PFAS in Medtech:
A Longstanding Record of Safety

Background

The per- and polyfluoroalkyl substances (PFAS) used in medical technologies have a long track record of safety for more than 50 years across millions of devices without evidence of adverse health effects and are critical to the delivery of life-saving and life-sustaining medical innovations for the patients who depend on them. The U.S. Food and Drug Administration (FDA) has evaluated the use of PFAS in medtech and found no reason to restrict their continued use in devices. The PFAS used in medical devices are a diverse group of large-molecule plastic materials, known as fluoropolymers, distinct from the small-molecule PFAS associated with environmental concerns.

As the FDA states, "The PFAS used in medical devices are not the same as those identified as being potentially harmful to people in other contexts. The PFAS materials used in medical devices (known as fluoropolymers) have a long history of use."

FDA Center for Devices and Radiological Health, PFAS in Medical Devices Resource Page

Demonstrated Safety and Criticality

Water-insoluble PFAS (e.g., fluoropolymers) used in medical devices are very unlikely to cross through cell membranes and cause toxicity. An independent safety review by ECRI, an organization designated as both an Evidence-based Practice Center (EPC) and Patient Safety Organization (PSO), drawing on more than 1,750 peer-reviewed articles and real-world surveillance data, found no conclusive evidence of patient health risks associated with polytetrafluoroethylene (PTFE), one of the most commonly used fluoropolymers in medtech.

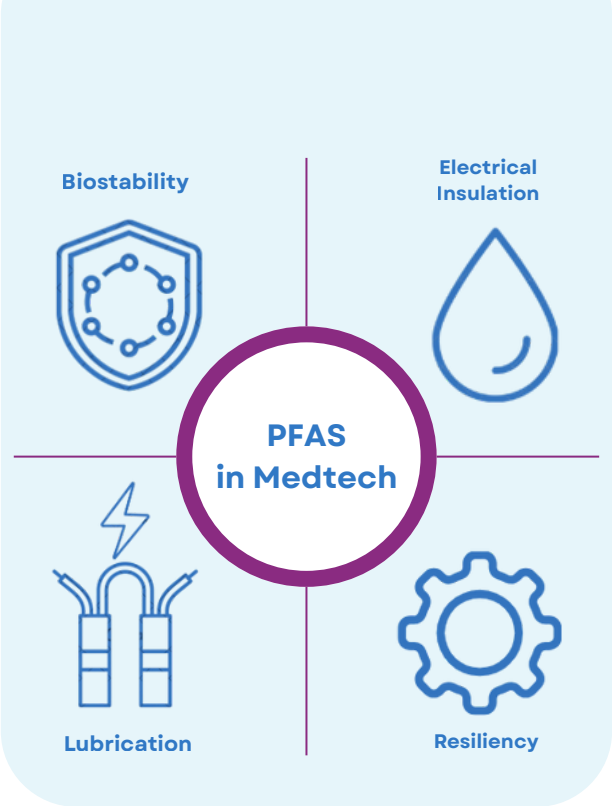
The U.S. Department of Defense (DoD) has also recognized PFAS use in medtech as "critical to military readiness and national security" and called for an informed approach that distinguishes between different types of PFAS while protecting domestic supply chains.

Office of the Assistant Secretary of Defense for Energy, Installations, and Environment
2025 Report: Critical Per- and Polyfluoroalkyl Substance Uses

AdvaMed
The Medtech Association

Fluoropolymers in Medical Devices

Medical devices are essential for patient care, with many critical technologies – such as cardiovascular stents, pacemakers, vascular grafts, guidewires, blood collection bags, instruments and equipment, and many more – relying on the unique properties of fluoropolymers.



According to the FDA PFAS resource page, "currently, no other materials exist that can perform the critical roles of fluoropolymers in these devices" and that “fluoropolymers are typically comprised of molecules that are too large to cross through cell membranes and, as a result, are very unlikely to cause toxicity to patients.”

Fluoropolymers are essential to producing innovative medtech that meet the FDA’s rigorous safety standards and deliver indispensable properties required for safe and effective performance, including:

Unique, Unsubstitutable Properties of Fluoropolymers

Biostability: Allow devices to remain in the body for extended periods without degradation, preventing potentially life-threatening issues for patients. A recent study on implanted cardiac leads, which contain fluoropolymers found that no new chemical species were generated over more than a decade.

Lubrication: Provide the necessary lubrication for devices like stents in cardiac care and delivery systems used in minimally invasive surgeries.

Electrical Insulation: Ensure reliable function in devices by safely insulating electrical components, such as the wires that connect a pacemaker to the heart.

Resiliency: Withstand sterilization, transport, storage, and use without compromising performance.