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POLYMER INSIGHTS:

PC, PEI and Sulfones for Transparent Medical Applications

Presented by:

Laurent Hazard, Ph.D. Technical Development Manager
Eva Heintz, Ph.D. Global Marketing Manager, Healthcare

SPECIALTY POLYMERS

Meet the presenters

Laurent Hazard, Ph.D.

Laurent Hazard is currently Technical Development Manager at Solvay Specialty Polymers, focusing on Healthcare, Consumers & Construction and Aerospace markets. Laurent has more than 20 years experience working with polymers and helping customers design better products with them. He started working with Solvay Automotive as a Research engineer in 1997 and joined Solvay Advanced Polymers as a material & simulation expert in 2008. He relocated to Alpharetta, GA in 2013 to lead the Technical Development team.

Eva Heintz, Ph.D.

Eva Heintz is currently the Global Marketing Manager for Healthcare. Eva brings 12 years experience within the polymer field, in both, R&D and Business Development side. Eva has a Ph.D. in Chemistry from Georgia Institute of Technology and remains actively involved in developing STEM students for the future.

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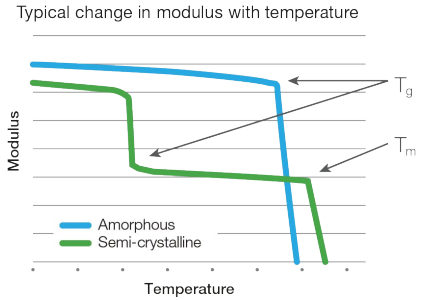
PC, PEI and Sulfones for Transparent Medical Applications

- Overview of transparent polymers for healthcare
- 6 sulfone polymer case studies
- Thermal and mechanical properties
- Sterilization compatibility
- Chemical resistance
- Design and processing
- Conclusion and Q&A

Key performance factors for medical applications

Depending on the final applications, material selection will be based on a combination of the following performance attributes:

- Thermal stability
- Strength and stiffness
- Toughness
- Resistance to chemical aggression
- Sterilization compatibility
- Regulatory approvals
- Design & processing aspects



