EPO-TEK® MED-301

Technical Data Sheet
For Reference Only
Biocompatible/Spectrally Transparent Epoxy
ISO 10993 Tested/Fully Compliant

Date:	October 2018
Rev:	V
No. of Components:	Two
Mix Ratio by Weight:	20 : 5
Specific Gravity:	Part A: 1.15 Part B: 0.87
Pot Life:	1-2 Hours
Shelf Life- Bulk:	One year at room temperature

Biocompatible Certified Cure: 65°C / 1 Hour

Alternative biocompatible cure schedules may be possible, but have not been certified. Contact med@epotek.com with any questions.

NOTES:

- Container(s) should be kept closed when not in use.
- Filled systems should be stirred thoroughly before mixing and prior to use.
- Performance properties (rheology, conductivity, others) of the product may vary from those stated on the data sheet when bi-pak/syringe packaging or post-processing of any kind is performed. Epoxy's warranties shall not apply to any products that have been reprocessed or repackaged from Epoxy's delivered status/container into any other containers of any kind, including but not limited to syringes, bi-paks, cartridges, pouches, tubes, capsules, films or other packages.
- Syringe packaging will impact initial viscosity and effective pot life, potentially beyond stated parameters.
- *TOTAL MASS SHOULD NOT EXCEED 25 GRAMS*

Product Description: EPO-TEK® MED-301 is a biocompatible, spectrally transparent, very low viscosity, room temperature curing epoxy. Additional characteristics are: self-leveling, short pot-life, and ease of application, either by dispensing or manual operation. EPO-TEK® MED 301 is used often in molding headers in pacemakers, cochlear implants and neurostimulator implants, as well as bonding in many other types of medical devices. When longer pot-life, lower stress and large-scale manufacturing is needed, EPO-TEK® MED 301-2 can usually be interchanged.

Typical Properties: Cure condition: 65°C / 1 Hour Different batches, conditions & applications yield differing results.
Data below is not guaranteed. To be used as a guide only, not as a specification. * denotes test on lot acceptance basis

PHYSICAL PROPERTIES:			
* Color (before cure):	Part A: Clear/Colorless	Part B: Clear/Colorless	
* Consistency:	Pourable liquid		
* Viscosity (23°C) @ 100 rpm:	100-200	cPs	
Thixotropic Index:	N/A		
* Glass Transition Temp:	≥ 65	°C (Dynamic Cure: 20-200°C/ISO 25 Min; Ramp -10-200°C @20°C/Min)	
Coefficient of Thermal Expansion (CTE):			
Below Tg:	59	x 10^{-6} in/in°C	
Above Tg:	134	x 10^{-6} in/in°C	
Shore D Hardness:	75		
Lap Shear @ 23°C:	> 2,000	psi	
Die Shear @ 23°C:	≥ 15	Kg	5,334 psi
Degradation Temp:	335	°C	
Weight Loss:			
@ 200°C:	0.59	%	
@ 250°C:	0.83	%	
@ 300°C:	2.23	%	
Suggested Operating Temperature:	< 285	°C (Intermittent)	
Storage Modulus:	420,622	psi	
* Particle Size:	N/A		

OPTICAL PROPERTIES:		
Spectral Transmission:	≥ 98% @ 360-1660	nm
	≥ 95% @ 1680-2060	nm
Refractive Index:	1.5193 @589	nm

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Selected Applications for EPO-TEK® MED-301

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Fiber and Electro-Optics

- Impregnating fiber optic image bundles and light guides; adhesive for flexible endoscopes; adhesion to Vyton® rubber and plastic optical fibers
- Transmission of VIS and NIR light signals in camera/video electro optics
- 3D Dentistry camera and imaging tools
- General, all-purpose fiber optic assembly and repair adhesive

Radiation and Imaging

- Adhesive for scintillator crystal array fabrication
- Opto-underfills between scintillator and photodiode array, for medical/dental imaging equipment

