ePTFE supply chain challenges due to regulation updates
Minimize supply and environmental risks with porous UHMWPE membrane alternative

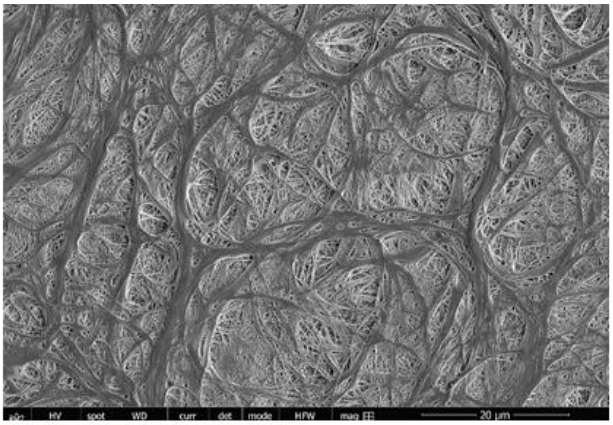
Background
Per- and polyfluoroalkyl substances (PFAS) are a large class of synthetic chemicals that contain stable carbon-fluorine bonds and are also known as "forever chemicals" due to their non-degradable nature. PFAS have been increasingly observed to contaminate water and soil and can in turn end up in food and the human body. Next to their serious effects on the environment, PFAS have been found linked to serious health problems such as cancer, immune system suppression, liver damage and reduced fertility, to name a few.[i] Because of this, the EU and some US states have recently enacted regulatory changes aimed at reducing and ultimately prohibiting their use.[ii,iii,iv]

PTFE (Polytetrafluoroethylene) is a synthetic fluoroalkyl polymeric material widely used in the medical device industry due to its chemical inertness and low friction coefficient. However, PTFE resin is typically produced via suspension or emulsion polymerization using PFAS. Thus, it can also be considered a "forever chemical" as it does not degrade in the environment. The ongoing PFAS regulatory trend casts a shadow on the longevity of the use of PTFE as an industrial and medical material. There is risk that PTFE will be phased out except for limited applications where no alternative material can be found.

ePTFE (expanded PTFE) is a special form of PTFE featured with a porous structure typically containing node-fibril components. Oftentimes, ePTFE exists in either a sheet or tubular form with thickness in the range of tens to hundreds of µm. ePTFE is widely used as a critical material in a variety of implantable medical devices such as covered stent grafts and left atrium appendage occlusion devices. PFAS regulatory shifts are expected to have a significant impact on the future availability and adoptability of ePTFE for the medical device industry, and early adaptors have already started looking for alternative materials.

Porous UHMWPE membrane as an alternative for ePTFE

Ultra-high molecular weight polyethylene (UHMWPE) is often considered an alternative material to PTFE due to its chemical and physical similarities. Both polymers are semi-crystalline and have a long saturated linear C-C backbone. They differ only in the type of atoms attached to the backbone with PTFE having all fluorine atoms and UHMWPE hydrogen atoms. Both are chemically inert with good biocompatibility and a low coefficient of friction. However, there are some differences that should be considered depending on the application. PTFE undergoes large strain plastic deformation at low force while UHMWPE is more stable and does not show such an easy deformability. PTFE has a high melting temperature that amounts to >320 °C while UHMWPE melts below 140°C, which endows the latter easier processability.[v,vi] Compared with PTFE, UHMWPE is significantly more wear resistant which allows its use as the bearing surface in hip and knee arthroplasty in contrast to PTFE.[vii] These differences are due to the size and electronegativity differences between



Ulteeva Purity™ Membrane SEM Image

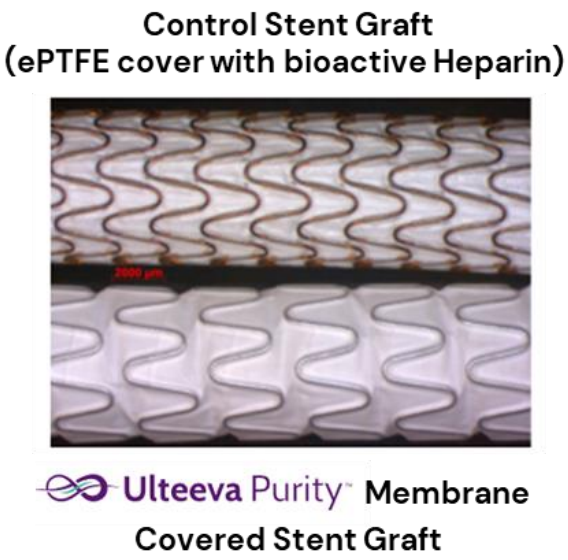
fluorine and hydrogen atoms, which alters chain conformation in the solid state.

