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Rationale of KARL STORZ SE & Co. KG for the PFAS Restriction Proposal

General time unlimited exemptions for medical devices

The industry associations assume that there are about 500,000 different medical devices in the EU. Within our company there are more than 3,500 different products (own production) directly affected not overseeing supply chain-products by now for lack of information. These directly affected PFAS products sum up to 1 Bn € turnover which is 50%. 95% of our products would not be covered by present derogations making endoscopy and minimally invasive surgery in general no longer possible within the EU.
Just for Germany there are 60,2 Million hospital procedures (Statistisches Bundesamt (Destatis), 2022 covering 15,8 Mio surgical procedures, 13,8 Mio imaging procedures, 14,6 Mio non-surgical, therapeut. treatments, 10 Mio. diagnostic procedures, 6 Mio “additional procedures”. We and our peers assume that most of the first two subcategories are PFAS-dependent procedures (29.6 Mio; 49,2%).

https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Gesundheit/Krankenhaeuser/Publikationen/Downloads-Krankenhaeuser/operationen-prozeduren-5231401217014.pdf?__blob=publicationFile

European numbers for some of the main **urological treatments** in Europe total to **2,968,546** (2023)

Interventional BPH Procedures	**Stone Management Procedures**	**Urinary Incontinence Procedures**	**Prostate Cancer Treatment Procedures**	**Nephrostomy Procedures**	Erectile Dysfunction Management Procedures
375,765	1,543,374	50,385	902,424	92,156	4,443

Source: iData Research 2022 – Europe Market Report Suite for Urological Devices: with Impact of Covid-19; Geography: Germany, France, U.K., Italy, Spain, Benelux, Scandinavia, Austria, Switzerland and Portugal

In addition, **Cystoscopies**, which are mainly diagnostic, sum up to **970,384** (2023)
Source: iData Research 2022 – Global Market Report Suite for Single-Use Endoscopes; Geography: Germany, France, U.K., Italy, Spain, Scandinavia

A precautionary principle needs to be pursued to ensure patient care. Patient care already is tense for various reasons (chip crisis, MDR,...) must definitely not be compromised by any PFAS restriction. With the introduction of EU 2017/745 (MDR) many niche applications disappeared from the market, affecting pediatrics, neuro and others (including our own portfolio). DG SANTE is well aware of these discontinuation situations.
A even more granular solution with thousands of derogations is urgently to be avoided. Individual exceptions for different applications lead to confusion and predictable chaos.
A general exemption of all medical devices is necessary to ensure patient safety and care. If the legislator deems appropriate a negative list could be considered excluding certain medical devices where alternatives are proven and available.

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General time-unlimited exemption for fluoropolymers

Scientifically it is questionable at least intensively debated to consider fluoropolymers within the very same group of PFAS. Anderson concludes after consultation with an expert panel that “all PFAS” should not be grouped together. (Anderson et. Al. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts; Regulatory Toxicology and Pharmacology 134 (2022) 105226).
“…persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be define on a

case-by-case manner. Most panelists agreed that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS.”
Anderson: “…US EPA further removes from consideration chemicals for which vapor pressure cannot be calculated, which would presumably remove most, if not all, polymeric PFAS.”
Many of the medical devices on the market are high tech products going to technological limits. In order to ensure functionality, patient and user safety on a daily basis, the high-performance materials used in these products cannot be substituted according to the current state of technology and science.

A own report by the IKV Aachen, which is enclosed with the consultation, shows that fluoropolymers cannot be substituted for very representative applications for minimally invasive surgery at present. This conclusion is also reached by the Ministry for the Environment, Climate and Energy Management of Baden Württemberg within the Think Tank "Industrial Resource Strategies". A corresponding report is expected to be published by the end of the year. The specialty of their approach is to use KI screening all technical literature for potential substitution materials. A preliminary presentation within the think tank identified no substitute for high end medical device applications we as KARL STORZ served as a flagship application.
The use of these high-performance polymers should be regulated according to a benefit - risk principle. This essential use principle is also described in the European Green Deal and the EU Chemicals Strategy as a prerequisite of a regulation. A description was published by Cousins 2019 (The concept of essential use for determining when uses of PFASSs can be phased out) in Environmental Science - Processes & Impacts.

Many medical devices cover niche markets and the requirements for the materials used are already very high. Various verifications such as biocompatibility according to ISO 10993, DIN EN ISO 60601 etc. must be carried out. These requirements originate from the (EU) 2017/745 Medical Device Regulation, which was created for this purpose. MDR even regulates use of CMR-substances, endocrine disruptors and phthalates in certain situations when the benefit-risk analysis is positive Annex I, 10.4.1.ff. An extension to chemicals of concern could easily be adopted.

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As a company we can trace back the use of fluoropolymers for 6 decades. No issue of biocompatibility is recorded. Evidence with (external lab services) biocompatibility tests for each of our products with body contact is available including the proof of very high biocompatibility of fluoropolymers (PTFE, FEP, PFA, PVDF, ETFE, ECTFE, FKM,) has been kept in the company for more than 60 years. Likewise, scientific studies show that fluoropolymers do not exhibit toxic effects on humans (Anderson et. Al. Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts; Regulatory Toxicology and Pharmacology 134 (2022) 105226) with reference to multiple further investigations.
As the risk of changing quality of materials is unacceptable to the legislator (MDR), supply and inventory of the supply chain must be ensured and qualified. Likewise, changes in materials and even changes in raw material supplier are significant changes. Significant

changes make the existing certificate of the medical device void in the first place. It further leads to recertification of products in the EU and all those countries basing their market access on the “CE-certification”.
Expectable bottle necks.

It is necessary to ensure the supply chain and the resulting availability. Alternatively, there is a risk that, due to changes of the material or the supplier (which are significant changes), the approval bodies in the EU will be further strained and many medical devices, including PFAS free ones, will not be recertified in time. CE-certificates of all medical devices need recertification every 5 years.
Capacity of test-labs also needs to be considered. From our experience with the transition to MDR we already know that a year for a waiting list is easily possible.

PFAS in supplier or manufacturing processes.

It must also be considered that medical devices rely on supplier processes such as coatings. All optical elements need anti-reflective coatings, special band-pass filters need coatings as well. These coating processes take place in high vacuum to avoid contamination with residual particles of the vacuum chamber. Contamination could result from evaporation of sealings, lines or alike. To our knowledge only fluoroelastomers and fluoropolymers allow high quality coating. Contamination in the coating would destroy the functionality of the coating and thus of the product.
A typical rod-lens-endoscope consists of typ. 40 optical surfaces. Without coating each surface reflects 4% of the incoming light (physical laws). After 40 uncoated surfaces light intensity goes down by 80%. Anti-reflection-coatings with 99,9% transmission (0,1% loss) there is only a loss of 4% in the complete system. Compromising the quality of the reflection coating from 99,9% to 99,6% increase losses to 15% in the system. The effect on light intensity is one thing compromising contrast is likewise affected. Impaired image contrast

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means impaired information for the surgeon discriminating tiny nuances in tissue structures for the corresponding diagnosis.
This impairs quality of care and results in an unacceptable patient risk, such as failure to detect a critical tumor in the tissue. See
Restriction Report Consultation PFAS Risk-Evaluation: PFAS restriction effects on endoscopic healthcare provision in the EU attached to the consultation.

Duration of recertifications.

Provided that there is a substitute material!
A material change in a medical device such as a resectoscope slide (example attached to consultation file) or the electrode isolation mean the standard test for biocompatibility also studies with the medical device in the field.

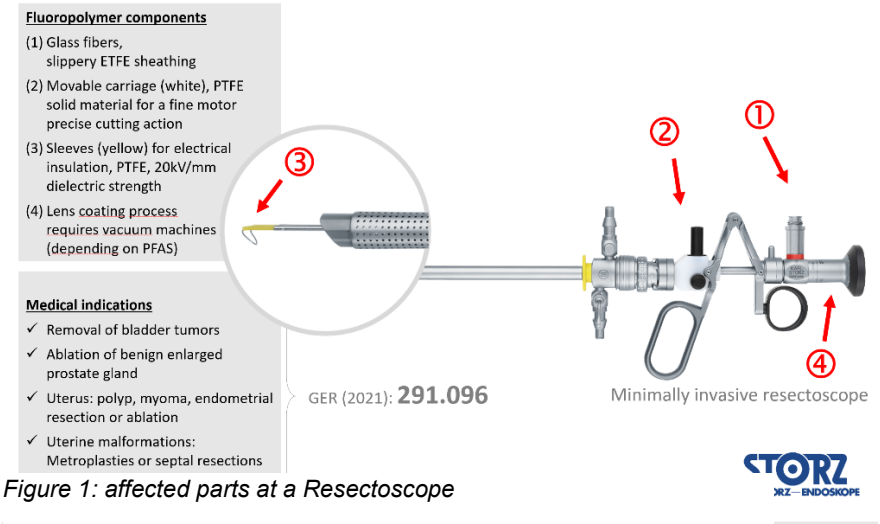

Figure 1: affected parts at a Resectoscope

In addition, there are tests for reprocessing and the resulting testing of electrical safety. Since this may also change the handling or use of the product, extensive worst case scenarios must be tested and also documented. This requires a new IFU and instructions for reprocessing for these products.

The duration of such a product change with existing material is estimated to be 3 years in the best case. Here possible longer approval times in the non-European areas are not considered.
The estimated costs for a transition of the existing product portfolio of KARL STORZ to PFAS free products are between 2.5 and 3 billion euros if there exist material substitutions which is not the case and not expected to be available within the next 10 or more years. This estimate is based on the current cost of the MDR transition, constraining about 300 technician and engineers for now more than 6 years, efforts are ongoing. The MDR transition mainly focused on documents. Products were not substantially modified for that purpose. With an upcoming PFAS restriction many thousand different products need to be changed and qualified.

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Furthermore, such a far-reaching regulation makes it necessary to ensure production for the medical devices used worldwide. In order to adequately supply the markets outside the EU, it is necessary to relocate production to non-EU countries. The relocation requires investments of between 0.5-1 billion euros. It should also be borne in mind that the current jobs in the European production sites will therefore no longer be needed. Of the current 8800 employees worldwide, 3000 would no longer be able to perform their current work in the European plants.
The dimension of the numbers show that these challenges could be prohibitive for a company of our size, going out of business is not an unlikely scenario.

Enforcing regulation

KARL STORZ sees a strong potential for irritation in international business relationships. In the USA, PFAS regulations most likely will exclude fluoropolymers and corresponding products are legally considered “PFAS free”. The EU will be cut-off of substantial trade streams from the US since those products are PFAS-containing in the EU. This leads to massive problems with international suppliers for a uniform understanding. Therefore, we recommend a harmonization of the international regulations.

It must also be ensured that sufficient analytical methods and capacities are available. The natural and medical science institute at the university tubingen (NMI) found out that there are no Methods available to completely analyse PFAS content in goods or packaging (Report is attached). Enforcement of PFAS restrictions is not possible for EU customs authorities when controlling imported goods therefore asymmetrically impairing EU-manufacturers which easily can be controlled by authorities.
Also a large-scale information about the rights and obligations of the REACH regulation must be ensured. Otherwise, small and medium-sized companies will not be able to guarantee PFAS-free products and production processes. This is already a challenge in supplier communication. Art. 33 REACH Regulation.

Emissions

Emissions from the production of PFAS materials cannot be controlled by KARL STORZ.

No PFAS emissions are known to occur during the manufacture or intended use of medical devices.

At the end of life, waste is classified according to the European Waste Catalogue Regulation. Here, infectious or potentially infectious wastes are assigned to group 18 "Wastes from human medical or animal care and research".

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The Closed Substance Cycle Waste Management Act (European Directive 2018/851/EU on waste) further defines the handling of the classifications. Accordingly, group 18 is to be disposed of.

