



SOLVAY

asking more from chemistry®



High-Performance Plastics for

Healthcare

**SPECIALTY
POLYMERS**



Discover More Plastics with More Performance

High-Performance
Medical Grade Plastics

Udel® PSU

Veradel® HC PESU

Radel® PPSU

AvaSpire® PAEK

KetaSpire® PEEK

Ixef® PARA

Solviva® Biomaterials
for Implantable Devices

Eviva® PSU

Veriva® PPSU

Zeniva® PEEK


SOLVIVA®
BIOMATERIALS



Broadest selection of high-performance thermoplastics for implantable and medical devices.

Global technical and regulatory support tailored to meet the unique demands of your project.



With over **25 years of experience** as a leading materials supplier to the healthcare industry, Solvay provides the **reliability, experience and innovation** that medical device manufacturers expect from their partners.

ISO 10993:1 biocompatibility testing has been performed and compatibility with **sterilization methods** has been evaluated. **FDA Master Access Files (MAF)** are available for our products.

High-Performance Medical Grade Plastics

For limited exposure applications having **less than 24 hours** contact with bodily fluids and tissue.

Surgical instruments, cases and trays, medical devices and equipment have **different performance requirements** that benefit from our **many different polymers**.

- Reusable and single-use instruments and devices
- Tailored levels of chemical compatibility
- Transparent, opaque and gamma-stabilized colors
- Standard colors supported in our Master Access Files
- Design options for hybrid and metal conversions
- Extensive library of supporting data

Solviva® Biomaterials for Implantable Devices

For long-term exposure applications having **more than 24 hours** contact with bodily fluids and tissue.

Manufactured in our **ISO 13485** and cGMP compliant dedicated facility in Georgia, USA. Materials tested in our **ISO 17025 labs**.

- Hundreds of regulatory approvals in US, Europe, China and other regions
- Available in pellets, rod stock and plate
- Filled, high flow and low flow grades
- Product traceability and change notification
- Direct shipping and billing to processors
- Validated process

High-Performance Medical Grade Plastics

For limited exposure applications having **less than 24 hours** contact with bodily fluids and tissue.

Udel® PSU

polysulfone

- High-heat resistance
- Good chemical resistance
- Good hydrolytic stability
- Good drop impact resistance and strength
- Opaque and transparent colors

Veradel® HC PESU

polyethersulfone

- Higher heat resistance than Udel® PSU
- Good chemical resistance
- High flow rate
- Highest stiffness of all sulfone polymers
- Transparent

Radel® PPSU

polyphenylsulfone

- Extended high-heat resistance
- Withstands more than 1,000 cycles of steam sterilization
- Excellent chemical resistance
- Superior toughness and impact properties
- Opaque and transparent colors

AvaSpire® PAEK

polyaryletherketone

- Better chemical resistance than Radel® PPSU
- Good fatigue and temperature resistance
- Good impact resistance
- Glass and carbon fiber reinforced grades
- Excellent aesthetics and colorability

KetaSpire® PEEK

polyetheretherketone

- Industry's highest performing thermoplastic
- Best-in-class chemical resistance
- Excellent fatigue and heat resistance
- Good impact resistance
- Glass and carbon fiber reinforced grades

Ixef® PARA

polyarylamide

- Single-use application material of choice
- Highest stiffness and strength
- High flow for excellent moldability
- Exceptional surface finish
- Suitable for metal replacement
- Opaque gamma-stabilized colors

Solviva® Biomaterials

For use in implantable devices having **more than 24 hours** contact with bodily fluids and tissue.

Eviva® PSU

polysulfone

- Good strength and toughness
- Excellent dimensional stability
- Weldability
- Transparent or opaque white
- Long history of use in cardiovascular, neurovascular, drug delivery and dental applications

Veriva® PPSU

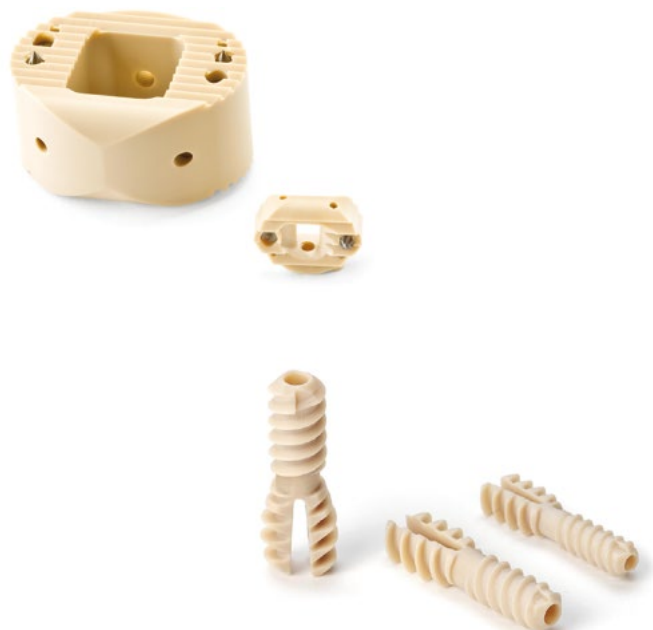
polyphenylsulfone

- Excellent toughness and impact resistance
- Good insulation properties
- Transparent or opaque white
- For use in for implantable wire coatings

