

Ultra Light-Weld[®] 204-CTH-F Flexible Catheter-Bonding Adhesive

APPLICATIONS	FEATURES	RECOMMENDED SUBSTRATES	BIOCOMPATIBILITY
Balloon/Lumen	Solvent Free	• PC	 ISO 10993 Hemolysis
Hub/Lumen	 UV/Visible Light Cure 	• PVC	 ISO 10993 Cytotoxicity
 Marker Band 	Blue Fluorescing	• PU	 ISO 10993 Implantation
 Thermistor Potting 	Flexible	• ABS	(14 days)
		• PET	 ISO 10993 Intracutaneous
		• PEBA	ISO 10993 Systemic Toxicity

Dymax MD[®] Medical Device Adhesive 204-CTH-F is designed for rapid bonding of flexible and rigid plastics typically used in the manufacture of catheters and similar medical devices. This product fluoresces blue for in-line inspection under low-intensity "black" light (365 nm). Dymax MD[®] Medical Device adhesives contain no nonreactive solvents and cure upon exposure to light. Their ability to cure in seconds enables faster processing, greater output, and lower processing costs. When cured with Dymax light-curing spot lamps, focused-beam lamps, or flood lamps, they deliver optimum speed and performance for medical device assembly. Dymax lamps offer the optimum balance of UV and visible light for the fastest,

deepest cures. This product is in full compliance with the RoHS Directives 2002/95/EC and 2003/11/EC.

UNCURED PROPERTIES *		
Property	Value	Test Method
Solvent Content	No Nonreactive Solvents	N/A
Chemical Class	Acrylated Urethane	N/A
Appearance	Colorless Transparent Liquid	N/A
Soluble in	Organic Solvents	N/A
Density, g/ml	0.99	ASTM D1875
Viscosity, cP (20 rpm)	500 (nominal)	ASTM D1084

CURED MECHANICAL PROPERTIES *		
Property	Value	Test Method
Durometer Hardness	D58	ASTM D2240
Tensile at Break, MPa [psi]	17 [2,500]	ASTM D638
Elongation at Break, %	200	ASTM D638
Modulus of Elasticity, MPa [psi]	110 [16,000]	ASTM D638

OTHER CURED PROPERTIES *		
Property	Value	Test Method
Refractive Index (20°C)	1.50	ASTM D542
Boiling Water Absorption, % (2 hr)	3.8	ASTM D570
Water Absorption, % (25°C, 24 hr)	2.8	ASTM D570
Linear Shrinkage, %	2.0	ASTM D2566
Glass Transition T _g , °C	62	DSTM 256 [‡]

* Not Specifications

N/A Not Applicable

DSTM Refers to Dymax Standard Test Method

ADHESION		
Substrate	Recommendation	
ABS acrylonitrile-butadiene-styrene	✓	
PC polycarbonate	✓	
PEBA polyether block amide	0	
PET poly(ethylene terephthalate)	0	
PI polyimide	✓	
PMMA poly(methyl methacrylate)	0	
PS polystyrene	✓	
PU polyurethane	✓	
PVC poly(vinyl chloride)	✓	

Recommended Adhesive
 o
 Limited Applications

st Requires Surface Treatment (e.g. plasma, corona treatment, etc.)



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ACCELERATED AGING DATA

Clas	a ta matal la	n akaar Damart ()/ a	finitial strength
	Glass-to-metal lap shear. Report % of initial strength. Cured under 5000-EC @ 100 mW/cm ² for 15 sec		
	Jurea under	5000-EC @ 100 mw/c	m for 15 sec
	23°C RT	Accelerated Aging @ 60°C, 0% RH	Accelerated Aging @ 60°C, 55% RH
7 Days	100	100	100
14 Days	113	95	84
28 Days	108	100	80
56 Days*	93	84	61
*Per ASTM F19	980, assuming C	$factor = 2.0, 56 Days at 60^{\circ}$	C = approximate 2 years
	PC-PC lap shear. Report % of initial strength.		
Cured under BlueWave [®] LED Prime UVA @ 10 W/cm ² for 5 sec.			2 10 W/cm ² for 5 sec.
	23°C RT	Accelerated Aging @ 60°C, 0% RH	Accelerated Aging @ 60°C, 55% RH
7 Days	100	100	100
14 Days	104	123	93
28 Days	108	98	61
56 Days*	111	89	62
*Per ASTM F1980, assuming Qfactor = 2.0, 56 Days at 60°C = approximate 2 years			

CURING GUIDELINES

Fixture time is defined as the time to develop a shear strength of N/mm^2 [10 psi] between glass slides. Actual cure time typically is 3 to 5 times fixture time.

