Biocompatible/High Temperature Epoxy

ISO 10993 Tested/Fully Compliant

**Date:** September 2018  
**Rev:** IV  
**No. of Components:** Two  
**Mix Ratio by Weight:** 10 : 1  
**Specific Gravity:** Part A: 1.20 Part B: 1.02 Syringe: 1.19  
**Pot Life:** ≤ 3 Hours  
**Shelf Life- Bulk:** One year at room temperature  
**Shelf Life- Syringe:** 6 months at -40°C

**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.  
- If product crystallizes in storage, place container in warm oven until crystallization disappears. Please refer to Tech Tip #7 on website.  
- **TOTAL MASS SHOULD NOT EXCEED 25 GRAMS**

**Product Description:** EPO-TEK® MED-353ND is a biocompatible, high temperature, high Tg, and high strength epoxy. It has decades of use and reliability in medical device designs worldwide. Medical applications span from fiber optics and endoscopes, to implants, to diagnostic equipment, to imaging modalities, to surgical tooling. It has high adhesion to SST, titanium, ceramics, glass and most plastic, as well as high chemical and moisture resistance.

**Typical Properties:** Cure condition: 150°C / 1.5 Hours  
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:

<table>
<thead>
<tr>
<th>Property</th>
<th>Part A</th>
<th>Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color (before cure)</td>
<td>Clear</td>
<td>Amber</td>
</tr>
<tr>
<td>Consistency</td>
<td>Pourable liquid</td>
<td></td>
</tr>
<tr>
<td>Viscosity (23°C) @ 50 rpm</td>
<td>3,000-5,000 cPs</td>
<td></td>
</tr>
<tr>
<td>Thixotropic Index</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Glass Transition Temp</td>
<td>≥ 90 °C (Dynamic Cure: 20-200°C/ISO 25 Min; Ramp -10-200°C @20°C/Min)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Below Tg</th>
<th>Above Tg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore D Hardness</td>
<td>51 x 10⁶ in/in°C</td>
<td>178 x 10⁶ in/in°C</td>
</tr>
<tr>
<td>Lap Shear @ 23°C</td>
<td>&gt; 2,000 psi</td>
<td></td>
</tr>
<tr>
<td>Die Shear @ 23°C</td>
<td>≥ 10 Kg</td>
<td>3,556 psi</td>
</tr>
<tr>
<td>Degradation Temp</td>
<td>413 °C</td>
<td></td>
</tr>
<tr>
<td>Weight Loss</td>
<td>0.48 %</td>
<td></td>
</tr>
<tr>
<td>Suggested Operating Temperature</td>
<td>&lt; 350 °C (Intermittent)</td>
<td></td>
</tr>
<tr>
<td>Storage Modulus</td>
<td>464,126 psi</td>
<td></td>
</tr>
</tbody>
</table>

* Particle Size: N/A

### OPTICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectral Transmission</td>
<td>&gt; 89% @ 860-1600 nm</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.5701 @589 nm</td>
</tr>
</tbody>
</table>
Selected Applications for EPO-TEK® MED-353ND

Fiber and Electro-Optics
- Impregnating and terminating fiber optic image bundles and light guides, adhesive for flexible endoscopes, adhesion to plastic and glass optical fibers, structural and near hermetic sealing of glass, ceramic and metals
- Manufacture of all kinds of endoscopes, such as, laryngoscopes, gastroscopes, broncho-scopes and micro ophthalmoscopes; healthcare optics for colonoscopy, urology, and otolaryngology

Imaging Technologies
- OCT using NIR laser for cardiac and ophthalmic imaging
- Endoscopy with camera and video interface
- Ultrasound imaging, capsule endoscopes for GI tract viewing and monitoring
- Temperature probes integration, subcomponent bonding and final assembly of MRI and CT machines

Ultrasound / Ultrasonic
- Adhesive for catheter delivered surgical mapping, 3D imaging and mapping catheters; catheter ultrasound for cardiac therapy, such as AFib treatments
- Front-end ultrasound fabrication adhesive responsible for PZT arrays
- Back-end PZT processes enabling transducers, ultrasound probe repair adhesive

Life Sciences and MicroFluidics
- DNA and gene sequencers, readers and amplification circuits
- Potting, over-coating and weather proofing, fitness style wrist watches and wearable devices

Device and Diagnostics
- Sensor integration and subcomponents for respiratory, anesthesia, vapor and suction; gas and liquid flow monitoring
- SpO2, patient monitoring; capnography, gas analyzers and flow meters
- Widely used adhesive for pressure and pH monitoring catheters

Implantable Devices
- Subcomponents for Ventricular Assist Devices (VAD) fabrication including pumps, coils and magnets
- Adhesive for ophthalmic implants; plastic bonding in intraocular lens (IOL)
- Micro sensors for intraocular pressure
- Hearing aids and implants; acoustic circuits and structural assembly
- Enabling neurostimulator technologies used for sleep apnea, bladder control and other conditions
- Adhesive for pacemakers, ICDs and IPGs
- Neurovascular implants treating aneurysm, stroke, epilepsy and Parkinson’s Disease

Surgical Tools
- High power laser optics for general, reconstructive and cosmetic surgery
- Dental device adhesive, lighting or hand instrument
- Adhesive for neurovascular surgical delivery systems and coils for treating aneurysms
- Fabrication of RF Ablation catheters, electro-surgical tool for tissue removal
- Laser for peripheral artery disease (PAD); atherectomy technologies
- Adhesive for neurovascular surgical delivery systems and coils for treating aneurysms
- Fabrication of RF Ablation catheters, electro-surgical tool for tissue removal
- Laser for peripheral artery disease (PAD); atherectomy technologies
- Impregnating coil motors in orthopedic bone saws

**Strength of MED-353ND with Disinfectant Soaking**

**MED-353ND Test Parameters**
- Adhesive cured: 150°C/1hr
- 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
- 360 cycles (5d) for GA - estimated
- 500 cycles for PAA - estimated

**Index of Refraction vs. Wavelength EPO-TEK® MED-353ND**

MED-353ND Bonding Strength to Various Plastics

**MED-353ND Test Conditions**
- Adhesive cured: 150°C/1hrs (PEEK, PEI), 15°C/1.5hrs (PPS), 110°C/2hrs (PC)
- 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

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**Biocompatibility Approvals**
- EPO-TEK® MED-353ND cured at 150°C for 1.5 hours has been tested and is ISO 10993 Certified, meeting Hemolysis (10993-4), Cytotoxicity (10993-5), Implantation (10993-6) 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-353ND may resist sterilization technologies such as autoclave steam, gaseous technologies, gamma radiation and liquid disinfectants, the glue joints may differ. All users need to determine the suitability of MED-353ND for their given application.
- MED-353ND was found compatible with 100 cycles of Sterrad® 100NX at standard concentration. With prior Sterrad® generation models, it received an “excellent” compatibility rating after 500 cycles.
- MED-353ND is generally regarded for resisting few cycles of ETO and gamma radiation.
- MED-353ND can survive more than 360 cycles of liquid sterilization based on glutaraldehyde (3.4% concentration) and peracetic acid (0.23% concentration before significant deterioration of the glue joint.

**Packaging Availability**
- EPO-TEK® MED-353ND 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:
- A video tutorial on handling frozen syringes can be found here: