SpecialFocus

PERFORMANCE PLASTICS ARE ENGINEERING THE FUTURE OF MEDICINE

MEDICAL & LIFE SCIENCES

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Fluoropolymers in Medical Devices: Applications and Critical Properties

Fluoropolymers such as PTFE, PVDF and PFA are foundational to innovations in microfluidic drug delivery, diagnostics, and minimally invasive surgical systems. Their high chemical resistance, temperature stability, and biocompatibility position them as indispensable materials for fluid handling components, including micropumps, valves, and precision tubing.

These miniature systems operate on the microscale, transporting tiny volumes of liquid through channels only micrometers wide. Ensuring accuracy and sterility in such environments demands materials capable of maintaining purity under mechanical, chemical and thermal stress — and fluoropolymers deliver.

They're the unsung heroes of everything from targeted drug delivery to advanced diagnostics. Few materials match the synergistic performance of the fluoropolymer family across all these critical parameters.

Examples aremicropumps, which are engineered to move minuscule quantities of fluid or gas with extreme precision. Widely adopted in biomedical and high-tech fields, these devices form the heart of microfluidic systems and demand chemically inert, flexible materials that won't contaminate or degrade under rigorous use.

Five Essential Fluoropolymers: Shared Strengths and Unique Advantages

In life science and diagnostics, five fluoropolymers lead the pack: PTFE, PVDF, PFA, FEP and ECTFE. While these materials share key strengths, each also offers unique characteristics optimized for specific medical environments.

Shared performance advantages include:

1. Biocompatibility

- Safe for short- and long-term biological contact
- Compliant with standards like ISO 10993-5 and ISO 13485

2. Low Surface Energy (<36 dynes/cm)

- Prevents fluid adhesion
- Ensures smooth, laminar flow in drug delivery and reagent transport

- Enhances patient safety and pharmaceutical integrity

What sets them apart:

- **Fully fluorinated types** (PTFE, PFA, FEP)
  - Exceptional chemical resistance and ultra-low porosity
  - Preferred for applications requiring ultra-high purity and contamination control
- **Partially fluorinated types** (PVDF, ECTFE)
  - Strong dielectric behavior and mechanical rigidity
  - Higher surface energy allows better adhesion for coatings and structural integration

Essential Fluoropolymers for Medical Applications		
Property	**Fully Fluoroinated (FEP, PFA, PTFE)**	**Partially Fluoroinated (PVDF, ETFE, ECTFE)**
Biocompatibility	Excellent for vivo use - meets USP Class VI & ISO 10993 standards	Good biocompatibilty with added mechanical strength & dielectric properties
Diagnostics & Labware	PTFE-coated surfaces in PCR plates; sample prep trays and fluidic chips	PVDF membranes in protein sequences, blotting and biosensors
Drug Delivery Systems	PFA & PTFE in microfluidic pumps, manifolds and valves for injectable therapy	PVDF in implantables reservoirs and controlled release systems
Medical Devices	PTFE liners in guiding catheter for coronary stents; FEP tubing in neurolgical catheters	PVDF in ligament replacements and patches; ETFE in surgical instrument housings
Surface & Purity	Ultra smooth, non-porous, chemically inert - ideal for sterile enviroments	Higher surface energy supports coatings, bonding and structural integrity
Thermal & Chemical Resistance	Stable up to 300*C, used in autoclavable tubing, sterile connectors and chemical-resistant seals	Suitable for moderate heat & chemical expousure in diagnostic housing and fluid containers

Heat Shrink Tubing: Elevating Performance in Surgical and Interventional Devices

Fluoropolymers are manufactured in forms such as sheet, rod and tubing — each serving targeted roles. Tubing stands out for its versatility, available in both rigid and flexible variants. Among these, heat shrink fluoropolymer tubing has emerged as a key component in surgical and interventional device design.

In addition to previously noted properties — biocompatibility, low surface energy and minimal leachables — heat shrink tubing offers the following:

- **Exceptional Lubricity (Low Friction Surface)**

Biocompatibility	USP Class VI, ISO 10993	USP Class VI, ISO 10993	USP Class VI, ISO 10993	ISO 10993 (emerging)	USP Class VI, ISO 10993	USP Class VI, ISO 10993
Sterilization Compatibility	EtO, steam, gamma	Steam, EtO, dry heat, gamma	All standard methods	Gamma, steam, EtO	Gamma, steam, EtO	Gamma, steam, EtO; radiation stable
Shrink Ratio	1.6:1 to 2:1	~2:1 (less predictable)	~2:1	1.6:1 to 2:1	1.6:1 to 2:1	N/A (typically machined)
Recovery Temperature (°C)	110–200	~327	150–175	200–240	250–280	180–200
Clarity	High	Opaque	Moderate	Low	High	Low to moderate
Lubricity / Friction	Excellent (low friction)	Excellent	Moderate	Moderate	Excellent	High rigidity
Chemical Resistance	Excellent	Best-in-class	High	Excellent	Best-in-class	Exceptional (low permeability)

