



Global Distributor of Henkel LOCTITE (800) 888-0698 info@ellsworth.com

# **Medical Product Selector Guide**

Adhesives for Medical Device Assembly



(Henkel) Excellence is our Passion



# **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.

### **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.

### **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
- 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



TECHNICAL DATA SHEETS AND MATERIAL DATA SAFETY SHEETS ARE AVAILABLE ON THE WEB AT: www.henkelna.com/medicaladhesives

KEV: *Estimated † Made-to-order items	Hysol <sup>®</sup> Two-Part RT Cure Epoxies & Urethanes			Hysol®		Hysol® Two-Part RT		Hysol® Two-Part RT		Hysol <sup>®</sup> Two-Part RT Cure Enovies &		One-Part Heat Cure Epoxies		One-Part Heat Cure Epoxies		<b>EPOXIES &amp;</b>	Accelerators	Primers/	Purpose	General			Toughened/				Low Odor/			Insensitive	Surface		CYANOACRYL.	Silicones	Nuva-Sil®			Flashcure®			Visible	Indigo®							Acrylics	UV/Visible							LIGHT CURING			
	M-11 FL <sup>***</sup>	M-06 FL***	M-121 HP™	M-31 CL**	M-21 HP™	3984""	<u>3981</u> ""	URETHANES	7701 <sup>™</sup>	<u>713</u> ™	4014 <sup>™</sup>	4013 <sup>™</sup>	<u>★ 4903</u> ™	<u>★ 4902</u> <sup>™</sup>	4861 <sup>™</sup>	4206"	<u>435</u> <sup>m</sup>	4601	4081	4031	4541 <sup>™</sup>	4061"	4011 <sup>™</sup>			5056"	5055**	4	4311 <sup>™</sup>	430/	4306	3556	3555	<u>3554</u> ""	3979**	<u>3974</u> ***	3972**	<u>3971</u> <sup>™</sup>	3944"	3943**	3942"	3936"	3933™	2006	7766	3027m	3341	3311"		Product										
Cure Method:         Cure Opph Conditions:           Indipo:=         High Warelength Visible         UVI Acrylos: 100 mW/mr, 10 sess.           Indipo:=         High Warelength Visible         Indipo:=         200 mW/mr, 10 sess.           M = Modative         Indipo:=         200 mW/mr, 10 sess.         10 sess.           RT = Hoom Temperature         Indipo:=         200 mW/mr, 10 sess.           VI = Utraviolet         Nue SIP: 70 mW/mr, 30 sess.           VI = Vitable         Nue SIP: 70 mW/mr, 40 sess.	Clear	Off-White	Amber	Ultra-Clear	Off-White	Light Grey	<b>Transparent/Yellow</b>		Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	-	Transparent/Light Yellow	Transparent/Light Yellow	Translucent/White	Transparent/Light Yellow-Green	Ulear/Pale Green	Clear/Pale Green	Clear/Light Yellow	Clear/Light Yellow	Clear/Light Yellow	Transparent/Hazy	Translucent/Colorless	Transparent/Hazy	Transparent/Hazy	Pale Yellow	Transparent/Hazv	Transparent/Hazy	Transparent/Hazv	Transparent/Hazy	Transportent/Linzy	Transnarent/Hazy	Transparent/Hazy	Clear/Straw	Clear/Pale Straw		Appearance										
titions: mW/cm², 10 secs. bulb mW/cm², 10 secs. po® Cure Jet" po® Cure Jet" Pressure Hg Arc	z	z	z	z	Z	Y	Y	ĺ	z	z	z	z	z	z	z	z	z	z	z	N	N	z	z	z		z	z	z	- ~	< -	< -	-	~	×	×	Y	Y	Y	<b>~</b> ·	~	~		- ~	< -	< -	< 7	. <b>,</b>	< Z		Fluorescent										
Substrates: TP = Thermoplastic G = Glass ME = Metal E = Elastomers C = Ceramics		RT 3		RT	( )	н	Ŧ		N/A	N/A	Μ	z	Μ	2	z	Μ	Z	≤	≤	Ν	м	Ξ	≤	M		UV,V	UV. V	IIV V M	UV. V. M			Indigo	Indigo®	Indigo®	UV, V	UV, V	UV, V	UV, V	UV.V	UV.V	UV,V	UV.V				UV, V	UV, V	UV, V		Cure Method										
	3,800 (mixed)	38,000 (mixed)	11,000 (mixed)	6,000 (mixed)	37,000 (mixed)	25,500	5,300		ω	ω	ω		ω	500	200	200	4,000	375	175	50	5	1,300	Gel	20	100	006		2.200	525	22 000	1.050	175	20	4,850	1,000	300	58,000	5,000	4,500	300	5.000	6.000	1,100	10,000	3.250	5 500	1 100	300	450	300		Viscosity (cP)								