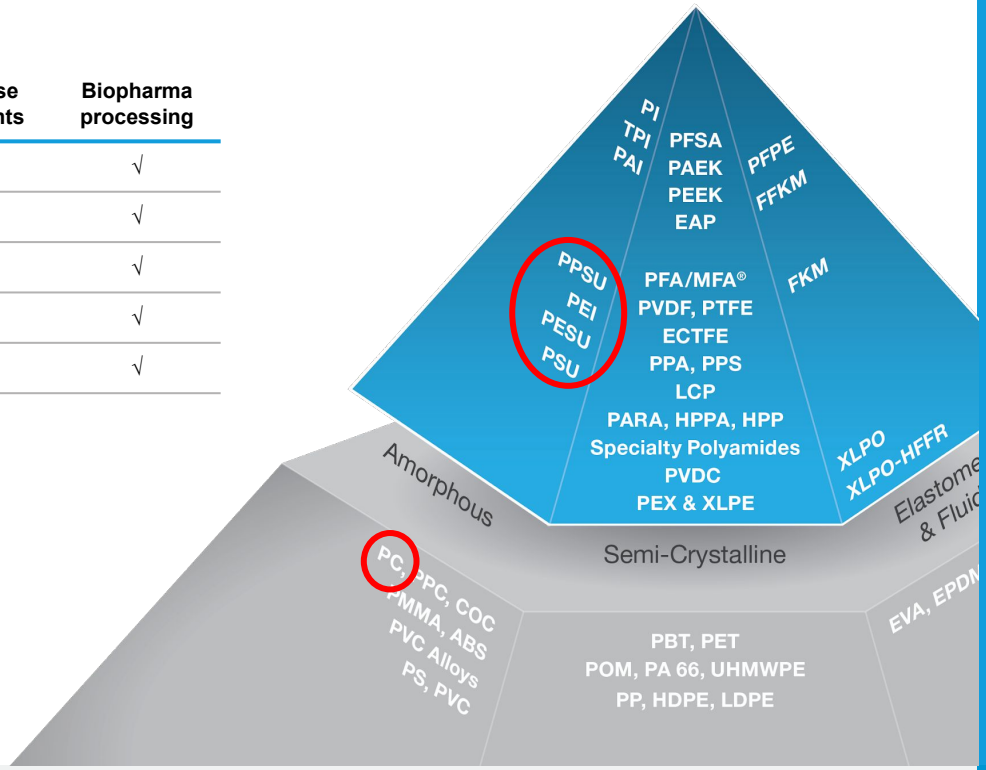
Solvay biocompatibility testing

Test	Method	Veradel® HC PESU	Radel® PPSU	Udel® PSU
Physico-chemical	ISO 10993-18	√	√	√
Cytotoxicity	ISO 10993-5	√	√	√
Sensitization	ISO 10993-10	√	√	√
Intracutaneous toxicity	ISO 10993-10	√	√	√
Acute systemic toxicity	ISO 10993-11	√	√	√
Extractables and leachables	USP Class VI	√	√	√
Post-gamma radiation mechanical performance	USP Class VI	√	√	√

Medical grade plastics

Typical applications

	Sterilization Cases & Trays	Reusable Medical & Dental Devices	Single-Use Instruments	Biopharma processing
Radel® PPSU	√	√		√
PEI	√	√	√	√
Veradel® HC PESU		√	√	√
Udel® PSU	√	√	√	√
PC		√		√



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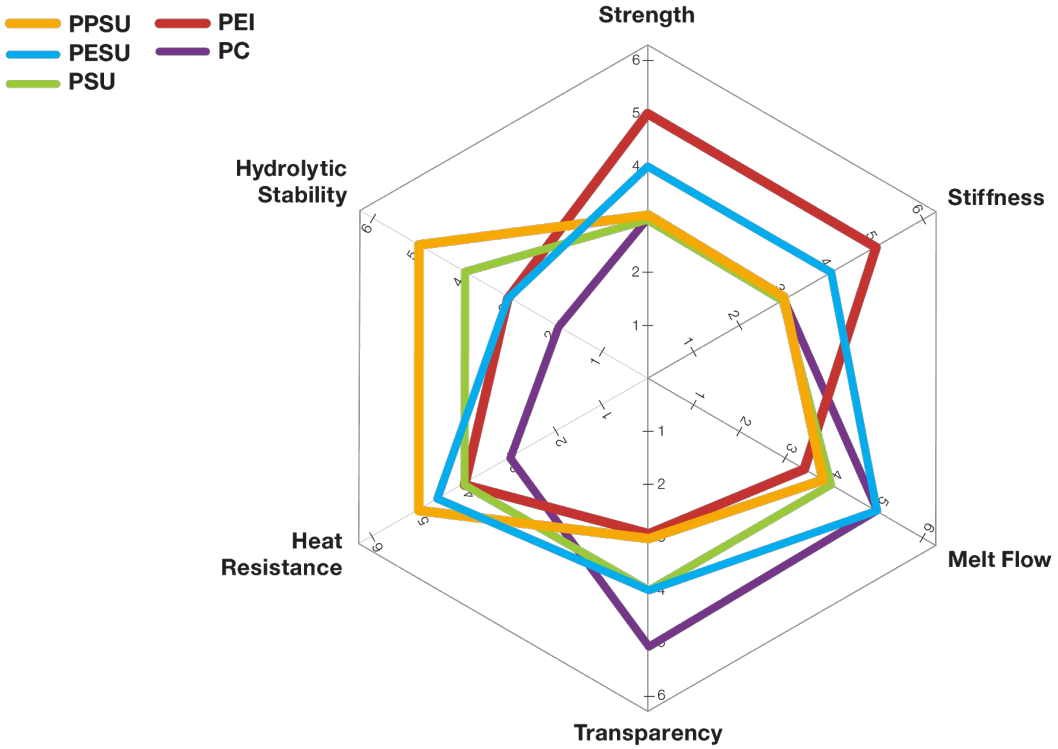
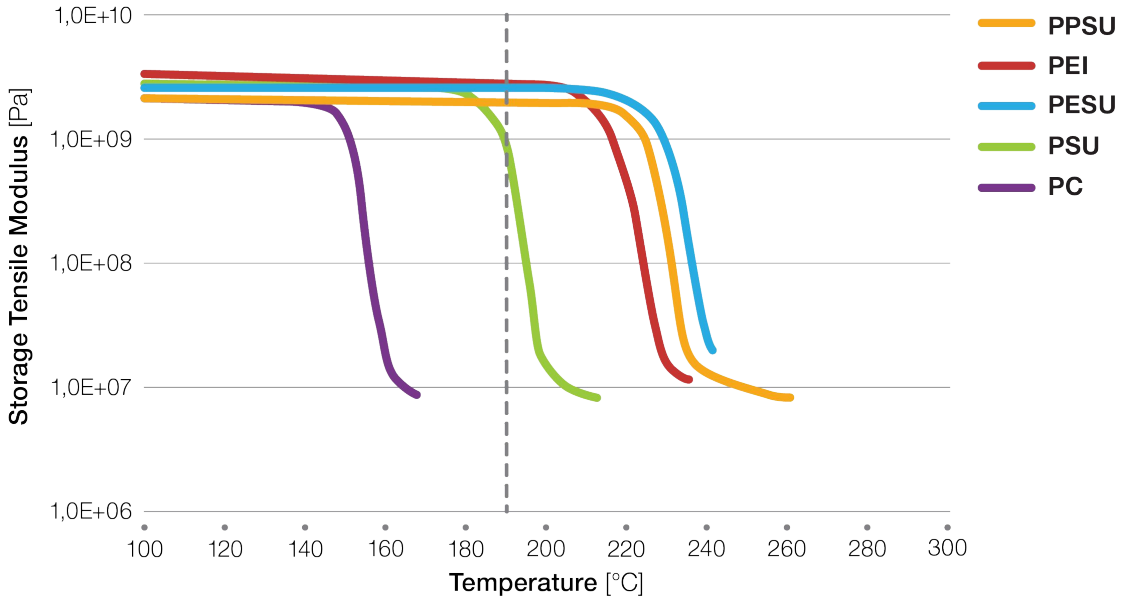
Material overview



