American Chemistry Council

PERFORMANCE FLUOROPOLYMER PARTNERSHIP

# FLUOROPOLYMERS ARE ESSENTIAL TO MEDICAL DEVICES AND MODERN HEALTHCARE

Fluoropolymers, a distinct class within the broader family of PFAS chemistries, are critical to the modern medical devices that help diagnose, treat, and prevent illnesses and allow us to live happier, healthier lives. Fluoropolymers have enabled breakthroughs in diagnostics, surgery, and chronic dise ase management due to their unique chemical and physical properties.

The U.S. Food and Drug Administration estimates that more than 250,000 approved medical devices rely on fluoropolymers to help enable long-term reliability, minimally invasive procedures, safer implantation inside the body, and resistance to infections or other reactions.

## Medical Devices Enabled by Fluoropolymers

- Pacemakers
- Defibrillators
- Surgical meshes
- Ablation catheters
- Vascular grafts
- Brain shunts
- Surgical instruments
- Laboratory equipment
- Endoscopy
- IV lines

## Benefits of Fluoropolymers in Medical Devices

**Biocompatibility** – Safer for use in the body, reducing adverse reactions or cross-infections.

**Heat tolerance** – Allows devices to undergo repeated, high-temperature sterilization cycles.

**Chemical resistance** – Helps to withstand harsh disinfectants and medical-grade cleaning solutions.

**Durability** – Helps increase lifetime of medical implants, lowering risk of failure and need for replacement.

**Non-stick surfaces** – Reduces bacterial contamination, improving sterilization and helping reduce clogging in tubes.

**Reduced Friction:** Used in vascular grafts in dialysis patients for smooth movement of blood through the graft and overall biological stability.

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## Fluoropolymer Applications in Medical Devices

### Laboratory testing and sample collection

Fluoropolymer-lined vials and pipettes help prevent contamination and resist harsh chemicals used in diagnostic tests.

### Catheters and IV lines

Medical-grade fluoropolymer tubing provides flexibility, biocompatibility, and chemical resistance, helping prevent clotting and reducing risk of infections.

### Endoscopy and imaging devices

Fluoropolymers are used in flexible endoscopy tubing, helping ensure smooth operation, reduced frictions, and easy sterilization.

### Surgical instruments

Fluoropolymer coatings on surgical tools have non-stick properties that minimize tissue adhesion.

### Blood pressure monitors and diagnostic equipment

Fluoropolymer-coated tubing in blood pressure cuffs and other diagnostic devices helps ensure durability and resistance to wear and tear.

### Implantable devices

Fluoropolymers are used in vascular grafts, stent-grafts, and surgical meshes to reduce risk of failure and infections, and they help increase the lifetime of implants.

### Heart patches

Fluoropolymers are used to make various layers of heart patches to reduce the risk of complications due to tissue attachment and equipment failure.

## Safety of Fluoropolymers in Medical Devices

Fluoropolymers have been used in clinical medicine and health care for more than 50 years without any documented adverse health effects related to their chemical nature. Fluoropolymers used in medical devices have undergone extensive biocompatibility evaluations under ISO 10993 and USP Class VI standards, which assess cytotoxicity, genotoxicity, carcinogenicity, and more.

*"The PFAS materials used in medical devices (known as fluoropolymers) have a long history of use. The best-known of these materials is polytetrafluoroethylene (PTFE), which is used in multiple consumer products, and was first used in a medical device in the 1950s. The FDA's evaluation is that currently there is no reason to restrict their continued use in devices."* – U.S. Food and Drug Administration, August 6, 2025

## Experts Agree

> *[A] class of PFAS, known as fluoropolymers, possesses unique qualities critical to medical devices and tools used in cardiac electrophysiology, the manufacturing processes of those tools and devices, and the procedural delivery of those devices. Fluoropolymers have been used in clinical medicine for more than 50 years with no clinical evidence of disease association.*

> *No known polymeric material or other chemicals have a constellation of qualities comparable with fluoropolymers. Even if alternative materials were identified, replacing medical use fluoropolymers would require years, even decades, of extensive research and development to ensure that the substituted material will have acceptable and consistent performance.*

Heart Rhythm, the official journal of the Heart Rhythm Society, the Cardiac Electrophysiology Society, and the Pediatric & Congenital Electrophysiology Society

https://www.heartrhythmjournal.com/article/S1547-5271(25)02518-4/fulltext

For more information, visit fluoropolymerpartnership.com