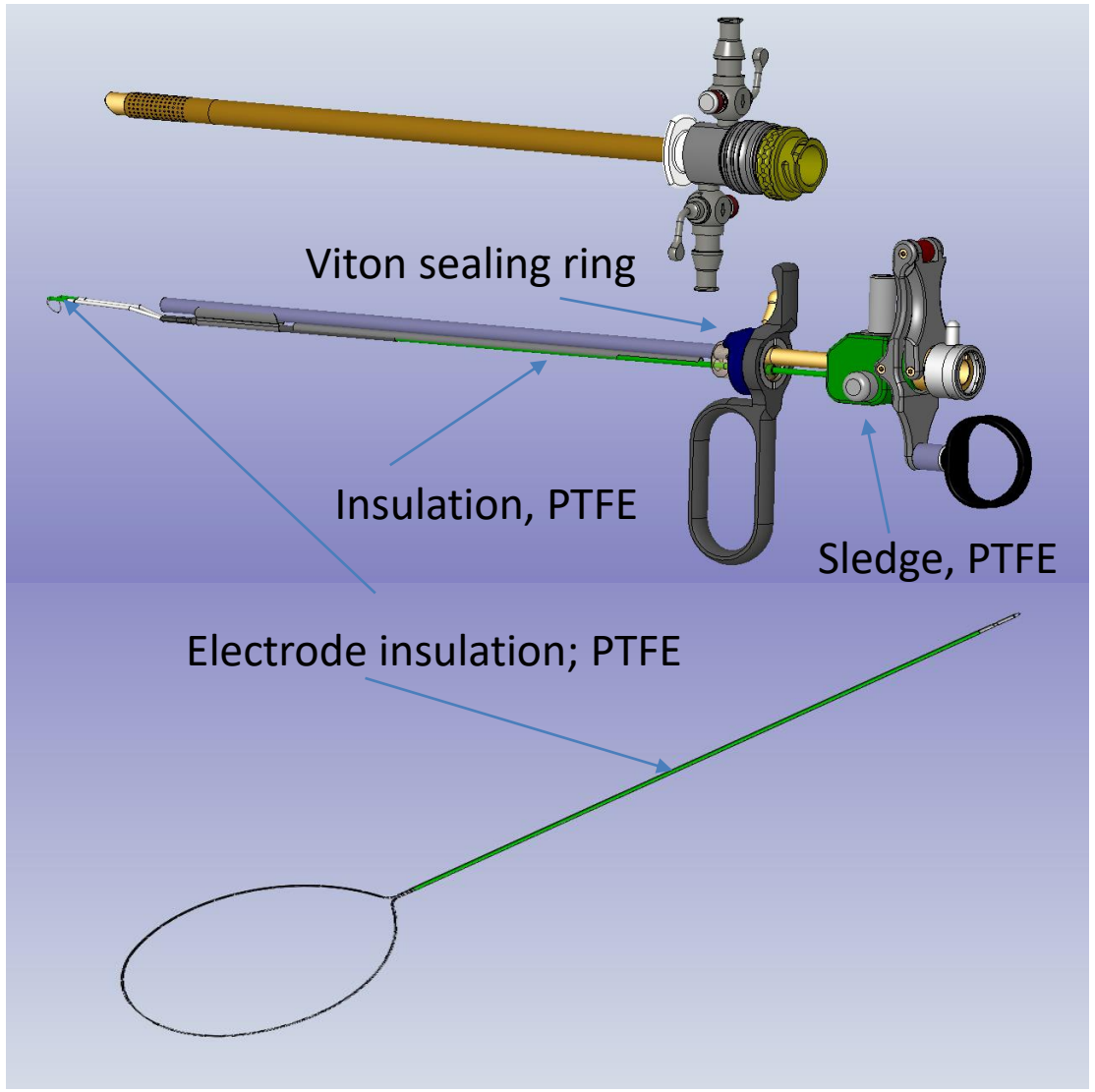
Specific information on handling, transport and final disposal/disposal is additionally provided for this group by the LAGA (Bund/Länder-Arbeitsgemeinschaft Abfall): Vollzugshilfe zur Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes.
It is clear from the LAGA that the waste in group 18 may not be sorted or recycled but must be sent directly for thermal recycling.
A study by the KIT shows that no PFAS are emitted into the environment during incineration in industrial plants. Umweltbundesamt, the German Federal Environmental Agency (UBA), was involved in designing the study according to personal communication with the authors.

Tuttlingen, 2023 September 22nd

Michael Banghard

i. A. Michael Banghard
Team Lead Material Compliance
Global Patient Health & Regulatory Compliance

General derogation for medical devices and implants (human/veterinary)



Mono and Bi-Polar Systems

Sledge **PTFE bulk material**: electrical insulation, reduced friction coefficient, possibility to reprocessing. Absolut need to secure patient and user saftey.

Electrode insulation **PTFE sheath**: ensure functionality, ensure patient safety.

Viton sealing: Neccesary for reprocessing, and use with hospital cleanig agents.

No alternative materials available. Tests with other high performace polymers failed (eg. PEEK).
Patient and user safety is not guaranteed.

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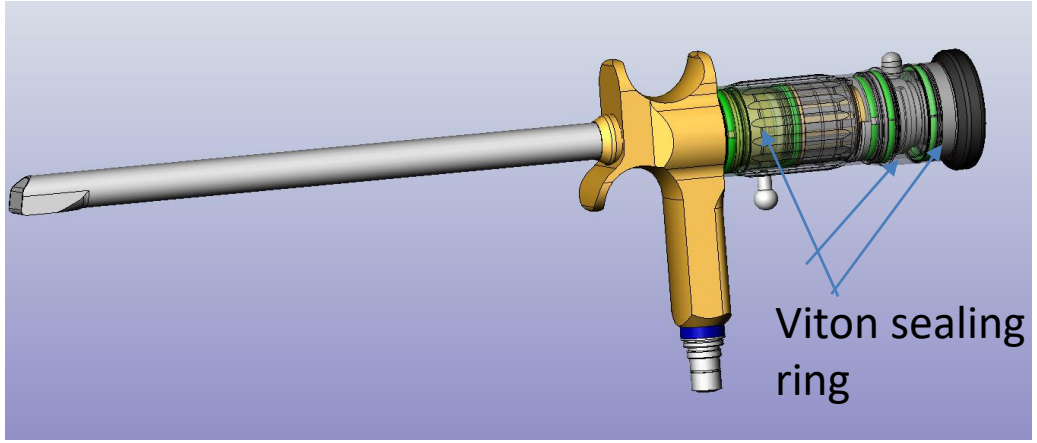
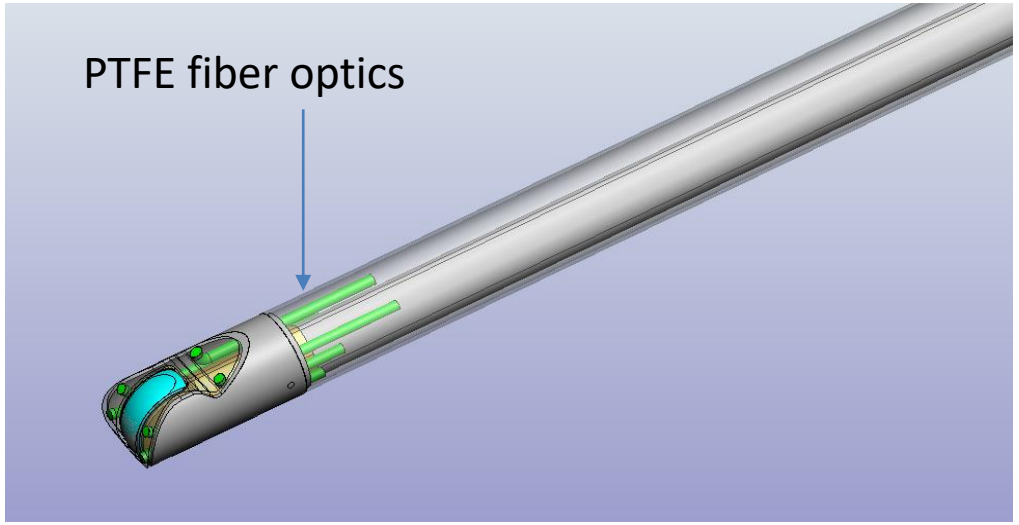
General derogation for medical devices and implants (human/veterinary) example rigid endoscope



Viton sealing: Neccesary for reprocessing, and use with hospital cleanig agents.

Essential for reliability and reusability of rigid edoscopes

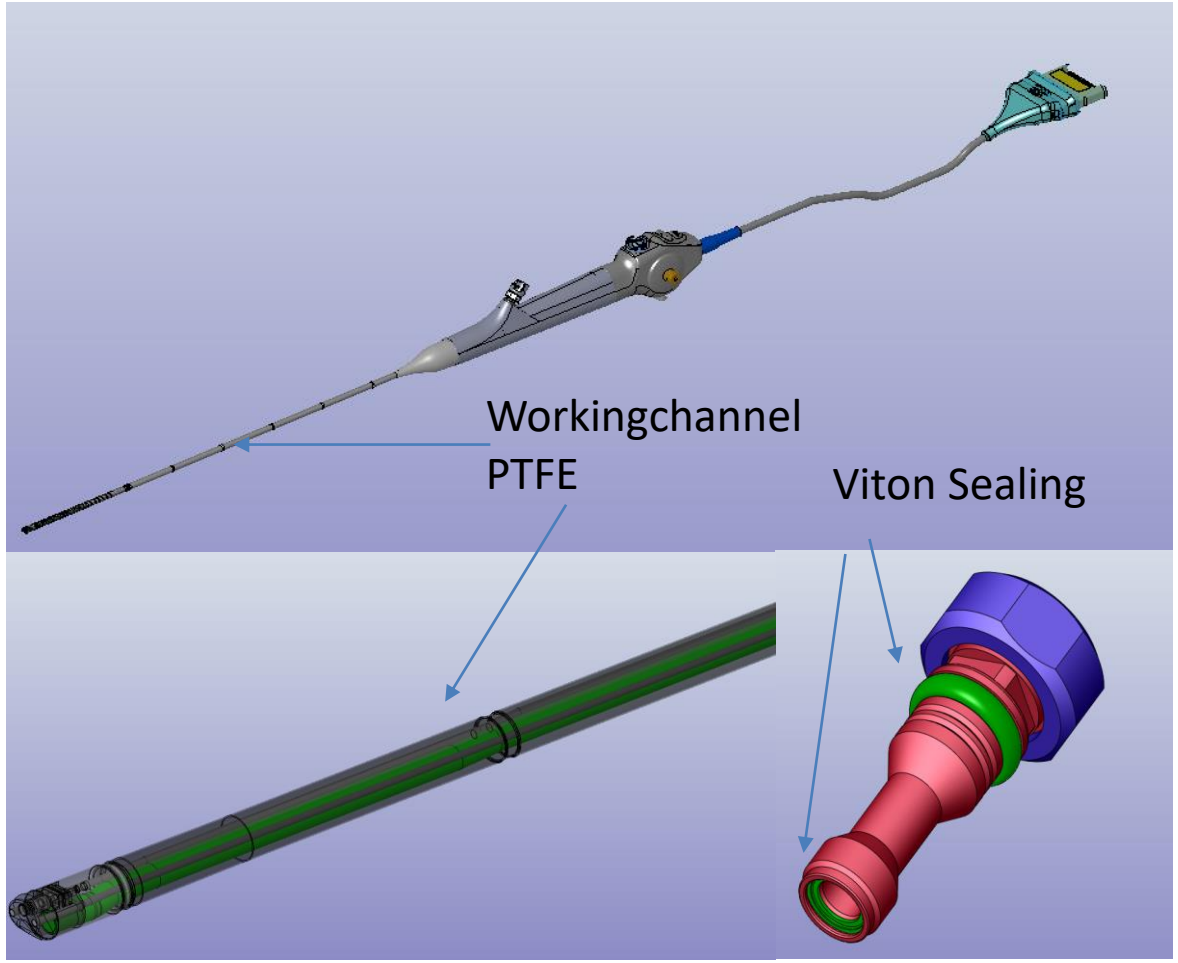


Shrinking tube ensures the long-lasting imaging qualities for rigid endoscopy. Ensures possibilty for reliable and safe diagnostics. Other tubes degrade during reprocessing with the consequece of extremly high danger for patient and user safety during use.

No alternative materials available.

KARL STORZ—ENDOSKOPE

General derogation for medical devices and implants (human/veterinary) example flexible endoscopy



PTFE Workingchannel: Friction reducing effect for probes through endoscope. Use of special probes for biopsy, manipulations and more.

Essentiell to ensure a cell and tissue repellent surface to provide clean and sterile surfaces.

Viton Sealing rings are essential to ensure the functionality of the endoscope. Resistance to cleaning and sterilization agents are absolutly essential.

No alternative materials are available.

