biocompatible adhesives & sealants

Biothane™ Polyurethane Systems for medical devices



a biocompatible solution

Biothane Systems are primarily derived from castor oil, a natural material. Once cured, this chemistry is inherently hydrophobic, making Biothane Systems ideal for medical applications involving contact with water-based fluids. They have been used in critical areas of the biomedical market such as blood and human tissue contact since 1975.

These Biothane Systems have been tested extensively for biocompatibility using the industry's most comprehensive standard, ISO 10993. Cytotoxicity and hemolysis results are available for all standard Biothane Systems, while additional tests can be performed to meet customer requirements. **Aurorium** has a long history of regulatory compliance and can offer support in approving and navigating the compliance process.

Each Biothane System consists of two liquid components – the Vorite[™] Prepolymer and the Polycin[™] Polyol, which when mixed together cure at room temperature to yield the crosslinked urethane. Every batch produced goes through rigorous control and validation by **Aurorium**'s Quality Control department, including incoming raw materials, intermediates, and final product compliance to customer-driven specifications.

Biothane Systems are an excellent choice for structural bonding of specialized medical device components such as catheters and specialty filters. Biothane Systems are compatible with a wide variety of substrates including metals, plastics, glass. As a modular solution, Biothane Systems are formulated to provide high strength and flexibility, as well as suitable processability for the application at hand. Recognizing that different products and designs require specialized approaches, Biothane Systems exhibit a wide range of processing and performance properties, including the following:

 Optimized viscosity to achieve sufficient penetration, bubble release, or controlled flow



- Adaptable cure behavior to suit assembly processes at various temperatures
- Adjustable hardness and flexibility to meet device requirements
- Compatibility with various sterilization techniques
- Resistance to solvents typically used in medical applications



optimized pot life

- Increased working window improves adhesive utilization
- Fewer changeovers and consistent quality
- Reduced consumable spend



faster cure time

- Reduced production cycle time
 enables capacity increase
- Lower energy consumption
- Optimized throughput

customizable solution

- "Building Block" system allows
 for customization
- Unique fit to specific manufacturing processes

the benefits of modular technology

When designing a sealant system, it is important to consider the desired flow and cure behavior of the adhesive following precise application to an assembly. Critical factors in determining the optimal viscosity and cure performance include part geometry, application method, and process design.

Once the two components of a Biothane System are combined, the viscosity begins to increase as the chemical reaction develops a cross-linked polyurethane network. The rate of this reaction increases at elevated temperatures.

The modular technology of these two-part Biothane Systems enables Aurorium to build a custom-tailored solution from a broad spectrum of pot-life and cure behavior to suit any assembly process.

The following viscosity and cure properties can be determined via oscillatory rotational rheology experiments:

Pot-Life is the time until viscosity surpasses a usable value for a given application method Gel Point is the time at which the fluid polymer mixture transforms into a 3-dimensional cross-linked network Work Cure is the time when sufficient strength is achieved to advance the assembly to the next processing stage

Pot-Life



Design Capability Ranges

Pot-Life to 10K cP, at 25°C	2-85 minutes
Gel Point, at 65 °C	6-40 minutes
Work Cure, at 65 °C	13-45 minutes

Shaded areas in the charts represent the design capability ranges as compared to the typical performance of Biothane 90-M1, the current standard Biothane System for catheter assemblies.



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catheters and small medical devices

Assembly of catheters and other modular medical devices typically requires multiple applications of small quantities of sealant to adhere to tubing, seal ends, and coat sensors.

For these applications, users typically repackage the Polycin and Vorite Components in pre-measured cartridges, bi-packs, or syringes for ease of handling smaller mix quantities. Cartridges can be mounted in automatic dispensing equipment, or bi-packs can be hand-mixed to deliver the desired product quantity for assembly.

Longer pot life of the adhesive is important in these applications, as it allows for maximum utilization of the material before the mixture thickens too much. The assembly can then be cured at room temperature or cured more quickly using elevated temperature.





catheters

oxygenators



pacemakers



Biothane™	System Components		Viscositv ¹	Gel Time at	Hardness ²	Tensile	Elongation ²		
System	Vorite™ Prepolymer	Polycin™ Polyol	(cP)	25°C (min)	(Shore D)	Strength ² (psi)	(%)	reatures	
90-M1	689	640-M1	2100	80	72	5000	150	Higher hardness, Longer pot-life, High strength and toughness	
228	689	936	2400	50	65	2675	136	Faster reactivity for higher through-put, More efficient production	
252-M1	689	940-M4	2000	55	65	3300	115	Mid-range viscosity and reactivity, Designed for larger membrane pores	
255	689	1679-M3	2500	90	45	2035	130	Lower hardness, Longer pot-life	

¹ Brookfield LVT viscometer measurement

² Physical properties measured at full cure after one week at 23°C

 $^{\rm 3}$ Vorite 2040 is stable at temperatures as low as –5°C

Data shown is typical for a representative sample of these systems.

specialty hollow fiber membrane filters

Biothane Systems for filter sealants and adhesives are specially formulated to meet the rigorous demands of varied applications – such as dialyzers, oxygenators, and pharmaceutical filters, while meeting the biocompatibility test standards.

In these applications, device assembly processes can vary widely in order to ensure optimal wetting and penetration, and a bubble free casting. Furthermore, filter cartridge cuttability is guided by compound hardness, relying on a tight window of hardness to enable clean cuts.

The range of Biothane Systems available for these applications provides the desired strength, flexibility, mechanical properties, pot life, and hardness. For example, Biothane Systems 331 and 335 develop high hardness quickly for process speed optimization, whereas Biothane System 337 develops hardness more slowly for a wide cutting window range.





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dialyzers

oxygenators

bioreactors

Biothane™	System Components		Viscositv ¹	Gel Time at	Hardness ²	Tensile	Elongation ²		
System	Vorite™ Prepolymer	Polycin™ Polyol	lycin™ (cP) 25°C (min) (Shore D) Strength²(psi) (%) Polyol		(%)	Features			
252-M1	689	940-M4	2000	55	65	3300	115	Mid-range viscosity designed for larger membrane pores	
265	689	12	6000	75	75	6800	7	High viscosity, strength, and hardness	
331	2040	1964	650	6.5	71	3685	125	For high through-put operations, Low temperature storage ³	
332-M1	2040	1679-M3	650	55	55	1590	145	Low viscosity, Low temperature storage ³	
335	2050	1964	700	7	71	3710	135	For high through-put operations, Steam sterilizable	
337	2050M1	2566	750	8.5	65	3200	150	Longer cutting window provides production flexibility	

working with us

Your partner for a better future; **Aurorium** is focused on providing solutions that enhance drug delivery, feature biocompatibility for optimized performance, and support human health.

Customers partner with **Aurorium** due to our long history and extensive knowledge in developing polyurethane adhesives and sealant solutions for the medical industry. Our team of application experts understand that specialty medical devices require materials with unique properties to optimize product performance and processing efficiencies. Formulation expertise combined with the modular Biothane System platform enables **Aurorium** to offer our customers the ability to design a system that meets their precise needs.



a world of possibilities

We believe in the power of possibility; through specialty ingredients and performance-enhancing materials, **Aurorium** makes it possible for companies around the world to create life-improving products that make the world a better place. The key industries **Aurorium** serves include personal & home care, healthcare, coatings, energy & electronics, food & beverages, agriculture, transportation, and paper & packaging.

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