For UHMWPE to serve as an alternative to ePTFE, porous UHMWPE membranes are needed. The good news is, such a medical grade porous UHMWPE membrane is available in the market today. Ulteeva Purity™ membrane, produced by the Biomedical division of dsm-firmenich, can be used as a long-term implantable material, and with a low coefficient of friction which is not only an alternative to ePTFE but also offers additional performance/processing advantages. For example, the low processing temperature during integration with Nitinol stents does not impair the property of the Nitinol, and it has irradiation sterilization potential while ePTFE does not.[viii]

Biocompatibility and long-term biosafety of Ulteeva Purity™ membrane

Medical grade UHMWPE has a long clinical history as an implantable material. Its molded form has been widely adopted as the bearing surface component used in hip/knee protheses for more than half a century, and its fiber form featured with high modulus and high strength enabled the birth of high strength suture 2 decades ago and has become the gold standard for soft tissue repair. Fabric made of UHMWPE fiber has also been recently used in cardiovascular device components such as heart valve leaflets.[ix]

Ulteeva Purity™ membrane with the same UHMWPE chemistry can therefore be expected to also have excellent biocompatibility and long-term biosafety. Selective biocompatibility tests following ISO 10993 such as cytotoxicity, hemolysis, sensitization, irritation, acute systemic toxicity, and implantation (intramuscular and intravascular) were performed confirming its biological safety.[x]



In addition, angiographic, radiographic, and histological evaluations show that in a 90-day ovine peripheral artery stenting study, Ulteeva Purity™ membrane covered stent grafts exhibit similar and non-inferior performance compared to a legacy stent graft in the market using an ePTFE cover with a heparin coated lumen surface. This further corroborates its biocompatibility and biosafety, and highly suggests the great promise as an alternative endograft material for blood-contact implantable device applications.[xi]

Summary

The impact of the ongoing tightening of PFAS regulation on medical device industry is gradually unfolding, and there is a risk of the ultimate abandonment of PTFE and ePTFE materials. Forward-looking medical device companies have already started working on alternative solutions. Medical grade UHMWPE has shown great potential to be an alternative to PTFE for most if not all medical applications with the potential of additional performance and processing benefits. Selecting Ulteeva Purity™ UHMWPE porous membrane allows medical device companies to minimize risk by leveraging a medical grade material that is supported by test data and is delivered by a supplier with over 100 years of combined polyethylene technical experience.

If you would like more information about this topic or considerations related to Ulteeva Purity™ Membrane and the potential for use in your medical product, please reach out to dsm-firmenich at https://www.dsm.com/biomedical/en_US/company-info/get-in-touch.html

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[i] Environ Health. 2022; 21: 51. Official health communications are failing PFAS-contaminated communities
[ii] https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal
[iii] https://stateline.org/2022/09/22/states-take-on-pfas-forever-chemicals-with-bans-lawsuits/
[iv] April 10, 2024 FACT SHEET: Biden-Harris Administration Takes Critical Action to Protect Communities from PFAS Pollution in Drinking Water | https://www.whitehouse.gov/briefing-room/statements-releases/2024/04/10/
[v] UHMWPE Biomaterials Handbook Ultra High Molecular Weight Polyethylene in Total Joint Replacement and Medical Devices Book, Third Edition, 2015
[vi] Gogoleva OV, et al., FarEastCon - Materials and Construction II, 992 MSF: 2020, pp.398-402.
[vii] Wear, 158 (1992) 193-211.
[viii] Chipară et al, Polymer Degradation and Stability 37(1), 1992, pp. 67-71.
[ix] Basir A et al, Interact Cardiovasc Thorac Surg 25(6) 2017, pp. 942-949.
[x] Data on file at dsm-firmenich (TD-00013)
[xi] Data on file at dsm-firmenich (TD-01206-A)