≯	-65 to 250	-65 to 250	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300		N/A	N/A	-65 to 220	-65 to 180	-65 to 220	-65 to 220	-65 to 125	-65 to 250	-65 to 250	-65 to 160	-65 to 160	-65 to 160	-65 to 180	-65 to 180	-65 to 180	-65 to 180		-65 to 300	-65 to 300	-65 to 200	-65 to 240	-001 01 000	-05 to 180	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-65 to 300	-00 10 000	-00 to 200	-65 to 300	-65 to 300	-65 to 300		Temp. Range (°F)										
	45 (D)	45 (D)	85 (D)	85 (D)	80 (D)	75 (D)	84 (D)		N/A	N/A	65 (Barcol)	65 (Barcol)	66 (D)	65 (D)	80 (A)*	80 (D)*	80 (D)*	80 (D)*	80 (D)*	80 (D)*	80 (D)*	80 (D)*	80 (D)*	80 (D)*		43 (A)		45 (A)	84 (D)	82 (D)	82 (D)	68 (D)	77 (D)	75 (D)	56 (D)	77 (A)	68 (D)	66 (D)	50 (D)*	69 (D)	76 (D)	55 (D)	57 (D)	67 (D)	60 (D)	66 (D)	27 (D)	64 (D)		Shore Hardness	ТҮРІ									
	1,860*	15,000*	216,000*	362,000*	226,000*	566,000	345,000		N/A	N/A	200,000*	200,000*	78,100	57,900	63,250	120,200	120,000*	200,000*	200,000*	200,000*	200,000*	200,000*	200,000*	200,000*		195*	650*	145	270.000	202,900	250,700	154,000	203,000	220,000	54,780	4,800	66,750	95,000	57.000	64.000	142,900	24.500	47.000	90 700	A1 100	01 500	3,600	97,000		Modulus (psi)	CAL PROD									
	170	74	10	∞	8	1.1	3.0		N/A	N/A	2	2	85	155	4*	18	15*	2*	2*	2*	2*	2*	2*	2*		170	8	350	5.2	2.2	2.2	3	11.2	6.3	227	100	88	93	8	271	15	300	79	200	280	125	02.2	265		Elongation Tensile Cure Depth (%) (psi) (in.)	TYPICAL PRODUCT ATTRIBUTES									
The data provided represent typical properties. Please consult Henkel's Technical Data Sheets for more detailed data and test methods.	490	1,300	5,910	8,000	5,700	5,540	8,970		N/A	N/A	4,000*	4,000*	2,040	2,085	1,800*	3,664	3,600	4,000*	4,000*	4,000*	4,000*	4,000*	4,000*	4,000*		765	870	435	7.250	4,840	4,720	4,320	5,850	6,150	2,620	2,280	3,370	3,700	3.000	3.480	4,200	2.780	1.600	2,000	2,000	2,830	2,200	3,300		Tensile (psi)	RIBUTES									
	>0.50	>0.50	>0.50	>0.50	>0.50	>0.50	>0.50		N/A	N/A	0.003	0.010	0.004	0.004	0.008	0.005	0.005	0.004	0.002	0.008	0.010	0.004	0.005	0.008		0.25	0.22	0.35	0.16	0.17	0.15	0.40	0.40	0.35	0.08	0.11	0.25	0.16	0.15	0.12	0.11	0.08	0.04	0.10	0.12	0.08	0.12	0.09		Cure Depth (in.)										
	TP, G, ME, E, C	TP, G, ME, E, C	TP, G, ME, C	TP, G, ME, C	TP, G, ME, E, C	TP, G, ME, C	TP, G, ME, C		TP, E	N/A	TP, ME, E	TP, ME, E	TP, ME, E	TP, ME, E	TP, ME, E	TP, ME, E	TP, ME, E	TP, ME	TP, ME	TP, ME	TP, ME, E, C	TP, ME, E	TP, ME, E	TP, ME, E		TP, G, ME, E	TP. G. ME. E	TPGMEE	TP. ME. E	TP ME E	TP, ME, E	TP, G, ME	TP, G, ME	TP, G, ME	TP, G, ME	TP, G, ME, C		TP, ME	≤	TP.G. ME	≦ i		TP G. MF	TD C ME	TP G ME	TP G ME		TP, G, ME		Substrates (TP, G, ME, E, C)										
		Ξ	Ultra-strength epoxy, excellent thermal shock resistance, 120-minute worklife	Epoxy offering excellent impact resistance, 30-minute worklife	Epoxy offering high peel and shear strength, 20-minute worklife	Superior thermal, chemical and sterilization resistance; highest modulus	Superior thermal, chemical and sterilization resistance; moderate viscosity		Adhesion promoter for cyanoacrylates, for use on low-energy plastics	Speeds fixture time for cyanoacrylates, 10-minute worklife	General purpose for metal and plastic bonding	General purpose, gap filling	High flexibility, medium modulus	Very high flexibility, low modulus		Impact resistant, withstands 250°F continuous for 2,000 hours	