PTFE / ePTFE[1] Components for Medical Devices
Essential Use of PTFE in the Scope of the PFAS Regulation Proposal

PTFE is used in many applications as critical component. In the current proposal for future PFAS regulation, it is considered to be as potentially harmful as any other short chain or low molecular weight PFA substances. Hence, a complete ban of PTFE on the European market, is called for.

Lenzing Plastics is in favor of a stringent PFAS restriction. However, PTFE as a polymer shall be excluded, generally, as being rated as Polymers of Low Concern (PLC) [2,3]. And especially the usages, we are showing here, demonstrate that use of PTFE in the described ways and application areas is both: very safe and very crucial.

Banning PTFE within EU would be a severe drawback in medical treatments for European citizens, leading to a 3rd class health care in our region, as a whole.

1. Why PTFE is used in medical applications and for what specific products at Lenzing Plastics

PTFE is a well-known material for excellent performance even in the most challenging class 3 for medical devices, i.e. in permanent implants. The utilization of PTFE in medical devices has gained considerable momentum over the past few decades, proofing its suitability for the most demanding applications. Its excellent biocompatibility, some call it bio-inertness, is reflected in many medical device registrations around the world. Regarding our e.g. PTFE sutures, we and all our respective customers, too, performed and easily passed biocompatibility testing according to ISO 10993[4,5] and/or FDA requirements. Studies have also proven none or only insignificant inflammatory responses and tissue reactions, upon contact with PTFE components, reducing risk of adverse or even rejection reactions in patients. In addition, PTFE is a very stable material with no polymeric degradation long-term. Its non-reactive nature ensures the preservation of the device's structural integrity and prevents the release of harmful substances into the patient's body. The most outstanding property is, however, the flexibility combined with softness and absolute smooth and non-adhesive surface. The low coefficient of friction of PTFE reduces wear and tear in moving parts of medical devices, leading to improved durability and efficiency. In devices that come into contact with blood, such as vascular grafts or heart valves, PTFE has proven to be highly hemocompatible. It minimizes the risk of clot formation and platelet activation, ensuring safe and efficient blood flow.

1.1. ePTFE suture yarns

Lenzing Plastics is converting PTFE resin into different components for medical devices for more than 15 years now, and can look back at experience of PTFE processing of several decades. Especially in the area of heart valve manufacturing, PTFE yarns and sutures of Lenzing Plastics are the first choice for most of the leading players globally. At the beginning in sewing rings of

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[1] Expanded polytetrafluoroethylene, or ePTFE is having a microporous structure
[2] B. Ameduri, H. Hori, *Chem. Soc. Rev.,* **2023***, 52,* 4208
[3] B.J. Henry,J.P. Carlin, J.A. Hammerschmidt, R.C. Buck, L.W. Buxton,H. Fiedler, J. Seed, O. Hernandez, *Integr. Environ. Assess. Manag.,* **2018***, 14,* 316
[4] Foosin Medical Supplies Inc., Ltd.*, Biocompatibility study,* **2017**
[5] Lenzing Plastics, *Cytotoxicity tests*, **2023**

conventional valves, lately as suture to fix the leaflets on the frame of minimal invasive valves for aortic, mitral or tricuspid repair. Here, the continuous dynamic exposure to stress and release for trillions of cycles is very hard to withstand for common materials. Lenzing Plastics PTFE sutures have proven to be the best choice for such challenges. They are e.g. also used in replacing the chordae tendineae that link the mitral heart valve leaflets to the papillary muscles for opening and closing the valve again and again and again.