Ultrasound/Ultrasonic

- Adhesive for catheter delivered surgical mapping and imaging catheters
- Front-end ultrasound fabrication adhesive responsible for PZT arrays
- General all-purpose ultrasound probe repair adhesive

Life Sciences and MicroFluidics

- Enabling microfluidic drug delivery via catheter devices; micro-motors and ultrasonics for sensing liquid and gas flow rates
- Adhesive for active optical alignment in spectrophotometry, fluoroscopy and microscopy
- General adhesive for specialized diagnostic equipment

Device and Diagnostics

- Potting resin over LD and PD chips in pulsed oximetry
- Adhesive for gas analyzers, flow meters, pressure and pH monitoring catheters
- Fabrication of glucose sensors; implantable or external
- Potting, over-coating and weather proofing for activity trackers (wearable devices including fitness watches)
- Patient monitoring electrodes and cables including: ECG and temperature probes

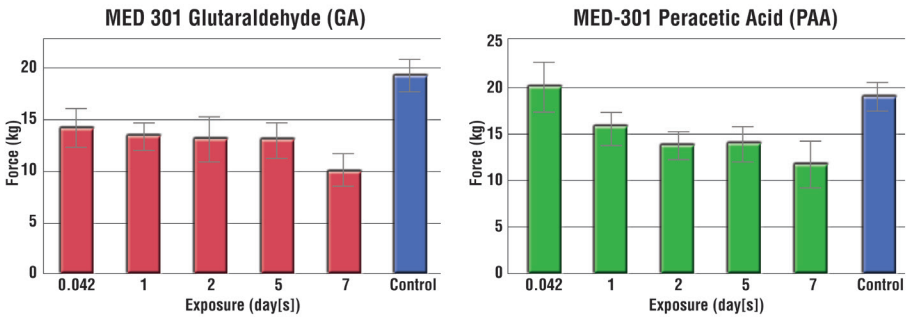
Implantable Devices

- Molding headers over implantable microelectronic packages in ICDs, pacemakers and cochlear implants
- Potting Cu coils and motors used in LVAD and BiVAD blood pumps
- Adhesive for ophthalmic implants; plastic bonding in intraocular lens (IOL), septum bonding and final assembly for diabetic implants; gluing bio-polymers used for IOP drainage; smart drug delivery of pharmaceuticals
- Header potting for neurostimulators/neuromodulators used for epilepsy, Parkinson's, pain management and sleep apnea control

Surgical Tools

- Hand held UV cure light guide for curing dental fillings
- Potting PCBs into metals shafts of hand held orthopedic instruments
- Laser optics (surgical tool for optometry)
- Adhesive for neurovascular surgical probes, electrodes and delivery systems.
- Fabrication of Rf Ablation catheters with structural bonding to PEEBAX®

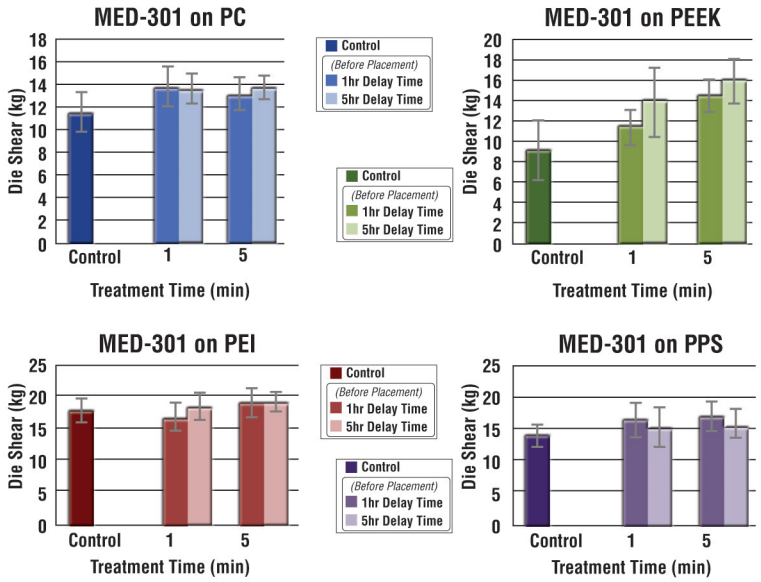
Strength of MED-301 with Disinfectant Soaking



