



SOLVAY

asking more from chemistry®



High-Performance Plastics for

Healthcare

**SPECIALTY
POLYMERS**



Discover More Plastics with More Performance

High-Performance
Medical Grade Plastics

Radel® PPSU

Udel® PSU

Ixef® PARA

AvaSpire® PAEK

KetaSpire® PEEK

PrimoSpire® SRP

Solviva® Biomaterials
for Implantable Devices

Zeniva® PEEK

Veriva® PPSU

Eviva® PSU

Proniva® SRP


SOLVIVA®
BIOMATERIALS



Solvay offers the industry's broadest selection of high-performance thermoplastics for implantable and non-implantable medical devices. We also provide global technical and regulatory support.

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



Based on biocompatibility testing as defined by ISO 10993:1, our healthcare products demonstrate no evidence of cytotoxicity, sensitization, intracutaneous reactivity or acute systemic toxicity. Compatibility with various sterilization methods is product specific and includes gamma radiation, ethylene oxide, vaporized hydrogen peroxide and steam.

High-Performance Medical Grade Plastics

Performance requirements for medical equipment, cases and trays, surgical instrumentation and other non-implantable medical devices vary widely, but they share a common need for the high performance that Solvay's medical grade plastics provide. These materials are suitable for limited exposure applications that are in contact with bodily fluids or tissue for less than 24 hours.

- Reusable and single-use devices
- Compatible with cleaning agents and disinfectants
- Transparent, opaque and gamma-stabilized colors
- FDA Master Access File (MAF) supported color palettes
- Silicon overmolding for ergonomic designs
- Enable metal-to-plastic conversion

Solviva® Biomaterials for Implantable Devices

Solviva® Biomaterials are offered for use in implantable medical devices, specifically those that are in contact with bodily fluids or tissue for more than 24 hours. Our dedicated production facility in Georgia, USA, is ISO 13485 compliant and operates under the relevant aspects of current Good Manufacturing Practices. All materials are tested in accredited laboratories that have ISO 9001 certification and are ISO 17025 accredited.

- Over fifty 510(k) clearances and numerous CE marks
- Meet ASTM F2026-2014 (PEEK only) and YY/T 0660-2008
- Streamlined contract negotiations
- Ship directly to processors
- Process validation
- Product traceability

More Plastics with More Performance

High-Performance Medical Grade Plastics

Radel® PPSU polyphenylsulfone

Super-tough, high-heat, transparent plastic that has excellent chemical resistance and the ability to withstand more than 1,000 cycles of steam sterilization without significant loss of properties. Opaque and transparent colors are available.

Udel® PSU polysulfone

Tough, high-strength transparent plastic that offers higher heat resistance and better hydrolytic stability than polycarbonate. PSU retains mechanical properties and dimensional stability when exposed to steam and oxidizing agents. Opaque and transparent colors are available.

Ixef® PARA polyarylamide

Uniquely combines high strength and stiffness with an exceptional surface finish, making it an excellent candidate for metal replacement. Opaque gamma-stabilized colors are available.

AvaSpire® PAEK polyaryletherketone

Versatile family of products which bridges the gap between sulfone and ketone based polymers. Benefits include improved aesthetics and ductility versus traditional PEEK materials.

KetaSpire® PEEK polyetheretherketone

PEEK is one of the industry's highest performing polymers and it retains its excellent mechanical and chemical resistance properties at high temperatures. Glass fiber and carbon fiber-reinforced grades provide a wide range of performance options.

PrimoSpire® SRP self-reinforced polyphenylene

One of the stiffest, strongest unreinforced thermoplastics available, offering exceptional hardness, high compressive strength and excellent dimensional stability after repeated steam sterilization.

Solviva® Biomaterials

Solvay's family of thermoplastic biomaterials are offered for use in implantable medical devices for short-term and long-term exposure. Only products designated as part of the Solviva® family of biomaterials may be considered as candidates for medical applications implanted in the human body and devices that are in contact with bodily fluids or tissues for greater than 24 hours.

Zeniva® PEEK polyetheretherketone

PEEK is one of the most biostable plastics available and it exhibits high strength and stiffness along with excellent toughness and fatigue resistance. This material meets ASTM F2026 -2014 requirements as a PEEK polymer for surgical implant applications.

Proniva® SRP self-reinforced polyphenylene

Among the world's stiffest and strongest unreinforced plastics, offering exceptional biocompatibility and hardness.

Veriva® PPSU polyphenylsulfone

Combines unsurpassed toughness with transparency and excellent biocompatibility.

Eviva® PSU polysulfone

Transparent, biocompatible polymer that offers high strength and toughness.

