

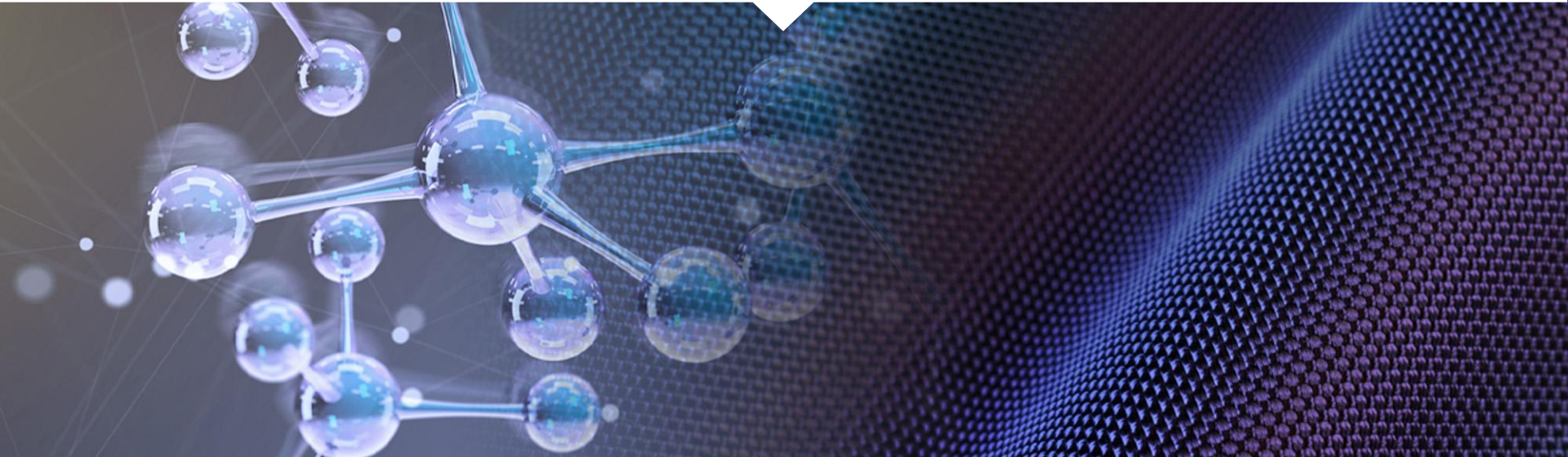
How Plastics can Broaden your design Options



Progress beyond

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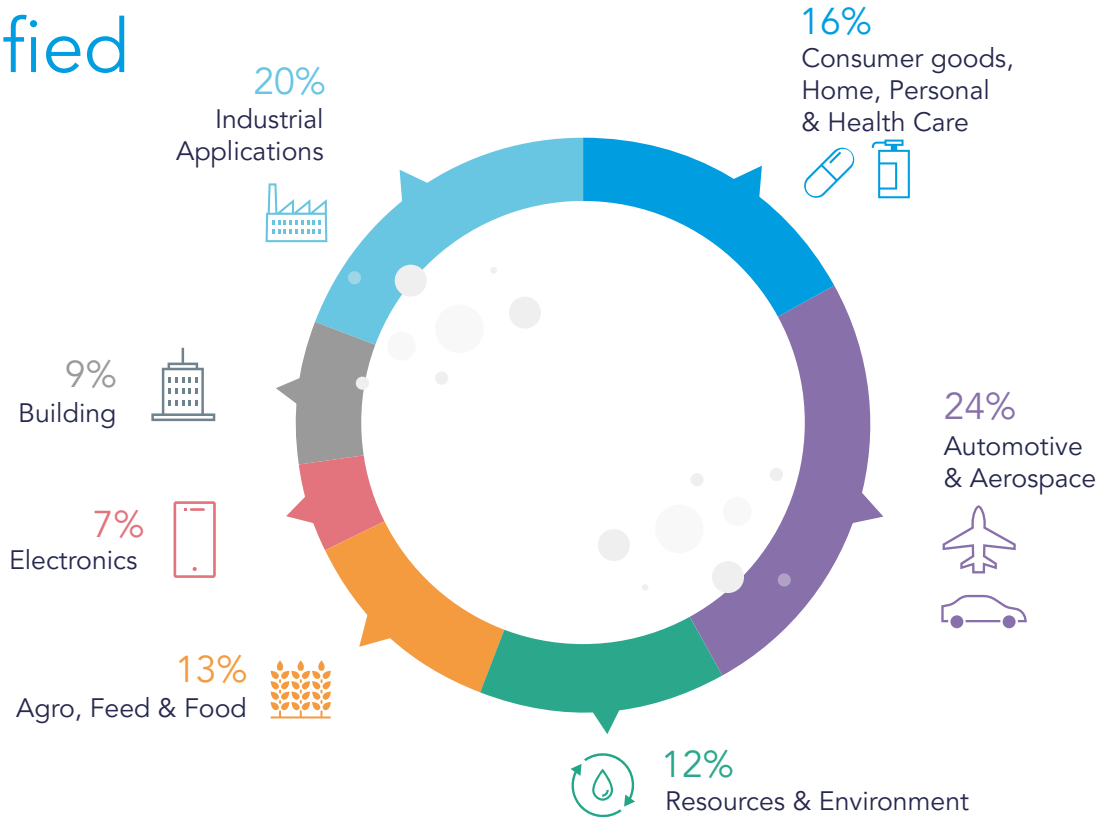
Polymers for Healthcare



