

206-CTH SERIES FLEXIBLE CATHETER ADHESIVES

APPLICATIONS

- Balloon /Shaft
- Hub/Shaft
- Needle/Hub
- Potting

FEATURES

- Resilient
- Fluoresces for Easy Inspection
- Moisture Resistant

BONDS

- Stainless Steel
- Polycarbonate
- Polystyrene
- Polyurethane
- Polyamide
- PMMA

BIO-APPROVALS

- ISO 10993-Elution Systemic Injection, Intracutaneous, Implantation, Hemolysis
- USP Class VI requirements are met as a result of the ISO 10993 tests conducted

INTRODUCTION

Dymax MD[®] Medical Device 206-CTH Series adhesives are designed for rapid bonding of transparent or translucent acrylic, polycarbonate, PVC alloys, ABS, polyurethane, and polystyrene, as well as metal substrates. Solvent-free, low viscosity, visible and UV light curing adhesives, 206-CTH Series dispense easily and cures quickly for precise quantity and placement of adhesive. The **built-in fluorescence** provides a method to insure in-line quality control utilizing optical scanners. Dymax MD[®] Medical Device adhesives cure in seconds upon exposure to either UV or visible light. Matching Dymax MEDI-CURE[®] lamps produces the optimum balance of UV and visible light for the fastest, deepest cures.

TYPICAL UNCURED PROPERTIES

Solvent Content		None - 100% Reactive Solids	
Chemical Class		Urethane (Meth) Acrylate	
Appearance		Straw/Clear	
Solubility		Alcohols/Chlorinated Solvents/Ketones	
Toxicity		Low	
Flash Point		>95°C (200°F)	
Viscosity (20 rpm)	206-CTH	135 cP (nominal)	ASTM D-1084
	206-CTH-T	5,000 cP (nominal)	ASTM D-2556

TYPICAL CURED PROPERTIES

Durometer Hardness		D65	ASTM D-2240
Elongation at Break		110%	ASTM D-638
Tensile at Break		2,800 psi	ASTM D-638
Modulus of Elasticity		230,000 psi	ASTM D-638
Water Absorption (24 h)		1.0%	ASTM D-570
Thermal Limit (brittle/degrades)		-55° to 180°C (-65°/+350°F)	DSTM D-200*
Linear Shrinkage		1.1%	ASTM D-2566

*DSTM refers to Dymax Standard Test Method

TYPICAL LIGHT CURE DATA

Lamp	MC-5000	MC-4000	UVC-6 Conveyor*
Light Type	UV/Visible	UV/Visible	UV/Visible
Lamp Type	5" x 5" Flood	3/16" Spot	1" x 6" Focused Beam
Maximum Lamp Intensity @ 365 nm	300 mW/cm ²	4000 mW/cm ²	8000+ mW/cm ²
Intensity @ Time Of Test @ 365 nm	150 mW/cm ²	1800 mW/cm ²	4000 mW/cm ²
Adhesive Absorption Range (nm)	300-500	300-500	300-500
Equipment Output Range (nm)	300-500	300-500	300-500
Cure Speed (Sec)			
Fixture Between Glass Slides	1	1	1
Tack Free Surface Cure	10	20	5
Nominal Cure Depth (0.125")	4	5	2
Cure Depth In 1 Minute (Inch)	>0.25	>0.25	>0.25

*Equipped with Fusion "D" Bulb

The required intensity and cure time should be determined during the initial process validation stage. Factors that should be considered during process validation which can affect the adhesive cure rate and depth of cure include but are not limited to: the part geometry, bond-gap size, percent light transmission through the substrate at 365 nm and 436 nm, distance from the light source to the adhesive bond area, UV and visible light intensity and spectral output of the light source, the desired margin of safety to be built into the process and minimum and maximum exposure times.

DISPENSING AND HANDLING ADHESIVE

Dymax 206-CTH Series adhesives are available in syringes. They may be dispensed with a variety of automatic bench-top syringe applicators or other equipment as required. Direct questions relating to dispensing and curing systems for specific applications, should be referred to the Dymax Technical Center at (860) 482-1010.

STORAGE AND SHELF LIFE

BIOCOMPATIBILITY & STERILIZATION

Dymax Medical Device adhesives are subjected to various biocompatibility tests in accordance with USP Class VI and/or ISO 10993 recommendations for disposable medical devices. The completed tests are identified on each Product Data Sheet, certificate copies of which are available upon request. Unless otherwise noted on the PDS, these adhesives have not been tested for prolonged or permanent implantation. In all cases, it is the user's responsibility to determine and validate the suitability of these adhesives in the intended medical device.

SME Technical Paper #AS91-397, 1991 advises that "All adhesives are toxic in their raw or uncured state. Complete cure...is required to retain Class VI certification status." It is recommended that biocompatibility testing of the completed device be done following sterilization to eliminate the effects of minor process variations and contamination during assembly. The sterilization methods of choice are gamma irradiation and ethylene oxide. Sterilization by autoclaving may be limited to certain applications. Gamma irradiation is known to polymerize unsaturated systems. However, it remains the user's obligation to ascertain the effectiveness of such a procedure.

SAFETY

Wear impervious gloves and/or barrier cream. Repeated or continuous skin contact with liquid adhesive will cause irritation and should be avoided. Do not wear absorbent gloves. Remove adhesive from skin with soap and water. Never use solvents to remove adhesive from skin or eyes.

CAUTION

For industrial use only. Avoid breathing vapors. Avoid contact with eyes and clothing. In case of contact, immediately flush with water for at least 15 minutes; for eyes, get medical attention. Wash clothing before reuse. Keep out of reach of children. Do not take internally. If swallowed, vomiting should be induced at once and a physician called. For specific information, refer to the Material Safety Data Sheet before use.

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Store material in cool, dark place when not in use. Do not expose to UV light or sunlight. Material may polymerize upon prolonged exposure to ambient light. Replace lid immediately after use. Product has a one year shelf life when stored below 90°F in the original, unopened container.

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