Low viscosity, toughened and surface insensitive	Low viscosity, minimizes need for ventilation, reduces frosted residue		Medium viscosity, minimizes need for ventilation, reduces frosted residue	High viscosity, ideal for acidic substrates and in dry environments	Wicking viscosity, ideal for acidic substrates and in dry environments	Low viscosity, ideal for acidic substrates and in dry environments	Medium viscosity, ideal for acidic substrates and in dry environments	-	Medium viscosity, superior heat and humidity resistance	Low viscosity, high adhesion to silicone and polycarbonate	Hinh viscosity hinh tear strength cures in shadowed areas	Toughened, rapid tack-free surface and shadow curing	Teuchennel model from outform and blockers outing	Rapid tack-free surface and shadow curring, low viscosity	Medium viscosity, visible-only curing, ideal for select translucent materials	Medium viscosity, visible-only curing, ideal for select translucent materials	Low viscosity, visible-only curing, ideal for select translucent materials	Gel viscosity, fluoresces red, tack-free curing	Highly flexible, ideal for joining different substrates that undergo thermocycling	Superior tack-free curing, moderate viscosity	Superior tack-free curing, low viscosity	Superior Surface curing, verv flexible	Touch superior tack-free curing	High performance, rapid tack-free curing	Highly flexible, excellent on PC and other thermoplastics, minimal stress cracking	<ul> <li>Figure 1 and other thermonlastics minimal stress cracking</li> </ul>	Superior sterilization resistance	Superior sterilization resistance, excellent adhesion to various thermoniastics	Highly fluorescent, superior sterilization resistance	Excellent on highly tlexible PVC and other difficult-to-bond substrates	Flexible, excellent on PVC and most thermoplastics		) Features										
The day ta Sheets f	30678 5		30680 5		30671 5	36768	36766		19886 1	_	20269	20268	1875847	1875841	37708	28628	40994	18692	18688	18682	18690	18686	18680	41255		1214249	1212167	1010341	1401791	3/441	3/439	1072223	1072221	1072199	1402562	1135733	36294	36792	38210	36480	36483	32304	N/A	00+00	88736	30484	23/92	19736		ltem # F										
The data provided represent typical properties. heets for more detailed data and test methods.	50 ml dual	50 ml dual			50 ml dual	30 ml 3	30 ml		1.75 fl. oz.	1.75 fl. oz.	20 g			20 g 1		20 g	_	20 g		_			20 g	_		25 ml 1:	_		1 oz. 1									_	-	_	_		+	2 E			+	-		okg. Size	PRODU									
	N/A I			4	N/A	37299† 1	37297 1				18014 1	18013 1	875840	1875842 1	-	N/A	_	18693 1		18683 1				41256 1				1	1401789 1						1402563 30		_	_		_			32040 1							Pkg. Size Item # Pkg. Size	PRODUCT ORDERING									
typical program and test r	N/A <u>M-</u>		-	=	N/A M-	1 liter 3			16 fl. oz. Z	N/A J	1 lb. 4	_		1 lb. <u>4</u>	-					_			1 lb.			┥	+		1 b.				┢		300 ml <u>3</u>			+	+		+	┥	liter 3	╈	+				╞		RING									
operties. nethods.	M-11 FL <sup>™</sup>	M-06 FL <sup>™</sup>	M-121 HP***	M-31 CL**	M-21 HP***	<u>3984</u> ""	<u>3981</u> ""		7701 <sup>™</sup>	<u>713</u> ™	4014 <sup>™</sup>	4013	<u>1903</u> <sup>**</sup> ★	4902 *** ★	4861	4206	435	4601	1081 <sup>™</sup>	4031	4541 <sup>™</sup>	4061	4011	431 <sup>™</sup>		5056	5055	5940***	4311"	4307	4300	3556	3555	<u>3554</u> ""	<u>3979</u> ""	<u>3974</u> ""	<u>3972</u> **	<u>3971</u> ™	3944"	3943***	3942""	3936""	3933"	2020	3007Im	<u>3921</u>	3341	3311		Product										

