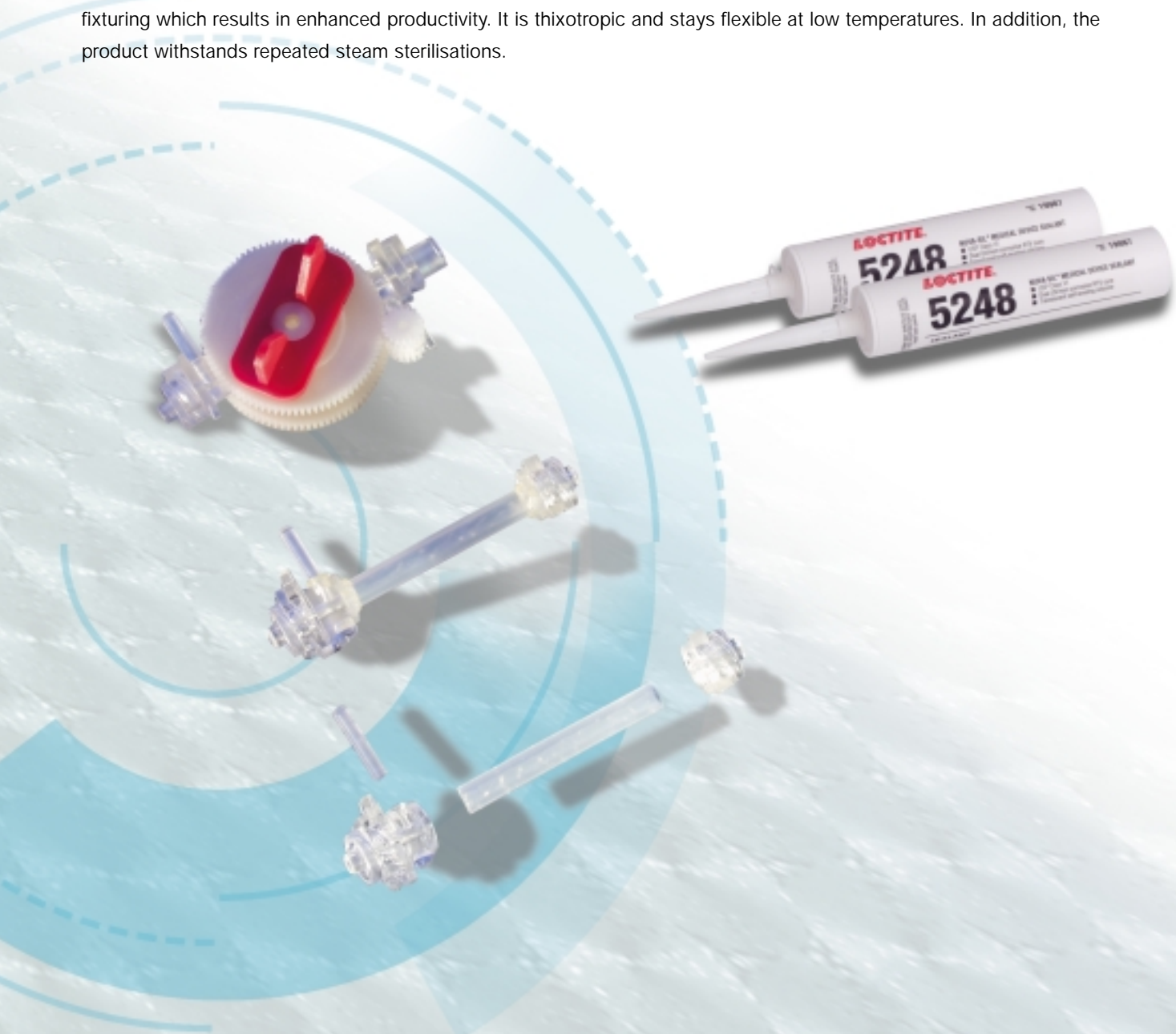
Loctite® high-performance structural adhesives provide high peel and shear strength on a wide variety of plastics, metals and glass. When cured, these thermoset plastics offer superior thermal and chemical resistance, as well as high cohesive strength and minimal shrinkage. Loctite® two-part epoxies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