Effects of temperature on modulus



Data based on datasheets Solvay & Sabic

Measurements Solvay R&D

Case Study:
Ricordi Chamber

- Application: Isolate healthy pancreatic tissue cells for clinical transplants
- Material: Radel® PPSU R-5000
- Processing method: injection molding
- Main Value Proposition:
  - Resistance to 1000 autoclave cycles
  - Lightweighting and cost efficiency vs stainless steel
  - Transparency
  - Exceptional toughness
  - Hydrolytic stability at high temperatures
  - ISO 10993 biocompatibility

Source: Press release - Feb 11, 2016

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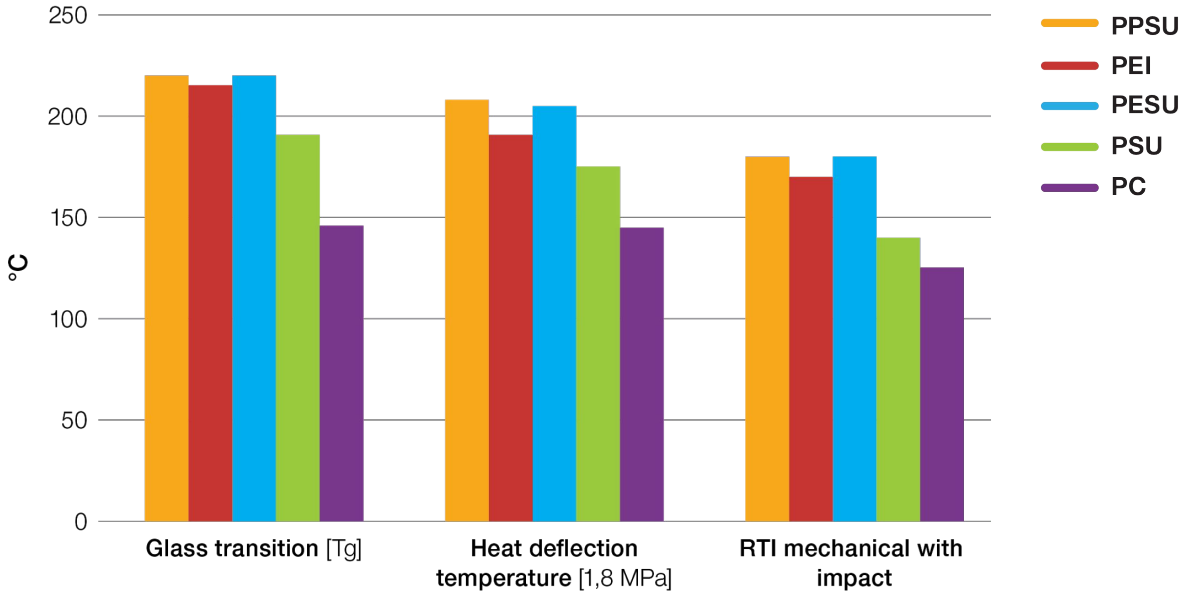
Thermal properties



