PFAS PUBLIC CONSULTATION: INITIAL BRIEF PFAS IN MEDICAL DEVICES, VETERINARY MEDICINE, RESEARCH AND LIFE SCIENCE

ANNEX: FEP AND PTFE USED IN PTCA CATHETERS

CLAIM: Full exemption of FEP and PTFE for the use in catheters

Use of PFAS [List of applications within medical/ veterinary/ life science sector]

Cardiovascular diseases are the leading cause of death in the EU (EUROSTAT)[1]. They cover a broad group of medical problems that affect the circulatory systems (heart and blood vessels), often resulting from atherosclerosis, the abnormal build-up of plaque, that is made – among other constituents – of cholesterol or fatty substances that are deposited on the inside walls of a persons' arteries. Some of the most common diseases that affect the circulatory system include ischaemic heart disease (heart attacks) and cerebrovascular diseases. The number of in-patients with diseases of the circulatory system discharged from hospitals across ther EU was 10,3 million in 2019 (EUROSTAT)[2]. In 23 EU member states for which data are available, there were 1,0 million transluminal coronary angioplasty procedures conducted in 2020 (Eurostat).[3]

The case of cardiovascular catheters is broad end encompasses angioplasty balloon catheters, stent delivery catheter systems, guidewires. It also touches specific related instruments, introducers, guidewires, disposable cardiovascular surgical instruments, catheters using radioisotopes and distal support systems. Per 100000 inhabitants, Transluminal Coronary Angioplasty was executed 256,9 times in Belgium, 191,8 times in Bulgary, 196,3 times in Czechia, 176,7 times in Denmark, 393,2 times in Germany, 208,0 times in Estonia, 114 times in Spain, 271,2 times in France, 462,2 times in Croatia, 195,9 times in Italy, 154,8 times in Cyprus, 329,2 times in Latvia, 264,1 times in Lithuania, 102,5 times in Luxembourg, 210,8 times in Hungary, 187,9 times in Malta, 229,1 times in the Netherlands, 306,1 times in Austria, 212,7 times in Poland, 114 times in Portugal, 220,6 times in Finland, 180,3 times in Sweden,[4]

Specific Use Case:

Systems to prevent restenosis – PTCA Catheters

Over a million PTCA interventions are being performed EU-wide. Interventional cardiology in European countries is ever expanding, and the one-use instruments require MDR approval. Surgical invasive devices, catheters, intended for transient use, which were regulated in the past by Directive 90/385/EEC/ and Directive 93/42/EEC and now in the transition period towards MDR Reg. 2017/745 for medical devices. Similarly, medical devices for veterinary intervention had been governed by Directive 2010/63/EU.

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[1] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cardiovascular_diseases_statistics

[2]https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cardiovascular_diseases_statistics#Cardiovascular_healthcare

[3] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cardiovascular_diseases_statistics#Cardiovascular_healthcare

[4] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Surgical_operations_and_procedures_performed_related_to_diseases_of_the_circulatory_system,_2015_and_2020_(per_100_000_inhabitants)_Health2022.png

The introduction of MDR has surfaced the lengthy way to obtain approval and how far-reaching the consequences can be of finding approval for catheters and guidewires that are on the market at this point in time.

PTFE liners and coatings are being used in these catheters and guidewire systems to enhance low-friction operation of the instrumentation. There is no known alternative available today, which is confirmed by non-PFAS component manufacturers of PTCA FEP is the ideal heatshrink additive.

The liners are very thin, around 200µm max, which results in very limited amounts to be emitted to the environment per catheter. The producers of catheters are companies outside of the EU, such as Medtronic, BD, Boston Scientific, ABottt, Microtech, Microport, …

Essential quality of PTFE (polytetrafluoroethylene) PTCA (Percutaneous Transluminal Coronary Angioplasty) catheters and guidewires:

1. Low Friction: Fluoropolymers have a very low coefficient of friction, which reduces the resistance and allows smooth movement of the catheter or guidewire through the blood vessels. This property is essential to minimize frictional resistance and ensure easy navigation through the tortuous anatomy.

2. Lubricity: The low friction properties of fluoropolymers provide excellent lubrication, reducing the likelihood of injury or damage to the blood vessels during the insertion and navigation process. This lubricity is critical for safe and effective procedures.

3. Biocompatibility: Fluoropolymers are highly biocompatible materials, meaning they are well-tolerated by the human body and do not cause adverse reactions or stimulate an immune response. This is essential for medical devices that come into contact with the blood or the vascular system, as they need to be compatible with the body's tissues and fluids.

4. Chemical Resistance: Fluoropolymers have exceptional chemical resistance, making them suitable for use in PTCA catheters and guidewires that may be exposed to various chemicals and fluids during the procedure. This resistance helps ensure the integrity and longevity of the devices.

5. Clarity and Radiopacity: Some fluoropolymers, such as PTFE, can be made radiopaque by incorporating fillers or additives, allowing for better visibility under X-ray fluoroscopy. This allows the physician to precisely visualize the catheter or guidewire during the procedure, aiding in accurate placement and positioning.