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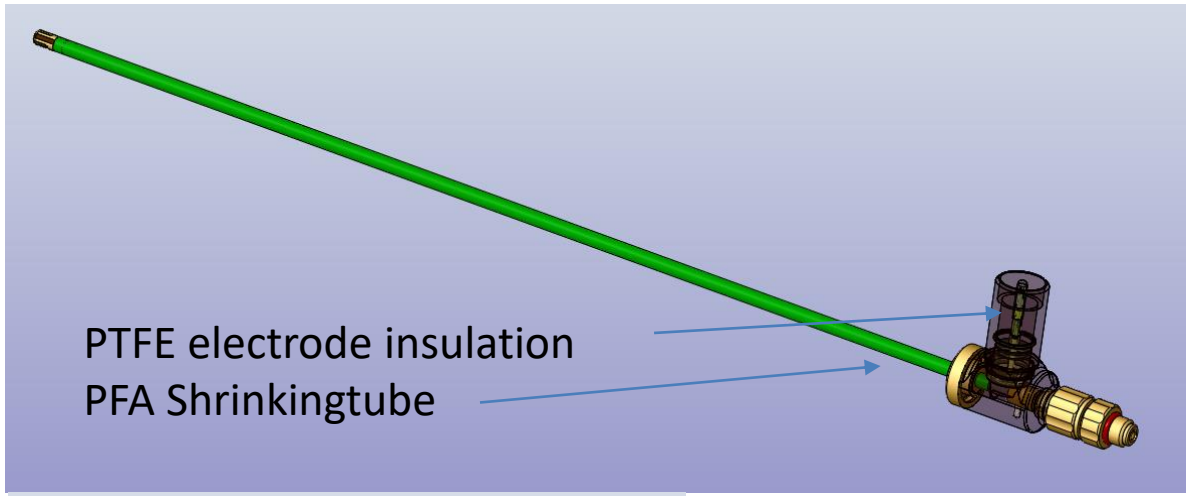
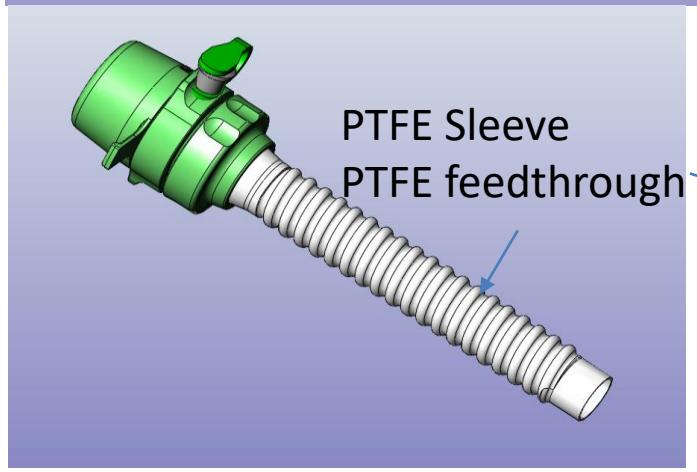
General derogation for medical devices and implants (human/veterinary) example HF electrosurgery





PTFE electrode insulation: for electrical insultion through the instrument.

PFA shrinkingtube. Electrical insulation and reducing friction coefficient through the trocar.

Also essential for reprocessing and ensure patient safety and atraumatic access to body.

Reduces inflammations after surgery

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General derogation for medical devices and implants (human/veterinary)
example electrical devices

1	Funktionstasten	5	Anschlussbuchse für Netzkabel
2	Freigabetaster für manuelle Positionierung	6	Videokabel
3	Anschlussbuchse für Lichtleitkabel (Produktunterseite)	7	Blenden-Filter-Drehrad
4	Anschluss für Roboterarm		

Medical electrical devices require advanced semiconductors to ensure function and safety to patients. These semiconductor processes rely on PFAS in e.g. photolithography, or high vacuum processes.

Without these electrical devices, the instruments shown above would not work and patients could not be treated.

These complex devices are used for optical diagnostics as well as for controlling HF surgical instruments. Various functions are controlled centrally by the operating room staff.

Insufflators, for example, pump up the patient with CO2 to create sufficient space in the abdominal cavity for the surgeons. These electrical devices have an extremely high level of safety. Inferior semiconductors can lead to failure of these devices. There is an extremely high risk of patient injury or death.

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General derogation for medical devices and implants (human/veterinary) technical specification regarding electrical, mechanical, and biocompatible properties of Fluropolymers in medical use

electrical insulation regarding ISO 60601
5300 V / 4 A
tracking resistence CTI > 600V
Frequencies: 300 kHz - MHz range
thickness of isolator:200-400 µm
atraumatic usability
extreme low coefficient of friction; frictions force through trocar test < 5N tensile force
mechanical strength (KARL STORZ penetration test) min 20 N
biocompatible regarding DIN EN ISO 10993
suitable for laser marking
suitable for tampon printing; adhesion of print should last 10000 cycles trocar test.

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General derogation for medical devices and implants (human/veterinary) technical specification regarding electrical, mechanical, and biocompatible properties of Fluropolymers in medical use

„chemical resistance for pH2 up to ph 14 reagrding hospital cleaning agents
steam sterilization min 134°C for min 10 min.
reprocessing up to 300 cycles“

The methods for reprocessing and sterilizing medical instruments depend on the user. The distributors validate a method which is then also recommended. Hospitals and users are not bound by these instructions and can reprocess the instruments using their own processes. Some are attached as PDF.

Extension of exemption periods

Extension of exemption periods to at least **20 years** for hard chrome plating, etc.

Testing of alternative of materials / components: 2 years (material sufficiently researched and available).
Mechanical testing, testing of production processes, testing of biocompatibility, reprocessing, etc.

Reliability testing: 5 years

Redesign of product for alternative solution: 2 years
Constructive Changes, etc.
Testing of in-situ performance: 2 years

Product specific requirements (e.g. clinical trials or notified body approval): 2 years

Global approvals (if additional requirements apply):5 years

Other stage(s)(please specify):
Total time to develop: 18 years

We as KARL STORZ estimate to redesign 3,500 different products including an estimated 50,000 individual parts.
These extensive volume will congest and overburden our development resources by far.

KARL STORZ—ENDOSKOPE

INSTITUT FÜR KUNSTSTOFF VERARBEITUNG | in Industrie und Handwerk an der RWTH Aachen

Final report on the R&D project

„Material selection for the substitution of PTFE in medical applications"

Client:	**KARL STORZ SE & Co. KG**
Ordner number IKV:	077792
Order date:	20.07.2023

Aachen, 04.09.2023

Prof. Dr. rer. nat. Rainer Dahlmann
- Scientific director -

The report comprises 7 pages and 2 tables.

1 Executive Summary

KARL STORZ SE & Co. KG manufactures a wide range of medical devices that use materials containing per- and polyfluoroalkyl substances (PFAS) with their unique spectrum of properties. One example is electrical insulation for minimally invasive surgery. Due to the field of application, the requirements are comparatively high. In addition to the required biocompatibility, high electrical requirements, a low coefficient of friction and extensive chemical resistance at elevated temperatures are necessary for the application.

This consulting project aims to identify and evaluate materials as substitutes for the currently used PTFE as a **reusable electrode insulation for minimally invasive surgery**. To this end, a search profile was drawn up based on the requirements and a search was made in material databases and technical literature for suitable materials.

With an initial search based on plastics with biocompatibility and good electrical properties (high tracking resistance, high dielectric strength, high volume resistivity), the following plastics were identified: PEEK, POM-H, PA66, PI, PP, PE-UHMW, and a parylene coating. Experimental tests at Karl Storz showed that PEEK has a insufficient tracking resistance with 150 V for electrical insulation for minimally invasive surgery. All other plastics identified had better electrical properties than PEEK, but lower than PTFE. Here, practical tests must prove the electrical suitability. The mechanical properties are adequate for all grades. Only PTFE, PEEK, PI and Parylene can meet the required thermal stability over 140 °C. The friction properties of the identified plastics against metals are at a low level for all materials. The chemical resistance of PTFE to various chemicals is very good. Only PEEK and Parylene have similar resistance. POM, PA66, and PI are rather non-resistant to strong acids and alkalis. PP and PE-UHMW are sensitive to oxidizing chemicals. POM, PA66, PP and PE-UHMW are also flammable. In the event of an electric arc occurring, extensive injuries to the surrounding tissue cannot be prevented.

Due to the temperature resistance, PI and a coating with Parylene are initially suitable. However, PI has only limited resistance to concentrated acids and alkalis and comparatively low tracking resistance. In addition, the water absorption of up to 5 % is high and thus dimensional stability is not given. Here, experimental tests must be carried out to determine the extent to which chemicals used cause the plastic to be unusable at an early stage, whether the electrical properties are adequate and whether swelling in use is significant. Possibly, an alternative is to coat one of the identified plastics with Parylene. However, only PEEK and PI can be considered as a base layer because of their temperature resistance. In the case of PI, when used as a monomaterial, swellability can be problematic, and in the case of PEEK it must be checked whether the electrical properties are sufficient in combination with the coating.

Based on the research, no equivalent substitute material currently allows the replacement of PTFE without any restrictions or compromising required material specification for the reusable electrode insulation for minimally invasive surgery.

2 Problem / Aim of the investigations

KARL STORZ SE & Co. KG (the offeree) manufactures a variety of endoscopic instruments for human and veterinary medicine. A variety of PFAS-containing materials with their special range of properties are used in this applications.

PTFE is currently used as the base polymer because it combines high chemical resistance to media with simultaneously high thermal resistance and dielectric strength, low static friction and stiffness appropriate for the application. This poses major challenges for material selection, as typically, one of these requirements is not met by most plastics, making a material substitution non-trivial. Therefore, a holistic view of the respective component is required, as changed material properties will necessitate an adaptation of the design.

In this consulting project, materials are to be identified and evaluated as substitutes for the PTFE currently in use. With the help of a questionnaire from the IKV, the requirements will be listed and a search profile for the research will be developed. Here, the materials available on the market are examined with regard to their suitability for meeting the extensive requirements and possible candidates are selected. The identification and evaluation of materials is for **reusable electrode insulation for minimally invasive surgery** with the following requirements or conditions of use:

- Electrical requirements:
    - Electric insulation
    - Tracking resistance: CTI ≥ 600 V
    - 5300 V / 4 A; frequency: 300 kHz – MHz range
- Biocompatibility according to DIN EN ISO 10993; MDR; REACH, FDA
- Very low coefficient of friction for safe use (Force in the trocar test < 5N)
- Chemical and thermal resistance:
    - Cleaning at 40 – 60 °C: neutral-enzymatic to strong alkaline, followed by neutralization based on citric or phosphoric acid (possibly hydrofluoric acid)
    - Disinfection: hot water up to 95 °C; glutaraldehyde, peracetic acid/ H_2O_2 up to 60 °C; peroxides, perchlorates, o-phthaladialdehyde (OPA)
    - Sterilisation: steam up to 140 °C at 3 bar for 18 min; H_2O_2 in plasma up to 60 °C, hot air up to 140 °C
- Other requirements: Available as tubing in various dimensions or extrudable
    - Minimum dimension:

- Inner diameter: 0,69 ± 0,02 mm
- Outer diameter: 1,11 +0,05/-0,00 mm
- Wall thickness: 0,21 mm

The aim is to identify a suitable material for the product in question, taking into account the various stresses that occur and the other material properties mentioned above.

3 Methodology

A search profile for identification was derived from the requirements listed.

- Electrical properties
  - High dielectric strength
  - High tracking resistance
  - High volume resistivity
- Mechanical stability
  - Young´s modulus
  - Tensile strength
  - Fracture strain
- High Continuous operating temperature
- Low coefficient of friction
- High chemical resistance to various media from acidic to alcalic

First, a search was made for materials with focus on electrical properties (dielectric strength, tracking resistance and volume resistivity) and biocompatibility according to ISO 10993. Subsequently, mechanical properties (stiffness, tensile strength and elongation at break), continuous service temperature, coefficient of friction, chemical resistance and other relevant information on the material were listed for the identified materials.

4 Results

As an alternative to the currently used PTFE, the following polymers were identified based on electrical properties as well as biocompatibility: PEEK, POM-H, PA66, PI, PP, PE-UHMW, and a parylene coating. The overview of these and other properties are listed below [1, 2, 3, 4, 5, 6].

Plastic type	Dielectric strength [kV/mm] (IEC60243-2)	Tracking resistance (CTI)	Volume resistivity [Ω cm] (IEC 60093)	Young's modulus [MPa]	Tensile strength [N/mm^2]	Fracture strain [%]	Continuous operating temperature [°C]
PTFE (reference)	48	>600	>10^{18}	410	25 – 36	350 – 550	260
PEEK	15 – 24	150	5*10^{16}	3600	90	50	250
POM – H	38 – 50	>600	>10^{15}	1600 – 3200	62 – 70	25 – 70	110
PA66	60	>600	10^{12}	2000	77 – 84	150 – 100	100
PI	200	>300	>10^{16}	3000 - 3200	75 – 100	/	260
PP	50 – 65	>600	>10^{17}	1100 - 1300	21 – 37	20 – 800	100
PE-UHMW	30 - 40	600	>10^{15}	700 - 800	30	300 – 400	80
Parylene - coating	200	/	>10^{15}	2400 – 3200	45 – 75	2 – 30	~275

Plastic type	Biocompatibility ISO 10993	Friction coefficient against steel [-]	Chemical resistance	Further information
PTFE (reference)	Yes	100 Cr6: 0,25	Universal chemical resistance, insolubility in all known solvents below 300 °C	
PEEK	Yes	Steel 1.4301 0,4 – 0,5	Unstable to strong mineral acid (e.g. hydrofluoric acid); low swelling in some solvents	
POM – H	Yes	100 Cr6: 0,25 – 0,5 Steel 1.4301: 0,2 – 0,5)	Not resistant to strong acid (pH < 4), to strong oxidizing agents and not resistant to alkalis	flammable
PA66	Yes	100 Cr6: 0,5 – 0,75 Steel 1.4301: 0,47 – 0,6	Not resistant to strong alkaline solutions and strong acids; water absorption: 3 - 9 %	flammable
PI	Yes	100 Cr6: 0,5	Not resistant to concentrated acids, bases, amines; water absorption: 2 - 5 %	
PP	Yes		Not resistant to strong oxidizing agents; swellable	flammable
PE-UHMW	Yes		Not resistant to strong oxidizing agents	flammable
Parylene - coating	Yes		Oxidation resistant up to approx. 80 °C, resistant to all organic solvents up to 150 °C	Not conventionally processable

The listes properties of different polymers show, that PEEK has a similarly high continuous operating temperature. But experimental tests at Karl Storz have shown that PEEK has an insufficient tracking resistance for electrical insulation for the application in minimally invasive surgery tools. All other identified plastics have better electrical properties than PEEK, but lower than PTFE. Here, practical tests must prove the electrical suitability. The mechanical properties of PTFE and the tested PEEK are sufficient for the application. The mechanical properties of the other plastics identified lie between those of PTFE and PEEK, which is why they are suitable.