  - Facilitates smooth insertion and withdrawal of catheters and introducers
  - Reduces tissue trauma and procedural time
- **Precise Heat Shrink Capabilities**
  - Shrinks uniformly around complex device geometries
  - Provides secure encapsulation and integration with hybrid materials

These attributes make heat shrink tubing not just a protective barrier — but a performance enhancer. It streamlines device navigation through biological systems, supports procedural accuracy, and contributes directly to improved patient outcomes.

Injection Molding Fluoropolymers: The Engine Behind Scalable Complexity

Injection molding offers an advanced manufacturing route for fluoropolymer components, especially where small features, tight tolerances and intricate geometries are required — applications where machining simply falls short.

Key Fluoropolymers for Molding: PFA, PVDF and ECTFE

While these materials are already prized for their resilience, it's the molding process that unlocks their full potential:

- **Precision and Repeatability**

- Mitigates machining issues like deformation from thermal expansion
- **Scalability and Cost-Efficiency**
  - Economical in large production runs despite high tooling costs
  - Minimizes waste and labor compared to subtractive methods
- **Cleanroom Compatibility**
  - Supports ISO 7/8 manufacturing for sterile medical components
  - Reduces particulate generation versus machining
- **Sterilization Resilience**
  - Molded parts withstand EO, gamma, steam and dry heat sterilization
  - Maintain mechanical integrity without requiring post-processing treatments
- **Design Flexibility**
  - Enables overmolding, insert molding and multi-shot configurations
  - Facilitates ergonomic designs and integration of sensors or hybrid materials

Compared to machining, which is limited to shaping and subtracting from stock, injection molding enables transformative design freedom, true scalability and enhanced performance.

Fluoropolymers: Driving the Next Generation of Medical Devices

Looking ahead, fluoropolymers will play an increasingly central role in the evolution of life science technologies. Their unique blend of chemical resistance, biocompatibility and precision fluid handling makes them not just compatible with innovation — but foundational to it.

For performance plastics professionals, this is a pivotal moment to lead the charge —by formulating specialized compounds, pioneering advanced molding techniques, and partnering across the healthcare supply chain. In a world where purity, reliability, and clinical performance are non-negotiable, fluoropolymers aren't just facilitating progress.

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See chart below for more information.

Fluoropolymer Comparison for Injection Molded Medical Use						
Category	**PTFE**	**FEP**	**PVDF**	**ECTFE**	**PFA**	**PCTFE**
Moldability	Cannot be injection molded; processed via compression or machining	Requires specialized tooling for injection molding	Readily injection molded; consistent flow	Precision Moldabilty thermal control essential	Smooth flow and suited for complex geometries	Narrow processing window and risk of degradation
Sterilization Compatibility	EtO, gamma, steam, dry heat	Gamma, Steam and EtO	Compatible with all common sterilization techniques	Excellent tolerance to sterilization	Outstanding sterilization resistance; gamma and steam stable	EtO, and steam; retains properties under radiation
Regulatory Compliance	Fully biocompatible (USP Class VI, ISO 10993)	Biocompatible; approved for contact with bodily fluids	Medical grades meet USP Class VI and ISO 10993	Emerging biocompatibility	Strong compliance profile; meets USP Class VI and ISO 10993	Biocompatible; used in pharmaceutical packaging and medical components
Chemical Resistance & Purity	Exceptional resistance	Slightly less than PTFE	Strong chemical barrier, suitable for high-purity fluid systems	Excellent chemical resistance and low permeability	PTFE-like resistance with higher purity and clarity	Excellent chemical resistance; extremely low gas permeability and moisture absorption
Mechanical Properties	Very low friction but limited structural strength	Flexible, not as tough under load	Rigid and abrasion-resistant; good for connectors and housings	Tough and dimensionally stable; resists fatigue	Extremely tough, durable and chemically inert	High compressive strength, dimensional stability, and rigidity; ideal for seals and valves
Typical Medical Applications	Vascular grafts (as ePTFE), liners, patches (non-molded)	Tubing interfaces, valves, transparent molded components	Connectors, valves, fluid control housings	Chemically resistant housing, sterile pump bodies	High-purity fluid contact components, syringe parts, critical seals	Syringes, blood filters, UV-sterilized components, cryogenic seals and precision packaging

Charts courtesy of Pexco, LLC.