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Prevalence and Toxicity Evaluation of the Types of PFAS Found in Medical Device Extractables and Leachables Datasets

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Background and Purpose: Medical devices (MDs) have the potential to release a wide range of chemical constituents during patient use. Several common components of MDs, such as seals, valves, stoppers, packaging, lubricants, and coatings, are constructed from materials consisting of per- and polyfluoroalkyl substances (PFAS). While PFAS regulations have been increasing rapidly across the world, most do not make the distinction between fluoropolymers and non-fluoropolymers. This distinction is important, as fluoropolymers have very different chemical, physical, and biological properties compared to non-fluoropolymers (Henry *et al.*, 2018). Additionally, regulatory agencies across the world have differing definitions of PFAS, ranging from a few select PFAS (*e.g.*, perfluorooctanoic acid [PFOA]) to the broad European Union (EU) definition of "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)" (OECD, 2021).

Objective: There is a clear need for identification of the types of PFAS that are in MD extractable profiles. To address this need, we leveraged two large databases of MD extractable profiles and analyzed the types of PFAS from approximately 19,000 chemicals. Our objectives are:

1) To determine the types of PFAS found using different regulatory definitions; and

2) To determine whether the broad types of these PFAS are associated with reproductive/developmental toxicity, genotoxicity, and carcinogenicity.

Methods: Published lists of MD constituents from hundreds of extractable and leachable studies (Borton and Coleman, 2025; Builee *et al.*, 2025) were compiled and filtered to contain only unique fluorinated compounds. The fluorinated constituents were classified as PFAS using various regulatory definitions, including that of the EU, the United States (US) Toxic Substances Control Act (TSCA), and the Canadian Environmental Protection Act (CEPA) list. The PFAS was further categorized as polymers and non-polymers based on categories described in Henry *et al.* (2018). A comparative analysis was conducted on the fluorinated compounds to assess the percentage of concordance between the list of PFAS in MD extractable profiles according to different regulatory definitions. Literature searches were conducted for chemical-specific toxicity data for the PFAS categories *via* the data aggregator ToxPlanet (*i.e.*, a federated search engine that extracts content from 500+ websites and databases, such as CompTox and the European Chemicals Agency [ECHA] CHEM).

Results: We found that approximately 2.6% (N = 488) of the 19,075 chemicals extracted from MDs are fluorinated. Of those 2.6% fluorinated chemicals, approximately 48.7% were considered PFAS according to the EU definition, 24.6% were considered PFAS according to the TSCA definition, and only 1.6% were considered PFAS according to the Schedule 1 substances list published by CEPA. Among the three PFAS definitions, 242 (1.3% of the MD constituents) were found to be unique PFAS – 2 were polymers and 240 were non-polymers. Further, 11% of the fluorinated chemicals had chemical-specific

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toxicological data available according to the CompTox chemicals dashboard, and only 6% had an oral and/or inhalation point of departure (POD).

Conclusions:

- Our results suggest that approximately 1.3% of chemicals extracted from MD extractable and leachable profiles are PFAS; therefore, the likelihood of patient exposure to PFAS through medical devices is low. However, extractable and leachable studies are only conducted on patient-contacting components, whereas most PFAS regulations impacting medical devices are determined based on the entire device (*i.e.*, patient- and non-patient-contacting components).

- PFAS detected in MD extractables are likely to originate from both patient-contacting components and processing aids.

- Notably, only two PFAS polymers were identified in this dataset. Since fluorinated side chain polymers are known to break down into non-polymer constituents, this finding does not indicate a lack of PFAS polymers in MDs. Further, fluoropolymers, such as polytetrafluoroethylene (PTFE), were not found in this dataset.

- There is a paucity of data for PFAS in MD extractables; however, available data show that PFAS chemicals have a wide range of toxicity.