

MD® MEDICAL DEVICE ADHESIVES 215-CTH-SV01-UR-SC Product Data Sheet

Encompass® 215-CTH-SV01-UR-SC **LED Optimized Catheter Assembly Adhesive**

APPLICATIONS

- Balloon/Lumen
- Hub/Lumen
- **Manifold Bond Joints**

FEATURES

- LED Optimized 385nm
- . Blue to Colorless upon Cure
- Ultra-Red® Fluorescing
- Adhesion to a Range of
 - Difficult to Bond Substrates

RECOMMENDED SUBSTRATES

- Nylon12
- PEBA
- PC
- ABS
- TPU

BIOCOMPATIBILITY

- ISO10993-4 Hemolysis
- ISO10993-5 Cytotoxicity
- ISO10993-6 Implantation
- ISO10993-10 Intracutaneous
- ISO10993-11 Systemic Toxicity

Dymax 215-CTH-SV01-UR-SC is an LED-curable adhesive designed for bonding and assembly of next-generation catheter designs using Nylon 12, PEBA, and other difficult to bond substrates. It's formulated with Encompass® technology that combines the color change benefits of Dymax See-Cure with Últra-Red® fluorescing for visual verification in all stages of production. The blue color aids in verification of adhesive placement and transitions to colorless upon exposure to sufficient light energy, indicating full cure has been achieved. The bright red fluorescence contrasts extremely well on plastics that naturally fluoresce blue in color (like PVC), and assists with post-cure visual inspection of the bond area. 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 ideal balance of UV and visible light for the fastest, deepest cures. This product is in full compliance with RoHS2 directives 2015/863/EU and 2011/65/EU.

UNCURED PROPERTIES *		
Property	Value	Test Method
Solvent Content	No Nonreactive Solvents	N/A
Chemical Class	Acrylated Urethane	N/A
Appearance	Blue Translucent Liquid	N/A
Soluble in	Organic Solvents	N/A
Density, g/ml	1.01	ASTM D1875
Viscosity, cP (20 rpm)	1,100 (nominal)	DSTM 502

CURED MECHANICAL PROPERTIES *		
Property	Value	Test Method
Durometer Hardness	D55	ASTM D2240
Tensile at Break, MPa [psi]	11.0 [1,600]	ASTM D638
Elongation at Break, %	300	ASTM D638
Modulus of Elasticity, Mpa [psi]	105 [15,300]	ASTM D638

OTHER CURED PROPERTIES *		
Property	Value	Test Method
Cured Appearance	Colorless	N/A
Refractive Index (20°C)	1.50	ASTM D542
Boiling Water Absorption, % (2 h)	5.2	ASTM D570
Water Absorption, % (25°C, 24 h)	10.6	ASTM D570
Linear Shrinkage, %	2.2	DSTM 614 [‡]
Glass Transition T _g , °C	77	DSTM 256 [‡]
CTEα ₁ , μm/m/°C	141	ASTM E831
CTEα ₂ , μm/m/°C	225	ASTM E831

Not Specifications

Not Applicable

DSTM Refers to Dymax Standard Test Method

ADHESION	
Substrate	Recommendation
ABS acrylonitrile-butadiene-styrene	✓
PA polyamide	✓
PC polycarbonate	✓
PEBA polyether block amide	✓
PETG poly(ethylene terephthalate)glycol	✓
PI polyimide	✓
PMMA poly(methyl methacrylate)	✓
PS polystyrene	0
PVC poly(vinyl chloride)	✓
SAN styrene-acrylonitrile	✓
TPU thermoplastic polyurethane	✓

© 2018 Dymax Corporation. All rights reserved. All trademarks in this guide, except where noted, are the property of, or used under license by Dymax Corporation, U.S.A

Technical Data collected 12/2017 Rev. 03/15/2018 ISSUE DATE: October, 2017

Dymax Corporation +1.860.482.1010 | info@dymax.com | www.dymax.com

Dymax Europe GmbH +49 611.962.7900 | info_de@dymax.com | www.dymax.de

Dymax Engineering Adhesives Ireland Ltd. +353 21.237.3016 | info_ie@dymax.com | www.dymax.ie

Dymax Oligomers & Coatings +1.860.626.7006 | info_oc@dymax.com | www.dymax-oc.com

Dymax UV Adhesives & Equipment (Shanghai) Co. Ltd. +86.21.37285759 | dymaxasia@dymax.com | www.dymax

Dymax UV Adhesives & Equipment (Shenzhen) Co. Ltd. +86.755.83485759 | dymaxasia@dymax.com | www.dymax

Dymax Asia (H.K.) Limited +852.2460.7038 | dymaxasia@dymax.com | www.dymax.com.cn

Dymax Asia Pacific Pte. Ltd. +65.6752.2887 | info_ap@dymax.com | <u>www.dymax-ap.com</u>

Dymax Korea LLC +82.2.784.3434 | info_kr@dymax.com | www.dymax.com/kr

o Limited Applications Requires Surface Treatment (e.g. plasma, corona treatment, etc.)