Zeniva® PEEK

polyetheretherketone

- Industry's most biostable plastic
- Meets ASTM F2026-2016 requirements
- Excellent resistance to chemicals and steam sterilization
- Highest toughness and fatigue resistance
- Pellets, rods and plates available in neat and filled grades
- Suitable for load-bearing applications such as spine and orthopedic implants



Typical Applications

	Orthopedics	Sterilization Cases & Trays	Medical & Dental Devices	Single-Use Instruments	Hemodialysis Membranes	Implantable Devices
High-Performance Medical Grade Plastics						
Udel® PSU		√	√	√	√	
Veradel® HC PESU	√		√	√		
Radel® PPSU	√	√	√			
AvaSpire® PAEK	√		√			
KetaSpire® PEEK	√		√			
Ixef® PARA	√		√	√		
Solviva® Biomaterials						
Eviva® PSU						√
Veriva® PPSU						√
Zeniva® PEEK						√

These categories represent areas where Solvay healthcare plastics are commonly used and do not imply fitness for use.



Biological Safety

With more than 25 years of healthcare experience, we understand the industry's global biological safety concerns and offer comprehensive regulatory support.

- Healthcare polymers tested for ISO 10993 biocompatibility
- Robust data dossiers, including FDA Master Access Files (MAF)
- Region-specific regulatory specialists to assist and support requests for submissions, petitions and certificates

Biocompatibility testing

Test	Method	Eviva® PSU Veriva® PPSU	Zeniva® PEEK	Veradel® HC PESU	Radel® PPSU Udel® PSU	AvaSpire® PAEK KetaSpire® PEEK	Ixef® PARA
Complete characterization ⁽¹⁾	ISO 10993-18	√	√				
Physico-chemical	ISO 10993-18			√	√	√	√
Cytotoxicity	ISO 10993-5	√	√	√	√	√	√
Sensitization	ISO 10993-10	√	√	√	√	√	√
Intracutaneous toxicity	ISO 10993-10	√	√	√	√	√	√
Acute systemic toxicity	ISO 10993-11	√	√	√	√	√	√
Subchronic toxicity	ISO 10993-11	√	√				
Genotoxicity	ISO 10993-3	√	√				
Bone and muscle implant tests	ISO 10993-6	Muscle	√				
Hemolysis	ASTM F-756	√	√				
Pyrogenicity	USP 151	√	√				

⁽¹⁾Including exhaustive extractions and risk assessment



Sterilization

Solvay's healthcare plastics are compatible with a full range of sterilization technologies.

Medical device companies should validate the material and device performances under the conditions that best simulate the intended use.

Exposure to chemicals and disinfectants exposure in combination with associated sterilization method should be considered to assess their cumulative effect on the material.

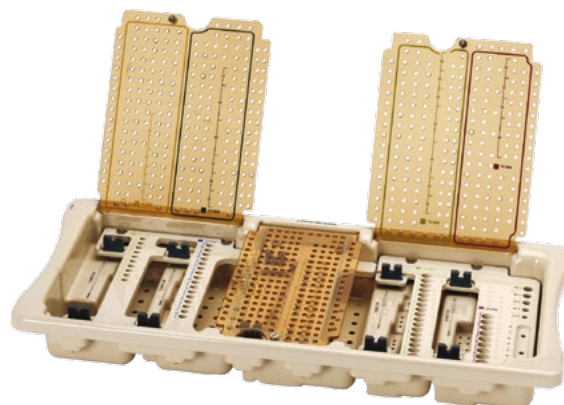


Compatibility with sterilization methods

	Steam 18 minutes at 134 °C			Ethylene Oxide Gas 100 cycles	Vaporized Hydrogen Peroxide 200 cycles	High-Energy Gamma Radiation 40 kGy
	10 cycles	100 cycles	1,000 cycles			
High-Performance Medical Grade Plastics						
Udel® PSU	√	√		√	√	√
Veradel® HC PESU	√	√		√	√	√ ⁽¹⁾
Radel® PPSU	√	√	√	√	√	√
AvaSpire® PAEK	√	√	√	√	√	√
KetaSpire® PEEK	√	√	√	√	√	√
Ixef® PARA	√			√		√
Solviva® Biomaterials						
Eviva® PSU	√	√		√	√	√
Veriva® PPSU	√	√	√	√	√	√
Zeniva® PEEK	√	√	√	√	√	√

Contact your Solvay representative for information specific to Solviva® Biomaterials

⁽¹⁾ Veradel® HC PESU is compatible with high-energy gamma radiation but there is a drop in ductility.