Data based on datasheets Solvay & Sabic

Case Study: Sensors

- Application: medical, laboratory and biopharma
- Material: Veradel® HC PESU A-301
- Main Value Proposition:
  - Flowability for design of thinner walls, complex shapes and different cross sections
  - High transparency
  - Continuous temperature of use up to 399° F/204°C
  - ISO 10993 biocompatibility standards
  - Master Access File on record with FDA

Source: Press release - Feb 10, 2016

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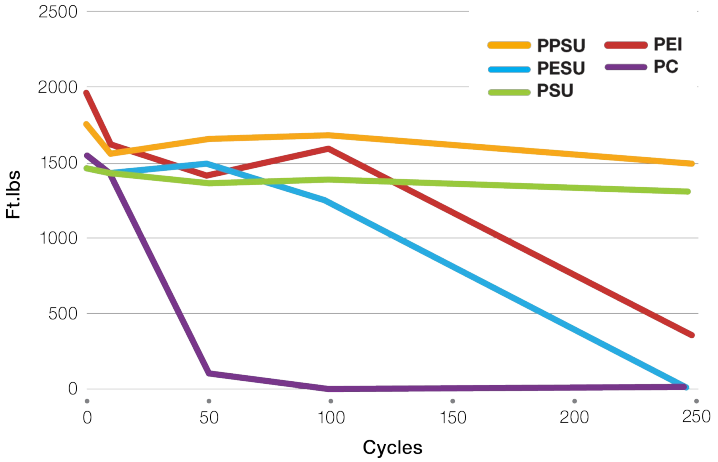
Sterilization compatibility

Sterilization methods

	Steam (up to 134°C for 18 minutes)			Ethylene Oxide	Hydrogen Peroxide	Gamma Radiation
	10 cycles	500 cycles	1,000 cycles	100 cycles	200 cycles	40 kGy
PPSU	✓	✓	✓	✓	✓	✓
PEI	✓	✗	✗	✓	✓	✓
PESU	✓	✗	✗	✓	✓	✓
PSU	✓	✓	✗	✓	✓	✓
PC	✓	✗	✗	✓	✓	✓

Impact resistance after repeated steam sterilization



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Case Study:
Slide Stainer Carousel

- Application: slide stainer systems used for hematology and microbiology applications
- Material: Radel® PPSU (injection molded)
- Main Value Proposition:
  - High transparency
  - Superior chemical resistance
  - Exceptional toughness
  - Resistance to repeated steam sterilization
  - Greatly expanded design options
  - Compatibility with ultrasonic welding

Source: Press release - Mar 24, 2015

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Case Study: Sensor Housing

"Due to the success and performance of our sensor products, PendoTECH intends to continue using Udel® PSU polymer in a range of new sensors and other products under development"

→ Dennis Annarelli, PhD, Technical and Quality Manager at PendoTECH

- Application: sensors for single-use biopharma processing
- Material: Udel® PSU injection molded
- Main Value Proposition:
  - USP Class VI certification (before and after gamma irradiation)
  - Transparency
  - Moldability
  - Ease of use vs stainless steel
  - Excellent thermal and chemical resistance
  - Exceptional dimensional and hydrolytic stability