- Solvay Highlights
- Healthcare Portfolio
- What does it mean to be a Healthcare material
 - Relevant Biocompatibility
 - Chemical and sterilization data
 - Integrated material selection, design and regulatory approach
- Single Procedure Instrument example

We provide solutions to diversified markets

In % of Group sales

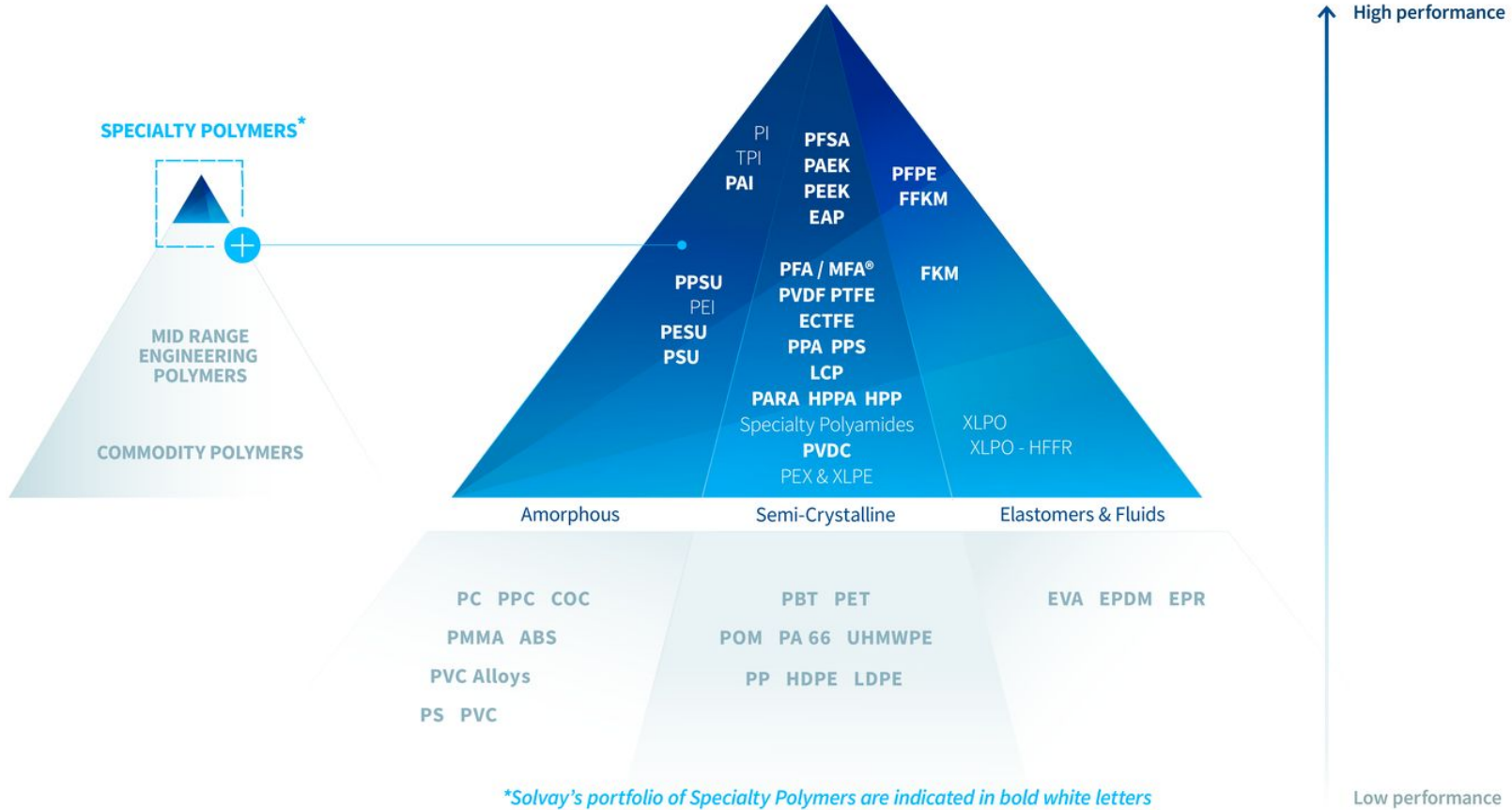


TOP 3
Market position
in ~ 90% of
portfolio



53%
Net sales
generated by
sustainable
solutions

The Polymer "Pyramid"



Material Selection | General Overview



High-Performance Plastics

No patient contact Applications

- KetaSpire[®] PEEK
- Radel[®] PPSU