Only PTFE, PEEK, PI and Parylene can meet the required thermal stability of 140 °C under superheated steam. The friction of the identified plastics against metals is overall at a low level. However, comparable tests with constant test conditions are not available for all plastics, which is why a quantitative comparison is not possible without further tests.

The chemical resistance of PTFE to various chemicals is very good. Only PEEK and Parylene are similarly resistant. POM, PA66 and PI are rather non-resistant to strong acids and alkalis. PP and PE-UHMW are susceptible to oxidizing chemicals. POM, PA66, PP and PE-UHMW are also flammable. In the event of an electric arc occurring, possible extensive injuries to the surrounding tissue cannot be prevented.

5 Conclusion and Outlook

Due to the temperature resistance, led PI and a coating with Parylene are initially suitable. However, PI has only limited resistance to concentrated acids and alkalis and comparatively low tracking resistance. In addition, water absorption is high at up to 5 %, which can limit the mobility of the insulation and thus make handling more difficult. Experimental tests must be carried out to determine the extent to which chemicals used cause the plastic to be unusable at an early stage, whether the electrical properties are adequate, and whether swelling during use is significant. An alternative would be to coat one of the identified plastics with Parylene. However, only PEEK and PI can be considered as a base layer because of their temperature resistance. In the case of PI, when used as a monomaterial, swellability can be problematic, and in the case of PEEK it must be checked whether the electrical properties are sufficient in combination with the coating.

Based on the research, no equivalent substitute material currently allows the replacement of PTFE without compromising required material specification such as the electrical properties, temperature resistance or chemical stability for the reusable electrode insulation for minimally invasive surgery.

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KARL STORZ — ENDOSKOPE	**Test report** **Resectoscope with Bipolar Loop, Insulation Tube PTFE vs. PEEK**	Version BA

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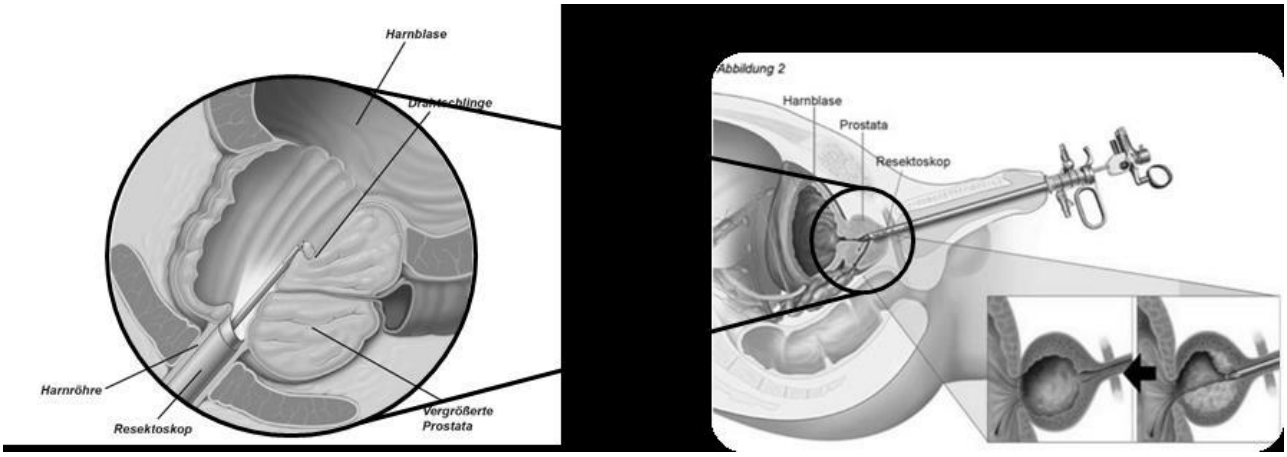
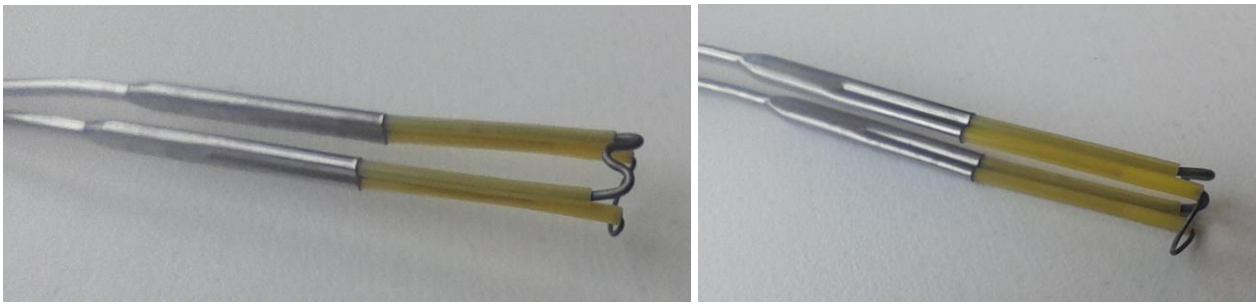
1 Initial situation: Use of PTFE "Teflon" tubing as insulation in resectoscopes

Resectoscopes have been used in medicine for decades, for example in urology for the removal of superficial tumors in the urinary bladder or for benign enlargement of the prostate in men.
KARL STORZ, as one of the world market leaders in resectoscopes, has been selling these resectoscopes for decades.



The illustration above shows the common use in the removal "resection" of tissue in a benign enlarged prostate. The resection loop can be seen on the left in the section.



The illustrations show a so-called bipolar resection loop in the current sales version, viewed from above (left) and from the side (right). The electrical insulation is made of PTFE.

Using high-frequency cutting current, tissue is removed with the thin semicircular metal loop. The yellow tubes are used for electrical insulation and are made of PTFE "Teflon". In these loops, the insulation must withstand voltages of up to 800Volts. In other embodiments, even up to 4000Volts or 20 kV/mm The safe insulation provided by Teflon hoses has been proven by millions of worldwide applications of such loops over the past decades. In addition, PTFE combines further, extraordinary properties. It is biocompatible according to DIN EN ISO 10993, it does not adhere to dirt or tissue, it shows no stick-slip effect with low friction, and it is very temperature-stable for the reprocessing procedures in hospitals.

2 For the selection of substitute materials for PTFE

In principle, ceramics have a high electrical dielectric strength. Due to the design of minimally invasive surgery, thin walls must be used, about 0,2 mm. This can be manufactured even with ceramic materials, but during its application the resection loops are subjected to a pressure load. Such thin ceramic sleeves would break sharply in the body and could injure both the urethra or the urinary bladder. According to the current state of the art, ceramic sleeves cannot be used as a substitute.

With regard to alternative plastic materials we first make a ”Gedankenexperiment”. For this purpose, we divide medically certified polymers into those that are less expensive than PTFE and those that are high priced. The described use of PTFE for electrical insulation of resection loops has been going on for decades. The global market is occupied by over 20 competitors. Therefore, the drive to reduce manufacturing costs is an important motivation to improve market success relative to competitors.

Despite high market pressure, no more favorable substitute than PTFE has yet appeared on the market or even established itself. With the above justification, market pressure and decades of experience, it can be assumed that there is no comparably good but cheaper substitute material on the market.

Even after intensive research, we are not aware of any equivalent alternative materials to PTFE (Teflon), even at higher prices. With the above in mind, it nevertheless makes sense to test high-priced polymers for their suitability, since this has not been demanded by the market so far.

Current prices for high performance polymers (all medical grad):

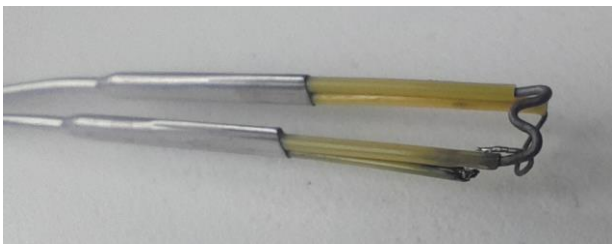
PEEK Tube 7,71 € / meter
PTFE Tube 2,92 € / meter

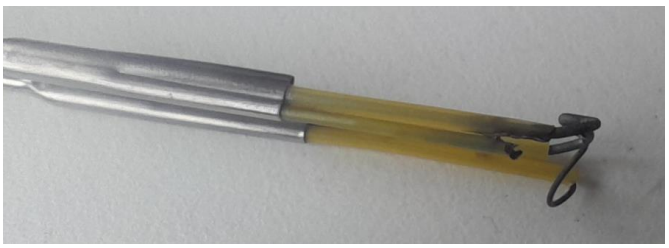
3 Test: Application test on meat with test slings in which one of the four Teflon hoses was replaced by a hose made of PEEK

With PEEK, we have a very high-priced high-performance polymer that is also certified for use in medical technology .

Therefore, we modify resection loops and replace the PTFE insulation with one made of PEEK.

During in vitro experiments with several such modified loops, electrical breakdown repeatedly occurred after only a few seconds, manifesting itself as a bright flash of light.





The figures show a modified loop with insulation made of PEEK. The loop is shown after realistic in vitro use. The loop is destroyed, the material of the cutting loop made of tungsten (melting temperature T= 3.422°C) is partially melted, The image is in the same perspectives as the previous images of a new, non-modified loop.

The combination of lower dielectric strength and tracking resistance of the high-performance polymer PEEK is not sufficient for this application. Breakdown occurs and a carbon track is created that is electrically conductive. As a result, any breakdown or flashover leads to irreversible complete destruction of the loop. After such an event with extremely high heat generation for a short time, body tissue adheres firmly to the destroyed loop. In the attempt to remove the loop from the urinary bladder, perforation may occur and the immediate need to convert the minimally invasive surgery to open surgery may occur. A standard operation would thus become a medical emergency, which cannot be tolerated under any circumstances due to inferior material selection.

4 Conclusion

According to the current state of the art, PTFE cannot generally be replaced by any other material for use in surgical instruments for high-frequency surgery (also known as electrosurgery). In addition to the best technical data regarding dielectric strength and tracking resistance, PTFE is also characterized by high fault tolerance. If a brief flashover does occur due to mechanical damage or improper handling of the instrument, this does not necessarily lead to irreversible total failure. In many cases, the material remains intact and no irreversible carbon trace forms on the surface. In the case of PEEK, every voltage flashover, no matter how brief, on the material surface leads to a carbon trace and irreversible total failure.

Risk-evaluation of the effects of a restriction of PFAS on endoscopic healthcare provision in the EU

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Submitted by:	**Karl Storz SE & Co. KG**
Prepared by:	**Karl Storz SE & Co. KG**
Substance:	**Per- and polyfluoroalkyl substances (PFAS)**

Contents

Aim and Scope

The aim and scope of this document is to quantify effects of a restriction of per- and polyfluoroalkyl substances (PFAS) from use in the design and manufacturing of life-saving medical devices. Since it is unfeasible to provide a comprehensive socioeconomic risk-assessment across all known diagnostic and therapeutic interventions requiring the use of medical devices containing PFAS, this document will evaluate the effects based on two selected use cases in the field of endoscopic cancer diagnosis and treatment.

PFAS in medical devices

Polymeric materials are widely used in the manufacturing of medical devices because of the ease of fabrication, flexibility, and their biocompatible nature as well as their wide range of mechanical, electrical, chemical, and thermal behaviors. Among the group of Per- and polyfluoroalkyl substances (PFAS), polytetrafluorethylene (PTFE, brand name Teflon) is a material that is also widely used in medical devices (Teo et al. 2016). PTFE has a very low coefficient of friction, is heat resistant and chemically inert. These properties make the material currently irreplaceable for purposes where low friction, heat-stability for disinfection and low toxicity are required. It is used for devices such as tubing, endoscopes, cannulas, catheter linings, synthetic blood vessels and surgical sutures (Teo et al. 2016).

In the manufacturing process of flexible endoscopes, among other uses, „expanded PTFE“ (ePTFE) is being used as the material of choice for making the working channels and other critical parts such as sealings. Working channels are being used to insert instruments into the body cavity during endoscopic procedures. All reusable endoscopes must go through a strict reprocessing flow including manual or automatic cleaning in addition to sterilization. This process is highly regulated at a global level to prevent crossed and nosocomial infections. The use of PFAS with an excellent chemical and heat resistance withstand the disinfection and sterilization required after each use. Thus, without

materials like ePTFE, reusable endoscopes could no longer fulfill the stringent regulatory requirements, not only in terms of medical safety, but also in terms of sustainability.

