an alternative to forever chemicals used in medical devices

PC Technology™ Coatings

background

Per- and polyfluoroalkyl substances (commonly known as "PFAS") represent a class of chemicals that have been used in diverse industrial and consumer applications since their emergence in the 1940s. Characterized by their versatility and longevity, the use of these substances has permeated many facets of contemporary life: PFAS can be found in non-stick cookware, grease and stain resistance fabric treatments, water-repellency applications, and in firefighting foams. **PFAS have been dubbed "forever chemicals" due to their resistance to biodegradation and potential for bioaccumulation in living organisms.**[1]

PFAS (forever chemicals) are used in a wide variety of healthcare applications, including:

catheters | **stents** | **needles** | **surgical mesh** | **medical devices**

PFAS prevalence and persistence

PFAS are omnipresent in today's global landscape as they are slow to degrade in natural environments due to their chemical structure and properties. As PFAS infiltrate our environment, they have been detected at very low levels in certain water bodies, our food chain, and even in living tissues. While the potential health impacts caused by the presence of PFAS are not currently known, the universal presence of PFAS in our world is creating consumer alarm and questions about long-term effects.

PFAS compounds are not confined to specific domains; they traverse various mediums, including water bodies, air space, aquatic life, and terrestrial soil. Their existence across geographical boundaries highlights their global presence.[2]

health implications of PFAS exposure

Scientific research has begun to unravel the complex relationship between PFAS and human and animal health. The results of these studies suggest potential health hazards may be associated with long-term PFAS exposure. There is an increasing body of evidence pointing to the detrimental effects of PFAS on living organisms.[3]

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undesirable PTFE coating on medical devices

In the medical device industry, polytetrafluoroethylene (PTFE), a fluoropolymer has been widely used as a low friction coating for guidewires, mandrels, hypodermic tubes, coil wires and needles. Although PTFE itself is not considered a PFAS category chemical, the raw materials used to manufacture PTFE, including perfluorooctan sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) are in the PFAS category. Therefore, increasing efforts have been made by device manufacturers to find more sustainable PTFE coatings and/or alternatives to PTFE coatings.

an excellent alternative to PTFE

PC Technology Coatings are well-established biomedical coatings that have been in clinical use in medical devices for many years. PC Technology Coatings mimic the outer layer of biological cell membranes (Figure 1), giving them intrinsic biocompatibility, high wettability, and outstanding lubricity; positioning them to be excellent alternative to PTFE coatings.

PC Technology™

- a proprietary platform of methacrylate polymers incorporating PC
- biomimetic, biocompatible, synthetic, and bioinert materials
- truly multiple functions; a wide range of applications that are clinically proven

Evolution and Development of PC Technology

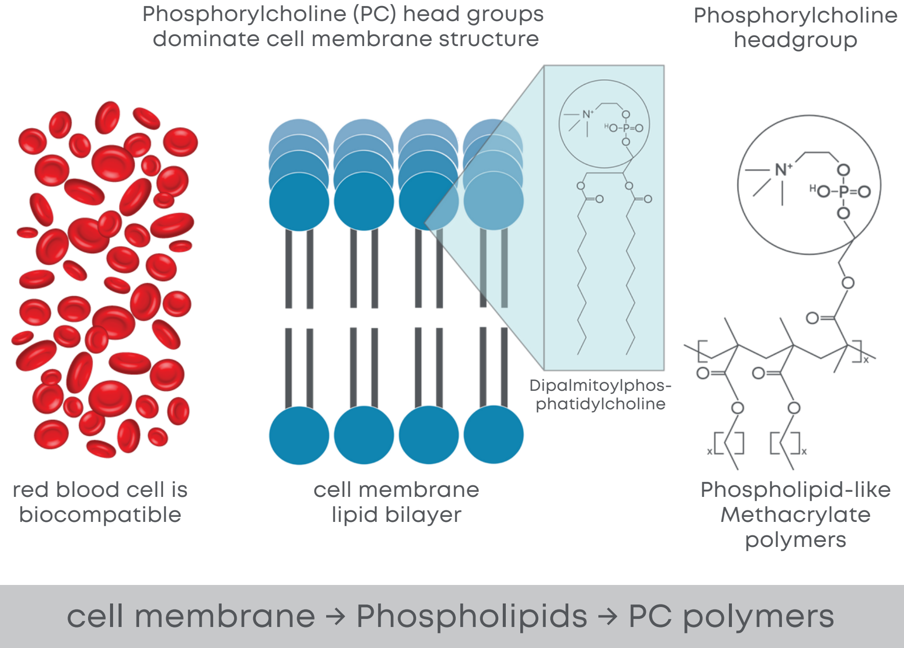

Figure 1

highly lubricious coatings

PC Technology Coatings have a strong affinity for water and can be formulated to be highly wettable and lubricious, properties which make them capable alternatives to PTFE where low friction is required.

As demonstrated by the coefficient of friction (COF) data in Table 1, PC Technology Coatings significantly reduce friction of polyvinylchloride (PVC) catheters.[4]

Kinetic COF of uncoated and PC Technology coated PVC catheters

Friction Test	Uncoated	Coated
1	0.57	0.08
2	0.57	0.08
3	0.57	0.08
4	0.57	0.08
5	0.57	0.08
6	0.57	0.08
average	**0.57**	**0.08**
reduction	**86%**	

Table 1

superior hemocompatibility

PC Technology has not only proven to be an excellent alternative to the PTFE coating for guidewires but also shows excellent blood compatibility.