Cleaning & Disinfecting

Multiple factors must be considered when evaluating compatibility with cleaning agents and disinfectants, including

- Material selection
- Type of reagent
- Reagent concentration
- Temperature and time
- Residual or applied stress on fabricated part

Stress can be caused by an external load applied during use or by a residual internal stress in the molded part due to processing. Evaluation of the finished device should consider how stress and reagent interaction could lead to cracking.

Performance of the material and device should be evaluated under the design criteria and conditions that best simulate the intended use. Exposure to cleaners and disinfectants as well as the associated sterilization method should be considered to assess their cumulative effect on the material.

Compatibility with hospital disinfectants

Disinfectant	Udel® PSU	Veradel® HC PESU ⁽¹⁾	Radel® PPSU	AvaSpire® PAEK	KetaSpire® PEEK	Ixef® PARA
Aseptisol®	Excellent	Excellent	Excellent	Excellent	Excellent	Not Tested
Bleach solutions, 10 %	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Cavicide®	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Envirocide®	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Cidex®	Excellent	Excellent	Excellent	Excellent	Excellent	Not Tested
Lysetol® FF	Good	Good	Excellent	Excellent	Excellent	Not Tested
Grotanat®	Poor	Good	Excellent	Excellent	Excellent	Not Tested
Hydrogen peroxide, 3 %	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Isopropyl alcohol, 70 %	Good	Good	Excellent	Excellent	Excellent	Excellent
Manu-Klenz®	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Phenols, 2 %	Good	Good	Excellent	Excellent	Excellent	Excellent
Puristeril Plus®	Excellent	Excellent	Excellent	Excellent	Excellent	Not Tested
Quaternaries	Good	Good	Excellent	Excellent	Excellent	Excellent
Sani-Cloth® HB	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Sani-Cloth® Plus	Poor	Good	Excellent	Excellent	Excellent	Excellent
Sporota® 100	Good	Good	Excellent	Excellent	Excellent	Not Tested
Super Sani-Cloth®	Good	Good	Excellent	Excellent	Excellent	Excellent
Wex-Cide®	Poor	Good	Excellent	Excellent	Excellent	Excellent

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⁽¹⁾ Expected compatibility of Veradel® HC PESU with hospital disinfectants



Design Freedom

Solvay's medical-grade plastics are easily processed using standard molding techniques. With the exception of Ixef® PARA compounds, they can be extruded into thin films and into stock shapes for machining and low-volume production.

Processing and fabrication

Processing	Udel® PSU	Veradel® HC PESU	Radel® PPSU	AvaSpire® PAEK	KetaSpire® PEEK	Ixef® PARA
Injection molding	√	√	√	√	√	√
Extrusion	√	√	√	√	√	
Thermoforming	√	√	√			
Machining	√	√	√	√	√	
Pad printing	√	√	√	√		√
Overmolding	√	√	√	√	√	√
Laser etching	√	√	√	√	√	√

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Customize your look with color

Colors are used for brand identity and size differentiation. Solvay's standard colors are supported with ISO 10993 biocompatibility testing and FDA Master Access Files (MAF).

Custom colors of Solvay medical-grade plastics are available through our partners.

Color availability

	Transparent	Opaque
Radel® PPSU	√	√
Veradel® HC PESU	√	
Udel® PSU	√	√
Ixef® PARA		√ ⁽¹⁾
AvaSpire® PAEK		√

⁽¹⁾ Gamma stabilized colors available.

Technical and Regulatory Support

As a resource to your design and engineering team, we can provide the product development, technical and regulatory support you need to grow your business globally.