PFAS or “forever chemicals” come in contact with human beings and the environment mostly from food, household products, drinking water and other exposure in everyday life. Researchers have linked most of the health and ecosystem effects to these sources.

Fluoropolymers like PTFE have been demonstrated to meet the OECD criteria for polymers of low concern during the in use phase of their lifecycle. However, questions remain regarding waste handling at the end of useful life for products containing fluoropolymers. Municipal incineration of PTFE using best available technologies (BAT) has been shown not to pose a significant source of the studied PFAS and could be considered an acceptable form of waste treatment (Korzeniowski et al. 2022). Therefore, fluoropolymers like PTFE should not be considered part of the planned restriction of PFAS.

We support the restriction and replacement of PFAS from applications, where the associated risks clearly exceed the benefits associated with their use, or where there are replacement technologies available.

Based on contemporary requirements regarding the inherently safe design of medical devices, however, without PFAS such as ePTFE, a huge number of life-saving medical devices could no longer be sold and used clinically, which would significantly affect global patient care and the life of millions of people all around the globe.

The role of endoscopy in medicine

Endoscopy concerns the visualization of concealed body cavities. It is a medical technology and not a clinical speciality in its own right. Today it is daily routine in many medical fields.

Endoscopy is employed in a wide variety of medical and surgical disciplines for diagnosis and treatment. It is routinely used in, amongst others, the different subdisciplines of ear-nose-throat medicine, pneumology, gastroenterology, abdominal surgery, urology, gynecology, and also sports medicine. Users are found in all strata of healthcare systems, from endoscopic specialists to ambulatory healthcare centers and day clinics as well as all types of hospitals from primary health care to university hospitals.

Our internal organs are composed of manifold internal surfaces which have been made accessible by the use of endoscopes. A multitude of benign and malign changes occur on the surfaces of tissues and inner and outer lining of organs, the epithelia. Epithelia turn over at some of the fastest rates in the body. For epithelial layers to maintain constant cell numbers essential to their functions, the number of cells that divide must match those that die. Failure to do so can result in aggressive tumors and their invasion into other tissue.

It is important to understand that surface structures can be visualized considerably better and more precisely with optical procedures than with other imaging procedures thanks to the color rendering and the excellent spatial resolution. As a result, with the current technical possibilities, all procedures of “virtual endoscopy” via imaging modalities using interpolation procedures only appears to be as accurate but are in practice considerably inferior to optical procedures (Kramme 2016).

Analysis of impacts of a PFAS restriction on selected cancers diagnosed and treated by endoscopy

Epidemiology and costs of cancer in the EU

Cancer is the second leading cause of death in developed countries, making it a global public health problem. In 2008, 2.45 million people were diagnosed with cancer and 1.23 million died because of cancer in the 27 countries of the European Union (EU). Cancer cost the EU €126 billion in 2009, with health care accounting for €51.0 billion (40%). Productivity losses because of early death cost €42.6 billion and lost working days €9.43 billion. Hence, 60% of the economic burden of cancer was incurred in non-health-care areas (Luengo-Fernandez et al. 2013). The most common cancers in the EU in 2020 were breast cancer, colorectal cancer, prostate cancer, lung cancer, bladder cancer, skin cancer, pancreatic cancer, gastric cancer and renal cancer (Dyba et al. 2021). The number of cancers in the EU is projected to increase to 4.75 million cases and 2.55 million deaths in 2040 primarily as a result of population ageing and growth. This represents an overall increase in mortality of 32%, which is an additional 620 000 people dying each year ((Wild et al. 2019), IARC 2020, https://gco.iarc.fr/tomorrow/en/dataviz/bars).

The role of endoscopy in cancer diagnostics and treatment

Cancer survival improves when it is detected early. Early detection of cancer or precancerous change allows early intervention to try to slow or prevent cancer development and lethality. Tissue biopsy, the current gold standard for cancer diagnosis, offers reliable results. Skin biopsies can be obtained by needles or punches. When it comes to other anatomies, and especially to internal organs, biopsies can only be obtained by surgical access or minimally invasive by endoscopy. The endoscope is used through a natural body orifice or small incision to view the organ in question for abnormal or suspicious areas, and in order to obtain a small amount of tissue for study.

Endoscopic biopsies for the detection and management of cancer are irreplaceable. As the German Urologic Society (DGU) states it on their website concerning cystoscopy: “cystoscopy-replacing alternative examination procedures do not exist. Cystoscopy is required in all guidelines for the diagnosis and follow-up of bladder carcinoma, but also for many other bladder diseases as obligatory and indispensable. A guideline-based medicine without cystoscopy is not possible. Due to demographic developments and the predicted 20 percent increase in the need for urological care, a further increase in the number of cystoscopies can be expected in the coming years.”(DGU 2019, https://www.urologenportal.de/pressebereich/pressemitteilungen/presse-aktuell/presse-archiv/pressemitteilungen-aus-dem-jahr-2019/arbeitsgemeinschaft-der-leitenden-krankenhausaerzte-der-deutschen-gesellschaft-fuer-urologie-ev-dgu-diagnostische-zystoskopien-duerfen-nicht-aus-urologischen-praxen-verdraengt-werden-21112019.html)

In Germany in 2021 a total of 3.147.578 endoscopic biopsies have been taken for diagnosis in hospitals, among these more than 550.000 from the upper alimentary tract, and 260.000 from the lower gastrointestinal tract (Statistisches Bundesamt). Moreover, a total of 3.083.712 diagnostic endoscopies have been performed in 2021, among those 157.515 urethrocystoscopies and 129.894 laryngo- and pharyngoscopies (Statistisches Bundesamt 2023). These numbers do not include ambulatory endoscopies, such as cystoscopies performed in outpatient settings.

The role of endoscopy in bladder cancer diagnostics and treatment

The medical, ethical and socioeconomic consequences of a market withdrawal of endoscopes due to PFAS ban on bladder cancer shall be evaluated in the following.

Macrohematuria is the (visible) presence of blood in the urine and it can be a symptom of bladder cancer (BC). Bladder cancer is a disease in which the cells lining the urinary bladder lose the ability to regulate their growth and divide uncontrollably to form a tumor. The disease generally presents with physical symptoms and is diagnosed using cystoscopy and lab tests. Between 5% and 10% of all patients referred to urological departments attend because of hematuria. In several studies, cancer of the bladder or upper urinary tract was found in up to 1% of patients presenting with hematuria (Bolenz et al. 2018). Thus, approximately 0.05 to 0.01% of patients presenting to urologists with macrohematuria may suffer from bladder cancer.

BC is the 10th most common cancer type worldwide, with an estimated 549,000 new cases and 200,000 deaths in 2018. Approximately 3.0% of all new cancer diagnoses and 2.1% of all cancer deaths are due to bladder cancer, and bladder cancer has a higher prevalence in higher income countries (Saginala 2020). Bladder cancer accounts for 157.500 new cases and 49.200 deaths in the EU in 2020 (Dyba et al. 2021).

According to contemporary diagnostic BC guidelines, the final diagnosis is based on cystoscopy examination of the bladder and histological evaluation of the tissue (Powles et al. 2022). Cystoscopy is endoscopy of the urinary bladder via the urethra and is one of the most common procedures in urology practices. It is most often performed using white light, and is carried out with a specific endoscope, a cystoscope. There are two main types of cystoscopy—flexible and rigid—differing in the flexibility of the cystoscope. Flexible cystoscopy under local anaesthesia is associated with better patient acceptance, particularly in men. Many cystoscopes have extra tubes to guide other instruments for surgical biopsies or procedures to treat urinary problems (working channels). Compared to less invasive diagnostic modalities such as MRI, cystoscopy can observe the tumor size, position, shape, and surface nourishing blood vessels more clearly and intuitively under direct vision. Further, the accurate local staging of bladder carcinoma is key, as it has significant prognostic implications and determines treatment options.

In a recent US study, among an estimated 10.8 million visits to urologists by patients with hematuria from 2006 to 2012, cystoscopy was planned or performed only after 34.7% of visits. The authors conclude that 144,937 cancers—representing 1.3% of the entire hematuria cohort—may have been missed among hematuria patients who did not undergo cystoscopy in that period. The majority of these missed cases were among moderate-risk patients (91,640, 63% of missed cases). On an annual basis, there were 20,704 missed cancer cases per year in the US due to underuse ofcystoscopy, on average (David et al. 2017).

Further to the initial diagnosis, cystoscopy and cytology are recommended to be done at 3 months following transurethral resection of bladder tumor for surveillance. For low-risk tumors, annual cystoscopy alone is sufficient. High-risk tumors should be followed up with a more intense schedule: cystoscopy every 3 months for 2 years, 6 months for 2 years, and then annually, with cytology at frequent intervals.

This data shows the significant impact for not only the availability but also the systematic application of cystoscopic surveillance in health care systems from a societal perspective. A ban of PFAS in endoscopes would mean that almost none of the prognosed annual 549,000 patients diagnosed with bladder cancer would be detected at all or early enough to prevent disease progression. Further, diagnosed patients could not be treated by endoscopic resection of bladder carcinoma, or followed-up for disease surveillance.

Given a global age-standardized rate of 5.6/100,000 for newly detected bladder carcinoma (Saginala 2020), and 0.05 to 0.1% of urologic patients presenting with macrohematuria to urologists who

finally are diagnosed with bladder cancer, 549,000 annual new cases of bladder carcinoma represent up to between 275 million and 550 million patients with macrohematuria globally who could not be given the chance to detect, prevent, cure or control their fatal disease, and in the long run subjecting 549,000 patients dying annually from the disease. The current 5-year survival with BC averages 70% in Europe, this is to the largest part caused by the high level of care, and in that respect to the availability of cystoscopy (Richters et al. 2020).

The role of endoscopy in upper respiratory tract cancer diagnostics and treatment

In 2012, the estimated incidence of upper respiratory tract cancer (laryngeal, oropharyngeal and hypopharyngeal) was close to 300,000 patients a year, with close to 180,000 deaths secondary to these cancers (Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries). By 2020, the incidence was 184,615 for larynx, 133,354 for nasopharynx, 98,412 for oropharynx and 84,254 for hypopharynx (grand total of 500,635). The death rate was 266,590 (Laryngeal and Hypopharyngeal Cancer_ Statistics _ Cancer.Net). With the rising rate of these anomalies and the increased cost of health care, cost-effectiveness become a critical factor in oncology where patient-centered care is the norm. Minimally invasive technologies and a rapid workup fit this trend. Rigid and flexible digital endoscopy and their progression can address these issues by improving the assessment of these lesions in the upper respiratory tract. Furthermore, some of these endoscopes have working channels for tools used for biopsies and to perform surgical procedures. The digital capabilities allow for high-quality documentation for sharing with other professionals and as a mean to compare lesions throughout time.

Digital video rigid and flexible laryngoscopes have proven to be more accurate in establishing the extent of laryngopharyngeal carcinoma, to detect secondary primary tumors and to improve office-based diagnostic and therapeutic procedures. Having patients under anesthesia may not be necessary for the diagnostic workup of these carcinomas anymore. Rigid and flexible laryngoscopes may reduce costs, decrease diagnostic workup time, avoid pre-operative evaluation by anesthesiologists and prevent the risks of general anesthesia in patients who already have a significant compromise of the airway. Moreover, timely diagnosis and treatment may decrease anxiety improving functional and oncologic outcomes. Schutte et al reported on a good success percentage per initial biopsies of the upper respiratory tract, and shorter workup and treatment times with laryngoscopy. No statistically significant difference was found when comparing flexible and rigid laryngoscopes (see tables and figures below) (Wellenstein et al. 2017).

Table 2. Success Percentage of Initial Biopsies per Site.

Biopsy Site	Office-Based Flexible Endoscopic Biopsy	Rigid Laryngopharyngoscopy	*P* Value
Oropharynx	100% (n = 10)	95.3% (n = 43)	NS
Hypopharynx	100% (n = 8)	92.0% (n = 50)	NS
Supraglottis	84.0% (n = 25)	88.5% (n = 26)	NS
Glottis	100% (n = 10)	75% (n = 12)	NS
Other[a]	—	100% (n = 4)	—
Total	92.5% (n = 53)	91.1% (n = 135)	NS

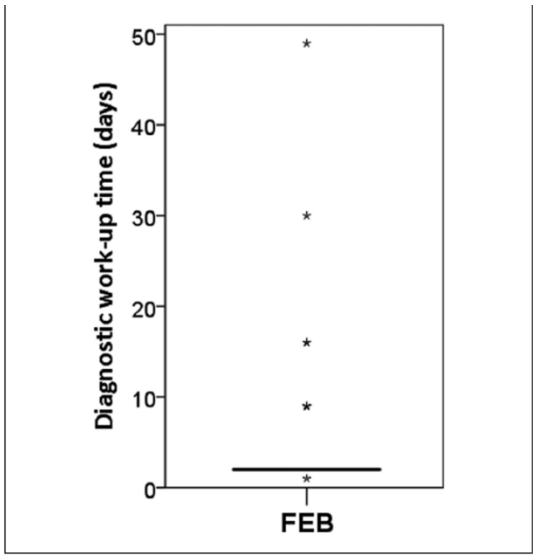

Figure 1. Box plot of duration of the diagnostic process.
Abbreviation: FEB, flexible endoscopic biopsy (office-based).