Overall, PTFE plays a crucial role in PTCA catheters and guidewires by providing low friction, lubricity, biocompatibility, chemical resistance, and visibility, all of which are essential for safe and effective percutaneous coronary interventions.

FEP (Fluorinated Ethylene Propylene) is used in heat shrink tubing components of PTCA (Percutaneous Transluminal Coronary Angioplasty) catheters and guidewires and is a crucial fluoropolymer for several reasons:

1. Lubricity: FEP has excellent lubrication properties, which allows for smooth navigation and advancement of the catheter or guidewire through the blood vessels. This reduces friction and resistance, making the procedure easier and more comfortable for both the healthcare professional and the patient.

2. Biocompatibility: FEP is biocompatible, meaning it does not elicit any adverse reactions or harm to the body when it comes into contact with blood or tissue. This is important for patient safety and to ensure the catheter or guidewire can be used safely during the procedure.

3. Flexibility: FEP is highly flexible and can be easily bent or maneuverer without compromising its integrity. This allows the catheter or guidewire to navigate through complex anatomical structures, such as tortuous blood vessels or narrow lesions, with minimal trauma or damage.

4. Non-reactive: FEP is resistant to chemical reactions and does not react with either the body tissues or the contrast agents used during the PTCA procedure. This ensures that the catheter or guidewire remains stable and reliable throughout the procedure, without compromising the accuracy of imaging or the effectiveness of the treatment.

Overall, FEP provides the necessary properties of lubricity, biocompatibility, flexibility, and non-reactivity, making it a crucial material for PTCA catheters and guidewires. Without FEP, these devices would be less efficient, more traumatic, and potentially harmful to the patient.

No hazardous properties justifying a restriction [Argumentation on properties of PFAS used]

FEP: no acute toxicity, CAS number 25067-11-2

PTFE: no acute toxicity CAS, 9002-84-0

Identification of PFAS used [List of substance names incl. EC/ Cas-Number]

FEP: no acute toxicity, CAS number 25067-11-2

PTFE: no acute toxicity, CAS 9002-84-0

Emissions

During the end of life [If available: Studies on waste management and emissions]

It is estimated that less than 10 grammes of PTFE and fluoropolymer are present in the catheter sets.

Emissions from incineration

The total weight of fluoropolymer is estimated to be way below 10g per catheter set, resulting in very limited emissions. It is mandatory to send surgical waste to the incinerator.

For information regarding PFAS emission during incineration, please refer to the information stated in the EuPC brief on PFAS in medical devices, veterinary medicine, research and life science.

Emissions during recycling

Recycling is not allowed.

Analysis of alternatives

Description of Alternatives [Names, Properties, Availability, Discussion of properties compared to PFAS: Key points why PFAS are needed]

No alternatives known at date of submission, as confirmed by value chain partners and experts involved.

Time needed for substitution/potential socio-economic effects

Minimum 20 years / proposed: time unlimited exemption

Socio-economic impact [Market volume and sales on EU level, Quantities and Tonnages of production, Impact on supply chain and public health]

There is no known alternative for PTFE and FPE in the inner lining and heat-shrinkage material for PTCA catheters. This is also true for diagnostic catheters.

Most of the producers of catheters are producing outside the EU. It is unlikely that anywhere else in the world a restriction on use of fluoropolymers in catheters for PCTA will occur, and this may impact the reliability of the supply chain.

Without availability of PCTA catheters, over 1,0 million patients are at risk to be confronted with supply chain shortages that may affect their access to cariological surgical interventions that can save lives.

The use of inferior materials may cause specific problems.

Systems to prevent restenosis

Kink-resistance: The components of the guide wires, embolic protection devices, viance crossing catheters, directional atherectomy systems, micro catheters, PTA balloons, gooseneck snares, microsnares, Distal Access Catheters, Neurovascular Micro Catheters, CTO Micro Catheters, Long Sheats, Guiding Catheters, Diagnostic Catheters, PTCA Guidewires, Hydrophilic Guidewires.

Guide wire fracture[5] can lead among other complications, to coronary bifurcation lesions, pulmonary haematoma, postoperative myocardial infarction and cause life-treatening situations and additional need for complex surgical intervention to rescue the life of the patient. Entrapment and fracture of coronary angioplasty hardware are rare complications of percutaneous coronary interventions (PCI- for which cardiac surgery is sometimes required. Incidence of these complications are around 0,2 %. Wire wedging into distal or winding vessels, wire cutting by rotational or directional coronary atherectomy and structural failure are the main causes of fracture mechanisms.[6]

Guide catheters and catheter components for coronary angiography contain PTFE liners for low friction and FEP. These catheters are braid for pushability and steerability, PBAX is at the outside for flexibility.

[5] Balbi M., Bezante G.P., Brunelli C., Rollando D.; Guide wire fracture during percutaneous transluminal coronary angioplasty: Possible Causes, Management, 2010, Interactive Cardiovascular and thoracic Surgery, Vol. 10 issue 6, p 992-994

[6] Hartzler GO, Rutherford BD, McConahay DR. Retained percutaneous transluminal coronary angioplasty equipment components and their management, Am J Cardiol, 1987, vol. 60 (pg. 1260-1264)