Technical & Regulatory Support

At Solvay, we understand the importance of responsive customer support and work hard to earn your confidence in us as a materials supplier. Our dedicated healthcare team provides the product development, technical and regulatory support you need to grow your global business. Please contact us for assistance with:

- Material recommendations
- Designing with plastics
- Moldflow® process modeling
- Finite element analysis
- Fabrication and assembly techniques
- Product testing
- Failure analysis
- Global regulatory submission assistance

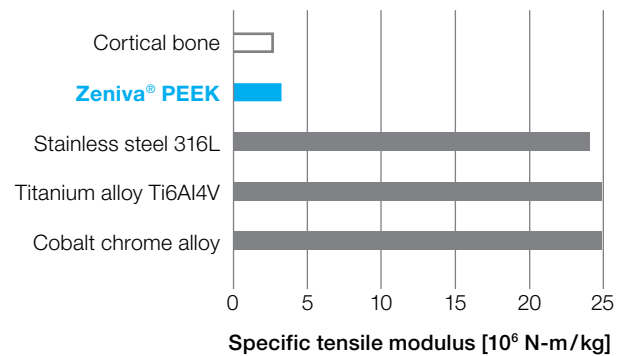
Typical Applications

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

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

Comparison of stiffness-to-weight ratios

Tensile modulus/density



Biological Safety

As a proactive partner with healthcare OEM's for more than 25 years, we understand the stringent industry requirements designed to ensure biological safety and protect the public's health, and we offer comprehensive regulatory support.

- Global standardization based on ISO 10993 methods
- Robust data dossiers, including FDA Master Access Files (MAFs) for materials used in long-term implantable and limited body contact applications
- Region-specific regulatory specialists can assist and support your submissions, petitions, and certificate requests

Biocompatibility testing

Test	Method	Zeniva® PEEK	Veriva® PPSU Eviva® PSU	AvaSpire® PAEK KetaSpire® PEEK	Radel® PPSU Udel® PSU	Ixef® PARA
Complete characterization*	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 10993-5	√	√			
Bone and muscle implant tests	ISO 10993-6	√	Muscle			
Hemolysis	ASTM F-756	√	√			
Pyrogenicity	USP 151	√	√			

* Including exhaustive extractions and risk assessment



Sterilization

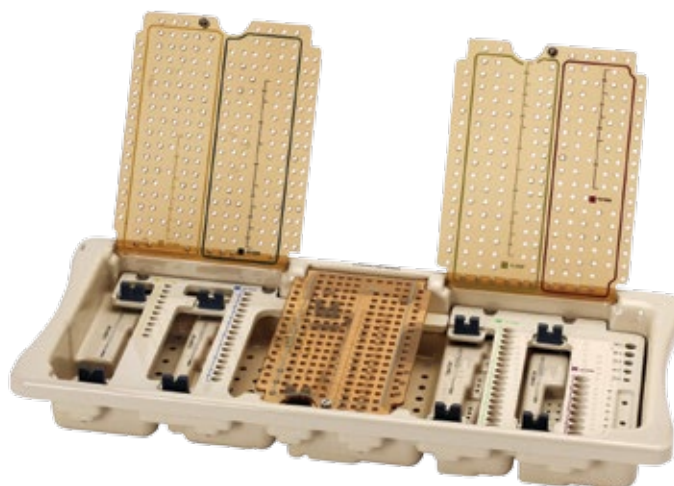
Solvay's healthcare plastics cover the gamut of sterilization technologies. Reusable devices are chemically washed and disinfected prior to any sterilization procedure. Those that are steam sterilized may be exposed to other chemicals, such as morpholine, which are often used in central steam sterilization systems to inhibit corrosion in the lines. For this reason, manufacturers should check performance under conditions that best simulate the intended use of the fabricated part in order 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	1000 cycles			
High-Performance Medical Grade Plastics						
Radel® PPSU	√	√	√	√	√	√
Udel® PSU	√	√		√	√	√
Ixef® PARA	√			√		√
AvaSpire® PAEK	√	√	√	√	√	√
KetaSpire® PEEK	√	√	√	√	√	√
PrimoSpire® SRP	√	√	√	√	√	√
Solviva® Biomaterials						
Zeniva® PEEK	√	√	√	√	√	√
Proniva® SRP	√	√	√	√	√	√
Veriva® PPSU	√	√	√	√	√	√
Eviva® PSU	√	√		√	√	√

Contact your Solvay representative for information specific to Solviva® Biomaterials



Cleaning & Disinfecting

Compatibility with cleaning agents and disinfectants is an important consideration when selecting materials for healthcare applications. Chemical resistance varies considerably among plastics and is largely dependent on molecular structure. Other influential factors include:

- Type of reagent
- Reagent concentration
- Temperature
- Exposure time
- 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. Residual stress can be minimized

by adjusting processing conditions. It's important to be familiar with a material's performance under unstressed and stressed conditions as some reagents having no effect on unstressed plastic can cause cracking when stressed.

The table below gives a general indication of the compatibility of our medical grade plastics with commonly used hospital disinfectants. Because performance and design criteria are application specific, manufacturers should check performance under conditions that best simulate the intended use of the fabricated part. This includes cleaning and disinfecting followed by sterilization in order to assess their cumulative effects on the material.