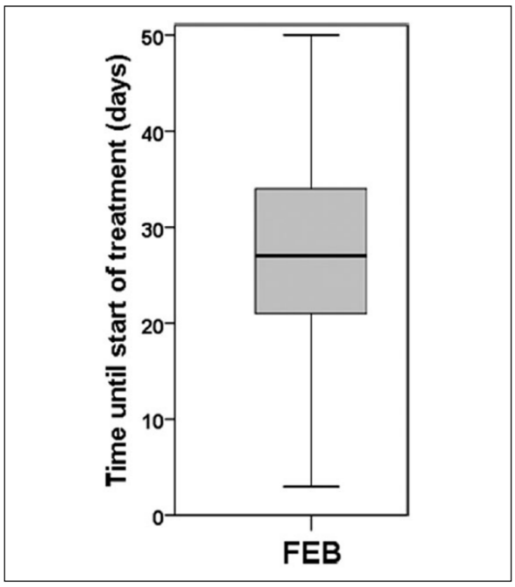

Figure 2. Box plot of time until start of treatment.
Abbreviation: FEB, flexible endoscopic biopsy (office-based).

Wellenstein et al reported on their results with office-based management of patients with benign and premalignant laryngeal lesions (Wellenstein et al. 2017). Their series included 30 consecutive procedures. Patients who fulfilled the inclusion criteria underwent a laryngoscopic biopsy prior to the definitive procedure. A CO2 laser flexible laser fiber was used to perform all the procedures. No complications occurred in 29 patients (one patient developed severe gag reflex preventing the laryngoscopy from being completed). The Voice Handicap Index (VHI) had a mean score of 44 prior to the resections. This score dropped to 14 at 6-months follow-up. Most of the patients had no residual or recurrent disease (19). They concluded that the use of flexible CO2 laser fibers through the working channels of flexible laryngoscopes is a safe and effective procedure.

Hartl and Brasnu reported on the oncologic results related to the surgical management of early glottic cancer (Hartl und Brasnu 2015). They compared the use of CO2 laser via laryngoscopy (TLM) versus radiation therapy (RT). Furthermore, they highlighted how TLM has significantly surpassed the use of open conservation laryngeal surgery, displaying complete and oncologically sound resection with less morbidity and without compromising oncological outcomes. They concluded that for early-stage glottic squamous cell carcinoma T1-T2, TLM is the most relevant surgical option today, with rates of local control and laryngeal preservation ranging from 85% to 100% and low morbidity.

Socioeconomic risk-assessment of a PFAS restriction on endoscopy

We agree that there are detrimental health and environmental effects associated with the use of PFAS. However, the main bulk of such effects comes from the use of PFAS in products that are used, and food and water that are consumed in millions of households around the world.

The PFAS used in components of endoscopes are in limited contact with the internal anatomy of the patient.

Furthermore, rigid and flexible endoscopy have been used in millions of patients for many years for indications such as the ones described in the background. To date, we cannot find a scientific report

in the literature discussing clinical risks or adverse health reactions due to the PFAS contained in some parts of the endoscopes. With the objective information provided here, a special consideration should be given to the use of PFAS in these devices to ensure safe and effective reprocessing of these products.

The case of cycstoscopy and endoscopy oft he upper respiratory tract for the prompt and accurate diagnosis and treatment of carcinomas serve as strong examples. Without PFAS, these rigid and flexible endoscopes could not be disinfected and sterilized properly hence, could not be used for the benefit of these patients.

The socioeconomic impact would be massive by slowing the diagnosis and treatment flow with an expectable spike in the number of deaths secondary to these carcinomas. Furthermore, the increase in cost would put a dent in health economics and outcomes.

The fact that the direct benefits provided to the health systems by endoscopy massively outweigh the indirect PFAS risks clearly shows that a comprehensive ban for PFAS in medical devices is not acceptable ethically and from asocioeconomic perspective. Careful thought must be given to the implications of supply chain change or transition of materials that would require a significant timeframe with the consequent clinical and socioeconomic impact. Today, alternative materials with comparable properties are not yet known, and gaps in the provision of life-saving care to patients due to a regulatory ban of an entire class of design materials are incompatible with the protection of the life and health of EU citizens

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Analytik von polyfluorierten und perfluorierten Alkylsubstanzen (PFAS)

Die Bestimmung von polyfluorierten und perfluorierten Alkylsubstanzen (PFAS) stellt auf Grund der großen Stoffvielfalt (geschätzt: > 10000 Substanzen) mit verschiedensten chemischen Strukturen und Isomerengemischen, sowie unterschiedlichster Polarität eine große Herausforderung an die Analytik. Standard- und Referenzsubstanzen, die zur Kalibrierung von Analysegeräten genutzt werden müssen, sind oft nicht verfügbar. Standards, die zur analytischen Bestimmung der (PFAS) Substanzen zur Verfügung stehen, sind hauptsächlich im Bereich der Umweltanalytik (beispielsweise zur Analyse von Wasser- und Bodenproben) und nur für einzelne Substanzen (<100) verfügbar [1]. Mit der Norm DIN 38409-59:2022 DE [2] steht ein Verfahren zur Messung des Summenparameters adsorbierbares organisch gebundenes Fluor (AOF) zur Verfügung. Eine eindeutige Zuordnung zu Einzelsubstanzen ist damit aber nicht möglich. Eine weitere Analysemöglichkeit, auch für Feststoffproben, bietet der Total Oxidizable Precursor (TOP)-Assay. Das Analysenprinzip des TOP-Assay besteht darin, unbekannte PFAS Vorläuferverbindungen oxidativ in Perfluorcarbonsäuren (PFCA) umzuwandeln, die somit quantifizierbar sind. Damit ist es möglich in Screening-Verfahren PFAS-Gehalte in Umweltproben abzuschätzen. Das Konzept des TOP-Assay ist selektiver als beispielsweise Messungen der Summenparameter EOF (extrahierbare organische Fluorverbindungen) und AOF. Eine detaillierte Studie zur genaueren Bewertung der Möglichkeiten und Grenzen der TOP-Assay-Methodik und deren Aussagekraft wurde 2022 veröffentlicht [3].
Zusammenfassend lässt sich sagen, dass nach dem derzeitigen Stand der Forschung, und unserem Kenntnisstand, die Analytik der ca. 10.000 Einzelsubstanzen in Medizinprodukten nicht möglich ist. Hier besteht erheblicher Forschungsbedarf, mit Fokus auf der Entwicklung geeigneter Methodenanalytik.

[1] Stand der PFAS-Analytik, Nachweisgrenzen und Summenparameter Dr. Manfred Sengl, Hanna Ulrich LfU, Ref. 75/76 21.10.2021
[2] DIN 38409-59:2022 DE DIN 38409-59:2022 DE
Deutsche Einheitsverfahren zur Wasser-, Abwasser- und Schlammuntersuchung - Summarische Wirkungs- und Stoffkenngrößen (Gruppe H) - Teil 59: Bestimmung von Adsorbierbarem Organisch Gebundenem Fluor, Chlor, Brom Und Iod (AOF, AOCl, AOBr, AOI) mittels Verbrennung und nachfolgender Ionenchromatographischer Messung (H 59)
[3] Studie zur Aussagekraft des Total Oxidizable Precursor-Assays (TOP-Assay) von methanolischen Bodenextrakten und wässrigen Eluate, LUBW Landesanstalt für Umwelt Baden-Württemberg Oktober 2022

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Herrn Dr. Martin Leonhard
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Sehr geehrter Herr Dr. Leonhard,

vielen Dank für Ihre Anfrage. Sie hatten uns gebeten zu bewerten, in wie fern sich eines unserer Institute in die Forschung zu bestimmten Ersatzwerkstoffen bereits einbringt oder einbringen kann. Es geht um Substitute für PFAS-Substanzen, spezifischer um Substitute zu Fluorpolymeren wie etwa PTFE, deren Nutzung in der EU weitreichend eingeschränkt werden soll. Diese Hochleistungswerkstoffe zeichnen sich dadurch aus, dass sie besonders inert sind und zum Beispiel in der Medizintechnik wegen der Kombination einzigartiger Eigenschaften wie Biokompatibilität, Reinigbarkeit, hoher elektrischer Durchschlagsfestigkeit, geringer Reibung und hoher Temperaturstabilität bisher in vielen Fällen als alternativlos betrachtet werden.

Als „Die Forschungsuniversität in der Helmholtz-Gemeinschaft" schafft und vermittelt das Karlsruher Institut für Technologie (KIT) Wissen für Gesellschaft und Umwelt. Ziel ist es, zu den globalen Herausforderungen maßgebliche Beiträge in den Feldern Energie, Mobilität und Information zu leisten. Dazu arbeiten mehr als 9 000 Mitarbeiterinnen und Mitarbeiter auf einer breiten disziplinären Basis in Natur-, Ingenieur-, Wirtschafts- sowie Geistes- und Sozialwissenschaften zusammen.

Leider konnten wir am KIT kein Institut identifizieren, das Materialforschung zur Ermittlung äquivalenter Ersatzsubstanzen für PFAS – und speziell für Fluorpolymere wie PTFE – durchführt.

Karlsruhe, den 19. April 2023

Prof. Dr. Thomas Hirth
Vizepräsident für Transfer und Internationales

Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions

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Significance and Motivation

A recent study by Conversio, a consultancy based in Germany, has shown that at its end-of-life approximately 85% of all fluoropolymers end up in waste-to-energy recovery incinerators. A subsequent question of regulators was: Do fluoropolymers get fully incinerated without any formation of short chain or long chain PFAS? A recent project executed by the Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS) was conducted to assess the same.

Experimental Parameters

Main applications of the four highest volume fluoropolymers (PTFE, PVDF, PFA and FKM) representing more than 80% of commercial fluoropolymer production based on data from Pro-K (German association of polymers processors) were considered. Post-use samples from these applications were incinerated as a mixture under standard operating conditions for municipal and industrial waste incineration. Figure 1 presents the experimental conditions. Experiments were conducted under two sets of conditions over a period of 9 days. The first experiments were conducted at a process setting of 860°C and 2.0 s residence time. These experiments were conducted in three stages. Initially, background tests were performed using natural gas and 100 kg/h wood chips. This was followed by the same fuel conditions with the addition of 320 g/h of fluoropolymer. The final test involved switching back to background conditions. The duration of each of these tests ranged from 9 – 13 hrs. A second set of experiments was conducted at a process setting of 1100°C and 2.0 s residence time. These tests were conducted in the same sequence as the first set of tests. The feed rates for the wood chips and the fluoropolymer mixture were identical to the tests at 860°C and 2.0 s residence time. The test duration for this second set of tests also ranged from 9 – 13 hrs.

test	parameters	number of HF and PFAS sampling	locations	duration [hrs]	RUN	date / remarks		day
start-up with natural gas and oil				24		25.2.23; 10 a.m.	day 1 and 2	
starting solid feeding (wood chips)				24		26.2.23; 10 a.m.		
background of rotary kiln / combustion chamber with oil, natural gas and 100 kg/h wood chips	T_{PCC}: 860 °C; 2.0 s	3	Top of post-combustion chamber (E1b), after boiler, stack	11	1	27.2.2023; 9 am	day 3	Monday
solid fuel: woodchip (100 kg/h) + 320 g/h FP together with oil and natural gas		no		9		feeding of fluoropolymers over night		
		3		11	2	28.2.2023; 9 am	day 4	Tuesday
background of rotary kiln / combustion chamber with oil, natural gas and 100 kg/h wood chips		no		13		stop feeding flouropolymers in the evening		
		3		11	3	01.03.2023; 9 am	day 5	Wednesday
Change of temperature post combustion chamber				12		over night		
background of rotary kiln / combustion chamber with oil, natural gas and wood chips	T_{PCC}: 1100 °C; 2.0 s	3	Top of post-combustion chamber (E1b), after boiler, stack	11	4	02.03.2023; 9 am	day 6	Thursday
solid fuel: woodchip (100 kg/h) + 320 g/h FP together with oil and natural gas		no		9		feeding of fluoropolymers over night		
		3		11	5	03.03.2023; 9 am	day 7	Friday
background of rotary kiln / combustion chamber with oil, natural gas and 100 kg/h wood chips		no		13		stop feeding flouropolymers in the evening		
		3		11	6	04.03.2023; 9 am	day 8	Saturday
shut down				24			day 9	

Material	Mass fraction [wt.-%]
PTFE tubes	63,00
PTFE tape	7,00
PVDF	18,00
PFA	6,00
FKM rubber	6,00

mass flow = 320 g/h

Figure 1: Experimental setup

The fluoropolymers were fed as a mixture at relative proportions that correspond to the mass fractions sold in the European marketplace. These data are also shown in Figure 1. Suspension and emulsion polymerized PTFE application samples represented about 70 mass percent of the fluoropolymer feed rate.