CURING GUIDELINES

The vivid blue color of this adhesive transitions to colorless when fully cured. The charts below provide information on cure time required to transition from blue to colorless using different light sources and adhesive thicknesses. Cure rate is dependent upon many variables including lamp intensity, distance from the light source, and required depth of cure. The times and belt speed for the transition listed below are based on lab results and are intended for reference only.

Dymax Curing System (Intensity)	MX-150™ 365nm RediCure® (15 W/cm²) ^B
Adhesive Thickness, mm [mil]	Time to complete transition, s ^A
0.10 [4]	1
0.20 [8]	1
0.41 [16]	1
0.81 [32]	1

Dymax Curing System (Intensity)	MX-150™ 385nm PrimeCure® (15 W/cm²) ^B
Adhesive Thickness, mm [mil]	Time to complete transition, s ^A
0.10 [4]	3.5
0.20 [8]	3
0.41 [16]	1.5
0.81 [32]	1.5

Dymax Curing System (Intensity)	MX-150 [™] 405nm VisiCure® (15 W/cm²) ^B
Adhesive Thickness, mm [mil]	Time to complete transition, s ^A
0.10 [4]	36.5
0.20 [8]	30
0.41 [16]	20.5
0.81 [32]	12

Dymax Curing System (Intensity)	BlueWave [®] 200 (10 W/cm²) ^c
Adhesive Thickness, mm [mil]	Time to complete transition, s ^A
0.10 [4]	1.4
0.20 [8]	1.2
0.41 [16]	1
0.81 [32]	1

- A Curing through light-blocking substrates may limit the ability of See-Cure adhesives to transition from blue to colorless and may require additional time and/or intensity. These times/speeds are typical for curing through 100% UV and Visible light-transmitting substrates.
- B Intensity was measured over the UVA/Visible range (350-450 nm) using a Dymax ACCU-CAL™ 50-LED Radiometer.
- C Intensity was measured over the UVA range (320-395 nm) using a Dymax ACCU-CAL™ 50 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™ 150 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.

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 must ultimately determine and qualify the appropriate curing parameters required for their unique application.

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.
- All bond surfaces should be clean and free from grease, mold release, or other contaminants prior to dispensing the adhesive.
- 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 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.
- 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.
- Light curing generally produces some heat. If necessary, cooling fans
 can be placed in the curing area to reduce the heating effect on
 components.
- 8. At the point of curing, an air exhaust system is recommended to dissipate any heat and vapors formed during the curing process.

DISPENSING THE RESIN

This material may be dispensed with a variety of manual, semi-automated, and fully automated fluid delivery systems. Small area applications including beads and small dots can be achieved using hand-held Dymax dispensing systems like our SD-100 syringe dispenser and our Micro-Dot syringe dispenser. Questions relating to and defining the best fluid delivery system and curing equipment for specific applications should be discussed with the Dymax Application Engineering Team.

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 six-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.

CLEANUP

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. Cleanup of cured material may require mechanical methods such as ultrasonic bath, water jet, vacuum tweezers, air knife and/or warming to aid in the removal.

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.

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 Safety Data Sheet before use.

The data provided in this document are based on historical testing that Dymax performed under laboratory conditions as they existed at that time, and are for informational purposes only. The data are neither specifications nor guarantees of future performance in a particular application. Dymax does not guarantee that this product's properties are suitable for the user's intended purpose.

Numerous factors—including, without limitation, transport, storage, processing, the material with which the product is used, and the ultimate function or purpose for which the product was obtained—may affect the product's performance and/or may cause the product's actual behavior to deviate from its behavior in the laboratory. None of these factors are within Dymax's control. Conclusions about the behavior of the product under the user's particular conditions, and the product's suitability for a specific purpose, cannot be drawn from the information contained in this document.

It is the user's responsibility to determine (i) whether a product is suitable for the user's particular purpose or application and (ii) whether it is compatible with the user's intended manufacturing process, equipment, and methods. Under no circumstances will Dymax be liable for determining such suitability or compatibility. Before the user sells any item that incorporates Dymax's product, the user shall adequately and repetitively test the item in accordance with the user's procedures and protocols. Unless specifically agreed to in writing, Dymax will have no involvement in, and shall under no circumstances be liable for, such testing.

Dymax makes no warranties, whether express or implied, concerning the merchantability of this product or its fitness for a particular purpose. Nothing in this document should be interpreted as a warranty of any kind. Under no circumstances will Dymax be liable for any injury, loss, expense or incidental or consequential damage of any kind allegedly arising in connection with the user's handling, processing, or use of the product. It is the user's responsibility to adopt appropriate precautions and safeguards to protect persons and property from any risk arising from such handling, processing, or use.

The specific conditions of sale for this product are set forth in Dymax's Conditions of Sale which are available at https://www.dymax.com/index.php/en/resources/sales-terms-conditions. Nothing contained herein shall act as a representation that the product use or application is free from patents owned by Dymax or any others. Nothing contained herein shall act as a grant of license under any Dymax Corporation Patent.

Except as otherwise noted, all trademarks used herein are trademarks of Dymax. The "®" symbol denotes a trademark that is registered in the U.S. Patent and Trademark Office.

The contents of this document are subject to change. Unless specifically agreed to in writing, Dymax shall have no obligation to notify the user about any change to its content.