- Material recommendations
- Designing with plastics
- Moldflow® process modeling
- Finite element analysis
- Fabrication and assembly techniques
- Product testing and failure analysis
- Global regulatory submission assistance
- On-site materials training
- On-site processing support



Typical Properties

Property ⁽¹⁾	Units	Udel® P-1700	Udel® GF-120	Veradel® HC PESU	Radel® R-5000	Ixef® 1022	Test Method
Polymer type		PSU	PSU	PESU	PPSU	PARA	
Fiber reinforcement		Unreinforced	20 % glass	Unreinforced	Unreinforced	50 % glass	
Tensile strength	MPa	70	97	88.9	70	280	ASTM D638
	ksi	10.2	14.0	12.9	10.1	40.6	
Tensile modulus	GPa	2.5	6.0	2.7	2.3	20.0	ASTM D638
	ksi	360	540	390	340	2,900	
Tensile elongation at break	%	50–100	3	25–75	60–120	1.8–1.9	ASTM D638
Flexural strength	MPa	106	148	125	91	400	ASTM D790
	ksi	15.4	18.5	18.1	13.2	58.0	
Flexural modulus	GPa	2.7	5.5	2.6	2.4	19	ASTM D790
	ksi	390	550	380	350	2,760	
Izod impact, notched	J/m	69	53	53	690	110	ASTM D256
	ft-lb/in	1.3	1.0	1.0	13.0	2.1	
Izod impact, unnotched	J/m	No break	480	No break	No break	850	ASTM D4812
	ft-lb/in	No break	9	No break	No break	16	
HDT ⁽²⁾ at 1.82 MPa (264 psi)	°C	174	180	200	207	230	ASTM D648
	°F	345	356	392	405	446	
CLTE ⁽³⁾ flow direction	ppm/ °C (°F)	56 (31)	23 (13)	49 (27)	56 (31)	1.5 (0.8)	ASTM D696
CLTE ⁽³⁾ transverse direction	ppm/ °C (°F)	56 (31)	56 (31)	49 (27)	56 (31)	4.6 (2.5)	ASTM D696
Water absorption, 24 hours	%	0.3	0.2	0.5	0.4	0.2	ASTM D570
Specific gravity		1.24	1.40	1.37	1.29	1.64	ASTM D792

Contact your Solvay representative for information specific to Solviva® Biomaterials

⁽¹⁾ Actual properties of individual batches will vary within specification limits

⁽²⁾ Heat deflection temperature

⁽³⁾ Coefficient of linear thermal expansion, average value between 0–150 °C (32–302 °F)



Property ⁽¹⁾	Units	AvaSpire® AV-651	AvaSpire® AV-651 GF30	AvaSpire® AV-651 CF30	KetaSpire® KT-880	KetaSpire® KT-880 GF30	KetaSpire® KT-880 CF30	Test Method
Polymer type		PAEK	PAEK	PAEK	PEEK	PEEK	PEEK	
Fiber reinforcement		Unreinforced	30 % glass	30 % carbon	Unreinforced	30 % glass	30 % carbon	
Tensile strength	MPa	87	156	184	100	162	223	ASTM D638
	ksi	12.6	22.7	26.7	14.5	23.5	32.3	
Tensile modulus	GPa	3.0	9.9	20.7	3.7	10.8	20.9	ASTM D638
	ksi	430	1,440	3,000	530	1,560	3,020	
Tensile elongation at break	%	> 40	2.9	1.5	10–20	2.8	1.7	ASTM D638
Flexural strength	MPa	124	234	262	153	260	321	ASTM D790
	ksi	18.0	34.0	38.0	22.2	37.7	46.6	
Flexural modulus	GPa	3.1	9.4	17.2	3.8	10.5	17.9	ASTM D790
	ksi	450	1,360	2,500	550	1,530	2,600	
Izod impact, notched	J/m	69	107	59	53	69	64	ASTM D256
	ft-lb/in	1.3	2.0	1.1	1.0	1.3	1.2	
Izod impact, unnotched	J/m	No break	960	590	No break	850	640	ASTM D4812
	ft-lb/in	No break	18	11	No break	16	12	
HDT ⁽²⁾ at 1.82 MPa (264 psi)	°C	190	213	212	160	315	315	ASTM D648
	°F	374	415	414	320	599	599	
CLTE ⁽³⁾ flow direction	ppm/ °C (°F)	54 (30)	19 (11)	6 (3)	47 (26)	20 (11)	7 (4)	ASTM D696
CLTE ⁽³⁾ transverse direction	ppm/ °C (°F)	53 (29)	52 (29)	48 (27)	50 (28)	66 (37)	57 (32)	ASTM D696
Water absorption, 24 hours	%	0.2	0.2	0.2	0.1	0.1	0.1	ASTM D570
Specific gravity		1.29	1.52	1.42	1.30	1.53	1.41	ASTM D792

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⁽¹⁾ Actual properties of individual batches will vary within specification limits

⁽²⁾ Heat deflection temperature

⁽³⁾ Coefficient of linear thermal expansion, average value between 0–150 °C (32–302 °F)





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Safety Data Sheets (SDS) are available by emailing us or contacting your sales representative. Always consult the appropriate SDS before using any of our products.

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