U.S. FOOD & DRUG ADMINISTRATION

FDA Position on the Safety and Critical Importance of Fluoropolymers in Medical Devices

In August 2025, the U.S. Food & Drug Administration (FDA) published an official statement about the essential role that fluoropolymers, a PFAS chemistry, play in life-saving medical devices. FDA clearly distinguishes fluoropolymers from other PFAS and emphasizes that they have been used safely in medical devices for decades. FDA also highlights specific applications for which no alternative materials can provide the same benefit and concludes that "currently there is no reason to restrict their continued use in devices."

SPECIFICALLY, THE FDA REPORT STATES THE FOLLOWING:

> "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."

> "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. 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."

> "Some PFAS, typically those chemicals comprised of small molecules, have been linked to health concerns and have been detected in drinking water and other parts of our environment. The PFAS used as components in medical devices are different. Many medical devices rely on plastic materials comprised of large molecules (known as fluoropolymers), which are part of the PFAS family and have been safely used for decades."

> "Medical devices are critical components of health care delivery, and a large number rely on the unique properties of PFAS. Some of these devices are necessary to save and sustain lives, including cardiovascular stents, pacemakers, vascular grafts, and guidewires."

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> "Currently, no other materials exist that can perform the critical roles of fluoropolymers in these devices. The materials have unique properties that are essential for devices to function. They provide:
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> - Lubrication for devices such as the stents used to treat heart problems, and delivery systems used in minimally invasive surgical procedures.
> - Electrical insulation in, for example, the wires that lead from a pacemaker to a person's heart.
> - Biostability, allowing medical devices to remain in the body for long periods of time without the threat of degradation (breaking down). Degradation of medical devices in the body could lead to pieces of the devices breaking off in the body, which could potentially cause life threatening medical issues for patients."

> "FDA monitors the safety of fluoropolymers in medical devices based on available scientific information. The FDA partnered with ECRI for an independent safety review. ECRI, designated as a Patient Safety Organization by the U.S. Department of Health and Human Services, collected data from over 1,800 health care provider organizations around the country. . . . The ECRI review found no conclusive evidence of patient health issues associated with PTFE as a material."

The FDA statement on the benefits and safety of fluoropolymers echoes those made by other U.S. federal agencies.

- In 2025, the U.S. Department of Defense reaffirmed that PFAS are essential to the performance, safety, and reliability of mission-critical systems from advanced batteries and microelectronics to protective gear and medical devices. The agency acknowledged that many PFAS applications have no viable substitutes and that developing replacements could take 10 to 25 years or more.
- In 2024, the U.S. Department of Energy released a study detailing the importance of fluoropolymers to government, military and defense, and numerous critical U.S. industries.
- In 2023, the U.S. Department of Defense issued a report underscoring the potential risks to national security if access to fluoropolymers is restricted and emphasizing the need for continued access to fluoropolymers to support military readiness and sustainment.

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