The main operational parameters for the two sets of tests are summarized in Figure 2. The temperature of the flue gas outlet exiting the rotary kiln was in the range of 800-900°C. The temperature of the flue gas post-combustion chamber outlet was very close to the targets for these tests (860°and 1100°C in the combustion chamber for setting 1 and 2, respectively). The O_2 and CO measurements for setting 1 and 2 varied somewhat. For setting 1, the values were 11.2 vol % dry and 0.2 mg/m^3, respectively, while for setting 2 the O_2 measurements were somewhat lower (7.0 % with an increase in the CO concentration (1.2 mg/m^3). The water vapor concentration as measured in the boiler exit ranged from 6.2% in setting 1 to 8.49% in setting 2.

			setting S1	setting S2
		unit	RUN 1, 2, 3	RUN 4, 5, 6
Rotary kiln	mass flow wood chips	kg/h	98	98
	main air	m_N^3/h	418	423
	mass flow heating oil	kg/h	61	46
	volume flow natural gas	m_N^3/h	4	4
	volume flow combustion air	m_N^3/h	872	753
	inclination	°	2	
	rotation speed	rev p.m.	0.2	0.4
	temperature flue gas outlet	°C	800 - 900	
	thermal power	MW	1.1	0.9
combustion chamber	volume flow natural gas to burner D4.1	m_N^3/h	22	35
	sum of volume flow combustion air to burner D4.1	m_N^3/h	671	429
	volume flow natural gas to burner D4.2	m_N^3/h	22	35
	sum of volume flow combustion air to burner D4.2	m_N^3/h	671	428
	residence time	s	2	
	temperature flue gas post-combustion chamber outlet (with control)	°C	860	1095
	CO (level E2)	mg/m^3	0.2	1.2
	O_2 (level E2)	Vol.-% dry	11.2	7.0
	thermal power	MW	0.46	0.72
	total thermal power rotary kiln and post combustion chamber	MW	1.59	1.67
boiler / fluegas	volume flow	m_N^3/h	3958	3238
	O_2	Vol.-% dry	11.9	9.0
	CO	mg/m^3	1.35	1.64
	water vapour	Vol.-% wet	6.20	8.49

Figure 2: Main operational parameters at two experiments

There were multiple sampling locations for this study. Flue gas was sampled near the exit of the combustion chamber (location 1), at the exit of the boiler (location 2), and at the entrance to the stack (location 3), while liquids and residues were also sampled and analyzed after each RUN (see Figure 3, Test facility sampling locations).

The test facility BRENDA comprises a rotary kiln with a post-combustion chamber, a boiler for heat recovery and a flue gas cleaning system, which complies with German emission regulations (17 BImschV). The thermal power of the rotary kiln is of maximum 1.5 MW, while that of the post-combustion chamber is about 1 MW, which results in a total thermal output of BRENDA of maximum 2.5 MW.

The fluoropolymers mixture after blending with wood chips and consequent weighing was delivered to the rotary kiln. To secure optimal combustion conditions, natural gas and heating oil were supplied additionally to the rotary kiln, while the post combustion chamber was supplied with natural gas only.

The mass flow of the fluoropolymers mixture was set at 320 g/h, which corresponds to a pure Fluorine mass flow of 230 g/h. This level increases the fluoropolymer ratio to fuel, while at the same time keeps the Fluor-concentration below the total halogen limit of 1%, as set by the legislature.

The combustion gases of the rotary kiln enter the post combustion chamber (PCC). It contains two natural gas burners staggered in an antiparallel manner, with a slight shift to each other. The temperature and the residence time in PCC were adjusted mainly with the help of the above mentioned burners, supported by a slight shift of about 200 kW into the post combustion chamber.

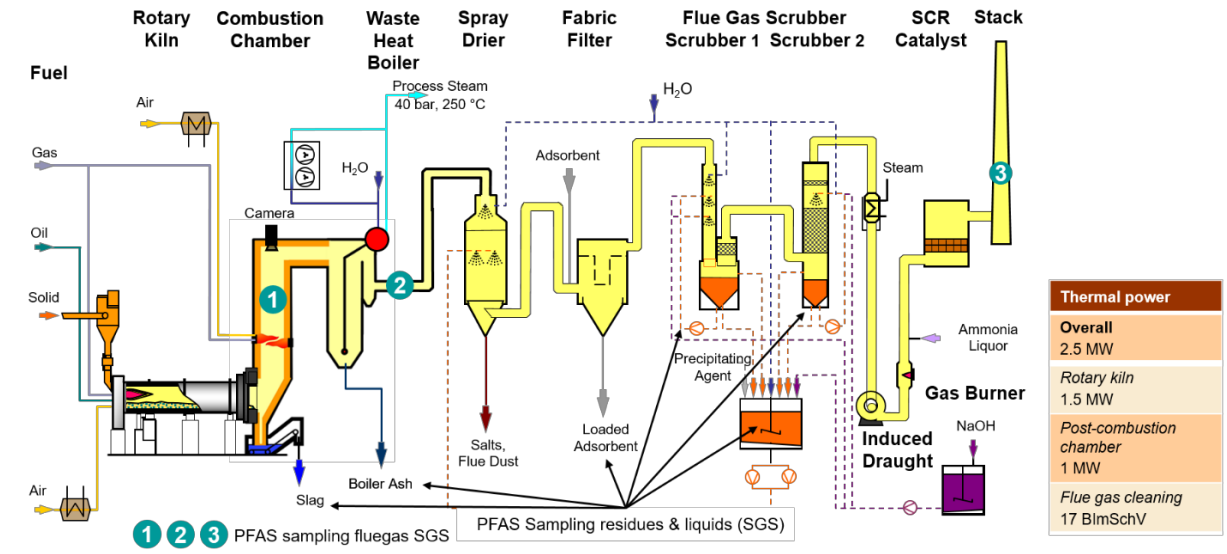

Figure 3: Test facility-BRENDA at KIT

The minimum residence time is calculated according the methodology of the German Technical Supervision Agency ("TÜV") from 2007. The data which were published in the report were re-calculated and then adapted to the operational conditions in this study (Setting 1 and Setting 2). Figure 4 presents the layout of the post combustion chamber with the geometry relevant for the determination of the residence time.

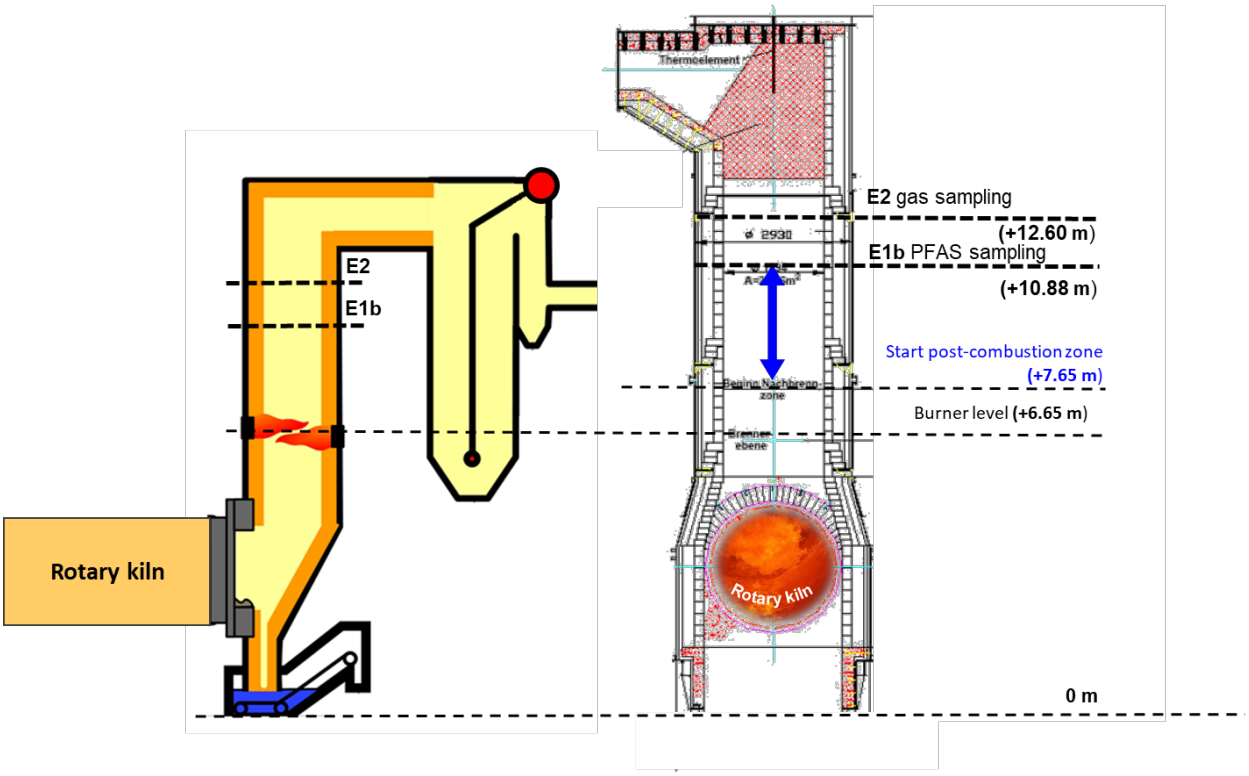

Fig. 4: BRENDA layout with details relevant for the residence time

Table 1 shows the detailed values for the design of the settings.

The volume flow of the required flue gas amount to reach the two seconds was calculated with a target value search.

Table 1. Parameters calculated for the residence time in the PCC

PFAS Project, Level E1b		
	setting 1	**setting 2**
Start post combustion zone [m] 1 meter above the burners	7.65	7.65
Temperature in the post combustion chamber (PCC) [°C]	860	1100
Volume flow V_{PCC} [m_N^3/h wet] after boiler	3947	3257
Cross section PCC [m^2]	2.82	2.82
Volume flow V_{PCC} [m^3/h]	16,382	16,382
Height h [m] level E1b	10.88	10.88
Residence time from start PCC zone to level E1b [s]	**2.00**	**2.00**

The two seconds are the residence time of flue gas from start of post-combustion zone until PFAS sampling point E1b, calculated with calibrated temperature measurements on the top of post combustion chamber (PCC).

The flue gas was sampled for both short-chain and long-chain PFAS in addition to organic and inorganic fluoride. Volatile organic C_1-C_4 fluorocarbons were also sampled using a tedlar bag at all three sampling locations. At location 2, gas-phase HF was measured in near real-time using a tunable diode laser (TDL). The purpose of the three gas-phase sampling locations was to assess the potential emissions of PFAS at different locations in the system and to use this data to assess potential sources of PFAS in this system. PFAS sampling of residues and liquids is also shown in Figure 3. In addition to these three sampling points, flue gas scrubber water upstream of the SCR catalyst was collected and analyzed for PFAS.

Table 2 provides a list of analytes measured in this study and the Limit of Quantification (LOQ). In addition to PFAS and fluoride ion, volatile C_1-C_4 fluorocarbons and trifluoroacetic acid (TFA) were also measured. The C_1-C_4 fluorocarbons were measured by gas chromatography coupled to mass spectrometry (GC-MS). Adsorbable organic fluoride (AOF) was measured using Combustion Ion Chromatography (CIC) and inorganic fluorine in impinger samples were measured by Ion Selective Electrode. TFA was measured using Ion chromatography (IC) and long chain PFAS from impinger samples were measured using Ultrahigh-Performance Liquid Chromatography coupled to tandem Mass Spectrometry (UPLC-MS/MS). HF was also measured at the post-combustion zone location using TDL spectroscopy.

Appendix 1 presents a list of long-chain PFAS measured in this study.

Table 2. Analytes and reporting limits

Analyte	LOQ
Volatile C1-C4 Compounds	5-30 ug/m^3
(CF4, CHF3, C2F6, C2HF5, CF2=CF-CF3, cy-C4F8)	
Adsorbable Organic Fluorine	2 ug/L
Inorganic Fluorine	0.1 ug/L
Trifluoroacetic Acid	0.02 ug/L
PFAS (see Appendix for list of compounds measured)	0.02 ug/L

Note: LOQ for AOF, Inorganic fluorine, TFA, and PFAS are for aqueous samples.

Experimental Results

Fluorine Recoveries

Fluorine recoveries ranged from 69 to 84% using the TDL (at sample location 2). The variability in these data from run to run was low. In contrast, the impinger data analyzed at the same sample location showed about 10 to 20% lower fluorine recoveries. The data are summarized in Table 3. The TDL data provide strong evidence for complete mineralization of fluoropolymer feed mixture.

