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PFAS in Medtech

Per- and polyfluoroalkyl substances, known as PFAS, are a broad class of over 12,000 substances that are found in a variety of consumer, commercial and industrial products, including medical devices and their packaging. PFAS can essentially be divided into two separate classes: water-soluble PFAS and water insoluble PFAS.

Why are PFAS chemicals used for medical device products and packaging?

- PFAS has unique properties that cannot be substituted like: flexibility, rigidity, sterility, penetrability, thermal stability, resiliency, ergonomic, degradation proof, chemical resistance, and low friction coefficient.
- Due to their unique properties of thermal stability, chemical resistance, and low friction devices like catheters, pacemakers, and wire coatings in radiological machinery rely on PFAS, as well as packaging for surgical tools, implantables, and syringes that require sterilization.

PFAS Used in Medical Devices

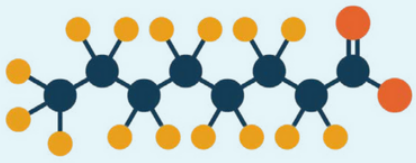
- Water insoluble PFAS (e.g. fluoropolymers) are a larger, higher molecular weight PFAS molecule that are inherently stable, insoluble in water, and less bioavailable. Given their size, molecular weight, and water/lipid insolubility they are too large and too water/lipid repelling to cross cell membranes and therefore pose minimal risk to human and ecological health relative to water-soluble PFAS. Due to their unique properties of thermal stability, lubricity, and chemical resistance, fluoropolymers are essential in medical devices.

PFAS Found in the Environment

- Low molecular weight PFAS have many applications in other industries and are water-soluble. Due to their low molecular weight and water/lipid solubility, these PFAS can permeate water, soil, and cells. The most studied and regulated of this class are PFOA and PFOS, as examples. These types of PFAS have been demonstrated to accumulate in the human body and cause adverse health effects through consumption of drinking water, fish, crops, breast milk, in utero, and through exposure to certain food packaging or carpeting.

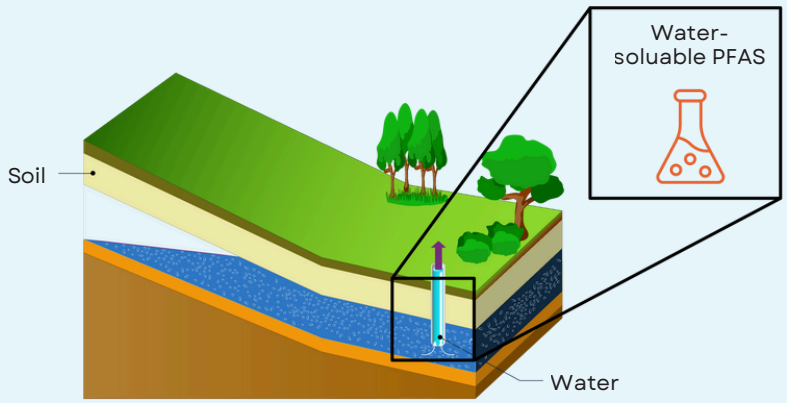
PFAS

Water-soluble - small molecule



Water insoluble - fluoropolymer, a long-chain of repeated monomer units

WATER-SOLUBLE PFAS IN THE ENVIRONMENT



*Source: EPA Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report

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What is the alternative to PFAS?

At this time, there is no material that can substitute PFAS or it's unique properties necessary to meet FDA standards for a medical device and its packaging.

- **FDA Review Process:** The FDA must validate medical device products as safe and resilient enough to withstand sterilization, transport, storage, and normal use so that the products can function as intended without any damage or harm to the patient. PFAS is critical to the design and production of high performance devices. The medical device package must pass the FDA's "shake, rattle, and roll" product test.

- **Patient Safety:** The FDA considers human health and safety risks before a device can make it on the market. The device must undergo multiple tests to prove biocompatibility and toxicological safety in compliance with international biocompatibility standard ISO 10993.

- **Supply Chain:** The complexity of the supply chain means information can take years to disseminate to the manufacturer, and substitutions or changes to product design require extensive and costly compatibility studies. Any changes in the device or package would then subject the item to resubmission to the FDA, further restricting patient access to proper healthcare and treatment.

FDA Regulated Medical Devices and Products that include PFAS:

Implantable devices

Prosthetics

Circuit boards, leads, foil in large equipment such as MRI, CT, and mammography machines

Instruments and equipment (shears, cutters, staplers) used in minimally invasive, endoscopic surgical procedures

Blood collection bags, suction devices used in respiratory therapy and for anesthesia, IV solution bags

Guide wires and delivery systems used in minimally invasive procedures to navigate through a patient's anatomy

Bottom Line

Banning all PFAS in medical devices and products would effectively ban access to lifesaving technologies for patients. A targeted, risk-based scientific approach that recognizes existing rigorous FDA oversight is essential to protect patients, preserve access, and prevent supply chain disruptions in critical medical technologies.