Dymax Curing System (Intensity)	Fixture Time or Belt Speed ^A
2000-EC (50 mW/cm ²) ^B	1 sec
5000-EC (200 mW/cm ²) ^B	1 sec
BlueWave [®] LED Prime UVA (10 W/cm ²) ^C	0.6 sec
BlueWave [®] 75 (5.0 W/cm ²) ^B	0.4 sec
BlueWave [®] 200 (10 W/cm ²) ^B	0.4 sec
UVCS Conveyor with one 5000-EC (200 mW/cm ²) ^D	8.2 m/min [27 ft/min]
UVCS Conveyor with Fusion F300S (2.5 W/cm ²) ^D	8.2 m/min [27 ft/min]

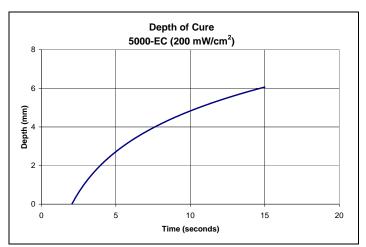
- A Curing through light-blocking substrates may require longer cure times if they obstruct wavelengths used for light curing (320-450 nm for UV/Visible light curing and 320-400 nm for UV-light-only curing). These fixture times/speeds are typical for curing thin films through 100% lighttransmitting substrates.
- B Intensity was measured over the UVA range (320-395 nm) using a Dymax ACCU-CAL[™] 50 Radiometer.
- C Intensity was measured over the UVA/Visible range (250-450 nm) using a Dymax ACCU-CAL[™] 50-LED Radiometer.
- D At 53 mm [2.1 in] focal distance. Maximum speed of conveyor is 8.2 m/min [27 ft/min]. Intensity was measured over the UVA range (320-395 nm) using the Dymax ACCU-CAL[™] 100 Radiometer.

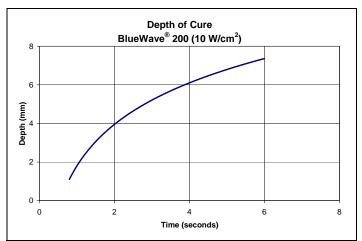
Full cure is best determined empirically by curing at different times and intensities, and measuring the corresponding change in cured properties such as tackiness, adhesion, hardness, etc. Full cure is defined as the point at which more light exposure no longer improves cured properties. Higher intensities or longer cures (up to 5x) generally will not degrade Dymax light-curable adhesives.

Dymax recommends that customers employ a safety factor by curing longer and/or at higher intensities than required for full cure. Although Dymax Application Engineering can provide technical support and assist with process development, each customer ultimately must determine and qualify the appropriate curing parameters required for their unique application.

DEPTH OF CURE

The graphs below show the increase in depth of cure as a function of exposure time at two different lamp intensities. A 9.5 mm [0.37 in] diameter specimen was cured in a polypropylene mold and cooled to room temperature. It was then released from the mold and the cure depth was measured.







