

BYMAX

Adhesion testing with formulations of Eastman Tritan[™] copolyester

Joining forces

Dymax Corporation evaluated its light-curable medical device adhesives using various formulations of Eastman Tritan[™] copolyester as substrates.

- Lap shear studies were conducted on clear formulations of Tritan (MX711, MX731, MX811) as well as opaque Tritan (MXF121).
- Lipid resistance testing was performed only with the clear formulations of Tritan.

Summary

The results summarized in the table show that Dymax adhesives provide good to excellent adhesion with application-matched formulations of Tritan:

- Aging samples generally had a positive impact on bond strength of the adhesives.
- Submersion in the Intralipid solution did not significantly impact the bond strength.

Lap shear testing

Clear and opaque samples were bonded with applicationmatched adhesives and bond strength was measured following (1) conditioning at room temperature; (2) 20-day dry heat conditioning to simulate \geq 6 months aging.

Lipid resistance study

For random bonded clear samples, bond strength was tested after soaking in Intralipid^{*} 20% (20% IV fat emulsion) for 48 and 96 hours. A control set was also tested.

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		TESTING		RESISTANCE		
		Room temp.	20-day aging at 55°C	Control	48 hr soak	96 hr soak
Category	Adhesive	Avg max	. load (lbf)	Avg	max. load	(lbf)
Eastman Tritan [®] copolyester MX711 adhesion study						
Needle bonding	1161-M	106.66	120.77			
	1402-M	105.30	112.94			
	1403-M	117.21	121.20			
	1405M-T-UR-SC	105.48	107.29			
Catheter bonding	209-CTH	112.60	114.57			
	215-CTH-UR-SC	100.90	188.03			
Plastic assembly	1121-M	129.83	140.42	130.24	133.38	126.83
	1161-M	106.66	120.77	120.51	108.70	101.53
	1180-M	120.14	112.43	106.34	103.18	110.51
Eastman Tritan [™] copolyester MX731 adhesion study						
Needle bonding	1161-M	97.33	123.44			
	1402-M	100.33	91.87			
	1403-M	105.16	104.87			
	1405M-T-UR-SC	92.71	92.86			
Catheter	209-CTH	87.86	90.95			
bonding	215-CTH-UR-SC	129.59	180.22			
Plastic assembly	1121-M	132.79	129.16	98.42	100.89	86.02
	1161-M	97.33	123.44	100.54	93.33	88.59
	1180-M	84.38	90.53	95.70	100.03	94.42
Eastman Tritan	copolyester MX811	l adhesion s				
Needle bonding	1161-M	106.33	114.37			
	1402-M	99.06	109.89			
	1403-M	114.04	131.91			
	1405M-T-UR-SC	113.68	113.16			
Catheter bonding	209-CTH	114.20	124.45			
	215-CTH-UR-SC	140.71	177.48			
Plastic assembly	1121-M	117.51	133.33	129.56	115.24	89.89
	1161-M	106.33	114.37	123.43	102.06	105.30
	1180-M	104.04	99.92	110.65	104.64	103.81
Eastman Tritan	copolyester MXF12					
Needle bonding	1161-M	141.12	139.91	—	—	—
	1402-M	128.92	135.74			
	1403-M	142.81	150.31	—	—	—
	1405M-T-UR-SC	123.22	121.64			—
Catheter bonding	209-CTH	152.55	150.46	—	—	—
	215-CTH-UR-SC	189.41	196.41			
Plastic assembly	1121-M	131.36	150.83			
	1161-M	141.12	139.91	_		—
	1180-M	123.44	125.39	—	—	—
Airway management	112-MSK-UR-SC	128.83	138.31	—	—	—

Eastman **TRITAN**[™]

copolyester

CLEAR TRITAN ADVANTAGES

For clear fluid management components and blood contact devices, clear formulations of Tritan offer:

- Reduced cracking and breaking because of exceptional chemical resistance to oncology drugs and carriers, hospital disinfectants, plasticizers, bonding solvents, and adhesives
- No annealing required
- $\cdot No color shift after gamma/e-beam sterilization$
- Free of BPA, halogens, and other chemicals of concern
- No black specks

OPAQUE TRITAN ADVANTAGES

For housings and enclosures for electronic medical devices, opaque formulations of Tritan offer:

- Durability (less cracking and breaking) after disinfection with a wide variety of hospital disinfectants
- Free of BPA, halogens, and other chemicals of concern
- True color match and retention
- · UL 94 FR V-2 flammability rating

For details on these studies or complete information about clear and opaque formulations of Eastman Tritan[™] copolyester, contact your Eastman representative.

Dymax provides system solutions in which chemistry, material, and equipment work seamlessly together with maximum efficiency, giving our customers a competitive advantage they can't get anywhere else.



The results of **insight**

Eastman Chemical Company

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It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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