TREXIN INSIGHT PAPER

May 14, 2024

EXPLORING PFAS USE IN MEDICAL TECHNOLOGY

A brief summary into the role of PFAS in the Medical Technology industry.

INTRODUCTION

In the dynamic landscape of healthcare innovation, the integration of chemicals and technologies continues to redefine the boundaries of medical practice. Among these transformative elements are per-and polyfluoroalkyl substances (PFAS), a group of chemicals totaling approximately 15,000 in number.[1] PFAS have ascended as prominent components within the Medical Technology (MedTech) space. While PFAS have advanced the field, their integration has sparked debates concerning their implications and the associated responsibilities within healthcare, highlighting the delicacy between their benefits and drawbacks. In this Trexin Insight Paper (TIP), we will explore the multifaceted role of PFAS in MedTech, examining their impact, the diverse applications in medical devices and implants, and the challenges surrounding the search for reliable alternatives.

WHY ARE PFAS USED IN MEDTECH?

PFAS are widely used in MedTech due to their usefulness and multifaceted impact. These chemicals play a role in essential healthcare equipment. PFAS, characterized by remarkable chemical resistance, durability, lubricity, and biocompatibility, boast a unique composition marked by strong carbon-fluorine bonds, providing them with exceptional durability and inertness.[2][3] Due to the their extremely strong bond, PFAS are hard to break down, leading to their long-lasting nature.[4] This inherent strength and durability of PFAS, along with their specific properties well-suited for a diverse array of applications within MedTech, make them challenging to adequately replace.

WHERE DO WE SEE PFAS IN MEDTECH?

PFAS are found in an extensive spectrum of medical devices and products where they play a role in enhancing functionality and longevity. One notable application of PFAS in MedTech is in the manufacturing of medical implants and devices, particularly in high-frequency signals products like pacemakers, MRI imaging devices, and CT machines.[5][6] In these devices, PFAS function as insulators, helping to prevent the need for frequent replacement of implants by using special materials called fluoropolymers.[7] The durability and biocompatibility of PFAS are key factors contributing to their efficacy in this regard, thereby demonstrating the role of PFAS in MedTech.

Beyond medical devices and instruments, PFAS are employed in various less invasive medical applications including blood collection bags, IV solution bags, and guide wires utilized in minimally invasive procedures.[8] Additionally, they play

[1] https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCT
[2] https://www.medtecheurope.org/wp-content/uploads/2023/10/230907_medtech_europe_pfas_position_paper_final.pdf
[3] https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/overly-broad-pfas-restrictions-could-endanger-healthcare-quality-and-cost
[4] https://news.3m.com/PFAS-in-the-Medical-Industry
[5] https://www.advamed.org/wp-content/uploads/2024/03/One-pager-final-PFAS-AdvaMed-2023.08.22.pdf
[6] https://www.npr.org/sections/health-shots/2019/04/22/708863848/scientists-dig-into-hard-questions-about-the-fluorinated-pollutants-known-as-pfa
[7] https://www.npr.org/sections/health-shots/2019/04/22/708863848/scientists-dig-into-hard-questions-about-the-fluorinated-pollutants-known-as-pfa
[8] https://www.advamed.org/wp-content/uploads/2024/03/One-pager-final-PFAS-AdvaMed-2023.08.22.pdf

a role in maintaining the sterile environment required in hospitals.[9] PFAS are a common feature in protective garments worn by healthcare professionals, such as surgical gowns and gloves, where their unique properties provide contaminant resistance.[10] However, the ubiquity of PFAS in commercial products has prompted both skepticism and interest regarding the exploration of alternatives, highlighting the ongoing search for viable substitutes.

WHY IS THERE A SEARCH FOR ALTERNATIVES TO PFAS?

Concerns over the health and environmental effects of PFAS have prompted a search for reliable alternatives. Given PFAS' slow breakdown, it's believed that a significant portion of the United States population has been exposed to these chemicals.[11] Persistent in the environment, they move through soils and contaminate drinking water sources, while also accumulating in fish and wildlife.[12] Ongoing studies indicate that exposure to certain PFAS compounds correlates with adverse health effects, including heightened risk of some cancers and compromised immune function.[13] Notably, these concerns extend beyond health sectors, affecting the MedTech industry. Consequently, the search for substitutes arises from the need to mitigate potential risks associated with PFAS exposure.

ARE THERE RELIABLE ALTERNATIVES TO PFAS?

A significant factor contributing to the prevalence of PFAS in MedTech is their dependability and robustness. Despite efforts to find alternatives, "there are either no alternatives, or only proposed options of alternatives."[14] While some materials may mimic specific characteristics of PFAS, achieving a comparable alternative remains elusive. Often, the only proposed alternative to a given PFAS use is another type of PFAS, like "alternative fluorination process that reduce the potential for unintentional manufacture of PFAS".[15] While some alternative materials might match selected property values of PFAS, "the risk of equipment failure, need of early replacement, cross-contamination and other unwanted consequences could increase without PFAS", potentially compromising performance or efficiency on patients' devices.[16][17]

Another obstacle in identifying alternatives to PFAS is the lengthy approval process. The FDA approval process can span months, years or even decades, involving extensive development time and regulatory obligations.[18] According to FDA estimates, the journey from device conception to market availability averages between 3 to 7 years.[19] This involves stages such as initial device ideation, preclinical testing of prototypes, navigating the regulatory pathway, and eventual FDA evaluation.[20] Despite valid concerns that exist around the prospect of the continued use of PFAS, medical necessity will continue to exist before sufficient alternatives can be approved.

[9] https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/overly-broad-pfas-restrictions-could-endanger-healthcare-quality-and-cost
[10] https://noharm-europe.org/articles/news/europe/toxic-and-persistent-chemicals-medical-textiles
[11] https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas
[12] https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html
[13] https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas
[14] https://www.medtecheurope.org/wp-content/uploads/2023/10/230907_medtech_europe_pfas_position_paper_final.pdf
[15] https://www.epa.gov/system/files/documents/2024-03/april-kluever.pdf
[16] https://news.3m.com/PFAS-in-the-Medical-Industry
[17] https://www.epa.gov/system/files/documents/2024-03/april-kluever.pdf
[18] https://www.fusfoundation.org/posts/the-complex-ecosystem-of-a-medical-device-startup/
[19] https://www.fda.gov/patients/learn-about-drug-and-device-approvals/device-development-process
[20] https://www.fda.gov/patients/learn-about-drug-and-device-approvals/device-development-process

CONCLUSION

In numerous medical equipment and devices, PFAS are at the forefront of MedTech, facilitating various sectors in the medical industry. From life-saving technologies to important medical devices, PFAS play a role in different outcomes. As concerns regarding environmental and health impacts continue to mount, the future of PFAS lies in the development and adoption of safer and more sustainable alternatives. It is imperative that these alternatives uphold the highest standards of patient care while mitigating adverse impacts. The next TIP in this series will delve deeper into the future trajectory of PFAS in MedTech, exploring diverse perspectives. For guidance on evaluating the use and presence of PFAS in your supply line, please contact one of our PFAS Advisors listed below.

This TIP was written by Bo Youman. Bo welcomes comments and discussion on this topic and can be reached at bo.youman@trexin.com.