Compatibility with hospital disinfectants

	Radel® PPSU	Udel® PSU	Ixef® PARA	AvaSpire® PAEK	KetaSpire® PEEK	PrimoSpire® SRP
Aseptisol®	Excellent	Excellent	Not Tested	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	Not Tested	Excellent	Excellent	Excellent
Lysetol® FF	Excellent	Good	Not Tested	Excellent	Excellent	Excellent
Grotanat®	Excellent	Poor	Not Tested	Excellent	Excellent	Not Tested
Hydrogen peroxide, 3%	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Isopropyl alcohol, 70%	Excellent	Good	Excellent	Excellent	Excellent	Excellent
Manu-Klenz®	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Phenols, 2%	Excellent	Good	Excellent	Excellent	Excellent	Excellent
Puristeril Plus®	Excellent	Excellent	Not Tested	Excellent	Excellent	Not Tested
Quaternaries	Excellent	Good	Excellent	Excellent	Excellent	Excellent
Sani-Cloth® HB	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Sani-Cloth® Plus	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Sporota® 100	Excellent	Good	Not Tested	Excellent	Excellent	Not Tested
Super Sani-Cloth®	Excellent	Good	Excellent	Excellent	Excellent	Excellent
Wex-Cide®	Excellent	Poor	Excellent	Excellent	Excellent	Excellent

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Design Freedom

Solvay's healthcare 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. For detailed processing information, visit www.healthcarepolymers.com.

Processing and fabrication

	Injection Molding	Extrusion	Thermo-forming	Machining	Pad Printing	Over-molding	Laser Etching
Radel® PPSU	√	√	√	√	√	√	√
Udel® PSU	√	√	√	√	√	√	√
Ixef® PARA	√				√	√	√
AvaSpire® PAEK	√	√		√	√	√	√
KetaSpire® PEEK	√	√		√		√	√
PrimoSpire® SRP	√	√		√	√	√	√

Contact your Solvay representative for information specific to Solviva® Biomaterials

Customize Your Look With Color

Set yourself apart from the competition by using color to create a fresh, exciting look for your products. Colors can also provide a quick visual reference for differentiating sizes.

Where transparency is important, consider Udel® PSU and Radel® PPSU resins, which in their natural state have a near water-white and light amber color respectively. They are available in a range of vibrant transparent colors that deliver a clear advantage over metal without compromising performance.

Solvay also offers a wide range of opaque colors for several of its medical grade plastics. Opaque and transparent Radel® PPSU colors and Ixef® PARA gamma-stabilized colors are supported by FDA Master Access Files (MAF) and demonstrate no evidence of cytotoxicity, sensitization, intracutaneous reactivity or acute systemic toxicity.

Color availability

	Transparent	Opaque	Gamma-Stabilized
Radel® PPSU	√	√	
Udel® PSU	√	√	
Ixef® PARA		√	√
AvaSpire® PAEK		√	



Typical Properties

Property ⁽¹⁾	Units	Radel® R-5000	Radel® RG-5030	Udel® P-1700	Udel® GF-120	Ixef® 1022	PrimoSpire® PR-9250	Test Method
Polymer type		PPSU	PPSU	PSU	PSU	PARA	SRP	
Fiber reinforcement		Unreinforced	30 % glass	Unreinforced	20 % glass	50 % glass	Unreinforced	
Tensile strength	MPa	70	120	70	97	280	152	ASTM D638
	ksi	10.1	17.4	10.2	14.0	40.6	22.0	
Tensile modulus	GPa	2.3	9.2	2.5	6.0	20.0	5.5	ASTM D638
	ksi	340	1,330	360	540	2,900	800	
Tensile elongation at break	%	60–120	2	50–100	3	1.8–1.9	5–7	ASTM D638
Flexural strength	MPa	91	173	106	148	400	234	ASTM D790
	ksi	13.2	25.1	15.4	18.5	58.0	34.0	
Flexural modulus	GPa	2.4	8.1	2.7	5.5	19	6.0	ASTM D790
	ksi	350	1,170	390	550	2,760	870	
Izod impact, notched	J/m	690	75	69	53	110	59	ASTM D256
	ft-lb/in	13.0	1.4	1.3	1.0	2.1	1.1	
Izod impact, unnotched	J/m	No break	640	No break	480	850	1,600	ASTM D4812
	ft-lb/in	No break	12	No break	9	16	30	
HDT ⁽²⁾ at 1.82 MPa (264 psi)	°C	207	210	174	180	230	151	ASTM D648
	°F	405	410	345	356	446	304	
CLTE ⁽³⁾ flow direction	ppm/ °C (°F)	56 (31)	18 (10)	56 (31)	23 (13)	1.5 (0.8)	31 (17)	ASTM D696
CLTE ⁽³⁾ transverse direction	ppm/ °C (°F)	56 (31)	56 (31)	56 (31)	56 (31)	4.6 (2.5)	31 (17)	ASTM D696
Water absorption, 24 hours	%	0.4	0.3	0.3	0.2	0.2	0.1	ASTM D570
Specific gravity		1.29	1.53	1.24	1.40	1.64	1.19	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 °C - 150 °C (32 °F - 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 °C - 150 °C (32 °F - 302 °F)





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