Source: Solvay press release – Oct 13, 2017

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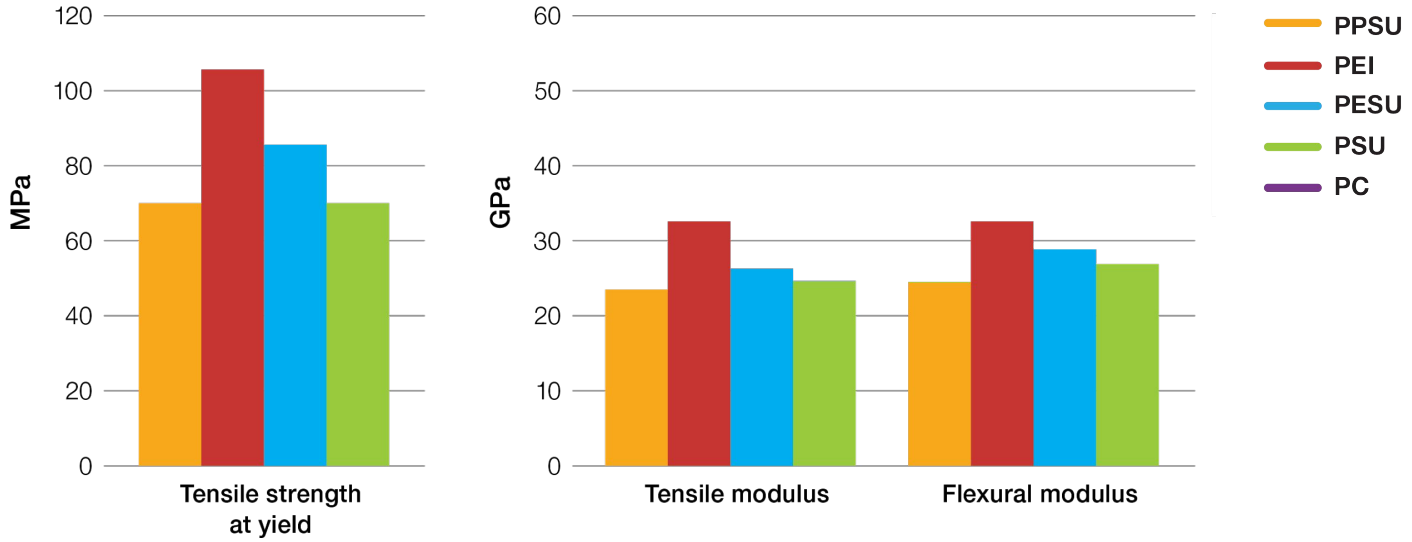
Tensile strength and modulus data



Data based on datasheets Solvay & Sabic

Case Study: Microtubes

- Application: microtubes for catheter, endoscopy and laparoscopic instruments
- Veradel® HC PESU benefits:
  - Biocompatibility (ISO 10993 standards for cytotoxicity, irritation and acute systemic toxicity)
  - Compatibility with sterilization and chemical sterilants
  - Transparency
  - Rigidity
  - Flexibility in design options
  - High flow rate for extruding thin-walled microtubes

Source: Press release - Dec 6, 2017

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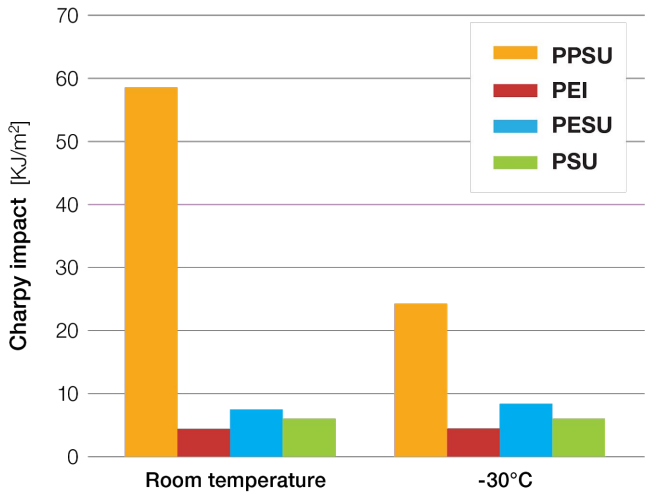
Impact properties

Notched Charpy Impact



Gartner Falling Dart Impact

Test plaques heat aged at 190°C (375°F) for 170 hours

Radel® PPSU withstands over 100 Joules (75 ft-lbs) of force without cracking or breaking.

PEI shatters with only 40 Joules (30 ft-lbs) of force.