Table 3: Fluorine Recovery (TDL Measurement)

Run	Settings	HF (TDL)	volume flow @standard wet conditions	volume flow @270 °C	Fluorine	Fluorine Recovery
		mg/m_B^3 wet Gas	[m_N^3/h]	[m_B^3/h]	g/h	%
2	860°C, > 2s, oil + nat. gas + wood chips + 230 g/h F	23.50	3,956	7,866	175.64	76%
		23.93	3,952	7,859	178.62	78%
		25.80	3,943	7,841	192.16	84%
5	1100°C, > 2s, oil + nat. gas + wood chips + 230 g/h F	25.44	3,299	6,560	158.53	69%
		26.58	3,231	6,424	162.23	71%
		26.93	3,217	6,397	163.64	71%

Long-chain PFAS

A large majority of the PFAS measured in impinger samples were near or below reporting limits (>98% of data collected at 860°C and >96% of data collected at 1100°C). Table 3 presents PFAS data for 4 compounds where measurements exceeded reporting limits in several cases. Of particular note is a HFPO-DA measurement which exceeded reporting limits by a factor of 47. Maximum PFBA, PFBS, and 6:2 FTS measurements exceeded reporting limits by much lower factors, ranging from 9 – 12.

These data was re-analyzed to assess the veracity of data. The results are also presented in Table 4. The results indicate that the high measurement values for HPFO-DA could not be reproduced. The results for PFBA and PFBS were also lower when re-analyzed. The lack of reproducibility of data and the lower

measurement values upon re-analysis suggests that cross-contamination is a possible reason for high measurement values for HPDO-DA, PFBA, and PFBS in the initial analysis.

PFAS analyses of wastewater and ash residue samples indicated a large majority of the samples were below reporting limits. One notable exception was a deslagger water bath sample where HFPO-DA was a factor of 16 above the report limit.

Table 4. PFAS Analysis of Impinger Samples

Initial Analysis

PFAS Compound	RL (ng/m^3)	# > RL	ng/m^3 (max)
PFBA	2.8	5	35.8
PFBS	1.4	22	19.5
6:2 FTS	1.4	17	12.5
HFPO-DA	1.4	31	66.3

Re-Analysis

PFAS Compound	RL (ng/m^3)	# > RL	ng/m^3 (max)
PFBA	2.8	0	2.8
PFBS	1.4	7	10.7
6:2 FTS	1.4	11	16.2
HFPO-DA	1.4	16	25.2

Note: For each data set, the total number of measurements equal 54: 27 for each combustion condition.

Short-chain PFAS

TFA was non-detect for all 76 impinger samples analyzed, at a reporting limit of 14 $\mu g/m^3$ (ppb).

Volatile Fluorocarbons (FC)

Tetrafluoromethane (CF_4) was the only volatile FC detected in the GC-MS analysis. Values of CF_4 at stack were near detection limits (20-27 $\mu g/m^3$) and detected in 2 of 14 samples. The results are considered questionable because CF_4 was only detected in one post-combustion sample. There is no plausible reason for larger CF_4 values downstream of the combustion unit unless a non-combustion source is considered.

Discussions

There is one prior published pilot-scale study of the combustion of PTFE (Aleksandrov et al. 2019). Combustion tests were performed at two conditions: 870°C and 4 s residence time and 1020°C and 2.7 s residence time and wood chips were used as the supplemental fuel. The prior study burned 0.3 wt % PTFE. Sampling was performed at a single location, downstream of the waste heat boiler. Thirty-one PFAS compounds were sampled and analyzed (see Table 1 of Aleksandrov et al. for a list of PFAS measured).

Fluorine recoveries were determined indirectly via IR water vapor measurements. The fluorine recoveries ranged from 56 to 78%, with three of the four tests yielding recoveries less than 70%. Eleven PFAS compounds were detected from the combustion and/or control samples and each at a level above 100 ng/m^3 in at least one sample. PFOA was detected in all but one sample and at values as high as 2.7 $\mu g/m^3$ (see Table 3 of Aleksandrov et al.).

The current study differs from the prior test in two important ways. The fluorine recoveries in this study were determined from direct spectroscopic measurements and were above 70% in five of the six tests. Secondly, PFAS reporting limits were on the order of 1 ng/m^3 or less and a large majority of samples (>98%) were at or below reporting limits. The current study provides strong evidence that incinerating a mixture of fluoropolymers under representative municipal waste combustion conditions leads to complete mineralization of the C-F bonds, no significant emissions of long-chain PFAS, and no significant emissions of TFA or light fluorocarbons such as CF_4 or C_2F_6. The prior study did not provide evidence that the PFAS detected were from sources other than the combustion of PTFE.

Conclusions

The study clearly demonstrated that fluoropolymers are converted to inorganic fluorides and carbon dioxide. The inorganic fluorides detected were hydrogen fluoride. A large majority of samples indicated that long-chain PFAS were below levels of 1 ng/m^3 (> 99% of samples associated with 860°C condition and > 98% of samples associated with 1100°C condition). There were no short chain PFAS detected post incineration. TFA was non-detectable in all samples with a reporting limit of 14 $\mu g/m^3$. **The results confirm that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment.**

The main reason to include fluoropolymers in the EU PFAS restriction proposal was persistence (resistance to degradation in the environment) in the environment. The absence of organic fluorides and more specifically PFAS in tests representative of municipal waste incineration confirms complete mineralization of fluoropolymers and provides critical data in support for exempting Fluoropolymers from the EU REACH PFAS restriction proposal.

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Appendices

1. List of long-chain PFAS analytes analyzed in this study

Common Name[a]	Abbreviated Name	CAS[b] Registry Number	Isotopic Pre-Extraction Pair
Perfluoroalkylcarboxylic acids (PFCAs)			
Perfluorobutanoic acid[1,3,4]	PFBA	375-22-4	$^{13}C_4$-PFBA
Perfluoropentanoic acid[1,3,4]	PFPeA	2706-90-3	$^{13}C_5$-PFPeA
Perfluorohexanoic acid[1,2,3,4]	PFHxA	307-24-4	$^{13}C_2$-PFHxA
Perfluoroheptanoic acid[1,2,3,4]	PFHpA	375-85-9	$^{13}C_4$-PFHpA
Perfluorooctanoic acid[1,2,3,4]	PFOA	335-67-1	$^{13}C_4$-PFOA
Perfluorononanoic acid[1,2,3,4]	PFNA	375-95-1	$^{13}C_5$-PFNA
Perfluorodecanoic acid[1,2,3,4]	PFDA	335-76-2	$^{13}C_2$-PFDA
Perfluoroundecanoic acid[1,2,3,4]	PFUnDA	2058-94-8	$^{13}C_2$-PFUndA
Perfluorododecanoic acid[1,2,3,4]	PFDoA	307-55-1	$^{13}C_2$-PFDoA
Perfluorotridecanoic acid[2,3,4]	PFTrDA	72629-94-8	$^{13}C_2$-PFDoA
Perfluorotetradecanoic acid[2,3,4]	PFTeDA	376-06-7	$^{13}C_2$-PFTeDA
Perfluoro-n-hexadecanoic acid	PFHxDA	67905-19-5	$^{13}C_2$-PFHxDA
Perfluoro-n-octadecanoic acid	PFODA	16517-11-6	$^{13}C_2$-PFDoA
Perfluorinated sulfonic acids (PFSAs)			
Perfluoro-1-butanesulfonic acid[1,2,3,4]	PFBS	375-73-5	$^{13}C_3$- PFBS
Perfluoro-1-pentanesulfonic acid[1,3]	PFPeS	2706-91-4	$^{13}C_3$-PFHxS Or $^{13}C_3$-PFBS
Perfluoro-1 -hexanesulfonic acid[1,2,3,4]	PFHxS	355-46-4	$^{18}O_2$-PFHxS or $^{13}C_3$-PFHxS
Perfluoro-1-heptanesulfonic acid[1,3]	PFHpS	375-92-8	$^{13}C_4$-PFHpA
Perfluoro-1-octanesulfonic acid[1,2,3,4]	PFOS	1763-23-1	$^{13}C_4$-PFOS
Perfluoro-1-nonanesulfonic acid[3]	PFNS	68259-12-1	$^{13}C_4$-PFOS
Perfluoro-1-decanesulfonic acid[3]	PFDS	335-77-3	$^{13}C_4$-PFOS
Perfluorododecane sulfonate	PFDoS	79780-39-5	$^{13}C_4$-PFOS
Perfluorinated sulfonamides (FOSAs)			
Perfluoro-1-octanesulfonamide[3,5]	FOSA	754-91-6	$^{13}C_8$-FOSA
N-Methylperfluorooctanesulfonamide [5]	MeFOSA	31506-32-8	d3-MeFOSA
N-ethylperfluorooctanesulfonamide [5]	EtFOSA	4151-50-2	d5-EtFOSA
Perfluorinated sulfonamidoacetic acids (FOSAAs)			
N-methyl perfluorooctanesulfonamidoacetic acid[2,3]	MeFOSAA	2355-31-9	d3-MeFOSAA
N-ethyl perfluorooctanesulfonamidoacetic acid[2,3]	EtFOSAA	2991-50-6	d5-EtFOSAA
Fluorotelomer sulfonates (FTS)			
1H,1H,2H,2H-Perfluorohexane sulfonic acid[1,3]	4:2 FTS	757124-72-4	M2-4:2 FTS
1H,1H,2H,2H -Perfluorooctane sulfonic acid[1,3]	6:2 FTS	27619-97-2	M2-6:2 FTS
1H,1H,2H,2H -Perfluorodecane sulfonic acid[1,3]	8:2 FTS	39108-34-4	M2-8:2 FTS
1H,1H,2H,2H-perfluorododecane sulfonate (10:2)	10:2 FTS	120226-60-0	M2-10:2 FTS
Fluorinated Replacement Chemicals			
4,8-Dioxa-3H-perfluorononanoic acid	ADONA[1]	919005-14-4	$^{13}C_4$-PFOS
Hexafluoropropylene Oxide Dimer Acid	HFPO-DA (GenX)[1]	13252-13-6	$^{13}C_3$-HFPO-DA
Additional Targets			
Decafluoro-4-(pentafluoroethyl)cyclohexanesulfonate)[4]	PFecHS	67584-42-3	$^{18}O_2$-PFHxS

Fluorinated Replacement Chemicals			
9-Chlorohexadecafluoro-3-oxanonane-1-sulfonic acid	9Cl-PF3ONS (F-53B Major)[1]	756426-58-1	$^{13}C_4$-PFOS
11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid OR 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonate[a]	11Cl-PF3OUdS (F-53B Minor)[1]	763051-92-9 83329-89-9	$^{13}C_4$-PFOS

Perfluorinated sulfonamide ethanols (FOSEs)			
2-(N-methylperfluoro-1-octanesulfonamido)-ethanol[5]	N-MeFOSE	24448-09-7	d7-N-MeFOSE
2-(N-ethylperfluoro-1-octanesulfonamido)-ethanol[5]	N-EtFOSE	1691-99-2	d9-N-EtFOSE
Additional Targets			
Nonafluoro-3,6-dioxaheptanoic acid[1,5]	NFDHA	151772-58-6	$^{13}C_5$-PFHxA
Perfluoro(2-ethoxyethane)sulfonic acid[1,5]	PFEESA	113507-82-7	$^{13}C_3$-PFBS
Sodium perfluoro-1-dodecanesulfonate[5]	PFDoS	1260224-54-1	$^{13}C_4$-PFOS
Perfluoro-4-methoxybutanoic acid[1,5]	PFMBA	863090-89-5	$^{13}C_5$-PFPeA
Perfluoro-3-methoxypropanoic acid[1,5]	PFMPA	377-73-1	$^{13}C_4$-PFBA
3:3 Fluorotelomer carboxylic acid[5]	3:3 FTCA	356-02-5	$^{13}C_2$-FHEA
5:3 Fluorotelomer carboxylic acid[5]	5:3 FTCA	914637-49-3	$^{13}C_2$-FHEA
7:3 Fluorotelomer carboxylic acid or 3-perfluoropheptyl propanoic acid[4, 5]	7:3 FTCA or FHpPA	812-70-4	$^{13}C_2$-FOEA
2H-perfluoro-2-decenoic acid[4]	8:2 FTUCA or FOUEA	70887-84-2	$^{13}C_2$-FOUEA
2-perfluorodecyl ethanoic acid[4]	10:2 FDEA	53826-13-4	$^{13}C_2$-FDEA
2-perfluorooctyl ethanoic acid[4]	8:2 FTA or FOEA	27854-31-5	$^{13}C_2$-FOEA
2H-perfluoro-2-octenoic acid[4]	6:2 FHUEA	70887-88-6	$^{13}C_2$-FHUEA
2-perfluorohexyl ethanoic acid[4]	6:2FTCA or 6:2 FHEA	53826-12-3	$^{13}C_2$-FHEA