# BIOCOMPATIBILITY

All LOCTITE<sup>®</sup> 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.



**CERTIFICATES OF COMPLIANCE ARE AVAILABLE ON THE WEB AT:** www.henkelna.com/medicaladhesives



#### USA

For your local LOCTITE® Adhesive and Sealants Specialist, for your nearest authorized LOCTITE® product distributor, to place an order, to arrange an in-plant seminar, or for technical product assistance, call: 1.800.LOCTITE (562.8483)

#### **Henkel Corporation**

One Henkel Way Rocky Hill, CT 06067 TEL: 1.800.LOCTITE (562.8483) TEL: 860.571.5100 FAX: 860.571.5465 www.henkelna.com/industrial www.henkelna.com/loctite

#### CANADA

To arrange an in-plant seminar, or for technical product assistance, call: 1.800.263.5043 (within Canada)

#### Henkel Canada Corporation

2515 Meadowpine Blvd. Mississauga, Ontario, Canada L5N 6C3 TEL: 1.800.263.5043 (within Canada) TEL: 905.814.6511 FAX: 905.814.5391 www.loctite.ca

#### MEXICO

For your local LOCTITE® Adhesive and Sealant Specialist, for your nearest authorized LOCTITE® product distributor, to arrange an in-plant seminar, or for technical product assistance, call: 52.55.3300.3669 (within Mexico)

To place an order, 52.55.3300.3644 (within Mexico)

#### Henkel Capital, S.A. de C.V.

Boulevard Magnocentro No. 8 Piso 2 Centro Urbano Interlomas 52760 Huixquilucan, Estado de México FAX: 52.55.3300.3019 www.loctite.com.mx

#### **CENTRAL AMERICA**

For your local LOCTITE® Adhesive and Sealants Specialist, for your nearest authorized LOCTITE® product distributor, to place an order, to arrange an in-plant seminar, or for technical product assistance, call: 506.277.4868 (within Costa Rica)

#### Henkel Costa Rica Ltda.

100 Mts Sur y 50 Mts Oeste de Celebrity Lovable 101-3007 San Joaquin de Flores Heredía, Costa Rica TEL: 506.277.4800 FAX: 506.277.4883 www.loctite.com.mx

#### SOUTH AMERICA

For your local LOCTITE® Adhesive and Sealant Specialist, for your nearest authorized LOCTITE® product distributor, to place an order, to arrange an in-plant seminar, or for technical product assistance, contact:

#### **Henkel Diadema**

Rua Karl Hüller, 136 CEP: 09941-410 Diadema-SP São Paulo, Brazil TEL: 0800.704.2334 (within Brazil) TEL: 55.11.3205.8955 FAX: 55.11.3205.8766 www.loctite.com.br

#### Henkel Argentina S.A.

Nicolás Avellanda, 1357, B1642EYA San Isidro, Buenos Aires, Argentina TEL: 0800.888.0213 (within Argentina) TEL: 54.11.4001.0100 FAX: 54.11.4001.0158 www.loctite.com.ar

#### Henkel Chile Ltda.

Av. Laguna Sur 9551 Pudahuel Santiago, Chile TEL: 800.223.005 (within Chile) TEL: 56.2.381.7300 FAX: 56.2.641.8143 www.loctite.com.cl

#### Henkel Colombiana S.A.

Calle 17 No. 68b-97 Bogotá D.C., Colombia TEL: 01800.0114173 (within Colombia) TEL: 571.423.8900 FAX: 571.425.1331 www.loctite.com/co

#### Henkel Venezolana S.A. Urbanizacion Industrial Pruinca

Calle 2, Edificio Henkel Guacara – Estado de Carabobo, Venezuela TEL: 0800.436.5300 (within Venezuela) TEL: 58.245.560.2611 FAX: 58.245.560.2660 www.loctite.com.ve

### www.henkelna.com/medicaladhesives

*e* ELLSWORTH

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