Further info: https://www.lenzing-plastics.com/en/markets-and-solutions/medical-components-hygienic-products/yarns-for-heart-valves/

Figure 1: https://www.edwards.com/de/devices/Heart-Valves/Transcatheter-Sapien-3

Beside all cardiovascular applications, our suture is gold standard in dental surgery. PTFE sutures are ideal for all implant, periodontal and bone grafting procedures where use of a monofilament suture, exhibiting low bacterial adhesion, is desirable. They are particularly soft, biologically inert and chemically non-reactive. Unlike other synthetic monofilament sutures, the material is exceptionally well tolerated in the oral cavity[6]. Also, PTFE sutures are ideal for reducing inflammation potential, bleeding and other side effects that can arise when bringing tissue edges together[7]. Removal of a temporary implant made of PTFE, in contrast to alternative materials, is easy and appreciated by patients, due to PTFE's inherent smooth surface and gliding characteristics.

Lenzing Plastics is supplying suture yarns on the spool/reel. Manufactured according to Medical Standard, ISO 13485, in a controlled or clean room environment, respectively, following the required strict standards of quality and contamination control.

Different families of PTFE sutures are available, tailored to the specific need of the end use. There is an S version (= soft), focusing totally on the strengths of PTFE – softness and flexibility. Alternatively, an HS version (= high strength) can be supplied, with much higher tenacity, yet, compared to S, lower flexibility.

Further info: https://www.lenzing-plastics.com/en/markets-and-solutions/medical-components-hygienic-products/ptfe-suture-material/

Figure 2: https://www.bbraun.com/en/products/b2/elasyn.html

[6] S. Parrini, A. Bovicelli, G. Chisci, Antibiotics, **2023**, *12*, 562
[7] M. Dang, J.G. Thacker, J. Hwang, G. T. Rodeheaver, S.M. Melton, R.F. Edlich, Arch. Surg., 1990, 125, 47

1.2. ePTFE tubing

Over the years we started to apply and use the outstanding benefits of PTFE/ePTFE in other components than yarns and sutures. In the field of ePTFE tubes we, currently, focus on covers for stents, especially peripheric stents. Due to the smooth and hydrophobic nature of PTFE and it's low friction, damage of the vessel surface is prevented and restenosis tendency highly reduced. Balloon expandable stents are at risk of being expanded more than targeted. Consequently, the covering tube needs to have sufficient safety capacity before breakage. With a strict control of porosity, inner diameter and wall thickness, we can provide very stable and reliable stent covers that withstand extremely high radial expansion forces without breaking.

Further info: https://www.lenzing-plastics.com/en/markets-and-solutions/medical-components-hygienic-products/eptfe-tube-and-stent-covering/

Figure 3: https://www.bentley.global/product/begraft-peripheral

1.3. PTFE / ePTFE tape

More and more implants are designed and applied minimally invasive, in order to enable the treatment, in general (e.g. for weakened or elderly patients, not tolerating a conventional surgery anymore) or, to enhance patient safety. I.e. enable faster recovery, thus, reducing health care costs. Consequently, compression of the radially large medical device is necessary ("crimping"), in order to make it small enough for transferring it into the catheter that is, finally, induced into and guided through the vessel. In order to protect the device during the latter process, wrapped PTFE tapes, exhibiting lowest friction and a clean and smooth surface are a perfect production auxiliary item. Lenzing Plastics is offering a broad range of different tape thicknesses, widths and densities, depending on the very need of the device manufacturer.

Further info: https://www.lenzing-plastics.com/en/markets-and-solutions/medical-components-hygienic-products/eptfe-tube-and-stent-covering/

1.4. ePTFE laminate/patch

In some applications the benefits of PTFE need to be combined with those of other materials to reach the optimum product performance for the patient. E.g. warp knitted PP fabrics are laminated with ePTFE membranes as permanent hernia implants. Or, ePTFE membrane is merged with PU for high-end wound care products (skin replacement), in case of severe burn injuries, prior to the required skin transplantation. A product that has proven to be gold standard for meanwhile decades[8].

Further info: https://www.lenzing-plastics.com/en/markets-and-solutions/medical-components-hygienic-products/

The above-mentioned applications are not exhaustive. They are, as well, continuously expanded into further innovative products that support patients all over the world to recover faster and better from their diseases or injuries.