MED-301 Test Parameters

- Adhesive cured: 65°C/2hrs
- Surfaces: 2mm x 2mm ceramic onto glass substrates
- # of estimated cycles based on retaining >50% of initial strength
- 1 cycle defined as 20 min exposure
- 500 cycles for GA - estimated
- 500 cycles for PAA - estimated

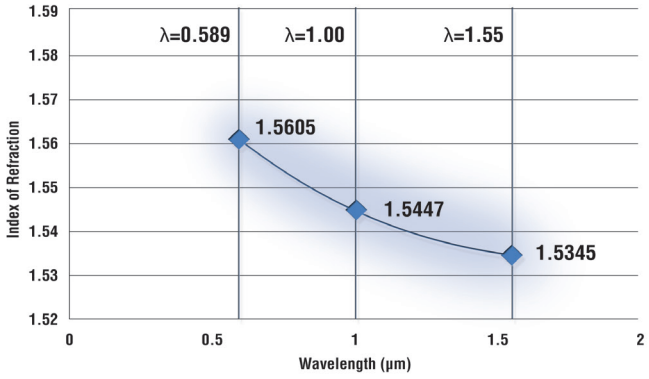
MED-301 & Bonding Strength to Various Plastics



MED-301 Test Conditions

- Adhesive cured: 65°C/2hrs
- Surfaces: 2mm x 2mm ceramic onto plastics
- Oxygen plasma, 100ml/min flow rate
- 12 chips per substrate
- 1min and 5 min exposure time comparison
- Delay time = the duration after plasma etch, before die placement

Index of Refraction vs. Wavelength EPO-TEK® MED-301



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Biocompatibility Approvals

- EPO-TEK® MED-301 cured at 65°C for 1 hour has been tested and is ISO 10993 Certified, meeting Hemolysis (10993-4), Cytotoxicity (10993-5), Implantation (10993-6) for two weeks, and also for **twelve weeks**, Intracutaneous (10993-10), Sensitization (10993-10) and Systemic Toxicity (10993-11) test protocols.

Sterilization Information

- Epoxy performance is most influenced by surface preparation and cleanliness, overall process and handling, and finally proper curing selection. While bulk samples of MED-301 may resist sterilization technologies such as autoclave steam, gaseous technologies, gamma radiation as well as liquid disinfectants, the glue joints may differ. All users need to determine the suitability of MED-301 for their given application.
- Gamma radiation/ion beam will discolor MED-301, thus altering its appearance.
  See Technical Tip # 29: Gamma Sterilization for Medical Devices and its Effect on Epoxies for more information.
  http://www.epotek.com/site/files/Techtips/pdfs/techtips_29.pdf
- MED-301 is generally regarded for resisting few cycles of ETO and gamma radiation.
- MED-301 can survive more than 500 cycles of liquid disinfection based on glutaraldehyde (3.4% concentration) and more than 500 cycles of peracetic acid (0.23% concentration) before significant deterioration of the glue joint.

Packaging Availability

- EPO-TEK® MED-301 is available in specialty packaging such as Pre-Mixed Frozen Syringes (PMF), Bi-Paks, or bulk (A & B containers).
- A Bi-Pak video tutorial can be found here:
  http://www.epotek.com/site/technical-material/application-video-tutorials/117-effective-handling-and-mixing-of-epo-tek®-bi-packs.html
- A video tutorial on handling frozen syringes can be found here:
  http://www.epotek.com/site/technical-material/application-video-tutorials/231-proper-receiving-and-thawing.html

Medical Grade EPOXY TECHNOLOGY EPO-TEK®

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