Typical Applications	Product	Pack Size	Viscosity (mPa.S.)	Stersilation Methods	Max Gap	Adhesive Properties	Suitable Substrates
Bond/seal endoscopes, Bond/seal catheters, Bond/seal artherectomy 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	Tough off-white	Metals, ceramics, glass, rigid plastics
	M-31CL	50 ml 200 ml	6,000 (mixed)	ETO Gamma Radiation Steam	0.5 mm	Clear Low Viscosity	Metals, ceramics, glass, rigid plastics
	M-121HP	50 ml 200 ml	11,000 (mixed)	ETO Gamma Radiation Steam	1 mm	Amber Peel resistant	Metals, ceramics, glass, rigid plastics

Speciality Flexible Adhesive

Loctite® light and moisture curing speciality 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 (m.Pa.S.)	Sterilisation Methods	Cure Depth	Adhesive 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 thermo-plastics and thermosets
Stainless Steel	■ ■ +	▲ +	■	▲ ■ ■ +	▲ ■ ■ +	◆ ●	●	▲ ■ ■ +
Glass	▲ +	▲ +		▲ +	▲ +	◆	▲*	▲ +
Rubber	■ ■		■ ■	■ ■	■ ■	●	●	■ ■
PC (polycarbonate)	▲ ■ ■	▲	■ ■	▲ ■ ■ +	▲ ■ ■ +	◆ ●	●	▲ ■ ■ +
PVC	▲ ■ ■	▲	■ ■	▲ ■ ■	▲ ■ ■	◆ ●	●	▲ ■ ■ +
Silicone	◆ ●	◆	●	◆ ●	◆ ●	◆ ●	●	◆ ●
PE/PP and other difficult to bond plastics	●	▲*	●	●	●	●	●	●
Other thermoplastics and thermosets	▲ ■ ■ +	▲ +	■ ■	▲ ■ ■ +	▲ ■ ■ +	◆ ●	●	▲ ■ ■ +

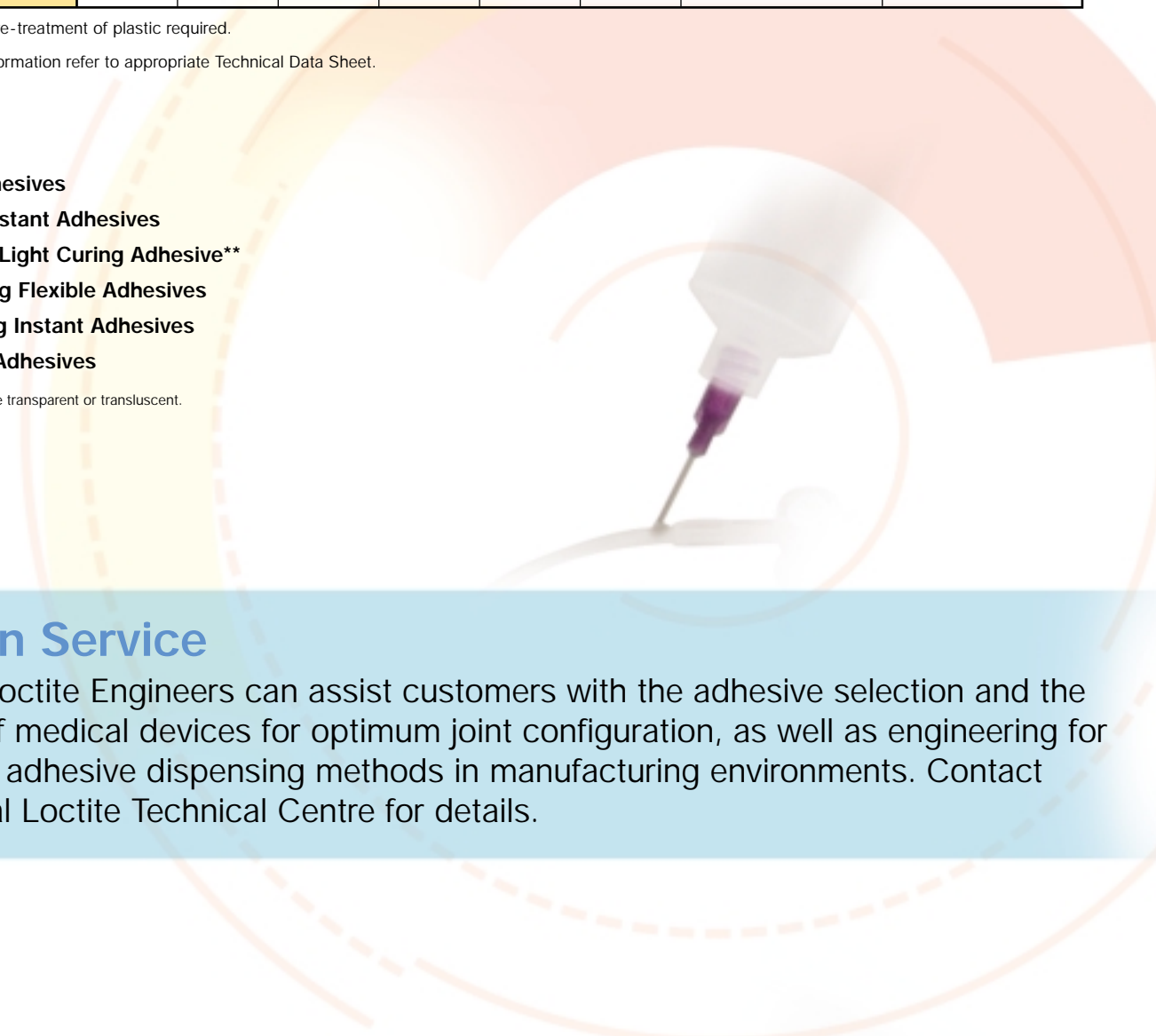
*Corona or plasma pre-treatment of plastic required.
Note: For further information refer to appropriate Technical Data Sheet.

