

PFAS in Medical Devices

PFAS (per- and polyfluoroalkyl substances) and their possible relationship to people's health has been a recent topic of public interest. This page may help you better understand why certain PFAS are used in medical devices.

PFAS are a very broad and diverse group of chemicals with wide industrial uses. There are thousands of different kinds.

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.

Not All PFAS Are the Same

PFAS are a large group of more than 15,000 chemicals that are used in a variety of products. They are not all the same. 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.

Fluoropolymers Used in Medical Devices

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.

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:

- 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.

In addition, 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.

FDA Safety Study on PFAS in Medical Devices

As with other materials, the FDA monitors the safety of fluoropolymers in medical devices based on available scientific information. The FDA partnered with [ECRI External Link Disclaimer](#) 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 review, delivered in 2021, used:

- Over 1,750 published and peer reviewed scientific articles.
- ECRI real-world surveillance network of clinics and health care providers through its Patient Safety Organization.

The ECRI review found no conclusive evidence of patient health issues associated with PTFE as a material.

The FDA continues to monitor the safety of medical devices and the materials that they are made of. The FDA will update this page as appropriate to keep the public informed as additional information becomes available.

If you have questions about fluoropolymers in medical devices, contact the [Division of Industry and Consumer Education](#).