- Udel[®] PSU
- Veradel[®] PESU
- Ixef[®] PARA
- Amodel[®] PPA

High-Performance Medical Grade Plastics

*Limited exposure < 24 hours
BioPharma (USP Class VI)*

- KetaSpire[®] PEEK
- AvaSpire[®] PAEK
- Ixef[®] PARA HC and GS
- Radel[®] PPSU
- Udel[®] PSU
- Veradel[®] HC PESU

Solviva Biomaterials for Implantable Devices

*Prolonged exposure, 24 h - 30 d
Permanent exposure > 30 days*

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

Healthcare Portfolio Focus

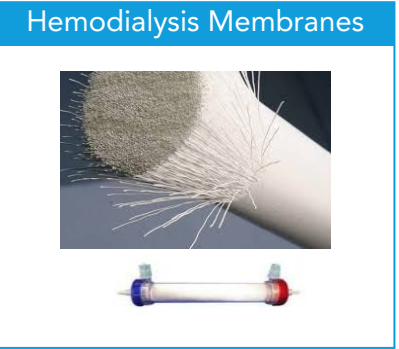
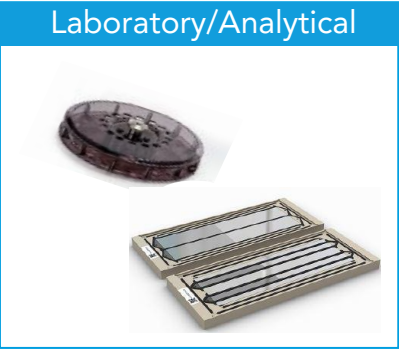
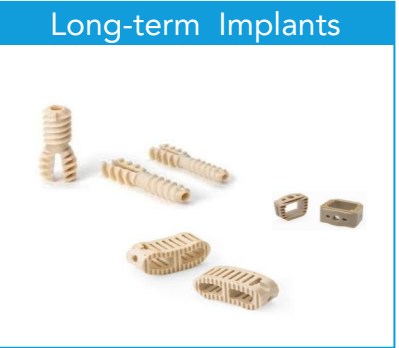
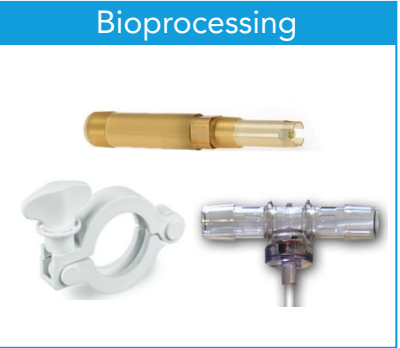