[8] https://www.biovision.de/en/products/epigard

2. Manufacturing

2.1. PTFE processing

At Lenzing Plastics, we source PTFE polymer as resin from leading suppliers, globally. For many years already, free from PFOA and PFOS. Due to the PFAS campaign, 3M as one of the last remaining PTFE producing companies announced to stop PTFE polymer production in Europe and shut down the plant, completely. Consequently, in the future, import from other parts of the world will be required. We blend the resin with lubricant (volatile *iso*-alkanes) and extrude it into a rod which is, then, calendared into a film. The lubricant is fully evaporated during the process, during heating up and drying the film. The exhaust air is treated thermally to destroy all potentially harmful substances or particulates. No generation of short-chain PFAS (e.g. perfluoroalkyl carboxyl acids or their salts) could be identified in the course of the process, so far. Next step is stretching of the film/tape, for orienting the polymer chains, thus, applying strength to the tape. And finally, it is slit and, if required, twisted into round filaments.
In summary, at Lenzing Plastics, PTFE is converted physically from a resin into a film and tape, subsequently. No other PFAS substances are added/generated during the process.

2.2. Raw material manufacturing:

Our suppliers did phase out of usage of PFOS and later PFOA already. Long before the radical restrictions legally were enforced. For selected PTFE resins (Suspension PTFE), they are not using any PFAS polymerization aids. For fine powder resins (Emulsion PTFE) there is still no viable alternative existing[9,10]. However, R&D is in progress to resolve that[11]. Introduction of a strict regulation for raw material manufacturing practice in this regard would be highly appreciated by Lenzing Plastics.

3. End of product lifecycle

PTFE is a very stable and long-lasting product[12]. In most of the applications, including Medical it is - among other reasons - used because of its longevity. Therefore, products made of PTFE are less often exchanged, replaced and disposed than alternative materials. But at one point of time, e.g. when the human with PTFE implant passes away, also the PTFE components are disposed. If incinerated in state-of-the-art facilities, no PFAS are emitted into the air[13,14]. Due to the strong carbon fluorine bond (the strongest that carbon could have to any other atom), there will not be any negative impact on the environment, if placed on landfill: PTFE will not be dissolved through water, as it is not soluble therein and will not degrade to smaller particles[15]. Thermal degradation will only happen at drastically elevated temperatures and long exposure at the same time.

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[9] B. Ameduri, *J. Fluorine Chem.,* **2023***, 267,* 110117

[10] B. Ameduri, J. Sales, M. Schlipf, *ICRL,* **2023***, 1,* 18

[11] R. Chauhan, G. Kumar, P.s. Rao, N. Soni, B.s. Bhattacharya, A. Dutta, A. Shukla, A.M. Patel, *PCT Application,* **2020***,* WO 2021/070159 A1

[12] B. Ameduri, H. Hori, *Chem. Soc. Rev.,* **2023***, 52,* 4208

[13] K. Aleksandrov, H.J. Gehrmann, M. Hauser, H. Mätzing, D. Pigeon, D. Stapf, M. Wexler, *Chemosphere,* **2019***, 226,* 898

[14] W. Tsang, D.R. Burgess Jr., V. Babushok, Combustion Sc. and Technol., 1998,139, 1

[15] B.J. Henry,J.P. Carlin, J.A. Hammerschmidt, R.C. Buck, L.W. Buxton, H. Fiedler, J. Seed, O. Hernandez, *Integr. Environ. Assess. Manag.,* **2018***, 14,* 316

From technical viewpoint, also recycling is feasible. However, due to the very low amounts of PTFE material, here, it is challenging to organize collection of material for recycling. Furthermore, in the context of permanent implants and the respectful treatment with the remains of a human being, recycling is for obvious reasons not an option.

4. Conclusion

For the sake of all European Union citizens and their access to state-of-the-art health care, independent from their financial status, we call for a general exemption (not only extended derogation time) for the use of PTFE in all medical devices to be included in a future PFAS regulation.

In case of any question, we are available to provide further details.

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