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

**One substrate has to be transparent or translucent.

Design Service

Henkel Loctite 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. Contact your local Loctite Technical Centre for details.



Loctite® Dispensing Equipment

Henkel Loctite offers a comprehensive range of 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.



Loctite® 97006 **Digital syringe** **dispenser system**

This is a fully-integrated system that will dispense products from water-thin to paste-thick from 10 g and 25 ml plastic-syringes.



Loctite® 97008

2 litre Integrated Semi-automatic Controller
(valve has to be selected and ordered separately)

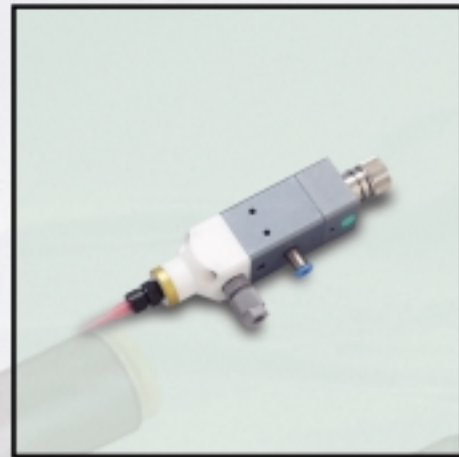
Loctite® 97009

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



Loctite® 97113 **Stationary applicator valve**

Slim, lightweight and user-friendly valve with a suck-back feature that eliminates product dripping and stringing at the end of the dispense cycle. The Dispense Valve applies products in dots, drops and beads.



Loctite® 97134 **Dispensing Valve CA**

For exact application of Loctite products. It shows no suckback, so it is specifically suitable for CA's. Used as a stationary applicator unit. It is mounted directly at the dispensing position.

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.



Loctite® 97033

High intensity spot curing system designed to emit UVA and visible light (blue light) for extremely fast curing. Ideal for high-volume production and short cycle times.



Loctite® 97034

High intensity spot curing system designed to emit UVC light for fast surface cure as well as UVA and visible light (blue light).



Loctite® 97035 **UVALOC**

Cure system for manual loading of the curing cabinet. Designed to emit UVA, UVC and visible light.