Five commercial 0.014” guidewires were used and evaluated during routine percutaneous transluminal coronary angioplasty (PTCA) procedures in 1998.[5] A 2 - 3 centimeter long distal spring coil was cut from each of the guidewires and examined by scanning electron microscopy (SEM). Thrombi were categorized as “no thrombus”, “limited thrombus” and “significant thrombus” as illustrated by the SEM images in Figure 2.

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A thrombus is a blood clot formed in the circulatory system and when dislodged a thrombus becomes free-floating, and/or trapped within a blood vessel, which can block blood flow. This blockage can lead to significant health effects like stroke, heart attack, or even death.

SEM images of typical guidewires without and with limited and significant thrombus

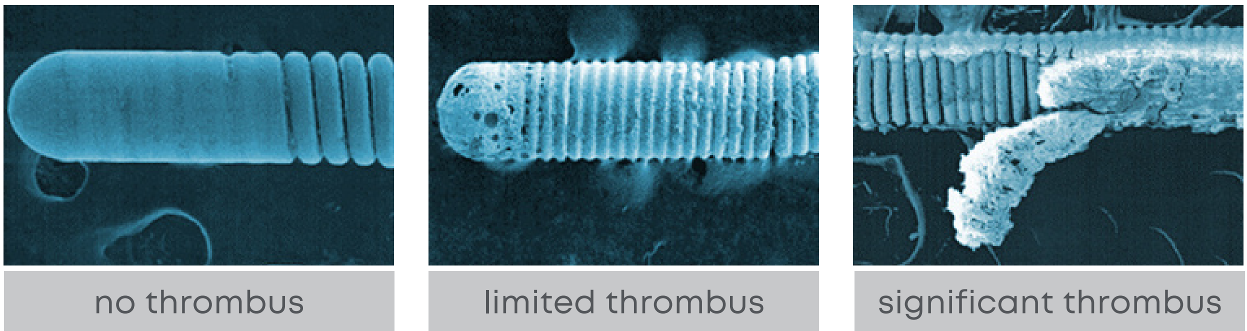

Figure 2

Thrombi, both limited and significant, were observed in 81.3% and 37.5% of two of the Commercial Manufacturers' guidewires as shown in Table 2. In contrast to these PTFE coated guidewires, PC Technology coated guidewires showed no thrombus. The data clearly demonstrates the superior hemocompatibility of PC coating versus PTFE and indicates that PC Technology Coatings can be excellent alternatives to replace PTFE on the guidewires.

Observations of different thrombi in % of the guidewires evaluated

Manufacturers	Coatings	No thrombus	Limited thrombus	Significant thrombus	Total thrombus
Aurorium (Biocompatibles UK)	PC Technology	100.0	0.0	0.0	0.0
Commercial Guidewire Manufacturer #1	PTFE	18.8	12.5	68.8	81.3
Commercial Guidewire Manufacturer #2	PTFE	62.5	12.5	25.0	37.5
Commercial Guidewire Manufacturer #3	Silicone	0.0	20.0	80.0	100.0
Commercial Guidewire Manufacturer #4	Hydrophilic	25.0	37.5	37.5	75.0

Table 2

resistant to bacterial biofilm formation

Fluoroplastic ventilation tubes coated with PC Technology Coatings were found to resist bacterial biofilm formation. Test samples were incubated in *S. aureus* and *P. aeruginosa* solutions in tryptone soy broth at 37°C for 5 days. After incubation test samples were forcefully rinsed 10 times with 10 mL sterile saline solution to wash away any free or planktonic bacteria, then analyzed by scanning electron microscopy (SEM).[6] As shown in Table 3, only PC Technology coatings resisted biofilm formation after incubation in both *S. aureus* and *P. aeruginosa* solutions.

Biofilm formation on uncoated, silver-oxide impregnated and PC Technology coated fluoroplastic ventilation tubes

Test samples	*S. aureus*	*P. aeruginosa*
Uncoated fluoroplastic tube	No bacterial biofilm	Dense biofilm slime
Silver-oxide impregnated fluoroplastic tube	Thick bacterial biofilm	Thick bacterial biofilm
PC Technology fluoroplastic tube	No bacterial biofilm	No bacterial biofilm

Table 3

conclusion

As we navigate the future PFAS landscape, the development and adoption of PFAS alternatives is imperative. Our reliance on these substances necessitates a proactive approach to mitigate their potentially far-reaching effects on health and the environment. Aurorium's PC Technology is an excellent alternative to PFAS as these coatings have been shown to be highly lubricous, have superior hemocompatibility and resist bacterial formation.

learn more about our healthcare solutions

Your partner for a better future; focused on providing solutions that enhance drug delivery, feature biocompatibility for optimized performance, and support human health

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footnotes

[1] "Our Current Understanding of the Human Health and Environmental Risks of PFAS."
https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas

[2] "PFAS Explained"
https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas

[3] Fenton SE, Ducatman A, Boobis A, DeWitt JC, Lau C, Ng C, Smith JS, Roberts SM. "Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research", Environmental Toxicology Chemistry. 2021 Mar;40(3):606-630

[4] Data on file, Aurorium, 2007-2019

[5] Gobeil F, et al, "Thrombus formation on guide wires during routine PTCA procedures : a scanning electron microscopic evaluation" , Canadian Journal of Cardiology, 2002 Mar, 18(3), 263-269

[6] Berry JA, et al, "In vitro resistance to bacterial biofilm formation on coated fluoroplastic tympanostomy tubes", Otolaryngology – Head and Neck Surgery, 2000 Sep, 123 (3), 246-251

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Revised 29-JAN-24