- A simplified product grid of Solvay plastics used for medical devices.
- Listed products are commercially available polymers with ISO 10993 compliance.
- Solviva® implantable grades are circled.

Ultra Polymers		KetaSpire® PEEK Zeniva® PEEK AvaSpire® PAEK
High Performance Polymers	Radel® PPSU Veriva® PPSU Udel® PSU Eviva® PSU Veradel® PESU	Ixef® PARA HC/GS Kalix® HPPA* Amodel® PPA*
	Amorphous	Semi-Crystalline

*General purpose polymers

Focus Applications



Material Selection | General Overview



Requirement	Ixef [®] PARA	Radel [®] PPSU Veriva [®] PPSU Udel [®] PSU Eviva [®] PSU Veradel [®] PESU	KetaSpire [®] PEEK Zeniva [®] PEEK AvaSpire [®] PAEK
Biocompatibility	●	●	●
Single-Use	●	●	●
Repeated Steam Sterilization	●	●	●
Disinfection Resistance	●	●	●
High stiffness	●	●	●
Thin walled parts	●	●	●
Friction & Wear grades	●	●	●
Colorability	●	●	●

Material Selection | Biocompatibility Support



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

Material Selection | Sterilization Performance



	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
AvaSpire® PAEK	●	●	●	●	●	●
KetaSpire® PEEK	●	●	●	●	●	●
Ixef® PARA	●	●	●	●	●	●
Udel® PSU	●	●	●	●	●	●
Radel® PPSU	●	●	●	●	●	●

Material Selection | Disinfectant Compatibility



Retention of Tensile and Impact Properties | Stress Crack Resistance 7-day Exposure Under Strain at 23°C

	Ixef [®] , Amodel [®] , Radel [®] , Kalix [®]	Udel [®] PSU	PC	PC/ABS	PC/PBT
IPA 70%	●	●	●	●	●
Cidex [®] (2.4% Gluteraldehyde)	●	●	●	●	●
Clorox [®] Bleach (8.25% Sodium Hypochlorite)	●	●	●	●	●
Vesphene [®] IISE	●	●	●	●	●
Virex [®] TB	●	●	●	●	●

Good = no cracking, > 90% retention of properties

Fair = mixed failure modes, i.e., no cracking but loss of mechanical properties

Poor = crazing and/or < 90% retention of properties

● Good

● Fair

● Poor

Material Selection | Quality Systems



Healthcare Focused Regulatory Support

- Global coverage
 - Thousands of medical device clearances
(Spine, Orthopedics, ENT, Cardiovascular, Dental, Gastrological, Urological, Neurological)
 - Robust FDA Master Access Files & Technical Files for Medical Grade Polymers
 - Dialogue with regulatory bodies
- Direct support from Solvay RAPS experts for device submission questions and informational meetings



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Single-Procedure Instruments | Application Examples



Torque Limiting Instruments

Application: Single-procedure, precision torque limiting instruments for securing medical device implants

Innovation: Very high stiffness, surface finish and available colors enabled the design of a single-procedure device for this procedure

Product and processing: Ixef[®] PARA injection molding

Advantages:

- High precision, torque limiting
- Colorability
- Metal-like stiffness and strength
- Biocompatibility
- Exceptional surface finish
- Compatibility with Gamma sterilization



“There is growing demand worldwide for one-way instruments that are sterile pack and surgery ready to provide clinically robust solutions at a lower lifecycle cost than reusables.”

Lane Hale, president and CEO, ECA Medical Instruments.