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Case Study: Instrument Container

- Application: Hygiene Sterility Maintenance Container for Dental Instruments
- Material: Radel® PPSU
- Main Value Proposition:
  - Excellent chemical resistance and biocompatibility
  - High heat resistance and excellent hydrolytic stability
  - Transparency and mechanical properties retained after 3000 steam sterilization cycles
  - Cost effective alternative to stainless steel and aluminum
  - Efficient alternative for sterilization paper and pouches

Source: Press release – Mar 21, 2017

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Chemical resistance

	PPSU	PEI	PESU	PSU	PC
Inorganic acids	★★★★★	★★★★★	★★★★★	★★★★★	★★★★★
Inorganic bases	★★★★★	⛔	★★★★★	★★★★★	⛔
Inorganic salts	★★★★★	★★★★★	★★★★★	★★★★★	★★★★★
Alcohols	★★★★★	★★★★	★★★★	★★★★	★★★★
Aliphatic hydrocarbons	★★★★★	★★★★★	★★★★★	★★★★★	★★★★★
Aromatic hydrocarbons	★★★	★★★	⛔	⛔	☒
Esters, ketones, aldehydes	★★★★	★★★	⛔	⛔	☒
Chlorinated hydrocarbons	☒	☒	☒	☒	☒

Key

⛔ - Swelling and dissolving

☒ - Crazing

★★★ - Moderate resistance

★★★★ - Good resistance

★★★★★ - Excellent resistance

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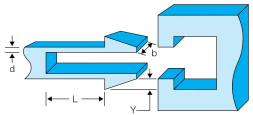
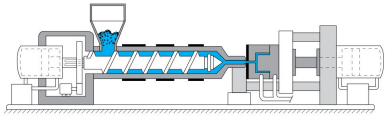
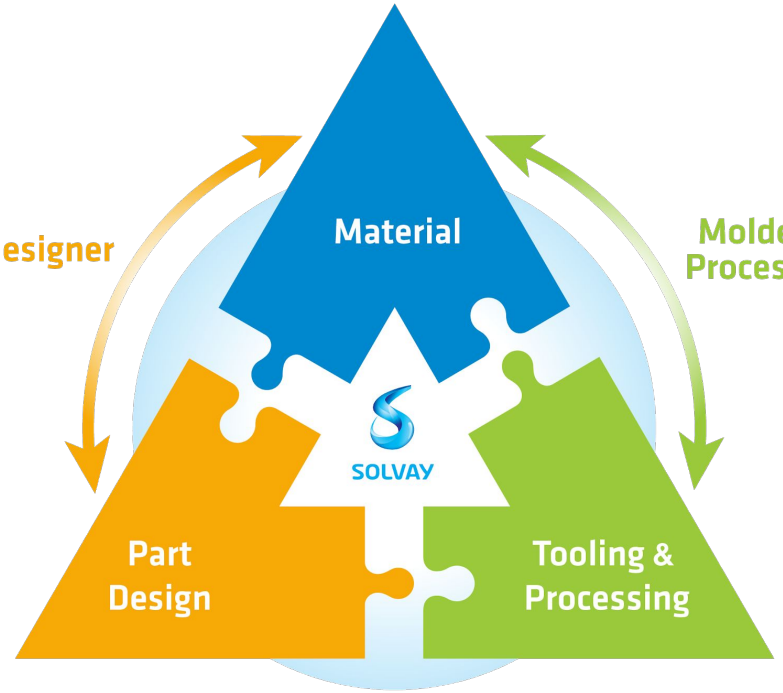
Design and processing





Performance
Geometry
Lifecycle
Regulations
Cost
Etc.

Designer



Molder/ Processor

Processing
Tooling
Moldability
Cycle time
Yield, margin
Etc.

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Submit request

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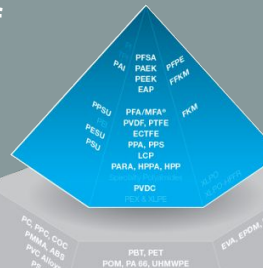
Working with Specialty Polymers

Broadest range of high performance materials



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Permanent exposure, < 30 days

- Veriva® PPSU
- Eviva® PSU
- Zeniva® PEEK

SOLVIVA® BIOMATERIALS

High performance medical grade plastics

Limited exposure < 24 hours

- Ixef® PARA
- Radel® PPSU
- Veradel® HC PESU
- Udel® PSU
- AvaSpire® PAEK
- KetaSpire® PEEK

Solutions Provider for Key Market Segments:

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- Medical devices
  - Single use
  - Reusable
  - Implantable
- Biopharma processing
- Filtration
- Additive Manufacturing
- Sterilization cases and trays

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