OPTIMIZING PERFORMANCE AND HANDLING

- This product cures with exposure to UV and visible light. Exposure to ambient and artificial light should be kept to a minimum before curing. Dispensing components including needles and fluid lines should be 100% light blocking, not just UV blocking.
- 2. All bond surfaces should be clean and free from grease, mold release, or other contaminants prior to dispensing the adhesive.
- 3. Cure speed is dependent upon many variables, including lamp intensity, distance from the light source, required depth of cure, bond gap, and percent light transmission of the substrate.
- 4. Oxygen in the atmosphere may inhibit surface cure. Surfaces exposed to air may require high-intensity (>100 mW/cm²) UV light to produce a dry surface cure. Flooding the bond area with an inert gas, such as nitrogen, can also reduce the effects of oxygen inhibition.
- 5. Parts should be allowed to cool after cure before testing and subjecting to any loads.
- 6. In rare cases, stress cracking may occur in assembled parts. Three options may be explored to eliminate this problem. One option is to heat anneal the parts to remove molded-in stresses. A second option is to open the gap between mating parts to reduce stress caused by an interference fit. The third option is to minimize the amount of time the liquid adhesive remains in contact with the substrate(s) prior to curing.
- 7. Light curing generally produces some heat. If necessary, cooling fans can be placed in the curing area to reduce the heating effect on components.
- At the point of curing, an air exhaust system is recommended to dissipate any heat and vapors formed during the curing process.

DISPENSING THE ADHESIVE

This material may be dispensed with a variety of manual and automatic applicators or other equipment as required. Questions relating to dispensing and curing systems for specific applications should be referred to Dymax Application Engineering.

CLEAN UP

Uncured material may be removed from dispensing components and parts with organic solvents. Cured material will be impervious to many solvents and difficult to remove. Clean up of cured material may require mechanical methods of removal.

PERFORMANCE AFTER TEMPERATURE EXPOSURE

Dymax light-curable materials typically have a lower thermal limit of $-54^{\circ}C$ [-65°F] and an upper limit of $150^{\circ}C$ [300°F]. Many Dymax products can withstand temperatures outside of this range for short periods of time. Please contact Dymax Application Engineering for assistance.

BIOCOMPATIBILITY

Polymerized Dymax MD[®] Medical Device adhesives are biocompatibility tested in accordance with ISO 10993 and/or USP Class VI. The completed tests are listed on each product data sheet. Copies of the test reports are available upon request. In all cases, it is the user's responsibility to determine and validate the suitability of these adhesives in the intended medical device. These adhesives have not been tested for prolonged or permanent implantation, and are only intended for use in short-term (<29 days) or single-use disposable-device applications. Dymax does not authorize their use in long-term implant applications. Customers using these materials for such applications do so at their own risk and take full responsibility for ensuring product safety and biocompatibility.

STERILIZATION

Compatible sterilization methods include gamma irradiation and ethylene oxide. Sterilization by autoclaving may be limited to certain applications. It remains the user's obligation to ascertain the effect of sterilization on the cured adhesive.

STORAGE AND SHELF LIFE

Store the material in a cool, dark place when not in use. Do not expose to light. This product may polymerize upon prolonged exposure to ambient and artificial light. Keep covered when not in use. This material has a minimum 12-month shelf life from date of shipment, unless otherwise specified, when stored between 10°C [50°F] and 32°C [90°F] in the original, unopened container.

GENERAL INFORMATION

This product is intended for industrial use only. Keep out of the reach of children. Avoid breathing vapors. Avoid contact with skin, eyes, and clothing. Wear impervious gloves. Repeated or continuous skin contact with uncured material may cause irritation. Remove material from skin with soap and water. Never use organic solvents to remove material from skin and eyes. For more information on the safe handling of this material, please refer to the Material Safety Data Sheet before use.

RECOMMENDED DYMAX LITERATURE	
LIT010A	Guide to Selecting and Using UV Light-Curing Systems
LIT012B	MD [®] Adhesives for Medical Device Assembly
LIT077	Chemical Safety
LIT133	UV Light-Curing System Safety Considerations
LIT159	ACCU-CAL™ 50 Radiometer
LIT206	Flood and Focused-Beam UV Light-Curing Systems
LIT218	BlueWave [®] 200 UV Light-Curing Spot Lamp
LIT267	BlueWave [®] LED Prime UVA Spot-Curing System
LIT276	ACCU-CAL™ 50-LED Radiometer
LIT290	ACCU-CAL™ 150 Radiometer

Literature is available through our website, <u>www.dymax.com</u>, or by calling any Dymax location.