Medtronic

Substances of Very High Concern

As a society, we are becoming more conscious of the impact chemicals have on our daily lives. The concern is both related to absorption by humans and the wider environmental impact from contamination. What may be foremost in people's minds are the risks associated with food contaminants such as Bisphenol A (BPA), heavy metals, phthalates, and so called forever chemicals, such as Polyfluoroalkyl Substances (PFAS).

The risks to human and environmental health from the use of chemicals within the manufacture of medical devices is also something that needs attention. Although for the general population the risks of exposure to chemicals from medical devices is less, the removal of harmful chemicals from medical devices – particularly those used on pregnant women and in pediatric and neonatal care and where there is prolonged exposure – is crucial.

Scientific research continually evaluates chemicals for potential hazardous effects on humans and the environment. One substance now associated with adverse health outcomes is DEHP, or di (2-ethylhexyl) phthalate. This is a chemical commonly added to plastics to increase their flexibility. DEHP is a plasticizer that is used in a variety of products, including the production of polyvinyl chloride (PVC) plastics. Plasticizers were added to PVC to create a soft, durable, transparent polymer that can then be utilized in a variety of products such as food packaging and medical devices. DEHP is not covalently bonded to the PVC polymer chains and so there is a potential for some for the chemical to be extracted out of medical products, exposing patients through ingestion, inhalation, or through contact with mucous membranes. DEHP can easily migrate from a medical device to a patient during a medical procedure involving devices or equipment containing phthalate.[1,2]

Several global studies have been conducted that focused on the leaching of DEHP from medical devices like oxygen masks, blood bags, infusion tubing, peritoneal dialysis bags and tubing, and catheters.

Toxic health effects from the exposure of phthalates includes neurological effects, DNA damage, oxidative stress, asthma with negative impact on lungs, effects on the reproductive system, liver impairment, and gastrointestinal effects.[2] Despite the short half-lives in tissues, chronic exposure to phthalates will adversely influence the endocrine system and functioning of multiple organs, which has negative long-term impacts on the success of pregnancy, child growth and development, and reproductive systems in both young children and adolescents.[6]

In the pediatric intensive care unit, leaching of DEHP has been associated with impaired cognitive development in children after critical illness. In another recent study, researchers collected medical products from an intensive care unit and tested for phthalates. DEHP was found to be present at the highest concentration in PVC cannulas used in neonates. It was also found in products labeled as DEHP free. In this study, DEHP was found in 99% of the medical supplies tested.[3]

Due to these findings, there have been regulatory efforts to restrict or limit the use of DEHP in certain products, especially those intended for use by vulnerable populations such as children or pregnant woman. Alternatives to DEHP are being explored and implemented in various industries to reduce potential health risks associated with its use. It's important to stay informed about regulations and guidelines related to DEHP and similar substances, especially if you are using products that may contain them. Some of the agencies that have taken steps to reduce DEHP use include the US Food and Drug Administration, the Ministry of Health, Labor and Welfare, Health Canada, and the European Commission.[4] The reduction of the use of DEHP in the European Union is governed by the European Union's REACH Regulation (EC 1907/2006). Under this regulation, the European Chemicals Agency (ECHA) maintains a list of Substances of Very High Concern (SVHC).

The European Union Medical Device Regulation (MDR 2017/745) also reinforces the restriction on the use of SVHC in medical devices. The use of substances which are carcinogenic, mutagenic, or toxic to reproduction (CMR) or have endocrine-disrupting properties with a concentration above 0.1% weight are only allowable if a detailed technical justification substantiates that alternative substances, materials, or designs are not viable.

Currently the US Environmental Protection Agency (EPA) is conducting a risk evaluation of high priority chemicals including phthalates. The EPA is required to conduct this risk assessment per the Toxic Substances Control Act. This assessment will determine if phthalates pose an unreasonable risk to vulnerable populations and present options for next steps to ensure adequate protection from harm.[5]

Medtronic has taken steps to remove DEHP from its products. Furthermore, Medtronic continually evaluates all regulations related potentially harmful substances to ensure that all risks to patients are minimized. When the ECHA published the first *Candidate List of SVHCs* under the REACH regulation in 2008, it contained 15 substances. By 2020, the candidate list had exceeded 200 substances and continues to grow.[7]

In addition to ensuring that Medtronic conforms with regulations related to the substances used in the formulation and manufacture of medical devices, the devices also undergo extensive testing to ensure they comply with biological safety requirements. Medtronic tests all devices to ensure that they comply with the requirements of ISO 10993-1:2018.[8] This involves extensive testing to ensure the device meets all the requirements for biological safety, taking into consideration the wide and complex range of biological hazards that can arise from the use of a medical device. Medtronic also ensures that any substances derived from an animal origin are rendered non-viable and do not provide any safety concern regarding the transmission of viruses and other transmissible agents to patients and users.

Shiley™ neonatal and pediatric tracheostomy tubes and Shiley™ flexible adult tracheostomy tubes are manufactured from materials that do not contain DEHP. Some of the Shiley™ endotracheal tubes product lines are also manufactured from materials that do not contain DEHP, including Shiley™ oral/nasal endotracheal tubes with TaperGuard™ cuff, Shiley™ pediatric oral/nasal endotracheal tubes, cuffless and with TaperGuard™ cuff, and Shiley™ oral/nasal endotracheal tubes with intermediate cuff. Activities are ongoing to fully convert the complete Shiley™ product portfolio to a non-DEHP formulation.

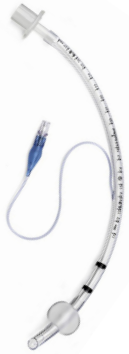
Shiley™ pediatric tracheostomy tubes, with TaperGuard™ cuff and cuffless

Shiley™ flexible adult tracheostomy tubes, with TaperGuard™ cuff and cuffless

Learn more about the Shiley™ tracheostomy tube portfolio

Shiley™ endotracheal tubes with TaperGuard™ cuff and optional preloaded stylet

Shiley™ pediatric endotracheal tubes, with TaperGuard™ cuff and cuffless



Shiley™ endotracheal tube with intermediate cuff

Learn more about the Shiley™ endotracheal tube portfolio

DAR™ mechanical filter

DAR™ mechanical filter HME

DAR™ electrostatic filter HME

DAR™ HME

DAR™ HME for tracheostomized patients

DAR™ extension tube

Learn more about DAR™ filters, HMEs, and breathing circuits

DAR™ closed suction system

Learn more about DAR™ closed suction system devices

The DAR™ product portfolio, including a range of filters and heat and moisture exchangers, breathing circuits, and closed suction system devices, has also been substantially converted to a formulation not made with DEHP.

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4. Maguire S, Haury F, Jew K. An in vitro comparison of tracheostomy tube cuffs. *Med Devices (Auckl)*. 2015;8:185-192.
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